# MEASURING AND MANAGING FOOT MUSCLE WEAKNESS

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A thesis submitted in fulfilment of the requirement for the degree of

Doctorate of Philosophy

***Faculty of Health Sciences***

**The University of Sydney**

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# CANDIDATE'S CERTIFICATE

I, *Penelope Jane Latey*, hereby declare that the work contained within this thesis is my own and has not been submitted to any other university or institution for any higher degree.

I, *Penelope Jane Latey*, hereby declare that I was the principal researcher of all work contained in this thesis, including work published with multiple authors.

I, *Penelope Jane Latey*, understand that if I am awarded a higher degree for my thesis titled *Measuring and managing foot muscles weakness* being submitted herewith for examination, the thesis will be lodged in the University Library and be will available immediately for use. I agree that the University Librarian (or in the case of the department, the Head of the Department) may supply a photocopy or microform of the thesis to an individual for research or study or to a library.

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29th June 2018

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This is to certify that the thesis titled *Measuring and managing foot muscle weakness* submitted by *Penelope Jane Latey* in fulfilment of the requirements for the degree of Doctorate of Philosophy is in a form ready for examination.

Professor Joshua Burns

The University of Sydney and Sydney Children's Hospitals Network

19th June 2018

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I feel very privileged to have shared this time learning with you all.

# DEDICATION

This thesis is dedicated to those that are no longer in this world, though of this world: my parents Heather and Fred Schubach, a special companion Craig Johnston and friend Narelle Smith.

*Intelligence is something we are familiar with, an old book, an old friend.*

*But what is wisdom?*

*If intelligence is the ability to speak, wisdom is the capacity to listen.*

*If intelligence is the ability to see, wisdom is the capacity to see far.*

*If intelligence is an eye, wisdom is a telescope. ……. To see ……. beyond the first dimension or context; of time and space and being.*

*Wisdom in other words, is perspective.*

*(Wrangham and Peterson 1997)*

# ABSTRACT

Foot problems with accompanying foot pain are highly prevalent, affecting 24% of the population at any given time. Foot pain is associated with intrinsic foot muscle weakness and reduced toe flexor strength. Foot muscle weakness is caused by disease, injury, inactivity and ageing, with disabling functional consequences. Measuring and managing intrinsic and extrinsic foot muscle weakness can be challenging. Exercise is known to improve muscle weakness, however ensuring participant engagement and adherence to the correct technique is often difficult to achieve. Biofeedback may improve both accuracy in performance and adherence. The purpose of this thesis is to determine the level of association between foot muscle weakness and pain, develop a safe biofeedback foot exercise device and evaluate its feasibility to guide performance of exercise skill and adherence. *Chapter One* of this PhD thesis describes the intrinsic foot muscles and critically reviews the available literature on foot muscle measurements. The causes and consequences of foot muscle weakness, various foot exercises, limitations to performance skill and adherence are appraised. The results of a systematic review on the relationship between foot pain, muscle strength and size are presented in *Chapter Two*. Eight studies were identified evaluating the relationship between foot pain and foot muscle strength (n=6 studies) or size (n=2 studies). There was evidence of a significant association between foot pain and muscle weakness when pain is of high intensity, and weakness measured by toe flexion force. *Chapter Three* presents a reproducibility study assessing the size of abductor hallucis and the medial belly of flexor hallucis brevis muscles by ultrasound in 21 participants aged 26-64 years, and identified their relationship with toe strength, foot morphology and balance. Intra-rater reliability was excellent for both the abductor hallucis ($ICC_{3,1}$ = 0.97, 95%CI 0.94 to 0.99) and medial belly

of flexor hallucis brevis ($ICC_{3,1}$ = 0.96, 95%CI 0.96 to 0.98). Significant associations were identified between cross-sectional area of abductor hallucis and great toe flexion force measured by pedobarography (r=0.623, p=0.003), foot morphology measured by arch height in sitting and standing, foot length and truncated foot length (r=0.597, p=0.004 to r=0.580, p=0.006), balance measured by the maximal step length test (r=0.443, p=0.044). A significant association was also identified between cross-sectional area of the medial belly of flexor hallucis brevis and foot morphology measured by the Foot Posture Index, foot length and truncated foot length (r=0.544, p=0.011 to r=0.451, p=0.040). After controlling for physical body size, cross-sectional area of abductor hallucis remained a significant correlate of great toe flexor strength (r=0.562, p=0.012). *Chapter Four* describes the development and construction of the 'Archie' biofeedback medical device. This process included the redesign and build of the housing, a significant upgrade to Archie's safety features, new electronic circuitry and substantially improved visual feedback. The feasibility of the Archie biofeedback device is evaluated in *Chapter Five* by repeat testing with 30 healthy adults (aged 23-68 years) performing four types of foot exercises using Archie to guide arch movement and foot placement. All participants performed the foot exercises on Archie alone (to measure consistency) and with biofeedback (to measure device effectiveness). Seventeen of 19 (89%) arch movement and foot location variables were collected consistently with Archie during the foot exercises. Archie with biofeedback significantly improved foot location adherence for all exercises (p=0<009). Twenty-nine of 30 (97%) participants reported that Archie with biofeedback helped correctly perform the exercises. Archie appears to be a safe, feasible biofeedback system to assist participants with performing foot exercises and improve adherence using the correct technique. Archie merits further research to explore the longitudinal benefits in community-based clinical trials to treat foot muscle weakness.

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# OUTLINE OF THE THESIS

This section outlines the stages of research undertaken to better understand the consequences of foot weakness, the challenges in measuring the small muscle of the foot and the development and evaluation of the 'Archie' biofeedback device to assist with strengthening foot muscle weakness.

This PhD thesis contains six chapters:

*Chapter One* details the background to the thesis, measuring and managing foot muscle weakness, critically reviews the available literature and presents the problem to be addressed, whilst stating the directions and aims and of the thesis.

*Chapter Two* reports the results of a systematic review on the relationship between foot pain, muscle strength and size.

*Chapter Three* presents a study evaluating the reproducibility of assessing the size of abductor hallucis and the medial belly of flexor hallucis brevis muscles by ultrasound and identify their relationship with toe strength, foot morphology and balance.

*Chapter Four* describes the methods of the development and rebuild of 'Archie' biofeedback device.

*Chapter Five* presents a study testing the feasibility of the Archie biofeedback with repeat testing on healthy adults to determine the consistency and effectiveness of practicing specific foot exercises using the correct technique.

*Chapter Six* discusses the results and limitations of the thesis, explores the implications of the thesis for clinical and research practice and identifies future research directions.

# DISSEMINATION OF RESEARCH

Parts of the research presented in this PhD thesis have been published (or submitted) and presented in the following journals and conferences:

**Peer-reviewed papers**

**Latey PJ.** Burns J. Hiller CE. Nightingale EJ. Relationship between foot pain, muscle strength and size: a systematic review. *Physiotherapy* 103(1):13-20, 2017. doi:10.1016/j.physio.2016.07.006

**Latey PJ.** Burns J. Nightingale EJ. Clarke JL. Hiller CE. Reliability and correlates of cross-sectional area of abductor hallucis and the medial belly of the flexor hallucis brevis measured by ultrasound. *Journal of Foot and Ankle Research* 2018, 11:28 | Published on: 7 June 2018 https://doi.org/10.1186/s13047-018-0259-0

**Published abstracts**

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**Latey, P**., Burns, J., Nightingale, E., Clarke, J., & Hiller, C. (2016). Correlates of ultrasound cross-sectional area of abductor hallucis and flexor hallucis brevis. *Foot and Ankle Surgery, 22*(2), 79. doi:10.1016/j.fas.2016.05.195

**Conference presentations: podium**

**Latey PJ,** Burns J, Nightingale E, Clarke J, Hiller C. Factors associated with real-time ultrasound, toe flexion strength and structural measures of the foot.

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4th Congress of the International Foot and Ankle Biomechanics (i-FAB) Community Seoul, South Korea. April 2014

# CHAPTER ONE

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# Introduction and literature review

## 1. Background to thesis

Foot problems with accompanying foot pain affects 24% of the population at any given time.[1] Muscle weakness, a major foot problem resulting from disease, injury, inactivity or ageing,[2] can produce debilitating deformity and disability.[3-5] Several studies have reported toe flexor weakness and reduced intrinsic foot muscle size in people with diabetic peripheral neuropathy,[2, 3] foot pathologies such as plantar fasciitis,[4, 5] and toe deformities such as hallux valgus.[6, 7] Foot muscle weakness is also associated with poor balance, increased risk of falls and impaired gait in older adults.[8-14]

Exercise interventions to improve foot muscle strength have shown a range of positive outcomes. Studies of foot exercise to improve toe flexion strength have shown reduction of pain in hallucis rigidus,[15] increased one leg jumping distance and vertical jumping height in healthy adult males[16] and improvement of some aspects of motor function in the elderly.[17] Foot exercises have been used in conjunction with taping and foot mobilisation for improving hallux valgus[18] and to increase the cross-sectional area of the abductor hallucis in participants with mild to moderate hallux valgus.[19] The short foot exercise, performed by approximating the metatarsal heads towards the heel without toe flexion, causing elevation of the arch,[20] has been reported to improve intrinsic foot muscle performance during static unilateral balancing and functional balance tasks [21] and increases cross-sectional area of abductor hallucis in people with pes planus.[22] Therefore, foot exercises that focus on maintaining good foot placement and function may help manage foot pain and reduce disability related to foot muscle weakness.

Supervised exercise is frequently cited as being effective for the treatment of painful musculoskeletal pathologies associated with muscle weakness.[23] However, the cost of ongoing care may limit face to face interventions. Home exercise practice is an alternative,

but can be limited by poor performance skill and low adherence rates.[24] Factors affecting exercise adherence include forgetfulness and motivation.[25] Nonetheless, biofeedback has been shown to improve exercise adherence in studies such as balance training and interventions for post stroke gait, and sit-to-stand transfers in older patients.[26] Biofeedback has been used to improve adherence to practice and with movement pattern retraining after an injury or illness associated with compromised neuromuscular function,[27] including post stroke.[28] Using a device that provides real-time biofeedback of plantar arch pressure to improve foot muscle control, while recording foot placement and quantity of practice, may improve foot function and exercise adherence.

Therefore, a novel biofeedback device, known as 'Archie', was designed and constructed to assist with strength training of foot arch muscles (Patent pending: PCT/AU2016/050437). The Archie device simultaneously measures and provides real-time biofeedback of arch movement and foot location via pressure change in an inflatable arch bladder and sensors embedded in a footplate. Biofeedback is provided via a computer interface displaying arch movement and foot location. The main focus of this PhD thesis is to investigate the feasibility of using Archie to provide biofeedback of correct arch movement and foot location during four foot exercises to specifically aid strength training of foot muscles.

## 1.1 Overview of the intrinsic foot muscles

The intrinsic foot muscles originate and insert within the foot[29] and reside either on the plantar or dorsal aspect of the foot, with four layers of intrinsic muscles on the plantar aspect and a single layer on the dorsum of the foot. The plantar intrinsic foot muscles can be classified by position and innervation or grouped in regions or layers from superficial to deep.[30-32] (Table 1.1) The forefoot can be categorised into functional segments or rays from first/great to fifth toe, with each ray including a phalangeal, metatarsal and related tarsal bone and their associated muscles. The intrinsic foot muscles usually act across several joints, with various interconnections to the extrinsic foot muscles (Table 1.2).

**Table 1.1** Intrinsic foot muscles, origin, insertion and action

| Muscle, aspect and innervation | Origin and Insertion | Action |
|---|---|---|
| **a. Medial plantar intrinsic foot muscles** | | |
| Abductor hallucis<br>(first layer)<br>Innervation: medial plantar nerve | Origins: tuber calcanei, flexor retinaculum and plantar aponeurosis, superficial to the plantar aspect of the navicular bone [30]<br>Insertions: variations include; medial sesamoid ligament and medial sesamoid bone (59%), proximal phalanx (39%), medial sesamoid bone (2%) [33] (Figure 1) | Elevation of the medial arch [34]<br>More active medial arch elevator when the interphalangeal joint is not flexed [35] |
| Flexor hallucis brevis<br>(third layer)<br>Innervation: medial plantar nerve | Origins: medial cuneiform bone, long plantar ligament and most commonly a Y-shaped origin- medial arm provided by tibialis posterior tendon and lateral arm by peroneus longus tendon [36]<br>Insertions: has two heads; medial head is combined with abductor hallucis and extends to the medial sesamoid bone, lateral head joins adductor hallucis and inserts into the lateral sesamoid bone and proximal phalanx [30] (Figure 2) | Plantarflexion of great toe<br>Great toe adduction (medial head) |
| Adductor hallucis<br>(third layer)<br>Innervation: deep branch lateral plantar nerve | Origins: has two heads; oblique head is divided into medial and lateral parts, attaches to lateral cuneiform bone and the bases of second and third metatarsals. [37] Less common origins include: fourth metatarsal, plantar calcaneal cuboid ligament, long plantar ligament and tendon sheath of peroneus longus. Transverse head attaches to capsular ligaments of 3rd-5th metatarsophalangeal joints and the deep transverse ligament.<br>Insertions: lateral sesamoid bone of the great toe. (Figure 3) | Tensor of the plantar arches,<br>Adducts great toe<br>May plantar flex the proximal phalanx [30] |
| **b. Central plantar intrinsic foot muscles** | | |
| Flexor digitorum brevis (first layer)<br>Innervation: medial plantar nerve | Origins: under surface of the tuber calcanei and the proximal part of the plantar aponeurosis.<br>Insertions: middle phalanx of 2nd-4th digits via divided tendons. (Figure 4) | Flexion of middle phalanges [29, 30, 38] |
| Four lumbricals (second layer)<br>Innervation :medial plantar 1st,2nd and 3rd;lateral plantar 4th nerve | Origins: medial surfaces of individual tendons of flexor digitorum longus.<br>Insertions: medial margin of 2nd-5th proximal phalanges and radiates to the extensor aponeurosis | Flexion of metatarsophalangeal joints [30]<br>Contribute to extension of interphalangeal joints [39] |
| Quadratus plantae (second layer)<br>Innervation: lateral plantar nerve | Origins: variable [36], with two slips from the medial and lateral margins of the plantar surface of the calcaneus<br>Insertions: lateral margin of flexor digitorum longus tendon | Contributes to foot plantarflexion with flexor hallucis longus and flexor digitorum longus |
| Three plantar interossei (fourth layer)<br>Innervation: deep branch lateral plantar nerve | Origins: medial side of 3rd-5th metatarsals, may receive additional fibres from long plantar ligament.<br>Insertions: base of 3rd-5th digit proximal phalanges | Adduct and pull the third, fourth and fifth digits towards the second digit [30] |

| | | |
|---|---|---|
| Four dorsal interossei (fourth layer)<br>Innervation: deep branch lateral plantar nerve | Origins: lateral surface of the metatarsals delineating the corresponding intermetatarsal space [36].<br>Insertions: two heads from the opposing surfaces of all the metatarsal heads and from the long plantar ligament | Adduction of the toes<br>Plantarflexes metatarsophalangeal joint with plantar interossei [30] |
| **c. Lateral plantar intrinsic foot muscles of the fifth digit** | | |
| Abductor digiti minimi or quinti (first layer)<br>Innervation: lateral plantar nerve | Origins: lateral process of tuber calcanei, lower surface of calcaneus, tuberosity of 5th metatarsal, plantar aponeurosis<br>Insertion: proximal phalanx. (Figure 5) | Supports the lateral arch of the foot<br>Flexes and abducts 5th toe [30] |
| Opponens digiti minimi (third layer)<br>Innervation: lateral plantar nerve | Origins: long plantar ligament and peroneus longus tendon sheath<br>Insertion: 5th metatarsal | Plantarflexion of 5th metatarsal<br>Supports plantar arch, however is frequently absent [30] |
| Flexor digiti minimi brevis (third layer)<br>Innervation: lateral plantar nerve | Origins: base 5th metatarsal, long plantar ligament and peroneus longus tendon sheath<br>Insertions: base of 5th digit proximal phalanx and merges with the abductor digiti minimi [30] | Plantarflexion of 5th toe |
| **d. Intrinsic foot muscles on the dorsum of the foot** | | |
| Extensor digitorum brevis<br>Innervation: lateral plantar nerve | Origins: calcaneus near entrance to the tarsal sinus, and one side of inferior extensor retinaculum (Figure 6)<br>Insertions: three or four tendons to the dorsal aponeurosis or the middle phalange of the second to fourth digits | Dorsiflexion 2nd-4th digits. |
| Extensor hallucis brevis<br>Innervation: deep peroneal nerve | Origins: superior lateral calcaneus near the entrance to the tarsal sinus, splits off from its common origin with extensor digitorum brevis<br>Insertion: dorsal aponeurosis of the great toe [30] (Figure 6) | Dorsiflexion of great toe |

### 1.1.1 Anatomical variations

Many intrinsic foot muscles have a number of anatomical variations. Variations include different pathways or attachments, and additional or absent muscles.[36, 39-41] These variations increase the difficulty in determining which specific muscles contribute to different foot movements.

### 1.1.2 Medial muscles of the foot

The medial foot muscles of the first ray include the *abductor hallucis* and the *flexor hallucis brevis*, and in a broader sense the *adductor hallucis*[30, 37] (Table 1.1a) as only the oblique head of the latter forms part of this region (Figure 1.1).

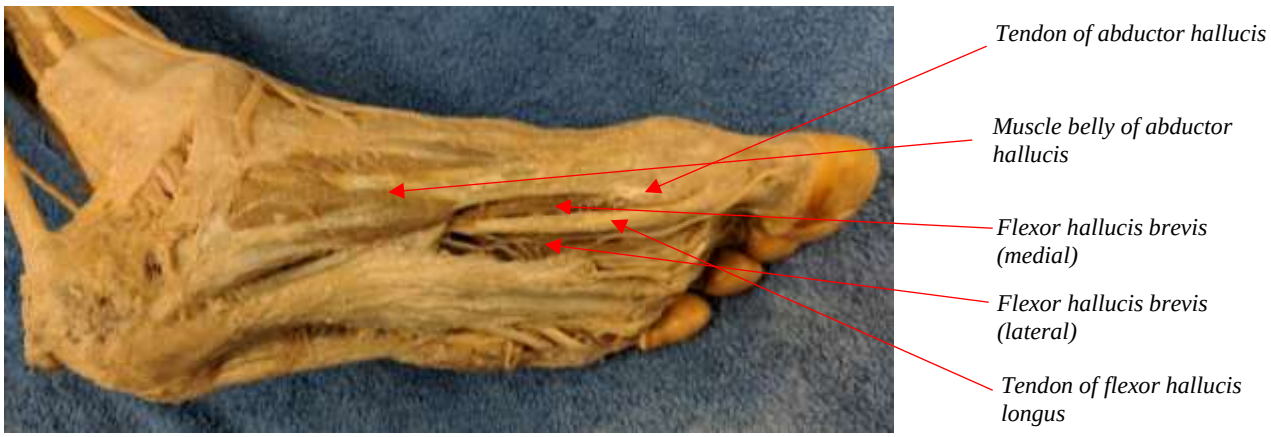



**Figure 1.1:** Medial plantar aspect of the foot, inferior retinaculum removed (source: PJ Latey)

Abductor hallucis has three segments which Tosovic and colleagues hypothesise act differently due to their architecture and contraction time: the most posterior multipennate segment produces the bulk of the force for abducting the great toe whereas the shorter two segments act as stabilisers.[42] The abductor hallucis has the greatest physiological cross-

sectional area (6.68cm²) compared to any other intrinsic muscle [29] and may have fibres blended with flexor hallucis brevis.[34]

Flexor hallucis brevis muscle bellies underlie both adductor hallucis and abductor hallucis muscles proximally,[43] with the lateral head often inseparable from the oblique head of the adductor hallucis at the insertion.[36] (Figure 1.2) This probably contributes to the reported difficulties in identifying the borders of flexor hallucis brevis.[44] (Figure 1.3) An anatomical cadaveric study has shown that the insertion of the oblique head of adductor hallucis attaches to the navicular and aligns with the flexor hallucis brevis lateral fibres 20% of the time.[37]

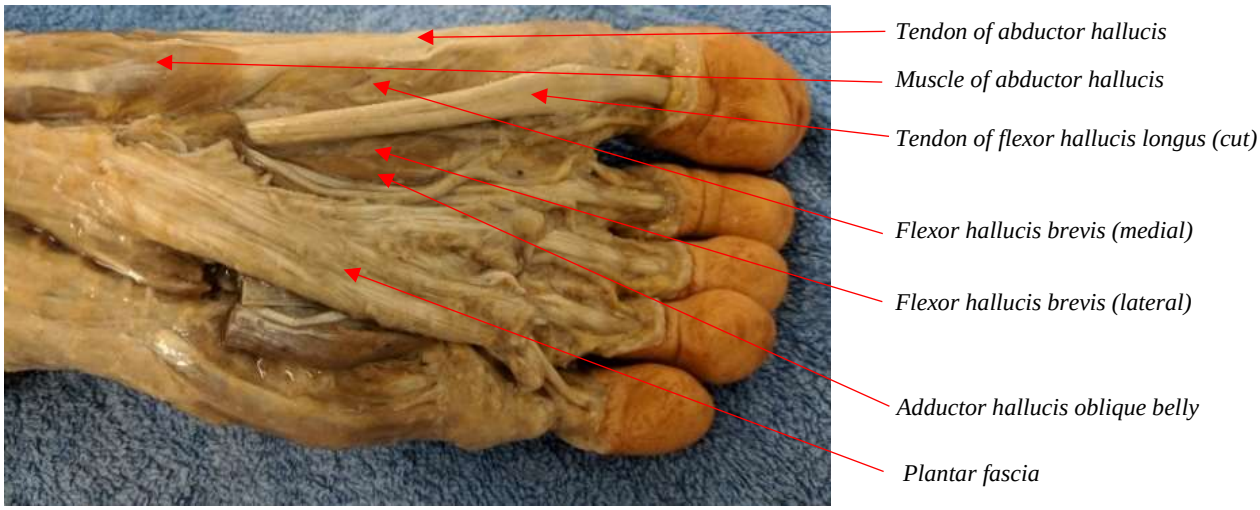



**Figure 1.2**: Planar aspect of the forefoot. (Source: PJ Latey)

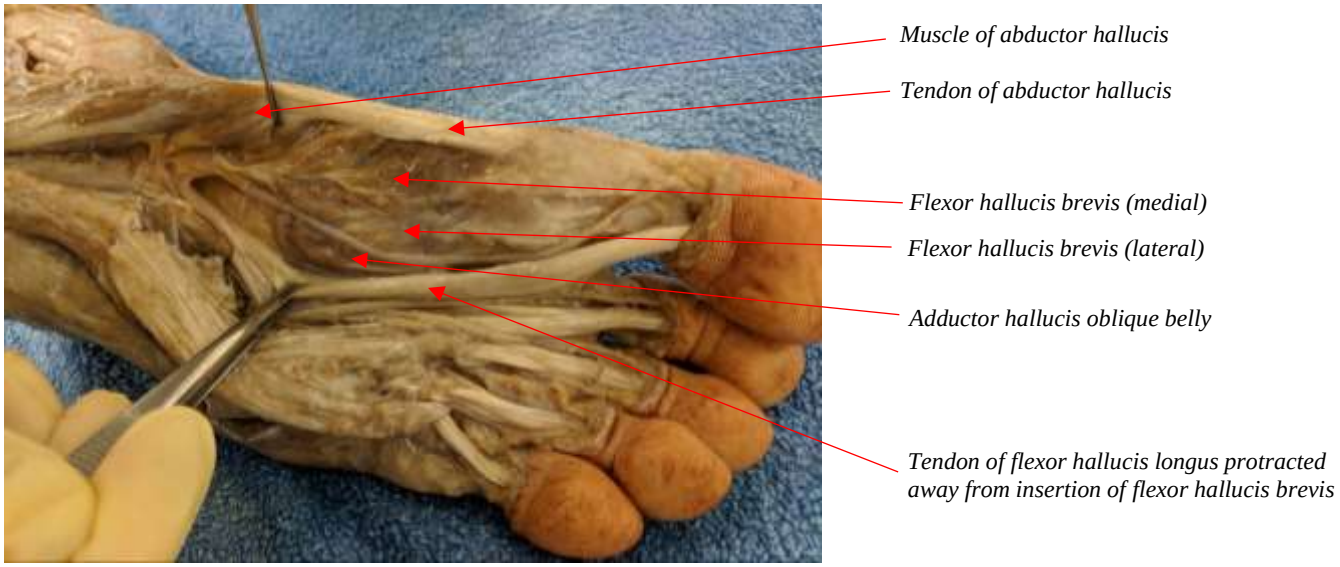



**Figure 1.3:** Plantar aspect of the forefoot, proximal detail of flexor hallucis brevis (source: PJ Latey)

### 1.1.3 Central muscles of the foot

The central foot muscles include *flexor digitorum brevis* (Figure 1.4), the four *lumbricals*, *quadratus plantae*, and three plantar and four dorsal *interossei*.[30, 37] (Table 1.1b) The tendons of flexor digitorum longus run between the divided tendons of flexor digitorum brevis and insert distally to the terminal second to fourth phalanges.[36] Therefore, flexion of the phalanges at their interphalangeal joints is not primarily an intrinsic foot muscle activity due to the distal attachment of the extrinsic muscles. However, as the lumbricals modulate movements of the flexor hallucis longus, flexor digitorum longus and quadratus plantae, they assist by providing directional alignment to the proximal phalanges and initial sensory feedback to ensure intrinsic foot coordination.[45] In addition, the quadratus plantae displays a high degree of fibre variation[36, 46] and variability in its pattern of attachment.[47]

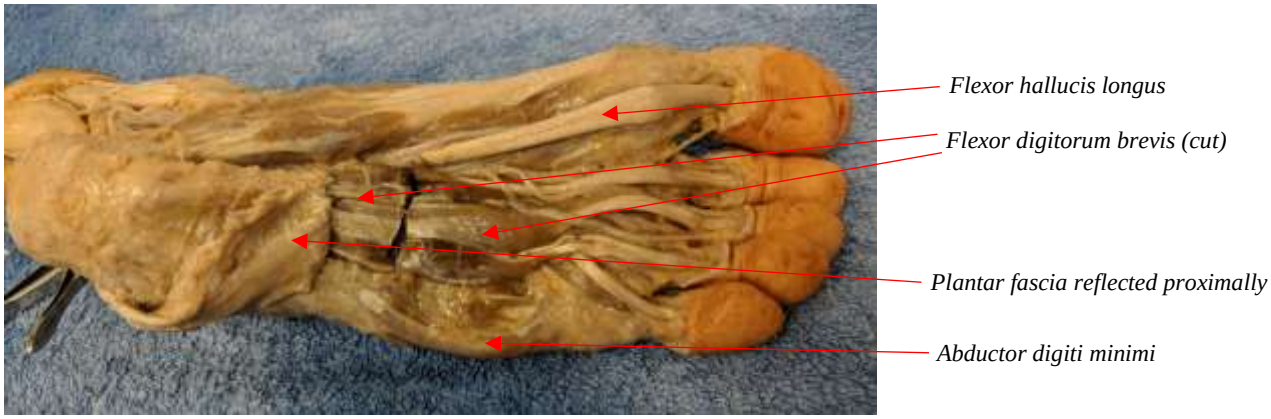



**Figure 1.4**: Plantar aspect of the foot. (Source: PJ Latey)

### 1.1.4 Lateral muscles of the fifth digit

The *abductor digiti minimi* is the longest muscle of the fifth digit (Figure 1.4). The *flexor digiti minimi brevis* merges with the abductor digiti minimi.[30] (Table 1.1c) The *opponens digiti (minimi)* or *quinti*, may be absent.[30] If present, atrophy is significantly associated with advancing age, calcaneal spur, and plantar fasciitis.[48] This muscle group displays a high degree of variability,[36] with an overlapping fifth toe thought to be a congenital deformity.[49]

### 1.1.5 Dorsal muscles of the foot

Unlike the plantar intrinsic foot muscles, those on the dorsum of the foot have few variations. Some individual tendons may be absent in e*xtensor digitorum brevis* and an occasional fifth digit slip has been reported.[30, 39] *Extensor hallucis brevis* (also called the extensor digitorum brevis to the first toe) may have an accessory medial head to the second toe.[36] (Table 1.1d) (Figure 1.5)

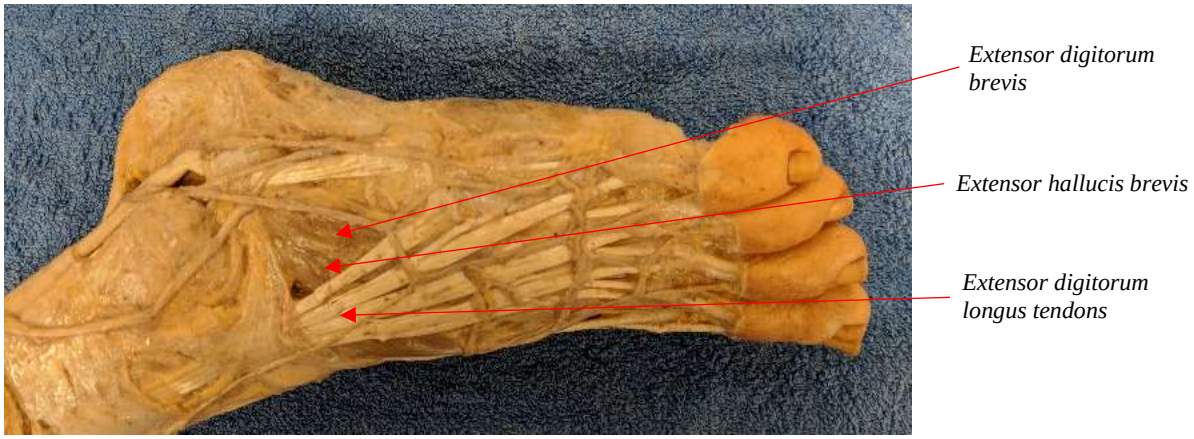



**Figure 1.5**: Dorsal lateral aspect of the foot (Source: PJ Latey)

### 1.1.6 Anatomical relationships between the extrinsic and intrinsic muscles

Our understanding of the actions of the intrinsic foot muscles can be informed by observing the various direct fascial interconnections with the extrinsic foot muscles (Table 1.2). Some intrinsic and extrinsic foot muscles act synergistically to articulate and stabilise the foot due to their direct anatomical connections.

**Table 1.2** Extrinsic foot muscles with interconnections to intrinsic foot muscles

| Extrinsic muscle | Action | Interconnection with intrinsic muscle |
|---|---|---|
| Anterior extrinsic foot muscles of the lower limb - Innervation: deep peroneal nerve | | |
| Tibialis anterior | Dorsiflexes foot at the ankle;<br>Supinator and stabiliser of the medial longitudinal arch [30] | None |
| Extensor hallucis longus | Dorsiflexes foot at the ankle [30] | None |
| Extensor digitorum longus | Dorsiflexes foot at the ankle [30] | Extensor digitorum brevis is incorporated on the lateral aspect of the extensor digitorum longus at the phalanx<br>Contraction of both muscles is considered a single action [36] |
| Peroneus tertius (tendon) | Aids dorsiflexion and foot pronation<br>Can be absent | Extension to extensor digitorum longus [36] |
| Lateral extrinsic foot muscles of the lower limb - Innervation: superficial peroneal nerve | | |
| Peroneus longus | Pronates the foot<br>Aids plantarflexion. Assists in stabilising the lateral longitudinal arch [30] | Oblique head of adductor hallucis originates from the mid-section of the peroneus longus tunnel<br>1st dorsal interossei usually arises from a slip from peroneus longus. Some fibres of flexor hallucis brevis insert on peroneus longus tendon groove [36] |
| Peroneus brevis | Pronates the foot, aids plantarflexion<br>Assists in stabilising the lateral longitudinal arch [30] | None |
| Peroneus quartus | Aids dorsiflexion and foot pronation<br>Frequently absent[36] | None |
| Superficial posterior extrinsic foot muscles of the lower limb - Innervation: tibial nerve | | |
| Soleus | Plantarflexes ankle | None |
| Gastrocnemius | Plantarflexes ankle | None |
| Plantaris | Aids plantarflexion | None |
| Deep posterior extrinsic foot muscles of the lower limb - Innervation: tibial nerve | | |
| Tibialis posterior | Plantarflexes ankle<br>Supination (non-weight-bearing) [30] | Medial part directly attaches to navicular bone<br>Lateral part inserts into three cuneiform bones.<br>This tendon forms the medial arm of the Y-shaped origin of flexor hallucis brevis and origin of the first lumbrical [36] |
| Flexor digitorum longus | Plantarflexes great toe<br>Assists supination<br>Supports the arch of the foot [30] | All four lumbricals may arise from tendon of flexor digitorum longus, or only 2nd, 3rd, 4th lumbricals [36]<br>Flexor digitorum brevis and flexor digitorum longus have shared synovial sheath at their insertion site [30] |
| Flexor hallucis longus | In non-weight bearing plantarflexes the digits then the foot, acts as a supinator<br>In weight bearing - assists in support of the plantar arch [30] | Quadratus plantae may arise from the tendon of flexor digitorum longus and flexor hallucis longus [50]<br>Tendon origin of 1st lumbrical and transverse head of adductor hallucis are connected to flexor hallucis longus [36] |

The interconnectedness of these muscles (Table 1.2) makes it challenging to isolate intrinsic from extrinsic muscle force with current measuring techniques. However, it is notable that, of the muscles of the first ray, abductor hallucis has no extrinsic muscle connections, while the flexor hallucis brevis and adductor hallucis have multiple connections with extrinsic foot muscles. Even so, abductor hallucis does have fibrous connections with the common tunnel of the flexor digitorum longus and the flexor hallucis longus tendons and is also adherent to the tunnel of the tibialis posterior tendon.[36] The extrinsic foot muscles of the first ray include: extensor hallucis longis, flexor hallucis longus, tibialis posterior, tibialis anterior, and peroneus longus muscles.[51] Aside from the first lumbrical, no intrinsic foot muscles directly attach to the first metatarsal. The first lumbrical, along with the transverse head of the adductor hallucis, may strengthen the connection between the first and second metatarsals.

The first metatarsal head sustains the greatest force during the push-off phase in gait.[52] Any movement restriction or problem in the great toe impacts normal function of the whole foot.[53] Therefore, the short great toe flexor muscles, abductor hallucis and flexor hallucis brevis play an important role maintaining functional gait, guiding plantarflexion of the great toe and supporting the first ray. In addition, the range of attachments and accessory muscles suggest, as in other parts of the musculoskeletal system, a large range of alternate preferential muscle sequences or compensatory processes can be activated to maintain normal function, upright stance and gait.[54, 55] Therefore, variable compensatory muscle sequencing contributes to difficulties in determining the strength of the intrinsic foot muscles and appropriate interventions for intrinsic foot muscle weakness.

### 1.1.7 Evolution of the foot muscles

Humans are the only bipedal primate with a highly modified foot which has adapted and changed during evolution from other primates.[56] The modified foot is characterised by: loss of plantar grip, loss of prehensile capacity, medial translation of the functional axis from the third digit ray to the second and most notably, loss of mobility of the first ray which has become adducted against the second toe.[57, 58]

Changes in some of the intrinsic foot muscles are evidence of the development from quadruped to bipedal gait. It has been hypothesised that humans evolved two hands from two of the feet.[59] However, a refutation of this hypothesis is that the quadratus plantae has no analogous muscle in the hand. Quadratus plantae has two heads: the small lateral head is present in other mammals; the large medial head arises from the medial surface of the calcaneus and is unique to humans.[60] In humans, the two heads unite at an acute angle and end in a flattened band inserting into the posterior surface of the tendons of flexor digitorum longus. It has been postulated that the quadratus plantae has an important evolutionary role related to the ability to evert the foot.[61] Some disagree, suggesting this muscle has little if any role in eversion, its prime role being to support flexor digitorum longus.[47] The high degree of fibre variation in the quadratus plantae[46] and variability in its pattern of attachment makes the role of this muscle unclear.[47]

The adductor hallucis may also have modified during evolution to upright stance. The oblique head of the adductor hallucis stabilises the transverse tarsal joint in stance phase and is considerably more developed than the transverse head. Arakawa and colleagues[37] hypothesise that, since the great toe does not need to be opposed to grasp, the transverse head of adductor hallucis is evolutionarily degenerative in humans.

Development of short toes evolved in the genus *Homo* around 2 million years ago. Humans have short pedal phalanges in relation to body size compared to other primates. Modern human forefoot proportions might be selected as part of a suite of morphological and behavioural adaptations for endurance running.[62] It has also been proposed that the lateral side of the hominin foot evolved first, to stabilise mid-tarsal flexibility as an adaptation to increased terrestriality, and the medial side followed.[63]

The first ray and medial longitudinal arch have changed the most dramatically in alignment and aspect in human striding bipedal gait.[64] The first ray is the most heavily loaded ray of the forefoot with the first metatarsal head sustaining up to 119% of body weight during propulsion.[52] Therefore, first ray (Figure 1.6) intrinsic muscle strength and control is of particular importance to the role of the modern foot.[65]

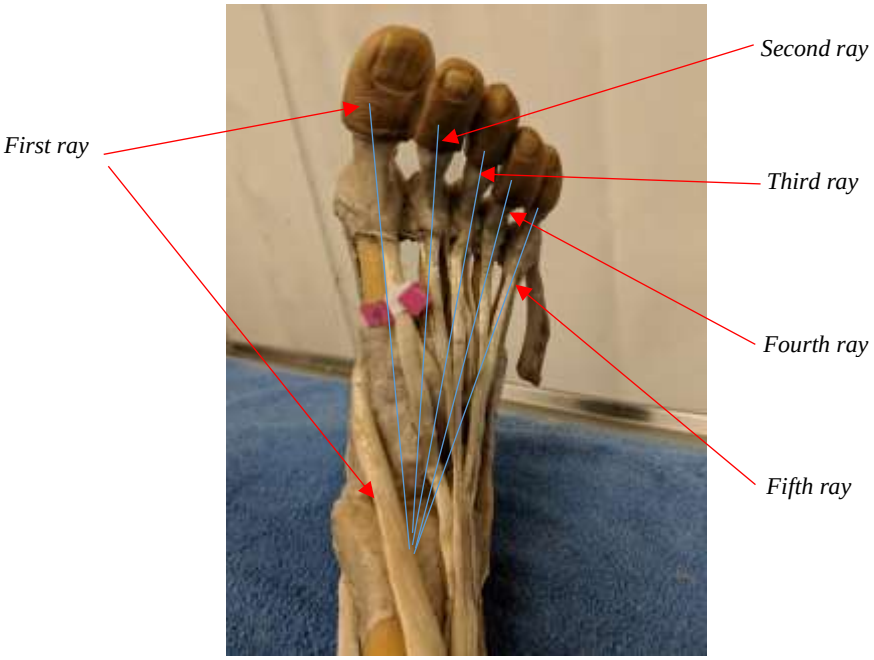



**Figure 1.6**: The rays of the foot, comprised of each phalange, metatarsal and related tarsal bone, all terminating at the calcaneus. (Source: PJ Latey)

## 1.2 Foot muscle function

The intrinsic foot muscles help maintain the alignment of the medial longitudinal arch (Figure 6) during static balance and dynamic tasks[66-68] and assist in the gait cycle.[36] Foot muscle activity also helps distal blood flow and venous return.[69]

### 1.2.1 Medial arch height, balance and dynamic activities

Intrinsic foot muscle strength contributes to maintaining the height of the medial longitudinal arch, balance and dynamic activities. The height of the medial longitudinal arch is, in part, controlled by the intrinsic foot muscles, [68] which help maintain foot alignment. The abductor hallucis muscle acts as a dynamic elevator of the medial longitudinal arch, [34] with arch height lowered by intrinsic foot muscle fatigue.[67] Therefore, change in arch height could be considered a predictor of intrinsic foot muscle activity and strength. However, evidence of the relationship between arch height measures, foot strength and dynamic function is inconsistent.[70-72]

Toe flexion strength has been shown to be an important determinant of balance, with toe flexion weakness related to reduced single leg balance time in older people,[73, 74] increased postural sway and reduced functional ability in older adults.[8, 14] The abductor hallucis, flexor digitorum brevis and quadratus plantae muscles increase in activity with increasing postural demands and help maintain balance in a medial-lateral direction.[68] Improvement in static and functional balance tasks, and decreased arch deformation, have been achieved with intrinsic foot muscle strength training.[21] As arch deformation increases during dynamic activities such as stair descent,[75] controlling arch height may also help maintain balance during dynamic activities. Intrinsic foot muscle activity assists in regulating leg stiffness during rapid

rhythmic activity, such as hopping.[76] Other dynamic movements, such as jumping performance, improve with increased toe flexor strength.[77-79] Since improvement in static and functional balance tasks, and decreased or controlled arch deformation, have been achieved with intrinsic foot muscle strength training, [21] maintaining intrinsic foot muscle strength is important for many static and dynamic activities.

### 1.2.2 Gait

The intrinsic foot muscles assist in the gait cycle and are synchronously active during walking.[80] A study of muscular activity using electromyography of the abductor digiti minimi, abductor hallucis, extensor digitorum brevis, flexor digitorum brevis and flexor hallucis brevis showed these intrinsic foot muscles were inactive during the initial part of the stance phase of the gait cycle and active in the latter half of the stance phase.[81]

The intrinsic foot muscles help dissipate load during the stance phase.[31] Reports from motion capture studies suggest that the foot transfers into a more stable configuration during mid-stance for initial and final propulsion[82] with intrinsic foot muscle activity facilitating efficient foot–ground force transmission during locomotion.[83] Intrinsic foot muscle activity provides fine-tuning control and assistance with propulsion.[84] Even so, foot movement during the gait cycle varies from person to person[54] with this variation reflected in the conflicting findings regarding first ray instability.[85] However, any restriction of movement or pathology affecting muscles of the first ray, such as hallucis rigidus or severe hallux valgus,[86] impacts normal function of the whole foot,[53] with strength in the first ray essential in the toe-off phase during walking.[87]

Walking speed in younger adults has been correlated with the cross-sectional area of flexor digitorum brevis and abductor hallucis muscles and toe flexor strength.[88] Diminished toe

flexor strength has also been correlated with compromised gait[89] and an increased risk of falling in older adults.[8] These findings confirm the importance of intrinsic foot muscles in maintaining efficient gait, particularly with ageing.

### 1.2.3 Venous return

The small foot muscles assist in distal venous return due to the convoluted and intermuscular course of the plantar veins.[90] Blood is expelled from the foot during stance by weight-bearing compression of the plantar veins in combination with muscular contractions around these veins with a directional flow from deep to the superficial plantar veins between the muscles of the foot.[91] These different foot pump mechanisms are likely to be active at slightly different points in the stance phase of the gait cycle.[69] Movement of the first metatarsophalangeal (MTP) joint leads to compression and emptying of the plantar veins. The connection between the first MTP joint capsule and veins indicates a 'toe–ankle pump', rather than a foot-ankle pump, with a significant increase of venous blood flow during motion of the MTP joint.[92] Thus, motion of the great toe is of particular importance for distal blood flow. Specific exercise movements that increase the toe-ankle pump may improve intrinsic foot muscle quality and foot health.

## 1.3 Measuring intrinsic foot muscles

Numerous measures and procedures have been used to determine intrinsic foot muscle characteristics. These include measuring toe flexion force, muscle activity, and muscle volume or cross-sectional area. Dynamic and static tests are used individually and in combination with various foot alignment measures such as the height of the medial longitudinal arch and the Foot Posture Index to characterise the foot.

### 1.3.1 Force measures

Methods of measuring foot muscle strength include toe flexor force collected with a hand-held or externally stabilised dynamometer, load cell or strain gauge,[93-96] customised toe grip device,[97] plantar pressure platform,[98-100] or the paper grip test.[101, 102] (Figures 1.7, 1.12, 1.13 and Chapter 3 Figures 2-3) These tests require the participant to flex or press down onto the measuring device with the great toe individually, the lesser toes, or all the toes either at the metatarsophalangeal joint with the interphalangeal joint kept straight or with additional interphalangeal joint flexion to grip the device.

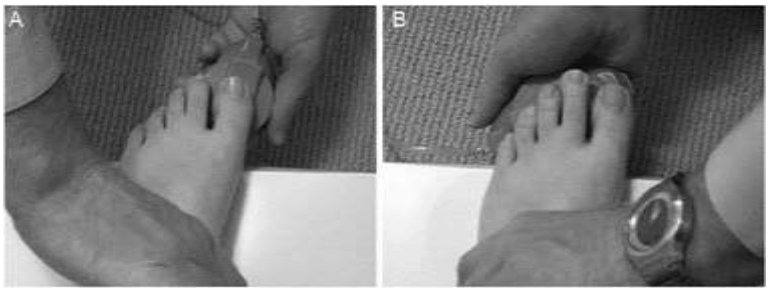



**Figure 1.7**: Hand-held dynamometry measuring toe flexion force of the great and lesser toes [4]

There are contrasting results for hand-held dynamometry in the literature with both good [93, 95] and poor reliability reported.[103, 104] This may in part be due to the use of different test positions, which have included sitting,[105] standing [4] and supine.[95] Various supported foot, lower limb and leg positions have been explored to evaluate any change in foot muscle forces using a customised toe flexion dynamometer,[106] strain gauge[107] and toe grasping or gripping devices [108, 109] in part to minimise the contribution of extrinsic foot muscles during toe flexion. A custom device to measure toe flexion strength in individuals with plantar fasciitis has been reported to have excellent reliability ICC 0.99.[96] Similarly Ridge and colleagues develped a fixed toe flexion measuring device and a novel doming strength test,[108] with intra and inter rater reliability ranging from ICCs 0.71 to 0.99 for both devices (Figure 1.12).

However, the anatomical structure, with the extrinsic foot muscles inserted distal to the intrinsic foot muscle, mean it is likely that toe gripping is primarily reliant on extrinsic foot muscle strength.

Plantar pressure platforms have been used to determine toe flexor strength and report excellent reliability, with standing considered a more reliable position than sitting (ICCs sitting 0.89, 95%CI 0.86 to 0.92; standing 0.92, 95%CI 0.84 to 1.00).[98, 99] Although the paper grip test was originally developed for patients with leprosy, [101] it has been validated against a pressure platform for measuring toe flexor strength in healthy adults,[98] and in diabetics with peripheral neuropathy.[110]

Unfortunately, many of these toe flexion tests do not entirely exclude extrinsic foot muscle activation.[56, 101] Toe flexion may be achieved with a range of movement tactics, such as flexion at the interphalangeal joints, flexion at the metatarsophalangeal joints, elevation of the medial longitudinal arch and supination of the foot, and approximating the foot towards the ankle, with both the intrinsic and extrinsic muscles contributing to the movement.[30, 36] Therefore, while completely differentiating between intrinsic and extrinsic foot muscle is impossible in a clinical setting, identifying and focusing attention on the small muscles of the foot needs to be taken into consideration when implementing toe flexion to ensure the small foot muscles are the prime movers during this activity.

### 1.3.2 Muscle activity measures

Electromyography (EMG) assesses muscle activity with surface or invasive intramuscular electrodes.[111] Surface EMG using electrodes placed mid abductor hallucis showed a decreased medial arch height when the muscle activity of the abductor hallucis was ablated[66]

and when the muscle was fatigued, [67] and highlights the important contribution of the abductor hallucis muscle in maintaining the medial longitudinal arch. Muscle imbalance in the intrinsic muscles has been observed in those with hallux valgus, using surface electrodes to record action potentials occurring in muscles underlying the skin, with abductor hallucis reduced in abduction, compared to adduction with adductor hallucis in those with hallux valgus.[112] Drawbacks in the use of surface EMG include amplitude cancellation, crosstalk between muscles and spatial variability, [113] potentially limiting reliability and validity of this measure.

Ultrasound guided intramuscular (needle) EMG of plantar intrinsic foot muscles has shown increasing synchronised recruitment of the abductor hallucis, flexor digitorum brevis and quadratus plantae in response to medial postural sway.[68] One of the few studies examining the reliability of fine wire and surface EMG of the lower limb muscles, has reported EMG values to be highly variable for gastrocnemius (ICC values <.40) or negative for tibialis anterior and peroneus longus, in people with rheumatoid arthritis. This suggests that the use of EMG to monitor muscle activity in people with inflammatory musculoskeletal diseases should be used with caution.[114] In addition, needle EMG only records the activity of the muscle fibril it is directly inserted into, not the whole muscle, and may not be a true measure of the whole muscle contraction.[115]

### 1.3.3 Muscle morphology – cross-sectional area and volume measures

Cross-sectional area imaging using computerised tomography (CT),[116] magnetic resonance imaging (MRI)[117] or ultrasound[118] is used to measure muscle size or morphology and enables measurement of specific muscles and foot regions. CT is highly accurate,[119] but the gold

standard for measuring muscle cross-sectional area is high-resolution T1-weighted MRI.[5] Muscle quality, physiological cross-sectional area[120] or volume.[121] can be measured by MRI. The quality of intrinsic foot muscles has been established using MRI, using a 5-point scale ranging from healthy to indistinguishable.[122] MRIs of the foot can be evaluated according to muscle groups,[123] regions,[84] or by dividing the foot into two (forefoot and hindfoot at 50% truncated foot length[5]) or three (forefoot, midfoot and hindfoot[117]) sections (Table 1.3). Although MRI and CT have a high level of accuracy,[124] their cost and lack of portability render them prohibitive in the clinical setting.

Ultrasound is a non-invasive, non-ionising and relatively inexpensive method of assessing muscle morphology. Similar to MRI, muscle quality or echo intensity can be used to determine the levels of fat infiltration in muscle and is assessed by computer-aided grayscale analysis with values determined by an index of arbitrary units, ranging between 0 (black) and 255 (white) increasing fat infiltration.[125, 126] Ultrasound has been reported to have good reliability for measuring the thickness and cross-sectional area of the abductor hallucis (ICC = 0.79-0.98),[127] and excellent reliability for measuring the cross-sectional area of the abductor hallucis, flexor hallucis brevis, flexor digitorum brevis, quadratus plantae and abductor digiti minimus  with ICC values ranging from 0.83 to 0.99.[7, 118, 128]

However, ultrasound cross-sectional area values of the lower limb is dependent on position,[129] with significant differences reported between supine, prone and standing ultrasound, and with significant increases in cross-sectional area of abductor hallucis and flexor digitorum brevis in the standing position.[130] Furthermore, there is a high level of variability of measures between cross-sectional area with MRI and volumetric measures of the forefoot, compared to measures of abductor hallucis and flexor digitorum measured by ultrasound (Table 1.3). This suggests that measuring muscle cross-sectional area with

ultrasound and developing different scanning positions warrants further exploration, to ensure accuracy of the specific muscles measured. New scanning positions and ultrasound techniques and their association with measures of muscle strength are discussed in further detail in chapter 3.

**Table 1.3** Literature review of cross-sectional area values for abductor hallucis and flexor hallucis brevis by ultrasound and MRI

| Author | Equip ment | Population gender | Age (years) | CSA AbH Mean ± sd (cm²) | Transducer alignment/region | CSA FHB Mean ± sd (cm ²) | Transducer alignment/region |
|---|---|---|---|---|---|---|---|
| Abe [88] | US | Sports active adults (17w, 17m) | 20-35 | 2.46±0.77 | Medial hindfoot, inferior to medial malleolus | N/A | |
| Angin [131] | US | Normal foot (49) | 23±4 | 2.75±0.34 | Medial hindfoot, inferior to medial malleolus | 2.97±0.46 | Plantar, proximal forefoot thickest portion |
| | | Pronated foot+8 (49) | 24±6 | 2.36±0.47 | | 2.66 ±0.46 | |
| Battaglia [130] | US | Non/weight-bearing | 25.5±4 | 2.47±0.93 | Thickest portion from medial calcaneus distally towards the 1st metatarsal | N/A | |
| | | Weight-bearing (17w, 9m) | | 2.60±0.91 | | | |
| Lobo [23] | US | Healthy adults no HV (16w, 4m) | 42±12 | 2.74± 0.64 | Medial hindfoot thickest potion between medial calcaneal tuberosity and navicular tuberosity | 2.13±0.65 | Plantar mid forefoot thickest portion |
| | | Healthy adults with HV (18w, 2m) | 46±11 | 2.22± 0.49 | | 1.57±0.41 | |
| Mickle [132] | US | Healthy adults (5w, 5m) | 32±10 | 2.56±0.89 | Medial hindfoot thickest portion between medial calcaneal tuberosity and navicular tuberosity | 2.45±0.53 | Plantar, proximal forefoot thickest portion |
| | | | | 2.45±0.94 | Medial hind foot inferior to medial malleolus | | |
| Zhang [44] | US | Runners; Normal foot (17) | 26±6 | 2.62±0.56 | Medial hindfoot, inferior to malleolus, thickest portion | Unable to determine | |
| | | Pronated foot+ 6.6 (9) | 23±2 | 2.74±0.39 | | | |
| Latey [133] | US | Healthy adults (15w, 6m) | 39±10 | 2.16±0.60 | Medial, mid foot inferior to navicular tubercle thickest portion | 1.44±0.35(M) | Medial-plantar mid metatarsal thickest portion |
| Kura [29] | Muscle volume* | Cadavers (3w, 8m) | | 6.68±2.07 | | 1.80± 0.75 FHB(M)<br>2.12± 0.84 FHBL | |
| | | | | | Total CSA: FHB and AbH | | |
| Green [84] | MRI | Healthy adults (2m) | 27.5 | | 3.00 mean | | Medial foot |
| | | | | | Total CSA : FHB, FDB, Quadratus plantae, lumbricals and AbH | | |
| Kurihara [123] | MRI | Healthy adults (12w, 14m) | 20±2 | | 5.87±1.34 | | Forefoot 20% of Truncated foot length |

Legend: w, woman; m, male; M, medial *PCSA: Dissection, calipers and water displacement

## 1.4 Foot muscle weakness: causes and consequences

Foot muscles are affected by disease, inactivity and ageing.[134] However, determining if foot muscle weakness is causal or consequential to some foot pathologies is challenging, as research is usually undertaken after the onset of deformity or disease. The causes of intrinsic foot muscle weakness include: Charcot-Marie-Tooth disease, diabetes mellitus and chemically induced peripheral neuropathy.[3, 93, 135-137] Other familial or acquired diseases such as muscular dystrophy,[138, 139] polio,[140, 141] brain or spinal cord disorders such as amyotrophic lateral sclerosis,[142, 143] multiple sclerosis,[144, 145] stroke,[146] and arthritis[147] cause muscle weakness. Foot muscle atrophy can be caused by spinal injuries that result in damaged or injured nerves, including severe disc herniation with nerve root involvement[148] and immobilisation treatments post trauma or specific injury to the foot or lower limb.[149, 150] Foot muscle weakness is also caused by age related sarcopenia.[151, 152]

The contributing factors that cause foot muscle weakness are variable and include high levels of pain, [153] moderate to severe toe deformity,[6, 154] ongoing inactivity,[134] and inappropriate footwear.[155] The following sections 1.4.1 to 1.4.5.4 describe the most common causes of intrinsic foot muscle weakness, the consequences and contributing factors linked to foot muscle weakness.

### 1.4.1 Peripheral neuropathy

Peripheral neuropathy causes loss of sensation, paraesthesia, dysesthesia, pain, and muscle atrophy affecting the toes and foot.[156] Peripheral neuropathy associated with diabetes mellitus, Charcot-Marie-Tooth disease and some chemotherapy treatments cause foot muscle weakness, reduced foot muscle volume[3, 93, 135-137] and loss of intrinsic foot motor units.[157]

Diabetic peripheral neuropathy reduces foot muscle volume,[2, 158, 159] with intrinsic foot muscle atrophy present[160] even before the detection of neuropathy and impaired motor function.[137] Plantar muscle density has also been reported to be significantly lower in individuals with diabetes, likely due to fatty infiltration.[161] Half as much lean muscle tissue and twice as much intramuscular adipose tissue volume has been observed in the intrinsic foot muscles of people with diabetes related peripheral neuropathy, compared to controls.[162]

### 1.4.2 Arthritis

Research investigating foot muscle weakness in people living with arthritis is limited; however, osteoarthritis in the great toe has been associated with toe flexion weakness and pain[15] and foot-related disability.[163] Research suggests arthrogenic muscle inhibition is a factor in muscle weakness associated with osteoarthritis.[164] Although arthrogenic muscle inhibition has been primarily studied in the arthritic knee and ankle,[164, 165] it is likely to occur in any joint and may be associated with altered neuromuscular activation patterns around injured joints leading to muscle loss or limited muscle activation.[147] Therefore, foot muscle weakness due to osteoarthritis can be caused by pain, pain avoidance strategies and arthrogenic muscle inhibition.

The majority of those with rheumatoid arthritis report previous or current foot problems.[166] High levels of isolated fatty atrophy of the abductor digiti minimi (quinti) muscle has been reported in people with rheumatoid arthritis.[167] Arthrogenic muscle inhibition has also been reported to prevent muscle activation in those with rheumatoid arthritis.[168] In addition, research on experimentally induced rheumatoid arthritis in animals has found muscle loss associated with skeletal muscle protein breakdown; hence, muscle atrophy is associated with

the disease itself and not simply with decreased mobility.[169] Therefore, foot muscle weakness due to rheumatoid arthritis can be caused by pain, arthrogenic muscle inhibition and composition changes within muscles tissue.

### 1.4.3 Injuries and inactivity

Substantial and rapid loss of muscle mass and volume occur with limb immobilisation.[149, 150] Immobilisation due to casting causes muscle atrophy, with lower limb muscle volume decreased by 16.2 (5.6)%, within 29 days, reduced pennation angle of gastrocnemius with decreased line of force in the muscle,[170] and biochemical changes with anabolic resistance to protein nutrition.[171] Thus, immobilisation results in disuse muscle atrophy arising from biochemical changes in addition to the morphological changes.[170] While these studies investigated extrinsic foot muscles, it is likely that similar changes would occur in the small muscles of the foot.

### 1.4.4 Ageing and sarcopenia

Sarcopenia and increased fat infiltration are a normal part of ageing.[151, 172] Prevalence of sarcopenia in healthy ambulatory community dwelling participants over 45 years has been reported as 9% from 45 years, up to 64.3% for those over 85 years old.[173] Ultrasound measurements of muscle thickness, pennation angle and echogenicity are associated with skeletal muscle strength in the elderly,[174] with ageing negatively affecting muscle mass.[175] Age and gender significantly affect muscle thickness and are associated with fat infiltration.[176] Furthermore the decline in muscle size with aging may be due to the loss of muscle fibres as well as a decline in muscle fibre size, specifically type-II muscle fibres.[177]

Sarcopenia appears to affect the size of the small foot muscles with significant age related differences reported in the thickness of the small foot muscles, measured by ultrasound.[178]

### 1.4.5 Consequences of disease and ageing

The consequences of foot muscle weakness associated with peripheral neuropathy are wide-ranging (Table 1.4). Individuals with diabetic peripheral neuropathy have impaired balance and reduced walking velocity,[179, 180] increased intrinsic foot muscle deterioration, foot deformity and frequent ulceration.[162, 181, 182] Regardless of aetiology, peripheral neuropathy impairs distal sensory and motor ability leading to muscle weakness[183] and limitations in physical function including walking ability, reduced muscle power, endurance and agility.[184, 185]

The majority of people with symptomatic radiographic foot osteoarthritis report foot pain and disability.[186] Intrinsic foot muscle weakness associated with osteoarthritis has also been linked with knee osteoarthritis.[187] People with mid foot osteoarthritis were more likely to report multiple comorbidities, with 65% suffering foot pain.[188]

Almost all people (97%) who have long-standing rheumatoid arthritis report foot pain and disability,[166] with the majority of patients having a foot deformity, the most frequent being hallux valgus (62.5%).[189] Foot problems associated with rheumatoid arthritis, have a moderate to severe effect on quality of life, with the most significant impact, on shoe wear variety and walking ability.[190]

The consequences of foot muscle weakness in older adults (mean age 80.1 SD 6.4 years) is extensive and includes the increasing likelihood of foot-related disability[191] and disabling foot pain.[192] Age-related foot muscle weakness can impair balance and compromise

functional ability.[13, 73, 193, 194] Foot muscle weakness has been significantly associated with increasing falls and compromised or altered gait patterns in older adults.[9-12, 14, 89, 195, 196] Mickle and colleagues found a significant reduction in hallux flexor strength with no difference in quadriceps muscle strength associated with a higher risk of falls.[10] Small foot muscle atrophy in older adults may also contribute to the progression of toe deformities.[7, 10, 197] It has also been reported that toe flexion strength and the cross-sectional area of selected intrinsic foot muscles compared to extrinsic foot muscles are significantly reduced in older adults,[198] suggesting intrinsic foot muscles are particularly vulnerable to muscle loss apart from sarcopenia (Table 1.4).

Some disability or reduced physical function may primarily be caused by a disease itself, such as in peripheral neuropathy and rheumatoid arthritis [156, 166, 183] rather than caused by foot muscle weakness. However, weakness in the small foot muscles is an integral pathophysiological manifestation of many diseases and determining whether the impact on quality of life such as increasing disability is caused by disease or foot muscle weakness remains challenging.

### 1.4.6 Contributing factors

There are numerous contributing factors that cause weakness in the small foot muscles. Some contributing factors can exacerbate the consequences of foot muscle weakness and are linked to a broad range of problems that can reduce physical function.

### *1.4.6.1 Pain*

Foot pain is an unpleasant sensory and emotional experience following perceived damage to any tissue distal to the tibia or fibula.[199] Muscle disuse atrophy can be caused by pain and subsequent pain avoidance strategies,[134] with significant associations reported between severity of pain and magnitude of muscle disuse atrophy.[200] Both toe flexor weakness and reduced cross-sectional area of some small foot muscles are associated with foot pain.[153]

Common causes of foot pain with associated foot muscle weakness and intrinsic foot muscle atrophy include toe deformities such as hallux valgus,[201-203] and plantar fasciitis.[5, 96, 204] However, reduced abductor hallucis cross-sectional area related to hallux valgus is only significant for moderate and severe hallux valgus,[6] and reduced toe flexion strength in people with plantar heel pain could be causal or consequential.[4]

Heel pain or plantar fasciitis[4, 5, 96, 204] has been reported in both non-athletic populations[205] and in runners.[206] Heel pain has also been associated with ageing and a pronated foot posture [207, 208] and is likely to have a significant negative impact on foot-specific and general health-related quality of life.[209]

The experience of pain can be influenced by multiple factors and can affect muscle activity.[210] Psychological factors may contribute not only to the experience of acute pain but also to the development of chronic pain.[211] In addition as pain is bi-directional, ongoing foot pain is likely to exacerbate foot muscle weakness, which could potentially heighten or prolong the experience of pain. Foot pain is therefore a predisposing and maintaining factor in the aetiology of problems related to foot muscle weakness. The association between pain and muscle weakness is more fully explored in Chapter 2.

### *1.4.6.2 Foot and toe deformity*

While the extremes of foot type, pes planus[131, 212] and pes cavus,[213, 214] are associated with foot muscle weakness, detailed study of this area are beyond the scope of this thesis. However, the over-pronated or pes planus foot is associated with foot muscle imbalance and reduced first ray intrinsic foot muscle size.[131] Foot muscle weakness in the pes cavus foot associated with Charcot-Marie-Tooth disease has been reported to limit balance and mobility [215] and reduce quality of life in children.[184] The majority of people with pes cavus experience foot pain, and problems such as metatarsalgia, sesamoiditis and plantar heel pain.[216]

The consequences of foot muscle weakness associated with toe deformities are varied (Table 1.4), and can depend on the severity of the deformity.[154] Toe deformities may contribute to instability and poorer balance, resulting in an increased risk of falling in older people.[217] Osteoarthritis of the great toe is associated with toe flexion weakness.[163] People with hallux valgus and high levels of pain are more likely to have intrinsic muscle atrophy and impaired satisfaction with their health than people who have hallux valgus without pain.[218] As hallux valgus is a highly heritable joint deformity,[219] it is unlikely foot muscle weakness is the initial factor causing the deformity. Since muscle loss related to hallux valgus is only significant for moderate and severe presentations,[6] intrinsic foot muscle weakness may be the consequence of the deformity and also influence progression of the deformity.

### *1.4.6.3 Footwear*

Inappropriate footwear might contribute to foot muscle weakness. Toe flexor weakness and heel pain have been associated with footwear discomfort[220] in older females.[155] While

footwear is frequently implicated in the development of hallux valgus, and associated with foot muscle weakness, supportive evidence is lacking.[221] Interestingly, habitually shod runners transitioning to minimalist shoes show an increase in foot muscle volume primarily in the forefoot.[222] This is discussed in more detail in section 1.5.3.

**Table 1.4:** Summary of evidence of consequences of foot muscle weakness

| Consequence | Problem or population |
|---|---|
| Disability | Plantar heel pain [209] |
| | Older adult [191, 192] |
| Foot deformity | Pes cavus [223] |
| Increased likelihood of foot deformity | Peripheral neuropathy [162, 181, 182] |
| Toe deformity | Hallux valgus [7, 10, 197] |
| Reduced physical function | Older adult [8] |
| Impaired balance | Peripheral neuropathy [179, 180] |
| | Older adult [8, 13, 73, 193, 194] |
| Compromised gait | Hallux valgus [224, 225] |
| | Hallux rigidus [226, 227] |
| | Diabetic peripheral neuropathy [12] |
| | Older adult [8, 89, 195] |
| Increased risk of falls | Toe deformities [225] |
| | Older adult [14, 192] |
| Reduced (health-related) quality of life | Painful hallux valgus [154] |
| | Charcot-Marie-Tooth disease [184, 185] |
| | Older adults [14] |

### 1.4.7 Summary of causes and consequences of foot muscle weakness

The causes of muscle weakness are described with particular attention to: peripheral neuropathy, osteoarthritis, rheumatoid arthritis, ageing, inactivity, foot deformity and footwear. Since the consequences of foot muscle weakness can be disabling, with the quality of life frequently effected, ascertaining the strength of the relationship between foot pain and foot muscle weakness is warranted. If foot muscle weakness is significantly linked with foot pain, determining the efficacy of foot muscle exercises may also contribute to pain reduction and provide new exercise treatment options to reduce functional disability.

## 1.5 Interventions for foot muscle weakness

Foot problems, deformities or systemic diseases with associated intrinsic foot muscle weakness may be managed with a range of therapeutic foot exercises. Foot exercises can be performed in different stances or positions with and without assistive devices or supervision.

### 1.5.1 Foot exercises

Prescribing and teaching the correct foot exercise is challenging due in part to the complexity and density of the anatomy of the foot. While in general it is understood that exercising the feet is beneficial,[228] it is only recently in conjunction with improved techniques for measuring the intrinsic foot muscles, that more muscle specific foot exercises are being trialled. As the anatomy of the foot has been more closely observed and different ways of describing foot movement explored,[55] new ways of understanding the variations of foot articulation and stabilisation strategies for effective foot function are being postulated.[229] This includes an

understanding that there is individual variability in sequential movement strategies within the foot. [54]

When studying foot dysfunction, addressing specific intrinsic foot muscles weakness and not just the larger extrinsic foot muscles should be primary to a treatment plan.[230] Attention to targeting specific foot muscles and the sequencing between activation of various intrinsic foot muscles focusing on control before increasing strength and endurance,[231] is crucial. This is particularly important during musculoskeletal rehabilitation of foot related diseases or deformities, in order to then improve functional skills such as balance and walking. Therefore, a detailed review of the literature on specific foot muscle exercises will inform appropriate clinical treatment and exercise prescription skills.

Foot exercises are commonly performed in the seated position, with variations on the short foot exercise (Figure 1.8) and toe flexion activities such as towel gathering or attempting to pick up small objects (Figure 1.12), frequently prescribed. Foot exercises can be performed in a variety of body postures or stances including: seated with hips and knees at 90°, long sitting with hips at 90° and knees neutral, and standing. The exercises are usually mastered in the supine or seated position before attempting the double leg stance or the more challenging single leg stance, depending on ability. Some positions, such as a plantar flexed foot, are considered to reduce the activation of the extrinsic foot muscles.[106] Foot exercises can be performed with and without assistive or resistive devices, such as stretch bands, weights or custom strain gauges or load cells (Figure 1.13 and Figure 1.14). The following are a selection of foot exercises that have been used in research.

*1.5.1.1 Short foot exercise:*

Performed by approximating the metatarsal heads towards the heel without toe flexion, causing elevation of the arch. (Figure 1.8)The forefoot and heel remain on the ground and is frequently taught with passive remodelling of the foot.[20] It can be performed while sitting with the hip and knees in 90 flexion or in standing. The position is maintained for five seconds.[232]

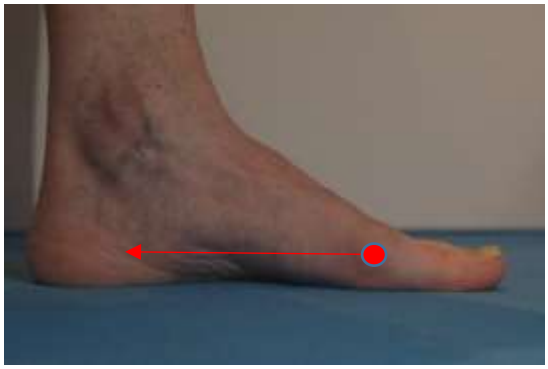


**Figure 1.8**: Short foot exercise (source: PJ Latey)

Jung and colleagues found abductor hallucis activity to be significantly greater during the short foot exercise (Figure 1.8) than during the toe curl exercise in single-leg standing.[35] The short foot exercise has also been reported to improve intrinsic foot muscle performance during static unilateral balancing and functional balance tasks.[21] The exercise position was held for five seconds and was repeated for up to three minutes a day for four weeks (approximately 30 times). The difficulty was increased by starting in sitting and progressing to double leg stand and single leg stance, when the participant was able to perform the exercise correctly.[21] Two studies found the cross-sectional area of the abductor hallucis and great toe flexor strength significantly greater in asymptomatic adults and recreational runners with pes planus after using foot orthoses and practising the short foot exercise compared with individuals who only used foot orthoses.[44, 233] The short foot exercise was performed in one leg stance, finger tips

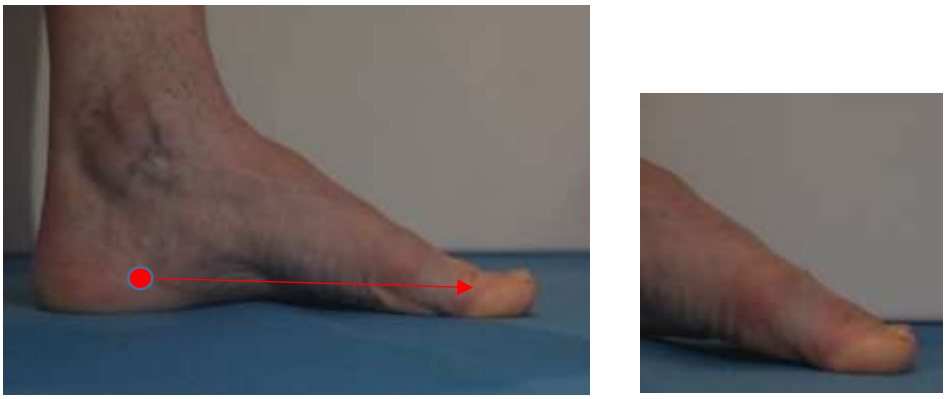
on wall. Initially three sets of five repetitions were performed twice daily, with a holding time of five seconds, if the exercise was performed correctly repetitions were increased up to five repetitions per set, the next progression increased holding time to ten seconds. Participants were monitored weekly for performance precision and regularity of practice for a period of eight weeks.[233]

A comparison of maximal activation of the abductor hallucis during five foot exercises, (short foot, toe flexion, forefoot abduction, great toe abduction, and toe spread out), found the highest activation of the abductor hallucis was with the great toe abduction exercise, followed by the toe-spread-out exercise.[232] This suggests that the short foot exercise primarily activates the mid plantar muscles of the foot. It has been hypothesised that the three segments of abductor hallucis act differently with the most posterior multipennate segment producing the bulk of the force for abducting the great toe whereas the shorter two segments act as stabilisers.[42] Therefore, since the forefoot remains on the floor for the 'classic' short foot exercise, and surface EMG placement was 1-2 cms posterior from navicular, activity of the largest segment of abductor hallucis, which primarily abducts the great toe, may not have been recorded.[42] Even so, activation of the abductor hallucis [234] and flexor digitorum brevis [235] is increased with an inclined ankle during these foot exercises, supporting the hypothesis that the shorter segments of abductor hallucis act primarily as stabilisers.

*1.5.1.2 Foot doming - arch elevating:*

Similar to the short foot exercise, the heel and distal phalanges remain on the ground during the arch elevation while the toes remain long.[108] In contrast to the short foot, the forefoot is elevated as well as the mid foot, and at the metatarsophalangeal joints.[236] The heel is drawn towards the toes, with minimal tibialis anterior activation, in correct foot arch elevating

(Figure 1.9). Foot arch elevation or doming was first proposed by Latey.[237] Common clinical practice is to first perform the exercise under supervision, then practice three to five repetitions in sets for three, increasing to eight repetitions, once or twice per day. However, there is little research on foot arch elevation or doming and it can be mistaken for the short foot exercise.[238]



a) b)

**Figure 1.9**: Foot doming (a), with detail of metatarsophalangeal joints lifting (b). (Source: PJ Latey)

*1.5.1.3 Toe press - flexion of the first metatarsophalangeal joint*:

In the long sitting position with the foot held at the first MTP joint and the ankle remaining in neutral, pressure is applied to the proximal phalanx in the direction of extension (Figure1.10).

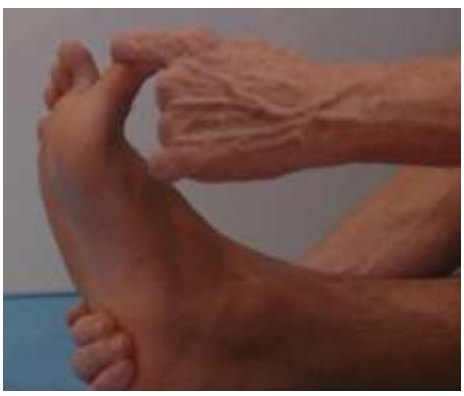


**Figure 1.10**: Flexion of the first MTP joint (source: PJ Latey)

During the procedure resistance is provided by a clinician's finger and can be maintained against the maximal isometric force for five seconds.[232]

A study on osteoarthritis of the great toe reported increased toe flexion strength and reduced pain post this great toe flexion exercise intervention. The toe flexion task was performed with the assisting clinician providing direction and resistance as above, plus home practice.[15] During the first three visits, 10 isometric great toe flexion (contractions) were performed with a holding time of 10 seconds each. During the last nine visits, five sets of eight repetitions of the great toe isotonic strengthening were performed with 12 seconds rest between each set. The isometric great toe contractions were also performed at home three times a day, 10 repetitions for a 10 second hold, with the floor being the resistance. Treatment was provided three times per week for four weeks.[15] However, as the intervention was multifaceted; with sesamoid mobilisation, gait retraining as well as toe flexion strength exercises, it cannot be determined which intervention was most successful in increasing toe flexion strength.

*1.5.1.4 Toes spread out exercise:*

There are two toe spread out exercises reported. During both, the toes are spread with the forefoot and phalanges flared medially and laterally. The exercise is usually performed seated in a chair. The toes are spread and heel raised, the heel is then lowered to the ground increasing the medial longitudinal arch and held for 5 secs[232] and is similar to heel raises with weight bearing on toes while seated.[17] Nagai and colleagues included this exercise in a foot exercise program which comprised: alternate heel and toe lifting, towel gathering, bean bag transfer as well as weight bearing on toes. The intervention lasted eight weeks with practice performed daily of 20 repetitions twice, for the alternate heel toe lifting exercise.[17]

Another toe spreading exercise is performed by keeping the foot flat on the ground then lifting all the toes while keeping the metatarsal heads and heel on the floor, then pushing the fifth toe down towards the lateral direction and pushing the great toe down towards the medial direction, slowly spreading the toes.[239] (Figure 1.11)

The second toe spread out exercise has been shown to result in greater activation of the abductor hallucis compared to the short foot exercise, and may help to balance the ratio of abductor hallucis and adductor hallucis activity in those with mild hallux valgus.[239] It has been reported to increase the cross-sectional area of the abductor hallucis in participants with mild to moderate hallux valgus when participants practiced the toe spread out exercise for 20 minutes per day, four days per week with supervision for one day per week, for eight weeks after two days training for a total of two hours under supervision.[19] However, the need for high levels of supervision may limit its clinical application.

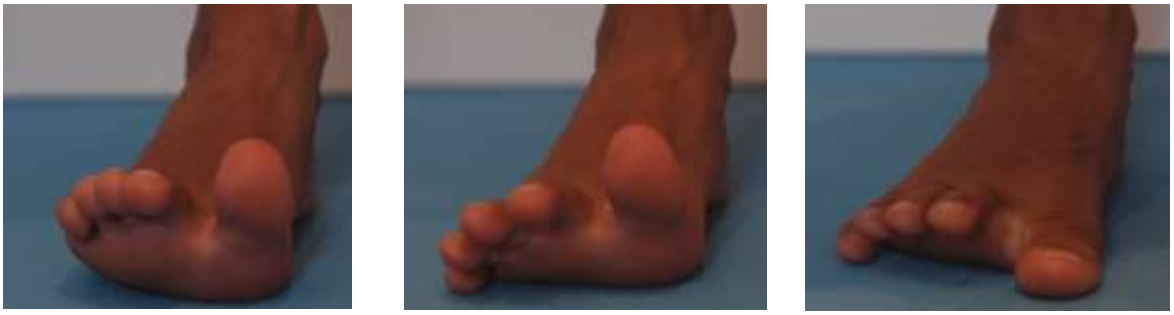


**Figure 1.11**: Toes spread out

a) Lifting b) Fifth toe down c) Great toe down

(source: PJ Latey)

Abduction of great toe, forefoot adduction and alternate heel and toe lift have also been reported to be effective.[232] The abduction of the great toe has been reported to activate the

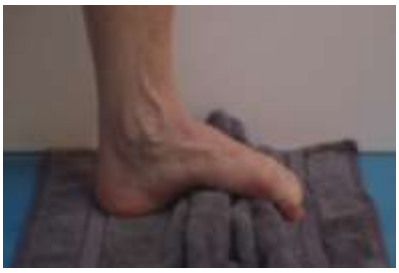
abductor hallucis muscle more than the short foot exercise.[232] Even so, performing the toes spread out and great toe abduction can be challenging, with separate toe extension or abduction of the great toe requiring high skill levels.

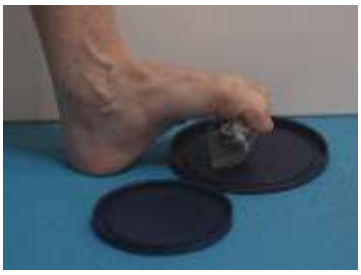
### 1.5.2 Toe flexion exercises with devices

Toe flexion strength exercises are based on the action of flexing all of the toes through all the phalangeal joints. They may be performed with or without clinician support or with an assistive device. Some versions of this exercise minimise or stop flexion at the metatarsophalangeal joints, other versions include metatarsophalangeal joint flexion.

#### *1.5.2.1 Toe flexion grasp:*

In the toe flexion grasp exercise with towel gathering,[228] bean bag transferring[17] and marble lifting,[240] (Figures 1.12 a, b, c) the toes are allowed to curl under, towards the plantar aspect of the foot. For the towel curl exercise, a towel is placed under the foot to be tested. The person is asked to slowly curl the toes and gather the towel beneath the foot with interphalangeal (IP) and metatarsophalangeal (MTP) flexion of their toes,[35] lift and transfer a beanbag, or pick up a marble.





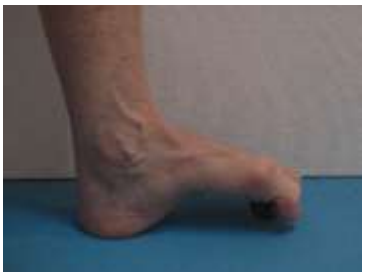


**Figure 1.12:** Toe grip exercise
a) Towel gathering b) Beanbag transfer c) Marble lift
(source: PJ Latey)

These exercises have been part of a supervised training program of foot and ankle strength in sitting and have been effective in improving some aspects of muscle strength (including toe flexion strength), physical function and quality of life in the elderly.[17] The intervention lasted eight weeks with practice performed daily of: 20 repetitions twice of alternate heel and toe lifting, completely gathering the towel five times on both feet or for those who could not gather the towel attempting to for five minutes, bean bag transfer of 10 bean bags of 30 grams each into a basket, and weight bearing on toes 20 times, twice.[17]

A similar foot exercise intervention performed at home, reported no difference in the foot strength of participants however the homework adherence was very poor.[240] Toe grasp exercises that include picking up objects require a similar action to using a custom toe grasp dynamometer.[241] Due to the more distal anatomical insertions of the extrinsic foot muscles, flexor hallucis longus, and flexor digitorum longus, compared to flexor hallucis brevis and flexor digitorum brevis, it is most likely that the toe grasp exercises recruit the extrinsic foot muscle more than the intrinsic foot muscles, as the metatarsophalangeal joints flex along with all the phalanges. It is also noticeable that the tibialis anterior tendon is taut and suggesting that muscle is highly active, probably assisting to elevate the medial longitudinal arch.

*1.5.2.2 Toe flexion or gripping with custom strain gauges and devices:*

Toe flexion or gripping exercises are also performed with a range of custom resistance devices (Figure 1.13). These devices may limit ankle or lower leg movement.[108, 242]

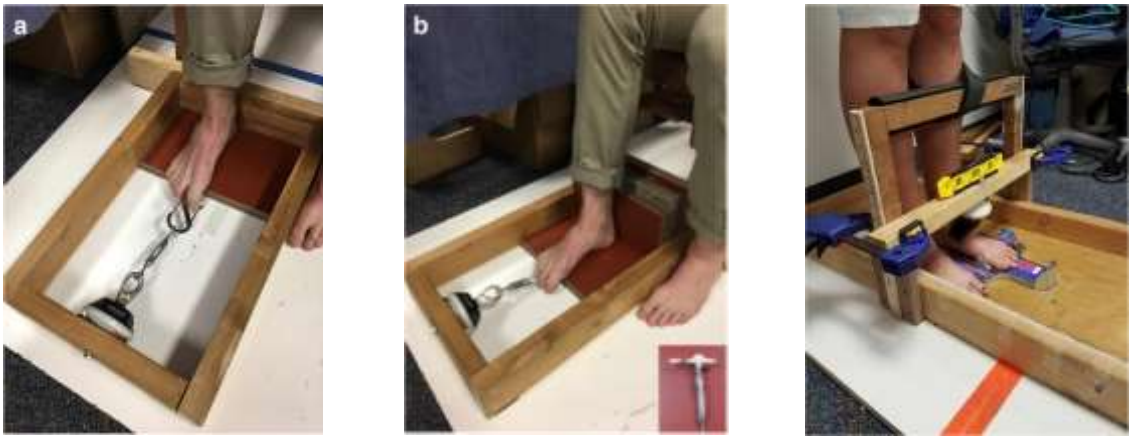



**Figure 1.13:** Ridge and colleagues testing toe flexion and doming strength [108]

Toe grip strength training with a custom resistance device has been reported to significantly improve foot muscle strength scores, foot arch shape and movement performance,[16] with the physiological cross-sectional area of the flexor digitorum brevis moderately associated with a 4-toes flexion task.[88] Toe grip strength training has been completed in different positions such as standing, seated, knees at 90° as well as straight legged seated.[241, 243, 244] A study in the long seated position with the hips at 90° and both bare feet in maximum plantarflexion, the toe interphalangeal and metatarsophalangeal joints were stabilised and then flexed against a 3kg load (Sanko Seikohjyo Co., Ltd., Tokyo, Japan), performed 200 reps once per day for 8 weeks.[16] This study found this resistance exercise significantly increased toe flexion strength. However study participants were twelve healthy males aged 29±5 years old with high levels of fitness and this regime may not be applicable to other populations.

Since these toe grasp or gripping devices all cause the foot to strongly flex at the mid phalangeal and metatarsophalangeal joints, due to the anatomical relationship between the intrinsic and extrinsic muscles, extrinsic foot muscle activation would contribute substantially to the completion of this task. These devices require a movement comparable to the toe grasp task with towel gather or toe picking up objects, however the individual is able to exert variable amounts of force on these devices, which may make them more useful in a research

context, although the quality of the movement or foot muscle control is not monitored, but may be restricted or stabilised with ankle strapping (Figure 1.14).

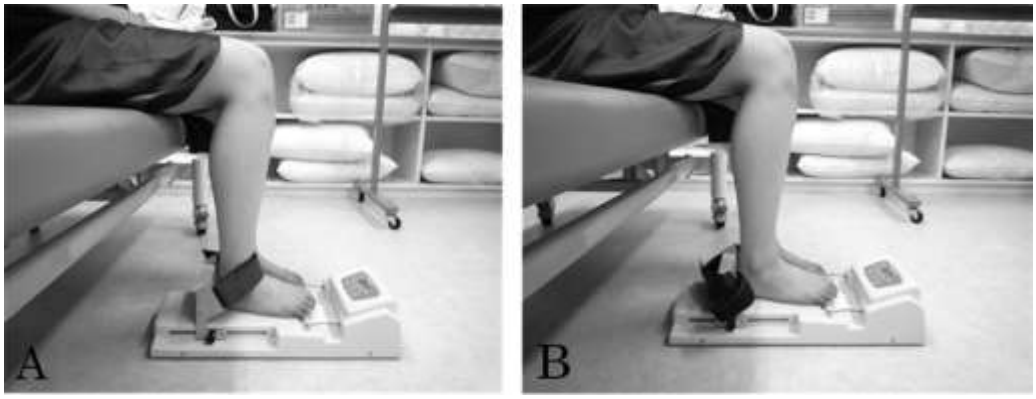



**Figure 1.14** A comparison between toe grip strength with and without ankle stabilisation [242]

### 1.5.3 Foot muscle exercise for the fit - running and minimalist shoes

Wearing minimalist shoes while running may provide exercise for the small foot muscles. Bare foot or minimalist running has been reported to increase forefoot muscle volume.[222] Similarly, the cross-sectional area and thickness of the abductor hallucis has been reported to increase after training programs in minimalist five-toe shoes compared to traditional shoes.[245, 246] Using minimalist shoes during running may increase the volume or size of some intrinsic foot muscles in adults,[247] but injury is a risk associated with transitioning too quickly to minimalist footwear.[245] There is some disagreement in the field and the mostly low quality studies currently reported show that no definite conclusions can be made regarding their safety and efficacy.[248]

### 1.5.4 Limitations to foot exercise

There are several limitations to exercise treatment. Currently, minimal evidence-based training is available for clinicians, and there is limited access to appropriate exercise

prescription providers. Foot orthosis are the commonly accepted treatment for foot pain.[249] Too frequently, implementation of regular prescribed foot exercises is low. This may be due to poor compliance with maintaining home practice [240] as well as difficulty in performing foot exercises correctly. The few studies that have reported successful foot exercise interventions for those with problems or pathologies associated with foot muscle weakness, have all included supervised practice.[15, 19, 233] Even though supervised exercise can help strengthen the foot compared to unsupervised exercise in older adults, [250] the cost of face-to-face treatment plans, initial supervision and ongoing guidance reduce the availability of appropriately targeted foot exercise interventions.

Exercise home practice adherence is affected by the consistency, duration, quality of performance and perceived difficulty.[24] Factors affecting exercise adherence include forgetfulness, and motivation.[25] However, additional motivating factors including feedback can improve exercise adherence in balance training and post stroke gait, or sit-to-stand transfers in older patients.[26]

Biofeedback has been used to assist in retraining movement patterns after injury or an illness associated with compromised neuromuscular function,[27] including post stroke.[28] A home based video game stepping program has been found to improve gait and balance in older adults.[251] Adherence for this home program was high, measured digitally as well as from self-report surveys at the end of the intervention period, with only one participant out of the 16 not completing the intervention.[251] This suggests that biofeedback with a device providing both data saving and reviewing capabilities may encourage home exercise adherence.

Maintaining the correct foot alignment and muscle recruitment patterns are challenging in a home setting. Often pain avoidance strategies compromise muscle recruitment as people with

lower limb or foot injuries decrease the load on the injured limb and reduce general physical activity.[134] For some people, performing very specific exercises is difficult due to poor motor skills.[252] Ensuring correct foot alignment as well as care with the choice of exercise and 'dose' while exercising at home is important. Accurate guidance of muscle recruitment is crucial, as this assists those with poor motor control, minimises pain avoidance strategies and engages the specific muscles to be targeted for improved skill acquisition to increase intrinsic foot muscle strength.

The performance skill required for foot exercise efficacy noted in this review of the literature informed the choice of exercise to be performed in the trial on the foot exercise device evaluated in this thesis. Since an EMG study of healthy people noted that abductor hallucis was unable to be consciously activated in 19% of normal people, [253] deliberate performance of arch elevation with toes spread, with tactile and visual biofeedback on arch movement may improve abductor hallucis activation. In addition, as performance skill and adherence is difficult, it was decided to use one specific manoeuvre that incorporates foot doming and toe spreading with elongated mid phalangeal and metatarsophalangeal flexion, arch doming heel to toe, when testing the device. See Chapter 4 and Chapter 5 for details of exercise selection and outcomes of this trial.

## 1.6 Summary of Chapter 1

This chapter describes the foot musculature and the evolution of the modern foot. The function of the intrinsic foot muscles is then evaluated. Measurement procedures are described and the difficulties in isolating the intrinsic foot muscles from actions of the extrinsic foot muscles are also discussed. The causes and consequences of foot muscle weakness are reviewed and the significance of foot musculature in pain and disability. It identified the importance of intrinsic foot muscle exercise for treatment. Foot exercise interventions are appraised, with performance skill and practice adherence determining their efficacy.

## 1.7 Aims of thesis

The aims of the work presented in this thesis are to:

- Conduct a systematic review to evaluate the relationship between foot pain and foot muscle weakness, or muscle size as a proxy for weakness (Chapter Two).
- Assess the reproducibility of measuring the size of the abductor hallucis muscle and the medial belly of the flexor hallucis brevis muscles using ultrasound measures, and identify their relationship with toe flexion strength, foot morphology and balance (Chapter Three)
- Develop and construct a novel biofeedback medical device, known as ‘Archie’ (patent number PCT/AU2016/050437) (Chapter Four).
- Investigate the feasibility of using ‘Archie’ to provide biofeedback of correct arch movement and foot location during four foot exercises (Chapter Five).

## 1.8 Significance

Ageing, disease and inactivity are causes of foot muscle weakness, resulting in foot deformity, disability and reduced quality of life. These diverse problems are frequently linked to pain. Exercise is known to improve muscle weakness but can be limited by difficulty maintaining performance skill and low adherence to practice. Adherence to home exercise programs may be improved with precise movement guidance for explicit muscle recruitment and motivational support. The studies conducted in this thesis on measuring and managing foot muscle weakness may provide a solution to this health burden.

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# CHAPTER TWO

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## Relationship between foot pain, muscle strength and size:

## a systematic review

# PREFACE

In Chapter 1 the causes and consequences of foot muscle weakness were identified, including a relationship between pain and muscle loss. Since foot pain is common and disabling, and thought to be associated with muscle weakness. Understanding the relationship between pain and foot weakness will help identify effective treatment targets.

The aims of this chapter was to conduct a systematic review to evaluate the relationship between foot pain and foot muscle weakness, or muscle size as a proxy for strength.

**Dissemination of research**

The study in this chapter has been published in the *Journal of Physiotherapy*, which has an impact factor of 3.010.

**Latey PJ.** Burns J. Hiller CE. Nightingale EJ. Relationship between foot pain, muscle strength and size: a systematic review. *Physiotherapy* 103(1):13-20, 2017. doi:10.1016/j.physio.2016.07.006

The abstract of this study has been published in the *Journal of foot and ankle research*

**Latey, P. J**., Burns, J., Hiller, C., & Nightingale, E. J. (2014). Relationship between intrinsic foot muscle weakness and pain: a systematic review. *Journal of Foot and Ankle Research, 7*. doi:10.1186/1757-1146-7-S1-A51

This study has been presented as a poster presentation

**Latey, P. J**., Burns, J., Hiller, C., & Nightingale, E. J. Relationship between intrinsic foot muscle weakness and pain: a systematic review.

4th Congress of the International Foot and Ankle Biomechanics (i-FAB) Community Seoul, South Korea. April 2014

# AUTHORSHIP STATEMENT

The co-authors of the paper *'Relationship between foot pain, muscle strength and size: a systematic review'* confirm that *Penelope Jane Latey* has made the following contributions:

Conception and design of the research

Collection and extraction of data

Analysis and interpretation of the findings

Drafting and revising of the manuscript and critical appraisal of content

As the primary supervisor for the candidature upon which this thesis is based, I can confirm that the above authorship attribution statement is correct.

Professor Joshua Burns

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Systematic review

# Relationship between foot pain, muscle strength and size: a systematic review

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**Abstract**

**Background** Foot pain is common and disabling and thought to be associated with muscle weakness. Understanding the relationship between pain and weakness may help identify effective treatment targets.
**Objectives** To conduct a systematic review to evaluate the relationship between foot pain and foot muscle weakness, or muscle size as a proxy for weakness.
**Data sources** Electronic databases and reference lists were searched for all years to April 2015.
**Eligibility criteria** Full-text articles were retrieved based on the question 'Does the study evaluate an association between foot pain and foot muscle weakness or size?'
**Data extraction and synthesis** Two reviewers independently screened eligible studies, extracted data and completed a methodological rating.
**Results** Eight studies were identified evaluating the relationship between foot pain and foot muscle strength ($n = 6$) or size ($n = 2$). Four studies reported a significant relationship between pain and toe flexor force. One study reported a significant relationship between heel pain and reduced forefoot muscle size. One study reported an inconsistent association depending on measurement technique. One study reported no association between pain and hindfoot muscle size. One study reported no association between low to moderate pain and toe flexion force.
**Limitations** Due to data heterogeneity, no data were pooled for meta-analysis.
**Conclusion** There is evidence of a significant association between foot pain and muscle weakness when foot pain is of high intensity and primarily measured by toe flexion force. However there is inconsistent evidence that lower intensity foot pain is associated with other measures of foot muscle weakness or size.

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*Keywords:* Pain; Foot; Muscle strength; Skeletal muscle weakness; Muscle size; Systematic review

## Introduction

Foot pain has been reported to affect 14–42% of the adult population [1–3]. Foot pain is disabling and has been reported to compromise important day to day functional tasks such as walking, stair ascent and descent [4]. Both foot muscle weakness and foot pain can lead to poor balance as well as increasing the risk of falls in older adults [5]. Foot pain is associated with various foot deformities and pathologies that have also been linked to foot muscle weakness, such as hallux limitus, hallux valgus, and plantar fasciitis/plantar heel pain [6–10].

The cause–effect relationship between foot pain and foot muscle weakness is bidirectional. One theoretical model of pain-related inactivity has been largely based on the fear

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avoidance model [11]. While inactivity can cause reduced muscle strength, there are inconsistent links between inactivity or deconditioning among individuals with chronic pain relative to pain-free controls [12]. However, the opposite has also been proposed whereby weakness of muscles that assist in supporting the medial longitudinal arch of the foot may lead to excessive strain on other arch supporting structures, namely, the plantar fascia resulting in plantar heel pain [13]. Further, muscle weakness has also been associated with voluntary activation failure and poor antagonist co-activation in other clinical populations [14,15]. Overall, while there is a commonly held clinical opinion that muscle atrophy occurs in the presence of pain, the exact mechanism is complex and multifactorial.

Strength measures of the foot are commonly used clinically to assess toe flexion, ankle dorsiflexion and plantarflexion as well as foot inversion and eversion power. Devices used to measure foot strength include hand–hand dynamometry and similar strain gauges, load cells, plantar pressure systems and the paper grip test [16–20]. The validity and accuracy of these techniques are generally well-established [17,19,21].

However foot muscle strength is reliant on both intrinsic and extrinsic foot muscles, and due to the architecture of the foot and limitations of measuring techniques, the measurement of intrinsic strength in isolation is difficult, if not impossible [22]. Indeed toe flexor strength measures do not entirely differentiate between the force generated by the intrinsic and extrinsic foot muscles because many of the intrinsic and extrinsic muscles follow similar muscle lines of action and have adjacent insertions, particularly in the forefoot [18,23].

One alternative is the use of imaging to quantify muscle size, as a proxy measure of strength. Imaging the cross-sectional area (CSA) or volume of muscles can distinguish between the intrinsic and extrinsic foot musculature. Measuring muscle CSA or volume using MR imaging has been reported to be highly accurate and reliable [22,24]. Similarly, measuring CSA with real-time ultrasound of abductor hallucis, flexor hallucis brevis, flexor digitorum brevis, quadratus plantae and abductor digiti minimus muscles has also been reported as reliable [25]. However while imaging has been reported to have a high correlation with direct measures of muscle force, reduced muscle CSA cannot fully explain muscle weakness [26–28].

Given the high prevalence of unresolved chronic foot pain, the aim of this systematic review was to evaluate the relationship between foot pain and foot muscle weakness, as well as muscle size as a proxy for strength, to help identify potential targeted treatment approaches.

## Methods

This systematic review was conducted according to the PRISMA statement [29].

### *Data sources and searches*

A comprehensive search of electronic databases (MEDLINE, CINHAL, AMED, AgeLine, Scopus, SPORTDiscus, Web of Science) was conducted for all available papers to April 2015. The search strategy is available in online supplement Figure 1. Reference lists of all full text reviewed papers were hand-searched to identify any additional studies.

### *Study selection*

Titles and abstracts of all identified records were assessed independently by two reviewers (PJL and EJN). Clearly ineligible papers were rejected from further analysis. Eligible full-text articles were retrieved for detailed evaluation according to the following screening question: 'Does the study examine or evaluate an association between foot pain and foot muscle weakness or size?' The exclusion hierarchy consisted of the following terms: duplicate or thesis, not an original study (review paper), no foot muscle weakness/strength measures, no foot pain measures, no association between foot muscles and pain reported (Online supplement Figure 2). Any inconsistencies regarding inclusion of studies were resolved by a third reviewer (CEH).

### *Data extraction and quality assessment*

The following data were extracted independently by two reviewers (PJL and EJN): publication details (author, year), sample characteristics (age, gender, height, weight), inclusion and exclusion criteria, study methodology (study design, outcome measures, statistical tests) and results. Authors were contacted for incomplete data.

Studies were assessed for methodological quality using a modified Quality Index Tool [30] independently by two reviewers (PJL and EJN). Any disagreements remaining after a consensus meeting were resolved by a third reviewer (CEH). The Quality Index Tool has been shown to have high internal consistency and inter- and intra-rater reliability [30]. A subset of the Quality Index Tool was used, depending on whether the items were relevant to the type of study (Online supplement Figure 3). The original scale consists of 27 items. Nine items were ruled not applicable for the assessment of cross-sectional studies (items 4, 8, 13, 14, 17, 19, 23, 24 and 26) as they relate specifically to intervention studies. For single group studies a further three items were ruled not applicable (items 5, 21 and 22). Items 9 and 27 were considered not relevant for all studies (losses to follow up and power calculations) and were omitted from the study. The omitted items were removed from scoring. One item [20] assessing the validity and reliability of outcome measures was expanded into four separate items due to the variability of these measures and the subsequent effects on the accuracy of the outcomes. To allow comparisons between

the categories of studies and adjusting for the varying total items scored, the results are presented as percentage scores.

*Data synthesis and analysis*

Quality assessment was only used to evaluate the findings of papers in a descriptive manner rather than to cull papers. Studies with equivalent pain methodologies and foot strength measures were considered for meta-analysis if the pooled data had moderate heterogeneity [31]. A narrative synthesis of the findings from the included studies was structured around the various measures used to determine any relationship between foot pain and foot muscle weakness/size.

## Results

A total of 10,170 records were retrieved by the electronic database search. After removal of duplicates 6539 were screened. A further five studies were identified by hand searching reference lists of the final papers identified. Of the final 34 full papers examined, eight papers were deemed eligible for inclusion and data extraction [6,8,10,13,20,32–34] with one author contacted for further data [20] (Online supplement Figure 2).

*Quality assessment and risk of bias*

Quality assessment scores ranged from 55 to 85% (mean 74%) with six of the eight studies assessed as being of high quality, scoring >75% (Table 1). The majority of studies clearly reported participant inclusion/exclusion criteria and procedures for measuring foot pain, muscle strength or muscle size. However, not enough information was given to ascertain the reliability of the measurements in two studies [6,33]. External validity was only fair, with the proportion of those asked who agreed to participate not stated [6,8,10,13,20,32–34]. Internal bias was high with the assessor not blinded to the majority of procedures and measures [6,10,13,20,32,34].

*Study characteristics*

The total number of participants from the eight studies was 1023. Sample size ranged from eight [8] to 312 participants [32]. Two studies matched age and gender between symptomatic and asymptomatic participants [10,33]. Participants exhibited a variety of foot pain aetiologies including non-specific foot pain [33], disabling foot pain in older adults [32], osteoarthritis of the first metatarsophalangeal joint (OA of the 1st MTPJ) [34], painful hallux limitus [6], painful hallux valgus [20] and plantar heel pain (including plantar fasciitis) [8,10,13]. Age ranged from 22 to 86 years, with the youngest mean age being 33 years (SD 5.8) [6] and the oldest mean age being 71 years (SD 6.5) [32] (Tables 2 and 3).

Table 1
Methodological quality assessment scores of the included studies(Modified scale based on Downs and Black 1998).

| Studies | Items | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 a | 20 b | 20 c | 20 d | 21 | 22 | 23 | 24 | 25 | 26 | % |
| Allen *et al.* 2003 [10] | 1 | 1 | 1 | N/A | 2 | 1 | 1 | N/A | 0 | 0 | 0 | N/A | N/A | 0 | 1 | N/A | 1 | N/A | 1 | 1 | 1 | 1 | 1 | 1 | N/A | N/A | 1 | N/A | 80 |
| Chang *et al.* 2012 [8] | 1 | 1 | 1 | N/A | 1 | 1 | 1 | N/A | 1 | 0 | 0 | N/A | N/A | 1 | 1 | N/A | 1 | N/A | 1 | 1 | 1 | 1 | 1 | 1 | N/A | N/A | 0 | N/A | 80 |
| Hurn *et al.* 2014 [20] | 1 | 1 | 1 | N/A | 2 | 1 | 1 | N/A | 1 | 0 | 0 | N/A | N/A | 0 | 0 | N/A | 1 | N/A | 1 | 0 | 1 | 1 | 1 | 1 | N/A | N/A | 1 | N/A | 75 |
| Mickle *et al.* 2011 [32] | 1 | 1 | 1 | N/A | 0 | 1 | 1 | N/A | 0 | 1 | 0 | N/A | N/A | 0 | 0 | N/A | 1 | N/A | 1 | 0 | 1 | 1 | 1 | 1 | N/A | N/A | 1 | N/A | 65 |
| Munteanu *et al.* 2012 [34] | 1 | 1 | 1 | N/A | N/A | 1 | 1 | N/A | 0 | 1 | 0 | N/A | N/A | 0 | 0 | N/A | 1 | N/A | 1 | 1 | 1 | 1 | N/A | N/A | N/A | N/A | 1 | N/A | 75 |
| Schmid *et al.* 2009 [33] | 1 | 1 | 1 | N/A | 0 | 1 | 1 | N/A | 1 | 0 | 0 | N/A | N/A | 1 | 1 | N/A | 1 | N/A | 1 | 0 | 0 | 1 | 0 | 0 | N/A | N/A | 0 | N/A | 55 |
| Shamus *et al.* 2004 [6] | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 0 | 1 | 0 | 1 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 76 |
| Sullivan *et al.* 2015 [13] | 1 | 1 | 1 | N/A | 1 | 1 | 1 | N/A | 1 | 1 | 0 | N/A | N/A | 0 | 1 | N/A | 1 | N/A | 1 | 1 | 1 | 1 | 1 | 1 | N/A | N/A | 1 | N/A | 85 |

Items were scored as 'yes': (score = 1), 'no' (score = 0) and 'unable to determine' (score = 0), with the exception of item 5 which was scored from 0 to 2 (0 = 'no', 1 = 'partial', 2 = 'yes'), or 'N/A' not applicable.

Table 2
Summary of participant characteristics, levels of pain intensity, duration and toe flexion strength measures, and the main findings.

| Study | Participants | Pain intensity or frequency | Pain duration | Muscle strength measures | Main finding |
|---|---|---|---|---|---|
| Allen *et al.* 2003 [10] | $n=20$ heel pain aged 45 (SD 9) yrs, 80%♀ $n=20$ controls aged 43 (SD 8) yrs, 80%♀ | Binary: Yes/No | 20 (SD 33) mths | Strain gauge (N): Great toe flexion | Heel pain: 88 (SD 40) N vs controls: 135 (SD 61) N ($P<0.05$) |
| Hurn *et al.* 2014 [20] | $n=60$ painful hallux valgus aged 51 (SD 15) yrs, 88%♀ (No control) | 0–100 VAS Average: 19 (SD 18) mm Worst: 40 SD(29) mm | >4 wks | Load cells (N): Toe flexion Paper grip test: Great toe & lesser toe flexion | Univariate correlation between toe flexion [61(SD 28) N] and: Average pain: $r=-0.10$, $P=0.43$ Worst pain: $r=-0.10$, $P=0.44$ Univariate correlation between Paper grip test and: Average pain: Mean Difference 13 mm, $P=0.002$ Worst pain: Mean Difference 26 mm, $P=0.003$ |
| Mickle *et al.* 2011 [32] | $n=312$ generalised foot pain aged 71 (SD 7) yrs, 49%♀ split analyses: | Frequency of participants with disabling pain (Manchester Foot Pain and Disability Index): a. Pain some days/most days: 50% b. Pain on most/every day: 26% | Not reported | Pedobarophraphy (N): Great & lesser toe flexion | a. Great toe flexion Pain group: 13 N (range 1–14) vs Controls: 15 N (range 13–16) ($P<0.05$) Lesser toes $P>0.05$ b. Great toe flexion Pain group: 12 N (range 10–13) vs Controls: 14 N (range 13–15) ($P<0.05$) Lesser toes Pain Group: 9 N (range 8–10) vs Controls: 11 N (range 10–11) ($P<0.05$) |
| Munteanu *et al.* 2012 [34] | $n=151$ painful 1st MPJ OA aged 55 (SD 11) yrs, 37% ♀ (No control) | Foot Health Status Questionnaire (0–100): 57 (SD 19) | 40 (SD 36) mths | Pedobarophraphy (kg): Great toe flexion | Univariate correlation between great toe flexion [5 (SD 3) kg] and Pain intensity ($r=-0.035$, $P=0.341$) |
| Shamus *et al.* 2004 [6] | Randomised controlled trial: [a]Exp Group: $n=10$ painful hallux limitus aged 33 (SD 6) yrs, 75%♀ (Controls $n=10$) | 0–10 Verbal Pain Scale: 7 (SD 2) | Not reported | Dynamometer (kg): Great toe flexion | a. Great toe flexion: Exp: pre rx 2 (SD 1) kg post rx 5 (SD 2) kg ($P<0.001$) b. Pain Exp: pre- 7 (SD 2) post-rx 0 (SD 1) ($P<0.001$) |
| Sullivan *et al.* 2015 [13] | $n=202$ heel pain aged 55 (SD 14) yrs, 65%♀ $n=70$ controls aged 48 (SD 17) yrs, 60%♀ | Binary: Yes/No | Median 10.0 (IQR 4–24) mths | Dynamometer (N): Great & lesser toe flexion | Great toe flexion Heel pain: 152 (SD 35) N vs controls: 168 (SD 35) N ($P=0.047$) Lesser toe flexion Heel pain: $114.5\pm27.4$ N vs control: 127 (SD 26) N ($P=0.032$) |

*Notes*:
[a] Exp: experimental group data included only; rx: post intervention.

Table 3
Summary of participant characteristics, levels of pain intensity, duration and muscle size measures, and the main findings.

| Study | Participants | Pain intensity | Pain duration | Muscle size measure | Main finding |
|---|---|---|---|---|---|
| Chang *et al.* 2012 [8] | $n = 8$ heel pain aged 44.9 + 8.4 yrs, 88%♀ Control: Other limb | Revised Foot Function Index (0–10): 6.5 + 3.9 | Pain > 3mnths | MRI volume ($cm^3$): forefoot, hindfoot, whole foot | Forefoot volume ($cm^3$) Heel pain: 63.4 $cm^3$ vs controls: 67.5 $cm^3$ ($P = 0.03$) No difference for hindfoot or whole foot ($P > 0.05$) |
| Schmid *et al.* 2009 [33] | $n = 80$ generalised foot pain aged 48 (range 20–86) yrs, 54%♀ $n = 80$ controls aged 48 (range 23–84) yrs, 54%♀ | Binary: Yes/No | Not reported | MRI cross-sectional area ($cm^2$): hindfoot | No significant difference in mean cross-sectional area between foot pain and control groups ($P > 0.05$) Large variability of muscle size across all $n = 160$ |

*Meta-analysis*

A meta-analysis was considered by pooling data from Allen *et al.* [10] and Sullivan *et al.* [13]. Pooled data demonstrated substantial heterogeneity ($I^2 = 70\%$, $chi^2 = 3.32$, $P = 0.07$) [31] and with only two studies able to be compared, a meta-analysis was not conducted.

*Pain measures*

The assessment of foot pain varied between studies. Three studies simply reported the presence or absence of pain [10,13,33]. Four studies assessed pain severity utilising a 10 or 100 point visual [8,20,34] or verbal analogue scale [6]. Pain severity ranged from 18.8 (SD 17.7) [20] on a 100 point scale to 6.8 (SD 1.6) [6] on a 10 point scale. Hurn and colleagues also determined average and worst pain over the previous four weeks [20]. Mickle *et al.* [32] examined the frequency of disabling foot pain in older adults utilising two definitions from the Manchester Foot Pain and Disability Index (MFPDI). Definition A was disabling foot pain either on some days or most day(s) and Definition B was disabling foot pain on most or every day(s). Three studies reported duration of pain ranging from, on average 4 to 40 months [10,13,34].

*Muscle strength measures*

Six studies evaluated foot muscle strength using a toe flexion task (Table 2). Munteanu *et al.* asked participants to maximally flex each hallux against a MatScan pressure platform (Tekscan, South Boston, MA, USA) in a seated position to measure hallux flexion force [34]. Similarly, Mickle and colleagues, asked participants to maximally flex each hallux or the lesser toes onto an Emed pressure platform (Novel GmbH, Munich, Germany) both in seated and standing [32]. The remaining four studies measured toe flexion in sitting using a type of hand-held dynamometer or strain gauge, namely a custom mounted 'mini-weighter' [10]; modified pinch gauge (B&L Engineering, Santa Fe, CA, USA) [6]; hand-held dynamometer (J Tech Commander PowerTrack II J Tech Medical, Salt Lake City, UT, USA) [13]; or a custom mounted load cell (GK 2126-50, Gedge Systems, Melbourne, Australia) to measure great toe flexion and adduction with the participant's leg braced at 30° [20]. One study also used the paper grip test to measure great and lesser toe flexion strength [20].

*Muscle size measures*

Two studies used MR imaging to measure CSA [33] or volume [8] as a proxy for muscle strength (Table 3). Schmid *et al.* examined fatty muscle atrophy at the hindfoot (abductor digiti minimi, flexor digitorum brevis, abductor hallucis and quadratus plantae) captured in line with the bony insertion of the tibiocalcaneal ligament. Slices were taken in the coronal plane mid talocrural joint using T1-weighted (repetition time msec/echo time msec, 572/14; section thickness, 3–3.5 mm) and T2-weighted (4139/86; section thickness, 3–3.5 mm) images [33]. Chang and colleagues evaluated T1-weighted images of the entire length of the foot acquired perpendicular to the plantar aspect of the foot using a spin-echo sequence (repetition time = 500 ms, echo time = 16 ms, averages = 3, slice thickness = 4 mm, gap between slices = 0 mm, field of view = 120 mm × 120 mm, flip angle = 90°, matrix = 512 × 512). They assessed the hindfoot and the forefoot muscles separately, defined by dividing the foot at 50% of truncated foot length, as well as the total foot, determined by adding the forefoot and hindfoot together [8].

*Associations between foot pain and foot muscle weakness or size*

Five studies reported a significant relationship between foot pain of various aetiology, and reduced toe flexor force [6,10,13,20,32] and one study reported a significant relationship between forefoot muscle size and heel pain [8] (Tables 2 and 3). Of these, two studies reported both positive and no association between pain and weakness depending on muscle strength measure or MRI region of interest [8,20]. The majority of studies reporting higher pain levels by participants (mean >6/10 or equivalent on a numerical rating scale) reported an association with foot muscle weakness or size [6,8,32]. Of the studies reporting a longer pain duration

(minimum three months), three studies demonstrated an association between toe flexion and foot pain [8,10,13]. Two studies reported no association between foot pain and muscle weakness [34] or size [33].

## Discussion

We identified eight studies evaluating the relationship between foot pain and foot muscle weakness, or muscle size as a proxy for strength. Six studies reported a significant relationship between foot pain and foot muscle weakness or muscle size [6,8,10,13,20,32]. However there is some inconsistency in the findings depending on the types of foot pain reported, severity of pain, pain scale methodology and the muscle strength/size measurement technique (Tables 2 and 3).

The intensity, frequency or duration of pain reported may be factors that determine the association between foot pain and muscle weakness or size. Two of the four studies that reported pain intensity identified an association [6,8] with average pain intensities of 6.5–6.8/10, which is considered disabling or severe [35,36]. The other two studies that did not find an association reported lower pain intensities of 56.6/100 [34] and 18.8–40.1/100 [20], suggesting that lower pain intensity levels do not influence toe flexor muscle strength. Mickle and colleagues also found that not only was disabling foot pain associated with reduced hallux flexion strength, but when pain was more frequent it was significantly associated with both reduced hallux flexor and lesser toe flexion strength compared to those with no foot pain [32]. Significant associations have previously been reported between severity of pain and magnitude of muscle disuse atrophy [37]. Duration of pain was inconsistently associated with toe flexion weakness. Three studies reported duration of pain [10,13,34] and two studies reported pain duration only as an inclusion criteria [8,20]. Of the four studies reporting a longer pain duration (minimum three months), three studies demonstrated an association between toe flexion and foot pain [8,10,13]. The study by Munteanu and colleagues did not find an association between toe flexion and foot pain, yet curiously their cohort reported the longest duration of pain [34].

The majority of studies that investigated foot muscle weakness using standardised measures of toe flexion force identified an association between foot pain and muscle weakness [6,10,13,20,32]. However the study by Hurn *et al.* reported inconsistent results: toe flexor strength measured with a load cell was not associated with foot pain, while toe flexor strength measured by the paper grip test was related to pain [20]. This study was also the only study to vary the seated position by limiting the degree of knee flexion to 30°. While Mickle and colleagues have reported substantially reduced toe flexor force on a pressure platform with the knee at 30° flexion [17], it is yet to be determined if the degree of knee flexion reliably causes significant changes to the recruitment of the foot muscles. The results of the two studies using plantar pressure measures to determine toe flexor force were contradictory [32,34]. Participants with OA-associated 1st MPJ pain reported in Munteanu *et al.* [34] were primarily male and middle aged (mean 54.5 years), whereas the cohort of generalised foot pain in Mickle *et al.* [32] had no gender bias and were considerably older (mean 71 years). It is known that toe flexor strength reduces with age [5,38] and the presence of disabling pain can lead to pain avoidance strategies, muscle dysfunction and disuse atrophy [11,27,37]. Therefore pain avoidance strategies [12,37] such as limiting load and muscle activation, may not have been induced in the younger, primarily male sample [34]. In summary, multiple factors related to the widely divergent participant groups as well as differing pain types and levels may explain the conflicting outcomes.

Measures of muscle size by MRI or ultrasonography are able to differentiate between intrinsic and extrinsic foot muscles. Chang and colleagues reported a significant association between pain and decreased muscle volume in the forefoot. This was the only study retrieved examining the relationship between muscle size of the forefoot and foot pain using MRI, which is considered the gold standard for measuring specific muscle size [22]. At the hindfoot two studies reported no association between foot pain and hindfoot muscle size on MRI [8,33]. Interestingly Schmid and colleagues noted a large range of fatty infiltration amongst participants [33] suggesting that variability of muscle composition as well as size needs to be considered. A lack of an association between foot pain and hindfoot muscle size is unsurprising as the majority of plantar muscle bulk is located in the forefoot region so the hindfoot is less likely to exhibit significant deterioration in muscle size in relation to foot pain. Since the various pressure or force measuring systems are unable to entirely exclude the actions of the extrinsic foot muscles during toe flexion, the study by Chang and colleagues provides the only evidence that supports the association between foot pain and intrinsic foot musculature. However a limitation of Chang *et al.* is that it does not compare toe flexion force or foot function with forefoot muscle size [8].

It is interesting that plantar fasciitis/heel pain is associated with toe flexor weakness [10,13] or forefoot muscle size [8], while some great toe pathologies such as OA of the 1st MPJ were not associated with either foot muscle weakness or reduced muscle size [34]. This apparent anomaly may be due to a number of factors such as the specific pathology examined, severity or frequency of pain, muscle strength/size measures, and the area of foot measured. Plantar fasciitis is primarily characterised by thickening of the plantar fascia and plantar soft tissue pain [39], whereas osteoarthritic pain primarily stems from the synovium and surrounding joint tissues [40]. The more localised joint pain may not affect muscle strength or size, compared to the dispersed soft tissue symptoms of plantar heel pain. Also a high frequency of ongoing pain was one of the inclusion criteria for those with plantar fasciitis [8,10,13]; while pain frequency was not reported by Munteanu and colleagues for their sample of OA of the 1st

MPJ [34]. These factors may explain the lack of consistent association reported in great toe pathologies.

The clinical implications of identifying an association between weakness and pain relate to the direction of the cause–effect relationship. If weakness is a precursor to foot pain, progressive resistance strength training or other foot exercises might be effective. For instance the randomised controlled trial by Shamus *et al.* provides some evidence for strength training as an effective intervention for painful hallux limitus [6]. However, since the intervention was multifaceted, consisting of toe flexor strengthening exercises, sesamoid mobilisation and gait training, it remains unclear which aspect of the treatment reduced the foot pain. If weakness is a consequence of foot pain, suggesting disuse atrophy is associated with inactivity or deconditioning or the fear avoidance model [14], identifying another influential target for treatment such as degenerative joint disease or local soft tissue trauma is warranted.

*Limitations*

Only English language articles published in peer review journals were included in this systematic review. Due to heterogeneity of the types of foot pain, muscle strength and size measures, no data were pooled for meta-analysis. We excluded a number of studies that did not investigate an association between foot pain and muscle weakness but examined foot muscle size/strength as they relate to deformity [41], various pathologies [42] or functional ability [5]. These clinician-reported, observer-reported and aetiology-specific outcome measures might have yielded important relationships; however the focus of this review was on patient-reported outcomes of pain and objective outcome measures of muscle weakness/size. While the cross-sectional evidence reported in this review identifies several relationships between foot pain and foot muscle weakness, it does not determine causality. Longitudinal cohort studies are required to assess the risk of developing foot pain in relation to intrinsic and extrinsic foot muscle weakness, and the effect of improving foot strength on foot pain resolution.

## Conclusion

Based on the current literature there is evidence of a significant association between foot pain and foot muscle weakness when foot pain is of high intensity and primarily measured by toe flexion force. However there is inconsistent evidence that lower intensity foot pain is associated with other measures of foot muscle weakness or size.

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## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.physio.2016.07.006.

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# SUPPLEMENTARY MATERIAL

**Figure 1:** Search strategy and search terms for foot pain, muscle strength and size.

| | |
|---|---|
| Subject heading | (1) Exp. Foot |
| Keywords | (2) The foot or foot bones or foot joint<br>Mid foot or medial longitudinal arch or foot arch/arch<br>Forefoot or hallux or toes or great toe or toe joint<br>Rear foot or heel or plantar<br>First metatarsophalangeal joint or metatarsophalangeal<br>Ankle or ankle joint or talocrural or subtalar<br>Tarsal bones or metatarsal or metatarsal bones |
| Combine | (3) 1 and 2 |
| Subject heading | (4) Exp. Muscle |
| Keywords | (5) Muscle Cramp or muscle strength or muscle Fatigue Hypertonia or muscle Tonus or skeletal muscle |
| Combine | (6) 4 and 5 |
| Subject heading | (7) Exp. Weak |
| Keywords | (8) Weakness or atrophy or muscle atrophy or degenerative Fatigue or muscle fatigue<br>Strength or muscle strength or power or force |
| Combine | (9) 7 and 8 |
| Combine | (10) 6 and 9 |
| Subject heading | (10) Exp. Pain |
| Keywords | (11) Painful or acute pain or chronic pain or musculoskeletal pain<br>Discomfort or sore or ache or uncomfortable |
| Combine | (12) 10 and 11 |
| Combine | (14) 3 and 10 and 12 |
| Limit | (13) Limit to humans and all adults (18 years plus) |

**Figure 2:** Flow chart of study selection

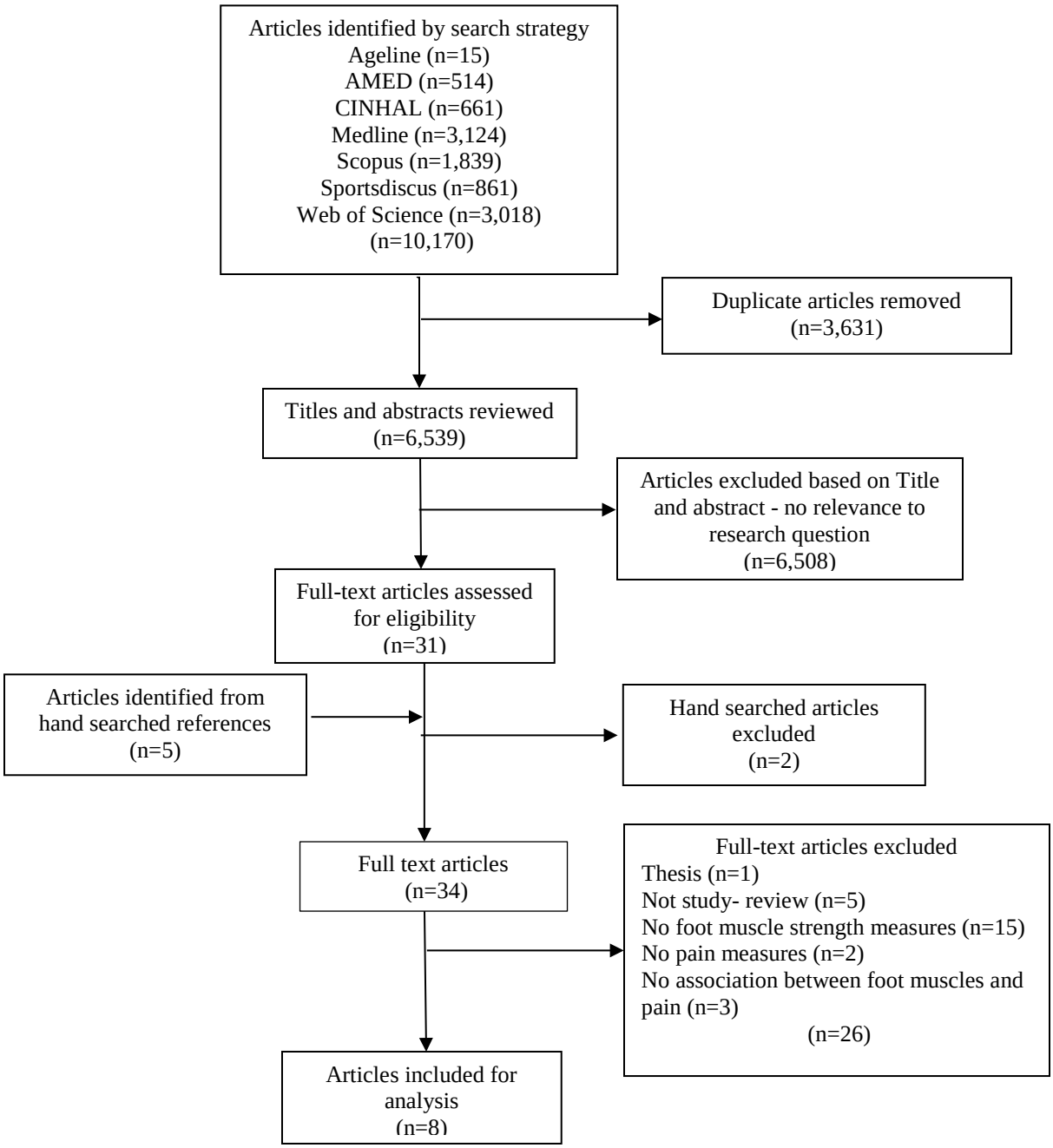

**Figure 3:** Quality Index Tool items adapted from Downs and Black (29)

| Item | Question |
|---|---|
| **Reporting** | |
| 1 | *Is the hypothesis/aim/objective of the study clearly described?* |
| 2 | *Are the main outcomes to be measured clearly described in the Introduction or Methods section?* |
| 3 | *Are the characteristics of the patients included in the study clearly described?* |
| 4 | *Are the interventions of interest clearly described? (RCT only)* |
| 5 | *Are the distributions of principal confounders in each group of subjects to be compared clearly described?* |
| 6 | *Are the main findings of the study clearly described?* |
| 7 | *Does the study provide estimates of the random variability in the data for the main outcomes?* |
| 8 | *Have all important adverse events that may be a consequence of the intervention been reported? (RCT only)* |
| 10 | *Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?* |
| **External validity** | |
| 11 | *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?* |
| 12 | *Were those subjects who were prepared to participate, representative of the entire population from which they were recruited?* |
| 13 | *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive? (RCT only)* |
| **Internal validity** | |
| 14 | *Was an attempt made to blind study subjects to the intervention they have received? (RCT only)* |
| 15 | *Was an attempt made to blind those measuring the main outcomes of the intervention? Also applied to Cross-sectional as well as RCT to determine if assessor was blinded to readouts of repeat measures?* |
| 16 | *If any of the results of the study were based on "data dredging", was this made clear?* |
| 17 | *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls? (RCT only)* |
| 18 | *Were the statistical tests used to assess the main outcomes appropriate?* |
| 19 | *Was compliance with the intervention/s reliable? (RCT only)*<br>*Were the main outcome measures used accurate (valid and reliable)?* |
| 20 a | *Foot muscle strength measures clearly described.* |
| 20 b | *Foot muscle strength measures, reliable or referenced reliable.* |
| 20 c | *Pain measures clearly described.* |
| 20 d | *Pain measures reliable or referenced reliable.* |
| 21 | *Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?* |
| 22 | *Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?* |
| 23 | *Were study subjects randomised to intervention groups?* |
| 24 | *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?* |
| 25 | *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?* |
| 26 | *Were losses of patients to follow-up taken into account? (RCT only)* |

# CHAPTER THREE

## Reliability and correlates of cross-sectional area of abductor hallucis and the medial belly of the flexor hallucis brevis measured by ultrasound

# PREFACE

The systematic review presented in Chapter 2; Relationship between foot pain, muscle strength and size, reported significant associations between foot pain and toe flexion force muscle.

Since toe flexion force is associated with foot pain and only limited evidence of foot pain associated with reduced intrinsic foot muscle size or cross-sectional area. Exploring the relationship between selected intrinsic foot muscles of the great toe and toe flexion force, foot morphology and balance would improve our understanding of muscle specificity, and any relation of muscle size or strength even when scaling for body dimensions.

The aims of this study were to assess the reproducibility of assessing the size of abductor halluces and the medial belly of flexor hallucis brevis muscles measured by ultrasound, and identify their relationship with toe strength, foot morphology and balance. This research also trialed scanning foot muscles while seated, which could be transferred to a clinical setting for patients with reduced mobility.

## Dissemination of research

The study in this chapter has been published in the *Journal of Foot and Ankle Research* which has an impact factor of 1.405

**Latey PJ.** Burns J. Nightingale EJ. Clarke JL. Hiller CE. Reliability and correlates of cross-sectional area of abductor hallucis and the medial belly of the flexor hallucis brevis measured by ultrasound. *Journal of Foot and Ankle Research* 2018, 11:28 | Published on: 7 June 2018 https://doi.org/10.1186/s13047-018-0259-0

The abstract of this study has been published in the following journal *Foot and ankle surgery*, which has an impact factor of 1.348

**Latey P**, Burns J, Nightingale E, Clarke J, Hiller C,: Correlates of ultrasound cross-sectional area of abductor hallucis and flexor hallucis brevis. *Foot Ankle Surg* 2016, **22:**79.

This study has been presented as a podium presentation at the following conference:

**Latey PJ,** Burns J, Nightingale E, Clarke J, Hiller C. Factors associated with real-time ultrasound, toe flexion strength and structural measures of the foot.

6th Congress of the International Foot and Ankle Biomechanics (i-FAB) Community Berlin, Germany June 2016

# AUTHORSHIP STATEMENT

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The co-authors of the paper '*Reliability and correlates of cross-sectional area of abductor hallucis and the medial belly of flexor hallucis brevis measured by ultrasound'* confirm that *Penelope Jane Latey* has made the following contributions:

Conception and design of the research

Collection and extraction of data

Analysis and interpretation of the findings

Drafting and revising of the manuscript and critical appraisal of content

As the primary supervisor for the candidature upon which this thesis is based, I can confirm that the above authorship attribution statement is correct.

Professor Joshua Burns

University of Sydney and Sydney Children's Hospitals Network (Randwick and Westmead)

June 19, 2018

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RESEARCH Open Access

# Reliability and correlates of cross-sectional area of abductor hallucis and the medial belly of the flexor hallucis brevis measured by ultrasound

Penelope J. Latey[1], Joshua Burns[1,2], Elizabeth J. Nightingale[1], Jillian L. Clarke[2] and Claire E. Hiller[1*]

## Abstract

**Background:** Weakness of the intrinsic foot muscles is thought to produce deformity, disability and pain. Assessing intrinsic foot muscles in isolation is a challenge; however ultrasound might provide a solution. The aims of this study were to assess the reproducibility of assessing the size of abductor halluces (AbH) and the medial belly of flexor hallucis brevis (FHBM) muscles, and identify their relationship with toe strength, foot morphology and balance.

**Methods:** Twenty one participants aged 26–64 years were measured on two occasions for muscle cross-sectional area using a Siemens Acuson X300 Ultrasound System with 5-13 MHz linear array transducer. Great toe flexor strength was measured by pedobarography, the paper grip test and hand-held dynamometry. Foot morphology was assessed by foot length, truncated foot length, Foot Posture Index (FPI) and dorsal arch height. Balance was measured by the maximal step test. Intra-class correlation coefficients ($ICC_{3,1}$) were used to evaluate intra-rater reliability. Pearson's correlation coefficients were performed to assess associations between muscle size and strength, morphology and balance measures. To account for the influence of physical body size, partial correlations were also performed controlling for truncated foot length.

**Results:** Intra-rater reliability was excellent for AbH ($ICC_{3,1} = 0.97$) and FHBM ($ICC_{3,1} = 0.96$). Significant associations were found between cross-sectional area of AbH and great toe flexion force measured standing by pedobarography ($r = .623$, $p = .003$),), arch height measured sitting ($r = .597$, $p = .004$) and standing ($r = .590$, $p = .005$), foot length ($r = .582$, $p = 006$), truncated foot length ($r = .580$, $p = .006$), balance ($r = .443$, $p = .044$), weight ($r = .662$, $p = .001$), height ($r = .559$, $p = .008$), and BMI ($r = .502$, $p = .020$). Significant associations were found between cross-sectional area of FHBM and FPI ($r = .544$, $p = .011$), truncated foot length ($r = .483$, $p = .027$) and foot length ($r = .451$, $p = .040$). Significant partial associations were found between AbH and great toe flexion force in standing by pedobarography ($r = .562$, $p = .012$) and FHBM and the FPI ($r = .631$, $p = .003$).

**Conclusions:** Measuring the cross-sectional area of AbH and FHBM with ultrasound is reproducible. Measures of strength, morphology and balance appear to relate more to the size of AbH than FHBM. After controlling for physical body size, cross-sectional area of AbH remained a significant correlate of great toe flexor strength and might be a useful biomarker to measure early therapeutic response to exercise.

**Keywords:** Ultrasound, Pedobarography, Dynamometry, Intrinsic foot muscles, Arch height, Toe flexor strength

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## Background

Intrinsic foot muscle weakness is related to common foot pathologies and deformities [1–4] and may be caused by neuromuscular conditions such as diabetic neuropathy [5, 6] and Charcot-Marie Tooth disease [7, 8]. Reduction in toe flexion strength is associated with an increased risk of falling in older adults [9, 10]. The intrinsic great toe muscle abductor hallucis acts as a dynamic elevator, [11] helps maintain balance in a medio-lateral direction [12] and supports the medial longitudinal arch [13]. Improving toe flexion strength can minimise the effect of foot muscle atrophy induced by disease or deformity, [14, 15] and improve upright dynamic functional movement [16]. The ability to reliably measure the cross-sectional area of the small first ray muscles may be an important early biomarker of treatment strategies for foot muscle weakness.

The toes are stabilised and acted on by both intrinsic and extrinsic foot muscles. Accuracy in evaluating the strength of intrinsic great toe muscles and their specific contribution to dynamic balance, or their relationship to foot morphology remains a challenge [17]. Toe flexion force measures do not distinguish intrinsic from extrinsic foot muscles [18]. Muscle specificity can be determined by size or cross-sectional area; however muscle size does not entirely explain differences in strength [19]. Since the first ray performs as one functional unit, [20] ascertaining if there is an association between the cross-sectional area of abductor hallucis (AbH) and the medial belly of flexor hallucis brevis (FHBM) muscles with measures of toe flexion force may provide a more accurate picture of the role these muscles have in medial longitudinal arch support and great toe muscle weakness.

Imaging cross-sectional area using Computerised Tomography (CT) [21] Magnetic Resonance Imaging (MRI) [22] or ultrasound [23] enables analysis of specific muscles and regions of the foot. Although MRI and CT have a high level of accuracy, [24] they are usually not immediately available in research or clinical practice due to cost. Ultrasound is a non-invasive, non-ionising and inexpensive method of assessing muscle morphology or size. Measuring cross-sectional area using ultrasound of AbH, flexor hallucis brevis, flexor digitorum brevis, quadratus plantae and abductor digiti minimus muscles in supine or prone has been reported as highly reliable [1, 23, 25]. However, previous studies have not scanned the person in an upright position. In a clinical situation with a broad population base there can be limitations on patient's movement ability. Some patients are unable to turn over from supine to prone or even lie down flat on a treatment table due to various problems such as: severe back problems, [26] obesity, [27] positional vertigo [28] or sarcopenia [29]. Cross-sectional area of the lower limb can also be affected by position [30]. Therefore the scanning position was modified to determine if scanning the medial foot in seated, with the ankle in a mid-range neutral position was as reliable as the supine or prone positions. As scanning the foot on its plantar aspect was impractical with the participant seated, and on reviewing the anatomical pathways of FHB, only the medial fibres of FHB were scanned.

The aims of this study were to assess the reproducibility of assessing the size of abductor halluces (AbH) and the medial belly of flexor hallucis brevis (FHBM) muscles, and identify their relationship with toe strength, foot morphology and balance. Since the cross-sectional area and muscle thickness of the ABH, FHB, flexor digitorum brevis, quadratus plantae and lumbricals have been shown to be associated with toe flexor strength [31] we hypothesised that a decreased size of AbH and FHBM scanned in the seated position would be similarly related to toe flexor weakness. The relationships between muscle size and foot morphology were explored as, despite the understanding that some variability in muscle thickness, [32] size [33] and strength [34] may be attributed to participant characteristics, the effect of foot morphology on muscle size has yet to be determined.

Toe flexion strength has been shown to be important determinant of balance, [35] and is related to increased single leg balance time in older adults [36]. Correspondingly, reduced toe flexion strength has been associated with impaired balance, [37] increased postural sway and reduced functional ability in older adults [38]. More specifically, AbH, flexor digitorum brevis and quadratus plantae muscles increase activity with increasing postural demands and help maintain balance in a medial-lateral direction [12]. Therefore we also hypothesised that a greater cross-sectional area of AbH and FHBM would be associated with better balance.

## Methods

### Participants

Twenty one participants were recruited from the University of Sydney and general population via an advertisement. Participants were healthy adults, 18 to 65 years of age, able to walk barefoot and unaided. Study exclusion criteria were a history of a musculoskeletal or systemic disease (e.g. Diabetes type 2), acute familial or acquired foot problem (e.g. Charcot Marie Tooth Syndrome) or injury affecting foot or lower limb joint motion, foot surgery, or severe foot pain (≥7on a 0–10 point scale).

### Measures and procedures

All participants attended two data collections 2–4 weeks apart. At the first data collection, participant characteristics were recorded, including age, sex, height, weight and dominant foot (determined by asking with which foot the participant kicked a ball). All other measures were taken of the dominant foot three times at each data collection

session to determine reliability of testing procedures and the measures used. Data collected at the first session was kept in a locked cabinet until all data collections were completed. The second data collection was completed without the researcher having access to the first data set.

### *Ultrasound*

Ultrasound cross-sectional area of AbH and FHBM were measured using a Siemens Acuson X300 Ultrasound System (Siemens Medical Solutions, Inc., Mountain View, California, USA) with 5-13 MHz linear array transducer. Each non-weight bearing ultrasound image was collected with participants seated on a raised plinth with their leg relaxed, knee flexed 90°.

The lateral border of the participant's stabilised foot rested on the thigh of the seated researcher, with the ankle positioned in neutral. The plantar aspect of the foot faced towards the floor, to allow contiguous transducer access to both the medial and plantar aspects of the foot. To identify the AbH muscle the researcher first palpated, then marked the navicular tubercle. Ultrasound gel was placed between the skin and transducer to remove air artefact and ensure good transducer to skin contact. The transducer was then placed on the navicular tubercle and the long axis of the transducer moved inferiorly in a directly perpendicular line across the mid arch of the medial longitudinal arch to identify AbH in cross section (Fig. 1a, c). To identify the FHBM muscle, the medial sesamoid bone was first palpated, then marked and ultrasound gel placed on the participants' skin in line with the 1st metatarsal bone. The end of the transducer was used to locate the medial sesamoid bone, and the long axis of the transducer aligned with the longitudinal aspect of the muscle belly. The transducer was moved proximally along the FHBM until only the proximal edge of the medial sesamoid bone and its acoustic shadow could be observed on the image. The thickest part of the muscle was then identified and the transducer was rotated 90° at 50% of transducer length. The transducer was then translated inferiorly towards the plantar aspect of the foot within the coronal plane until a clear image of the FHBM muscle could be visualised. The FHBM was thus scanned perpendicularly to the muscle, to capture its maximal cross-sectional area. This scanning location was on the medial-plantar aspect of the foot, mid metatarsal (Fig. 1b, d). The cross-sectional area was determined by tracing the muscle outline of the scanned images and the area was calculated by the Siemens Acuson program software.

### *Muscle strength*

Toe flexor strength of the dominant foot was measured with pedobarography using the Emed® pressure platform, paper grip test and hand held dynamometry. A standing position was used for the Emed® [39] paper grip test and hand held dynamometry measuring devices [4, 18, 40]. The following procedure was repeated for each strength test. The participant was first familiarised with the toe flexor task by passive demonstration of the movement

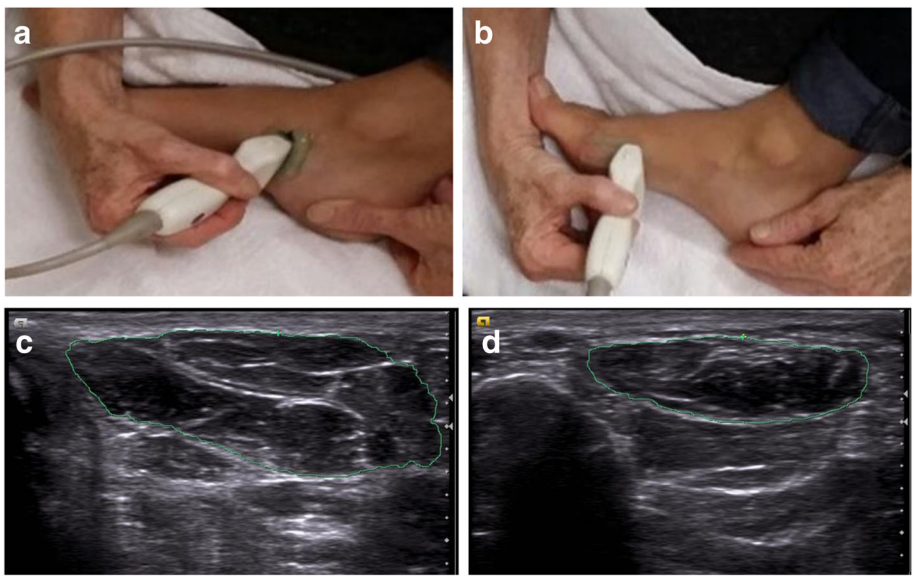


**Fig. 1** Ultrasound transducer placement, scanned image and outlined circumference. **a** Transducer placement to scan the AbH muscle, **b** Transducer placement to scan the FHBM muscle, **c** Ultrasound image of the cross-sectional area of AbH outlined, **d** Ultrasound image of the cross-sectional area of FHBM outlined

required, followed by active practice until the participant could perform the test correctly. Subsequently, three consecutive contractions of 3 to 5 s for the toe flexor task were recorded. Verbal encouragement was given during each contraction.

For the toe flexor testing using the Emed®-AT/2 capacitance pressure distribution platform (Novel GmbH, Munich, Germany), sensor area 360 mm × 190 mm containing 1377 sensors, resolution 2 sensors/cm2 (recording frequency 25 Hz), participants were instructed to press down on the platform as hard as possible using only their great toe. Directions were given to elongate the toes and elevate the mid arch by pressing distal ends of the toes down while keeping their heels on the platform. For both tasks the participant's torso remained upright with arms crossed in front of their chest, palms up and looking straight ahead. Peak forces were recorded by the software [39]. An Emed® Mask (Novel GmbH, Munich, Germany) was created for the great toes to determine maximal force and mean pressure during the great toe flexor task (Fig. 2).

The procedure for the paper grip test was similar to that for the pressure platform test. Participants stood and were directed to press the great toe, then the lesser toes downwards while attempting to hold a card down with the toes. This was a modified position from de Win's, and was a pass/fail test of three consecutive attempts [18].

Great toe flexion strength was assessed using a hand held dynamometer (Commander Muscle Tester, JTech Medical, Salt Lake City, UT USA). A customised support system was placed beneath the feet to maintain the foot and toes in a neutral position (Fig. 3). Testing was completed as per the procedure for the toe flexor task using the pressure platform. In standing, a secure bar was provided for participants to hold lightly to maintain balance while performing the task. Participants then kept the lower limb still while pressing as strongly as possible onto the force sensor of the hand held dynamometer [35].


**Fig. 2** Pedobarography- Emed Pressure Map of standing great toe flexion with 2-toes Mask applied

### *Foot morphology*

Foot alignment was measured using the Foot Posture Index (FPI), foot length (total and truncated) and dorsal arch height. The FPI consists of six criteria, [41] summed to provide a score from − 12 to + 12 for a supinated or pronated foot respectively with reported acceptable reliability [42].

Foot length and truncated foot length of the dominant foot was measured with the participant sitting in a chair with ankle, knees and hips flexed at 90°. Their feet were placed on a platform with an embedded ruler to measure full foot length from mid-heel to longest toe tip and truncated foot length from mid-heel to mid-first metatarsophalangeal (MTP) joint. Dorsal arch height in sitting and standing was measured with a digital height gauge with carbide scribe (Allendale Electronics Ltd., Hoddesdon Herts. UK). The gauge was placed at 50% of foot length to determine the Dorsal Arch Height (DAH) [43]. Arch Height Ratio (AHR) was determined by dividing the DAH by truncated foot length. This method has been shown to be a reliable and valid measure of arch height [44]. Foot arch mobility was determined by subtracting standing weight bearing dorsal arch height from sitting dorsal arch height [43].

### *Balance*

Functional balance was tested with the maximal step length test. This test is a reliable predictor of mobility, balance and fall risk [45]. Participants stood behind a cross taped on the floor, with arms folded across the chest and palms up. They stepped with each leg (right then left) and in each direction (forward, side, back) as

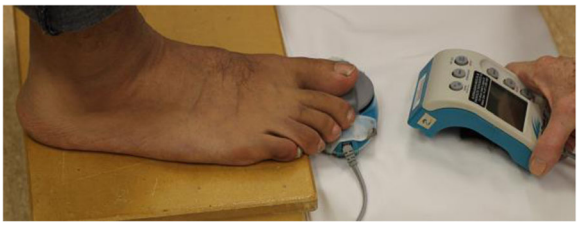

**Fig. 3** Dynamometry during the standing great toe press

far as possible; paused while distance was recorded, then returned to the starting position. The standing foot remained firmly planted [46]. Distance was recorded only if balance and body posture were maintained throughout the test. Balance of the dominant leg was determined by averaging the total length stepped in each direction.

### Statistical analysis

Analysis was performed in SPSS for Windows v22.0 (IBM SPSS Inc., Chicago, IL). Intra-rater reliability of the variables was assessed with intraclass correlation coefficients ($ICC_{3,1}$). Kappa was used to evaluate the Paper Grip test, with values ≤0 indicating no agreement and 0.01–0.20 none to slight, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 substantial, and 0.81–1.00 as almost perfect agreement [47]. Correlation analyses between intrinsic foot muscle size and anthropometrics (age, weight, height, BMI) foot morphology (foot length, truncated foot length, FPI, arch height), strength measures (hallux force by pedobarography and dynamometry) and balance (maximal step length test) were conducted with Pearson's correlation coefficient. To account for the influence of physical body size a partial correlation was performed. The controlling variable was selected based on the variable with the highest and most consistent Pearson's correlation coefficient for both AbH and FHBM muscles.

## Results

Participants were aged 39.5 ± 10.0 years (range 26–64 yrs.); female (15/21), BMI (23.8 ± 3.3 range 19-30Kg/$m^2$), right foot dominant (19/21), FPI + 2.6 ± 1.5, (FPI of 2.4 ± 2.3 for adults is considered normal [48]), with Arch height flexibility .35 mm (Table 1). Due to low body weight, one participant's data was excluded from all pedobarographic analysis as they were unable to generate acceptable force.

Intra-rater reliability for the ultrasound measures of cross-sectional area were excellent for AbH and FHBM (Table 2). The standing paper grip test had a Kappa value of 0.203, ($p$ = 0.148) which is considered only slight reliability [49].

Correlations between cross-sectional data are presented in Table 3. Positive significant associations were found between AbH cross-sectional area and the majority of participant characteristics ($r$ = .502 to $r$ = .625), arch height sitting ($r$ = .597, $p$ = .004), standing ($r$ = .590, $p$ = .005), toe flexion force using pedobarography ($r$ = 623, $p$ = .003) and maximum dominant step ($r$ = .443, $p$ = .044); and between FHBM cross-sectional area and foot length ($r$ = .451, $p$ = 040), truncated foot length ($r$ = .483, $p$ = .027) and FPI ($r$ = .544, $p$ = .011).

Partial correlations controlled by truncated foot length are presented in Table 4. Positive significant partial correlations, were found between AbH cross-sectional area and toe flexion force using Pedobarography ($r$ = 0.562, $p$ = .012) and between FHBM cross-sectional area and the FPI ($r$ = .631, $p$ = .003).

**Table 1** Participant characteristics of the sample ($n$ = 21)

| Variable | [a]Value |
|---|---|
| *Participant characteristics* | |
| Age (y) | 39.5 ± 10.0 |
| Sex, Female (%) | 15 (71%) |
| Body weight (kg) | 65.5 ± 12.6 |
| Height (m) | 1.65 ± 0.08 |
| BMI (kg/$m^2$) | 23.8 ± 3.3 |
| Dominant foot, right | 19 (90%) |
| *Foot morphology* | |
| Foot Posture Index (− 12 to 12 score) | 2.6 ± 1.5 |
| Foot length (cm) | 24.2 ± 1.3 |
| Truncated foot length (cm) | 17.5 ± 0.91 |
| Arch Height – sit (cm) | 6.97 ± .75 |
| Arch Height – stand (cm) | 6.62 ± .74 |
| Arch Height – mobility (cm) | .35 ± .17 |

[a]Values: mean ± SD
*Key: y* year, *kg* kilogram, *m* metres, *BMI* body mass index, *cm* centimetres

## Discussion

We found excellent reproducibility for ultrasound cross sectional area measures of AbH and FHBM while seated. Positive significant associations were found between the cross-sectional area of AbH and the majority of participant characteristics, toe strength determined by pedobarography, foot morphology; foot length and arch height, and balance. When controlling for truncated foot length, the association with toe strength determined by pedobarography remained consistent. Associations between the cross-sectional area of FHBM were limited to one foot morphology measure.

In this study the ultrasound transducer placement and position of participant was modified from previous studies on the reliability of ultrasound cross-sectional area measures [23, 25]. To maintain consistency of the seated ankle neutral position we scanned AbH by aligning with the navicular tubercle, this also ensured all three segments of the AbH muscle were imaged (Fig. 1a) [50]. As well as the impracticality of scanning the plantar aspect of the foot with the participant seated, variations in FHB anatomy influenced our scanning position. The lateral head of FHB is often inseparable from the oblique head of the adductor hallucis at the insertion [51] with difficulties in identifying the borders of FHB reported [52]. Furthermore, an anatomical cadaveric study has shown that 20% of insertions of the oblique head of adductor hallucis attach to the navicular and align with FHB lateral fibres [53]. Therefore, only the medial part of the FHB(M) muscle was scanned

**Table 2** Reproducibility of ultrasound cross-sectional area, pedobarography, hand-held dynamometry and balance measures

| Variable | Trial 1 (mean ± SD) | Trial 2 (mean ± SD) | $ICC_{3,1}$ | 95% CI | |
|---|---|---|---|---|---|
| *Ultrasound ($cm^2$)* | | | | | |
| CSA Abductor Hallucis | 2.16 ± 0.60 | 2.16 ± 0.63 | 0.97 | 0.94 | 0.99 |
| CSA Flexor Hallucis Brevis | 1.45 ± 0.35 | 1.45 ± 0.36 | 0.96 | 0.90 | 0.98 |
| *Pedobarography (N)* | | | | | |
| Great toe press task ($n = 20$) | | | | | |
| Stand maximum force great toe | 117.8 ± 33.8 | 128.1 ± 42.9 | 0.75 | 0.48 | 0.89 |
| *Hand-held dynamometry (N)* | | | | | |
| Stand – great toe | 124.9 ± 28.8 | 119.4 ± 28.3 | 0.75 | 0.48 | 0.89 |
| *Balance (cm)* | | | | | |
| Mean maximal step right | 89.3 ± 12.3 | 88.7 ± 12.37 | 0.83 | 0.63 | 0.93 |

*Key: ICC* Intraclass correlations coefficients, *CSA* Cross-sectional area, *cm* centimetres, *N* newtons
Notes-Pedobarography Emed Pressure Platform $n = 20$

in the coronal plane on the medial-plantar aspect of the foot at about mid metatarsal in this study (Fig. 1b). This may explain the smaller cross-sectional area of FHBM from previously reported cross-sectional area FHB measures (Table 5) [23, 25, 54]. The participant was placed in seated ankle neutral for scanning both muscles to minimise any potential positional muscle size changes [30, 55]. The intra-rater reliability of the seated position and the scanning method of the AbH and FHBM was equivalent to previous studies [23, 25]. The excellent reliability of this approach suggests that for people with difficulty lying supine or prone, the seated position is a good alternative to determine cross-sectional area of these foot muscles.

Cross-sectional area of AbH had significant associations with the majority of participant characteristics and foot morphology. Increasing body size was related to increasing AbH size. Associations between increased arch height and increased cross-sectional area of AbH was due to anatomical dimensions as the association became non-significant when controlling for truncated foot length. Also, the majority of

**Table 3** Pearson's correlations between ultrasound cross-sectional area and participant characteristics, foot morphology, pedobarography, hand-held dynamometry and balance measures

| | Abductor Hallucis | | Flexor Hallucis Brevis (Medial) | |
|---|---|---|---|---|
| Variable | *R* | *p* | *r* | *p* |
| *Participant characteristics* | | | | |
| Age | 0.070 | 0.763 | −0.205 | 0.373 |
| Weight | 0.662** | 0.001 | 0.305 | 0.179 |
| Height | 0.559* | 0.008 | 0.372 | 0.097 |
| BMI | 0.502* | 0.020 | 0.158 | 0.495 |
| *Foot morphology* | | | | |
| Foot length | 0.582* | 0.006 | 0.451* | 0.040 |
| Truncated foot length | 0.580* | 0.006 | 0.483* | 0.027 |
| Foot Posture Index | 0.214 | 0.352 | 0.544* | 0.011 |
| Arch height sit | 0.597** | 0.004 | 0.062 | 0.790 |
| Arch height stand | 0.590** | 0.005 | 0.089 | 0.702 |
| *Hand-held dynamometry* | | | | |
| Standing great toe force | 0.011 | 0.964 | −0.075 | 0.747 |
| *Pedobarography* | | | | |
| Stand max force great toe[a] | 0.645** | 0.002 | 0.349 | 0.132 |
| *Balance* | | | | |
| Maximum step Right | 0.443* | 0.044 | 0.356 | 0.113 |

*Key: BMI* Body mass index
[a]Missing data $n = 20$ ***significant $p < 0.005$, * significant $p < 0.05$*

**Table 4** Partial Pearson's correlations (controlling for truncated foot length) between ultrasound cross-sectional area and foot morphology, pedobarography, hand-held dynamometry and balance measures

| | Abductor Hallucis | | Flexor Hallucis brevis (medial) | |
|---|---|---|---|---|
| Variable | *r* | *p* | *r* | *p* |
| *Foot morphology* | | | | |
| Foot Posture Index | 0.275 | 0.240 | 0.631* | 0.003 |
| Arch height sit | 0.403 | 0.078 | −0.257 | 0.274 |
| Arch height stand | 0.437 | 0.054 | −0.185 | 0.436 |
| *Hand-held Dynamometry* | | | | |
| Stand great toe force[a] | 0.010 | 0.965 | −0.087 | 0.714 |
| *Pedobarography* | | | | |
| Stand max force great toe[a] | 0.562* | 0.012 | 0.21 | 0.389 |
| *Balance* | | | | |
| Maximum step Right | −0.029 | 0.903 | −0.046 | 0.848 |

*Abbreviations:* [a]*Missing data n = 20 * significant p < 0.05*

participants had decreased arch flexibility according to McPoil and colleagues' dorsal arch height norms [43]. However since arch height lowers with increased load [56] and with plantar muscle fatigue, [13, 57] the limited findings of the current study indicate maintenance of the height of the medial longitudinal arch may be more related to the cross-sectional area of AbH situated mid to hindfoot rather than the fore foot FHBM muscle.

In contrast, the cross-sectional area of FHBM had a substantially different pattern of association with strength, morphology and balance variables. A larger cross-sectional area of FHBM was significantly associated with a higher FPI (more pronated) even when controlled for truncated foot length. Zhang and colleagues reported a significantly larger AbH (> 4.3%) and flexor digitorum brevis (> 18.7%) associated with a more pronated FPI (6.6), [52] (Table 5) but they did not analyse FHB due to difficulty in identifying the muscle border. They proposed that the larger forefoot muscles of people with more pronated feet contribute to control of the forefoot abduction motion during gait. Interestingly, this contrasts with Angin and colleagues study comparing normal (FPI 1.3 ± 1.2) and pronated (FPI 8.1 ± 1.7) feet [54]. They report significantly smaller FHB (− 8.9%) and AbH (− 12%) in pronated feet compared to normal feet [54]. These varying findings regarding associations between AbH, FHB and flexor digitorum brevis cross-sectional area and their relationships with foot type, [52, 54] are similarly noted in studies examining intrinsic foot muscle size with age and gender, [58, 59] foot deformity [33, 60, 61] and plantar fasciitis [62, 63].

Some of the results of our study contrast with previous literature reporting positive associations between measures of cross-sectional area and toe flexion force [33, 58, 59, 64]. No association was found between cross-sectional area of either AbH or FHBM and toe flexor force measured by hand held dynamometry, which was unexpected. Previously, cross-sectional areas of intrinsic foot muscles determined by MRI were significantly correlated to measures of toe flexor strength using a toe grip dynamometer [31, 65]. Studies reporting good reliability for toe flexion used supported dynamometers with ICCs $_{3,1}$ ranging from 0.931 [31] to 0.97 [2] or had participants braced or self-stabilised with ICC's$_{3,1}$ ranging 0.81 for hallux plantar flexion [66] to 0.95 for foot inversion [40]. The contrasting finding in our study may be due to the technique used to complete the hand held dynamometry measures in this study [67] (Fig. 3).

A significant association was found between cross-sectional area of AbH and great toe flexion strength measured by pedobarography. The positive relationship between increasing force and cross-sectional area was maintained even when controlling for physical dimensions, supporting previous findings [31, 65, 68]. This suggests that the cross-sectional area of AbH may be a useful early biomarker for foot muscle weakness. In contrast, no association was found between cross-sectional area of FHBM and toe flexion force. Muscle architecture, including shape and pennation angles, reaction time, innervation, fibre type and size, influences muscle force [69–72]. Ledoux [71] reported more than double pennation in AbH, which Tosovic and colleagues suggest has three segments, with each segment acting differently due to their pennate angle and fibre type [50, 71]. Furthermore, conflicting reports of forefoot or hindfoot muscle weakness in runners with plantar fasciitis [3, 62, 63] and the complexity of intrinsic foot muscle weakness associated with claw toes [60] suggests we may need to consider differentiation between fore, mid and hindfoot muscles when examining toe flexion strength related to foot problems.

**Table 5** Literature review of cross-sectional area values for AbH and FHB (M) by ultrasound and MRI.

| Author | Equipment | CSA AbH Mean ± sd ($cm^2$) | Transducer alignment/region | CSA FHB Mean ± sd ($cm^2$) | population | Transducer alignment/region |
|---|---|---|---|---|---|---|
| Abe[59] | US | 2.46±0.77 | Medial hindfoot, inferior to medial malleolus | N/A | Sports active adults | |
| Angin[54] | US | 2.75±0.34 | Medial hindfoot, inferior to medial malleolus | 2.97±0.46 | Normal foot | Plantar, proximal forefoot thickest portion |
| | | 2.36±0.47 | | 2.66 ±0.46 | Pronated foot+8 | |
| Battaglia[76] | US | 2.47±0.93 | Thickest portion from medial calcaneus distally towards the 1st metatarsal | N/A | Healthy adults non w/b | |
| | | 2.60±0.91 | | | Weight/bearing | |
| Lobo[61] | US | 2.74± 0.64 | Medial hindfoot thickest potion between medial calcaneal tuberosity and navicular tuberosity | 2.13±0.65 | Healthy adults no HV | Plantar mid forefoot thickest portion |
| | | 2.22± 0.49 | | 1.57±0.41 | Healthy adults with HV | |
| Mickle[20] | US | 2.56±0.89 | Medial hindfoot thickest portion between medial calcaneal tuberosity and navicular tuberosity | 2.45±0.53 | Healthy adults | Plantar, proximal forefoot thickest portion |
| | | 2.45±0.94 | Medial hind foot inferior to medial malleolus | | | |
| Zhang[52] | US | 2.62±0.56 | Medial hindfoot, inferior to malleolus, thickest portion | Unable to determine | Runners; Normal foot | |
| | | 2.74±0.39 | | | Pronated foot+ 6.6 | |
| Current study | US | 2.16±0.60 | Medial, mid foot inferior to navicular tubercle thickest portion | 1.44±0.35(M) | Healthy adults | Medial-plantar mid metatarsal thickest portion |
| Kura[72] | Muscle volume* | 6.68±2.07 | | 1.80± 0.75 FHB(M)<br>2.12± 0.84 FHBL | | |
| | | | Total CSA: FHB and AbH | | | |
| Green[78] | MRI | | 3.00 mean | | | Medial foot |
| | | | Total CSA : FHB, FDB, Quadratus plantae, lumbricals and AbH | | | |
| Kurihara[31] | MRI | | 5.87±1.34 | | | Forefoot 20% of Truncated foot length |

*PCSA: Dissection, calipers and water displacement

Key: CSA: cross-sectional area, FHB: flexor hallucis brevis, AbH: abductor hallucis, M: medial, FDB: flexor digitorum brevis, AbH abductor hallucis, PCSA: physiological cross-sectional area, w/b: weight bearing, (M): medial

Variations in muscle cross-sectional area or toe flexion force could be due to gender differences [73] or age related sarcopenia [50, 74]. Research to acquire the reference values for ultrasound cross-sectional area of various lower limb and foot muscles reported significant effects of age and sex on muscle thickness and echogenicity, [32] associated with fat infiltration [75]. We found a significant association between the size of AbH and sex, with males generally having a larger AbH, but no association between age and AbH or FHBM muscle size. Mickle and colleagues [58] reported significant age related difference between selected intrinsic and extrinsic foot muscles. They found significant differences in toe flexion force and FHB cross-sectional area but no significant difference in AbH or flexor digitorum brevis cross-sectional area between young and older participants. Change or reduction in muscle size may also be due to stance, [76] or loss of muscle fibres as well as decline in muscle fibre size, specifically type-II muscle fibres [75, 77]. The difference in patterns of association between cross-sectional areas of the AbH and FHBM muscles, foot morphology and toe flexion force may be due to the small number of participants evaluated in this study, the scanning positions used, as well as the architecture of the foot.

Balance, tested via maximal step length [45] was found to be significantly associated with AbH of the dominant leg. This suggests a positive relationship between muscle size and balance, somewhat supporting previous research, [16] and our hypothesis that a greater cross-sectional area of AbH and FHBM would be associated with better balance. Since only the size of the AbH was positively associated with toe flexion force, it is likely that strength

of the AbH muscle plays a more important role in maintaining balance than FHBM. This result is also consistent with reports of increased activity of the abductor hallucis, flexor digitorum brevis and quadratus plantae muscles during a more demanding balance task [12]. However the relationship between AbH size and balance was not maintained after controlling for physical body size. This finding, along with the foot morphology results, highlights some associations may be entirely dependent on anthropometric variations.

There were several limitations to this study. First, only 21 healthy adults were evaluated from a sample of primarily female middle-aged adults, with less mobile or stiffer arched feet (Table 1), reducing the generalisability of the findings. Further, the small sample size resulted in a lack of statistical power with the possibility of Type 1 errors occurring as multiple comparisons were performed. Second, as this was a cross-sectional study no causality can be inferred. Third, only two muscles were measured in this study limiting comparisons with studies evaluating other intrinsic foot muscles.

## Conclusion

Measuring the cross-sectional area of AbH and FHBM muscles with ultrasound in the seated position is reproducible. Measures of toe flexion strength determined by pedobarography, foot morphology and balance appear to relate more to cross-sectional area of AbH than FHBM. While the first ray muscles may act as a unit, these forefoot and hind foot muscles exhibit different patterns of association between the variables. After controlling for physical body size, cross-sectional area of AbH remains a significant correlate of great toe flexor strength.

#### Abbreviations

AbH: Abductor hallucis muscle; CSA: Cross-sectional area; FDB: Flexor digitorum brevis; FHB: Flexor hallucis brevis muscle; FHBM: Flexor hallucis brevis medial muscle belly; HV: Hallux valgus; ICC: Intra-class correlations

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#### Availability of data and materials

The data sets generated or analysed during the current study are available from the corresponding author on reasonable request.

#### Authors' contributions

The conception and design of the study was undertaken by all authors. Acquisition of data was undertaken by PJL. Analysis and interpretation of data was undertaken by all authors. Drafting the article was undertaken by PJL. Revising and editing was undertaken by all authors. All authors have read and approved the final version of the paper submitted.

#### Ethics approval and consent to participate

The Human Research Ethics Committee of the University of Sydney approved the study (Protocol No. 2012/2849) and participants provided written informed consent.

#### Competing interests

The authors declare that they have no competing interests.

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# CHAPTER FOUR

## Development and construction of the Archie biofeedback medical device

# PREFACE

Foot pain is common and related to muscle weakness and reduced muscle size (Chapter 2), and muscle size can be measured reliably using ultrasound. The next step is to identify a treatment for muscle atrophy and weakness. The aim of this chapter is to describe the research and design process that was undertaken to develop and construct the Archie biofeedback device to assist with exercising the small muscles of the foot.

Chapter 4 is organised in two sections. Section one describes the original Archie foot biofeedback device, developed in 2008 for assisting foot exercise practice, and the redesign and build process to create the final Archie. Section two describes the bench testing and observational studies of the new components, modules and systems of the final Archie that was undertaken to ensure the device was ready for pilot testing (Chapter 5).

The original Archie was developed in 2008 to explore a cost-effective way of assisting foot exercise practice. This work was undertaken as part of post graduate studies (MSc) completed in 2011 “Examination of the role of Pilates in the correction of dysfunctional feet and associated effects on postural stability in the older adult”. The original Archie required modification and redesign to improve its operation and enhance its functionality. This process included the redesign and build of the housing, a significant upgrade in Archie’s safety features, new electronic circuitry, firmware, software and substantially improved visual feedback. A timeline depicting the development of the Archie biofeedback device from ideation, through redesign, build and bench testing, culminating in a pilot clinical trial is shown below (Figure 4.0).

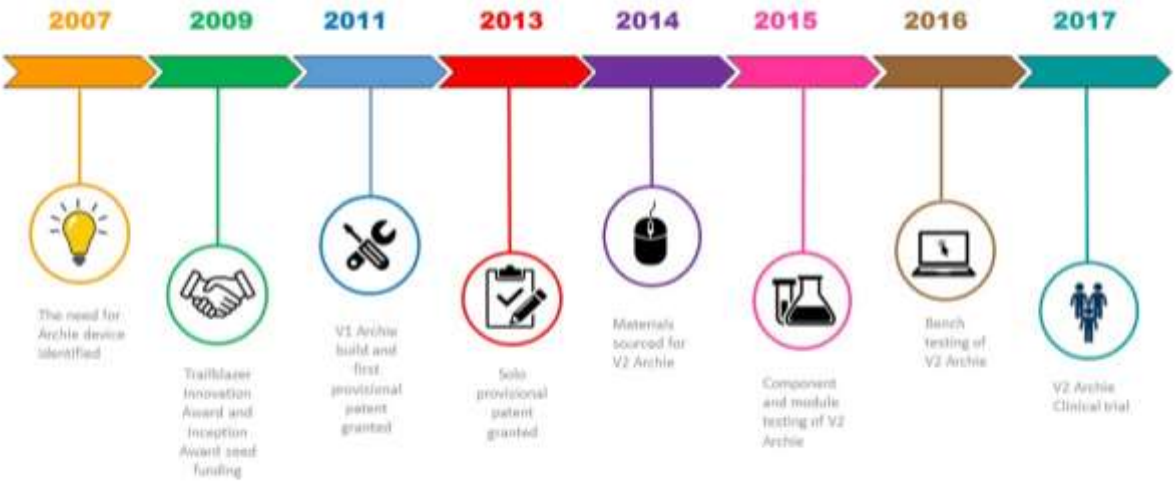



**Figure 4.** Time line of Archie development

The development of the original Archie (patent number PCT/AU2016/050437) was supported by the following grants and awards:

- Uniquest, Trail blazer award in 2008 of $2,000 (Student runner up)

- UTS, Innovation seed grant in 2009 of $10,000. Student build of original prototype Archie

- UTS, Uniquest partnership grant, funding provisional patent 2010-2012

## Glossary

The following terms are used throughout this chapter to describe components relating to the development, construction and testing of the Archie device.

**Physical structures:**

**Footplates**

*Sensor footplate* – physical housing and rigid structure on which the foot is placed to complete exercise tasks, containing two sensor systems which record and send feedback of foot movement during exercise tasks.

*Support footplate* – solid structure for non-exercising foot mirroring the shape of the sensor footplate to provide same height support.

**Inserts -** rigid custom built structures embedded into the sensor footplate providing secure internal housing enclosures for the PCBs, air pump and solenoid.

**Covers -** clear or translucent removable rigid or flexible top cover to provide a smooth surface over sensor footplate, protects foot locator system.

**Connectivity –** connection between the Archie sensor footplate and PC with wireless Bluetooth® activation and control commands.

**Power management -** battery, battery charging, monitoring and power status feedback

**Status indicators -** implemented using LEDs **(**light emitting diodes) to provide status and connectivity information to the user, situated on the sensor footplate.

**Sensor systems:**

**Bladder system sensor system**

Provides visual and digital information on the pressure under the arch of tested foot. It consists of a rubber membrane secured in a frame with an air inlet port located in the middle of a custom made rigid base.

*Rubber membrane* – stretchable rubber on which the arch of the foot is placed that expands when inflated with air to fill the arch.

*Pressure Sensor* – solid state device that measures bladder air pressure from -5cmH2O to 100cmH2O. Connected to bladder with PVC tubing.

*Bladder module* - Integrated three-piece unit to provide support for the rubber membrane with base, frame, and air inlet port, sealed with adhesive and screws.

*Air pump* – electronically activated pump for inflating the bladder.

*Solenoid valve* (pressure release valve) – seals the bladder for it to be inflated and provides automatic deflation if over inflation occurs.

**Foot locator sensor system**

Sensor system that provides visual and digital information on sensor contact between great toe, fifth toe and heel.

*Proximity sensors* – sensors which activate within a given spatial parameter. Detected via electrostatic field changes. Does not rely on direct contact with the sensor, separated from the foot by a plastic cover that the foot must be in contact with.

*Membrane switches* – Switches that require a small force to be applied across a membrane, in order to be activated.

*Toe locator tracks* – Track recesses on which the toe locator sensors or switches can be adjusted, allows the toe locators to be moved for individual foot length differences.

**Software:**

**PCBs** – printed circuit boards; support and electrically connect electronic components to one another through a series of related circuits using conductive tracks and pads etched from one or more sheet layers of copper laminated onto or between sheet layers of non-conductive substrate.

**GUI** - graphical user interface, is a type of user interface that allows users to interact with software through graphical controls and visual indicators instead of text-based commands on a computer.

**Archie GUI** - GUI based computer program which allows the researcher to control the sensor footplate and receive, display and save sensor data in real-time.

**Arch-analyser** - GUI based computer program which allows the researcher to view and analyse raw data produced by Archie GUI and save the results to USB.

**Packetyser** - GUI based computer program which provides a utility function to extract data from files created by Arch-analyser GUI and organise it into an SPSS statistical package for Windows v22.0 (IBM SPSS Inc., Chicago, IL) or Excel compatible format for data analysis and save the result to USB.

# SECTION ONE:

## From *Original* to *Final* Archie: re-design and build

## 4.1 Description of Original – ‘Archie’

The Archie biofeedback device was intended to assist in the performance of foot exercises with real-time visual feedback to encourage specific toe and foot movements to improve intrinsic foot muscle strength. The original Archie measured foot arch movement, via the deformation of a bladder under the arch recording pressure change and foot location via information from proximity sensors located under the great toe, fifth toe and heel. This information was, simultaneously processed to provide biofeedback by means of a visual display. (Figure 4.1)

Original Archie consists of two sensor systems. Sensor system one consists of a manually inflatable bladder with release valve and sensor system two consists of adjustable toe and fixed heel proximity sensors embedded into a rigid footplate with a removable rigid cover, a hand held controller to display visual feedback via LEDs, mains power connection and a support footplate

**Figure 4.1**: Original Archie, sensor footplate with hand held air pump and biofeedback control screen

### 4.1.1 Original Archie components

The original Archie biofeedback device was made up of five components shown in Figure 4.2:

1. Sensor footplate encased in a plastic cover with a moulded, curved heel placement locator to protect the movable proximity sensors
    a. Arch bladder with air intake valve
    b. Foot locators with proximity sensors
2. Hand held control device with LED visual biofeedback display
3. Hand operated air pump with a valve to inflate/deflate bladder
4. Support footplate with a heel locator cup for non-testing foot.
5. Power supply - all interactive components were connected via cables, with the device powered from the sensor footplate using an AC to DC wall adaptor.

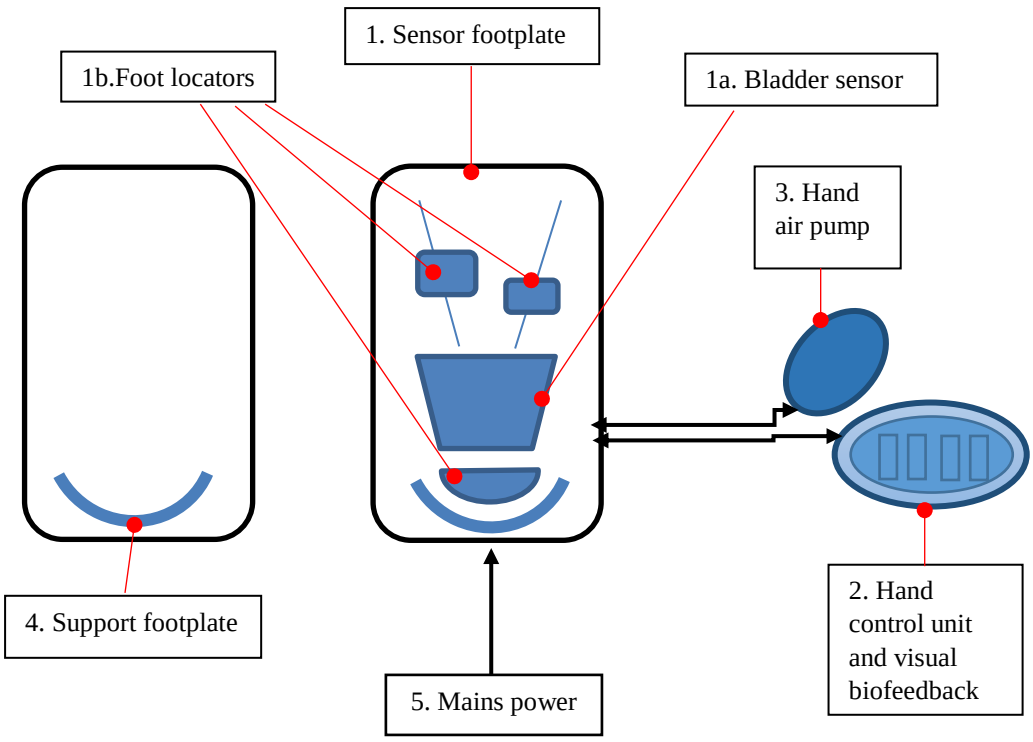



**Figure 4.2**: Block diagram of the original Archie device

### 4.1.2 Sensor footplate - Bladder system

The bladder component of original Archie was designed to provide relative measures of arch movement. The bladder was inflated with air to fill the space under the arch of the user's foot. Change in pressure inside the inflated bladder was created by any movement in the height of the arch, this pressure information was sent to the hand-held controller. The user received feedback of arch pressure on a light emitting diode (LED) display. The bladder was made of semi-rigid plastic with an asymmetrically positioned air intake valve attached to the base, close to the heel. Bladder inflation and deflation was achieved via manual pump and valve control, with air intake tubes primarily external to the footplate.

### 4.1.3 Sensor footplate - Foot locator system

The foot locator system, sensed contact between the great toe, fifth toe and heel with proximity sensors mounted in the footplate. This provided information to the user regarding their foot placement via an LED display. The heel sensors were fixed into the base, the toe sensors were mounted on recessed toe locator tracks that were adjustable to accommodate different foot lengths and ensure contact with the sensors.

### 4.1.4 Hand-held controller with user interface

The original Archie hand-held controller was constructed of molded rigid plastic. An internal printed circuit board (PCB) supported three single round LEDs, a separate parallel LED array, and microcontroller. The top cover included a foot like shape, circles and arrows which were backlit by LEDs. All control, warning and status lights and feedback were embedded within the original Archie hand-held controller, which provided two switches for the user to

control the sensor footplate. A three position switch allowed the user to select left foot, right foot and power off and a single position switch reset the sensor footplate. The hand inflation bulb and valve for the bladder was situated adjacent to the hand-held controller.

The hand-held controller (Figure. 4.3 a, b) also provided the feedback interface which displayed:

- Power status
- Toes and heel contact on the foot locator proximity sensors for both right and left feet.
- Change in bladder pressure with a twenty stage sequential LED array lighting up from one to twenty LEDs depending on an individual's arch movement.
- Overload bladder pressure warning.

a) b)

**Figure 4.3.** Hand-held controller display face (a), with internal LED array and PCB (b)

### 4.1.5 Original Archie limitations and upgrade

Original Archie underwent preliminary bench testing during 2013. During testing some components malfunctioned or failed and design limitations compromised device functionality. Firstly, the bladder sensor system was compromised by materials failure and the foot locator system was unable to be economically replicated. Secondly, the hand-held biofeedback component could not capture and store raw data which was required for research

and the connectivity and status feedback was hard for the user to interpret. Thirdly, complete specs of the PCBs were unavailable and difficult to replicate. Fourthly, due to cabling between the hand-held controller and sensor footplate the connectivity was unreliable and a trip hazard.

The original Archie needed to be upgraded to fix the limitations described above. The upgraded device (final Archie) required a microcontroller based system with new firmware to manage the new functionality which included sending accurate data to a personal computer (PC) that replaced the hand-held controller. This provided improved visual biofeedback and failure monitoring. An upgrade of original Archie's capabilities to include Bluetooth® connectivity was also considered important. The final Archie functional requirements were determined in consultation with electronic and instrumentation engineer John Eisenhuth (B. Eng.) Professional Officer, The University of Sydney.

### 4.2 Final Archie: From inception to clinical trial-ready

Three final Archie units were built. Initially the footplate and some components of original Archie were used to test the final bladder system. One final Archie was used for ongoing component and module testing, while system and user repeat testing were completed on two final Archies, prior to commencement of the clinical trial on the feasibility of the device. The clinical trial required two fully functional final Archie devices.

Development of final Archie included firstly, redesigning and building the external physical housing and creating inserts to mount the new hardware such as the air pump, solenoid and the PCBs. Secondly, replicating or modifying the bladder system and the foot locator system. Thirdly, the electronics hardware was upgraded with new firmware for the microcontroller

based control electronics and new PC based software for user interaction and feedback. The electronics upgrade included: power management incorporating an indwelling rechargeable battery and a voltage regulator, battery charger and battery charge LED indicators. Wireless connectivity was implemented with an embedded off-the-shelf Bluetooth® module. Fourthly, a computer based GUI (Archie GUI) was also developed to control the sensor footplate and receive real-time sensor data from the sensor footplate via a Bluetooth® connection.

### 4.2.1 Sourcing and testing new materials

New materials were sourced using new as well as established suppliers or were available within The University of Sydney, Faculty of Health Sciences research support workshop. Each new component or module underwent three phases of testing. First, components were individually tested for reliability of function to avoid single point of failure for each subsystem. Second, testing was undertaken in conjunction with the relevant module and system structures in which they were to be house and finally all components, modules and sensor systems were user tested with the final Archie devices.

### 4.2.2 Final Archie - functional description

The final Archie device consists of an electronic inflatable bladder with air valve and solenoid (bladder sensor system) and adjustable toe and fixed heel membrane switches (foot locator sensor system) embedded into a rigid footplate with a removable silicon cover. These sensor systems provide real-time dual visual feedback and optional guidance using target lines displayed on a PC, with microcontroller and wireless connectivity. In addition to these features, the final Archie has data saving and analysis capability. (Figure 4.4)

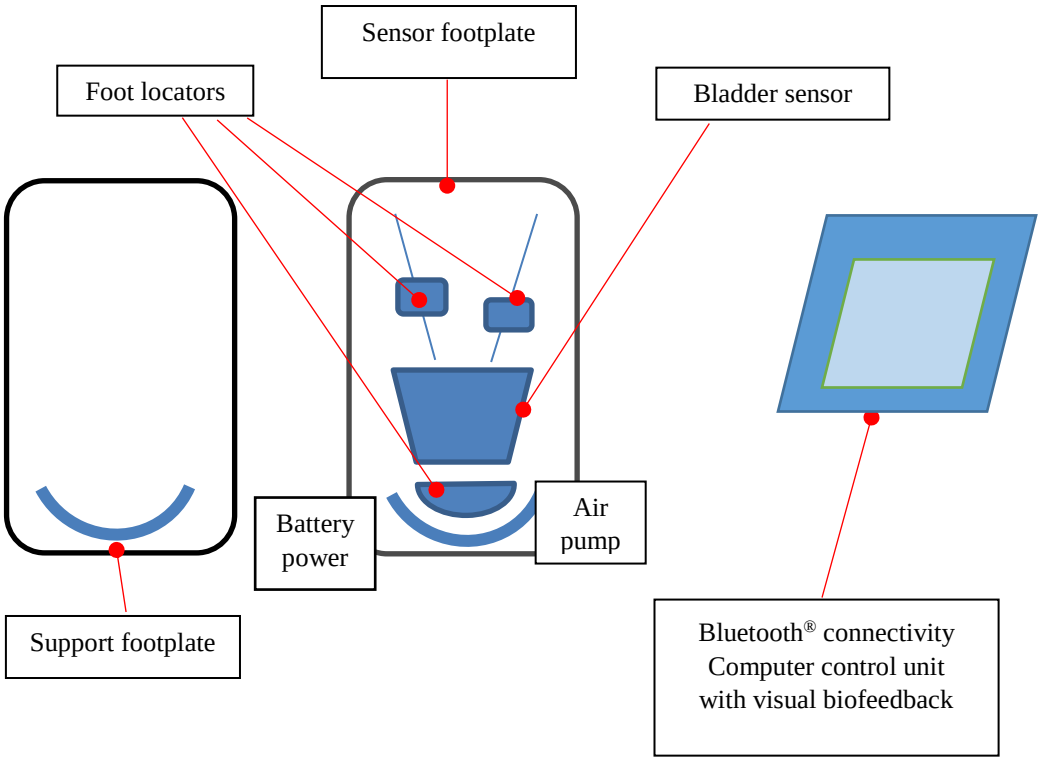



**Figure 4.4** Block diagram of the final Archie device design

### 4.2.3 Sensor footplate build

The sensor footplate build consisted of the routing of the physical housing with a layered design, creating 3D printed inserts and the construction of the bladder and foot locator systems. The physical housing of the sensor footplate needed to be sufficiently robust to safely withstand adult body weight, provide secure inserts to house the electronics, pump and solenoid and allow easy access for repair and maintenance. The new sensor footplate was constructed out of a series of six custom designed layers of computer routed 6 mm thick acrylic. The design for each layer of the sensor footplate was computer drawn (CAD - Sketch up), then converted into a readable program for the computer-controlled router (X-carve CNC router, Inventables, Inc. Chicago, IL 60661 USA).

Initial routing trials to construct the footplate were compromised due to debris generated during the carving phase clogging the rollers on which the carving tool moved and low motor power. These problems were resolved by adding a vacuum extraction system to remove debris generated during routing and increasing the router motor current. To ensure a uniform depth of cut across the entire layer being carved a stabilising platform was firmly secured to the routers base and levelled by routing the work area to the same depth.

The physical housing of the sensor footplate is formed from six mm layers of uniquely designed and cut acrylic sheet. (Figures 4.5 and 4.6). The six layers were stacked on top of each other in their respective positions and secured with six screws that could be removed to allow access to the internal systems for efficient repair or to upgrade parts. Each layer was cut so that when they were stacked together compartments would be created. These compartments were for the inserts to house the indwelling hardware and cabling.

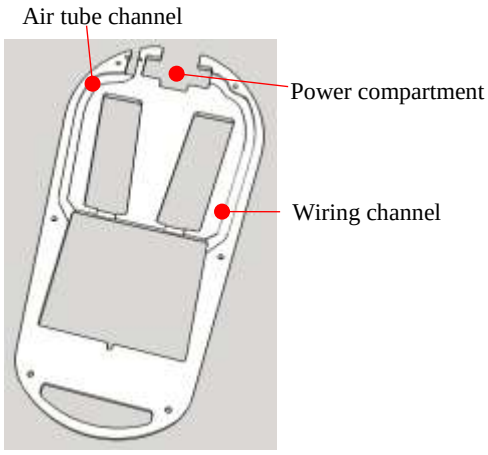



**Figure 4.5** Lower middle layer

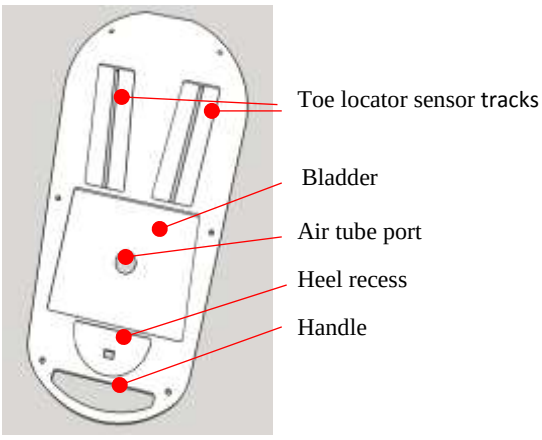



**Figure 1.6** Top layer

The top layer was designed with recesses in which to embed the bladder and fixed heel sensor. Toe locator tracks which are two angled indented tracks (4° orientation off mid line) for sliding and adjusting the toe sensors, were embedded into the design. The tracks ensure a graded spacing between the toe sensors providing increasing breadth with length, to fit a

range of foot sizes from small to large.  A cut-out was provided to act as a handle as well as serve as an anchor point for the heel alignment cup.

### 4.2.4 Inserts

The compartments created in the acrylic layers were filled with insertable crush resistant mounts for the air pump, solenoid, battery and PCBs. Compartments were designed with shapes of fixed size into which 3D printed plastic inserts could be placed. The inserts were designed using SketchUp CAD software and printed with a 3D printer (UP Plus 2, 3D printing system, Tiertime Technology. Beijing, China). An example of the physical housing for the control PCB is shown in Figure 4.7.

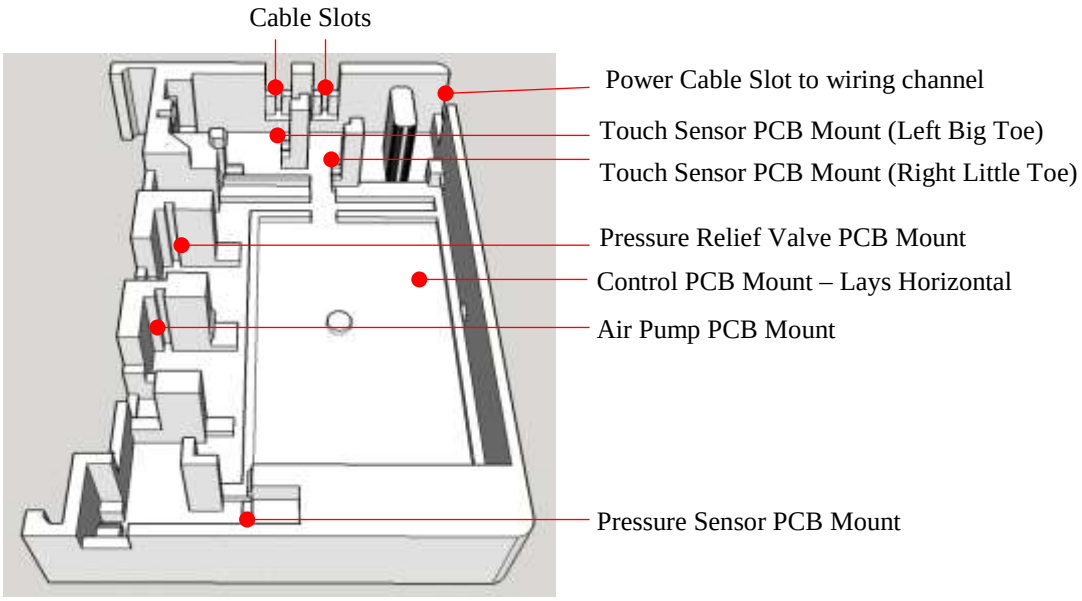



**Figure 4.7**: Control PCB housing example

## 4.3 Bladder sensor system

The Bladder sensor system consists of an inflatable bladder that resides under the arch of the foot and includes the following components: the bladder membrane, frame, adhesive sealant,

inlet port, tubing, solenoid valve, pump and pressure sensor. Changes in plantar arch space cause changes to the pressure in the air bladder which is detected by the pressure sensor. The pressure signal is sent wirelessly to a PC for real-time biofeedback, data collection and storage. This provides the user with a visual display of arch movement during the performance of the foot exercises.

### 4.3.1 Membrane selection

The bladder membrane material of original Archie had become quite stiff creating resistance to inflation which compromised its ability to deform to an individual's plantar arch space. Replacement materials for the bladder membrane were investigated and included: silicone, orange lightweight nitrile rubber, black medium weight rubber and a grey latex and rubber mix.

Subsequent bench testing led to the use of a medium weight rubber, normally used for blood pressure cuffs and other medical applications, for the final Archie bladder membrane (Mentone Educational Supplies, QLD Australia).

### 4.3.2 Bladder construction

As the bladder was the only deformable part in Archie, with the potential to fail either with air leaks from material degradation or valve failure, it was essential to re-design and build a new fully enclosed self-contained bladder such that if it failed, a new bladder unit could easily be inserted into the sensor footplate. Different designs were trialled to ensure the bladder shape would accommodate different foot arch sizes and shapes, consideration was given to the availability of materials, ease of construction and use.

The final Archie bladder design consists of a base, membrane and frame. The membrane is positioned between the base and frame which are held together using screws. The base provides a solid, non-porous backing on which the membrane is mounted. A hole and a circular recess in the center of the base is provided for attachment of the air inlet port. The edges of the base have been routed leaving a raised trapezoid to assist with positioning the frame and sealing the membrane. The frame consists of a trapezoidal cut-out through which the membrane expands when inflated. Screw fixing patterns for the external casing of the arch bladder and a routed inset for the central air intake valve were added (Figure 4.8). During assembly, an adhesive-sealant is applied between the membrane and base to provide a leak proof seal.

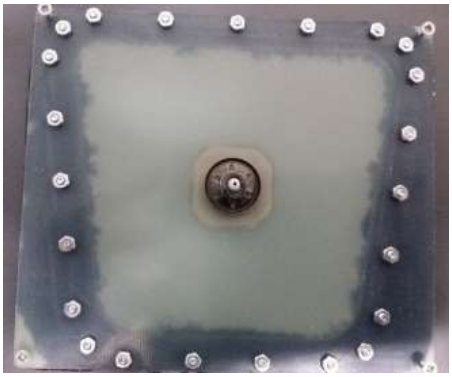


**Figure 4.8**: Final Archie mounting base with air intake valve

The design features of the bladder sensor system of the final Archie can be summarised as including a trapezoidal bladder shape, a fiberglass laminate base and frame with an air inlet port, a rubber membrane that is secured between the fiberglass base and frame as shown in Figure 4.9.

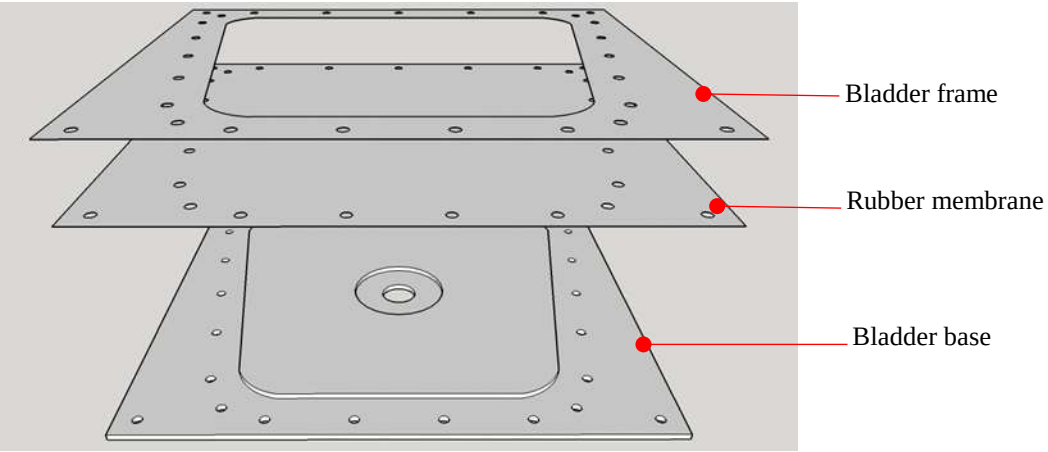



**Figure 4.9**: Bladder assembly design

### 4.3.3 Adhesives and fixing agents

The join between the base and membrane is critical for leak free operation of the bladder. The join must withstand frequent inflation cycles as well as regular over pressure events caused by foot movements on the bladder. Therefore various fixing methods were trialled to construct a durable air tight interface. All methods consisted of applying a sealant to the base - bladder interface and fastening the frame to the base to apply pressure to the join. Initially 3-D printed rivets were designed and tested. Unfortunately these proved too bulky and could not provide enough pressure to adequately seal the join. Rivets and machine screws were also tested, with machine screws being chosen for the final design.

Adhesive sealants were tested for both flexibility and adhesion on the most promising substrates to be used for the bladder frame and base. Sealants tested included: Permatex Adhesive, Sealant Clear RTV and Silicone Adhesive. A silicone-based sealant in combination with 2.5mm machine screws was most effective in creating an air tight seal.

The final Archie bladder design is shown in Figure 4.10 and 4.11, illustrating the hole and circular recess where the air inlet port is mounted in the final Archie. The sides of the base

have been routed into the raised trapezoid and fastening holes have been pre-drilled to ensure the bladder is air tight.

**Figure 4.10:** The new bladder base

**Figure 4.11:** Final bladder

### 4.3.4 Air pump and solenoid

The manual inflation bulb and valve of original Archie were replaced with an air pump (Koge KPM, New Taipei City, Taiwan R.O.C) and 3 Volts DC solenoid valve. The solenoid valve is controlled electronically. The valve provides air pressure release when the bladder is switched off or loses power, or when the user chooses to deflate the bladder using a GUI control. The pressure sensor's signal is continually monitored and if an over pressure condition is detected the solenoid is deactivated, deflating the bladder and ensuring protection of the bladder and pressure sensor. (Figure 4.12).

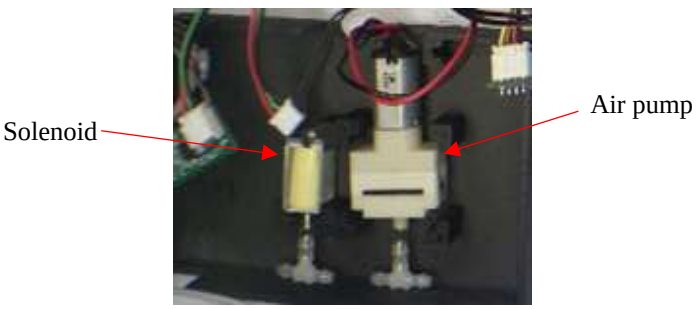



**Figure 4.12:** Air pump and solenoid

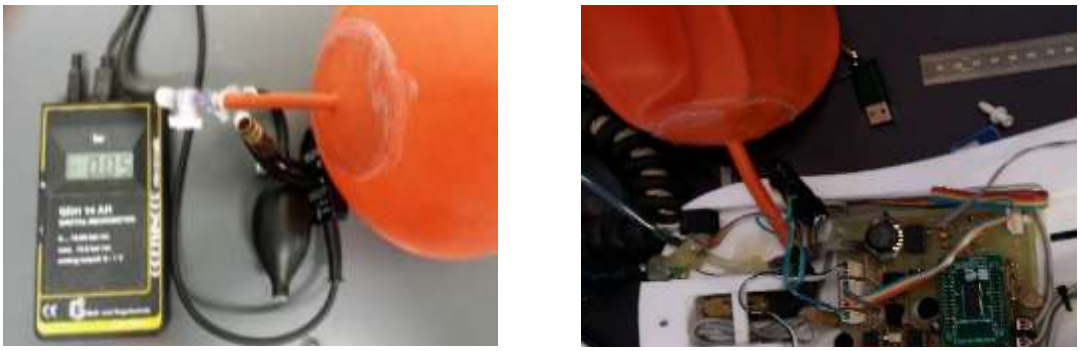
### 4.3.5 Air inlet port

The bladder's air inlet port allows the bladder to be connected to air distribution tubing. In the final Archie, the air inlet port was moved to the centre of the bladder's base in order to minimise the risk of occlusion by the user's foot and to allow both left and right feet to be tested (Figure 4.10). Pathways for internal air intake tubing were included in the layer designs of the sensor footplate. However, this limited the space for the valve under the bladder unit and led to modifications to the physical housing layer design. Numerous custom air inlet ports were fabricated and tested. Initially, a 3D printed valve was trialled in an early bladder prototype but it was unexpectedly porous and was unable to maintain inflation and was too bulky. Other valves trialled were also incompatible because they required a large nut in order to be fastened to the base. The valve finally chosen consisted of a brass tube braised to a washer and held in place by a push-on fastener instead of a nut. This combination was compact and airtight.

### 4.3.6 Bladder Sensor system initial testing

The new air pump and connecting tubes were tested for air leaks and maximum inflation. This was first done with a commercially available off-the-shelf air bladder with new connectors and the original Archie manual air pump bulb, external to the device. All original Archie tubes, internal connectors and valves (Cole-Parmer Inc., Illinois, USA) were replaced and tested for leaks. First, component tests were completed external to device and then repeated with the tubes installed in the final Archie (Figure 4.13 a, b). Further testing for leaks was completed with the final Archie bladder, external to the final Archie sensor footplate. The bladder test was a repeat inflation test to determine if the air pump could maintain 0.05 bar, (1 bar =100kilopascals) which is equivalent to the pressure of 50 cm of

water. A 20% change in pressure over one hour was considered a failure. Details of the bladder sensor system testing, including test procedures and results, can be found in Section 2: 4.7.1.



a) b)

**Figure 4.13** External testing of pump (a) for correct inflation and testing within original Archie (b)

### 4.4 Foot locator sensor system: proximity sensors and membrane switches

The foot locator sensor system is designed to detect the presence of the great toe, fifth toe and heel of the user's foot. The toe sensors are mounted on sliding adjustable rigid supports within the toe locator tracks of the sensor footplate while the heel sensor is fixed and embedded at the rear of the sensor footplate. The sensors underwent component and module testing with proximity sensors replicating the original Archie sensors and then using membrane switches.

#### 4.4.1 Proximity sensors

Capacitive based proximity sensors were initially trialled for inclusion in the final Archie. Although they reliably detected finger presses, their in-built compensation circuit made them

unsuitable for use in detecting each foot sensor. The compensation circuit compromised the proximity sensors ability to detect the presence of the toes and heel after a relative short period of time and would indicate loss of contact. The only way to re-establish a positive contact was to reset the sensors, by completely lifting the foot off, then replacing the foot to establish contact. Completing this manoeuver would directly affect the pressure wave generated by the bladder, as the arch was no longer in contact with the bladder, thereby compromising the intended purpose of Archie to provide continuous feedback of both arch movement and foot location during the performance of the foot exercises. The proximity sensors were replaced with membrane switches. Further details of the testing procedures for the proximity sensors can be found in Section 2: 4.8.1.

### 4.4.2 Membrane switches

A series of membrane switches were tested during final Archie's development. A circular off-the-shelf membrane switch was initially used to determine the activation load on which to base the design of the custom membrane switches. Three protectively coated custom membrane switches (VMG Print Group), a great toe, fifth toe and heel switch (Set 1) were tested for activation load to ensure their ability to detect the presence of the foot and maintain its correct location (Figure.4.14). Known activation pressures were applied to various points over the surface of the switches. Pressures required to activate the switches were found to be inconsistent and much higher than the specified maximum activation pressure of 100g/cm2.

A second set of switches (Set 2) were designed and built by the manufacturer, VMG Print Group after in-house factory testing to meet the specifications of the off-the-shelf switch. Tests were conducted with each component and module. The results for both the new toe and heel switches demontrated that the switches activated consistently within the required load over repeated trials, and were found to be fit for purpose. Further details of the membrane switches bench testing can be found in Section 2: 4.8.2 to 4.8.7.

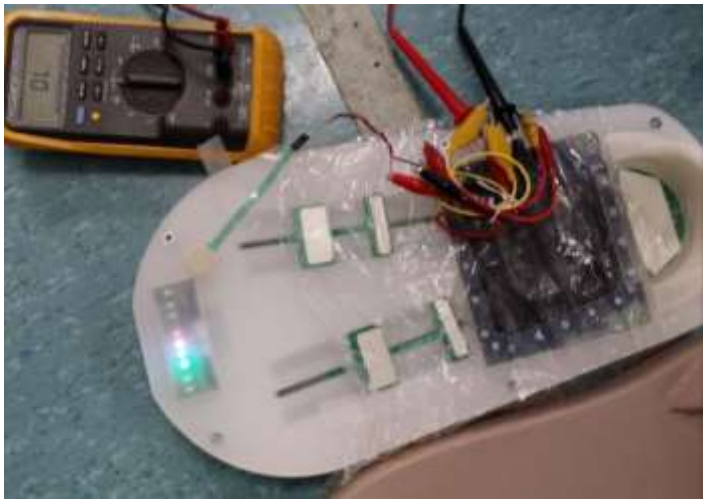


**Figure 4.14**: Membrane pressure switches module testing

## 4.5 User interface

A major improvement to original Archie was the method of feedback delivery, from a LED display on a hand-held controller to a visual interface displayed on a PC. The new PC interface is a custom designed software program called Archie GUI. Archie GUI provides a means of controlling the sensor footplate, processing the sensor information to generate biofeedback, and saving data for later analysis. The first Archie GUI was used for testing the original Archie sensor footplate, the second Archie GUI was used for the final Archie devices. Further details of the user interface bench testing can be found in Section 2: 4.9.

### 4.5.1 Biofeedback development

The biofeedback upgrade process was completed in stages, first the original Archie command codes for the sensor footplate and the pressure sensor signal that were orginally sent to the handheld controller were intercepted and sent to Archie GUI. Command codes were sent via an RS232 cable to the USB converter as ASCII strings. The pressure sensor signal generated by the bladder was digitised and sent to Archie GUI, via USB, using a National Instruments NI USB-6210. National Instruments Corporation Austin, TX, USA. The ASCII character strings were decoded and actions taken by Archie GUI were based on the characters within the string.

The pressure sensor data was displayed in real-time on a graph. New control (microcontroller and Bluetooth® radio module), power management, pressure and contact sensor PCBs were then developed and integrated into the system as outlined in Figure 4.15.

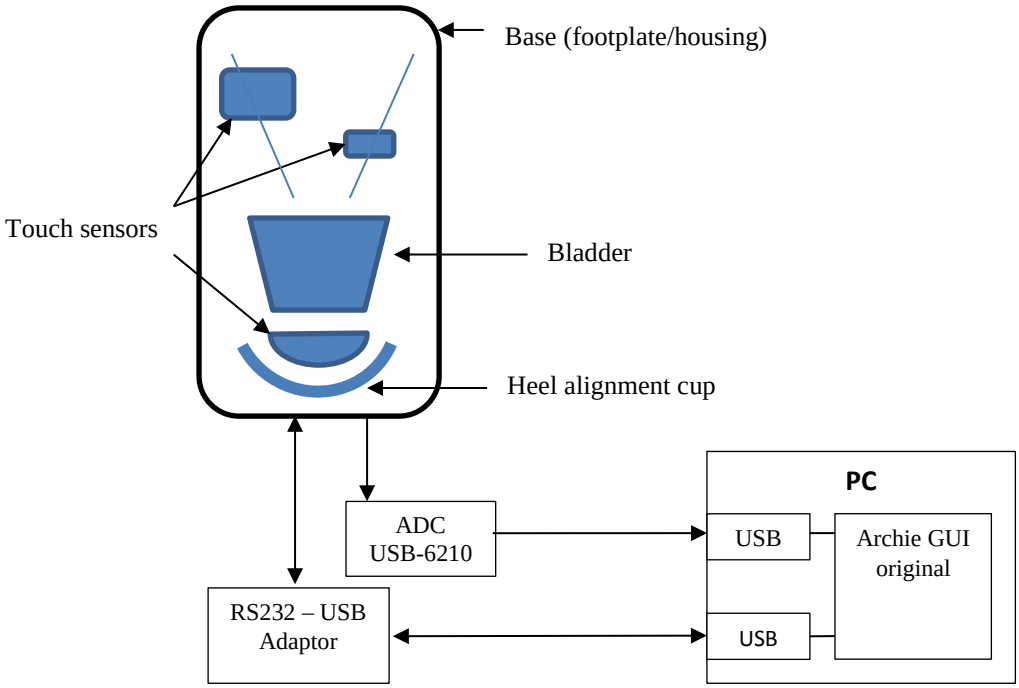



**Figure 4.15:** Block diagram of intercept and recoding

### 4.5.2 Archie GUI

The Archie GUI to be incorporated in the final Archie was developed in two stages. The first Archie GUI was designed using Embarcadero C++Builder XE8 which is an interactive development environment that provides tools and components that support rapid GUI development and tested in original Archie. Following this initial testing phase, modifications were undertaken and Archie GUI was modified to enable the operation of final Archie. (All GUI development used Embarcadero C++Builder XE8 interactive development environment). The Archie GUI in the final Archie provides the functions listed below:

- Power on/off - status
- Device connectivity - connected/disconnected
- Foot selection, left/right
- Bladder inflation/deflation

- Monitor or view sensor data start/stop
- Valve close/open
- Name of test or exercise task
- Capture (Save sensor data) start/stop
- Input of user ID and test information
- Graph control
    - zoom axis
    - cursor X or Y - On/Off
    - target line use - On/Off
    - target line slope – Positive/Negative

The redesign and build of the biofeedback component included changing the displays for both sensor systems which substantially improved functionality. Dynamic visual data display components are provided for the bladder sensor system and the foot locator system and a static exercise test reminder sequence is provided to cue the user for each test. These improvements were made for ease of use and better visibility, enabling clearer interpretation of the data display.

#### 4.5.2.1 Bladder sensor system GUI

The visual data biofeedback display component for the bladder sensor system is made up of three modules and includes a real-time graph that occupies the majority of the PC screen as well as optional assistive guidance provided by cursors and guidance or target lines (Figure 4.16).

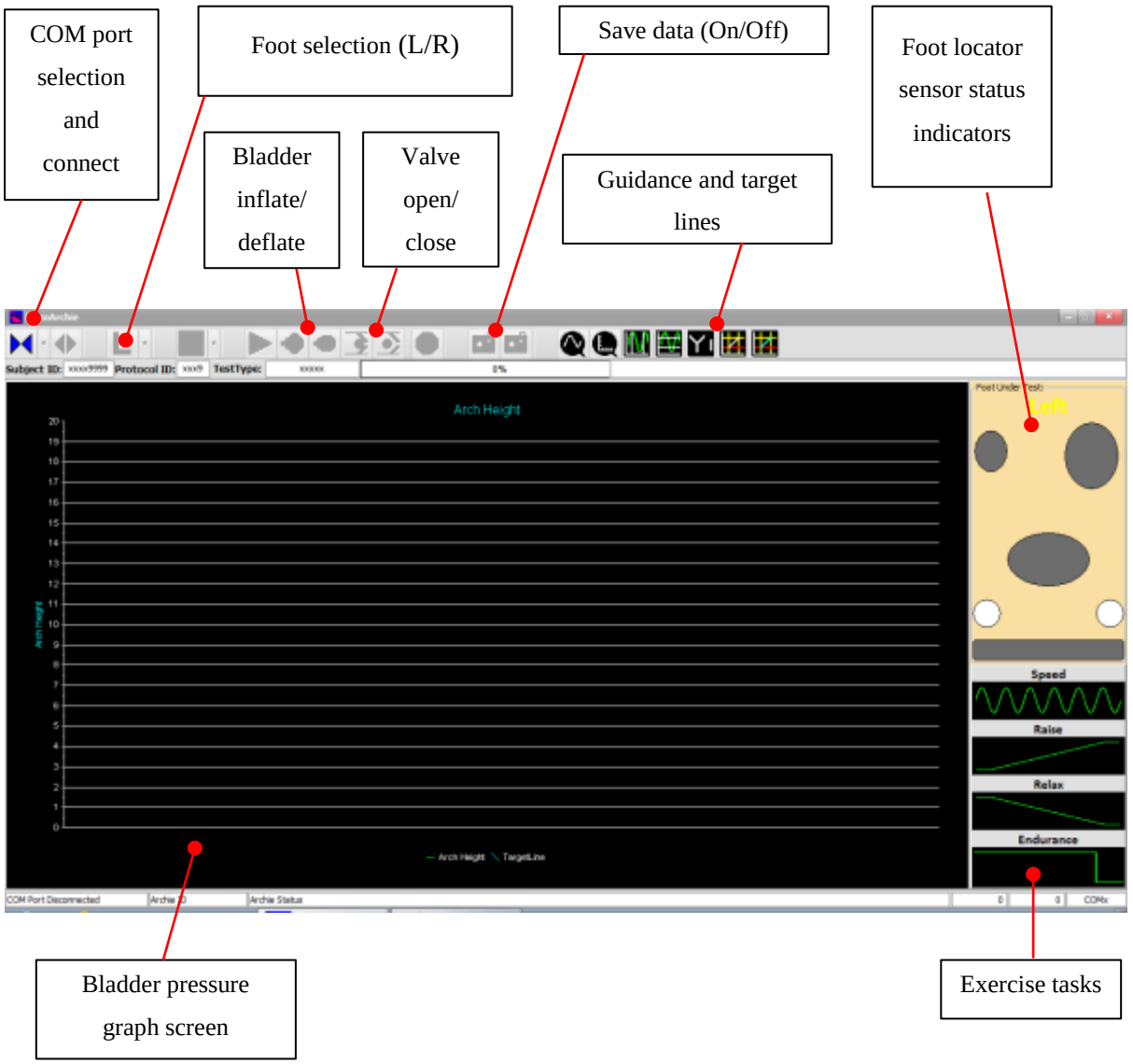



**Figure 4.16:** Data display methods: control buttons - top of screen, Biofeedback - central screen

*4.5.2.1.1 Real-time graph*

The real-time graph provides a visual representation of the elevation of the arch of the foot. As arch height increases pressure inside the bladder decreases. The pressure signal is inverted so that the displayed signal increases with arch elevation. The pressure signal is not an

absolute measure of arch height but a relative measure of pressure changes under the arch of the foot.

The operating pressure for the bladder was set at 50% of full inflation, with graph units calculated as a scale based on the following information. The maximum pressure specified by the manufacturer SMI for the ultra-low pressure digital sensor for the bladder (Compound gauge) is 100cm of $H_2O$. The pressure scale used for the functional operation of the bladder, ranges from minimum pressure =1638 Y axis counts to maximum pressure = 14745 Y axis counts. This is equal to a maximal range of 17.8 converted to arbitrary units (a.u.). Such that if 1638=0 and 14745=20, arbitrary units could be created from 0 to 20 units, and scaled equidistant along the 'Y' axis. The 'X' axis records temporal measures and is equal to 100 samples per second or one sample every 10 milliseconds.

*4.5.2.1.2 Line cursors*

The cursors provide control for data capture, data examination and can act as target lines. The two coloured movable 'X' cursors are vertical lines inserted into the pressure graph that mark points along the X axis and can provide start and finish visual goals for each exercise task. The two coloured 'Y' cursors are horizontal lines inserted into the pressure graph that mark points along the Y axis and can provide upper and lower visual goals for each exercise task. The guidance or target lines are diagonal coloured lines inserted into the pressure graph. These can be positioned and oriented on the graph by changing the slope determined by temporal-spatial parameters and provide guidance or target lines to follow during the raise and relax arch procedures.

#### 4.5.2.2 Foot locator sensor system GUI

The visual data display component for the foot locator sensor system is located on the upper right section of the GUI. It consists of three ovoid shapes positioned relative to one another to represent the great toe, fifth toe and heel. A rectangular shape below the ovoid shapes summarises the combined state of the ovoid shapes. The foot locator shapes provide feedback to the user about contact of the great toe, fifth toe and heel with the sensor footplate by changing colour. With no contact, shapes remain grey, with contact shapes change to green. Each shape is activated individually depending on the contact state of its corresponding toe or heel. The size of the great toe and fifth toe shapes are different with the larger shape indicating the great toe of the foot being tested. The rectangular shape is green when all foot locators record contact and changes to red if contact with any of the foot locators is lost.

Simultaneously to the development of Archie GUI, exercise tasks were being bench tested. These tests included performing different foot exercises, positions and exercise sequences.These tests were completed with lab colleagues to determine the impact of the feedback screen on an individuals ability to complete four foot exercises. Tests were completed under two conditions, with the visual feedback screen and without the visual feedback screen. Further details of the foot exercise testing can be found in Section 2: 4.9.1.

Following the bench testing of the exercsie tasks, the full screen display was revised in reponse to user feedback and researcher observation. The bladder's pressure display graph was reversed to reflect the actual movement of the arch so that the signal increased as the users arch elevated. Changes relating to the foot locator system included changing the colours representation of the toe and heel sensors on the upper right of the screen from beige to green and simplying the representation of the toe and heel display to more clearly represent foot

contact. The exercise tasks to be tested in the feasibility trial were identified during this process. Visual depiction of the four test exercises was added to the lower right of the screen to remind the user of the exercise sequence. A static idealised visual representation of each specific signal pattern required for each exercise, with the name for each task was displayed (Figure 4.16). Section 2: 4.9.1 and 4.9 of this chapter provides further details of the foot locator sensor system bench testing.

## 4.6 Electronics

The upgrade of the original Archie to the final Archie required new electronics and PCBs. Each PCB (an example is provided in Figure 4.17) provided a specific function and all PCBs connected to a microcontroller on the control PCB.

**Figure 4.17:** Example of PCBs mounted in inserts during testing

The final Archie PCBs included: a power PCB for power and battery management, a control PCB for the mircocontroller and wireless connectivity, two sensor PCBs for the pressure sensor and the membrane switches and an LED PCB for the status and warning lights.

### 4.6.1 Power PCB

The original Archie electrical cable connection, that used an AC to DC power adapter, was replaced with a rechargeable indwelling battery (Li-Ion 1000mA 3.7V 53mm x36mm x 6mm) and support components in the final Archie. Power status and re-charge support of the battery was managed on the power PCB.

### 4.6.2 Microcontroller and connectivity PCB

In the original Archie the control of the sensor footplate was implemented with a microcontroller that managed the interaction between the footplate sensors and the hand-held controller. The final Archie also utilises a microcontroller which manages the extended functionality provided by new components that include, a battery, battery management, wireless Bluetooth® connectivity, power status LEDs, indwelling air pump and solenoid valve. (Figure 4.18)

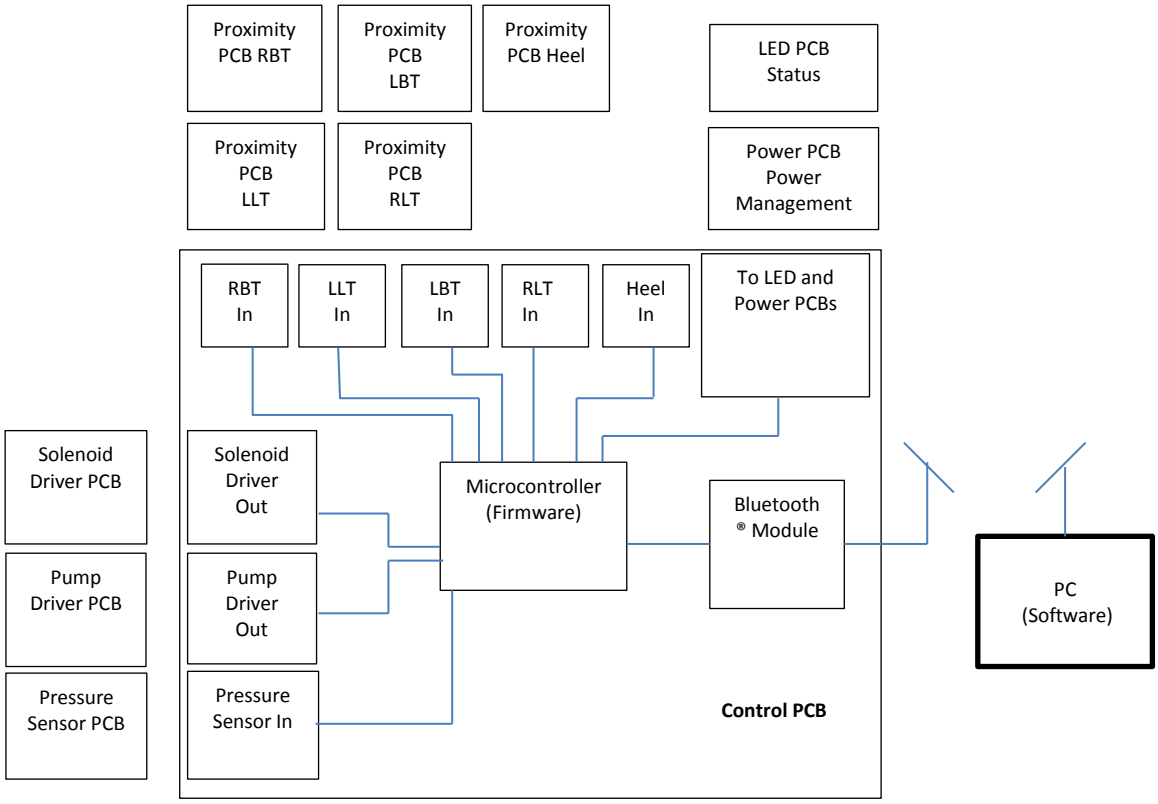



**Figure 4.18**: Block diagram of the PCB designs

### 4.6.3 Sensor system PCBs

Two unique PCB designs were used for the sensor systems. One design, for the membrane switches, provided a voltage change indicating switch activation that signalled the microcontroller. The second design was for the pressure sensor which provided temporal serial digital data to the microcontroller which was embedded in the main insert (Figure 4.19).

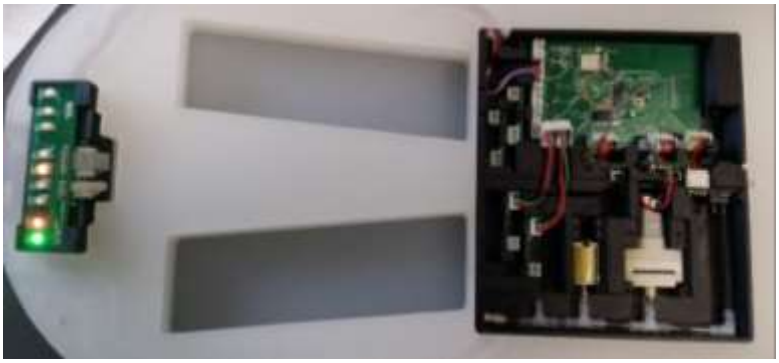


**Figure 4.19**: Final Archie PCBs, air pump and solenoid with LEDs inserted into second layer at the end of the new sensor footplate

### 4.6.4 Status and warning lights

LEDs were placed at the top of the active footplate protected under one layer of laminated plastic (Figure 4.20). The LEDs provide status information on power, battery charge, connection status and fault conditions. The LED subsystem is managed by the microcontroller.

The LED status lights in the final Archie indicate:

- Power (external power source on/off )
- Battery charging status (fully charged/charging )
- Battery Level (1Hz, 90%DC, <80% charged; 1Hz, 50%DC, 60% - 40% charged; 1Hz, 10%DC, 20% - 10% charged; 2Hz, 10%DC,<10% charged)
- Bluetooth® Connectivity (‘On’ when connected - range approximately 10 m)
- Bluetooth® Mode (Active – On, Deep Sleep – Flashing)
- Error (malfunction detected in the air pump or solenoid)

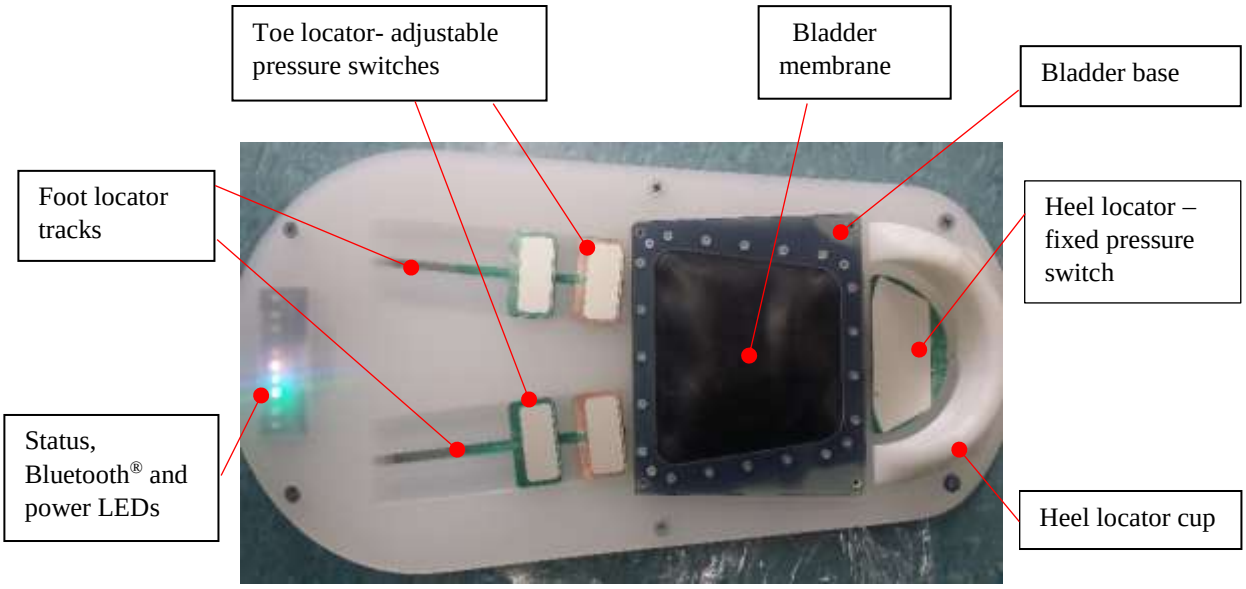



**Figure 4.20:** Final Archie sensor footplate power status on

# SECTION 2:

## Bench and pilot tests of the final Archie biofeedback device

## 4.7 Testing the final Archie biofeedback device

In conjunction with the physical rebuild and the development of the final Archie (Figure 4.20), a series of bench tests and observational studies were completed. These studies first tested the bladder sensor system and foot locator system separately. Bladder sensor system testing included:  the bladder air seal for retaining pressure, the air release valve and solenoid, and the ability of the bladder to record changes in load and height over time. Foot location sensor system testing included: the proximity sensors, and two sets of membrane switches. The first test procedure for all foot location system sensors or switches was to determine activation under different loads, the second test procedure was to determine activation with feedback. In addition user testing was completed focusing on the development of the biofeedback interface and pilot testing the exercises that accompany Archie and the Arch-analyser GUI.

### 4.7.1 Bladder sensor system tests

The new bladder system components underwent a series of tests to determine if they were fit for purpose. First, components testing was undertaken to determine if the bladder air pressure was maintained over time and the solenoid valve was activated to deflate the bladder at the preset maximum pressure threshold. Second, the bladder module was tested to determine its ability to respond to different loads. Third, the bladder system was bench tested for reliability of inflation duration. Fourth, testing was undertaken with lab colleagues during different procedures. These procedures included: testing the sensitivity of the pressure sensor that activates the air release valve in seated, double leg stance and single leg stance, and during exercise task performance.

### 4.7.2 Bladder pressure tests

To determine if the new bladder was air tight, repeat pressurisation tests were initially conducted with it installed in original Archie footplate. Pressure within the bladder was measured using an Oscilloscope (Tektronix TDS360 Two channel digital real-time oscilloscope 200MHz 1GS/s. Tektronix. Beaverton, Oregon 9707 USA) connected to the output of the original Archie's on-board pressure sensor with a range of 0-5 volts. The bladder maintained pressure with no change over a series of five repeated 24 hour periods, with a steady 1 volt reading on the oscilloscope. Therefore each bladder was replicated and re-tested prior to being installed into the newly designed final Archie sensor footplates.

### 4.7.3 Pressure and solenoid tests

Tests were completed with lab colleagues to ascertain the reliability of each bladders' air pump and solenoid air valve and to determine the most functional range of sensitivity for the pressure sensor to activate the air release valve. If the air release valve was activated the bladder would deflate. The air pump test required monitoring repeat inflation and observing pressure with the Archie GUI, with the inflation process stopped when operating pressure was met. The maximum allowable pressure was set to the maximum pressure capability of the pressure sensor. Two pressures sensor ranges were tested during the performance of a foot exercise in three positions, sit, stand (double leg stance), single leg (stance): a low range of: -5cm$H_2O$ to 40cm$H_2O$ and high range of: -5cm$H_2O$ to 100cm$H_2O$.

Table 4.1 shows the results of sensitivity testing of the pressure sensor and the activation of the solenoid valve when the bladders maximum allowable pressure was exceeded. The air pump test required one to three inflations for the majority of positions. However the results of

the single leg stance, when performed by one colleague with pes planus, with no inflation occurring and instant air valve release activation, informed later test procedures.

**Table 4.1**. Example of user tests of bladder: low and high range pressure valve sensitivity

| | **Low Range valve** | | **High Range valve** | |
|---|---|---|---|---|
| Position | Inflation No. | Time to Fail (secs) | Inflation No. | Time to Fail (secs) |
| sit | 3 | 10 | 1 | 25 |
| sit | 3 | 10 | 1 | 18 |
| sit | 3 | 7 | 2 | 15 |
| stand | 3 | 15 | 2 | 22 |
| stand | 3 | 10 | 2 | 17 |
| stand | 2 | 1 | 3 | 15 |
| single leg | 0 | 0 | 2 | 0 |
| single leg | 0 | 0 | 1 | 0 |
| single leg | 0 | 0 | 1 | 0 |

The low range pressure sensor was extremely sensitive, with overpressure more likely to occur (Table 4.1). When overpressure occurred the firmware activates the solenoid which deflates the bladder to prevent damage to the bladder and sensor. The high range pressure sensor was found to have better functionality for the experimental tasks with minimal deflation interrupting the completion of the task. Based on the results of these pressure tests, the higher range pressure sensor was used in the final bladder sensor system.

### 4.7.4 Bladder module load and height tests

The bladder modules of both final Archies were tested to determine their ability to respond to different loads using a vernier height guage and a series of weights. Each bladder was inflated to approximately 50% of its maximum pressure (operating pressure) and set on continuous 90 seconds data save mode, using Archie GUI. A series of seven known weights were placed on

each bladder, then removed in sequence, ensuring there was a ‘no load’ pressure recorded at the end of each cycle. Figure 4.21 shows the visual display from the Archie GUI on the increasing and decreasing loading of the bladder. The following weights were sequentially placed on the bladder: 0.5kg, 1kg, 0.5kg, 0.5kg, 0.2kg, 0.2kg and 0.1kg for a total of 3kg (Figure 4.22). As the graph was inverted for user functionality, an actual gain in pressure occurred in loading both bladder units with weights.


**Figure 4.21:** Arch-analyser GUI, screenshot of loading and unloading the bladder

The first analysis that was completed on the bladder pressure recorded by Archie GUI from the series of weights being directly placed on the bladder used raw data that recorded the absolute pressure differences. Each pressure recorded was compared for each equivalent weight over a series of 11 repeat trials for the two final Archie devices, designated Archie 2 and Archie 3.

Absolute difference was calculated with paired-samples t-test (Table 4.2). As the air pump inflated the bladder at slightly different initial pressures the relative change over the seven load changes for each series was evaluated. Therefore a second analysis was completed on the relative change of pressure recorded by Archie GUI for each series of increasing loads (Table 4.2.1, Figures of Graphs 4.23.1 to 4.23.4). Each relative change in pressure was compared over the entire series of weight increase.

For the first analysis on the raw data, the results of the bladder module load tests are shown in Table 4.2. For Archie 2, absolute value load changes, there was no significant difference between the means of the trials of each load ($p>0.53$). When the same testing procedure was conducted on Archie 3, the result was the same with no significant difference between the means of the trials of each load ($p>0.17$) suggesting good reproducibility.[1]

**Figure 4.22**: Archie device load testing, for bladder pressure reliability

**Table 4.2**: Paired sample t-test for test-retest reliability of absolute values of bladder pressure under different loads in the final Archies

| Load | Trial 1 Mean (SD) | Trial 2 Mean (SD) | Mean difference (SD) | p-value |
|---|---|---|---|---|
| **Archie 2** | | | | |
| 0 kg | 10.61 (.07) | 10.56 (.10) | .04 (.10) | .177 |
| 0.5 kg | 8.97 (.06) | 8.95 (.10) | .02 (.08) | .510 |
| 1.5 kg | 5.74 (.08) | 5.75 (.09) | -.01 (.10) | .685 |
| 2.0 kg | 4.22 (.10) | 4.20 (.12) | .02 (.13) | .645 |
| 2.5 kg | 2.88 (.13) | 2.56 (.12) | .02 (.10) | .603 |
| 2.7 kg | 2.40 (.15) | 2.38 (.12) | .02 (.12) | .527 |
| 2.9 kg | 1.98 (.17) | 1.93 (.13) | .05 (.15) | .274 |
| 3.0 kg | 1.77 (.16) | 1.73 (.12) | .03 (.14) | .418 |
| 0 kg | 10.70 (.10) | 10.70 (.15) | .00 (.12) | .962 |
| **Archie 3** | | | | |
| 0 kg | 11.04 (.67) | 11.12 (.53) | -.12 (.76) | .613 |
| 0.5 kg | 9.36 (.64) | 9.50 (.51) | -.14 (.72) | .542 |
| 1.5 kg | 6.08 (.55) | 6.19 (.44) | -.11 (.66) | .595 |
| 2.0 kg | 4.56 (.62) | 4.68 (.47) | -.12 (.72) | .583 |
| 2.5 kg | 3.22 (.66) | 3.36 (.52) | -.14 (.76) | .548 |
| 2.7 kg | 2.75 (.68) | 2.88 (.52) | -.13 (.78) | .594 |
| 2.9 kg | 2.33 (.69) | 2.47 (.52) | -.14 (.79) | .558 |
| 3.0 kg | 2.13 (.69) | 2.28 (.50) | -.15(.78) | .533 |
| 0 kg | 11.16 (.73) | 11.26 (.55) | -.10 (.80) | .688 |

Unit 0-20 arbitrary units, N=11 inflations per load

**Table 4.2.1**: Paired sample t-test for test-retest reliability of relative change in values of bladder pressure under different loads with different raters in the final Archie

| Variable | Trial 1 (mean ± SD) | Trial 2 (mean ± SD) | Mean Difference (±SD) | 95% Confidence Interval | t | P Value |
|---|---|---|---|---|---|---|
| **Test-retest Archie 2 RGS** | | | | | | |
| 0.5 kg | 1.60 ± 0.04 | 1.61 ± 0.02 | -0.01 ± 0.05 | -.04 – 0.02 | -0.734 | 0.480 |
| 1.5 kg | 4.79 ± 0.06 | 4.79 ± 0.05 | 0.00 ± 0.09 | -.05 – 0.05 | 0.038 | 0.970 |
| 2.0 kg | 6.36 ± 0.09 | 6.34 ± 0.09 | 0.02 ± 0.14 | -.07 – 0.12 | 0.511 | 0.621 |
| 2.5 kg | 7.70 ± 0.09 | 7.69 ± 0.07 | 0.01 ± 0.14 | -.08 – 0.10 | 0.284 | 0.782 |
| 2.7 kg | 8.18 ± 0.09 | 8.15 ± 0.06 | 0.03 ± 0.14 | -.06 – 0.12 | 0.722 | 0.487 |
| 2.9 kg | 8.63 ± 0.10 | 8.59 ± 0.09 | 0.04 ± 0.16 | -.07 – 0.15 | 0.829 | 0.427 |
| 3.0 kg | 8.85 ±0.11 | 8.78 ± 0.08 | 0.06 ± 0.17 | -.05 – 0.18 | 1.303 | 0.222 |
| **Test-retest Archie 2 PJL** | | | | | | |
| 0.5 kg | 1.62 ± 0.03 | 1.61 ± 0.04 | 0.012 ± 0.06 | -.02 – 0.05 | 0.671 | 0.518 |
| 1.5 kg | 4.85 ± 0.07 | 4.81 ± 0.05 | 0.045 ± 0.10 | -.03 – 0.11 | 1.422 | 0.185 |
| 2.0 kg | 6.38 ± 0.08 | 6.35 ± 0.07 | 0.03 ± 0.09 | -.03 – 0.09 | 1.224 | 0.249 |
| 2.5 kg | 7.70 ± 0.10 | 7.71 ± 0.09 | -0.01 ± 0.12 | -.09 – 0.07 | -0.197 | 0.848 |
| 2.7 kg | 8.17 ± 0.11 | 8.21 ± 0.12 | -0.04 ± 0.15 | -.14 – 0.06 | -0.876 | 0.402 |
| 2.9 kg | 8.59 ± 0.13 | 8.65 ± 0.11 | -0.06 ± 0.15 | -.16 – 0.04 | -1.288 | 0.227 |
| 3.0 kg | 8.81 ± 0.13 | 8.85 ± 0.11 | -0.04 ± 0.15 | -.14 – 0.06 | -0.864 | 0.408 |

For the second analysis, the results of the relative load changes, calculated with paired-samples t-tests (Table 4.2.1) comparing the loading of the bladder for two raters ( PJL and Rylee Grace Spaulding (RGS), lab colleague), were not statistically significant for all variables, p=0.185 to p=970. The results of the correlations ($ICC_{3,1}$) comparing each complete series of loading, of the relative change in pressure recorded by the Archie GUI, for 11 repetitions, completed by two different raters on two different days, are shown in the graphs below (Figures 4.27.1 to 4.27.4). The results of the series correlations for the relative change in bladder pressure, comparing the loading of the bladder for two raters (PJL and Rylee Grace Spaulding (RGS), lab colleague), tested at different times was excellent, with a correlation of $r^2 \geq 0.997$, p=0.001 for all circumstances (PJL set one $r^2$=0.9967, PJL set two $r^2$=0.9971, RGS set one $r^2$=0.9947, RGS set two $r^2$=0.9970).

These series correlation results, for relative load changes from operational inflation unloaded to sequentially increasing loads over the 90 second endurance save mode, show excellent repeatability. The bladder sensor system of both final Archies store, save and display pressure data consistently.

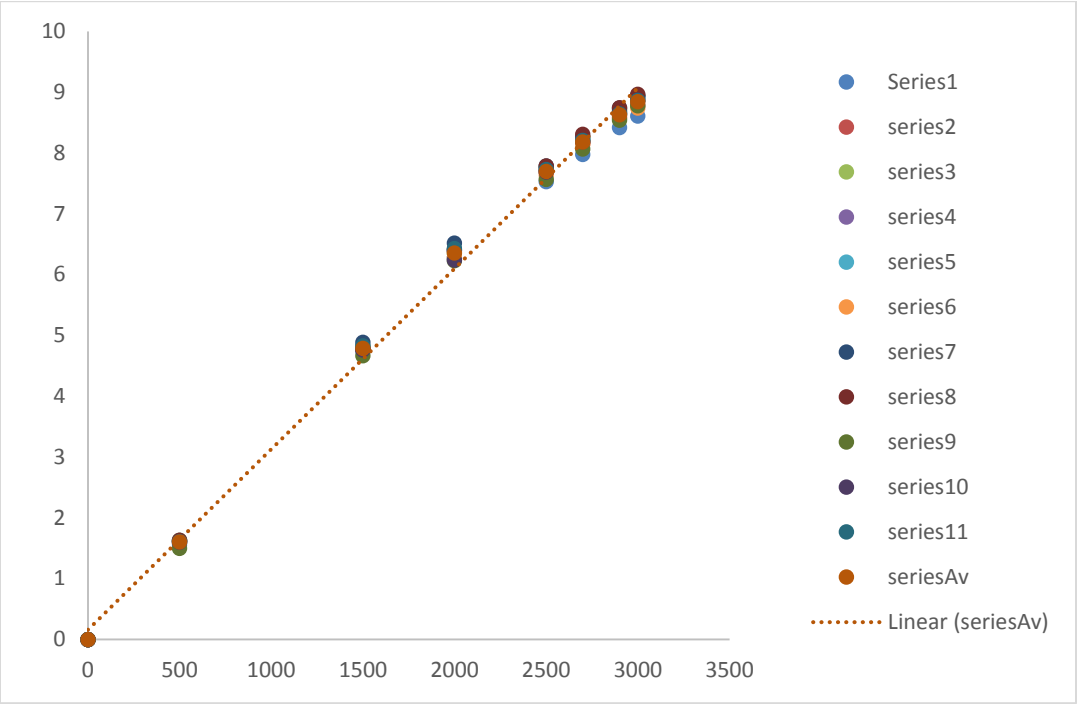



**Figure 4.23.1:** Graph of relative pressure change with increasing loads for Tester RGS time 1, final Archie

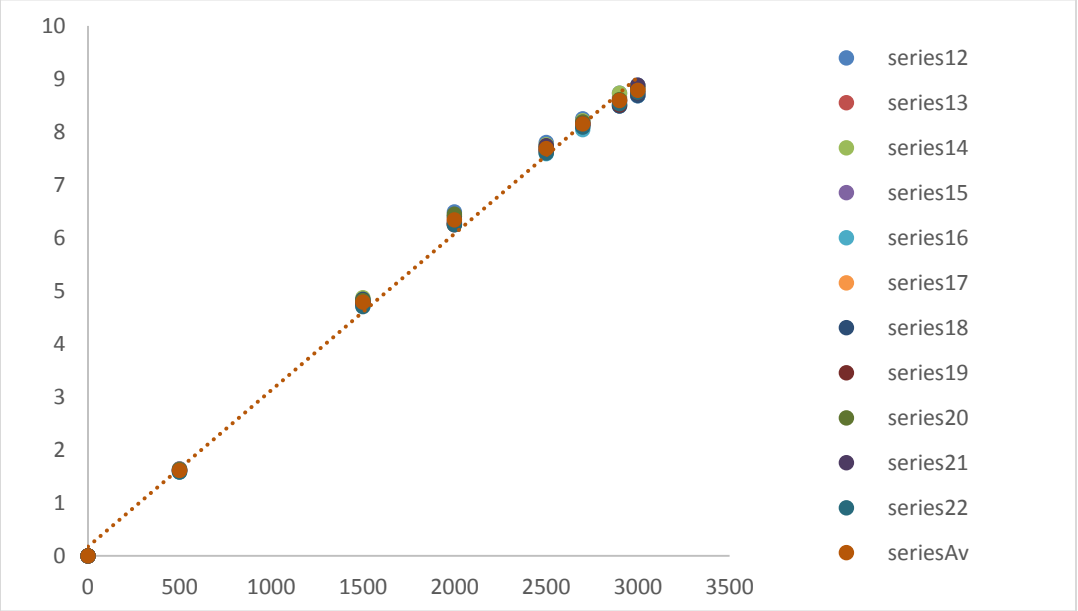



**Figure 4.23.2**: Graph of relative pressure change with increasing loads for Tester RGS time 2, final Archie

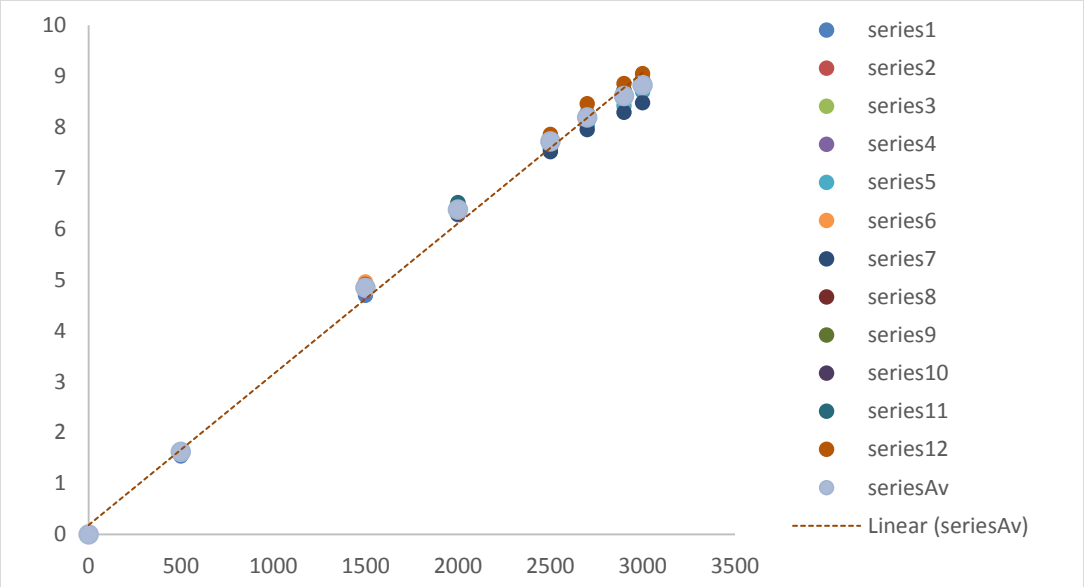



**Figure 4.3.3:** Graph of relative pressure change with increasing loads for Tester PJL time 1, final Archie

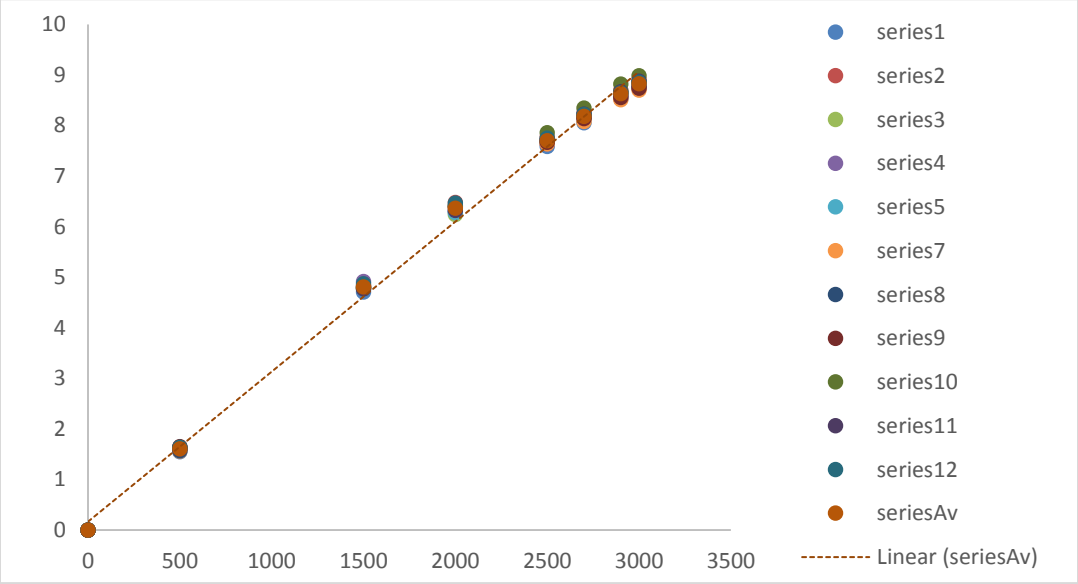



**Figure 4.23.4**: Graph of relative pressure change with increasing loads for Tester PJL time 2, final Archie

## Graphs 1 to 4 legend:

*Series*- name of each test set, each set is a sequence of colour coded increasing weights placed on the operationally inflated bladder, from 0 to 3000grams.

*Y values* – arbitrary units determined from relative bladder pressure values

*X values* – gram weights added in a sequence- 500, 1000, 500, 500, 200, 200, 100 grams

### 4.7.5 Bladder module height and pressure levels over time

Two test procedures of different durations were completed to determine the ability of the bladder to maintain height and pressure over time. It is essential that the bladder maintain pressure for the duration of the exercise testing procedures. A *long duration* test of 90 minutes, (time required to complete three sets of all exercises) and a *short duration* test of 10 to 60 seconds, (time required to complete each individual exercise) was conducted.

### 4.7.6 Long duration test

The long duration bladder module test was conducted for the bladders of the final Archie. Each bladder was inflated to its operating pressure and monitored for 90 minutes**.** Bladder height was assessed using a vernier height gauge and the bladder pressure was assessed using the Arch-analyser program (Table 4.3). Data were recorded at four time points at, time point 1; the start, time point 2 at 30 minutes, time point 3 at 60 minutes and time point 4 at 90 minutes, on two occasions. Paired samples t-tests were conducted to evaluate any change in the height and pressure and showed a statistically significant decrease in bladder height ($p=0.001$) and bladder pressure ($p=0.001$) for the bladder of Archie 2, from time point 1 to time point 4. The results for the long duration test using the bladder of Archie 3 showed that there was no change in bladder height and a statistically significant difference ($p= 0.018$) in bladder pressure.

**Table 4.3:** Long duration bladder tests, vernier height and pressure tests with final Archies in millimetres

| Test | Inflation Time 1 | Vernier Height | Inflation Time 2 | Vernier Height | Inflation Time 3 | Vernier Height | Inflation Time 4 | Vernier Height | Initial Bladder Pressure | Final Bladder Pressure |
|---|---|---|---|---|---|---|---|---|---|---|
| **Archie 2** | | | | | | | | | | |
| 1 | 1.50pm | 16.51 | 2.20pm | 15.36 | 2.50pm | 14.45 | 3.20pm | 13.20 | 10.48 | 14.31 |
| 2 | 1.30pm | 16.26 | 2.00pm | 15.41 | 2.30pm | 14.79 | 3.00pm | 14.06 | 10.67 | 13.26 |
| 3 | 3.15pm | 16.23 | 3.45pm | 15.14 | 4.15pm | 14.02 | 4.45pm | 12.95 | 10.74 | 13. 85 |
| 4 | 3.30pm | 16.50 | 4.00pm | 16.10 | 4.30pm | 15.00 | 5.00pm | 12.12 | 11.56 | 16.89 |
| 5 | 1.35pm | 16.78 | 2.05pm | 16.38 | 2.35pm | 16.09 | 3.05pm | 15.08 | 10.63 | 12.81 |
| 6 | 3.15pm | 16.62 | 3.45pm | 16.27 | 4.15pm | 16.50 | 4.45pm | 14.27 | 10.43 | 13.52 |
| 7 | 2.30pm | 16.92 | 3.00pm | 16.22 | 3.30pm | 15.48 | 4.00pm | 14.08 | 10.82 | 13.97 |
| **Archie 3** | | | | | | | | | | |
| 1 | 1.30pm | 15.46 | 2.00pm | 15.46 | 2.30pm | 15.46 | 3.00pm | 15.46 | 11.32 | 11.98 |
| 2 | 2.30pm | 15.78 | 3.00pm | 15.78 | 3.30pm | 15.78 | 4.00pm | 15.78 | 11.69 | 12.04 |
| 3 | 4.15pm | 17.27 | 4.45pm | 17.27 | 5.15pm | 17.27 | 5.45pm | 17.27 | 11.32 | 11.78 |
| 4 | 11.40am | 15.28 | 12.10pm | 15.28 | 1.10pm | 15.28 | 3.10pm | 15.28 | 12.27 | 13.16 |
| 5 | 3.00pm | 16.12 | 3.30pm | 16.12 | 4.00pm | 16.12 | 4.30pm | 16.12 | 12.47 | 12.49 |
| 6 | 12noon | 16.54 | 12.30pm | 16.54 | 1.00pm | 16.54 | 1.30pm | 16.54 | 10.73 | 11.95 |

The results of the long duration test demonstrated that there was a statistically significant increase in pressure over 90 minutes, however as the Arch-analyser graph was inverted for user functionality, a loss of pressure occurred in both bladder units over the duration of the test. Whilst a loss of pressure was noted, the amount of air leakage was relatively small (Table 4.3). These results dictated a study protocol inclusion of regular re-inflation at the beginning of each exercise test, even if the bladder appeared fully inflated.

### 4.7.7 Short duration test

Short duration tests were completed on both final Archie bladder modules to assess their ability to reliably record change in bladder height and pressure for the time to complete each exercise task, using two test procedures and assessed using the Arch-analyser GUI. The first procedure involved ongoing re inflation of the bladder to operating pressure, the second procedure involved repeat deflation and re-inflation of the bladder to operating pressure. The height and pressure of the final Archie bladder modules were recorded for a total of 60 seconds, with pressure recorded at the start time of 0 seconds and at 10 second intervals, with seven time points recorded. To compare the values of the different time point's Archie data were analysed with paired t tests. The results for procedure one, comparing time point 0 to time point 1 (10 seconds) for Archie 2, was not significant ($p=0.289$), and for procedure two bladder deflate-inflate, was significant ($p=0.001$). The results for procedure one, comparing time point 0 to time point 1for Archie 3, was not significant ($p=0.104$), and for procedure two bladder deflate-inflate, was significant ($p=0.001$).The height of the bladder did not change during either test procedure for both final Archies.

For each bladder, the range, mean pressure and coefficient of variation of the two test procedures were analysed with the Arch-analyser GUI (Table 4.4). For the results of procedure one with Archie 2: mean pressure 10.48 (range 0.06) to 10.89 (range 0.44), with a coefficient of variation from 0.015 to 0.101; and with Archie 3:  mean pressure 10.58 (range 0.02) to 10.79 (range 0.16) was recorded, with a coefficient of variation from 0.041 to 0.003. For the results of procedure two with Archie 2: mean pressure of 10.42 (range 0.26) to10.86 (range 0.20), with a coefficient of variation from 0.035 to 0.076; and with Archie 3: mean pressure 10.74 (range 0.15) to 11.28 (range 0.15) was recorded, with a coefficient of variation from 0.028 to 0.042.

**Table 4.4:** Short duration bladder pressure tests, 10 second and total test time intervals for procedures one and two with final Archies

| Test No | Time code 0 sec | Pressure pre-test-no air | Start pressure T0-5 | Pressure T1 10-20sec | Pressure T2 20-30sec | Pressure T3 30-40sec | Pressure T4 40-50sec | Pressure T5 50-60sec | Pressure T6 60-70sec | Total T Range | Total T mean press | CoV | Vernier Height T0-6sec |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Archie 2 Procedure One: pre-inflate** | | | | | | | | | | | | | |
| 1 | 11.56 | | 10.63 | 10.79 | 10.82 | 10.88 | 10.93 | 10.97 | 10.99 | 0.4395 | 10.8870 | 0.1013 | 55.54 |
| 2 | 11.57 | | 10.68 | 10.69 | 10.71 | 10.73 | 10.74 | 10.76 | 10.78 | 0.1234 | 10.7389 | 0.0317 | 55.52 |
| 3 | 11.59 | | 10.48 | 10.49 | 10.51 | 10.52 | 10.54 | 10.55 | 10.57 | 0.1017 | 10.5338 | 0.0270 | 55.63 |
| 4 | 12.01 | | 10.64 | 10.63 | 10.63 | 10.64 | 10.65 | 10.66 | 10.67 | 0.0665 | 10.6541 | 0.0170 | 55.40 |
| 5 | 12.03 | | 10.67 | 10.66 | 10.67 | 10.68 | 10.69 | 10.70 | 10.71 | 0.0719 | 10.6900 | 0.0178 | 55.19 |
| 6 | 12.05 | | 10.44 | 10.45 | 10.46 | 10.47 | 10.48 | 10.49 | 10.50 | 0.0624 | 10.4764 | 0.0169 | 55.92 |
| 7 | 12.07 | | 10.56 | 10.56 | 10.57 | 10.58 | 10.59 | 10.60 | 10.61 | 0.0597 | 10.5861 | 0.0152 | 55.73 |
| 8 | 12.09 | | 10.66 | 10.66 | 10.65 | 10.66 | 10.67 | 10.67 | 10.68 | 0.0556 | 10.6600 | 0.0133 | 55.40 |
| 9 | 12.11 | | 10.60 | 10.60 | 10.60 | 10.61 | 10.61 | 10.62 | 10.63 | 0.0570 | 10.6138 | 0.0150 | 55.83 |
| 10 | 12.12 | | 10.47 | 10.48 | 10.48 | 10.48 | 10.49 | 10.50 | 10.50 | 0.0583 | 10.4848 | 0.0134 | 55.94 |
| **Archie 2 Procedure Two: deflate/inflate** | | | | | | | | | | | | | |
| 11 | 12.16 | 16.9484 | 10.6657 | 10.74 | 10.81 | 10.85 | 10.89 | 10.91 | 10.94 | 0.1980 | 10.8644 | 0.0674 | 55.05 |
| 12 | 12.18 | 16.9399 | 10.4410 | 10.52 | 10.58 | 10.62 | 10.64 | 10.67 | 10.69 | 0.2591 | 10.624 | 0.0574 | 55.54 |
| 13 | 12.20 | 16.8788 | 10.4843 | 10.55 | 10.59 | 10.57 | 10.66 | 10.69 | 10.71 | 0.2984 | 10.6341 | 0.0679 | 54.92 |
| 14 | 12.22 | 16.9201 | 10.5262 | 10.58 | 10.65 | 10.69 | 10.72 | 10.74 | 10.76 | 0.0258 | 10.6967 | 0.0630 | 55.13 |
| 15 | 12.24 | 16.9516 | 10.6492 | 10.67 | 10.72 | 10.76 | 10.79 | 10.81 | 10.83 | 0.2157 | 10.7670 | 0.0566 | 54.97 |
| 16 | 12.27 | 16.9217 | 10.5479 | 10.58 | 10.62 | 10.66 | 10.69 | 10.72 | 10.74 | 0.2306 | 10.6726 | 0.0550 | 55.44 |
| 17 | 12.28 | 16.9339 | 10.6884 | 10.71 | 10.73 | 10.77 | 10.80 | 10.82 | 10.84 | 0.2130 | 10.7843 | 0.0484 | 55.14 |
| 18 | 12.31 | 16.9252 | 10.6285 | 10.66 | 10.68 | 10.67 | 10.70 | 10.73 | 10.74 | 0.1709 | 10.7065 | 0.0348 | 55.09 |
| 19 | 12.33 | 17.0093 | 10.3605 | 10.40 | 10.37 | 10.33 | 10.51 | 10.45 | 10.43 | 0.2631 | 10.4214 | 0.0759 | 55.11 |
| 20 | 12.35 | 16.9225 | 10.6015 | 10.63 | 10.59 | 10.62 | 10.66 | 10.67 | 10.69 | 0.1831 | 10.6453 | 0.0433 | 54.94 |

| Test No | Time code 0 sec | Pressure pre-test-no air | Start pressure T0-5 | Pressure T1 10-20sec | Pressure T2 20-30sec | Pressure T3 30-40sec | Pressure T4 40-50sec | Pressure T5 50-60sec | Pressure T6 60-70sec | Total T Range | Total T mean press | CoV | Vernier Height T0-6sec |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Archie 3 Procedure One: pre-inflate** | | | | | | | | | | | | | |
| 1 | 11.09 | | 11.25 | 10.86 | 10.76 | 10.75 | 10.76 | 10.79 | 10.82 | 0.1601 | 10.7847 | 0.0408 | 52.92 |
| 2 | 11.11 | | 10.65 | 10.59 | 10.58 | 10.59 | 10.60 | 10.60 | 10.62 | 0.0176 | 10.6029 | 0.0143 | 53.44 |
| 3 | 11.12 | | 10.67 | 10.63 | 10.62 | 10.61 | 10.62 | 10.63 | 10.63 | 0.0719 | 10.6227 | 0.0129 | 53.48 |
| 4 | 11.14 | | 10.65 | 10.65 | 10.61 | 10.59 | 10.60 | 10.60 | 10.61 | 0.0800 | 10.6135 | 0.0183 | 53.43 |
| 5 | 11.15 | | 10.58 | 10.56 | 10.55 | 10.56 | 10.56 | 10.57 | 10.57 | 0.0597 | 10.5672 | 0.0084 | 53.40 |
| 6 | 11.17 | | 10.64 | 10.59 | 10.58 | 10.58 | 10.59 | 10.59 | 10.59 | 0.0773 | 10.5905 | 0.0127 | 53.56 |
| 7 | 11.19 | | 10.61 | 10.58 | 10.57 | 10.57 | 10.57 | 10.58 | 10.58 | 0.0692 | 10.5808 | 0.0094 | 53.62 |
| 8 | 11.21 | | 10.57 | 10.53 | 10.51 | 10.52 | 10.52 | 10.52 | 10.52 | 0.0868 | 10.5251 | 0.0136 | 53.17 |
| 9 | 11.23 | | 10.57 | 10.54 | 10.58 | 10.58 | 10.58 | 10.59 | 10.59 | 0.1126 | 10.5796 | 0.0204 | 53.43 |
| 10 | 11.25 | | 10.57 | 10.57 | 10.58 | 10.58 | 10.58 | 10.58 | 10.58 | 0.0203 | 10.5810 | 0.0033 | 53.67 |
| **Archie 3 Procedure Two: deflate/inflate** | | | | | | | | | | | | | |
| 11 | 11.27 | 16.9217 | 10.6580 | 10.67 | 10.71 | 10.73 | 10.76 | 10.76 | 10.75 | 0.1465 | 10.7424 | 0.0283 | 53.46 |
| 12 | 11.30 | 16.9267 | 10.9219 | 10.95 | 10.95 | 10.95 | 10.96 | 10.99 | 11.00 | 0.1845 | 10.9762 | 0.0419 | 53.06 |
| 13 | 11.32 | 16.8951 | 10.8286 | 10.85 | 10.88 | 10.90 | 10.93 | 10.94 | 10.96 | 0.1614 | 10.9215 | 0.0364 | 53.25 |
| 14 | 11.34 | 16.9787 | 10.7469 | 10.78 | 10.77 | 10.79 | 10.82 | 10.83 | 10.85 | 0.1384 | 10.8128 | 0.0320 | 53.09 |
| 15 | 11.38 | 16.9317 | 10.7992 | 10.81 | 10.87 | 10.83 | 10.91 | 10.89 | 10.87 | 0.1438 | 10.8731 | 0.0331 | 53.33 |
| 16 | 11.41 | 16.8979 | 10.8186 | 10.85 | 10.89 | 10.90 | 10.91 | 10.93 | 10.94 | 0.1695 | 10.9138 | 0.0299 | 53.17 |
| 17 | 11.43 | 16.8957 | 11.1479 | 11.19 | 11.23 | 11.21 | 11.25 | 11.27 | 11.29 | 0.1736 | 11.2492 | 0.0332 | 53.06 |
| 18 | 11.45 | 16.928 | 11.2013 | 11.23 | 11.25 | 11.28 | 11.30 | 11.31 | 11.33 | 0.0068 | 11.2900 | 0.0368 | 53.25 |
| 19 | 11.48 | 16.8958 | 11.2077 | 11.24 | 11.24 | 11.27 | 11.29 | 11.30 | 11.32 | 0.1465 | 11.2828 | 0.0332 | 53.07 |
| 20 | 11.51 | 16.9197 | 10.7622 | 10.79 | 10.81 | 10.84 | 10.86 | 10.88 | 10.89 | 0.1831 | 10.8549 | 0.0389 | 53.45 |

Legend: Arch pressure output is recorded as arbitary units. Vernier height is recorded in millimetres.

The consistent low range of mean pressure and low coefficient of variation indicates that the bladder modules of both final Archies provide reliabile pressure data for short duration tests. However there was a noticable change in the coefficient of variation when the bladders were first inflated.This change was not present post initial pressurisation. The results of the paired sample t-tests completed with both final Archies confirm that the bladder must be preinflated with a repeat inflation sequence, before each exercise test.

### 4.8 Foot locator tests sensor system

The foot locator system of the final Archie was tested to determine if the components, modules and system were fit for purpose. Proximity sensors were initially tested for the final Archies. This was completed in two stages.The first test procedure for all foot location system sensors, was to determine individual sensor component activation under different loads. The second test procedure was to determine user activation of all three proximity sensors with feedback. As the proximity sensors did not meet functional requirements, new custom membrane switches (first and second design) were then similarly tested, first via component activation with different loads and second, user activation with feedback.

#### 4.8.1 Proximity sensor tests

The proximity sensors (PCF8883 specifications) were tested for consistent component activation over time. First with manual single digit sensor activation of each sensor and then second, with a foot placed on the three sensors concurrently (great toe, fifth toe and heel). The manual single

sensor activation time was recorded for each proximity sensor 11 consecutive times. The time to fail (from activation to deactivation) varied enormously (Table 4.5). Test times for proximity sensor activation were between 0 to 120 seconds for the great toe, 0 to 140 seconds for the fifth toe, and 0-150 seconds for the heel.

**Table 4.5:** Component manual testing of proximity sensors, individual activation of each sensor in final Archies

| Test no | Great toe | 5th Toe | Heel | Comments |
|---|---|---|---|---|
| **Archie 2** | | | | |
| 1 | 120 | 55 | 60 | |
| 2 | *80 | 90 | 120 | *slight wobble |
| 3 | 9 | *0 | 90 | *initial contact no signal change |
| 4 | 105 | 130 | *20 | kept contact very steady |
| 5 | **0 | 140 | 70 | **initial contact no signal change |
| 6 | 100 | 60 | 55 | |
| 7 | 90 | *0 | 60 | *moved along sensor but stayed off |
| 8 | *45 | 50 | **0 | *slight movement |
| 9 | 10 | *10 | 70 | *slight movement |
| 10 | *15 | 20 | 35 | *moved finger |
| 11 | *5 | 25 | 35 | *hand wobbled but did not lift |
| **Archie 3** | | | | |
| 1 | *6 | 30 | 65 | *slight movement |
| 2 | 110 | 60 | 80 | pressing very firm and steady |
| 3 | 95 | 120 | 105 | pressing very firm and steady |
| 4 | 2 | 20 | *35 | *slight movement |
| 5 | 45 | *5 | 120 | *hand wobbled but did not lift |
| 6 | 30 | 130 | 65 | |
| 7 | 90 | 45 | 150 | kept contact very steady |
| 8 | *12 | 24 | 90 | *slight movement |
| 9 | 20 | 50 | 105 | |
| 10 | *10 | 0 | 80 | *hand wobbled but did not lift |
| 11 | 45 | 15 | 60 | |

Legend: Time in seconds, *very slight movement, **moved and stayed off

Similarly, the second test, from activation to deactivation time of the proximity sensors using a human foot, were also extremely variable. Tests times recorded for maintaining sensor activation ranged from 2 to 17 seconds for the great toe, 0 to 8 seconds for the fifth toe, and 5 to 30 seconds for the heel. The fifth toe sensor deactivated with minor movements of the digit, in contrast the heel sensor intermittently registered contact even if there was no heel contact with the plate. All the proximity sensors were very sensitive to subtle movements. During this testing, re-establishing positive contact for the user was achieved only by completely lifting the foot off the proximity sensors and placing it back on. Completing this manoeuver directly affected the pressure signal generated by the bladder system, as the arch was no longer in contact with the bladder, entirely compromising continuity of the Archie biofeedback display.

Subsequent to these tests, procedures were changed in an attempt to control for sensor activation inconsistencies. To minimise the limitations of the proximity sensors, users were directed to lift their foot off between all tasks and only place the foot on the device at the beginning of the required task. However, during further testing the proximity sensors continued to intermittently deactivate during the experimental procedures and not all exercises were able to be completed. The proximity sensors were unable to continuously sense foot location during the required tasks, and were replaced with membrane switches.

### 4.8.2 Membrane switch design – Set One

A small circular off-the-shelf membrane switch was initially used to determine the activation load on which to base the design of the new membrane switches. The activation load is the weight in grams applied to a switch using a $1cm^2$ neoprene rubber spacer that causes the switch

to close. The rubber spacer simulates the properties of a human toe. Manual and human bench test results on the circular switch found that the custom membrane switches needed to be activated with a load of 30-60 grams and robust enough to sustain repeated weights of up to approximately 100kgs. VMG Print Group, 3081 Australia accepted the design brief and supplied three protectively coated custom membrane switches, a great toe, fifth toe and heel switch – set one (Figure 4.24).

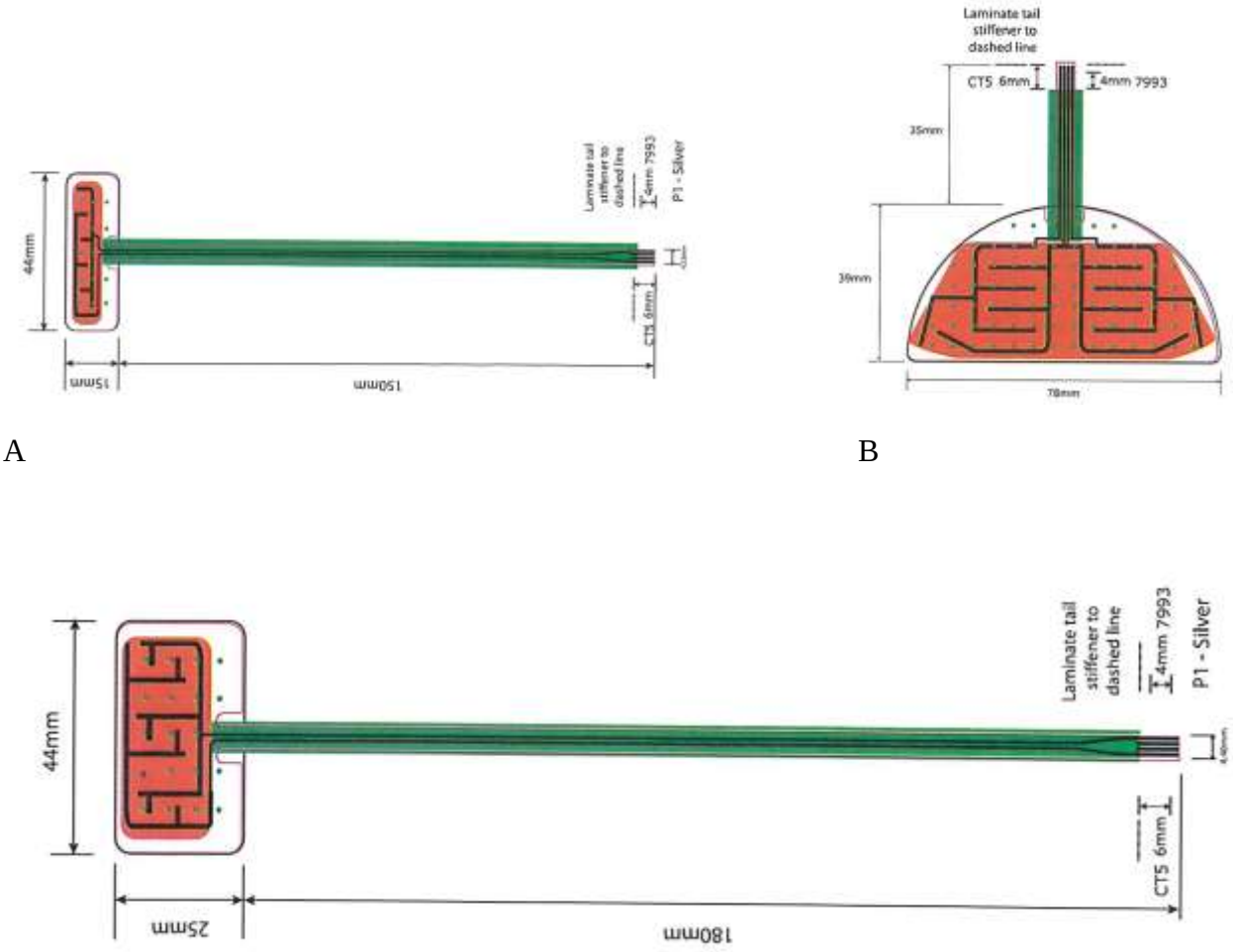



**Figure 4.24.** Designs of custom membrane switches – set one;

A: Fifth toe membrane switch; B: heel membrane switch; C: Great toe membrane switch.

Dielectric spacer array: green dots, top circuit silver shorting pad: orange. Graphics supplied by VGM Print Group

Activation load testing of the membrane switches was completed in two stages. The first test procedure for all foot location system membrane switches, was to determine activation under different loads for each component, the second test procedure was to determine user activation with feedback.Therefore component and module testing with the switches independent of the device was undertaken before user system testing was undertaken with the toe and heel switches installed in the sensor footplate.

*4.8.2.1 Component tests of membrane switches – Set One*

Tests were completed to determine the activation load of the new custom membrane switches, with manual and independent loading of a digital weigh scale (Figure 4.25), SF -718 with a capacity: 500 +/-0.01 gm (Jiangyin Suofei Electronic Technology Co., LTD. Jiangsu, China). Gradually increasing loads were placed on the toe switch via a spacer, with a Fluke 87 True RMS Multimeter,( John Fluke Co.Inc. Everett, Washington. USA) set to measure pressure contact with visual and sound activation. When the circuit was activated the load on the weigh scale was recorded.

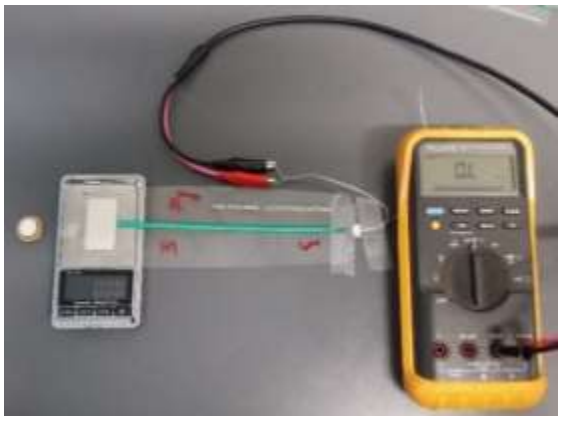


**Figure 4.25**: Voltmeter and digital weigh scale for testing membrane switches

The load to activate the first set of membrane switches was found to be both considerably higher than the design brief (127.84 to 361 grams), and exceeded the maximum range of the weigh scale (Table 4.6). However, as it could not be predicted if these activation loads would be too high to turn the set one membrane switch on when load was applied by a person, the second procedure with user testing was initiated.

**Table 4.6**: Comparison of manual testing of round, large and small rectangular membrane pressure switches - set one

| Test ID | Switch type | 1 | 2 | 3 | 4 | 5 | 6 | Load Device | Pressure device placement-comments |
|---|---|---|---|---|---|---|---|---|---|
| | Round | | | | | | | | |
| 1 | | 125.84 | 120.46 | 101.98 | 120.78 | 125.91 | 123.55 | circle | only one spot had a signal |
| | Mid rectangle | | | | | | | | |
| 2 | | 194.98 | 0-load | 0-load | 318.73 | 334.34 | 275.82 | rectangle | near edge mid shape |
| 3 | | 317.21 | 361.00 | 334.23 | 3.17.21 | 0-load | 0-load | circle | mid switch |
| 4 | | 232.00 | 349.00 | 332.73 | 349.74 | 0-load | 302.64 | circle | moved 1 -2mm - over 500gm no signal |
| 5 | | 227.72 | 152.79 | 127.87 | 127.84 | 127.85 | 127.85 | rectangle | far long edge |
| | Small rectangle | | | | | | | | |
| 6 | | 0-load | 0-load | 0-load | 0-load | 0-load | 0-load | circle | one small spot 1-2mm activated switch |
| 7 | | 0-load | 0-load | 344.12 | 378.46 | 0-load | 0-load | digit | |

Legend: O-load: overload; Load unit of measure =grams

*4.8.2.2 User tests of membrane switches – Set One*

The set one membrane switches were inserted into the sensor footplate and tested with the assistance of three lab colleagues to confirm activation within the foot locator system. The off-the-shelf round switch and set one custom membrane switches were tested with three people of different body weights (54kg, 60kg and 85kg) to compare the activation load of the set one membrane switches with the off-the-shelf round membrane switch (Table 4.7).

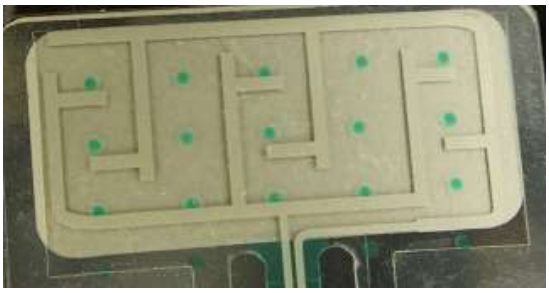


**Figure 4.26:** Rectangular custom membrane switch showing overlap in dielectric spacer array in green dots

The toe press task was completed in three positions, sitting upright with hands by their sides, sitting and leaning forwards or sitting leaning forwards whilst pressing their hands on the active leg. The activation of the great toe, fifth toe and heel indicators on the Archie GUI were recorded. Activation was coded as 'on', pressure was detected by the membrane switch and recorded by the GUI, 'off', no pressure was detected by the membrane switch or recorded and 'no contact' if the toe was not in contact with the membrane switch on visual inspection. Inconsistent activation was noted across the membrane switches for the different stances and body weights. Activation of the fifth toe switch was particularly inconsistent, possibly explained by the placement of the dielectric strips and adjacent supporting dots being either too close to the dielectric strip or almost on top of it (Figure 4.26).

**Table 4.7:** Individual testing with final Archie using round and set one membrane switches

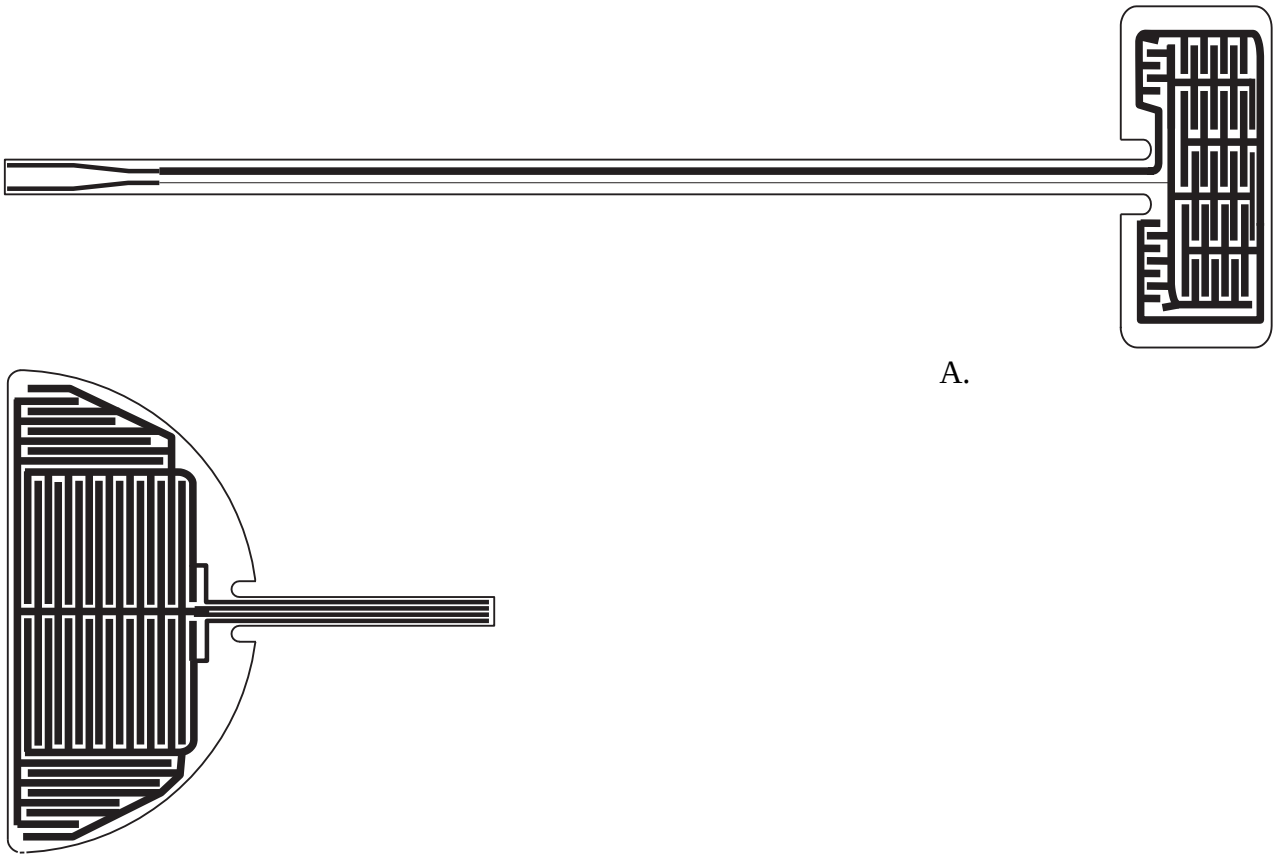
| User weight | Test No | Great toe | Lesser toe | Heel | Position | Great toe | Lesser toe | Heel | Position |
|---|---|---|---|---|---|---|---|---|---|
| | | **Round pressure switch** | | | | **Set one custom switches** | | | |
| | 1 | no contact | no contact | off | seated | off | no contact | off | seated |
| 54kg | 2 | on | no contact | on | leaning | off | no contact | on | leaning |
| | 3 | on | on | on | press | on | no contact | on | press |
| | 4 | off | no contact | on | seated | off | no contact | off | seated |
| | 5 | on | no contact | on | leaning | off | no contact | off | leaning |
| | 6 | on | no contact | on | press | on | no contact | on | press |
| | | | | | | | | | |
| | 1 | on | on | on | seated | off | off | off | seated |
| 60kg | 2 | on | on | on | leaning | on | off | on | leaning |
| | 3 | on | on | on | press | on | off | on | press |
| | 4 | on | on | on | seated | on | off | on | stand |
| | 5 | on | on | on | leaning | on | off | on | press |
| | 6 | on | on | on | press | | | | |
| | | | | | | | | | |
| | 1 | on/int | on | on | seated | off | no contact | off | seated |
| 85kg | 2 | on | on | on | leaning | off | no contact | on | leaning |
| | 3 | on | on | on | press | on | no contact | on | press |
| | 4 | on/int | on | on | seated | on | no contact | on | standing |
| | 5 | on | on | on | leaning | on | no contact | on | press |
| | 6 | on | on | on | press | | | | |

Legend: on - colour change to foot shape display, no contact - no observable contact by toe to the sensor, off – no colour change to foot shape display, on/int – colour change to foot shape display intermittently on

The inconsistent outcomes of component and module testing with increasing loads using the set one membrane switches compared to the off-the-shelf switch and system tests with people of different weights, confirmed these membrane switches were not fit for purpose. (Table 4.7) The need for greater sensitivity, particularly to the fifth toe switch, was identified during these test procedures. A new set of membrane switches were required with a lower activation pressure that more closely matched the specifications of the round off-the-shelf switch.

### 4.8.3 – Membrane switch design - Set Two

The modified design brief for the second set of membrane switches was to achieve <60grams activation load, improve switch sensitivity on the edges, improve the consistency of activation pressure over the whole switch and add a protective layer. Two new custom membrane switches comprising of a single switch for the great toe and fifth toe and a separate heel switch (Figure 4.27), were designed and supplied by VMG Print Group, 3081 Australia.



A.

B.

**Figure 4.27**: Designs of new custom membrane switches – set two;
A: Great and fifth toe; B: heel; Graphics supplied by VGM Print Group

Set two membrane switches underwent identical testing to set one membrane switches. Specifically, the first test procedure involved component and module testing independent

of the device and the second test procedure involved system testing using lab collegues, with the toe and heel switches installed in the sensor footplate.

*4.8.3.1 Component tests of membrane switches – Set Two*

The rectangular great toe/fifth toe and semi-circlular heel set two membrane switches were tested to determine the activation load across the body of each switch. The component tests of the set one membrane switches, testing procedures were repeated, with a circuit created with a multimeter and digital weigh scale to determine load activation as outlined earlier in Section 4.8.2.

To ensure a thorough investigation of the switch capabilities, each switch was divided into regions and test repetitions increased. Slightly diffferent load testing was completed depending the switch type. The load to activate the rectangular, great toe/fifth toe switch was recorded in 12 different locations on the membrane switch and repeated eight consecutive times to determine the average load required to activate the switch. Similar test procedures were repeated with the heel membrane switch.The load to activate the heel switch was recorded in 11 different locations on the membane switch and repeated six consecutive times with the average activation load determined. The great/fifth (rectangular)toe switch recorded an average activation load range between 29.03gms to 32.15gms (Table 4.8.1). The heel switch recorded an average activation load range between 19.29 to 19.31gms (Table 4.8.2).

**Table 4.8.1:** Activation load in grams of great and fifth toe membrane switch - set two

| Test | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | Average load |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 40.00 | 17.68 | 22.00 | 36.54 | 30.80 | 21.85 | 36.45 | 39.10 | 30.68 | 33.00 | 36.00 | 27.29 | 30.95 |
| 2 | 40.00 | 17.68 | 24.00 | 30.78 | 30.80 | 21.87 | 31.65 | 39.16 | 33.00 | 39.00 | 36.00 | 38.56 | 31.88 |
| 3 | 40.00 | 17.70 | 24.80 | 33.68 | 23.00 | 21.87 | 36.39 | 30.68 | 36.33 | 41.00 | 41.82 | 38.56 | 32.15 |
| 4 | 45.00 | 17.69 | 21.98 | 36.45 | 21.86 | 21.86 | 36.41 | 39.33 | 30.68 | 41.00 | 32.95 | 27.29 | 31.04 |
| 5 | 39.98 | 17.68 | 21.96 | 36.43 | 21.86 | 21.85 | 40.29 | 36.34 | 36.33 | 41.00 | 21.65 | 27.26 | 30.22 |
| 6 | 42.88 | 17.70 | 21.99 | 30.8 | 24.56 | 21.88 | 36.41 | 30.68 | 36.39 | 41.87 | 21.60 | 21.56 | 29.03 |
| 7 | 38.00 | 17.68 | 21.87 | 36.46 | 21.86 | 21.84 | 36.41 | 36.31 | 36.33 | 47.00 | 27.26 | 27.26 | 30.69 |
| 8 | 39.00 | 17.70 | 21.89 | 33.61 | 21.86 | 21.83 | 42.00 | 36.31 | 33.00 | 36.00 | 27.24 | 27.29 | 29.81 |

**Table 4.8.2:** Activation load in grams of heel membrane switch - set two

| Test | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | Average load |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 13.96 | 13.97 | 34.73 | 13.97 | 34.81 | 13.83 | 13.82 | 13.85 | 26.21 | 19.42 | 13.85 | 19.31 |
| 2 | 13.97 | 13.93 | 34.71 | 13.98 | 34.78 | 13.70 | 13.91 | 13.90 | 26.20 | 19.45 | 13.82 | 19.30 |
| 3 | 13.97 | 13.95 | 34.75 | 13.95 | 34.76 | 13.77 | 13.93 | 13.88 | 26.19 | 19.46 | 13.85 | 19.31 |
| 4 | 13.96 | 13.92 | 34.70 | 13.96 | 34.73 | 13.74 | 13.90 | 13.86 | 26.20 | 19.46 | 13.77 | 19.29 |
| 5 | 13.95 | 13.96 | 34.72 | 13.97 | 34.73 | 13.73 | 13.91 | 13.87 | 26.21 | 19.44 | 13.76 | 19.30 |
| 6 | 13.96 | 13.95 | 34.71 | 13.96 | 34.77 | 13.79 | 13.82 | 13.87 | 26.20 | 19.45 | 13.81 | 19.30 |

Set two toe and heel membrane switches activated consistently within the required load ranging from 28.54gms to 30.81gms over repeated trials. The set two switches were therefore embedded into the final Archie sensor footplates for system testing with users and to assess the feedback reliability with the PC monitor.

*4.8.3.2 User tests of membrane switches - Set Two*

The same procedures as the previous user tests for the set one membrane switches were completed to determin if the Archie GUI interface activated consistently when the membrane switches were pressed with a persons foot. Colleagues were seated with either with their right or left foot (pre-selected on the Archie GUI) and pressed their great toe fifth toe and heel down. The screen interface display of the toe and heel placement

indicators turned on for all consecutive tests. The results of these tests confirmed that the set two membrane switches activated under human pressure consistently and the foot locator shapes on the user display also activated correctly using the Archie GUI for both the right and left foot settings, on the computer display screen and therefore fit for purpose. The second set of membrane switches were installed into the final Archie devices to be used in the clinical trial phase (Figure 4.28). The consistently similar behaviour for both final Archies bladder and foot location sensor systems, by the completion of this bench testing shows the redesign and build of the final Archie is easy to duplicate.

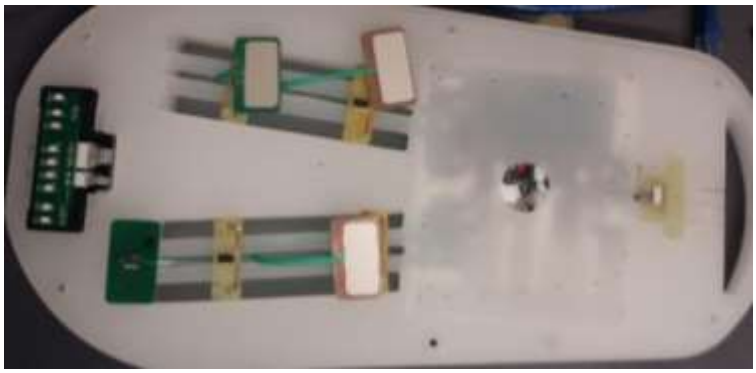


**Figure 4.28:** Modifying the footplate to install the Set Two membrane switches

## 4.9 User testing – biofeedback and exercise tasks

All bladder and foot locator system bench tests utilised the Archie GUI to provide biofeedback to the user. Pilot testing of the exercises were completed to improve feedback clarity with modifications made to Archie GUI to improve its usefulness, as well as the requirements for data collection. Testing was also undertaken to determine which exercises were most relevant for the subsequent feasibility trial, the safe duration for the exercises,

incorporating screen capture and saving times, and to confirm the final exercise sequence to be undertaken for the feasibility trial.

### 4.9.1 Exercise tasks on the sensor footplate

Tests were completed using the final Archie with lab colleagues to ascertain which toe and foot movements to trial, the optimal sequence of the exercise tasks, the duration of each exercise and in what position (seated, double leg stance and single leg stance) users could correctly perform the exercises.

Five foot exercises were initially trialled including: great toe press down, fifth toe lift and press down, heel lifts, arch elevation with elongated toe press and forefoot active elevation (doming [2]) and arch elevation without intentional toe press–forefoot relaxed (short foot [3]) (examples Figure 4.29 a, b, c).

a) Great toe press, lesser toes flare b) Great and lesser toe press, heel lift c) Arch elevation with toe press

**Figure 4.29:** Examples of foot exercise tests with the sensor footplate (a, b, c)

However, as home exercise practice adherence is challenging,[4] choosing only a small number of exercises to complete was important. Therefore, in this thesis one specific manoeuvre that incorporates foot doming (arch elevation) and toe spreading was performed.

The foot doming task was subcategorised into four different exercises.

The four exercises to be used in the feasibility trial were:

1. **Speed:** sequential isotonic muscle contractions to elevate and lower the arch in as large a range as possible and as quickly as possible.
2. **Arch elevation:** gradual isotonic concentric contraction of the foot arch muscles to lift the arch as high as possible.
3. **Arch lowering:** pre-test arch elevation then a gradual isotonic eccentric contraction of the foot arch muscles, to lower the arch.
4. **Endurance:** elevate the arch and maintain that controlled elevation in an isometric contraction of the foot arch muscles.

These four exercises were chosen because the movements performed during each exercise contribute to functional activity. The speed exercise was included as dynamic movement such as hopping requires intrinsic foot muscle activity[5] and rapid rhythmic movement improves with increased toe flexion strength.[6-8] Both concentric and eccentric exercises were included as literature on training interventions report a significant difference between these training modalities. Traditionally strength training has focused on concentric exercise particularly if muscle hypertrophy is the goal.[9] It is commonly thought that eccentric muscle control is harder to acquire, however increased slow-twitch, fibre type 11,[10] fibre length and distal hypertrophy occurs with eccentric muscle training more than with concentric training.[11] Eccentric muscle training is more effective than concentric muscle training, post Achilles tendinopathy,[12] for improving bilateral neuromuscular activation, strength and walking speed post stroke.[13] Therefore while arch elevation was apparently more functional and easier to practice, as fibre type II reduction is attributed to ageing,[14] practicing a controlled eccentric arch lowering manoeuver was considered most important.

The endurance exercise was included as the ability to maintain arch height, may also assist help maintain balance.[15]

Position of exercises: Three exercise positons were tested, seated with knees at 90°, double leg stance and single leg stance. The exercises in the double leg stance and single leg stance position were found to be very challenging for some lab colleagues to complete. Therefore only the seated position was used for the feasibility trial.

The duration of all exercises and data capture times were tested to determine how long a person was able to successfully and safely complete each exercise and to determine how much time was needed to prepare, capture and save the data. Times considered to complete the exercises ranged from 10 seconds to 180 seconds of data capture. Various full screen display saving times were also tested. The initial testing time for the endurance exercise (180 seconds) was based on a reliable neck muscle endurance test.[16] However during bench testing not all colleagues were able to maintain arch elevation for this duration. Therefore to ensure user test completion and consistent data capture, the endurance test time was reduced to 90 seconds.

In conjunction with exercise testing, a one minute single screen data capture saving time was tested. This length of full screen data capture time was determined to be too long. Repeat refreshment of the PC screen to 3 minutes was also trialled. Tests were then completed with both shorter full screen data display and different refresh rates, from one minute to 30 seconds to observe user functionality and determine the most effective screen refresh rate. During exercise testing it was observed that additional time was needed to prepare for the performance of the exercise and a pre-data capture time was needed to ensure that the data was saved correctly with a clear completion time at the end of the

exercise. Therefore clean data capture entailed saving a preparatory stage data capture, exercise performance data capture and finish stage data capture for each exercise performed.

The observational testing with colleagues established the most efficient and safe duration for data capture for the test sequence, speed, arch elevation and arch lowering exercise. The optimal sequence of data capture and exercise sequence was determined as a total 30 second full screen capture with 10 second data preparation, 10 second test time and 10 second end. For the endurance arch lift it was determined that a 90 second data capture with 10 second preparation, 60 seconds test time 20 second end, was the most efficient.

### 4.10 Development of Arch-analyser

Arch-analyser data analysis software was developed by John Eisenhuth in collaboration with PJ Latey. It is designed to open, modify and analyse Archie data files created by Archie GUI and save the results of the analysis in comma delimited text files that can be easily imported into Microsoft Excel.

The Arch-analyser provides two graph viewing panes (Figure 4.30). The upper viewing pane displays raw data and allows individual data traces to be selected and loaded onto the lower viewing pane. The lower viewing pane provides buttons on a tool bar for the control of the X and Y cursors. These cursors can be moved to select an area of interest so that detailed analysis of the area between the cursors can be done. Analysis functions are provided using buttons on the tool bar.


**Figure 4.30:** Arch-analyser visual interface and analysis screen

### 4.10.1 Analysis and data extraction

The Arch analyser GUI provides analysis and extraction of data short cuts for each of the four exercises.

1. **Speed:** number of cycles, mean amplitude, amplitude coefficient of variation, mean period, period coefficient of variation and foot location.
2. **Arch elevation:** relative range, slope, coefficient of determination and foot location.

3. **Arch lowering:** relative range, slope, coefficient of determination and foot location.
4. **Endurance:** relative range, mean range, coefficient of variation, area ratio and foot location.

These outcome measures are all generated from the digital output of the bladder sensor and foot locator systems saved data (Archie GUI) and calculated using the mathematical functions of the Arch-analyser GUI. Aside from the foot location variable all other variables are calculated from any change in bladder pressure caused by change in arch height.

The speed analysis uses a peak detection algorithm to identify each peak and trough of a sinusoidal waveform. Cycles are the number of peaks within an interval (between the vertical cursors X1to X2) that occur after the first peak: the number of cycles denotes how quickly the participant can sequentially elevate and lower their arch. The amplitude is the difference in the magnitude of the wave between the peaks and troughs: this indicates the range in arch height caused by lifting and lowering during the speed exercise. The coefficient of variation gives an indication of the variation of the amplitude normalised to the mean.

For the speed exercise, the period between each peak is also determined. The periods are summed together and the mean, variance and coefficient of variation of the periods is calculated. The coefficient of variation gives an indication of the variation of the period normalised to the mean: the smaller the coefficient of variation the less variation in the period. The period is used to determine how quickly a participant can raise and lower the

arch while maintaining the greatest possible range and indicates how quickly the participant can activate and relax the small foot muscles under the arch.

For the arch elevation, lowering and the endurance exercise, the relative range was calculated from the difference between the maximum arch height and minimum arch height measured within the test interval (X1 to X2). The relative range of arch movement indicates how much the participant can elevate or lower the arch from as relaxed as possible to as high as possible or from as high as possible (elevation) to as relaxed as possible (lowering) slowly, in a fixed time interval. Any reduction in the relative range indicates participants focus more on arch muscle control than on absolute range of motion in the arch.

'Slope or gradient' describes the direction (positive or negative) and steepness of the line produced by the change in arch height during the arch elevation, and the arch lowering exercises in a fixed time interval. The calculation is defined by the ratio of vertical change over horizontal change or time interval (Slope = Range (X1 – X2) / Interval). The slope indicates the participants' arch height range during the gradual concentric or eccentric contraction of the small foot muscles.

The guidance lines were created by calculating the line of best fit during a pre-test practice arch elevation or lowering manoeuver to determine the range in arch height. The duration of the test was a fixed interval and the slope of the guidance line was calculated using the equation (slope = Range (X1 – X2) / Interval). The coefficient of determination (r2) is a statistical measure of how well a regression line approximates the real data points (guidance line) and was calculated using the equation: $R2 = 1 – SSres/SStot$, with SSres = sum of residuals = $\sum(yi – Yi)2$ from i = 1 to n and SStot = total sum of squares = $\sum(yi – meanY)2$ from i = 1 to n. An r2 of 1 indicates that the regression line perfectly fits the

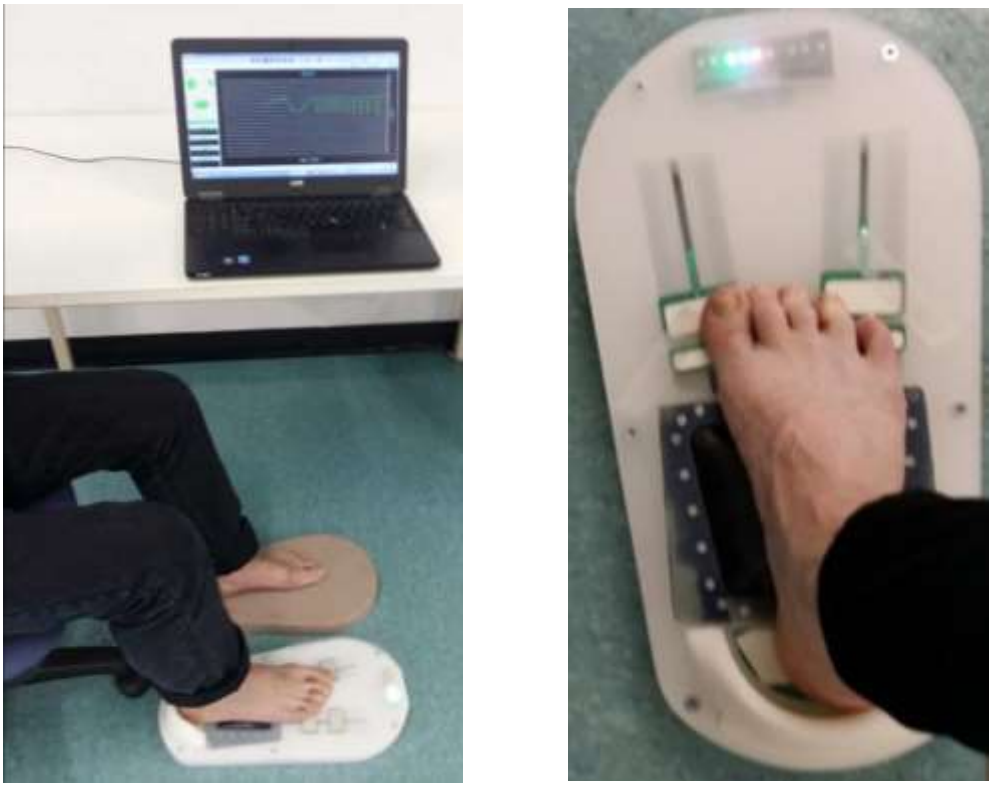
data. An increase in the coefficient of determination (closer to 1) denotes higher performance skill of the participants'' ability to follow the guidance line of best fit during the arch elevation or lowering task.

Along with the relative range, the mean range was also calculated for the endurance task. The coefficient of variation was calculated to determine the variation or the consistency of the participants arch elevation over 60 seconds (CoV = Standard Deviation/Mean): the smaller the coefficient of variation, the less variation in the arch elevation data. For the endurance task, a reduction in the coefficient of variation denotes improved performance skill, indicating increased ability to maintain a steady small foot muscle contraction or arch lift for 60 seconds.

Area ratio was calculated from the area under the pressure signal determined by arch height, expressed as a percentage. The total possible area was 80% of the initial range, multiplied by test duration. Increased area ratio indicates improved performance skill by consistently maintaining an increased arch elevation.

Foot location adherence was calculated for all exercises by determining the percentage of time the great toe, fifth toe and heel remained in contact with the membrane switches during testing. Increased foot location indicates improved ability of the participant to maintain correct contact with the heel and both the great and fifth toe membrane switches, ensuring foot alignment is kept within the same plane during each exercise.

Data from the Arch-analyser was organised with a custom 'Packetyser' GUI. The Packetyser is a GUI based computer program which provides a utility function to extract data from files created by Arch-analyser and organised into an SPSS for Windows v22.0 (IBM SPSS Inc., Chicago, IL) compatible format and save the result to USB. Data is organised into excel and SPSS with Packetyser GUI.



a) b)

**Figure 4.31.** Final Archie sensor footplate and PC biofeedback (a), close up of sensor footplate (b)

## 4.11 Summary and review of chapter 4

This chapter describes the process that was undertaken over a period from 2014 to 2017 to re develop, build and test the final Archie device (Figure 4.3.1). There were both drawbacks and benefits to working with a small team of students. While using a student group allowed the first prototype to be built in an economic way ($12,000), some features of the device did not have good user functionality. During later bench testing, some components were found to be unreliable and as the original student team had completed their study, there was no continuity of skills. The redesign and build of the device required a significant upgrade in Archie's safety features, new electronic circuitry, firmware, software and substantially improved visual feedback: discussion with the initial building

team may have reduced component choice and testing time. Dysfunctional outsourced custom components costs were over $3,000 and very time consuming, causing delays to the start of the trial. However, this lack of information did ensure very thorough documentation and bench testing strategies of the final device. Each component that was changed or modified on the initial Archie was individually tested for reliability and durability with a series of observational studies and then tested again once they were embedded into the final Archie for system functionality for the user. This included the bladder sensor and foot locator system tests, as well as development of the biofeedback visual display and pilot exercise tests with volunteers. This preliminary testing was conducted to identify the most appropriate feedback to enhance performance skill for the user in preparation for the study on the feasibility of the final Archie. (Chapter 5).

Acknowledgment: I would like to thank all the staff and students of the Musculoskeletal Health Research Group for their assistance during Archie bench testing, particularly: Dr Maria Eliza Aguila, Shiek Abdullah Bin Ismail, Sarah Kobayashi, and Rylee Grace Spalding.

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# CHAPTER FIVE

## Feasibility trial of the Archie biofeedback device to strengthen foot musculature

# PREFACE

This thesis reviewed the causes and consequences of foot muscle weakness, the difficulties of measuring the intrinsic foot muscles and appraised exercise interventions for improving foot muscle weakness. However foot exercise interventions are primarily effective when performance skill is maintained and practice adhered to. Biofeedback may help exercise performance and adherence, however no foot exercise device of this kind is available.

Chapter 4 detailed the extensive process that was undertaken from 2014 to 2017 to construct and bench test the final Archie biofeedback device in preparation for a feasibility trial. This process involved the redesign and build of the housing, a significant upgrade in Archie's safety features, new electronic circuitry, software and substantially improved visual feedback. Each component that was changed or modified on the original Archie was individually tested for reliability and durability with a series of observational studies and then tested again once they were embedded into the final Archie for system functionality for the user.

The aim of the research presented in chapter 5 is to conduct a feasibility study on a foot exercise biofeedback device 'Archie' to determine its consistency and effectiveness to assist participants with performing foot exercises and improve adherence to the correct technique.

**Dissemination of research**

The study in this chapter has been prepared for submission and in the format required by *Archives of Physical Medicine and Rehabilitation.*

# AUTHORSHIP STATEMENT

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The co-authors of the paper '*Feasibility trial of the Archie device to strengthen foot musculature'* confirm that *Penelope Jane Latey* has made the following contributions

- Conception and design of the research
- Collection and extraction of data
- Analysis and interpretation of the findings
- Drafting and revising of the manuscript and critical appraisal of content

As the primary supervisor for the candidature upon which this thesis is based, I can confirm that the above authorship attribution statement is correct.

Professor Joshua Burns

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June 19, 2018

**Title:** Feasibility trial of the Archie biofeedback device to strengthen foot musculature

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# Feasibility trial of the Archie biofeedback device to strengthen foot musculature


### Abstract

**Background:** Foot muscle weakness resulting from disease, inactivity and aging, can produce deformity, pain and disability. Foot strength can be increased with exercise, however participant engagement and adherence to the correct technique is often challenging. The aim of this study was to investigate the feasibility of using a novel medical device, known as 'Archie', to provide biofeedback of correct arch movement and foot location during four foot exercises.

**Methods:** Archie was constructed to simultaneously measure and provide real-time biofeedback of arch movement via pressure change in an inflatable arch bladder, and foot location adherence via sensors embedded in a footplate (Patent pending: PCT/AU2016/050437). Thirty participants (63% female, aged 23-68 years) performed a series of four foot exercises on Archie alone (to measure consistency of the protocol) and with biofeedback (to measure effectiveness of the Archie device). The four foot exercises and associated arch movement variables were: speed of arch elevation and lowering (cycles, mean amplitude, amplitude coefficient of variation, mean period, period coefficient of variation) controlled arch elevation and controlled arch lowering (relative range, slope, coefficient of determination), endurance of maintaining an elevated arch (relative range, mean range, coefficient of variation, area ratio). Foot location adherence was also calculated for all exercises by determining the percentage of time the great toe, fifth toe and heel contacted the footplate sensors during testing. To assess consistency of the protocol, exercises were completed twice without biofeedback and compared using one-way repeated measures ANOVA with pairwise comparisons. To assess the effectiveness of the Archie device,

exercises were completed with the biofeedback interface, and compared to Archie without biofeedback using one-way repeated measures ANOVA with pairwise comparisons. Participants were also asked if Archie with biofeedback helped them perform the four exercises with correct technique.

**Results:** Seventeen of 19 (89%) arch movement and foot location variables were collected consistently with Archie during the four foot exercises. Archie with biofeedback improved foot location adherence for all exercises ($p=0.003$-$0.008$), as well as coefficient of determination for controlled arch elevation ($p<0.0001$) and endurance area ratio ($p=0.001$). Twenty-nine of 30 (97%) participants reported that Archie with biofeedback helped correctly perform the exercises. There were no adverse events reported.

**Conclusion:** Archie appears to be a feasible biofeedback device to assist participants with performing foot exercises and improve adherence to the correct technique.

**Key Words:** intrinsic foot muscles, toe flexion, exercise adherence, biofeedback

## Introduction

Foot muscle weakness resulting from disease, inactivity and aging,[1] can produce foot deformity, pain and disability.[2-4] For example, peripheral neuropathy causes foot muscle weakness, reduced foot muscle volume and disabling cavovarus foot deformity.[5] Several studies have also reported an association between loss of toe flexor strength or intrinsic foot muscle size, and high intensity foot pain,[3] plantar fasciitis[6, 7] and painful hallux valgus.[8, 9]

Toe flexor and foot arch exercises focused on maintaining intrinsic foot muscle strength and functional control[10] may mitigate the progression of foot deformity such as hallux valgus.[11] Slowing the development of disabling and painful deformities by addressing foot muscle weakness has been shown to improve quality of life.[8, 12] Strengthening foot musculature may also reduce the associated risk of falls and loss of balance in older people.[4, 13] Supervised practice of the short foot exercise in particular, which is performed by approximating the metatarsal heads towards the heels without toe flexion, improves static unilateral balance[14] and increases cross-sectional area of abductor hallucis in people with pes planus.[15] Even though toe flexor and foot arch exercises are routinely prescribed to improve foot muscle strength, maintaining adherence to exercise is challenging[16] thereby limiting its impact on health outcomes.[17]

Ensuring correct exercise technique is also challenging due to the specificity of muscle activation required to complete some foot exercises.[18] Biofeedback has been used to improve adherence and movement patterns, for gluteus medius activation post stroke,[19] muscle re-education to improve gait parameters in older adults with Alzheimer's[20] and increase abdominal muscle activity in women with chronic low back pain.[21] Using a device that provides real-time biofeedback of plantar arch pressure to improve foot muscle control, while

recording foot placement and quantity of practice, may improve foot function and exercise adherence.

We designed and constructed a biofeedback device, known as 'Archie', to assist with strength training of foot arch muscles (Patent pending: PCT/AU2016/050437). The Archie device simultaneously measures and provides real-time biofeedback of arch movement and foot location via pressure change in an inflatable arch bladder and sensors embedded in a footplate, respectively. Biofeedback is provided via a computer interface displaying arch movement and foot location. The aim of this study was to investigate the feasibility of using Archie to provide biofeedback for adherence to correct technique of arch movement and foot location during four foot exercises.

## Methods

*Participants*

Thirty participants were recruited from the University of Sydney and the general population via advertisement. Invited participants were healthy adults (aged 18 to 68 years) able to walk 50m barefoot unaided. Study exclusion criteria were: presence of a peripheral or inherited neuropathy (e.g. Diabetes or Charcot-Marie-Tooth disease), an injury affecting foot or lower limb joint motion, history of foot surgery, or severe foot pain (≥70 on a 0-100 point scale) in the previous 6 months. The University of Sydney Ethics Committee approved the study (Project No. 2016/188) and participants provided written informed consent.

*Physical characteristics*

All testing for each participant was performed on one occasion. Age, sex, height, weight and BMI were collected. Foot length was measured from the dominant foot (determined by

asking with which foot they kicked a ball). Foot alignment was measured using the Foot Posture Index (FPI). The FPI is a reliable weight bearing measure consisting of six items, summed to provide a score from -12 to +12 for a supinated or pronated foot, respectively [22].

*Archie biofeedback device*

Archie is a medical device designed and constructed to assist with exercising foot muscles using the correct technique (patent no: PCT/AU2016/050437). Archie consists of two sensor systems: an electronically-controlled inflatable bladder with air pump and air release valve; and adjustable toe and heel sensors embedded into a rigid footplate protected by a removable silicon cover. The device is wirelessly connected to a laptop with a custom designed graphical user interface ('Archie GUI'), with control buttons to operate all electronic systems in the sensor footplate. The Archie GUI provides dual visual feedback via guidance lines and data saving capability. Archie GUI also calculates a variety of variables generated from the raw data (Table 4, Figure 1 and 2). The Archie device measures change in the bladder pressure caused by foot arch movement and foot location using footplate sensors to provide corresponding real-time biofeedback by means of a visual display to actively guide the user's foot during a series of foot exercise tasks.

*Archie exercise protocol*

The components of the Archie device were explained to the participants, who were then taught a specific arch elevation manoeuvre similar to the short foot exercise.[10] This involved performing an elevation and lowering of the longitudinal plantar arches and metatarsophalangeal joints, pressing elongated distal toes downwards, while drawing the heel slightly towards the toes. Participants sat, with their knees at about 90°, dominant foot on the Archie device. The participant was familiarised with the specific movement required for each of the four exercises:

1. Speed: sequential isotonic muscle contractions to elevate and lower the arch in as large a range as possible and as quickly as possible. Completed in 10 seconds during a 30 second data capture mode.

2. Arch elevation: gradual isotonic concentric contraction of the foot arch muscles to lift the arch as high as possible. Completed in 10 seconds during a 30 second data capture mode.

3. Arch lowering: pre-test arch elevation then a gradual isotonic eccentric contraction of the foot arch muscles, to lower the arch. Completed in 10 seconds during a 30 second data capture mode.

4. Endurance: elevate the arch and maintain that controlled elevation in an isometric contraction of the foot arch muscles. Completed in 90 seconds during a 130 second data capture mode.

All data were saved for a minimum of 10 seconds pre and post exercise performance to ensure clean data capture. To mitigate any learning affect between trials, participants practiced to ensure correct execution of the arch elevation and lowering manoeuvres before using the Archie device. Three correctly executed repetitions were recorded for each exercise. The set of four exercises were repeated three times on the Archie device, with 15 minutes rest between bouts. The first and second bout of the four foot exercises were completed without biofeedback, with timing for exercise completion provided by an observable stopwatch, to assess consistency of the exercise protocol, then the third bout used the biofeedback interface with guidance lines, to assess the effectiveness of the Archie biofeedback device.

*Outcome measures*

Foot arch pressure was measured with the Archie device by registering change in pressure in the inflatable bladder under the arch of the foot and simultaneously monitoring foot location

using the sensor footplate. Archie GUI recorded the signals generated by the sensor system and custom software, and determined the following variables:

1. Speed: number of cycles, mean amplitude, amplitude coefficient of variation, mean period, period coefficient of variation.
2. Arch elevation: relative range, slope, coefficient of determination.
3. Arch lowering: relative range, slope, coefficient of determination.
4. Endurance: relative range, mean range, coefficient of variation, area ratio.

Foot location adherence was also calculated for all exercises by determining the percentage of time the great toe, fifth toe and heel correctly contacted the footplate sensors during testing. See Table 4 for selection of variables and data calculations.

Participants were also asked if Archie with biofeedback helped perform the four foot exercises with correct technique based on a validated patient satisfaction survey.[23] The survey included a 'yes/no' response regarding the perceived usefulness of the device, and a series of 0 - 100mm visual analogue scales (with 0 being harder to exercise and 100 easier to exercise) on perceived ability to complete the exercises with Archie biofeedback. An option for comments was provided at the end of each survey.

*Statistical Analysis*

Data were collected and managed using Archie GUI, custom software and REDCap (Research Electronic Data Capture, Nashville, TN USA).[24] Statistical analysis was performed using SPSS Windows v22.0 (IBM SPSS Inc., Chicago, IL) for Archie data and SAS 9.4 statistical package for survey data. Descriptive statistics were generated to characterise the sample. One-way repeated measures ANOVA with pairwise comparisons were computed to

assess the consistency of the exercise protocol between trial 1 and trial 2 (prior to biofeedback), and the effectiveness of the Archie biofeedback device between trial 2 and trial 3. Perceived ability to complete exercises were analysed with paired sample t-tests. Results were considered significant if $p<0.05$.

## Results

Participant characteristics are described in Table 1. Twenty two (73%) participants exercised or played sport often or always. Six (20%) participants reported previous foot problems in the last 6 months: in the heel (n=1), great toe with mild hallux valgus (n=3), and swelling in the lesser toes, or cramps in the fore- and mid-foot (n=2). Of those with foot problems, one reported no pain and five (17%) reported occasional foot pain, 2 reported pain in the non-dominant foot, 3 reported some pain, ranging from 8-30 mm on a 0-100 mm scale in the dominant foot.

Regarding consistency of the foot exercise protocol, there was no difference between bout 1 and 2 for 17 of 19 (89%) arch movement or foot location variables using Archie ($p>0.05$). Speed foot location ($p=0.021$) and arch lowering slope ($p=0.026$) worsened during bout 2 (Table 2). Regarding effectiveness of Archie with biofeedback, foot location adherence improved for all exercises ($p=0.003$-$0.008$), as well as coefficient of determination for controlled arch elevation ($p<0.0001$) and endurance area ratio ($p=0.001$). Variables that worsened with biofeedback were arch elevation relative range ($p=0.004$) and slope ($p=0.028$), and endurance relative range ($p<0.001$) (Table 2 and Table 4 for performance indicator variables).

Self-report perception of ability to perform all exercises improved with biofeedback: speed 72.6±14.8 mm to 81.7±12.6 mm ($p=0.001$), arch elevation 71.3±15.1 mm to 79.9±14.4 mm ($p=0.010$), arch lowering 60.6±22.2 mm to 72.2±18.5 mm ($p=0.020$), endurance of

maintaining arch elevation 76.2±16.2 mm to 84.5±10.0 mm (p=0.010). Twenty-nine of 30 (97%) participants reported that Archie with biofeedback helped correctly perform the exercises. There were no adverse events reported.

## Discussion

The main finding of this study was that the Archie biofeedback device helped almost all participants perform the four foot exercises. Biofeedback from the footplate sensors improved foot placement during all exercise tasks, demonstrating that speed of arch elevation and lowering, controlled arch elevation and arch lowering, and endurance of maintaining an elevated arch were performed with the correct technique once the biofeedback device was activated. Archie also demonstrated that the exercise protocol displayed good consistency, with 89% of variables unchanged between trials, prior to activating the biofeedback device.

Perceived ability to complete the arch lowering exercise was the most difficult (60.6±22.2mm) and the endurance of maintaining an elevated arch was the easiest to perform (76±16.2mm) on the 0-100 mm scale. With biofeedback, speed of arch elevation and lowering improved by 13%, controlled arch elevation by 12%, arch lowering improved by 19%, and endurance of maintaining an elevated arch improved by 11%. Interestingly, even though eccentric training was considered more challenging[25] participant perceived ability to complete the arch lowering exercise was most improved with biofeedback. The considerable perceived improvement in the arch lowering exercise and comments such as "*the biofeedback made a huge difference in how I perceived that I performed the tasks, especially the arch relaxing (lowering) task*" (Table 3) substantiates the positive effect biofeedback had on perceived performance skill even for the most difficult exercise. Since self-efficacy is inherently motivating,[26] this positive reinforcement may improve exercise adherence.

The Archie biofeedback device corrected foot location adherence for all four exercises. This occurred even for the speed task, with its complex requirements to complete a series of sequential isotonic contractions, to elevate and lower the arch as quickly as possible. The substantial improvement for the foot location task emphasises the importance of feedback to enhance correct foot placement, which may assist effective intrinsic foot muscle recruitment. However, a significant decrease in arch relative range was observed in arch elevation and endurance tasks, and the arch elevation slope also worsened. The reduction in arch elevation range and, therefore reduced slope (angle of elevation), were most likely due to participants conscious attention to improving muscle control[27] and prioritising skill acquisition.[28] The use of a guidance line appeared to encourage participants to limit range in preference for control of arch movement with comments about the guidance line such as "*made it harder to reach highest marker, while helps to recreate expected pattern*". Similarly, the significant improvement in keeping to the line of best fit for arch elevation and the ability to maintain initial range for the duration of the endurance exercise using biofeedback, showed the participant's ability to improve performance skill using guidance lines.[29]

Biofeedback has been used with good effect in rehabilitation programs,[30] with evidence showing it provides multiple benefits,[31] post stroke, such as improved walking ability,[32] increased gait symmetry, and loading on the affected side.[19] Visual biofeedback increases effectiveness during training for improved dynamic balance,[33] weight shifting in standing, and reduced postural sway,[34] in a research setting. Home exercise programs that included biofeedback have been shown to improve a range of diverse problems such as gait insufficiency post incomplete spinal cord injuries,[19] and sphincter control for faecal incontinence.[35] Complex biofeedback systems for neuromotor rehabilitation intended for home use have been developed, such as wearable technology[36] and game based exercise.[33] A drawback is that these systems do not provide a direct measure of any given exercise or task,

but report functional changes. Archie delivers biofeedback via a unique real-time measure of change in arch height and foot location to specifically aid strength training of foot muscles. The specificity of the Archie feedback informs the clinician or user and allows interventions to be tailored and modified for individual requirements.

Aside from the positive self-reported effects of the Archie biofeedback device, participants also specifically commented on the sensation of the inflatable bladder under their arch, such as "*Feeling the bladder under the arch helped enormously*". It is likely the bladder under the arch may offer improved plantar sensory input. Reduced plantar sensory input alters balance control in healthy adults.[37] Since tactile plantar stimulation and sensory enhancing insoles improve postural control in a medio-lateral direction,[38, 39] the sensory feedback from the inflated bladder may increase small foot muscle activation which assists in balance control.[40] In addition, participants reported that the foot location sensors "*Works well to see how your foot position changes are shown on the screen, to feedback if you are doing it correctly, especially with the speed test*" and the real-time display provided a "*screen with good stimuli to do the exercises properly*". The visual depiction of pressure under the arch simultaneously with foot location, provided self-supervision of correct form thus reducing the likelihood of substitution movements, such as foot supination instead of arch elevation.

This study has several limitations. First, only 30 primarily active adults participated in this study and the results should not be generalised outside this population. Further studies with patient groups known to have foot muscle weakness such as those with peripheral neuropathy or an older population are necessary for a definitive conclusion on the effectiveness of the biofeedback based foot exercise program Second, as there was no control group, some learning effects may have biased the final outcomes. Third, there was no blinding of either participant or assessor, which could be a source of further bias. Fourth, the choice or

sequence of exercise tasks or fatigue may have also affected the results. Therefore longitudinal studies trialling different exercise sequences with participants randomly selected into active intervention or control groups, with assessor blinding would provide verification on the usefulness of the intervention. In addition it is recommended that the outcome variables (Table 4) be examined with different doses of exercise and diverse patient groups, to determine exercise specificity and responsiveness. This study only used the seated position, future studies progressing to double and single leg stances or with an incline would enable more challenging training programs to be trialled. Additional exercises could also be explored in order to generalise the benefits of Archie to other resistance strength training programs.

In conclusion, the Archie biofeedback device appears to be a safe and feasible system to assist participants with performing foot exercises and improve adherence to the correct technique. The Archie device merits further research to explore the longitudinal benefits in community-based clinical trials to treat foot muscle weakness.

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## Declarations

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Competing interests: Penelope J Latey has a patent pending on the device. The other authors declare that they have no competing interests.

All authors contributed to the conception and design of the study. The acquisition of data was undertaken by Penelope J Latey. The Archie device was built, software written and preliminary testing by John Eisenhuth and Penelope J Latey. Analysis and interpretation of data was undertaken by all authors. Drafting the article was undertaken by Penelope J Latey. Revising and editing was undertaken by all authors. All authors have read and approved the final version of the paper submitted.

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**Table 1:** Participant characteristics of the sample (n=30).

| Participant characteristics | Value |
|---|---|
| Age, y | 37.47 ± 12.7 |
| Sex, Female no. (%) | 19 (63%) |
| Body weight, kg | 67.6 ± 15.3 |
| Height, cm | 167.2 ± 7.2 |
| BMI, $kg/m^2$ | 24.0 ± 4.2 |
| Dominant foot, right | 28 (93%) |
| Foot Posture Index (score) | 0.8 ± 1.1 |
| Foot length, cm | 24.6 ± 1.5 |

Values are mean ± SD unless otherwise stated Abbreviations: y, year; kg, kilogram; m, metres; BMI, body mass index; cm, centimetres

**Table 2:** Trial 1 and 2 shows the consistency of the foot exercise protocol without biofeedback, and Trial 3 shows the effectiveness of the Archie device with the biofeedback.

| Variable | Trial 1<br>Mean ± SD | Trial 2<br>Mean ± SD | Trial 3<br>Mean ± SD |
|---|---|---|---|
| Speed cycle | 13.0 ± 5.0 | 13.6 ± 5.6 | 12.9 ± 5.9 |
| Speed mean Amplitude | 2.6 ± 1.4 | 2.7 ± 1.2 | 2.9 ± 0.9 |
| Speed Amplitude CoV | 2.8 ± 1.9 | 2.9 ± 2.7 | 2.1 ± 1.5 |
| Speed mean Period | 0.8 ± 0.3 | 0.8 ± 0.3 | 0.8 ± 0.3 |
| Speed Period CoV | 0.5 ± 0.5 | 0.4 ± 0.7 | 0.5 ± 0.7 |
| Speed foot locator compliance | 36.6 ± 34.4 | 21.6 ± 25.4* | 30.0 ± 31.6$^{\#}$ |
| Arch elevation relative range | 4.0 ± 1.8 | 4.3 ± 1.5 | 3.3 ± 0.8$^{\#}$ |
| Arch elevation slope | 0.4 ± 0.2 | 0.4 ± 0.2 | 0.3 ± 0.1$^{\#}$ |
| Arch elevation CoD | 0.7 ± 0.3 | 0.7 ± 0.2 | 0.9 ± 0.1$^{\#}$ |
| Arch elevation foot locator compliance | 37.9 ± 37.5 | 32.6 ± 33.6 | 52.0 ± 34.1$^{\#}$ |
| Arch lower relative range | 4.2 ± 1.7 | 3.8 ± 1.7 | 3.3 ± 0.9 |
| Arch lower slope | -0.4 ± 0.2 | -0.35 ± 0.2* | -0.3 ± 0.1 |
| Arch lower CoD | 0.9 ± 0.1 | 0.8 ± 0.2 | 0.9 ± 0.1 |
| Arch lower foot locator compliance | 28.6 ± 29.6 | 29.5 ± 28.4 | 50.0 ± 34.2$^{\#}$ |
| Endurance relative range | 4.5 ± 1.6 | 4.75 ± 1.7 | 3.5 ± 1.1$^{\#}$ |
| Endurance mean range | 3.5 ± 1.8 | 3.9 ± 1.9 | 3.4 ± 1.2 |
| Endurance CoV | 0.3 ± 0.4 | 0.1 ± 0.2 | 0.1 ± 0.1 |
| Endurance area ratio | 73.6 ± 22.1 | 77.3 ± 17.6 | 89.1 ± 14.1$^{\#}$ |
| Endurance foot locator compliance | 36.0 ± 35.1 | 46.0 ± 35.6 | 70.8 ± 36.4$^{\#}$ |

*Significant difference between trial 1 and 2 ($p<0.05$). $^{\#}$ Significant difference between trial 2 and 3 ($p<0.05$).

Legend: CoV coefficient of variation, CoD coefficient of determination. Foot locator variable range from 0-100, all other variables range 0- 20 arbitrary units.

**Table 3**: Survey comments on Archie exercise protocol performed with biofeedback

| Thematic grouping | Comments |
|---|---|
| General positive | Everything worked well |
| | Much easier |
| Biofeedback helped | Biofeedback made the task easier and my foot muscles seemed to improve |
| | Everything worked well |
| | Simply. the visualisation works very well |
| | The feedback worked all to get the exercise correctly |
| | The biofeedback was fantastic and was very helpful in the tasks |
| | Good to get feedback, hard to reach some of the highest markers, helps to recreate the expected patterns |
| Specific biofeedback helped | I felt that the graphs were a huge help for me to perform the tasks as they were described to me. |
| | Seeing my progress on the screen was good |
| | Seeing the monitor gave good feedback on whether I'm doing the task correctly or not |
| | The feedback helped to understand the concept of slowly lifting up and lowering down, and having the feedback helped with endurance and know that 'i'm doing the right thing. |
| Negative comments | Concentrating on the new task (lowering the arch) and looking at the screen was difficult. |
| | Fatigue affected the latter results. |
| **Specific biofeedback components** | |
| Bladder | Bladder provided useful tactile feedback |
| | Feeling the bladder under the arch helped enormously with arch awareness. |
| | The pressure under the arch was very helpful and informative |
| Foot locators | Works well to see how your foot position changes are shown on the screen, to feedback if you are doing it correctly, especially with the speed test. |
| | ….assisted specially with the little toe |
| Visual display | It was easier to understand what I was supposed to do with visual feedback. |
| | The biofeedback made a huge difference in how I perceived that I performed the tasks, especially the arch relaxing task. |
| | The screen really helps to complete the tasks. |
| | The screen was a good stimuli to do the exercises properly |
| | Pressure waves & guidance line of best fit (helped). |
| | The guide and feedback when doing lifting up and lowering down helped with controlling the movement. |
| | Help in most tasks but not helpful for me with the eccentric task*. |

Legend: eccentric task*, arch lowering

**Supplementary Table 4:** Archie data outcome variables; description, calculation and performance indicator

| Exercise | Variable | Description and Calculation | Performance indicator |
|---|---|---|---|
| Speed | | Uses a peak detection algorithm to identify each peak and trough of a sinusoidal waveform. | |
| | Cycles | Number of peaks following the first peak in an interval. Peaks between X1 and X2 in 10 seconds. | How quickly the participant can sequentially elevate and lower their arch. |
| | Mean amplitude | Mean magnitude of the wave or the difference between a peak and trough. | Range for the arch lifting and lowering during the fast muscle activation and relaxing.* |
| | Amplitude coefficient of variation | Variation of the amplitude normalised to the mean. (CoV = Standard Deviation/Mean). | Quality of the arch lift and lower. A decrease in the CoV denotes higher performance skill. |
| | Mean period | Mean period (time interval) between each peak. | How quickly the participant can activate and relax the small foot muscles under the arch. |
| | Period coefficient of variation | Variation of the period normalised to the mean (CoV = Standard Deviation/Mean). | A decrease in the CoV denotes higher performance skill. |
| Elevation and lowering | | | |
| | Relative range | Difference between the maximum and minimum arch height, defined by the vertical cursors X1 to X2. | How much the participant can lift or lower the arch from relaxed to as high as possible or from as elevated as possible to relax the arch.* |
| | Slope | Ratio of vertical change over horizontal change or time interval (Slope = Range(X1-X2) / Interval) in 10 seconds. | How well the participant can control the gradual concentric or eccentric contraction of the small foot muscles. |
| | Coefficient of determination | $r^2$ is a statistical measure of how well a regression line approximates the real data points collected, calculated by ($R^2$ = 1 –SSres/SStot) ,while following a guidance line calculated by using a pre test practice (slope = Range (X2 – X1) / Interval). | An increase in the coefficient of determination (closer to 1) denotes higher performance skill of the particpants ability to follow the guidance line. |
| Endurance | | | |
| | Relative range | Range of arch elevation from pre elevation to arch elevation. | How much the participant can elevate the arch.* |
| | Mean range | Mean range over the time interval of the exercise. | Determines the participants ability to maintain arch elevation over the duration of the exercise. |
| | Coefficient of variation | Variation or the consistency of the participants arch elevation over 60 seconds (CoV = Standard Deviation/Mean). | Ability to maintain a steady small foot muscle contraction or arch lift for 60 seconds. A decrease in the CoV denotes higher performance skill. |
| | Area ratio | Area under the pressure signal divided by the total possible area expressed as a percentage (total possible area is 80% of the user's initial range multiplied by test duration). | Increased area ratio indicates improved performance skill by consistently maintaining an increased arch elevation. |
| All exercises | | | |
| | Foot location | Percentage of time the great toe, fifth toe and heel contacted the membrane switches during testing. | Increased foot location indicates improved ability of participant to maintain correct contact with heel, great and fifth toe membrane switches, ensuring foot alignment is kept within the same plane during each exercise. |

Key: * Comparisons can be made with mean amplitude or relative range to explore any relationship between range and exercise: X1, first cursor; X2, second cursor; CoV, coefficient of variation; CoD coefficent of determination; SSres = sum of residuals = $\sum(yi - Yi)^2$ from i = 1 to n; SStot = total sum of squares = $\sum(yi - meanY)^2$ from i = 1 to n

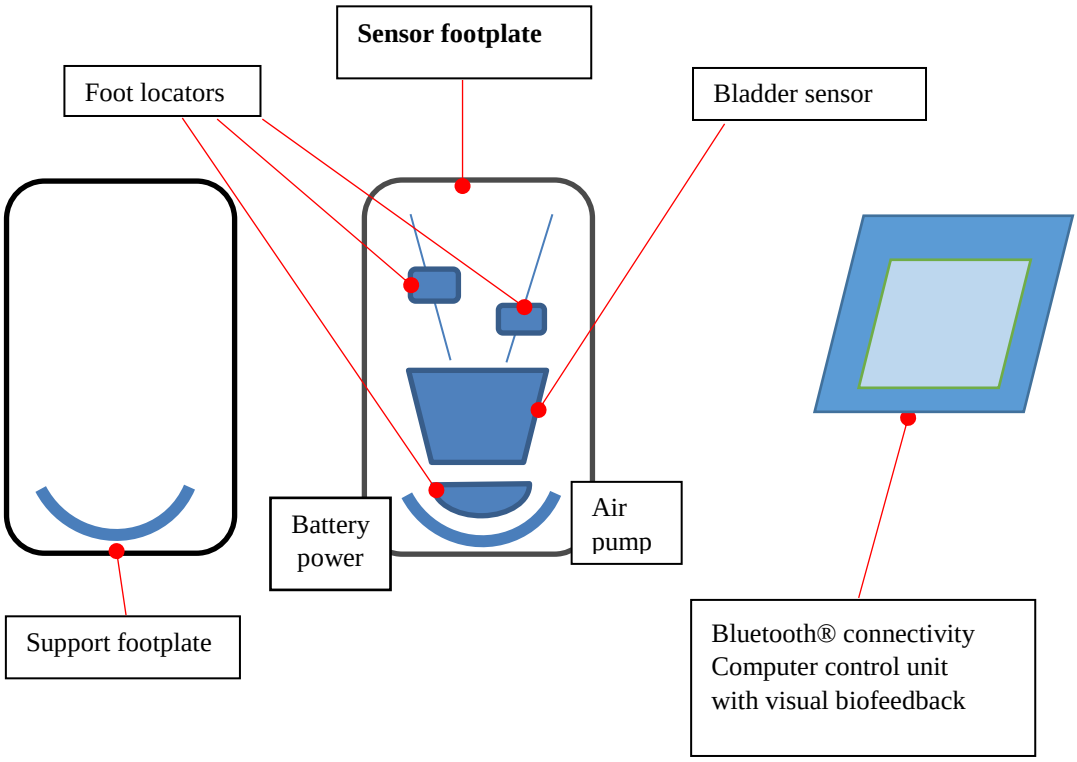


**Figure 1**: Block diagram of the final Archie device design

**Figure 2.** Image of the Archie biofeedback device

# CHAPTER SIX

## Concluding remarks

## 6.1 Overview of the main findings

A diverse range of diseases, inactivity and ageing cause foot muscle weakness, variously resulting in foot deformity, disability and reduced quality of life. These problems are frequently linked with foot pain. Since pain is bi-directional, and may exacerbate these diverse problems, a systematic review was undertaken to explore the association between foot muscle weakness and pain. The first main finding relating to the aims of the thesis, was that foot muscle weakness is associated with pain, when pain is high and primarily measured by toe flexion (Chapter 2). However, there are some conflicting findings regarding the link between foot muscle weakness and pain due to variations in pain aetiology, foot problems and measurement methods. These findings highlighted the difficulty distinguishing between intrinsic and extrinsic foot muscles.

Strength in the intrinsic foot muscles of the great toe is affected by a number of diseases and toe deformities, but difficult to measure. Therefore a study was undertaken to determine the reliability of measuring abductor hallucis and the medial belly of flexor hallucis brevis muscle size and evaluate any association between measures of the cross-sectional area and toe flexion strength, foot morphology and balance (Chapter 3).

While measuring foot muscle weakness remains challenging, the second main finding relating to the aims of the thesis found that the cross-sectional area of abductor hallucis and the medial belly of flexor hallucis brevis can be reliably measured with ultrasound. This study has identified an objective and sensitive outcome measure of muscle gain and growth that could be used to determine foot exercise response. Furthermore, the size of abductor hallucis was significantly correlated with great toe flexion strength, even when scaled to minimise the effect of body dimensions. However only one association was found between

the cross-sectional area of the medial belly of flexor hallucis brevis and a foot morphology measure. While these first ray muscles may act together, as observed from the systematic review (Chapter 2), where specific foot regions show different associations between foot muscle size and pain,[1] the flexor hallucis brevis and abductor hallucis exhibit different patterns of association between toe flexion strength foot morphology and balance. The results of this study informed the choice of exercise in the subsequent study. Since only the size of abductor hallucis was positively associated with toe flexion force, exercises that targeted the abductor hallucis muscle were considered most important to explore with a novel assistive foot exercise device.

Exercise is known to improve muscle weakness but can be limited by difficulty maintaining quality performance and low adherence to practice.[2] Biofeedback may ensure that the exercises are being correctly performed and assist in motivating practice, thereby giving people the opportunity to exercise in their own home. Therefore work undertaken in Chapter 4 to construct a novel biofeedback medical device Archie, included substantially improved tactile and visual real-time feedback. Preliminary testing to enhance performance skill, ensure safety and functionality for the user was undertaken in preparation for the final study evaluating the Archie biofeedback device to consistently and effectively assist with foot exercise adherence and quality of movement.

The third main finding relating to the aims of the thesis reported in Chapter 5 showed that performing selected foot exercises with Archie is a safe and feasible system to assist participants with performing foot exercises and improve adherence to the correct technique. The Archie device might provide an effective treatment for foot muscle weakness for a diverse range of problems.

## 6.2 Clinical implications of this thesis

There are a number of clinical applications from the research reported in this thesis. First there are a variety of reliable methods to measure foot muscle strength and size. Second, ultrasound of toe muscles can be undertaken in a reliable way in a seated position, giving greater flexibility for clinicians. Third, Archie can be used to deliver biofeedback for correct performance of intrinsic muscle exercise and due to its portability can then be taken home for ongoing exercise.

### 6.2.1 Foot pain and weakness

The evidence from the systematic review of a significant association between foot pain and muscle weakness when foot pain is of high intensity and primarily measured by toe flexion force confirms clinicians should include not only questions regarding pain levels, but also suggest clinicians could test toe flexion strength of their patients using pedobarography or hand-held dynamometry. Inconsistency in the types of foot pain reported, severity of pain, and pain scale methodology suggest pain reporting practices should be reviewed. Therefore in clinical practice it is recommended that pain should be discussed thoroughly with patients, not only using severity rating scales, such as numerical rating scales, but also asking about pain duration and frequency. Additionally, determining the effect and impact of their foot pain using a standardised tool such as the Foot Function Index,[3] as part of case history taking and differential diagnosis procedure would be beneficial. Even though there are limitations to the Foot Function Index[4] recording self-perceived disability and activity limitation along with pain would improve prognosis.

In exploring the association between foot muscle weakness and pain, the multiple pain aetiologies, from general foot pain,[5] joint specific pain[6, 7] and hindfoot pain,[1, 8, 9] make it difficult to separate disuse leading to muscle atrophy, or pain causing inactivity which leads to atrophy. However, this highlights the bi-directional nature of pain.

An important issue is that toe flexion strength procedures do not entirely exclude extrinsic foot muscle activation,[10, 11] with results varying due to measuring position or testing device, such as the paper grip test and toe flexion load cells.[12] Therefore including a range of muscle testing procedures, such as ultrasound (and toe flexion testing with palpation) of selected intrinsic foot muscles may improve patient treatment procedures and exercise prescription, particularly of complex problems.

### 6.2.2 Reliable ultrasound measures in a seated position

This was the first study to use a seated position to measures the cross-sectional area of the abductor hallucis and the flexor hallucis brevis muscles using ultrasound. Considering the good intra-rater reliability of the seated position and the modified scanning sites determined by bony landmarks, inter-rater reliability testing and dissemination of these ultrasound techniques are justified, as scanning in seated rather than supine of prone may improve client comfort in research or clinical practice. The seated position could therefore be used for scanning these muscles in people with reduced mobility or positional difficulties due to problems such as severe back pain,[13] obesity,[14] positional vertigo[15] or sarcopenia.[16]

Other intrinsic foot muscles could be scanned in a seated position, such as extensor hallucis brevis and extensor digitorum brevis or abductor digiti minimi. Comparisons between

scanning the intrinsic foot muscles in supine, prone seated and standing may also contribute to our understanding of distal oedema and venous return.[17]

The use of ultrasound scanning of the intrinsic foot muscles, may also provide early diagnosis, as a bio-marker for some diseases such as peripheral neuropathy,[18] sarcopenia,[19, 20] or to improve specificity of muscle identification when; examining disuse atrophy related to arthrogenic muscle inhibition,[21] or muscle fatty atrophy in people with rheumatoid arthritis.[22]

### 6.2.3 Feasibility of exercise delivery

Archie displayed good consistency delivering the exercise protocol, with 89% of variables unchanged between two bouts, prior to activating the biofeedback device and no adverse events occurred. The specific arch doming manoeuvre used in the trial and the four exercises were safe and reproducible. As the Archie biofeedback device also helped almost all participants perform the four foot exercises correctly teaching the exercises using Archie in the clinical setting and then providing the device for home use may be an economic alternative to ongoing clinic supervised rehabilitation.[23]

## 6.3 Research implications of the thesis

There are a number of research implications from the work in this thesis. First, Archive is ready for randomised controlled trials using pedobarography, dynamometry and ultrasound as reliable and sensitive outcome measures to increase strength and reduce pain in a variety of clinical populations. Second, pain should be measured consistently to ensure comparison across studies. Third, ultrasound measures should be scaled when comparing between groups.

### 6.3.1 Measure pain consistently

Some of the variable findings regarding the association between foot muscle strength or size and pain was due to how pain was reported. The lack of homogeneity of the methods for reporting pain highlights the difficulty in determining the association between muscle size and pain. The site of foot pain should be recorded using a body chart with lateral, medial, dorsal and plantar perspectives. Visual analogue scales of pain report a numerical value of severity, with pain levels > 6/10 usually considered disabling, depending on pathology.[24, 25] However, frequency and duration of pain need to be considered. The one study reporting frequency of pain,[5] noted more regional weakness with reduced toe flexion strength, for both the great and lesser toes in those reporting a higher frequency of pain. In addition, while the majority of studies reporting duration of pain demonstrated an association between the variables,[1, 8, 9] the one study finding no association between toe flexion and foot pain reported the longest duration of pain.[7] Therefore future studies reporting pain should include validated pain duration and frequency scales, as well patient reported levels of self-perceived disability and activity limitation such as the Foot Health Status Questionnaire[12] and the revised Foot Function Index.[26]

### 6.3.2 Scale ultrasound measures

To reduce the effect of participant dimensions on the measuring procedures, different methods of scaling or normalising toe flexion force and ultrasound cross-sectional area data were explored. Previously toe flexion force or strength measures have been scaled in a variety of ways. Scaling force measures have been undertaken using: percentage of height and weight,[27 28, 29] divide by body mass,[30] divide by foot or toe length.[29] Body Mass Index,

although not a direct measure of adiposity, has also been used as a surrogate for body composition to scale strength measures.[31] Recent research suggests that scaling force to fat free mass is a more accurate way to scale strength measures.[32]

Measures of muscle cross-sectional area have been infrequently scaled. Research examining ultrasound cross-sectional area or muscle morphology of the intrinsic foot muscles in a healthy population,[33, 34] or those with the foot deformity hallux valgus,[35, 36] did not report scaled or normalised data. A study of healthy young adults scaled toe flexion force measures to weight, but did not scale measures of cross-sectional area.[37] Bus and colleagues, when examining intrinsic foot muscles of the diabetic foot with MRI, normalised muscle cross-sectional area as a percentage of the total foot cross-sectional area measured.[38] Research to acquire the reference values for ultrasound cross-sectional area of various lower limb and foot muscles report significant effects of age and sex, on muscle thickness and echogenicity, associated with fat infiltration.[39]

In chapter 3 truncated foot length was used to complete partial correlations and minimise the effect of body dimensions. Correlations between measures of truncated foot length were most consistent for abductor hallucis (r=580, p=0.006) and for the medial belly of flexor hallucis brevis (r=0.483, p=0.027). While the association with toe strength determined by pedobarography and the size of abductor hallucis remained consistent in this study, further research on scaling cross-sectional area is needed. Scaling to fat free mass may provide a more accurate measure of muscle size, particularly if being compared with other scaled variables.

## 6.4 Limitations

The findings of this thesis must be considered in the light of some limitations in each study.

The systematic review (Chapter 2) only included English language articles published in peer review journals. Due to heterogeneity of the types of foot pain, muscle strength and size measures, no data were pooled for meta-analysis. While the cross-sectional evidence reported in this review identified several relationships between foot pain and foot muscle weakness, it did not determine causality.

The study on the reliability and correlates of the cross-sectional area of abductor hallucis and flexor hallucis brevis measured by ultrasound (Chapter 3), only evaluated 21, primarily female middle-aged adults. This reduces the generalisability of the findings and as this was a cross-sectional study no causality could be inferred between toe flexion strength, muscle size and balance. Further, the small sample size resulted in a lack of statistical power with the possibility of Type 1 errors occurring as multiple comparisons were performed. Since only two muscles were measured in this study, comparisons with studies evaluating other intrinsic foot muscles were limited.

Limitations of the feasibility trial of the Archie biofeedback device in Chapter 5 included sample size, lack of control group, lack of blinding and a cross-sectional design. Only 30 primarily active adults participated in this study so caution should be applied when generalising the findings beyond a relatively healthy cohort. As there was no control group, some learning effects could have affected the results and lack of blinding of either participant or assessor, may have biased the final outcomes. The Archie device merits further research

to explore the longitudinal benefits in community-based clinical trials to treat foot muscle weakness.

## 6.5 Future Research

There are a number of directions for future research from this thesis.

### 6.5.1 Interaction between foot pain and muscle weakness

While the systematic review found an association between foot pain, foot muscle weakness either measured by toe flexion force or muscle size, further research exploring the nature of the relationship would improve our understanding of the effect of pain on muscle weakness, or vice versa. Therefore longitudinal cohort studies are required to assess the risk of developing foot pain in relation to intrinsic and extrinsic foot muscle weakness, and the effect of improving foot strength on foot pain resolution. If foot muscle weakness is the cause of foot pain,[40] Archie may be used as an aid to improve performance and adherence to muscle building interventions.

### 6.5.2 Clinical trials on foot muscle strengthening with Archie

The results of the Archie feasibility study were extremely positive and further research about this promising biofeedback device is suggested. A longitudinal study with healthy adult participants randomly selected into exercise intervention, exercise with biofeedback or control group, with assessor blinding would provide verification on the usefulness of the intervention. Subsequent to this, a prospective, sham-controlled randomised trial is also

required to evaluate the efficacy of Archie biofeedback on foot muscle weakness in a variety of populations such as people with diabetes and Charcot-Marie-Tooth disease. Exploration of exercise 'dose' and duration are critical next steps. Another area of interest is varying the sequence, frequency or type of foot exercises to better target special populations such as obese individuals and those with severe peripheral neuropathy where they might not be able to see or feel their feet. Alternatively, Archie could be used to measure the foot muscle performance of people with diabetes or toe deformities to understand severity and likelihood of response to treatment. For example, those with no ability to lift their foot arch this may be an indicator of limited capacity to exercise and for those unable to maintain correct foot location seated exercise may be safer than attempting standing exercise.

If intrinsic foot muscle weakness can be identified early, specific foot exercises could be prescribed and monitored with Archie, as a preventative intervention. For example, early identification of muscle weakness would potentially minimise or limit the progression of painful hallux valgus[41] or hallucis rigidus,[42] before the first MTP joint range is limited or severe deformity is present.[43] People diagnosed with diabetes or undergoing chemotherapy could be taught safe foot exercise to minimise the likelihood of foot muscle weakness caused by peripheral neuropathy.[44]

Several modifications are suggested for further trials using Archie. These include changes to the intervention protocol, such as testing other foot exercises, including the classic short foot,[45] toe spread out,[46] alternate heel rise[47] and toe extensions[48] that have been shown to improve intrinsic foot muscle strength in a supervised research setting. Future studies could also provide more challenging foot exercise programmes, to increase intrinsic foot muscle strength and fine tune performance accuracy in the very fit and active such as dances and

athletes. These training programs need to be explored in order to generalise the benefits of Archie to other resistance strength training programs.

Targeted foot exercise interventions practiced with Archie may be used to manage or slow the loss of foot muscle related to inactivity, arthritis and sarcopenia. Furthermore, with an increasing aging population, improving foot strength and function may reduce foot pain, improve balance [49, 50] and lessen the incidence of falls.[5, 51, 52] Any restriction of movement or pathology affecting muscles of the first ray,[53] impacts normal function of the whole foot,[54] with strength in the first ray essential in the toe-off phase during walking.[55] If foot muscle strength can be either maintained or improved, disability associated with foot muscle weakness may be reduced.[52, 56-61] This will potentially minimise costs of medical intervention and assist people with disabling foot problems to maintain quality of life.

### 6.5.3 Extending Archie capabilities

Several modifications to the Archie system are suggested for further trials, such as modifying the interface or feedback. Various changes could be made to the visual display including adding pictorial shapes as goals accompanying movement on the bladder pressure signal on the PC display, similar to emoji's. A gaming style interface,[62] displaying preset target ranges that act as reminders or rewards for completing the tasks, could provide encouragement for practice adherence. Feedback could be provided in other ways such as auditory feedback. Auditory feedback could be given via music or sounds associated with arch movement and foot location. This form of biofeedback would be useful for people with vision impairments.

### 6.5.4 Industry partnering

For future trials consideration should also be given to the benefits of transposing the manufacture of the Archie device from a small number of units for research into an industry partnership. While each Archie currently costs approximately $550.00 in materials alone, the fabrication of individual PCBs and custom components amounted for more than half of the expenditure. Replicating fifty Archies would reduce those costs substantially, by economies of scale. Therefore, commercial manufacture would allow considerable cost efficiency and reduced unit cost.

### 6.5.5 Remote monitoring and e-health

Home exercise programmes are effective for adults, particularly if they provide feedback about progress.[23] However, maintaining adherence to home practice is multidimensional, with pain and lack of motivation reducing the likelihood of correct execution of exercises.[63] Perceived performance accuracy and strength gains are inherently motivating and encourages practice. Archie provides the ability to save, store and send test results, and could provide instant messaging, remote monitoring and encouragement via PC or mobile phone and provide assistance for those outside major population centres.

## 6.6 Concluding statement

Foot pain and weakness are prevalent and disabling. Exercise can improve muscle weakness but is often limited by poor adherence rates. Biofeedback may increase adherence to home exercise programs through precise movement guidance and motivational support. The Archie biofeedback device may be a solution to debilitating foot muscle weakness. Archie is a safe

and feasible system to improve the technique and adherence of foot exercises while providing a unique real-time measure of change in arch height and a foot location sensor system to specifically aid in strengthening foot muscles. Archie is ready for randomised controlled trials using pedobarography, dynamometry and ultrasound as reliable and sensitive outcome measures to increase performance skills to improve foot strength and reduce pain in a variety of clinical populations.

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# APPENDIX

Appendix one: Additional material for *Reliability and correlates of cross-sectional area of abductor hallucis and the medial belly of flexor hallucis brevis measured by ultrasound*

Appendix two: Additional material for *Feasibility of the Archie biofeedback device to strengthen foot musclature*

# APPENDIX ONE

*Reliability and correlates of cross-sectional area of abductor hallucis and the medial belly of flexor hallucis brevis measured by ultrasound*

1. Human Research Ethics Committee letter of approval to undertake study
2. Advertisement
3. Participant Information Statement
4. Participant consent form

THE UNIVERSITY OF SYDNEY

**Research Integrity**
Human Research Ethics Committee

Wednesday, 20 March 2013

Reliability of clinical measures associated with hallux valgus (Bunions)
Associate Professor Joshua Burns
Clinical and Rehabilitation Sciences; Faculty of Health Sciences
Email: joshua.burns@sydney.edu.au

Dear Joshua

I am pleased to inform you that the University of Sydney Human Research Ethics Committee (HREC) has approved your project entitled "**Reliability of clinical measures associated with hallux valgus (Bunions)**".

Details of the approval are as follows:

**Project No.:** **2012/2849**

**Approval Date:** **18 March 2013**

**First Annual Report Due:** **18 March 2014**

**Authorised Personnel:** **Burns Joshua; Nightingale Elizabeth Jean; Latey Penelope; Hiller Claire;**

**Documents Approved:**

| Date Uploaded | Type | Document Name |
|---|---|---|
| 24/01/2013 | Human Ethics Application Form | Corrections to Human Ethics Form: study design |
| 24/01/2013 | Other Type | Cover letter addressing corrections to human ethics application |
| 24/01/2013 | Advertisements/Flyer | Flyer broad cast |
| 24/01/2013 | Organisation Approval | Permission letter for advertisement placement |
| n/a | Participant Information Statement | Participant Information Statement Version 1 11/11/12 |
| n/a | Participant Consent Form | Participant Consent Form Version 2 29/10/12 |
| n/a | Instrument | AQoL-6D |
| n/a | Instrument | Manchester-Oxford Foot Questionnaire (MOxFQ) |
| n/a | Instrument | Data Collection Sheet Version 3 30/10/12 |

HREC approval is valid for four (4) years from the approval date stated in this letter and is granted pending the following conditions being met:

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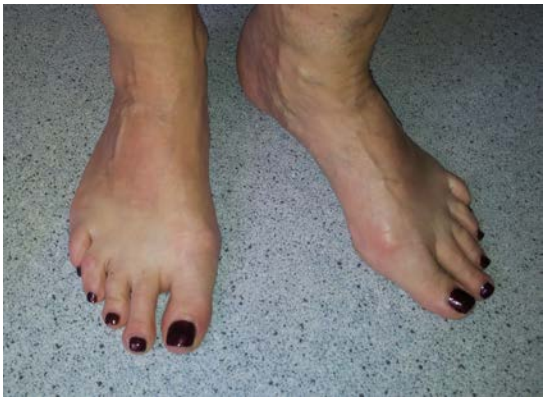
THE UNIVERSITY OF SYDNEY

# Measuring Feet



## Can you help us to find a reliable range of foot measures?

We are looking for participants for a research study that examines: shape, function and comfort levels of the foot. The aim is to assess different tests and measuring devices to assist in finding the most reliable way of determining foot structure and function.

**Who can volunteer?**

Participants must be healthy adults aged 18+ years who have not had a major foot problem in the last six months, and currently don't have an illness that may stop them being able to walk barefoot for 20 meters.

If you would like more information, please contact

Penny Latey,
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# Reliability of clinical measures associated with hallux valgus (Bunions)

## PARTICIPANT INFORMATION STATEMENT

### (1) What is the study about?

This study considers the reliability of measures of the foot and ankle. Measures of strength, flexibility and foot posture will be investigated. Measures reporting high test-retest reliability will be used for a subsequent study looking at an exercise intervention for people with bunions.

### (2) Who is carrying out the study?

The study is being conducted by Penelope Latey (PhD student) under the supervision of A/Prof Joshua Burns

### (3) What does the study involve?

*This study assesses a variety of tests to measure and record information about the foot. Each measure will be taken three times, on two separate occasions.*

*During the first session background information, including height, weight, age and your regular shoe wear will be obtained. You will also be given*

*two questionnaires to answer relating to foot health and function and quality of life. These questionnaires may completed at the time of your first session or be taken home, completed, and returned at the second session.*

*The tests include:*

- *The structure of the foot including shape, alignment and arch height will be measured, under multiple conditions (sit, stand; with foot muscles active and passive).*
- *Pressure patterns under the foot will be recorded while stepping on a pressure plate*
- *The muscles under the sole of the foot with be examined with ultrasound to look at muscle size*
- *Strength of the big toe and ankle will be measured with two devices requiring you to press first your great toe then your smaller toes onto a pressure plate or a dynamometer.*
- *Big toe and ankle range of motion will be measured using a goniometer.*

**(4) How much time will the study take?**

Participation in the study will require two sessions at the AMRG lab. At the first session you will be given the questionnaires, which will take about 25minutes to complete. The physical testing and measuring at each of the two sessions, will take a further 1 ½ hours.

**(5) Can I withdraw from the study?**

This study is completely voluntary and you may withdraw at any time. You may stop testing at any time if you do not wish to continue and the information provided will not be included in the study.

**(6) Will anyone else know the results?**

All aspects of the study, including results, will be strictly confidential. Information will be coded and only the researchers will have access to study information. Any publication of the results from this study will not involve identifiable individual participant information.

**(7) Will the study benefit me?**

There will be no direct benefits to participants.

**(8) Can I tell other people about the study?**

Yes. The research team encourages you to tell others about the study.

**(9) What if I require further information about the study or my involvement in it?**

An information sheet is provided and if you have any further questions the following researchers involved with the project will be happy to answer them: Penelope Latey 93519562, Claire Hiller 9351 9108, and Elizabeth Nightingale 9351 9401.

**(10) What if I have a complaint or any concerns?**

Any person with concerns or complaints about the conduct of a research study can contact The Manager, Human Ethics Administration, University of Sydney on +61 2 8627 8176 (Telephone); +61 2 8627 8177 (Facsimile) or ro.humanethics@sydney.edu.au (Email).

# This information sheet is for you to keep

THE UNIVERSITY OF SYDNEY

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# PARTICIPANT CONSENT FORM

I, .....[PRINT NAME], give consent to my participation in the research project

TITLE: **Reliability of clinical measures associated with hallux valgus (Bunions)**

In giving my consent I acknowledge that:

1. The procedures required for the project and the time involved have been explained to me, including any inconvenience, risk, or discomfort, and their implications, and any questions I have about the project have been answered to my satisfaction.

2. I have read the Participant Information Statement and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.

3. I understand that being in this study is completely voluntary – I am not under any obligation to consent.

4. I understand that my involvement is strictly confidential. I understand that any research data gathered from the results of the study may be published however no information about me will be used in any way that is identifiable.

5. I understand that I can withdraw from the study at any time, without affecting my relationship with the researcher(s) or the University of Sydney now or in the future.

6. I understand that I can stop the interview or tests at any time if I do not wish to continue; the information provided will be erased and will not be included in the study.

7. I consent to:

- Receiving Feedback YES ☐ NO ☐

If you answered YES to the "Receiving Feedback" question, please provide your details i.e. mailing address, email address.

**Feedback Option**

**Address:** _____

_____

**Email:** _____

..... .....

Signature

.....

Please PRINT name

.....

Date

# APPENDIX TWO

*Feasibility of the Archie biofeedback device for foot strengthening*

1. Human Research Ethics Committee letter of approval to undertake study
2. Site specific Ethics Committee letter of approval to undertake study
3. Advertisement
4. Participant Information Statement
5. Participant consent form
6. Device Brochure
7. Confidentiality Agreement
8. Archie Device Assessment
9. Participant characteristics and data collection sheets
10. Equipment procedures
11. Participant questionnaires and surveys

THE UNIVERSITY OF SYDNEY

**Research Integrity & Ethics Administration**
Human Research Ethics Committee

Monday, 23 January 2017

Prof Joshua Burns
Clinical and Rehabilitation Sciences; Faculty of Health Sciences
Email: joshua.burns@sydney.edu.au

Dear Joshua

The University of Sydney Human Research Ethics Committee (HREC) has considered your application.

After consideration of your response to the comments raised your project has been approved.

Approval is granted for a period of four years from **23 January 2017** to **23 January 2021**

**Project Title:** **Feasibility, reliability and validity of a biofeedback device ("Archie™") to assess dynamic foot muscle strength**

**Project No.:** **2016/881**

**First Annual Report Due:** **23 January 2018**

**Sites Approved:** **University of Sydney, Cumberland**

**Authorised Personnel:** **Burns Joshua; Hiller Claire; Latey Penelope; Nightingale Elizabeth Jean;**

**Documents Approved:**

| Date Uploaded | Version number | Document Name |
|---|---|---|
| 26/08/2016 | Version 1 | Advertisement |
| 29/11/2016 | Version 1 | Letter from RPA CTSC |
| 19/11/2016 | Version 2 | version 2 appendix to protocol |
| 18/10/2016 | Version 1 | Dean approval for trial |
| 18/10/2016 | Version 1 | GCP Training |
| 26/08/2016 | Version 1 | Confidentiality agreement |
| 19/11/2016 | Version 2 | Participant consent from |
| 26/08/2016 | Version 1 | PIS |
| 26/08/2016 | Version 1 | Participant info and foot problems/pain |
| 26/08/2016 | Version 1 | Foot tasks |
| 26/08/2016 | Version 1 | Foot tasks with Archie biofeedback |
| 26/08/2016 | Version 1 | Foot function index |
| 01/09/2016 | Version 1 | Site specific assessment form |
| 19/11/2016 | Version 1 | Clinical Trial Protocol on Archie device |
| 26/08/2016 | Version 1 | Unexpected/Adverse event form |

Research Integrity & Ethics Administration
Research Portfolio
Level 2, Margaret Telfer Building (K07)
The University of Sydney
NSW 2006 Australia

T +61 2 9036 9161
E human.ethics@sydney.edu.au
W sydney.edu.au/ethics

ABN 15 211 513 464
CRICOS 00026A

**ADDRESS FOR ALL CORRESPONDENCE**
RESEARCH DEVELOPMENT OFFICE
ROYAL PRINCE ALFRED HOSPITAL
CAMPERDOWN NSW 2050

TELEPHONE: (02) 9515 7035
EMAIL: fiona.guan@sswahs.nsw.gov.au
**REFERENCE: X16-0395**

13 October 2016

Dr M Faedo
C/- Ms P Engelmann
Ethics Administration Manager
Research Integrity
Level 2, K07 Margaret Telfer Building
UNIVERSITY OF SYDNEY NSW 2006

Dear Dr Faedo,

**Re: Protocol No X16-0395 - "Feasibility, reliability and validity of a biofeedback device**
**(˜Archie") to assess dynamic foot muscle strength"**

As requested, the Clinical Trials Sub-committee has considered the above protocol at its meeting of 26 September 2016.

The Sub-committee recommends that the HREC of the University of Sydney consider approving it, subject to receipt of additional information:

- Justification for retaining the data for future studies.

In addition, the Sub-committee made the following recommendations:

- The Sub-committee noted that ultrasound muscle measurements are highly variable between participants, and recommended that the investigators consider using changes within participants alone in the analysis.

- The Sub-committee recommended the addition of witness' name and signature in the Participant Consent Form.

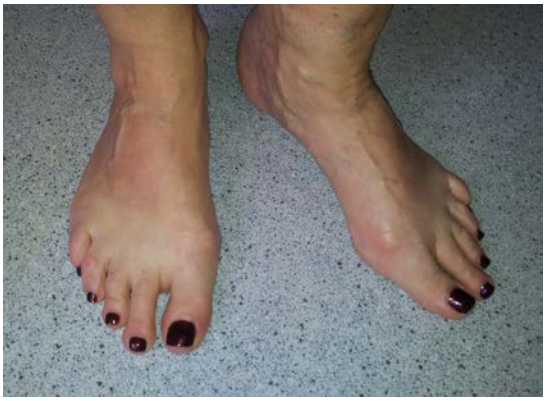
Please note that the Sub-committee has considered only the scientific aspects of the study, and the University's HREC should review the ethical aspects of the study and the information / consent and other documents.

Yours sincerely,

Fiona Guan

**Executive Officer**
**Clinical Trials Sub-committee (RPAH Zone)** CTEX\APPUSYD\16-09

# Measuring and exercising your feet



## Would you like to see how you can move the arch of your foot and find out if it helps you exercise your feet?

**Do you think you may have weak feet or problematic feet or you're just interested in exercising your feet?**

We are looking for participants for a research study that examines the reliability of a device that measures foot arch movement and the feasibility of doing specific foot movements.

The aim is to assess a biofeedback exercise device with a range of people to assist in determining if the device assists to help practice foot exercises.

**Who can volunteer?**

Participants must be healthy adults aged 18+ years who have not had a major foot problem or foot surgery in the last six months, and currently don't have an illness that may stop them being able to walk barefoot for 50 meters.

If you would like more information, please contact

Penny Latey,
9351 9017
email plat6993@uni.sydney.edu.au

THE UNIVERSITY OF SYDNEY

**Discipline of Physiotherapy**

**Faculty of Health Sciences**

**Professor Joshua Burns**

Room S223
Cumberland Campus
The University of Sydney
NSW 2006 AUSTRALIA
Telephone: +61 2 9351 9617
Email: plat6993@uni.sydney.edu.au
Web: http://www.sydney.edu.au/

# Feasibility, reliability and validity of a biofeedback device ('Archie') to assess dynamic foot muscle strength

## PARTICIPANT INFORMATION STATEMENT

You have been invited to participate in this study because you have responded to our advertisement and meet the eligibility criteria of the study. This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

### (1) What is this study about?

This research study is about foot muscles, measuring foot movement and practicing foot exercises with a new device called 'Archie'. *Archie is a small platform on which to place your foot incorporating specially designed sensors that are intended to assist you to move different parts of your foot.*

**Purpose:** This study examines the reliability, validity and feasibility (these terms are further explained below) of Archie to measure and monitor foot movement.

**Aims:** To determine if Archie is an accurate and reliable device to assess foot strength and assist with foot exercises.

**Significance:** The results of this study will provide information for further research to see if the use of Archie can improve the treatment of a range of foot problems associated with weak feet.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

**(2) Who is running the study?**

The study is being carried out by the following researchers at The University of Sydney:

| | |
|---|---|
| Professor Joshua Burns | joshua.burns@sydney.edu.au |
| Dr Claire Hiller | claire.hiller@sydney.edu.au |
| Dr Jean Nightingale | jean.nightingale@sydney.edu.au |
| Ms Penelope Latey (PhD Student) | plat6993@uni.sydney.edu.au |

Penelope Latey is conducting this study as the basis for the degree of PhD at the University of Sydney. This will take place under the supervision of Professor Joshua Burns.

While there are no direct financial benefits to the researchers or institution during the conduct of this study, there is potential benefit to the research student, who owns the patent on the Archie device. If the results of this research are positive, further studies will be completed to use the device with different populations that may in turn result in the commercialisation of the device.

**(3) What will the study involve for me?**

*Initially the consent form will be signed and information will be obtained of your height, age and weight. You will also be given questionnaires to answer relating to general health, foot health, exercise and the use of Archie, to be completed either at the time of your attendance at the AMRG Lab or be taken home, completed, and returned by pre-paid post.*

*This study uses a variety of tests to measure and record information about your foot to determine the reliability or repeatability of measures using the new device called Archie. Then, the measures from Archie will be compared to other measures of foot strength or size to ascertain the validity of the device. Finally, the practicality of using the Archie for foot exercises with a computer screen will be evaluated by survey, to determine the feasibility of using the device.*

*The following physical measures will be completed during the course of this study*

- *The structure of the foot including shape, alignment and arch height will be measured*
- *The muscles under the sole and top of the foot with be examined with ultrasound to look at muscle thickness*
- *Strength of the big toe will be measured with a device where you will be required to press first your great toe then all your toes into a pressure plate*
- *Arch volume and change in pressure under the arch of the foot during lifting and relaxing the mid foot with the Archie device.*

**(4) How much of my time will the study take?**

Participation in the study will require you to attend the Cumberland Campus. The physical testing and surveys will take about 3.5 hours.

**(5) Who can take part in the study?**

Adults with or without foot problems can take part in this study. However, those with neuromuscular diseases that severely reduce muscle strength, any acute or severe chronic foot pathologies and deformities, a history of previous foot ulcers or recent (in previous three months) foot or ankle surgery, unable to walk more than 50 metres unaided, who have practiced prescribed foot exercise in the previous three months or being unable to understand the information sheet and consent form, are excluded.

**(6) Do I have to be in the study? Can I withdraw from the study once I've started?**

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney. If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by notifying any of the investigators, by telephone or email. If you decide to withdraw from the study, we will not collect any more information from you. Any information that we have already collected, however, will be kept in our study records and may be included in the study results.

**(7) Are there any risks or costs associated with being in the study?**

*While it is highly unlikely that being involved with this study may cause you any harm, including physical, psychological or social risks, you may experience some minor temporary physical discomfort related to exercising your foot muscles, such as a foot cramp. Please report any adverse events to the Investigator. While the risks of potential harm are low, they are equivalent to the regular risks in conducting normal daily life.*

*The costs associated with being in the study include: the time to travel and be tested and the inconvenience of attending the AMRG Lab for half a day.*

**(8) Are there any benefits associated with being in the study?**

There is no direct benefit to participating in this research. These preliminary studies are the first on the use of a foot biofeedback device. If the results of the study are positive and assist in the practice of the foot exercises with the Archie device, we intend to conduct further research with a population that may benefit such as people with moderate peripheral neuropathy.

**(9) What will happen to information about me that is collected during the study?**

This study will collect information about some of your physical health and your ability to do a series of foot movements. We may video or photograph your feet, however we will ensure that your identity will remain confidential as this information will be de-identified. The videos or photos may be used for analysis and to illustrate the foot exercises in journal articles.

Data collected will be entered into REDcap which is a secure program that the University of Sydney uses to store information. All personal information will be kept confidential. This study does not require the disclosure of personal life actions or experiences that might be considered outside normal legal activity. However in the unlikely event that any information disclosed would require mandatory reporting, or be subject to court orders or subpoenas, or related to any illegal activity, your privacy is revoked. Participants may have access to copies of their personal information.

Hardcopy data will be kept in a locked filing cabinet at the Arthritis and Musculoskeletal Research Group Lab facility, at the University of Sydney. The data collected in this project may be used for any other related future research projects. The data will be kept secure for 15 years; access will be limited to the researchers of this study, after which time it will be destroyed.

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

The results of the study will be published within a PhD student's thesis, as well as in relevant journal publications, or conference presentations, but you will not be individually identified in these publications.

We will keep the information we collect for this study, and we may use it in future projects. By providing your consent you are allowing us to use your information in future projects. We don't know at this stage what these other projects will involve. We will seek ethical approval before using the information in these future projects.

**(10) Can I tell other people about the study?**

Yes, you are welcome to tell other people about the study.

**(11) What if I would like further information about the study?**

When you have read this information, Penelope Latey, who will be available at the time of consent, will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to email Professor Joshua Burns, Dr Claire Hiller or Dr Jean Nightingale or Penelope Latey (Ph. 9351 9017).

**(12) Will I be told the results of the study?**

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a one page lay summary. You will receive this feedback after the study is finished.

**(13) What if I have a complaint or any concerns about the study?**

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney, project number 2016/881. As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- Fax: **+61 2 8627 8177 (Facsimile)**

**This information sheet is for you to keep**

THE UNIVERSITY OF SYDNEY

**Discipline of Physiotherapy**
**Faculty of Health Science**

ABN 15 211 513 464

**Professor Joshua Burns**

Room 0152
C43 – Cumberland Campus
The University of Sydney
NSW 2006 AUSTRALIA
Telephone: +61 2 9351 9017
Email:
plat6993@uni.sydney.edu.au
Web:
http://www.sydney.edu.au/

**Feasibility, reliability and validity of a biofeedback device ('Archie') to assess dynamic foot muscle strength**

**PARTICIPANT CONSENT FORM**

I,..... [PRINT NAME], agree to take part in this research study.

In giving my consent I state that:

8. I understand the purpose of the study, what I will be asked to do, and any risks/benefits involved.

9. I have read the Participant Information Statement and have been able to discuss my involvement in the study with the researchers if I wished to do so.

10. The researchers have answered any questions that I had about the study and I am happy with the answers.

11. I understand that being in this study is completely voluntary and I do not have to take part. My decision whether to be in the study will not affect my relationship with the researchers or anyone else at the University of Sydney now or in the future.

12. I understand that I can withdraw from the study at any time.

13. I understand that my questionnaire responses cannot be withdrawn once they are submitted, as they are anonymous and therefore the researchers will not be able to tell which one is mine.

14. I understand that personal information about me that is collected over the course of this project will be stored securely and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.

15. I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me.

I consent to:

- **Video-recording** YES ☐ NO ☐
- **Photographs** YES ☐ NO ☐
- **Being contacted about future studies** YES ☐ NO ☐
  - **Receiving feedback about my personal results** YES ☐ NO ☐

**Would you like to receive feedback about the overall results of this study?**

**YES** ☐ **NO** ☐

If you answered **YES**, please indicate your preferred form of feedback and address:

☐ Postal: _____

☐ Email: _____

SIGNED BY

_____
Print Name

_____ _____
Signature Date

_____
Print Name of Witness

_____ _____
Signature of Witness Date

# Device Brochure
## Archie Biofeedback Device

The Archie Device was initially developed during the completion of Penelope Latey's MSc (Research) at the University of Technology, Sydney 'The role of Pilates in the correction of dysfunctional feet and associated effects on postural stability in the older adults'.

### Rationale that led to the development of the device

Depending on age, foot problems with accompanying foot pain can effect up to 24% of the population. Furthermore foot pain can compromise functional movement leading to poor balance as well as increasing the risk of falls in older adults. Foot muscle weakness has been associated with various foot deformities, pathologies and with falls and impaired gait. Recent research has reported a significant increase in toe flexor strength post programs of specific foot exercises. However, maintaining face to face intervention options are limited by a high cost burden and poor retention rates of ongoing care. 'Archie' was developed to address the difficulty of maintaining correct foot exercise practice.

**Archie device**

Archie (patent pending #PCT/AU2016/050437) has three main components:

1) Support foot plate- is for the non-measuring no-interactive foot to be placed on to ensure balanced lower limb alignment.

2) Sensor foot plate with indwelling hardware- is for the active foot to be placed on to complete a series of foot movements or tasks that involve exercising different parts of the foot or toes.

3) Computer program and interactive screen with visual feedback- sends feedback from the sensor foot plate to the computer screen to provide information on different parts of the foot; heel great toe, little toe and arch movement.

Archie is a versatile biofeedback device and can be used to practice a range of foot movements or tasks, from individual toe movements, mid arch elevation and relax. Archie has the capacity to record and provide graphic, temporal and spatial feedback using a multiple sensor system.

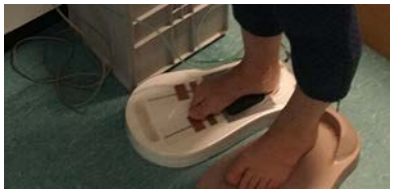
The foundation exercise tasks are:

Task 1: Reaction speed: The rate at which the participant can lift and relax the mid foot or arch repeatedly, over consistent range for 20 seconds, while maintaining contact with the great toe little toe and heel sensors

Task 2: Concentric motor control: The participant’s ability to smoothly and gently elevate the mid foot-arch in the sagittal plane while maintaining contact with the great toe little toe and heel sensors

Task 3: Eccentric motor control: The participant’s ability to smoothly and gently lower the mid foot–arch in the sagittal plane, after lifting the arch as high as possible, while maintaining contact with the great toe little toe and heel sensors

Task 4: Endurance: The participant’s ability to continually lift and hold up the mid foot–arch while maintaining contact with the great toe little toe and heel sensors

 **Standing on Archie foot plates**

The data generated by these tasks are recorded and stored on the devices hardware and computer program. The stored data can be analysed via excel and other statistical programs such as SPSS.

Initial proof of concept has been completed. However the devices ability to provide useful feedback and function robustly with repeated use with participants who have different body dimensions, foot types, those with mild to moderate foot pathologies or deformities, age and agility has yet to be determined.

Archie is built with a series of plastic laminates, 3-D printed components and both custom and premade valves and circuitry. Semi sealed with a removable cover for ease of cleaning, with no sharps, heat or direct electrical impulses for safe use with problem feet. It is a wireless battery operated device, with a recharging facility, with a fully downloadable computer program that functions with windows 7 or above.

Archie has been rebuilt with the assistance of the Professional Officer at U. Sydney, John Eisenhuth.

# Confidentiality Agreement

**CONFIDENTIALITY AGREEMENT**

**BETWEEN** **Penelope Jane Latey** of 23 Avon Street, Glebe, 2037, in the State of New South Wales, Australia

**AND** **UNIVERSITY OF SYDNEY**, Cumberland Campus, 75 East street, Lidcombe, 2141
In the state of New South Wales, Australia.

**AND** **MR/MS** _____ of ……(institution)

In …….. .(Address).

**BACKGROUND:**

A. The parties wish to have discussions in relation to the Project.

B. In the course of those discussions there will be disclosure of Confidential Information.

C. The Confidential Information has a unique value to the Discloser, and may be the basis of applications for patents.

D. The Discloser will be prejudiced by any unauthorised use or disclosure of the Confidential Information, may be precluded from being granted patents, and may suffer financial loss as a result of unauthorised disclosure or unauthorised use of the Confidential Information.

**THIS AGREEMENT PROVIDES**

**1. MEANINGS**

In this Agreement, the following words have the following meanings:

**Confidential Information** means information relating to the Project (whether disclosed in writing or orally) including inventions; discoveries; facts; data; ideas; manner, method or process of manufacture; method or principle of construction; chemical composition or formulation; techniques; products; prototypes; processes; names; know how; routines; specifications; drawings; trade secrets; technology methods; computer programs; works in respect to which copyright subsists; circuit board layouts; business plans; and other knowledge and includes any information developed or derived from the information disclosed

**Discloser** means a party to this Agreement which discloses Confidential Information to the other party

**Project** means the measuring and managing of intrinsic foot muscles at the University of Sydney by Penelope Latey in the Faculty of Health Sciences, including such technologies, methods and devices relating to this research.

**Purpose** means the Recipient evaluating the Confidential Information to enable the parties to explore a possible research collaboration relationship in relation to the Project.

**Recipient** means a party to this Agreement to whom Confidential Information is disclosed.

**2. DISCLOSURE**

2.1 The Discloser will disclose the Confidential Information to the Recipient as soon as practicable after the date of this Agreement.

2.2 The Recipient acknowledges that all of the Confidential Information disclosed to it by the Discloser shall at all times remain the absolute property of the Discloser.

**3. USE OF CONFIDENTIAL INFORMATION**

3.1 The Recipient must use the Confidential Information only for the Purpose, and must not use the Confidential Information for any other purpose.

3.2 The Recipient must not lodge any patent application or any other application for the statutory protection of the Confidential Information.

**4. EMPLOYEES AND DIRECTORS**

The Recipient may only disclose Confidential Information to a director, officer or employee who is bound by obligations of confidentiality to the Recipient at least to the extent imposed upon the Recipient by this Agreement and who has a need to know the Confidential Information for the Purpose.

**5. CONFIDENTIALITY**

5.1 Other than under clause 4, the Recipient must keep the Confidential Information secret and confidential and ensure that unauthorised persons do not have access to the Confidential Information.

5.2 The Recipient must not disclose to any person or make known in any manner any part of the Confidential Information.

**6. ENDING OF CONFIDENTIALITY**

The Recipient shall be relieved from the Recipient's obligations of confidentiality in this Agreement in respect to any part of the Confidential Information which:

(a) the Recipient can show was in the possession of as at the date of the disclosure; or

(b) the Recipient can show is or becomes part of the public domain otherwise than by a breach of this Agreement; or

(c) the Recipient can show was received in good faith from a person entitled to provide it to the Recipient; or

(d) the Recipient can show was independently developed by the Recipient's employees who did not have access to the Confidential Information.

**7. DISCLOSURE BY REASON OF LEGAL OBLIGATION**

(a) If the Recipient is required by law to make a disclosure of any part of the Confidential Information the Recipient must immediately notify the Discloser of that requirement and provide full particulars relating to the requirement to disclose, and its extent.

(b) The Recipient must postpone any disclosure required pursuant to paragraph (a) for as long as the Recipient is able to, without prejudicing the Recipient's own position.

(c) Unless the Discloser is able to secure some relief to the Recipient to any legal obligation to disclose the Confidential Information, the Recipient is relieved from its obligations in this Agreement, but only to the extent of the legal obligation to disclose, and not further.

**8. INFRINGEMENT OF CONFIDENTIALITY**

If the Recipient learns or believes that:

(a) any unauthorised person has come into possession of any part of the Confidential Information;

(b) any unauthorised person is doing anything in contravention of rights that attach to and arise from the Confidential Information,

the Recipient must immediately report full particulars to the Discloser, and must provide to the Discloser all reasonable assistance and information it may request with respect to that information.

**9. DURATION OF CONFIDENTIALITY**

The duration of the obligations in this Agreement is five years from the date of last signature of this Agreement.

**10. RETURN OF CONFIDENTIAL INFORMATION**

10.1 The Discloser may at any time by notice in writing to the Recipient require the return to it of the Confidential Information.

10.2 Within 14 days of receipt of such a notice or if the obligations in this Agreement cease, the Recipient must deliver to the Discloser all Confidential Information in its possession disclosed or provided by the Discloser together with all copies of all Confidential Information in its possession:

(a) provided by the Discloser; or

(b) which the Recipient has for any reason made.

10.3 Any part of the Confidential Information which cannot conveniently be returned by the Recipient to the Discloser shall be completely destroyed in such manner and at such time as directed by the Discloser, including by deletion from all computer records and electronic or magnetic storage devices.

**11. MISCELLANEOUS**

11.1 This Agreement is made and entered into in New South Wales.

11.2 No variation to this Agreement shall be binding upon the parties unless that variation is in writing, and is signed by all the parties to this Agreement.

11.3 Any waiver shall be an effective waiver only if the waiver is expressly set out in writing and signed by the party making the waiver.

SIGNATURES OF PARTIES

This Agreement shall be effective when signed by all parties, and its effective date is the latest of the dates set out below.

| | |
|---|---|
| SIGNED | SIGNED |
| BY | BY |
| _____ | _____ |
| Print Name | Print Name |
| _____ _____ | _____ _____ |
| Signature Date | Signature Date |
| _____ | _____ |
| Print Name of Witness | Print Name of Witness |
| _____ | _____ |
| Signature of Witness | Signature of Witness |

SIGNED on behalf of the University of Sydney

BY

_____

Print Name

_____ _____

Signature Date

_____

Print Name of Witness

_____

Signature of Witness

# Archie Device Assessment

**How to Assess Archie Data**

**Testing procedures**

There will be four different tasks tested including; speed, concentric motor control, eccentric motor control and endurance during the correct medial longitudinal arch lift, toe press task. Each test will have a specific grading for the quality of the task completed. Base line range will be determined for each participant by the participant completing a few fast practice elevations and lowers.

*1. Speed:*

The speed task is to be completed over a continuous period of 30 seconds. The repetitions of peaks during that time will be "smoothed out". The range of average peaks and troughs will be collected.

*2. Concentric Motor control:*

The lower and upper pressure will determine the line of best fit for the motor control task 2. An example of the ideal line of best fit for the concentric motor control task will be generated for use by the researcher to compare the participant's line of best fit to the ideal line of best fit. The researcher will score the quality of the participant's task on a likert scale.

*3. Eccentric Motor control:*

The upper and lower pressure will determine the line of best fit for the motor control task 3. An ideal line of best fit motor control, example will be generated for use by the researcher to compare and make qualitative judgments and for the participant to assist in guiding the correct motor control technique.

*4. Endurance:*

The endurance task is to be completed to a minimum of 90seconds with range within .5 volt change considered a fail.

The grading sheet is a combination of dichotomous data (correct start), numerical values (number of repetitions or time taken) and qualitative data (how close to the ideal wave or line of best fit did each participant attain) with the likert scales below.

**GRADE SHEET: ID No…….……Data No**

**……..….Date……..……**

**Task 1 speed**

| 0 | 1 | 2 | 3 | 4 | No reps: | comments |
|---|---|---|---|---|---|---|
| Maintains range high and low | Mostly maintains range | Maintains range 50% of the time | Mostly does not maintain range | Definitely does not maintain range | Starts on<br>Cue<br>Yes/No | |

**Task 2 Concentric motor control**

| 0 | 1 | 2 | 3 | 4 | No reps: | comments |
|---|---|---|---|---|---|---|
| Maintains angle of elevation | Mostly maintains angle | Maintains angle 50% of the time | Mostly does not maintain angle | Definitely does not maintain angle | Starts on<br>Cue<br>Yes/No | |

**Task 3 Eccentric motor control**

| 0 | 1 | 2 | 3 | 4 | No reps: | comments |
|---|---|---|---|---|---|---|
| Maintains angle of lowering | Mostly maintains angle | Maintains angle 50% of the time | Mostly does not maintain angle | Definitely does not maintain angle | Starts on<br>Cue<br>Yes/No | |

**Task 4 Static endurance**

| 0 | 1 | 2 | 3 | 4 | No mins | comments |
|---|---|---|---|---|---|---|
| Maintains start position | Mostly maintains position | Maintains position 50% of the time | Mostly does not maintain position | Definitely does not maintain position | Starts on<br>Cue<br>Yes/No | |

**The Archie GUI and Arch Analyser GUI are the programs that captures and processes the data from the pressure wave**

**Data collected by task**

*1. The speed task:*

Pick up and zoom in to data over a continuous period of 30 seconds.

Smooth out the repetitions of peaks during that time.

Record the range and frequency of average peaks and troughs.

*2. Concentric Motor control:*

Pick up and zoom in to data over a continuous period of 30 seconds.

Record the lower and upper pressure

Determine the line of best fit; record angle or degrees

*3. Eccentric Motor control:*

Pick up and zoom in to data over a continuous period of 30 seconds.

Record the upper and lower pressure

Determine the line of best fit; record angle or degrees

*4. The Endurance task:*

Pick up and zoom in to data over a continuous period of 130 seconds.

Record steady lower pressure

Determine the range from rest to elevation

Record time: this task is to be completed to a minimum of 90seconds, with range within .5 volt change considered a fail.

# Participant Characteristics and Data Collection Sheets

**Feasibility, reliability and validity of Archie Biofeedback device**

This survey is about your general health, characteristics and reporting or describing any foot problems, deformities or foot pain that you may have sustained over the last 3 months

Participant ID ……
Date……..

Date of birth..... M / F Weight.....
Height.....BMI.....

Highest level of education attained…….

General health:

Do you suffer from HBP, Diabetes, vascular disease, balance problems, Arthritis etc?

Past_____
_____

Current_____
_____

Medications:

Past_____
_____

Current_____
_____

Foot pain levels of intensity: on a scale of 0-10, if 0 is no pain and 10 the worst possible; mark the 10cm line below with the level of foot pain you experience.

I.....I.....I

0 1 2 3 4 5 6 7 8 9 10

Treatment: Massage Physical therapy Exercise

Other: _____

For the following questions: Circle only one

Visit a Podiatrist: Y/N Frequency_____

Wear Orthotics: Y/N What type: Rigid Semi-rigid Soft

How long have you worn orthotics:_____

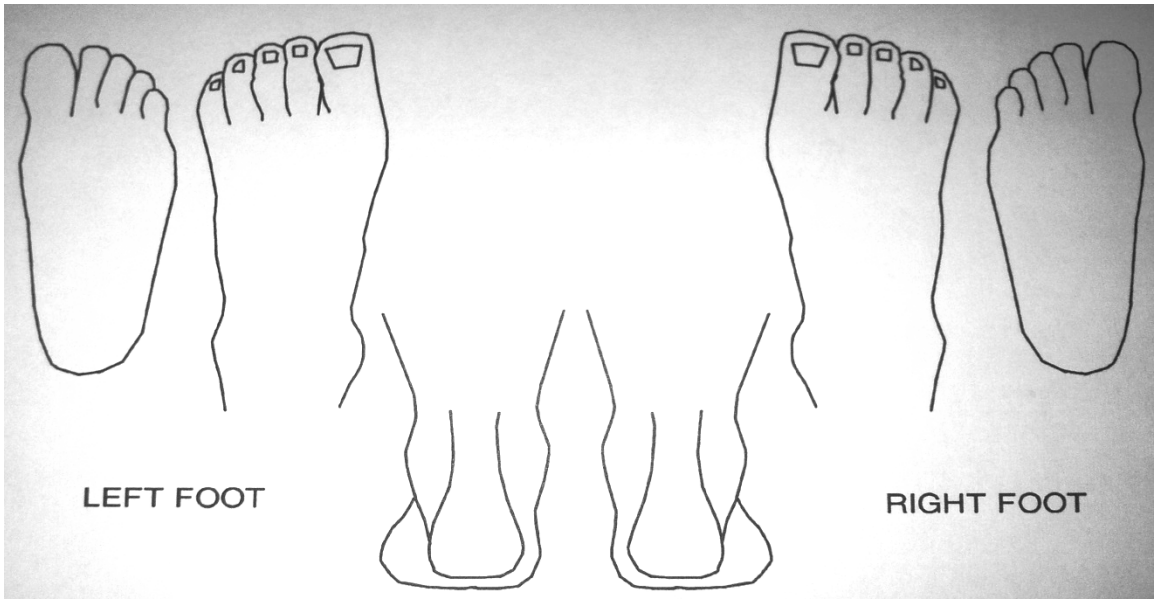
How often do you use your orthotics: Every day all day less than 2 hrs. P/day occasionally

_____

**Self-reported specific foot problems in the previous six months mark with x**

| | Y | N | Where |
|---|---|---|---|
| Any foot problem | | | |
| Corn or callus | | | |
| Nail problem | | | |
| Athletes foot | | | |
| Swollen feet | | | |
| Bunions | | | |
| Verrucae/plantar wart | | | |
| Injury or operation | | | |
| Sprain or strain | | | |
| Cut or other open wound | | | |
| Break | | | |
| Any operations | | | |
| Foot deformity | | | |
| Flat feet | | | |
| High-arched feet | | | |
| Any toe or foot deformity | | | |

Where: Great Toe, Lesser Toes, Ball of foot- MPJs, Forefoot, Mid/arch; inside arch – Medial Arch, outside arch – Lateral Arch, anterior heel, posterior heel



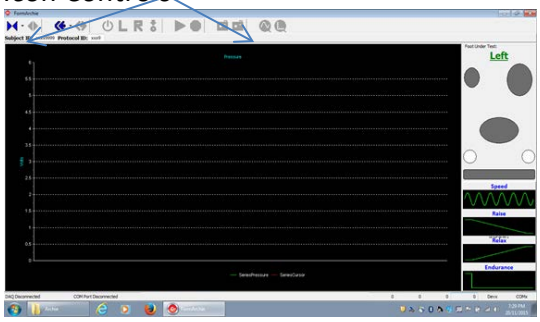

Garrow, A. P., Silman, A. J., & Macfarlane, G. J. (2004). The Cheshire Foot Pain and Disability Survey: a population survey assessing prevalence and associations. [Comparative Study]. *Pain, 110*(1-2), 378-384.

# Equipment procedures

## Archie set up

Archie device is made up of three components: Computer program and screen, passive foot support and a foot suppo*rt* with multiple foot sensors.

*Icon Controls*




**Instructions For Researcher**: *Configuration of machine*

1. Turn on computer, open Archie program with Archie icon, set arrows together on, drop down menu set COM6

2. Turn on Sensor foot plate, check that it is connected to the computer; LED light blue and the battery is charged; slow flashing LED light green.

3. Set R/L Foot:

Place active sensor footplate to the right and passive foot support to left at an appropriate angle to match participant's natural foot/lower leg alignment in the sagittal plane, to measure the right foot.

4. Check GT and LT placement on sensors, for both left and right feet.

To move toe sensors into the correct position remove plastic cover and adjust as needed, replace clear cover over sensor foot plate.

5. Check that all sensors work by asking participant to do a practice lift for each great toe, little toe and heel, separately.

6. Set test; speed, concentric control, eccentric control or endurance in drop down menu

7. Set green arrow: to on- red hexagonal to turn on pressure wave

8. Ask the participant to practice arch elevation and flatten to ensure range of arch pressure does not drop below the lower readable threshold. At the end of the practice run on the device

9. Set save; green camera - red camera glows; to stop saving set red camera

10. Set arch sensor ONLY when foot in place (Hex plus green arrow)

Type in Subject ID, set protocol ID set Archie on and test type

***Participants Positioning***

Ask the participant to start in sitting, with feet about hip width apart and mid foot aligned to patella in sagittal plane, with the knee flexed at approximately 90º. The dominant foot will be placed on the sensor footplate and the non-dominant foot on the support footplate.

To measure the left foot change the sensor foot plate and support foot plate to opposite sides.

Confirm toe sensors in correct place or reset foot positional sensors of the great and 5$^{th}$ toe sensors to measure the left foot.

# Participant Questionnaires and Surveys

Exercise history, Foot exercise tasks and tasks with Archie biofeedback computer screen

## Survey of participant exercise and physical activity history

**Participant ID**……
**Date**……..…….

**1. Have you had negative feelings or bad experience with sport, exercise or physical activity?** (Circle only one)

Never Seldom Sometimes Often Always

**2. Have you had positive feelings or good experience with sport, exercise or physical activity?** (Circle only one)

Never Seldom Sometimes Often Always

**3. During leisure do you prefer to move around?** (Circle only one)

Never Seldom Sometimes Often Always

**4. During leisure do you prefer to sit/recline?** (Circle only one)
Never Seldom Sometimes Often Always

**5. Do you start an exercise program but are unable to continue?** (Circle only one)

Never Seldom Sometimes Often Always

**6. How often do you participate in sport, exercise or physical activity?** (Circle only one)

Never Seldom Sometimes Often Always

**What type of sport, exercise or physical activity do you do regularly?**

**7.** Past_____ Times per week- Duration of Activity-

**8.** Present_____ Times per week- Duration of Activity-

# Foot Exercise Tasks Survey

This survey is about the foot exercise tasks that you have undertaken while using the Archie foot platform.

**Participant ID**……
**Date**……..……

1. **Were you satisfied with how the 4 foot movement tasks were explained?** (Circle only one) **Y/N**

2. **Please rank the following exercise tasks from easiest (1) to most difficult (4) or circle no difference (X)**
   ____ Speed
   ____ Arch lift up
   ____ Arch lower down
   ____ Endurance
   X no difference

For the following questions please place a cross (X) on the line at the point that best represents your opinion

5. **How would you rate your ability to do the speed exercise (Exercise Task 1)**

Negative I---------- I ----------I Positive

6. **How would you rate your ability to do the arch lift exercise (Exercise task 2)**

Negative I---------- I ----------I Positive

7. **How would you rate your ability to do the arch lower exercise (Exercise task 3)**

Negative I---------- I ----------I Positive

8. **How would you rate your ability to do the endurance exercise (Exercise task 4)**

Negative I---------- I ----------I Positive

9. **In general, how did the instructions affect your ability to complete the foot exercise tasks?**
(Circle only one)
   a) Help
   b) Hinder
   c) No effect

10. **Tell us what worked well and what needs improvement**

_____

_____

# Archie with Biofeedback Survey

This survey is about the foot exercise tasks that you have undertaken while using the Archie foot platform with the visual biofeedback from the computer screen

**Participant ID**……..

**Date**……..…….

**1. Were you satisfied with how the 'Archie' biofeedback device with computer screen enabled you to complete the tasks?**
(Circle only one) **Y/N**

**2. Please rank the following tasks from easiest (1) to most difficult (4) or circle no difference (X)**

____ Speed
____ Arch lift up
____ Arch lower down
____ Endurance
X no difference

For the following questions please place a cross (X) on the line at the point that best represents your opinion

**3. How would you rate your ability to do the speed task with Archie plus computer screen (task 1)**

Negative I----------i----------I Positive

**4. How would you rate your ability to do the arch lift task with Archie plus computer screen (task 2)**

Negative I----------i----------I Positive

**5. How would you rate your ability to do the arch lower task with Archie plus computer screen (task 3)**

Negative I----------i----------I Positive

**6. How would you rate your ability to do the endurance task with Archie plus computer screen (task 4)**

Negative I----------i----------I Positive

**7. In general, how did the use of Archie plus computer screen affect your ability to complete the foot exercise tasks?**
(Circle only one)

d) Help
e) Hinder
f) No effect

**8. Tell us what worked well and what needs improvement**

_____

_____

# Rating the different components of Archie

**9. What visual feedback from the computer screen was most important to you?**
Please rank the following from 1 (most important) to 5 (least important)

_____ Toe and heel position sensors
_____ List of exercise tasks with visual representation of each task
_____ Save and store buttons
_____ Up and down pressure wave of arch movement (Y axis)
_____ Position of line relative to full screen (X axis)

**10. What feedback on the position of the foot arch and toes was most important to you?**
Please rank the following from 1 (most important) to 5 (least important)
_____ Big toe
_____ Little toe
_____ Heel sensor
_____ Bladder under arch up and down pressure wave of arch movement (Y axis)
_____ High bladder pressure warning light

**How would you rate the following parts of Archie?**

**11. Using the foot platform with sensors, part of Archie for learning how to do the foot exercise tasks correctly** (circle only one)

a) Help
b) Hinder
c) No effect

Tell us what worked well and what needs improvement

_____

_____

**10. Using the computer screen, part of Archie for learning how to do the foot exercise tasks correctly** (circle only one)

a) Help
b) Hinder
c) No effect

Tell us what worked well and what needs improvement

_____

_____