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Design and Development of Alternative Vectorthotic Insole

Technical Report : Redesign Collaboration Healthy Step UK CVF Funded, 2017

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HEALTHY STEP (SENSOGRAPH) LIMITED, (registered number 3124863), with its registered address at Unit E209 Warmco Industry Park, Manchester Road, Mossley OL5

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1. Project Definition

1.1. Background

Healthy Step has a successful foot orthotics and rehabilitation range. The company currently one of the main sells to one main distributor and through them to the NHS. There is a growing area of business in the private market and internet (direct to the patient) sales.

There is a perceived opportunity to develop a new brand of devices based upon the existing range that:

- Exude quality and performance and would therefore carry a higher price point
- Are only available to clinics and clinicians allowing clinics to set their own prices and be unaffected by Healthy Step's direct to patient internet sales.
- Are not available direct to the patients.
- Focus on the business aspirations of the clinician and/or their practice.
- Allowing them to realise greater profit by "selling"/prescribing quality, branded, performance devices that deliver adaptable clinical treatments with a quality retail feel and offering.

1.2. Outline Project Development ideas

- a) <u>Creative review of the product</u>
 - Creative brainstorm and ideas for the range
 - Future underside of the shell redesigns possibilities
 - Any possible enhancements to the current design
 - Stage I
 - Creative possibilities for deliverable required for first deadline
 - Stage II
 - Creative possibilities for deliverable required for second deadline
 - Stage III
 - From understanding of the product range, market and key features develop any future (post CVF) design features that could be extracted from the current product
- b) Ideas for the Alleviate brand:
 - Colour ways
 - Stage I enhancements
 - Post CVF

- c) Enhancing the Vectorthotic range encompassing:
 - Revamped and branded range
 - Improved features & quality enhanced additions
 - Stage I (Appendix A)
 - diagnostic heel raise (possibility of differing materials)
 - 'click-in' forefoot additions
 - Stage II
 - Midfoot section that locates on top of the existing shell
 - Midfoot materials soft vs hard, dual density
 - Branded Product Packaging ideas
 - Clear see through box

• Cavity to allow exposure, visibility and 'touching' of the device.

This performance orthotic range aspires to be as effective as a functional foot orthotic (FFO). It is adaptable and customisable to meet the needs of the busy clinical environment as an off the shelf solution. The Vectorthotic device is a very successful polyprop device which adaptions can be clipped into.

- d) Support for the new brand website animation
 - 30-60 second animation
 - High impact
 - Stage I primary care conference: target audience is a wide range of public healthcare sectors
 - Stage II COPA conference encompassing elite sports: target audience are physics, chiro, osteopaths and any connections to elite sports like sports therapists.
 - Suggestions:
 - 3D 360 degree views of product demonstrating interchangable heel wedges, bidirectional (varus and valgus, medial and lateral) forefoot wedges
 - o Introducing key enhancements
 - Unique shock absorbing top cover highlighting the retail quality design
 at this stage its multi-functional i.e. For all activities
 - Diagnostic heel raise breaks out to show 'click-in' graduations to enable differing raise graduations
 - o Demonstrate heel device re-pitching with application of heat
 - Highlight that plastic heel raises do not compress over time

Deliverables

- Modification to the existing forefoot pieces (2° and 4° variants) in 3D package to allow them to locate into the underside of the shell.
- 3D printed prototypes to display at conference (Colour TBC) in size C.
- Creation of diagnostic heel raise addition to the range as per rough diagram Angled 'top'part' needs to click in using existing cavities in the underside of the shell.
- 3D printed prototypes in (2°, 4° & 6° variants) to display at conference (Colour TBC) in size C.
- New part to be created to form the basis of any ongoing partnership. This will be an additional arch profile, contoured to rest on top of the existing device shell (specifications to be agreed and worked upon as part of the project). New part to be created in 3D CAD packages enabling a midfoot part to locate on top of the existing shell
- 3D printed (Polyprop and Compressive material such as urethane) prototypes to use for further product development ideas, inspiration and focus groups (Colour TBC) in size C.

• Enhancements

2. Research and Literature Review:

2.1 Bi-directional Forefoot Wedges

Need to be bi-directional, but may need more than just the central peg. We would also suggest to any wearer that their podiatrist use some superglue when they are satisfied and no further



2.2 Heel raise

- Multi-height
- Clickable
- Angled 'top'part' needs to click in using existing cavities in the underside of the shell.



Figure 2. Heel Uplift Design

There are two ways to create a heel lift. The above is common, but it has the net effect of declining the calcaneal bone on the sagittal (Side) plane. This actually pronates the foot by causing declination of the talus (and subsequent elevation at the talonavcular joint) which sits upon the calcaneus.



Figure 3. Heel Height adjustment

It has been the norm for devices and manufacturers to supply raises in wedge form and we want to be different.

2.3 Midfoot part

Understanding of foot mechanics and motion is generally poorly understood and belief systems have evolved. A clinician is taught and should consider all of these.

One should consider paradigms as different ways of looking at the same problem or part thereof.

The general acceptance is that at heel strike the foot pronates remains stable in midstance and then supinates through propulsion



Figure 4. Typical line of pressure progression (barefoot)

2.4 Podiatric Paradigms

This work is based on the seminal papers by those authors providing alternative podiatric models to those proposed by Root et al in the 1970's. The most recent paper obtained was the comprehensive article by Eric Lee appraising the historical root model of podiatric biomechanics which brought the theory to the present day by considering the paradigm shift first suggested by Payne in 1998.

2.5 The Root model

Since the publication of Normal and abnormal function of the foot in 1977, 'Rootian' biomechanics has been widely taught in podiatric colleges across the world, but before this work emerged there was no uniform or widely accepted podiatric theory of foot biomechanics to guide therapy (Payne 1998) and indeed Root suggested that to understand foot function fully, an intimate knowledge of foot morphology was necessary (Lee 2001). Lee reports that the desire to understand and classify structural variations of the feet motivated Root to focus on what were considered pt be the major functional joints of the foot and it was while taking a shower one day that root realised that variances of the rearfoot (calcaneal inversion/eversion) might alter the position at which the Subtalar joint is neither pronated nor supinated (Lee 2001). This idea was developed into the concept of the subtalar joint neutral position.

The Root paradigm meant is synonomous with STJ neutral and Root's determinance of the joint being triplanar. Aligned with the interest of STJ function was the morphological importance Root applied to defining 'normal' so as to then be able to define abnormal.

Much like any theory or hypothesis, much of what Root conceptualised was based on observation and common sense. When it comes to functional anatomy root developed open and closed chain examination protocols to back up his theory and also the thinking of normal and abnormal compensation occurring for varying morphological situations. It could be suggested that Root integrated some philosophy into his concepts to bridge the gap between the art of the consistent observations he was making, and forming those into a science which led Payne to identifying the problems with traditional theory.

The Root model gave the podiatry profession a framework within which old data could be examined afresh and new data sought. This framework provided a forum for future practitioners to further the understanding of the function of the foot. As Lee stated a paradigm shift had occurred in podiatric medicine away from previous work based on classic orthopaedics put forward by Schuster in 1927 (Lee 2001).

2.6 The Saggital Plane Facilitation Of Motion Model

This model is based on the work of Dr Howard Dananberg. He found patients with defining clinical signs of pedal pronation also displayed compensation strategies that inverted the foot away from asymptomatic normal range of motion first mtp joints. From this the functional saggital plane blockade *of* hallux dorsiflexion was hypothesised (Lee 2001). Dananberg

made his findings in the early eighties using the electrodynogram which in terms of modern day equipment equated to a force platform or in-shoe pressure measurement system. The saggital plane theory built on the work of Bojsen-Moller who identified that push-off can be performed about one of two axes, High gear and low gear. High gear being the more desirable position for effective propulsion because the calcaneocuboid joint is in it's close packed position and stable and there is more effective tightening of the plantar fascia facilitating the windlass effect described by hicks and the wedge and truss model also developed by Hick's. These three autosupportive (Dananberg 1993, Lee 2001) mechanisms formed the base of Dananberg's work (1986, 1993, 1996, and 2000).

Dananberg's work can be more easily understood if one considers the three rockers of the lower limb as described by Perry (1992); The heel rocker, ankle rocker and forefoot rocker.





These rockers can be clearly visualised on the vertical element of a force time graph. Generally this sinusoidal fashion perpetuating movement which is disturbed when it comes up against functional hallux limitus and the efficient forward movement of the COM is disrupted causing compensations to occur which affect the progression of the centre of mass over the passive supporting limb (Dananberg 1993). In his papers (1986, 1993, 1996, and 2000), Dananberg describes autosupportive mechanisms and the two elements that make up functional hallux limitus: Focal and global.

Focal is the failure of the first metatarsophalangeal joint to dorsiflex during the single limb support phase of gait regardless of the available range of motion present during the non-weightbearing exam. Global is a momentary halt at the metatarsophalangeal pivotal point for forward motion preventing effective movement of the body from behind to ahead of the planted weightbearing foot. This action occurs during the period of greatest power input designed for forward motion (Dananberg 1993)

2.7 The Kirby Model

Dr Kevin Kirby modified a technique shown to him by Dr John Weed to assess how much pronation control a patient required on an orthoses to find points across the planar foot where pressure in a dorsal direction produced no pronation or stipulation to create a straight line. He corresponded these points of no rotation to the transverse plane spatial position of the subtalar axis. Kirby's drive came from the question of when extra pronation control features would be used in an orthosis. (Lee 2001)

Kirby realised that ground reaction force (GRF) lateral to this transverse axis would cause pronation of the subtalar joint while medial pressure inversion. Patients with a medially deviated subtalar axis would have a greater area lateral to the axis and therefore ground reaction forces would produce a greater pronation moment.

He gradually realized that the plantar representation of the subtalar joint axis explained all the numerous clinical observations that were not adequately explained by the established Root model (Lee2001).

These were described by Lee (2001) and I refer the reader to the work of Lee for a detailed, in depth review of these observations. The results of Kirby's model lead him to question certain Rootian dogma and introduce the Kirby skive. Kirby's work served as the foundation for the work of Fuller who also considered foot function in the transverse plane.

2.8 The Fuller model

Fuller considered Kirby's theory of SARLE (Subtalar joint Axis Rotational Equilibrium) and applied it to the relationship to the location of the foot's centre of pressure pathway. Fuller's theory as well as that of Kirby relies on the theories of moments acting about ma rotational axis. Lee lays out a summary of the concept of fuller in his review of 2001. The approximate spatial position of the subtalar joint axis was ascertained using the methods described by Kirby and using an in-shoe pressure measurement system (EMED, but he could have used FScan or RS Scan) the path of the COP was determined.

Fuller suggested that after finding the COP and spatial location of the STJ, moments could be calculated. However even without calculating the moments involved Fuller proposed three pedal categories and within each of the foot types he considered potential anatomical sites that would resist external pronation moments, or generate and internal equal and opposite supination moment:

- COP Lateral to the STJ axis this indicates GRF's lateral to the axis thus creating a pronation moment which supinatory structures have to resist.
- COP beneath the STJ axis A balanced foot. No internal supination moment is required to counteract GRF's.
- COP medial to the STJ axis an indication that GRF's are medial to the axis creating a supination moment which anti-pronatory structures have to resist.

Thus, in Fuller's model the problem of mechanically induced pedal pain and pathology is approached by suggesting excessive pronation per se is not necessarily the cause of the patient's pain; rather, the pain is caused by the stress on the anatomical structure that is thought to limit excessive pronation (Lee 2001). In a personal communication with Lee in 1998, Fuller said "to reduce the patient's pain, the attending practitioner must either reduce the stress or transfer the stress to some other structure."

Although the personal communication with Lee was in 1998, Fuller's work was not published until 1999. A full year before though McPoil and Cornwall concluded that the COP pattern was not an effective tool for the assessment of the effectiveness of foot orthoses and suggested that its unreliability led it to be of little use in assessing the effectiveness of foot orthoses or to describe foot movement during walking.

Chronologically, one wonders which came first the Fuller model or the Tissue Stress model. The Tissue Stress Model was proposed by McPoil and Hunt in 1995 and yet in personal communication to Eric Lee (1998 cited in Lee 2001) Fuller eluded to stress reduction or the transfer of stress to other structures.

The goal of these authors was to reduce tissue stress to levels which are tolerable on the active individual (Lee 2001), and in defining this goal they identified three problems in the Root model.

- The reliability of measurement procedures
- The position of subtalar joint neutral
- Criteria for normal foot alignment.

After considering these problems the authors proposed a new model whereby keeping a structure below the 'microfailure' region, thus keeping tissue stress at a tolerable level preventing any overuse injury (McPoil and Hunt 1995). Payne (1998) summarised the examination and management process for this model:

Based on the finding, the examiner determines whether the patient's complaint is caused by excessive mechanical loading (Lee 2001). Payne (1998) described their approach as a useful starting point in developing optimal intervention strategies (below).

2.9 Gait Analysis



Figure 6. Gait Analysis

A standard human gait is classically described to start at heel strike of one foot and end at toe off of the other limb with two phases involved, stance and swing. After spending a lot of time reading books included in the reading list such as Watkins (1999) and Whiting & Zernike (1998).

Perry (1992) argues the approaches for evaluation of the gait cycle which after reading opened my eyes to a whole new way of describing what my patients are doing and most importantly when. Perry (1992) presents a table for the breakdown of the gait cycle which in the origins and principles session was agreed to be the most complete description of the evaluation of the gait cycle.

3. Project Development:

3.1 Problem

Healthystep required a redesign of some of their existing product the *Vectorthotic* a multipiece product which aims to solve imperfect arch formations of the foot and a quasi-finished untested idea to solve fallen arches.

Healthystep provided CAD data for the existing products. This was imperfect and needed modifications from the start. Patent searches were carried, but have not been detailed in this report. Various 3D CAD packages were used. Rough test models were tested by the team and feedback was sought from the company in briefings and meeting. Test models were created using the 3D printers available including *Ultimaker, Big Builder, 3D systems Multimaterial* ProJet MJP 5500X *Printing* 3D printer. The final models were made using the company imaterialise.

3.2 Initial Requirements

Healthystep required modifications to snap fit modules that form part of their existing multipiece orthotic – Vectorthotic.



Figure 7. Current Vectorothic (Authors Own, 2016)

The vectorthotic enables the heel, ball and midsection of the foot to be supported, allowing for say 2,4 or 6 degree height increment to be applied for comfort. Fig 7 shows the soft

overlay, the polymer base, heel tilt and front tilt additive. Healthy Step required modifications to the snap fit elements of the Vectorthotic. The existing hard polymer base was to be kept the same to keep manufacturing tooling cost to a minimum, however the heel tilt ad the forefoot tilt pieces had to be redesigned to improve the product. An existing three part product for fixing to the Vectorthotic insole was modified for improvement. The previous method of securing the forefront part to the base was to glue it down, a click fit system would need to be designed to replace this. After the piece was fitted it created a lip at the front of the product that created a step in the base, this needed to be dealt with. The heel needed to have a raising piece as well as a tilt feature, it would be no more than 6mm but must offer 1 or 2 mm increments to achieve this. The Narrow nature of the current heel meant that soles of shoes were dug into, and the full heel could not be used to support the insole, therefore the heel had to be wider and better fitting into shoes/trainers. The middle feature, on top of the base but underneath the soft cover, an arch raising piece would need to be designed and added so the customer could have the option of supporting the arch of the foot.

An animation showing the component parts, an exploded view to demonstrate to clients at trade fairs, conferences and on the web was also required.

3.3 Company

Healthy step is a company that produces products for the National Health Service and private practitioners and the public. With twenty years experience in the field of functional foot orthosis: Their 'primary driving force was our recognition of the practitioners need to be able to prescribe their patients with a tailored, functional, high quality foot orthoses, right there in the clinic' (HealthyStep. 2016).

3.4 Foot Conditions

Conditions such as Pes Planus, commonly known as flat feet, or Achilles tendonitis are debilitating conditions *(HealthyStep. 2016).* If flat footed, a low arch needs great bracing. High arches known as pes cavus can result in greater force being exerted on the ball or heel of the foo (painfreefeet,2016). These conditions may be inherited or caused through injury or age (webmd. 2016). Women who are pregnant may need extra plantar support *(Noo.2010).*

3.5 Orthotics

Orthotics are products that aim to give greater support and comfort to people who have problems with their feet, as outlined above Older people are more likely to need orthotics, as are bariatric adults (footvitals. 2016).

3.6 Existing Competitor Products

Existing orthotics range from brakes to insoles. The following insole typologies gave an insight in to the competitor products in function and style.



Figure 8. Vasyli Easyfit 6° Custom Orthotics (physique. 2015)





These orthotics have been designed for use in 'hard-to-fit footwear' (physique. 2015). They consist of 'Dual density orthotic with a softer overlay to allow for the "normal" amount of pronation, while preventing over or excess pronation with a higher density orthotic shell'. This reduces pain and can be used to help with problems such as 'over pronation such as anterior knee pain, plantar fasciitis, lower leg and foot arch pain' (physique. 2015).



Fig 10 a.: Elevate Orthotics Insole Kit (Ebay. N.d.) b.Dr Foot (Dr Foot,2010)

Similar in part to Healthystep's Vectorthotic in that it consists of multiple parts to allow for a tailored fit. Once in place, these are less easy to pull apart or modifiy (talamade,2016). imilar to Vectorthotic, the Dr Foot orthotic incorporates a multiplec system, allowing for a range of heights to be achieved across the plane of the foot and for modifications to be made after setting (DrFoot, 2010).



3.7 Development of Middle Piece : First Iteration

Fig 11: Initial design (Authors Own, 2016)

The initial design had three contact points, the rear pins, the middle rectangle and the corner grips. Each iteration was tested by printing and gripping into the insole.

The shape was changed to fit the front better. The corner grips were removed as it seemed they pushed the piece away from the insole instead of gripping it. The rear pin grips were also better shaped to fit the hole better.



Fig 12 a, b. Development (Authors Own, 2016)

The front was changed to fit around the edge better and more grips were added because it required more friction. The rear pin grips were also rounded on the edge to make it stronger.



Fig 13 a, b. Development (Authors Own, 2016)

The ends were extended to match the edge of the insole piece, primarily for visual benefit. The rear of the piece thinned out at the end so it didn't affect the height of the insole



Fig 14: Side view.

The height was reduced by making the piece as thin as possible.



Fig 15 a, b. Development

Fillets were put on the end pieces to make it again, more visually appealing eradicating the sharp edges. The additional grips were removed because they weren't needed, and if anything it hindered the grip of the forefoot piece. The CAD model was completely redesigned at this point as the surface modelling was over complicated ruined the detail of the edge.



Fig 16 Development

The middle piece was then angled backwards to fit the backward loft of the insole hole. This allowed for a tighter fit. The front edge was modified to match the requirements of Healthystep. It needed to be long enough to match the front edge of the insole and thin enough for it not to affect the height of the insole.

3.8 Development of Middle Piece : Iteration Heel Tilt

Quick sketch printed models were created to understand how the heel pieces stacked and fit together. This was also an opportunity to see the potential for thinner components. The aim was to stack the heel pieces with a tilt built in- shape development was key for this.



Fig 17: Heal Tilt shape iteration

Further CAD development of the heel pieces meant they fit to better together and rounded the base pieces better. As seen below, the tilt piece fit much better to added stackable pieces.

Fig 18 : Heel stacking test (Authors Own, 2016)

Fig 19 : Middle Piece Iterations

Fig 20:Middle Piece Iterations

Fig 20 : Middle Piece Iteration (Authors Own, 2016)

Fig 21: Middle Piece Iteration (Authors Own, 2016)

Fig 22: Middle Piece Iteration

Iterations: Arch Support: The Arch of the foot needed extra support and after seeing current products that do this a piece needed to be designed to achieve this. Alias modelling was used to create the curved feature as seen below:

Fig 23: Arch Support iterations

Fig 24: Arch Support iteration

The final design: was developed through numerous printing and matching It up with the top surface, and eventually the optimal shape was achieved.

4. Results

Three new attachments were created to fit with the existing polymer base. a 2 degree heal piece that can clip onto the orthotics with the ability to have a 1mm to 6mm raise attached to it, a mid- foot piece that could be glued to the surface of the vector and a front foot piece that gave a 2 degree raise with a lip but the final product did not clip fully into place. The final iterations were printed using a FDM printer and the final designs were printed using laser sintering, this compromised accuracy.

Healthystep gave feedback on the final product:

'These all look good. The midfoot fits really well. The heel raise and 2/1 extra pieces are a good fit and look incredible. The forefoot piece, now that Is printed in the PA look really smart. The only issue is that the forefoot part doesn't stay fast, in falls out'

Fig 25: Orange vector with 3D printed front, mid and heal pieces (Parker, 2016)

Fig 26: Person stood on vector orthotic with heal and mid foot piece attached (Parker, 2016)

Fig 27: White heal piece with the 2mm and 1mm (Parker, 2016)

Fig 28: Orange vector with 3D printed front, mid and heal pieces side View (Parker, 2016)

Fig: 29 Yellow vector underside with heal piece and forefront piece (Parker, 2016)

Fig 30: Yellow vector side view with heal piece and forefront piece (Parker, 2016)

Fig 31: Yellow vector side view with heal piece and forefront piece (Parker, 2016)

Potential Future Considerations

Fig 32: Future considerations

If there was a possibility to change the base tooling a completely new clip feature could be designed with potential to improve performance as outlined above.

Heel, ball and arch orthotic components of the existing vectorthotic were improved during the course of this project. Completion was a great live experience for the team although some issue with 3D modelling and printing tolerances as it had an impact on the first phase of iterations. This inaccuracy had a bearing on the printing of the snap fit parts of the orthotic but with product testing and feedback from the client these were overcome. Budget restrictions had an impact on the type of printing available for iterations, which partly compromised the outcome with regards to fit.

Company recently invested in a new mid range 3D printing machine to be used for mass customised product development and employed a Product Design placement student to further develop service they offer.

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Appendices:

The company, Students and staff signed Assignment of IP? Do we need here? So we could use in the future from here?

ASSIGNMENT OF IP RIGHTS

THIS ASSIGNMENT is made between:

HEALTHY STEP (SENSOGRAPH) LIMITED, (registered number 3124863), with its registered address at Unit E209 Warmco Industry Park, Manchester Road, Mossley OL5 9AY (**we, us**); and

YOU: []

YOUR ADDRESS: []

BACKGROUND:

- (A) We have engaged you to prepare and produce on our behalf the work, which is described below.
- (B) The Works are to be created by you or the various persons named in the Schedule ("the Authors") who were employed by you and in the course of their employment to be the authors of the Works.
- (C) You have agreed to assign to us all such intellectual property rights including copyrights and rights in the nature of copyright as you may in the future own in the Works.

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The **Works:** [A brief description of the Works]

The Authors: [Insert names of people that created the Works]

Date: []

We agree to the terms of this Assignment including the Operative Provisions attached.

SIGNED by []
for and on behalf of
Healthy Step (Sensograph) Limited

SIGNED by [insert name]	
for and on behalf of	
[INSERT NAME]	

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- 2 You hereby represent and warrant to us that:-
 - 2.1 save as may be specifically disclosed to us pursuant to clause 2.4 and agreed to and accepted by us the Works will be original works that have not been copied identically or substantially in whole or in part from any other work or material which is the subject of any intellectual property rights owned by any third party and that the exercise by us of the rights assigned to us will not infringe the rights of any third party;
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