Monitoring the suitability of the fit of a lower-limb prosthetic socket using an artificial neural network in commonly encountered walking conditions

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Abstract

Prosthetic sockets are still routinely designed without the aid of quantitative measurement, relying instead on the experience and skill of clinicians. Sockets remain the most common cause for complaint regarding the suitability of a prosthesis, and poor pressure distribution is implicated in many forms of unacceptable care outcomes.

Monitoring pressure distribution has been effectively restricted to laboratory settings, and only limited work has examined conditions other than flat walking. In this work, a transtibial amputee completed static and dynamic tasks on flat ground, on slopes and with changes to prosthetic materials and alignment. This was achieved using a set of wireless measurement nodes and custom LabView and MATLAB code, using external strain measurements and a neural network to understand the internal pressure distribution.

Future work will focus on modifying the software to be more user-friendly for a clinical operator, and in simplifying the required hardware. Although the system in its current form facilitated the desired measurements effectively, it required engineering support to function accurately. Improving the reliability and stability of the system will be necessary before routine use is possible.

1. Introduction

Lower-limb amputees represent a significant population requiring long term provision of assistive technology for cosmetic, postural and functional purposes[1]. In such devices, the prosthetic socket is a key component – the interface between the residual limb and the device, it is responsible for the successful application of the forces generated from standing and walking onto the tissues of the stump. Sockets are designed and constructed on an individual basis in order to account for the particular qualities of the residuum, the requirements of the limb suspension method, the preferences of the user and the clinician and the specifics of the design intent of the prosthetist [2][3]. As such, sockets are produced on an artisanal basis, with only general design considerations grounded in biomechanical theory [4].

Empirical measurement of design of prosthetic sockets has a limited and often contradictory history [5]. Limb-Socket interface pressure distribution has been examined with various means in the past 60 years. This measure has been of particular interest as pressure is linked to inappropriate socket fit, and in turn poor fit is related to discomfort, pain, poor function, tissue injury and deleterious skin conditions [6]. A new mechanism of measurement using artificial neural networks has many advantages over existing methods [7], with the potential for extended monitoring of the interface in situations outside the laboratory. In this article, the methods for obtaining measurements from conditions other than flat walking are discussed.

2. Measurement Methods

2.1 Artificial Neural Network Pressure Estimation

The technique of using an artificial neural network has been explained in detail elsewhere (e.g. Sewell et al. [8]) - only a brief description of the method and the specifics of this implementation are included here.

The technique relys on training an artificial neural network (ANN) to associate the deformation of the socket wall (measured using strain gauges) with the internal pressure distribution creating that deformation. In the later measurement case, an estimate of the pressure distribution (the desired clinical assessment) can be made using the external strains only. Such an approach has various advantages over existing methods. It can measure any position on the socket surface, and does not damage the socket (unlike through socket transducers [9]). There is no interference with the interface (as in array measurements [10]) and it is not affected by changes to the device liner configuration or walking conditions (which limits the use of FEA modelling[11]). For these reasons, the ANN method is attractive.

To overcome the issue of producing sufficient training cases for the network to successfully converge on a solution, two assumptions are made concerning the system. Firstly, that strains vary linearly with applied force. This is thought to be reasonable for the anticipated range of applied forces, and the materials in use (Northplex, North Sea Plastics Ltd., Strathclyde, UK). The assumption means that two measurements (an unloaded state and one applied load) can be used to the effect of any magnitude load in that position. Secondly, linear superposition is used to combine the effects of loading in different positions. By creating a seed file containing the effects on the external strain sensors from loads in each position of interest, by scaling and summing the effects in random combinations, a training file that covers the entire spectrum of potential load distributions. Care must be taken that the chosen locations broadly cover the areas of applied load: failure to do this will mean that other experimental loads will create additional deformation of the socket that will be unaccounted for in the training process. 1000 superposition training cases were generated. Figure 1 shows the loading rig and socket in use: the central metal arm is brought into contact with the socket wall in positions of interest via a set of springs. This applies a consistent, constant force to the defined load position.

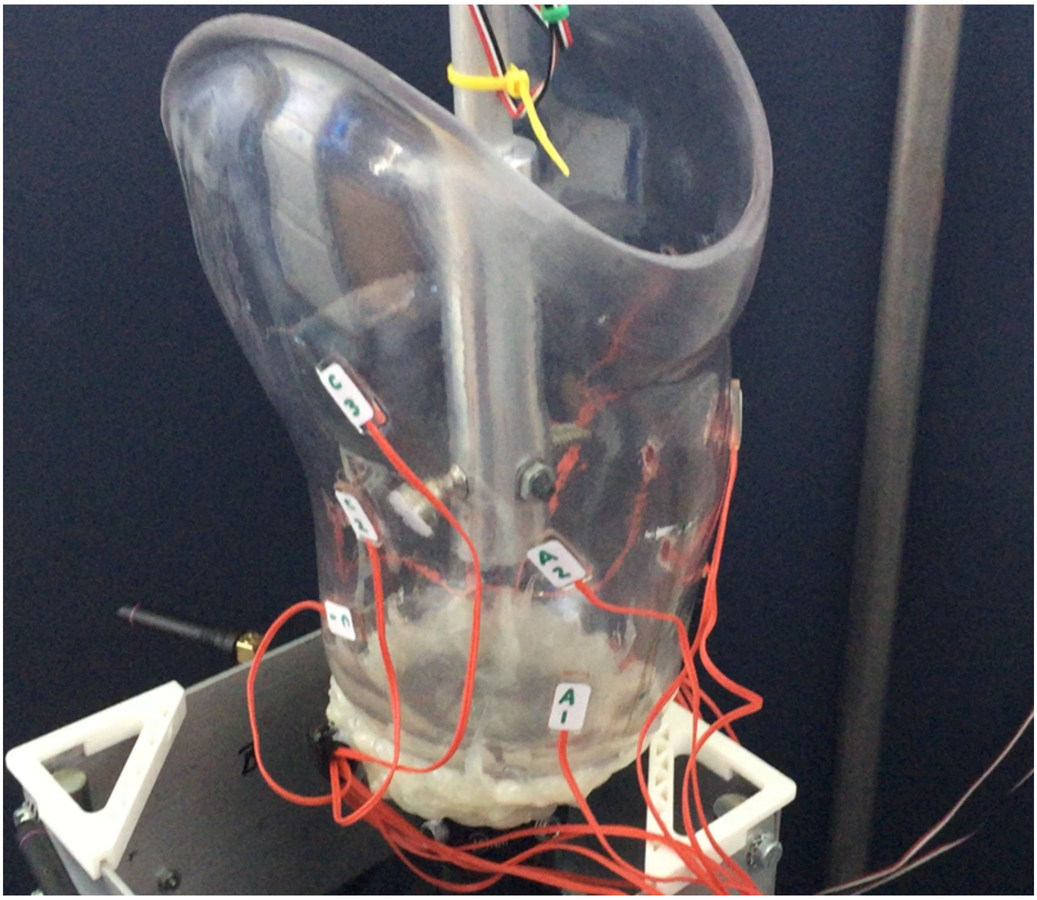

Figure 1. The transtibial prosthetic socket, intrumented with 12 strain gauges connected to the wireless collection rig.

Improvements to generalisation performance of the network can be made by including noise injection on the training data [12]. In this application, prior work has established that modifying each input strain by up to ±5% of the value (magnitude and direction randomly assigned for each value) can improve the overall accuracy of the response on the test data [13]. This was applied to the complete test file. To overcome poor performance in occasions where one load position dominated, the superposition cases were supplemented with so-called 'isolated' loads – cases where only one position was loaded and the remainder set to zero. 50 such cases of random magnitude between zero and the applied load were produced for each test position.

Prior work has also demonstrated that individual networks may train successfully but remain poorly performing on real-life cases [14]. For this reason, an ensemble of 100 networks trained using an identical process (differing only in the initial random weights and biases and in the order of application of training cases) was produced. The mean of each pressure estimate was used in order to counteract the random error between individual network estimates [15].

Networks were constructed using an 11-16-8 node architechture, with a poslin-tansig configuration of transfer functions in a feedforward backpropagation arrangement. Training was conducted using the Levenburg-Marquant training algorithm[15]. Inputs were the 11 strain gauge voltages (a 12th gauge was collected and left unloaded to act as a dummy gauge for temperature compensation), and 8 outputs represented the 8 measurement positions investigated (two levels of four positions in the cardinal direction).

Strain gauges (WFLA-2-350-11-1L, Tokyo Sokki Kenkyujo Co Ltd, Tokyo, Japan) were fixed to the external surface of the socket in distributed positions and orientations. Loading was carried out using an instrumented spring loaded arm. Gauges were placed in a quarter-bridge configuration, and collected at 16Hz using three VLink (Lord Microstrain, Williston VT, USA) collection nodes, and transmitted wirelessly to the host PC. Data were collected and processed using LabView (National Instruments, Austin TX, USA). Neural networks were produced using MATLAB (Mathworks, Natick MA, USA).

2.2 Participant Details

The participant recruited for testing was an experienced transtibial amputee who completed informed consent for his participation. Full details are included in table 1.

Table 1. Participant Details

Participant Details	Description
Age	54
Gender	Male
Amputation Reason	Trauma
Time Since Amputation	24 years
Residuum Description	Short, bony
Prosthesis Description	Total Surface Bearing socket, with vacuum suspension and a 'Silcare' liner. Echelon foot/ankle.

2.3 Test Description

The measurement nodes were fitted to a set of hinged aluminium plates, which were clamped to the prosthesis pylon such that the system was contained below and around the prosthesis. There were no issues with maintaining suspension.

The participant was given time to acclimatise to wearing the device (which was mounted on a socket based on a recent cast of the residuum, and produced by a registered prosthetist).

The participant completed some static standing tests with their prosthetic foot in contact with a force platform (Kistler, Winterthur, Switzerland). They were asked to apply around 25%/50%/75% of their weight through the amputated side, with forces and strains measured for approximately 5 seconds.

Dynamic measures were made with the participant walking though the laboratory space at a comfortable self-selected speed. Recordings were made of c.8 seconds, corresponding to around 5 separate gait cycles. Subsequently, the participant was asked to walk up and down a slope of 5°, again at a self-selected pace.

2.4 Ethical Approval

The study was approved by the Bournemouth University Ethics Committee (Reference 12229). The participant gave informed consent for participation in the study.

3. Results

This report is focussed on the methods used to generate the results, rather than the outcome and interpretation of measurement.

Wearing the test socket and measurement equipment did not seem to have an impact on the participants movement. There was no issue with loss of suspension of the prosthesis in any part of the study, and although the additional mass was reported as 'noticable' by the participant, neither he nor the prosthetist felt that the walking pattern used was adversely affected. The device did not impede the movement of the other limb, or change the positioning on the prosthetic side.

Use of the system facilitated collection of data at 16Hz in each measurement condition. The participant was able to complete walking on the flat ground and up and down 5° slopes without issue or requiring other assistive devices.

Following the tests, the participant reported that the socket was equivalent in comfort and fit to their customary device. They expressed a slight preference for the alternative liner used during testing. Example pressure readings from a single stance phase are shown for flat walking and slope walking both up and down hill (Figure 2a-2c) .

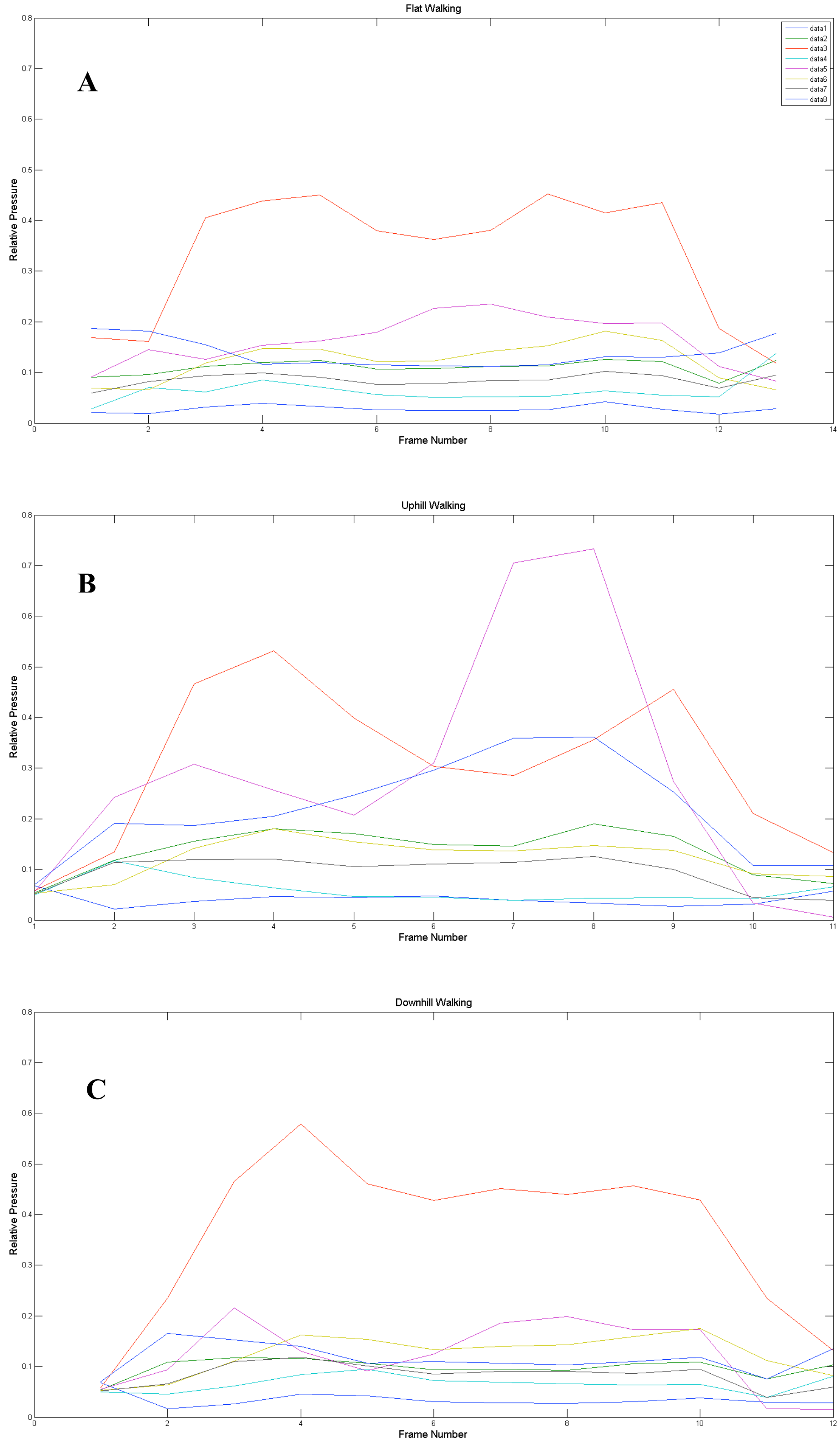

Figure 2a. Pressures from one stance of flat walking
Figure 2b. Pressures from one stance of slope walking (uphill)
Figure 2c. Pressures from one stance of slope walking (downhill)

4. Discussion

This example session used a single, experienced traumatic amputee. Although this meant that a wide range of tests could be completed quickly, it does limit the applicability of the study. Traumatic amputees are typically more capable and more able to adapt to challenging walking conditions than other groups of amputees [16]. However, they are also only a small, somewhat different segment of the overall amputee population, and are over-represented in many aspects of prosthetics research – for example in a recent systematic review of studies examining socket pressure and device alignment changes, potentially as many as 73% of all study participants were traumatic amputees [17] compared to an estimated population percentage of 45% [18]. It could be anticipated that walking perturbation would have a greater impact on the gait pattern of a more representative participant.

The addition of the measurement rig did not appear to have a significant effect on the walking pattern employed. The measurement rig had a weight of around 1kg. only limited research exists on the impact of adding mass to prostheses – however it is thought that only limited effects are present on competent walkers [19]. The effect of additional distal mass was mitigated by mounting the device symmetrically around the pylon. Figure 3 shows the participant wearing the test socket and measurement device.

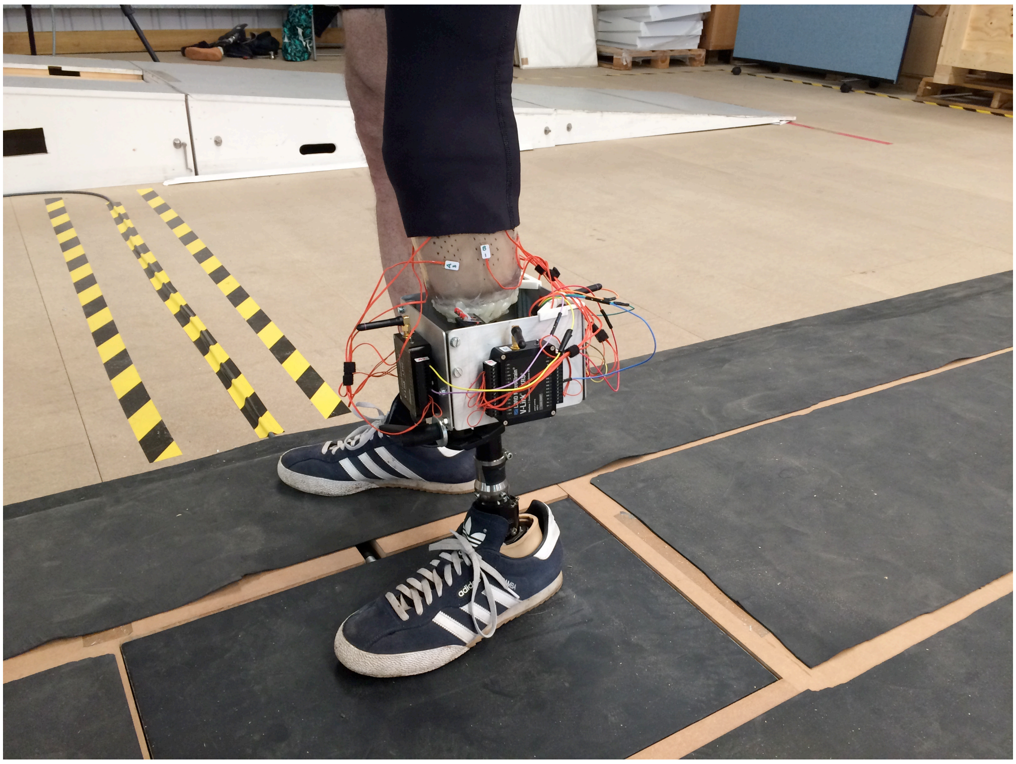

Figure 3. The test participant wearing the test socket and measurement device

The use of telemetry rather than a tethered connection substaintially improved the practicality and convenience of measurement. Previous measurement systems and prior iterations of this device maintained a wired connection between the participant and the host PC. This was done in the past as a result of equipment limitations, and more recent systems rely on a large number of sensing elements - making wireless connectivity more difficult. The system in use requires only 12 sensing elements to cover the socket surface. Removing the cable connector frees the participant restriction in the choice of motion, it makes the participant able to move into position for additional test runs more quickly and it greatly enhances the ability to complete more complex tasks. In this study, this was performed on slopes.

Measurements taken demonstrated the differences produced during distinct walking conditions. This has been shown in previous measurement systems [20,21] and has a grounding in biomechanical theory [22]. The anticipated changes in socket pressure during walking arise from the application of the ground reaction force to the stump via the pseudo-joint of the socket. Likewise, the modification of this force/moment by the change in the alignment of the foot relative to the socket has also been reported previously. To the authors knowledge no pressure distribution data exists that reports the combination of alignment changes and walking on slopes – this system made testing this combination straightforward and safe.

Some disadvantages of using the system were also evident. The mounting system used meant that attaching the system to the participant was somewhat inconvenient. The fact that the neural network training relies on the sensing elements remaining in the same position and orientation mean that these stayed attached. The desire in strain gauge sensing to retain a short and similar wire length [23] had the effect of making the prosthesis harder to adjust. This can be mitigated in future designs but with the compromise of additional connection elements.

The custom software in use also restricted the use of the system to an experienced operator. The prototype design retained many controls and options in order to allow troubleshooting and fine-tuning of the collection process. These are not expected to be required and are not desirable for routine clinical use [24]. Work is ongoing to develop the software into a more clinician-friendly system.

The results demonstrate that the use of artificial neural networks to provide a wireless, convenient and non-invasive measurement of structural loads. In addition to this medical device application, the principle of this measurement technique has been used to evaluate other situations including marine plates and aircraft wing ribs[25,26]. The methods have the potential to solve numerous monitoring problems.

5. Conclusions

The study demonstrated the practical capability of the artificial neural network socket pressure measurement system to perform evaluations on a transtibial amputee in more challenging walking conditions than have been regularly assessed. The participant was able to complete walking tasks whilst walking on slopes with a considerable change in alignment of the prosthesis without the system causing an adverse effect on the free movement being undertaken.

Estimates of pressure distribution time-series were made that demonstrated meaningful changes in the timing, magnitude and distribution of loading of the socket surface. The results support the extension of the design to longer duration measurments and to measurements outside the laboratory which have not been examined using previous devices. Doing so will enhance the knowledge that clincians have concerning the design and prescription of their devices. Work will be required in order to convert the system into a clinically acceptable device. Adaptation of the technique to solve other clinical engineering and other measurement problems in general is encouraged.

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