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RESEARCH ARTICLE

Performance Evaluation and Rectification of Prosthetic Sockets: A Machine Learning Approach Using Wearable Sensors

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ABSTRACT This study demonstrates a data-driven decision support system to aid in rectification of prosthetic sockets aimed at improving overall comfort perceived by amputees. Prosthetic technology, particularly in the realm of socket design, plays a pivotal role in rehabilitation for individuals with limb amputations. Prosthetic sockets, which serve as the critical interface between the residual limb and the artificial limb, enable amputees to walk without the need for invasive implants that connect directly to the bone of the residual limb. This study focuses on the role of intra-socket pressure in socket performance and its impact on optimal socket rectifications for improving comfort in transfemoral amputees. Employing thin Force Sensing Resistor (FSR) sensors, the research measures dynamic pressure variations across individual gait cycles. To explore the effects of altered pressure distribution on socket performance, a clinical trial was conducted consisting of four different socket configurations across several participants, one of which was with no pad inserted and three of which incorporated a silicone pad to modify the dynamic pressure profiles. With data from multiple participants including specific dynamic pressure features extracted from FSR sensors, and subjective feedback of comfort, a Multi-Layer Perceptron (MLP) model is trained to establish predictive relationships between intra-socket pressure and appropriate rectification action. The findings suggest that the MLP agent is more accurate at suggesting rectification actions to prosthetists when compared to simpler classification algorithms such as Random Forest, XGBoost and Logistic regression, laying the foundation for future advancements in prosthetic design.

INDEX TERMS Comfort assessment, force resistive sensors, multi-layer perceptron, trans-femoral prosthetic.

I. INTRODUCTION

Lower-limb amputations create a problem in rehabilitation that still remains difficult to solve. There are an estimated

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40 million amputees worldwide, amongst whom an estimated 26% are transfemoral amputees [1]. Amputees usually require an interface to connect the amputated limb and artificial limb. These interfaces act to aid in performing daily activities such as walking, running, etc. For an interface to be reliable and usable, it must provide a stiff coupling between

the user's skeleton and the rest of the prosthesis in order to facilitate control without causing pain or discomfort [2], [3] whilst also improving factors such as functionality, ease of use, performance and safety [4]. The most commonly used non-intrusive prosthetic interface known as a socket, serves as an interface between the residual limb and prosthetic limb without the need for surgery [5]. Despite there being multiple methods to interface the amputated limb to prosthetic limb, the fact remains that abandonment rates can be up to 58% [6]. With such a high incidence rate of transfemoral amputation combined with the high rates of dissatisfaction with fitting, it is imperative to provide a confidence inspiring prosthetic to assist in the physical rehabilitation and social re-integration of affected amputees. In context of transfemoral sockets, two categories exist. Ischial containment socket (ICS) and sub-ischial type of which Quadrilateral sub-type is most common [5]. Ischial containment sockets extend above the ischium which imply that the ischium is contained for support. This provides strong medial-lateral stability along with better femoral control and alignment and hence does not necessitate a suspension mechanism. However, due to the added containment of the ischium, ICS sockets can be restrictive and uncomfortable. Sub-ischial type sockets do not cover the ischium and instead rely on the use of compression struts or vacuum suspension. Due to reduced containment, sub-ischial sockets are more comfortable with better range of motion. In addition to the role of socket type, the proper distribution of load on the amputated limb is also vital in determining socket comfort. In attempts to quantify the discomfort caused by various factors such as pressure, shear, volume fluctuations and temperature, perceived comfort scales have been used [7]. These scales may allow prosthetists to deduce, over several repeated fits what works for each individual amputee. Further, within the ICS sockets, there are different methods to suspend and secure the limb. The most commonly known types are vacuum-assisted and pin-lock or pin suspension sockets [8]. This study will focus on pin-lock suspension sockets due to the high usage rate and availability of individuals for clinical trials.

Currently, prosthetists are limited to touch and feel to improve the comfort of prosthetic sockets. This implies that amputees must undergo repeated fitting sessions with the prosthetist until they arrive at an acceptable fit. In addition, a comprehensive assessment of a prosthetic socket fit by a prosthetist usually accounts only for on-the-day comfort assessment. Most complications for poor fit of the socket arise after several days or even months from fitting [9]. These complications usually relate to changes in volume, temperature, fatigue from use, and excessive perspiration accumulation within the interface. For example, high perspiration can further lead to rashes and general discomfort. By enabling the measurement of pressure in the socket-stump interface and relating these physical measurements to psychophysical measurements, it may be possible to assess the performance and suggest improvements without the requirement of amputee feedback. The prospect of being

able to use pressure to quantify and modify the performance of a socket proposes an alternative to rectification suggestions as compared to the method of using touch and feel.

Rectification suggestions can be provided to either prosthetists or amputees through mediums like mobile devices, promoting self-care and reducing strain on the healthcare system. Alternatively, rectifications can be made autonomously using actuators embedded in the socket-stump interface. These actuators allow for dynamic adjustments over extended periods, improving comfort by accommodating factors such as volumetric fluctuations in the amputated limb [10]. To enable such dynamic adjustments, continuous physical measurements are required throughout the day. This highlights the need for integrating measurement devices, such as force-resistive sensors, into the socket-stump interface. These measurements can then assess the prosthetic socket's fit, and potentially serve as input for real-time socket adjustments in addition to offering feedback to prosthetists and amputees.

In light of these challenges and opportunities, this study presents a comprehensive methodology for evaluating and improving prosthetic socket performance using a machine learning-based approach. By integrating intra-socket pressure measurements with psychophysical feedback from transfemoral amputees across multiple socket configurations, the study aims to develop a predictive model that assists in socket rectification decisions. The subsequent sections detail related work in sensor technologies and psychophysical assessment, followed by the proposed methodology, clinical trial design, data analysis strategies, model development, and validation. Through this framework, this study aims to demonstrate the viability of data-driven rectification agents in enhancing prosthetic comfort and supporting evidence-based prosthetic care.

II. RELATED WORK

Psychophysical scales are invaluable in assessing perceived effort of humans [7]. In physical rehabilitation centers, scales such as the Visual Analogue Scale (VAS) and the Borg Scale allow prosthetists to experiment with various dependent variables, such as the geometry of the prosthetic socket, to observe their impact on comfort. From an amputee's perspective, the VAS spectrum appears continuous implying their pain does not take discrete jumps [11]. Unlike the VAS scale, the Borg Scale provides discrete steps which amputees could relate their pain/discomfort through. Thus, through measurable metrics related to pain and effort, these scales may help determine which geometry best suits individual amputees. Beyond the initial fitting sessions, psychophysical scale inputs can be useful for assessing comfort over extended periods of use.

In further fittings, it may be important to rely less on amputee feedback and develop a system to use previous measurements attained from monitoring dynamic conditions such as pressure and temperature to extrapolate a relationship

between measured conditions and discomfort. However, due to the low correlation between aforementioned monitored conditions and psychophysical scales across different individuals, it is challenging to establish consistent associations between the two. Machine learning may offer a compelling solution due to its ability to create complex relationships between its inputs and outputs. With repeated measurements spanning across numerous individual amputees, it may be possible to build a substantially large dataset that will train a machine learning model to suggest rectification actions not only within the amputees of the training set but even outside due to the generalizability of the model [12]. In addition to psychophysical scales, other factors such as weight, height, residual muscle composition, and the nature of the amputation may also play crucial roles in building these relationships.

Development of new sockets such as the compression/release stabilization (CRS) socket focuses on the biomechanical properties of tissues and the improvement of liner and socket materials to improve interface rigidity by focusing on relative motion between femur and socket rather than focusing on the highly non-homogeneous residual limb [13]. The main novelty of such a socket is the inclusion of four longitudinal pre-compression bars and four adjacent release regions. The release regions allow some relief for the compressed tissue which improves comfort and reduces chance of ischemia whilst maintaining sufficient compression on the residual limb in the pre-compression bars [14]. The redistribution of pressure and shear to more tolerant anatomical regions do demonstrate an improvement in overall comfort of the socket. This in turn proves that physical phenomena have a significant effect on overall performance and hence acceptance of the prosthetic socket. However, research into the exact mathematical psychophysical to physical relationships in an attempt to quantify socket discomfort has been largely neglected. Efforts have been made to develop psychophysical relationship between pressure and discomfort [15] for specific anatomical regions. Although these studies evaluate the relationship of individual anatomical regions pressure and discomfort, an overall performance indication of the prosthetic socket has yet to be developed. However, difficulty in recruiting a sufficiently large and representative group of amputated individuals in combination with the lack of sufficiently reliable dynamic data to create these relationships has severely limited further studies.

A. INTRA-SOCKET MONITORING

The performance of a prosthetic socket is highly dependent on the pressure distribution within the socket, making the development of reliable pressure monitoring or estimation systems critical. Recent advancements in computational simulations have enabled the estimation of intra-socket static pressure and shear forces during activities such as the donning procedure and static standing. Finite element analysis (FEA) simulations have long been a viable alternative for estimating

intra-socket pressure due to their advantages in non-necessity of clinical trials and poor performance of the alternative ultra-thin sensors in direct measurements [16], [17], [18]. However, accurately determining pressure distributions across the socket-stump interface in different anatomical regions remains challenging due to the computational demands posed by the complex, heterogeneous composition and hyper-elastic properties of the amputated limb.

Recent advances in ultra-thin pressure sensors have addressed these challenges, facilitating more direct and accurate pressure measurements. Prosthesis monitoring techniques have increasingly incorporated flexible sensors designed for conformal, body-worn wearables, which can convert external stimuli, such as mechanical deformation, into measurable electrical signals [19]. A variety of sensing mechanisms are available, including resistive, piezoelectric, capacitive, and triboelectric technologies.

For this study, a sensor with sufficiently high resolution, accuracy and low geometric profile is required. The aforementioned performance characteristics ensure repeatability between clinical trials. The low geometric profile ensure the thickness of the sensor does not affect the pressure in the anatomical region it is measuring. In addition, the hysteresis must also be minimal to ensure accurate readings throughout the dynamic load cycle during the walk activity. Hence, a magnetite quantum tunneling supersensor (QTSS) will be used. QTSS sensors operate by tunneling electrons through insulative barriers surrounding magnetite particles. In these sensors, conduction only occurs at the point of stimulus, unlike most conductive materials where conduction occurs throughout the material [20]. When pressure is applied to QTSS materials, they undergo a proportionate change in resistance, spanning several orders of magnitude, transitioning from an insulator to a metallic-like conductor. This makes them ideal for pressure sensing. With a larger dynamic range than conventional piezo-resistive pressure sensors, QTSS materials have been screen-printed onto PET sheets to create pressure sensor arrays for conformal pressure sensing within prosthetic sockets.

Other sensor types, such as Fiber Bragg Grating (FBG) sensors, have proven effective in transtibial sockets [21]. However, due to their pressure measurement range (up to 35 kPa), FBG sensors are unsuitable for use in transfemoral sockets, where significantly higher pressure ranges of 100–180 kPa are observed. An alternative approach involves permanently modifying the socket by introducing three-axis transducers, which allow for the dynamic measurement of both pressure and shear at the intra-socket interface. However, these studies often overlook psychophysical measurements of comfort.

More recent developments include thin sensors capable of fitting into the socket without altering its surface conformity, thus preserving the accuracy of pressure readings. These sensors enable precise pressure measurement while maintaining socket comfort and fit [22], [23].

In addition to measurement through clinical trials directly on the amputee, FSR sensors can also be used in a mechatronics twin. The mechatronics twin replicates the geometry, material properties of the amputee limb and socket as well as the dynamics of the interface [24]. These dynamics are estimated through powerful simulations [25]. It must also be noted that having more sensors does not necessarily contribute to more interface clarity. Redundant sensors can introduce unnecessary cost and complexity. Having a sparsely populated sensor array may be crucial [26].

B. ARTIFICIAL NEURAL NETWORKS

An Artificial Neural Network (ANN) is a biologically inspired computational model consisting of processing elements called neurons and connections between them and bound through coefficients (weights) [27]. These connections allow a defined mathematical relationship between the input layer and targets output layer. The outputs are usually a probability distribution of classes or regression of the input.

The multilayer perceptron (MLP) is the most known and most frequently used artificial neural network. Fundamentally, the signals are intended to be transmitted within the network in one direction: from input to output [28]. This implies that the output of a neuron does not affect the behavior of the neuron itself. This is known as a feed-forward architecture. The layers between the input and output layers in such a feed-forward MLP are known as hidden layers. These hidden layers serve to capture complex relationships between the inputs and outputs that are commonly difficult to interpret by humans. The choice of the size of these hidden layers is commonly identified through trial and error in an incremental fashion [29]. Hence, MLPs play a significant role in create data-driven relationships in complex regression/classification problems.

C. SOCKET COMFORT SCORE

As gait is the most frequent activity performed by amputees in their daily lives, it is imperative to understand how to improve comfort for this specific activity. By measuring dynamic pressure and shear during gait in conjunction with recording an individuals subjective feedback of comfort, an increasingly accurate psychophysical-physical relationship can be derived. It has been discovered that correlations exist between physical measurements such as heart rate, and psychophysical measurements such as the CR10 borg scale have been conducted [30]. This same principle has been applied to the measurement of socket discomfort to compare pressure to subjective borg scale feedback [31]. However this is limited to sensitivity in specific anatomical regions and not the socket as an entirety.

In efforts to explain how Borg scale ratings relate to performance measurements, extensive analyses must be made into methods to effectively communicate these inferred effort/performance to the prosthetist. This can provide a better clinical assessment and, ultimately, the rehabilitation of the amputee [32]. Methods to provide prognoses on prosthetic

fit and comfort include assessing said comfort by producing individual pressure maps detailing the pressure present in different anatomical regions. The maps are then used to generate rectification maps which may suggest fabrication a new, more comfortable socket.

In the effort of training an MLP to predict which rectification produces the best comfort outcome, it is crucial to have a standardized comfort score. A simple 11 point numerical rating scale (NRS) exists to rate the comfort of the socket between 0 and 10 [33]. Amputees are asked to rate the comfort of their socket and independently report it. In a similar fashion, prosthetists also produce the NRS independently. The findings show that there are strong correlations between these subjective scores and prosthetists' ratings.

Comfort may also be characterized in terms of gait asymmetry such as in the form of a gait asymmetry function [34]. In a healthy subject the gait asymmetry may be more indicative of socket performance. For an amputee, gait compensations to account for changes in weight distribution of the amputated limb and prosthetic are difficult to quantify. When considering pressure, socket performance can be compared on a scale equivalent to the CR10 Borg scale from 0-10 as shown in Table 1.

TABLE 1. CR10 borg scale.

| | |
|-----|------------------------------------|
| 0 | Nothing at all |
| 0.3 | |
| 0.5 | Extremely weak(almost negligible) |
| 1 | Very weak |
| 1.5 | |
| 2 | Weak |
| 2.5 | |
| 3 | Moderate |
| 4 | |
| 5 | Strong |
| 6 | |
| 7 | Very strong |
| 8 | |
| 9 | |
| 10 | Extremely strong (almost the most) |
| 11 | The most I can bear |

This scale is a very simple numerical list involving participants to rate their exertion on the scale during activity such as level-ground walking. The higher values indicate higher levels of physical stress and fatigue [7]. This is usually a method used to indicate exertion and not necessarily pain. However, for the purpose of this study, the Borg scale is used due to its widespread use and simplicity. The CR10 is on the same scale as the commonly used NRS [35].

III. THE DATA-DRIVEN RECTIFICATION FRAMEWORK

To establish a relationship between physical measurements and socket performance, a rigorous methodology should be ensured. Such a methodology involves key elements such as clinical trials, participant feedback, and expert assessment. Without the measurements gathered from real-world trials,

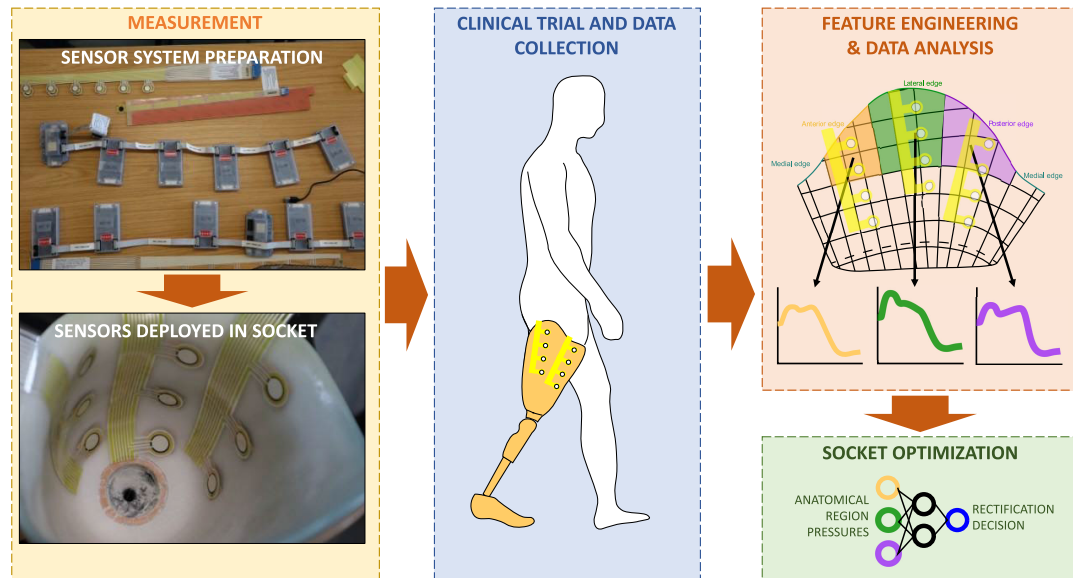


FIGURE 1. Overview of the rectification process involving measurement, clinical trials and data collection, feature engineering & data-analysis and socket optimization.

existing assumptions may be further expanded through the use of less accurate methods such as FEA simulations as mentioned in subsection II-A. By collecting data through clinical trials and subsequently approaching interpretations of the relationship between this collected data and socket performance from multiple perspectives, and hence defining a data-driven agent's decision making capabilities, a more comprehensive conclusion may be possible. An overview of methodology involving the process of prosthetic assessment and rectification is explained in Fig. 1.

A. DATA COLLECTION

Various methods exist for extracting the dynamic distribution of socket-stump interface pressure during gait. Although finite element analysis exists, simulating the pressure distribution in a pin-lock suspension socket proves to be difficult due to the different layers including socket liner, and possibly a sock between the stump and the socket. Simulating the pressure accurately in such a case requires precise and accurate measurements of material properties of the socket, liner, sock and non-homogeneous hyper-elastic properties of the amputated limb. It also requires high definition 3-D scans of the internal socket surface and amputated limb. To reduce these uncertainties, an intra-socket measurement system based on Force resistive sensor is used. The system contains several sensors which are distributed appropriately to ensure coverage across anatomical regions.

1) CLINICAL TRIAL

For this study, a group of amputees were chosen to participate in a clinical trial. The clinical trial contained nine participants of which two were excluded. This resulted

in seven participants in the study as shown in Table 3. The inclusion and exclusion criteria are listed in Table 2.

Participants were recruited from the amputee rehabilitation services by South Tees NHS Hospitals. Participants records were screened initially to identify participants that are eligible according to the inclusion and exclusion criteria. Eligible participants were asked directly by their doctor in consultation or contacted to participate in the study. If participants agreed to participate, they were scheduled to attend the biomechanics data collection in biomechanics laboratory of Teesside University.

Participant evaluation, residual limb evaluation and anthropometric measures were performed under the guidance of a standard documentations and guidelines by the same prosthetist. Information regarding condition of the skin and tissue, circulation, pain, joint function, and muscle strength were recorded. The level of activity of the subjects were also assessed. participants meeting the inclusion and exclusion criteria after the screening visit were invited to attend the biomechanics data collection in biomechanics laboratory of Teesside University. Subjects included in the trial are shown in Table 3.

Temporary socket modification during the data collection was achieved by placing silicone pads inside the socket in predetermined areas that are known to be pressure sensitive. The sequence of modifications was consistent across participants. Prior to the trials, the residual limb geometry and socket were scanned, after which the QTSS sensors were adhered to the socket surface as shown in Fig. 1. Sensor calibration was performed before each configuration to ensure accuracy. Each participant underwent dynamic pressure measurement under four socket configurations—one unmodified and three with targeted pad insertions.

TABLE 2. Inclusion and exclusion criteria for clinical trial.

| Inclusion Criteria | Exclusion Criteria |
|---|--|
| Participants with a trans-femoral amputation | Current psychiatric disorders that compromise the safety of persons present at the trial and/or interfere with the course of the tests |
| Participants who have passed the four phases of rehabilitation | Alterations of the Central Nervous System (CNS) such as: dementia, brain tumors, degenerative pathologies |
| Participants who have K2, K3 or K4 movement functional capability (K levels classification) | Diagnosed addiction to alcohol or drugs |
| Participants with pin-lock suspension prosthetic socket | Active infection and ulceration in the residual limb |
| Participants whose femur (of the amputated limb) is at least 15 cm in length from the perineum, and who have a minimum of 10 cm between the end of the residual limb and the axis of the knee joint | Major amputation in the contralateral limb |
| Capacity to provide informed consent | Medical device implant, e.g., pacemaker, due to electronics used |
| Participants over 18 years of age | Being on dialysis due to effects of dialysis on residuum |
| Use of prosthetic knee | Body weight less than 45 or greater than 125 kg |
| – | Does not give consent |

TABLE 3. Relevant subject information.

| Subject Code | Age (yrs) | Gender | Mass (kg) | Height (m) | Amputation Side | Age of Amputation (yrs) |
|--------------|-----------|--------|-----------|------------|-----------------|-------------------------|
| UK001 | 76 | Male | 91 | 1.73 | Left | 17 |
| UK002 | 65 | Male | 64 | 1.74 | Left | 50 |
| UK004 | 57 | Female | 75 | 1.60 | Left | 12 |
| UK006 | 69 | Male | 88 | 1.73 | Right | 19 |
| UK007 | 51 | Male | 84 | 1.80 | Left | 28 |
| UK008 | 52 | Male | 74 | 1.85 | Right | 28 |
| UK010 | 56 | Male | 85 | 1.86 | Left | 54 |

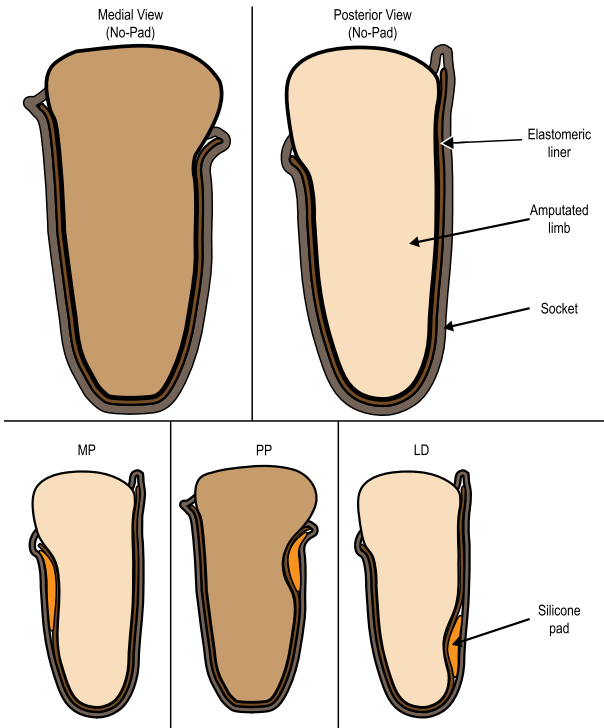


FIGURE 2. Various socket configurations used for clinical trial depicted on a right-legged socket. Without pad inserted (NP), with pad inserted in the Medial Proximal region (MP), with pad inserted in the Posterior Proximal region (PP), and with pad inserted in the Lateral Distal region (LD).

Walking trials were repeated with each modification. In each configuration (one unmodified configuration and 3 modified configuration(s)), the walking trial was repeated five times.

Upon completion of each trial in each configuration, the participant was asked to indicate the level of comfort or discomfort experienced when walking with each socket configuration using a validated perceived effort scale. The various configurations achieved by inserting silicone pads in Medial Proximal, Posterior proximal and lateral distal anatomical regions are shown in Fig. 2.

The locations of the pads are chosen to relieve pressure in commonly known pressure sensitive regions such as the Medial Edge, Femoral Relief and Posterior Gluteus Fold [23]. This is to provide added support in the load bearing anatomical regions that may experience less pain and have higher rigidity. For example, residual muscle in the anterior regions on the residual limb may indicate that it is a load bearing region due to its higher rigidity and can hence tolerate higher pressures. An unwrapped map providing a more detailed understanding of how anatomical regions are divided is shown in Fig. 3

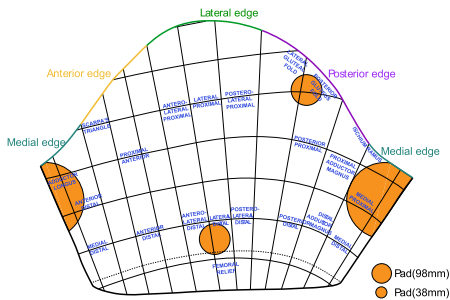


FIGURE 3. Anatomical region map with Silicone Pad locations.

Socket geometry was rectified with silicone pads and trials repeated with each modification as shown in Fig. 2. Here, socket is still referring to their own socket but its inner surface geometry were temporarily modified with silicone pads with a thickness of 10 mm. (Ossur, Iceross Pads®). To be able to produce a sub-optimal fitting socket and create discomfort, the pads were located at the pressure sensitive regions, but the exact location of the pads were selected based on the geometry of each participants's residual limb by the prosthetist. An example of inserted pad in the socket can be seen in the below images. The sensor arrays were inserted between liner and socket to measure socket-residual limb interface pressures during the tasks. The sensors and pads were interfaced with skin directly.

2) DYNAMIC DATA COLLECTION

The participants walk for six minutes on level ground, with six repetitions, approximately one minute per cycle. The speed is the maximum safe and comfortable speed for the participants. The first 20 steps are considered a conditioning of the sensels and are subtracted from the analysis. Sensels here refers to individual sensor nodes on a sensor strip provide by the manufacturer.

The individual perceived effort in Borg Scale ratings is collected from the experiment. For assessment of the effect of different socket configurations across participants, the borg scale ratings are averaged and shown in Fig. 4.

TABLE 4. Mean borg scale ratings across anatomical regions and socket configurations (NP = No Pad, MP = Medial proximal, PP = Posterior proximal, LD = Lateral distal).

| Socket Configuration | NP | MP | PP | LD |
|----------------------|------|------|------|------|
| Anterior Distal | 0.17 | 0.17 | 0.17 | 0.17 |
| Anterior Middle | 0.17 | 0.17 | 0.17 | 0.17 |
| Anterior Proximal | 0.17 | 0.46 | 0.38 | 0.17 |
| Posterior Distal | 0.95 | 0.79 | 1.12 | 1.50 |
| Posterior Middle | 0.17 | 0.54 | 0.17 | 0.17 |
| Posterior Proximal | 0.88 | 1.24 | 1.04 | 0.46 |
| Medial Distal | 0.17 | 0.17 | 0.17 | 0.17 |
| Medial Middle | 0.17 | 0.17 | 0.17 | 0.17 |
| Medial Proximal | 0.91 | 1.12 | 0.17 | 0.59 |
| Lateral Distal | 0.95 | 1.30 | 1.12 | 1.12 |
| Lateral Middle | 0.17 | 0.17 | 0.17 | 0.17 |
| Lateral Proximal | 0.46 | 0.42 | 0.17 | 0.17 |

In addition to studying the effects of the socket configuration on comfort, it may be imperative to understand the sensitivity of each anatomical region. For example, low average borg scale ratings may indicate that certain anatomical regions are less prone to contributing towards discomfort. The aggregated Borg scale ratings of socket performance across all participants and all socket configurations tested in this study is shown in Fig. 4. For each anatomical region, the mean and standard deviation of perceived exertion were computed by pooling ratings from every trial condition. This bar plot therefore represents the culmination of the entire dataset, capturing the overall distribution of discomfort across anatomical regions, independent of individual differences or specific

socket modifications. The data indicates that Lateral Distal and Posterior Distal anatomical regions have the highest Mean borg scale ratings. The high standard deviation in these anatomical regions also implies that they vary significantly between amputees and socket configurations. This indicates these regions are more sensitive to discomfort when compared to other anatomical regions. These sensitivities may be attributed to high weight bearing load and/or scar tissue at amputation site.

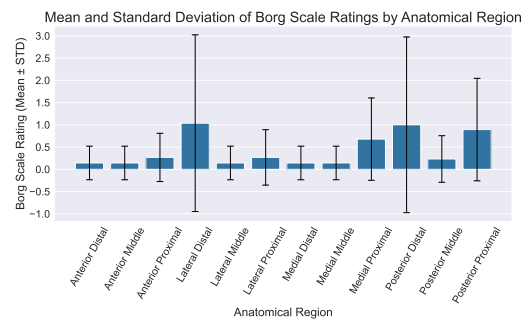


FIGURE 4. Mean and standard deviation of Borg scale ratings across anatomical regions, aggregated over all participants and socket configurations.

3) DATA REFORMATTING

It is well known that gait patterns are highly individual when it comes to amputees. These differences can be assessed by comparing spatiotemporal parameters such as step length, width and time [36]. Temporal asymmetries are especially more significant in Transfemoral amputees due to increase instability and discomfort during the stance-phase. As a result, physical measurements such as pressure and shear may prove to be more important to utilize in performance metrics. The conducted clinical trial ensured that data was recorded along with time-stamps for various sub-phases of the stance-phase through the use of a gait monitoring device as seen in Table 5. The expressed time windows are used to interpolate time-dependent pressure in terms of percentage stance phase as seen in Fig. 5.

TABLE 5. Gait events summary.

| Event | First Occurrence (%) | Gait Value | Monitor |
|-------------|----------------------|------------|---------|
| No-event | ~1 | 1 | |
| Heel-strike | 5 | 4 | |
| Mid Stance | 20 | 5 | |
| Toe-off | 50 | 2 | |
| Mid-swing | 82.5 | 3 | |

4) RECTIFICATION EFFECT

To achieve rectification of socket morphology, prosthetists generally must create a new socket to account for subjective discomfort expressed by amputees. This requirement to modify the prosthetic socket demands extensive time and fabrication costs. By modeling the effect of rectification on certain anatomical regions on pressure, prosthetists can

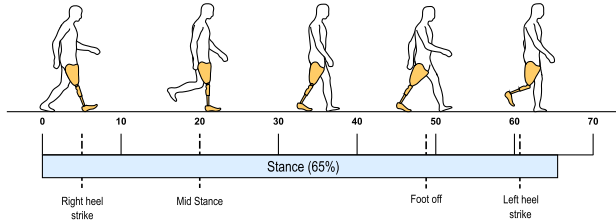


FIGURE 5. Breakdown of stance phase sub-phases expressed as percentage for a right-legged amputee.

further understand how rectifications in one regions may also affect pressure in other anatomical regions. In this section, the effect of different silicone pads on dynamic pressure profiles as compared to No-Pad configuration is shown. Pressure is normalized to the weight of the amputee. Fig. 6 shows how pressure in each anatomical region is affected by various socket configurations. The placement of silicone pads is illustrated in Fig. 2.

B. SOCKET PERFORMANCE INDEX

The performance of a prosthetic socket maybe difficult to evaluate. As explained in subsection II-C, a comfort score may be defined based on psychophysical scale. In this study this SCS will be referred to as performance index. Based purely on Borg scale ratings, one may assume the overall performance or comfort of the socket might be the mean over Borg scale indications across all anatomical regions.

In an effort to keep the performance indicator linearly and simplistically related to Borg Scale indications, the mean Borg Scale rating across all anatomical regions is used and represented in Equation 1.

$$PI = \frac{1}{n} \sum_{i=1}^n B_i \quad (1)$$

where B_i denotes the Borg scale indication at anatomical region i , where $i = 1, 2, \dots, n$, and n represents the total number of anatomical regions assessed in the prosthetic socket. The performance indicator PI is defined as the mean Borg scale score across anatomical regions.

Applying this Performance Index equation on trial data, a bar-plot is derived as shown in Fig. 7.

It is be noted that there is small increase in performance index for the rectification action of adding a pad in the Medial Proximal region. The rectification action of adding a pad in the Lateral Distal region shows the lowest Performance index across clinical trial subjects.

C. RECTIFICATION ASSISTANT

In the process of assessing the performance of a socket, it is also useful to provide a suggestion to the prosthetist to make a rectification. The rectification may be suggested in several ways. Use of participant specific parameters such as weight in addition to physical measurements are known

to improve predictor performance [37]. A feed-forward MLP classifier is used to make this prediction. In the trial presented, multiple configurations of the socket provide equally good performance. Therefore, a one-hot representation of the correct class may not necessarily be used. Instead, soft labels are used to represent correct predictions in the training data.

The dimensions of the input layer of the MLP for time series sensor data is $d_{in} = n * m$. Where, n is the number of time steps and m is the number of sensors. A non-linear ReLU function is used to relate the input features to pre-output layers as shown in Equation 2.

$$\mathbf{h}^{(l)} = \text{ReLU}(\mathbf{W}^{(l)}\mathbf{h}^{(l-1)} + \mathbf{b}^{(l)}), \quad l = 1, 2, 3 \quad (2)$$

where $\mathbf{h}^{(0)} = \mathbf{x}$ is the input vector, $\mathbf{W}^{(l)}$ are the weights and $\mathbf{b}^{(l)}$ are the weights and biases of the l -th layer.

$$\mathbf{z}^{(4)} = \mathbf{W}^{(4)}\mathbf{h}^{(3)} + \mathbf{b}^{(4)} \quad (3)$$

In a classification problem such as in this study, a softmax is applied to the output layer to ensure a probability distribution which sums to unity and shown in Equation 4.

$$\mathbf{y} = \text{softmax}(\mathbf{z}^{(4)}) \quad (4)$$

The softmax function provides a single correct class i.e. rectification as output so as to avoid confusion to the prosthetist. During training, loss function selection is paramount to ensuring high prediction accuracy. A Categorical Cross-Entropy (CCE) allows for a single output class prediction and soft labeling on training inputs. Unlike Kullback-Leibler divergence loss function which also accepts a probability distribution in the training labels, CCE only involves the difference between the training and target distributions. Kullback-Leibler divergence involves the estimation of the entropy of the training distribution which is given by $H(p) = -\sum_i p_i \log p_i$ where $p = [p_1, p_2, \dots, p_C]$ is the target distribution (the soft label for a single training sample), and C is the total number of classes (socket configurations). The entropy $H(p)$ measures the uncertainty in the target distribution, and remains constant during training because the dataset is fixed. This implies Kullback-Leibler divergence is more computationally demanding without a clear advantage. Also, Binary Cross-Entropy (BCE) is used for multi-label classification scenarios. For example, it may be used to design an agent with the goal of suggesting a combination of socket configurations (i.e. adding multiple pads simultaneously). This deems BCE inappropriate for the use case of suggesting a single pad or No-PAD as rectification action. Hence, a CCE loss function is used.

In preparation for training, the socket configurations with the least mean over borg values across anatomical regions are indicated by a one-hot representation. For example, for a training input sample consisting of mean borg values of $[0, 0, 0.167, 0.0412]$ for No-PAD, LD, MP, PP respectively, the one-hot representation would be $[1, 1, 0, 0]$ since No-PAD and LD have the lowest mean borg scale values. Secondly, they are constrained to be a minimum of 1×10^{-8}

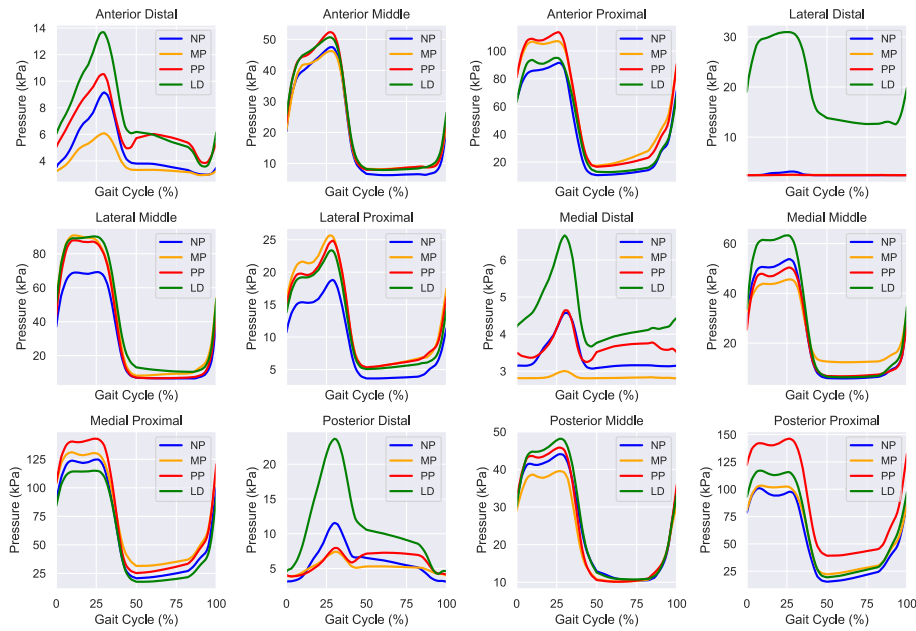


FIGURE 6. Anatomical region pressure averaged across all participants and gait cycles for various socket configurations during gait.

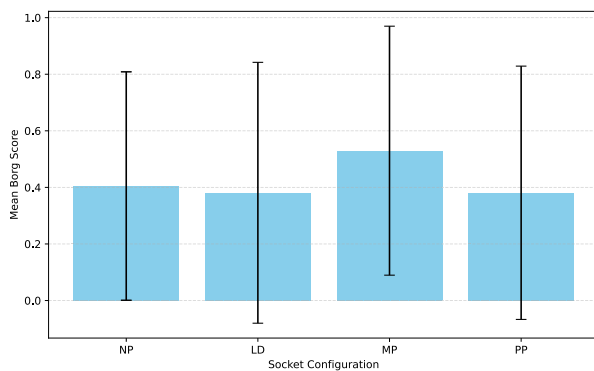


FIGURE 7. Distribution of Performance Index across participants, anatomical regions, and socket configurations.

to prevent $\log(0)$ estimations in the loss function. Finally, the outputs are normalized to sum to unity ($[~0.5, ~0.5, 1 \times 10^{-8}, 1 \times 10^{-8}]$ in the example). This is to ensure the output corresponds to a probability distribution and not one-hot labeling. In contrast to the training outputs, the prediction outputs will be a single rectification suggestion predicted from pressures and standard-deviations in pressures derived in the clinical trial under the No-Pad configuration. This is representative of a scenario where an amputee visits a clinic and pressure measurements and rectifications suggestions are to be made based solely on level-ground walking activity performed with their current fit as previously expressed in Fig. 1. To identify the optimal MLP configuration, a search is done including MLPs with up to three hidden layers.

To achieve this the input layer consist of $101 \times 12 \times 2$ inputs, which includes dynamic pressure and standard-deviation

in pressure corresponding to each percentage of stance phase from 12 anatomical regions. The final layer is a probability distribution of the rectification to be or not to be made, with each output corresponding to one socket configuration as described in Fig. 2. Early stopping was triggered when validation loss failed to improve by more than 1×10^{-6} over 100 epochs, and the learning rate was reduced by a factor of 0.5 after 20 stagnant epochs, down to a minimum of 1×10^{-6} . Bayesian optimization identified the optimal configuration as a shallow classifier, equivalent to a multinomial logistic regression with a softmax output.

IV. RESULTS

Using a neural network based agent results in various improvements compared to a more simplistic model. Table 6 shows that when used to predict an optimal rectification action, an MLP performs marginally better with 38.57% test accuracy when compared with algorithms such as Random Forest, XGBoost, Logistic regression. OneVsRest used in Random Forest and Logistic Regression refers to treating the output as a single prediction. For example, the No-Pad configuration can be compared to “Any Pad” which includes MP, PP and LD configurations. This is repeated for all classes and the highest is chosen as the prediction. This is due to the binary outputs of Random Forest and Logistic Regression whereas there are multiple prediction classes in this study. The improvements shown by MLP could be in part due to the soft distribution of probabilities in training outputs. MLP handles this better due to the use of CCE loss function which allows for soft probabilities as opposed to one-hot representation in classification problems.

TABLE 6. Mean accuracies (%) for classification algorithms on rectification action prediction.

| Algorithm | Train Acc. | Val. Acc. | Test Acc. |
|---------------------------|------------|-----------|-----------|
| MLP | 62.29% | 52.71% | 38.57% |
| Random Forest (OneVsRest) | 99.97% | 38.57% | 36.86% |
| XGBoost (MultiOutput) | 58.00% | 35.57% | 34.14% |
| Logistic Reg. (OneVsRest) | 100.00% | 32.43% | 31.57% |
| Random Choice | 35.71% | 35.71% | 35.71% |

A participant-wise cross-validation strategy was employed to ensure robust model evaluation. In each iteration, one participant was reserved as the test set, another participant was assigned as the validation set, and the remaining participants were used for training. This process was repeated so that every participant served as the test set exactly once, resulting in seven distinct train-validation-test splits. Further, the experiment is repeated across different seeds. The network parameters are initialized over 100 random seeds to ensure that the various prediction algorithms are compared fairly. A primary random seed 42 is used to generate and set secondary random seeds during network initialization for all comparisons. The rectification actions produced by the various algorithms show that MLP has a marginal advantage. It maintains a train accuracy on par with the validation accuracy and test accuracy. This indicates that overfitting is not present. Whereas in Random Forest, it is observed that the training accuracy is almost 100%. This indicates that the algorithm is overfitting to the training set. This can also be observed in the validation accuracy being slightly lower than random choice.

TABLE 7. Per-participant test accuracy summary (%) for MLP in comparison to random selection.

| Participant | Mean Accuracy (%) | Random Accuracy (%) |
|-------------|-------------------|---------------------|
| 001_UK1 | 72 | 50 |
| 002_UK1 | 11 | 25 |
| 004_UK1 | 30 | 25 |
| 006_UK1 | 81 | 50 |
| 007_UK1 | 29 | 25 |
| 008_UK1 | 34 | 25 |
| 010_UK1 | 13 | 25 |

Further comparison as shown in Table 7 reveals that the MLP performs better than random in five out of seven participants. The random predictions of participants 001_UK1 and 006_UK1 are higher as two socket configuration resulted in equal comfort levels indicating they are equally correct rectifications to make. It is also observed that participants 002_UK1 and 010_UK1 have significantly lower test accuracies than other participants.

V. DISCUSSION

The clinical trial provided several key insights into the effect of rectification on pressure and ultimately the socket performance. By adjusting the socket geometry through the

introduction of silicone-pads, modifications are made to the pressure distribution and hence overall socket comfort. Subsequently, the effects of the pressure on overall comfort can be drawn from a domain expert's perspective using Table 4 and Fig. 6.

SOCKET ADJUSTMENTS AND THEIR EFFECTS

10 mm Thickness Reduction at Medial Proximal Area of the Socket(MP)

- Slightly improved perceived comfort at Posterior Distal region.
- The peak pressure was increased from 195 kPa to 215 kPa at Medial Proximal region.

10 mm Thickness Reduction at Posterior Proximal Area of the Socket(PP)

- Slightly improved perceived comfort at Medial Proximal region.
- Slightly reduced perceived comfort at Posterior Distal and Posterior Proximal regions.
- The peak pressure was increased from 190 kPa to 219 kPa at Posterior Proximal region.

10 mm Thickness Reduction at Lateral Distal Area of the Socket(LD)

- Slightly improved perceived comfort at Posterior Proximal, Medial Proximal, and Lateral Proximal regions.
- Slightly reduced perceived comfort at Posterior Distal and Lateral Distal regions.
- The peak pressure was significantly increased from 8 kPa to 163 kPa at Lateral Distal region.

Adding to domain expert's feedback, machine learning methods prove to be promising assessment tools despite a lack of large number of training samples. In this study, it is shown that Neural networks perform notably better than methods such as random forest in regards to validation accuracy and marginally better in terms of test accuracy. This indicates that socket performance cannot be easily assessed by observing anatomical region specific pressure across gait cycles. In other words, a simple regression model may not be sufficiently complex to capture the relationship between spatial features in the subjective feedback based training data. This further limits the explainability of such models and hence need not be shown to the prosthetist in aims to produce rectification suggestions. Approaching socket performance as a continuous scale allows for finer comparisons between socket configurations, simplifying the process of distinguishing between better or worse sockets. Implying that introducing more socket configurations into the clinical trial may improve the model's performance for a given amputee, however does little to address the variability between amputees. Table 7 further indicates that participants 002_UK1 and 010_UK1 have less representative response to pressure across gait cycle than other participants. This may be due to differing sensitivity to discomfort in anatomical regions as compared to other participants in the trial.

VI. CONCLUSION

The inferred domain knowledge in complement to the MLP shows that a data-driven agent can provide rectification suggestions to a prosthetist. Prosthetists may use the rectification agent in combination with pressure maps as seen in Fig. 3 to assert their own solution for improving comfort. In addition, they may also use the rectification agent when higher confidence levels of prediction are presented. Based on the socket performance evaluation of the MLP algorithm, a test accuracy of 38.57% is achieved. This is marginally better than all other tested algorithms. It is to be noted, although there are 28 trials, there are four trials corresponding to each of the seven participants in different socket configurations. Hence, each trial participant contributes to one training sample. This may be the cause of variations in test accuracies between participants. With future implementations of the suggested agent in assessing optimal rectification action in conjunction with a study involving a larger pool of participants, the same method may be applied to different amputations such as transtibial or even upper-limb amputees. In addition, the proposed approach could be enhanced by integrating it with a fuzzy inference engine, as suggested in [38]. As the fuzzy rules are inferred based on a domain expert's knowledge, an agent which combines both a data-driven inference from the proposed MLP agent and a fuzzy inference agent may be designed with tools such as LangChain [39].

Such agents can be used not only to assess the socket but also to make dynamic rectifications through the usage of dynamically altering socket geometry. For example, when there is considerable accumulation of sweat within the socket-stump interface. As a remedy, an increase in pressure in pressure-tolerant anatomical regions of an amputated limb may produce clearances in pressure sensitive areas. These clearances may act as passages for moisture to exit the socket-stump interface and improve circulation, thus preventing condensation and collection of perspiration within the socket.

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