



Shruti Turner <sup>1,2,\*</sup>, Shivali Jain <sup>3</sup>, Akhil Patel <sup>3</sup>, Matthew O. Hopkins <sup>1,2</sup> and Alison H. McGregor <sup>1,2</sup>

- <sup>1</sup> Centre for Blast Injury Studies, Imperial College London, London SW7 2AZ, UK;
- matthew.hopkins@imperial.ac.uk (M.O.H.); a.mcgregor@imperial.ac.uk (A.H.M.)
  <sup>2</sup> Sackler Musculoskeletal Laboratory, Department of Surgery and Cancer, Imperial College London, London W12 0BZ, UK
- <sup>3</sup> Faculty of Medicine, Imperial College London, London SW7 2AZ, UK; shivali.jain15@imperial.ac.uk (S.J.); akhil.patel16@imperial.ac.uk (A.P.)
- \* Correspondence: s.turner17@imperial.ac.uk

**Abstract:** Obtaining a good socket fit is an iterative process dependent on the skill and experience of the prosthetist creating it and requires individualisation based on the size and shape. There is no standard measurement system used to aid prosthetic socket creation despite the severe impacts on physical health and quality of life if one is ill fitting. Pressure sensors embedded in a prosthetic socket were used to collect data at the socket–residuum interface. To choose an interpolation method, the sensor array was simplified to a 2D grid with a border for extrapolation and tested using previously collected walking test pressure data. Four multivariable interpolation methods were evaluated to create a colour map of the pressure data. Radial basis function interpolation was chosen, as it produced a clear image with a graduated interpolation between data points, and was used to create a colour map across the surface of a 3D prosthetic socket model. For the model to be accessible to clinical audiences, a desktop application was created using PyQt to view the model. The application allowed for connection to the sensors via Bluetooth, with the pressure data updating on the 3D model in real time. Clinician feedback on the application showed the potential for a clinical product; however, further development informed by feedback from rehabilitation clinicians and prosthesis users is required.

Keywords: prosthetics; prosthetic socket; prosthetic socket fitting; visual feedback; rehabilitation; amputation

### 1. Introduction

The prosthetic socket is the point of load transfer between the body and the prosthesis and is a complex interface [1,2]. Obtaining a good socket fit is an iterative process dependent on the skill and experience of the prosthetist creating it, requiring individual adaptation based on the size and shape of each user's residual limb [3,4]. The socket is not an ideal environment for the residual limb due to the load distribution over anatomy and tissues that have not evolved for this purpose. The bony prominences and skin on the residual limb are subjected to a hot, moist environment with greater loading conditions compared with pre-amputation [5]. Therefore, the residual limb is highly susceptible to complications—including skin tissue breakdown—that can lead to deep tissue injury and the formation of pressure ulcers [6–9]. A critical factor in the development of pressure sores is the presence of shear in the soft tissues, often present due to movement of the residual limb [10]. Pressure sores negatively affect the quality of life of 62% of prosthesis users, frequently prohibiting prosthetic use [6,8,11,12].

There is no standard measurement system used to aid prosthetic socket creation, despite the severe impacts on physical health and quality of life if one is ill fitting. The knowledge to solve patient-reported problems or adapt the socket for different needs is gained only with years of experience [3,4]. The process of fitting a socket is made more



Citation: Turner, S.; Jain, S.; Patel, A.; Hopkins, M.O.; McGregor, A.H. A Visual Feedback Tool for Quantitative Pressure Monitoring in Lower-Limb Prosthetic Sockets. *Prosthesis* **2021**, *3*, 394–405. https://doi.org/10.3390/ prosthesis3040035

Academic Editor: Winnie Jensen

Received: 4 October 2021 Accepted: 15 November 2021 Published: 18 November 2021

**Publisher's Note:** MDPI stays neutral with regard to jurisdictional claims in published maps and institutional affiliations.



**Copyright:** © 2021 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https:// creativecommons.org/licenses/by/ 4.0/). difficult for those who have lost sensation in their residual limbs due to nerve damage, burns, or skin grafting. These individuals cannot provide feedback to prosthetists if the socket is uncomfortable due to ill fit or high pressure, and are thus more susceptible to skin breakdown and the development of pressure sores.

Another issue affecting socket fit is the volume fluctuation of the residual limb [13,14]. The socket is fitted to the conditions at a single point in time; however, the residual limb changes shape and size [13]. Changes to the residual limb are influenced by a variety of factors, including time since amputation, activity levels, and even the weather. The socket is rigid and cannot adapt to these changes in the limb, altering the pressure distribution within the socket [13] and potentially exacerbating skin breakdown.

Published literature shows that effective biofeedback methods have been used in people with lower-limb amputations alongside conventional techniques for monitoring and assessing loading, motion symmetry, and improving gait [15,16]. Biofeedback in these settings is most commonly presented visually, with auditory and haptic methods (delivering feedback via a method of touch, e.g., using sub-threshold electrical stimulation on the skin to signal a change in environment) also popular techniques [15]. Although biofeedback is effective in both clinical and non-clinical settings, it is particularly beneficial during the early stages of rehabilitation [15]. Using biofeedback technologies is generally received well by trial participants and increases motivation to complete sustained rehabilitation [17,18], though there have been usability issues reported within the elderly population [15]. Visual feedback during rehabilitation has been shown to positively influence rehabilitation and can be used as outcome measures as well. It is also clearly an area where new technologies are embraced positively by users.

Methods to measure the environment inside the prosthetic socket have been developed and tested for several decades. Due to their associated medical implications, pressure and shear are of particular interest [19–23]. Few commercial technologies exist, and they have limitations similar to devices used in research studies, generally including high costs [24–26] Research studies either use commercial technologies [19,20] or focus on the development of new sensors [21–23]. It is more common for commercial products to also focus on the user interface for the display and interpretation of the collected data. A drawback of current interfaces is the difficulty to map the measurements to the exact locations on the socket. This adds time and complexity for clinicians to use the technologies, as they must understand the information portrayed and then mentally transpose this into the socket. This method can reduce the use of the technology in time-sensitive cases and increase abandonment rates. Many user interfaces only work with their associated sensors, with some also being platform- and device specific, and many requiring an internet connection. Dependence on specific devices is costly, and the requirement of the internet to use the sensors limits the accessibility of their technologies. Low resource environments may not have the budget to pay for the different technologies on top of the sensor hardware, and wireless internet access is not guaranteed, particularly in remote settings. Furthermore, research technologies frequently require specialist technical knowledge and licensed software (e.g., MATLAB) [21-23], making them less suitable for a clinical environment.

Sensor placement is important, as the quantity and location affect spatial resolution and accuracy. Using too few sensors to cover a large area may lead to misleading results due to reduced spatial resolution. It is also important to consider the anatomy of the residual limb that needs to be captured. For each prosthesis user, specific locations of interest may vary; however, each will have areas of higher load tolerance and more sensitive areas, e.g., bony prominences. Arguably, it is most important to capture the pressure at the sensitive areas to target issues reducing user comfort. However, this local approach does not allow for the evaluation of the overall socket design or distribution of pressure.

The integration of sensors into the prosthetic socket is complex. The sensors must not impact the ability to shape or modify the socket or negatively affect the comfort of the prosthesis user. Generally, sensor hardware is not waterproof and is affected by heating methods used to make minor modifications to the socket's shape. The sensors used in research and commercially are generally placed between the socket and the residual limb [24–26]. However, this placement can disrupt the interface of the socket and the residual limb, which may cause discomfort and an uneven surface leading to skin breakdown.

The research team has created a network of 144 piezoresistive pressure sensors, which are low cost to manufacture. The sensors are arranged in strips of 12 sensors, 2 cm apart, an example of which is shown in Figure 1. The sensors are placed lengthways proximally to distally along the socket, with the aim of total surface coverage and no strip more than 2 cm apart [27]. The resistance of the piezoresistive material that acts as the sensor changes depending on the amount of pressure applied. Therefore, with varying pressure, the output voltage of the sensors changes when in a voltage divider instrumentation circuit. The sensors were examined for pressure up to 400 kPa, the expected pressure range in the prosthetic socket [27]. Although the sensors demonstrated hysteresis with loading and unloading, static drift, and some temperature response, the sensors were deemed appropriate for use to understand pressure distributions in the prosthetic socket [27]. The sensor strips are connected to a control board with an inertial measurement unit (tri-axis accelerometer, gyroscope, and magnetometer) to detect and measure movement. Data from each device were collected at a rate of 200 Hz. The control board also contains a Bluetooth transmitter that transfers the data wirelessly. Before the start of the current study, the data were received by a desktop application written in C# which saved the data in a comma-separated value (CSV) file.



**Figure 1.** Image of one sensor strip attached to a 3D-printed block for exanimation of response under load, with 12 sensors and a connector head on the top to allow connection to the control board.

The aim of this study was to create an initial proof-of-concept real-time feedback tool to display a complete surface colour map of pressure from the sensors created by Hopkins et al. on a 3D socket model for clinicians [27]. The quantitative information is intended to guide the prosthetists with their fitting by providing additional information that previously they would not have had. The feedback tool is also intended to aid communication with prosthesis users during the socket fitting process and to aid movement re-education or highlight issues with the socket that may present during rehabilitation. Clinician feedback was sought to determine the potential clinical benefit of the tool from the perspective of socket fit and rehabilitation and to gain feedback to guide future development. A future iteration of the tool using this information will be tested with prosthesis users in the clinical environment.

# 2. Results

# 2.1. Software Creation

Multiple multivariate interpolation methods for unstructured data were run on a uniform 2D grid, representing an ideal sensor distribution to determine the appropriateness of different methods (Figure 2). The data shown in the figure are from one time point in a gait cycle for the participant. Only the radial basis function and nearest-neighbour interpolation methods extrapolated outside the sensor array's measured points. The Clough–Tocher and linear interpolation methods only interpolated within the boundaries of the sensor locations. Extrapolation is necessary to allow clinicians to visualise the pressure distribution across the whole socket, not only the area enclosed by sensors as they will not necessarily be located at the socket boundaries. The pressure values are represented using a colour gradient, from the lowest in blue, through green, and the highest in red. The colour gradient can be changed if desired.



**Figure 2.** The 2D output of pressure sensor data with (**a**) radial basis function, (**b**) Clough–Tocher, (**c**) nearest-neighbour, and (**d**) Linear interpolation methods from a single time point.

The nearest-neighbour interpolation method showed squares of colours between the sensor locations used for interpolation. For extrapolation, the colours from the interpolation are shown as rectangles given the locations of sensor measurements in the grid. Given that the interpolation is performed by locating the nearest measured sensor values, there are squares of starkly different colours adjacent to each other, representing a 'jump' in pressure values. The radial basis function interpolation instead creates a smooth colour gradient

across the 2D grid using the sensor values. The pressure map has no 'jumps' and shows a graduated change in pressure.

The interpolation methods were tested on four time points across a gait cycle for a participant. Whilst the pressure distribution changed at the different time points, the methods of each interpolation did not. All methods created images with similar characteristics at the different time points, i.e., ability to extrapolate, pixelated appearance, or smooth gradient, showing the timepoint in the gait cycle did not impact the appropriateness of the interpolation methods.

The radial basis function was chosen as the interpolation method to use due to the clarity of the image which was deemed most interpretable. A colour map was created on the surface of a transtibial socket model for a single time point of data (Figure 3). The interpolation created a colour map representing the estimated pressures across the entire surface, using the 144 measured values distributed across the surface in 12 lines of 12 sensors.



**Figure 3.** Radial basis function interpolation applied to a 3D computational model of a prosthetic socket using data.

The Python code creating the model was improved to update the colour map when new data were given to it. This improvement was vital to allow the creation of a dynamic model that could be updated in real time from the Bluetooth data transmitted from the sensor hardware.

To allow clinicians to use the 3D model in a clinical environment in a time-efficient manner which requires no training or coding experience, the desktop application was created with a simple user flow (Figure 4) to demonstrate the possibility of using 3D visualisation in real time as a visual feedback tool for clinicians. The application allowed users to connect to the sensor hardware and view the updating 3D socket model with only button clicks.

A graphical user interface was created with two screens and two buttons to navigate between the screens. Navigating to the second screen initiates the connection to the Bluetooth sensors via a dialog box with an 'OK' action button, which triggers the host device to scan for the sensors. The main window is disabled whilst the application is scanning for the sensors, and another dialogue box is shown to confirm that the sensors are connected to the host device.



Figure 4. User flow of feedback tool.

Once sensors are connected, and the test session started using a 'Start/Stop' button in the main window, a stream of data is received by the application, and the pressure values are extracted to feed the function that creates the pressure map on the 3D model. The window can be resized, and the model can be reorientated by clicking and dragging. Clicking the 'Start/Stop' button breaks the Bluetooth connection with the sensors.

## 2.2. Clinician Feedback

Clinician interviews were evaluated to determine the tool's clinical potential and to understand areas for further development. Participants were positive that the tool was easy to use and did not require specialist knowledge. They noted that the 3D model was easy to interpret and purely represented the level of pressure present.

Both prosthetists and physiotherapists believed the pressure information displayed on the 3D model would be more useful for prosthetists in the clinic. However, physiotherapists also stated that it would help them better communicate socket issues. Some prosthetists did not believe the tool would add value to their practice, as they made well-fitting sockets and used prosthesis user feedback to guide them, although they did acknowledge there could be a benefit to the tool for teaching and research purposes. One prosthetist believed the tool would only be useful if it provided information about shear. The benefit of the tool in aiding communication with prosthesis users was also highlighted. In general, prosthetists stated that prosthesis users wanted to know what was occurring within their socket, and therefore noted that objective information on pressure locations may help socket acceptance.

Prosthetists and physiotherapists expressed an interest in viewing the movement information of the prosthesis user alongside the 3D model. Participants believed that the information would allow them to more easily pinpoint when problems with the prosthesis may occur.

Some participants expressed that it would be more helpful for the application to be accessible on a mobile device, e.g., smartphone or tablet, even if that meant a simpler tool was created. However, the majority did not have a problem with the tool being available on a desktop or laptop for clinical application. It was noted that some prosthetic components, such as microprocessor control knees, require a laptop to program and evaluate anyway, so the additional use of the computer for socket monitoring would not be an issue.

#### 3. Discussion

A proof-of-concept real-time feedback tool to display the pressure measurements from the sensors created by Hopkins et al. [27] for clinicians was created. A radial basis function interpolation method was used to create a colour map of pressure across the surface of a 3D prosthetic socket model using measured values from 144 sensors embedded in a real socket. The tool created was intended to be an initial version to determine the possibility of creating a full colour map that updates in real time from received Bluetooth data and to receive initial feedback from clinicians on the benefits to their practice. With the project scope being to create a testable proof-of-concept software for clinician feedback, certain assumptions and simplifications were made. This enabled the establishment of the value of the software before investing resources into creating a final product.

For the sensor hardware to be useful in a clinical environment, the information relevant to clinicians and people with amputation(s) must be displayed in an easy-to-understand manner, requiring little interpretation or training and no additional technical knowledge. Clinicians are busy and have a short timeframe in which to see and treat patients; the technology must not be a burden for them to use to ensure adoption into clinical practice.

Data visualisation was kept in the simplest form, relaying pressure information: no analysis or post-processing was carried out on the data. A further analysis adds complexity and time, which is not always available or possible in the clinical environment when treating patients. After an initial consultation with target users regarding the clinical application, further functionality for data analysis, such as reporting numerical metrics and comparisons, can be implemented.

Choices for programming language were limited due to the complexity of the mathematics required in a short space of time to create a colour map that updates in real time. Python is a versatile language, particularly useful for complex mathematics; however, desktop applications are not typically written in Python due to the way the code is distributed and run. It is possible to re-write the application and model in C++ using the VTK and PyQT frameworks, which may yield an application which is more efficient to run, particularly with added functionality in later versions. For the proof-of-concept, however, Python was sufficient to demonstrate the possibility of creating such a feedback tool.

The interpolation methods evaluated were the built-in methods of the functions used and chosen purely based on subjective observation. From the four interpolation methods assessed, only one was suitable as it provided smooth colour gradients between values and extrapolated data. It would be prudent to evaluate further methods of interpolation which may be less computationally expensive. The chosen radial basis function method provided a clear pressure map, making it easy to understand the data presented. However, a limitation of choosing a method producing a smooth gradient is that it may be misleading in terms of accuracy. Whilst the nearest-neighbour method of interpolation was less clear to read, there was no indication of the relationship between pressures in different locations. For these reasons, clinical testing is vital with an improved version of the tool to determine the acceptability of the interpolation method chosen.

Before implementation of the software in the clinical environment, it is important to map the sensor locations more precisely from each socket to its corresponding 3D model. Each person's socket should be created as a 3D model with the exact sensor locations, using current scanning technologies. This will increase the accuracy of the interpolated colour map. For the proof of concept, this was not deemed a necessity due to the increased cost and complexity of adding this before receiving feedback from clinicians of the technology's potential clinical utility.

Commercial technologies are available that provide live visual feedback of pressure within the socket. Novel.de has created Pliance sensors that can measure the pressure and load distribution of any object on a 2D grid, similar to the initial testing of interpolation methods in the current study [24] In contrast to the sensors developed by Hopkins et al., which were used to inform the software created in this study, the Pliance sensors do not cover the entire surface of the socket, only a target area. The Pliance system must be wired to a Windows computer via a control unit for data transfer to enable visualisation, which limits the accessibility and usefulness of the tool.

F-Socket, created by Tekscan [26], is well used in research studies [28–34]. The sensors are connected via USB to a computer with a range of 100 m [26]. As such, it is not

wireless, creating a limited movement range and application. The wireless capabilities of the system created in this study allow for wider clinical applications compared to the F-Socket. However, the F-Socket software provides more detailed information compared to the created software in this study about peak pressures in the socket, centre of force, and force–time graphs [26]. The software displays both 2D and 3D data and allows for side-by-side comparisons of different test sessions, either providing information about the socket as a whole or focusing on regions of interest [26]. Both graphical data and movie files can be imported and exported into the software [26]. These additional features of the F-Socket software should be considered for future iterations of the software created in this study.

The Adapttech INSIGHT system [25] is the most similar to the tool created in this paper; however, it only shows a circular interpolation around each sensor rather than a colour map across the entire socket. Generally, only four strips of eight sensors are used for testing [35]; therefore, little of the socket area is covered. The Adapttech software is only available for iOS devices (typically iPad), which receives the data and displays them in real time, as well as saving it for future access (acting as a patient record system), and requires a wireless internet connection for use. The localised interpolation around each sensor does not give an impression of the overall pressure distribution and was potentially misleading. The interpolation of the pressure is radial and centred around each sensor's location. Therefore, where the distance between sensors is larger than the interpolation is shown as blue which depicts the standard pressure within the socket. This implies that there are no high-pressure areas in the region between the sensors and that the areas directly around the sensors had decreasing amounts of pressure (as the interpolation between high pressure and standard pressure will always have a negative gradient).

The existing commercial technologies are associated with high costs and have limitations for their usage, e.g., requiring an internet connection or a device with a specific operating system. The application created in this study can be used on any laptop or desktop computer with a Bluetooth connection. The platform-agnostic and internet-independent nature of the application allows this tool to be accessible to a broader audience, especially in low-cost and remote settings, as additional costs to meet the application requirements are not incurred. If Bluetooth connectivity is not built in, a dongle can be used instead.

In addition, an advantage of this new tool is that it could be used with different pressure sensor technologies which transmit data via Bluetooth, with only minor changes to the code. The proof-of-concept tool has been created to complement the sensors created by Hopkins et al. [27]; however, it can be adapted to allow easy connection to different hardware. To use the created software with different sensors, further investigation of the hardware would be needed to determine the appropriateness of the interpolation methods and real-time updating. This would require the hardware to have an appropriate sampling frequency and spatial resolution. The Python script required to receive Bluetooth data from the hardware needs to be individual for different sensors. Whilst data communication is not standard due to the differences in the way developers choose to structure the data transmitted, the Bluetooth protocols remain the same. To facilitate easy change, only one script in the code needs to be changed.

The feedback from prosthetists and physiotherapists is vital for the development of any software to be integrated into the clinical environment. These are the primary end users of the feedback tool in its current form, and therefore, their needs should be catered for. The initial design has shown promise of clinical value; however, further work is required to have greater benefit in the clinical environment. Functionality should be added to monitor the motion of the prosthesis user during the testing period to facilitate an easier understanding of the movement that causes the different pressures in the socket. It is also vital to test the technology with prosthesis users as, though they are not directly using the tool, they must accept this new technology into their treatment plan. Without the acceptance of prosthesis users, uptake of this new technology may be limited. A proof-of-concept application has been created which demonstrates the technological feasibility of creating an application to display real-time pressure information across the surface of a prosthetic socket. However, the tool must be tested with prosthetists, physiotherapists, and prosthesis users to understand the clinical utility of the tool. Such consultation is vital before progressing with the development of the application, to ensure it meets the needs of the target users and provides maximum value.

Before the application can be used to receive personal data via Bluetooth, it is essential to build in the required data security characteristics of the application to protect the data. It would also be beneficial to add functionality to allow users to select the sensors they would like to connect to after scanning the surrounding area—both the functionality to choose the type of sensors being used (e.g., brand) and also specifically which sensors to connect to (instead of defining one address in the code).

#### 4. Materials and Methods

Given the limitations of existing products, it was decided the feedback tool must function as a cross-platform tool. The software needed to be compatible with different pressure sensor technologies, with only minor technical adjustments. The proof-of-concept tool has been created to complement the sensors created by Hopkins et al. [27]. It was created to be easy to use, requiring no additional training, technical knowledge, or use of the internet. The pressure data from the sensors should be updated in real time, as the application receives them to allow for the data to be used immediately for clinical decision making. Immediate use of the data means the tool can be used in consultations, giving instant feedback to inform clinical decision making.

Previously collected pressure data of a walking test, using the Hopkins et al. sensors at a rate of 200 Hz, in a CSV file was used to evaluate different interpolation methods. The study was approved by NRES Committee London–Riverside (ICREC reference: 15/LO/1633, IRAS project ID: 177122). The data were collected from a 24-year-old female participant with a unilateral, transtibial amputation and used a total surface bearing socket. All 144 sensors were used in the socket of the participant, arranged in 12 strips of 12 sensors distributed around the prosthetic socket. The raw data were used, without any post-processing that may alter the signals, to minimise the computational time required to perform these methods. It was deemed appropriate to use the raw data to minimise any latency that may impact the pressure map updating in real time. Due to the application being created in a sandbox environment (isolated from any external network connection, e.g., Bluetooth, internet) when using personal data, there was no need to focus on data security aspects for the proof-of-concept application.

To choose an appropriate interpolation method, a 2D  $156 \times 156$  grid was used to include the  $12 \times 12$  sensor array (evenly distributed) and a border for extrapolation. Whilst the sensors in the socket may not be evenly distributed, this idealised representation was deemed appropriate to assess interpolation methods, as the sensors are distributed across the inner surface of the socket. The grid was created using built-in functions from the NumPy [36] library in Python and visualised using matplotlib [37]. Sensor data collected through participant testing and saved into CSV files were imported into Python for use. Five time points were tested from a single gait cycle of the participant, each 250 milliseconds apart. Figures were generated with the four different interpolation methods for each time point. The time points were chosen to assess whether there was a difference in how the interpolation was performed across the gait cycle.

Four multivariable interpolation methods were evaluated, each compatible with unstructured data, and therefore appropriate for both 2D and 3D data: Clough–Tocher (CT) [38], radial basis function (RBF) [39], nearest neighbour [40] (NN) and linear N dimension (LND) [41]. The most appropriate interpolation method was identified based on the observed clarity of the image, ease of interpretation of the pressure distribution in the socket, and the ability to extrapolate outside the boundaries of the sensor data. The

chosen interpolation method from the 2D testing was taken forward for testing on a 3D socket model.

A computational model of a prosthetic socket was obtained by laser scanning a casting mould of a transtibial prosthetic socket. The model was cleaned up, including fixing any holes and artifacts produced during the scanning process, using Geomagic Wrap [42], 3-Matic was used to add thickness to the model, simulating that of a socket. The 144 vertices representing the sensors were picked out manually using Paraview (Various Locations, USA). For the proof of concept, the real-life sensor locations were approximated on the model: evenly distributed in 12 lines of 12 sensors to represent the sensor strips.

The 3D model was imported into Python, and the sensor locations and values were assigned to the relevant vertices. The Visualisation Toolkit library was used to create a colour map using the chosen radial basis function interpolation from the 2D testing between the vertices assigned sensor values.

For the model to be accessible to a clinical audience, it was decided that a desktop application was required for them to view the model. The creation of the application would also allow connection to the Bluetooth sensors, with the data being used to update the colour map on the 3D model, as data were received in real time.

PyQt was chosen to create the desktop application's graphical user interface (GUI) and additional functionality, as it allows for the application to run on all major operating systems. For running the application, the host device requires a Bluetooth connection. PyQt's Bluetooth module was utilised to implement the relevant Bluetooth functionality. The sensors' Bluetooth address was specified in the code for simplicity, so the host device searches for and connects to only the specified sensors in this proof-of-concept application.

To evaluate the clinical benefit of the tool, feedback interviews with rehabilitation clinicians (eight prosthetists, seven physiotherapists) were conducted. The feedback methods were approved by the Imperial College London Joint Research Compliance Office [ICREC Reference: 20IC6373]. The interviews occurred via video conferencing and each lasted no more than one hour. During the feedback session, the desktop application was demonstrated to the participants showing the process of opening the application, inputting prosthesis user details, connecting to the sensors, and showing the updating 3D model as data were fed into it. The responses to questions asked during the interviews were used to determine the benefit of the tool and areas to be prioritised for future development.

### 5. Conclusions

Visual feedback has been shown to have a positive effect on rehabilitation when it complements traditional methods. The proof-of-concept tool created in this study provides live information about the pressure distribution inside a prosthetic socket when linked to an appropriate sensor network. A desktop application was created that can run on any of the standard operating systems, has no requirement for internet connection, can be connected to any sensor network with minor changes to the code, and has been designed to be easy to use without the requirement for technical knowledge or training.

Further improvements and testing should be completed; however, the current application shows the potential of a clinical product. End-user feedback is vital for the development of both the design and functionality of this application. Feedback from rehabilitation clinicians in the clinical environment, the end users of this tool, should be used to guide further improvements.

**Author Contributions:** Conceptualisation, S.T. and A.H.M.; data curation, M.O.H.; formal analysis, S.T.; investigation, S.T., S.J. and A.P.; methodology, S.T., S.J. and A.P.; software, S.T.; supervision, M.O.H. and A.H.M.; validation, S.T., M.O.H. and A.H.M.; visualisation, S.T., S.J. and A.P.; writing—original draft preparation, S.T., S.J. and A.P.; writing—review and editing, S.T., S.J., A.P., M.O.H. and A.H.M. All authors have read and agreed to the published version of the manuscript.

**Funding:** This work was conducted under the auspices of the Royal British Legion Centre for Blast Injury Studies at Imperial College London. The authors would like to acknowledge the financial support of the Royal British Legion. No grant number is given. **Institutional Review Board Statement:** The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board (or Ethics Committee) of Integrated Research Application System (IRAS: 177122 and 20 October 2015).

Informed Consent Statement: Informed consent was obtained from all subjects involved in this study.

**Data Availability Statement:** The data presented in this study are available on request from the corresponding author. The data are not publicly available due to ethics restrictions on participant data.

Conflicts of Interest: The authors declare no conflict of interest.

## References

- 1. Safari, R.; Meier, M.R. Systematic review of effects of current transtibial prosthetic socket designs—Part 1: Qualitative outcomes. *J. Rehabil. Res. Dev.* **2015**, *52*, 491–508. [CrossRef] [PubMed]
- 2. Mak, A.F.; Zhang, M.; Boone, D. State-of-the-art research in lower-limb prosthetic biomechanics-socket interface: A review. *J. Rehabil. Res. Dev.* **2001**, *38*, 161–173.
- 3. Haggstrom, E.E.; Hansson, E.; Hagberg, K. Comparison of prosthetic costs and service between osseointegrated and conventional suspended transfemoral prostheses. *Prosthet. Orthot. Int.* **2013**, *37*, 152–160. [CrossRef] [PubMed]
- 4. Pezzin, E.L.; Dillingham, T.R.; MacKenzie, E.J.; Ephraim, P.; Rossbach, P. Use and satisfaction with prosthetic limb devices and related services. *Arch. Phys. Med. Rehabil.* **2004**, *85*, 723–729. [CrossRef] [PubMed]
- Ghoseiri, K.; Safari, R. Prevalence of heat and perspiration discomfort inside prostheses: Literature review. J. Rehabil. Res. Dev. 2014, 51, 855–868. [CrossRef]
- 6. Hagberg, K.; Brånemark, R. Consequences of non-vascular trans-femoral amputation. *Prosthet. Orthot. Int.* **2001**, *25*, 186–194. [CrossRef]
- Klute, G.K.; Huff, E.; Ledoux, W. Does Activity Affect Residual Limb Skin Temperatures? *Clin. Orthop. Relat. Res.* 2014, 472, 3062–3067. [CrossRef]
- 8. Stekelenburg, A.; Gawlitta, D.; Bader, D.L.; Oomens, C.W. Deep Tissue Injury: How Deep is Our Understanding? *Arch. Phys. Med. Rehabil.* **2008**, *89*, 1410–1413. [CrossRef] [PubMed]
- 9. Webber, C.M.; Davis, B.L. Design of a novel prosthetic socket: Assessment of the thermal performance. *J. Biomech.* 2015, 48, 1294–1299. [CrossRef]
- 10. Bouten, C.V.; Oomens, C.W.; Baaijens, F.P.; Bader, D.L. The etiology of pressure ulcers: Skin deep or muscle bound? *Arch. Phys. Med. Rehabil.* 2003, *84*, 616–619. [CrossRef]
- 11. Pirouzi, G.; Abu Osman, N.A.; Eshraghi, A.; Ali, S.; Gholizadeh, H.; Abas, W.A.B.W. Review of the Socket Design and Interface Pressure Measurement for Transtibial Prosthesis. *Sci. World J.* **2014**, 2014, 1–9. [CrossRef] [PubMed]
- Portnoy, S.; van Haare, J.; Geers, R.P.; Kristal, A.; Siev-Ner, I.; Seelen, H.A.; Oomens, C.W.; Gefen, A. Real-time subject-specific analyses of dynamic internal tissue loads in the residual limb of transtibial amputees. *Med. Eng. Phys.* 2010, 32, 312–323. [CrossRef] [PubMed]
- 13. Paternò, L.; Ibrahimi, M.; Rosini, E.; Menfi, G.; Monaco, V.; Gruppioni, E.; Ricotti, L.; Menciassi, A. Residual limb volume fluctuations in transfemoral amputees. *Sci. Rep.* **2021**, *11*, 1–11. [CrossRef]
- 14. Sanders, J.E.; Fatone, S. Residual limb volume change: Systematic review of measurement and management. *J. Rehabil. Res. Dev.* **2011**, *48*, 949–986. [CrossRef]
- 15. Escamilla-Nunez, R.; Michelini, A.; Andrysek, J. Biofeedback Systems for Gait Rehabilitation of Individuals with Lower-Limb Amputation: A Systematic Review. *Sensors* 2020, 20, 1628. [CrossRef]
- 16. Miled, H.M.; Youssef, I.B.H.; Boudoukhane, S.; Salah, S.; El Ayeb, M.; Jellad, A.; Frih, Z.B.S. Interest of visual biofeedback rehabilitation on balance in the lower limb amputee. *Ann. Phys. Rehabil. Med.* **2017**, *60*, e53. [CrossRef]
- 17. Quiñones, I.; Vela, E.; Pérez, A.I.; Alessi, A.; Urrusti, J.L.; Cepeda, D. Biofeedback system for transfemoral amputees rehabilitation. 2009 *Pan Am. Health Care Exch.* 2009, 148–152. [CrossRef]
- Tamburella, F.; Moreno, J.C.; Valenzuela, D.S.H.; Pisotta, I.; Iosa, M.; Cincotti, F.; Mattia, D.; Pons, J.L.; Molinari, M. Influences of the biofeedback content on robotic post-stroke gait rehabilitation: Electromyographic vs joint torque biofeedback. *J. Neuroeng. Rehabil.* 2019, *16*, 1–17. [CrossRef]
- 19. Dou, P.; Jia, X.; Suo, S.; Wang, R.; Zhang, M. Pressure distribution at the stump/socket interface in transtibial amputees during walking on stairs, slope and non-flat road. *Clin. Biomech.* **2006**, *21*, 1067–1073. [CrossRef]
- 20. Dakhil, N.; Evin, M.; Llari, M.; Mo, F.; Thefenne, L.; Liu, T.; Behr, M. Is skin pressure a relevant factor for socket assessment in patients with lower limb amputation? *Technol. Health Care* **2019**, *27*, 669–677. [CrossRef]
- 21. Sanders, E.J.; Lam, D.; Dralle, A.J.; Okumura, R. Interface pressures and shear stresses at thirteen socket sites on two persons with transtibial amputation. *J. Rehabil. Res. Dev.* **1997**, *34*, 19–43. [PubMed]
- Carrigan, W.; Nothnagle, C.; Savant, P.; Gao, F.; Wijesundara, M. Pneumatic actuator inserts for interface pressure mapping and fit improvement in lower extremity prosthetics. In Proceedings of the 2016 6th IEEE International Conference on Biomedical Robotics and Biomechatronics (BioRob), Singapore, 26–29 June 2016; pp. 574–579.

- Laszczak, P.; McGrath, M.; Tang, J.; Gao, J.; Jiang, L.; Bader, D.; Moser, D.; Zahedi, S. A pressure and shear sensor system for stress measurement at lower limb residuum/socket interface. *Med. Eng. Phys.* 2016, *38*, 695–700. [CrossRef] [PubMed]
- 24. Novel. Pliance Sensors. Available online: https://www.novel.de/wp-content/uploads/2019/06/pliance\_sensor\_piano\_en.pdf (accessed on 2 April 2020).
- 25. AdaptTech. How It Works. 2007. Available online: https://www.adapttech.eu/howitworks#howinsightworks (accessed on 26 October 2020).
- 26. Tekscan. F-Socket System. Available online: https://www.tekscan.com/products-solutions/systems/f-socket-system (accessed on 26 February 2021).
- 27. Hopkins, M.; Vaidyanathan, R.; McGregor, A.H. Examination of the Performance Characteristics of Velostat as an In-Socket Pressure Sensor. *IEEE Sens. J.* 2020, 20, 6992–7000. [CrossRef]
- 28. Ali, S.; Abu Osman, N.A.; Eshraghi, A.; Gholizadeh, H.; Razak, N.A.B.A.; Abas, W.A.B.B.W. Interface pressure in transtibial socket during ascent and descent on stairs and its effect on patient satisfaction. *Clin. Biomech.* **2013**, *28*, 994–999. [CrossRef] [PubMed]
- 29. Eshraghi, A.; Abu Osman, N.A.; Gholizadeh, H.; Ali, S.; Abas, W.A.B.W. Interface Stress in Socket/Residual Limb with Transtibial Prosthetic Suspension Systems During Locomotion on Slopes and Stairs. *Am. J. Phys. Med. Rehabil.* **2015**, *94*, 1–10. [CrossRef]
- 30. Al-Fakih, E.A.; Abu Osman, N.A.; Adikan, F.R.M. Techniques for Interface Stress Measurements within Prosthetic Sockets of Transtibial Amputees: A Review of the Past 50 Years of Research. *Sensors* **2016**, *16*, 1119. [CrossRef]
- 31. Convery, P.; Buis, A.W.P. Conventional patellar-tendon-bearing (PTB) socket/stump interface dynamic pressure distributions recorded during the prosthetic stance phase of gait of a transibilial amputee. *Prosthet. Orthot. Int.* **1998**, 22, 193–198. [CrossRef]
- 32. Neumann, E.S.; Wong, J.S.; Drollinger, R.L. Concepts of Pressure in an Ischial Containment Socket: Perception. *JPO J. Prosthet. Orthot.* **2005**, *17*, 12–20. [CrossRef]
- 33. Kahle, J.T.; Highsmith, M.J. Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure, and preference: Ischial containment versus brimless. *J. Rehabil. Res. Dev.* **2013**, *50*, 1241–1252. [CrossRef]
- 34. Polliack, A.A.; Sieh, R.C.; Craig, D.D.; Landsberger, S.; McNeil, D.R.; Ayyappa, E. Scientific validation of two commercial pressure sensor systems for prosthetic socket fit. *Prosthet. Orthot. Int.* **2000**, *24*, 63–73. [CrossRef]
- 35. AdaptTech. Webinar. 2020. Available online: https://www.adapttech.eu/webinar (accessed on 26 October 2020).
- 36. Nbsp. NumPy. 2021. Available online: https://numpy.org/ (accessed on 15 May 2021).
- 37. MatPlotLib. 2021. Available online: https://matplotlib.org/ (accessed on 15 May 2021).
- Python. Scipy.Interpolate.CloughTocher2DInterpolator. Available online: https://docs.scipy.org/doc/scipy/reference/ generated/scipy.interpolate.CloughTocher2DInterpolator.html#scipy.interpolate.CloughTocher2DInterpolator (accessed on 12 September 2018).
- 39. Python. Scipy.Interpolate.Rbf. Available online: https://docs.scipy.org/doc/scipy/reference/generated/scipy.interpolate.Rbf. html#scipy.interpolate.Rbf (accessed on 12 September 2018).
- Python. Scipy.Interpolate.NearestNDInterpolator. Available online: https://docs.scipy.org/doc/scipy/reference/generated/ scipy.interpolate.NearestNDInterpolator.html (accessed on 12 September 2018).
- 41. Python. Scipy.Interpolate.LinearNDInterpolator. Available online: https://docs.scipy.org/doc/scipy/reference/generated/scipy. interpolate.LinearNDInterpolator.html#scipy.interpolate.LinearNDInterpolator (accessed on 12 September 2018).
- 42. GoMeasure3D. Geomagic Wrap Software. Available online: https://gomeasure3d.com/geomagic-wrap-software/ (accessed on 4 May 2020).