

ORIGINAL RESEARCH

Evaluating the Effectiveness of Transtibial Prosthetic Socket Shape Design Using Artificial Intelligence: A Clinical Comparison With Traditional Plaster Cast Socket Designs



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Abstract

Objective: To investigate the feasibility of creating an artificial intelligence (AI) algorithm to enhance prosthetic socket shapes for transtibial prostheses, aiming for a less operator-dependent, standardized approach.

Design: The study comprised 2 phases: first, developing an AI algorithm in a cross-sectional study to predict prosthetic socket shapes. Second, testing the AI-predicted digitally measured and standardized designed (DMSD) prosthetic socket against a manually measured and designed (MMD) prosthetic socket in a 2-week within-subject cross-sectional study.

Setting: The study was done at the rehabilitation department of the Radboud University Medical Center in Nijmegen, the Netherlands.

Participants: The AI algorithm was developed using retrospective data from 116 patients from a Dutch orthopedic company, OIM Orthopedie, and tested on 10 randomly selected participants from Papenburg Orthopedie.

Interventions: Utilization of an AI algorithm to enhance the shape of a transtibial prosthetic socket.

Main Outcome Measures: The algorithm was optimized to minimize the error in the test set. Participants' socket comfort score and fitting ratings from an independent physiotherapist and prosthetist were collected.

Results: Predicted prosthetic shapes deviated by 2.51 mm from the actual designs. In total, 8 of 10 DMSD and all 10 MMD-prosthetic sockets were satisfactory for home testing. Participants rated DMSD-prosthetic sockets at 7.1 ± 2.2 (n=8) and MMD-prosthetic sockets at 6.6 ± 1.2 (n=10) on average.

Conclusions: The study demonstrates promising results for using an AI algorithm in prosthetic socket design, but long-term effectiveness and refinement for improved comfort and fit in more deviant cases are necessary.

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Transtibial amputation is one of the most prevalent forms of amputation, with a cumulative incidence of approximately (7.4/100,000) in the Netherlands in 2012–2021 and a mean number of

amputations of 1260 per year.¹ Amputations may arise from vascular diseases, traumatic events, or cancer, significantly impacting the affected patient's quality of life.^{2,3} To enhance well-being and mobility, a transtibial prosthesis presents a potential solution.⁴

The prosthetic socket is the patient's residual limb interface and is pivotal. Its primary objective is establishing a comfortable,

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secure, and stable connection between the residual limb and the prosthetic device. The shape of a prosthetic socket needs to be well-designed considering the patient-specific shape of the stump. An optimal socket shape design limits the movement between the residual limb and the socket, which could otherwise cause soft-tissue damage and could ultimately lead to nonuse of the prosthesis and a decrease in quality of life. In the manual design process of transtibial prosthetic sockets, both the shape capture and the socket design are carried out manually using plaster. This process is time-consuming and requires the prosthetist's knowledge and experience to create a high-quality prosthetic socket shape.^{5,6}

Consequently, a recent trend toward digitization has emerged in patient-specific socket design.⁵⁻¹⁰ This digital process utilizes 3-dimensional (3D) scanners to generate a digital model of the residual limb, design software to refine the 3D model into the desired socket shape, and 3D printing to fabricate the created model.⁸ While this digital approach offers numerous benefits, the success of the digital design process still heavily depends on the prosthetist's expertise and experience. Despite sophisticated software and technology, manual adjustments are still performed, albeit in a digital format.¹¹

One potential solution for this knowledge and experience dependency could be to standardize the design process. Standardization, in this case, is the process of eliminating or reducing any operator effects on the design process to achieve the same or similar results. Some studies have attempted to standardize the corrections made to the positive mold by, for example, calculating mechanical interactions between the socket and the residual limb to gain insight into pressure distribution (finite element analysis), knowledge-based tools, and mathematical functions to support the prosthetist during the design process.^{9,12-14} However, these studies do not integrate data from a more extensive data set, including multiple patients and their prosthetic designs.

Artificial intelligence (AI) is a popular technique for performing automated tasks and is increasingly integrated into various medical domains. However, despite the growing availability of data accompanied by the digitization trend in prosthetic socket design, the implementation of AI within prosthetics remains limited.^{7,15-17}

Therefore, the objective of this study was to explore the feasibility of using an AI algorithm to make the shape design of transtibial prosthetic sockets less operator-dependent. The first phase of this research encompassed the development of the AI algorithm, while the second phase entailed a comparative study to assess the satisfaction of prosthetic socket shapes designed with the developed AI algorithm and those created with the traditional manual plaster cast method.

Methods

This study was divided into 2 phases: (1) AI algorithm development and (2) comparing 2 types of prosthetic sockets. The

List of abbreviations:

AI	artificial intelligence
DMSD	digitally measured and standardized designed
FEA	finite element analysis
MMD	manually measured and designed
SCS	socket comfort score

Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) was used to prepare the manuscript and ensure methodological quality. Ethical approval for this study was obtained from Radboud University Medical Center, Nijmegen, the Netherlands (number 2021-8142).

Phase 1: AI algorithm development

Study design, participants, and data collection

Phase 1 was a cross-sectional study in which all available pseudonymized data from patients with transtibial amputations were retrospectively gathered at the orthopedic company OIM Orthopedie, Assen, the Netherlands. Patients were eligible for inclusion if they were above 18 years of age. Data from both initial prosthetic sockets and replacements were included. For each patient, a pair of 3D stereolithography files were provided, representing the residual limb 3D scan and the corresponding 3D design of the prosthetic socket shape. The scans of the residual limb were obtained using the M4D Scanner (Rodin4D, Mérignac, France), and sockets were designed by experienced prosthetists using Rodin4D software (Rodin4D).

Algorithm development

Initially, the 3D scan of the residual limb and the corresponding model of the prosthetic socket shape were oriented using a small set of anatomical reference points. For patients with a right-sided transtibial amputation, their data were mirrored along the midline to simulate a left-sided amputation. The models underwent resampling using MeshMonk, a morphable model toolbox. With the use of MeshMonk, it is ensured that all meshes have a uniform construction of all 3D coordinates.¹⁸

Next, the data set was split into a training set and a test set, with the test set comprising 15% of the entire data set. The average adjustments were initially applied, followed by fine-tuning through DiffusionNet to give more weight to patient-specific adjustments. DiffusionNet is an AI algorithm used for processing 3D geometric data. The average adjustments and the adjustments through the AI algorithm were employed to automatically determine the shape of the prosthetic socket based on the residual limb's shape.¹⁹ As an output, the algorithm computed the distance of each point on the residual limb model to the prosthetic socket in the direction of the vertex normal. These distances represent the necessary modifications to the residual limb's shape for obtaining the prosthetic socket shape design.¹⁸ Figure 1 illustrates the workflow for predicting a prosthetic socket shape using AI.

The network was optimized to minimize the error of the vertex normal distances on the training set and evaluated on the test set.

Phase 2: comparison of 2 types of prosthetic sockets

Study design and participants

After developing the AI algorithm in phase 1, its performance was assessed in phase 2 through a within-subject cross-sectional study. The participants tested 2 types of prosthetic sockets: the manually measured and designed (MMD) prosthetic socket (MMD-prosthetic socket) and the digitally measured and standardized designed (DMSD) prosthetic socket (DMSD-prosthetic socket), in which the socket shape was predicted by the AI algorithm developed in phase 1. Adults with transtibial amputation and no socket-related problems were eligible for inclusion. Participants were

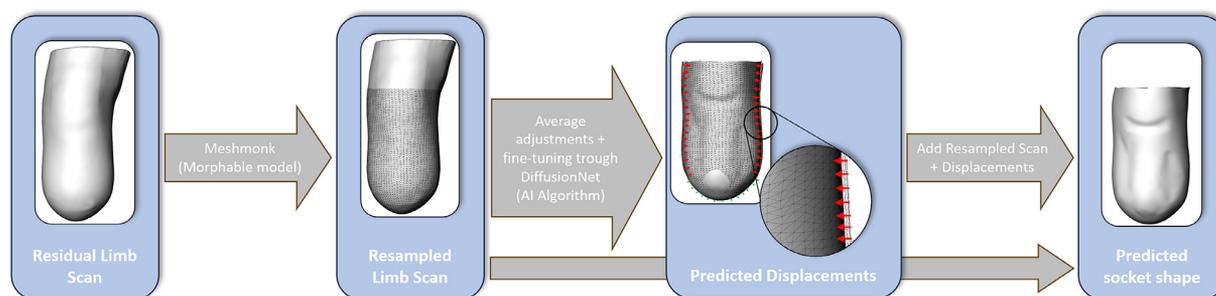


Fig 1 The workflow of predicting the prosthetic socket shape using artificial intelligence (AI) is illustrated. First, the aligned scan of the residual limb is resampled using MeshMonk to ensure uniform construction of all 3-dimensional coordinates. The average adjustments were initially applied, followed by fine-tuning through DiffusionNet (the AI algorithm trained using the existing data set). The predicted distances represent the adjustments needed to shape the residual limb into a prosthetic socket design. These distances serve as output data to develop the predicted socket shape.

randomly selected from the database of Papenburg Orthopedie, Ravenstein, the Netherlands. Written informed consent was obtained from the participants before the intake.

Transtibial prosthetic socket fabrication

For each participant, 2 prosthetic sockets were made: (1) MMD-prosthetic socket: a single prosthetist with 32 years of experience manually captured the stump geometry and designed the socket shape using plaster; (2) DMSD-prosthetic socket: the stump geometry was digitally captured using the Einscanner H (Shining 3D, Huangzhou, China), and the socket shape design was accomplished by the AI algorithm, integrated into the design software 3DMedX, 3D Lab Radboud University Medical Center, Nijmegen, the Netherlands.

To ensure the blinding of both the participant and the independent raters, both sockets were manufactured using an Ultimaker S5 3D printer (Ultimaker, Utrecht, the Netherlands) with Tough PLA material (Ultimaker). Additionally, a trimline tool was employed to design the proximal part of both sockets, and the adapter connection was positioned and connected identically to ensure uniform prosthetic alignment. Only the researcher and prosthetist knew which socket was the MMD- or the DMSD-prosthetic socket.

Transtibial prosthetic socket alignment

The prostheses were aligned using the standard methodology: bench alignment, static alignment, and dynamic alignment. The LASAR Posture 3D (OttoBock) was used for the static alignment.²⁰ To ensure that both prosthetic sockets were aligned equally, both sockets were aligned with the same prosthetic foot. An Xtend Connect adapter (Loth Fabenim, Nieuwegein, The Netherlands) allowed the prosthetic foot to be changed independently to each socket (fig 2).

Study procedure

The participants had 3 appointments with the research team: (1) measurement of the residual limb to obtain the stump geometry; (2) alignment of the prosthetic limb with both sockets; and (3) final evaluation of the prosthetic sockets.

During the second appointment, both prosthetic sockets were used for at least 30 minutes, after which a decision had to be made regarding the suitability of testing one or both sockets at home. The treating prosthetist and an independent physiotherapist evaluated both the prosthetic sockets fitting on a 0-10 scale (where 0

means the poorest fit and 10 means best fit) and the participant evaluated the comfort of the socket using a socket comfort score (SCS, a scale of 0-10, where 0 means most uncomfortable and 10 means most comfortable 0-10).²¹ If a socket scored satisfactorily ($SCS \geq 6$), it was approved for home testing. If necessary ($SCS < 6$) and possible, the socket volume and/or trimline were manually corrected using heating and molding. After adjustments, the socket was re-evaluated. All modifications were carefully documented.

All satisfactory sockets were worn for 1 consecutive week during daily living, and the sequence was randomized using drawing lots. The participants were asked to rank user satisfaction for each prosthetic socket.



Fig 2 Set-up of the prosthetic socket with Xtend Connect adapter (1.) and the Actigraph sensor (2.) to measure wearing time. The Xtend Connect adaptor consists of a base unit with a male pyramid adaptor placed under each socket (LTHA100-BM) and 1 female adaptor (LTHA100-QF) to connect the sockets independently to the foot.

During the third appointment, the fitting of both prosthetic sockets was rated by an independent prosthetist and an independent physiotherapist.

Outcome measures

A self-designed questionnaire was used to assess prosthetic socket satisfaction because existing questionnaires were deemed insufficiently specific (see [Supplemental Appendix S1](#), available online only at <http://www.archives-pmr.org/>). The self-constructed questionnaire includes 1 validated element: the SCS. The prosthetic sockets were evaluated both in stance and during gait to minimize the influence of alignment. Additionally, any pressure points or potential skin issues caused by the prosthetic sockets and the number of thin cotton stump socks (Loth Fabenim) worn were documented. Any additional comments, findings, and recommendations were also recorded.

To verify that the prosthetic sockets were indeed tested at home, 2 Actigraph activity sensors (ProCare BV, Amsterdam, the Netherlands) were affixed to each prosthetic socket (see [fig 2](#)). These sensors measured the duration of wear and the number of steps taken while wearing the prosthetic socket.

Statistical analysis

Mean and standard deviation values were calculated for the SCS provided by the participant, the prosthetic socket fitting provided by the independent prosthetist and the independent physiotherapist, and the average hours of usage and steps taken per day for each type of prosthetic socket. Pairing sample *t* tests were conducted to test significance. Effect sizes were calculated using Cohen's *d* to assess the magnitude of differences in satisfaction ratings between the 2 types of prosthetic sockets.

Results

Phase 1: AI algorithm development

Demographic details data set

The data set used in this study comprises 116 3D scans of residual limbs along with corresponding socket shapes designed by 19 different prosthetists ([Table 1](#)).

AI results

The predicted prosthetic shapes matched the actual prosthetic shape designs in the test set with a deviation of 2.51 mm ([fig 3](#)).

Phase 2: Comparison of 2 types of prosthetic sockets

Participants

We enrolled 10 participants with transtibial amputations ([Table 2](#)).

Outcome measurements

Eight out of 10 DMSD-prosthetic sockets and all 10 MMD-prosthetic sockets were deemed satisfactory and could be tested at home. The 2 DMSD-prosthetic sockets that received

Table 1 Demographic characteristics of included patients were used to create the artificial intelligence algorithm

Gender		
Male	n = 71	(61%)
Female	n = 30	(26%)
Unknown	n = 15	(13%)
Age		
Mean (y)	65.9 ± 16.1	
Unknown	n = 18	
Side of amputation		
Left	n = 60	(52%)
Right	n = 56	(48%)
Liner material		
Copolymer	n = 14	(12%)
Silicon	n = 85	(73%)
Poly-urethane	n = 2	(2%)
Unknown	n = 15	(13%)
Liner thickness		
3 mm	n = 15	(13%)
6 mm	n = 76	(66%)
Unknown	n = 25	(21%)
Suspension type		
Pin	n = 34	(29%)
Cushion	n = 60	(52%)
Seal-in	n = 3	(3%)
Lanyard	n = 2	(2%)
Unknown	n = 17	(14%)
K-level		
1	n = 10	(9%)
2	n = 33	(28%)
3	n = 43	(37%)
4	n = 15	(13%)
Unknown	n = 15	(13%)

unsatisfactory ratings from all assessors had a socket volume that was too small, making it impossible to fit the socket properly. Another DMSD-prosthetic socket was also slightly tight; however, by slightly bending the proximal back of the socket to create more space, this socket was not excluded. In all other cases, no adjustments had to be made to the socket shape. In some cases, stump socks were added to achieve a proper fit. The decision to add stump socks was made collaboratively between the physical therapist, prosthetist, and participant to achieve the best possible fit for the prosthetic socket. One sock was added for the DMSD-prosthetic sockets for 3 participants. For the MMD-prosthetic sockets, 1 sock was added for 3 participants, while 2 socks were added for 1 participant.

Based on all independent assessments, a unanimous agreement was reached that the DMSD-prosthetic socket was preferred over the MMD-prosthetic socket in 2 out of 8 cases. The participant, the independent prosthetist, and the independent physiotherapist scored the DMSD-prosthetic sockets on average with respectively 6.6 ± 1.2 , 6.5 ± 1.0 , and 6.1 ± 0.9 ($n=8$) and the MMD-prosthetic socket with respectively 7.1 ± 2.2 , 7.0 ± 0.9 , and 6.7 ± 1.1 ($n=10$) during gait. Differences were not statistically significant; effect sizes were 0.43, 0.50, and 0.71, respectively, based on $n=8$. No pressure points or wounds were observed for either the DMSD-prosthetic socket or the MMD-prosthetic socket after 1 week of testing for each socket. The summarized satisfaction

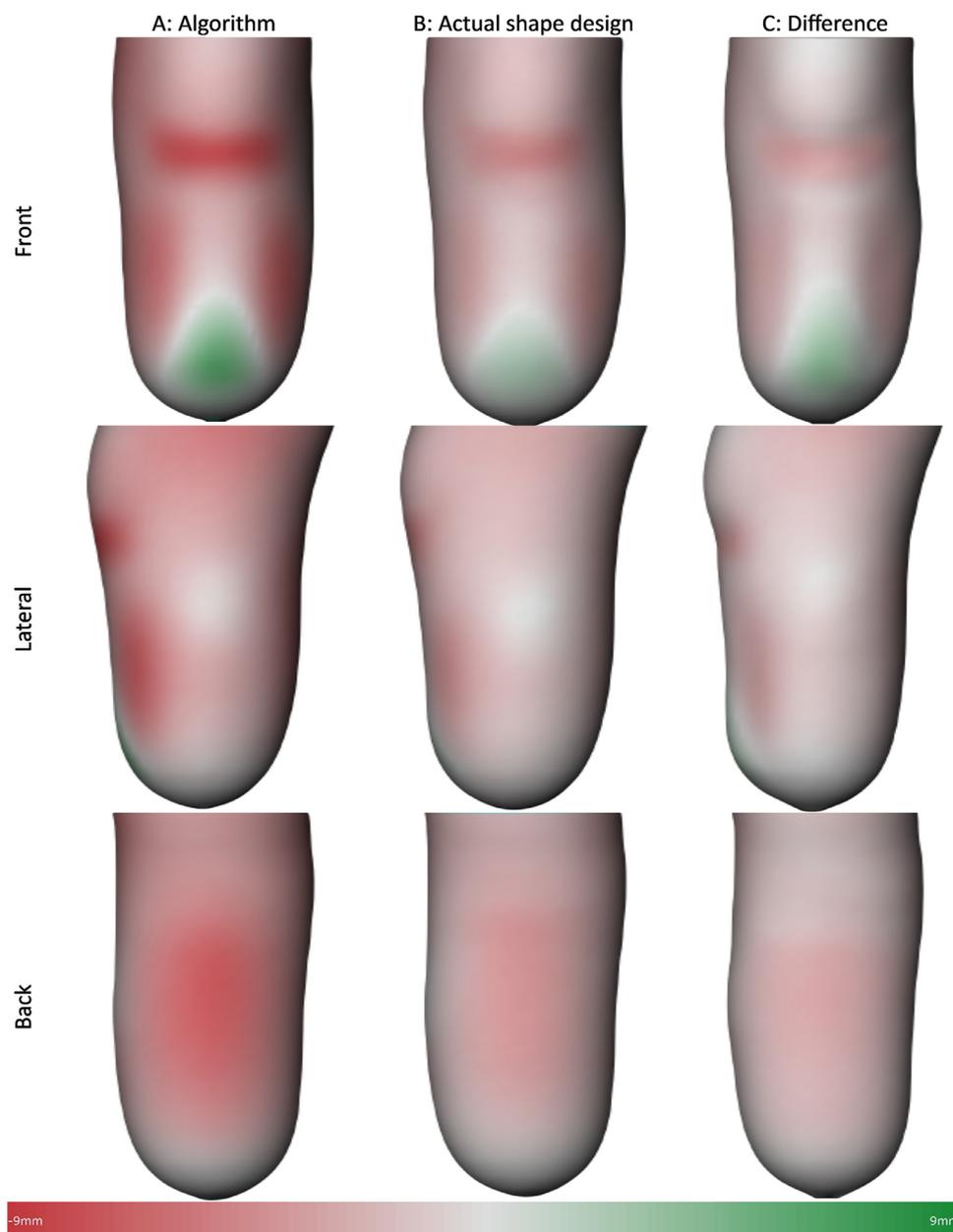


Fig 3 Prosthetic socket shapes derived from residual stumps within the test set are shown in front, lateral, and back views. A represents the average predictions generated by the algorithm, while B displays the average actual prosthetic socket shapes from the test set. C illustrates the mean deviation between algorithm predictions and the actual prosthetic shape design. The prosthetic socket shape deviation ranges from -9 mm to $+9$ mm. Green shades indicate an outward correction (increased volume compared to the stump), observed at the end of the tibia. Conversely, red shades signify an inward correction (reduced volume compared to the stump), particularly around the stump and notably at the lateral and medial sides compared to the tibia, the patella region, and the back of the stump. White indicates no change in volume observed at the fibula head.

scores are shown in [Table 3](#). In [Supplemental Appendix S2](#), the scores per participant are presented.

The activity measurements ([Supplemental Appendix S3](#)) revealed that most patients used both prosthetic sockets equally. The DMSD-prosthetic socket was worn for an average of 11.6 ± 3.1 hours per day with an average of 2583 ± 1706 steps ($n=8$). The MMD-prosthetic socket was worn for an average of 10.0 ± 3.5 hours per day and included an average of 2918 ± 2622 steps ($n=10$).

Discussion

The primary aim of this study was to investigate the feasibility of using AI to make the shape design of transtibial prosthetic sockets less operator-dependent. This research involved the development of an AI algorithm trained to predict the shape of transtibial prosthetic sockets based on the 3D morphology of a residual limb. To assess the effectiveness of the developed AI algorithm, a comparative evaluation was conducted with 10 participants, wherein

Table 2 Characteristics of the participants and their prostheses

Patient number	1	2	3	4	5	6	7	8	9	10
Sex	Female	Male	Male	Male	Male	Male	Male	Male	Male	Male
Age (y)	65	69	57	27	73	69	66	75	57	79
Body mass (kg)	59	90	121	63	75	90	105	110	70	72
Length (cm)	156	194	182	172	168	179	180	180	173	172
Amputation side	Left	Right	Right	Left	Right	Left	Left	Left	Left	Both
Reason of amputation	Trauma	Diabetes	Diabetes	Trauma	Diabetes	Tumor	Diabetes	Diabetes	Infection	Diabetes
Amputation year	2019	2017	2016	2012	2022	2017	2017	2020	2023	2019
Number of worn prosthetic sockets	3	3	5	15-20	3	3	4	3	3	4
Number of years of use of a prosthesis	3	5	2	10	0,5	4,5	6	25	11	4

DMSD-prosthetic socket shapes were compared with MMD-prosthetic socket shapes.

Although 2 of the 10 DMSD-prosthetic sockets could not be fitted because of insufficient socket volume, the results for the remaining 8 participants showed consistency. The mean SCS scores from the perspectives of the participants and prosthetists were relatively closely aligned and not statistically significant, indicating the potential of AI in transtibial prosthetic socket design. However, from the physiotherapist's perspective, there is more room for improvement, considering the effect size of 0.71, although the SCS means were also not statistically significantly different. Nevertheless, these statistics remain challenging to contextualize given the minimal detectable change of the SCS (2.7 points) and the small sample size.²² However, these results can be used for an a priori sample size calculation for future larger studies.

Comparing the results of this study with those of other research is challenging due to the scarcity of studies performed in the field of AI for prosthetic socket shape design. Moreover, to the best of the author's knowledge, no studies have been found that employ data-driven prosthetic socket design and test the design on participants with transtibial amputations. Nevertheless, there are noteworthy trends where research groups aim to achieve similar objectives, aiming to make the shape design more resilient than solely relying on the expertise of a patient's prosthetist. For instance, the application of finite element analysis to seek support for socket shapes.^{12,13} However, there are substantial barriers to the clinical implementation of these techniques, including challenges in obtaining imaging data, lengthy solver times for the models, and the need for a trained user to develop and interpret the finite element model.⁷

Table 3 Satisfaction scores for the MMD- and DMSD-prosthetic socket after 1-week testing at home

	MMD-Prosthetic Socket:	DMSD-Prosthetic Socket:
Socket comfort score participants		
Stance:		
Mean (\pm SD):	7.5 \pm 2.2	7.1 \pm 1.6
Median (2 ^e -3 ^e quartile):	8.5 (5.5-9.0)	6.5 (6.0-8.8)
Gait:		
Mean (\pm SD):	7.1 \pm 2.2	6.6 \pm 1.2
Median (2 ^e -3 ^e quartile):	8.0 (4.8 -9.0)	6.0 (6.0-7.8)
Preferred socket choice participants:	8/10	2/8
Fitting score independent prosthetist		
Stance:		
Mean (\pm SD):	7.0 \pm 1.3	6.6 \pm 0.7
Median (2 ^e -3 ^e quartile):	7.5 (6.5 -8.0)	6.5 (6.0-7.0)
Gait:		
Mean (\pm SD):	7.0 \pm 0.9	6.5 \pm 1.0
Median (2 ^e -3 ^e quartile):	7.0 (6.8-8.0)	6.0 (6.0-7.8)
Preferred socket choice prosthetist:	8/10	2/8
Fitting score independent physiotherapist		
Stance:		
Mean (\pm SD):	6.7 \pm 1.3	6.9 \pm 1.1
Median (2 ^e -3 ^e quartile):	7.0 (6.0-7.3)	6.5 (6.0-7.8)
Gait:		
Mean (\pm SD):	6.7 \pm 1.1	6.1 \pm 0.9
Median (2 ^e -3 ^e quartile):	6.5 (6.0-7.3)	6.5 (5.0-7.0)
Preferred socket choice prosthetist:	8/10	2/8

Abbreviations: DMSD, digitally measured and standardized designed; MMD, manually measured and designed.

Study limitations

The developed AI algorithm exhibited a mean deviation of 2.51 mm from the test set; however, the absence of established standards for acceptable variation in prosthetic socket shapes complicates the interpretation and clinical value. The data collected in this study comprises socket designs created by a single prosthetist per patient, leaving the effect of interobserver and intra-observer variability uncertain. Diverse data for the test set is crucial to evaluating the algorithm effectively. Addressing this, a new test set needs to be created by multiple prosthetists who must fabricate sockets for the same stumps, subsequently assessed by an independent prosthetist, the participant, and a physiotherapist to determine acceptable variation. This approach will facilitate a more accurate assessment of whether the AI algorithm's predictions fall within an acceptable range.

The accuracy of the AI algorithm depends on the quantity and quality of data. One limitation of this study is the lack of diversity in the data used to train the algorithm. The current algorithm is trained on data from a limited range of residual limb lengths, thicknesses, and types. Therefore, the algorithm might not generalize well to all different types of residual limbs. This was also observed for 2 DMSD-prosthetic sockets that were unsuitable for use because of their small volumes, resulting in an improper fit around the residual limb. Both of these residual limbs were narrower compared to the residual limbs of the other participants included in phase 2. It is possible that the AI algorithm might not have been adequately trained with data from narrower residual limbs, leading to a relatively excessive reduction in volume in the prosthetic socket design. Similarly, relatively thick residual limbs had a wider fit because of relatively less volume reduction. To address this limitation, more data from a broader range of residual limb sizes and shapes should be included in the training data of the AI algorithm.

Furthermore, the performance of the AI algorithm might be enhanced when patient-specific information is presented to the algorithm. The data set used in phase 1 was collected retrospectively and, therefore, included missing patient characteristics and had a limited set of variables, making it impossible to include patient-specific information in the development of the AI algorithm. However, we anticipate that incorporating data such as body mass index, time after amputation, reason for amputation, and gender could be valuable in developing the AI algorithm, resulting in even more personalized socket designs.

The influence of different types of prosthetic sockets, such as suction and pin and/or lock suspension systems or the use of pre-load during stump geometry measurements, is also relevant for a prosthetic socket design. However, because of the relatively small data set available and the absence of this information for a significant portion of the data set, it was not used in the development of the AI algorithm. The predictions made in this study represent an average across different socket techniques. To further enhance accuracy, it would be valuable to distinguish the unique characteristics and variables associated with each type of prosthetic socket.

Another essential factor is the quality of the data set. Ideally, the data set should consist of scans of well-designed prosthetic sockets of users with a high satisfaction score. The current data set lacks information on satisfaction levels, whether the prosthetic sockets were actually worn by the patients, and whether manual adjustments to the socket volume were made later on. Hence, it is crucial to collect feedback regarding the comfort and fit of the prosthetic socket to ensure the accuracy of the source data. This feedback can then be used in data selection and to train the AI algorithm in identifying critical features of well-designed prosthetic sockets to optimize the fit.

When conducting a comparative study, it is essential to consider all variables that could affect SCS. While socket volume, both in general and specific areas, significantly influences the comfort ratings of the socket, it is crucial to recognize that additional factors, such as trim lines (particularly their height at the calf) and alignment, also influence the SCS. Efforts have been made to keep most factors equal between the MMD and DMSD-prosthetic sockets. However, achieving a completely identical alignment proved challenging, which may have affected the evaluation of the socket shapes. It would be useful to conduct research with more objective measurement methods to assess prosthetic socket comfort. For example, pressure sensors in the socket can measure the contact of specific areas of the residual limb. Further research is needed to explore whether validated measurement methods can be used in this regard.

In this study, activity sensors were used to monitor participants' wearing time and the number of steps taken with the prosthesis. Results indicated that both the MMD-prosthetic socket and the DMSD-prosthetic sockets were worn similarly. However, activity levels were found to be lower compared to the literature. A systematic review by Wong et al,²³ which encompassed 21 papers, concluded that participants with transtibial prostheses took an average of 5929 ± 3047 steps per day. The reduced activity level among the included participants in this study may have influenced perceptions of socket comfort and the likelihood of developing pressure spots.

The AI algorithm created in this study has been integrated into the design software 3DMedX[®] (3D Lab Radboud University Medical Center, Nijmegen, The Netherlands), which streamlines the entire design process in a standardized and automated manner. With the aid of this software, patients with limited computer or digital design knowledge can digitally design a prosthetic socket in just 3 minutes. Furthermore, the potential benefits of this software may extend to low-income countries. The data gathered from Dutch prosthetists can be valuable in assisting colleagues in other regions with fewer skills and experience using a data-driven design approach through a user-friendly software platform.

Conclusions

The results of this study demonstrate the potential of AI algorithms to make the design process of transtibial prosthetic sockets less operator-dependent. AI-designed prosthetic sockets showed proximate satisfaction levels to manually designed sockets using plaster, indicating that AI technology could provide a feasible and effective solution for prosthetic socket shape design. This could potentially lead to a faster production process and a more consistent fit for people with an amputation. Further research and development are needed to enhance the AI algorithm's performance.

Keywords

3D printing; 3D scanning; AI; Artificial intelligence; Design; Prosthetic socket; Standardized; Transtibial; Transtibial amputation

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