

## Chapter 9

# PCAD: Prosthetic Comfort by Design—An Educational Innovation in Prosthetic Measurement

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### Abstract

Over 40 million people with lower-limb amputation have to overcome significant challenges to acquire and use a prosthetic device. For patients seeking to regain mobility, the most important aspect in rehabilitation is the fit and comfort of a simple low-cost connecting socket. But, with each socket currently crafted entirely by hand, the existing trial-and-error fitting approach can take many hours of clinical time, and multiple visits. With ongoing resource and skill shortages, the biggest issue now facing providers and payers of prosthetic care is the time it takes for a prosthesis to be designed, produced, and delivered. Healthcare systems seek cost-effective solutions that drive productivity and improve outcomes. By modernising prosthetic care provision through advanced digital fitting and fulfilment technologies, prosthetic comfort by design (PCAD) can enhance patient accessibility to significantly improve the quality of life for millions of prosthetic users worldwide.

Based on extensive patient-centric research conducted at the United Kingdom's (UK) leading prosthetic teaching centre, PCADs have developed a transformative, digital limb-scanning solution that dramatically improves the productivity of socket fitting process. What used to take hours, now takes seconds. Our proprietary solution produces an accurate 3D representation of a limb under "loaded" conditions to provide a more reliable socket fit, reduced tissue pressure, and improved long-term patient comfort. The image is then converted into a digitised software measurement model with which to rapidly deliver an ultra-comfortable, uniquely fitted socket produced using modern fabrication techniques. Data produced also provide a unique patient record that can then be used to monitor limb health, track physical changes over time, or submitted as evidence for reimbursement purposes with healthcare payers. Integrating seamlessly into today's modern clinics, PCAD's process is data driven, consistent, and automated; such that socket fitting is no longer limited by the availability, skill, and experience of individual human prosthetist's to improve the productivity of prosthetic care provision.

**Keywords:** *Prosthetics, Shape-capture, Socket, CAD, CAM*

### Introduction

Worldwide incidence of amputation in the developed world is estimated to be around 1.5/10,000. Numbers are rising due to increased life expectancy and the rise in non-communicable diseases such as diabetes (forecast to reach 522 million by 2030)<sup>1</sup>. The diabetic population has an increased risk of lower

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<sup>1</sup>J. Aaron Barnes et al., "Epidemiology and Risk of Amputation in Patients With Diabetes Mellitus and Peripheral Artery Disease," *Arteriosclerosis Thrombosis and Vascular Biology* 40, no. 8 (June 25, 2020): 1808–17, <https://doi.org/10.1161/atvbaha.120.314595>.

limb amputation compared with the general population and is a focus for worldwide patient care<sup>2</sup>. In the United Kingdom (UK) there are approximately 75,000 prosthetic limb users, 60% of these are transtibial (below the knee) amputations<sup>3</sup>.

The WHO estimates 35–40 million people currently require prosthetic/orthotic services, with only 1 in 10 persons having access, most being in richer nations<sup>4</sup>. A significant global workforce shortfall exists in the field of prosthetics/orthotics, with a limited number of training programs worldwide<sup>5,6</sup>. Prosthetic treatment spans a person's lifetime, with users receiving ongoing evaluation, provision of devices, maintenance, repair, and replacements over time. Statistics present the current unmet need and highlight the likelihood of significant underservicing of those who require prosthetic care.

Arguably, the most important aspect of a prosthetic limb is the socket fit, which provides the interface between the limb user and the prosthesis. Poorly fitting sockets cause pain, tissue breakdown, and reduced activity. To design an appropriately fitting socket that provides the user with comfort and functionality, the shape of the person's limb must be captured accurately and reliably.

Traditionally, when a person is deemed to need a new artificial limb, their residual limb is cast to capture the shape (Figure 1).



**Figure 1:** Conventional transtibial residual limb shape capture using Plaster of Paris.

As the shape is captured in an unloaded condition, the cast must be filled and modified in a laborious fashion by a skilled artisan clinician. It is not possible to routinely accurately measure the loaded shape of the residual limb in clinic. No record of the volume, circumferential, or diameter measures is currently possible in a controlled repeatable way. Such measurements are taken using simple tape measures and diameter sticks and are prone to be inaccurate, which in turn leads to multiple reworkings.

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<sup>2</sup>World Health Organization: WHO. "Diabetes," November 14, 2024. <https://www.who.int/news-room/fact-sheets/detail/diabetes>.

<sup>3</sup>F. Davie-Smith and H. Scott, "The Scottish Physiotherapy Amputee Research Group (Sparg)," *Physiotherapy* 101 (May 1, 2015): e300–301, <https://doi.org/10.1016/j.physio.2015.03.496>.

<sup>4</sup>World Health Organization: WHO. "Assistive Technology," January 2, 2014. <https://www.who.int/news-room/fact-sheets/detail/assistive-technology>.

<sup>5</sup>United Nations. "Convention on the Rights of Persons with Disabilities (CRPD) | Division for Inclusive Social Development (DISD)," n.d. <https://social.desa.un.org/issues/disability/crpd/convention-on-the-rights-of-persons-with-disabilities-crpd>.

<sup>6</sup>World Health Organization: WHO. WHO Standards for Prosthetic and Orthotics, 2017. <http://apps.who.int/iris/bitstream/10665/259209/1/9789241512480-part1-eng>.

Modification has demonstrated variable results between and within clinicians (Figure 2)<sup>7</sup>. The resulting socket fit is variable and may result in pain, skin breakdown, and socket refit. Additional appointments are inconvenient for prosthetic users as they are inefficient to clinical services and may result in increased travel (increasing environmental impact) and waste of materials should socket remakes be required<sup>8</sup>.



**Figure 2:** Conventional transtibial residual limb shape modification using Plaster of Paris.

Pressure systems using air and water are commonly used to capture shape to simulate loaded conditions. Shapes captured under pressurised conditions have demonstrated the creation of prosthetic sockets with lower peak pressures in a more repeatable manner with no modification required (Figure 3)<sup>9</sup>. Current pressure systems use traditional messy Plaster of Paris or expensive direct socket manufacture techniques to capture shape.



**Figure 3:** Pressure casting transtibial residual limb shape capture using Plaster of Paris (Ossur Icecast™).

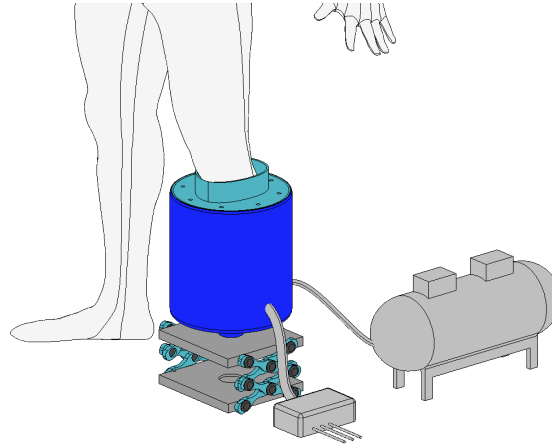
Computer-aided design (CAD) scanners may also be used to capture the shape of the residual limb (Figure 4). Currently, CAD systems are generally handheld and require considerable practitioner skill and time. Although these systems are highly accurate, they replicate the process of capturing the limb

<sup>7</sup>Nadhira Al Shuaili et al., “Transtibial Prosthetic Socket Design and Suspension Mechanism: A Literature Review,” *JPO Journal of Prosthetics and Orthotics* 31, no. 4 (2019): 224–45, <https://doi.org/10.1097/jpo.0000000000000258>.

<sup>8</sup>Eddie Suyi Yang, Navid Aslani, and Anthony McGarry, “Influences and Trends of Various Shape-capture Methods on Outcomes in Trans-tibial Prosthetics,” *Prosthetics and Orthotics International* 43, no. 5 (2019): 540–55, <https://doi.org/10.1177/0309364619865424>.

<sup>9</sup>Mohammad Reza Safari and Margrit Regula Meier, “Systematic Review of Effects of Current Transtibial Prosthetic Socket designs—Part 2: Quantitative Outcomes,” *The Journal of Rehabilitation Research and Development* 52, no. 5 (January 1, 2015): 509–26, <https://doi.org/10.1682/jrrd.2014.08.0184>.

in a seated (unloaded) position. The shape obtained therefore requires further modification to ensure optimal prosthetic socket fit during standing and walking. Similar to traditional Plaster of Paris modification, time-consuming CAD adjustments made by individual clinicians are based on subjective interpretation and require substantial practitioner expertise.



**Figure 4:** PCAD transtibial residual limb shape capture (Concept).

Although CAD and pressure systems are routinely used, these two methods have never been combined to capture the shape of a residual limb. The ability to achieve this in an automated manner would enable repeatable, quantified, loaded shape capture at lower cost and in less time, without the need for additional artisan modification. This would reduce costs for health services while providing improved fit and comfort for users.

An independent market report (Hauring-Medical-Management, 2020) was commissioned to assess the potential market for the PCAD™ system. Interviews were conducted with clinicians, sales representatives, and major commercial company executives. Consensus was highly positive regarding the potential of weight-bearing shape capture technology within this \$1.3 billion market. No competitor systems currently exist.

This paper describes the construction of a preliminary alpha prototype (PCAD™ system). The project involves design and build of a pre-commercial prototype PCAD™ system to satisfy MHRA regulatory requirements for a Randomised Control Trial in a prosthetic NHS centre in which a series of outcome measurements will provide a practical, clinical, and economic evidence bases to assist technique adoption.

## Results and Discussion

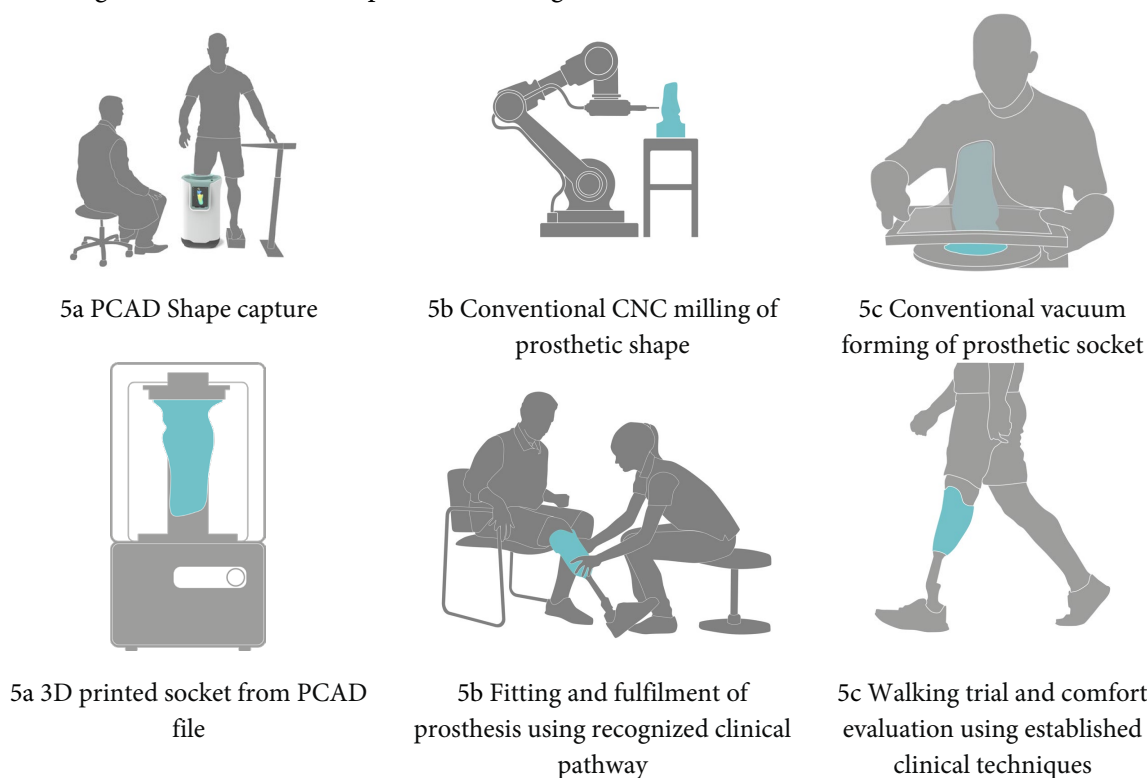
PCAD™ has a simple concept: Scanning must be conducted under loaded conditions to avoid variable post-scan modification.

Patients insert their residual limb into a tank aperture between parallel bars. The unit is pressurised representing load (Figure 4).

The prosthetist presses a button on the keyboard or screen, initiating multiple scanners that capture the residual limb in 2–3 seconds. A CAD file is reconstructed on-screen, the tank is depressurised, and the patient removes their residual limb. As no modification of the scan is required, an MPEG/JPEG file is

displayed to the clinician and patient to confirm that the shape has been accurately captured. A hidden STL file is then sent to an approved PCAD™ manufacturer for prosthetic socket production. Using approved manufacturers allows economies of scale, reducing per-limb costs and ensuring consistent quality. Cost savings are passed to clinics, supporting economical purchasing while maintaining a sustainable business model.

By combining pressure and CAD technologies, PCAD™ enables efficient, automated socket fitting, delivering enhanced comfort and reduced pain for patients. The system can be used by clinicians at all levels, providing a consistent measurement process that produces sockets correctly fitted on the first attempt, without variable modification stages. PCAD™ has the potential to improve overall industry performance and standardisation among clinicians and is fully compatible with centralised fabrication of sockets using traditional or additive manufacturing techniques, thereby improving quality and reducing costs (Figure 5). Central manufacture ensures quality, consistency, and significant cost savings. Centralised data further enable analysis and continuous improvement of fit as PCAD™ learns from a large dataset of scans and prosthetic fittings.



**Figure 5:** PCAD patient journey within established clinical pathways.

As can be seen from the workflow diagram in Figure 5, the PCAD system not only fits with existing clinical pathways, it also removes some steps and therefore reduces the time to achieve an accurate residual limb capture. This is valuable for prosthetic clinics and for patients. Our innovation, therefore, has real tangible economic, patient care, and healthcare delivery benefits and efficiencies.

PCAD has already progressed early laboratory R&D limb scanning concept (TRL3), through a functional “looks like” alpha prototype (TRL4), a de-risked System Architecture prototype (TRL5), and recently completed development of a fully functional Clinical Investigation prototype (TRL6).

The clinical trial unit was successfully built to exacting ISO approvals standards, and tested on patients during an approved Health Research Authority (HRA) Formative User Study in June 2025. The pilot clinical investigation study was undertaken at the Leeds prosthetic teaching hospital, in partnership with Steeper Group, one of the largest NHS providers. The investigation demonstrated to ability to scan, measure, and fit custom prosthetic sockets and that PCADs scanning unit could fit within existing workflows to improve clinic efficiency.

The study involved six patients in a randomised controlled trial and evaluated the performance of the PCAD scanning system compared with conventional unloaded CAD methods that required onscreen modification. Patients were scanned using both a currently used scanner (Biosculptor™) and a novel automated scanner (PCAD) and randomly allocated a prosthetic socket created by one or other methods.

Results demonstrated considerable potential for time savings with accurate scanning when using the PCAD system. Further technical refinement is needed to optimise the sealing process and height adjustment mechanism in order to enhance user experience, improve the process of physical entry to the system, and improve scan quality and efficiency. Funding has been secured to advance these developments (TRL 6/7) within the medical device regulatory framework (Figure 6).



**Figure 6:** PCAD transtibial residual limb shape capture clinical investigation.

PCAD technology will facilitate service delivery worldwide where the scanner can be used in-situ in different locations for limb shape capture and the data file sent for socket production within existing external manufacturing sites in centralised manufacturing hubs. The service then has the potential to

be offered in many locations where the rates of amputation are increasing and where services are not currently available.

## Intellectual Property

PCAD's operations are founded on a defined Intellectual Property (IP) strategy. Core Background IP (BIP), owned by the University of Strathclyde, will be licensed to PCAD alongside relevant know-how. Key assets have been filed, with prosecution in progress and an EU patent granted.

The patented PCAD™ shape capture technique enables efficient, loaded scanning of residual limbs, producing accurate, modifiable-free data and facilitating longitudinal monitoring. This innovation enhances prosthetic fit quality and provides a basis for broader clinical applications, including diabetic and vascular volume assessment and orthotic scanning.

## Conclusion

By shifting from plaster casting to digitally enabled workflows captured under loaded conditions, prosthetic provision can become more efficient, more affordable and more accessible, ultimately improving comfort and outcomes for patients while enhancing productivity for clinicians. PCAD has been conceived and invented for this purpose. Realising this digital future has the potential not only to transform prosthetic care delivery but also to narrow longstanding inequities in global access.

## Acknowledgements

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