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Design of manikin for testing of residual-limb shape-capture method: Technical note

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Abstract—Consensus is still lacking on how best to capture the shape of a residual limb. Computer-aided design systems have not proven more accurate, repeatable, or reliable than traditional plaster of paris methods. Research is limited in design, relates to clinical trials, and is based on opinions and clinical experience. Many outcome measurements are based on qualitative estimations of prosthetic fit or patient feedback rather than quantitative measurements. Research must identify the most accurate, repeatable, and reliable methods for residual-limb shape capture under conditions most likely to enhance socket fit. Measurement is difficult because a reference grid is required for identifying the residual limb's axis for ensuring direct comparison. This article describes a manikin production method for testing the shape capture of the residual limb. Diameters and volume were measured at specific levels with a programmable computer numerical control milling machine and a displacement tool, with a combined accuracy of 5 micrometers.

Key words: artificial limbs, CAD, computer-aided design, manikin, measurement, plaster of paris, prosthetics, rehabilitation, residual limb, shape capture, transtibial.

INTRODUCTION

The best method of residual limb shape capture with computer-aided design (CAD) has not yet been conclusively determined. Commercially available systems use both contact and noncontact methods and employ different modes of shape capture (mechanical digitizers, electromagnetic scanners, optical laser systems, and digital photography). Additionally, available systems do not permit the limb to be loaded while data are collected.

Consensus is growing that the shape of the residual limb must be captured accurately and consistently, although the degree to which this is required continues to be debated [1–3]. If CAD is to be accepted as a method of shape capture, it must be scientifically validated, affordable, and easy to use. Furthermore, CAD must also be at least as accurate, repeatable, and reliable as traditional plaster of paris (POP) methods.

Ideally, an actual residual limb would be used to test and compare the shape-capture methods. The objective of using an actual residual limb would be to explore the effect of limb shape and tissue compliance on CAD sensing, particularly where systems rely on a contact method of shape capture. However, for assessing and comparing scanning systems, a fixed system of reference is needed. In an actual residual limb, this would be the underlying skeleton, but determining the location of the skeleton in a living person requires an imaging technique such as X-rays or magnetic resonance imaging. Therefore, evaluating systems in vivo is not practical. A further source of

Abbreviations: CAD = computer-aided design, CNC = computer numerical control, POP = plaster of paris.

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difficulty would be changes in the shape and volume of the unsupported residual limb over time. The use of a cadaveric residuum would allow access to the skeleton; a more practical alternative to this is the use of a manikin.

Testing of CAD systems has been previously investigated on hard, shaped plaster models [4–5]; hard or compressible foam models [5]; or foam models with the addition of cotton socks and a gel liner [6]. Hard models may be perfectly adequate for testing noncontact systems. However, during an evaluation of a CAD system that contacts the residual limb during the shape-capture process, deflecting or changing the shape of a hard model by exerting pressure would be difficult. Changes in user pressure may more strongly affect measurements of a deformable shape than a hard shape, because measurements would be susceptible to deformation when force is applied. While deformable shapes are more realistic, foam is compressible and may allow smaller volumes to be recorded if pressure from a contact CAD system was applied during the shape-capture process. To reduce this effect, a volume-consistent deformable manikin is required.

Because transtibial amputation is the most common level of amputation, accounting for almost half of the 5,000 new referrals to prosthetics service centers each year in the United Kingdom [7], manufacturing the manikin in the shape of a transtibial residual limb seemed appropriate.

This article describes the design and production method of a manikin to test the shape capture of the residual limb with a variety of systems. The manikin was designed to be deformable with constant volume. To achieve this, we selected medical-grade, two-part silicone rubber (model RTV6166, General Electric Company; Fairfield, Connecticut), which has proven successful for simulating tissue while maintaining constant volume [8]. This material is deformable but exhibits linear behavior to at least 30 percent strain with a stiffness of 780 N/m.

Figure 1.
Manikin skeleton structure (model ME43™; Adam,Rouilly; Sittingbourne, Kent, United Kingdom).

METHODS

We used an anatomical functional model of a right knee joint to simulate the shape, size, and location of the skeletal structure within the manikin (model ME43™, Adam,Rouilly; Sittingbourne, Kent, United Kingdom) (**Figure 1**). A "muscle" was fixed in position on the posterior aspect of the skeletal model to represent the deformable nature of musculature within a residual limb. The muscle, then placed in a polypropylene net to simulate the muscle fibers, consisted of a condom filled with hydroscopic granules mixed with water. The muscle maintained a constant volume but was more deformable than the silicone that surrounded it (**Figure 2**).

We produced a POP cast replicating the dimensions of a transtibial residual limb, corresponding to the tibial diameter and length measurements of the manikin skeleton (**Figure 3**). We used a hexagonal mandrel pole to ensure that alignment could be reproduced [9]. We placed the plaster model into the Deckel computer numerical control (CNC) milling machine (Michael Deckel GmbH & Co KG; Weilheim, Germany) so we could accurately place

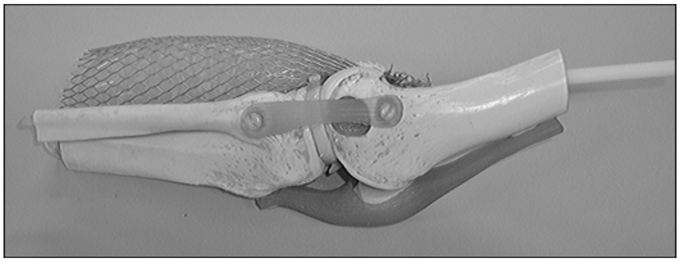

Figure 2.
Skeleton of manikin with “muscle” attached.

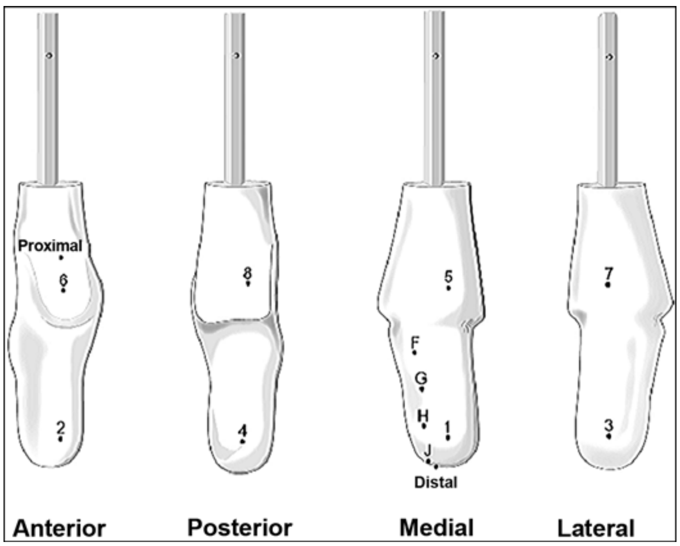

Figure 3.
Illustration of transtibial residual-limb model showing views of landmark positions F, G, H, and J. Numbers used for orientation of model for reference when model is scanned with computer-aided design machine

the data lines and reference points (**Figure 3**) to map the surface (**Figure 4**). These data lines and reference points provided the baseline for future shape comparisons.

We measured the diameters of the shape three times at four intervals (points F, G, H, and J), using a programmable data acquisition system. The plaster model was removed and replaced between each of the three measurements. The system consisted of a displacement transducer (series 543 1DF Dynamic Indicator, Mitutoyo America Corporation; Aurora, Illinois), mounted on the Deckel programmable CNC milling machine. The system was accurate to 5 µm. We then plotted the surface coordinates and positioned the landmarks to calculate anteroposterior diameters, mediolateral diameters, and volumes

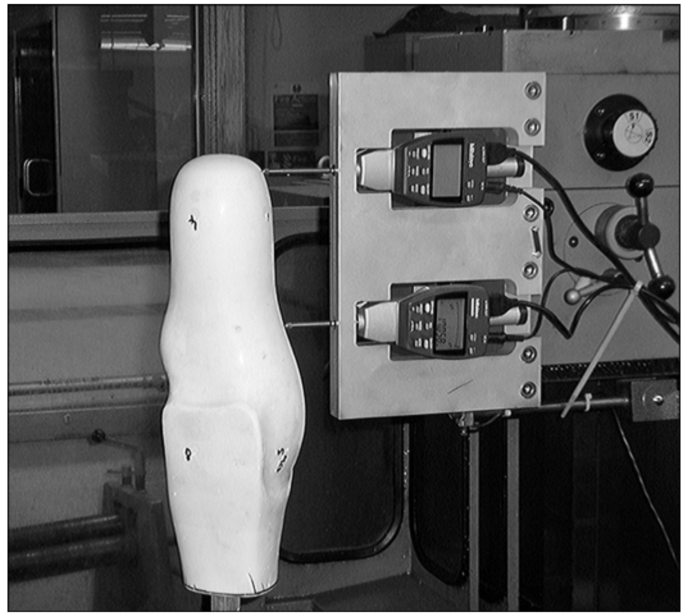

Figure 4.
Placement of reference marks on transtibial residual-limb model.

between levels. We calculated the mean value of three scans taken by the dynamic indicator measurement system. The volume of the shape was then determinable between any two circumferential lines between levels F and the end of the model.

We draped a Northplex™ (North Sea Plastics, Ltd; Glasgow, Scotland) former over the plaster model. Once draped, the plaster model and former were placed into the copying jig [9] to allow a hexagonal mandrel post to be bonded distally. We then carefully removed the Northplex™ former from the model and bivalved it so that it could be mechanically fitted together. To provide an outer “skin” to the model, we then built up layers of silicone around the inside of the plastic former. We used Otto Bock silicone (617H44 silicone gel, shore hardness 50, Otto Bock HealthCare; Minneapolis, Minnesota), which was swilled around the plastic former in several layers until the thickness of the opaque silicone was approximately 3 to 4 mm (**Figure 5**).

We fixed the anatomical knee joint in 5° flexion and bonded it to a wooden top plate (shaped to fit the proximal aperture of the Northplex™ former) with the hexagonal mandrel post attached (**Figure 6**).

We then repositioned the former within the copying jig and bonded the top plate to the proximal end of the plastic former, which contained the skeletal model and

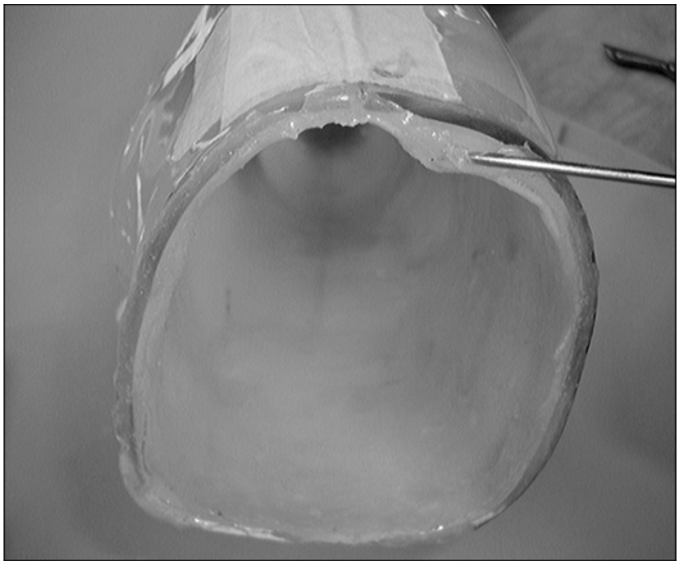

Figure 5.
Outer silicone “skin” of transtibial residual-limb model.

Figure 6.
Attachment of proximal plate and alignment post to transtibial residual-limb model.

muscle (**Figure 7**). This repositioning left a void that was filled by injecting two-part silicone rubber (RTV6166, General Electric Company) through a hole in the top plate.

Once the silicone cured, we removed the skeletal manikin from the bivalved plastic former and transferred the positions of the landmarks through the clear plastic to the model (**Figure 8**). To validate the accuracy of the copying procedure and determine whether errors had been introduced during the filling procedure, we placed the original former within the jig and filled it three times with POP (**Figure 9**). We then remeasured the diameters and volumes of each plaster cast at each landmark using the data acquisition system and compared them with the original plaster cast.

To ensure that the original shape of the manikin remained constant in all positions, we took digital photographs of the manikin with a camera mounted on a tripod. A scale was added (**Figure 10**). Photographs taken at six consecutive 5 min intervals were inputted into Adobe Photoshop (CS3 extended edition, Adobe Systems Inc; San Jose, California), which allowed us to convert the photographs and measure to scale at each landmark position.

To ensure that the manikin recovered its original dimensions following deformation, we traced it with an electromagnetic scanner six times and photographed it before and after each trace. Again, no difference was observed in the landmarks measured on photographs taken after each trace.

RESULTS

Following the copying procedure, we noted no difference between the dimensions of the original and filled casts. Thus, the surfaces had been reproduced to an accuracy of 5 µm. We observed no difference in the measurement of landmarks on photographs taken at different times. The manikin’s shape remained stable over this period, which we considered longer than the period required to complete a typical CAD scan and was therefore considered appropriate for use. We observed no difference in the landmarks measured on photographs taken after

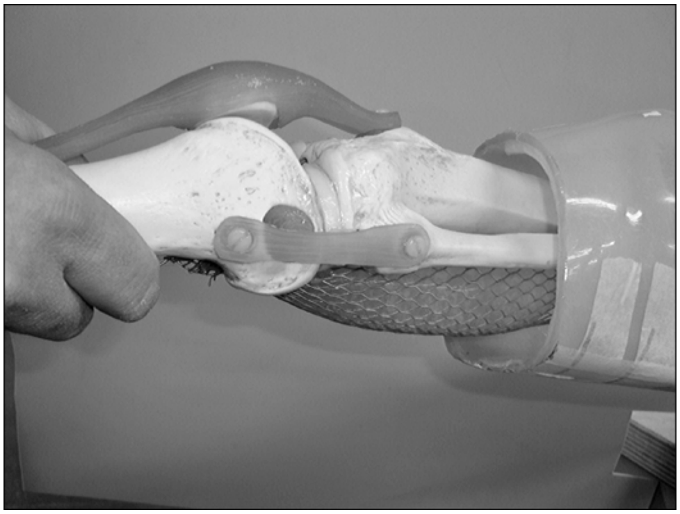

Figure 7.
Placement of skeletal manikin into former of transtibial residual-limb model.

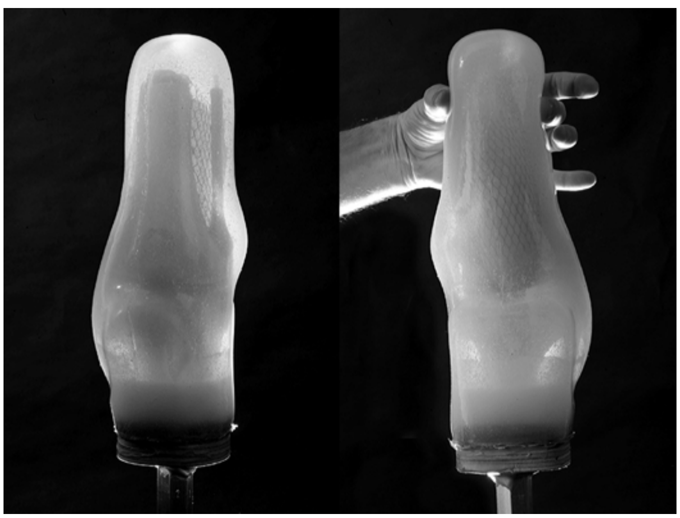

Figure 8.
Deformable manikin.

each trace that indicated the recovery of manikin dimensions following tracing.

DISCUSSION AND CONCLUSIONS

Notably, the manikin represented a deformable shape of dimensions similar to those of a transtibial residual limb. Our manikin cannot claim to replicate all residual

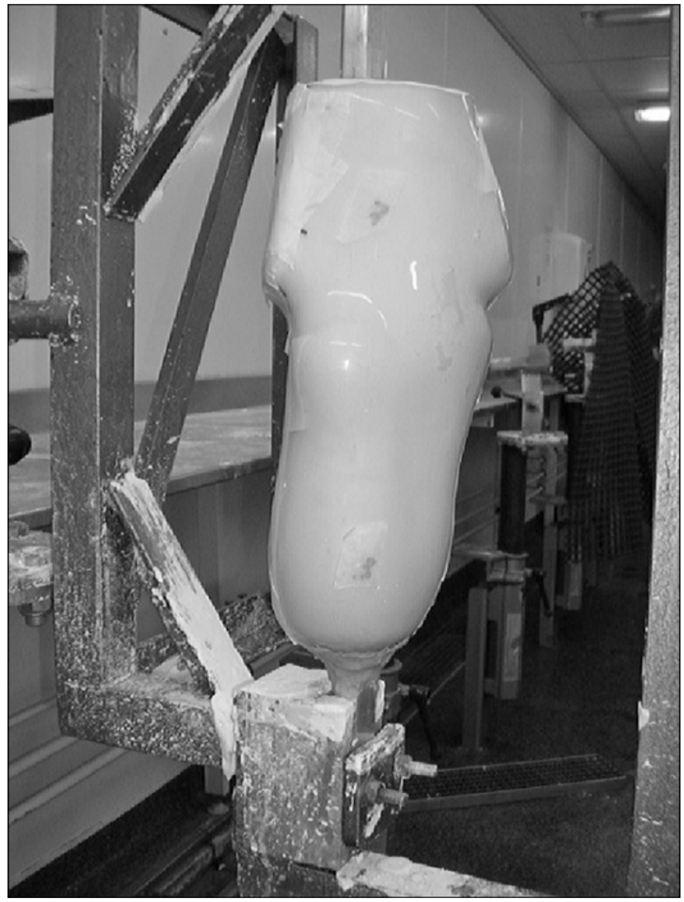

Figure 9.
Validation of copying for the transtibial residual-limb model: placing original former within jig and filling three times with plater of paris.

limbs because tissue consistency differs from patient to patient. Many different types of residual limbs exist, some with stiffer and some with less stiff properties than the manikin. During analysis of shape-capture systems, results obtained apply only to the manikin used. Creation of a manikin permits one to assess the effect of deformation on measurements obtained by CAD sensing, particularly important for systems that rely on a contact method of shape capture. For noncontact systems, additional parameters such as hair, skin color, surface texture, and scar tissue could be important. However, in practice, these factors are eliminated when the residual limb is covered by a sock during the scanning process.

Because data acquisition is the necessary first step of any shape-capture process, with the consequent socket design depending on the data acquired, the reliability, repeatability, and accuracy of data acquisition are crucial

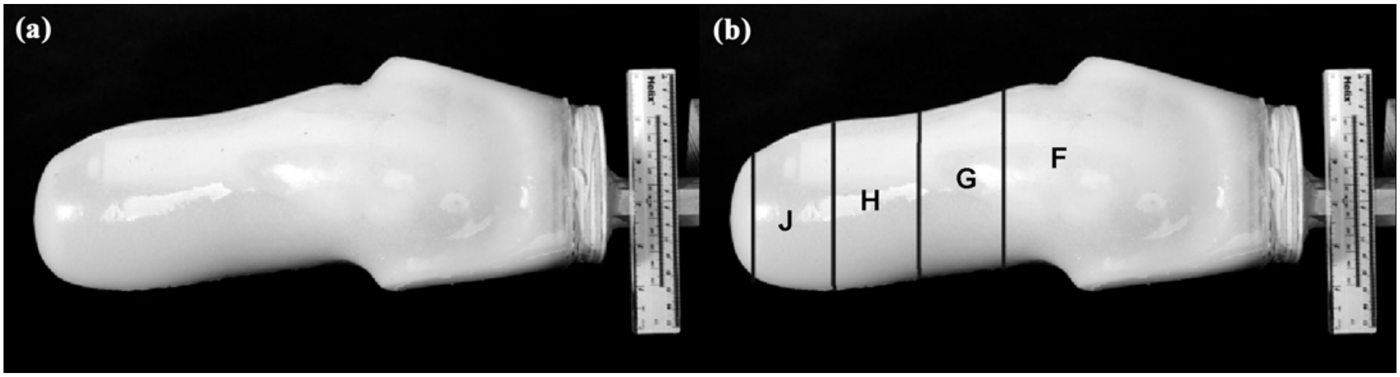

Figure 10.
Checking manikin dimension levels of transtibial residual-limb model at landmark positions F, G, H, and J.

to the final product. If errors are not identified, they may jeopardize the success of prosthetic treatment in clinical practice. The accuracy required to capture the shape of a residual limb and produce a good prosthetic outcome is still debated, and the reported evidence is very limited [1–3].

Once one knows the dimensions of a deformable manikin, one can measure and statistically analyze the accuracy or repeatability of results to determine their significance. Arguably, the technical capability of CAD systems could be tested with much simpler nondeformable models. However, the creation of a manikin allows results to be compared with those obtained with POP, to show whether CAD systems produce results that are at least as repeatable and accurate as traditional methods on a more realistic deformable model. This understanding will contribute to the body of knowledge required to determine the future role of CAD in the capture of residual-limb shape [10].

Ideally, in vivo studies can assess shape-capture systems used on actual patients. An in vivo study would have to overcome considerable difficulties such as the location of a central axis and controlling volume fluctuations but, if successful, could provide useful clinical data-capture information. Information gathered in vivo would extend the knowledge gained from manikin studies to also account for residual-limb variability.

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Critical revision of manuscript for important intellectual content: A. McGarry, A. W. P. Buis, B. McHugh.
Administrative, technical, or material support: J. Duers
Statistical analysis: A. McGarry.
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