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Technical note

Technical note: Computer-manufactured inserts for prosthetic sockets

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ABSTRACT

The objective of this research was to use computer-aided design software and a tabletop 3-D additive manufacturing system to design and fabricate custom plastic inserts for trans-tibial prosthesis users. Shape quality of inserts was tested right after they were inserted into participant's test sockets and again after four weeks of wear. Inserts remained properly positioned and intact throughout testing. Right after insertion the inserts caused the socket to be slightly under-sized, by a mean of 0.11 mm, approximately 55% of the thickness of a nylon sheath. After four weeks of wear the under-sizing was less, averaging 0.03 mm, approximately 15% of the thickness of a nylon sheath. Thus the inserts settled into the sockets over time. If existing prosthetic design software packages were enhanced to conduct insert design and to automatically generate fabrication files for manufacturing, then computer manufactured inserts may offer advantages over traditional methods in terms of speed of fabrication, ease of design, modification, and record keeping.

1. Introduction

Computer aided socket design and manufacturing (CAD/CAM) was introduced to prosthetics in the 1980′s [1,2]. CAD/CAM has matured over the past 30 years into a complete fabrication technology. It is used regularly by approximately 24% of prosthetists to make sockets for people with limb loss [3]. Using a digitized shape of the residual limb as a starting point, the prosthetist designs the socket shape, implementing software specific for prosthetic socket design. Once the shape file is created, a socket is fabricated by carving a positive model and then thermoforming a socket or by using a direct fabrication technique [4]. Compared with traditional socket design and fabrication methods, CAD/CAM offers advantages in terms of speed of fabrication, ease of design modification, and record keeping [5].

The purpose of this research was to extend CAD/CAM to the design and manufacturing of stiff socket inserts. Socket inserts are typically used to modify instead of replace sockets. CAD/CAM of inserts may offer advantages over traditional insert design and fabrication methods, similar to how they do so with prosthetic sockets. As a first step towards this objective, we present methods for design and fabrication of computer-manufactured plastic inserts. Results testing shape accuracy and performance on people with trans-tibial limb loss are presented.

2. Methods

Inserts were fabricated in three steps. First, the socket to receive the insert was digitized and a computer 3-dimensional (3-D) surface generated. This surface was the insert external shape. Then computer aided design software was used to design the insert internal shape and to generate a solid model. A solid model was necessary so as to use 3-D additive manufacturing technology for fabrication. The insert was fabricated in three pieces that interlocked together and fit within the prosthetic socket.

2.1. Creating the insert external surface shape

The insert external surface was designed to match the existing socket internal surface. To shape the insert, first the internal socket shape to receive the insert was measured.

Scan internal socket shape: To digitize the inside socket surface, we used a high-quality industry digitizer (FaroArm Platinum, FARO Technologies, Lake Mary, Florida) mounted within a custom frame and base (Fig. 1). A 6.00 mm diameter scanning tip was used for all sockets in the present study. The base held a standard pyramid adaptor so that a socket could be firmly secured with its longitudinal axis oriented vertically. Data acquisition software provided with the scanner (Geomagic, Design X, 3D Systems, Rock Hill, South Carolina) was implemented. The manufacturer also provided a reference jig that we attached to the frame. Calibration was performed before each use.

We scanned points on the inside of the socket at the brim and at the distal end, and fit a spline to each set of points so as to

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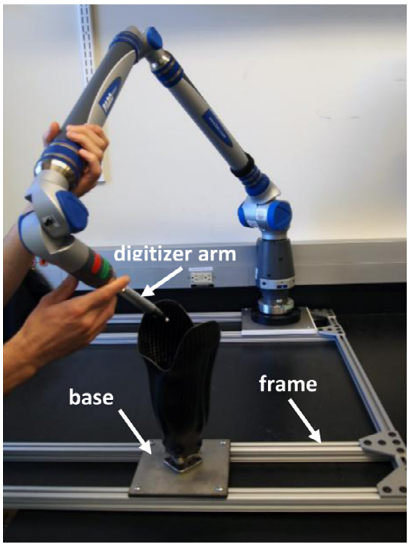

Fig. 1. Custom frame and base used for socket digitization.

establish the upper and lower contours of the socket (Fig. 2a) (*Scanner Accuracy* was set to 0.02 mm). With the scanner in a point cloud acquisition mode, we then sequentially scanned patch regions of the socket until the complete socket shape between the brim and bottom surface was digitized (Fig. 2b).

The collected data was visually inspected to identify and remove any outlier points that were not near the surface formed by the cloud (e.g., from the scanner arm skipping out of the socket at the proximal edge). If there were large holes of no data points in a region then additional scanning in that region was conducted.

Create mesh: Once the shape was visually acceptable on the computer screen, the *Construct Mesh* function in the software was used to create an adaptive spherical covering over the point cloud. Each sphere contained one or more of the original points and generated a single new auxiliary point based on the mesh density and relative location of the neighboring points. When every original point was encompassed within a sphere, auxiliary points within three intersecting spheres were connected to create a face. Redundant faces were removed, creating an entire mesh [6](Fig. 2c).

Additional scanning was conducted if there were large holes, and the surface was re-meshed. The *Rewrap* function in the software was executed which used adaptive basis functions to create a new point structure [7]. User input values for mesh edge lengths, capture accuracy, overall smoothing factor, and mesh density in high curvature areas were included in the algorithm.

Because the scanner recorded the position of the center of the ball at the end of the probe, not the outer surface where the ball contacted the socket, we offset the data outward a distance the radius of the ball (3.00 mm) to create the true socket surface.

Create 3-D surface: The mesh was converted to a 3-D surface so that a solid model could be generated. To do this step, we drew axial splines (Fig. 2d) and perimeter splines (Fig. 2e) onto the mesh so that the socket was defined as a collection of 4-sided sections. A boundary fit command was executed which created a series of fitted closed contours from the mesh.

2.2. Design insert

Uniform thickness insert: With the external shape of the insert defined as a 3-D surface, we projected inward normals to create a second surface, the internal shape of the insert, as well as two other surfaces, the proximal edge and the distal edge. If an insert was to be of uniform thickness, these manipulations were easily executed using the software. The four surfaces were grouped together to create a solid model (Fig. 2f) that was then converted to Standardized Graphic Exchange (STEP) file format.

Non-uniform thickness insert: To design a non-uniform insert, the shape was imported into a commercial prosthetics software

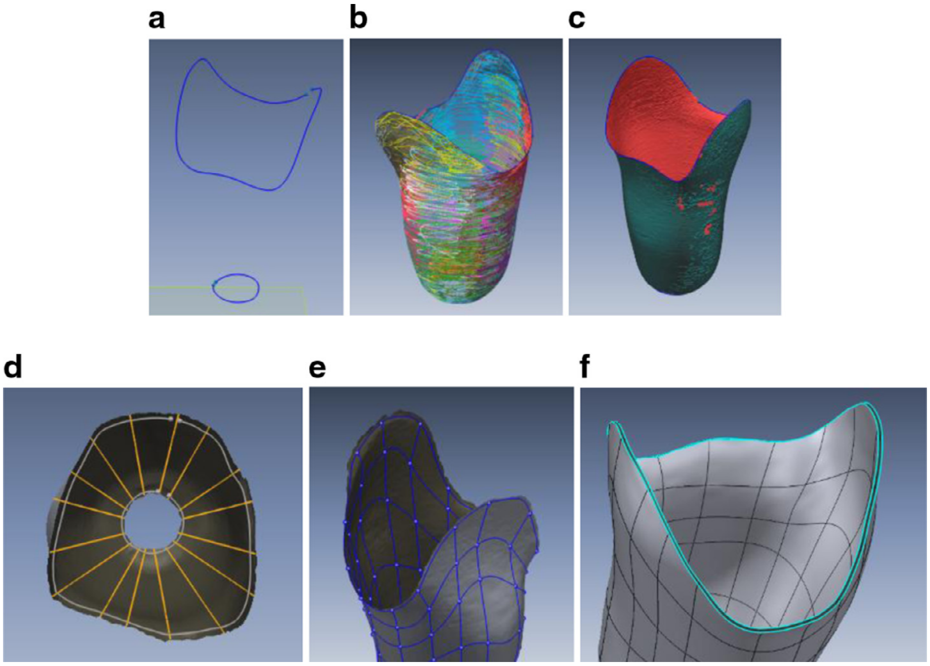

Fig. 2. a–f. Socket digitization and model formation. (a) Splines at the socket proximal and distal end. (b) Scanned patch regions of the socket. Each patch is a different color. (c) Holes in the scanned socket surface resulting from the digitization process. The holes illustrated are minor; additional scanning does not need to be performed for this socket. (d) Top-view of the socket illustrating axial splines. (e) Socket defined as a collection of 4-sided sections. (f) Solid model of a uniform thickness insert ready for fabrication.

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