Design and Fabrication of Implants for Amputation Prosthesis

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Statement of Purpose: It is now widely accepted that 'fit' and 'fill' of the bone canal is critical to the success of cementless load bearing metal implants and there exists a wide variation to the anatomic size and shape of this canal in the normal population. When fit does not appear to be optimal with an off-the-shelf device, surgeons should consider the use of a custom designed prosthesis. Although the need of customized implants has been partly addressed in total hip arthroplasty and oral-maxillo-facial bone surgeries, limited number of attempts has been made to extend this approach to amputation prostheses. This study presents designing and fabricating a unitized implant with external and internal structures closely resembling the natural bone for amputation prostheses based on a computed tomography (CT) scan of the patient's joint.

Methods: A typical process flow chart used to design custom implant for amputation prostheses is shown in **Figure 1**.

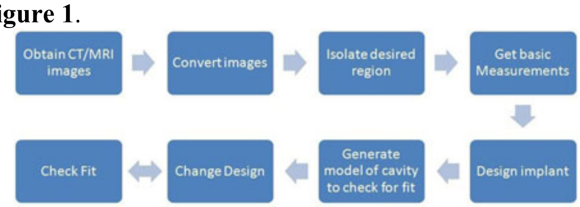
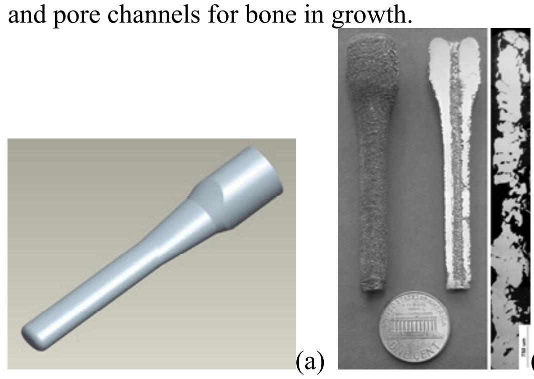


Figure 1. Process flowchart for designing implants for amputation prostheses [1].

The implant design process was started with the acquisition of a CT scan of a healthy dog's (forelimb) radius. This scan image data was imported into Mimics (Materialise Inc., CA, USA) for editing and 3D reconstruction. Segmentation masks are used in Mimics to highlight the regions of interest, which are then further processed to create the models. The custom implant designing stage was initiated by measuring the dimensions of the radius cavity from a Mimics generated 3D model using 3-Matic software (Materialise Inc., CA, USA). The final design (**Figure 2)** had a long stem that fits inside the bone cavity and an elliptical tapered head to suit the top portion of the bone cavity. The physical models of bone and final custom designed implants were made with acrylonitrile butadiene styrene (ABS) using FDM Titan™ (Stratasys Inc., MN, USA) to check the interfacial contact area and fit. Then the final custom designed implant was made out of Ti6Al4V alloy using the LENS™-750 (Optomec Inc., Albuquerque, NM) equipped with a 500W Nd-YAG laser. The porous stem part of the implant was made at a laser power of 200 W, scan speed of 12 mm/s with a powder feed rate of 41 g/min and the dense head portion was processed at 400 W, 16 mm/s and 12 g/min.

Results: A LENS™ processed custom design Ti6Al4V alloy implant is shown in **Figure 2b**. The cross section of the implant clearly shows the interconnected porosity in the lower portion (stem) and fully dense head portion without any porosity. The rough surface morphology with interconnected porosity in the stem portion of the implant improves the osteoconductive properties of the metal implant by providing good anchorage for cell attachment and pore channels for bone in growth.



(a) (b)

Figure 2. (a) Final implant design (b) actual custom design Ti-6Al-4V alloy implant (left), its cross section (middle) and high magnification microstructure showing porosity (right).

The fit between the 3D CAD models of bone and implant was also measured using CT scan data. The custom made implant filled between 66% and 98% of the corresponding bone cavity and the fill rates of virtual implant and actual implant in the bone canal are very close. Lower fill rate at the bottom portion of the implant is due to change in cross section does not allow us to design an implant with larger cross section at the bottom to suit the bottom portion of the bone cavity and small section at the top. The contact area between the implant and the bone varied between 0 and 74% along the length of the implant. Maximum contact area was observed at top portion of the implant and no contact was observed at the bottom portion of the implant. Higher fill rates and contact areas are usually required to decrease the amount of bone removal during surgery. Since the amount of bone removal during surgery depends on the implant-bone fit characteristics, it can be seen from the differences between bone-implant contact areas of a straight implant (20-23%) and the current customized implant (40-70%) that with latter design significantly less bone removal can be achieved. In general, approximately 50-60% less bone removal may result from current customization of the implant leading to faster bone ingrowths thus decreasing the rehabilitation period for the patients.

Conclusions: A methodology to design and fabricate customized implants for amputation prosthesis based on sectional medical images and rapid manufacturing technologies is presented. Using these custom prostheses that have a direct connection to the skeletal structure can aid with problems of load transfer, proprioception and maintaining fit in amputees. Furthermore, application of LENS™ in the fabrication of custom fit implants can be economical and incorporate desired porosity characteristics to improve long-term stability due to enhanced biological fixation and osseointegration.

References:

1. DeVasConCellos P. et al., *Rapid Prototyping J.* 2009; revised version submitted.