Patient specific implants for amputation prostheses: Design, manufacture and analysis

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Introduction

Amputation of the lower extremity is a common procedure in the USA with 135,000 new amputations being performed each year (1). It is estimated that one out of every 200 people in the USA has had an amputation or limb loss (1, 2). Currently the critical component of lower limb amputations is the socket to couple the prosthesis and the transfemoral stump; the socket transfers the load between the prosthesis and the residual limb. Considerable advances have been made in the field of amputation prosthetics during the last decade. However, many amputees still develop problems at the prosthesis-skin stump interface such as the development of blisters, skin irritation, pressure ulcers, and cysts (3–6). Other concerns with the current socket interface technique include residual limb pain, inefficient load transfer, lack of proprioception, absence of tactile feedback, loss of fit of the prothetic, reduced range of hip flexion and discomfort when sitting (7–9). The majority of the problems associated with the current prosthetic socket can be addressed by using a prosthesis that has direct connection to the appendicular skeleton through an osseo-integrated metal implant. Osseo-integrated transfemoral prostheses may not only eliminate the skin problems and residual limb pain but may also allow better sitting comfort for amputees (10). One important advantage of using osseo-integrated intramedullary implants is increased proprioception (11). Patients also report improved feedback control of their prosthesis, thus promoting better psychological acceptance of the limb substitute (11–13). Amputees can walk further and lead a more active life than amputees who are using a conventional prosthetic socket (11–13).

Worldwide over 100 transfemoral amputees have been successfully fitted with transfemoral osseo-integrated prostheses (11, 14). These initial results demonstrate that osseo-integrated prostheses having direct anchorage with bone tissue improve the perception and overall quality of life of the amputee (14). Nevertheless, two major challenges associated with this approach...
are mechanical failure of the abutment and a lengthy rehabilitation program of up to six months (12, 13, 15). Other complications which may be associated with transfemoral osseointegrated amputation prostheses include superficial infections at the skin-implant interface, skin breakdown, pain and implant loosening (12, 13, 15). Some of the skin problems have been treated with oral administration of antibiotic medications (14). Since microbial adhesion and inflammatory cells are associated with implant-skin interfaces, the use of bioactive coatings that decrease bacterial adhesion could eliminate infections (16, 17). Similarly, optimizing the pore volume fraction, pore size in porous coated implants, surface topography and modification of dense implants and design modifications such as a porous flange just below the skin penetrating area, have been shown to produce an effective barrier for infection (18–22). Finally, aseptic implant loosening due to stress shielding might be a potential issue leading to implant loosening. Implant loosening and mechanical failures are direct consequences of alterations in load transfer to the bone of the amputation stump (12). Therefore, to shorten the entire rehabilitation period and to eliminate problems associated with improper load transfer and superficial infections at the skin-implant interface, great care should be taken in the macroscopic and microscopic design and fabrication of transfemoral prostheses for amputees, because successful implantation of these devices can potentially improve the overall life of the prostheses, and consequently the activity level and general health of the patients.

Design and fabrication of best-fit load bearing bone implants require accurate recreation of the macro- and microgeometry of the bone envelope into which the implant will be seated. There is clear evidence from clinical and experimental studies that a close geometric fit between an implant and the endosteal bone canal is essential for mechanical stability, uniform physiological load transfer and long-term success (23–25). Therefore, custom made implants with the exact anatomical shape of the endosteal bone canal, based on computed tomography (CT) data, have been developed, which show better short- and mid-term results compared to conventional implants (23–29). Use of porous metals in place of fully dense material has been shown to effectively reduce the modulus mismatch and associated stress-shielding (30–33). Also, the interconnected porosity increases the bone-implant interfacial bond via bone ingrowth through the pores (34). Although the porosity can decrease the strength and toughness of the implants, ingrown bone can potentially increase the strength of the bone-implant composite by a factor of three or four (35).

The use of customized dense implants has been explored and well documented, but there remains a knowledge gap in regard to value of incorporation of site specific optimal porosity in these custom implants (23–29). Therefore, the primary objective of this work was to design and fabricate a unitized Ti6Al4V alloy implant with external structures closely resembling the natural endosteal bone and with appropriate porosity in specific regions for amputation prostheses. The external shape of the implant was designed by extracting three-dimensional (3D) geometrical data of anatomical bone structure from computed tomographic (CT) images, using 3D medical image processing software, to suit the endosteal bone cavity. The stem of the implant was designed to be porous in order to better match the modulus of the implant to that of the surrounding bone, and also enable bone tissue ingrowth for long-term fixation of the bone. An additional advantage of implants that have a porous structure includes inhibition of skin-implant interfacial infections (18–20).

We have previously reported that introduction of porosity during the fabrication step using a laser based additive manufacturing technology offers several advantages for metallic implant fabrication (31). In this paper, we describe the design and fabrication of implants for amputation prostheses with Ti6Al4V alloy using previously described laser based additive manufacturing technology (31). The evolution of the implant design, from the proof of concept stage through to the production of second-generation implants, is discussed with specific emphasis on implant geometry and implant-bone interfacial clearance obtained via CT imaging. Finally, we summarize the main conclusions of this work in comparison to current practices.

Materials and methods

Computed tomographic image data processing

Radii chosen randomly and harvested from the cadavers of nine dogs that were euthanatized for reasons unrelated to our study, were used to design and optimize the amputation implant. For the purpose of this study, the implant design process began with the acquisition of CT images of each radius. This image data was imported into the commercial software for editing and 3D reconstruction. In this work, we used CT images with an X-Y resolution of 512 x 512 pixels and the images were retro-reconstructed into 1 mm slices. Segmentation masks were used to highlight the regions of interest, which were then further processed to create the implant models. A segmentation mask with a threshold value of 226 Hounsfield units was used to exclude the cancellous bone creating a cavity for the implant for further processing. Filling of unwanted voids was accomplished by using several editing techniques such as cavity fill, draw, and local thresholding. The region-growing function, which connects all voxels within the threshold that are physically connected to the initially selected voxel, was used to complete the isolation of the hard tissue. Figure 1A shows one typical segmented mask of the radius of a dog. The segmented masks thus created were converted into a 3D model of the isolated radius (Fig. 1B) using the ‘calculate 3D’ function in the Mimics software.

Implant design

Proof of concept design

The proof of concept implant designing stage was initiated by measuring the dimensions of the radial cavity (n = 1) from a Mimics generated 3D model using commercial software 3-Matic. This software...
was used to design, modify and optimize the implant to suit the bone cavity, and then finally to export the computer-aided design (CAD) as a .stl file format to manufacture custom implants using a laser based additive manufacturing technique<sup>b</sup>. The bone cavity was not uniform from distal to proximal, and also the bone curved caudally and narrowed in the proximo-medial direction (Fig. 2A). This peculiar shape of the bone posed constraints on the cross-section of the implant along the length and X-Y direction. Therefore, a profile of the cavity was created by taking slices of the bone and measuring the key dimensions in a radial direction at various intervals along the bone. A 3D CAD model of the first iteration implant is shown in Figure 2B. To produce a finalized design, we went through two different iterations of implant development and the fit was checked digitally by assembling the parts and also with physical models. The final design (Fig. 2C) had a long stem that fitted inside the proximal bone cavity and an elliptical tapered head to suit the distal bone cavity. The cylindrical portion of the head with threads was intended to provide structural support for the attachment of the prosthesis.

First generation designs

The design process for the first generation implants was different from the design process used for the proof of concept design. The primary difference was the method used to design the stem of the implant. For the first generation implant design, the bone model was created in Mimics using the same method as for the proof of concept but further processing steps were changed. A model of the bone cavity was generated by performing a closing morphology operation providing a mask of the bone with the cavity filled in. Thereafter, a Boolean operation (logical function using algebra sets) was performed to subtract the cortical bone geometry from the mask, leaving a mask of the bone cavity. The generated bone mask was used as the implant stem. To design and attach the implant head, the bone cavity was converted into a .stl file and imported into 3-Matic. The implant head must protrude from the amputee stump, giving a rigid anchor for attachment of the exoprosthesis. The first generation implant design was completed in 3-Matic by attaching a cylindrical head closely matching with the diameter of the distal bone model. The implant stem and head interface were then gradated to create a smooth transition between the stem and the head. This also ensured a tight fit between the implant and the distal portion of the bone cavity. Figures 2D, 2E and 2F show the models of bone canal, the designed implant and the virtual assembly of the implant and the bone, respectively.

Second generation designs

After analyzing and testing the first generation design of the implants we realized that improvements could be made in terms of fit and fill, as well as tolerance to withstand compressive forces. The proposed design changes in terms of fine-tuning threshold values and creating a flange in the distal region of the implant were intended to increase fit and fill of the bone and result in uniform transfer of loads between the implant and the bone. The general implant design route for second generation implant design was very similar to the process used for the first generation designs except the threshold values were optimized to achieve a better fit and fill compared to first generation designs. In addition, the graded transition between the stem and the head of the implant was improved by creating a flange at the transition.
Fig. 2 Radius bone isolated from the forelimb of a dog from computed tomographic (CT) imaging data and computer-aided design models of a custom-designed implant. A) Highlighted cross sections show the profile of the bone cavity rotating and slanting downwards. Note the cross section at Section 1 is smaller than at Section 2. B) Proof of concept implant design. C) Proof of concept implant virtually inserted into the bone model (dog 1). D) First generation implant stem matching with the bone cavity (dog 3). E) First generation implant stem with cylindrical head attached and smooth transitional area between head and stem. F) First generation implant virtually assembled with corresponding bone model (dog 3).
Implant (Fig. 2E) was replaced with a flange having a cross-section corresponding to that of the cortical bone. This flange was then transitioned into a cylindrical abutment to which the exoprosthesis could be attached. The flange was designed to be flush against the transversely osteotomized surface of the bone and not push against the endosteum of the bone when loaded in compression. To achieve this, the perimeter of the osteotomized bone surface was extruded and converted into a solid. This solid was then joined with the implant stem, creating a flange that transitioned the implant in the bone. Figures 2G, 2H and 2I show digital models of the bone canal, implant and assembly of implant in bone, respectively. Note that the cross section of the distal radius was identical to the flange of the implant.

Fabrication of physical models and custom Ti6Al4V alloy implants

After designing the implant and checking with the virtual 3D model of the bone, physical models of bone and custom designed implants were made with acrylonitrile butadiene styrene using fused deposition modelling (FDM). Fused deposition modelling is an additive manufacturing technology used for the production of actual parts for direct application using a 3D CAD model of the object. The physical models made using FDM Titan™ were aimed at initial checking for implant-bone interfacial fit and bone cavity fill. The acrylonitrile butadiene styrene physical model of the second iteration was then created and the fit was greatly improved (Fig. 3). The final custom designed implants were made with Ti6Al4V alloy using a laser based additive manufacturing technique equipped with a 500 W Nd–YAG laser (31). Being a CAD and layer based manufacturing process, LENS™ gives significant advantages over conventional manufacturing methods in terms of tailoring microstructure, shape, size and internal architectures particularly of porous structures in one operation by controlling different process parameters (31, 36–42). By exploiting the capabilities of LENS™, the stem portion of the custom implant was made porous and was graded into the fully dense region at the head portion of the design to support the prosthetic attachment. The porosity in the stem portion allows the potential for bone and soft tissue ingrowth into the implant but also reduces the stiffness mismatch between the bone and the implant. Both of these modifications potentially increase the long-term stability and life of the implant. The porous 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 (to achieve approximately 25% porosity) and the dense portion was processed at 400 W, 16 mm/s and 12 g/min.

Surgical implantation, fit and fill analysis

Radii, chosen randomly from each dog, were harvested from the cadavers of nine dogs that were euthanatized for reasons un-
related to our study. Bones (n = 9) were cleaned and kept frozen until the implants were manufactured and the surgical procedures performed. The osteotomized radii were measured from the distal end based on the digital bone models in order to ensure correct placement of the implant. Following implantation surgery, CT imaging of the bone with the Ti6Al4V alloy implant inside was performed. The custom-processed metal implants were fixed in respective cadaveric bones and the construct was then examined using a flat panel amorphous silicon high-resolution CT with 225 keV micro-focus tube at 0.1 mA current. The maximum resolution of the tomography machine was 5 μm/pixel. Data were acquired using Data Acquisition System V2.1.4 (system part of the ‘flat panel amorphous silicon high-resolution CT system’) and then processed in an octa-core central processing unit server using Data Processing System Version 1.3.10. The output format for each sample was 500 x 500 bitmap images. The serial images were converted to black and white, and the area of the implant and the area of the bone cavity were calculated from the CT images and the data were used to calculate the percent fill using standard image analysis software. The percent fill was analyzed at three different locations along the length of the implant-bone interface. The first cross-section was within 5 mm of the distal end of the bone, the second section was in the middle portion of the implant, and the third was within 5 mm of the proximal end of the implant.

**Compression Testing**

Uni-axial compression testing was carried out to compare effectiveness of load carrying capacity of different designs. Compression testing was performed on six first generation implants as well as the three second generation implants. The head portion of the implant and proximal end of the bone were ground flat to ensure good alignment of the load platen with the bone-implant assembly. A special compression test setup was designed and tests were carried out using a universal testing machine (Fig. 4). The testing was performed with a crosshead speed of 5 mm/min and ran until bone fracture detection (15% drop in the load) was triggered. The force and displacement recorded during compression testing were used to calculate the failure load and stress.

**Results**

**Patient specific Ti6Al4V implants**

Typical custom designed Ti6Al4V alloy implants fabricated using LENS™ are shown in Figure 5A. All implants were made with ~25% porosity in the stem region and ~0% porosity in the head region. The cross-section of proof of concept design implant (Fig. 5B) showed interconnected porosity in the stem portion and a fully dense head portion without any porosity. The total porosity in the stem of the implant was found to be in the range of 20–30%, and the pore size was between 60–800 μm. Final assembled proof of concept implant for amputation prostheses is shown in Figure 5C. All metal implants had rough surface morphology with interconnected porosity in the stem portion of the implant. Visual observation of the implant-bone assemblies showed overall good fit, which corresponded very well with the
visual fit of virtual models (Fig. 2F and 2I).

**Fit and fill analysis**

**Proof of concept design**

Typical CT images at various sections of the LENS™ processed custom design Ti6Al4V alloy implant are shown in Figure 6A and 6B. Figure 6C shows a longitudinal view of the implant inside the bone. The fill between the CAD models of bone and implant was measured and the results are summarized in Table 1. The custom made implant filled between 36% and 98% of the corresponding bone cavity. A large variation in fill was observed along the length of the implants and lowest fill was at the lower portion of stem region of the implant. In general, the fill rate was observed to gradually increase from the bottom to top portion of the implant. Lower fill rate at the bottom portion of the implant was due to the peculiar shape of the bone cavity which decreased in cross-sectional size from proximal to distal (Fig. 2A). Such a change in cross section did not allow for a design with larger cross section at the bottom to suit the proximal portion of the bone cavity and small section at the distal portion. The maximum contact area was observed at the distal end (top) of the implant and no contact was observed at the proximal end (stem portion) of the implant.

**First generation designs**

Compared to the proof of concept design, the first generation designs were found to be more patient specific because the bone cavity was used as the geometry for the implant stem. A schematic diagram alongside the CT image at the different locations along the implant is shown in Figure 6D. The percent fill of first generation implant designs are reported in Table 1. A contact area in the range of zero to 44% was observed for proof of concept designs and it was between five and 65% for first generation implant designs.

**Second generation designs**

The proposed design changes in terms of refining thresholds increased the fill of the bone from 58% in the first generation designs to 83% in the second generation implant designs (Table 1). Moreover, the addition of a flange in the second generation implant designs considerably improved the load transfer from the implant to the bone before failure (Table 2). Compared to the first generation models, the second generation designs showed a relatively larger bone cavity fill percentage. This was achieved by keeping the implant stem as close to full size as possible while still having a design that would fit into the bone cavity without requiring removal of any bone. Bone marrow and soft tissue were not manifested on the CT images and therefore could not be considered as filled space. Figure 6E shows a schematic of the
implant inside the bone and where along the implant, the cross sections were observed and measured for fill.

**Compression testing**

Table 2 summarizes the maximum force and stress endured by the cadaver bone with different implant designs inserted into them. In all of the trials, the implants showed no signs of deformation or fracture and it was the distal portion of the bone that failed by cracking. The mean maximum failure stress for the first generation designs (9.8 MPa) was considerably less than for second generation designs (76 MPa).

**Discussion**

It is known that osseointegration is essential to the long-term success of bone anchored implants by improving the stability and preventing implant loosening (10–14, 20–22, 43). In recent years, osseointegrated implants for attachment of prostheses has been used as effective treatment for transfemoral or upper limb amputations (20–22). The R. Brånemark® and ESKA® systems are two of the most prominent implants thus far and these have been described in numerous case studies and used in developments involving osseointegration in Europe (14, 44). In addition the development of the Intraosseous Transcutaneous Amputation Prosthesis (ITAP) and its use in animals in the UK has been reported (20–25). However, there are currently no human patients that have undergone this procedure for prosthesis attachment in the United States.

Materials selection is the first step of designing an implant. The most popular system currently uses pure titanium (CP-Ti). In the present work, the implants were made with Ti6Al4V alloy, which has also been studied as a suitable implant material (20–25, 34, 38). The 20% to 30% porosity in the implant stem and 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. Both of these factors have been identified to increase biological fixation of implants to living tissue (20–25, 32, 34). The 20% to 30% total porosity in the stem and the modulus of laser processed porous Ti6Al4V alloy with similar porosity has been found to be in the range of 10 to 20 GPa, which is very close to the modulus of human cortical bone (10–30 GPa) (34). This reduces the stiffness mismatch and thereby can lower the chances of stress shielding; this is one of the major problems of implants currently in use (30–33). Moreover, porous Ti6Al4V alloy implants with approximately 25% po-
Table 1 Fill (%) of different custom-made implant designs in the radial bone canal of the dogs.

<table>
<thead>
<tr>
<th>Dog number</th>
<th>Top (distal)</th>
<th>Middle</th>
<th>Bottom (Proximal)</th>
<th>Mean</th>
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<tbody>
<tr>
<td>Proof of concept design</td>
<td>98.3</td>
<td>66.1</td>
<td>76.5</td>
<td>80</td>
</tr>
<tr>
<td>First generation designs</td>
<td>2</td>
<td>81.9</td>
<td>58.9</td>
<td>58.8</td>
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<tr>
<td>3</td>
<td>68.6</td>
<td>57.9</td>
<td>55.2</td>
<td>61</td>
</tr>
<tr>
<td>4</td>
<td>70.6</td>
<td>66.6</td>
<td>48.4</td>
<td>62</td>
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<td>5</td>
<td>56.6</td>
<td>48.1</td>
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<td>6</td>
<td>64.6</td>
<td>56.4</td>
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<td>Mean (%)</td>
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<td>57.58</td>
<td>47.32</td>
<td>57.79</td>
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<tr>
<td>Second generation designs</td>
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<td>90.37</td>
<td>80.54</td>
<td>76.07</td>
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<tr>
<td>8</td>
<td>88.77</td>
<td>80.13</td>
<td>75.9</td>
<td>81.60</td>
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<tr>
<td>9</td>
<td>88.45</td>
<td>82.79</td>
<td>81.11</td>
<td>84.12</td>
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<tr>
<td>Mean (%)</td>
<td>89.20</td>
<td>81.15</td>
<td>77.69</td>
<td>82.68</td>
</tr>
</tbody>
</table>

Table 2 Maximum compressive force/stress to failure of first and second generation implants.

<table>
<thead>
<tr>
<th>Dog number</th>
<th>Force (N)</th>
<th>Stress (MPa)</th>
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<tbody>
<tr>
<td>First generation designs</td>
<td>2</td>
<td>1152.9</td>
</tr>
<tr>
<td>3</td>
<td>1055.6</td>
<td>12.57</td>
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<td>4</td>
<td>886.5</td>
<td>7.02</td>
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<td>5</td>
<td>905.3</td>
<td>11.95</td>
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<tr>
<td>6</td>
<td>1250.0</td>
<td>9.74</td>
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<tr>
<td>Mean (%)</td>
<td>1050.0</td>
<td>9.83</td>
</tr>
<tr>
<td>Second generation designs</td>
<td>7</td>
<td>12818.75</td>
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<tr>
<td>8</td>
<td>6395.63</td>
<td>66.83</td>
</tr>
<tr>
<td>9</td>
<td>5132.81</td>
<td>55.86</td>
</tr>
<tr>
<td>Mean (%)</td>
<td>8115.73</td>
<td>76.06</td>
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Porosity have been shown to induce a faster rate of in vivo tissue generation and integration compared to the samples with lower pore volume (34). Therefore, the rough surface morphology and interconnected porosity in the present amputation prosthesis can increase biological fixation of the implant to the living tissue (20–22, 25, 30, 34, 45). Finally, infection is always a concern with implants and especially with transcutaneous implants (20, 25). A porous implant could improve soft tissue integration which can reduce the risk of infection and could potentially provide a superior seal at the skin-implant interface (20–22, 25).

The implant design is also a critical factor in the success of amputee treatment. Individual variation in the geometry of the bone canal means that the best fit may require a patient specific implant. In the present work, the proposed design changes between the first and second generation designs greatly improved the fill of the bone within the implant. The average fill of the bone cavity improved from 58% in the first generation designs to 83% in the second generation implant designs. The improvement in the fill rate is attributed to the finer adjustment of thresholds during segmentation and isolation of hard tissue from the soft tissue. Present patient specific implants have advantages over generic models because they do not require as much removal of bone during surgery. This can potentially reduce uneven bone remodelling due to mechanical damage and decrease the rehabilitation period for the amputees. The CT image of assembled Ti6Al4V alloy implant-cadaver bone showed 40% to 70% physical contact area between the bone and the metal implant. Although no reported literature is available on custom implants for amputation prosthesis, the contact area between straight custom-made femoral prostheses and the bone was 20% to 23%, which is considerably lower than the values achieved in our work (47). 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 the latter design, relatively less bone removal will be necessary (47). In general, approximately 50% to 60% less bone removal may result from customization of the implant (48). This leads to faster bone ingrowth, thus potentially decreasing the rehabilitation period for the patient and preventing related problems like muscle and joint stiffness (48–50). The design is made and prototyped to fit with a high amount of precision and a press-fit is all that should be required. In our procedures performed with cadaveric models, the fit was excellent and implantation was very simple. The implant design is not modular and would not require a second surgery after a six month healing period, which is required for conventional transfemoral osseointegrated fixation systems (14, 24). This may result in a longer initial healing phase, but the overall recovery time could be quicker (23, 25).
Table 3  Comparison of the different methods used to attach the amputation prostheses (14, 23, 24).

<table>
<thead>
<tr>
<th>Tissue integration</th>
<th>Proprioception</th>
<th>Recovery time</th>
<th>Number of surgeries</th>
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<tr>
<td>Tissue integration</td>
<td>Proprioception</td>
<td>Recovery time</td>
<td>Number of surgeries</td>
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<td>ITAP = intraosseous transcutaneous amputation prosthesis.</td>
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Conflict of interest
None declared.

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1. Statistics about Amputation. [website]. RD; Right.