CUSTOM PROSTHESES
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Key points:
- With advances in computing power and software, custom prostheses are becoming a more practical option for patients with complex orthopedic problems.
- Custom prostheses involve multiple steps: implant and instrument (CAD) design, implant and instrument fabrication and finish, quality control, and surgical rehearsal.
- Custom prostheses may be done for a variety of purposes including limb sparing, revision arthroplasty, and placement of implant in patients with unique anatomy.

Custom prostheses are used to manage complex orthopedic situations. For total joint arthroplasties, custom implants are used to manage bone loss, abnormalities in bone shape or structure, or unusual bone sizes. Custom implants may be used as part of limb-sparing procedures, to fill large bone defects or to replace a missing bone or limb segment.

FABRICATION OF CUSTOM PROSTHESES

Custom metal implants are generally designed and fabricated by bioengineers within commercial or academic laboratories. Some commercial fabrication laboratories are free standing, others are part of large medical implant companies. In veterinary medicine, several companies offer custom implants, including BioMedtrix (Boonton, NJ), INNOPLANT (Hannover, Germany), Kyon Pharma (Boston, MA), Synthes Vet (West Chester, PA) and Veterinary Instrumentation (Sheffield, UK) (Table 1).

Table 1. Implant companies offering custom orthopedic implants to veterinarians

<table>
<thead>
<tr>
<th>Company*</th>
<th>BioMedtrix, LLC, Boonton, New Jersey</th>
<th>INNOPLANT, Hannover, Germany</th>
<th>Synthes Vet, West Chester, Pennsylvania</th>
<th>Veterinary Instrumentation Limited, Sheffield, United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Custom division</td>
<td>BioMedtrix-Customs</td>
<td>INNOPLANT Medizintechnik</td>
<td>Surgeon Response Group (SRG)</td>
<td>V.I. Custom implants</td>
</tr>
<tr>
<td>Creation date</td>
<td>1989</td>
<td>2005</td>
<td>2007</td>
<td>1985</td>
</tr>
<tr>
<td>Design capabilities</td>
<td>In house</td>
<td>In house</td>
<td>In house</td>
<td>In house</td>
</tr>
<tr>
<td>Fabrication and finishing</td>
<td>In house and business association with multiple human implant vendors</td>
<td>In house</td>
<td>In house or approved vendors</td>
<td>In house</td>
</tr>
<tr>
<td>Quality control</td>
<td>In house</td>
<td>In house</td>
<td>In house</td>
<td>In house</td>
</tr>
<tr>
<td>Products</td>
<td>Total joints and trauma for veterinary applications</td>
<td>Custom metal, plastic or biodegradable implants for the management of deformities, trauma, and neoplasia</td>
<td>Implants with FDA clearance (510K or other) Modification of almost any implant from the Synthes catalog.</td>
<td>Plates and screws</td>
</tr>
<tr>
<td>Most common products</td>
<td>Total hip replacements (cemented and cementless), elbow replacements, knee replacements and intramedullary fixator system</td>
<td>Custom hip prostheses for humans</td>
<td>Arthrodesis implants, design and production of special surgical instruments</td>
<td>Medial pantarsal bone plates</td>
</tr>
<tr>
<td>Particular expertise</td>
<td>Biomechanical analysis for the development of medical prostheses</td>
<td>Custom total hip prostheses</td>
<td>Patient specific implants for craniomaxillofacial (CMF) applications</td>
<td>Custom hybrid joint arthrodesis plates</td>
</tr>
</tbody>
</table>

* Listed in alphabetical order. This is not a list of all companies providing custom implants in human and veterinary medicine.
Custom implants are often based on a patient imaging, usually computed tomography (CT) scan images. These images are converted into 3-D computer models that are then exported into modeling or computer aided design (CAD) software (Marcellin-Little et al. 2008; Marcellin-Little et al. 2010b). Implants are then created using CAD software. Haptic feedback devices may be used to manipulate and modify 3-D computer models to create implants. These implants may have complex features and geometries. Implants intended to replace cortical bone or to sustain high mechanical loads are named structural implants. They most often have a solid metal core. Solid custom implants are most often made of titanium alloy (Ti6Al4V), but they may be made of cobalt-chromium alloy (Co-Cr), commercially pure (CP) titanium, or less commonly, of stainless steel.

Structural implants may be machined, cast, forged, or may be made using direct metal fabrication, also known as freeform fabrication, additive manufacturing or layered manufacturing. Direct metal fabrication relies on an electron or laser beam that repeatedly melts thin layers of metal powder to construct 3-D objects (Marcellin-Little et al. 2010a). Layer thicknesses may be as thin as 50 µm. Electron beam melting (EBM) was first reported as part of a Morgan Larsson’s Master of Science thesis at Chalmers University (Göteborg, Sweden). Arcam AB (Mölndal, Sweden) first commercialized an EBM machine in 2003. As an alternative, laser-based processes have been developed so that metal parts can be fabricated by lasers. These processes include selective laser melting (SLM, 3D Systems, Rock Hill, SC), laser engineered net shaping (LENS, Optomec, Albuquerque, NM), and direct metal laser sintering (DMLS, EOS GmbH, Krailling, Germany). Implants made by use of direct metal fabrication may have solid and porous portions that have structural and non-structural roles. Our research group has, for research purposes, assessed the biocompatibility of EBM-processed titanium alloy (Haslauer et al. 2010) and has fabricated custom titanium alloy plates that fit the surfaces of the distal aspect of the femur and the proximal aspect of the tibia (Marcellin-Little et al. 2008; Marcellin-Little et al. 2010b). These plates had acceptable mechanical properties when evaluated in vitro. Clinically, our group has made EBM-processed and DMLS-processed implants placed on the maxilla, the radius, the tibia, and the calcaneus of dogs and cats. The clinical performances of these implants have been satisfactory, based on their proper fit and the absence of infection, inflammatory response, or mechanical failure.

APPLICATIONS OF CUSTOM IMPLANTS

Custom orthopedic implants may have a structural role of buttressing a bone or neutralizing the forces placed on that bone. Non-structural implants are usually made of porous metal. They may be used to fill defects in bones, often in conjunction with a joint replacement or a limb sparing procedure, after trauma or tumor removal. Custom implants are, by definition, produced in limited numbers. They may be made in small batches, for example, for the reconstruction of the acetabulum with bone loss after aseptic loosening in humans (Sporer et al. 2010). These small-batch implants may be used in areas of the body with consistent anatomic features, such as long bones. Alternatively, custom implants may be patient-specific, N-of-1 products. Patient-specific custom implants are used in areas of the body where an exact fit is deemed necessary.

Custom designed implants have been available for decades, but modern customization started in the early 1990s, after the introduction of software packages for conversion of medical images. The most popular custom implant used in primary arthroplasty has been the prosthetic
Custom prosthetic stems were introduced in the late 1980s. These stems were based on three-dimensional CT modeling (Aldinger et al. 1988; Robertson et al. 1987) or on a mold of the intramedullary cavity prepared during surgery (Mulier et al. 1989; Robinson et al. 1996). Custom femoral cups and stems have been used in large patient cohorts. One report mentioned that 1,123 custom hip stems were implanted between 1992 and 1994 and described 61 consecutive patients with hip dysplasia that were less than 40-years old at the time of surgery (Akbar et al. 2009). Seventy-two cementless custom cups and stems were implanted and followed for 10 to 16 years (mean, 14 years). Over the study period, 70 stems (97%) and 67 cups (93%) remained stable (i.e. free of loosening or revision).

The Identifit system (DePuy, Warsaw, IN) gave surgeons the ability to reproduce patient-specific femoral offset, version and height and to achieve a high-percentage canal fill. However, the results of 53 primary Identifit prostheses were deemed disappointing, with 17% of the stems requiring revision after a mean follow-up period of only 30 months (Robinson et al. 1996). Custom stems have been used in patients with severe skeletal deformities. In a small case series of 14 primary hip arthroplasties for 9 patients with skeletal dysplasia, the mean functional hip score (Harris hip score) increased from 45 (range, 24 to 58) to 72 (range, 47 to 89) over a mean follow-up period of 3 years (Osagie et al. 2011). However, 21% of the procedures required revision at the time of follow-up. Custom stems have also been used to manage patients with bone loss after failed primary hip arthroplasty. One report described 17 patients who received custom hydroxyapatite-coated cementless stems with two 6.5-mm-diameter distal cross-locking screws (Sotereanos et al. 2006). Mean follow-up duration was 5.3 years. The mean functional hip score improved from 35 (range, 18 to 53) to 76 (range, 40 to 87) over the study period.

Structural custom implants have been used in cranio-maxillo-facial surgery for the reconstruction of bone defects (Singare et al. 2006). As discussed above, most cranial implants are made of PMMA. The infection rate associated with the use of PMMA cranial implants is relatively high and may require implant removal. In a series of 99 patients with warfare-related craniectomy defect reconstruction, successful reconstruction was achieved in 95% of patients (Kumar et al. 2011). The complication rate was 27% and the reoperation rate was 18%. Five implants were removed because of infections. This infection rate was low compared to the rate after placement of bone flaps from bone banks in the theater of war or the infection rate from previous reports. This lower infection rate was considered to be the result of stringent enrollment criteria, including excellent soft-tissue coverage, no preoperative clinical, biochemical (based on erythrocyte sedimentation rate), or radiographic evidence of infection (based on computed tomographic evaluation). Since metal (titanium) implants have a lower infection rate than PMMA implants, research aimed at the fabrication of cranial implants using direct metal additive manufacturing is ongoing. Because solid cranial metal implants may be heavy and may cause discomfort, titanium mesh implants have been used (Tadros et al. 2008). Custom implants that may be made of PMMA or titanium have also been used to fill orbitofacial defects (Scholz et al. 2007). In a case series of nine consecutive patients with orbitofacial defects, with a mean follow-up of 4.3 years (range, 6 months to 10 years), no significant complications occurred (Groth et al. 2006).

Silicone carpal bone prostheses were first implanted in the 1970s. They appear to have good subjective long-term benefits. In one report involving 32 patients, 25% of the implants were removed within 10 years and the remaining 75% were satisfactory (Vinnars et al. 2002).
another report, however, lytic bone lesions, as a result of silicone synovitis, were identified in 37 of 39 patients who had received silicone scaphoid or lunate implants and the authors recommended not performing replacement of carpal bones with silicone implants (Egloff et al. 1993). Structural carpal lunate and scaphoid prostheses made of titanium have been used (Swanson titanium carpal lunate and carpal scaphoid implants, Wright Medical Technology, Arlington, TN). The long-term success of these implants has been satisfactory (Swanson et al. 1997).

In veterinary medicine, specialized implants that are produced in small numbers are emerging. For example, bone plates with shapes that match the surface of the proximal portion of the tibia are available from several manufacturers (Langenbach et al. 2010). Synthes Vet (West Chester, PA), for example, has six plates that cover the range of tibial sizes seen in companion animals. Specialized plates are also available for carpal and tarsal arthrodebes (McKee et al. 2004). These plates have mechanical advantages over conventional bone plates, including lower construct compliance, less angular deformation, and lower peak plate strains (Guillou et al. 2011; Guillou et al. 2008). A custom feline total knee implant that was also intended for use as a human metacarpophalangeal joint prosthesis was described in the early 1980s (Walker et al. 1983). A custom total knee replacement implant was implanted in a dog in June 2005 (Liska et al. 2007). The dog had a chronic, highly-comminuted femoral condylar fracture resulting from a gunshot wound. A custom implant was prepared by machining a medial condylar augment in titanium alloy (Ti6Al4V). The augment had porous proximal, distal, medial and lateral surfaces. The augment was cemented to a conventional femoral component. The procedure was clinically successful and a loss of stability of the bone-cement or cement-implant interfaces was not identified on follow-up radiographs made 4 years after surgery. Other custom total custom total knee implants have been implanted more recently in cats and dogs in the UK, Germany, and in the United States. In hip replacement, a custom hip stem was used for limb sparing in a dog with osteosarcoma of the proximal portion of the femur. The long stem was fixed to an allograft of the proximal portion of the femur and to the host femoral shaft using PMMA (Liptak et al. 2005). Our research group has designed and fabricated custom hip stems for the canine femur. These porous stems with a low modulus of elasticity were designed for research purposes with the intent to create a stem that would decrease bone strain in the proximal portion of the femur when the joints are loaded (Harrysson et al. 2008; Marcellin-Little et al. 2010a). A similar concept and fabrication process could be used to make prosthetic stems for very large or small patients or for patients with femora with an abnormal shape. Structural custom metal implants have been used in a few companion animals. In one report, a custom metal implant was used to replace a fractured central tarsal bone in a greyhound (Yocham et al. 1988). A metal block was cut from square-stock titanium alloy, machined, and hand-finished. The block was fixed with a bone screw inserted mediolaterally into the fourth tarsal bone. The dog returned to racing 14 weeks after surgery and raced successfully for 7 months afterwards.

Transdermal osseointegrated implants have been placed in companion animals (Drygas et al. 2008; Fitzpatrick et al. 2011). These custom implants are designed to replace the distal portion of the thoracic or pelvic limb. Transdermal osseointegration is an active research area in laboratory animals and clinical application in humans is expanding (Lundberg et al. 2011; Sullivan et al. 2003). Since 2005, our research group has implanted six transdermal osseointegrated implants on the radius, tibia, or calcaneus of cats and dogs. The implants made by our research group are custom-made to match the inner or outer surfaces of the recipient
bones. The initial postoperative fixation of implants may be achieved through press-fit augmented by bolts or screws. The long-term bone fixation may be achieved through bone growth into porous metal surfaces, including plasma sprayed titanium, porous tantalum, or porous titanium. The skin-implant interface may have a locking flange used to prevent skin retraction. The transfer of autogenous mucosal tissue has been proposed as an alternative to the simple apposition of skin to a smooth or textured metal rod. The clinical results of transdermal osseointegrated implants appear promising and should be validated through a larger case series followed prospectively for a longer period of time.

Porous metal augments have been used to fill bone defects in humans undergoing revision arthroplasties or limb sparing. The commercially-available porous metal implants include Tritanium Dimensionalized Metal™ (Stryker Orthopaedics, Mahwah, NJ), Regenerex (Biomet, Warsaw, IN), Stikcite (Smith and Nephew, Memphis, TN), and Trabecular Metal (Zimmer, Warsaw, IN) (Levine 2008). The most common use of porous metal implants is premanufactured metal augments used to enhance the fixation of the acetabular cup in humans with peri-prosthetic bone loss. These augments may be posterosuperior augments, in patients with loss of acetabular dome (i.e., the human equivalent of the dorsal rim), or anterior medial augments, in patients with segmental bone loss of the anterior or posterior columns (i.e., the human equivalent of the ilium or ischium) (Sporer et al. 2010).

In veterinary medicine, a porous tantalum augment was used in a dog with radial osteosarcoma, as part of a limb sparing procedure (MacDonald et al. 2010). A low-grade surgical site infection was diagnosed 80 days after surgery, and it was managed conservatively. A pulmonary lesion consistent with metastatic disease was diagnosed on thoracic radiographs 248 days after surgery. The owner described the dog’s quality of life as very good 332 days after surgery.

ENDNOTES
6. Advancing medicine, Dr. Erick Egger talks about a successful surgery using a new prosthetic limb procedure under testing at Colorado State University, dvm Newsmagazine, October 1, 2008.

REFERENCES
References available upon request