Haptic-Based Design Software Plays Vital Role in Revision Hip Implant Case

Kevin Atkins

Demand for personalized implants is increasing, since younger patients and longer life spans mean that more patients are receiving their first joint replacements earlier in their lifetime. When implant materials wear out, patients may need second or even third implants, called revision implants. Thermoplastic Products Corporation [1](TPC) uses Sensable's Freeform [2] to deliver them in a novel way—restoring patients to well being, while allowing their surgeon to experience computer-based surgical planning as well.

TPC is a custom medical specialty service bureau, an emerging business category that is increasingly handling these types of challenging cases. With over 36 years of expertise, TPC has nearly a dozen medical patents to its credit, and uses a wide variety of software including Pro/E, SolidWorks, Freeform, and specialized CT/MRI segmentation software to design implants.

Recently, a surgeon asked TPC to help a woman in her early sixties who originally suffered from severe osteoarthritis and whose second hip implant had failed. CT scans revealed extensive degradation of her existing pelvic bone structure such that the second hip implant done just four months earlier had dislocated, its cup sinking deeper into the bone and no longer capable of holding the ball of her femur in place (Figure 1).

Figure 1: Displaced cage hip dislocation

Although active throughout her life, the woman was now wheelchair-bound from pain and sections of the failed implant were riding dangerously close to many life-critical organs. The traditional method of treating this medical emergency is to manufacture a custom-shaped implant of traditional cobalt chrome (CoCr) or titanium, or to create one in the OR with a stock replacement cup that is augmented with the same materials. The latter option was ruled out, as it would necessitate the patient being open and exposed to infection for a long period during surgery. A CoCr custom implant was also problematic, with long lead times and a potential for repeated failure.

Since this was to be her third surgery in less than two years, her surgeon wanted to give her the best chance of a positive outcome and sought out a newer trabecular metal material that encourages new bone cells to grow into the implant. Such in-growth would better stabilize the entire pelvis rather than rely on the typical bone cement and fixation screws.

Unfortunately, custom trabecular-metal implants have a 24-week lead time and there was significant risk that the implant likely would not fit the patient, given the speed at which her hip was degrading. The patient would also be in extreme

discomfort and remain wheelchair bound for that six-month waiting period. A custom trabecular implant would also cost five to ten times more than the traditional CoCr or off-the-shelf options, which was an additional consideration.

The surgeon asked TPC if it was feasible to create a customized solution for the patient using an off-the-shelf pre-formed cup and augment made of trabecular material, while leaving in place the existing femoral component of her present implant. The surgeon would need extreme care in locating the fixation screws in her intact pelvis, where the bone ranged from 20 mm to as little as 1 or 2 mm thick. For proper function and to allow her to walk without pain or a limp, he also needed intensive surgical planning to precisely define the angle of placement of the new hip socket onto what remained of her pelvis, and to minimize the removal of intact bone required for support.

Delivered in Two Days

Using Sensable's Freeform, TPC designed, sourced, and provided the needed cup and augments in just two days—starting from a CT scan on Wednesday morning to obtaining available components delivered for surgery by that Friday morning. TPC's team completed a total design in under an hour—at least five times faster than if working with traditional CAD software. The surgeon was also able to visualize the surgery on Freeform and streamline the surgical planning process.

"This case represented an amazing marriage of technology and medicine, that benefitted the patient tremendously," said Richard H. Hallock, MD, Orthopedic Institute of Pennsylvania [3]. "This woman was walking again thanks to this custom implant," he said in reference to the implant designed using Freeform. "Doing preoperative planning this way let me save valuable time in the operating room, so we also minimized the minutes when the patient was open and exposed to infection."

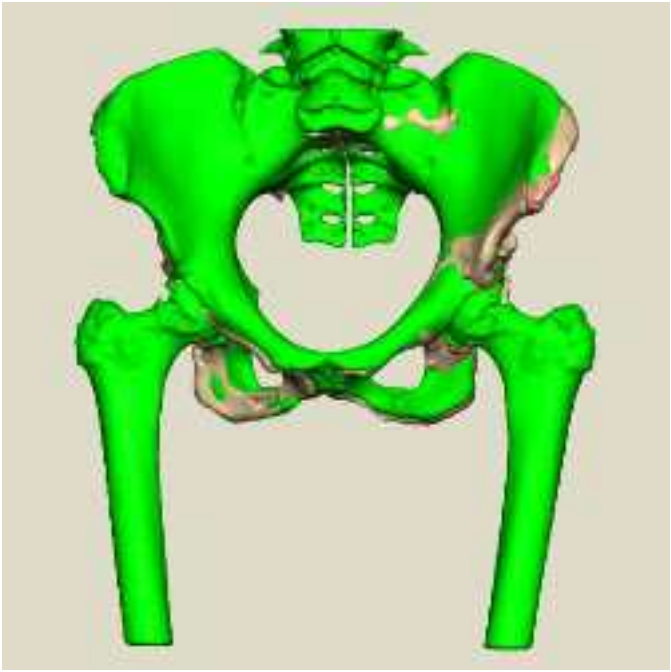

Figure 2: Mirrored hip view

After converting the patient's CT scan into an STL file, TPC used Freeform to make a mirror image of the patient's intact, healthy right hip and then overlay it for reference on the left (Figure 2). The mirror image (colored green) provided a reference for where her pelvic bones and femur (colored pink), should align.

The designer moved the cup in 3D space within the patient's pelvis to verify it would fit with the existing intact cage, and would not impinge upon nearby organs. Because Freeform uses voxels, or 3D pixels, Freeform designs can be readily moved and reshaped like clay—making it perfect for designing the organic, highly sculptural shapes, such as those found in the human body. The solution also readily imports STL files converted from digital medical images, such as MRIs, CT scans, and X-rays.

When the design was complete, TPC used Freeform to measure components on screen and verify the precise size of augments and an acetabular cup, and then determine that off-the-shelf components could, in fact, be used to create the custom solution that the surgeon required.

Haptic Interface Enhances Surgical Planning
In an unusual marriage of CAD software and surgical planning, the surgeon himself used Freeform to create and review the surgical plan. In Freeform, users hold a haptic device, instead of a mouse—physically feeling what they see on screen.

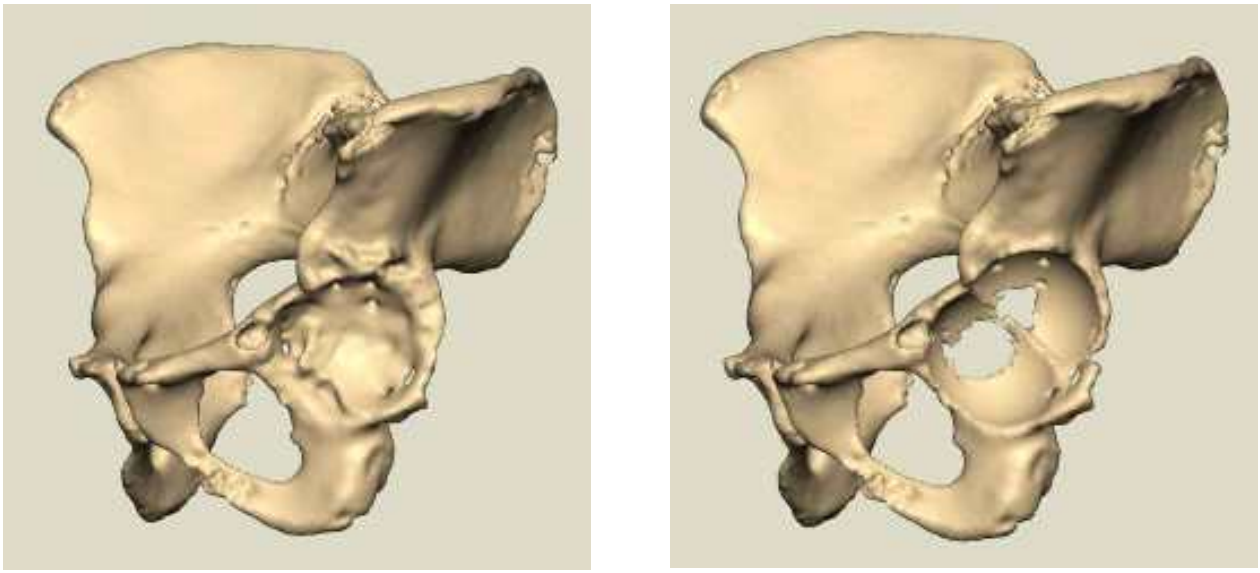

Figure 3: Before (left) and after (right) reaming views of acetabulum

Dr. Hallock visited TPC's offices when it was time to design the fixation screw locations. He personally "felt" the cup's angle of insertion and verified that his planned bone reaming (to clean up the acetabulum) (Figure 3) for the new parts would still leave enough pelvic bone intact to be stable. Using visuals in Freeform

that placed long rods through the proposed screw holes, and feeling the various thicknesses of the intact pelvic bone, he reviewed TPC's designated choices for screw fixation and verified they would retain the components without threatening the stability of, or penetrating, the pelvic bone.

Once the design was complete, TPC provided Freeform's measurements for component ordering. TPC also made a 3D printed study model on its rapid prototyping printer for the surgeon's final approval and his real-time reference during the surgery. The surgery was successful and the patient was walking again, without pain.

"Sensable's Freeform is the only tool we've found that allows us to design these revision custom implants to fit the patient exactly, and the one tool we couldn't do without," said TPC owner Barry Fell. "With Freeform's design flexibility and output to downstream manufacturing processes, we could let the patient's unique anatomy drive the custom device or solution, delivering an exceptional design that fits better, faster," Fell added.

Kevin Atkins is a product manger at Sensable, provider of the Freeform organic 3D design and manufacturing application. For over 25 years, he has been involved with leading digital modeling technology, both as a user and as a software designer. His expertise and experience covers a wide range of models from complex medical implants and surgical procedures to organically sculpted toys, stylized product design, and functional engineering.

Links:
[1] http://www.tpcdesign.net/
[2] http://www.sensable.com/
[3] http://www.oip.com/