FHC

Facts

Challenge

Manufacturing of STarFix patient-matched frameless stereotactic fixtures.

Solution

Small-batch production of precision surgical components using a FORMIGA P 100.

Results

- Comfort and care: customized design fosters patient well-being and shortens OR time
- Precision: highest-quality production to strict standards required for medical applications
- Improved functionality: parts consolidation resulting in simpler designs with more features
- Economic: uses less material, provides faster manufacturing turnaround times

Patient and procedure customized Platform illustrating flexibility of form possible with SLS fabricated Platform (Source: FHC, Inc.).

FHC Switches to EOS Technology for Manufacturing of Stereotactic Platforms for Neurosurgery

Additive manufacturing of customized surgical tools achieved high precision

Short profile

FHC's commitment to Innovation through Collaboration has supported the neuroscience community for more than 40 years through the design and manufacture of unique microelectrodes and a broad range of research and clinical instrumentation, including micro-positioning devices for acute and chronic recording/stimulating preparations.

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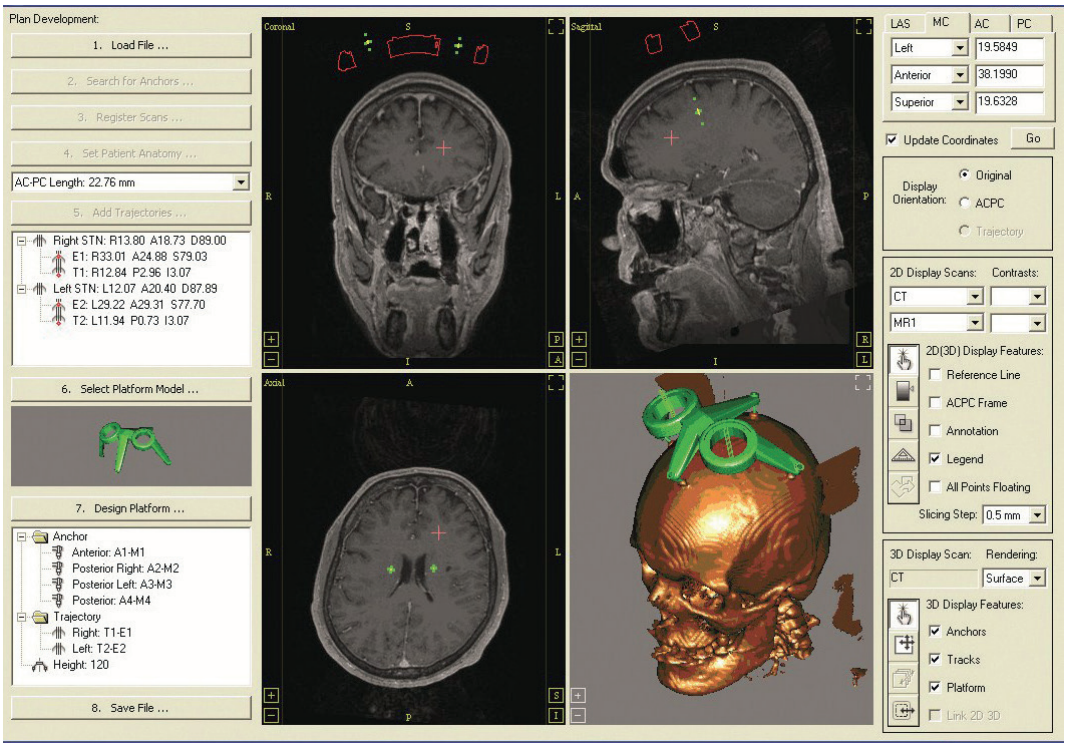
Brain surgery requires devices and instrumentation that are manufactured to the highest levels of precision. Deep Brain Stimulation (DBS), which treats acute symptoms of various diseases, targets areas of the brain that are measured in millimetres. Yet every person's brain geometry is unique. FHC—a worldwide leader in innovative neuroscience products for more than 40 years—collaborated with a leading neurosurgeon to transform traditional stereotaxy using a 3D-modelling process based on each patient's anatomical coordinates. The first application of this new STarFix technology is the award-winning, patient-matched, frameless microTargeting™ Platform, which offers greater patient comfort, increased accuracy and time savings in the operating room (OR). Using the FORMIGA P 100 to laser sinter the Platform, FHC achieves precision results at reduced costs within record delivery times.

Challenge

Neurologists with patients who suffer from Parkinson's disease, essential tremor or dystonia that are not well-controlled by medication have increasingly been referring them for DBS surgery. Some 8,000 such surgeries are now performed each year. However, to prevent movement during the procedure, traditional stereotactic frames fix the patient's head in place for many gruelling hours of awake imaging, target identification and electrode implantation within brain tissues. The FDA-cleared Platform, developed in the late 1990s and now in use in hospitals around the world, provides a custom mounting interface between patient and device that allows for the surgical plan to be built directly into the geometry of the fixture in advance of the OR. Patients enjoy movement and relative comfort, neuronal targeting and lead placement are more efficient, and OR time is reduced to an average of two hours in a bilateral procedure. Although FHC had been using various additive manufacturing technologies to produce the Platform before, as demand for the new device grew they wanted to reduce production turnaround



FHC's WayPoint™ Navigator Planning Station allows the surgeon to choose target and entry points, and combines those with anchor locations to create the Platform design (Source: FHC, Inc.).

times, lower costs, and more easily accommodate surgeon's special designs—all while increasing the precision of their finished products. "We are also looking to expand development of enabling products into other surgical specialties such as orthopaedics," said Fred Haer, FHC CEO and STarFix President. "Laser sintering from EOS offers a solution to these multiple needs."

Solution

"We're very pleased with the advancements in additive manufacturing we've seen since the STarFix technology was patented in 2001," says Haer. "To meet our most exacting standards, we moved our primary production of the fixture to an EOS system in 2011."

Unlike traditional, large, universal stereotactic frames, each STarFix device is both patient- and procedure-customized in advance from MRI and CT data. FHC planning software locates 3 or 4 anchor attachment points in the skull and then allows the surgeon to input a selected target and trajectory. These inputs create a custom-formed stereotactic guide that attaches precisely to the anchors, aligning the microdrive for recording and DBS lead placement. This same "growing to a desired shape" customization is reflected in the design flexibility and precision provided by laser sintering. Following the parameters of an intelligent, independent solid model provided by the planning software, the fixture is "grown" inside the FORMIGA P 100 in only a matter of hours using PA 2201 polyamide powder.

Results

The switch to manufacturing the Platform with EOS technology has provided numerous benefits to FHC. "Our new machine is smaller, lighter and more accurate than what we were using previously," says STarFix Chief Technology Officer Ron Franklin. "Plus, we've been able to add new features to the Platform while reducing materials and processing costs."

Parts consolidation enabled by laser sintering has allowed FHC to fine-tune the STarFix design, reducing assembly time in the OR. "We're now able to build more of the parts right into the Platform with additional features that simplify the mounting of various devices so it's more precise," says Franklin. One example is a metal indexing ring that was formerly screwed onto the platform by the surgeon during the surgery. "Now we can incorporate that function within the finished fixture," says Franklin. "This saves us the effort of having to provide that machined part separately and saves the hospital OR time because they don't have to sterilize the part and keep track of small, loose screws during surgery."

Materials savings are another benefit of additive manufacturing. "We found it was more economical to use EOS' high-quality polyamide," says Franklin. "Another thing we like about the FORMIGA P 100 is that there is no overflow material needed in the build envelope." Since all material added to the system is used, there is less material consumption.

Response time to the doctor's needs is a key driver at FHC. "We typically receive a patient file during the working day, consult with the physician as needed to confirm the design, start manufacturing that afternoon and can send back the finished Platform the next day," notes Haer. "This means about a 48-hour turnaround in the US, 72 to Europe."

"We anticipate even greater product improvement opportunities from the switch to laser sintering as we go forward. Having the flexibility of a technology that can create patient-specific solutions rather than one-size-fits-all can result in both hospital economies and better patient outcomes,"

Fred Haer,
FHC CEO and STarFix President

"The trend in medical devices is to create customized products. EOS technology provides us with patient-specific product manufacturing while enabling us to control costs as we speed delivery to our surgical customers."

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