Company Finds ‘Spine-Tingling’ Alternative to Surgical Device Redesign

Tom Solon and Peter Fatone

The Project: An accelerated lead was needed on a lead screw in a spinal surgical device that would enable fewer turns to generate the necessary motion without increasing the load.

The Solution: A custom assembly consisting of a combination metal-screw, polymer-based nut, and bushing system was provided that fit into the original device, eliminating any need for a redesign.

Whether it’s a horror movie, a first love, or a bad job interview, there’s an endless list of things that can send a chill up one’s spine. Synthes Spine [1]. with help from Haydon Kerk Motion Solutions [2], is doing its best to ensure that patients can feel those chills.

The end product is a device that is significantly smaller and weighs about

half as much as its precursor.

That may be a stretch, but the fact is Synthes Spine, a developer of orthopedic implants, designs extremely advanced instruments for spine surgery. Among the most notable are the Luminary ALIF (anterior lumbar interbody fusion) Disc Preparation and Implant Insertion Instruments–a toolkit filled with the necessary tools to insert a spacer into the spine in an open surgical procedure.

The centerpiece of the toolkit is a device called the Synthes Quick Inserter/Distractor (SQUID). This screw-based, hand-operated instrument goes into the gap where the spacer will be placed, pushes the implant into the proper position, and then withdraws without damage to the tissue or bone structure. This is a far better alternative to the method used before the SQUID–having the surgeon physically hammer the spacer into place.

While the ALIF procedures are common, there are viable alternative approaches to the spine. A surgeon can employ a lateral approach, or 90-degree offset from straight anterior. This option preserves the anterior longitudinal ligament and avoids patient vasculature (blood vessels). While it has other distinct benefits, the decision to use the anterolateral approach is based on several factors.

“The surgical approach depends on many variables,” said Peter Fatone, the engineer with Synthes Spine responsible for the latest SQUID design. “While it can simply be a matter of surgeon preference, it can also depend on whether the patient previously had a surgery in that same plane. Many times, if they’ve already had an anterior surgery, it’s hard to get through the scar tissue, so the alternative is to come in from a different direction.”

Regardless of why it’s done, the lateral approach was a welcome addition to a surgeon’s arsenal. The only hitch, from Synthes’ perspective, was that the SQUID that was used in the anterior procedure would not work for the lateral approach–at least not in its current incarnation because the instrument was too large; unlike in the other approaches, the SQUID would have to fit inside a retractor.

While the existing anterior device could certainly be used as a foundation for the redesign, adjustments would have to be made to make it work for the lateral approach. But it wasn’t just the physical dimensions that Fatone wanted to address; there were ergonomic and financial issues as well.

“I thought there were areas of opportunity to make the device work for the lateral approach but also to make it more efficient from the previous design, as well as [to reduce] manufacturing costs,” Fatone explained. “The redesign would make it easier for surgeons to turn the device. I also wanted a solution that wouldn’t require lubrication.”

“The tool that we had was already very effective,” he emphasized. “We just needed to do some reconfiguration so that it would work with the lateral approach. And as

long as we were redesigning it anyway, I figured, ‘Why not improve some other areas as well?’”

To help him in reengineering the product, Fatone enlisted the services of Haydon Kerk Motion Solutions, a leading manufacturer of precision lead screw and anti-backlash nut assemblies, stepper motor based linear actuators, and linear rail and guide systems. Tom Solon, an application engineer with Haydon Kerk, recalls the overarching challenge associated with the project.

“The big issue was the amount of force that was required to turn the handle,” he said. “Reducing the force would increase the ease of motion and decrease the fatigue the surgeon would experience during the procedure. Plus, the less pressure you exert on a device like that within a surgical procedure, the less chance of damaging the tissue. Clearly, an alternative screw design would be the solution.” Kerk precision rolled lead screws create exceptionally smooth motion and would prove to be the foundation for a custom solution requiring surprisingly low effort from the surgeon.

Fatone came up with a drawing of the design he wanted, but assumptions were made about what Haydon Kerk could provide. His initial design utilized a metal for the screw that was not typically used by Haydon Kerk and hardened steel for the two nuts in the device. Haydon Kerk normally works with metal screws and plastic nuts. Metal nuts were specified because Synthes, Spine and Haydon Kerk engineers expressed concerns about whether plastic could handle the load necessary to perform the task.

Using Fatone’s design as an initial “road map,” Haydon Kerk engineers supplied Fatone with a prototype of the redesigned tool. Fatone was pleased with the initial direction but decided on some incremental geometry and design changes. It was at this point in the process that Haydon Kerk’s flexible manufacturing capabilities began to really pay off.

“Haydon Kerk wasn’t locked into a single process when things changed,” Fatone stated. “The ability to move quickly and adapt to changing requirements and results were critical factors in our decision to use Haydon Kerk.”

“Haydon Kerk was able to produce the solution, but it didn’t perform quite as well as we had anticipated,” he added. “So we made some material changes, which greatly improved the performance. A few more design changes eventually produced the final version. Haydon Kerk’s ability to change its approach so quickly was a key benefit throughout the process.”

“Early in the project, we did struggle because we were trying to make the nuts out of steel,” said Solon. Metal-on-metal without lubrication is not the best way to minimize friction. Kerk lead screws have a reputation for low friction and reduced wear. Rapid prototyping by Haydon Kerk and immediate testing by Synthes Spine proved a polymer nut could be employed. “The fact that we have a high-quality screw with very smooth surface areas made the use of a classic polymer-based nut practical, whereas a rougher screw would not have worked, since friction and wear

would have been restrictive in that regard.”

“There were two threaded nuts in the original design,” said Solon. “But then it became clear that it would be virtually impossible to get the two threaded nuts timed in such a fashion that they could both carry any load. So we figured out a way to move to one nut and a bushing, which simplified the design and the implementation, as well as making it less expensive and easier to manufacture.”

Ultimately, Haydon Kerk produced a custom assembly consisting of a combination metal-screw, polymer-based nut, and bushing system that is compatible with all of the environmental constraints of the operating room, as well as providing high mechanical efficiency and ease. The lead screw, polymer nut, and bushing combination were able to fit into the original design of the tool, meaning that the inherent design of the device did not have to change. This translated to significant time and dollar savings for Synthes Spine. And in terms of design advantages, that was only the tip of the iceberg.

The end product is a device that is significantly smaller and weighs about half as much as its precursor. The initial release proved hugely successful, and Synthes Spine expects to produce about 200 of the devices during the year. One of the early surgeons to use the new SQUID initially doubted it was working properly because actuation required so little force. Upon realization that all was working well, the surgeon was very pleased with the device.

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The elements that resulted in such a well-received product are no mystery to Fatone. “The thread-rolling technology [of the Haydon Kerk lead screw] and their ability to provide a full custom nut solution were probably the two biggest factors in the success of the project,” he said. “But, it was not just their technical expertise per se; it was Haydon Kerk’s willingness to do whatever was necessary to meet our engineering objectives. Haydon Kerk treated this project like it was their own device, not ours.”

He also noted that their willingness to switch course was instrumental. “Rather than continue down a path that would clearly not pan out, Haydon Kerk didn’t hesitate to tap other resources within the company to find a better direction.”

Solon credited Fatone’s involvement as another contributing factor. “His commitment to the project, as well as his involvement, was invaluable,” Solon said. “Peter had a vision for what this new product could do, and he didn’t just delegate it to someone else. He stayed with it every step of the way.” Fatone followed the project from the design phase, through meetings with the Haydon Kerk manufacturing team, all the way to the operating room where he observed surgeries and reviewed performance with the surgeons.

Somewhere out there are many people with healthier spines who are glad that he–and Haydon Kerk–did just that.

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