Sandia's rapid prototyping expertise could help surgeons alleviate chronic back pain

By Bill Murphy

THIS IS SPINAL TAP — Terry Litts (14184) demonstrates a template developed using rapid prototyping technology. The template, which fits precisely over the target area of a patient's spine, allows an orthopedic surgeon to precisely control placement of the pedicle screws that are commonly used in spinal fusion surgery. (Photo by Randy Montoya)

Who doesn't know someone with a bad back?

It's one of those universal physical complaints doctors deal with all the time, a condition experienced by millions of Americans. For most of those so afflicted, occasional back pain is a fact of life, something to tough out and endure. For thousands of others it is literally unendurable, a pain so intense and relentless as to become incapacitating.

When it gets that bad, physicians will try "a," they'll try "b," they'll try "c"— and *then*, if nothing else helps, they'll look at surgery as an option.

Back surgery involving spinal fusion, which is called for in the case of intractable back or neck pain related to disc degeneration and/or instability that doesn't respond to other therapies, is problematic: it can and does succeed in reducing pain and restoring mobility for lots of patients. But it's a tricky, difficult, unforgiving procedure that doesn't always work.

Now, with the help of Sandia rapid prototyping expertise, these spinal fusion operations may become a more consistently successful and effective treatment, thus delivering thousands of people from lives of chronic pain.

Maintaining proper alignment

As an orthopedic surgeon at University Hospital in Albuquerque, Dr. George Brown has done his share of back surgeries. Dr. Brown explains that the biggest challenge in the surgery is maintaining proper alignment of the so-called pedicle screws. These are, as the name suggests, actual screws that are inserted into the spine. These screws are used to correct deformity, and/or treat trauma. Similar to other bone screws, pedicle screws may be used in instrumentation procedures to affix rods and plates to the spine. The screws may also be used to immobilize part of the spine to assist fusion by holding bony structures together.

Many techniques — including lots of hi-tech computer-assisted processes — have been developed in recent years to help docs get the best possible alignment of pedicle screws. Brown realized, though, that none of the techniques were as effective as surgeons would like them to be. He wanted something better.

Clint Atwood turned him on

About the time Dr. Brown was pondering the challenges of pedicle screw alignment, he heard a talk from Sandia rapid prototyping evangelist Clint Atwood (1314) and soon became a true believer. (If you've heard Clint talk about his passion, you will understand how he wins converts.) Rapid prototyping is an advanced manufacturing technology that enables you to generate real-world 3-D models from virtual 3-D computer renderings. In the post-Cold War era, with DOE downsizing its manufacturing capabilities, rapid prototyping was seen as a way to streamline the development cycle for certain weapon components. Dr. Brown wasn't interested in the weapon application, of course. He immediately saw rapid prototyping as a solution to the pesky pedicle screw alignment problem.

To appreciate the difficulty, visualize a spinal column. It's not solid bone. Rather, it's hollow in the center where the spinal cord travels from the brain down through the spine. The column is a series of articulated vertebrae. The front and back sections of each vertebra are connected by bone structures called pedicles. When you perform a fusion surgery, you're trying to rigidly link these front and back portions of the column together. Where are you going to put the screws? Why, through the pedicles. Straightforward — except that the pedicles aren't really all that big, and they're canted at an angle. They didn't evolve with a surgeon's needs in mind.

How could they *not* miss

And consider this: when you're operating on the patient, you can't *see* the pedicles. You're drilling down through them from back to front, not into them from the side. A surgeon does a prodigious amount of planning before going into a fusion surgery, devising the angle for the screw placement based on MRI imagery. That's helpful, but on the operating table, it's still in the surgeon's hands to get the screws in the right place. And sometimes, even the very best surgeons miss. When you weigh the technical complexity of the operation, you have to ask yourself, "How could they *not* miss from time to time?"

Back to Dr. Brown: He envisioned a way to use rapid prototyping to make a 3-D model — a jig — in which the pedicle screw placement would be almost foolproof. Armed with some R&D funding from UNM, he came to Sandia with his concept, hoping to partner with the Labs on an effort to apply this industrial technology to the healing arts.

Alan Parker, Manager of Mechanical Engineering Dept. 14184, thought Brown's concept sounded like a good challenge for his team. Researcher Mark Ensz and technologists Daryl Reckaway and Terry Litts were assigned the project. They're experts at turning computer models into real objects.

Mark explains how the process works: The doctor orders an MRI or CAT scan for the patient. He or she then works with the data from the scan, tweaking the bit-mapped MRI images (to compensate for certain limitations in MRI imagery) and highlighting the region of interest. The process is done layer by layer, as the MRI data come in swaths of 2 mm to 5 mm — you stack them together to get the whole picture. After the doc has cleaned up the image to his or her satisfaction, the layers are combined together as a 3-D computer model (using off-the-shelf Mimics software from Materialize, Inc.). This model, virtually a perfect image of the area of the spine where the surgery will occur, enables the physician to pre-plan the trajectory of the pedicle screws.

A perfect replica of the spine

So far, there is nothing unfamiliar here; similar techniques have been in use for some time. However, it's at this point that things start to depart from current practices. Up to now, the MRI/Mimics data has been used as a visualization tool. In the UNM/Sandia approach, the doctor takes the process to the next step: he or she actually "drills" the holes through the pedicles in the computer model of the spine, carefully indicating on the image precisely where the holes will be. Mark then takes these images with the "holes" drilled in them, and converts those holes — i.e., the trajectories through the pedicles — into separate, mathematically defined files. Then, the original 3-D file of the spine and the new file of the trajectory are combined into a rapid prototype-compatible file. This file is then "printed," either on a stereolithography machine or a selective laser sintering machine, as a solid real-world model of the spine, with the pedicle screw trajectories in place. (The machines build, layer by layer, a solid model of the computer file, using an epoxy or nylon material.) The model is a perfect replica of the patient's spine at the area where the surgery will occur. Now, the next step is where the real beauty of Brown's original concept shines through.

Mark, Daryl, and Terry make a second model, a reverse image of the spine model, one that slips over the vertebrae of the spine as snugly as a dainty foot in a glass slipper. This model also has trajectory holes in it — and they align perfectly with the holes in the first model. In other words, what you have is a perfect jig. It can fit in only one place on the patient's spine and, because it has trajectory holes in place, it guides the surgeon's drill with computer-aided precision. When you drill through the jig, you *have* to have perfect alignment, because it's already been worked out in the 3-D model.

More precise, less invasive surgery

The process, in addition to allowing more precision than any alternative method, should also make spinal fusion surgeries much less invasive — the surgeon needs to open only a small area in the immediate area of interest.

Brown and his Sandia partners have been perfecting the technique over the past couple of years. The tests done with cadavers, Mark says, have been highly successful and the interest level in the orthopedic community has been high. Brown is pursuing a National Institutes of Health grant to further refine the technique, including doing the procedure on real patients, alleviating real pain with a real-world 21st century solution.

Sometime in the next few years, if Brown's research continues to advance as successfully as it has so far, every major hospital in the nation could have its own rapid prototyping shop, manufacturing not just spines, but hips, shoulders, and other body parts that wear out due to age or trauma.