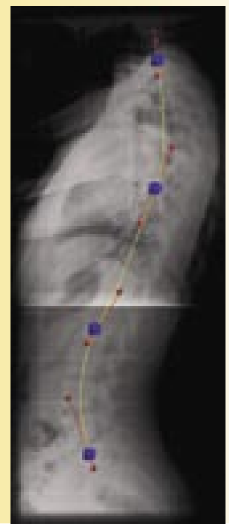
Harry Dankowicz and Don Leo

Photo by Michael Kiernan

This side-view two-dimensional radiograph shows spinal deformity in a scoliotic patient in an upright stance and coarse spinal geometry for three-dimensional reconstruction.



A step forward by design for spinal fusion surgery

Virginia Tech and Wake Forest researchers team up to advance scoliosis treatment technology

A teenager lies unconscious on an operating table, her spinal column exposed as a surgeon struggles to bend a titanium rod with a hand-held tool. The rod must be shaped into an angle that will help correct the patient's severe spinal deformity. After the surgeon wrestles the rod into an approximate angle, he bolts it to the vertebrae along a section of the spine.

Corrective surgery for scoliosis – a descriptive term for abnormal curvature of the spine – has advanced through the past few decades, with increases in the success rate and decreases in the time and discomfort of recovery. Surgery can reduce the magnitude of the spinal curvature, limit progression of the problem, and help shape a well-balanced spine in scoliosis sufferers. However, certain aspects of the procedure could use a technological boost.

"Shaping and affixing the rods to the patient's spine during scoliosis surgery can take several hours. The process of shaping rods with a hand tool is tiring to the surgeon and potentially increases the risk to the patient," says Harry Dankowicz, an associate professor of engineering science and mechanics at Virginia Tech. He is leading a collaborative effort to develop what could become one of the next advancements in the surgical treatment of scoliosis.

Working with Dankowicz are Don Leo, a professor of mechanical engineering at Virginia Tech, and Dr. Jeffrey Shilt, an associate professor of pediatric orthopaedic surgery at the Wake Forest University School of Medicine.

Dankowicz, Leo, and Shilt, all affiliated with the Virginia Tech–Wake Forest University School of Biomedical Engineering and Sciences, have created hardware and software that can help surgeons plan and carry out procedures aimed at correcting each patient's particular spinal deformity.

Scoliosis affects between 2 and 3 percent of the population – an estimated 6 million people in the United States, according to the National Scoliosis Foundation. The condition usually is idiopathic (the result of unknown causes) and typically develops during childhood. In 2003, the Virginia General Assembly passed legislation requiring scoliosis screening in public schools for grades five through 10. Although the onset of scoliosis affects about the same number of male and female children, teenage girls are several times more likely to develop severe curvature of the spine.

Many sufferers are able to forego medical treatments, but scoliosis can progress to severe spinal deformity, accompanied by chronic pain, limited mobility, and even difficulty breathing. Each year, the foundation notes, about 30,000 children are fitted with braces as a corrective measure and another 38,000 undergo spinal fusion surgery.

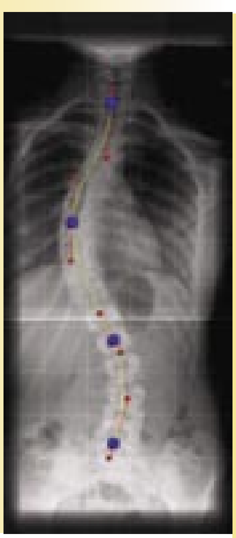
The idea for the Virginia Tech–Wake Forest collaboration was launched in December 2001 during the early days of the establishment of the joint School of Biomedical Engineering and Sciences, when Dankowicz and Leo visited Shilt in Wake Forest's Department of Orthopaedic Surgery.

During a discussion of scoliosis treatments, Shilt described the difficulties in performing corrective surgery and the need for new technology.

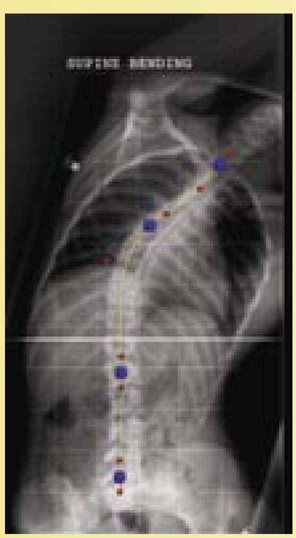
Dankowicz and Leo returned to Blacksburg with a goal in mind.

Currently, in preparing to operate on a patient with idiopathic scoliosis, a surgeon inspects two-dimensional X-rays of the spine and then refers to a classification scheme that helps identify curvature patterns and determine surgical techniques. The surgeon may be aided by software that helps measure the two-dimensional curvatures of the patient's spine.

This front-back two-dimensional radiograph shows spinal deformity in a scoliotic patient in an upright stance and coarse spinal geometry for three-dimensional reconstruction.



This front-back two-dimensional radiograph shows spinal deformity in a scoliotic patient during sideways bending and coarse spinal geometry for three-dimensional reconstruction.



"This project is an excellent example of how Virginia Tech and Wake Forest can work together to advance research goals in biomedical engineering. It also involved faculty members and students, who were able to learn some valuable design skills." Don Leo, *professor of mechanical engineering at Virginia Tech*

With the objective of advancing the computer–aided technology associated with scoliosis surgery, Dankowicz, in consultation with Shilt, developed software that uses two–dimensional X–rays to create three–dimensional images of a patient's spine. This software is designed to aid a surgeon in a number of ways.

First, the software's three–dimensional images can be manipulated and rotated to provide complete and detailed views of a patient's spine, enabling the surgeon to thoroughly analyze the spinal deformity before surgery begins.

The software also can search the most sophisticated and commonly used curvature classification scheme – the Lenke method – and determine the classification that most precisely matches a patient's particular spinal deformity. A Lenke method diagnosis, which is based on criteria from all known curvature types, enables a surgeon to locate the areas of the spine where rods should be attached and to determine how the rods should be shaped to most successfully correct the curvature. In addition to finding a Lenke classification to match a patient's scoliosis, the software Dankowicz and Shilt created can evaluate the statistical reliability of the classification.

Finally, the software can communicate computer–aided–design information to a hardware tool that will bend titanium rods to precise specifications indicated by the Lenke classification and the surgeon's analysis of a patient's spinal curvature. An initial prototype of the hardware tool was developed over a period of two years by students advised by Leo and Dankowicz in the mechanical engineering senior design course. Hosted by Shilt, several of the students attended spinal fusion surgeries at the Wake Forest University Baptist Medical Center.

The researchers are now working to perfect the software and hardware system. Second–generation development and integration of the hardware tool with a software–based control architecture is being pursued by Dankowicz and his research group at Virginia Tech. Shilt is testing the software's effectiveness as a modeling and classification tool from a surgeon's point of view.

"This project is an excellent example of how Virginia Tech and Wake Forest can work together to advance research goals in biomedical engineering," says Leo. "It also involved faculty members and students, who were able to learn some valuable design skills." In addition to collaborating on the project, Dankowicz and Shilt served together on the graduate committee for Dean Entrekin, a master's degree student who was part of the research team.

The researchers have provisional patents on both the software and the hardware tool through Virginia Tech Intellectual Properties Inc. and are exploring options for licensing of the inventions.

The software environment allows three-dimensional manipulation of computer-generated three-dimensional reconstruction of the vertebral column.

The software environment makes possible three-dimensional evaluation of computer-generated three-dimensional reconstruction of the vertebral column from digital radiographs.

Photos by Michael Kiernan

Software, developed by researchers with the Virginia Tech-Wake Forest University School of Biomedical Engineering and Sciences, creates three-dimensional images of the spine that can be manipulated for detailed examination. The medical team can then communicate with machinery that will bend a titanium rod to the surgeon's specifications. A rod, with the precise connection points and shape to correct the curvature of the spine, is ready before surgery begins.

"This proposed software and hardware system could significantly decrease the time and physical effort required of the surgeon in designing and shaping the rods used in spinal fusion," Dankowicz says. "Reducing the time required for surgery could reduce the exposure of a patient to potential infections."

Dankowicz notes another equally important advantage of the new system. "The increased accuracy of the computer–aided–design, as compared to manually shaped rods used as spinal implants, is expected to improve the likelihood of a successful outcome of spinal fusion surgery."

Dankowicz, who recently received a coveted National Science Foundation (NSF) Presidential Early Career Award for Scientists and Engineers for his research in the instability of dynamic systems, has for several years studied methods of preventing fall–related injuries. Among his goals is the design of prosthetic and orthotic devices that could reduce instability for people, such as the elderly, who are at risk of injury from falls. He also has worked with researchers in the Virginia–Maryland Regional College of Veterinary Medicine on an exoskeletal device for equine limb disorders and injuries.

For Leo, the scoliosis treatment technology was the first opportunity to work in the area of medical devices, but his research in dynamics and control of active material systems has attracted significant grants, including an NSF Faculty Early Career Development Program Award. Currently, Leo is leading a multi–university team of researchers in development of a new class of materials, using plant protein structures in an attempt to mimic biological systems.

- Liz Crumbley, College of Engineering