

■ Putting East Tennessee on the Map

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Bristol Surgeon First in Country to Acquire Images of Spine Stabilization System on Operative Patient

A small town practice shouldn't discredit the ability of a physician to participate in major research studies, and Morgan Lorio, MD, FACS, of Neuro-Spine Solutions, P.C. in Bristol, TN, is a prime example of this fact. Lorio has been the lead clinical investigator of a research study investigating the Stabilimax NZ Dynamic Stabilization System. Used primarily to correct degenerative lumbar spinal stenosis, the potential of this system has received much attention because of the growing incidence of the condition among baby boomers.

The concept of the Stabilimax NZ device is based on the "Neutral Zone Theory" developed by Monohar Panjabi, PhD. Basically speaking, the "neutral zone" of the spinal disc is the area where there is a stable laxity in normal posture allowing for pain free motion.¹ This movement is dependent on three units. The "control unit" is the brain; the "active unit" is extensor spinal muscles; and the "passive unit" is the bony spinal column.² When one of these units is degenerative, then the others must compensate, resulting in painful spine motion. When a disc is degenerated, then the neutral zone is increased and pain results.

Additionally, the concept of the center of rotation of spinal discs has received focus. Analogous to dropping a ball in a large bowl—it moves within that bowl a great deal. If you drop the same ball into a champagne glass, it is more constrained, allowing for less movement of the ball.³

Researchers in the study are interested in allowing for pain free motion within the "neutral zone" but also in an active, constrained fashion to stabilize the center of rotation. Ideally, to treat this situation is to find the area in which the disc could move without pain, but not limit the motion so much as to cause the disc to be rigid, as in spinal fusion.

The Stabilimax NZ is a motion preserving device that shrinks the neutral zone in a degenerative spine to within the pain free zone, allowing for more normal spine motion.

"These types of motion devices do several things for the patient and the surgeon," said Lorio. "[They] limit the amount of time of the surgery, limit or lessen muscle violation, thereby avoiding other morbidities such as back pain or blood loss. They allow us to tackle cases in older patients, which before, we couldn't get them off the table safely.

As Lorio explained, the ideal net result is that no other operation will be required. "The initial investment in this technology should offset future investments in that person," said Lorio.

New Imaging Technology

Lorio has to date performed nineteen of these surgeries and now has turned his attention to acquiring images of operative patients. "We are trying to determine who needs which device," said Lorio. "With approximately seventy-five motion devices coming to market, we believe it is prudent for surgeons to risk stratify their patients for each device's unique kinematic signature. The goal would be first and foremost to alleviate pain, secondly to improve function, and lastly to avoid adjacent level degeneration in the current thirty-seven percent of patients compromised by fusion technology."

Lorio and his team are innovators and have partnered with Ortho Kinematics to acquire images that are much more conducive to evaluating spinal disease.

"The Ortho Kinematics system is a device that standardizes trunk bending while obtaining three hundred images versus the two total images that result from conventional testing," said Lorio.

On November 4th, Lorio and his staff used the Ortho Kinematics system to acquire the first images in the country to study an

operative patient with the Stabilimax NZ Motion Stabilization Device.

"Currently, there has been no data acquired here in the United States," explained Lorio. "It's one thing to get static images and see the device is there, but you don't see what's happening when the patient bends. This is the first time motion data will be used to actually see how these devices work."

Lorio's work is putting East Tennessee on the map for spine technology. While choosing such an area may seem unusual, Adam Deitz, CEO of Ortho Kinematics, explained, "Dr. Lorio is very well-known in the spine community as an early adopter of advanced spine technology. He has really established a name for himself as a leader. So from the standpoint of his reputation, he's an obvious person to want to work with. More than that, he understands the motion preserving technology that we are working with in such a way that he can add a lot of value to the development of the technology."

As Deitz noted, right now, when surgeons want to assess the motion of the spine, they do so with technology that is over seventy years old. "They do it in a way that is horribly crude and has been shown time and time again to be ineffective," said Deitz. "We can provide the same type of data but in a much more precise and useful manner."

Obviously, there is great potential for increased standard with the partnership between Lorio and Ortho Kinematics. "He is using an advanced system that is motion preserving technology. We provide diagnostic information about the motion of the spine. It couples up perfectly with the type of surgery he is doing right now," said Deitz.

Continued Deitz, "The strength of Dr. Lorio's reputation is why we wanted to be in Eastern Tennessee and why we choose Bristol over other larger institutions. The hospital, and in particular the radiology department, have been extremely accommodating. You've got a good size community hospital that is willing to be accommodating and to host these new cutting edge technologies, which really becomes a venue for providing the best available technologies to their patients, despite the fact it isn't a major research institution. That commitment, from the industry's standpoint and from our standpoint, makes it a very attractive place to do business."

The Future of Spinal Surgery

This exciting acquisition of images is just the beginning of what Lorio sees as the future of spine care. "I think we are only seeing the tip of the iceberg of where this is going," said Lorio. "When you do a true study, the end result is what the study bares—either good data or bad data. It may indicate you are going down the wrong path, and you have to try other venues. However, if we determine the neutral zone hypothesis is correct, there will be smaller, less invasive, less painful improvements on this application of Panjabi's theory.

Continued Lorio, "Several companies are coming forward that are looking at this technology and saying, 'yes, we believe in maintaining this motion, but maybe we need more motion.' So we have to determine 'how much motion?' The only way to determine how much motion, and quantify it specifically, is to see it in a broad spectrum. We would like to use Ortho Kinematics for this and other studies."

As Lorio sees it, such imaging can be used for preventive care as well, and plans to work with Deitz to use the technology for other studies and evaluate other devices.

"Americans value their quality of life. When we look at where healthcare dollars go, we have to be prudent and use evidence-based solutions that are fiscally responsible to address what we are trying to treat, and in this particular case, preserve spinal motion."

More information about the Stabilimax study is available at www.legandbackpainstudy.com or www.neurospinesolutions.net.
VIDEO: <http://www.youtube.com/watch?v=sZO6UfKiTyg>

References:

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