Clinical Symposium I: Pedicle-Based Posterior Non-Fusion Stabilization

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INTRODUCTION

Diminution of lower back pain has been a goal of lumbar surgery for degenerative conditions for many years. Spinal surgeons have been trying to optimize their diagnostic and surgical techniques in order to maximize pain reduction and minimize tissue trauma at the operative level while maximizing the longevity of the surgical construct. Lately, adjacent level issues have been a more highly debated issue. The adjacent level has been one of the reasons behind the introduction of the artificial lumbar disc. Other motion-sparing technologies have been developed and are under investigation or are in use nationally as well as internationally. Inter-spinous and pedicle-based posterior dynamic stabilization, nucleus replacement, annular repair techniques, and disc regenerative techniques are all examples of such technologies. Unfortunately there are a lot of unanswered questions. Among the many unresolved issues is that of adjacent level degeneration. While there are some published data on the incidence of adjacent level degeneration in spinal fusion surgery in the lumbar spine, there are no long-term Class I data. The preliminary results of prospective randomized FDA trials, which have included lumbar fusions as well as arthroplasty in similar cohorts of patients, are the closest we have to such data. However, prior to reaching any definitive conclusions, we need long-term results regarding the incidence of adjacent level disease and the possible beneficial effects of motion-sparing technologies.

The concept of pedicle screw instrumentation without attaining a fusion is one that in the past has been known for having complications and being fraught with hardware failure, loosening and "instability." The role of pedicle-based dynamic stabilization and fixation without fusion has been more recently debated in the literature, and some authors have reported it as a viable technology for pain reduction and possible sparing of the adjacent levels. Such systems are thought to stabilize (to a physiologic range), rather than fuse or excessively restrict motion. Currently there are a number of pedicle-based dynamic stabilization systems that are either in use or under investigation worldwide. Given the paucity of long-term data regarding the outcomes of pedicle-based dynamic stabilization, we believe that identifying some of the potentially important variables and concepts can be of benefit to the future of this technique. In this

symposium we discuss and expand on such concepts with experienced clinicians as well as researchers who have been studying these devices and techniques on a national and international level.

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QUESTION #1 Given the knowledge we have today, what characteristics would you want in your ideal posterior nonfusion pedicle-based device? Please discuss the biomechanical characteristics that you find important for a dynamic stabilization system to accommodate, especially with reference to: pedicle-to-pedicle distance change, reestablishing a center of rotation, anterior/posterior shear control, rotational dampening effect, and vertical offloading.

Cunningham: First and foremost, I think it's important to understand that from a structural standpoint, a given lumbar functional spinal unit or multisegmental lumbar specimen represents a 3-column structure. Specifically, there are anterior, middle, and posterior columns, with each segment containing a 3-joint complex. This is composed of the anterior intervertebral disc and posterior facets working in concert to afford motion or kinematic properties to the motion segment. To this end, posterior dynamic spinal stabilization must re-establish and offer a range of kinematics—both loads and motions—to effectively restore and preserve motion, with or without the facets, to this 3-column structure. Or alternatively, reconstruction of the posterior column, I believe, will most likely be augmented with an intradiscal prosthesis; this could be a nucleus pulposus replacement [NPR] or total disc replacement [TDR] in the presence of 3-column pathology. So to that end, these devices, being posterior dynamic spinal stabilization in concert with a device in the anterior-middle column, must work synergistically to restore kinematics to the operative motion segment. This is the challenge we face from a biomechanical standpoint, and I believe that the 2 terms—"synergistic" and "restoration" —are 2 concepts we should keep in mind with reference to dynamic spinal stabilization.

The kinematic requirements for posterior dynamic spinal stabilization are multifactorial. Loads in the posterior column are approximately 20% of the entire lumbar spine. However, this can change based on the conditions of spinal destabilization, segmental degeneration or surgical reconstruction. In terms of the interpedicular distance kinematics, based on a presentation from our laboratory given at Spine Arthroplasty Society in 2006, this can range to about 2.5 millimeters per motion segment under flexion-extension. The intervertebral disc height, range of motion, and translation are all important kinematic properties of dynamic stabilization and must be addressed.

I think probably one of the principal challenges we face and the leading research issue is that related to the operative and adjacent level instantaneous axes of rotation [IAR] and how this may be influenced by dynamic spinal stabilization. The effect of an altered IAR on pain in my opinion is uncertain—at this point we don't know. However, from a kinematic/biomechanical standpoint, reestablishing the normal instantaneous centers of rotation is an important consideration for implant functionality and longevity. What we don't want to have is a condition of competing centers of rotation. Specifically, how does the implant's center of rotation, which is dictated by its position and intrinsic mechanics—how is that influenced by the spine, and are these competing? Or more importantly, it we have 2 implants in place, one anterior and one posterior, is there in fact a competition between those centers of rotation? What I don't know is the pain implication of these competing centers of rotation, but what this does create is the condition of undue stress at the prosthesis bone-metal interface and I believe an increased propensity for device loosening or migration. This is particularly important as we consider the dualistic approach of combined anterior-posterior [AP] dynamic reconstruction.

Anterior-posterior shear and rotational dampening are also a consideration here. Normal AP translation under flexion-extension is about 2 millimeters per motion segment in the lumbar spine, and again, this is a coupled-motion response to flexion-extension rotational moment. The facets themselves act as a positive stop under flexion-extension loading as well as axial rotation and the posterior dynamic spinal stabilization device should mimic this in the form of a soft stop. Specifically, the lumbar intervertebral disc for example can be torqued up to 22° but with facets in place it's limited to about 5°. So as we get to the limit of these segmental ranges of motion under flexion-extension or lateral bending, the device itself should have a soft stop to work in concert with the anatomical structures and preserve segmental kinematics. The elastic regions of segmental motion, that is, motion out of the neutral zone, are areas of increased stress at the bone-metal interface, and it's in these regions specifically that the device must offer some rotational and compressive damping. Vertical off-loading or eccentric loading, this simply implies a condition in which dampening components within the device must engage, and again, offer a soft stop under the extreme loading conditions of axial compression/rotation, lateral bending, and flexion-extension, all of which should serve to minimize stress at the bone-metal interface.

Patwardhan: Pedicle-to-pedicle distance change is linked with the location of the center of rotation. For example, if you consider an L4–L5 segment as the L4 vertebra flexes on L5, the pedicle-to-pedicle distance will increase in proportion to the angle of flexion and the distance of the pedicle from the center of rotation. So if the device, a pedicle-based nonfusion device, allows a change in the pedicle-to-pedicle distance that is less than what is normal in a healthy segment, then the center of rotation will move posteriorly toward the device, and this can alter the relationship between the facets and the disc in terms of how they share the load acting on the spine during activities of daily living. So I think it is desirable that the pedicle-based nonfusion device has a distance between the pedicles that is close to what it would be in healthy segments in order to maintain the relationship of the center of rotation.

The next thing I want to address is the concept of vertical offloading. As the intervertebral disc begins to degenerate, it begins to lose some of its height. It causes the annular fibers to bulge, and because the annular fibers are integrated with pain fibers this can induce pain. As the disc begins to lose its height, the loading on the endplate of the vertebrae becomes abnormal compared to what it is in a healthy disc. This is also thought to produce pain. So some amount of vertical offloading of the disc may be beneficial in those patients who have a load-bearing deficiency in their disc because of degenerative changes. So what I'm saying is it is beneficial to have the device share some of the vertical load at least in these types of patients. Regarding, A-P [anterior/posterior] shear control, again as the disc begins to degenerate, it not only loses its vertical load-carrying capacity, but also it loses its ability to resist anterior shearing motion. In a healthy segment both the disc and the facets resist the anterior shearing of the L4 and L5. So if the L4–L5 disc is degenerated, most of the anterior shear resistance responsibility will go on the facet joints, and if this is not offset in some way, in the long term, the facets will eventually degenerate. This is one of the points that is mentioned in Dr. Kirkaldy-Willis's degenerative cascade. So if you consider a scenario where a patient has a degenerative disc and a decompressive surgery was performed that compromises the facets, then both the anatomical components that are responsible for shear resistance are now compromised, and so the responsibility of anterior load sharing would fall on the posterior dynamic stabilization device. So it is beneficial to have that ability in the device.

Finally, the question of rotational dampening effect ... I think what this really means is whether the device offers a graded resistance to angular motion of the segment. A healthy spinal segment has a gradual increase in flexion angle with gradual application of loading. This is because the disc, the posterior longitudinal ligament, the ligamentum flavum, the facet joints, and all the other posterior ligaments provide resistance to angular motion. Now if the stiffness of the disc is substantially reduced due to degeneration or denucleation, then the stability of the spine will be compromised, and this can lead to increased activity on the part of the muscles to restore stability to the spine. The increased muscle loads in turn can cause stresses in the tissues and eventually, in the long term, cause tissue damage or pain. So in this scenario, the posterior dynamic stabilization device can augment the stability of the compromised segments by providing greater resistance, or this rotational dampening effect, to angular motion. So those are all important characteristics, and I have tried to explain the relevance of those desirable characteristics as far as restoring function to a compromised spinal segment.

Bertagnoli: The ideal system should be able to control the motion segment so it will function in a more natural way. That means that it should be able to reduce the hypermobility of the segment so that it comes back to the normal situation. We do not want the new system to change the natural sense of rotation a lot. It would be ideal if the natural center for rotation and the center of rotation that's controlled by the posterior pedicle screw-based system were not different, or at least we should see only a minimal shift from the natural center of rotation. The system should also be able to do translation and what we call negative shear force by advancing more or less in an anterior direction so that we also are able to control the possibility of there being a lot of initial degenerative spondylolisthesis and further degeneration of the disc. This is one of the goals of the system, that it should help to support the already affected disc in such a way that disc degeneration does not progress any further, or at least if there is any progression, it should delay the time of its progression. This is something an ideal system should allow. The system should also allow a kind of natural motion. If the patient is bending forward we increase the pedicle distance. Also, we have translation to the prompt on a natural movement pattern, so it should not be a simple hinge construct. It should really allow three-dimensional natural movement of the segment in such a way that it will unload the facet joint and allow movement of the joint. It is also important that it should not harm the natural tissue in a significant way so that we have to do a very aggressive surgery. A couple of implants, as we know, are only applicable when you make a big destruction of the posterior anatomy, like creating a complete laminectomy so that the implant by itself can be anchored safely onto the spine. This would be a little too aggressive.

Stoll: The discussion of the posterior nonfusion, pedicle-based device implies the discussion of lumbar instability. By definition a pedicle-based system is a stabilizing device, and all of the existing systems to a certain extent are load-

sharing. They unload the natural stabilizing structures—the disc, the facet joints, the ligaments, and the muscles—which are weakened by degeneration. These structures cannot withstand the applied loads, generate pain and dysfunction, and deteriorate further. Pain is either generated by these structures directly through their nociceptors expressed with local lumbar low back pain, or it is indirectly generated by the compressed nerve roots expressing radicular pain and dysfunction. The stabilizing device should act on both expressions. It should neutralize excessive loads and reduce pathological motion. This mechanism would be in correspondence with Panjabi's theory of the neutral zone, bringing this back to the normal. By stopping further deterioration, the device should also stop the development of degenerative deformities, such as degenerative spondylolisthesis and degenerative scoliosis.

Ideally, the system should share load in each plane, but of different degrees. Most important in my view is its action in the sagittal plane, a restriction of flexion and extension as well as translation. Translation is especially important in degenerative spondylolisthesis, where we frequently observe a hypermobility with extensive translational motion. Some effect on the rotation of the segment in addition is desirable. This pedicle-to-pedicle distance should be controllable for each instrumented segment and for each side individually. "Controllable" means that the distance can be determined by the surgeon applying distraction or compression segmentwise and sidewise. That means the system can counteract lordosing and kyphosing positions, and it can counteract the development of degenerative scoliotic deformity by inducing distraction on the concave side and compression on the convex side.

QUESTION #2 At which stage of the degenerative cascade do you envision a dynamic stabilization system to be most efficacious? Please discuss disc vs. facet degeneration and instability.

Cunningham: The primary issue here is at what stage of the degenerative cascade would a dynamic spinal stabilization system be most efficacious, and I think that the answer to that will be, in part, determined by the outcomes of the ongoing reimbursement issues for TDR [total disc replacement]. Surgical intervention using dynamic spinal stabilization will take place when surgeons know that insurance companies are going to pay for it. This is one of the principal issues we have right now with these devices. We simply can't get the insurers to offer reimbursement. But to answer the question a little more scientifically, we need to consider instability/pathology of the intervertebral disc versus facet degeneration. The degenerative cascade of the motion segment is a cyclic feedback response between the facet and the intervertebral disc. Each has the ability, in my opinion, to influence the kinematics of the motion segment, the instantaneous axis of rotation, and the load or kinetics between the anterior and posterior columns. This degenerative cascade at one level, which basically feeds back between the facet and the disc, has the capacity to continue and propagate to the adjacent levels. The timing for surgical intervention using a pedicle-based dynamic stabilization system would be for spinal stenosis, provocative facet pain coupled with degeneration or 50% collapse of the intervertebral disc. Obviously, surgical intervention at an earlier time point in this symptomatic cascade is better than later. However, again, it's probably going to be dictated by the surgeon's ability to be reimbursed.

Patwardhan: Although the indications may depend on the characteristics of the dynamic stabilization system, I think from a biomechanical point of view, their use is contraindicated in the late stages of spinal degeneration. In the early stage of the degenerative cascade described by Kirkaldy-Willis, the disc's load-bearing ability is somewhat reduced but the disc height is not yet substantially reduced and the facets are not affected—that's the early stage of the degenerative cascade. In this case a posterior dynamic stabilization device could be used to limit the amount of angular motion of the segment, thereby restoring the stability. As the disc begins to lose its height, you will need a device that could also provide some vertical offloading particularly at the posterior annulus. In a more advanced stage of the degenerative cascade, some decompressive surgery involving the facets may be needed to relieve symptoms. In that case you would also need a device that will also restore the stability after a wide posterior decompression.

Bertagnoli: That's a very simple question on the one hand but a very complicated answer on the other hand. Degeneration of the segment affects anterior as well as posterior elements. Especially if we have the typical start in the front of the disc we lose the pressure into our interdiscal space, and we have a typical height loss in the intervertebral disc distance, and with this we would see an effect on the posterior structure. That means that the facet joints run into a posterior position that

will induce secondary reactions from the body by hypertrophy of the facet joints and joint capsules, and with this we see a significant increase in negative proprioception, which leads to degeneration of the whole motion segment. It should be a biomechanical fact that the maturity of the body load is running into the entry portion of the segment, running through the vertebrae and through the discs. We know that the posterior structures are like facet joints, and the posterior structures carry approximately 35% of the load. This type of system can be used most efficaciously in the middle stage of degeneration. In this stage the disc by itself still has the appropriate height to allow motion of the segment, and the motion is typically in the hypermobile stage. This is the ideal stage for a system that includes all the biomechanical features we discussed in response to question 1: to delay the progressive deterioration of the whole motion segment to the effect that it will control the motion so as to not allow the segment to run into the end range of the hypermobility that is causing all the pain.

Stoll: A dynamic stabilization system must be efficacious in the stage of degenerative instability of a spinal segment. Spinal degeneration apparently starts with the degeneration of the disc followed by the degeneration of the facet joints. Cadaver and biomechanical studies demonstrate that these stabilizing structures while degenerating lose resistance to translational and rotational forces generating instability. Only in a late stage of degeneration the segment may—or may not—undergo restabilization. Degeneration and instability can generate low back pain on one hand and/or it can develop radicular pain and dysfunction on the other with disc herniation, disc protrusion, and the osteoarthritic hypertrophy of the facet joints resulting in stenosis. Hypermobility can provoke dynamic stenosis. Developing deformities such as spondylolisthesis and scoliosis furthermore contribute to stenosis, especially foraminal stenosis. Direct decompression by itself may create instability or increase preexisting instability labeled post-decompression or iatrogenic instability. This can occur in both above-mentioned forms.

Analyzing instability further, two manifestations can be differentiated. The first manifestation of instability is spontaneous degenerative segmental hypermobility or pathological motion. Segmental hypermobility can produce and is frequently combined with dynamic stenosis and may progress to deformity as olisthesis and scoliosis. The progression of a degenerative deformity like spondylolisthesis and scoliosis is a second manifestation of instability that we label “chronic instability” or “slow instability” in contrast to hypermobility, although the two forms often coexist. Degenerative deformity develops over time, an unstable condition that may or may not eventually be stopped by the natural course of restabilization. In chronic or slow instability olisthetic and scoliotic deformity frequently are combined. Degenerative scoliosis typically starts with a segmental unilateral olisthetic slip inducing a rotational deformity with scoliosis.

In my personal practice a posterior dynamic stabilization system is typically applied in cases with spinal stenosis that is combined with instability as described above. Ideal indications are dynamic stenosis and stenosis with early stages of degenerative spondylolisthesis. More and more frequently we encounter stenosis with early stages of degenerative scoliosis, and here I see another important indication for a posterior pedicle-based dynamic stabilization system. Typically these are elderly patients, some with osteoporosis. With a sole decompressive procedure, instability and deformity frequently are worsened. In these cases there is no need for a correction of the deformity, but it is essential to stop its progression.

Generally speaking, each grade and character of degenerative instability needs an adapted stabilizing procedure. Low-grade instabilities may well be treated with an interspinous device, more pronounced instabilities need a dynamic pedicle-based system, and high-grade instabilities or high grade deformities, as for example a grade 2 spondylolisthesis, need a fusion procedure. The choice of stabilizing implants becomes more and more wide and has to be expanded further. The segmentwise adapted combination of implants with different stabilizing capacities has to be feasible. That is for the hardware. But the spine surgeons definitely have to refine their understanding and classification of different stages of degenerative instabilities to enable them to determine the correct stabilizing procedure. And this has to be determined not only for an individual case but also for each spinal segment that has to be treated. Although there are no detailed analyses and few discussions in the literature about the relationship between degenerative stenosis and instability, once degenerative spondylolisthesis is accepted as a manifestation of instability, the evidence clearly supports the benefits of adding a stabilizing procedure to direct decompression. Before spondylolisthesis can be documented, there can be hypermobility of the segment with dynamic or permanent stenosis. But no specific terminology or precisely defined criteria are widely accepted in the spine community for the diagnosis of such an unstable condition of stenosis with instability. As a consequence, clinical studies that examine the surgical treatment of degenerative stenosis, with few exceptions, do not define this condition as a distinct pathological entity. However, such a condition definitely exists and warrants specific surgical treatments.

QUESTION #3 Do you envision dynamic stabilization systems to be used in conjunction with artificial disc replacement? If so, please discuss the case scenarios.

Cunningham: Yes, well most certainly they'd be used in combination with TDR. Quite frankly, I think that's likely to be the best application for posterior dynamic spinal stabilization. I would anticipate that the frequency of the surgical intervention procedures for posterior reconstruction alone would be equal to that of combined anteroposterior reconstruction. In other words, the occurrence of surgical reintervention for posterior dynamic fixation alone would probably be 50% and the remaining 50% would be a combined anterior-posterior construct. Again, the degenerative cascade affects both the facet and the intervertebral disc. So in cases of spinal stenosis requiring posterior decompression with a symptomatic degenerative disc, obviously the surgeon will reconstruct both symptomatic regions. If a patient requires posterior decompression with an asymptomatic intervertebral disc, the surgeon will manage it from the posterior alone. The devices should have application either posterior alone, or in concert for an anterior-posterior reconstruction.

Patwardhan: Yes, I can envision two possible scenarios of combination for artificial disc and posterior dynamic stabilization. First of all, if you use a disc prosthesis that has a single ball-and-socket type articulation, that type of articulation offers resistance to anterior shear loads; however, it has no resistance to angular motion. Based upon our experience in the lab, we know that after total disc replacement using such a device, the stability of the implanted segment may be compromised. A posterior dynamic stabilization device that provides a graded resistance to angular motion could be used to restore stability in such a scenario. The second scenario applies to a prosthesis that is unconstrained in anterior shear, for example, those with a mobile-bearing, such as the mobile-core Charité. If a prosthesis is unconstrained in anterior shear, that means it cannot resist anterior shear motion, unlike a ball-and-socket type device. In such a case, the facets would bear the entire anterior shearing load, and therefore a posterior dynamic stabilization device that can share some of the anterior shear would be able to restore the facet loads to near normal values and prevent the facets from being overloaded. However, the combination of motion preservation and dynamic stabilization may not work if the posterior stabilization device does not allow interpedicular distance change consistent with the design of the disc prosthesis.

Bertagnoli: We would see them [dynamic stabilization systems] in conjunction with artificial disc replacement because we are already doing this type of construct, which we call 360-degree motion preservation applications. If there has been a fusion in the past and still in the present we control the anterior column by support of the cage and the posterior column using pedicle screws or facet screws and other devices that will limit the motion and the posterior elements. With motion preservation technologies we can now control the anterior as well as the posterior column facet pain and high hypermobility and a high degree of degeneration of the facet joints. In this scenario it's very beneficial if we reconstruct the motion segment from the anterior as well as posterior with a combination of anterior and posterior motion-sparing devices. The only problem is that if we're using devices with the center of rotation as with other systems we have to match the posterior devices or the kinematic actions of the anterior devices so we will see no counteraction of one after the other. If this is the case we won't have good mobility in the segment because one device will block the other device. A combination of these devices should be very well defined so that those implants are working conjunctively and not against each other.

Stoll: Not with the actual type of total disc replacement. From their biomechanical behavior these implants are not suitably matched with the available dynamic pedicle-based systems. Moreover, such a combined procedure would be much too invasive with respect to the envisioned indications. Once a TDR has failed due to facet joint problems one could consider a posterior stabilization with a dynamic system. Hopefully, disc replacement is developing further. If we have improved and clinically reliable nucleus replacement devices available, one could imagine their combination with posterior dynamic stabilizing systems.

QUESTION #4 Please discuss some of the advantages of a pedicle-based dynamic stabilization device over a fusion system, dividing the advantages into those which you see as potential versus those which you see as likely.

Cunningham: One of the potential advantages and the one that we're all hoping for is that there would be a decreased incidence of adjacent segment disease with the use of a dynamic spinal stabilization systems and, thereby, reduce the frequency of patient return to the operating room. That would be a potential advantage. Likely advantage, yes, these are in comparison to the graft materials used in conventional arthrodesis. First of all, a non-arthrodesed segment using dynamic spinal stabilization obviates the need for autogenous graft. There's a certain amount of patient morbidity associated with the autograft donor site. Second, it also decreases the potential incidence of disease transmission using allograft. One of the likely advantages here is motion preservation, both at the operative and adjacent levels. We can anticipate that the operative level of motion is going to be preserved and there may be less hypermobility at the adjacent levels. And third, one of the likely advantages is the patients' perception of the surgical procedure as well as the postoperative outcome. I anticipate that their activity levels are going to be higher with quicker return to work times.

Patwardhan: I can think of two advantages. If you are able to restore stability using a posterior dynamic system while preserving some amount of motion, it's a potential advantage over fusion. There are some clinical data from the disc prosthesis literature that shows that preserving the motion may save the adjacent levels from accelerated degeneration. But the comparison between artificial disc replacement and dynamic stabilization may not be appropriate, as many of the stabilization devices tend to reduce ROM below the level of the healthy intact spine. Of course, there is no definitive data in the literature about the amount of motion required to protect the adjacent levels. For these reasons, I would call this a "potential" advantage. The second advantage with a posterior dynamic system over fusion, in my opinion, is that we have a better likelihood of preserving the musculature, during surgery for the implantation of a transpedicular stabilization device as compared to transpedicular fusion systems. To achieve a posterolateral fusion you have to strip the muscles completely off the transverse processes to allow the placement of bone graft, whereas for a transpedicular stabilization device, it would require much less muscular disruption. Muscle disruption can be a potential cause for failure of posterolateral fusion, and some people refer to this as "fusion disease." In the case of dynamic stabilization, you would necessarily have a lesser amount of muscle disruption, and therefore in my opinion, that's an advantage over fusion.

Bertagnoli: Dynamic stabilization as opposed to the fusion system has clear benefits, number one, because we will control the motion segment in a way that will restabilize the segment without an irreversible definite solution. By using a motion-sparing device like the pedicle-screw dynamic system we may be able in the future to replace disc function with a different motion-sparing device that will delay the degenerative situation for the next 10 to 15 or 20 years. The benefit for the patient is that it will buy him more active time in the active part of his life. Some people discuss fusion as a definitive permanent solution, but unfortunately it isn't. We know the high rate at which fusion patients develop degeneration of the next level, caused mainly by overloading of the adjacent segment because fusion is fixing the position of the patient, which is usually the upright position. If the patient is sitting or standing and needs to flatten his spine he's changing the position of the pelvis so that the segment cannot go into the needed position and the adjacent segment has to compensate. Most of the time this leads to more rapid degeneration. Potentially [with a pedicle-based system] we can decrease the amount of adjacent segment degeneration compared to [what could be done with] the fusion device. Obviously we allow motion and we allow the different positions of the spine during sitting, walking, lying down, and other sedentary positions. The more obvious advantage is that the pedicle screw-based device allows more motion than one can expect potentially with a fusion device. Another more obvious advantage is that we can go back into the system and change the motion-sparing part with the fusion part quite easily so that we can convert the pedicle screw-based motion sparing device into a fusion if that's needed. We also can use this type of device for multilevel applications. The more difficult job would be to use anterior devices like disc prostheses because we can bridge a couple of segments using a screw-based system. A potential benefit of this device could be that, according to the needs of different stages of degeneration, we could use a more mobile portion in one segment and a more fixed position in another segment and a more rigid or flexible portion in another part of the system. This flexibility or dynamic features of the system can be varied in each segment.

Stoll: A potential advantage of a pedicle-based dynamic system over a fusion system is its ability to maintain some functional mobility and by that having the potential of not overloading adjacent segments. This is obviously interesting in multisegmental instrumentations.

Now, it is likely or even certain that the advantage of a dynamic system is that it is less invasive. There is no necessity for bony fusion with additional tissue preparation, there are no bone harvesting problems, and less surgical time is needed. There is less peri- and postoperative morbidity. Based upon our series of [procedures done with] a dynamic pedicle-based system there is evidence that the general complication rate as well as the device-dependent complication rate is low compared to data from many published studies of standard pedicle-based fusion procedures. This may be due to its lesser invasiveness. Screw breakages are very rare, and the rate of screw loosening is low. It is hypothesized that, due to its lower stiffness, a dynamic pedicle system, and therefore also the screw-bone interface, may see less load than conventional internal fixator systems. Load transfer is substantially different, since the screws are not rigidly linked by a rod. Peaks of maximal loads transferred to the screws may be flattened by the elasticity of the connection and the subsequent load sharing with anatomical structures. This may explain the low implant failure rate in this series.

QUESTION #5 Which case scenarios would you see as potential contraindications to the use of a pedicle-based dynamic stabilization system?

Cunningham: Well, first and foremost, would be a condition of osteopenia or osteoporosis. I believe the one potential area for concern, which is the weakest link in the use of a dynamic spinal stabilization system, is the condition of osteoporosis. Long-term functionality of pedicle-based dynamic spinal stabilization implants is primarily dependent on prolonged fixation at the bone-metal or bone-pedicle screw interface. Starting out with a condition of decreased bone mineral density would be an area of concern and contraindication. Stand-alone dynamic spinal stabilization is also contraindicated in cases of degenerative disc disease. Once the facets are removed, the prevailing question of concern is, Can one obtain pain-free motion in the presence of a degenerative disc? Patients do very well by removing that painful degenerative disc, then having a total disc replacement. So the question becomes, Are we going to be able to restore and preserve pain free motion with dynamic spinal stabilization alone? So those would be the two areas I consider contraindications.

Patwardhan: I think it depends upon the abilities of the posterior dynamic stabilization device. They all have different abilities, so the devices that cannot resist anterior shear, as I said before, should not be used when there is anterior-posterior instability or listhesis, such as in unstable spondylolisthesis, where the L4 or L5 vertebra slips forward in relation to the inferior vertebra—it indicates that the patient's spine at that level is unable to resist anterior shear. So if a posterior dynamic device is not able to resist shear, then that would also be a contraindication. Rotational instability, which can be caused by, for example, facet tropism or any torsional injury, would also be a potential problem, because most of these devices do not resist torque or rotational type of motion very effectively. The third contraindication would be a severely degenerated segment, because all of these devices rely on soft-tissue balance, so that in a severely degenerated segment the soft tissues' properties are also substantially altered from a healthy segment, and so, in my opinion that may not allow the proper functioning of a posterior dynamic system.

In pedicle-based dynamic systems screw loosening may be an issue, especially for a stiff device. Therefore, this may be a contraindication in the presence of osteopenia or osteoporosis. If the pedicle screws are at risk of loosening the longest possible screws should be used to get a better purchase in the vertebral body.

Bertagnoli: Contraindications are situations when the anchor of the device is not enough to transmit loads into the system or from the system into the spine or the spine into the system. In cases with bone density problems, like osteoporosis, this is a contraindication. For example in fusion the load transmission is from the pedicle screw into the spine because of the 90˚ load, which means we put a lot of pressure on the screw anchor, and we know from the fusion construct that will loosen it. The fact that these systems are more flexible [can cause problems] in 5% to 15% of cases. This is one of the most likely contraindications. We do not have distance in the prompt, so that the whole segment is not able to move adequately. These are cases where the systems may be contraindicated. Other contraindications might be spondylolisthesis patients, who would be better controlled by a fusion device.

Stoll: Grade 2 and more spondylolisthesis, isthmic spondylolisthesis, higher-grade degenerative scoliosis, tumor, vertebral fracture, and infection.

QUESTION #6 What do you believe is the mechanism of action for these devices in the clinical setting? (That is, which of the biomechanical effects of these devices affords pain relief?)

Cunningham: Well, the clinical mechanism of action is simply to provide the same or improved clinical benefit in terms of VAS [visual analog scale] and ODI [Oswestry Disability Index] scores as that of a conventional spinal arthrodesis procedure, while preserving spinal kinematics and potentially decreasing the incidence of adjacent-level disease. To achieve this, the implanted posterior dynamic system alone or posterior implant combined with an intervertebral device must work synergistically to restore kinematics to the operative motion segment. The intervertebral disc and posterior facets should be off loaded to permit pain free motion preservation.

Patwardhan: As I explained in my answer to number 1, the mechanisms are 3-fold. First, restoration of the neutral zone and stiffness in the high flexibility region, to the level of the index segment without completely eliminating the motion. Second, relieving the pain in some patients by restoring height and vertical offloading at the posterior annulus and the third mechanism is restoration of the normal motion between the disc and facets, by restoring the center of rotation to its intact location. Those are the 3 possible mechanisms by which these devices can work in a clinical setting.

Bertagnoli: Actually there are many theories on what is causing the pain or what causes low-back pain. There is what we call stone in the shoe hypothesis. If you don't walk in a shoe you will not feel any pain. You'll feel discomfort but not pain, but as soon as you walk in the shoe you will feel the pain. Another theory is from Panjabi. He talks about a neutral zone. If the spine is in the neutral zone there will be no loss of proprioception. He's promoting that the dynamic portion of the segment as well as the static portion and the linkage system should be in a well-defined harmony. We will see hypermobility. This will cause a significant loss of control of the dynamic portion, which will cause pain. My theory is close to this neutral zone theory. We call it active zone theory. That means we look at the healthy segment, and this segment allows a certain range of motion. If this segment of the disc loses its function it gets a disability in a way that we typically have more motion than normally because we do not have the same resistance of the ligament due to the laxity. It means that we will induce proprioception that's causing pain in the very end positions of the motion segment. The segment now allows more mobility. In other words we try to cut away or break off the very end portion of the motion segment by using a dynamic system, and that's something we can customize by using a different type of dynamic linkage system, so that by cutting out the very end of the painful portion of motion we go back to an active zone. That means if we use an active zone that allows enough motion and does not involve muscles in the very end stage we will be able to reduce the proprioception that causes pain.

Stoll: The main mechanism of action of such a device is the fact that it supports the natural stabilizing structures, which are weakened by degeneration and which generate pain and dysfunction. The device unloads these structures, reduces pathological motion, blocks further deterioration and the recurrence of stenosis, and stops the development of degenerative deformities.

QUESTION #7 What approach seems in your mind to be the optimal way in which to insert these devices to provide the best clinical effect? Discuss the midline conventional approach versus the paraspinal muscle-sparing approach.

Cunningham: The posterior surgical approach would be dictated by the pathology present. In cases requiring decompression of the spinal canal, a midline approach is certainly going to be indicated. The purpose of the surgical

intervention is to first alleviate or treat compression of the neurologic structures and then secondarily offer segmental fixation. If segmental instrumentation without spinal decompression is indicated, a muscle-preserving Wiltse-type approach offers the advantages of preserving the midline paraspinal musculature. In my opinion, there's a significant biomechanical benefit to dynamic spinal stabilization by preserving the paraspinal musculature and reducing muscle ischemia secondary to prolonged retraction, which can be obtained using a Wiltse approach to the posterior spine.

Patwardhan: Since I'm not a surgeon, I'm not really qualified to address the surgical approach, but I think it makes biomechanical sense to use the approach that is the least disruptive—they call it the muscle-sparing approach, meaning it causes the least disruption of muscles, because after all muscles are the main dynamic stabilizers in our joints. From what I've read, the paraspinal approach better preserves the muscles' function as the dissection is done through the intermuscular interval and preserving the dynamic spinal stabilization function of the muscles is clearly an advantage. Also minimally invasive techniques for implantation will have an advantage.

Bertagnoli: We have used Dynesys and other systems as well. Using a motion-sparing device is a very important issue because we also have to protect the dynamic portion of our motion segment—the muscles. If you strip the muscles or indurate the muscles by using the classic approach you are counteracting the normal motion pattern. The only logical way to use a pedicle screw motion-sparing device is as a muscle-splitting device where you split the muscles or modify and separate the muscles. That means you do not harm the posterior section of the segment at all. At least you significantly minimize the trauma to the soft tissue using this type of device. The active motion is only caused by muscular function. In order to restore muscular function we have to preserve it.

Stoll: I prefer the midline approach in cases where a direct decompression is needed. This is the case in the vast majority of my patients. A paraspinal Wiltse approach is appropriate once only stabilization is intended.

QUESTION #8 Do you believe the indications for pedicle-based devices to be similar or different compared with those for interspinous-process devices? What are the similarities and differences?

Cunningham: On the continuum surgical intervention, I would suggest that interspinous stabilization devices would precede pedicle-based dynamic spinal stabilization implants. Again, the pathology present here would dictate the course of surgical intervention, be it stand-alone interspinous or pedicle-based dynamic spinal stabilization. From a biomechanical perspective, interspinous stabilization affords 1-column stabilization. That's posterior stabilization, which has the capacity to reduce segmental flexion-extension motion and has little effect on axial rotation or lateral bending. Pedicle-based dynamic spinal stabilization, in fact, offers 3-column stabilization to the functional spinal unit. So it's biomechanically more challenging for a pedicle-based dynamic system compared to an interspinous stabilization device. I think from a clinical standpoint that interspinous posterior stabilization devices have better application in the elderly as the posterior elements over time retain their bone mineral density versus the osteopenic pedicle and vertebral body. So, in the elderly patient the surgeon can obtain excellent fixation across the spinous processes and not have to worry about loosening at the transpedicular site, whereas pedicle screw-based fixation is of course bone mineral density dependent.

Patwardhan: An interspinous-process device is unlikely to restore stability in axial rotation. We have done numerous studies on such devices in the lab, and we have seen that once a decompressive surgery is performed and the segment becomes unstable in axial rotation, it is very difficult to restore that motion to within the normal limits using the interspinous-process device. The same is true for lateral bending and anterior-posterior shearing motion. So I think there is a much better chance to restore stability in all these planes using the pedicle-based system than the interspinous-process device. That's one biomechanical difference in terms of their function. Another difference is that transpedicular devices can be designed to target the neutral zone in decreasing segmental instability. Whether interspinous devices can achieve this

remains to be studied. Finally, if the decompressive surgery requires the spinous process to be removed, for example after a laminectomy, then of course you cannot use an interspinous-process device.

Bertagnoli: Clearly, yes, because if you're looking for interspinal devices, most are expansion blockers. They do not allow active motion. They allow directly or indirectly increasing the posture in such a way as to stretch the ligaments. That means we create more space in the spinal canal. We allow indirect or sometimes direct decompression of spinal stenosis. The problem with most interspinal devices is that we fix the segment in the neutral or kyphotic position. If the patient extends he can no longer use the segment for an active motion or for flexing from flexion into extension. Most of the implants are not able to control active motion. The pedicle screw-based systems are able to control extension as well as natural rotation and all the other components of motion. That is the clear difference. Indication-wise there is also a big difference. The interspinal implant should be used mainly in situations where a decompression of the spinal canal is needed indirectly. In this kind of case it makes more sense to use an interspinal device. Pedicle-based devices can be used in conjunction with interspinal devices in patients with instability and stenosis.

Stoll: Both are posterior stabilizing devices and logically there is an overlap of indications. Historically the first one that actually pushed the idea of interspinous stabilization, Jacques Senegas from Bordeaux, France, suggested the use of interspinous spacers in cases where a direct decompression for stenosis had been performed to stop a further compression of the posterior aspect of the segment. Later, the idea of indirectly decompressing the segment with interspinous devices was introduced, by just distracting the posterior elements. Biomechanically available interspinous spacers have a substantial stabilizing effect only in the sagittal plane on extension. But they have no significant effect on flexion, translation, and motion in other planes. With that capacity of load sharing in extension they can address early stages of instability. They can prevent the recurrence of stenosis, but data on their long-term effect are not available or not yet convincing. The devices may be able to unload the facet joints and even the posterior aspect of the disc to some extent. But data on their effect in low back pain, facet pain, and discogenic pain are still very sparse. In conclusion my perception is that interspinous stabilization may be an important contribution to the spine surgeon's armamentarium in the treatment of the multiple stages of segmental instability.

QUESTION #9 Do you believe that muscle action and soft-tissue balance may play important roles at the instrumented, nonfused segment? If so, are the biomechanical models presently used representative of the clinical setting, and can we make appropriate conclusions from these on the basis of bench-top experiments?

Cunningham: Well, the answer to that question—does muscle action and soft tissue balance affect spinal stability of a nonfused segment—is most definitely "yes." If you review the literature in this area, you'll see that over the past 18 years we have accumulated about 140 articles related to the effect of muscle action on spinal stability. The first person to report this and provide a very nice study, more or less a landmark study, is that of Panjabi in 1989. He investigated the effect of muscle coactivation with biomechanical loading and basically concluded that the spinal column, devoid of musculature, is incapable of carrying normal physiologic loads. In an in vitro experiment, the effect of stimulated intersegmental muscle forces on spinal instability was investigated. The study basically highlighted the concept that increased physiologic loads can significantly alter the ranges of motion by increasing the compressive loads across the spine, and in fact, Panjabi concluded that the neutral zone is a better indicator of spinal instability than range of motion, where these muscle coactivation forces are applied. Some of the current in vivo models which are used to compute forces on internal loads are kinematic-based methods using nonlinear finite elements and surface EMG activity, which can be performed in volunteers. The current in vitro models used to compute muscle forces and loading would be similar to the "follower load" described by Patwardhan et al and muscle force replication [MFR] in the cervical and lumbar spine, which has been reported by Drs. Panjabi and Wilke. I think one of the principal areas of concern here is whether or not the ranges of segmental motion produced and quantified in the laboratory setting are predictive of those obtained in the clinical setting when using dynamic spinal stabilization. One of the very first studies, and probably the most recent study in this area was reported by our laboratory and published in the *Journal of Neurosurgery* in which the global range of motion of lumbar arthroplasty was compared. We compared an in vitro cadaveric model in the laboratory to 267 Charité patients with the specific objective of looking at the segmental kinematics of both the operative and adjacent levels under flexion-extension loading and found in fact that they were nearly identical in terms

of a global range of motion. So to this, then yes, biomechanical modeling using a conventional 6-degrees-of-freedom spine simulator testing strategy can predict the in vivo clinical operative and adjacent level range of motion.

Patwardhan: Yes, muscles are the most important dynamic stabilizers of any joint in the body. And naturally their action should be incorporated in biomechanical models whether they're bench-top models, working with cadaveric specimens, or they are computer-based models such as finite-element models. Regardless of what type of model it is, it should incorporate the important dynamic stabilizing effect of muscles on the joints. Muscle forces stabilize our spine in vivo and allow us to sustain the large compressive loads during activities of daily living. And because biomechanical testing is so important in understanding the spine's behavior in disease and developing new treatments, if you ignored the effect of the muscles, it can lead to erroneous conclusions regarding the effectiveness of different treatment methods. But it is very difficult to incorporate these muscles in experiments on cadaveric spines and in computer models because there are so many muscles that are active in every activity, and one really doesn't know what role individual muscles play in load sharing. So it is very difficult to have a detailed representation of these muscles in any experiment, whether it is bench-top experiment or a computer model. However, in our lab we have pioneered the use of what we call the follower-load method of spine testing, and it is being used now in a number of laboratories in the United States and around the world. I'm not going to go into the details of how this model works ... it's extensively published in the literature. This model allows evaluation of the spine's response at the implanted level as well as at adjacent levels; it is a laboratory model that simulates the physiologic load and the stabilizing of the muscles. It is my belief that such a model will allow clinicians to better understand how treatments work and better evaluate new technologies as the care of spinal disorders evolves in the future. We have been using this model to look at artificial disc replacements and also posterior dynamic systems. And we see a substantial difference in the conclusions depending upon whether you incorporate the models' muscle loading or not. To summarize, it is essential to include muscle action in biomechanical models, and the follower load model allows at least one way of doing that at the present time.

Bertagnoli: I think I have answered number 9 already in number 7 and number 8. I think we have run through the theories. I mostly think the active zone is the new theory we have brought into the world. That's a kind of mixed answer of the questions I've already answered.

Stoll: Muscle action is playing a role with these devices. They are load sharing by principle and to more or less extent depending on the load-bearing capacities of the natural stabilizing structures. The muscle is one of these addressed structures. It is essential that biomechanical models for the evaluation of dynamic stabilizing systems take this into consideration. State-of-the-art testing machines substitute trunk loads with preloads and refined follower loads. These approximate the clinical setting at the time of implantation but they are unable to evaluate the long-term behavior of the interface of implant and living tissue. Dynamic stabilizers are prostheses, and unlike rigid pedicle systems for fusion they depend on the long-term reliability of the interface. This is a decisive limitation of bench-top experiments with dynamic stabilization systems.

CONCLUDING REMARKS

Our understanding of posterior non-fusion stabilizaton systems and their clinical relevance has come a long way in the past few years. Yet there clearly are many areas of scientific debate. This symposium posed some of the pertinent questions in this debate to two renowned biomechanics experts and two highly experienced surgeons. In their responses, the participants gave a fair balance of our current knowledge of these systems. The reader can clearly see that much work needs to be done to get a better understanding of this technology.

In their expert responses to our symposium questions, the effects of various biomechanical parameters in the design of these systems were well addressed, and there was a general consensus among the four faculty. What remains to be addressed is the relative importance of each of these characteristics and whether one characteristic may be more important in a clinical setting compared to another. This may spawn different devices with emphasis on differing characteristics that may then make the devices more applicable in a clinical setting. For example, if vertical offloading

is desired it may be necessary to offer more stability than mobility for that segment. As addressed by Dr. Stoll it does seem important that each individual segment be addressed and stabilized according to its individual needs. Hence, in a particular system there may need to be variability, in what biomechanical properties are appropriate to stabilize that individual level. The ability to vary the parameters for each individual segment and from patient to patient may be more important than the "one cookbook fits all" approach.

The ability to combine such variations in parameters with present artificial disc devices and maintain global motion may be challenging biomechanically, which has been addressed by the panel. It also appears conceptually that intervention with pedicle-based posterior non-fusion systems may be more desirable in the earlier stages of degeneration in order to maintain mobility and protect and preserve the disc. The ability of these devices clinically to actually prevent adjacent segment degeneration is still speculative, and long-term data is needed. Indications and acceptance are going to be dictated by reimbursement issues, as eloquently articulated by Bryan Cunningham

The choice of approach for these pedicle-based devices is gaining consensus and a muscle sparing minimally invasive approach is certainly desirable. The paraspinal muscle sparing approach lends itself well to this technology and our recently published work would support this concept.[1]

The need to have a standardized model for testing these devices in vitro has also been well received. Dr. Patwardhan's technique of the follower-load method of spine testing, as he described in this Symposium, is becoming the accepted technique and the closest way we have today of replicating the muscle forces

The participants have done a wonderful job in addressing many challenging and thought-provoking questions. We plan for this symposium to be the first of many such scientific discourses on the merits and demerits of this exciting technology.

REFERENCES

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