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Adding fusion to decompression fails to improve clinical outcomes in treatment of lumbar stenosis

The presence of degenerative spondylolisthesis is often considered grounds for performing fusion surgery in combination with decompression surgery for the treatment of lumbar spinal stenosis, in an attempt to combat postoperative instability. According to a new study published in the *New England Journal of Medicine*, the addition of fusion was not associated with improvements in clinical outcomes for lumbar stenosis patients with or without degenerative spondylolisthesis. The direct costs of this more complicated surgery were also shown to be significantly higher.

The primary outcome of the multicentre, open-label clinical superiority trial was Oswestry Disability Index score. Secondary outcomes included European Quality of Life-five dimensions (EQ-5D) scores, visual analogue leg and back pain scales, Zurich Claudication Questionnaire (ZCQ) scores and a six-minute walk test. Data for non-ZCQ and walk test scores were collected from the Swespine registry, which assesses patients preoperatively, and at one, two and five years postoperatively according to a questionnaire. The Swespine registry contains data from over 80% of all patients who have undergone spinal surgery procedures since 1998.

Lumbar stenosis diagnosis was diagnosed according to typical magnetic resonance imaging symptoms, with trial inclusion requiring stenosis at one or two adjacent vertebral discs. Degenerative spondylolisthesis assessment was performed by lateral radiography, defined by 3mm or more of disc slippage in relation to the next lower segment. Two-hundred and forty-seven participants aged between 50 and 80 years of age underwent randomisation, stratified by the presence or lack of spondylolisthesis. One-hundred and thirteen participants (67 with degenerative spondylolisthesis) were assigned and treated by decompression with fusion, while 120 (68 with degenerative spondylolisthesis) were assigned and underwent decompression-only procedures. Five patients did not complete follow-up.

Lead author, Peter Försth

"For the primary outcome, we found no significant interaction between type of treatment and presence of spondylolisthesis," the authors noted with regards to results at two years. Oswestry Disability Index scores were not found to be significantly different between the decompression-only group (mean ODI score=24, difference from baseline=-15) and the decompression-with-fusion group (mean ODI score=27, difference from baseline=-17). Baseline stratification analyses revealed similar outcomes for those participants with degenerative spondylolisthesis in both treatment groups. No significant differences between the procedures were noted in secondary outcomes, again, with or without the presence of degenerative spondylolisthesis.

At five years, 138 patients provided follow-up outcomes information, with 94 enrolled too late in the trial to complete five-year assessment. "The lack of superiority of decompression seemed to persist at five years," noted the authors, who found no significant differences in any measured outcomes. The fusion group revealed a mean ODI of 27 (difference from baseline=-14), while the decompression-only group reported a mean ODI of 28 (difference from baseline=-15). The data again revealed similar results for participants with and without degenerative spondylolisthesis.

A health economic evaluation of the procedures in 233 patients, revealed that, "the more technically advanced procedure of decompression plus fusion was associated with higher costs, but not with greater clinical benefit". The mean direct costs were calculated to be US$6,800 higher for fusion procedures due to increased implant costs, longer operation times and extended hospital stays. Indirect costs at two years—including visits to healthcare professionals, number of days receiving any benefits and the number of patients using analgesics to treat back problems—were similar in the two treatment groups.

Authors noted a paucity of strong, published data supporting the common view that the combined fusion procedures may reduce instability for patients exhibiting degenerative spondylolisthesis. Recognising that "the natural course of untreated degenerative

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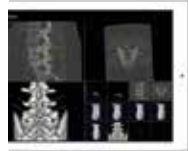

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Five-year data suggest limited cervical disc arthroplasty benefits

Two presentations at the annual conference of the International Society for the Advancement of Spine Surgery (6–8 April; Las Vegas, USA) have revealed potential benefits for cervical disc arthroplasty over anterior cervical discectomy and fusion (ACDF). Both using prospective, randomised, five-year clinical trial data based on LDR's Mobi-C artificial cervical disc, one presentation suggested that arthroplasty could have benefits over ACDF at two levels, whilst the other suggested benefits in favour of arthroplasty in patients younger than 50.

The first study compared results for one- and two-level procedures for both treatment types. Within the one-level cohort, 164 patients were treated by arthroplasty and 81 by ACDF. For the two-level cohort, 225 were treated by arthroplasty, and 105 by ACDF. The researchers assessed outcomes according to visual analogue scale scores for neck and arm pain, Neck Disability Index, range of motion, short form-12 score, patient satisfaction and reoperation rate.

The only significant differences found between one- and two-level procedures were found in those patients treated by ACDF. Both lower success rates and lower improvements were found in the two-level ACDF group—compared with the one-level group—for mean Neck Disability Index. Additionally, lower improvement in short

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spondylolisthesis has been reported to be benign," the authors note that their study has found "no significant difference between the two treatment groups in the amelioration of back pain, regardless of the presence of preoperative degenerative spondylolisthesis."

Responding to a paper by Ghogawala *et al* in the same issue of the *New England Journal of Medicine*, which has reported moderately superior scores for fusion surgery on the Medical Outcomes Study 36-Item Short-Form Health Survey, the authors of this study argue that higher dropout and reoperation rates hamper comparison. The study may be limited by a potential for confirmation bias in patient self-reported outcomes. A lack of "validated and reliable imaging studies to identify signs of instability", may also limit the study, according to authors. Noting the similar outcomes among those spondylolisthesis patients with fairly serious slips (≥7.4mm) to those of other participants, the authors claim that their results were not biased by a failure to use flexion-extension radiography.

Commenting on the implications of their results, the authors noted that decompression-only surgery is "not only…associated with a lower treatment cost per patient but also can save resources by releasing surgical capacity as a consequence of shorter operating time and hospitalisation." Not only is the procedure potentially cost-saving for institutions, but its more complicated alternative "did not result in clinical outcomes that were superior to those with decompression surgery alone."

Spinal News International spoke to the lead author of the study, Peter Försth, about the implications of the research.

Given your results, do you think that physicians should still perform the combined procedures?

Not in standard cases of spinal stenosis on one to two lumbar levels, regardless of any degenerative spondylolisthesis. This makes up the vast majority of cases!

Are there any cases in which the combined approach might be an optimal method of treatment?

If there is a marked deformity like scoliosis, there might still be indication to complete the decompression with a fusion. There might also be an indication for fusion in a few cases which risk the development of instability after decompression. Today, however, we lack validated measures to detect these cases.

What else can physicians learn from these results?

Regardless of surgical method, the patients had good results from the surgery. In spite of their high age—the mean was 67 years—they had improved functional outcomes and better life quality two years after surgery. The objective six-minute walk test performed by physiotherapists in the study showed a significant improved walking capacity two years after surgery.

What is the next step for research in this area?

The next step is to identify predictors of inferior outcome from our radiological follow-up, currently under investigation.

Another important need is the development of radiological methods to investigate stability in the lumbar spine, as today's method with the use of flexion/extension X-ray testing has very low levels of accuracy and repeatability.

Five-year data suggest limited cervical disc arthroplasty benefits

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form-12 was observed in the two-level ACDF group compared with the one-level group (8.8 vs. 14, respectively). The rate of reoperations was also higher for the two-level ACDF group (16.1%) than any other group in either cohort (11.1% for one-level ACDF, 4% for two-level arthroplasty and 3% for one-level arthroplasty. The authors suggest that "these results that cervical disc arthroplasty has potential benefits over ACDF, particularly for two-level procedures."

The second presentation aimed to address the paucity of data analysing the interaction between age and outcomes for ACDF and cervical disc arthroplasty procedures. Participants (n=575) were randomised 2:1, with 389 treated by arthroplasty, and 186 by ACDF. Outcomes data including visual analogue scales, Neck Disability Index and secondary operation rates were collected and subjected to univariate analysis—stratified by age—and multivariate analysis by logistic regression.

No significant difference was found in outcomes results among participants in either treatment group according to age. However, the rate of secondary operation was significantly higher for participants younger than 50 treated by ACDF, when compared with the same age group treated by cervical disc arthroplasty. Within the ACDF group, results showed higher rates of secondary operation within the under-50s group, but these only trended towards significance. The authors concluded that, "a higher rate of subsequent surgery in ACDF patients less than 50 years old suggests that cervical disc arthroplasty may provide a benefit over ACDF for these patients."

Whilst randomised control trials have suggested benefits of cervical disc arthroplasty over ACDF in the past, clinically-significant results have been sparse (see page 4). The follow-up length of this data may improve its clinical relevance, even if its results only provide limited support to cervical disc arthroplasty.

The study used LDR's Mobi-C artificial cervical disc

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Similar benefits for arthroplasty and cervical fusion in real-world patients vs. trial participants

Seeking to "go beyond the evidence presented by randomised control trials", a group of researchers has used the international Spine Tango registry to compare the results of randomised control trials with those of real-world patients treated by either single-level total disc arthroplasty or anterior cervical interbody fusion procedures for degenerative disc disease or disc herniation. Their research, published in *The Spine Journal,* confirmed borderline significant results in favour of arthroplasty, trending towards superiority. Given that significance was not reached in patients beyond the inclusion criteria of randomised control trials, the results suggest that the clinical superiority of arthroplasty could be negligible.

The authors—who won an "Outstanding Paper" award from the North American Spine Society—conducted research in three stages. They began with a 1:1 matched study, comparing results from nine randomised control trials with that of a cohort of the Spine Tango registry (n=987 of 75,890) who met standard trial exclusion criteria (n=739). The registry data catalogues surgical records from a number of European hospitals, as well as outcomes data in the form of self-reported Core Outcome Measures Index (COMI) survey results, which include graphic scales for recording neck and arm pain. A propensity score-matched analysis of total disc arthroplasty vs. anterior interbody fusion was conducted, with all arthroplasty cases (n=190) matched, and 359 fusion patients remaining unmatched. Neck and arm pain results (mean difference (MD): 0.6 and 0.7 points, respectively) did not differ significantly between the two treatments, whilst significant scores in favour of total disc arthroplasty were found for COMI scores (MD: 0.8). When compared in terms of postoperative changes in each variable, COMI scores (MD: -1) were again significantly greater for total disc arthroplasty. Neck (MD: -0.5) and arm pain (MD:-0.7) changes did not differ significantly.

The second stage of research involved the study of both procedures in patients from the registry who would normally fail the exclusion criteria of randomised control studies. This cohort included, for example, patients over the age of 60 and those with pre-existing spondylosis. Within this group, 27 had undergone total disc arthroplasty, whilst 221 had been treated by anterior cervical interbody fusion (n=248). No significant differences were noted in the outcomes data between these two groups. However, it was observed that those patients undergoing arthroplasty were likely to be younger than fusion patients, and less likely to have undergone C7–T1 surgery.

The third element of this research took the form of a long-term follow-up study. Two-year follow-up data was available for certain patients (n=149) within the Spine Tango registry cohort. Again, the arthroplasty patients were generally younger than the fusion patients. Whilst short-term data had revealed greater improvements and lower pain scores in the total disc arthroplasty group, the long-term data failed to reveal significant differences between the treatment groups.

> Overall, the results showed a trend towards superiority for total disc arthroplasty, with significantly better treatment outcomes observed in patients meeting strict inclusion criteria. The authors suggest that this may reflect "tighter indications for surgery". Whilst other research has found long-term improvements in neck pain associated with arthroplasty, this was not borne out by the Spine Tango data. Long-term results were shown to be relatively stable over time, with both procedures bearing sustained improvements in treatment outcomes up to five years.

The authors note that their research was limited in a number of ways.

Firstly, participation in the registry was voluntary, which could leave it open to selection bias. Furthermore, participating clinics were not required to record data for all patients treated at their centres, nor can it be guaranteed that data recorded is complete. Patient-reported results may also be subject to expectation bias. It is possible that patients may have reported more favourable outcomes for those treatments they perceive to be "novel".

The researchers noted that the randomised control trial model is the "gold standard" study design for the analysis of treatment efficacy. Given this data, they note that further studies could be required to assess treatments according to terms outside of whether or not they meet or surpass current standards. "Although these trials provide evidence about the relative efficacy of treatments in selected patients, additional studies may be needed to measure the relative effectiveness in broader populations," write the authors. Documenting patients efficiently in-hospital can provide data which reaches beyond that of randomised control trials, the authors claim, stating, "The need for cost-effective, multi-source, and widely-shareable data collection has never been greater".

Study "lends further credence" to view that facet joint tropism may have developmental aspects

An international, large-scale multicentre study indicates that facet joint tropism—also known as facet joint angulation asymmetry—may be developmental in origin or may be a combination of developmental aspects and secondary changes of degenerative effects. This finding goes against the traditional view that facet joint tropism is purely secondary to remodelling changes as a result of degenerative spondylolisthesis.

Writing in *Scoliosis and Spinal Disorders*, Dino Samartzis (University of Hong Kong, Hong Kong) and others report that there is "still a lack of general understanding" about how facet joint tropism develops, adding that it "remains controversial whether facet joint tropism is a pre-existing developmental phenomena or secondary to progressive remodelling of the joint structure due to degenerative changes". They explain that the "traditional" view has been that degenerative spondylolisthesis alters kinematics and load distribution, which may lead to secondary changes such as facet joint tropism. They also note that that facet joint tropism may increase degenerative changes (by increasing motion and instability changes), according to an emerging, alternative view. Instead of resulting from degenerative spondylolisthesis, facet joint tropism may in fact play a role in its cause.

The aim of the study, which was undertaken by the AOSpine Asia Pacific Research Collaboration Consortium, was to explore the developmental origins of facet joint tropism. It "addressed the occurrence of facet joint tropism of the lower lumbar spine (L3–S1) in a degenerative spondylolisthesis patient model within the Asia Pacific Region to determine if facet tropism occurred at levels with degenerative spondylolisthesis and at those adjacent to non-degenerative spondylolisthesis segments," Samartzis *et al* commented.

In the study, the authors identified 349 patients with single-level degenerative spondylolisthesis. In this population, 34.7% had tropism at one level, 28.7% had tropism at two levels, and 14.3% had tropism at three levels—only 22.3% did not have tropism at any levels. However, tropism was most prevalent in patients with degenerative spondylolisthesis at levels L4–L5 (76.5% of patients).

Samartzis *et al* report that 50.6% of patients with degenerative spondylolisthesis at levels L4–L5 had tropism, compared with 47.1% of patients with degenerative spondylolisthesis at levels L3–L4 and 31.1% of those with degenerative spondylolisthesis at levels L5–LS1. Furthermore, they found that while tropism was more common at an L4–L5 degenerative spondylolisthesis than at adjacent non-degenerative spondylolisthesis levels, "similar tropism rates were noted at adjacent levels in relation to a L5–S1 degenerative spondylolisthesis and at higher rates at adjacent levels in relation to a L3–L4 degenerative spondylolisthesis." The authors noted, "In the setting of degenerative spondylolisthesis levels with L3–L4 or L5–S1, the immediate adjacent and more distal levels had similar tropism rates between each other".

According to Samartzis *et al*, the finding that tropism is present at lumbar levels "with and without" degenerative spondylolisthesis is "contrary to the traditional thought that such facet orientation is secondary to remodelling changes as a result of the degenerative spondylolisthesis". They added that, instead, their study "lends further credence" to the view that facet joints "directly or indirectly" may play a role in degenerative disc changes. However, the authors noted that their study does not exclude tropism being secondary to degenerative spondylolisthesis. "In fact, in some individuals, this [tropism] could be a combination of developmental and secondary changes," Samartzis *et al* stated, concluding that further studies are needed.

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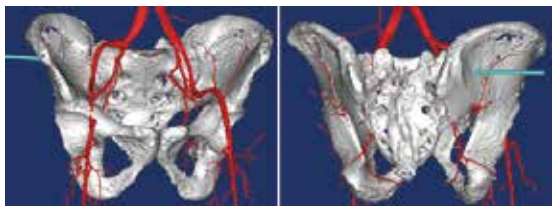
Insertion of percutaneous sacroiliac screws using augmented reality navigation is feasible and accurate

During a pilot study published in *International Orthopaedics*, an experienced orthopaedic surgeon was able to successfully and accurately place percutaneous sacroiliac screws into a number of cadavers using a new augmented reality (AR) navigation system. The study authors hope that AR navigation will provide "a valuable tool for assisting percutaneous sacroiliac screw insertion in live surgery."

Conventional modern surgical navigation systems—using fluoroscopy and computed tomography (CT) imaging—hold a number of drawbacks for surgeons. As well as exposing both surgeon and patient to radiation, the visualisation of navigational data on monitors can impede surgical outcomes. Visualisation takes place at a different viewing angle to the surgical site, requiring unfamiliar hand-eye coordination techniques. This steepens the learning curve for new surgeons, and can hinder concentration and cause distractions. The aim of this pilot study from the Shanghai Jiao Tong University School of Medicine, Shanghai, China, was to assess the feasibility and accuracy of a head-mounted AR-based navigational system, which could address some of these problems. Principal investigator, Qiugen Wang, told *Spinal News* International, "AR can provide an intuitive visualisation for the surgeon of three-dimensional images of virtual planning and of internal critical anatomical structures."

The AR system consisted of an optical see-through head-mounted display, an optical tracking system a graphical workstation with a liquid crystal display monitor. The head-mounted display was connected to the workstation, and, using infrared-reflecting markers, the optical tracking system was able to capture the position of objects such as the drill, the head-mounted display and the pelvis. This system allows the surgeon to view virtual images of the surgical site, which correspond to head movements in real-time. The virtual images are projected onto the transparent screen of the head-mounted display, which should allow a surgeon to see the real world unhindered. This allows for native hand-eye coordination, which could theoretically mediate the steep learning curve, and potential distraction, associated with visualisation through a conventional monitor.

Three-dimensional models of each of the pelvis and vessels for the six cadavers in the study were created preoperatively with CT data and Mimics (Materialise, Belgium) planning

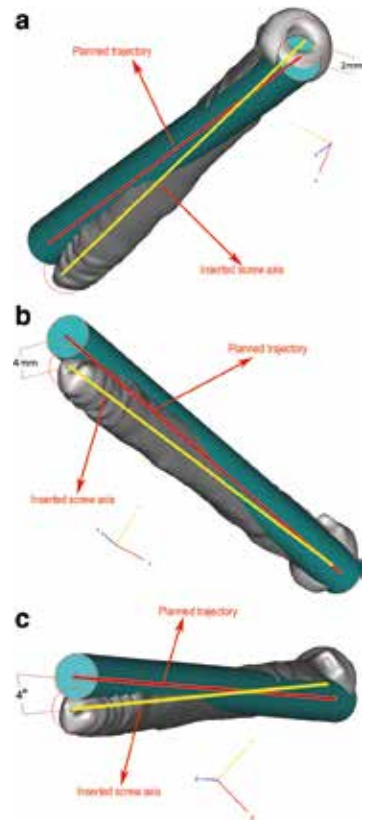


Preoperative 3D reconstruction of the pelvis, planned trajectory, and adjacent vessels

Intraoperative drilling under the augmented reality-based navigation with virtual images superimposed on the head-mounted display

software. This allowed for the virtual planning of ideal sacroiliac screw trajectories, which were modelled by cylinders. Twelve percutaneous screws were placed in the cadavers—which had intact pelvises—by an experienced orthopaedic surgeon, who was allowed time before the surgeries to familiarise himself with the AR navigation system. Post-operative CT images were compared with the ideal screw trajectory cylinder models by two independent raters, to assess the outcomes of each surgery.

All 12 screws were placed successfully, with no perforations. The mean time required for the experiment was 13.6±2.2 mins, and for the procedure was 11.1±2 mins. The mean deviation between the planning cylinders and the actual placement of screws was 2.7±1.2mm (1.3–5.5mm) at the bony entry point of the screw, and 3.7±1.1mm (1.1–5.2mm) at the tip. The mean angular deviation was 2.9°±1.1° (1.6–4.8°), and the mean distance between the centres of the planning cylinders and the inserted screw at the level of the nerve root tunnel region on the sagittal plane was 3.6±1mm (1.4±4.7mm). Whilst the result showed lower accuracy than other study results for CT-3D-fluoroscopy navigation, the authors presume that this level of accuracy is acceptable assuming that the planning cylinder "is always positioned more than 5mm away from the outer cortical margin on the sagittal plane near the nerve root tunnel area. The authors write that a comparison between the accuracy of



Measurement of the distance between the centres of the planned trajectory and the inserted screw at various points

the AR system and current navigation systems would be an important area for future research.

The accuracy could be improved, they write, by further refinement of the software and instrumentations used for the procedure, and by training users to be more familiar with the system. "I believe that with the constant development of AR technology, it will eventually become a part of the surgical routine," Wang told *Spinal News International*.

The study was limited by the small number of cases, and by the normal physiology of the cadavers. Further research into the use of the system in cases with sacroiliac fractures or dislocations would be necessary to test the application of AR to cases more serious than those with minimal sacroiliac joint displacement.

Safe and reproducible reduction technique significantly improves high grade spondylolisthesis in young patients

Neurological injury, pseudoarthrosis and progressive deformity are just some of the risks associated with the surgical management of high grade spondylolisthesis in young patients. A presentation chronicling fourteen years of experience treating the condition with a progressive reduction technique has shown the procedure to safely offer good functional and radiological outcomes.

Winning "The Charles D Ray Award for Best Clinical Paper" at the International Society for the Advancement of Spinal Surgery (ISASS; 6–8 April, Las Vegas, USA), the retrospective analysis was intended to address the controversy surrounding *in situ* fusion vs. reduction, and the use of closed postural reduction techniques vs. open reduction instrumentation. An ideal technique, the presentation noted, would promote motion with minimal segments fused, would sustainably resolve symptoms and restore near-normal balance to the sagittal vertical axis.

The researchers followed 27 patients with spondyloptosis (17), grade four spondylolisthesis (7) or grade three spondylolisthesis (3) who underwent a reduction technique at the Apollo Hospital (Chennai, India) between 1998 and 2012. This technique involved "positioning the hips in extension with traction, pedicle screw fixation, correction of lumbosacral kyphosis with a specific distraction manoeuvre, wide decompression, and gradual reduction of the deformity and maintenance of reduction with interbody fusion."

The procedures were assessed according to a modified Oswestry Disability Index scores and visual analogue scores, as well as clinical and radiological measures. Follow-up took place at one, three and six months, and annually after the first year. All patients' spondylolisthesis was reduced to at least grade two, with solid fusion present at six months in all cases. A mean postoperative slip angle improvement of 42° was noted (45–3°), as was a mean sacral slope improvement of 22° (13–35°). Significant improvements in visual analogue scale and modified Oswestry Disability Index scores were observed with good functional outcomes reported in all but one patient. The poor outcome was due to a deep infection which required implant removal. One revision surgery was required due to screw misplacement on the third day after surgery.

The researchers found that their reduction technique, whilst technically challenging, was safe. It offered generally good results, which had been reproduced over almost fifteen years in young patients with high grade spondylolisthesis.

The benefits of computer-assisted surgery

NICOLAS DEA

COMMENT & ANALYSIS

Surgical technologies are becoming more diverse and more easily accessible. Most do not have true added value, but others, like neuromonitoring for complex deformity procedures, are now incorporated in day-to-day practice, and have become standard of care, writes Nicolas Dea.

Surgical navigation systems have been integrated in cranial neurosurgery practice for years, but have only recently became readily accessible for spinal surgery. The computer-assisted surgery (CAS) technique involves the use of intraoperative navigation that necessitates preoperative or intraoperative 2D or 3D imaging linked to a navigation unit. It allows the surgical team to increase pedicle screw placement accuracy, create precise osteotomies in deformity and tumour cases, and achieve post-implantation screw assessment, among other applications.

Multiple systematic reviews have demonstrated the superiority of CAS technique compared to others for pedicle screw placement.[1] Accuracy rates of above 95% are commonly reported with CAS compared to rates as low as 50% for the free-hand technique. Yet, most misplaced screws do not cause any problems and are totally asymptomatic. Misplaced screws can, however, result in irreversible neurological damage, biomechanically weaker constructs, lower fusion rates, vascular injuries and higher reoperation rates. We must therefore aim for proper screw placement; something CAS has proven its superiority for.

There are not only better accuracy rates with the CAS technique. The ability to obtain a confirmatory intraoperative computed tomography scan may also obviate the need for a postoperative scan. Less postoperative imaging can not only reduce costs, but can also limit radiation exposure to patients. CAS has furthermore been shown to significantly reduce the amount of radiation delivered to operating room staff ,[2] a problem that we should be particularly aware of, especially given the rising usage of minimally-invasive techniques which rely heavily on intraoperative guidance. CAS also constitutes an invaluable teaching tool for surgeons working with residents and fellows. Moreover, it can allow for tumour-free osteotomy creation in primary tumour cases, promoting appropriate margins and lower recurrence rates. Computer-assisted surgery could also potentially obviate litigation issues for surgeons and hospitals.

So why has CAS not yet become the standard of care? An interesting survey revealed that high acquisition costs and longer operative time were the main obstacles against a more widespread usage of this technology.[3] As many physicians have experienced, there is definitely a learning curve associated with the use of CAS in surgery. However, once we become familiar with using computer-assisted techniques, navigated cases may actually be even shorter to perform.[4]

And what about the cost-effectiveness? In an era when health expenditure is rising exponentially, cost-effectiveness analyses are mandatory to responsibly manage scarce healthcare resources. To answer this question, we recently conducted a cost-effectiveness analyses comparing CAS to traditional fluoroscopy-guided techniques.[5] We performed a full economic evaluation using rigorous patient-level data outcomes and methodology, and showed that acquisition costs might not be as prohibitive as previously anticipated. Based on lower surgical revision rates, computer-assisted surgery can even be cost-saving in high volume centres. An incremental cost-effectiveness ratio of US$23,288 per reoperation avoided was calculated for the computer-assisted surgery group. Based on a reoperation cost of US$27,768 this new technology becomes cost-saving for centres performing more than 168 instrumented spinal procedures per year.

For most cases, especially less demanding interventions, computer-assisted surgery might not change outcomes—traditional techniques may remain completely appropriate. However, with no concrete disadvantages, I do not see any reason why we should not embrace this new technology with the ultimate goal of making surgery safer for our patients.

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Nicolas Dea is a neurosurgeon at the Centre Hospitalier Universitaire de Sherbrooke, as well as director of the neurosurgery program at the Université de Sherbrooke (both Sherbrooke, Canada)

The limits of intraoperative fluoroscopic navigation

Whilst intraoperative fluoroscopic navigation may offer a number of benefits to spinal surgery, uptake in the field is still relatively low. Jeff McConnell talks to *Spinal News International* about the limits of this technology.

What can intraoperative fluoroscopic navigation enable physicians to achieve?

There is an important difference, here, between fluoroscopic imaging and fluoroscopic navigation. I use fluoroscopic imaging frequently to localise bony anatomy to assist in placing pedicle screws percutaneously in the spine. It is truly "real-time" imaging. A disadvantage is that the images obtained are two-dimensional. Capturing these images also leads to radiation exposure. Fluoroscopic navigation can be done in different ways, all based on obtaining anteroposterior and lateral fluoroscopic images using an aftermarket reference frame attached to the C-arm. The images are then correlated using computer software with a pre-operative computed tomography (CT) scan. The simplest software system that I have seen simply requires the surgeon to plot screw direction with triangulation, and then line up the starting point on the skin with fluoroscopy. As long as you maintain the proper angle of trajectory, then placement should be successful. This can be fiddly, and it takes time to plot each screw. This seems less accurate to me.

What are the main problems associated with the use of this technology?

The main problem with live fluoroscopic imaging is the radiation that both patient and surgeon are exposed to, particularly the cumulative life-time dose that surgeons receive. CT-based navigation—such as with an O-arm—is better for the surgeon, but there remains

Jeff McConnell

a significant radiation dose for the patient. Navigation is also based on the patient's position when the scan was done. If the spine moves relative to the reference frame then accuracy is compromised. In the case of percutaneous surgery, or surgery involving multiple levels, O-arms are not as useful or accurate. In my opinion, CT-based computer navigation systems and robotic systems are not completely accurate when you are interested in the 1–3mm range.

What risks are associated with intraoperative exposure to radiation?

Radiation brings a cancer risk for both patient and surgeon. This accumulates over time for the surgeon. Thyroid cancer and lymphoid cancers are the most common. Even a single whole spine preoperative CT scan can increase a patient's risk of cancer.

The risk of breast cancer is higher in women who had repeated spine X-rays as adolescents when monitored for scoliosis during growth. Such risks have been fairly well mitigated by the fact that X-ray machines today are more efficient, and the cumulative doses from digital X-rays are magnitudes less.

What do physicians need to keep in mind when using these kinds of navigation systems?

Sometimes a combination of direct vision, tactile feedback and navigation is the best way to minimise problems. I like the PediGuard (SpineGuard) technology, for example, as it provides both tactile and directional auditory feedback, and can help to prevent pedicle bone perforation. I use it an adjunct to neuromonitoring in deformity cases and for one- or two- level fusion cases in the lumbar spine it can eliminate the need for monitoring altogether.

When using navigation systems, physicians must understand the level of accuracy required prior to starting each procedure, and the level of accuracy your navigation system will provide. Surgeons should be familiar with how to do surgery in an open fashion without navigation, should the computer fail or operate incorrectly. Navigation does not perform the surgery for you and does not eliminate complications. Navigation does not make a less experienced surgeon better.

Jeff McConnell is a spinal and orthopaedic surgeon at OAA Orthopaedic Specialists, Allentown, USA, and a clinical assistant professor of surgery at Pennsylvania State University, Hershey, USA

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Intraoperative navigation:

Intraoperative navigation is becoming more and more popular with the advent of minimally invasive spinal surgery. Whilst uptake of the technology is limited by start-up costs, it can potentially benefit screw placement accuracy and rates of surgical revision. Charles H Crawford III, Patrick Hahn and Nicholas Haden speak to *Spinal News International* about intraoperative navigation for spinal surgery, investigating some of the technology on the market

What are the benefits of surgical navigation systems for spinal surgery?

Charles Crawford: I think it allows us to be more accurate with our spinal instrumentation leading to increased confidence. This allows us to concentrate on other parts of the surgery. Overall, this kind of technology allows us to do complicated surgeries more safely.

Nicholas Haden: I see navigation in spinal surgery as a major benefit whenever enhanced detail of the anatomy would be helpful to the surgeon. It does not replace the use of a "map"—I still follow the apparent anatomy—but it is good to have a "satnav" to reinforce your interpretation, and to allow you to make difficult journeys you would not consider without that support.

Many surgeons who are not yet using navigation perceive its use to be only for the improved placement of pedicle screws, particularly percutaneous screws. I think what navigation brings to the table is so much more than that. It does enhance instrumentation accuracy, and with intraoperative imaging allows confirmatory imaging at completion whilst still on the table, but in my practice I have found many more advantages.

A minimally invasive practice lends itself to high radiation, the long-term consequences of which are a concern for us all. Intraoperative imaging with an Arcadis (Siemens) system involves relatively low radiation for the patient and effectively zero for the surgical team. Gone are the days of hours in lead aprons!

Patrick Hahn: The correct position of pedicle screws ensures a good pullout strength in the bone, a good control of rotation and the possibility of repositioning the respective vertebral body. Faulty positioning can lead to injury to neural structures, the chest and the abdominal region, and poses an increased risk of instability. Accuracy in positioning the screws is therefore of the utmost importance. In literature, the rate of faulty screw positions is reported to be 10% to 40%, with the rate of required revision up to 6.6%.

To achieve an optimal position of the pedicle screw without injuring the walls of the pedicle, it is necessary to select the correct point of insertion of the screw into the vertebra, the correct spatial placement of the screw through the pedicle, and a perfect screw diameter-to-pedicle diameter fit. This is important in critical regions such as the upper

cervical spine, the cervicothoracic or upper thoracic region, and can be improved with navigation.

Another scope of application for navigation is the partial or complete resection of vertebral bodies or pathological changes, as critical structures can be deliberately spared here.

Navigation can take place in real-time using preoperative imaging, or with data obtained intraoperatively. With good technique, it is possible to minimise radiation to the patient, surgeon and technicians.

Nicholas Haden: I am convinced that navigation is a part of the future of spinal surgery. The more surgeons who use it, the quicker we will learn where it is advantageous and what are the pros and cons of its use, as well as identify areas for development. Encouraging early adopters is never a problem, but supporting those surgeons starting to use it in the future during their learning curve will be most enhanced by visitation and mentorship programmes.

What are the main problems associated with the use of this technology?

Charles Crawford: There are two types of errors that can happen with these systems. Sometimes, there are computer errors, which are extremely rare. These systems are machines and—just like every computer or machine—they can have maintenance or software issues.

There is also the possibility for user error, and I think that is the biggest potential error to pay attention to. With more experience, these difficulties become much less frequent. Going through surgical training requires learning multiple new things. If we are to keep pace with advancements in technology, that learning must continue through our careers.

Nicolas Haden: The human-technology interface is potentially the weakest point in navigation, and optimising this will be a significant challenge for the systems going forward.

The need for a reference array to be invasively placed is undesirable in minimally invasive cases. There are already some alternatives available, but I see this, along with active monitoring of the patient position and location, as likely challenges and areas for imminent development.

Technological progression—particularly in the quality of intraoperative imaging—is happening at such a pace that, no sooner has a unit equipped itself, its "shiny, new" purchases are potentially out of date. Future-proofing to allow upgrades in an easy and cost-efficient manner will be highly desirable.

At the moment encouraging and promoting the use of navigation amongst non-adaptors, and then supporting them in their progress through the learning curve, is a challenge facing the industry.

One of the next challenges for us as surgeons will be ensuring that spinal surgeons of the future are adequately trained to undertake procedures with and without the support of navigation technology.

Charles Crawford: Surgeons are accustomed to learning new procedures with new instruments and techniques—I do not think that navigation is that much more difficult, other than the fact that you do rely on radiology technicians, and others, in the operating room. The person using the system has to understand the potential ways that errors can occur, and try to minimise them. In my experience, Medtronic did a really nice job with providing support and training.

Patrick Hahn: In addition, the system must take place without disturbing or restricting surgical workflow.

Charles Crawford: Another issue, nowadays in healthcare, is cost. Justifying the increased cost is something that we all have to pay attention to. But, doing surgery in a safer and more accurate way can potentially decrease cost as well—we just have to prove that to the stakeholders.

Medtronic StealthStation

- 120+ integrated surgical instruments available
- Interfaces with iMRI, iCT, C-arms, and the O-arm
- Optical or electromagnetic tracking
- Software includes screw placement planning

Charles Crawford discusses his experience with the Medtronic StealthStation, which offers the largest range of surgical instruments, each viewable in real-time onscreen.

Charles Crawford: The StealthStation uses an intraoperative computed tomography (CT) machine to gather images, which it transfers to a computer. A camera-type device can see where the surgical instruments are positioned in space relative to the patient's body, and that helps us to see the things under skin, muscle or bone during surgery.

What is your experience of the StealthStation?

This is something I was introduced to over seven years ago. I have, over time, become more and more comfortable operating with it at my hospital. I have come to trust the system, and to see new applications for it. Because of this, my usage has increased significantly over the years.

What are the key benefits of this system?

You can do intraoperative CT scans with this system, which gives us a significant amount of information about how the patient is positioned during spine surgery. We can also re-image the patient during surgery, if this becomes necessary—I really like this feature.

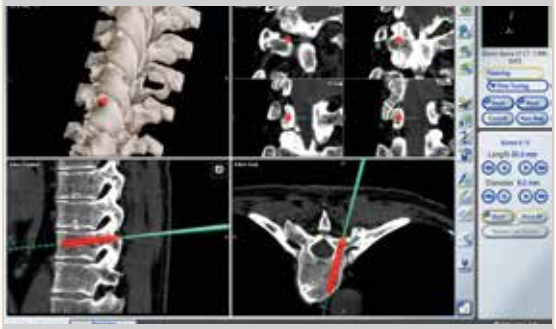
Because Medtronic makes surgical implants and instruments, they have coordinated the navigation system with their products. This means that you can actually look at the size and the shape of their instruments and implants intraoperatively, and you can customise them for the patient. We primarily use the system to place bone screws in the spine, which can be planned using software. We can fit the perfect size screw to the patient's anatomy using the navigation system.

The system is also portable, so we can take it from one operating room to another easily. This way it is possible for multiple surgeons to use it in different locations at the same hospital in a single day.

Charles H Crawford III is a paediatric and adult orthopaedic spinal surgeon at the Norton Leatherman Spine Center, Louisville, USA. He is a paid consultant for Medtronic

Existing solutions

Brainlab system



- Range of instruments including third party products can be visualised in real-time
- Common imaging devices and modalities can be integrated for navigation
- Multiple treatable indications from placement of C1–C2 screws, pedicle screws to tumour surgery
- Various clinical papers note benefits such as radiation reduction, improved accuracy and efficiency

Installed in almost 1,000 centres across 70 countries, the Brainlab system offers broad compatibility with common 2D and 3D C-arms, CT imaging, and the Airo mobile intraoperative CT.

I use a single-screen Curve platform, consisting of camera, workstation and screen, with 3D and MRI/CT merge software, used with an Arcadis 3D C-arm for intraoperative imaging.

The navigation application can be used either with surface registration for open surgery, 2D registration, (both using preoperative CT) or 3D intraoperative imaging. The latter facilitates less invasive approaches and percutaneous introduction of instrumentation, allowing navigation on the acquired images or following merge with a preoperative CT. The benefits of using imaging acquired in the operative position are particularly apparent with unstable fracture surgery, as well as in the very mobile cervical spine.

My practice and experience with the application has changed over the last few years, as I have gone from having to rely on surface matching and occasional 2D matching with open cases, to being able to deliver far less invasive approaches and percutaneous instrumentation with the intraoperative use of 3D imaging which—wherever possible—I merge with preoperative CT to enhance image quality, or MRI to guide decompressive or resection surgery.

My practice—which is delivered in a tertiary neurosurgical and major trauma centre—involves the full spectrum of urgent tumour, trauma, infection surgery, as well as intradural tumours, and degenerative whole spine pathologies. I now use the navigation applications for all cases where instrumentation is to be placed, or where tumour resection benefits from the kind of accuracy that I would have desired in cranial surgery—eg. nerve sheath tumour resection in the cervical spine where the vertebral artery is in proximity.

My default is to use navigation and to not do so if there is an active reason not to.

Why do you use this system?

As a neurosurgeon, my first exposure to Brainlab was in cranial surgery, and for this reason alone I had a leaning towards that product rather than its competitors. In the early days, I think spinal navigation products lagged behind their cranial counterparts significantly. Brainlab seemed to overcome the technological problems more effectively than their competitors. The software and camera technology for the most up-to-date version of the spinal package is so far ahead of what it was, and is as accurate and reliable as the cranial version which I have long been comfortable to rely on.

The current system is user-friendly and in the main very intuitive, which avoids the highly undesirable trawling through manuals to optimise use!

Brainlab has been particularly responsive to feedback and looking at future avenues for development which is definitely highly desirable in any product as a surgeon you chose to use.

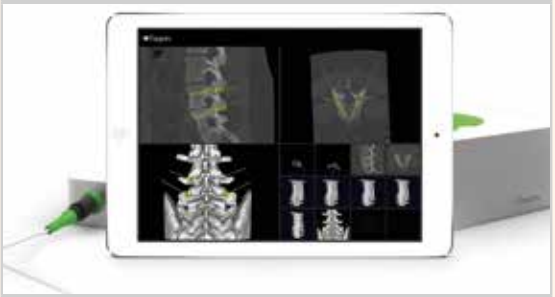
Have you experienced any problems with the system?

In several years of use I have had only two cases where the navigation accuracy was lost, and I had to resort to traditional imaging techniques. In one of these cases it was not until after erroneous placement of a pedicle screw that this became obvious, which potentially reflects the weakness of technology and human interface. The patient came to no harm, but the problem was probably movement of the reference array.

Otherwise, having overcome persuading the NHS to fund investment in the technology, the only problems have been riding the learning curve and, in the early days, facing the inevitable extra effort and time require to do this. As we all know "taking the whole team with you" when using any kind of new technology or procedure can be challenging, although ultimately rewarding and exciting.

Nicolas Haden is a consultant neurosurgeon based at Derriford Hospital, Plymouth, UK. He has delivered educational talks for Brainlab internal meetings and attended meetings of the Depuy Synthes/Brainlab Spinal Navigation Expert Group

Fiagon system



- Software can superimpose CT and MRI, preoperatively determine screw length/diameter
- 3D C-arms compatible with automatic registration
- Offers range of spinal instruments, as well as detachable localisers to incorporate others
- Sensor embedded into operating table mat

The Fiagon system uses electromagnetic technology for pedicular navigation. Patrick Hahn, who has used the system for three years, discusses his experiences with the product.

The Fiagon system uses an electromagnetic field (EMF), which is generated to detect instruments in a three-dimensional operative area during procedures. The system continuously tracks the instruments and the patient's anatomical structure. It can correct static errors using special calibration and correction methods, taking errors attributable to the position and alignment of the navigating instrument into account. This leads to improved position precision in the working area adapted for the application.

A special field generator is placed under the patient. The instruments used are equipped with signal coils positioned inside the tips. To match anatomical structures, a patient localiser is attached to the spinous process of the vertebral body to be instrumented. This localiser can be detected in the magnetic field.

For navigation, Fiagon's CenterPointer, AwlPointer, SpinePointer instruments are used. Additionally, special navigation clamps can be attached to external instruments and then be navigated using this. The CenterPointer is used for surface matching and to open the pedicle. The AwlPointer is used to open the vertebral body in the corresponding trajectory, and to determine the screw length needed. The SpinePointer can be used to probe the pedicle in order to detect and visualise malpositions and injuries to the surrounding cortical bone. All instruments used are comparable with the standard instruments for spine surgery. Cannulated screws or K-wires are not necessary for procedures.

A mapper cage is used for intraoperative 3D registration. This allows for a quick intraoperative registration of patients with all standard 3D C-arms or mobile CT-scanners in patients without preoperative scans.

What are its best features?

The easy handling of the system, the intraoperative matching, and the nearly unchanged surgical procedure for the surgeon. The reduction of intraoperative exposure to radiation for the surgeon and the entire surgical team is another advantage.

Navigation is carried out virtually, in real-time, in a 3D data set. An exact intraoperative assessment is therefore possible in all planes, without changing or affecting normal standard procedures. Automatic registration means that no preoperative CT scan is required.

The intraoperative multiplanar visualisation in real-time also provides a considerable advantage over 2D visualisation with a fluoroscopic data set.

Clinical results, too, demonstrate a highly accurate technique for pedicle screw placement.

In addition, due to the positioning of the patient on the field generator and matching using a minimised patient localiser, there are no components of the navigation system that interfere in the surgical site. The surgeon's workflow is not disturbed. The Fiagon electromagnetic tracking technique is free of line-of-sight issues and allows navigation at the tip of a surgical instrument.

Another advantage of EMF navigation compared to other navigation systems is the position of the reference coil near the tip of the instruments, which can result in lower torsion errors.

Patrick Hahn is an orthopaedic surgeon at the Center for Spine Surgery and Pain Therapy, Center for Orthopedics and Traumatology of the St. Elisabeth Group-Catholic Hospitals Rhine-Ruhr St. Anna Hospital Herne/Marien Hospital Herne University Hospital/Marien Hospital, Witten, Germany. He was also the lead author on clinical and preclinical studies of the Fiagon system

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Profile Virginie Lafage

Virginie Lafage entered the world of spinal research by chance, after an engineering project drove her to a biomechanics lab in Paris, France. Since then, she has moved to the USA, become an executive member of the International Spine Study Group, and now directs the Department of Spine Research at the Hospital for Special Surgery (New York City, USA). She speaks to *Spinal News International* about the current state of spinal research, and where she believes its future lies.

Why did you decide to become a researcher in the field of spinal surgery?

In fact, spinal surgery was not part of my initial career plan. I was interested in technology, so pursued mechanical engineering at university. To complete a project in my final year of study, I needed to use specific software only available at the Laboratory of Biomechanics in Paris. It was there that I fell in love with the engineering methodology used to understand the human body. So, I came back for a Master's, and ultimately a PhD.

Mechanical engineering provided a mental framework for problem solving. Looking for a field to make use of this tool, I was fortunate to be surrounded by the right people at the right time.

Who have been your career mentors and what wisdom did they impart?

My PhD was directed by Wafa Skalli, who has been a great mentor. She taught me how to be rigorous and cautious in the interpretation of results. I continue to work with her today, co-directing PhD students.

During my Master's degree, I met Jean Dubousset, who codirected my PhD. He is an incredibly passionate man, inspiring me to continue into his field. He not only pushed me to my current career, but shared his passionate attitude and taught me how to focus on the entire body instead of just a focal pathology. Jean Dubousset ultimately encouraged me to move to New York to work with Frank Schwab and Jean-Pierre Farcy, as I had completed engineering school, a Master's, a PhD and post-doctoral training at the same place. I did not know who they were, but I went!

Farcy, too, has a real passion for his patients. I spent many hours learning about the clinical aspects of spinal surgery and patient evaluation from him. I was also introduced to Frank Schwab, who then became my research partner and closest collaborator for my entire US career. Schwab has amazing analytical skills and the brilliance to understand the future of spinal surgery and deformity research. He also provided me with abundant opportunities to take on leadership roles. Now, all of our work comes from a place of shared passion and decision-making.

You moved from Paris to New York City, in 2005. What have been the biggest differences for your work?

I intended to stay in New York for a few months, but now it has been 11 years! In the USA, I have found that collaborative work is really embedded in the culture. This approach to projects is extremely pragmatic. We develop a concept, publish it with others, and then welcome people to build upon this concept. We also use study groups more than in France. When you put ten people together, you are more likely to move forward.

I think, in France, we try to do things as perfectly as possible ourselves. We refine our concepts again and again, sharing them only once they are fully mature. Sometimes this is a good approach, and sometimes perhaps the team-based approach is better.

I enjoy New York because it is extremely dynamic in the way people think and the way people work. And from a logistical standpoint, it is easy to travel between New York and Europe, which is important to me–I can maintain relationships with my friends, family, and colleagues in Europe.

What do you think has been the biggest development in spinal surgery during your career?

The biggest development in the past 10 years has been the use of data. Analyses of large data sets have led to identifying best practices by looking at what works and what just does not. We can start using big data to guide the transformation of surgery from an art to an applied technical science.

Of course we are also learning that general rules and algorithms do not apply evenly to all patients. Data has in fact led to a more personalised understanding of patients.

Outside of your own work, what has been the most interesting paper that you have seen in the last 12 months?

Probably a project investigating the impact of adult spinal deformity on quality of life (Pellisé *et al*, *Eur Spine J*, 2015) developed by the European Spine Study Group, led by Ferran Pellisé (Barcelona, Spain). The authors compare the disease burden of adult spinal deformity (ASD) to other chronic conditions. We used to think about ASD as a bigger brother of idiopathic scoliosis. But, we now realise that it is associated with a high level of disability, and can be as disabling as conditions like diabetes and heart disease. We cannot simply dismiss ASD as merely low back pain and a crooked spine—we must consider the real impact on quality of life for the patient. People seek treatment because they cannot function any more.

Of your own research, what are you most proud of, and why?

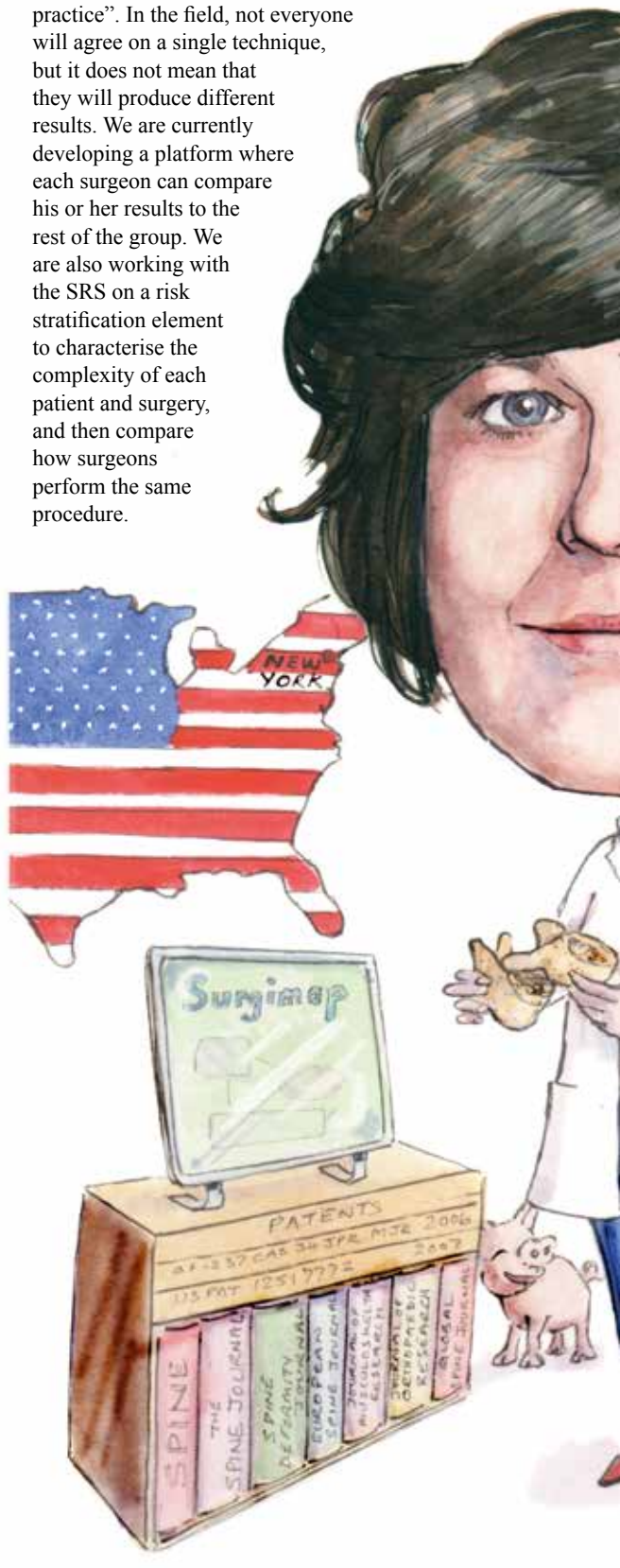
I am most proud of our efforts to understand the clinical impact of sagittal alignment and the importance of preoperative planning. While the concept is not new, ten years ago it was perceived as just an academic exercise. Collaboratively, we have been able not only to demonstrate its clinical impact on patient-reported outcomes, but also to identify patient-specific thresholds that were subsequently integrated into the Scoliosis Research Society (SRS)-Schwab classification. People are now taking over the project, refining it, and asking us to offer an operating-room solution This is a new challenge. It started as a clinical question, and now it is a technical one.

What has been your most memorable project?

When I first arrived in New York, Frank Schwab and I were working on a porcine model of fusion-less adolescent idiopathic scoliosis surgery. We operated on small pigs, inducing deformities that resembled the condition. We then applied corrective surgery, using a tethering technique to redirect the force of the animal's growth to three-dimensionally realign the spine. Schwab and I operated on about 50 pigs. What makes it so memorable is how unexpected it all was. I went from finite element modelling in Paris to chasing pigs, taking X-rays, and performing surgeries right after landing in New York. Thinking back to it still makes me shake my head in disbelief. But, more importantly, this project shaped my understanding of the clinical side of spine surgery and its implications in spine surgery research.

You have been involved in the International Spine Study Group (ISSG) for several years—how has this group developed?

The ISSG started in 2008, and has evolved into an extremely productive academic group. Originally focused on thoracolumbar deformity, the ISSG expanded to cervical deformity, and later to multiple subgroups. One group focuses on "best practice". In the field, not everyone will agree on a single technique, but it does not mean that they will produce different results. We are currently developing a platform where each surgeon can compare his or her results to the rest of the group. We are also working with the SRS on a risk stratification element to characterise the complexity of each patient and surgery, and then compare how surgeons perform the same procedure.



As a team, we are all very passionate about the ISSG and its future. One key element to its success is the camaraderie between all the researchers. We truly enjoy working together, debating ideas and sharing goals for the future of spinal research. In addition, it provides an excellent avenue for young clinicians or researchers to become involved in research.

What are your current main research interests?

The most important endeavour now is to make sure that research findings are available at the point of care. For that, we need to develop the infrastructure to bring updated information to the key decision-makers.

We are also interested in soft tissues, muscles and ligaments. When you take an MRI slice of a patient and look at it in the transverse plane, the vertebrae are tiny compared to the rest of the body. Perhaps soft tissue differences—the mechanical behaviour of the muscles, for example—will have an impact on postoperative compensation and behaviour.

Another interest is in taking a closer look at the blurry line that divides "deformity" and "degenerative" pathologies. In extreme cases, there are surely distinct differences between the two; in moderate cases, the separation is less clear. Where exactly does deformity start and degeneration end? If there is overlap, perhaps there is a global principle that we need to identify.

You have been appointed as Director of Spine Research at the Hospital for Special Surgery. What has this entailed?

The transition to the Hospital for Special Surgery has brought new opportunities, allowing us to expand and apply our research to the concepts of degenerative conditions, paediatrics and soft tissue analysis. In addition to academic collaborations with other clinical, biomechanical, radiological, and statistical departments in the hospital, we also have the opportunity to work with internal administration. This provides a base for us to examine and research what needs attention from the academic, administrative, and patient-centred point of view.

You have been involved in many spinal societies. Why do you think that societies are important?

Societies have a big role that changes over one's career. As a young researcher, the main purpose of a society is to present work, and to disseminate your research. When you get older, you attend society meetings to learn from other people. Societies allow you to get feedback on your work and to network with people with interesting perspectives that may lead to future collaborations. We also have to give back to societies—to take part in committees and direct the future of research.

What are the three questions in spinal medicine that still need an answer?

1. What is the best treatment for each patient? We have enormous amounts of data on thresholds and standards for populations, but we are now realising that the ideal treatment result for each patient depends on a multitude of factors.
2. How do we make intraoperative adjustments based on our preoperative plans? There have been major advancements in planning technology, but there is a lack of intraoperative technology to give real-time feedback.
3. How do we utilise a multidisciplinary approach to the patient to achieve the best continuum of care, long after the operation is over?

What advice would you give to someone who was starting their career in spine medicine research?

Firstly, I would advise them to get training in non-medical fields, and to travel to meet people with different approaches. Then they need to find a good partner. I was very fortunate to meet Frank Schwab. Our different skills complement each other; he has clinical knowledge, and I have engineering knowledge. It is very important to find someone who will care about your career, who will push you, and train you and vice versa. Those people are not around every corner!

Outside of medicine, what are some of your interests?

I enjoy spending time with my colleagues abroad as well as the members of my lab. Nothing compares to the simple joy of sharing a meal and great conversation with friends. Some of these have led to wonderful and innovative projects. My long-term partnership and friendship with Frank Schwab led to our development of SurgiMap, a cross-platform software for surgical planning. It allowed us to channel our creative energy into a program combining research, surgery, and novel uses of technology.

Fact File

Education

1995–1998	Mechanical Engineering degree, Ecole Nationale Supérieure d'Arts et Métiers (ENSAM), Paris, France
1998–1999	Master's degree in Biomechanical and Medical Engineering, ENSAM
1999–2002	PhD in Biomechanics, Laboratoire de Biomécanique", ENSAM

Hospital appointments

2005–2006	Research Associate, Maimonides Medical Center, Brooklyn, USA
2006–2008	Research Scientist, NYU Hospital for Joint Diseases, New York City, USA
2008–2009	Director of Spinal Biomechanics Laboratory, NYU Hospital for Joint Diseases, New York City
2010–2015	Director of Spine Research, Spine Service, NYU Hospital for Joint Diseases
2015–	Director Spine Research, Spine Service, Hospital for Special Surgery, New York City

Society membership

- International Spine Study Group – Executive committee
- Scoliosis Research Society (SRS) – Active member
- North American Spine Society (NASS) – member
- Congress of Neurological Surgeons (CNS) - Member
- Spine Arthroplasty Society (SAS) – Member
- AO Spine – Member

Editorial review positions

- *Spine*
- *The Spine Journal*
- *Spine Deformity Journal*
- *European Spine Journal*
- *Journal of Musculoskeletal Research*
- *Journal of Orthopedic Research*

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The great debate: Hybrid vs. fusion for two-level lumbar degenerative disc disease

Jack E Zigler, Texas Back Institute, Plano, USA, and Louis G Jenis, Massetcheutses General Hospital, Boston, USA, debate the benefits and pitfalls of hybrid and fusion approaches to two-level lumbar degenerative disc disease.

Lumbar hybrids for two-level lumbar degenerative disc disease

Jack E Ziger

A small number of patients develop two-level functionally disabling mechanical low back pain in their productive years, fail to improve with at least six months of conservative therapy, and are candidates for surgery. They have traditionally been offered two-level fusion.

In the two-level ProDisc-L vs. 360 fusion study, reported in *J Bone Joint Surg Am* as a level one prospective multicentre randomised trial, 237 patients at average age 41.8 years were enrolled and surgically treated.[1] At 24 months after surgery, 89.9% of total disc and 90.5% of fusion patients reported Oswestry Disability Index improvement from baseline. The mean score in the ProDisc-L group was an improvement of 34.5 points (53%); the fusion group showed an average improvement of 26 points (41.2%) (p=0.0424). In that study, Oswestry Disability Index success criteria of ≥15 point improvement was met by 73% of ProDisc-L and by 60.3% of fusion patients (p=0.0497). Secondary surgical procedures at the index level occurred in 2.4% of ProDisc-L and 8.2% of fusion patients (p=0.0497). Finally, narcotics usage was significantly lower in ProDisc-L (36.4%) compared to fusion patients (61%; (p=0.0017).

This represents the strongest scientific data we have regarding the clinical and radiographic outcomes of these two surgical treatments in patients who have failed at least six months of conservative treatment. Uniform patient selection was a key strong point of the study, because historic multiple-level fusion studies have included patients with disparate pathologies, ages, and levels, making interpretation difficult. This study offered us excellent treatment guidelines for those 42-year-old patients with disabling two-level lumbar degenerative disc disease. Unfortunately, two-level arthroplasty never completed US Food and Drug Administration approval, and two-level fusions are often denied in the USA by insurance carriers as "experimental."

Hybrid constructs for two-level lumbar degenerative disc diseases were borne out of insurance necessity, not out of science. Surgeons recognised the altered mechanics of a two-level fusion in a 40-year-old, and patients wanted to maintain some motion and help protect the rest of their lumbar spine. Several analyses of hybrid constructs, both prospective and retrospective, demonstrated similar clinical outcomes with measurable motion at the arthroplasty level.

A *post-hoc* analysis of a consecutive series of two-level hybrids from the Texas Back Institute studied 135 patients with at least 12 months' follow-up. Eighty-three of these patients had a stand-alone anterior lumbar interbody fusion (ALIF) at the fusion level, while 52 had a 360 fusion done at the arthrodesis level. Both groups improved in Oswestry Disability Index significantly from baseline. The hybrid ALIF patients trended better, although the difference was not significant. Both groups' pain scores also improved significantly from the preoperative scores, but the difference between cohorts was not significant. Reoperation rates were significantly lower in the ALIF group (3.6% vs. 23.1%; p<0.01).

There is no long-term data yet available on adjacent level degeneration or adjacent level disease. We do have strong radiographic data published on radiographic changes above single-level 360 fusion vs. artificial disc replacement (showing a 3:1 difference).[2] There are also published in vitro studies showing increased adjacent level intradiscal pressures above a fusion as compared to levels above an artificial disc replacement.[3]

It is felt by many surgeons that a two-level fusion in a young person is less than optimal, given its association with future surgery. Hybrid constructs offer shorter operating room time, less blood loss and quicker recovery than a two-level fusion, as well as better motion with a mobile arthroplasty device at the transition level. Most importantly, they offer the potential for a lower incidence of anatomic adjacent level disease, which should translate to a lowered incidence of adjacent level surgeries occurring while the individual is still in their economically productive years.

Although there are clearly instances when fusion is necessary, such as the presence of posterior instability, if the indication for the second level is discogenic pain due to internal derangement, a hybrid construct using a stand-alone ALIF at the fusion level is clearly a reasonable option.

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Lumbar fusion for two-level degenerative disc disease

Louis G Jenis

The patient who describes chronic low back pain in the presence of two-level disc degeneration (L4L5/L5S1) presents a challenging clinical scenario. There is great controversy about which surgical treatment option is best, or whether surgery is even an alternative at all. When surgery is considered, options include fusion vs. total disc replacement or a hybrid construct. However, numerous issues must be weighed. Are these interchangeable treatments, or are they competitive for same patient? Are they complementary strategies for a heterogeneous population of degenerative disc disease? Does total disc replacement provide better clinical outcomes and the proposed downsides of fusion?

To answer these questions we need to assess the literature for evidence-based data for guidance. The literature is replete with studies reporting clinical and radiographic outcomes after lumbar fusion but vary based on study design, surgical indications and techniques. There have been at least 18 randomised controlled trials published depicting surgical outcomes for degenerative disc disease, with numerous level one data studies confirming some beneficial effect of surgery vs. conservative treatment. When the total disc replacement literature is analysed the data is less consistent, although, there is some evidence of effectiveness.

In terms of pain relief and functional outcomes, there are numerous level three and a few level one studies confirming that total disc replacement accomplishes at least comparable improvement in both the short and longer term, as shown in the Charité five-year follow-up study, among others.[1-3]

At the index level of surgery, a primary goal of total disc replacement is to restore or maintain range of motion. Literature and clinical experience confirm that these are challenging procedures, and must be performed technically well with appropriate indications to achieve these results. Early follow-up studies suggest that range of motion is maintained with a trend to better outcomes with optimal placement of the device, while longer term data report conflicting results of index level degeneration and the impact on range of motion may actually decrease with time.[4-6] Variable results have been published regarding the progression of facet joint degeneration at the index level, and the effects remain unclear at this time. Is progressive facet arthrosis part of the natural history and degenerative cascade, or is it a failure of total disc replacement to prevent this occurrence in the long term?

One of the major proposed goals of total disc replacement—and often cited as a primary indication in clinical practice—is to maintain or 'normalise' motion at the adjacent level and at least slow down or prevent the development of adjacent segment degenerative changes or symptoms. While this is a theoretical goal, it remains very controversial as numerous causes of adjacent segment degenerative changes and symptoms have been described. While the literature lacks any level one supportive data, systematic reviews consisting of retrospective data and case reports and longer term level II and III publications suggest a higher incidence of adjacent segment degenerative changes after fusion.[7-8] A potential higher risk of requiring additional adjacent segment surgeries after fusion or total disc repleacement is not established at this time.

So what can we make of this data and the controversial decision on how to treat the patient with two-level lumbar degenerative disc disease? The literature suggests equivalence in clinical outcomes and possible loss of range of motion at the index level with time, while the adjacent segment issues are controversial and remain multifactorial. I would argue that two-level fusion remains the standard of care at this time.

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Interspinous process fixation vs. pedicle screw fixation

KEE D KIM

COMMENT & ANALYSIS

Kee D Kim explores new one-year outcomes data supporting the use of interspinous process fixation as an alternative to the use of pedicle screws.

Do we still need to use pedicle screws as an adjunct to interbody fusion? Supplemental pedicle screw fixation became a standard of care after suboptimal outcomes from standalone threaded cylindrical interbody cages popularised during the 1990s. This may sometimes be unnecessary with advances in standalone interbody technology. Wide-footprint anterior and lateral lumbar cages allow for good disc height restoration with distraction of annulus and longitudinal ligaments, and indirect neural decompression. However, an adjunctive posterior fixation is still desirable in many cases. Interspinous process fixation (ISPF) may be a lower risk and less challenging alternative to pedicle screw fixation. Until now, no prospective, randomised study has been performed comparing the two as an adjunct to circumferential fusion.

Our study was designed as a non-inferiority randomised trial to compare the outcomes between ISPF and pedicle screw fixation when treating symptomatic disc degeneration and/or mild spondylolisthesis (≤grade II) in a real-world practice. We used the Aspen system (Zimmer Biomet) for ISPF. To best represent the current diverse surgical practice, investigators chose the posterior approach (minimally invasive or open pedicle screw placement), fixation type (unilateral or bilateral pedicle screws) and interbody approach (anterior or lateral). A randomisation of 2:1—ISPF to pedicle screw fixation (control) patients—was used. The non-inferior margin was 10 Oswestry Disability Index (ODI) points in accordance with previously reported values of minimal clinically-important difference. The primary outcome measure was ODI, and secondary outcome measures included perioperative outcomes, patient reported outcome scores (Short Form-36 survey, Zurich Claudication Questionnaire and Visual Analogue Scale) complication/revision profiles, and fusion.

While two-year follow-up data will not be available until June 2016, our podium talk at the 2016 ISASS meeting offered a detailed look at outcomes through one year. As may be a surprise to some, follow-up outcomes with ISPF were comparable and often favourable to those of pedicle screw fixation in most metrics. ISPF demonstrated a mean ODI decrease of 3.6 points greater than pedicle screw fixation patients at 12 months. Mean ODI decrease was also greater for ISPF patients at earlier follow-up of six weeks, three months, and six months ($p \geq 0.12$).

No significant differences were observed between either cohort for mean improvement in patient-reported outcomes. Brantigan, Steffee and Fraser interbody fusion scores were not significantly different ($p=0.33$) as assessed by an independent radiology group (mean 11.4 months). Interestingly, 93% of ISPF patients demonstrated fusion, supporting robust interspinous bony fusion as support for the overall strength of the construct. Two ISPF (3%) and four pedicle screw fixation subjects (10.8%) required secondary surgical interventions, with one symptomatic pseudoarthrosis in each cohort.

Two-year follow-up will be telling with respect to the maintenance and longevity of outcomes. At one year, however, data supports the use of ISPF as an adjunct to circumferential fusion.

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Spinal surgery is “entirely failing” to address sexual health

NSpine is surveying female patients to investigate the effects of anterior spinal surgery with regards to scars, sexual function and relationships as part of a pilot study. The group is also looking at the prevalence of sexual dysfunction in patients with chronic back pain. Bronek Boszczyk talks to *Spinal News International* about NSpine’s research, and about the upcoming “Sex and the Spine” symposium at SpineWeek (16–20 May; Singapore). This multidisciplinary symposium will cover topics from physiology to body image with regards to the impact of spinal surgery on sexual health.

How can spinal health affect sexual health in general?

Somewhere in the region of 60–80% of people who have ongoing back pain have some form of disturbance in their sexual health. Whilst only a few studies address this, surveys of our own patients have found that the incidence is quite high. And then, of course, there are conditions complicated by neurological compromise such as spinal cord injury and cauda equina involvement. These patients have a very high incidence—virtually 100%—of some manner of sexual health disturbance.

A further aspect is sexual health and body image. The impact thereof is very, very poorly understood—even evaluated—in adolescents, for example, who are affected by scoliosis or kyphosis.

How can spinal surgery itself affect sexual health?

We know that performing anterior spinal surgery in men leads to certain difficulties, such as retrograde ejaculation. What we do not understand is the impact that such surgery can have specifically on women. Some preliminary results have shown that up to 40% of our patients have changes in their menstrual cycle, and roughly 30% have changes in their sexual activity after anterior spinal surgery. But, these results are yet to be properly evaluated. A further finding is that the placement of incisions on the abdomen has a far higher impact on women’s body image and sexual health than we have been aware of.

What kind of research has been done in this area?

Specific to spine, not very much. There are some validated questionnaires, but they have not really been used prospectively in spinal research. Our research is probably one of the first to specifically assess these aspects in women. We intend, after our pilot study, to do a number of investigations on the impact of low back pain, the impact of post-surgery, and the specific impact of anterior surgery.

Are there are cases in particular which might require the consideration of sexual health, or is it something which affects spinal surgery generally?

Back pain generally correlates with sexual health issues. The other area in particular that we have come across which can be related to sexual health is cauda equina syndrome—where patients have neural impairment of their sacral roots with neurological dysfunction. For those that have complete dysfunction, it is very difficult to find treatment. But it is probably possible to find treatment for those with partial dysfunction. Some therapeutic attempts are being made but, again, accessing this is very difficult, and many people simply do not talk about this kind of problem.

We are also not adequately aware of the effects of anterior spinal surgery. When we perform lumbar disc replacements or anterior fusions in women, we do not fully understand the impact this can have, yet many of us are going more and more down the route of offering these kinds of procedures, due to the favourable outcome in relation to back pain.

Are there any postoperative treatments available to promote sexual function?

There are, but not specifically for spine. Within spinal cord injury and severe cauda equina there are individual therapists who address this. Patients can tap into these options if already in treatment for one of these conditions. But, many of our patients have less severe cauda equina syndrome where sexual dysfunction is not obviously apparent to their clinicians. These issues are often never raised in consultation. People feel uncomfortable talking about them, which can lead to the failure of relationships and marriages, simply because people do not know where to turn.

When patients—or our physiotherapists—do ask us what can be done, we know that there is a plethora of tools on the market. We have no collected information about patients who have successfully gone through treatments—often by trial and error. We simply do not have the insight to say what may or may not work.

How do you think physicians can encourage communication about what is often a very sensitive issue?

This is one of the big problems; none of us is trained how to do this. As consultants, we very rarely have these discussions—we sometimes have them with men—but with virtually never with women. We have found that women tend to speak to their physiotherapist and, whilst our physiotherapists recognise the problem, they struggle with the lack of knowledge of what resources they can tap into.

Bronek Boszczyk

This goes down to such basic issues as when can you re-engage in sexual activity after you have had spinal surgery, and how you should do so. And, more importantly, what help is available for people who have some sort of neurological dysfunction? What is normal and what is not normal in the case of cauda equina syndrome? We struggle tremendously to know what resources are available and what actually works.

What are the biggest issues that spinal disorders and spinal surgery can raise for body image?

We have come across three body image issues, really. One is in cases of adolescents with scoliosis; we simply do not know to what degree this affects healthy body image in adolescence.

The second issue is with scar placement. Whilst this appears to be completely irrelevant for men, the location of scars on the abdomen seems to have a far higher impact than we have understood before for women. Interestingly, virtually all of these patients—nearly 100%—had not discussed this with their healthcare providers. When our physiotherapists contacted patients to follow up on their questionnaires, however, they started reporting a whole range of issues of which we had not been aware.

The third issue we have come across is in the adult deformity group—and this goes more towards mature women with regards to body-shape image when they develop a progressive adult deformity. We know from clinical practice that losing posture or waistline can have a real impact on women, but this has simply not been addressed at all with regard to sexual health.

How can physicians address issues of body image and sexual health?

This is something we have to establish. We need to create forums which talk about openly about body image issues, and perhaps offer additional training in these areas. I think there is a need for training so that physiotherapists and surgeons can recognise problems and encourage people to discuss them openly. In many cases, too, you will need male and female practitioners available for patients to speak with.

We also need to engage in research questionnaires which can serve as resources for us to tap into. We really need to establish a working relationship with sexual counsellors, therapists—all of these professionals that are already available, but perhaps are not directing their assets specifically to spinal patients.

Is spinal surgery failing to address the impact of spinal disorders and treatment on sexual health?

It is entirely failing to address this. Spinal surgery as a subspeciality is simply not systematically assessing sexual health. The Oswestry Disability Index includes a question on sexual health, but it is a very simple one: “does this affect your sex life?” Nothing follows on from that in a more detailed manner.

I am not aware of any institution routinely assessing this as part of the whole treatment aspect of spinal disorders. We are far more likely to address peoples’ psychosocial behaviour in accordance with back pain than their sexual health, for example. We simply are not addressing the impact of spinal surgery at all—especially in women.

The Sex and the Spine symposium in Singapore will get together sexual therapists, physiotherapists, spinal surgeons, and other healthcare professionals involved in this treatment. We hope to address the topic again at a multidisciplinary session at the 2017 NSpine meeting. We need to begin to share ideas and experiences in this way to better address sexual health issues.

Bronek Boszczyk is a consultant spinal surgeon at Nottingham University Hospitals, Nottingham, UK. He is also the director of NSpine, which will be running the symposium “Sex and the Spine: Everything you always wanted to know about sex and the spine but were afraid to ask” during SpineWeek 2016, Singapore

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Full-endoscopic spine surgery: A new paradigm

MIGUEL CASIMIRO

COMMENT & ANALYSIS

Technology has always been in the service of surgery as a means to improve safety, precision, efficacy and—hopefully—patient outcomes. Endoscopic techniques allow for minimally invasive access, high-definition quality images, and a better illumination of the operative field. It is progressively becoming the gold standard for many everyday procedures, across most of the surgical fields. However, writes Miguel Casimiro, its application in spinal surgery has been slow, and limited to a few pioneer centres.

The lack of a natural cavity, the narrow working field, and the fear of causing neuronal damage have stopped spinal surgeons from exploiting the endoscopic technique. In recent years, developments in image quality, thinner endoscopes, hardware ergonomics, and adapted tools have allowed for a safer endoscopic approach to the spine.

All around the world, spinal surgeons are progressively accepting the advantages of minimally invasive surgery. We are investing time and money in the change from the former paradigm of open surgery to that of minimally invasive, tubular or percutaneous surgery. So, the question and the challenge is, why not walk the extra mile towards an even less invasive surgery? Why not apply this training effort to endoscopic spinal surgery?

In order to do so, surgeons must be convinced of its versatility, efficacy and costs. Can we treat the same pathologies? Is it safe? Can it deliver outcomes as good as they are now? How much training time is involved? And, what are its associated complications? Only once we are convinced on these points can we surpass the natural resilience to change.

Full-endoscopic spinal surgery is certainly minimally invasive and versatile. The most common spinal procedures—such as everyday decompressive surgeries for lumbar or cervical herniated discs—can be safely treated with this technique. Once the endoscopic drilling abilities are mastered, the approach can be used in the treatment of central or lateral segmental spinal stenosis and for foraminal decompressions. It can be used with less frequency in the treatment of thoracic herniated discs, or in the treatment of space-occupying lesions like epidural cysts, abscesses, haematomas or tumours. The major limitation, so far, is in the treatment of instability. The difficulty is related to the need to use bulky hardware—like fusion-enhancing devices—through the small endoscopic working channels. However, this might change in the near future. An endoscopic interbody fusion technique has already been developed, and is currently undergoing clinical trial.

In order to address the different pathologies and their anatomical nuances—after all, an extra-foraminal herniated disc is different from a central canal disc protrusion—different endoscopic surgical approaches to the spine can be used. A full-endoscopic posterior approach to the cervical spine can be employed in the treatment of foraminal stenosis or lateral herniated disc. An anterior approach can also be used for the same purpose or, more often, for the medial-located herniated disc, with the advantage of being a less expensive and motion-sparing decompression treatment compared to the gold standard fusion techniques. For the lumbar segment, the interlaminar approach allows a very versatile way to explore the epidural space of the lateral recess, with very familiar anatomic landmarks for the surgeon trained in the current microsurgical techniques.[1] Even so, the learning curve for this approach seems to be more gradual than for the transforaminal or far lateral lumbar endoscopic approaches that access the spine from a more posterior and lateral direction. With the combination of these approaches, one can access either the more medial and lateral spinal canal or the foraminal and extra-foraminal regions. So, with knowledge and training for all of these different approaches, we can treat the vast majority of spinal pathology though full-endoscopic techniques.

One should naturally expect a learning curve. Although not demanding, the endoscopic technique is new for the majority of spine surgeons. The handling of the endoscope and the mastering of new surgical tools will take time. Most studies show that it takes an average of around 20 to 30 cases for a surgeon to feel confident in his or her performance. Both surgeon and patient must be aware of this. One should expect the need to redo or convert some cases, and to take more time to treat a simple herniated disc, for example. Learning from the experience of others and studying the new anatomic surgical landmarks and safe entry zones are fundamental to avoid complications. The meticulous selection of the first few cases, and the knowledge of the limitations of each surgical approach, are paramount.

However, all this effort, in the end, seems to pay off. The conclusions of randomised trials comparing endoscopy vs. open surgery for the treatment of lumbar disc disease are as expected. Both techniques are efficient in decompressing the nerve root with an excellent relief of preoperative complaints, but, the endoscopic patients have less postoperative wound-related pain, less functional limitations and a shorter rehabilitation time. This is what we might expect of a technique which aims to accomplish the same goals as the surgical procedure, but through a less invasive manner.

An important concern is whether we can achieve the same efficacy on the decompression through a small skin opening. Another concern is related to the fear of higher rates of neurological complications and dural tears. In experienced hands, as in conventional surgery, these undesired events should be rare. In fact, dural tears can be slightly less frequent in recurrent herniated lumbar disc cases treated through an endoscope. So, even in more demanding cases, full-endoscopic approaches seem to achieve excellent results. The Ruetten group in Germany recently reported similar positive outcomes for the treatment of segmental lumbar stenosis. The full-endoscopic approach was associated with reduced operative time, fewer complications (including dural tears) and, again, shorter rehabilitation time.[2]

Evidence is starting to pile up that full-endoscopic procedures can be safe, better tolerated by patients, and as efficient as gold standard spinal procedures.

I believe that recent technical advances in image quality, the versatility of new endoscopes, and the actual mind-set of spinal surgeons with the current trend towards minimally invasive approaches presents the perfect context for the success of this technique. Minimally invasive spine surgery might be the present, but full-endoscopic surgery will surely soon be its new paradigm.

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Non-caucasian race and non-private insurance type may be significant predictors of mortality following surgical treatment for cervical spondylotic myelopathy

Recent literature has associated posterior-only approaches to the treatment of cervical spondylotic myelopathy with increased mortality. According to a paper presented at the 2016 meeting of the International Society for the Advancement of Spinal Surgery (ISASS: 6-8 April, Las Vegas, USA), non-caucasian race and non-private medical insurance are independently predictive of receiving posterior-only approaches in the USA.

Commenting on the importance of the study, lead author, Shearwood McClelland III, told *Spinal News International* that, "This study is the first to examine the impact of patient demographics on the surgical approach to cervical spondylotic myelopathy; this is important because the morbidity and mortality of surgery differs markedly according to the surgical approach chosen." McClelland *et al* conclude, therefore, that non-caucasian race and non-private medical insurance may significantly increase the risk of mortality in the treatment of cervical spondylotic myelopathy.

Aiming to determine the effect of race and insurance status on the surgical approaches used for treatment, researchers used records from the US Nationwide Inpatient Sample (NIS) hospital discharge database from 2001 to 2010. The database contains resources on all discharges from a stratified random sample of hospitals across the USA. The database was searched using a number of diagnosis and treatment codes, to discover how different patients with cervical spondylosis with myelopathy had been treated. The researchers searched for treatment by anterior cervical discectomy, posterior only approaches, combined anterior and posterior approaches or decompression of the spinal canal, all including fusion/refusion at C2 or below. The NIS database also recorded demographic information, the source of admission and primary payer details.

Of the 220,736 adult admissions for cervical spondylotic myelopathy treated by surgery, a multivariate analysis revealed that those patient variables which increased the likelihood of treatment by anterior-only surgical treatment were female sex (OR=1.39; CI=1.34-1.43), private insurance (1.19; CI=1.14-1.25) and non-trauma centre admission type (OR=1.29-1.39; CI=1.16-1.56). Those factors reducing the chance

Shearwood McClelland III

of treatment by anterior approaches included no-charge insurance type (OR=0.48; CI=0.37-0.62), hispanic race (OR=0.64; CI=0.59-0.70) and black race (0.76; CI=0.72-0.80), as well as trauma centre admission type (OR=0.76; CI=0.72-0.80) and admission from court/law enforcement (OR=0.11; CI=0.04-0.32).

Non-caucasian races were shown to predict treatment by posterior-only approaches, including hispanic race (OR=1.51; CI=1.38-1.66), asian/pacific island race (OR=1.40; CI=1.15-1.70) and black race (OR=1.39; CI=1.32-1.47). Non-private insurance status, trauma centre admission type and admission from another hospital were among the other factors associated with an increased risk of treatment by posterior-only surgical approaches. A decreased chance of receiving this treatment was correspondingly found for variables including female sex (OR=1.39; CI=1.34-1.43), private insurance (OR=1.19; CI=1.14-1.25) and non-trauma centre admission type (OR=1.29-1.39; CI=1.16-1.56).

McClelland told *Spinal News International* that, "The main limitation of this study is its reliance on the Nationwide Inpatient Sample database, which comprises only United States patients and does not include federal hospitals."

Future research should be directed towards patient outcomes associated with these techniques, claims McClelland, who told *Spinal News International* that, "The implications of this study should spur future prospective investigations by surgeons. Patients should also be made aware of the different approaches, and should have a firm understanding during preoperative counselling as to the reason their surgeon recommends a particular operative approach for their condition."

Low back pain's "subtle threat" to developing countries' healthcare systems is growing

Rates of low back pain in the developing world have surpassed those of the developed world, with its prevalence growing in urban populations. A cross-sectional population-based study of 22,952 participants residing in Tehran, Iran, published in *Spine*, has found a one-year prevalence rate of 42.1%, at an estimated annual cost of US$7.1 million for the city.

Seeking to estimate the burden of low back pain on the city, and its biological and physical correlates, researchers used a four-stage sampling method to obtain a representative sample of the population. Using the 22 districts of Tehran as strata, 120 blocks were chosen at random from each stratum. In each block, eight households were selected at random, before participants themselves were chosen according to age and gender.

In "one of the largest urban population surveys in back pain epidemiology and its potential associated factors…conducted to date", participants were initially surveyed by the "Urban HEART questionnaire - Tehran Model" to garner basic information such as age, sex and occupation. Quality of life was assessed by Iranian General Health Questionnaire (GHQ-28), which screens for psychiatric disorders. The researchers collected physical activity data by use of an Iran-specific Global Physical Activity Questionnaire (GPAC), developed by the World Health Organisation.

In addition to one-year prevalence results, the researchers found that 36.2% of participants were experiencing low back pain at the time of the survey, while 12.2% reported chronic low back pain. The authors write that these results are higher than both global and national Iranian mean low back pain prevalence values reported in literature. Sick leave due to low back pain was reported by 1.73% of participants in this study, with a mean of 24.12 days lost for these subjects. The mean work days lost due to illness was 0.41 in the overall study population.

A logistical regression analysis was determined which variables were most associated with low back pain. The researchers discovered that participants who had never been married were significantly less likely to report low back pain, with those currently married 1.5 times as likely to report current pain, when adjusted for other variables. Housewives were significantly more likely to report low back pain, which the authors speculate may be due to the repetitive nature of housework, often requiring bending and torsional movements. Women were significantly more likely to report low back pain, as were those with a higher body mass index, and those with lower levels of education.

Participants who scored more than six in the GHQ-28 questionnaire were roughly twice as likely to report low back pain, independent of other factors. Achieving more than six points was taken by the authors as an indication of psychological disorder, in keeping with the literature. Given that major depressive disorders are the second highest cause of disability in Iran, the authors suggest that "devising preventative and management strategies for these factors could play an effective role in preventing chronic lower back pain", as well as addressing overall disability levels.

Whilst physical activity was associated with both acute and chronic low back pain, no significant associations could be drawn when tested as an independent variable. This analysis may be confounded by factors such as body mass index, suggest the authors.

The researchers report that this study is limited mainly by its reliance on participant self-reporting, leaving data open to participant recall bias and lapses in memory. The authors advise that the direct assessment of the severity of low back pain should be investigated in future research.

The authors conclude that low back pain could result in "a significant economy impact for many subjects, families and health care systems" in Tehran. Given the aging population of the city, the economic burden of low back pain is likely to rise. The authors suggest that, "educational programs, appropriate rehabilitation protocols, and preparation of a national guideline for low back pain management" might help to combat this challenge, which may be indicative of low back pain as "a subtle threat to urban populations in developing countries."

Screw placement accuracy in instrumented spinal fusion

CLAUDIO LAMARTINA

COMMENT & ANALYSIS

Screw placement accuracy is a critical point in instrumented spinal fusion, especially in difficult deformity cases There is a real, established risk of pedicle screws malposition and related complications, reported in literature at a range of 8–30%, writes Claudio LaMartina.

When screw malposition is symptomatic, it can cause radicular pain or neurological signs, vascular or visceral injuries. Moreover, the asymptomatic malposition can be detrimental for the stability of the construct, creating the mechanical base for a hardware failure. In order to avoid pedicle screw malposition, some deformity surgeons have adopted intraoperative X-rays, with standard anteroposterior and lateral projection, to check the screw position during the implant. This is not sufficient, however, since a persistent malposition rate is reported, even when the implant is X-ray-guided, compared to the hand-free technique. The intraoperative use of computed tomography (CT) scanning, with the introduction of the O-arm, has demonstrated the ability to reduce malposition rates. At the same time, however, this has increased radiation exposure. This is a problem for both patients and surgeons; idiopathic deformity patients are usually young girls, and the radiation dose repeated for each implanted screw is not suitable for them. In addition, with the routine application of this technique, the radiation exposure for surgeons and operating theatre staff increases dramatically.

Navigation and robotic procedures for spinal deformities have some limitations. The first is related to radiation exposure, as already discussed. These powerful technological products need a detailed radiological preoperative work-up, thus exposing the patient to the same global amount of radiation as intraoperative control technique. The second limitation is related to the lengthening of the procedure by the set-up of these systems, which require time and staff.

Lastly, deformity surgery is difficult, and its learning curve is long. Mistakes are not tolerated, which produces a growing issue among the junior spinal surgeons. The free-hand technique of an experienced surgeon has been reported as the most reliable method for screw placement, but it is not easily reproducible. The ideal system for placing pedicle screws should guarantee:

1. Low radiation exposure
2. Reproducibility
3. No extra operative time

In my opinion, the Medacta MySpine technology has the potential to address these three areas.

MySpine is a new technology that allows a custom-made guidance for pedicle screw insertion. It consists of 3D-printed guides manufactured according to the spine of each patient, allowing a precise and safe pedicle screw insertion. MySpine is a low-radiation exposure system, made possible by the creation of a low-dose CT scan protocol. This very specific diagnostic tool is the only radiation dose that the patient will receive. Details of the bony anatomy of the patient are then used to build a 3D model of their vertebrae. Once the 3D anatomy of the patient is created, a dedicated virtual environment can be projected for preoperative planning. Each virtual vertebra is instrumented on this platform. It is possible to choose the best trajectory, entry point, screw length and convergence, taking all the time necessary. When planning is completed, the 3D data from the patient's anatomy and from our "planned" screws are merged, and a proper guide is created with a 3D printer. Each guide is coupled with the 3D reconstruction of the corresponding vertebra. These components are then sterilised and prepared for intraoperative use. Once the surgeon has accurately dissected the posterior aspect of the spine at the desired levels, a mask is applied on each corresponding vertebra. The two operative tubes on both sides of the mask allow a safe and precise preparation of the pedicle and screw placement. Each passage of pedicle screw insertion (pedicle preparation, pedicle feeler use and screw implant) is addressed by the guides and can be visualised by a window at the bottom of the tubes.

Different cadaveric studies have been published on this system, and a prospective, randomised trial will be soon completed. This trial aims to compare screw placement accuracy in deformity patients operated with standard free-hand technique vs. the MySpine technology. Preliminary data are encouraging, but we are looking for solid evidence, based on large numbers. However, the Medacta MySpine technology appears to be a path towards a more accurate pedicle screw implant and fewer related complications.

Claudio LaMartina is an orthopaedic surgeon at the Galeazzi Orthopedic Institute in Milan, Italy

Product News

Two K2M systems receive additional FDA clearance

K2M has received 510(k) clearance from the US Food and Drug Administration (FDA) for expanded indications of its Mesa Mini and Denali Mini spinal systems.

The Mesa Mini and Denali Mini spinal systems function as adjuncts to fusion, providing stabilisation of the posterior cervical and thoracic spine. Both systems were previously cleared for use in the posterior thoracic spine, from T1-T3. The new clearance allows for the systems to be used in the posterior cervical spine, from C1-C7, in addition to the thoracic spine.

The systems are 3.5mm diameter rod systems that offer all-inclusive answers for rigid posterior fixation of the cervicothoracic regions of the spine. The systems feature multiple hook and rod options, and instrument technology designed to facilitate more efficient intraoperative use of the systems.

FDA approves EOS imaging's spineEOS 3D planning software

The FDA has approved spineEOS, an online 3D planning software for spinal surgery based on EOS stereoradiographic 2D/3D imaging from EOS imaging. This follows CE marking reported by *Spinal News International* in March 2016.

The spineEOS online 3D planning software is intended for adults suffering from degenerative or deformative spine conditions, as well as for paediatric patients with adolescent idiopathic scoliosis. It is designed to allow a surgeon to create a treatment plan to achieve optimal sagittal alignment from pelvic and vertebral 3D data obtained in the functional standing position from an EOS exam. The planned surgery and virtual post-correction 3D anatomy are designed to precisely plan for the 3D shape and length of the spinal implants. It can also be shared pre-operatively to engage the patient in the intended course of therapy, and should be accessible in the operating room through a custom planning report.

EOS imaging has also received approval from the Chinese Food and Drug Administration (CFDA) to market the EOS system in the country. It can now be marketed in 51 countries.

First EOI FLXfit 3D expandable cage implantation performed

The first procedure using the FLXfit expandable cage from Expanding Orthopedics (EOI) has been performed by William D Smith at the University Medical Center in Las Vegas, USA.

Smith, who specialises in minimally invasive spine surgery, says, "Many of my L1–L5 patients are treated through a lateral approach. However, the L5–S1 disc space cannot be accessed laterally. Furthermore, the L5–S1 disc space, located at the end of the construct and has the largest segmental lordosis angle, is critical for the anterior column support and for the restoration of the spinal alignment balance. The optimal device for this level should provide large surface support as well as the ability to restore the natural lordosis angle through a minimally invasive approach."

One-year follow-up transforaminal lumbar interbody fusion (TLIF) data on the cage were presented at the 2016 meeting of the International Society for the Advancement of Spinal Surgery (ISASS; Las Vegas, USA) by Jean-Charles Le Huec, head of the Ortho-Spine Department, Bordeaux University Hospital, France.

Le Huec explains, "The FLXfit enables in-situ lordosis correction in a simple and effective surgical procedure. The cage's…angular expansion allows [one] to dial in the lordosis angle and to fit it to the patient's anatomy."

He notes, "All patients underwent a successful instrumented TLIF procedure without any short term complication[s]. Lordosis correction of 8 degrees (±2.1 degrees) was achieved, allowing restoration of the sagittal alignment with no cage subsidence."

FDA clears Renovis Surgical 3D-printed titanium standalone cervical cage

Renovis Surgical has received 510(k) clearance from the FDA to market the Tesera SC.

The Tesera SC porous titanium cervical interbody fusion system features a three-screw design and a locking cover plate to prevent screw backout. Implants are available in two lordotic angles with varying heights and footprints for proper intervertebral height restoration, along with advanced instrumentation designed to reduce operative steps.

Tesera implants are created by additive manufacturing (3D printing). They are designed to create a highly porous surface structure to allow for bone ingrowth to the implant surfaces. According to a company release, this can maximise strength, stability and biologic fixation.

Calendar of events

16–20 May
SpineWeek 2016
Marina Bay Sands, Singapore
E: spineweek@medicongress.com
W: www.spineweek.org

19 May
NASS-CAOS: Injection and Stimulation Workshop
E: registration@spine.org

20–21 May
NASS: Lumbar Spinal Injections
Burr Ridge, USA
E: registration@spine.org

1–4 June
5th World Congress of MIS Spine Surgery & Techniques
Jeju Island, Korea
E: info@wcmisst.org
W: wcmisst.org/

1–3 June
17th EFORT Congress
Geneva, Switzerland
E: EFORTregistration@mci-group.com
W: www.efort.org

30 June–2 July
Spine 2016
Valencia, Spain
E: spine@neuroconferences.com
W: spine.conferenceseries.com

13–16 Jul
IMAST 23rd Annual Meeting
Washington, USA
E: info@srs.org
W: www.srs.org/imast2016

20–23 July
NASS: Summer Spine Meeting
Miami, USA
E: registration@spine.org

27–39 July
SIS 24th Annual Scientific Meeting
New Orleans, USA
W: www.spinalinjection.org/?page=24ASM

28–30 July
V COMINCO
São Paulo, Brazil
E: contato@cseventos.net
W: www.cominco.com.br

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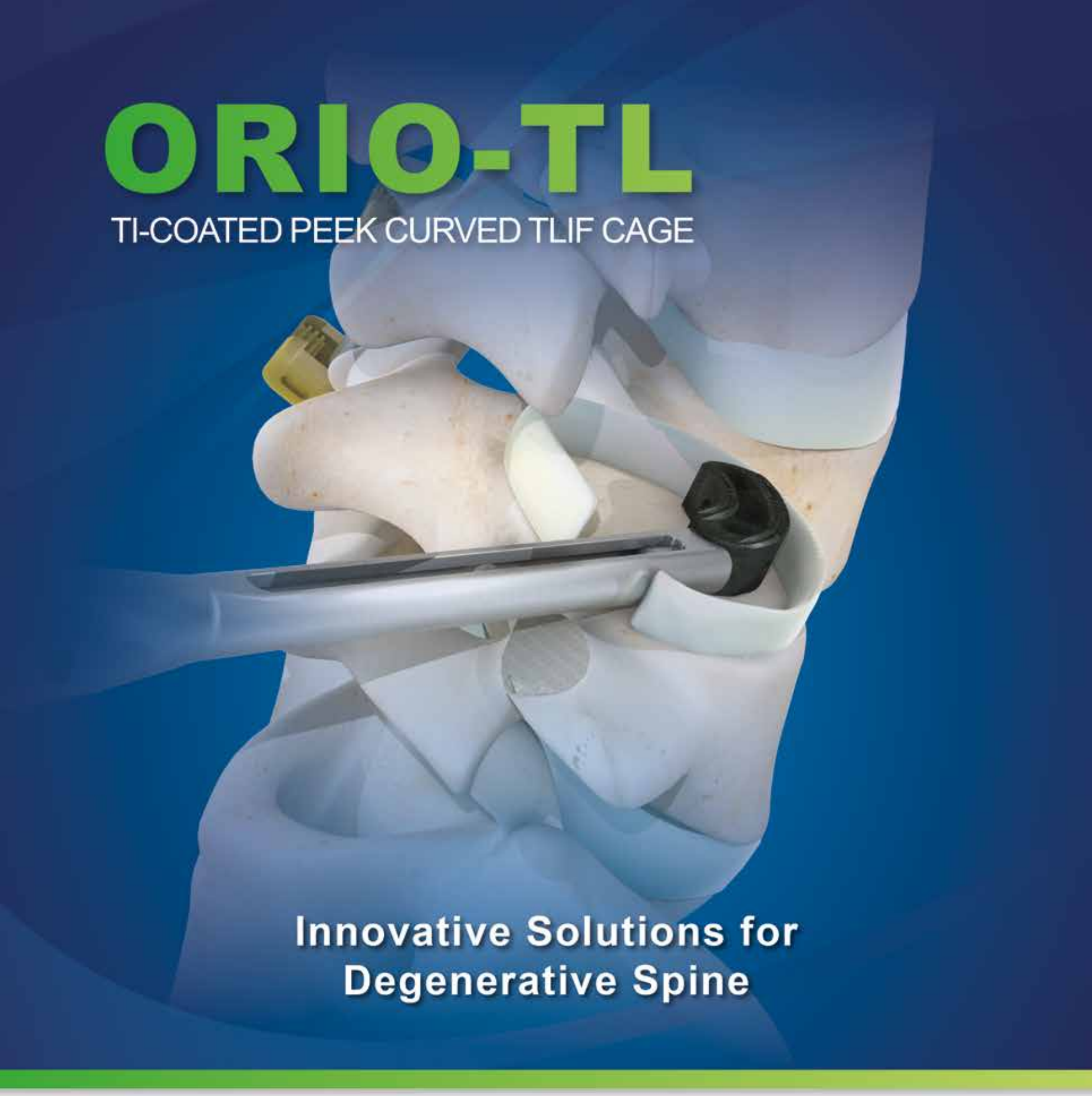

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