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Surgery more effective than physiotherapy in treating cervical radiculopathy

At mid- to long-term follow-up (five to eight years), surgery is more effective than physiotherapy in treating cervical radiculopathy, according to a study presented at the meeting of the Cervical Spine Research Society European Section (CSRS-ES; 27–28 May, London, UK). The presentation won the Mario Boni Award, given for the meeting's best oral presentation.

Markus Engquist, Ryhov Hospital, Jönköping, Sweden, who presented the data, told the audience that although anterior cervical decompression and fusion (ACDF) is a commonly used surgical procedure to treat cervical radiculopathy, "the knowledge of the effects compared with non-surgical treatment is scarce".

Engquist and colleagues randomised 59 patients to ACDF with a titanium implant followed by physiotherapy, or the same structured physiotherapy programme alone for at least three months. Patients were followed by unbiased observer for five to eight years. The outcome measures were disability assessed with the Neck Disability Index (NDI), neck and arm



Markus Engquist

pain assessed with Visual Analogue Scale (VAS) scores, and patients' global assessment and health

status assessed with EQ-5D. Engquist told delegates that there were no significant differences between the two

groups before randomisation.

Patients were included if they were between 18 and 65-years-old, if a diagnosis of cervical radiculopathy was supported by magnetic resonance imaging (MRI) scans and if their symptoms had persisted for between eight weeks and five years at one or two levels. Any patients who had undergone previous cervical spine surgery or had suffered from another spinal disease in the past year were not included. Engquist *et al* also excluded any patients with myelopathy or a history of neck distortion.

The surgical group was treated with ACDF with a BAK/C (Zimmer) device for one-level procedures or

with a Hedrocel (Zimmer) device and plate for two-level procedures. No iliac crest grafts or bone substitutes were used in the surgical group.

The non-surgical group was treated with neck-specific and general exercises, pain coping and pacing care. Patients in this group were treated twice a week for a period of three months. Over the course of the follow-up, eight patients crossed over from the non-surgical to the surgical group.

Engquist told the audience that "significant improvement compared to baseline was seen in both groups and for all outcome measures." NDI was

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One third of adult spinal deformity patients experience implant-related complications

Nearly one third of patients undergoing adult spinal deformity surgery experience a radiographic or implant-related complication, according to a study published ahead of print in the journal *Spine*. Furthermore, just over one half of these complication patients required a reoperation within two years of surgery, significantly affecting quality of life scores.

The International Spine Study Group conducted this multicentre, prospective review of surgical adult spine deformity patients to assess the incidence, risk factor and impact of radiographic and implant-related complications on health-related quality of life (HRQOL) measures.

HRQOL was measured using the Oswestry Disability Index (ODI), General Health Survey (SF-36), and Scoliosis Research Society (SRS-22r) measures at baseline, six weeks, one year and two years postoperatively. Univariate testing was performed "as appropriate", and multivariate logistic regression modelling was used to determine independent predictors of implant-related complications. The team analysed 245 patients that met the inclusion

criteria.

The Study Group reports that the incidence of implant-related complication was 31.7%, of which 52.6% required reoperation. Rod breakage accounted for 47% of the implant-related complications, and proximal junctional kyphosis for 54.5% of radiographic complications.

Univariate analysis identified potential risk factors for implant-related complication including weight, American Society of Anesthesiologists score (ASA), revision, stopping fusion in the lower thoracic spine, worse SRS-Schwab classification modifiers (pelvic tilt, pelvic incidence minus lumbar lordosis, sagittal vertical axis), higher T1 spino-pelvic inclination, and higher T1 slope.

The authors write that independent predictors of complications as identified on multivariate logistic regression included: ASA score (odds ratio 1.75, $p=0.029$) and sagittal vertical axis modifier (odds ratio 3.43, $p=0.0001$). The implant-related complications and non-complications groups each experienced significant improvement over time, as measured on the ODI ($p=0.0001$), SF-36 ($p=0.0001$), and SRS-22r ($p=0.0001$). However, the rate of improvement over time was less for patients with implant-related complications (SRS-22r $p=0.043$, SF-36 $p=0.0001$).

The complications observed "significantly affected HRQOL measures". The authors suggest that baseline patient characteristics and parameters of the SRS-Schwab classification may be used in future "to help identify patients at greater risk" of implant-related complications.

"According to our study," the authors write, "patients that had more comorbidities and more significant deformity in the sagittal plane were at greater risk. Identifying risk factors is the first step in the effort to decrease these types of complications".

"Collectively, these findings emphasise the importance of further studying ways to decrease these types of complications as a means of improving patient outcomes," the authors conclude.



Spinal deformity implant-related complications

- The rate of implant-related complications was 31.7%
- Of these cases, 52.6% required reoperations
- Rod breakage accounted for 47% of all implant-related complications

Surgery more effective than physiotherapy for treating cervical radiculopathy

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reduced with a mean difference of 21 score per cent in the surgical group, compared with a score difference of 11 score per cent in the non-surgical group ($p=0.03$). Mean scores for neck pain, as measured by VAS, were reduced by 39mm in the surgical group compared with 19mm for the non-surgical group ($p=0.01$), while mean arm pain fell by 33mm for surgical patients and 19mm in the non-surgical patients ($p=0.01$).

EQ-5D scores reflected the improvements in physical outcome measures with patients in the surgical group enjoying a mean increase of 0.29 compared with a 0.14 increase in the non-surgical group. Furthermore, 93% of surgical patients rated their symptoms as “better” or “much better” than before surgery, compared with 62% in the non-surgical group ($p=0.005$).

Although both groups saw significant improvements in clinical and patient-reported outcomes, “ACDF with physiotherapy yielded superior results compared with physiotherapy alone,” Engquist said. Although this study population was small, the current lack of randomised studies on this

subject and the fact that no others have followed up to two years lends weight to the study’s findings, Engquist explained.

Spinal News International interviewed Markus Engquist following his presentation, to find out more about the study and about his experience of this year’s CSRS-ES meeting.

Were there any notable complications in the surgical group? How many of these required reoperations?

Fortunately, no patients required secondary surgery during the follow-up period of five to eight years, and we have not seen any implant loosening. Nor were there any major complications such as infections, deep venous thrombembolism or increased neurologic deficit. We did not record the incidence of dysphagia, but as this is such a common complication, it may well have occurred among our patients as well as in most other ACDF series.

When would you still recommend non-

surgical treatment?

With very few exceptions, I think it is reasonable to recommend a trial of structured physiotherapy for all patients in the early phase of cervical radiculopathy, perhaps the first three months, before making any surgical decision. For patients who have substantial residual symptoms after that, ACDF provides a good alternative for greater and more rapid improvement, which can also be expected to last for at least five to eight years.

Do you have any further studies in progress or planned to look further at this subject?

We have another paper about patient-related factors affecting the treatment result (surgical or non-surgical) for patients with cervical radiculopathy that has been accepted for publication in an upcoming issue of *Spine*.

Your study won the Mario Boni Award—what does this recognition mean to you and your co-authors?

Having worked with this study for more than 10 years, it is great to receive the Mario Boni Award as an acknowledgement that our results are of interest for the international faculty. It is also a

nice boost for my self-confidence as I am defending my thesis on this subject at the University of Gothenburg in October.

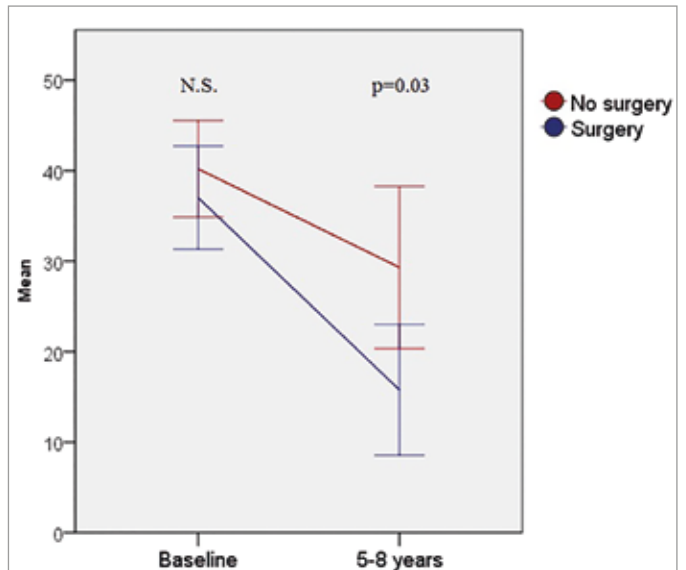
What is the value of meetings like CSRS-ES?

For me, conferences of this kind are probably the most valuable ones. They deal with a limited subject compared to the enormous conferences like AAOS (American Academy of Orthopaedic Surgeons), but still reach researchers from all over the world.

What do you think

were the highlights of this meeting?

It is difficult to choose from such a large number of presentations, but two presentations that I personally found very interesting were “Non-operative treatment modalities prior to cervical surgery affect patient outcomes: an analysis of 1,818 patients” by Passias *et al* and “Cervical intervertebral disc degeneration: assessment by quantitative magnetic resonance imaging and histology” from Michopoulou *et al*. And, of course, who would want to miss the meeting’s gala dinner at St Paul’s Cathedral?



Five- to eight-year improvement in NDI scores for the two groups following treatment

Most cited research papers focus on non-surgical treatments for low back pain

The “top 100” most cited papers in lumbar spine research have been listed by the journal *Spine*, with the most popular papers looking at non-operative treatments.

Samuel K Cho and colleagues of Icahn School of Medicine at Mount Sinai, New York City, USA, performed a literature review to analyse and quantify the most important research papers on lumbar spine surgery. Their results raise some interesting “questions, trends and observations”, including the finding that the two most cited studies focus on situations when spinal surgery should not be performed.

The goal of the analysis was to identify the 100 most frequently cited papers relevant to lumbar spine surgery and published in spine-related journals. The number of citations by subsequent papers is a key measure of the relevance and importance of medical studies.

Out of more than 16,500 papers matching the search criteria, 322 were cited at least 100 times. The top ranked paper, cited more than 1,000 times, was a 1990 study showing that many people have common spinal abnormalities on magnetic resonance imaging (MRI) scans despite having no back pain or other symptoms. A 1994 study on a similar topic was the second most cited paper, highlighting the need for a “clear correlation” of patients’ symptoms and imaging findings.

The third most cited paper was a 2000 review of the Oswestry Disability Index for assessing the impact of low back pain on patients’ lives. Overall,



low back pain was the most common topic, addressed by 23 of the top 100 papers. Other frequent topics included spinal biomechanics and degenerative disc disease. About half of the papers were published during the 1990s, and most originated in the USA.

Reflecting the current emphasis on evidence-based practice, the most frequently cited author is not actu-

ally a spinal surgeon. That researcher, Richard Deyo of Oregon Health and Science University, Portland, is a leading authority on patient outcomes research.

The other two most frequently cited authors were Scott D Boden of Emory University, Atlanta, USA, and James Weinstein of the Dartmouth Institute, Lebanon, USA. All three of these “most prolific” authors contributed to the SPORT study—a pivotal clinical trial comparing the benefits of surgery versus non-surgical treatment for sciatica from herniated lumbar discs.

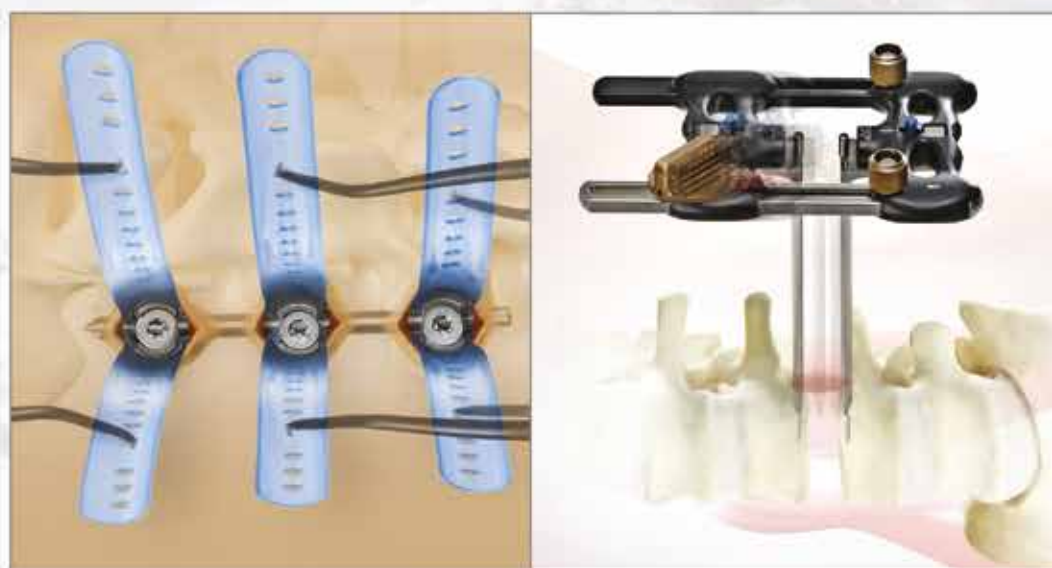
Over the years, rates of spinal surgery have risen, but with wide regional variations. Meanwhile, there are persistent questions about which patients truly benefit from surgery for the common and costly problem of low back pain. Many of the top cited studies reflect the current emphasis on evidence-based practice, seeking to define groups of patients and characteristics associated with beneficial effects of spinal surgery.

Within the limitations of the review methods used, Cho and colleagues believe their study provides unique insights into the development and trends of the “challenging subspecialty” of lumbar spine surgery. The researchers add, “This paper identifies those individuals whose contributions to the ever-growing body of knowledge have provided guidance and suggestions for further investigation.”

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INSITE data indicate efficacy of minimally invasive sacroiliac joint fusion

Delegates at the annual meeting of the International Society for the Advancement of Spine Surgery (ISASS; 15–17 April, San Diego, USA), received an update out to six months on the INSITE trial, which compares the use of minimally invasive sacroiliac joint fusion using iFuse implants (SI-Bone) with non-surgical management to treat chronic sacroiliac joint dysfunction.

Peter Whang, Yale University School of Medicine, USA, told delegates that previous studies indicate that up to 15% of chronic low back pain can be attributed to the sacroiliac joint, and though promising case series have been published previously, there still exists a “paucity of high-quality prospective randomised controlled clinical trials”. Despite this lack of data, interest in the field—both clinical and commercial—is growing.

The six-month data from INSITE—a multicentre randomised controlled trial—has gone some way in addressing this paucity, indicating that the minimally invasive fusion approach using triangular implants was significantly more successful than non-surgical treatment.

In the sacroiliac joint fusion group, mean joint pain improved from 82.3 (0 to 100 scale) at baseline to 29.8 at six months—a 53-point drop. By contrast, the non-surgical group showed little improvement with only a 12-point drop from 82.2 to 70.4. Six-month improvement in pain was 40.5 points greater in the surgery group ($p < 0.0001$). Disability scores (measured using the Oswestry Disability Index) improved by 30 points in the surgery group vs. 4.9 points in non-surgical patients (difference in means, $p < 0.0001$).

Quality of life outcomes, as measured by EQ-5D and SF-36, showed statistically significant differences in improvements in the iFuse group compared to non-surgical management for all subdomains. The study’s primary clinical endpoint was overall treatment success defined as patients who achieved clinically significant pain improvement (≥ 20 point drop in Visual Analogue Scale score), no device-related complications, no neurologic worsening, and no reintervention. The fusion group saw 81.4% of the patients achieve overall treatment success compared with 23.9% for the non-surgical group.

Interview

Peter Whang spoke to *Spinal News International* about the study, and about what the data means for the ongoing debate over sacroiliac joint treatment.

How has the treatment of sacroiliac joint pain developed?

Back pain is still not well-understood and we know that there are a lot of different things that can cause it. Obviously, as spinal surgeons, we tend to focus on the lumbar spine—is it the disc, is it the facet joint, is it neurocompression? The one condition that I think has become better recognised as a source of axial back pain is the sacroiliac joint, and that is really something that has come to the forefront in the past several years and something that we have gotten a lot better at identifying and treating.

In the past when we thought someone had sacroiliac joint pain there were not many good treatment options. We used things like medication, physical therapies, injections and nerve ablations, but none of those really represented good long-term solutions because sacroiliac joint



Peter Whang

dysfunction is a mechanical problem. The challenges up to this point have been diagnosing the problem correctly and finding reliable treatments. In the past, sacroiliac joint fusions were done via an open technique causing a lot of damage to soft tissues, and this was largely for people who had major pelvic injuries from car accidents and things like that. With the advent of less invasive fusion procedures, we now have a more effective way to treat this pain.

Why has attention on the sacroiliac joint increased in recent years?

I think that now we have alternative approaches with minimally invasive techniques that cause less damage we are more willing to approach the problem. I also think one important step forward is that we have good data from the INSITE trial, suggesting that this minimally invasive fusion may be superior to non-operative care. Obviously with new technologies the burden of proof is on us to show that it is better than the existing options. That is exactly what this data are showing, that this method not only has potential but actually does appear to provide better outcomes than non-operative care.

How can you be sure that symptoms are associated with problems in the sacroiliac joint?

I think, as with any condition, diagnosis is critical. The success of this and any other procedure we do is based on establishing that correct diagnosis—if you have someone with hip arthritis or a degenerative disc and you treat the sacroiliac joint, they are not going to improve. The suc-

cess is contingent upon establishing the fact that the pain is arising from the sacroiliac joint.

I think something that is important is a patient’s response to injections. If you inject local anaesthetic into the joint and that was the source of the pain, the patient should have temporary relief—and that means 50% or more relief, which is what I look for when I am talking to my patients. If their pain was gone for eight hours after the injection then I am pretty convinced that the pain is coming from the sacroiliac joint. If the pain is helped a little bit for five minutes and then it was no different, I am going to focus on other things in the lumbar spine or the hip. So I think that, in particular for the sacroiliac joint, it is really important that we establish the correct diagnosis because there are a lot of different things that can cause similar symptoms.

Are more and better data the way to convince the sceptics?

Yes. I do not blame them for being apprehensive. We see new techniques all the time and it is up to us to show through good studies that what we have is as good as or better than existing options. So I certainly would not fault someone for being unsure as this is something that has only more recently come to the forefront. As physicians talk more about it, hopefully we will get more comfortable with the idea.

At this point I can say that, when the diagnosis is correct, I have been shocked with how well people do. I always say that if my lumbar spine patients did as well as my sacroiliac joint patients I would be a happy man.

Do you think these results could be reproduced by other systems on the market?

I think that there is potential for different materials and different surgical approaches—some of the implants take a different approach and a different trajectory. I do not think you can really translate the data from a study like the INSITE trial which uses a specific shape, material and surgical approach to comment on any other techniques, because I think there could potentially be big differences. For example, if you have a screw as opposed to a triangular implant you have to take a different trajectory, which may give different results. This study was specific to the iFuse procedure, which is different to a lot of other procedures on the market.

Can we expect to see a proliferation of sacroiliac joint fusion devices and techniques in the future?

Yes. And at that point there will need to be comparative studies done comparing different materials, shapes, trajectories and so on. This field is still in its infancy and ours is the landmark study showing that this specific technique has the potential to be better than non-operative care. Once this is legitimised then we can start talking about other implants and material and I think that is when the comparative studies will come—INSITE is the foundation for these future comparative studies.

What is the current state of the sacroiliac joint treatment debate?

I think the controversy is still there. I think that certainly sacroiliac joint-mediated pain and fusion for this condition is now better accepted, and I think that the fact we are seeing debates at major meetings is a step forward—a few years ago people would not have even been talking about this.

Up until this point there has not been a lot of good data. There have been retrospective studies or small series of patients showing that this technique may be effective, but you really have not had that high level prospective randomised data. That is what we are going to be seeing with the INSITE trial. I am not surprised that there is still some controversy surrounding this technique, but I think that the results of this study will go a long way to settling things and hopefully convincing people that this is something that has merit.

Mesenchymal stem cell allograft requires further study prior to routine use as an adjunct to fusion

A study presented at the annual meeting of the International Society for the Advancement of Spine Surgery (ISASS; 15–17 April, San Diego, USA) warned that, despite their growing popularity, mesenchymal stem cells used as an adjunct for cervical discectomy and fusion do not necessarily result in improved outcomes.

Traditionally, anterior cervical discectomy and fusion (ACDF) procedures have employed tricortical autograft from the iliac crest, achieving fusion rates of 92–100%. However, this method can also result in significant complications, with pain, infection, haematoma and nerve injury reported in as high as 20–30% in some case series. The risk of these complications has encouraged bioengineering efforts to identify alternatives to iliac crest harvest.

“Allogenic bone grafts containing live mesenchymal stem cell allograft have recently gained popularity and currently account for more than 17% of all bone grafts and bone graft substitutes utilised in spine surgery,” Steven McAnany, Mount Sinai Medical Center, New York, USA, told the assembled delegates. Despite this, he continued, little is known about the actual clinical success of stem cell allograft when used in fusion surgeries.

In their study, McAnany and colleagues focused on the use of cellular bone matrices with stem cell allograft for ACDF procedures, carrying out a retrospective review of a prospectively matched cohort of patients with radiological assessment of fusion as the primary endpoint, with reoperation rates as a secondary endpoint. The study included a consecutive series of 57 patients treated with ACDF and a cellular bone matrix with stem cells, and an age and comorbidity-matched cohort of 57 patients treated with ACDF and structural allograft.

In the stem cell allograft group, patients were treated with Osteocel (NuVasive)—a first generation cellular bone matrix harvested from cadaveric bone and made using proprietary techniques aimed at preserving stem cells—while those in the control group were treated with Vertigraft (DePuy). Both groups were also treated with an anterior plate.

Of the 57 cases in both cohorts, 29 (50.9%) were single-level and 28 (49.1%) were two-level ACDFs. There were no significant differences in patient age, gender, comorbidity burden or body mass index.

At one-year follow-up, 50 (87.7%) patients in the stem cell allograft group demonstrated a solid fusion, compared to 54 (94.7%) in the control group ($p=0.19$). Seven (12.3%) stem cell allograft patients demonstrated failed fusion at one year, four of whom were

symptomatic and underwent revision surgery with a posterior cervical fusion. The remaining three patients were asymptomatic and did not require a secondary intervention. The three (5.3%) patients with failed fusion in the control group all underwent revision surgery.


“This is the first non-industry sponsored study to analyse a matched cohort

assessing the one-year arthrodesis rates associated with a non-structural stem cell allograft in one- and two-level ACDF procedures,” McAnany told delegates. He continued, “Although not statistically significant, patients treated with stem cell allografts demonstrated lower fusion rates compared to a matched non-stem cell cohort.”

McAnany said that unknowns still exist with regards to cellular bone matrices and stem cell allograft—data are currently limited and it is unknown whether the cells in question will survive. Questions also remain over the cost-effectiveness of this method, especially given that fusion rates were lower than with structural allograft (although there was no significant difference).

McAnany concluded by saying that further long-term studies with larger sample sizes are warranted before stem cell allografts are incorporated into routine clinical practice. “Surgeons should use stem cell adjuncts with caution until further evidence shows improved fusion rates and cost-effectiveness,” he said.

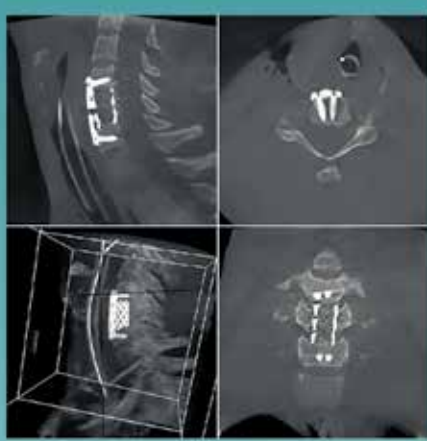
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Treating compression fractures with Vessel-X

Vessel-X (Spirit Spine) is a device used to undertake “vesselplasty” procedures, designed to restore vertebral body height following a vertebral compression fracture using a non-stretchable PET (polyethylene terephthalate) container. The container is inflated using low viscosity, biocompatible cement (Osteo-G, Spirit Spine), which then percolates through the mesh lining into the void. Vessel-X lifts up the endplates and then fills the void with biocompatible material, while maintaining the height correction.

New clinical trials for Vessel-X began in France in May, with the first follow-up results expected at the end of this year. *Spinal News International* spoke to Bambang A Darwano, Pluit Hospital and Gading Pluit Hospital, Indonesia, and Jean-Denis Laredo, Hôpital Lariboisière and Université Paris-Diderot, France, about their experiences using the platform, and where they believe it sits in the range of techniques used to treat vertebral compression fractures.

Why would you use Vessel-X instead of vertebroplasty or kyphoplasty?

Laredo: As soon as you have a large cortical break (sometimes you have no more cortical bone), especially when the posterior vertebral body cortex is involved, there is a risk of leakage when using vertebroplasty or kyphoplasty.

In such situations, using Vessel-X is helpful since the container retains cement when you start the injection, at which time the cement is fluid. Once the container is filled, the pressure starts to build after several minutes and the cement starts to slowly filtrate through the container's pores. The cement is harder at that time, meaning there is less risk of leakage.

The most important point is that you have less pressure overall, because the Vessel-X retains it, decreasing the risk of cement leakage compared to using plain vertebroplasty. Compared with balloon kyphoplasty, in which you can lose part of the height you just regained when you deflate and retrieve the balloon prior to cement injection, with vesselplasty there is no loss of vertebral body height.

Bambang: With vertebroplasty, when you inject cement into the fractured vertebra, the pressure forces the cement to the fracture site and can cause leakage. Using high viscosity cement such as in vesselplasty is safer compared with the low viscosity cement. Also, vertebroplasty technique is not designed to restore the vertebral body height.

Kyphoplasty is designed to restore the vertebral body height by creating a void using a balloon inflated by an injection of water. The balloon is then removed and the void it created is filled with cement. When injecting the cement, it will once again go to the weakest area—the fracture site—and lead to a leakage. Furthermore, in-between balloon removal and



Bambang A Darwano

cement injection, there will be some collapse of the void created.

For what indications would you use this procedure?

Laredo: There is one indication that I am certain about the advantage of Vessel-X, and that is in bone metastases, where our main problem is leakage of cement. I used it recently to carry out a procedure at the first cervical vertebra, which was mostly destroyed by multiple myeloma. The procedure was very risky, but I was able to reconstruct the C1 lateral mass using Vessel-X without any cement leakage. Another indication may be osteoporotic fractures with an intravertebral cleft (osteonecrosis) where there is no tendency to heal, a condition sometimes called Kummel's Disease. In such cases, it is usually possible to regain much height of the vertebral body by using vesselplasty.

Why do you think Osteo-G is a better cement to use than plain PMMA?

Bambang: If we use PMMA inside the osteoporotic vertebra, the stiffness of PMMA remains constant throughout the patient's life, but the surrounding bone density is constantly degrading because of ageing and sometimes also due to osteoporosis. The result is a stiffness mismatch at the interface, which can lead to a loosening of PMMA or fracture of the osteoporosis bone. Osteo-G is bioactive cement, contains only 8% PMMA as a scaffold, and is mainly

SrHA (strontium hydroxyapatite) and calcium sulphate. The Osteo-G induces a new bone formation at the interface and avoids the problems associated with PMMA. A CT scan at six months after the procedure shows the new bone at the interface compare to CT just after injection. An animal study conducted at Hong Kong University shows the same result at the interface.

Do physicians need extra training to carry out the procedure?

Laredo: You do not need extra training if you are used to performing balloon kyphoplasties. You just have to have the seller with you when you are doing the first procedure, because any different type of device has specific technical needs. It takes around 15–20 minutes longer than vertebroplasty or kyphoplasty.

What are the risks of using Vessel-X?

Laredo: So far I have not encountered any problems.

Bambang: I have completed more than 1,000 vesselplasty procedures using Vessel-X since 2004. The cost is equal to using balloon kyphoplasty and up to this point I have experienced no negatives effects when using Vessel-X—if it is done properly. Of course we do still have to face the possibility of leakage.

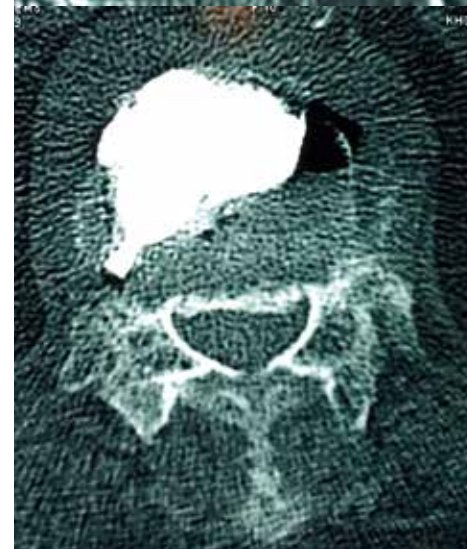
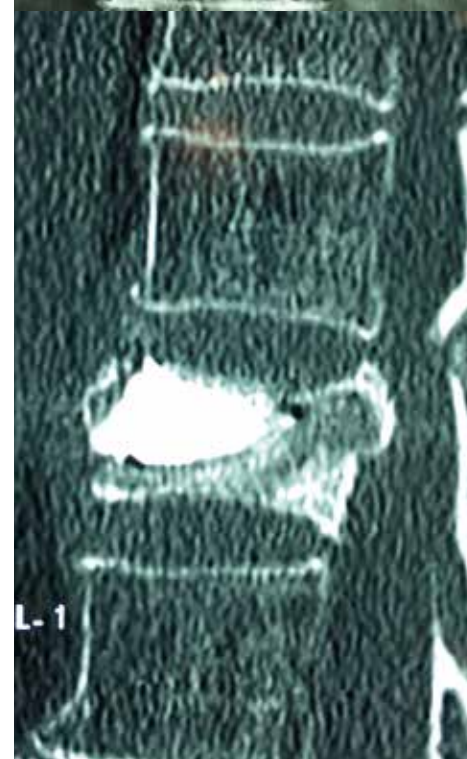
Do you think this will become a more popular procedure?

Laredo: I have been using Vessel-X for less than one year and I only know of one other neuroradiologist in Paris using it—it is not that well-known in France at the moment. We only recently received the authorisation to buy it officially. In the French system, to buy a new medical device, you have to prove that it provides a better service compared with other available treatments.

I believe it will become more popular if it continues to do well, which I think it will. The question is whether it is worth the price, and if it is bringing good results, which it has been, then the answer to that question is yes.

Bambang: Once other physicians understand the concept of vesselplasty and the necessary steps to carry out the procedure successfully, I believe that many doctors will begin using it. The procedure's safety, the ability to prevent leakage and the benefits associated with using bioactive cement all make this an attractive option.

Post-procedural X-rays of a 74-year-old Kummel's Disease patient successfully treated with Vessel-X



Vertebroplasty and kyphoplasty equally effective in reducing vertebral compression fracture pain and disability

A study published online by the *Journal of NeuroInterventional Surgery* suggests that vertebroplasty and kyphoplasty are equally effective in reducing pain and disability in patients suffering from vertebral body compression fractures.

Vertebral body compression fractures are a significant cause of disability worldwide and can cause disability secondary to pain, spinal deformity, reduced pulmonary function, impaired mobility and depression. Both conservative and interventional techniques have been used to treat such fractures.

Avery J Evans, University of Virginia, Charlottesville, USA, and colleagues write that “While the overall utilisation rate of kyphoplasty and vertebroplasty has decreased since the publication of negative sham trials in 2009, these procedures are still commonly performed and represent a significant source of healthcare expenditure costs.” Kyphoplasty is performed more frequently than vertebroplasty—nearly 75% of patients undergoing spine augmentation in the USA receive kyphoplasty, the authors write—largely due to the perception that it is safer and more effective. However, studies comparing the two procedures are generally non-randomised or meta-analyses of non-randomised prospective studies. As such, Evans and colleagues carried out this, the third randomised controlled trial on the topic.

The authors enrolled 115 patients at nine US centres in their trial, who were then randomly assigned to treatment with either vertebroplasty (56, 48.7%) or kyphoplasty (59, 51.3%). Primary endpoints for this study were pain measured on a 0–10 scale and disability assessed using the Roland-Morris Disability Questionnaire. Outcomes were assessed at three days, one month, six months and one year following the procedure. The mean age of the full cohort was 75.6 years, 71% of which were women. The authors note that “baseline demographic and clinical characteristics were similar by random assignment,” ($p>0.05$).

Evans *et al* report that “reductions in average pain, pain frequent and functional limitations due to pain were substantial after surgery, while remarkably similar by treatment assignment.” Mean baseline pain scores were 7.4 for the kyphoplasty group and 7.9 for vertebroplasty. Three days after the treatment, these scores had fallen to 4.1 for kyphoplasty and 3.7 for vertebroplasty. At 30 days the mean pain scores fell to 3.4 for kyphoplasty and 3.6 for vertebroplasty, and at one year the scores were 3.0 for kyphoplasty and 2.3 for vertebroplasty (all time points $p>0.05$).

In terms of disability scores, a similar improvement across time points was reported. At baseline the scores were 17.3 for the kyphoplasty group and 16.3

in the vertebroplasty. Three days after treatment these scores fell to 11.8 for kyphoplasty and 10.9 for vertebroplasty. At 30 days the kyphoplasty group’s mean

disability score was 8.6 compared to 8.8 in the vertebroplasty group, and at one year 7.5 for kyphoplasty and 6.7 for vertebroplasty (all time points $p>0.05$).

“There was essentially no evidence of a differential response in clinical improvement between treatment with kyphoplasty and with vertebroplasty,” the authors write. They go on to note

that the results “could have a significant economic impact as they suggest that the less costly a less used procedure—vertebroplasty—is equally effective in all measures when compared with kyphoplasty.” That said, the authors do conclude that the comparative long-term benefits have yet to be clarified, and that the sample size of this study is “modest”.

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First operation with individualised 3D-printed cervical titanium implant completed

For the first time, a patient with a degenerative cervical spine condition has been treated with an individualised 3D-printed titanium fusion implant. The operation was planned and performed by Uwe Spetzger, professor and chairman of the Department of Neurosurgery of the Klinikum Karlsruhe, Karlsruhe, Germany. Spetzger is also the current president of the annual meeting of the German Society of Neurosurgery.

The implant was designed by EIT (Emerging Implant Technologies) GmbH, a newly-formed company that is producing 3D-printed implant solutions. EIT partnered with 3D Systems in the 3D design and manufacturing process.

This additive manufacturing method allows the material to mimic the trabecular bone structure. EIT cellular titanium with micro-, macro- and nanostructural features provides high stability and speeds up the bone healing and fusion process. The company believes that the design of the device provides an optimal biomechanical and biological environment for natural bone ingrowth without the need to add bone graft. The individualisation of the implant means that it fits exactly to the patient's individual anatomy, unlike

mass-produced alternatives.

The goal of the individualisation of a series implants is to reduce typical implant-related complications such as migration, subsidence or delayed fusion, all of which are related to insufficient implant-to-bone contact of standard implants.

Stephanie Eisen, chief executive officer of EIT believes that "In two to three years we will be able to provide an individualised series implants at reasonable cost. Individualisation will deliver better implants, faster and easier surgery and better patient outcome. The reoperation rates in spine surgery are by far higher than for example with hip or knee implants. It is our mission to change this."

Uwe Spetzger, who led the procedure,



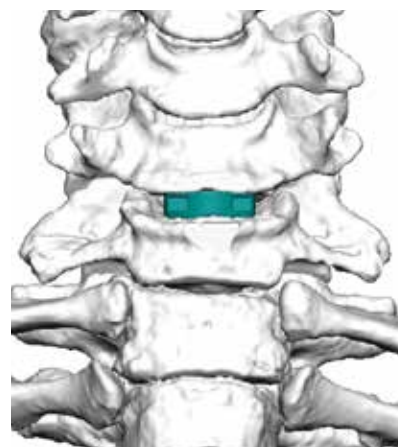
Uwe Spetzger

spoke to *Spinal News International* about the implantation, and the benefits of using 3D printed titanium technology.

Do you have previous experience of using 3D printed technology in surgery?

Yes, I use the standard cellular titanium EIT cervical cage regularly in my clinical practice for central cervical fusion procedures. I like using it because using this cage means we do not need to use hydroxylapatite as cage filler.

Why did you decide to treat this patient with a 3D



The implant placed in a simulation

printed implant?

This patient had an unusual endplate anatomy. This would have required us to remove parts of the cortical endplate and flatten the surface to achieve a good fit for a regular implant, which would have resulted in an increased risk of cage subsidence. As such, we looked to avoid these problems by using the 3D printed implant.

How long does it take and how much does it cost to create an individualised 3D printed titanium implant?

The company that made the implant does not yet provide individualised implants on a regular basis. In this case, it took about three weeks for the simulation and adaptation with the help of 3D systems necessary to produce the implant that we used. The cost for the clinic would currently be around €2,000 for this individually 3D printed cage. The company is now working on cost reduction by optimising its processes, so hopefully this cost will be reduced in future.

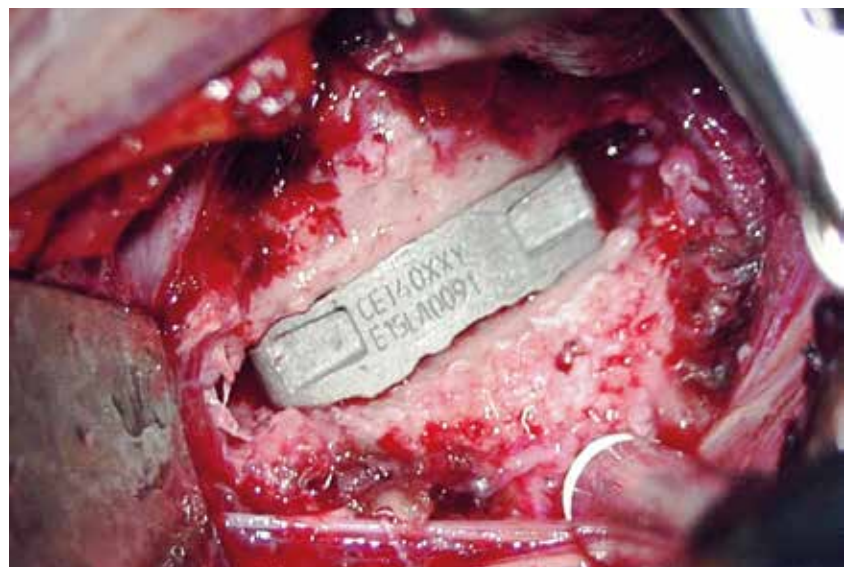
We have already seen plastic 3D implants being used. Is titanium better?

Titanium implants provide better biocompatibility. PEEK cages are normally used because they have better imaging characteristics. The cellular titanium structure that we used in this case has 80% porosity and, therefore, has significantly reduced artefacts in computed tomography and magnetic resonance imaging scans.

What is the future for individualised 3D-printed implants?

We believe that individualised implants will reduce common complications such as migrations or subsidence and pseudoarthrosis, by providing a maximised implant-to-bone contact area. This reduces peak loads and provides an optimal load transfer.

We are fascinated by the possibilities of this new technology combining modern computer-aided design and custom-made manufacturing of a high-tech cervical implant. The future of patient individualised spinal implants has begun.



The implant in situ



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The Great Debate: Treating adult degenerative scoliosis

Minimally invasive surgery

Juan S Uribe, University of South Florida, Tampa, USA



In most cases of adult degenerative scoliosis, some element of a less invasive surgical approach can be integrated in the surgical plan to attenuate the high surgical morbidity that has become commonplace in open deformity surgery. While the surgical correction possible in open surgery for spinal deformity is broad, the costs at which it is gained—substantial blood loss, high complication rates, and broad denervation of posterior musculature—are substantial^{1,2} and, in many cases, avoidable. The consequence of complications in spine surgery is no better illustrated than by Glassman *et al* who found that a major complication in spine surgery results in significantly lower functional outcomes long term with lower patient satisfaction.³

It is true that, historically, minimally invasive surgery in the correction of spinal deformity has been limited to those patients with mild coronal curve and minor sagittal imbalance, including early findings from these authors. This perspective is growing less and less accurate, though, as emerging results are published on modern minimally invasive approaches in the treatment of more complex, including sagittal, spinal deformity.

Efficiently treating the anterior column with interbody fusion has been shown to correct spinal deformity similarly to posterolateral fusion, though with fewer levels needed to achieve similar radiographic results.⁵ This is the true definition of minimally invasive

spine surgery.

The foundation of sagittal plane restoration relies mainly on spine releases at critical anatomical structures followed by reduction and stabilisation manoeuvres. If a particular technique—either open or minimally invasive—meets those requirements, the balance is restored or preserved. Modern minimally invasive approaches for sagittal plane correction include anterior column realignment using the lateral approach for interbody fusion paired with anterior longitudinal ligament release. Using this technique, outcomes of which have been published in more than a dozen papers, can correct up to 28 degrees per level⁶ with an average of 111ml of blood loss.

These results are comparable with Smith-Peterson or even pedicle subtraction osteotomies, though with one tenth of the surgical morbidity. This advancement in minimally invasive deformity correction techniques, along with others now emerging, has revolutionised the armamentarium available and has presented a viable option for deformity surgeons. To this point, minimally invasive applications allow for a much more selective use of procedures. “Hybrid” approaches can utilise minimally invasive anterior interbody fusion with selective anterior column realignment levels followed by percutaneous posterior lumbar fixation (with select Ponte osteotomies, if needed) and open thoracic surgery for continuation of sagittal correction, as one example. This continuum of choices allows for individualised treatment plans for each patient—utilising appropriate technology in the applications where they are needed.

We support the constructive criticism and scrutiny of the minimally invasive techniques by open deformity leaders that challenge and motivate advances in deformity correction techniques. We would simply argue that there is a broad continuum of modern approaches and manoeuvres to be employed, in a patient-by-patient basis, and exclusively using one technique, whether minimally invasive or open, serves no one.

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“Minimally invasive applications allow for a much more selective use of procedures.”

Open surgery

Steven Glassman, University of Louisville, Louisville, USA



Selection of an optimal treatment strategy often depends upon a clear definition of the pathology, and this is particularly true for adult degenerative scoliosis. The term “adult degenerative scoliosis” may be applied to a patient with spinal stenosis, a well-balanced 20 degree curve or a patient with a 60 degree rotatory scoliosis with sagittal imbalance. The treatment of these two patients is obviously dramatically different.

Open surgical treatment for adult degenerative scoliosis is well-established both for small curves requiring stabilisation to facilitate adequate decompression and for substantial deformity where realignment is a critical element of the treatment plan.^{1,3,4} This benefit of open surgical treatment has been demonstrated in multiple case series, and has been additionally validated in a systematic review by Ledonio *et al*.² Most recently the consensus regarding established techniques for deformity correction has been reiterated through an Appropriate Use Criteria study performed by Rand/UCLA and presented at last year’s Scoliosis Research Society meeting (10–13 September 2014, Anchorage, USA).

In contrast, the literature regarding minimally invasive treatment for adult degenerative scoliosis is quite limited, and often highlights the limitations of the technique. Many of the original studies focused on potential complications of minimal access lateral approaches, particularly the risk of neuropraxia associated with the transpoas technique. Even if you accept the argument that transient neuropraxia is not really a complication, or that it is only part of the “learning curve”, the basic capabilities of minimally invasive surgical deformity correction are still in question. The existing literature demonstrates that

minimally invasive surgery can reliably correct small coronal deformities and achieve indirect foraminal decompression, but it also seems clear that restoration of sagittal alignment is unreliable. As sagittal plane alignment has become widely recognised as the primary driver of health status in adult deformity patients, it is difficult to understand the rationale for a surgical strategy that provides suboptimal sagittal plane correction.

While I would concede that there are a small number of very experienced minimally invasive surgeons with the ability to correct more substantial deformities, this is certainly not the norm. In a very reasonable algorithm for the use of minimally invasive surgical treatment in adult spinal deformity, Praveen Mummaneni and Juan S Uribe have laid out my position in this debate with great clarity.⁵ The essence of their algorithm is that patients with very minimal deformity are well treated with minimally invasive techniques, and I agree with that assessment. They also recommend that patients with substantial spinal deformities require open surgical techniques.

Minimally invasive techniques have improved substantially over the past several years, and they are certainly in fashion. Unfortunately, not all fashion is good, nor is it necessarily appropriate for everyone. I support the continued work of thought leaders, like Juan Uribe, who are advancing our capabilities in this arena. At present, however, for the majority of surgeons, open treatment of adult degenerative deformity is the reliable and appropriate choice.

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“Open treatment of adult degenerative deformity is the reliable and appropriate choice.”

Treating gunshot injuries to the spine



JAY M ZAMPINI

COMMENT & ANALYSIS

Perhaps one of the more inspiring patients I have treated is also one with a most devastating and poignant story. In contrast to the often unconvincing, “I don’t know what happened; I was minding my own business, on my way to church (and/or my grandmother’s house) and this dude just came up and shot me,” hers was a case of road rage turned violent. She was young and educated, working to get out of a bad neighbourhood in North Philadelphia, USA. She was involved in a minor motor vehicle collision. The other driver became enraged during the “discussion” following the event, and produced a handgun, shooting her in the back as she ran and tried to hide. She presented with a gunshot injury to the thoracolumbar junction with neurologic function that rapidly progressed to complete paraplegia.

Traumatic injury to the spinal cord is a life-changing event for any patient. Gunshot injuries currently represent the third most common cause of spinal cord injury (SCI) and produce approximately one in five of all SCIs in the USA. Both before and after injury, these patients represent an “at-risk” population. The average SCI patient is typically injured at an age of maximal fiscal productivity and half of the time is unmarried or unemployed, meaning that this is a population with socioeconomic disadvantages which are only likely to worsen following injury. Hospital readmission appears to be the rule, not the exception, and can contribute to a cost of care that approaches US\$5m over the life of an SCI patient.

Treatment of spinal gunshot injuries can often seem something of an enigma, with very little high-quality evidence and contradictory conclusions to guide treat-

from several sources, we have made reasonably consistent conclusions about indications for surgical treatment and bullet removal, antibiotic prophylaxis, MRI safety, and metal toxicity.

The fundamentals of surgical treatment for spinal gunshot injuries are no different from those for any other spinal condition: decompress all compressed nerves and stabilise anything unstable. Empirical observation, however, has suggested that patients with injuries cranial to T12 and who present with complete and static cord injuries seldom recover function with surgical treatment. These patients often have more significant complications following surgery. A progressive loss of neurologic function, particularly at T12 and caudal, certainly represents a justifiable indication for surgical decompression. The osseous injuries are rarely unstable until overzealous decompres-

sion renders them so. Notable exceptions are bilateral pedicle fractures and vertebral body injuries caused by the so-called “high energy” firearms—those with a muzzle exit velocity of greater than 2,000ft per second. A computed tomography (CT) scan should be evaluated for the factors typically associated with vertebral instability including comminution and fragment displacement.

High energy means high comminution and fragment spread. In these patients, the benefit of surgical decompression and stabilisation would outweigh the risk of additional complications and can lead to accelerated rehabilitation, if not frank neurologic improvement.

I can recall learning throughout my residency in orthopaedic surgery that all bullets should be removed from

fluid-filled spaces in the body. The dissolution of the lead would lead to the ensuing lethargy, encephalopathy, anaemia, and possibly death from lead

poisoning. What initially sounded like an old orthopaedic wives’ tale, if there is such a thing, is relatively well supported by several small case series and case reports of such toxicity from bullets in synovial fluid. In reports of spinal gunshot injuries, evidence for lead poisoning has been documented to result from retained bullets in cerebrospinal fluid (CSF) or the intervertebral disc, albeit even more rarely than with bullet exposure to synovial fluid. Urgent excision of the bullet fragments may not be necessary although the patient should be counselled about the symptoms that may develop even years in the future. Bullets should be removed from the spinal canal if the fragments are thought to be the cause of a progressive neurologic deficit or if migration leads to neurologic changes. Again, the best evidence suggests that bullets removed from segments cranial to T12 offer little chance of neurologic recovery.

Following the theme of sparse and contradictory evidence in spinal gunshot injury treatment, conclusions about antibiotic use for infection prophylaxis are equally mixed. Several authors have recommended up to fourteen days of antibiotics if the gunshot penetrated the abdominal cavity while others have noted that severe infections still occur in up to 10% of cases with a prolonged course of treatment. At this time, it appears that 24–48 hours of antibiotic treatment is sufficient to reduce the risk of infection in spinal gunshot injuries while minimising the potential for su-

perinfections and drug resistance.

A final controversy encircles the use of MRI following spinal gunshot injuries with retained bullet fragments. The rationale for fear of the MRI follows this syllogism: bullets are metallic objects; MRIs displace metallic objects; therefore MRI is not safe for use with retained bullets. Materials typically used to manufacture bullets—copper and lead—are nonferromagnetic, though some ferromagnetic properties have been observed to result from metallic impurities. Several reports of up to 1.5 Tesla MRI scans performed on patients with retained bullets have repeatedly dismissed this fear, showing no displacement of the fragments or injury as a result of the scans. Of course, every

patient should be considered individually, with a personal assessment of risk and benefit of the MRI. Missile fragments in the brain or eye, for example, may

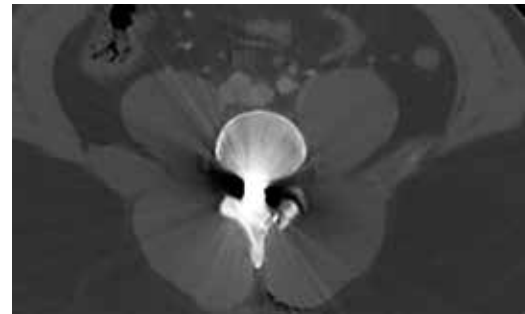
prove too risky

and preclude MRI as with other metallic fragments. Certainly, this is a situation where the basic science and empirical observations suggest MRI to be safe, even though indoctrination and medicolegal fear seem to counterbalance the issue. The patient should be at the centre of any decision to perform MRI in this situation and should be duly educated in the consent process.

Spinal gunshot injuries comprise a startlingly common cause of one of

the worst possible survivable effects of trauma. The decisions for treatment should be made with one part evidence and one part fundamental and basic science. So what, then, would be the best treatment for the patient I described above, whose imaging shows a stable spine with bullet fragments and bone in the spinal canal at T12 and a worsening exam? I took her to the operating room for decompression and repair of a traumatic CSF leak. Although she was never able to walk again, she did regain some meaningful lower sacral root function. The inspiring part of the story is the enlightened attitude she brought to each follow up; she worked hard to return to work and life, never showing anger or regret after what would otherwise devastate most of us.

Jay M Zampini is a spine surgeon in the Department of Orthopaedic Surgery at Harvard Medical School and a member of the Division of Spine Surgery at the Brigham and Women’s Hospital in Boston, USA



CT scan showing a nullet lodged in the spine



A caudal spinal gunshot injury

“Gunshot injuries currently represent the third most common cause of spinal cord injury and produce approximately one in five of all spinal cord injuries in the USA.”

ment decisions. Should retained bullets be removed? Are the injuries unstable? Can a patient undergo a magnetic resonance imaging (MRI) scan with retained bullets? Do patients really develop lead poisoning? My colleagues and I have recently reviewed the body of spinal literature to formulate an understanding of the key concepts surrounding spinal gunshot injuries. Piecing together data

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Profile Hyun Bae

Hyun Bae began his medical studies at Columbia University, where he graduated with a degree in biomechanics. Having interacted with numerous medical students in Columbia's orthopaedics lab, he decided that orthopaedic medicine was the career path he wanted to follow. With his mind set on a life in medicine, he went on to earn his medical degree, cum laude, at Yale University School of Medicine. His career to date boasts an impressive list of research projects and achievements. Much of this has focused on intervertebral disc repair, while he has also carried out research on mesenchymal stem cells. His work has led him to challenge, where suitable, accepted or "tried and true" methods of treatment and to always strive for improved techniques and fresh ideas. He spoke to *Spinal News International* about his career highlights so far, and about what he believes the future holds for spinal medicine.

Why did you decide to become a doctor and why, in particular, did you decide to specialise in the spine?

My parents emigrated from Korea to provide a better education and opportunity for the family in the USA. I never did, nor was I allowed to, take that for granted. Like many immigrants I was very driven and ambitious, so being a doctor was always up there as an option since before I got into college. What really put the nail in the coffin for me was when I was studying biomedical engineering at Columbia University as an undergraduate, where I realised that what was waiting for me after graduation was not the career path I wanted for myself. At this time I was heavily involved in an orthopaedics research lab, still in the field of engineering, but enjoying mentorship from the many medical students who came and went from this lab. With one fell swoop I knew that I wanted to be a doctor and I knew what specific field I wanted to be in.

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

Henry Bohlman was my director during my fellowship at Case Western Reserve University. He taught me that the spine was not like traditional orthopaedics—it required more thoughtfulness and more finesse, because you are dealing with the neural elements. In his time the field of spinal surgery was undergoing a renaissance. He not only taught me the science of spine but truly the art of spine care. He taught me that complications were always right around the corner and that preparation and diligence were paramount.

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

I think it has been bone morphogenic proteins. I still find it incredible that we were one of the first and still few surgical fields that use recombinant proteins in surgery. I think the power of this technology is somewhat lost on the generation that does not have experience harvesting iliac crest for autograft. It is taken for granted now, but making bone out of really nothing is an incredible feat of modern day molecular medicine.

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

The *Spine Journal* ran an article by one of my past fellows—Nomaan Ashraf—about using stem cell allograft in cervical fusion. The paper showed that the use of allograft material enhanced with stem cells actually resulted in a lower fusion rate than of standard allograft in fusion. People automatically hear buzzwords like "stem cells" and expect instantaneous and superior results. This paper shows that these expectations may not be realistic.

Of the research you have been involved with, which piece are you proudest of and why?

My work in intervertebral disc repair has been a specific passion and singular pride of mine. It is incredibly challenging, but developing a biologic solution to disc degeneration would be greatly impactful.

What are your current research interests?

The above-mentioned research in intervertebral disc repair is always on my plate, and lately I have been specifically looking at using mesenchymal stem cells to achieve such repair.

What makes your work on intervertebral disc repair so challenging?

The disc is an amazing structure. With all discs combined, it is the largest avascular structure in the body. It is so challenging because the bioavailability and pharmacokinetics are so demanding. The disc has little to no blood supply and getting nutrients to the disc is incredibly challenging. The intradiscal pressure can be 15 times the normal blood pressure, and therefore getting any type of drug to be delivered through the capillary system, which is the typical drug delivery mode, is nearly impossible. That is why I think direct intradiscal injection is an advantageous mode of delivering therapy.

You have been involved in a lot of research on motion preservation technology. Why is this important and how do you see this area developing in the future?

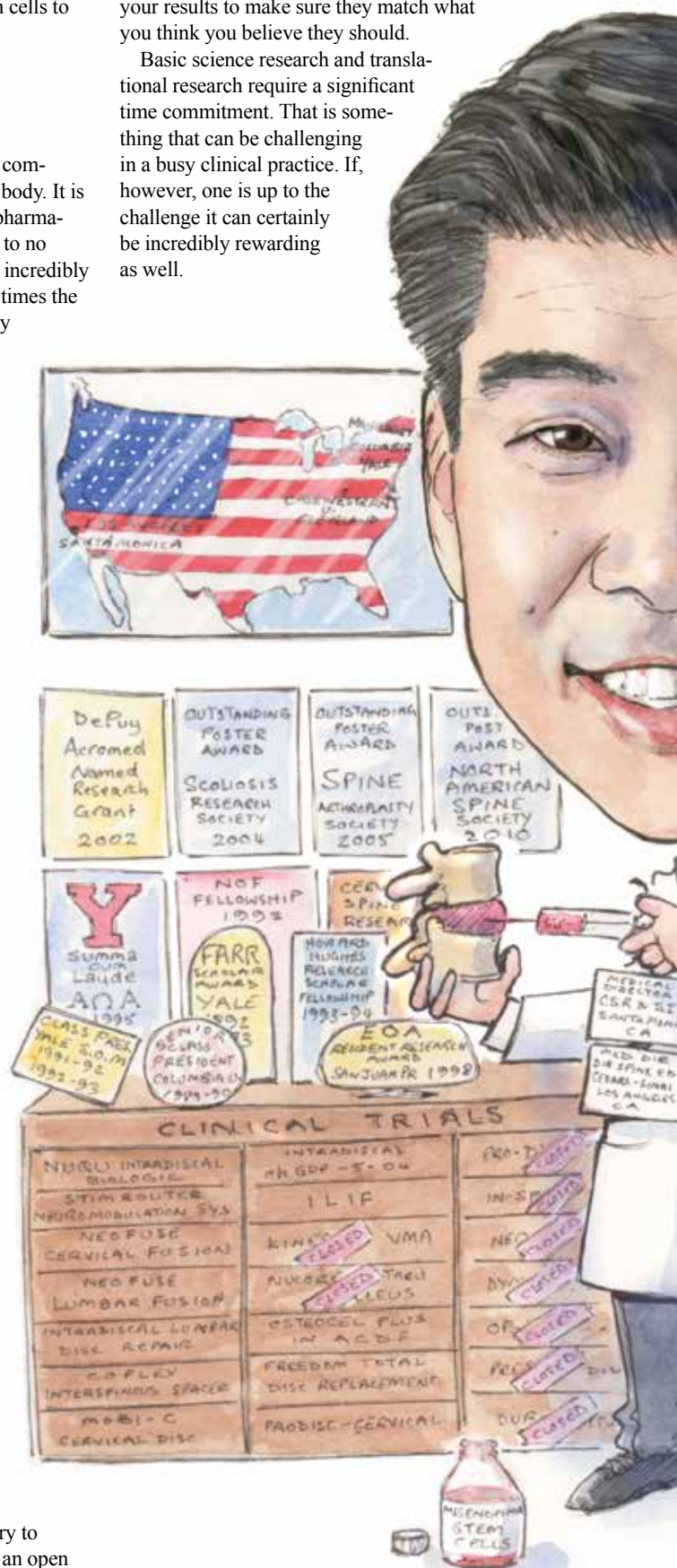
Fusion is important and necessary, but it is absolutely a non-physiologic solution with severe limitations. With the approval of new minimally invasive techniques and devices to replace fusion procedures and preserve motion, more surgeons are realising that fusion may not be the best solution. It may not even be a good solution. A greater acceptance of motion preservation technology will really push the envelope for innovators to create and advance the field in the future.

As someone with a research background, what advice would you give to those starting out on their medical research careers?

First of all, I think people classify me as a researcher because I am involved in translational and basic science research. But I think the term research really means that you have an academic process in the way you go about obtaining and processing knowledge. We all do this by analysing outcomes and techniques in the effort to improve our skills and deliver better patient care. To me that is a form of research. I do feel that having some academic initiative or an academic reference in the way you go about treating your patients is very important. Whether you do basic science research or not, what is important is that you use academic rigor in the information that is presented to you. It is one of the most important things I try to teach to my fellows. I try to teach them to keep an open

mind but to use academic rigor in everything that they read and everything that somebody tells them—make sure that you yourself have researched it before you actually apply that to patients and continuously review your results to make sure they match what you think you believe they should.

Basic science research and translational research require a significant time commitment. That is something that can be challenging in a busy clinical practice. If, however, one is up to the challenge it can certainly be incredibly rewarding as well.



What have you learned from attending scientific meetings? Do you think such meetings will continue to be important in the modern, technologically-connected world?

There is no question that there is great value in interacting with fellow scientists and peers at scientific meetings. Many new ideas and solutions to tough problems have come about thanks to these personal human interactions—you just cannot generate the same type of information exchange over the phone or via email. Perhaps in future there will be a more efficient venue for exchanges so interactions can happen more frequently and conveniently, such as using virtual venues—maybe with 3D or virtual reality glasses that will mimic the human-to-human experience.

What has been your most memorable case?

My very first case as a fellow at the VA was removal of a thoracic spine tumour. It was a patient with significant comorbidities including renal dialysis and who had not walked in over two weeks. He had a T8 lesion compromising his spinal canal. I did not have any experience performing a thoracotomy, let alone a vertebrectomy on my own. I presented it to Henry Bohlman hoping to get guidance and surgical assistance. I still remember the words like it was yesterday, he just said, "Wow. That really is a

tough first case. Good luck!" I did a lot of reading that night.

What advice would you give to someone who was starting their career in spinal surgery?

Spinal surgery is fraught with complications. You need to have excellent indications because things do not always turn out the way you might expect. I would also say that it is important to always challenge the paradigm that fusion is the gold standard treatment.

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

1. Where is the pain generator?
2. Can we improve on our current diagnostic tools in spine?
3. Where do we draw the line between industry being involved and when do they become too involved?

What do you think is the role of industry in spinal research?

That is a really tough question. The industry has to have some involvement. I understand the sentiment that the industry can be too involved, but current non-industry funding sources are few and far between. The National Institutes of Health funding rate has dropped and is now below 10%. Therefore, the industry does and needs to play a vital role in funding research. Of course, an inherent interest exists, but many therapies and trials fail. I am currently involved in the Mesoblast mesenchymal stem cell study for intradiscal disc repair and there is no question that to run a phase I/phase II/phase III clinical study across many disease entities requires many millions of dollars. Ultimately the study could fail but if it is successful then many patients would stand to benefit as well as the sponsor. This is no different than any chemotherapeutic or other drug trials. Without a commercial interest, many fantastic drugs and therapies would not exist.

In terms of diagnostic tools, what developments are currently making the biggest difference?

I think in terms of diagnostic tools, what is happening in functional magnetic resonance imaging (MRI) in trying to figure the source of pain and how people respond to pain is certainly the most interesting.

I think as far as future developments go, spine imaging does need to take another evolutionary step. We need to take another step like the one we have taken from computed tomography to MRI, I to develop some kind of functional MRI that will decipher pain generated by intradiscal disease. Really, to find out what the pain generator is and what patients with disc degeneration truly have pain. Which patients have pain related to the disc and more importantly which patients do not. I think imaging that is truly correlated with pain will certainly be the next paradigm shift.

What do you think will be the next big development in spinal medicine?

Stem cells have an incredible potential to treat diseases, but until now it has seemed more science fiction than true science. We are still in the beginning stages of translating the promise of stem cells from the bench to the bedside. Hopefully in the near future we will be able to demonstrate true evidence-based efficacy of stem cell therapies not only for the spine but for other major diseases as well. When this occurs this will be an inflection point that defines the future of modern medicine.

Outside of medicine, what are some of your hobbies and interests?

Golf, tequila, my beautiful wife and my three wonderful, rambunctious daughters.

Fact File



Appointments

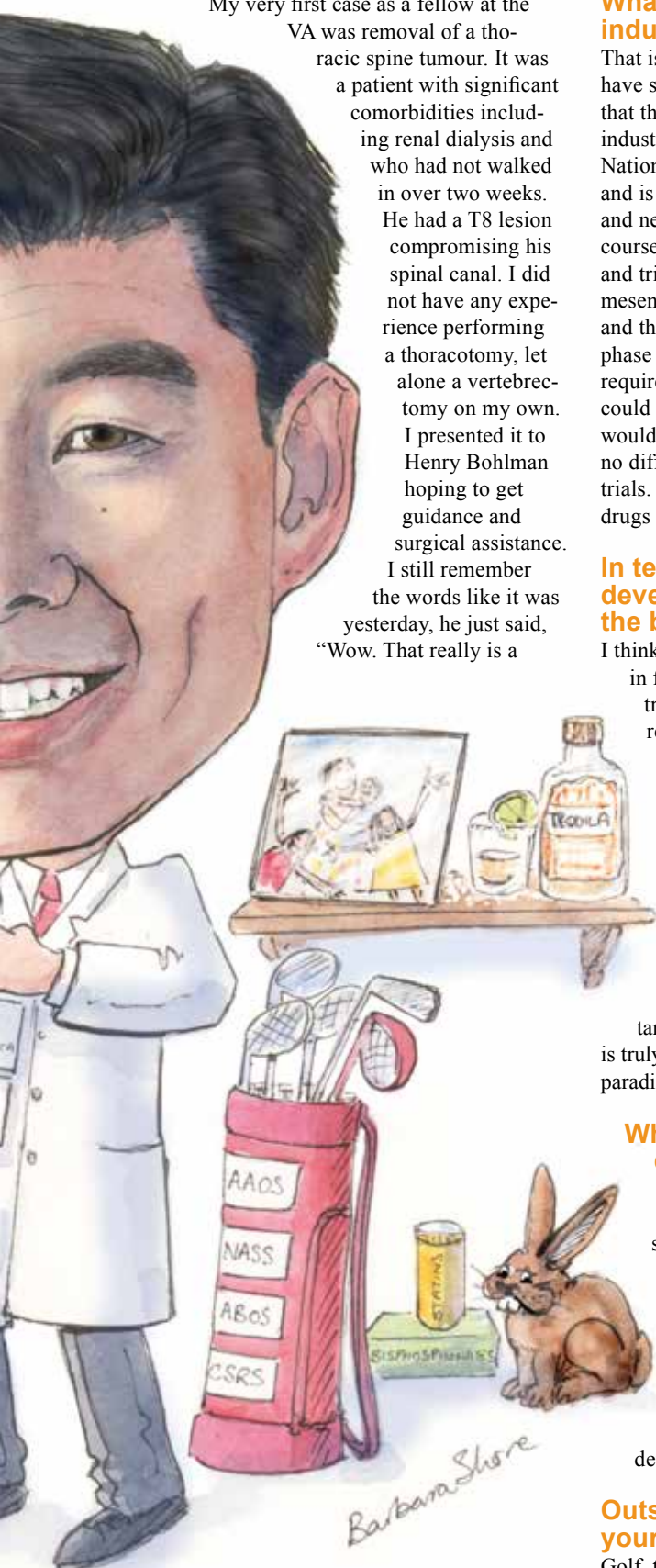
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|-----------|---|
| 2012 | Medical director, director of Spine Education Spine Center, Division of Orthopaedic Surgery, Department of Surgery, Cedars-Sinai Medical Center, Los Angeles, USA |
| 2009 | Medical director, director of Research Center for Spinal Restoration and The Spine Institute Santa Monica, USA |
| 2009–2012 | Co-fellowship director Spine Center, Division of Orthopaedic Surgery, Department of Surgery, Cedars-Sinai Medical Center, Los Angeles, USA |
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Education

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| 2000–2001 | Spine surgery fellowship, Case Western Reserve University, Cleveland, USA |
| 1996–2000 | Orthopaedic surgery residency, Hospital for Special Surgery, New York City, USA |
| 1995–1996 | General surgery internship, Northshore University Hospital, Manhasset, USA |
| 1995 | MD (Cum laude), Yale University School Medicine, New Haven, USA |
| 1993–1994 | Molecular and cell biology, NIH Howard Hughes Research Fellow, Howard Hughes Medical Institute, Bethesda, USA |
| 1990 | BS, bioengineering and biomechanics, Columbia University, New York City, USA |

Honours

- | | |
|------|--|
| 2010 | Outstanding Paper Award, North American Spine Society |
| 2005 | Outstanding Paper Award, Spine Arthroplasty Society |
| 2004 | Outstanding Paper Award, Scoliosis Research Society |
| 2003 | Basic Science Grant Award, Cervical Spine Research Society |
| 2002 | DePuy Acromed Named Research Grant |
| 1998 | Eastern Orthopaedic Association Resident Research Award |



Paradigm shift in blood management for surgery in metastatic spine diseases



NARESH KUMAR

COMMENT & ANALYSIS

Surgical management is one of the major treatment modalities in metastatic spine diseases, the other two being radiotherapy and chemotherapy. Surgery for such diseases is potentially complex, often requiring complex reconstruction resulting in prolong operative times, leading to significant blood loss, writes Naresh Kumar.

In a recent meta-analysis, we found that the pooled estimate of the blood loss occurring during spinal tumour surgeries was 2,180ml (95% confidence interval; 1,805–2,554ml). However, the studies included in meta-analysis did not classify the data based on type of tumour, type of surgery and quantum of surgery. Hence, we conducted a retrospective analysis of our database which included 259 patients undergoing spinal tumour surgeries between 2005 and 2014. The analysis revealed that type of tumour, type of surgical approach and level of decompression were significant predictors of intraoperative blood loss and therefore, we need to take into account these factors when we evaluate the amount of blood loss during spinal tumour surgery.

Currently, allogeneic blood transfusion is the gold standard for blood replenishment at most centres worldwide, placing an enormous burden on the limited and precious blood bank resources. Although allogeneic blood transfusion has become safer with better testing, there remain deleterious effects such as immune system compromise or transfusion-related acute lung injury from its exposure. As a consequence, there has been an increase in the length of intensive care unit and hospital stays resulting in higher treatment costs. Furthermore, allogeneic transfusion may be associated with a worse prognosis, including all-cause mortality and cancer-related

mortality. The logical solution to reduce these problems will be finding methods either to reduce intraoperative blood loss or to replenish the lost blood without taking recourse to allogeneic transfusion.

In order to reduce intraoperative blood

“Our findings support the notion that intraoperatively salvaged blood could be used safely and effectively as an alternative to allogeneic blood transfusion.”

loss, a number of measures are applied preoperatively and intraoperatively. These involve assessment and correction of coagulopathy, preoperative embolisation, antifibrinolytic drugs like Tranexamic acid, prevention of hypothermia, intra-operative ligation of feeding vessels, bipolar electrocautery, and haemostatic agents like Gelfoam or thrombin (FloSeal, Baxter).

Among the above methods, preoperative embolisation has been shown to be a reasonably effective method in reducing intraoperative blood loss. Several studies investigated upon renal and thyroid cancer primaries have demonstrated that the patients who received embolisation had less intraoperative blood loss compared with those who did not. However, if the primary cancer of haematological origin, embolisation does not seem to work as the

predominant blood supply arises from a fine capillary network within the tumour, not from large segmental feeder vessels and hence they are not responsive to embolisation. We analysed the data on preoperative embolisation in patients undergoing spine tumour surgery and showed that embolisation was most effective in surgery for primary spine tumours and less so for metastatic spine tumour surgery.

Using Tranexamic acid is also shown to be an economical and effective method for reducing blood loss in spinal surgery. It has been demonstrated that patients who received Tranexamic acid had significant reduction of blood loss and required less blood transfusion than patients who received placebo.

Modern minimally invasive surgical approaches are recently-evolved techniques and have shown to be effective in minimising blood loss. Like in degenerative spinal conditions, the advent of minimally invasive surgery for metastatic spine disease

has definitely brought clear-cut reduction in intraoperative blood loss and lesser wound problems.

In cases where there is an excessive bleeding despite using the above-mentioned measures, the ideal method would be to salvage the lost blood during surgery and reinfuse it. Intraoperative cell salvage has emerged as a practical blood replenishment strategy in major spine surgeries such as for scoliosis and in trauma surgeries. Using cell salvage, the lost red blood cells during surgery can be salvaged and returned to the patient instead of being discarded. However, the biggest barrier has been proving the safety of salvaged blood for reinfusion, especially in cancer surgery, and allaying fears of reinfusing tumour cells to the patient via salvaged blood.

Evidence has, however, accumulated supporting the use of cell salvage in different surgical disciplines, such as gynaecological, hepatobiliary, gastrointestinal, urological and lung cancer surgery.¹ Some studies have illustrated that the blood which passed through cell salvage and another additional filter, namely a leucocyte depletion filter, was devoid of tumour cells and hence safe for reinfusion. Some other studies suggested that intraoperatively salvaged blood can be a simple and cost effective method for replacement of allogeneic blood transfusion. Nevertheless, there remain many controversies among orthopaedic and spine surgeons worldwide on the use of intraoperative cell salvage in surgery for metastatic spine disease, and there has been no evidence in the literature supporting its use in such surgeries.¹

My colleagues and I conducted a large non-reinfusion study including 50 consecutive patients to evaluate the safety of cell salvage-leucocyte depletion filter-processed blood since October 2011. Our study showed that after passing through both cell salvage and a leucocyte depletion filter, no viable tumour cells could be detected in the samples using cell block technique.² The study of samples from a subset of these patients using a flowcytometry technique also demonstrated that the number of tumour cells in the filtered salvaged blood, if any, was significantly lower than amount of circulating tumour cells in the patients' blood.³ Our findings support the notion that intraoperatively salvaged blood could be used safely and effectively as an alternative to allogeneic blood transfusion during spinal tumour surgery. The validation of the safety and efficacy of salvaged blood in metastatic spine tumour surgery is mandated through clinical trials.

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Naresh Kumar is an orthopaedic surgeon at the National University Health System, Singapore

News in brief

Zimmer completes combination with Biomet

Following the receipt of US Federal Trade Commission clearance, Zimmer has completed the acquisition of Biomet in a cash and equity transaction currently valued at approximately US\$14bn. Zimmer has now changed its corporate name to Zimmer Biomet Holdings, Inc. The company will trade on the New York Stock Exchange

and the SIX Swiss Exchange under the ticker symbol “ZBH”.

“We are excited to move forward as one company and to pursue new opportunities that benefit patients, healthcare professionals and employees around the globe,” said David Dvorak, president and chief executive officer of Zimmer Biomet.

“Over the past several months, our integration planning teams have been working to

ensure that we capture the best of both companies and create a seamless and efficient transition. I look forward to continuing to work closely with our employees for the benefit of all of our stakeholders.”

Medtech announces sale of first Rosa Spine robot in Europe

Medtech has announced the first sale of its Rosa Spine robot in Europe. The first Rosa


Spine robot was purchased by Amiens University Hospital in Amiens, France, a centre for the treatment of brain and spine disorders. The neurosurgery department, led by Johann Peltier, is renowned for its state-of-the-art equipment in imaging systems and robotics and its scientific work.

The hospital already owns a Rosa Brain robot, which has been helping surgeons perform cranial surgery since 2011.

Amiens University Hospital was also one of the very first to use Rosa Spine in clinical trials led by Anthony Fichten and Michel Lefranc earlier this year.

Bertin Nahum, president and founder of Medtech said: “This first sale in Europe, just a few months after receiving market approval, is extremely encouraging and a clear example of the interest generated by our technology for treating brain and spine disorders.”

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Percutaneous osteosynthesis in bone cancer patients



FRÉDÉRIC
DESCHAMPS

COMMENT & ANALYSIS

Percutaneous osteosynthesis is a very new technique that consists of inserting screws into bone structures through a very small skin incision (of less than 10mm). The technique is now performed percutaneously by interventional radiologists due to the development of cannulated screws that can be inserted coaxially over a guide pin, and due to the level of accuracy possible with CT or flat panel guidance, writes Frédéric Deschamps.

Metastatic bone disease is a very common clinical occurrence in cancer patients. A pathological fracture can result in significant pain and loss of function. Prophylactic fixation before a fracture occurs is an issue of utmost importance. In addition, insufficiency fractures can occur in cancer patients because of osteoporosis, which may be primary (related to age) or secondary (related to the use of steroids, radiation of pelvic malignancies, etc). Percutaneous osteosynthesis is a very new technique that consists of inserting screws into bone structures through a very small skin incision (of less than 10mm). This technique was initially developed by orthopaedic surgeons to stabilise non-displaced bone fractures during open surgery. The technique is now performed percutaneously by interventional radiologists due to the development of cannulated screws that can be inserted coaxially over a guide pin, and thanks to the level of accuracy possible with CT or flat panel guidance. The procedures can be performed under general anaesthesia or conscious sedation by an interventional radiologist, either in an interventional CT room or in an angiosuite equipped with a cone-beam CT.

The interventional radiologist first drills a Kirschner wire across the fracture/the tumour under CT fluoroscopy guidance or under cone-beam CT guidance, using dedicated guidance software. A 3D image must then be obtained via CT or cone-beam CT to assess the proper direction of the track and to measure the appropriate length of the screw to be inserted. Ideally, the screw should be long enough to reach the distal subchondral bone. The 8mm cannulated self-drilling tapping screw (Asnis III cannulated screws; Stryker) is placed over the Kirschner wire and slid down to the cortical bone with the use of a cannulated screw driver. Once the proper positioning of the screw is

confirmed by a new 3D acquisition, the Kirschner wire is withdrawn and the skin entry point is sutured.

The indications for percutaneous osteosynthesis are twofold: firstly, it is a palliative technique for patients suffering from pathological or non-pathological non-displaced fractures and, secondly, it provides prophylactic consolidation, in association with cementoplasty, for patients with impending pathological fractures due to osteolytic metastases.

Palliation of pathological or non-pathological fracture

For patients suffering from pathological or non-pathological fractures, the goal of percutaneous osteosynthesis is to achieve stabilisation of the fractures, which will result in pain palliation. Ideally the fracture should be non-displaced because it is not possible to provide a percutaneous anatomic reduction of fracture fragments. However, in certain cases, namely in non-surgical patients, stabilisation of a displaced fracture was performed without reduction. Technically, the screws must be inserted perpendicularly to the fracture and across the fracture. We currently do not perform cementoplasty in association with fracture stabilisation because there is a risk of cement leakage through the fracture line, and because the mechanical property of the cement is not appropriate in locations submitted to torsion forces. However, in certain cases, small amounts of cement were injected through a second puncture in order to improve the screw tip's anchorage.

Prophylactic consolidations of osteolytic metastases

For patients with impending osteolytic metastases, the decision to perform percutaneous osteosynthesis plus cementoplasty instead of cementoplasty alone is driven by the fact that the strengthening

“ This technique is a minimally invasive procedure that avoids extensive surgical exposure and the accuracy of CT- or flat panel-guidance results in high technical success rates and very low complication rates for screw placement. ”

properties of the cement are strong in compression but weak for tensile or shear stresses. This explains why cementoplasty alone is only appropriate for the consolidation of osteolytic metastases located in the cotyle and in the vertebrae. Technically, we insert the screws across the osteolytic metastases first and then inject the cement into the osteolytic metastases. For good consolidation, the screws must enter a strong bone cortical and their tips must be advanced as far as possible, ideally reaching the distal subchondral bone. We then use a dedicated cementoplasty needle for injecting cement. This needle is inserted through the same track of the screws in parallel. We start the injection close to the tips of the screws and continue the injection during the removal of the needle. We always try to fill the entire osteolytic metastases.

In conclusion, percutaneous osteosynthesis provides pain palliation for pathological and non-pathological fractures, as well as prophylactic consolidation of osteolytic metastases in bone cancer patients. The technique must be considered as part of the therapeutic arsenal of interventional radiologists for two main reasons. First, because it is a minimally invasive procedure that avoids extensive surgical exposure, and second, because the accuracy made possible by CT or flat panel guidance results in high technical success rates and very low complication rates for screw placement.

Frédéric Deschamps is an interventional radiologist at the Gustave Roussy Cancer Campus, Villejuif, France. He has reported no disclosures pertaining to the article

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The move towards nonopioid pain management



**MATTHEW J
MCGIRT**

COMMENT & ANALYSIS

The high prevalence of opioid related adverse events and costly consequences to our society has prompted many to critically look at our practice of outpatient opioid prescription. As a result, multiple stakeholders in US healthcare are adopting non-narcotic pain management solutions, education, and awareness programmes.

In the hospital setting, intravenous and oral narcotics remain the mainstay of acute pain management. When administered under nurse supervision or through patient-controlled anaesthetic devices, the historical assumption has been that narcotics offer the best balance between safety and effectiveness for acute pain control. Based on several recent and reproducible study results, this notion is now being challenged.

Recently, investigators sampling administrative Medicare records from 2010–2012 found that opioid related adverse events occur in up to one out of every eight patients undergoing

spine surgery,¹ whether it be cervical² or low back surgery.³ Even when intravenous narcotics are administered through patient-controlled devices, specifically aimed at maximising safety of inpatient narcotic use, they appear to introduce greater safety concerns than previously recognised. In a recent analysis of 1998–2012 national Medicare records, our research team recently observed that patient-controlled anaesthetic use for pain control after low back surgery was associated with an increase in opioid-related adverse events independent of extent of surgery or patients' comorbidities.⁴ Despite

patient-controlled narcotic delivery in an observed hospital environment, almost one in ten patients experienced an opioid related adverse event.⁴

Over 50% of hospital admissions include the administration of narcotics.⁵ An estimated one third of all hospital adverse events are related to adverse drug events, affect approximately two million hospital stays annually, and prolong hospital length of stay by an average of two to five days.⁶ With close to a million preventable complications per year arising from in-patient narcotic prescription, one has to consider whether it is time for a large and rapid paradigm shift for hospital-based pain control, particularly within a US healthcare system that is currently operating with unsustainable cost increases. As recent studies are suggesting, inpatient narcotics are not only associated with preventable deaths and adverse events, they also increase length of stay, reduce mobilisation, increase cost of the episode of care, and lead to greater resource utilisation in the immediate post discharge period. Furthermore, narcotic use has recently been recognised as reducing the short and long-term benefits of musculoskeletal treatments, including spine surgery.^{7–8}

In a healthcare reform era aimed at improving the value (quality/cost)

of services by increasing quality and reducing cost of that care, inpatient narcotic use contradicts the value-based reform movement as it reduces safety and healthcare quality while increasing utilisation and cost of care. Multi-modal, non-opioid pain management paradigms should be supported and implemented in the hospital setting to increase the value and efficiency of not only musculoskeletal care, but all hospital based care. As we begin to more critically look at US healthcare opportunities for quality improvement and its value-based evolution, our hospital-based narcotic practices represent low hanging fruit. No one stands to benefit more than our patients.

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Oral steroids for acute sciatica produce limited improvement

Among patients with acute sciatica caused by acute radiculopathy, a short course of oral steroids resulted in only modest improvement in function and no significant improvement in pain, according to a study published in the *Journal of the American Medical Association*.

Acute sciatica is most frequently associated with a herniated disk in the lumbar spine, occurring in more than one in 10 people sometime in their lives. Currently used treatment options include advice, education, self-care and medications (including oral steroids), followed by various physical modalities, epidural steroids and surgery if pain persists. Although oral steroids are used by many physicians and have been included in some clinical guidelines, no large-scale clinical trials of oral steroids for sciatica have been conducted.

“These findings suggest that a short course of oral steroids (prednisone) is unlikely to provide much benefit for patients with sciatica due to a herniated disk in the lower back,” says lead author Harley Goldberg, a spine care specialist at Kaiser Permanente’s San Jose Medical Center, USA. “Despite its widespread use, we found that oral steroid treatment for acute sciatica is only modestly effective for improving function and is ineffective for reducing pain.”

The randomised, double-blind, placebo-controlled clinical trial involved 269 adults with radicular pain persisting three months

or less; functional impairment with a score of at least 30 on the Oswestry Disability Index score and a herniated disk confirmed by magnetic resonance imaging.

Study participants were given either a tapering 15-day course of oral prednisone or a placebo. The prednisone-treated group showed a small but greater likelihood of achieving at least a 30-point, or 50%, improvement in function at three weeks and at 52 weeks. However, there was no statistically significant difference between groups in changes in pain at either the three-week or 52-week time points.

Whether the small improvement in function—without a subsequent improvement in pain—merits use of oral steroids for patients with sciatica is a difficult decision and, ultimately, becomes a personal one that must be weighed by individual patients and their care providers,” notes lead author Andrew Avins, a senior scientist at the Division of Research.

“More work is needed to identify which patients will have significant benefit from non-invasive therapies for acute radiculopathy associated with a herniated lumbar disk,” notes Goldberg.

Minimally invasive posterior lateral interbody fusion may offer better outcomes than open surgery

David Jones, Carolina Neurosurgery and Spine Associates, Greensboro, USA, told delegates at the annual meeting of the International Society for the Advancement of Spine Surgery (ISASS; 15–17 April, San Diego, USA) that minimally invasive posterior lumbar interbody fusions may offer a promising alternative to open surgery.

This procedure is one of many less invasive techniques that are being increasingly used to minimise surgical morbidities and speed up patient recoveries. Jones and colleagues wanted to explore the perioperative outcomes of this minimally invasive approach with the more traditional open procedure.

Jones explained that the approach is performed through a midline but medialised exposure, which “allows for a full decompression under direct visualisation, interbody fusion, and stabilisation with bilateral screws.” This means that morbidity is reduced by restricting muscle dissection to within the pars and facets. The use of cortical pedicle screws with a medial-to-lateral trajectory provides “the stability of traditional pedicle screw fixation,

with the added advantages of greater cortical bone purchase and preservation of paraspinal innervation given the more medialised exposure,” Jones said.

The team conducted a multicentre, institutional review board-approved, non-concurrent, controlled, observational evaluation of patients indicated for posterior interbody fusion at one to two contiguous lumbar levels. Morbidity as measured by estimated blood loss and length of hospital stay were the primary outcome measures, with visual analogue scale (VAS) back and leg scores collected preoperatively and postoperatively at two and six weeks as secondary outcome measures.

Nineteen open surgery patients and 21 minimally invasive patients were analysed, with foraminal stenosis as the



David Jones

most frequent diagnosis. Jones reported that the mean surgery time was comparable between the two groups (open: 132 minutes, minimally invasive: 136 minutes; $p=0.697$). However, in both blood loss (open: 42% of patients lost more than 300cc, minimally invasive: 14%; $p=0.049$) and mean length of hospital stay (open: 3.1 days, minimally invasive 1.7 days; $p<0.001$) the minimally invasive

groups had the advantage.

In terms of intraoperative complications, there were two dural tears in the open group and one in the minimally invasive group, as well as one implant deformation in the minimally invasive group, which was replaced during surgery without further complication.

Postoperatively two open and four minimally invasive patients developed superficial wound infections, all of which resolved. There was one case of screw back out due to poor bone quality, one revision due to cage migration and one patient with ileus and hyponatremia in the open group.

Both groups enjoyed improvements in preoperative VAS scores in the follow up period, though minimally invasive patients had significantly better scores than those of the open group, both for back ($p=0.02$) and leg ($p=0.03$) pain. At six weeks follow-up the minimally invasive group had “significantly less back pain” ($p=0.03$).

Jones told attendees that his results suggested “the feasibility of a less invasive approach for posterior lumbar interbody fusion, with reduced blood loss, shorter hospital stay, and reduced perioperative morbidity.” He closed by noting that future studies with a larger number of patients would provide more detail on what is still an emerging, though promising, procedure.

“The less invasive approach for posterior lumbar interbody fusion has reduced blood loss, shorter hospital stay, and reduced perioperative morbidity.”

LLIF is faster and causes less blood loss than ALIF

A lateral lumbar interbody fusion (LLIF) presents a less invasive and faster procedure than an anterior lumbar interbody fusion (ALIF) for the treatment of degenerative disc disease and/or spondylolisthesis, according to a study presented at the annual meeting of the International Society for the Advancement of Spine Surgery (ISASS; 15–17 April, San Diego, USA).

Ke D Kim, University of California Davis Medical Center, Sacramento, USA, presented the results of a prospective, multicentre (eight sites), comparative study of the intraoperative outcomes of single-level LLIF and ALIF involving 103 patients.

Due to the ability to preserve midline back muscles and avoid vessel mobilisation, LLIF with a retroperitoneal transpsoas approach has become an increasingly popular minimally invasive procedure for the treatment of degenerative changes to the spine. That said, Kim explained that traversing the psoas still carries the risk of neural injury, making neuromonitoring essential any surgery of this type.

Kim suggested that “inherent” benefits of this approach include “decreased intraoperative blood loss, operative time, length of hospital stay and length of incision”. Though these benefits have been documented in past studies, Kim *et al* believe that “robust prospective data comparing LLIF with traditional approaches, particularly ALIF, are still limited”. In this study, Kim and colleagues hoped

to gain such data, which could prove to be “highly telling in the characterisation of LLIF as an efficacious lumbar fusion modality”.

Forty-six patients were randomised to the ALIF group and 57 to LLIF. As Kim and colleagues expected, LLIF patients experienced a significantly less intraoperative blood loss (mean difference=96.7ml, $p=0.0006$), a shorter surgery (mean difference=60.9 minutes, $p<0.0001$), and a short incision length (mean difference=4.9cm, $p<0.0001$) than patients in the ALIF cohort. However, the ALIF group did have the benefit requiring less fluoroscopy time, with a mean of 41.4 seconds less exposure than the LLIF group ($p=0.0002$).

Despite the additional fluoroscopy time required, the study shows that LLIF results in less blood loss, a shorter surgical time and shorter incisions. Kim and colleagues thus suggest that the next step is to collect data regarding interbody fusion rates and patient-reported outcomes associated with the procedure, data they believe “will be compelling”.

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One-year survival for minimally invasive lumbar discectomy comparable to open surgery

Minimally invasive lumbar discectomy surgery produces survival rates comparable to open discectomy, according to data presented at the annual meeting of the International Society for the Advancement of Spine Surgery (ISASS; 15–17 April, San Diego, USA).

Despite the lower risk of soft tissue injury, reduced operative time and faster recovery associated with minimally invasive techniques, there is still “a paucity in the literature comparing the lasting effects of minimally invasive and open techniques for lumbar discectomies”, explained Andrew J Park, Rush University Medical Centre, Chicago, USA, who presented the data.

Kern Singh and his colleagues hoped to address this paucity somewhat by retrospectively analysing the outcomes of

minimally invasive and open discectomies in a series of 269 who underwent surgery for degenerative spinal pathology patients between 2007 and 2013.

A Kaplan-Meier survival analysis was performed to determine the incidence and prevalence of revision surgeries at 12 months. Differences in survival distributions were identified with the Log-Rank comparison tests and a p value of ≤ 0.05 was used to denote statistical significance. The team recorded the patients’ age, ethnicity, comorbidities and body mass index.

There were no significant demographic differences between the two groups.

Singh’s team reported that the Kaplan-Meier analysis predicted a survival rate of 93.4% (n=71/76) for the open group, and 86.5% (n=167/193) in the minimally invasive group. Comparison analysis “demonstrated no significant differences in survival distribution between the two cohorts” (p=0.13). Thirty-one (11.5%) patients required reoperation for persistent or worsening symptoms, but the index surgical technique did not significantly impact the type of revision procedure (arthrodesis vs decompression, p=0.17).

Park told delegates that his analysis demonstrated that minimally invasive lumbar discectomy procedures are associated with comparable one-year survival to traditional open approaches. “As such,” he explained, “in addition to the potential perioperative advantages of these novel



Lead author Kern Singh

“Patients who undergo a minimally invasive lumbar discectomy may expect similar mid-term benefits to those undergoing a traditional open procedure.”

techniques, patients who undergo a minimally invasive lumbar discectomy may expect similar mid-term benefits to those undergoing a traditional open procedure.”

He did note that future studies are required to analyse long-term differences in survival between the two groups, as these “may demonstrate different findings”.

Cervical spondylotic myelopathy is one of the most impactful medical conditions for quality of life and physical function

Cervical spondylotic myelopathy (CSM) is a greater burden on quality of life and physical health status than diabetes, cancer and cardiac disease, among other conditions. Virginie Lafage, New York University Langone Medical Center, New York, USA, addressed delegates at the annual ISASS meeting (15–17 April, San Diego, USA), telling them that CSM “warrants similar research and health policy attention as more well-studied diseases affecting the general population.” She presented results of findings from a collaborative study conducted through AOSpine North America and the International Spine Study Group (ISSG).

CSM is a relatively prevalent and serious condition, representing the most common cause of spinal cord impairment in elderly patients worldwide. However, Lafage noted, “to date, the specific comparative magnitude of the impact of CSM on general health status is unknown”.

For this reason, Lafage and colleagues compared the Short Form 36 physical component score (SF-36 PCS) values of

other diseases to those of CSM to assess its relative impact on health status. The team used a post-hoc analysis of a prospective, multicentred database of 285 CSM patients from the previously completed AOSpine North America CSM study. Descriptive statistics were used to characterise mean age, gender distribution and health related quality of life, and SF-36 scores from the myelopathy patients were compared with US normative values and disease-specific

norms.

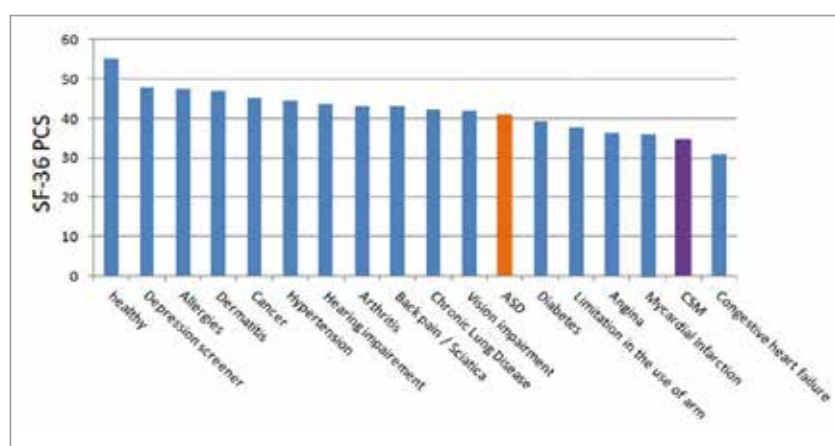
Lafage reported that the CSM patients’ baseline health scores revealed disability and myelopathy—SF-36 PCS 34.5±9.8, Neck Disability Index 41.3±20.5, modified Japanese Orthopaedic Association score 12.8±2.8 and Nurick grade 4.1±1.0. Although there were no statistically significant differences between CSM patients of different age groups in terms of SF-36 PCS, when the myelopathy age groups were compared to age-matched normative data, younger patients had a greater offset in SF-36 PCS scores than older patients (p<0.05) and were more affected in relation to asymptomatic individuals of their age.

Myelopathy patients had a “significantly different SF-36 PCS compared to a normal healthy population and their scores were significantly worse than any other acute or chronic disease state reported except for congestive heart failure,” (p<0.05). This remained true of most other spinal-pelvic pathologies, with scores for CSM patients even lower than those of some types of adult thoraco-lumbar spinal deformity, lumbar spinal stenosis and hip osteoarthritis patients.



Virginie Lafage

Lafage concluded that CSM is “a debilitating disease that significantly impacts quality of life and physical function, even more so than diabetes, cancer and myocardial infarction.” She continued, saying that the results of the study “highlight the severe comparative impact of cervical spondylotic myelopathy on physical function,” and that the condition warrants further health policy attention.



“CSM is a debilitating disease that significantly impacts quality of life and physical function, even more so than diabetes, cancer and myocardial infarction.”

Product News

SpineCraft announces FDA approval of Astra spine system for deformity correction and complex spine procedures

SpineCraft has received regulatory clearance from the US Food and Drug Administration (FDA) to market its comprehensive posterior spinal fixation system—the Astra spine system.

The Astra spine system is SpineCraft's next generation deformity correction technology, designed by industry leading spine professionals to treat a range of pathologies. The system is optimised for use with advanced instrumentation developed specifically for complex spine procedures. The implants are designed with proven technology that allows intraoperative flexibility to choose rod diameter and material types while maintaining a low profile and providing exceptional strength.

The system is intended to provide immobilisation and stabilisation of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine; severe spondylolisthesis (grades 3

and 4) of the L5–S1 vertebrae; degenerative spondylolisthesis with evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumour and failed previous fusion (pseudo-arthritis).

Aurora Spine launches minimally invasive Vox lateral interbody system with TiNano

Aurora Spine has launched a new product in its line of next-generation minimally invasive lumbar interbody cages. Vox is Aurora Spine's modern, minimally invasive lateral lumbar interbody fusion (LLIF) system featuring TiNano titanium spray coating technology. The company says that the TiNano-coated PEEK cages will allow for the possibility of bone ongrowth due to its porous structure.

The first surgery using the device was performed by Daniel Williams at First Health Moore Regional Hospital in Pinehurst, USA. "I perform many lateral lumbar procedures each year. The Aurora Spine Vox system is easy to use and I believe the TiNano coated interbody cages provide my patients with a quicker path to recovery," he says.

The combination of the Vox TiNano coated cage along with the Zip Ultra minimally invasive fixation implant together make up Aurora Spine's Screwless Procedure. The company also notes that all Aurora Spine products are pre-packaged sterile.

"We designed the Zip interspinous fusion system and TiNano coated interbody cages to improve spine patient outcomes, drive continued



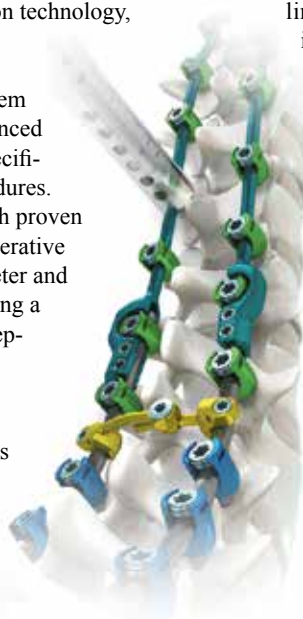
Vox lateral interbody system with TiNano

surgeon interest, and bolster our relevance as a key innovator in spine," says Trent J Northcutt, Aurora's president and chief executive officer. "Aurora Spine's minimally invasive Screwless Procedure is designed to provide unique benefits that deliver value to hospitals and patients around the world."

InVivo Therapeutics announces enrolment of third patient in pilot spinal cord injury trial

A third patient has been enrolled in InVivo Therapeutics' ongoing pilot trial of its investigational Neuro-Spinal Scaffold in patients with acute spinal cord injury at the Carolinas Medical Center, part of the Carolinas HealthCare System in Charlotte, USA.

Dom Coric, of the Carolina Neurosurgery and Spine Associates and Chief of Neurosurgery at Carolinas Medical Center, together with William Bockenek, chief medical officer at Carolinas Rehabilitation, are co-principal Investigators at this site. Coric, along with Mark Smith of the Carolina Neurosurgery and Spine Associates, performed the third Neuro-Spinal Scaffold implantation into an acute spinal cord injury patient. The implantation took place about three and a half days after the injury. Coric says, "The implantation procedure went smoothly and the patient is doing very well. It has been rewarding to be involved in this clinical study, and I look forward to following the



The Astra spine system



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Technical Advances
in Neurosurgery



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SCIENTIFIC PREVIEW: SPINE



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BERNHARD MEYER: A multicenter prospective randomized controlled clinical trial to evaluate the effectiveness and safety of a percutaneous interspinous device versus standalone decompressive surgery in degenerative lumbar spinal stenosis with neurogenic intermittent claudication

The NICE study is one of the 3 randomized controlled trials (RCT), which recently provided level 1 evidence for the effectiveness of interspinous devices (IPDs) in the treatment of neurogenic intermittent claudication due to lumbar stenosis. Only the indication as stand-alone devices was taken into account, but not their application as soft stabilization device following decompression. The NICE study confirms the results of the prior two RCTs. Stand alone IPDs are as effective as standard decompression for alleviating symptoms of NIC due to symptomatic lumbar stenosis with an advantage of secondary endpoints (i.e. surgical time and blood loss etc) for IPDs. However, divergent results were seen for safety aspects. The prior RCTs showed a 3 times higher reoperation rate for the IPD group, questioning their use. This was not seen in the NICE study, which leaves room for interpretation why this is the case. The decision on how to deal with these data is very difficult and controversial. While some may argue against the use of stand alone IPDs in general, others see a window of indication in patients with multiple comorbidities, especially those under anticoagulation.

Bernhard Meyer will give this talk in the Spine Plenary Session at EANS 2015 on Monday October 19.

Confirmed speakers on spine topics include:

Massimo Balsano
Adrian Casey
Bernhard Meyer
Alexander Muacevic
Daniel Refai

The Scientific Programme Overview is now available on www.eans2015.com. We look forward to welcoming you to Madrid!



patient's progress."

Nanovis Spine receives 510(k) clearance of its FortiBridge cervical plating system

Nanovis Spine has announced the launch of the company's FortiBridge cervical plate system. The company says that the FortiBridge cervical plates allow for high angulation screw placement with a smooth, oesophagus-friendly profile. The system offers a full range of short and long sizes in either steam sterilisable or individually sterile packaging formats.

A company press release notes that FortiBridge cervical plates are designed to complement the Nanovis' FortiCore cervical interbody implant system. FortiCore implants are different from other interbody implants because of FortiCore's deeply porous titanium scaffold. Furthermore, PEEK Optima (Invivo) is injection moulded into the scaffold for "exceptional" integration, while the PEEK centre gives the implant imaging and mechanical properties preferred by surgeons.

Aesculap receives FDA approval for the activL artificial disc for one-level lumbar use

Aesculap has received a letter of approval from the US Food and Drug Administration (FDA) allowing the commercial sale of the activL artificial disc for the treatment of one-level lumbar degenerative disc disease.

The activL artificial disc features cobalt chromium endplates which affix to the patient's vertebrae with bone-sparing spikes for initial stabilisation. It is the first lumbar artificial disc with a mobile ultra-high molecular weight polyethylene core that supports both controlled translational and rotational movement similar to the movement of the healthy lumbar spine. The company says it offers the widest range of foot-

prints and heights, including an 8.5mm design, which is the lowest height construct available.

In the investigational device exemption (IDE) trial, the activL artificial disc demonstrated non-inferiority in overall trial success compared to conventional total disc replacement designs. In the analysis of primary outcomes from the IDE trial, the activL was non-inferior to the control devices tested

but also had a greater overall success rate ($p < 0.0001$). During their respective IDE trials, these conventional disc designs were compared to fusion surgery.

"The activL IDE trial outcomes add to the extensive body of evidence supporting the use of lumbar total disc replacement in risk stratified patients," says Rolando Garcia of Aventura Medical Center, Aventura, USA, and activL IDE trial lead investigator who earlier this year co-authored the International Society for the Advancement of Spine Surgery's position statement on lumbar total disc replacement. "Lumbar total disc replacement is a well-tested technology which should predictably lead to better outcomes and fewer complications than fusion surgery. I am excited to be able to offer the activL technology to my patients."

The activL artificial disc is indicated for reconstruction of the disc at one level (L4-L5 or L5-S1) following single-level discectomy in skeletally mature patients with symptomatic degenerative disc disease with no more than Grade I spondylolisthesis at the involved level. The artificial disc is implanted using an anterior retroperitoneal approach. Patients receiving the activL artificial disc should have failed at least six months of non-operative treatment prior to implantation of the device.

ApiFix adolescent idiopathic scoliosis device reaches 50-patient milestone

The minimally invasive ApiFix system has now been used to correct scoliosis in 50 adolescents since the system was approved for marketing in Europe.

A clinical study of the system published in the journal *Scoliosis* concluded that "there are many drawbacks to the current gold standard of adolescent idiopathic scoliosis surgery, which are almost nonexistent with the use of ApiFix: considerable blood loss leading to blood transfusions, neurologic deficit including spinal cord lesions, late infections, pseudoarthrosis, limitation of spinal motion also affecting non-fused levels, back pain and disc degeneration in the non-fused spinal segments. Almost all of these complications can be avoided by the use of ApiFix."

FortiBridge



activL

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Product News

Centinel Spine granted allogeneic bone graft indication for its anterior lumbar product family

Centinel Spine has been granted clearance by the US Food and Drug Administration (FDA) for its STALIF Midline, Midline II and Midline II-Ti (Ti-Active) devices for use with allogeneic bone graft in lumbar spinal fusion procedures.

All of Centinel Spine's stand-alone, no-profile, integrated interbody systems are indicated for use with both autograft and/or allogeneic bone graft in lumbar and cervical spinal fusion procedures. Both STALIF C and

STALIF C-Ti, used in anterior cervical discectomy and fusion (ACDF) procedures, received their allogeneic clearance in late 2014.

Jon I White, Irvine Orthopaedic Associates, Irvine, USA, commented, "In my practice, I prefer to use Midline II for my anterior spinal fusion procedures as it provides the best stability and offers many unique features. The new allogeneic indication gives me additional peace of mind that I am providing the best care for my patients. In my opinion, Midline II is the safest and easiest product to use."

Centinel Spine also says that Midline II

also provides the STALIF benefits of compressive fixation with the horizontal inclination of its lag screws. "My patients have great clinical outcomes and are pleased that their surgery can be performed standalone, from the front only" continued White.



Midline II

FDA approves IDE trial of Freedom system

Stimwave has received US Food and Drug Administration (FDA) investigational device exemption (IDE) approval to launch an 80-patient clinical trial of the Freedom spinal cord stimulation system.

The system is available in an eight-electrode array, which provides additional programming and placement options for patients, including the use of high-frequency stimulation.

The FDA has also approved Stimwave's high frequency study using an external pulse generator. The randomised study will compare conventional stimulation programming settings of five to 1,500Hz frequencies to those of a higher 10,000Hz frequency to measure pain relief outcomes, patient prefer-

ences, reduction in opioid usage, and reduction in adverse events, compared with conventional internal pulse generator products.

This is "the first time an injectable high frequency platform utilised with different parameter settings to truly assess the patient response and the best mechanism to enable long-term control of chronic pain and ability to reduce opioid dependency," said Porter McRoberts, Holy Cross Hospital, Fort Lauderdale, USA, principal investigator of the study.

The device uses an injectable microchip, implanted in an outpatient procedure through a standard needle without general anaesthesia or a large surgical incision, that delivers small pulses of energy to electrodes near surrounding nerves. The device will be used in both study cohorts.

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Published by:

BIBA Medical,
526 Fulham Road
London, UK
SW6 5NR
Tel: +44 (0) 20 7736 8788
Fax: +44 (0) 20 7736 8283

Printed by:

Buxton Press

Reprint requests and all correspondence regarding the newspaper should be addressed to the editor at the above address.

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October 2015

Calendar of events

26-30 July

Spine Across the Sea
Kohala Coast, Hawaii, USA
W www.spine.org

28 July-1 August
International Spine Intervention Society 23rd Annual Meeting
Las Vegas, USA
W www.spinalinjection.org

21 August
SI Joint Pain: Advances in Diagnosis and Treatment

Chicago, USA
W www.broad-water.com/event/si-joint-pain-advances-in-diagnosis-and-treatment

2-4 September
EUROSPINE 2015
Copenhagen, Denmark
W www.eurospine2015.eu

26-30 September
Congress of Neurological Surgeons 65th Annual Meeting
New Orleans, USA
W www.cns.org

30 September-3 October
Scoliosis Research Society 50th Annual Meeting and Course
Minneapolis, USA
W www.srs.org

14-17 October
NASS 2015
Chicago, USA
W www.nassannualmeeting.org

18-21 October
EANS 2015

Madrid, Spain
W www.eans2015.com

24-25 October
International Spine Intervention Society: Clinical Anatomy and Imaging of the Spine
Fort Worth, USA
W www.spinalinjection.org

5-7 November
Society for Minimally Invasive Surgery Global Forum '15
Las Vegas, USA
W www.smissglobalforum.org

5-6 November
SBPR 2015
Bournemouth, UK
W www.sbpr.info

20-21 November
XXIIInd Brussels International Spine Symposium
Brussels, Belgium
W www.spinesymposium.com

20-21 November
2nd Annual Value in Healthcare Forum
Chicago, USA
W www.broad-water.com/event/2nd-annual-value-in-healthcare-forum/

3-5 December
43rd CSRS Annual Meeting
San Diego, USA
W www.csrs.org

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