SPINAL NEWS
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Cervical disc arthroplasty proponents buoyed by long-term data

Though short-term studies have already shown cervical disc arthroplasty in the cervical spine to be as safe and effective as anterior cervical discectomy and fusion (ACDF), long-term data have been lacking. However, new five and seven-year data have been announced indicating that cervical total disc replacement may now be considered a "standard of care" treatment. Thierry Marnay, one of the pioneers of artificial disc surgery, said that he now hopes that artificial discs will become accepted as important tools in spine surgery "after so many years of fighting".

The panel discuss their findings with delegates

At the annual meeting of the International Society for the Advancement of Spine Surgery (ISASS; 14–17 April, San Diego, USA), a session on motion preservation gave delegates food for thought with the annoucnement of exciting new cervical total disc replacement data.

The Bristol-Cummins device, the first modern artificial disc, was introduced in 1991. The device proved unsuccessful due to unacceptably high failure rates—of the 18 patients implanted with the device, there were three screw pull outs, one screw breakage, one subluxed joint and dysphagia reported in all 18 patients. However, since this first project the field has moved on considerably, with several companies researching cervical disc arthroplasty solutions as a motion-preserving alternative to ACDF.

Five-year data

Michael Hisey of the Texas Back Institute, Denton, USA, presented five-year (60-month) data of a prospective, randomised, FDA investigational device exemption (IDE) clinical trial for the Mobi-C cervical disc (LDR Spine) for the treatment of symptomatic degenerative disc disease. Eighty-one patients were randomly allocated to receive ACDF with allograft bone and anterior plate, with 164 patients receiving Mobi-C. The study involved 23 centres in the USA. As this was a post-approval study, the data faced a more stringent set of overall success criteria than previously-presented Mobi-C results.

To measure the success of the two procedures, the study authors used range of motion scores and patient-reported outcomes including neck disability index (NDI), visual analogue scale (VAS) leg and arm pain, SF-12 mental and physical component scores and patient satisfaction levels. Adverse events, neurological failure and subsequent surgery rates were also recorded. Composite success criteria included 25% improvement in NDI, no device-related subsequent surgeries, no neurological deterioration and no adverse events deemed to be major complications.

The results from the total disc replacement group found that NDI, VAS neck pain and SF-36 physical component score improved more in the Mobi-C group than in the ACDF group in the short-term (3–6 months after surgery), balancing out to non-inferiority at five years. SF-12 mental component and patient satisfaction scores were all non-inferior to ACDF group at all time points in the follow-up, with 92% of Mobi-C patients and 83.9% of ACDF patients being "very satisfied" with their treatment at five years.

As would be expected, the range of motion for patients in the Mobi-C group was significantly better than those receiving ACDF, and the greatest difference was seen in flexion/extension tests. Hisey explained that range of motion for the Mobi-C group was "improved and maintained" throughout all time points, while it was significantly reduced at all time points

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Kiva system non-inferior to balloon kyphoplasty for vertebral compression fracture treatment

Published ahead-of-print by *Spine*, the KAST study has demonstrated non-inferiority of the Kiva system (Benvenue Medical) to balloon kyphoplasty for the treatment of vertebral compression fractures.

Kiva VCF treatment system

The KAST study is a pivotal, multicentre, randomised control trial to evaluate the safety and effectiveness of the Kiva system in treatment of patients with painful, osteoporotic vertebral compression fractures.

Sean Tutton, Medical College of Wisconsin, USA, and colleagues write that "Optimal treatment for vertebral compression fractures should address pain, function, and deformity." The authors believed, and decided to analyse whether, the Kiva system could be classified as such a treatment.

The study involved 300 subjects with one or two painful osteoporotic vertebral compression fractures, who were randomised to blindly be treated with Kiva (n=153) or balloon kyphoplasty (n=147), after which they were followed-up for 12 months. The primary 12-month endpoint was a composite defined as a reduction in fracture pain by at least 15mm on the visual analogue scale (VAS), maintenance or improvement in function on the Oswestry Disability Index (ODI), and absence of device-related serious adverse events. Secondary endpoints included cement usage, extravasation, and adjacent level fracture.

Tutton and colleagues report "A mean improvement of 70.8 and 71.8 points in VAS, and 38.1 and 42.2 points in ODI" in the Kiva and balloon kyphoplasty groups, respectively, and that there were no device-related serious adverse events. The authors note that "Despite significant differences in risk factors favouring the control group at baseline, the primary endpoint demonstrated non-inferiority of Kiva to balloon kyphoplasty." Furthermore, analysis of secondary endpoints revealed superiority with respect to cement use and site reported extravasation and a positive trend in adjacent level fracture warranting further study.

As such, Tutton *et al* write, "The KAST study successfully established that the Kiva system is non-inferior to balloon kyphoplasty based on a composite primary endpoint assesment incorporating pain, function, and serious device related adverse events for treatment of vertebral compression fractures due to osteoporosis. Kiva was shown to be non-inferior to balloon kyphoplasty and revealed a positive trend in several secondary endpoints."

Cervical disc arthroplasty proponents buoyed by long-term data

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in the ACDF patients.

Importantly, subsequent surgery rate results favoured the artificial disc group at each follow-up time point. The rate of subsequent surgery increased for both procedures as time went on, and was almost four times greater for the ACDF group than the Mobi-C group at five years (11.1% ACDF, 3% Mobi-C, p<0.05). Also significant was the difference in the rates of adjacent segment disease reported between the two groups. At five-year follow-up, instances of adjacent segment disease were greater in the ACDF group at both the inferior adjacent segment (Mobi-C 37.1% vs ACDF 55.2%, p=0.051) and the superior adjacent segment (Mobi-C 37.1% vs ACDF 54.7%, p=0.0228).

Measuring the overall success of the study, Hisey and colleagues found a "statistical non-inferiority of total disc replacement at all time points" when compared with the ACDF group for one-level treatment. At five-year follow-up, the overall success rate for the Mobi-C group was 61.9% compared to 52.2% in the ACDF group.

Mobi-C at two levels

In addition to Hisey *et al*'s data on the one-level use of Mobi-C, Dom Coric of Carolina Neurosurgery and Spine Associates, Charlotte, USA, presented separate five-year results on the use of the device to treat two-level symptomatic degenerative disc disease.

Conducted at 24 US centres, the FDA IDE trial saw 225 patients treated with the Mobi-C device and 105 treated with ACDF at two contiguous levels with symptomatic cervical spondylosis. NDI, VAS and SF-12 scores were collected out to 60 months (five years) and neurological exam results and patient satisfaction were also recorded.

Overall clinical success required the maintenance or improvement of all components of neurological evaluations, NDI improvement of 15 points (30%) from baseline, no reoperation at index or adjacent levels, no device-related adverse events and no Mobi-C intra-operative changes in treatment. Based on these criteria, Coric told delegates that 61% of Mobi-C patients achieved success compared with 31% ACDF patients (p<0.0001), with a higher rate of success at all time points out to, and including, five years.

The rate of subsequent surgery in the Mobi-C group at five years was 7.1%, with the risk increasing by 1.4% each year after the surgery. Comparatively, in the ACDF group the five-year rate was 21% with each year bringing a 4.2% chance of subsequent surgery (p=0.0006). Index level reoperation rates were 4% for the Mobi-C and 16.2% for ACDF (p=0.0003) and adjacent level reoperation rates were 3.1% for Mobi-C and 11.4% for ACDF (p=0.0004).

At five-year follow-up, the proportion of patients who were "very" or "somewhat" satisfied and who would "definitely" or "probably" recommend Mobi-C treatment to a friend was 96.4%, compared with 89.5% in the ACDF group (p=0.04).

Prestige LP cervical disc

Mobi-C cervical disc

Explaining that the Mobi-C "showed statistically significant greater clinical improvement in general and disease-specific outcome measures compared to ACDF", Coric proposed that cervical total disc replacement should be "considered a standard of care treatment" for patients with one- and two-level cervical spondylosis from C3–7".

Seven-year data

Todd Lanman, University of California, Los Angeles, USA, added his data to the mix with seven-year (84-month) results for the use of a different device—the Prestige LP (Medtronic)—for cervical arthroplasty versus ACDF.

The prospective, multicentre, IDE trial was designed as a Bayesian non-inferiority trial (when posterior probability of efficacy is ≥0.95), with an assessment of superiority built in as a secondary study objective. The Prestige LP group consisted of 280 patients, with 265 in the ACDF group.

Lanman and colleagues found that the median recovery time before returning to work for patients undergoing cervical disc arthroplasty with the Prestige LP device was 40 days—20 fewer than in the ACDF group (60 days).

The study found the Prestige LP to be "statistically non-inferior in NDI success at 84 months after surgery", with an 86.1% success rate of Prestige compared with 80.1% in the ACDF group. Once again, as would be expected, "angular motion at adjacent levels above and below was significantly improved at 84 months without hypermobility" in the Prestige LP group. The authors also note that the Prestige was found to be non-inferior to ACDF for VAS arm and neck pain and SF-36 physical and mental component scores, and superior in neurological and overall success rates.

In terms of postoperative revisions, the rates were low for both groups, at 0.4% (1) for the Prestige LP and 2.1% (5) for ACDF. Fourteen (5.8%) Prestige devices were removed, compared with 21 (10.2%) removals in the ACDF group.

According to the Bayesian statistical method at 84 months and excluding functional spinal unit measurements, Lanman told delegates that the Prestige LP was "statistically superior in overall success" with a posterior probability of superiority of 98.5% postoperatively.

Though the data are encouraging, Lanman told delegates that there remain questions to be answered, including the impact of cervical disc arthroplasty on adjacent level disease and the potential to use the device at multiple levels.

Such successful cervical disc arthroplasty results over such long time periods will surely provide great encouragement for proponents of the procedure and the technology that goes with it.

Postoperative spine dressing changes are unnecessary

At the annual meeting of the Society for the Advancement of Spine Surgery (ISASS, 14–17 April, San Diego, USA), Ravinder-Raj Bains of the Kaiser Oakland Medical Center, Oakland, USA, presented eye-opening findings of a 15-year study focusing on surgical site infections, and whether regular postoperative dressing changes are necessary.

The study was a retrospective review of spine surgery patients from 1999 to 2013 using the medical centre's infection control database. In January 2005, a new infection control protocol was introduced, by which postoperative dressing changes were delayed. As such, the researchers were able to compare the surgical site infection rates from 1999–December 2004 with the rates from January 2005–2013.

Bains described this new protocol to attendees. The surgical site is washed with Hibiclens the night and morning before the surgery takes place. The surgery itself is followed by "meticulous" wound closure using monofilament with antibiotic ointment over the wound/skin glue and iodine-impregnated steristrips. In order to maintain a sterile post-operative environment, a sterile field dressing with a gas-permeable barrier is used. Following this, the patient is given antibiotics via an IV for 48 hours and their dressing is not changed for five days.

During the 15-year period studied there were 8,613 instrumented spine fusion cases performed by five surgeons, with a total of 154 postoperative surgical site infections reported. From 1999–2004 the infection rate was 3.9% (97/2,473). From 2005–2013, following the change in postoperative dressing protocol, the combined infection for all cervical, thoracic and lumbar instrumented cases rate fell to 0.93% (57/6,158) (p<0.0001).

Bains noted that the reduction in infection rates was most significant for posterior cervical and posterior lumbar surgeries. In this patient population, infection rates fell from 3.2% (6/186) before the protocol change to 0.5% (4/815) after it (p=0.0041). Another notable reduction in infection rates was seen in posterior lumbar instrumented fusion patients, in whom rates dropped from 5.5% (65/1,179) to 1.1% (32.2,890) following the implementation of the revised protocol. For thoracic fusion cases, infection rates fell from 4.9% (5/102) to 1.4% (5/364) (p=0.0451) after the new methods were introduced.

Bains and colleagues believe that their results rely on the application of a sterile dressing in the operating room. This sterile dressing may then "serve as a barrier to nosocomial pathogens during hospitalisation," he explained. Postoperative dressing is, if applied correctly, a safe, simple and cost-effective method of reducing infection rates, saving "substantial" time and costs, concluded Bains.

Bains addressing the ISASS audience in San Diego

Discussing his findings after the presentation Bains touched on the difficulty of challenging entrenched attitudes regarding postoperative infections, as despite sharing his team's findings with the other surgical departments in their medical centre, the other departments are yet to adopt the new protocol.

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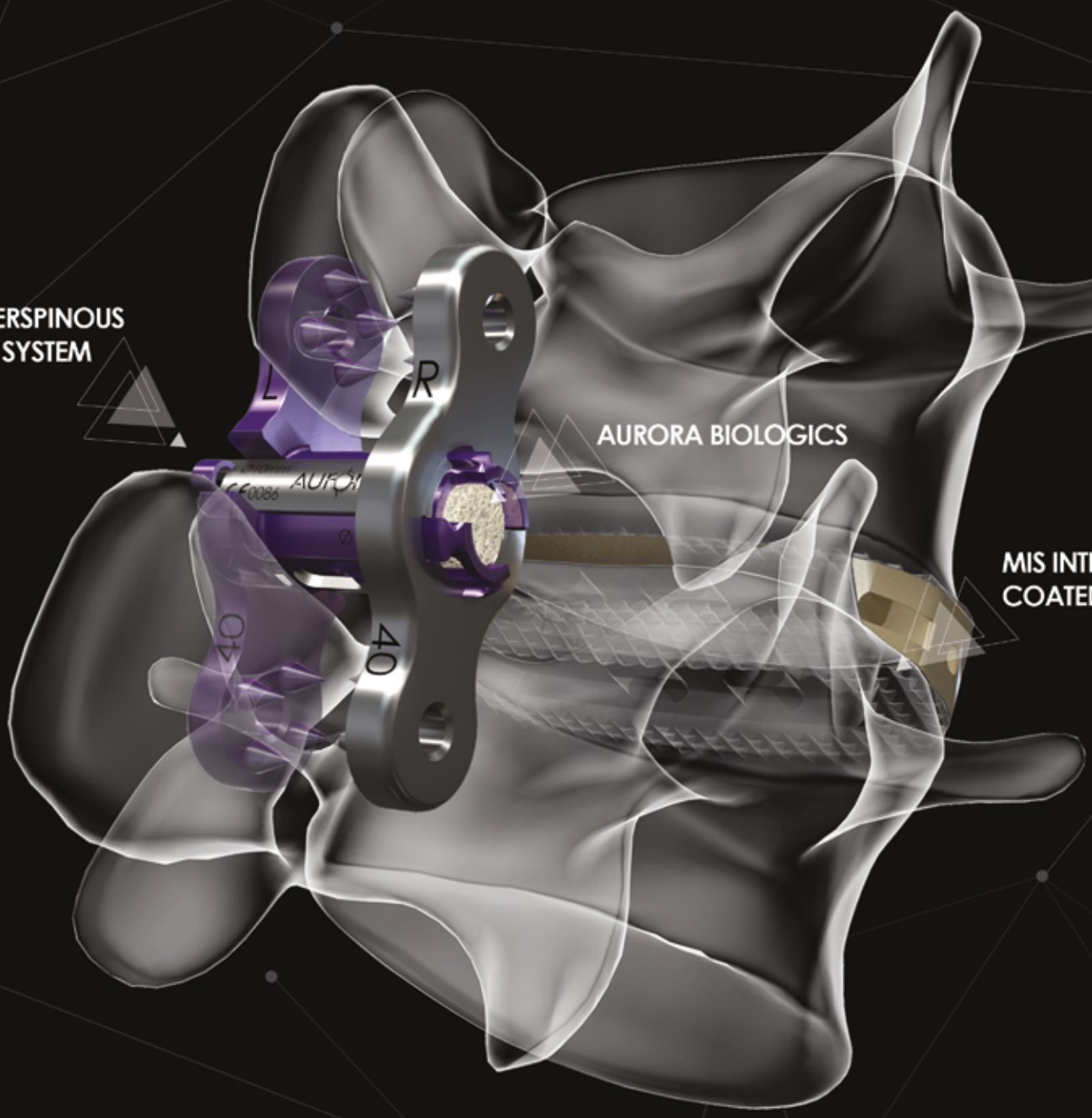

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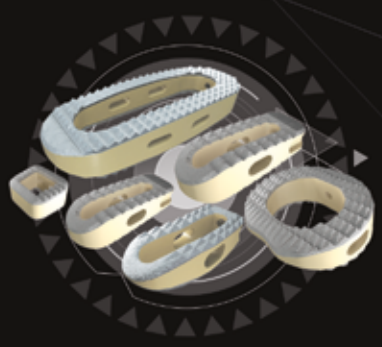

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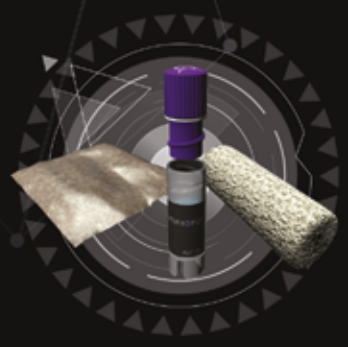

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Reducing radiation exposure during spine surgery

SEBASTIAN DECKER

COMMENT & ANALYSIS

Radiation exposure due to the use of image intensifiers during spine surgery remains a significant source of potential harm for both patients and surgeons with potential long-term health issues such as cancer, suggests Sebastian Decker.

Intraoperative imaging is often mandatory for spine surgery. Accordingly, different studies have concentrated on the issue of radiation in the operating room. While patients are mostly exposed only during a single surgery, doctors and all other operating room staff are exposed regularly for many years, with spine surgeons generally exposed to higher radiation levels compared with the exposure during other orthopaedic surgeries.[1]

Recently, radiation exposure during spine surgery has been given much attention as a result of the trend towards minimally invasive surgery, in which fluoroscopy guidance is essential, for example during percutaneous pedicle screw placement,[2] kyphoplasty[3] or minimal invasive interbody fusion techniques.[4,5] Radiation exposure has also been analysed for open surgery techniques.

To protect staff members, limits for occupational radiation exposure have been defined for different regions of the body: 50 rem/year for extremities, 50 rem/year for skin, and 15 rem/year for eyes, as well as <5 rem/year in any one year and only 2 rem/year averaged during five years for the whole body (these values may differ slightly in between different countries). Knowledge about the risks of radiation exposure, the use of protective gear and barriers, as well as the relevance of a great distance as to the inverse-square law, are strongly recommended for fluoroscopy users.[6] Particular attention should be paid to often unprotected areas such as the axilla or eye. However, 2,700 lateral lumbar interbody fusions could still be performed each year before exceeding occupational dose limits.[6]

Surgeons are especially exposed to radiation as they stand near its source. Scattered radiation therefore mainly hits the surgeon standing close to the X-ray tube.[1] A reversed setup with the radiation source of the image intensifier on the contralateral side reduces scattered radiation for the surgeon (by a factor of six to eight); however, care should also be taken by other people in the operating room.[7] They should therefore increase distance to the patient and image intensifier during fluoroscopy to attach value to the inverse-square law. Moreover, adjusting pulsed modes significantly decreases radiation exposure by a factor of six.[7] The highest radiation exposure during spine surgery is detected during anteroposterior lumbar spine imaging.[7]

While operating room staff are exposed to radiation regularly, patients are only exposed during their own surgery. They obviously cannot be protected against X-rays in the same way as operating room staff. Modern techniques like O-arm imaging offer three-dimensional visualisation of the spine intraoperatively and have been proven to increase accuracy during some procedures like posterior stabilisation.[8] While staff usually keep sufficient distance or even leave the room, radiation exposure for patients is as described for abdominal computed tomography (CT) scans.[9] Therefore the need of three-dimension imaging should be pondered carefully.[10] Severe obesity also is a risk factor for high radiation exposure for both patients as well as operating room staff. A higher radiation dose is needed to gain acceptable contrasts for subsequent interpretation of the images, which directly enters the body of the patient. Moreover this results in higher scattered radiation which affects the surgeon and all other medical staff in the operating room.

While the experience of the surgeon is known to reduce the amount of radiation needed intraoperatively, a new technique becoming more popular also helps to decrease intraoperative radiation: the use of navigation software.[11] However, it has to be emphasised that a CT scan is needed before the use of this software. The radiation exposure to the surgeon therefore decreases while overall radiation exposure of the patient still remains high.

As a general recommendation, the need for intraoperative radiation should be evaluated well before being applied. All medical staff, especially surgeons, involved in spine surgery with radiation exposure need profound knowledge of how to minimise individual radiation exposure. This includes general knowledge about radiation, of protective gear and also of the handling of the image intensifier being used. A laser, usually available with the image intensifier, can be used to mark the spot on the skin where the quality of imaging will be best, before triggering the radiation to avoid useless radiation. Moreover, the staff member responsible for triggering the radiation beam should announce it before they do so, to ensure that their colleagues are fully aware. The position of the image intensifier on the floor should be marked if the same position is intended to be reached multiple times to receive equal imaging without the need of multiple images to find the intended position for optimal imaging. In my experience, direct sensitisation is most important to best protect everybody involved in a surgery of this kind.

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Sebastian Decker is an orthopaedic surgeon at the Hannover Medical School, Hannover, Germany

News in brief

Health Canada greenlights IMRIS ceiling-mounted intraoperative CT

IMRIS has announced that VISIUS iCT, a ceiling-mounted intraoperative computed tomography (CT) scanner, has received Health Canada licensing allowing for sales and marketing in the country.

VISIUS iCT provides personalised dose management and diagnostic imaging during surgical procedures to assist surgeons in decision making. Developed for the neuro and spine surgery markets, VISIUS iCT has the 64-slice Siemens SOMATOM Definition AS scanner as its core technology.

The scanner moves in and out of the operating room using ceiling-mounted rails, allowing multiple room configurations to meet clinical requirements and increase use without compromising images or exam speed. Patient transport and floor-mounted rails used in other systems are eliminated, freeing up operating room space and allowing movement of surgical equipment and simplified infection control.

VISIUS iCT has several software applications such as 3D volume rendering to assist surgical planning and dose reduction which considers each patient's unique characteristics to maximise image quality and minimise dose. The system software allows healthcare practitioners to visualise dosage prior to scan and adjust settings based on the clinical need with detailed dosage reports produced after each scan.

EOS imaging announces first Belgian installation

The Pellenberg campus of the University Hospitals Leuven network has become the first hospital in Belgium to install the EOS system.

The University Hospitals Leuven consists of five separate hospitals forming the largest hospital network in Belgium, and one of the largest in Europe. The Pellenberg campus is an ESSKA (European Society for Sports, Traumatology, Knee Surgery and Arthroscopy)-accredited teaching centre, and is the first University Hospitals Leuven campus to acquire the EOS imaging system. A second EOS system will be installed later in 2015 in the University Hospitals Gasthuisberg campus, making the Leuven network the second European hospital network after Assistance Publique–Hôpitaux de Paris, to acquire multiple systems.

The EOS system provides full-body 2D and 3D stereoradiographic images of patients in functional positions. The exams require a radiation dose 50–85% less than digital radiology and 95% less than basic computed tomography scans. The new Micro Dose option, recently cleared by the Food and Drug Administration, allows a further step towards the "as low as reasonably available" principle by bringing paediatric spine follow-up exams at the dose level equivalent to a week of natural day-to-day background radiation.

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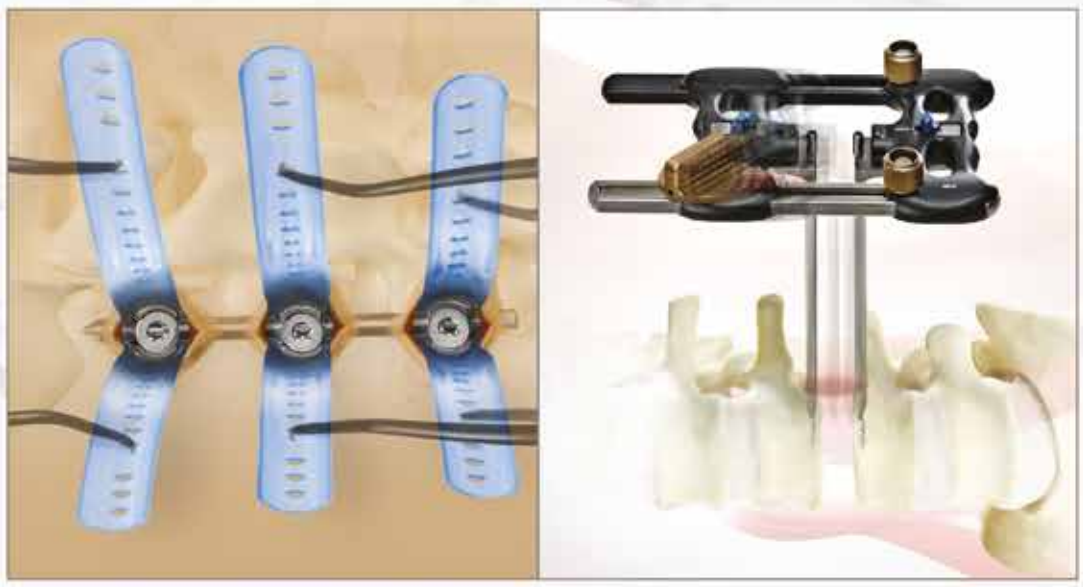

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The use of photographs can improve patient satisfaction following scoliosis surgery

AKIF ALBAYRAK

COMMENT & ANALYSIS

Scoliosis clinical and radiographic outcomes can be obtained by surgical treatment. Measuring a procedure's success increasingly focuses on the appearance of the patient. Akif Albayrak writes that the use of pre- and postoperative patient photographs allows patients a better perspective of surgical impact, thus enhancing their satisfaction with the treatment.

In the past, the main parameters of scoliosis patient evaluation were angle correction and body balance, but current considerations include the importance of the effect of surgery on quality of life and on the self-esteem of the patient in question.

In scoliosis surgeries, aesthetic concerns are often more prominent than vital functions. In these operations, the main concerns that are dealt with—eg. back hump, shoulder imbalance and breast asymmetry—are all crucial elements of a healthy posture and therefore essential for a proper self-image.

The Scoliosis Research Society-22 (SRS-22) survey is currently the most frequently used survey for evaluating outcomes of scoliosis treatment. Several studies have shown major improvement after surgery in all outcome domains of the SRS-22 including pain, function/activity, self-image/appearance, mental health and satisfaction.

The clinical evaluation of scoliosis is typically performed from the posterior view. However, this is not a good view for patient self-evaluation as the patient cannot see themselves from that position. In addition to the impossibility of self-evaluation from the posterior view, self-evaluation of surgical outcomes is limited by a patient's memory—they often forget their preoperative appearance after a long period of follow-up.

My colleagues and I, having undertaken a study examining solutions to these problems, believe that the best indicator of cosmetic improvement is to gauge the patient's opinion by showing them pre- and postoperative photographs of themselves.

As noted, over time there is a possibility that patients may forget their condition prior to surgery, which might lead to a decline in patient satisfaction.

Example of pre- and postoperative photographs showing aesthetic improvement

In my opinion, pre- and postoperative photographing and documentation will become very useful devices in such cases. By reminding patients of preoperative conditions and the improvements achieved, a degree of permanency in patient satisfaction will be obtained, which is important from both patients' and surgeons' point of view.

In our study we showed 60 patients such photographs, to help them recall their preoperative appearance. When we showed the patients and their relatives the pre- and postoperative photographs, they were able to better judge the residual deformity and improvement provided by surgery. As such, they could decide whether the residual postoperative deformity was within acceptable limits.

> ***"In a surgery where aesthetic concerns come first, photographic documentation will give patients an objective, evidential view, which will enable them to evaluate the changes brought by surgery with great clarity."***

In our work we also showed the patients a view that they otherwise could not see, photographing them in Adam's forward bend and standing positions. With this method, a significant difference was observed between photograph and non-photograph groups in questions 10 (about self-image), 18 (about function and activity), and 21 (about satisfaction) of the survey ($p \leq 0.05$).

Our aim was to show the patients how their backs appeared to other people before surgery and compare the pre- and postoperative appearance.

The patients who were reminded of their preoperative back appearance were more satisfied with their appearance after the surgery, and this was confirmed with the increase in some SRS-22 scores.

In our study on Lenke Type I scoliosis patients, we formed homogeneous patient groups to emphasise our point by avoiding deviations, which means cases of extreme corrections are too rare to draw a significant conclusion out of them. However, in another study of ours currently in progress, we are comparing patients with extreme correction levels to those with normal correction levels in the sagittal plane. In the coming months we expect to have data regarding the relationship between severity of correction and satisfaction.

Though we did not focus on differences between age groups, I believe that differences in self-image will be less between the adolescent period and the adult period because aesthetic concerns present themselves in every age. However, a difference in self-confidence will be expected to arise in favour of older patients.

I believe that the use of pre- and postoperative photographing will provide many benefits for both patients and surgeons. In a surgery where aesthetic concerns come first, photographic documentation will give patients an objective, evidential view, which will enable them to evaluate the changes brought by surgery with great clarity. The satisfaction and conviction of patients and their immediate families about the success of surgery will greatly benefit from this method and it will also serve as hard evidence in case of an adverse claim or a lawsuit of malpractice.

Akif Albayrak is a spine surgeon at Baltalimani Metin Sabanci Bone and Joint Diseases Education and Research Hospital, Istanbul, Turkey

News in brief

Daiichi Sankyo and Asubio Pharmaceuticals merge

Daiichi Sankyo, the US subsidiary of Daiichi Sankyo Company, has merged with its US-based sister company, Asubio Pharmaceuticals. Asubio Pharmaceuticals projects will be integrated into Daiichi Sankyo Inc, led by Mahmoud Ghazzi.

Asubio Pharmaceuticals' parent company, Asubio Pharma Co, which is based in Japan, will continue to operate as a wholly owned subsidiary of Daiichi Sankyo Co, with a focus on discovery research.

Asubio Pharmaceuticals's ongoing clinical trial in patients with acute spinal cord injury has already completed enrolment. Analysis and dissemination of the data will now be managed by Daiichi Sankyo.

"Consolidating the current Asubio US projects under the company's overall research and development organisation helps us streamline our operations," said Glenn Gormley, senior executive officer and global head of research and development, Daiichi Sankyo Company, and executive chairman and president, Daiichi Sankyo.

NuVasive chief executive officer resigns following board investigation

Nuvasvie's chief executive officer, Alex Lukianov, has resigned from the company after an independent investigation overseen by the company's board found that he had engaged in actions "not representative of the high standards by which NuVasive operates".

The company said that Lukianov did not comply with expense reimbursement and personnel policies.

Lukianov leaves with a US$900,000 severance payment, equal to one year's salary, according to a US Securities and Exchange Commission filing that accompanied the news. The company is also paying Lukianov US$500,000 to act as a consultant for 18 months.

One- and two-level total cervical disc replacements shown to be equally effective

New long-term data regarding one- and two-level total cervical disc replacement has been published in *Spine*, indicating that there is no difference in long-term clinical outcomes between the two procedures.

Anterior discectomy and fusion have been in use since the mid 1900s. The procedure's low complication rate and high clinical success rate has made it a popular method of treating degenerative disc disease. In recent years, however, total disc replacement has gained popularity as it results in a better range of motion for patients and has been shown to be "at least as safe and effective as anterior cervial discectomy and fusion" (ACDF).

Though previous studies have shown the safety and efficacy of one-level total disc replacement, this study examined the results of multi-level total disc replacement, for which "evidence is minimal".

The study, led by Hyun W Bae, Cedars Sinai Spine Center, Los Angeles, USA, reports on a prospective, randomised, multicentre FDA investigational device exemption trial using total disc replacement as surgical treatment of degenerative disc disease at one or two contiguous levels of the cervical spine at 48 months follow-up. Two-year results of the study were previously published in 2013, showing that cervical total disc replacement is a safe and effective alternative to anterior cervical discectomy and fusion.

Hyun W Bae

Patients were randomised in a 2:1 ratio (total disc replacement: ACDF) at 24 sites. Ultimately, 164 patients received total disc replacement (Mobi-C, LDR Medical) at one level and 225 patients received total disc replacement at two contiguous levels. An additional 24 patients (15 one-level, nine two-level) were treated with total disc replacement as training cases. Outcome measures included the neck disability index, visual analogue scale (VAS) neck and arm pain, SF-12 physical and mental component summary, range of motion, major complication rates, and secondary surgery rates. Patients received follow-up examinations regularly up to four years after surgery.

Bae and colleagues report "no statistically significant difference between one- and two-level total disc replacement groups for all clinical outcome measures. Both total disc replacement groups experienced significant improvement at each follow-up when compared to preoperative scores."

There were no statistical differences between groups in clinical outcomes, overall complication rates, and subsequent surgery rates, and therefore, "two-level total disc replacement is as safe and effecytive as one-level total disc replacement in indicated patients".

Bae told *Spinal News International*, "The results finally demonstrate what is intuitive—that the clinical results from multi-level artificial disc are similar to single level disc replacements. I think, however, that we will continue see divergence in results compared to one level fusions and even more so in multi-level fusion."

Avoid misconceptions by educating patients and restoring the doctor-patient relationship


LYNDA J-S YANG


CHEERAG UPADHYAYA


KATE W-C CHANG


DONALD TOMFORD

COMMENT & ANALYSIS

The doctor-patient relationship is central to the practice of medicine, and is one that has evolved over time. In the past, ailing patients expected the doctor to treat their medical conditions and assuage consequent psychosocial concerns. These patients bestowed trust upon their physician because advanced medical knowledge was not easily available to the general public, and because patients' knowledge about their medical conditions was derived primarily from their doctors who were revered as fonts of knowledge within society.

The power granted to the erudite doctor shifted the burden of illness from the patients to the doctor, and the patients felt better because doctors offered explanations, and therefore hope and support for healing. In return, payment as currency or material items/services was made directly to the doctor. With medicine being art as much as science, the doctor met the patients' expectations since the patients' medical realism relied upon direct communication and education by the doctor to the patient.

The doctor-patient relationship has evolved into a "healthcare service provider-consumer" relationship, and legitimate patient education has waned. Rapid advances in technology and social media have altered the dynamic of the sacrosanct doctor-patient association. The constant ability to communicate via any number of means (texting, voice, social media, etc), all through a personal mobile device, has fundamentally changed what society views as a meaningful relationship. This constant and immediate ability to communicate has created a desire for instant gratification. People now expect 24/7 virtual availability, rather than taking the time to develop a close relationship with one's personal doctor through face-to-face encounters. In this new era, what was once a deep personal relationship becomes a simple mechanical interaction, not unlike "buy now" or "chat now" buttons on websites or via in-person instant appointments in department store clinics. Instead of direct communication and education by doctor to patient, instant access to information and adoption of virtual or transient relationships has resulted in education of patients by any number of "healthcare service providers", such as *Google* and *WebMD*.

Similarly, the increasing demand for healthcare services has led to necessary changes in the payment model in the USA. Further inadvertent disruption of the doctor-patient relationship/education has accompanied the introduction of the insurance intermediary. The vast amount of money in healthcare has resulted in a situation where the business of healthcare has demeaned doctors and patients to mere service providers and consumers. Medical treatments are now "healthcare products", and hospitals and health systems are now "healthcare ecosystems". This terminology has depersonalised the doctor-patient relationship and contributed to the perception that healthcare is simply a product that can be bought and sold, not unlike buying and selling cars or home products on *Amazon* or *Craigslist*. Companies now show costs alongside healthcare, so that patients can choose treatments on a financial basis, with education being provided by "consumer" reviews. Consumers of healthcare seek to establish quality of care through the same means that it is established for other services. Rating systems for healthcare service providers are now available on business rating websites such as *Angie's List* and similar services. *US News* and *World Report* rank hospitals and specialties annually, and preliminary results (personal communication) from a survey of patients and providers indicate that such rankings are primary quality indicators—perhaps by default, because valid medical education by doctors to patients has been compromised to increase the efficiency of the virtual healthcare industry. Although virtual healthcare can be cost-effective in many aspects of medicine, it is as yet impossible in surgery as its very nature requires an intimate doctor-patient relationship with retention of direct education to avoid patient misconceptions, unrealistic expectations, and poor outcomes.

A significant example of patient misconception/poor education was presented in a recent report.[1] In a survey of patients presenting to a general neurosurgical spine clinic at a tertiary care centre, more than 50% of patients indicated that they would undergo spine surgery based solely upon imaging abnormalities, even without symptoms. If the patient has no symptoms, what does the patient expect to gain through undertaking the risk of surgery? Should surgeons treat imaging reports rather than patients? Virtual medicine would favour the former, but ethical surgery would favour the latter. Further patient misconception is reflected in the 1/3 of patients who believed that back surgery was more effective than physical therapy in the treatment of back pain without leg pain, and the 17% of patients believed that back injections were riskier than back surgery. These misconceptions were even noted to persist in patients who had already undergone previous spinal surgery. Similarly, a study of patient education aides found that 70% of patients believed CT or MRI results were more important than a physician's examination in deciding the appropriateness of surgical intervention.[2] With misconceptions such as these, it is no surprise that another report found that a surgeon's recommendation against surgical intervention was associated with lower satisfaction scores in patients with spinal disorders.[3] Poor patient education leads to patient misconceptions, unrealistic expectations, and lower satisfaction.

Lower patient satisfaction has considerable implications for both patient outcomes and for the medical community. The Centers for Medicare and Medicaid Services (CMS) rates providers through the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (GC-CAHPS) surveys based on patient experiences. Similarly, the Hospital Consumer Assessment of Healthcare Providers and Systems (H-CAHPS) survey rates hospitals via consumer reporting. This information is not only being utilised in decisions regarding hiring of doctors but is also being tied to physician reimbursement. The CMS website notes that the "CAHPS surveys are an integral part of CMS' efforts to improve healthcare in the USA". Some CAHPS surveys are used in value-based purchasing (pay for performance) initiatives rather than in fee-for-service reimbursement—instead of only paying for the number of services provided, the quality of services provided is a more valued but ill-defined parameter which requires further investigation. Quantitative and qualitative studies geared towards identifying key concepts related to patient/consumer satisfaction can be used to refine our understanding of value in medicine. Until quality of healthcare is reliably defined, the current system of poorly-educated consumers (patients) with significant misconceptions who are purchasing healthcare products (medical treatments) from a service provider (surgeon) will lead to a failure to meet their expectations, resulting in lower satisfaction and further degradation of the necessary intimacy of the doctor-patient relationship.

The underlying scourge of medicine today is the lack of valid patient education, but this is also a prime opportunity for our profession. The original role of the doctor was not only to heal and comfort patients, but also to teach them. Indeed, the word doctor is derived from the Latin *docere*—to show, to teach, cause to know. We must teach, educate, and inform our patients in an unbiased and respectful manner while retaining the dignity of the doctor-patient relationship. As society evolves with technology, we must educate by appropriately employing new means of communication at our disposal, such as face-to-face video communication, email, websites, mobile applications and other technologies to enhance efficiency. However, we doctors should remain the primary medical educators. If we do not teach our patients, then we are just service providers who deliver a product to the consumer within the healthcare ecosystem and industry. Doctors can and should continue to teach patients and counsel them about their treatments, so that patients can make rational decisions about their treatment plans. The restoration of the doctor-patient relationship based in education and trust will improve patient satisfaction and outcomes to define true value in a value-based purchasing system. Only we have the education, training, and clinical experience to be able to do this, and only through teaching can we re-establish that central doctor-patient relationship that has long comforted and healed patients.

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***Cheerag Upadhyaya** is a neurosurgeon at Saint Luke's Marion Bloch Neuroscience Institute, University of Missouri, Kansas City, USA. **Kate W-C Chang** is a researcher, **Donald Tomford** is a chief department administrator and **Lynda J-S Yang** is a neurosurgeon, all at the Department of Neurosurgery, University of Michigan, Ann Arbor, USA*

Microdecompression is equivalent to open laminectomy for central stenosis of the lumbar spine

Minimally invasive decompression—microdecompression—is equivalent to laminectomy in the surgical treatment of central stenosis of the lumbar spine, according to new data published by the *British Medical Journal*.

Lead author Ulf S Nerland, Department of Neurosurgery, St Olav's University Hospital, Trondheim, Norway, suggests that the surgical trend towards minimally invasive procedures "has not been backed by solid evidence," something he claims "is often the case in surgery". This is, according to the authors, also true of microdecompression, for which no comparative studies have been performed, "Except for a small and probably underpowered trial that reported promising results".

Using prospective data from the Norwegian Registry for Spine Surgery, the researchers identified 885 patients with central stenosis of the lumbar spine who underwent surgery at 34 Norwegian orthopaedic or neurosurgical departments. Patients were treated from October 2006 to December 2011.

The main outcome measure used was the change in Oswestry Disability Index (ODI) score one year after surgery. Secondary endpoints were quality of life (EuroQol EQ-5D), perioperative complications, and duration of surgical procedures and hospital stays. A blinded biostatistician performed predefined statistical analyses in unmatched and propensity matched cohorts.

Nerland explains that "The study was powered to detect a difference between the groups of eight points on the ODI at one year, with 721 patients (81%) completing the one year follow-up."

Equivalence between microdecompression and laminectomy was shown for ODI (difference 1.3 points, 95% confidence interval −1.36 to 3.92, $p<0.001$ for equivalence).

The duration of surgery for single level decompression was shorter in the microdecompression group (difference 11.2 minutes, 95% confidence interval 4.9 to 17.5, $p<0.001$), but after propensity matching the groups did not differ ($p=0.15$). Patients in the microdecompression group had shorter hospital stays, both for single level decompression (difference 1.5 days, 95% confidence interval 1.7 to 2.6, $p<0.001$) and two-level decompression (0.8 days, 1 to 2.2, $p=0.003$).

Analysing the shorter hospital stays of the microdecompression patients, Nerland *et al* suggest that "A likely explanation is that microdecompression reduces surgical trauma, allowing earlier mobilisation after surgery. However, it is also possible that surgical units adapting to minimally invasive techniques may be prone towards shorter hospital stays."

"Microdecompression consistently shows good clinical results, now adding equivalence to laminectomy at one year follow-up and a beneficial risk profile", report the authors. "Theoretically, microdecompression may also induce less postoperative instability and reduce the need for later spinal instrumentation."

Study co-author Sasha Gulati, told *Spinal News International*, "We found favourable outcomes and low complication rates for both microdecompression and laminectomy, and the results can also be used for benchmarking purposes when evaluating other surgical techniques for spinal stenosis."

Left to right: Øyvind Salvesen, Sasha Gulati and Ulf S Nerland. Photo credit: St Olavs Hospital, Trondheim, Norway

Minimally invasive TLIFs successful at two years in a tertiary care centre

At the annual meeting of the International Society for the Advancement of Spine Surgery (ISASS, 14–17 April, San Diego, USA), a research paper from Guy's and St Thomas' NHS Hospital, UK, shed light on two-year outcomes of minimally invasive transforaminal lumbar interbody fusions (TLIF) in a tertiary care hospital.

Presented by Vivian Elwell, the prospective study involved 91 patients and examined the two-year clinical and radiological outcomes of the procedure, which, thanks to its ability to limit tissue trauma and speed up recovery, has been growing in popularity.

The mean age of the 91 patients (39 female, 52 male) was 55. Seventy four (81%) had been diagnosed with degenerative disc disease and 17 (19%) had been diagnosed with lumbar spondylolisthesis. Seventy-seven (85%) underwent a one-level fusion, and the remaining 14 underwent a two-level fusion.

The clinical outcomes for both one- and two-level fusion were encouraging. Visual analogue score (VAS) back pain fell from 58 to 23 after two years, VAS leg pain fell from 55 to 15 and Oswestry Disability Index (ODI) scores fell from 51 to 21. Furthermore, Elwell told delegates that mean physical and mental component scores improved at each time point and were maintained at one year.

In their radiological analysis, the team found that there was no evidence of any potential radiolucency, collapse and/or resorption of the graft at 12 months. Two complications (one dural tear and one bone graft migration) required further conservative treatment. One anterior revision surgery was required to address pseudoarthrosis and one posterior revision surgery was required to address misplaced screws.

Elwell concluded that the procedure could be considered safe and effective with good to excellent clinical outcomes, high radiological fusion rates and reduced early operative morbidity. She told attendees, "Once radiological fusion is achieved, patients have a steady uphill course towards improved functional recovery and reduced pain."

Robotics in spine surgery

Spinal News International spoke to four experts on surgical robotic assistance in spine surgery to find out about the current capabilities of robotic systems, and what the future may hold.

What robotic systems are currently most widely used?

Isador Lieberman: One of the most popular systems is the Renaissance (Mazor Robotics). I use this system and was actually involved in its design and development over the last 15 years. I have used it in over 500 cases to insert over 4,000 screws over the past five years.

Enrico Tessitore: To my knowledge, Mazor's Renaissance system and the Rosa Spine (Medtech) are the most used robotic systems for spine. I have experience with the previous version of Renaissance—the Spine Assist system.

Bawarjan Schatlo: The Spine Assist (Mazor) and the Renaissance are the most widely used robotic systems—there are currently over 77 centres using them. The Rosa Spine system developed by Medtech has recently obtained CE approval for pedicle screw placement but for now is less widely used. Personally, I have been using the Mazor system since 2009.

Srinivas Prasad: The most widely used robotic system available today for spinal surgery is the Renaissance guidance system from Mazor Robotics. This has been purpose-built for spine surgery. There are other surgical robotics platforms that have been applied to spinal procedures though they are not yet consistently marketed or used for this application.

For what procedures have robotic systems been used so far?

Lieberman: Placing screws is the main application. Soon to come are semi-automated decompressions and also osteotomy planning. However, the current systems we have are designed for screw placement.

Tessitore: Pedicle screw fixation is the most common surgical procedure for which robotic systems are currently used.

Schatlo: In terms of specific procedures, there are cases, such as revision or deformity surgeries where anatomic landmarks are less evident than in others. In these cases, robotic assistance may facilitate surgery.

Prasad: The specific application that has been targeted by Mazor is the placement of thoracolumbar pedicle screws. Most of the literature and evidence available today pertains to this application. I believe that robotics companies like Intuitive Surgical have enjoyed tremendous success and growth in applications that "level the playing field" for surgeons. For example, most general surgeons could do laparoscopic cholecystectomies (removal of the gall bladder) without a robot before the advent of Intuitive's da Vinci system (which has also been used for spinal procedures), so marketing a US$1m device that enables surgeons to do this procedure laparoscopically did not make sense and did not sell units. On the other hand, few surgeons could perform laparoscopic prostatectomies (removal of the prostate) before da Vinci, but the robot enabled any well-trained surgeon to quickly offer laparoscopic solutions that they could not offer without it. I believe that robotic applications that "level the playing field" in this way, enabling spinal surgeons to provide a service they could not otherwise perform, will be central to the success of robotics systems in spinal surgery, as well as of the companies that produce them.

Isador Lieberman

Enrico Tessitore

> ***"Robotic systems will be adopted more widely when they enable spine surgeon to perform procedures more safely, efficiously and efficiently."***
>
> *Srinivas Prasad*

Mazor Robotics' Renaissance

How clinically effective are they?

Lieberman: Studies so far have shown robotic systems to be very effective in the accurate placement of screws. Traditionally the reported screw misplacement rate for free hand spine surgery runs from 5–10%, for fluoroscopic guided from 3–7%. For navigation and robotic guidance the screw misplacement rate is less than 1%.

Tessitore: The studies carried out using robotics have so far shown an ability to improve surgical accuracy in pedicle screw fixation when using these systems.

Schatlo: If surgical effectiveness is measured in pedicle screw accuracy, a review of all data will hint towards an increased accuracy when using the robot correctly.

Prasad: There is literature to suggest that the accuracy of surgical robotics is at least comparable to other techniques for placement of pedicle screws. Other techniques frequently use intra-operative fluoroscopy or intra-operative navigation systems.

Are these robotic systems cost-effective?

Lieberman: Studies are still investigating this aspect of the technology. I have no doubt that the use of robotic systems will prove to be less expensive over time. It is important to consider revision surgery—what is the cost of one revision spine surgery? If the robotic guidance eliminates a number of revisions per year then it will obviously be cost effective. Unfortunately, insurers and hospitals look at it differently, and insurers see added cost per case and hospitals see increased capital outlay. If we can somehow quantify the number of revisions avoided by integrating robotic guidance, then the answer to the question of cost-effectiveness will be clear.

Mazor Robotics' Renaissance

Robotic assistance in spine surgery is a fast developing proposition. The concept of fully robotic surgeons is still science fiction, but the number of spine surgeons using robot technology worldwide continues to grow as additional systems are developed and existing ones refined. Proponents of surgical robotic assistance say that its use minimises radiation exposure by removing the need for intraoperative CT or X-ray imaging, and reduces the number of complications and reoperations thanks to the ability to accurately pre-plan procedures using 3D models of a patient's anatomy.

Tessitore: At the moment, robotic systems are very expensive. That said, their use may reduce the number of misplaced screws and the resulting costs of repeat surgeries.

Schatlo: Cost effectiveness is a difficult entity to assess. It depends on different variables. One of these variables is the number of surgeons at your institutions, whether you are a teaching hospital and how difficult your cases are. With its potential superiority over pedicle screw placement using free hand technique, the goal should be to minimise revision surgeries for screw misplacement. Since revision surgeries for screw misplacement are relatively rare, it will take a larger number of cases to assess cost effectiveness in terms of return of investment. However, for every single patient you operate on, the peace of mind to have had assistance could itself be a return on investment.

Prasad: They are fairly expensive for the problem that they solve but there is conjecture that improvements in accuracy may translate into material financial benefit—from reduced morbidity, fewer revision surgeries, and so on. Moreover, from a hospital's standpoint, there is marketing value in offering cutting-edge technologies and the premise is that bringing new operative patients to the hospital will, in time, pay for the system.

What are some of the problems associated with the use of robotic technology?

Lieberman: It is important to overcome the mentality that the robot is doing the work, as this leaves surgeons lacking in self-confidence. Surgeons must think of the robot much like an airline pilot thinks of their on-board computer; the pilot still flies the plane, the on-board computer facilitates their-flight plan. Likewise, the surgeon must get into the habit of creating a pre-operative plan and allowing the robot to facilitate it. In addition, similar to all new technology, when it works it is great, when it crashes it is very difficult to implement plan B; you must be prepared for both.

Tessitore: Surgeons have reported that using robotics can be time consuming, and there can also be some degree of inaccuracy in the surgeries. Also, there is a significant learning curve associated with robotic technology use, as well as the need for dedicated scrub nurse training.

Schatlo: I believe that by using robot technology, our residents have a harder time learning to place screws with fluoroscopic control or freehand.

Prasad: The primary drawbacks of using robotic assistance are their cost and the learning curve for surgeons.

The da Vinci system ©2015 Intuitive Surgical, Inc

What do you believe are the main barriers standing in the way of large-scale adoption of robotic surgical assistance by spinal surgeons?

Lieberman: Continuing the answer from above, surgeons are reluctant to adopt new ways to do something unless of course it is beneficial to them, ie. unless they get paid to do it. So far, insurers have been reluctant to recognise the use of robotics as a medical necessity. Recently, after reviewing their medical policies, some insurers have now revised their stance and do recognise robotic guidance as medically indicated.

Tessitore: I would say that the main barrier is definitively the financial cost of the systems themselves.

Schatlo: As long as a surgeon is comfortable with techniques of pedicle screw placement, they should be fine with robotic assistance. Image guidance is not, as such, a prerequisite for performing instrumented spine surgery. However, it is a nice add-on to have; much like driving an automatic car takes some tasks out of the driver's hands and lets them focus on others. The convenience of such a technology will become evident with time.

Prasad: I am very enthusiastic about the promise of robotics in spine surgery. There are applications that I believe would enjoy tremendous value from robotic technologies but, as is often the case, the procedures that need it most are not the most common or profitable applications in spine surgery. Volume drives sales and most companies, robotic and otherwise, target the high-volume procedures or techniques. In turn, the high volume procedures are performed widely and comfortably. It is tough to sell an expensive piece of hardware to a surgeon who can already comfortably perform the procedure without it. I believe that robotic systems will be adopted more widely when they enable spine surgeons to perform procedures more safely, efficaciously and efficiently. Once robotic technologies enable us to perform procedures that we could not otherwise perform, they will become an integral part of our armamentarium.

Isador Lieberman *is a spine surgeon at the Texas Health Plano Hospital, USA; he acts as a consultant for Mazor Robotics.*
Enrico Tessitore *is a neurosurgeon at the Hôpitaux Universitaires de Genève, Switzerland.*
Bawarjan Schatlo *is a neurosurgeon at the University Hospital Göttingen/Georg-August University, Germany.*
Srinivas Prasad *is a neurosurgeon at Jefferson University, Philadelphia, USA.*

Bawarjan Schatlo

Srinivas Prasad

Medtech's Rosa Spine

Profile Michael Fehlings

Michael Fehlings (University of Toronto, Canada) was encouraged to enter the medical profession by his grandfather, eventually specialising in neurosurgery. He cites the intellectual and technical challenges of neuroscience and precise surgery combined with the ability to help individuals as his role's most appealing aspects. A prolific researcher of spinal neurology and spinal cord injury, he has also been involved in several societies and medical journals during his career, believing that sharing local knowledge and experiences can lead to an improved and more useful global perspective on the big questions facing medical science.

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

I was inspired to become a doctor by my grandfather who felt that medicine is perhaps the noblest profession and one that was well suited to my skills and personality. It has indeed been an excellent fit for me in that it combines intellectual pursuits and challenges while at the same time focussing on trying to help individuals and to make an impact on the health of society. I decided to specialise in neurosurgery because I felt that it combined the pursuit of the challenges of neuroscience with the technical attributes of doing a precise surgery. It was really this combination that had tremendous appeal to me.

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

I have had many career mentors, the two most significant ones being Charles Tator and Alan Hudson. Charles Tator was my PhD supervisor and the individual who taught me about neuroscience and spinal cord injury. He really inspired me to focus on the area of spinal neurosurgery and spinal cord injury. Alan Hudson was my professor of neurosurgery and was enormously influential in terms of my career development as a spinal neurosurgeon. Alan inspired me to focus in the area of spinal surgery and undertake postgraduate training in this emerging subspecialty. Another individual who had significant impact on my formative years was Paul Walker, who at that time, was the surgeon-in-chief after I had attained my first appointment as an assistant professor at the University of Toronto. Paul facilitated my formation of a combined multi-disciplinary spinal programme, and was very influential on my development.

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

The development of internal fixation approaches to reconstruct the spine from the occiput down to the sacrum has dramatically influenced our ability to decompress and reconstruct virtually any condition in the spine. In particular, the development of lateral mass fixation, occipital cervical fixation, anterior cervical locking plates and pedicle screw fixation have been enormous advances. In addition, there have been significant technical advances in microneurosurgery as well as in our ability to approach virtually any area of the spine successfully.

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

I think the most fascinating work that I have seen has been the research pioneered by Reggie Edgerton at UCLA and Susan Harkema in Louisville, USA, related to the use of epidural stimulation to activate the central pattern generators of the lumbar spinal cord in individuals with complete spinal cord injury. Activation of these centres appears to promote significant endogenous plasticity and to enhance recovery of function. If this work is supported by larger clinical trials, this could represent a major breakthrough in the area of traumatic spinal cord injury.

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

I feel that one of my major contributions has been in the area of spinal cord injury and, specifically, the definition of post-traumatic ischaemia as a key secondary injury event. The critical translation of this into the clinical arena arose out of the STASCIS (Surgical Timing in Acute Spinal Cord Injury Study) clinical trial which determined that early surgical decompression of traumatic spinal cord injury resulted in a major improvement in neurological function. The STASCIS trial and the work around this has redefined how acute traumatic spinal cord injuries are managed. The concept that has emerged from this work is one of "Time is Spine" wherein early intervention for traumatic spinal cord injury is critical.

What are your current research interests?

My current research interests reflect my passion to understand the pathobiology of central nervous system injury and methods to improve the outcomes. I continue to have major research interests in traumatic spinal cord injury and am focusing on neuroprotective approaches, bioengineered strategies and stem cell-based regenerative neuroscience. This work has also been extended to cervical spondylotic myelopathy. It has involved the conduct of clinical trials to validate the significant role of surgical decompression to influence the outcomes of patients with cervical spondylotic myelopathy. Parallel to this, we have developed unique animal models to mirror human cervical myelopathy in the laboratory setting and we are currently studying the pathobiology of cervical spondylotic myelopathy in animal models. In addition, I have a significant clinical and research interest in the area of spinal oncology and have a focus, in particular, on optimal methods to treat metastatic epidural spinal cord compression.

What does the future of regenerative medicine for spinal cord injury look like?

Regenerative approaches for spinal cord injury would certainly be combinatorial in nature. The role of surgical decompression and reconstruction of the unstable spine is critical in optimising the milieu for recovery. Neuroprotective strategies to facilitate optimal recovery and preservation of neural structures are important. Rehabilitation approaches to influence plasticity are critical to any treatment paradigm. Undoubtedly, both bioengineered strategies to influence the milieu of the injured spinal cord and to serve as scaffolds to facilitate repair would be complementary to stem cell-based strategies to replace lost cells and to regenerate neural circuits.

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

This is a challenging question to answer as we have many issues that need addressing. But if I was pinned down, the following are the three critical issues, in my opinion. First, finding an optimal approach to repair the injured central nervous system. This is absolutely

> ***I have seen remarkable advances in the treatment of spinal cord injury and spinal conditions over the last 25 years. These advances have greatly influenced our ability to effectively treat a variety of spinal conditions.***

critical as neurological deficits are the rate-limiting determinant of quality of life and of outcomes of an individual with a spinal condition. The second critical issue is to define the pathobiology and optimal treatments for neuropathic pain. Neuropathic pain is a key issue which arises after peripheral nerve injury and injury to the brain and spinal cord. We lack effective solutions for this disabling condition and unlocking the key to neuropathic pain will have dramatic impact on the outcomes of patients. The third key issue, in my view, is to convince a society and peers that surgical treatments for spinal conditions are highly effective and also cost effective for society and should be supported.

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

I feel the next big development will relate to regenerative neuroscience technologies. This will involve both unique bioengineered strategies to influence soft tissue regeneration in the spinal cord and the adjacent paraspinal structures including the intervertebral discs. In addition, I feel that induced pluripotent stem cells offer considerable promise as a technique to regenerate damaged neural structures and paraspinal elements.

I have seen remarkable advances in the treatment of spinal cord injury and spinal conditions over the last 25 years. These advances have greatly influenced our ability to effectively treat a variety of spinal conditions. I am optimistic that the trajectory over the next 10–20 years will be very positive and that spinal surgeons have a major role in society to help patients recover from the impact of disabling spinal conditions.

You have been active in many medical societies during your career. What have you learned from these experiences?

My involvement in medical societies including the American Association of Neurological Surgeons, Cervical Spine Research Society, AOSpine and others has taught me the critical need for a global perspective in terms of collaborative opportunities and the importance of reaching out beyond one's own local environment. These medical societies have also taught me the importance of learning from others and of fellowship opportunities.

What has been your most memorable case?

Early on in my career, I treated a young individual with a bilateral facet dislocation at C6–7 and complete traumatic quadriplegia. I treated this individual with an early procedure involving a reduction of the locked facets and a surgical procedure to decompress the spinal cord and to reconstruct the spinal column. Remarkably, this individual made a major neurologic recovery and essentially walked out of hospital a week after his admission. This case has stood by me over the years as validation of the concept that "Time is Spine" and that early surgical decompression of traumatic spinal cord injury is of critical importance.

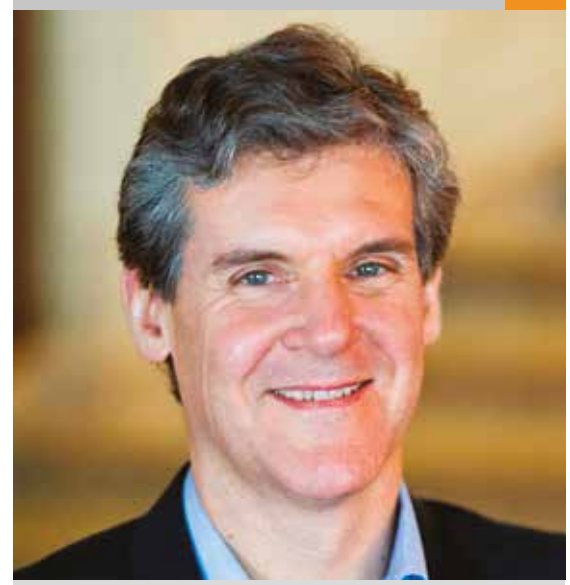
What advice would you give to someone who was starting their career in spinal surgery?

I would advise individuals that spinal surgery is an exciting, dynamic field one that is based on solid evidence but also one that needs many questions to be addressed. I would advise individuals undertaking a career in spinal surgery to consider the best interests of their patients first and also to be inspired to develop new therapeutic approaches to influence the outcomes of spinal conditions.

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

I enjoy cycling, wine, travel, the arts, being in nature and, above all else, my friends and family.

Fact File



Appointments

2014	Vice chair research, Department of Surgery, University of Toronto, Toronto, Canada
2011	Halbert chair in neural repair and regeneration, University Health Network, Toronto, Canada
2008	Co-director, University of Toronto Spine Program, University of Toronto, Toronto, Canada
2001–2014	Medical director, Krembil Neuroscience Center, University Health Network, Toronto, Canada
2000	Professor, Department of Surgery, University of Toronto, Toronto, Canada
1997	Senior scientist, Toronto Western Research Institute, Toronto, Canada
1994	Head, spinal program, Toronto Western Hospital, Toronto, Canada

Selected other experience

2012	President, Cervical Spine Research Society
2010	Director, International Research Development, Rick Hansen Institute
2008–2010	Chairman, *Journal of Neurosurgery: Spine*
2007	Chairman, AOSI Outcome & Clinical Research Committee, AOSpine International
2007	Chair, Medal Award in Surgery Committee, Royal College of Physicians & Surgeons of Canada
2006–2010	Chair, Joint Section of Neurotrauma and Critical Care, American Association of Neurological Surgeons
1988	Deputy editor-in-chief, *Spine*

Education

University of Toronto	MD (1983) Medicine
University of Toronto	PhD (1989) Neuroscience
University of Toronto	FRCSC (1990) Neurosurgery
NYU Medical Center	PDF (1992) Spinal Cord Injury

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Spinal manipulation for acute and sub-acute low back pain

MICHAEL SCHNEIDER

COMMENT & ANALYSIS

According to Michael Schneider, the vast majority of patients (>85%) with an acute episode of low back pain will not have any serious spinal abnormality or disease as the cause of their symptoms.[1] Of these patients who seek treatment, most will be told they have non-specific mechanical back pain.

There is a general belief among physicians that non-specific mechanical low back pain is a self-limiting disorder that will improve regardless of the type of treatment provided.[2] This is generally true—about two-thirds of acute back pain cases improve rapidly within the first four to six weeks[3]—yet about a third of patients report persistent back pain one year after an acute episode.[4] Quick recovery from an acute episode and a return to normal function are therefore important goals in the appropriate clinical management of non-specific mechanical back pain.

Management

Current clinical practice guidelines for the management of acute low back pain suggest that physicians provide patients with advice to remain active, over-the-counter medications such as non-steroidal anti-inflammatory drugs (NSAIDs), and self-care options.[5] For patients who do not improve with self-care options, physicians are advised to consider other evidence-based non-pharmacological treatment options, including spinal manipulation.

Evidence-based medicine is the judicious use of the best current evidence combined with clinician experience and patient preferences.[6] Some patients have a preference for non-pharmacological treatment options. Others may have significant interference with activities of daily living and prefer not to take a "watchful waiting" approach to the management of their acute or sub-acute back pain. For these patients, it is preferable to take a more proactive approach to their back pain including the use of spinal manipulation and exercise. In these cases, spinal manipulation can be a valuable first-line treatment option.

My colleagues and I recently published a randomised trial[7] that compared four weeks of management with two types of spinal manipulation or with usual medical care (as described above). The results provide evidence for the effectiveness of both management approaches. The responder analysis showed that up to 50% of the patients in the medical care group showed moderate or substantial improvement at four weeks. This suggests that current guideline-based medical management of low back pain will lead to good outcomes in about one half of patients within four weeks.

However, the spinal manipulation (manual thrust) group achieved substantially more improvement in clinical outcomes compared with the usual medical care group—50–90% of patients receiving manual manipulation showed moderate to substantial improvement at four weeks. This suggests that a greater proportion of patients will be returned to normal function at four weeks when spinal manipulation is added as a front-line treatment option, rather than waiting for patients to exhaust self-care options.

Our trial also compared the clinical effectiveness of two common types of manipulation: manual-thrust manipulation and mechanical-assisted manipulation. The reason for this research question was that many chiropractors use mechanical instruments as a substitute treatment for manual-thrust manipulation, with the belief that they are therapeutically equivalent. The results of this study question that assumption. The proportion of patients in the mechanical-assisted group who achieved moderate (>30%) or substantial (>50%) reductions in self-reported disability and pain at the end of treatment (four weeks) was about the same as the proportions of responders in the usual medical care group. The manual-thrust group had significantly more responders at four weeks than either the mechanical-assisted or usual medical care groups.

Conclusion

Non-specific low back pain has a generally favourable prognosis, and can usually be managed with guideline-based medical care that includes advice to stay active, self-care options, and judicious use of NSAIDs. However, the early addition of manual-thrust spinal manipulation appears to lead to significantly greater reductions in pain and improved function at four weeks. The belief in therapeutic equivalence between manual-thrust manipulation and mechanical manipulation devices is not supported by the current evidence. Spinal manipulation (manual-thrust) can be a valuable treatment option in guideline-based medical care for low back pain.

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Michael Schneider is an associate professor of physical therapy at the University of Pittsburgh, Pittsburgh, USA

Physical therapy and surgery produce same results for stenosis in older patients

Symptoms of lumbar spinal stenosis were relieved and function improved in as many patients utilising physical therapy as those taking the surgical route, University of Pittsburgh researchers announced, with the publication of a two-year study in the *Annals of Internal Medicine*.

The researchers believe that this is the first study that clearly compared outcomes between surgery and an evidence-based, standardised physical therapy approach for lumbar spinal stenosis. This condition has seen decompression surgery become one of the fastest-growing procedures for older populations.

A total of 169 patients aged 50 and over set to undergo decompression surgery agreed to be randomly assigned into two groups—those who would have the procedure, and those who would go through two standardised, evidence-based physical therapy sessions per week for six weeks. After both groups were re-examined at six months, one year and two years, patient outcomes appeared to be equal. There were no detectable differences between the groups in how their pain abated and the degree to which function was restored in their backs, buttocks and legs.

"Probably the biggest point to put across to physicians, patients and practitioners is that patients do not exhaust all of their non-surgical options before they consent to surgery. And physical therapy is one of their non-surgical options," says principal investigator Anthony Delitto, chair of the Department of Physical Therapy, Pitt School of Health and Rehabilitation Sciences, as well as a member of Pitt's Health Policy Institute and a consultant to University of Pittsburgh Medical Center.

"The idea we had was to really test the two approaches head to head," he says. "Both groups improved, and they improved to the same degree. Now, embedded in that, there are patients who did well in surgery, and patients who failed in surgery. There are patients who did well in physical therapy, and there are patients who failed with physical therapy. But when we looked across the board at all of those groups, their success and failure rates were about the same."

The research project also revealed issues surrounding physical therapy appointments in the USA and the cost of co-payments. Most patients did not complete the physical therapy regimen assigned to them by Medicare and prescribed by the researchers, and one-third of the patients failed to complete even half of the regimen. Another 16% did not show for a single treatment, even though they had agreed to consider physical therapy.

"One of the big things that we know held patients back from physical therapy were co-payments," Delitto explaines. "Patients were on Medicare, and a lot of them were on fixed incomes. Some of those co-payments had to come out of pocket at US$25–35 per visit. That adds up, and some of the patients just could not afford it."

A quarter of opioids prescribed for chronic pain are being misused by patients

New estimates suggest that 20–30% of opioid analgesic drugs prescribed for chronic pain are misused, while the rate of opioid addiction is approximately 10%, reports a study in *PAIN*, the official journal of the International Association for the Study of Pain.

"On average, misuse was documented in approximately one out of four or five patients and addiction in approximately one out of ten or eleven patients," who were prescribed opioids as part of their treatment for chronic pain, write Kevin E Vowles, University of New Mexico, USA, and colleagues. The researchers note an extremely wide variation in reported rates of misuse, abuse, and addiction and raise questions about the benefits of widespread opioid use for chronic pain, given the harmful consequences.

Vowles *et al* reviewed published studies to produce "updated and expanded" estimates of rates of problem opioid use. The authors note that over the past 15 years, the amount of opiods being perscribed to chronic pain patients has increased significantly This increase has coincided with an increase in opioid-related problems, such as dependence, withdrawal, and overdose. Estimates were calculated using data from 38 reports, with adjustments for study sample size, quality, and methods. Three specific types of problem opioid use were recorded: misuse, abuse, and addiction. The study found very high variability in specific rates of opioid misuse and addiction identified across different studies—ranging from less than 1% to more than 80%.

On adjusted analysis, the average rate of opioid misuse was estimated at 21–29%. Misuse was defined as using opioids contrary to instructions, regardless of harmful or adverse effects.

Adjusted average rates of opioid addiction—defined as continued opioid use with actual or potential harmful effects—ranged from 8–12%. Only one study analysed the rate of opioid abuse, ie. intentionally using the drugs for non-medical purposes.

Reported rates of opioid addiction were lower for studies with a "primary focus" on this issue. Otherwise, studies with different characteristics yielded comparable rates of problem opioid use.

Amid the ongoing "opioid epidemic", this review provides informed estimates of specific types of problem opioid use. Vowles and colleagues draw special attention to the high rate of opioid misuse. They write, "If it is accurate that approximately one in four patients on opioids display patterns of opioid misuse, but not addiction, then perhaps more efficient targeting of treatment resources would be of benefit." For example, even low-intensity interventions, such as patient education and monitoring, might be a viable alternative to simply not prescribing the medications for those at risk of misuse.

The researchers also note that 35 of the 38 studies reviewed were conducted in the USA. This "curious finding… suggests that this issue is of both high interest and is perhaps a problem that is somehow uniquely relevant to the USA," they write.

Vowles *et al* discuss the documented rates of opioid misuse and addiction in light of the "clinical reality of chronic pain treatment." They conclude, "We are not certain that the benefits derived from opioids, which are rather unclear… compensate for this additional burden to patients and health-care systems."

The authors conclude by calling for further research, including relevant information on patient and pain-related characteristics and focusing on specific types of problematic opioid use. Such studies are needed, they say, to provide accurate data for clinicians and policy-makers to make properly-informed decisions.

The study was funded by a grant from the Center for Health Policy at the Robert Wood Johnson Foundation Center for Health Policy at the University of New Mexico.

Marijuana legalisation offers US chronic pain patients an alternative treatment option

Michael A Finn, University of Colorado, USA, presented a study at the annual meeting of the International Society for the Advancement of Spine Surgery (ISASS, 14–17 April, San Diego, USA) examining the use of marijuana by chronic back pain patients in the US state of Colorado.

In recent years there has been a growing interest in the use of marijuana to treat a range of chronic pain conditions. The medical marijuana movement has gathered significant support in the USA, with 24 states now having legalised medical marijuana and a further nine states with pending legislation.

Colorado legalised the use of medicinal marijuana in 2000, and according to Finn, there are now over 115,000 patients registered for its use in the state. However, in 2012 along with several other states (Alaska, Oregon and Washington) and the District of Columbia, the recreational use of marijuana was made legal in Colorado. Given its easy availability thanks to legalisation, Colorado offered the researchers an interesting opportunity to study marijuana self-medication for chronic spine pain conditions.

Finn and colleagues at the University of Colorado carried out their investigation looking to describe patterns of marijuana usage in patients presenting to a tertiary care clinic in Colorado and to assess its efficacy in relation to other pain medications. All adult patients presenting at the clinic were offered enrolment in the study, and following their consent were given a brief survey regarding their marijuana use.

Of the 200 patients offered enrolment, 184 (92%) agreed to take part (101 females, 83 males). Of these 184, 35 (19%) reported that they used marijuana for pain. Though users tended to be younger than non-users (users average age was 44 vs non-users 54, $p<0.05$), other demographic factors "were comparable".

Of the 35 users, 17% used only marijuana to treat their pain, while 54% used it in combination with other narcotics. Eighty three per cent of users believed that marijuana "moderately" or "greatly" relieved their pain. Interestingly, only 45.5% of users had a medicinal marijuana licence, most of which (73%) were given primarily for back pain. Therefore, before 2012 when recreational marijuana usage became legal in Colorado, 54.5% of these users would not have had legal access to this method of pain relief.

On average, the patients used marijuana 1.6 times per day, with the most regular method inhalation of the smoked plant material (90.3%), as opposed to oral ingestion (45.2%) or inhalation of vaporised plant material (29%).

Eighty-one per cent of users believed that marijuana works better than or equal to other narcotics used to treat their pain, while 88% reported that it worked better or equal to nerve-targeting medications and 89% thought it was better than or equal to non-steroidal anti-inflammatory medications.

A variety of adverse effects of marijuana were reported, the most common of which were weight gain (35%) and difficulty concentrating (27%). Despite this, 60% of users reported no adverse effects, and only six patients (17% of users) believed that such adverse effects were "significant".

As Finn suggested, more research is necessary to examine the true effects of marijuana on this population and to evaluate what it can bring to the treatment of spine pain conditions. As movements for further decriminalisation and legalisation across much of the western world gather support and publicity, marijuana—medicinal or otherwise—will become the focus of increased attention for researchers and physicians as patients look for new alternatives to treat their chronic pain conditions.

Musings of an octogenarian surgeon

ROBERT MULHOLLAND

COMMENT & ANALYSIS

In the play "*As You Like It*" the melancholy Jacques describes the "seven ages of man". A tribute to the much greater health experienced in the developed world is that the octogenarian is not in the sixth or seventh age now, but in the fifth: "the Justice in fair round belly with good capon lined with eyes severe and beard of formal cut full of wise saws and modern instances". In the context of our profession, the experienced surgeon has gained wisdom through experience, and is now ready to impart it to younger colleagues, writes Robert Mulholland.

In surgical disciplines, there are various physical reasons why a surgeon should discontinue operating much past their 70th year. These include vision and manual dexterity, and the ability to withstand stress and long operating sessions. It is also important for surgery as a whole that older surgeons make way for younger surgeons in their intellectual and physical prime. I was happy to stop operating at 65 because I found the anxiety and stress of operating was becoming burdensome, and as the senior surgeon I was expected to work on the difficult cases which were technically demanding and lasted many hours. One aspect of seniority and past experience is that one is more aware of risks and complications, having previously experienced them, and this awareness plays a role in the stress of the procedure.

However, it would be a loss to the profession if stopping one aspect of surgery meant that the surgeon would no longer contribute to their speciality. In my view, this would be especially unfortunate in our speciality of spinal surgery, where the operation is but part of the expertise the surgeon brings. We have experience that we can pass on to younger colleagues, giving a perspective that might otherwise be lacking.

One such perspective is on diagnosis. It is an interesting feature of most journal articles that they deal with treatment and outcome, yet seldom diagnosis. Experience in diagnosis is built on the experience of individual cases. One of the reasons that anecdotal cases are valued is because they act as proxy for experience—they stick in the mind—and are called upon when the clinician faces a similar problem. Diagnostic skills improve because one has seen cases like that in the past, and long experience is central to the acquisition of diagnostic skill. This is one area in which older surgeons can greatly assist our younger colleagues.

Examination should be carefully targeted to confirm a diagnosis. As a student I was always taught to conduct a thorough physical examination. I developed the view that in the field of spinal surgery this was inappropriate. The examination must be very carefully targeted. A general routine examination is inevitably cursory, and so unless it is very carefully targeted, physical signs will be missed.

Following examination, never diagnose the untreatable, or if you do, constantly reassess your diagnosis. The introduction of the term "non-specific back pain" is in my view a disaster as both patient and doctor are deceived. It is not a diagnosis; it is a statement that a diagnosis has not been made. Once labelled it is often the case that further review of the diagnosis is not carried out, patients may be sent to a pain clinic for six-monthly injections and they steadily accumulate a large variety of pills, but a diagnosis is not reviewed. It is certainly my view that this diagnosis should never be made in the absence of a magnetic resonance imaging (MRI) scan. MRI scans are cheap, non-invasive, and should be regarded as part of the clinical assessment in today's world.

An essential feature of gaining diagnostic and clinical practice experience is the follow-up of patients. It is to my mind a very retrograde step that in recent years, follow-up of patients has become severely constrained in the British NHS. I believe that orthopaedic and spinal surgeons are at risk of not being aware of outcome, and therefore not able to fully inform patients or guide their own practice.

Older surgeons also have experience with the struggle to alter entrenched beliefs, which is always difficult. One in our speciality in particular has been the function and role of fusion in treating back pain. The success of fusion in treating back pain was unpredictable and much of this unpredictability was related to the psychological aspects of the disorder. We became very aware of these in the 1970s and 1980s, but despite filtering out patients with such problems, results did not greatly improve. Fusion could be very successful, but was unpredictable. The concept was that back pain was due to abnormal movement and thus failure was deemed to be due to persistent movement, and hence failure was treated by redoing the fusion, with usually lamentable results, and inevitably psychological damage.

However, with the advent of pedicle fixation, which was so rigid, we could not truly say that persistent movement was the cause of pain. As a result, we felt that the cause was failure of fusion. But how had the fusion failed? It had in my view failed because the fusion was not load bearing. My concept that mechanical low back pain was a failure of the disc to transmit load normally, despite being supported by peer reviewed biomechanical studies, has only been accepted in the last few years. This has of course led to an explosion of surgical devices that allow movement, but alter loading patterns. Sadly, many of these devices are not properly designed or researched. I am now firmly of the view that the aim of surgery for mechanical back pain is to create a normal loading pattern over the disordered segment. An interbody fusion is the best, a successful disc replacement is possibly better, but sadly the latter has the grave disadvantage that failure carries a very heavy penalty, including risk to life.

It is difficult to alter entrenched attitudes, for example the concept that rigid fixation aids union. Surgeons still instrument a posterolateral fusion in lytic spondylolisthesis, despite Volvo Award-winning papers which show it is both unnecessary and carries risks. Posterolateral fusion was never primary bone union and rigid fixation only acts to protect it from the loading that is necessary for fusion to occur—a fact acknowledged by our fracture surgeons, but not appreciated by our spinal surgeons.

As an experienced surgeon, I am well aware that all branches of orthopaedics have a problem with their relationship to industry. In spinal surgery this is particularly a potential problem, as much educational support is given by industry, and innovative ideas from surgeons can only become reality by close collaboration with industry. However the possibility of a surgeon making a vast fortune from the success of an implant that they designed, if it is successful, must create a great temptation to assess results with tinted spectacles. It is important that we maintain proper standards for new products and techniques, regardless of any relationship with industry.

We have lived through a most exciting time in spinal surgery with remarkable new advances, especially in the field of instrumentation. The octogenarian has seen enthusiasms come and go and hence is in a position to caution. Herein is a danger that their experience may make them unduly cautious. They are there to advise and caution, not dictate, because as dictators they will crush innovation.

I was stimulated to write these musings initially as I wished to persuade my younger colleagues, and indeed myself, that the octogenarian could still contribute to their speciality and should not feel that he should devote himself to boules or golf, or sink into "senile and inept repose" (Hillarie Belloc). I think we can contribute and advise because we have seen so much. However, we must not try to dominate, as the caution of age will dampen innovation.

News in brief

St Jude Medical announces intent to acquire Spinal Modulation

St Jude Medical has exercised its option to acquire Spinal Modulation, developer of the Axium neurostimulator system. Following the completion of this acquisition, St Jude Medical will be the only manufacturer to offer radiofrequency ablation, spinal cord stimulation and dorsal root ganglion stimulation therapy solutions for the treatment of chronic pain.

Axium received CE mark approval in 2011 for the management of chronic pain. In 2014, Spinal Modulation announced that enrolment in its ACCURATE US IDE trial had been completed and its pre-market application was submitted to the FDA in support of marketing approval in the USA.

Mazor Robotics reports orders for Renaissance systems

Mazor Robotics received orders and delivered three Renaissance systems, one in the USA and two internationally, in the first quarter of 2015 ending 31 March.

In the USA, the Renaissance system was purchased by Arrowhead Hospital, located in Glendale. Arrowhead is owned by one of the nation's largest investor-owned healthcare services companies and represents the sixth Renaissance system installed through its hospital network. Internationally, the systems were installed at hospitals in Germany and Taiwan, representing the twelfth and fourth systems installed in those countries, respectively.

Minimally invasive stabilisation for metastatic lesions

Minimally invasive spinal stabilisation could be a safer approach to treating metastatic lesions, according to Abdulkader Hamad, of the Robert Jones Agnes Hunt Orthopaedic Hospital, Oswestry, UK.

At the annual meeting of the British Association of Spinal Surgeons (BASS, 18–20 March, Bath, UK), Hamad presented results of a study examining whether minimally invasive stabilisation for metastatic lesions leads to improved functional outcomes, in what is a "complex group of patients".

The study was a prospective case series of 51 consecutive patients (21 male, 30 female, mean age 60) with spinal metastasis treated with a minimally invasive procedure. To assess outcomes, the authors used Karnofsky Performance Status (KPS), Frankel grading, blood loss, and the number and type of surgical complications.

Minimally invasive fixation was perfumed without decompression in 46% (23) of patients, with an average blood loss of 88ml. The approach was combined with limited mini-decompression in the remaining 54% (28) of patients with an average blood loss of 209ml.

The mean preoperative KPS score was 54, and had improved in 53% of patients (27) at discharge, while 41% (21) remained the same and 6% (3) worsened. Of the 44 patients with pain as an indication for surgery, 42 (95%) reported improvement in pain. Hamad also reported that "half the patients with preoperative neurology improved with decompression and fixation by one Frankel grade".

In terms of complications and revisions, two patients converted to open surgery and six suffered from medical complications. One patient had a surgical complication (transient foot drop) and four patients required revision surgery (three for hardware loosening and one for a medially displaced screw).

To further assess the safety of the procedure, Hamad *et al* carried out computed tomography (CT) assessment of screw placement in 31 of the patients. They found that "91% of screws had excellent placement, 98% had an uncompromised hold and there were no neurological events related to screw misplacement".

These results show that a minimally invasive approach to stabilisation for spinal metastatic lesion patients is "a safe and effective way to treat this difficult group of patients", Hamad said. Compared to other methods of surgery, this minimally invasive approach resulted in "significantly" reduced morbidity and fewer complications. Given the potentially short prognosis for this group of patients, a less invasive and less traumatic approach could significantly improve the short-term quality of life for these patients.

Back pain represents a major and increasing burden on the NHS

Claire Spolton-Dean, Royal Gwent Hospital, Newport, UK, told BASS 2015 delegates that back pain is a "huge" burden on the "limited and stretched resources of the UK's National Health Service (NHS)."

Presenting to delegates at the annual meeting of the British Association of Spine Surgeons (BASS, 18–20 March, Bath, UK), Spolton-Dean explained that back pain presented a significant financial burden to individual patients, individual hospitals, and the NHS as a whole. The presentation was based on a study conducted in collaboration with Francis Brooks, Royal Gwent Hospital, Newport, UK.

Spolton-Dean and colleagues studied over 19,000 admissions recorded on the hospital's trauma database from 2004–2013, identifying 1,161 caused by back pain. The average age of these patients was just over 51 years, with "slightly more females than males, correlating with chronic pain trends".

The study's figures indicated an increase in admissions for back pain of 60% from 2004–2013—significantly higher than the population growth during this time period. The admissions of the patients totalled 43.3 years, or 15,790 days (average stay of 8.1 days). Although 83.3% of patients underwent a magnetic resonance imaging (MRI) scan, only 29% required surgical intervention. The remaining 71% were treated with "good and regular analgesia and support from our physiotherapy team".

Spolton-Dean told attendees that such a high number of admissions, 88.5% of which came directly from the Accident & Emergency department, is resulting in unsustainable costs for the hospital. The cost of an average admission with an MRI scan and overnight stay was around £2,000, resulting in an annual cost to the hospital of £335,000 and £3.3m over the past 10 years.

Also of note was that chronic back pain is associated with depression, low socioeconomic status and unemployment, all issues that are "not easily changed". Given its location in a relatively deprived area of Wales, the team at the Royal Gwent Hospital experienced this first-hand. Because the incidence of back pain seems to be increasing, it stands to reason that more and more working age adults will develop such a problem, exacerbating some patients' already vulnerable economic position.

Spolton-Dean suggested that the study "raises the question of whether we can utilise our resources in a more appropriate manner, for example by providing rapid access clinics with access to MRI scans and pain and physiotherapy support, which would be a more cost-effective method of management".

Vertebral compression fractures in multiple myeloma patients can be successfully treated with balloon kyphoplasty

Anand Patel, Royal Orthopaedic Hospital, Stanmore, UK, presented data at the British Association of Spinal Surgeons meeting (BASS, 18–20 March, Bath, UK) suggesting that balloon kyphoplasty is an effective method of treating vertebral compression fractures in multiple myeloma patients.

Patel told delegates that multiple myeloma is "the most common haematological malignancy involving vertebrae and causing vertebral compression fractures, leading to substantial morbidity, poor quality of life and increased healthcare costs." Spinal cord compression occurs in 11–24% of multiple myeloma cases. According to Patel, balloon kyphoplasty can "reduce pain, improve function and quality of life and partially restore lost vertebral body height", hence this investigation of its potential use in this patient population.

The study examined 127 multiple myeloma patients who underwent balloon kyphoplasty from January 2008–June 2014. Outcome measures were visual analogue scale (VAS) scores for pain and the Roland-Morris Disability Questionnaire, Oswestry Disability Index (ODI) and EQL-5D for functionality. In total, 356 painful vertebral compression fractures were treated with balloon kyphoplasty in 145 operations.

The most common fractured vertebral level was T12 (12% of patients), followed by L2 (9.6%), and T11 and L1 (9.4%). The median spinal instability neoplastic score was 11 (range 10–13).

Following treatment, 69% of patients experienced rapid pain relief and became independent of analgesia. Furthermore, mobility and functionality "markedly improved within a mean time of six weeks". VAS scores improved from ≥6 to 1.1±2 following the balloon kyphoplasty, and 61% of patients' mobility improved gradually with an associated improvement in functionality. Mean ODI scores fell from 51.2 to 40.4 post-kyphoplasty ($p<0.05$) and reductions were reported for VAS leg (2.0 pre, 0.8 post-procedure, $p<0.05$) and back (6.9 pre, 2.6 post-procedure, $p<0.05$) pain. There were no reported complications.

"Balloon kyphoplasty is a safe procedure for the management of vertebral compression fractures", said Patel, that "provides rapid and sustained pain relief and can improve functionality and quality of life".

New ALIF approach to preserve the psoas via a single incision

At the annual meeting of the British Association of Spinal Surgeons (BASS, 18–20 March, Bath, UK), Sean Molloy, Royal National Orthopaedic Hospital, Stanmore, UK, told delegates of the results of a novel extensile psoas-preserving single incision surgical approach for anterior lumbar interbody fusion (ALIF) from L1–S1.

Molloy told delegates that the lateral retroperitoneal approach has been commonly used for many years for ALIF procedures from L1–L5, though a separate Pfannenstiel approach is used if access to L5–S1 is required. The traditional lateral transpsoas technique was developed to eliminate the need for an anterior surgeon and retraction of the great vessels, with the potential for shorter operative times. However, with this method, L4–L5 is the most difficult level to access, and L5–S1 is inaccessible. This procedure has also been associated with complication rates of up to 50%, the most common of which include anterior thigh numbness, radiculopathy, iliopsoas and quadriceps weakness.

Molloy and colleagues developed a psoas-preserving approach, which avoids the complications associated with the traditional approach, and also allowed access to L5–S1. They employed the technique in treating a prospective series of 40 patients undergoing anterior lumbar interbody fusion using porous tantalum cages as part of two-stage complex lumbar reconstructions from L1–S1. The team employed Oswestry Disability Index (ODI) and visual analogue scale (VAS) scores to measure outcomes.

Mean length of stay following surgery was 2.5 days, with mean blood loss of less than 200mls. There were no reports of transient or permanent neurological, vascular or visceral injuries. The mean VAS score improved from 8.1 preoperatively to 3.2 postoperatively, while the mean ODI score improved from 49.1 to 20.3.

Molloy commented, "The technique described is a safe, psoas-preserving, one-incision approach that avoids the potential complications of standard transpsoas surgery. It may also be used in an extensile fashion to provide access from L1–S1 for multilevel lumbar surgery and complex reconstructive procedures, thus avoiding the need for a two-incision approach."

Acrylic cages are good alternatives to bone graft and PEEK in anterior cervical discectomy and fusion

A study published ahead-of-print by the *Journal of Spinal Disorders and Techniques* suggests that novel acrylic cages, composed of polymethylmethacrylate (PMMA) and methacrylate, are as clinically effective as PEEK cages and bone graft in promoting fusion following an anterior cervical discectomy (ACDF).

The study authors, led by Majid Reza Farrokhi, Shiraz Neuroscience Research Center, Shiraz University of Medical Sciences, Shiraz, Iran, designed an acrylic cage to use in ACDF procedures, as, although there are many options for restoring physiologic disc height and enhancing spinal fusion, they believed that "the ideal device, which would provide immediate structural support and subsequent osteointegration and stability, has not been identified yet," and use of existing devices can result in cage subsidence, migration or failure.

The prospective, single-blind randomised controlled clinical study enrolled a total of 64 patients who were randomly allocated to undergo ACDF either with acrylic interbody fusion cage filled with bone substitute (n=32) or PEEK cage (n=32). Nurick's grading was used for quantifying the neurological deficit. Clinical and radiological outcomes were assessed preoperatively, immediately after surgery, and subsequently at two, six and 12 months follow up using Odom's criteria and dynamic radiographs (flexion-extension) and computed tomography scans, respectively.

The authors report that there was a statistically significant improvement in the clinical outcomes of the acrylic cage group compared with the PEEK cage group (mean difference: -0.438, 95% confidence interval -0.807 to -0.068; p=0.016). There was a statistically significant difference in disc space height increase between the two groups at the six- and twelve-month follow-up. The acrylic cage achieved higher fusion rate than the PEEK cage (96.9% vs 93.8%). The intervertebral angle demonstrated a significant difference among the two treated groups throughout the follow-up period. The authors also found that their acrylic cage was significantly cheaper (US$100) than the PEEK alternative (US$800).

The acrylic cage used

Farrokhi *et al* write that "Clinical improvement, disc spacing height, intervertebral angle and fusion rate in the patients of the acrylic cage group was better than the PEEK cage group." They conclude that an acrylic cage "can be a good, safe and economical alternative compared to commercially available PEEK cages in ACDF at 12-month follow-up."

Alex Vaccaro, editor-in-chief of the *Journal of Spinal Disorders and Techniques*, told *Spinal News International* that "The PEEK cage costs eight times more than the acrylic cage, but it did not lead to an improvement in fusion rates or clinical outcomes. While physicians should always strive to provide the best available healthcare to their patients, understanding the scarcity of healthcare resources is also critical. When two products offer equivalent outcomes, surgeons must consider the economics of each treatment when deciding which is best for their patients."

News in brief

European Commission clears pending Biomet–Zimmer merger

The European Commission has conditionally cleared Zimmer's proposed acquisition of Biomet.

The clearance is conditioned upon Zimmer entering into agreements with a suitable buyer to divest certain assets comprising the remedy package previously submitted to the European Commission. This annoucnement follows the recent clearance from the Japan Fair Trade Commission.

The transaction remains subject to clearance by the US Federal Trade Commission, as well as other customary closing conditions.

Zimmer will acquire Biomet in a cash and stock transaction valued at approximately US$13.35bn, including the assumption of net debt. Zimmer expects the deal to be completed in July.

Product News

SImmetry

Launch and first commercial use of updated Zyga SImmetry sacroiliac joint fusion system

Zyga Technology has announced the launch and first commercial use of an updated SImmetry sacroiliac joint fusion system. The surgery was performed by Brett Menmuir at the Reno Orthopedic Clinic in Nevada, USA.

"The ability to use sacroiliac joint fusion as a treatment modality is incredibly important for the effective management of my patients presenting with sacroiliac dysfunction," stated Menmuir. "What makes the SImmetry system unique is its ability to decorticate effectively within the joint, removing cartilage and debriding the articulating surfaces to create the optimal environment for arthrodesis and a successful clinical outcome."

First patient implant of Arena-C HA Enhanced cervical intervertebral body fusion device

The Arena-C HA with PEEK-OPTIMA HA Enhanced, manufactured by SpineFrontier, is a spinal implant device that is produced with a "revolutionary" new biomaterial to enhance spinal fusion technology. Jacob Rosenstein of USMD Hospital in Arlington, USA, used the implant in an anterior cervical discectomy and fusion procedure to treat a patient who was suffering from spinal cord compression and myelopathy as a result of degenerative disc disease that was producing severe cervical stenosis.

SpineFrontier says that PEEK-OPTIMA HA Enhanced shares all of the properties of PEEK-OPTIMA Natural, which aids in stabilising the cervical spine, but it has been compounded with hydroxyapatite (HA), a naturally occurring compound in bony structures. HA promotes the formation of a direct interface between the implant and bone, without intervening soft tissue. This is the first implant to be made with HA, and was approved for use by the Food and Drug Administration in October 2014.

Stryker Spine receives FDA clearance for new lumbar plating device

Stryker Corporation's Spine Division has received 510(k) clearance from the US Food and Drug Administration (FDA) for the LITe plate system, an anterior and lateral lumbar plate system. Comprised of five one-level, slim lumbar plates, the LITe system features the WingSpring locking mechanism, a high degree of screw angulation, and simplified instrumentation. This product adds to Stryker Spine's anterior lumbar interbody fusion (ALIF) portfolio, which also features Aero-AL and the LITe anterior retractor. Stryker says that Aero-AL is currently the only in-line chor-based ALIF device that compresses across the interbody.

The company has also launched a new anterior cervical plating system—Tempus. Featuring a secondary locking mechanism which offers visual and tactile confirmation, large graft windows, and a low 2.2mm profile design, Tempus complements Stryker's current offering of anterior cervical plates. Tempus is available in one to five level plating options with fixed and variable self-drilling and self-tapping screws.

joimax receives 510(k) clearance for Percusys pedicle screw-rod system

joimax's Percusys percutaneous pedicle screw-rod system has received 510(k) clearance from the US Food and Drug Administration (FDA).

The Percusys system is a multi-functional implant for use during spinal stabilisation procedures. Joimax says that its screw and instrument design enables a safer and more effective surgical technique with minimal steps for the surgeon. The single, small instruments allow flexibility to perform surgery through a percutaneous, minimally invasive or open approach.

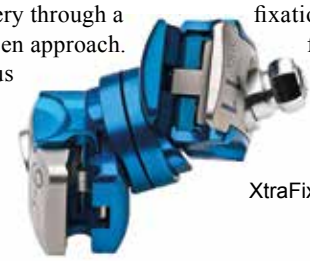
"During development, the main focus was on the ease-of-use of the system," says Frank Hassel, specialist for spine surgery from Freiburg, Germany, who was instrumental in Percusys' development. "The idea was to reduce the complexity in instrumentation and simplify stabilisation procedures to minimise the potential damage of soft tissues and improve overall patient outcomes."

Percusys implants comprise single-packaged, sterile, and pre-assembled pedicle screws with lengthening shaft and set-screw. All screws are colour-coded according to their diameter, cannulated, fenestrated, self-cutting and self-drilling. Each surgical step is carried out using the lengthening shaft, which is tightly connected to the tulip. The assembly allows for direct manipulation and does not require additional instrumentation. Shearing off the lengthening shaft can be done by a 360-degree rotation of the shaft breaker.

Zimmer debuts new modular external fixation system

Zimmer Holdings has announced its new, "more efficient" external fixation system for trauma patients.

Available in both small (6mm) and large (11mm) systems, the XtraFix external fixation system from Zimmer is a modular system that offers surgeons advances in design technology and materials. The XtraFix system allows surgeons to eliminate steps, as well as bars and clamps from the external fixation process, saving time, costs and energy.



XtraFix

"The design philosophy of the XtraFix external fixation system is based on increasing efficiency above all else," explained Nate Folkert, president, Zimmer Trauma. "Each component of the XtraFix system incorporates only the most useful features from the many different systems currently on the market and combines them into one time-saving and highly efficient device. It enables surgeons to build rigid external constructs using fewer components in less time."

The recently released small (6mm) system gives surgeons the ability to connect small and large systems with a single clamp. This transitional feature enables surgeons to accommodate small extremity fractures in larger constructs. In addition, the XtraFix 3D bar/pin-to-bar/pin design means pins can be placed where the fracture dictates, not the fixator, and flexible configurations means constructs require fewer components.

LITe plate system

Benvenue Medical signs group purchasing agreement With Novation for the Kiva treatment system

Benvenue Medical has signed a group purchasing agreement for the Kiva vertebral compression fracture treatment system with Novation. The three-year contract became effective in March, paving the way for Novation to offer the Kiva system.

The Kiva system was selected through the Novation Innovative Technology programme, which is designed to ensure that members have access to innovative health care technology. The process includes review by a clinical member council or task force to determine whether the technology represents incremental advantage for members. Benvenue Medical says that the Kiva system is the first clinically proven new approach to the treatment of vertebral compression fractures in over a decade.

Kiva clinical data submitted to Novation include a prospective, randomised, controlled clinical study comparing Kiva outcomes against those of balloon kyphoplasty. In addition, in multiple published studies comparing Kiva with balloon kyphoplasty, Kiva consistently improved patient outcomes in cement extravasation, cement volume and improvement in kyphotic correction. Kiva has also been shown to reduce the adjacent level fracture rate as compared with balloon kyphoplasty, as well as to significantly reduce the rate of readmissions relative to balloon kyphoplasty.

Tempus

Product News

FDA clears K2M Nile alternative fixation spinal system

K2M has received 510(k) clearance from the US Food and Drug Administration (FDA) to market the Nile alternative fixation spinal system for complex spinal deformity cases. K2M also received a CE mark for Nile.

Nile features low-profile implants and light ergonomic instruments intended to provide stabilisation between the spine and the rod, and to allow for reduction, translation, compression and distraction while sparing the anatomy. The Nile implants are comprised of bands, clamps and set screws designed to attach to titanium or cobalt chrome rods of various sizes and are also compatible with K2M's Mesa Rail.

The colour-coded Nile band is woven to provide strength and maintain structure, with exposed metal leaders attached on both sides. The low-profile clamps aim to assist compression and distraction along the rod, and provide versatility with independent band and rod locking mechanisms. The Nile Tensioner, inspired by K2M's patented Cricket technology, requires no assembly and also provides adjustable travel distance to allow for large reduction, as well as controlled, sequential reduction.

The first surgical case globally using this system was performed by Brian Hsu, at Westmeade Children's Hospital in Sydney, Australia, and the first surgical case in the USA using Nile was completed by Burt Yaszay, a paediatric orthopaedic surgeon, at Rady Children's Hospital in San Diego.

X-spine launches anterior lumbar standalone fusion system

X-spine Systems has announced the market launch of its US Food and Drug Administration-cleared, Irix-A lumbar integrated fusion system.

Incorporating "state of the art" biomaterials and manufacturing processes, Irix-A combines a polymer body with an integrated titanium ring for added strength and durability, a titanium plasma coating of bone-apposing surfaces and a resilient locking mechanism for screw fixation, according to an X-spine press release. Irix-A is implanted in an anterior approach at one or two contiguous levels of the lumbosacral spine (L2-S1 inclusive).

Meditech Spine Talos devices cleared by the FDA

Meditech Spine has received US Food and Drug Administration (FDA) 510(k) clearance to market the next generation of its Talos line of interbody devices. These cervical intervertebral fusion devices rely on the implantable polymer from Invibio Biomaterial Solutions, PEEK-OPTIMA HA Enhanced. The new material solution enables the medical device manufacturer to maintain the same design features of the existing implants.

The cages are intended for use in skeletally mature patients with degenerative disc disease of the cervical spine at one level from C2–T1. Talos-C (HA) cervical intervertebral body fusion devices are intended to be used with autologous bone graft to facilitate fusion. Meditech Spine says that PEEK-OPTIMA HA Enhanced as the novel material for these interbody cages contributes to the fusion process, as it is strong, versatile and based on PEEK-OPTIMA polymer compounded with hydroxyapatite (HA), an osteoconductive material for enhancing bone apposition.

Calendar of events

2–6 May
83rd AANS Annual Scientific Meeting
Washington, DC, USA
W www.aans.org

14–16 May
XXXVIII Congresso Nazionale SICV & GIS
Rome, Italy
W www.gis-italia.org

14–16 May
4th ISCoS and Asia Joint Scientific Meeting
Montreal, Canada
W www.iscosmeetings.org

20–23 May
AO Spine Global Spine Congress
Buenos Aires, Argentina
W www.gsc2015.org

22–24 May
International Spine Intervention Society 2015 European Congress
Vienna, Austria
W www.spinalinjection.org

26–28 May
31st Annual Meeting of the Cervical Spine Research Society-European Section (CSRS-ES)
London, UK
W www.csrs-london2015.com

27–29 May
16th EFFORT Congress
Prague, Czech Republic
W www.efort.org/prague2015

8–12 June
42nd ISSLS Annual Meeting
San Francisco, USA
W www.issls.org/annual-meetings/future-meetings

19–23 June
9th World Congress of the International Society of Physical and Rehabilitation Medicine
Berlin, Germany
W www.isprm.org

22–28 June
NSpine 2015: The Craniocervical to Cervicothoracic Spine
Nottingham, UK
W www.nspine.co.uk

8–11 July
22nd International Meeting on Advanced Spine Techniques
Kuala Lumpur, Malaysia
W www.srs.org/imast/2015

26–30 July
Spine Across the Sea 2015
Kohala Coast, Hawaii, USA
W www.spine.org/pages/events.aspx

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

Spinal News team

Editors-in-chief:
Professor Gunnar Andersson (USA)
Professor Afshin Gangi (France)
Dr Jean-Baptiste Martin (Switzerland)
Dr Alexis Kelekis (Greece)
Dr Kieran Murphy (Canada)
Dr Tarun Sabharwal (UK)

Publisher:
Roger Greenhalgh

Head of Publishing:
Marcio Brito

Editor:
David Brennan
dbrennan@bibamedical.com

Design:
David Reekie

Layout:
Tim Parker

Advertising:
Noora Lobo
noora@bibamedical.com

Subscriptions:
Susan Couch
susan@bibamedical.com

Please contact the *Spinal News International* team with news or advertising queries
Tel: +44 (0)20 7736 8788

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London, UK
SW6 5NR
Tel: +44 (0) 20 7736 8788
Fax: +44 (0) 20 7736 8283

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