ROUNDUP360

Spine

For other Roundups in this issue that cross-reference with Spine see: Oncology Roundup 3.

Standing straighter may reduce falls

Falls are an increasing problem in the ageing population. Not only do falls place patients at risk of fractures, but patients will often lose confidence and independence. Spinal pathology accounts for a number of potential explanations for falls, including radicular pain and neurological compromise. Researchers in **Nagoya (Japan)** set out to examine a less commonly implicated cause for falls, that of sagittal spinal alignment. The researchers investigated the effect of spinal sagittal alignment on the incidence of falls amongst a cohort of 100 patients, all of whom underwent measurements of spinal alignment, range of movement, balance, muscle strength and gait analysis in conjunction with a general medical examination and spinal radiographs. Subjects' balance was assessed using movement of the centre of pressure (COP) to produce an envelope area which give an objective measure of standing balance. Patients were noted to become more unsteady as they became older with a large envelope area, however, there was a negative correlation with lumbar lordosis and sacral inclination angles in those patients who had reportedly fallen over in the past year (n = 12). The fallers group were significantly older, with higher lumbar lordosis angle, sacral inclination angle, grip strength, back muscle strength, 10-m gait time, height of the intervertebral disc and osteophyte formation. The research team concluded (perfectly reasonably) that there are a range of factors, all of which contribute to falls in the elderly, but these all relate to maintenance of balance and stability. The novel factors identified all relate to the spinal sagittal alignment and raise the interesting prospect that interventions aimed at improving spinal alignment and balance may prevent falls.[1] Here at *360* our thoughts are with those elderly patients who are prone to falls. In recent years they have had to suffer the indignity of having their carpets and pets confiscated, footwear changed and even sometimes being obliged to use the not so fashionable hip defender; now it looks as if this isn't enough and they must also stand up straighter.

Operative management of congenital kyphosis

Kyphotic deformity is less well studied than the more common scoliosis. However, adolescents with severe kyphosis often suffer more respiratory complications and deformity than those with scoliosis. There is little evidence to guide the spinal surgeon in the selection of treatment options and as a benchmark for surgical outcomes. Surgeons in **Istanbul (Turkey)** aimed to evaluate the functional and surgical results of closing wedge osteotomy for these patients. They retrospectively evaluated the results of a series of ten patients who had previously undergone surgery with a closing wedge osteotomy and posterior instrumentation and fusion. The patients were a mean of 12.5 years (8 to 18) at the time of surgery, and the research team evaluated their radiographic outcomes (local kyphosis, correction, global kyphosis and sagittal balance) and complication rate. Patients were followed up for around five years and presented with around 70° of local kyphosis which was corrected (and stayed corrected) to around 30° post-operatively. By final follow-up, a correction rate of around 54% had been achieved with sagittal balance reducing to 20 mm post-operatively.[2] There were no serious complications (including neurological deficit, deep infection or deaths), however, there were a number of implant-related complications, including failure and loosening of screws. Closing wedge osteotomy with posterior instrumentation appears to be a safe and effective method for treating sagittal plane deformity in the adolescent spine.

Athletic discectomy

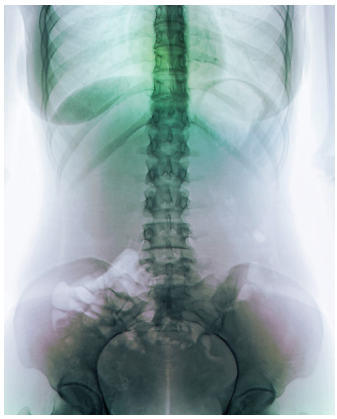
Like many other musculoskeletal diagnoses in athletes, disc herniation can be not only debilitating, but can inhibit, and be caused by, play. In serious, semi-professional and professional athletes, any time away from play is detrimental. Surgeons in **Sapporo (Japan)** make the case for microdiscectomy in athletes presenting with lumbar disc herniation, reasoning that this established procedure offers the benefits of rapid return to physical activity and alleviation of radicular type symptoms. Identifying that there are no previous reports of the technique in the athletic population, they report a retrospective series of 25 competitive athletes all presenting with a symptomatic lumbar disc prolapse who underwent microdiscectomy. Outcomes were assessed with the SF-36 and Japanese Orthopaedic Association (JOA) score. Of the 25 athletes, 92% returned to sporting activities, with the remaining two cases failing to return to sports for unrelated reasons. Of those who successfully returned to sports, the authors report that over 80% were able to return to their pre-morbid activity levels, whereas the remaining four patients were unable to do so due to residual pain. On average, athletes took ten weeks to return to pre-injury levels of sporting activity. Over the entire group, mean improvements were seen in the JOA score of over 80%, and there were significant improvements in all subscales of the SF-36.[3] This is probably a paper which ought to have been written some time ago. The authors report impressive results with an established technique in the highly demanding patient group of athletes. We are certain this won't change the practice of many clinicians as we are sure the majority of spinal surgeons are already offering microdiscectomy to athletic patients. However, while not new, it is heartening to see current practice does actually work.

Lumbar spine stenosis worsens with time

Despite the relative frequency of patients with lumbar spinal stenosis, there is a paucity of information concerning the prognosis, short- and long-term outcomes of the disease. Surgical epidemiologists in **Wakayama (Japan)** have reported a longitudinal cohort study to investigate the prognosis of conservatively treated lumbar spine stenosis. The research team designed a prospective evaluation of 34 patients, all of whom underwent diagnostic MRI scanning at the time of presentation. The patients were on average 58 years old at the time of presentation and all had received over a decade of conservative treatments (including advice, physiotherapy and medication, but not surgical decompression). The patients were followed up through use of the JOA score, VAS scores for pain, Johnson's classification and MRI scanning. During the course of the study, one patient was lost to follow-up and four died. Around one in three patients experienced improvement in their symptoms whilst 30% worsened. The investigators noted that the axial MRI scan recorded a significantly smaller dural sack diameter in the patients who failed to improve (less than 50 mm^2).[4] While conservative treatment is variably practised across the western world, it is heartening to see that not only can conservative treatment be successful in the majority of patients, but that these authors have provided an evidence base for selecting patients for conservative or operative treatment based on MRI graded spinal stenosis.

Flexible stabilisation?: spinal stenosis revisited

The Coflex device is not the first designed to maintain intervertebral height and relieve pain in spinal stenosis; the most recent foray into this implant segment is the X-Stop. Spinal spacers work by 'jacking out' the vertebrae to reduce nerve root impingement associated with spinal stenosis. Coflex has a slightly different design rationale to other spacers, and is designed to be used as a flexible fixation and spacer device after decompression in preference to posterior fusion. It is implanted to sit between the laminae and provide a 'flexible alternative' to traditional fusion. Up to two adjacent levels can be instrumented, however, as this is a modified spacer the risk of erosion of the lamina and posterior processes is still present. A collaborative multicentre randomised controlled trial originating in **Baltimore (USA)** was designed to test the safety and efficacy of Coflex interlaminar stabilisation as part of the FDA approval process. The study was designed to compare decompression plus either Coflex or standard posterior pedicle screw instrumented fusion in patients with stenosis or spondylolisthesis. The study team conducted a well designed randomised controlled trial (Level I evidence), to which they recruited 322 patients randomised in a 2:1 ratio. Patients were recruited over a four-year period from 21 sites across the USA. The primary outcome measure was the Oswestry Disability Index (ODI) with secondary outcomes of re-operation, device-related complications and recurrence of symptoms. The study team managed to follow up over 95% of patients in both groups. There was a non-significant difference favouring the Coflex group with regards to the primary outcome of ODI. Secondary outcomes of operative time and length of stay were significantly lower in the Coflex group. Both demonstrated significant improvements in VAS scores and ODI scores from baseline. Surprisingly, the Coflex group had a significantly different improvement in the secondary outcome measures of the SF-12 and all domains of the Zurich Claudication questionnaire when compared with the fusion group. Although there was a broadly similar adverse event rate between the two interventions, there was a non-significant elevated risk of re-intervention in the Coflex group (10.7% *versus* 7.5%) but improved adjacent segment motion at two years.[5] It certainly seems that not only has the Coflex system been



demonstrated not to be inferior to the current standard of care, but also there are some interesting potential benefits associated with the system. We await slightly longer-term follow-up with baited breath; after all, a fusion is usually a static operation, while problems with mobile segment stabilisations tend to occur at mid-term follow-up.

Do epidural steroids cause spinal fractures?

When you think about it, the practice of regularly injecting steroids into the locality of undoubtedly osteopenic bone in elderly patients with compressive radiculopathy may not be without its risks. However, the practice has, to our knowledge here at *360*, never been examined from a safety perspective, with sufficient numbers of patients to establish if there is a subsequent risk of lumbar vertebral collapse. This is precisely the question investigators in **West Bloomfield (USA)** set out to answer. They used a large retrospective comparative case series (Level III evidence) and were able to draw on the results of 50 354 patients with spinal diagnoses. Of these, 3415 patients were found to have received a lumbar spine steroid injection of one variety or another. The study group consisted of 3000 patients randomly selected from this cohort who were matched to a control group of patients, and there were no significant differences with respect to age, predicted propensity score, sex, race, hyperthyroidism, or steroid use. Outcomes were assessed as the incidence of subsequent primary vertebral fractures and a fracture-free survivorship analysis model was used to establish the risk of steroid injections and fracture.[6] This elegant little study effectively demonstrated that each successive injection increases the relative fracture risk by an odds ratio of 1.21 (95% CI 1.08 to 1.30). We applaud the authors for recognising for the first time this excessive risk of fragility fractures in the spine when steroid injections are used. We would wholeheartedly agree with the authors that the patients with high risk of fragility fractures should be approached cautiously when recommending steroid injections.

Who does well with cervical myelopathy?

Predicting outcomes for patients with cervical myelopathy is difficult, and spinal surgeons often counsel patients that they are operating to prevent progression, not to improve symptomatology. That said, many patients do in fact see a clinically significant improvement following decompression for spondylotic myelopathy. Researchers in **New York (USA)** designed a prognostic study with the aim of clarifying which patients do well, and which less so, following surgery for cervical myelopathy. The researchers examined a consecutive series of 248 patients, all of whom had a confirmed diagnosis of cervical myelopathy and underwent surgical intervention. Patients had a mean age of 59 years and the severity of myelopathy was graded using the Nurick grades. The authors undertook a comprehensive multivariant analysis and established that patients with Nurick grade 2 had the highest chance of symptom resolution and normalised gait following surgery. The factor predictive of little or no improvement was a long duration of symptoms, which was independent of the Nurick grade. Patients who improved most

had symptoms for only 11 months on average.[7] This useful study adds greatly to our understanding of cervical myelopathy, and in particular it seems to us here at *360* that in systems where there is significant healthcare rationing or long waiting times, patients presenting with symptoms of myelopathy should be prioritised to maximise their chances of a successful surgical outcome.

Secretly adverse to BMP-2?

In a rare foray into orthopaedic research and literature, the British Medical Journal has recently published a gem of a paper from **York (UK)**. Worried that there may be some bias in the recent industry-reported adverse events associated with rhBNP-2 in spinal fusion surgery, the study team set about establishing if the industry-reported efficacy and side effects profile was in line with data published elsewhere. The researchers used three different data sources: individual participant data, industry funded reports and other publically available data (conference and journal published reports). The manufacturer (Medtrong, Minneapolis, USA) provided the research team with individual participant data and their internal reports for all participants in commercially funded studies. Other data were identified through searching of indexed literature and conference abstracts. Outcome data were cross-checked between individual participant outcome data and outcomes reported in publications, while effectiveness data were evaluated through use of meta-analysis of randomised controlled trials from the three different data sources. The authors were unable to use this method for adverse events, so numbers and types of adverse events were simply compared between different data sources. The review included 32 publications, reporting outcomes from 11 of 17 manufacturer-sponsored studies. The randomised controlled trials reported between 56% and 88% of known effectiveness outcome data. The meta-analysis data presented by the authors in York demonstrated effectively identical outcome data for pain levels and fusion rates. Sadly, the majority of known adverse events were not reported in the reviewed journal articles. Less than a quarter of known adverse events (533/2302) were reported in the literature. The reporting of adverse events related to the infuse preparation was even poorer, with only around 11% of known adverse events reported.[8] The authors of this investigation conclude that a lot of data are not published and in the public domain. While randomised controlled trials are laudable and provide an evidence base for treatments we use, the data are only as good as the interpretation. It is disappointing, but not surprising, to us here at *360* that adverse events data appear to have been collated by the company and not shared with clinicians or patients.

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