



■ EDITORIAL

Thoracolumbar spinal treatment without screws

EXAMPLES OF CLINICAL PROFICIENCY

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Raymond Roy-Camille was the first to describe pedicle screw fixation of the spine.¹ In the mid-1960s, this was considered a radical deviation from normal spinal surgical practice. It took three decades for the notion of segmental fixation of the spine utilising the pedicles as an anchor point for screws that could be connected to rods or plates, to become widely accepted. From the mid-1990s onwards, increasing numbers of surgeons became trained in the use of sophisticated spinal implants and concomitantly, sales of spinal instrumentation rapidly increased. In 2015 the spinal implant market is estimated to be worth £7 billion a year worldwide, potentially growing to £10 billion by 2020 as the general trend continues for more instrumentation to be used across a wider range of pathologies.²⁻⁴

Good scientific evidence to justify the huge increase in the use of expensive implants has lagged behind the rapid expansion in the sector. For 30 years, there has been vigorous debate on the question of whether stable thoracolumbar burst fractures should be treated surgically at all. There is evidence on both sides, but the non-operative treatment argument is strongly supported by a considerable body of Level I evidence that makes it difficult for the surgical enthusiast to argue to the contrary.⁵⁻⁷ Modern, minimally invasive pedicle screw systems have been promoted as solutions to avoid some of the well-known problems of open fixation (infection, loss of muscle function, post-fixation pain, need for secondary surgery), but follow-up is short and there is still a dearth of clinical effectiveness and cost effectiveness evidence to support them.⁸

Surgical treatment for axial spinal pain has been, and remains, controversial except for a number of very well defined conditions, one of which is lytic spondylolisthesis.⁹ When Wiltse and Hutchinson¹⁰ described fusion for the condition, no instrumentation was ever discussed as none was available. Meticulous surgery including proper decortication of the transverse process / sacral ala, pars interarticularis

and facet joints with abundant cortico-cancellous bone graft taken from the posterior iliac crest laid over the decorticated surfaces was the benchmark operation. Since the mid-1990s there has been an increasing trend for this condition to be treated with pedicle screw instrumentation, often supplemented by interbody devices to provide a '360° fusion', but with less attention paid to the quality of posterior bone grafting. The argument for such majorly invasive treatment is that alignment of the spine is restored to the normal sagittal profile and the 'instability' inherent in the spondylolisthesis is stabilised. However, there is no convincing evidence that addition of instrumentation in single level fusions for low-grade slips is more effective than a well-executed uninstrumented fusion.¹¹ Despite this, the trend for more implants to be used, year on year, continues, often fed by the inventiveness of the engineer and the skill of the marketeer.

In this issue of the *Bone & Joint Journal*, there are two papers that describe treatments that buck the modern trend of instrumenting the thoracolumbar spine. The first¹² is an observational study examining the natural history of patients who have thoracolumbar burst fractures without neurological deficit. The patients were all encouraged to get up and walk as soon after their injury as pain allowed and return to activity as expeditiously as possible with minimal bracing, which acted only as a "reminder" that they had broken their spines. This could be described as a form of "benign neglect" - a concept that was widely accepted in many branches of medicine in the past, but one that has become increasingly discarded as defensive medicine has demanded that doctors intervene in all sorts of conditions without letting 'nature take its course'. The study is different from the mainstream because of its long functional follow-up of between two and 17 years. In addition, there are very few other published studies that use video evidence of patients doing press ups, sit ups and running across a sports field as outcome measures a few

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months after injury. More traditional patient-reported outcome measures (PROMs) were used for the final follow-up and they attest to the validity of this form of treatment in the long term. The authors quite correctly question the orthodoxy of surgical management of certain patterns of spinal fracture, given the evidence from theirs and previous studies that supports non-surgical treatment.

The second paper by Tsirikos et al¹³ describes the traditional Wiltse approach to single level, low-grade, lytic spondylolisthesis – uninstrumented postero-lateral fusion using autologous bone graft. There are two significant similarities between it and the paper from Jaffray et al;¹² an unfashionably long follow-up of between three and ten years and good clinical results with a low rate of complications. Neither of these is typical of many of the papers reporting the results of instrumented spinal fusions.¹⁴

The interested reader might ponder on the concept of “going backwards” as a way of getting to the future. In the case of these two studies, the spinal enthusiast would consider not using implants to treat the spine a retrograde step. The flip side of that argument has to be: show me the proof! For Jaffray et al’s patients with a fracture, rapid mobilisation was achieved (one argument for fracture fixation is rapid and safe mobilisation) and there were very good long-term outcomes, despite the persisting kyphosis (another argument for fixation is to correct the kyphosis to prevent long-term pain and disability). The evidence suggests that the long-term outcome of non-operative treatment for these fractures is better than surgical treatment and persisting kyphosis does not seem to have an adverse effect on pain many years after the injury.^{5,7} Therefore, fixation of the fractures could only have resulted in the same outcomes at best and poorer outcomes, secondary to probable complications of surgery, at worst. Equally, the spondylolisthesis patients recovered quickly, had excellent rates of fusion and in the majority of cases returned to completely normal function often including high-level sport. These results match the best outcomes from studies of instrumented fusion but with a much lower rate of complication.¹⁴

The clinical effectiveness of both treatments clearly has been established in these studies. In addition, there is a strong argument for cost effectiveness implied (but not explicitly defined) as neither group of patients needed expensive implants or extra treatment for complications. Therefore, these treatments might be considered clinically proficient. The prevailing mood is to define and increase value in health care, which means that both clinical and cost effectiveness are important.¹⁵ Porter’s definition of *Healthcare Value* is a relatively narrow metric consisting of *Quality / Cost*.¹⁶ A wider measure to understand not only the value in a treatment, but also its appropriateness, might also be described in terms of *Clinical Proficiency*, which would be defined as *Clinical Effectiveness / Cost Effectiveness*. The unit of measurement is of course already in wide use, that being the Quality Adjusted Life Year (QALY).¹⁷ Clinical effectiveness is crucially dependent upon PROMs¹⁸

and cost effectiveness on good economic and financial data.¹⁹ When it comes to spinal surgery in Britain, the British Association of Spinal Surgeons through the British Spine Registry (BSR)²⁰ has promoted the move towards universal PROMs collection, using a core dataset. The three core tools are: Visual Analogue Score for Back and Leg Pain (VAS), Oswestry Disability Index (ODI)²¹⁻²³ and the EQ-5D.²⁴

At a global level the International Consortium for Health Outcomes Measurement (ICHOM: www.ichom.org) has concurrently adopted the same core dataset for the longitudinal assessment of treatment for lower back disorders.²⁵ Should these initiatives be successful, it is anticipated that “Big Data” from national and international spinal registries will become widely available. If such data are to be used logically and appropriately to inform the decision-making processes of patients, Commissioners, clinicians and policy makers it must be carefully handled, and for which the inherent strengths and weaknesses within the registries must be recognised and accounted.²⁶⁻²⁸

In parallel with the anticipated increased involvement of spine care providers in registries that will provide clinical effectiveness data, there will also need to be a greater engagement in cost effectiveness and cost utility work to provide the information that defines the denominator of the Clinical Proficiency equation.⁴

To spinal surgeons who argue that a wide array of expensive implants are an unequivocal requirement in order to allow them to offer appropriate treatment to their patients with stable thoracolumbar fractures or single level low-grade lytic spondylolisthesis, Commissioners and the patients they represent should say: Prove it! If they cannot, options with established Clinical Proficiency such as non-operative treatment for such fractures and uninstrumented fusion for such slips should be the only treatments commissioned. Adopting Clinical Proficiency as a metric to assess healthcare appropriateness may provide cash-strapped budget holders with a decision-making tool that promotes logical allocation of scarce resources across a wide spectrum of interventions. It will be incumbent upon the clinicians who provide care, in collaboration with and funded by their managers in secondary care, to produce the data to support this process through universal engagement with registries and a much greater recognition of their role in the financial and budgetary aspects of healthcare delivery.

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