Dynamic Lumbar Stabilisation with an Interspinous Implant

a report by

Nick Boeree

Orthopaedic Spinal Surgeon, Southampton University Hospital

The concept of dynamic stabilisation of the lumbar motion segment using an interspinous device was first introduced by Professor Jacques Sénéga in the 1980s. His original first-generation implant comprised a titanium interspinous process spacer to accommodate load sharing and to limit extension. This was combined with two Dacron bands that controlled flexion movements. In contrast with other forms of instrumentation, this design required no direct fixation to bone, eliminating the risks of screw loosening or failure. Furthermore, since all anatomically important structures were preserved, the procedure was entirely reversible and preserved the entire range of alternative surgical options such as disc replacement and fusion. The survivorship of these first-generation implants has been impressive. A retrospective study of 142 patients who underwent surgery in France between 1987 and 1995 revealed that the actuarial survivorship of the implant was 84.1% at 10 years. In contrast with usual survivorship behaviour, the rate of failure actually decreased very notably with the passage of time. Furthermore, unlike multi-level fusion constructs, patients who underwent instrumentation of two or more levels fared no worse than those with single-level procedures.

Although these first-generation implants clearly fared well, conceptually it was considered that certain design changes might be advantageous. Alternative materials to titanium and slight changes in implant design offered the possibility of a modulus of elasticity closer to that of bone, providing potentially better stress shielding of the spinous processes. Similarly, a flatter band would distribute loads more effectively and could also be combined with an alternative, more controlled and consistent means of band tightening. These changes led to the second-generation implant, the Wallis stabilisation system.

Description of the Wallis Implant

The new interspinous spacer is fabricated from polyetheretherketone (PEEK), which has a modulus of elasticity very close to that of bone. Two spaces in the body of the implant also introduce a small degree of compressibility. The two flat Dacron weave bands are anchored at corresponding spinous process. To secure the bands back to the implant, the Wallis stabilisation system.

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Clinical Applications

In treating primary discogenic back pain, the Wallis system can be used to provide stability and support in degenerative lumbar lesions of Pfirrmann grade IV or less with or without Modic 1 bone changes. In more advanced degenerative disease, with marked loss of disc height and significant annular disruption, the motion segment is unlikely to benefit from the load sharing and support provided by the implant. The Wallis system should also be considered in patients presenting with very large disc protrusions (with or without a history of back pain), since in these situations the significant loss of nuclear material is likely to destabilise the disc. For the same reason, the implant is also indicated in cases of recurrent disc protrusion.

Patients with a partial or complete sacralisation of L5 who present with a disc protrusion at L4/5 are also likely to benefit from the stability and stress protection at this level provided by the Wallis implant. Sacralisation of L5 transfers additional stress to the L4/5 level, increasing the risk for these patients of future low back pain if left unprotected. In a similar vein, the Wallis implant can be used adjacent to a fusion ("top-off"), particularly if the level concerned shows evidence of some early
Degenerative change. This can effectively save levels in the lumbar fusion procedure. Furthermore, the implant provides an alternative to extending a fusion in patients presenting with symptomatic degenerative disease adjacent to a previous fusion, although again the use of the Wallis system should be limited to Pfirrmann grade IV or less.

The Wallis system can be used with benefit in cases of canal stenosis, where undercutting procedures are likely to destabilise. The use of the interspinous spacer will augment any decompressive procedure, helping to open up the lateral recess and the neural foramina. Contraindications include osteoporosis (–2.5 or greater) and any situation in which the posterior arch is deficient or unstable. This will include pars defects, previous laminectomy and spina-bifida occulta. While the device can be used with minor degrees of degenerative spondylolisthesis (1–3mm), it would be inappropriate to rely on the device in the more unstable advanced slips. The particular anatomy at L5/S1, where the spinous process of the sacrum is usually low and oblique, is generally unsuitable for safe implantation of the Wallis device.

A prospective, single-arm, open study of the second-generation implant is under way in eight centres in Europe, South America and Africa. Preliminary results are very promising. Most notably, the overall visual analogue scale (VAS) pain reported by patients improved from 7.0 (±2.1) pre-operatively to 1.1 (±1.5) at one year. Functional improvement was considerable, as indicated by significant improvements in the Oswestry Disability Index (ODI), which improved from a mean of 57 pre-operatively to 10 and his ODI from 54 to 15. These results were maintained at two years (radiographs and magnetic resonance imaging (MRI) scans). Further scans at one year (right picture) at the same sagittal section show that disc height has been maintained and that there has been some improvement in T2 signal return from the affected disc.

Case 1 – a 23-year-old woman presented with a history of two years of intermittent but at times quite severe low back pain. This had required courses of non-steroidal anti-inflammatory medication and physiotherapy treatment and a lumbar steroid epidural without any lasting benefit. His radiographs and scans are shown in Figure 2. Discectomy was clearly required, but several factors placed this patient at higher risk with respect to increasing symptoms of low back pain. However, given her age and taking into account her loss of one motion segment due to the sacralisation of L5, the author was reluctant to consider a fusion.

Wallis stabilisation was undertaken in 2002. The patient has had a very satisfactory outcome in terms both of her sciatica and her history of back pain. She reported mild episodes of low-back pain, requiring very occasional analgesia over the first year, but this improved as she was able to start exercising and reducing her weight. At her last review she continued working and reported that she has “forgotten about her back”.

Case 2 – in 2002 a 55-year-old light manual worker presented with a two-year history of significant back pain, which he considered represented about 70% of his overall problem, the remaining 30% comprising left-sided sciatica. He had no neurological symptoms or signs except for his leg pain. He had been moved to lighter duties but had been unable to work for the four months prior to presentation, during which time he underwent physiotherapy treatment and a lumbar steroid epidural without any lasting benefit. His radiographs and scans are shown in Figure 3. It was considered by the author that fusion was required at L5/S1 and discectomy at L4/5, but in an attempt to avoid extending the fusion to include this level Wallis stabilisation was undertaken at the same time as the posterior lumbar interbody fusion (PLIF) at L5/S1. The patient made a good recovery, returning to light duties after four months and to normal duties at eight months. At one year he reported mild, intermittent low-back pain. His VAS improved from 75 to 10 and his ODI from 54 to 15. These results were maintained at two years (radiographs and magnetic resonance imaging (MRI) scans). After which point he declined further review but indicated that he had no on-going back problem.
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Discussion

Safety

The Wallis stabilisation system exposes the patient to very little additional risk or operative morbidity compared with procedures such as discectomy or decompression and is certainly far less destructive and invasive than alternative procedures such as fusion or disc replacement. The safety of the procedure has been confirmed in a multicentre study in which there were a low number of post-operative complications necessitating revision procedures. Among the 262 patients in this study, only 11 of the implants have been removed, including three replaced by another Wallis. The first-generation Wallis retrospective findings provide further evidence of the innocuous nature of the system. The system obviates bony purchase such as pedicle screws to secure the implant in place, reducing both the risk and seriousness of any complications. Pedicle screws are a significant cause of complications in posterior fusion procedures. Dynamic stabilisation systems that rely on pedicle screws have high rates of toggling-related screw loosening and screw breakage. This is not surprising since, in such systems, the screws will continue to be subjected to repetitive loading. Revision procedures in such situations are complicated and compromised by screw failure. In contrast, it will be appreciated that with the Wallis system, even if structural failure of the implant were to occur (which in fact is almost unknown), the failure mode is safe and does not compromise any options, including a revision Wallis procedure or some alternative surgery.

Reversibility

When a Wallis has to be removed or replaced by another Wallis, the revision procedure is straightforward. The procedure is fully reversible, leaving other surgical possibilities open, including fusion and disc replacement. Revision of failed fusion or disc replacements is much more difficult and risky.

Pain Relief

The clinical efficacy of the implant against pain is supported by the observed significant post-operative improvement in VAS pain scores. This is further reflected in the excellent functional recovery and the marked reduction in analgesic usage.

Adjacent Segment Preservation

The finite element model predicts that the Wallis system should not affect the mechanical loading of adjacent segments. There should therefore be a much lower risk of symptomatic adjacent level disease compared with the rate seen in fusion procedures. The evidence available thus far confirms this to be the case. In a series of lumbar fusion patients with more than five years follow-up, Gillet reported a 20% rate of revision surgery to extend the arthrodesis to adjacent segments. At levels adjacent to fusion, Ghiselli et al. reported a re-operation rate of 16.5% at five years and 36.1% at 10 years in 215 patients who had undergone posterior lumbar arthrodesis. The latter figure is almost double the rate of all revisions for all causes combined in the long-term retrospective Wallis study, at a follow-up interval of between 10 and 18 years. This clearly suggests a much lower rate of adjacent level degeneration. Disc replacement has been shown to be at least as effective against low-back pain as fusion, but is often preferred in view of its putative protective action against adjacent level degeneration. However, a factor to consider is growing concerns that some disc designs may contribute to facet joint changes. In contrast, in view of the unloading effect the Wallis system has on the facet joints, many users have begun applying it to patients with facet joint syndrome with good clinical results. This was not among the predetermined indications specified for the Wallis International Study.

Potential Disc Restoration

Although it is still too early to determine whether the treated disc tissue actually heals, there is good MRI evidence of disc rehydration at follow-up. Improvement in the T2 weighted signal is seen in approximately 50% of paired MRI studies. This is likely to be a reflection of the off-loading of the discs.

Conclusion

There are a number of matters that deserve emphasis with the Wallis stabilisation system. Perhaps of primary importance for surgeons and patients alike will be the good clinical results that are seen with this technique. The results obtained thus far demonstrate that the efficacy of the new implant is at least as good as that of fusion. No doubt a contributory factor in those good results, and certainly a matter taken into account by patients and clinicians, is the simple, minimally invasive and low-risk nature of the surgery. Benefits that come with these advantages are a short hospital stay, quick recuperation and an early return to work. Long-term advantages derive from the anatomically conservative nature of the surgery, which means that, while the procedure will offer support and protection to the existing motion segment, all surgical options are still preserved for the future should they become necessary. As a result, Wallis stabilisation represents a real alternative for many young patients with symptomatic degenerative disc disease for whom fusion, or even a disc prosthesis, might seem too radical or associated with unacceptable uncertainties in the longer term. This technique is rapidly being adopted by surgeons as part of the growing spectrum of surgical techniques for lumbar degenerative disorders.

Figure 3: Case 2 Radiographs and Scans

Pre-operative MRI scans are shown on the left. His radiographs and MRI scans at two years following PLIF at L5/S1 and Wallis stabilisation at L4/S are shown on the right.

References

Protection

The Wallis implant is a highly innovative non-fusion technology used to treat low back pain associated with degenerative instability of intervertebral motion segments.

Designed to provide support in both flexion and extension, the implant unloads both the disc and facet joints while maintaining lumbar lordosis. As the Wallis procedure preserves anatomy, it is reversible and leaves all future surgical options open.