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Pain Relief and Intervertebral Disc Rehydration Following Wallis[®] Interspinous Device Implantation: a Case Report.

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ABSTRACT

Introduction: Degeneration of the lumbar motion segment is the primary cause of low back pain in many individuals. Therefore, new minimally invasive treatments are being sought.

Patient Profile: A 47-year old man presented with severe low back pain and radicular symptoms of several years duration. Lumbar MRI revealed severe desiccation, loss of disc height, and an annular tear with right lateral disc protrusion at L4-5.

Interventions/Outcomes: After conservative treatment failed, the patient received a Wallis[®] interspinous spacer at the affected level. 100% subjective pain relief was obtained at 3 months post-op. Nucleus pulposus rehydration on MRI was observed.

Discussion: Controversy exists over whether disc dehydration is a reliable indicator of low back pain; however, interspinous spacers seem to alter abnormal motion segment's biomechanics in a way that results in alleviation of low back pain and increased range of motion. With the advent of biologic therapy, this may provide an intriguing minimally invasive treatment modality, although further research is needed.

INTRODUCTION AND PATIENT PROFILE

Degeneration of the lumbar motion segment is the primary cause of low back pain in many individuals. This not only includes intervertebral disc degeneration, but facet joint abnormalities as well. This is generally understood to be due to increased axial and torsional forces over an extended period of time, similar to the development of arthritis in other joints.¹⁻⁴ Beyond conservative therapies, the standard of care has generally been instrumented fusion. However, fusion surgery has many drawbacks, such as a long recovery period, loss of work productivity, lack of symptom resolution, and adjacent-level degeneration. More recently, disc arthroplasty has been implemented, with clinical results showing better symptom resolution, faster return to work, and less co-morbidity when compared to traditional lumbar fusions.^{5,6}

The Wallis[®] interspinous implant (Zimmer Spine, Austin, TX) was developed as an alternative to these more invasive procedures. Whereas disc arthroplasty utilizes an anterior approach through the abdominal cavity, implantation of the Wallis[®] is done through a small posterior incision with minimal damage and risk to surrounding tissues. The device is a spacer made of polyether ether ketone (PEEK) and is inserted into the interspinous space of the degenerated motion segment. Two stabilizing bands are subsequently looped around the adjacent spinous processes and secured to the device (Figure 1). Results of the first-generation Wallis[®] device, with a titanium spacer and used in Europe during the 1980s, showed favorable outcomes regarding pain relief and increased physical functioning.^{7,8} The newest generation system, which is made of the PEEK material, has been used to a great extent in Europe over the past decade with good results.⁹ This report documents our experience with one patient in particular who received this device.

A 47-year old male patient presented to our clinic with severe low back and right leg pain that had been ongoing for nearly eight years. He denied any precipitating trauma, bowel/urinary incontinence, or saddle paresthesia. His Oswestry Disability Index (ODI), a validated tool measuring how low back pain interferes with one's daily activities, was 52, and he had a lumbar Visual Analog Scale (VAS) of 75mm and a right leg VAS of 60mm. The VAS is a 100-millimeter line that a patient places a mark on indicating pain severity, with 0 being none and 100 being the worst. Physical examination demonstrated tenderness to palpation in the lumbar paraspinal region and full strength and intact sensation in the lower extremities. Straight leg testing was negative. Lumbar MRI revealed severe disc desiccation with minimal loss of disc height and an annular tear and right lateral disc protrusion at the L4-5 level.

INTERVENTIONS AND OUTCOMES

After undergoing several months of conservative treatment with no symptom resolution, it was decided to pursue non-fusion surgical treatment by enrolling the patient into a clinical trial comparing the Charité™ artificial disc to the Wallis® system. The enrollment and entire study process was approved by the Western Institutional Review Board.

The patient was randomized to receive the Wallis® device, which was implanted at the L4-5 level without complication in the manner described by Sénégas.⁷ While the patient did have a disc protrusion seen on imaging, no discectomy was performed at the time of surgery. He was seen at 6-week, 3-month, 6-month, and 12-month follow-up visits in accordance with study protocol. At each of those visits ODI and VAS questionnaires were administered. The patient's condition had dramatically improved to the point where he was no longer taking narcotic or non-

narcotic medications for pain management at six weeks post-op, and by three months post-op his ODI and VAS scores had returned to zero and he reported he was subjectively pain-free.

In addition, upon review of the patient's protocol-mandated two-year MRI, we noticed an interesting phenomenon regarding the treatment level. Whereas the pre-operative MRI documented rather severe desiccation of the nucleus pulposus of the L4-5 disc (Figure 2), the two-year post-operative MRI demonstrated increased T2 signal intensity at the central and posterior portion of the nucleus (Figure 3), indicating rehydration of the disc space. We also noticed the previously visualized disc protrusion seemed to have diminished slightly. What makes this case unique is that no other patients at our study site developed disc rehydration, although several had similar clinical improvement, and the trial itself did not include disc rehydration as primary or secondary endpoints.

DISCUSSION

Remarkably, this is not the first documented instance of disc rehydration following insertion of an interspinous stabilization device. S negas has published multiple articles on the Wallis[®] system, and found that a significant number of patients receiving the device demonstrated increased disc rehydration on MRI.¹⁰ A recently published paper also notes that the MRI scans of several patients showed improvement in Modic grades as well as disc rehydration.¹¹

Currently there is controversy over whether disc dehydration is a reliable indicator of discogenic back pain and if rehydration adequately correlates with improvements in a patient's pain and function, and if interspinous spacers should be the preferred treatment option. A recent review article by Gazzeri, et al. posits that there is insufficient evidence for or against placement

of an interspinous device for the treatment of lumbar stenosis, and that laminectomy may be a better treatment option, although its study in patients without stenosis is limited.¹² Nonetheless, it seems that interspinous spacers alter the abnormal motion segment's biomechanics in a way that results in symptom alleviation. Our theory to explain the improvement noted on imaging studies of these patients is based on the idea that these devices reduce load on the intervertebral disc and facet joints, which allows cartilaginous cells in the disc to properly begin the self-healing process. It has been demonstrated that excessive loads on the intervertebral disc can limit the healing properties of intervertebral chondroblasts, and can even lead to further degeneration.¹³ Another paper also showed that biomechanical stresses can diminish proteoglycan synthesis in the disc, and ultimately play a role in the intervertebral disc self-repair mechanism.¹⁴ In addition, another study showed that interspinous spacers can reduce intradiscal pressures.¹⁵ S en eg as demonstrated that the Wallis[®] system also decreases biomechanical stress on the intervertebral disc⁷, and similar results were replicated.¹⁰

After reviewing the literature and comparing our own experience with the Wallis[®] device, especially in this single patient, it appears that interspinous spacers may be a viable treatment for certain indications of low back pain due to degenerative disc disease. Some possible weaknesses to this device exist, however; one rare event in particular, also seen with a similar spacer called the X-Stop[®], is the device loosening and backing out of the interspinous spacing, causing severe pain and movement restriction requiring removal.¹⁶

With the recent advent of biologics technology, an intriguing treatment for degenerative disc disease might emerge. For example, the combination of interspinous spacers such as the Wallis[®] device with an intradiscal injection of the patient's own marrow-derived stem cells with associated growth factors could prove to be a beneficial, minimally-invasive treatment. Possible

therapies such as these are certainly worth investigating in the near future, particularly as clinical trials on the efficacy of minimally invasive treatments utilizing biologics begin to provide the scientific spine community with reasonable data.¹⁷⁻¹⁸

LEARNING POINTS

1. Low back pain, while multifactorial, often can be due to degeneration of the lumbar motion segment secondary to repetitive use, trauma, or inflammation.
2. Interspinous spacers have shown promise in treating discogenic back pain by altering the abnormal biomechanics of the motion segment and alleviating strain on the intervertebral disc and supporting structures.
3. Intervertebral disc rehydration may indicate healing of an injured disc and subsequent pain relief, and may provide an avenue for focused regenerative treatment.
4. With the advent of biologic technology, new therapies combining these minimally invasive techniques may provide a better treatment for selected cases of low back pain.

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TABLES AND FIGURES:



Figure 1. Wallis[®] device shown in lumbar motion segment model. Lateral view (left) and posterior view (right).

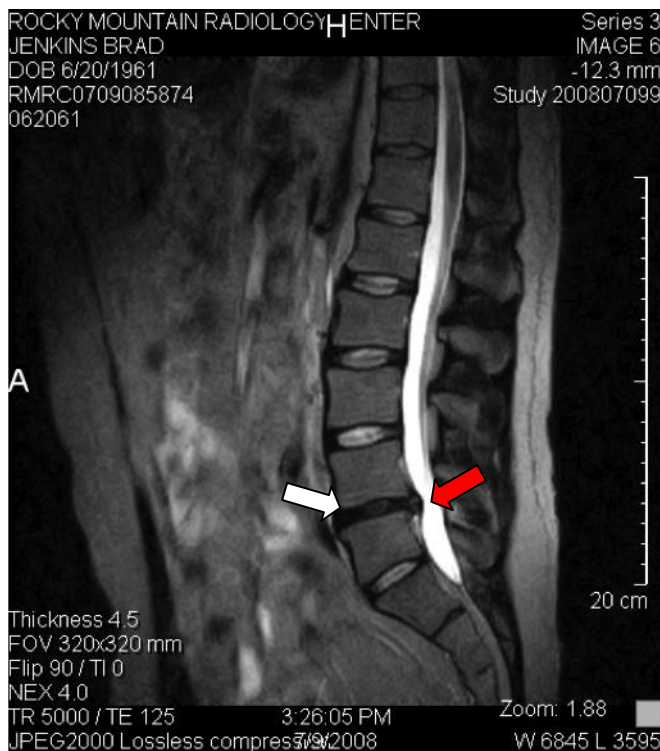


Figure 2. Pre-operative MRI. Note the dessication at L4-5, with loss of T2 signal intensity throughout the nucleus pulposus (white arrow). The posterolateral disc protrusion can be seen as well (red arrow).



Figure 3. 24-month MRI. The nucleus pulposus of the L4-5 disc shows distinct rehydration (white arrow). The Wallis[®] device can be seen in the L4-5 interspinous space (red arrow).