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ORIGINAL ARTICLE

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Mechanical supplementation by non-rigid fixation in degenerative intervertebral lumbar segments: the Wallis system

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Abstract A first-generation implant for non-rigid stabilization of lumbar segments was developed in 1986. It included a titanium interspinous blocker and an artificial ligament made of dacron. Following an initial observational study in 1988 and a prospective controlled study from 1988 to 1993, more than 300 patients have been treated for degenerative lesions with this type of implant with clinical and mechanical follow-up. After careful analysis of the points that could be improved, a second-generation implant called the "Wallis" implant, was developed. This interspinous blocker, which was made of metal in the preliminary version, is made of PEEK (polyetheretherketone) in the new model. The overall implant constitutes a "floating" system, with no permanent fixation in the vertebral bone, to avoid the risk of loosening. It achieves an increase in the rigidity of destabilized segments beyond normal values. The clinical trials of the first-generation implant provided evidence that the interspinous system of non-rigid stabilization is efficacious against low-back pain due to degenerative instability and free of serious complications. The first-generation devices achieved marked, significant resolution of residual low-back pain. These results warrant confirmation. A randomized clinical trial and an observational study of the new implant are currently underway. Non-rigid fixation clearly appears to be a useful technique in the management of initial forms of degenerative intervertebral lumbar disc disease. This method should rapidly assume a specific role along with total disc prostheses in the new step-wise surgical strategy to obviate definitive fusion of degenerative intervertebral segments. At present, the Wallis system is recommended for lumbar disc disease in the following indications: (i) discectomy for massive herniated disc leading to substantial loss of disc material, (ii) a second discectomy for recurrence of herniated disc, (iii) discectomy for herniation of a transitional disc with sacralization of L5, (iv) degenerative disc disease at a level adjacent to a previous fusion, and (v) isolated Modic I lesion leading to chronic low-back pain.

Keywords Non-rigid fixation · Degenerative lumbar disc · Low-back pain

Introduction

We began studying and developing non-rigid stabilization of lumbar segments in 1984, because at that time it was already clear that the progress achieved in these techniques in other joints of the locomotor system would sooner or later be applicable to the joints of the vertebral column. The current continued use of intervertebral fusion procedures, which totally eliminate mobility, cannot be attrib-

uted solely to insufficient mastery of spinal prosthesis techniques or ligament reconstruction. Spinal surgeons also continue to use fusion because of the unique organization of the intervertebral articulations forming a kinetic chain. This multi-articular system provides the capacity to compensate relatively well for damage to a single segment, regardless of whether such lesions result from a degenerative process or surgical fusion.

From 1984 to 1986, we carried out biomechanical cadaver studies, mechanically testing various non-rigid systems of stabilization of lumbar intervertebral segments. Ultimately, we opted for a "floating" system with no bony fixation, because it is illusory to hope for durable functioning of a system that includes, for example, pedicle screw fixation. The system that we developed and first implanted in 1986 included a titanium interspinous blocker and an artificial ligament made of dacron. The results of an initial observational study were published in 1988 and 1991 [6, 7]. This was followed by a prospective controlled study from 1988 to 1993 [8]. Since then, more than 300 patients have been treated for degenerative lesions with this type of implant, with clinical and mechanical follow-up.

Despite satisfactory findings and the absence of serious complications, the initial device was never commercially developed while waiting for assessment of long-term results. Finally, after careful analysis of the points that could be improved, we have developed a second-generation implant called the "Wallis" implant, which is awaiting use with a maximum of precautions. A randomized clinical trial and an observational study of the new implant are currently underway.

Basic concepts

As in any dynamic system, a mobile intervertebral segment undergoes acceleration inversely proportional to the moment of inertia when it is submitted to a force. The rigidity of the system limits the displacement. This braking action preserves a margin of security and helps protect against tissue lesions involving the disc or the intervertebral ligaments. "Rigidity" is a mechanical parameter defined in terms of load for a given displacement. It corresponds to the slope of the load/deformity curve.

The stretching of the elements of articular union leads to a force resisting the displacement. The dissipation of kinetic energy in the form of heat is mediated by the viscoelastic properties of the connective tissue (passive damping). This damping phenomenon would, in fact, be quite insufficient to protect the disc if it were not constantly supplemented by a much more effective active damping provided by the reflex contraction of the powerful paravertebral muscles. Although the dynamic equilibrium of the intervertebral articular system is dependent on a combination of muscle activity and tension of the passive elements of union, the active system constantly protects the passive elements, which consequently are never submitted to the limits of their elasticity under normal conditions.

Under these specific mechanical conditions, the intervertebral disc cells that produce the extracellular matrix exhibit normal activity. These cells are, in fact, mechanodependent, as demonstrated by Lotz and Chin [2]. They function normally only under a precise range of mechanical loading. Outside of this range, they initiate apoptosis. When loading is excessive or the active system of damping is deficient, the passive system represented by the disc and intervertebral ligaments can be overloaded and rupture. If these lesions are not excessively severe, or if the lesional process takes place over time analogously to stress fractures, cell activity can repair the damage, as is the case in any connective tissue. However, when the constraints persist, the reparative process can be overwhelmed, and irreversible degenerative lesions develop if the loss of rigidity persists. Laxity or a diminution in the rigidity of an intervertebral segment is constant in the degenerative process, as demonstrated by Ebara et al. [1] and Mimura et al. [3]. This is true regardless of the stage of degeneration. At the beginning of the degenerative process, before alteration of the disc height, an increase in the range of motion is observed on bending studies because of the greater laxity. When the disc lesions are more severe, intervertebral mobility is reduced because of the narrowing of the disc space. However, mechanical testing shows that the system is still less rigid than normally, the decrease being reflected by an increase in the neutral zone.

Basically, nonetheless, the disc tissue, notably the annulus, has healing capacity, as do all connective tissues. In fact, an indisputable healing process can be observed in the intervertebral disc, with a fibroelastic reaction and neovascularization, at least at the beginning of degenerative lesions. However, the persistence of excessive mechanical loading leads to the failure of this healing process, similar to that observed in pseudarthrosis of long bones or in meniscal lesions.

The principle of mechanical supplementation by nonrigid fixation consists in both increasing the rigidity of the intervertebral system and limiting the amplitude of mobility to stop the irreversible course of the degenerative lesions, and possibly, in some cases, to foster the healing of the least severe lesions.

The Wallis implant

We believe that it is not possible to rigidify all joint elements of the intervertebral segment with a simple system. In designing the implant (Fig. 1, Fig. 2), we decided to supplement only damping of the motions of flexion and rotation. We chose to limit extension with an interspinous blocker, which is intended to act as a posterior shock absorber. This interspinous blocker, which was made of metal in the preliminary version, is now made of PEEK

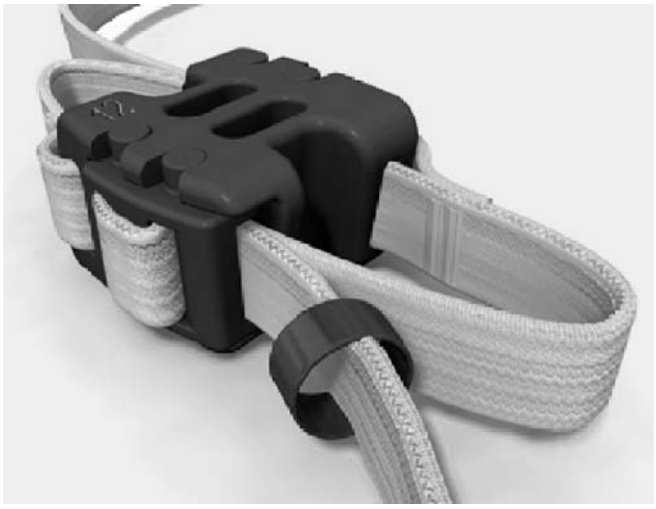

Fig. 1 The non-rigid fixation "Wallis" implant

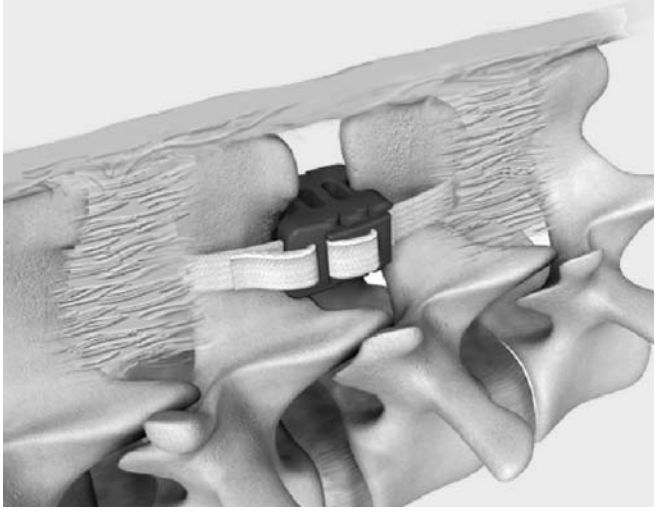

Fig. 2 Schematic view of the Wallis implant in place

(polyetheretherketone) in the "Wallis" model. Thanks to its shape and the properties of PEEK, the new blocker has much greater elasticity (the PEEK blockers are 30 times less rigid than the former, titanium, model). Moreover, the use of an interspinous blocker confers substantial mechanical advantages, as shown by Minns et al. [4]. When the spinal column is submitted to loading, the interspinous blocker displaces the mechanical constraints dorsally and reduces the load upon the disc and the facet joint system (by as much as 50% for a blocker 12 mm in thickness).

In addition, the implant includes two ligaments made of woven dacron that are wrapped around the spinous processes and fixed under tension to the blocker. This is facilitated by the design of the implant and dedicated instrumentation. The ligaments resist traction of 200 daN and stretch approximately 20% before failure by overloading.

The overall implant constitutes a "floating" system with no permanent fixation in the vertebral bone, which might otherwise expose it to the risk of loosening. As yet unpublished mechanical human cadaver studies conducted on the implant have shown that it permits a reduction in the mobility of intervertebral segments previously destabilized by discectomy and that it achieves an increase in the rigidity of the destabilized segment beyond normal values.

Furthermore, animal studies have shown that it was possible to obtain fibrous healing of a disc space after total discectomy by use of non-rigid fixation, whereas in the absence of fixation, only complete destruction of the intervertebral tissue is observed.

Clinical results

From 1988 to 1993, we carried out a non-randomized prospective controlled study comparing two homogeneous groups of patients, both of which underwent surgery for recurrence of herniated disc after an initial L4-L5 discectomy [8]. One group was treated by a second discectomy alone (group A), whereas the other group underwent discectomy and implantation of the first-generation device. Before the second intervention, all patients underwent neurologic examination, assessment of pain on a visual analog scale, and a functional evaluation using the Oswestry score. The preoperative radiologic work-up included conventional X-rays and dynamic bending films in all patients, as well as myelography followed by computed tomography, or, in most of the patients, magnetic resonance imaging (MRI). There were 40 patients in each group. At follow-up, the same clinical assessments that were obtained preoperatively were performed again, and MRI was obtained systematically. The mean follow-up after the intervention was 3 years and 4 months (range 1 year to 4 years and 8 months).

Group A (discectomy alone) included 26 men and 14 women, the average age of whom was 41 years (range 22–58 years). Twenty-eight of these patients (70%) had no motor deficits. Among the remaining 12 patients (30%), seven (17%) had a motor deficit evaluated at 3 or 4 on the ASIA scale, three (7.5%) had a deficit of 2, and two (5%) had a deficit of 0 to 1. In every case, patent recurrence of herniated disc was observed during the operation. The following complications were observed in group A: two superficial infections, four cases of intraoperative dural tear, and, subsequent to one of the latter, one infectious meningitis, which healed without sequelae.

Two patients in group A were reoperated because of chronic low-back pain. They underwent lumbar fusion. A neurostimulation device was implanted in one patient who had constant pain.

Group B (discectomy and implant) included 29 men and 11 women, the average age of whom was 42 years

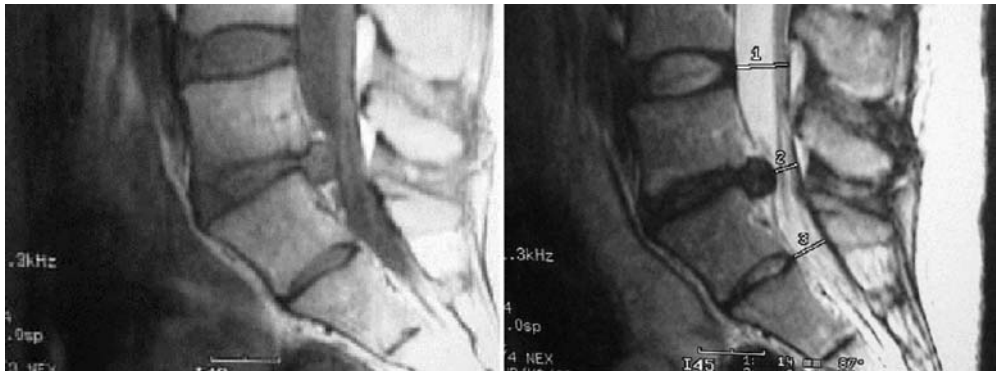

Fig. 3 Recurrence of herniated disc

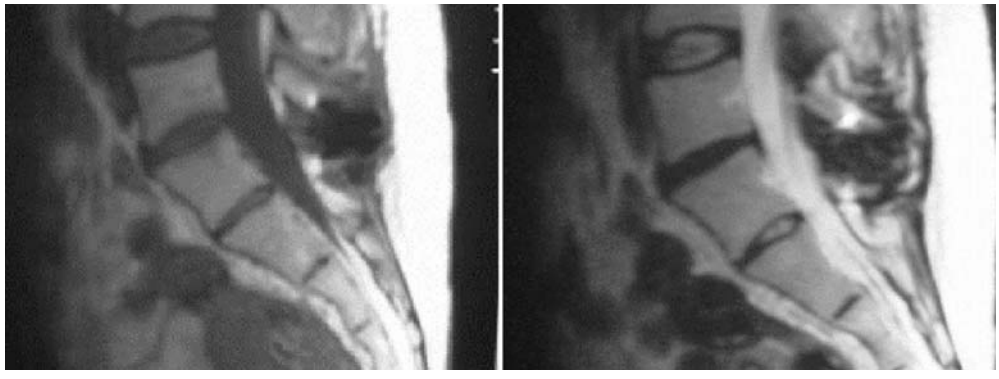

Fig. 4 Magnetic resonance imaging aspect 11 years after non-rigid fixation

(range 25–62 years). In 20 patients (50%), there was no detectable motor deficit before the second intervention. Among the remaining patients, 14 (35%) had a motor deficit evaluated at 3 or 4 on the ASIA scale, five (12.5%) had a deficit of 2, and one (2.5%) had a deficit of 0 to 1. In 38 patients, we found a patent recurrence of disc herniation, and in two cases, the nerve-root compression was caused by migration of biocompatible osteoconductive (hydroxyapatite) polymer that had been inserted in the disc space during the initial intervention.

The complications in group B were essentially limited to dural violation (seven cases) with no resulting adverse consequences. No case of infection or worsening of neurologic deficit occurred. None of the spinous processes was fractured and none of the dacron ligaments failed.

Three patients in group B underwent revision surgery, one for persisting low-back pain 3 months after the procedure. The revision operation showed that the ligament was loose due to failure of the system of fixation to the metallic blocker. Arthrodesis was performed after removal of the implant. In two patients, a second revision operation was necessary after a new recurrence of disc herniation in the same segment. In one, the implant was easily removed after discectomy and arthrodesis was performed. In the other patient, after decompression, the implant was left in place with a satisfactory result. In all three of these revision procedures, the excellent tolerance of the implant was confirmed. The non-rigid fixation device was found embedded in a homogeneous fibrous mass with no sign of inflammatory reaction.

Analysis of clinical results

The percentage of improvement in low-back pain over the preoperative VAS score was 52% at follow-up in group A (discectomy alone) and 74% in group B (discectomy and implant). Nerve root pain was improved by 87% in group A and by 92% in group B.

At follow-up, 20% of the patients in group A were no longer taking analgesic medication, as opposed to 42.5% in group B. The Oswestry functional score in group A changed from 54.7 (SD ±16) preoperatively to 22 (SD ±11) at follow-up. In group B, the mean preoperative score was 58.2 (SD ±22) and 16.4 (SD ±10) at follow-up.

In the patients who received the implant, we studied the course of the instability of the segment involved using dynamic bending films. The preoperative disc space height varied from 2 to 10 mm. In eight patients, a postoperative diminution in disc height was observed (mean 2 mm) and in three patients, an approximately 3-mm ventral displacement of the cephalad adjacent vertebral body was noted with no correlation to the clinical outcome of these patients.

The angle of flexion-extension mobility varied from 0° to 12° (mean 5°). In four patients, the angle of mobility was greater than 10°.

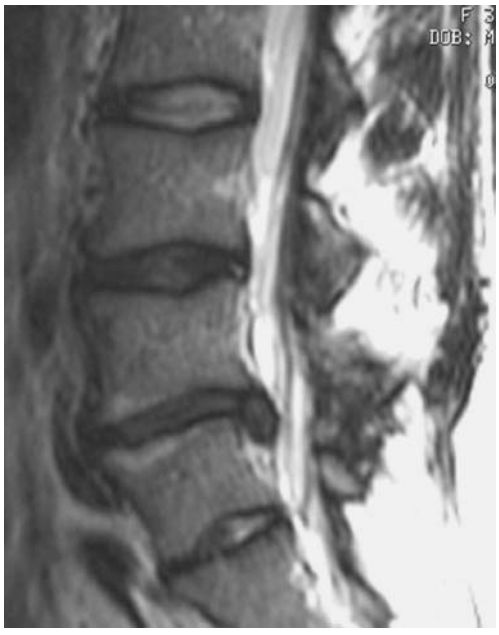

Fig. 5 Recurrence of herniated transitional disc at L4-L5 (due to sacralization of L5)

Postoperative analysis of the MR images (Fig. 3, Fig. 4) showed marked improvement in the bony lesions on both sides of the operated disc. In six cases, exacerbation of adjacent disc lesions was visible.

Discussion

The clinical trial results of the first-generation implant provide evidence that the interspinous system of non-rigid stabilization is efficacious against low-back pain due to degenerative instability, while remaining technically straightforward to implement and free of serious complications. Moreover, in case of failure, removal of the implant poses no technical problem, and revision by arthrodesis, if necessary, has proven to be simple.

The first-generation devices achieved marked, significant resolution of residual low-back pain. The functional improvement assessed using the Oswestry score was less marked, because it fails to distinguish between nerve-root pain and purely low-back pain.

We believe that these results warrant confirmation and that they can be improved by use of the second-generation implant, concerning which two clinical trials are currently underway.

Non-rigid fixation clearly appears to be a useful technique in the management of initial forms of degenerative intervertebral lumbar disc disease. This method should rapidly assume a specific role along with total disc prostheses in the new step-wise surgical strategy to obviate definitive fusion of degenerative intervertebral segments.

At present, we consider that the Wallis system can be used for lesions of grade II, III, and IV in the MRI classification proposed by Pfirrmann et al. [5] in the following indications:

- Discectomy for voluminous herniated disc leading to substantial loss of disc material
- A second discectomy for recurrence of herniated disc
- Discectomy for herniation of a transitional disc with sacralization of L5 (Fig. 5, Fig. 6)
- Degenerative disc disease at a level adjacent to a previous fusion
- Isolated Modic I lesion leading to chronic low-back pain

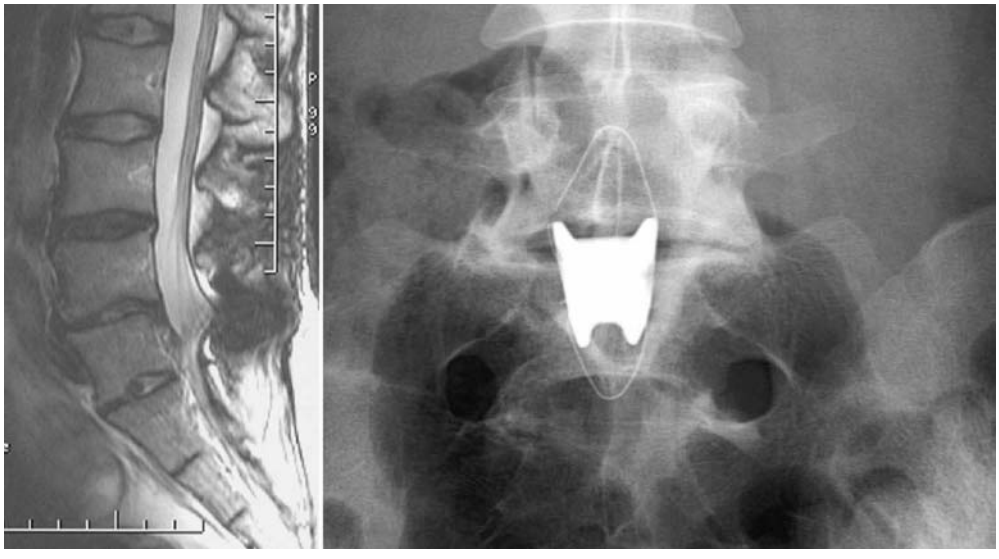

Fig. 6 Same patient as in Fig. 5, 8 years after discectomy and non-rigid stabilization (first-generation implant with titanium blocker)

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