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ORIGINAL ARTICLE

Does Wallis implant reduce adjacent segment degeneration above lumbosacral instrumented fusion?

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Abstract Delayed complications following lumbar spine fusion may occur amongst which is adjacent segment degeneration (ASD). Although interspinous implants have been successfully used in spinal stenosis to authors' knowledge such implants have not been previously used to reduce ASD in instrumented lumbar fusion. This prospective controlled study was designed to investigate if the implantation of an interspinous implant cephalad to short lumbar and lumbosacral instrumented fusion could eliminate the incidence of ASD and subsequently the related reoperation rate. Groups W and C enrolled initially each 25 consecutive selected patients. Group W included patients, who received the Wallis interspinous implant in the unfused vertebral segment cephalad to instrumentation and the group C selected age-, diagnosis-, level-, and instrumentation-matched to W group patients without interspinous implant (controls). The inclusion criterion for Wallis implantation was UCLA arthritic grade <II, while the exclusion criteria were previous lumbar surgery, severe osteoporosis or degeneration >UCLA grade II in the adjacent two segments cephalad to instrumentation. All patients suffered from symptomatic spinal stenosis and underwent decompression and 2–4 levels stabilization with rigid pedicle screw fixation and posterolateral fusion by a single surgeon. Lumbar lordosis, disc height (DH), segmental range of motion (ROM), and percent olisthesis in the adjacent two cephalad to instrumentation segments were measured preoperatively, and postoperatively until the final evaluation. VAS, SF-36, and Oswestry Disability Index (ODI) were used. One patient of group W developed pseudarthrosis: two patients of group C deep infection and one patient of group C ASD in the segment below instrumentation and were excluded from the final evaluation. Thus, 24 patients of group W and 21 in group C aged 65+ 13 and 64+ 11 years, respectively were included in the final analysis. The follow-up averaged 60 ± 6 months. The instrumented levels averaged 2.5 + 1 vertebra for both groups. All 45 spines showed radiological fusion 8–12 months postoperatively. Lumbar lordosis did not change postoperatively. Postoperatively at the first cephalad adjacent segment: DH increased in the group W ($P = 0.042$); ROM significantly increased only in group C (ANOVA, $P < 0.02$); olisthesis decreased both in flexion ($P = 0.0024$) and extension ($P = 0.012$) in group W. The degeneration or deterioration of already existed ASD in the two cephalad segments was shown in 1 (4.1%) and 6 (28.6%) spines in W and C groups, respectively. Physical function (SF-36) and ODI improved postoperatively ($P < 0.001$), but in favour of the patients of group W ($P < 0.05$) at the final evaluation. Symptomatic ASD required surgical intervention was in 3 (14%) patients of group C and none in group W. ASD remains a significant problem and accounts for a big portion of revision surgery following instrumented lumbar fusion. In this series, the Wallis interspinous implant changed the natural history of ASD and saved the two cephalad adjacent unfused vertebra from fusion, while it lowered the radiographic ASD incidence until to 5 years postoperatively. Longer prospective randomized studies are necessary to prove the beneficial effect of the interspinous implant cephalad and caudal to instrumented fusion. We recommend Wallis device for UCLA degeneration I and II.

Keywords Adjacent segment degeneration · Wallis · Lumbar fusion · Disc degeneration

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Introduction

Lumbar fusion has been used to reduce persistent conservative treatment axial back pain and/or segmental instability. Decompression and fusion in symptomatic degenerative spondylolisthesis (grades I, II) has been followed by very good functional results [49]. Furthermore, wide decompression for significant symptomatic spinal stenosis often associated with the loss of segmental lumbar lordosis may jeopardise segmental stability of the lumbar spine that makes an additional stabilization mandatory.

Although instrumented lumbar spine fusion is a commonly performed procedure, its role remains debated, and moreover, delayed complications may occur, amongst which is adjacent segment degeneration (ASD).

Adjacent segment degeneration describes nearly any abnormal process that develops in the mobile segment next to a spinal fusion and although the exact mechanism remains uncertain, altered biomechanical stresses (hypermobility, olisthesis, disc height (DH) loss, instability) appear to play a key role in its development [4, 16, 19, 30, 33, 34, 39, 47]. Although several clinical and radiological criteria have been introduced to define segmental spinal instability there is no consensus as regard its definition.

Although most often the criteria to determine ASD are based solely on radiographic findings [2, 7, 19, 28, 30, 34, 39, 41, 59] reporting an ASD incidence ranging from 8 to 100%, the symptomatic incidence of ASD is significantly lower ranging from 5.2 to 18.5% [7, 28, 31], while the rate of re-operation rate for symptomatic ASD ranges from 2.7 to 20% [16, 58].

There is a controversy regarding the risk factors involved in the development of ASD [2, 11, 12, 22, 28, 40, 41, 47, 57–59]. Non-rigid, dynamic or flexible instrumentations for lumbar spine have been developed to reduce ASD [17, 18, 27]. These implants are either fixed in the pedicles, or secured between the spinous processes of adjacent vertebrae [38, 48]. Long-term results showed several significant drawbacks and implant-related complications in the non-rigid pedicle fixed instrumentations [18, 54].

The interspinous process implants, that are currently used for the treatment of neurogenic Claudicatio, reduce pathologic extension at the symptomatic spinal levels and intradiscal pressure and facet load, preventing narrowing of the spinal canal and neural foramens [36, 46, 59, 61].

Amongst these interspinous process implants a "second" generation implant for non-rigid stabilization of lumbar segments, called Wallis system, has been developed [48]. A recent in vitro biomechanical and finite-element analysis of the Wallis showed that this implant reduces motion without suppressing it and lowers stress in the disc fibres and annulus matrix [32].

The hypothesis of this prospective randomized comparative study was if the Wallis interspinous implant, inserted in the unfused segment cephalad to instrumented lumbar fusion, could reduce the incidence of ASD.

Materials and methods

From May 2001 to March 2002, we carried out a prospective controlled study comparing two consecutive homogenous groups of 25 consecutive patients each, who underwent surgery for degenerative spinal stenosis, spondylolisthesis, loss of segmental lordosis or combined in the same period. Group W included patients who received the Wallis implant in the unfused segment cephalad to pedicle screw instrumentation and group C patients without interspinous implant, who were selected subsequently to match the characteristics of the patients of group W and were used as controls. All 50 patients, who were initially enrolled in this study were treated with the wide decompression and posterior transpedicular rigid fixation and fusion. All surgeries were performed by the first author who is a senior spine surgeon. The surgeon was unaware preoperatively that patient was going to be included in each group to avoid bias in patient's selection. The ethics committee of this institution approved this study.

The *inclusion* criteria were the following degenerative spine disease (spinal stenosis, spondylolisthesis, loss of segmental lordosis), 2–4 instrumented vertebrae and fusion in the lumbar and lumbosacral spine, modified arthritic UCLA scale grade $\leq$II [15] without olisthesis or lytic lesion in the cephalad the instrumentation segment, and informed consensus.

The *exclusion* criteria were the following: severe osteoporosis, loss of lumbar lordosis [28], previous lumbar surgery–fracture, lack of motion (ankylosis), UCLA > II arthritic grade in the adjacent segment cephalad to instrumentation, spondylolisthesis, and acquired spinous process insufficiency.

The *radiographic* criteria for ASD in the cephalad segment above to instrumentation were the development of olisthesis, disc collapse, increased segmental range of motion (ROM), deterioration (>grade II) of modified UCLA arthritic grade (Table 1) [15, 19, 30, 33, 47].

The *clinical* criteria for ASD were the worsening of low back pain, despite radiographic solid fusion in the instrumentation area and the absence of any surgery-related complication. In this study, the vertebral segment cephalad to instrumented fusion was selected for several documented reasons: (1) this is the most frequent localisation of ASD [3]; (2) symptomatic ASD in the lower lumbar and

Table 1 Arthritic grade for intervertebral disc degeneration

	UCLA grading for intervertebral space degeneration		
	Disc space narrowing	Osteophytes	Endplate sclerosis
I	(−)	(−)	(−)
II	(+)	(−)	(−)
III	(+/−)	(+/−)	(−)
IV	(+/−)	(+/−)	(+)

Grade is based upon the most severe radiographic evident on plain radiographs

(+ present, − absent, +/− either present or absent)

lumbosacral instrumented fusion is very rare (<3%) [15]; and (3) with exception of few studies, all clinical and biomechanical studies address cranial segment degeneration following the rigid lumbar/lumbosacral instrumentation [39].

All patients were clinically assessed preoperatively and postoperatively with the SF-36 (physical function domain) and Oswestry Disability Index (ODI) score and the pain magnitude with Visual Analogue Scale (0–10 scale, VAS). The preoperative radiological work-up included conventional standing whole spine roentgenograms (lumbar lordosis, and DH and UCLA grading in the cephalad segment), sitting lateral dynamic bending films to measure olisthesis and ROM and supine oblique views for spinal fusion determination. The radiological parameters that were measured preoperatively to the latest evaluation included: T_{12}–S_1 lumbar lordosis, ROM (flexion and extension) in degrees of the vertebral segment immediately cephalad to instrumentation, olisthesis of the vertebra cephalad instrumentation (in flexion and extension), anterior and posterior standing DH.

As instability was defined as any sagittal translation of the adjacent vertebral body above fusion greater than 3 mm and/or angle change greater than 10° between two adjacent vertebrae.

CT scans, MRI were made in most, but not in all cases and thus were not included in the evaluation of the ASD changes as others also quite recently did [52]. The radiographic changes were evaluated by a senior orthopaedic radiologist and spine surgeon who did not participate in surgery and thus did not know to which group each patient belong.

Surgical technique and Wallis interspinous implant

The second generation Wallis implant, that was used in this study is a interspinous blocker, which is made of PEEK (polyetheretherketone). Due to its shape (Fig. 1) and the properties of PEEK, the implant has much greater elasticity (30 times less rigid than titanium) than the first generation titanium implant. 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. Wallis (Abbot, USA) is fixed to the spine by two polyester bands looped around the proximal and distal spinous processes of the instrumented level and reattached to the spacer by means of two clips that are visible on plain radiographs. Four implant sizes (10, 12, 14, and 16 mm) are available to fit individual interspinous distances. While during the surgical procedure, the smallest size that had sufficient stability on the two laminae is chosen to avoid reduction of lumbar lordosis [42]. Wallis confers substantial mechanical advantages [32]: 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. The Dacron 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 in the risk of loosening. Mechanical human cadaver studies [48] have shown that Wallis 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. There is no implant for the L5/S1 segment and thus it cannot be used below a L4/L5 fusion [63].

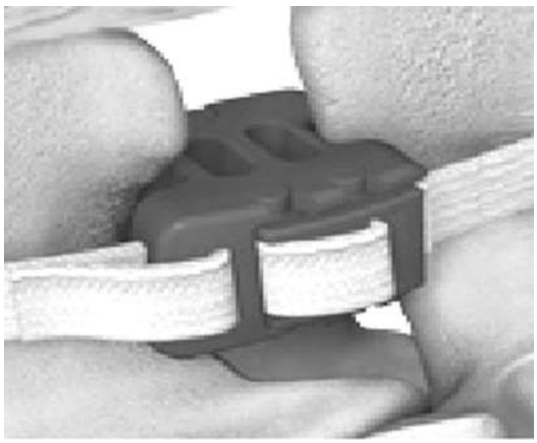

Fig. 1 The Wallis implant

Rigid pedicle screw instrumentation was used in this series for both groups. Care was taken to avoid to harm the facet joints adjacent to instrumentation (avoidance opening of facet joint capsule and lateral insertion of the pedicle screws. For technical reasons (too narrow space between spinous process and pedicle screw tulips), the Wallis device was inserted immediately after pedicle screw insertion and decompression; then the longitudinal rods were assembled after appropriate contouring. In all patients

were used autogenous local bone derived from decompression and decortication mixed with coralline HA (50:50) for posterior and intertransverse fusion.

One-way ANOVA was used to show the changes of each parameter in a group and *t* test for differences in a parameter between the two groups.

Results

Four patients were excluded from the final evaluation for different reasons: one patient of group W for pseudarthrosis; two patients of group C for deep infection that required re-operation and one patient of group C for ASD in the segment below instrumentation.

Twenty-four patients of group W and 21 patients of group C, who showed radiological fusion 8–12 months postoperatively were included in the final evaluation. The age of the patients of groups W and C averaged 65 ± 13 years (range 32–72 years) and 64 ± 11 years (range 33–71 years), respectively.

The instrumented levels in both groups averaged 2.5 ± 1 (range 2–4).

The Wallis was most often inserted in the L_3/L_4 segment in 14/24 cases of group W, while the adjacent segment cephalad to instrumentation was the L_3/L_4 in 15/21 cases of C group.

The follow-up observation averaged 54 ± 6 months.

T_{12}–S_1 lordosis (Fig. 2) did not postoperatively change until the final evaluation in any group, while no difference between individuals of different groups was shown in all periods of observation (W group, ANOVA, $P = 0.35$ vs. C group, ANOVA, $P = 0.41$).

Standing anterior DH (Fig. 3) did not postoperatively change in W group (ANOVA, $P = 0.26$) and C group (ANOVA, $P = 0.69$).

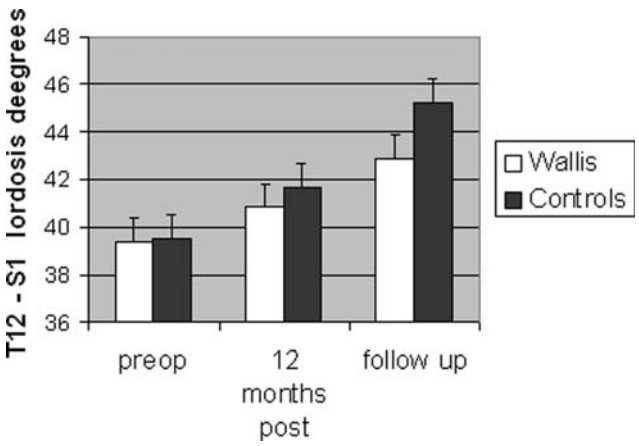

Fig. 2 Comparative plotting of T_{12}–S1 lordosis changes preoperative to the last evaluation

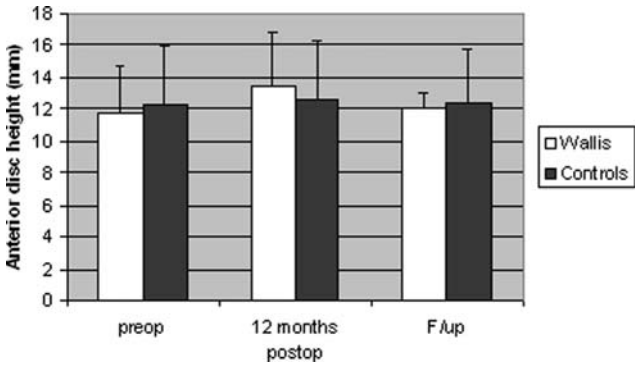

Fig. 3 Changes of anterior disc height (mm) preoperatively and postoperatively to the latest evaluation

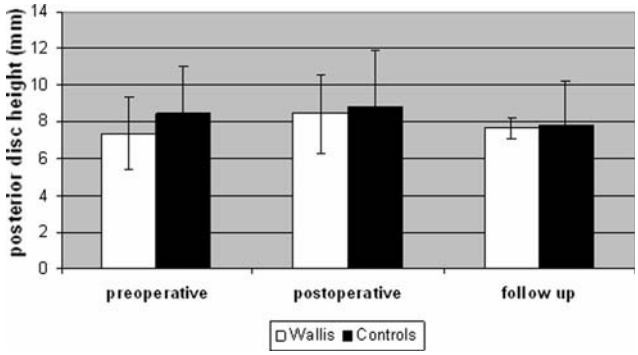

Fig. 4 Changes of posterior disc height (mm) preoperatively and postoperatively to the latest evaluation

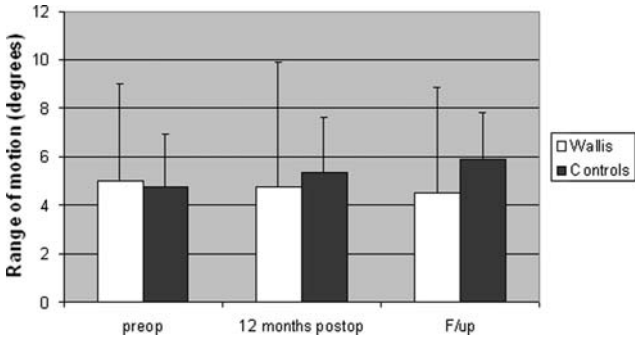

Fig. 5 Range of motion in the cephalad segment above instrumentation

Standing posterior DH (Fig. 4) increased immediately postoperatively ($P = 0.042$) in the W group, while it did not change in the C group ($P = 0.44$).

The ROM (Fig. 5) at the cephalad to the instrumentation segment did not significantly postoperatively change (ANOVA, $P = 0.5$) in the W group, while it significantly increased at final evaluation (ANOVA, $P < 0.02$) in the spines of the group C.

Wallis decreased significantly ($P = 0.0024$) the percent amount of olisthesis in flexion of the vertebra cephalad to instrumented spinal segments a year postoperatively, while

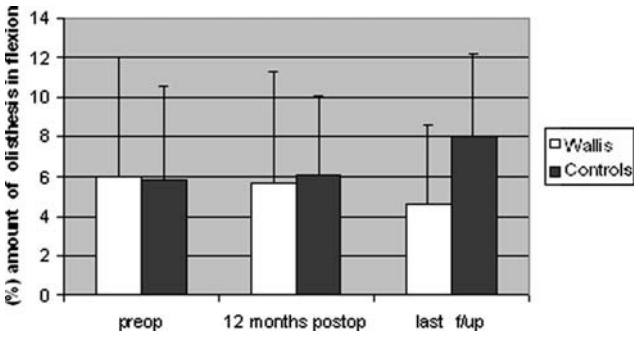

Fig. 6 Percent amount of olisthesis in flexion preoperatively to the last evaluation. Wallis decreased significantly ($P = 0.0024$) the percent amount of olisthesis

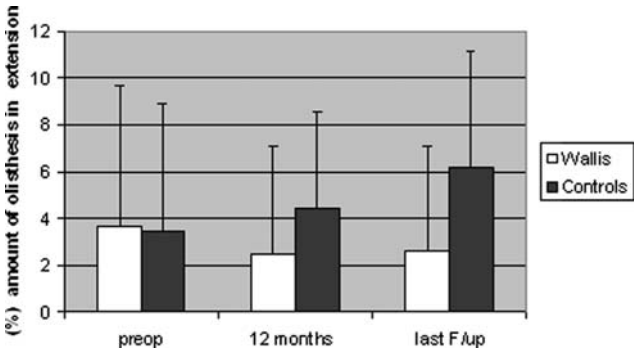

Fig. 7 Percent amount of olisthesis in extension preoperatively to the last evaluation. Wallis decreased ($P = 0.012$) the amount of olisthesis in extension

it insignificantly ($P = 0.31$) decreased at the final evaluation (Fig. 6).

Wallis decreased postoperatively significantly ($P = 0.012$) the amount of olisthesis in extension (retrolisthesis) of the cephalad instrumentation vertebra one-year follow-up postoperatively (Fig. 7), while it remained unchanged at the final evaluation ($P = 0.28$).

Physical function domain (SF-36) improved ($P < 0.001$) postoperative (1 year) in an equal amount in the patients of both groups (Fig. 8). At the last evaluation, there was a statistically significant ($P = 0.05$) difference in favour of the patients of W group.

Oswestry Disability Index decreased significantly ($P < 0.005$) in an equal amount in the patients of both groups a year postoperatively (Fig. 9). At the final observation, there was a significant difference ($P < 0.05$) in ODI score in favour of the patients of W group.

Visual Analogue Scale score (lumbar spine) averaged preoperatively 7.2 ± 2.1 and 7.4 ± 3 in the patients of groups W and C, respectively, and improved postoperatively to 3 ± 2 and 3.6 ± 3 in groups W and C, respectively.

Degeneration or deterioration of already existed low-grade degeneration (UCLA $\leq$ II) in the adjacent segment cephalad to instrumentation was shown in 1 (4.1%) and 6

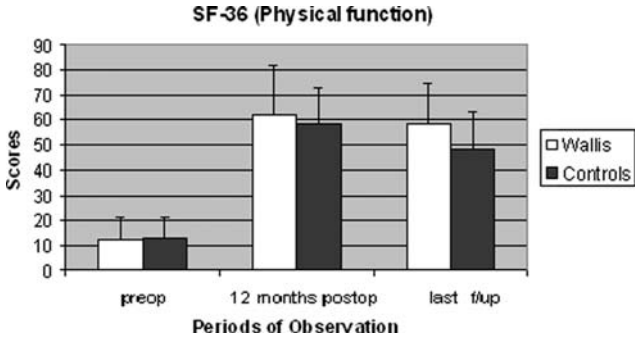

Fig. 8 SF-36 (physical function domain) changes preoperative until the final evaluation

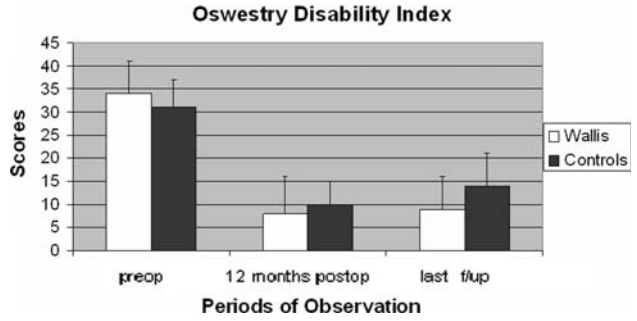

Fig. 9 ODI changes preoperatively to the last evaluation

(28.6%) spines in W and C groups, respectively. The levels involved in ASD are shown in Table 2.

Symptomatic ASD required surgical intervention was shown in 3 (14%) patients of group C with UCLA grade-IV degeneration (disc space narrowing, osteophytes and end-plate sclerosis) (Table 1; Figs. 10, 11, 12) in the first cephalad segment, while no patient from group W needed intervention (Figs. 13, 14, 15) (Table 3).

Complications

In one patient of group W and two patients of group C accidentally occurred intraoperatively dural violation that was immediately sutured without further problems.

Two patients of group C developed deep infection in the early postoperative phase (6–12 days postoperation) that required re-operation (wound drainage and continuous irrigation plus intravenous antibiotics).

Table 2 Levels of ASD in above instrumentation segments

Group	Segment		
	L2–L3	L3–L4	L4–L5
Wallis	0[a]	1[a], 1[b]	0[a]
Controls	1[a], 1[b]	4[a], 4[b]	1[a], 1[b]

[a] One level above instrumentation

[b] Two levels above instrumentation

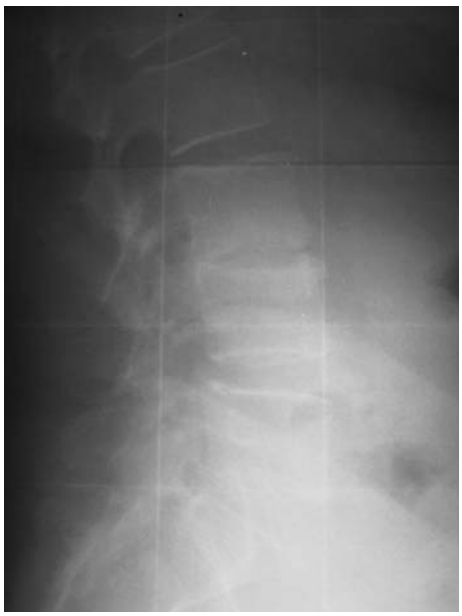

Fig. 10 Standing lateral roentgenogram of a 60-year-old female patient suffering from degenerative disc disease L3/L4

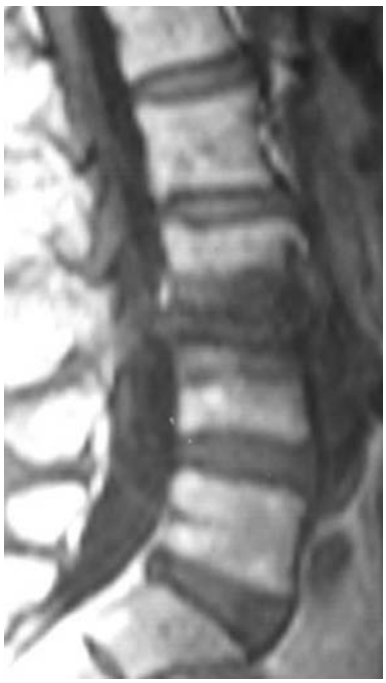

Fig. 11 Lateral MRI view showing severe degeneration in the segment L3/L4 of the patient of Fig. 10

In one patient of group W and one of group C, there were observed incidentally at the final observation remote simple osteoporotic compression fractures (AO type A1.1.1) 4 and 5 levels cephalad to instrumentation. These fractures were not linked to any known trauma and were clinically silent.

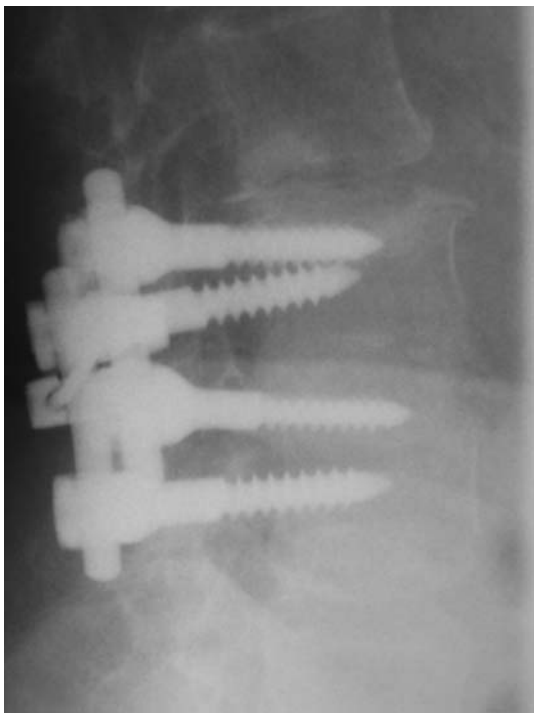

Fig. 12 Lateral roentgenogram of the patient of Figs. 10 and 11, 34 months postoperatively showing collapse of this disc. No interspinous implant was inserted at the L2/L3 segment. This patient was revised because of intractable pain 38 months postoperatively

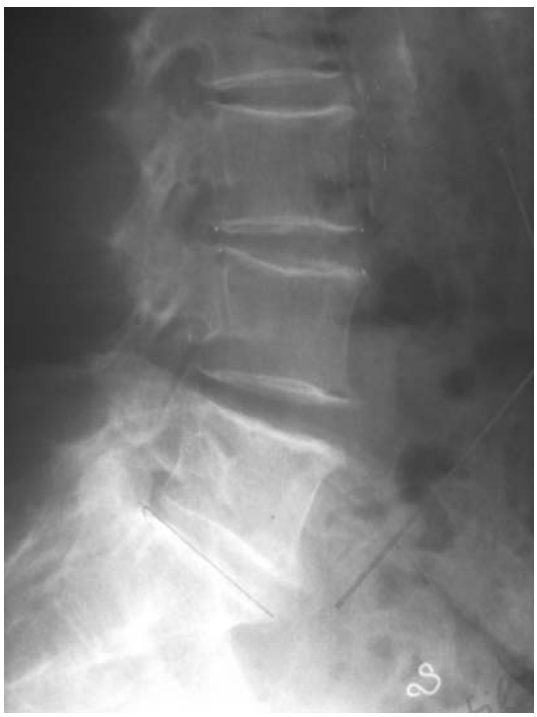

Fig. 13 Lateral roentgenogram of a 58-year-old female patient with degenerative disc disease and disc herniation at the segment L4/L5. UCLA degeneration II at the L3/L4 segment

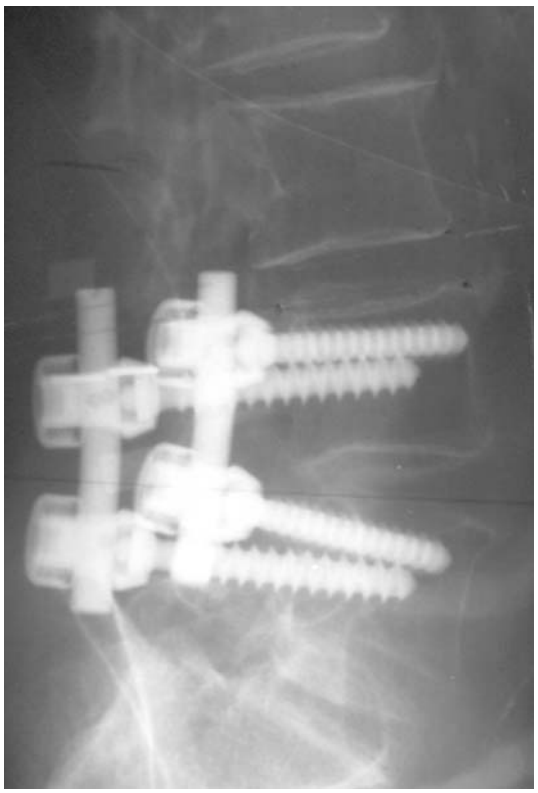

Fig. 14 Lateral roentgenogram of the patient of Fig. 13, 57 months after L4/L5 laminectomy and discectomy plus instrumented fusion. At the segment L3/L4, a Wallis has been inserted (*arrow*). Note the normal height of the disc L3/L4

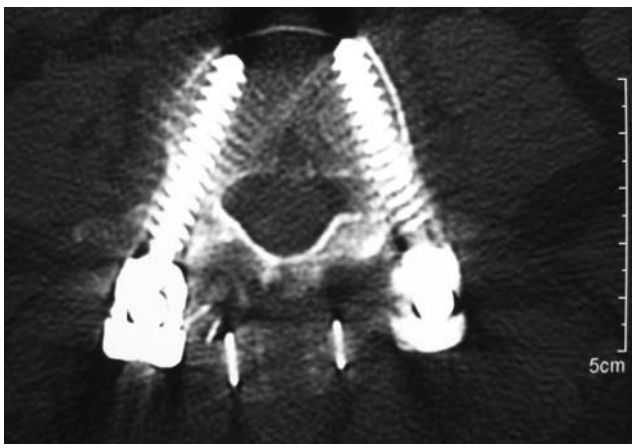

Fig. 15 Axial CT view of the patient of Figs. 13 and 14 showing the correct position of the Wallis implant close to the spinous process

Discussion

Lumbar spine fusion is a common procedure in spine surgery to improve the pain and clinical outcome of patients with failed conservative treatment for lumbar degenerative disease and degenerative spondylolisthesis by eliminating segmental instability, which is recognised as a cause of low back pain. Indications comprise degenerative disorders and spondylolisthesis (grades I, II) [20, 24, 49]. During the last years, lumbar fusion has been increasingly criticised [6], while clinical studies have shown similar long-term follow-up results with conservative treatment [8, 14]. Side effects of lumbar fusion include ASD, pseudarthrosis, bone-graft morbidity, high rates of re-operation, implant failure, and sagittal spinal imbalancing. More specifically, spinal fusion alters the biomechanics of the spine and the loss of motion at the fused levels is at least theoretically compensated by increased motion at other unfused segments resulting in ASD [33].

Adjacent segment degeneration is a common long-term sequela or complication of spinal fusion surgery. The exact aetiology is uncertain but alterations in facet loading, hypermobility, and increased intradiscal pressure at the segments adjacent to fusion mass is believed to play a key role [15, 21, 35, 44, 51, 60]. Superior segment facet violation or laminectomy has recently shown in vitro to destabilize the adjacent level in transpedicular fixation [9].

Radiological disc degeneration (ASD) is all too common (5.2–100%) complication that the initial good results following a posterior spinal fusion degrade as adjacent mobile segments proximal to the fusion degenerate over time compromising the late outcome of many short and mid-term successes [1, 16, 26, 33, 43, 53]. There is an increasing concern, regarding the long-term consequences of these asymptomatic changes; however, correlation of ASD and clinical outcome is still unclear [46, 52].

The reported incidence of symptomatic ASD is significantly lower (5.2–18.5%) than the radiologic ASD. ASD incidence is higher in patients with transpedicular instrumentation (12.2–18.5%) compared with patients fused with other forms of instrumentation or with no instrumentation (5.2–5.6%). Evidence of radiographic degeneration, however, does not necessarily lead to a poor clinical outcome of surgery [21, 52]. A recent clinical study [52] showed that the incidence of ASD (DH reduction) in the first cephalad adjacent segment 10 years following 360° instrumented lumbar fusion averaged 21%, while in the second adjacent level averaged 16%. In our series, the incidence of ASD both in the first and second cephalad adjacent segment following posterolateral transpedicular fixation without Wallis averaged 28.6%, while in the Wallis group it was 4.1%. Thus, although different fusion methods and imaging techniques were used in Schulte's and ours series it seems that the addition of Wallis protected not only the first but also the second cephalad segment from ASD. In our series, the incidence of radiographic ASD cephalad to instrumentation was 4.1% in the patients who received interspinous implant, significantly lower compared with patients without spacer in

Table 3 Arthritic grade for intervertebral disc degeneration in first cephalad segment

UCLA+	Wallis group[a]		Control group[a]	
Grading	Preoperatively	Postoperatively	Preoperatively	Postoperatively
I	17	17	16	15
II	7	6	5	2
III	0	1	0	1
IV	0	0	0	3
	24	24	21	21

Grade is based upon the most severe radiographic evident on plain radiographs

[a] Number of patients listed according to UCLA grading

which it was 28.6%. Although the most common segment involved in ASD was the L3/L4 in 5/7 spines, no conclusion can be drawn regarding correlation between levels involved in ASD and clinical outcome because of small sample of patients. In the present study, the incidence of symptomatic ASD in the cephalad segment that required surgical intervention was 14% and was limited only in the patients without Wallis (group C).

However, to solve the complication of ASD several flexible or even dynamic devices have been used with controversial results [17, 43, 50, 52]. It has been proposed that non-fusion motion preservation surgery may prevent accelerated ASD because of the protective effects of continuing segmental motion. Dynesys have been used for motion preservation since 1994 to allow mobile load transfer, and provide controlled motion, thereby off-loading the facet joints and posterior disc [51]. Because of the rigidity of Dynesys some authors have doubted the protective effect of this construct on adjacent segment [23, 51, 55, 56]. A recent prospective clinical study with 2 years of follow-up showed with the use of MRI that disc degeneration at the bridged and cranial adjacent segment continue (20%) despite Dynesys dynamic stabilization [29]. Others [27] compared three posterior pedicle-screw instrumentations (rigid, semi-rigid and dynamic) and found no differences in the incidence of ASD after a follow-up of 4 years.

With the exception of a few studies, all of the biomechanical and clinical studies address cranial segment degeneration [15, 39], because ASD caudal to a fusion is significantly less common [10]. The explanation for this is that in the adjacent segment cephalad to a fusion there is increased mobility compared with the adjacent caudal segment [5]. A recent clinical study showed that ASD occurred in 89% of the cases cephalad to lumbar fusion, 3.7% of the cases caudal and combined cephalad and caudal in 7.5% of the cases [10]. For these reasons, in our study, we investigated the mobility and associated degenerative signs only the vertebral segment cephalad to instrumented lumbar fusion. In our series of 45 followed up patients only one (2.2%) developed ASD caudal to instrumentation.

Most of the previous relative studies have correlated "static" radiographic criteria (DH, traction spurs, osteophytes, etc) with clinical symptoms [3, 37, 45]. Others have additionally used advanced imaging techniques as computed tomography (CT), magnetic resonance imaging (MRI) [13, 25, 53, 63]. In this study, we used the "statistic" radiographic criteria (UCLA arthritic grading system) that has been successfully used by others [15] along with dynamic motion parameters for the cephalad ASD (ROM, olisthesis). Schulte recently used DH reduction on plain roentgenograms as a measure of ASD. In the present study, we were able to show that the increased ROM and olisthesis in the control group should be responsible for the higher incidence of radiological incidence of ASD in this group when compared with the Wallis group.

To reduce the incidence of ASD by preserving motion, several implants of non-rigid or even dynamic stabilization of lumbar intervertebral segments have been developed. Some of them (Graf, Dynesys) were secured to the spine by pedicle screw fixation systems [17], while other implants are secured in the interspinous space [38, 48]. Although early results of pedicle-screw systems of flexible intervertebral stabilization have been encouraging [17] some long-term results have revealed possible drawbacks [18, 54], including increased lumbar lordosis, stretching of the Dacron parts, and malpositioning and loosening of pedicle screws leading to increased re-operation rate.

Recently, several implants have been developed with non-bony fixation, some connecting spinous processes, and laminae [5, 42] other connecting two adjacent spinous processes [38].

Amongst these implants is the Wallis, a "second" generation PEEK implant for non-rigid interspinous stabilization of lumbar segments, which was used in our series cephalad to the uppermost instrumented lumbar vertebra to preserve motion and reduce ASD incidence in this transitional unfused segment. A recent comparative biomechanical study showed that Wallis reduced the ROM and load on the disc and articular processes stresses, while it increased loads transmitted through the spinous processes [43]. In our series, Wallis implant controlled the ROM of the cephalad not fused vertebra and restored the DH at this segment without reduction of the global lumbar lordosis and sagittal balance until the latest observation 60 months after index surgery.

Using an MRI-based classification, some investigators inserted the Wallis implant to treat disc degeneration grades II–IV [33, 62]. In our study, we used the Wallis implant also in patients with UCLA I and II degeneration in the segment cephalad to instrumentation.

Senegas reported 7% re-operation rate, within 3 months postoperatively due to the loosening of the previous generation implant in a discectomy population that was treated with the Wallis implant because of persistent low back pain. No loosening or re-operation of the second generation Wallis was shown in the present series.

There are limitations to our study, as there are several inherent difficulties in studying ASD. First, the definition of ASD, not to mention the specific definition of radiographic ASD and clinical ASD, differs from study to study. In this study, we studied clear static radiographic along with dynamic parameters. The latter seems to be in accordance with others (Schulte), who recently used plain radiological criteria (DH) to evaluate ASD. Second, MRI was not used to define the degree of ASD in the segment cephalad instrumentation; however, there are no evidence-based studies to support any link between pain and MR-positive signal. Third, ASD in the "unprotected" segment cephalad to rigid fixation may be a physiological process and not the results of stress concentration even after short fusion? Finally, the outcome evaluation questionnaires (VAS, SF-36 and ODI) specific enough to differentiate the origin of pain (ASD degeneration vs. other aetiology of postoperative pain).

In accordance with previous observations, the incidence of clinically important ASD was significantly less than that of the radiographic ASD. Thus, surgeons should be aware that radiographic evidence of disc space narrowing and degenerative changes do not necessarily correlate with symptoms [43].

In this series, the Wallis interspinous implant changed the natural history of ASD in the free segment cephalad to 2–4 levels instrumented rigid lumbar fusion and reduced until to 5 years postoperatively in an equal rate the incidence of the radiographic and symptomatic ASD in the two adjacent segments cephalad to instrumented lumbar fusion. The remote fractures in the thoracolumbar spine seem not to be related to spine surgery but to natural history of the degenerative disease and ageing process.

We recommend the use of interspinous implants such as Wallis in UCLA I and II grades to protect the two adjacent cephalad to short (2–4 vertebrae) rigid fixation segments in the lumbar spine. However, for more severe arthritic changes (UCLA $\geq$ II) we strongly recommend inclusion of degenerated segments into the fusion.

Prospective randomized comparative studies with greater number of patients, more levels of instrumentation and longer follow-up are necessary to definitively support the conclusions of this study and to determine the usefulness of the Wallis to protect adjacent unfused mobile lumbar segments.

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Adjacent segmental degeneration following Wallis interspinous stabilization implantation

Biomechanical explanations and the value of magnetic resonance imaging

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Abstract

Adjacent segmental degeneration (ASD) is a major issue after pedicular fixation. This study examined the degeneration of the adjacent levels due to the insertion of the Wallis interspinous stabilization system compared with discectomy, using magnetic resonance imaging (MRI).

Thirty-eight patients diagnosed with lumbar degeneration disorders at L4-L5 were reviewed: 19 patients underwent discectomy and Wallis system implantation (group A), and 19 patients underwent discectomy (group B). The Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) were assessed preoperatively and postoperatively. ASD was evaluated by MRI.

There was no difference in the preoperative ODI scores between the 2 groups (non-normal distribution, median, 50 (40, 50) vs 50 (50, 50), $P = .331$), but the postoperative ODI scores were different (non-normal distribution, median, 0 (0, 32) vs 20 (20, 30), $P < .005$). Similar results were observed for VAS. In group A, ASD occurred in 4 patients (21.1%) in the disc and 8 (42.1%) in the facet joint at L3/4, and in 4 (21.1%) in the disc and 5 (26.3%) in the facet joint at L5/S1. In Group B, ASD occurred in 3 patients (15.8%) in the disc at L3/4, and in 4 (21.1%) in the disc at L5/S1. In general, there was no difference between the 2 groups ($P > .05$), except at L3/4 ($P = .015$).

ASD of the facet joint in the cranial segment occurred after Wallis system implantation, suggesting that the Wallis system cannot prevent ASD of the facet joint, but could have some other benefits for the discs.

Abbreviations: ASD = adjacent segmental degeneration, BMI = body mass index, FOV = field of view, MRI = magnetic resonance imaging, ODI = Oswestry Disability Index, TE/TR = echo time and repetition time, VAS = visual analog scale.

Keywords: adjacent segmental degeneration, disc, facet joint, pedicular fixation, Wallis system implantation

1. Introduction

Acute or progressive disc lesions lead to instability of the spinal segments.[1,2] Currently, pedicular fixation (fusion) is the gold standard treatment in terms of increasing the biomechanical rigidity and clinical fusion rates because pedicle screws are the strongest component of spinal implants.[3] Adjacent segment degeneration (ASD) is the development of a pathology at the mobile segment next to a lumbar or lumbosacral spinal fusion.[4] Several reports revealed that ASD could be accelerated due to the relative immobility of fused spinal segments transferring stress to adjacent segments after fusion.[5–7] Symptoms and signs of ASD include pain, stenotic lesions, and instability, leading to additional surgeries such as extended fusion and neural decompression.[8] Unfortunately, there is currently no relevant literature about the prevention of ASD.

To reduce the incidence of fusion-related morbidity, non-fusion technologies have been developed, such as the Wallis interspinous stabilization system.[9] Although the implant offers some advantages over fusion (e.g., motion of the involved levels and small operation wound), the efficacy of non-fusion implants in the prevention of ASD is now well established.[3,8]

ASD was first described using x-ray indexes such as disc height and segmental range of motion, [10] but a previous animal study suggested that the changes in x-ray indexes were less sensible than those extracted from magnetic resonance imaging (MRI),[11] as supported by a study in humans. [12]

Nevertheless, it is poorly known whether the use of the Wallis system could prevent ASD. Therefore, the aim of the present study was to compare the patients who underwent discectomy and Wallis system implantation with the patients who underwent discectomy only, based on MRI examinations.

2. Methods

2.1. Study design and patients

Patients diagnosed with lumbar disc herniation at L4-L5 and operated (by the same surgeon) at the Department of Orthopedic

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Table 1

Grading of intervertebral disc degeneration.

Grade	Signal from nucleus and inner fibers of annulus	Distinction between inner and outer fibers of annulus at posterior aspect of the disc	Height of the disc
1	Uniformly hyperintense, equal to CSF	Distinct	Normal
2	Hyperintense (>presacral fat and <CSF) ± hypointense intranuclear cleft	Distinct	Normal
3	Hyperintense through <presacral fat	Distinct	Normal
4	Mildly hyperintense (slightly >outer fibers of annulus)	Indistinct	Normal
5	Hypointense (=outer fibers of annulus)	Indistinct	Normal
6	Hypointense	Indistinct	<30% reduction in disc height
7	Hypointense	Indistinct	30–60% reduction in disc height
8	Hypointense	Indistinct	>60% reduction in disc height

Grades 1, 2, and 3 are based on the signal intensity of the nucleus and inner fibers of annulus. For Grade 4, the margins between the inner and other fibers of the annulus at the posterior margin of the disc are indistinct. For Grade 5, the disc is uniformly hypointense, but there is no loss of disc space height. For Grades 6, 7, and 8, there is progressive loss of disc space height. These could be broadly classified as mild, moderate, to severe loss of disc space height. Very occasionally, although obvious disc collapse is present, the hyperintense signal from the nucleus and inner fibers of the annulus is present. This is referred to by a double entry, for example, 4/7, with the former reporting the disc signal and the latter the degree of collapse.

Surgery, Tongji Hospital affiliated to Tongji Medical University of HUST, in 2009 and 2010, were retrospectively reviewed after a 2-year follow-up. The project was approved by the institutional review boards and the ethics committee of Tongji Hospital affiliated to Tongji Medical University of HUST and followed the tenants of the Declaration of Helsinki. The need for informed consent was waived by the committee because of the retrospective nature of the study.

The inclusion criteria were: (1) history of lumbar disc herniation; (2) symptoms of sciatic and low back pain; and (3) failure of conservative treatment. The exclusion criteria were: (1) any other type of vertebral fracture; (2) patients without any indication for surgery or refused surgery; (3) adjacent segments with disc degeneration grade >5 and/or facet degeneration grade >2 according to MRI (Table 1[13] and Table 2[14]); (4) history of cardiovascular or cerebrovascular diseases, trauma, or cancer; (5) lost to follow-up; or (6) missing data.

During the study period, 100 patients were treated at our center, but after excluding patients lost to follow-up and those with missing data, and after matching the 2 groups for age, gender, and occupation, only 38 patients remained.

2.2. Surgery

The treatment approach was decided by the surgeon in consultation with patients. After oral and written explanations on the details of the surgery, all participants signed a written surgical informed consent. After discussion, the patients underwent either discectomy and Wallis implantation (n = 19, group A) or discectomy only (n = 19, group B).

The indications for discectomy were: (1) symptoms of lumber spinal cord or nerve root compression; (2) conservative treatment did not produce satisfactory outcomes; and (3) willing to undergo surgery. The indications for Wallis system implantation were: (1) the sequence was stable and (2) no complications.

2.3. Data collection

Age, gender, body mass index (BMI), and duration of pain were collected preoperatively. The intensity of pain according to the visual analog scale (VAS) and Oswestry disability index (ODI) were collected preoperatively and postoperatively. The VAS ranged from 0 (no pain) to 10 (worst pain imaginable). The patients were asked to mark a point on the scale corresponding to their pain at that time. The ODI questionnaire contained 6 statements (denoted levels 0–5) in each of the 10 sections related to impairments such as pain and abilities such as personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling. In each section, the patient chose the statement that best described his/her status. If the limitation fell between 2 levels, the higher point value was selected. The chosen statements received scores 0 to 5 corresponding to the level indicated. The total scores could range from 0 (the highest level of function) to 50 (the lowest level of function).

2.4. MRI

All patients had undergone magnetic resonance imaging (MRI) before and 6 months after operation. The lumbar spine MRI examination of each participant was done by the same clinical 1.5T system (Signa 1.5 T HD, GE Healthcare, Waukesha, WI) using a 4-channel Phased Array CTL Spine Coil. T1-weighted fast spin-echo sagittal images with effective echo time and repetition times (TE/TR) of 10/400 ms, T2-weighted fast spin-echo sagittal images with TE/TR of 102/3000 ms and T2-weighted fast spin-echo axial images with TE/TR of 120/3000 ms were included in

Table 2

Grading of the facet joint degeneration.

Grade	Criteria
1	Uniformly thick cartilage covers the articular surfaces completely. Articular processes have a thin layer of cortical bone. No osteophyte.
2	Cartilage covers the entire surface of the articular processes but with erosion of the irregular region evident. Cortical bone of the articular processes is focally thickened. Possible or small osteophyte.
3	Cartilage incompletely covers the articular surfaces, with regions of the underlying bone exposed to the joint. Thickened cortical bone covers less than half of the articular processes. Definite and moderate osteophyte.
4	Cartilage is absent except for traces on the articular surfaces; dense cortical bone covers greater than half the articular process. Large osteophyte.

the examination. The field of view (FOV) was 360 mm and the matrix was 128×128, whereas 5-mm sections with a 1-mm section gap was used. There were 6 averages and the echo train length was 72 seconds.

The visual grading of intervertebral disc degeneration and the facet joint degeneration were based on the T2-weighted images and adjacent levels. Two operators (8 and 5 years of experience in MRI of the spine, respectively) graded the disc and facet joint in L3/4, L4/5, and L5/S1. The *G* value, defined as a measure of segment (disc and facet joint) degeneration, was obtained by adding the grades of invertebral disc degeneration (Table 1) and facet joint degeneration (Table 2). The difference in the *G*-value after surgery was defined as $\Delta G = G_{\text{postoperational}} - G_{\text{preoperational}}$ of intervertebral discs and facet joints of L3/4, L4/5, and L5/S1. Positive ΔG_{disc} and ΔG_{facet} values indicate that the grade of the intervertebral discs and facet joints worsened after surgery and the segment was marked as ASD. Negative ΔG_{disc} and ΔG_{facet} values indicate that the grade improved after surgery. The interobserver reliability of image grading was assessed using the kappa score. The final results were determined according to the results by 1 neuroradiologist.

2.5. Statistical analysis

Interobserver analyses of all MRI measurements showed fair to excellent agreement. Changes in scores from before to after surgery were calculated. Normally distributed data are presented as mean ± standard deviation and were analyzed using the Student *t* test. Non-normally distributed data are presented as median (min, max) and were analyzed using the Mann–Whitney *U* test. SPSS 23.0 (IBM, Armonk, NY) was used for statistical analysis. Two-sided *P*-values $<.05$ were considered statistically significant.

3. Results

Table 3 presents the characteristics of the patients. There were no differences in age, gender, BMI, and pain duration between the 2 groups (all $P > .05$). The median preoperative ODI scores in groups A and B were 50 (40, 50) and 50 (50, 50), respectively (non-normal distribution; $P = .331$). The postoperative ODI scores were 0 (0, 32) and 20 (20, 30), respectively (non-normal distribution; $P < .005$). The median preoperative VAS scores in group A and B were 9 (9, 10) and 10 (9, 10) (non-normal distribution; $P = .079$). The postoperative VAS scores were 0 (0, 6) and 2 (2, 4) (non-normal distribution; $P = .067$).

Table 3

Characteristics of the patients.

Data		Group A	Group B	*P*
N		19	19	–
Gender	Male	11	10	1.00
	Female	8	9	
Age, years		47.5 ± 13.7	47.3 ± 13.2	.96
BMI, kg/m^2		22.6 ± 1.9	22.5 ± 1.8	.87
Duration of pain		56 m, 2 weeks-17 years	37 m, 2 weeks-10 years	–
Preoperative ODI*		50 (40, 50)	50 (50, 50)	.331
Postoperative ODI*		0 (0, 32)	20 (20, 30)	<.005
Preoperative VAS*		9 (9, 10)	10 (9, 10)	.08
Postoperative VAS*		0 (0, 6)	2 (2, 4)	.07

BMI = body mass index, ODI = Oswestry disability index, VAS = visual analog scale.
* Non-normal distribution. Presented as median (range) and analyzed using the Mann–Whitney *U* test.

Table 4

Occurrence of ASD in the 2 groups.

	A	B	*P*
Disc L3/4	4	3	.484
Disc L5/S1	4	4	.869
Facet joint L3/4	8	0	.015
Facet joint L5/S1	5	0	.217

3.1. Occurrence of ASD

For all patients (n = 38), ASD occurred in 7 patients (18.4%) in the disc and 8 (21.1%) in the facet joint at L3/4, and in 8 (21.1%) in the disc and 5 (13.2%) in the facet joint at L5/S1. For group A, ASD occurred in 4 patients (21.1%) in the disc and 8 (42.1%) in the facet joint at L3/4, and in 4 (21.1%) in the disc and 5 (26.3%) in the facet joint at L5/S1. For group B, ASD occurred in 3 patients (15.8%) in the disc at L3/4 and in 4 (21.1%) in the disc at L5/S1 (Table 4).

3.2. Changes in G value during follow-up

The comparison of the $G_{\text{preoperational}}$, $G_{\text{postoperational}}$, and ΔG value of the discs and facets in the 2 groups are summarized in Table 5 and Fig. 1. There was no difference between the 2 groups for ΔG_{disc} ($P > .05$), but there was a difference for ΔG_{facet} at L3/4 ($P = .015$) but not at L5/S1 ($P = .217$). In Fig. 2, the ΔG_{disc} of the 2 groups were negative, and the changes in MRI were obvious. Detailed MRI examination of a patient from group B at the facet joints of L3/4, L4/5, and L5/S1 is shown in Fig. 3. Preoperatively, cartilage covers the surfaces of the articular processes with some erosion; the cortical bone of the articular processes is focally thickened with small/moderate osteophyte. After operation, regions of the underlying bone are exposed to the joint, with moderate/large osteophyte.

4. Discussion

ASD after lumbar spinal fusion is a potential cause of further spinal surgery, which is disquieting to both patients and surgeons. The Wallis system can be used to stabilize the spine, but its effect on ASD is unknown. Therefore, the aim of the present study was to examine the degeneration of the adjacent levels due to the insertion of the Wallis interspinous stabilization system compared with discectomy, and using MRI. The results showed that in group A, ASD occurred in 4 patients (21.1%) in the disc and 8 (42.1%) in the facet joint at L3/4, and in 4 (21.1%) in the disc and

Table 5

Comparison of the $G_{\text{preoperational}}$, $G_{\text{postoperational}}$, and ΔG of the discs and facets in the 2 groups.

G value†	Level (*P*-values) L3/4	L5/S1
$G_{\text{pre-disc}}$	.137	.079
$G_{\text{post-disc}}$	.530	.238
ΔG_{disc}	.484	.869
$G_{\text{pre-facet}}$	.693	.289
$G_{\text{post-facet}}$	.034*	.050
ΔG_{facet}	.015*	.217

* $P < .05$ was considered to be statistically significant.
† The *G* value is obtained by adding the disc degeneration grade (Table 1) to the facet degeneration grade (Table 2), as assessed by 2 radiologists.

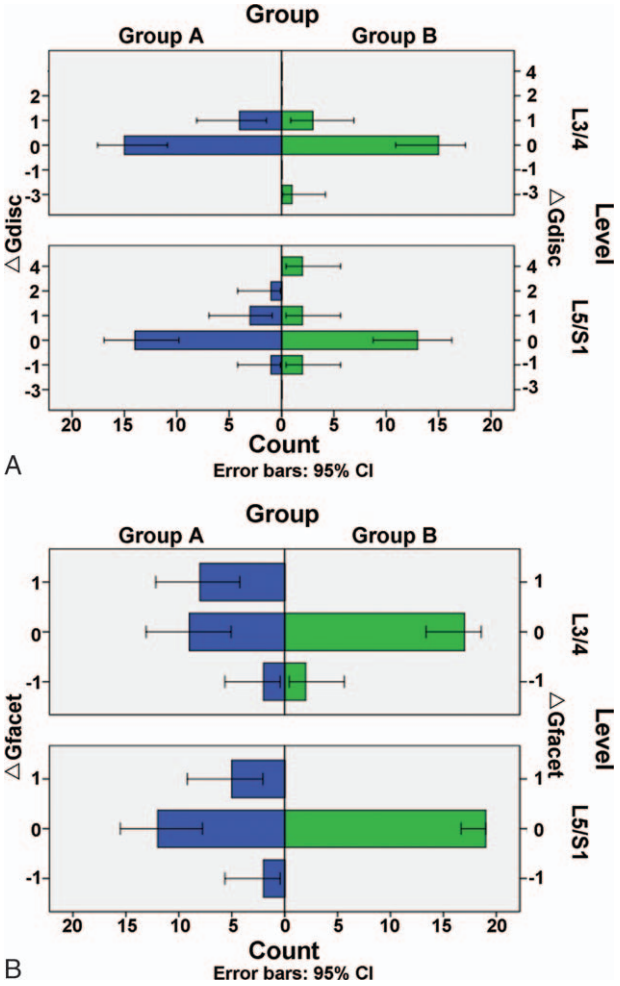

Figure 1. (A) ΔG in the discs at L3/4 and L5/S1 in groups A and B. At L3/4, there were 4 cases of ASD ($\Delta G > 0$) of the discs in group A, whereas 3 cases of ASD were found in group B. At L5/S1, there were 4 cases of ASD, whereas 4 cases of ASD were observed in group B. (B) ΔG in the facets at L3/4 and L5/S1 in groups A and B. At L3/4, there were 8 cases of ASD ($\Delta G > 0$) of the facets in group A. At L5/S1, there were 5 cases of ASD in group A. ASD = adjacent segmental degeneration.

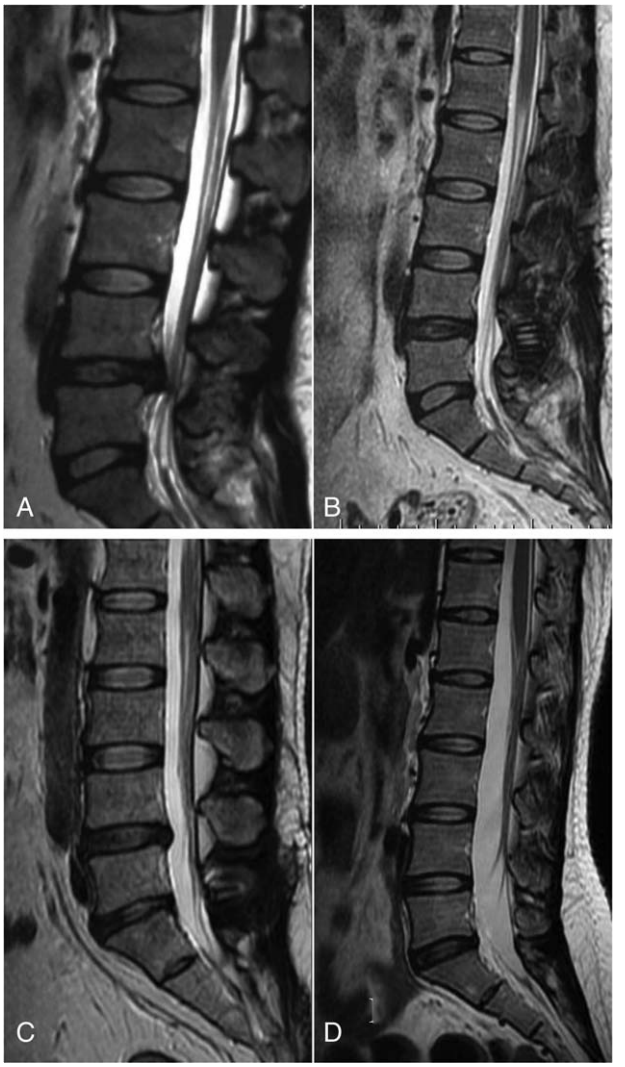

Figure 2. (A) A patient from group A before operation. The T2 signal at L4/5 is mildly hyperintense (slightly more than the outer fibers of annulus), and there is no distinction between the inner and outer fibers of annulus at the disc. The $G_{preoperational}$ is 4. (B) The same patient from group A after operation. The T2 signal at L4/5 is hyperintense (more than the outer fibers of annulus), and there is a distinction between the inner and outer fibers of annulus at the disc. The $G_{preoperational}$ is 3. (C) A patient from group B before operation. The T2 signal at L4/5 is mildly hyperintense (slightly more than the outer fibers of annulus), and there is no distinction between the inner and outer fibers of annulus at the disc. The $G_{preoperational}$ is 4. (D) The same patient after operation in group B. The T2 signal at L4/5 is hyperintense (more than the presacral fat and cerebrospinal fluid) and hypointense compared with the intranuclear cleft. There is a distinction between the inner and outer fibers of annulus at the disc. The $G_{preoperational}$ is 2.

5 (26.3%) in the facet joint at L5/S1. In Group B, ASD occurred in 3 patients (15.8%) in the disc at L3/4, and in 4 (21.1%) in the disc at L5/S1. In general, there was no difference between the 2 groups ($P > .05$), except at L3/4 ($P = .015$). Therefore, ASD of the facet joint in the cranial segment occurred after Wallis system implantation, suggesting that the Wallis system cannot prevent ASD of the facet joint, but could have some other benefits for the discs, highlighted by the significantly lower ODI scores in group A compared to group B.

Biomechanical changes of ASD consist of increased intradisc pressure, increased facet load, and increased mobility after fusion.[4,15] It is presumed that the motion is transferred from the fused level to the close free level, and therefore the incidence of proximal ASD is much higher than that of distal ASD.[6] X-ray indexes such as disc height and segmental range of motion can describe ASD to some degree,[10] but MRI indexes provide more reliable data.[11] However, fusion surgery may cause artifacts with imaging. From the results of the present study, it seems that ASD occurs above the operated segment after implantation of the Wallis system, especially at the facet joint. Based on several studies, after spinal fusion, increased stress on the adjacent facet joints and a change in the load of the adjacent disc have been proved.[6,7,16] In the studies of spinal fusion, several authors support the point of view that the load is shifted to the free and mobile cranial lumbar segments for compensation.[6,7,17] Therefore, ASD always occurred in the facet joints above the reconstructed segment. Akamaru et al[18] demonstrated that the highest increase in motion is the cranial segment (L3/4) to L4/5 after its hypolordotic floating fusion. In addition, the change in joint orientation is a major risk factor in the degenerative process of that segment.[17,18] The Wallis implants can restrict the motion

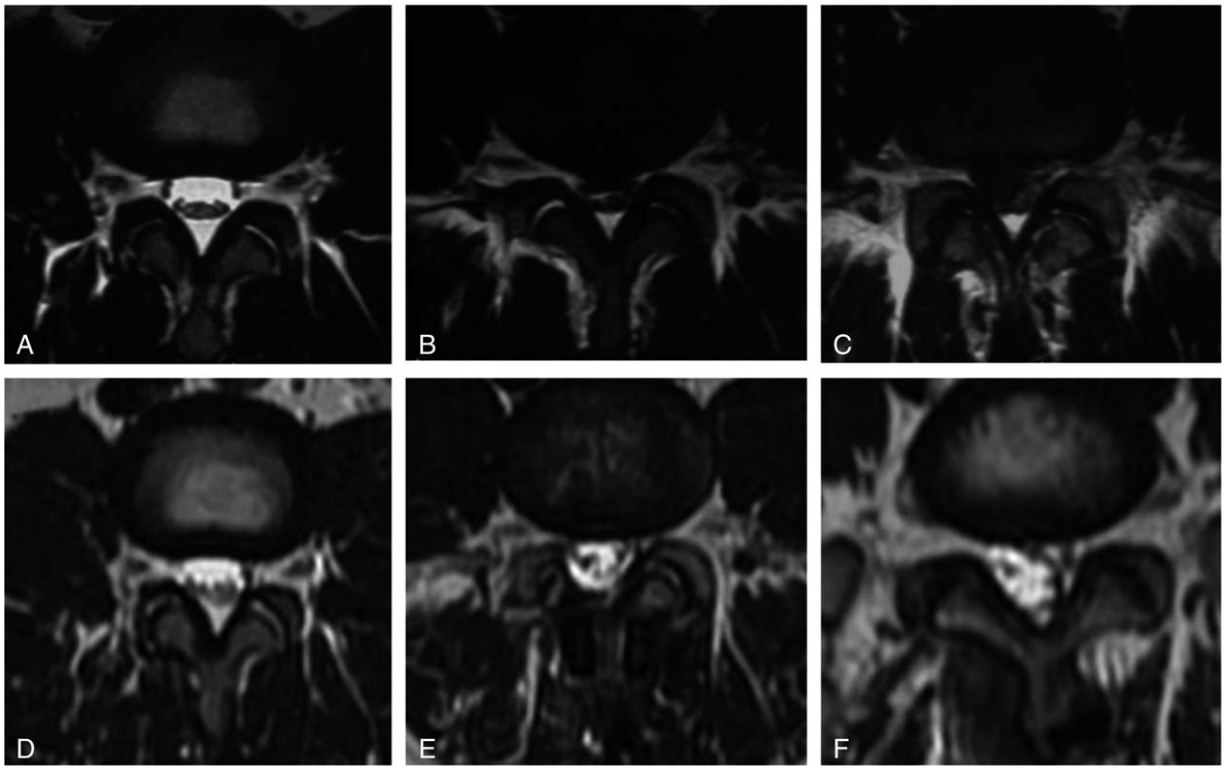

Figure 3. A patient from group B. (A) Before operation, the T2 signal of the facet joints at L3/4 cartilage covers the entire surface of the articular processes but with erosion of the irregular region; the cortical bone of the articular processes is focally thickened with small osteophyte. The $G_{preoperational}$ is 2. (B) The facet joints at L4/5 before operation, the $G_{preoperational}$ is 2. (C) The facet joints at L5/S1 before operation, the $G_{preoperational}$ is 3. The cartilage incompletely covers the articular surfaces, with regions of the underlying bone exposed to the joint. Thickened cortical bone covers less than half of the articular processes, with moderate osteophyte. (D) After operation, the T2 signal of the facet joints at L3/4. Cartilage incompletely covers the articular surfaces, with regions of the underlying bone exposed to the joint. Thickened cortical bone covers less than half of the articular processes, with moderate osteophyte. The $G_{postoperational}$ is 3. (E) The facet joints at L4/5 after operation, the $G_{postoperational}$ is 3. (F) The facet joints at L5/S1 after operation, the $G_{postoperational}$ is 4. The cartilage is absent except for traces on the articular surfaces, dense cortical bone covers greater than half the articular process with large osteophyte.

of the lumbar spine. The Wallis implant consists of an interspinous spacer that limits the extension and 2 bands that secure the implant in the interspinous space and limit flexion.[9,10] Therefore, the motion and the load is shifted from L4/5 to the adjacent segments (L3/4 and L5/S1) after Wallis system implantation atL4/5, especially at the cranial segment (L3/4). The reason for ASD at the L5/S1 facet in this study could be due to damage to the posterior structure resulting from the implantation, but this requires further investigation.

In some studies, the intradisc pressure was strongly reduced in extension after the implantation of the Wallis system,[19] but without difference in all other loading directions (flexion, lateral bending, and axial rotation), which has been observed in the present study. Nevertheless, the use of an interspinous implant could cause adjacent level facet pain or accelerated facet joint degeneration. [19] At the implanted level, the mean peak pressure, average pressure, contact area, and force were significantly reduced, but there were no significant changes at the level above the implant. The implant appears to redirect a large portion of the load away from the intervertebral disc and to transfer that load to the spinous processes. In a study by Adams et al,[20] there was a paradoxical decrease in posterior annular pressure during hyperextension at the tested level. They attributed this observation to the facet joints acting as a fulcrum and redirecting most of the force from the respective disc. When using the Wallis system, the lumbar spine is kept slightly flexed, meaning that the anterior part of the intervertebral disc is compressed, keeping the articular facets separated during movement of the lumbar spine.[21] As superior-segment facet contact has been presumed to play a role in the onset of ASD, it is unclear why the Wallis system does not prevent ASD. Nevertheless, additional mechanical studies are necessary to characterize the spinal changes leading to ASD. Unfortunately, there is currently no relevant literature about the prevention of ASD and the present study does not allow drawing conclusions about ASD prevention. Additional studies are also necessary to address these issues.

The present study is not without limitations. The sample size was small, from a single center, and was operated by a single surgeon. The ODI scores were self-assessed and could be more severe than in reality. No patient with pedicular fixation (fusion) could be included as controls because the fixation affected MRI quality. Finally, the follow-up was short and was based on retrospective data.

In conclusion, ASD of the facet joint in the cranial segment occurred after Wallis system implantation, suggesting that the Wallis system cannot prevent ASD of the facet joint, but could have some benefits for the discs.

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Middle-period curative effect of posterior lumbar intervertebral fusion (PLIF) and interspinous dynamic fixation (Wallis) for treatment of L45 degenerative disease and its influence on adjacent segment degeneration

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Abstract. – OBJECTIVE: To study middle period curative effect of posterior lumbar intervertebral fusion (PLIF) and interspinous dynamic fixation (Wallis) in the treatment of L45 degenerative disease and its influence on adjacent segment degeneration.

PATIENTS AND METHODS: 66 patients with lumbar L45 degenerative diseases were selected for study. The patients were randomly divided into PLIF operation group and Wallis operation group with 33 cases in each group. The patients were analyzed for T1ρ value, functional score and UCLA classification of L3/4 and L5/S1 segment in different periods of two groups of patients.

RESULTS: The level of T1ρ for L3/4 and L5/S1 segment in two groups between preoperative period and last follow-up showed a decreasing trend, while level of T1ρ value of L3/4 segment in PLIF operation group was significantly lower than Wallis group. Within group comparison, the level of T1ρ for L3/4 segment in PLIF operation group until the last follow-up was significantly lower than that before operation. While comparing two groups, ODI scores after operation for PLIF group and Wallis group was significantly lower than those before operation and JOA score was significantly higher than that before operation. The UCLA grade of L3/4 and L5/S1 segment of the two groups was significantly improved compared with that at the time of the last follow-up.

CONCLUSIONS: Both PLIF and Wallis methods are effective for the treatment of lumbar degenerative disease of L45. Wallis operation has slight advantage in slowing down the speed of intervertebral disc degeneration in the upper adjacent segment of the patient.

Key Words:
PLIF (posterior lumbar interbody fusion), Wallis (interspinous dynamic fixation), L45 degenerative diseases, MRI.

Introduction

Posterior lumbar interbody fusion (PLIF) is often used in clinic for the treatment of patients with lumbar degenerative disease and the effect of treatment is quite promising. But there are reports also pointed out that PLIF operation has great influence on the adjacent segment degeneration and could not fully protect the patient's lumbar spine[1]. In recent years, the application of interspinous dynamic fixation (Wallis) in developed countries has been widely used. Its main role is to restrict the occurrence of abnormal activity in the diseased segment and make sure that all the other sections are in a controllable range of security, finally reduce the probability of occurrence of adjacent segment degeneration[2-3]. In this study, we compared the efficacy and safety of PLIF and Wallis in mid term, by using T1ρ-MRI (T1ρ-Magnetic Resonance Imaging). We first detected the soft bone marrow nuclear protein polysaccharide of the patients and then evaluated the comparative degeneration of lumbar intervertebral disc.

Patients and Methods

Patients and Selection Criteria

66 patients with lumbar L45 degenerative disease in Traditional Chinese Medicine Hospital Zhengzhou were selected for treatment during Jan 2010 to May 2014. The cases include 35 males and 31 females, with age between 39-60 years and average age of 53.4±2.7 years. The patient's inclusion criteria was as reported earlier[4-5],

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a) All the patients are to be consistent with the standard on diagnosis of WHO on lumbar degenerative disease. b) The X-ray and MRI diagnosis shows interbody angle greater than or equal to 11 degrees and slipping greater than 3mm and gliding less than 1 degree. c) All patients having symptom of lumbago that is difficult to tolerate. d) Preoperative University of California at Los Angeles grading (University of California, UCLA, Los Angeles, CA, USA) showing that it is less than or equal to level II. Exclusion criteria for patient's was- a) The preoperative degeneration or gliding and instability of the adjacent segment L3/4 and L5/S1 segment. b) The patients with other types of vertebral fractures. c) The patients without indication for surgery. d) The patients refused surgical treatment.

Patients' Grouping

According to the digital method, patients were randomly divided into two groups, the PLIF operation group and Wallis operation group with 33 cases included in each group. There were 18 males and 15 females in the PLIF operation group, aged between 39-58 years old with average age of 52.9±3.3 years. There was 4-26 months' time from beginning of symptoms to operation, with average time of 16.2±3.4 months. There were 16 cases of L4/5 disc herniation and 17 cases of lumbar spinal stenosis. There were 17 males and 16 females in the Wallis operation group, being aged 40-60 years and average age of 52.7±3.1 years. The time was 4-28 months from symptoms starting to beginning of operation, with an average interval of 16.5±3.7 months. There were 19 cases of L4/5 disc herniation and 14 cases of lumbar spinal stenosis. The gender, age and time from symptom starting to operation time and the condition of the two groups of patients were compared and the difference observed was not statistically significant ($p > 0.05$), which is comparable.

Research Method

After anaesthesia of patient, prone and middle posterior position was selected for operation. For PLIF group, lower limb nerve symptoms side was selected for inter laminar decompression by fenestration. Subsequently, back nerve root was released and nucleus pulposus was removed. After scrapping the cartilage plate of the adjacent vertebral body, it was foisted into autogenous bone to intervertebral fusion cage. As posterior interbody is fused, internal fixation was performed with pedicle screws. For Wallis group, the spine of the lesion area was opened on the opposite side of affected area. The excision of the yellow ligament was performed after the removal of the spines. If disc herniation is more evident, decompression was performed by fenestration on the lamina located in root symptoms side. The nucleus pulposus was removed, the upper and lower margin of the spike was trimmed, lamina was polished and spine pad was inserted with suitable model after testing model through spreader.

The bundle was allowed to close the upper or lower margin of the spine as it passes through the fixed segment of the spine. When the lock was firmly fixed, the bundle was locked in clockwise manner. Once it is successful, towel was punched in the upper and lower spine, separated ligamenta supraspinale was sewed, catheter was drained and finally surgical cut was closed. Two groups were treated with antibiotics for first day of operation and 5 days after operation patients' were recommended for out of bed activity. The patients' were recommended to avoid bending for up to 3 months and later on they can resume normal activities.

Observation Index

X-ray and lumbar spine MRI was performed 1 month before and 1 year after operation until the last follow-up. Philips 1.5 Tesla MR was implemented for examination of patients. The short echo time T1WI: TE was 8 ms, TR was 540 ms, vision FOV was 200 mm and the thickness of 2-3 mm was used for analysis. In addition, T2WI: TE was 100 ms and TR was 1900 ms. After collecting data, T1ρ value map through processing with postprocessing software and T1ρ value (ms) was determined by using Image J software, selecting the average value after determination for 3 times.

Effect Evaluation

The recovery condition of patients is accessed through Oswertry dysfunctional index (ODI) and Japanese Orthopaedic Association Scores (JOA)[6,7]. Among them, lower ODI score and higher JOA score was found to be beneficial for patients.

Statistical Analysis

SPSS13.0 statistical software analysis (SPSS Inc., Chicago, IL, USA) was adopted for comparing data by using x^2 test. Measurement data was expressed by (Mean±SD), providing *t*-test. $p < 0.05$ was considered as statistically significant.

Table I. The comparison of level obtained from T1ρ value between with two groups of patients in different periods for L3/4 and L5/S1 segment (e.g., Mean±SD).

Group name	L3/4				L5/S1			
	Before operation	1 month after operation	1 year after operation	Last follow-up	Before operation	1 month after operation	1 year after operation	Last follow-up
PLIF operation	115.5±8.8	111.4±11.9	105.8±10.6	91.4±10.5	95.5±7.6	94.7±9.9	93.2±7.5	91.2±12.4
Wallis operation group (n=33)	112.3±9.7	107.6±8.3	106.8±10.2	106.5±13.9	96.8±8.4	95.3±7.6	93.8±8.8	92.4±10.6
t value	1.404	1.505	0.391	4.979	0.659	0.276	0.298	0.423
p value	0.165	0.137	0.698	0.000	0.512	0.783	0.767	0.674

Results

Comparison of levels of T1ρ in two groups of patients for different periods of L3/4 and L5/S1 segment is shown in Table I. The level of T1ρ value of L3/4 and L5/S1 segment in two groups between preoperative period and the last follow-up showed a decreasing trend. The level of T1ρ value of L3/4 segment in PLIF operation group until the last follow-up is significantly lower than that of Wallis operation group (Table I). When the level of T1ρ value of L3/4 segment 1 year before and after operation between two groups and the level of T1ρ value of L5/S1 segment between two groups between preoperative period and last follow-up was compared, the difference is not statistically significant ($p > 0.05$). Within group comparison, the level of T1ρ value of L3/4 segment in PLIF operation group until the last follow-up is significantly lower than that before operation (Table I). Comparison of functional scores of two groups of patients with different periods is shown in Table II. The ODI score and JOA score are compared between the two groups during the preoperative period and the last follow-up and the difference is not statistically significant ($p > 0.05$). Within group comparison, the ODI scores after 1 month of operation, after 1 year of operation and at the time of last follow-up in PLIF operation group and Wallis operation group were significantly lower than those before operation and the JOA scores of those were significantly higher than those before operation.

Comparison of UCLA standard grade of two groups of patients before operation and at the time of the last follow-up is shown in Table III. The UCLA grade of L3/4 and L5/S1 segment of the two groups was significantly improved compared with that at the time of last follow-up. But there is no significant difference of the comparison between the two groups ($p > 0.05$) as shown in Table III.

While comparing surgical complications and follow-up time of two groups, there was 1 case of dural laceration in the PLIF operation group.

Table II. Comparison of functional scores of two groups of patients with different periods (data is shown as Mean±SD)

Group name	ODI score				JOA score			
	Before operation	1 month after operation	1 year after operation	Last follow-up	Before operation	1 month after operation	1 year after operation	Last follow-up
PLIF operation group (n=33)	35.8 ± 10.2	13.9 ± 8.4	8.9 ± 5.2	8.6 ± 6.1	13.2 ± 3.5	15.1 ± 3.9	15.2 ± 4.2	15.9 ± 5.1
Wallis operation group (n=33)	36.7 ± 8.3	11.2 ± 6.6	8.7 ± 3.4	7.9 ± 5.2	12.8 ± 3.1	15.0 ± 5.2	15.3 ± 5.5	15.8 ± 4.9
t value	0.393	1.452	0.185	0.502	0.491	0.088	0.083	0.081
p value	0.696	0.151	0.854	0.618	0.625	0.930	0.934	0.936

Table III. Comparison of UCLA standard grade of two groups of patients before operation and at the time of the last follow-up.

Group name	L3/4						L5/S1				
	Before operation		Last follow-up				Before operation		Last follow-up		
	I	II	I	II	III	IV	I	II	I	II	III
PLIF operation group (n=33)	19	14	7	14	8	4	24	9	17	10	5
Wallis operation group (n=33)	18	15	5	13	12	3	22	11	19	11	3
Z value	1.178	2.036	1.125	1.984							
p value	0.164	0.089	0.334	0.277							

After the implementation of the repair, there was no cerebrospinal fluid leakage. There were 2 cases of urinary tract infection, while there was 1 case of urinary tract infection after operation in Wallis operation and recover after treatment with antibiotics. The follow-up period of the PLIF operation group was 6 to 26 months and the average follow-up time is 15.4±3.3 months. The follow-up period of the Wallis operation group is 7 to 28 months and the average follow-up time is 15.6±4.2 months.

Imaging analysis of two groups of patients with different preoperative and the last follow-up is shown in Figures 1 and 2. Figure a and figure b shows degenerative instability combined with mild slipping of PLIF for preoperative L4/5 segment. L3/4 and L5/S1 segment are classified as grade III and IV by UCLA grade. Figure c and figure d shows that the fixation position is better at the time of the last follow-up after performing PLIF operation and intervertebral fusion is satisfied. Figure e and figure f display that Wallis preoperative L4/5 segment appears degenerative instability. Figure g and figure h show that the fixation position is better at the time of the last follow-up after performing Wallis operation and section stability effect is satisfied.

Discussion

Lumbar spine is an important for supporting human body as well as for trunk movement. Almost all of the body's activity increases the burden on the lumbar spine and excessive activity, overload can accelerate the aging of the lumbar spine, resulting in formation of secondary pathological changes, which ultimately brings severe pain for patients. For more serious lumbar degenerative diseases, the clinical treatment is mainly

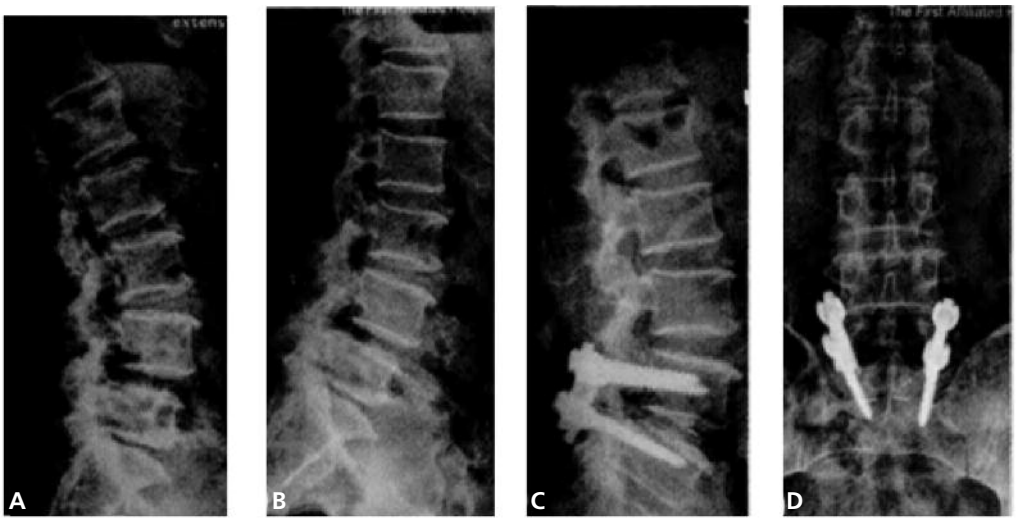

Figure 1. The imaging before and after PLIF operation is shown in Figure A-D. Figure a shows before operation, Figure B is 1 month after operation, Figure C is 1 year after operation and figure d is last follow up.

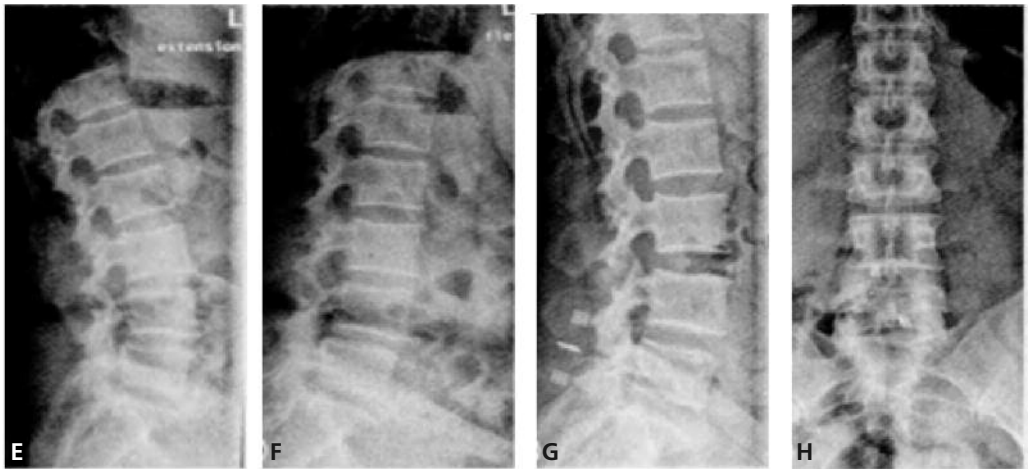

Figure 2. The imaging before and after Wallis operation is shown in Figure E-H. Figure a shows before operation, Figure B is 1 month after operation, Figure C is 1 year after operation and Figure D is last follow up.

treated by surgery and PLIF and Wallis are included in the application of the surgical plans which are more common in usage. Both of the two methods provide good curative effect and pays close attention to them at home and abroad[8,9]. However, for the comparison of the efficacy of PLIF and Wallis treatment of vertebral L45 degenerative disease and the effect on the adjacent segment degeneration, there is no relevant report available in clinic. Considering this, we designed this study to provide more comprehensive data of operation for treatment of degenerative disease of L45.

We found that the level of T1ρ value of L3/4 and L5/S1 segment in two groups between preoperative period and the last follow-up showed a decreasing trend, but the level of T1ρ of L3/4 segment in PLIF operation group until the last follow-up was significantly lower than that of Wallis operation group. The level of T1ρ for L3/4 segment in PLIF operation group until the last follow-up was significantly lower than that before operation, while the difference of the Wallis operation group was not significant. Wallis dynamic fixation in comparison to PLIF operation slowed down the speed of intervertebral disc degeneration in the upper adjacent segment. It also confirms the hypothesis that when using dynamic fixed system to limit the abnormal activity of the segment in a controllable range, changing the mode of self-loading of the moving segment is beneficial to reduce the proportion of the intervertebral disc degeneration of adjacent segment after the operation. In the past, there were reports that[10,11] in the process of conventional MRI imaging, the use of metal internal fixation devices may lead to a decrease in image quality, thus, affecting the detection results. Because the echo time has an important influence on the image quality, we used short echo time in scanning and selection of the center of median sagittal plane of same area of nucleus to record as a region of interest, supplementing the method of increasing the bandwidth to scan. The results showed that when comparing between the groups, the level of T1ρ for L3/4 segment 1 year before and after operation and the level of T1ρ for L5/S1 segment between preoperative period and the last follow-up were compared, and the difference was not statistically significant, which shows that the metal fixation needle does not significantly affect the level of measurement of MRI-T1ρvalue. It also shows that T1ρ-MRI technology has high feasibility for the evaluation of the status of the intervertebral disc degeneration in the condition of internal fixation.

In addition, we also found that there is no significant difference in ODI and JOA scores between the two groups before operation and till the last follow-up. Within group comparison, the ODI scores after 1 month of operation, 1 year of operation and the last follow-up of PLIF operation group and Wallis operation group were significantly lower than those before operation, and JOA score was significantly higher than that before operation. This suggests that two surgical procedures may result in a certain degree of adjacent segment degeneration of the intervertebral

disc, conforming to relevant report results of foreign people such as Dario et al[12] and Zhang[13]. The UCLA grade of L3/4 and L5/S1 segment at the time of the last follow-up in the two groups was significantly improved in comparison with before operation. But the difference was not significant between the groups. This suggests that the effect of lumbar internal fixation on the degeneration of intervertebral disc is relatively small, which mainly involves the upper adjacent intervertebral disc. In Table III, 3 cases of PLIF operation group and 4 cases of Wallis operation group are reported. The progress is UCLA IV grade, conforming again to this. This also suggests that PLIF and Wallis can obtain better medium-term effects.

The patients' operative complications and the follow-up time of the two groups were compared and the difference was not significant. This suggests that the safety of PLIF and Wallis was better, which coincides with earlier reports[14-16]. The mechanism could be that in both PLIF and Wallis operation the aim is to reduce the stress of the intervertebral disc and intervertebral joint at the same time. This can restrict the local activity of the spine. Wallis dynamic fixation system has also the advantages of simple operation, less trauma, etc.[17-20]. While PLIF was applied widely and the fixed effect were better. Although the two will cause the upper adjacent segment degeneration but the difference is not significant. So actually both have higher safety[21,22].

Conclusions

Both PLIF and Wallis operation are beneficial for the treatment of lumbar degenerative disease of L45, having high security. Wallis operation has a slight advantage in slowing down the speed of intervertebral disc degeneration in the upper adjacent segment of the patient.

Conflict of Interest

The Authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

A prospective randomised controlled trial to assess the efficacy of dynamic stabilisation of the lumbar spine with the Wallis ligament

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Abstract
Purpose This prospective randomised control study is to demonstrate whether or not there is a clinical benefit from inserting a Wallis implant on the functional recovery of patients who have undergone lumbar decompression surgery.
Method Sixty consecutive patients with an average age of 58 years (34–81) who were selected for primary lumbosacral decompression were randomly assigned into two groups with equal number of patients, decompression alone or decompression with Wallis implant. The patients had an average follow-up of 40 months. Patients were assessed by visual analogue scale (VAS) (Boonstra et al., Int J Rehabil Res 31:165–169, 2008; Price et al., Pain 17:45–56, 1983) pain score for back and leg pain, and the Oswestry Disability Index questionnaire (ODI) (Smeets et al., Arthritis Care Res (Hoboken) 63:S158–S173, 2011).
Results The results in both the groups did not reveal a significant difference in the clinical outcome assessment of back pain score or ODI. With the Wilcoxon two-sample test, no difference in median values was achieved (p value 0.0787 for ODI and p value 0.1926 for back pain). The average ODI in the Wallis group dropped from 50.93 to 29.11. The average VAS for the Wallis group back pain dropped from 7.79 to 4.22.
Conclusion The Wallis implant is a safe medical device. This study revealed a reduction in pain and functional disability in patients treated with decompression surgery for lumbar stenosis, with or without Wallis. The Wallis group improved more, but it was not statistically significant. The risk of complications is lower than other interspinous devices [18, 19].

Keywords Lumbar spine surgery · Spinal stenosis · Wallis ligament · Lumbar decompression

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Introduction

Interspinous devices are now commonly used in lumbar spine surgery [1]. The efficacy of these implants remains unclear [1, 2]. The Wallis ligament is a dynamic stabilising interspinous device which when placed between the spinous processes distracts and unloads the posterior elements of the spine, changing the centre of rotation of the disc to increase the spinal canal and neural foramina [3]. Since Wallis ligament approval, many of these implants have been used in lumbar spine surgery worldwide [3, 4]. However, there is no published data comparing decompression of lumbar spine versus decompression and implantation of second generation Wallis ligament.

Symptomatic lumbar spinal stenosis affects a significant number of adults over 65 years of age [10]. Acquired spinal stenosis results from degenerative changes, local infection, trauma or previous spinal surgery [11].

In degenerative spinal stenosis it has been suggested that disc degeneration and disc collapse are precursors to facet joint hypertrophy and progressive thickening of ligamentum flavum [19].

During extension of lumbar spine, the posterior annulus of the disc protrudes posteriorly and the ligamentum flavum bulges anteriorly leading to narrowing of central canal, lateral recesses of the spinal canal and the neural foramens [4, 19]. Flexion of the lumbar spine relieves the

bulging of ligamentum flavum leading to an increase in size of central canal [19, 22, 25]. However, the exact cause and mechanism of pain generation in this condition still remains unclear and is a subject of debate [1, 4, 19].

In degenerative lumbar spondylosis, surgery is an effective treatment in relieving symptoms of lumbar spine stenosis [12] and is superior to conservative treatment in long-term evaluations [23–25], however, there is no clear evidence about the most effective conservative technique [26]. As a definitive surgical management option Herkowitz showed superior results when decompression was combined with fusion in situ [27] but it has drawbacks such as lack of reversibility and loss of movement.

Currently there are limited published data on whether supporting the posterior elements with an interspinous implant following lumbar spine decompression improves function [12, 13].

The Wallis implant is an interspinous process device that maintains a constant level of distraction in extension while decreases the distraction in flexion [20]. The Wallis implant decreases pressure in the posterior endplates and in the facet joints of the instrumented levels [16].

Interspinous devices due to their kyphogenic property lead to various beneficial effects like increase in size of spinal canal, increase in size of the neural foramina, decrease in intra-discal pressure especially in the region of the posterior annulus and the posterior end-plate and finally to unloading of the facet joints [13, 14].

Flexion of the lumbar spine relieves the bulging of the ligamentum flavum leading to an increase in size of the central canal [9, 24, 25]. Spinal fusion leads to static stabilisation of spine, whilst dynamic stabilisation devices lead to a small reduction of motion [20].

These beneficial physiological effects are believed to be responsible for symptomatic relief observed in cases of lumbar stenosis treated with these interspinous devices with less recurrent back pain and leg pain [13, 22].

Medium and long-term results of the first generation Wallis implant have been favourable [16–19, 21]. The current Wallis implant has key components made of PEEK (polyetheretherketone) to create an implant with a modulus of elasticity that resembles that of the posterior vertebral elements [20, 21].

The objective of this prospective randomised control study is to demonstrate whether or not there is a clinical benefit from inserting a Wallis implant on the functional recovery of patients who have undergone lumbar decompression surgery.

Therefore, our null hypothesis is that there is no difference between decompression alone versus decompression plus insertion of Wallis ligament on functional recovery and on pain score.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Failed conservative treatment for 6 months	Spinal stenosis at more than two levels
Male or female of skeletal maturity, age greater than 18 years	Significantly compromised vertebral bodies at affected levels, e.g., previous surgery
Lumbar spinal levels from L2 to S1	Back or leg pain of unknown aetiology
Spinal stenosis at one or two consecutive levels	Systemic or local infections
No sign of segmental instability	Severe obesity (BMI greater than 40)
	Significant metabolic, autoimmune, peripheral vascular disease

Materials and methods

Ethical approval was granted to conduct the study by an independent committee.

A total of 60 patients with documented evidence of symptomatic spinal stenosis confirmed by clinical and MRI findings were recruited from the Croydon University Hospital Spinal Unit for this study with inclusion and exclusion criteria as per Table 1.

Patients were assigned to a control group (decompression alone, non-Wallis) or to the other (decompression and Wallis) by a random number generator before the trial started. There were no significant differences in the demographics of both groups.

Patients with spondylolisthesis were not included, only patients with nerve root compression with clinical and radiological confirmation were included in the study.

The patients were assessed preoperatively and postoperatively at 6, 12, 24, 36 and 48 months using questionnaires to assess back pain scores with VAS and ODIs in all patients [14–16]. No data were excluded for any reason.

In the Wallis group there were 19 female and 11 male and in the non-Wallis group there were 16 female and 14 male. In the Wallis group there were four patients that underwent two-level decompression whereas in the non-Wallis group to there were 14 two-level decompressions. 59 patients were available for follow-up, as one patient died during the follow-up period of causes unrelated to the operation.

All operations were performed by a single senior surgeon. The same standard surgical technique was performed on all patients, in the cases where the Wallis implant was used care was taken not to over distract the segment. All patients were prescribed exercises to strengthen the lower back muscles. Details of intraoperative and postoperative

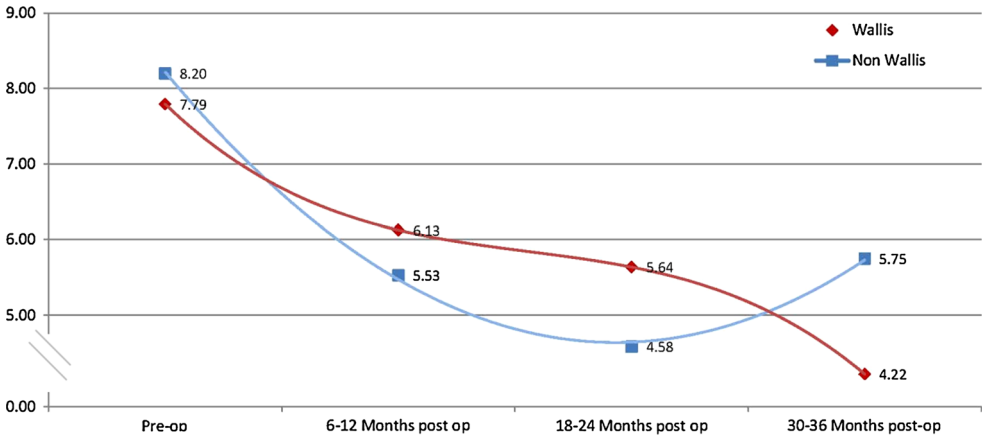

Fig. 1 Conjugated VAS scores for Wallis and non-Wallis operations

Table 2 Preoperative scores

Preoperative variable	Wallis implant	Summary statistics	*p* value
Back pain	No	8.2 ± 1.8 [30] (2.0, 8.0, 10.0)	0.9577
	Yes	7.9 ± 2.5 [30] (0.0, 8.0, 10.0)	
Right leg pain	No	6.7 ± 2.8 [26] (0.0, 7.5, 10.0)	0.6808
	Yes	6.7 ± 3.3 [24] (0.0, 8.0, 10.0)	
Left leg pain	No	6.5 ± 3.0 [23] (0.0, 8.0, 10.0)	0.2374
	Yes	5.4 ± 3.3 [23] (0.0, 7.0, 10.0)	
ODI	No	58.3 ± 18.1 [30] (18.0, 59.0, 91.0)	0.0899
	Yes	50.6 ± 14.8 [30] (20.0, 52.0, 72.0)	

complications, adjacent segment involvement after the surgical procedure and reoperations and revisions were collected at each follow-up. The mean duration of follow-up was 40 months.

Results

30 subjects had decompression with a Wallis Implant and the other 30 had decompression without a Wallis implant. At baseline, gender, age, back pain, right leg pain, left leg pain and Oswestry Disability Index (ODI) were statistically tested for equivalence between Wallis and non-Wallis procedures. Back pain change from baseline and ODI change from baseline were then calculated (Fig. 1).

For the 30 subjects that did not have a Wallis 53.3 % (16/30) was female and 46.7 % (14/30) was male. For the remaining 30 subjects, 63.3 % (19/30) was female and 36.7 % (11/30) was male. The comparison between gender and decompression was statistically examined with a Fisher's exact test; no difference was detected (*p* value 0.6010).

At surgery, the age summary for subjects that did not have a Wallis was 56.4 ± 12.9 [30] (34.0, 55.5, 76.0). For subjects that did have a Wallis, the age summary was 59.6 ± 13.4 [30] (35.0, 58.0, 81.0). Using the Wilcoxon two-sample test, no difference in median values was achieved (*p* value 0.3783).

Prior to surgery, four patient-reported outcomes were collected. They were back pain, right leg pain, left leg pain and ODI. The summary statistics by surgical procedure are presented in Table 2. In addition, the *p* value from the Wilcoxon two-sample test is also provided.

The entire preoperative patient-reported median values were not statistically, significantly different for the two groups.

The change from baseline for back pain and ODI was also calculated. The summary statistics by surgical procedure are presented in Table 3. In addition, the *p* value from the Wilcoxon two-sample test is also provided.

Both changes from baseline median values were not statistically significant.

All tests were two-sided and performed at a type I error rate of 0.05; no tests were adjusted for multiplicity.

There were no complications and no reoperations in either group.

Discussion

Until this study there was limited literature on the Wallis implant. Currently there is only level IV evidence to

Table 3 Postoperative scores

Change from baseline variable	Wallis implant	Summary statistics	*p* value
Back pain VAS	No	2.7 ± 2.4 [29] (0.0, 2.0, 9.0)	0.1926
	Yes	3.5 ± 3.4 [29] (−6.0, 4.0, 8.0)	
ODI	No	10.6 ± 19.3 [29] (−33.0, 12.0, 58.0)	0.0787
	Yes	19.3 ± 24.0 [29] (−49.0, 22.0, 56.0)	

suggest efficacy of Wallis implant in lumbar spine disorders [20]. Prior studies only address first generation Wallis implants, use small groups of patients and have limited follow-up of the patients [14, 16, 21].

Our study is the first to study the second generation Wallis implant, with a large group of patients (60) with a long average follow-up period (40 months), and to have preoperative ODI and VAS scores. For first time the patients are followed up at regular periods with only one drop out.

Our results are comparable to other studies on previous generation's Wallis device. Our study agrees with previously published studies that implantation of posterior interspinous process spacer device leads to improvement in ODI scores and VAS scores for backache and leg pain.

We have shown that at the Wallis device is safe with a low complication rate, but there is a lack of statistical significance regarding the effectiveness for use in patients with degenerative disc disease and lumbar canal stenosis. However, short-term and medium-term results of this implant are encouraging, further larger studies should follow as we have shown a benefit in small numbers of treated patients in the Wallis group.

Conflict of interest No funds were received in support of this study. No benefits in any form have been received from a commercial party related directly or indirectly to the subject of this manuscript.

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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

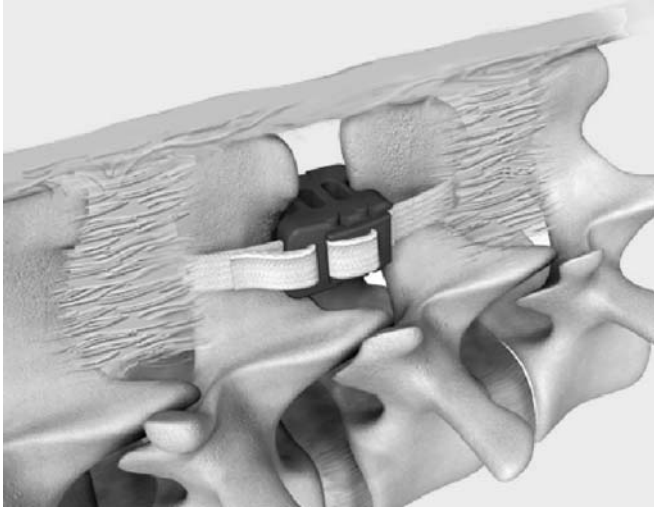

Fig. 2 Schematic view of the Wallis implant in place

(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

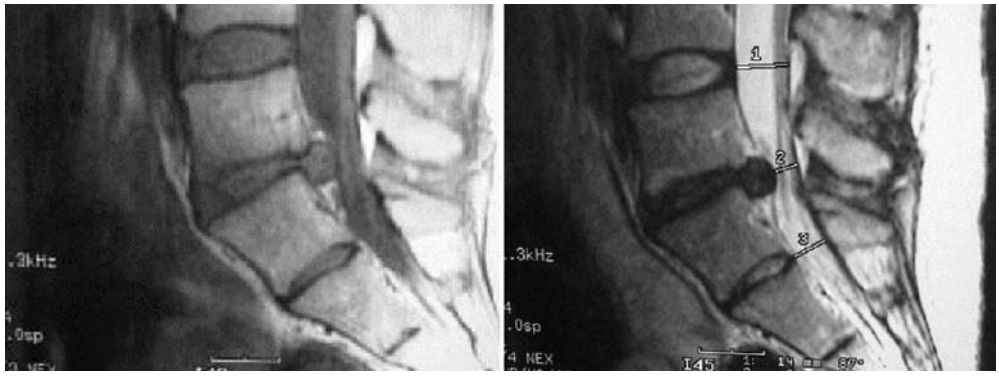

Fig. 3 Recurrence of herniated disc

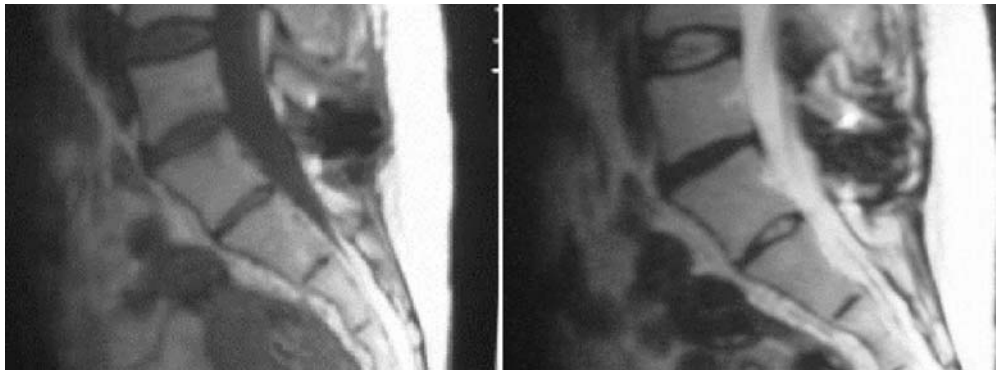

Fig. 4 Magnetic resonance imaging aspect 11 years after non-rigid fixation

(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°.

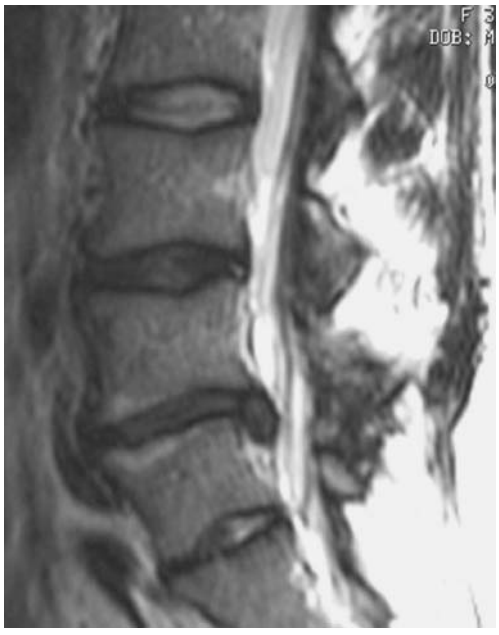

Fig. 5 Recurrence of herniated transitional disc at L4-L5 (due to sacralization of L5)

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

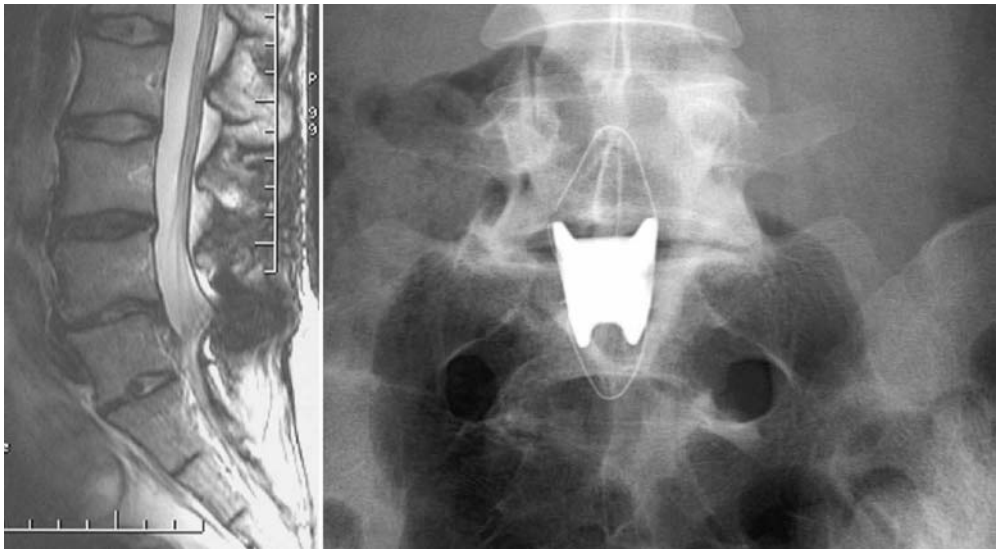

Fig. 6 Same patient as in Fig. 5, 8 years after discectomy and non-rigid stabilization (first-generation implant with titanium blocker)

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BMC Musculoskeletal Disorders

RESEARCH ARTICLE Open Access

Posterior dynamic stabilization in the lumbar spine – 24 months results of a prospective clinical and radiological study with an interspinous distraction device

Dorothea Daentzer[1*], Christof Hurschler[2], Frank Seehaus[2,3], Christine Noll[1] and Michael Schwarze[2]

Abstract

Background: Interspinous distraction devices (IDD) are due to maintain or restore intersegmental range of motion (iROM) in a controlled fashion with the aim of stabilization the affected level dynamically. The following study is the first to present clinical and radiological data with the Wallis® spacer during a follow-up of 24 months.

Methods: Ten patients underwent posterior dynamic stabilization (PDS) of the lumbar spine with an IDD (Wallis® spacer) and were controlled clinically and radiologically after 3, 6, 12, and 24 months in a prospective study design. Pain intensity, functional disability and life quality were assessed by use of subjective scores. Motion analyses were performed with the help of lateral functional x-rays to determine the iROM of the operated segments and total ROM (tROM) of the lumbar spine. In addition, roentgen stereophotogrammetric analysis (RSA) was used to measure the iROM of the treated levels.

Results: During the postoperative course pain and disability most clinical scores were significantly improved. After 24 months we observed statistically significant reduction in back pain intensity with a mean value of 6.0 on visual analog scale (VAS) before surgery and of 2.7 at the latest evaluation. The leg pain was also decreased without statistical significance from 4.7 preoperatively to 2.1 at final follow-up. The functional disability according to Oswestry Disability Index (ODI) and Roland-Morris Disability Questionnaire (RM) was decreased both with statistical significance at all examination dates with a mean value in ODI of 40.0 % before operation and of 17.3 % after 2 years and an initial mean value in RM of 55.2 and of 23.5 % after latest follow-up. After 24 months, the results of the health related quality of life score also showed much better values with only two exceptions. The iROM of the treated levels was reduced during each follow-up examination with preserved residual mobility. Directly postoperatively and after 3 and 12 months intersegmental mobility was statistically significantly decreased with an average iROM of 6.62° before operation and of 2.69° few days after surgery, of 3.79° and 3.16° 3 and 12 months later. At 6 (4.37°) and 24 (4.01°) months follow-up iROM was also but not statistically significantly reduced. The mean tROM did not change significantly during all postoperative controls.

Conclusions: The radiological findings support the thesis of posterior dynamic stabilization by the used implant. The positive clinical findings should be interpreted with caution because of the limited number of patients and the missing control group.

Keywords: Interspinous distraction device, Lumbar spine, Posterior dynamic stabilization, Roentgen stereophotogrammetry, Wallis implant, Wallis spacer

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Background

Interspinous distraction devices (IDD) are fixed between two adjacent spinous processes of the lumbar spine and are intended to maintain or restore segmental motion while avoiding disadvantages of rigid spinal fusion [1]. Therefore, they control intervertebral motion and act as a posterior dynamic stabilization (PDS) system. However, indication for IDD are still under discussion to date. Some authors use solely IDD [2, 3], while additional use of IDD after decompressive procedures to prevent instability and to keep the operated level in a rather flexed position to maintain the spinal canal and neuroforamen open is more commonly applied [4–8]. Furthermore, IDD are assumed to unload and to protect the facet joints and to avoid accelerated adjacent-segment degeneration [1].

The first IDD device certified for clinical use is the "Wallis® spacer" [9]. Long-term results have been published by its developer Sénégas et al. but without a control group [10]. The aim of the following publication is to show the postoperative course continuously during a follow-up period of 24 months and to assess pain intensity, functional disability and health related quality of life. Furthermore, intersegmental range of motion (iROM) and total ROM (tROM) of the lumbar spine were analyzed by the use of conventional functional x-ray imaging in addition to roentgen stereophotogrammetric analysis (RSA) [11]. We were thus able to determine iROM during various activities and also to evaluate the remaining segment mobility after treatment with different surgical techniques such as fusion or arthroplasty [12–17].

To the authors' knowledge, no investigation on PDS was conducted with a high-accuracy method such as RSA to date. Therefore, in this study the radiological data including RSA is to demonstrate the in vivo mobility after implantation of an IDD (Wallis® spacer).

Methods

Ten patients (seven women and three men, mean age 64.4 years) were included in this prospective single-centre study which was approved by the Institutional Review Board (Hannover Medical School No. 4809) after biometrical power calculation of number of cases. All participants provided consent. Inclusion criteria were therapy resistant or progressive back and/or leg pain under conservative treatment due to spinal canal stenosis with ($n = 3$) or without disc prolapse ($n = 4$), slight degenerative spondylolisthesis ($n = 2$, in one person with spinal canal stenosis) and facet joint arthrosis ($n = 1$). Exclusion criteria were spondylolisthesis more than grade one, segmental scoliosis, trauma, tumor, infection and osteoporosis which was excluded by Dual-X-Ray-Absorptiometry. Eight patients had a typical neurogenic intermittent claudication. The most affected level was L4/5 in nine cases, one person was treated in L2/3. We used the iROM and tROM as a surrogate metric for spine stability.

Implant and operation

The implant (Wallis® spacer, Zimmer Spine SAS, Bordeaux, France) was inserted between two neighboring vertebral arches and additionally fixed with two tension bands of polyester which were wrapped around both adjacent spinous processes. Eight patients also had decompressive surgery with ($n = 3$) or without ($n = 5$) removal of a disc prolapse.

For RSA, three to five tantalum markers with a diameter of 1 mm were inserted in the posterior bony structures of each adjacent vertebra (lamina, articular process, spinous process).

Clinical evaluation

All patients filled out a questionnaire with assessment of their intensity for back and leg pain by the visual analog scale (VAS), of their functional impairment by the Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire (RM) and of their health related quality of life by the Short-Form-36 Health Survey (SF-36) directly after inclusion into the study before operation and at further follow-up dates after 3, 6, 12, and 24 months. Furthermore, walking distance was documented and all persons had clinical and neurological examination during each control by the same examiner.

Radiological analysis and RSA

Conventional functional x-rays of the lumbar spine were performed in a standardized manner pre- and postoperatively (between 3 and 10 days), as well as at each follow-up date. These images were analysed in regard to the tROM of the lumbar spine by measuring the angle between the first lumbar vertebra (upper endplate of L1) and the endplate of the sacrum (S1) and then calculating the difference between the extension and flexion images. The iROM between the upper and lower vertebrae of the operated segments was calculated building the difference of the intervertebral angles in extension and flexion using the Cobb method (Fig. 1).

For RSA, radiographs were taken up to ten days after surgery and at 3, 6, 12, and 24 months post-op in a uniplanar setup using a carbon-fiber calibration box (box10, Medis specials). The angle between the x-ray paths was 40 deg. X-ray tubes (Digital Diagnost, Philips) exposed standard photostimulated luminescence plates with the dimension of 350 × 430 mm without the use of scatter grids. The plates were digitized resulting in an eight bit gray-scale image with a resolution of 125 dpi. X-ray cathode voltage was 125 kV and time-current was 40 mAs. No double examinations were conducted to minimize x-ray exposure of the patients. Persons were positioned

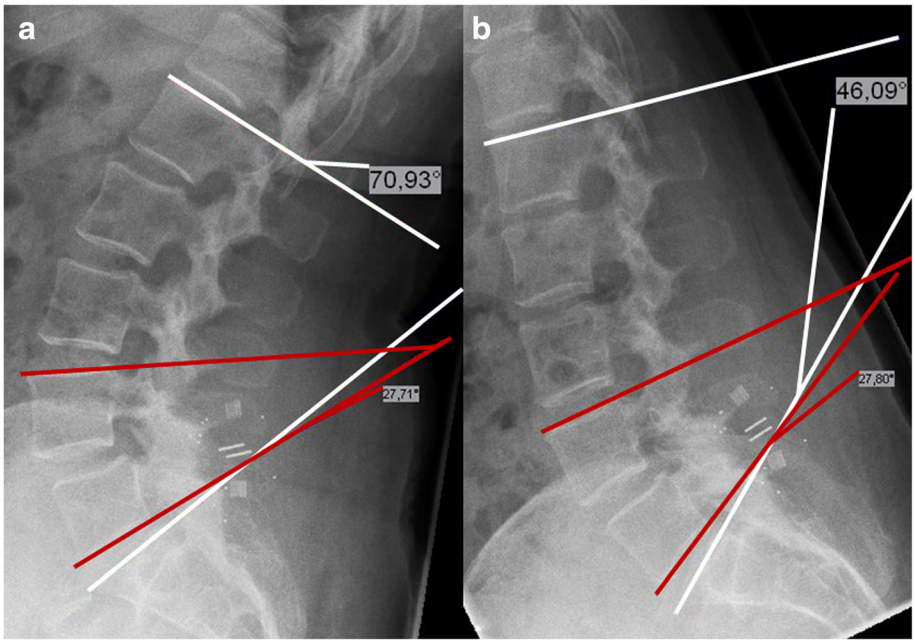

Fig. 1 Measurement of the segmental and total lumbar angle. Measurement in the lateral roentgenogram was performed with the Cobb method with the implant fixed between the spinous processes of L4 and L5. The red lines show the segmental angle measured between the upper endplate of L4 and the lower endplate of L5, the white lines label the total lumbar angle measured between the upper endplate of L1 and the endplate of S1. **a**: Extension, **b**: Flexion

in standardized extension and flexion position lying on the right side by an experienced examiner [18]. They lay on a flat table with the calibration box directly under the examined area of interest. Spinal segment motion was calculated using the MBRSA software (Version 3.31, Medis specials) with a standard protocol and a single examiner. The markers in the upper and lower vertebrae constituted the rigid bodies. Rigid body error threshold was 0.50 mm, with one exception at a single follow-up where 0.57 mm was required. The lower rigid body was used as reference, with the coordinate system aligned to the calibration box. Rotations around the z-axis (perpendicular to the image plane) were calculated, whereas positive rotation corresponds to flexion.

Statistical analysis

For statistical analysis of all data the *t*-test for related samples with a significance level of $p < 0.05$ was chosen to investigate differences at follow-up dates compared with the preoperative values.

Results

Clinical results

The intraoperative course was uneventful in all ten patients. Only one woman needed follow-up surgery because of a wound healing problem without an infection. None of the patients had postoperative neurological complications. One male patient was excluded from the study within the first 3 months because of conversion to fusion surgery due to persisting complaints. The follow-up data of the remaining nine patients are presented here.

Walking distance

Before surgery, the walking distance was reduced in eight patients to between 10 and 2000 m with a mean of 182 m. After 24 months, five patients had no more restrictions in walking. In the other four persons, the average walking distance had increased to at least 250 m and up to 2000 m (mean 1563 m).

Clinical outcome

A statistically significant decrease in back pain and functional disability (ODI and RM) was observed for all patients at every follow-up interval (Fig. 2, Table 1). Patients also showed reduced leg pain, which was however statistically significant only at 3 months follow-up.

The data from the SF-36 were improved in six of the eight items (all but for mental health and vitality) with statistical significant differences with regard to physical function, role-emotional, social function and pain (Fig. 3).

Radiological results and RSA

Before surgery, iROM of the operated segments measured by Cobb's method was 6.62° ± 3.30° (Fig. 4, Table 2). Directly after operation it was decreased to 2.69° ± 2.96° with inconstant increasing during the further course to

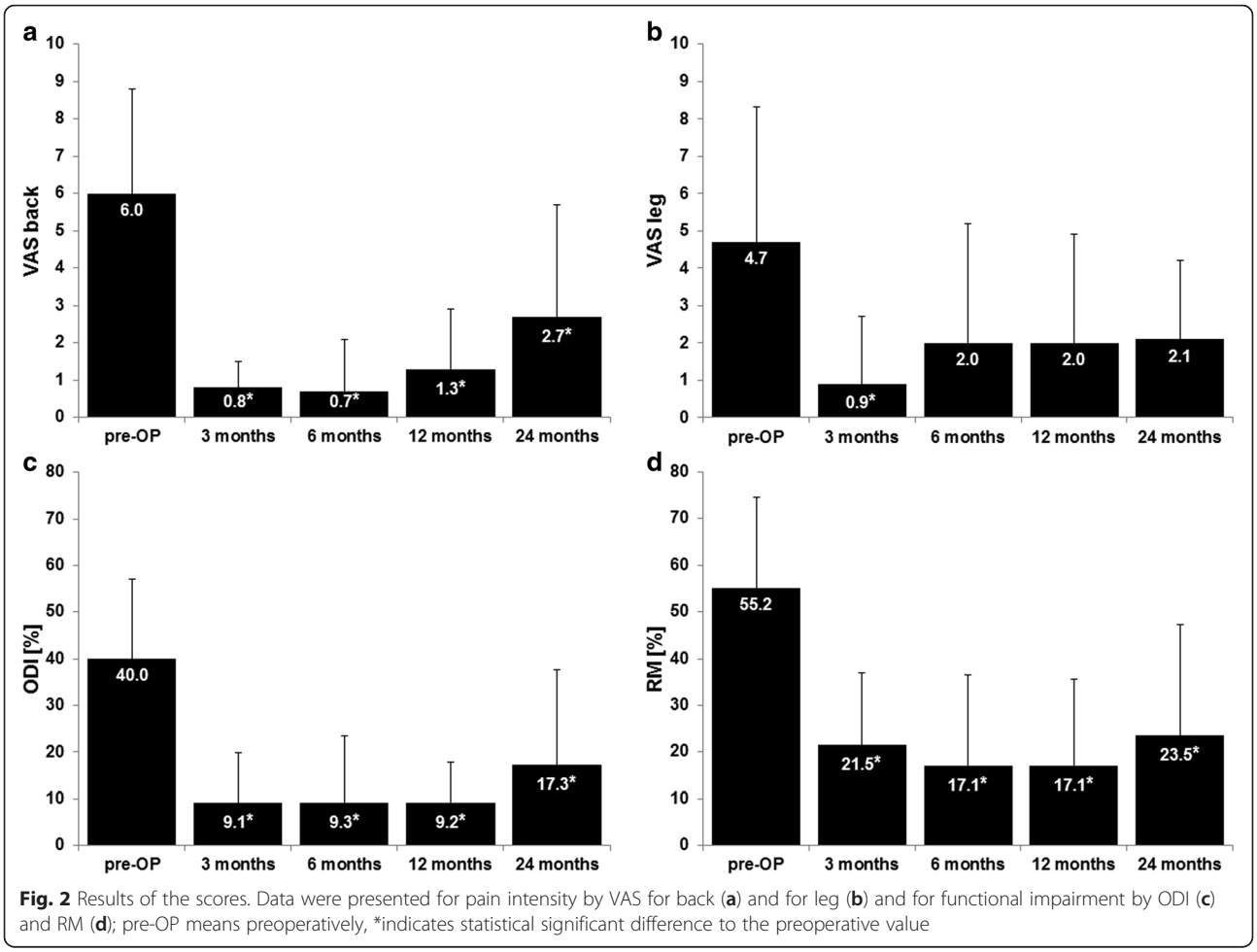

Fig. 2 Results of the scores. Data were presented for pain intensity by VAS for back (**a**) and for leg (**b**) and for functional impairment by ODI (**c**) and RM (**d**); pre-OP means preoperatively, *indicates statistical significant difference to the preoperative value

3.79° ± 2.38° after 3 months, 4.37° ± 2.88° after 6 months, 3.16° ± 3.48° after 12 months and 4.01° ± 4.15° after 24 months.

Segmental ROM of the treated levels calculated with RSA could be determined for the first time directly after surgery and was 2.89° ± 1.89° with inconsistent increase over the follow-up period to 5.50° ± 4.21° after 3 months, 7.80° ± 5.23° after 6 months, 4.90° ± 3.33° after 12 months and 6.73° ± 4.82° after 24 months (Fig. 4, Table 2). As the RSA tantalum markers were not in situ before surgery, we could not compare to the preoperative values.

The discrepancy of the conventionally determined iROM and the intervertebral motion measured by RSA was low with a mean of 2.90° (SD: 2.07), but varied among patients. The quality of the RSA was assured by determining mean rigid body error (0.31 ± 0.49 mm) and condition number (80 ± 21).

The tROM before operation was 26.01° ± 10.29° with reduction to 19.65° ± 5.67° some days later. During the whole follow-up we did not observe any statistical significant differences to the initial value (26.63° ± 8.19° after

Table 1 Pain intensity for back and leg and functional disability

Time	VAS back		VAS leg	
	mean ± SD	*p*-value	mean ± SD	*p*-value
Pre-OP	6.0 ± 2.8		4.7 ± 3.6	
3 months	0.8 ± 0.7	0.000*	0.9 ± 1.8	0.009*
6 months	0.7 ± 1.4	0.001*	2.0 ± 3.2	0.059
12 months	1.3 ± 1.6	0.004*	2.0 ± 2.9	0.058
24 months	2.7 ± 3.0	0.042*	2.1 ± 2.1	0.060
	ODI		RM	
	mean ± SD	*p*-value	mean ± SD	*p*-value
Pre-OP	40.0 ± 17.1		55.2 ± 19.4	
3 months	9.1 ± 10.7	0.012*	21.5 ± 15.5	0.009*
6 months	9.3 ± 14.2	0.002*	17.1 ± 19.5	0.005*
12 months	9.2 ± 8.6	0.002*	17.1 ± 18.5	0.002*
24 months	17.3 ± 20.3	0.017*	23.5 ± 23.9	0.006*

Mean values for VAS back and leg and for ODI and RM; *p*-values are referred to preoperative value;
SD standard deviation, *pre-OP* preoperatively
*shows statistical significant differences between follow-up and preoperative data with *p*-value less than 0.05

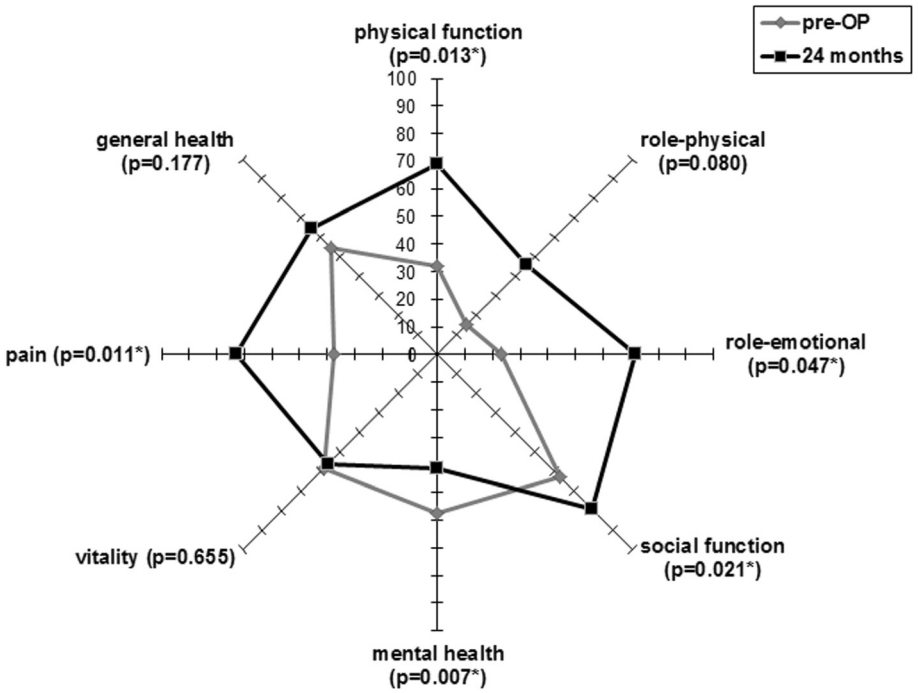

Fig. 3 SF-36 before operation and 24 months later. pre-OP means preoperatively, *indicates statistical significant difference to the preoperative value

3 months, 28.35° ± 6.77° after 6 months, 25.73° ± 7.68° after 12 months and 31.45° ± 7.87°) (Fig. 5, Table 2).

Discussion

In this study we present clinical and radiological findings after PDS with an IDD with the main focus of evaluation of the in vivo intervertebral and total lumbar spine mobility by the use of conventional functional x-ray imaging and with high-accuracy RSA during a follow-up of 24 months.

The analysis of the iROM of the treated segments shows statistical significant reduction directly after operation and after 3 and 12 months with still but not significant decreased ROM after 6 and 24 months when compared to the preoperative value. This course corresponds somewhat to data from literature with stronger decrease of iROM shortly after operation (from 9.28° preoperative

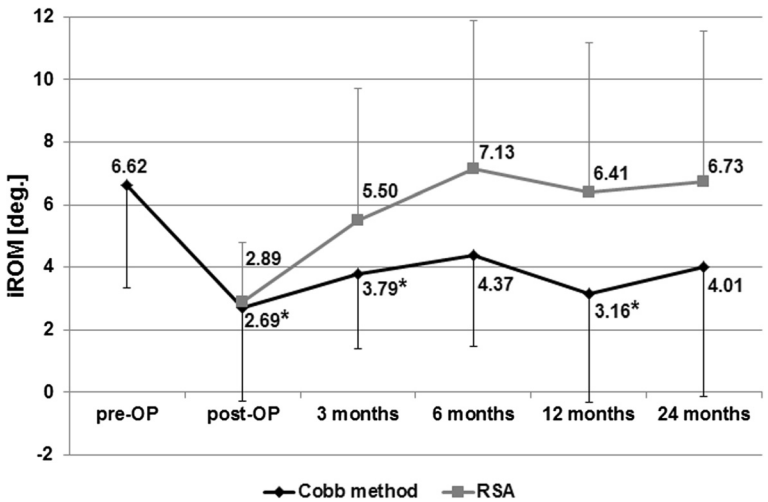

Fig. 4 Development of the iROM in degree (deg.) to the different time points. pre-OP means preoperatively, post-OP means soon after surgery, measured by the Cobb method and RSA, *indicates statistical significant difference to the initial angle

Table 2 iROM and tROM during the postoperative course

Time	iROM, mean ± SD (deg.)			tROM, mean ± SD (deg.)	
	Cobb method	*p*-value	RSA	Cobb method	*p*-value
Pre-OP	6.62 ± 3.30		-	26.01 ± 10.29	
Post-OP	2.69 ± 2.96	0.010*	2.89 ± 1.89	19.65 ± 5.67	0.056
3 months	3.79 ± 2.38	0.034*	5.50 ± 4.21	26.63 ± 8.19	0.283
6 months	4.37 ± 2.88	0.161	7.13 ± 4.77	28.35 ± 6.77	0.204
12 months	3.16 ± 3.48	0.040*	6.41 ± 4.75	25.73 ± 7.68	0.399
24 months	4.01 ± 4.15	0.175	6.73 ± 4.82	31.45 ± 7.87	0.051

The ROM-data were calculated from the difference of angles in flexion and extension; *p*-values are referred to preoperative value;
SD standard deviation, *pre-OP* preoperatively, *post-OP* postoperatively
*shows statistical significant differences between follow-up and preoperative data with *p*-value less than 0.05

to 4.75° postoperative) and slight increase in the following time period (6.65° at last follow-up) which is the only available publication about this topic [2]. However, in the retrospective study by Sobottke et al. the 18 patients with the Wallis® implant had a follow-up of only 7.2 months. These data nevertheless suggest that IDD have the capability to provide dynamic stabilization of the affected levels in the lumbar spine. We also have no reasonable doubt, that this effect could be maintained 24 months and beyond, although data with a follow-up longer than 2 years are still not available.

In interpretation of the iROM data several limitations should always be kept in mind. We have to consider the intra- and interobserver variability up to 8.8° when using the Cobb method [19, 20]. Furthermore, patients show intra-subject variability in spine mobility which is for pre- and postoperative condition, especially after dynamic stabilization. Furthermore, spine mobility depends on the patient's cooperation during examination and condition with possible restricted mobility in case of pain.

It should be noted, that since RSA relies on the intraoperatively implanted tantalum markers, it can only provide data postsurgically and cannot capture the preoperative referenced ROM. Intervertebral ROM measured with RSA showed a similar tendency to the values of iROM determined by Cobb method with slight but not uniform increase of ROM with increasing follow-up time. The RSA based iROM observed in our study were constantly higher than the values measured conventionally. This is different to a comparative study with patients after lumbar disc replacement by Park et al. who found a mean difference in segmental motion of 2.4° between RSA and digital Cobb technique with lower values for RSA [17]. The overall discrepancy of the conventionally determined iROM and the data measured by RSA was low in our patients (2.90°). While the Cobb method generally has an intra- and interobserver variability up to 8.8° RSA is known to be the most exact method for motion analysis with an accuracy between 0.15° and 1.15° [19, 20]. For clinical decision

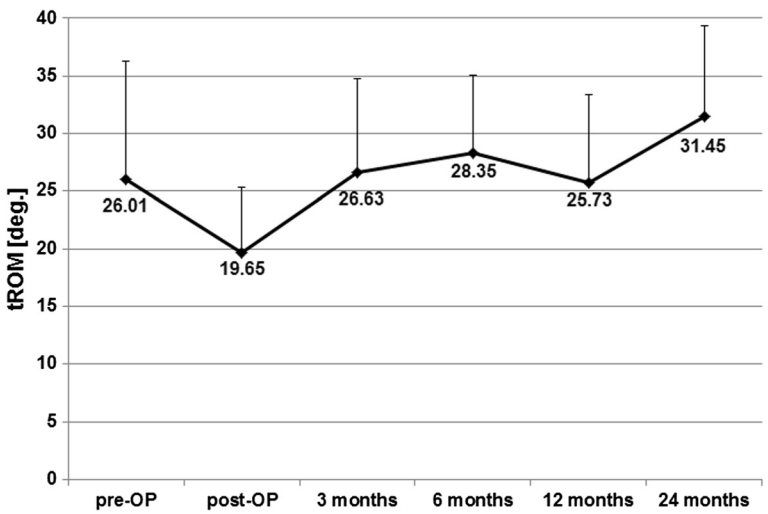

Fig. 5 Development of the tROM in degree (deg.) to the different time points. pre-OP means preoperatively, post-OP means soon after surgery, measured by the Cobb method L1 to S1

making, the Cobb method's accuracy is sufficient, for certain research questions RSA should be applied.

The direct postoperative mobility of the total lumbar spine was clearly but not significantly reduced, maybe because of patient's discomfort or wound pain a few days after surgery, with a continuous increase during the further time period with one exception after 12 months with again slight decrease. The tROM after 24 months was the highest but without statistical significance, probably due to the relatively small number of cases we investigated.

Our radiological findings concerning iROM correlate well with other biomechanical studies. In an experimental test setup with analysis of four different IDD all implants showed significant and more than 50 % decrease of extension without any stabilizing effect in lateral bending or axial rotation but with strong reduction of intradiscal pressure [21]. Only the Wallis® spacer demonstrated a tendency to restabilize the specimens in flexion nearly to the values to the intact condition. Similar findings were published by Lafage et al. [22], who evaluated iROM of the Wallis® implant in vitro and by finite-element analysis. Mainly reduced flexion-extension ROM without suppressing overall mobility with lowered stress in the disc was found. In another experimental study the Wallis® spacer underwent biomechanical analysis against intact condition and a semi-rigid pedicle-screw based implant [7]. Again the IDD lead to primary stabilizing effect with restriction of motion predominantly in the sagittal plane.

Summarizing our radiological results and the findings of the experimental studies, the effect of IDD can be considered as proven with regards to stabilizing the addressed lumbar segment. In addition to the cited biomechanical studies, we have now observed that the stabilizing influence of the investigated IDD is not only of short-term nature, but has a mid- to long-term effect at least to the minimum of 24 months we were able to follow-up.

We are aware that the clinical results of the presented study should be interpreted with caution because of the monocentric study design without any control group and the small number of patients. However, there is a lack of data from prospective trials dealing with the Wallis® spacer without additional fusion procedures in another level to date. One retrospective study with this device was published by its developer and demonstrated a survivorship of this system of 82.8 % at 10 years and of 75.9 % at 14 years but gave no information regarding radiographic findings [10]. Sobottke et al. retrospectively analyzed 18 persons treated with the same implant without decompression and observed statistical significant pain reduction in the postoperative course [2]. The strength of our clinical trial is the prospective study design with continuous monitoring of pain intensity for back and leg, functional disability and health related quality of life with a follow-up period of 24 months. The data of the scores as well as the development of the walking distance are very promising with almost always significant improvement, but we cannot compare our findings with patients who underwent other surgical techniques such as decompression without an IDD or isolated implantation of IDD without decompression because of the lack of a control group.

Regarding clinical results two systematic reviews were published comparing IDDs with decompressive surgery in patients with spinal canal stenosis [23, 24]. Wu et al. performed a meta-analysis of two randomized controlled trials and three non-randomized prospective comparative studies with 204 patients in the IDD group and 217 persons in the decompression collective [23–29]. Five different devices were investigated (X-STOP, Aperius®, Coflex®, DIAM™, distraXion). Both treatment groups showed mostly significant improvement in clinical outcome scores (VAS for back and leg, ODI and RM). However, after pooled analysis the authors observed no significant difference between IDD and decompression patients. Furthermore, they found a similar complication rate but a significantly higher incidence of reoperations with 19.3 % in the IDD group than in the decompression collective with 6.9 %. Similar results were found by Hong et al. who conducted a meta-analysis with 20 studies including 3155 patients after implantation of an IDD (X-STOP, Aperius®, Coflex®, DIAM™, Wallis®, SPIRE®) and 50,983 patients after decompression [24]. In summary, both surgical procedures led to clinical improvement but without significant difference between the two treatment options for improvement rate, VAS for back and leg or ODI. Again, reoperation rate was higher in IDD group than in decompression group (16.5 % versus 8.7 %).

Radiological findings were mostly not the focus of these studies and were only rarely reported. Thus, in the investigation of Kim et al. the used DIAM™ and Coflex® spacers led to decreased iROM in the affected level directly after operation with increasing during time with values close to the initial data at the last follow-up after an average of 71 months [27]. The reported iROM was always clearly higher than in our study and the differences were not statistically significant.

Conclusions

According to the radiological results of this study, the used Wallis® implant stabilizes dynamically expressed by mostly significant reduction of intervertebral ROM of the operated lumbar spinal segments. The positive clinical findings should be interpreted with caution because of the small number of patients and the lack of a control group.

Ethical standards

All procedures have been approved by the local ethics committee and have been performed in accordance with the ethical standards of the institutional and national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

DD, CH, FS, CN and MS have made substantial contributions to conception, design and statistical analysis of the study. All authors read and approved the final manuscript.

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Original article

Minimum 5-year follow-up study on the effects of the Wallis dynamic stabilization system in the treatment of lumbar degenerative disease

Chen Zheng, Peng Baogan, Li Duanming, Pang Xiaodong and Yang Hong

Keywords: *Wallis; lumbar degenerative disease; adjacent segment disease; adjacent segment degeneration*

Background Short-term outcomes of the Wallis system in the treatment of lumbar degenerative disease (LDD) have been shown to be effective, whereas there is a paucity of studies on the mid–long-term effects of the treatment of the Wallis system. This study was to evaluate the mid–long-term effects of the Wallis dynamic stabilization system in the treatment of LDD.

Methods A total of 26 patients who received the treatment of the Wallis system between February 2008 and January 2009 were included in the study, with 14 patients (Group 1) with L4/5 disc herniation and 12 patients (Group 2) with L5/S1 disc herniation and L4/5 intervertebral disc degeneration (IDD). Visual analog scale (VAS) and Oswestry Disability Index (ODI) were used to evaluate the clinical outcomes and lumbar X-rays and MRI were obtained to observe imaging changes before and after operation.

Results The mean follow-up period was (63.50±2.12) months. The mean ODI and VAS scores decreased obviously three months and five years after operation (P <0.05). In Groups 1 and 2, L4/5 Cobb angle and range of motion (ROM) decreased and L4/5 posterior disc height increased at the last follow-up (P <0.05). There were no statistically significant changes in L4/5 anterior disc height and L3/4 University of California at Los Angeles grading before and after operation. There was no statistically significant change in Pfirrmann grading system of L4/5 IDD in Group 2 before and after operation. Adjacent segment degeneration at the last follow-up was found in two patients (2/26, 7.69%) and Modic changes in L4/5 endplates were detected in one patient (1/26, 3.85%).

Conclusions The mid–long-term effects of the Wallis system in the treatment of LDD were satisfied. The Wallis system, as a dynamic stabilization system, which can preserve some ROM of the fixed segment, sustain the lumbar stabilization, and prevent adjacent segment disease and fixed segment degeneration, is an effective instrument to treat LDD.

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Lumbar degenerative disease (LDD) such as lumbar disc herniation, lumbar segmental instability, and lumbar spinal canal stenosis, which is mainly caused by lumbar disc degeneration, is the most common disease in spinal diseases. For LDD, the therapeutic methods include conservative and operative treatment. Operative treatments including decompression and/or interbody fusion in general are considered and offer significant symptomatic improvement in neurological function, pain relief, and amelioration in quality of life.[1,2] However, complications such as segmental spinal instability and narrowing of intervertebral space were often observed after simple decompression,[3] and delayed complications that included lumbar stiffness and adjacent segment disease (ASD) were found after interbody fusion,[4] which made the effects of the treatment of decompression and interbody fusion under suspicion. For the past few years, a non-fusion concept, which is aimed to maintain the implanted segment stabilization, preserve motion of the fixed segment, and prevent ASD, has received far more attention.[5,6] In this study, 14 patients with L4/5 intervertebral disc herniation (IDH) as Group 1 were treated with implantation of the Wallis interspinous system in L4/5 segment and 12 patients with L5/S1 IDH and L4/5 intervertebral disc degeneration (IDD) as Group 2 received the Wallis interspinous implant in L4/5 segment cephalad to pedicle screw instrumentation in L5/S1 segment. The main reason of the Wallis system implanted in Group 1 is to maintain implanted segment stabilization, preserve motion of the instrumented segment, and prevent further degeneration of L4/5, and in Group 2 to prevent further degeneration or deterioration of already existing L4/5 disc degeneration. Short-term outcomes of the Wallis system in the treatment of LDD have been shown to be effective, whereas there is a paucity of studies on the mid–long-term effects of the treatment of the Wallis system. To evaluate the mid–long-term effects of the Wallis dynamic stabilization system, we observed the results of the treatment for the 26 patients by means of minimum 5-year follow-up.

METHODS

Patients

The study was carried out with the approval of the

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hospital ethics committee. We conducted a retrospective, observational, single-center study on the effect of the Wallis system in the treatment of LDD. A total of 32 patients were treated by the Wallis system between February 2008 and January 2009. We chose the patients with LDD treated by the Wallis system at the single level of L4/5 for this study. Exclusion criteria were as follows: (1) patients with degenerative lumbar scoliosis or degenerative spondylolisthesis of more than 1°; (2) lumbar disease such as tumor, infection, and various metabolic bone disorders; (3) bone mineral density (BMD) test T-score of –2.5 or lower; (4) spinous process fracture; and (5) lost to follow-up.

The study population finally enrolled 26 patients (12 males and 14 females), with the mean age of 37 years (range 27–56 years), who were treated with implantation of 26 sets of the Wallis systems (Zimmer, USA). Group 1 included 14 patients with massive L4/5 IDH who underwent disc excision and received the Wallis interspinous implant in L4/5 segment and Group 2 included 12 patients with massive L5/S1 IDH and L4/5 IDD who received the Wallis interspinous implant in L4/5 segment cephalad to instrumented fusion in L5/S1 segment in this study. In Group 1, L4/5 herniated discs were all massive. In Group 2, L4/5 intervertebral disc degeneration graded with the modified Pfirrmann MRI classification proposed by Griffith et al[7] varied between the Grades 4 and 6 preoperatively.

Operative technique

After the success of general anesthesia, each patient was placed prone on a plain management table. The involved skin area was prepared aseptically with ethyl alcohol and povidone−iodine and then draped in sterile fashion. A midline skin incision centered over the involved lumbar segment was made. Then, subcutaneous tissue and lumbodorsal fascia were cut off. Subsequently, subperiosteal dissection was performed to expose vertebral plates and spinous processes. The supraspinous ligament was detached from the spinous processes of L4 and L5. The interspinous ligament between L4 and L5 was removed. After L4/5 disc excision in Group 1, the appropriate size of implant was chosen in neutral position of physiological lumbar lordosis to fit the trimmed interspinous space and avoid kyphosis of the instrumented segment. The lordosis of the lumbar column was verified with an image intensifier before final fixation of the implant. The surgeon threaded the cord around the spinous processes of L4 and L5 and through the Wallis interspinous implant. When tension had been applied, the extremity of the cord was blocked by firmly lodging a taper beside it in the spacer. The supraspinous ligament was reattached to each spinous process by transfixing sutures. Location of the implanted segment was confirmed with an image intensifier in the operating room. The wound was closed in layers over a drain after completion of the spinal procedure.

Rigid pedicle screw instrumentation was used in L5/S1 segment in Group 2. The surgeons should take care not to harm the facet joint capsule adjacent to the fused segment. Cage filled with autogenous local bone derived from decompression was used for interbody fusion.

Patients were encouraged to begin walking on the third day after the surgical intervention. Isometric exercises were prescribed to maintain the muscle tone of the trunk and rehabilitation was pursued with emphasis on tightening the low back muscles. Patients were generally checked at three months and 12 months after the operation at our outpatient spinal unit and thereafter once a year.

Evaluations

Clinical findings

The Oswestry Disability Index (ODI, version 2.0)[8] and visual analog scale (VAS) were used to evaluate the clinical outcome before and after surgery.

Radiological evaluations

Radiographic studies were conducted in all patients and results were evaluated by three independent spine surgeons. Radiographs were obtained before and three days, three months, 12 months, and five years after surgery in all patients. We measured the heights of the Wallis implanted segment, which included L4/5 HV (height of ventral intervertebral space; Figure 1) and HD (height of dorsal intervertebral space; Figure 1) at each time point mentioned above. To evaluate lumbar physiological curvature, we measured L4/5 range of motion (ROM) in hyperextension and hyperflexion (Figure 2) and L4/5 Cobb angle in the neutral position.

To observe degeneration of the Wallis implanted segment

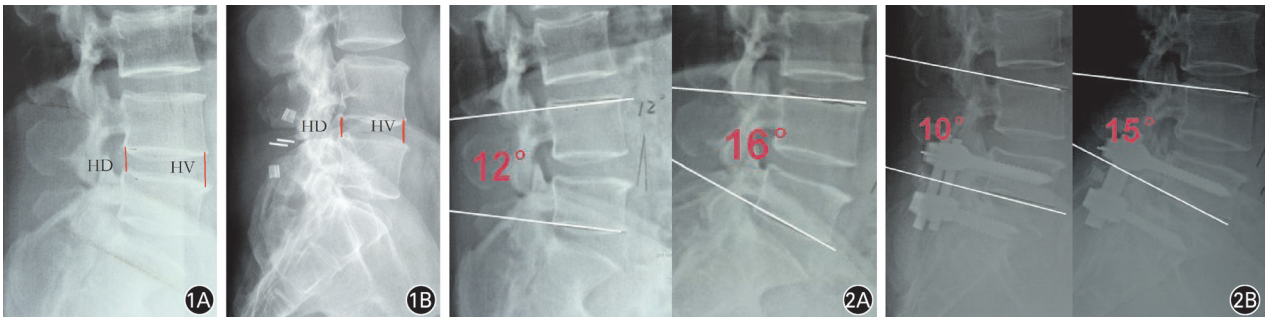

Figure 1. HV and HD at L4/5 segment before (**1A**) and after operation (**1B**).
Figure 2. L4/5 range of motion before (**2A**) and after operation (**2B**).

(L4/5) and adjacent segment (L3/4), MRI was obtained between preoperative and postoperative 1-year and 5-year follow-up in all patients. We evaluated the degeneration of L4/5 and L3/4 segments, according to UCLA grading of degeneration of intervertebral disc[9] and modified Pfirrmann grading system for lumbar IDD.[7]

Statistical analysis

Variables were presented as means±standard deviation. Paired-samples *t*-test was used to test the difference in ODI, VAS, HV, HD, ROM, and Cobb angle between preoperative and postoperative follow-up. Because the data of VAS for low back pain and leg pain at the last follow-up were abnormal distribution, Wilcoxon rank sum test was used to test the difference in VAS for low back pain and leg pain between the preoperative and last follow-up. Wilcoxon rank sum test was also performed to detect degeneration of adjacent segment according to UCLA grading system and L4/5 segment in Group 2 according to Pfirrmann grading system. Statistical analysis was performed using SPSS16.0 (SPSS Inc., USA). Significant level was defined as P <0.05 (α=0.05).

RESULTS

Clinical outcomes

A total of 26 patients with LDD at our department between February 2008 and January 2009 were included in the study. The mean follow-up period was (63.50±2.12) months (range from 60.00 to 68.00 months). The mean ODI score decreased from 36.92±2.00 preoperatively to 10.19±1.81 at three months postoperatively (P <0.05) and 3.92±1.20 at the last follow-up (P <0.05). The mean VAS score for low back pain reduced from 7.19±0.90 preoperatively to 2.92±1.02 at three months postoperatively (P <0.05) and 0.65±0.62 at the last follow-up (P <0.05). The mean VAS score for leg pain decreased from 8.04±0.96 preoperatively to 2.73±0.92 at three months postoperatively and 0.58±0.64 at the last follow-up (P <0.05; Table 1).

Results of radiographic imaging

On the basis of preoperative and postoperative radiographic imaging (Table 2), standing L4/5 HD in Groups 1 and 2 increased obviously at the last follow-up (P <0.05, Figure 1). Conversely, L4/5 HV did not change at the last follow-up (P >0.05, Figure 1). L4/5 segments in Groups 1 and 2 preserved some ROM at the last follow-up (P <0.05, Figure 2). There was no statistical significance in Pfirrmann grading system of L4/5 IDD in Group 2 before and after operation (Table 3 and Figure 3). UCLA grading of degeneration of intervertebral space at L3/4 segment in all patients showed no statistical significance between preoperative and postoperative follow-ups (Table 4). Obvious degenerative changes at L3/4 segments were not seen in most patients at the postoperative 1-year and 5-year follow-up. At the last follow-up, L3/4 disc degeneration was detected in two patients (7.69%, 2/26) and narrowing of intervertebral space and Modic changes in L4/5 endplates were found in one patient of Group 1 (3.85%, 1/26).

Table 1. Mean score of VAS and ODI (n=26)

Item	Preoperation	Postoperation 3 months	Postoperation 5 years
Low back pain	7.19±0.90	2.92±1.02*	0.65±0.62†
Leg pain	8.04±0.96	2.73±0.92*	0.58±0.64†
ODI	36.92±2.00	10.19±1.81*	3.92±1.20*

Paired-samples *t*-test is used to test the difference between the preoperative and postoperative three months and last follow-up values (*P <0.05 is statistically significant). Wilcoxon rank sum test is used to test the difference between the preoperative and last follow-up values (†P <0.05 is statistically significant).

Table 2. Radiographic results of L4/5 segment

Item	Group 1 (n=14)		Group 2 (n=12)	
	Preoperation	Postoperation 5 years	Preoperation	Postoperation 5 years
HV (mm)	11.64±0.84	11.86±1.29†	13.00±0.95	12.91±1.08†
HD (mm)	6.93±0.92	8.29±0.83*	7.83±1.03	8.75±0.75*
ROM (°)	5.36±0.93	2.43±0.51*	5.17±0.94	2.92±0.67*
Cobb angle (°)	13.57±1.02	14.93±1.07*	13.33±1.07	14.00±0.85*

Paired-samples *t*-test is used to test the difference between the preoperative and five years after operation values (*,†P <0.05 is statistically significant).

DISCUSSION

The Wallis dynamic stabilization system constitutes a floating system with no permanent fixation in the vertebral bone. By loading interspinous mechanical stress to unload most mechanical pressure in the posterior intervertebral disc and zygapophysial joints,[10] the Wallis system could restore the height of the intervertebral space and intervertebral foramens, so that it could relieve pain and improve clinical

Table 3. Pfirrmann grading of L4/5 intervertebral disc in Group 2 (total n=12)

Grade	Preoperation (n)	Postoperation 1 year* (n)	Postoperation 5 years* (n)
4–5	11	10	9
6	1	1	1
7	0	1	2
8	0	0	0

Wilcoxon rank sum test is used to test the difference between the preoperative and postoperative 1-year and last follow-up values (*P <0.05 is statistically significant).

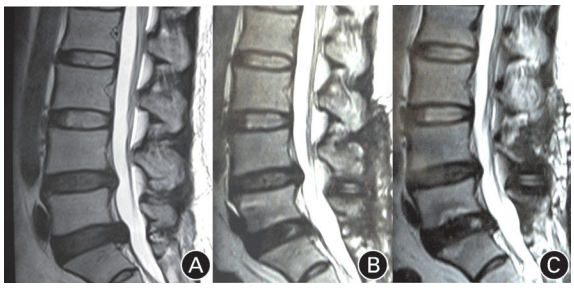

Figure 3. MRI before operation (**A**), MRI image one year (**B**) and five years (**C**) after operation in Group 2.

Table 4. UCLA grading of L3/4 segment (total n=26)

Grade	Preoperation (n)	Postoperation 1 year* (n)	Postoperation 5 years* (n)
I	19	18	18
II	7	7	6
III	0	1	2
IV	0	0	0

Wilcoxon rank sum test is used to test the difference between the preoperative and postoperative 1-year and last follow-up values (*P <0.05 is statistically significant).

outcome. In addition, Sengas[11] found that the Wallis system could decrease ROM at the instable segment and achieve an increase in the rigidity of destabilized segments beyond normal values. Likewise, in a study reported by Schulte et al,[12] additional implantation of the Wallis system could lead to reduction of ROM in the fixed segment compared to the situation after decompression alone: 66% in flexion-extension, 6% in lateral bending, and 5% in axial rotation. The present study showed that compared to other interspinous dynamic systems, the Wallis system tended to form a more stable condition in flextion.[13,14] In our study, considering that discectomy of massive herniated disc in Group 1 could inflict segment instability and low back pain after operation and the patients were young, we decided to make the Wallis system as a bridge therapy. Moreover, in case of failure, removal of implant posed no technical problem, and revision by fusion, if necessary, had proven to be simple. The final clinical outcome and radiographic evaluation showed that no patient relapsed and L4/5 segment preserved some ROM in Groups 1 and 2. HD increased in Groups 1 and 2 at the last follow-up. However, narrowing of intervertebral space and Modic changes in L4/5 endplates were found in one patient of Group 1. Besides, Braz et al[15] found that resorption of spinous processes resulting in the loosening of implant led to reducing long-term stability of the implant in the animal model. We have not discovered any patient as reported above yet.

Lumbar interbody fusion is the most common treatment for LDD, but it could alter the biomechanics of the spine. Loss of motion at the fused levels is at least theoretically compensated by increased motion at adjacent unfused segments resulting in ASD.[16-18] The exact etiology of ASD is uncertain but associated with alterations in facet loading, hypermobility, and increased intradiscal pressure at the segments adjacent to fusion mass.[19-21] Since the 1980s, an attempt was made to use dynamic stabilization to treat LDD to reduce the incidence of ASD.[22-24] It has been reported that non-fusion motion preservation surgery may prevent accelerated ASD. The concept of the Wallis interspinous dynamic stabilization system was first proposed by Senegas.[11] He thought that Wallis system could make an influence on load transfer by means of lowering mechanical pressure in the intervertebral disc and zygapophysial joints. Wike et al[14] deemed that the Wallis system could reduce abnormal load by means of limiting abnormal sagittal motion effectively. In addition, by the Wallis system, mildly degenerative disc could be recovered biomechanically and biochemically. A study with regard to lumbar biomechanical measurement reported by Li et al[25] found that after lumbar interspinous fixation, the stiffness and stability of cephalad adjacent segment increased. They thought that the interspinous fixation system had protective effective on cephalad adjacent segments. Likewise, Korovessis et al[26] reported that the Wallis system could change the natural history of IDD and decrease the incidence of ASD. Previous studies[10,27] also reported that Wallis system, which could unload the pressure of posterior disc, could reduce discogenic low back pain. In our study, the final X-ray and MRI showed the ASD (L3/4) in just two patients of Group 1 (7.69%, 2/26) at the final follow-up. The mechanism of the ASD is not clear, and likely related to the natural course of disc degeneration.

Decompressive surgery could lead to degeneration of the responsible segment as a consequence of instability which could result from facetectomy.[3] Meanwhile, fusion surgery could result in loss of motion in the target level.[2] However, the Wallis system could unload the facet joints, restore foraminal height, and provide sufficient stability especially in extension but still allow motion in the implanted segment.[13] The Wallis system implanted in Group 2 was aimed to halt degeneration or deterioration of already existing IDD (L4/5 segment) in our study. Encouragingly, deterioration of disc degeneration was not found at L4/5 segments, which corresponded with the result reported by Korovessis et al.[26] The intradiscal pressure after implantation was reduced in the L4/5 degenerative segment and the Wallis system could change the natural history of the already degenerative disc.[14] To sum up, the Wallis system implanted in degenerative segment could prevent or halt degeneration of the responsible level.

To balance the motion and stability in fixed segment has always been a hope for the treatment of LDD. In our study, we conducted a minimum 5-year follow-up for 26 patients and the result of the follow-up was satisfactory, which indicated that the Wallis system, which could settle the problem of motion and stability at the fixed segment, was a new choice for the treatment of LDD.[28] Besides, our study adds to existing evidence that suggests Wallis system could stop or prevent the natural history of ASD.

In conclusion, compared with the traditional fusion, the Wallis system as a new concept and technique is a quantum jump beyond doubt. Though the Wallis system could not replace interbody fusion, at least it could become a bridge between fusion and non-fusion.[29,30] In our study, the mid–long-term effects of the second-generation Wallis dynamic stabilization system in the treatment of LDD were satisfactory, but it was unfortunate that the sample size was small. In order to further validate the mid-long-term effects of the Wallis system, we expect multi-center large sample analysis.

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Dear Editor:

This is a manuscript by SUN Peng- Fei and JIA Yu –Hua, It is submitted to be considered for publication in your journal. This paper is new and original ,it is the result of our work about posterior dynamic lumbar stabilization in lumbar degenerative disease in Chinese patients .Neither the entire paper nor any part of its content has been published or has been accepted elsewhere. It is not being submitted to any other journal and all the authors listed have approved the manuscript that is enclosed. I have read and have abided by the statement of ethical standards for manuscripts . We believe the paper may be of particular interest to the readers of your journal.

We trust that the manuscript meets the high standard of your journal and are looking forward to your positive response.

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Thanks very much for your attention to our paper.

Sincerely yours,

JIA Yu –Hua

Title page

Preliminary evaluation of posterior dynamic lumbar stabilization in lumbar degenerative disease in Chinese patients

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Running title ; dynamic lumbar stabilization in lumbar degenerative disease

Preliminary evaluation of posterior dynamic lumbar stabilization in lumbar degenerative disease in Chinese patients

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Abstract

Background The aim of the present study was to assess the safety and efficacy of the dynamic stabilization system in the treatment of degenerative spinal diseases in Chinese patients.

Methods The clinical outcomes of 20 patients with lumbar degenerative disease treated by posterior decompression with the Wallis posterior dynamic lumbar stabilization implant were studied. All of the patients completed the visual analogue scale and the Chinese version of the Oswestry Disability Index. The following radiologic parameters were measured in all patients: global lordotic angles and segmental lordotic angles (stabilized segments, above and below adjacent segments). The range of motion was then calculated.

Results Nineteen patients (95%) were available for follow-up. The mean follow-up period was 27.25 ± 5.16 months (range 16 - 35 months). The visual analogue scale decreased from 8.55 ± 1.21 to 2.20 ± 1.70 (P <0.001), and the mean score on the Chinese version of the Oswestry Disability Index was improved from 79.58% ± 15.93% to 22.17% ± 17.24% (P <0.001). No statistically significant changes were seen in the range of motion at the stabilized segments (P = 0.502) and adjacent segments (above, P = 0.453; below, P = 0.062). The good to excellent result was 94.4% at the latest follow-up. No complications related to the use of the Wallis posterior dynamic lumbar stabilization occurred.

Conclusions It is found to be both easy and safe to use the Wallis posterior dynamic lumbar stabilization implant in the treatment of degenerative lumbar disease, and the early therapeutic effectiveness is good. The Wallis system provides an alternative method for the treatment of lumbar degenerative disease.

Keywords: *lumbar degenerative disease; low back pain; prosthesis; treatment outcome*

Degenerative disc disease is often treated by spinal fusion. Several papers have shown that a few years after surgical treatment of a degenerative disc, discs in adjacent segments may also become affected. [1] It is casually hypothesized that the load reduction of a slightly degenerative disc may postpone fusion surgery and adjacent disc disease. Based on studies in which patients with partial disc fusion showed the same clinical outcomes as patients with solid disc fusion, it could be hypothesized that a reduction in, rather than an elimination of, segmental motion results in the alleviation of pain. [2] These findings suggest the need for alterative procedures and techniques that do not require fusion for the treatment of painful degenerative spine disease. [3] As a consequence, various kinds of dynamic stabilization systems have recently been developed. Of these, an interspinous dynamic stabilization system (the prototype of the current Wallis implant) was designed to stiffen unstable operated degenerate lumbar segments. There has been some controversy related to the use of the Wallis system, rather than disc fusion in the treatment of patients with degenerative spine disease. [4] Furthermore, there are no reports concerning the application of this dynamic stabilization system in Chinese patients, who have a slightly different lifestyle to Western patients. The primary objective of the present study was the determination of the safety and effectiveness of this system in Chinese patients with degenerative spine disease. The clinical and radiological outcomes of these patients are presented.

METHODS

Basic information

Between November 2005 and August 2009 at a single institute, we retrospectively studied 20 patients with a mean age of 61 ± 6.98 years (range 46 - 70). The patients had undergone posterior dynamic stabilization by one surgeon using the Wallis System. They experienced symptoms which were resistant to any conservative treatment for an average of 74.8 ± 105.73 months (range 8 - 260 months). Ten patients (50%) had hypesthesia or parasthesia on the affected sensory dermatomes, and five patients (25%) had mild weakness in the affected lower extremities. There was no past preoperative medical history which affected the result of the operations. Patients with osteoporosis (T-score at or below -2.5), malignancy, active local and/or systemic infection, and degenerative scoliotic or kyphotic deformities were excluded (Table 1).

Preoperative evaluation

The patients completed the visual analogue scale (VAS) and Chinese version of the Oswestry Disability Index (ODI). Anteroposterior and lateral standing dynamic (flexion and extension views) radiographs of the lumbar spine were taken in all patients both before and after surgery until the last follow-up. The global and segmental lordotic angles (stabilized segments, above and below adjacent segments) were measured using Cobb's method with the PACS program (M-view. Ver.5.4, Infinitt Technology). The global lordotic angles were measured from the upper endplate of vertebra T12 to the upper endplate of the sacrum. The segmental lordotic angles (stabilized segments and adjacent segments) were measured from between the upper end plates of the corresponding segments. After measuring the angles, the range of motion (ROM) in the stabilized segments and adjacent segments was calculated.

Follow-up evaluation

The following data were collected: VAS, Chinese version of the ODI, pain medication, complications and patient satisfaction. The plain radiographs (anteroposterior and lateral standing) and dynamic radiographs (flexion and extension views) were measured at the designated times until the last follow-up.

Surgical procedure

All operations were performed by a single surgeon, with the patient in a neutral position, using the standard surgical procedure for posterior lumbar spine surgery. After the supraspinous ligament was detached, the interspinous space was trimmed with a gouge and a high-speed drill to create a trapezoid shaped opening to prevent the posterior displacement of the spacer. A groove for the cord was cut in the lamina with a high-speed drill, or the sacral crest was perforated transversely to enable the cord to be threaded through it. The spacers were chosen to fit the trimmed interspinous space and avoid kyphosis of the instrumented segment. The lordosis of the lumbar column was verified using an image intensifier prior to final fixation of the implant. The surgeon threaded the cord around the spinous processes. When tension had been applied throughout all levels, the extremity of the cord was blocked by firmly lodging a taper beside it in the metal spacer. The supraspinous ligament was reattached to each spinous process using separate transfixing sutures. Two of the cases included in the present study had simple lumbar instability and received only interspinous system implantation. The remaining 17 cases were complicated with protruding intervertebral discs, so they underwent simultaneous window laminectomy and nucleus pulposus enucleation at the time of implantation of the dynamic stabilization system.

Statistical analysis

The clinical and radiologic results were analyzed using Wilcoxon's Signed Rank test. *P* values of less than 0.05 were considered statistically significant. All analyses were carried out using SPSS Ver. 12.00K (SPSS, Inc., Chicago, IL, USA).

RESULTS

Clinical outcome

The VAS for back and leg pain decreased from a preoperative mean value of 8.55 ± 1.21 (range 6 - 10) to a postoperative mean value of 2.20 ± 1.70 (range 0 - 5) (P <0.001). The number of patients using pain medication decreased from 19 patients (100%) preoperatively to five patients (26.3%) postoperatively. After the operation, 14 patients (78.7%) did not use analgesics and 11 patients (57.8%) were completely free of back and leg pain. There were no newly developed neurologic deficits or aggravation of neurological symptoms.

The preoperative Chinese version of the ODI was 79.58% ± 15.93% (range 22 - 89%), indicating that the average patient had a severe disability. At follow-up, it was 22.17 ± 17.24% (range 2 - 57%), which corresponds to moderate disability. This improvement was also

statistically significant (P <0.001) (Table 2). At the last follow-up, 17 patients (89.5%) were satisfied with the result of surgery, but two patients (10.5%) were not.

Radiologic follow-up

The global lordotic angles and segmental lordotic angles (stabilized segments, above and below adjacent segments) were measured using lateral standing radiographs, including flexion and extension views, of patients standing in the neutral position. The ROM of the global levels was 14.72 ± 7.66° before the operation and 13.92 ± 8.68° at the last follow-up. This change was not statistically significant (P = 0.002). Preoperatively, the ROM in the stabilized segments was 5.17 ± 3.84° and postoperatively it was 4.04° ± 3.10° (P = 0.502). The ROM in the upper segments was 2.58 ± 2.23° preoperatively and 3.03 ± 3.43° postoperatively (P = 0.453). In the lower segments the ROM was 2.96 ± 3.43° preoperatively and 2.64 ± 2.52° postoperatively (P = 0.062). There was no statistically significant change in the ROM. Radiologic changes in the disk-height ratio (DH) postoperative of the stabilized segment were increased significantly from a preoperative value of 15.7 ± 4.5% to a postoperative value 18.6 ± 5.9% (P = 0.002). In the last follow up, the restored DH of the ISU group was lost (13.8 ± 6.6%, P = 0.027) relative to the postoperative DH (Figures1 and 2). Percentage changes in the disc height of the adjacent segment did not differ significantly (Table 3).

DISCUSSION

It is well known that rigid spinal fixation systems increase the risk of complications, such as mechanical failure, osteoporosis and adjacent segment degeneration. [1,5] To avoid these adverse effects, the achievement of ideal stiffness is important. Thus, dynamic stabilization devices would appear to represent a notable technological advantage. [6] Researchers have developed various posterior vertebral stabilizing devices to preserve adjacent mobile segments. The Wallis system is one of many new posterior-approach dynamic stabilizing implants that follow the basic principle of “flexion-extension stability”. As an alternative to fusion, dynamic stabilization systems have various advantages, such as allowing for greater physiologic function and reducing the inherent disadvantages of rigid instrumentation and fusion. [7] The dynamic stabilization system appears to stabilize the spinal segments without fusion across the intervertebral disc or the facet joints. [8] These stabilized segments seem to retain some mobility, which may help to reduce pain and prevent further degeneration of adjacent segments. The interspinous dynamic stabilization system (the prototype of the current Wallis implant), with preservation of the disc and facet, may create a favorable environment in the motion segment by reducing the loading on these joints and allowing more normal motion. [9] The resumption of mobility in a moderately degenerated disc and facet joint may also slow the degenerative spinal process. [10]

The dynamic stabilization system has been in clinical use for more than 10 years in Europe. However, there have been no reports on the use of the Wallis system in China. Despite the different lifestyle of the Chinese, our clinical and radiological outcomes agree favorably with the published data on dynamic stabilization systems. The clinical outcomes of patients

involved in the present study improved significantly during the follow-up period. [11] The system decreased posterior fibrous annulus pressure through tensile distraction of the posterior spinous processes. [12] The device also decreased articular process pressure and reduced the pain transmitted from these overloaded joints to the brain via the medial branch of the dorsal root ganglion.[13] After interspinous internal fixation in cadaver studies researchers discovered increased loading of lumbar articular joints during flexion. Our study is an *in-vivo* examination, which restricts observation of these theoretical results. However, at the latest follow up we did not observe obvious osteophytes around the articular joint and that may be the result of a decrease in the loading pressure on the articular joint surface. [14]

The dynamic stabilization system seems to not only preserve segmental motion, but also to maintain the patient's own lumbar kinematics. [15] Posterior dynamic stabilization systems have stabilization effects in all three primary directions and tend to reduce mobility. They also allow for motion in the axial rotation. However, in flexion and extension, the ROM of the dynamic device is clearly higher. The dynamic device provides a controlled motion that may allow more load to be distributed to the bridged segment and less stress to be concentrated on the implant. [16] Theoretically, these dynamic devices have the advantage of reduced stress shielding, protecting the adjacent segment from degeneration and diminishing implant failure. [17]

Interspinous stabilization of degenerative lumbar segments is not only effective, but is also safe over the long term. [18] The reason for the reduced complication rate may have been the fact that the implant linked the vertebrae without screws or other means of transfixing the cortical bone. Pedicle screw placement is a well-documented source of complications in posterior fusion procedures. [19] Early loosening attributed to toggle-related osteolysis around screws have been reported in pedicle screw-based dynamic stabilization systems. [20]

In conclusion, the present study revealed that a dynamic stabilization system could preserve segmental motion with stability and clinical improvement. This first long-term analysis of an interspinous dynamic lumbar stabilization system in Chinese patients provides promising information. However, in our study it is difficult to arrive at a firm conclusion concerning the clinical efficacy of posterior dynamic lumbar stabilization for several reasons. The sample size was not large and the study design involved a retrospective review without randomization. Finally, our study did not include other kinds of posterior dynamic lumbar stabilization, only the Wallis system. Therefore, further research and prolonged follow-up observations are required to determine the long-term effectiveness of this treatment.

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Figure legends

Figure 1

The postoperative X-ray of simple vertebral canal decompression showed that height of intervertebral space decreased significantly

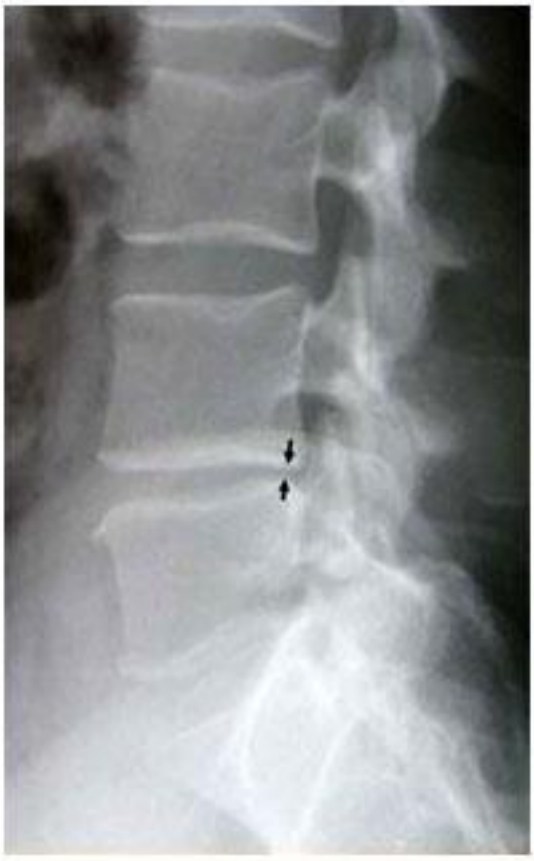

Figure 2

The postoperative X-ray of Wallis implant in lumbar degenerative disease showed that height of intervertebral space was well maintained .

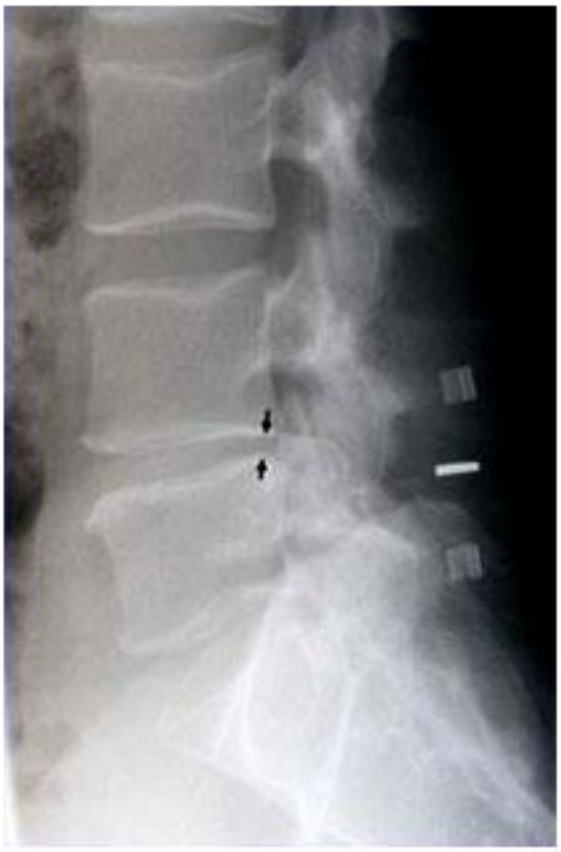

Table 1
Demographic data

Characteristic	number
No. of patients	20(19 followed up)
Age(years)	61±6.98
(range)	46-70
Gender (male:female)	13:6
Duration of symptom(months)	74.8±105.73
Follow-up period (months)	27.25±5.16
Perioperative data	
Operation time(min)	123.32+31.25
Estimated blood loss (ml)	200+18
Hospital stay(days)	11.8+7.3
Distribution of segments treated	
L3-4	6
L4-5	10
L5-S1	3

Table 2

Clinical outcome

Methods	preoperative	postoperative
VAS	8.55±1.21	2.20±1.70
ODI	79.58%±15.93%	22.17%±17.24%
No. of analgesics	19 patients (100%)	5 patients (26.3%)

Table 3
Radiological outcome

Variables	preoperative(^{0})	postoperative(^{0})
Global lorditic angle		
Flexion	26.01± 8.51	26.95±8.96
Neutral	39.72±10.24	41.82±8.32
Extension	48.30±11.62	47.62±9.25
ROM	14.72±7.66	13.92±8.68
Segmental lorditic angle of stabilized segment		
Flexion	9.35±5.26	10.02±5.78
Neutral	14.56±5.12	14.85±3.56
Extension	17.40±5.12	17.86±5.32
ROM	5.17±3.84	4.04±3.10
Above adjacent Segmental lorditic angle		
Flexion	6.43±3.12	7.45±3.25
Neutral	8.06±3.12	8.10±2.36
Extension	9.62±5.21	10.21±2.36
ROM	2.58±2.23	3.03±3.43
Below adjacent Segmental lorditic angle		
Flexion	10.32±3.26	10.44±3.68
Neutral	12.35±5.36	12.28±6.23
Extension	14.45±8.72	14.56±4.52
ROM	2.96±3.43	2.64±2.52
Changes in disc height percentage (%, mean ± SD)		
stabilized segment	0.157±0.045	0.186 ±0.066
Above Segmental	0.130±0.051	0.129±0.042
Below Segmental	0.140±0.031	0.138±0.012

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Clinical Study

Minimum 5 year follow-up of multi-segmental lumbar degenerative disease treated with discectomy and the Wallis interspinous device

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ABSTRACT

We evaluate the clinical effects and radiological findings of the Wallis interspinous device (Zimmer, Warsaw, IN, USA) for the treatment of multi-segmental lumbar degenerative disease after a minimum 5 year follow-up period. A total of 26 adult patients underwent a primary discectomy followed by fixation of the segment with the Wallis interspinous device between December 2007 and August 2008. Twelve men and 14 women with an age range of 43 to 56 years (average: 47.6) were included. The visual analogue scale (VAS) for low back and leg pain, Oswestry Disability Index (ODI), foraminal height (FH), anterior disc height (aDH) and posterior disc height (pDH), range of motion (ROM) and Pfirrmann grades were obtained and compared before and after surgery. The VAS and ODI significantly decreased postoperatively ($p < 0.05$). The postoperative FH and pDH values increased significantly compared with the preoperative levels ($p < 0.01$) and the increase in the FH and pDH values remained statistically significant during the follow-up period. There were no statistically significant changes in the aDH values before and after surgery ($p > 0.05$). Also, there were no statistically significant changes in the ROM and Pfirrmann grade at the instrumented level and at the cephalad-adjacent segment ($p > 0.05$). In our study, no patient underwent further surgery because of a re-prolapse or progression of index level degeneration or adjacent segment disease. The Wallis interspinous device was a useful alternative for treating multi-segmental lumbar degenerative disease and it offered a significant minimum 5 year symptom control.

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1. Introduction

Lumbar degenerative diseases are common clinical problems. Due to more frequent use of CT scans and MRI, an increasing number of patients are diagnosed with multi-segmental lumbar degenerative disease. This is challenging for surgeons because it is difficult to determine which segment is the primary cause of the symptoms. The segment adjacent to the instrumented level might undergo accelerated degeneration after surgery.

Lumbar fusion surgery is often performed to treat multi-segmental lumbar degenerative disease that has not responded to conservative measures. Despite the reported benefits of fusion surgery, many complications can occur. These complications include instrumentation failure, pseudarthrosis and loss of motion [1]. Additionally, the accelerated degeneration of spinal motion segments that are adjacent to a rigidly fused segment has become increasingly recognized as a disadvantage of spinal fusion surgery. Fusion surgery is hypothesized to increase the loads acting on the adjacent segments which potentially leads to accelerated degeneration [2]. In view of these fusion surgery limitations and risks, many investigators are developing motion-sparing alternatives for degenerative conditions.

The Wallis interspinous device (Zimmer, Warsaw, IN, USA) is an interspinous spacer and an alternative for treating degenerative conditions. The Wallis interspinous device can restore segmental stiffness to unstable degenerate segments while preserving intervertebral mobility after decompression [3]. It strongly stabilizes and reduces disc pressure in extension [4]. Moreover, it may delay the need for irreversible and more invasive surgical management and leads to significant pain relief and significant changes at the intervertebral space over short-term follow-up periods [5]. It can delay the natural history of disc degeneration with a significant reduction of the clinical and radiological incidence rates of adjacent segment disease [6]. The purpose of this study was to evaluate the clinical results and radiographic outcomes of the Wallis interspinous device to treat multi-segmental lumbar degenerative disease after at least a 5 year follow-up period.

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2. Materials and methods

This work was supported by the Natural Science Foundation of China (81372002, 31170925), Key Project of Shanghai Science and Technology Commission (12411951300, 09411953800). Our study protocol was approved by the Fudan University Zhongshan Hospital Ethics Committee.

2.1. Patient population

In conducting the study, we retrospectively reviewed clinical notes and radiology records of patients from our institution. The postoperative follow-up times as well as functional outcomes were ascertained from follow-up clinical notes and phone calls. Two experienced spine surgeons evaluated radiological parameters independently during follow-up. Between December 2007 and August 2008, 36 patients with multi-segmental lumbar degenerative disc disease underwent a primary lumbar disc excision followed by fixation of the segment with the Wallis interspinous device, by the same surgeon, at our institution. All of the patients had low back and leg pain even after conservative treatment for at least 6 weeks. Every patient had a preoperative lumbar MRI and was diagnosed as having multi-segmental lumbar degenerative disease. In our study, the pathological changes of the instrumented segment were due to disc herniation, which were treated with a discectomy and fixed with the Wallis interspinous device. The segments adjacent to the instrumented segment were affected by black discs, disc herniations or spinal stenosis and conservative treatment was appropriate for the adjacent segments.

Twenty-six patients with complete clinical and radiographic data were available for evaluation. Twelve of the patients were men and 14 women, with an age range of 43–56 years (average: 47.6). The average length of follow-up was 66.8 months (range: 60–70). Ten patients were excluded from our study: four patients who could not to be contacted during the final follow-up period, four who did not have a radiographic examination 1 year after the surgery and two who had no back or leg-pain and were not willing to have an X-ray during their final follow-up.

2.2. Inclusion and exclusion criteria

The inclusion criteria were as follows: each patient was diagnosed with multi-segmental lumbar degenerative disease and their MRI showed multi-segmental lumbar degeneration. The symptom-causing segment was a single level (determined by electromyography or the pain distribution or neurological deficit) and required surgery, and segments adjacent to the instrumented segment could be treated conservatively.

The exclusion criteria were as follows: incomplete data, scoliosis, spondylolisthesis, segmental instability, acquired spinous process insufficiency, osteoporosis, severe multi-segmental lumbar disc herniation or stenosis and inability to determine the symptom-causing segment.

2.3. Clinical evaluation

The patients were clinically assessed with the visual analogue scale (VAS; 0–10 scale) for low back and leg pain. Functional disabilities were measured with the Oswestry disability index (ODI) score. We determined the VAS and ODI scores preoperatively, at 3 months postoperatively and at the last follow-up examination.

2.4. Radiological and imaging evaluations

Digital radiographic parameters were measured on digitalized radiographs with the standard software system used at our hospital for viewing and measuring distances in radiographs (Centricity Enterprise Web; version 3.0; GE Healthcare, Little Chalfont, UK). For validation, two experienced spine surgeons performed the measurements twice and the averages were used for the statistical analyses.

The plain X-rays of the lumbar spine were performed preoperatively, at 3 months postoperatively, 1 year postoperatively and at the last follow-up examination. The foraminal height (FH), anterior disc height (aDH) and posterior disc height (pDH) were measured from the lateral radiographs [5].

2.4.1. FH

The maximum distance between the inferior margin of the superior vertebral pedicle and the superior margin of the inferior vertebral pedicle was defined as the FH.

2.4.2. aDH and pDH

The aDH and pDH were measured in the planes of the anterior and posterior surfaces of the adjacent vertebral bodies. The distance between the vertical line of the superior endplate tangent and the inferior endplate tangent was measured.

2.4.3. Range of motion (ROM)

Flexion-extension radiographs were performed preoperatively and during the last follow-up examination. The intervertebral angle between the superior endplate tangent and the inferior endplate tangent of the vertebral segment was measured. A kyphotic angle was classified as a negative value and a lordotic angle was classified as a positive value. The ROM for one segment was the difference of the intervertebral angle between the extension and flexion radiographs. The ROM was measured at the level in which the Wallis interspinous device implants were inserted and at the cephalad-adjacent segment.

2.4.4. Pfirrmann grade

Every patient underwent an MRI preoperatively and at last follow-up examination using the same parameters and MRI scanner (T2-weighted, 1.5T, repetition time [TR] 3500 ms, echo time [TE] 84 ms, slice thickness 4.0 mm, distance factor 20%, acquisition matrix 240×320, band width 161 Hz/pixel). Disc degeneration observations from the MRI were rated from grades 1–5 using the Pfirrmann classification system [7]. The instrumented level and cephalad-adjacent segments were evaluated.

2.5. Surgical methods

The focal neurological signs and electromyography determined the level in which the Wallis interspinous device was inserted. Disc excision and root decompression were initially accomplished with a unilateral approach. The patients underwent a limited disc excision. The Wallis interspinous device was fixed to the spine by two polyester bands that were looped around the proximal and distal spinous processes at the instrumented level and reattached to the spacer by means of two clips which were visible on plain radiographs. The implant constituted a floating system with no permanent fixation in the vertebral bone. The patients were encouraged to begin walking on the first postoperative day with a lumbar orthosis for 3 weeks. Isometric exercises were prescribed to maintain trunk muscle tone. After discontinuation of the lumbar orthosis, emphasis was placed on rehabilitation to tighten the lower back muscles.

2.6. Statistical analyses

Student's *t*-tests were performed for the ODI, VAS, FH, aDH, pDH and ROM comparisons. The rank sum test was used for the Pfirrmann

grade comparison. p values less than 0.05 were considered to be statistically significant. The statistical analyses were performed using SPSS Statistics (version 19; IBM Corporation, Armonk, NY, USA).

3. Results

The average age at the time of surgery was 47.6 years (range: 43–56; Table 1). The average length of follow-up was 66.8 months (range: 60–70). Twelve patients had two-level segmental degeneration, 10 had three-level segmental degeneration and four had four-level segmental degeneration. A typical radiological image is shown in Figure 1.

3.1. Clinical evaluation

The ODI and VAS values are shown in Table 2. The mean ODI dropped from 62.6 preoperatively to 13.0 postoperatively ($p = 0.00$). The mean VAS for low back pain dropped from 5.20 to 2.01 ($p = 0.00$) and the VAS for leg pain dropped from 7.48 to 2.74 ($p = 0.00$). During the follow-up period, the Wallis interspinous device offered significant and long-lasting symptom control.

Table 1
Characteristics of patients with multi-segmental lumbar degenerative disease treated with the Wallis interspinous device[1]

Characteristic	n
Number of patients	26
Average age (years)	47.6 (range: 43–56)
Sex (male:female)	12:14
Average weight (kg)	74.6 (range: 63–87)
Comorbidities	
Diabetes	5
Hypertension	4
Smoking history	12
COPD	1
Coronary artery disease	2
Number of degenerated segments	
2	12
3	10
4	4

COPD = chronic obstructive pulmonary disease.
[1] Zimmer, Warsaw, IN, USA.

3.2. Radiographic outcomes

The postoperative FH values increased significantly compared with the preoperative FH values. However, the FH values decreased during the follow-up period, but during the last follow-up, these values remained significantly increased compared with the preoperative values ($p = 0.00$; Table 3).

The postoperative pDH values increased significantly compared with the preoperative levels ($p = 0.00$). During the follow-up period, pDH values decreased, however, during the last follow-ups they remained significantly increased compared with the preoperative values ($p = 0.00$; Table 3). There were no significant changes in the aDH values (Table 3).

Table 4 shows the ROM values at the instrumented and cephalad-adjacent segment levels. The ROM levels at the instrumented level tended to decrease. However, no significant changes were observed at the instrumented ($p = 0.22$) or at the cephalad-adjacent segment levels ($p = 0.37$).

Table 5, 6 show the Pfirrmann grade at the instrumented and cephalad-adjacent segment levels. No significant changes were observed at the instrumented ($p = 0.06$) or cephalad-adjacent segment levels ($p = 0.16$).

4. Discussion

Lumbar fusion surgery is commonly performed to improve the clinical outcomes of patients for whom conservative treatment for multi-segmental lumbar degenerative disease has failed. Over recent years lumbar fusion has been increasingly criticized [8]. The side effects of lumbar fusion include pseudarthrosis, loss of lumbar motion, high reoperation rates and adjacent segment

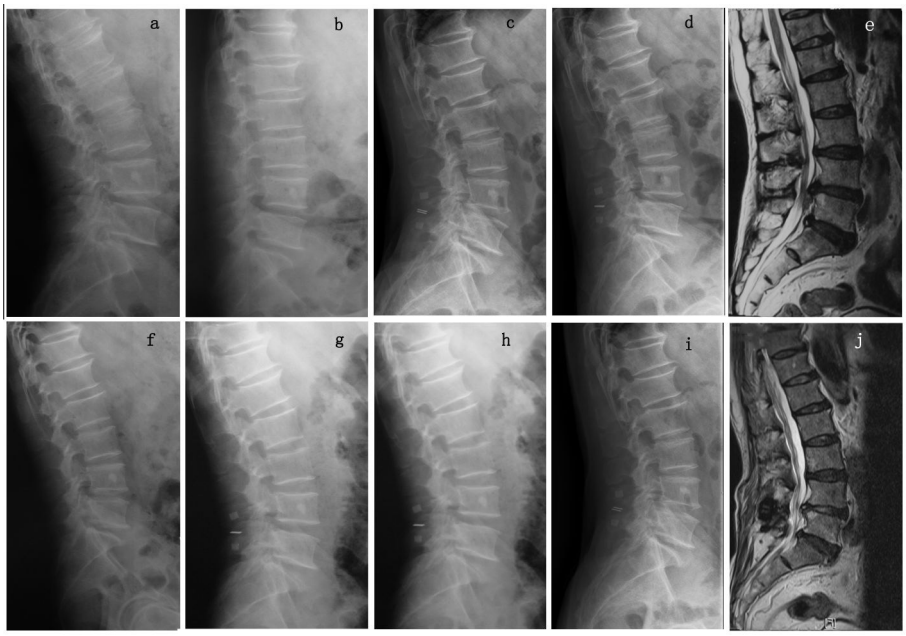

Fig. 1. The Wallis interspinous device (Zimmer, Warsaw, IN, USA) was inserted into the L4–5 level of this patient with multi-segmental lumbar degenerative disease. a, b) preoperative flexion and extension radiograph; c, d) flexion and extension radiograph at last follow-up; e) preoperative lateral T2-weighted MRI showing L4–5 disc herniation; f) preoperative lateral radiograph; g) lateral radiograph 3 months after surgery; h) lateral radiograph 1 year after surgery; i) lateral radiograph 5 years after surgery; j) lateral T2-weighted MRI 5 years after surgery.

Table 2
ODI and VAS during follow-up of multi-segmental lumbar degenerative disease patients treated with the Wallis interspinous device[1]

	Preoperatively	3 months postoperatively	Last follow-up
Leg pain VAS	7.48 ± 0.86	2.74 ± 0.87*	3.49 ± 1.76*
Low back pain VAS	5.20 ± 2.64	2.01 ± 0.87*	2.35 ± 1.54*
ODI (0–100)	62.6 ± 14.0	13.0 ± 8.4*	15.7 ± 13.4*

All values are presented as the mean ± standard deviation.
ODI = Oswestry disability index, VAS = visual analog scale.
* significant statistical difference compared with preoperatively.
[1] Zimmer, Warsaw, IN, USA.

Table 3
Mean FH, aDH and pDH during follow-up of multi-segmental lumbar degenerative disease patients treated with the Wallis interspinous device[1]

	Preoperatively	3 months postoperatively	1 year postoperatively	Last follow up
aDH (mm)	10.39 ± 1.60	10.07 ± 2.13*	10.92 ± 1.90*	10.93 ± 2.34*
pDH (mm)	8.27 ± 1.13	9.22 ± 1.03**	9.08 ± 1.21**	9.00 ± 1.35**
FH (mm)	17.80 ± 1.45	22.50 ± 1.41**	22.12 ± 1.53**	21.42 ± 1.68**

All values are presented as the mean ± standard deviation.
aDH = anterior disc height, FH = foraminal height, pDH = posterior disc height.
* no significant statistical difference compared with preoperative value.
** significant statistical difference compared with preoperative value.
[1] Zimmer, Warsaw, IN, USA.

Table 4
Mean ROM during the follow-up of multi-segmental lumbar degenerative disease patients treated with the Wallis interspinous device[1]

Range of Motion (°)	Preoperatively	Last follow up
Instrumented level	7.68 ± 4.32	7.12 ± 4.81*
Cephalad-adjacent segment	7.38 ± 2.91	7.43 ± 4.37*

All values are presented as the mean ± standard deviation.
* no significant statistical difference.
[1] Zimmer Inc., Warsaw, IN, USA.

Table 5
Pfirrmann grade at the instrumented level during the follow-up of multi-segmental lumbar degenerative disease patients treated with the Wallis interspinous device[1]

Instrumented level	Preoperatively (n)	Last follow up* (n)
Grade II	0	2
Grade III	8	10
Grade IV	18	14
Grade V	0	0

* no significant statistical difference.
[1] Zimmer, Warsaw, IN, USA.

Table 6
Pfirrmann grade at the cephalad-adjacent segment during the follow-up of multi-segmental lumbar degenerative disease patients treated with the Wallis interspinous device[1]

Cephalad-adjacent segment	Preoperatively (n)	Last follow up* (n)
Grade II	10	8
Grade III	6	8
Grade IV	10	10
Grade V	0	0

* no significant statistical difference.
[1] Zimmer, Warsaw, IN, USA.

disease [1]. Ghiselli et al. [9] reported, by means of a Kaplan–Meier survivorship analysis, that 16.5% of their observed patients who had a lumbar fusion had new disease that warranted a second procedure at an adjacent level within the first 5 years after the index procedure. Additionally, 36.1% will had new disease within the first 10 years after the index procedure. Therefore, various dynamic stabilization systems have recently been developed. In particular, spinous spacers have been designed to stabilize the segment after depression due to disc disease while preserving motion [10].

The Wallis interspinous device is a floating system that consists of a polyether ether ketone (PEEK) block. Because the Wallis interspinous device does not contain metal, it is convenient for patients who require an MRI during their follow-up examinations. The Wallis interspinous device can provide pain relief and restore and maintain motion and stability at the instrumented level. The purpose of this study was to evaluate the clinical results and radiographic outcomes of the Wallis interspinous device to treat multi-segmental lumbar degenerative disease with at least a 5 year follow-up period.

4.1. Biomechanics of Wallis

The Wallis interspinous device has an interspinous spacer made of PEEK, which restricts intervertebral extension, and two woven Dacron ribbons, which are wrapped around the spinous processes and fixed under tension to limit intervertebral flexion. In addition to limiting extension, the interspinous block is intended to maintain the neuroforaminal height and unload the posterior disc and zygapophyseal joints. Biomechanical studies have shown that the Wallis interspinous device reduces the ROM at the instrumented level without significant changes in the ROM of the adjacent segments and reduces load on the disc and facet joint process stresses, therefore, it increases the loads transmitted through the spinous processes [11]. It reduces the mobility of the intervertebral segments previously destabilized by discectomy [12]. In our study, the ROM at the instrumented level decreased after surgery. A finite element analysis suggested that the Wallis interspinous device lowers stress in the disc fibers and annulus matrix which might contribute to its ability to relieve pain [13].

4.2. Clinical evaluation and recurrence of low back pain and leg pain

In our study, the average ODI score of 15.7 at last follow-up indicated little disability in our subjects. The leg and low back pain levels were also moderately low. The clinical outcomes suggest that the Wallis interspinous device is an effective technique for multi-segmental lumbar degenerative disease. Folman et al. [14] published a retrospective study to evaluate the Wallis interspinous

device. Thirty-seven patients underwent primary lumbar disc excision followed by fixation with the Wallis interspinous device. After an average follow-up period of 16 months, 13% of the patients had recurrent herniations. They concluded that the Wallis interspinous device was most likely incapable of reducing the incidence of recurrent herniation.

In the current study no patient suffered from a recurrent disc herniation after surgery. Our mean patient age was 47.6 years which was older than the mean age of the Folman report patients (mean: 36 years). We hypothesize that the postoperative activities of the younger patients might have increased their observed recurrent herniation rate.

4.3. Radiographic outcomes and rehydration

Anatomically the loss of disc height induces subsidence and subluxation of the articular processes. The superior process of the lower vertebra then slides cephalad and anteriorly which causes the ligamentum flavum to bulge anteriorly and compress the nerve roots [5]. Cinotti et al. [15] identified a significant correlation between disc height and FH. A posterior disc height of 4 mm and an FH of 15 mm is likely to lead to nerve compression. In our study, the FH and pDH values were significantly changed postoperatively compared with the preoperative values. During the follow-up period, the FH and pDH values appeared to decrease. One explanation for this could be implant breakdown. However, the Wallis interspinous device is composed of relatively soft materials (PEEK). However, the increase in the FH and pDH values remained statistically significant compared with the preoperative levels over the follow-up period. Sobottke et al. [5] observed a trend to deterioration of the radiological improvement over time. However, pain scores (VAS) did not increase despite this loss of correction. We hypothesize that this long-term effect requires further observation. In our study, the fixation of the interspinous implants did not affect the aDH values.

MRI of patients with the Wallis interspinous device have demonstrated that the implant is capable of inducing rehydration of the degenerated nucleus pulposus [16]. In 2005, Boeree [17] presented results of a multicenter/multinational study in the UK examining the Wallis interspinous device and reported that rehydration of the nucleus was observed on the postoperative MRI. Rehydration of the nucleus was also observed on the our study. There was no statistical difference in the preoperative and postoperative disc degeneration levels as measured by the Pfirrmann grade.

4.4. Adjacent segment degeneration and adjacent segment disease

Adjacent segment degeneration is a radiographic diagnosis [18]. Adjacent segment disease is defined as a condition in which a patient has relief of symptoms for a period of time after the index operation but newly developed symptoms are compatible with lesions in adjacent segments, as demonstrated in radiological images [19–21].

We evaluated for adjacent segment degeneration in the cephalad-adjacent segment because discectomy and fusion has been shown to increase the motion of the cephalad-adjacent segments and increase disc compression at the adjacent motion segments in cadaveric studies [18]. In our study, the ROM and disc degeneration of the cephalad-adjacent segment did not change significantly postoperatively compared with the preoperative measurements. To some extent, the Wallis interspinous device may have protected the cephalad-adjacent segment from degenerating.

The adjacent segment disease incidence after fusion ranges from 5.2–18.5%, whereas the reoperation rate for adjacent segment disease ranges from 2.7–20% [22]. In our study, none of the patients suffered from adjacent segment disease or needed reoperations. The adjacent segment disease incidence was significantly lower compared with the incidence after fusion surgery.

4.5. Limitations

One limitation of our study is that it lacked a control group for comparison. As mentioned in the introduction, lumbar fusion is always performed to treat multi-segmental lumbar degenerative disease and there are many disadvantages of this treatment. A matched population of lumbar fusion patients would provide the most ideal control group to evaluate the clinical outcomes, radiographic parameters and the degenerative changes in the adjacent segments. Discectomy alone would also be a good control group. We could produce more valid conclusions with both a discectomy alone cohort as a negative control and a fusion alone group as a positive control. Another limitation of this study is that our follow-up period was relatively short. We observed that a decrease in the FH and pDH values as well as the adjacent segment disease rate were potential long-term complications. Longer follow-up examinations should be continued for more data.

5. Conclusions

The Wallis interspinous device is an effective treatment alternative for multi-segmental lumbar degenerative disease and the device was associated with significant and long-lasting symptom control.

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Conflicts of Interest/Disclosures

The authors declare that they have no financial or other conflicts of interest in relation to this research and its publication.

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Experience with the Second-Generation Wallis Interspinous Dynamic Stabilization Device Implanted in Degenerative Lumbar Disease: A Case Series of 50 Patients

Dejeneratif Lomber Hastalıkta İmplante Edilen İkinci Nesil Wallis İnterspinöz Dinamik Stabilizasyon Cihazı Deneyimi: 50 Hastalık Bir Olgu Serisi

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ABSTRACT

AIM: This study aimed to evaluate the short- to medium-term outcomes of the second-generation Wallis interspinous dynamic stabilization device for treatment of lumbar degenerative disease.

MATERIAL and METHODS: Fifty patients with lumbar degenerative disease treated from August 2007 to September 2009 were included in this retrospective study. The Japanese Orthopedic Association (JOA) score and the Oswestry Disability Index (ODI) were used for therapeutic efficacy evaluation. Odom's criteria were used to evaluate postoperative outcome with regard to symptoms. Anteroposterior X-rays were obtained after surgery. All patients were followed up for 2 years.

RESULTS: Based on Odom's criteria, 22, 24 and 4 patients had excellent, good, and fair results respectively. The JOA score at 3, 12, and 24 months after surgery was significantly higher than before surgery (all $p < 0.001$), and the ODI score at 3, 12, and 24 months after surgery was significantly lower than before surgery (all $p < 0.001$). The posterior intervertebral disc height and the neural foramina height at 12 and 24 months after surgery was significantly higher than before surgery (both $p < 0.001$).

CONCLUSION: Implantation of the second-generation Wallis interspinous dynamic stabilization device produced satisfactory clinical outcome at short- and medium-term follow-up in patients with lumbar degenerative disease.

KEYWORDS: Lumbar degenerative disease, Wallis interspinous implant, Postoperative outcome, Dynamic instrumentation, Lumbar interspinous spacer, Non-rigid fixation

ÖZ

AMAÇ: Çalışma, lomber dejeneratif hastalığın tedavisi için ikinci nesil Wallis interspinöz dinamik stabilizasyon cihazının kısa ve orta vadeli sonuçlarını değerlendirmeyi amaçlamıştır.

YÖNTEM ve GEREÇLER: Ağustos 2007 ile Eylül 2009 tarihleri arasında tedavi edilen 50 lomber dejeneratif hastalık olgusu bu retrospektif çalışmaya dahil edildi. Terapötik etkinlik değerlendirme için Japon Ortopedi Derneği (JOA) skoru ve Oswestry Engellilik İndeksi (ODI) kullanıldı. Semptomlar ile ilgili postoperatif sonuçları değerlendirmek için Odom kriterleri kullanıldı. Ameliyat sonrası anteroposterior röntgenler çekildi. Tüm hastalar 2 yıl boyunca takip edildi.

BULGULAR: Sonuçlar Odom kriterlerine göre sırasıyla 22, 24 ve 4 hastada mükemmel, iyi ve makul oldu. Ameliyattan sonra 3., 12. ve 24. aylarda JOA skoru ameliyat öncesine göre anlamlı derecede yüksek (tümü $p < 0,001$) ve ameliyattan sonra 3., 12. ve 24. aylarda ODI skoru ameliyat öncesine göre anlamlı derecede düşük (tümü $p < 0,001$) bulundu. Ameliyattan sonra 12. ve 24. ay posterior intervertebral disk ve nöral foramen yüksekliği ameliyat öncesine göre anlamlı derecede yüksek bulundu (her ikisi $p < 0,001$).

SONUÇ: İkinci nesil Wallis interspinöz dinamik stabilizasyon cihazının implantasyonu lomber dejeneratif hastalığı olan hastalarda kısa ve orta vadeli takipte tatmin edici klinik sonuçlar verdi.

ANAHTAR SÖZCÜKLER: Lomber dejeneratif hastalık, Wallis interspinöz implantı, Postoperatif sonuç, Dinamik enstrümantasyon, Lomber interspinöz boşluk, Non-rijid fiksasyon

INTRODUCTION

Lower back pain is the main symptom of lumbar degenerative disc disease. Presently, most researchers still consider that lower back pain in lumbar degenerative disc disease is caused by the instability of motion segments, and that this instability can be eliminated by stabilizing the affected segment. Based on the aforementioned theory, degenerative lower back pain has been treated mainly by lumbar fusion surgery using rigid fixation. Though the fusion rate of lumbar internal fixation is as high as 90%, but the clinical satisfaction rate has been reported to be considerably lower (4). Meanwhile, adjacent segment degeneration (ASD) due to stress concentration after lumbar fusion surgery (6) may induce new lower back pain, and fusion surgery inevitably results in loss of partial function of the lumbar spine.

In recent years, some investigators have proposed that the abnormal distribution of intradiscal stress loading due to abnormal motion is the direct reason for degenerative lower back pain, and since the pain is not related to the segmental instability caused by abnormal activity, they suggested the concept of dynamic stabilization (8). Dynamic stabilization is also known as soft fixation or flexible fixation. The so-called dynamic fixation system is an internal fixation system which can preserve the activity of the motion segment and change the load transmission simultaneously without spinal fusion using bone grafts being performed. The intention is to alter the load bearing pattern of the motion segment, as well as to control any abnormal motion at the segment. The hypothesis behind dynamic stabilization is that control of abnormal motions and more physiological load transmission would relieve pain, and prevent adjacent segment degeneration because it permits a certain degree of motion in the fixed segment (7).

Several dynamic stabilization devices have been developed. These devices include the Colfex, Wallis, DIAM, and X-STOP (3, 5, 19). The Wallis dynamic stabilization system was one of the earliest interspinous dynamic stabilization devices used in clinical practice. The first-generation Wallis system was developed in 1986. The material used for interspinous distraction was titanium. The interspinous spacer was fixed between the upper and lower spinous processes by two artificial polyester bands. Sénégas et al. (12) developed the second-generation Wallis system based on the first-generation device, which that group also developed. It is mainly different from the first-generation system in that polyether ether ketone (PEEK) is used for the spacer instead of the titanium alloy. The elastic modulus of PEEK matches that of the structure posterior to the vertebral body more accurately, which decreases the load-bearing of the lumbar spine in the standing position and absorbs the vibration energy during exercise. The whole system forms a "floating" device between two spinous processes. It is not a permanent fixation of the lumbar spine. It may reduce the load on the posterior portion of the annulus fibrosus and increase the stability of the unstable segment. Therefore, we hypothesized that implantation of the second-generation Wallis device would lead to a good clinical outcome in patients with degenerative lumbar disease.

Only a few studies have evaluated the outcomes of implanting the second-generation Wallis device (11). Therefore, the aim of the current study was to evaluate the short- to medium-term clinical results of implanting the second-generation Willis interspinous dynamic stabilization device in patients with degenerative lumbar disease.

MATERIAL and METHODS

This retrospective study was conducted from August 2007 to September 2009 at our hospital. A total of fifty patients were included in the current study. This is a purely clinical observational study without any form of support or involvement from the manufacturer of the Wallis device.

Patients

Demographic characteristics of the patients are presented in Table I. There were 30 male patients and 20 female patients. The mean age of the patients was 51.6±9.6 years. The mean disease duration was 4.2±2.7 years (range, 1 to 11). Forty-six patients had a single-segment lesion and 4 patients had a two-segment lesion. L3,4 was involved in 4 patients, L4,5 in 42 patients, and both L3,4 and L4,5 in 4 patients. Ten patients had discogenic lower back pain; 18 had recurrent lumbar disc herniation after surgery; 8 had degenerative lumbar instability, defined as recurrent low back and leg pain with restricted movement of lumbar spine flexion/extension, and X-ray showing anterior-posterior vertebral displacement of ≥3 mm or endplate angle ≥15 degrees without intervertebral spondylolysis; 6 had lumbar spinal stenosis, and 8 had voluminous herniated disc. Forty-six patients underwent single-segment application of the Wallis device and 4 underwent two-segment application of the device, which is composed of a pad and two polyester bands. Lumbar anteroposterior, bilateral oblique and dynamic X-rays, discography, CT or MRI were carried out before surgery to confirm the diagnosis

Inclusion and Exclusion Criteria

Patients were included if they had (1) Discogenic lower back pain: intractable lower back pain without typical nerve root symptoms and signs; physical examination and imaging examinations excluded lumbar disc herniation, tuberculosis, tumor and other diseases; lumbar MRI showed degeneration in one or several discs; and lumbar discography induced typical concurrent pain. (2) Recurrent lumbar disc herniation after surgery: the symptom was relieved at least more than 6 months after lumbar discectomy, and recurrent lumbar disc herniation occurred after that in the ipsilateral or contralateral lumbar segment or adjacent segments. (3) Degenerative lumbar instability: repeated lower back pain and leg pain, and lower back extension and flexion were restricted; dynamic X-ray showed equal to or more than 3 mm anteroposterior displacement or equal to or more than 15^0 of endplate angles,

Table I: Baseline Characteristics of the Study Populations

	Lumbar Degenerative Disease (n=50)
Age, yr	51.6 ±9.6
Disease course, yr	4.2 ±2.7
Gender	
Male	30 (60.0)
Female	20 (40.0)
Pathologies	
Single-level	46 (92.0)
Double-level	4 (8.0)
Location	
L3,4	4 (8.0)
L4,5	42 (84.0)
L3,4 + L4,5	4 (8.0)
Symptoms	
Discogenic low back pain	10 (20.0)
Recurrent lumbar disc herniation (post-op)	18 (36.0)
Degenerative lumbar instability	8 (16.0)
Lumbar spinal stenosis	6 (12.0)
Voluminous herniated disc	8 (16.0)
Pain Location	
Low back pain	24 (48.0)
Low back and leg pain	26 (52.0)
Surgical method	
Wallis implantation	24 (48.0)
Wallis implantation + decompression	26 (52.0)
Operative time, min	35.4 ±5.5
Operative blood loss, ml	70.4 ±22.5

The continuous variables were presented as mean and standard deviation; The categorical variables were presented as count and percent.

and the imaging examination showed no spondylolysis. (4) Huge lumbar disc herniation: diagnosis in accordance with lumbar disc herniation and the protruded part exceeded 50% of the spinal canal in the imaging picture. (5) Lumbar spinal stenosis: imaging examination showed decreased sagittal diameter or axial diameter of the spinal canal; there were moderate to severe nerve compression symptoms with or without mild lower back pain; and there were intermittent claudication and serious or progressive neurologic dysfunction. All patients received regular conservative treatment for at least 6 months, but outcomes were poor.

Conversely, patients were excluded if they had (1) osteoporosis, (2) scoliosis or lumbar spondylolisthesis due to spondylolysis, or (3) mild lumbar disc herniation.

Treatment

The patient was placed in the prone position after receiving general anesthesia. The patient's waist was maintained in the natural position. A posterior midline incision was made in the lower back. Bilateral paraspinal muscles were routinely exposed and dissected. The supraspinous ligament was completely dissected and pulled aside. The integrity of the supraspinous ligament was maintained maximally. The interspinous ligament of the affected segment was removed. The inferior margin of the upper spinous process and the superior margin of the lower spinous process were trimmed to make the interspinous space match the shape of the interspinous pad of the second-generation Wallis device. The implant size was decided on according to the template size. The interspinous pad was installed between the spinous processes, and the polyester bands in the upper and lower ends of the pad were used to pass through the adjacent interspinous spaces respectively and pulled tightly. Two ends of the polyester bands were passed through an anchoring device and the latter was locked at the root of the polyester bands. The supraspinous ligament was fixed to the spinous process. Discectomy or spinal decompression was performed in advance for 24 patients with typical nerve root symptoms and signs, and then the second-generation Wallis device was implanted to proactively prevent iatrogenic instability or reduce recurrent disc disease post-operatively.

The drainage tube, which was inserted to prevent post-operative wound hematoma, was removed 24-48 h after surgery. The patient started walking after wearing a back brace. Activities like running, jumping and waist weight-bearing were started 10-12 weeks after surgery. The back brace, which was placed in the polyester strip to prevent loosening of the strip, was discarded 1 month after surgery.

Outcome Evaluation

The operative time and intraoperative blood loss were recorded. Outcome evaluation was carried out 3, 12 and 24 months after surgery. The degree of postoperative symptom improvement was evaluated using Odom's criteria (9). Excellent: All preoperative symptoms relieved; able to carry out daily activities without impairment. Good: Minimal persistence of preoperative symptoms; able to carry out daily activities without significant interference. Fair: Definite relief of some preoperative symptoms, but physical activities were significantly limited. Poor: Symptoms and signs unchanged or exacerbated. We conducted a questionnaire survey of patients by having them fill out the Japanese Orthopedic Association (JOA) scoring system, and Chinese version of the Oswestry Disability Index (ODI). The postoperative scores were compared with the preoperative scores.

Anteroposterior X-ray examination of the lumbar spine was carried out after surgery to evaluate the presence of displacement and loosening of the Wallis device, and fractures of the spinous processes and lamina. The preoperative and postoperative height of the intervertebral disc space and the

Table II: Comparison of Preoperative and Postoperative Efficacy in 50 Patients

	Pre-operation	After 3 months	After 12 months	After 24 months	p-value
JOA	12.0 (10.0, 14.0)	25.0 (21.0, 27.0) †	26.0 (21.0, 28.0) †	25.0 (21.0, 26.0) †	<0.001*
Oswestry	13.0 (11.0, 15.0)	5.0 (4.0, 7.0) †	5.0 (4.0, 6.0) †	5.0 (4.0, 6.0) †	<0.001*

The continuous variables were presented as median and inter-quartile range (IQR), and compared with the repeated measurements by the Friedman test.
** indicates a significant difference among the repeated measurements; † indicates a significant difference compared with the pre-operation.*

Table III: Comparison of Preoperative and Postoperative Imaging Measurements in 50 Patients

	Pre-operation	After 12 months	After 24 months	p-value
Posterior intervertebral disc height, cm	0.71 (0.58, 0.88)	1.02 (0.87, 1.12) †	0.99 (0.88, 1.14) †	<0.001*
Neural foramina height, cm	1.11 (0.99, 1.19)	1.72 (1.62, 1.89) †	1.72 (1.65, 1.80) †	<0.001*

The continuous variables were presented as median and inter-quartile range (IQR), and compared with the repeated measurements by the Friedman test.
** indicates a significant difference among the repeated measurements; † indicates a significant difference compared with the pre-operation.*

height of the spinal root canal were measured according to Wang's method using the image measurement software (18). The height of the intervertebral disc space was defined as the distance between the inferior margin of the upper endplate and the superior margin of the lower endplate on the X-ray film. The height of the neural foramina was defined as the distance between the apex of the superior articular process and the margin of the inferomedial angle of the superior vertebral pedicle.

Statistical Analysis

Continuous variables were presented as median and inter-quartile range (IQR), and compared with the repeated measurements by the Freidman test. When a significant difference between the repeated tests was apparent, multiple comparisons were performed using the Bonferroni procedure with type-I error adjustment. SAS software package version 9.2 (SAS Institute Inc., Cary, NC, USA) was used for the statistical analysis. All statistical assessments were evaluated at a two-sided P value of 0.05.

RESULTS

Comparison of Preoperative and Postoperative Efficacy

Table II summarizes the operative efficacy from pre-operation to 24 months after surgery. The JOA score after surgery was significantly higher than before surgery (all p<0.001). But, there was no significant difference in the score among the three post-operative evaluations. The ODI score after surgery was significantly lower than before surgery (all p<0.001). However, there was no significant difference in score among the three follow-up evaluations. In addition Odom's criteria were used to assess outcomes 24 months after surgery, and outcome was excellent in 22 patients, good in 24 patients and fair in 4 patients. No patients had processus spinosus fracture during 2 years of follow-up.

Comparison of Preoperative and Postoperative Imaging Measurements

Table III summarizes the imaging measurements from before surgery to 24 months after surgery. The posterior intervertebral disc height after surgery was significantly higher than before surgery (all P<0.001). But, there was no significant difference between measurements at 12 and 24 months after surgery. The neural foramina height after surgery was significantly higher than before surgery (all p<0.001). However, there was no significant difference between measurements at 12 and 24 months after surgery.

Results of Imaging

No fracture of a spinous process or lamina occurred during the postoperative follow-up period. Typical cases are shown in Figures 1(A-F), 2(A-D), 3(A-B).

DISCUSSION

In this study, we found that implantation of the second-generation Wallis interspinous dynamic stabilization device in 50 patients with degenerative lumbar disease resulted in excellent or good outcomes in 46 (92%) patients at 2-year follow-up based on Odom's criteria. There was also significant improvement in the JOA score and ODI score. Radiographic imaging showed that there was a significant increase in posterior intervertebral disc height and neural foramina height. Also, there were no occurrences of spinous process or lamina fracture during follow-up.

The long-term safety and efficacy of the first-generation Wallis dynamic stabilization device have been proven in clinical practice (13). The reoperation rate within 10 years after surgery due to recurrent disease in the affected segment and ASD was 17.2% (14). Even after 13 years, 80% of patients with satisfactory outcomes could avoid revision or spinal fusion surgery (13). The second-generation Wallis device has been gradually applied in clinical practice and preliminarily has achieved excellent outcomes. A study of 129 patients with lumbar spinal stenosis who underwent implantation of the second-generation Wallis device showed that the device can reliably control the clinical symptoms over a long time (15). In a multicenter, large-sample prospective clinical study of the Wallis device there was improvement in the visual analogue scale score and JOA score after surgery (2). The results of the current study showed that lower back pain improved

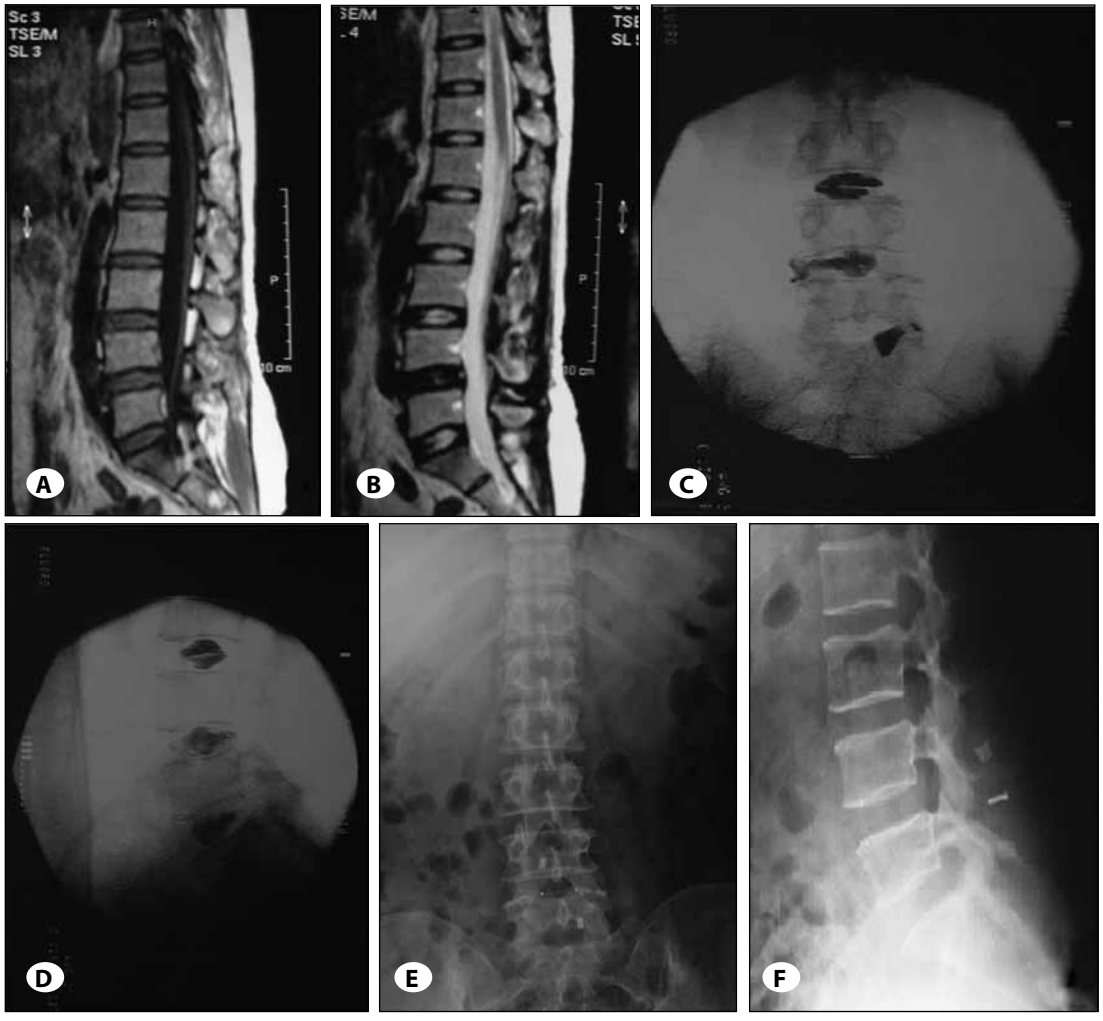

Figure 1: A 48-year-old female patient with discogenic low back pain. **A, B)** Preoperative MRI showed intervertebral disk degeneration and high intensity zone on T2-weighted MRI in L4,5. **C, D)** The results of lumbar discography showed the internal annular disruption and pain reproduction response in L4,5. **E, F)** The lumbar X-ray image after surgery.

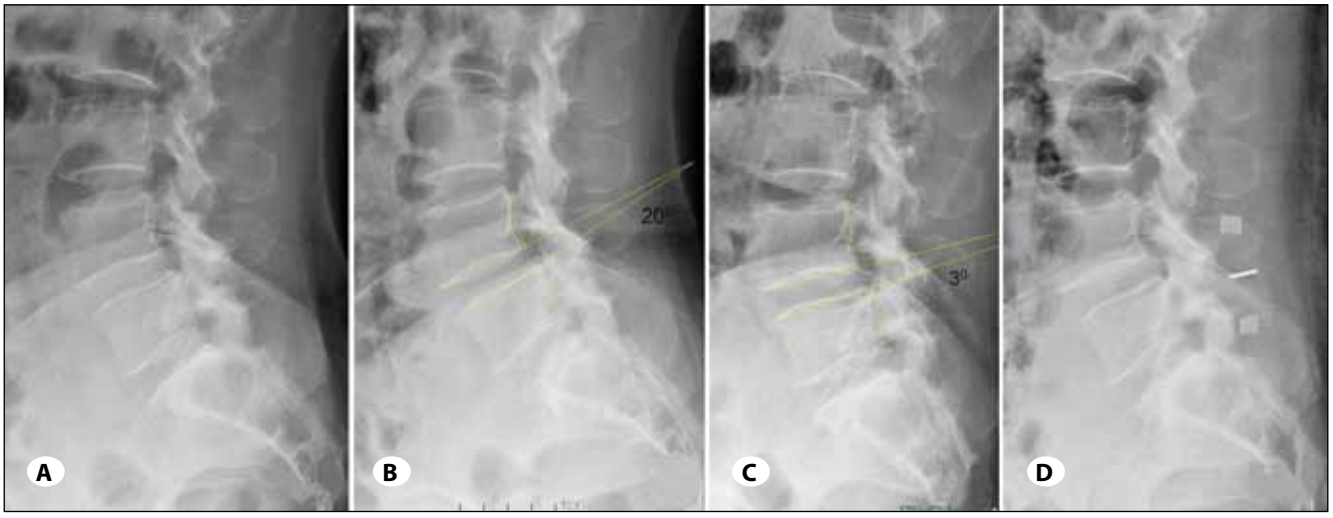

Figure 2: A 44-year-old female patient with lumbar instability. **A)** Lateral position film. **B)** Extension position film. **C)** Flexion position film. **D)** Neutral position film. Preoperative flexion-extension position X-ray showed lumbar spine instability. Postoperative X-ray at 1 year showed no loss of intervertebral height.

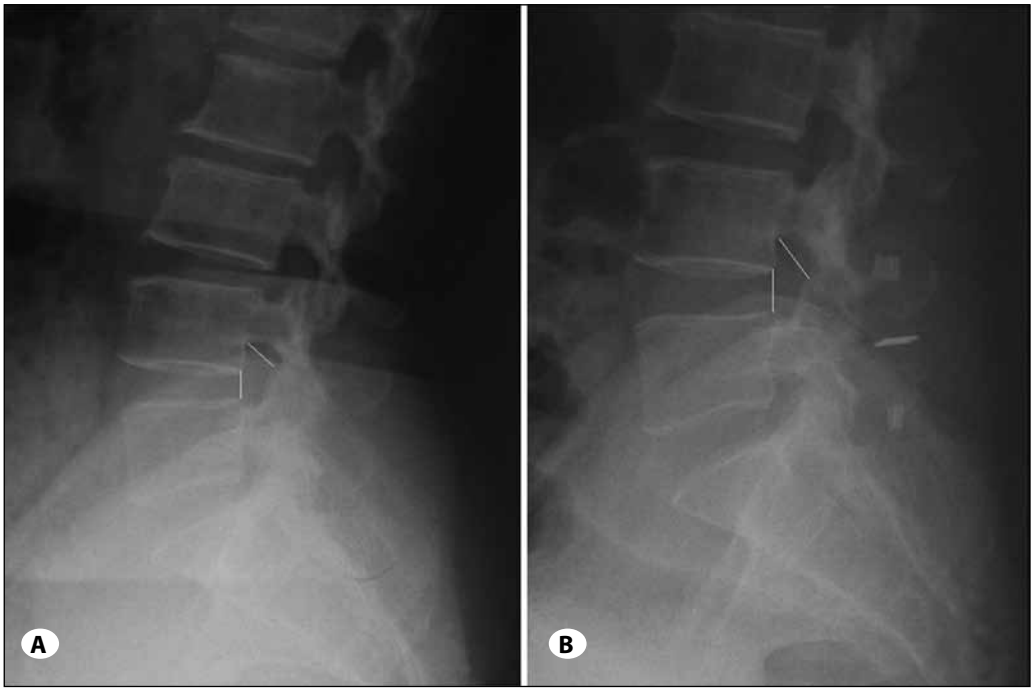

Figure 3: A 52-year-old female patient with lumbar spinal stenosis. **A)** Preoperative lateral lumbar image; the edge height of the L4,5 intervertebral disc space was 0.70 cm, the neural foramina height was 0.95 cm. **B)** Postoperative lateral lumbar image; the edge height of the L4,5 intervertebral disc space was 0.97 cm, the neural foramina height was 1.60 cm.

significantly after surgery in all 50 patients. Ninety-two percent of patients had good to excellent outcomes based on Odom's criteria. And there was significant improvement during follow-up in the JOA score and ODI score. Our results suggest that the second-generation Wallis device has a positive effect on patients' short- and medium-term clinical outcomes.

There is a significant correlation between nerve root entrapment and disc space height together with neural foramina height, that is, an increase in disc space height may enlarge the neural foramina height and subsequently improve nerve root compression (18). In our study, disc space height and neural foramina height were obtained as imaging parameters before and after surgery. The results showed that after applying the Wallis device, the disc space height increased from 0.71 (IQR: 0.58, 0.88) cm before surgery to 1.02 (IQR: 0.87, 1.12) cm at 12 months after surgery, and was maintained at 0.99 (IQR: 0.88, 1.14) cm 24 months after surgery, and the neural foramina height increased from 1.11 (IQR: 0.99, 1.19) cm to 1.72 (IQR: 1.62, 1.89) cm 12 months after surgery and was maintained at 1.72 (IQR: 1.65, 1.80) cm 24 months after surgery. There was no significant collapse in disc space height and neural foramina height over time. The Wallis device maintains disc height by the effect of interspinous distraction, which stretches the creased ligamentum flavum, improving spinal canal volume and neural foramina volume, thereby theoretically relieving the stenosis in the spinal canal and neural foramina, and consequently decompression of the spinal canal and nerve root occurs. This suggests that the Wallis device can be used for mild spinal stenosis or neural foramina stenosis. In addition, it also can be used for the loss of disc space height after removing huge disc fragments.

The Wallis device is mainly indicated for: (1) loss of a large amount of disc tissue after discectomy for a huge disc herniation; (2) recurrent disc herniation after discectomy; (3) disc herniation associated with sacralization of L5 requiring discectomy; (4) degenerative disc disease in the adjacent segment after spinal fusion; and (5) lower back pain caused by the Modic type I lesion (13). Besides the indications mentioned above, we included the lumbar degenerative diseases discogenic lower back pain and degenerative spinal instability in the current study. Theoretically, mild spinal stenosis and neural foramina height stenosis are indications for the Wallis device. Although our study proved that satisfactory clinical outcomes could be achieved with inclusion of lumbar degenerative diseases, further studies should be carried out to confirm the safety and efficacy of the Wallis device in the treatment of lumbar degenerative diseases and lumbar spinal stenosis.

It has been reported that mechanical or chemical stimulation of pain-sensitive nerve endings by degenerative tissue during disc degeneration is the pathophysiological basis of discogenic pain (17). Many researchers have reported treating discogenic lower back pain using spinal fusion (1, 16). However, it has rarely been reported that discogenic lower back pain has been treated with a non-fusion technique. In this study, 10 patients with discogenic lower back pain underwent implantation of the Wallis device and achieved excellent clinical outcomes. We speculate that this may be related to the fact that the Wallis device changes the mechanical load transmission pattern in the disc of the fixed segment, and restricts "abnormal motion" of the affected segment. In a previous study, we found that the flexion/extension range of the stabilized segments decreased, but

the corresponding lateral bending and axial rotation did not decrease significantly (10). Moreover, it has advantages compared to traditional spinal fusion surgery because it does not need bone grafting, so there are no donor site complications; there is little intraoperative bleeding; surgical trauma is mild; operative time is short; patients recover quickly; and it can be carried out under local anesthesia, and hence, it is very suitable for older patients with serious heart and lung diseases. In addition, compared with lumbar spine fusion it reduces the incidence of ASD (7).

Our study had several limitations. The study was retrospective in design. The sample size of 50 patients was small. The follow-up period was 2 years which is relatively short for evaluating the outcome of surgery for degenerative lumbar disease as degenerative changes in adjacent segments more than 2 years after surgery. Finally, there was no control group for comparison with the treatment group.

In conclusion, we found that implantation of the second-generation Wallis interspinous dynamic stabilization device for treatment of degenerative lumbar disease produced mostly good to excellent short- to medium-term outcomes. It is particularly noteworthy that excellent outcomes were achieved in patients with discogenic lower back pain. Long-term outcomes of implantation of the Wallis device in patients with degenerative lumbar diseases should be evaluated in future studies.

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ORIGINAL ARTICLE

Clinical evaluation of a lumbar interspinous dynamic stabilization device (the Wallis system) with a 13-year mean follow-up

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Abstract The authors determined current health status of patients who had been included in a long-term survivorship analysis of a lumbar dynamic stabilizer. Among 133 living patients, 107 (average age at surgery, 44.2±9.9 years) completed health questionnaires. All patients had initially been scheduled for decompression and fusion for canal stenosis, herniated disc, or both. In 20 patients, the implant was removed, and fusion was performed. The other 87 still had the dynamic stabilizer. Satisfaction, Oswestry disability index, visual analog scales for back and leg pain, short-form (SF-36) quality-of-life physical composite score, physical function, and social function were significantly better ($p \leq 0.05$) in the patients who still had the dynamic stabilization device. SF-36 scores of the fused subgroup were no worse than those reported elsewhere in patients who had primary pedicle-screw enhanced lumbar fusion. This anatomy-sparing device provided a good 13-year clinical outcome and obviated arthrodesis in 80% of patients.

Keywords Lumbar spine · Degenerative disease · Dynamic stabilization · Spinous processes · Tension bands

All index operations were performed in the Unité de Pathologie Rachidienne, Centre Hospitalier Pellegrin, Bordeaux.

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Background

Interspinous spacers combined with tension bands around the spinous processes for lumbar segmental stabilization were developed in the early 1980s [23]. The initial version of this system was upgraded to the current Wallis dynamic stabilization device in 2001 [24]. Indications for these devices have been the need to stabilize symptomatic degenerative lumbar spine segments, imparting rigidity while preserving intervertebral mobility. One of the goals of restoring stiffness to unstable degenerate segments is to recreate mechanical conditions that could permit consolidation of altered intervertebral soft tissues [9, 16]. Above all, dynamic stabilization is intended to relieve low back pain related to instability and thus delay the need for irreversible, more invasive surgical management [25].

The system's long-term safety and efficacy has recently been confirmed in a 14-year retrospective study [25]. The latter study was an actuarial survivorship analysis of the first-generation device showing that it effectively obviated the need for arthrodesis or total disc replacement (TDR) in over 80% of patients throughout the follow-up period, which ranged from 9 to 17 years.

The purpose of the present study was to evaluate the long-term clinical results of the first-generation lumbar dynamic stabilization system.

Materials and methods

Implants

The implant (Figs. 1 and 2) included a double-braided woven polyester (Dacron) cord fixed to a titanium spacer and, when more than one intervertebral segment was

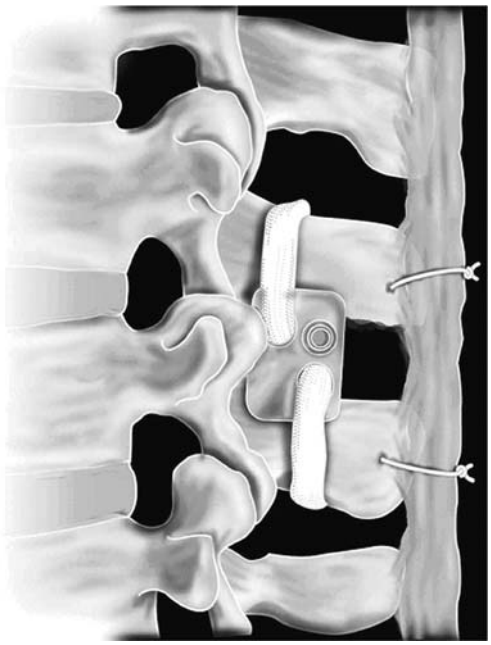

Fig. 1 The first-generation Wallis dynamic stabilization device

treated, additional interspinous spacers made of polyacetal (Hostaform) were used. The implants created a semi-constrained system designed to stabilize the intervertebral axis of extension and flexion and reduce the mobility of the instrumented segment. The spacers placed between the spinous processes were intended to produce an unloading effect, reducing pressure in the facet joints and posterior portion of the intervertebral endplates in lordosis. There was a radiodense marker inside the cord throughout its length. The polyacetal spacers were radiolucent.

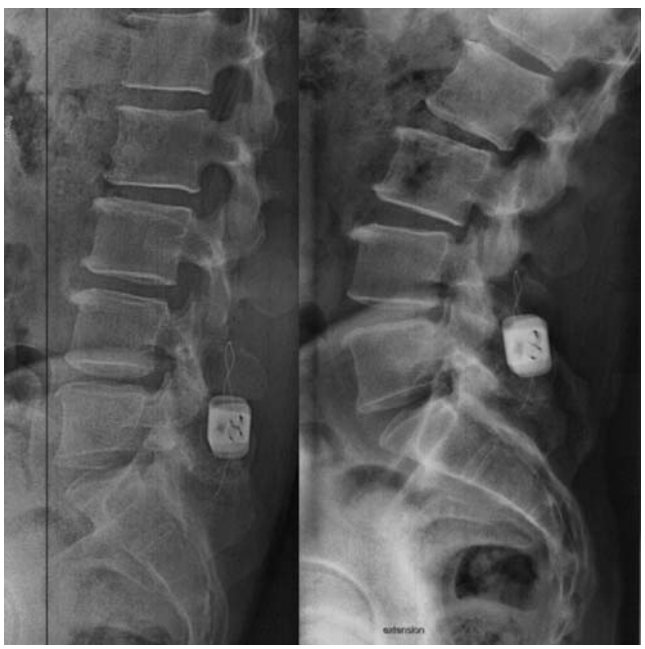

Fig. 2 Bending films of a 46-year-old quantity surveyor who was operated 11 years earlier at L4-5 for painful disc protrusion and narrow canal with a good long-term clinical outcome

Surgical technique

After the supraspinous ligament was detached, the interspinous space was trimmed with a gouge and a high-speed drill to create a trapezoid opening so as to prevent the posterior displacement of the spacer. When instrumenting the L5-S1 space, if the first sacral spinous process was atrophic, a groove for the cord was cut in the lamina with a high-speed drill, or the sacral crest was perforated transversely to thread the cord through it. The spacers were chosen to fit the trimmed interspinous space and avoid kyphosis of the instrumented segment. The lordosis of the lumbar column was verified using an image intensifier before final fixation of the implant.

The first spacer (the only spacer if a single level was instrumented) was made of titanium, delivered attached to a lone woven polyester cord. The surgeon threaded the cord around the spinous processes and through the spacers in figure-8 fashion. When tension had been applied throughout all levels, we blocked the extremity of the cord by firmly lodging a taper beside it in the metal spacer. The supraspinous ligament was reattached to each spinous process using separate transfixing sutures.

Postoperative care

Patients were encouraged to begin walking the first day after the intervention and wore a lumbar orthosis for 3 weeks. Isometric exercises were prescribed to maintain the muscle tone of the trunk. After discontinuation of the lumbar orthosis, rehabilitation was pursued with emphasis on tightening the lower back muscles. Patients were generally seen between 1 and 2 months after the operation then again after 6 months if they lived within a 50-mile radius of our spinal unit. At discharge from the unit and at follow-up visits, we urged them and their general practitioner to consult us if any low back or leg problem persisted or subsequently developed.

Patients

We recently published a paper on the actuarial survivorship of 142 first-generation Wallis devices [25]. The patients were requested to participate in a long-term retrospective clinical survey when they were contacted by telephone. Two additional patients who had not been interviewed by telephone presented spontaneously for a follow-up visit, during which they also completed the clinical questionnaire, leading to a total of 144 patients.

Eleven of the 144 patients were deceased when the clinical survey was performed, leaving 133 available patients. Among them, there were two patients who refused to respond to the questionnaire, 24 who agreed to respond but failed to follow through, and 107 (80%) who completed the questionnaire. There were no differences in those followed and those lost to follow-up evaluation in terms of gender breakdown (p=0.4), age at operation (p=0.3), body mass index (BMI; p=0.5), number of levels operated (p=0.16), and indications (p=0.4).

Outcome measures

The follow-up questionnaire contained questions regarding patient satisfaction, an Oswestry disability index (ODI) [3], visual analog scales (VAS) [11] for self-reported back pain and leg pain, and a short-form 36 (SF-36) quality-of-life survey [14, 18].

Statistical analysis

Comparison of patient subgroups was performed using the Chi^2 test for patient satisfaction, Student's t test for ODI and VAS findings, and the non-parametric Mann–Whitney U test for the SF-36 values. A p value of 0.05 was considered to be significant.

Results

Among the 107 patients who responded to the questionnaire, review of hospital charts indicated that the index operation was performed for isolated canal stenosis (n=39), canal stenosis and herniated disc (n=22), isolated primary herniated disc (n=13), isolated recurrent disc (n=21), and other diagnoses (n=4). The information on the indication for surgery was missing from eight of the hospital charts.

The majority of the 107 patients who completed the questionnaires were male (73%), and the average age at the time of surgery was 44.2±9.9 years (range, 21–66 years). The average length of follow-up was 13.5±2.7 years (range, 8.3–19.6 years).

Twenty-three of these patients had a subsequent lumbar operation. In 20 of these patients, the implant or implants were removed, and fusion was performed. The purpose of this paper was being able to investigate the long-term clinical outcome of patients with dynamic stabilization; the patients from whom the implant was subsequently removed and who had arthrodesis (n=20/107) were analyzed separately. The other subgroup (n=87/107) included the 84 patients who had never been reoperated and the three patients who were reoperated at the index or adjacent levels but still had a functional implant. There were no differences in these two subgroups in terms of gender breakdown (p=0.2), age at operation (p=0.3), BMI (p=0.8), number of levels operated (p=0.9), or indications (p=0.9). Likewise, the percentages of response to the survey were similar, 81% (n=87) of the 107 living patients who still had the implant versus 77% (n=20) among the 26 living patients who had undergone fusion after removal of the implant. Follow-up after the index operation of the patients who still had the implant was 13.2±2.6 years. The patients subsequently revised to fusion, responded to the questionnaire 15.1±2.7 years after the index operation and 10.6±4.8 years after the revision procedure.

Long-term clinical outcome

The satisfaction of the patients who still had the dynamic stabilization was high, with 95% reporting that they were either very satisfied or satisfied with their surgery, and 91% indicating that they would certainly or probably have the procedure if they were confronted with the same choice. The details of patient satisfaction are provided in Table 1. In both questions used to assess patient satisfaction, there was a significant difference between the subgroup of patients who still had the dynamic stabilizer at follow-up and the subgroup of patients in whom the device had been removed and the segments stabilized by fusion.

Table 1 Long-term patient satisfaction and willingness to undergo operation under the same circumstances

		Patients who still had first-generation Wallis implant at follow-up	First-generation Wallis patients revised to fusion	p value
Patient satisfaction	Very satisfied	51 (58.6%)	5 (25.0%)	p<0.001
	Satisfied	32 (36.8%)	8 (40.0%)	
	Dissatisfied	3 (3.4%)	3 (15.0%)	
	Very dissatisfied	1 (1.1%)	4 (20.0%)	
Willingness to have operation again	Certainly	67 (77.0%)	9 (45.0%)	p<0.02
	Probablement	12 (13.8%)	5 (25.0%)	
	Probably not	7 (8.0%)	2 (10.0%)	
	Certainly not	1 (1.1%)	4 (25.0%)	

The patients' report of disability in terms of the ODI was relatively low as can be seen in Table 2. The self-reported pain levels in the low back and legs are also shown in Table 2. The disability scores, low back pain and leg pain of the patients who still had the implant were roughly half of the corresponding values of the patients who had a fusion procedure to replace the implant. Regarding the pain scores, the difference between the two subgroups was highly significant.

Regarding the reported SF-36 quality-of-life assessment, the average value of all eight parameters as well as the average calculated physical composite score (PCS) and mental composite score were higher in the subgroup of patients who still had the first-generation Wallis implant. This difference was close to significant for bodily pain ($p=0.07$) and role-physical ($p=0.06$) and reached significance for physical function ($p=0.05$), PCS ($p<0.05$), and social function ($p<0.02$). Age- and gender-adjusted SF-36 scores at follow-up assessment are shown in Fig. 3 according to whether or not the patients still had the implant at follow-up. The age- and gender-matched SF-36 values of the general French population are included for reference. Table 3 allows comparison of the long-term SF-36 values of our two subgroups with long-term values reported by Glaser et al. [8] in patients who had undergone primary pedicle-screw enhanced lumbar fusion. One should remember that, as stated above, fusion was performed to stabilize the lumbar spine if and when the first-generation Wallis implant was removed. The scores in Table 3 were computed by subtracting patient scores from the appropriate age/gender general population cohort so that negative values indicate function below that of the cohort and positive scores indicate function better than the average person in the cohort.

Discussion

This cohort study was retrospective and consequently suffers the limitations of that design. There was no control group and no randomization. Furthermore, the decision to stabilize the operated lumbar spine was up to the individual surgeons. Although almost all the patients agreed to complete the questionnaire, only 80% of the 133 patients who were possible candidates for this study responded to the survey. However, there was no significant difference between the patients lost to follow-up evaluation and the followed group in terms of age at operation, sex, BMI, number of levels operated, or indications. This does not prove that the patients who responded were representative of the total population, but it is inconsistent with the existence of a selection bias. Other long-term studies of patients operated for lumbar degenerative disc disease have attrition rates ranging from as low as 0% [4] to as high as 53% [8] of still-living patients. Our overall attrition rate of 20% was similar to those of two other reports, which lost 16% and 19% of surviving patients to long-term follow-up, respectively [10, 12]. Another shortcoming of the present study was the lack of preoperative clinical data. In a recently published retrospective study of TDRs, David chose to classify the patients' functional status as excellent, good, fair, or poor, arguing that the ODI, VAS, and SF-36 outcome questionnaires in use today were either not validated measures or were not in widespread use when his patients were operated resulting in the absence of baseline data to compare [4]. Nevertheless, we felt these scores would be of particular interest in this 13-year follow-up because they are all validated and self-reported scores, which are theoretically difficult to influence. Furthermore, as noted by Glaser et al. [8], the SF-36 values can be compared to those of the age- and gender-matched general population. These clinical scores also permit comparisons among the different subgroups of the study.

The present long-term clinical results in the patients who still have the implant suggest that dynamic stabilization is an effective technique for the lumbar degenerative disorders we treated. The 95% level of patients "satisfied" or "very satisfied" was high, even compared to the 82% satisfaction rate reported for posterior fusion patients at long-term [8]. The average ODI score of 19% indicates little disability. The self-reported leg and low back pain levels are also moderately low. Furthermore, the quality-of-life scores

Table 2 Long-term disability and pain outcomes

	Patients who still had first-generation Wallis implant at follow-up		First-generation Wallis patients revised to fusion		*p* value
	Nb	Mean ± SD	Nb	Mean ± SD	
ODI (0 to 100)	85	19.3±16.8	20	30.7±23.3	$p<0.04$
Low back pain VAS	86	25.6±22.1	19	43.7±29.9	$p<0.003$
Leg pain VAS	86	19.4±23.1	18	44.7±32.9	$p<0.001$

ODI Oswestry disability index, *VAS* visual analog scale

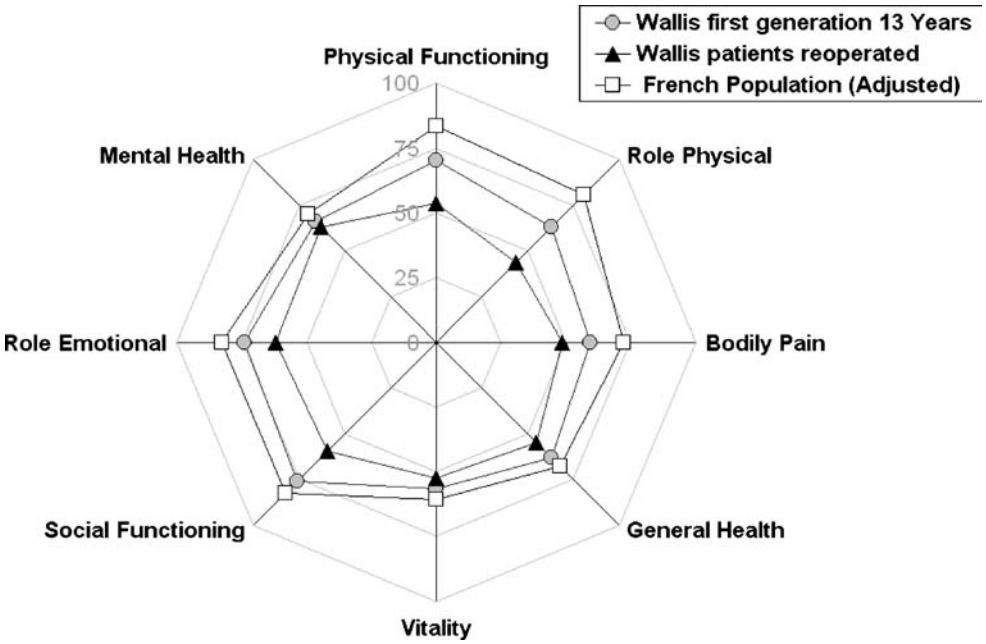

Fig. 3 SF-36 outcome of the two patient subgroups compared with SF-36 values of the general population

were only slightly below those of the age- and gender-matched general population. Our long-term clinical results are even comparable to those of TDR patients [4].

Just as important as the promising outcome itself, were the large significant differences observed between the patients who still had the implant and those in whom the implant was removed and replaced by arthrodesis. The significantly poorer clinical outcome of the patients in whom the dynamic stabilization device was replaced by a fusion procedure would suggest either that prior use of the interspinous stabilization device somehow induces a greater failure rate of subsequent arthrodesis, or that any patient who undergoes fusion might expect this significantly poorer outcome. The report on long-term clinical outcome of pedicle-screw enhanced fusion cited above with our results is consistent with the second hypothesis [8]. Their quality of life compared to the general population was super imposable with that of our fusion subgroup. The same was true for the reported long-term pain levels (approximately 3/6 and only 26% were using less pain medication at 10 years than at the time of their primary osteosynthesis) [8]. Interestingly, the pain level reported by their fusion patients at long-term follow-up was similar to the level reported by the same patients shortly after having the arthrodesis, suggesting that more was involved than a problem of progressive postoperative deterioration.

The present study shows that the long-term clinical outcome of our subgroup that still had the first-generation Wallis implant was better than that of fused patients, justifying the development of lumbar dynamic stabilization

Table 3 Reduction of SF-36 values when compared to country-, age-, and gender-matched general population

SF-36 scale	Patients who still had first-generation Wallis implant at follow-up			First-generation Wallis patients revised to fusion			Primary fusion patients with 13-year follow-up[a]		
	Nb	Mean	SD	Nb	Mean	SD	Nb	Mean	SD
Physical function	85	−13.0	26.8	20	−29.8	33.0	94	−25.5	28.0
Role-physical	86	−17.6	43.9	20	−37.2	42.1	94	−37.8	41.8
Bodily pain	87	−12.6	26.9	20	−23.1	26.9	93	−15.8	42.1
General health	86	−4.6	22.7	20	−12.6	21.4	94	−12.6	22.6
Vitality	85	−3.8	18.8	20	−8.4	19.6	94	−26.6	26.0
Social function	87	−6.3	22.2	20	−22.7	27.3	94	−5.1	20.6
Role-emotional	84	−8.9	41.1	20	−21.2	46.3	94	−15.9	24.6
Mental health	85	−3.6	19.5	20	−6.3	24.0	94	−20.5	29.8

SD standard deviation

[a] From Glaser et al. [8]

in the 1980s. Various hypotheses may explain why patients with dynamic stabilization have less pain and disability than fusion patients and quality of life close to that of subjects of the same age who have never had lumbar surgery. Perhaps the original hypothesis was founded that mechanical normalization of the treated segment permits healing of the intervertebral disc, as recently confirmed in animal studies [16]. It is also possible that motion preservation may indeed achieve better long-term clinical results than fusion in the remaining adjacent and non-adjacent untreated lumbar segments. A 10-year follow-up of TDR patients is consistent with the latter hypothesis [4, 17].

In patients who have a lumbar arthrodesis, the clinical results related to the outcome of the index levels and of the remaining untreated levels are well documented. Concerning the index level, low back pain should be resolved if it originates in the disc, vertebral body endplates, or facet joints of a successfully fused intervertebral segment. However, pseudarthrosis can be a source of low back pain after fusion. Etminan et al. estimated that roughly 15% of attempted spinal fusions result in pseudarthrosis [6]. Complications of arthrodesis might also affect subsequent quality-of-life and disability scores [20].

In fused patients, the motion patterns of the residual intact motion segments are modified in proportion to the extent and rigidity of the fused segments, and this may accelerate the degenerative process at the initially intact levels [26]. This notion of accelerated degeneration of motion segments adjacent to fused segments is controversial. Because genetic factors play a greater role than mechanical factors in the development of degenerative disease in intervertebral motion segments [1, 27], authors of some imaging and biomechanical studies have contended that the added constraints on segments around a lumbar arthrodesis should play a negligible role in the subsequent course of degeneration in the unfused segments [21, 22]. However, the cited studies do not provide corresponding clinical results, which are more relevant to therapeutic decision making than purely genetic, in vitro mechanical, or imaging aspects [2, 5]. The long-term clinical findings achieved by the present dynamic stabilization device, despite the study limitations, are not only very acceptable but possibly even better than results obtained with primary fusion. Therefore, although the predominant role of genetics in intervertebral degeneration is undeniable in unoperated subjects, the mechanical alterations resulting from lumbar fusion may play an important role in the long-term clinical results of surgically treated patients. Consistent with our findings, other long-term studies have shown disturbingly high rates of clinically significant symptoms in lumbar segments not included in previous fusion procedures [7, 13]. Their findings along with the present clinical data and our previous survivorship analysis [25] would suggest that use of dynamic stabilization instead of fusion in certain indications might reduce the number of secondary lumbar procedures during the first 10 years after the initial operation. The impact of dynamic stabilization could be even greater at present, given a recent report demonstrating a paradoxical increase in the rate of reoperations after lumbar fusion in spite of improvements in instrumentation and techniques during the last decade [19].

Today, there exist other interspinous dynamic stabilization systems, but they are fundamentally different from the first- and second-generation Wallis devices, which have hard interspinous spacers and strong tension bands [28]. Other types of dynamic stabilization devices are also being proposed for degenerative disorders of the lumbar spine. While most of these devices are recent, the first-generation Wallis implant was initially used in patients close to 20 years ago [15]. To the best of the authors' knowledge, this is the first long-term study of clinical outcome for any kind of interspinous dynamic stabilization system.

Conclusion

Clinical results of lumbar dynamic stabilization with the first-generation Wallis system at long-term follow-up evaluation are reviewed. This relatively superficial and easily reversible surgical procedure, which preserved spinal anatomy, was applied in patients who had been scheduled for fusion for painful degenerative lumbar conditions. A 13-year clinical outcome in terms of pain level, disability, quality of life, and patient satisfaction was excellent, especially in the patients who were not subsequently converted to arthrodesis. The quality of life of these patients approached values of the age- and gender-matched general population. The first-generation Wallis dynamic stabilization system successfully delayed stabilization by arthrodesis and provided outcomes comparable to the more technically demanding TDR procedures.

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Comments

Luciano Mastronardi, Roma, Italy

This is a very interesting article on a large series of patients with various type of lumbar instabilities treated with the interspinous device Wallis. I think any spine surgeon would find the data analysis complete, the follow-up adequate, and the results promising.

Even if I am not completely convinced that the interspinous device Wallis, which I use time by time, can avoid a lumbar fusion in a very high percentage of cases, I think that the readers will enjoy this experience. A multicenter, randomized study comparing the results of standard fixation and interspinous techniques would be very useful for the future.

Hatem Sabry, Jack Jallo, Philadelphia, USA

The authors of this article have conducted a retrospective study aimed at evaluating the health status of the patients who underwent a lumbar dynamic stabilization procedure. This is a well-written article covering a relatively large number of patients treated with the Wallis dynamic stabilizer and with a long-term follow-up of 13 years.

The authors concluded that the patients had excellent clinical results in terms of pain, disability, and quality of life. The question that comes to mind of course after reading this article is how these patients would compare to others managed conservatively. The answer to this would ideally be provided by a randomized, controlled study.

Yet, we cannot ignore that this study brings to light an important, less invasive, and somewhat underestimated alternative to traditional decompression and fusion of the spinal canal.

Li-Yang Dai, Shanghai, China

Senegas et al. provided a relatively large series of patients treated with interspinous process spacers for degenerative disorders of the lumbar spine. Their results of long-term follow-up are interesting and show success in the patients with implants survived. This clinical report suggests that satisfactory long-term results could be achieved when these devices are applied in appropriately selected patients. I congratulate the authors on adding to our knowledge in lumbar spine surgery.

As the authors pointed out, this study might be limited in its retrospective nature. It is difficult to determine whether the improvement of the clinical symptoms is the result of decompression or dynamic stabilization, or both of them. Therefore, a randomized, controlled study should be required for comparing the results between interspinous device insertion and fusion, although the authors found that better clinical outcome was noted at follow-up in the patients who still had the dynamic stabilizer than the patients who received subsequent fusion.

Another limitation of this study might be the heterogeneity of enrolled patients with regard to surgical indications. As generally believed, the interspinous process spacers are indicated for the patients with neurogenic claudication resulting from lumbar spinal stenosis. Our previous study showed that the capacity of the spinal canal is influenced by flexion-extension motion of the lumbar spine with a significant increase from extension to flexion (1). The advantage of using interspinous process spacers may lie in the enlargement of the spinal canal and decrease in painful motion by restricting the extension or increasing the flexion of lumbar spine. So far, as we know, there are no studies showing that interspinous process spacer insertion would be more advantageous than simple discectomy in the treatment of disc herniation. In fact, recurrence of disc herniation after the use of interspinous process devices in the primary discectomy has been reported (2). Concern remains regarding the role of the interspinous process spacers in the treatment of disc herniation.

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ORIGINAL ARTICLE

Interspinous implants (X Stop®, Wallis®, Diam®) for the treatment of LSS: is there a correlation between radiological parameters and clinical outcome?

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Abstract Neurogenic intermittent claudication, caused by lumbar spinal stenosis (LSS), usually occurs after the age of 50 and is one of the most common degenerative spinal diseases in the elderly. Among patients over the age of 65 with LSS, open decompression is the most frequently performed spinal operation. The recently introduced interspinous spacers are a new alternative under discussion. In this retrospective study, we reviewed medical records and radiographs of patients with LSS and NIC treated from June 2003 to June 2007. All included patients ($n = 129$) were treated with interspinous implants (X Stop® Wallis®, or Diam®). Evaluations of pain, using a visual analog scale (VAS), and radiographic signs, using two-plane X-rays of the lumbar spine, were performed preoperatively (preop), postoperatively (postop) and after discharge (FU 2–3). Gender ratio (m:w) was 1.1:1. Mean age of the patients was 60.8 ± 16.3 years. Foraminal height, foraminal width, foraminal cross-sectional area, intervertebral angle, as well as anterior and posterior disc height changed significantly ($P < 0.0001$) after implantation of the interspinous device. Postoperatively, symptom relief (VAS) was significant ($P < 0.0001$). The X Stop implant improved (in some cases significantly) the radiographic parameters of foraminal height, width, and cross-sectional area, more than the Diam and Wallis implants; however, there was no significant difference among the three regarding symptom relief. FU 1 was on average 202.3 ± 231.9 and FU 2 527.2 ± 377.0 days postoperatively. During FU, the radiological improvements seemed to revert toward initial values. Pain (VAS) did not increase despite this "loss of correction." There was no correlation between age and symptom improvement. There was only very weak correlation between the magnitude of radiographic improvement and the extent of pain relief (VAS). The interspinous implant did not worsen low-grade spondylolisthesis. Provided there is a strict indication and fusion is not required, implantation of an interspinous spacer is a good alternative to treat LSS. The interspinous implant offers significant, longlasting symptom control, even if initially significant radiological changes seem to revert toward the initial values ("loss of correction").

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Keywords Interspinous spacer · Interspinous process device · Interspinous process decompression · Lumbar spinal stenosis · Neurogenic intermittent claudication

Introduction

Neurogenic intermittent claudication (NIC), caused by lumbar spinal stenosis (LSS), usually occurs after the age of 50 [29] and is one of the most common degenerative spinal diseases in the elderly [20, 39].

Therapy options run the gamut from conservative management with non-steroidal antiinflammatory drugs, braces for instability, physical therapy, and epidural injections, to surgery. Operative therapy has shown significantly better results than conservative management [1, 9, 26, 41]. Open decompression is the most frequent spinal operation for patients over 65 years with LSS [8, 19, 21].

The more recently applied interspinous spacers are an alternative under discussion. These devices are used either as "stand alone" implants or to augment open decompression by preventing instability [4, 33]. The main principle for these implants is to limit the dynamic extension of the concerned segment. Early clinical trials are promising [2, 35, 43], and long-term studies are still pending.

It is well known in cases of back pain that even with modern techniques (MRI, CT), there is often no correlation between radiologic and clinical signs. Pain-free patients can show considerable degenerative changes radiographically [1, 3, 28, 35], and correspondingly, the radiologic extent of LSS shows no correlation with the magnitude of symptoms [36]. Radiologic studies have demonstrated that the use of interspinous devices affects changes of spinal alignment as well as the dimensions of the spinal canal and neural foramina [22, 30, 34]. To our knowledge, no study has confirmed the correlation between plain X-ray changes post-implantation of various interspinous spacer devices and clinical outcome. The purpose of this study was to examine the relationship between radiographic changes of the concerned vertebral segments prior to and after implantation of three different interspinous spacer devices (X Stop, Diam, and Wallis) and clinical outcome (VAS).

Methods

In this retrospective study, we reviewed the medical records and radiographs of LSS patients with NIC treated from June 2003 to June 2007. All included patients ($n = 129$) felt relief in flexion and were treated with one of the following interspinous implants:

- X Stop® (Medtronic, Tolochenaz, Switzerland)

The X Stop implant is an all-titanium (PEEK-surrounded since end of 2004) oval spacer with two lateral wings to prevent lateral migration. It is inserted as two components.

- Wallis® (Abbott Spine, Bordeaux, France)

The Wallis implant is a floating system, consisting of a PEEK (Polyetheretherketone) block. It is augmented by two woven Dacron ribbons, which are wrapped around the spinous processes and fixed under tension.

- Diam® (Medtronic, Tolochenaz, Switzerland)

The Diam implant is a silicon core covered by a polyester sleeve. It is held in position by three mesh bands, two around each spinous process and one around the supraspinous ligament.

All implantations were performed by the same experienced surgeon (PS). Evaluations of pain, using a visual analog scale (VAS), and radiographic signs, using two-plane X-rays of the lumbar spine, were performed preoperatively (preop), postoperatively (postop) and after discharge (FU 2–3).

The measuring program DicomWorks (digital Imaging and Communications in Medicine) v 1.3.5© 2000 (Philippe Puech & Loic Boussel, Lyon, France) was used to quantify radiologic parameters. Radiographic measurements were carried out by two independent experienced physicians. The radiologic parameters were determined as follows:

- Foraminal height (FH) (cm)

Maximum distance between the inferior margin of the pedicle of the superior vertebra and the superior margin of the pedicle of the inferior vertebra.

- Foraminal width (FW) (cm)

The anterior–posterior width of the foramen measured in the horizontal plane as extension of the tangent of the inferior endplate.

- Foraminal cross-sectional area (FA) (cm^2)

The margins of the foramen were marked with the cursor, and the program DicomWorks measured the cross-sectional area of the foramen.

- Anterior disc height (aDH) and posterior disc height (pDH) (cm)

The anterior and posterior disc heights were measured in the planes of the anterior and posterior surfaces of the adjacent vertebral bodies. Therefore, the distance between the intersections of the vertical line of the tangent of the superior endplate and the tangent of the inferior endplate was measured. The vertical line started

at the superior-anterior, respectively superior-posterior edge of the lower vertebra.

- Intervertebral angle (IA) (°)

The angle between the tangent of the superior endplate and that of the inferior endplate of the vertebral segment was measured. A kyphotic angle was measured as a negative ("−") value and a lordotic angle as positive ("+").

- Listhesis

The grade of listhesis was measured according to Meyerding. The antelisthesis was marked with "+" and the retrolisthesis with "−".

- Diameter of the superior endplate (*D*) (cm)

Diameter of the superior endplate of the inferior vertebral body of the deformed segment.

- Multiplication factor for standardization of measured values

For correction of differences in magnification of radiographs, the postoperative measurements of FH, FW, FA, aDH and pDH were multiplied by the quotient of the diameters of the respective superior endplates (e.g. *D* preop/*D* postop, *D* preop/*D* FU 2).

Statistics

Owing to the observational nature of this study, all outcome variables were analyzed in a purely explorative manner, and thus no formal adjustment of *P* values for multiple comparisons was carried out. Explorative comparisons were performed between described groups—respecting the actual scale levels as well as distributional characteristics—using appropriate parametric and non-parametric test statistics [e.g. *t* test, ANOVA, rank statistics (Wilcoxon–Mann–Whitney) and contingency table analysis] as well as measures of stochastic association (e.g. correlation analyses). Depiction of observed effects was given by histograms, box plots and scatter grams. Dimensional demographic variables (e.g. age) and diseases were summarized by mean, median, standard deviation (SD), standard error (SE), quartiles, minimum, and maximum if appropriate. Qualitative demographic variables (e.g. gender) and disease characteristics as well as potential prognostic categories were summarized by counts and percentages. Differences were considered to be significant at a probability level of 95% ($P < 0.05$). Statistical evaluation was done with SPSS 16.0.

Results

General

Gender ratio (m:w) was 1.1:1. Mean age of the patients was 60.8 ± 16.3 years (median 64, range 18–91). Forty-eight percent of the patients were ≥65 years, 51.2% <65 years, 24.8% <50 years, and 12.4% <40 years. There was no statistical difference in age by gender.

The frequency distribution of concerned vertebrae showed 72.9% for the segment L4/5, 15.5% for L3/4, 5.4% for both L2/3 and L5/S1, and 0.8% for L1/2.

The X Stop was implanted in 78 (60.5%) patients, the Diam in 33 (25.6%), and the Wallis in 18 (14.0%). If an X Stop was applied, the most frequently used size was 14 mm, in 66.2% of the cases, followed by 12 mm in 19.5%, 16 mm in 13.0%, and 10 mm in 1.3%.

At follow-up (FU), all patients were examined radiologically and clinically. The first postoperative examination (postop) was at 4 ± 21.7 days (median 1.0, range 1–29) after the operation and included all patients (100%). Mean FU 1 was 202.3 ± 231.9 days (median 97.0, range 6–878) post surgery, which 35.7% of patients attended. A third postoperative examination (FU 2) with only 8.5% of the patients represented, took place on average 527.2 ± 377.0 days (median 423.0, range 240–1,494) postoperatively.

Spacer without differentiation (total sample)

Foraminal height (FH)

Foraminal height postoperatively increased significantly ($P < 0.0001$) compared with preoperatively, but decreased in the FU period (see Fig. 3). At FU 1, the mean percentile increase compared with preoperative measurements was 9.2 ± 9.5% (see Table 1). At FU 2, it was 5.6 ± 7.0%. The increased FH remained statistically significant ($P < 0.05$) over the entire FU period. The decrease between postop and FU 1, although not between FUs 1 and 2, was also significant ($P < 0.001$).

Foraminal width (FW)

Foraminal width postoperatively increased significantly ($P < 0.0001$) compared with preoperatively, but decreased in the FU period (see Fig. 3). At FU 1, the mean percentile increase compared with preoperative measurements was 17.0 ± 21.8% (see Table 1) and at FU 2 was 8.2 ± 18.7%. The increased FW remained statistically significant

Table 1 Mean radiological and clinical (VAS) changes between preop, postop and FU 1 with standard deviation (SD) and range (min–max)

	X Stop				Diam				Wallis				All			
	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max
FH																
pre (cm)	1.93	0.30	1.10	2.67	1.90	0.32	1.23	2.61	2.01	0.25	1.32	2.41	1.93	0.30	1.10	2.67
pre–post																
(cm)	**0.33**[a]	0.17	−0.04	0.71	0.25	0.18	−0.07	0.66	0.22	0.14	0.02	0.50	0.29	0.20	−0.07	0.71
(%)	17.5	10.5	−1.8	46.7	13.7	9.8	−2.7	34.9	10.8	6.1	1.1	21.6	15.6	10.1	−2.7	46.7
post-FU 1 (%)	−5.6	6.9	−23.3	11.7	−9.3	4.7	−16.3	−3.8	−6.7	4.5	−13.0	−1.6	−6.3	6.3	−23.3	11.7
FW																
pre (cm)	0.92	0.34	0.24	1.90	0.67	0.27	0.25	1.27	0.82	0.29	0.32	1.41	0.84	0.33	0.24	1.90
pre–post																
(cm)	0.19	0.18	−0.21	0.68	0.27	0.21	0.00	0.69	0.17	0.21	−0.13	0.56	0.21	0.20	−0.21	0.69
(%)	28.3	36.8	−32.8	182.9	52.0	50.4	0.0	180.0	24.2	31.5	−21.0	83.3	34.1	41.4	−32.8	182.9
post-FU 1 (%)	−10.4	12.5	−48.8	16.7	−8.8	13.5	−30.2	3.7	−1.1	16.8	−23.8	28.6	−8.2	13.8	−48.8	28.6
FA																
pre (cm^2)	1.57	0.45	0.68	2.79	1.40	0.51	0.54	2.77	1.62	0.38	1.05	2.41	1.53	0.46	0.54	2.79
pre–post																
(cm^2)	**0.51**[b]	0.26	−0.02	1.20	0.43	0.29	0.03	1.07	0.33	0.33	−0.17	0.93	0.46	0.28	−0.17	1.20
(%)	35.5	21.0	−1.1	104.4	36.2	29.1	1.1	109.3	20.7	20.4	−9.1	62.0	33.6	23.8	−9.1	182.9
post-FU 1 (%)	−11.4	8.5	−27.0	11.2	−12.1	19.4	−45.1	1.6	−9.2	7.7	−23.1	2.0	−11.0	10.0	−45.1	11.2
IA																
pre (°)	6.21	4.89	−5.00	16.00	8.26	4.97	−7.00	17.00	9.28	3.58	5.00	15.00	7.2	4.9	−7.0	17.0
pre–post (°)	2 **5.52**[c]	3.36	1.40	−12.00	−3.76	4.58	11.00	−12.00	−4.53	2.67	0.00	−11.00	−4.90	3.70	11.00	−12.00
post-FU 1 (°)	2.3	3.3	8.0	−5.9	3.1	3.0	7.0	0.0	1.9	2.8	7.0	−2.0	2.3	3.1	8.0	−5.9
aDH																
pre (cm)	1.07	0.40	0.33	1.94	1.38	0.32	0.53	2.21	1.32	0.30	0.89	1.86	1.18	0.40	0.33	2.21
pre–post																
(cm)	−0.15	0.18	−0.68	0.20	−0.09	0.18	−0.35	0.38	−0.11	0.19	−0.56	0.24	−0.13	0.18	0.68	−0.38
(%)	−12.6	16.7	−52.0	32.6	−4.9	18.1	−31.3	71.7	−8.2	12.0	−30.1	16.0	−10.0	16.8	−52.0	71.7
post-FU 1 (%)	4.7	18.1	−41.6	47.6	4.4	15.6	−18.1	27.3	2.1	7.5	−6.9	18.9	4.1	15.8	−41.6	47.6
pDH																
pre (cm)	0.59	0.22	0.00	1.17	0.77	0.18	0.34	1.21	0.65	0.23	0.11	1.01	0.64	0.22	0.00	1.21
pre–post																
(cm)	0.27	0.15	−0.09	0.58	0.22	0.17	−0.21	0.68	0.20	0.15	0.01	0.59	0.25	0.16	−0.68	0.38
(%)	52.8	39.5	−7.7	216.7	33.2	36.0	−23.9	200.0	40.7	39.2	1.2	163.6	46.0	39.2	−23.9	216.7
post-FU 1 (%)	−17.9	18.8	−100.0	3.1	−13.1	7.5	−19.1	−1.7	−14.8	13.6	−33.3	0.0	−16.6	16.6	−100.0	3.1

Table 1 continued

	X Stop				Diam				Wallis				All			
	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max
VAS																
pre	67.2	26.4	0.0	100.0	59.5	23.2	0.0	100.0	57.5	31.0	0.0	100.0	63.8	26.4	0	100
pre–post	−26.3	36.5	50.0	−100.0	−34.0	34.3	40.0	−92.0	−14.7	34.4	55.0	−100.0	−26.7	35.8	55.0	−100.0
post-FU 1	−0.5	31.6	60.0	−80.0	−2.6	41.9	75.0	−82.0	2.6	31.2	59.0	−60.0	−0.6	34.6	75.0	−82.0

pre preoperative values, *pre–post* changes between preoperative and postoperative values, *post-FU 1* changes between postoperative values and values at follow-up 1

[a] Significant difference X Stop versus Diam and Wallis

[b] Significant difference X Stop versus Wallis

[c] Significant difference X Stop versus Diam

($P < 0.001$) over the entire FU period. The decrease between postop and FU 1, but not between FUs 1 and 2, was also significant ($P < 0.001$).

Foraminal cross-sectional area (FA)

Foraminal cross-sectional area postoperatively increased significantly ($P < 0.0001$) compared with preoperatively, but decreased in the FU period (see Fig. 3). At FU 1, the mean percentile increase compared with preoperative measurements was 19.6 ± 17.5% (see Table 1) and at FU 2 was 5.3 ± 12.1%. The increased FA remained statistically significant (<0.001) over the entire FU period, and the decrease over the FU period was also significant ($P < 0.05$).

Intervertebral angle (IA)

The use of an interspinous spacer led to a significant ($P < 0.0001$) decrease in the mean IA, but increased in the FU period (see Table 1). At FU 1, the mean IA measured +4.1° ± 4.5° (median 5.0, range −4.00–12.9), at FU 2 it was +5.2° ± 3.4° (median 4.0, range −1.00–11.0). When compared with the preoperative measurements, the increased IA remained statistically significant (<0.05) over the entire FU period.

Anterior disc height (aDH)

The aDH postoperatively decreased significantly ($P < 0.0001$) compared with preoperatively (see Fig. 3). At FU 1, the mean percentile decrease in aDH compared with preoperative measurements remained at 10.0 ± 14.2% (see Table 1), and at FU 2 was 8.6 ± 11.0%. The decreased aDH remained statistically significant ($P < 0.05$) over the entire FU period although the changes within the FU period were not significant.

Posterior disc height (pDH)

The pDH postoperatively increased significantly ($P < 0.0001$) compared with preoperatively (see Fig. 3). In the FU period, the pDH decreased. At FU 1, the mean percentile increase in pDH compared with the preoperative measurements was 21.7 ± 22.2% (see Table 1) and at FU 2 was 22.0 ± 31.7%. The increased pDH remained statistically significant ($P < 0.05$) over the FU period, with the decreases between postop and FU 1, and postop and FU 2, also significant (<0.001).

Spondylolisthesis

The differences in spondylolisthesis between preop and postop are depicted in Table 2. The changes over the entire course are shown in Table 2.

VAS

The VAS postoperatively decreased significantly ($P < 0.0001$) compared with preoperatively. At FU 1, the patients gave a mean VAS of 34.5 ± 32.5 (median 30.0, range 0.0–100.0) (see Table 1), and at FU 2 reported 33.5 ± 33.2 (median 30.0, range 0.0–100.0). Therefore, improved clinical symptoms (VAS) remained significant ($P < 0.0001$) for the entire FU. The differences within the FU period were not significant.

For the variable pairs "difference in pain" and "difference in Foraminal cross-sectional area (FA)" we found a significant ($P < 0.05$), but with a correlation coefficient of $r = 0.33$ a clinically questionable correlation.

Gender comparison revealed significantly more preoperative pain among females ($P = 0.018$), and no statistically significant postoperative difference. There was no correlation between age and changes in symptoms (VAS) (see Figs. 1, 2).

Differentiation among spacers (X Stop® Wallis®, Diam®)

Comparing the preoperative and postoperative results, we found:

- The X Stop group showed a significantly larger change in FH than the other two groups, Diam ($P = 0.045$) and Wallis ($P = 0.034$). The difference between Wallis and Diam was not significant ($P = 0.613$) (see Fig. 3).
- The differences in FW among the individual spacer groups were not significant, but the increased FW tended ($P = 0.052$) to be more with Diam than with X Stop (see Fig. 3).
- The difference in FA between X Stop and Wallis was statistically significant ($P = 0.022$) (see Fig. 3).
- The difference in IA between X Stop and Diam was significant ($P = 0.022$).
- There were no significant differences in aDH and pDH among the groups (see Fig. 3).
- The postoperative radiological changes relative to preoperative measurements are shown in Fig. 3. Differences among the individual spacers (X Stop, Diam, Wallis) in radiographic and clinical (VAS) improvements were not significant in the FU period up to the time of FU 1 (see Table 1). A statistical evaluation of the particular implants at FU 2 was not useful due to the small numbers of examined patients at that time.
- The differences in VAS between the individual spacer groups were not significant, but the improved VAS

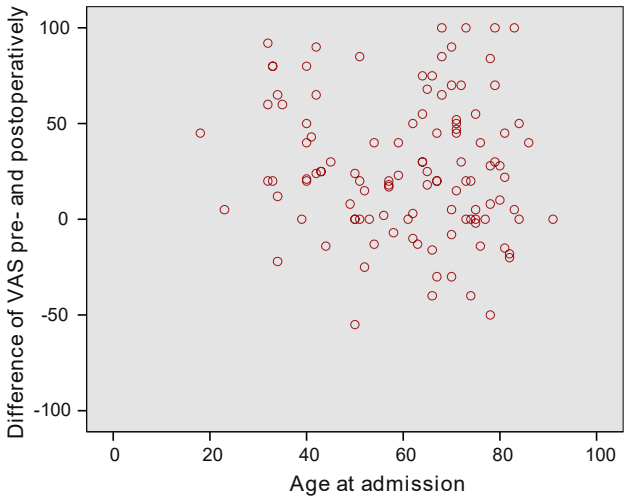

Fig. 1 Scatterplot illustrating the correlation between age and extent of pain relief

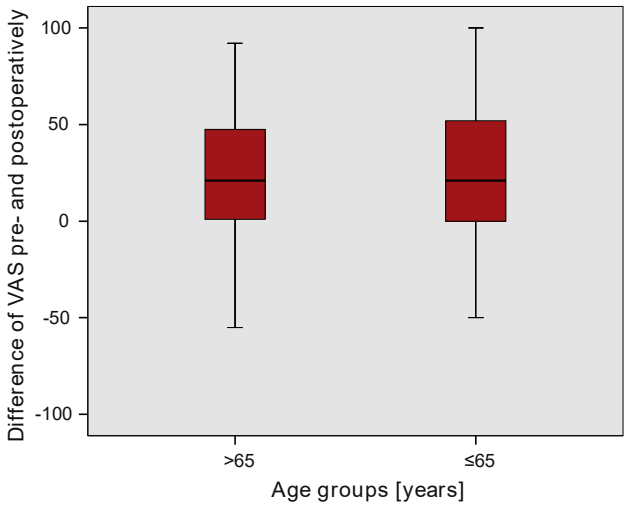

Fig. 2 Boxplot illustrating pain relief between age groups

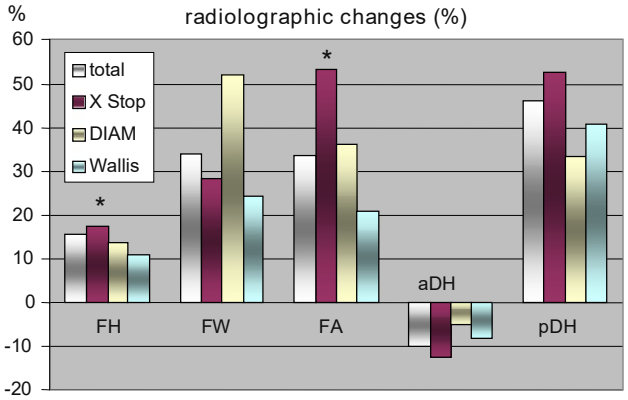

Fig. 3 Relative radiographic changes, preoperative versus postoperative (*significance between X Stop and the other implants $P < 0.05$)

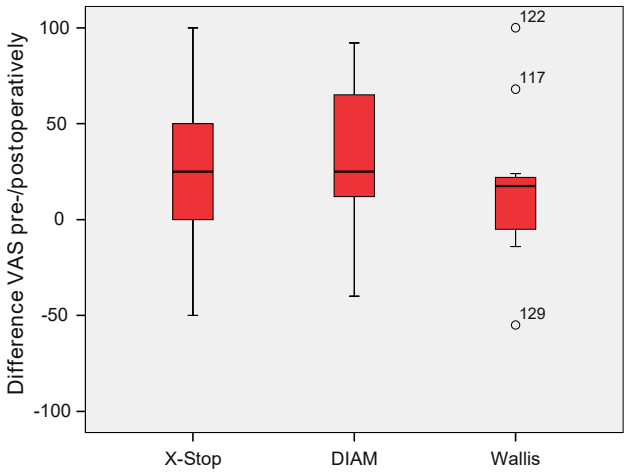

Fig. 4 Boxplot illustrating differences in VAS pre- and postoperatively regarding the particular implants

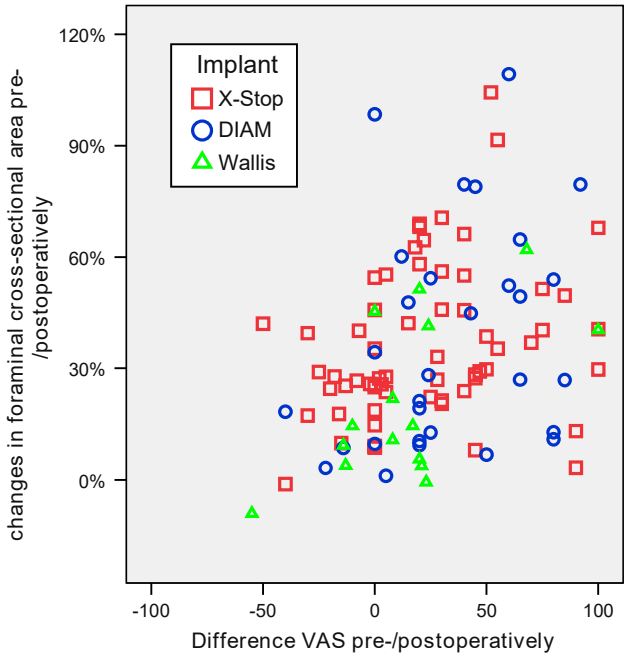

Fig. 5 Scatterplot illustrating the correlation of differences in VAS and foraminal cross-sectional area ($r = 0.33$; $P < 0.05$)

scores tended ($P = 0.083$) to be greater with Diam than with Wallis (see Fig. 4).

- There was no correlation between the pre- and postoperative radiological changes and the decrease in symptoms (VAS preop–postop) among the individual groups (see Fig. 5).
- The different sizes of X Stop led neither to significant percentile changes of the measured radiological parameters, nor to significant differences in symptoms between preop, postop, and the entire FU period.

Discussion

Lumbar spinal stenosis is caused by degenerative changes in the spinal canal, e.g. osseous or ligamentous hypertrophy, disc protrusion, and/or degeneration of the disc and instability [23]. Hasegawa et al. and Cinotti et al. identified a significant correlation between disc height and foraminal height [7, 14]. A posterior disc height of 4 mm and foraminal height of 15 mm quite likely lead to nerve compression, although this does not equate to radicular symptomatology [14].

Anatomically, the loss of disc height induces subsidence and subluxation of the articular processes. The superior process of the lower vertebra then slides cephalad and anteriorly, causing the ligamentum flavum to bulge anteriorly, compressing the nerve root [7, 14].

Along with degenerative changes, movement alters spinal canal volumes. Extension of the spine leads to bulging of the ligamentum flavum and the posterior anulus fibrosus into the spinal canal and the lateral recesses. This creates tightness, which may cause NIC [27, 30]. Although extension leads to the reduction in the volumes of the spinal canal, lateral recesses, and foramina [3, 6, 12, 18, 31], flexion causes enlargement by stretching the ligamentum flavum and the posterior longitudinal ligament. In maximal extension, the ligamentum flavum can become 2 mm thicker than in flexion [12, 27, 31]. Anatomical studies have shown that the diameters of both spinal canal and foramina become significantly larger in flexion and significantly smaller in extension [12, 27, 30, 32]. Radiological studies have identified a 16% decrease in the diameter of the spinal canal and a 21–24% decrease in the foraminal cross-sectional area in extension compared with flexion [12, 34].

The normal sagittal diameter of the lumbar spinal canal measures 15–18 mm. A diameter measuring 10–14 mm is deemed "relative stenosis," and one below 10 mm as "absolute stenosis" [5, 10, 32, 37, 38]. However, the extent of LSS does not appear to correlate with the severity of symptoms [13, 36]. In the literature, parameters for critical foraminal stenosis are mentioned at a posterior disc height of 4 mm or a foraminal height of 15 mm [14]. The mean measures we determined preoperatively (posterior disc height 0.64 ± 0.22 cm; foraminal height 1.93 ± 0.30 cm) are a bit higher.

These anatomic and radiographic findings, as well as the symptomatic improvement with spinal flexion, led to the development of the interspinous implant, which is particularly involved in limiting extension in the affected vertebral segment [11, 24, 33]. To date, the X Stop implant has been best examined in the scientific literature [2, 11, 17, 24, 35, 37, 43]. In a prospectively randomized, controlled multicenter trial, Zucherman et al. examined the clinical

results of 191 patients with NIC who were treated either conservatively or operatively with an X Stop. At the 2-year FU, the operated patients had significantly better results [43]. In our study as well, a significant improvement in symptomatic complaints (VAS) was seen postoperatively. Patients noted a significant ($P < 0.0001$) pain decrease of 26.7 ± 35.8 (VAS 0-100) at postop (Table 1). In subsequent FU (1–2), further discrete improvements of symptoms were evident. The best pain relief was noted for patients who received the Diam (34.0 ± 34.2), followed by the X Stop (26.3 ± 36.5), and the Wallis (14.7 ± 34.4) implants (see Fig. 4), although differences between implants were statistically not significant. A tendency ($P = 0.083$) was noted for better results using the Diam over the Wallis implants.

In a study of 26 patients with LSS, Siddiqui et al. found on positional MRI that cross-sectional areas of the spinal canal and foramina increased after implantation of an X Stop [34]. Richard et al. used MRI to examine the effects of the X Stop on the dynamic cross-sectional area of the spinal canal and foramina (in 15° flexion and 15° extension) of eight lumbar spines (L3/4). Following the X Stop implantation, the cross-sectional area of the spinal canal increased by 18% and the foramina by 25% in extension. No significant change was observed on adjacent levels [30].

We performed no sectional imaging postoperatively, and hence did not determine spinal canal diameters directly. However, because significant correlations between sagittal diameter of the foramina and spinal canal size [7], and between increased disc height with diminished disc protrusion via ligamentotaxis and thinning of the ligamentum flavum [12, 27, 31] have been previously identified, our measured radiographic changes can be extrapolated to indicate widening of the spinal canal. Thus in our study, all postoperative radiological measurements showed significant changes (see Table 1). In evaluating the individual implants, it was noteworthy that the X Stop implant led to a significantly greater increase in FH than the Diam and Wallis implants.

In a randomized controlled trial, Anderson et al. found that patients with NIC caused by degenerative spondylolisthesis derived significantly better clinical results (ZCQ, SF-36) from the implantation of an X Stop than patients treated conservatively. As well, after 2 years, there was no increased degree of spondylolisthesis (average preoperatively 14.29% and at 2-year FU 14.19%). Only 2° more kyphosis was identified [2]. Over the entire FU of our study, there were no significant changes to the degree of spondylolisthesis (see Tables 2, 3). What was noticeable, however, was a statistically significant ($P < 0.0001$) postoperative increase in kyphosis of the concerned segment, 4.9° ± 3.7°. In further FU, a decrease was observed, but

Table 2 Changes of the degree of antelisthesis between preop and postop

Degree of antelisthesis preoperatively	Degree of antelisthesis postoperatively				
	Not done	0	1	2	Total
Not done	20	2	0	0	22
0	0	54	1	0	55
1	0	2	47	2	51
2	0	0	0	1	1
Total	20	58	48	3	**129**

Table 3 Change of antelisthesis over entire course (%)

Degree of antelisthesis	preop		postop		FU 1		FU 2	
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)
Not done	22	17.1	20	15.5	7	15.2	2	15.4
0	55	42.6	58	45.0	19	41.3	6	46.2
1	51	39.5	48	37.2	20	43.5	5	38.5
2	1	0.8	3	2.3				

the differences, compared with preop measurements, remained statistically significant ($P < 0.05$).

Finally, a regression of all postoperative radiological changes toward the initial values was observed in the FU 1 and 2 periods (see Table 1). It is not clear, to what this "loss of correction" should be attributed. One explanation, for the Diam and Wallis implant groups, at least, might be attributed to implant breakdown. They are composed of softer materials (silicone, PEEK). The X Stop, on the other hand, is constructed of titanium. Because of its barrel-shaped form and angled edges, however, the implant could intersperse with the surrounding soft tissues and depending on the bone density, even displace or fuse with bone of the spinus processes. In any case, the measured differences among the implants were not significant.

The use of interspinous implants leads to significant improvements in both radiologic parameters and subjective pain complaints. However, the magnitude of symptomatic relief (VAS) does only very weakly correlate ($r = 0.33$; $P < 0{,}05$) with that of radiographic changes (see Fig. 5). Therefore, it appears that neither the initial radiologic grade of LSS [36], nor the postoperative radiographic changes correspond directly to clinical symptoms. One explanation for this would be that the position of the nerve root ganglion, with the largest diameter of the nerve root, varies both among individuals and according to the spinal level [15]. In over 50% of cases, the nerve root ganglion lies in the intraforaminal region [15]. In such cases, there would be less intraforaminal space compared with individuals with the ganglion

in an extraforaminal position. As well, the average cross-sectional area of the nerve root varies between 10 and 30% of the average cross-sectional area of the foramen [16]. Another explanation of the dichotomy between radiographic evidence and clinical complaints is that the size of the foramina alters dynamically not only in flexion and extension, but also with axial rotation and lateral bending [12]. Axial load also appears to impact dural sac cross-sectional area on MRI [25, 40, 42]. The X Stop and Wallis implants work predominantly to limit extension and flexion, with only minor checks to axial rotation and no effects on lateral bending [33].

On gender-based comparison, female patients complained of significantly more preoperative pain than males ($P = 0.018$). Postoperatively, however, there were no gender-related differences. Thus, it appears that females benefited slightly more from the intervention.

There was no correlation between age and postoperative symptom improvements (see Figs. 1, 2).

Keypoints

- The implantation of an interspinous spacer leads to significant pain relief (VAS).
- The implantation of an interspinous spacer leads to significant changes of foraminal height, width, cross-sectional area, intervertebral angle, and anterior/posterior disc heights.
- There is only very weak correlation between the magnitude of radiographic improvement and the extent of pain relief (VAS).
- The interspinous implant does not worsen low-grade spondylolisthesis.
- During FU, the radiological improvements seem to revert toward initial values ("loss of correction").
- Pain (VAS) does not increase despite this "loss of correction".
- The X Stop implant improves (in some cases significantly) the radiographic parameters of foraminal height, width, and cross-sectional area more than the Diam and Wallis implants; however, there is no significant difference among the three regarding symptom relief.
- The size of the X Stop implant has no statistical impact on either the percentile change in radiologic measurements or symptom improvement.
- There is no correlation between age and symptom improvement.
- Female patients complained of significantly more preoperative pain than males, however there were no significant postoperative differences.

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