State of the art and advances in Interspinous implants

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Summary

Lumbar spinal stenosis is a common condition in elderly patients and also one of the most common reasons to perform spinal surgery at an advanced age. Classical treatment is based on wide or limited surgical decompression, procedure for which many variants have been reported. However it can be a heavy intervention in elderly patients and carries a risk of iatrogenic instability.

Lumbar stenosis is a dynamic phenomena as the diameter and surface of the spinal canal decreses during sagittal extension due to bulging of the disc.

The rationale of the interspinous implants is to restrain extension thus avoiding the occurrence of neurogenic claudication. Over the time, however, their indications have widened to other degenerative conditions. In vitro studies have showed an effect of intradiscal pressure and unloading of facet joints.

Evidence remains, however sparse as to their effectiveness. There is limited clinical evidence as to their results in spinal stenosis but not much in other indications.

The use of a tension band has been reported but its true effect never truly analyzed. In an in-vivo animal study we reported the effect of a novel interspinous device with an added tension band on segmental instability. It decrease abnormal flexion motion and restores spinal stiffness.

Key words: lumbar spine stenosis, interspinous stablization, animal study

INTRODUCTION

Lumbar spinal stenosis is a very common condition in elderly patients and also one of the most frequent reasons to perform spinal surgery at an advanced age. (38)

Stenosis and claudication have been described as early as 1883 (20), however, the modern description of this pathology was performed by Verbiest in the fifties (43).

Spinal stenosis can lead to radiculopathy or neurogenic claudication and can be induced by different factors, of which a number are related to degenerative processes. The participation of so-called congenital stenosis is still subject of debate.

Some definitions need to be clarified. The classic symptom characterizing spinal stenosis is neurogenic claudication. The pathophysiology of this phenomenon is not entirely understood. However Porter has proposed an elegant theory (28,29). In this explanation claudication is caused by the venous pooling, induced by the stenotic impairment of venous drainage at root level, and will only occur if stenosis (central and/or lateral) is present at two adjacent levels. This situation is, however, not the rule and many stenotic patients do not present with true neurogenic claudication. Often complaints linked to stenosis are sciatic pain due to the direct compression of neural structures.

Identification of stenotic images in the mid and exit zones of the foramen have been made possible by MRI studies and it was found that stenosis could be found in up to 80 % of subjects over seventy (32)

LUMBAR SPINAL STENOSIS AND MOTION

Lumbar spinal stenosis (LSS) is characterized by a narrowing of the spinal canal with encroachment of the neural structures from degenerated or hypertrophied osteoligamentous structures. Decreased disc height, bulging of the posterior annulus and buckling of the ligamenta flava are among the most common viscoelastic structures contributing to LSS; while hypertrophic facet joints and laminar thickening are among the major osteogenic contributors to the narrowing of the spinal canal and neuroforamina. It is well established that the diameter of the spinal canal decreases during extension [4] which in turn amplifies stenotic conditions in the presence of degenerative changes.

The functional status of the spine has also been studied in relation to stenosis and the worsening of symptoms during extension. It has been shown that subjects with stenosis changes inducing a have abnormal patterns motion in sagittal extension (39). This suggests a sort of proprioceptive protective behaviour in case of potentially stenotic movements.

DECOMPRESSIVE PROCEDURES

When conservative treatment fails in LSS patients, the standard of care consists in surgical decompression. However decompressive lumbar spinal surgery carries a risk of instability as a consequence of the degenerative

nature of LSS (7). Segmental instability is often considered a cause for low back pain mostly related to degenerative processes. Subsequently, more invasive methods have been developed including rigid stabilization and fusion systems with pedicle screw fixation [30].

Accelerated adjacent segment disc degeneration from abnormal load sharing is also a possible problem, with implantation of rigid systems [23]. As a result, dynamic stabilization systems have been developed which try to prevent overloading of adjacent spinal segments.

Some of these involve implants secured to the spine by pedicle screw fixation such as the Graf [8] and Dynesis [36] systems. In spite of encouraging early results of pedicle-screw systems for flexible intervertebral stabilization [9, 6], some long-term results were less optimistic [10, 31]. Increased lumbar lordosis, stretching of the Dacron parts, mal-positioning, and/or loosening of pedicle screws have been reported as reasons for failure.

Moreover, decompressive procedures and/or semi-rigid fixation may be heavy and complication prone procedures for elderly patients.

RATIONALE AND DEVELOPMENT OF INTERSPINOUS IMPLANTS

Because of the dynamic nature of spinal stenosis and neurogenic claudication it appeared logical to prevent the harmful extension motion of affected segment(s) by fitting some kind of device between adjacent spinous processes.

The first interspinous implant, the Wallis (Abbott Spine), was not proposed as a treatment for stenosis but as an alternative to fusion in disc degeneration and instability and was used with a tension band around the spinous processes. (34). This implant uses Polyetheretherketone (PEEK), is fixed to the spine by two bands looped and tensioned around the adjacent spinous processes [33].

It was hypothesized that, combined with a tension band, stabilisation could also be obtained in flexion, thus avoiding the need for pedicle screw fixation [33]. Little biomechanical data exists to support these notions.

In the following years, different interspinous implants have been developed to assist in providing dynamic spinal stabilization in order to avoid or supplement LSS decompression. The principle of all these systems consists of inserting the spacer between the spinous processes at the stenotic level in order to increase the intervertebral space, stretch the ligamenta flava and posterior annular fibers, thus enlarging both the central canal and neuroforamina [1, 24]. Little is known however, about how these interspinous implants influence the in vivo range of motion (ROM) of the lumbar spine.

Moreover, they offer the advantage of being much less invasive then pedicular systems, some even being implanted percutaneously. The procedure is fast and without major difficulty and not linked to any major complications. If needed it can even be performed in lateral prone and under local anesthesia.

Several such experimental implants have been developed, some connecting spinous processes and laminae [22], others placed between two adjacent spinous processes with a spring [21], one with a silicone implant [26].

A number of devices are in commercial use and that number grows rapidly.

The X-stop Interspinous Process Distraction System (Medtronic) is the first device having been proposed specifically for spinal stenosis and has been the subject of a multicenter prospective controlled study which, despite some methological flaws, gave the first evidence supporting use of an interspinous device. It compared the device with non operative treatment with a Zurich Claudication Questionnaire [47] and quality of life as measured with SF-36 also appears improved (12). Clinical results results seem to be maintain at 4 years (18). Cadaveric studies show that X-Stop appears to decrease intra-discal pressure (37) and unload the facet joints [45] while not modifying adjacent level kinematics (24)

The Coflex (Paradigm Spine) is a U shaped titanium device attached to the adjacent processes. The shape allows for a certain degree of elasticity and appears to restore a degree of stability in destabilized cadaveric spines mostly in extension (42). A non randomized study comparing Coflex with PLIF and decompression in patients with stenosis and instability showed similar clinical results but less hypermobility at adjacent segments in the Coflex group. A modified version with more rigid attachement to the processes appear to efficient to restore a certain degree of stability in motions other than extension in destabilized cadaver spines and could be used as an adjunct fixation for fusion surgery (16)

The Diam (Medtronic) is a polyester encased silicone implant secured with a band to the spinous process.

Fig. 1. **a** Insertion of the In-Swing® interspinous device is accomplished via a unilateral approach. **b** Following insertion the wings of the device automatically open **c** on the contralateral side thus securing the implant between the spinous processes. **d** Following insertion, longitudinal pressure cranially and caudally insure its placement
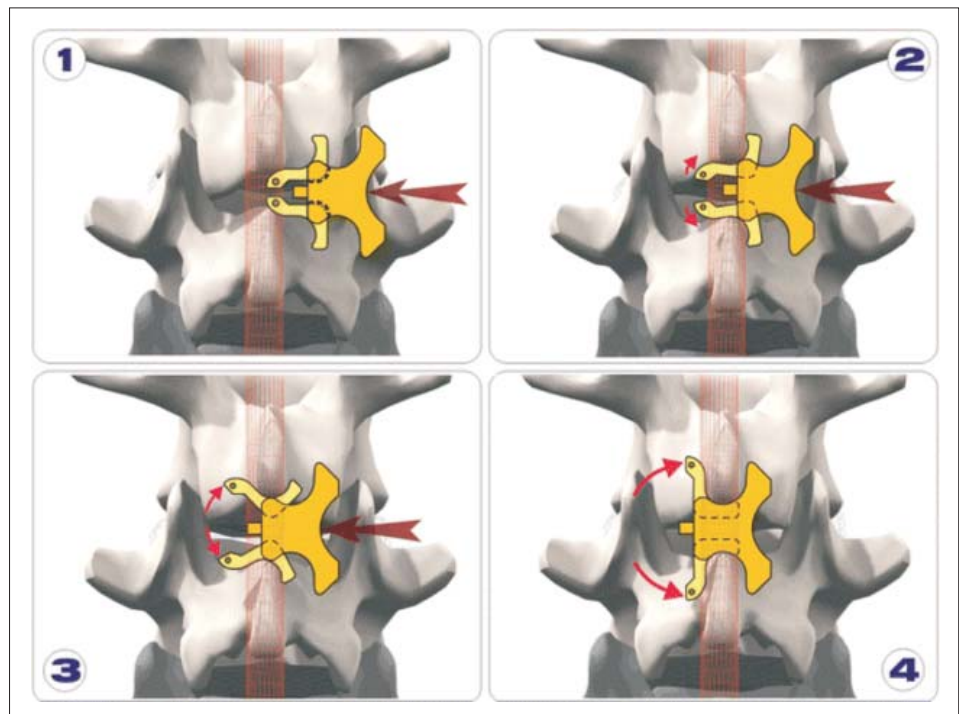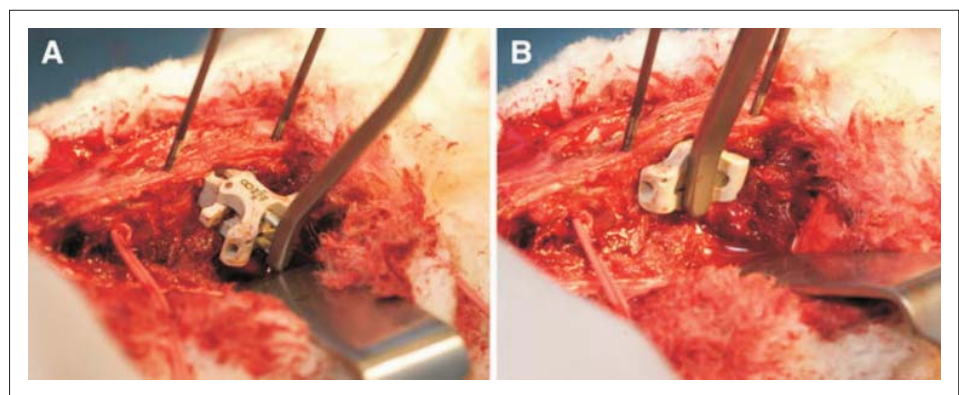

Fig. 2. Insertion of the 8-mm InSwing® interspinous device demonstrating **a** the self-pivotating (*opening*) L-shaped wings allowing for unilateral insertion. **b** Once inserted through the interspinous space the wings automatically open on the contralateral side securing the implant between the spinous processes

Contrarily to the two previous devices it allows for unilateral insertion. A cadaveric study showed that the device can restore the increased motion observed after discectomy (27). The safety of the device was assessed at one year compared to similar surgery without implantation. There were no differences in clinical results measured by VAS and MacNab outcome or disc height but some processes fractures and a slight kyphosis. (17). A restrosprctive study showed good results but was methodologically flawed (41)

Other devices are becoming available in increasing number but without much data. Some are to be used percutaneously like the Aprius (Medtronic) or the Inspine (Synthes). While an appealing solution, percutaneous insertion may be challenging in the presence of marked facet hypertrophy, often present in elderly degenerative patients.

While some surgeons (and companies) try to stretch the indications of interspinous implant beyond spinal stenosis, like instability, or associated with discectomy, there is no evidence in those domains and failures has been reported when used to prevent recurrent disc herniations (5) or in presence of degenerative spondylolisthesis (44)

Although rare, some complications have also been reported including foreign body responses to polyethylene wear (14)

A recent biomechanical study compared the behaviour of Coflex, Diam, Wallis and X-Stop on intradiscal pressure and restabilization of destabilized spinal segments. The four implants strongly stabilized and reduced intra-discal pressure in sagittal extension but had almost no effect in the other planes of motion. (45)

ADDED VALUE OF A TENSION BAND

The InSwing (Orthofix Spinal Implants) is a novel device allowing unilateral insertion with self locking and self positioning thanks to a self opening wing system (Fig. 1). Once open the vertical pressure of the adjacent spinal processes keeps the wings locked in open position. The instrumentation allows for a unilateral insertion (Fig. 2) by means of mirrored hook-shaped tension band inserters who are passed blindly around the adjoining spinous processes, allowing to stay close to the bone without involving the erector spinae muscle on the other side. It also differs from other devices in that it can be used alone or with a tension band around the adjacent processes. Cadaveric studies showed that a calculated tensioning torque of the band has a direct effect on stabilization and opening of disc and foramens (2).

An in-vivo animal study demonstrated the important stabilizing effect of the banding during flexion [11]. Ten adolescent Merino lambs (24–30 kg) were used for the study. A destabilization procedure was performed at the level of L1–L2 on both sides, thus simulating an instability resembling stenotic degenerative spondylolisthesis. Following general anesthesia, the animal was placed in a side-lying posture and lateral radiographs were taken

in full flexion and extension of the trunk. Each radiograph was centered at the level of L1–L2. The same radiographic protocol was repeated following the insertion of an 8-mm InSwing® interspinous device at L1–L2. This insertion required only a minimal dissection of the paraspinal muscles on the left side. The supraspinous ligament remained intact as did the paraspinal muscles on the contralateral side. Finally, a tension band (Fig. 3) was passed in the implant and around the L1 and L2 spinous processes and tightened to 1 N/m, another new set of flexion–extension radiographs were acquired. The tension was obtained with a proprietary dynamometric band tightening device provided by the implant manufacturer and enforced by securing the band with metal clips. Intersegmental ROM was assessed in each of the conditions and compared using Cobb's method at the superior endplate of L1 relative to the inferior endplate of L2 (Fig. 4). Following the first test condition, the L1–L2 destabilization procedure, the mean total sagittal plane intersegmental ROM was $6.3 \pm 2.7°$. After instrumentation with the InSwing® interspinous implant, the mean total sagittal plane ROM was reduced by 15.9% to $5.3 \pm 2.7°$. The addition of the tension band, the third test condition, resulted in a 42.9% reduction in total sagittal plane ROM to $3.6 \pm 1.9°$, as compared to the initial ROM results following the destabilization procedure. These reductions in total sagittal plane ROM, as a result of the implant itself ($P = 0.47$) and then the addition of the tension band ($P = 0.06$), were not statistically significant. The mean observed lumbar flexion ROM following the destabilization procedure was $14.3 \pm 1.8°$. The addition of the interspinous implant without the tension band resulted in an insignificant ($P = 0.74$) 1.4% reduction in lumbar flexion. In contrast, a 15.4% reduction in lumbar flexion ROM was observed when comparing mean results following the destabilization procedure ($14.3 \pm 1.8°$), to readings made after instrumenting with the InSwing® interspinous implant and securing with the tension band ($12.1 \pm 3.0°$). This reduction in lumbar flexion ROM with the addition of the implant and tension band was statistically significant ($P = 0.01$). Figure 5 summarizes the mean changes in lumbar extension, flexion, and ROM from the initial condition, pre-implant, to those measurements obtained following implantation with the interspinous device, and those with the addition of the tension band to the interspinous device.

Additionally this in vivo animal study was used to determine the effect of the interspinous implant on lumbar spine stiffness during exposure to acute dorsoventral loading. The same lambs were mechanically tested in vivo using a validated computer controlled force application apparatus designed to quantify dorsoventral (DV) stiffness (15). The anesthetized sheep were placed prone on a stainless steel operating table, which included a rigid (wood) support beneath the abdomen (just caudal to the ribcage). The support was designed to orient the long axis of the sheep spine parallel to the operating table and perpendicular to the load actuator and secondarily to

stabilize the trunk. Foam blocks were also placed on either side of the sheep abdomen to further stabilize the trunk along the medial–lateral axis (Fig. 6). Oscillatory (2 Hz) loads (~5% of body weight) were applied to the L2 spinous process using the stylus of the actuator under load control and with the animals lying prone on an operating table. Load and displacement at L2 were collected at a sampling rate 2500 Hz. DV stiffness (load/deformation, N/mm) were determined over six trials of 20 cycles of loading, and averaged. Four spinal conditions were examined: the initial intact condition (A), following a destabilisation procedure at the L1-L2 level simulating a stenotic degenerative spondylolisthesis (B), following the insertion of an 8 mm InSwing® interspinous device at L1-L2 (C), and again with the implant secured by means of a tension band tightened to 1 N/m around the interspinous processes of L1 and L2.(D). Stiffness comparisons for each condition were performed using a one-way balanced analysis of variance (ANOVA). To specifically identify which pairs of means (i.e., which conditions) were different, if any, a Tukey's honestly significant difference (hsd) multiple comparison test was employed at a significance level of ?=0.05.

The mean stiffness (± standard deviation) for the intact (A), destabilisation (B), InSwing® (C), and InSwing® with tension band (D) conditions were 4.99±0.89 N/mm, 4.89±0.82 N/mm, 4.82±0.92 N/mm, and 5.00±1.20 N/mm, respectively. Results from the one-

Fig. 3. The tension band is looped through pre-fabricated holes in the InSwing® interspinous device and subsequently secured around the adjacent spinous processes of L1 and L2 and then tightened to a tension of 1 N/m and fixed with metal clips

Fig. 4. Sagittal plane radiographs of the ovine lumbar spine demonstrating the Cobb method of lumbar analysis of L1–L2 of the initial condition (**a**) and with the InSwing® device in place (**b**)
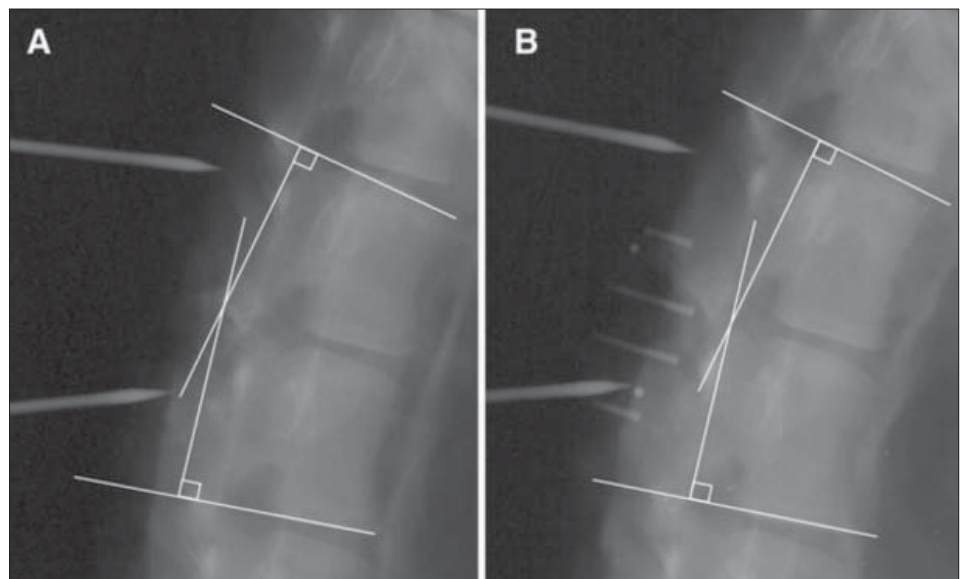
way ANOVA confirmed that significant differences (P<0.0001) exist in the mean stiffness between the following conditions: (A) and (B), (A) and (C), (B) and (D), and (C) and (D). In contrast, there were no significant differences in mean stiffness between conditions (A) and (D), and (B) and (C).

The InSwing° interspinous device, with the addition of the tension band, restored spinal stiffness back to the intact condition.

The importance of the tension band is confirmed in our findings showing that the addition of the tension band significantly reduced lumbar flexion ROM providing increased stability to the lumbar spine.

Only a few other studies have investigated interspinous implants secured with tension bands. Floman et al. [5] used the Wallis device after primary disc excision in the hope of reducing recurrent disc herniation. In their non-randomized study, they found the implant to probably be incapable of reducing the incidence of recurrent herniation. In a literature review by Christie et al. [3], the mechanisms of action and effectiveness of interspinous distraction devices were investigated. They [3] report dynamic stabilization as a system that favorably alters the movement and load transmission of a spinal motion segment, without the intention of fusion of the segment. In other words, such a system would restrict motion in the direction or plane that produces pain, or painful motion, but would otherwise allow a full ROM. The authors of that study report that, despite some variation in their proposed indications, interspinous implants share the mechanism of limiting extension of the lumbar spine and, as a result, appear to improve clinical symptoms [3].

Fig. 5. Mean changes in lumbar extension, flexion, and range of motion (ROM) from the initial pre-implant condition to those measurements obtained following the implantation of the interspinous device and with the addition of the tension band. Error bars represent the standard deviations of the mean. The *asterisk* denotes a significant difference ($P < 0.05$)
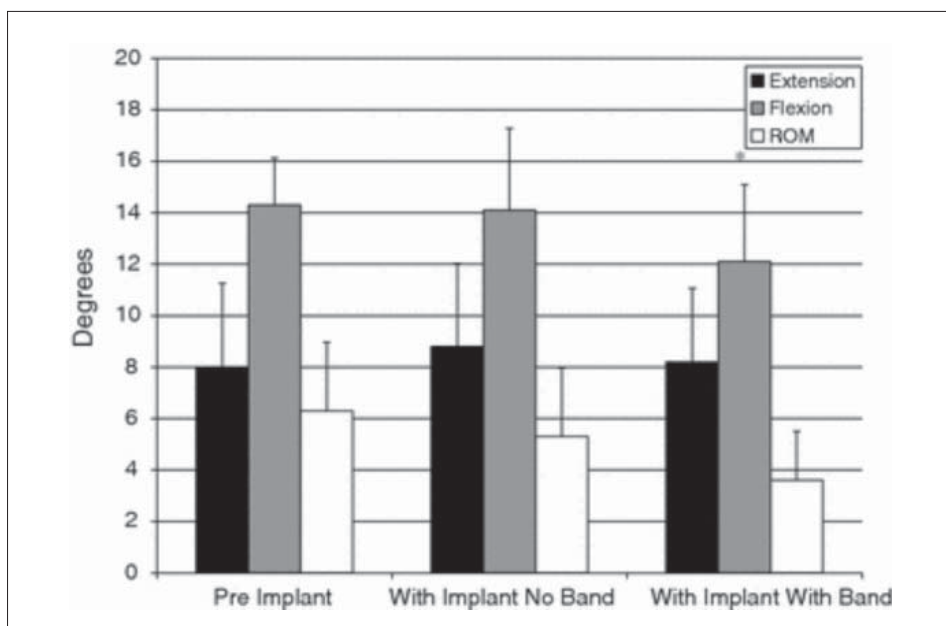

Fig. 6. Schematic diagram of the computer-controlled mechanical testing apparatus positioned over the ovine L3 spinous process of the prone-lying sheep. The apparatus consisted of an actuator assembly comprised a voice coil actuator, linear variable differential transformer, load cell, and stainless steel indenter. The actuator assembly was attached to a stainless steel and aluminum load frame that was rigidly mounted to the stainless steel operating table. Wood and foam supports were used to position and stabilize the sheep trunk and abdomen during the application of dorso-ventral forces
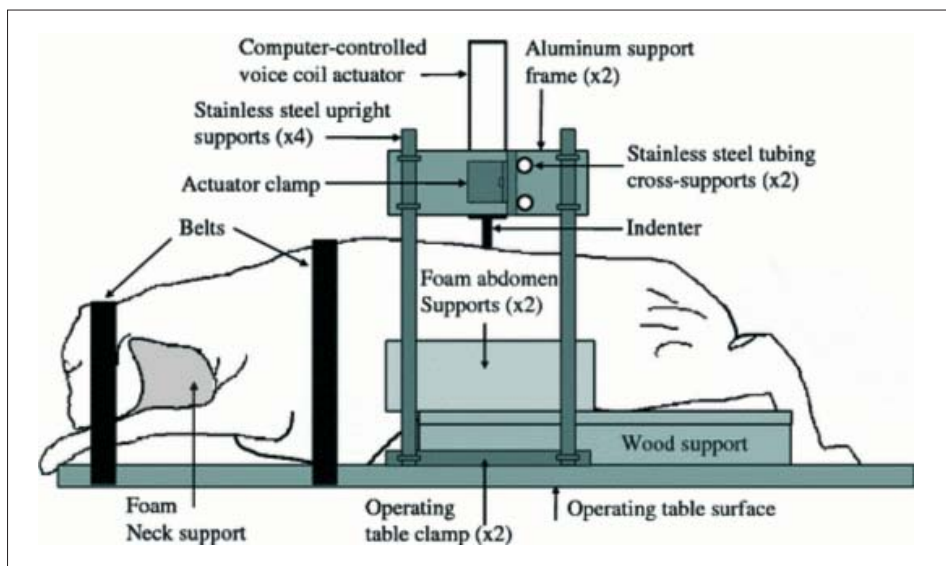
Degenerative spondylolisthesis however, often causes segmental instability leading to segmental spinal stenosis resulting from the anterior slip of the cephalad vertebra. In the current study, an appreciable linear decrease in intersegmental ROM was observed following the introduction of the InSwing® interspinous device, which was further accentuated with the addition of the tension band. These findings therefore promote the indication for the use of such implants to increase spinal stability; at least in the sagittal plane. Indeed, we believe that the observed reduction of flexion in this study corresponds with a decrease of anterior slippage in degenerative spondylolisthesis. To which extent a 15% limitation of flexion as observed in the current study would equate to a similar reduction in the human cannot be ascertained from these data. Further in vivo in human studies will assist in understanding the clinical utility of the InSwing®.

In related work, Kim et al. [17] researched the effects of the DIAM, by looking at disc height, 1 year after surgery. The study did not however include an evaluation of the kinematic stabilization effects of the implant. Phillips et al. [27] performed an in vitro study similar to the current study using the DIAM. In their work, these researchers investigated changes in motion of the lumbar spine with the DIAM device, after partial facetectomy and discectomy, in flexion–extension, lateral bending, and axial rotation. Their specimens were tested under the following conditions: (1) intact; (2) after unilateral hemifacetectomy at L4–L5; (3) #2 and discectomy; and (4) #3 with DIAM. Angular motion values at the operated and adjacent segments were assessed. Their findings suggest that insertion of the DIAM device after discectomy restored the angular motion to below the level of the intact segment in flexion–extension [27]. The authors concluded that the DIAM device is effective in stabiliz-ing the unstable segment, reducing the increased segmental flexion–extension, and lateral bending motions observed after discectomy. Their study did not investigate the use of the implant with or without the tension band, nor did it give any indication as to the amount of tension applied on the band.

The interspinous device investigated tended to reduce the total sagittal ROM at the level of the implant, however the results were not significant. The addition of a tension band was found to significantly stabilize the spine in flexion. To our knowledge, this is the first in vivo study radiographically showing the advantage of using an interspinous device (InSwing®), to stabilize the spine in flexion. These results are particularly important in light of the non-fusion devices currently proposed for patients with clinical symptoms of instable degenerative spondylolisthesis.

Results of a prospective study at one year showed marked clinical improvement as measured by ODI and VAS as well as increase of the foramen surfaces (40). After two years follow-up In this group of 34 patients with lumbar stenosis and claudication VAS decreased from 6.4 to 2.6 and ODI from 52 to 38. In addition foramen surfaces increased by an average of 16 % .

CONCLUSIONS

Interspinous implants represent a logical treatment for spinal stenosis and , indeed, there is acceptable evidence to support that indication. There are many products on the market but we feel that a unilateral approach and total preservation of the supraspinous ligament are paramount characteristics. The latter ligament plays a non negligible role in the stability of the spine in flexion.

Care must be taken not to extend the indications without further evidence to avoid too a wide use which will result in inevitable failures.

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