



Different Interspinous Stabilization Systems: Market Evaluation

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Introduction

The interspinous spacers are those devices that placed between the spinous processes of contiguous vertebrae, act by dynamically stabilizing the vertebral segment in the sagittal plane. The principle of implanting a spacer between adjacent spinous processes was used by F. Knowles in the 1950s to discharge the posterior ring in patients with herniated discs and thus achieve pain relief [1,2]. Senegas et al. [3] who in 1986 designed a system of dynamic normalization stabilization (mechanical normalization system) to stiffen the degenerated lumbar segment operated, using an interspinous titanium block to limit the extension and a tension band (Dacron) around the spinous processes, to secure the implant and limit bending. This implant, which was designed as the first generation of the current Wallis, so that it restored more physiological mechanical conditions in the treated degenerate segment, could not only alleviate or prevent the pain related to instability but decrease the range of disc destruction at that level. It was also suggested that if the interspinous stabilization system preserved more mobility in the treated segment than a fusion would do, then the degenerative process at adjacent levels would progress more slowly [4,5].

Several devices of this type have entered the market in recent years. In addition to the Wallis, mentioned above, there is the Coflex designed by Jacques Samani in 1994 and retaken today as U device, the Diam, X-Stop, Lixus etc [6]. All of them try to decrease the extension movement. Biomechanical studies have shown that certainly the extension decreases with the placement of the spacer while the flexion, axial rotation and lateral inclination remain unchanged [7]. These implants, by distracting the interspinous space and limiting the extension, reduce the posterior pressure of the annulus fibrosis. of the disc, the narrowing of the spinal canal, the bulging of the yellow ligament, and theoretically expand the intervertebral foramen and discharge the facets join [8-10]. For all these reasons, these implants are used in degenerative disc disorders and Lumbar Canal stenosis [11,12].

In a multicentre study for the treatment of lumbar stenosis with the X-Stop interspinous device, which produced interspinous distraction and indirectly decompression, reported a 59% satisfaction in relation to 12% in patients who had not undergone surgery [13].

Senegas et al. [3], in a retrospective analysis on the results of the placement of the interspinous dynamic stabilization device designed

by them (first generation of the current Wallis), in 142 patients with degeneration of the lumbar segments reported an 80% permanence of the implant (14 years follow-up), without needing a new reoperation. They attributed the good results to the long-term protection of the degeneration of the adjacent segment by the preservation of the movement since it is in itself a procedure of extra-articular nature in which, except the interspinous ligament, the rest of the elements remain intact, it is a reversible surgery and the rest of the surgical variants remain open.

In the report of Reyes Sánchez et al. on the result of corneal ligamentoplasty in the treatment of lumbosacral instability, 95% improvement was reported, with a single case that was reoperated because there was no variation in low back pain with respect to the preoperative period and an instrumented arthrodesis was performed. Another case presented wound dehiscence and soft tissue infection, which they attributed to the poor preparation of the skin [14]. In biomechanical studies performed for the evaluation of the U interspinous spacer as a lumbar stabilizer, it was determined that the models representing microsurgical decompression (partial laminectomy combined with partial fascetectomy) to release the root presented a partial instability, whereas Models with total laminectomy completely destabilized the vertebral segment and therefore required rigid transpedicular instrumentation to restore stability. It was concluded that U, by influencing the control of movement in the plane of flexion-extension and axial rotation, offered a non-rigid fixation and had the ability to return the destabilized samples in which it was inserted at its normal range of motion [15].

In our prospective control trial, historic group + a new device in a cohort of 100 patients with degenerative Lumbar disc degeneration 50 underwent surgical treatment in which the U device was placed and 50 control individuals were treated with discectomy alone.

Patients underwent serial follow-up evaluations (clinical test). And radiographic assessment was used to determine outcome Up to ten years follow-up data were obtained in all patients.

Aim: Use the device in order to prevent or delay the clinical symptoms after discectomy: LAST step Lumbar Instability. With a follow-up of Two years 90 % vs. 60 % without evidence of any clinical or radiological instability. We have five years follow up for the new device at L5 S1 with good results so far (Figure 1).

Conclusion

Our study shows that the U new device was more effective than discectomy Group in the management of degenerative lumbar disc herniation regarding lumbar instability.

The best to use was at L4/ L5, at L5 / S1, depends on the Spinous Process of S1 Now with our device 90 % of the patients have implant the device Vs. Historic device; you can perform up to 3 levels. Improvement with U new device was statistically significant $p < 0.01$. To have real answers to know what happened after disc surgery and to avoid the next step: lumbar instability at the level of surgery. We are done 5 years follow up, with good results, but we think a long period of follow-up it will be necessary in order to know if it is useful or not.

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Figure 1: L5 S1 New device after 5 years follow-up.

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