Posterior dynamic stabilization of the lumbar spine with the Accuflex rod system as a stand-alone device: experience in 20 patients with 2-year follow-up

Alejandro Reyes-Sánchez · Barón Zárate-Kalfópulos ·
Isabel Ramírez-Mora · Luis Miguel Rosales-Olivarez ·
Armando Alpizar-Aguirre · Guadalupe Sánchez-Bringas

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Abstract Decompression surgery for lumbar spinal stenosis is a common procedure. After surgery, segmental instability sometimes occurs, therefore, different methods for restabilization have been developed. Dynamic stabilization systems have been designed to improve segmental stability. In this study, clinical results of patients with lumbar spinal stenosis that underwent decompression and stabilization with the Accuflex dynamic system are presented; clinical, radiographic, and magnetic resonance imaging (MRI) findings are fully described. Improvements in all clinical measurements, including visual analog scale for back and leg pain, Oswestry disability index, and SF-36 health status survey were noticed. At a 2-year follow-up, 22.22% of patients required hardware removal due to fatigue while in 83% of them no progression of disk degeneration was observed after implantation of the Accuflex system. Additionally, as demonstrated by the MRI images at follow up, three patients (16%) showed disk rehydration with one grade higher on the Pfirrmann classification. Although a relatively high hardware failure was observed (22.22%), the use of the dynamic stabilization

system Accuflex posterior to decompression procedures, showed clinical benefits and stopped the degenerative process in 83% the patients.

Keywords Dynamic spine stabilization · Spinal stenosis · Disk herniation · Disk regeneration · Dynamic rods

Introduction

Many different surgical treatments for degenerative lumbar spinal stenosis exist. Decompression surgery is one the most used therapies [6, 20, 26]. After decompression, segmental instability can occur; it could be caused either by degenerative segmental disease of the disk, joints and ligaments, or as a consequence of the surgical decompression itself [3, 15], therefore, different methods for restabilization have been developed. Spinal fusion is an accepted treatment for segmental instability, although it still presents major disadvantages and complications [7]. Accelerated adjacent segment degeneration, pseudarthrosis, spinal canal stenosis due to secondary facet joint arthrosis and hypertrophy, and donor-site morbidity associated with the harvesting of autologous bone grafts have been reported [2, 4, 10, 11, 22].

Dynamic stabilization (DS) systems have been designed to improve segmental stability. These methods reduce the loading across the intervertebral disk and posterior elements, which relieve pain, limit degeneration, and preserve motion [12, 13, 19]. DS does not harm the affected disk, and recently, it has been shown that it slows down degeneration by providing a favorable environment for disk regeneration [1, 8].

The Accuflex system (Globus Medical, Inc) includes a dynamic rod and 6.5-mm pedicle screws made of titanium

A. Reyes-Sánchez
Division of Special Surgery, Instituto Nacional de
Rehabilitación, Mexico Distrito Federal, Mexico

B. Zárate-Kalfópulos (✉) · L. M. Rosales-Olivarez ·
A. Alpizar-Aguirre · G. Sánchez-Bringas
Department of Spinal Surgery, Instituto Nacional de
Rehabilitación, Calzada México Xochimilco No. 289,
Colonia Arenal de Guadalupe, Delegación Tlalpan,
C.P. 14389 Mexico Distrito Federal, Mexico
e-mail: bzarate@inr.gob.mx; baronzk@hotmail.com

I. Ramírez-Mora
Magnetic Resonance Department, Instituto Nacional de
Rehabilitación, Mexico Distrito Federal, Mexico

alloy. The rod has double helical cuts that create flexibility, transforming a rigid rod into a dynamic one allowing motion primarily in the flexion–extension mode. The amount of flexibility depends on the number of circumferential cuts made within the specified length of the rod: the more spiral cuts there are, the more flexible the rod is. The technique for Accuflex implantation is nearly identical to that used for the standard pedicle screw/rod construct, although a more precise positioning of the rod between the pedicle screws is needed [12].

The purpose of the study is to report the clinical outcome, radiological, magnetic resonance imaging (MRI) findings, and complications in a series of patients with lumbar spinal stenosis and dysfunctional segment motion (DSM) that underwent lumbar spine instrumentation with the Accuflex rod after microsurgical decompression. Though a high hardware failure was observed, stabilization of the affected segments was accomplished for most patients. MRI and X rays images in successful implants showed a decrease in segment degeneration after 2 years.

Materials and methods

Study design

In a prospective study, clinical and radiologic data of patients treated with microsurgical decompression and stabilization with the Accuflex dynamic rod device. This study includes a consecutive series of 20 patients with a diagnosis of lumbar stenosis and DSM; they were treated in our Institution with the same assessment and surgical protocol during a 2-year period. DSM is defined as a type of instability related to disk interspace or vertebral body degenerative changes that result in pain of spinal origin, usually worsened by activity and improved by inactivity [27].

The preoperative evaluation included standard anterior-posterior, lateral and lateral flexion–extension radiographic views of the lumbar spine, electromyography, and MRI. Patients with moderate or high-grade isthmic spondylolisthesis (Meyerding grade II–IV) were excluded as candidates for implantations of Accuflex rod.

Clinical and radiological examinations

The patients were assessed in the outpatient clinic preoperative and at 24 months after surgery. Clinical evaluation was performed by one author (BZK). The protocol consisted in a clinical examination, pain evaluation visual analog scale (VAS) for leg and back, scoring according to Oswestry disability index, and SF-36 as a general health status survey. Radiologic follow-up was assessed after

2 years with standard plain anterior-posterior, lateral and lateral flexion–extension radiographic views of the lumbar spine.

Surgical technique and implant design

The surgical protocol was based on the standard midline dorsal approach and a microsurgical decompression of the nerve roots involved was performed as well. If necessary, the decompression was completed with microsurgical discectomy. Under imaging control, the pedicle screws were positioned and the Accuflex rod was secured in the screws (a 540° helix cut Accuflex rod was used). Patients were mobilized the day after surgery without bracing and no limitations for daily activities were imposed.

MRI protocol

In order to document degenerative changes on the intervertebral disk and vertebral platforms, postoperative MRI was taken after 2 years and compared with the preoperative one. MRI was performed using a 1.5 T MR (Signa Excite HD; GE Medical Systems, Milwaukee, WI, USA) before surgery and at 24-month follow-up. The imaging protocol for all examinations consisted of sagittal and transverse T1- and T2-weighted fast spin-echo sequences.

Qualitative image analysis

Disk degeneration was graded on T2-weighted sagittal and axial images by using the five-point scale according to the method of Pfirrmann [17]. Endplates and adjacent bone marrow changes were graded according to the Modic system [14].

Statistics

Descriptive and frequency analyses were used to describe the baseline patient characteristics and categorical outcomes: relationships between categorical variables were examined using contingency tables with χ^2 /Fisher exact test, The Mann–Whitney *U* test was used to examine differences between two main outcome groups. The level of significance was set at $P < 0.05$.

Results

A total of 20 consecutive patients were included in this study. One patient was lost at 18-month follow-up and another become pregnant during the study; these two patients were excluded from the data analysis. The results are then based on the analysis of 18 patients (women

14, men 4) before and after surgery. The mean age was 44.05 years (range 24–60). Comorbidity was found in three patients, one (5.60%) has diabetes mellitus type 2 and two patients (11.1%) were documented as smokers.

Preoperative diagnosis was lumbar spinal stenosis and DSM at L4–L5 in 15 patients (83.3%), at L5–S1 in two patients (16.7%). The mean duration of surgery was 130 min (range 118–180), with an average blood loss of 200 ml (range 150–300). Intraoperatively, one patient had a dural tear which was closed with a primary suture and fibrin glue.

VAS for back pain improved from 7.9 (range 6–10) to 2.8 (range 1–8) at 24 months. Improvements were noticed on VAS for right and leg pain from 3.6 (range 0–9) to 1.11 (range 0–7) and from 4.7 (range 0–9) to 0.83 (range 0–4) at 24 months, respectively. The Oswestry score improved significantly from preoperative to 24 months from 55 (range 34–80%) to 24% (range 4–52%).

There was a significant improvement in almost all areas in the SF-36 health survey, except for those regarding general mental health and vitality, energy or fatigue (Table 1).

After 2-years of follow-up, four patients (22.22%) required removal of the dynamic system due to fatigue. One of them had rupture of the flexible rod, a different one a rupture at the two caudal transpedicular screws, and the remaining two had rupture of one caudal pedicle screw. In one patient, screw misplacement was retrospectively documented, and with the other three, material was placed in an appropriate manner. In three of these four patients with hardware failure, we found further degeneration of the intervertebral disk by one grade on the Pfirmann classification as observed on the 24-month MRI. Besides the hardware removal none of these patients required additional lumbar spinal surgery (Fig. 1).

Presence of motion was observed at 2-year follow-up from dynamic (flexion–extension) X rays. Based on the images, we found an average of 4.2° for the dynamic

Fig. 1 Two types of Hardware Failure were seen. Rupture of the flexible rod and rupture of pedicle screws. **a** Rupture of the flexible rod, **b** rupture of one caudal pedicle screw

angulation (range 0° – 10°) by manual measurements. The intersomatic space was measured in standard lateral X rays with a height of 11.11 mm on average (range 17–12 mm).

In preoperative MRI, 9 patients had grade II degeneration and another 9 grade III, at 24-month follow-up 11 patients had grade II, 5 patients grade III and 2 patients grade IV. This means that 12 patients (66.66%) had not changes at follow-up (an MRI example from this group is shown in Fig. 2). Three patients (16.66%) showed less degeneration by one grade (Fig. 3); and three patients (16.66%) showed more degeneration in one grade. These last three patients had rupture of the dynamic system and degeneration on Pfirmann classification.

Modic changes in the vertebral platforms remained the same in the preoperative MRI and during follow-up. We found no Modic changes in 14 patients, Type 1 Modic Changes in 3 patients, and type 3 Modic Changes in 1 patient.

Table 1 SF36 results

	Preoperative	24-month follow-up	P
Physical functioning	24.36	63.24	0.001
Role limitations	2.78	62.5	0.001
Bodily pain	30.69	64.86	0.0001
Social functioning	44.44	73.61	0.001
General mental health	56.67	58.22	1.0
Role limitations due to emotional problems	12.96	59.3	0.004
Vitality, energy or fatigue	46.11	57.50	0.002
General health perceptions	51.39	63	0.002
Health compared to last year	38.89	75	0.02

Fig. 2 Clinical studies of a 46-year-old female with lumbar spinal stenosis at L4-L5. **a, b** Preoperative MRI sagittal and axial cuts. **c, d** 24-month follow-up, MRI demonstrates no progression of the degenerative process

Discussion

Stability of the motion segment after decompression is a major clinical concern, fusion is considered to be the treatment of choice, however, and average 68% of patients have shown positive results with it [24]. Additionally, adjacent segment degeneration, pseudarthrosis, spinal canal stenosis, and donor-site morbidity associated with the harvesting of autologous bone grafts have been described [11, 22].

Dynamic stabilization systems seek to alter the mechanical loading of the motion segment by unloading the disk, with no loss of motion required by fusion surgery [16, 21]. Dynamic spine devices have not been widely used and there is little reporting about them on the medical literature. Results from several studies are contradictory in terms of clinical outcome, radiographic, implant failure and reoperation rates.

In this study, a high implant failure was observed (22%) using the Accuflex system. Other dynamic stabilization systems have shown high rates of revision surgery and hardware failure. For example, Würigler-Hauri et al. [27] in a prospective study evaluated 37 patients with lumbar

spinal stenosis treated with decompression and stabilization with Dynesys and 224 screws were implanted. At 12-month follow-up, there were four cases with broken screws, two misplaced, and two loosen systems. Of the 37 patients, seven (19%) required surgical revision.

Welch et al. [25] in a multicentric study reported 101 patients with lumbar spinal stenosis and degenerative spondylolisthesis with a 12-month follow-up. Fifteen of 101 patients required 18 reinterventions at the time of the 1-year follow-up evaluation, from these, 11% underwent 13 procedures related to the spine or the index surgery. Ten of the 18 reinterventions were revision surgeries performed at the same spinal level. Finally, three of these cases required removal of the stabilization system.

Grob et al. [5] in a retrospective study of 31 patients with a 2-year follow-up reported that 6 of 31 patients (19%) required further surgical intervention; 3 patients required revision surgery at the same spinal level with removal of the system. Stoll et al. [23] in a multicenter study of 83 patients, with a mean follow-up time of 38.1 months, reported one screw misplacement, 3 patients needed implant removal and conversion into spinal fusion with rigid instrumentation, screw removal due to loosening in

Fig. 3 MRI of a 42 years old female with lumbar stenosis at L4-L5. **a, b** Preoperative MRI in T2 sagittal and axial cut. **c, d** 24-month follow-up shows disk rehydration

one case, and 7 cases with radiological signs of screw loosening at follow-up.

Conversely, different studies have shown more positive results. For example, Bordes-Monmeneu et al. [1] in a series of 94 patients treated at a first level 66 patients and second level 27 patients, reported only two complications associated to pedicle screws: one misplacement, and one breakage. Schnake et al. [19] in a study of 19 patients with spinal stenosis and degenerative spondylolisthesis reported 3 screws in 3 patients with possible loosening and only one screw breakage after the 52-month follow up.

The Accuflex rod has undergone extensive biomechanical testing to prove its safety as a posterior stabilization construct. Testing has been performed in multiple modes including compression/tension, axial rotation, sagittal rotation, compression, and pure shear. The results of these tests have demonstrated that the rods can withstand the normal stress exerted on the lumbar spine with an adequate fatigue life (10 million stress movements without fracture) [12]. In this study, however, a high fatigue rate was observed (22.22%) with only one case of screw misplacement that could explain it. Challenges still exist regarding the long-term tolerance of dynamic implants, especially on the screw bone interface and the fatigability of the composite materials. Cyclical loading and unloading of the device as consequence of daily physical activity can cause screw loosening or implant break, on the other hand, these

devices need to work in harmony with the intact soft tissue supporting structures of the motion segment. Ideally, dynamic systems should be implanted with minimal damage to the muscular and ligamentous structures that participate in normal spinal motion. Dynamic stabilization presents some disadvantages such as higher risk of iatrogenic lesions attributable to the implantation of a transpedicular system, additional costs for the device, the revision surgery for hardware removal, and increased duration of surgery and hospital stay. More studies should be performed in order to determine if dynamic stabilization justifies all these difficulties instead of completing decompression alone.

In 83% of our patients, no progression of disk degeneration was seen after implantation of the Accuflex system. Additionally, as demonstrated by the MRI images at follow up, three patients (16%) showed rehydration with one grade higher on the Pfirrmann classification. This observation is an interesting feature of the dynamic stabilization systems: external devices may provide the right conditions for biological attempts of regeneration [8]. In theory, the easiest way to restore the height of the disk is distraction [8, 9]. In an in vivo study with New Zealand white rabbits, external load on the lumbar spine was applied to induce disk degeneration over 28 days. After compression of the disk, one subgroup of animals underwent dynamic distraction for 28 days and histological, radiological, and

biomechanical examinations were performed afterwards. The compression lead to a decrease of disk height, disorganization of the annulus architecture, and increased apoptosis of the annulus and cartilage endplate; these changes were reversible after distraction. Disk height increased and the number of apoptotic cells decreased, the authors concluded that axial dynamic distraction can induce disk regeneration in rabbit with moderate intervertebral disk degeneration [9]. Putzier et al. [18] in a clinical study of 84 patients that underwent nucleotomy of the lumbar spine as treatment for disk prolapse, performed dynamic stabilization with Dynesys in 35 patients with an average follow-up of 34 months. The examination included radiographs, MRI, physical examination, and subjective patient evaluation using Oswestry score and VAS. At the follow-up time, a significant increase in the Oswestry score and in the VAS for pain was observed on the nonstabilized group. The dynamic stabilized group showed no progression of disk degeneration, but accelerated segmental degeneration was observed in the solely nucleotomized group. There were not implant-associated complications. The study group concluded that dynamic stabilization system is useful to prevent progression on initial degenerative disease of lumbar spine segment after nucleotomy. In a different study, Bordes-Monmeneu et al. [1] showed in MRI at 9-month follow-up after implantation of Dynesys rehydration in 9 of 20 cases in his series.

In our study, we demonstrated that dynamic stabilization does not harm the disk and slows down degeneration. Furthermore, it may allow rehydration of the disk to some extent. At present, surgical implantation of dynamic stabilization devices is an invasive procedure, resulting in the disruption of the muscle and ligamentous structures [16]. Further prospective and randomized clinical trials are needed to prove that dynamic stabilization systems present advantages over traditional surgeries such as decompression alone or spinal fusion, especially better clinical outcomes and decrease of the reoperation rate. Standards need to set in order to determinate the amount of stabilization that a nonfusion construct should provide and the moment of the degenerative cascade when a dynamic system is going to be used. The knowledge and application of these two key factors will traduce in better clinical outcomes.

Conclusions

This study reports the results of implantation of Accuflex semirigid system after microsurgical lumbar decompression. High incidence of implant failure was observed.

The use of the dynamic stabilization system Accuflex posterior to decompression procedures, showed clinical

benefits and stopped the degenerative process in 83% the patients.

There is still insufficient evidence to suggest that dynamic stabilization results in better outcomes than does fusion or decompression alone in lumbar spinal stenosis.

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