

HYBRID CONSTRUCTIONS OF THE LUMBOSACRAL SPINE. PRELIMINARY WORK – 20 CASES

CONSTRUÇÕES HÍBRIDAS DA COLUNA VERTEBRAL LOMBOSSACRAL.
TRABALHO PRELIMINAR – 20 CASOS

CONSTRUCCIONES HÍBRIDAS DEL RAQUIS LUMBOSACRO.
TRABAJO PRELIMINAR – 20 CASOS

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ABSTRACT

Objective: To present the philosophy used, and demonstrate how and why we decided to protect the level adjacent to a bone union. **Methods:** In the selection criteria of 620 patients who had undergone surgery between January 2007 and August 2011 due to degenerative pathology, instability and stenosis of the lumbosacral canal, 30 patients were selected with Pfirmann grades 3 and 4, from which six were lost to follow-up and four refused surgery, leaving 20 patients who underwent surgery. The mean age of the patients was 46 years (range: 22 to 71), with 11 men (55%) and 9 women (45%). **Results:** The follow-up of the cases was 6 months to 2 years, and so far, no clinical or radiological worsening has been observed, or loosening of the instrumentation in any case. **Conclusions:** we understand that protection of the adjacent level through the use of semi-rigid rods in PEEK is a good alternative, as it is not necessary to approach the ligament or pedicles of the level adjacent to the fusion.

Keywords: Hybrid cells; Vertebral spine; Intervertebral disc degeneration.

RESUMO

Objetivo: Apresentar a filosofia utilizada e como e por que decidimos proteger o nível adjacente a uma fusão. **Métodos:** No critério de seleção de 620 pacientes operados entre janeiro de 2007 e agosto de 2011 devido a patologia degenerativa, instabilidade e estenose do canal lombossacral, foram escolhidos 30 pacientes com estágios 3 e 4 de Pfirmann, dos quais seis foram perdidos na consulta pós-operatória e quatro recusaram a cirurgia, restando 20 pacientes que foram submetidos à cirurgia. A idade média dos pacientes era 46 anos (faixa: 22 a 71), sendo 11 homens (55%) e 9 mulheres (45%). **Resultados:** O acompanhamento dos casos é de 6 meses a 2 anos e, até o momento, não se evidenciou piora clínica ou radiológica, nem afrouxamento da instrumentação em nenhum caso. **Conclusões:** Entendemos que a proteção do nível adjacente por meio do emprego de hastas semirrígidas em PEEK seria uma boa alternativa de proteção, devido ao fato de não ser necessário abordar o ligamento ou os pedículos do nível adjacente à fusão.

Descritores: Células híbridas; Coluna vertebral; Degeneração do disco intervertebral.

RESUMEN

Objetivo: Presentar la filosofía utilizada y como y por qué decidimos proteger el nivel adyacente a una fusión. **Métodos:** En el criterio de selección de 620 pacientes operados entre enero de 2007 y agosto de 2011 por patología degenerativa, inestabilidad y estenosis del conducto lumbosacro, se seleccionaron 30 pacientes con estadios de Pfirmann 3 y 4, de los cuales seis se perdieron en la consulta postoperatoria y cuatro rechazaron la terapéutica quirúrgica, quedando 20 pacientes que fueron intervenidos quirúrgicamente. La edad promedio de los pacientes fue de 46 años (rango: 22 a 71 años), siendo 11 hombres (55%) y 9 mujeres (45%). **Resultados:** El seguimiento de los casos es de 6 meses a 2 años y hasta el momento no se evidenció empeoramiento clínico radiológico, ni aflojamiento de la instrumentación en ningún caso. **Conclusiones:** Entendemos que la protección del nivel adyacente mediante el empleo de barras semirrígidas en PEEK sería una buena alternativa de protección debido a que no es necesario abordar el ligamento o los pedículos del nivel adyacente a la fusión.

Descriptores: Células híbridas; Columna vertebral; Degeneración del disco intervertebral.

INTRODUCTION

Advances in No fusion technology for the treatment of degenerative disc disease and associated pathologies have entered a new era in spinal surgery.

The new technologies bring different procedures to the traditional methods of fusion (discectomy and arthrodesis with instrumentation) that prevent the normal physiology of the functional unit of the spinal segment, altering the joint surfaces, and blocking two or more vertebrae to operate as a single unit. The techniques of No fusion seek to provide stability, while maintaining the mobility and function of the spine.¹

Traditional fusion methods for the treatment of symptomatic segment disc disease that include discectomy and fusion (with or without decompression) are considered the standard treatment for degenerative disc disease. However, this procedure creates various problems and disadvantages, including loss of spinal mobility and flexibility, permanent changes in movement and biomechanics, collapse of the graft with suboptimal sagittal balance, and pain at the graft site.

In addition, one of the prevalent concerns following fusion of one or more levels is load transfer to the adjacent level, requiring reoperations due to adjacent segment degeneration.

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The long-term results of fusion techniques show a 10-year reoperation rate of up to 27.5%. These results have raised concern over the post-fusion adjacent disc degeneration.² Many articles have reported that the disc and joint surface adjacent to the fusion, particularly at the cephalic level, undergo one or more of the following changes to their biomechanics: increased stress, increase in mobility or segmental displacement, and increased intradiscal pressure. All these factors, combined with the patient's age (50 years or over is the most important predictive factor), the length of the implant (the longer the implant the higher the likelihood of degeneration), location close to the cranio-spinal junction (higher likelihood of degeneration), sagittal balance and lower lordosis (leading to greater disc degeneration), greater rigidity of the implant and higher fusion mass (higher likelihood of degeneration of the adjacent intervertebral disc). The literature reports an increase in the rate of symptomatic degeneration, requiring surgery.

Gillet³ reports that of 37 patients with single-level fusion, 32% had adjacent segment degeneration and 11% required reoperation. In the same article, of 26 patients with two-level fusion, 31% presented degenerative changes and 27% required reoperation. However, when 27 patients with three- or four-level fusions were considered, 66% had degeneration of the adjacent segment, and 33% required reoperation.

The authors conclude that there is a need to find more reconstructive surgical procedures for the management of symptomatic degenerative spine that is resistant to conservative treatment. With regard to the transition segment predisposed to degeneration, Gillet also mentions that a possible solution for treating the entity is to perform some kind of "preventive reinforcement" of the adjacent level.

The change of thinking in the development of fusion implants is based on instrumentation designs that decompress the spinal segment and allow controlled movement of the functional spinal unit, while at the same time, freeing and protecting it from excessive forces of movement.

We are now in an era of dynamic spinal instrumentation.

MATERIAL AND METHODS

According to the inclusion criteria, 620 operated patients were selected between January 2007 and August 2011 for degenerative pathology, instability and stenosis of the lumbosacral canal. Of the total 30 patients were selected with Pfirrmann grades 3 and 4; six were lost in the postoperative consultation and four refused to undergo surgery, leaving 20 patients, who were surgically treated by the same team in charge of surgical pathology of the spine at the Hospital Militar Central de Buenos Aires, Sistema de Obra Sociales, and a private practice. The average age was 46 years (range 22 to 71 years). Males 11-(55%) and females 9-(45%).

The patients underwent instrumented arthrodesis of the lumbosacral spine, with protection of the segment adjacent to the fusion. The pool of 20 patients was divided into four groups of five patients each.

All the patients had degenerative disc disease, or spondylolisthesis of isthmic and/or degenerative origin.

According to the inclusion criteria, nuclear magnetic resonance imaging was used to determine the level of degeneration of the intervertebral disc, and a score was assigned, as described by Pfirrmann et al.,⁴ with preventive surgery being indicated for Pfirrmann grades 3 and 4, without radiological signs of instability. Surgery was contraindicated for Pfirrmann grade 5 injuries.

This technique, known as "topping off" the fusion, involves a combination of a rigid system and a flexible system attached to the adjacent segment. Another alternative is to perform the fusion by adding a proximal interspinous spacer.⁵

The goal is to maintain or restore the intervertebral movement in a controlled manner, either by restricting movement of the ends or by decreasing the kinetic energy involved in movement. The aim of this technique is to decrease stress above or below the lumbar fusions.^{6,7}

To protect the adjacent level, the first group received a DIAM[®]

silicone interspinous device with polyester bands'. In the second group, a lateral-insertion interspinous spacer was used, with supra- and interspinous ligament preservation without a polyester band, using a Winglock[®] spacer; in the third group a system of dynamic bars was used with B-DYN[®] pedicle screws. In the fourth group, a system of Polyetheretherketone (PEEK) Optima[®] semi-rigid rods of 5.5 mm in diameter was used.

Surgical Material

Due to the fact that different devices were used, with different characteristics, each presenting different implantation techniques and biomechanics, we divided the series into four groups.

Group 1

In all five cases, a vertebral fixation system was used, with Coligne Advance[®] pedicle screws. This system has the following characteristics:

- Self-tapping, tapered screws.
- Shank diameter: 4.2; 5; 6 and 7 mm.
- Shank length: 35; 40; 45 and 50 mm.

Modalities: monoaxial and polyaxial. For the indications of fusion, the classic criteria of Rothman-Simeone were followed.

For protection of the adjacent level, the a DIAM[®] device for intervertebral assisted motion was used, which consists of a silicone core with measurements of 8mm to 14mm and polyester bands for the ligamentoplasty. These are inserted into the interspinous adjacent spaces. The purpose of its biomechanical design is to control the movement of flexion and extension in the implanted segment.^{8,9}

Group 2

In all five cases, a vertebral fixation system was used, with Coligne Precisión[®] pedicle screws. This system has the following characteristics:

- Self-tapping, tapered screws.
- Shank diameter: 4.2; 5; 6 and 7 mm.
- Shank length: 35; 40; 45 and 50 mm.

Modalities: monoaxial and polyaxial.

In this group, a WINGLOCK[®] interspinous spacer device was used to protect the adjacent level. Its design is based on a system of locked titanium wings with a threaded PEEK core. Available sizes range from 8mm to 14mm and it is inserted laterally, using a minimally invasive approach, to preserve the supra and interspinous ligament. The device comes with two polyester bands, which can be used to perform ligamentoplasty if desired. In our case series, we did not place the bands. The purpose of the biomechanical design of this system is spacing of the vertebral segment with locking of its extension.¹⁰⁻¹²

Group 3

In all five cases, a vertebral fixation system was used, with Coligne Infinity[®] pedicle screws. This system has the following characteristics:

- Self-tapping, tapered screws.
- Shank diameter: 4.2; 5; 6 and 7 mm.
- Shank length: 35; 40; 45 and 50 mm.

Modalities: monoaxial and polyaxial.

In this group, a system of dynamic bars with B-DYN[®] pedicle screws was used to protect the adjacent level. The characteristics of this system are: titanium material, rod diameter 5.5 mm, with the characteristic that it has a rod fixed with a drum with a core of silicone that absorbs the impact of this device, which is attached to a movable bar with a bioelastic ring inside it. The purpose of the biomechanical design of this system is to control the movement of the implanted segment using 1 mm traction control, 2 mm compression, flexion and extension, providing polyaxiality of 14 degrees.¹³

Group 4

In all five cases, a vertebral fixation system was used, with titanium pedicle screws. This system has the following characteristics:

- Self-tapping, tapered screws.
- Shank diameter: 4.2 ; 5; 6 and 7 mm.
- Shank length: 35, 40, 45 and 50 mm.
- Modalities: monoaxial and polyaxial.

The characteristic of this system is the fact that the locking buttons are flat, and they are definitively locked with 6 pounds of torque.

In this group, semi-rigid PEEK Optima® rods of 5.5 mm in diameter were used.¹⁴

To reduce potential complications, correct selection of the patient is necessary, in terms of: (a) weight; (b) age; (c) activity; (d) mental disorders; (e) alcoholism; (f) drug addiction; (g) sensitivity to metals.

Preoperative planning: to determine the diameter and the length of the screws to be used, spinal radiographies were performed in the front and profile positions, and MRI without contrast; in some cases (birth defects), a CT scan was requested.

Intraoperative planning: patients were operated on in the genu-pectoral (knee-chest) position with knees and hips flexed at 110° and 90°, respectively. Identification of the level and calculation of the pedicle angle under intraoperative radioscopy. Posteromedial route and pedicle entry point according to the technique of Roy-Camille, with resection of the lower joint in the L5-S1 space. The entry orifice is made with a square tip, preparation of the pedicle with initiator, palpation of the five walls, radioscopy control, and insertion of drill and screws.

RESULTS

From January 2007 to January 2011, 20 patients were operated on, with an average age of 46 years (range 22 to 71 years). Males 11 (55%) and females nine (45%).

In terms of etiology, of the 20 patients, six (30%) cases had degenerative disc disease associated with stenosis of the lumbosacral canal; there was one (5%) case of pure degenerative disc; two (10%) cases of degenerative disc disease associated with degenerative spondylolisthesis; four (20%) cases of degenerative spondylolisthesis type three in the Wiltse (1969) classification and grade one in the Meyerding classification; six (30%) cases of isthmic spondylolisthesis Wiltse type two, of which five were grade 1 and one grade 2 in the Meyerding classification; and one (5%) case of stenosis of the lumbar canal associated with degenerative adjacent syndrome.

The levels at which the protection was performed were three cases L2L3 (15%) (1 DIAM/1 winglock/1 B-Dyn), seven at level L3L4 (35%) (1 DIAM/2 winglock /1 B-Dyn/3 bars PEEK), ten at level L4L5 (50%) (3 DIAM/2 winglock/3 B-Dyn/2 bars PEEK, and one case at level L5S1 (5%) (1 winglock).

Of the 20 cases, eight (40%) underwent 360 degrees arthrodesis

using intersomatic fusion with the transformational technique, and the 12 (60%) remaining cases underwent posterolateral fusion. Autologous graft was used in all cases.

In relation to the degree of degeneration of the disc to be protected, there were eight cases (40%) of Pfirrmann grade 3 and 12 cases (60%) of Pfirrmann grade 4.

In relation to surgical complications, there was one case (5%) of error committed in the insertion of the device - case six. (Table 1)

The follow-up of the cases is from 5 years to 2 years, until no worsening is seen in the clinical symptoms/radiology, or loosening of the device in any case.

DISCUSSION

Based on the description of the concept of dynamic stabilization of the lumbar spine given by Senegas¹⁵ for the development of the Dynesys® dynamic system for neutralizing mobility of the lumbar spine, described by Dubois,¹⁶ more of these devices have been developed than never before in the history of spinal surgery, and the development of new hybrid systems have opened up the possibility that these could reduce deterioration of the disc adjacent to a fusion surgery. To date, there is no scientific or convincing evidence, in the literature, of the long-term effectiveness or safety of these covering systems. It is necessary to evaluate the advantages and disadvantages of implementing these new techniques, and various types of flexible pedicle screw systems have been developed (e.g. Surgicraft Graf ligament, Bioflex System, Medtronic Peek rods and Depuy Spine (approved by the US FDA), Isobar AccuFlex™®, and coverage systems (e.g. DTO™, DSS™, CosmicMIA™, Viper). It has been reported that they provide dynamic stabilization, along with a consequent reduction of degeneration in the adjacent segment.^{17,18} Maserati *et al.*¹⁹ conducted a retrospective analysis of a population, and concluded that it was a promising alternative for multilevel fusion, with the potential to prevent degeneration of the adjacent disc. However, in a recently-published prospective, randomized clinical trial involving 60 patients, which compared fusion using a hybrid system device fusion device with conventional fusion, after more than 6 years of follow-up, clinical outcomes did not differ between the groups (ODI, VAS). Although the hybrid fusion showed less progression of degeneration in the adjacent segment, there was a higher rate of implant failure. This study group does not recommend prophylactic dynamic stabilization.²⁰ In general, to date, there is no convincing evidence that these systems provide any clinical benefit whatsoever. It is still unclear whether the radiologically-visible adjacent degeneration is important for the clinical outcome. Fusion of the spinal segments leads to higher forces that act on the adjacent levels and can result in adjacent segment deterioration (ASD).

Table 1. Overview of data.

Case	Date of Cx	Age and Sex	Dx	Tto	Implant for protection	TLIF	Pfirrmann Grade
1	04-11-07	36F	Isthmic Spondylolisthesis L5 G1	Fusion L5S1	DIAM L4L5	YES	4
2	04-22-07	42F	Isthmic Spondylolisthesis L5 G1	Fusion L5S1	DIAM L4L5	NO	3
3	05-15-07	56M	LCS*+Degenerative Listhesis L4L5	Fusion L4L5	DIAM L3L4	YES	4
4	07-18-07	65M	LCS L3-S1	Fusion L3-S1	DIAM L2L3	NO	4
5	09-25-07	57F	Degenerative Spondylolisthesis +LCS L5S1	Fusion L5S1	DIAM L4L5	NO	3
6	11-24-09	68M	LCS L3-S1	Fusion L4-S1	WL L3L4	NO	3
7	07-13-10	22M	Isthmic Spondylolisthesis L5 G1 L5S1	Fusion L5S1	WL L4L5	YES	3
8	05-11-10	51F	Degenerative Discopathy L5S1	Fusion L5S1	WL L4L5	YES	3
9	05-18-10	59F	ASD + LCS L2-S1	Cx Revision + Fusion L3-L5	WL L2L3 and L5S1	YES	4
10	06-20-10	57M	LCS L4L5	Fusion L4L5	WL L3L4	YES	4
11	03-10-11	33F	Isthmic Spondylolisthesis L5G1	Fusion L5S1	B-DYN L4L5	YES	3
12	05-02-11	42M	Isthmic Spondylolisthesis L5 G2	Fusion L5S1	B-DYN L4L5	YES	3
13	05-20-11	59M	Segmental Instability + LCS L3-S1	Fusion L4-S1	B-DYN L3L4	NO	3
14	06-07-11	52M	LCS L2-L5	Fusion L3L4L5	B-DYN L2L3	NO	4
15	06-25-11	62M	LCS L5S1	Fusion L5S1	B-DYN L4L5	NO	4
16	03-27-11	36M	LCS L5S1	Fusion L5S1	PEEK Bar L5S1	NO	4
17	04-06-11	71F	Degenerative Spondylolisthesis	Fusion L4L5	PEEK Bar L5S5	NO	4
18	06-08-11	68M	Degenerative Spondylolisthesis	Fusion L4L5	PEEK Bar I4I5	NO	4
19	07-07-11	65F	Degenerative Spondylolisthesis	Fusion L4L5	PEEK Bar L4L5	NO	4
20	08-13-11	29F	Isthmic Spondylolisthesis L5 G1	Fusion L5S1	PEEK Bar L5S1	NO	4

Adjacent instability is reported even 12 months after surgery.²¹ The average rates vary. In a retrospective study, Cheh *et al.*²² identified radiography with ASD in 42.6 % of patients (mean follow 7.8 years). Clinical ASD was found in 43%. Other authors have reported incidence of ASD of up to 24% (30-month mean follow-up). In this study, instability occurred with greater frequency above the fusion. Yang *et al.*²³ found a significant correlation between the clinical outcomes and ASD. In a one-year study by comparing the follow-up of 30 patients undergoing various spinal procedures (fusion, discectomy, decompression), Kumar *et al.*²⁴ found that the incidence of radiographic changes in levels above the operated region were twice as high after fusion as after other procedures. In contrast, validated scales and functional tests (for example, SF-36) showed no significant differences in the result. The author concludes that radiographic changes do not necessarily lead to functional deterioration in all patients, following fusion of the lumbar spine for degenerative disc disease. There is other evidence to suggest that radiological degeneration of the upper adjacent segment is not correlated with clinical outcomes.²⁵ In a follow-up of 215 patients submitted to arthrodesis of lumbar spine, Ghiselli *et al.*²⁶ report a rate of adjacent segment deterioration of 16.5% after 5 years. This rate increased to 30.1% after ten years of follow-up. However, a previous review suggests that there may be a correlation between fusion and development of adjacent segment degeneration in comparison with arthroplasty.

This correlation appears to be even stronger when we observe the adjacent segment disease, thus emphasizing the impact of fusion procedures on adjacent segments.²⁷

This is a preliminary work, to which new cases will be added, and a fifth control group that did not receive a mobile topping off of the adjacent segment.

CONCLUSIONS

The short-term results appear to be encouraging for hybrid systems of dynamic stabilization with pedicle screws, and semi-rigid rods are in their early stage and it is clear that long-term clinical studies are required to analyze its efficiency in relation to traditional fusion procedures.

Although all the devices studied differ in their concept and design, their biomechanical functions at the adjacent level are similar, therefore we understand that protection for the adjacent level through the use of semi-rigid PEEK rods would be a good alternative for protection due to the fact that it is not necessary to address the ligament or the pedicles of the adjacent level of the fusion.

All authors declare no potential conflict of interest concerning this article.

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