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The LP-ESP Lumbar Disc Prosthesis: Concept, Development and Clinical Experience

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1. Introduction

Because of its impairment of patients' personal, social, and professional lives, degenerative disk disease has become an important public health problem with multiple dimensions. The current therapeutic strategy remains controversial and is also a medical and surgical challenge. Conservative treatment, based mostly based on physical therapy, constitutes the first-line approach, but persistent symptomatic disease may be treated surgically in selected patients [1-4]. Lack of pain relief, stiffening of the lumbar spine, non-union, sagittal balance misalignment, bone graft donor site morbidity, and, last but not least, adjacent segment disease are the pitfalls of intervertebral fusion that led to the idea of total disk replacement (TDR) [5-12]. Since 1966 and Fernström's first TDR implantation [13], many designs and concepts have been proposed [14-23]. The devices are usually articulated implants, and their mobility depends on the designs of the bearing surfaces. Ball-and-socket two-piece prostheses have 3 degrees of freedom in every rotation around a single fixed center of rotation. Three-piece devices allow additional translation components, providing 5 degrees of freedom. Articulated TDRs have demonstrated their clinical utility in several patient series. Specifically, the non-inferiority of TDR versus fusion is now generally accepted [18-20, 24]. However, in vitro testing of the two types of implants reveals that both designs have biomechanical advantages and limitations.

Because the healthy human intervertebral disk has a deformable elastic structure with 6 degrees of freedom, elastomeric one-piece intervertebral prostheses might be the most physiological implant for mimicking physiologic levels of shock absorption and flexural stiffness. Designing such a device is challenging, especially when we remember the Acroflex® prostheses: the elastic rubber failed so rapidly in vivo that only 28 were implanted in all [25-26].

The LP-ESP® (lumbar disk prosthesis-elastic spine pad) was developed over a 20-year period. Improvements in technology have made it possible to solve the problem of the bond between the elastic component and the titanium endplates. After successful in vitro and in vivo evaluation, the LP-ESP has been authorized for clinical use in Europe since 2005. The goal of this paper is to present its innovative concept and the clinical results and radiological outcomes over its 7 years of use. In addition to measuring range of motion, we were specifically interested in the quality of the kinematics and thus investigated the mean center of rotation at both the instrumented and adjacent levels. Changes in spinal posture were also a major point of the study.

2. Implant design

The design of the LP ESP® prosthesis is based on the principle of the silent block bush (Figure 1). The LP-ESP® is a one-piece deformable implant including a central core made of silicone gel with microvoids and surrounded by polycarbonate urethane (PCU) securely fixed to titanium endplates. The endplates have five anchoring pegs to provide primary fixation and are covered by a textured T 40 titanium layer (60 µm thick) and hydroxyapatite to improve bone ingrowth (Figure 2).

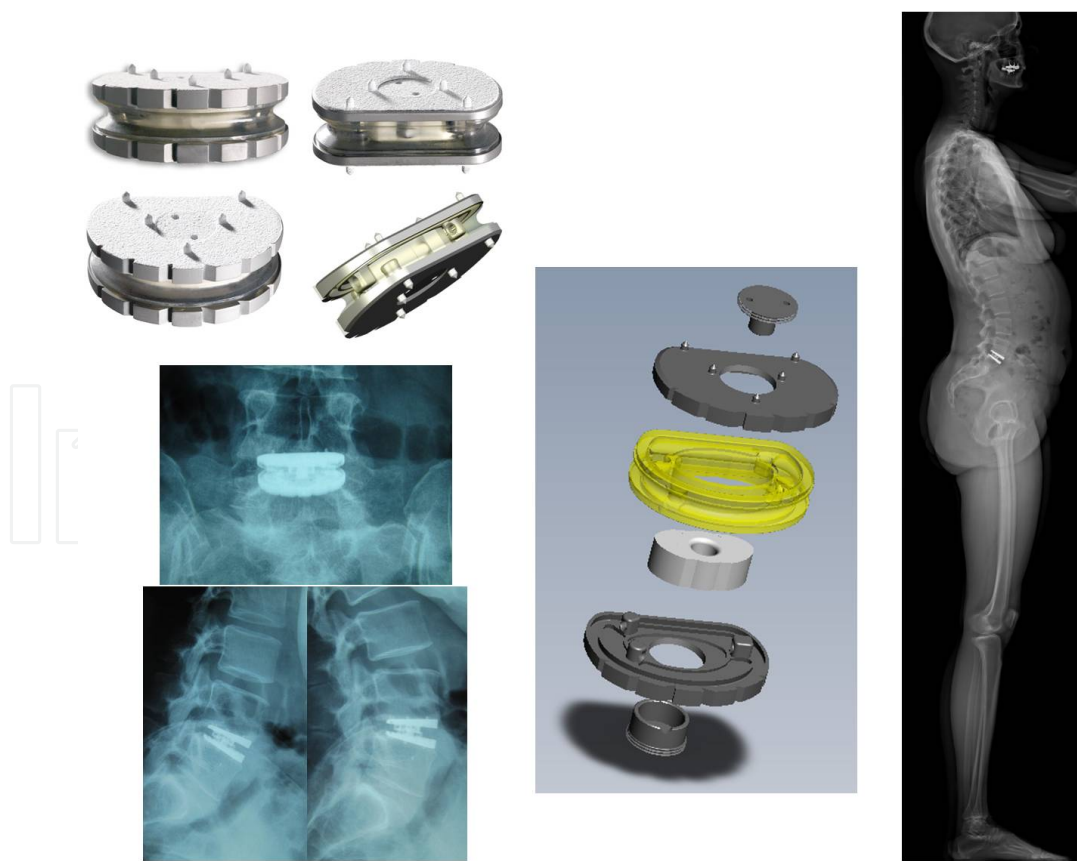


Figure 1. The design of the LP ESP® prosthesis is based on the principle of the silent block bush

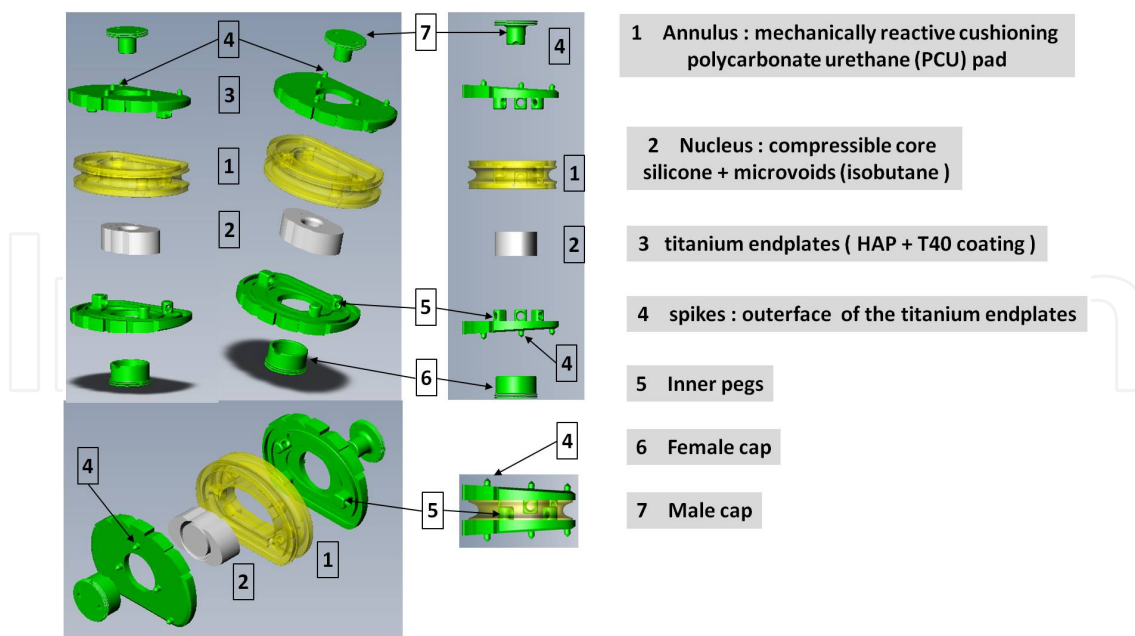


Figure 2. The LP-ESP[®] is a one-piece deformable implant including a central core made of silicone gel with microvoids and surrounded by polycarbonate urethane (PCU) securely fixed to titanium endplates.

Depending on the size, the titanium endplates differ in thickness and angulation. The prostheses are available in two thicknesses (10 and 12 mm), each with 3 angles of lordosis (7°, 9°, and 11°). Regardless of the model, however, the mechanically active cushion and the mechanical properties of the prosthesis are the same: The differences in thickness of the lordotic angle do not affect the prosthesis's mobility or its cushioning, even shock-absorbing, effect.

Accordingly, the peripheral cushion (that is, the annulus) is securely fixed to the titanium alloy endplates by adhesion-molding technology. This attachment is reinforced by a peripheral groove without the addition of glue. This process of fixation avoids fluid infiltration and the risk of fatigue fractures of the interface, despite the very different mechanical properties of the polymer and the metal endplates. The PCU annulus is stabilized by supplementary pegs located on the internal surface of both metal endplates. The geometry and position of the pegs, between the peripheral groove and the central area of the endplates, were planned to control rotational mobility (Figures 3 and 4). The polymer molding was designed to prevent all direct contact between the upper and lower pegs.

The core or nucleus is composed of a compressible silicone structure containing isobutane microbubbles. This core is injected after the annulus surrounding it has been molded. Two titanium caps allow the core to be contained at the moment of the injection. These two pieces are firmly secured to the titanium plates: they also play a mechanical role by their contactless fit, because they contribute to limiting shearing during antero-posterior and medio-lateral translation. The cushioning and compressing effects are obtained on the one hand by the contactless interlocking of the male and female caps and, on the other hand, by crushing the annulus between the two metal plates. The same components limit the shearing effect when the endplates are inclined to the horizontal (Figure 5).

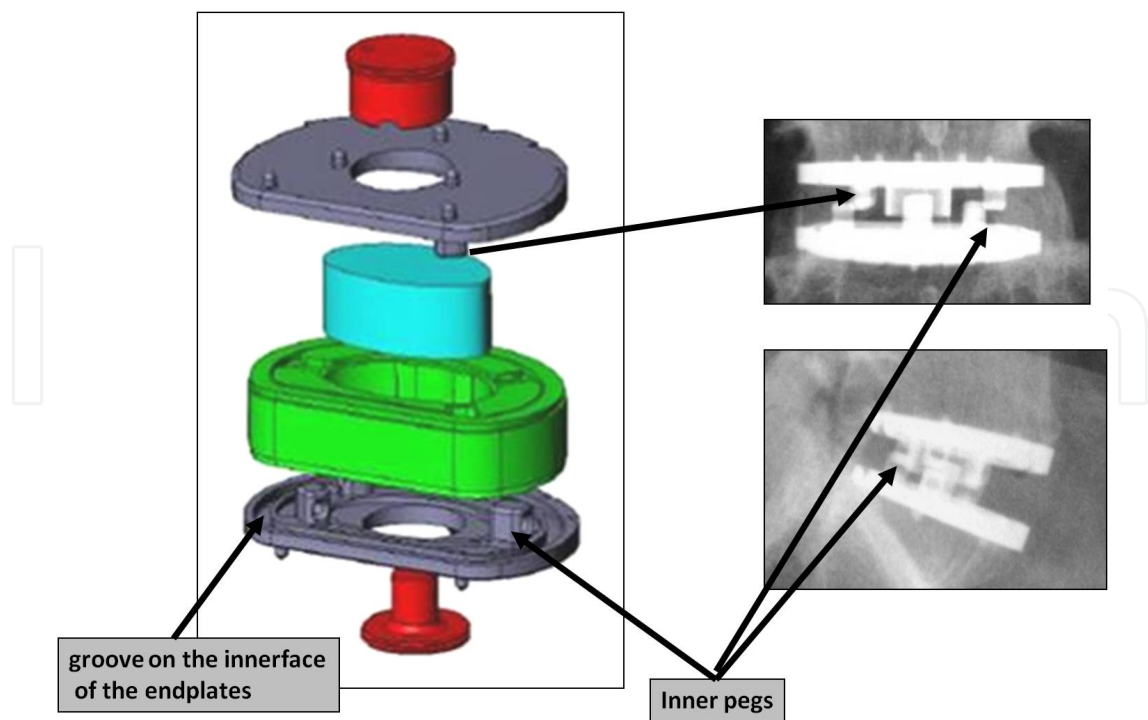


Figure 3. The LP-ESP[®] is a one-piece deformable implant including a central core made of silicone gel with microvoids and surrounded by polycarbonate urethane (PCU) securely fixed to titanium endplates.

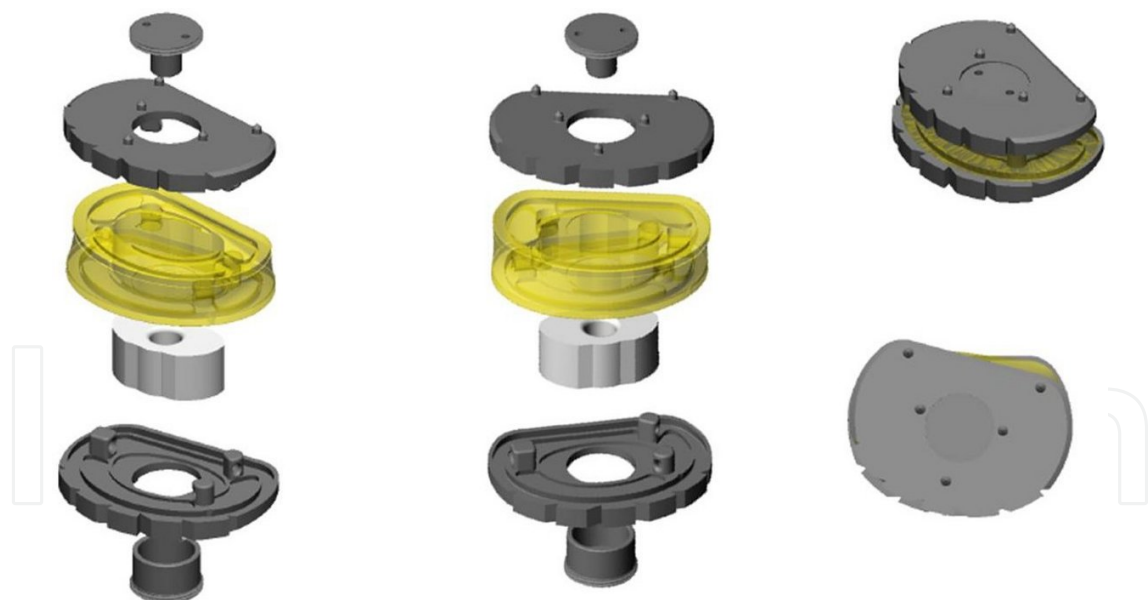


Figure 4. The geometry and position of the pegs, between the peripheral groove and the central area of the endplates, are planned to control rotational mobility

This design and the adhesion-molding technology differentiate the LP ESP prosthesis from other monoelastomeric prostheses, for which the constraints of shearing during rotations or movement are absorbed at the plastic/titanium interface because of the molding technology

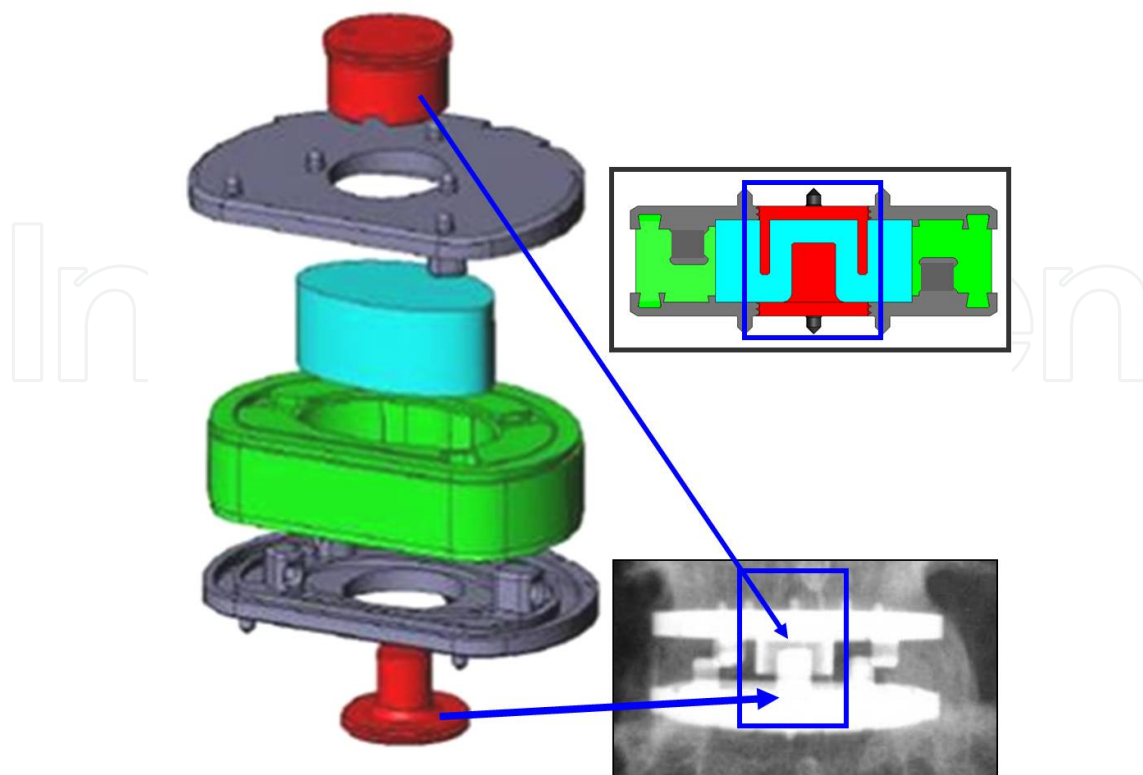


Figure 5. The cushioning and compressing effects are obtained on the one hand by the contactless interlocking of the male and female caps and, on the other hand, by crushing the annulus between the two metal plates.

used in their design. The attachment is obtained by the penetration of the polymer through small holes in the endplates. This process creates multiple interfaces and potential fatigue lesions of the anchoring mechanism due to inhomogeneous loading during flexion-extension, lateral inclination, and rotation. Thus, in these designs, the plastic monobloc cushion secured to the titanium plates flows into the space between them during compression, creating an area of friction and wear.

On the whole, in the LP ESP, the constraints of the interface between the PCU cushion and its titanium seating are reduced. These are principally constraints of compression:

- between the exterior of the male cap and the interior of the female cap for translations;
- between the pegs for the rotation ;
- between the titanium endplates for flexion.

The principle of the LP ESP® makes it possible to reproduce the anisotropy of the healthy disk, and the design allows modification of the return torque (without modifying the other parameters of the prosthesis. For example:

- bringing the pegs closer together increases stiffness in rotation without modifying either translation or compression;

- diminishing the clearance between the male and female caps increases the stiffness of translation without modifying either rotation or compression;
- modifying the ratio between the small and large diameters of the elliptic form of the cushion changes the ratios of the return torques between flexion/extension and lateral flexion without modifying stiffness in compression or rotation.

3. Manufacturing process

The manufacture of this complex implant includes 6 stages, each with its own quality control for each piece:

- Stage 1: Machining titanium (TA6V) plates and male and female caps and 3-dimensional check of each unit.
- Stage 2: Preparation of the annulus made of PCU.
 - Electrochemical treatment of the interior surfaces of the TA6V plates
 - Preparation and quality control of materials including drying PCU granules at 85°C for 4 h to reduce their humidity to less than 0.1%
 - Molding the PCU annulus between the two titanium endplates with a 22-ton vertical injection press (the endplates are pre-positioned in a mold that makes it possible to define the external geometry and to preserve the ovoid-shaped housing of the core).
 - Visual check of each unit, followed by testing compression of the implant without its core.
- Stage 3: Preparation of the core.
 - Placement of the female cap by screwing it in
 - Injection of a silicone-based component through the opening of the male cap
 - Screwing in the male cap as the injection starts
 - Cold polymerization
- Stage 4: Implant checks.
 - dimensional check of each unit,
 - testing rigidity while compressed by an axial load)
 - destructive testing of the first and last pieces of each lot by axial traction of the 2 metal endplates and then visual examination of the polymer parts (annulus and core).
- Stage 5: Two-stage spraying for final preparation of the anchoring endplates:
 - the T40 coating by plasma in a vacuum
 - and the layer of hydroxyapatite by plasma in a controlled atmosphere (inert gas)

Testing is performed as required by the standards:

ASTM F 1185-03 (2009) Standard Specification for Hydroxylapatite Composition for Surgical Implants

ISO 5832-2:1999 Surgical implants-- Metal-based products -- Part 2: Non-alloy titanium

ASTM F 1044: Standard test method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings

ASTM F 1147: Standard test method for Tension Testing of Calcium Phosphate and Metallic Coatings

ASTM F 1609: Standard Specification for Calcium Phosphate Coating for Implantable Materials.

ISO 13779-1: Hydroxyapatite - Part 1: Hydroxyapatite-based ceramic.

ISO 13779-2: Hydroxyapatite - Part 2: Hydroxyapatite-based coatings.

ISO/CD 13779: Hydroxyapatite - Chemical analysis and characterization of crystallinity and phase purity

- Stage 6: processing in a class 100 clean room workstation
- Stage 7: sterilization by gamma radiation (min: 25 kgray; max: 40 kgray) according to a special validated process

4. Design stages

After an initial patent application in 1994 by R. ROY CAMILLE, different avenues of research were explored, with the scientific expertise of the CEA (Commissariat à l'Énergie Atomique, Fontenay aux Roses, France) and the industrial expertise of FH Industry for further R & D (Heimsbrunn, France).

The preliminary stages involved optimizing the choice of PCU, the development of the attachment of the annulus to the metal endplates without chemical adhesives, the definition of the pegs and caps, and the implementation of reliable techniques for polymer molding and injection.

Biocompatibility tests were performed by BIOMATECH, a subsidiary of NAMSA (Northwood, Ohio, USA).

Human implantation began in 2004 with the first generation of LP ESP® implants, which used endplates without lordosis (40 implantations, all complying with the Huriet Act, which defines French ethical requirements) (Figure 6).

A second generation of implants with lordotic endplates (7°, 9°, and 11°) was introduced in 2005 — LP ESP 1 (Figure 7).

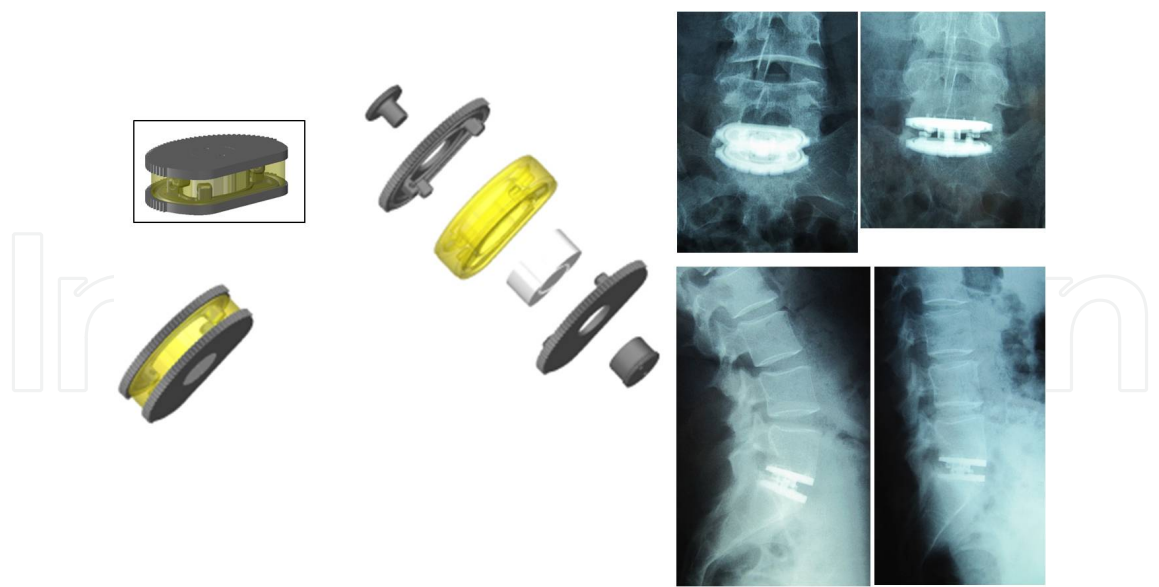


Figure 6. First generation of lumbar ESP® (2004) : endplates without lordosis

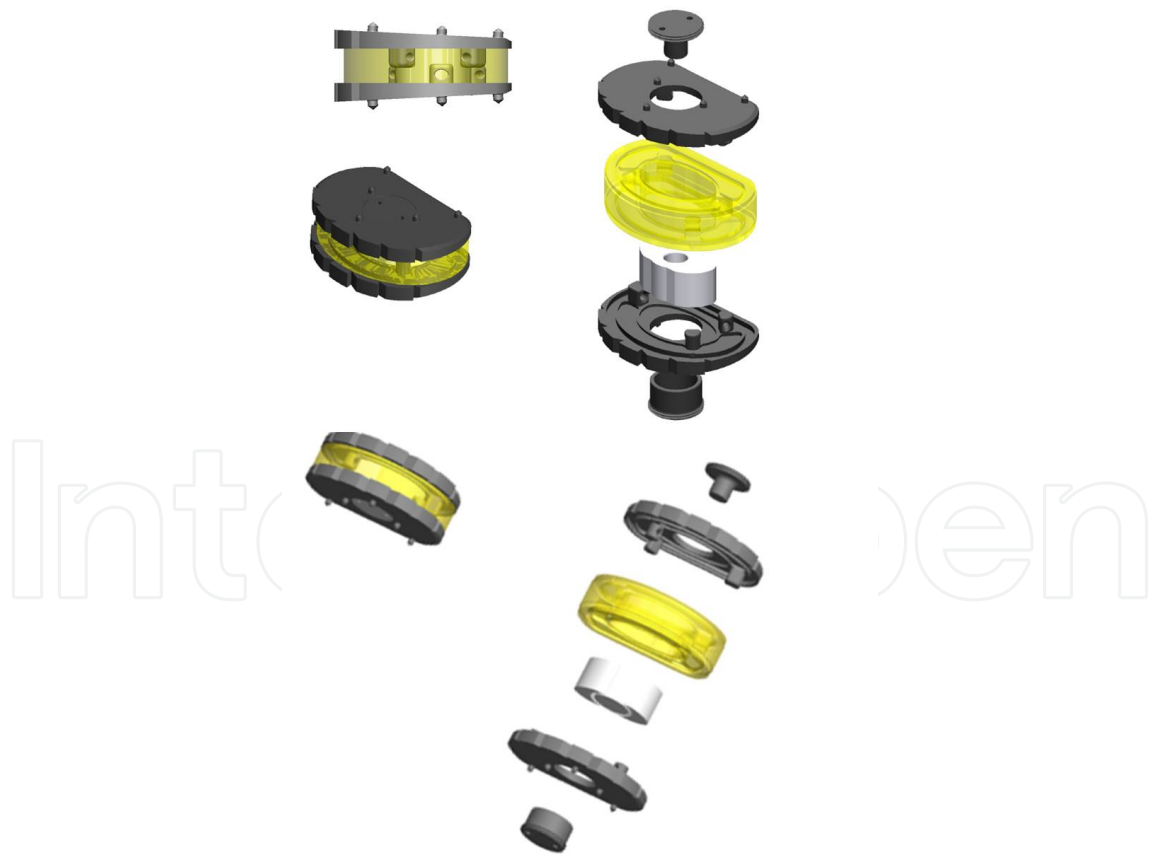


Figure 7. Second generation of lumbar ESP® (2005) : the shape of the endplates provides lordosis

A final change was made to the PCU annulus in 2006: its periphery is no longer rectilinear but was recessed somewhat during the molding process. This change did not modify the attachment of the cushion of the LP ESP 2[®] prosthesis but made it possible to reduce its stiffness during compression by 30% without changing its characteristics for flexion/extension, lateral incline, or rotation (Figure 8).

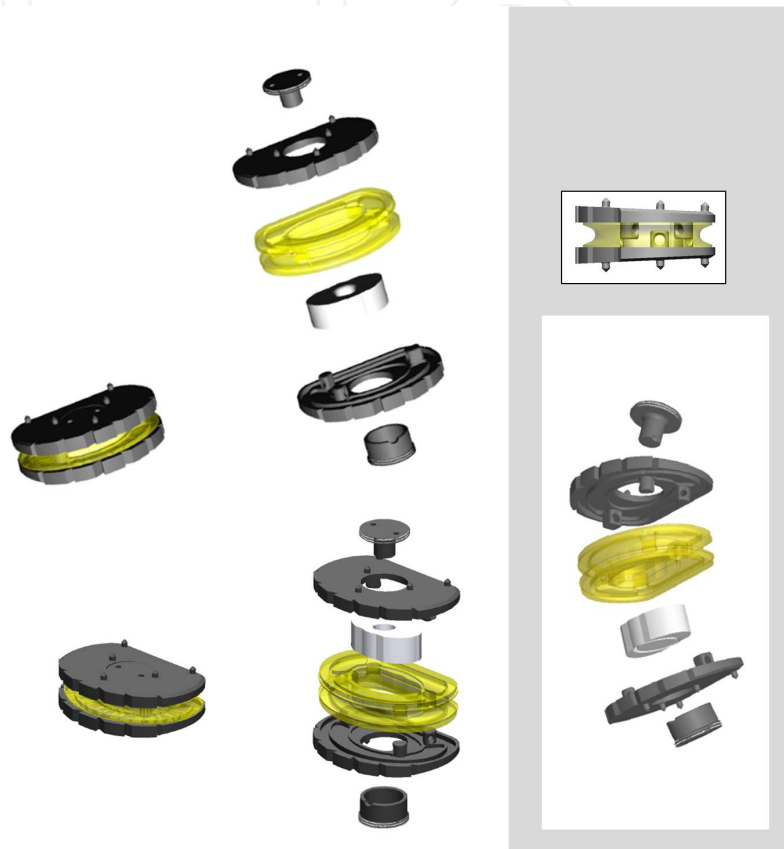


Figure 8. Last generation of lumbar ESP[®] (2006) : anterior recess in the PCU annulus to reduce stiffness during compression

This ESP prosthesis received CE marking in 2005, making it the first elastomeric lumbar prosthesis to be validated and authorized for marketing.

5. Mechanical properties

The "silent block bush" design of the LP ESP[®] prosthesis avoids the disadvantage of centers of rotation that are fixed or controlled by the implant design, as observed in disk prostheses based on an articulated design. In addition, in each direction solicited, the prosthesis offers resistance that increases with the amplitude of the movement. In this sense, the LP ESP[®] cannot be compared to first-generation implants. It meets the mechanical criterion of 6 degrees of freedom and provides a cushioning effect while restoring elastic recovery

properties. Its mechanical properties are close to those reported in the literature for the normal disk (see Table 1).

Pure moments applied in increments up to a maximum value of 10 N-m	References	Level	Natural disk
flexion extension	Panjabi [27]	L4/L5	6°
		L5/S1	4°
	Campana	L1/L2	4°
		L4/L5	7°
	Yamamoto [28]	L1/L2	5°
		L4/L5	7.5°
	Panjabi	L4/L5	4°
		L5/S1	2°
lateral flexion	Campana [29]	L1/L2	4.1°
		L4/L5	6.1°
	Yamamoto	L1/L2	5°
		L4/L5	5.7°
	Panjabi	L4/L5	2°
		L5/S1	1°
	Campana	L1/L2	2.4°
		L4/L5	3.4°
Torsion	Yamamoto	L1/L2	2.3°
		L4/L5	2.2°
	Gardner- Morse [30]		2420 N/mm
axial compression	Virgin [31]		3000 N/mm
	Kemper [32]		1835 N/mm
	Bouzakis [33]		1700 N/mm
Variable according to the loading speed, values retained for 0.1 m/s			
Elastic recovery»			yes

Table 1. Comparison of the mechanical properties of the LP ESP 2° prosthesis with those of the natural disk

6. Biomechanical assessment

The originality of the concept of the ESP® prosthesis led to innovative and intense testing of various sorts.

6.1. Structural tests

a. Creep tests

After continuous compression to 1250 kN for 2928 hours (122 days), the height loss was 0.2 mm. In the 8 hours following load removal, the residual height loss was 0.1 mm.

b. Influence of the pegs included in the PCU annulus to control rotations

Tests were performed for combined compression and rotation: the pegs included in the PCU annulus absorb approximately 50% of the torque.

c. Assessment of the cohesion of the prosthetic cushion and the metal endplates:

The tests were performed for mediolateral and anteroposterior exertion applied to one of the metal endplates, with the other plate attached to the test machine (figure 9). For implants 12- and 10-mm thick, respectively, a force of 450 and 800 N was required to obtain a gap of 1 mm between the 2 endplates in the anteroposterior direction and 550 and 600 N in the mediolateral direction.

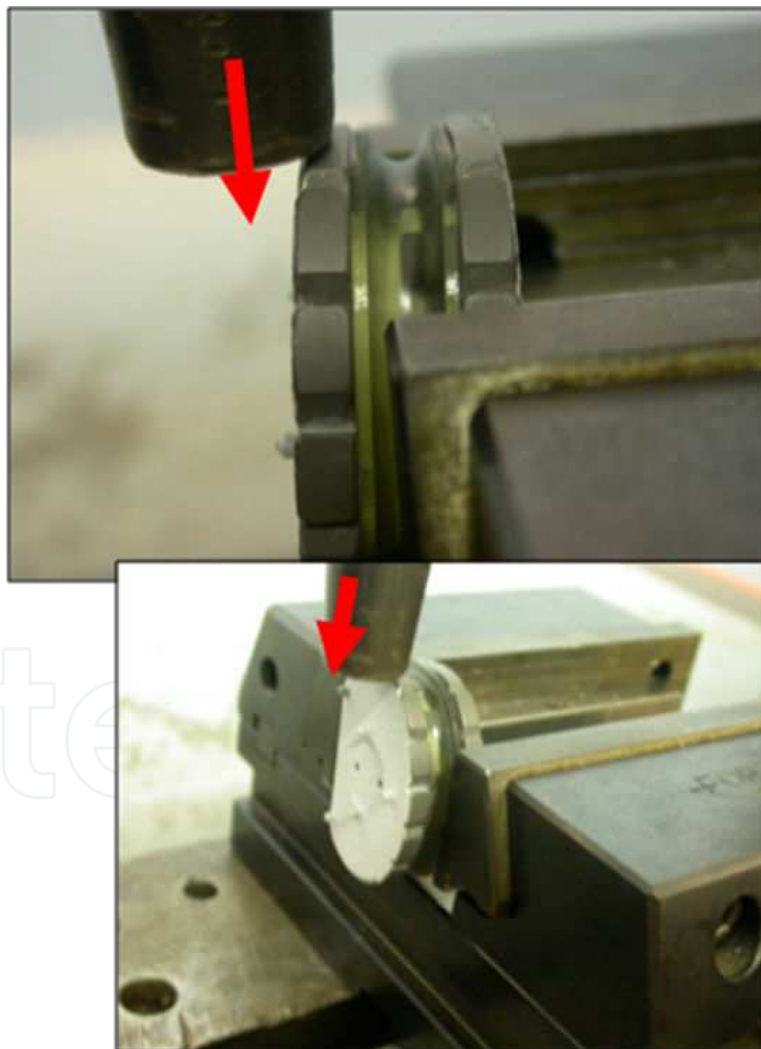


Figure 9. Assessment of the cohesion of the prosthetic cushion and the metal endplates: the tests were performed for mediolateral and anteroposterior exertion applied to one of the metal endplates, with the other plate attached to the test machine

d. Maximum compression tests

These tests were inspired by the experimental protocol of Virgin [31], who stated that a natural healthy disk is irreversibly injured by a load of 3 to 11 kN. After application of a force of 4,800 N (100 h) and then 9,200 N (64 h), we did not observe irreversible destruction of the implants. Compression tests and then compression-shearing at an angle of 45° were performed on the same samples to obtain successive compressions of 2 mm, 3 mm, and 6 mm. These tests show the implant's excellent tolerance of these compression-shearing mechanisms.

e. Tests to validate the final stage of coating on the exterior side of the metal plates

Adding a further final coating of porous titanium and spraying hydroxyapatite on the implant in its permanent form causes its temperature to rise. During the coating process, the disc is cooled by compressed air so that the ambient temperature remains stable at 21°C. Tests were performed to verify the absence of any effect from this rise on the mechanically active cushion in view of the known risk of PCU deterioration at 120°C. These tests demonstrated that the temperature did not reach a level of risk to the PCU.

6.2. Fatigue and wear tests

Wear tests were conducted in a 3-axis motion simulator according to the following protocol:

- 10 million cycles of flexion, extension, and lateral tilting
- Frequency = 4 Hz
- Loads of 135 to 1350 N
- Inclination of the prosthesis at 45° to reproduce the sagittal orientation of the disk in functional situations (Figure 10)
- In a demineralized water bath at 37° C

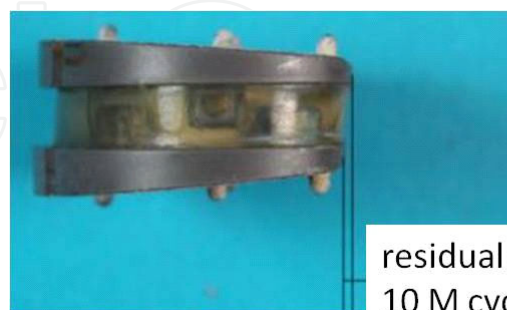


Figure 10. Wear tests were conducted in a 3-axis motion simulator (frequency = 4 Hz, loads of 135 to 1350 N), The inclination of the prosthesis was 45° to reproduce the sagittal orientation of the disk in functional situations. The gap between the metal plates was measured after each series of 10 million cycles.

Tests have even been extended to 40 million cycles without any observation of signs of mechanical failure. No loss of cohesion was seen. The residual gap between the metal endplates was 0.55 mm after 20 million cycles and 0.78 mm after 40 million cycles. Loss of mass after 20 million cycles was less than 0.5 % (very low absorption of saline solution and slight degradation of the endplates coating).

6.3. Biostability tests

This test was conducted according to the requirements of ISO standard 10993-13/ biological evaluation of medical devices, Part 13: Identification and quantification of the decay products of polymer-based medical devices.

The biostability of the implant was assessed by analysis of the particles collected during the filtration of the demineralized water bath, after a wear test of 10 million cycles under a load of 1350 N. This study used a scanning electron microscope (SEM LEO1455VP), equipped with an energy-selective spectrometer (EDS OXFORD). No particles from the component materials of the prosthesis were found.

The tests looking for salted out or released matter showed the emission of <1 mg/kg methylene diphenyl 4-4 diisocyanate and of 64.9 mg/kg of 4-4 methylene diamine. These results are consistent with the data in the literature [34].

6.4. PCU aging test

The specific PCU used for the LP ESP prosthesis is not oxidized during storage (bionate 80A (DSNM Biomedical, The Netherlands) according to master file MAF844). Kurz demonstrated that five years of shelf aging has little effect on the mechanical properties of the PCU and concludes that the bionate 80A material has greater oxidative stability than ultra-high molecular weight polyethylene following gamma irradiation in air and exposure to a severe oxidative challenge [35]. Tests were performed after artificial aging in water at 80°C followed by 10 million compression cycles at loads ranging from 150 to 1250 N. In the absence of published standards in the literature, the temperature was determined in comparison with that recommended for aging plastics, including UHMWPE (ASTM standard F 2003: Accelerated aging of ultra-high molecular weight polyethylene after gamma irradiation in air) and the axial load is that recommended by ISO standard 18192 (Intervertebral spinal disk prostheses — Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test) for wear tests. It was not observed significant changes in the stiffness of the implants tested.

No modification of the Fournier transform infrared spectrum or any modification of the mean molecular weight (ASTM standard D 5296) was observed. The chemical composition and organization of the atomic bonds therefore remained identical because oxidation or natural cross-linkage would have modified the atomic organization and thus the spectrum. These results are consistent with the literature [34].

7. Biocompatibility tests

They were performed by Biomatech (*Chasse-sur-Rhône, France*).

All the materials were studied separately and in their final assembly, meeting the specifications for biocompatibility tests described in ISO standard 10993 (Biological Evaluation of Medical Devices).

Cytotoxicity test according to ISO standard 10993-5

Sensitization test according to ISO standard 10993-10

Test of irritation or intradermal reaction according to ISO standard 10993-10; acute systemic toxicity according to ISO standard 10993-11 Chromosomal genotoxicity (Hearts test, and chromosomal anomalies according to ISO standard 10993-3)

The implants also meet the criteria of the FDA's subacute sensitization test (following FDA - Guidelines for Toxicity Tests Chapter IV).

8. Clinical results

8.1. Evaluation process:

As of today, more than 2000 LP ESP II prostheses have been implanted. No complication related to the materials has been reported. Our clinical experience is based on prospective studies of clinical and radiologic assessment. The time points were 3, 6, 12, and 36 months. The intensity of back pain was evaluated with a Visual Analog Scale (VAS). Disability was assessed with the Oswestry Disability Index (ODI) [36-37, 39]. FDA criteria consider an improvement in the ODI at 2 years equal to or greater than 15% as success. The SF 36 was used to assess global health status [40]; the quality of life dimension of this test (SF-36) is composed of two subscores, the physical component summary (PCS) and the mental component summary (MCS), expressed as percentages [40-44]. The results of this score were compared to data known for a normal population [45]. In addition, the GHQ28 was used to investigate psychological distress [46].

Radiographs of the lumbar spine were prospectively collected for the studies. The time points for the radiological evaluation were 3, 6, and 12 months. The X-ray films were digitalized with the VXR12® scanner (Vidar System Corporation) and analyzed with Spineview® software (Surgiview Corporation, Paris, France), the precision and reliability of which has previously been reported [47]. The analysis was performed by a single observer who was not involved in patient selection, surgical procedures, or follow-up examinations. Kinematics parameters were studied at the level of implantation and the adjacent upper level on the flexion/extension X-rays. Range of motion (ROM) was measured to describe angular mobility quantitatively. As Champain et al. [47] has

reported 2° accuracy for the measurement of ROM with Spineview®, we considered that the prosthesis had no motion if the measured range of motion was less than 3°. For mobile levels, the mean center of rotation (MCR) was recorded to assess motion qualitatively, as previously described. An orthogonal coordinate system centered at the posterior superior corner of the lower vertebra, with the X axis along the posterior wall and the Y axis along the endplate, was used to describe the location of the MCR. The percentage of MCRs in a correct or normal location was determined according to the method of Tournier et al [48].

Lateral views in standing position (lumbar spine including femoral heads) were used to assess the sagittal balance indicators, as defined by Duval and Beaupere [49].

- Sacral slope (SS): angle between the endplate of S1 and the horizontal line,
- Pelvic tilt (PT): the angle between the vertical line and the line connecting the center of the S1 endplate to the center of the femoral head. The middle of the line connecting the two femoral heads was used when those were not exactly superimposed;
- Segmental lordosis (SL): the angle between the upper endplate of the superior vertebra and the lower endplate of the inferior vertebra (for L5S1, the upper L5 endplate and the upper S1 endplate).

8.2. Clinical results

Clinical outcomes can be assessed from one of our prospective series of 120 patients. The mean operative time was 92 min (standard deviation, SD: 49 min). The mean blood loss was 73 cc (SD: 162 cc).

Analysis of the VAS showed a preoperative baseline of 6.6, a strong decrease to 3.7 points at 3 months, and a stable score of 3.6 through 36 months. The VAS thus decreased by 45%.

The baseline preoperative ODI score was 47.3%; it decreased regularly to 19.5% at 36 months, that is, a reduction of 40%. Overall, 77% of the patients had an ODI score at 36 months that improved by more than 15 points compared with the preoperative score. At 36 months after surgery, 90% of the patients showed an improvement of more than 15% compared with the preoperative value and 83% more than 25% (Tables 2 and 3).

The baseline preoperative GHQ28 score was 64.2; it began to fall at 3 months and remained at 52.2 at 36 months. This indicates an improvement of this psychological score of 18.7%.

The preoperative baseline SF 36 PCS score was 32.3%; it increased to 48.8% at 3 months and reached 56.8% at 36 months, for an increase of 24,5%.

The preoperative baseline SF 36 MCS score was 42.9%; it increased regularly and reached 57.9% at 36 months, for an increase of 15%.

Mean±SD	PRE OP	3 MO	6 M	12 M	24 M
VAS	6.6±1.7	3.7±1.9	3.4±2.1	3.5±2.3	3.4±2.4
ODI (%)	47.6±14.6	30.3±17.6	24.5±17.6	21.8±16.3	20.6±17.3
GHQ 28	64.2±15.6	52.5±14.7	52.7±15.8	52.2±15.4	50.6±15.4
SF 36 PCS (%)	32.4±34.8	48.4±39	51.9±39.3	55.6±39.8	59±39.2
SF 36 MCS (%)	42.3±34.0	50.8±34.6	52.8±35.6	53±36.3	58.7±34.6

Table 2. Description of the different evaluations performed

improvement/preoperative status	3 M	6 M	12 M	24 M
ODI improvement of 15 points	53	69	72	76
ODI improvement of 15%	72	82	85	85
ODI improvement of 25%	59	75	82	83

Table 3. Improvement in ODI score compared with preoperative score (in % of the population)

8.3. Radiological outcome

The radiological results can be analyzed from another prospective series of 41 patients (20 L5S1 and 21 L4L5 implantations) for whom postural and kinematic indicators can be evaluated.

Table 4 summarizes the changes in the radiological indicators of sagittal balance over time. Patients did not have major balance disorders before or after implantation. SS, PT, SL, and DH all changed significantly between the preoperative period and all other time points.

	Pre-op	3 months	6 months
Pelvic incidence (PI)	54.1° ± 14.6		
Sacral slope (SS)	36.5° ± 10.6	39.2° ± 5.7	40.8° ± 8.5
Pelvic tilt (PT)	16.7° ± 7.8	15.1° ± 6.7	13.2° ± 8.2
Segmental lordosis (SL)	19.4° ± 6.7	26.6° ± 5.3	27.9° ± 6.9
Discal height (DH)	28.5% ± 10.3	50.7% ± 7.4	50.3% ± 5.0

Table 4. Radiological parameters in standing position over time (mean + SD). Changes in SS, PT, SL, and DH were significant between the preoperative measurements and all other time points.

The average range of motion in flexion-extension at the one-year follow-up was 5.0° (SD: 4.8°) (Table 5). The ROM increased significantly from 3 to 12 months, from 3.4 ° to 5.0°. With the 3° cut-off point, 66% of patients demonstrated mobility at one-year. The average ROM for the

mobile prostheses was 6.9° (SD: 4.5). The average ROM of the prosthesis was 6.4° (SD: 4.9) at L5S1 and 7.9° (SD: 3.3) at L4L5.

	3 months	6 months
ROM at the prosthetic level	3.4° (2.5)	3.1° (2.8)
% of mobile prostheses	66%	60%
ROM of the mobile prostheses	4.4° (2.1)	4.6° (2.8)
ROM at the adjacent upper level	7.5° (5.1)	7.5° (4.2)

Table 5. Range of motion of the prosthesis and the upper adjacent disk over time. Mean (SD). The instrumented level reached a physiological range of motion similar to the adjacent level above it at between 6 and 12 months.

The MCR was in a normal location for 43% at 3 months, 42% at 6 months, and 87.5% at 12 months. Another prospective series of 74 implants seen at least 2 years after surgery allows analysis of the prostheses with more than 5° of mobility in flexion-extension: the mean mobility at L4L5 was 8.2° and at L5S1, 7.6°, for a global mean mobility of 7.9°. Table 6 compares these values with data from the literature for the same criterion of minimum mobility at 5°.

Author	Year	Follow-up	Type of Prosthesis	L3-L4 ROM	L4-L5 ROM	L5-S1 ROM	Global ROM
Gioia [50]	2007	2	Charité III	8	10.3	8	8.7
Bertagonil [51]	2005	2	Prodisc	-	-	-	6.5
Guyer [52]	2009	2	Charité	-	6.5	6	6.3
		5		-	6	6.3	6.2
David [53]	1993	1	Charité	2	9.4	6.4	5.9
Siepe [54]	2007	1	Charité III	-	7.2	5.9	6.5
Zigler [55]	2012	5	Prodisc	-	-	-	7.7
Delamarter [56]	2011	2	Prodisc L	7.8	6.2		7.0
the series	2012	2	LP ESP	-	8.2*	7.6*	7.9*

Table 6. Mobility described in the literature of implants restoring more than 5° of segmental mobility

9. Discussion

The geometry of the LP ESP® prosthesis allows limited rotation and translation with resistance to motion aimed at avoiding overload of the posterior facet joints. The center of rotation can vary freely during motion. This viscoelastic prosthesis achieves 6 degrees of freedom including

vertical translation; it provides a cushion and may allow shock absorption. It thus differs substantially from other current prostheses, which are 2- or 3-piece devices involving 1 or 2 bearing surfaces and providing 3 or 5 degrees of freedom, with no or very little resistance, and no elastic return. A 20-year research program has demonstrated that this concept provides mechanical properties very close to those of a natural disk.

In addition, the biostability of the implant was demonstrated: no particles from the component materials of the prosthesis were found after a wear test of 10 million cycles under a load of 1350 N.

These experimental data should be considered in relation to previously reported results from Nechtow et al. [57] of wear rates of 16.59 ± 0.96 mg/million cycles for ProDisc_L and 19.35 ± 1.16 mg/million cycles for Charite, and from Grupp et al. [58] of wear rates ranging from 0.14 ± 0.06 mg/million cycles to 2.7 ± 0.3 mg/million cycles for Active L.

Moreover, the size and morphology of the UHMWPE particulates observed in these studies are similar to those described in total hip and knee replacements [59], the osteolytic potential of which is well known.

Seven years after the first implantation, we can document in a solid and detailed fashion the course of clinical outcomes and the radiological postural and kinematical behavior of this prosthesis. The clinical data show early and stable improvement of clinical status, while the radiological data show immediate improvement of local lordosis and discal height at the instrumented level and associated adaptation of the sacral slope. At 3 and 12 months, 66% of cases had physiological mobility at the instrumented level, with secondary self-adjustment of the center of rotation in flexion/extension.

We acknowledge that more studies with more patients and more follow-up would be useful in the future to assess long term reliability. Nonetheless, the series reported here describe the outcomes that might be expected by surgeons and patients over the first 7 years. These encouraging results are basically similar to the clinical results reported by Tropiano [60] et al. with the Prodisc II® and the clinical data of the SB Charite®, as reported by McAfee et al [61]. Although the preoperative radiological parameters showed no major imbalance in spinal posture compared to the global population, SS, PT, and SL improved significantly immediately after implantation. These results are consistent with those reported in literature with articulated prostheses [48, 62, 63].

We note that publications do not appear to report significant sagittal misalignments after prosthetic implantation, whereas lumbar fusion may deleteriously alter the sagittal balance of the spine, including a decrease in the SS and lumbar lordosis [6,7]. The increased segmental lordosis might be related to the lordotic shape of the prosthesis but also probably to the fact that arthroplasty, in contrast to fusion, allows the lumbar spine to find a new balance spontaneously. It has not yet been demonstrated, however, that this self-adaptation of the sagittal balance protects against adjacent level degeneration. Unlike arthrodesis, the preservation or restoration of some mobility with a total disk replacement aims at limiting overload of the adjacent levels.

The optimal ROM after TDR for limiting adjacent segmental disease has not yet been established. Huang et al [64] reported a series of 42 Prodisc I[®] implantations with 8.7 years of follow-up, and 24% of the junctional levels showed radiological signs of degeneration. In their study, the mean ROM of the disk prostheses adjacent to junctional disease was significantly lower than the mean ROM of the prostheses adjacent to a radiologically normal disk, i.e., 1.6° versus 4.7°. Prevalence of junctional degeneration was 0% among patients with ROM of 5° or more and 35% among those with less than 5°. The authors did not conclude that 5° was the trigger value for avoiding adjacent degeneration, as 65% of patients with less than 5° did not develop adjacent segmental degeneration. In our series, the LP-ESP[®] device provides mobility levels similar to those with articulated prostheses such as Prodisc, which vary according to the series from 3.8° to 13.2° [62, 64].

We recognize that assessing spinal kinematics with static X-rays in flexion and extension is subject to bias, given the same-day variations due to inconsistent effort during flexion/extension [65]. Nonetheless, flexion/extension X-rays are easily available and cause less irradiation than continuous motion analysis with in vivo fluoroscopy. Quality of movement is also an issue. The LP-ESP is a novel one-piece deformable but cohesive interbody spacer that provides 6 full degrees of freedom about the 3 axes. This allows instantaneous axis rotation change freely, as in the normal disk, while preventing facet overloading.

MCR, initially defined by Percy [66], is a pivot point about which a vertebra appears to move and is thought to reflect the quality of movement of a segment. As disk arthroplasty develops, this indicator appears to be an informative parameter for studying the quality of spinal movement imposed by the prosthesis. The coordinates of the MCR for LP-ESP[®] prosthesis appears similar to those of the natural disk described in literature. After one year of follow-up, we found the MCR in a physiological area in 87.5% of the patients. With the same methods, Tournier et al. [48] reported a normal MCR for 51% of patients receiving the Maverick[®], 66% of those with the Prodisc[®] (both of which have 3 degrees of freedom), and 80% with the SB Charite[®] (5 degrees of freedom). These results suggest that less constrained prostheses, i.e., those with more than 3 degrees of freedom, are associated with more normal MCR locations. In addition, we observed that the MCR location tends to improve during the first year. However, this must be interpreted while bearing in mind the uncertainty of the MCR measurement reported by Tournier et al., specifically at the L5-S1 level.

10. Conclusion

The concept of the LP-ESP[®] prosthesis is different from that of the articulated devices currently used in the lumbar spine; it allows 6 degree of freedom with elastic return and is intended to respect the spontaneous instantaneous axis of rotation and to reduce facet forces. Our series provide encouraging clinical results about pain, function, kinematic behavior and radiological sagittal balance after implantation of the LP-ESP[®].

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