

Lumbar Disc Replacement

AcroFlex design and results

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Abstract

The AcroFlex prosthesis is unique when compared to other current devices, as it has an elastomeric core sandwiched between two titanium endplates. The purpose of this design was to optimize shock absorption qualities. This paper reviews the design of the AcroFlex Disc and relevant design and outcomes of two pilot studies carried out on 28 patients using the AcroFlex prosthesis. Although clinical outcomes of the pilot studies were successful, the pivotal randomized trial has not been carried out due to detection of mechanical failure of the elastomer on thin cut CT scans. The implications of this for the AcroFlex and other arthroplasties are discussed. © 2004 Elsevier Inc. All rights reserved.

Keywords:

AcroFlex; Intervertebral disc; Wear

Introduction and background

Artificial discs used clinically can be classified under three main groups. First, those that involve nuclear replacement alone are effectively nuclear spacers (eg, the Fernstrom endoprosthesis [1,2] and the Ray prosthetic disc nucleus (Raymedica Inc., Bloomington, MN) [3]). Second, low-friction arthroplasty perhaps best describes disc replacement devices such as the Charité (DePuy Spine, Raynham, MA) [4–10] and ProDisc (Synthes, Inc., Paoli, PA) that apply the design principles commonly used in total hip and knee arthroplasty. However, the AcroFlex Lumbar Disc, (DePuy Spine, Inc., Raynham, MA) the subject of this paper, has different design features, setting it apart from the other two groups.

The design of the AcroFlex prosthesis includes the use of an elastomer to replicate the elasticity of the normal

human intervertebral disc. An earlier version of the current device (sandwiching a polyolefin-based rubber core sandwiched between titanium end plates) was used in six patients who underwent disc replacement between 1988 and 1989. Five of the six patients were reported to have maintained disc function for several years after this surgery [11,12].

A second-generation device was developed. Its design was similar to the first except that the core was made of silicone instead of rubber. This prosthesis was implanted in eight patients between 1993 and 1994. One mechanical failure of the artificial disc occurred 6 months later in a patient with a prior fusion at an adjacent level.

Based on the experience gained from these small series, the device was modified, returning to the use of a rubber material but with a redesign of the core, the shape of the end plate periphery was optimized, and the bone–metal interface of the end plate was changed. In addition, the manufacturing procedures were improved to include automated processes, including optimized methods for bonding the rubber to the end plate.

The AcroFlex prostheses that were used in this series consist of three primary components: two ASTM F-136 implant grade titanium end plates (Ti-6Al-4V ELI alloy) bound together by a hexene-based polyolefin rubber core. The end plates are machined from a single piece of material. For the initial design used in the first pilot study, the surfaces

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for contact with the bony end plates were flat with attached porous beads and a single crescent ridge for bony fixation (Fig. 1). In the modified design that was used in the subsequent pilot study, the metal end plates were domed in both the coronal and sagittal planes, were porous beaded with 4 to 6 tapered fins for bony fixation and had a central anterior/posterior slot for device insertion (Figs. 1 and 2).

Chemlok 205 primer and Chemlok 250 adhesive (Lord Corporation, Cary, NC) are used to facilitate the bond between the titanium end plate and the rubber. Commercially pure titanium beads (ASTM F67 Grade II) are sintered to the end plates along the bone and rubber interfaces.

The application of an artificial disc within the disc space is intended to function in conjunction with the remaining lateral annulus (approximately 3 to 5 mm in thickness), posterior elements and surrounding musculature. The AcroFlex disc is available in multiple sizes to accommodate anatomical variations. The titanium end plate's size range is based on direct measurements of lumbar vertebrae, as well as data from the literature. The size range measurements are based on lateral and A-P measurements of the vertebral end plates. The heights of the assemblies, 9 mm, 11 mm and 13 mm, are based on surgeon experience, and they have been correlated with the clinical literature.

The shape of the titanium end plate design is intended to mimic the anatomical shapes of the vertebral end plate, while providing the maximum surface area at the site of contact between the implant and vertebral end plate. The intent is to lessen the risk of implant subsidence into the vertebral body.

The rubber-to-titanium end plate interface incorporates pure titanium beads sintered within a set boundary ridge. The beads are employed to increase the surface area of contact between the rubber and the titanium end plate. The beads allow the rubber to flow into the interdigitating spaces during the molding process, thereby increasing the integrity of the mechanical interface. The rubber-to-titanium interface uses a primer and adhesive component that chemically bonds to the rubber and titanium substrate. The set boundary at the rubber-to-end plate interface is raised above the beaded surface. This feature works in conjunction with the end plate perimeter radius. The set boundary feature or raised "ridge" offers the leading edge of the rubber-to-titanium bond site



Fig. 1. The third-generation AcroFlex implants used for (left) the Pilot 1 and (right) the Pilot 2 studies.

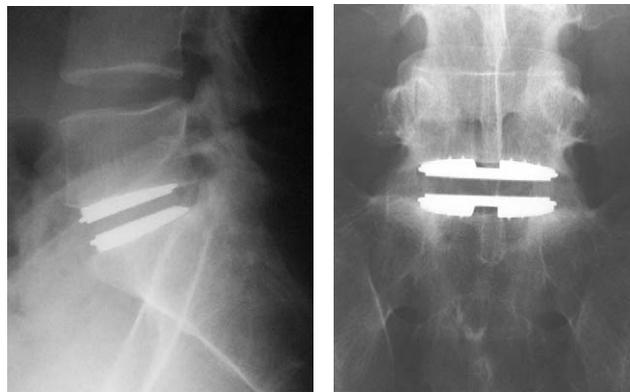


Fig. 2. Anteroposterior and lateral radiographs of the lumbosacral spine 12 months after insertion of a Pilot 2 implant at L5-S1.

strain relief from high stress during movement. The intent of the feature is to enhance the endurance limit of the implant.

The wedging of the implant occurs in the titanium end plate rather than the rubber. Finite element analysis predicts a better stress distribution along the rubber-to-end plate surface when compared with designs that incorporate wedging within the rubber annulus. The intent of this feature is to distribute the anatomical loads more evenly along the rubber surface, thereby enhancing the endurance limit of the implants.

The rubber thickness incorporates an annulus design intended to reduce the potential for nicking and/or tearing when bulging in vivo. The rubber annulus feature is designed with an inset smooth radius. The radius has been optimized through extensive finite element analysis to work in conjunction with the titanium end plate ridge and perimeter radius to reduce the stress concentration along the leading edge of the rubber-to-end plate interface.

The AcroFlex elastomer is a polyolefin-based rubber. A synthetic rubber was chosen because of rubber's inherent ability to perform simultaneous complex movements. Extensive biomechanical testing [13] suggested that the AcroFlex rubber had a high fatigue life, and an array of in vitro testing, including studies on wear particles [14], indicated the device to be biocompatible.

Design of pilot studies

The primary objectives of the studies were to evaluate the design, safety and performance of the AcroFlex Lumbar Disc. The secondary objectives were to refine the surgical technique and to assess the effectiveness of disc replacement for patients with symptomatic disc degeneration that is unresponsive to nonsurgical treatment.

Based on the experience gained from the first pilot study that commenced in April 1998, the end plates of the device were changed from flat to contoured, as detailed above. Apart from this and the inclusion of two-level procedures in the second pilot study (which commenced in February 2000),

the inclusion and exclusion criteria were similar for both studies.

Inclusion criteria were the following:

- One or two levels (Pilot 2 only) of symptomatic disc degeneration at the L4–L5 or L5–S1 level(s)
- Disabling back pain with or without associated referral type leg symptoms, refractory to conservative nonsurgical treatment for a minimum of 6 months before enrollment in the study
- Provocation discography that demonstrates internal disc disruption and reproduces the patient's typical pain at the target level and fails to reproduce the patient's typical pain at adjacent levels
- Male and female patients between the ages of 30 and 55 years of age
- The patient must voluntarily sign a patient informed-consent form
- The subject must be physically and mentally willing to comply with all the study follow-up requirements, including the routinely scheduled diagnostic testing, physical examinations and medical outcomes testing.

The exclusion criteria were the following:

- Previous lumbar surgery with the exception of discectomy and chemonucleolysis at the target level
- A lumbosacral angle at the target level that is too steep to allow adequate access by a direct anterior approach
- Significant central or lateral recess spinal stenosis
- Spondylolisthesis
- Systemic disease that would impact on the ability to assess the patient's condition relative to the spine surgery during the follow-up period
- Morbid obesity to the extent that disc-replacement surgery using the anterior approach is not technically feasible or advisable
- Alcohol and/or drug abuse
- The presence of three or more positive Waddell signs
- Structural scoliosis
- Major psychiatric disorder or mental condition that would compromise the patient's ability to comply with the follow-up requirements of the study or affect his or her ability to provide informed consent
- Current involvement in litigation related to the spinal condition or involvement in pursuing legal action related to the spinal condition.

The pilot studies were prospective and nonrandomized. Independent evaluation that included completion of a case report form took place preoperatively (within 3 months of surgery), postoperatively, at the time of discharge from the hospital and at 6 weeks, 12 weeks, 6 months, 12 months and 24 months.

The follow-up evaluations consisted of physical and X-ray examinations as well as patient self-assessment for pain using a visual analogue scale. Three outcome instruments

were used during the course of the studies; the Short Form-36 (SF-36), the Low Back Outcome Score (LBOS) and the Oswestry Disability Index (ODI); patients completed the forms preoperatively and at the 12- and 24-month follow-up intervals. Details of any complications and/or reoperations were recorded.

Surgical procedure

The surgical technique for insertion of the AcroFlex Lumbar Disc included a direct anterior retroperitoneal approach through a 5- to 7.5-cm transverse skin incision. The left anterior rectus sheath was longitudinally divided 1 cm from the midline a distance of 6 to 8 cm. The rectus muscle was retracted laterally and the retroperitoneal space exposed distal to the arcuate line. When exposure was tight at L5–S1 and for all cases at L4–L5, the lateral portion of the posterior rectus sheath was divided a distance of 2 to 5 cm, starting from the distal free fold. At L5–S1 the anterior annulus was exposed distal to the bifurcation of the inferior vena cava, whereas the L4–L5 annulus was exposed between the vessels and the sympathetic chain, which was retracted laterally. To achieve the necessary wide exposure of the anterior annulus at L4–L5, the inferior vena cava and left common iliac veins were mobilized, usually after division of the iliolumbar vein. The anterior annulus was excised and the disc space extensively cleared but with preservation of the lateral annulus to aid stability. In cases where the disc space was narrow, its height was restored. The end plates were prepared to bleeding bone and shaped to fit the prosthesis, preserving as much bony end plate as possible. Trial implants accompanied by anteroposterior and lateral radiographs were used to confirm the appropriate size, orientation and position for the prosthesis.

The early postoperative management was similar to that after an anterior lumbar interbody fusion.

Additional imaging

Although it was not part of the original protocol, patients were invited, as from November 2000, to undergo detailed imaging of their implants at the 12- and 24-month follow-up using the newly acquired technology of serial thin section computed tomography (CT) scanning. This multislice CT scanner imaged the entire implant plus the adjacent bony end plates and vertebrae to a depth of 5 mm. The sections were 0.5 mm thick and were overlapped by 50%, thus providing architectural details that are accurate to 0.25 mm.

Results of pilot studies

A total of 28 patients were entered into the Adelaide pilot studies. Eleven patients (Pilot 1) were treated in 1998–1999 with an AcroFlex prosthesis with flat end plates (Fig. 1); and 17 patients (Pilot 2) received, from February to December 2000, one or two AcroFlex prostheses with contoured

end plates (Fig. 2). Tables 1 to 5 detail the data for the two groups separately and in combination.

Overall the sex distribution was equal, the average age was 41 years (range, 30 to 54 years), and the average duration of back pain was 33 months (range, 9 to 120 months; Table 1). Fifty percent of patients were not working because of their back condition, and 54% had workers' compensation claims. There were no significant differences between Pilot 1 and Pilot 2 patients for any of the demographic characteristics that were recorded.

Nineteen implants were inserted at L5–S1 alone, five at L4–L5, and in four cases implants were inserted at both levels (Table 2). Overall the average operation time was 130 minutes (range, 75 to 195 minutes) with a significant amount of this time used to obtain satisfactory radiographic images. The average estimated perioperative blood loss was 178 ml (range, 15 to 1,500 ml). The average hospital length of stay was 6 days (range, 2 to 16 days).

There was a progressive improvement in outcome assessed by the ODI (Table 3) and the LBOS (Table 4) for Pilot 1 throughout the study period. At 2 years the average improvement was 23 points using the ODI and 22 points with the LBOS. Pilot 2 patients improved up to 12 months but not thereafter. For the total series, there was improvement in five of the eight SF-36 subscales.

The overall complications are listed in Table 5. There was partial forward displacement of one implant at L5–S1 in a patient in Pilot 1. Revision surgery has not been required, and the patient has had a satisfactory subjective outcome. No implant displacements occurred in Pilot 2 patients. Of

particular concern was the demonstration with serial thin section CT of rubber tears in 36% of patients (5 of 11 for Pilot 1; 5 of 17 for Pilot 2). The majority of lesions were minor anteroinferior peripheral tears (Fig. 3). Plain radiographs revealed heterotopic bone formation in only one patient (Pilot 1), and this was noted to be extensive (autofusion). However multisection CT demonstrated small to moderate amounts of annular and periannular ossification (Figs. 3 and 4, top) in most patients, not detected with plain radiographs (the case of autofusion is demonstrated in Fig. 4, bottom).

Revision surgery

One patient in Pilot 2 underwent revision surgery after her 12-month follow-up. The indication was unremitting severe pain for which a cause could not be found. At the time of surgery the implant was noted to be pristine in appearance with no adverse soft tissue or bony reaction but with no bone ingrowth. After conversion to an interbody fusion supplemented by pedicle screw fixation and posterolateral grafting, there has been little improvement in her condition despite CT evidence of graft consolidation.

Another seven patients underwent revision procedures 2 to 4 years after their disc replacement surgery. In two instances (both in Pilot 1 patients) there was more extensive anterior disruption of rubber, with associated osteolysis and accompanying deterioration in the clinical condition, leading to the need for revision surgery approximately 3 years

Table 1
Demographics at baseline

	All % (n)	Pilot 1 % (n)	Pilot 2 % (n)
Study (N)	100 (28)	39 (11)	61 (17)
Male	50 (14)	64 (7)	41 (7)
Working status			
Working full time	29 (8)	36 (4)	24 (4)
Working part time	14 (4)	9 (1)	18 (3)
Not working	50 (14)	55 (6)	47 (8)
Student/housewife/ retired	7 (2)	0 (0)	12 (2)
Smoking status			
Current smoker	39 (11)	46 (5)	35 (6)
Quit smoking	18 (5)	9 (1)	24 (4)
Never smoked	43 (12)	46 (5)	41 (7)
Workers compensation or litigation	54 (15)	46 (5)	59 (10)
No other general medical conditions	39 (11)	36 (4)	41 (7)
Previous traditional discectomy	14 (4)	9 (1)	18 (3)
Previous microdiscectomy	11 (3)	0 (0)	18 (3)
Previous chemonucleolysis	4 (1)	9 (1)	0 (0)
Previous treatments	14 (4)	9 (1)	18 (3)
	Average (range)	Average (range)	Average (range)
Age (years)	41 (30–54)	41 (32–53)	41 (30–54)
Height (cm)	169 (154–191)	170 (154–183)	168 (155–191)
Weight (kg)	80 (58–133)	85 (65–133)	77 (58–104)
Body mass index	28 (18–42)	29 (24–41)	27 (18–42)
Duration of back pain (months)	33 (9–120)	32 (12–84)	34 (9–120)

Table 2
Operative characteristics

	All % (n)	Pilot 1 % (n)	Pilot 2 % (n)
Levels treated (1)			
L5–S1 alone	68 (19)	91 (10)	53 (9)
L4–L5 alone	18 (5)	9 (1)	24 (4)
L4–L5 and L5–S1	14 (4)		24 (4)
	Average (range)	Average (range)	Average (range)
Operative time (min)	130 (75–195)	136 (115–195)	126 (75–195)
Estimated blood loss (ml)	178 (15–1500)	261 (15–1500)	124 (18–300)
Hospital length of stay (days)	6 (2–16)	7 (4–12)	6 (2–16)

after the index procedure. In both cases the operative findings included the presence of a granulomatous reaction to rubber debris with bony end plate erosions and failure of significant bone ingrowth onto the beaded metal end plate surfaces. In each case the implant was removed and an interbody fusion supplemented by pedicle screw fixation and posterolateral grafting was carried out; the progress in both patients has been satisfactory to date. A Pilot 2 patient (Fig. 2) who developed a significant anterior rubber tear 3 years after the initial surgery underwent the same revision procedure at which time a similar granulomatous reaction was encountered. Despite approaching these cases from the opposite side (right retroperitoneal), two of the three anterior revisions with granulomatous adhesions were complicated by tears to the left common iliac vein that were difficult to repair. The other four patients (one Pilot 1, three Pilot 2), one of whom had rubber failure, were managed by posterolateral fusion with pedicle screw and rod fixation without removal of the AcroFlex prosthesis. The preliminary results from the eight revision procedures show a satisfactory result for those done for implant failure but not for those where the sole indication was unremitting pain. Likewise, the out-

come appears to be improved when the implant is removed and converted to an interbody fusion.

Discussion and future directions

There is a close similarity in the data obtained from Pilot 1 and 2 patients that supports assessing the results of the total population for the purposes of analysis. The modification to the design of the prosthesis used in Pilot 1 achieved its objective of making insertion of the implant easier for the Pilot 2 group. Moreover, radiographic evaluation demonstrated improved contact between the bony and metal end plates in Pilot 2 cases with no cases of implant displacement or subsidence. However, in a separate study (Ross ER, unpublished data, 2001) of the Pilot 2 implant in 13 patients carried out in Manchester, UK, there were 7 cases of anterior displacement of implants with revision surgery required in 3 patients within 2 years. These events were attributed to differences in technique, which included the use of a transperitoneal approach and extensive removal of annulus.

Most of the instruments used for measuring outcome demonstrated that significant improvement occurred from baseline to 12 months. In addition, for Pilot 1 patients there

Table 3
Oswestry Disability Index

	All average	Pilot 1 average	Pilot 2 average
ODI percent score*			
At baseline	49.3	51.1	48.2
At 6 months	39.0	38.0	39.7
At 12 months	38.9	39.6	38.4
At 24 months	34.4	28.0	38.5
Average change from baseline†			
At 6 months	−8.4	−11.5	−6.5
At 12 months	−10.5	−11.5	−9.8
At 24 months	−14.8	−23.0	−9.1

There are no statistically significant differences between Pilot 1 and Pilot 2 on the ODI.

ODI=Oswestry Disability Index.

* The ODI measures level of disability on a scale of 0 to 100%, so the larger the value the more disabled.

† Negative changes in ODI indicate improvement.

Table 4
Low Back Outcome Score

	All average	Pilot 1 average	Pilot 2 average
LBO score*			
At baseline	17.7	18.3	17.3
At 12 months	30.4	32.2	29.1
At 24 months	33.0	40.4	28.0
Average change from baseline†			
At 12 months	12.8	13.9	11.9
At 24 months	15.4	22.1	10.8

There are no statistically significant differences between Pilot 1 and Pilot 2 on the LBOS.

LBOS=Low Back Outcome Score.

* The larger the LBOS, the better the subject.

† Positive changes in LBOS indicate improvement.

Table 5
Complications

	All (28)	Pilot 1 (11)	Pilot 2 (17)
Nerve root irritation	2	0	2
Autofusion	1	1	0
Partial anterior disc expulsion	1	1	0
Minor anterior polyolefin tear	7	3	4
Large anterior polyolefin tears	3	2	1
Pulmonary embolus	1	1	0
Retrograde ejaculation	1	0	1

was a significant improvement in outcome from 12 months to 2 years. The lack of improvement in the Pilot 2 cohort after 12 months may have been related to the timing of the written and verbal advice to patients that tears in the polyolefin had been detected in a number of Pilot 1 implants.

The pilot studies were carried out to assess the safety and efficacy of the device, and subject to a satisfactory outcome, the intention was to proceed with a randomized controlled trial comparing AcroFlex Lumbar Disc replacement with interbody fusion. Although the overall clinical results up to 2 years appeared to be satisfactory, the planned randomized controlled trial did not eventuate. The detection on thin section CT scans of cases of mechanical failure in the elastomer demonstrated that the current model was adversely affected by the *in vivo* loads of everyday life. This finding was unexpected given that the device was extensively tested in the laboratory and had easily withstood the range of described normal *in vivo* loads on the lumbar intervertebral disc [13]. However, because of coupled movements, the actual loads on the annulus of the intervertebral disc during activity are likely to be far greater than has been described to date. Clearly, this has important implications for the design of artificial discs. In the case of the AcroFlex prosthesis, it is yet to be established whether a redesign of the internal architecture can overcome this deficiency.

The AcroFlex experience has highlighted two major obstacles to be overcome in the production of a successful artificial disc. The first is the avoidance of wear particle

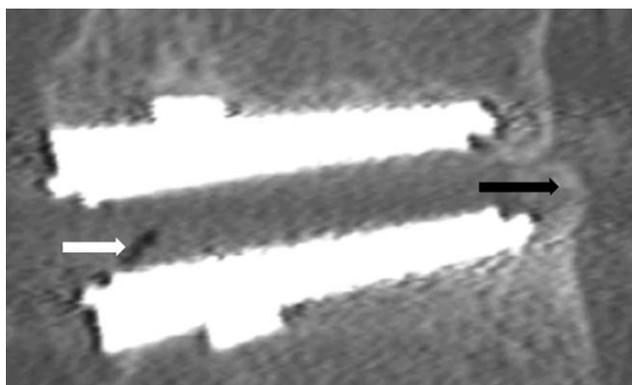


Fig. 3. Polyolefin tear (white arrow) and posterior new bone formation (black arrow) seen on sagittal reconstruction view from multislice computed tomography of L5–S1 AcroFlex (Pilot 1) 2 years after surgery.

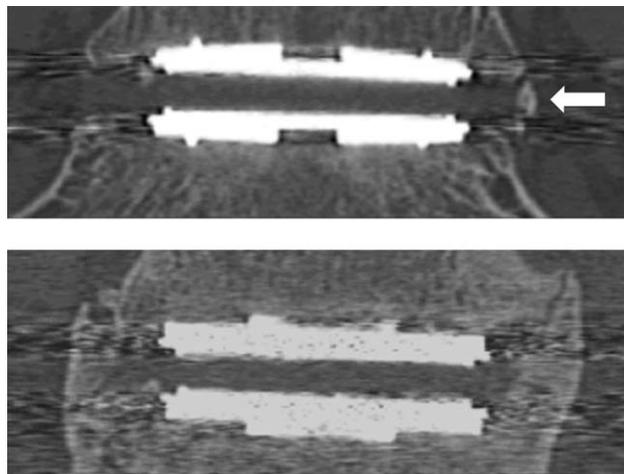


Fig. 4. Coronal reconstruction views from multislice computed tomography 2 years after surgery showing (top) minor ectopic bone (white arrow) around Pilot 2 implant and (bottom) “auto fusion” around Pilot 1 implant.

formation, the reason for revision surgery in four cases in this series. Although there are no published papers on osteolysis from wear particles with articulating disc implants such as Charité and ProDisc, a case of severe osteolysis from polyethylene wear in a Charité prosthesis was recently reported (P Licina, personal communication, 2003). Moreover, the experience with total joint replacement elsewhere in the body suggests it is just a matter of time before more cases of osteolysis are reported with these devices. The early detection of wear particles in the AcroFlex study was made possible by the availability of serial thin section CT with an accuracy of 0.25 mm. It would not have been recognized with commonly used CT scans let alone plane radiographs that are commonly used as the basis for imaging artificial discs.

The second hurdle to overcome in the development of artificial disc replacement is periannular ossification that may lead to autofusion [5]. Although periannular ossification was recognized on plain radiographs in only one case in the pilot studies, its presence was detected with thin section CT in most cases. The concern is that this may lead to progressive stiffening of the motion segment.

The assessment of serial thin section CT scans at 12 monthly intervals (up to 5 years in two patients) suggests that peripheral elastomer failure and periannular ossification, if they occur, develop in the first 12 months and do not necessarily progress after this time. This implies that periannular ossification is a protective response to the instability created by surgery rather than simply a reaction to the presence of a foreign body. In particular, the extensive annulus removal required to insert the prosthesis dramatically reduces resistance of the motion segment to torsion, and until such time as there is bone ingrowth onto the beaded metal end plates, the elastomer is unlikely to restore this important function of the normal motion segment.

The average change in LBOS at 12 months is similar to that reported from our center for a group of 70 patients with discogenic low back pain treated by anterior lumbar interbody fusion [15]. Although total disc replacement has the potential to protect against the development of symptomatic adjacent-level degeneration attributed to fusion, this is yet to be proven. The current Food and Drug Administration Investigational Device Exemption study testing Charité against fusion will not address the issue of protection against adjacent-level degeneration, as the follow-up time is only 2 years. This is far too short an interval given the results of a 10-year magnetic resonance imaging follow-up after anterior lumbar interbody fusion [16] that demonstrated essentially normal adjacent discs in 68% of cases.

Conclusions

- The AcroFlex studies have highlighted the potential problem for disc replacement surgery of wear particles leading to osteolysis, and the need for high-resolution thin section CT in the assessment of patients taking part in the various trials of this developing technology.
- There was a discrepancy between the life expectancy predicted from mechanical testing of the AcroFlex prosthesis and implant life experienced in vivo that can be explained by a failure of standard testing to measure coupled movements. Clearly, this experience highlights the importance of introducing new technology with caution irrespective of the results of bench testing.
- Thin section CT scanning has revealed a higher than expected incidence of periannular ossification that may have an adverse impact on the function of the spinal motion segment after disc replacement.
- Anterior revision surgery, particularly in the presence of granulomatous reaction from wear particles, presents a major challenge for those involved with total disc replacement surgery.
- Despite these concerns, the pilot studies with the AcroFlex prosthesis have demonstrated sufficient improvement in patient outcome to support the development

and careful clinical trialing of artificial disc replacement devices.

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