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Ten-year survival and clinical outcome of the AcroFlex lumbar disc replacement for the treatment of symptomatic disc degeneration

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Abstract

BACKGROUND CONTEXT: We have previously reported on the osseointegration, stability, and preserved motion of the AcroFlex lumbar disc replacement (LDR) in a nonhuman primate model. Detailed biomechanical testing of the device predicted implant survival for at least 10 years of in vivo use. Significant improvements in the clinical outcome were reported at 2 years. However, mechanical failure of the polyolefin rubber was detected by fine-cut computed tomography (CT) in a number of subjects within 2 years. As a result, no further devices were implanted.

PURPOSE: To report on the 10-year survival and clinical outcome of the AcroFlex elastomeric LDR when used for the treatment of one- or two-level symptomatic disc degeneration between L4 and S1.

STUDY DESIGN: Prospective nonrandomized clinical trial with a mean 10-year follow-up.

PATIENT SAMPLE: Twenty-eight patients with symptomatic disc degeneration who underwent AcroFlex LDR at *one or two* levels.

OUTCOME MEASURES: *Clinical:* Visual Analog Score for back pain, Oswestry Disability Index (ODI), Low Back Outcome Score (LBOS), and Short Form-36 (SF-36). *Survival:* Kaplan-Meier analysis over 10 years with *first revision surgery* as the end point. *Radiographic:* Dynamic flexion/extension radiographs at 2 years. Magnetic resonance imaging (MRI) and CT scans at 10 years.

METHODS: Twenty-eight subjects (14 male, mean age 41 years) with symptomatic disc degeneration unresponsive to nonsurgical treatment were enrolled into a prospective nonrandomized trial of the AcroFlex LDR. Visual analog score for back pain, ODI, LBOS, and SF-36 questionnaires were administered preoperatively at 6 months, 1, 2, and 10 years after the index procedure. All subjects were invited to undergo an MRI and for those with the device remaining in situ, a lumbar CT scan. Kaplan-Meier survival analysis was performed with *first revision surgery* as the end point.

RESULTS: At a mean of 9 years, 8 months (range, 8 years, 8 months–11 years, 3 months) after surgery, 17 of 28 patients did not require a revision surgery, representing a cumulative survival of 60.7%. In contrast, 11 of 28 patients (39.3%) underwent a total of 14 revision procedures; 9 of 11 patients underwent a conversion to anterior lumbar interbody fusion supplemented with pedicle screw fixation. Indications for a revision included device failure in seven and disabling pain in four patients. Mean time to revision was 3 years, 10 months (range, 23 months–8 years, 4 months). Mean

FDA drug/device status: Investigational and not approved for this indication (AcroFlex artificial disc [lumbar]).

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ODI at 10 years for *nonrevision* cases was 27.5 (±17.6) compared with 41.8 (±26) for *revision* cases. Mean improvement over 10 years in the ODI for *nonrevision cases* was 17.9 (±16.9) compared with 12 (±16.1) for *revision* cases. Similar trends were observed in LBOS and SF-36 scores. Radiographic findings in the *revision* group included midsubstance tears in the rubber, osteolysis, and implant displacement. CT findings in 11 of 17 *survivors* included heterotopic bone formation (85%), osteolysis (50%), and subsidence (14%). Magnetic resonance imaging in 14 of 23 subjects at the final follow-up demonstrated an *adjacent-level disc degeneration* in 68% of those with the AcroFlex LDR in situ and in 40% of those who had been converted to fusion. Skip-level disc degeneration was present in 44% of those with AcroFlex device in situ and in 20% of those who had been converted to fusion.

CONCLUSIONS: The cumulative survival was 60.7% at 10 years when the *first revision surgery* was taken as the end point. The etiology of the implant failure prompting the revision included failure of osseointegration, midsubstance elastomeric tears, and osteolysis. Further use of this implant is not justified. The incidence of adjacent-level disc degeneration for the AcroFlex was comparable with that observed adjacent to the spinal fusion. Salvage procedures involving conversion to spinal fusion are technically demanding, but appear to improve outcomes modestly. © 2013 Elsevier Inc. All rights reserved.

Keywords: Lumbar disc replacement; Artificial disc; Elastomeric total disc replacement; Clinical outcomes; Radiological outcomes

Introduction

Although there is some evidence that spinal fusion may be successful in relieving pain [1], it clearly does not replicate the normal kinematics of the motion segment. Some would argue that creating a stiff segment in the spine creates abnormal stresses, which predispose to adjacent-level disc degeneration [2].

Artificial disc replacements have been under development for more than 25 years with the express aim of producing pain-free motion for the treatment of symptomatic disc degeneration, in contrast to the spinal fusion, which seeks to *abolish* painful motion. Existing artificial discs act as low-friction devices with articulating surfaces, which are either metal-on-polyethylene or metal-on-metal [3]. Randomized controlled trials comparing these devices with lumbar fusion have shown outcomes after disc replacement to be at least *equivalent* to those observed after spinal fusion [4–6]. Although such devices allow controlled motion, they do not replicate the *elasticity* of the normal human intervertebral disc. This has led to the emergence of the next generation of disc replacement: the compliant artificial disc; the forerunner of which was the AcroFlex lumbar disc replacement (LDR) (DePuy-AcroMed, Inc., Raynham, MA, USA).

The AcroFlex LDR comprises two titanium end plates bound together by a hexene-based polyolefin rubber core. The device allows six degrees-of-freedom segmental motion, with translations and rotations about the three independent axes, theoretically reducing stress concentrations. In short, the device mimics physiological levels of shock absorption and flexural stiffness. An earlier version of the device was implanted in six patients between 1988 and 1989. Four of six patients had satisfactory results with an average follow-up of 3.4 years after surgery [7,8].

A number of preclinical studies were carried out on the most recent version of the AcroFlex LDR: Serhan et al. [9] used 120 discs to characterize the range of motion (stiffness) in axial compression, torsion, and shear of the device. The device replicated many of the physiological characteristics of the in vivo functional spinal unit. Quasi-static testing showed that the device is able to withstand more than 47,000 N in compression, more than 14 mm in compressive-shear, and more than 60° in torsional shear. Fatigue and durability testing showed the smallest device (worse case scenario) *endurance limit* to exceed 3,400 N compression and more than 5 mm of compressive shear translation out to 10 million cycles. In short, the study demonstrated that the failure modes of the device contained *sufficient safety margins* to support the use of the device in a clinical trial.

Moore et al. [10] tested the proprietary polyolefin rubber compound in vitro in two animal models. Laboratory-generated polyolefin rubber particles were injected into either the dorsal subcutaneous air pouches of 30 rats or placed directly onto the lumbosacral dura and nerve roots of nine sheep. Histologic section of the tissues from, and remote from, the site of implantation were examined for evidence of inflammation and wound-healing responses. The polyolefin rubber particles induced only localized tissue responses that were consistent with a normal foreign body reaction to large nontoxic particles. There was no evidence of particle migration from the site of implantation and no evidence of local or systemic toxic effects.

Cunningham et al. [11] investigated the biocompatibility, osseointegration, and multidirectional flexibility of the AcroFlex device at 6 and 12 months postimplantation in a nonhuman primate model using 20 animals. No significant pathological changes were evident at either time point. Plain radiographs showed no evidence of radiolucency or loosening of any prosthetic vertebral end plate. Histomorphometric analysis demonstrated an excellent

ingrowth at the implant-bone interface. One animal was noted to have an extravasation of the polyolefin core considered secondary to the insufficient curing of the core. All other devices remained intact.

Fraser et al. [12] reported the early results of a prospective clinical study involving 28 patients with symptomatic disc degeneration in whom the AcroFlex prosthesis was placed at one *or* two levels (L4/L5 and/or L5/S1). Although clinical outcomes of the pilot studies were successful, fine-cut computed tomography (CT) detected mechanical failure of the elastomer in 10 of 28 (35.7%) subjects. As a result, no further devices were implanted beyond December 2000 [12]. This article reports on the 10-year survival and ultimate clinical outcome of the initial 28 patients.

Materials and methods

This study was a prospective single device, single surgeon independent clinical and radiological follow-up of 28 patients who received the AcroFlex LDR for the treatment of one- or two-level symptomatic disc degeneration between April 1998 and 2000. Research and Ethics Committee approval was obtained before the commencement of the study.

All cases had a comprehensive trial of conservative treatment including pain management and physical therapy aimed at strengthening the core muscles before consideration of the index surgery. The inclusion and exclusion criteria for the study are listed in Figs. 1 and 2, respectively.

The first 11 patients (Pilot 1) received the AcroFlex implant with flat end plates (Fig. 3, Top) in April 1998. To improve the fit within the disc space and the ease of insertion, the metal end plates were modified and the next 17 patients (Pilot 2) received one or two AcroFlex implant(s) with contoured end plates in February 2000 (Fig. 3, Bottom).

The surgical technique for the insertion of the AcroFlex LDR used a left-sided, direct anterior retroperitoneal approach through a 5–7.5 cm transverse skin incision. A detailed description of the procedure has been previously published [12].

Both clinical and radiological outcomes were assessed. Clinical outcomes were assessed using the following validated questionnaires; Visual Analog Score for back pain, Oswestry Disability Index (ODI), Low Back Outcome Score (LBOS), and Short Form-36 (SF-36) at the following time points; preoperatively, 6 months, 1, 2, and 10 years after the index procedure. The clinical results at 2 years have been reported [12]. Complications arising from the index surgery and any subsequent revision surgeries were

EVIDENCE & METHODS

Context
Many different disc and nucleus replacement technologies have been developed, with some having been abandoned. There are few independent long-term outcome studies of previously promising devices. The authors present their 10-year outcomes with AcroFlex lumbar disc replacement.

Contribution
The revision rate was nearly 40% due to device failure or severe pain. Revision surgeries resulted in only moderate symptom or functional improvement. The authors concluded further use of the implant is not justified.

Implication
Metal-on-metal hip replacements were used widely in the early 1970s, only to be abandoned due to high failure rates. Yet the technology was resurrected in the 2000s under the assumption that brighter minds, better materials, alternative techniques, and newer technologies had overcome the previous generation's problems. However, widespread failure and patient morbidity had again followed. In the spine, we should be wary of so-called new and improved technologies that are being advocated for a second go-around. As clinicians, prior to adopting new technologies with theoretical advantages, we should know our own history. This study is a must-read in considering any new and unproven disc replacement technologies in order to avoid making the same mistakes twice.

—The Editors

1. One or two levels (Pilot 2 only) of symptomatic disc degeneration at the L4-L5 or L5-S1 level(s).
2. Disabling low back pain with or without associated referral type leg symptoms, refractory to conservative nonsurgical treatment for a minimum of 6 months prior to enrolment in the study.
3. 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.
4. Male and female patients between the ages of 30 and 55 years of age.
5. The patient must voluntarily sign a patient informed consent form.
6. 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.

Fig. 1. Inclusion criteria.

1. Previous lumbar surgery with the exception of discectomy and chemonucleolysis at the target level.
2. A lumbosacral angle at the target level that is too steep to allow adequate access by a direct anterior approach.
3. Significant central or lateral recess spinal stenosis.
4. Spondylolisthesis
5. Systemic disease that would impact on the ability to assess the patient's condition relative to the spine surgery during the follow-up period.
6. Morbid obesity to the extent that disc-replacement surgery using the anterior approach is not technically feasible or advisable.
7. Alcohol and/or drug abuse
8. The presence of three or more positive Waddell's signs.
9. Structural scoliosis.
10. 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.
11. Current involvement in litigation related to the spinal condition or involvement in pursuing legal action related to the spinal condition.

Fig. 2. Exclusion criteria.

recorded for all the subjects over the study period. For subjects undergoing revision procedures in which the AcroFlex device was explanted, specimens were taken and sent for histologic examination.

Radiological assessment for all subjects at 2 years included lateral radiographs of the lumbar spine in flexion and extension to assess the range of motion at the level of interest (Fig. 4, Left and Right). At 10 years, a repeat magnetic resonance imaging (MRI) scan (T1 and T2 sagittal and T1 and T2 axial) of the lumbar spine was carried out for those patients with the device remaining in situ, and a fine-cut CT scan was performed through the level of the retained AcroFlex devices. The justification for the fine-cut CT scan was the previous detection of an elastomeric failure in 36% of patients at 2 years [12].

Fig. 3. The AcroFlex implants used for (Top) Pilot 1 and (Bottom) Pilot 2 studies (with permission Fraser RD et al. [12]).

All radiological images were reviewed by an experienced consultant radiologist. The extent of disc degeneration in the nonoperated lumbar discs was assessed by an MRI using a previously validated assessment [13]. Each disc was examined for signal intensity (normal, reduced, or absent), morphologic appearance of the posterior annulus (flat, bulging, contained herniation, or extruded nucleus pulposus), and the presence of spinal stenosis (mild, moderate, or severe). The presence of *any* abnormality was defined as disc degeneration. Advanced disc degeneration was considered if the signal intensity was absent or there was disc herniation or extrusion, spinal stenosis, or subsequent surgery at that level.

CT scans were examined for the presence of an implant failure, heterotopic bone formation, osteolysis, and an implant subsidence (graded as none, mild, moderate, severe) at the index level(s).

Statistical analysis

Statistical analysis was completed using the GraphPad software version 5.04 for Windows (GraphPad Software, Inc., San Diego, CA, USA). Continuous variables were summarized using mean values (range), mean improvements, and percentages. Statistical significance was set at $p<.5$.

The Kaplan-Meier method was used to display the survival probability of the subject remaining free of any revision procedure over the course of the study. The mean length of time for subjects to reach the end point of interest (first revision surgery) was recorded

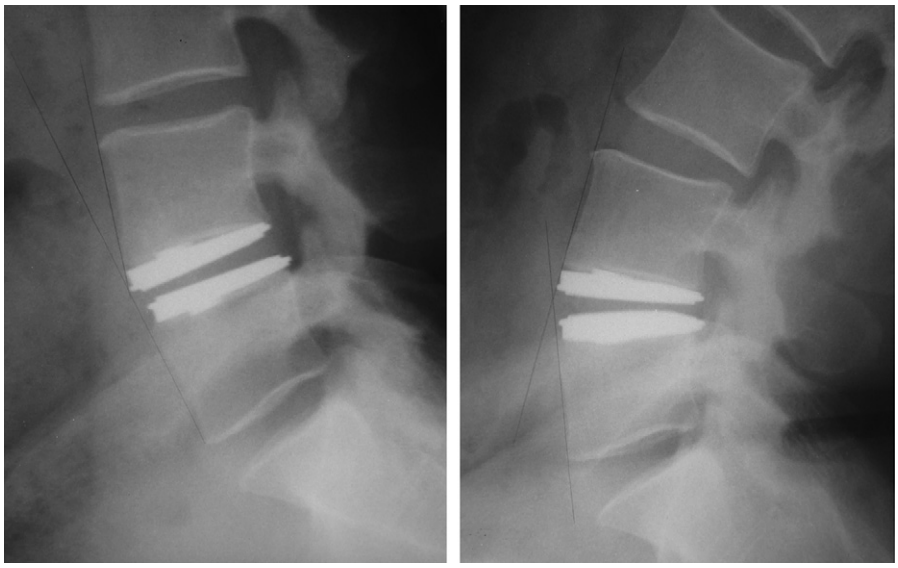

Fig. 4. (Left) Lateral flexion radiograph and (Right) Lateral extension radiograph at 24 months. Thirty-seven-year old woman with AcroFlex (Pilot 1) total disc replacement at L4/L5. Arc of motion at L4/L5=10°. Note the increase in the posterior disc height in flexion.

for those subjects undergoing the first revision procedure within 10 years.

For those subjects who were lost to the follow-up, missing data was imputed from the last observation carried forward.

Results

Demographics

The mean age at the time of surgery was 41 years (range, 30–54 years). There were 14 male and 14 female subjects. Seven of 28 (25%) subjects had previously undergone partial discectomy at the index level. The mean duration of back pain was 33 months (range, 9–120 months). Other baseline demographic data are shown in Table 1.

Thirty-two AcroFlex devices were implanted in 28 subjects (24 subjects underwent a single-level disc replacement and four subjects underwent a two-level disc replacement). For the primary LDR procedure, the mean operation time was 130 minutes (range, 75–195 minutes), the mean estimated blood loss was 178 mL (15–1,500 mL), and the mean length of hospital stay was 6.1 days (range, 2–16 days).

The mean follow-up period was 9 years, 8 months (range, 8 years, 8 months–11 years, 3 months). Long-term clinical follow-up was available for 23 of 28 subjects. Two subjects were lost to the follow-up having moved with no forwarding address available. A further two refused the ongoing involvement despite two telephone requests and one failed to return a complete set of outcome questionnaires.

Table 1
Baseline demographic data, Pilot 1, and Pilot 2

	All N (%)	Pilot 1 n (%)	Pilot 2 n (%)
Study N	28 (100)	11 (39)	17 (61)
Male	14 (50)	7 (64)	7 (41)
Working status			
Not working	14 (50)	6 (55)	8 (47)
Student/housewife/retired	2 (7)	0 (0)	2 (12)
Current smoker	11 (39)	5 (46)	6 (35)
Workers compensation or litigation	15 (54)	5 (46)	10 (59)
No other general medical conditions	11 (39)	4 (36)	7 (41)
Previous disc surgery	7 (25)	1 (9)	6 (36)
Previous chemonucleolysis	1 (4)	1 (9)	0 (0)
Previous treatments	4 (14)	1 (9)	3 (18)
	Mean (range)	Mean (range)	Mean (range)
Age at the time of surgery (y)	41 (30–54)	41 (32–53)	41 (30–54)
Body mass index (kg/m^2)	28 (18–42)	29 (24–41)	27 (18–42)
Duration of back pain (mo)	33 (9–120)	32 (12–84)	34 (9–120)

Table 2
Mean ODI at the baseline and various time points out to 10 years for all subjects, Pilot 1, and Pilot 2

	All (N=28)	Pilot 1 (n=11)	Pilot 2 (n=17)
Mean ODI percentage score (1)			
At baseline	49.3	51.1	48.2
At 6 mo	39.0	38.0	39.7
At 12 mo	38.9	39.6	38.4
At 24 mo	34.4	28.0	38.5
At 10 y	33.7	28.9	37.5
Mean change in ODI percentage score from the baseline (2)			
At 6 mo	−8.4	−11.5	−6.5
At 12 mo	−10.5	−11.5	−9.8
At 24 mo	−14.8	−23.0	−9.1
At 10 y	−15.6	−22.2	−10.7

ODI, Oswestry Disability Index; LBOS, Low Back Outcome Score.
The ODI measures the level of disability on a scale of 0% to 100%. The higher the value the greater the disability.
Negative change in the ODI indicates improvement.
There are no statistically significant baseline differences in LBOS between Pilot 1 and Pilot 2.

Table 3
Mean LBOS at the baseline and various time points out to 10 years for all subjects, Pilot 1, and Pilot 2

	All (N=28)	Pilot 1 (n=11)	Pilot 2 (n=17)
Mean LBOS (1)			
At baseline	17.7	18.3	17.3
At 12 mo	30.4	32.2	29.1
At 24 mo	33.0	40.4	28.0
At 10 y	36.4	43.7	30.8
Change from the baseline (mean) (2)			
At 12 mo	12.8	13.9	11.9
At 24 mo	22.1	22.1	10.1
At 10 y	18.7	25.4	13.5

LBOS, Low Back Outcome Score.
The larger the LBOS, the better the subject.
Positive changes in LBOS indicate improvement.
There are no statistically significant baseline differences in LBOS between Pilot 1 and Pilot 2.

Clinical outcomes

At 10 years, the mean improvement for the whole cohort in ODI was 15.6 points (Table 2), in LBOS was 18.7 points (Table 3), and in the physical component score of the SF-36 was 10.9 points.

Subjects who received the Pilot 1 implant did marginally better in terms of ODI and LBOS than those who received the Pilot 2 implant: The mean improvement in the ODI after 10 years was 22.2 points for Pilot 1 compared with 10.7 points for Pilot 2. The mean improvement in LBOS after 10 years was 25.4 points for Pilot 1 compared with 13.5 points for Pilot 2.

Revision procedures

A total of 11 of 28 (39.3%) subjects required revision procedures within 10 years of the index surgery. The indication for a revision surgery was an implant failure in seven and ongoing disabling pain in four subjects. Disabling pain was defined as that having a significant impact on the quality of life and one where the patient was not prepared to continue with the current situation. Disabling pain was attributed to the failure of the device to osseointegrate in two, facet joint arthropathy in one, and no obvious cause in one.

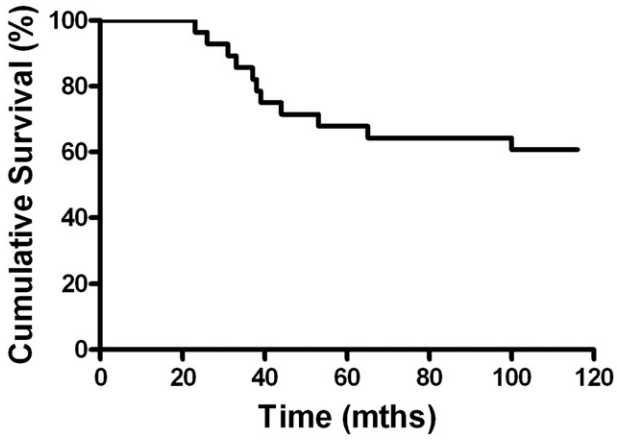

Fig. 5. Kaplan-Meier survival analysis of the AcroFlex 1 lumbar disc replacement with *first revision procedure* as the end point (N=28).

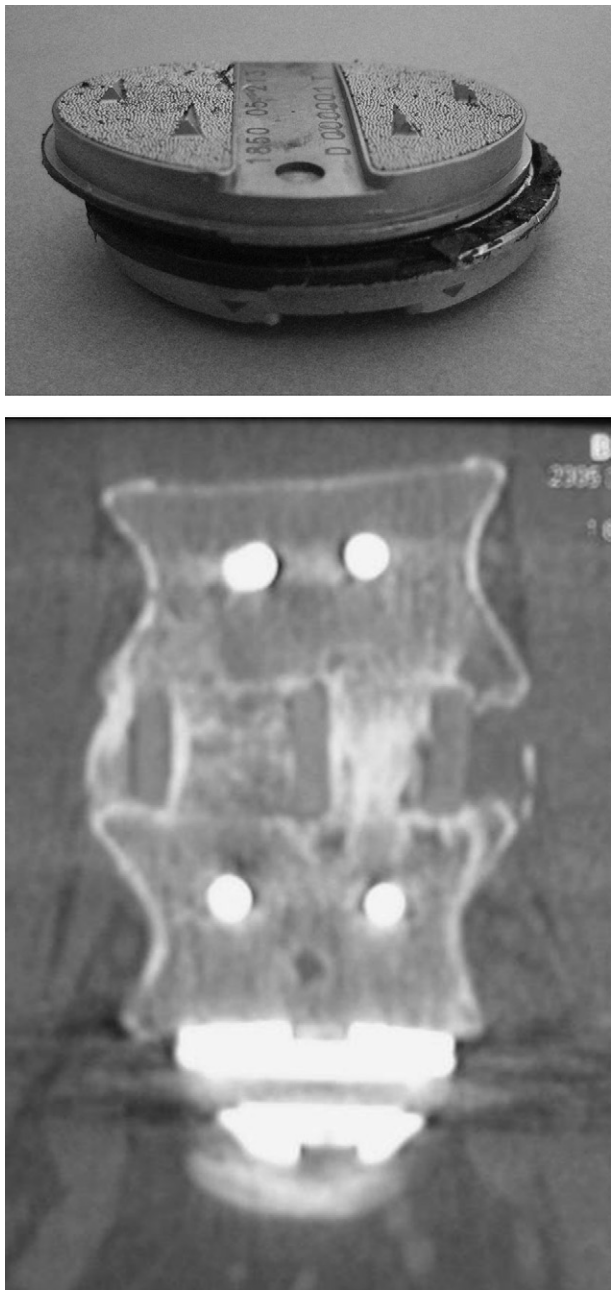

Fig. 6. Catastrophic failure of the AcroFlex lumbar disc replacement (LDR) at L4/L5 revised initially to instrumented posterolateral fusion. However, progressive osteolysis adjacent to the implant prompted removal of the device (Top) and conversion to anterior lumbar interbody fusion with a carbon-fiber cage. Coronal and sagittal computed tomography scan (Bottom) with solid arthrodesis at L4/L5. Note intact AcroFlex LDR at L5/S1.

The mean time to the first revision procedure was 3 years and 10 months (range, 23 months–8 years, 4 months). A Kaplan-Meier survival analysis taking the *first revision procedure* as the end point is shown in Fig. 5. The

Table 4
Final clinical outcomes (mean absolute values) at 10 years and change in the clinical outcome measures preindex procedure to the final outcome, stratified into no revision and revision categories

	All cases (N=23)	No revision (n=14/23)	Revision (n=9/23)
Final ODI (mean absolute value)		27.5±17.6	41.8+22.6
Final LBOS (mean absolute value)		41.8+18.4	29.3+19.5
Final SF-36 PHC (mean absolute value)		40.2+11.2	34.8+11.1
SF-36 MHC (mean absolute value)		45.3+14.9	44+14.9
Change in the ODI	−15.6±16.5	−17.9±16.9	−12±16.1
Change in LBOS	+18.05±15.3	+21.6±16.4	+12.5±12.0
Change in SF-36 (PHC)	+10.9±11.5	+13.2±11.4	+7.3±11.4

ODI, Oswestry Disability Index; LBOS, Low Back Outcome Score; SF-36, Short Form-36; PHC, physical health component; MHC, mental health component.

Final clinical outcomes at 10 years were available for 23 of 28 subjects.

cumulative survival of the AcroFlex LDR over 10 years was 60.7%.

Eleven of 28 subjects (39.3%) had a total of 14 revision procedures; 4 of 11 subjects had an instrumented posterolateral fusion without the removal of the implant initially. Two of these four proceeded to the subsequent removal of the implant and conversion to a circumferential fusion. A further seven subjects underwent the removal of the Acroflex LDR and conversion to anterior lumbar interbody fusion supplemented with pedicle screw fixation.

Instrumented posterolateral fusion as a revision strategy for failed disc replacement was found to be safe, but not particularly effective. In the four cases there were no intraoperative complications; however, one subject developed a postoperative deep venous thrombosis requiring anticoagulation. Only one of these four subjects was definitely improved by the surgery.

Nine prostheses were removed; seven at the initial revision procedure and two after a failed instrumented posterolateral fusion. This was a difficult surgery. A *right*-sided retroperitoneal approach was used. In six of these nine cases, catastrophic failure of the device was noted (Fig. 6) with particulate debris and an intense granulomatous reaction encasing the left common iliac vein. In three of these cases, a tear of the left common iliac vein occurred that was primarily repaired. The mean blood loss in this subgroup was 500 mL (range, 350 mL–2.3 L). Other operative findings included osteolysis, polyolefin rubber failure, and no evidence of bony ingrowth on the titanium end plates of the implant. Histologic analysis of the granulomatous tissue revealed rubber particles in 85% of cases with an osteoclast activation in 29% of samples.

The revision rate for Pilot 1 subjects was higher at 45% (5/11) compared with 35% (6/17) for the Pilot 2 subjects. This may have been a result of the design change from the flat end plates of the device used in Pilot 1 to the contoured end plates used in Pilot 2. The revision rate was higher for male subjects (42.9%, 6/14) compared with the female subjects (35.7%, 5/14). The revision rate was higher at the L5/S1 level (42%, 10/24 disc replacement levels) compared with the L4/L5 level (25%, 2/8 disc replacement levels). The revision rate for the subjects undergoing single-level disc replacement was higher at 41.6% (10 of 24) compared with 25% (1 of 4) for subjects undergoing two-level disc replacement.

Although all subjects improved in terms of ODI, LBOS, and SF-36 physical component score over the duration of the study, disability as measured by the ODI at 10 years was *higher* for those subjects who had undergone *revision procedures*. Mean ODI at 10 years was 41.8 (±26) for revision cases compared with 27.5 (±17.6) for nonrevision cases. Mean improvement over 10 years in the ODI for the revision cases was 12 (±16.1) compared with 17.9 (±16.9) for the nonrevision cases (Table 4). Similar trends were observed in LBOS and SF-36 scores with the subjects undergoing *revision* achieving *less* significant improvements than the *nonrevision* subjects. Although revision surgery is possible as a salvage procedure, the outcomes

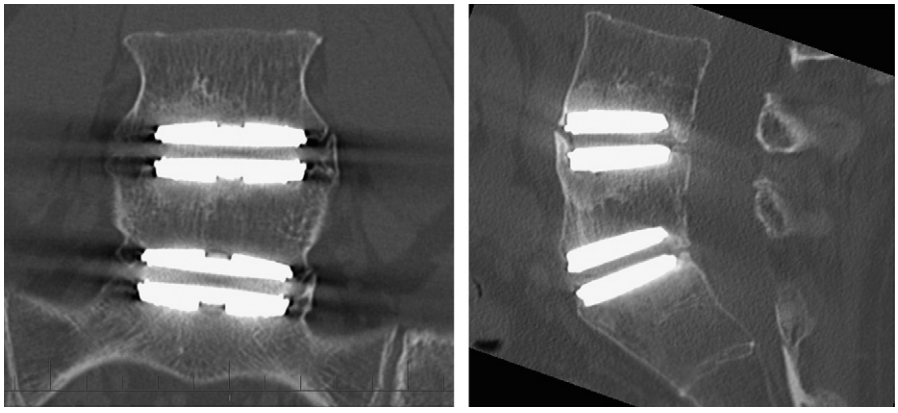

Fig. 7. (Left) Coronal and (Right) sagittal computed tomography scans from one 48-year-old male (Pilot 2) with a two-level AcroFlex lumbar disc replacement in situ. Note the extensive heterotopic bone formation (white arrows) at both levels.

clearly remained inferior when compared with those patients who did not require a revision.

Radiological outcomes

Lateral flexion-extension radiographs of the lumbar spine demonstrated a mean arc of motion of 6.4° preoperatively, reducing to a mean of 3.3° at 12 months and increasing to a mean of 6.6° at 24 months at the operated level(s) (Fig. 4, Left and Right). The mean anterior native disc height measured 14.9 mm preoperatively, increasing to a mean of 20.7 mm at 12 months and reducing to a mean of 16.9 mm at 24 months at the operated level(s). The mean posterior native disc height measured 3.3 mm preoperatively, increasing to a mean of 8.2 mm at 12 months and reducing to a mean of 7.1 mm at 24 months at the operated level(s). Radiographic findings in the *revision* group (n=11) at a mean of 3 years, 10 months (range, 23 months–8 years, 4 months) included midsubstance tears in the rubber in 63.7% (7/11), osteolysis in 27% (3/11), and end plate radiolucency/subsidence in 45.4% (5/11).

CT scans were available at the 10-year follow-up for 11 of 17 (65%) *nonrevision cases* through 14 AcroFlex LDR levels. Heterotopic bone formation was evident in 85.7% (12/14) disc levels and regarded as ''severe'' (probably equivalent to a fusion) in 50% (7/14) levels (Fig. 7, Left and Right). Osteolysis was present in 50% (7/14) of disc levels and regarded as ''severe'' (extending across more that 50% of the end plate) in 28.6% (4/14) levels. Subsidence was noted in 14.3% (2/14) disc levels. Only 14.3% (2/14) of the retained discs showed no evidence of heterotopic bone formation, osteolysis, or subsidence.

From the 23 subjects contacted 10 years after their index surgery, 14 agreed to undergo a repeat MRI scan of the lumbar spine; 9 *survivors* with the AcroFlex device(s) in situ and 5 *revision cases* that had been converted to spinal fusion. For those subjects with the AcroFlex device in situ, 67% (6/9) had the evidence of adjacent-level disc degeneration and 44% (4/9) had the evidence of ''skip'' disc degeneration. For those subjects that had been converted to spinal fusion, 40% (2/5) had the evidence of adjacent-level disc degeneration and 20% (1/5) had the evidence of ''skip'' disc degeneration.

Discussion

This detailed study represents an independent long-term follow-up of the original elastomeric AcroFlex LDR carried out for the treatment of symptomatic disc degeneration by a single surgeon. Detailed preclinical and biomechanical testing predicted implant survival for at least 10 years of in vivo use. Early clinical results were encouraging. The timely detection of mechanical failure once in clinical use, however, led to the prompt cessation of further device implantation.

The cumulative survival of the AcroFlex LDR at 5 years was 67.9% and at 10 years was 60.7%, using *first revision procedure* as the end point for the Kaplan-Meier survival analysis. It is clear that the revision rates at the index level of 32.1% at 5 years and 39.3% at 10 years are not acceptable.

Low-friction disc replacements by comparison have been reported with revision rates of 7.5% at 6.6 years [14], 7.7% (7/90) at five years [4], and up to 25% by others using the Charite artificial disc (DePuy Spine, Raynham, MA, USA) [15–17]. Short-term follow-up studies of the ProDisc-L (Synthes Spine, Westchester, PA, USA) disc replacement have reported revision rates of 3.7% (6/161) within 2 years [5]. The FlexiCore disc replacement (Stryker Spine, Allendale, NJ, USA) is a metal-on-metal device with reported reoperation rates of 4.5% (2/44) within 2 years where reoperation was defined as the surgery to remove or replace the FlexiCore device and/or provide supplemental instrumentation [6]. However the *overall* reoperation rate in this series was 18.1% (8/44) at 2 years.

Complications rising from total disc replacement may be related to the *surgical approach* (eg, vascular injury, nerve root damage, and retrograde ejaculation) and range from 2.1% to 18.7%; to the *prosthesis* (eg, subsidence, migration, implant displacement, implant failure, and end plate fracture) and range from 2% to 39.3%; and to the *treatment* (eg, wound and ongoing pain) ranging from 1.9 to 62% [18]. Reoperations at the index level in this literature review occurred in 1% to 28.6% of cases [18].

In the case of the AcroFlex disc replacement, reoperations at the index level were because of the device failure in seven and disabling pain in four, with the mean time to revision of 3 years and 10 months. Revision surgery revealed midsubstance delamination with the release of rubber particles, extensive osteolysis, and little or no osseointegration across the end plate.

Serhan et al. [9] carried out fatigue and durability testing of AcroFlex LDR and demonstrated the *endurance limit* to exceed 3,400 N compression and more than 5 mm of compressive shear translation out to 10 million cycles. This protocol predicted a device survival of more than 10 years, and yet a high number of the AcroFlex devices in clinical use had failed within this period. With hindsight, perhaps a biomechanical testing protocol that involved *coupled* motion in combination with the cyclic loading out to 15 million cycles (equivalent to 10–15 years of normal use) would have been a more rigorous protocol to detect device failure.

Furthermore, biomechanical testing in isolation cannot take into account the interaction between the device and the biological responses from the host. It is not clear whether rubber particles stimulated the osteoclastic activity and subsequent osteolysis. The biological response to rubber particles was investigated in the preclinical studies and demonstrated a normal foreign body reaction *without* the evidence of particle migration. However the effect of rubber particles on bone was not specifically tested. We postulate that the lack of bony ingrowth at the bone-implant

interface allowed the rubber particles to access this interface with the subsequent development of osteolysis. The baboon study demonstrated osseointegration; however, the devices were undersized and a number of motion segments fused spontaneously encasing the device with probable limited segmental motion.

It is often argued that preserving motion will reduce the risk of adjacent-level disc degeneration. Although the numbers are small in this study, there was no evidence that the AcroFlex disc replacement reduced the risk of adjacent-level disc degeneration when compared with those cases that had been revised to spinal fusion. Perhaps, the most potent driver of disc degeneration is genetic susceptibility and not a stiffened segment?

As the quest for truly viscoelastic devices continues [19,20] it is clear that there is a need to explore new materials that are both safe and robust through thorough biomechanical evaluation, in vivo animal models with longer term follow-up, and a need for careful consideration of translating animal model findings to the human spine [3]. Similarly, the onus falls onto the responsible clinician to provide meticulous radiological and clinical follow-ups of such cohorts and to accurately report complications and index-level revision surgery.

Key points

- The cumulative survival of the AcroFlex lumbar disc replacement over a mean of 9 years, 8 months using *first revision* as the end point was 60.7%.
- Detailed preclinical and biomechanical testing *did not* predict device failure.
- The mean time to the first revision was 3 years, 10 months, with an overall revision rate of 39.3% (11 of 28 subjects) at 10 years.
- Indications for a revision surgery included device failure in seven and disabling pain in four subjects.
- Revision surgery, although difficult, resulted in improvements in the levels of disability and physical function.
- The AcroFlex lumbar disc replacement did not protect against an adjacent-level disc degeneration when compared with those subjects who underwent fusion.

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