Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial

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Object. A prospective, randomized clinical trial was conducted to compare the Prestige II Cervical Disc with anterior decompression and fusion for the treatment of single-level degenerative disease. Standardized clinical outcome measures and radiographic examinations were used at prescribed postoperative intervals to compare the treatment groups.

Methods. Patients with symptomatic single-level cervical disc disease who met the inclusion/exclusion criteria defined in the protocol were randomized to receive the Prestige II disc or iliac crest autograft fusion. All patients underwent a standardized neurological and radiographic examination and completed outcomes questionnaires (Neck Disability Index and Short Form–36) preoperatively and at each postoperative interval (6 weeks and 3, 6, 12, and 24 months). Two independent radiologists reviewed all x-ray films and assessed motion at the treated level and adjacent segments. Standard statistical methods were used to compare all outcome measures.

Preliminary results in 55 patients enrolled in the study are presented. Several patients have reached the final (24-month) follow-up interval. Clinical and radiographic results are encouraging, with significant improvement seen in both treatment groups. Radiographic results show that the Prestige II disc maintains motion at the treated level without adjacent-segment compromise.

Conclusions. Cervical spine arthroplasty is an exciting and rapidly developing surgical treatment option. An objective comparison with fusion is important to advance this option. This is the first prospective randomized trial in which cervical arthroplasty is compared with fusion. The preliminary results from this limited number of patients indicate that the Prestige II disc is potentially a viable alternative to fusion for primary cervical disc disease; however, further clinical studies with larger sample sizes will be required to show statistical equivalence.

Key Words • cervical disc herniation • cervical arthroplasty • arthrodesis • spondylosis

Cervical arthroplasty is an exciting and rapidly advancing treatment option for spine surgeons. The rationale behind motion-sparing spinal implants is based primarily on the growing evidence that spinal fusion may contribute to adjacent-segment degeneration. For example, Hilibrand, et al.6 reported adjacent-segment disease in approximately 25% of patients with single-level ACDFs 10 years after the initial procedure.

In a radiographic study, Wigfield, et al.10 reported significantly increased motion at levels adjacent to an anterior or cervical fusion when compared with segments adjacent to a level treated with the Prestige Cervical Disc System. In a biomechanical cadaveric study, DiAngelo, et al.2 reported statistically significant differences in motion seen at levels adjacent to a simulated fusion when compared with intact specimens and those implanted with the Prestige artificial cervical disc.

Goffin and coauthors15 investigated radiological evidence of new or progressive adjacent-segment spondylotic 5 years after anterior fusion. They found evidence of spondylotic progression in 92% of their 180 patients, with a correlation between the radiological findings and clinical deterioration. Most recently, Kulkarni, et al.,7 reported a magnetic resonance imaging short-term follow-up study conducted after cervical corpectomy and fusion. Accelerated spondylotic changes adjacent to the fused segment were recognized in 75% of the 44 patients studied.

Prior to scientifically conducted investigations such as these, many spine surgeons theorized about the effects of fusion on adjacent-segment disease based on their own clinical experience. For decades, surgical procedures have been refined to facilitate anterior decompression of the cervical spinal cord and the exiting nerve roots, and these procedures became the mainstay of surgical treatment of cervical disease. Nevertheless, it was also recognized that after a simple anterior cervical discectomy, a spontaneous

Abbreviations used in this paper: ACDA = anterior cervical discectomy and arthroplasty; ACDF = anterior cervical discectomy and fusion; AP = anteroposterior; DDD = degenerative disc disease; NDI = Neck Disability Index; SF-36 = Short Form–36; VAS = visual analog scale; VB = vertebral body.
fusion of the treated segment can appear in up to 90% of cases. To prevent cervical kyphosis after discectomy, primary stabilization procedures became more important to maintain the sagittal balance of the cervical spine. Many treatment options now exist for internal fixation of the cervical spine; these range from traditional bone grafting with a tricortical iliac crest autograft to allografts or synthetic spacers filled with autograft or recombinant human bone morphogenetic protein—2.

The clinical outcome after an anterior cervical decompression and fusion procedure for either a cervical disc herniation or spondylosis is very satisfactory and has become the gold standard. As we become more aware of the possible long-term effects of cervical arthrodoses on the adjacent-segment degeneration, however, it seems appropriate and justified to investigate new treatment options such as cervical arthroplasty. The goal of these new devices is preservation of motion of the functional spinal unit after a successful decompression of the neurological structures. It must be demonstrated that the maintenance of motion will last over an extended time period and that the adjacent segments undergo lesser degenerative changes compared with those in the fusion group. Our study is a first attempt to formulate some answers to the open questions regarding cervical arthroplasty.

**Early Experience**

**Bristol–Cummins Disc.** In the late 1980s, British neurosurgeon Brian Cummins became increasingly frustrated by the number of adjacent-segment surgeries he was performing in patients he had previously treated with ACDF. Cummins was determined to develop a solution and began collaborating with a medical engineer at his institution, Frenchay Hospital in Bristol, United Kingdom. The final design featured a ball-and-socket mechanism, which was placed into the disc space and fixed to the anterior cervical spine by bone screws driven through anterior phalanges into the adjacent VBs (Fig. 1). The ball component was slightly smaller than the socket, which allowed for slight translatory movements. The devices were manufactured from No. 316 stainless steel in the Frenchay Hospital machine shop. The Bristol–Cummins disc was designed to be implanted using a standard Smith–Robinson technique.

In 1991 Cummins received Ethics Committee approval to begin implanting the devices in patients with end-stage cervical disease who had undergone multiple previous cervical fusions, in an attempt to stop the cascade of subsequent fusions and maintain some motion in these severe cases. In all, 22 devices were implanted in 20 patients. The results were reported in 1998 and it was demonstrated radiographically that the device continued to function, with good clinical outcomes in the majority of patients.

Additionally, when 16 of the patients were evaluated again in 2003, radiographic examinations performed for this long-term follow up demonstrated that the device still functioned 12 years postoperatively (JT Robertson, unpublished data).

The Bristol–Cummins device showed clinical viability in principle despite its obvious engineering shortcomings. The device was too large for the majority of patients, with an interbody height of 11 mm and an anterior phalange height of 14 mm each. At least one device was manufactured out of specification, with the ball being larger than the socket. Several screw breakages were reported; however, weaker fenestrated titanium screws were used in many cases. Additionally, a galvanic reaction between the stainless steel implant and the titanium screws may have caused further material weakening. One of the devices was explanted because of improper sizing and persistent pain. Evaluation of the explanted device showed virtually no wear. Many issues associated with use of the Bristol–Cummins disc are clearly related to the extreme biomechanical environment seen in the end-stage patients who were treated with the device on an ethics committee–approved humanitarian basis.

The Bristol–Cummins experience paved the way for cervical arthroplasty by showing that a metal-on-metal ball-and-socket device could relieve pain while maintaining motion at the treated level over a long-term follow-up duration.

**Prestige I Disc.** In 1998, a prospective observational clinical trial was initiated on a refined version of the Bris-
Preliminary results with Prestige II cervical disc
	on a larger scale. The 15 patients who were enrolled had either radiculopathy or myelopathy and radiologically confirmed cervical disc herniation or posterior VB osteophytes. Eligibility for the study required that patients had undergone previous surgery at an adjacent level, had congenital fusion, or displayed radiological evidence of adjacent-level DDD. After anterior decompressive surgery all patients received the Prestige I implant. Follow-up visits were required until 2 years postsurgery and included clinical examination, radiological assessment, and evaluation of the patients by questionnaires. The authors could demonstrate that all devices maintained motion over time at the treated levels, with reestablishment of the disc height. The procedure was considered safe and the implant was stable with no dislocation of the components. Two screws broke with no clinical consequences, but no screws pulled out. Data obtained at 24 months compared with preoperative data from the questionnaires indicated improvement in all aspects of the patients’ function and quality of life. The study’s sample size was too small for any clinical changes to reach statistical significance.

The pilot study was successful and allowed for pursuit of further development and the application of the device on a larger scale.

CLINICAL MATERIAL AND METHODS

Prestige II Disc Implant Design

The initial Bristol–Cummins artificial disc was redesigned as the Prestige I disc to allow for more physiological motion with a reduced profile. The Prestige I device is a metal-on-metal construct with articulating surfaces and variable point loading. The lower component, which previously had been a hemispherical cup, was replaced with a shallow ellipsoidal saucer to permit translation, allowing 2 mm of freedom in the AP plane. Rotation of the upper component is achieved by allowing the hemisphere of the joint to glide in the saucer. The incongruent interface between the two components of the joint allows the upper vertebral component passively to find its own axis of rotation as determined by the facet joints and coupled motions of the adjacent vertebrae. The rolling mechanism in the saucer also reduces friction and thus reduces wear debris. The joint allows 10° flexion and extension movements, a translation of 2 mm, and maximum lateral bending of 10°. The anterior plates of the device are anatomically contoured to fit the anterior surface of the adjacent vertebrae. The screw-locking mechanism that secures each component to its respective VB is slightly convergent, with a fixed-angle geometry similar to the Ori-on anterior cervical plate (Medtronic Sofamor Danek), which increases the pullout strength. An additional locking screw mechanism inhibits loosening of the unicortical fixation screws.

With the Prestige II Disc (Fig. 3; Medtronic Sofamor Danek), the designers built on the Prestige I experience by incorporating further design improvements such as reduced profile, bone ingrowth surfaces, and additional sizes, while maintaining the proven articulation. Two sizes of prosthesis in the AP dimension (12 and 14 mm) allow proper adaptation to individual anatomy. For each of these devices, two different heights are available (6 and 8 mm).

Biomechanical Testing

Biomechanical testing of the device was performed independently at the School of Biomechanical Engineering and the Department of Neurosurgery at the University of Tennessee Health Science Center in Memphis, Tennessee.2

An in vitro biomechanical study was conducted to compare a group of intact human cadaveric cervical spines with those implanted with the artificial joint and other specimens treated with a simulated cervical anterior fusion with plating. A programmable testing apparatus was used that replicated physiological flexion/extension and lateral bending. Comparing the intact harvested cadaveric spines with the those implanted with the artificial joint, we found no significant difference (p > 0.05) in the normalized motion data at the superior, implanted, or inferior motion segment unit during all modes of loading: flexion, extension, lateral bending, and rotation. The motion segments with the artificial disc in place mirrored the kinematics of the intact spine. This was in contrast to the comparison of the simulated fusion specimens with the intact specimens. Application of an anterior cervical plate decreased motion across the fusion site relative to the intact and artificial joint conditions. The reduced motion was compensated by a significant increase in motion at the adjacent segments. Static and fatigue tests of the device were also performed. At no point was a permanent deformation or failure of the implant seen, even with cyclic loading up to 3000 N.

Study Design

A multicenter, prospective, randomized controlled study was conducted. Four centers were involved in the study: Department of Neurosurgery, Frenchay Hospital in Bristol, United Kingdom; Department of Neurosurgery,
**TABLE 1**

Demographic information in 55 patients treated with artificial discs or fusion*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Prestige II Disc</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>no. of patients</td>
<td>27</td>
<td>28</td>
</tr>
<tr>
<td>age (yrs)</td>
<td>44 ± 9.9</td>
<td>43 ± 6.9</td>
</tr>
<tr>
<td>sex (%)</td>
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<td></td>
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<tr>
<td>male</td>
<td>17 (63.0)</td>
<td>12 (42.9)</td>
</tr>
<tr>
<td>female</td>
<td>10 (37.0)</td>
<td>16 (57.1)</td>
</tr>
<tr>
<td>tobacco (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>yes</td>
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<td>11 (39.3)</td>
</tr>
<tr>
<td>no</td>
<td>13 (50.0)</td>
<td>17 (60.7)</td>
</tr>
<tr>
<td>alcohol (%)</td>
<td></td>
<td></td>
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<tr>
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<td>22 (84.6)</td>
<td>17 (63.0)</td>
</tr>
<tr>
<td>no</td>
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<td>10 (37.0)</td>
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<tr>
<td>work status (%)</td>
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<tr>
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<td>9 (33.3)</td>
</tr>
<tr>
<td>no</td>
<td>14 (51.9)</td>
<td>18 (66.7)</td>
</tr>
</tbody>
</table>

* SD = standard deviation.

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Demographic Variables

Overall, 55 patients were enrolled in the study; 27 were randomized into the investigational group, receiving ACDA with the Prestige II disc, and 28 entered the control group, receiving ACDF with iliac crest autograft. The mean age of patients in both groups was very similar: 44.3 years in the former and 43.2 years in the latter group. There was a predominance of men in the ACDA group (17 men, 10 women), with an inverse predominance in the ACDF group (12 men, 16 women), but the patients’ sex had no statistical significance between the groups. In other demographic variables like tobacco and alcohol use, workers’ Compensation status, race, and education level there was no statistically significant difference between the groups (p > 0.05; Table 1).

Inclusion and Exclusion Criteria

The trial was designed to compare the Prestige II Cervical Disc System with a control procedure in which iliac crest autograft was used for anterior cervical fusion for the surgical treatment of single-level DDD. Inclusion criteria consisted of cervical DDD, defined as an intractable radiculopathy or myelopathy caused by neuroradiologically documented disc herniation or osteophyte formation. Only patients with single-level disease in C4–5 to C6–7 were eligible for the study protocol. Unresponsiveness to nonoperative treatment for approximately 6 weeks, or the presence of progressive symptoms or signs of nerve root compression while nonoperative management continued was required. Patients had to be older than 18 years of age and the preoperative NDI score had to be higher than 30. We excluded patients with previous surgical treatment of the cervical spine or those presenting with a cervical spine condition other than symptomatic cervical disc disease that required surgical treatment. Patients with osteopenia, osteoporosis, osteomalacia, or cancer were also excluded.

Candidates for the clinical trial received information about the study and were asked if they would participate. After signing the informed consent document, participating patients were randomized according to a schedule generated using the Statistical Analysis System. Treatment randomization was 1:1 overall (investigational/control) at each site.

Enrollment and Preoperative Work-Up Procedures

At the time of enrollment, the patients completed several questionnaires: the NDI, the SF-36, and a VAS relating to both neck and arm pain. In addition, a detailed neurological examination was performed and analgesic requirements, employment status, smoking status, and preexisting medical conditions were documented. Radiological preoperative workup included AP, lateral, and flexion/extension studies of the cervical spine in addition to neuroradiological documentation of the neuronal compromise.

Follow-Up Procedures

Follow-up evaluations were assessed by one clinician who was directly involved in the surgery. Patients were followed up according to the protocol at 6 weeks and 3, 6, 12, and 24 months postsurgery. Clinical evaluation, with particular attention paid to neck and upper-limb function, was completed by obtaining radiological studies of the cervical spine, as was done in the preoperative setting. All radiographs were pooled and submitted for site-independent radiological review. The patients completed the same questionnaires as before surgery, and they reported any adverse events. These events were documented and an appropriate treatment was prescribed as clinically merited.

RESULTS

Follow-Up Duration

At the time of this report, 37 patients had been evaluated at the 12-month follow-up interval and nine at the 24-month interval.

Adverse Events

The severity of adverse events was assessed according to the World Health Organization recommendations: Grade 1 is noticeable to the patient but does not interfere with routine activity; Grade 2 interferes with routine activity but responds to symptomatic therapy or rest; and Grade 3 events significantly limit the patient’s ability to perform routine activities despite symptomatic therapy.

Control Group. In the ACDF (control) group 19 adverse events were registered. Three were related directly to the surgical procedure: one graft was too small and had to be replaced during the initial surgery, another graft was contaminated and had to be replaced, and the third patient had a hematoma at the graft harvest site that required revi-
Preliminary results with Prestige II cervical disc

Fifteen adverse events did not lead to permanent disability and resolved after a mean period of 3 months. Of these 15 cases, 11 consisted of intermittent neck and arm pain. The majority of the 19 adverse events (16) were Grade 2.

Two Grade 3 events were registered; both involved secondary myelopathy requiring additional adjacent-level surgery. The symptoms resolved in one case but those related to the other adverse event were considered permanent. Additionally, three patients with continuous neck pain were considered permanently affected and required symptomatic treatment.

Investigational Group. During the same period of observation, 17 adverse events were noted in the ACDA (artificial disc) group. One Grade 2 adverse event was due to a malposition of the Prestige disc. Five weeks postoperatively, this patient reported cervical pain and posterior cervical rigidity. Treatment with narcotic and nonsteroidal antiinflammatory medication was started. In addition, use of a hard cervical collar was initiated at that time, but the condition remained at the 3-month evaluation. The patient continued to have neck pain and some limitation of motion, while remaining neurologically intact. Flexion/extension radiographs revealed no movement of the joint secondary to improper placement of the prosthesis. The artificial joint was removed approximately 4 months after the initial placement, and the patient underwent a fusion with an anterior cervical cage. Thereafter, this patient had a good clinical condition at follow-up evaluations.

Fourteen events were not permanent and resolved with appropriate symptomatic treatment after 3 months. Residual neck pain was the symptom in six cases. In one case a transient recurrent palsy on the right side required a lopogedectomy; the patient’s voice recovered after 3 months. Another patient reported moderate dysphagia that lasted for 3 months before spontaneous recovery.

Only one Grade 3 adverse event was registered. This patient suffered from pancreatitis, which was considered a permanent event but not one related to the surgical procedure. The other two permanent events (Grade 2) were continuous neck pain in one case and shoulder pain in the other, with no evidence of neurocompression on postoperative imaging studies.

In the ACDA group there were 13 Grade 2 events and three Grade 1 events overall, in addition to the one Grade 3 event. There was no significant difference compared with the distribution of adverse events in the ACDF group.

The frequency of reported events also did not show a significant difference between the two groups. Based on this information, the implantation procedure for the Prestige disc can be considered as safe as the classic Smith–Robinson procedure for ACDF. In addition, there were no surgically related late complications in the ACDA group.

There were no device-related failures during the follow-up period. All the artificial discs maintained their position in the intervertebral space with no incidence of joint dislocation. There was no subsidence of any of the devices into the VB bone.

Radiographic Outcomes

Two independent radiologists reviewed and carefully evaluated the pre- and postoperative flexion and extension x-ray films of the cervical spine. The findings are limited as of the writing of this report, with a radiological analysis at 12 months for 22 patients in the ACDA group and 14 patients in the ACDF group. Measurements were made using the straight edges of the implant’s endplates as reference points on radiographs acquired with the patient in lateral flexion and extension positions (Fig. 4). The motion angles were measured at the treated level, the upper adjacent level, and the lower adjacent level in both groups. Motion analysis showed maintenance of motion in the ACDA group and no significant motion in the ACDF group (Fig. 5).

The mean preoperative motion at the treated level was 5.9° in the ACDA group and 6.3° in the ACDF group. At 3 months the movement in the ACDA group was preserved, with a mean motion of 6.5° at the treated level compared with 1.6° in the ACDF group. At 12 months, the artificial disc demonstrated angular motion with a mean value of 5.9°. As expected, the fusion group showed no significant preservation of motion, with a mean angular motion of 1.1°, which is considered to be no movement. No statistically significant differences were seen in adjacent-level motions in the limited sample of patients analyzed at 12 months.

Neck Disability Index

The NDI is a questionnaire containing 10 questions that is used to measure cervical pain and disability associated with activities of daily living. A lower score on the NDI represents less neck pain and disability. The NDI questionnaire was administered preoperatively and at each postoperative interval. At all postoperative intervals, both treatment groups showed improvement from preoperative scores (Fig. 6 upper). The improvement seen in the treatment groups was statistically equivalent (p ≤ 0.05, noninferiority margin = 10) up to the 24-month follow-up interval (follow-up review has yet to be completed at this interval).

Neck Pain Frequency and Intensity

The VAS was used to measure neck pain frequency and intensity. Adding the numerical rating scores for neck pain frequency and intensity created a 20-point composite neck pain score (Fig. 6 center). Neck pain scores were improved at all postoperative periods from the preoperative scores for both treatment groups. There is statistical significance for improvement in neck pain from the preoperative score within each group; however, statistical equivalence could not be shown between the two groups.

Arm Pain Frequency and Intensity

Arm pain was assessed according to the same methods as neck pain, by using a numerical rating scale for both the frequency and intensity of the pain. The mean arm pain scores improved after surgery in both treatment groups at all postoperative intervals (Fig. 6 lower). Statistical equivalence between treatment groups (p ≤ 0.05; noninferiority margin = 10) was demonstrated at each postoperative interval up to the 24-month follow up (follow-up review has yet to be completed at this interval).
General Health

The SF-36 questionnaire was used to measure patients’ general health status. The questionnaire was administered preoperatively and at each follow-up interval. The SF-36 was analyzed using its physical and mental summary components. The ACDA group showed improvement similar to the ACDF group at all postoperative intervals in both the physical and mental component categories (Fig. 7). The differences in scores between the treatment groups were not statistically significant.

DISCUSSION

Despite being far from an accepted standard, the concept of artificial disc replacement is gradually becoming a reality. The possibility of being able to maintain motion in a functional cervical motion unit and thereby minimize adjacent-segment degeneration is exciting. Biomechanical studies have shown that a disc replacement creates less adjacent-level strain than fusion and decreases the motion of the adjacent levels compared with fusion. Nevertheless, the gold standard surgical treatment for cervical disc herniation or spondylosis remains anterior decompression and fusion. Most spine surgeons agree that an anterior cervical discectomy and arthrodesis is among the most reliable and successful procedures they have to offer their patients. On the other hand, surgeons are becoming aware that there might be an independent effect of the fusion itself on the adjacent segments, and that they are trading motion of the diseased segment for neurological benefit and pain relief.

With the emergence of new nonfusion technologies, spine surgeons must sort out the advantages and potential disadvantages of these new devices. The only way to answer questions about success or failure lies in rigorous analysis of collected data from clinical trials. Intermediate and long-term outcome–based studies are necessary to prove superiority or equality to the current standard of ACDF. The best evidence of treatment benefit is evaluated by conducting randomized prospective clinical trials comparing two treatment procedures.

Because the results of anterior fusion are very satisfying it will be difficult to prove short-term superiority of cervical arthroplasty. When planning the present study, we considered the equal clinical outcomes between the groups to be a primary success of the new technology. The intended benefits of the device, like preservation of motion and elimination of adverse influence on the adjacent segments, are long-term benefits that cannot be assessed before several years of observation have been completed. To the best of our knowledge this is the first study in which ACDF is compared with ACDA in a prospective, randomized fashion. The clinical and radiographic results show that the Prestige II disc alleviates pain and symptoms comparably.
Preliminary results with Prestige II cervical disc

Most outcome measures seem to favor the Prestige II disc, although the differences are not statistically superior, demonstrating only a trend. Radiographic analyses show the Prestige disc maintaining motion at the treated level without actual adjacent-segment compromise. It is evident that the observation period is too short to make any statement concerning the benefit of the preserved motion. Nevertheless, applying the principles of the biomechanical studies, the natural history of segment degeneration should be positively influenced. Intraoperative and postoperative adverse events are similar between the treatment groups. Further clinical trials are currently underway with larger sample sizes and greater statistical power to confirm the preliminary results of the present study.

CONCLUSIONS

There are many cervical disc prostheses currently in various stages of development and clinical usage. At the time of this report, only limited short-term clinical results have been presented for most of these devices. The only other cervical disc replacement device with prospective intermediate-term outcome data reported in the literature is the Bryan Cervical Disc System. It is important that the clinical outcomes for this procedure are well understood, because this technology will be incorporated into medical practice. The preliminary clinical experience gained with the Prestige Cervical Disc in well-designed prospective studies is an important step in this direction. Additional long-term follow-up findings in all patients who receive the implants is mandatory and will be published.

Disclosure

Mr. Metcalf is an employee of Medtronic Sofamor Danek. Dr. Porchet has no financial interest in the company.

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