Acta Orthop. Belg., 2011, **77**, 224-229

ORIGINAL STUDY

Single level cervical arthroplasty with the Discocerv® prosthesis : A preliminary report

Ahmed ENAN, Mohammad ABU-HEGAZY, Mohamed ABO-HEGY, Ashraf AL-KERDANY

From Mansoura University Hospital, Mansoura, Egypt

The authors conducted a prospective non-randomised study about a new cervical disc prosthesis : the Discocerv® Cervidisc Evolution. Fourteen patients (10 men and 4 women) were treated at a single mobile level, between July 2006 and November 2008. Their mean age was 40.8 years (range 31-56), and the mean clinical follow-up period was 12.8 months (range 9-18). Diagnosis was disc herniation (n = 12) and stenosis (n = 2). The VAS for neck pain, the VAS for radiating pain and the Neck Disability Index decreased significantly at last follow-up ($p < 0.05$). According to Odom's criteria 81.6% of the patients had a good or excellent outcome. The range of movement of the cervical spine as a whole and of the treated functional segmental unit were preserved at final follow-up, which suggests that the disc prosthesis might prevent osteoarthritis at adjacent levels. The neutral sagittal alignment of the cervical spine as a whole and of the functional spinal unit showed kyphosis shortly after surgery, but lordosis was practically restored at final follow-up.

Keywords : cervical arthroplasty ; Discocerv® Cervidisc Evolution ; clinical outcome ; radiological outcome ; mobility ; adjacent level osteoarthritis.

INTRODUCTION

Anterior cervical discectomy and fusion currently remains the standard treatment for disc herniation and degenerative disc disease refractory to conservative therapy. Recently, however, cervical total disc replacement has generated significant interest as a potential alternative, because of the well-known risks and complications associated with cervical fusion (*12,27*). Biomechanical studies have shown that fusion alters adjacent level kinematics, resulting in increased biomechanical stresses ; this may lead to accelerated degeneration at adjacent segments in 7 to 25% of the cases (*2,6,7, 16,25*). A recent clinical study reported that disease-free survival rates after fusion were 89% at 5 years, 84% at 10 years and only 67% at 17 years (*14*). Further potential morbidities associated with cervical fusion include the possibility of decreased total cervical range of motion, pseudarthrosis, graft donor site morbidity, and instrumentation-related complications (*5,15,26*).

Recently, cervical arthroplasty with artificial cervical discs has gained attention as an alternative

■ Ahmed Enan, MD, Professor of Orthopaedic Surgery.
■ Mohammad Abu-Hegazy, MD, Lecturer Neurology.
Faculty of Medicine, University of Mansoura, Mansoura, Egypt.
■ Mohamed Abo-Hegy, MD, Orthopedic Fellow.
■ *Mansoura University Hospital, Mansoura, Egypt.*
■ Ashraf Al-Kerdany, MD, Consultant Neurosurgeon.
Ministry of Health, Egypt.
Correspondence : Dr Ahmed Enan, Department of Orthopaedic Surgery, Mansoura University Hospital, El-Gomhoria street, Mansoura, Egypt.
E-mail : aenan2002@yahoo.com

No benefits or funds were received in support of this study

to traditional fusion. It can be used to restore and maintain mobility and function of the involved cervical spinal segments (*8,10*). The theoretical advantages of disc arthroplasty include : maintenance of range of movement, avoidance of adjacent segment degeneration, restitution of disc height and spinal alignment, and greater maintenance of maneuverability. Furthermore, this procedure shows decreased surgical morbidity, avoidance of complications from instrumentation or postoperative immobilization, and earlier return to the previous level of function (*1*). The first Cervidisc® cervical mobile prosthesis (*23*) was implanted on June 11, 1999. At the 7 years follow-up, a persisting mobility was found in 96% of 52 implanted devices, despite a high rate of subsidence of the lower component (*22*). This very encouraging result led to redesign this ceramic on ceramic prosthesis to a titanium on titanium prosthesis called Discocerv® Cervidisc Evolution. The first Discocerv® prosthesis was implanted on April 4, 2006 ; since then, more than 300 cases were reported in 14 countries around the world.

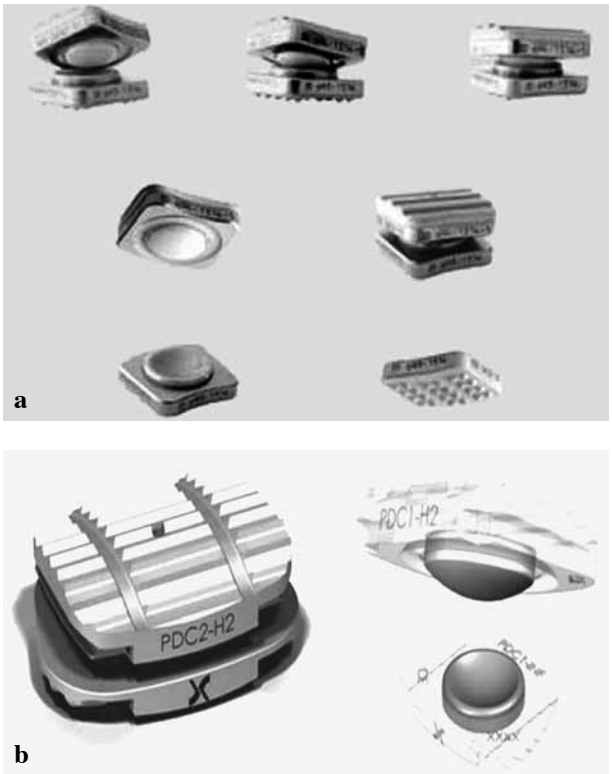

Fig. 1. — Two generations of cervical disc prostheses : a. Cervidisc® (ceramic on ceramic) : note the square shape of the device, looking like a cage and implanted in one piece ; b. Discocerv® Cervidisc Evolution (titanium on titanium) : the shape of the device, convex cranially in the sagittal plane and convex caudally in the frontal plane, was designed to fit exactly into the disc space, so avoiding subsidence.

PATIENTS AND METHODS

The authors performed 14 arthroplasties with the DISCOCERV® Cervidisc Evolution (Fig. 1) between July 2006 and November 2008 at the Royal Commission Hospital, Jubail, Kingdom of Saudi Arabia. The study included 10 men and 4 women, whose mean age was 40.8 years (range 31-56). The mean clinical follow-up duration was 12.8 months (range 9-18). The inclusion criteria were : degenerative disc disease, disc herniation, with neck and radicular pain, with or without neurological deficit, and failure of conservative treatment. Exclusion criteria were : active infection, vertebral osteoporosis, vertebral tumour, injury, local deformity, instability, previous surgical treatment, rheumatoid arthritis, metabolic bone disease, obvious lack of mobility at the level concerned, and combination with fusion at another level.

All patients had a detailed neurological examination preoperatively. Pain evaluation was performed using the well-known visual analog scale (VAS), respectively for neck pain and for radicular pain (10 cm = unbearable pain). All patients completed an Oswestry Neck Disability Index questionnaire (NDI) (*24*) as to the activities of daily living : the higher the score, the worse. Odom's criteria (*18*), from poor to excellent, were used to evaluate the clinical outcome in general. It was explained to and consented from the patients that if intraoperatively arthroplasty could not be done, an interbody fusion would be performed instead.

Static and dynamic plain radiographs were obtained on day 1 and at 1, 6, and 12 months postoperatively. The neutral sagittal alignment of the cervical spine as a whole was assessed as the Cobb's angle between the inferior margins of the vertebral bodies C2 and C7, in the neutral position. The angles were determined with quantitative measurement analysis software, using extrapolative algorithms. Lordosis was considered as a negative value and kyphosis as a positive value. The range of movement of the cervical spine as a whole was defined as the difference between the angles in full flexion and full extension (Fig. 2). The functional spinal unit (FSU) angle (*11*) was used to analyze movement at the level of the proposed

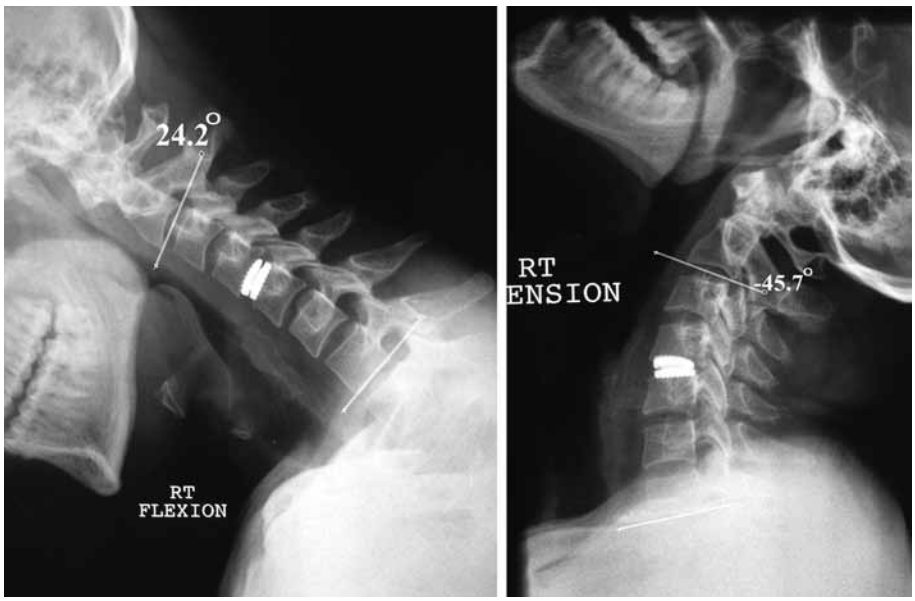

Fig. 2. — Lateral view : the range of movement (ROM) of the cervical spine as a whole was defined as the difference between the Cobb's angles C2C7 in full flexion and in full extension.

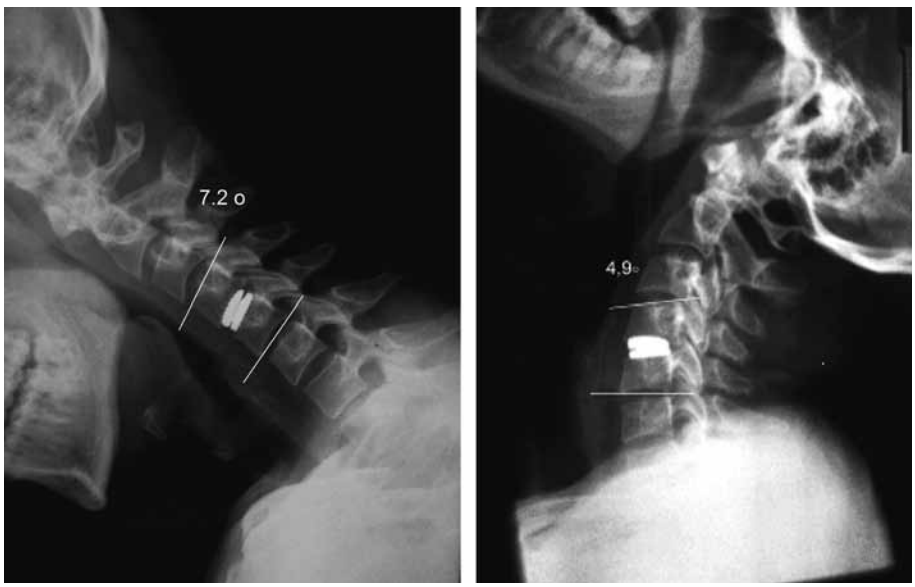

Fig. 3. — The postoperative range of movement (ROM) of a functional segmental unit *(FSU)* C4C5 : from 4.9° to 7.2°

arthroplasty. This angle was formed by lines drawn at the superior margin of the superior vertebral body and at the inferior margin of the inferior body. Again, lordosis was seen as a negative value, and kyphosis as a positive value. The neutral FSU angle and the mobility of the FSU angle were calculated respectively on the static and on the dynamic (Fig. 3) lateral radiographs. Only mobile discs were treated, so that the effect of the prosthesis on mobility could be assessed. All patients had a CT-scan and MRI. All imaging studies were independently reviewed.

Statistical analysis : the data were coded and entered into a computer using the Statistical Package for Social Sciences (SPSS) version 15.0 (Chicago, IL, USA). Results were presented as means with standard deviation

(SD). A parametric paired sample t-test was used to compare the preoperative and the postoperative values. A p value < 0.05 was seen as statistically significant.

Surgical procedure

The operation was performed under general anaesthesia, with the patient supine and the chin fixed with tape. A right anterior pre-sternocleidomastoid incision was made, under fluoroscopic control for the selection of the right level. The surgeon stood on the right side of the patient and the assistant at the head. After incision of the anterior longitudinal ligament the disc was excised with rongeurs and/or curettes. The cartilaginous endplates were removed with a curette, without disturbing the bony endplates. Subsequently, a bilateral foraminal decompression was performed with a Kerrison or with a high speed drill. The posterior longitudinal ligament was always opened in order to remove any extruded disc fragment and to enhance interbody distraction. Two different flat probes were now inserted, one after the other, to determine the width of the intervertebral space and thus the size of the most suitable prosthesis. The prosthesis covering the largest part of the endplate was chosen so as to obtain a better load distribution on the vertebral endplates. If the prosthesis was too small, it could migrate, and if it was too large, it could interfere with mobility. The prosthesis was finally inserted under slight distraction of the intervertebral space, avoiding any secondary displacement or dislocation. The correct location of the implant was checked with the image intensifier. Ideally, the posterior edge of the prosthesis was aligned with the posterior wall of the cervical spine, in order to obtain an optimal location of the mean center of rotation. On the antero-posterior view the implant was supposed to be seated exactly on the midline. Haemostasis, rinsing, drainage and closure. A cervical collar was not applied.

RESULTS

Fourteen prostheses were inserted in 14 patients. The preoperative clinical diagnosis was herniated cervical disc in 12 patients, and cervical stenosis in 2 patients. The following levels were treated : C4C5 : 2 patients or 14.3% ; C5C6 : 10 patients or 71.4%, and C6C7 : 2 patients or14.3%. The size of the prostheses varied from 14 to 17 mm. The mean duration of the operation was 75.6 ± 20.4 min (range : 80-120 min). All patients could stand up on the same day and had full mobility of their neck at the time of discharge. The hospital stay was 3.5 ± 1.4 days (range : 2 to 7 days). No peroperative complications were noted, except for excessive bleeding in one patient, without any further consequences. Other complications of cervical arthroplasty, such as device migration, infection or neurological damage, did not occur in our study. The mean follow-up period was 12.8 months (range : 9 to 18).

Clinical outcome

All patients recovered completely from their preoperative paresis and sensory loss. The VAS score for neck pain decreased from a mean preoperative score of 6.1 to 3.1 at 1 year, which was significant according to the paired sample t-test. The VAS score for radiating pain also improved significantly from a mean preoperative score of 7.1 to 2.2. The NDI improved significantly ($p < 0.05$) from a mean preoperative score of 68 % to a score of 25% at final follow-up. According to Odom's criteria 81.6% of the patients had a good or excellent outcome.

Radiological analysis

The mean preoperative mobility of the *cervical spine as a whole* was 49.8 ± 11.7° (mean ± standard deviation). Postoperatively, the range of motion decreased to 32.4 ± 9.8° at one month, but slightly increased to 53.1 ± 15.6° after one year (gain not significant). The mean preoperative mobility of the chosen *functional spinal unit* was 12.2 ± 4.5°, decreased to 7.9 ± 3.2° at one month, but slightly increased to 12.9 ± 2.9° at 1 year (gain not significant). In other words, the treated segment preserved its preoperative mobility. The mean neutral preoperative angle C2C7 of the cervical spine as a whole was -13.5 ± 10.2° and thus lordotic. One month after surgery it was -9.3 ± 6.2°, and thus less lordotic. At final follow-up it improved to -11.0 ± 4.9°, but the initial lordosis was not completely recovered. Again, the difference was not significant statistically. Also the neutral alignment of the functional spinal unit was ultimately recovered. Subsidence of the prosthesis was not observed in any patient.

DISCUSSION

Anterior cervical decompression and fusion, with or without instrumentation, is a widespread surgical intervention for cervical spondylotic myelopathy and cord compression due to acute disc prolapse (*17*). However, anterior fusion has often led to a reduced mobility and to stress on adjacent levels (*3*). Hilibrand *et al* (*13*) noted a rate of 2.9% per year of developing adjacent segment disease.

Spinal arthroplasty aims at preservation of mobility ; it has a relatively short history. Despite the ease of access to the cervical spine, spinal disc replacement surgery has historically concentrated on the lumbar spine (*4*). In 1966 Fernstrom (*9*) introduced an intercorporeal prosthesis which consisted of a stainless steel ball inserted into the center of a lumbar disc after laminectomy. Goffin *et al* (*10*) were first to describe the Bryan cervical disc prosthesis for the management of cervical spondylosis in 2002. Their prospective multicenter study led to good results in 86% of the patients at 6 months, and to 90% at 1 year postoperatively. Moreover, at 1 year motion was preserved in 88% of patients and only one migration was noted. These results were confirmed at longer follow-up, and several other authors (*10,19*) reported similar clinical improvement rates and preservation of motion (a mean of 7.8° per FSU at 2 years). A multicenter, prospective, randomized study (*21*) about the Prestige ST disc prosthesis versus anterior cervical fusion for single level degenerative disc disease showed that the device maintained motion (a mean of 5.9° per FSU) after 12 months. Moreover, the prosthesis scored better than fusion as to VAS, NDI and SF-12 criteria. In a study on 82 Cervitech Porous Coated Motion artificial discs in 53 patients with degenerative disc disease associated with radiculopathy and myelopathy, Pimenta *et al* (*20*) reported significant improvement assessed by means of VAS, NDI, and Treatment Intensity Gradient Test (TIGT), at 1 year follow-up. More specifically, 80% of the patients had good or excellent results at 1 week, improving to 90% at 1 month (Odom's criteria). Only one migration was observed at 3 months.

The authors' results are in full agreement with the previously reported data. In this relatively short-term series, 100% of patients with a single-level arthroplasty demonstrated preservation of mobility of the cervical spine as a whole and of the treated functional spinal unit. The differences between pre- and postoperative situation were not significant. Of course, motion was restricted in the early postoperative period due to neck pain or patients' non-compliance to movements as an early response to surgery. The maintenance of the ROM of adjacent segments in the late period (cervical spine as a whole) indirectly reflects the possibility of preventing adjacent segment disease after arthroplasty. In the current series the C2C7 neutral Cobb's angle became less lordotic in the early postoperative period (a loss of 4.2° of lordosis) and nearly returned to the preoperative values within a year (a loss of 2.5°). Also the neutral Cobb's angle of the FSU was preserved after one year. This result was in sharp contrast with the findings of Pickett *et al* (*19*) who reported that at final follow-up the neutral FSU angle became more kyphotic, while the neutral C2C7 angle was preserved.

There are general concerns related to the use of disc arthroplasty with regard to material wear and the ability of these disc prostheses to maintain motion. Another concern is whether disc arthroplasty may lead to the recurrence of osteophytes. Finally, there is concern that in patients with kyphotic alignment or in those in whom the arthroplasty device is placed in a kyphotic alignment, progressive kyphosis may occur following cervical disc arthroplasty, leading to recurrence or worsening of myelopathic symptoms. These questions cannot be answered without long-term follow-up and a specifically designed study to address such issues.

REFERENCES

1. **Anderson PA, Rouleau JP.** Intervertebral disc arthroplasty. *Spine* 2004 ; 29 : 2779-2786.
2. **Auerbach JD, Wills BP, McIntosh TC, Balderston RA.** Evaluation of spinal kinematics following lumbar total disc replacement and circumferential fusion using in vivo fluoroscopy. *Spine* 2007 ; 32 : 527-536.
3. **Cherubino P, Benazzo F, Borromeo U, Perle S.** Degenerative arthritis of the adjacent spinal joints following anterior cervical spinal fusion : clinicoradiologic and

statistical correlations. *Ital J Orthop Traumatol* 1990 ; 16 : 533-543.

4. **Cummins BH, Robertson JT, Gill SS.** Surgical experience with an implanted artificial cervical joint. *J Neurosurg* 1998 ; 88 : 943-948.
5. **Deyo RA, Nachemson A, Mirza SK.** Spinal-fusion surgery – the case for restraint. *N Engl J Med* 2004 ; 350 : 722-726.
6. **DiAngelo DJ, Robertson JT, Metcalf NH *et al.*** Biomechanical testing of an artificial cervical joint and an anterior cervical plate. *J Spinal Disord Tech* 2003 ; 16 : 314-323.
7. **Eck JC, Humphreys SC, Lim TH *et al.*** Biomechanical study on the effect of cervical spine fusion on adjacent-level intradiscal pressure and segmental motion. *Spine* 2002 ; 27 : 2431-2434.
8. **Enker P, Steffee A, McMillin C *et al.*** Artificial disc replacement. Preliminary report with a 3-year minimum follow-up. *Spine* 1993 ; 18 : 1061-1070.
9. **Fernstrom U.** Arthroplasty with intercorporeal endoprosthesis in herniated disc and in painful disc. *Acta Chir Scand* 1966 ; 357 Suppl : 154-159.
10. **Goffin J, Casey A, Kehr P *et al.*** Preliminary clinical experience with the Bryan Cervical Disc Prosthesis. *Neurosurgery* 2002 ; 51 : 840-845.
11. **Goffin J, Geusens E, Vantomme N *et al.*** Long-term follow-up after interbody fusion of the cervical spine. *J Spinal Disord Tech* 2004 ; 17 : 79-85.
12. **Guyer RD, McAfee PC, Hochschuler SH *et al.*** Prospective randomized study of the Charité artificial disc : data from two investigational centers. *Spine J* 2004 ; 4 (6 Suppl) : 252S-259S.
13. **Hilibrand AS, Carlson GD, Palumbo MA, Jones PK, Bohlman HH.** Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. *J Bone Joint Surg* 1999 ; 81-A : 519-528.
14. **Ishihara H, Kanamori M, Kawaguchi Y, Nakamura H, Kimura T.** Adjacent segment disease after anterior cervical interbody fusion. *Spine J* 2004 ; 4 : 624-628.
15. **Lipson SJ.** Spinal-fusion surgery-advances and concerns. *N Engl J Med* 2004 ; 350 : 643-644.
16. **Maiman DJ, Kumaresan S, Yoganandan N.** Biomechanical effect of anterior cervical spine fusion on adjacent segments. *Biomed Mater Eng* 1999 ; 9 : 27-38.
17. **McCormack BM, Weinstein PR**. Cervical spondylosis. An update. *West J Med* 1996 ; 165 : 43-51.
18. **Odom GL, Finney W, Woodhall B.** Cervical disk lesions. *JAMA* 1958 ; 166 : 23-28.
19. **Pickett GE, Mitsis DK, Sekhon LH, Sears WR, Duggal N.** Effects of a cervical disc prosthesis on segmental and cervical spine alignment. *Neurosurg Focus* 2004 ; 17 : E5.
20. **Pimenta L, McAfee PC, Cappuccino A, Bellera FP, Link HD.** Clinical experience with the new artificial cervical PCM (Cervitech) disc. *Spine J* 2004 ; 4 (6 Suppl) : 315S- 321S.
21. **Porchet F, Metcalf NH.** Clinical outcomes with the Prestige II cervical disc : preliminary results from a prospective randomized clinical trial. *Neurosurg Focus* 2004 ; 17 : E6.
22. **Ramadan AS.** A new mobile cervical disc prosthesis (Cervidisc™) : preliminary results of the first 22 implanted devices. In : Kaech DL, Jinkins JR (eds). *Spinal Restabilization Procedures : Diagnostic And Therapeutic Aspects Of Intervertebral Fusion Cages, Artificial Discs And Mobile Implants*. Elsevier, Amsterdam, 2007.
23. **Ramadan AS, Maindron-Perly V, Schmitt P.** Cervidisc concept, six years follow-up and introducing Cervidisc II : Discocerv. In : Kim DH, Cammisa FP Jr, Fessler RG (eds). *Dynamic reconstruction of the spine*. Thieme Medical Publishers, New York, 2006.
24. **Vernon H, Mior S.** The Neck Disability Index : a study of reliability and validity. *J Manipulative Physiol Ther* 1991 ; 14 : 409-415.
25. **Wigfield CC, Skrzypiec D, Jackowski A, Adams MA *et al.*** Internal stress distribution in cervical intervertebral discs : the influence of an artificial cervical joint and simulated anterior interbody fusion. *J Spinal Disord Tech* 2003 ; 16 : 441-449.
26. **Wipperman BW, Schratt HE, Steeg S, Tscherne H.** Complications of spongiosa harvesting of the iliac crest. A retrospective analysis of 1,191 cases. *Chirurg* 1997 ; 68 : 1286-1291.
27. **Zigler JE.** Lumbar spine arthroplasty using the ProDisc II. *Spine J* 2004 ; 4 (6 Suppl) : 260S-267S.