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Clinical Article

Intervertebral disc replacement for cervical degenerative disease – clinical results and functional outcome at two years in patients implanted with the Bryan® cervical disc prosthesis

V. Heidecke[1,2], W. Burkert[2], M. Brucke[2], N. G. Rainov[1,2]

[1] Department of Neurosurgery, Klinikum Augsburg, Augsburg, Germany
[2] Department of Neurosurgery, Faculty of Medicine, Martin-Luther-University Halle-Wittenberg, Halle, Germany

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Summary

Background. This is a prospective study of patients with degenerative cervical disease who underwent ventral discectomy and disc replacement with the Bryan® cervical disc prosthesis. The objective was to investigate clinical outcome at 2 years of patients implanted with the Bryan® disc and to evaluate function of the implant itself.

Methods. Fifty-four consecutive patients with cervical disc herniation and/or spondylosis with preserved mobility in the affected spinal segments were enrolled. Patients presented clinically with cervical radiculopathy and/or myelopathy with or without neck pain. A standard anterior cervical discectomy was carried out and a Bryan® disc was implanted in the affected levels. A total of 59 prosthetic discs were implanted, in 49 patients at a single level and in 5 at two adjacent levels. The neurological status was evaluated pre-operatively and at one and two years thereafter. Plain X-rays, CT, and MRI were used for pre-operative diagnostics. Post-operative follow-up was done by X-rays.

Findings. All patients had an excellent or good neurological outcome according to the Odom criteria. Loss of function (motion range $<3°$) was found in 7 (12%) out of 59 Bryan® discs at two years after surgery. Heterotopic ossification (HO) of the McAffee grades 1–4 was seen in a total of 17 (29%) segments. There were no implant dislocations or migrations.

Conclusions. Implantation of the Bryan® disc resulted in excellent or good neurological outcome in all patients. The surgical technique was safe and without complications. Twelve percent of the implanted Bryan® discs lost mobility at two years, mainly due to HO. A trend was seen towards development of HO in the operated segments.

Further investigations with longer follow-up periods and with a control group (e.g. fusion with intervertebral cage) will be necessary for a definitive assessment of the long-term functionality and benefits of artificial cervical discs.

Keywords: Bryan® disc; cervical degenerative disc disease; anterior approach; ventral discectomy.

Introduction

Anterior cervical discectomy and interbody fusion is a well-established treatment for degenerative disc disorders and spinal canal stenosis [5, 10, 14, 23]. The rigid fusion however, also leads to a reduction in normal cervical spine motion and to increased biomechanical stress at spinal levels adjacent to the fusion, which in turn accelerates degenerative changes of the discs at these levels [3, 4, 15, 17]. Hilibrand *et al.* have documented the occurrence of symptomatic adjacent-segment disc degeneration at a relatively constant incidence of 2.9% per year [12].

Artificial prosthetic discs were designed to replace degenerate cervical discs while obviating the problems

Correspondence: Dr. Volkmar Heidecke, Department of Neurosurgery, Klinikum Augsburg, Stenglinstrasse 2, 86156 Augsburg, Germany. e-mail: nikolai.rainov@klinikum-augsburg.de

associated with rigid interbody fusion [1, 3]. Potential benefits of the use of artificial cervical discs include maintaining a physiological motion range in the affected segment, restoring disc height, and correcting spinal misalignment [6, 21]. The preservation of intervertebral motion may also restore normal loads on facet joints, ligaments, endplates, and reduce degenerative changes in the adjacent vertebral segments [25]. On the other hand, potential disadvantages of the artificial disc may include implant migration and material wear, with high cost as an additional limiting factor [8, 9].

In this study, we describe the clinical, radiographic and functional outcome of patients with degenerative cervical spine disease who underwent anterior discectomy and were implanted with the Bryan® cervical disc prosthesis (Medtronic Inc., Minneapolis, MN) in one or two segments.

Patients and methods

Patient population

This prospective study was approved by the institutional Ethics Committee and was performed at a single neurosurgical center (Department of Neurosurgery, Martin-Luther-University Halle, Germany). A total of 54 consecutive patients (32 females and 22 males) with a mean age of 46.7 years (range 26.0–58.4 years) were enrolled prospectively in the study and were treated by standard anterior cervical discectomy and subsequent implantation of a Bryan® cervical disc prosthesis (Bryan® disc, Medtronic Inc., Minneapolis, MN). This selected group of patients represented 15% of all spinal degenerative disease patients treated within this time frame at the same center.

Inclusion criteria for enrolment were disc herniation and/or spondylosis with preserved mobility in the affected spinal segment. Patients presented clinically with cervical radiculopathy and/or myelopathy with or without neck pain. Exclusion criteria were advanced kyphotic deformity, spondylolisthesis, or translational instability of the cervical spine. Further exclusion criteria were insulin-dependent diabetes, advanced osteoporosis, ankylosing spondylitis, and rheumatoid arthritis. Patients above the age of 60 years were also excluded from the study.

Evaluation criteria

Each patient was followed for two years post-operatively using the Odom criteria for clinical neurological evaluation, and with cervical X-ray imaging for radiological evaluation. Complications of surgery were evaluated within the first two post-operative weeks. Post-operative X-ray images were compared with baseline radiographs to identify changes in the position and shape of the cervical spine and to detect possible dislocation of implants. The range of motion in the respective segments was measured in degrees. Heterotopic ossification (HO) was evaluated according to the McAffee criteria, where grade 0 means none and grade 4 means advanced HO with functional immobilisation of the segment [16].

Hardware and surgical technique

The Bryan® cervical disc prosthesis (Medtronic Inc.) has been available since the year 2000 and first systematic clinical reports were published in 2002 [8]. This cervical disc prosthesis consists of a polyurethane nucleus designed to fit between two titanium alloy shells and filled with lubricant (sterile saline) [3, 8, 9].

The surgical procedure for implantation of the Bryan® cervical disc has been described in detail previously [8, 9, 26].

Results

Fifty-four patients were enrolled in this study. In 49 patients, a single segment ventral discectomy and Bryan® disc implantation was carried out, and in 5 patients two

Table 1. *Distribution of cervical spinal segments implanted with the Bryan® disc*

Cervical segments	No. of Bryan® discs (%)
C4-5	18 (31)
C5-6	33 (56)
C6-7	8 (13)
Total	59 (100)

Table 2. *Clinical outcome at two years according to the Odom criteria [13]*

No. of of patients	Score	Description
43	excellent	All preoperative symptoms relieved. Neurological deficits improved
11	good	Minimal persistence of preoperative symptoms. Neurological deficits unchanged or improved
0	fair	Some pre-operative symptoms improved, others unchanged or slightly improved
0	poor	Pre-operative symptoms unchanged or exacerbated

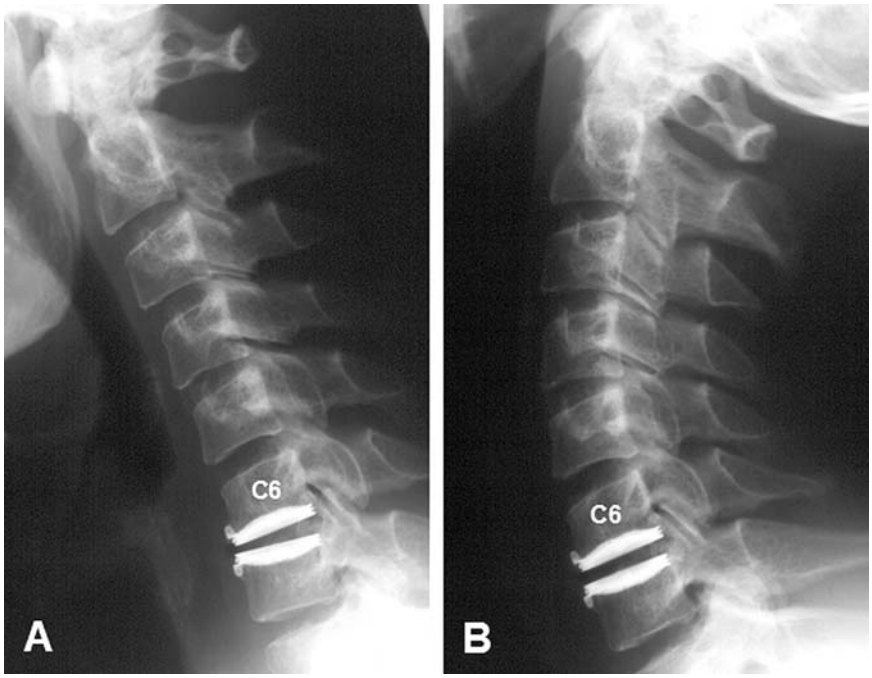

Fig. 1. Lateral X-ray radiographs in flexion (A) and extension (B) of the cervical spine taken one week after implantation of a Bryan® disc in the C6/7 segment. Note the correct alignment of the prosthetic disc and the physiological range of mobility in the implanted spinal segment

adjacent segments were treated (Table 1). Prosthetic discs with diameters from 14 to 18 mm were used.

According to the Odom outcome criteria [18], 43 patients had excellent and 11 good outcome at two years after surgery (Table 2).

Neuroradiological follow-up (lateral and A-P X-rays) in the first week after surgery demonstrated correct position and function of the implants in all patients (Fig. 1).

Table 3. *Neuroradiological assessment of functional outcome two years post-operatively*

Total no. of levels	Functional levels* (%)	Degree of function**	Non-functional levels*** (%)
59	52 (88)	$6^\circ \pm 3^\circ$	7 (12)

* Flexion/extension $\geq 3^\circ$.
** Mean $\pm$ SD.
*** Flexion/extension $\leq 3^\circ$.

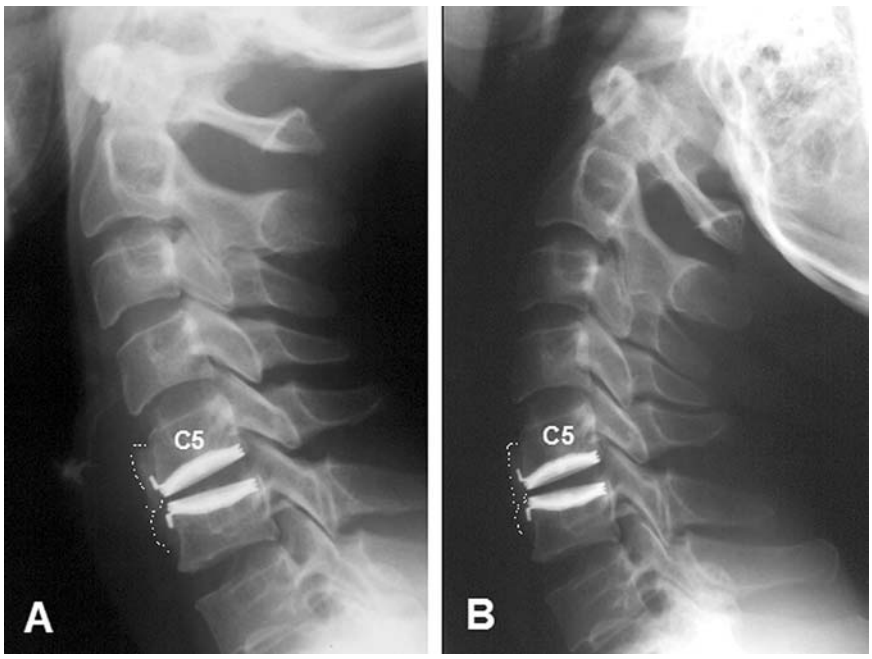

Fig. 2. Lateral X-ray radiographs in flexion (A) and extension (B) of the cervical spine taken two years after implantation of a Bryan® disc in the C5/6 segment. Note the ventral heterotopic ossification around the disc (McAffee grade 4). There is no useful motion range of the Bryan® disc in this segment

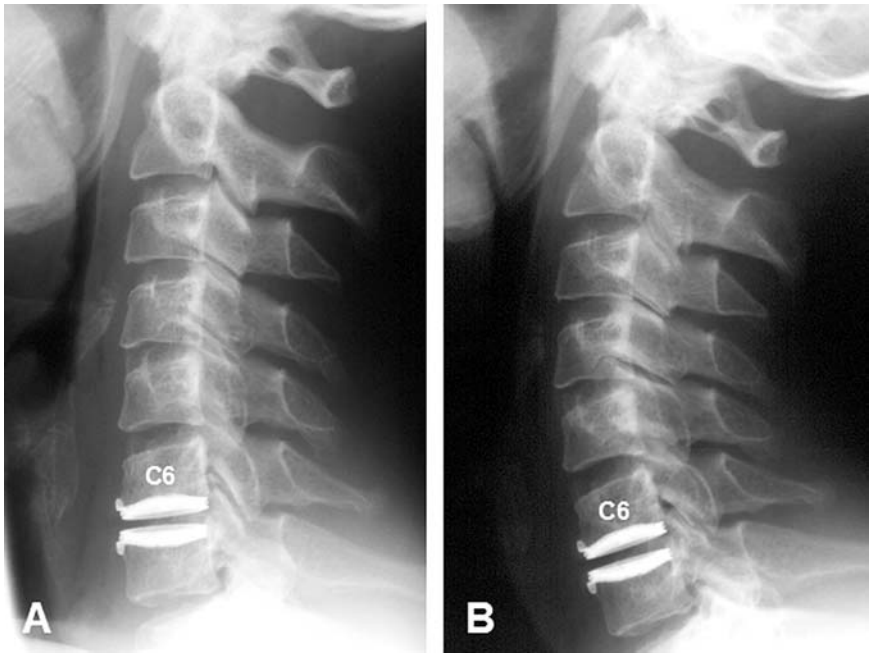

Fig. 3. Lateral X-ray radiographs in flexion (A) and extension (B) of the cervical spine taken two years after implantation of a Bryan® disc in the C5/6 segment. Note the complete loss of segmental motion without visible heterotopic ossification

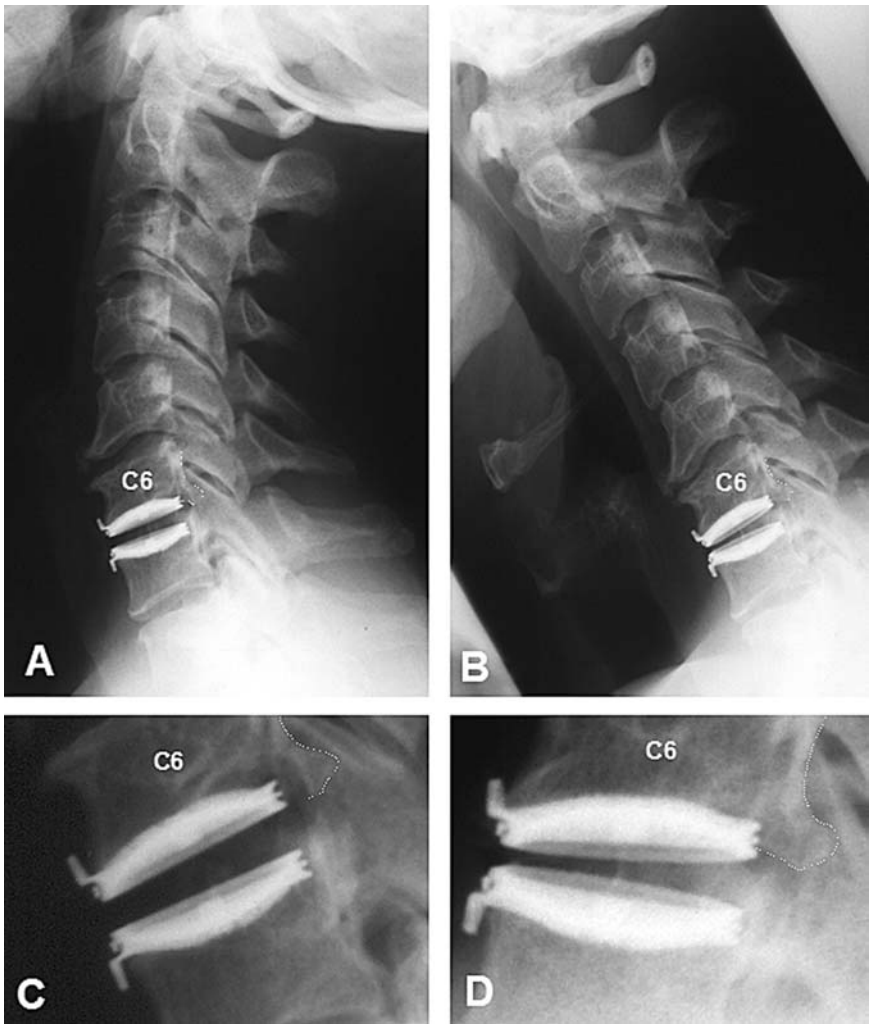

Fig. 4. Lateral X-ray radiographs in extension (A) and flexion (B) of the cervical spine taken one year after implantation of a Bryan® disc in the C6/7 segment. Note the heterotopic ossification at the dorsal edges of the vertebral bodies, particularly at C6, with osteophytes narrowing the intervertebral foramen and compressing the C7 nerve roots (C and D)

Minimal kyphotic deformities of the respective segments in the first week after implantation were disregarded as inherent to the construction of the Bryan® disc [7, 26].

There was no migration and no dislocation of the artificial discs during the follow-up period. Dynamic lateral X-rays at two years demonstrated loss of function (defined as a motion range $\leq 3^{\circ}$) in 7 patients (12%) with single level implants (Table 3). Of these 7 patients with loss of function, 5 demonstrated advanced HO of grades 3 and 4 according to McAffee (Fig. 2), and 2 had no HO (Fig. 3). In the remaining 52 treated segments, HO of grades 1 and 2 (without loss of segmental motion) were seen in 12 further levels (20%); HO grades 3 or 4 were not seen.

We have not observed any intra-operative or early post-operative complications due to the Bryan® disc. The sole long-term complication was noted in a patient with single level disc replacement who developed radicular neurological symptoms due to newly occurred dorsal osteophytes one year after surgery. In order to remove the osteophytes and to decompress neural structures in the intervertebral foramen, the dysfunctional Bryan® disc had to be removed and replaced with an intervertebral cage and plate, which resulted in full neurological recovery (Fig. 4).

With regard to surgery-related complications, there was only one early post-operative retropharyngeal haematoma that warranted surgical evacuation a few days after the initial procedure.

Discussion

This study prospectively investigated 54 patients with degenerative cervical spinal disease who underwent anterior cervical discectomy and implantation of a total of 59 Bryan® cervical discs in one or two segments. All patients had excellent or good long-term clinical neurological outcome (according to the Odom criteria). Loss of function in the treated level was noted at two years after surgery in 7 (12%) patients with single level Bryan® discs. Heterotopic ossification of McAffee grades 1–4 was seen in a total of 17 treated levels (29%). There were no instances of implant dislocation or migration.

Clinical studies with the Bryan® cervical disc

Several clinical studies with the Bryan® disc have been carried out and reported in the last few years [6–8, 20, 22, 24, 26, 27]. In 2002, Goffin *et al*. reported their experience with the Bryan® cervical disc prosthesis in patients with single-level degenerative cervical disc disease and reported 60 patients at 6 months and 30 patients at one year follow-up [8]. At one year, there was no measurable subsidence of the devices. Evidence of device migration was detected in two patients. There was no evidence of spondylotic bridging at the implanted disc space, and no devices were explanted or surgically revised.

Robertson *et al*. compared changes after single-level discectomy with subsequent cervical fusion or with artificial disc implant [22]. Patients received implants of either the Affinity® cage or the Bryan® disc. The Bryan® disc cohort consisted of 74 patients and in the Affinity® cage cohort there were 158 patients. In the cage fusion series, the incidence of symptomatic adjacent-level disc disease was statistically greater than in the Bryan® disc group [22]. Pickett *et al*. prospectively recorded the long-term outcome of 96 Bryan® discs implanted in 74 patients [20]. Neurological worsening occurred post-operatively in 3 patients. HO and spontaneous fusion occurred in 2 patients. There was a trend toward increased kyphosis post-operatively. Shim *et al*. implanted 61 patients with the Bryan® disc and followed them for 6 months [26]. The authors reported a subjective clinical improvement rate in 39 patients (64%), while 8 patients (17%) reported failure. The spinal curve became more kyphotic after surgery and the authors concluded that the Bryan® disc failed to restore the physiological lordotic angle in the respective segment [26]. Fong *et al*. enrolled prospectively 10 patients with degenerative disease treated with single level Bryan® discs [7]. The authors concluded that, although segmental motion seemed preserved, Bryan® disc implantation resulted in a propensity towards kyphotic orientation. Our general experience confirms the observations of the above authors [7, 20, 26], although specific measurements of the angle of segmental kyphosis were not a part of our study protocol.

Heterotopic ossification

Occurrence of advanced HO in cervical segments implanted with a prosthetic disc can reduce or completely abolish segmental mobility. In 2003, McAfee *et al*. [16] classified HO radiologically into 5 severity degrees (from 0 = no HO, to 4 = severe HO with segmental immobility). This classification is widely used to describe ventral and dorsal hyperosthotic changes in the cervical spine.

Leung *et al*. investigated HO and motion preservation in Bryan® cervical disc replacement at one year after

surgery [13]. Ten of the 90 studied patients showed HO grades 1 and 2, and 6 had grades 3 and 4 HO. Ten artificial discs were shown to have movement of less than 2° on flexion and extension X-rays, with 4 of these patients having HO grades 3 or 4. Male sex and older patients were significantly associated with development of HO. There was a strong association of the occurrence of HO with subsequent loss of movement of the implanted artificial disc [13]. Further examples of HO and bony fusion around the Bryan® disc were presented by Bartels and Donk and by Parkinson and Sekhon [2, 19].

In our study, there was a relatively high degree of HO (17 segments, 29%). Advanced HO (grades 3 and 4) mostly correlated with loss of function of the implanted discs (5 discs). However, in two discs with loss of function there was no HO (McAfee grade 0). In these examples without HO, the respective functional segment may have been immobilised by an increased rigidity of facet joints and ligaments. Other published studies demonstrated HO in 17.8% of all treated segments [20]. Since we meticulously removed bone dust and bone fragments from the treated segments at the end of surgery to avoid HO, surgical technique appears to play no major role for the occurrence of HO and segment immobility. Non-steroidal anti-inflammatory drugs (NSAID) were not routinely used in our study because of insufficient evidence for their efficacy against post-surgical HO of the spine.

In our study, loss of motion in the implanted segments has been observed in 7 out of 59 implanted discs (12%). This is comparable with the results of Leung *et al.* (11%) [13]. Although our study did not extend beyond two years of follow-up, individual patients have been followed outside of the study for up to 42 months. In these, there was a trend towards development of HO in the implanted segments and also in segments adjacent to these. The trend towards advanced HO coincided with a trend towards loss of motion in further implanted segments beyond the 7 segments described at two years follow up.

The current literature on functional cervical disc replacement describes relatively short follow-up times of implanted patients, with no systematic follow-up beyond three years postoperatively [8, 13, 21, 22]. It may therefore underestimate the number of non-functional implants, which would appear after a longer follow-up period. Based on our current experience with the Bryan® disc, we believe that advanced HO associated with loss of motion does increase with increasing time after surgery.

In conclusion, the use of the Bryan® disc in our study resulted in an excellent or good clinical neurological outcome in all patients. However, in terms of functional outcome of the implant, 12% of the implanted discs had lost mobility at two years, mostly due to advanced HO. For these, the necessity of implanting an artificial disc instead of an intervertebral cage should be discussed, but remains outside of the scope of the present study.

The question of reduced adjacent-disc degeneration after Bryan® disc implantation also remains open and cannot be answered without a significantly longer follow-up study.

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Comment

This paper by Heidecke *et al.* confirms the clinical and radiological data that have been described by others about the 1- and 2-year follow-up results after cervical disc replacement with the Bryan disc. I do not agree with the statement that postoperative kyphosis, as seen by Heidecke *et al*. in a number of cases, is due to the mechanics and the design of the prosthesis as such. It has been my experience that, if patients with preoperative kyphosis are excluded, postoperative kyphosis can consistently be avoided by a little change in the surgical technique, namely by changing the angle of the milling guide and bringing it down to a line that is parallel to the cranial endplate of the caudal vertebral body.

I agree with the authors when they explain that heterotopic ossification is not due to the presence of an excess of bone dust after the milling procedure. I also have always extensively irrigated the operation field after the milling, and still sometimes there was HO, however most of the times there was not. We, at my centre, are now looking at preoperative mechanical and genetic factors that might predispose to bone deposits after disc replacement surgery.

The authors suggest that heterotopic ossification will probably in the long run occur in a majority of patients, even with progression over time. I believe this statement can not be made at this point in time. The authors themselves do not provide detailed data that might support their suggestion. We, at the University of Leuven, have been following our patients now up to 4 and 6 years postoperatively. Our findings have been presented many times at a number of international meetings. Whereas we saw sometimes progression of HO over time in patients who did already present with HO at 2 years follow-up, we did almost never detect any HO if we looked at patients who had at the time of the operation no or only limited disc degeneration at the adjacent levels. This even holds true for 4 or 6 year follow-up examinations.

J. Goffin