Quality of life and radiological outcome after cervical cage fusion and cervical disc arthroplasty

Marc Röllinghof, Kourosh Zarghooni, Lisa Hackenberg, Alexander Zeh,
Florian Radetzki, Karl-Stefan Delank

From the Department of Orthopaedic and Trauma Surgery, Universities of Halle and Cologne, Germany

In this retrospective comparative study, 42 patients with single-level cervical radiculopathy were operated upon, either with Shell™ cage fusion (23 patients) or with Prestige™ cervical disc arthroplasty (19 patients). The mean follow-up (FU) was 17.5 months (range : 5.6-42.1 months). Both treatments significantly improved all clinical parameters (VAS, ODI, SF36) ($p < 0.001$), without statistically relevant differences between the two groups. From a radiological viewpoint there was an obvious but statistically non-significant increase in the segmental height for both treatment groups. Segmental angle also increased in both groups, and the increase was significant ($p < 0.05$).

As expected, range of motion (ROM) decreased significantly ($p < 0.05$) in the fusion group, while it was preserved in the arthroplasty group. Significantly more ($p < 0.05$) adjacent level degeneration class 1 to 4 was evident in the fusion group (8/23 or 34.8%) than in the arthroplasty group (3/19 or 15.8%). Two fusion patients (2/23 or 8.7%) developed painful clinical adjacent level disease requiring arthroplasty. The major conclusion was that significant adjacent level degenerative changes occurred in the cage group. Retained motion at the operative site seems to decrease the incidence of adjacent level degeneration. Implant subsidence was recorded at FU in 8 out of 42 patients (19%).

It occurred significantly ($p < 0.05$) more often in the fusion group (6/23 or 26.1%) than in the arthroplasty group (2/19 or 10.5%)), but it did not cause clinical symptoms. As in other studies, there is no explanation as to why better radiological results did not translate into better clinical outcomes within the time limits of the study.

Keywords : anterior cervical discectomy and fusion (ACDF) ; cervical disc arthroplasty ; cervical arthrodesis ; PEEK cage ; Prestige arthroplasty.

Anterior cervical discectomy and fusion (ACDF) is an established procedure for surgical treatment of cervical radiculopathy and myelopathy secondary to anterior compression from osteophyte or soft disc prolapse *(26)*. Anterior discectomy and fusion was pioneered five decades ago by Cloward *(5)*,

■ Marc Röllinghoff, MD, Consultant.
■ Alexander Zeh, MD, Consultant.
■ Florian Radetzki, MD, Resident.
■ Karl-Stefan Delank, MD, PhD, Professor.
Department of Orthopaedic and Trauma Surgery, University of Halle and Cologne, Germany.
■ Kourosh Zarghooni, MD, Consultant.
■ Lisa Hackenberg, Student.
Department of Orthopaedic and Trauma Surgery, University of Cologne, Germany.
Correspondence : Marc Röllinghoff, MD, Dept of Orthopaedic and Trauma Surgery, University of Halle, Magdeburger Str. 22, 06112 Halle, Germany.
E-mail : marc.roellinghoff@gmx.de

Dereymaker and Mulier (7), and Smith and Robinson (22). The use of anterior iliac bone graft for anterior interbody fusion has been the gold standard for many years. Although fusion is successfully achieved with autologous iliac bone grafts, various studies have documented donor site complications (1,9,21). To prevent such complications, artificial cages made of various materials including titanium, carbon fibre, and poly-etheretherketone (PEEK) have been studied and applied in humans as potential substitutes for auto-grafts in interbody fusion. PEEK cages are bio-compatible, radiolucent, and have a modulus of elasticity similar to bone. But in recent years, the concept of total disc arthroplasty has emerged as a new paradigm for the surgical management of discogenic pathology. As an alternative to ACDF, an artificial disc serves to replace the symptomatic degenerated disc, to restore the functional bio-mechanical properties of the motion segment, and to protect neurovascular structures (6). Single-level fusion does not seem to significantly alter global mobility, but there is evidence that cervical arthrodesis increases stress on the non-operated discs (23). Because of the reported concerns of progressive adjacent segment degeneration and motion loss after ACDF, disc arthroplasty is being implemented with promising early results (2). The preliminary data suggest that single-level disc arthroplasty is at least as effective as fusion for the relief of radiculopathy, myelopathy, and axial pain (2,19,23). It remains unclear which effect arthro-plasty will have on the prevention of adjacent seg-ment disease, although some evidence suggests that it is more favourable (18).

The primary purpose of this study was to compare the clinical and radiological outcomes of two techniques for single-level cervical radicu-lopathy : (1) fusion with Shell™ cage (AMT Company, Nonnweiler, Germany) filled with hydroxyapatite paste (Ostim®, Heraeus Kulzer GmbH, Hanau, Germany) as bone graft substitute, and (2) Prestige™ cervical disc arthroplasty (Medtronic Sofamor Danek, Inc., Memphis TN, USA). Shell™ cages are made of polyetherether-ketone (PEEK), a benzene ring polymer, which is radiolucent.

MATERIALS AND METHODS

Patients

Between January 2006 and October 2009, 57 patients underwent anterior cervical discectomy for single level cervical spine disease. Inclusion criteria for the study were : 1. single level cervical degenerative disc disease (DDD), 2. fusion with Shell™ cage or arthroplasty with Prestige cervical disc. Exclusion criteria were : active systemic infection, metabolic disease, steroid use, diabetes mellitus, and cervical spine disease of more than one level. Forty-two out of 57 patients were available for follow-up in this retrospective study (22 males, 20 females). The cage group consisted of 23 patients (13 males, 10 females) (54.8%) , and the arthroplasty group of 19 patients (9 males, 10 females) (45.2%) . The mean age, at the time of surgery, was 50.3 ± 11.2 years (range 29-82 years). The mean follow-up (FU) was 17.5 ± 10.6 months (range 5.6-42.1 months). None of the patients had undergone previous cervical surgery, but two patients developed clinical adjacent level disease after fusion, requiring arthroplasty. Anterior cervical discectomy was performed at a single level from C3 to Th1 (Fig. 1), with the most frequently operated levels being C5C6 (35.7%) and C6C7 (42.9%).

Operative procedure

The indication for anterior cervical discectomy was painful herniated vertebral disc of the cervical spine which had failed to respond to conservative treatment lasting at least 4 weeks. A herniated disc was diagnosed by computed tomography or magnetic resonance imag-ing in combination with clinical examination. From January 2006 to December 2007 all patients were treated with cage fusion. From January 2008 to October 2009, all patients underwent cervical disc arthroplasty. Each operation was performed by one of three senior spine surgery specialists. All patients were treated with a standard surgical procedure using the Smith and Robinson approach (22) for both groups. After micro-surgical discectomy, the cage or the disc replacement device was placed between the endplates using a specif-ic inserter. The optimum size of the implant needed to restore disc height was determined using lateral fluo-roscopy. Postoperatively, all patients wore an anatomic elastic collar for 2 weeks and received physiotherapy after 2 weeks.
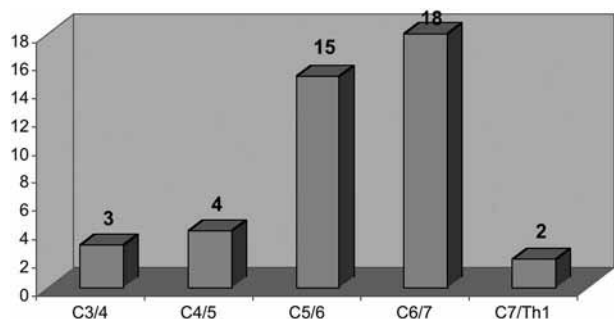
Fig. 1. — Overview of treated levels (N = 42) with Shell™ cage fusion (N = 23) and Prestige™ cervical disc arthroplasty (N = 19).

Clinical outcome

Because Cologne University Hospital took part in the international "Spine Tango" registration, the "Spine Tango" questionnaire, based on a Visual Analogue Scale (VAS), the Oswestry Disability Index (ODI), and the SF-36 (total), was used preoperatively, postoperatively, and after a mean of 17.5 months. A 10 cm VAS was used to evaluate outcome regarding level of pain. The ODI is one of the most commonly used validated clinical outcome measures for individuals with spine pain. It is a reliable and responsive condition-specific assessment tool which is suited for use in clinical practice (25). In addition, the patients' medical records were analyzed to determine the nature and extent of postoperative complaints.

Radiological outcome

Radiological evaluation included static AP (anterior-posterior) and lateral radiographs, plus dynamic (flexion/ extension) lateral radiographs for all patients pre- and postoperatively, and at FU. An independent consultant assessed the radiographs to eliminate bias. Analysis of the radiographs consisted of evaluation of segmental height, segmental angle, range of motion (ROM), adjacent level degeneration and subsidence. Mean segmental (segment = two involved vertebrae) height was the average of the anterior and posterior segmental height. The segmental angle was the angle formed by the lower endplate of the upper vertebral body and the upper endplate of the lower vertebral body, on a lateral radiograph. The range of motion (ROM) was measured at the index level in maximum flexion and extension. Motion was considered blocked if < 3°. Adjacent level *degeneration* above

and below the index level was assessed after a mean follow-up (FU) of 17.5 months, according to the Kellgren classification (12). Clinical adjacent level *disease* was defined as symptomatic herniated vertebral disc, mechanical neck pain, or symptomatic sagittal or coronal imbalance. The tendency towards subsidence of the implant (cage/prosthesis) was recorded in a semi-quantitative manner (13) : no obvious subsidence, minor subsidence, i.e. implant penetrated the endplate to a maximum of 2 mm, and major subsidence, i.e. implant penetrated more than 2 mm.

Data collection and statistical analysis

Radiographs were analyzed independently by a consultant radiologist and one of the authors. All results were assessed by two different persons and averaged when necessary. The data were expressed as mean ± standard deviation (SD). The comparison between non-parametric interval-scale variables was done using the Wilcoxon Signed Ranks Test. Results were considered significant when the p-value was less than 0.05. All statistics were performed using SPSS 16.0 (SPSS 16.0, Inc. Chicago, Illinois, USA).

RESULTS

Clinical outcome

The mean pain index score (VAS) decreased significantly (Table I) postoperatively and at FU (p < 0.001) for both groups. In the cage group there was a slight rebound effect, from 1.8 postoperatively to 3.0 at follow-up, but this was not statistically significant. Furthermore, quality of life was enhanced significantly by both techniques. The average preoperative Oswestry score (ODI) was 44 for the cage group and 53 for the prosthesis group ; these scores decreased significantly (p < 0.001), immediately after surgery, to 26 for cages and to 29 for prostheses, and decreased again significantly (p < 0.001) at follow-up to 15 and 16. Also the SF-36 total score improved significantly for both groups, immediately postoperatively (cage : p = 0.014, prosthesis : p = 0.003), and further at follow-up (p < 0.001 and p < 0.001, respectively). However, no significant differences between the two operative techniques were ascertained as far as VAS, ODI and SF-36 were concerned.

Table I. — Quality of life significantly improved after both procedures, with no significant difference between both procedures

VAS						
	N	Preop	Postop	Sig. (two-tailed)	Follow-up	Sig. (two-tailed)
Cage	23	7.9 ± 2.8	1.8 ± 2.2	0.001	3.0 ± 3.0	0.001
Prosthesis	19	8.7 ± 1.8	3.2 ± 2.6	0.001	2.9 ± 2.8	0.001
Oswestry (ODI)						
Cage	23	44 ± 24	26 ± 24	0.001	15 ± 17	0.001
Prosthesis	19	53 ± 20	29 ± 20	0.001	16 ± 15	0.001
SF36 (total)						
Cage	23	46 ± 24	58 ± 26	0.014	68 ± 22	0.001
Prosthesis	19	37 ± 20	57 ± 16	0.003	65 ± 20	0.001

Table II. — Radiological evolution

Cage								
	N	Preop	Postop	At follow-up	no	yes	minor	major
Segmental angle °	23	3.5 ± 1.1	6.4 ± 2.0*	5.6 ± 2.2*				
Segmental height mm	23	40.7 ± 4.1	42.7 ± 5.1	42.0 ± 4.9				
ROM °	23	5.8 ± 2.2	2.1 ± 1.7*	1.5 ± 1.2*				
Subsidence	23				17	6	3	3
	N	class 0	class 1	class 2	class 3	class	No	Yes
Adjacent level degeneration	23	15	3	2	1	2		
Adjacent level disease	23						21	2
Prosthesis								
	N	preop	postop	at follow-up	no	yes		
Segmental angle °	19	3.7 ± 0.9	5.5 ± 2.3*	5.4 ± 2.2*				
Segmental height mm	19	41.1 ± 6.3	42.8 ± 5.3	42.1 ± 5.6				
ROM °	19	6.1 ± 2.2	5.1 ± 2.7	5.7 ± 3.2				
Subsidence	19				17	2	2	0
	N	class 0	class 1	class 2	class 3	class 4	No	Yes
Adjacent level degeneration	19	16	2	1	0	0		
Adjacent level disease	19						19	0

* = p < 0.05.

Radiological outcome

The *mean segmental height* before treatment was 40.7 mm in the cage group and 41.1 mm in the prosthesis group (Table II). After treatment, there was an obvious increase in the segmental height for both treatment groups, but this was not statistically significant. At FU, there was a slight decrease of segmental height in the cage group from 42.7 mm to 42.0 mm, and in the prosthesis group from 42.8 mm to 42.1 mm. Regarding the *segmental angle*, there was a significant increase, postoperatively, from 3.5° to 6.4° in the cage group and a comparable increase from 3.7° to 5.5° in the prosthesis group. At FU, there was a slight decrease in the cage group from 6.4° to 5.6°, whereas in the prosthesis group nearly the same segment angle was preserved. As expected, *range of motion (ROM)* decreased significantly in the cage group from 5.8° preoperatively to 2.1° postoperatively, and to 1.5°

at FU. In the prosthesis group ROM was 6.1° preoperatively and 5.1° postoperatively. Motion was maintained in this group with 5.7° ROM at FU. Moreover, 91.1% (21/23) of the treated levels were mobile (ROM > 3°) at a mean follow-up of 17.5 months. *Adjacent level degeneration* at FU was graded according to the Kellgren classification (*14*) (Table II). In the cage group there were 3 (13.0%) class 1, two (8.7%) class 2, one (4.3%) class 3, and two (8.7%) class 4 cases, while 65.2% had no adjacent level degenerative changes. In the prosthesis group there were 2 (10.5%) class 1 cases and one (5.2%) class 2 case, the remainder (84.2%) showed no degenerative changes at the adjacent levels. In other words, there was significantly more (p < 0.05) adjacent level degeneration of class 1 to 4 in the cage group than in the prosthesis group. Two of the cage patients had severe degenerative changes (class 4) and developed painful clinical adjacent level disease treated with anterior cervical discectomy and Prestige cervical disc arthroplasty (hybrid situation). *Subsidence* was recorded in 8 of 42 patients (19%). It occurred significantly (p < 0.05) more often in the cage group (6/23 or 26.1%) than in the prosthesis group (2/19 or 10.5%). None of the subsidence cases required revision surgery because there were no clinical symptoms.

Complications

There was a temporary swallowing dysfunction, which disappeared after one week, in 6 out of 23 (26.1%) cage patients and in 4 out of 19 (21.1%) prosthesis patients. There was a temporary hyperaesthesia at the operated level in 2 out of 23 (8.7%) cage patients and in 1 out of 19 (5.3%) prosthesis patients. At FU two patients (2/23 : 8.7%) of the cage group had developed painful clinical adjacent level disease which required arthroplasty. No anterior or posterior dislocation of either cage or prosthesis was evident at FU. There were no cases of implant breakage or displacement.

DISCUSSION

Clinical outcome

This study shows that single-level implantation of Shell™ cages and Prestige™ cervical disc arthroplasty (Fig. 2) leads to significant improvement of mean pain index score (VAS) and quality of life (ODI, SF 36). However, no significant differences were ascertained between the two operative techniques, although there was significantly more (p < 0.05) adjacent level degeneration of class 1 to 4 in the cage group than in the prosthesis group. Two patients (2/23 or 8.7%) in the cage group developed painful clinical adjacent level disease which required arthroplasty. According to the literature, anterior cervical discectomy and fusion for cervical spine disease induces significant improvement in the clinical condition (*15,16*). In a prospective, comparative study, Lied *et al* (*16*) treated

Fig. 2. — AP and lateral views of (left) a 49-year-old female with Shell™ cage implantation C5C6, and (right) a 44-year-old male with Prestige cervical disc arthroplasty C4C5.

258 patients, either with autologous bone grafts (181 patients), or with PEEK cages (77 patients). Both groups showed similar clinical outcomes, without donor site morbidity in the PEEK cage group. On the other hand, cervical disc arthroplasty is emerging as a viable alternative to fusion in the treatment of cervical disc disease (*3*).

Radiological outcome

Segmental height and angle. Regarding the radiological results, the segmental height increased slightly in both treatment groups, and the segmental angle increased significantly in both groups (p < 0.05). Thus, radiologically, both treatments are able to restore single level cervical disease.

Range of motion and adjacent level degeneration. ROM decreased significantly in the cage group, as was expected. In contrast, segmental motion was maintained in the prosthesis group : 91.1% (21/23) of the prostheses were still mobile (ROM > 3°) at a mean follow-up of 17.5 months. Similarly, Beaurain *et al* (*2*) found that 85.5% (65/76) of the levels treated with arthroplasty were mobile at the 2 year follow-up. In the current study there were significantly more class 2 to 4 degeneration cases (*12,13*) in the cage group. In the prosthesis group 84.2% of the patients had no degenerative changes at the adjacent level, compared to the cage group with only 65.2%. The authors believe that this difference in mobility might be related to the development of more radiological changes in the adjacent segments of the cage group. Biomechanical and kinematic studies support the idea that preservation of motion at the operative site helps lessen the incidence of adjacent level degeneration (*8,10*). In 2005, Robertson *et al* (*20*) did a prospective study comparing the incidence of radiologic changes with symptomatic adjacent level disease after fusion (ACDF) and after implantation of a Bryan cervical disc. In the cage fusion series, the incidence of symptomatic adjacent level disease was also significantly higher than in the artificial disc group (p = 0.018).

Subsidence. Subsidence was noted significantly more often in the cage group (6/23 or 26.1%) than in the prosthesis group (2/19 or 10.5%) at follow-up. None of the subsidence cases required revision surgery because there were no clinical symptoms. The subsidence was most likely due to the smaller contact area and the four pins of the Shell cage, which might stress the upper and lower plates of the index segment. The Prestige cervical disc contains 2 additional rows of teeth, 2.3 mm long, as well as a porous titanium surface (*6*), enlarging the surface area in contact with the upper and lower plates. In a retrospective comparison of six different intervertebral disc spacers for cervical arthrodesis, Meier and Kemmesies (*17*) also reported a tendency towards subsidence with the use of PEEK cages. Kast *et al* (*11*) compared subsidence after implantation of Solis™ cages and Shell™ cages, both made of polyetheretherketone (PEEK). They reported significantly more subsidence in the Solis group (42%) than in the Shell group (15%). They felt that the limited contact area of the Solis cages might be the reason (*13*).

Weaknesses

The size of the study and the follow-up period were relatively small. Thus the results are limited and preliminary. Studies with longer follow-up might show more important radiological changes or others.

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