Interbody fusion following ACD for treatment of cervical radiculopathy or cervical myelopathy is thought to have several advantages compared with discectomy alone.37,41

There is no consensus, however, regarding the optimum substrate for cervical fusion.46 Iliac crest autografts are most commonly used12,13,38 and yield fusion rates between 83 and 97%.7,33 Bone graft harvesting at the iliac crest, however, results in additional patient-related pain and discomfort.4,32,35 Recently, RTCs have been introduced as a new fusion device applicable in the anterior cervical spine. Clinical experience, thus far, is limited, and at this time these devices have not been approved by the Food and Drug Administration.2,10,21

The purpose of this study was to assess the safety and efficacy of RTC fusion compared with standard iliac crest autograft grafting in the treatment of cervical disc disease.

CLINICAL MATERIAL AND METHODS

Clinical and Demographic Characteristics

Thirty-six patients with symptomatic one- or two-level cervical disc disease (spondylosis and/or herniated cervical disc) refractory to adequate conservative treatment were recruited consecutively for this study. Patients with ossification of the posterior longitudinal ligament, previous cervical disc surgery, and/or spinal instability were excluded. All patients underwent anterior cervical microdiscectomy in which standard techniques were used. In the first 18 patients, iliac crest autograft fusion was performed. In the next 18 patients, RABEA RTCs (RABEA; Signus, Alzenau, Germany) were inserted in the intervertebral disc space.

First, data were collected prospectively in a control group, which consisted of a consecutive series of 18 patients with cervical disc disease who underwent tricortical iliac crest autograft fusion. In the second arm of the study, the next 18 consecutive patients underwent RTC fusion and were followed prospectively. Evaluation of outcome included radiological and clinical assessments.

Prospective controlled study of rectangular titanium cage fusion compared with iliac crest autograft fusion in anterior cervical discectomy

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Object. The complications of autogenous bone grafting compel spine surgeons to seek alternative methods for cervical spinal fusion. This prospective study was conducted to evaluate the safety and efficacy of using rectangular titanium cage fusion compared with the widely performed iliac crest autograft fusion.

Methods. A total of 36 patients with cervical disc disease in whom an anterior approach was indicated for discectomy were included in this prospective controlled study. The first 18 consecutive patients received iliac crest autograft; the next 18 consecutive patients received rectangular titanium cages. The intergroup demographic and clinical data were comparable. All patients attended follow up for 1 year. According to Odom criteria, 15 (83%) of 18 patients in both groups experienced good to excellent functional recovery. According to the Patient Satisfaction Index, 17 (94%) of 18 patients in both groups were satisfied. The evaluation of neck pain and arm pain did not indicate statistically significant differences between either group. Fusion was present after 1 year in 16 (89%) of 18 patients who received iliac crest autografts and in 15 (83%) of 18 patients who received rectangular titanium cages. In the autograft group, a pseudarthrosis was present in one patient and marked hip pain was observed in three patients. In the cage group, there was one case of temporary vocal cord paresis but no implant-related complications.

Conclusions. The authors conclude that the use of titanium cages in anterior cervical discectomy constitutes a safe and efficient alternative to iliac crest bone autograft.

KEY WORDS • anterior cervical discectomy • anterior cervical fusion • interbody cage • bone graft
The demographic and clinical data were comparable between groups. Mean age at surgery was 51 years in the iliac crest autograft group and 52 years in the RTC group. The mean duration of preoperative symptoms was 15 and 13.5 months, respectively. The sex ratio, the pattern of clinical presentation (radiculopathy compared with myelopathy), and the number of treated levels were similar in both groups (Table 1).

### Surgical Procedures

Surgical procedures were performed using the common Smith–Robinson anterolateral approach via a right-sided skin incision. The posterior longitudinal ligament was excised thoroughly to ensure adequate neural decompression. Gentle decortication of the endplates was performed using a curette. In the iliac crest autograft group, a tricortical iliac crest graft was then harvested using a standard osteotome technique. The tricortical graft was adjusted to fit into the slightly distracted disc space and countersunk into position.

In the RTC group, the size and shape of the cage was selected based on both the preoperative imaging studies and the intraoperative measurements. The cages were not filled with bone or other material. The RABEA cage has a cuboid form, is hollow, and has fenestrated surfaces on all sides. The upper and lower surfaces have 1-mm toothed spikes that assist in the positive anchorage of the implant between the VBs. It is produced from forged titanium alloy, which is magnetic resonance imaging compatible. Many size variations are available (Fig. 1).

Postoperatively, all patients wore a hard cervical orthosis for 6 weeks.

### Assessment of Outcome

Functional outcome was assessed according to Odom criteria.28 Outcome was defined as excellent in patients without complaints referable to cervical disc disease and who were able to perform their daily routines without impairment; good outcome was defined as intermittent discomfort related to cervical disc disease that did not significantly interfere with work; satisfactory outcome was defined as subjective improvement but limited physical activities; and poor outcome was defined as an absence of improvement or worsened condition compared with preoperative status.

To evaluate satisfaction with the postoperative result, the PSI was applied.14,30 The PSI is a modified subitem of the North American Spine Society outcome questionnaire. It is scored as follows: 1) “Surgery met my expectations”; 2) “I did not improve as much as I had hoped but I would undergo the same operation for the same results”; 3) “Surgery helped but I would not undergo the same operation for the same results”; and 4) “I am the same or worse as compared to before surgery.” In clinical outcome the improvement of sensory and motor radiculopathy, as well as myelopathy, were evaluated. Pain was assessed by a VAS, as described in detail by Scott and Huskisson.36 Changes in patients with myelopathy were rated according to the Nurick classification of disability in spondylotic myelopathy.27

Radiological evaluation included criteria for fusion and the position of the implant. Standard radiographs were assessed for luencies in the immediate vicinity of the implants. It was not possible to determine the growth of bone through the cage on the radiographs. Stability was assessed using an overlay method of lateral flexion–extension radiographs. They were aligned to superimpose VBs to determine the presence or absence of motion. Each operative segment was deemed fused if there was less than 2° of segmental movement on lateral flexion–extension views and if less than 50% of the anteroposterior distance of the interface between the endplates and the implants was radiolucent. Two degrees of motion were used as the upper limit to compensate for experimental error and variation (Fig. 2).

Analysis of the position of the implant considered subsidence (migration of the graft into the superior and/or inferior VB of > 2 mm) and significant graft extrusion (>

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**TABLE 1**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Iliac Crest Autograft</th>
<th>RTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>no. of patients</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>mean age ± SD (yrs)</td>
<td>51 ± 12</td>
<td>52 ± 12</td>
</tr>
<tr>
<td>male/female</td>
<td>11:7</td>
<td>11:7</td>
</tr>
<tr>
<td>mean duration of symptoms (mos)</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>clinical presentation (radiculopathy/myelopathy)</td>
<td>10/8</td>
<td>10/8</td>
</tr>
<tr>
<td>single-/two-level procedure</td>
<td>14/4</td>
<td>13/5</td>
</tr>
<tr>
<td>C3–4</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>C5–6</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>C6–7</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>C4–6</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>C5–7</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

* SD = standard deviation.

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Fig. 1. Photograph showing the RABEA cage equipment. Although the smooth test cages (blue color, at right) are used to fit the properly sized cage into the disc interspace, the implant cages (at left) are characterized by spikes for anchorage into the endplates. Two exemplary sizes and the implant holder are depicted.
2 mm). In the iliac crest autograft group, radiographs were also studied for graft collapse.

All patients underwent 3-month clinical follow-up examination as well as extensive reassessment at 1 year postoperatively.

**Statistical Analysis**

The Mann–Whitney rank-sum test was used to analyze differences in the preoperative clinical and demographic characteristics (age, duration of symptoms, VAS score, and Nurick grade) and in clinical outcome variables between groups (Odom criteria, PSI, motor and sensory deficit improvement, VAS score, and Nurick grade). The Wilcoxon signed-rank test was used to analyze intragroup change. The Fisher exact test was used to analyze intergroup differences in fusion and implant-related complications. Statistical significance was set at \( p < 0.05 \).

**RESULTS**

**Clinical Outcome**

Outcome of motor and sensory radiculopathy was equally successful in both groups (\( p = 0.943 \) and 0.940, respectively). Patients with myelopathy fared somewhat less well, but there was significant improvement (post-compared with preoperative: \( p = 0.031 \) [iliac crest autograft group] and \( p = 0.016 \) [RTC group]) with no differences in outcome between groups (\( p = 0.867 \)) (Fig. 3). The evaluation of arm pain before and after surgery, according to the VAS, showed highly significant improvement in both groups (post- compared with preoperative: \( p < 0.001 \) [iliac crest group]; \( p < 0.001 \) [RTC group]; \( p = 0.702 \) [both groups]). The relief of neck pain was less pronounced, but again highly significant and demonstrated a similar degree in both groups (post- compared with preoperative: \( p = 0.001 \) [iliac crest group]; \( p = 0.005 \) [RTC group]; \( p = 0.692 \) [both groups]) (Fig. 4).

According to Odom criteria, 83% of patients in both groups experienced good to excellent functional recovery (\( p = 0.824 \)). According to the PSI, 93% of patients in both groups were satisfied and would undergo the same operation for the same results (\( p = 0.987 \)) (Fig. 5).

**Adverse Events**

Three patients suffered severe pain (> 3 of 10 on the
VAS lasting > 6 months) at the site of iliac crest harvesting. One patient in the iliac crest autograft group developed a pseudarthrosis. The patient underwent reoperation and fusion was achieved with autologous bone and a plate system. One case of transient recurrent nerve palsy was documented in the RTC group. There were no implant-related complications after placement of the RTCs (complications in four of 18 patients in the iliac crest autograft group and zero of 18 patients in the RTC group [p = 0.045]).

Radiological Outcome

Graft collapse was demonstrated in three out of 22 levels in the iliac crest autograft group. One iliac crest autograft demonstrated slight extrusion with resulting pseudarthrosis (Fig. 6). Subsidence was seen in eight of 23 implants in the RTC group. Subsidence in the RTC group did not correspond with any clinical symptoms. It was more frequent early in the series (in four of the first five patients), when partial removal of the cortical endplates was performed in an attempt to promote rapid osseous growth and fusion. As a result of this observation, thereafter only the disc material was thoroughly removed, which subsequently reduced the rate of subsidence. Radiologically, the degree of subsidence was unchanged in all affected levels at 12 months compared with 3 months postoperatively, indicating no progression of subsidence over time.

With regard to fusion, RTCs proved to be equivalent to iliac crest autografts (p = 1.000). Ninety-one percent of the surgically treated segments (89% of patients) in the iliac crest autograft group and 87% of those (83% of patients) in the RTC group were considered stable and showed no signs of motion in flexion–extension on lateral radiographs (Table 2).

DISCUSSION

The anterior approach to the cervical spine has become an accepted route for treatment of a large number of cervical spine disorders including spondylosis, herniated discs, fractures, and neoplastic lesions. Since its introduction by Cloward and by Smith and Robinson, several technical modifications for ACD have been developed.12,13,33 No consensus regarding the optimum technique, however, has yet been established. Controversial debates in cervical disc surgery are focused on issues such as the use of either autograft or allograft material to maintain disc height, the role of plate-related stabilization, or whether any graft or plate is necessary at all.3,11,24

Many surgeons have believed that decompression alone will suffice.1,6,15,34,37,48 It has been accepted that the surgically treated disc level would undergo settling and some kyphotic angulation and, in the majority of patients, would then fuse. More than 20 years ago, Wilson and Cambell48 reported good or excellent outcome in 85% of patients after ACD without fusion. Their follow-up period of 6 months, however, was relatively short. Martins25 reported clinical success in 92% of the patients after ACD with or without fusion at 10-month follow up. In the group undergoing ACD alone, a relevant kyphotic deformity developed in 10% of patients. Savolainen, et al.,34 recently conducted a randomized study of one-level anterior cervical procedures in which outcomes in patients who were treated with simple ACD were comparable with those who underwent iliac crest graft placement with or without plating.

Other surgeons have argued that microdiscectomy alone is associated with a short-term increase in pain, long-term narrowing of the decompressed foramina, and increased stress on the adjacent disc levels secondary to loss of the normal sagittal alignment of the spine.37,41 Maintenance of disc height and fusion is desirable, be-
cause the loss of disc height and the resultant increased motion is thought to be involved in the pathophysiology of spondylosis. Watters and Levinthal\(^4\) reported that patients who underwent ACD and fusion experienced earlier resolution of their presenting symptoms and a slightly greater chance for long-term success than those who underwent ACD alone. In the fusion group, a greater number of complications (16 compared with four) were demonstrated, which were primarily related, however, to the iliac crest donor site (15 of 16). They concluded that neither procedure was ideal.

Harvesting autogenous bone from the iliac crest can occasionally be associated with marked blood loss. The most important problem, however, is postoperative graft site–related pain. Sawin, et al.,\(^3\) reported a morbidity rate of 25.3% (morbidity included pain, hematoma, fracture, and meralgia paresthetica). The disturbing discomfort in the early postoperative period often resolves with time, yet some authors have shown that residual pain may continue for as long as 24 months after surgery. In the present study, three patients (16.6%) reported ongoing donor site–related pain for more than 6 months.

Avoiding the morbidity associated with the iliac crest has prompted some surgeons to use alternatives such as allografts. The disadvantage of allogenic bone, most commonly iliac crest, is that it may collapse in up to 30% of patients, with a mean height loss of 50%.\(^7\)\(^,\)\(^9\)\(^,\)\(^4\)\(^9\) When using allografts the surgeon must also take into account the costs of a bone bank and a strict program of quality control. Concerns regarding the risks of transmissible agents such as acquired immune deficiency syndrome virus further restrict the use of allograft bone.

A variety of bone substitutes have also been described. Polymethylmethacrylate is an excellent cement for orthopedic prostheses, but it fails to meet the demands required for an interbody fusion device.\(^3\)\(^,\)\(^4\) Although PMMA may be useful in reconstruction after resection of tumors, its use after discectomy is associated with necrosis of adjacent vertebrae.\(^9\) In some studies PMMA fared worse than simple discectomy alone, and it has been suggested that PMMA acts only as a spacer that hinders fusion.\(^4\)

The initial results following the use of HA appeared encouraging. Thalgott, et al.,\(^4\) used treated coral for bone replacement. The combined use of this product and a rigid internal fixation device was strongly recommended. In another study, the authors relied on an alumina core coated in HA, having found HA blocks to be too brittle.\(^8\)

In one frequently quoted report the authors claimed BOP to be a safe, biocompatible, osteoconductive matrix.\(^2\) In subsequent studies, however, authors could not support these claims. The lucency of the BOP graft made radiological assessment difficult. High rates of graft col-

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**Figure 5:** Bar graph demonstrating functional outcome evaluated according to Odom criteria and PSI in the iliac crest autograft and RTC groups. Both implants yielded a similar outcome.

**Figure 6:** *Left:* Lateral radiograph revealing slight iliac crest autograft extrusion (arrow) resulting in pseudarthrosis. *Right:* Radiograph demonstrating cage subsidence without consequences regarding fusion. Bridging bone can be observed anterior to the cage.
lapse or extrusion were noted.\textsuperscript{20} Examination of biopsy specimens of the polymer obtained at reoperation showed a foreign-body, giant cell reaction and no evidence of biodegradation or osseous conduction. It was concluded that BOP acted only as a spacer.

The ideal cervical fusion substitute should result in fusion in all patients and offer maximum comfort for the patient. It should avoid painful autograft sites and associated soft-tissue morbidity, obviate the need for cervical orthosis, and not impede subsequent radiological investigations. It should provide immediate stability in compression and resist axial displacement, minimize neck pain, and maintain spinal alignment and foraminal height. In addition to a high fusion rate, clinical success depends on the maintenance of interspace height and sagittal balance. The latter is accomplished by avoiding collapse of the graft during its incorporation.

All these factors led many authors in recent years to study the results associated with fusion cages. Most of the studies, however, have not been controlled, are retrospective, or lack adequate follow-up periods.\textsuperscript{2,3,10,21,26,31} There are only few prospective reports with the appropriate number of patients and longer follow-up periods in which cages are compared with controls. Hacker, et al.,\textsuperscript{17} conducted a prospective, controlled, randomized, multicenter clinical study of a threaded titanium cage, the BAK/C cage. They reported successful fusion for one-level procedures at 12 months in 97.9\% of patients in the BAK/C group and in 89.7\% of those in a bone graft group. The complication rate in the bone graft group was 20.4\% compared with an overall complication rate of 11.8\% in those treated with BAK/C. The authors concluded that clinical outcome after threaded cage—assisted cervical fusion cage is similar to that achieved by bone autografting after ACD. Cage—assisted fusion, however, has a lower risk of complications.\textsuperscript{17} Bartels, et al.,\textsuperscript{5} recently examined the use of rectangular carbon fiber cages in 13 consecutive patients with symptomatic cervical disc herniation and reported good results with regard to restoration of the foraminal height and of lordosis, as well as a low incidence of subsidence at 1 year postoperatively.

Pilot studies with the RABEA cage reported by al-Hami\textsuperscript{2} and Lange, et al.,\textsuperscript{21} yielded promising results. In neither study was a control group included, and there were no available data about lateral flexion—extension radiographs. Cage technology obviates the need for harvesting iliac crest or using allografts. Rectangular cages with spiky indentations are autostabilizing and further immobi-

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**TABLE 2**

<table>
<thead>
<tr>
<th>Radiological assessment at 1-year follow-up examination</th>
<th>No. of Patients (no. of levels)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>Iliac Crest Autograft</td>
</tr>
<tr>
<td>total no. of patients (levels)</td>
<td>18 (22)</td>
</tr>
<tr>
<td>collapse of &gt; 2mm</td>
<td>2 (3)</td>
</tr>
<tr>
<td>subsidence of &gt; 2mm</td>
<td>1 (1)</td>
</tr>
<tr>
<td>extrusion of &gt; 2mm</td>
<td>1 (1)</td>
</tr>
<tr>
<td>fusion</td>
<td>16/18 (20/22)</td>
</tr>
</tbody>
</table>

* not applicable

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lization by a plate is not necessary. An interface with the esophagus, which is common to all plate devices and may provoke dysphagia, is not present with cervical cages. Because the cages are sunk just below the vertebral surface, they constitute essentially a “no profile” device for stabilization. In situ stabilization of the cages by axial compression is further enhanced by the spikes firmly secured into the adjacent endplates. This fact has now led us to change our policy regarding postoperative orthosis. All patients in whom cages are implanted wear only a soft collar for 6 weeks.

One drawback of titanium cages is the potential for artifacts in the vicinity of the cage observed on magnetic resonance imaging studies. This could be relevant in the case of a neurologically complicated. Nevertheless, lesser field strength and the use of fast spin–echo techniques can reduce titanium artifacts.\textsuperscript{6,29,39} A second source of criticism could be the fact that solid fusion cannot be easily and definitely determined from simple radiographic analysis alone. Because the device is not radiolucent, it is difficult to determine on radiographs whether solid osseous fusion has occurred (osseous trabeculation, evidence of bone formation in and around the device). Nevertheless, histological examinations of the tissue obtained in the hollow spaces from removed cages after second-look surgery in the studies of Lange, et al.,\textsuperscript{21} and Carvi, et al.,\textsuperscript{10} confirmed sufficient bone growth in these areas. Newly formed bone, as a result of a differentiation process in different stages, could be demonstrated. Although solid incorporation of the cage into adjacent bone is desired for stability, it may complicate revision surgery. Partial corpectomy would then be necessary.

A final point of criticism could be the relatively high incidence of cage subsidence (in the present study eight [35\%] of 23 levels). This seems to be a common complication with the use of any metallic device.\textsuperscript{47} In our study, cage subsidence occurred without causing any clinical significance. It was more frequently observed early in the series and is attributed to overaggressive removal of the endplates to “overpromote” fusion, because no bone material was inserted in the cage. It has been observed rarely since we began applying a less aggressive technique, without any consequences concerning fusion. All cases of subsidence occurred within 3 months of surgery and showed no progression over time, probably as a result of fusion. Thus far, no long-term data on subsidence of cages in the cervical spine are available.

In the present study, similar fusion rates and clinical outcomes were present in both groups of patients. The obvious advantage of the cage is the immediate relative stability (in compression) resisting axial displacement, the ability to act as an incompressible spacer maintaining spinal alignment and foraminal height, and most importantly the absence of harvest site morbidity. The benefit related to the use of a cage compared with traditional material may be more a matter of avoiding the indirect morbidity rather than obtaining superior results.

**CONCLUSIONS**

The results of our study suggest that RTCs are a safe and effective alternative to bone autografting after ACD.
Rectangular titanium cage fusion

for treatment of cervical disc disease. Based on these results, a larger prospective, controlled, randomized trial has been initiated at our institution.

Disclaimer

The authors have no financial interest in the instrumentation or methodology advanced in this manuscript.

References


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