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Mid-Term and Long-Term Clinical and Radiological Outcomes of a Carbon I/F Stand-Alone Cage in Anterior Lumbar Interbody Fusion

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ABSTRACT

Study Design: Retrospective cohort study.

Objective: The current study was undertaken to determine the midterm and long-term radiological outcomes, complications and functional status of patients who underwent a single-level anterior interbody lumbar fusion (ALIF) procedure.

Summary of Background Data: Low back pain affects 70%–90% of the general population at some point in their life, and in general, the majority are best treated by nonsurgical therapy. However, a lumbar fusion can be considered in selected cases. In previous decades, lumbar interbody fusion procedures have gained popularity. Despite the approach used, stand-alone interbody fusion is becoming less popular due to poor fusion rates. When studying ALIF procedures, the addition of instrumentation results in higher fusion rates. Nevertheless, long-term follow-up can give either unexpected or similar insights into certain procedures that should be available in the current literature. Therefore, the current study was undertaken to determine the midterm and long-term radiological outcomes, complications, and functional status of patients who underwent a single-level ALIF procedure.

Methods: A cohort of 50 patients was studied following stand-alone ALIF for midterm and long-term follow-up of 6.6 years and 19.7 years, respectively. Primary outcome measurements were disability using the Oswestry Disability Index (ODI) score and pain scores using the visual analog scale, and the MOS 36-item Short-Form Health Survey (SF-36) was used to evaluate the quality of life. In addition, radiographic assessment was performed to indicate the number of solid fusions.

Results: After a mean of 19.7 years, we had a loss to follow-up of 34%. Functional measurements revealed an ODI of 41 for both time points and an SF-36 physical component score around 41.4 and 40.8 for the midterm and long-term follow-up, respectively. The mental component of the SF-36 was 48.7 and 49.9, respectively. The assessment of interbody fusion revealed only 66% and 70% solid fusion after 6.6 years and 19.7 years, respectively.

Conclusions: In concordance with previous studies, the outcome of midterm and long-term results in this study showed that the I/F cage in ALIF procedures is a safe treatment option for single-level interbody fusion. The radiological results corroborate literature regarding stand-alone interbody fusion, and additional instrumentation is likely to increase fusion rates. However, functional measurements reveal that the postsurgical situation remains likely worse than patients in a healthy Dutch population but possibly better that in a back pain population.

Lumbar Spine

Keywords: ALIF, carbon I/F cage, fusion, midterm results

INTRODUCTION

Low back pain affects 70%–90% of the general population at some point in their lives, and in general, the majority are best treated by nonsurgical therapy.[1,2] However, a lumbar fusion can be considered in case of persistent symptomatic degenerative disc disease, degenerative scoliosis, spondylolistheses, and/or spondylolysis. In previous decades, lumbar interbody fusion procedures have been popularized as an adjunct to increase fusion rates by adding intrinsic stability to the postoperative construct. In general, interbody fusion procedures can be through an anterior, a lateral, a transforaminal, or a posterior route. Various techniques have been described for such approaches with their own advantages and disadvantages. Despite the approach used, stand-alone interbody fusion is becoming less popular.

In the case of an anterior lumbar interbody fusion (ALIF) procedure, the authors use additional instrumentation, such as an anterior plate or posterior translaminar or pedicle screws. However, when trying to pursue a long-term follow-up of a certain technique, new insights might have altered current practice. We believe that for stand-alone ALIF procedures, this might be the case since postoperative fusion and possible pseudarthrosis have been described as being more prevalent in ALIF with a stand-alone cage compared to ALIF with a cage and combined with pedicle instrumentation.[3,4] Nevertheless, long-term follow-up can give either unexpected or similar insights into certain procedures that should be available in current literature.

Therefore, the current study was undertaken to determine the midterm and long-term radiological outcomes, complications, and functional status of patients who underwent a single-level ALIF procedure with use of a stand-alone carbon fiber Brantigan-I/F cage[5,6] for lumbar degenerative disc degeneration and grade 1 degenerative spondylolisthesis performed by a single senior spine surgeon in 1 institution.

MATERIALS AND METHODS

Study Design and Study Population

After institutional approval by the medical ethics committee was obtained, all consecutive 73 patients who underwent an ALIF procedure with use of a stand-alone (Brantigan) I/F cage (Acromed, Cleveland, Ohio) filled with an iliac crest bone graft were approached to participate. All patients were operated on by a single surgeon in the period 1993–2002. All patients were treated conservatively for their low back pain for at least 6 months prior to the operation with physical therapy and anti-inflammatory medication. Patients were included in case of failed conservative treatment and a radiographically confirmed (plain radiography and MRI scan) single-level degenerative disc disease involving L3–L4, L4–L5, or L5–S1 with or without mild degenerative spondylolisthesis (Myerding, grade 1). Exclusion criteria were multilevel disc disease, spondylolisthesis greater than grade 1, spondylolysis, or prior operative procedures on the spine. All patient files were retrospectively analyzed regarding length of stay, operative time, perioperative and postoperative complications, and revision rates. After this evaluation, all patients were seen in our outpatient clinic for follow-up measurements on 2 separate occasions—between December 2003 and October 2004 to collect midterm results and between November 2013 and February 2014—to collect long-term results. During each follow-up, their postoperative functioning levels (36-item Short-Form Health Survey [SF-36]), radiographs, and satisfaction with the surgical results were assessed. A patient's global assessment of treatment success was included, expressed as "good," "fair," or "poor." If patients were without any pain or disabilities, the score was excellent or good. If patients were able to do their normal work without pain or disability and suffered pain only during heavy tasks, they scored fair. If patients did not have any result of the operation and still suffered from daily pain and were not able to work or return to daily activities, they scored poor. Their "return to work" status was related and specified to their back pain and postoperative back status. Clinical examination included a standard neurological examination.

Intervention

All patients were operated through a left mini-open incision, retroperitoneal approach. After exposing the disc space, the anterior longitudinal ligament was excised, and the disc space was prepared for the cage while preserving the integrity of the bony end plates. The ALIF procedure was performed with a carbon I/F cage filled with an iliac crest autograft within the cage. The procedures were performed by a single senior spine surgeon (AJG). Mobilization started on the first postoperative day. Patients were allowed to mobilize with a lumbosacral orthosis for the first 6 weeks after the surgery. Physical therapy was started during this period. Patients were instructed to avoid bending, lifting, and trunk rotation for the first 12 weeks.

Primary Outcome Measures

Disability was measured using the Oswestry Disability Index (ODI).[7] A lower score indicates less disability, and a score below 22 is considered "normal." The visual analog scale (VAS) score[8] (0 indicating no pain, 10 indicating the worst possible pain) was used for evaluation of pain. The SF-36 was used to evaluate the quality of life of patients,[9] with higher scores representing a higher quality of life. The 36 questions were summarized into 2

measures pertaining to physical health and mental health.

Secondary Outcome Measures

Radiographic Assessment

Plain radiographs in lateral, antero-posterior, and flexion-extension views of the lumbar spine were made at routine intervals (at 6 weeks, 3 months, 6 months, 1 year postoperation, and both study follow-up visits at 6.6 years [3.1–11.1 years] and 19.7 years [16–24 years]), respectively. The most recent radiographs were independently interpreted for intervertebral fusion by 2 experts (2 independent and nonaffiliated orthopedic surgeons) who were blinded to clinical pretest data and outcome. In case of disagreement, consensus was reached by discussion. Fusion was assessed using a 3-point radiographic score as described by van Dijk et al[10] in 2002 and defined as bridging trabecular bone connecting the adjacent vertebral bodies through the implants (RS 2). In case of bone ingrowth with the cage securely fixed to the vertebral bone above and below but with a radiolucent discontinuity in the fusion mass, it was rated as RS 1. If there was no ingrowth of bone within the cage, the fusion was rated as RS 0 and considered as pseudarthrosis.

Additional Surgical Procedures

Supplementary surgical procedures (eg, revisions or supplemental fixations) following primary surgery were regarded as a failed ALIF and these patients were excluded from further analysis.

Adverse Events and Complications

All complications up to 6 weeks after the surgical procedures were recorded and evaluated for their severity and relationship with the spinal implants and the ALIF procedures.

Statistical Analysis

Student *t* tests were used for normally distributed continuous data, nonparametric tests for skewed continuous data, and Mann-Whitney tests for nominal data. Data were checked for normality and described as mean and standard deviation or as median and interquartile range. All statistical analysis was done with SPSS Statistics (IBM Corporation, Armonk, New York), version 20.

The intra- and interobserver agreement between the 2 observers was calculated using computer-calculated kappa statistics (Microsoft Office Excel 2007, Microsoft, Redmond, Washington; http://www.statstodo.com): Cohen's kappa (κ) for intraobserver reliability and Fleiss kappa for interobserver reliability. The Landis and Koch interpretation of kappa values ($\kappa > 0.8$ equals almost perfect correlation, $\kappa = 0.6$–0.8 as substantial agreement, $\kappa = 0.4$–0.6 as moderate agreement, $\kappa = 0.2$–0.4 as fair agreement, and $\kappa < 0.2$ as slight correlation) were used. Evaluation of statistical differences between kappa values was calculated with a 95% confidence interval, and differences were considered significant when the upper and lower boundaries did not overlap.

Table 1. Patient demographics.

	Midterm[a]	Long-Term[b]
Total patients	50	33
Female, n (%)	20 (40)	21 (64)
Age at surgery, mean (range), y	42 (21–60)	42.3 (21–60)
Age at follow-up, mean (range), y	49 (31–67)	62.5 (44–80)
Working status, n (%)		
Not working	16 (32)	11 (33)
Working full-time	28 (56)	19 (58)
Working part-time	6 (12)	3 (9)
Non smoking/smoking, n (%)	38 (76)/12 (24)	26 (79)/7 (21)
RS 0, nonsmoking/smoking	0 (0)/2 (17)	0 (0)/1 (14)
RS 1, nonsmoking/smoking	12 (32)/3 (25)	8 (31)/1 (14)
RS 2, nonsmoking/smoking	26 (68)/7 (58)	18 (69)/5 (72)
Level of surgery, n (%)		
L2–L3	2 (4)	1 (3)
L3–L4	0 (0)	0 (0)
L4–L5	10 (20)	6 (18)
L5–S1	38 (76)	26 (79)

[a]Mean, 6.6 y; range, 3.1–11.1 y.
[b]Mean, 19.7 y; range 16–24 y.

RESULTS

Patient Follow-Up

Table 1 shows the patient demographics. Of the 73 eligible patients, 58 patients agreed and were included and subsequently approached for analysis. Of these 58 patients, 50 were available for clinical midterm follow-up in our outpatient clinic. The 8 patients who were excluded either declined participation in this study (N = 4) or had supplementary pedicle instrumentation (N = 4). The carbon I/F cage was implanted at L5–S1 in 38 patients (76%), L4–L5 in 10 patients (20%), and L3–L4 in 2 patients (4%). In all patients, autologous bone was used from the iliac crest to impact the carbon fiber I/F cages. Of the 50 patients of whom midterm results were collected, 33 returned for long-term follow-up measurements.

Table 2a. Functional and pain scores.

	Midterm[a] (n = 50)	Long-Term[b] (n = 33)
ODI, mean ± SD, 0–100	40.7 ±17.7	40.7 ±13.5
SF-36, mean ± SD, 0–100		
Physical component	41.4 ±11.6	40.8 ±11.3
Mental component	48.7 ±10.4	49.9 ±10.2
VAS, mean ± SD, 0–10 cm	3.5 ±2.5	2.8 ±2.2

Abbreviations: ODI, Oswestry Disability Index; SF-36, 36-item Short-Form Health Survey; VAS, visual analog scale.
[a]Mean, 6.6 y; range, 3.1–11.1 y.
[b]Mean, 19.7 y; range 16–24 y.

Table 2b. SF-36 results from this study compared with the Dutch reference population (Aaronson et al[11] and a general spine surgical population Zanolli et al[12]).

	SF-36, Physical Component	SF-36, Mental Component
This study (midterm/long-term)	41/41	49/50
Aaronson et al[11]	83	77
Zanoli et al, DDD[12]	30	57
Zanoli et al, mean[12]	37	62

Abbreviations: DDD, degenerative disc disease; SF-36, 36-item Short-Form Health Survey.

Primary Outcome Measures

All clinical results are presented in Table 2. No ODI, VAS, or SF-36 scores were available from before the surgery. At the first follow-up measurements, only 5 patients (10%) had an ODI score of 22 or lower, indicating a normal level of disability. At the final follow-up visit, 2 patients (4%) had a score below 22. The RS scores did not influenced the ODI, VAS, and SF-36 scores.

The 36 questions were summarized into 2 measures pertaining to physical health and mental health, as presented in Table 2a. Additionally, subscale scores were calculated and compared with results from the general Dutch population and lumbar spine patients[11,12] (Table 2b).

Secondary Outcome Measures

Radiographic Assessment

Table 3 shows the assessment of interbody fusion, with only 66% and 70% solid fusion following midterm and long-term follow-up, respectively. The intraobserver reliability of the observers demonstrated moderate and substantial agreement ($\kappa = 0.56$ and $\kappa = 0.68$, respectively). Between the 2 observers, a substantial interobserver agreement ($\kappa = 0.63$) was found.

Adverse Events and Complications

Patients' admission charts were reviewed on adverse events that occurred during or within 6 weeks after surgery. No adverse events were recorded during surgery. One postoperative ileus (and therefore increased length hospital stay) was observed in the current patient group. Wound healing disturbances did not occur, and urinary retention requiring replacement of the temporary catheter occurred once. Neurologic deficits did not occur in the postoperative phase.

DISCUSSION

In this study of a cohort of 50 patients treated with a stand-alone carbon fiber I/F cage in ALIF, the clinical outcome and radiographic fusion rates were retrospectively evaluated at a mean follow-up period of 6.6 years and 19.7 years, respectively. The results demonstrate that a stand-alone ALIF I/F cage provides satisfactory midterm and long-term clinical results compared to a previous study.[13] In addition, when comparing our result to the study by Horsting et al[14] (describing 10-year results of ALIF with additional posterior fixation), the results are comparable with respect to both functional outcome (SF-36) and pain (VAS). However, the same study describes an average ODI of 16.8 during 10-year follow-up, while our study describes an ODI of 41.8 at 6.6-year and 43.1 at 16.4-year follow-up.

Primary Outcome Measures

With regard to the primary outcome measures, no preoperative data sets were available for analysis, limiting the outcome measurements in this study. However, when comparing our postoperative data with the 1-year data available in the current literature, similar results were found.[13,15] With regard to the SF-36 1-year data, however, we found a markedly higher score compared to the study by Li et al.[13] We found no further studies or data with a similar long-term follow-up period that could be compared to the outcome of the present study. We therefore compared the results with the average SF-

Table 3. Radiographic scores (RS).[a]

	Midterm[b] (n = 50), n (%)	Long-Term[c] (n = 33) n (%)
RS 0	2 (4)	1 (3)
RS 1	15 (30)	9 (27)
RS 2	33 (66)	23 (70)

[a]RS 0 = pseudarthrosis; RS 1 = bone ingrowth with radiolucent discontinuity; RS 2 = bridging trabecular bone within cages.
[b]Mean, 6.6 y; range, 3.1–11.1 y.
[c]Mean, 19.7 y; range 16–24 y.

36 scores of the Dutch population and lower back pain patients.[11,12] The current study showed that patients had better SF-36 scores after ALIF compared to patients but had not reached the levels of the average population.

Secondary Outcome Measures

The fusion rates found in the current study results are in line with radiographic fusion rates as reported by Li et al.[13] The complexity of interpreting plain radiographs has long been recognized, which is likely to increase with more complex criteria, causing lower observer reliability.[16] For this reason, the radiographic data were assessed using the criteria as defined by van Dijk et al,[10] which provide a simple and validated set of criteria.[16] The substantial agreement between the 2 observers in this study was comparable with previous described results ($\kappa = 0.52$).[22]

Overall complication rates in the current study were low (4%) and in concordance with the literature.[13,15,17,18] One of the frequent complications of lumbar interbody fusion and stand-alone ALIF in particular is pseudarthrosis. Grubb and Lipscomb[3] reported a significant difference between a combined interbody fusion and pedicle instrumentation (circumferential) and interbody fusion alone. In a group of 101 patients, 53 were treated with interbody fusion and pedicle instrumentation, and 49 patients were treated with interbody fusion alone. Results showed that the instrumented group had a pseudarthrosis rate of 6%, while the fusion stand-alone cage group experienced a pseudarthrosis rate of 35%. Pseudarthrosis can occur due to biomechanical limitations in stabilization of the ALIF with a stand-alone cage. Lund et al[4] reported that the cages decrease the intervertebral movement in flexion and lateral bending. However, spinal stabilization in extension and axial rotation was limited. Hence, some surgeons recommend that ALIF be supplemented by a posterior pedicle instrumentation despite the increased risk on adverse events.[13,19] However, few results were published on this carbon fiber monosegmental stand-alone cage, in which L*ü*bbers et al[20] reported a series of 22 patients with excellent results and found similar results compared to Cho et al,[21] who retrospectively reported an overall fusion rate of 88,3 % with a mean follow-up of 21 months. No differences were found in the interbody fusion rate (RS = 2) between smokers and nonsmokers (72% versus 69%, respectively). However, pseudarthrosis (RS = 0) was found only in the smoking group (n = 1).

Limitations

The assessment of fusion in the current study was done using plain radiographs. Recent literature has shown that interbody fusion can probably be better evaluated using CT scans;[22] however, for research purposes, it is difficult to obtain permission for CT scan of the patients due to the radiation dose. Therefore, x-rays are more appropriate. Furthermore, intraoperative testing is considered to be the gold standard, which, for obvious reasons, has not been performed in our patients.[14,23,24] Another limitation is the number of patients who were lost to follow-up between the midterm and long-term measurements.

CONCLUSIONS

In concordance with previous studies, the outcome of midterm and long-term results in this study showed that the I/F cage in ALIF procedures is a safe treatment option for single-level interbody fusion. The radiological results corroborate literature regarding stand-alone interbody fusion, and additional instrumentation is likely to increase fusion rates. However, functional measurements reveal that the postsurgical situation remains likely worse than patients in a healthy Dutch population but possibly better that in a back pain population.

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