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Long-term randomised comparison between a carbon fibre cage and the Cloward procedure in the cervical spine

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Abstract A prospective randomised study. To compare the long-term outcome of anterior cervical decompression and fusion (ACDF) with a cervical intervertebral fusion cage (CIFC) and the Cloward procedure (CP). We have previously shown that the 2 year outcome of ACDF with the CIFC is the same as for the CP. The fusion rate in CIFC group was, however, only 55%, compared to 85% in CP group. The long-term outcome of CIFC is poorly documented. Ninety-five patients with at least 6 months duration of neck pain and radicular arm pain were randomly allocated for ACDF with the CIFC or the CP. Radiographs were obtained at 2 years. Questionnaires about pain, disability (Neck Disability Index, NDI), distress, quality of life and global outcome were obtained from 83 patients (87%) (43 CIFC, 40 CP) at a mean follow-up time of 6 years (range 56–94 months). There were no significant differences in any outcome variable between the two treatments. For both CP and CIFC the pain intensity improved ($P < 0.0001$) whereas the NDI was

unchanged at long-term follow-up compared to preoperatively. In the CIFC group patients with a healed fusion had significantly less mean pain (24 mm) and NDI (26%) than patients with pseudarthrosis (42 and 41, respectively). Furthermore, the mean pain and NDI reported by CIFC patients with a healed fusion was significantly less than in healed CP patients (37 and 38, respectively). The long-term outcome is the same for the CIFC and the CP, with similar improvements of pain but with considerable remaining functional disability. However, in the subgroup of patients with healed CIFC the outcome was clearly better than for the non-healed CIFC group, and also clearly better than for the healed CP group. Thus, if the healing problem associated with the CIFC can be solved the results indicate that a better outcome can be expected with the cage than with the CP.

Keywords Cervical spine · Disc · Cage · Cloward · Outcome

Introduction

Several authors [5, 6, 9] have reported the results of anterior cervical decompression and fusion (ACDF) in patients with cervical disc disease. Most studies have

been short-term and have demonstrated an improvement in pain, neurological deficit and functional disability [18, 21, 22, 27, 30]. Long-term follow-up studies are mostly retrospective [2, 7, 9, 10, 14] with no assessment of functional disability and therefore of limited

potential for firm conclusions on the effectiveness of the treatment.

Cage techniques have the potential advantages of restoring disc height, prevention of graft collapse, indirect foraminal decompression and fusion in lordosis [25]. However, except for reduced donor site pain, preservation of lordosis, and a higher pseudarthrosis rate, we found the same short-term clinical outcome with a cervical intervertebral fusion cage (CIFC) and the Cloward procedure (CP) [27].

Some authors [15, 29] have reported an increased risk of accelerated degeneration of adjacent segments after spinal fusion, with the risk of deterioration of the outcome with long-term follow-up. Gore and Sepic [9] reported that about one third of the patients had recurrent pain after a pain free period after ACDF. Since fusion in lordosis, which we have shown is possible with the cage [27], may protect from adjacent segmental problems, the long-term effect of ACDF with the cage may be better than standard autograft methods as the CP. The long-term clinical outcome of the use of fusion cages has not previously been reported. The purpose of the present study was to compare the long-term outcome of ACDF with CIFC and the traditional CP.

Patients and methods

After obtaining informed consent 103 consecutive patients at the University Hospital of Linköping, Sweden were randomised (1995–1998) to either the CIFC (AcroMed, Cleveland, Ohio) [27] or the CP [6]. All patients had preoperative MRI and clinical findings of cervical nerve root compression. The inclusion criteria were at least 6 months duration of neck pain and radiculopathy of degenerative origin with corresponding MRI and clinical findings. Exclusion criteria were myelopathy, psychiatric disorder, drug abuse and previous spine surgery.

All patients asked to take part agreed to participate. In the outpatient clinic 52 patients were randomly assigned to the CIFC and 51 patients to the CP by the attending nurse drawing one of two notes stating CP or CIFC. Thus, through the investigation, each patient had a 50% likelihood of being operated on by CIFC or the CP. The randomisation resulted in a similar distribution of age, gender, number of levels operated on and duration of symptoms and smoking habits between the two groups [27].

Eight patients (3 patients randomised to the CIFC and 5 to CP-group) changed their mind about surgery and were never operated on, leaving 95 patients remaining in the study.

Preoperatively and at 1 and 2 year follow-ups all patients had a standard clinical examination, radiographs (antero-posterior, lateral and oblique) and

answered questionnaires. About 86% of patients completed the 2 year follow-up, as reported previously [20, 27].

At a mean long-term follow-up of 76 months (range 56–94 months) questionnaires were sent to all 95 patients. The mean age at follow-up was 53 years (range 36–73). Eighty-three patients (87%), 40 patients in the CP group and 43 patients in the CIFC group answered the questionnaires. Out of the 12 patients not responding (6 patients randomised to CIFC and 6 to CP) 8 patients did not return questionnaires despite several reminders, 3 had died from reasons unrelated to the surgery, one man sustained a whiplash injury 6 weeks after surgery and was therefore excluded.

Fifty-two out of the 83 patients were operated on at one level, 28 patients at two levels and 3 patients at three levels. Postoperatively all patients used a Philadelphia collar for 6 weeks and most of them received physiotherapy after removal of the collar.

Outcome measurements

Pain was quantified by a horizontal 100 mm Visual Analogue Scale (VAS) (0, no pain; 100, worst imaginable pain) for neck-related “pain right now” [24].

Neck specific disability was quantified by the Neck Disability Index (NDI). The 10 sections of the NDI (pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation) are scored from 0 to 5, added together and transformed to a percentage (0%, no pain or difficulties; 100%, highest score for pain and difficulty on all items) [28].

Work status (employee, in search of work, student, on parental leave, age retirement, disability pension, sick retirement) was documented.

Distress was quantified with the Distress and Risk Assessment Method (DRAM) [13], which is an integration of a psychosomatic (Modified Somatic Perception Questionnaire) and a psychological (Modified Zung depression index) assessment system.

Health-related quality of life was assessed by the EuroQol five dimensions self-classifier which addresses mobility, self-care, every day activities, pain and anxiety/depression [3]. For each dimension one of three hierarchical levels is chosen (1, no problem; 2, moderate problem; 3, severe problem) and converted to a score (0, death; 1, perfect health). Current health state was also measured on the EuroQol vertical VAS (0, worst imaginable; 100, best imaginable).

The global outcome, as assessed by the patient, was measured on a six-grade scale (1, complete relief; 2, much better; 3, better; 4, unchanged; 5, worse; 6, much worse). Whether the expectations of surgery were fulfilled was measured on a four-grade scale (1, yes,

completely; 2, yes, partially; 3, no, not at all; 4 = do not know).

Surgical technique

The Cloward procedure was performed according to standard techniques using bicortical iliac autograft harvested through a 5 cm skin incision using a Cloward dowel cutter [6]. The CIFC surgical technique [27] is similar to the technique used in the Smith-Robinson tricortical graft procedure [23]. The disc, posterior longitudinal ligament, and osteophytes, including the posterior part of uncinat process, are removed. Endplate cartilage is removed with high-speed burr and curette. The subchondral bony endplate is roughened by the burr until it bleeds, although care is taken so that it can function as a bearing surface to the implant. Cancellous bone is harvested from the iliac crest using a 3 cm incision and a 4×4 mm cortical hole and packed in the 7° wedged cage. After complete filling and packing of the cage with cancellous bone, the cage with the largest width and depth that can be introduced is inserted into the disc space.

Statistical methods

For unpaired two-group comparisons the two-tailed Student's *t* test was used for parametric data and Mann-Whitney *U* test for non-parametric data. For three-group comparisons of the main outcome pain (VAS) and NDI repeated measures one-way analysis of variance (ANOVA) with Bonferroni/ Dunn post-hoc test was used. $P < 0.05$ was considered statistically significant. Primary outcome variables were pain (VAS) and NDI. To prevent chance significant findings due to multiple comparisons only primary outcome measurements were used in subgroup analysis. Bivariate correlations were studied using Pearson correlation coefficient.

The study was approved by the Ethics Committee at the Faculty of Health Sciences, Linköping University.

Results

At long-term follow-up there were no significant differences in outcome between the CP and the CIFC groups. The median neck pain was, however, non-significantly lower in CIFC patients than in CP patients ($P = 0.06$) (Table 1).

The mean pain intensity improved significantly from preoperatively to long-term follow-up in the CP as well as the CIFC group (Table 2). From short-term (2 years) to long-term the pain intensity was unchanged in the CP

Table 1 Long-term outcome after anterior cervical decompression and fusion with the Cloward procedure (CP) or the Cervical intervertebral fusion cage (CIFC)

	CP	CIFC	P-value
Pain and problems			
Pain (mm VAS) mean	39	32	0.28
Arm pain median	4 (0–9)	3 (0–9)	0.83
Neck pain median	4 (0–7)	3 (0–9)	0.06
Numbness median	3 (0–10)	3 (0–10)	0.54
Headache, %yes	19 (68)	13 (56)	0.41
Dizziness, %yes	15 (62)	10 (48)	0.32
LBP last 6 months, <i>n</i> (%) yes	26 (65)	27 (63)	0.84
Disability, NDI mean	38	32	0.18
Distress, DRAM <i>n</i> (%)			
Normal	9 (24)	18 (43)	0.28
At risk	2 (53)	12 (29)	–
Distressed, depressive	3 (8)	8 (17)	–
Distressed, somatic	6 (16)	4 (10)	–
Work status <i>n</i> (%)			
Employee	12 (31)	17 (40)	0.97
In search of work	1 (3)	0 (0)	–
Age retirement	3 (8)	2 (5)	–
Part time employee / disability pension	4 (10)	2 (5)	–
Sick retirement	19 (49)	21 (50)	–
General health			
EQ thermometer mean	60	59	0.80
EQ-5D mean	0.69	0.54	0.29
Global outcome			
Effect of surgery <i>n</i> (%)			
Complete relief of problems	6 (15)	6 (14)	0.61
Much better	15 (37.5)	23 (53)	–
Better	11 (27.5)	6 (14)	–
Unchanged	4 (10)	2 (5)	–
Worse	4 (10)	3 (7)	–
Much worse	0 (0)	3 (7)	–
Expectations of surgery fulfilled <i>n</i> (%)			
Yes, completely	13 (32)	16 (37)	0.70
Yes, partially	17 (42)	20 (46)	–
No, not at all	9 (22)	6 (14)	–
Do not know	1 (2)	1 (2)	–

group, but improved in the CIFC group ($P = 0.04$) (Fig. 1).

The NDI, however, was not significantly different at long-term follow-up compared to preoperatively (Fig. 2). In contrast to pain, the NDI deteriorated in both the CP group ($P = 0.0001$) and the CIFC group ($P = 0.004$) between short-term and long-term follow-up.

At long-term CIFC, patients with a healed fusion at 2 years had lower mean general pain and NDI than CP patients with a healed fusion ($P < 0.05$). Furthermore, in the CIFC group, patients with a healed fusion had lower pain as well as lower NDI than patients with pseudarthrosis ($P = 0.02$) (Table 2, 3). For pain this was significant already at short-term ($P < 0.05$), but for NDI only at long-term.

Among patients with pseudarthrosis there were no differences between the two treatments either in pain or in NDI. In the CP group there were no significant differences in pain or NDI between patients with a healed fusion or not, possibly reflecting the low number of

Table 2 Mean pain (VAS) preoperatively, 2 years and 6 years according to treatment with the Cloward procedure (CP) and the cage (CIFC), and according to fusion status at 2 years

		Preop	2 years	6 years	P-value (Pre vs. 6 years)
CP	All	69	33	38	< 0.0001
	Healed	70	35	37	< 0.0001
	Non-healed	67	25	42	0.12
CIFC	All	66	41	32	< 0.0001
	Healed	64	33	24	< 0.0001
	Non-healed	68	54	42	0.003

patients with pseudarthrosis in the CP group. As reported earlier, the 2 year pseudarthrosis rate was much lower in the CP group (15%) than in the CIFC group (44%) ($P=0.02$) [27].

There was no correlation between degree of kyphosis or “disc height” on one hand (at 2 years) and pain or NDI on the other hand at long-term follow-up. This was true also for the CP and the CIFC groups analysed separately, and also for subgroups of healed and non-healed CP and CIFC patients. In the CP group the mean kyphosis was 0.4° and 1.4° in healed and non-healed patients, respectively ($P=0.76$). In the CIFC group the segments were on average in lordosis, -1.7° in healed patients and -3.9° in non-healed patients ($P=0.34$). However, although the CIFC group on average was in lordosis, the difference between healed CP and healed CIFC patients was not significant ($P=0.28$). Similarly, the “disc height” at short-term was not statistically different between healed and not healed patients.

There were no significant differences in pain and disability in patients operated on at one level compared to more than one level. However, patients operated on at one level had significantly less numbness than those who had at least a two level surgery ($P=0.02$).

Fig. 1 Pain preoperatively, at short-term and at long-term follow-up. Mean pain improved ($P<0.0001$) from preoperatively to long-term follow-up similarly after the Cloward procedure (CP) and the cervical intervertebral fusion cage (CIFC). The pain intensity was unchanged in the CP group from short- to long-term follow-up but improved in the CIFC group ($P=0.03$). At long-term there was no significant difference between the CP and the CIFC. Mean values and 95% confidence intervals are presented

During the follow-up time seven patients operated on with the CIFC and three with the CP had an additional cervical spine surgery ($P=0.21$).

Discussion

The study verifies the short-term results with no long-term differences between the CIFC and the CP in any outcome variable [27]. There are many retrospective reports on positive long-term effects of ACDF such as decreased pain, regression of neurological symptoms, and high rates of a satisfactory global outcome [2, 7, 9, 10, 14]. The present results are more modest and more in line with earlier prospective reports, confirming that retrospective studies have a tendency to overestimate outcomes [11, 17, 19, 21, 22, 30].

Comparisons with other reports are, however, difficult. Differences between countries regarding insurance systems and economical incentives to work most likely affect many outcome variables. Furthermore, the relative nature of VAS and probably also of disability scores, such as the NDI must also be considered. The patient's reference frame changes over time and a score of e.g. VAS pain of 50 does not necessarily mean the same the day before surgery as compared to 6 years later. The only truly valid comparisons in outcome studies are between randomised groups, as in the present study.

In the short-term, the cage as well as the CP resulted in improved pain as well as disability. In the long-term, however, the pain remains improved whereas the NDI deteriorated. The effect of pseudarthrosis on pain was demonstrated already at short-term, but on disability not until long-term. A reason for this may be that the outcome variable pain is more sensitive to change than the NDI, as suggested by the results, showing a clearly larger improvement in pain (VAS) than in the NDI. In

Fig. 2 Neck Disability Index (NDI) preoperatively, at short-term and at long-term follow-up after the Cloward procedure (CP) and the cervical intervertebral fusion cage (CIFC). For both treatment groups at long-term the NDI was not significantly different from preoperatively. The NDI deteriorated ($P<0.01$) in both groups between short- and long-term follow-up, and there was no statistical difference between the groups at long-term. Mean values and 95% confidence intervals are presented

Table 3 Mean NDI preoperatively, 2 years and 6 years according to treatment with the Cloward procedure (CP) and the cage (CIFC), and according to fusion status at 2 years

		Preop	2 years	6 years	P-value (Pre vs. 6 years)
CP	All	36	26	38	0.41
	Healed	37	27	38	0.67
	Non-healed	29	22	36	0.27
CIFC	All	33	27	32	0.96
	Healed	31	26	26	0.40
	Non-healed	37	30	41	0.27

fact, the NDI showed rather modest changes over time for both treatment groups as well as for subgroups. It may be that the NDI, more than neck pain, is influenced by a variety of problems such as low-back pain and psychological distress. In the present study many of the patients did report low-back pain, a high degree of distress, a reduced general health and many were on long time sick leave.

There is still some controversy about the importance of fusion for a good outcome of surgery for cervical disc disease [26]. Although no differences in the short-term outcome between anterior discectomy with and without fusion has been reported [1], the considerably worse outcome observed in patients with pseudarthrosis in the present study supports the concept of obtaining fusion for a good outcome. At short-term we found less segmental kyphosis and better preserved "disc height" in the CIFC patients than in the CP patients. However, we could not demonstrate any impact of segmental kyphosis or "disc height" on short-term outcome [27]. This finding can now be extended to the long-term. The reason for a better outcome of healed cage patients than healed Cloward patients is unclear. Although not a significant difference, however, the healed cage patients were in slight lordosis whereas the healed Cloward patients were in slight kyphosis, which may be of importance for the long-term outcome.

Since no difference in outcome could be demonstrated between the two randomised treatment groups, a discussion of the long-term outcome of the total material seems appropriate. In the combined total material, 61% of patients reported complete relief of problems or were much better, and 80% were satisfied with the results of surgery, which is in line with other global long-term results [9, 10]. Interestingly, Zoëga et al. [30] reported that 81% of patients were satisfied with the results after one-level ACDF, despite no apparent improvement in pain or function. This is somewhat in agreement with our study, and verifies previous results showing that outcome is influenced by the method by which it is measured [11], and the relative nature of many outcome variables.

The health-related quality of life at long-term follow-up was quite low (EQ-5D 0.61). The level can be compared with a Swedish survey in which EQ-5D values

ranged from lowest (0.66) in patients with low-back pain to highest (0.79) in patients with asthma [4].

In the present study 36% of patients returned to full-time work, which is similar to the rates reported by several previous Scandinavian authors [7, 11, 19]. However, compared to Goldberg et al. [8] and Mayer et al. [16], who reported 97 and 81% rates of return to work, our rate was low. Return to work is influenced not only by success of treatment but also by factors such as the patients' occupation and tasks, the labour market and the health insurance system. Return to work is therefore difficult to compare over time and between countries.

In patients with non-specific neck pain, psychological distress and psychosomatic problems have been shown to predict a bad outcome [12]. In the present study, distress was not quantified preoperatively. At long-term, however, 66% of the patients were classified as distressed or at risk of distress, verifying the short-term results in another study [19]. Similarly, Mayer et al. [16] reported 47% of patients having abnormalities on Beck Depression Inventory one year after ACDF. Data suggesting even more depressed patients was reported by Zoëga et al. [30] who found no improvement of the depression index compared to preoperatively. Obviously, patients with degenerative cervical spine disorders often suffer from psychological distress, a factor that probably should be taken more into account in patient selection as well as in postoperative rehabilitation [30].

Patients not available for long-term follow-up showed no difference in any variable quantified, either before surgery or at the short-term follow-up, compared to the rest of the patients. Thus, the relatively small number of patients not included at long-term follow-up (12/95 = 13%) does not seem to bias the final result.

One can conclude that the long-term outcome was the same for the cage and the Cloward procedure. The results also show that the long-term outcome is affected by the status of the fusion. The fact that patients with a healed cage fusion had a better outcome than patients with a healed Cloward suggests that the use of the cage may be advantageous, presupposing that the fusion does heal. Design changes of the fusion cage, or the addition of a plate may improve fusion rate and thereby the outcome. The carbon-fibre cage studied, used as a stand alone device, obviously results in a much too high

symptomatic pseudarthrosis rate to be recommended in ACDF.

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