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ORIGINAL ARTICLE

# Investigation of clinically important benefit of anterior cervical decompression and fusion

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**Abstract** The objectives of the prospective randomized study are to investigate the clinically relevant change after anterior cervical decompression and fusion (ACDF) using measures of pain intensity (visual analog scale, VAS) and neck disability index (NDI). And to determine the number of subjects showing persistent pain and disability at 6-year follow-up. To investigate the possibility of differences in outcome between ACDF with the cervical intervertebral fusion cage (CIFC) and the Cloward procedure (CP). Clinically relevant change and residual, postoperative pain intensity and disability after ACDF have been investigated a little. Ninety-five patients with neck and radicular arm pain lasting for at least 6 months were randomly selected to receive ACDF with the CP or the CIFC. Questionnaires concerning pain and NDI were obtained from 83 patients (87%) at a mean follow-up time of 76 months (range 56–94 months). When evaluating clinical benefits regarding pain intensity 6 years after ACDF, according to different cut-off points and relative percentages, symptoms improved in 46–78% of patients. Improvement in NDI was seen in 18–20% of patients. Approximately 70% of the patients had persistent pain and disability at 6-year follow-up. There was no clinically important difference following CP versus CIFC. Thirty millimeter and 20% in pain intensity and NDI, respectively, are reasonable criteria to suggest a clinically relevant change after ACDF. Before patients undergo ACDF, they should be informed that they have an approximate 50% probability of achieving pain relief and little probability of functional improvement. The findings demonstrate that there is poor evidence for difference between CIFC and CP.

**Keywords** Relevant change · Outcome · Radiculopathy · Cervical · Spine

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## Introduction

Anterior cervical decompression and fusion (ACDF) is an established and frequently used method for managing radiculopathy due to cervical disc disease. Although several reports support this approach as effective [5, 6, 13], studies using patient-centered functional outcome measures [17, 21, 26, 27, 31, 35, 37] have shown poorer effectiveness, with substantial levels of residual symptoms (deficit) in subjective and objective evaluations [28–30]. Peolsson et al. [28] found that approximately one third of their study patients had lingering disabilities in objective variables such as strength and range of motion 1 year after ACDF with a cervical intervertebral fusion cage (CIFC). Furthermore, approximately two thirds of the patients had residual problems according to subjective variables such as pain intensity, neck disability index (NDI), distress and risk assessment method (DRAM), and general health [28] and were still persistent at 3-year follow-up [30]. These findings were replicated in a 2-year follow-up after ACDF with the traditional Cloward procedure (CP) and the CIFC; approximately 70% of patients exhibited deficits based on pain intensity and NDI [29]. There are no reports

addressing the degree of deficit more than 3 years after ACDF.

Definition of clinically relevant change is important in order to investigate meaningful individual improvement. According to Deyo et al. [8], there is limited understanding of the meaning and clinical relevance of certain outcome measures. In recent years different methods, such as cut-off points and percentage relief of symptoms, have been used in an attempt to define clinically relevant change [3, 22, 25, 30, 32]. Peolsson et al. [30] conducted a small study, where 23 ACDF patients completed a study questionnaire [30], and a cut-off point was set to define a clinically relevant change between preoperative data and follow-up. They reported that 50–78% of study patients without pain (visual analog scale, VAS <10 mm), and disability (NDI <20%, normal on DRAM, general health VAS <25 mm) 6 months after ACDF with CIFC were still healthy at a 3-year follow-up. Eighty-three to 100% of patients with pain and disability at a 6-month follow-up also exhibited persistent symptoms 3 years after surgery, showing stability over time. This is the only investigation of ACDF outcome in which, a cut-off has been used to define clinically relevant change, and no study in ACDF patients has used percentage relief of symptoms to define clinically relevant change.

A prospective randomized study by Peolsson et al. [31] is the only study that has compared the postoperative outcome of traditional CP and CIFC as long as 6 years after ACDF. There were no significant differences in outcome between CP and CIFC groups for any variable. Relative to preoperative measurements, postoperatively the main outcome variables pain intensity and NDI were improved and unchanged, respectively, with both surgical techniques [31]. Degree of kyphosis, ‘‘disc height,’’ or number of surgery levels had no correlation to pain intensity or NDI [31]. Peolsson et al. did not attempt to evaluate clinically important benefit, residual pain or disability after ACDF, or the strength of evidence of clinically relevant differences between outcomes with CP and CIFC.

The purpose of the present study was threefold. First, to evaluate the degree to which ACDF offers a clinically important benefit in terms of change in pain intensity and NDI over time and clinically relevant change after surgery. Second, to determine the frequency of residual pain and NDI approximately 6 years after ACDF. Third, to evaluate the strength of evidence for differences between postoperative outcomes with CP and CIFC.

## Materials and methods

### Patients

All patients (103) invited to participate in the study agreed to do so, and all provided informed consent. All patients’ preoperative magnetic resonance imaging (MRI) results and clinical signs were consistent with cervical nerve root compression. Study inclusion criteria were neck pain for a minimum of 6 months in duration and radiculopathy of degenerative origin with compatible MRI and clinical findings. Exclusion criteria were myelopathy, psychiatric disorder, drug abuse, and previous spine surgery.

In an outpatient clinic, patients were randomly assigned (between 1995 and 1998) to ACDF with CIFC ($n$ = 52) (AcroMed, Cleveland, Ohio) [35] or CP, with autograft ($n$ = 51) [6, 35] by the attending nurse, who picked one of two notes. Thus, each patient had a 50% probability of being operated on by CIFC or CP. The randomization procedure yielded similar group distributions of age, gender, smoking habits, number of levels operated upon, and duration of symptoms [35].

Preoperatively and at 1- and 2-year follow-ups, all patients received a standard clinical examination and radiographs (anteroposterior, lateral, and oblique), and answered questionnaires. At a mean long-term follow-up of 76 months (range 56–94 months) questionnaires were sent to all patients who had been operated upon.

Eight patients changed their mind about surgery and were not operated upon, leaving 95 study participants. Eighty-nine patients (94%) completed the 2-year follow-up [29, 35]. Eighty-three patients (87%): 40 in the CP group and 43 in the CIFC group, 43 women and 40 men, answered the questionnaires at long-term follow-up. Of the 12 nonresponders, three had died from reasons unrelated to the surgery, and one was excluded by virtue of his sustaining a whiplash injury 6 weeks after CP. The mean age at 6-year follow-up was 53 years (range 36–73).

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

### Treatment

Surgery was performed in a standardized fashion as previously described [31, 35]. The Cloward procedure was performed using bicortical iliac autograft and in the CIFC surgical technique, cancellous bone is harvested from the iliac crest and packed in the 7° wedged cage [31, 35]. Fifty-two of the 83 patients were oper-

ated upon at one segmental level, 28 at two levels, and three at three levels.

The postoperative treatment included a Philadelphia collar for 6 weeks, and after removal of the collar, most patients received conventional (not designed for the study) physiotherapy via primary care facilities.

During the previous year before answering the ''6-year'' follow-up questionnaire, 26 patients (32%) had received treatment; primarily physiotherapy, to address neck problems.

## Evaluation at 6-year follow-up

At the 6-year follow-up, answers to questions about: gender, age, neck problems, headache, dizziness, arm pain and numbness, back problems, work status, health-related quality of life, current health, distress; and global outcomes such as effect of surgery and fulfillment of surgery expectations were documented [31]. Here, only the results of further (as stated in the purpose) analysis of the main outcome data of pain and NDI are presented. Baseline and 2-year outcome data were previously reported by Vavruch et al. [35] and 6-year outcome data by Peolsson et al. [31].

### *Pain*

Pain intensity was quantified by a horizontal 100 mm VAS (0 = no pain, 100 = worst imaginable pain) for ''pain right now'' [33].

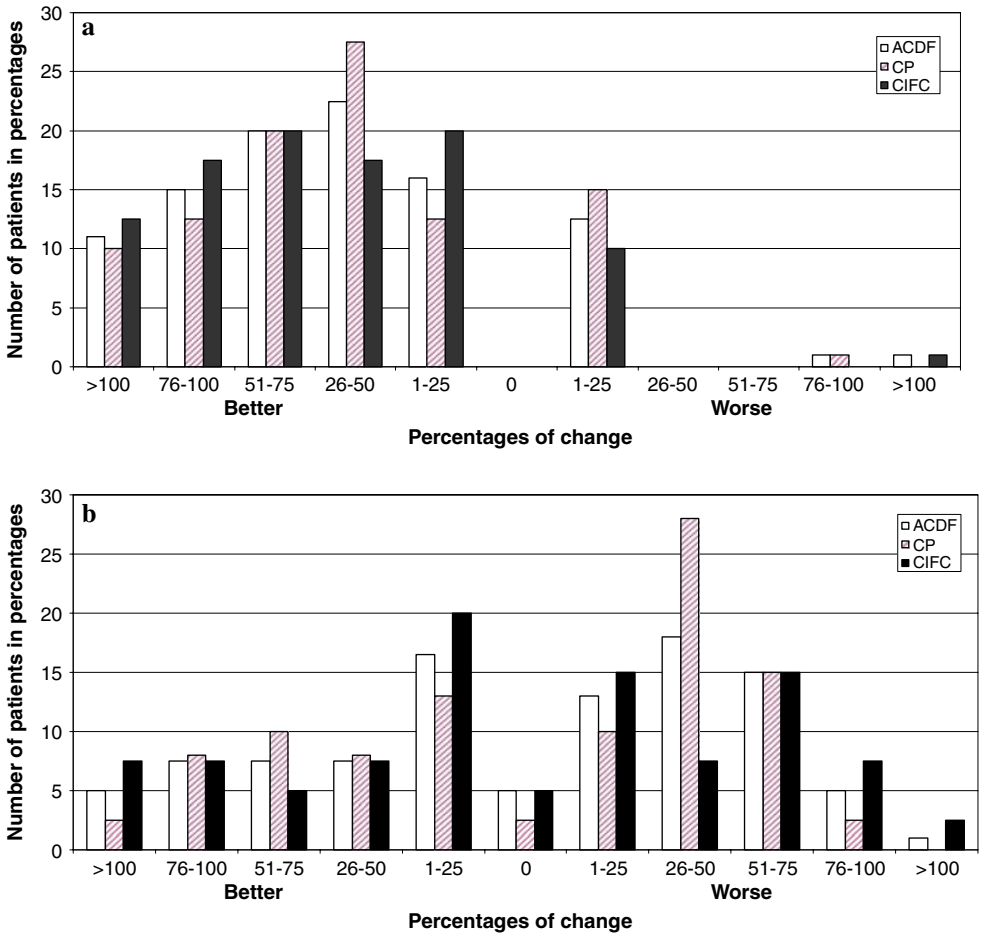


**Fig. 1** **a** Relief (percentage change) of pain intensity ($n$ = 80) at 6-year follow-up compared to before surgery [Anterior cervical decompression and fusion (*ACDF*) with the Cloward procedure (*CP*) or a cervical intervertebral fusion cage (*CIFC*)]. Clinically important benefit was defined as more than 50% relief of pain from baseline to 6-year follow-up. **b** Relief (percentage change) of neck-specific disability ($n$ = 79) (NDI) at 6-year follow-up compared to before surgery [Anterior cervical decompression and fusion (*ACDF*) with the Cloward procedure (*CP*) or a cervical intervertebral fusion cage (*CIFC*)]. Clinically important benefit was defined as more than 50% relief of NDI from baseline to 6-year follow-up

*Disability*

Neck-specific disability was quantified using the NDI. The ten sections of the NDI (pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation) are scored from 0 to 5, summed, and transformed to a percentage (0% = no pain or difficulties, 100% = highest score for pain and difficulty on all items) [36].

Statistical methods

Descriptive statistics with mean, standard deviation, 95% confidence interval (CI); number of patients, and percentage of patients were used. For paired and unpaired two-group comparisons, the paired and unpaired two-tailed Student's *t* tests were used, respectively. $P < 0.05$ was considered statistically significant.

To define a residual pain intensity and neck specific disability, cut-off points of VAS score ≥10 mm [7] and NDI ≥20% [10] were used.

Change from the preoperative period to long-term follow-up and from short-term to long-term follow-up was defined as a difference in pain intensity ≥10 [7] and ≥30 mm [18] on VAS and a difference in NDI ≥20% [10, 24].

Percentage relief (relative benefit) of pain or disability (NDI) at long-term follow-up was calculated for each patient as the difference between baseline and follow-up pain or disability score divided by the baseline score and converted to a percentage [25, 32]. Clinically relevant change was defined as more than 50% relief of pain or disability from baseline to long-term follow-up [25].

A clinically important difference between the outcome (pain intensity and NDI) of CP and CIFC was defined as a difference of > 15% [32] and was calculated as the difference between the group means for CIFC and CP, divided by the group mean for CP, converted to a percentage. The degree of evidence for a difference in outcome between the two treatment methods was characterized as follows: Grade A > 15% difference, $P < 0.05$, randomized controlled study (RCT); Grade B > 15% difference, $P < 0.05$, controlled clinical trial (CCT), Grade C+ > 15% difference, nonsignificant change, RCT or CCT; Grade C < 15% difference, any study design [14]. Grade A was considered strong evidence, Grade B good evidence, Grade C+ poor evidence, and Grade C no evidence.

## Results

Seventy-eight percent of the patients reported a lessening of pain intensity and 8% a worsening of pain intensity at the 6-year follow-up compared to preoperative levels when using the cut-off point of ≥10 mm. When using ≥30 mm as the cut-off point, 51% reported a lessening of pain intensity and no one, a worsening. The mean pain intensity decreased from 68 mm to

**Table 1** Changes in pain intensity and neck disability index (NDI) from before surgery (preop.) to the 6-year follow-up and from the 2-year to the 6-year follow-up

| | Preop. to 6-year follow-up | | | Two-year to 6-year follow-up | | |
|---|---|---|---|---|---|---|
| | ACDF | CP | CIFC | ACDF | CP | CIFC |
| **Pain** *n* (%) | | | | | | |
| *n* | 80 | 40 | 40 | 69 | 34 | 35 |
| ±10 mm | | | | | | |
| Better | 62(77.5) | 32(80) | 30(75) | 28(40.5) | 13(38) | 15(43) |
| Unchanged | 12(15) | 5(12.5) | 7(17) | 28(40.5) | 13(38) | 15(43) |
| Worse | 6(7.5) | 3(7.5) | 3(7.5) | 13(19) | 8(24) | 5(14) |
| ±30 mm | | | | | | |
| Better | 41(51) | 22(55) | 19(47.5) | 14(20) | 7(20.5) | 7(20) |
| Unchanged | 39(49) | 18(45) | 21(52.5) | 47(68) | 21(62) | 26(74) |
| Worse | 0(0) | 0(0) | 0(0) | 8(12) | 6(17.5) | 2(6) |
| **NDI** *n* (%) | | | | | | |
| *n* | 79 | 39 | 40 | 70 | 34 | 36 |
| Better | 14(18) | 7(18) | 7(18) | 4(6) | 1(3) | 3(8) |
| Unchanged | 49(62) | 25(64) | 24(60) | 44(63) | 23(68) | 21(58) |
| Worse | 16(20) | 7(18) | 9(22) | 22(31) | 10(29) | 12(33) |

Changes in pain intensity: cut-off point ±≥10 and ±≥30 mm, respectively, on visual analog scale

*NDI* cut-off point ±≥20%

Anterior cervical decompression and fusion (ACDF) with the Cloward procedure (CP) or a cervical intervertebral fusion cage (CIFC)

35 mm ($P < 0.0001$, Fig. 1). Between follow-ups, pain for 41% of the patients lessened and pain in 33% of the patients increased ($P = 0.29$) when ≥10 mm was used as the cut-off point (Table 1). When ≥30 mm was used as the cut-off point, pain in the majority of the patients (68%) was determined to be unchanged between follow-ups, and pain in 20% of the patients was determined to be improved (Table 1).

When defining a relevant change as more than 50% reduction of pain intensity, 46% of the patients were determined to experience a long-term clinically important benefit of ACDF. Two percent of the patients experienced a clinically relevant worsening after ACDF (Fig. 1a).

Using a cut-off point of ≥20%, at the 6-year follow-up, NDI for 18% of the patients was improved compared with preoperative levels, while NDI for 20% of the patients was worse ($P = 0.49$). From the 2-year to the 6-year follow-up, NDI for approximately 6% of the patients improved, and NDI for approximately 30% of the patients worsened; this represented a significant worsening ($P < 0.0001$) in NDI between follow-ups (Table 1 and Fig. 2).

When defining a relevant change as more than 50% relief of disability on NDI, 20% of the patients experienced a 6-year clinically important benefit of ACDF. Twenty-two percent of patients experienced a clinically relevant worsening of symptoms (Fig. 1b).

Residual problems in the form of high pain intensity and NDI were present in 79 and 71% of the patients, respectively, at the 6-year follow-up. Of the patients exhibiting deficits at the 2-year follow-up, 88 and 84% had residual deficits in pain and NDI, respectively, at the 6-year follow-up (Fig. 3). Forty-seven percent and 58% of patients, who had no pain and disability at the 2-year follow-up, respectively, were still healthy at the 6-year follow-up.

There was a slightly greater than 15% difference in outcome between the traditional CP and CIFC groups at long-term follow-up, clinically important, but non-significant both for pain intensity and NDI. The degree of evidence was determined to be C+, poor evidence for a clinically important difference between the treatment methods, slightly favoring CIFC (Table 2).

## Discussion

Both cut-off points and relative benefit were used to analyze the clinically important benefit of ACDF at a 6-year follow-up. For NDI, the different analysis methods yielded the same results: 20% of patients improved and worsened. For pain intensity, the relative benefit analysis showed that pain improved in 46% of the patients while pain worsened in only 2% of the patients; in contrast, analysis with a ≥10 mm cut-off point determined that pain improved in 78% of

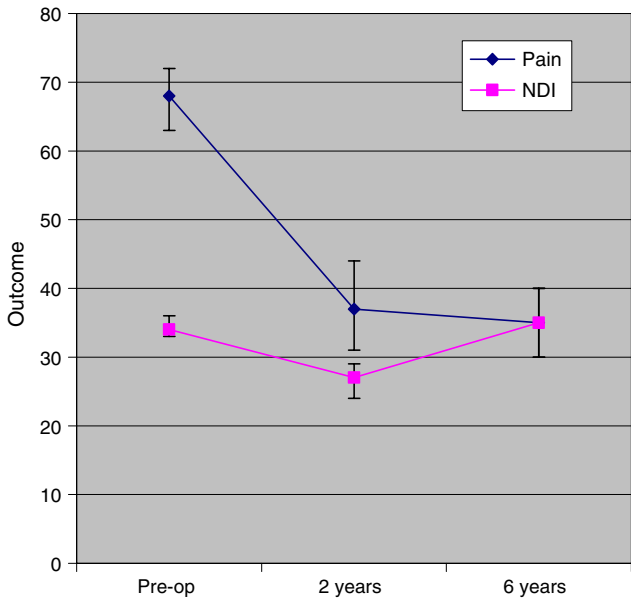


**Fig. 2** Pain intensity (visual analog scale) and neck disability index (*NDI*) preoperatively and at 2-year and 6-year follow-up to ACDF. Pain was decreased at 6 years compared to preoperative measurement ($P < 0.0001$) and was unchanged between the 2-year and 6-year follow-up ($P = 0.29$). NDI was unchanged ($P = 0.49$) at the 6-year follow-up compared to preoperative levels, but deteriorated between 2 and 6 years ($P < 0.0001$). Mean values and 95% upper and lower CIs are presented

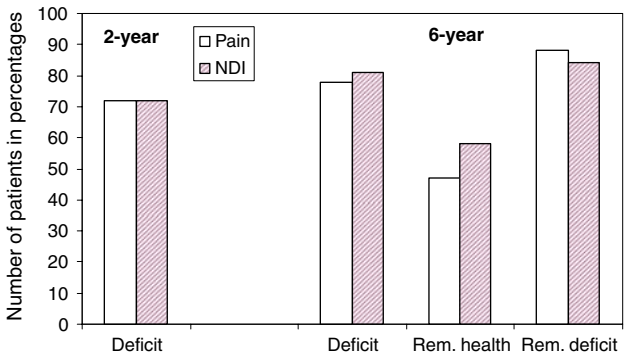


**Fig. 3** Patients with persistent pain and disability (deficit) [defined as pain intensity on visual analog scale (VAS) ≥10 mm, neck disability index (*NDI*) rating ≥20] 2 years (data presented only for those who remained in the study at the 6-year follow-up) and 6 years after surgery (anterior cervical decompression and fusion) and stability of deficit from the 2- to 6-year follow-up [Remaining, (Rem.) health, patients healthy at the 2- and 6-year follow-up; Rem. deficit, patients with deficit at the 2- and 6-year follow-ups]

patients and worsened in 8% of patients. Use of a relative percent change of 50% in pain intensity seems reasonable, but using a 10-mm change on the VAS as a cut-off point for minimally clinical relevant change seems insufficient for such a major medical intervention as ACDF. To minimally determine clinically relevant change in pain intensity, the cut-off point of ≥10 mm needs to be adjusted.

When the cut-off point was defined as more than a 30-mm change, as recommended by Klooster et al. [18], pain improved in 47.5% of the patients, and no patient's pain worsened; results roughly similar to those from the analysis of relative benefit. As mentioned above, 46% of the patients achieved at least 50% relief of pain, which is comparable to the results of Pauza et al. showing that 40% of study patients experienced 50% relief of pain after intradiscal electrothermal treatment for discogenic low-back pain [25]. Klooster et al. [18], studying patients with arthritis treated with local corticosteroid injection, defined truly meaningful, individual improvement as a minimal 30-mm or 55% reduction of pain intensity on VAS, which also seems a reasonable recommendation for ACDF patients.

One possible interpretation of the differences in the two primary ACDF outcome measures, with worse results of NDI than pain intensity, is that NDI is a more complex parameter and therefore, more influenced by other problems such as back pain and distress. The differences in these outcome measures could also be the result of false-positive effects of pain intensity due to the use of painkillers. An alternative explanation for the lack of marked change in NDI is that surgery only marginally affects this outcome [11].

At the long-term evaluation, 70% of patients had continued deficits with respect to both pain intensity and NDI. Similar results in this [29], as well as in other data [17, 28, 30] have previously been reported for both CP and CIFC at 2-year follow-up. The high deficit rate may reflect inadequate patient selection. However, the patients in this study did not differ from those participating in other studies with regard to age, duration of symptoms, or number of operated segmental levels [1, 12]. At the 2-year follow-up, the proportion of patients with continued problems was lower (44%), when estimated by overall outcome (Odoḿs criteria) than by pain intensity and NDI [29]. Zoëga et al. [37], reported that 81% of patients were satisfied with the results after one-level ACDF, despite no improvement in pain and function. In the present study, 80% of the subjects reported satisfaction with the surgery [31]. This is better than when studying outcomes such as pain intensity and NDI and is consistent with the findings of Zoëga et al. [37] and other overall long-term results [13, 14]. These results verify previous findings showing that the measurement method influences determinations of surgery outcome [17]. Despite a more functional evaluation in the present study, the differences with respect to other long-term evaluations [4, 9, 13, 14, 23] might be explained by the use of a prospective rather than retrospective design. Retrospective studies have limited potential for firm conclusions regarding the effectiveness of a specific treatment.

Of the patients with deficits at 2-year follow-up, approximately 80% also had deficits at the 6-year follow-up as determined with both pain intensity and NDI. This is consistent with the results of Peolsson et al. [30], where deficit stability between the 6-month and 3-year follow-up after ACDF with CIFC was 100 and 92% for pain intensity and NDI, respectively. These results suggest that short-term follow-up might be used to predict persistent deficits. Early identification is important in order to, among other things, provide patients with more individualized and structured rehabilitation, with exercises to improve neck strength, neck muscle endurance, and neck proprioception [15, 16, 32], and/or a rehabilitation with a multidimensional approach including behavior therapy [19, 20] in order to minimize suffering and sick leave. Today there is very sparse knowledge about the most effective rehabilitation after ACDF and whether or not

**Table 2** Comparison of pain intensity (visual analog scale) and neck disability index (NDI) at the 6-year follow-up between patients who had undergone anterior cervical decompression and fusion with the Cloward procedure (CP) or cervical intervertebral fusion cage (CIFC)

| | CP | | | CIFC | | | Difference | |
|---|---|---|---|---|---|---|---|---|
| | *n* | Mean (SD) | Dis. *n* (%) | *n* | Mean (SD) | Dis. *n* (%) | *P* value | (%) |
| Pain | 40 | 40(24.2) | 34(85) | 41 | 33(25.2) | 30(73) | 0.17 | 18 |
| NDI | 39 | 38(21.7) | 30(77) | 41 | 32(21.1) | 27(66) | 0.19 | 16 |

The persistent pain and disability [deficit rate (dis.)] (deficit in pain intensity ≥10 mm and in NDI ≥20%). Clinically important difference (in percentage) between the traditional CP and CIFC was defined as > 15%

rehabilitation improves the results of surgery. There is also insufficient evidence for comparing the effects of physiotherapy and surgery in patients with cervical radiculopathy [2, 26, 27].

The long-term outcome in patients with cervical disc disease might improve when taking into account predictive factors of a good functional outcome [29], leading to stricter inclusion criteria for surgery.

The cut-off points used to determine residual deficits as well as change between measurements may be challenged, and if other cut-off points had been used the results would have been different. However, in other studies [28–30] the cut-off points for different subjective variables yielded approximately the same degree of residual deficit and in some way the variables verify each other. Also the use of a 50% relative benefit could be challenged. A 50% change in pain intensity is commonly used in pharmaceutical examination of new painkillers (personal communication 19 March, 2004 with the European Agency for the Evaluation of Medicinal Products). Both cut-off points and relative benefit need to be judged with respect to potential risk and economic costs of the intervention.

There was poor evidence for clinically important differences in pain intensity and NDI between CP and CIFC. Shono et al. [34] reported that a carbon-fiber-composite cage packed with cancellous bone graft had biomechanical advantages compared to iliac bone graft alone. Vavruch et al. [35] and Peolsson et al. [31] reported no significant difference in 2-year or 6-year clinical improvement of CIFC compared to CP, which is consistent with the findings in this study where other statistical analysis were used.

There were no significant differences in background and outcome data when comparing the two surgical techniques at the 6-year follow-up [31].

Dropout analysis of the 6-year follow-up showed no significant differences in background data or subjective or objective measurements before surgery or at the 6-year follow-up between those who answered the questionnaire and those who did not, which means that the patients included in the analysis are representative of the ACDF population.

The results of the measurements did not differ when nonparametric and parametric analyzes were compared.

Power analysis (80% power and a 5% significance level) showed that to detect statistically significant changes between preoperative data and 6-year follow-up data, 11 and 9,000 patients were needed for measurements of pain intensity and NDI, respectively. Thus, the clinical importance of a statistically significant NDI difference in a very large material can be questioned. In large studies, a minor change may be significant, but not necessarily clinically important. Therefore, and to calculate power in the planning of future studies, the knowledge of clinically important change is important.

## Conclusions

It could be concluded that 30 mm and 20% in pain intensity and NDI is reasonable to suggest as criteria for a clinically relevant change after ACDF. Before undergoing ACDF, patients should be informed that they have an approximate 50% probability of achieving pain relief and little chance of functional improvement. The findings suggest that these outcomes are stable between 2 and 6-year follow-ups, and that there is poor evidence for difference between the surgical techniques CP and CIFC. Further studies are needed that focus on the clinically relevant benefit of ACDF.

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