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A comparison between the carbon fiber cage and the Cloward procedure in cervical spine surgery:

A 10-13 year follow-up of a prospective randomized study

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Abstract

Study design. 10-13 year follow-up of a prospective randomized study.

Objectives. To compare the 10-13 year outcomes of anterior cervical decompression and fusion (ACDF) with a cervical intervertebral fusion cage (CIFC), and the Cloward procedure (CP) using a broad clinical and patient-centered assessment.

Summary of Background Data. There are few prospective studies and none with a follow-up of 10 years or more.

Methods. Patient questionnaires completed 10 years or more following ACDF. Seventy-three patients (77%) responded. Radiographs were obtained at 2 years.

Results. Apart from greater fulfillment of preoperative expectation ($p=0.01$) and less headache ($p=0.005$) in the CIFC group compared to the CP group, there were no significant differences in the outcomes of the two surgical methods. Pain intensity improved in comparison to preoperative levels in both the CIFC and CP groups ($p<0.0001$), but the Neck Disability Index (NDI) only improved in the CIFC group ($p=0.04$). Only those with a healed fusion benefited from an improved NDI ($p=0.02$). There was no deterioration in pain intensity or NDI after the 2-year follow-up.

Conclusions. The outcomes of the two surgical methods, with a few exceptions, were equal at 10-13 year follow-up, and there was no deterioration in outcome after the 2-year follow-up.

Pain intensity improved more than disability, which may indicate that further improvement of physical function requires early more extensive postoperative rehabilitation. Despite persisting disability, repeat surgery was relatively uncommon.

Key words: cervical spine, disc, cage, Cloward, outcome.

Key points

- Apart from greater fulfillment of preoperative expectation and less headache in the CIFC compared to the CP group, there were no significant differences in the outcomes of the two surgical methods ten or more years after surgery.
- Pain intensity improved in comparison to preoperative levels in both the CIFC and CP groups, but the NDI only improved in the CIFC group. There was no deterioration in outcome after the two-year follow-up.
- Only patients with a healed fusion benefited from an improved NDI, otherwise the relationship between radiological findings and clinical outcome was weak.
- Pain intensity improved more than disability, which may indicate that further improvement of physical function requires early postoperative rehabilitation.
- Despite persisting disability, repeat surgery was relatively uncommon.

Mini Abstract/Précis

The outcomes of the two methods, anterior cervical decompression and fusion with a cervical intervertebral fusion cage and the Cloward procedure were, with a few exceptions, equal at 10-13 year follow-up of a prospective randomized study. There was no deterioration in outcome after the 2-year follow-up.

Introduction

Several long-term follow-up studies have shown that the outcomes of anterior cervical decompression and fusion (ACDF) are good.¹⁻⁶ Most of these studies are, however, retrospective¹⁻⁶ and lack patient-centric data such as persisting problems with the activities of daily life resulting from radiculopathy and/or neck pain and dysfunction. Apart from the previously published 6-year follow-up of the present study,⁷ we are not aware of any other prospective studies with 5 or more years of follow-up and no other prospective randomized studies with more than 2 years of follow-up. Comparisons between these two surgical methods, the Cloward procedure (CP) and the cervical intervertebral fusion cage (CIFC or Brantigan cage) made at 10 years or more post ACDF have not previously been published, nor have sub-group analyses of healing status and repeat surgery been made.

The cage technique has the theoretical advantages of restoring disc height and preventing graft collapse, thereby supporting fusion in lordosis and enhancing decompression of the spinal nerve root.⁸ Earlier follow-up studies^{7, 8} have not shown any significant difference between CP and CIFC, apart from a higher rate of pseudarthrosis with the CIFC technique. Increased risk of accelerated degeneration in adjacent segmental levels following fusion^{5, 9} with subsequent recurrence of pain^{1, 5} has been reported. Whether the use of a cage can prevent collapse and kyphosis of the fused level/levels, and reduce long-term symptoms, is still the subject of some debate.

The aim of this study was to compare the outcomes of ACDF with CIFC with those of ACDF with CP ten years or more after surgery, using a broad clinical and patient-centered assessment.

Materials and Methods

This study was carried out at a university hospital in the south of Sweden between 1995 and 1998. Informed consent was obtained from all participants. 103 consecutive patients with both clinical and MRI evidence of cervical nerve root compression were randomized to treatment with either autograft (CP)¹⁰ or autograft plus CIFC (AcroMed, Cleveland, Ohio).⁸ The inclusion criteria were radiculopathy of degenerative origin, of at least six months' duration with or without neck pain. Exclusion criteria were myelopathy, psychiatric disorder, drug abuse and previous spinal surgery.

All patients who were asked to participate agreed to do so. Fifty-two patients were randomly assigned to the CIFC group and 51 to the CP group. Randomization was achieved by an attending nurse drawing one of two lots marked CP or CIFC. The two groups did not differ significantly in age, gender, number of operated levels, duration of symptoms or smoking history.⁸

Eight patients (three randomized to CIFC and five to CP) changed their minds and declined surgery, leaving 95 patients in the study.

Before surgery, and at one and two years following surgery, patients were asked to complete a questionnaire and to undergo a standard clinical examination and plain radiography (antero-posterior, lateral and oblique).⁸ Questionnaires were also completed six years after surgery.⁷

Ten years or more after surgery (mean 138 months, SD 10, range 120-154) a further questionnaire was sent to the remaining 90 patients (four had died for unrelated reasons and one had developed a whiplash-associated disorder six weeks after surgery). Seventy-three patients, (34 men and 39 women, mean age 59 years (SD 8.6, range 42-79)), completed the questionnaire (39 patients in the CIFC group and 34 patients in the CP group). Of these, 46 had undergone surgery at one level, 24 at two levels and 3 at three levels. Eight patients in the CIFC group and two in the CP group had undergone additional surgery at least once ($p=0.07$).

Out of the 17 patients who did not respond to the questionnaire, seven had developed other diseases such as cancer and stroke, which made it difficult for them to answer accurately. One patient returned the questionnaire uncompleted, but stated that he felt well. Nine patients failed to return the questionnaire despite several reminders. In other words, 77% of those who had originally undergone surgery answered the questionnaire.

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

Surgical technique

The Cloward procedure was performed according to standard techniques using a bicortical iliac autograft harvested through a 5 cm skin incision using a Cloward dowel cutter.¹⁰ The CIFC surgical technique⁸ is similar to the Smith-Robinson technique¹¹ but uses a carbon fiber cage rather than a tricortical graft.⁸

Postoperatively, all patients used a Philadelphia collar for six weeks, and most of them received routine physical therapy including basic ergonomics, light shoulder movements and exercises to improve active range of neck motion in primary care after removal of the collar.

Parameters

Background data included: age, gender (1=man, 2=woman), surgical technique (1=CP, 2=CIFC),⁸ number of operated levels,⁸ segmental height (mm),⁸ angle of segmental lordosis/kyphosis⁸ (radiological variables prior to surgery and at 2-year follow-up), number of additional surgery (1=no additional surgery, 2=at least one additional surgery; included both the same (reoperation) and adjacent level/ levels), preoperative, 2-year and 6-year values of pain intensity (“right now”, mm on Visual Analogue Scale (VAS)) and Neck Disability Index (NDI, in percentages).^{7, 8}

Healing status (1=fused, 2=pseudarthrosis) was assessed by a radiologist and a spinal surgeon at the 2-year follow-up.⁸ Fusion was classified into four types according to the presence or absence of bridging bone anteriorly and/or through the disc space.⁸ Type 1A was defined as the presence of bridging bone anteriorly and through the disc space; 1B as bridging bone present anteriorly but not through the disc space; 2A as no bridging bone anteriorly but present through the disc space; and 2B as a total absence of bridging bone. Pseudarthrosis was defined as 2B healing, and fusion was defined as absence of 2B healing at any operated level.⁸ At the two year follow-up the fusion rate was 86% in the CP group and 62% in the CIFC group.⁸ Typically the failed fusion in the CIFC group was of the “locked in fusion” type, with a radiolucent horizontal zone through the center of the cage.

Pain and numbness

Pain intensity was quantified by a horizontal 100 mm VAS (0=no pain, 100=worst imaginable pain) for neck-related “general” pain “right now”.¹² Pain “right now” was also rated on VAS by specific location – neck, arm and head. Distribution of symptoms on a seven-point scale (0=no symptoms, 6=most distal (in the hand)) was measured with pain drawings.¹³ Patients were asked if they had had neck problems during the previous 6 months (1=yes, 2=no). Frequency of neck pain, arm pain, headache, numbness and weakness in the hand were measured on a five-point scale (1=never, 5=constantly). The use of painkillers was measured on a four-point scale (1=several times a day, 4=never).

Disability

Neck-specific disability was quantified by 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 converted into a percentage (0% = no pain or difficulties, 100% = highest score for pain and difficulty on all items).¹⁴

The impact of neck symptoms on activities of daily life was rated on a 6-point scale (1= not at all, 6=extremely high degree).

Sickness absence was rated as yes (=1), no (=2), and would not have been in work even if free of neck problems, i.e. retired.

Self-efficacy and coping

The Self-Efficacy Scale (SES)^{15, 16} was used to measure the patients' perceived ability to carry out common daily activities despite pain. SES comprises of 20 items, each rated on an 11-grade scale (0=no confidence, 10=very confident). The individual item scores are summated, giving a maximum score of 200 (reflecting high confidence in performance).

General health and global outcome

Health-related quality of life was assessed by a patient reported outcome – the EuroQol five dimensions (EQ5D). This measure addresses mobility, self-care, usual activities (e.g. work, study, housework, and family or leisure activities), pain, and anxiety/depression.¹⁷ One of three hierarchical levels is chosen for each dimension (1=no problems, 2=some problems, 3=severe problems) and converted to a index (0=death, 1=perfect health). Current health status was also measured on the EuroQol (EQ) thermometer (0=worst imaginable, 100=best imaginable).¹⁷

The global outcome (modified Odom), as assessed by the patient, was measured on a six-grade scale (1=complete relief of problems, 2=much better, 3=better, 4=unchanged, 5=worse, 6=much worse).

The importance of perceived change in symptoms from neck and arm compared to before surgery was rated on an eleven-point scale (0=not at all important, 10=very important).

The extent to which preoperative expectations of surgery were met was measured on a three-grade scale (1=yes completely, 2=yes partially, 3=no not at all).

Statistical Methods

The two-tailed Student's t-test was used for parametric data and the Mann-Whitney U-test for non-parametric data in unpaired two-group comparisons. Repeated measures of one-way analysis of variance (ANOVA) with the Bonferroni/Dunn post-hoc test were used for four-group comparisons of the main outcomes of pain intensity (VAS) and NDI. The Pearson correlation coefficient was used to evaluate bivariate correlation. A p-value of ≤ 0.05 was considered statistically significant.

Results

At follow-up 10 years or more after surgery there were no significant differences between the outcomes of the two surgical methods, except for greater fulfillment of preoperative expectation ($p=0.01$) and lower intensity of headache ($p=0.005$) in the CIFC group compared to the CP group (Table 1).

At 10-yr-plus follow-up, pain intensity had improved in comparison to preoperative levels in both the CIFC and CP groups ($p<0.0001$), but the Neck Disability Index (NDI) had only improved in the CIFC group ($p=0.04$), (Fig. 1 and 2).

There was no deterioration in pain intensity or NDI in either treatment group between the 2-year and 10-year-plus follow-up ($p=0.09-0.97$, Fig. 1 and 2).

There was no change in pain intensity in either group between the 6-year and 10-year-plus follow-up (total $p=0.40$, CP $p=0.18$, CIFC $p=0.85$, Fig. 1). There was an improvement in NDI (total $p=0.0004$) in the CP group between the 6-year and the 10-year-plus follow-up ($p=0.001$), but NDI remained unchanged in the CIFC group ($p=0.07$, Fig. 2).

Both those with healed fusion and those with pseudarthrosis (of those who answered the 10-year-plus follow-up questionnaire 70% had a healed fusion at the two-year follow-up when the radiology was obtained, 82% in the CP group and 58% in the CIFC group) had lower pain intensity (CP $p<0.0001-0.03$, CIFC $p=0.0002-0.003$) compared to preoperatively (Table 2), but the NDI only improved in those with healed fusion (CP $p=0.02$, CIFC $p=0.02$) (Table 3). In the CIFC group, but not in the CP group ($p=0.34-0.43$) individuals with healed fusion reported significantly lower pain intensity ($p=0.03$) and NDI ($p=0.02$) than those with pseudarthrosis. Individuals with healed fusion had significantly lower pain intensity ($p=0.02$) and neck-specific disability ($p=0.04$) at 10-year-plus follow-up than those with

pseudarthrosis. In patients with pseudarthrosis, as in those with full healing, there was no significant difference in pain intensity or NDI between the treatment groups ($p=0.11-0.97$).

At ten years, neither pain intensity nor NDI showed a significant correlation with either preoperative or 2-year measurements of disc height, kyphosis, or number of operated levels ($r=0.23-0.14$, $p=0.10-0.96$). The correlation between preoperative and 10-year values was weak for both pain intensity and NDI ($r=0.11-0.39$, $p=0.0006-0.37$).

The 10-year-plus outcome parameters that correlated best with pain intensity and NDI were the EQ thermometer, self-efficacy, modified Odom and neck problems impact of daily life ($r=0.62-0.80$, $p=0.0006->0.0001$).

Individuals who had undergone additional surgery at least once had higher pain intensity in the arm ($p=0.007$) and neck ($p=0.003$), higher frequency of daily hand numbness ($p=0.004$), neck problems ($p=0.006$) and headache ($p=0.03$) than individuals who had not had additional surgery. Those who had undergone additional surgery also had a higher NDI score ($p=0.006$) and lower self-efficacy related to the neck ($p=0.01$) with a greater impact on daily life ($p=0.002$), lower general health (EQ thermometer $p=0.008$, EQ5D $p=0.008$), lower self-rated effect of surgery ($p=0.005$) and lower fulfillment of preoperative expectation ($p=0.03$) than those who had not had additional surgery. There were 10 patients eventually with an additional surgery; of those 6 (8%) were reoperations (same level /-s). Of the additional surgery, 6 were among those with pseudarthrosis at 2 years (3 reoperation and 3 on adjacent level) and 4 patients among those with healed fusion (3 reoperation and 1 on adjacent level) ($r=0.62$, $p=0.07$). Of the three patients with a solid fusion who underwent reoperation, 2 had a laminectomy combined with foraminotomy and one has a foraminotomy 2-3 years after the ACDF. All additional surgery were done on the 1990ties.

Discussion

At follow-up 10 years or more after ACDF there were, with a few exceptions, no differences in the outcomes of the two treatments methods, as shown in earlier reports from the same study^{7, 8}. The CIFC group had higher fulfillment of preoperative expectation ($p=0.01$) and a lower intensity of headache ($p=0.005$) compared to the CP group. This difference was not evident in the earlier follow-ups.^{7, 8} Greater fulfillment of preoperative expectation in the CIFC group was surprising, particularly as pseudarthrosis and additional surgery were more common in the CIFC group than in the CP group. In addition, symptoms usually associated with pseudarthrosis, i.e. greater pain intensity and higher NDI, seemed more common in the CIFC group than in the CP group. There was a suggestion of an association between healed CIFC and fewer persisting symptoms and less disability, but this did not reach statistical significance. Unfortunately we do not have long term radiological data, an obvious weakness of the study. Interestingly we could document an effect of fusion status at 2 years only on long term NDI, but not on long term pain. The significance of this is, however, unclear.

There was a moderate, but non-significant relationship between pseudarthrosis and additional surgery ($r=0.62$, $p=0.07$). Patients who underwent additional surgery had a worse long-term clinical outcome than those who underwent a single procedure. Of course, those that needed further surgery were more likely to have had an unsatisfactory result from the first procedure, and it is hard to tell what the long-term clinical outcome of these patients would have been if they not undergone this further surgery. Unfortunately, radiological evaluation was not done at the 10-year follow-up which is a weakness in this study. On the other hand, disc height and kyphosis have been shown to have minimal significance for clinical outcome both in earlier follow-ups^{7, 8} and at 10-year follow up of ACDF in this study ($r=-0.01$ to -0.20 , $p=0.10-0.92$). One could postulate that the more pronounced segmental kyphosis¹⁸ and the lower disc height seen in the CP group compared to the CIFC group at 2 year follow-up⁸ would eventually have

progressed to involve adjacent segmental levels,¹⁹ leading to more intense headaches with increasing flexion of the lower cervical spine and subsequent compensatory extension of the upper cervical spine to maintain optimal sight.

In both treatment groups, pain intensity improved ($p < 0.0001$) from preoperative levels at 10-year follow-up, irrespective of whether or not fusion had occurred, and there was no change compared to the 6-year follow-up ($p = 0.04$). Only those with a healed fusion improved in NDI compared to before surgery ($p = 0.02$), showing the importance of healed fusion in lowering the long-term disability level.

One might have expected deterioration in NDI and an increase in pain intensity at 10-year follow-up in comparison with the 2-year follow-up, due to expected progressive degeneration of adjacent segmental levels, with increasing kyphosis and decreasing intervertebral height.^{5, 20} Surprisingly, this was not the case. This could be due to asymptomatic³ or even absent degeneration at adjacent levels, with a low correlation between radiological/MR findings and clinical symptoms as shown in this and other studies.^{3, 21} It also illustrates the stability of outcomes over time.²² It may also imply that the evaluation instruments used, although well-validated^{13, 23, 24} may be relatively insensitive.

Good clinical outcomes of ACDF have been reported in retrospective follow-up studies of five years or longer.^{1-6, 25} Thorell et al⁴ reported that patients with longer follow-up (2 years or more, average 8 years) have less pain and improved function, but Wang et al⁵ and Gore and Sopic¹ reported a recurrence of neck pain on long-term follow-up, probably due to cage subsidence. To our knowledge, there are, with the exception of the 6-year follow-up⁷ of the present study, no other prospective randomized studies of ACDF with more than two years of follow-up. The results of the present prospective study are less striking than those of the retrospective studies.^{2-6, 25} This may reflect differences in study design, with a risk of overestimating benefits in retrospective studies, but the difference in outcome parameters

used was probably also significant, with broader and more patient-centered parameters being used in the present study. Cultural differences and differences in healthcare and social insurance systems could also have affected the results.

Despite significant improvement in pain intensity and generally beneficial outcomes in about 80% of patients in both treatment groups, the improvement in NDI was less impressive. These results are similar to those of a smaller study²² which showed that surgical outcome is influenced by the method of evaluation. An accurate evaluation of outcomes requires detailed evaluation of a broad range of parameters.

One could conclude that the outcomes of the two surgical methods, with a few exceptions, were broadly equal after 10 years or more, and that there was no deterioration between the 2-year and 10-year postoperative assessments. Function improved less than pain, which suggests that better functional improvement may require the early introduction of more extensive postoperative rehabilitation such as specific exercises to improve neck muscle function and also behavioral approaches to minimize fear of movement. Despite persisting disability, however, repeat surgery was relatively uncommon.

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Table 1) Long-term outcomes (10-13 yrs) of anterior cervical decompression and fusion with either the Cloward procedure (CP) or the cervical intervertebral fusion cage (CIFC).

	CP	CIFC	P-value
Pain (mm VAS) mean	35(28.6)	35(24.9)	0.95
Painkillers n(%) daily	11(34)	12(32)	0.93
Arm pain (mm VAS) mean	34(26.2)	31(27.3)	0.67
Pain radiation to arm (Werneke) (6=most distal) median	6(0-6)	6(0-6)	0.12
Daily arm pain n(%) yes	14(42)	15(42)	0.40
Daily hand weakness n(%) yes	18(55)	16(46)	0.50
Daily hand numbness n(%) yes	13(39)	13(35)	0.45
Neck pain (mm VAS) mean	33(25.3)	30(27.1)	0.61
Neck problems in last 6 months n(%) yes	27(82)	29(76)	0.57
Daily neck problems n(%) yes	19(58)	12(32)	0.11
Neck problems impacting on daily life, n(%) quite severe/extremely severe	17(59)	16(50)	0.40
Headache (mm VAS) mean	33(32.1)	14(19.3)	0.005
Daily headache n(%) yes	11(34)	6(17)	0.06
NDI (%) mean	31(18.6)	27(18.7)	0.36
Effect of surgery n(%)			0.06
Complete relief of problems	3(9)	5(13)	
Much better	10(29)	19(49)	
Better	13(38)	11(28)	
Unchanged	5(15)	1(2.5)	
Worse	3(9)	2(5)	
Much worse	0(0)	1(2.5)	
Expectations of surgery met n(%)			0.01
Yes, completely	7(21)	21(55)	
Yes, partially	21(64)	13(34)	
No, not at all	5(15)	4(11)	
Importance of change in neck/arm problems compared to before surgery, (10=very important) median	8(0-10)	8(0-10)	0.88
Neck-related sick-leave n(%)			0.16
Yes	12(38)	11(30)	
No	11(34)	8(21)	
Would not have been in work even if free of neck problems i.e. retired	9(28)	18(49)	
Self-efficacy mean	141(43.0)	150(34.6)	0.35
EQ thermometer (mm) mean	64(18.6)	69(24.2)	0.28
EQ 5D mean	0.67(0.22)	0.71(0.26)	0.49

Table 2. Mean pain intensity in millimeters (Visual Analogue Scale, 0= no pain, 100= worst imaginable pain) before surgery (pre-op), at 2 years, 6 years, and 10+ years by treatment method (Cloward procedure (CP) or cage (CIFC)) and by fusion status (obtained at 2 years postoperatively). P-values (P) for comparison between preoperative and 10+ years are presented.

		Pre-op	2 yr	6 yr	10 yr	P (Pre v.10 yr)
	All	69	33	38	35	<0.0001
CP	Healed	70	35	37	33	<0.0001
	Non-healed	67	25	42	43	0.03
	All	66	41	32	35	<0.0001
CIFC	Healed	64	33	24	25	0.0002
	Non-healed	68	54	42	46	0.003

Table 3. Mean Neck Disability Index (NDI) in percentage of neck specific disability (0= no difficulties, 100= highest score for difficulty) before surgery (pre-op), at 2 years, 6 years and 10+ years by treatment method (Cloward procedure (CP) or cage (CIFC)) and by fusion status (obtained at 2 years postoperatively). P-values (P) for comparison between preoperative and 10+ years are presented.

		Pre-op	2 yr	6 yr	10 yr	P (Pre v. 10yr)
	All	36	26	38	31	0.21
CP	Healed	37	27	38	30	0.02
	Non-healed	29	22	36	36	0.15
	All	33	27	32	27	0.11
CIFC	Healed	31	26	26	21	0.02
	Non-healed	37	30	41	35	0.61

Figure Legends

Figure 1. Neck-related pain intensity on a visual analogue scale (VAS) in mm before surgery, at, 2 years, 6 years and 10+ years after anterior cervical decompression and fusion for disc disease. Pain intensity improved between the pre-op stage and follow-up ($p < 0.0001$). There were no significant differences between the surgical methods used, the Cloward procedure (CP) and the cervical intervertebral fusion cage (CIFC). Mean values and 95% confidence intervals are shown.

Figure 2. Neck-specific disability rated on the neck disability index (NDI), shown in percentages (%) at pre-op, 2 years, 6 years and 10+ years after anterior cervical decompression and fusion with the Cloward procedure (CP) or the cervical intervertebral fusion cage (CIFC). There was no significant difference in NDI between CP and CIFC at 10+ years follow-up, and scores were not improved for the whole group compared to pre-op. But when analysis was done for each treatment groups, CIFC improved ($p = 0.04$) at 10-yr follow-up in comparison to pre-op. Mean values and 95% confidence intervals are shown.

Figure 1.

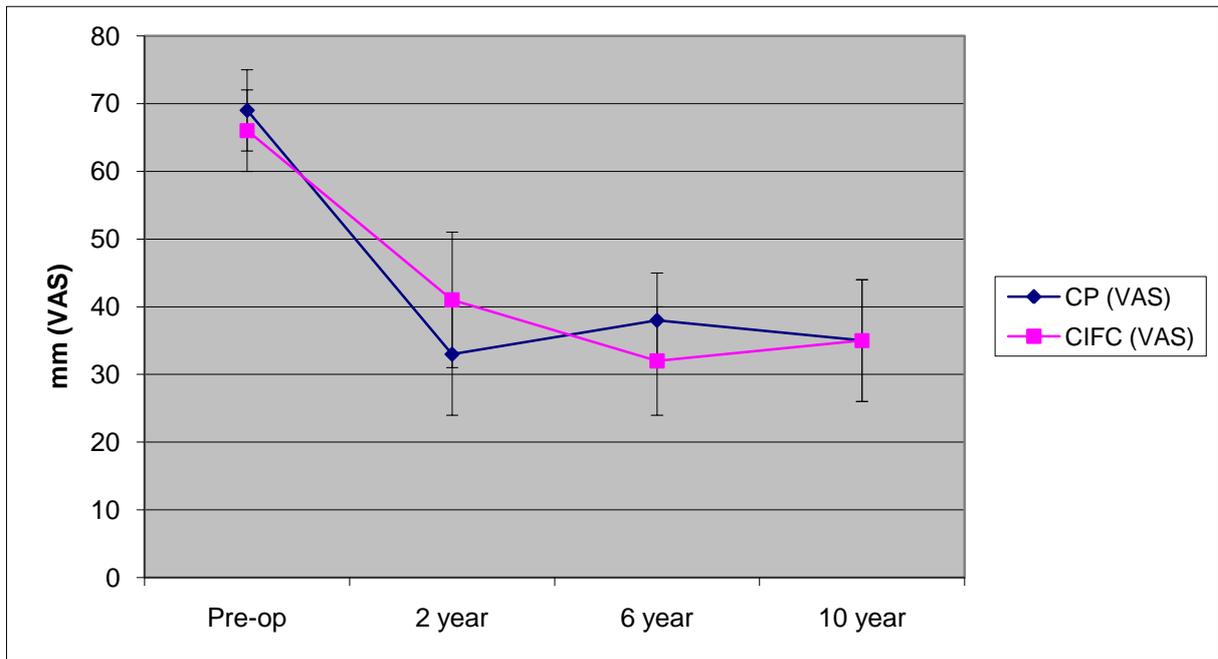


Figure 2.

