### PATIENT-REPORTED SURVEY TO ASSESS CLINICAL STATUS AND SURGICAL OUTCOME AFTER ANTERIOR CERVICAL DISCECTOMY AND FUSION USING AN ALLOGRAFT WITH A FIXED ANGLE OF INCLINATION

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SUMMARY – Degenerative cervical disc disease can be surgically treated by various procedures, one of which is anterior cervical discectomy and fusion (ACDF). It is used to stabilize the spine and decompress neural structures of the spinal canal. However, measuring its impact on postoperative clinical status and surgical outcome is difficult. That is the reason why patient-reported surveys are commonly used to assess clinical status and surgical outcomes. To evaluate the surgical outcomes of ACDF with an allograft with a fixed angle of inclination at one cervical level, we conducted a prospective study on 60 patients over one year. We used a structured patient-reported survey based on the visual analog scale (VAS), Oswestry Disability Index (ODI), and Odom questionnaire. Most patients experienced significant reduction in pain intensity in their arms and neck after undergoing ACDF with a carbon wedged-shaped allograft with a fixed inclination angle of 7°. This improvement was equally represented across all age groups and levels of the cervical spine operated on. Most patients also experienced a decrease in postoperative disability, as measured by the ODI, regardless of their age or the level of the cervical spine operated on. The majority of them rated their outcomes as either excellent or good, which was true across all age groups and levels of the cervical spine. In conclusion, patient-reported clinical status and outcome surveys are valuable and easy-to-perform tools for evaluating the quality of life of patients suffering from degenerative cervical disc disease after ACDF with a carbon cage having a fixed inclination angle.

Key words: Cervical disc degenerative disease; Anterior cervical discectomy and fusion; Wedge-shaped cage with fixed inclination angle; Patient-reported outcomes

#### Introduction

Degenerative cervical spine refers to conditions such as intervertebral disc disease, spondylosis, spinal

stenosis, and spondylarthrosis, which occur due to prolonged osteodegenerative changes that can affect the stability of the cervical dynamic segment<sup>1,2</sup>. To treat these conditions, various surgical procedures are used to stabilize the spine and decompress neural structures of the spinal canal<sup>3</sup>, including the anterior approach which remains an elegant and efficient method to deal with the majority of cervical spine

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Received December 18, 2023, accepted March 25, 2024

pathologies<sup>4</sup>. Over the past few decades, minimally invasive surgical techniques have been developed to preserve the natural curvature of the cervical spine and improve the effectiveness of surgical treatment<sup>5</sup>. Anterior cervical discectomy and fusion (ACDF) is a frequently used surgical technique to treat degenerative disc disease of the cervical spine and restitute cervical lordosis, resulting in solid bone fusion and spinal stability<sup>6,7</sup>. However, the impact of these techniques on postoperative clinical status and the functional capacity of the cervical spine can vary and have different effects on the outcome<sup>8,9</sup>.

Patient-reported outcome measures are important instruments commonly used for assessing symptom severity and treatment success in patients suffering a degenerative cervical spine disease<sup>10</sup>. We conducted a prospective study on 60 patients who underwent ACDF with a wedge-shaped allograft with a fixed inclination angle at one cervical level over one year. To evaluate their clinical status and surgical outcome, we used a structured patient-reported survey based on visual analog pain score (VAS), Oswestry Disability Index (ODI), and Odom questionnaires.

### Material and Methods

All patients underwent ACDF at one level using a wedge-shaped carbon allograft with a fixed inclination angle of 7°, which was placed in the desired intervertebral space to achieve intracorporeal fusion. All patients were subjected to a set of preoperative and postoperative patient-reported surveys including psychometric, subjective responses to the preoperative and postoperative intensity of pain on a one-dimensional numerical ten-point VAS11. The same survey was also based on a customized ODI questionnaire that included 10 numerical categories of questions covering the intensity of pain, patient habits, behavior, and social life. Based on the answers, the exact percentage of disability could be accurately calculated. It was rated as the lowest degree of disability (0-20%), moderate (21%-40%), severe (41%-60%), daily severe (61%-80%), or complete disability (81%-100%)<sup>12</sup>. The surgical treatment outcome was evaluated using the Odom criteria questionnaire, categorizing patient outcomes into four groups as follows: excellent, good, partially successful, and unsuccessful<sup>13</sup>. By analyzing data from the questionnaires, conclusions were made on the impact of the ACDF method using carbon allograft with a premeditated angle of inclination on

patient clinical status, postoperative functional capacity of the cervical spine, and outcome of surgical treatment.

The investigated sample was intended to be demographically homogeneous. All patients participating in the surveys voluntarily filled out their self-reported set of questionnaires in terms of anonymity. Patients voluntarily and anonymously completed the survey before and after surgery, and we analyzed data to assess surgical outcome. This prospective study was approved by the institutional Ethics Committee.

#### Statistical analysis

Absolute and relative frequencies were calculated for nominal variables, and the Fisher exact test was applied to test the significance of differences. The mean (M) and standard deviation (SD) were calculated for continuous variables, and the t-test for dependent samples was applied to test the significance of differences. The Kolmogorov-Smirnov test was used to test the normality of distributions. The level of statistical significance was set at alpha 0.05.

SPSS for Windows (version 17.0, SPSS Inc. Chicago, IL, USA) and Microsoft Excel (version of Office 2007, Microsoft Corporation, Redmond, WA, USA) were used on statistical analysis.

### Results

### Sample characteristics

As part of a year-long prospective study conducted from January to December 2022, 60 patients underwent surgery using the ACDF method and were included in the research. Gender distribution was equal, with 30 (50%) men and 30 (50%) women participating in the study. The distribution of both men and women across age groups was also equal, with 56.7% of patients aged <50 and 43.3% of patients aged >50. The mean age of patients was 49.1±9.7 years. The majority of patients underwent surgery at the C5/C6 level (n=31, 51.7%), followed by C6/C7 level (n=17, 28.3%) and C4/C5 level (n=11, 18.3%). Only one (1.7%) patient underwent surgery at the C3/C4 level. Patient distribution is illustrated in Figure 1.

# Analysis of pain intensity in the arms and neck before and after surgery (VAS)

There was a statistically significant difference in the mean pain intensity before and after surgery in the arms and neck (p<0.001) (Table 1). Comparison of the mean pain intensity in the arms and neck according to the cervical level operated on showed a statistically significant difference before and after surgery (p<0.001) (Table 2).

Comparison of pain intensity in the arms and neck before and after surgery between two age groups of patients (younger and older than 50 years) yielded no statistically significant difference. There was a statistically significant difference in the mean pain intensity in the arms and neck before and after surgery in both groups of patients regardless of age (p<0.001).

# Analysis of preoperative and postoperative disability (ODI)

Patient distribution according to the degree of disability before and after surgery (ODI) is shown in Figure 2. There was a statistically significant difference in the degree of disability before and after surgery (p<0.001). Before the surgery, the lowest degree of disability (0-20%) was recorded in 2 (3.3%) patients, moderate degree (21%-40%) in 5 (8.3%), and severe degree of disability (41%-60%) in 8 (13.3%) patients. Daily severe disability (61%-80%) was recorded in 37 (61.7%) and complete disability (81%-100%) in 8 (13.3%) patients. After the surgery, the lowest degree of

disability (0-20%) was recorded in 45 (75.0%) patients, moderate degree (21%-40%) in 6 (10.0%), and severe degree of disability (41-60%) in 8 (13.3%) patients. Daily severe disability (61%-80%) was recorded in one (1.7%) patient, and complete disability (81%-100%) in none of them (0.0%).

Patient distribution according to the degree of disability before and after surgery, depending on the cervical level operated on is shown in Table 3. There was a statistically significant difference in the degree of disability before and after surgery in the group of patients operated on at the C4/C5 level, C5/C6 level, and C6/C7 level (p<0.001).

# Analysis of surgical outcome according to Odom criteria

Patient distribution according to surgical outcome (Odom) is shown in Figure 3. According to Odom criteria, surgical outcome was assessed as excellent in 26 (43.3%), good in 25 (41%), partially successful in 7 (11.7%), and unsuccessful in 2 (3.3%) patients.

There was no statistically significant difference in surgical outcome among patients according to their age (p=0.670). There was no statistically significant difference in surgical outcome according to the cervical level operated on either (p=0.876) (Table 4).

VAS	Before surgery M ± SD	After surgery M ± SD	ť*	р
Arms	8.1±1.8	1.9±2.3	18.131	<0.001
Neck	8.1±1.2	2.4±2.2	19.000	<0.001

Table 1. Mean pain intensity (VAS) in the arms and neck before and after surgery

VAS = visual analog scale; M ± SD = mean ± standard deviation; \*t-test for dependent samples

Level operated on	VAS	Before surgery M ± SD	After surgery M ± SD	t*	р
0.4/5	Arms	7.1±3.1	2.0±2.4	5.864	<0.001
C4/5	Neck	7.6±1.0	2.8±2.5	7.634	<0.001
05/06	Arms	8.2±1.3	1.9±2.3	12.753	<0.001
C5/C6	Neck	8.3±1.0	2.5±2.0	12.954	<0.001
0/107	Arms	8.5±1.3	1.7±2.4	11.957	<0.001
C6/C7	Neck	8.1±1.4	1.9±2.3	11.804	<0.001

Table 2. Mean pain intensity (VAS) in the arms and neck before and after surgery according to cervical level operated on

VAS = visual analog scale; M ± SD = mean ± standard deviation; \*t-test for dependent samples

Table 3. Patient distribution according to degree of disability (ODI) before and after surgery depending on cervical level operated on

Degree of disability (ODI)	Operated level, n (%)							
	C3/C4		C4/C5*		C5/C6**		C6/C7**	
	Before surgery	After surgery	Before surgery	After surgery	Before surgery	After surgery	Before surgery	After surgery
Lowest degree of disability (0-20%)	1 (100.0)	0	1 (9.1)	7 (63.6)	0	24 (77.4)	1 (5.9)	14 (82.4)
Moderate degree of disability (21%-40%)	0	1 (100.0)	1 (9.1)	0	3 (9.7)	3 (9.7)	1 (5.9)	2 (11.8)
Severe degree of disability (41%-60%)	0	0	2 (18.2)	4 (36.4)	3 (9.7)	3 (9.7)	3 (17.6)	1 (5.9)
Daily severe disability (61%-80%)	0	0	7 (63.6)	0	21 (67.7)	1 (3.2)	9 (52.9)	0
Complete disability (81%-100%)	0	0	0	0	4 (12.9)	0	3 (17.6)	0

ODI = Oswestry Disability Index; \*p=0.001; Fisher exact test; \*\*p<0.001; Fisher exact test

	Operated level, n (%)				
Odom criteria	C3/C4	C4/C5	C5/C6	C6/C7	
Excellent	0	5 (45.5)	13 (41.9)	8 (47.1)	
Good	1 (100.0)	2 (18.2)	14 (45.2)	8 (47.1)	
Partially successful	0	4 (36.4)	2 (6.5)	1 (5.9)	
Unsuccessful	0	0	2 (6.5)	0	

Table 4. Patient distribution according to surgical outcome depending on cervical level operated or	distribution according to surgical outcome de	lepending on cervical level operated o	n
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p=0.876; Fisher exact test

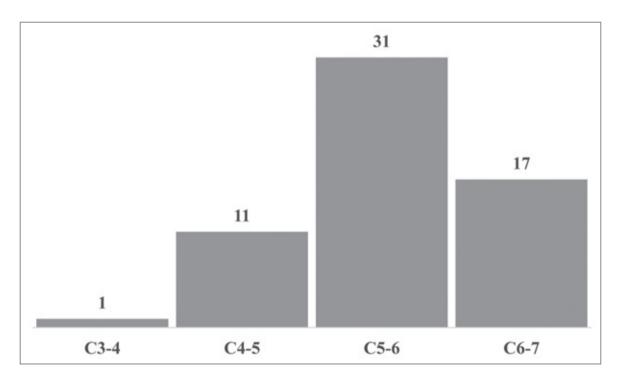
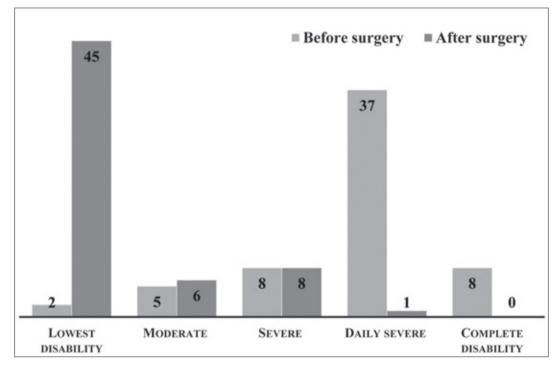


Fig. 1. Patient distribution according to cervical level operated on.



*Fig. 2. Patient distribution according to degree of disability before and after surgery (Oswestry Disability Index).* p<0.001; Fisher exact test

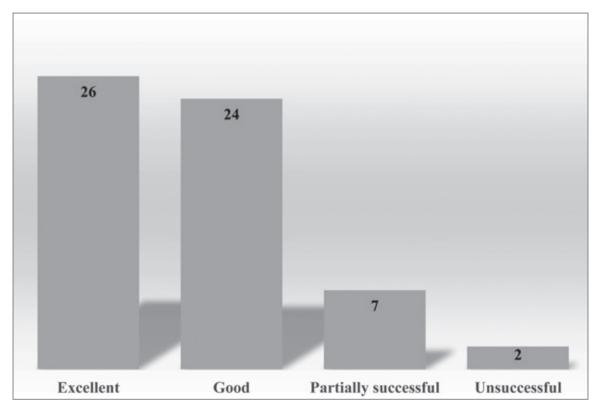


Fig. 3. Patient distribution according to surgical outcome (Odom criteria).

### Discussion

Achieving a satisfactory quality of life is the most important goal of every neurosurgical treatment of patients with cervical degenerative disease. Remembering this, assessing the intensity of pain and postoperative disability by patient-reported VAS and ODI questionaries makes them important measuring instruments addressing the overall impact of pain on patient daily lives. Odom criteria are reliable in assessing patient satisfaction with treatment outcomes following ACDF surgery with a carbon wedge-shaped allograft that has a fixed 7-degree angle of inclination. The study found the surgical method of ACDF with kyphotic allograft to be reliable in reducing chronic pain in the arms and neck. It also helps in restoring cervical lordosis, diminishing postoperative disability and improving surgical outcome of patients suffering from a degenerative disc disease of the cervical spine. Additionally, study results confirmed that certain patient-reported surveys were dependable tools for forecasting postoperative clinical status, degree of disability, and success of surgical treatment.

# Analysis of pain intensity in the arms and neck before and after surgery (VAS)

Pain is a complex perception defined as an unfavorable sensation caused by actual tissue injury<sup>14</sup>. The International Association for the Study of Pain (IASP) defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage and it further states that pain is a personal experience, influenced to varying degrees by biological, psychological, and social factors<sup>15</sup>. Both the IASP and World Health Organization recognize the impact of pain on a patient's overall quality of life, including their physical, emotional, mental, and financial well-being<sup>16</sup>. Pain is an individual experience, and its intensity can be evaluated using various subjective (self-reported) and objective measures such as the VAS<sup>11</sup>.

In our study, we observed a significant reduction in the mean pain intensity in the arms and neck after ACDF surgery across all cervical levels operated on, as assessed by VAS (p<0.001) (Tables 1 and 2). The reduction in pain intensity was equally represented across all age groups and levels of the cervical spine that were operated on. These findings were in line with similar studies<sup>17-19</sup>. The Swiss Public Health Institute<sup>20</sup> and other studies have also reported similar results, showing a long-term reduction in pain after ACDF surgery<sup>21</sup>.

# Analysis of preoperative and postoperative disability (ODI)

It is important to distinguish between pain in the arms and neck and disability caused by that pain. Therefore, pain and disability are not the same item. Disability refers to the reduction of a person's ability, which results from disease and injury, to meet personal, social, or professional requirements and includes activities that cannot be performed due to pain<sup>22</sup>. This encompasses vocational and non-vocational activities, activities of everyday life, and self-care.

Chronic pain in the arms and neck can lead to a decrease in the quality of life, worse psychological and psychosocial functions, and overall poorer health compared to healthy individuals of the same age and gender. To measure functional capacity and quality of life in patients with arm and neck pain, there are questionnaires such as the multidimensional ODI, which are most detailed when evaluating responses to therapeutic interventions<sup>12</sup>.

The distribution of patients in our series according to the degree of disability before and after surgery (ODI) is shown in Figure 2. Before surgery, the majority of patients (61.7%) had daily severe disability, while most of them (75%) had the lowest degree of disability after surgery (Table 3, Fig. 5).

Distribution of patients according to the degree of disability based on age showed a statistically significant difference before and after surgery regardless of their age (p<0.001). In both age groups, the number of patients with daily severe disability significantly decreased after surgery. Our results were consistent with those of similar studies<sup>23</sup>, confirming that the ODI is the most comprehensive self-reported scale for measuring postoperative disability after ACDF.

The distribution of patients according to the degree of disability before and after surgery depending on the cervical level operated on is shown in Table 3. It showed a significant decrease in postoperative disability at all operated levels (p<0.001). When compared to the literature data, the results are not different from the results in similar studies<sup>24</sup>.

#### Surgical outcome analysis according to Odom criteria

In recent years, surgical outcomes have been increasingly linked to patient subjective indicators such as their quality of life and treatment satisfaction<sup>25</sup>. The Odom criteria, a self-reported qualitative scale originally created to assess outcomes after lumbar discectomy, is now commonly used to evaluate surgical outcomes after ACDF. Hence, the criteria can successfully be applied to report outcomes of cervical spine surgery as well<sup>13</sup>.

Our series of patients yielded similar results to those found in comparable literature<sup>26-28</sup>, with more than 80% of patients experiencing an excellent or good surgical outcome according to the Odom criteria (Fig. 3). Therefore, this method is reliable and easy to perform when assessing outcomes after ACDF surgery.

The most common cervical level operated on in our series was C5/C6, followed by C6/C7. However, when comparing surgical outcome after ACDF at different cervical levels, we found no statistically significant difference among the groups (p=0.876) (Table 4). This was because the outcome was mostly excellent or good in a large number of patients after ACDF with a wedge-shaped carbon allograft, regardless of the level operated on. This finding is consistent with those from other studies<sup>26-28</sup>.

The finding was also consistent across all age groups. We found no significant difference in surgical outcome according to age in our series of patients. This suggests that age is not an important factor in determining the ACDF postoperative outcome, as assessed by the Odom criteria. Overall, the Odom criteria are a reliable and effective method for assessing outcomes after ACDF surgery, and our results support their use in clinical practice.

It is important to acknowledge some limitations to our study, which was non-randomized and conducted within a single institution in a limited number of patients. Therefore, we recommend that comprehensive multicenter research be conducted on a wider sample to further validate our results.

#### Conclusion

After undergoing ACDF surgery with a wedgeshaped carbon allograft with a fixed inclination angle, patients experienced a significant reduction in pain intensity in their arms and neck. This reduction was assessed by the VAS scale, a reliable method for measuring pain in patients with degenerative cervical disc disease.

The majority of patients reported a decrease in postoperative disability, as measured by the ODI, regardless of their age or the level of the cervical spine that was operated on. Therefore, the ODI is a valid and easy-to-use patient-reported indicator of clinical status before and after ACDF.

When assessing surgical outcomes by the Odom criteria, the great majority of patients rated their outcomes as either excellent or good. This was true across all age groups and levels of the cervical spine that were operated on.

Patient-reported clinical status and outcome surveys are valuable and easy-to-perform tools to evaluate the quality of life of patients suffering from a degenerative cervical disc disease after ACDF with a wedge-shaped carbon cage having a fixed angle of inclination.

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Sažetak

#### ANKETIRANJE BOLESNIKA U PROCJENI KLINIČKOG STATUSA I ISHODA LIJEČENJA NAKON PREDNJE CERVIKALNE DISKEKTOMIJE I FUZIJE ALOGRAFTOM S UNAPRIJED ODREĐENIM KUTOM NAGIBA

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Degenerativna bolest intervertebralnog diska vratne kralježnice može se kirurški liječiti različitim postupcima uključujući prednju cervikalnu diskektomiju i fuziju (ACDF). Ovaj se postupak koristi za stabilizaciju kralježnice i dekompresiju neuralnih struktura spinalnog kanala. Međutim, mjerenje njegovog utjecaja na poslijeoperacijski klinički status i kirurški ishod nije jednostavno. To je razlog zbog čega se anketiranje operiranih bolesnika obično primjenjuje za procjenu ishoda kirurškog liječenja. Kako bismo procijenili kirurške ishode nakon ACDF-a pomoću klinasto oblikovanog umetka s unaprijed određenim kutom nagiba na jednoj razini vratne kralježnice proveli smo prospektivnu studiju na 60 operiranih bolesnika tijekom jedne godine. Koristili smo strukturiranu analizu anketa koje su popunjavali operirani bolesnici na temelju vizualne analogne ljestvice, Oswestry pokazatelja onesposobljenosti i Odom upitnika ishoda liječenja. U većine bolesnika nastalo je značajno smanjenje intenziteta boli u rukama i vratu nakon ACDF-a s klinasto oblikovanim karbonskim umetkom s unaprijed određenim kutom nagiba od 7º. Poboljšanje je bilo jednako zastupljeno u svim dobnim skupinama i razinama operirane vratne kralježnice. U većine bolesnika smanjena je poslijeoperacijska onesposobljenost mjerena Oswstry pokazateljem, neovisno o njihovoj dobi ili razini operirane vratne kralježnice. Većina njih ocijenila je ishode liječenja izvrsnim ili dobrim, što je vrijedilo u svim dobnim skupinama i operiranim razinama vratne kralježnice. U zaključku, klinički status i ishodi liječenja koje su prijavili anketirani bolesnici vrijedni su i jednostavni alati za procjenu kvalitete života bolesnika s degenerativnom bolesti intervertebralnog diska vratne kralježnice nakon kirurškog liječenja pomoću klinasto oblikovanog karbonskog umetka (alografta) s unaprijed određenim kutom nagiba.

Ključne riječi: Degenerativna bolest intervertebralnog diska vratne kralježnice; Prednja cervikalna diskektomija i fuzija; Umetak klinastog oblika s unaprijed određenim kutom nagiba; Ishodi liječenja koje navodi bolesnik