



Kolegium Nauk Medycznych

Uniwersytet Rzeszowski

Adam Kazimierz Bębenek

**„Osiadanie implantów międzytrzonowych w operacyjnym
leczeniu choroby zwyrodnieniowej odcinka szyjnego kręgosłupa
– znaczenie kliniczne oraz radiologiczne czynniki ryzyka”**

Rozprawa doktorska w oparciu o cykl publikacji naukowych
w dziedzinie nauk medycznych i nauk o zdrowiu
w dyscyplinie *nauki medyczne*.

Promotor: Prof. dr hab. n. med. Andrzej Maciejczak

Promotor pomocniczy: dr n. med. Bartosz Godlewski

Rzeszów, 2024 r.

Promotor

Prof. dr hab. n. med. Andrzej Maciejczak

Klinika Neurochirurgii Uniwersytetu Rzeszowskiego
Szpital Wojewódzki im. Św. Łukasza w Tarnowie

Promotor pomocniczy

dr n. med. Bartosz Godlewski

Oddział Kliniczny Ortopedii i Traumatologii Narządu Ruchu
z Pododdziałem Chirurgii Kręgosłupa
Szpital Św. Rafała SCANMED S.A. w Krakowie.

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Rozdział I. – Wykaz publikacji będących podstawą rozprawy doktorskiej:

Niniejsza rozprawa doktorska zatytułowana: „*Osiadanie implantów międzytrzonowych w operacyjnym leczeniu choroby zwyrodnieniowej odcinka szyjnego kręgosłupa – znaczenie kliniczne oraz radiologiczne czynniki ryzyka*” powstała w oparciu o cykl trzech, monotematycznych artykułów naukowych opublikowanych w międzynarodowych czasopismach naukowych, indeksowanych w bazie PubMed oraz znajdujących się na liście „Journal Citation Reports” (Thomson Reuters).

Na dysertację składają się następujące artykuły:

1. **Bębenek A.,** Godlewski B. (2023). “*Anterior cervical discectomy and fusion (ACDF) with and without plating: a comparison of radiological and clinical outcomes*” *Advances in Clinical and Experimental Medicine*: 10.17219/acem/172062. DOI: <https://doi.org/10.17219/acem/172062>., (MEIN: 140 pkt.; IF: 2.1)
2. **Bębenek A.,** Dominiak M, Godlewski B. “*Cervical Sagittal Balance: Impact on Clinical Outcomes and Subsidence in Anterior Cervical Discectomy and Fusion.*” *Biomedicines*. 2023; 11(12):3310. <https://doi.org/10.3390/biomedicines11123310>. (MEIN: 100 pkt.; IF: 4.7)
3. **Bębenek A,** Dominiak M, Karpiński G, Pawełczyk T, Godlewski B. “*Impact of Implant Size and Position on Subsidence Degree after Anterior Cervical Discectomy and Fusion: Radiological and Clinical Analysis.*” *Journal of Clinical Medicine*, 2024; 13(4):1151. <https://doi.org/10.3390/jcm13041151>. (MEIN: 140 pkt.; IF: 3.9)

Łączna wartość *Impact Factor* według *Thomson Reuters Journal Citation Reports*, na rok powstania dysertacji wynosi: 10,700
Łączna wartość punktów *Ministerstwa Nauki i Szkolnictwa Wyższego* na rok 2024 wynosi: 380.0

Rozdział II. - Wprowadzenie:

Choroba zwyrodnieniowa kręgosłupa szyjnego jest powszechnie uznawana za chorobę o charakterze cywilizacyjnym. [1] Biorąc pod uwagę wyniki pochodzące z Europejskiego Ankietowego Badania Zdrowia – EHIS 2019 r., opublikowane przez Główny Urząd Statystyczny w Polsce, bóle krzyża oraz kręgosłupa szyjnego (karku) zajmują kolejno od 2. do 4. miejsca w rankingu najczęściej pojawiających się chorób i dolegliwości u osób dorosłych. Bóle szyi występują już w populacji osób w wieku 15-29 lat z częstością 3,3 na 100 respondentów i częstość ich występowania stopniowo wzrasta o średnio 5,3 punktów procentowych na każde kolejne 10 lat ocenianej populacji. Tak prezentujące się dane statystyczne pokazują konieczność prowadzenia badań w tej materii oraz poprawiania zarówno standardów diagnostyki i leczenia, jak również profilaktyki schorzeń kręgosłupa.

Choroba zwyrodnieniowa odcinka szyjnego kręgosłupa, zwana w literaturze spondylozą szyją jest wynikiem złożonego patomechanizmu, w którego kolejnych etapach biorą udział wszystkie elementy strukturalne odcinka szyjnego kręgosłupa. Podstawą zmian jest degeneracja krążka międzykręgowego z obniżaniem wysokości przestrzeni międzykręgowej. Powoduje to powstanie patologicznego wzorca przenoszenia obciążeń mechanicznych w obrębie zajętego segmentu. To z kolei prowadzi o aktywacji kostnienia i powstania osteofitów. Obrazu choroby dopełnia przerost stawów międzykręgowych i pogrubienie więzadeł żółtych. [2] Powoduje to utratę prawidłowego kształtu kręgosłupa

szyjnego w płaszczyźnie strzałkowej, co wytrąca głowę z jej położenia w rzucie środka ciężkości ciała oraz zaburza widzenie na wprost. Jej utrzymanie w takim położeniu, wymaga pojawienia się mechanizmów kompensujących, w postaci adaptacji krzywizn w pozostałych odcinkach kręgosłupa, co wymaga dużego nakładu energetycznego ze strony mięśni posturalnych. Zjawisko to nazywa się utratą balansu strzałkowego. Pojawiają się także zmiany kształtu połączenia czaszkowo-kręgosłupowego mające na celu utrzymanie widzenia na wprost, co również jest mechanizmem energochłonnym. [3,4] W przypadku większości pacjentów, opisane zmiany są klinicznie nieme. Objawowe przypadki prezentują zazwyczaj cechy radikulopatii takie jak ból o charakterze korzeniowym, osłabienie siły mięśniowej w zakresie mięśni unerwianych przez drażniony korzeń lub zaburzenia czucia odpowiadające dystrybucją dermatomowi drażnionego korzenia. [5] W sytuacji, gdy zmiany chorobowe wywierają nacisk na rdzeń kręgowy, pojawiają się z kolei objawy mielopatii, takie jak drętwienie i niezgrabność w zakresie ruchów rąk, zaburzenia chodu, a także, w późniejszym stadium choroby, zaburzenia oddawania moczu i stolca oraz tetrapareza. [2]

Kluczem do obniżenia współczynnika chorobowości zwyrodnienia kręgosłupa szyjnego jest odpowiednia profilaktyka tego schorzenia. Modyfikacja stanowiska pracy oraz utrzymywanie ergonomicznych wzorców ruchów i postaw są bez wątpienia ważnymi czynnikami prewencyjnymi. [6] W sytuacji wystąpienia choroby wdrożone leczenie może mieć charakter zachowawczy, opierający się na stosowaniu analgetyków doustnych, ćwiczeniach rehabilitacyjnych, terapii manualnej, nadoponowych i

transforaminalnych iniekcjach sterydowych, a także innych formach fizykoterapii. [7,8] Alternatywą, a także w przypadku nieskuteczności continuum terapii, staje się leczenie chirurgiczne.

Złotym standardem w leczeniu operacyjnym choroby zwyrodnieniowej odcinka szyjnego kręgosłupa w Europie Zachodniej i Środkowo-Wschodniej pozostaje przednia szyjna discektomia ze spondylodezą międzytrzonową, określana skrótowo jako ACDF (*ang. Anterior Cervical Discektomy & Fusion*). [9] Zabieg składa się z dwóch zasadniczych etapów: odbarczenia oraz implantacji przeszczepu, w miejsce usuniętego dysku, w celu wytworzenia zrostu sąsiednich trzonów. Podczas odbarczenia elementów nerwowych kanału kręgowego i otworów międzykręgowych operator usuwa z przestrzeni międzykręgowej wszelkie zmiany patologiczne, powodujące ucisk i drażniące korzenie nerwowe lub rdzeń kręgowy. Działanie to ma spowodować ustąpienie objawów choroby: bólu korzeniowego oraz karku, osłabienia kończyn, zaburzeń czucia oraz innych zaburzeń wynikających z obecnej radikulo- lub mielopatii. [10] Z kolei poprzez implantację materiału do odpowiednio przygotowanej przestrzeni międzykręgowej zapewnia się warunki do wytworzenia zrostu kostnego permanentnie wyłączającego z ruchu (stabilizującego) dany segment i zapobiegającego mechanicznym przeciążeniom powodującym dalszy postęp choroby. [11–13]

ACDF jako procedura cechuje się uogólnionym współczynnikiem występowania powikłań oscylującym na poziomie 13,2-19,3 [%]. [14] Ze względu na ich charakter można je podzielić

na związane z procedurą odbarczenia struktur nerwowych w kanale kręgowym oraz z procesem tworzenia się zrostu kostnego pomiędzy zespolonymi trzonami kręgow. [15] Do najważniejszych powikłań związanych z procedurą operacyjną odbarczenia kanału kręgowego zaliczamy: pooperacyjną dysfagię (1,7 - 9,5 [%]), nasilenie przedoperacyjnej mielopatii (3,3%), nasilenie objawów radikulopatii (1,3%), krwiak w ranie pooperacyjnej (1,3 - 5,6 [%]), zakażenie rany pooperacyjnej (0,1 - 1,6 [%]) oraz perforację przełyku (0,3 - 0,9 [%]). [14] Wymienione stany kliniczne obserwowane są najczęściej w trakcie lub bezpośrednio po zabiegu operacyjnym. Druga grupa powikłań ma bardziej przewlekły charakter, gdyż powstawanie zrostu kostnego, a tym samym obserwacja związanych z tym powikłań, ma miejsce po 6 - 12 miesiącach od operacji. Do tej kategorii zalicza się pseudoartroza (2,3%) rozumiana jako częściowy lub całkowity brak zrostu zapewniający stabilność zespolonych trzonów, dysfunkcja elementów instrumentarium (0,9%), choroba sąsiedniego poziomu (2,7%) oraz zagłębienie się implantu w sąsiednie trzony - osiadanie (21%), które ze względu na swoją wysoką częstość występowania (zakres od 0-83%), nieujednoliconą definicję oraz kwestionowane znaczenie kliniczne, bywa nieuznawane za powikłanie ACDF i określane mianem fenomenu. [11,14,16,17]

Niniejsza dysertacja poświęcona jest właśnie zjawisku osiadania, *ang. subsidence*, które ze względów wspomnianych powyżej wymaga podejmowania dalszych badań na rzecz wyjaśnienia jego dokładnego charakteru.

Osiadanie jest pojęciem definiowanym przez badających je autorów na wiele sposobów. Choć ogólna idea zjawiska, polegająca na zagłębieniu się implantu międzytrzonowego w operwowany segment wydaje się intuicyjna, to jednak techniczna definicja pozwalająca na jednoznaczne rozpoznanie i pomiar zaawansowania wciąż nie została ujednoczona. W przeglądzie systematycznym pochodzącym z 2014 r. Isaac O. Karikari et al. przedstawili zestawienie w którym zawarli informację o tym, jak poszczególni autorzy, zajmujący się tym zagadnieniem rozumieli pojęcie osiadania. [18] Niektórzy definiują osiadanie jako obniżenie wysokości segmentu ruchowego kręgosłupa, czyli odległości między centralnym punktem górnej blaszki granicznej kręgu położonego wyżej, a centralnym punktem dolnej blaszki granicznej kręgu położonego poniżej. Inni z kolei uważają, że o osiadaniu mówimy wówczas, jeśli dojedzie do obniżenia wysokości przestrzeni międzykręgowej. Jeszcze inni twierdzą, iż zjawisko to występuje wtedy, gdy można zaobserwować zagłębienie się implantu w zainstrumentowany trzon. [16,18] Uściślenia wymaga nie tylko sama definicja, ale również punkt odcięcia po którym uznajemy obecność osiadania. W literaturze posługiwano się bowiem wartościami bezwzględnymi, wyrażonymi w milimetrach, jak i względnymi, wyrażonymi w postaci współczynnika. W odniesieniu do bezwzględnych wartości liczbowych najczęściej znajdujemy informację o progach w postaci 2, 3 lub 4 [mm], choć są i tacy, którzy stwierdzają obecność osiadania na podstawie dowolnej wartości większej od zera. [18–21] W przypadku wartości względnych najczęściej spotykamy ilorazy zmiany danej wartości parametru

(najczęściej wysokości przestrzeni międzykręgowej) w dniu obserwacji w stosunku do wartości wyjściowej, definiowanej najczęściej jako wartość parametru na dzień po wszczepieniu implantu. Spotykanymi punktami odcięcia dla występowania osiadania są wówczas wartości takiego współczynnika sięgające 10, 20 lub 30 [%]. [18,22,23] Dotychczas nie ustandaryzowano ani sposobu pomiaru osiadania czy wartości punktu odcięcia, ani nie stworzono klasyfikacji jego zaawansowania.

Zjawisko osiadania cechuje również niejednoznaczność kliniczna. Pod względem wpływu na efekt terapeutyczny leczenia operacyjnego, wyrażonego w najbardziej rozpowszechnionych skalach VAS (Visual Analogue Scale) oraz NDI (Neck Disability Index) oceniających odpowiednio nasilenie bólu oraz stopień niepełnosprawności spowodowany chorobą, wyniki badań naukowych pozostają rozbieżne. [16,24–26] W swoich pracach Kast et al., Lee et al. oraz Kim et al. podają istnienie zależności między występowaniem osiadania, a gorszym wynikiem leczenia. [27–29] Równie liczne są jednak doniesienia o braku takiego związku. [16,30,31] Podłoże tej rozbieżności może mieć charakter wieloczynnikowy. Wpływ na to mogą mieć rozumiane w różny sposób definicje osiadania oraz wybrane wartości punktów odcięcia dla rozpoznania osiadania.

Czynniki ryzyka odpowiedzialne za występowanie tego zjawiska również nie są jednoznacznie określone. W literaturze znajdujemy badania naukowe, które można zaszeregować do jednej z dwóch zasadniczych grup na podstawie kierunku poszukiwań

czynników ryzyka. Pierwsze z nich związane są z czynnikami ogólnoustrojowymi. Zaliczamy do tej grupy choroby metaboliczne, wiek, płeć oraz gęstość kośćca. Pozaustrojowym czynnikiem, wykazującym się istotnością statystyczną w zakresie podwyższonego ryzyka opóźnionego zrostu lub braku zrostu, jednak nie osiadania, okazał się być nikotynizm. [5,32] Starszy wiek co do zasady zwiększa ryzyko osiadania, podobnie jak płeć żeńska, jednak dane te wiązać można ze spadkiem gęstości kości w grupie kobiet po menopauzie i osób starszych. Przegląd systematyczny opublikowany przez Dhar et al. w 2023 r. udowadnia jednak, że nie istnieje istotnie statystyczna zależność między wiekiem, a występowaniem zjawiska osiadania. [33] Z kolei w kwestii gęstości kości zależność taka została wykazana dla przedoperacyjnej gęstości zespalanych trzonów kręgów wyrażonych w jednostkach Hounsfielda. [34] Drugą grupą czynników są te związane z implantem, jego położeniem anatomicznym w segmencie, rozmiarem czy materiałem z jakiego został wykonany oraz tym czy dla dodatkowego wzmocnienia zastosowano konstrukcję z płytki szyjnej oraz śrub. Umownie określa się je mianem radiologicznych czynników ryzyka, ze względu na ocenę ich występowania z wykorzystaniem zdjęć RTG odcinka szyjnego kręgosłupa. [16,33] Wiadomo, że lokalizacja i rozmiar implantu mogą wpływać na zjawisko osiadania – implanty umieszczone bliżej przedniej lub tylnej korówki trzonu zapadają się rzadziej, jak również implanty o polu powierzchni lepiej dopasowanym do pola blaszki granicznej instrumentowanego segmentu cechują się niższym ryzykiem osiadania. [33,35,36] Podobnie w przypadku materiału z którego wykonano implant.

Historycznie, wszczepianym materiałem były, wykorzystywane już w 1955 r. przez R.A. Robinsona i G.W. Smitha, podkowiaste przeszczepy kostne. Zastąpione następnie przez trójkorówkowe przeszczepy kostne pochodzące z talerza kości biodrowej. [16] Aktualnie do najczęściej używanych materiałów należy PEEK (polyether-ether-ketone) oraz stopy tytanu. Wiadomo, że PEEK jest materiałem cechującym się najmniejszym współczynnikiem osiadania [33] Rozbieżne wyniki dotyczą również wpływu doboru wysokości implantu. Nie ustalono jednoznacznie, czy za duże lub za małe implanty wpływają na częstotliwość osiadania. [16] We wspomnianym wcześniej przeglądzie systematycznym autorstwa Dhar et al. wykazano, że dodatkowa instrumentacja w postaci konstrukcji z użyciem płytki szyjnej i śrub zmniejsza ryzyko osiadania. [33]

Rozdział III. – Cele i założenia rozprawy doktorskiej:

Głównymi celami niniejszej pracy doktorskiej była ocena radiologicznych czynników ryzyka osiadania i ich wpływu na efekt kliniczny zabiegu.

W pierwszej pracy wchodzącej w skład cyklu publikacji dokonano syntezy dotychczasowej wiedzy na temat wpływu stabilizacji operowanego segmentu płytką na zjawisko osiadania.

W drugiej publikacji celem było zbadanie czy przedoperacyjne parametry balansu strzałkowego w odcinku szyjnym, mogą mieć wpływ na częstość osiadania oraz efekt kliniczny zabiegu. Dotychczasowa literatura jest w tej materii niezmiernie uboga. Według najlepszej wiedzy autora, w chwili powstawania drugiej publikacji istniała tylko jedna praca autorstwa Lee et al. traktująca na temat relacji parametrów szyjnego balansu strzałkowego do zjawiska osiadania. [37]

Trzecia publikacja wchodząca w skład cyklu traktuje o czynnikach ryzyka osiadania związanych z rozmiarem oraz położeniem implantu w przestrzeni międzykręgowej. Choć doniesienia na ten temat wydają się liczne, to większość autorów badała te zmiany w oparciu o wartości bezwzględne, a nie współczynniki konkretnych parametrów. W efekcie takie postępowanie mogło być nieoptymalne pod względem dostosowania do zmienności osobniczej pacjentów. [16] Dodatkowo rzeczony artykuł traktuje o zależności między głębokością osiadania, a efektem klinicznym operacji, co również nie zostało szeroko zbadane w literaturze. [38]

Rozdział IV. – Materiały i metody:

W ramach złożonego projektu badawczego realizowanego w Oddziale Klinicznym Ortopedii i Traumatologii Narządu Ruchu z Pododdziałem Chirurgii Kręgosłupa Szpitala Św. Rafała w Krakowie, zatwierdzonego przez Komisję Bioetyczną Krakowskiej Akademii im. Andrzeja Frycza Modrzewskiego (uchwała nr 8/2019), przeprowadzono jednoośrodkowe badanie obserwacyjne w ramach którego oceniono 193 pacjentów operowanych w latach 2019-2021 w Pododdziale Chirurgii Kręgosłupa z powodu choroby zwyrodnieniowej odcinka szyjnego kręgosłupa, potwierdzonej w przedoperacyjnym badaniu rezonansu magnetycznego odcinka szyjnego kręgosłupa oraz niereagującej na leczenie zachowawcze. Zakwalifikowano 104 osoby, jednak w zależności od zamierzonego protokołu badania, pełnej oceny dokonano odpowiednio u 94 i 95 osób. Wszyscy pacjenci zostali poddani zabiegowi przedniej discektomii szyjnej ze spondylodezą międzytrzonową (ACDF). Wszyscy operowani byli techniką Robinson-Smith z odbarczeniem struktur kanału kręgowego i implantacją cage'a międzytrzonowego metodą „stand-alone” (bez wzmocnienia konstrukcją płytowo-śrubową). Radiologicznych pomiarów dokonano poprzez wykonanie zdjęć RTG odcinka szyjnego kręgosłupa AP, bocznych oraz zdjęć czynnościowych w następujących punktach czasowych: dzień przed operacją, dzień po operacji, miesiąc, 6 miesięcy oraz 12 miesięcy po zabiegu. Dodatkowo obecność wydolnego zrostu kostnego została powtórnie sprawdzona w przeprowadzonym badaniu tomografii komputerowej odcinka szyjnego kręgosłupa w dniu, gdy wykonywano kontrolne zdjęcie RTG po 12 miesiącach.

Oceny efektu klinicznego dokonywano w punktach czasowych tożsamych z punktami czasowymi kontroli radiologicznej z użyciem wystandaryzowanych i zwalidowanych narzędzi – do oceny bólu, skali Visual Analogue Scale (VAS) oraz do oceny stopnia niepełnosprawności spowodowanego chorobą, skali Neck Disability Index (NDI).

Analiza statystyczna przeprowadzona została w oparciu o oprogramowanie MedCalc® Statistical Software 20.104 oraz TIBCO Statistica® 13.3. Doboru wykonywanych testów statystycznych dokonywano stosownie do charakteru ocenianych zmiennych losowych.

W odpowiednich sekcjach dotyczących materiałów i metod poszczególnych publikacji wchodzących w skład niniejszej dysertacji wyszczególniono oceniane parametry radiologiczne, wybrane punkty odcięcia wartości tychże parametrów oraz parametrów klinicznych, a także pozostałe odrębności pomiędzy protokołami poszczególnych badań składowych.

Rozdział V. – Treść publikacji wchodzących w skład rozprawy doktorskiej:

Reviews

AHEAD OF PRINT 

Anterior cervical discectomy and fusion (ACDF) with and without plating: A comparison of radiological and clinical outcomes

*Adam Bębenek^{A-F}, *Bartosz Godlewski^{A-F}

Department of Orthopaedics and Traumatology, with Spinal Surgery Ward. Scanmed – St. Raphael Hospital, Cracow, Poland

A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of the article

Advances in Clinical and Experimental Medicine, ISSN 1899-5276 (print), ISSN 2451-2680 (online)

Adv Clin Exp Med. 2024

Abstract

Treatment for degenerative disc disease of the cervical spine primarily aims to decompress neural structures and preserve the former height of the disc space and foramina. Popular methods include anterior cervical discectomy and fusion (ACDF) using cages with plates or without plates (standalone cages). However, it is still debatable whether a plate is necessary for enhanced treatment outcomes. This paper reviews current literature reports, adding insights from the authors' experience. A literature search was performed with keywords related to ACDF with or without cervical plating. We analyzed the titles and abstracts to identify all potentially relevant studies. Out of these, a total of 28 original research and 5 systematic reviews/meta-analyses met our inclusion criteria. The success of surgery for cervical disc disease depends fundamentally on the appropriate decompression of neural structures. This is the main determinant of postoperative clinical improvement measured according to scales capturing changes in pain intensity and quality of life. An ideal replacement for natural components of the human body does not exist, even though more and more refined solutions are developed every year. A comparison of treatment outcomes using non-plated (standalone) cages and cage + plate systems requires separate analysis of radiological and clinical outcomes. Both methods have their advantages and disadvantages. Radiological outcomes are slightly better with cage + plate systems, and clinical outcomes are comparable.

Key words: anterior cervical discectomy and fusion, standalone cervical cages, cervical plates, self-anchoring cervical cages, ACDF outcomes

Address for correspondence

Bartosz Godlewski

E-mail: bartoszegodlewski@wp.pl

Funding sources

None declared

Conflict of interest

None declared

* Both authors contributed equally to this work.

Received on June 16, 2023

Reviewed on August 23, 2023

Accepted on September 8, 2023

Published online on September 28, 2023

Cite as

Bębenek A, Godlewski B. Anterior cervical discectomy and fusion (ACDF) with and without plating: A comparison of radiological and clinical outcomes [published online as ahead of print on September 28, 2023]. *Adv Clin Exp Med*. 2024. doi:10.17219/acem/172062

DOI

10.17219/acem/172062

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Introduction

The cervical segment of the spinal column is a complex anatomical and biomechanical structure. It exhibits the highest degree of mobility among all spinal segments, making it a pivotal component in the preservation of overall sagittal balance and functional integrity. The curvature of the cervical segment is shaped by a range of factors, such as muscle tone distribution in the neck and the shoulder girdle or the shape of the thoracic and lumbosacral segments. The curvatures of individual spinal segments influence each other. Regrettably, similar to other spine regions, the cervical segment is susceptible to degenerative alterations that may necessitate surgical intervention. The primary aim of the treatment for degenerative disc disease of the cervical spine is to decompress neural structures and preserve the former height of the disc space and foramina. Anterior cervical discectomy without the simultaneous insertion of a graft or cage is not recommended because there is a possibility of future instability and kyphotic malalignment of the cervical spine.¹ Anterior cervical discectomy and fusion (ACDF) is currently the gold standard for surgical treatment of degenerative disc disease of the cervical spine. An interbody implant should have a size that produces a tight interference fit and maximizes the dimensions of the graft–vertebral body interface. Popular methods include an ACDF using a standalone cage or a cage with a cervical plate. However, it is still debatable whether a plate is necessary for enhanced treatment outcomes. Both methods have their advantages and disadvantages. Most surgeons believe that plating is not necessary for single-level surgery, but operations on multiple levels require additional strengthening of the fixation obtained using a cervical plate. This paper reviews current literature reports, with insight added from the authors' experience. Anterior cervical plates may increase interbody fusion rates and stability, maintain or improve cervical sagittal alignment, and prevent subsidence, particularly in multiple-level ACDFs. However, anterior plating may also be associated with potential disadvantages and complications. The complications associated with plate fixation consist of esophageal soft tissue damage, neurovascular injuries and dysphagia. The success of surgery for cervical disc disease depends fundamentally on the appropriate decompression of neural structures. This is the main determinant of postoperative clinical improvement measured using scales which show changes in pain intensity and quality of life.

Objectives

The aim of this study was to compare the clinical and radiological outcomes of ACDF with a standalone cage to ACDF performed with a cage with a cervical plate.

Materials and methods

This paper reviews current literature reports and also offers insight from the authors' experience. Relevant published studies indexed in MEDLINE were first identified using PubMed and then reviewed by the authors. A literature search was performed with keywords related to ACDF with or without cervical plating, such as "anterior cervical discectomy and fusion", "standalone cages", "cervical plates", "self-anchored cervical cages", "zero-profile cervical cages", "cervical alignment", "subsidence", "fusion rate", and "ACDF outcomes". We studied the titles and abstracts of identified articles and full texts of all potentially meaningful academic papers. Out of these, 28 original research articles and 5 systematic reviews/meta-analyses met our inclusion criteria necessary to compare the radiological and clinical outcomes of surgery for cervical disc disease using standalone cages or cages with cervical plates. Then, we supplemented the analyzed literature with other original contributions, review articles and case reports that do not directly compare ACDF with standalone cages and ACDF with cage + plate, but do describe important aspects of surgery for cervical disc disease such as subsidence, adjacent segment disease (ASD), cervical alignment, types of interbody implants and cervical plates, materials that implants are made of, and complications after ACDF. In our experience, original reports contain more practical advice and information, while meta-analyses/systematic reviews are more mathematical/statistical in nature, analyzing large numbers of cases. Radiological outcome refers to parameters such as fusion rate, IDH, subsidence, and cervical alignment, assessed based on postoperative imaging. Clinical outcome refers to the changes in parameters assessing the quality of life and pain. When comparing the radiological and clinical results of ACDF with stand-alone cages compared to cage + cervical plating, the type of implant and the technique of implant fixation in the interbody space should also be considered. The recently popular zero-profile implants consisting of a cage fixated to the adjacent vertebral bodies with screws introduced through the implant are usually included in the same group as typical standalone cages, which are placed in the interbody space without using additional fixation. There are, undoubtedly, differences between these 2 types of implants that affect their biomechanics. Nevertheless, to ensure a common methodology and a

large number of studies needed to compare treatment outcomes, authors often do not draw finer distinctions concerning the type of interbody implant, the material used to produce the implant, the implant's surface area, the presence or absence of spikes/serration for anchoring in the interbody space, or the presence or absence of a dedicated space to be filled, for example, with fusion-promoting hydroxyapatite. To make a more systematic comparison of individual groups, we grouped reports concerning typical standalone cages and zero-profile cages, also known as self-anchoring or self-locking cages.^{2,3} Similarly, most studies comparing ACDF procedures with standalone cages or cages + plates did not distinguish between the distinct types of plates, i.e., wide plates fixed to each vertebral body with 2 screws or narrower plates fixed to each vertebral body with 1 screw. The most significant difference between traditional cage and plate structures and the zero-profile implant is that the zero-profile implant uses no additional plate fixed to the anterior surface of the vertebral body.

Results

The ACDF is a commonly used and successful surgical treatment for patients with cervical disc disease. Neural decompression should be combined with interbody stabilization or additional placement of a cervical plate. The neurosurgeon and orthopedist communities have not yet developed an unequivocal position on the necessity of cervical plating with ACDF procedures. It has been questioned whether plate fixation is necessary, especially in single-level fusion, irrespectively of its disadvantages. Most surgeons believe that plating is not necessary for single-level surgery, but operations on multiple levels require additional strengthening of the fixation obtained using a cervical plate. This is not done to prevent spinal instability but to strengthen the cage, expedite fusion and preserve the postoperative height of the disc space near physiological cervical alignment.⁴⁻⁷ At the same time, awareness of the postoperative complications believed to be related to the presence of an anterior plate has been contributing to a rising interest in non-plated techniques such as standalone cages. It has been shown that the design of zero-profile implants provides a similar degree of biomechanical stability conferred by anterior plating, simultaneously avoiding increased retraction and anterior bulk connected with plating.

Cervical cages and plates

At present, the most commonly used interbody cages in cervical spine procedures comprise of polyetherether-ketone (PEEK) implants, titanium-

coated PEEK cages and titanium implants. Apart from the type of material, the implants are made of, their shape and surface morphology also play an essential role in obtaining fusion.⁸ Implant surface morphology can be two-dimensional (2D) or three-dimensional (3D). Most 2D surfaces have irregularities emulating indentations produced by the action of osteoclasts. These indentations generally serve to promote a beneficial response of bone tissue to such morphology.^{9,10} For better anchoring in the interbody space, implant manufacturers offer implants with corrugated surfaces and additional protruding titanium spikes placed (immersed) in upper and lower implant surfaces. Furthermore, the so-called hybrid implants are also available, comprising an interbody cage connected to a plate (cage and plate as one device). In contrast to 2D implants, the porous surfaces of 3D implants are characterized by an interconnected porous spatial network to enhance bone integration and produce mechanical locking (entanglement) of bone and implant surfaces.^{11–13} Unlike traditional titanium implants, more recent 3D titanium implants build with porous surfaces produced with laser 3D print technologies are not a source of significant artifacts in postoperative magnetic resonance imaging (MRI) assessment, thus allowing for a detailed postoperative evaluation of the anatomical structures of the cervical spine. The PEEK implants with a porous surface manufactured with 3D technology are relatively new on the market. Laboratory studies have demonstrated that porous PEEK increases osteoblastic differentiation of cells in vitro and improves osseointegration in vivo compared to both smooth and titanium-coated PEEK. These results have been ascribed to improved mechanical bone locking by the implant's porous spatial surface.⁸ A wide variety of plating systems are available. The placement of early devices was associated with piercing the posterior cortex of the vertebral body (bicortical fixation). Contemporary cervical plating systems are designed for unicortical placement to avoid posterior bicortical penetration of the cervical vertebra so that neural structures are not injured. New third-generation systems represent dynamic semi-constrained plates designed to prevent stress shielding. Ideally, plates should be available in narrow and wider varieties and they should provide for small increments in plate length. Screws should ideally be marketed in variable lengths and offer variable placement angulation capability, there should be rescue screws matching the corresponding standard screw in length, and the screws should be easy to place with a reliable locking mechanism.^{14–15}

Dysphagia

While the most common complication of ACDF is dysphagia, its mechanism is not fully elucidated, with hypotheses including damage to the esophagus, soft tissue edema, hematoma, and adhesions/scarring around the plate.¹⁶ Most

papers indicate a statistically lower rate of dysphagia following non-plated ACDF, with 1 report even showing a link (positive correlation) between cervical plate thickness and dysphagia.¹⁷ Additionally, another study found improvement in the symptoms of dysphagia following the removal of a cervical plate and release of plating-induced adhesions. It reported on a series of 31 patients who had their anterior plates surgically removed due to persistent dysphagia following ACDF. There were extensive adhesions around the periphery of the cervical plate that attached the esophagus to the prevertebral fascia and anterior cervical spine. Surgery brought about a significant improvement to mild or no dysphagia in 27 patients.¹⁸ A few high-quality systematic reviews and meta-analyses have confirmed that standalone cages are superior to cage + plate systems in reducing the risk of dysphagia.^{19–22} The duration of dysphagia symptoms was also longer with plated compared to non-plated cages.²³ In multiple-level procedures, cervical plating requires more extensive surgical access and is associated with more soft tissue injury that may affect clinical status. Another important aspect of cervical plating surgery is the possibility of complications such as loosening or breakage of the screws stabilizing the plate, or plate dislocation. Of further importance is the fact that the use of cervical plates increases the cost of the procedure.^{24–28} If a revision procedure is necessary for a patient with a standalone cage, there is obviously no need to remove a previously placed plate, and so the duration of the surgery may be shorter with less blood loss, less retraction of the surrounding tissues, and a reduced risk of postoperative dysphagia.

Adjacent segment disease (ASD)

A significant aspect of surgery for cervical disc disease is the risk of ASD. Biomechanically, the abolition of mobility within a disc space should lead to the adjacent motion segments below and above the operated segment partly taking over the mobility of the non-mobile segment. Adjacent segment disease is the product of several factors – an accumulated result of natural degeneration and biomechanical changes following fusion within the original motion segment operated on, such as ROM changes of the adjacent segments, changes in the sagittal profile of the spine, and increased intradiscal pressures in the adjacent discs.²⁹ Symptomatic ASD is the most common underlying cause of revision surgery following ACDF, in up to as many as 47% of patients.³⁰ The possibility of symptomatic ASD occurrence is higher after single-level fusion than multilevel one, especially if the non-fused segments belong to levels C4–C6. Artificial disc replacement has gained increasing enthusiasm as a motion-sparing alternative to fusion. Nevertheless, despite conducting multiple clinical trials and follow-up studies, the reduction of ASD has not been evidenced when artificial disc replacements are performed instead of fusion. Most of the available published reports indicate a lower risk

of ASD with standalonedisc cages than following cage + plate procedures.^{16,19,21–23,31–37}

Subsidence and intervertebraldisc height (IDH)

Implant subsidence after ACDF is a widely known, undesirable effect that should be prevented. Reduced disc space height may lead to foraminal stenosis. A review of implant subsidence data in the available literature reveals the superiority of cage + plate procedures over the placement of standalone cages regarding the prevention of this undesirable phenomenon. Subsidence can be reduced if the mechanical properties of vertebral endplates are retained to the greatest extent possible during the surgery. From a pathophysiological angle, some of the endplates need to be removed so that bone union can occur, but injury to endplates facilitates subsequent sinking of the cage into the vertebral bodies. Cage subsidence occurs more often when endplates are removed. Implant subsidence has been defined in several ways. Two definitions see it as the immersion length of the cage (in millimeters) beyond the borders of the adjacent endplates or as the percentage reduction in interbody space height. The decreased interbody space height may produce foraminal stenosis. The risk of cage subsidence is higher in the presence of a smaller anteroposterior cage diameter, more posterior placement of the cage in relation to the vertebral body, and a smaller cage surface area resulting in endplate coverage.³⁸ There is a significant relationship between subsidence and a coefficient representing the ratio of the implant surface area to the surface area of bone of the adjacent vertebral bodies: Subsidence is significantly less frequent for coefficient values ≥ 0.37 .³⁹ Cage subsidence may adversely affect spinal biomechanics and alignment, be the cause of segmental kyphosis and contribute to ASD. Additional anterior plate fixation is recommended when endplates are removed.⁴⁰

Cervical alignment

The normal lordotic alignment of the cervical spine is crucial for ensuring good motion and function of the cervical spine. Alignment in the sagittal plane is important for the distribution of stress across fixation devices. Loss of cervical lordosis theoretically increases the risk of ASD as a kyphotic alignment of the cervical segment accelerates degenerative changes in that segment by augmenting biomechanical stress on the anterior portion of the vertebral bodies of adjacent segments.⁴¹ The most marked alterations in lordosis and intervertebral space height are seen immediately after surgery, with baseline values subsequently usually

decreasing gradually over time, but postoperative values at 12 or 24 months are still better than baseline. The curvature of the cervical segment is shaped by a range of factors, such as muscle tone distribution in the neck and the shoulder girdle or the shape of the thoracic and lumbosacral segments. The curvatures of individual spinal segments influence each other. Cervical spine surgery introduces slight modifications to the pre-surgical anatomic relations. Efforts are always made to restore the near-anatomical relationships; however, it is important to note that complete restoration of physiological cervical alignment cannot be guaranteed, and the anatomical changes visible in immediate postoperative radiographs may not be permanent. The preservation of better parameters of cervical alignment following cage + plate procedures is particularly visible after multiple-level surgery, while following single-level surgery, differences between the groups are less evident, or, in some reports, no significant differences are noted.^{20,22,23,42-44} Appropriate rehabilitation appears quite important for maintaining normal spinal curvatures. A meta-analysis by Cheung et al. indicates that cage + plate procedures are associated with better postoperative radiographic appearances, with near-normal values of indices of cervical lordosis and disc space height and lower rates of implant subsidence.⁴⁵ Another meta-analysis/systematic review by Liu et al. provided slightly diverging data regarding disc space height as it failed to find a statistically significant difference in disc space height between preoperative, immediate postoperative and last-follow-up radiographs in patients with non-plated (standalone) compared to plated cages. At the same time, the authors confirmed better preservation of cervical alignment following cage + plate procedures.²³

Fusion rate

Regarding the possibility of obtaining better fusion, results vary, but most reports indicate the superiority of cage + plate procedures over the implantation of standalone cages, with fusion occurring earlier following cage + plate surgery than after standalone cage implantation.⁴⁶⁻⁴⁸ Contrarily, Nabhan et al. in their radiographic analysis of fusion progression following plated compared to non-plated single-level cervical fusion did not reveal any statistical differences between both groups. Three-dimensional analysis of segmental motion (left-right, craniocaudal and posterior-anterior) failed to reveal statistical differences at any postoperative follow-up visits. The results obtained using visual analogue scale (VAS) were also not different between the groups.²⁴ A biomechanical study of cadavers subjected to 2-level ACDF with either a standalone cage or cage + plate performed by Nayak et al. concluded that a standalone cage confers comparable rigidity/stability to cage + plate.⁴⁹ Scholz et al. demonstrated no differences in flexion/extension,

lateral bending or axial rotation between the standalone cage and cage + plate groups.⁵⁰ The most significant difference when comparing the zero-profile and traditional cage and plate structures is that the zero-profile implant has no additional plate attached to the anterior aspect of the vertebral body. Connecting the anterior plate to adjacent vertebrae with straight locking screws provides a strong anterior tension band and very rigid fixation, whereas only intersegmental fixation is obtained using the zero-profile device. We know from biomechanical studies that the self-locking standalone cage provides less cervical spine stiffness than the locking plate in 2- or 3-level instrumentation.^{51,52} Gandhi et al. studied, among others, the degree of fusion in cases when surgery was necessary on account of ASD. Their analysis of such procedures did not detect a substantial difference in fusion at the site of previous surgery between patients bearing standalone cages compared to cage + plate systems.² An optimal radiographic outcome following ACDF is defined as complete fusion without implant subsidence. However, even with implant subsidence, it is still possible for complete fusion at the implant site to occur later. Even if, initially, there is a disruption of endplate continuity and penetration of the implant towards an adjacent vertebral body, it is still possible for complete fusion to occur around the implant. The use of computed tomography (CT) is a reliable, modern approach to evaluating fusion status. The plate curve reduces the likelihood of loss of global cervical lordosis and the fusion segment angle, while also preventing cage subsidence during the fusion process.⁵³

Clinical outcomes

Divergent data are provided in the literature regarding fusion, implant subsidence and cervical alignment, and their direct impact on the patient's clinical status. The success of surgery for cervical disc disease depends mostly on the appropriate decompression of neural structures. This is the main determinant of postoperative clinical improvement measured according to scales capturing changes in pain intensity and quality of life. Subsidence and disruption of the physiological spinal curvatures may contribute to ASD and pain. Some state that complete fusion (arthrodesis) improves the clinical outcome, while others claim that fusion does not correlate with clinical outcomes.⁵⁴⁻⁵⁷ Karikari et al. reported that the finding of implant subsidence was not directly related to the patient's clinical status or symptoms in most cases.⁵⁷ The changes in cervical spine alignment and disc space height are not reflected directly in the quality of life or pain intensity. Surgical outcomes are primarily related to adequate decompression of the spinal cord and nerve roots. The focus for the operating surgeon should be on adequate decompression of neural structures and necessary stabilization, while restoration of ideal physiological cervical alignment should not be attempted as the latter does not contribute decisively or directly to

treatment outcomes. Still, it should be borne in mind that when cervical lordosis is restored or maintained, this may reduce the future likelihood of ASD.^{58–60}

Key differences between standalone cage compared to cage + plate procedures

Based on the analyzed literature and our own experience of many years in surgery for cervical disc disease, we summarized the most significant differences between standalone cage and cage + plate procedures, and presented the analyzed information in Table 1.

Limitations

Including standalone cages and zero-profile cages, also known as self-anchoring or self-locking cages, in one group, despite some differences between them, is not an ideal solution, but it was done intentionally to systematize comparable treatment methods.

Table 1. Summary of key differences between standalone cage compared to cage + plate procedures

Criterion	Standalone cage	Cage + plate
Fusion	inferior fusion indices	superior fusion indices
	longer time to fusion	shorter time to fusion
Intervertebral disc height	inferior preservation of disc space height achieved	superior preservation of disc space height achieved
Subsidence	greater risk	lower risk
Cervical alignment (multiple-level surgery)	inferior cervical alignment indices	superior cervical alignment indices
cervical alignment (single-level surgery)	similar cervical alignment indices	similar cervical alignment indices
Dysphagia	lower rates of dysphagia	higher rates of dysphagia
	shorter time to resolution of dysphagia	longer time to resolution of dysphagia
Adjacent segment disease	lower risk	higher risk
Surgery duration	shorter	longer
Cost of surgery	lower	higher
Technical difficulty of revision/repeat surgery	less	more
Clinical outcomes (pain, quality of life)	comparable	comparable

Conclusions

An ideal replacement for natural components of the human body does not exist, even though increasingly more refined solutions appear every year. A comparison of the outcomes of standalone cage and cage + plate procedures should separately analyze radiological and clinical outcomes. Both methods have their advantages and disadvantages. Overall, radiological outcomes are

slightly better following cage + plate procedures, while clinical outcomes are comparable.

ORCID iDs

Adam Bębenek <https://orcid.org/0000-0002-6687-1517>

Bartosz Godlewski <https://orcid.org/0000-0003-0673-1480>

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Cervical Sagittal Balance: Impact on Clinical Outcomes and Subsidence in Anterior Cervical Discectomy and Fusion

Adam Bębenek , Maciej Dominiak  and Bartosz Godlewski * 

Department of Orthopaedics and Traumatology, with Spinal Surgery Ward, Scanned—St. Raphael Hospital, 30-693 Cracow, Poland; bebenek.adam.24@gmail.com (A.B.); maciej.dominiak92@gmail.com (M.D.)

* Correspondence: bartoszgodlewski@wp.pl



Citation: Bębenek, A.; Dominiak, M.; Godlewski, B. Cervical Sagittal Balance: Impact on Clinical Outcomes and Subsidence in Anterior Cervical Discectomy and Fusion. *Biomedicines* **2023**, *11*, 3310. <https://doi.org/10.3390/biomedicines11123310>

Academic Editors: Elisa Belluzzi and Assunta Pozzuoli

Received: 29 November 2023

Revised: 11 December 2023

Accepted: 12 December 2023

Published: 14 December 2023



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Abstract: Degenerative disease of the cervical spine leads to sagittal imbalance, which may affect treatment results. The purpose of this study was to evaluate changes in selected cervical sagittal balance parameters and their effects on subsidence and clinical outcomes of the procedure. This study encompassed a total of 95 evaluated patients who underwent anterior cervical discectomy and fusion (ACDF). Selected cervical sagittal balance parameters were assessed using lateral projection X-rays: C2–C7 spinal vertical axis (C2–C7 SVA), spinocranial angle (SCA), C7 slope, C2–C7 lordosis, and the segmental Cobb angle. Measurements were collected the day before, the day after, and 12 months after surgery. Changes in clinical parameters was assessed using the VAS and NDI scales. Subsidence was defined as a loss of intervertebral height of more than 30% of the baseline value. Among all the assessed parameters, only the C2–C7 SVA demonstrated a statistically significant difference between the groups with and without subsidence: 26.03 vs. 21.79 [mm], with $p = 0.0182$, preoperatively and 27.80 vs. 24.94 [mm], with $p = 0.0449$, on the day after surgery, respectively. We conclude that higher preoperative and postoperative C2–C7 SVA values might contribute to an elevated risk of implant subsidence. Furthermore, both the SCA and C7 slope could conceivably influence the clinical outcome, respectively impacting pain, as assessed by the VAS and the disability, as evaluated through the NDI scale.

Keywords: ACDF; subsidence; sagittal balance

1. Introduction

Degenerative spinal disease not only leads to symptoms related to nerve structure irritation within the spinal canal and intervertebral foramina, but also contributes to the restricted mobility of specific spinal segments [1]. This compromised mobility results in the inability to effectively counterbalance the abnormal positioning of the body's center of gravity. Consequently, the deviation of the body's center of gravity from its usual axis prompts compensatory postural adjustments to restore the disrupted sagittal balance [1,2]. Nevertheless, this process operates within a detrimental cycle. Triggered by compensatory adjustments, peripheral joints become susceptible to accelerated degeneration. This, in turn, curtails their mobility, thus leading to the transmission of excess strain to the spine. Consequently, this exacerbates the advancement of spinal degeneration and amplifies the existing imbalance [1–3]. The described phenomena inevitably manifest in the cervical spine, which, due to its heightened mobility, is anticipated to counterbalance the disorder and uphold a horizontal gaze [4,5]. Central to the progression of these degenerative changes seems to be the occurrence of hyperlordosis, which causes simultaneous overloading of the intervertebral joints and the intervertebral disc [1]. In 2018, Ling et al. conducted a comprehensive literature review aimed at identifying the optimal parameters for evaluating sagittal balance in the cervical region [5]. While commonly employed metrics comprise the C2–C7 lordosis, C0–C2 lordosis, and the global cervical angle (Harrison method), Ling et al. highlighted the cervical sagittal vertical axis (cSVA), spinocranial angle (SCA), T1 slope/C7 slope, and C2–C7 lordosis as most valuable, owing to their correlation with spinopelvic balance [5,6]. Alterations in cervical sagittal balance (CSB) parameters have been investigated in both asymptomatic populations and instances necessitating surgical interventions for lesions; however, the latter group has been characterized by a more limited number of reports [4,7–10]. Anterior cervical discectomy and fusion (ACDF), the established gold standard treatment for cervical myelopathy, continues to be the prevailing procedure employed for cervical degenerative disease [11]. The procedure involves spinal canal decompression followed by the precise implantation of an intervertebral device. Careful selection of the implant, tailored to the disc space, offers the potential to adjust cervical sagittal balance, thereby influencing the broader spinopelvic sagittal balance to some extent [5,7]. One of the complications associated with ACDF, related to the implantation of the mentioned cage, is the phenomenon of subsidence, which involves the settling of the implant into the fused vertebral bodies [12,13]. The causes of this phenomenon might be attributed to bone density disorders or other risk factors that interfere with the osteointegration [12,14]. Studies have

been undertaken to evaluate this process based on the relationship between the implant materials and the bone density, thereby assessing subsidence incidence and fusion rates [15,16]. Translational research based on nuanced laboratory, biomechanical, and radiological data appears to be necessary, as the subsidence phenomenon is still regarded as clinically inconclusive; however, there are reports suggesting that it can deteriorate treatment outcomes and impact balance [12,17–19]. The objective of this study was to assess how alterations in CSB parameters influence the clinical outcomes of the procedure measured by the VAS (visual analogue scale) and NDI (neck disability index), as well as the incidence of subsidence during a 12-month follow-up period.

2. Materials and Methods

2.1. Study Design

A single-center, observational study was conducted with 104 patients operated on at the authors' center between 2019–2021 for cervical disc disease. Inclusion criteria were as follows: diagnosed cervical degenerative disc disease on preoperative MRI that did not respond to conservative treatment, age ≥ 18 , and eligibility for single- or double-level ACDF surgery. Exclusion criteria included ages younger than 18 years, comorbidities that disqualified the patients from surgery, diagnosed osteoporosis, and those requiring three or more levels of surgery. During the study period, a total of 193 individuals were evaluated, of which 104 met the study criteria. As 9 patients were lost during follow-up, the images from the remaining 95 were assessed (Figure 1). The subjects' mean age was 51, with a median of 50. The youngest participant was 31, while the eldest was 71. Among the participants, 67 (71%) were women (Table 1).

Characteristics:	Value:
Age, y, mean (range) (SD)	51, (31-73) (10,24)
≥60 y, n (%)	19 (20%)
Gender: female, n (%)	67 (71%)
Type of spinal fusion:	
Single-level, n (%)	30 (32%)
Double-level, n (%)	65 (68%)
C3/C4, n	2 (2,1%)
C4/C5, n	0 (0%)
C5/C6, n	26 (28,4%)
C6/C7, n	2 (2,1%)
C3-C5, n	4 (4,2%)
C4-C6, n	15 (15,8%)
C5-C7, n	46 (48,4%)
Implant material:	
PEEK, n (%)	57 (60%)
TC-PEEK, n (%)	38 (40%)

Table 1. Characteristics of the study population (n = 95).

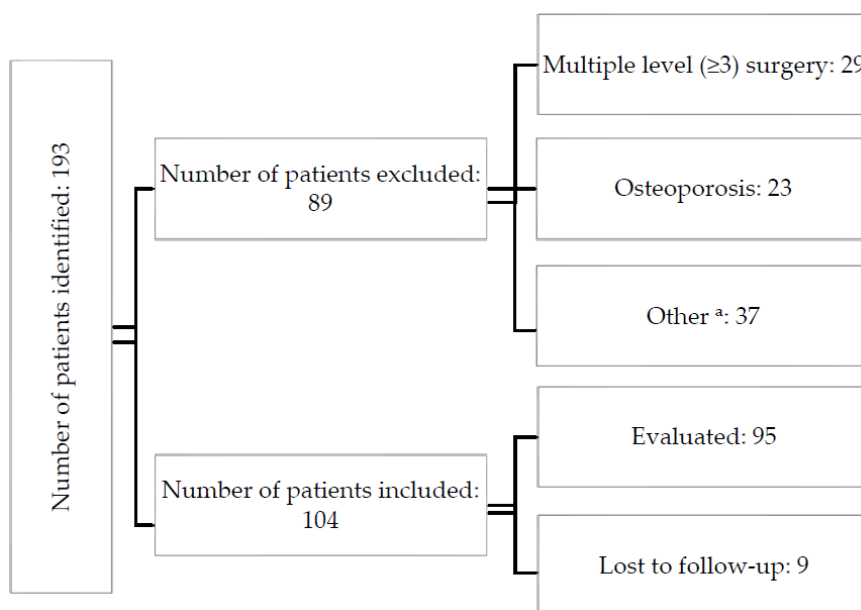


Figure 1. The chart introducing the patients' flow throughout the study. a—the "other" group encompassed patients who had active rheumatologic/metabolic diseases or had previously undergone surgery at a different level.

2.2. Procedure & Implants:

All procedures were performed with the same surgical technique from the Smith-Robbinson approach. [17] All implanted intervertebral devices had the same length (11.5 mm) and width (14 mm), and thus the same surface area. They differed only in height and the material from which they were made. PEEK (polyether-ether-ketone,) and TC PEEK (titanium-coated PEEK) implants from a single manufacturer (Aesculap Chifa, CeSPACE® Implants, Tuttlingen, Germany), were used, with a range of possible heights of 4-8 mm. Each implant was filled with nanoparticle hydroxyapatite from the same manufacturer. (B Braun, Nanogel® Hydroxyapatite, Melsungen, Germany) We used only stand-alone cages, without plating.

2.3. Radiological Assessment & Subsidence Criteria:

Radiological parameters were assessed using X-rays in lateral projection at five time points: 1) the day before the surgery, 2) the day after the surgery, 3) one month after the surgery, 4) six months after the surgery, and 5) twelve months after the surgery. All radiographs were obtained at the authors' centre always using the same equipment and following the same procedure. Measurements were collected with an accuracy of one decimal place. C2-C7 sagittal vertical axis (cSVA), spino cranial angle (SCA), C7 slope, C2-C7 lordosis, and segmental angle (Cobb) parameters were chosen to assess sagittal balance (Tab. 2, Fig. 2). These parameters were selected based on a comprehensive systematic review conducted by Ling et al. in 2018, which recognized them as the most effective and dependable for evaluating CSB. [5] The established values for the measured parameters were those provided by Ling and Le Huec.[2,5] The criterion for subsidence was defined as the depression of the implant into the border plate by at least one-third of the intervertebral space's height. (Fig. 3) [14,21]

Table 2. Cervical Sagittal Balance parameters selected for the study: definitions.

Parameter:	Description:
C2-C7 Saggital Vertical Axis (cSVA)	The distance from the posterior, superior corner of C7 to the plumbline from the centroid of C2.
Spino cranial angle (SCA)	The angle is measured as the deviation between the slope of C7 and the straight line that connects the midpoint of the C7 end plate to the midpoint of the sella turcica.
C7 slope	Angle between a horizontal line and the superior endplate of C7.
C2-C7 lordosis	Angle between C2 and C7 lower endplates.
Segmental angle	Cobb's angle between lower endplates of fused vertebrae.

2.3. Clinical Assessment

On the days when follow-up images were taken, clinical outcome was assessed using visual analogue scale (VAS) and neck disability index (NDI) scales [22,23]. A neck disability index (NDI) score of <15 points was considered indicative of mild disability with minimal interference in daily activities. Similarly, a visual analog scale (VAS) score of <1 point implied the absence of pain requiring medication.

2.4. Statistical Analysis

The comparison of quantitative variables between the groups was performed using either the Mann–Whitney test or the Student's t test for independent variables. To perform a multivariate evaluation of the effect of selected radiological parameters on subsidence, we utilized statistical analysis through logistic regression using the Wald test. A significance level of 0.05 was adopted for the analysis, thereby considering p values below 0.05 as indicating significant relationships. In instances where there were discrepancies in the statistical significance between univariate and multivariate tests, we prioritized the results of the multivariate tests. All calculations were carried out using MedCalc[®] statistical software version 20.104 and TIBCO Statistica[®] 13.3.

2.5 Ethical Approval

The research was approved by the Bioethics Committee of the Andrzej Frycz Modrzewski University in Cracow (Resolution 4/2019) and was conducted in compliance with the Declaration of Helsinki. All

qualified patients gave written consent to participate in the study.

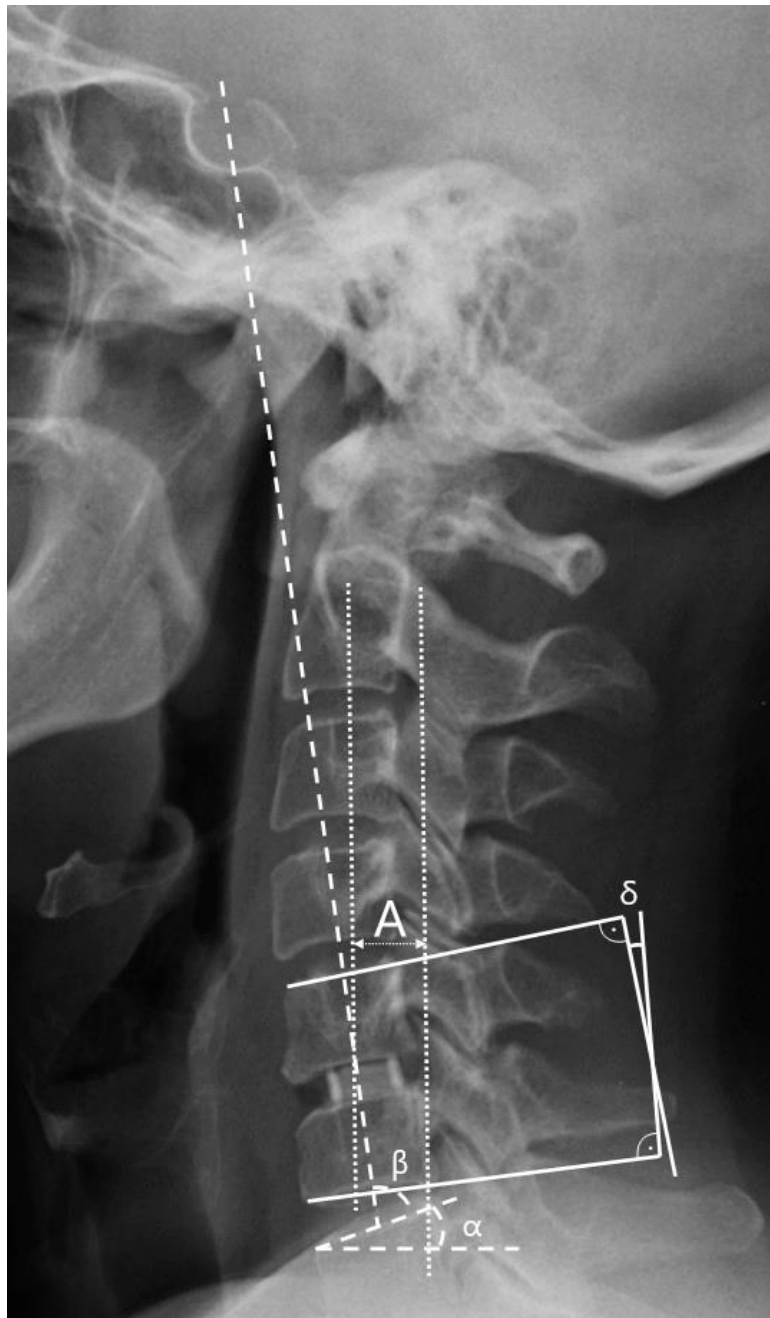


Figure 2. Measurement of individual selected parameters of cervical sagittal balance: A—C2–C7 sagittal vertical axis (C2–C7 SVA); α —C7 slope; β —spinocranial angle (SCA); δ —segmental (Cobb) angle.

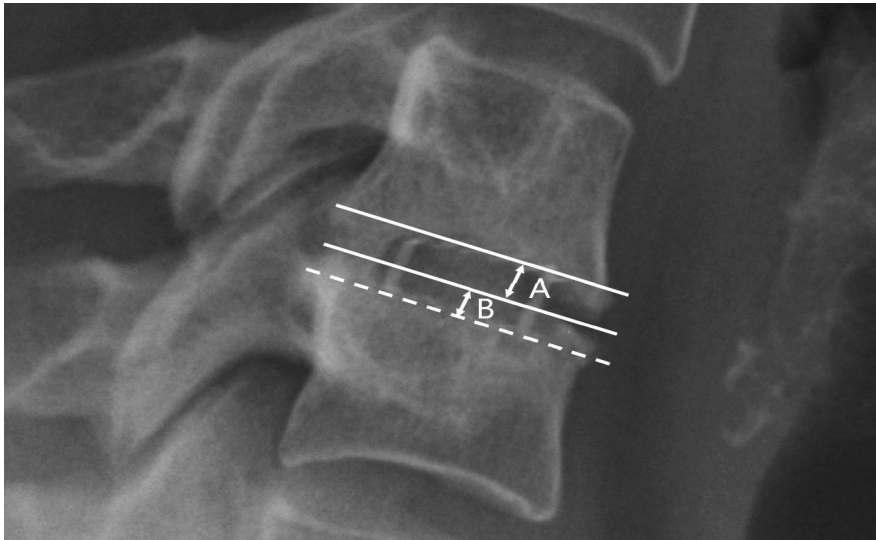


Figure 3. Assessment method for implant subsidence in fused vertebrae: B—subsidence depth; A—intervertebral height. Subsidence was defined as $(B/A) \geq 0.3$.

3. Results

3.1. CSB Parameters

The preoperative measurements of the sagittal balance parameters within the cervical segment were recorded as follows: for the C2–C7 sagittal vertical axis (SVA), a mean of 23.5 mm (SD \pm 11.5 mm) and a median of 22 mm were recorded; for the spinocranial angle (SCA), a mean of 81° (SD \pm 9.8°) and a median of 79.8° were recorded; for the C2–C7 lordosis, a mean of 9.5° (SD \pm 10.7°) and a median of 8.6° were recorded; for the C7 slope, a mean of 20.5° (SD \pm 7.7°) and a median of 21° were recorded; and for the segmental Cobb angle, a mean of 6.2° (SD \pm 6.1°) and a median of 5.5° were recorded. The postoperative sagittal balance parameters, measured from images taken the day after surgery, exhibited the following values: for the C2–C7 SVA, a mean of 26 mm (SD \pm 10.6 mm) and a median of 24.4 mm were recorded; for the SCA, a mean of 79.5° (SD \pm 7.3°) and a median of 79.9° were recorded; for the C2–C7 lordosis, a mean of 9.9° (SD \pm 8.7°) and a median of 8.3° were recorded; for the C7 slope, a mean of 22.6° (SD \pm 7.4°) and a median of 21.5° were recorded; and for the segmental Cobb angle, a mean of 7.3° (SD \pm 7.4°) and a median of 6° were recorded (Table 3). Following a 12-month follow-up period, an additional set of radiographs was conducted to assess the selected cervical sagittal balance (CSB) parameters. During this evaluation, the parameters measured were as

follows: for the C2-C7 SVA, a mean of 22.3 mm (SD \pm 10.7 mm) and a median of 22.4 mm were recorded; for the SCA, a mean of 79.9° (SD \pm 8.3°) and a median of 79.7° were recorded; for the C2-C7 lordosis, a mean of 10.9° (SD \pm 8.7°) and a median of 9.6° were recorded; for the C7 slope, a mean of 20.3° (SD \pm 7.2°) and a median of 19.7° were recorded; and for the segmental Cobb angle, a mean of 6.1° (SD \pm 6.5°) and a median of 5.6° were recorded (Table 3). The alterations in the values of the examined parameters at the 12-month mark, compared to the values prior to the surgery, were as follows: for the Δ C2-C7 SVA, a mean of 5.8 mm (SD \pm 5.7 mm) was recorded; for the Δ SCA, a mean of 7.1° (SD \pm 5.1°) was recorded; for the Δ C2-C7 lordosis, a mean of 7° (SD \pm 7.8°) was recorded; for the Δ C7 slope, a mean of 5.1° (SD \pm 3.7°) was recorded; and for the Δ Cobb segment angle, a mean of 4.9° (SD \pm 5.1°) was recorded (Table 3).

Parameter:		Preoperative ^a	Postoperative ^b	After 12 mo follow-up ^c	Δ pre-12m ^d
C2-C7 SVA [mm]	Mean:	23,5 (SD \pm 11,5)	26 (SD \pm 10,6)	22,3 (SD \pm 10,7)	5,8 (SD \pm 5,7)
	Median:	22	24,4	22,4	-
SCA [°]	Mean:	81 (SD \pm 9,8)	79,5 (SD \pm 7,3)	79,9 (SD \pm 8,3)	7,1 (SD \pm 5,1)
	Median:	79,8	79,9	79,7	-
C2-C7 lordosis [°]	Mean:	9,5 (SD \pm 10,7)	9,9 (SD \pm 8,7)	10,9 (SD \pm 8,7)	7 (SD \pm 7,8)
	Median:	8,6	8,3	9,6	-
C7 slope [°]	Mean:	20,5 (SD \pm 7,7)	22,6 (SD \pm 7,4)	20,3 (SD \pm 7,2)	5,1 (SD \pm 3,7)
	Median:	21	21,5	19,7	-
Segmental angle [°]	Mean:	6,2 (SD \pm 6,1)	7,3 (SD \pm 7,4)	6,1 (SD \pm 6,5)	4,9 (SD \pm 5,1)
	Median:	5,5	6	5,6	-

Table 3. Sagittal balance parameters—results of measurements in the assessed time points: ^a—1 day before the surgery; ^b—the day after the surgery; ^c—after 12-month follow-up; and ^d—average difference between the parameter value measured before the surgery and the value measured at the 12-month follow-up.

3.2. Clinical Outcomes

Prior to surgery, the preoperative assessment employing the VAS and NDI scales indicated mean scores of 5.9 (SD \pm 2.3) and 23.8 (SD \pm 8.78), respectively [points]. One month after surgery during the follow-up visit, these scores were reduced to 2.4 (SD \pm 2.33) for the VAS and 14 (SD \pm 7.7) for the NDI [points]. Upon completing the 12-month follow-up, the scores further decreased to 2.2 (SD \pm 2.0) for the VAS and 10.9 (SD \pm 8.7) for the NDI. Throughout the 12-month follow-up period, the absolute respective changes in the clinical parameters under study exhibited a mean of 3.7 (SD \pm 2.7) points for the VAS and 13.1 (SD \pm 9.9) points for the NDI. Our study also assessed the occurrence and relationship of the anticipated clinical endpoints with the sagittal balance parameters in the cervical region. A statistically significant difference was noted for the SCA in the groups with VAS $<$ 1 and VAS \geq 1, 84° vs. 79° ($p = 0.0307$), as well as for the alteration in the C7 slope values during the 12-month follow-up: 6.8° vs. 4.7° ($p = 0.0453$). Concerning the second assessed endpoint, i.e., for the NDI $<$ 14 points, a significant statistical difference emerged for the C7 slope value after the 12-month follow-up, 19° vs. 22° ($p = 0.0406$), as well as for the segmental angle value after 12 months: 6.8° vs. 3.8° ($p = 0.0417$) (Table 4).

		NDI \leq 14 pts			VAS $<$ 1 pts		
		N of Patients (%)		p Value ^a	N of Patients (%)		p Value ^a
		Yes	No		Yes	No	
SVA 12 M [mm]	12 M	22.6	21.9	0.3223	23	19.5	0.3204
	Δ	5.4	7.4	0.2112	6.0	5.7	0.4210
SCA 12 M [°]	12 M:	80.2	79.3	0.4809	84	79	0.0307
	Δ	7.4	6.2	0.4777	8.6	6.9	0.3059
C2–C7 lordosis 12 M [°]	12 M:	10.33	10.8	0.7635	8.8	9.7	0.6678
	Δ	5.8	7.7	0.7310	8.5	6.6	0.2221
C7 slope 12 M [°]	12 M:	19	22	0.0406	18.1	20.9	0.1339
	Δ	5.4	4.1	0.0522	6.8	4.7	0.0453
Segmental angle 12 M [°]	12 M:	6.8	3.8	0.0417	4.9	5.7	0.5224
	Δ	5.1	4.7	0.7832	5.5	4.6	0.5812

Table 4. Selected cervical spine balance parameter values based on clinical outcomes as assessed by VAS and NDI scales. a—multivariate logistic regression model, including all cervical spine balance parameters at specific time points as quantitative variables.

3.3. Subsidence

Out of the 95 patients evaluated, the phenomenon of subsidence was observed in 38 (40%) cases. The preoperative measurement of the sagittal balance parameters within this subset of patients revealed the following: for the C2–C7 SVA, a mean of 26.03 mm was recorded; for the SCA, a mean of 81° (SD ± 9.8°) was recorded; for the C2–C7 lordosis, a mean of 9.5° (SD ± 10.7°) was recorded; for the C7 slope, a mean of 20.5° (SD ± 7.7°) was recorded; and for the segmental Cobb angle, a mean of 6.2° (SD ± 6.1°) was recorded. Among all the assessed parameters, only the C2–C7 SVA demonstrated a statistically significant difference between the groups with and without subsidence: 26.03 vs. 21.79 [mm], with $p = 0.0182$ preoperatively, and 27.80 vs. 24.94 [mm], with $p = 0.0449$ on the day after surgery, respectively (Table 5).

Parameter	Subsidence	Preoperative		Postoperative		After Follow-Up	
		Mean	<i>p</i> Value	Mean	<i>p</i> Value	Mean	<i>p</i> Value
C2–C7 SVA [mm]	Yes	26.03	0.0478 ^a	27.80	0.0491 ^a	23.09	0.4722 ^b
	No	21.79	0.0182 ^c	24.94	0.0449 ^c	21.81	0.3499 ^c
SCA [°]	Yes	81.39	0.7687 ^b	79.38	0.8089 ^b	79.95	0.9969 ^b
	No	80.78	0.8476 ^c	79.75	0.4435 ^c	79.95	0.4758 ^c
C2–C7 lordosis [°]	Yes	9.30	0.8197 ^a	9.03	0.5818 ^a	10.64	0.6134 ^a
	No	9.69	0.5080 ^c	10.49	0.8073 ^c	11.05	0.9191 ^c
C7 slope [°]	Yes	21.07	0.5388 ^b	22.64	0.9589 ^b	20.37	0.9565 ^a
	No	20.07	0.5080 ^c	22.56	0.7244 ^c	20.29	0.7051 ^c
Segmental (Cobb) angle [°]	Yes	5.82	0.8405 ^a	6.02	0.0406 ^a	7.39	0.0072 ^a
	No	6.43	0.4745 ^c	8.22	0.1738 ^c	4.12	0.0144 ^c

Table 5. Dependence of the occurrence of subsidence on selected cervical sagittal balance parameters over time: a—Mann–Whitney U test; b—t-test for independent variables; and c—multivariate logistic regression model, including all cervical balance parameters in certain time point.

4. Discussion

Spinopelvic sagittal balance has been a widely studied concept since the 1990s [24–27]. While research has primarily concentrated on the thoracolumbar segment, where balance has been established through extensive studies of asymptomatic populations, the cervical region of the spine is gaining prominence. Due to its substantial mobility, the cervical segment primarily functions to compensate for changes occurring in the lower spinal sections [2,5]. However, pathological changes, which are most commonly degenerative in nature, can disrupt the inherent sagittal balance of the cervical segment to such an extent that it becomes incapable of fulfilling its function [4,28]. The surgical treatment undertaken often leads to spondylodesis between

individual vertebral bodies in the cervical region, which, by reducing the number of mobile segments, impairs the ability to maintain its own balance and compensate for changes in spinopelvic balance. For this reason, it is important to think about the possible impact on CSB as early as the treatment planning stage. Numerous researchers have conducted investigations into the assessment of radiological parameters related to CSB. These studies have observed alterations in these parameters in cases of pathology and have explored their correlation with clinical indicators [4,7,9,29–33]. In a comprehensive literature review published in 2018 by Ling in collaboration with Le Huec, they highlighted the C7/T1 slope, cervical sagittal vertical axis (cSVA), and spinocranial angle (SCA) as pivotal parameters in assessing CSB [5]. These parameters have a significant impact on overall balance, with the SCA serving as a well-correlated indicator of C2–C7 lordosis [5,8]. The current study aimed to assess the temporal evolution and its impact on clinical parameters, as indicated by the VAS and NDI scales, of the aforementioned CSB parameters. Furthermore, alterations in these parameters were scrutinized in a cohort of patients who experienced implant subsidence, which were juxtaposed with a group where this phenomenon was absent.

4.1. Cervical Sagittal Balance and Subsidence

The scientific literature lacks an abundance of investigations into the correlation between subsidence and CSB parameters. Notably, in 2017, Lee et al. published a study involving 41 patients, wherein they revealed that a T1 slope $< 28^\circ$ might constitute a risk factor for subsidence [19]. In our study, we did not observe a statistically significant difference in the C7 slope in the groups with and without subsidence at any evaluated time point (Table 4). Since C7 and T1 are considered as corresponding parameters, we conclude that our results do not reflect the findings of Lee et al. [2,5,19]. Furthermore, a statistically significant distinction between the subsidence and nonsubsidence groups was evident in the cSVA parameter, both preoperatively (26.03 vs. 21.79 mm, $p = 0.0182$) and postoperatively (27.80 vs. 24.94 mm, $p = 0.0449$), as revealed by multivariate analysis. The authors postulate that a higher cSVA might influence subsidence by unevenly distributing the forces exerted by the implant on the vertebral body endplates. Asymmetric pressure on the endplate could be prompted by an imbalanced SVA, thereby potentially contributing to subsidence. Nevertheless, drawing definitive conclusions is challenging due to the paucity of information on this topic in the existing literature. This finding, though applicable to the current study population, might

lack statistical significance when extended to a broader cohort. The subsequent parameter displaying statistical relevance was the segmental angle ($^{\circ}$), thereby showcasing a difference of 4.12° vs. 7.39° ($p = 0.0144$) in patients with and without subsidence, respectively, after the 12-month follow-up. The authors attribute this disparity to the reduction in segmental lordosis resulting from the implant's collapse into the vertebral bodies.

4.2. Cervical Sagittal Balance and Clinical Outcomes

Two clinical endpoints were assessed: VAS < 1 point and NDI 14 points, which were indicative of complete pain resolution and neck disability that does not impede regular functioning [22,23], respectively. The study aimed to determine if specific cervical sagittal balance parameters could predict higher scores in the VAS and deterioration in the NDI scores. In 2020, Zaidman et al. published a paper revealing a statistically significant negative correlation between C2–C7 lordosis (C2–C7 regarding the Cobb angle) and NDI scores, thereby indicating that lower lordosis corresponds to higher NDI scores. Other authors have also endeavoured to explore the impact of cervical sagittal balance parameters on clinical outcomes [19,34]. Current knowledge indicates that alterations in cervical sagittal balance contribute to susceptibility to adjacent segment disease, thus consequently impacting treatment outcomes negatively [35,36]. In a 2012 study, Tang et al. demonstrated a positive correlation between the C2–C7 sagittal vertical axis (SVA) and the neck disability index (NDI) while finding a negative correlation with the SF-36 scores [37]. Building upon this, we hypothesize that C2–C7 SVA values influence clinical parameters and quality of life. However, our study did not yield results aligning with the aforementioned correlations, as both the visual analogue scale (VAS) and NDI values of the C2–C7 SVA were comparable (Table 5). Nevertheless, a significant statistical difference in the spinocranial angle (SCA) values was observed in patients with VAS < 1 and ≥ 1 , specifically for 84 vs. 79 degrees, respectively, with $p = 0.0307$. This implies that, in our study population, higher SCA values correlated with improved pain relief. It is worth noting that the SCA values in both groups were found to be within the established normal range of 83 ± 9 degrees [5,8]. Consequently, it is plausible to postulate that the spinocranial angle (SCA) plays a significant role in influencing pain relief, although the precise mechanisms remain elusive. Similarly, the pattern observed for the C7 slope is noteworthy; it exhibited a statistically significant disparity between the group with NDI ≤ 14 points and the group with NDI > 14 points, thus registering 19° versus

22° , respectively, with a p value of 0.0406. This implies that individuals with smaller C7 slope angles were associated with mild or minimal disability. Deciphering whether these selected parameters are inherent characteristics of the studied population or indeed exert tangible influence on the settlement and clinical outcomes of the procedure presents a challenge. Consequently, further research involving more extensive cohorts is imperative to refine and advance the realm of surgical intervention for spinal conditions.

4.3. Study Limitations and Prospectives

Certainly, our study is not without limitations, with the foremost among them being the modest sample size and the single-center nature of the investigation. Furthermore, the absence of established and universally accepted standards for sagittal balance parameters in the cervical spine poses a considerable challenge in precisely characterizing a balanced spinal configuration. This constraint is undeniably significant. However, the authors firmly believe that this work underscores the critical significance of contributing data pertaining to this matter. Consequently, it underscores the pressing need for intensified research endeavours aimed at enhancing the quality of care and ultimately ensuring the well-being of patients.

5. Conclusions

Attaining favourable clinical outcomes in anterior cervical discectomy and fusion (ACDF) treatments is a complex process influenced by multiple factors. Cervical sagittal balance parameters may play an important role in this issue. The present study indicates a possible influence of the C7 slope and spinocranial angle (SCA) on the clinical effects expressed in the NDI and VAS scales, respectively. Despite these insights, the authors advocate for a comprehensive approach, thus stressing the consideration of global sagittal balance over isolated cervical parameters during surgical planning. Regarding subsidence, higher pre- and postoperative sagittal vertical axis (SVA) values might impact its incidence rate. However, this phenomenon may depend on a variety of other factors such as the patient's bone quality, implant type, and size or plating. The authors would like to underscore that while sagittal balance parameters are significant, they are part of a larger framework, which prompts a thorough evaluation of the full spectrum of risk factors available in the literature for treatment success.

Author Contributions: A.B.—manuscript preparation and editing, literature review, images preparation, data collection, and data analysis; M.D.—member of the surgical team and data collection; B.G.—critical review of the manuscript, supervision of the project, head of the department, and chief operator. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: The research was approved by the Bioethics Committee of the Andrzej Frycz Modrzewski University in Cracow (Resolution 4/2019—24 January 2019) and was conducted in compliance with the Declaration of Helsinki. All qualified patients gave written consent to participate in the study.

Informed Consent Statement: Informed consent was obtained from all of the subjects involved in the study.

Data Availability Statement: The datasets analysed during the current study are not publicly available due to legal constraints but are available from the corresponding author upon reasonable request.

Conflicts of Interest: The authors declare no conflict of interest.

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Article

Impact of Implant Size and Position on Subsidence Degree after Anterior Cervical Discectomy and Fusion: Radiological and Clinical Analysis

Adam Bębenek ^{1,*}, Maciej Dominiak ¹, Grzegorz Karpiński ¹, Tomasz Pawelczyk ² and Bartosz Godlewski ^{1,*}

¹ Department of Orthopedics and Traumatology, Spinal Surgery Ward. Scanmed—St. Raphael Hospital, 30693 Cracow, Poland

² Department of Affective and Psychotic Disorders, Medical University of Lodz, 92216 Lodz, Poland; tomasz.pawelczyk@gmail.com

*Correspondence: bebenek.adam.24@gmail.com (A.B.); bartoszgodlewski@wp.pl (B.G.)



Citation: Bębenek, A.; Dominiak, M.; Karpiński, G.; Pawelczyk, T.; Godlewski, B. Impact of Implant Size and Position on Subsidence Degree after Anterior Cervical Discectomy and Fusion: Radiological and Clinical Analysis. *J. Clin. Med.* **2024**, *13*, 1151. <https://doi.org/10.3390/jcm13041151>

Academic Editor: Sebastian Głowiński

Received: 3 January 2024

Revised: 12 February 2024

Accepted: 16 February 2024

Published: 18 February 2024



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Abstract: Background: Implant subsidence is recognized as a complication of interbody stabilization, although its relevance remains ambiguous, particularly in terms of relating the effect of the position and depth of subsidence on the clinical outcome of the procedure. This study aimed to evaluate how implant positioning and size influence the incidence and degree of subsidence and to examine their implications for clinical outcomes. Methods: An observational study of 94 patients (157 levels) who underwent ACDF was conducted. Radiological parameters (implant position, implant height, vertebral body height, segmental height and intervertebral height) were assessed. Clinical outcomes were evaluated using the Visual Analogue Scale (VAS) and Neck Disability Index (NDI). Subsidence was evaluated in groups according to its degree, and statistical analyses were performed. Results: The findings revealed that implant-to-endplate ratio and implant height were significant risk factors associated with the incidence and degree of subsidence. The incidence of subsidence varied as follows: 34 cases (41.5%) exhibited displacement of the implant into the adjacent endplate by 2–3 mm, 32 cases (39%) by 3–4 mm, 16 cases (19.5%) by ≥ 4 mm and 75 (47.8%) cases exhibited no subsidence. Conclusions: The findings underscore that oversized or undersized implants relative to the disc space or endplate length elevate the risk and severity of subsidence.

Keywords: subsidence; degenerative; disc; cervical; spine; spondylosis; intervertebral; ACDF

1. Introduction

Anterior cervical discectomy and fusion (ACDF) is a commonly employed surgical intervention for cervical spondylopathy, utilizing the Smith–Robbinson approach. The procedure entails two key stages, namely decompression and implantation. During the decompression phase, the operator removes any material that may cause pressure, irritate nerve roots, or affect the spinal cord from the intervertebral space [1]. Through the strategic implantation of material into the affected disc space, we are able to generate the requisite conditions for fusion to take place. This process stabilizes the impacted segment and effectively mitigates the potential for disease progression [2–4]. Recent advancements in materials technology have led to a shift away from the traditional use of iliac grafts in medical procedures. Due to the complications associated with harvesting these grafts, allogenic alternatives are now being used instead [4,5]. The ultimate objective of ACDF is to achieve a successful bone fusion at the operated level, which is crucial for the therapy’s effectiveness. Unfortunately, complications may arise for various reasons. Some of these complications may be directly related to the surgical procedure, such as dysphagia, postoperative bleeding, CSF leakage, discomfort, or Horner’s syndrome. Additionally, further complications may arise over time as a result of graft placement. Key among them are subsidence, pseudoarthrosis and cervical malalignment [6,7]. The above-mentioned complications are interrelated. Theoretically, the subsidence phenomenon can cause cervical malalignment, which, as a result of non-physiological biomechanical loads on the segment, increases the risk of pseudoarthrosis. Pseudoarthrosis, in turn, causes instability, which exacerbates the aforementioned non-physiological loads manifested by increasing osteo-chondral changes that can aggravate the clinical manifestations of spondylopathy [7,8]. Numerous researchers have invested considerable effort and resources to expand our understanding of subsidence, recognizing its importance. Noordhoek et al. conducted a comprehensive analysis in 2018, revealing that subsidence occurs on average in 20.2% of cases, with a range of 0% to 83%. However, the impact on clinical outcomes remains uncertain due to the varying results and the potential for bias in the studies examined [7]. Different authors have varying definitions for subsidence, leading to inconsistent criteria based on absolute values or numerical ratios [8–13]. To assess the operated level and compare preoperative and postoperative states, X-rays are used. They enable the monitoring of bone fusion and the detection of subsidence. In this article, the authors put forth a hypothesis suggesting a potential correlation between the depth of subsidence and clinical outcomes. Moreover, they undertake an investigation into the potential impact of radiological parameters pertaining to implant dimensions and positioning on the incidence and degree of subsidence.

2. Materials and Methods

2.1. Study Design

The observational study was conducted exclusively at a single center, involving a cohort of 104 patients who underwent anterior cervical discectomy and fusion (ACDF) surgery for cervical disc disease spanning the period from 2019 to 2021. Patients eligible for inclusion exhibited diagnosed cervical degenerative disc disease that was unresponsive to conservative treatment, confirmed via preoperative MRI scans. Inclusion criteria stipulated an age range between 18 and 65 years and suitability for either single- or double-level ACDF surgery. The exclusion criteria encompassed individuals outside the age range (older than 65 years or younger than 18 years), those with concurrent osteoporosis or active rheumatologic/metabolic diseases, prior surgical intervention at a different level, and patients necessitating three or more levels of surgical intervention. Among the 193 individuals assessed during the study timeframe, 104 fulfilled the predetermined inclusion criteria (Figure 1).

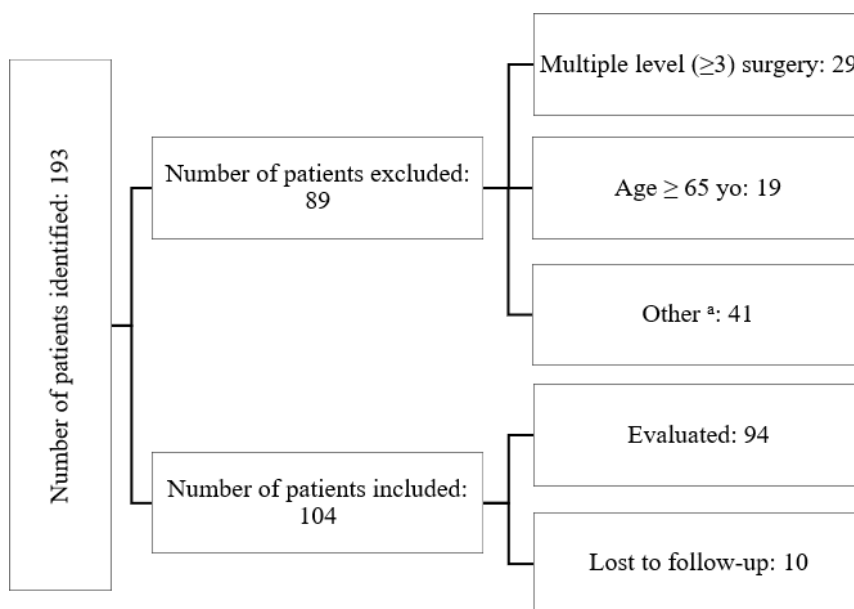


Figure 1. The chart introducing the patients flow throughout the study; ^a—the “other” group encompassed patients who had active rheumatologic/metabolic diseases or had previously undergone surgery at a different level.

2.2. Procedure and Implants

All surgeries adhered to the standardized Smith–Robbinson approach. The intervertebral implants utilized in all cases shared identical dimensions, measuring 11.5 mm in length and 14 mm in width, ensuring uniform surface area across all implants. Variations were only observed in terms of height and material composition. Specifically, the study included 85 implants composed of poly-ether-ether-ketone (PEEK) and 72 titanium-coated PEEK (TC) implants sourced from a single manufacturer (Aesculap Chifa, CeSPACE® Implants, Tuttlingen, Germany). These implants offered a height range of 4–8 mm, with a mean of 6.3 mm and a median of 6 mm. Each implant featured a nanoparticle hydroxyapatite filler obtained from the same manufacturer (B Braun, Nanogel® Hydroxyapatite, Melsungen, Germany). Notably, stand-alone cages were exclusively used, and plating was omitted from the procedures.

2.3. Radiological Assessment, Clinical Evaluation and Subsidence Criteria

Radiological assessments were conducted via X-rays in lateral projection at five distinct intervals: (1) the day preceding the surgery, (2) the immediate postoperative day, (3) one month post-surgery, (4) six months post-surgery, and (5) twelve months post-surgery. All radiographic images were acquired at the authors' facility, employing consistent equipment and adhering to standardized procedures. Measurements were meticulously obtained with a precision of 0.1 mm. The assessed radiological parameters, illustrated in Figure 2, underwent evaluation. Clinical outcomes were appraised using the Visual Analogue Scale (VAS) and Neck Disability Index (NDI) during the follow-up imaging sessions. Subsidence was recognized in case implant displacement into the adjacent endplate by ≥ 2 mm. To assess the degree of subsidence, 3 categories were created based on the magnitude of implant displacement compared to the radiographs taken the day after surgery: (1) implant displacement into the adjacent endplate by ≥ 2 mm and < 3 mm, (2) implant displacement into the adjacent endplate by ≥ 3 mm and < 4 mm, and (3) implant displacement into the adjacent endplate by ≥ 4 mm. The measurement method is depicted in Figure 3.

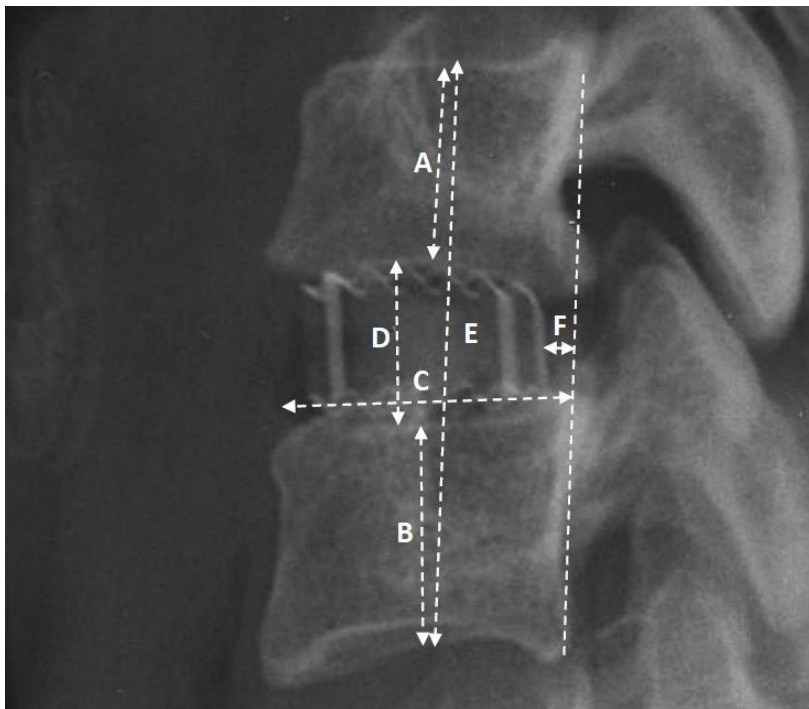


Figure 2. The image of the operated segment in the lateral projection, showcasing the selected radiological parameters utilized in the study: A—height of the upper body; B—height of the lowerbody; C—length of the lower endplate; D—height of the intervertebral space; E—height of the segment; F—distance of the implant from the medial column (posterior longitudinal ligament).

2.4. Statistical Analysis

The comparison of quantitative variables between the groups was performed using either the Mann–Whitney test, Student’s *t*-test for independent variables or the Welch T-test. In the case of an analysis of more than two groups, Kruskal–Wallis or ANOVA tests were performed. The analysis utilized a significance level of 0.05, wherein *p*-values below 0.05 were deemed to signify significant relationships. Statistical computations were performed using MedCalc® Statistical Software version 20.104 (MedCal Software Ltd., Ostend, Belgium) and TIBCO Statistica 13.3 (TIBCO Software Inc., Palo Alto, CA, USA). The study received approval from the Bioethics Committee of the Andrzej Frycz Modrzewski University in Cracow (Resolution 4/2019—24 January 2019) and adhered to the principles outlined in the Declaration of

Helsinki. All patients and/or their legal guardian(s) gave their written consent, were informed about the purpose and conduct of the study, and knew that the data acquired would be submitted for publication.

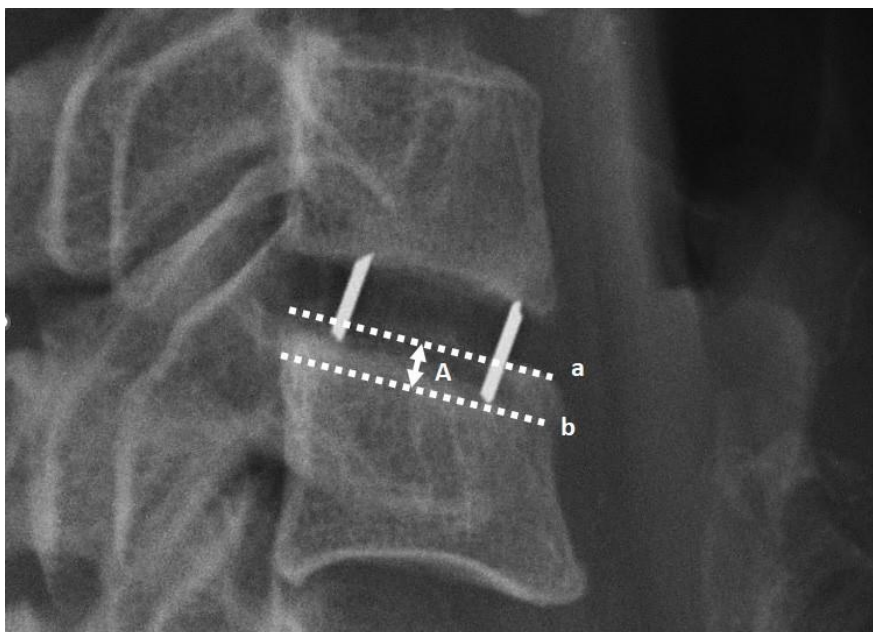


Figure 3. The image illustrates the subsidence measurement method based on the displacement of the cage into the adjacent endplate. ‘A’ represents the depth of cage displacement, ‘a’ refers to the line tangent to the endplate, and ‘b’ represents the line tangent to a passing through the lowest point of the cage.

3. Results

3.2. Participants

Among the cohort of 104 eligible patients, comprising 76 women and 28 men, the mean age was 51 years, with a median age of 50 years. During the 12-month follow-up period, 10 patients were lost to follow-up, resulting in the evaluation of images from 94 patients (representing 157 intervertebral spaces). Among these, 31 cases involved a single level, while 63 cases involved double levels. Over the course of the 12-month period, there was an average clinical improvement of 3.6 points in the Visual Analogue Scale (VAS) scores and 14 points in the Neck Disability Index (NDI) scores. No statistically significant difference was observed in terms of gender, age, type of implant and number of levels instrumented (p value > 0.05) (Table 1).

Table 1. Characteristics of the study population ($n = 94$).

Characteristics	Value
Age, year, mean (range)	50 (31–65)
Gender: female, n (%)	67 (71.3%)
Type of implant:	
PEEK, n (%)	85 (54.1%)
TC-PEEK, n (%)	72 (45.9%)
Type of spinal fusion:	
Single-level, n (%)	31 (33%)
Double-level, n (%)	63 (67%)
C3/C4, n	2 (2.3%)
C4/C5, n	0 (0%)
C5/C6, n	27 (28.9%)
C6/C7, n	2 (2.3%)
C3–C5, n	4 (4.5%)
C4–C6, n	15 (16.1%)
C5–C7, n	43 (45.9%)
VAS, pts, mean:	
Preoperative	5.9
1 month after the surgery	2.4
6 months after the surgery	2.2
12 months after the surgery	2.2
Δ VAS	3.6
NDI, pts, mean:	
Preoperative	24
1 month after the surgery	14
6 months after the surgery	11
12 months after the surgery	10
Δ NDI	14

3.2. Subsidence and Implant Placement

Regarding the segment height (E), the average values were as follows: 36.4 mm before surgery, 38.6 mm the day after surgery, 37.3 mm after one month, and 36.5 mm and 36.1 mm after 6 and 12 months, respectively. The height of the intervertebral space (D) exhibited the following averages: 5.7 mm before surgery, 8.6 mm the day after surgery, 7.9 mm after one month, and 7.1 mm and 6.7 mm after 6 and 12 months, respectively. The mean height of the implant used was 6.16 mm, with a median of 6 mm. Additionally, the average length of the endplate (C) was 21.5 mm, while the mean distance of the implant from the medial column (F) was 4.2 mm. Furthermore, the mean heights of the upper (A) and lower (B) vertebral bodies were 15.4 mm and 15.8 mm, respectively.

In terms of subsidence, within the study group of 157 intervertebral spaces, the frequencies were as follows: 82 cases (52.2%) exhibited displacement of the implant into the adjacent endplate by ≥ 2 mm, whereas 34 cases (41.5%) exhibited displacement of the implant into the adjacent endplate ≥ 2 and < 3 mm, 32 cases (39%) exhibited displacement of the implant into the adjacent endplate by ≥ 3 and < 4 mm, 16 cases (19.5%) exhibited displacement of the implant into the adjacent endplate by 4 mm, and 75 (47.8%) cases exhibited no subsidence. The average ratio of the distance of the cage from the middle column divided by the length of the endplate. (F/C on Figure 2) was 0.19. However, this ratio did neither exhibit statistical significance as a factor influencing occurrence nor the degree of subsidence (Table 2). Another statistical analysis was conducted to assess the relationship between the cage-to-endplate length ratio and its contribution to subsidence. The average cage-to-endplate ratio was 0.52, and it was found to be statistically significant for subsidence: 0.51 vs. 0.53 with $p = 0.0448$. However, no significant relationship was observed for the degree of subsidence (Table 2). Furthermore, when the aforementioned ratio was divided by the cage distance and referred to as the cage–endplate distance ratio, it demonstrated no statistical significance for subsidence: 0.22 vs. 0.17 ($p = 0.1273$) and no significant differences were found for subsidence degree. The ratio of implant height to intervertebral space height before surgery averaged 0.94 and exhibited statistical significance as a factor affecting subsidence: 1.18 vs. 1.1 ($p = 0.0367$), with a greater ratio for the subsidence group. Moreover, this ratio was found to be a statistically significant factor influencing the degree of subsidence with means of 1.1, 1.16 and 1.3 for groups of ≥ 2 and < 3 [mm], ≥ 3 and < 4 [mm] and ≥ 4 mm, respectively ($p = 0.0447$). Similarly, the ratio of implant height to segmental height before surgery averaged 0.17 and demonstrated statistical significance as a factor influencing subsidence occurrence ($p = 0.0322$) and its degree ($p = 0.0389$). Additionally, the ratio of vertebral body height before surgery to implant height was also analyzed and evaluated for its impact on both subsidence incidence rate and depth. Both the above and below vertebrae had a ratio of 0.4 and did not prove to be statistically significant as a risk factor for subsidence (Table 2).

	Subsidence		Subsidence Degree			
	Yes	No	≥2 and <3 [mm]	≥3 and <4 [mm]	≥4 [mm]	
	Number of disc spaces: (%)	82 (52.2%)	75 (47.8%)	34 (41.5%)	32 (39%)	16 (19.5%)
Parameters						
Cage-to-endplate length ratio ¹	Mean:	0.51	0.53	0.52	0.51	0.50
	Coefficient:	T = 1.79^b			H = 1.04 ^d	
	p value	0.0448^b			0.5947 ^d	
Cage-endplate distance ratio ²	Mean:	0.22	0.17	0.29	0.18	0.15
	Coefficient:	Z = 1.53 ^a			H = 2.79 ^d	
	p value	0.1273 ^a			0.2477 ^d	
Cage distance to endplate length ratio ³	Mean:	0.20	0.19	0.22	0.19	0.17
	Coefficient:	Z = -0.92 ^a			H = 2.24 ^d	
	p value	0.3602 ^a			0.3255 ^d	
Cage-to-preoperative intervertebral space height ratio ⁴	Mean:	1.18	1.1	1.1	1.16	1.3
	Coefficient:	Z = 2.14^a			H = 4.69^d	
	p value	0.0367^a			0.0447^d	
Cage-to-preoperative segmental height ratio ⁵	Mean:	0.18	0.16	0.16	0.18	0.2
	Coefficient:	-1.53^c			F = 2.54^e	
	p value	0.0322^c			0.0389^e	
Cage to upper vertebral body height ratio ⁶	Mean:	0.41	0.40	0.41	0.42	0.40
	Coefficient:	T = -0.54 ^b			F = 0.32 ^e	
	p value	0.5893 ^b			0.7237 ^e	
Cage-to-lower vertebral body height ratio ⁶	Mean:	0.40	0.40	0.40	0.41	0.37
	Coefficient:	Z = 0.27			F = 2.27 ^e	
	p value	0.7855 ^a			0.1100 ^e	

Table 2. Dependence of the occurrence and degree of subsidence on selected radiological ratios. a—statistical analysis using Mann–Whitney test; b—statistical analysis using independent *t*-test; c—statistical analysis using Welch test; d—Kruskal–Wallis test; e—univariate ANOVA; 1—the ratio between the length of the cage and the length of the endplate (11.5/C in Figure 2); 2—the quotient obtained by dividing the ratio of cage length to endplate length by the distance of the cage from the middle column [(11.5/C)/F in Figure 2]; 3—the ratio was calculated by dividing the distance of the cage from the middle column by the length of the endplate (F/C in Figure 2); 4—the ratio between the height of the implant and the preoperative intervertebral space (implant height/D in Figure 2); 5—the ratio between the height of the implant and the preoperative segmental height (implant height/E in Figure 2); 6—the respective ratio between the implant height and the upper vertebral body height (implant height/A in Figure 2) and lower vertebral body height (implant height/B in Figure 2). Statistically significant results in bold.

3.3. Subsidence and Clinical Outcome

Following a 12-month postoperative assessment, VAS and NDI scores were also evaluated in two distinct groups: one with subsidence and the other without. In the subgroup with subsidence, the mean VAS score registered was 2.3, whereas without subsidence recorded a mean VAS score of 2.0.

Nevertheless, this disparity did not achieve statistical significance ($p = 0.1123$). Conversely, a substantial discrepancy was observed in the NDI scores ($p = 0.0105$) between the two cohorts, with the subsidence group presenting a mean NDI score of 12.4 and the group without subsidence exhibiting a mean NDI score of 8.5 points (Table 3). To examine the association between clinical outcomes and the degree of subsidence, a statistical analysis of VAS and NDI scores was conducted within subgroups categorized by varying depths of subsidence. The findings revealed that there was no statistically significant difference in the VAS scores relative to the depth of subsidence ($p = 0.4733$). However, a significant difference emerged with respect to the NDI scores, which exhibited an increasing trend in values corresponding to deeper levels of subsidence ($p = 0.0459$) with a mean of 10.7 pts for the 2–3 mm subgroup, 11.9 pts for 3–4 mm and 13.5 pts for ≥ 4 mm of implant migration into adjacent endplate (Table 3).

Table 3. Dependence of the Visual Analogue Scale (VAS) and Neck Disability Index (NDI) values on degree of subsidence. a—statistical analysis using Mann–Whitney test; b—statistical analysis using Kruskal–Wallis test. Statistically significant results in bold.

Subsidence n (%):	VAS Score after 12 Months				NDI Score after 12 Months			
	Mean [pts]:	Median [pts]:	Z coefficient a:	p value a:	Mean [pts]:	Median [pts]:	Z coefficient a:	p value a:
Y 82 (52.2%)	2.3	2.0	-1.59	0.1123	12.4	9.0	-2.56	0.0105
N 75 (47.8%)	2.0	1.5			8.51	7.0		
Subsidence degree [mm], n:	Mean [pts]		H coefficient b:	p value b:	Mean [pts]:		H coefficient b:	p value b:
≥ 2 and < 3	34	1.9			10.7			
≥ 3 and < 4	32	2.2	1.52	0.4733	11.9		7.84	0.0459
≥ 4	16	2.5			13.5			

4. Discussion

Since the mid-20th century, ACDF has been the established treatment for cervical degenerative disc disease. Initial approaches to intervertebral space fusion using autograft from the iliac plate resulted in a high incidence of local complications, leading researchers to explore implants made from alternative materials [3,7,9].

Presently, commonly used cages are composed of materials such as stainless steel, titanium, carbon fiber, polymethyl-methacrylate (PMMA), and polyether-ether-ketone (PEEK) [7]. While artificial cages are designed to theoretically preserve lordosis, restore intervertebral space height, and promote bony fusion through enhanced osteointegration, complications such as fusion failure, kyphotic malalignment of the cervical spine, and subsidence can still arise [14]. This study focuses on the phenomenon of subsidence, investigating its radiological risk factors and the clinical implications based on the degree of implant migration into adjacent endplates.

Subsidence is a frequently encountered phenomenon; however, its precise definition, particularly concerning the specific depth of this occurrence, remains a subject of uncertainty and ambiguity in certain aspects [8,15]. Karikari et al. presented fundamental variations in the definition of subsidence in their 2014 article, evaluating the impact of different subsidence depth measures on radiological and clinical outcomes through a systematic review. Their work consolidates various approaches to assess subsidence, incorporating diverse cutoff points, at times interpreted as absolute values and occasionally as ratios [15]. Karikari et al. center their study on identifying risk factors for subsidence and evaluating pseudoarthrosis and fusion based on definitions established by previous researchers. They underscore the necessity for research geared towards establishing precise cutoff values for subsidence depth. Nevertheless, their investigation does not encompass a comprehensive analysis of how the depth of subsidence influences the clinical outcomes of the procedure [15]. In this study, our specific focus centers on the precise examination of the relationship between subsidence degree and clinical outcomes, taking into consideration various aspects of implant size and positioning.

During the procedure, the operator can choose to place the implant closer to the anterior or posterior surface of the vertebral body, where it is in proximity to the respective cortical bone, forming the anterior or posterior wall. Alternatively, the implant can be positioned more centrally without additional support. Previous authors have addressed this topic, suggesting a relationship between the distance of the implant from the anterior surface of the vertebral body and the occurrence of subsidence, as well as a correlation between the ratio of implant length to endplate length and subsidence [8,16–18]. The findings of this study confirm such relationships in terms of implant length to endplate length ratio. A lower incidence of subsidence was noted when the ratio of implant length to endplate length was higher: 0.50 vs. 0.53 ($p = 0.0448$). Regarding the cage-endplate to distance ratio, which reflects the

positioning of the implant within the intervertebral space, no statistically significant differences were observed. It is advisable to strive for maximum overlap between the implant length and the endplate length in order to minimize the risk of subsidence.

The appropriate matching of implant height to segmental or intervertebral space height has also been considered by other authors [7,17,19]. Implants with greater height may exert more pressure on adjacent endplates than their smaller counterparts, potentially increasing the incidence of subsidence [7,17]. In 2007, Barsa and Suchomel investigated whether the degree of distraction, defined as the ratio of preoperative to postoperative disc space height, has an impact on subsidence. However, their findings at that time did not yield statistically significant results [19]. In a 2012 publication, Yamagata et al. reported a higher incidence of subsidence with 6.5 or 7.5 mm implants compared to 4.5 and 5.5 mm implants. They defined subsidence as the implant being recessed into the adjacent lamina by at least one-third of its height. Considering the range of implants used (4.5–7.5 mm), it can be inferred that the observed subsidence corresponded to a recess of approximately 1.5–2.5 mm. Additionally, their study revealed a stronger association between the ratio of implant height to segment height and the occurrence of subsidence [17]. Consistent results were obtained in our study. In the case of subsidence incidence, we obtained a statistically significant difference for both the cage-to-segmental height ratio ($p = 0.0322$) and cage-to-preoperative intervertebral space height ratio ($p = 0.0367$). In addition, a decrease in the values of the described ratios was observed as the degree of subsidence increased (Table 2). Therefore, it is reasonable to assume that the selection of an oversized implant affects subsidence by creating too much stress on the endplates of the fused vertebral bodies. Moreover, the greater the load, the greater the degree of subsidence. Precisely sizing implants to match the intervertebral space is crucial in preventing subsidence.

The heterogeneity described at the beginning of the discussion is also evident in the clinical significance of subsidence. Indeed, there is a discrepancy in the results concerning the relationship between subsidence and the patient's clinical condition [7]. Studies by Kast et al., Lee et al., and Kim et al. report the presence of an association between subsidence and worse clinical outcomes [20–22]. However, numerous reports suggest the absence of such a relationship [7,23–25]. In our study, we assessed the VAS and NDI scale scores following a 12-month follow-up period and examined their relationship with the incidence and degree of subsidence. All patients demonstrated improvement, with average score reductions of 3.6 points on the VAS scale and 13.64 points on the NDI scale (Table 1). Furthermore, the NDI score after 12 months exhibited a statistically

significant difference between the groups with and without subsidence with $p = 0.0105$ (Table 2). Additionally, we observed an increase in mean NDI scale values as the degree of subsidence escalated ($p = 0.0459$). Hence, it is reasonable to infer that both the occurrence and degree of subsidence may indeed influence the clinical outcome of the procedure.

5. Conclusions

The occurrence of subsidence continues to pose uncertainties regarding its impact on the outcomes of surgical interventions for spinal degenerative disease. While discrepancies exist in the impact of implant dimensions and positioning on the likelihood of subsidence, these variables merit meticulous consideration during surgical strategizing. Implants that exceed appropriate dimensions relative to the disc space or inadequately match the length of the border plate may escalate the susceptibility to subsidence and intensify its severity. Furthermore, the findings of this study suggest a conservative assumption that subsidence impacts the clinical efficacy of treatment, implying a potential inverse correlation between the degree of subsidence and treatment outcomes.

Author Contributions: Conceptualization, A.B. and B.G.; methodology, A.B.; software, T.P. and A.B.; validation, A.B. and B.G.; formal analysis, T.P.; investigation, A.B.; resources, B.G.; data curation, A.B., M.D. and G.K.; writing—original draft preparation, A.B.; writing—review and editing, A.B.; visualization, A.B. and G.K.; supervision, B.G.; project administration, B.G. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: The research was approved by the Bioethics Committee of the Andrzej Frycz Modrzewski University in Cracow (Resolution 4/2019—24 January 2019) and was conducted in compliance with the Declaration of Helsinki. All qualified patients gave written consent to participate in the study.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The datasets analyzed during the current study are not publicly available due to legal constraints but are available from the corresponding author upon reasonable request.

Conflicts of Interest: The authors declare no conflicts of interest.

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Rozdział VI. - Wnioski oraz realizacja celów rozprawy doktorskiej:

Osiadanie implantów międzytrzonowych w chorobie zwyrodnieniowej odcinka szyjnego kręgosłupa jest zjawiskiem o niejednoznacznym nie tylko klinicznie, ale i radiologicznie. [16] Pomimo względnie stałej definicji zjawiska osiadania, nie zostały dotychczas ustalone standardowe wartości punktów odcięcia dla stwierdzania jego obecności lub oceny jego zaawansowania. [18] Celem niniejszego cyklu publikacji była ocena radiologicznych czynników ryzyka jego wystąpienia, a także sprawdzenie wpływu jego występowania i stopnia zaawansowania na efekty kliniczne leczenia operacyjnego. W pierwszej publikacji dokonano, poprzez przegląd aktualnej literatury, porównania efektów klinicznych oraz radiologicznych zabiegów przedniej discektomii szyjnej ze spondylodezą międzytrzonową z oraz bez stabilizacji operowanego segmentu płytka szyjną. Jednym z wątków tego artykułu stało się zjawisko osiadania, które poprzez bezpośredni wpływ na wysokość międzykręgową może być czynnikiem ryzyka powstawania stenozy otworowej, a tym samym prowadzić do pogorszenia efektów leczenia operacyjnego. Należy również podkreślić, iż osiadanie powoduje zaburzenia krzywizny kręgosłupa szyjnego w płaszczyźnie strzałkowej (*ang. cervical alignment*) co dodatkowo może powodować pogorszenie efektu klinicznego. [29] W toku rzeczzonego przeglądu systematycznego ustalono, iż czynnikami ryzyka o charakterze radiologicznym są: pozycja implantu w przestrzeni międzykręgowej (implanty położone bardziej grzbietowo osiadają częściej), powierzchnia styku implantu z blaszką graniczną (implanty

o polu powierzchni zbyt małym w stosunku do pola powierzchni blaszki granicznej osiadają częściej) oraz dodatkowa stabilizacja z wykorzystaniem płytki szyjnej. [39]

Tematem drugiej publikacji stały się zaburzenia balansu strzałkowego w odcinku szyjnym kręgosłupa oraz ich związek z osiadaniem. Jako, że osiadanie może wpływać na krzywiznę strzałkową kręgosłupa (*ang. cervical alignment*), zaś bardziej kompletnym i zaawansowanym pojęciem opisującym zmiany w kształcie i funkcji odcinka szyjnego kręgosłupa jest balans strzałkowy, temu właśnie zagadnieniu poświęcono drugą publikację. Spośród wyselekcjonowanych na podstawie opublikowanego w 2018 r. przez Ling'a oraz Le Huec'a przeglądu literatury dotyczącego najbardziej rzetelnych parametrów balansu strzałkowego, przeprowadzono analizę ich wpływu na osiadanie. Wybrano następujące: C2-C7 sagittal vertical axis (C2-SVA), Spinocranial angle (SCA), C7 slope, C2-C7 lordosis oraz segmental angle. Wykazano istotną statystycznie różnicę w zakresie C2-SVA w grupie pacjentów z osiadaniem oraz bez w dzień przed zabiegiem oraz dzień po zabiegu, odpowiednio 26.03 vs 21.8 [mm] oraz 27,8 vs 24,9 [mm]. Na tej podstawie wysunięto przypuszczenie, że większe wartości C2-SVA odzwierciedlające przesunięcie środka ciężkości głowy do przodu względem prawidłowej linii grawitacji, powodują nierównomierny nacisk na implant międzytrzonowy z koncentracją siły na jego przedniej części. Taka dystrybucja obciążenia może powodować punktowe, przeciążenie kości i promować jej resorpcję, co ostatecznie prowadzi do zagłębienia się implantu w przyległy trzon – osiadania. Hipotezę tą dodatkowo wydaje się potwierdzać

fakt, że w przypadku segmentów ocenianych po 12 miesiącach, kiedy to najczęściej dochodzi do stabilnego wzrostu kostnego, nie obserwujemy podobnej zależności. Można zatem wnioskować, że zachowanie wartości C2-SVA zbliżonej do 20 mm może stanowić czynnik prewencji osiadania. Biorąc pod uwagę dotychczasowe, dość ubogie w tym zakresie, doniesienia naukowe, odkrycie to stanowi *novum*. Warto zaznaczyć, że w 2017 r. Lee et al. opublikowali pracę, w której wykazali, iż T1 slope (parametr tożsamy z C7 slope [4]) $>28^\circ$ jest czynnikiem ryzyka osiadania. Poza C2-SVA nie wykazano, aby inne wyselekcjonowane parametry szyjnego balansu strzałkowego stanowiły czynniki ryzyka dla zjawiska osiadania.

W trzeciej publikacji sprawdzono wpływ radiologicznych czynników związanych z pozycją i rozmiarem implantu na występowanie i zaawansowanie zjawiska osiadania, a także odniesiono to do efektów klinicznych leczenia w badanej populacji chorych. W zgodności z literaturą pozostaje obserwacja, iż implanty o powierzchni zbyt małej w stosunku do blaszki granicznej ulegają zapadnięciu. [23,36,40] Nie zaobserwowano jednak, aby geometryczne położenie implantu bardziej brzusznie (bliżej przedniej powierzchni trzonu kręgu) wpływało na częstość i zaawansowanie osiadania. W ocenie autorów, można przypuszczać, iż nie tyle pozycja, a odpowiednie dopasowanie rozmiaru implantu do anatomii blaszek granicznych wpływa na osiadanie. Obciążenie rozkłada się na blaszce granicznej równomiernie na powierzchni implantu. Oznacza to, że na jednostkę pola powierzchni blaszki granicznej przypada odpowiadająca, przenosząca obciążenie

jednostka pola powierzchni implantu. Zgodnie w prawem Delpecha-Wolffa, w sytuacji, gdy obciążenie jest wysokie, zaś stosunek rozmiaru implantu do rozmiaru blaszki granicznej pozostaje w nierównowadze, może dochodzić do punktowego przekroczenia progu optymalnego obciążenia kości i jej resorpcji, co w efekcie skutkuje osiadaniem implantu. Przepuszczalnie dzieje się tak do momentu, aż ustalony zostanie nowy układ równowagi sił, dostosowany do możliwości wzrostowych kości. Hipoteza ta, znajduje odzwierciedlenie w literaturze. [35] Potwierdzono również wpływ rozmiaru implantu między trzonowego na występowanie i zjawisko osiadania. Implanty zbyt wysokie w stosunku do wysokości międzykręgowej i wysokości segmentu osiadają częściej, zaś nierównowaga ich stosunku do wyżej wymienionych parametrów wpływa na zaawansowanie tego procesu. Prawdopodobny patomechanizm tego zjawiska jest zbliżony do tego obserwowanego w przypadku niedostosowania rozmiaru implantu do długości blaszki granicznej. Wnioskować można zatem, że oba zjawiska są ze sobą ściśle związane i zasadne wydają się próby znalezienia relacji między rozmiarem i położeniem implantu, tak, aby zminimalizować ryzyko osiadania. W zakresie pozostałych wyselekcjonowanych radiologicznych czynników ryzyka nie znaleziono różnic istotnych statystycznie.

Kliniczne znaczenie zjawiska osiadania zbadano z użyciem skal VAS (Visual Analogue Scale) oraz NDI (Neck Disability Index). W przypadku VAS nie zaobserwowano istotnych statystycznie różnic w wynikach punktowych po 12 miesiącach obserwacji u pacjentów, u których pojawiło się zjawisko osiadania oraz u tych, u

których jego wystąpienia nie odnotowano. W zakresie stopnia zaawansowania osiadania, nie stwierdzono związku pomiędzy wynikami w skali VAS, a głębokością osiadania. Znaleziono natomiast korelację między stopniem osiadania, a jakością funkcjonowania wg skali NDI. Spostrzeżenia te pozostają w zgodzie z literaturą przedmiotu, gdyż zjawisko osiadania wydaje się być niejednoznaczne klinicznie [16] Autor niniejszej dysertacji wysuwa hipotezę, że rozbieżność w wynikach VAS i NDI wynika z dokładności tych skali. Skala VAS bierze pod uwagę tylko dolegliwości bólowe uchwycone w ustalonych punktach czasowych oceny klinicznej. Powodować to może pewne wypaczenie wyników, gdyż ból w chorobie zwyrodnieniowej kręgosłupa nie zawsze jest parametrem o stałym występowaniu i nasileniu. Skala NDI jest narzędziem wielokrotnie bardziej złożonym, oceniającym kilka aspektów życia chorego. [26] Oznacza to, że choć bólu nie obserwujemy w badanych punktach czasowych, to pacjenci cierpieć mogą z powodu niepełnosprawności związanej z chorobą w innych aspektach życia. Na tej podstawie, ostrożnie sformułować można stwierdzenie, że osiadanie wpływa na kliniczne efekty leczenia choroby zwyrodnieniowej w odcinku szyjnym kręgosłupa.

Konkludując założenia i cele niniejszej dysertacji należy przypuszczać, iż zjawisko osiadania traktowane powinno być jako powikłanie leczenia operacyjnego choroby zwyrodnieniowej odcinka szyjnego kręgosłupa techniką ACDF. Profilaktyka osiadania powinna się opierać o dobranie odpowiedniego rozmiaru implantu do operowanego przypadku, położenia w segmencie oraz przedoperacyjnych warunków anatomicznych pacjenta.

Zlekceważenie opisanych relacji, może wpływać na wynik leczenia, skutkując obniżeniem jakości życia pacjentów poddanych interwencji operacyjnej.

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Rozdział VIII. – Streszczenie w języku polskim:

Niniejsza praca doktorska, powstała w oparciu o cykl publikacji. Podjęto w niej tematykę osiadania implantu międzytrzonowego w leczeniu choroby zwyrodnieniowej krążków międzykręgowych odcinka szyjnego kręgosłupa. W analizie oparto się na radiologicznych czynnikach ryzyka osiadania oraz jego wpływu na wynik kliniczny leczenia. W tym celu przeprowadzono badanie obserwacyjne będące składową większego projektu badawczego o charakterze prospektywnym, oceniające pacjentów zakwalifikowanych do leczenia z powodu dyskopatii szyjnej oraz operowanych metodą ACDF. Spośród 193 osób w populacji chorych poddanej ocenie, do badania zakwalifikowano 104 pacjentów. U wszystkich wykonano ACDF jedno- lub dwupoziomowy z zastosowaniem implantów międzytrzonowych wykonanych z PEEK (polyetheretherketone) z lub bez dodatkowej powłoki tytanowej. Oceny radiologicznej operowanych poziomów dokonywano u pacjentów dzień przed zabiegiem oraz dzień po, miesiąc, 6 miesięcy i 12 miesięcy po operacji. W tych punktach czasowych uzyskiwano również dane kliniczne za pomocą skal VAS (Visual Analogue Scale) oraz NDI (Neck Disability Index). Oceniono radiologiczne czynniki ryzyka związane z rozmiarem implantu, jego położeniem w przestrzeni międzykręgowej oraz z anatomicznymi warunkami operowanego segmentu. Dodatkowo wykonano ocenę wpływu parametrów balansu strzałkowego w odcinku szyjnym kręgosłupa na występowanie osiadania. Zebrane dane poddano analizie statystycznej. Zaobserwowano zależność między wysokością implantu, a wysokością przestrzeni międzykręgowej oraz

wysokością segmentu ruchowego kręgosłupa w zakresie częstości występowania osiadania implantu oraz zaawansowania tego zjawiska. Zbyt duże, w stosunku do operowanych przestrzeni, implanty osiadały częściej. W zakresie parametrów balansu strzałkowego zaobserwowano, że im bardziej zaburzony balans mierzony parametrem C2-SVA tym większe ryzyko osiadania. Ocena kliniczna ujawniła wpływ osiadania na bóle kręgosłupa szyjnego i jakość funkcjonowania chorego, a także korelację ze stopniem osiadania. Wszystkie powyższe informacje pozwalają wysunąć przypuszczenie, że osiadanie jest powikłaniem wpływającym na efekt kliniczny leczenia operacyjnego w chorobie zwyrodnieniowej krążków międzykręgowych odcinka szyjnego kręgosłupa. Ponadto, aby minimalizować jego ryzyko należy poświęcać odpowiednio dużo uwagi odpowiedniemu dopasowaniu implantu do warunków anatomicznych operowanego segmentu.

Rozdział IX. – Streszczenie w języku angielskim:

This doctoral dissertation is founded upon a series of research publications delving into the intricacies of interbody implant subsidence in the management of degenerative cervical intervertebral disc disease. The thesis centers on an analysis of radiological risk factors associated with subsidence and its implications for treatment outcomes. To this end, an observational study was conducted as part of a comprehensive prospective research endeavor, focusing on patients undergoing treatment for cervical discopathy via the anterior cervical discectomy with fusion (ACDF) technique. Out of an initial pool of 193 individuals, 104 patients meeting the study's criteria were included. The ACDF procedures, spanning one or two levels, entailed the utilization of PEEK (polyetheretherketone) interbody implants, with or without an adjunct titanium coating. Radiological evaluations were conducted preoperatively, postoperatively, and at subsequent intervals of one, six, and twelve months. Concurrent clinical assessments employing the Visual Analogue Scale (VAS) and Neck Disability Index (NDI) scales were undertaken. Radiological risk factors, including implant size, intervertebral space location, and segmental anatomical characteristics, were meticulously evaluated. Furthermore, the influence of sagittal balance parameters within the cervical spine on subsidence incidence was scrutinized. Statistical analyses revealed a correlation between implant-to-space height ratios and subsidence occurrence and severity, with oversized implants demonstrating a higher propensity for subsidence. Notably, disruptions in sagittal balance, as evidenced by the C2-SVA parameter, were associated with heightened subsidence risk. Clinical

evaluations underscored the impact of subsidence on cervical spine pain and functional quality, revealing correlations with subsidence severity. Collectively, these findings underscore subsidence as a consequential complication influencing the clinical outcomes of surgical interventions for degenerative cervical intervertebral disc disease. To mitigate subsidence risk, meticulous attention must be paid to aligning the implant appropriately with the anatomical conditions of the treated segment.

Rozdział X. – Zgoda komisji bioetycznej:



KRAKOWSKA AKADEMIA im. Andrzeja Frycza Modrzewskiego

KOMISJA BIOETYCZNA

ul. Gustawa Herlinga-Grudzińskiego 1, 30-705 Kraków
tel. 12 252 45 23, fax: 12 252 45 23

e-mail: komisja.bioetyczna@afm.edu.pl

Kraków, 24.01.2019r.

Uchwała nr 4/2019

Komisji Bioetycznej Krakowskiej Akademii im. Andrzeja Frycza Modrzewskiego

z dnia 24 stycznia 2019r

w sprawie wydania opinii nr KBKA/4/O/2019

Dotyczy określonego poniżej wniosku o wydanie opinii złożonego do Komisji Bioetycznej
Kierownik tematu (wnioskodawca): dr Tomasz Pardała

Miejsce zatrudnienia:

Krakowska Akademia im. Andrzeja Frycza Modrzewskiego,
Wydział Lekarski i Nauk o Zdrowiu; Klinika Ortopedii i Traumatologii 30-705 Kraków, ul.
Gustawa Herlinga-Grudzińskiego 1.

Tytuł projektu badawczego: Implanty z materiału PEEK (polyetheretherketone) a implanty z
materiału PEEK pokryte warstwą tytanową w leczeniu chirurgicznym choroby dyskowej
kręgosłupa szyjnego - ocena wzrostu kostnego, zjawiska osiadania implantów, zmian
dotległości bólowych i jakości życia. Randomizowane badanie kliniczne

Komisja po zapoznaniu się z w/w wnioskiem wyraża pozytywną opinię w sprawie
przeprowadzenia badań określonych we wniosku. Po zakończeniu badań wnioskodawca jest
zobowiązany przedstawić Komisji raport końcowy.
Badanie może być prowadzone do 31.12.2021r.

Uchwała podpisana przez następujących członków Komisji Bioetycznej (w oryginale właściwe podpisy):

Prof. dr hab. Krzysztof Rytlewski (przewodniczący)
Dr Małgorzata Pasek (Z-ca przewodniczącego)
Dr hab. Agata Baldys – Waligórska
Dr hab. Olga Dryla
Prof. dr hab. Stanisław Kwiatkowski
Dr Janusz Legutko
Dr hab. Andrzej Muszala
Prof. nadzw. dr hab. Leszek Pawłowski
Mgr Anna Szetela
Dr Jarosław Zawiliński

ODPIS

Potwierdzam odbiór
Grodzicki

Komisja Bioetyczna
Krakowskiej Akademii
im. Andrzeja Frycza Modrzewskiego
ul. Gustawa Herlinga-Grudzińskiego 1, 30-705 Kraków

Sekretarz
Komisji Bioetycznej
Marta Banach
mgr Marta Banach

Przewodniczący Komisji Bioetycznej
Krakowskiej Akademii
im. Andrzeja Frycza Modrzewskiego
Prof. dr hab. n. med. Krzysztof Rytlewski

Rozdział XI. – Oświadczenie autora:

Załącznik nr 4 do Zarządzenia nr 228/2021 Rektora Uniwersytetu Rzeszowskiego z dnia 1 grudnia 2021 roku w sprawie ustalenia procedury antyplagiatowej w Uniwersytecie Rzeszowskim

OŚWIADCZENIE

doktoranta/osoby ubiegającej się o nadanie stopnia naukowego doktora.

lek. Adam Bębenek

Imię (imiona) i nazwisko

*Klinika Neurochirurgii Uniwersytetu Rzeszowskiego
Szpital Wojewódzki im. Św. Łukasza w Tarnowie*

Nazwa jednostki

Nauki medyczne

nazwa dyscypliny

Oświadczam, że moja rozprawa doktorska pt.: „*Osiadanie implantów międzytrzonowych w operacyjnym leczeniu choroby zwyrodnieniowej odcinka szyjnego kręgosłupa – znaczenie kliniczne oraz radiologiczne czynniki ryzyka.*”

- 1) została przygotowana przeze mnie samodzielnie*,
- 2) nie narusza praw autorskich w rozumieniu ustawy z dnia 4 lutego 1994 roku o prawie autorskim i prawach pokrewnych (t.j. Dz.U. z 2021 r., poz. 1062) oraz dóbr osobistych chronionych prawem cywilnym,
- 3) nie zawiera danych i informacji, które uzyskałem/am w sposób niedozwolony,
- 4) nie była podstawą nadania tytułu zawodowego lub stopnia naukowego ani mnie ani innej osobie.

Ponadto oświadczam, że treść pracy przedstawionej przeze mnie do obrony, zawarta na przekazywanym nośniku elektronicznym, jest identyczna z wersją drukowaną.

Adam Bębenek
.....
(miejscowość, data)

Adam Bębenek
.....
(czytelny podpis autora pracy)

* uwzględniając merytoryczny wkład promotora pracy

Rozdział XII. – Oświadczenia współautorów:

Kraków, 20.02.2024

Dr n. med. Bartosz Godlewski

Kierownik Pododdziału Chirurgii Kręgosłupa
Oddział Kliniczny Ortopedii i Traumatologii Narządu Ruchu z Pododdziałem Chirurgii
Kręgosłupa; Szpital Św. Rafała SCANNED S.A. w Krakowie.

OŚWIADCZENIE

Jako współautor prac:

1. **Bębenek A.**, Dominiak M, Godlewski B. Cervical Sagittal Balance: Impact on Clinical Outcomes and Subsidence in Anterior Cervical Discectomy and Fusion. *Biomedicines*. 2023; 11(12):3310. <https://doi.org/10.3390/biomedicines11123310>.
2. **Bębenek A.**, Godlewski B. (2023). Anterior cervical discectomy and fusion (ACDF) with and without plating: a comparison of radiological and clinical outcomes [published online ahead of print, 2023 Sep 28]. *Advances in Clinical and Experimental Medicine*: 10.17219/acem/172062. DOI: <https://doi.org/10.17219/acem/172062>.
3. **Bębenek A.**, Dominiak M, Karpiński G, Pawelczyk T, Godlewski B. Impact of Implant Size and Position on Subsidence Degree after Anterior Cervical Discectomy and Fusion: Radiological and Clinical Analysis. *Journal of Clinical Medicine* 2024; 13(4):1151. <https://doi.org/10.3390/jcm13041151>.

Oświadczam, iż mój własny wkład merytoryczny w przygotowanie, przeprowadzenie i opracowanie badań oraz przedstawienie pracy w formie publikacji polegał na:

- opracowaniu koncepcji badań
- kuratelii nad danymi
- nadzorze realizacji działań badawczych
- recenzji oraz krytycznej ocenie przygotowywanych manuskryptów

Jednocześnie wyrażam zgodę na przedłożenie ww. prac przez lek. Adama Bębenka jako część rozprawy doktorskiej w formie spójnego tematycznie zbioru artykułów opublikowanych w czasopiśmie naukowym.

Oświadczam, iż samodzielna i możliwa do wyodrębnienia części ww. pracy wykazuje indywidualny wkład lek. Adama Bębenka polegający na:

- opracowaniu koncepcji badań
- zbieranie i przetwarzanie danych
- przeprowadzenie analiz statystycznych
- opracowaniu, interpretacji i przedstawieniu wyników
- przygotowaniu oraz redakcji manuskryptu

dr n. med.
Bartosz GODLEWSKI
specjalista neurochirurg



.....
(podpis współautora)

Kraków, 20.02.2024

Lek. Maciej Dominiak

Oddział Kliniczny Ortopedii i Traumatologii Narządu Ruchu z Pododdziałem Chirurgii Kręgosłupa: Szpital Św. Rafała SCANNED S.A. w Krakowie.

OŚWIADCZENIE

Jako współautor prac:

1. **Bębenek A.**, Dominiak M, Godlewski B. Cervical Sagittal Balance: Impact on Clinical Outcomes and Subsidence in Anterior Cervical Discectomy and Fusion. *Biomedicines*. 2023; 11(12):3310. <https://doi.org/10.3390/biomedicines11123310>.
2. **Bębenek A.**, Dominiak M, Karpiński G, Pawelczyk T, Godlewski B. Impact of Implant Size and Position on Subsidence Degree after Anterior Cervical Discectomy and Fusion: Radiological and Clinical Analysis. *Journal of Clinical Medicine* 2024; 13(4):1151. <https://doi.org/10.3390/jcm13041151>.

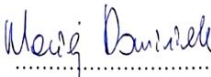
Oświadczam, iż mój własny wkład merytoryczny w przygotowanie, przeprowadzenie i opracowanie badań oraz przedstawienie pracy w formie publikacji polegał na:

- zbieranie i przetwarzanie danych

Jednocześnie wyrażam zgodę na przedłożenie ww. prac przez lek. Adama Bębenka jako część rozprawy doktorskiej w formie spójnego tematycznie zbioru artykułów opublikowanych w czasopismach naukowych.

Oświadczam, iż samodzielna i możliwa do wyodrębnienia części ww. pracy wykazuje indywidualny wkład lek. Adama Bębenka polegający na:

- opracowaniu koncepcji badań
- zbieranie i przetwarzanie danych
- przeprowadzenie analiz statystycznych
- opracowaniu, interpretacji i przedstawieniu wyników
- przygotowaniu oraz redakcji manuskryptu


.....
(podpis współautora)

MACIEJ DOMINIAK
PEKATZ
3538344

Łódź, 20.02.2024

Dr hab. n. med. Tomasz Pawelczyk, Prof. UM w Łodzi
Adiunkt, Klinika Zaburzeń Afektywnych i Psychotycznych
Uniwersytet Medyczny w Łodzi

OŚWIADCZENIE

Jako współautor prac:

1. **Bębenek A.**, Dominiak M, Karpiński G, Pawelczyk T, Godlewski B. Impact of Implant Size and Position on Subsidence Degree after Anterior Cervical Discectomy and Fusion: Radiological and Clinical Analysis. "*Journal of Clinical Medicine*" 2024; 13(4):1151. <https://doi.org/10.3390/jcm13041151>.

Oświadczam, iż mój własny wkład merytoryczny w przygotowanie, przeprowadzenie i opracowanie badań oraz przedstawienie pracy w formie publikacji polegał na:

- przeprowadzenie analizy statystycznej wyników

Jednocześnie wyrażam zgodę na przedłożenie ww. prac przez lek. Adama Bębenka jako część rozprawy doktorskiej w formie spójnego tematycznie zbioru artykułów opublikowanych w czasopiśmie naukowym.

Oświadczam, iż samodzielna i możliwa do wyodrębnienia części ww. pracy wykazuje indywidualny wkład lek. Adama Bębenka polegający na:

- opracowaniu koncepcji badań
- zbieranie i przetwarzanie danych
- opracowaniu, interpretacji i przedstawieniu wyników
- przygotowaniu oraz redakcji manuskryptu


.....
(podpis współautora)

Kraków, 12.03.2024

Lek. Grzegorz Karpiński

Oddział Kliniczny Ortopedii i Traumatologii Narządu Ruchu z Pododdziałem Chirurgii Kręgosłupa; Szpital Św. Rafała SCANNED S.A. w Krakowie.

OŚWIADCZENIE

Jako współautor prac:

1. **Bębenek A.**, Dominiak M, Karpiński G, Pawełczyk T, Godlewski B. Impact of Implant Size and Position on Subsidence Degree after Anterior Cervical Discectomy and Fusion: Radiological and Clinical Analysis. *Journal of Clinical Medicine* 2024; 13(4):1151. <https://doi.org/10.3390/jcm13041151>.


Oświadczam, iż mój własny wkład merytoryczny w przygotowanie, przeprowadzenie i opracowanie badań oraz przedstawienie pracy w formie publikacji polegał na:

- zbieranie i przetwarzanie danych

Jednocześnie wyrażam zgodę na przedłożenie ww. prac przez lek. Adama Bębenka jako część rozprawy doktorskiej w formie spójnego tematycznie zbioru artykułów opublikowanych w czasopiśmie naukowych.

Oświadczam, iż samodzielna i możliwa do wyodrębnienia części ww. pracy wykazuje indywidualny wkład lek. Adama Bębenka polegający na:

- opracowaniu koncepcji badań
- zbieranie i przetwarzanie danych
- przeprowadzenie analiz statystycznych
- opracowaniu, interpretacji i przedstawieniu wyników
- przygotowaniu oraz redakcji manuskryptu


.....
(podpis współautora)

Rozdział XIII. – Dorobek naukowy:

Oryginalne pełnotekstowe prace naukowe – chronologicznie			
Lp.	Opis bibliograficzny pracy	IF	MNiSW
1.	Stanuszek A., Bębenek A. , Milczarek O., Kwiatkowski S.: <i>Return to play in children with shunted hydrocephalus</i> . Journal of Neurosurgery. Pediatrics 2021; 29(1):1-9 p-ISSN:1933-0707 e-ISSN:1933-0715 DOI: 10.3171/2021.7.PEDS21127	2,713	100,0
2.	Bębenek A. , Milczarek O., Kwiatkowski S.: <i>Potential Risk Factors for Ventriculoperitoneal Shunt Implantation in Paediatric Patients with Posthemorrhagic Hydrocephalus of Prematurity Treated with Subcutaneous Reservoir: An Institutional Experience</i> . Neuropediatrics 2022; 53(1):1-6. p-ISSN: 0174-304X e-ISSN: 1439-1899 DOI: 10.1055/s-0041-1732311	1.400	70,0
3.	Godlewski B., Bębenek A. , Dominiak M., Karpiński G., Cieślik P., Pawełczyk T.: <i>PEEK versus titanium-coated PEEK cervical cages: fusion rate</i> . Acta Neurochirurgica 2022; 164(6):1501-1507 DOI: 10.1007/s00701-022-05217-7 p-ISSN: 0001-6268 e-ISSN: 0942-0940	2.400	100,0
4.	Godlewski B., Bębenek A. , Dominiak M., Karpiński G., Cieślik P., Pawełczyk T.: <i>Subsidence following cervical discectomy and implant-to-bone ratio</i> . BMC Musculoskeletal Disorders 2022; 23(1), Article number: 750 p-ISSN: 1471-2474 DOI: 10.1186/s12891-022-05698-8	2.300	100,0

5.	Godlewski B., Bębenek A. , Dominiak M., Bochniak M., Cieślik P., Pawełczyk T.: <i>Reliability and utility of various methods for evaluation of bone union after anterior cervical discectomy and fusion</i> . Journal of Clinical Medicine 2022; 1(20), 6066 p-ISSN: 2077-0383 DOI: 10.3390/jcm11206066	3.900	140,0
6.	2. Godlewski B., Bębenek A. , Dominiak M., Bochniak M., Cieślik P., Pawełczyk T.: <i>Adjacent segment mobility after ACDF considering fusion status at the implant insertion site</i> . European Spine Journal 2023; 32(5):1616-1623, Epub 2023 Mar 14. p-ISSN: 0940-6719 e-ISSN: 1432-0932 DOI:10.1007/s00586-023-07634-3	2.800	100,0
7.	Bębenek A. , Dominiak M, Godlewski B.: <i>Cervical Sagittal Balance: Impact on Clinical Outcomes and Subsidence in Anterior Cervical Discectomy and Fusion</i> . Biomedicines 2023; 11(12), 3310. p-ISSN: 2227-9059 e-ISSN: 2227-9059 DOI:10.3390/biomedicines11123310	4.700	100,0
8.	Bębenek A. , Dominiak M., Karpiński G., Pawełczyk T., Godlewski B.: <i>Impact of Implant Size and Position on Subsidence Degree after Anterior Cervical Discectomy and Fusion: Radiological and Clinical Analysis</i> . Journal of Clinical Medicine 2024; 13(4), 1151. p-ISSN: 2077-0383 https://doi.org/10.3390/jcm13041151	3.900	140,0
Suma punktów (I A) :		24.113	850,0

Prace poglądowe – chronologicznie:			
L.p.	Opis bibliograficzny pracy	IF	MNiSW
1.	Bębenek A. , Godlewski B.: <i>Anterior cervical discectomy and fusion (ACDF) with and without plating: a comparison of radiological and clinical outcomes.</i> Advances in Clinical and Experimental Medicine 2023; [published online ahead of print, 2023 Sep 28] 10.17219/acem/172062. p-ISSN:1899-5276 e-ISSN:2451-2680 DOI: 10.17219/acem/172062	2.100	140,0
Suma punktów (III A) :		2.100	140,0

Opisy przypadków – chronologicznie:			
L.p.	Opis bibliograficzny pracy	IF	MNiSW
1.	Godlewski B., Dominiak M., Bębenek A. : <i>Revision procedure after surgery for atypical hangman's fracture primarily performed only from posterior approach – an attempt to maintain head rotation: case report.</i> International Medical Case Report Journal 2023; 16: 377–383. p-ISSN:1179-142X DOI:10.2147/IMCRJ.S419321	0.900	40,0
2.	Bębenek A. , Dominiak M., Karpiński G., Godlewski B.: <i>Irreducible L5/S1 spondyloptosis in over 20 years after neglected trauma treated with modified Grob's technique – case report.</i> International Medical Case Report Journal 2023; 16: 537–543. p-ISSN:1179-142X DOI:10.2147/IMCRJ.S428840	0.900	40,0
Suma punktów(IVA):		1.800	80,0

Typ publikacji	ilość	IF	MNiSW
I. Oryginalne pełnotekstowe prace naukowe (bez streszczeń zjazdowych i konferencyjnych, prac w suplementach czasopism, listów do redakcji oraz udziału autora wymienionego w dodatku (appendix) jako uczestnika badań wielośrodkowych).			
A. w czasopismach posiadającym „impact factor”	8	24.113	850,0
B. w czasopismach nieposiadających „impact factor”			
II. Rozdziały w podręcznikach / materiałach konferencyjnych			
A. międzynarodowych			
B. krajowych			
C. autorstwo monografii			
III. Prace pogładowe (bez streszczeń, zjazdowych i konferencyjnych, prac w suplementach czasopism, listów do redakcji oraz udziału autora wymienionego w dodatku (appendix) jako uczestnika badań wielośrodkowych)			
A. w czasopismach posiadającym „impact factor”	1	2.100	140,0
B. w czasopismach nieposiadających „impact factor”			
IV. Opisy przypadków			
A. w czasopismach posiadającym „impact factor”	2	1.800	80,0
B. w czasopismach nieposiadających „impact factor”			
V. Inne prace (m.in., streszczenia, skrypty wykładów i ćwiczeń, poradniki zawodowe, prace popularno-naukowe, prace w suplementach czasopism, recenzje oraz wznowienia publikacji).			
a. w języku obcym			
b. w języku polskim			
VI. Streszczenia ze zjazdów			
c. międzynarodowych			
d. krajowych			
Razem:	11	28.013	1070,0

Cytowania na dzień 20.02.2024

Web of Science Core Collection: 12 ; Index Hirscha: 2 (z autocytowaniami)

8; Indeks Hirscha : 2 (bez autocytowań)

Scopus: 15; Index Hirscha: 2 (z autocytowaniami)

9; Indeks Hirscha: 2 (bez autocytowań)