Acta Neurochirurgica (2024) 166:40
https://doi.org/10.1007/s00701-024-05930-5

ORIGINAL ARTICLE

Bone resorption around the annular closure device during a postoperative follow-up of 8 years

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Received: 24 July 2023 / Accepted: 3 December 2023

Abstract

Objective Annular closure device (ACD) implantation is considered to be an effective means of preventing reherniation after microdiscectomy; however, there is an issue: the bone may resorb around the ACD. The causes of vertebral bone resorption remain unexplored; the dynamics of changes in bone resorption around the ACD have not yet been assessed or characterized.

Methods One hundred thirty-three patients underwent ACD implantation after microdiscectomy, and 107 of them were followed up for 8 years after surgery (Oswestry, VAS). Lumbar CT scans helped characterize the bone resorption area around the ACD.

Results The median of follow-up was 85 [74; 93] months (from 73 to 105 months). The prevalence of bone resorption around the ACD was up to 63.6%, and it was mainly around the polymer mesh of the ACD (70.6%). The resorbed bone volume increased with time and reached its maximum of 5.2 cm^3 (12% of the vertebral body volume) once a sclerotic rim developed around the bone resorption area. No differences in VAS pain intensity or in Oswestry Disability Index were found between patients with resorption and patients without it ($p > 0.05$). The volume of the intervertebral disc before surgery is a predictor of bone resorption (OR = 0.79, $p = 0.009$): if it is less than 13.2 cm^3, the risk of bone resorption increases significantly ($p < 0.05$).

Conclusion The majority of patients (up to 63.6%) with implanted ACDs have vertebral bone resorption around them. The bone resorption area around the ACD mesh increases with time to up to 12% of the vertebral body volume, with no clinical evidence, though. The formation of a sclerotic rim prevents the bone resorption area from further growth. If the volume of the intervertebral disc before surgery is less than 13.2 cm^3, the risk of bone resorption increases significantly.

Keywords Lumbar disc herniation · Microdiscectomy · Annular closure device · Bone resorption · Recurrent herniation

Introduction

Intervertebral disc herniation is more common in the working-age people and is therefore of great socio-economic importance. However, hernias in patients who have undergone microdiscectomy recur at a rate of up to 18% within 2 years [1], requiring re-operation in almost 80% of cases [14]. Recurrent disc herniation occurs due to advancing disc degeneration and migration of disc fragments through the defect in the annulus fibrosus [8, 15]. To reduce the risk of disc reherniation, aggressive discectomy is performed in some cases. Additionally, implants and methods have been developed that, when used in combination with discectomy, serve the purpose [2, 15].

To prevent recurrent disc herniation, it was proposed to use ACD implants closing annulus fibrosus defects after limited discectomy. ACD implantation was demonstrated to reduce disc re-herniation to 1.5–2.9% of the device patients, with the rates of complications being comparable [4, 6]. However, ACD implantation as a mean to prevent reherniation is possible only in a subpopulation of patients, whose discs are high and the defect in the annulus fibrosus is large [16]. At the same time, some studies indicate that shortly after ACD implantation vertebral endplate resorption occurs around the implant, and the prevalence of such resorption

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Published online: 27 January 2024

events reaches 84–99% [5, 16]; however, they were not found to be associated with clinical symptoms or clinical outcomes [5, 6]. Bone resorption areas around the ACD increase in size and number over time [3]; however, a number of questions remain unanswered: How large can these resorption bone areas be? Will resorption destroy the vertebral body completely? What are the predictors of bone resorption? Can the resorption process be reversed? What is the largest bone resorption area when the condition has to symptoms?

Some authors associate bone resorption with a mechanical irritation of the endplate at the contact site with the polymer mesh [5], some suggest a faster progression of degenerative changes in the upper vertebral endplate [10], where the mesh is placed, and some suspect infection around the ACD [9].

This study is based on our ACD experience and represents a retrospective analysis of data prospectively collected during a postoperative follow-up of 8 years (our previous work describes the implications of ACD implantation within the first year after microdiscectomy [6]). When considering long-term effects, we wanted to learn more about bone resorption.

The purpose of the study is as follows: to characterize bone resorption around the ACD. The study hypothesis is that a permanent contact between the ACD mesh and the vertebral endplate provokes bone resorption, but the growth of the bone resorption area is a self-limiting process.

Materials and methods

Patient population

This study represents a retrospective analysis of data from all consecutive patients who have undergone limited discectomy and implantation of the Barricaid Annular Closure Device (Intrinsic Therapeutics, Inc. Woburn, MA, USA). ACD implantation was indicated for reducing reherniation and reoperation rates in patients with radiculopathy (with or without back pain) attributed to posterior or posterolateral herniation with neural compression confirmed by MRI. ACD implantation was used to treat a large annular defect (4–6-mm tall and 6–10-mm wide) with a minimum posterior disc height of 5 mm at the level of surgery following limited primary discectomy at a single lumbar level.

The criteria for exclusion from the current study were the unwillingness or/and inability to continue participation in the study and the unwillingness or/and inability to be assessed by CT.

Outcome assessments

Patients were assessed on admission and in the postoperative period up to the present. For convenience, the postoperative visits were at 12 months (mandatory), at 3–5 years (optional), and at 6–8 years (mandatory) after surgery. Patient-reported outcomes included leg and back pain intensity measured with the Visual Analog Scale (VAS) and Oswestry Disability Index (ODI).

Imaging

Magnetic resonance imaging (MRI) and multisite computed tomography (CT) of the lumbar spine were performed in all patients at the time of observation. All MRI scans included T1- and T2-weighted sagittal images. MRI scans were used to detect intervertebral disc protrusions and/or hernias and/or reherniation, to assess the degree of intervertebral disc degeneration according to Pfirrmann grades [12], to ascertain the presence and type of Modic changes [11], and to evaluate endplate damage according to Rajasekaran [13], all at the level of surgery.

CT of the lumbar spine was performed in all patients on a 64-slice Siemens SOMATOM go.TOP CT system. The CT scans told us about the position of the implant, about whether or not there was an event of bone resorption around the implant elements, and if there was, we were given enough information to calculate the volume of the resorbed bone using the syngo.via Workstation (Fig. 1). The endplate defect was evaluated at three points: at its edges and in its middle. The evaluation was repeated in three planes: axial, frontal, and sagittal. Based on these measurements, the syngo.via imaging software isolated the defect and calculated its volume.

The volume of the intervertebral disc was calculated as $V = \pi * r^2 * h$, where π is *3.14*, r is the radius of the disc, and h is the intervertebral disc height (Fig. 2). To determine the intervertebral disc height, h, on the sagittal CT scans, measurements were taken at three points—in the anterior, middle, and posterior sections—at the level of the spinous processes, the three values were averaged, and the result was taken as the target value. The disc radius, r, was determined by reading the axial CT scans. The disc was considered to be a conditional circle.

Bone resorption was acknowledged if postoperative CT scans revealed a bone loss area around the ACD mesh or anchor in the vertebral body through the vertebral endplate.

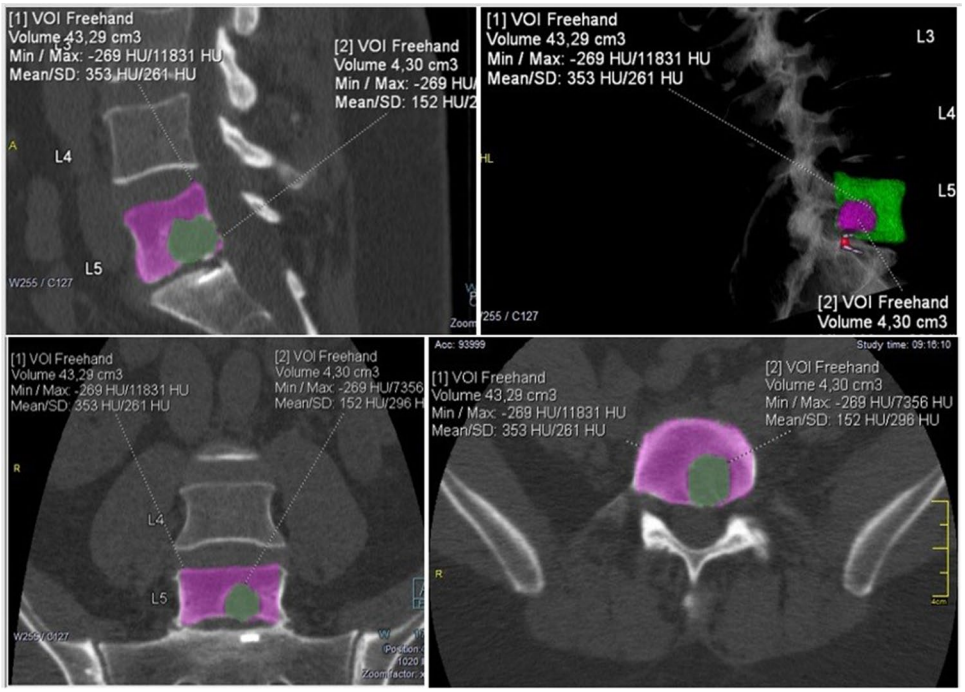

Fig. 1 Measuring the volumes of the vertebral body and resorbed bone around the ACD mesh. Explanations are given in the text

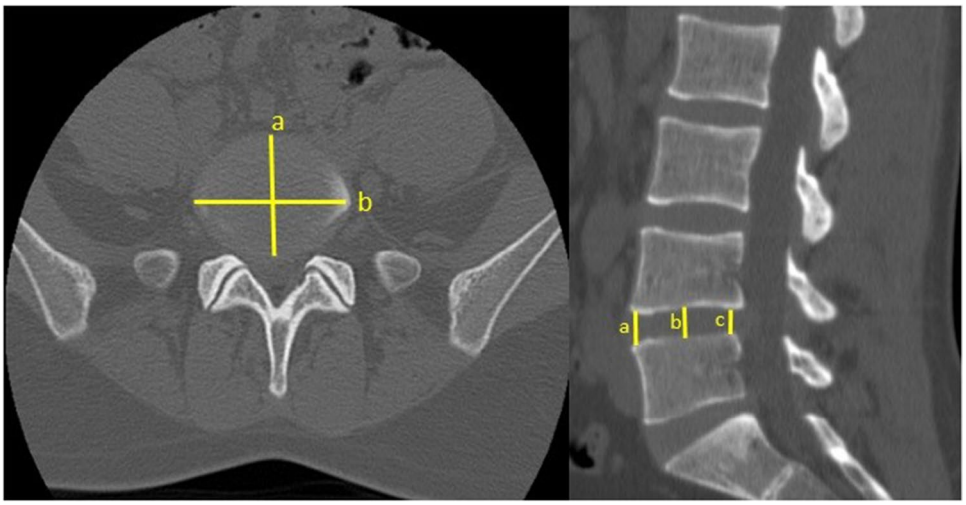

Fig. 2 Calculating the disc radius (*r*) and measuring the intervertebral disc height (*h*) by reading the CT scans of the lumbar spine in the axial and the sagittal plane

Statistical analysis

The hypotheses about the equality of the sample distributions for continuous indicators at different time points were tested using the Wilcoxon criterion; the between-group comparisons at each time point were carried out using the Mann–Whitney U-criterion. Binary and categorical indicators were compared using two-sided Fisher's exact criterion. The effects of potential prognostic factors on the risk of bone resorption were explored using univariate and multifactorial logistic regression models. The statistical hypotheses were tested at a critical significance level of 0.05, i.e., the difference was considered statistically significant at $p < 0.05$.

All statistical calculations were carried out using RStudio (version 2021.09.2 Build 382–© 2009–2022 RStudio, Inc., USA, URL https://www.rstudio.com/) in the R programming language (version 4.0.2, URLhttps://www.R-project.org/).

Results

A total of 771 patients underwent lumbar microdiscectomy between October 2013 and October 2016 in a single hospital. Of them, 150 (19.46%) met preoperative eligibility

criteria for ACD implantation and 133 (18.47%) underwent lumbar microdiscectomy and ACD implantation after intraoperative assessment [16] of the annular defect size. Thus, the study included 133 patients with ACD implantation, 73 (54.9%) patients were men, and the median age was 38.3 [27.6; 49.2] years. A detailed description of the patients and the results of their surgery with ACD implantation in a 1-year follow-up were provided in our previous article [6]. The median of the follow-up period in the current study was 85 [74; 93] months (from 73 to 105 months). Only 19.5% of the patients (26/133) were lost to follow-up (Fig. 3), and 80.5% (107/133) were available at 6–8 years following surgery. Only 16 patients were available at 3–5 years following surgery, since this visit was optional.

Within 1 year following surgery with ACD implantation, four reoperations were performed (for a detailed description, see our first article on the matter [6]). Within the subsequent follow-up periods, three patients (2.8%, 3/107) had recurrent disc herniation at 3.5, 4.5, and 7.5 years, respectively. In two patients (1.9%, 2/107), recurrent disc herniations were detected on the MRI scans of the lumbar spine, but they were asymptomatic (that is, they had no clinical manifestations), and so no additional surgery was deemed necessary.

Scores for back and leg pain severity and Oswestry Disability Index improved significantly withing a postoperative follow-up of 8 years (Fig. 4).

The resorbed bone around the ACD was observed in the majority of the patients, 68 (63.6%, 68/107), starting from month 6 after surgery (Table 1).

In 39 patients (36.4%), no bone resorption around the ACD was observed, and the follow-up period for these patients was up to 92 months (Fig. 5). Bone resorption had identical rates of occurrence at L4–L5 and L5–S1 (42.5% vs. 57.5%, respectively, $p = 0.186$) and none was detected at L3–L4.

In 70.6% (48/68) of all cases with bone resorption, it was around the ACD mesh, and the resorption area was normally in the form of a rounded or a multi-chamber cavity in the vertebral body. In 29.4% (20/68) of cases, resorbed bone was observed around the ACD anchor and appeared as a thin (not thicker than 1 mm) in the form of a double halo corresponding to the adjacent osteolytic lesions. Only in one case, when the anchor was installed

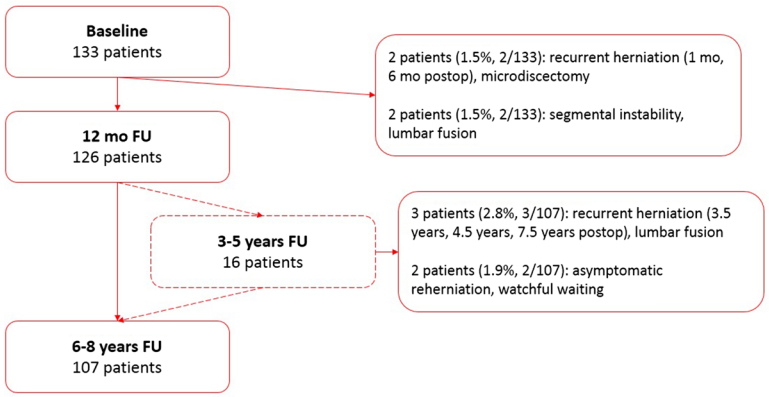

Fig. 3 Flowchart of the study visits, the number of patients, and reoperations

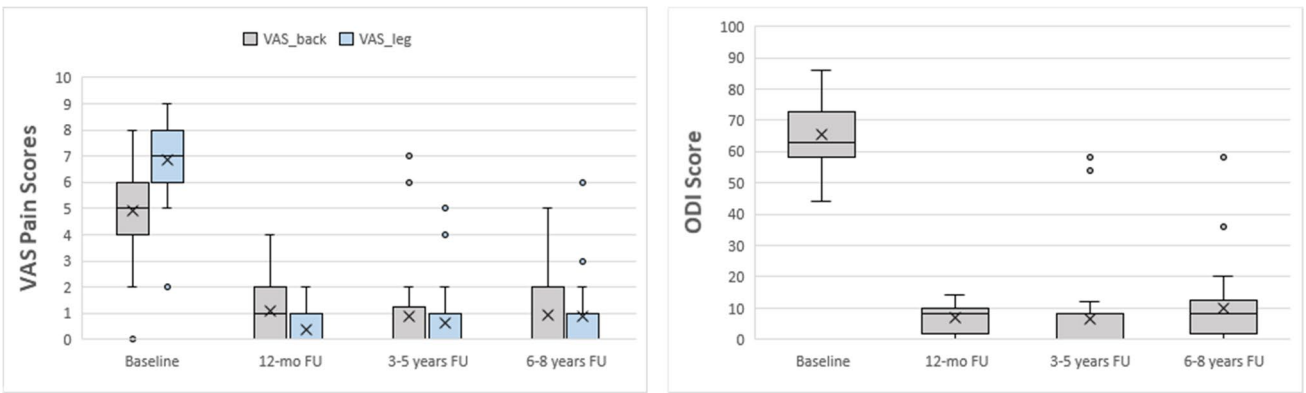

Fig. 4 Summary of back pain, leg pain, and ODI scores within 8 years of follow-up

Table 1 The main characteristics of the patients at the time of observation

Evaluation parameters	Observational period				*p*-value
	On admission	12-month FU	3–5-year FU	6–8-year FU	
Number of patients	133	126	16	107	
Patients with bone resorption (*n* patients with resorption / *n* patients at this visit)*100%	-	1.5%	43.8%	63.6%	
Resorbed bone volume around the ACD, cm^3 (MED [IQR])	-	0.28 [0; 1.61]	0.81 [0.36; 2.75]	1.9 [0.91; 3.35]	12-month FU vs. 3–5-year FU, $p=0.014$ 12-month FU vs. 6–8-year FU, $p=0.002$ 3–5-year FU vs. 6–8-year FU, $p=0.014$

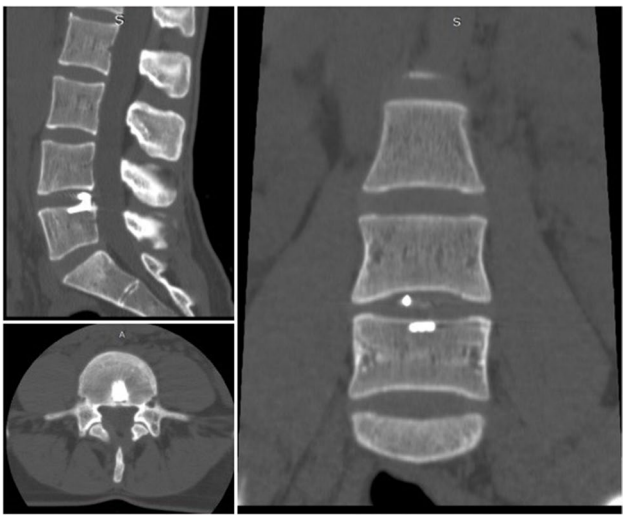

Fig. 5 CT scans of the lumbar spine. 4.5 years after microdiscectomy and ACD implantation; no endplate resorption. The ACD mesh is displaced leftward in the intervertebral disc space

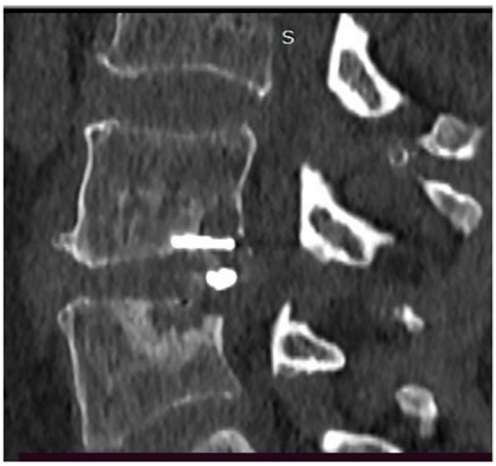

Fig. 6 Bone resorption around the ACD anchor in the overlying vertebral body and around the ACD mesh in the underlying vertebral body

to L4, the bone resorption area around the anchor had a rounded shape and invaded the vertebral body (Fig. 6).

Six patients (8.8%, 6/68) that had the bone resorbed around the anchor had none of it around the mesh; later, these patients were found to have developed sclerotic rims around the resorption areas (Fig. 7).

The CT scans of the lumbar spine revealed that the volume of the resorbed bone increased with time ($p<0.05$) (Table 1). In a long term (6–8 years), all these patients' resorption areas had sclerotic rims and were not growing any longer. In some cases, resorption areas even shrank due to sclerosis (Fig. 8B, C). The maximum resorbed bone volume was 5.2 cm^3 at 84 months following surgery, which amounts to 12% of the vertebral body volume.

The position of the ACD mesh was found to be incorrect in 29.9% of patients (32/107): there were leftward and rightward displacements/migrations within the disc space as well as inversions towards the spinal canal (in 9.3% of patients, 10/107). However, because no signs of nerve compression were observed, no additional surgery was deemed necessary (Fig. 7a, b, c).

The patients with bone resorption had a longer follow-up period than their no-resorption peers (88 months vs. 83 months, respectively, $p=0.025$) (Table 2). The groups did not differ with respect to their within-group sex ratio, surgical level, herniation type, VAS pain intensity in the back and the leg, or the Oswestry Disability Index ($p>0.05$).

The patients with bone resorption had smaller intervertebral disc volumes before surgery than their non-resorption peers (10.9 cm^3 vs. 13.2 cm^3, respectively, $p=0.019$) (Table 3).

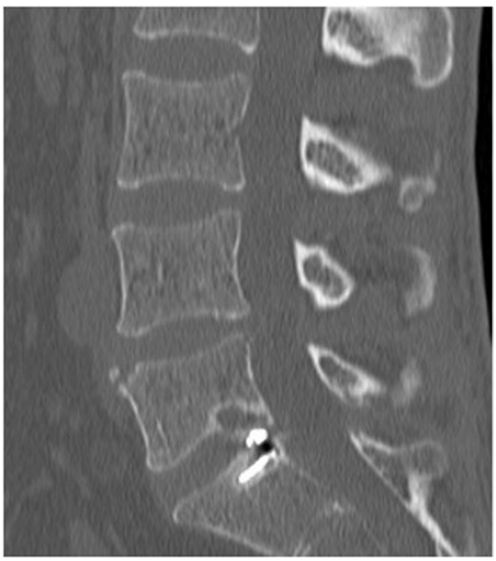

Fig. 7 The resorption area around the ACD mesh in L5 and a double halo around the ACD anchor in S1

The groups of patients did not differ with respect to the volume of tissue removed by microdiscectomy (% of the total disc volume; this is the volume of the removed sequester and the volume of free-lying fragments from the disc cavity), the area of the annulus fibrosus defect, the degree of disc degeneration according to Pfirrmann, the presence and types of Modic changes, or the degree of endplate damage according to Rajasekaran ($p > 0.05$).

The prediction of bone resorption

Predictors of bone resorption around the ACD were identified using logistic regression. One of them was the volume of the intervertebral disc before surgery (OR = 0.79, $p = 0.009$): the smaller the volume, the higher the chances of bone resorption. Using ROC analysis, the threshold value of the disc volume before surgery was determined to be 13.2 cm^3, at which the risk of bone resorption around the ACD increases significantly (AUC = 68.4, a sensitivity of 85%, a specificity of 52.4%; $p < 0.05$).

The effect of total endplate score on the risk of bone resorption before surgery does not reach statistical significance ($p > 0.05$), nor does the presence or type of Modic changes ($p > 0.05$). This implies that neither presence nor absence of endplate defects before surgery has any relevance to bone resorption after ACD implantation. None of the other factors (follow-up period, age, degree of disc degeneration, area of the annulus fibrosus defect) was found to be associated with bone resorption either ($p > 0.05$).

Discussion

In recent years, the number of publications relating to the repair of annulus fibrosus defects after removal of a disc herniation has increased due to a growing popularity of ACD implantation. On the other hand, the authors of most ACD implantation works have affiliations with the "Barricaid" manufacturer, as they explicitly state in the *Disclosure Information*. Here we present an independent and unbiased analysis of information on ACD experience gathered from a long-time observation.

Most ACD studies assess the rates of recurrent disc herniation and reoperations. However, an important aspect of ACD implantation is the occurrence of bone resorption around the implant, especially in a long term.

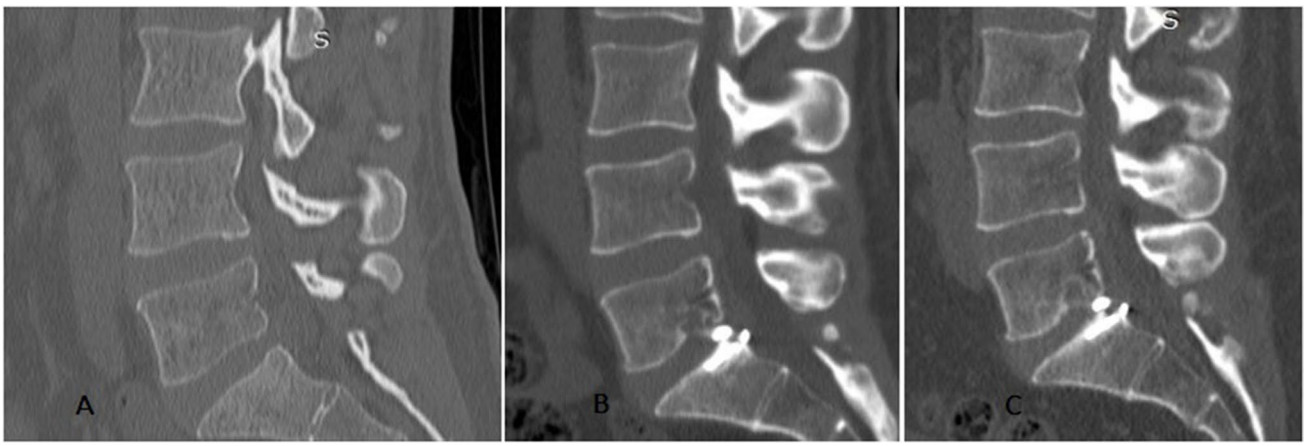

Fig. 8 **A** CT scans of the lumbar spine before surgery (no endplate resorption); **B** 4 years after surgery (the resorption of the lower endplate of L5 around the ACD mesh, the resorbed bone volume is 1.6 cm ^{3}); **C** 6 years after surgery (a sclerotic rim around the bone resorption area, a decrease in resorbed bone volume to 1.3 $cm.^3$)

Table 2 Comparison of the main clinical characteristics between the groups of patients with and without bone resorption around the ACD (MED [IQR], *p*-value)

Indicators		Without bone resorption ($N=39$)	With bone resorption ($N=68$)	*p*-level
Age		44 [37; 50]	39.5 [34; 46.25]	0.277[U]
Sex		F, 20 (51.3%) M, 19 (48.7%)	F, 32 (47.1%) M, 36 (52.9%)	0.791[F]
BMI		25.18 [23.18; 29.07]	26.87 [24.11; 30.81]	0.358[U]
Follow-up, months		83 [76; 88]	88 [73.25; 96.5]	0.025[U]
Level, quantity (%)	L3–L4 L4–L5 L5–S1	3 (7.7%) 17 (43.6%) 19 (48.7%)	0 (0%) 29 (42.6%) 39 (57.4%)	0.186[F]
VAS back		2 [0; 2]	0.5 [0; 2]	0.648[U]
VAS leg		0 [0; 0]	0 [0; 0]	0.658[U]
Oswestry		10 [8; 16]	8 [3.5; 16.5]	0.603[U]

The superscript symbol "[U]" indicates the significance levels *p* achieved in an unpaired Mann–Whitney *U* test; the superscript symbol "[F]" indicates the significance levels achieved in two-sided Fisher's exact test

Table 3 Comparison of preoperative radiological characteristics between the groups of patients with and without bone resorption around the ACD (MED [IQR], *p*-value)

Indicators		Without bone resorption ($N=39$)	With bone resorption ($N=68$)	*p*-value
Volume of the removed hernia (cm^3)		1.5 [1; 1.8]	1.5 [1; 1.8]	0.994[U]
Disc volume (cm^3)		13.2 [9.3; 17.8]	10.9 [8.8; 12.35]	0.019[U]
Area of the annulus fibrosus defect (mm^2)		48 [45; 50]	50 [45; 50]	0.832[U]
Volume of removed bone (% of the total disc volume)		11.2 [8.3; 16]	11.9 [9.78; 16.48]	0.579[U]
Degrees of disc degeneration (Pfirrmann grades)	Grade 1 Grade 2 Grade 3 Grade 4 Grade 5	- 3 (7.6%) 32 (82.1%) 4 (10.3%) -	- 5 (7.4%) 49 (72.1%) 14 (20.5%) -	0.633[F]
Modic types	None I type II type III type	26 (66.7%) 7 (17.9%) 6 (15.4%) -	49 (72.1%) 13 (19.1%) 6 (8.8%) -	0.694[F]
Degrees of endplate defects (Rajasekaran grades)	Grade 1 Grade 2 Grade 3 Grade 4 Grade 5	3 (7.7%) 5 (12.8%) 22 (56.4%) 9 (23.1%) -	- 10 (14.7%) 41 (60.3%) 15 (22.1%) 2 (2.9%)	0.808[F]

The superscript symbol "[U]" indicates the significance levels *p* achieved in an unpaired Mann–Whitney *U* test, and the superscript symbol "[F]" indicates the significance levels achieved in two-sided Fisher's exact test

We showed the presence of bone resorption in 43.8% of ACD patients at 3–5 years of follow-up, and in 63.6% of ACD patients at 6–8 years of follow-up. Thomé et al. [17] wrote that vertebral end plate changes around the ACD implant occurs in 20.2% of ACD patients and in 1.4% of no-ACD patients, the between-group difference being significant at $p<0.001$, but without any clinical symptoms. Kienzler et al. [5] monitored the condition of the endplates after closing annulus fibrosus defects for 14.67 ± 4.77 months in ACD patients, and found that 99% of them had endplate defects of varying severity. According to Kuršumović et al. [7], the rates of vertebral endplate changes around the ACD progressively increased with time, with 85% of cases found affected at 2 years following surgery.

There are two explanations for this difference in the rates of the bone resorption around the ACD. One is the differences in the definition of the phenomenon. We considered two things separately: (1) bone resorption in the vertebral body and (2) endplate defects after Rajasekaran [13], while Thomé et al. [17] and Kuršumović [7] treated any vertebral endplate disruption, including bone resorption, as the same thing. The other is that our study concerns a longer follow-up period and a more in-depth analysis of bone resorption characteristics.

In our study, bone resorption occurred mainly around the mesh (70.6%, 48/68), while the other 29.4% (20/68) appeared as minor changes around the anchor. Whether the ACD anchor was inserted to the upper or the lower endplate, it was not associated with the presence or absence of bone resorption ($p > 0.05$). A large multi-chamber bone resorption area occurred around the ACD mesh, no matter whether in the upper or in the lower endplate. Kienzler et al. [5] reported larger vertebral endplate changes around the ACD in the lower endplate. Changes around the anchor were minimal [5], and a subsidence of the occlusion component into the adjacent vertebral endplate was observed in 36% of the ACD patients [7].

According to our data, the average resorbed bone volume was 1.1 cm^3, that is, 2.5% of the vertebral body volume, and the largest bone resorption volume was 5.2 cm^3, or 12% of the vertebral body volume. According to Kuršumović et al. [7], the resorption volume does not normally exceed 1% of the vertebral body volume, with the highest figure being some less than 8%. Our values are 1.5–2 times the value of the normal 1% and the highest 8% due to a longer follow-up period (8 years). Despite such a large volume of the resorbed bone in the vertebral body, the volume was not found to be associated with clinical symptoms ($p > 0.05$).

All resorbed bone areas, large and small, increase with time, although in some authors' opinion, only the small ones do [7]. We showed that the bone resorption area expands until a sclerotic rim forms, apparently preventing further expansion.

According to literature data, the predictors of bone resorption are decrease in disc height, the presence of endplate disruption before surgery [7], and the location of the anchor [5].

We showed that the volume of the intervertebral disc before surgery is a predictor of bone resorption (OR = 0.79, $p = 0.009$): the smaller the disc, the higher the chances of bone resorption. We did not find disc height to be a predictor of bone resorption ($p > 0.05$), although this parameter is related to the intervertebral disc volume (the taller the disc, the larger its volume). Surprisingly, ACD implantation neither led to defects if they had not been there before surgery nor exacerbated them if they had been there before surgery ($p > 0.05$).

In our opinion, bone resorption around the ACD is a result of close contact between the ACD mesh and the vertebral endplate. This contact eventually causes osteolysis and resorption. Close contact between the ACD mesh and the vertebral endplate is due to an insufficient height of the disc. Although ACD implantation strictly conformed to the indications for surgery, all technical requirements were met and the disc height was > 5 mm, we still observed a large number of bone resorption events around the ACD. However, given the associations established, this height (> 5 mm) may not be enough to prevent the vertebral bone from resorption. Therefore, when planning ACD implantation, considerations should be given to taller discs. The threshold value of the disc volume before surgery was determined to be 13.2 cm^3, at which the risk of bone resorption around the ACD increases significantly. Based on this, the height of the disc should be at least 7 mm to ensure a non-resorptive ACD position. Given this recommended disc height (> 7 mm), we expect that the subpopulation of patients eligible for ACD implantation will be even smaller than we have registered, less than 18.47% of all the patients who underwent lumbar microdiscectomy. However, these data still require further testing.

Thus, according to our data, bone resorption with a volume amounting to 12% of the vertebral body volume takes place around the implant mesh and the affected zone grows with time without clinical symptoms. The bone resorption area seems to stop expanding at a certain point and in some cases even shrinks within the sclerotic rim. Bone resorption has no implications for the clinical outcomes; however, this phenomenon should be kept in mind when choosing the tactics for further fusion surgery, should surgery be indicated. This is an exciting issue and we are planning to proceed with it in the future.

Conclusion

The majority of patients (up to 63.6%) with an implanted ACD had vertebral bone resorption around it. Bone resorption around the ACD mesh expanded with time to a volume of up to 12% of the vertebral body volume without clinical symptoms. The bone resorption area stops expanding and in some cases even reverses, once a sclerotic rim has developed. If the volume of the intervertebral disc before surgery is less than 13.2 cm^3, the risk of bone resorption around the ACD increases significantly.

Acknowledgements The authors would like to thank Vitaliy Lukinov for providing statistical analysis and to thank Vladimir Filonenko for his help with the translation and correction of this manuscript.

Author contribution All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by AS, AK, OL, and AP. The first draft of the manuscript was written by AS, AK, OL, and AP and then all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Data availability The datasets generated during the current study are not publicly available, but are available from the corresponding author on reasonable request.

Declarations

Ethics approval The study was performed according to the Helsinki Declaration and was approved by the Local Ethical Committee of NRITO (№03/16–1 of 12.01.2016).

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent to publish There is no identifying information included in this article.

Conflict of interest The authors declare no competing interests.

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Comments

This is an industry-naive series of more than a hundred lumbar disc patients that underwent microdiscectomy plus implantation of an annular closure device (ACD). The authors are to be congratulated for their long-term follow-up (of 8 years) and their thorough imaging-based analysis of the ACD-associated endplate changes. The main messages of the manuscript can be summarized as follows:

1. ACD implantation can be performed in a subpopulation of approximately 20% of lumbar disc patients (with high discs and large annular defects).
2. ACD implantation seems to reduce the reherniation rate in this high-risk group to less than 5% at long-term follow-up.
3. Endplate changes occur in the majority of implanted segments mostly in close vicinity to the mesh of the implant, grow over time until a sclerotic rim develops, but do not cause symptoms. These characteristics make an infection, which has been previously discussed, highly unlikely.

Although this is a retrospective analysis (of prospectively collected data) and the rates and the sizes of the endplate changes differ somewhat from previous publications, the investigator-driven nature of the study plus the lack of study support and conflicts of interest makes this an important contribution to the literature on the ACD topic, as the low reherniation rates and the clinical irrelevance of the endplate changes seen in the potentially biased industry-sponsored studies are confirmed.

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