Radiological Evaluation of Fusion Rates, Cervical Alignment and Postoperative Swelling Following Anterior Cervical Discectomy and Fusion Involving either a Standalone Anchored Cage Construct or Cage and Plate Combination

Abstract

Objectives: Compare the success of ACDF using either anchored cages alone (ACA) or cage and plate (CAP) constructs with regards to radiologic outcomes including fusion, cervical alignment and prevertebral soft tissue swelling.

Methods: X-rays from 113 patients undergoing ACDF with either ACA (n=43) or CAP (n=70) were obtained. Fusions were assessed using Brantigan, Steffee, Fraser criteria. Cervical alignment was measured using the Cobb angle method. Prevertebral soft tissue swelling (STS) was measured from anterior surface of vertebral bodies C4-7 to anterior edge of soft tissue. Measurements were made pre-operatively, immediately post-operatively, <3months post operatively and at final follow up.

Results: There was no significant difference in the attainment of fusion at any level. ACA constructs used in 2 level ACDF achieved a significantly greater degree of lordosis at final follow up (p=0.019). CAP led to significantly greater levels of (STS) at the C5/6 level immediately and at <3 months post-op.

Conclusion: ACDF using ACA is comparable to using CAP with regards to several parameters and appears favourable in terms of STS and cervical alignment following two level fusions.

Introduction

Since its origin in 1958 Smith and Robinson's anterior cervical discectomy and fusion (ACDF) technique has firmly established itself a method of allaying the burden of cervical radiculopathy and myelopathy[1]. During its evolution an array of adaptations have endeavoured to maximise its durability and tolerability to patients. Modifications have range from alterations to the construct's composition and fixatives to the development of zero profile stand-alone cages[2,3,4]. Comparisons of ACDF outcomes following application of anchored cage alone devices (ACA) and cage and plate constructs (CAP) are common. The number of successful fusions accomplished by each construct is a popular measure although a degree off variability exists in published literature about how they compare. Whilst some studies demonstrate no significant differences, others have identified CAP as achieving a significantly greater fusion rate [5,6,7,4]. There is therefore uncertainty about the relative efficacy of the two techniques with regards to fusion. Another increasingly frequently assessed parameter is change in cervical alignment. Cervical alignment is important to maintain patient quality of life and more recently has being investigated for a link to cervical myelopathy[8,9]. Changes in cervical lordosis measured by the cobb angle are regularly documented however there is a lack of consensus on their relationship with ACA and CAP compares. Results vary from superior lordotic angles reported in the CAP group to no significant differences detected to significantly better lordosis in ACA ACDF [6,7,8,10,11]. As well as studying the effects of ACDF on the spine itself, its impact on surrounding structures is the subject of review. Prevertebral soft tissue swelling (STS) is a commonly reported complication. Although its clinical correlation is not definite, it is believed to promote acute dysphagia, the most commonly reported complication of ACDF [12,13]. Whilst some groups have identified that it is unlikely associated with long term dysphagia, others have demonstrated a link between significant soft tissue swelling and short term dysphagia [12,14]. This potential link makes soft

tissue swelling a relevant comparative measurement. Since both ACA and CAP constructs are used in this spinal surgical department it is relevant to compare their outcomes with one another and see how they fall in with the growing body of literature.

Aims and Objectives

- Evaluate how successfully Anchored Cage Alone or Cage and Plate devices achieve fusion of cervical vertebrae following ACDF.
- Compare the influence of ACA and CAP constructs on cervical alignment.
- Identify the relative impact of ACA and CAP constructs on prevertebral soft tissue swelling.

Methods

Database

A database of patients undergoing ACDF between 2012 and 2016 was constructed from the hospitals Clinical Portal and radiology software (Impax). Inclusion criteria: ACDF at 1-3 levels between C4 and T1 due to radicular pain or myelopathy. Exclusion criteria: Surgery for trauma, tumours, infections, spondylolisthesis, or revisions, absence of pre-operative X-rays or post-operative follow up <3 months. Measurements of cervical alignment and swellings were taken from lateral x-rays in four defined time periods: Preoperatively, Immediately Postoperatively (1-5 days), ≤3 Months postoperatively, and at Final Radiographic Follow up (>3 months).

Cervical alignment

Cervical lordosis, defined as the angle at the intersection of two lines running parallel to the inferior endplates of C2 and C7 respectively, was measured on Impax. Examples are shown in Appendix 1. Measurements were taken at the defined intervals and repeated one week apart after which respective averages were calculated.

Swellings

Impax was used to quantify STS at the C4-C7 levels in mm during each of the defined intervals. STS was measured as the distance between the midpoint of the anterior surface of the vertebral body and the anterior edge of the soft tissue. Examples can be seen in Appendix 1. Repeat measurements were taken and averages calculated.

Fusions

Three assessors including two consultant spinal surgeons blindly assessed the same 113 lateral radiographs taken at final follow up on two occasions, at least week apart, according to the Brantigan, Steffee, Fraser fusion criteria. Inter- and intra-observer reliabilities were calculated and a means of the 6 assessments were used to determine ratings.

Statistics

Statistical analysis was carried out using the Independent Samples t Test, Chi-Squared and Cohen's Kappa Coefficient on SPSS. Significance was defined as $p = \leq 0.05$.

Results

Demographics

113 patients were included in this study, 43 following ACA and 70 CAP ACDF. The demographics for this group are displayed in Table 1

Table 1. Table Demonstrating Demographics of Studied Population

	ACDF Cage Alone	ACDF Cage + Plate
No. Patients	43	70
Mean Age (Range)	48.79 (32-77)	53.4 (33-79)
Primary Underlying Diagnosis		
Radiculopathy	37	53
Myelopathy	5	17
Unknown	1	0
No. Levels Fused		
1	27	8
2	15	47
3	1	15
Mean No. Levels Fused	1.4	2.1
Mean Op Time/Hrs (Range)	1.7 (1-3)	1.75 (1-3)
Follow up/Months (Range)	10.47 (3-54)	13.77 (3-50)

Table 1 displays the demographics for patients undergoing ACDF with either a cage alone or a cage and plate including, mean age, underlying diagnosis, number of levels fused, mean operation time and follow up.

Fusions

A total of 205 levels were operated on, the distribution of these between ACA and CAP patients is depicted in Figure 1.

Figure 1. Pie Charts Comparing Fusions by Levels and Implants

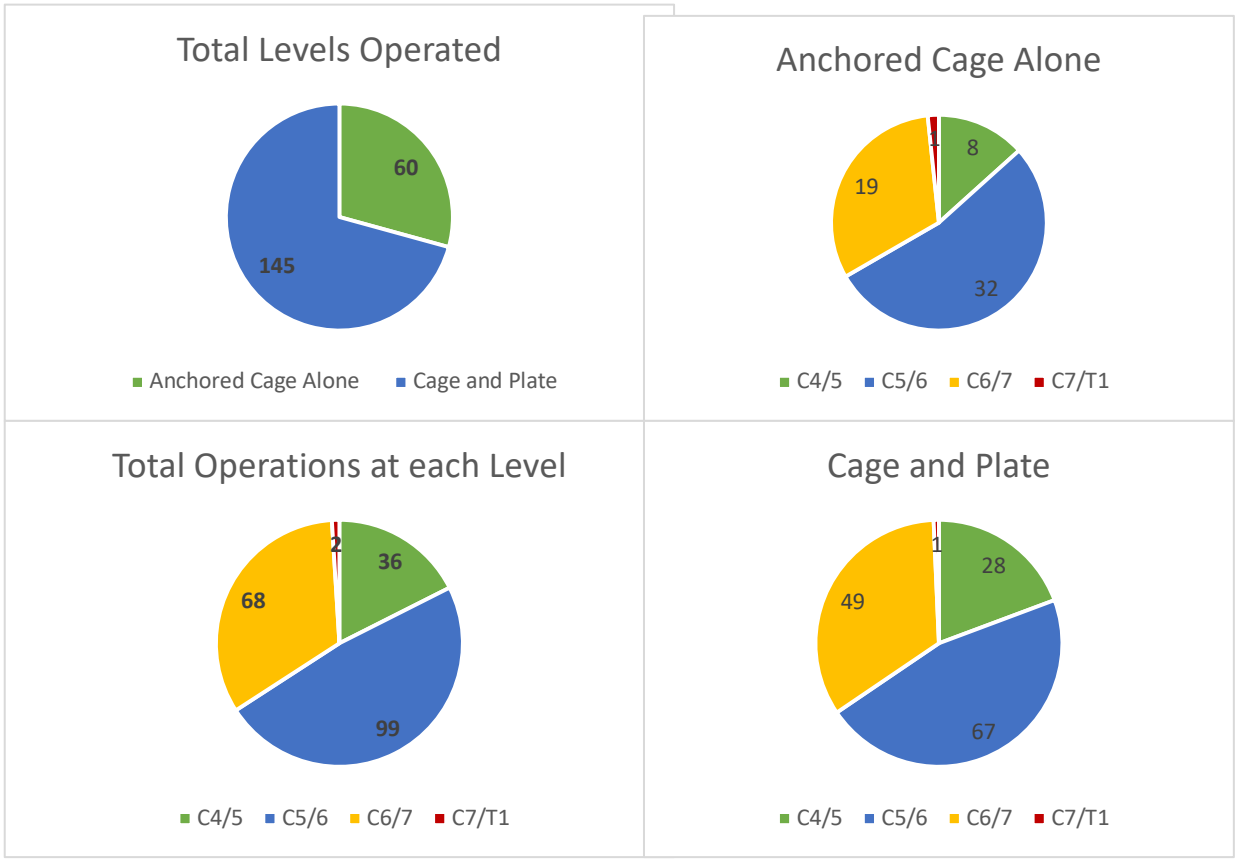

Figure 1. A compares total number of ACA and CAP fusions. B compares total number of operations at each level. C and D show how many of the fusions occurred at each level in the ACA and CAP groups, respectively.

More CAP than ACA were used (145 vs 60). The Most commonly operated level was C5/6 (99/205) and the least commonly operated level was C7/T1 (2/205). Table 2 displays the number of successful fusions at each level.

Table 2. Table Showing Number of Successful Fusions by Implant and Level

	Cage Alone	Cage and Plate	Total
C4/5	8/8	27/28	35/36
C5/6	29/32	64/67	93/99
C6/7	18/19	47/49	65/69
C7/T1	1/1	1/1	2/2
Total	**56/60**	**139/145**	**195/205**

Table 2 displays the number of successful fusions/ the total number of operations undertaken at each level. Results are displayed for cage alone fusions, cage and plate fusions and total number of fusions.

Chi-Square analysis identified that there was no significant association between the type of construct used and number of successful fusions at any level; C4/5 p=0.618, C5/6 p=0.339, C6/7 p=0.516, C7/T1=n/a (n=2). These results therefore suggest that use of a cage alone or in combination with a plate did not significantly influence fusion rates at any level C4-T1.

The Kappa statistic was used to assess inter-rater and intra-rater reliability for assessment of fusions using x-ray. Intrarater reproducibility was good (range 0.41-0.89) however interrater reproducibility was poor (range 0.05-0.49). These results indicate x-ray is a poor imaging modality for assessing fusion.

Cervical Alignment

Only fusions at 1 or 2 levels were included for analysis as only one 3 level case had a cage alone construct. Demographics for patients included are shown in Table 3.

Table 3. Demographics of Patients Assessed for Changes in Cervical Lordosis Following ACDF

	1 Level		2 Levels	
	Cage Alone	**Cage and Plate**	**Cage Alone**	**Cage and Plate**
No. Patients	18	2	10	25
Mean Age (Range)	47 (32-67)	45.5(43-48)	49.4 (32-77)	55 (33-72)
Follow up/Months (Range)	12.69 (32-62)	6(5-7)	10.05 (3-54)	13.46 (3-50)

Table 3 shows demographics for patients who had measurements of cervical lordosis taken. Number of patients, mean age and mean follow up in months is displayed for patients who had 1 or 2 levels of fusion with ACA or CAP.

55 patients were available for comparison; 20 with a single level of fusion (18 ACA and 2 CAP) and 35 patients with two levels of fusion (10 ACA and 25 CAP). In patients undergoing one level of fusion there were no statistically significant differences between the changes in cervical lordosis between ACA and CAP patients (p=0.970 and p=0.866, respectively). However in patients with two levels of

fusion a significantly greater change in cervical lordosis was identified in the ACA group at final follow up (p=0.019).

Swelling

As with cervical alignment only patients with fusions at one or two levels were assessed. Table 4 displays the demographics for this group.

Table 4. Demographics of Patients Assessed for Changes in Prevertebral Soft Tissue Swelling Following ACDF

	1 Level		2 Levels	
	Cage Alone	**Cage and Plate**	**Cage Alone**	**Cage and Plate**
No. Patients	27	8	15	47
Mean Age (Range)	46.5 (31-67)	44.9 (37-53)	52.33 (32-65)	54.15 (33-79)
Follow up/Months (Range)	10.19 (3-26)	6.88 (3-17)	9.37 (3-54)	14.18 (3-50)

97 patients had suitable x-rays. More ACA were used in the single fusion level group and more CAP were used in the two level fusion group. The results of the independent t test used to compare mean extent of swelling at levels C4/5, C5/7, C6/7 and C7/T1 between ACA and CAP are displayed in Table 4.

Table 4. Table Showing Outcome of Independent t Test used to Compare Levels of Swelling C4-7 Following ACDF with ACA or CAP

	1 Level			2 Levels		
	t Value	Mean Difference(mm)	Significance	t Value	Mean Difference(mm)	Significance
Pre C4	-0.9	1.28	(p=0.373)	0.25	1.93	(p=0.802)
Pre C5	-0.28	0.52	(p= 0.778)	1.3	1.62	(p=0.198)
Pre C6	0.16	0.21	(p=0.878)	0.49	0.45	(p=0.629)
Pre C7	0.1	0.16	(p=0.921)	1.15	1.23	(p=0.257)
Immediate post C4	-1.41	2.84	(p= 0.169)	-0.911	1.51	(p=0.366)
Immediate post C5	-1.14	2.39	(p= 0.262)	-2.544	3.86	*(p= 0.014)
Immediate post C6	0.29	0.5	(p=0.771)	-2.012	2.44	*(p=0.049)
Immediate post C7	0.56	0.92	(p=0.586)	-1.935	2.38	(p=0.058)
≤3 months C4	-1.39	1.7	(p=0.177)	-1.346	1.05	(p=0.184)
≤3 months C5	0.08	0.14	(p=0.939)	-3.04	3.81	*(p= 0.004)
≤3 months C6	0.17	0.21	(p=0.868)	-2.51	2.63	*(p=0.015)

≤3 months C7	1.16	1.96	(p=0.258)	-1.02	1.37	(p=0.313)
Final follow up C4	-0.05	0.07	(p=0.961)	-0.35	0.32	(p=0.727)
Final follow up C5	0.52	1.01	(p=0.606)	-1.62	2.02	(p=0.111)
Final follow up C6	0.32	0.48	(p=0.749)	-3.03	3.22	*(p=0.004)
Final follow up C7	-0.36	0.68	(p=0.719)	-1.6	1.89	(p=0.116)

Table 4. Table shows t value, mean difference and significance for comparisons of soft tissue swelling between ACA and CAP using the Independent t Test. Results are shown for C4-7 at the preoperative, immediate post-operative, ≤3 months post-operative and final follow up time intervals. * indicates significance.

There was no significant difference in the degree of prevertebral swelling following ACDF at one level between ACA devices and CAP devices at any level or time point. However following two level ACDF swelling in the immediate postoperative period and at <3months follow up was significantly higher in the CAP group (immediate postop C5 p=0.014, C4 p=0.049, ≤3 months post op C5 P=0.004, C4 p=0.015). Additionally at final follow up swelling at C6 was still significantly greater amongst the CAP implants (p=0.004). Figure 2 shows how the STS varied at levels C5 and C6.

Figure 2. Graphs Showing Prevertebral Soft Tissue Swelling at Levels C5 and C6 Following ACDF

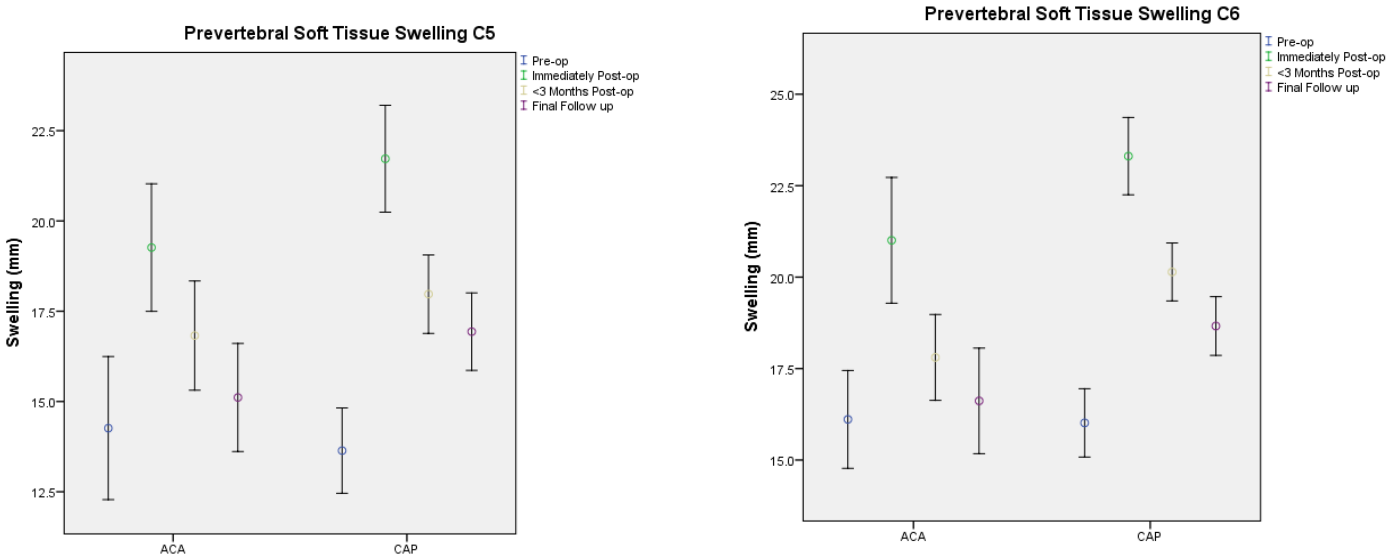

Figure2. Graphs show mean soft tissue swelling with 95% confidence intervals for defined time intervals at the C5 and C6 levels.

These results indicate ACDF at 2 levels involving a plate leads to significantly more prevertebral STS not only initially but for several months than when the operation is carried out with a cage alone.

Discussion

This retrospective evaluation has used radiologic parameters to compare the efficacy of ACDF using either ACA or CAP in 113 patients. Assessment of 205 operative levels identified no significant differences in the attainment of fusion. This suggests that a similar level of success can achieved

using either a ACA or CAP. Song *et al.* and Lee *et al.* contradict this finding instead demonstrating significantly greater levels of fusion in CAP[11,12]. However several studies have similarly demonstrated near equal rates of fusion at between 6 month and 24 month follow up with the percentage of successful fusions for both ACA and CAP consistently above 95% [6,5,16,15]. Another finding was that the technique used to assess fusion demonstrated poor inter-rater reliability despite significant intra-rater reliability. A potential reason is that the criteria used was too subjective. A more objective and frequently used measure of fusion involves looking for <2 degrees of movement between spinous processes on lateral flexion/extension views as well as assessing bone formation[6]. However the retrospective nature of this investigation meant the necessary images were not available. Despite the drawbacks, the results of this investigation seem to be in keeping with much of the literature which demonstrates equal fusion outcomes for ACA and CAP.

Following 2 levels of fusion the use of ACA led to a significantly greater increase in cervical lordosis at final follow up. An investigation by Kim *et al.* also indicated a tendency for ACA to increase cervical lordosis following ACDF (n=48)[8]. However the study differed in that it only looked at single level fusions and follow up was only 3 months. Unfortunately there were too few patients in the current study to assess lordosis at 1 level. The results of other studies which compared ACA and CAP in single and two level fusions differed slightly in that whilst cervical lordosis increased postoperatively, no significant differences between the devices were seen at up to follow up ranging from 6 to 24 months [4,6,10]. Therefore the results of the current study taken with the literature reviewed suggest that cervical alignment following ACDF is at least as good when using ACA as CAP when carrying out 1-2 levels of fusion. A potential reason for the differences between the studies could be that some surgeons apply a straight plate whereas others may apply a bend plate. The relationship between cervical lordosis following ACDF and clinical outcome has only been investigated in recent years. It has been demonstrated that following 1 and 2 level ACDF maintaining or restoring cervical lordosis was associated with significantly improved neck pain disability index scores [17]. This highlights the importance of taking cervical alignment measures into consideration.

A final significant finding was that the use of CAP in 2 level ACDF leads to greater prevertebral soft tissue swelling between C5-C6. A study by Hofstetter *et al.* found very similar results, identifying that CAP produces significantly higher levels of swelling, and furthermore that it was greatest between C5/6-C6/7 levels with higher levels not showing statistical significance[16]. Although no direct link was made Hofstetter *et al.* also demonstrated significantly higher rates of dysphagia at >3 months in the CAP group which supports the proposal by Song *et al.* that significantly increased soft tissue swelling may be linked to dysphagia [16,12]. The current investigation did not have reliably documented information on dysphagia following ACDF so comparisons unfortunately couldn't be made. However taken with current literature the demonstrated differences in soft tissue swelling suggest the use of ACA is at least as good if not better than CAP in terms of effects on soft tissue swelling and therefore possibly acute dysphagia.

Limitations of this study stem from the fact it is retrospective. Key problems faced included unavailability of suitable x-rays and a lack of consistent documentation of factors such as smoking and dysphagia and patient reported outcomes. Although 3 level fusions (n=16) were included in the fusion aspect only one ACA was used meaning comparisons could not reliably be made for certain outcomes. Additionally there was a selection bias for the selection of ACA constructs for single level fusions and CAP for over two level fusions. A prospectively designed study would allow many of the drawbacks to be overcome and would help to confirm the results of the current investigation.

Conclusion

This investigation has demonstrated that ACDF at 1-3 levels yields similar outcomes with regards to rates of fusion whether using ACA or CAP. Additionally the use of a ACA devices in two level ACDF results in significantly less prevertebral swelling in the lower cervical spine at beyond 3 months and significant increases cervical lordosis. Overall this study has found that ACA is comparable to CAP with regards to several parameters and that it appears favourable to CAP in terms of STS and Cervical alignment measurements in 2 level fusions.

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Appendix 1

Figure 3 demonstrating measurements of soft tissue swelling at levels C4-C7 pre- and post-operatively

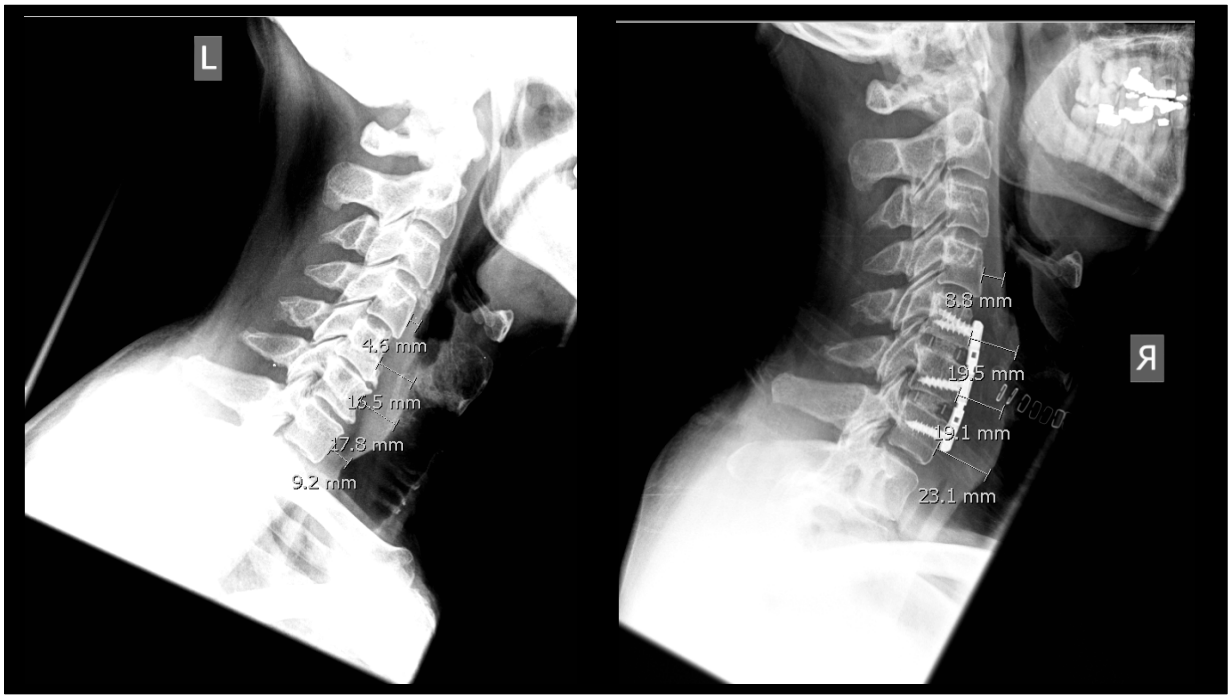
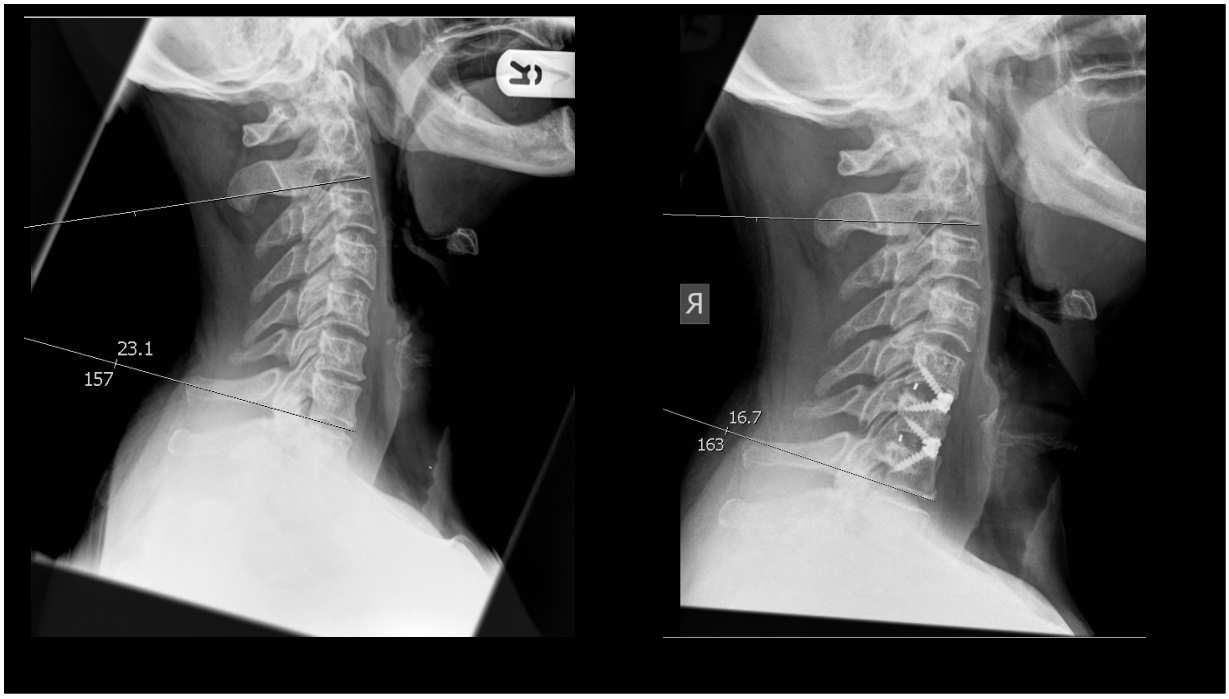


Figure 4 demonstrating the measurement of cervical lordosis pre- and post-operatively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