

Cervical Disc Replacement and Potential for Multiple Level Surgery

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Abstract

Background: Cervical disc replacement using the Mobi-C implant has shown promising outcomes in improving postoperative evaluation scores beyond the FDA guidelines of 1 to 2 levels, indicating its potential efficacy in addressing multi-level disc pathologies. The FDA approvals for 1 to 2 are based on established long term safety and effectiveness. However, there is limited evidence for 3 or 4 level cervical disc replacement. Cervical disc Arthroplasty has proved effective in preventing the unwanted negative impacts of cervical fusion which are pseudoarthrosis, and adjacent segment disease. Extending the application of the Mobi-C implant to multiple levels in cervical disc replacement surgeries may offer a viable alternative to traditional fusion techniques, potentially preserving motion and reducing the risk of adjacent segment degeneration. In this study the aim was to follow-up patients who had CDR surgery to see if the multiple level group was having comparable results to 1-2 level CDR surgery.

Methods: A retrospective cohort analysis of 63 patients. Which looked at Patient reported outcomes pre-operatively and post operatively was done. We looked at QVAS, EQVAS, JOA, NDI, and EUROQOL. Statistical analysis was done using R and Python software.

Results: Of the 63 patients, 15 underwent 1-level, 30 underwent 2-level, 12 underwent 3-level, and 6 underwent 4-level CDR. Median age was 56.7 years (IQR 53–61). At 3–24 months follow-up, significant improvements were observed in JOA (effect size ~0.3–0.4) and QVAS (effect size ~0.3) across all groups ($p < 0.05$). In 4-level cases, improvements were significant for JOA, QVAS, and EUROQOL but not for NDI or EQVAS. Compared to the standard group, patients with 3–4 levels reported greater improvements in functional outcomes (JOA) and pain reduction (QVAS), though disability and global health measures were not significantly different. No major perioperative complications were recorded.

Conclusion: For well selected patients using the recommended indications and contraindications there is a role for 3 and 4 level cervical disc Arthroplasty and it can be performed safely.

Keywords: Cervical, Disc Replacement, Multiple Level, Mobi-C.

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Abbreviations

EUROQOL: European Quality of life Score (also known as EQ-5D)

EQVAS: The Visual Analogue Scale Component of EuroQol. Used to Rate Health on a Scale of 1-100

QVAS: Quadruple Visual Analogue Scale

JOA: Japanese Orthopaedic Association score

NDI: Neck Disability Index

CDR: Cervical Disc Replacement

ASD: Adjacent Segment Disease

ACDF: Anterior Cervical Discectomy and Fusion

PRO: Patient Reported Outcomes.

Introductions

Cervical disc replacement surgery has been performed since around 2003 aimed at preserving motion, thus solving the adjacent segment diseases that followed anterior neck fusions, and it has progressed

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through many different designs of prosthesis since the first few operations were done. The main driving force for cervical disc replacement procedures has been based on the search of a device that could mimic the kinematics of the intervertebral disc thus reduce adjacent segment diseases that usually followed Anterior cervical discectomy and Fusion [1]. The best way to mimic the human body is to preserve motion in joints and this principle has been applied successfully in orthopedic surgery, particularly in hip and knee replacement surgeries [2]. One of the factors that have slowed down uptake for CDR has been the fact that ACDF procedures have had good long-term results only complicated by adjacent segment diseases in other cases particularly high in two levels and above [3]. The reported incidence of ASD varies widely. ASD is one of the reasons that account for accounts for reoperations after spine surgery. CDR has been seen reduced risks of ASD in cervical spine surgeries especially with two levels of CDR. Some studies have shown that there to be no statistically significant difference in the rate of ASD and reoperations in one level CDR compared to one level ACDF [4]. The challenge with the available prosthesis on the market is that they are indicated for up to two levels of surgery and not beyond. However, many centres have reported good results with the use of some of these implants for multiple level CDR, that is for 3 and 4 level Cervical disc replacement surgeries. A study looked at 116 patients who had 3 level CDR and 23 patients who had 4 level CDR, concluded that CDR may be performed safely and effectively in appropriately selected patients [5]. This was based on significant improvements based on patient reported outcomes which they followed.

Materials and Methods

A retrospective cohort analysis of 63 patients PRO was done. The data was collected at 3 months, 6 months, 1 year and 2 years post operatively. This study aimed to evaluate the effectiveness of the Mobi-C implant for multiple levels of disc replacement

beyond the FDA guidelines of 1-2 levels. The focus was on assessing pre-operative and post-operative outcomes using various clinical scores and surgical parameters. The following Patient reported outcomes were considered, QVAS, EQVAS, JOA, NDI, and EUROQOL. Statistical analysis was done using R software.

Results/ Observations

A total of 63 patients were included in the study. Table 1, shows the demographic distribution of the patients, separated into male and female according to the number of levels of CDR surgeries done. For example, 8 male patients and 7 females had 1 level CDR making a total of 15 patients for 1 level CDR, A Total of 30 patients had 2-Level CDR, 12 patients had 3-level CDR, and 6 patients had 4-level CDR. Average Follow-up of 17 months, with a minimum of 3 months for 3 patients, 6 months for 13 patients and at least 24 months for 39 patients. The average age distribution of the patients was 56.7 years. The average theatre time was 156 minutes, the minimum was 60 minutes, and maximum was 5.5 hours (This was a 2-level revision case). Table 2 shows a more detailed description of the age distribution per number of levels operated.

Table 1: Demographic Distribution of the Patients.

Characteristic	Level 1	Level 2	Level 3	Level 4
Male	8	9	7	3
Female	7	21	5	3
Total	15	30	12	6
Age (yrs)	37-74	31-78	53-81	46-72
Median (IQR)	49(17.00)	56.5(10.75)	60(15.0)	62(15.75)

Table showing a summary of the distribution of the patients according to the number of levels of CDR surgeries done.

Table 2: The table summarizes patient demographics by number of operated levels (1–4), reporting Median (IQR) for Age, Height, Weight, and BMI at Pre-op and Post-op. (Demographics are unchanged by surgery, so Pre- and Post-op values are identical.) Single-level cases are older (65 [58–73] yrs) than multi-level groups (~54–56 yrs), while anthropometrics are consistent across levels: Height ≈1.7 m (IQR 1.7–1.8), Weight ~70–72 kg, and BMI ~24–25 kg/m², indicating a largely normal-weight cohort.

Characteristic	Level 1 Pre-op	Level 1 Post-op	Level 2 Pre-op	Level 2 Post-op	Level 3 Pre-op	Level 3 Post-op	Level 4 Pre-op	Level 4 Post-op
Sex								
Male	8	8	11	11	4	4	4	4
Female	7	7	19	19	8	8	2	2
Age (yrs)								
Median (IQR)	65.0 (58.0-3.0)	65.0 (58.0-3.0)	54.5 (46.8-61.2)	54.5 (46.8-61.2)	54.5 (53.0-58.2)	54.5 (53.0-58.2)	55.5 (53.5-68.0)	55.5 (53.5-68.0)
Height, m								
Median (IQR)	1.7 (1.7-1.8)	1.7 (1.7- 1.8)	1.7 (1.7-1.8)	1.7 (1.7-1.8)	1.7 (1.7-1.8)	1.7 (1.7-1.8)	1.7 (1.7-1.8)	1.7 (1.7-1.8)
Weight, kgs								
Median (IQR)	70.0 (68.0-8.0)	70.0 (68.0-78.0)	72.0 (68.0-86.2)	72.0 (68.0-86.2)	71.0 (67.2-76.8)	71.0 (67.2-76.8)	71.5 (68.2-74.8)	71.5 (68.2-74.8)
BMI, Kg/m²								
Median (IQR)	23.3 (23.0-5.0)	23.3 (23.0-25.0)	24.6 (23.4-26.2)	24.6 (23.4-26.2)	24.5 (23.0-24.9)	24.5 (23.0-24.9)	24.0 (23.1-24.4)	24.0 (23.1-24.4)

A statistical analysis of the JOA, NDI, EUROQOL, QVAS, and EQVAS was separated into objective 1 comparing Pre-op and post op scores for 3 level surgery, objective 2 comparing Pre-op and post-op scores for 4 level surgery and objective 3 comparing the post op scores between the standard group (1-2 levels) and the multiple level group (3-4 levels). Objective 4 looked at the effect of post op time (Follow-up) on the outcomes.

Objective 1: Comparison of Pre-op and Post-op Scores for 3 Levels

Variables Involved: JOA, NDI, EUROQOL, QVAS, and EQVAS. Paired t-tests were used to compare pre-op and post-op scores for patients who had surgery at 3 levels. Each clinical score was tested for statistical significance. Significant improvements were observed in all five scores, with p-values < 0.05. Box plots were generated to compare pre- and post-op scores, with p-values annotated on the graphs. Refer to Figure 1.

Objective 2: Comparison of Pre-op and Post-op Scores for 4 Levels

Variables Involved: JOA, NDI, EUROQOL, QVAS, and EQVAS. Paired t-tests were conducted to assess the statistical significance of the differences in pre-op and post-op scores for patients with 4 levels. JOA, EUROQOL, and QVAS showed significant improvements, while NDI and EQVAS did not reach statistical significance. Box plots were created to compare scores across 4 levels, with p-values presented on the graphs. Refer to Figure 1.

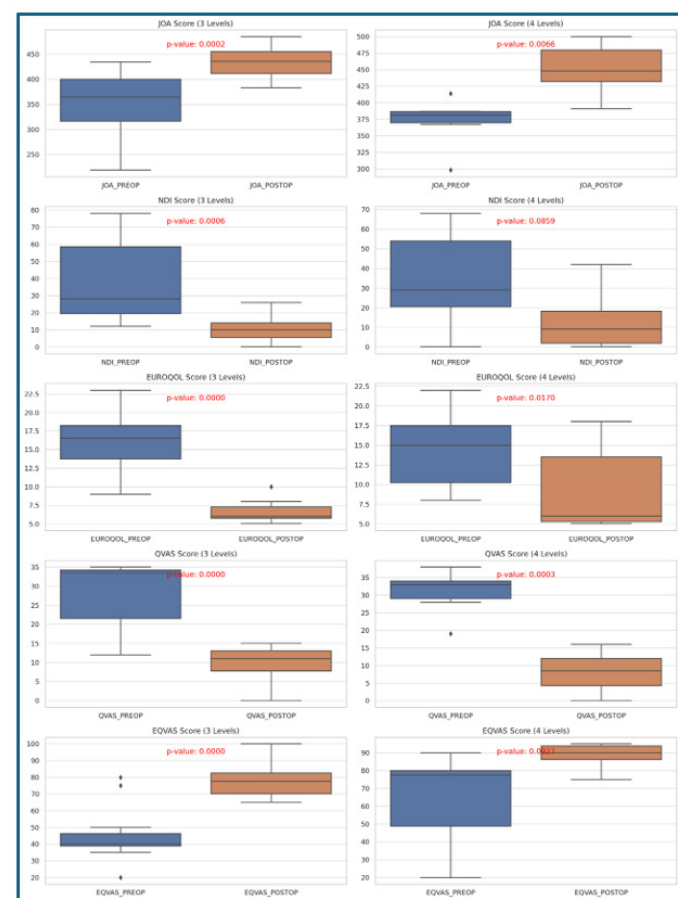


Figure 1: The box plots show the pre-op and post-op scores for both 3 levels and 4 levels, along with the p-values for each

comparison. The significant differences are clearly highlighted, with p-values provided on the graphs for each score.

Objective 3: Comparing Post-op Scores Between Standard (1-2 levels) and the Multiple Level (Treatment) Group (Non-Parametric)

Variables Involved: JOA, NDI, EUROQOL, QVAS, EQVAS (post-op). Mann-Whitney U tests were used to compare post-op scores between the standard (1-2 levels) and treatment (3-4 levels) groups. Statistically significant differences were observed for JOA and QVAS, with p-values < 0.05. Other scores (NDI, EUROQOL, EQVAS) showed no significant differences. Refer to Figure 2.

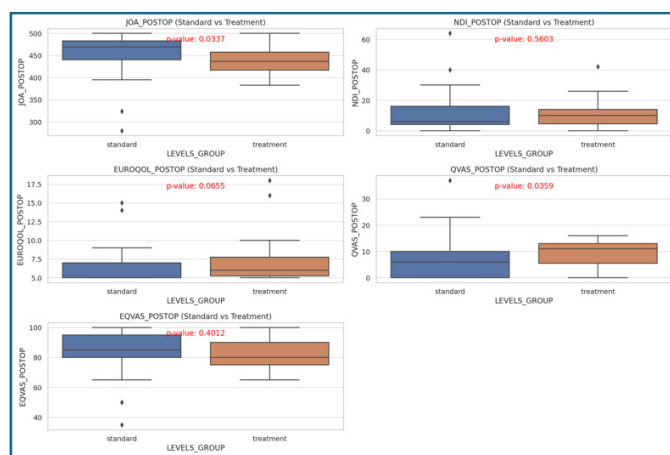


Figure 2: The box plots above show the comparison of post-op scores between the standard (1-2 levels) and treatment (Multiple level groups) groups, with the corresponding p-values displayed for each score. N.B. Standard group refers to 1-2 levels and the treatment group refers to 3 & 4 multiple levels.

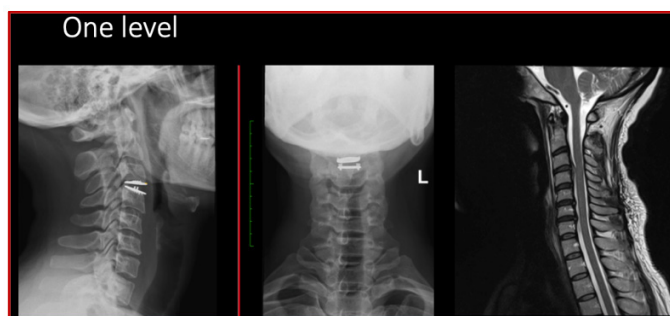


Figure 3: Case 1 presented with single level radicular pain and required a 1-level disc replacement surgery at C3/4.

Objective 4: Post-op Time (in months) Influence on Outcomes

Variables Involved: Post-op time, JOA, NDI, EUROQOL, QVAS, EQVAS.

Regression analysis** was used to model the relationship between post-op time (in months) and post-op outcomes. A positive correlation was observed between post-op time and JOA score improvements, especially in the 3-level and 4-level group. QVAS showed a notable negative trend, indicating reduced pain over time in the treatment group. Weak correlations were observed for NDI, EUROQOL, and EQVAS. Scatter plots

and regression lines were generated to visualize the relationships between post-op time and outcomes. Refer to Figure 3.

Objective 5: Comparison of Scores between Pre-op and Post-op Scores for 1 Level Only and for 2 Level Only.

Variables Involved: JOA, NDI, EUROQOL, QVAS, and EQVAS. Figure 7 shows that patients with both 1-level and 2-level surgeries have substantial improvements in patient outcomes across all metrics. This indicates that the surgeries have a positive impact regardless of the number of levels involved

The overall analysis was conducted using R and Python Version 3.11. The rank-biserial correlation was done and this is a non-parametric effect size measure used to quantify the magnitude of difference between two paired samples—especially when using Wilcoxon signed-rank tests. It's useful for analysing ordinal or non-normally distributed data, like clinical scores.

- Its values range from -1 to 1
- 0 means no effect
- Positive values mean improvement (e.g., post-op scores better than pre-op)
- Negative values mean deterioration
- Magnitude interpretation:
 - ~0.1: Small effect
 - ~0.3: Moderate effect
 - ≥0.5: Large effect

Interpretation of Results of this test was as follows: Effect sizes ranged from small to moderate, indicating moderate practical significance in JOA and QVAS outcomes.

This means:

- JOA and QVAS scores showed moderate improvements post-surgery, not just statistically ($p < 0.05$), but also with practical/clinical relevance.
- In contrast, other scores (e.g., EQVAS, EUROQOL, NDI) might have been statistically significant, but had smaller effect sizes, suggesting the actual magnitude of change might not be clinically meaningful in all patients.
- The box plots drawn show this visually: clearer separation between pre-op and post-op for JOA and QVAS scores compared to the others.

Discussion

Across all five clinical metrics, patients undergoing surgery at 3 levels experienced significant improvements from pre-op to post-op. The statistical significance across all metrics implies that multi-level Mobi-C implants led to better functional outcomes, lower disability, reduced pain, and enhanced quality of life and overall health. For patients undergoing surgery at 4 levels, significant improvements were seen in JOA, QVAS, and EUROQOL scores, but NDI and EQVAS scores did not reach significance. This suggests that while functional outcomes and pain reduction are substantial, the overall disability and perceived health state improvements may not be as pronounced when increasing the number of levels involved in surgery. (Results shown in Figure 1). Even though patients who have multiple level disc replacement surgery may not have marked improvement in disability there is a definite marked improvement of pain and functionality. In this study only 18 patients were followed up,

however there is potential for patients to benefit from multiple level disc replacement surgery.

The results shown in Figure 2, illustrate the differences between the two groups and highlight which comparisons show significant results. The Multiple level (treatment) group, which underwent more extensive surgery (3-4 levels), showed significant improvements in functional outcomes (JOA) and pain levels (QVAS) compared to the standard group. However, no significant difference was found for disability (NDI) or overall health state (EQVAS). This is an important observation and can be explained by the fact that patients who have debilitating diseases in 3 or 4 levels start off from a worse position due to magnified symptoms, so there is a much wider gap between their pre-op scores and post-op scores. This group of patients has been excluded from CDR procedures in most centres based on implant design and indications and yet the group has potential to benefit more. Refer to Figure 3 showing a single level CDR, Figure 4 showing a 3 level CDR and Figure 5 showing a 4 level CDR.

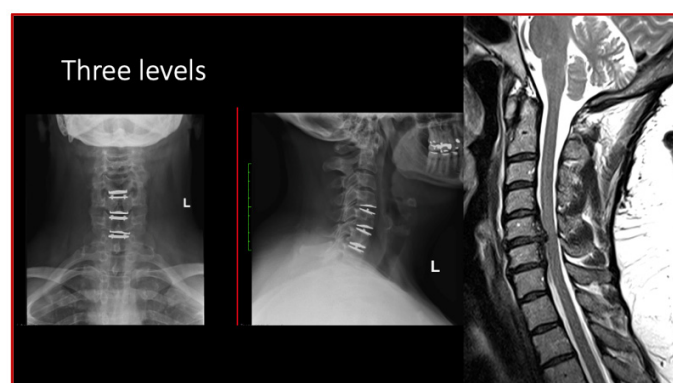


Figure 4: Case 2 presented with radiculopathy, neck pain and myelopathic symptoms and signs. The patient required 3-level disc replacement surgery at C4/5, C5/6 and C6/7.

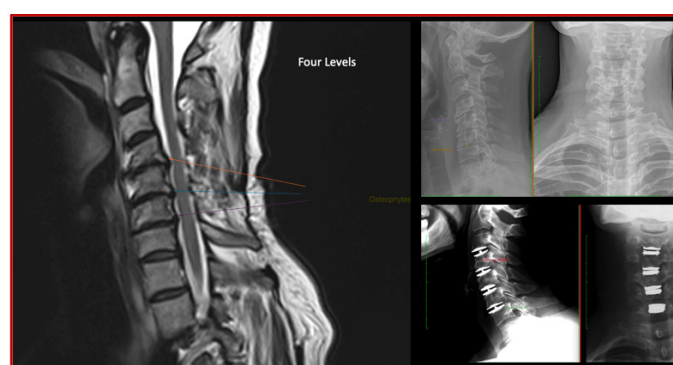


Figure 5: Case 3 presented with severe headaches, neck pain and multiple level radiculopathy. The patient required 4-level disc replacement surgery at C3/4, C4/5, C5/6 AND C6/7.

Studies have explored off-label indications for cervical disc arthroplasty (CDA), including 3- and 4-level procedures, hybrid constructs, revision surgeries, and cases involving degenerative disc disease or ossification of the posterior longitudinal ligament [6].

The results shown in Figure 6 demonstrate how over time during follow-up the scores improve in some of the scores. JOA POSTOP: There appears to be a positive trend in both groups, suggesting that the functional outcomes improve with time post-op, though the trend is slightly stronger in the multiple level (treatment) group. QVAS POSTOP: The multiple level (treatment) group shows a stronger negative correlation, meaning pain decreases over time post-op more effectively in this group compared to the standard group. This is the group that we tend to ignore according to the FDA guidelines. Therefore, we may need to strongly consider multiple level surgeries for CDR as JOA POSTOP for both groups functional outcomes improve with time QVAS POSTOP, the patients who will have had multiple level CDR tend to improve significantly over time post op.

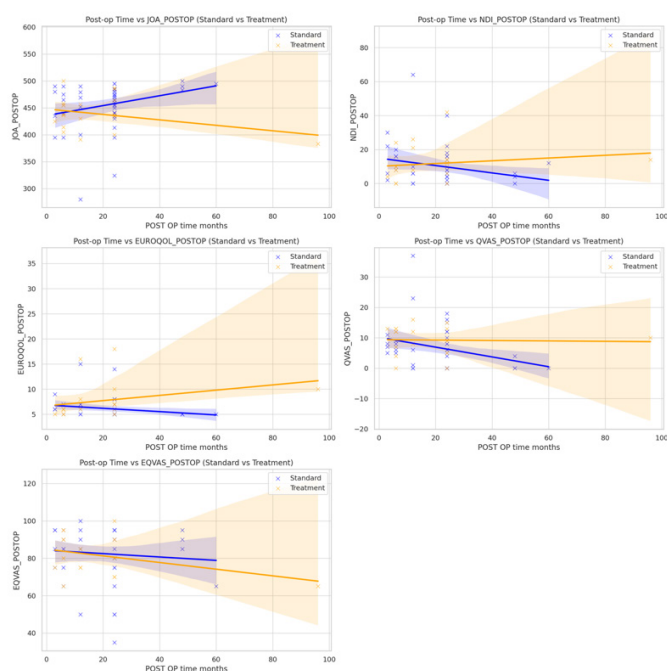


Figure 6: Scatter plots with regression line demonstrating how post-op time (In months) affects each of the five post op scores.

With 1 and 2 level surgeries there is a positive impact regardless of the number of levels involved. The improvements seem to be more pronounced in the 2-level surgery group, particularly for metrics like JOA, NDI, QVAS, and EUROQOL. This might imply that patients undergoing more extensive surgeries also experience greater relief in symptoms, likely because they had more severe conditions pre-operation. Metrics related to pain (QVAS) and quality of life (EUROQOL, EQVAS) consistently show positive outcomes, demonstrating that both 1-level and 2-level surgeries significantly reduce patient discomfort and improve perceived health. Figure 7 shows results for 1 and 2 level surgeries.

Several clinical studies have indicated that CDA leads to improved long-term outcomes, reduced risk of adjacent segment degeneration, and better preservation of cervical motion compared to traditional fusion procedures. Disc replacement using the Mobi-C implant on multiple levels beyond FDA guidelines has shown promising outcomes [7-12]. Research on

1-level CDA using Mobi-C implants demonstrated favourable short-term outcomes, with improved range of motion, pain scores, and patient satisfaction, without the need for revision surgeries or significant complications [13]. Additionally, a multi-centre study reported significant improvements in clinical outcomes, neck disability index, pain levels, and segmental range of motion at 10 years post-CDA, supporting the long-term efficacy and safety of the procedure for 1- or 2-level cervical degenerative disc disease cases [14].

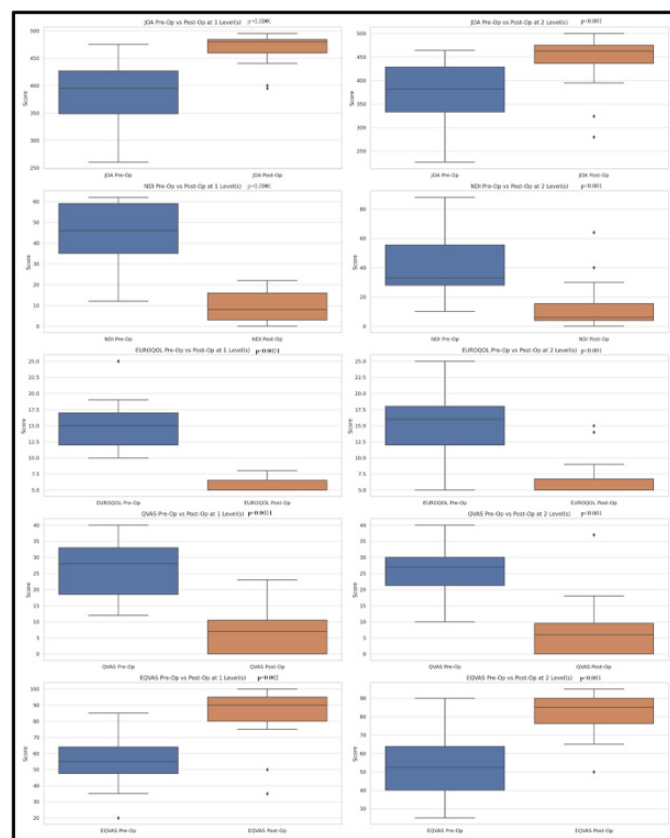


Figure 7: Shows both 1-level and 2-level surgeries. Substantial improvements are noted in patient outcomes across all metrics.

Patient selection in cervical disc replacement surgery will always be a challenging scenario. If one is guided by strictly following FDA indications and contraindications this tends to exclude multiple level surgery. Pierce et al noted that there is current lack of level-1 evidence to confirm effectiveness of CDR outside of the current FDA indications [15]. A level 4 evidence paper 5, which looked at long term outcomes at 3 and 4 levels CDR concluded that there were statistically significant improvements in patient reported outcomes with a low rate of revisions after a 7 year follow-up period.

In our study we have noted that, when patients are well selected using the recommended indications and contraindications by FDA as a baseline and allow for 3 and 4 levels, there is a potential role for 3 and 4 level cervical disc Arthroplasty and it can be performed safely. Such findings should trigger extended use of CDR to allow for level 1 evidence to be collected.

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