

Feasibility of 1, 2, 3 and 4 level Cervical Viscoelastic Total Disc Replacement In An Emerging Country: A Pilot Study

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Objective:

To evaluate the feasibility and preliminary two-year postoperative outcomes of cervical viscoelastic total disc replacement (cVTDR) across 1 to 4 levels in an emerging country. This study aims to address the limitations of traditional anterior cervical discectomy and fusion (ACDF), including technical complexity, higher complication risks, greater inventory requirements, and limited infrastructure in resource-constrained settings, and highlight cVTDR as a simplified and effective alternative.

Methods:

A prospective pilot study was conducted on six patients (mean age 50.67 years; five females, one male) diagnosed with cervical degenerative disc disease. Fourteen AxioMed® Freedom Cervical Discs were implanted across single to four levels (C3–C7). Outcome measures included the Neck Disability Index (NDI), Visual Analog Scale (VAS) for pain, range of motion (ROM) assessments, intraoperative blood loss, and radiographic evaluations. Results were compared with single- and two-level cVTDR historical data.

Results:

Patients demonstrated significant clinical improvements, with mean NDI scores decreasing from 67.33 to 16 and VAS scores from 9.5 to 1.83 at the two-year follow-up. ROM was preserved across all treated segments, with no reported complications, revisions, readmissions, adjacent segment disease, heterotopic ossification, or device failures.

1 **Conclusions:**

2 Cervical VTDR is a feasible and effective non-fusion alternative for managing cervical
3 degenerative disc disease across 1 to 4 levels, offering a simplified solution to the challenges
4 faced in emerging countries. Its streamlined design minimizes technical demands, reduces
5 inventory needs, and avoids complications associated with ACDF, making it a reliable choice
6 in resource-constrained healthcare systems. Further research with larger samples and
7 extended follow-up will help confirm these promising findings.

8

1 **Introduction**

2 Cervical degenerative disc disease is a major cause of disability worldwide, often
3 necessitating surgical intervention when conservative treatments fail. Anterior cervical
4 discectomy and fusion (ACDF) remains the standard treatment for symptomatic cervical disc
5 degeneration, myelopathy, and radiculopathy¹. While effective, ACDF alters spinal
6 biomechanics, increasing intradiscal pressure and abnormal motion at adjacent levels (4),
7 contributing to adjacent segment disease (ASD) in up to 92% of patients within five years,
8 with an annual incidence of 2.9%²⁻⁴.

9 Multi-level ACDF with plate fixation have better outcomes, however the fusion rates decline
10 as the number of levels increases, leading to the increased need for revision surgeries ^{5,6}.

11 Longer operative times, greater technical complexity, and the need for posterior
12 instrumentation further elevate complication risks ⁷. Additionally, bone graft substitutes such
13 as demineralized bone matrix, hydroxyapatite, and beta-tricalcium phosphate introduce
14 potential complications, even in single- and two-level ACDF⁸. These limitations have driven
15 the development of motion-preserving alternatives to mitigate the biomechanical drawbacks
16 of fusion.

17 Cervical total disc replacement (TDR) was introduced in the 1990s as an alternative to
18 ACDF, preserving segmental motion and eliminating the need for plates, screws, interbody
19 cages, and bone grafts ⁹. Traditional articulating TDRs (ATDRs), modeled after hip and
20 knee replacements, restore motion using ball-and-socket designs. These early TDRs
21 demonstrated clinical utility in the literature, establishing non-inferiority to ACDF¹⁰⁻¹⁴.

1 However, the intervertebral disc is not naturally articulating; it is viscoelastic, allowing for
2 multidirectional movement and shock absorption. Consequently, ATDRs have been
3 associated with complications such as osteolysis, heterotopic ossification (HO), device
4 migration, and loss of sagittal balance¹⁵⁻¹⁷. These limitations have necessitated further
5 advancements in disc replacement technology.

6 Viscoelastic total disc replacement (VTDR) was developed as the next generation of TDR to
7 better replicate the biomechanics of a healthy disc. Unlike ATDRs, AxioMed® VTDR
8 features a single-piece viscoelastic design that provides natural shock absorption, six degrees
9 of motion, and lordotic alignment^{18,19}. A post-market analysis (PMA) European
10 demonstrated significant improvements in Neck Disability Index (NDI), Visual Analog Scale
11 (VAS) scores, and neurological function over two years in single- and two-level cervical
12 VTDR (cVTDR) patients, with no device failures, explantations, or radiographic evidence of
13 heterotopic ossification or osteolysis²⁰. However, the feasibility and outcomes of multi-level
14 applications remain unexamined.

15 This evaluation is particularly relevant in emerging countries, where motion-preserving spine
16 surgery remains underexplored. Complex spinal procedures such as multi-level ACDF
17 require specialized expertise, advanced instrumentation, and robust healthcare infrastructure,
18 all of which are often limited in resource-constrained settings. Additionally, revision
19 surgeries for ASD, nonunion, or hardware failure further complicate long-term treatment
20 planning. A motion-preserving solution that reduces surgical complexity, inventory demands,
21 and sterilization requirements could be highly beneficial.

Most TDR research has focused on single- and two-level applications, leaving outcomes at three and four levels largely unexamined, despite promising results in a recent four-level cervical disc arthroplasty study²¹. A critical gap remains in assessing the feasibility, safety, and clinical effectiveness of VTDR in multi-level applications, particularly in resource-limited settings. The objective of this pilot study was to assess the feasibility of 1-, 2-, 3-, and 4-level cervical VTDR in Jamaica, an emerging country, over a two-year follow-up period and determine whether its results align with previously published single- and two-level data.

Materials and Methods

Study Design

This prospective cohort pilot study enrolled six consecutive patients in 2017 from a single center in Jamaica who underwent cVTDR with the AxioMed® Freedom Cervical Disc (FCD) across multiple levels. All surgeries were performed by an experienced orthopedic spine surgeon, assisted by a neurosurgeon, at a single hospital facility. Written informed consent was obtained from all participants before enrollment. As an early feasibility study, the small sample size was intended to provide preliminary insights into the safety and clinical outcomes of multilevel cVTDR in a resource-limited setting.

Inclusion and Exclusion Criteria

Candidates were considered for surgery only after a minimum of six weeks of failed conservative treatment. Indications for cVTDR surgery included symptomatic cervical

degenerative disc disease with radiculopathy, herniated cervical disc(s) with mild facet signal changes suggestive of degeneration. Exclusion criteria included malignancy, infection and unstable chronic medical conditions.

Assessment Parameters

Comprehensive clinical and radiographic assessments were conducted pre- and postoperatively. Clinical evaluation included the Neck Disability Index (NDI) and Visual Analog Scale (VAS) for pain to assess functional improvement and pain relief. Radiographic assessments focused on device positioning, postoperative complications, and the need for revision surgeries.

Surgical Technique

Patients were positioned supine under general anesthesia. Using an anterior cervical approach, a horizontal midline incision was used to access the surgical level(s). A total discectomy was performed using a high-speed burr and curettes. The posterior longitudinal ligament was preserved whenever possible to maintain segmental stability. The endplates were prepared without keel cuts, and an implant trial was used to determine the appropriate width and height. Due to inventory constraints, only 8-degree cVTDR implants were available, and the closest fitting size was selected for each patient. Higher degree lordosis was not indicated due to lack of substantial kyphosis. The selected disc was then inserted midline in the prepared disc space. For multilevel cases, the same technique was repeated at each affected level.

Statistics

Statistical analyses were executed utilizing Visual Studio (VS) Code (version 1.83.2), the Anaconda3 (Python 3.11.4) kernel within VS Code, and a comprehensive suite of packages, including 'pandas,' 'numpy,' 'datetime,' 'matplotlib,' 'altair,' 'seaborn,' 'statsmodels,' 'math,' 'pingouin,' and 'scipy.' The Mann-Whitney U test was used to compare VAS and NDI scores between this cohort and previously published single- and two-level VTDR outcomes by Chin et al.²⁰, as it is a non-parametric method suitable for comparing two independent groups without assuming normal distribution. Cohen's d was calculated to measure the effect size, indicating the magnitude of differences in pain and disability outcomes.

Results

The study cohort consisted of six patients, five of whom were female, with a mean age of 50.7 years (SD 14.1). The mean weight was 153.5 pounds (SD 21.9), and the average BMI was 24.7 (SD 6.1). A total of 14 cVTDRs were implanted at cervical levels C3 through C7 (Table 1). Two patients received single-level cVTDR at C5-6 (Figure 1), one patient underwent a two-level cVTDR at C4-5 and C5-6 (Figure 2), two patients received three-level cVTDR at C4-5, C5-6, and C6-7 (Figure 3), and one patient underwent a four-level cVTDR from C3 to C7, which included treatment for significant ossification of the posterior longitudinal ligament (OPLL) (Figure 4). The mean blood loss was 41.7 cc (SD 12.9), and all patients were discharged within 48 hours post-operation with immediate clinical

improvement. No intraoperative or postoperative complications, including infections, hematomas, or neurological deficits, were reported.

Significant postoperative improvements were observed across all outcome measures. Preoperative VAS scores decreased from a mean of 9.5 to 1.83 postoperatively, reflecting an 80.7% reduction ($p = 0.013$). Similarly, NDI scores improved from 67.3% preoperatively to 16% postoperatively, representing a 76.2% improvement ($p < 0.001$). Comparatively, in Chin et al.²⁰ reference cohort, VAS scores improved from 63 mm to 15 mm (76.2% reduction, $p < 0.001$), and NDI scores improved from 48% to 4% (91.7% improvement, $p < 0.001$). Over the two-year follow-up period, no revision surgeries, readmissions or device failures were reported in either group.

Radiographically, all VTDR implants remained stable at the two-year follow-up. One implant in a single-level VTDR patient showed slight postoperative misplacement following a motor vehicle accident but remained stable over time (Figure 1). No radiographic evidence of HO was observed based on the McAfee classification²².

Statistical analysis

The analysis revealed significant pain relief and functional improvement in both the study and reference cohorts. Postoperative VAS scores were significantly lower in the study cohort compared to the reference cohort ($U = 1.0$, $p = 0.048$, $r = 0.68$). Similar statistical significance was observed for NDI scores ($U = 10.0$, $p = 0.048$, $r = 0.68$), indicating comparable clinical outcomes between the two groups.

Cohen's d was calculated to assess the effect size of observed improvements. The effect size for VAS was large ($d = 4.68$ for the study cohort and $d = 3.56$ for the reference cohort), indicating a substantial reduction in pain for both groups. Similarly, the effect size for NDI was large ($d = 3.76$ for the study cohort and $d = 4.79$ for the reference cohort), demonstrating significant reductions in disability. These effect sizes confirm that the observed improvements were both statistically significant and clinically meaningful.

Discussion

This study evaluated the feasibility of cervical viscoelastic total disc replacement across single and multi-level applications over a two-year period in an emerging country. It aimed to expand current knowledge on VTDR's performance across multiple levels, an area with limited published data, and to explore its potential as an alternative to ACDF, which is associated with high risks of ASD due to its impact on cervical motion.

Key Findings

cVTDR demonstrated substantial improvements in clinical outcomes, with reductions of 80.7% in VAS scores and 76.2% in NDI scores, indicating significant pain relief and functional improvement. No complications, revisions, or device failures were reported over the follow-up period, underscoring the device's safety and reliability in the study cohort. These results align with prior study by Chin et al.²⁰ that showed similar improvements in NDI and VAS scores, supporting the consistency of the implant's clinical efficacy.

1 Additionally, radiographic assessments showed stable implant positioning, with no HO,
2 osteolysis, or device migration, further suggesting the device's durability.

3 *Comparison with Similar Research*

4 Sheng et al.²³ conducted a systematic review and meta-analysis examining the risks of HO
5 and fusion following cervical articulating TDR. Analyzing eleven studies with at least 10
6 years of follow-up, involving 1140 patients, they found that the overall incidence of HO was
7 70% at 10 years, 60% at five to six years, and 50% at one to two years postoperatively.
8 Specifically, the incidence of severe HO (grades 3 or 4) was 37%, while mild HO (grades 1
9 or 2) was 30% at the 10-year follow-up.

10 Risk factors for HO include a high degree of ossification before surgery²⁴, insufficient
11 endplate coverage of the prosthesis²⁵⁻²⁷, intervertebral space height change before and after
12 surgery ≥ 1.8 mm²⁵, excessive intervertebral space distraction²⁸ and disk space angle change
13 during operation > 5 degrees²⁹ may lead to higher incidences of HO. The above patient
14 characteristics and surgical details may vary between studies. ProDisc-C (Centinel Spine,
15 West Chester, PA, USA) had the highest pooled overall HO rate (86%) at 10 years of follow-
16 up. Bryan (64%) and Prestige LP (62%) prostheses had a lower pooled overall HO rate.

17 Three critical factors contributing to the low incidence of HO and complications were
18 identified. First, a proper surgical technique, which avoids excessive burring of the endplates,
19 likely reduced the risk of fusion^{30,31}. Second, the cVTDR's non-articulating design does not
20 rely on perfect centralization for effective functioning, reducing the likelihood of abnormal
21 kinematics seen in earlier devices that required precise placement^{32,33}. Third, minimizing

1 dead space in the disc cavity through proper implant sizing further mitigated the risk of HO,
2 as evidenced by the absence of complications even in cases where slightly undersized
3 implants were used^{15,34}.

4 *Limitations*

5 This study has several limitations. The small sample size limits the generalizability of
6 findings to larger populations, and the single-center nature of the study may restrict
7 applicability across different clinical settings. A two-year follow-up, while informative, is not
8 sufficient for assessing long-term complications such as late-onset HO or implant wear. The
9 absence of a control group or direct comparison with ACDF limits the ability to
10 comprehensively evaluate cVTDR's advantages over fusion. Furthermore, no economic
11 assessment was conducted, leaving questions regarding cost-effectiveness, particularly in
12 resource-limited settings.

13 *Clinical Relevance*

14 The results of this study are promising for the application of cVTDR as a non-fusion
15 alternative in managing cervical DDD, particularly across multiple levels. The absence of
16 complications and revision surgeries suggests that cVTDR may reduce the need for
17 reoperations, providing a cost-effective option that also preserves cervical motion. The cost
18 of the implant will be determined by market forces, but the cost of inventory, transportation,
19 and osteobiologics is expected to be higher for fusion compared to the AxioMed[®] disc, which
20 comes sterile-packed with a compact instrument kit containing mostly an inserter and trials.
21 Additionally, the average cost of readmission for ACDF is approximately \$25,000³⁵, further

emphasizing the potential cost savings with cVTDR. Its viscoelastic, non-articulating design simplifies the implantation process, which could be beneficial in diverse clinical settings, including those where specialized surgical expertise may be limited. The favorable radiographic outcomes observed even in multi-level cases support cVTDR's reliability as a solution for managing cervical disc disease without the risks associated with fusion.

Implications for Further Research

Larger, multi-center studies are essential to confirm these findings and evaluate cVTDR's performance across varied clinical settings. Extended follow-up periods are necessary to fully assess the device's durability and to monitor for late-onset complications, such as HO or implant failure. Comparative studies with ACDF and other TDR systems would provide a more comprehensive understanding of the device's relative advantages. Additionally, future research should include economic analyses to determine cost-effectiveness, especially in low- and middle-income settings where healthcare budgets may be constrained.

Conclusion

Cervical viscoelastic total disc replacement showed significant clinical improvements and radiographic stability across 1 to 4 cervical levels over two years, with reduced pain and disability scores and no complications or revisions. These results align with previous single- and two-level studies, highlighting cVTDR as a reliable, motion-preserving alternative to fusion, especially in multi-level cases. Conducted in Jamaica, an emerging country, this pilot study demonstrates cVTDR's feasibility in resource-constrained settings, where reduced

inventory needs and simplified procedures are particularly beneficial. Consistent outcomes across multiple surgeons indicate reproducibility and support broader clinical use. The potential cost savings, including reduced reoperations, readmissions and lower inventory demands, further emphasize cVTDR's value. This study offers preliminary evidence of cVTDR's effectiveness, warranting further research to confirm long-term safety, efficacy, and cost-efficiency in diverse clinical environments.

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Figure Legend

Figure 1: Single-level C5-6 case: (A) Intraoperative photo of the implanted AxioMed® disc, (B) Lateral fluoroscopic image, (C) Postoperative lateral radiograph.

Figure 2: Two-level C4-6 case: (A) Preoperative magnetic resonance imaging (MRI), (B) Intraoperative photo, (C) Postoperative lateral radiograph.

Figure 3: Three-level C4-7 case: (A) Preoperative magnetic resonance imaging (MRI), (B) Intraoperative photo showing 2 of the 3 AxioMed® discs, (C) Postoperative lateral radiograph.

Figure 4: Four-level C3-7 case with ossification of the posterior longitudinal ligament: (A) Preoperative magnetic resonance imaging (MRI), (B) Postoperative lateral radiograph and (C) Postoperative sagittal computed topography (CT) showing stable AxioMed® implants.

1 Table 1: Patient demographics, levels treated, and complication overview

Age	Sex	Number of Level(s)	Level	Complications
54	F	Single	C5-6	None
31	M	Single	C5-6	None
39	F	Two	C4-5, C5-6	None
60	F	Three	C4-5, C5-6, C6-7	None
70	F	Three	C3-4, C4-5, C5-6	None
54	F	Four	C3-4, C4-5, C5-6, C6-7	None

2

Figures 1







Figures 4

