

1    **Structured Abstract**

2    **Study Design:**

3    Prospective cohort pilot study.

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5    **Objective:**

6    To evaluate the feasibility, safety, and preliminary 2-year postoperative outcomes of

7    AxioMed<sup>®</sup> (AxioMed LLC, Burlington, MA, USA) single-piece, 8-degree lordotic cervical

8    viscoelastic total disc replacement (VTDR) in Jamaican patients and compare the results to

9    previous European study findings.

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11   **Summary of Background Data:**

12   This investigation offers a post-market analysis (PMA) of the clinical and radiographic

13   outcomes in Jamaican patients who received the AxioMed<sup>®</sup> cervical VTDR. It builds upon a

14   European study by emphasizing 2-year postoperative outcomes.

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16   **Methods:**

17   Fourteen AxioMed<sup>®</sup> Freedom Cervical Discs (FCD) with 8-degree lordosis were implanted in

18   six Jamaican patients with cervical degenerative disc disease and followed for two years.

19   Assessment parameters included the Neck Disability Index (NDI), Body Mass Index (BMI),

20   Visual Analog Scale (VAS) for pain, intraoperative blood loss, and radiographic assessment.

21   These results were compared with findings from the European cohort.

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**Results:**

The Jamaican cohort included five females and one male (mean age: 50.67 years). VTDR from single to four levels from C3 to C7 demonstrated significant improvements in clinical outcomes, with mean NDI scores improving from 67.33 to 16, and VAS scores reducing from 9.5 to 1.83 at the 2-year follow-up, mirroring the positive results observed in the European cohort. There were no complications, revisions, or device failures in either cohort. One device in the Jamaican cohort remained stable despite a suboptimal position and a subsequent motor vehicle accident. In both cohorts, there were no incidence of heterotopic ossification.

**Conclusion:**

The AxioMed® cervical disc replacement demonstrated comparable success in both Jamaican and European patients, with significant improvements in clinical outcomes over the two-year follow-up period. Its effectiveness in treating cervical degenerative disc disease with herniation in Jamaican patients suggests that it could be an alternative option for those seeking to avoid fusion procedures in developing countries.

**Keywords:**

AxioMed® viscoelastic disc replacement; Degenerative disc disease (DDD); Cervical spine; Total disc replacement (TDR); Jamaica.