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4-YEAR RESULTS OF A PROSPECTIVE MULTI-CENTRE STUDY ON 200 SINGLE-LEVEL CERVICAL DISC PROSTHESES: CLINICAL AND RADIOGRAPHIC OUTCOME

Introduction/Aim

Despite encouraging outcomes after cervical total disc replacement (cTDR), critical debates regarding heterotopic ossification (HO) and the prevalence of adjacent level degeneration (ALD) are ongoing.

Materials and Methods

In this prospective multi-centre study 200 subjects underwent single-level cTDR (activ® C , Aesculap AG, Tuttlingen) for the treatment of symptomatic cervical degenerative disc disease. Assessments were performed preoperatively, at discharge and again at 6 weeks, 6 months, and at one, two and four years. Qualitative and quantitative radiographic analyses were done by an independent core lab.

Results

NDI and VAS neck and arm pain decreased significantly from baseline to the four-year follow-up. Mean improvement for NDI was 20, for VAS severity and frequency of neck pain 26.4 and 28 and for VAS arm pain 30.7 and 35.1, respectively. Neurologically most patients (86.4%) improved, with 76.1% non-symptomatic cases. Subsequent reoperations were reported for 7%, including 3% device removals. In 2.5% a subsidence >3mm was recorded, one case with a migration >3mm. No further adverse events were observed. Segmental lordotic alignment changed from -2.4°(preop) to -6.2° at four years. Postoperative height was maintained during the four-year follow-up. HO (grade III-IV) was present in 27.1% of cases and 82.4% showed segmental mobility. ALD occurred in 28.2%, 4.5% thereof required surgery.

Conclusions

These mid-term results confirm the effectiveness of this semi-constrained cTDR. It preserves motion for most subjects; but further long-term observations are required to confirm these findings.