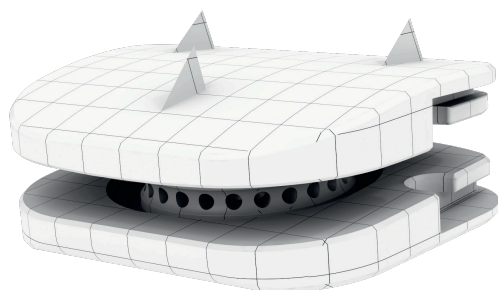


BAGUERA® C
CERVICAL DISC PROSTHESIS



TWO-YEARS PROSPECTIVE CLINICAL FOLLOW-UP
BY SPINEART



CERVICAL ARTHROPLASTY USING BAGUERA[®]_c:

OVERVIEW OF TWO-YEAR, PROSPECTIVE, CLINICAL FOLLOW-UP DATA REGISTRY

POPULATION

118 patients were included in BAGUERA[®]_c Registry, from 5 different hospitals in Europe, with two years prospective follow-up, through five follow-up visits, from 6 weeks to 2 years. The population studied includes 54 males (45.8%) and 64 females (54.2%), aged at the surgery time between 30 and 74 years. A total of 98 subjects were treated exclusively by TDR using BAGUERA[®]_c, 70 subjects at 1 level, 25 subjects at 2 levels and 3 subjects at 3 levels. The rest of studied population, 20 subjects, underwent HYBRID surgery with 1 level TDR using BAGUERA[®]_c for 14 subjects, 2 levels for 6 subjects. A total number of 149 BAGUERA[®]_c cervical disc prostheses were implanted in 118 subjects at 4 cervical levels: C3-C4, C4-C5, C5-C6 and C6-C7.

OVERALL SUCCESS EVALUATION

- No implant-related adverse events were recorded. No patient needed subsequent surgery. Three surgery-related adverse events were recorded.
- A clinical improvement of more than 20% of the NDI score after two years was observed in 81.8% of the TDR patients. In the HYBRID group, this improvement was observed in 50.0% of the patients.
- The neurological examination concerning reflexes, motor function and sensitivity revealed a stable or improved status in all patients in both groups.
- An improvement of more than 20% of the VAS score for neck pain was observed in 75.5% of the patients in the TDR-only group, and 55.0% of the patients in the hybrid group after two years. The minimum 20% improvement of the VAS score for arm pain was observed in 77.6% of the patients in the TDR-only group, and 70.0% of the patients in the hybrid group. All VAS Patient Satisfaction scores show more than 70% satisfaction, with a net positive trend after 3 months post-operative until the end of the observation period for TDR surgeries, with the best results for TDR 2 levels surgeries (91.11% satisfaction).
- A 15% or more improvement in quality of life as evaluated by the Short Form 36 questionnaire was recorded, respectively in 76.5% (TDR group) and 60.0% (HYBRID group) for the physical component of the questionnaire, and in respectively 77.6% (TDR group) and 50.0% (HYBRID group) for the mental health component of the questionnaire.

CONCLUSION

Total disc replacement using BAGUERA[®]_c device for the treatment of symptomatic cervical degenerative disc disease is a safe procedure with a low complication rate and in this study, no device-related adverse event. The best results were observed in patients of maximum 50 years of age, with no previous cervical or other spinal surgeries and with preoperative functional disabilities greater than 30% as evaluated by NDI.

TDR is an effective surgical treatment of one or two levels symptomatic cervical degenerative disc disease, whether used alone or in combination with other techniques. Functional improvement is slightly less frequent (30%) when HYBRID surgery is applied.