BAGUERA®C Study #16002

Cervical Arthroplasty using BAGUERA® C: A two-year, prospective, clinical follow-up data registry. Retrospective radiographic evaluation

Not FDA approved. Non-US study
Region: Europe
Status: Completed

Pilot study for registration in various countries

Primary Objectives:

1. *Motion* at the treated level after two years of total disc replacement (TDR) using Baguera C prosthesis, evaluated by its range of motion (ROM) between flexion and extension; motion occurs when ROM value is at least 2°;
2. *Disc height restoration* after two years of total disc replacement (TDR) using Baguera C prosthesis.

Secondary Objectives:

1. *Motion* at the adjacent level after two years of total disc replacement (TDR) using Baguera C prosthesis, evaluated by its range of motion (ROM) between flexion and extension; motion occurs when ROM value is at least 2°;
2. *Overall cervical alignment,* evaluated as overall lordosis by measuring C2-C7 ROM;
3. *Balance of the spine*, evaluated by the angle of functional spine unit (FSU) at the treated level;
4. *Impact on adjacent levels,* evaluated by the upper adjacent angle and the upper disc height.

Indication - condition: Symptomatic cervical degenerative disc disease one or two levels from C3 to C7

Study type: Observational, prospective data collection (registry), retrospective analysis, multicenter cohort study

Patients enrolled: 96

Primary outcomes:

- ROM FSU : Range of motion (ROM) of the Functional Spine Unit (FSU)
- HEIGHT: Disc Height

Secondary outcomes:

- UPPER ROM: Range of motion of the Upper Functional Spine Unit
- ROM C2-C6: Range of motion of C2-C6 levels
- ROM C2-C7: Range of motion of C2-C7 levels
- ANGLE FSU: Angle of the Functional Spine Unit
- UPPER ANGLE: Angle of the Upper Functional Spine Unit
- ANGLE C2-C6: Angle of C2-C6 levels
- ANGLE C2-C7: Angle of C2-C7 levels
- UPPER HEIGHT: Disc Height of the Upper Functional Spine Unit