Clinical and Radiographic Outcomes on a Series of 249 Patients Treated with Single and Multilevel Baguera C Cervical Disc Replacement at 2-year Follow up

G. Maestretti1, P. Tropiano2, P. Fransen3, D. Noriega4, R. Srour5, P. Otten6, P. Vally7, J.-P. Lejeune8, A. Chatzisotiriou9, P. Alcaraz10

1Hopital Cantonal de Fribourg, Orthopedie, Fribourg, Switzerland, 2CHU Hopital Nord, Marseille, France, 3Clinique du Parc Leopold, Bruxelles, Belgium, 4Hospital Clinico Universitario de Valladolid, Valladolid, Spain, 5Hopital Pasteur, Colmar, France, 6Hopital Cantonal de Fribourg, Fribourg, Switzerland, 7Clinique Saint Paul, Fort de France, France, 8Clinique Saint Joseph, Liege, Belgium, 9AHEPA University Hospital, Thessaloniki, Greece, 10Hospital General de Mallorca, Palma de Mallorca, Spain

Background context: Single level cervical disc replacement is an alternative to traditional anterior cervical fusion in treating some cases of cervical Degenerative Disc Disease. Fusion techniques for multilevel pathology are currently documented and remain to be compared to clinical outcomes of multilevel cervical disc replacement.

Design: This is an observational European prospective and multi-centric study - data reported at ten European sites including single, multilevel cases and adjacent to interbody cages.

Objective of the study: To compare safety and efficacy of cervical disc replacement with the Baguera C prosthesis in single and multilevel DDD. Patients were followed up postoperatively at different intervals at 1, 3, 6, 12 and 24 months.

Patient Sample: 249 patients were enrolled in this study. 171 patients were treated at 1-level, 41 treated at 2 levels and 2 patients were treated at 3 levels. Additionally the Baguera C was used adjacent to a fusion with a cage in 35 patients. The diagnosis was cervical degenerative disc disease between C3 and C7 with symptomatic DH. Population was 106 male 143 female, average age 46 (25-71).

Methods: Clinical assessment included VAS scores for arm and neck pain and Neck Disability Index (NDI). Range of motion (ROM) from flexion/extension lateral view were measured.

Results: Of all NDI scores recorded, 86,50 % demonstrated at least 15 points improvement at two years follow up from pre-op scores. 85,1% of VAS arm Pain scores demonstrated an improvement by ≥ 2 points from pre-op scores and 50,8% for VAS neck Pain scores. The breakdown by levels and adjacent to an interbody cage shown that 80% of reported NDI scores demonstrated at least a 15 point improvement post operatively for two level disc replacement. 82,4% demonstrated a greater than 2 points improvement in VAS arm pain and 53,3% for VAS neck pain. For patients that received both Baguera C and an interbody cage, 72,7% demonstrated a greater than 2 point improvement in VAS arm pain and 41,7% for VAS neck pain.

Three (1,8%) cases of subsidence and 4 cases of implant loosening/displacement due to inappropriate sizing were reported.

Available radiographic findings show on average a ROM of 8,2 ° at 2 years and an overall change in cervical lordosis of 5° from pre-op.

Conclusion: With regards to effectiveness, clinical outcomes demonstrated a significant improvement for both the total population (n=249) and for the single level total disc replacement population (n=171). Given these outstanding results single and multilevel TDR with Baguera C can be considered to be safe. Additionally, no significant difference was observed between single and multilevel TDR groups regarding clinical, functional and radiological results. Follow up for this series need however to be extended for up to 5 years at least. The role of the Baguera C prosthesis in multilevel cases as well as in cases to a fused level still need further evaluation although these preliminary results are encouraging.