



Arthroplasty with the Baguera[®]C Cervical Disc Prosthesis: A Review of the Scientific Background, Clinical and Radiographic Evidences

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Abstract

Purpose: Cervical disc prostheses were designed to preserve motion and to avoid adjacent level degeneration. Although many implants are used, few presented clinical results. Also, prosthesis being different, the published literature may not be generalized to all devices. The purpose of this review is to evaluate the clinical results of cervical disc replacement with the Baguera[®]C prosthesis and to compare these to the results of other prosthesis in the literature.

Method: We reviewed the peer-reviewed or published literature studying the Baguera[®]C cervical prosthesis clinical and radiological results.

Results: The studies analyzing analysis of the scientific data around the Baguera[®]C cervical prosthesis showed low complication rates, no recorded device-related adverse events, and demonstrated improvement of the NDI score, particularly for patients under 50, without previous cervical or spinal surgeries, with preoperative NDI greater than 30% and with small (+10%) differences between implant size and preoperative disc height

The monitoring of changes of the level cranial to the highest total disc replacement level showed protection against adjacent segment degeneration, with minimal if any influence on the evolution of the adjacent level over the two years observation period. Baguera[®]C prosthesis could compare favorably to some other types of prostheses by its shape, technique of implantation, and physiological center of rotation allowing a lower rate of HO.

Conclusion: Cervical disc replacement with the Baguera[®]C is a safe and effective procedure. The available data show the absence of increased degeneration of adjacent levels. The level of heterotopic ossification is equivalent or lower than with other similar implants.

Keywords

Cervical discopathy; Cervical arthroplasty

Abbreviations: HO: Heterotopic Ossification; TDR: Total disc replacement; NDI: Neck Disability Index; VAS: Visual Analog Score; FSU: Functional Spinal Unit; ROM: Range of Motion; FU: Follow Up; PDH: Preoperative disc height; BCH: Implant height; ACDF: Anterior Cervical Discectomy and Fusion

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Introduction

Cervical disc replacement by arthroplasty has become a common surgical option in the treatment of degenerative cervical disc pathologies.

It is considered to be a viable alternative to anterior cervical discectomy and fusion (ACDF) since several randomized studies with two-year follow-up using different implants showed either no statistical difference between two groups treated either by arthroplasty or by anterior fusion, or even slightly better results for the patient group treated by arthroplasty [1-4].

The Baguera[®]C cervical prosthesis (Spineart SA, Geneva, Switzerland) is a biomechanical device designed to be used for total disc replacement (TDR).

It consists of a high-density polyethylene (PE) nucleus that articulates between two titanium endplate components, with a porous coated exterior and a diamond-like carbon coated interior (Figure 1).

The implant allows a physiological rotation as well as translation in both the anterior-posterior (AP) (± 0.3 mm) and rotational ($\pm 2^\circ$) directions. The controlled mobility of the PE nucleus is designed to prevent excessive constraints on the facet joints, and its curve is designed to respect axial rotation movements. The inferior plate and PE design allow 0.15 mm elastic deformation to absorb shocks and vibrations.

Methods

We reviewed the peer-reviewed or published literature studying the Baguera[®]C cervical prosthesis clinical and radiological results.

Review of the Literature

Clinical results: Three series reported clinical results

The Maestretti et al. series: An observational European prospective and multi-centric study -gathered the results regarding safety and efficacy of a total of 249 patients [5,6].

The patients were included following the recommendations of the Belgian Neurosurgical Spine Society [7], and had to be between 18 and 60 years-old, with radiculopathy due to soft disc herniation and/or moderate uncarthrosis on 1 or 2 levels maximum.

171 patients were treated at 1-level, 41 treated at 2 levels. All the patients were suffering from symptomatic cervical degenerative disc disease between C3 and C7. The studied population covered 106 males, 143 females, mean-age 46 (25 to 71) at the time of surgery.

The patients were reviewed at 1, 3, 6, 12 and 24 months, evaluated using the Visual Analog Scale (VAS) for arm pain and neck pain and the Neck Disability Index (NDI). The range of motion (ROM) of the implant was radiologically assessed from flexion/extension lateral view, measured at all follow-up visits. The patients were also monitored for eventual complications.

For the single levels cases, 86.50 % of the patients demonstrated at least 15 points improvement of their NDI score at two years follow up from pre-op scores. For the VAS scores, 85.1% of the patients demonstrated an improvement of their VAS score for arm pain by \geq

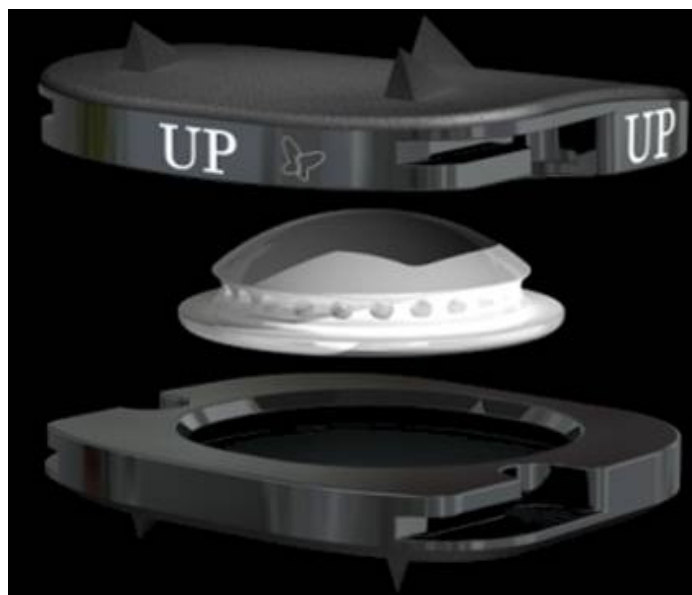


Figure 1: The three parts of the Bagera C prosthesis : On the upper endplate, the surface in contact with the vertebra is anatomically curved and has three fins for stability and a plasmapore coating for secondary bone integration, whereas the surface in contact with the polyethylene is coated with Diamotith® to reduce friction. The PE nucleus is clipped in the inferior endplate. The surface of the inferior endplate in contact with the vertebra shows the same characteristics as the upper endplate.

2 points from pre-op scores, and 50.8% of the patients demonstrated improvement for VAS neck Pain scores or the multiple levels cases, 80% of the patients demonstrated improved NDI scores with at least a 15 point improvement post operatively for two level disc replacements. 82.4% of the patients demonstrated a greater than 2 points improvement in VAS arm pain and 53.3% for VAS neck pain.

The Fransen et al. series: A prospective registry - aimed to investigate effectiveness of single or double-level total disc replacement (TDR) with the Bagera®C cervical prosthesis in respect of pain, neurological, functional and radiological outcomes after two years follow up [8-10]. The complications related to disc replacement with this implant, as well as the frequency and causes of subsequent surgeries were also studied, as well as the factors that could improve the effectiveness of this surgery.

The study included 95 patients, (42 males, 53 females), mean age 42.4 +/- 8.4. They underwent surgical treatment at 1 or 2 levels: C5-C6 (57 levels; 47.5%) and C6-C7 (51 levels; 42.5%). 70 patients underwent one level arthroplasty, 25 patients had two-level arthroplasty. In total, 120 prostheses were implanted. 17 adverse events were recorded in 15 patients. Three surgeries related adverse events were recorded: one Claude-Bernard-Horner syndrome, one dural tear and one adjustment of the size of the prosthesis during surgery.

A clinical improvement of more than 20% in the NDI score was observed in 81.8% of the patients. The neurological examination was unchanged or improved in all patients of both groups. An improvement of more than 20% in the VAS score for neck pain was observed in 75.5% of the patients. A 20% or more improvement of the VAS score for arm pain was observed in 77.6% of the patients. Finally 15% or more improvement in quality of life as evaluated by the Short Form 36 questionnaire was seen, respectively in 76.5 for the physical component of the questionnaire, and in 77.6% for the mental health component of the questionnaire

The mean preoperative range of motion (ROM) at the operated level was measured at 10.4° and 9.8° respectively in the one level and two levels patients. After two years, the mean ROM was 8.9° for single level prosthesis, and 9.2 for the two levels prosthesis and 96% of the prosthesis were mobile. The decrease in mobility observed after two years was on average less than 2°. The ROM at the upper adjacent level changed from 10.5° preoperatively to 13.6° after two years for single levels, and from 11.7° preoperatively to 10.9° after two years for the double-levels.

Radiographic data demonstrated mobility after two years post-surgery at the treated levels as well as at adjacent levels, with no signs of hypermobility at the adjacent level.

The Pointillart et al. series: An independent multicentric retrospective analysis of a clinical and radiographical database – evaluated the relationship between surgery outcomes (2 years FU), and the preoperative disc height (PDH)/implant height (BCH) ratio, in patients treated by TDR with the Bagera®C cervical prosthesis [11].

The study included 99 patients (46 males, 53 females) mean age 43.2 (29 to 70), all treated at 1 to 3 levels. Overall, 123 prosthesis (5, 6, 7 mm height) was implanted: 70,49,4 % respectively. Pre- and postoperative radiographic data were extracted by an independent evaluator from dynamic lateral radiographs: disc height, ROM (segmental, overall and at the upper level), segmental and overall lordosis. Self-reported questionnaires (VAS, NDI, and SF-36) were used for clinical assessment.

The highest mean segmental ROM (8.8°) was observed with a 5mm BCH, but better NDI, VAS and SF-36 scores were observed with 6 mm BCH. Better clinical results were observed with small (+10%) difference between implant size and preoperative disc height.

Radiographic Results

Adjacent level protection

The radiological findings show a non-significant loss of motion

after two years at the operated level, but slightly increased upper level and overall cervical motion after two years for the one level surgery. Multiple disc replacement seemed associated with non-significant decreased segmental and overall cervical motion.

In the preliminary study [5-7], the available radiographic findings showed on average a range of motion of 8.2° at 2 years and an overall change in cervical lordosis of 5° from pre-op. No HO was observed over the study period. There was no reported fusion in any of the cases.

Both papers by Fransen and Schils and by Alvin et al. show that the occurrence of heterotopic ossifications around the implant seems to be the rule rather than the exception, influenced by the selection of patients, the type of implant and the surgical technique [12,13].

Pre-operative and two years postoperative X-rays from 99 subjects enrolled into Bagera® Registry have been evaluated independently [14,15]. The results were obtained from a retrospective analysis of radiographic images, based on a registry type data collection.

The collected parameters were: the motion at the treated level two years after total disc replacement (TDR), evaluated by its range of motion (ROM) between flexion and extension (motion being defined by a ROM of at least 2°); disc height two years after TDR; motion at the adjacent level two years after TDR, evaluated by its ROM between flexion and extension (motion = ROM > 2°); overall cervical alignment, evaluated as overall lordosis by measuring C2-C7 ROM; balance of the spine, evaluated by the angle of functional spine unit (FSU) at the treated level; impact on adjacent levels, evaluated by the upper adjacent angle and the upper disc height. Additionally, the presence of HO at the treated level was evaluated 2 years after TDR, using a 5-grade scale (modified from McAfee et al.) [16].

A total of 123 prostheses could be analyzed: 4 prostheses implanted in C3-C4, 19 in C4-C5, 53 in C5-C6 and 47 in C6-C7.

At the treated level, the ROM decreased from 10.25° to 8.79° (ns) after two years in the one level TDR, from 9.8° to 9.15° (ns) in two-levels TDR. The decrease was more pronounced in the three levels TDR, dropping from 13.26° preoperatively to 5.99° (ns) after two years, but on a smaller cohort of patients.

The ROM at the upper adjacent level increased for the one level case (from 10.64° to 13.54°) but decreased compared to preoperative motion for the multiple level cases. Similar findings were observed with the C2-C7 ROM that increased compared to preoperative motion for the one level TDR, but decreased for the multiple levels TDR.

At the operated level, the angle changed from 5.62° preoperatively to 6.33° after two years for the one-level TDR, from 4.63° to 6.82° for the two-level TDR and from 8.21° to 3.93° for the three-levels TDR. Similar minor sagittal balance changes were observed at the level above the operated level and with the overall C2C7 angle.

The disc height at the operated level was slightly increased after two years, but no changes were observed at the upper adjacent level.

Heterotopic ossifications and design of the prosthesis

In the preliminary study the presence of heterotopic ossifications 2 years after TDR using Bagera® was evaluated for all 124 levels in 99 subjects treated by mono, two or three level TDR [5-7]. Signs of heterotopic ossification were found in 57 levels (46%); 43 levels (34.7%) presented HO grade 1 or 2 and 19.35% (24 levels) presented HO grade 3 or 4.

No associations were found between the presence of HO and clinical outcomes or cervical mobility but this could change with a longer follow up.

The occurrence of heterotopic ossifications with the Bagera® cervical disc prosthesis has also been specifically studied, in a comparative study by Noriega et al. [17]. 54 patients were included, 26 men and 28 women, mean age 48.3 (range 37-74 years), 42 patients at one level and 12 patients at two levels. A total of 66 prostheses were implanted with an average follow-up of 44 months. Three different artificial prostheses (types A – Bagera®, B – Prodisc C and C – PCM) were used.

67% of the Bagera® prosthesis showed either no or grade I HO, compared to 10.5% in group B. Grade III or grade IV HO was observed only in 18.5% of the Bagera® group, compared to respectively 73.8% in group B (Prodisc) and 65 % in group C (PCM).

Concerning vertebral mobility and based on a CT-based HO grading, these results show good success (i.e. HO grades 0 or I) in 28.8% prosthesis (17 Bagera® and 2 Prodisc C) and possible limitation in the range of vertebral motion (HO grade II) in 22.7% prosthesis (5 Bagera C, 3 Prodisc C and 7 PCM). Mobility was strongly diminished (HO grades III and IV) in 48.5% prosthesis (5 Bagera C, 14 Prodisc C and 13 PCM).

As no significant association of HO was found with the patients' age or gender, or the actual inter-vertebral prosthesis level, the factors significantly associated with HO severity (p<0.05) are the prosthesis type, the amount of blood loss and the duration/aggressiveness of the surgery.

Discussion

The common feature of the papers mentioned in this review, is some homogeneity regarding the indications for surgery, mainly radiculopathy due to soft disc herniation with minimal uncarthrosis, and regarding surgical technique, performed on 1 or 2 levels maximum with no attempt was made to create motion in an ankylosed segment.

The following contra indications were systematically excluded: severe uncarthrosis, severe facet arthritis, clinical or radiological myelopathy, spinal canal narrowing, fracture, infections, tumors, osteoporosis and severe osteopenia, segmental instability or spinal deformities, psycho-social distress, foreign body sensitivity to the implant materials and ossification of the posterior longitudinal ligament. This also gives some consistency to these different series.

Both the Maestretti series and the Fransen series showed excellent clinical results, although the longest follow-up did not exceed 2 years, which is limited.

These good clinical results and a very low rate of complications confirm that the concept of cervical disc replacement with this type of semi-constrained prosthesis is a safe and effective option in cervical disc surgery, with a robustly low record of device-related adverse events. In particular, the NDI score improvement confirms cervical arthroplasty as an effective surgical treatment of single or double level symptomatic cervical degenerative disc disease.

The patients that presented with the best results were adults of maximum 50 years of age, without previous surgeries for their cervical condition, without previous other spinal surgeries, and with preoperative functional disabilities evaluated by NDI greater than 30%. Better results were observed with small (+10%) difference

between implant size and preoperative disc height. This finding should be considered to be specific to this type of prosthesis. It could allow surgeons to obtain better clinical results by careful choice of the right implant size [18].

The radiological assessment of adjacent level degeneration over a two years period focused on the changes of the FSU cranial to the highest TDR level was done assuming that potential changes would reflect increased stress and more chances of further degeneration. In the one-level patients, a slightly increased ROM was observed. This increase was not observed in the two- and three levels patients who showed a slightly decreased ROM. Also, the measure of the adjacent FSU angle showed no significant sagittal balance changes and the adjacent FSU disc height was preserved. The interpretation of these data is that total disc replacement with this implant had little or no influence on the evolution of the adjacent level over the two years observation period. In that way, the radiological follow-up showed encouraging results in terms of preservation of mobility at the operated level and no radiological signs of adjacent segment degeneration

Although the occurrence of HO seems to be common, the rate of HO is variable depending on the type of the prosthesis. Hrabalek et al. had a 56% rate of HO using the Prodisc C prosthesis, and even 18% of fusion after 3-4 years [19]. Ryu et al. reported a HO rate of over 60% with the Bryan prosthesis and of 45% with the Prodisc prosthesis [20]. Yi et al. in their retrospective study of the difference of HO occurrence according to 3 different types of prosthesis reported an overall rate of 40.6%, but striking differences between implants, respectively 21% for the Bryan prosthesis, 52% for the Mobi-C and 71% for the Prodisc C [21].

The 33% rate of HO (grade 2 to 4) compares favorably with other results published in the literature with the Bryan, Mobi-C, Pro-Disc C, or Prestige, when no conflict of interests was identified [17].

This analysis reveals that the type of prosthesis is clearly of paramount importance. A center of rotation causing facet conflict should reduce motion and therefore promote progressive fusion. Extensive bone marrow exposure, either by using a keel for primary fixation or by drilling of the endplate could also release bone growth factors, or induce progressive heterotopic ossification. Therefore, the features of the Baguera C prosthesis, the anatomical shape, the implantation technique without drilling or keel, and a physiological center of rotation are the most likely explanations for a lower rate of HO.

Conclusion

The analysis of the scientific data around this cervical prosthesis shows a low complication rate, no recorded device-related adverse events, and excellent clinical results for the treatment of single or double level symptomatic cervical degenerative disc disease, with a demonstrated improvement of the NDI score. The best results are obtained for adults of maximum 50 years of age, with no previous surgeries for their cervical condition, no previous other spinal surgeries, with preoperative functional disabilities evaluated by NDI greater than 30% and with small (+10%) differences between implant size and preoperative disc height

The monitoring of changes of the level cranial to the highest total disc replacement level showed that implantation of this cervical disc prosthesis offered protection against adjacent segment degeneration, as there was little or no influence on the evolution of the adjacent level over the two years observation period.

The rate of HO is low (33%) and inferior to the rates of other devices published in the literature.

Longer follow up and more homogeneous series would be welcome to further confirm these promising results.

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