

One- or Two- Levels Treatment by Arthroplasty of Cervical Degenerative Disease. Preliminary Results after 5 Years Postoperative Controls

Fransen P^{1*}, Noriega D², Chatzistiriou A³ and Pointillart V⁴

¹Medical-Orthopedic Surgical Clinic, Principality of Monaco

²University Clinical Hospital of Valladolid (HCU), Valladolid, Spain

³St Luc Clinic, Thessaloniki, Greece

⁴Hospital Pellegrin Bordeaux, Bordeaux, France

*Corresponding author: Fransen P, Medical-Orthopedic Surgical Clinic, 10 Avenue d'Ostende, 98000 Monaco, Principality of Monaco, Tel: +377 9999 1000; E-mail: fransenp@yahoo.fr

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Abstract

Introduction: Although cervical arthroplasties have been widely used with some success over the last decade, long terms results are missing, particularly for the latest designed implants such as semi constrained prostheses.

Material and methods: 89 patients were enrolled in an observational study evaluating long term safety and potential complications related to the use of the cervical prosthesis Baguera[®] C. All patients had been treated at one or two levels between June 2009 and June 2011.

At the 5 years FU visit, the patients were evaluated clinically and neurologically, and with self-assessment questionnaires (NDI, SF12). Radiological examination was performed by lateral X-rays in neutral, flexion and extension positions.

Results: There were no reoperations at the arthroplasty level, no fracture of system components, no loss of fixation, and no migration nor subsidence. 17 patients had signs of adjacent level(s) degeneration.

The performance related to Baguera[®]C usage, was evaluated at 5+ Y. PO by three parameters: Range of Motion (ROM), NDI and SF-12 scores. ROM at the treated level was $8.6^{\circ} \pm 5.0^{\circ}$. 87.7% of the treated levels showed preserved motion.

NDI score was $19.5\% \pm 14.1\%$. 92% of the subjects reported NDI scores over 50%, and 74.2% of the subjects reported NDI scores under 30% and 45% of the subjects reported NDI scores under 10%.

The QOL Index and Patient Satisfaction (SF-12 scores) reached 48.5 ± 8.6 for the PCS physical score and 48.0 ± 10.5 for the MCS Mental score. Both SF-12 components, physical and mental, were close to a normal health status (50%).

Conclusion: Cervical disc replacement with the Baguera[®]C prosthesis shows excellent safety, clinical results and long-term motion preservation. There was no index or adjacent level reoperation after 5 years. Radiological progression of adjacent level degeneration was seen in a significant minority of cases, but without clinical expression.

Keywords: Cervical disc replacement; Motion preservation; Cervical disc disease

Introduction

Cervical total disc replacement with disc prostheses has been widely used over the last decade and has shown promising short-term results. However, although the selection criteria to find the adequate candidates for this surgery have improved over the years [1-3], long term results have long been missing particularly for the latest designed implants such as semi constrained prostheses. This could explain why anterior cervical discectomy and fusion procedure is still considered as

standard of care for 84.3% of the surgeons compared to only 7.3% for arthroplasty [4].

We evaluated the long-term safety, potential late complications and long-term performance related to the use of the cervical prosthesis Baguera C^{*}, a semi constrained cervical disc prosthesis (Spineart Inc, Switzerland) in an observational multicentric study.

Materials and Methods

89 patients (45 men, 44 women, aged 44.9 ± 6.9 years at the time of surgery) were operated using total disc replacement at one or two cervical levels between June 2009 and June 2011, in four different

European surgical centres. A total of 109 prostheses were implanted, 52 in C5C6 (47.7%), 39 in C6C7 (35.8%), 15 in C4C5 (13.8%) and 3 in C3C4 (2.8%) (Table 1).

Parameters	Postoperative controls			
	2Y		5+ Y	
Subjects (Overall)	N	%	N	%
Female	64	54.20%	44	49.40%
Male	54	45.80%	45	50.60%
Age (years, at the surgery time)	118	43.8 ± 8.9	89	44.9 ± 6.9
Baguera®C IMPLANTED	149		109	
Surgery details	N	%	N	%
TDR (overall)	98	83.10%	70	78.70%
TDR 1 level	70	59.30%	50	56.20%
TDR 2 levels	25	21.20%	20	22.50%
TDR 3 levels	3	0.80%	-	-
Hybrid surgery	20	16.90%	19	21.30%
Follow-up duration (years)			6.3 ± 0.6	

Table 1: Demography, surgery details and follow-up duration.

The Baguera C cervical prosthesis is composed of inferior and inferior titanium endplates, and of a high-density polyethylene (PE) guided semi-mobile nucleus inserted in the inferior endplate. The PE is in contact with the endplates through a diamond like carbon coating. Its stability is obtained by both fins and anatomical shape. It allows a mobility of 8° of arc in all directions.

All patients were available for the extended follow-up, according to the protocol, and had signed the informed consent for use of their data. Safety was assessed by the rate of surgical revision at the treated level, explanation, fracture of the system, migration and local neurological, vertebral or vascular complications.

At the 5 years follow up visit, the patients were assessed by clinical and neurological examination, Neck Disability Index (NDI) questionnaire and SF 12 self-assessment questionnaire. The radiological examination was done using plain standard lateral cervical X-ray images, performed in neutral, flexion and extension positions allowing measurements of range of motion angle (ROM).

The case report file was completed at each patient control visit, safety data were collected continuously, during the overall study period, using adverse events forms. Complications were reported in specific forms. This study was conducted according to the ISO 14155:2011 standard, to national regulations applicable in the participating countries and in agreement to the Good Clinical Practices guidelines.

Results and Discussion

There were no cases of surgical reoperation at the arthroplasty level, no fracture of system components, no loss of fixation, and nor any migration or subsidence. No vascular injury, neurological complications or vertebral fractures were reported. 17 patients had

radiological signs of adjacent level(s) degeneration. Four patients needed surgical intervention at another spinal (non-cervical) level (Table 2).

Parameters	Postoperative controls			
	2Y		5+ Y	
Heterotopic ossifications				
Grade 0 (No HO)	46	46.10%	-	-
Grade I, II	34	34.60%	-	-
Grade III, IV	19	19.30%	-	-
Complications				
Surgical revision at the index level/ Ex-plantation (Removal)	0	0%	0	0%
Surgery at the adjacent level	0	0%	0	0%
Loss of fixation, Migration	0	0%	0	0%
Subsidence	0	0%	0	0%
Neurologic functions				
Motor functions	113	-	-	-
Degradation	0	0%	-	-
Stable or improved	113	100%	-	--
Reflexes	113	-	-	-
Degradation	0	0%	-	-
Stable or improved	113	100%	-	-
Sensitivity	113	-	-	-
Degradation	1	0.90%	-	-
Stable or improved	112	99.10%	-	-
Neurological or vascular disorders	-	-	2	2.20%
Adjacent level degeneration	-	-	17	19.10 %
Serious complications (rate)	0	0%	0	0%

Table 2: Baguera®C safety parameters at 2 and 5 years postoperatively.

69 patients (77.6%) took no pain medication at all and 15 patients (16.9%) took Level 1 painkillers (frequently for two of them). Two patients took respectively Level 2 (2.2%) painkillers and two others Level 3 (2.2%) painkillers. One subject took homeopathic medication (1.1%). All subjects had normal clinical examinations. Neurological examination was normal in all but one patient who developed progressive new symptoms of C6 paraesthesia, possibly related to adjacent level degeneration.

The NDI questionnaires show an average functional disability of 19.5% ± 14.1%. 44 subjects (45%) noted 0 to 10% functional disability; 7 subjects (7.9%) noted at least 50% to 62% functional disability (Table 3).

Parameters	Postoperative controls			
	2Y		5+ Y	
NDI scores (%)	N (subjects)	Mean	N (subjects)	Mean ± SD
Overall	113	19.7 ± 14.0	89	19.5 ± 14.1
TDR 1 level	67	19.0 ± 16.2	50	17.2 ± 13.9
TDR 2 levels	24	13.6 ± 14.2	20	20.1 ± 17.1
TDR 3 levels	3	35.3 ± 23.4	-	-
Hybrid surgery	19	27.1 ± 15.1	19	24.9 ± 11.0
Pain medication (PM)			N (subjects)	%
No PM	-	-	69	77.50%
Level 1 PM	-	-	15	16.90%
Level 2 and 3 PM	-	-	4	4.40%
Homeopathic	-	-	1	1.10%

Table 3: Functional disability (NDI scores) and pain medications at 2 and 5+ years postoperatively.

The SF-12 scores were calculated after 5+ year controls for all 89 subjects using the Quality Metric SF-12V2 software. The PCS-12 and MCS-12 values, respectively of 48.53% and 48.01% are close to normal health. Vitality scores are slightly superior to normal health (50%). All other parameters are higher than 46% (Figure 1).

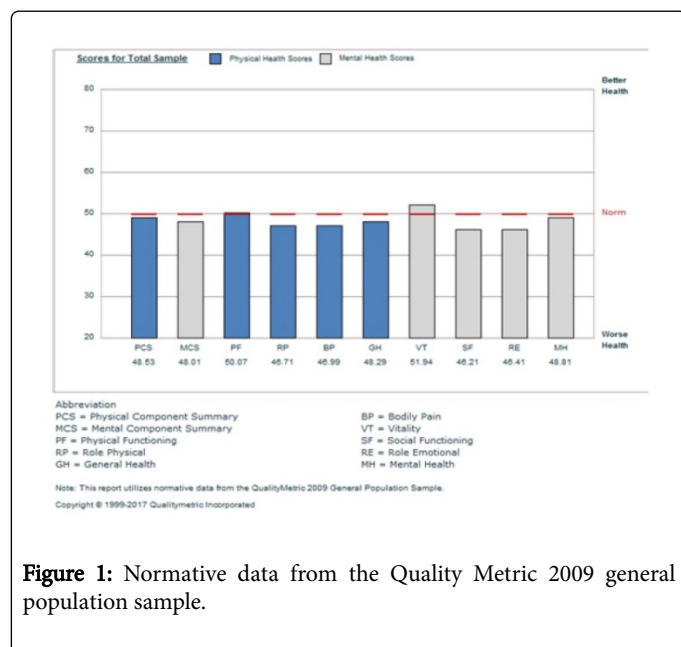


Figure 1: Normative data from the Quality Metric 2009 general population sample.

The motion at the treated level was evaluated by the range of motion for 106 cervical levels using flexion/extension X-rays. ROM data was missing for 3 treated levels, due to poor image quality.

The average ROM at the treated level was 8.6° ± 5°. Motion was considered preserved (ROM ≥ 2°) in 93 levels (87.7%) (Figure 2). Lack of motion (ROM < 2°) was observed in 13 levels (12.3%). (Table 4)

Parameters	Postoperative controls			
	2Y		5+ Y	
ROM (at the index level)	N (levels)	Degree	N (levels)	Degree
Overall	-	-	106	8.6° ± 5.0°
TDR 1 level	45	8.8° ± 4.6°	49	8.0° ± 5.2°
TDR 2 levels	27	9.2° ± 5.3°	38	9.3° ± 4.5°
Hybrid surgery	15	7.8° ± 0.4°	19	8.6° ± 5.1°
ROM (at the upper level)	N (levels)	Degree	N (levels)	Degree
TDR 1 level	55	13.5° ± 5.4°	-	-
TDR 2 levels	33	10.9° ± 5.1°	-	-
Hybrid surgery	5	7.2° ± 3.7°	-	-
MOTION (at the index level)	N (levels)	%	N (levels)	%
Preserved (ROM > 2°)	87	91.60%	93	87.70%
Lack of Motion (ROM < 2°)	8	8.40%	13	12.30%

Table 4: Motion at the arthroplasty (TDR) level and upper adjacent level at 2 and 5+ years postoperatively.

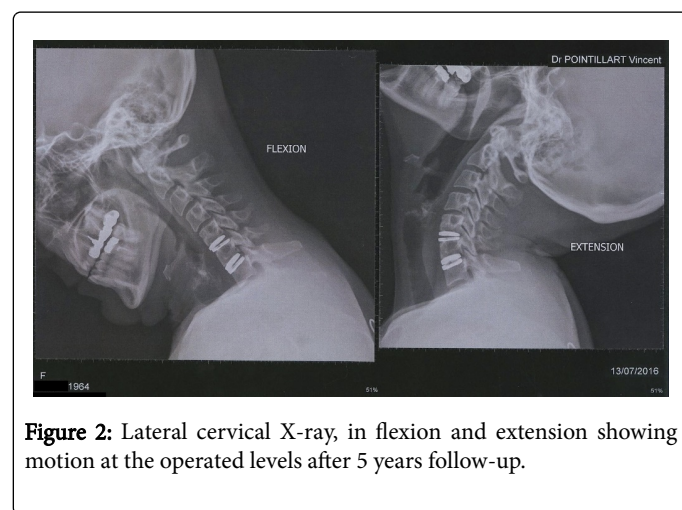


Figure 2: Lateral cervical X-ray, in flexion and extension showing motion at the operated levels after 5 years follow-up.

11 cases of mild anterior bone loss were observed, appearing as a blunting of the anterior corner of the vertebral bone, with no correlation to specific clinical symptoms, stable or completely reconstructed after 2 years postoperative controls.

Discussion

Although long term studies regarding cervical arthroplasties are not numerous, several randomized controlled trials have been published. Despite the fact that most of these RCT's were so called "industry driven", all were accepted by the American Food and Drug Administration that used very strict criteria to determine non-inferiority and superiority [5-13].

In the Turel et al. meta-analysis of all these FDA approved artificial cervical discs [14], all implants scored either superior or non-inferior to anterior cervical discectomy and fusion. Curiously, depending on the type of arthroplasty implant, different prosthesis scored differently, some showing superiority for NDI, some for secondary surgery, some for neurological success. The reason for these differences is unclear, but could be the consequence of differences in design, materials, surgical technique and biomechanics. It is fair to conclude that different prosthesis should be evaluated separately.

The longest available follow up has reached 10 years for 97 patients implanted with the Bryan cervical prosthesis by the Leuven group [15]. The prostheses were able to maintain motion at index level and more motion was associated with less degeneration over time at the level cranial to the prosthesis.

Despite these reports, the cost effectiveness of cervical arthroplasty remains a much-debated topic. In his study, Qureshi et al showed that both arthroplasty and anterior fusion were cost effective procedures [16], and that for arthroplasty to be more cost effective than fusion, artificial discs had to stay mobile for 14 years. Although this calculation is partially depending on and negatively impacted by the price of the implant, a low number of complications and reoperations for arthroplasty would certainly increase the attractivity of this procedure.

With a negligible rate of complications and reoperations, our study confirms on a much smaller scale, the results of the American College of Surgeons Database analysis, in which, Bhashyam et al reported a lower rate of reoperation and readmission for cervical arthroplasty (both 0.4%) than for ACDF (respectively 2.6% readmission and 1.2% reoperation) [17].

Our study group previously published favourable results with a two year follow up of a group of patients treated with the same device, reporting cervical mobility preservation in 80.6% of the patients, an HO rate of 54%, mostly grade I and II, no signs of subsidence and no signs of degeneration or kyphosis of the adjacent disc [18]. Clinically, after two years, there was an improvement of over 20% of the NDI in 81.8% of the patients, of over 20% of the neck pain in 75.5% and of 20% in arm pain in 77.6% [19].

The analysis of these 5 years follow-up results confirms the two-year results, with overall preservation of the ROM, and favorable NDI scores, and no reoperations. Despite this, 20.5% of the patients still take occasional level 1 painkillers, raising questions about the cause of these pains: Can they be qualified as chronic pain? Are they related to adjacent level degeneration or is it just caused by normal ageing and not significant? Burkhardt et al reported in a 28 years FU of ACDF patients, that 18% of them were still occasionally taking mild pain killers [20]. Our observation could reflect similar neck sensitivity in some patients. Compared to other published long term follow up studies, our data show superior or equivalent results, with regard to motion at the treated level, functional disability and health related quality of life questionnaires [21-27].

Our anterior bone loss observations could not be correlated to clinical symptoms, and may be the result of bone remodelling consecutive to the motion preservation effect of the operated cervical segment. In a similar observation with the same prosthesis. Heo et al. hypothesized that anterior bone loss may be associated with a higher level of physical activity [28].

These first results with the Baguera C prosthesis at 5 years FU add a brick to an already robust wall of evidence supporting that cervical arthroplasty in the right indications lowers the risk for reoperation, decreases the risk of adjacent level degeneration and comes with a minimal rate of adverse events. As an even longer follow-up will possibly answer more questions, all patients included in this analysis remain under continuous monitoring, with yearly check-up, until their 10 years post-surgery visit.

Conclusion

Cervical disc replacement with the Baguera C prosthesis shows an excellent record in terms of safety, clinical results and long-term motion preservation. There was no index or adjacent level reoperation after 5 years. Radiological progression of adjacent level degeneration was seen in a significant minority of cases, but without clinical expression.

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