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Radiographic Outcome and Adjacent Segment Evaluation Two Years after Cervical Disc Replacement with the Baguera®C Prosthesis as Treatment of Degenerative Cervical Disc Disease

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Abstract

Introduction: In many cases, cervical arthroplasty can avoid adjacent segment degeneration, by preserving the mobility of the operated level. In this paper, we present and analyze the radiological results of a cohort of patients who underwent cervical disc arthroplasty, with the Baguera®C cervical disc prosthesis.

Material and methods: 99 patients and a total of 123 prostheses were included in a retrospective analysis of radiographic images, based on a registry type data collection, with a two-year follow-up (FU). The radiological data was independently assessed for the range of motion, disc angle, disc height at the operated level and at the adjacent level, and for heterotopic ossifications (HO).

Results: At the operated level, the range of motion (ROM) decreased from 10.2° preoperatively to 8.7° (non-significant) after two years in the one level total disc replacement (TDR) group, from 9.8° to 9.1° (non-significant) in the two levels TDR group. The motion of the upper FSU changed from 10.6° preoperatively to 13.5° after two years in the one level TDR group, from 11.6° to 10.9° in the two levels group.

The disc height at the level of the operated FSU changed from 4 mm preoperatively to 7.1 mm after six weeks and 6.5 mm after two years for the one level TDR. The disc height at the level above the highest operated FSU changed from 4.24 mm preoperatively to 4 mm after six weeks and 4.2 mm after two years for the one level TDR, from 4.5 mm to 5.4 mm (6W) and 5.3 mm (2Y) for the two levels TDR.

No heterotopic ossification was observed in 46% of the patients. HO was observed, respectively 20.1% grade I, 14.5% grade II, 13.7% grade III and 5.6% grade IV. HO restricting mobility (grades III and IV) were seen in 19.3%. The prostheses were mobile in 80.6% after two years.

Conclusion: Cervical arthroplasty using the Baguera®C prosthesis, demonstrated 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. This motion preserving surgical treatment, either used alone or in combination with segmental fusion, shows encouraging results in term of adjacent level disease protection and appears, therefore, as safe and effective.

Keywords: Cervical disc; Ossification; Spondylarthrosis; Vertebrae

Abbreviations: TDR - Total Disc Replacement; ROM - Range Of Motion; FSU- Functional Spinal Unit; Ns: Non-Significant (Statistically); HO - Heterotopic Ossifications; FU - Follow-Up; COV - Coefficient Of Variation; SD - Standard Deviation; ICC - Intraclass Correlation Coefficient; PO - Post-Operative; SCDD - Symptomatic Cervical Disc Disease; PE - Polyethylene; DLC - Diamond-Like Carbon; AP - Antero-Posterior; ANOVA - Analysis of Variance

Introduction

Anterior cervical discectomy and fusion has been first introduced by Cloward and by Smith and Robinson [1,2] in 1958 and 1963 respectively. Although the clinical results were and still are excellent, the conversion of a functionally mobile spinal unit into an intersomatic fusion has disadvantages. The rigidity of a single fused segment is often well tolerated, but may cause increased strain at the levels i immediately adjacent to the fused segment [3].

Radiological changes have been described mainly above fused cervical discs. Cervical arthroplasty with artificial discs has been used for more than 10 years now, with clinical results equivalent or slightly superior to fusion in selected cases [4,5]. Theoretically, cervical arthroplasty could, by preserving the mobility of the operated level, avoid adjacent segment degeneration.

We describe the radiological results of a cohort of patients who underwent cervical disc arthroplasty, with single or double levels Baguera®C cervical disc prostheses.

Material and Methods

Based on a registry type data collection, we present a retrospective

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analysis of radiographic images. This allows for a quantitative assessment of the treatment's results, two years after implantation of the Baguera®C Prosthesis.

The registry contains data referring to subjects who underwent one- or multilevel arthroplasty using the Baguera®C prosthesis alone or in combination with other surgical treatments (i.e. arthrodesis, referred to as hybrid constructs), and were followed postoperatively for two years. All preoperative, intraoperative and postoperative follow-up visits were documented clinically and radiographically.

Primary and secondary objectives

Two primary objectives were defined: (i) 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°), and (ii) disc height restoration two years after TDR.

The four secondary objectives were defined as: (i) motion at the adjacent level two years after TDR, evaluated by its ROM between flexion and extension (motion being defined by a ROM of at least 2°), (ii) overall cervical alignment, evaluated as overall lordosis by measuring C2-C7 angle, (iii) balance of the spine, evaluated by the angle of functional spine unit (FSU) at the treated level and (iv) impact on adjacent levels, evaluated by the upper adjacent angle and the upper disc height.

Demographics

99 patients from five European investigation centers were included in the analysis. X-Ray images used for the radiographic assessment were collected during three visits: Pre-operative visit, 6 weeks follow-up and 2 years follow-up.

60 patients had one-level surgery, 30 patients had two-level surgery and 9 patients had three-level surgery. 18 patients were treated with hybrid constructs (12 operated at two-levels – one prosthesis, one fusion - and 6 operated at three-levels –one prosthesis, two fusions). 81 patients were treated by prosthesis implantation only (60 operated at one-level, 18 operated at two-levels and 3 operated at three levels).

A total of 123 prostheses were utilized: 4 prosthesis were implanted in C3-C4, 19 in C4-C5, 53 in C5-C6 and 47 in C6-C7.

Inclusion and exclusion criteria

To be included in the registry, the patients had to suffer from symptomatic cervical disc disease (SCDD) between C3 and C7, as defined by the following signs and symptoms: neck or arm pain and/or functional and/or neurological deficit caused by herniated nucleus pulposus and/or spondylarthrosis defined by the presence of osteophytes and/or disc height reduction as confirmed by MRI or X-ray. We included patients aged between 18 and 75 years, not responding to non-surgical treatment for a period of at least six weeks, or presenting signs of progressive nerve root compression despite conservative treatment. Finally, included patients had to be psychologically, physically and mentally able to comply with the treatment protocol.

Exclusion criteria were: severe injury or degeneration of the facet joints confirmed by X-ray, known allergy to any of the constituent materials, prior cervical fractures, severe spondylarthrosis at the treatment site (syndesmophytes and/or absence of mobility (ROM < 2°)), pain unrelated to the cervical disc disease, metabolic bone disease (osteoporosis), Paget disease, severe diabetes requiring daily insulin treatment, pregnancy, active infection (systemic or local), rheumatoid arthritis or other auto-immune disease, systemic disease, including AIDS/HIV and hepatitis or active malignancy.

Figure 1: Baguera®C prosthesis.

All included patients accepted to sign an informed consent form. The registry protocol was reviewed by the local ethics committee on each site. The radiological assessment was performed in a semi-automatic way by an independent evaluator (icoMetrix NV, Leuven, Belgium).

Implant characteristics

The Baguera®C cervical prosthesis (Spineart SA, Geneva, Switzerland) is a biomechanical device designed to be used for TDR. It consists of a high-density polyethylene (PE) nucleus that articulates between two titanium endplate components, with a porous-titanium-coated exterior and a bioceramic (DLC)-coated-interior, in contact with the PE nucleus (Figure 1). The primary stability is obtained by the convex shape of the superior endplate and by three fins on each endplates that allow safe anchoring of the prosthesis i mmediately after the release of the Caspar retractor used during the discectomy. The secondary stability is obtained by bone growth inside the porous titanium coating. The implant allows a physiological rotation as well as translation in both the antero-posterior (AP) (± 0.3 mm) and rotational (± 2°) directions. The controlled mobility of the PE nucleus is designed to prevent excessive constraints on the facet joints, and its rolling feature respects axial rotation movements. The concave superior aspect of the inferior plate and PE nucleus shape allow 0.15 mm elastic deformation to absorb shocks and vibrations

Radiological evaluation protocol

Radiographic images preoperatively, at 6 weeks follow-up and at 2 years follow-up were evaluated for 10 parameters in neutral, flexion and extension position, related to the following three measurements: range of motion (ROM), angles and height.

A semi-automatic process was setup and performed by icoMetrix NV. The manual part, the Annotations phase, used a graphical user interface specially developed for marking and capturing coordinates related to implant and cervical vertebrae. Four landmarks corresponding to the corners were used for vertebrae identification, and they were marked by an expert radiologist using mouse clicks (Figures 2a-2c). Coordinates were automatically recorded in a structured .xml format and used by the automatic component developed using Python (http://www.python.org) as input for all calculations.

Errors of measurement (coming from both manual and algorithmic components) were estimated for each parameter by an extensive reproducibility study: The absolute error, the relative error and the reproducibility coefficients were taken as the standard deviation (SD), the coefficient of variation (CoV) and the intra-class correlation (ICC) respectively. An ANOVA, two-way effect model, was used to quantify the absolute agreement.

The ROM (in degrees) describes the mobility of the observed spine unit. The angles that are used to transform the vertebrae above and below the Baguera®C between flexion and extension provide the range of motion (Figure 3). It was assessed using the flexion and extension images by using a registration (image alignment) algorithm,

which aims at matching two vertebrae in the flexion image with the corresponding vertebrae in the extension image. As a result, two transformations are obtained that describe the matching of the first vertebrae between flexion and extension and the second vertebrae between flexion and extension. Based on the difference between these two geometrical transformations, the range of motion was calculated. The same automatic procedure was used to evaluate the range of motion at the treated level, upper adjacent level, overall between C2 and C7 and overall between C2 and C6.

The disc angle (in degrees) is the angle between the plates of adjacent levels and represents the balance of the spine. It was assessed using neutral images after determination of four landmark points. These landmarks were positioned on the inferior corners of the vertebral body below the artificial disc and on the superior corners of the vertebra above the artificial disc. Once these points were in place, lines connecting the landmarks were automatically drawn (Figure 4). As a result, the angle between both endplates was calculated. The same semi-automated procedure was used to measure the angle of the FSU at the treated level, upper adjacent FSU, and the angle of the overall spine between C2-C7 and C2-C6. The FSU (functional spinal unit) is

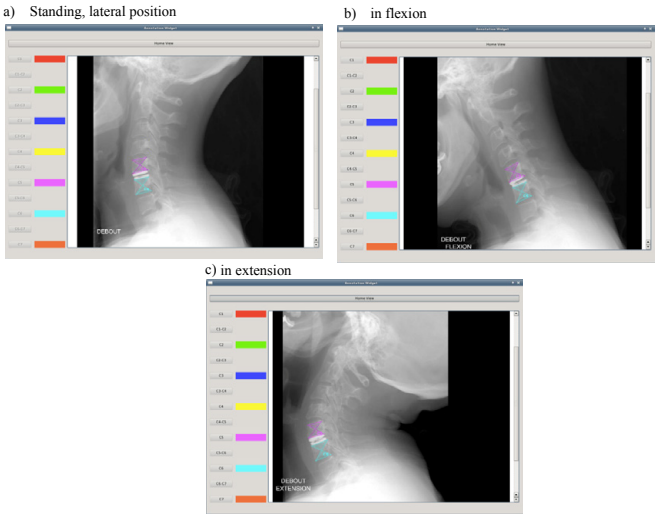

Figure 2: Radiographic images two years after surgery (annotated) Subjects who underwent 1 level (C5-C6) total disc replacement using Baguera®C.

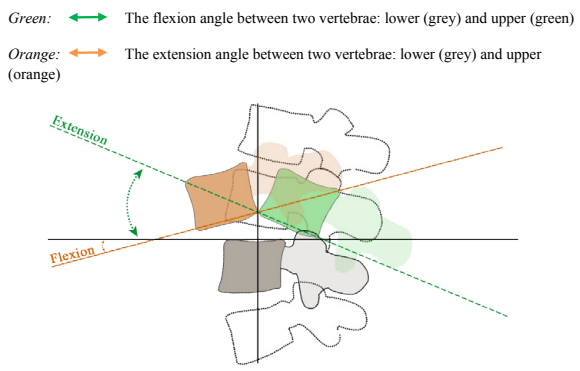

Figure 3: Range of Motion (ROM): The angles used to transform the vertebrae above and below the Baguera®C between flexion and extension provide the range of motion. Grey color is used for lower vertebra. Green and orange are used for upper vertebra in extension and flexion, respectively. The fixed reference for flexion and extension angles, corresponding to the superior plate of lower vertebra, is the black (horizontal) line.

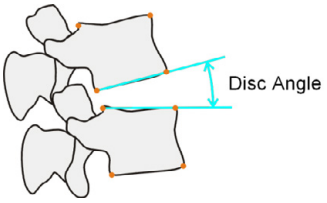

Figure 4: Disc angle.

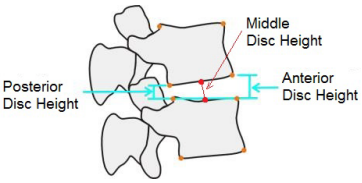

Figure 5: Disc height (middle).

the entity regrouping a disc, the two corresponding facet joints and the two adjacent vertebrae.

Disc height is the distance (in millimeters) between the upper plate of the lower vertebra and the lower plate of the upper vertebra: We used, as its measure, the middle disc height, i.e. the distance measured perpendicular to the plane of the top plate at mean distance (Figure 5). This distance is used to assess the disc height restoration. The disc height was assessed using neutral images, after calibration to cancel any magnification factor.

Heterotopic ossifications (HO) were addressed and classified according to the McAfee classification modified by Mehren et al. [6] The classification has a 5-points grading system: grade 0 = no HO; grade I = presence of HO but not in the interdiscal space; grade II = presence of HO in the interdiscal space; grade III = bridging of ossification with segment movement; grade IV = complete fusion without movement in flexion/extension.

Statistical analysis

The statistical analysis was performed using SAS®9.3 and results are presented as su mmary statistics, overall and by type of surgery, study visit, treated level, illustrated by tables and figures.

Comparisons between preoperative and postoperative values were performed and statistical significance of observed change in values was noted. The results with $p<0.05$ were considered significant. Only subjects with available data at all 3 visits (preoperative and postoperative at 6 weeks, 2 years respectively) were included in these comparisons.

Parametric (paired t-test) or non-parametric Wilcoxon (signed-rank) test was used depending on normality. The normality of distributions was evaluated by Shapiro-Wilcoxon (sign-rank) test.

Comparisons between preoperative and postoperative values were made using paired t-test for normal distributed data and Wilcoxon test when normality was not confirmed.

Results

Range of motion of the functional spine unit

At the operated level, the ROM decreased from 10.2 ° (preoperatively) to 8.7° (ns) after two years in the one level TDR, from 9.8° to 9.1° (ns) in two levels TDR. The decrease was more pronounced in the three levels TDR, dropping from 13.2° preoperatively to 5.9° (ns) after two years, but on a smaller cohort of patients (Table 1). Figure 6

illustrates all results for subjects who underwent one-level TDR, at pre-operative and postoperative visits (left) and by treated level at 2-year FU (right).

For the hybrid constructs, the ROM of the prostheses decreased from 10.7° to 6.9° after two years when implanted in association with one level fusion, and from 11.66° to 7.7° when implanted in association with two fused levels.

Range of motion of the upper functional spine unit

The motion of the upper FSU changed from 10.6° preoperatively to 13.5° after two years in the one level TDR group, from 11.6° to 10.9° in the two levels group and from 11.1° to 7.1° in the three levels group (Table 2). Figure 7 illustrates all results for subjects who underwent one-level TDR, at pre-operative and postoperative visits (left) and by treated level at 2-year FU (right).

Range of motion of the C2C7 levels and C2C6 levels

The overall range of motion of the C2C7 levels changed from 51.1° to 54° after two years in the one level TDR group, from 50.2° to 46.8° in the two levels group and from 60.7° to 32.3° in the three levels group (Table 3). Figure 8 illustrates all results for subjects who underwent one-level TDR, at pre-operative and postoperative visits (left) and by treated level at 2-year FU (right).

Not surprisingly, in the hybrid group the overall C2C7 ROM decreased according to the number of fused levels, changing from 48.2° preoperatively to 40.8° when the prosthesis was implanted in association with one level fusion, and from 75.2° to 28.5° when the prosthesis was implanted in association with two fused levels.

Similar tendencies were observed when measuring the C2C6 ROM.

Angle of the functional spine unit

At the operated level, the angle changed from 5.6° preoperatively to 6.3° after two years for the one level TDR, from 4.6° to 6.8° for the two-level TDR and from 8.21° to 3.93° for the three-levels TDR.

Angle of the upper functional spine unit

The angle of the level above the operated level changed from 7.4° preoperatively to 6.4° after two years for the one level TDR, from 6.8° to 7.6° for the two-level TDR and from 10.8° to 5.2° for the three-levels TDR.

Overall angle of the C2C7 levels and of the C2C6 levels

The overall C2C7 angle changed from 19.9° preoperatively to 12.8° after two years for the one level TDR, from 27.5° to 16.8° for the two-level TDR and from 20.7° to 13.2° for the three-levels TDR.

The overall C2C6 angle changed from 19.17° preoperatively to

Type of Surgery	BAGUERA®C implanted	Treated Levels	Pre-op		6W (PO)		2Y (PO)		Pre-op vs 2Y (absolute change)	
			Mean	SD	Mean	SD	Mean	SD	Mean	p-value
TDR	1	1	10.25	4.1	8.55	4.4	8.79	4.6	-1.3	ns
	2	2	9.80	4.7	6.90	3.4	9.15	5.3	-0.04	ns
	3	3	13.26	3.3	7.21	3.3	5.99	3.5	-6.43	ns
HYBRID	1	2	10.70	3.9	5.65	3.8	6.99	4.0	-4.72	0.05(*)
		3	11.66	3.2	7.59	3.0	7.75	0.4	-	-
(*) - p-value from Wilcoxon teste.										

Table 1: Range of Motion at the treated level (ROM-FSU) (degrees): Pre-operative vs. post-operative values. Summary statistics: Overall and by number of treated levels.

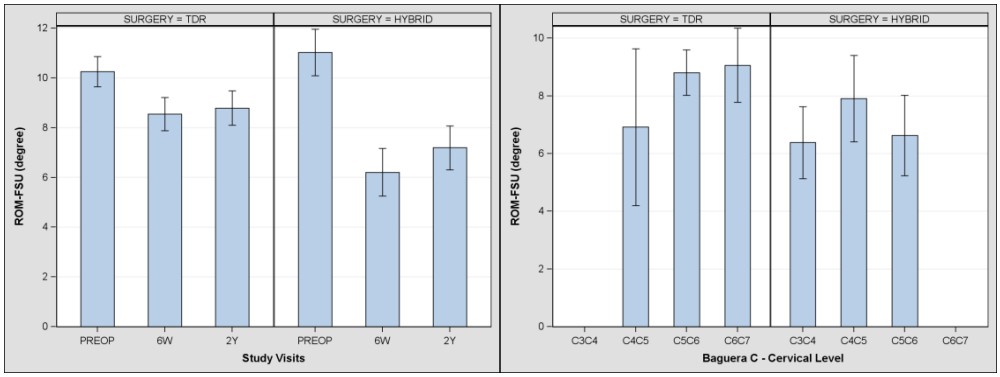

Figure 6: Range of Motion at the treated level (ROM-FSU). **Left:** Pre- and post-operative values for subjects treated by 1 level TDR using Baguera®C. Non-significant changes between pre-operative and post-operative data were observed. **Right:** Two years after surgery values, by treated level for subjects who underwent 1 level TDR using Baguera®C, by type of surgery (TDR, HYBRID).

Type of Surgery	BAGUERA®C implanted	Treated Levels	Pre-op		6W (PO)		2Y (PO)		Pre-op vs 2Y (absolute change)	
			Mean	SD	Mean	Mean	Mean	SD	Mean	p-value
TDR	1	1	10.64	5.2	10.91	5.0	13.54	5.4	2.79	ns
	2	2	11.66	4.7	7.86	3.6	10.94	5.1	-0.64	ns
	3	3	11.15	4.3	6.50	4.0	7.19	3.7	-3.78	ns
HYBRID	1	2	10.36	6.1	6.57	5.3	9.99	6.5	0.08	ns
		3	11.04	4.9	8.15	5.4	10.30	2.9	-2.86	ns

Table 2: Range of Motion at the upper adjacent level (UPPER ROM): Preoperative vs. postoperative values. Summary statistics: Overall and by number of treated levels.

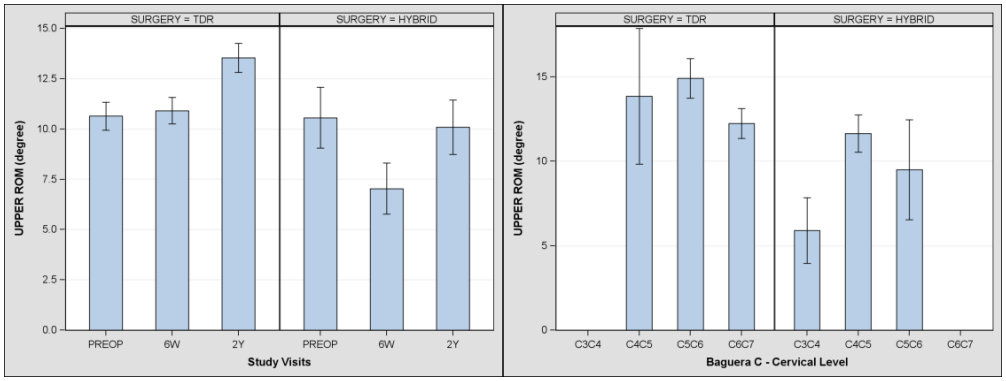

Figure 7: Range of Motion at the upper adjacent level (UPPER ROM). **Left:** Pre- and post-operative values for subjects treated by 1 level TDR using Baguera®C. Significant improvement (p=0.01) between pre-operative and 2 year's post-operative data. **Right:** Two years after surgery values, by treated level for subjects who underwent 1 level TDR using Baguera®C, by type of surgery (TDR, HYBRID).

Overall cervical ROM	Type of Surgery	BAGUERA®C implanted	Treated Levels	Pre-op		6W (PO)		2Y (PO)		Comparison: Pre-op vs 2Y	
				Mean	SD	Mean	SD	Mean	SD	Mean	p-value
C2-C7	TDR	1	1	51.50	15.0	43.93	15.4	54.03	11.6	5.32	ns
		2	2	50.20	13.7	37.82	15.4	46.88	8.9	-0.02	ns
		3	3	60.74	6.8	33.84	8.5	32.38	13.1	-	-
	HYBRID	1	2	48.20	21.1	42.34	5.4	40.86	14.1	-	-
			3	75.20	.	18.41	9.0	28.58	7.5	-	-
C2-C6	TDR	1	1	42.07	12.4	38.98	11.2	47.10	11.0	4.43	ns
		2	2	43.02	11.9	31.11	10.9	41.72	10.6	-1.13	ns
		3	3	44.53	0.8	28.40	7.2	28.62	7.0	-15.91	ns
	HYBRID	1	2	40.91	15.5	26.33	14.9	31.94	10.3	-6.47	ns
			3	38.46	9.3	18.39	12.5	29.53	9.7	-12.29	ns

Table 3: Overall cervical range of motion (ROM-C2C7 and ROM-C2C6) (degrees): Preoperative vs. postoperative values. Summary statistics: Overall and by number of treated levels.

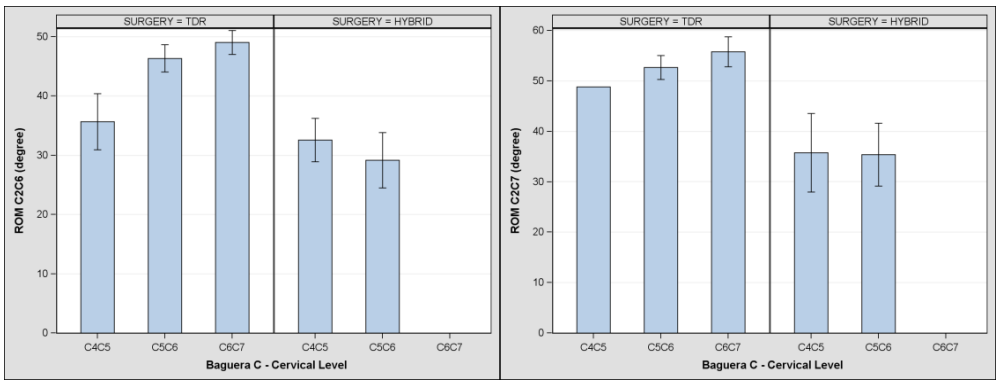

Figure 8: Overall cervical range of motion two years after surgery for subjects who underwent 1 level TDR using Baguera®C by treated level and type of surgery (TDR, HYBRID): ROM-C2C6 (left), ROM-C2C7 (right).

10.4° after two years for the one level TDR, from 24.7° to 15.8° for the two-level TDR and from 14.7° to 13.7° for the three-levels TDR

Disc height of the functional spine unit

The disc height at the level of the operated FSU changed from 4 mm preoperatively to 7.1 mm after six weeks and 6.5 mm after two years for the one level TDR, from 4. mm to 7.5 mm (6W) and 6.5 mm (2Y) for the two levels TDR and 5.1 mm to 7.6 mm (6W) and 7.3 mm (2Y) for the three-levels TDR.

Disc height of the upper functional spine unit

The disc height at the level above the highest operated FSU changed from 4.2 mm preoperatively to 4 mm after six weeks and 4.2 mm after two years for the one level TDR, from 4.5 mm to 5.4 mm (6W) and 5.3 mm (2Y) for the two levels TDR and 5.5 mm to 6.4 mm (6W) and 6.2 mm (2Y) in the three levels TDR.

Heterotopic ossifications

Heterotopic ossifications were measured at the operated level in all 99 patients, accounting for a total of 123 operated levels.

No HO was observed in 46% of the patients (grade 0).

The HO grade for the remaining 54% was: grade I (for 20.1%), grade II (for 14.5%), grade III (for 13.7%) and grade IV (for 5.6%).

HO restricting mobility (grades III and IV) were observed in 19.3% of the patients.

The prostheses were thus mobile in 80.6% of the patients after two years.

Discussion

Although this series covers a limited number of patients, and presents with limitations inherent to its retrospective nature, we found out that most published studies present the same structure and that therefore, a comparison with the literature data was reasonable.

Relevance of the measure

In order to ensure the clinical usability of these results, the relatively scarce, existing, literature was thoroughly reviewed. This provided the necessary insight on which measurements to perform, to evaluate spine mobility and balance [7-12], and on the values to expect: e.g. the ROMs as reported in Sasso et al. [9] or Bertagnoli et al. [8]. Based on these studies, we expected average ROMs to vary between 5° and 15°. Therefore, we aimed at achieving a standard error on the ROM measurement of around 1°, in order to be able to capture the differences between pre-op, 6 weeks and 2 years images. Thanks to the automated measure method, we achieved a sufficient precision in both angular and distance measurements.

Mobility at the operated level

Mobility at the treated level after two years of total disc replacement (TDR) using Baguera®C was evaluated by the range of motion (ROM) between flexion and extension; mobility is present when ROM value is at least 2°, or better 4° as suggested by J.Vital et al. [13,14].

The fact that motion slightly decreased after two years is not an issue because this diminish the constraint on facet joint that can be painful.

Two years after surgery, mobility at the operated level for patients treated by only TDR using Baguera®C was noted for 93%, 93.6% and 87.5% of treated levels, when one-level, two-levels and three-level TDR respectively was performed. In case of Hybrid treatment, mobility at the treated levels was observed for 81.8% and 100% of treated levels when one-level TDR was associated with one or respectively two-level arthrodesis. We observed better results for 1-level TDR (8.79°,) compared to results reported by Sasso et al. [5] and [9] reporting 8.79° and 6.7°, respectively), and Ryu et al. [15] reporting 7.9° for Bryan group and 4.1° for Prodisc group), the average values after 2 years post-surgery.

One explanation for these good results is that semi-constrained prostheses featuring a semi mobile nucleus could enable a more physiological movement than constrained prosthesis with a fixed center of rotation that could limit movement of the operated segment and cause painful friction of the facet joints.

Disc height at the operated level

The disc height was increased after TDR, changing from an average 4.44 mm (1level), 4.35 mm (2 levels) and 4.92 mm (3 levels) preoperatively to respectively 7.27 mm, 6.87 mm and 7.72 mm after two years. The increased disc height was constant between the 6W observation and the 2Y observation, showing no signs of subsidence.

Our data show better results in terms of disc height restoration after 2 years, (6.5 mm in average for 1 level TDR, 6.54 mm for 2 levels TDR), compared to published data by Ryu et al. [15], reporting at the last FU in average 3.3 mm for Bryan group and 3.5 mm for Prodisc group.

Adjacent level degeneration

Although the assessment of adjacent level degeneration over a two years period is debatable, we tried to monitor the changes of the FSU cranial to the highest TDR level, assuming that potential changes would reflect increased stress and more chances of further degeneration.

In the one-level patients, we observed a slightly increased ROM from 10.46° to 13.57°. This increase was not observed in the two- and three levels patients who showed a decreased ROM from 11.66° to 10.94° and from 11.15° to 7.19°, respectively in the two and three levels group.

Also, the measure of the adjacent FSU angle showed no significant sagittal balance changes and the adjacent FSU disc height was preserved. Our interpretation of this data is that TDR had little or no influence on the evolution of the adjacent level over the two years observation period.

Heterotopic ossifications

Several authors have studied heterotopic ossifications with various disc prosthesis [6,14-17]. In some studies, a high rate of HO occurrence and a limitation of mobility were observed: Suchomel et al. [17] studied 65 Prodisc C prostheses. HO was present in 86% of the patients after two years. During a 48-month period on the same cohort, they also found that significant HO (grade III) was present in 45% of the implants and that segmental ankylosis (grade IV) was present in another 18%, adding up to a total of 63% of non-mobile prosthesis. Also, Lee reported 77% HO in a group of patients treated with the Mobi C prosthesis, with two years FU [16], and Mehren reported 66.2% of HO only one year after cervical disc replacement with the Prodisc C prosthesis [6].

Other studies, however, report less concerning results: Tu et al. [14] reported a 50% general rate of HO with the Bryan prosthesis, with less than two years FU. Similarly Ryu et al. [15] reported 57% HO for the Bryan prosthesis and 47% HO for the Prodisc C on a small group of patients and with two years FU.

Our study scores show better results, with an overall HO grade of 54%, mostly grade I and II, explaining the rather high 80.64% rate of mobile implants after two years. We attribute these good results to the semi constrained and more physiological design of the prosthesis and to the careful selection criteria.

Finally, the fact that data from different cervical levels have been combined, may potentially influence the final results of this analysis and should therefore is considered as a limitation of this study.

Conclusion

Radiographic data coming from subjects enrolled in the Baguera®C Registry who met inclusion criteria for current analysis, demonstrate cervical mobility preservation in 80.64% of the patients, and an HO rate of 54%, mostly grade I and II.

There were no signs of subsidence of the prostheses. Measures at the level adjacent to the TDR showed no signs of degeneration, no signs of kyphosis and the adjacent disc height was preserved.

Cervical arthroplasty using the Baguera®C prosthesis is thus a safe, effective and motion preserving surgical treatment, either used alone or in combination with segmental fusion, showing encouraging results in term of adjacent level disease protection.

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