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ORIGINAL STUDY

Clinical results of cervical disc replacement with the Baguera C prosthesis after two years follow-up

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We studied pain, neurological, and functional outcomes of one and two-levels cervical arthroplasties using a semi-constrained prosthesis for symptomatic cervical degenerative discopathies.
Retrospective analysis of 95 patients in a multicentric registry over 2 years FU.
Implant-related complications, subsequent surgery and neurological deterioration were not observed. After two years, improvement of > 20% of the NDI was observed in 81.8%, of > 20% of the neck pain in 75.5% and of 20% in arm pain in 77.6%. A > 15% QOL improvement (SF 36 questionnaire) was recorded in 76.5% (physical) and in 77,6% (mental). Greater benefits of cervical arthroplasty were observed in patients under 50 without previous surgeries and with preoperative NDI > 30%, confirming a safe and effective technique

Keywords : Cervical disc degenerative disease ; cervical arthroplasty ; cervical disc herniation.

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 no statistical difference between two groups treated either by arthroplasty or by anterior fusion *(5,9)* or even slightly better results for the patient group treated by arthroplasty *(8,1)*.

This is the first publication investigating the effectiveness of single or double-level total disc replacement (TDR) with a semi-constrained cervical disc prosthesis (Baguera®C, Spineart, Switzerland) in respect of pain, neurological and functional. We also aimed to study the complications related to disc replacement with this implant, as well as the frequency and causes of subsequent surgeries, and to identify the factors that could improve the effectiveness of this surgery.

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MATERIALS AND METHODS

95 patients were analysed using a multicentric registry database. The overall observation period extended from June 2009 until June 2013. An enrolment period of 2 years was used, extending from June 2009 to June 2011.

Enrolment in the registry was performed prospectively. To be included in the registry, the patients had to suffer from symptomatic cervical disc disease (SCDD) affecting up to two vertebral levels 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 with signs of progressive nerve root compression despite conservative treatment. Finally they 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 titanium, polyethylene or Diamolith®, 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 autoimmune disease, systemic disease, including AIDS/HIV and hepatitis or active malignancy.

All included patients accepted to sign an informed consent form. The registry protocol was reviewed by the local ethics committees on each site.

We studied 95 patients, (42 males, 53 females), mean age 42,4 +/_8,4, with a mean BMI of 25.1 kg/m2 +/- 5,1. The preoperative VAS score was 59, 1 +/-26.9 for neck pain, and 63,8 +/-26,6 for arm pain. Preoperative NDI was 44,5 +/- 16,2. Preoperative SF 36 scores were 46,3 +/- 16,9 for physical health and 46,7 +/-22,3 for mental health.

The demographics and baseline data are summarized in Table I.

The Baguera®C cervical prosthesis (Spineart SA, Geneva, Switzerland) consists of a high-density polyethylene (PE) nucleus articulating between two titanium endplate components, with a porous coated exterior and a diamond-like carbon coated interior (Fig 1). The controlled mobility of the PE nucleus allows a physiological rotation, flexion, extension and translation and is designed to avoid excessive constraints on the facet joints.

The 95 patients underwent surgical treatment at 1 or 2 levels. The most frequently treated levels were C5/C6 (57 levels; 47,5%) and C6/C7 (51 levels ; 42,5%) (Table II). 70 patients underwent one level arthroplasty, 25 patients had two-level arthroplasty. A total of 120 prosthesis was implanted.

The prosthesis was inserted through a classical anterior cervical approach, exposing the anterior aspect of the cervical spine after gentle retraction of the oesophagus and trachea on one side, and of the carotid-jugular complex on the other side. Exposure was secured by the positioning of a retractor and axial distraction was obtained by a Caspar retractor. After a thorough discectomy, and complete decompression of the neurological structures, the posterior longitudinal ligament was systematically opened. The implant was then positioned after size checking by a template under fluoroscopy. The wound was then closed layer by

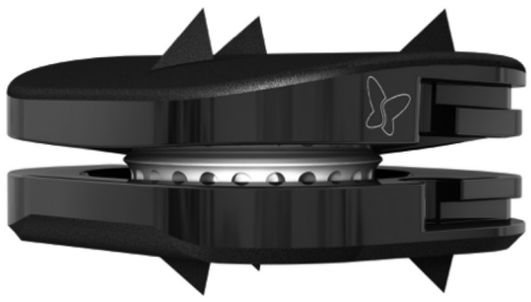


Fig. 1. — The Baguera®C cervical prosthesis consists of a high-density polyethylene (PE) nucleus between two titanium endplate components, with a porous coated exterior and a diamond-like carbon coated interior. The three fins on each endplates allow for immediate stability after the release of the Caspar retractor.

Table I. — Patients demographic and baseline characteristics

Demographic	1 level	2 levels	Overall
Overall	**70**	**25**	**95**
By Gender			
– Male (N)	31	11	42
– Female (N)	39	14	53
By treated levels (N subjects)	70	25	95
*Age (years)**	41.7 ± 9.0	44.4 ± 8.2	42.4 ± 8.4
*Height (cm)**	169.6 ± 9.1	168.3 ± 9.3	169.3 ± 9.1
*Weight (kg)**	71.7 ± 16.5	73.6 ± 16.4	72.2 ± 16.4
*BMI (kg/m2)**	24.9 ± 5.1	25.9 ± 5.1	25.1 ± 5.1
Baseline characteristics			
*Pain (VAS) **			
– VAS Neck	59.6 ±26.9	57.7 ± 27.4	59.1 ±26.9
– VAS Arm	65.4 ±26.0	59.6 ± 28.2	63.8 ±26.6
*Functional status NDI**	43.6 ± 16.5	46.9 ± 15.5	44.5 ± 16.2
Preoperative SF-36 scores:*			
– SF36 Physical Component	47.0 ± 17.2	44.1 ± 16.4	46.3 ± 16.9
– SF36 Mental Component	48.0 ± 22.9	43.1 ± 20.6	46.7 ± 22.3

* Data are presented as mean ± SD

layer. Patients were allowed to move immediately after surgery, and discharged the next day, with or without soft collar bracing depending on surgeon's choice.

RESULTS

Besides the need for subsequent surgeries, success rate was defined after 24 months of follow-up using four different parameters: a minimum 20% functional improvement as evaluated by the Neck disability index (NDI), a neurological improvement with regards to reflexes, motor and sensory function, a minimum 20% improvement of neck and arm pain as evaluated using the VAS score, and an minimum improvement in quality of life of 15% assessed by the Short Form 36 questionnaire.

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.

There were 2 serious adverse events (leading to rehospitalisation) noted for one patient. All were not directly linked to the cervical surgery: the patient had to be operated twice from de Quervain disease.

A clinical improvement of more than 20% in the NDI score was observed in 81,8% of the TDR patients. (Table III and IV).

The neurological examination for reflexes, motor function and sensitivity revealed a stable or improved status in all patients of both two groups.

An improvement of more than 20% in the VAS score for neck pain was observed in 75.5% of the patients. Likewise, the 20% or more improvement

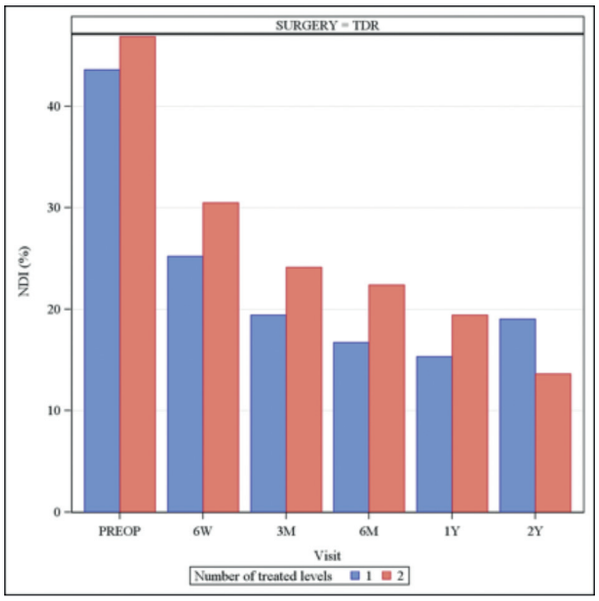
Table II. — Incidence of TDR using BAGUERA®C, by treated level

Treated level	1 TDR	2 TDR	Total implants par cervical level
C3-C4	-	1	1 (0.8%)
C4-C5	4	7	11 (9.2%)
C5-C6	32	25	57 (47.5%)
C6-C7	34	17	51 (42.5%)
Overall	*70 (58.3%)*	*50 (41.7%)*	*120 (100.0%)*

Table III. — Surgery overall success components, evaluated at 24 months post-surgery

Component	TDR (N=95)	
	N	%
NDI improvement ≥ 20%	79	83.2%
Neurological stability or improvement:	94	98.9%
Motor stability or improvement	95	100.0%
Reflexes stability or improvement	95	100.0%
Sensitivity stability or improvement	94	98.9%
VAS Neck Pain improvement > 20%	73	76.8%
VAS Arm Pain improvement > 20%	77	81.0%
SF-36 PHs improvement > 15%	75	78.9%
SF-36 MHs improvement > 15%	76	80.0%
No subsequent surgery	95	100.0%

Table IV. — Functional disability assessment: course of time for NDI scores: pre-operative and post-operative status



of the VAS score for arm pain was observed in 77.6% of the patients (Table III and IV).

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 (Table III and VI).

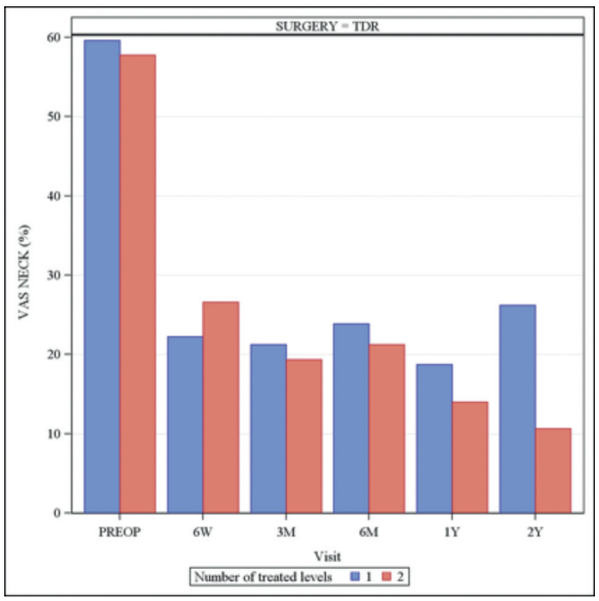
DISCUSSION

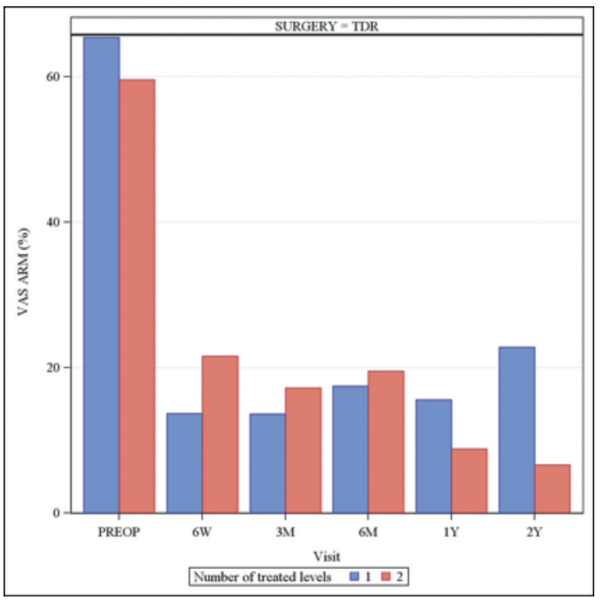
Several two-year clinical follow-up has regularly been reported for most cervical prosthesis, although with different definitions for success. Miao et al reported a reduction of the overall pain VAS from 7.2 to 1.4 two years after disc replacement with the Discover prosthesis (DePuy Spine, Raynham USA) (7). Philips et al reported a 20% NDI improvement in 75,1% of a patients series treated with the PCM disc after two-year follow-up *(10)*. Similar two-year follow-up results were published by Zigler et al and by Stulik et al using the Prodisc C (Synthes USA, West Chester, USA) *(13,17)*, by Wang et al using the Bryan Prosthesis (Medtronic Inc, Memphis, USA) *(14)*, by Peng et al with the Prestige LP artificial disc (Medtronic Inc, Memphis, USA) *(9)* and by Beaurain et al with the Mobi-C disc (LDR Medical, Troyes, France) *(2)*.

Despite the differences in methodology between these studies, the clinical results at two-year follow-up do not seem to be influenced by the type of implant. Our results show that TDR using the Baguera®C prosthesis can be considered a safe treatment for symptomatic cervical disc disease as we observed no implant related complications. Our clinical and safety results are at least equivalent to the ones found in previously published studies with other implants.

Depreitere et al presented guidelines for the rational use of cervical disc prosthesis *(3)*. In their

Table V. — Pain assessment: course of time for VAS Neck (left) and VAS Arm (right) scores

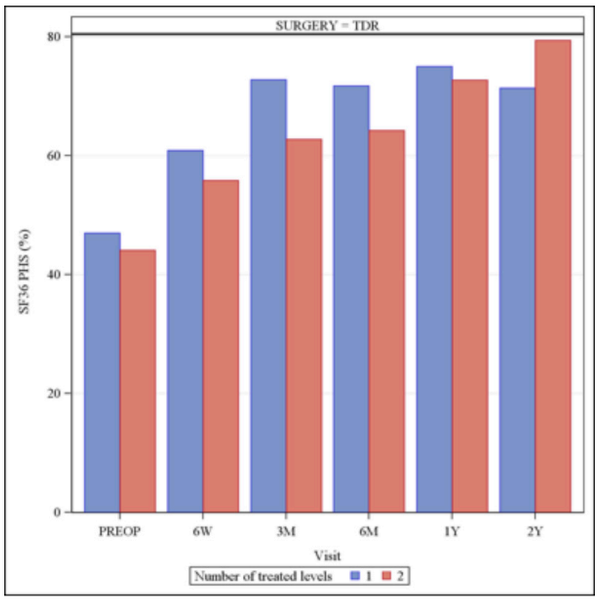


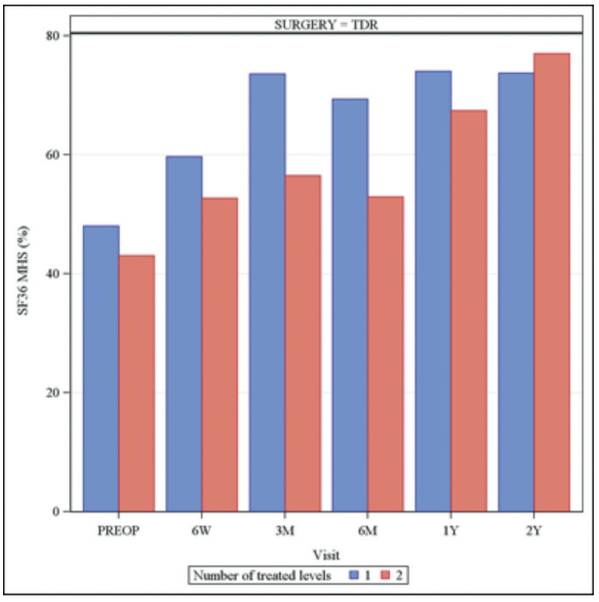


work, the ideal age for TDR was between 18 and 60, the best indications were radiculopathy due to soft disc herniation and/or moderate uncarthrosis in one or two levels. Severe uncarthrosis, facet arthritis, spinal canal narrowing and clinical or radiological myelopathy were considered as contraindications.

Our study completes these guidelines by finding that the rate of overall success is slightly reduced in patients having had previous spine surgical treatments and who underwent revesion surgery (TDR or fusion). We also confirm that clinical results are better for patients less than 50 years of

Table VI. — Quality of Life assessment: course of time for SF-36 physical (PHs) and mental (MHs) scores





age and with preoperative functional disabilities evaluated by NDI greater than 30%.

The importance of a thorough patient selection and of the choice of the implanted prosthesis has also previously been shown. Wu et al clearly showed that TDR for soft disc herniation produced less heterotopic ossifications (HO) than TDR for spondylosis *(15)*. Yi et al found that constrained fixed core prosthesis produced more HO than mobile core prosthesis *(16)*. Some of the longer term studies have showed similarly that constrained prosthesis had a higher rate of heterotopic ossification and early fusion *(6,13)*. This encouraged us to analyse the efficacy and safety of this semi-constrained prosthesis, assuming that not only the disc replacement would safely allow clinical improvement, but also that the design of the prosthesis could contribute to the prevention of facet conflict and preserve motion.

Although there might be rightful questions about the longevity of the cervical prosthesis in general in terms of motion, no publication mentioned that the progressive reduction of the range of motion of the prosthesis had any clinical relevance in terms of pain and disability *(1)*. This explains why, although likely, the cost effectiveness of these implants has not yet been demonstrated. Indeed, Qureshi et al showed that to be cost effective, a cervical prosthesis should remain functional and not require revision for a period of 14 years after surgery, a follow-up that has not been published for any implant to this date *(11)*.

CONCLUSION

Total disc replacement using the Baguera®C device for the treatment of symptomatic cervical degenerative disc disease is a safe procedure with a low complication rate and no recorded device-related adverse events. Four factors have been identified as significant for overall success of TDR surgery. The patients that presented with the best results were adults of maximum 50 years of age, with no previous surgeries for their cervical condition, and no previous other spinal surgeries, and with preoperative functional disabilities evaluated by NDI greater than 30%. These results also demonstrate, by the improvement of the NDI score improvements that it is an effective surgical treatment of single or double level symptomatic cervical degenerative disc disease.

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