BAGUERA® C

SCIENTIFIC PUBLICATIONS SUMMARY

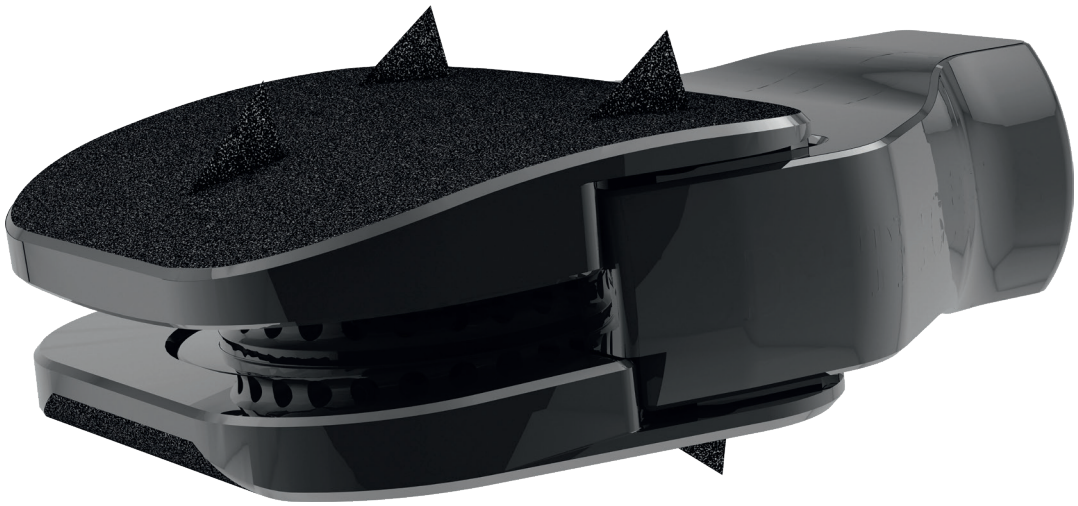
CONTENT

CONCEPT AND DESIGN

Powered in 2006 by a creative and pioneer team, BAGUERA® C was inspired by the black panther of the “Jungle book”: black and elegant, agile but discret, mature while irresistible.

The goal at this time was to replace the disc function and to drastically simplify the existing technologies in motion preservation. After several years of usage and clinical follow up, BAGUERA® C is still innovative while clinically validated, and is now a reference in the cervical arthroplasty segment.

BAGUERA® C is a cutting-edge device that respects Spineart’s philosophy, Quality, Innovation and Simplicity.



AT A GLANCE

Reduced MRI Artifact
Better Stress Distribution
Guided Mobile Nucleus
Anatomical Design

INDICATIONS

BAGUERA® C is a prosthesis intended as a replacement for a cervical intervertebral disc. The BAGUERA® C range is indicated for patient suffering from symptomatic cervical disc disease (SCDD) affecting one level or two adjacent levels between C3 and C7, as defined by the following signs and symptoms:

• Neck or arm pain, and/or

• Functional and/or neurological deficit accompanied by at least one of the following conditions confirmed by MRI or X-Ray:

  _ Herniated nucleus pulposus; and/or

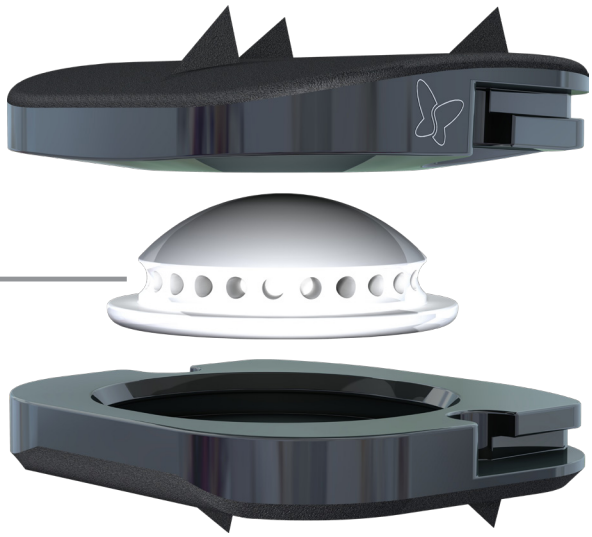
  _ Spondylarthrosis defined by the presence of ostheophytes; and/or

  _ Reduction of disc height.

• Age between 18 and 75.

• No response to non-surgical treatment for a period of at least six weeks, or symptoms or signs of progressive root compression despite conservative treatment.

IMPLANTS



REFERENCES

HEIGHTS	SMALL :13X16MM
5mm	CDP-TI 13 05-S
6mm	CDP-TI 13 06-S
7mm	CDP-TI 13 07-S

REFERENCES

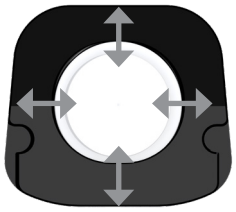
HEIGHTS	MEDIUM : 14X17MM
5mm	CDP-TI 14 05-S
6mm	CDP-TI 14 06-S
7mm	CDP-TI 14 07-S

REFERENCES

HEIGHTS	LARGE : 16X18MM
5mm	CDP-TI 16 05-S
6mm	CDP-TI 16 06-S
7mm	CDP-TI 16 07-S

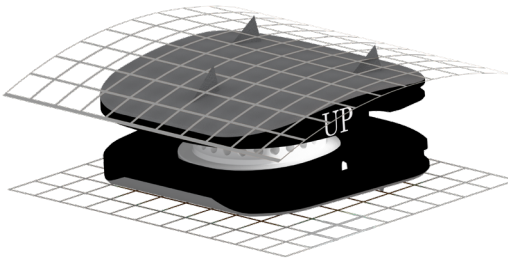
TECHNICAL FEATURES

GUIDED MOBILE NUCLEUS



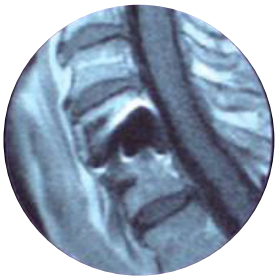
The guided mobile PE nucleus is designed to prevent excessive constraints on the facet joints. It allows 6 degrees of freedom.

ANATOMICAL DESIGN



The sloping anatomical design of the plates optimizes the fit between the device and the disc space, and maximizes the endplate coverage.

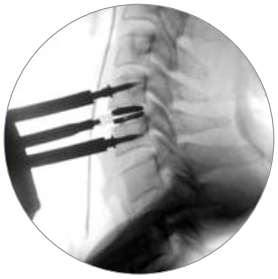
LIMITED MRI ARTIFACT



The titanium plates, coated with Diamond-Like-Carbon (DLC) reduce artifacts under MRI for a better postoperative follow-up.

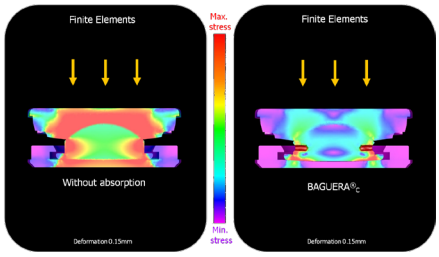
TECHNICAL FEATURES

RADIOLUCENT HOLDER



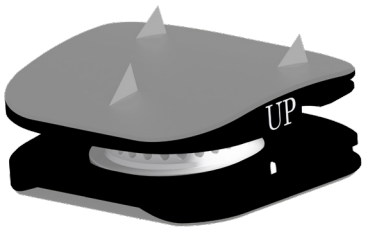
The radiolucent holder allows for both verification of the anterior position of the device and confirmation of the fitting accuracy. Thanks to this holder, the device is delivered pre-assembled for better handling.

BETTER STRESS DISTRIBUTION



Significantly lower contact pressure distribution on polyethylene central core

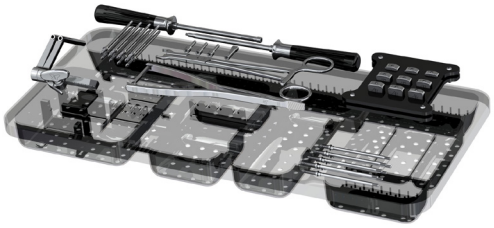
PRIMARY STABILITY



The 3 upper and 3 lower fins as well as the porous titanium coating are designed for primary and secondary stability.

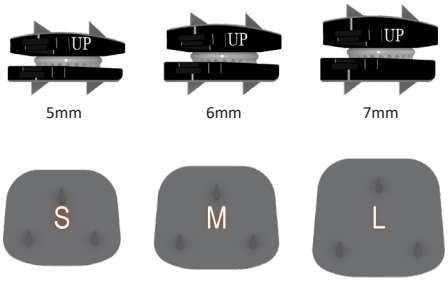
TECHNICAL FEATURES

COMPACT SET



The set includes 4 instruments, trials, and a lockable cervical distractor.

COMPLETE RANGE

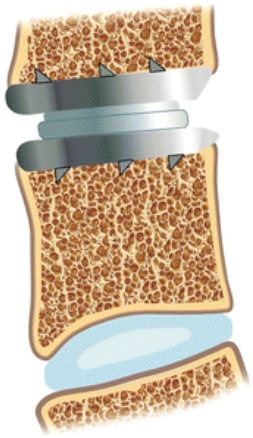


The prosthesis is available in 3 footprints, Small (13x16 mm), Medium (14x17 mm) and Large (16x18 mm) and 3 heights from 5 to 7 mm.

BACKGROUND INFORMATION

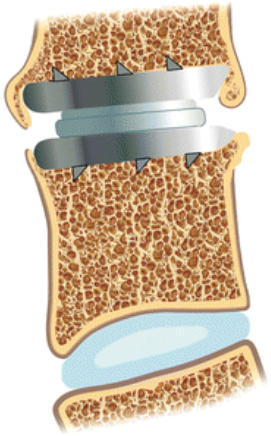
HETEROTOPIC OSSIFICATION (HO) IS THE PROCESS BY WHICH BONE TISSUE FORMS OUTSIDE OF THE SKELETON.

CLASSIFICATION OF HETEROTOPIC OSSIFICATION* (HO)

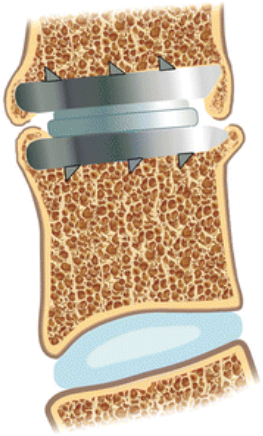


Grade 0 - No HO present

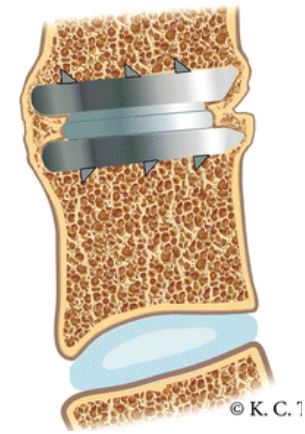
Grade 1 - HO is detectable in front of the vertebral body but not to the intersical space.



Grade 2 - HO is growing into the disc space, possible affection of the function of the prosthesis.



Grade 3 - Bridging ossifications which still allow movement of the prosthesis.



Grade 4 - Complete fusion of the treated segment without movement in flexion/extension.

* Sundseth, J., Jacobsen, E.A., Kolstad, F. et al. Eur Spine J (2016) 25: 2271.

HETEROTOPIC OSSIFICATION IN CERVICAL DISK SURGERY IS STILL A PROBLEM. WHAT ARE THE KEY FACTORS FOR A SOLUTION?

David Cesar Noriega, Ruben Hernandez Ramajo, Israel Sanchez-Lite, Borja Toribio, Emle Delen, Soner Sahin. World Neurosurg. 2016

ABSTRACT

Background: The aim of our study was to determine the presence of heterotopic ossifications (HO) in a series of patients with cervical disk arthroplasty treated with different type of prosthesis, as well as to analyze the most suitable systems for diagnosis.

Methods: A retrospective study of patients with cervical disk disease treated with cervical arthroplasty between May 2005 and December 2009, was performed. Patients were divided into 3 groups, depending on the prosthesis implanted: (Group A: Baguera C prosthesis, Group B: ProDisc prosthesis, and Group C: PCM prosthesis). The presence of heterotopic ossifications was evaluated with both, simple radiology and computed tomography.

Results: As a summary of the results on motion preservation, computed tomography scans showed that 63% of the cervical arthroplasties in Group A presented good mobility at the first check point (December 2010), whereas cervical arthroplasties in Group B and Group C had 74% and 65% severe motion restrictions, respectively (Grade III or Grade IV, according to McAfee classification).

The differences between groups were statistically significant when comparing Groups A and B, and Groups A and C ($P < 0.05$), but there were no differences between Groups B and C ($P < 0.05$). At the second check point (December 2014), the good mobility was just preserved in the 26% of the disk replacements (all in Group A).

Conclusions: Our results showed that, although cervical disks provide optimal mid-term results, the incidence of HO seems to increase with time. Long term studies, with a larger sample size should be conducted to evaluate the appearance of HO and cervical motion after total disk replacement.

TAKE AWAY

- 66 patients, total 78 prostheses
- Mean follow-up was 30.2 ± 9.2 months
- 3 groups : BAGUERA C (SPINEART), ProDisc (DePuy Synthes), PCM(NuVasive)
- Motion restriction (grade III and IV) were observed only in 18.5% in BAGUERA C group, 73.7% in ProDisc group and 65% in PCM group.

RADIOGRAPHIC OUTCOME AND ADJACENT SEGMENT EVALUATION TWO YEARS AFTER CERVICAL DISC REPLACEMENT WITH THE BAGUERA C PROSTHESIS AS TREATMENT OF DEGENERATIVE CERVICAL DISC DISEASE.

Fransen P, Hansen-Algenstaedt N, Chatzisotiriou A, Gonzalez Noriega DC, Verheyden J, Van Hecke W and Pointillart V. J Spine (2016)

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.

TAKE AWAY

- 99 patients, total 123 prostheses
- 2 years follow up
- The prostheses were mobile in 80% after two years. HO was observed respectively 13.7% grade III and 5.6% grade IV.
- No signs of subsidence and no signs of degeneration or kyphosis of adjacent disc, BAGUERA C is safe and effective.

ARTHROPLASTY WITH THE BAGUERA C CERVICAL DISC PROSTHESIS : A REVIEW OF THE SCIENTIFIC BACKGROUND, CLINICAL AND RADIOGRAPHIC EVIDENCES

Fransen and Pointillart, J Spine Neurosurg 2016

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.

TAKE AWAY

- Three series were included in the review:
  - **The Maestretti et al. series:** 249 patients, 24 months follow up. An observational European prospective and multi-centric study-gathered the results regarding safety and efficacy.
  - **The Fransen et al. series:** 95 patients, two years follow up. A prospective registry - aimed to investigate effectiveness of single or double-level total disc replacement (TDR) with the Baguera®C cervical prosthesis in respect of pain, neurological, functional and radiological outcomes.
  - **The Pointillart et al. series:** 99 patients, two years follow up. An independent multicentric retrospective analysis of a clinical and radiographical database –evaluated the relationship between surgery outcomes, and the preoperative disc height (PDH)/implant height (BCH) ratio, inpatients treated by TDR with the Baguera®C cervical prosthesis.
- BAGUERA C showed low complication rates, no recorded device-related adverse events and excellent clinical results.
- The available data show the absence of increased degeneration of adjacent levels.
- The level of heterotopic ossification is low (33%) and inferior to the rates of other devices published in the literature.

ONE - OR TWO - LEVELS TREATMENT BY ARTHROPLASTY OF CERVICAL DEGENERATIVE DISEASE. PRELIMINARY RESULTS AFTER 5 YEARS POSTOPERATIVE CONTROLS

Fransen P, Noriega D, Chatzisotiriou A and Pointillart J Spine 2018

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° ± 5.0°. 87.7% of the treated levels showed preserved motion.

NDI score was 19.5% ± 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.

TAKE AWAY

- 89 patients
- 1 or 2-levels treatment
- At least 5 years follow up
- Evaluation with NDI, SF12, X-ray radiological examination in neutral, flexion and extension
- Results :
  - No reoperations at the arthroplasty level, no fracture of system components, no loss of fixation, no migration or subsidence.
  - 17 patients had radiological signs of adjacent level degeneration but without clinical expression
  - 87.7% of the treated levels showed preserved motion

BIOMECHANICAL PUBLICATION

A BIOMECHANICAL ANALYSIS OF AN ARTIFICIAL DISC WITH A SHOCK-ABSORBING CORE PROPERTY BY USING WHOLE-CERVICAL SPINE FINITE ELEMENT ANALYSIS.

June Ho Lee, MD, PhD, Won Man Park, PhD,y Yoon Hyuk Kim, PhD,y and Tae-Ahn Jahng, MD, PhD.
Spine 2016

ABSTRACT

Study Design: A biomechanical comparison among the intact C2 to C7 segments, the C5 to C6 segments implanted with fusion cage, and three different artificial disc replacements (ADRs) by finite element (FE) model creation reflecting the entire cervical spine below C2.

Objective: The aim of this study was to analyze the biomechanical changes in subaxial cervical spine after ADR and to verify the efficacy of a new mobile core artificial disc Baguera C that is designed to absorb shock.

Summary of Background data: Scarce references could be found and compared regarding the cervical ADR devices' biomechanical differences that are consequently related to their different clinical results.

Methods: One fusion device (CJ cage system, WINNOVA) and three different cervical artificial discs (Prodisc-C Nova (DePuy Synthes), Discocerv (Scient'x/Alphatec), Baguera C (Spineart) were inserted at C5-6 disc space inside the FE model and analyzed. Hybrid loading conditions, under bending moments of 1 Nm along flexion, extension, lateral bending, and axial rotation with a compressive force of 50 N along the follower loading direction, were used in this study. Biomechanical behaviors such as segmental mobility, facet joint forces, and possible wear debris phenomenon inside the core were investigated.

Results: The segmental motions as well as facet joint forces were exaggerated after ADR regardless of type of the devices. The Baguera C mimicked the intact cervical spine regarding the location of the center of rotation only during the flexion moment. It also showed a relatively wider distribution of the contact area and significantly lower contact pressure distribution on the core than the other two devices. A «lift off» phenomenon was noted for other two devices according to the specific loading condition.

Conclusion: The mobile core artificial disc Baguera C can be considered biomechanically superior to other devices by demonstrating no «lift off» phenomenon, and significantly lower contact pressure distribution on core.

TAKE-AWAY

Study design:

- One fusion device (CJ cage system, WINNOVA) and three different cervical artificial discs (Prodisc-C Nova (DePuy Synthes), Discocerv (Scient'x/Alphatec), Baguera C (Spineart))
- Inserted at C5-6 disc space
- Finite Element model

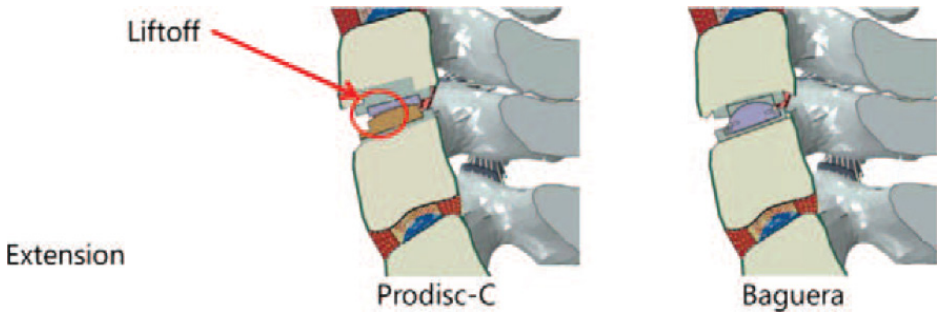
ABOUT CENTER OF ROTATION

Fig. 1

The BAGUERA C mimic the intact cervical spine regarding the location of center of rotation during flexion movement

ABOUT LIFT-OFF PHENOMENON

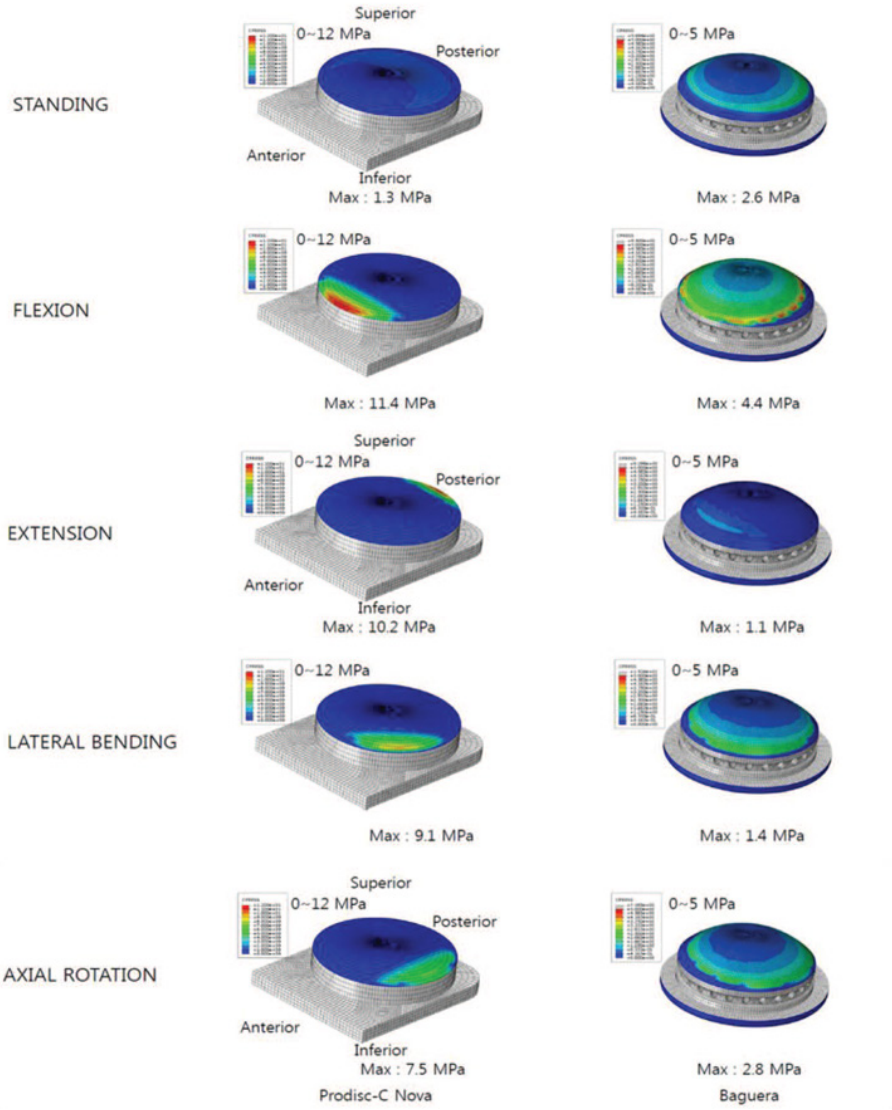
Lift off phenomenon: a partial detachment of the socket from the core.



Good contact to the upper plate from the core with well maintenance of the contact area for Baguera C. In contrast, a liftoff phenomenon was noted for the other two artificial discs during extension.

TAKE-AWAY

ABOUT STRESS DISTRIBUTION



Thanks to its design for mobile core and shock absorption function, the BAGUERA C showed:

- Wider distribution of the contact area
- Significantly lower contact pressure distribution on the core
- Better stress distribution
- Prediction a lower feasibility of the development of the wear inside the core in the long-term follow-up

N O T E

S P I N E A R T

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