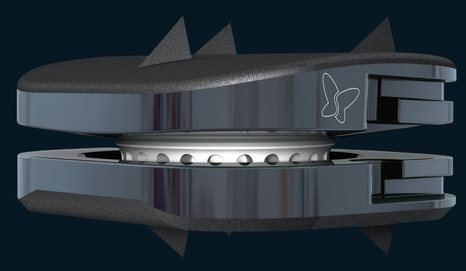
A NOVEL CERVICAL DISC REPLACEMENT DEVICE BAGUERA®C : DESIGN AND BIOMECHANICAL CHARACTERISTICS



Dr. G. MAESTRETTI, Dr. P. OTTEN

Hôpital Cantonal de Fribourg - Switzerland

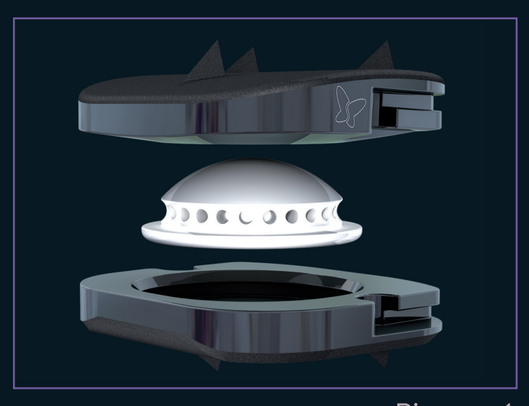
PURPOSE

The potential for spinal arthroplasty in the treatment of cervical DDD has been recently supported by clinical data. Pre clinical test in an in vivo loading environment are the success of such devices to confirm safety and efficacy. Our device is presently undergoing a series of performance evaluations.

MATERIAL AND METHODS

A - BAGUERA®C consists of a high density polyethylene nucleus that articulates between two titanium endplate components with a porous coated exterior and a Diamolith® coated interior.

Picture 1 : BAGUERA®C components



Picture 1

The titanium plates reduce artifacts with MRI and allow a post-op control.

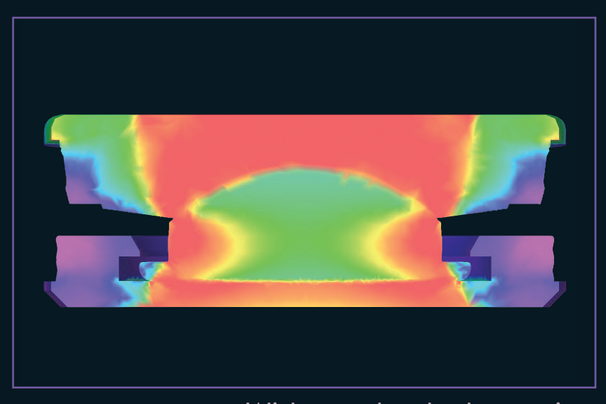
Picture 2 : BAGUERA®C MRI

Picture 2

The Diamolith® coating of the endplates improves sliding and cancels wearing.

B - Inferior plate shape and PE design allow 0,15 mm elastic deformation and absorb shock and vibration.

Picture 3 : BAGUERA®C shock absorption



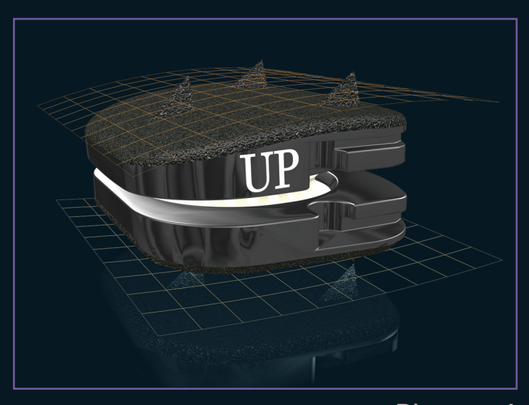
Without shock absorption

Picture 3

Shock absorption with BAGUERA®C

C - BAGUERA®C features a sloping and anatomical shape allowing easy insertion and a perfect fit between the vertebral endplates.

Picture 4 : BAGUERA®C sloping anatomical shape

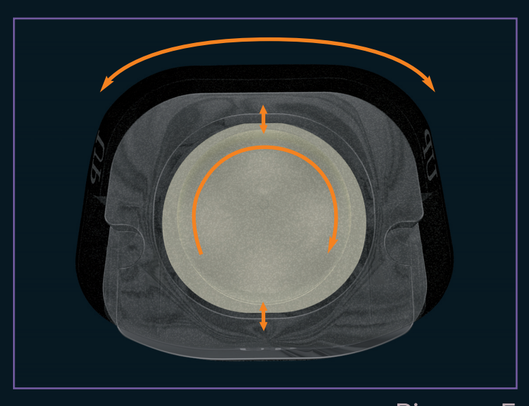


Picture 4

D - The 6 upper and lower fins guarantee the implant primary stability.

E - The PE mobility prevents excessive constraint of facet joints and its rolling feature respects axial rotation movements.

Picture 5 : BAGUERA®C mobile nucleus



Picture 5

F - BAGUERA®C is pre-assembled to facilitate the manipulation and insertion in OR.

G - The radiolucent fork allows checking of implant anterior positioning validating its primary stability.

RESULTS

Five BAGUERA®C prostheses were tested for mechanical resistance, fatigue and wear.

Mechanical resistance was tested with a static axial compression method under progressive loading of 1200 N . Dynamic compression fatigue tests under sinusoidal loading from 50 to 500 N was run for a duration of 10 millions cycles at 1 Hz. Wear was measured in flexion/extension and axial rotation. Tests presented no breakage of the implant. The PE insert was still mobile at the end of the tests and showed no loss of weight nor wear.

CONCLUSIONS

This new cervical prosthetic device BAGUERA®C shows promise based on its design. Preliminary biomechanical testing is favorable and implantation techniques are accommodating. Clinical investigations are forthcoming.

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