Until recently, the standard treatment for cervical degenerative disc disease (DDD) was anterior cervical discectomy and fusion (ACDF), which has proved to be an excellent treatment. However, the incidence of cervical adjacent-level disease and the loss of motion have led to the consideration of total disc replacement as an alternative solution. The potential for spinal arthroplasty in the treatment of cervical DDD has recently been supported by clinical data.

The BAGUERA® C disc is a biomechanical device designed to provide symptomatic relief and restore motion, thereby protecting adjacent levels from abnormal stresses. The device consists of a high-density polyethylene (PE) nucleus that articulates between two titanium endplate components with a porous coated exterior and a diamond-like carbon (DLC)-coated interior. The materials used in the design are known to provide excellent strength and durability (see Figure 1). These components assemble in such a way as to allow physiological rotations as well as translation in both the anteroposterior (AP) (±0.3mm) and rotation (±2°) directions. The controlled mobility of the PE nucleus prevents excessive constraint of facet joints, and its rolling feature respects axial rotation movements (see Figure 2). The inferior plate and PE design allow 0.15mm elastic deformation and absorb shock and vibrations (see Figure 3).

The titanium plates reduce possible artefacts when using magnetic resonance imaging and allow post-operative control.

The BAGUERA® C cervical disc prosthesis features a sloping anatomical shape, allowing easy insertion and a perfect fit between the vertebral endplates. The six upper and lower fins guarantee primary stability to the implant and prevent it from being expelled (see Figure 4).

The titanium plates reduce possible artefacts when using magnetic resonance imaging (MRI) and allow post-operative control (see Figure 5). The endplates are coated with Diamolith to improve sliding and eliminate wear debris. The device is pre-assembled to facilitate manipulation in the operating room (OR) and the insertion of the device. The radiolucent ‘fork’ makes it easy to check the anterior positioning of the implant, validating its primary stability (see Figures 6 and 7).

To ensure biomechanical reliability and durability, five cervical total disc replacement devices from Spineart (Geneva) were tested for mechanical resistance, fatigue and wear. Mechanical resistance was tested with a static axial compression method under progressive loading of 1,200N until collapse of the implant. Dynamic compression fatigue tests under sinusoidal loading from 50 to 500N were run for 10 million cycles at 1Hz. Wear was measured in flexion/extension and axial rotation via 150N load; tests were run for a duration of 10 million cycles at a frequency of 1Hz. In these tests there was no breakage of the implant, the PE insert was still mobile at the end of the tests and there was no loss of weight or signs of wear.

The surgical technique is straightforward and the specially designed tools ensure the simplicity of disc implantation. The procedure commences by placing the cervical distractor pins parallel to the endplates. The nuts are then attached to the screwdriver and the pins are locked (see Figure 8). At this point, a subtotal discectomy is performed. The interbody distractor is then inserted until the posterior vertebral wall has been reached to distract in parallel. Under X-ray control, a distraction is performed and maintained by the cervical distractor, and the discectomy is completed. The trial implant is then

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inserted into the disc space to determine the appropriate size of the device. Both an AP and a lateral X-ray control are required. In order to check the stability of the trial implant, the distraction should be released and then distracted again smoothly with the cervical distractor; the trial implant can then be removed. The implant holder is screwed onto the pre-assembled device, and the prosthesis is then ready to be inserted. This is followed by a profile control to check the correct positioning of the prosthesis. Thanks to the radiolucent fork, the image of the implant can be seen perfectly (see Figure 7).

This new cervical total disc replacement device shows promise based on its design. Preliminary biomechanical testing is favourable and implantation techniques are accommodating. Eight hundred and three BAGUERA® were implanted in 12 countries over a period of 18 months from February 2007 to August 2008. Early clinical data suggest that the BAGUERA® cervical artificial disc is a suitable cervical prosthesis disc with an easy introduction technique. A series of 21 radiographs were studied and measured. Clinical outcomes were recorded with the visual analogue scale (VAS) for neck, arm pain and satisfaction, and also with the Neck Disability Index.

Early radiographic results are at least comparable to those seen with other disc replacement techniques, and early clinical results are at least comparable to those seen with the fusion technique. However, additional data are required as long-term follow-up is necessary to determine the efficacy of this treatment in terms of the maintenance of implant mobility, with the additional upside of possible prevention of adjacent segment degeneration.
DISC REPLACEMENT