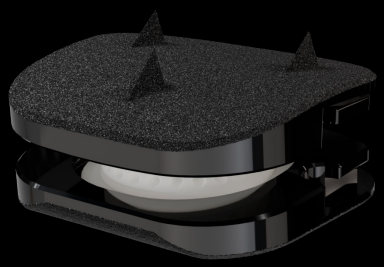
A NOVEL APPLICATION OF VITAMIN E CROSSLINKED POLYETHYLENE MATERIAL IN CERVICAL DISC ARTHROPLASTY



Ryan L Siskey (Exponent Inc, Philadelphia, PA), Jimmy Etchart (Spineart, Geneva, CH)

Cervical disc arthroplasty (CDA) has proven to be an alternative to cervical fusion for the treatment of symptomatic patients with degenerative disc disease. While in hip and knee arthroplasty the use of antioxidant stabilized polyethylene has become the state of the art, such is not the case for cervical disc arthroplasty. Periprosthetic osteolysis (PO) with cervical disc replacement is scarcely documented[1,2] or related to specific device designs[3].

The BAGUERA® C (Spineart, Geneva, Switzerland) is a semi constrained cervical disc prosthesis available on the EU market since 2007. Fransen et al.[4] have recently published the 10-year results from a prospective observational clinical study. In the US, the device is investigational and currently undergoing two randomized investigational device exemption (IDE) clinical trials to obtain pre-market approval (PMA) for single and two-contiguous level replacement in patients with symptomatic degenerative disc disease at C3-C7.

The device endplates are made of a titanium alloy coated with DLC (diamond-like carbon) on the articulating surfaces and polyethylene for the core (Figure 1).

FIGURE 1
The BAGUERA C cervical disc prosthesis with a VE-HXLPE nucleus

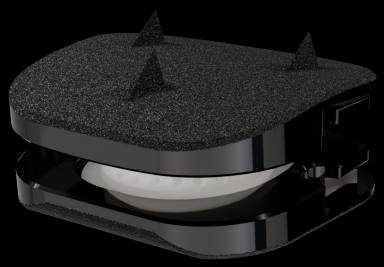
Its major differences with other implants are the unique interaction of a three-level stabilization system (three metal fins protruding from the endplate, anatomical shape and titanium plasma spray coating allowing osteointegration), a diamond-like carbon coating interface between the nucleus and the titanium endplates (to reduce friction, wear debris and increase the implant longevity) and a guided mobile nucleus, clipped in the implant and designed to allow six degrees of freedom thus preventing excessive constraints to the facet joints and avoiding posterior subluxation of the nucleus.

Through the ongoing collaboration with the Food and Drug Administration (FDA) as part of the IDE/PMA regulatory process, a series of in vitro studies were performed to establish the preclinical safety profile and wear performance to update the nucleus material from conventional UHMWPE to a Vitamin E-stabilized, highly crosslinked polyethylene (VE-HXLPE). Although VE-HXLPE has a successful clinical history as a wear-, fatigue-, and oxidation-resistant bearing material in large joint (hip and knee) total joint replacements[5,6], its long-term clinical performance for cervical disc arthroplasty remains to be determined.

The BAGUERA®C implant with a VE-HXLPE nucleus was evaluated under clean, impingement, and abrasive conditions. Clean and abrasive testing were guided by ISO 18192-1 and impingement was assessed as per ASTM F3295. For abrasive testing, the DLC coated endplates were scratched to simulate in vivo abrasion. The devices were tested for 10 million cycles (MC) under clean conditions, 5 MC under abrasion, and 1 MC under impingement.

Wear rates under clean and abrasive conditions were 0.6 ± 0.1 and 1.6 ± 0.6 mg/MC7 respectively (see Figure 2 and Figure 3). The VE-HXLPE components demonstrated evidence of burnishing and multidirectional micro-scratching consistent with micro-abrasive conditions with the DLC coated endplates. Under in vitro impingement, the nucleus demonstrated negligible mass loss rate (<0.0 mg/MC) with either the small or large endplate. The endplate-to-endplate contact resulted in regions that exhibited abrasive damage and removal of the DLC coating (7.7 ± 2.2. mg/MC for the superior endplate and 5.5 ± 2.1 mg/MC for the inferior endplate with the small endplate configuration) [7]. No functional or mechanical failure was observed across any of the wear modes.

SPINEART



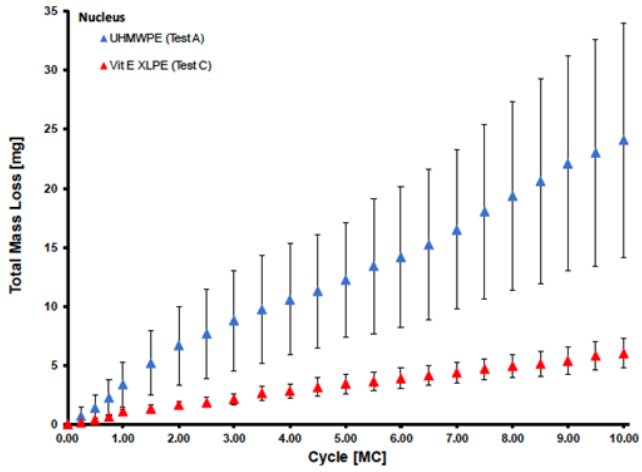


FIGURE 2
Average total mass loss for the VE-HXLPE components (Test C) compared to standard UHMWPE components (Test A) corrected for soaking (n=6) during the standard clean wear test. Error bars represent one standard deviation.

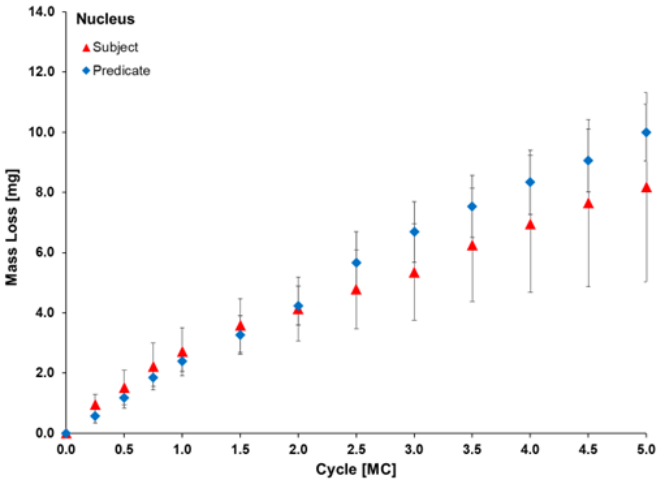


FIGURE 3
Average total mass loss for the VE-HXLPE components (Subject) compared to standard UHMWPE component

Overall, it was found that a VE-HXLPE-on-DLC/titanium cervical disc replacement design met and exceeded the benchmarks established by conventional UHMWPE cervical disc replacements under the same clean test conditions (0.9-6.3 mg/MC), [8] including when this specific design, with conventional UHMWPE, was evaluated (2.3 ± 1.0 mg/MC).[7]

The results of the in vitro tribological performance of VE-XLPE bearings in cervical disc replacement suggest that the adoption of this modern UHMWPE material could enhance the outcomes of CDA. The results of these tests, along with the outcomes of the ongoing IDE clinical trials, will be presented by Spineart to the U.S. FDA as part of a pre-market approval process.

REFERENCES

1. Tumialán LM, Gluf WM. Progressive vertebral body osteolysis after cervical disc arthroplasty. Spine. 2011;36(14):E973-E978.
2. Kang DG, Wagner SC, Lehman RA. Osteolysis in the setting of metal-on-metal cervical disc arthroplasty. Spine J. 2014;14(7):1362-1365.
3. Scott-Young M; Rathbone E; Grierson L. Midterm osteolysis-induced aseptic failure of the M6-C™ Cervical total disc replacement secondary to polyethylene wear debris. Eur Spine J. 2022; 31(5):1272-1282.
4. Fransen P; Noriega D; Chatzisotiriou A; Pointillart V. Cervical Disc Arthroplasty with the BAGUERA-C prosthesis: clinical and radiological results of a 10-year follow-up study.
5. Spece, H.; Yardbrough R.V; Kurtz, S.M. In Vivo Performance of Vitamin E Stabilized Polyethylene Implants for Total Hip Arthroplaty: A Review. J Arthroplast. 2022, 38, 970-979.
6. Spece, H.; Yardrough, R.V.; Kurtz, S.M. A Review of Early In Vivo Performance of Antioxidant Stabilized Polyethlyene for Total Knee Arthroplasty. J. Arthroplast. 2023, 38, 970.
7. Data on file at Spineart.
8. Siskey R, Ciccarelli L, Lui MK, Kurtz SM. Are PEEK-on-Ceramic Bearings an Option for Total Disc Arthroplasty? An In Vitro Tribology Study. Clin Orthop Relat Res. 2016 Nov;474(11):2428-2440.