Novel Accelerated Neutral Atom Beam Processing as a PEEK Surface Treatment: A Four-Month Preliminary Study using an Ovine Lumbar Intervertebral Spinal Fusion Model

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INTRODUCTION:

Intervertebral spinal fusion cages have been widely used in spinal surgery since their introduction in 1988[1]. Combined with autogenous bone grafting, this arthrodesis technique induces bone bridging between adjacent vertebrae using hollow intervertebral fusion implants that re-establish intervertebral height, provide mechanical stability, and potentially alleviate back and leg pain[2].

Over the last two decades, interbody cage implants have been manufactured from many biomaterials including titanium, carbon fiber-reinforced polymer, and polyetheretherketone (PEEK). In fact, PEEK implants provide optimal biocompatibility, biomechanical elasticity similar to bone, and radiolucency that substantially improves visualizing of healing. Recently, PEEK has been demonstrated to be highly inert eliciting a fibrous tissue surface reaction that delays early interbody fixation and osseointegration[3]. Surface treatments have been developed such as hydroxyapatite and titanium coatings that are limited by potential delamination and generation of debris from surgical impaction[4].

In this study, an accelerated neutral atom beam technology (ANAB) was developed to improve the bioactivity of PEEK surface. While modifying its surface to a depth of ≤ 2-3nm, ANAB employs a directed beam of neutral argon gas atoms with energies controlled over a range from a few electron volts (eV) to over 100eV per atom[5]. Using an ovine lumbar intervertebral fusion model, the safety and efficacy of this ANAB surface treatment was compared to a titanium coating applied on conventional PEEK intervertebral implants. Bone bridging and bone apposition were quantified in addition to histopathology scores. Adverse effects on selected systemic tissues and organs, serum biochemistry and hematology were also evaluated.

METHODS:

Sixteen (16) skeletally mature female sheep (Dorset Rideau Arcott Hybrids) underwent lumbar spinal fusion procedures at two non-contiguous sites (L2/L3 and L4/L5) using a retroperitoneal approach. The study protocol was approved by an IACUC committee and conformed to both AAALAC and CCAC regulations. Interbody fusion devices [PEEK interbody cages; 10x22x6-8mm (WxLxH), Vallum Corp.] were surface-treated with either an accelerated neutral atom beam processing ($1x10^{17}$ argon atoms/cm^2; ANAB, Exogenesis Corp.) or a plasma-sprayed titanium surface coating. The cages were then positioned using PLIF instrumentation without iliac crest bone graft supplementation, and stabilized with a veterinary plate and screws system (Veterinary Orthopedic Implants, VOI). Animals were allowed to recover and were followed for 4 months post-operation.

At termination, *en-bloc* L1/L6 lumbar segments were harvested and immersed in 10% neutral buffered formalin (NBF). The intervertebral units (L2/L3 and L4/L5) with adjacent end-plates were isolated using a diamond saw and transferred to 70% EtOH, scanned by Micro CT (Nikon XTH 225), sectioned in the A-P axis, processed for non-decalcified histology, infiltrated with PMMA, then microground and micropolished (Exakt 400 CS) in order to obtain non-decalcified slides of 60µm or less.

Histomorphometry was performed following Goldner's Trichrome staining in order to evaluate new bone formation and bone apposition under light microscopy. Histopathology was evaluated for prevalent inflammatory cells, necrosis/osteolysis, neovascularization, fibrous tissue, new bone formation, and bone bridging scores. One-way analysis of variance (ANOVA) was used with Dunnett's post-hoc test for multiple comparisons. A value of $p \leq 0.05$ was used to determine statistical significance.

RESULTS:

All animals were considered in healthy condition over the entire study period with the exception of one early death animal (at day 5), which was attributed to neither test nor control implants following macroscopic and surgical examination of the explant sites.

ANAB-treated cages demonstrated new bone formation within the internal graft space, vertebral end-plates, as well as ventral and dorsal aspects with partial bone bridging observed under both light microscopy (Fig. 1a) and micro-computed tomography (Fig. 1b).

Following an adapted version of ISO 10993-6 scoring, histopathology also showed a normal tissue reaction with no adverse effects that appeared similar for both ANAB and titanium surface-treated implants. Bone bridging as well as the quality of new bone formation appeared similar in both groups and seemed to normally progress during this 4-month healing time.

DISCUSSION:

Using an ovine interbody spinal fusion model, this novel accelerated neutral atom surface exhibited excellent safety and biocompatibility as evidenced by low inflammation and tissue reaction in absence of adverse effects. The overall intervertebral healing progressed in a normal fashion. After 4 months, the quality of new bone formation and bridging was relatively similar in both groups and appeared to normally progress, making this accelerated neutral atom beam processing a promising alternative to medical device surface treatment in absence of iliac crest autologous bone grafting.

SIGNIFICANCE/CLINICAL RELEVANCE:

Low back pain and lumbar instability associated with degenerative disc disease represent pathologies that are traditionally treated by interbody fusion using autologous bone grafting. A novel accelerated neutral atom beam surface technology applied to standard PEEK implants obtained osseointegration comparable to titanium coating on traditional PEEK interbody fusion devices.

REFERENCES:

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FIGURE 1:

Exakt-ground sagittal section showing partial bone bridging in presence of ANAB-surface treated PEEK intervertebral fusion cage visualized under (a) light microscopy (Goldner's Trichrome stain, 10X) and (b) corresponding 3-D reconstructed ANAB-treated radiolucent PEEK cage via micro-computed tomography (Micro CT; Nikon XTH 225, 18-µm resolution) following 4 months of implantation.