FULLY DENSE NANOCRYSTALLINE HYDROXYAPATITE AS A STRUCTURAL MATERIAL FOR SPINAL INTERBODY FUSION

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Statement of purpose: Hydroxyapatite (HA) has a long history of use as a bone graft subsitite material because of its similarities to native bone mineral and favorable interactions with boney tissue. However, the poor mechanical properties of HA have prevented its use in structural applications, such as interbody fusion devices (IBFs). This has restricted acceptable biomaterials for IBF design to primarily inert polymers (such as polyether-ether-ketone (PEEK)), metals (such as titanium), and machined allograft tissue. This study describes the characterization and pilot clinical results for a mechanically robust and pure nanocrystalline HA IBF. This material is the result of ceramic processing methods designed specifically for nanocrystalline ceramics that retain unique mechanical and biological properties. The benefits of this device are improved consistency and reliability compared to allografts, with mechanical performance equivalent to PEEK, while potentially having improved cellular responses over both allografts and PEEK.

Methods: Comprehensive mechanical tests were conducted to quantify the strength and durability of a full theoretically dense nanocrystalline hydroxyapatite cervical IBF following relevant ASTM standards of testing (ASTM F-2077, ASTM F-2267-04). Mechanical evaluation of the device included compression, torque, and shear-compression to static failure as well as cyclic endurance testing under physiological conditions to 5M cycles at physiological loads (n=6 per test).

Additional devices were subjected to either an in vivo or in vitro degradation condition. Degradation methods included a chronic rabbit muscle pouch model and real time aging in 37ºC simulated body fluid. Devices were removed at 4, 13, 26, and 52 weeks and tested in static and dynamic compression, shear, and torsion. Two additional devices were also subjected to accelerated aging in acidic conditions while under cyclic stress of combined compression and fully reversed torsion for 5M cycles, followed by another 5M cycles in the same loading configuration at physiological pH.

Nanocrystalline hydroxyapatite was also compared to PEEK and allografts to investigate the response of osteoblastic and fibroblastic activity to materials. In vitro testing via cell culture was performed and the osteoblastic adhesion, proliferation, alkaline phosphatase activity, and calcium deposition were measured. Additionally, fibroblast adhesion and proliferation was measured.

Following successful mechanical and in vitro testing, a pilot clinical study was performed. A traditional anterior cervical discectomy and fusion (ACDF) procedure was performed with anterior cervical plating. A total of 29 devices were placed in 21 patients in single (n=13) and two (n=8) cases. Patient evaluation metrics included intra and post-operative complications, additional surgeries, adverse events, pain scoring, and radiographic evaluation.

Results: The nanocrystalline HA IBF demonstrated biomechanical performance that was equivalent to a commercially available PEEK IBF with similar geometry. Static failure loads for the nanocrystalline HA IBF exceeded clinically relavent loads for torsion, compression, and shear by safety factors of 5.16, 4.81, and 4.28, respectively. Endurance testing in the same load configurations demonstrated factors of safety for torsion, compression, and shear of 1.67, 1.43, and 1.96, respectively at 5M cycles. Real time and accelerated degradation of the devices in various environments had no significant impact on mechanical performance.
Cellular assays demonstrated that nanocrystalline HA had significantly greater osteoblast attachment, proliferation, alkaline phosphatase activity, and calcium deposition than both PEEK and allografts ($p<0.01$ for all tests). Fibroblast attachment was statistically similar amongs all groups, and there was significantly lower fibroblast proliferation on nanocrystalline HA compared to both PEEK and allografts ($p<0.01$).

Clinical performance of the device demonstrated effectiveness of the device without any complications. No surgical or post operative complications were noted. Radiographic outcomes demonstrated device stability and function at follow-up time points ranging from 6 to 28 weeks.

Conclusions: The nanocrystalline HA device demonstrated biomechanical performance equivalent to that of a PEEK device. In vitro assays demonstrated favorable cellular responses compared to PEEK and allograft bone. The limited clinical experience suggests that nanocrystalline HA is an effective treatment for ACDF.