Examination of the osteoconductive, antibiofilm & biomechanical properties of a PEEK-ZEOLITE composite biomaterial for intervertebral spine fusion surgery

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ABSTRACT

Polyether ether ketone (PEEK) demonstrates intrinsic inertness and hydrophobic properties, thereby resulting in an inherent susceptibility to bacterial infections and reduced fusion capacity within the intervertebral space due to fibrous encapsulation [1,2]. CleanFuze™ (CF), a bioactive PEEK- silver zeolite composite that has received CE approval, is expected to have infection resistive and osteoblast stimulative effects due to silver ions and ceramic zeolite particles respectively. The goal of the study was to evaluate the efficacy of CleanFuze in preventing biofilm formation and in promoting osteoblast growth relative to PEEK; without compromising PEEK's biomechanics..

Keywords:peek,silver,zeolite,implantassociated infections, orthopedic biomaterial

1. INTRODUCTION

The primary biomaterials used for manufacturing interbody implants are polyetheretherketone (PEEK) and titanium; both of which are associated with inherent disadvantages. PEEK demonstrates intrinsic inertness and hydrophobic properties, thereby resulting in poor osteointegration and reduced fusion capacity within the intervertebral space. Despite its attractive osseointegrative properties, titanium suffers from poor imaging properties, may give rise to stress shielding which leads to subsidence and significantly greater technical difficulty in revision situations. The critical need for a material which combines the beneficial aspects of the two materials i.e. handles, images and has the modulus of PEEK while possessing the osteointegrative (OI) properties of titanium, led to the development of a new PEEK- Zeolite composite for spinal applications. The new PEEK composite has previously been demonstrated by our group to be osteoconductive in a critical sized rabbit femoral defect model. The zeolite (aluminosilicates) in these composites can also be loaded with metallic ions, such as silver, to also provide for antibiofilm properties which have also been previously demonstrated via a rabbit spine infection model.

2. METHODS

2.1 Flow cell biofilm bioreactor assay (ASTM E2647)

S.aureus (ATCC 6538) biofilm quantification was done using a Flow cell Bioreactor Model with low shear and continuous flow. Growth conditions as detailed in ASTM E2647 at 37°C were used to grow an initial inoculum dosage of 1.5*104cfu's into biofilms on PEEK and CleanFuze coupons (dia=12.5mm) after 48 hrs. The quantification of biofilm/cm2 was done via colony count technique

2.2 Invitro peri-operative contamination model

Competitive colonization between a previously published GFP induced MRSA strain3 and MG-63 osteoblast-like cells (ATCC CRL-1427 TM) for CleanFuze and PEEK (~1.23 cm2) was studied. Osteoblast growth on these bug inoculated surfaces was compared to their respective un-inoculated controls. GFP-MRSA bugs were seeded 4hrs prior to the introduction of osteoblasts.Cell proliferation was quantified by Alamar Blue assay while bacterial viability was done using colony count technique at two time points-Day 3 and 7.

2.3 Dynamic Biomechanical Testing

22x8 PLIF CleanFuze and PEEK cages were tested for dynamic compression and torsion (ASTM F2267-03, F2267-04) in PBS at 37 ± 3°C.Testing was done to ensure device clearance from a FDA biomechanical standpoint.

3.RESULTS AND DISCUSSION

3.1 Flow cell biofilm bioreactor assay

Data at the end of 48 hrs, tabulated below, demonstrates that CleanFuze is actively anti-biofilm while PEEK is susceptible to colonization.

SPECIMEN	Initial Inoculum (CFU/cm2)	± SD	Colony Count -48 hrs (CFU/cm2)	± SD
CLEANFUZE	13274	328	752	125
PEEK	13274	328	2,831,858	38000

Table 1: Flow cell bioreactor assay colony counts after 48 hrs.

3.2 Invitro peri-operative contamination model

CleanFuze being actively antibiofilm in nature is able to protect osteoblasts from destruction by MRSA unlike infected PEEK. Infected CleanFuze shows three times greater proliferation compared to even uninfected PEEK controls as shown below in Fig.1 and Fig.2..

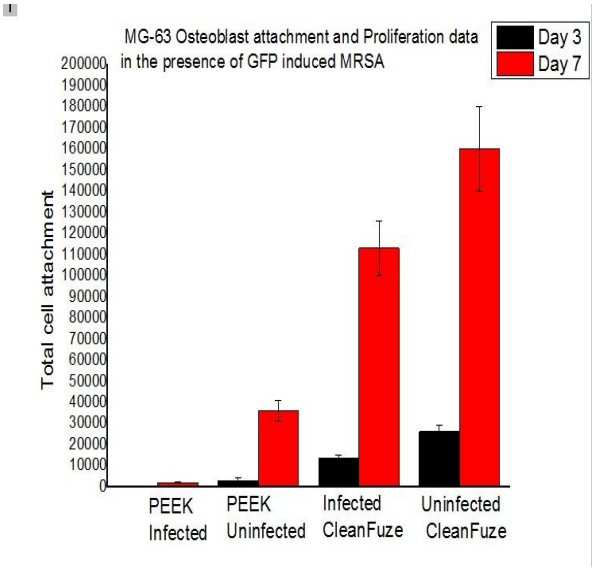

Fig 1.Osteoblast proliferation

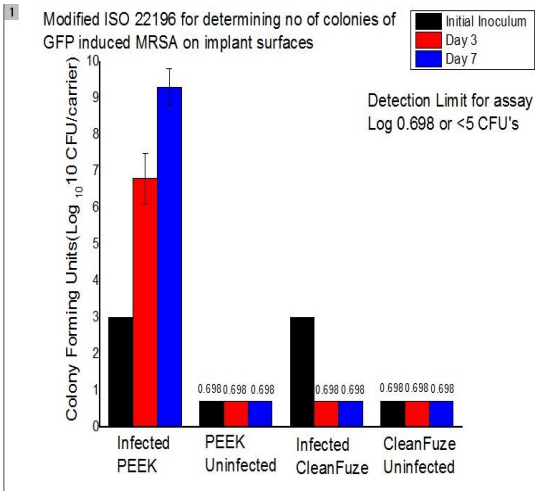

Fig.2 Colony counts of MRSA on implant surfaces

3.3 Dynamic biomechanical testing

CleanFuze was able to withstand a load of 4000N at 5 million cycles under compression and 5N.m at 5 million cycles under torsion. PEEK failed at 3750N after 925,018 cycles under compression and under torsion, failed at 5N.m after 502,794 cycles. CleanFuze implants surpass the minimum criteria set by the FDA for implant approval and possess superior biomechanical properties relative to PEEK cages for the exact same implant design.

4. CONCLUSIONS

CleanFuze demonstrates enhanced osteoblast proliferation and anti-biofilm activity; while improving upon PEEK's biomechanical properties, thereby allowing for an alternative biomaterial in spine and orthopaedics with improved characteristics.

REFERENCES

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