

Comparative Efficacy of Ceramic-Acrylic in Orthopedic Implantation: Implications for Future Applications

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Introduction: Many factors need to be considered when designing and developing a medical device. Biocompatibility, appropriate mechanical properties, and manufacturability are essential elements, along with ease of surgical use postoperative imaging criteria. The list of potential materials for implants often includes traditional metal alloys (SS, Ti, CoCr) and both non-resorbable (polyetheretherketone (PEEK)) and resorbable polymers, each with their own positive and negative features, related clinical needs, design challenges and manufacturing processes.

Additive manufacturing (AM), while not a new technology, has experienced a rapid increase in titanium alloy-based implants and more recently fused filament-based PEEK devices with complex architectures that would be difficult to produce with traditional manufacturing. An alternate use of AM is to produce a mold into which a material can be injected, thereby providing a simple means of creating complex structural materials. The key benefit of additive molding is that the resulting implants are fully isotropic, unlike additive parts made layer by layer. This study evaluated a new form of ceramic-acrylic biomaterial that is a composite of a novel acrylic-based crosslinking copolymer and calcium-based bioceramics. This material can be manufactured using additive molding to produce medical devices. The in vivo response of this new biomaterial was directly compared to titanium alloy and PEEK in a well-reported large animal bone ongrowth model based on microcomputed tomography (μ CT) and local cell and tissue reactions using histology.

Methods: This study was approved by an Ethics Committee. Three implant materials (Group 1: Ceramic-Acrylic; Group 2: Medical grade PEEK; Group 3: Titanium alloy) were manufactured into standardized test devices (6mm \varnothing x 9 mm height with three 1mm \varnothing channels; Figure 1) and sterilized via gamma irradiation. One sample from each group was evaluated using a Leica Stereozoom Microscope, Hitachi TM environmental electron microscope (eSEM) and a Mahr surface profiler to assess surface features. Twelve test devices were implanted bilaterally in eight adult sheep (wethers) model. Two sites were prepared in the cancellous bone of the medial distal femur and one in the medial proximal tibia for press fit implantation (5.5 mm \varnothing hole). Three devices were implanted line to line in the medial cortex of the tibial diaphysis (6.0 mm \varnothing hole). The sample size was n=4 per group per time point in cancellous as well as cortical bone. Two sheep were allocated for 3-, 6- and 12-week time points. Routine blood biochemistry and haematology was performed prior to surgery and at each time point. The hindlimbs were harvested for macroscopic dissection, anteroposterior and lateral Faxitron radiographs, μ CT, and serial sectioning of PMMA histology. The radiographs and μ CT were used to evaluate for any adverse bone reactions at the bone-device interfaces. Similarly, PMMA histology was used to assess local cell and tissue reactions as per ISO 10993-6 and general bone response.

Results: Stereozoom microscopy and eSEM for Group 1 (Ceramic-Acrylic) revealed a microporous surface and exposed calcium-based bioceramic, Group 2 (PEEK) had a smooth surface, and Group 3 presented the typical feature with titanium. The surface roughness (Ra, microns) for Groups 1, 2 and 3 was 2.02, 0.55, 3.64 respectively. All animals recovered from surgery uneventfully, blood work was unremarkable, and there were no infections or signs of adverse macroscopic reactions during dissection. Radiographs revealed no evidence of adverse bone reactions. Group 1 was slightly radio-opaque due to the presence of bioceramic, while Group 2 (PEEK) was radiolucent and Group 3 (Ti) was able to be seen radiographically. Microcomputed tomography demonstrated direct bone contact on the implant surface in all groups and bone ingrowth into the channels in Groups 1 and 2, which progressed with time. Artefact was present with Ti that precluded any definitive comments regarding bone within the implant channels. PMMA histology confirmed the μ CT findings for Groups 1 and 2 and demonstrated bone ingrowth into the channels of titanium. Isolated macrophages were found for all groups that decreased with time as normal bone healing and remodeling progressed. Group 1 had minimal to no reaction when compared to Groups 2 and 3 at each time point.

Discussion: The results of the current study demonstrated that devices made from a ceramic-acrylic biomaterial support both new bone ongrowth and ingrowth in a proven in vivo model. One of the primary advantages is the incorporation of calcium-based bioceramics, which have been demonstrated to enhance osseointegration by facilitating a bioactive interface that can promote bone cell attachment and proliferation. Radiographically, the presence of the bioceramic provided some radio-opacity that allowed the implants to be visible in both radiographs and μ CT. The radio-opacity of the ceramic-acrylic composite offers a distinct advantage as it allows for clear post-operative imaging, providing clinicians with the ability to assess implant placement and bone integration without the interference often encountered with metal alloys. Additionally, the surface topography and chemistry of the ceramic-acrylic was equivalent to predicate comparisons of commonly used materials such as PEEK and Ti. The microporosity of the ceramic-acrylic material is another significant feature that is designed to permit molecular transport, including BMPs and other cytokines, to facilitate healing.

In conclusion, the ceramic-acrylic composite material exhibits several attributes that can significantly impact the field of medical implants. The osseointegration capabilities provided by calcium-based bioceramics, the facilitation of molecular transport due to microporosity, the benefit of radio-opacity for imaging, and the manufacturing flexibility for producing high-strength isotropic structures collectively represent a substantial advancement in implant technology. These properties may lead to improved patient-specific treatments and have the potential to set a new standard in the design and application of implantable devices.

Significance/Clinical Relevance: The positive in vivo response and ease of manufacturability of this ceramic-acrylic biomaterial supports potential clinical applications in the future.

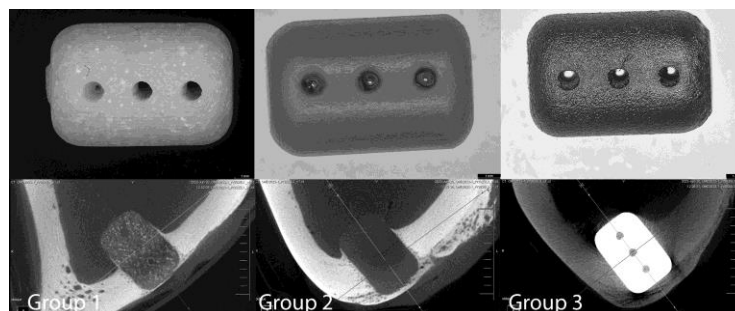


Figure 1: Top row: Stereozoom images of ceramic-acrylic, PEEK and Ti implants; Bottom row: μ CT images of implants in cortical sites at 12 weeks demonstrating an intimate bony interface for Groups 1 and 2 while artefact was present for Group 3.