

Comparison of Osseointegration between Dense CaO-SiO₂-P₂O₅-B₂O₃ Glass-ceramics (BGS-7), Hydroxyapatite, Titanium Alloy and PEEK using Rabbit Model

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ABSTRACT INTRODUCTION:

CaO-SiO₂-P₂O₅-B₂O₃ (BGS-7) glass ceramics are known to bond to bone directly and are mechanically stronger than HA, and thus, we undertook this study to determine whether BGS-7 could be used as an alternative intervertebral spacer material. The purpose of this study was to quantitatively and qualitatively assess four different kinds of disc type implant, i.e., BGS-7, titanium, PEEK, and HA, (those three materials are already used as an intervertebral cage or disc spacer) with regard to their osseous healing properties under non-loaded healing conditions.

METHODS:

Materials and Surgical Procedures

CaO-SiO₂-P₂O₅-B₂O₃ based glass-ceramic, named BGS-7, was prepared by the following method: A powder mixture of the nominal composition CaO 41.8, SiO₂ 35.8, P₂O₅ 13.9, B₂O₃ 0.5, CaF₂ 2.0, MgO 6.0 (wt%) was prepared and this mixture was melted at 1550°C for 2 hours in a furnace to form a glass plate. The glass powder was granulated with 10% deionized water and isostatically pressed into pellets that are 15 mm in diameter and 3 mm thick at 1000kg/cm². The pellets were sintered for 2 hours at 1050°C. The pellets were machined to be a 7mm long cylindrical bar with a diameter of 6mm connected to a 5mm cylindrical bar of diameter 4mm. The machined bars were rinsed in ultrasonic cleaner and dried at 100°C. The bars were sterilized by EO-gas. Titanium, PEEK and HA implants were prepared in the same way as those of BGS-7 implants.

Seventy two adult New-Zealand white male rabbits of average weight of 3.2 (±0.3) kg were kept individually in standard cages. This study was approved by the Standing Ethical Committee at the Laboratory for Animal Research at the Clinical Research Institute of our hospital. Surgical procedures were performed to iliums on both sides under general anesthesia. A fascial incision was placed along the superior border of the ilium and subperiosteal dissection was performed beneath this incision. Stepwise preparation of the implant bed was performed by drilling using 2 and 4mm drill bits and irrigating with normal saline. Four different implant types (BGS-7, titanium, PEEK and HA) were inserted in each rabbit (2 different implants were inserted on each side of each ilium) using a predetermined rotational sequence. After placing implants, facial tissue layers were repositioned and sutured after irrigation. Cefazoline 330 mg and penicillin G 400 mg were administered intramuscularly perioperatively for prophylaxis. Animals were subdivided into three groups (22, 24 and 26 animals in the 2, 4, and 8 week groups) according to time of sacrifice, which was conducted at 2, 4, and 8 weeks post-implantation.

Tensile Testing

Eight animals per group (2, 4, 8 week groups) were used for tensile testing and the others (14, 16, and 18 in the 2, 4, and 8 week groups) were used for histologic evaluations. For tensile testing, a stainless steel wire was coiled around the ilium and then inserted through the hole in an implant and adjusted such that it was perpendicular to the longitudinal axis of the implant. Tensile testing was performed using an Instron testing machine fitted with a calibrated load-cell of 10 N. The crosshead speed range was set at 5 mm/min.

Histomorphometric Analysis

Following sacrifice, bone-implant blocks were removed and fixed in formaldehyde. Undecalcified ground sections were prepared and H&E stained. One central section was prepared from each implant using a cutting unit (Exakt, Apparatebau, Norderstedt, Germany). Sections were ground along the longitudinal implant axis such that the implants were halved, and they were then reduced to a final thickness of ca. 20 µm by microgrinding.

Bone-implant slides were digitally photographed under a microscope (Olympus BX51TF, Japan). Histomorphometric evaluations of bilateral coronal implant halves were carried out after scaled calibration using a morphometry program (LEICA IM50 Image Manager, version 4.0). The

coronal halves of implant contours were used to compare implant types. Percentage lengths of direct bone-to-implant contacts with respect to total implant surfaces were measured in regions of interest. All measurements were made using a (X12.5) magnification objective.

Statistical Analysis

The four groups were compared using the nonparametric Kruskal-Wallis test. Analysis of variance was used to analyze the 2, 4, and 8 week groups. *P* values of <0.05 were considered significant.

RESULTS SECTION:

Tensile Test Analyses

The mean tensile strength of BGS-7 implants was significantly greater than those of titanium and PEEK at 2 and 4 weeks and than those of the other 3 implant types at 8 weeks. The mean tensile strength of HA was also significantly higher than those of titanium and PEEK at 2 and 8 weeks. The tensile strength of BGS-7 increased progressively according to the periods of breeding, but this was not significant. The mean tensile strength of titanium and PEEK at 4 weeks tended to be greater than those at 2 and 8 weeks (*p*>0.05).

Histomorphometric Analyses

Bone-to-implant contact values (which were measured as percentages) are listed in table 2. Statistical evaluations of these values for titanium implants showed means of 16.6% (±12.4), 33.7% (±12.6), and 17.6% (±8.6) at 2, 4 and 8 weeks, whereas PEEK implants revealed 9.4% (±8.1), 27.4% (±9.7), and 19.2% at these times (±12.1).

On the other hand, HA implants had direct contact percentage values of 49.6% (±23.7), 47.4% (±17.9), and 49.5% (±15.2) after 2, 4, and 8 weeks, and BGS-7 implants had values of 50.7% (±16.5), 55.1% (±17.0), and 56.7% (±16.7), respectively.

Evaluations of implants at 2, 4, and 8 weeks revealed that direct contact percentages were significantly higher for BGS-7 than for titanium (*p*<0.0001, *p*=0.0006, and *p*<0.0001 at 2, 4, and 8 weeks, respectively) and for PEEK (*p*<0.0001, *p*<0.0001, and *p*<0.0001). In addition, direct contact percentages for HA were significantly higher than those of titanium (*p*=0.0003, *p*=0.0238, and *p*<0.0001 respectively) and of PEEK (*p*<0.0001, *p*=0.0009, and *p*<0.0001 respectively). However, differences between BGS-7 and HA were not significant.

Furthermore, mean direct contact percentage for titanium at 4 weeks was significantly higher than at 2 and 8 weeks (both *p*=0.0002) and significantly higher than at 2 and 8 weeks for PEEK (*p*<0.0001, *p*=0.0062 respectively). Moreover, mean direct contact percentage for PEEK at 4 weeks was significantly higher than at 2 and 8 weeks (*p*<0.0001, *p*=0.0496 respectively) and significantly higher than those of titanium at 2 and 8 weeks (*p*=0.02, *p*=0.0051 respectively).

DISCUSSION:

HA and bioactive glass ceramics have been shown to be osteoconductive and to bond directly with bone. This direct bone apposition provides mechanical coupling between implants and surrounding bone, and the resulting bonds provide substantially higher interfacial attachment strengths to osseous tissues than can be achieved by metallic implants. In fact, bioactive ceramics, such as Bioglass, HA, and glass-ceramic A-W are covered by a surface apatite layer *in vivo*, which mediates integration with bone. Our evaluation of the four implant materials revealed qualitative and statistically significant histomorphometric differences. Moreover, histomorphometric results for BGS-7, PEEK, and titanium were found to be well correlated with tensile strength results. In the present study, tensile test results and histomorphometric analysis findings demonstrated that BGS-7 binds to bond better than PEEK, titanium, and HA. The direct bone bonding shown by BGS-7 in the present study, and its mechanical strength, suggest that it should be considered as a bone replacement material and as an intervertebral spacer.