A new composite made of polyurethane and glass ceramic in a loaded implant model: a biomechanical and histological analysis

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The biocompatibility and osseous integration of a new composite material made of polyurethane and a calcium silicophosphate ceramic was investigated in a loaded implant model in sheep and compared to that of commercially pure titanium. Six months after implantation, interfacial shear strength was higher between the titanium and bone than between the composite and bone. After 2 years, however, the shear strength was significantly higher in the composite group. Histologically, both implants were surrounded by bone and fibrous tissue and there were no signs of inflammation. Direct contact of bone on the composite surface increased significantly with time, whereas there was no time-dependent increase of bone contact on titanium. It can be concluded that the biocompatibility and osseous integration of the composite was very good in the loaded implant model used. It is therefore suggested that the new composite is a promising biomaterial for orthopaedic implants.

1. Introduction

Calcium phosphate ceramics are widely used as bone substitutes owing to their biocompatibility and osteoconductive properties which promote the apposition of bone. The disadvantage is that ceramics cannot be used as devices in load-bearing situations because of their relatively low fracture strength, brittleness and high susceptibility to fatigue failure.

To overcome this problem, composites have been developed to combine the osteoconductive capacity of bioactive ceramics with the mechanical properties of a polymer material. The original concept of such a ceramic–polymer composite was introduced by Bonfield *et al.* [1], who developed a class of materials based on polyethylene reinforced by hydroxyapatite or glass-ceramic that resulted in greater ductility and less stiffness than that of metals [1–3].

Recently, a composite has been developed combining polyurethane and a calcium silicophosphate glass ceramic. It has a modulus of elasticity of 2.2 GPa, close to that of cortical bone at 6–20 GPa [4, 5], thus making it suitable for load-bearing devices such as vertebral body replacement [6].

The purpose of the present study was to characterize the osseous integration and biocompatibility of this new polyurethane/bioglass composite in a loaded implant model in sheep. Pure titanium devices were implanted in a separate group and evaluated for comparison.

2. Materials and methods

2.1. Material

Two materials were investigated. One was a new composite developed by Biovision, Ilmenau, Germany. The vacuum-moulded material consists of 60% polyurethane and 40% granules (63–200 μm) of a calcium silicophosphate glass ceramic. The second material was a commercially pure titanium with a polished surface. The implants had a triangular shape – 24 mm in length, 14 mm in breadth and 6 mm thick – and a pre-formed slot where they were later divided into two parts after explantation. One part was used for biomechanical testing and the other for histological evaluation. In the biomechanical portion of the implant, a hole was tapped to provide fixation for an eventual push-out test. To prevent ingrowth of tissue into the hole, a polyurethane plug was inserted during implantation. To investigate bone ingrowth, two channels were milled out of the implants, 1 and 2 mm in diameter (Fig. 1).

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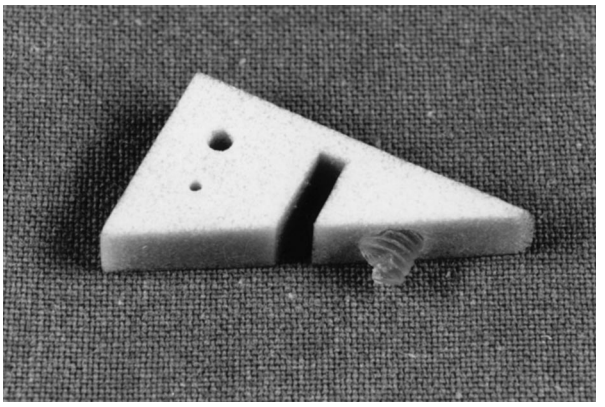

Figure 1 Composite implant. A slot was cut to allow separation of the implant into two parts for biomechanical and histological testing after explantation; the two holes, 1 and 2 mm in diameter, served as bone ingrowth channels.

2.2. Animal model

The devices were implanted into the right tibia of 36 adult female merino sheep with an average weight of 76 kg (range 64–96 kg). The animal experiment was approved by the German Regierungspräsidium (Tübingen, no. 519) and followed national regulations for the care and use of animals. Wedge-shaped defects were created by standardized osteotomy 3 mm under and parallel to the medial tibia plateau (Fig. 2) under general halothane anesthesia and premedication with thiobarbital (Trapanal®, BYK Gulden, Netherlands). One group (18 sheep) received the new composite and the other titanium. Both implants were press-fit into the defects. Immediately after the operation, all animals were allowed freedom of movement. Six animals of each group were sacrificed at 6, 12, and 24 months.

2.3. Biomechanical shear test

To determine the shear strength of the material–bone interface, a push-out test was performed. The tibiae were removed *post-mortem*, dissected of all soft tissue and morphologically analysed. The callus covering the implant on the medial side of the tibia was carefully removed and the polyurethane slug was taken out of the implant. Using special sawing instruments, standardized specimens were then dissected for the push-out test. The bone specimen, with the implant *in situ*, was positioned on to a metal block slotted underneath the implant to allow push-out (Fig. 3). Using a materials testing machine (Zwick 1454, Ulm, Germany) axial load was applied to the implant through a screw mounted into the pre-formed, tapped hole at a deflection rate of 2 mm min^{-1} until the implant was pushed out of the bone. From the load–displacement curve maximum force, F_{max}, was determined and the shear strength calculated ($s = F_{max}/A$, A = bone contact area).

2.4. Histological analysis

The dorsal section of the implants were designated for undecalcified bone histology evaluation. After embedding in methacrylate, a 70 μm slice was cut and surface-stained with paragon. The bone–implant interface was examined under light microscopy (Axiophot, Zeiss, Oberkochen, Germany). Qualitative aspects of the interface were noted, especially the

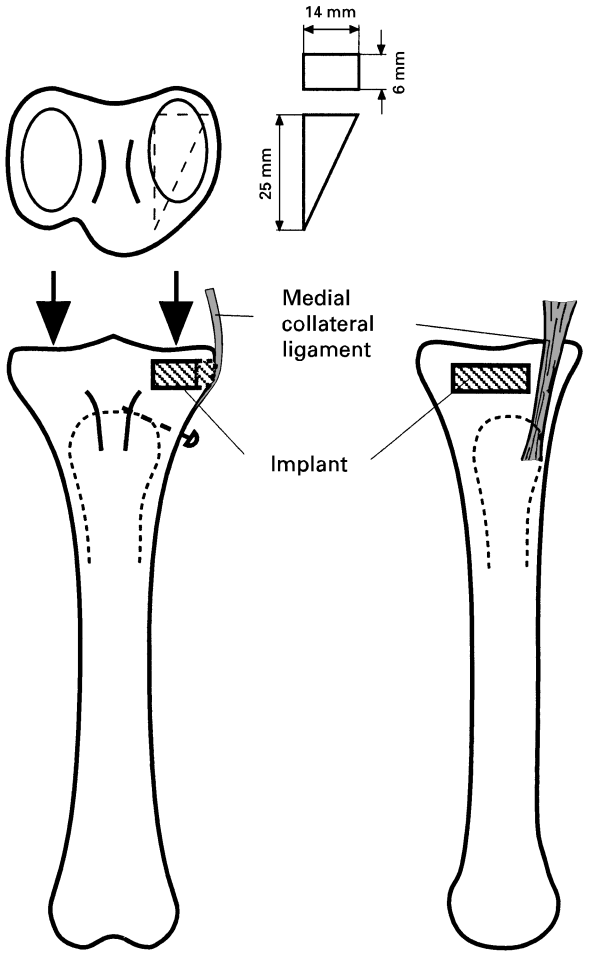

Figure 2 Loaded tibia implant model. A triangular implant was press-fit into wedge-shaped defects created by standardized osteotomy 3 mm under and parallel to the media tibia plateau (right: cranial view; left: medial view).

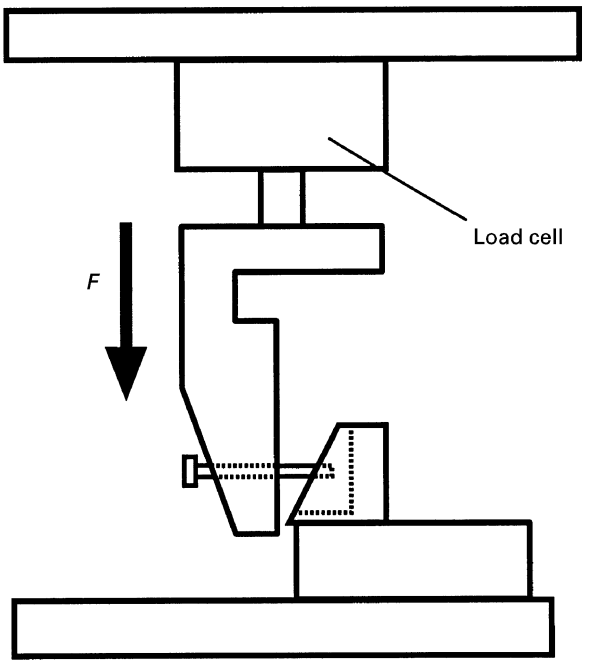

Figure 3 Biomechanical pull-out test. Load was applied axially.

presence or absence of inflammation. The extent of bone apposition was quantified as a percentage by measuring the linear surface of the implant available for apposition then dividing into that the linear surface to which bone was attached.

2.5. Statistical analysis

To determine significant differences among the materials and implantation periods, the mechanical data were analysed by non-parametric Mann-Whitney and Kruskal-Wallis tests for unpaired samples. The level of significance was 0.05.

3. Results

There were no post-operative complications with the surviving animals, and after 4 days they had regained a normal walking pattern. All six specimens of each material group, at both the 6 and 12 months intervals, were still enrolled but there were only five of each at 24 months, as one animal of each material group died of pulmonary disease, believed unrelated to the material in the last time period.

The morphological investigation of the tibia revealed intact joint surfaces over the implantation area. The implant surface on the medial side of the tibia in most cases was covered by a thin layer of bone and soft tissue with no distinguishing features between the implant materials.

After 6 months implantation, the push-out test showed significantly higher shear strength between titanium and bone (1.02 ± 0.57 MPa) than between composite and bone (0.27 ± 0.28 MPa; Fig. 4). After 1 year, there were no significant differences between the two materials (titanium, 0.73 ± 0.44 MPa; composite, 0.45 ± 0.43 MPa), and 24 months after implantation, the shear strength conversely was significantly higher in the composite group (1.66 ± 0.53 MPa) than in the titanium group (0.52 ± 0.65 MPa). When the influence of the implantation period was analysed, a significant increase of the shear strength in the composite–bone interface was found in contrast to an insignificant decrease in the titanium group (Fig. 4).

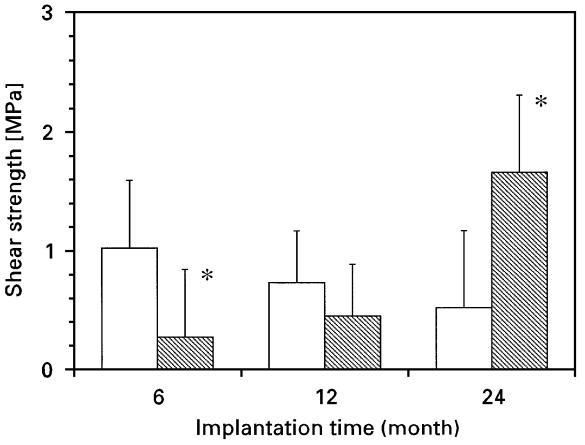

Figure 4 Shear strength of the titanium (white columns) and the composite (hatched columns) interface at various implantation times.

Histologically, both materials were surrounded by cancellous bone, bone marrow and fibrous tissue, and showed good biocompatibility. Neither in the titanium nor in the composite group were there any signs of inflammation, such as macrophages, giant cells or lymphocytes. Areas of direct contact between bone and implant were frequently observed (Figs 5–7); when quantified, no significant differences between titanium and composite were indicated at any time period (Fig. 8). These areas increased with increasing

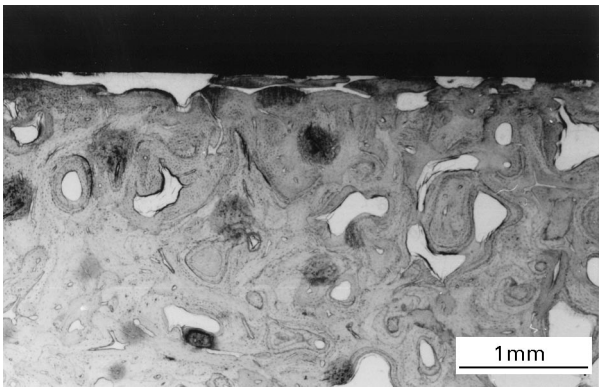

Figure 5 Titanium surrounded by bone, fibrous tissue and bone marrow 6 months after implantation; no inflammatory cells can be seen.

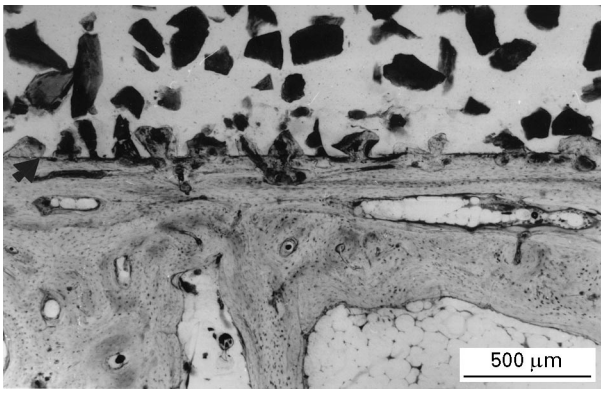

Figure 6 Polyurethane calcium silicophosphate composite 24 months after implantation; the implant is mainly surrounded by bone; the interface is marked by the black arrow at the left margin of the figure.

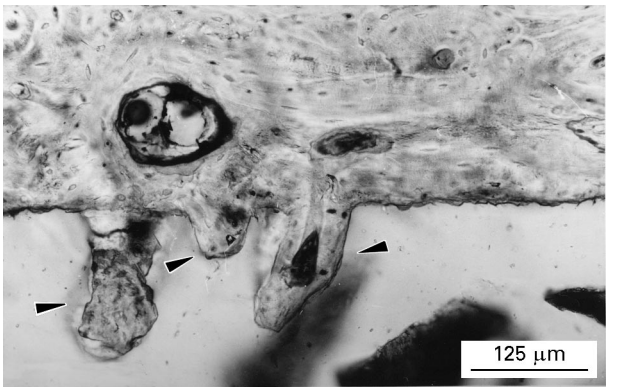

Figure 7 Polyurethane calcium silicophosphate composite 24 months after implantation; tooth-like bone ingrowth (arrows) can be observed at the composite surface.

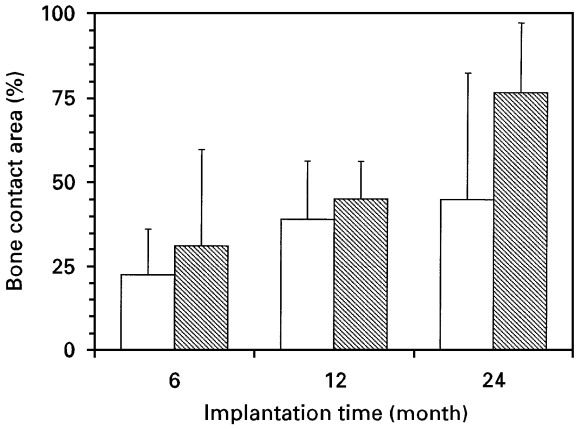

Figure 8 Bone contact areas related to the total implant surface (100%). The white columns represent the titanium and the hatched column the composite group.

implantation time (composite, $p < 0.05$), occupying 20%–33% of both material surfaces at 6 months, 40%–45% at 12 months, and 77% in the composite group and 45% in the titanium group at 24 months. Inter-individual variability was high for both materials in the earlier time periods, but settled down in the composite group at 24 months, at which time also a well-structured, tooth-like apposition could be observed.

4. Discussion

In the present study, we used a loaded implant model in sheep to investigate the osseous integration of a new composite made of polyurethane and a calcium silicophosphate glass ceramic through biomechanical evaluation of the interfacial shear strength and histological measurement of bone apposition.

It was shown that, in comparison to titanium, the new composite results in significantly higher interfacial shear strength 2 years after implantation. This may have been due to the increased mechanical interlocking between bone and implant surface in the composite which, unlike titanium, cannot be polished. Additionally, tooth-like bone ingrowth could be observed at the composite surface which would enhance the zones of bone contact and therefore osseous integration and implant stability.

Fixation between bone and an implant can be further achieved by chemical bonding. Calcium phosphate ceramics are referred to as bone-bonding or bioactive and there is evidence of chemical bonding using such surface-active materials [7–10].

Hench [7] postulated that a calcium phosphate-rich layer, formed at the implant–bone interface, supports the theory of chemical bonding. In the present study, bonding between the bone and composite could explain the increase in interfacial strength which was greater than the increase in bone contact area. To evaluate whether there is chemical bonding between the bone and the ceramic particles at the surface of the composite, current studies using scanning electron microscopy and energy dispersive X-ray analysis are underway to characterize the interface.

It can be concluded that the biocompatibility of the new composite was very good in the loaded implant model used. The osseous integration of the new composite was similar to titanium for short implantation times and significantly better than titanium after 2 years implantation. Therefore, it is suggested that the new composite is a promising material for orthopaedic implants.

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