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Optimizing a hydroxyapatite/tricalcium-phosphate ceramic as a bone graft extender for impaction grafting

B. GRIMM, A. W. MILES
Department of Mechanical Engineering, University of Bath, Claverton Down, Bath, BA2 7AY, UK

I. G. TURNER
Department of Engineering and Applied Science, University of Bath, Claverton Down, Bath, BA2 7AY, UK

The mechanical properties of morsellized bone allografts and synthetic hydroxapatite/tricalcium-phosphate (HA/TCP) ceramic extender materials for the use in impaction grafting revision hip surgery were investigated using two test methods: a basic compression test and an endurance test in an *in-vitro* model of an impaction grafted femur. Formalin fixed ovine bone graft was identified as mechanically similar to fresh human bone and thus suitable as an experimental material for *in-vitro* testing. For 1 : 1 volumetric mixes of bone allograft and synthetic extender, the granular ceramic's properties were varied in porosity, chemical composition, sintering temperature and particle size. Initial mechanical stability, a crucial prerequisite for clinical success in impaction grafting, was increased for all bone/extender mixes. A high porosity, tricalcium-phosphate rich ceramic of medium particle size and sintered at high temperatures was recognized as an optimized extender material for impaction grafting balancing the mechanical and biological demands. Using the extender without bone graft as a pure replacement is not recommended.

Introduction

There has been an increase in the number of total hip joint replacements (THR) performed every year as a consequence of demographic changes. In addition THR is performed increasingly on younger and younger patients with concomitant expectations in respect to their longevity. As a result of the foregoing, there has been an increase in the number of hip replacements presenting for revision. Considering the significantly higher cost of this revision surgery, in comparison to primary THR [1], revision hip replacement has become a considerable financial factor in the health system [2].

The major clinical problem encountered in revision surgery is bone stock loss as a consequence of osteolysis and the surgical factors associated with the removal of the implant. Impaction grafting revision THR compensates for femoral bone stock loss by compacting morsellized bone allograft into the femoral cavity. The compacted graft creates a new medullary canal for the insertion and cementation of a standard hip prosthesis [3, 4]. It provides initial mechanical stability and over time has the potential to be revascularized, resorbed and replaced by healthy bone. Impaction grafting has become an increasingly popular revision technique for addressing the problem of bone stock loss.

Limited availability of donor bone [5], risk of infection or rejection, variable graft quality and high cost have lead to the development of synthetic bone graft extenders. For the optimization of such materials, mechanical evaluation is crucial. Initial mechanical stability is paramount in order to establish a secure position for the implant in both the short and long term. In addition it is important to limit micromotion to a level where the desired graft revascularization and bone remodeling can take place [6]. An *in-vitro* model was developed to analyze the effects of different graft properties on initial mechanical stability. The model exposes the bone graft to loading conditions comparable to those, which lead to vertical subsidence, a dominant failure mode in clinical impaction grafting [7]. An ideal property profile of a ceramic as an extender for morsellized bone graft was identified.

Materials and Methods

The graft materials investigated were 1 : 1 volume mixes of bone and synthetic bioceramic. The bone was formalin fixed trabecular bone graft harvested from ovine humeral heads morsellized with a Norfolk bone mill using the coarse blade. The bioceramic was manufactured by TCM Associates Ltd, Neizing, UK and comprised granules of a hydroxyapatite/tricalcium-phosphate (HA/TCP) ceramic of different porosity (0%, 25%, 50%), sintering temperature (1050 °C, 1150 °C, 1200 °C) particle size (small 1–2 mm, medium 2–4 mm, large 4–6.3 mm) and composition (HA/TCP ratios 80/20 and 20/80). For comparative purposes, samples comprising pure bone graft as the gold standard in Impaction Grafting were also tested.

1. A basic quasistatic compression test on 10 cm^3 sample volumes of various bone grafts and synthetic materials was performed using a 20 mm diameter die and a hollow cylinder plunger closed with a porous disk on the compacting end to allow fluid drainage. A compression modulus was derived as the secant gradient of the measured stress-strain curve between a corresponding compression load of 25 N, allowing for initial settling of the material, and a 500 N peak load. Relaxation behavior was quantified as the relative drop in stress level 2 min after the plunger stopped its compacting movement. Within that time period most of the relaxation had occurred. This test was designed to compare fundamental properties of different graft materials and thus validate the use of ovine bone graft instead of human bone graft as an experimental material in the *in-vitro* model.

2. The *Impaction Grafting* model used a standardized impaction procedure, a fixed geometry and stiffness of the tube-cone set-up (Fig. 1) simulating the femur-stem components and controlled cyclic fatigue mimicking the gait cycle load pattern. The model, derived from the average dimensions of a human femur, comprised a 25 mm diameter metal tube and a metal cone of 120 mm length with decreasing diameter from 16 mm proximally to 5 mm distally. The tube was filled with bone graft, this was compacted and the cone driven into the tube with a device called the Impactometer [8, 9] using a dropping weight of a pre-set adjustable height (Fig.1). This allowed impaction energy and momentum to be controled and reproduced, thus eliminating the variability inherent in the manual procedure of clinical impaction grafting. Values used were calculated from the mass and geometry of the surgical impaction grafting tool kit and the frequency of hammer blows measured interoperatively. These measurements indicated individual hammer blows carried an impaction energy of 1.6 Nm and delivered an impaction momentum of 1.4 Ns.

After impaction the model was mounted in an Instron servohydraulic machine and cyclically block-loaded in compression at peak loads ranging from 0.2 to 2.0 kN in 0.2 kN steps for 5000 cycles each and subsidence was recorded. A haversine waveform and a cycling frequency of 2 Hz was used to resemble strain rates similar to the human gait. Subsidence of 5 mm or more was regarded as failure.

Results

The compression properties of fresh human and both fresh and fixed ovine bone graft were found to be similar with low compression moduli and high relaxation values. The formalin fixed and subsequently washed and air dried ovine graft as used in the *in-vitro* model described above was found to be about 15% stiffer than fresh human bone graft and showed ca. 10% less relaxation. The synthetic HA/TCP granules were distinctively stiffer and showed significantly less relaxation depending on their manufacturing properties such as sintering temperature, porosity and chemical composition (Table 1).

Using the *in-vitro* impaction grafting model, adding synthetic HA/TCP granules to natural bone graft signifi-

TABLE I Secant compression modulus and relaxation for morsellised bone grafts: Fresh human, fresh and fixed ovine

Bone graft	Human	Ovine	Ovine fixed	HA/TCP
Compression modulus [MPa]	3.65	4.22	4.27	11–56
Relaxation [%]	33.5	39.6	30.1	16.8–25.6

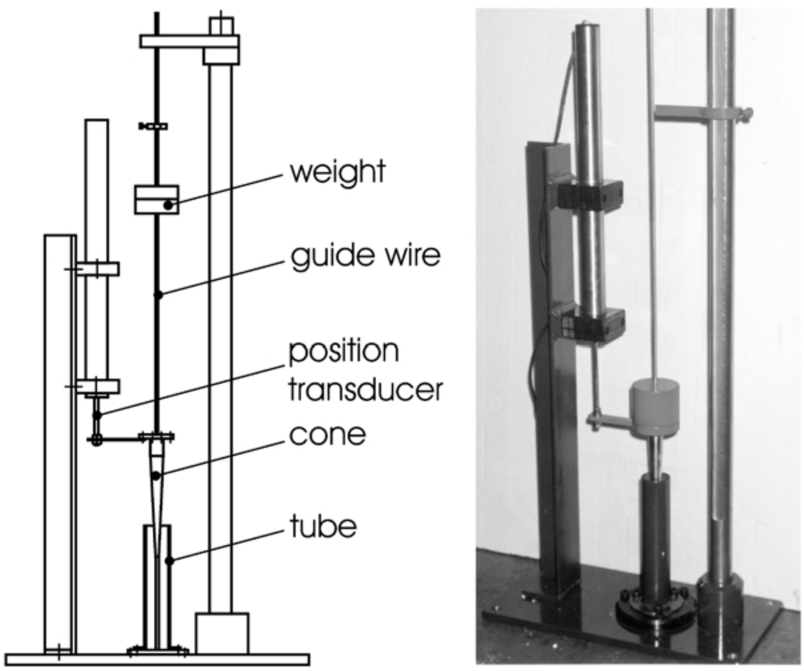

Figure 1 Impaction grafting model mounted in Impactometer for controlled graft compaction.

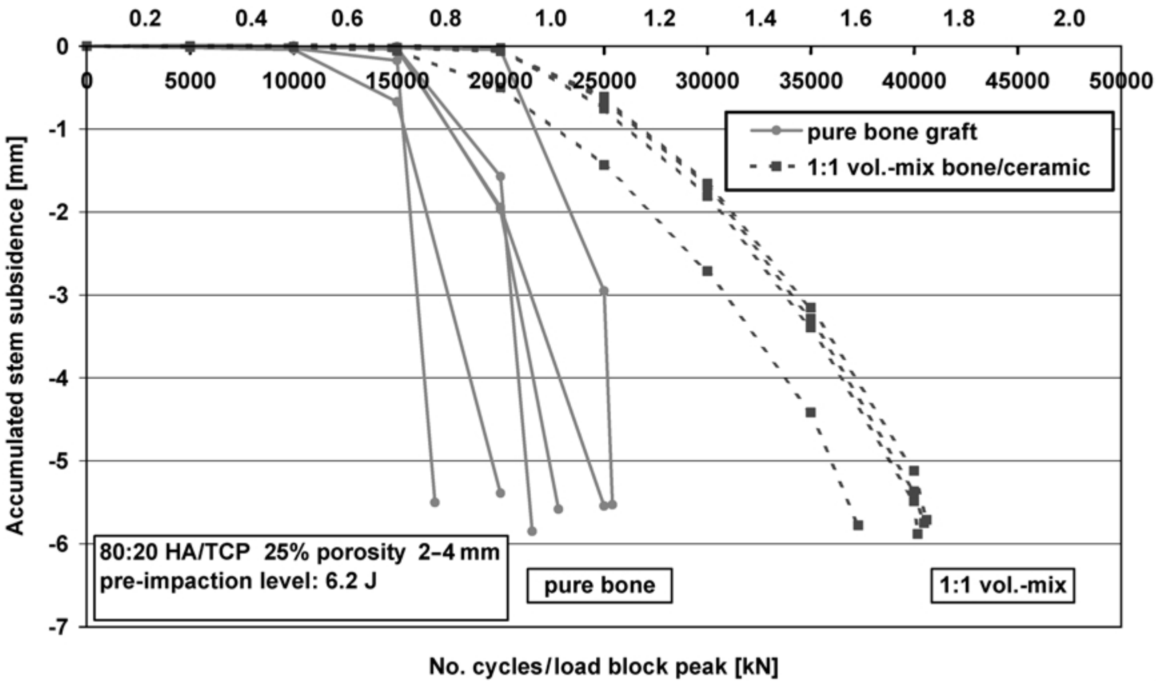

Figure 2 Stem subsidence for pure bone graft and 1 : 1 vol.-mixes bone/ceramic.

cantly improved mechanical stability against cyclic loading subsidence (Fig. 2). Compared with pure bone samples, the 1 : 1 volumetric mix of bone graft and ceramic extender also lead to less variable subsidence and less sudden failure and thus more predictable behavior (Fig. 2).

Increasing the porosity of the ceramic granules in the graft mixes slightly decreased the mechanical stability of the graft mix at the level of 25% porosity but had a more significant effect at the higher porosity levels of 50% (Fig. 3). However, the 1 : 1 bone/extender graft mix with the high porosity HA/TCP granules still resulted in noticeably higher initial mechanical stability than the pure bone graft samples (Fig. 3). Raising the sintering temperature of the HA/TCP from 1050 to 1150 °C increased stability, but the effect was less profound at the higher temperatures of 1200 °C (Fig. 4). Increasing the TCP content of the ceramic by reversing the HA/TCP ratio from 80 : 20 to 20 : 80 resulted in a slight drop in the initial mechanical stability (Fig. 5). Medium sized 2–4 mm ceramic particles in the 1 : 1 bone/extender graft mix gave the greatest initial mechanical stability when compared to both small (1–2 mm) and large (4–6.3 mm) granules of a similar nature (Fig. 6).

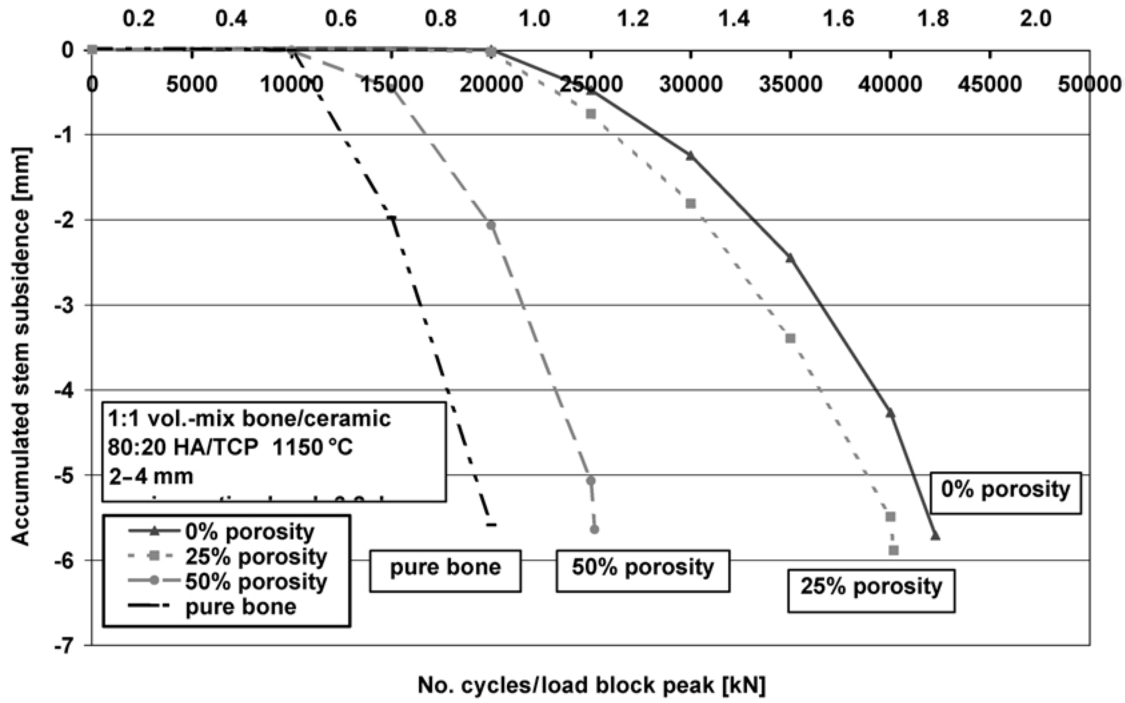

Figure 3 Stem subsidence for pure bone graft and 1 : 1 vol.-mixes bone/ceramic with varied porosity.

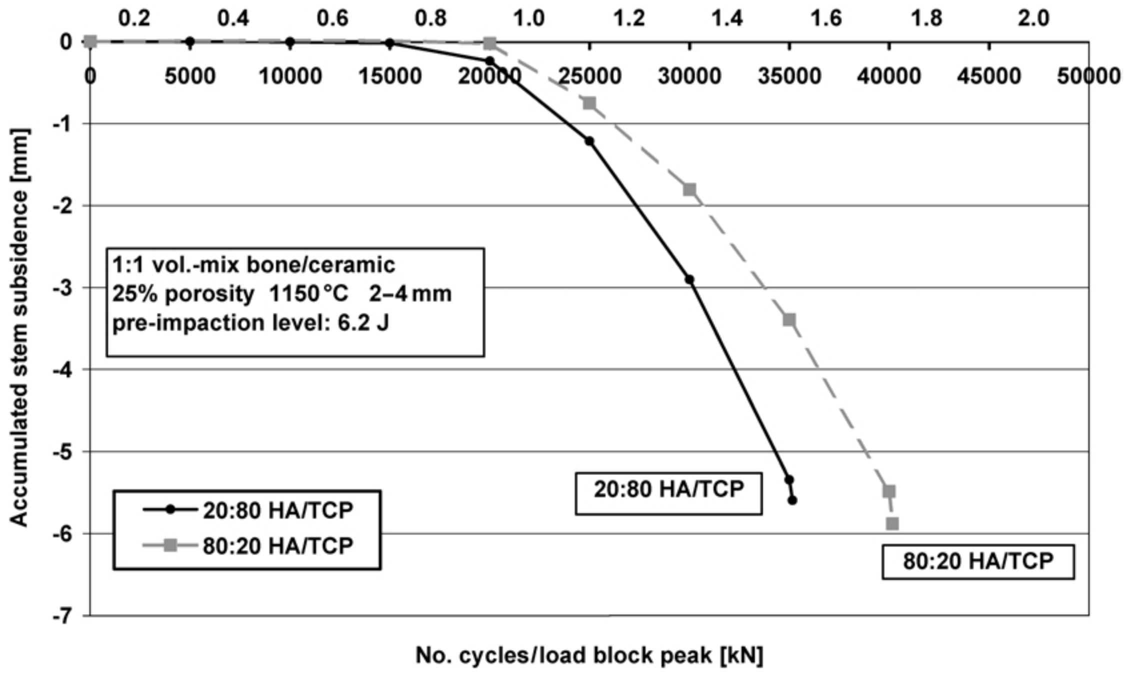

Figure 4 Stem subsidence for 1 : 1 vol.-mixes bone/ceramic with varied chemical composition.

Discussion

Formalin fixed ovine bone is a suitable model for replacing human bone in *in-vitro* mechanical tests of morsellised grafts, having very similar mechanical properties in compression. The slightly higher stiffness and lower relaxation of the fixed ovine bone graft relative to the gold standard human bone is the result of two effects. Firstly, the chemical fixation process causes polymeric crosslinking, and thus increased rigidity, in the organic components. Secondly, subsequent to fixation, the washing and air drying procedure employed further removes blood, fat, finer particles and tissue in the graft. As a result the ovine graft becomes slightly stiffer and less viscoelastic in comparison to the fresh human bone graft. This in turn compensates for the otherwise slightly lower stiffness and higher relaxation measured for freshly harvested ovine bone which usually contains slightly more fat and other soft tissue when compared to human bone (Table 1).

All HA/TCP granules tested as graft extenders in 1 : 1 volumetric mixes with bone graft increased initial mechanical stability and are therefore mechanically suited as bone graft extenders for clinical impaction grafting. This is as a result of the higher stiffness and lower relaxation values measured for the ceramic particles in comparison to morsellized bone. The ceramic

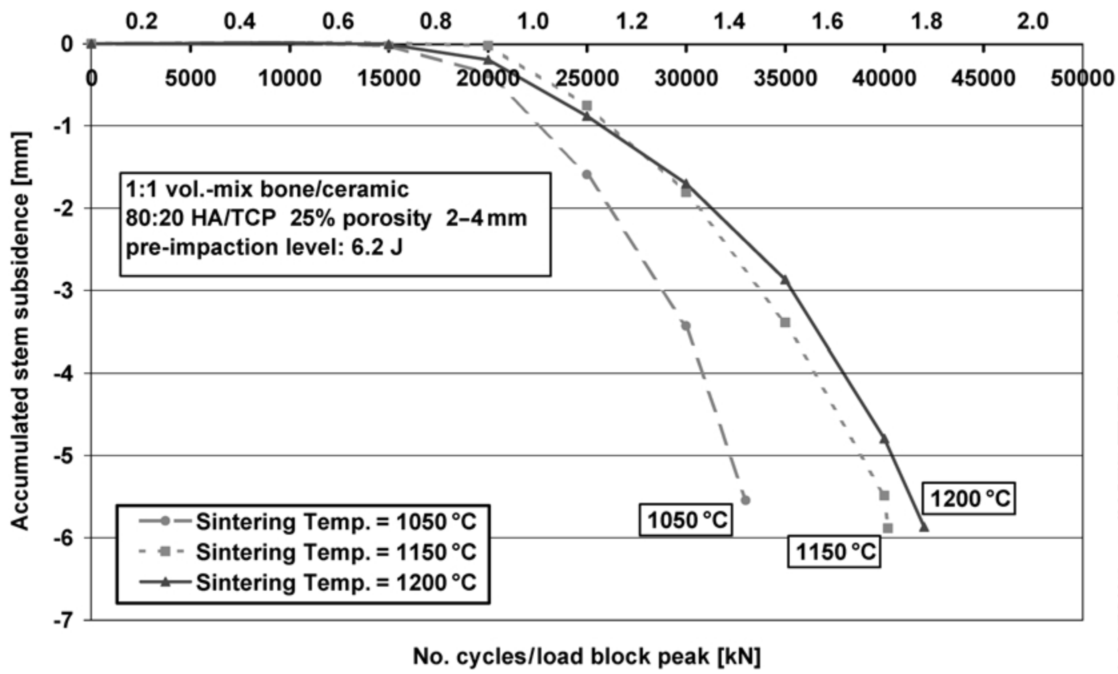

Figure 5 Stem subsidence for 1 : 1 vol.-mixes bone/ceramic with varied sintering temperature.

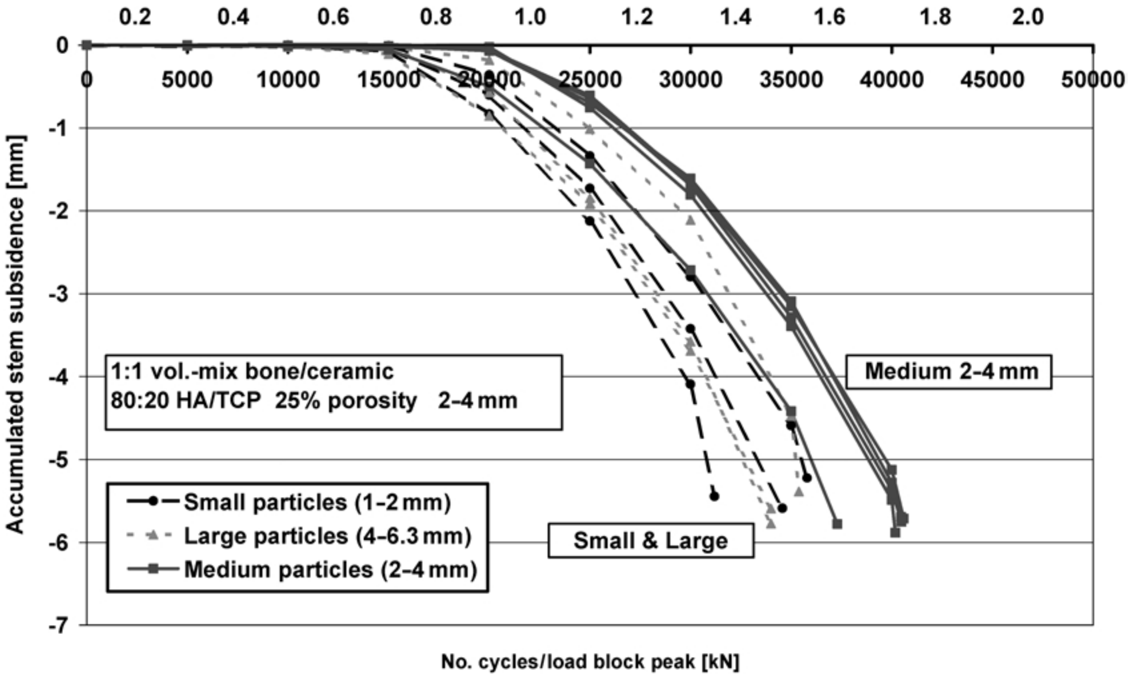

Figure 6 Stem subsidence for 1 : 1 vol.-mixes bone/ceramic with varied particle size.

granules are manufactured to exact and reproducible specifications. The manually morsellized bone graft, by nature, showed larger variations in both visual appearance and mechanical properties. As a consequence, graft mixes with a synthetic extender were not only more stable but consistently produced much less variable, and more predictable subsidence.

Mechanical stability was reduced as a result of raising both porosity levels and the TCP content of the HA/TCP ceramic. This correlated with the lower stiffness values observed for the pure granular ceramic. The effects must be considered in relation to the specification of an optimal ceramic bone graft extender as it is desirable to increase porosity for improved bone ingrowth or to raise the TCP content for faster *in-vivo* resorption rates and thus enhanced bone remodeling. Increasing the sintering temperature of the ceramic increased mechanical stability along with its higher stiffness. Therefore high sinterering temperatures could compensate for the stability lost with a highly porous and TCP rich ceramic. Medium sized granules resulted in superior mechanical stability relative to both small and large particles. Large granules do not distribute and rearrange well during impaction and thus compact less efficiently. They also create more void space and can fracture more easily leading to increased subsidence. Due to their large size relative to the gap between stem and endosteal wall, only a few or, in some cases, individual large granules could fill the space leading to high and unevenly distributed stresses in the graft material which could result in fracture and subsequent subsidence. Small particles do not interlock well and like sand, move more easily relative to one another reducing mechanical stability and thus leading to increased subsidence. Medium-sized particles seem to offer a compromise balancing the size dependent effects described and therefore potentially offering maximum stability.

Conclusions

HA/TCP ceramic granules were found to be suitable as a bone graft extender for impaction grafting THR. A highly porous, TCP-rich ceramic of medium 2–4 mm particle size sintered at high temperatures was found to be optimal to meet the biological requirements of bone resorption and mechanical demands of maximum stability. Graft mixes with a synthetic extender promise more consistent clinical results which are less dependent on the user and the donor bone quality. However, pure HA/TCP granules are much stiffer, less viscoelastic and more friable than human bone and therefore cannot entirely mimic the mechanical properties of the gold standard material in impaction grafting. As a pure material, ceramic granules in their current form do not have the viscoelastic and cohesive properties of natural bone [8] required for surgical handling and clinical impaction. Used on their own their friable nature could result in the production of potentially damaging wear particles. Consequently HA/TCP granules are recommended as an extender to enhance mechanical stability in a bone graft mix as opposed to a complete alternative to human bone graft.

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