INTRODUCTION: Impaction grafting compensates bone stock loss by impacting morsellised human allograft bone chips into the femoral cavity creating a new medullary canal for the fixation of a new implant. The graft serves as a mechanically stable and biologically active matrix for bone stock regeneration. Due to the popularity of this revision technique and other surgical procedures using bone grafts, demand for human allograft suitable for impaction grafting has outstripped supply. The study hypothesises that synthetic graft extenders such as calcium-phosphate based ceramics are being developed and have been successfully tested in-vitro. Testing the initial mechanical stability such synthetic graft extenders can provide in-vivo has required the use of complex in-vitro models and extensive fatigue tests. These can be time consuming, costly and require large quantities of precious donor bone and expensive prototype ceramics. The complexity of the model can increase measuring errors and reduce reproducibility especially when variability is introduced by cadaveric femurs and manual impaction. Thus the identification of synthetic graft extenders suitable for impaction grafting has been expensive, slow and non-standardised. This study shows how the results from a basic standardised compression test of bone grafts and extenders compare with the stability performance measured during endurance tests with a validated complex stem-femur impaction grafting model. The study demonstrates how this correlation can be used to reduce cost, increase speed and improve accuracy of identifying ceramic bone graft extenders potentially suitable for impaction grafting.

MATERIALS AND METHODS: Methods: Two test methods were employed: 1) a basic compression test and 2) a human-scaled stem-femur model endurance test. 1.) The compression test was performed using a 20mm diameter die and a 20 mm diameter hollow cylinder as a plunger. The cylinder was closed with a porous to allow liquid penetration. Sample volumes of 10cm³ were compressed quasi-statically at a crosshead speed of 0.05mm/s up to a peak load of 500N. The stress-strain curve was recorded. A compression modulus was calculated from the slope of the secant between the strains recorded at 25N to discard settling effects and the peak load of 500N. After a 2min relaxation period, samples were recompressed up to a peak load of 1000N and the weight fraction of sub-mm ceramic particles produced during compression was measured as dust. Six samples per group were tested and unpaired student t-tests were performed on the data. 2.) A tube and cone set-up was used to model the human femur and stem conditions in-vitro. The model consisted of a 25mm diameter metal tube and a metal cone of 120mm length with decreasing diameter from 16mm proximally to 5mm distally. The tube was filled with graft, the graft pre-compacted with a flat disk and the cone driven into the tube with a device called the Impactor®. A weight of a preset adjustable height drops along a guide wire onto the disk or cone allowing impaction momentum and energy to be controlled and repeated. After impaction the model was mounted in an Instron servo-hydraulic machine and cyclically block-loaded in compression at peak loads increasing from 0.2 in 0.2 kN steps of 5000 cycles each until failure at a maximum subsidence of 6mm. Materials: Pure human morsellised trabecular bone graft was tested as the gold standard. Fixed ovine graft harvested from sheep humeral heads was used as an in-vitro experimental graft. During the endurance test, 1:1 volume mixes of ovine graft and granules of various tricalcium-phosphate/hydroxyapatite ceramics were analysed while pure ceramics were tested with the die-plunger. The ceramic parameters varied were porosity (0%, 25%, 50%, 68%), particle size (1-2mm, 2-4mm, 4-6.3mm), sintering temperature (1050°C, 1150°C, 1200°C) and chemical composition (HA:TCP: 20:80, 80-20).

RESULTS: Fig. 1 shows that the stability of impacted graft against vertical subsidence under cyclic loading was slightly higher for than for pure human bone. Adding ceramic granules to the bone creating a 1:1 bone/yection mix increased stability significantly for all but one ceramic configuration (68% porosity). Stability was increased the higher the sintering temperature and the lower the porosity of the ceramic. Both particle size and chemical composition only had a small effect on stability against vertical subsidence. The slightly increased stability of ovine versus human bone, the significantly higher stability of all but one bone/ceramic mix and the effects of ceramic porosity, sintering temperature and chemical composition on stability correlated well with the stiffness moduli measured during compression of the pure ceramics (Fig.2). The higher the stiffness of the ceramic extender, the higher the stability against cyclic loading. The correlation was not confirmed when particle size was varied. The dust weight fraction after compression correlated well with the stiffness measurements and thus with stability against cyclic loading. Thus synthetic ceramics can significantly increase the mechanical stability when added to bone graft in clinical impaction grafting. The mechanical performance of such a bone/ceramic mix is improved when the ceramic compression stiffness is high and the dust produced under compaction is low. This correlation between dynamic stability and both stiffness and hardness allows the simple standardised die-plunger compression test to be used for the fast, cheap and reproducible identification of bone graft extenders with potential for clinical application. Expensive and time consuming endurance tests can be reduced. As load transfer mechanisms in a constrained geometry with dimensions close to the granule diameter change when different particle sizes are compressed (in-vivo: stem-femur, in-vitro: die-plunger), ceramic granules of identical particle sizes must be compared to draw meaningful conclusions about the mechanical performance of different synthetic grafts. Stiffness, dust fraction and thus stability are strongly affected by ceramic porosity. For mechanical requirements, it should be kept below ca. 50% even if biologically sub-optimal. Current ceramic bone substitutes are so different to bone graft that they should only be used as reinforcing extenders.

REFERENCES:

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