9 CONCLUSIONS

The initial mechanical stability in impaction grafting as the paramount pre-condition for clinical success was analysed using newly developed or adapted basic mechanical tests such as compression, shear and impaction tests and *in-vitro* endurance tests using an ovine and human sized model. Varied parameters were differently prepared human bone grafts as the gold standard in clinical impaction grafting, different xenografts as potential experimental grafts and a large variety of differently configured ceramic graft extenders pure and in bone/ceramic graft mixes of varied ratios. Also varied were process parameters such as impaction energies and forces.

The basic mechanical tests, in particular the die-plunger compression test, revealed highly relevant information. Varying human allograft preparation identified the usefulness of a Howex type bone mill and washing plus drying of the graft to improve graft stiffness or graft compactability for increased stability. The effect of irradiation or multiple freeze-thaw cycles on the mechanical properties was negligibly small confirming the use of these popular techniques for clinical application. Ovine bone graft provided stiffness, relaxation and recoil values similar to the gold standard human allograft and thus can be recommended as a suitable experimental graft for *in-vitro* testing. However, bovine bone graft was much stiffer and should not be advocated.

Compression tests also established that ceramic graft extenders have totally different mechanical properties when compared to bone grafts. Ceramics can be much stiffer and stronger but also more brittle and friable than bone grafts which, as a multiphase composite of trabecular chips, soft tissue and fluids, are ductile and viscoelastic and thus must be compacted densely to provide stability. Thus, the function of ceramic extenders in impaction grafting can never be to mimic bone allograft and substitute it completely but to enhance the mechanical properties of a graft mix. Strong, stiff and hard ceramic granules in a bone/ceramic mix clearly enhance stiffness and reduce viscoelastic relaxation by supporting the trabecular fragments in load bearing, reducing the volume fraction of weak soft tissue and by containing some of the fluid which would otherwise dampen the impaction blows. Bone and ceramic properties qualitatively and quantitatively combine in accordance with the mixing ratio.

Porosity was the ceramic parameter most sensitive to stiffness. A highly porous ceramic was even less stiff and thus potentially less stable in impaction grafting than pure bone graft. A similar, less intense stiffness reduction was found for lower sintering temperatures while different chemical composition ratios between the HA and TCP constituents only had a small effect.

Particle fracture, deformation and rearrangement are the displacement mechanisms at work under compression loading of particulate aggregates. Ceramic particle size with a granule to die diameter ratio varying between approximately 1.6 and 10 only led to a variable ratio-dependent combination of displacement mechanisms active during compression under such tight geometrical constraints. Small granules behave like an aggregate with bulk properties derivable from soil mechanics theory while load transfer in larger particles depends increasingly on the shape, position, packing and contact stresses between individual particles. Thus analysing ceramic grafts with die-plunger tests only produces relevant results when the particle size is fixed at a granule to die diameter ratio similar to the *in-vivo* conditions.

Shear box tests derive cohesion and shear angle as bulk properties of a particulate aggregate and thus only describe one aspect of the load bearing and displacement mechanisms. In combination with the high graft consumption, shear box tests are less suited for graft testing.

Endurance tests revealed that stem subsidence in compacted graft follows an exponential curve with a logarithmically constant subsidence rate after an initial set-in period. *In-vivo* this means quasi-stable stem position can be achieved even at high loads even if small early subsidence must be tolerated. Close qualitative and quantitative similarities between the ovine and human model mean that the simplifications of the latter, no cementation, conical stem and axi-symmetric loading are valid abstractions for reproducible and relevant *in-vitro* tests of impaction grafting.

Stability was most sensitively influenced by impaction intensity. The total amount of impaction energy delivered was more relevant than the peak force of the hammer blows. However, a minimum level higher than the load bearing forces found *in-vivo* should be met. Independent of impaction forces and energy, impaction set of the final hammer blow was related to stability via an exponential function shifted for different hammer momenta. This correlation would allow the design of an intra-operative stability feedback system.

The stability against subsidence measured for different grafts during endurance testing correlated well with the stiffness values measured during compression testing. Stability was higher for ovine than human graft. The stability of bone/ceramic mixes with all but one ceramic graft configuration was higher and variability lower than for pure bone. Pure allograft only reached similar high stability levels at very high impaction levels. The higher the ceramic fraction in a graft mix the higher the stability. Thus mixing errors in surgery do not negatively influence stability over pure allograft. Ceramic granules increased graft stability to the highest degree at low impaction energy level, thus reducing the sensitivity of the impaction grafting technique to variable surgical impaction input.

Ceramic porosity in a bone/extender mix affected stability most so that allograft extension with a highly porous HA decreased stability. Low sintering temperatures also made granules so friable that stability suffered and hardly exceeded the gold standard. Chemical composition had a small, almost negligible effect. With regards to particle size, a medium particle size was found to deliver the most stable compromise of the load bearing and displacement mechanisms at work in a particulate aggregate loaded within a tightly constrained geometry. As stability and graft incorporation or resorption are contrarily dependent on ceramic properties such as porosity, sintering temperature or composition, the optimal configuration must be a compromise between mechanical and biological requirements. With initial mechanical stability being the condition for biological activity it should be prioritised.

Stability in impaction grafting depends primarily on intense graft compaction. High impaction energies should be delivered with a minimum force above weight bearing until final impaction set falls below a stability correlated maximum. Extending allografts with strong and hard ceramic granules can increase stability, reduce variability and lower sensitivity to impaction levels advocating their use in clinical application. Mixing and charging of bone/ceramic mixes is a procedure tolerant to error. Surgical feedback from impaction set remains unaffected. Ceramic extenders should not be used as a full bone graft replacement as the viscoelastic soft tissue and fluid are required for compactability and handling. The development of new synthetic grafts can be simplified and made more cost efficient by pre-selection through die-plunger compression testing.

Recommendations for possible future work on the in-vitro stability analysis and the development of new synthetic bone graft extenders for impaction grafting are given below:

- Qualitative analysis of load transfer in the graft during compression, impaction and endurance testing by using transparent acrylic die-plungers and tube-cone models.
- Endurance testing of different stem geometries, in particular taper angles.
- Investigation into automated controlled graft impaction methods such as vibratory impaction. Calibration against stability levels achieved with standard manual impaction.
- Development of a suitable FE-Model considering both soil-like bulk and individual load transfer between particle phases.
- Development of an impaction feedback device for intra-operative use monitoring hammer set to indicating sufficient impaction or warning of femoral fracture or plug displacement.
- Calibration of stability and impaction from the human model with intra-operative and clinical follow-up data or equivalent study on impaction grafted human femora.