2 BACKGROUND

2.1 Total hip arthroplasty

Total hip arthroplasty (THA) is the artificial reconstruction of the hip joint to replace a dysfunctional or painful hip joint. Over the last 45 years hip arthroplasty has become a widely used and still growing surgical procedure to treat patients for the pain and reduced mobility most often associated with osteoarthritis, rheumatoid arthritis and hip fractures as a result of osteoporosis[1].

Osteoarthritis describes a joint disease characterised by the degeneration of the articular cartilage, hypertrophy of bone at the margins and changes in the synovial membrane [2]. In primary osteoarthritis cartilage degeneration is due to age-related wear or heredity. Secondary osteoarthritis is caused by another disease or condition such as obesity, repeated trauma or surgery to the joint, congenital abnormalities, gout, diabetes or other hormone disorders. Rheumatoid arthritis is an autoimmune disease which causes chronic inflammation of the joints and has no known cure and in the long term joint arthroplasty often becomes inevitable.

Osteoporosis is a degenerative bone disease depleting both the calcium and the protein from the bone mineral and the collagen resulting in a weakened bone structure and decreased bone density. Figure 2.1 compares healthy versus osteoporotic trabecular bone. A minor accident can lead to a fracture requiring hip arthroplasty. Osteoporosis is often associated with the hormonal changes occurring during female menopause or dietary insufficiencies with respect to calcium and vitamin D supply. Commonly osteoarthritis and osteoporosis appear together. There is a significant genetic influence on the probability of suffering from both osteoarthritis and osteoporosis.

Besides osteoarthritis, osteoporosis and rheumatoid arthritis, aseptic necrosis can lead to hip arthroplasty. Bone as a living tissue dies due to inhibited blood supply, a result of, for instance trauma, damaged blood vessels, embolism, steroid treatment, stress shielding from arthroplasty or various other diseases. In younger patients conditions for total hip replacements are less common but manifold. A major cause is hip fracture following an accident. Physiological deformities resulting from birth, conditions such as congenital hip

dysplasia or Perthes' disease during infancy and accidents inhibiting full motion can cause direct pain or in the long term accelerate the painful wear of cartilage. The same effect can result from excessive loading through abnormal activities such as hard physical labour or extreme sporting activity.

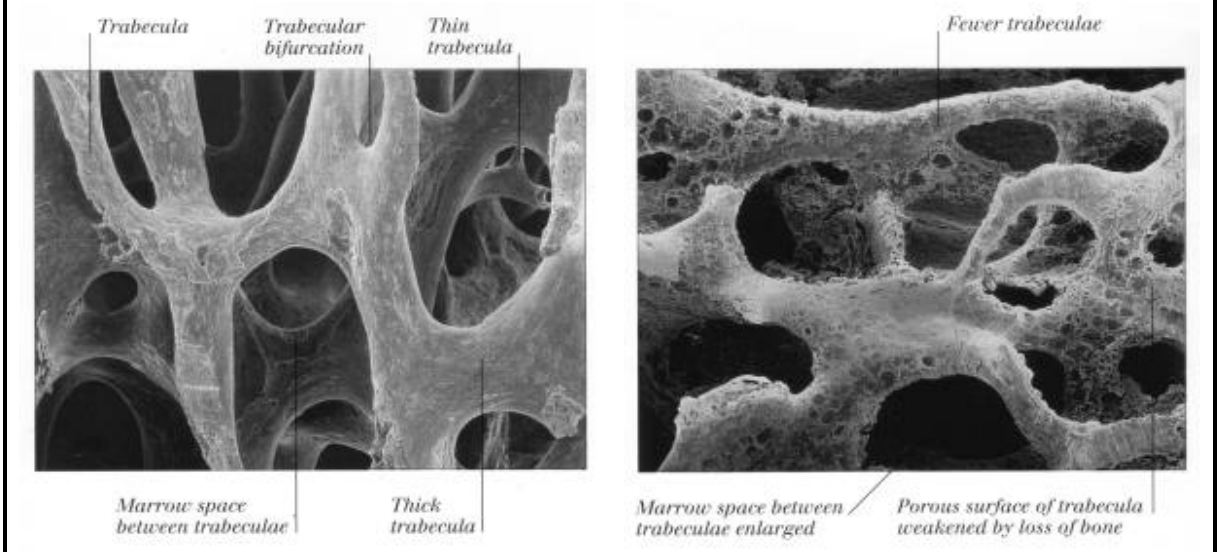


Figure 2.1: *Scanning Electron Beam Microscopy images from healthy and osteoporotic trabecular bone showing reduction in bone thickness and interconnectivity* [3].

In total hip arthroplasty both parts of the joint, the femoral head and the acetabular socket, are replaced. Figure 2.2 shows the anatomy of a hip joint in a cross-section through the human hip indicating the bones, muscles and tissue involved. During hip replacement surgery on the femoral side with a stemmed implant, the head is removed and a surgical grade chrome-cobalt steel alloy or titanium alloy stem with a metal or ceramic ball is inserted into the medullary canal of the femur. The stem is fixed using a polymethylmethylacrylate (PMMA) cement or inserted without cement by a press-fit (so called uncemented hip arthroplasty). Stems for cemented arthroplasty either have a roughened surface or matt finish to increase cement adhesion or are polished so that the tapered stem can migrate slightly and wedge itself into a stable position. Stems for uncemented arthroplasty have a contoured or porous surface or a hydroxyapatite coating to enhance bone ingrowth leading to a biological fixation.

On the pelvic side the cartilage of the acetabulum is removed and a hemispherically shaped hole is reamed out. A polymer or ceramic cup is inserted and fixed by a cut-in thread, screws bolted into the pelvis, hydroxyapatite coated shell, cement or a combination thereof. The cup acts as the pivot point for the ball of the stem and as the new pivot point of the operated hip.

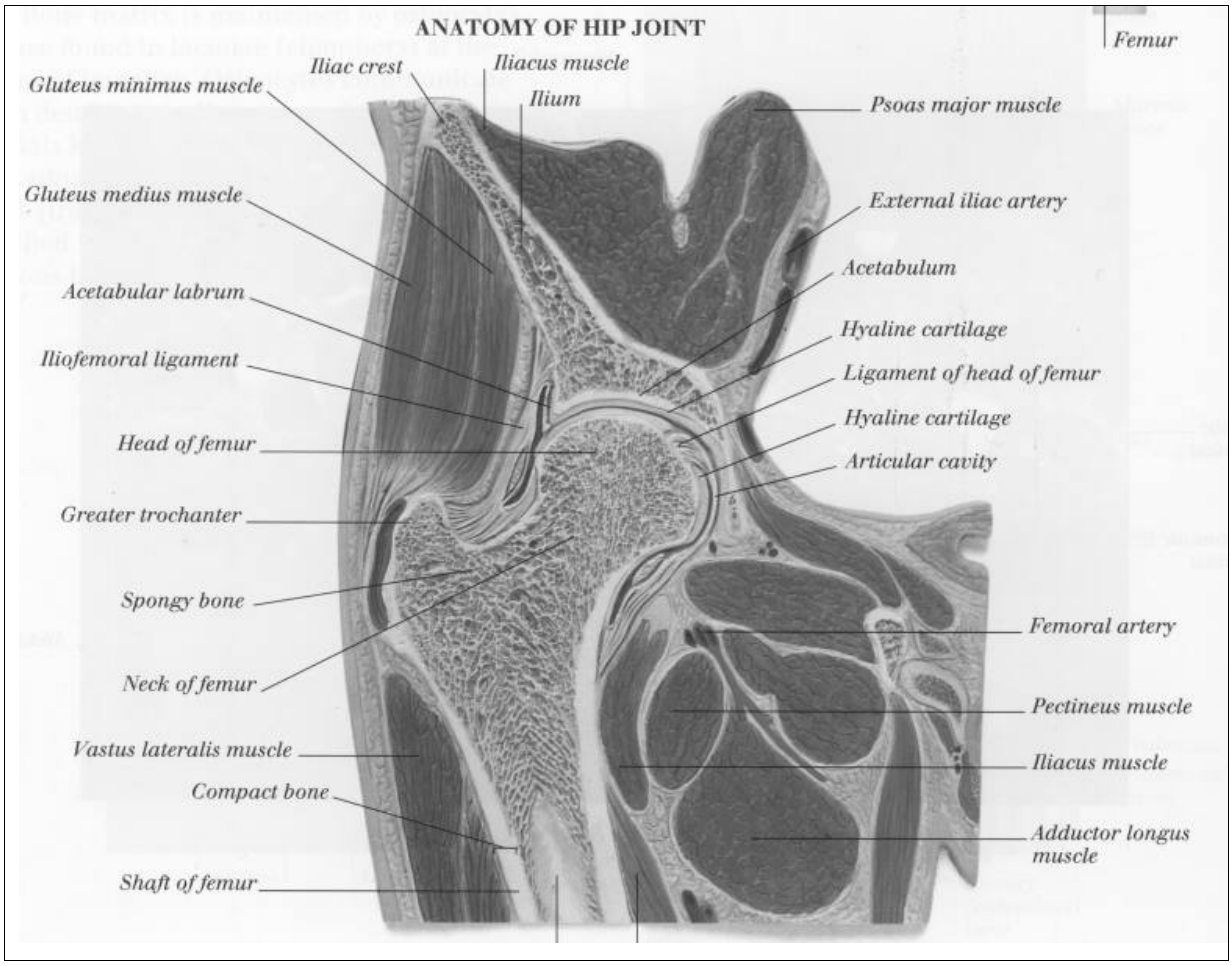


Figure 2.2: *Mediolateral cross-section through the human hip joint showing bones, muscles and other tissue*[3].

Depending on technique, cemented or uncemented, clinical diagnosis and surgeon's preference many different systems for total hip arthroplasty are being used. Stems can be one-piece including the ball or modular with a choice of threaded or press-fit balls of various materials and diameters. Besides materials choice, stems come in a variety of shapes and sizes. They can be tapered or non-tapered, have previously described varying surface properties and there are versions which have collars of various dimensions designed to rest on the calcar (cut surface of the neck of the femur) for added stability. According to the material and diameter of the ball a matching cup size and material is used, usually a high-density ultrahigh molecular weight polyethylene (HD-UHMW-PE) polymer or a ceramic. THA has been successfully carried out since the fifties when major advances in stem shape (Charnley) and material have been made. Table 2.1 gives an overview of the most commonly used design and material alternatives for THA. Figure 2.3 shows the successfully and widely used polished and tapered Exeter stem with modular chrome-nickel alloy steel ball and polyethylene cup, both cemented into the femur or acetabulum respectively.

• **stem material**	surgical grade chrome-nickel or chrome-cobalt steel, titanium alloys, CFR-composite (experimental)
• **stem shape**	tapered, double tapered, non-tapered, with collar, collarless, polished, matt finished, porous surface, porously coated with HA
• **stem fixation**	cementation with polymethylmethylacrylate (PMMA), press-fit, distal locking, calcar support by collar, bone ingrowth
• **ball material**	metal or ceramic
• **ball fixation**	one-piece with stem, modular: threaded or press-fit
• **cup material**	high density polyethylene, ceramic, steel, composite
• **cup fixation**	threaded cup, screwed into acetabulum with bolts, cementation with polymethylmethylacrylate (PMMA), combination, bone ingrowth

Table 2.1: *Design and material alternatives used in THA. Not all combinations are viable or currently in clinical use.*

In 1996, 730,000 hip joints were replaced worldwide, a number growing at an annual rate of approximately 5% [4]. In the USA alone the number of primary THA patients recorded in 1996 was 140,000 plus 30,000 partial hip replacements[5]. In the UK a steady number of ca. 40,000 patients per year have primary THA. The total average cost of a total hip joint replacement calculated from of all hip arthroplasties performed in the USA in 1996 was $20,290 including an average of 4.94 hospitalisation days[5]. In the UK a THA costs an approximate average of £4000 with a component price documented in 1995 ranging from £250 to £2000 depending on which of the 62 different THA systems available from 19 different companies on the UK market was used[6].

In a global survey carried out in 1998, surgeons from 30 countries and 6 continents reported using all cemented components in 35% of total hip replacements at an average cost of $1,536. Uncemented components were used in 31% at an average cost of $2,674, and hybrid reconstructions in 34% at an average cost of $2,114 [7]. The cost for identical implants from a single manufacturer can vary as much as 700% [7]. It is clearly visible that THA is one of the most expensive standard surgical procedures and represents a significant cost factor for the health services. Comparing the clinical success of cemented versus uncemented THA neither fixation technique can be identified as superior[8-10].

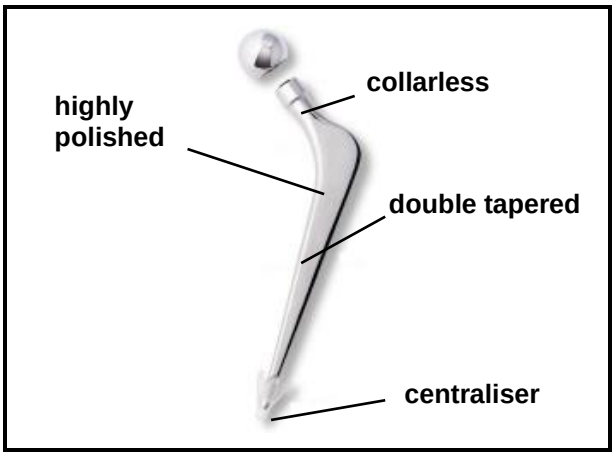


Figure 2.3:
Polished and tapered chrome-nickel steel Exeter hip stem and ball [11].

2.2 Failure modes of total hip arthroplasty

Although implant technology and surgical technique have advanced significantly, today, an increasing number of hip replacements fail prematurely and need to be revised. The expected lifetime of a primary hip replacement lies between 10 and 20 years. The average lifetime of a revised hip is significantly lower and varies greatly with surgical experience and the technique used. In total hip arthroplasties both the acetabular or the femoral component can fail. The major modes involved in premature failure of a primary hip replacement are[12-15].

- aseptic loosening
- migration (vertical subsidence, horizontal migration, rotational migration)
- wear of the articulating surfaces
- combinations of the above
- stem or femur fracture

Aseptic loosening describes the separation of the implant stem and femur leading to painful and further damaging relative movement of the implant and femur. Aseptic loosening can be the direct result of mechanical failure of the implant or implant interfaces or is caused indirectly by osteolysis, the destruction of living bone cells through activated osteoclast cells. The loss of all-around fixation and the resulting relative movement create critical stress patterns especially at the distal end of the stem. The loosening process accelerates with time and often subsidence occurs simultaneously. The relative movement also produces cement wear particles of cytotoxic dimensions or allows equally cytotoxic wear particles from the articulating ball and cup to migrate down the stem. Here they can further cause aggravation at the stem-cement interface and accelerate osteolysis. The wear particles become phagocytised, the macrophages enter into an activated state of metabolism and as a result release substances

that can lead to perioprosthetic bone resorption[16]. This further contributes to aseptic loosening, destroys the bone stock and can finally result in a fractured femur. Osteolysis and aseptic necrosis can also be caused by the implant stress-shielding the surrounding bone which deprives the bone cells of the required mechanical stimulus.

Migration describes the change in original position of the implant under physical loading. Subsidence of the stem occurs vertically in the distal direction. Horizontal migration of the proximal stem can result in the implant tilting in the varus or valgus direction. In addition, rotational displacement can occur. The amount of total migration occurring and the ratio of the directions described depend on the patient's physiology and activity, the type of implant and surgical technique used.

Today the total number of prematurely failing primary total hip replacements is increasing continuously despite the advances gained in technology and surgical technique. The reasons for this are:

- Higher life expectancy of the population, with the result that elder patients outlive the life of the implants. In 1996 almost 70% of all US patients treated for THA were older than 64 years of age, the majority females[5].
- More active lifestyles of the elderly population increase the loading of the implant and reduce its life. More often even re-revisions are becoming necessary.
- Total hip replacements failing today were often implanted in the past when the advanced technology currently in use was not available.
- Advanced technology and surgical experience have made total hip joint replacement available for higher risk patients previously not considered for THR such as younger patients or patients with complicated medical conditions.

These factors outweigh the improvements made with implant longevity. In 1996 in the USA 103,000 revision hip replacements were carried out, a number close to the 140,000 primary THAs carried out during the same time. The average cost of a hip revision which is far more complex than a primary surgery was $24,530 including 5.61 hospitalisation days, $4240 more than a primary THA (4.94 hospitalisation days)[5]. In the UK the annual number of THA revision has reached 10,000 and is growing rapidly at 5% each year. At an average cost of up to £10,000 per revised joint, twice the cost incurred for a primary joint, the additional burden for the National Health Service in the UK has already grown to £100,000,000 per annum[17].

2.3 Revision hip joint replacement – methods and problems

As an increasing number of THA cases require revision and as revision hip replacement cannot use the identical devices and procedures of primary surgery a variety of specific revision techniques and equipment have been developed. The major surgical problem with virtually all revision hip arthroplasties is the bone stock loss of the patient due to progressive osteolysis, osteoporosis, necrosis or excessive reaming required during removal of the primary implant. Figure 2.4 shows how bone stock loss prior to hip revision is graded using the Endo-Klinik system on which surgeons can base their choice of revision technique [18].

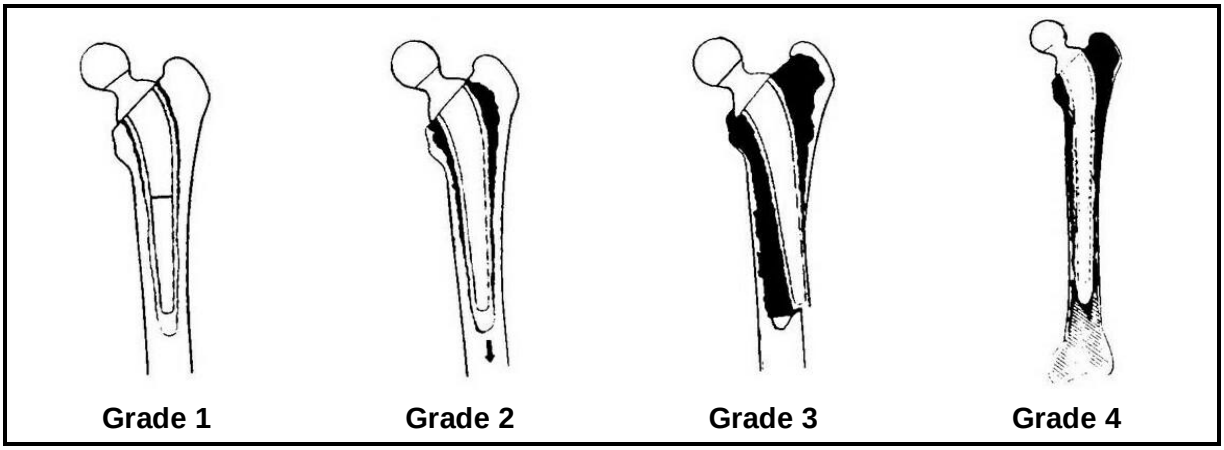


Figure 2.4: *Endo-klinik classification of Grades of bone stock loss* [18].

Uncemented Revision

Revision surgery must compensate the bone stock loss. In order to do so the revision techniques currently used are more or less adaptations of the procedures used in primary THA. For uncemented revisions specially made oversized stems are used to fill the larger void with an increased stem diameter. A greater stem length is employed to improve implant anchorage by increased leverage and contact area between bone and implant. Additionally stems can be distally locked with screws threaded through the femur and implant.

As uncemented THA relies on a press-fit and on bone on-growth onto the porous or hydroxyapatite coated stem surface, two problems occur. The residual bone in a typical revision case is generally very thin and not healthy with low osteogenic potential. Thus it might break under the press-fit load or it might not be vital enough to grow onto the implant creating a sufficiently strong biological bond. Another major disadvantage of such uncemented revisions is the difficulty of re-revising an uncemented hip revision. Furthermore the hospitals need to stock a large variety of specially shaped stems to accommodate the many different femoral canals and grades of bone stock loss found, which increases cost significantly.

Cemented Revision

Cemented revision uses the same components and technique as applied in a primary hip joint replacement. Bone stock loss is compensated by filling the enlarged medullary cavity with more PMMA-cement. Often a larger stem from the standard range is used to limit the additional cement volume necessary and ensure an optimum cement mantle thickness[19].

This technique has three major problems associated with it. During the exothermic curing of the cement, temperatures can rise up to 150°C which can result in further damage to the cells necessary for osteogenesis[9, 20-21]. A higher cement volume amplifies this effect and thus increases the surgical risk for the patient and reduces the chance for bone healing and recovery. The cement also releases toxic monomers into the bloodstream that could reach a health-damaging dose if cement volumes become too large. The polymeric cement adjacent to the bone can inhibit revascularisation of cells leading to further deterioration of the bone stock. Intensive research and long term clinical follow-up studies have identified a narrow window for the optimum cement mantle thickness of 2-4mm for optimum stability[22, 23]. Using larger cement volumes can increase the cement mantle thickness beyond the optimum level increasing the possibility that subsidence and misalignment could occur.

Impaction grafting

Impaction grafting is a relatively new revision technique first used in the early eighties by Sloof et al.[24] on the acetabular side and then developed to clinical success on the femoral side and made popular in 1992 by Gie et al.[25, 26]. Impaction grafting addresses the problem of bone stock loss fundamentally instead of just compensating for it. The large femoral cavity in hip revision affected by bone stock loss is filled with morsellised cancellous bone harvested from donor femoral heads. Bone graft is milled and the chips are impacted into the femoral cavity creating a new medullary canal of approximately the same dimensions as found in a femur reamed for primary hip arthroplasty. This allows the use of the standard cementation equipment and techniques. The standard set of stocked stems can be used and an optimum cement mantle thickness can be achieved. The impacted morsellised bone provides a mechanically stable and biologically active osteo-conductive matrix allowing healthy bone to regrow, integrate and resorb the donor bone[26]. The graft offers initial mechanical stability through its dense compaction and long term stability due to graft resorption and the replacement with mechanically strong new healthy bone. Thus re-revision becomes more viable. These combined advantages and the lack of problems associated with the alternative techniques have made impaction grafting a successful revision procedure. The fundamental differences between the cemented, uncemented and impaction grafting revision are summarised in Table 2.2.

	Revision Techniques		
	cemented revision	***uncemented revision***	***Impaction grafting***
Stem fixation	more cement to fill femoral cavity	Larger, specific design revision stem with optional distal locking	Impacting morsellised bone graft plus cementing primary stem
Advantages	+ simple and cheap	+ no cement	+ bone stock loss compensated + potentially new bone growth + identical stem and similar technique to primary
Disadvantages	- more toxic monomers - exothermic curing - blood pressure drop - critical cement mantle thickness (creep)	- high risk of bone fracture - hardly re-revisable - expensive additional stock	- insufficient donor bone available

Table 2.2: *Comparison of different revision techniques for total hip arthroplasty.*

2.4 Impaction grafting - the surgical procedure

In order to fully understand the complex surgical technique of impaction grafting and the implications for the design of an experimental test protocol, the impaction grafting procedure will be described in more detail as found in the literature[26-34]. Emphasis lies on the steps critical for clinical success and the materials and mechanical issues investigated in this study.
After the retrieval of the old primary implant the femoral canal is cleaned of residual cement and debris by reaming the cavity (Figure 2.5). This procedure further increases the bone stock loss inherent with revision cases. A press-fit polymer plug is inserted distally at a position which is calculated pre-operatively from x-rays so that the plug is positioned approximately 50mm distally from the most distal part of the stem. The distal plug closes the femoral canal distally so that morsellised bone graft can be compacted on top of it. The plug is threaded in order to accommodate a guide wire which is concentrically aligned with the femoral canal. The wire measures 5mm in diameter and ca. 500mm in length and serves to guide the surgical tools during impaction (Figure 2.6).

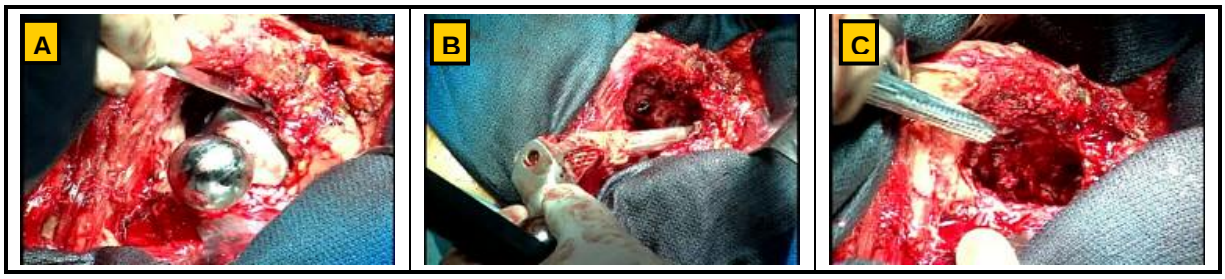
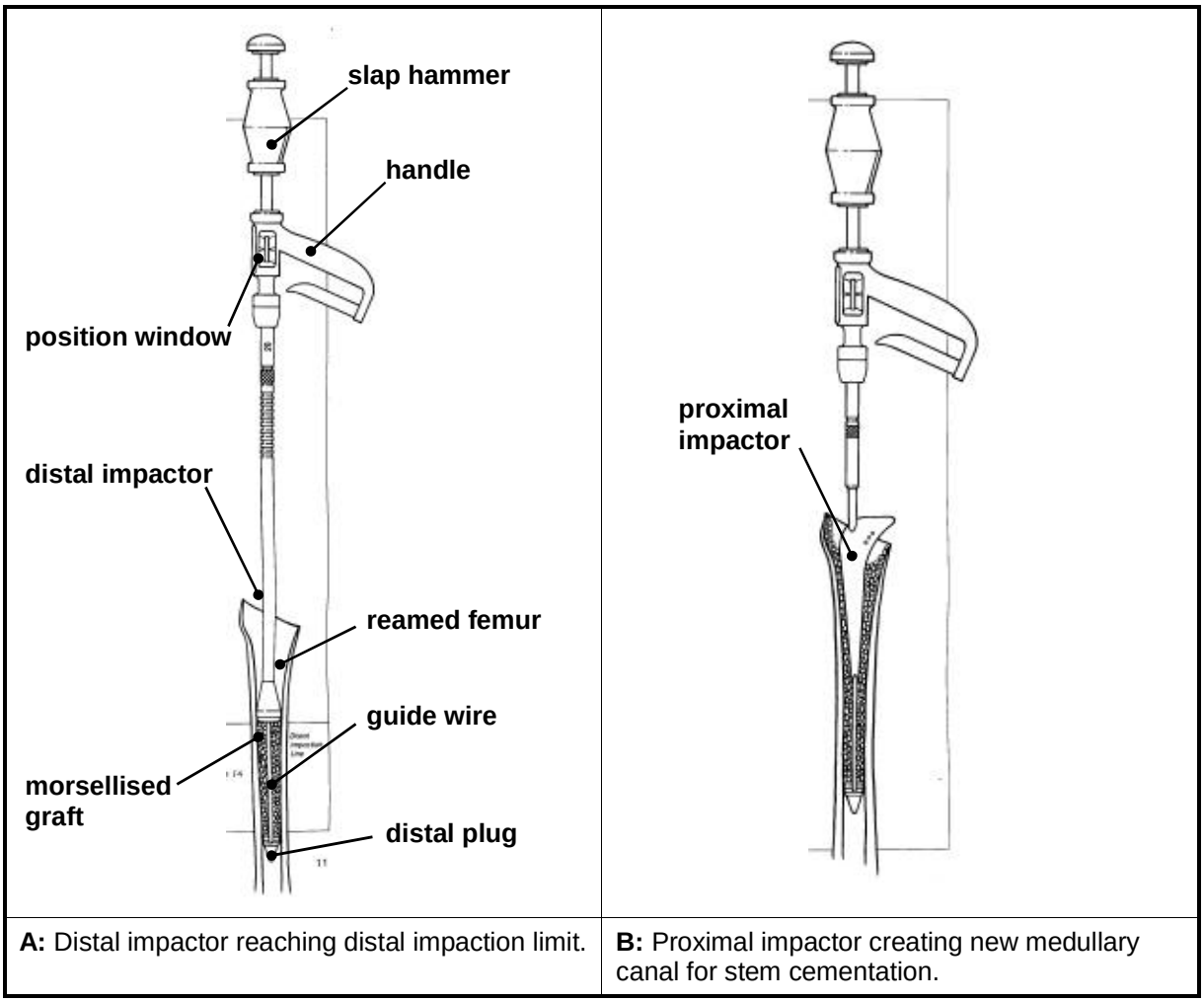


Figure 2.5: *Intra-operative photos of implant removal (A), removed implant (B) and reaming of the femoral canal (C)* [32].

Figure 2.6: *Intra-operative photos of determining plug insertion depth with the guide wire (A), plug insertion (B) and graft milling (C)* [32].

Generally fresh frozen or sometimes freeze-dried[35-37], irradiated[38, 39] or autoclaved[40] femoral heads harvested from screened donors are manually stripped of easily removable soft tissue and subsequently morsellised using a specifically designed bone mill (Figure 2.6). There are three basic types of bone mill available. One type, like the Norwich® bone mill, cuts the bone chips using knife-like blades as the edges of oval holes situated on the circumference of a hollow drum such as found in a cheese grater. The second type, as represented by the Tracer® bone mill, cuts and crushes the bone with a multitude of scrapers which are helically arranged around the drum and protrude at an increasing distance from it as found on coarse milling tools. The Howex® bone mill is a combination of both blades and sharp hooks. As a third variant, reciprocating blades are used (Lere® bone mill[41]). All mills create bone chips of various morphologies in a size range of ca. 0.5mm to 10mm. After milling, any cartilage and cortical bone obvious to the eye is manually removed. Some surgeons suggest rinsing the graft with tepid water[42] or a saline solution[43] in order to defat the bone.

The morsellised bone is then manually inserted into the femoral cavity and impacted using variously shaped distal and proximal impactors, which slide over the guide wire. The impactors are manually driven down the guide wire by the surgeon using a slap hammer of ca. 500g weight. Figure 2.7 shows a drawing of the StrykerHowmedica® revision tool kit and its application. At first the bone graft is pre-impacted using the distal impactors which are concentrically drilled cylinders with a wide conical end available in increasing size diameter (10-20mm) to accommodate different femur sizes and the proximally increasing diameter of the medullary canal. Graft is charged manually in individual steps and each charge is impacted by a set of hammer blows (Figure 2.8). This way bone chips are compacted distally until the graft reaches the distal impaction line which is calculated pre-operatively from x-rays and lies approximately at half the distance between the distal plug and the most proximal part of the trochanter.



A: Distal impactor reaching distal impaction limit.

B: Proximal impactor creating new medullary canal for stem cementation.

Figure 2.7: *Impaction Grafting tool kit and its application* [44].

Figure 2.8: *Intra-operative photos of graft charging (A), delivery of impaction hammer blows (B) and distal impaction (C)* [32].

Proximal impaction during surgery is documented in figure 2.9. The proximal impactors resemble the shape of oversized stems (phantom prosthesis) and thus create a new medullary canal, which is used to cement a standard polished double-tapered Exeter hip stem. Other systems such as the Charnley Elite, Zimmer CPT, Lubinus SP-II, or other non-polished stem designs [39, 45-52] have been successfully used as well as uncemented impaction grafting with for instance Biomet Bi-Metric stems[53]. Like during distal impaction, graft is charged in individual steps and compacted by sets of hammer blows. Finally handheld impactors are

used to compact the most proximal bone graft around the femur‘s neck. Then the guide wire is removed and the revision procedure follows that of a primary hip replacement. PMMA-cement is inserted into the newly created medullary canal, pressurised and a prosthesis is inserted using a wingless centraliser (Figure 2.9-2.10). Table 2.3 summarises a step-by-step introduction into the impaction grafting technique. Figure 2.11 displays a cross-section through an impaction grafted femur.

Figure 2.9: *Intra-operative photos of proximal impaction of reconstructed femur (A), handheld impaction (B) and completed impaction with phantom (C)* [32].

Figure 2.10: *Intra-operative photos of neo-medullary canal (A), retrograde cementing (B) and stem insertion (C)* [32].

1. Preparation	2. Impaction Grafting	3. Standard Cementation
• Removal of old prosthesis • Reaming and cleaning medullary canal • Optional repair of canal with mesh or strut grafts • Milling fresh human allograft bone chips from donor femoral heads	• Introduction of distal plug and guide wire • Manually filling cavity with morsellised graft • Distal impaction with flat impactor and sliding hammer • Proximal impaction with phantom and sliding hammer • Final proximal impaction with handheld impactor • Retrieval of guide wire	• Cement injection • Cement pressurisation • Stem introduction

Table 2.3: *Impaction grafting surgical procedure.*

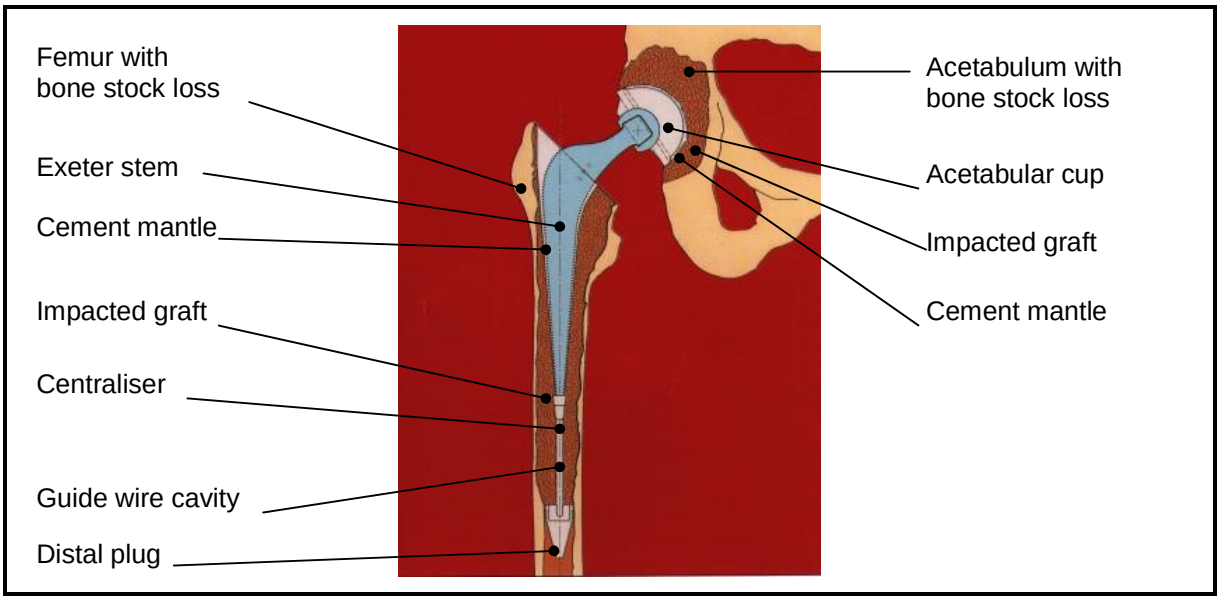


Figure 2.11: *Cross-section through impaction grafted hip* [44].

2.5 Problems with impaction grafting

Although impaction grafting has developed into a viable option for revision hip THR the problems with the technique have to be identified in order to understand the procedure's limitations and more importantly to address these weaknesses and find a solution. Clinical complications are intra-operative or post-operative fractures, stem migration (subsidence), dislocations, trochanteric nonunions or infections[32, 38, 49, 51, 53-59]. Another common problem is cement mantle defects such as areas absent of cement, cement voids and cement mantle fractures which are associated with subsidence[60-63]. Overall, the two major problem sources associated with impaction grafting are the complex surgical technique and the bone allograft [42, 51, 53, 64].

With regard to the surgical procedure, graft impaction has been identified as a major parameter influencing clinical success. A direct correlation between impaction quality and the mechanical stability can be expected. Comparing the rates of femoral fractures (4.4% to 25%) with the occurrence of subsidence (0%-19.3%) as listed in table 2.4 highlights the variability of the procedure and seems to identify a correlation between both problems. Less intense impaction characterised by a low fracture rate occurs with high levels of subsidence while at the same time a high rate of femoral fractures as a result of intense impaction is often associated with relatively low numbers of subsidence. A combination of relatively small numbers of fractures and subsidence show that some grafts can provide stability without too intense impaction.

Reference	Robinson [38]]	Malkani [51]	Pekkarinen [53]	Berry [55]	Fetzer [63]	Mikhail [52]	Savory [65]	Savory [66]
Fracture rate	5.3%	9.2%	25.0%	14.8%	12.0%	4.6%	5.6%	4.4%
Subs. rate	19.3%	0%	4.4%	0%	3.4%	18.6%	13.7%	6.2%

Table 2.4: *Correlation between fracture rates (max. blue) and subsidence rates (max. orange) for clinical follow-up studies. Subs. levels considered critical varied between 3 and 10mm.*

The manual impaction process is hard to control and therefore highly variable in quality. No objective instructions can be given to surgeons so that they need to rely on feel and experience. In addition no objective measure and no reproducible ways of intra-operative assessment of the achieved impaction levels are available as yet[67]. In impaction grafting surgeons find femoral canals of highly variable geometry, bone wall thickness and bone condition. This further complicates the decision about the right impaction level to ensure a mechanically sufficiently strong compaction on the one hand and to avoid a fracture of the weakened bone on the other. Apart from graft stability against failure it is also necessary to ensure a stiffness level which limits micromotion below levels required osteogenically for the graft revascularisation, incorporation and remodelling[68-70]. On the other hand, if the impacted graft is compacted too densely it might lack porosity inhibiting or delaying graft revascularisation as the precursor of any desired bone cell activities[71-73]. In summary, it can be said that impaction quality cannot be measured, cannot be controlled or reproduced and even if it could, the right impaction level balancing mechanical and biological requirements is unknown and can vary between cases. There might also be indications where impaction grafting cannot achieve short and long term stability at all. A large choice from an expensive impaction tool kit further complicates the procedure beyond the standard primary cement total hip arthroplasty. Intensive surgeon training is absolutely essential.

However the biggest source of concern in impaction grafting are the issues arising from the use of morsellised donor allograft. Firstly any donor bone is of undefined and varying quality depending on the age, sex, weight, health etc. of the donor. The bone graft will vary with respect to the trabecular strength, the cancellous interconnectivity, the ratio between cancellous and cortical bone, the fat, cartilage, blood and marrow content, the bone mineral density, the existence of growth factors and other aspects. All of these contribute to either mechanical stability directly like the trabecular strength or indirectly by affecting the impaction process like the viscoelasticity of the soft tissue. These variable parameters can also influence the ability of the graft to become revascularised and resorbed which is essential for long-term stability.

In addition to the donor dependent variability of the graft there is the effect that different sterilisation and storage methods can have on the bone graft. Originally, bone has been used in non-sterilised fresh condition or from frozen at various temperatures ranging from -20°C to -80°C for different periods of time[24-32]. Today, also freeze-dried[35-37] or autoclaved[40] bone graft is being used as well as sterilised graft from bone banks using γ-irradiation with dose levels ranging from 1 to 5 MRad[38, 39, 74-77]. These variable parameters could further affect the graft's mechanical properties and osteogenic potential to an unknown extent. This makes achieving reproducible graft properties virtually impossible.

The preparation of the morsellised bone chips using a manually operated bone mill also introduces unwanted variability. Particle size and morphology depend on the type of bone mill (rasp type, blade type) and the blade or rasp size chosen. Also manual feed speed and pressure, rotational speed of the blade or rasp and adjustment of the feeder alter the size profile of the bone chips. Other manual preparation steps can further lead to different properties of the morsellised bone chips. Often, before milling, soft tissue and cartilage is removed to a subjectively assessed extent or the femoral heads are sectioned in portions of variable size. After milling most surgeons discard cortical fragments and cartilage obvious to the human eye but by definition depending on personal choice. Other protocols recommend cortical bone chips to be included for improved stability[32]. Some surgeons wash the bone chips through a sieve[42, 43] which removes blood, potentially osteogenic tissue and small bone fragments below the grid size but of potentially stability enhancing dimensions. As the number of femoral heads usually required for an impaction grafting procedure is small and not discrete a surgical choice must be made as to which femoral heads and segments are prepared.

With bone graft, as with any donor organ, there is the risk of rejection due to antigenicity. Even though donors are screened for various diseases like HIV, Hepatitis B/C or Syphilis, there is also a risk of infection. Another disadvantage donor allograft shares with most donor organs is the limited availability. The increasing popularity of impaction grafting in revision hip arthroplasty has led to the situation where some bone banks and hospitals have already reported graft demands exceeding supplies[78]. This situation further contributes to increasing the high cost of revision surgery. Table 2.5 summarises the problems associated with the use of human donor bone graft.

Reproducibility	Infection	Supply
Donor variability: • age, sex, weight, health ***Sterilisation and handling:*** • Fresh, frozen, irradiated, freeze-dried, autoclaved ***Preparation:*** • Bone mill type, blade, • feed parameters • pre-sectioning, discarding, washing	***Infection:*** • rejection (antigenicity) • infection with HIV, Syphilis Hepatitis B/C, CJD, or other	***Supply:*** • low availability, • demand regionally higher then supply • high and increasing cost

Table 2.5: *Problems occurring with impaction grafting when using human allograft bone.*

The use of donor bone graft is intended to result in graft revascularisation, new bone formation, graft resorption and bone remodelling in the long term[33], a process which has been verified to variable, time-dependent qualities and extents in animal[71, 73, 79-81] and human clinical follow-up, biopsy and autopsy studies using radiographs[38, 39, 46, 50, 82-88], scinti-graphs[37, 49], dual-energy X-ray absorptiometry[89] or histology[45, 47, 90-92]. However the resorption rate of the compacted morsellised graft is unknown and variable depending on the patient, graft and procedural parameters described above[93]. At the same time the formation rate of new bone replacing the compacted graft is unknown. As the initial mechanical stability relies on the stability of the compacted graft and the newly grown bone is designed to provide long term stability, the rate of graft resorption and the rate of new bone formation need to be synchronised so that the initial stability decreasing with resorption is compensated by long term stability due to newly grown bone. Otherwise there might be a time window where total implant stability temporarily decreases to critical levels because the compacted graft is resorbed too fast and instead of the formation of new stable bone only unstable precursor tissues develop.

Initial mechanical stability is required post-operatively to allow early patient mobilisation and thus the mechanical healing stimulus[94]. Limiting micromotion to osteogenically tolerable levels is a fundamental condition for revascularisation and new bone formation which is meant to lead to long term stability. Thus initial mechanical stability is the most crucial factor for a successful impaction grafting procedure. In addition, an initially stable graft which was well impacted and has become reinforced by fibrous stroma could provide long term stability even if graft resorption and bone formation does not take place as desired[95].

2.6 Synthetic bone graft

2.6.1 Requirements for a synthetic bone graft alternative

It has been shown that human donor bone as a source of graft for impaction grafting suffers from variable properties, increasing supply deficiencies and cost implications. As a naturally sourced material, the properties of human graft cannot be altered in order to improve, for instance, initial mechanical stability or to optimise the resorption rate for a synchronised stability transfer from graft to newly formed bone. As a consequence, the search for alternative synthetic materials has begun. A synthetic graft could act as an extender for the available human bone in a graft mix. This way, the effects of variable bone grafts could be reduced, donor bone resources could be stretched, cost could be reduced and there could be the potential to optimise overall properties. Eventually a synthetic material could replace human bone entirely.

A synthetic bone graft would need to fulfil the originally required functions of the impacted natural bone graft, but as a synthetically made material, it could potentially also meet additional desired criteria. The original function of compacted morsellised bone allograft was to provide initial mechanical stability and osteogenic potential for graft incorporation, ensuring long term stability and allowing new bone stock to form. In theory, a synthetic alternative could not provide equal or even improved properties and potentially add functionality by, for instance, acting as a carrier for bone morphogenic proteins or antibiotics.

A strategy for finding a suitable material could be to mimic the fixed and variable properties of natural bone graft such as stiffness or viscoelasticity and the particle morphology or size distribution which have shown to give the best results when using morsellised allograft. Another route in defining the requirement list for bone graft alternatives would be to neglect the reference of human bone as the gold standard material and to theoretically and experimentally derive the desirable properties of an optimum material for impaction grafting. The strategy chosen might be different if one is either aiming at a bone graft extender material or if one searches for a full stand alone replacement material. In the first case the approach would allow the materials engineer to leave some of the required functions such as cohesion or compliance to the natural bone in the mix. In the second case, deriving the materials requirements solely on theoretical and experimental grounds could prove inefficient and even wrong considering that with morsellised allograft clinically successful results have been achieved. However such theoretical and experimental investigations could also help to improve current impaction grafting with human allograft. The allograft properties which can

be altered such as particle size, sterilisation method or fat content could be optimised. Using both strategies, table 2.6 defines requirements for the properties of a synthetic bone graft.

As the primary requirement the synthetic graft material must provide a high initial mechanical stability when compacted which equals or preferably exceeds that of morsellised allograft. The synthetic graft must have a high load bearing capacity and must not just be a cavity filler like most of the currently available synthetic bone products were designed to be. High initial mechanical stability serves two functions. First, the patient can become mobilised as early as possible contributing to the general healing process and providing the mechanical stimulus for bone growth. Secondly, a high initial mechanical stability limits the relative movement of the graft within itself and against the femoral wall and implant (micromotion) which has been found to be crucial for implant fixation, graft revascularisation and osseointegration[96]. Mechanical stability of a bone graft alternative must also include a certain hardness or graft integrity against producing wear particles of cytotoxic dimensions under impaction and loading. With cement and PE wear particles already significantly contributing to preliminary implant failure, a synthetic graft must not potentially cause osteolysis.

Mechanical	**Biological**
• Load bearing capacity (not just cavity filler) • Initial mechanical stability • Good compacting properties – impact stability – particle morphology – particle size distribution – cohesion and internal friction • Stiffness to limiting micromotion between graft/graft, graft/femur and graft/ implant • Equal or higher stability than bone when compacted • Long-term stability when not resorbed • Hardness against friability (no cytotoxic wear particles)	• Biocompatible • No infection risk or rejection potential • Osteoconductive • Possibly osteoinductive • Mechanical stability throughout bone resorption process
	Commercial
	• No long-term medical approval • Readily available materials type • Cost effective
	Other
	• Controllable and reproducible properties • Safe and easy handling during surgery • Long shelf life

Table 2.6: *Requirements list for a synthetic bone graft extender or full alternative.*

Besides providing initial mechanical stability the synthetic graft should have osseo-conductive or even osseoinductive potential for graft resorption and trabecular remodelling of new bone. This is seen as crucial because it ensures long term mechanical stability but also creates enough new bone stock to allow for a potential re-revision. In this context it has to be ensured that mechanical stability is retained during the process of graft resorption and bone remodelling during which the compacted particulate aggregate becomes finally replaced by a mechanically strong interconnected network of living bone. In order to maximise the potential

osseointegration of a graft material factors such as the chemical composition, particle morphometry, porosity and the presence of bone morphogenic proteins must be considered. Ultimately, these properties should be controllable and reproducible.

Another fundamental requirement is of course the biocompatibility of the material, which must not carry any infectious risk or rejection potential due to antigenicity. From a commercial standpoint the new synthetic material should require no long term medical approval but be readily available in order to rapidly compensate the bone allograft shortage. This would contribute to the general requirement of cost effectiveness. In addition practical concerns have to be taken into consideration when searching for a graft alternative such as safe and easy handling in the operating theatre and a long shelf live.

Considering the multitude and complexity of the listed requirements for a bone graft extender or replacement, the identification or composition will most likely be a compromise balancing for instance biological with mechanical requirements or commercial with handling requirements.

2.6.2 Commercial and experimental bone graft alternatives

Outside impaction grafting there has been, for many years, a growing demand for human bone graft alternatives for non-load bearing applications. Alternative and synthetic grafts are being used as void fillers in spinal fusion surgery or after tumour resection, in maxillofacial reconstruction or to enhance fracture healing[97]. Materials can be grouped into the following classes: Xenografts, naturally derived materials, synthetic materials, bioactive organic materials, composite materials and material mixes as listed in table 2.7. The materials are either already commercially available and in clinical use or have been used experimentally and described in publications or patent applications.

Xenografts are bone grafts harvested from a donor of a different species than the recipient. In human medicine xenograft has been used because of its dense and thus mechanically stable trabecular structure[98-107]. In order to reduce the risk of rejection and infection, the xenograft is denatured using various physical and chemical methods so that only the inorganic mineral remains. With it, the morphology of the natural bone mineral, the trabecular structure with its interconnected pores, stays intact and contributes to the desired strength and porosity. However, the disadvantages associated with all allografts remain. Property variation, limited availability and in particular the infectious and antigenetic risks have not made xenografts a viable graft alternative for the use in impaction grafting. Recently concerns about bovine

spongiform encephalopathy and its human derivative, the Creutzfeld-Jacob disease[108], made bovine xenografts unacceptable in both medical circles and in public opinion - an important factor for commercial considerations.

In addition to xenografts, other natural materials have been tested and used to replace human bone taking advantage of the inherent biocompatibility, porosity or a mineral phase similar to bone. From the materials listed in table 2.7, coral[109-116], egg shell[117-120], charcoal bamboo[121], nacre of marine shell[122, 123], whale rostrum[124], in particular fragments of coral have been used successfully in surgery. The structure of the coral exoskeleton is similar to that of cancellous human bone and its initial mechanical properties resemble that of bone. The high calcium carbonate content scaffolds with interconnected pores make coral highly osteoconductive and bioresorbable at variable rates depending on the porosity level. However, coral particles are friable and lack cohesion so that in impaction grafting surgery they would tend to powder under compaction and make efficient charging difficult. The other naturally sourced materials seem too exotic and untested yet to gain clinical and commercial acceptance other than in developing countries[121].

• **Xenografts** – Sterilised xenografts – Denatured xenografts (defatted, demineralised)
• **Naturally derived materials** – coral, shell, egg shell, bamboo
• **Synthetic materials** – Bone mineral mimicry: calcium-phosphate based ceramics (e.g. HA, TCP) – Other ceramics: e.g. bioglass, glass-ionomer – Polymers (often as matrix in composite)
• **Bioactive materials** – Demineralised bone matrix (DBM) – Growth factors (e.g. bone morphogenic proteins) in carrier material – Collagen fibres
• **Composite materials** – Particle reinforced polymers (e.g. ceramic particles) – Particle reinforced collagen fibre composite
• **Mixtures / Extenders** – Mixes with bone allograft – Mixes of different synthetic materials giving the desired properties in combination. – Mixes of the same synthetic materials combining different parameters (e.g. size, shape)

Table 2.7: *Synthetic bone graft alternatives available or in investigation.*

The synthetic materials used as bone replacement either fall into the categories of ceramics, polymers or composites thereof which could contain osteoinductive materials such as bone morphogenic proteins (BMP) or growth factors (GF)[97, 122, 123]. Within the ceramic group,

calcium phosphate based ceramics and specific bioactive glass types have achieved widespread use as bone replacement materials[124, 125]. Sintered or plasma sprayed calcium phosphates such as pure synthetic hydroxyapatite or tri-calcium phosphates, are chemically similar to the natural bone mineral. Thus they exhibit similar mechanical and biochemical properties and can be manufactured with the desired morphology and porosity at affordable costs. Mechanical properties such as compressive strength and biochemical properties such as the resorption rate can be controlled by changing chemical composition, porosity or sintering conditions such as temperature, time and pressure. The prevalent and successful use of calcium phosphate based ceramics as coatings on metal prostheses or cavity fillers in spinal surgery have lead to a wide reaching FDA approval and a general acceptance amongst surgeons. This combination of controllable mechanical and chemical properties, low manufacturing cost and legal and public approval makes calcium phosphate based ceramics an attractive choice for investigation as potential synthetic bone graft materials for the use in impaction grafting.

Bioglass and glass-ionomers are other clinically popular ceramics[124]. Bioglass[126-131] is a glass with a very specific combination of mineral components making the glass bioactive as can be seen in the phase diagram in figure 2.12. Bioglass can thus be resorbed and incorporated by the bone cells. Glass-ionomers are ceramics with ionic molecular endings making them very strong mechanically and chemically resistant[124]. They have been successfully used in extreme load-bearing and harsh environments such as those encountered as teeth cavity fillers. However, glass-ionomers do not resorb *in-vivo* limiting their potential as an ideal bone graft substitute for impaction grafting.

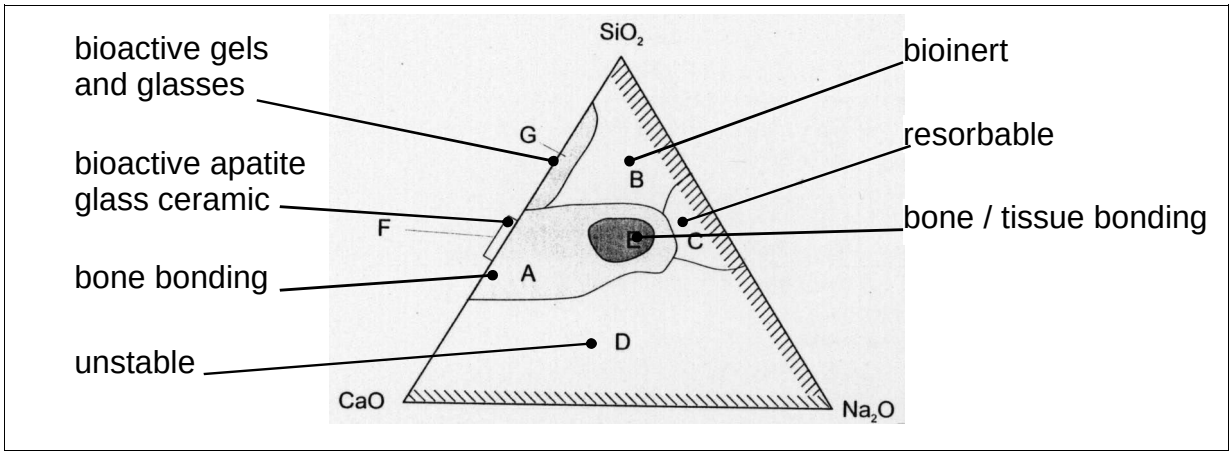


Figure 2.12: *Phase triangle of bioglass identifying the biological effects of phase compositions. Area A: Bone Bonding; B: bioinert; C: resorbable; D: unstable; E: bone and tissue bonding; F: bioactive apatite glass ceramic; G: bioactive gels and glasses* [132].

Analysing the most recent developments in the search for the ideal artificial bone substitute a new group of materials dominates current research interest[97]. Bioactive and resorbable polymers (e.g. polylactic-polyglycolic acids (PLA/PGA), polycaprolacton (PCL) or polyhydroxyalcanoates) either as a single phase or as the matrix of a composite reinforced by mineral particles or organic fibres such as collagen lead in recent publications and patent applications as it can be seen in figure 2.13. In addition, bone morphogenic proteins (BMP) and growth factors (GF) of various kinds have been investigated and added to the synthetic ceramics and polymer composites with the objective of making the synthetic material more osteoconductive or even osteoinductive.

The advantage of these polymeric materials and complex composites is that the properties can be tailored to produce application and patient specific materials. For use in impaction grafting such composites could theoretically be designed in such a way that stability would remain intact during graft resorption and bone remodelling. However most of these materials are currently just at an *in-vitro* experimental stage not optimised for a particular surgical application and as yet without clinical trials or FDA approval. Their application seems to be too far in the future to be worth considering as an immediate bone graft substitute for impaction grafting and this study. Such composites with an organic phase like BMP or growth factors could be seen as an intermediate step towards tissue engineered and genetically grown bone and cartilage which could eventually lead to the development of artificial organs.

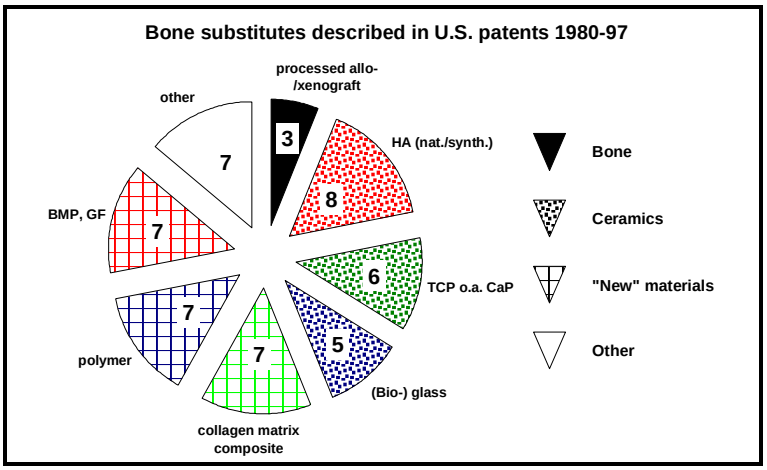


Figure 2.13:
Number of patent applications filed between 1980 and 1997 in the USA.

Material mixes are the last group of materials listed in table 2.7 and they seem to be a more realistic immediate alternative for morsellised allograft. Using any of the individual substitute materials mentioned above as a bone graft extender and not a full replacement could impart some of the properties to the bone allograft in the mix and not the substitute only. This approach reduces the requirements a synthetic bone graft has to fulfil material making it easier, faster and cheaper to develop. In a bone/extender mix the allograft could provide the

osteoinductive potential and cohesive properties and the synthetic material could just provide additional mechanical strength and improved reproducibility. However, a bone/extender mix retains or only reduces the disadvantages of allografts like the infectious and antigenetic risk or the property variability and limited supply. Mixing different graft materials forms a composite aggregate on a macroscopic scale and could offer similar advantages as the composites on a microscopic scale described before. Instead of combining all desired properties into one material, a graft mix could provide those by a combination of properties of individual materials mixed as needed. However, finding the optimum mixing ratio, defining the right properties of the individual phases to be mixed and standardising the clinical mixing process introduces a new and rather complex task. In addition, the newly created interfaces and potential unknown interactions between the components could introduce new unforeseen problems. However, before a new synthetic material has been established as a stand alone bone graft replacement, the extender solution is a viable medium-term solution. It is also the most realistic way forward in finding and marketing a full synthetic replacement.

NAME	MANUFACTURER	REF.	NAME	MANUFACTURER	REF.
Processed xenografts			**Tricalcium Phosphate and other CaPh**		
Luboc	Ost Développement, F	101-104	**Biosorb**	Aesculap, D	142,154-157
Oxbone	Bioland biomat., F	133-135, 142	**Norian SRS**	Norian, USA	158-161
Surgibone	Unilab Inc., CD	107, 116	**BoneSource**	Orthofix Inc., USA	161-165
Bio-Oss	Geistlich Söhne AG, CH	105, 106, 136-8	**Alpha BSM**	StrykerLeibinger, CH	166, 167
Orthoss	Geistlich Söhne AG, CH	139, 140	**Vitoss**	Orthovita, USA	168
Pyrost	Ostéo AG, CH	116,138-143	**Conduit**	StrykerLeibinger, CH	167
Biological hydroxyapatite			**Biphasic HA/TCP**		
Endobon	Merck, CH	137,138, 144-6	**Triosite**	Zimmer, USA	169-171
Pro-Osteon	Interpore Inc., Ca., USA	137, 147, 148	**Biocer**	Bioland biomaterial, F	172, 173
			Calciresorb 35	Céraver Ostéal, F	153
Synthetic hydroxyapatite			**Cerapatite 65**	Céraver Ostéal, F	153
Ossatite	MCP, F	149	**Ceraform**	Teknimed, F	174
Ceros	Mathys, CH	136, 150, 151	**BCP**	Bioland biomaterials, F	175
Cementek	Teknimed, F	152			
Cerapatite	Céraver Ostéal, F	153			
Composites and other materials					
Bioglass	US Biomat. Corp., USA	Bioactive glass			126-131
BioGran	Orthovita, USA	Bioactive glass			176-179
BoneSave	Stryker-H.-Osteonics, USA	HA/TCP granules			180,181
Collagraft	Zimmer, USA	HA/TCP and bovine collagen			122
Healos	Healos, USA	HA with bovine skin collogen fibres			182
Grafton	Osteotech, USA	Demineralised bone matrix (DBM) + glycerol			183
Dynagraft	DePuy Acromed, USA	Demineralised bone matrix			184,185
Cerapatite-C	Céraver Ostéal	β-TCP in bovine collagen fibre matrix			186
Collapat	Osteo AG, CH	Synthetic HA in collagen fibre matrix			187-190
Osteoset	Wright Med. Tech., USA	Sulfate of calcium dihydrate + Tobramycin			185,191-93
OP-1	Stryker Biotech, USA	Recombinant human BMP rhBMP-7 with type 1 collagen			122
Opteform	Exactech, USA	Polymer matrix with DBM and cortical cancellous bone chips			194
Immix	Osteobiologics, USA	Granular porous polylactide co-glycolide (PLG)			195
InFuse	Medtronic S. Danek, USA	Recombinant human BMP (rhBMP-2) in collagen sponge matrix			122

Table 2.7: *List of commercial or developmental synthetic bone graft materials.*

Weighing the advantages and disadvantages of the materials options discussed above against the requirement list defined in table 2.6, an investigation into calcium-phosphate based ceramics as a bone graft extenders and potentially as full replacements appears to be the most viable option. Therefore this thesis deals with the experimental investigation into the mechanical properties of such ceramics as a synthetic bone grafts for impaction grafting.

2.7 Experimental background

As described in sections 2.4 and 2.5, initial mechanical stability has been identified as the most crucial single factor determining clinical success in impaction grafting. It is the scope of this research work to investigate the initial mechanical stability of impacted particulate aggregates for the use in impaction grafting as influenced by varying impaction techniques and properties of the graft materials. Biological requirements which cannot be tested using *in-vitro* mechanical test regimes will only be considered theoretically. The experimental and clinical verification of biological and clinical assumptions lie outside the scope of this study. The intention is to built the foundations for future animal and human clinical studies.

In order to analyse the performance of various bone grafts and synthetic alternatives in terms of initial mechanical stability for the use in impaction grafting, suitable experimental methods had to be developed. To design meaningful experiments, the impaction procedure, the loading situation and the properties of the ceramic materials chosen as a graft substitutes need to be investigated more closely. Given the complexity of the impaction grafting technique and the loading environment it is essential to decide on a tolerable level of abstraction and standardisation for the laboratory experiments. This must allow investigation into the effects of isolated parameter changes on the system without sacrificing clinical relevance. Thus theoretical analysis of the mechanical loading situation (stem in femur) and the mechanically relevant parameters of the surgical procedure (graft milling and impaction parameters) must precede any decisions on experimental methodology.

The mechanical stability of a hip arthroplasty is stability against cyclic loading and thus the problem of fatigue. Therefore the experimental design tried to reduce the time per test to derive significant results, which is an important task when endurance properties are to be investigated. Apart from designing and conducting an endurance test it was the goal to measure the fundamental mechanical properties of graft specimens by using simple test regimes derived from standardised methods. It was hoped to correlate results from these fundamental tests to the findings gained from the complex endurance test which model the

clinical loading situation more closely. From this it was hoped to be able to draw sufficient conclusions for making predictions of graft performance in impaction grafting on the basis of these easily reproducible and basic tests only. Again clinical graft loading has to be researched first before test parameters can be defined. In addition, it was the goal of the experimental design to reduce the consumption of expensive bone graft and synthetic material, both of which have limited availability

2.7.1 The mechanical loading situation

In order to analyse the graft's ability to provide initial mechanical stability in an impaction grafted femur the loading conditions have to be analysed. The loading of the graft is the result of the physical loading of the stem which is transferred into the graft. This will depend on the geometry, elasticity, dimensions and interface properties of the system.

The physical loading of, for instance, the femoral head during human activities like walking, stair climbing or lifting objects has been well described and is a function of weight and activity level. Table 2.8 lists typical loads recorded *in-vivo* by Bergmann through an implantable multi-channel telemetry system[196-201]. Forces are given as a percentage of body weight for different activities. As expected the highest force acts proximally to distally and can reach peaks of 250% body weight when walking without aids. For a patient with for instance a body mass of *m*= 80 kg, this converts to 1962N and correlates with peak forces chosen experimentally.

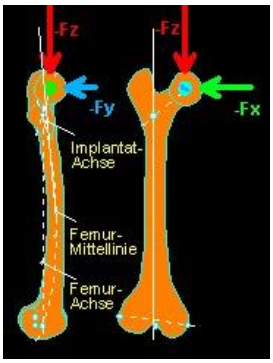
Co-ordinates Left femur			Peak force [% body weight]			
			resultant	proximal-distal F_z	medial-lateral F_x	ventral-dorsal F_y
	Activity	Standing	100	90	40	10
		Walking	260	250	75	30
		Jogging stairs	610	550	250	85

Table 2.8: *Peak forces on femoral head recorded for different activities in-vivo via an implantable multi-channel telemetry system [196-201].*

The resulting loads which the stem then transmits via the cement into the bone have also been well explained but are multiaxial and thus quite complex. They are determined by the lever arm which the femoral head provides for the hip reaction force, the dimension, taper and cross-sectional structure, elasticity modulus and surface morphology (e.g. polished, roughened or coated) of the stem and the geometry of the reamed medullary canal and the elastic behaviour of the anisotropic bone. Between stem and bone lies the cement mantle and mantle thickness, cement elasticity and creep properties also influence the static and dynamic loading of implant, cement and femur. The major loads on the cement are compressive (ca. 5 MPa) and shear (ca. 3-11 MPa). The stresses result in shear and debonding micromotion between cement and stem of up to 50µm and can lead to aseptic loosening of the stem[202].

In impaction grafting a further level of complexity is introduced with the creation of the additional graft interface. Nevertheless, one study by Voor *et al*[203] roughly estimates graft compression stresses at 1MPa. Additional interfaces are formed by the particulate graft in contact with the outer cement mantle towards and with the endosteal surface. The relative movement between impacted graft particles and the endosteal bone and in between the particles themselves is crucial when bone ingrowth and graft resorption are concerned. By analogy, porous surface treatments of the stem in uncemented hip replacements allow bone tissue to grow onto the prostheses to provide stable long-term fixation. If too much micromotion between the prosthesis and the bone is produced when the patient loads the joint in the immediate post-operative period, the bone will not grow onto the prosthesis. Instead of stable fixation, a fibrous, scar-like tissue may develop which can lead to pain and eventual failure of the procedure. This mechanism can lead to the failure in impaction grafting also. The compacted graft may still provide sufficient stability against permanent subsidence, but the desired osseointegration and bone remodelling may be inhibited. In order to achieve bone ingrowth and to avoid the formation of fibrous tissue only, graft stiffness has to be high enough to limit micromotion below 40 µm[204, 205].

The mechanical loading situation of the graft itself is further complicated because on a macroscopic scale it is a multiphase aggregate, which cannot be described by analogy to a bulk material such as cement. Particle and phase interactions have to be considered. The governing factors for the mechanical behaviour of the graft are:

- mechanical properties of bulk materials
- component/phase ratio
- particle size and size distribution
- particle morphology
- surface morphology
- compaction density
- fluid or gas pressure within the aggregate

A theoretical analysis of such a particulate aggregate system and the loading situation resulting from compaction, stem insertion and vertical loading can be based on analogies drawn from findings in civil engineering soil mechanics[206]. Equivalent loading regimes in civil engineering can be found mainly in foundation building, rampart design and pile driving. The mechanical stability of soil against such equivalent loading regimes is defined by the compression modulus and the shear strength as a function of cohesion and shear angle. This knowledge led to the choice and design of a compression test and a shear test as described later in chapter 4 and 5 respectively.

The civil engineering technique of pile driving allows huge vertical loads to be sustained on a post which is driven into dense soil by a dropping mass delivering individual hammer blows. A good analogy can be drawn with impaction grafting where the impaction of the proximal impactors and trial prosthesis correlate with the pile driving process and where the stem/graft system provides stability in a similar way to the pile/soil system. This background inspired the design for an experimental impaction device as described later in section 7.1.3.

However a major difference between soil mechanics theory and the situation in impaction grafting must be considered. Soil mechanics assumes the idealised situation of a homogeneously mixed aggregate of unlimited extension. All components such as foundation piles have dimensions of at least one magnitude larger than the particles the soil is made of. In impaction grafting however, the graft volume is limited and the graft mantle thickness of a few millimetres is relatively small compared to the stem dimensions. Even the size of individual graft granules can be equal or even larger than the graft mantle thickness. The geometrical constraints mean that the load transfer from the stem into the graft does not only rely on the mechanical loading capabilities of compacted particles in bulk, such as with piles driven into soil, but also on the stability of individual particles locked between implant and femoral canal. In addition, due to the complexity of the impaction grafting operation, the thickness of the cement mantle in impaction grafting is not as consistent as in a primary hip replacement and can even be partially missing creating a variable penetration depth into the graft or even a direct stem-graft interface[60]. This further distinguishes the reality of impaction grafting from the assumptions underlying soil mechanics. In combination with the given dimensional relationships it is definitely impossible to have load transfer pattern that can sufficiently be described with soil mechanics theory. Although one could speculate that interface locking of individual particles would increase the mechanical stability of the system it would become unstable when those particles suddenly fracture. Stability would also become less predictable because the number, position and orientation of such locking particles cannot be controlled. As

a consequence, smaller particles could, in contrast, provide more consistent stability. This is one of the questions this research work aims to investigate.

2.7.2 Geometry, dimensions and graft quantities

In order to design a relevant *in-vitro* experiment for testing mechanical stability in impaction grafting, the geometry and dimensions of the clinical system and graft quantities used have to be identified. In order to derive average dimensions essential for a standardised experimental procedure the following method was employed. A Sawbone® femur, a glass fibre reinforced epoxy femur of average standardised dimensions and bulk mechanical properties identical to bone, was used and an orthopaedic surgeon performed a standard impaction grafting procedure using a polished hip stem and X-change revision tool set, PMMA cement and formalin fixed human bone milled through a Norwich bone mill. The impaction grafted Sawbone was left to cure and then transversely cut into 11 cross-sections of 8-13 mm height (plus 1.25 mm loss per cut) from the proximal end at the greater trochanter to a distal position where no cement penetration was observed. For each cross-section the surface area of the stem, cement, bone graft and the cortical femoral bone were plani-metrically assessed and the average dimensions and graft volumes calculated to design the experimental set-up and procedure described in chapter 7. A typical cross-section from the experiment can be seen in figure 2.14. As a good approximation the average volume of compacted bone graft necessary for impaction grafting is ca. 50-60 cm^3. The corresponding graft volume prior to impaction will vary with impaction level. Some typical dimensions for impaction grafting are:

- Stem length: 120-180 mm
- Stem cross-section prox.: 21×9 mm
- Stem cross-section distal.: 7×7 mm
- Distance femoral neck-plug > 180 mm

Figure 2.14: *Transverse sections of an impaction grafted Sawbone® femur indicating the geometry of the biomechanical problem.*

2.7.3 Bone graft – source and preparation

Bone is a structural material as well as an organic metabolic tissue. Structurally bone serves as a support for the body against gravity, as a lever system for muscular action and as a protective shield for internal organs and for the blood-forming marrow within the bones. The primary metabolic function is to serve as a repository for calcium which is necessary for nerve conduction, muscle contraction, clot formation and cell secretion[207].

Bone is composed of cells with an extracellular matrix. The cells of bone include osteoblasts (bone forming cells), osteoclasts (bone destroying cells) and osteocytes (bone maintaining cells). The extracellular matrix consists of two phases, an organic phase or osteoid and an inorganic phase or mineral. The organic phase comprises approximately 50% of the bone by volume (25% by weight) and consists of 90 vol.% mainly fibrous collagen (Type I) and 10 vol.% amorphous ground substance (mainly bone morphogenic proteins such as glycoproteins and glycosaminoglycans). The collagen fibres are responsible for the high tensile strength of bone. The inorganic phase is the bone mineral, chemically a hydroxyapatite (HA) ceramic, which is a calcium phosphate based apatite ($M_{10}(XO_4)_6Z_2$) molecule with the chemical formula ($Ca_{10}(PO_4)_6(OH)_2$) (details see section 2.7.4 and table 2.11). The bone mineral constitutes approximately 50% of bone by volume and 75% by weight and is responsible for the bones excellent resistance against compressive stresses. The bone mineral formation is called calcification and takes place when high local calcium and phosphate concentrations occur as a result of the bone cell metabolism[207].

Bone is a composite of organic and inorganic phases and it forms two major types of bone. The lamellar bone is a highly organised and regularly orientated material, which forms slowly and characteristically contains layers of bone with collagen fibre orientation at right angles. The woven bone is poorly organised, is randomly orientated and has a lower mineral content than lamellar bone. It appears mainly during rapid bone growth or fracture repair and is then converted into lamellar bone as well. In impaction grafting, the formation of fibrous tissue and woven bone can start the graft remodelling process and when cancellous chips are resorbed and replaced by weak poorly organised bone, stability might temporarily drop.

Lamellar bone forms two different structures, the cortical and the cancellous bone. Cortical bone is made of numerous layers of lamellar bone on the outer (periosteal) surface of bone, forming a thick cortical plate. Cortical bone forms the diaphysis and the periosteal surfaces of the epiphysis of long bones such as the femur. On the inner (endosteal) surfaces of the bone, in particular towards the epiphysis a few layers of lamellar bone form thin spicules or

trabeculae projecting towards the bone marrow and forming a strong but lightweight lattice. This type of lamellar bone structure is called cancellous, trabecular or spongy bone. It is concentrated mainly in the epiphysis where it transfers the load from the joints into the diaphyseal section of the bone where there is less or no cancellous bone. The porous lattice structure of the cancellous bone is shown in figure 2.1.

Species		Density [g/cm3]	Water content [vol.-%]	Mineral ash fraction [vol.%]	Organic [vol.%]
Human	***cortical***	1.94	15.5	39.9	41.8
	cancell.	1.92	27.0	33.9	39.3
Monkey	***cortical***	2.09	23.0	42.6	41.1
	cancell.	1.89	27.1	32.9	40.1
Bovine	***cortical***	2.05	26.2	42.6	36.2
	cancell.	1.93	28.1	33.5	38.4
Equine	***cortical***	2.02	25.0	41.0	40.5

Table 2.9: *Characteristic cortical and cancellous bone properties for different species. Values compiled from a range of publications*[208, 209].

Mechanical property		Human	Bovine
Young's modulus [GPa]	*Longitudinal*	17-20	18-22
	Transverse	11-13	10-13
Tensile strength [MPa]	*Longitudinal*	80-150	90-170
	Transverse	51-56	50-55
Compressive strength [MPa]	*Longitudinal*	131-224	133-233
	Transverse	106-133	151-160
Shear strength [MPa]		53-70	70-76

Table 2.10: *Characteristic mechanical properties for cortical bone of different species loaded in two directions*[207].

Due to its complex organisational structure bone exhibits anisotropic mechanical properties. Furthermore properties change when the living bone is removed from its organic system and nutrient or hormone supply stops, the bone cells die and the organic material deteriorates. Some characteristic composition and mechanical properties for different bone types and sample orientations are given in table 2.9 and 2.10. The density of cancellous bone as a structural material, taking the porosity of the material into consideration and being called the "apparent density", lies between 0.15 and 1 g/cm^3. When compared to the density range of the bulk trabecular bone between 1.6 and 1.9 g/cm^3, this roughly converts to porosity levels between 50% and 90%. However the mechanical properties of the bulk bone will only be an indication of the properties a particulate aggregate of morsellised bone, containing fat, marrow and collagen will exhibit.

Bone properties do not only vary significantly depending on the age, size and health of the donor but also with the age and freshness of the tissue prior to clinical or experimental use and the method of storage and preservation. A common bone preservation method, which was used in this study, is fixing with formalin. Formalin is the short form for formol saline, a mixture of saline (water with dissolved sodium chloride in the same concentration as body fluid) and formaldehyde. The recommended fixing procedure for bone blocks uses a neutral 10 vol.% formalin solution in which the bone should be fixed for at least 48h, preferably longer, in a quantity at least 10-20 times the bone volume. The fixation time can be reduced to a few hours by heating the solution to 60ºC. Other fixative solutions like mercuric chloride-formalin or acid fixatives such as Bouin, Zenker, Davidson (sometimes called Hartmann's) or Carnoy's fluid do also decalcify the bone, which changes the mechanical properties significantly. Other fixative methods use ethylene oxide (ETO), UV-Light or irradiation. Irradiation is a popular fixative method as it allows effective sterilisation while the tissue can still to be used for implantation as irradiation is non-toxic and residual radiation remains at sub critical levels. Irradiation is used by bone and tissue banks to sterilise and store bone tissue for future clinical use. As a result, international standards recommend irradiation levels of 2.5 to 5MRad to ensure sterilisation and minimal effects on the mechanical properties of the tissue. Some samples tested in this study were irradiated with a 2.5 and 5MRad doses. For bone storage, freezing below -20ºC is appropriate for experimental tissue use. Bone banks and hospitals however usually store bone tissue at -80ºC.

For the production of morsellised bone in orthopaedic impaction grafting various types and makes of bone mills are available. Three major variants can be distinguished by their blade type and blade action, as represented by the Norwich® or Howex®, the Nijmegen and by the Tracer® bone mill. The standard bone mill used for sample preparation in this study was the popular Norwich bone mill as seen in figure 2.15. It operates with a rotating cylinder of 80mm diameter with individual blades of 5-15mm length formed by the edge of oval holes distributed across the outer surface. The Norwich bone mill can be fitted with two differently sized blade types. Surgeons prefer the coarse blade to produce coarse grafts for the femoral and in particular the acetabular side, where large chips or croutons are considered optimal. Thus for this study, graft was morsellised only with the coarse blade. With the Norwich bone mill the femoral heads often need to be pre-sectioned using a hacksaw so that fragments fit through the narrow feeder tube. It was discovered that the quality of the morsellised bone chips not only depend on the blade type used but also the distance set between the adjustable feeder tube and the rotating drum. If the distance is too large, bone fragments get caught between the drum, the feeder tube and frame and are not morsellised. Such large fragments need to be manually trimmed to size with a pair of sharp pliers after milling. If the distance is

too small, the combination of high milling torque and feeding pressure elastically deforms the mill in such a way that the blades cut into the steel feeder tube blunting the tool.

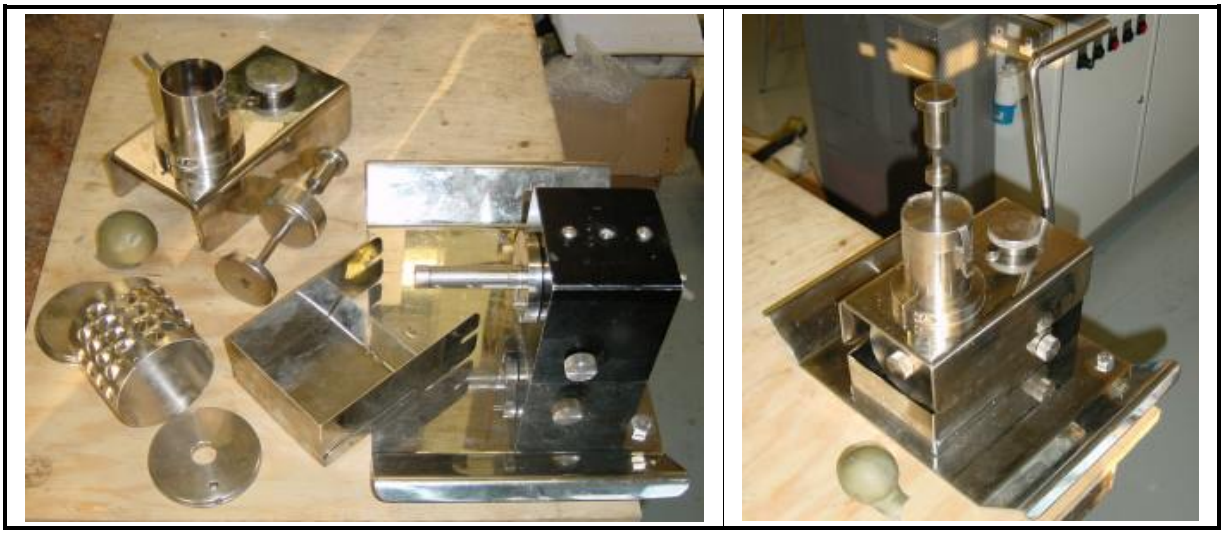


Figure 2.15: *Norwich® bone mill dismantled to show components (left) and assembled (right).*

The widely used Howex bone mill operates on the same principle as the Norwich bone mill. It differs with respect to the shape of the blades and how they are distributed across the rotating drum. The Howex mill employs long, straight blades with a number of short protruding hooks axially aligned on the outer drum surface as shown in figure 2.16 and 2.17. The hooks grip and fracture the bone and the intermediate blade sections cut slices out of the bulk femoral head. The morsellised chips visually appear more consistent than those the Norwich mill produces and the graft size difference between the coarse and fine blade is more pronounced. The construction of the Howex mill is much stiffer than the Norwich mill and the clearing space between feeder tube, drum and housing is constant. The manufacturer also claims preferable mechanical properties in graft chips milled with the Howex mill in comparison to its competition[40, 210].

Figure 2.16: *Morsellising graft with the Howex® bone mill.*

The Nijmegen bone mill also uses a rotating drum with integrated blades. However the drum-blade configuration more closely resembles that of a milling tool or ice-crusher with sets of individual hooks with short blades at their tips distributed helically across the rotating cylinder. The Nijmegen mill cuts but also fractures the bone into and offers larger clearance spaces between the individual blades to remove the morsellised graft from the milling space. Thus operation is more noisy but requires less force than a Norwich bone mill and it sticks less frequently due to the increased clearance space. The cutting speed is more even and the mill produces visually more consistently sized chips. The third type of bone mill is represented by the Tracer bone mill which is motor driven and uses reciprocating blades. The influence of bone mill types and blade size on the mechanical properties of morsellised bone graft was investigated in section 4.4.1

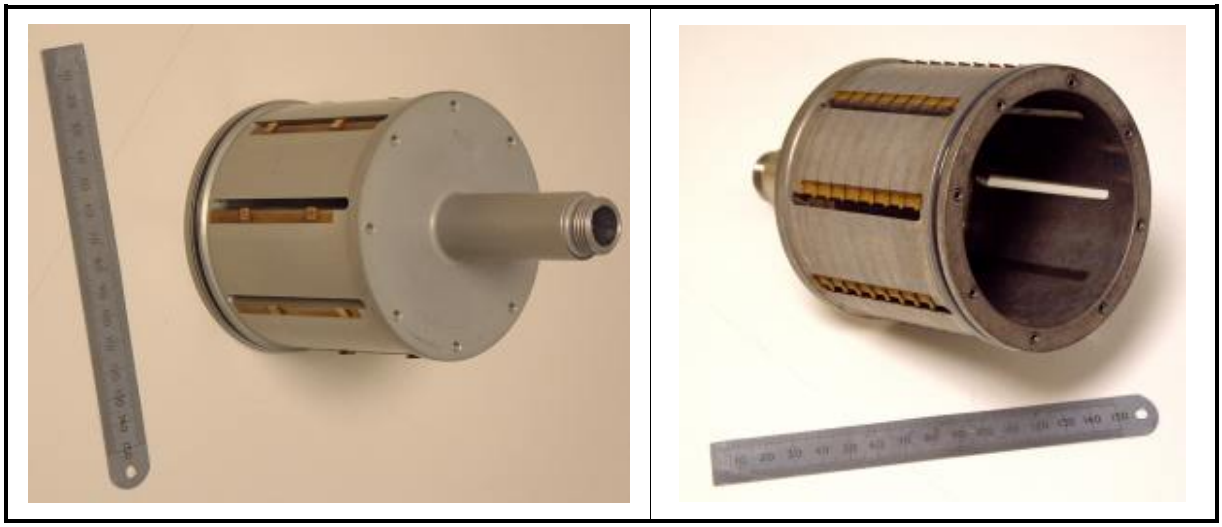


Figure 2.17: *The Howex® bone mill blades for coarse (right) and fine (left) bone chips.*

When femoral heads are fed through a bone mill, the resultant morsellised graft contains not only the desired cancellous bone chips but also fractured bits of cortical bone, fat, marrow, cartilage and other organic tissue such as collagen fibres and remains of tendons or ligaments. This cannot be avoided and in the operating theatre and during experimental sample preparation, cortical bone and other easily identifiable unwanted tissue were removed manually. It becomes obvious that the preparation of morsellised bone graft for impaction grafting is a procedure with high degree of variability when the long chain of factors is considered. Each step of the graft production sequence, the donor bone quality, bone mill and blade type, the manual operation and the subjective tissue removal process comes with a certain tolerance in quality which combine towards a highly variable final outcome. During experimentation in this study large graft volumes were prepared at once and then mixed to ensure constant conditions and technique in an attempt to reduce the variability.

2.7.4 Hydroxyapatite and Tri-calciumphospahte

As described in section 2.6.2 calcium phosphate based ceramics like synthetic hydroxyapatite and tri-calciumphosphate sintered into composites of different composition ratios were chosen to be the most viable alternative bone graft material. Their fundamental physical, chemical and mechanical properties are described below for reference and in order to understand the nature of the problems associated with the materials.

- **Hydroxyapatite**

Chemically, hydroxyapatite (HA) is a calcium phosphate based apatite ($M_{10}(XO_4)_6Z_2$) with the chemical formula ($Ca_{10}(PO_4)_6(OH)_2$) which is also called penta-calciumphosphate. Stoichiometric hydroxyapatite has a calcium to phosphate mol ratio of 1.67 and as such consists of 39.9% calcium, 18.5% phosphorus and 3.4% hydroxyl (weight percentages)[211]. Figure 2.18 shows the crystal structure of a stoichiometric hydroxyapatite molecule with a hexagonal structure (alternatively monokline). As hydroxyapatite appears naturally in the human body in bone, enamel and dentine, it has been accepted as a viable synthetic bone grafting material (see also chapter 2.6.2).

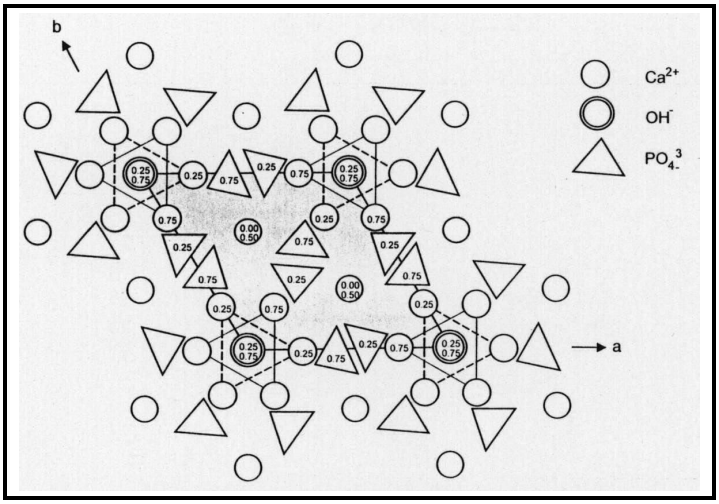


Figure 2.18:
Hexgonal molecular structure of synthetic stoichiometric hydroxyl-apatite projected into the a,b-plane. The triangles and single and double lined circles represent the ions and the numbers give their height in atomic units [Å] above the a,b-plane [211].

Biological hydroxyapatite is not stoichiometrically pure but contains several "impurities" reducing the calcium phosphate ratio. Sodium-, magnesium-, carbonate-, fluoride- and chloride ions replace the Ca^{2+} and PO_4^{3-} ions in the crystal structure, which mainly results in different solubility properties of the particular hydroxyapatite. Table 2.11 lists the weight percentages of the chemical elements in stoichiometric hydroxyapatite versus the biological “impure” variant. It can be seen that for instance the calcium weight percentage in bone is

almost just half of that of the stoichiometric hydroxyapatite. Therefore it can be expected that mechanical and biochemical properties of synthetic and biological HA will vary.

The manufacturing process of synthetic HA powder usually involves the precipitation from an aqueous solution, for instance through adding ammonium phosphate ($(NH_4)HPO_4$) to a calcium nitrate solution ($Ca(NO_3)_2$) at high pH-values (11-12 pH)[4]. For producing dense and solid bulk material from the powder, it is cold pressed and subsequently sintered between 1100 and 1200°C. Depending on sintering temperature, sintering time and powder or grain size distribution, dense bulk material with a pore content lower than 5% is formed. Hot pressing the powder does not significantly alter the properties. In order to create dense bulk hydroxyapatite with higher porosity as desired for bone on-growth, the HA powder can be mixed with organic additives as foaming agents which are burnt off during sintering[212]. An alternative procedure to produce a porous HA ceramic as a bone graft extender is to impregnate a sponge with a suspension containing ceramic powder.

Element	Bone [%]	Dentine [%]	Enamel [%]	Stoichiometric [%]
Ca	26.7	35.0	36.1	39.9
P	12.47*	17.1	17.3	18.5
CO_2	3.48**	4.0	3.0	
Mg	0.436	1.2	0.5	
Na	0.731	0.2	0.2	
K	0.055	0.07	0.3	
Cl	0.08	0.03	0.3	
F	0.07	0.017	0.016	
S	-	0.2	0.1	
Cu	-	-	0.01	
Si	-	-	0.003	
Fe	-	-	0.0025	* as PO_4^{3-}
Zn	-	0.018	0.016	** as CO_3^{2-}

Table 2.11: *Comparison of chemical composition of synthetic stoichiometric hydroxyapatite versus the biological hydroxyapatite in the human body (weight percentages) [4].*

Depending on the sintering conditions described, the powder purity and porosity created, a wide range of chemical and mechanical properties can be achieved. These can even be visually sensed or manually felt when extreme sintering temperatures or durations are compared. The fundamental mechanical properties of a bulk form of non-porous hydroxyapatite are listed in table 2.12. Some of the huge variation in compressive and tensile strength is due to different measuring methods involved[213-216].

	Density [g/cm3]	E-Modulus [GPa]	Comp. strength [MPa]	Tensile strength [MPa]	Bending strength [MPa]
Hydroxyapatite	3.05-3.15	80-120	300-900	40-200	100-120

Table 2.12: *Physical and mechanical properties of hydroxyapatite* [213-216].

- **Tri-calciumphosphate**

Tri-calciumphosphate ($Ca_3(PO_4)_2$) is another biomedically relevant calcium phosphate with a Ca/P Mol ratio of 1.5 versus 1.67 for hydroxyapatite. The manufacturing process for tricalciumphosphate (TCP) and the basic properties are similar to HA. Depending on crystal structure two tricalciumphosphate phases (β-rhombohedric, α-monoclinic, phase change between 1100°C-1350°C) are distinguished which are called α-TCP and β-TCP with β-TCP being the more stable and more widely used crystal structure.

	Porosity [%]		
β-TCP	**5**	**30**	**45**
Compressive strength [MPa]	150	100	15
Bending strength [MPa]	15	10	2

Table 2.13: *Compressive and bending strength of β-TCP as a function of porosity* [217].

The most significant differences in terms of properties relevant for the purpose of bone graft replacement between TCP and HA lie in their E-moduli and solubility rates. With an elasticity modulus of E= 24 - 65 GPa[4], TCP is significantly more compliant than HA with E= 80 - 120 GPa (see table 2.12). Also compressive and bending strength are significantly lower when comparing the values for HA in table 2.12 against the measurements for TCP as a function of porosity in table 2.13. Normalising the solubility rate of dense, non-porous HA in an aqueous solution at 37°C and at pH 7.3 to 1.0, a dense and non-porous TCP sample dissolves at a rate which is 25 times faster. Table 2.14 lists these results in comparison to other calcium phosphates and different applications of HA or TCP.

Material	Relative solution rate
Dense HA	1.0
HA-coating	2.1 - 8.8
Dense TCP	25.0
TCP-coating	218.0
Plaster	667.0
Tetra-CaP	0 (non soluble)

Table 2.14: *Normalised solubility rates in vitro in aqueous solution at 37°C and pH=7.3 for various calcium phosphates and applications* [218].

Table 2.15 compares how pure HA and pure TCP perform as a bone graft substitute with regard to clinically important properties such as Roentgen visibility, resorption behaviour and histological observation defining their potential for graft substitution. Both materials show osteoconductive potential with pure TCP resorbing much faster. Figure 2.19 and figure 2.20 show the reference x-ray diffraction (XRD) plots for HA and TCP and identity the difference in chemical composition of the crystals.

	Roentgen	Resorption	Histology	Substitution
HA	always visible	Only a few µm superficial resorption	Vital and active bone surrounds HA particles	No substitution but direct contact between bone and HA-surface. Osteoconduction: Bone ingrowth into porous structure.
TCP	complete dissolution within 1-2 years	After initial surface resorption, TCP disinter-grates into small particles and is decomposed by macrophages	Vital and active bone surrounds TCP particles	Partial deportation through macrophages. New bone formation between TCP particles.

Table 2.15: *Different reactions of hydroxyapatite and tri-calciumphosphate as bone replacement material in the human body* [219].

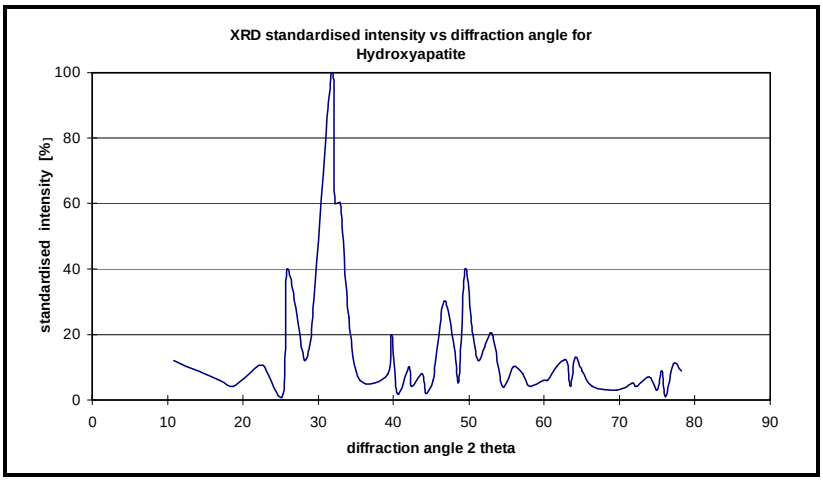


Figure 2.19: *Reference XRD signal intensity versus diffraction angle for stoichiometric HA.*

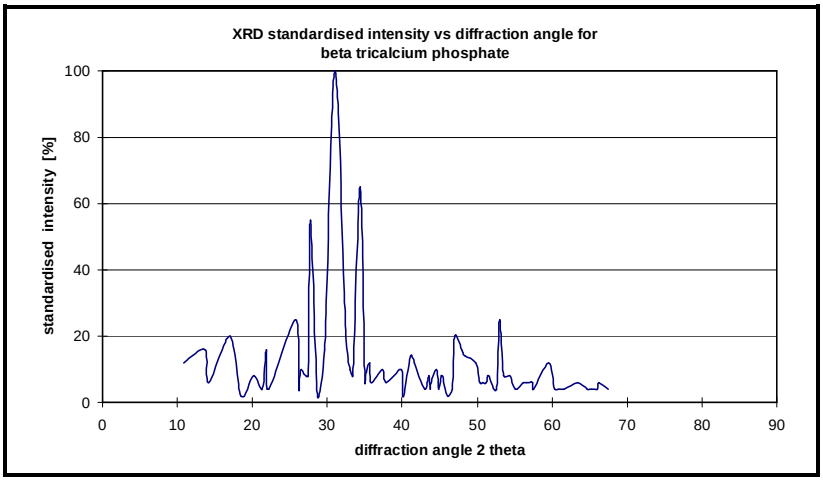


Figure 2.20: *Reference XRD signal intensity versus diffraction angle for stoichiometric TCP.*

- **Biphasic hydroxyapatite/tri-calciumphosphate**

Comparing the mechanical properties and the dissolution behaviour of single phase HA with TCP in tables 2.12 to 2.15 respectively, it can be seen that an individual material does not fulfil the desired property profile. Hydroxyapatite is significantly stronger and has an E-modulus of more than twice that of tri-calcium phosphate. However in dense form it dissolves at a rate 25 times slower when compared with TCP. In order to produce a material with the desired mechanical strength, elasticity and dissolution rate, various biphasic HA/TCP compositions have been developed as included in table 2.7.

For the experimental work in this research project, various biphasic hydroxyapatite/tri-calciumphosphate composites of different composition ratios, sintering conditions (mainly temperature variations) and porosities were used as bone graft substitutes. When sintering biphasic HA/TCP, diverse phase transitions can occur creating a multiphase CaPh ceramic with predominantly hydroxyapatite and tri-calciumphosphate phases. The x-ray diffraction plot of a typical ceramic composed of HA and TCP illustrating the multi-phase nature of the finished sintered product is shown in figure 2.21. Clearly visible are the characteristic calcium and phosphate peaks and the similarity of the plot with pure TCP due to the predominant TCP content. When composition percentages are given for a specific material, they refer to the weight ratio of the original hydroxyapatite and tricalcium phosphate powders before they were mixed and sintered and exclude any organic material or foaming agent added for pore creation.

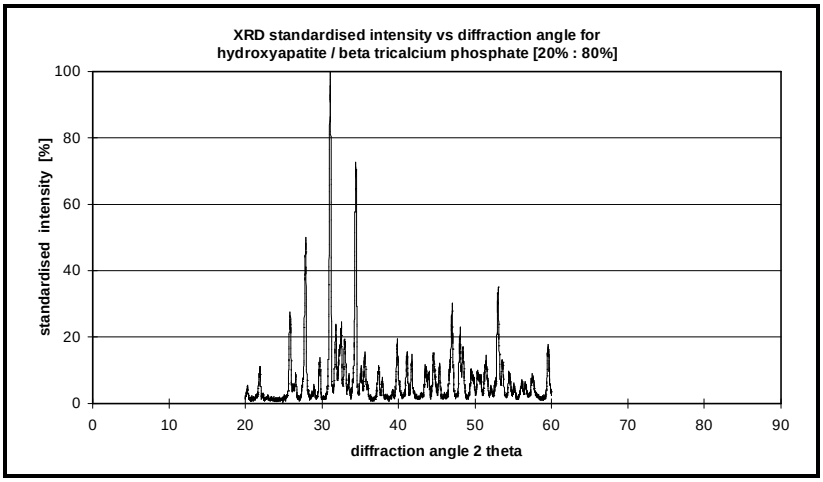


Figure 2.21:
XRD signal intensity versus diffraction angle for a 20:80 HA/TCP composite ceramic.

2.7.5 Shear test theory

A major task of this study was to identify potential correlations between the stability of graft materials against stem subsidence in impaction grafting which is a complex loading situation, and fundamental mechanical properties of the materials, which are relatively easy to determine and reproduce. *In-vivo* the grafts are loaded in compression and shear so that an analysis of the shear properties of bone grafts seemed appropriate. A so-called "shear-box" test was employed to measure basic shear properties like shear angle, cohesion and dilation[206]. These properties influence the mechanical stability against subsidence in impaction grafting, the compaction and the handling properties.

The failure criteria of particulate aggregates like soils or, by analogy, bone grafts, have been thoroughly investigated in civil engineering soil mechanics[206]. The shear resistance of soil as a particulate substance is considered to be one of the most critical mechanical properties determining the load bearing capacity of particulate non-coherent matter such as soils or, by analogy bone grafts.

In civil engineering practice a variety of standardised shear testing methods have been developed of which the shear box as shown in figure 2.22 is the most widely used [220-223]. The triaxial shear test [223], which does not predefine the shear loading axis and failure plane like the shear box is, despite this advantage, much less common. The uni-axial shear box test is more practical, cheaper and faster and, taking into consideration the high error tolerances inherent in shear testing, often more justified[222].

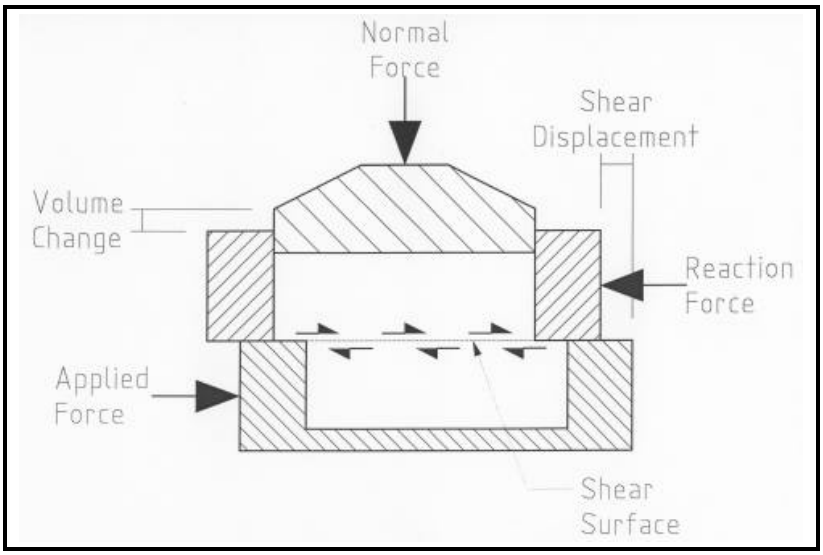


Figure 2.22:
CAD-drawing of shear box principle.

The shear resistance of soil or other particulate aggregates is governed by two characteristic properties, the cohesion or cohesion intercept c [N/m^2] and the internal friction measured as the shear angle or angle of shearing resistance φ. The cohesion c represents the maximum shear stress a soil can withstand without any normal stress being applied to it apart from its own weight. Cohesion is the result of binding or bonding forces in-between the soil's components or a consequence of humidity and water in the pores. The stability of a deep trench with vertical walls against collapse represents a graphic example of the effects of cohesion in civil engineering practice.

When a normal force is applied to the soil or particulate aggregate the granules are pressed against each other and friction forces increase counteracting the shearing forces. With rising normal forces the friction forces increasingly dominate the overall shear resistance of the material. The measured shear angle φ is analogous to a friction coefficient μ and represents the constant of proportionality between shear stress and normal stress. In civil engineering practice the shear angle φ also forms geometrically between level ground and the edge when unconstrained granules are poured to create a pile.

The theory of soil failure through shear is described by the Mohr-Coulomb failure criterion, giving the shear resistance or shear strength of a particulate aggregate as the sum of cohesive stress plus shear stress as a value proportional to the normal stress applied:

$$\tau_f = c + \sigma \cdot \tan\varphi \qquad \text{(equ. 2.1)}$$

τ_f : maximum failure shear stress — c : cohesion [N/m^2]
σ : normal stress on shear plane — φ : angle of shear resistance

In order to visualise the meaning and the effect of the cohesion intercept c and the angle of shearing resistance φ a graphical analysis of the effective major and minor principal stresses using the Mohr circle is represented in figure 2.23[206]. With the normal stresses on the x-axis and the shear stresses on the y-axis, the shear strength values calculated according to equ. 2.1 define a straight line (the Mohr-Coulomb envelope) with the cohesion intercept c as the shear stress measurement for a normal stress σ = 0 and the angle of shearing resistance φ representing the slope of the shear to normal stress correlation. At any stress condition below the Mohr-Coulomb envelope the particulate aggregate is stable. As soon as the line becomes a tangent on the Mohr circle characterising the stress situation, the material fails as a result of

excessive shear. In the illustration this stress-condition is identified by the point *P* where the normal stress onto the failure plain is *Q* and the shear stress leading to failure is τ_f.

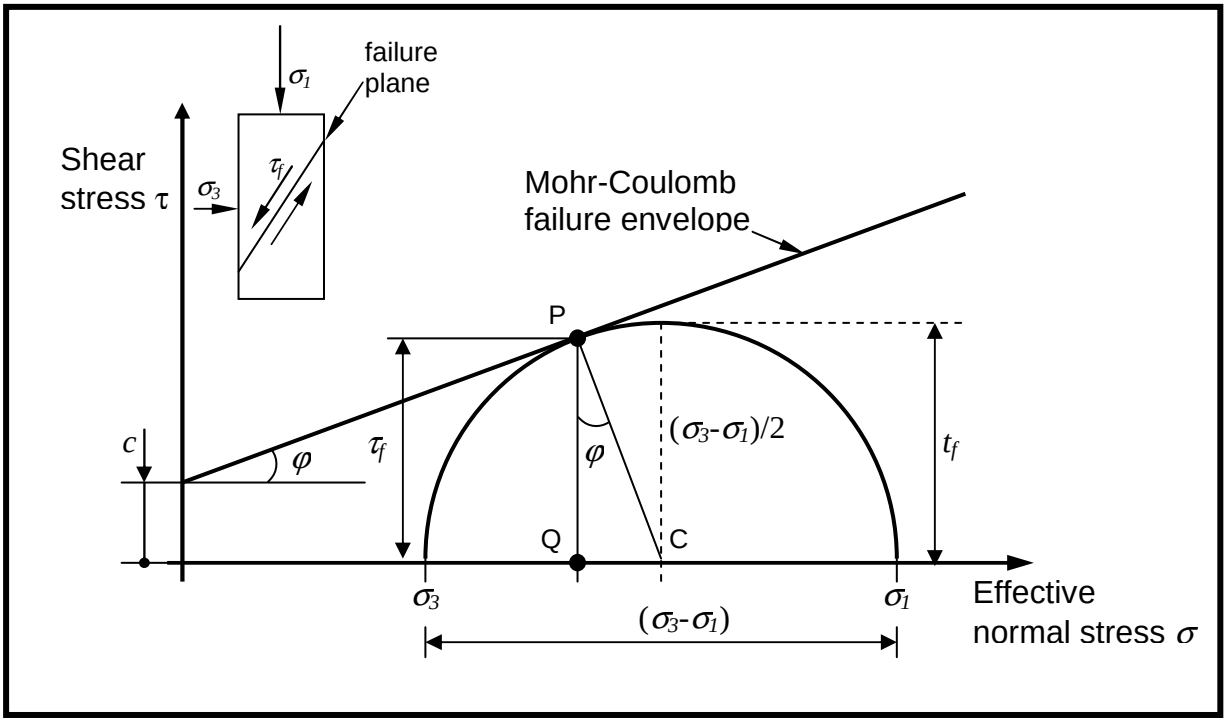


Figure 2.23: *Definition of the shear resistance values cohesion* c *and shear angle* φ *using the Mohr-Coulomb circle and failure criterion.*

2.8 Objectives of work

For this study a range of basic materials and complex endurance tests were designed to investigates the influence various bone grafts, synthetic graft substitutes and surgical process variables have on initial mechanical stability in impaction grafting. Two models for endurance testing the long term stability of impaction grafting were employed and two standard test procedures for deriving basic mechanical properties of graft materials were used. Endurance tests were performed with an ovine and a human sized model. The sheep model comprised an ovine hip stem, a manually performed cemented impaction grafting and off-centre dynamic vertical loading. The results were used to optimise the experimental design and procedure of a more standardised endurance testing model and to prepare a sheep animal study[25.19]. Considering the insights from the ovine model on the effects of manual impaction, cementation and off-centre loading, the human sized model for endurance testing was developed. It was then used to test stability for a broad range of graft and procedural parameters. Experimentation with this model included the use of a device called the "impactometer" which was designed for delivering controllable impaction energies. In

addition, as a stand-alone device, the impactometer enabled the compaction behaviour of different graft materials to be analysed.

As described in chapter 2.7.1, bone graft in impaction grafting is predominantly loaded in compression and shear. Thus, as basic materials tests, a standard compression test and a standardised shear test derived from soil mechanics[27,23] were employed to differentiate the mechanical performance of bone grafts and synthetic extender materials. Finally, correlations between the endurance tests and the standard tests were drawn in order to link basic graft properties to performance in impaction grafting. Such a relationship could potentially save time and cost during the development of new bone grafting materials. The experimental methods will be described and discussed in the following chapters:

- Die-plunger constrained quasi-static compression test (chapter 4)
- Shear box test according to soil mechanics theory (chapter 5)
- Ovine sized model endurance test with manual cemented impaction grafting (chapter 6)
- Human sized model endurance test with impactometer controlled, uncemented impaction grafting (chapter 7)

The graft materials tested were:

- Gold standard: Human bone
  varied preparation methods
- Exp. xenografts: Ovine, bovine bone
  varied preparation methods
- Synthetic extenders: HA/TCP ceramic
  varied configurations
- Bone/ceramic mixes
  varied mixing ratios