CHAPTER IV

CALCIUM PHOSPHATE CERAMICS: PREPARATION, PHYSICAL PROPERTIES, BIOMCOMPATIBILITY AND CLINICAL APPLICATIONS

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1. HYDROXYLAPATITE (HA) AND TRICALCIUM PHOSPHATE (TCP)

Hydroxylapatite and its increasing usefulness may revolutionise the discipline (of preprosthetic surgery).


1.1 Introduction

A great deal of research has been directed over many years towards the development of a synthetic implant material that is safe, non-antigenic and effective in the regeneration or replacement of lost or diseased bone. The inorganic component of human mineralised tissue is derived from calcium phosphate and a wide variety of calcium phosphate salts have been investigated in an attempt to discover the ideal implant material. However, when reviewing the work confusion is generated by the imprecise use of the terms hydroxylapatite and tricalcium phosphate as often the precise chemical formulae of the materials being investigated are not known or not included in the reports.

Currently the major synthetic calcium phosphate ceramics being researched for clinical use have two chemical structures; either hydroxylapatite (HA) \([\text{Ca}_{10}\text{(PO}_4\text{)}_6\text{(OH)}_2]\) or tricalcium phosphate (TCP) \([\text{Ca}_3\text{(PO}_4\text{)}_2]\). HA has a calcium to phosphate ratio of 1:37 (identical to that found in bone mineral) and TCP a ratio of 1:5 (Han et al 1984, Van Raemdonck et al 1984). Despite being chemically similar, TCP is not a natural component of bone and undergoes much faster bioresorption than HA. HA and TCP cannot strictly be referred to as alloplastic materials. An alloplastic material is by definition an inert foreign body used for implantation. HA and TCP, in contrast, do not have an inert relationship with their surrounding tissues and are classified as bioactive.
The clinical success of any implant depends on its biofunction, essentially the interaction between the implant’s construction, biomechanics and biocompatibility. These aspects of calcium phosphate ceramics will be dealt with in detail drawing on the excellent reviews by Jarcho 1986, Han et al 1984, Van Raemdonck et al 1984, and Frame 1987.

1.2 Preparation of calcium phosphate ceramics

The preparation of the ceramics HA and TCP involves two stages. In the first stage a powder of the correct chemical formula is produced and in the second the powder is submitted to high temperatures and pressures to create the crystal lattice structure.

1.2.1 Preparation of the powder

The powders are prepared, most commonly, from aqueous solutions of either brushite (CaHPO$_4$·2H$_2$O) or tricalcium phosphate (Ca$_3$(PO$_4$)$_2$) by either precipitation or hydrolysis at below 100°C. In the precipitation reaction the solution pH is made alkaline (pH 11-12) by the addition of concentrated ammonia (NH$_4$OH). The precipitate can then be collected and moulded while still wet.

The HA powder can by hydrolysed from calcium hydrogen orthophosphate (CaHPO$_4$) in a low concentration solution of sodium hydroxide (NaOH) over several hours at between 28 and 100°C or in 20 hours in boiling distilled water. The TCP powder can be hydrolysed from calcium orthophosphate (Ca$_3$(PO$_4$)$_2$) in an acidic solution between 40 and 80°C.

Technically the powders can also be created from nonaqueous systems by solid state reactions at above 900°C; however the products are unstable in the presence of water and this method is not applicable for biomaterials (Van Raemdonck 1984).

Both the powders created, Ca$_3$(PO$_4$)$_2$ (TCP) and Ca$_{10}$(PO$_4$)$_6$(OH)$_2$ (HA)
have an apatite crystal lattice (Klein et al 1983). $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ is physiologically stable in the presence of water and, as previously mentioned, is the inorganic component of bone. $\text{Ca}_3(\text{PO}_4)_2$, however, is physiologically unstable in the presence of water and reacts to form hydroxylapatite but

$$\text{H}_2\text{O} + 4 \text{Ca}_3(\text{PO}_4)_2 \rightarrow \text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2 + 2 \text{Ca}^{++} + 2 \text{HPO}_4^{-}$$

with defective crystal lattices (de Groot 1980). The unstable $\text{Ca}_3(\text{PO}_4)_2$ can also be referred to as the $\beta$-whitlockite phase.

### 1.2.2 Compaction and sintering

To produce a uniform crystal lattice from the powder it must be subjected to both pressure and temperature. This can be either a two or one stage technique. In the two stage technique the powder is isostatically compacted at pressures of 10 to 20 thousand p.s.i. (pounds per square inch). This creates a dense material called a 'green body' which is then subjected to temperatures between 1,000 to 1,300°C, a process called sintering. An alternative method of forming the 'green body' is to mould the wet precipitate powder, formed from the aqueous solution, into a cake of clay-like consistency. This is then dried for 15 hours at 90°C and produces a purer, denser and stonger ceramic than the compressed form (Han et al 1984).

The thermal chemistry of the calcium phosphates is extremely complex and great care must be exercised both in the preparation of the initial powders and in maintaining rigorous standardization in the production procedures. Subtle changes in the manufacturing process can result in a ceramic with unpredictable biochemical and mechanical characteristics, particularly its rate of bioresorption (Han et al 1984, Van Raemdonck et al 1984).

For example, incorrectly sintered products have weak crystal bonds
and an increased surface area leading to high resorption rates.

1.2.3 Macroporosity-chemically induced

There are two methods for preparing macroporous calcium phosphate ceramics. The first involves mixing the wet precipitate powder with a 1 to 10 per cent concentration of hydrogen peroxide solution. The mixture is then placed in a mould and allowed to dry. Oxygen is spontaneously released from the hydrogen peroxide forming macropores in the green body, which is then sintered.

The alternative and more commonly used method involves mixing the dry powder with naphthalene crystals. The mixture is compacted to produce the green body, the naphthalene then vapourised by sublimation and the residue sintered. Pore size is controlled by the size of the naphthalene particles used (Plate 4) but neither technique leads to a uniformity of interconnecting pore sizes.

1.2.4 Macroporosity - physically induced (Replamineform)

Another method of forming macroporous calcium phosphate ceramics but with uniform sized pores utilizes marine corals (genus Porites or Goniopora).

Coral taxonomy

<table>
<thead>
<tr>
<th>Kingdom:</th>
<th>Animalia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phylum:</td>
<td>Coelenterata</td>
</tr>
<tr>
<td>Class:</td>
<td>Anthozoa</td>
</tr>
<tr>
<td>Order</td>
<td>Scleractinia</td>
</tr>
<tr>
<td>Family:</td>
<td>Poritidae</td>
</tr>
<tr>
<td>Genera:</td>
<td>Porites &amp; Goniopora</td>
</tr>
</tbody>
</table>

(Holmes and Hagler 1988).

The coral can be hydrothermically converted into HA without losing the coral structure, creating a ceramic with approximate pore sizes of either 200 microns (Porites) or 500 microns (Goniopora) (White and Shors 1988) (Plate 5).

The process, called replamineform (replicated life forms) can, in fact,
A scanning electron photomicrograph of a chemically induced macroporosity (Permagraft™) (Reproduced from the Permagraft™ literature, Park Dental Research Corp.)

PLATE 5

A scanning electron photomicrograph of a physically induced macroporosity-Replamineform (Interpore. 200™ granules). The uniform size and shape of the pores is evident (Authors material, black bar = 200 microns).
reproduce the identical initial structure of the coral in materials as diverse as metals, plastic polymers or ceramics (White et al 1972). For conversion to ceramics, the organic component of the coral is first removed by decomposition using sodium hypochlorite solution. The permeability of the structure assists this decomposition. The remaining inorganic coral skeleton, which is chemically calcium carbonate (argonite), is then placed in a fluid medium of di-ammonium hydrogen orthophosphate \((\text{NH}_4)_6\text{HPO}_4\) and water for 24 hours at 300°C and 15,000 p.s.i. During this process the original calcium carbonate is completely converted to hydroxylapatite by the following chemical reaction (Han et al 1984).

\[
10\text{CaCO}_3 + 6(\text{NH}_4)_6\text{HPO}_4 + 2\text{H}_2\text{O} \rightarrow \\
\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2 + 6(\text{NH}_4)_2\text{CO}_3 + 4\text{H}_2\text{CO}_3
\]

1.3 Mechanical properties

Calcium phosphate ceramics possess considerable compressive strength, but are generally very brittle. They can therefore be inappropriate for load bearing environments where bending or twisting forces are applied. The use of granules rather than a block, however, does allow the investing bone to confer some strength and flexibility to the implant site (a situation similar to the structure of dental composite resins where inorganic particles are dispersed in an organic matrix). Porous ceramics are inherently weaker than the dense forms, relying on the ingrowth of bone for strength (Jarch 1986).

Lieblich and Topazian (1987) compared the strength of long bones augmented with either HA alone or mixed with autogenous bone. The HA alone was onlayed onto the humerus of six rabbits and the HA/bone mixture was onlayed onto the femurs of the same animals. The contralateral side served as the control.
The bones were harvested at six or 16 weeks and loaded across the long axis until fracture occurred. The humerus augmented with HA alone withstood an average of 37 per cent greater load than the control and the femur augmented with HA and bone withstood an average of 38 per cent greater load than the control. Comparisons could not be drawn between the relative strengths of the HA alone or combined with bone because of the different bones used, but both forms of augmentation were shown to strengthen the host bone. Interestingly, there was no failure under load along the implant/bone interface.

1.4 Biocompatibility (tissue response)

Calcium phosphate ceramics are the most biocompatible of all substances currently used in bone implantation. They exhibit no local or systemic toxicity, stimulate only minimal inflammatory or foreign body response, become integrated with bone without fibrous tissue encapsulation if in intimate contact and do not affect normal bone mineralization processes. Additionally they become strongly bonded to bone chemically rather than physically. This exceptional biocompatibility is a feature of all the calcium phosphate ceramics and is attributable to their calcium and phosphate composition (Jarcho 1981, Metsger et al 1982).

1.4.1 Subcellular ceramic/bone interface

The ability of calcium phosphate ceramics to bond directly to healthy bone is one of their major advantages. Osborn and Newesely (1980) determined two factors associated with the ceramic/bone interface, the first being the texture of the implant surface and the second the chemical nature of the implant, the factor they felt which dictated the host bone response. They classified implants into three groups depending on this response:

- Biotolerant materials such as stainless steel which elicited a
response of 'distant osteogenesis' indicating a soft tissue interface

- Bioinert materials such as alumina which elicited a response of 'contact osteogenesis' indicating formation of bone directly up to the implant surface

- Bioactive materials such as HA and TCP which elicited a response of 'bonding osteogenesis'. This is characterised by the osteogenesis' beginning directly on the implant surface and proceeding outwards, a physio-chemical phenomenon thatallowed for the calcium and phosphorous ions from the implant material to be included in the natural mineral metabolism.

Jarcho et al (1977) examined the cellular and subcellular aspect of the ceramic/bone interface. They implanted dense blocks and granules of HA into the cortical bone of canine femurs and showed histologically that the interface contained only normal calcified bone. They found a strong bond at the interface although the dense implants had no surface texture for mechanical attachment. They surmised, therefore, that the bond was chemical in nature. They noted also that there was an ordered perpendicular (epitaxial) deposition of bone which suggested an underlying collagen matrix with similar orientation. A further, more detailed, study by Jarcho (1978B) failed to show evidence of an underlying collagen matrix but instead observed an amorphous band of ground substance at the ceramic/bone interface with the collagen fibrils blending into this ground substance. The width of this narrow band (500 to 2,000 Angstrom) matched the width of the perpendicularly arranged bone mineral previously observed and they surmised that this ground substance could be similar to the natural bone cementing substance which is generally amorphous in structure and rich in mucopolysaccharides. They concluded that the bone/ceramic interface consists of an orderly array of bone mineral devoid of collagen fibres and is similar in nature to bone cementing substance.
1.4.2 Cellular ceramic/bone interface

The host tissue response to an implant is most critical at the cellular level. The clinical prognosis of a material can be determined by the degree of immune response it generates, which in turn is often indicated by the number of foreign body giant cells present. The other important factor for bone replacement materials is the necessity for them to interact favourably with both the organic and inorganic components of bone. In a clinical context this is usually evidenced by whether the host bone embraces the implant or whether connective tissue intervenes at the implant/bone interface (Plates 6 and 7).

Chang et al (1983) showed that when HA was placed as a subperiosteal onlay on canine mandibles there was a gradual increase in bone around the granules closest to the bone surface. Bone formed within three months when the granules were placed on a surface from which the cortex had been removed, but took six months when granules were placed on a surface with cortex intact. Tetracycline staining confirmed that it was new bone which was found in direct contact with the granule surfaces. Unfortunately, no bone was evident adjacent to the granules placed more distantly from the bone surface, instead they were encased in dense connective tissue. This suggested that proximity of the implant to osteoprogenitor cells is essential for the early initiation of ossification.

Gumaer et al (1986) conducted a long term histological assessment of both HA granules and dense blocks placed within defects created in the femurs of 18 dogs. Specimens taken after six and eight years showed both the granules and blocks encased in dense mature bone. Only on the periphery of the granules close to periosteum was there evidence of connective tissue and giant cells, whose presence suggests the potential for implant resorption.

Following the clinical application of HA granules and blocks for ridge augmentation, histological analysis of human biopsy specimens became
PLATE 6

A histological section of the bone/HA implant (I) interface in a rat femur, 120 days following implantation. Woven bone (B) is in close apposition to the implant surface with no intervening fibrous tissue. Healthy osteocytes can be seen close to the interface. (Authors material, Schmorl's stain, original magnification x 400).

PLATE 7

A histological section showing irregular HA granules (G) surrounded by bone, 120 days following implantation into a rat femur. Woven bone (B) is seen to surround the granules and to separate them from the overlying periosteum (P) with which the granules were in contact following implantation. The osteophilic and osteoconductive nature of HA is therefore demonstrated with the periosteally derived bone (PB) being formed in preference to fibrous infiltration. (Author's material, haematoxylin and eosin stain, original magnification x 100).
available. Biopsies are usually taken at the time of secondary procedures such as vestibuloplasty.

Beirne and Greenspan (1988) analysed biopsy material taken from four female patients who had undergone mandibular augmentation with HA granules alone up to six months previously. In each case the sample was taken from the superior border of the augmented ridge (furthest from the HA/bone interface). All specimens showed the same mild inflammatory response with the granules being surrounded by fibrous connective tissue. There was no evidence of bone adjacent to the granules in any specimen. A fifth patient (Beirne et al 1988) showed similar findings.

Chao and Poon (1987) took the opportunity to biopsy material close to the HA/bone interface while decompressing a mental nerve in one case and while removing ectopically placed granules in a second. The first biopsy, performed five months postaugmentation, showed loose connective tissue and new bone between the granules. In the second case, biopsied one year postaugmentation, the loose fibrous tissue had been replaced by mature lamellar bone directly adjacent to the implant surface. They did not biopsy the superior aspects of the ridges but noted that clinically the superficial granules appeared to be surrounded by fibrous tissue and were easily detached. These findings support the observations of Beirne and Greenspan (1985) that new bone formation is a product solely of the bone surface and not of the periosteum. A similar observation of new bone formation around deeply placed granules with fibrous tissue encircling the more superficial granules was reported by Page and Laskin (1987), who biopsied a single case 10 months postaugmentation.

The pattern of bone growth around a porous implant differs from that around a non-porous one. Shimazaki and Mooney (1986) compared the percentage bone ingrowth into three different types of porous blocks, two of HA with pore sizes of 200 and 500 microns and one of TCP with a pore size of 200 microns. Twenty four weeks following implantation into the tibias of
rabbits the percentage of bone in the pores varied from 56 per cent in the 500 micron HA to 52 per cent in the 200 micron HA to 45 per cent in the TCP block. It was also evident that the bone and vascular tissue advanced into the larger pores earlier than the smaller.

Little clinical data is available of bone ingrowth into porous blocks. Tio et al (1987) reported on two cases where they had access to biopsy specimens following augmentation with porous HA blocks. In one case, where the block had to be removed due to infection after one week, they showed growth of mesenchymal tissue into the peripheral pores with a fibrinous exudate occupying the more central pores. Not surprisingly, there was no evidence of ossification. In the second sample, removed 6 months postaugmentation, new bone was evident in the peripheral pores with further centres of ossification throughout the pore structure. However, on analysis the bone only occupied 18 per cent of the available pore space, the remaining space being filled by mesenchymal tissue. What bone was present had a trabecular pattern resembling cancellous bone and was woven in nature.

The use of HA combined with autogenous bone has been advocated as a method of achieving an increase in bone formation among the granules at the expense of fibrous connective tissue. However the technique does require a host donor site and ridges augmented with HA and autogenous bone mix have been shown to have a slightly increased degree of relapse compared with ridges augmented with HA alone (Kent et al 1983).

Block and Kent (1985) compared histologically canine mandibular sites augmented either with HA alone or HA and autogenous bone. Using nine dogs, they placed HA alone in one quadrant and HA mixed with autogenous cancellous bone (iliac crest) in the other quadrant. At 16 weeks new bone extended only 1-2mm into the HA alone sites but in the HA and bone sites active lamellar bone with Haversian systems was evident throughout the augmented ridge. There was also an increase in the vascular tissue
extending into the areas augmented with HA and bone. Areas of ossification isolated from the underlying bone also indicated that the grafted bone actively induced osteogenesis. Interestingly, the resulting ridges were clinically similar, both being firm and stable. They concluded that, where practical, the combination of HA and bone would be advantageous. These results were confirmed clinically by Gongloff (1986C) and Berger (1985) who showed new bone throughout ridges of three patients previously augmented with HA and autogenous bone.

Gongloff's more extensive study involved biopsies from 20 ridges augmented either with HA alone or HA and autogenous bone packed in collagen tubes. In the cases where the HA had been used alone the only new bone formation was directly at the HA/bone interface but where the HA and autogenous bone mix had been used new lamellar bone was present throughout the augmented area.

It is evident from these studies that new bone can be induced to cover granules or grow into the pores of HA blocks where they are in close apposition to the bone surface. However HA has no capacity to stimulate bone formation and the periosteum also does not appear to participate in new bone formation in these circumstances. To achieve bony rather than fibrous ingrowth in the more superficial aspects of an augmented area the HA needs to be combined with autogenous bone. This however negates some of the advantage of using this material, as a donor site is then required. Possibly the combination of HA and bone morphogenic protein (BMP) could be a solution.

1.4.3 Osteogenic stimulation

The ideal bone replacement material should be able to induce bone formation, either acting as a catalyst (remaining unchanged) or being slowly replaced by new bone. This osteogenic stimulation is partially achieved by autogenous cancellous or cortical bone but not, as yet, by alloplastic
materials. Boyne (1985) discussed the potential for bone replacement grafts to stimulate osteogenesis. He identified two lines of research: the development of an autogenous or allogeneous osteogenic material and the development of a bioacceptable osteophilic alloplastic material without osteogenic potential (solely a filling material).

Initially it was hoped that one material would be able to fulfil both the roles of inducing bone formation and filler. Some early work was encouraging. Albee and Morrison (1920) used a tricalcium phosphate slurry to investigate its potential for osteogenic stimulation. They placed the material either into defects created by the resection of part of the radius in rabbits or around artificially created fractures at the same site. They established the material’s biocompatibility and noted in both situations accelerated union when compared to non-implanted control sites, evidence, they felt, that showed the material stimulated osteogenesis.

Further research by others appeared to both prove and disprove this capacity for osteogenesis but unfortunately it is not always possible for the reader to identify exactly the calcium phosphate ceramic used, making comparisons or conclusions difficult. Ray and Ward (1952), for example, investigated the healing response to a 'synthetic' hydroxylapatite placed in bone defects created in an array of animals. The material was found to be biocompatible as the HA crystals were incorporated into the bone matrix but there was no evidence of induced bone formation. They concluded that the material played an inert role as a filler but healing, although slightly faster than in the control sites, was slower than when autogenous cancellous chips were used.

It is now clear that none of the calcium phosphate ceramics stimulate osteogenesis. They do not induce bone formation at sites away from bone (Chang et al 1983) and they do not increase the rate of bone growth (Piecuch 1982, McDavid et al 1979). However, they do have the ability to extend host bone calcification onto the implant surface from the recipient bone surface,
the bone growing over the implant in direct apposition. Boyne (1988) and Jarcho (1988) both used the terms osteoconductive and osteophilic (bone loving) to describe this characteristic of the calcium phosphate ceramics.

The osteogenic potential of autogenous bone is well known and its combination with ceramics has been shown to provide an osteogenic source to complement HA (Block and Kent 1985). Work by Urist and Strates (1971) and Urist et al (1978) has identified this osteogenic factor present in bone. They showed that acellular, devitalised and decalcified bone matrix contained a bone morphogenetic protein (BMP) which stimulated undifferentiated host cells to become osteogenic. Following implantation this matrix is resorbed and replaced by connective tissue. Certain undifferentiated cells in this replacement tissue then differentiated into osteoblasts and within 16 weeks some new bone had formed in 90 per cent of the grafted sites, even in non-bony sites such as muscle. Histologically, stem cells, osteoprogenitor cells and capillaries can be observed surrounded by osteoblasts. This osteogenic process, however, is very slow and more recently Urist et al (1984) have shown that BMP combined with TCP resulted in a twelve-fold increase in bone formation compared with the BMP matrix alone.

The finding of increased bone formation using a combination of BMP and calcium phosphate ceramic received support from Kaban et al (1985). They initially used BMP alone for ridge augmentation but found it took 10 months before the ridge was firm enough to bear a denture. The BMP was then mixed with autogenous bone or HA and the ridge became firm enough to accept a denture after three months.

Lattanzi and McCormick (1986) also found that a mixture of HA and BMP in the form of autolysed antigen-extracted allogenic bone (AAA) stimulated osteogenesis. They noted that the granules became totally encased in new bone within 30 weeks when the mixture was placed subperiosteally on rat calvaria.

This combination of an osteogenic substance (BMP) and an osteophilic
filler (HA) could ultimately become the ideal graft material, combining the two lines of research as outlined by Boyne (1985) and reducing drastically the need to harvest autogenous bone.

1.4.4 Ceramic/soft tissue interface

Calcium phosphate ceramics are well tolerated by soft tissue. Cameron et al (1977) placed TCP subcutaneously and intramuscularly in 12 dogs to test possible toxicity. After serum calcium and phosphorus levels were monitored and histological specimens examined, they concluded that the local tissue reaction was extremely benign with only the very occasional foreign body giant cell. A similar result using TCP was found by Ferraro (1979) when he placed the material in subcutaneous pockets. He also monitored the calcium and phosphorus serum levels and showed no abnormal rise during the period of implantation.

Drobeck et al (1984) studied the histological response of soft tissue to implanted granules and discs of dense HA in both rats and beagle dogs. They found no inflammatory response in either animal irrespective of implant shape. Both granules and discs were surrounded by fibrous capsules with a capillary rich matrix between the granules. They felt that these intergranular areas could act as revascularisation sites following augmentation and concluded that HA implanted subcutaneously produced little or no inflammatory response and is biocompatible irrespective of the implant shape.

Misiek et al (1984) also studied the soft tissue response to sharp or smooth dense HA granules. Using beagle dogs, they found that both shapes excited a mild inflammatory response which took longer to resolve around the sharp edged granules than the smooth. They felt that this could be important in a situation where the materials were onlaid, as the resulting inflammatory response could affect the incorporation of the granules into bone and enhance the possibility of dehiscence of the overlying mucosa.

This potential problem has not been apparent in clinical studies and
conversely it has been hypothesised that round granules have a greater ability to migrate. Both forms of granule have also been found to settle over time (Block and Kent 1984). It therefore appears that the surface shape of dense granules has no effect on clinical prognosis (Plates 8 and 9).

1.4.5 Porous ceramics and tissue ingrowth

Pore size is critical to successful bone ingrowth. Trabeculae of bone vary in size from 20 microns to over 100 microns, with trabeculae over 100 microns containing blood vessels. In compact bone the Haversian systems are between 50 microns and 250 microns. A porous implant therefore would need pores of 30 microns to 40 microns to support trabecular bone ingrowth and up to 200 microns to support compact bone ingrowth (Han et al 1984).

The interconnecting pore structure is also important as uninterrupted and unconstricted connection between the pores is required for bone ingrowth and to avoid dead space. The correct pore size with only small interconnecting pores hinders total bone ingrowth.

Provided a porous implant is stable and no interface movement occurs, ingrowth of bone into the pores is rapid. Cameron et al (1977), using a porous ceramic in the femurs of 12 dogs, showed bone forming around the implant after two weeks, within the periphery of the implant at three weeks, completely infiltrating the implant by four weeks and completely filling the pores by six weeks. Holmes (1979) placed replamineform HA implants into mandibular defects in dogs and noted an 11 per cent ingrowth of bone at two months, 46 per cent at four months and 88 per cent at six months, the initial woven bone changing to lamellar bone within the six months. A more recent study (Holmes and Roser 1987) supports this early work. Ten dogs received bilateral mandibular implants either of porous HA blocks or bicortical iliac crest autogenous grafts. The specimens were placed in surgically created ridge defects and retrieved at 11 and 17 months. Both types of implant united to the host bone but bone ingrowth was substantially
PLATE 9

A scanning electron photomicrograph of dense, smooth HA granules (Calcitite™ 2040). (Author's material, black bar = 400 microns).
greater and better vascularized in the HA blocks when compared with the autogenous grafts. Computer analysis of histological specimens showed the HA matrix to cover an average of 43 per cent of the total implant area, with the bone and soft tissue occupying the pores covering 45 and 12 per cent of the total area respectively. Ninety one per cent of the total implant surface was covered by new bone and this percentage did not diminish with time. Unfortunately they could not produce comparable data from the autogenous graft sites because of the difficulty of differentiating the original graft from the new bone. While acknowledging these impressive results, Holmes and Roser conceded that the grafts inserted were more like inlays rather than onlays and thus did not truly mimic an onlay augmentation procedure.

Finn et al (1980) also used porous HA blocks to augment the mandibles of nine dogs previously rendered edentulous. They chose a bilateral inlay osteotomy technique with cortico-cancellous bone being placed on one side and the blocks on the other. The animals were sacrificed over a period of 40 weeks and studied radiographically and histologically. Within two weeks connective tissue filled the pores, with woven bone and osteoid becoming apparent by three months. This remodelled to a lamellar pattern with the quantity approximately that of the autogenous graft site. Unfortunately the ridge crest and inlayed block in the final specimen (40 weeks) had moved creating minimal contact with the basal bone, so reducing the ability of new bone to infiltrate and allowing the pores to become filled with connective tissue.

Atkinson et al (1984) used porous HA as immediate root implants in guinea-pigs. They demonstrated fibrous and bony ingrowth within four weeks, the fibrous tissue occupied the 25-30 micron pores but bone only occurred in pores larger than 100 microns. The bone ingrowth reached a maximum by 12 weeks, never totally filling the available pores.

Hoogendoorn et al (1984) placed porous HA blocks into surgically created defects in the femurs of 14 dogs, the dogs being sacrificed in stages
up to three and a half years. At sixteen weeks bone growth into the implant was only at a very early stage when compared with an un-implanted defect which had almost completely filled with new bone. Bone ingrowth reached a maximum after 35 weeks with only about one third of the available pores occupied by bone.

Piecuch et al (1983) used 54 replamineform HA blocks to bilaterally augment surgically created atrophic ridges in 25 beagle dogs. The results were then evaluated clinically, radiographically and histologically over two years. Of the initial 24 implants 62.5 per cent were lost due to direct trauma from a hard diet. A change to a softer diet decreased subsequent losses to 16.5 per cent. An increase in block density, indicative of bone deposition was identified radiographically at six months, reaching a uniform density similar to the adjacent cortical plate by 18 months. There was no evidence of underlying bone resorption. Ingrowth of bone into the pores was demonstrated histologically at six weeks but was variable in amount. By 18 months dense bone had replaced most of the connective tissue which had initially filled the pores. Three implants showed no bone ingrowth at all, being separated by a thin layer of connective tissue from making contact with the cortical bone surface. Piecuch and colleagues expressed concern with the slow pattern of bone ingrowth and the crushing of non-infiltrated areas when the animals were returned to a solid diet, even after 18 months. This indicated, they felt, that a delay would be necessary before denture construction could be commenced if this material were used for augmentation in humans. This slow pattern of bone ingrowth and the potential of non-infiltrated areas to be crushed under masticatory forces have not been apparent clinically. If the blocks do not dehisce or become infected, dentures can be constructed after six to 10 weeks with no complications (Piecuch 1986). Jarcho (1986) explained the slow rate of bone penetration into porous blocks on the supposition of "unnatural" pore pathways. He compared this reluctance of bone to infiltrate with the free flowing growth
seen over the surface of dense, discrete granules.

There is no doubt that bone will grow into the pores of a ceramic implant but only at a rate and to an extent that is obviously dependent on unknown factors. One of these factors could be the phenomenon of stress shielding.

Bone exists in a dynamic state. It responds to physiological stress by remodelling, bone being deposited at the stress sites and resorbed in areas away from the stress. Theoretically, the porous implant protects the intraporous bone from the effects of stress and this 'stress shielding' can create an abnormal osteoporotic reaction. Pilliar et al (1979) screwed two types of metal plates (one with a porous surface, one without) onto the femurs of three dogs. Initial bone ingrowth into the porous surface was demonstrated but subsequently this bone underwent undesirable changes with intracortical porosity and resorption taking place, effects Pilliar et al attributed to stress shielding.

The long term results with porous HA achieved by Hoogendoorn et al (1984) and Piecuch et al (1983) could be a demonstration of this effect. The ingrowing bone has no physiological stimulation to continue penetration of the pores so leaving central areas of the implant unfilled. With the research spanning many animal groups it is not possible to assess the outcome in a clinical situation but the isolated cases of Tio et al (1987) mentioned in section 1.4.2 support the fact that only peripheral ingrowth occurs.

Whether or not this lack of ingrowth occurs because of stress shielding, the unfilled pores are a potential site for infection. Unfilled pores are, in effect, surgically created dead space and an ideal environment for bacterial proliferation which can be only poorly penetrated by either the immune system or systemic antibiotics. The high rate of infection (21 percent) following augmentation with blocks would seem to support this (Rooney et al 1988).

A crucial factor associated with the onset of infection appears to be
the time between the placement of the implant and any subsequent
dehiscence. Early dehiscence prior to connective tissue ingrowth allows the
pore system to become contaminated. Later exposure following connective
tissue ingrowth has a better prognosis as infection cannot penetrate the block
and local measures, such as reduction of the block to allow soft tissue
coverage, are appropriate (Piecuch 1986). It is therefore mandatory to
maintain any patient who has received a porous HA block on antibiotic
therapy for at least one month, by which time the pores should be totally
infiltrated by connective tissue.

1.4.6 Bioresorption

Philosophically, the concept of an implant material which is slowly
resorbed and replaced by host tissue is most appealing. However, the
biocompatibility of the breakdown products generated by this resorption adds
an important dimension. The factors which determine the rate and extent of
the resorption of calcium phosphate ceramics are still not fully understood.
Certainly the chemical composition of the material and its structure are
important.

Resorption appears to be initiated in two different ways. One involves
chemical dissolution in the biological fluids and the other a cell mediated
response with phagocytosis of ceramic particles taking place (Jarcho 1981).

Jarcho (1978A) showed that TCP is more readily dissolved than HA in
various fluid media. He further showed (Jarcho 1981) that when TCP and HA
preparations, similarly pure, dense and with the same ceramic microstructure,
were compared the TCP dissolved twelve times faster in acid solution and
twenty two times faster in alkaline solution. He conjectured that the
resorption rate was proportional to the TCP content of the ceramic and that
the higher the HA content the slower the resorption.

De Groot (1980) felt that the resorption rate could not be explained on
the basis of the calcium-phosphate ratios alone. He proposed .that
bioresorption was more determined by the structural characteristics of the material, particularly the density and microporosity. High density ceramics possess a much smaller surface area in proportion to mass than porous ones. Microporosity is created when individual particles of the ceramic do not fuse during the sintering process (Plate 10). These isolated particles are more vulnerable both to dissolution by fluid and to cellular phagocytosis. This second aspect was supported by Bhaskar et al (1971) who showed that during the early stages of healing within a calcium phosphate ceramic there was pronounced phagocytosis of small ceramic particles with some ceramic-containing vesicles occupying at least one third of the phagocytes volume. In contrast, pure, dense HA is almost without pores of any kind (Plate 11) and resorption over a period of time appears to be negligible.

Mors and Kaminski (1975), after studying resorption rates of TCP placed in surgically created palatal clefts in dogs, tentatively concluded that the differing rates of bioresorption could also be attributed to factors such as the vascularity of the surrounding tissue, the more vascular the greater the resorption rate.

It appears that, irrespective of whether the ceramic is HA or TCP, if the material has a highly crystalline structure and large material density it will be poorly resorbed. However, if the HA or TCP is porous, has an amorphous structure and a large surface area there will be more rapid resorption of TCP in comparison with HA.

Clear in vivo evidence of the resorption rates of TCP and HA are presently unavailable. For example, there has been conflicting evidence associated with the resorption rate of implanted TCP. Levin et al (1974) demonstrated total resorption of TCP placed in artificially created periodontal defects in dogs within 22 weeks whereas Ferraro (1979), also using dogs, showed evidence of TCP still present 18 months after implantation.

The evidence of dense HA resorption rates is clearer, with most studies agreeing that the rate is negligible, about 1 per cent a year.
PLATE 10

A scanning electron photomicrograph of a TCP granule surface. The microporosity associated with incomplete fusion of the individual crystals is evident. This increases the implants surface area and its potential for being resorbed by phagocytosis and chemical dissolution. (Author's material, black bar = 10 microns).

PLATE 11

A scanning electron photomicrograph of a dense HA granule surface. The lack of micro and macroporosity is evident. The boundaries of the individual crystals fused during manufacture can be identified. (Author's material, black bar = 10 microns).
However, significant resorption rates of porous HA have also been demonstrated. Holmes (1979) notes resorption of 29 per cent in two porous implants 12 months after implantation into canine mandibular defects.

Cutright et al (1972) recorded a rapid resorption rate of TCP blocks placed within the tibia of rats. The implants had visibly decreased at two weeks, the defect being filled directly by bone. By six weeks approximately 80 per cent of the TCP had disappeared and by seven weeks 95 per cent. They theorized that the mineral salts liberated from the TCP could be used to form new bone at the site.

Renooij et al (1985) radioactively labelled blocks of HA and TCP to trace the resorption products. They placed labelled HA and TCP into surgically created canine femoral defects. The radioactivity was measured in vivo for 22 weeks and the specimens retrieved after either 25 or 55 weeks. The HA blocks showed no resorption but by 22 weeks 25-30 per cent of the TCP had resorbed. The resulting radiolabelled products were located in both mononuclear phagocytes and multinuclear cells resembling osteoclasts. Renooij et al felt, like Cutright et al, that these osteoclast-like cells would synthesise the TCP compounds into natural hydroxylapatite; however they could demonstrate no conclusive evidence of this.

Klein et al (1983) investigated the resorption of a range of HA and TCP materials. Porosity, green body preparation and sintering temperature were all altered to give 10 different materials. The materials in groups of three were then implanted into the tibiae of 33 rabbits. The animals were sacrificed at 3, 6 and 9 months and the degrees of resorption were measured by radiography, microscopy and porosity measurements. They found the whole range of materials biocompatible and osteophilic, with bone around the HA products being both more compact and entering the implant pores more readily than around the TCP products. The porous TCP exhibited marked resorption while no resorption of the porous HA was detectable. They concluded that the rate of resorption was a product of both macro and
microporosity.

Shimazaki and Mooney (1985) compared two forms of porous HA blocks with a TCP block. The HA either had pore sizes of approximately 500 microns (genus *Goniopora*) or 200 microns (genus *Porites*). The three materials were implanted into defects in the tibias of rabbits and harvested over a period of 24 weeks. By 24 weeks 46.4 per cent of the TCP had resorbed; the *Goniopora* HA showed no resorption but the *Porites* HA had resorbed 27 per cent. They related this difference to the earlier ingrowth of new bone which occurred in the material with the larger pore size (section 1.4.2.). The bone overlying the implant acts as a shield from the resorption mechanisms. It is also true that the larger the pores of a block the less the surface area, therefore the less the number of crystals on the implant surface and the less the resorption rate.

The many factors that influence bioresorption make both definitive experiments and drawing conclusions difficult. The consensus appears to be that the calcium-phosphate ratio, the micro and macroporosity and certain environmental factors all play a part, that HA resorbs at about one per cent a year and TCP resorbs at a rate up to 20 times that of HA.

1.5 Summary

Table 5 has been formulated in an attempt to clarify the data concerning the preparation, physical properties and biocompatibility of calcium phosphate ceramics.
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HA</th>
<th>TCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical formula</td>
<td>Ca₁₀(PO₄)₆(OH)₂</td>
<td>Ca₃(PO₄)₂</td>
</tr>
<tr>
<td>Ca/P ratio</td>
<td>1:37</td>
<td>1:5</td>
</tr>
<tr>
<td>Present in bone</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Preparation</td>
<td>1) Formulate powder</td>
<td>2) Compact and sinter</td>
</tr>
<tr>
<td>Microporosity</td>
<td>Dependant on sintering process</td>
<td></td>
</tr>
<tr>
<td>Macroporosity</td>
<td>Chemical</td>
<td>Chemical</td>
</tr>
<tr>
<td></td>
<td>Physical (Replamineform)</td>
<td></td>
</tr>
<tr>
<td>Morphology</td>
<td>Blocks</td>
<td>Blocks</td>
</tr>
<tr>
<td></td>
<td>Granules - Smooth</td>
<td>Granules</td>
</tr>
<tr>
<td></td>
<td>- Irregular</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(dense or macroporous)</td>
<td>(microporous)</td>
</tr>
<tr>
<td>Mechanical properties</td>
<td>Brittle but good compressive strength</td>
<td></td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Bioactive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(interchange of Ca + P ions with bone)</td>
<td></td>
</tr>
<tr>
<td>Interface</td>
<td>Lamellar bone</td>
<td></td>
</tr>
<tr>
<td>- Bone</td>
<td>Fibrous tissue with minimal giant cells</td>
<td></td>
</tr>
<tr>
<td>- Soft tissue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteogenic potential</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>(osteophilic, osteoconductive)</td>
<td></td>
</tr>
<tr>
<td>Bioresorption rate</td>
<td>&lt; 1</td>
<td>≤ 20</td>
</tr>
<tr>
<td>(per cent, per year)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2. CLINICAL APPLICATIONS

From the osteological point of view, hydroxylapatite ceramic could be termed the ideal implant material.


The realisation that calcium phosphate ceramics are acceptable bone replacement materials has led to their clinical application in a diverse range of procedures in oral and maxillofacial surgery. It is interesting that the potential of these ceramics has been realised in the oral and circumoral region rather more than elsewhere in the body, although ceramics have also been used to effect in areas such as the ear (Van Blitterwijk et al 1983), trachea (Onishi et al 1988) and in orthopaedics.

Commercially, HA is produced in blocks and granules; TCP being only available in granules. Table 6 lists the products currently available, the most widely used and researched being non-porous granules (Calcitek\textsuperscript{TM} - Calcitek, Inc., Alveograft\textsuperscript{R} - Cook Waite) and macroporous granules and blocks (Interpore\textsuperscript{TM} - Interpore International).

Table 7 summarises the surgical applications for which the various forms of HA and TCP can be utilised. HA and TCP used purely as onlay grafts for atrophic alveolar ridge augmentation will be covered in Chapter V, discussion being limited in this section to their other maxillofacial applications:

- Root implants.
- Periodontal surgery.
- Dentate ridge augmentation.
- Augmentation osteotomies.
- Combined onlay augmentation.
- Orthognathic and reconstructive surgery.
<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Granule (G)</th>
<th>Block (B)</th>
<th>Size (M = mesh)</th>
<th>Resorbable (R) Non-resorbable (NR)</th>
<th>Macroporosity Porous (P) Non-porous (NP)</th>
<th>Particle shape Smooth (S) Irregular (IR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcitek™ 2060</td>
<td>G</td>
<td></td>
<td>0.2-0.4 mm 40-60 M</td>
<td>NR (HA)</td>
<td>NP</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.4-0.8 mm 20-40 M</td>
<td>NR (HA)</td>
<td>NP</td>
<td>S</td>
</tr>
<tr>
<td>Calcitite™ RM</td>
<td>B</td>
<td></td>
<td>Root implant</td>
<td>NR (HA)</td>
<td>NP</td>
<td>S</td>
</tr>
<tr>
<td>Calcitite™ Orthoblocks</td>
<td>B</td>
<td></td>
<td>Textured (Waffled) 0.5 mm depressions</td>
<td>NR (HA)</td>
<td>NP</td>
<td>S</td>
</tr>
<tr>
<td>Alveograft™</td>
<td>G</td>
<td></td>
<td>0.4-0.8 mm 18-40 M</td>
<td>NR (HA)</td>
<td>NP</td>
<td>IR</td>
</tr>
<tr>
<td>Periograft™</td>
<td>G</td>
<td></td>
<td>0.2-0.4 mm 40-60 M</td>
<td>NR (HA)</td>
<td>NP</td>
<td>IR</td>
</tr>
<tr>
<td>HA-1000™</td>
<td>G</td>
<td></td>
<td>0.42-0.84 mm 20-40 M</td>
<td>NR (HA)</td>
<td>?</td>
<td>S</td>
</tr>
<tr>
<td>Interpore 200™</td>
<td>G</td>
<td></td>
<td>0.45-1 mm up to 5x1.5x1.0cms</td>
<td>NR (HA)</td>
<td>P 0.2 mm</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td></td>
<td>up to 5x1.5x1.0cms</td>
<td>NR (HA)</td>
<td>P 0.2 mm</td>
<td>S</td>
</tr>
<tr>
<td>Interpore 600™</td>
<td>G</td>
<td></td>
<td>0.45-1 mm</td>
<td>NR (HA)</td>
<td>P 0.2 mm</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td></td>
<td>up to 5x1.5x1.0cms</td>
<td>NR (HA)</td>
<td>P 0.5 mm</td>
<td>S</td>
</tr>
<tr>
<td>Permagraft™</td>
<td>G</td>
<td></td>
<td>0.45-1 mm 18-40 M</td>
<td>NR (HA)</td>
<td>P 0.2 mm</td>
<td>IR (continued)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(continued)</td>
</tr>
<tr>
<td>Trade Name</td>
<td>Granule (G)</td>
<td>Size</td>
<td>Resorbable (R)</td>
<td>Porous (P)</td>
<td>Smooth (S)</td>
<td></td>
</tr>
<tr>
<td>----------------------------</td>
<td>-------------</td>
<td>-----------</td>
<td>----------------</td>
<td>------------</td>
<td>------------</td>
<td></td>
</tr>
<tr>
<td>Allotropat&lt;sup&gt;R&lt;/sup&gt; 25</td>
<td>G</td>
<td>35-60 M</td>
<td>NR (HA)</td>
<td>NP</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>Allotropat&lt;sup&gt;R&lt;/sup&gt; 50</td>
<td>G</td>
<td>18-36 M</td>
<td>NR (HA)</td>
<td>NP</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>Synthograft&lt;sup&gt;TM&lt;/sup&gt;</td>
<td>G</td>
<td>0.15-0.42 mm</td>
<td>R (TCP)</td>
<td>NP</td>
<td>IR</td>
<td></td>
</tr>
<tr>
<td>Augmen&lt;sup&gt;TM&lt;/sup&gt;</td>
<td>G</td>
<td>18-40 M</td>
<td>R (TCP)</td>
<td>P</td>
<td>IR</td>
<td></td>
</tr>
<tr>
<td>Osteogen&lt;sup&gt;R&lt;/sup&gt; (HA Resorb)&lt;sup&gt;TM&lt;/sup&gt;</td>
<td>G</td>
<td>0.3-0.4 mm</td>
<td>R (HA)</td>
<td>NP</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>Integral&lt;sup&gt;R&lt;/sup&gt;</td>
<td>Titanium, HA coated implant</td>
<td>NR (HA)</td>
<td>NP</td>
<td>?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ceros&lt;sup&gt;R&lt;/sup&gt; 80 (HA)</td>
<td>G</td>
<td>0.2-5.6 mm</td>
<td>NR (HA)</td>
<td>P 0.2-0.8 mm</td>
<td>IR</td>
<td></td>
</tr>
<tr>
<td>Ceros&lt;sup&gt;R&lt;/sup&gt; 82 (TCP)</td>
<td>G</td>
<td>0.2-5.6 mm</td>
<td>R (TCP)</td>
<td>P 0.2-0.8 mm</td>
<td>IR</td>
<td></td>
</tr>
<tr>
<td>Ostilit&lt;sup&gt;R&lt;/sup&gt;</td>
<td>G</td>
<td>1-2.5 mm</td>
<td>R (TCP)</td>
<td>?</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>1 x 2 x 3 cms</td>
<td>R (TCP)</td>
<td>?</td>
<td>?</td>
<td></td>
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* See Appendix I for company names.
<table>
<thead>
<tr>
<th>Clinical indication</th>
<th>Granules</th>
<th></th>
<th>Blocks</th>
<th></th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Solid</td>
<td>Porous</td>
<td>Solid</td>
<td>Porous</td>
</tr>
<tr>
<td>Extraction sockets</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
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<tr>
<td>Intrabony pathological defects</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Atrophic ridge onlay augmentation</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Interpositional grafts (osteotomies)</td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Facial augmentations</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Reconstruction of bone discontinuity</td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Intrabony periodontal lesions</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Maxillary clefts</td>
<td>x</td>
<td>x</td>
<td>(TCP preferred)</td>
<td></td>
</tr>
</tbody>
</table>

\[x = \text{Indicated}\]
2.1 Root implants

The realisation that non-infected retained roots and decoronated vital roots maintained alveolar ridge height and width was the origin for the HA root implant concept. The possibility of retarding ridge resorption by placing dense root-shaped HA blocks into extraction sockets has far-reaching potential for prosthetic treatment planning. Boyne (1988) identified the concept as an important area of alveolar bone research.

Initial research by Denissen and de Groot (1979), using dense HA root implants in dogs, produced favourable results and led to a clinical trial where 100 implants were placed in the extraction sockets of 10 patients. After one year no complications or loss of implants were recorded. A five year evaluation by Veldhuis et al (1984) of this original group, in conjunction with a further 112 implants placed in 14 patients, found that two implants had been lost with 30 per cent of the implants showing some dehiscence over the five years. Dehiscences were treated by reduction of the implant and closing the mucosa. Veldhuis et al made no direct measurements of height loss but concluded that the non-dehiscence observed in the remaining 70 per cent of the implants showed that height loss due to resorption must have stopped when the bone reached the implant surface. Without supporting evidence of direct measurement of bone loss, this conclusion must be regarded as unproven.

Quinn et al (1985) placed 92 dense HA implants in 49 patients and reviewed their progress for up to 31 months. Both maxillary and mandibular sockets were used with contralateral sockets acting as controls. Dentures were made immediately following socket healing. Mucosal tattoos were placed to assess resorption measurement but in seven patients (11 implants)
the tattoos were not visible at follow-up and these patients had to be excluded from the results. They found, despite the short follow-up time, that the width and height of the ridges on the implanted side were approximately twice that of the non-implanted side.

Kangvonkit et al (1988) achieved similar short term results after placing 96 implants in the anterior mandibles of 30 patients. Six implants were lost and 17 showed dehiscence. They demonstrated a mean resorption of 1.4mm in the implant group and 4.2mm in an unimplanted control group.

Kwon et al (1988) had less success with the technique. They placed 70 dense HA root implants in 10 patients, dentures being constructed following socket healing. At review between one and two years later, 37 implants (33 per cent) had dehisced and 19 (27 per cent) had been removed, one patient losing eight of nine root implants placed. Neither did they find any less of a decrease in mandibular bone height when statistically compared with a control group. They concluded that the root implants did not preserve alveolar bone height.

Brook et al (1988) also showed poor short term results. They placed 81 root implants in the mandibular region of 21 patients. Immediate dentures were placed and the patients reviewed after one year. They noted an overall loss of 15 implants (20 per cent) with the highest proportion (12) being lost from the canine sockets. They attributed this to canine root morphology making a tight fit for the root implant difficult. No comparison of resorption rates was made.

The difficulty of fitting solid root implants was addressed by Bell (1988) who compared the use of dense HA root implants with dense HA granules when placed in the extraction sockets of patients. The granules were found to be easier to place clinically as selecting, trimming and fitting the root implant was time consuming. Neither did the granules cause any of the postoperative problems such as prominence or dehiscence experienced with the blocks.
Block and Kent (1986) also compared the use of granules and solid root implants. They created a total of 40 extraction sites in five dogs. The granules and root implants were each then placed unilaterally in alternate sockets, the intervening sockets being left empty. Measurements of the ridge were then made over a period of 18 months and histological specimens collected at one, three and 18 months. They found neither material prevented alveolar ridge resorption, any height preserved being due to the prominence of the implant itself. Sockets implanted with granules retained a height 2-3mm greater than the root implant sockets which was attributed to the fact that the sockets could be totally filled with granules whereas the root implants had to be placed 2-3mm below the ridge crest. They concluded that neither form of HA preserved alveolar bone and conjectured that this could be because the material did not transmit to the bone any stimulating force as the HA was only indirectly loaded. However this theory does not explain the retention of alveolar bone around a buried root fragment which also does not transmit any stimulating forces.

More long term results of this technique are awaited. The concept of ridge preservation using HA is very exciting and would have important implications for the treatment planning of extractions and immediate dentures if the hopes for the technique are realised. The rate of dehiscence, however, indicates that bone resorption is continuing despite the presence of the implants, particularly from the buccal surface where resorption initially starts. Denissen et al (1985) concluded that HA root implants do not prevent physiological resorption of the cortical bone plates but rather the implant acts as a space maintainer and prevents horizontal resorption. Only long term analysis of resorption patterns will be able to confirm this suggestion.

2.2 Periodontal surgery

The ability for HA and TCP to fill periodontal bone defects following
curettage and root planing was quickly recognised by periodontists and both HA and TCP were produced in small granule sizes (40-60 mesh = 425-250 microns) specifically for periodontal applications.

Initial monkey studies by Boyne and Fremming (1982) showed that in the deepest parts of a surgically created periodontal lesion HA granules became surrounded by bone, whereas the more superficial granules were encased in fibrous tissue. In contrast, the control sites healed with complete bone regeneration and a new periodontal attachment.

Rabalais et al (1981), in the first human study, implanted 37 defects in eight patients and compared them with 29 control defects. They found no significant difference, measured clinically, between the two sites either in the amount of new attachment, pocket depth or recession; but there was a slight increase in the degree of bone infill in the implanted site noted at secondary surgery. Unfortunately, the lack of standardisation in both radiographs and clinical measurements made objective assessment difficult.

Froum et al (1982) clinically and histologically examined the healing of periodontal defects in patients previously treated by HA. They resected four blocks of bone with teeth either at two or eight months postimplantation. Histological examination showed no new bone or cementum adjacent to the HA granules and a long junctional epithelium rather than a connective tissue attachment to the root surface. They concluded that the HA acted as a biocompatible filler but did not enhance regeneration of lost periodontal structure.

Similar results have been found when TCP is used. Baldock et al (1985) implanted TCP into 13 defects in two patients. Clinical and radiographic measurements were complemented by block biopsies of two teeth at three, six and nine months. Clinically, there was a reduction in pocket depth and radiographically, a small infill of bone. Histologically, the granules were encased in fibrous tissue, there was a long junctional epithelium and minimal new bone or cementum formation.

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The initial enthusiasm among periodontists for HA and TCP has been tempered by these research results, particularly the histological evidence that minimal new bone or periodontal attachment is generated following their use. It is generally accepted that HA and TCP can act as biocompatible fillers but, as they do not induce osteogenesis, cementogenesis or reattachment, they have lost favour as a material for periodontal bone defects.

2.3 Dentate ridge augmentation

The local resorption of the buccal alveolar ridge surface following an extraction in an otherwise dentate patient can create a difficult aesthetic problem, particularly for the patient with a high smile line showing gingival tissue. The loss of buccal plate and therefore ridge width means that the cervical margin of a pontic must either be angled palatally to achieve a correct relationship with the cervical margins of the other teeth or unnaturally elongated to make mucosal contact. The placing of HA granules in these isolated defects can recreate the previous ridge contour, allowing a more aesthetically pleasing restoration.

The loss of anterior maxillary teeth and their replacement with a fixed restoration is a common occurrence; however the use of this augmentation technique has not been widespread. Apart from two reports of single cases (Cohen 1984, Hadeed et al 1983), only the studies by Brook and Lamb (1986, 1987) have been published. The technique described by Brook and Lamb involved two stages. The first stage was an incision through periosteum around the periphery of the augmentation site to allow the development of a band of fibrosis to limit subsequent granule migration. The second stage, following healing of the first, involved raising a palatal flap pedicled buccally, which exposed the surgical site directly. The correct quantity of HA granules, assessed from a preoperative waxed model, was then inserted (Fig. 15). In cases where the pontic was already in place, an alternative approach
A sagittal section through a partially dentate alveolar ridge following augmentation with HA granules (A). The buccally based palatal flap, when replaced, leaves an area of denuded palatal bone due to the increase in ridge width. (From Brook and Lamb 1986).

An illustration of the anterior sandwich osteotomy where the areas distal to the mental foramen have been augmented with HA granules rather than mobilising and elevating the lingual plate as in the visor osteotomy. (From Stoelinga et al 1986).
using a buccal incision adjacent to the site was used. They treated a total of 28 sites for 16 patients using these techniques and found that the new ridge contour was maintained without any complications; however the follow-up time was less than three years. For five other patients they implanted precarved porous HA blocks placed via the buccal approach but the results were disappointing, three of the blocks being lost to anaerobic infections.

It would appear that this technique, using granules, provides a simple solution to a difficult aesthetic problem and deserves further clinical trials. However, it seems that the use of porous HA blocks is contra-indicated and that dense HA granules are the material of choice.

2.4 Augmentation osteotomies

The use of autogenous bone blocks as an interpositional graft in augmentations was discussed in Chapter III. The natural extension of this procedure has been to substitute HA blocks for autogenous bone. This has the advantages of reducing surgical morbidity, allowing exact trimming of the block and knowing that the graft will not resorb. The nonresorption of HA is crucial to the success of this procedure and therefore it is surprising that Shepherd et al (1976), one of the first to experiment with this technique, elected to use resorbable TCP as an interpositional graft in experiments with dogs. However, they found no loss of augmented height even after replacement of the graft by host bone. To date, no further reports of TCP used in this way have been published.

Frame et al (1981) in a histological study in the dog, compared autogenous bone, freeze-dried allogenous bone and HA blocks inlayed into edentulous areas of the mandible. They found that the HA was as well accepted as the autogenous bone, with new bone in close apposition to the implant surface, whereas the freeze-dried allograft showed little bone in apposition. Frame and Brady (1984) then extended the concept to a clinical
application and inlayed a block of dense HA into the anterior mandible of one patient. The patient was followed for two years and showed marked aesthetic improvement and maintenance of the augmented height but no measurements were recorded.

Swart and de Vries (1985) had less success. They placed 13 HA inlay grafts in eight patients but lost, due to inflammation following dehiscence, part of the implant in four patients and the total implant in one. They also showed a decrease in augmented height gain ranging from 25 per cent up to 100 per cent in the case of the lost implant. They conceded that part of the problem could have been their surgical technique but felt that HA blocks were not suitable for inlay augmentation.

Stoelinga et al (1986) described a modification of their mandibular 'sandwich/visor' osteotomy technique, primarily to reduce damage to the inferior dental nerve which is inherent with the procedure. The anterior mandible was pedicled on lingual tissue and interpositional autologous bone blocks and bone chips placed. Distal to the mental nerve, however, the lingual bone was not mobilised as originally described in the 'three piece' osteotomy (Egbert et al 1986), instead the ridge was onlayed with HA granules mixed with cancellous bone (Fig 16). Twenty nine patients received this treatment and results showed an average loss of posterior height gain after six months of 32 per cent and after one year of 40 per cent. This result was comparable to that obtained in the 'three piece' osteotomy technique but without the same degree of dysaesthesia, although this was still reported to be as high as 31 per cent after one year.

Mercier and Zeltser (1986) also combined an anterior mandibular osteotomy, in this case a 'visor', with posterior augmentation using either HA granules or bone; sixteen patients receiving the HA and 16 autogenous iliac bone. They experienced some problems with the anterior visor segment rotating and resorbing after one year in both groups, but found the HA provided a superior ridge form to the autogenous graft with greater patient
satisfaction and less mental nerve dysesthesia.

2.5 Combined onlay augmentation

Kraut (1985) and Lew et al (1986A) independently updated the traditional technique of mandibular onlay grafting using rib, discussed in Chapter III, by the addition of HA granules to the bone chips.

Kraut treated six patients with a combination graft consisting of allogenous rib and a mixture of HA granules and autogenous bone chips. Working through either an extraoral labio-mental fold or submental incision the contoured rib was ligatured to the lingual aspect of the ridge crest with the HA mixture being placed buccally. The extraoral approach was utilised to avoid contamination of the graft and wound dehiscence. A height gain from 10mm preoperatively to a mean of 28.5mm postoperatively was recorded bilaterally, just distal to the mental foramen, with maintenance of 78 per cent of the gain after one year and 67 per cent after two years.

Lew et al (1986A) used the more conventional intraoral approach to place an autogenous rib on the lingual surface of the mandible, inserting a mixture of HA granules, blood and collagen both buccally and superiorly to the rib. Of the four patients who received treatment, two experienced subsequent wound dehiscence; in one case with substantial loss of HA and infection of the rib graft. Reviewing the cases after 18 months, minimal resorption was noted but no measurements were included in their report.

The rationale for this combination approach to onlay grafting is that the rib provides strength, support and an increased bone surface for the granules, while the presence of HA retards the normally fast resorption rate of the rib. The proof of this hypothesis awaits long term results but it already appears that the extraoral approach reduces the incidence of wound dehiscence; its use should possibly be investigated for a wider range of procedures where contamination of the graft would be detrimental and a
greater disadvantage than an extraoral scar.

2.6 Orthognathic and reconstructive surgery

The availability of both dense and porous HA blocks manufactured in a variety of shapes and sizes has made HA an attractive alternative to other materials traditionally used as grafts in orthognathic surgery.

Kent et al (1986B) outlined a range of orthognathic procedures where HA could be used and discussed the results achieved in 43 cases using granules and 66 cases using blocks (Table 8a and Table 8b). The blocks were selected intraoperatively using metal templates to gauge the correct size and were retained either by wires around the block, by grooving the block to engage the bone margin, or wedging it between the bone fragments. No blocks were lost from dehiscence or infection and no underlying bone resorption was observed. After one year the degree of relapse was also low, being less than 20 per cent in cases of maxillary advancement with downgrafting and negligible in genioplasties. They felt that in areas under functional stress, (e.g. a downgrafted maxilla) the blocks should be supplemented by a bone graft.

They also advocated the placement of blocks bilaterally following palatal osteotomies to minimise mucosal tension but Hiatt et al (1987) placed blocks in the palatal midline for 19 patients and reported only a single dehiscence.

Zeller et al (1986) had no complications and improved the patients' aesthetics following placement of seven dense HA blocks in genioplasty procedures.

Waite and Matukas (1986) used HA granules in combination with the Le Fort I osteotomy to augment a hypoplastic zygoma. A mixture of granules and collagen was placed inferior and lateral to the infra-orbital margin in 11 patients with no postoperative migration or infection evident after two years.
### TABLE 8a. USE OF HYDROXYLAPATITE (HA) GRANULES

<table>
<thead>
<tr>
<th>Surgical Procedure</th>
<th>No. of Patients</th>
<th>Follow-up (mo)</th>
<th>Amount of HA (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Range</td>
<td>Average</td>
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<tr>
<td>Genioplasty</td>
<td>21</td>
<td>4–38</td>
<td>16</td>
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<tr>
<td>Craniofacial augmentation</td>
<td>8</td>
<td>9–36</td>
<td>17</td>
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<tr>
<td>Cystic cavity</td>
<td>5</td>
<td>11–40</td>
<td>20</td>
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<tr>
<td>Mandibular continuity defect</td>
<td>8</td>
<td>8–39</td>
<td>16</td>
</tr>
<tr>
<td>Alveolar clefts</td>
<td>1</td>
<td>31</td>
<td>3</td>
</tr>
<tr>
<td>Totals</td>
<td>43</td>
<td>4–40</td>
<td>20</td>
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</tbody>
</table>

(From Kent et al 1986B)

### TABLE 8b. USE OF TEXTURED DENSE HYDROXYLAPATITE (HA) BLOCKS

<table>
<thead>
<tr>
<th>Surgical Procedure</th>
<th>No. of Procedures (%)</th>
<th>No. of Blocks (%)</th>
<th>Movement (mm)</th>
<th>Follow-up (mo)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Range</td>
<td>Average</td>
</tr>
<tr>
<td>Le Fort I advancement without bone</td>
<td>15 (22.7)</td>
<td>30 (25)</td>
<td>4–8</td>
<td>6</td>
</tr>
<tr>
<td>Le Fort advancement with bone</td>
<td>3 (4.5)</td>
<td>5 (4.2)</td>
<td>4–6</td>
<td>5</td>
</tr>
<tr>
<td>Le Fort down-grafting without bone</td>
<td>5 (7.6)</td>
<td>5 (4.2)</td>
<td>3–9</td>
<td>6</td>
</tr>
<tr>
<td>Le Fort down-grafting with bone</td>
<td>6 (9.1)</td>
<td>10 (8.3)</td>
<td>3–9</td>
<td>5</td>
</tr>
<tr>
<td>Maxillary widening</td>
<td>8 (12.1)</td>
<td>10 (8.3)</td>
<td>4–13</td>
<td>5</td>
</tr>
<tr>
<td>Le Fort III advancement</td>
<td>4 (6.1)</td>
<td>11 (9.2)</td>
<td>2–15</td>
<td>8</td>
</tr>
<tr>
<td>Mandibular advancement</td>
<td>3 (4.5)</td>
<td>4 (3.3)</td>
<td>6–15</td>
<td>10</td>
</tr>
<tr>
<td>Genioplasty down-grafting without bone</td>
<td>7 (10.6)</td>
<td>14 (11.7)</td>
<td>4–10</td>
<td>6</td>
</tr>
<tr>
<td>Genioplasty down-grafting with bone</td>
<td>4 (6.1)</td>
<td>4 (3.3)</td>
<td>3–6</td>
<td>5</td>
</tr>
<tr>
<td>Inferior border augmentation</td>
<td>5 (7.6)</td>
<td>11 (9.2)</td>
<td>6–10</td>
<td>8</td>
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<td>Contour deficit</td>
<td>2 (3.0)</td>
<td>3 (2.5)</td>
<td>8–10</td>
<td>9</td>
</tr>
<tr>
<td>Maxillary/mandibular subapical</td>
<td>4 (6.1)</td>
<td>13 (10.8)</td>
<td>2–6</td>
<td>4</td>
</tr>
<tr>
<td>Totals</td>
<td>66 (100)</td>
<td>120 (100)</td>
<td>2–15</td>
<td>6</td>
</tr>
</tbody>
</table>

(From Kent et al 1986B)
This technique avoids the difficult zygomatic osteotomy and unpredictable autogenous onlay graft. A further orbital application of HA was described by Zide (1986). He used dense HA blocks to correct a post-traumatic enophthalmos. One block was placed inferiorly to the globe over an orbital floor defect with further blocks being placed on the superior and lateral orbital walls. This resulted in a return to normal vision and elimination of diplopia. Souyris et al (1985) also used porous HA blocks (created from the coral genus Madreporaria) for various mid-facial osteotomies and reconstructive cases, but they provided minimal details of a limited number of cases.

Wolford et al (1987) used porous HA blocks for an extensive range of osteotomy procedures provided for a total of 92 patients. Nineteen mandibular osteotomies and 73 of the maxilla and midface were performed. Three hundred and fifty five blocks were placed, 294 in the maxilla, 41 in the mandible and 20 in the midface with fixation being achieved using miniplates. The patients were reviewed over two years and evaluated clinically.

Minimal complications were reported but included mid palatal implant dehiscence in six patients. Partial or total removal of five of the blocks was necessary but only one patient developed a subsequent oronasal fistula. This problem was rectified by bilateral relieving incisions, thus allowing the mid palatal mucosa over the implants to remain intact. In only one of the mandibular osteotomies was a block sufficiently displaced to warrant removal. Long term, four patients (4.3 per cent) required treatment for infection, with two palatal grafts and one alveolar graft requiring removal, the fourth being successfully managed with antibiotics. Biopsies were taken from nine patients between four and 16 months postsurgery. They showed no inflammation and ingrowth of bone occupying 18 per cent of the field area, 33 per cent was soft tissue and the balance (49 per cent) was the porous HA matrix.

HA blocks exposed to either the oral or nasal cavity soon after surgery were found to have the poorest prognosis; however there was evidence that
sections of a block could become infiltrated by bone while another part became infected. Communication of the blocks with the maxillary sinus, which is an inevitable occurrence in Le Fort I osteotomies, did not seem to compromise the blocks; in contrast two of the three blocks placed in alveolar clefts were lost. This difference was attributed to the haematoma that fills the sinus postoperatively permeating the pores and isolating the blocks from pathogens.

A further problem associated with the use of HA blocks in the grafting of alveolar clefts was investigated by Feinberg and Vitt (1988). Bone has traditionally been favoured for the early repair of alveolar clefts because it allows eruption of the impacted teeth that commonly line the cleft. Feinberg and Vitt compared the effects on erupting teeth of various materials placed in their path of eruption. They extracted the deciduous second and third mandibular premolar teeth of 40 kittens and grafted the resulting sockets with either TCP granules, porous HA granules or autogenous bone. Two kittens were then sacrificed from each group at five monthly intervals. They found that the presence of the HA both impeded eruption and distorted crown development whereas both the TCP and autogenous bone allowed normal eruption and development. It would therefore appear that in clefts or other areas through which teeth are liable to erupt HA granules or blocks are contraindicated.

There is no doubt that the use of HA blocks, either dense or porous, have a future in orthognathic and reconstructive surgery. However the porous blocks appear to be more vulnerable to infection. Long term results from both materials are still awaited.

2.7 Restoration of pathological tissue loss

The use of HA granules in pathological lesions has been reported from various centres. Roth (1984) used HA granules in cystic cavities larger than
2cm for 30 patients. He reported no complications, but strangely expected the HA to be resorbed and was surprised that it was still present after three years. Ferrari et al (1985) varied the technique by filling the cystic cavities with fibrin cement and placing only a layer of HA over the external bone defect to stop epithelial breakdown. No results were included in his paper.

Takahashi et al (1986) used HA granules in 104 cystic cavities and noted loss of some material in 15 per cent, a wound dehiscence rate of 12 per cent and an infection rate of 23 per cent. These complication rates appear unacceptably high but the authors expressed satisfaction with the technique.

Allard and Swart (1982) used a porous HA block to repair a defect in the orbital roof created by a cyst arising in the frontal sinus. The block was placed over the defect without complications.

Kurachi et al (1985) reconstructed the left body of a mandible, following resection of an ameloblastoma, with a dense HA block which was stabilised with wires, an A-O bone plate and intermaxillary fixation. There were no complications and a return to function and aesthetics was evident at 18 months.

Block et al (1986) reported the management of three cases of sclerosing osteomyelitis in the mandible. The infected areas were resected to nonsclerotic, bleeding, cancellous bone and the defect filled immediately with HA alone or mixed with bone. In two of seven other cases mentioned, dehiscence occurred which healed uneventfully without evidence of renewed infection.

Judging from these results, HA in granule form can be successfully used as an intra-bony filling agent for large defects. However, because HA is not osteogenic and only osteoconductive, the defects cannot heal any faster than if the cavity were left to organise and calcify naturally. Blocks, however, do have an important role to play as interpositional grafts following resections such as in the case of mandibular reconstruction detailed by Kurachi et al.
2.8 Endosteal implants

The ability of titanium to osseointegrate and the osteophilic nature of HA has led to their combination in the quest for the perfect endosteal implant. Block et al (1987B) compared three implants with different surfaces in dogs. One was smooth titanium, the second grit-blasted titanium and the third HA-coated titanium. They found that bone formation and maturation occurred earlier and at a faster rate on the HA-coated implants than on the other materials. The osteophilic nature of the HA was again demonstrated by the growth of bone extending up the implant interface superiorly to the alveolar crest.

These initial animal studies were developed into clinical use (Kent et al - personal communication) with a total of 558 titanium HA-coated implants being placed in 188 patients over three years and used to retain both fixed and removable prostheses. Minimal complications were encountered with only 14 implants being lost, mainly due to malalignment or substantial peri-implant bone loss. The possible use of these implants for orthodontic anchorage was suggested and Block et al (1987A) have used the same system to magnetically retain a hemimaxillectomy prosthesis.

The future for these titanium HA-coated implants appears bright but no definitive judgement can be made until a sufficient number have been in use for at least five years. Only then can they be assessed and compared with the Branemark system.

2.9 Conclusion

The suitability of calcium phosphate ceramics as bone replacement materials for certain surgical procedures has now been established in the short term. The work of Wolford et al (1987) and Kent et al (1986B) has shown the potential for the use of blocks in orthognathic cases although a degree of uncertainty still exists over their susceptibility to infection.
future for the titanium HA-coated endosteal implants also looks bright as they combine Branemark's sound research with the ability of the HA coating to bond biochemically to the host bone.

In contrast, the evidence of benefits associated with root implants is more equivocal as it appears alveolar ridge resorption is not halted by their presence. However the variation in resorption rates over time means that long term data is necessary and it is too early for a final judgment to be made.

The logic of filling intra-bony defects with HA seems less certain with no evidence that healing is promoted by the presence of HA. It is also apparent that HA granules are not the treatment of choice to fill periodontal bone defects. The unique nature of the periodontal tissues cannot be restored using HA and its use as a filler, despite reducing pocket depths clinically, does not address the problem of apical epithelial migration.

It therefore appears at this stage in HA development that its future use seems assured at least as a graft material in orthognathic surgery, as a coating for endosteal implants and possibly as an onlay augmentation material - a subject which is dealt with in detail in the Chapter V.
CHAPTER V

ONLAY AUGMENTATION OF THE ATROPHIC RIDGE
WITH HYDROXYLAPATITE (HA)
CHAPTER V

ONLAY AUGMENTATION OF THE ATROPHIC RIDGE
WITH HYDROXYLAPATITE (HA)

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1. CLINICAL TRIALS OF HA ONLAY AUGMENTATION

We restore, repair and make whole those parts of the face which nature has given, but which fortune has taken away, not so much that they may delight the eye but that they may buoy up the spirit and help the mind of the afflicted.

Gaspare Tagliacozzi (1546-1599)

1.1 Initial multicentre study - granules

In 1978 clinical trials using dense HA granules for alveolar ridge augmentation were started at Louisiana State University in a bid, as Tagliacozzi noted in the 16th century, to restore that 'which fortune has taken away'. The study was designed to assess the performance of the HA granules alone and in combination with autogenous bone. (Kent and Finger 1982)

The Kent classification of alveolar atrophy outlined in Chapter II was devised and 56 patients, spanning the classifications, selected. After insertion of HA, detailed surgical and postoperative information was collected, as was radiological and subjective clinical and functional evaluation data.

Following experimentation with various surgical techniques, a surgical protocol using a subperiosteal tunnel was developed as this method was found to be simple and effective in containing the HA granules. A vertical buccal incision extending from the sulcus to the ridge crest was used, either in the midline or bilaterally in the cuspid region. In the maxilla this approach also allowed for the provision of a submucous vestibuloplasty if required.

The granules of HA in preloaded syringes were 'wetted' with autogenous blood and injected in amounts ranging from 4 to 8gm for a segmental augmentation or 10 to 15gm mixed in a ratio of 1:1 with autogenous cancellous chips for a full ridge augmentation.
Following wound closure the granules were manipulated manually into a smooth ridge shape, surgical splints only being used in cases of severe maxillary atrophy. Postoperatively antibiotics were prescribed for one week, the splint, if present, was removed after three weeks and construction of new dentures commenced after four to six weeks. Twenty six patients received HA alone, 21 HA mixed with autogenous bone and nine had HA placed in conjunction with either a mandibular staple implant or a visor osteotomy.

The most frequent complication was paraesthesia of the lower lip following manipulation of the mental nerve. This affected 15 per cent of patients with 95 per cent of the affected nerves returning to normal within a year. Nine patients had delayed healing, three being caused by dehiscence, four by wound breakdown and in two the reason was not specified.

Clinical assessment found the ridges to be consistently firm, forming an excellent denture base without soft tissue mobility. There was evidence of granule migration in only three mandibular cases.

At regular intervals the patients were asked to assess their dentures for comfort, fit, speech, appearance, ability to eat, ability to taste and general satisfaction, with each criterion consistently rating good or excellent on a scale of poor, fair, good or excellent.

Comparison of the pre- and postoperative study casts was found to be difficult and not pursued but serial radiographs were standardised using anatomical landmarks and analysed using computerised image analysis. An augmentation height gain of over 100 per cent was demonstrated in some cases, a mean for the maxilla being 35 per cent with only a 10 per cent relapse of that gain over two years when HA was used alone or 20 per cent when used with bone.

Following these initial trials the study was extended to other universities with all the data being reviewed at a clinical conference dealing exclusively with the use of HA for atrophic alveolar ridge augmentation.

At the University of Alabama 35 patients with a range of atrophic
alveolar ridges were treated (Matukas and Castleberry 1982). They experienced some difficulty both with the syringe system, which jammed during delivery, and granule migration due to excessive periosteal elevation and overpacking. They also reported nine cases of wound dehiscence, two of which required surgical intervention. Following provision of dentures their patients noted a significant improvement, particularly in comfort and their ability to chew.

At Brookdale Hospital Medical Centre 50 patients were treated (Cranin 1982). Cranin's team modified the tunnel technique slightly to avoid placing HA over the mental nerve, leaving a void in that area. They found this eliminated postoperative paraesthesia. Radiographs were analysed and graded for HA quantity, material density and the adaption and proximity of the graft to the ridge. The results were then correlated with the patients' evaluation of their new dentures. The objective radiographic grades were found to correlate well with the patients' evaluation in all but the most severely atrophic ridges, where only one of four patients noted any improvement.

At the University of Minnesota 30 cases were treated, with results comparable to the previously mentioned studies (Waite 1982). Waite advocated the removal of hyperplastic tissue as a separate procedure thereby not involving such compromised tissue in the augmentation. He also felt that packing the HA too tightly reduced the quantity of fibroblastic repair matrix surrounding the granules, making a less stable ridge.

At the Mayo Clinic 29 patients were treated (Lund 1982). Lund made particular reference to a flabby anterior maxilla that responded well to subperiosteal tunnel augmentation with no evidence of HA granule migration. A progressive vestibular deepening was also noted with their cases over time but this was not explained.

Since these initial reports on the results of HA augmentation the multi-centre study has continued with periodic appraisals of the results. Seven

Table 9 tabulates the basic data from each of the seven papers and indicates that an examination of the results from paper 7 (Kent 1986) would represent the culmination of the published work. Relevant details from the other six papers are mentioned where appropriate.

By 1986, 208 patients aged between 25 and 75 (average 53 years) had been treated in the project: 64 were male, 144 female and a total of 228 ridges had been augmented. Alveograft (irregular granules) was used for the initial 55 and Calciite (rounded granules) for the remaining 173.

Seventy six per cent (173) of the augmentations were mandibular, 55 (24 per cent) maxillary, with the Class III atrophic ridge the most commonly augmented. In 25 cases the mandibular augmentation was supplemented by either a staple implant (13), another form of implant (six) or a visor osteotomy (six).

Sensation changes in the mental nerve were noted in 37 cases (21 per cent). The majority returned to normal within six months with no permanent disability recorded. Four cases of hyperaesthesia were corrected by excision of a fibrous cuff enveloping the nerve.

A secondary vestibuloplasty procedure was required in 32 cases (14 per cent), either to lower the sulcus in Class IV cases or to excise granules displaced by surgical error or premature splint removal.

Incision dehiscence, noted in 20 cases (9 per cent), closed by secondary intention requiring no surgical intervention.

Granule migration was evident in 17 cases (7 per cent) and treated by excision of the migrated mass.

Haematomas, which required aspiration, formed in 10 cases (4 per cent). A loose augmentation mass, indicating failure of the HA to unite to

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**TABLE 9**

**BASIC DATA FROM THE MULTICENTRE STUDY.**

<table>
<thead>
<tr>
<th>Papers</th>
<th>No. of Patients</th>
<th>Augmented Ridges</th>
<th>M</th>
<th>F</th>
<th>Age</th>
<th>Av Age</th>
<th>Follow Up Time (months)</th>
<th>Maxilla</th>
<th>Mandible</th>
<th>Other Procedures</th>
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<td>32</td>
<td>32</td>
<td>7</td>
<td>24</td>
<td>24-75</td>
<td>56</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>HA + Bone 3</td>
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<td></td>
<td></td>
<td></td>
<td>9</td>
<td>47</td>
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<td>3. Larsen et al 1983</td>
<td>63</td>
<td>66</td>
<td>12</td>
<td>41</td>
<td>28-78</td>
<td>52</td>
<td>1-24+</td>
<td>9</td>
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<td>16 Visors</td>
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<td>4. Rothstein et al 1984 (C)</td>
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<td>115</td>
<td>30</td>
<td>80</td>
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<td>HA 76</td>
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<td>5. Rothstein et al 1984 (B)</td>
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<td>207</td>
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<td>145</td>
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<td>6. Kent et al 1986 (A)</td>
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<td>228</td>
<td>64</td>
<td>144</td>
<td>25-75</td>
<td>58</td>
<td>1-72</td>
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<td>7. Kent 1986</td>
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bone, was found in only three cases (one per cent).

1.1.1 Assessment

The earlier papers, most notably Kent et al (1982, 1983) and Rothstein et al (1984B, 1984C), assessed in detail the postsurgical data. An overall surgical assessment was achieved by analysis of the postoperative orthopantomograms (OPT). Three parameters of measurement were used and combined. Firstly, the apposition of the HA to bone was noted; a 4mm separation being poor, no separation being scored as excellent. Secondly, maintenance of the HA in its intended position was recorded; with gross granule migration being scored as poor and no evidence of migration being excellent. Thirdly, the degree of bone infiltration around the granules, measured by increasing radiodensity was observed; with no increase in radiodensity being recorded as poor, complete radiopacity being excellent (Fig. 17).

The prosthodontic assessment utilised study models, the patients' questionnaires, a clinical evaluation of the dentures and the quality of the augmented ridge. The two assessments were then correlated (Fig. 18).

Rothstein et al (1984C) evaluated the responses to the patient questionnaire of 79 augmentation cases and presented pre- and post-implantation histograms of the parameters investigated (comfort, fit, speech, appearance, ability to eat, ability to taste and general satisfaction).

All the parameters showed increased patient satisfaction post-implantation. For example Figure 19 shows the general satisfaction parameter pre- and postimplantation and Figure 20 shows the denture comfort parameter.

1.1.2 Modifications

Kent et al (1986A), in the light of six years experience with HA augmentation, outlined modifications to the subperiosteal tunnel technique.
The radiographic assessment of results in 56 patients who received alveolar ridge augmentation with HA or HA and bone. (From Kent et al 1983).

A comparison of the surgical and prosthodontic assessments of 56 patients who received alveolar ridge augmentation with HA alone. (From Kent et al 1983).
FIGURE 19

Evaluation of general satisfaction with post-augmentation dentures by 79 patients.

FIGURE 20

Evaluation of denture comfort by 79 patients. (From Rothstein et al 1984C).

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They advised the use of a premade clear acrylic splint to limit granule migration both in the maxilla and mandible. Previously they had advocated the use of the existing denture but experience had shown dentures to be inadequate as they were invariably underextended. Kent et al recommended that the splint should have anterior teeth for aesthetics and be held in place for three weeks either by a midpalatal screw or circummandibular wires (other techniques for controlling granule migration will be discussed in a following section).

To reduce mental nerve dyseaesthesia they recommended that the mandibular subperiosteal tunnel be created in three separate sections without elevating the peristemeum in the mental foramen region as previously advocated by Cranin (1982). This avoids the HA granules being in close proximity to the nerve. In cases where the nerve is exposed along the length of the ridge crest they recommended that a split rib be onlayed over the nerve prior to the augmentation.

In those cases where autogenous cancellous bone chips were mixed with HA no definitive bone/HA ratio was found to be superior, a ratio of 1:1 being used with success in their series. They advocated the use of bone particularly for Class IV mandibular cases which lack width as well as height. Retention of HA granules alone in these cases was a problem. The increased relapse associated with the use of bone led them to recommend an augmentation gain in excess of 6mm immediately postsurgery to allow for subsequent relapse without substantial loss of the height gained.

Haematoma, supraperiosteal granule placement and granule movement were cited by Kent et al as causes of unstable HA. A bevelled delivery syringe, to avoid supraperiosteal placement, was advocated as a partial solution. They recommended the removal of any mobile mass of HA that did occur via a direct creetal incision. Reaumentation or supplementary augmentation could also be completed at the same time, care being taken to ensure some contact between the new and old HA.
With their extensive experience using HA for alveolar ridge augmentation, Kent et al were prompted to make a final comment which encapsulated the basic objectives of HA augmentation.

"Extreme height is not critical for successful denture reconstruction. Improved ridge form, a wide zone of fixed tissue and adequate sulcus depth are more important."

1.2 Clinical data from other centres - granules

Independent of the multicentre study of HA augmentation, other clinical results and observations of the technique have been published.

Alling (1984) reported two cases, one maxillary and one mandibular, in which HA mixed with cancellous bone was placed via a subperiosteal tunnel. Left mental nerve anaesthesia resolved within four months but no further postoperative details were given.

Golec (1984) reported four cases, two maxillary and two mandibular, as examples of the 150 he had performed using either HA alone or in combination with autogenous bone: Interestingly in one of the maxillary cases the subperiosteal placement of the HA and bone was combined with excision of vestibular hyperplastic tissue and a supraperiosteal vestibuloplasty with skin graft, followed by an anterior mandibular osteotomy to correct a class III malocclusion. This illustrates the potential for use of HA in conjunction with other preprosthetic surgical procedures. However, the unpredictability of the results due to one procedure compromising others, coupled with the increase in surgical morbidity will restrict this approach to only certain isolated cases.

Beirne et al (1986) augmented nine mandibular ridges using HA alone. In five cases the whole of the ridge was augmented, in the remaining four only the posterior sections. Granule migration occurred in the initial four
patients but was prevented by use of a splint in subsequent cases. Five cases required a subsequent vestibuloplasty and in these the opportunity was taken to obtain specimens of the augmented ridge for histological examination, as detailed by Beirne and Greenspan (1985) (Chapter IV Section 1.4.2).

The patients were reviewed up to 26 months postoperatively and a range of complications was noted. Five sustained paraesthesia or anaesthesia of the lip which, after a year, had resolved in only one case. Three lost granules from dehiscence, two had pain that resolved on removal of some granules, and one developed a giant cell granuloma which required repeated surgical excisions. This appears to be the only recorded case to date of a pathological lesion being associated with the use of HA.

Patients' subjective assessment of their dentures showed an improvement in retention, chewing ability and speech but no significant improvement in dental comfort, appearance or ability to taste.

Beirne et al gave no explanation as to the failure of the technique to provide improvement in denture comfort, and interpretation of all the patient responses must be guarded due to the small sample size. A combination of the high complication rate, particularly the neural symptoms and the need for secondary vestibuloplasties made Beirne et al guarded in their recommendation of the technique especially as they felt the resulting ridge was not of the same quality as one of normal bone.

1.3 Radiographic evaluation

Kent et al (1983) used orthopantomograms (OPT) taken at pre- and postoperative intervals for up to 18 months to analyse ridge stability (the percentage relapse over time). Twenty three mandibular and four maxillary ridges were evaluated; 16 received HA with bone and 11 HA alone.

The radiographs were standardised by selecting four anatomical points and measurements were made by a computerised image analysis system. A
range of points on and below the augmented ridges were measured. Analysis of the results showed some augmentation gains of over 100 per cent of the original ridge height with a mean gain of 53 per cent gain (8.6mm) in the mandible and 35 per cent (4.5mm) in the maxilla. Postoperative changes showed a relapse of less than 10 per cent for ridges augmented with HA alone and up to 20 per cent for HA with bone.

A further study (Block and Kent 1984) analysed the radiographs of 74 patients who had undergone augmentation six to 48 months previously. A comparison of relapse rates was made between the 32 cases where HA alone had been used and the 42 cases where the HA was combined with bone. A further comparison was made between cases where irregular granules and rounded granules had been used. Results were expressed by histogram (Fig. 21) which shows that the granule shape did not affect the degree of relapse. It also indicates that over the four years, ridges augmented with HA and bone reduced 10 per cent of their augmented height, in contrast to the ridges augmented with HA alone which reduced only 4 per cent over the same period. However a statistical analysis of the results failed to show any difference between the various materials and procedures used.

Rothstein et al (1984A) also developed a technique for standardizing and measuring panoramic radiographs which they tested for accuracy using pre- and postoperative films from 24 patients who had undergone HA augmentation to the mandible. The initial preoperative film was traced with subsequent films being placed in an enlarger so that the image could be adjusted to match the traced preoperative landmarks. Ridge heights in various positions were then traced and measured to the nearest 0.5mm along lines perpendicular to the average plane of the alveolar ridge. A controlled test to check if direct measurement from the radiographs was more accurate than the tracings found less variance with the tracing. Rothstein et al felt that the results achieved with this technique accurately represented the changes taking place.
Radiographic measurements of postoperative vertical heights of the mandible in 74 patients treated by augmentation with HA either alone or with bone.

HA1 are irregular shaped granules, HA2 are rounded granules.

(From Block and Kent 1984)
1.4 Maxillary augmentation - granules

Papers dealing specifically with HA augmentation in the hypermobile anterior maxillary ridge have been few. Larsen and McDonald (1984) briefly discussed the particular problems associated with the hypermobile anterior maxillary ridge and outlined the method of augmentation pioneered by themselves and Kent but did not discuss any treatment results.

Harle (1985) used the subperiosteal 'tunnel' technique originally described by Kent, and recorded the clinical experience of seven patients who had been treated by augmentation using smooth HA granules. He found the implants were well accepted with only one patient suffering mucosal sloughing following excessive pressure from a splint used to control granule migration. He concluded that maxillary ridges augmented by this method would withstand full denture function with minimum resorption. However he presented no data to substantiate this.

Lew (1986) described a technique to be used when an atrophic maxilla lacks the hypermobile flabby tissue in which to create a subperiosteal tunnel. His technique involved the creation of supraperiosteal mucosal flaps bilaterally from the palate posteriorly and from the vestibule and inner lip anteriorly. These flaps were then sutured edge to edge to the raised periosteum creating a large tunnel which can then be filled with HA granules (Fig. 22). The resulting palate and vestibular defects were then covered with a freeze-dried skin graft stabilised by a full coverage splint that also supported the augmented tunnel. Four cases treated using this technique had good initial healing and ridge stability but no details of prosthetic rehabilitation or long term results were included.

Another open mucosal flap technique was described by Barsan and Kent (1985) who used it for 12 patients. Equally applicable to mandible or maxilla, it is indicated for cases where the elasticity of the mucosa has been compromised. The technique is a modification of the lip switch procedure used for vestibuloplasties. A large supraperiosteal flap is raised inside the lip
FIG. 22

A. Placing the HA granules in one of the tuberosity tunnels created from palatal mucosa and pedicled buccally.
B. The fully augmented ridge showing the anterior flap pedicled from the palate and sutured to the buccal periosteum. The bilateral palatal mucosa donor sites have been skin grafted.

(From Lew 1985).

FIG. 23

A. The arrows indicate the position and direction the mucosal and periosteal flaps are raised.
B. The enlarged tunnel created by suturing the raised mucosal flap to the periosteal flap. The denuded vestibule heals by secondary epithelialisation.

(From Stevenson 1987).
and cheek extending over the ridge crest, the crestal periosteum is then elevated labially and the two edges anastomosed (Fig. 23), thus creating a substantial tunnel. HA is injected incrementally as the tunnel is closed and the resulting labial wound can be grafted with skin if necessary.

Both of these 'open' techniques have similar advantages and disadvantages when compared with the 'tunnel' technique. Advantages include control of the granules so avoiding displacement and migration, the ability to remove hyperplastic tissue concurrently, the maintenance of vestibular depth and in the case of Barsan and Kent's technique the elimination of a splint. Disadvantages include an increase in surgical time, the need for graft material, the possibility of lip inversion and the creation of a narrow sulcus.

1.5 Augmentation - HA and TCP blocks

The manufacture and use of HA blocks as root implants and as interpositional grafts following either orthognathic or augmentation osteotomies has been discussed in Chapter IV Section 2; however blocks have found less favour as onlay grafts. The dense blocks have not been favoured because they are both initially unstable due to the lack of soft tissue ingrowth and extremely difficult to shape and fit due to their hardness. This makes them more likely to dehisce through the ridge mucosa when loaded (Frame and Brady 1987). Their only advantage is that they rarely become infected if dehiscence does occur and so can be reduced in situ successfully (Jarcho 1986; Kent et al 1986B).

For onlay augmentation porous blocks have found more favour, despite the poor prognosis for porous blocks which dehisce early in the postaugmentation period. They are easy to cut and shape and quickly become stabilised by soft tissue ingrowth.

Following the experimental work of Piecuch et al (1983) who used
porous blocks to augment edentulous canine ridges, some clinical trials were undertaken. Piecuch (1986) used porous HA blocks to augment 14 ridges for 12 patients (five maxillary and seven mandibular). The blocks, precarved and soaked in antibiotic, were placed in subperiosteal tunnels and denture construction commenced after six to 10 weeks. In the initial two cases dehiscence, followed by unilateral loss of a block took place but did not occur in any subsequent cases. No secondary vestibuloplasties were necessary. The earlier canine studies had noted the crushing of the material when loaded prior to bone ingrowth; however this was not apparent clinically. Neither was there any evidence of underlying bone resorption.

Hupp and Tyson (1985) also reported the use of HA blocks in 16 patients, a total of 42 mandibular and five maxillary being placed. The blocks were preshaped on models, sterilised, placed in subperiosteal tunnels and secured by surgical splints. The blocks were stable after two weeks and dentures were constructed at three months with only three patients requiring a secondary vestibuloplasty. Short term review showed only one case of block migration but four mandibular blocks and one maxillary required removal, an 8 per cent and 20 per cent failure rate respectively.

A further report by Hupp (1986) presented results from 15 patients, each of whom had received three porous HA blocks for mandibular augmentation. The follow up time ranged from 17 to 26 months and it must be assumed that these cases are substantially the same as the ones detailed in the optimistic 1985 report. The median term results were in marked contrast to that earlier report. Fourteen of the patients had developed complications, 11 suffered mucosal ulceration and block dehiscence both before and after denture construction, in six cases the incision line dehisced and in two cases the blocks became infected. Of the initial 45 blocks, 18 had to be removed within 20 months. Hupp concluded that the use of blocks in conjunction with the subperiosteal tunnel technique was not without problems.

Peterson (1986) reached a similar conclusion after analysis of 30
who had received mandibular augmentation with porous HA blocks. Within one year 19 patients had experienced block dehiscence, some exposures lasting for as long as nine months despite treatment. Seven patients also developed dehiscence after denture construction, having originally had satisfactory healing. Peterson stopped short of not recommending the use of blocks but provided one novel and not very practical solution when he advocated the use of mucoperiosteal palatal grafts to 'reinforce' the atrophic ridge mucosa.

Rooney et al (1988) also experienced very negative results using porous HA blocks for mandibular augmentation. At the end of one year only 35 per cent of the 29 augmented ridges had retained their blocks and were supporting dentures. Thirty eight per cent of the patients were unable to wear any form of denture for the whole year. Dehiscence occurred in 79 per cent, infection in 21 per cent and 52 per cent required removal of one or more blocks.

Frame and Laird (1987), conscious of the problems associated with block dehiscence, particularly in the mandible, limited their use of blocks as onlays to the anterior maxilla with hypermobile tissue. The blocks were precarved on a study model and following sterilization placed in subperiosteal tunnels similar to the HA granule technique. A clear splint was used to check for pressure points and the blocks trimmed and adjusted as necessary. The splint was then secured in place with a palatal screw. For two weeks the patients were kept under regular review and the splint removed if mucosal ulceration became evident. The old relined dentures were refitted after one month and new dentures made after two months.

Five patients each received two blocks and were observed over a period of up to 18 months. Only one of the ten blocks dehisced and became infected necessitating removal, the others were found to be firm and stable. Frame and Laird concluded that the blocks could provide a satisfactory ridge form in the anterior maxilla but warned that dehiscence and infection were
major disadvantages.

The use of HA porous blocks for mandibular onlay augmentation appears to be contraindicated, the high rates of dehiscence and infection and the subsequent inability to wear a denture militate against their use. Their failure in this clinical application is in interesting contrast to the success of granules for ridge augmentation and to the success of blocks in other modalities. The work by Frame and Laird may still indicate a limited role for the blocks in the anterior maxilla where they are protected by the more substantial mucosal tissue but long term results are required. It appears self evident in hindsight that the concentration focused on the HA block/bone interface was misplaced in the context of onlay ridge augmentation where the quality of the overlying mucosal tissue has been found to be far more critical to the success or failure of the procedure.

Some interest in the use of TCP blocks for ridge augmentation has also been shown and the work of Nery et al (1978) using TCP blocks for onlay augmentation in dogs predates the research work on HA blocks. They demonstrated in histological specimens from 10 dogs, implanted with subperiosteal TCP blocks, that healing was uneventful and bone and soft tissue permeated the pores. Subsequent to this (Nery et al 1980) they constructed partial dentures that were worn successfully for six months by two dogs with TCP augmented ridges, despite occasional mucosal irritation and ulceration. Histologically the TCP blocks appeared healthy and unaffected by the loading and little evidence of TCP resorption was noticed.

Despite the success of these initial trials the use of TCP blocks for onlay augmentation appears not to have been pursued clinically, as no further work has been published. Swart and de Vries (1985), as noted in the previous chapter, used TCP blocks for interpositional grafts during mandibular augmentation but without success and this may also have been the experience with the blocks in an onlay situation.
2. CONTROL OF GRANULE MIGRATION

The idea of a splint of universal accommodation seems to have possessed in some degree the mind of every inventor; but it is also evident that, the more general the application of any particular apparatus, the more clumsy it becomes.

N.W. Kingsley, Oral Deformities, 1880

The problem of granule migration has exercised the minds of all surgeons who have undertaken augmentation with HA and as Kingsley points out, no one technique can accommodate all situations. Apart from the careful application of surgical technique, a number of particular measures have been developed. These measures can be either pre- or intraoperative, the latter being conveniently subdivided into physical and chemical. Predominantly, research has focused on migration in the mandible with only three papers mentioning the maxilla.

2.1 Preoperative

2.1.1 Volumetric measurement

Barrett (1985) mentioned that the wax used to create the idealised ridge form on the preoperative study model could be removed and packed into HA syringes as a volumetric reference to the quantity of granules required. Sorensen and Williams (1987) explained this principle in more detail rolling the wax collected from the study model into cylinders which are then used as a length measurement during the filling of the syringes so allowing only the correct volume of HA to be inserted and avoiding either under or over filling. Hall and Hupp (1985) advocated the immersion of augmented and
unaugmented models and measuring the displacement volumes, the differences being the volume of HA required. However no mention was made of the necessity to standardise the trimming of the model bases which would be a major source of error.

None of these techniques have gained acceptance due to a range of difficulties. All require an increase in laboratory time, they do not adequately reflect the clinical situation and they are very inaccurate.

2.2 Intraoperative - physical

2.2.1 Surgical splints

Surgical splints have long been used for wound protection following surgery. However, detailed instruction on splint fabrication for HA augmentation was not available until Barrett's description in 1985. He noted that splints had previously been recommended by Kent et al (1982) and Waite (1982), but no details given. Barrett outlined six uses for the splint:

- To eliminate or reduce granular migration.
- To prevent postoperative morphological irregularities.
- To protect underlying soft tissue.
- To maintain the HA material in a proper position.
- To provide maximum denture base adaption.
- To maintain the interarch space.

The technique he described involved creating an ideally shaped ridge with wax on a study model. The wax was then replaced with plaster by means of an interim vacuum template formed on the wax ridge into which the plaster was injected following removal of the wax. A number of templates were then constructed, each with an opening to facilitate syringe placement during the injection of the HA granules. On completion of the granule placement the final splint was ligated into position, remaining in situ for up to four weeks postoperatively. He indicated that the maxilla required a
minimum of three intermediate splints and the mandible four, the number being dependent on the different injection sites needed for the syringe during a complete augmentation.

Barrett's complicated technique was refined by Torres et al (1986). They simplified the process by making a stone duplicate model from the idealized wax-augmented study model. Only one vacuum-adapted, soft vinyl splint was then made which had an anterior 'U' shaped notch to facilitate the introduction of the HA syringe. They advocated then using the patient's existing denture, relieved over the augmented area and filled with a soft reline material as the postsurgical splint. Alternatively another hard acrylic resin splint, in the manner of the previous soft vinyl surgical splint, can be used. They justified the trouble taken to perfect the splint by commenting that excessive augmentation or placement of HA in an undesired location would adversely affect the subsequent fit of the denture and noted that HA has been shown to migrate even four weeks after implantation.

Other published splint designs have concentrated on the mandible. Lambert (1985) advocated a two-piece acrylic surgical splint, the posterior segment being stabilized by circummandibular nylon sutures prior to HA implantation; the anterior removable section being cold cured into place following augmentation. Pham (1985) advocated an open splint consisting only of an acrylic bar in the position of the denture flange periphery; Ten Bruggenkate et al (1987) also advocated an open splint, to assist in placing the HA syringe. In both cases the splint was ligated into place with circummandibular wires or sutures for three weeks postoperatively.

Splints have become the most widely used of the techniques to limit granule migration. They are easily fabricated, protect the surgical wounds and can provide an aesthetic function. However they require laboratory assistance and the use of an existing denture circumvents this while providing the other benefits. Kent et al (1986A) felt that dentures were unsatisfactory because they were underextended but in the cases detailed in this study they
have proved effective. The fitting surface corresponding to the augmented region is extensively relieved and the void filled with a soft surgical pack just prior to fixation. The pack also extends the flange maintaining the increased sulcus depth. Fixation using a midpalatal screw provides positive retention with minimal complications.

2.2.2 Subperiosteal tissue expanders (STE)

Tissue expansion using a saline filled balloon to stretch overlying skin has been successfully employed in plastic surgery. The physiological precedent for this technique has been the observation of tissue distention which takes place over a benign tumour, in pregnancy or in obesity. Research has shown that a highly vascularised capsule envelopes the implant balloon and this increased microvascularity allows the expanded tissue to be locally transposed to cover extensive raw areas left after the excision of tissue (Cherry et al 1983). The rationale for the use of a subperiosteal expander is to create, prior to HA augmentation, a subperiosteal tunnel so that when the augmentation is subsequently completed the overlying mucosa is under no tension. Another benefit is that fibrosis develops along the line of reflection created between the bone and the periosteum establishing a natural barrier which limits granule migration (Fig. 24).

Lew et al (1988B) reported on the clinical use of tissue expanders in augmentation and presented the results in five patients (three mandibular, two maxillary cases). Following placement, the expander was inflated incrementally with saline solution starting with 1ml, followed one week later by a further 1.5ml, three to four increments usually being required to obtain the desired expansion. One week following the final injection, the expander was deflated, removed and the tunnel created filled with HA granules. Complications encountered included two cases of wound dehiscence through the crestal incision, perforation of the expander by a needle rendering it ineffective, pain in one patient subsequent to overinflation and one case of
A labio-palatal section of an atrophic maxilla to show the relative position of a subperiosteal tissue expander (STE).

PLATE 12

A lateral cephalometric radiograph showing a subperiosteal tissue expander (STE) in situ in an atrophic maxilla. The STE has been outlined by flushing it with a radiopaque contrast medium.
sensation change due to manipulation of the mental nerve. Despite this high number of complications in such a small group, Lew et al concluded that the technique had less morbidity than the open envelope procedure, the only alternative for reconstruction of the severely atrophic (Class IV) ridge which lacks sufficient overlying soft tissue.

Bonomo (1986) also described the use of subperiosteal tissue expanders. He offered no clinical results but did outline the advantages of the tissue expander for augmentation stating that it minimised surgery, confined the HA to the resulting envelope, minimised the need for surgical splints or subsequent vestibuloplasty and preserved the mental nerve. He felt that the use of an STE also minimised the amount of HA needed, eliminated the possibility of any dehiscence or haematoma formation and was generally cost effective.

Personal experience with this technique in the maxilla and mandible (Plate 12) has confirmed the expander's effectiveness in both limiting granule migration and stretching the overlying mucoperiosteum. Some problems were experienced with the disparity of the expander size and the syringes carrying the HA granules but this can be rectified by using expanders of comparable diameter. The patients tolerated the expanders well and no infection was noted; however, they were unable to wear a denture during the period of expansion. Unfortunately the expanders are very expensive and because they can only be used once do not appear to be as cost effective as claimed by Bonomo.

2.2.3 Mattress sutures

Propper (1985) described the use of a series of horizontal mattress sutures to limit granule migration. They are placed along the base for the subperiosteal tunnel to compress the lingual and buccal tissue following the insertion of the HA granules. The sutures resist the tendency of the HA granules to lift the periosteum when compressed and help to maintain the
augmented height by preventing the granules packing down into a broad, low profile. Unfortunately this method is only applicable in the mandible and it has the tendency to reduce the HA/bone interface area.

2.3 Intraoperative - chemical

2.3.1 Collagen tubes

Shen and Gongloff (1986) and Gongloff et al in a series of papers (1985A, 1985B, 1986B) have detailed the use of collagen tubes packed with HA. They showed in the rat that collagen was a successful biodegradable container for the HA granules and provided support for up to four weeks without affecting the properties of the HA or impairing bone healing. A clinical trial using collagen tubes in 20 cases of ridge augmentation (Gongloff 1986C) unfortunately made no mention of the collagen tube's ability to limit migration but reaffirmed the favourable tissue response to the material.

Harvey et al (1985) used a microfillary collagen haemostatic agent, mixed with HA and placed subcutaneously along the inferior mandibular border in ten rabbits. They demonstrated minimal granule migration histologically and an acceptable host response; however no clinical trials were conducted.

Similar results were achieved by Beirne et al (1986). In a study run concurrently with their clinical cases, previously detailed in Section 1.2, they investigated collagen as a means of limiting granule migration. They created experimental defects in rat mandibles which were then filled with either HA alone, collagen alone, a combination of HA and collagen or left unfilled. They found most of the defects containing HA alone, or in combination with collagen, filled with fibrous tissue. The defects with collagen alone filled with adipose tissue. They concluded that the collagen neither interfered with nor stimulated bone healing but could act as an inert binder to confine HA granules, a role they found a surgical splint was unable to achieve.
Mehlisch et al (1987) in a large clinical study used blocks of purified fibrillar collagen mixed with HA granules to augment 99 ridges in 77 patients. The patients, following augmentation, were reviewed at regular intervals and assessments by the patient, prosthodontist and surgeon collected and presented in a similar manner to the previously mentioned multicentre study.

The composite blocks were found to be easy to place either as an open onlay or via a subperiosteal tunnel. The augmented ridge shape was stable and granule migration minimal without the need for surgical splints. Over the six month review period the height gain decreased 22 per cent which was attributed to the replacement of the collagen over time by fibrous connective tissue. The clinical assessments by the prosthodontist and surgeon showed marked improvement of the denture bearing area and the new dentures - a finding that was reinforced by the patient's assessment. Mehlisch et al concluded that the collagen improved the HA by making it easier to handle and place with minimal granule migration.

2.3.2 Fibrin adhesives

Bochlogyros et al (1985) used a fibrin adhesive mixed with HA granules to create a preformed flexible implant which could be individually adapted and detailed two clinical cases where this procedure had been used successfully. They concluded that the two substances used together were biocompatible and that this particular implant system would be clinically very versatile, either as a flexible rod for augmentation or as a flexible sheet to bridge osseous defects.

2.3.3 Polyglycolic acid

Silverberg et al (1986) showed, in the rat, that a mesh of polyglycolic acid would contain HA granules without displacement occurring. The mesh remained in place for six to twelve weeks before resorbing, providing a matrix to contain HA granules during the healing phase.
2.3.4 Plaster of Paris

Hanker et al (1988) mixed HA granules with plaster and found that the plaster was slowly resorbed over a period of weeks, being replaced by an infiltration of fibrovascular tissue while the HA granules become enveloped in new cancellous bone. They experienced problems, however, with the initial setting of the plaster due to contamination with blood and tissue fluids. Ideally, they recommended that the implant should be removed and trimmed after setting and before final implantation.

Frame et al (1987) augmented edentulous canine ridges with a slurry of plaster mixed with either porous or non-porous HA blocks. This was part of a larger study on bone formation around HA granules, previously mentioned in Chapter III Section 2.1.4.3. They found that the plaster both facilitated the initial granule manipulation and limited granule migration.

Reviewing the various physical and chemical methods to control granule migration it becomes evident that certain techniques have the greatest potential.

Of the physical methods the subperiosteal tissue expander stands out. It can be used in both jaws, provides a physiological fibrous cuff and reduces the overlying mucosal tension. Splints and mattress sutures are less versatile. Mandibular splints are difficult to retain in position, are liable to traumatisate the mucosa and allow lateral escape of the granules, however they work well in the maxilla. The mattress sutures are limited in use only to the mandible.

Of the chemical methods the use of collagen either mixed with HA or containing the HA within tubes appear to be the most successful alternative. The collagen is biocompatible and provides a rigid medium for the HA being replaced in time by dense fibrous tissue without a destructive immune response.
3. POSTAUGMENTATION PROSTHODONTICS

Preprosthetic surgery is only of value if a better prosthesis can be constructed as a consequence.


The minutiae of HA augmentation surgical technique that concerns the majority of published papers is not carried forward into a similarly detailed discussion of the prosthodontic aspects of the HA augmented ridge. The only comment on prosthodontics often being only that a new denture was constructed after six weeks.

Larsen et al (1983), for example, in their paper entitled 'Prosthodontic management of the hydroxyapatite denture patient: A preliminary report', actually concerned themselves only fleetingly with prosthodontic management, concentrating predominantly on the surgical technique and augmentation evaluation. Denture design and fabrication was started one to three months postoperatively and was left to the discretion of the prosthodontists. Both balanced and non-balanced occlusal schemes were used, as were both acrylic or porcelain and anatomic or non-anatomic teeth. No attempt at comparison was made and the dentures varied according to the needs of each patient.

Castleberry, discussing the factors involved in denture tolerance (Laskin 1982), stated that HA augmentation:

- Provided an adequate ridge for prosthetic support.
- Provided a proper extension for a peripheral seal.
- Provided an atraumatic contact with the denture base.
- Provided an acceptable facial contour.

Grisius and de Koozen (1984) outlined prosthodontic care following ridge augmentation. Dentures were made as soon as the patient was
symptom free. Cuspless teeth were used to minimize lateral forces and occlusally equilibrated to allow bilateral simultaneous contact in centric relation as well as lateral excursions. Anterior tooth contact in all positions was eliminated. To avoid the excessive forces generated by parafunction and to rest the tissues, the patients were instructed to leave the dentures out while sleeping.

Further follow up after the initial issue of the dentures was found to be very important. In an 18 month postoperative period, the average number of return visits was seven. Sixteen per cent did not require a denture reline, 66 per cent required one reline, 12 per cent required two and 6 per cent required three. Grisius and de Koomen advised a recall routine of weekly visits for the first three months, six monthly visits for the following two years and then yearly visits. They concluded that the cooperation between surgeons and prosthodontists established during treatment planning should continue postoperatively to evaluate both the surgical and prosthetic results so that modifications to techniques could be made where appropriate.

Ponichtera et al (1988) detailed their prosthodontic experience with 10 patients who had received onlay ridge augmentation with porous HA blocks. The dentures were constructed following a selective pressure impression technique and provision of a balanced occlusion achieved using centric and protrusive bite records on a fully adjustable articulator. Block dehiscence occurred, following provision of dentures, on four of the 12 augmented ridges (eight mandibular and four maxillary) with the blocks being lost in two cases. The 10 remaining augmented ridges became satisfactory denture bearing areas but certain prosthodontic difficulties were identified including some loss of vestibular depth, distal undercuts lingually and persistant pain over the implant edge. Like Grisius and de Koomen they also advocated careful and continued follow up, particularly in view of the poor prognosis if a block dehisced.
3.1 Prosthodontic problems

Desjardins (1985), in a thoughtful paper on the indications and problems of HA augmentation with granules, outlined in detail the potential prosthodontic problems, categorising them as:

- Granule diffusion.
- Irregular granule distribution and extrusion.
- Incorrect granule position.
- Excessive increase in alveolar ridge height.
- Paraesthesia.
- Granule settling and underlying bone resorption.

3.1.1 Granule diffusion

Desjardins identified first the problem of insufficient overlying keratinised mucosa, often with the cases requiring the greatest augmentation having the least available tissue. The obvious solution of mobilising further tissue allowed diffusion of the granules laterally away from the regions where they were needed. He felt that a splint, which provided pressure down onto the ridge, caused further lateral displacement of granules rather than containing them. However his paper predated the use of tissue expanders which specifically addresses this difficult problem.

The non-keratinised tissue of the vestibules which becomes the covering for the augmented ridge, he felt, was ill equipped to withstand the trauma generated by the denture and would continue to be mobile, something which Castleberry (Laskin 1982) discounted (Chapter II, Section 3.2). Desjardins also felt the technique did not provide for any sulcus deepening, leaving the denture limited in flange extension and he advocated a vestibuloplasty as a routine secondary procedure.

3.1.2 Irregular granule distribution and extrusion

Underfilling or overfilling the subperiosteal tunnel was also seen as a
hazard. The final ridge contour is dictated by intraoperative moulding, the effect of any overlying splint and to a lesser extent, the initial denture. Granules in an underfilled section of tunnel will then either compact or diffuse creating an irregular ridge. This in turn could create mucosal irritation under the denture. Conversely an overfilled tunnel will cause granules to extrude through the incision or into any surgically created supraperiosteal tunnels, changing for the worst the desired ridge contour.

3.1.3 Incorrect granule position

If the granules are placed lateral to the original ridge crest in the mandible or medial (palatally) in the maxilla, a more problematic interarch ridge relationship is created. In the mandible this lateral and anterior shift of the denture-bearing area can complicate tooth placement, often requiring a set-up with an occlusal crossbite. The external denture contour is also compromised becoming convex in form to accommodate the ridge profile. This creates unacceptable aesthetics due to a fullness in the labio-mental fold and also compromises the muscle control needed to maintain denture stability.

3.1.4 Excess increase in alveolar ridge height

Excessive augmentation, particularly in the mandible, forces the occlusal plane to be placed in a higher position than the natural teeth. Unacceptable aesthetics result, either with increased visibility of the anterior mandibular teeth, or a fullness of the labio-mental fold if the teeth are placed anterior to the ridge. Functionally, mastication and speech can also be affected, the occlusal plane being too high for the tongue to work efficiently. If the excessive augmentation is not uniform the resulting ridges are not parallel and stability is further compromised. The clinical reality however is that it is difficult to achieve any substantial ridge height increase, particularly on a scale to produce these detrimental effects.
3.1.5 Paraesthesia

Desjardins noted that it was not uncommon for mental nerve dysaesthesia, which often accompanies augmentation (21 per cent, Kent 1986), not to recover totally. He attributed this to the placement of granules on or near the nerve which are then compressed onto the nerve by the overlying denture. This problem was addressed by Kent et al (1986) when they advocated creation of three separate tunnels in the mandible leaving the tissue around the mental foramen undisturbed. However there was no indication that the percentage of patients suffering dysaesthesia had been reduced.

3.1.6 Granule settling and underlying bone resorption

Desjardins conceded that following the initial settling of granules in the first 6 months, further change is minimal even after provision of a denture. However he was not convinced that further changes, such as continuing bone resorption, were not taking place at the HA/bone interface.

The work of Grisius and de Koomen (1984), mentioned earlier in this section, on the number of relines required following augmentation, would tend to support Desjardins' fear as would the observations by Frame et al (1987) that cortical bone resorption took place beneath HA granules onayed on canine mandibles. However Block (1987), in reply to Frame et al, noted that their patients who had received HA augmentation had required less relines over a 5 year postsurgical period than non-augmented patients.

In his conclusion Desjardins urged caution and consideration of six points:

- That vestibuloplasty was the treatment of choice if it could provide acceptable results.
- That as little HA should be used as possible.
- That preprosthetic surgery should permit vertical as well as
horizontal denture extension.

- That non-keratinised mucosa should not be used to support a denture.
- That a vestibuloplasty is routinely indicated following augmentation.
- That augmentation should be avoided in the dominant jaw in prognathic or retrognathic cases.

Some of these points have validity, for example his second which rejects the premise that 'if a little is good, a lot is better'. This applies directly to HA augmentation but is equally relevant to the provision of any preprosthetic procedures or surgical intervention. It focuses attention on justifying the need for surgery prior to rather than after the actual surgery.

Some of the other considerations are more contentious. The decision whether or not to perform an augmentation or vestibuloplasty is usually based more on anatomy than personal preference. Certain clinical features contraindicate one while being an advantage to the other (Chapter II, Section 4). Equally the majority of clinicians have not found it necessary to follow an HA augmentation with a vestibuloplasty. Neither is HA augmentation likely to increase the ridge size sufficiently to create a noticeable skeletal discrepancy or insufficient freeway space.

Despite these points the caution expressed by Desjardins is justified. The ease with which HA can be placed may lead to its inappropriate use, either where augmentation is not indicated or where it's use would not improve the denture-bearing area. The patient would then have suffered the consequences of the surgery to no avail so discrediting the procedure in the minds of patient and prosthodontist. Lawson (1972) cautioned against this potential for over prescription of treatment when he wrote

"There is no advantage in having surgery for surgery's sake and bad surgery is worse than none at all."

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CHAPTER VI

ANTERIOR MAXILLARY AUGMENTATION USING HYDROXYLAPATITE: METHOD
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ANTERIOR MAXILLARY AUGMENTATION
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1. PATIENT SELECTION AND SURGICAL TECHNIQUE

Five things are proper to the duty of a chirurgian:

to take away that which is superfluous,
to restore to those places, such things as are displaced,
to separate those things which are joined together,
to join those which are separated,
to supply the defects of Nature.

Ambroise Paré, (1510-1590).

1.1 Patient selection

Patients who presented to the United Dental Hospital for the provision of new maxillary complete dentures were referred for possible inclusion in this study. Predominantly they complained of discomfort and instability particularly during eating, poor retention appeared to be less of a problem.

A detailed medical history was taken to identify any medical problems that could influence the surgical outcome and a series of conditions typical of geriatric patients were identified in the 15 patients finally chosen for this study (Table 10). Similarly, a medication and allergy history identified a cross-section of commonly prescribed medications and medication allergies (Table 10). No patient who could benefit from augmentation was excluded because of a medical condition.

A dental history was taken to record the length of time the patients had worn an upper denture and the length of time the current upper denture had been worn (Table 11). Due to the often considerable time which had elapsed since the patients had been rendered edentulous in the maxilla, no attempt was made to correlate the present ridge atrophy to their extraction history. Finally, the patients were questioned on the expectations they held
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<td>Rohypnol</td>
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<td>Penicillin</td>
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<tr>
<td>No.</td>
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<td>Sex</td>
<td>Age in years at operation</td>
<td>Total number of years wearing a full upper denture</td>
<td>Years wearing last set of dentures</td>
<td>Remaining mandibular teeth</td>
</tr>
<tr>
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<td>---------------------------</td>
<td>-----------------------------------------------</td>
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<tr>
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<td>73</td>
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<tr>
<td>7</td>
<td>JD</td>
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<td>15</td>
<td>VW</td>
<td>F</td>
<td>59</td>
<td>44</td>
<td>13</td>
<td>(removed 6 months prior to surgery)</td>
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</table>

**TABLE 11**

DEMOGRAPHIC DATA AND PAST DENTAL HISTORY OF THE PATIENTS CHOSEN FOR HA AUGMENTATION
for their new dentures in the light of their previous prosthetic record.

Each patient was then examined clinically with attention being paid to:

- The retention, stability and occlusion of the present dentures.
- The quality and integrity of any standing mandibular teeth.
- The mucosal health, particularly evidence of Candida albicans infection, denture hyperplasia or ulceration.
- The firmness and adequacy of the tuberosities.
- The degree and extent of the hypermobile tissue in the anterior maxilla.

All relevant details were recorded and the ridges classified according to the classification outlined by Kent et al (1982) (Chapter II section 2). (Table 11).

An orthopantomogram (OPT) and lateral cephalometric radiographs were obtained for each patient and checked for:

- Intrabony pathosis, including retained roots.
- The integrity of any mandibular teeth.
- The quantity, quality and contour of the mandibular and maxillary alveolar bone.
- The mandibular/maxillary skeletal relationship.

In certain cases Status X and/or intraoral radiographs were also taken, either to confirm information seen on previous films or in the hope that they could be compared pre- and postoperatively. However only the OPT and lateral cephalometric radiographs were subsequently used in assessment.

Having evaluated the information, a discussion was held with the patient, often in conjunction with the prosthodontist, on the prosthetic options available to the patient.

The patients who had hypermobile tissue on the anterior maxillary ridge of sufficient degree to compromise the stability and retention of a new denture were offered anterior ridge augmentation with HA. The procedure,
the potential postoperative sequelae and the prognosis were described to the patients and the necessity to return regularly for long term follow-up was stressed. They could then decide either to reject the advice and proceed straight to the provision of new dentures or elect to undergo the augmentation procedure. The group of patients who elected to undergo HA augmentation form the basis for this study. The first 15 patients treated have been analysed and the basic data is presented in Tables 10 and 11 and summarised in Table 12.

1.2 Preoperative preparation

Following acceptance into the program further data were collected including:

- Upper and lower alginate impressions.
- Photographs of the anterior maxilla taken at rest and displaced by a swab stick under pressure to demonstrate the degree of soft tissue mobility. (Plate 13)
- A questionnaire completed by the patient assessing the current upper denture.
- A questionnaire completed by the prosthodontist assessing the current upper dentures.
- An oral surgical assessment made from the clinical and radiographic appearance of the ridge.

The nature of these assessments will be described in detail in section 2.

No attempt was made to investigate any possible systemic aetiological factors associated with the maxillary atrophy. Obvious local factors such as retained mandibular anterior teeth were noted in six of the patients (Table 11).

For the five patients who exhibited clinical evidence of Candida albicans infection, anti-fungal medication was prescribed and advice on
### TABLE 12

**A SUMMARY OF THE PATIENT DATA**

- **Total number of patients**
  - Male: 9
  - Female: 6

- **Age range**
  - Range: 38-73
  - Average: 64 years

- **Years wearing full upper denture**
  - Range: 8-50
  - Average: 34 years

- **Years wearing last full upper denture**
  - Range: 0.2-15
  - Average: 5.5 years

- **Number with retained anterior mandibular teeth**
  - Count: 6

- **Classification (Kent) of maxillary ridge**
  - Number classified as II: 2
  - Number classified as III: 11
  - Number classified as IV: 2

- **Medical histories**
  - Diseases of the circulatory system: 5
  - Diseases of the respiratory system: 2
  - Diseases of the digestive system: 5
  - Diseases of the musculo-skeletal system: 5

- **Regular medications**
  - Analgesics: 8
  - Sedatives/tranquilisers: 3
  - Beta blockers: 2
  - Anti-angina: 2
  - Anti-gout: 1
  - Diuretics: 1

- **Patient allergies**
  - Penicillin: 4
  - Aspirin: 1
  - Gold: 1
  - Sulphonamide: 1
denture hygiene given. No surgery was performed until these infections were controlled.

In one case (Patient 14), extensive midline buccal hyperplasia was treated by confiscation of the maxillary denture and subsequent resection of the tissue using electrocautery and cryotherapy prior to the augmentation procedure.

From the alginate impression two study models were cast in stone. The first was preserved while the duplicate one was augmented with wax to the proposed postsurgical ridge shape. This augmentation was usually very modest as the patient’s problem was more often one of an acceptable ridge shape with excessive mobility rather than one with inadequate ridge form. The wax augmentation was added predominantly to the palatal aspect of the ridge, as it is only on the palatal aspect of the residual ridge crest that the HA granules can be placed in a stable situation. In contrast, the buccal aspect of the ridge provides no anatomical barrier to the displacement of granules up the lateral aspect of the maxilla.

A clear, rigid surgical template, used to assess intra-operatively whether the ridge was under- or over-augmented prior to wound closure, was then constructed; either directly on the waxed study model using a vacuum moulding technique or indirectly in heat cured acrylic processed on another study model duplicated from the one augmented with wax. The first technique was found to produce a satisfactory template with minimal laboratory time and was therefore used in the majority of cases.

Initially, an aesthetic surgical splint was also manufactured. This required the wax augmented study model to be duplicated a second time and construction of a heat cured acrylic base plate with anterior teeth. This splint was used to control granule migration, protect the surgical wound and provide an aesthetic replacement to the previous denture. However, in the absence of completing all stages of denture construction, such as a bite and try-in, the splint rarely fitted and was always in poor occlusion either with the
An anterior maxillary alveolar ridge being displaced by pressure from two swab sticks to show the degree of hypermobility prior to augmentation.

The fitting surface of the patient's maxillary denture being removed in the region of the anterior alveolar ridge prior to its use as a surgical splint.
# TABLE 13

**SUBMUCOUS VESTIBULOPLASTY WITH ANTERIOR MAXILLARY AUGMENTATION - SURGICAL DATA**

<table>
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<th>No.</th>
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<th>Number of HA syringes (1=0.75g)</th>
<th>Fixation of splint (No. of screws)</th>
<th>Splint worn (No. of weeks)</th>
<th>Post-op medication</th>
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</thead>
<tbody>
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<td>LA</td>
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<td>2</td>
<td>3</td>
<td>AM,AC,CH</td>
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<tr>
<td>2</td>
<td>BC</td>
<td>GA</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>AM,CH,AT</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>(Combined with mandibular submucous vestibuloplasty)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>DG</td>
<td>LA</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>AM,PC</td>
</tr>
<tr>
<td>4</td>
<td>EF</td>
<td>GA</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>CL,AC</td>
</tr>
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<td>5</td>
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<td>2</td>
<td>3</td>
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<tr>
<td>9</td>
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<td>2</td>
<td>3</td>
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<tr>
<td>10</td>
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<td>2</td>
<td>2</td>
<td>3</td>
<td>AM,AC</td>
</tr>
<tr>
<td>11</td>
<td>JT</td>
<td>OP1, LA</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>ER, P</td>
</tr>
<tr>
<td></td>
<td>OP2</td>
<td>LA</td>
<td>6</td>
<td>-</td>
<td>-</td>
<td>ER, PC</td>
</tr>
<tr>
<td>12</td>
<td>CH</td>
<td>LA</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>AM,AC,CH</td>
</tr>
<tr>
<td>13</td>
<td>LG</td>
<td>LA</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>AM, P</td>
</tr>
<tr>
<td>14</td>
<td>JP</td>
<td>OP1, LA</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>ER, P</td>
</tr>
<tr>
<td></td>
<td>OP2</td>
<td>LA</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>AM,AC,CH</td>
</tr>
</tbody>
</table>

**OP1** = 1st operation  
**OP2** = 2nd operation

AM = Amoxycillin  
ER = Erythromycin  
CL = Cephalexin  
AT = Amphotericin B lozenges  
CH = Chlorhexidine  
AC = Aspirin, Codeine phosphate compound  
PC = Paracetamol, Codeine phosphate compound  
P = Paracetamol
An intra-operative view of the anterior maxilla showing the initial supraperiosteal midline incision.

**FIG. 25**

A labio-palatal section of the maxilla in the canine region showing the relative positions of the key anatomical structures.
The technique of blunt dissection using surgical scissors to mobilise the vestibular mucosa for a submucous vestibuloplasty (supraperiosteal tunnel).

FIG. 26

The position and extent of the submucosal vestibuloplasty (supraperiosteal tunnel) relative to the periosteum and hypermobile tissue.
lower denture or standing teeth. The manufacture of these splints was therefore abandoned and the patients' old dentures adapted instead.

These dentures were converted into splints just prior to surgery by extensive relief of the fitting surface with an acrylic bur (Plate 14). The relief extended over the whole area of proposed augmentation including the palatal surface and buccal flange, although the height of the flange was not reduced. The relieved portion was then filled with disclosing wax and inserted into the patient's mouth. Areas where the wax layer was less than 3mm thick were further relieved. The wax was then removed and palatal holes sufficient to take stainless steel screws (as used in the Roberts finger plating kit) were cut and counter-sunk. The denture was then disinfected by soaking in aqueous chlorhexidine solution until required.

1.3 Surgical technique

Three patients elected to have the augmentations performed under general anaesthesia (Table 13). This was provided via a nasal endotracheal tube and supplemented with infiltrations of 0.5 per cent bupivacaine (Marcaine-Astra) with 1:200,000 adrenaline.

The remaining 12 patients chose to have the procedure under local anaesthesia. This was provided by 2 per cent lignocaine (Nurocaín-Astra) with 1:100,000 adrenaline supplemented by 0.5 per cent bupivacaine with 1:200,000 adrenaline. A range from 2 to 8ml lignocaine (average 6.3ml) and from 0 to 10ml bupivacaine (average 6.5ml) was used.

A midline mucosal incision extending from the vestibule to the alveolar ridge crest exposed the submucosal tissues (Plate 15, Fig. 25). The vestibular mucosa was then released from the submucosal tissues by blunt dissection using curved dissection scissors (Plate 16, Fig. 26). This creation of a submucosal tunnel bilaterally was originally described by Obwegeser (1964) and is referred to as a submucosal vestibuloplasty. The mobilised vestibular
mucosa is then displaced superiorly creating a deeper sulcus maintained by fibrosis of the mucosa to the underlying periosteum.

Following the creation of this supraperiosteal tunnel, the original incision was extended down to the alveolar bone through the periosteum. A bilateral subperiosteal tunnel was then created using a narrow Freer’s periosteal elevator (E.A. Beck and Co) (Plate 17, Fig. 27). This tunnel was extended to the posterior margin of the mobile ridge tissue, care being taken to raise as little periosteal tissue as possible on the palatal side of the ridge crest. Due to the uneven nature of the crest, difficulty was often experienced in keeping the elevator directly on the bone surface.

The subperiosteal and supraperiosteal tunnels were then joined by cutting the intervening periosteum as close to the mucosal surface as possible (Plate 18, Fig. 28). The periosteum was then reflected buccally creating an enlarged tunnel.

The overlying hypermobile tissue was also used to expand the tunnel by incising into the fibrous tissue numerous times from within the tunnel (Plate 19, Fig. 29). The scalpel was directed towards the mucosal surface where it could be located and controlled by manipulation of the overlying tissue with the other hand. If a perforation (buttonhole) did occur it was closed with simple interrupted 3/0 Vicryl™ or Dexon® sutures (Ethicon) prior to the placement of the HA granules. To check the success of these reverse incisions (which are an important aspect of the procedure), the tissue was expanded over a periosteal elevator placed within the tunnel so that any area requiring further incisions could be identified.

The tunnel is now ready for introduction of the HA granules, however the protocol developed for the American study suggests that at this stage the anterior nasal spine should be reduced with rongeurs. This step was advocated to improve the midline vestibular depth, but the procedure was found in this study to create unacceptable postoperative pain and tenderness and was discontinued.
The subperiosteal crestal tunnel being created using a narrow periosteal elevator. Note the palatal position of the elevator blade.

**FIG. 27**

The relative positions of the submucous vestibuloplasty (SMV) and the subperiosteal tunnel are illustrated, being separated only by the buccal periosteum.
The periosteum lying between the supraperiosteal (SMV) and the subperiosteal tunnels is displaced prior to being cut as close to the mucosal surface as possible.

FIG. 28

Supraperiosteal tunnel
Subperiosteal tunnel
Position of divided periosteum

The plane in which the buccal periosteum is divided to link the supraperiosteal and subperiosteal tunnels is illustrated.
The scalpel has been reversed to perform repeated incisions into the hypermobile tissue stopping short of mucosal perforation.

FIG. 29

A representation of the reverse incisions placed in the hypermobile tissue which allow expansion of the crestal tunnel.
The HA granules used in all cases were ALVEOGRAF® (Cook-Waite). These are non-porous, dense, irregularly shaped granules and are supplied in sterilised, pre-filled, disposable syringes each containing 0.75g of granules. The number of syringes required was dictated by assessment of numerous factors including the quantity of wax used to augment the preoperative study model, the size and length of the tunnel and observations following insertion of the surgical template. The number of syringes used ranged from two to 10 (average three) (Table 13).

The syringes were prepared by wetting the granules thoroughly with sterile normal saline solution which was dripped into the open end of the syringe (Plate 20). Any excess solution was expressed leaving the granules cohesive and malleable with a consistency similar to damp coarse sand.

The tunnel entrance was then retracted either by the Freer's periosteal elevator or via traction from a temporary black silk suture placed close to the wound margin. The syringe was introduced to the full depth of the tunnel, its position being gauged by finger palpation. The granules were then expressed as the syringe was slowly withdrawn (Plate 21, Fig. 30). Following completion of the filling bilaterally, finger pressure was used to manipulate the granules to produce a satisfactory ridge contour.

The clear acrylic template was then inserted and the extent of the augmentation assessed by compressing the template against the palatal and tuberosity tissues to cause blanching (Plate 22). If blanching was evident in the augmented area, the position was noted and the granules in that area redistributed. If a large void existed, the granules could be compacted using the rubber covered plunger from the granule syringe. In the midline below the incision, care was taken not to over-augment because of the tendency for the granules to dehisce through the incision.

Following granule placement the wound was closed. Either 3/0 Vicryl™ or Dexon® suture material was used and the closure completed in one layer with simple interrupted sutures. The suture in the depth of the sulcus
The HA syringe within the subperiosteal tunnel prior to placement of the HA granules.

FIG. 30

The position of the HA granules following implantation.
Sterile saline is introduced into the open end of the HA syringe and then drawn down amongst the granules by manipulation of the syringe plunger.

The surgical template in place (in this case following wound closure) to check the extent of the ridge augmentation. Note the tissue blanching in the unaugmented tuberosity region but no blanching of the anterior ridge.
incorporated the periosteum of the anterior nasal spine region to maintain sulcus depth (Plate 23). A final manipulation of the ridge was then possible particularly to distribute granules towards the midline. This was to avoid an augmentation defect in the midline developing into a postoperative cleft.

The denture, previously prepared as a surgical splint, was then inserted to check on its peripheral extension. If satisfactory, the relieved anterior section was filled with a soft mix of Coe-pak surgical dressing (Coe Industries). It was then reinserted immediately, in conjunction with the lower denture if previously worn, and the patient maintained in occlusion for the short time required for the material to set. Any excess material placed on the fitting surface extruded over the flange where it could be manipulated to act as a buccal flange extension, displacing and supporting the vestibular mucosa mobilised during the submucosal vestibuloplasty (Plate 24). The close fitting nature of the surgical dressing also stabilised the augmented ridge and prevented the formation of any tissue voids in which a haematoma or serotoma could form. The surgical dressing was also non-irritant to the tissues and, if all rough edges were smoothed prior to fixation, it caused no tissue trauma despite being in close apposition for three weeks.

Once the dressing had hardened and the occlusion found to be satisfactory, the denture (surgical splint) was secured in place. Initially, two selftapping screws were inserted, one each at the base of the right and left alveolar ridge in the first molar region. Despite using screws as long as 15 mm the depth of fibrous tissue encountered compromised this fixation. It was found that a single midline palatal screw which engaged the palatal bone was preferable (Plate 25, Fig. 31) (Table 13). To insert the screw the denture (surgical splint) was stabilised with finger pressure and a sterile water cooled surgical fissure bur used to drill a hole in the palatal mucosa and bone. The screw, selected for length by estimating the palatal, denture and surgical pack thicknesses, was then held in a curved haemostat, inserted and screwed tight. Care was taken to guard the pharynx during this procedure by a gauze swab
The midline incision closed with synthetic resorbable sutures. Note the expansion of the anterior alveolar ridge particularly on the palatal aspect.

The old denture (surgical splint) in place prior to fixation. The relieved anterior fitting surface has been filled with Coe-pak and the excess has extruded into the sulcus to support the mobilised vestibular mucosa.
The old denture (surgical splint) being secured by means of a mid-palatal screw. Note the use of haemostat forceps and a gauze pack to avoid inhalation of the screw.

**FIG. 31**

The use of the surgical splint to contain the HA granules and maintain the sulcus depth is illustrated.
placed in the posterior oral cavity.

Table 14 summarises the operative details.

1.4 Postoperative sequelae

The complete surgical procedure took between 20 and 30 minutes and the patient was then allowed to recover in a quiet environment away from the surgical room. In the immediate postoperative phase the surgical sequelae were explained again and advice given on how to minimise their effects. Particular mention was made of the inevitable mid-facial swelling and the development of both a periorbital and a gravity induced, moustache shaped ecchymosis (Plate 26).

A five day course of an appropriate antibiotic (Amoxycillin, Cephalexin or Erythromycin) and a two day supply of an appropriate oral analgesic (Aspirin or Paracetamol based) were routinely prescribed. A 0.2 per cent aqueous chlorhexidine mouthwash was occasionally provided. Advice of an appropriate soft diet, the use of ice packs to reduce swelling and instructions in haemorrhage control were also given.

The first postoperative check was made after about five days and a second at about 10 days. If the patient was symptom free the splint was then left in place for approximately three weeks. Removal of the screw and splint was quick and relatively pain free and local anaesthesia was found to be unnecessary. The surgery site was then cleansed, inspected and, if necessary, any remaining sutures were removed (Plate 27).

The surgical splint was then transformed into a denture by removing the temporary lining, filling the palatal hole with cold cure acrylic and relining with either Coe-pak, Coe-soft or Viscogel tissue conditioner (de Trey). A prosthodontic appointment was then arranged for construction of a new denture.
TABLE 14

A SUMMARY OF THE SURGICAL DATA

- Treated with submucous vestibuloplasty and anterior maxillary augmentation with HA 15

- Anaesthesia
  - Local 12
  - General 3

- Quantity of HA used. (1 syringe = 0.75g)
  - number of syringes 2-10 Average 3

- Splint
  - Fixation
    - 1 screw 4 patients
    - 2 screws 10 patients
    - 3 screws 1 patient
  - Worn
    - <1 week 1 patient
    - 3 weeks 12 patients
    - 4 weeks 2 patients

- Postoperative medication
  - Aspirin, Codeine phosphate compound 9
  - Paracetamol, Codeine phosphate compound 2
  - Paracetamol 3
  - Amoxicillin 12
  - Erythromycin 2
  - Cephalexin 1
  - Amphotericin B 1
  - Chlorhexidine 4
The typical distribution of postoperative ecchymosis determined by the facial tissue planes and gravity.

The typical appearance of the augmented ridge three weeks postoperative following the removal of the surgical splint. Note the continuing presence of the Vicryl™ suture material and the midline mucosal slough without granule dehiscence.
1.5 Prosthetic rehabilitation

Three prosthodontists were involved in the prosthetic care of the 15 patients included in this survey. The majority of the patients (13) were treated by one prosthodontist but patients 4 and 7 were referred by two other prosthodontists who each undertook their own patient's prosthetic rehabilitation.

The initial prosthetic appointment was made within a month of the surgical splint's removal, but unfortunately this did not always lead to an early completion of the new dentures. Table 18 records the number of weeks between the surgery date and the issuing of new dentures. In the majority of cases the dentures were issued within 20 weeks of surgery (average 16); however, in three cases the time lapse was much greater. Contact was lost with patient 2 while he was on holiday, aesthetic problems required remaking the denture for patient 4, and patient 10 needed HA augmentation of the mandible prior to new dentures being constructed. Unfortunately, this mandibular surgery was delayed by a cataract operation.

Denture construction was conventional as the augmented ridges required no special prosthodontic techniques. A functionally trimmed dental composition impression was taken in a stock tray, with an alginate wash secondary impression used to record fine detail. In certain cases a special tray was used and either an alginate, a rubber base or zinc oxide impression material used.

The working models were cast in dental stone and wax bite registration blocks fabricated. Following the trimming of the blocks and registration of the occlusion, the models were mounted in an anatomical articulator without the assistance of a face bow. Acrylic teeth were used throughout as the softer nature of the material was thought to diminish transmission of forces to the ridge tissue. Posterior cusp height was dictated by the ridge's capacity to withstand lateral movement. The less substantial the ridge, the less the cusp height and incline. At the try-in the occlusion was checked and if
### Table 15

**Times When Questionnaires Were Completed After Receipt of New Dentures**  
(Patients' Response - Red Dot, Prosthodontists' Response - Black Dot)

<table>
<thead>
<tr>
<th>No.</th>
<th>Initials</th>
<th>Weeks between operation and receipt of new denture</th>
<th>Months wearing new denture</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DR</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>BC</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>DG</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>EF</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>CS</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>HT</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>JD</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>MW</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>JS</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>EC</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>JT</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>CH</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>LG</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>JP</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>VW</td>
<td>16</td>
<td></td>
</tr>
</tbody>
</table>

Data from collection times to the left of the line were used for the initial assessment (1-3 months) and to the right for the subsequent assessment (3-14 months).
another functionally trimmed model was judged to be needed, a rubber base impression was taken within the denture base.

The dentures were then processed, issued and the patient requested to wear them for two weeks. A check bite was then taken and the dentures remounted on an articulator for any fine adjustment of the occlusion. This was a crucial step as minor occlusal discrepancies appear to cause more denture sore spots than overextension of the flanges. In cases where denture trauma to the mandibular mucosa had been a constant feature of all previous dentures, the new lower denture was lined with a Molloplast-B® soft liner (Regneri & Co. K.G., West Germany).

Following provision of the dentures, any further adjustments were provided on request or at the time of the surgical recall appointments. Of the six patients who have been wearing their new dentures for at least 14 months, only patient 3 has required a reline.
2. **ACQUISITION AND ANALYSIS OF DATA**

What we anticipate seldom occurs; what we least expect generally happens.

Benjamin Disraeli, (1804-1881), Endymion.

The manner in which the data for this research were collected and assessed was based on the work initiated in the American multicentre study previously discussed (Chapter V section I). This assessment involved:

- A subjective evaluation of their dentures by the patients.
- A clinical evaluation of the dentures and the denture-bearing area by the prosthodontist.
- A clinical, photographic and radiographic evaluation of the denture bearing area by the surgeon.
- A histological evaluation of any biopsy material.
- An objective evaluation of pre- and postoperative radiographs.
- An objective evaluation of pre- and postoperative dental study models.

The collection times for the patient and prosthodontic assessments are recorded in Table 15 and for the radiographs, photographs and models in Table 18.

2.1 **Patient questionnaire**

The questionnaire (Appendix II) used in this study was developed by Larsen et al (1983). The range of responses (excellent, good, fair and poor) is based on the Cornell Medical Index (CMI) and seven parameters were used to evaluate the patients' opinion of their current dentures. The parameters were comfort, fit, speech, appearance, ability to eat, ability to
<table>
<thead>
<tr>
<th>No.</th>
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<th>Pre-operative</th>
<th>Intra-operative</th>
<th>Months postoperative</th>
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</thead>
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</tr>
<tr>
<td>2</td>
<td>BC</td>
<td>***</td>
<td>.</td>
<td>6 7 8 9 10 11 12 13 14 15 16 17 18 19 20</td>
</tr>
<tr>
<td>3</td>
<td>DG</td>
<td>***</td>
<td>.</td>
<td>12 13 14 15 16 17 18 19 20</td>
</tr>
<tr>
<td>4</td>
<td>EF</td>
<td>***</td>
<td>.</td>
<td>17 18 19 20</td>
</tr>
<tr>
<td>5</td>
<td>CS</td>
<td>***</td>
<td>.</td>
<td>20</td>
</tr>
<tr>
<td>6</td>
<td>HT</td>
<td>***</td>
<td>.</td>
<td>19 20</td>
</tr>
<tr>
<td>7</td>
<td>JD</td>
<td>***</td>
<td>.</td>
<td>18 19 20</td>
</tr>
<tr>
<td>8</td>
<td>MW</td>
<td>***</td>
<td>.</td>
<td>17 18 19 20</td>
</tr>
<tr>
<td>9</td>
<td>JS</td>
<td>***</td>
<td>.</td>
<td>16 17 18 19 20</td>
</tr>
<tr>
<td>10</td>
<td>EC</td>
<td>***</td>
<td>.</td>
<td>15 16 17 18 19 20</td>
</tr>
<tr>
<td>11</td>
<td>JT</td>
<td>***</td>
<td>.</td>
<td>14 15 16 17 18 19 20</td>
</tr>
<tr>
<td>12</td>
<td>CH</td>
<td>***</td>
<td>.</td>
<td>13 14 15 16 17 18 19 20</td>
</tr>
<tr>
<td>13</td>
<td>LG</td>
<td>***</td>
<td>.</td>
<td>12 13 14 15 16 17 18 19 20</td>
</tr>
<tr>
<td>14</td>
<td>KP</td>
<td>***</td>
<td>.</td>
<td>11 12 13 14 15 16 17 18 19 20</td>
</tr>
<tr>
<td>15</td>
<td>VW</td>
<td>***</td>
<td>.</td>
<td>10 11 12 13 14 15 16 17 18 19 20</td>
</tr>
</tbody>
</table>
taste and general satisfaction.

A new questionnaire was then submitted to the patient following surgery and the fitting of new dentures. To avoid influencing responses, the patient was always left to complete the questionnaire alone and before any assessment or discussion by the prosthodontist or surgeon. In the event, the intervals of time at which the questionnaires were answered were dictated by the surgery date, (i.e. 3, 6, 12, 18 months postaugmentation), not the date when the new dentures were fitted. This was because of the variable lengths of time necessary to complete the dentures for each patient, a factor beyond the control of the writer. Thus the time intervals before the patients were asked to assess their new dentures are not uniform (Table 18). However, every patient except patient 1 was seen within three months of receiving the new dentures and the results can be usefully analysed if the responses are divided into two groups, namely, initial responses (1-3 months) and longer term (subsequent) responses (3-14 months).

2.2 Prosthodontic questionnaire

The questionnaire used for prosthodontic evaluation (Appendix III) was a simplified version of the one used in the multicentre study (Larsen et al 1983). The range of responses (excellent, good, fair and poor) was similar to the patients’ questionnaire and four parameters were evaluated; retention, stability, overall clinical assessment and mucosa health.

The questionnaire was completed in relationship to the dentures and denture-bearing area both preoperatively and at the time of the surgical recalls postoperatively. As described in the previous section, this meant that the responses were not all collected at uniform time intervals following provision of the new dentures (Table 15), but again the results can be divided into initial responses (1-3 months) and longer term (subsequent) responses (3-14 months).
2.3 Surgical evaluation

No questionnaire was used for the surgical evaluation. Instead, the denture-bearing area was assessed clinically and radiographically in conjunction with study models and photographs. The data from each source were then correlated and given a composite evaluation on a four point scale, excellent, good, fair or poor.

The preoperative clinical evaluation took into account the parameters of mucosal health, the degree and extent of the hypermobile tissue, the height, shape and width of the ridge and the vestibular depth. Postoperatively these aspects were reassessed with particular attention being taken of the degree of mobility still present. Also noted were any complaints or complications associated either with the surgical procedure or the presence of the HA granules. Details such as pain, tenderness, ulceration or sensation change were recorded, as was clinical evidence of granule migration, dehiscence or infection.

Photographs and study models were then utilised to allow pre- and postoperative comparisons of clinical features, the photographs illustrating the degree of mobility by displacement with a swab stick being particularly useful.

2.4 Histology

Only in patient 11 was the augmented ridge surgically exposed postaugmentation allowing the removal of material for histological examination. In this case the initial HA augmentation had not markedly reduced the hypermobility and a further augmentation with granules was performed. Prior to the placement of the granules at the second operation, two specimens were taken from midline ridge tissue as close to the HA/bone interface as possible. These two specimens were then submitted for routine histopathology.
2.5 Radiographs

Radiographs were taken at pre- and postoperative visits when appropriate. As mentioned in section 1.1 the OPT and lateral cephalometric radiographs were found to give the best three dimensional coverage of the augmented area and they were used in two separate types of assessment.

In the first, the pre- and postoperative radiographs were assessed using four parameters to evaluate the implanted HA granules. The parameters were; the degree of granule migration, the granules' apposition to the cortical bone surface, the radiodensity changes in the augmented areas and the alveolar ridge height increase.

The second method of assessment utilising the radiographs involved the production of composite ridge contour tracings from each set of pre- and postoperative radiographs. This allowed a direct comparison to be made of the ridge contours over time. In an attempt to standardise the radiographs for comparison purposes, a technique described by Rothstein et al (1984A) was adopted and modified.

They developed a method for standardising and measuring panoramic radiographs and tested it for accuracy using pre- and postoperative films from 24 patients who had undergone HA augmentation to the mandible. A direct tracing of the preoperative radiograph was made and placed on the image board of a photographic enlarger. The postoperative radiographs were then mounted sequentially in the negative cassette of the enlarger and their image projected onto the tracing. This image was then adjusted and focussed to match as near as possible the constant anatomical landmarks, such as the bony palate and pterygoid plates, recorded during the initial tracing. They then marked ridge heights in various positions and measured the difference between them to the nearest 0.5mm along lines perpendicular to the average plane of the alveolar ridge. When direct measurement from the radiographs was compared with those from the tracings they found less variance with the tracing method and concluded that the results achieved accurately.
represented the changes taking place.

In the present study a minor modification in the technique was employed with both the pre- and postoperative radiographs being placed in the enlarger (De Vere 504 colour enlarger with a 135mm lens). This change allowed the preoperative tracing to be enlarged significantly and by enlarging the subsequent postoperative images to match, an exaggerated tracing was created giving greater detail of the changes over time. From the preoperative image, identifiable features such as the zygomatic buttresses, nasal spines, pterygoid plates and antral outlines were traced as landmarks, as well as the ridge crest. Each postoperative film was then projected and the image adjusted and focussed until all the landmarks coincided as closely as possible. The HA radio-opacity was then traced in a colour contrasting with the previous tracings, and the process continued until a composite tracing had been produced for each patient.

The technique was found to work very well for the lateral cephalometric radiographs, but the distortions and superimposition in the anterior region of the maxilla inherent in the OPT made the tracings from those radiographs less accurate and of dubious assessment value. Therefore, only the tracings from the lateral cephalometric radiographs are included and assessed in the results. Neither was it possible to make direct quantitative measurements of the ridge height increases achieved by the granules. This was due to both the difficulty of accurately identifying the preaugmentation ridge profile on sequential postaugmentation radiographs and because of the inaccuracy inherent in interpreting radiographic images.

2.6 Study models

At the preoperative and most postoperative visits a maxillary alginate impression was taken in a stock tray (Table 16). Care was taken, particularly preoperatively, to avoid distortion of the hypermobile tissue by placing thinly
mixed alginate either side of the ridge before the tray was seated. The study model was then cast immediately and duplicated. The original was then stored and the duplicate used for evaluation and assessment.

The comparison of dental study models has always been problematic due to the difficulty of reproducing constant reference points to allow the matching of serial study models taken over a period of time. Kent et al (1982) did not attempt any study model measurement because of the inconsistency of their impression procedure and Rothstein et al (1984) limited their use of study models to a measurement of the ridge width.

Visual examination of the models in this study indicated an increase in both height and width of the HA augmented ridges but difficulty was experienced initially in trying to quantify this gain. Consideration was given to a technique using a spirograph to sequentially trace the ridge shapes and also to a technique where a strip of radio-opaque material could be onlayed over the ridge and standardised radiographs taken in profile. However, both of these methods proved to be too inaccurate.

Watt (1974), during discussion of morphological changes of the denture-bearing area, demonstrated that the palatal vault was the one constant feature in the maxilla over time. This finding was utilised in this study. The major part of the palate and the tuberosities are not affected by augmentation surgery and a method utilising them as a constant reference was developed to permit serial measurement of the cross-sectional area changes of the augmented ridge over the time of the investigation.

The technique involves sectioning the patients' dental models in a predetermined plane and then enlarging the cross-sectional face on a photocopier to produce a profile of the alveolar ridge which could be traced and quantitatively measured.

For each patient, all pre- and postoperative duplicated study models were marked with a cross-sectional plane which extended from a point on the left anterior ridge crest in the canine region across the palate and over the
An example of an original preoperative study model (left) with its duplicate (right) which has been sectioned in the predetermined plane.

The sectioned study models arranged on the photocopier glass in sequence of time. The pre-augmentation model is on the left followed by models taken at 3, 6 and 12 months postaugmentation.
contralateral tuberosity (Plate 28). The position on the anterior ridge crest was exactly one centimetre from the midline, identified as the centre of the incisive papilla. Points on the palatal vault and right tuberosity (which were unaffected by surgery) were then precisely selected in such a way as to provide a plane of section as near to a true cross-section of the ridge as possible. In practice these points could easily and reliably be determined on each series of models.

A line was drawn to connect these landmarks and the model sectioned with a hacksaw. The two cut surfaces were then cleaned and placed, cut surface downwards, on a photocopier (Toshiba BD-7815) (Plate 29). An image of the cut surfaces twice the normal size was then produced by a two stage enlargement, the accuracy being monitored by placing a centimetre scale adjacent to the sectioned study models and copying it concurrently. This x2 image enlargement was performed to facilitate the subsequent tracing of the ridge profile and to diminish, as much as possible, tracing error. Consequently, all absolute values were recorded as twice actual size. The values were not reduced by a factor of two to normal size because the results were analysed not as absolute values but on the basis of the proportional increase in size of the postaugmentation ridge compared with the pre-augmented ridge.

Only the profiles created from the larger sections of the divided models were selected for measurement. They were used in two separate ways, either to produce a composite tracing with each outline overlaying the others and marked in a separate colour, or as a single postoperative tracing superimposed on the preoperative image. The former recorded the changes in cross-sectional shape over time and highlighted the position and shape of any change in contour while the latter allowed direct quantitative measurement of cross-sectional area changes using a computerised image analysis system.

Image analysis allows the cross-sectional areas to be accurately
measured and compared. The Bioquant™ System IV in conjunction with a Hipad digitizing pad and cursor (supplied by Wild Leitz (Australia) Pty. Ltd., North Ryde, N.S.W.) operating with an NEC APC IV computer was used (Plates 30 and 31). This system has the capacity to measure areas within a traced line and so may be used to calculate the cross-sectional area if the profile of the ridge is digitized by tracing with the cursor from one point to another. In this study the ridge profile traced was determined by two standard points, namely, the highest part of the palatal vault and the deepest part of the vestibular sulcus. Beginning in the palate the profile was traced 12 times, the highest and lowest readings discarded and the mean area (in mm²) automatically calculated by the computer for the remaining 10 readings. The mean area of the ridge prior to augmentation was thus calculated for each patient. Tracings from the augmentation images were then individually overlayed on the corresponding preoperative tracing. This created areas between the two outlines which represented either increases or decreases in cross-sectional area (Appendix VI). Each area was then individually measured using the tracings as detailed above.

This procedure for directly measuring area change was adopted for two reasons. Firstly, because despite the palatal vault remaining constant the sulcus depth altered after augmentation and it was not always possible to accurately locate the anterior end of the tracing line and secondly, because it is more accurate to directly measure the actual difference between two quantities (in this case cross-sectional areas) rather than calculate the difference by subtracting the smaller quantity from the larger (Brinkworth 1968A). Following the collection of the data the preoperative area was expressed as 100 per cent and any changes in area recorded from the postoperative models were expressed as an increase or decrease in percentage of the original ridge cross-sectional area.

To test the reproducibility of this method the following experiment was conducted. Using a standard rubber mould of an edentulous maxilla, 10
The complete image analysis system with the digitizing pad on the left of the keyboard and the Bioquant™ System IV program displayed on the visual display unit of the NEC APC IV computer.

A detail of the digitizing pad showing the cross-haired magnifying cursor lying on a set of study model tracings. The areas of increase and decrease relative to the preoperative tracing are marked by + and - signs.
identical models were poured, sectioned, photocopied and traced as previously described. Each tracing was then measured 12 times using the digitizing pad and Bioquant™ System IV program. The highest and lowest readings were discarded, thus giving 10 readings for each of the 10 models.

Analysis of the results (Table 17) revealed a mean area value of 312.6 mm² for the 10 models with a range from 298.8 mm² (x2 of original size) to 323.9 mm² and a standard deviation (s.d.) of 9.30. In a population of results having a normal distribution, 95 per cent fall within the range of the mean ± 2 s.d. (Brinkworth 1968B). In this case 2 s.d. is equivalent to 6 per cent of the mean value \(\frac{9.30 \times 2 \times 100}{312.6} = 5.98\) per cent.

Thus, using a series of models cast from one mould and under the conditions of the experiment, it is concluded that measurements of area can be achieved with an order of accuracy of ± 6.0 per cent.
### TABLE 17

**EXPERIMENTAL MODEL TRACINGS**

<table>
<thead>
<tr>
<th>Model Number</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>All Models</th>
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<tbody>
<tr>
<td>Mean area (mm²)</td>
<td>305.3</td>
<td>317.8</td>
<td>310.1</td>
<td>305.4</td>
<td>323.9</td>
<td>318.9</td>
<td>322.9</td>
<td>320.8</td>
<td>298.8</td>
<td>302.2</td>
<td>312.6</td>
</tr>
<tr>
<td>Standard deviation (s.d.)</td>
<td>2.62</td>
<td>1.39</td>
<td>2.72</td>
<td>2.10</td>
<td>2.69</td>
<td>2.76</td>
<td>2.77</td>
<td>3.00</td>
<td>2.25</td>
<td>2.18</td>
<td>9.30</td>
</tr>
<tr>
<td>Standard error of the mean</td>
<td>0.83</td>
<td>0.44</td>
<td>0.86</td>
<td>0.66</td>
<td>0.82</td>
<td>0.87</td>
<td>0.88</td>
<td>0.95</td>
<td>0.71</td>
<td>0.69</td>
<td>2.94</td>
</tr>
</tbody>
</table>

Results of 10 measurements taken from each of 10 identical models and used to test the reproducibility of the analysis technique.