

**SURVEYS OF THE ATTITUDES AND EXPERIENCES OF DENTISTS AND
PATIENTS WITHIN NEW SOUTH WALES WITH RESPECT TO IMPLANT
TREATMENT MODALITIES**

A thesis submitted as a requirement for the degree of
Master of Dental Surgery

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SUMMARY

CHAPTER 1 - INTRODUCTION

Tooth loss has several implications for the individual, among which are functional and psychosocial considerations.

In recent decades progressively more stringent criteria for the success of dental implants have been proposed (Schnitman and Schulman, 1979; Cranin et al., 1982; McKinney et al., 1984; Albrektsson et al., 1986; Smith and Zarb, 1989). Both the Brånemark osseointegrated screw (Brånemark et al., 1977, 1984; Adell et al., 1986, 1990; Albrektsson 1988; Brånemark, 1988) and the Small Trans-osteal staple (Kent et al., 1984; Small and Misieck, 1986) satisfy Albrektsson's criteria. Originally the Brånemark osseointegrated screw pertained to the treatment of edentulous patients with fixed bridge units, however encouraging results are also being presented for the application of these fixtures to overdenture treatment for edentulous patients (Parel, 1986; Engquist et al., 1988; Naert et al., 1988), for a variety of fixed partial dentures both free standing and attached via a non-rigid connector for partially dentate cases with multiple missing teeth and for single tooth replacements (Ericsson et al., 1986; Jemt, 1986; de Clerq et al., 1988; Lewis et al., 1988a,b; Öhrnell et al., 1988; Jemt et al., 1989, 1991; Perri et al., 1989 van Steenberghe et al., 1989, 1990).

The objectives of this study were:

- a. to establish the awareness and needs of implant treatment modalities of partially dentate and edentulous prosthodontic patients within New South Wales,
- b. to assess the attitudes towards dental implants of active private general dental practitioners within New South Wales and their involvement with dental implant treatment modalities and
- c. to assemble demographic, functional and psychosocial profiles of patients attending the Centre for Osseointegrated Dental Implants associated with the University of Sydney as components of evaluation programmes for the provision of implant treatment ad modum Brånemark.

CHAPTER 2 - MATERIALS AND METHODS

Each phase of the investigation involved the administration of questionnaires, two cross-sectional analytical surveys and a cohort study.

Forms 1 and 1A contained awareness and needs variables of dental implants, potential explanatory variables included in the questionnaire were sociodemographic and dental history in nature, as well as aspects of the Health Belief Model (Kegeles, 1961, 1963a,b, 1974; Gift, 1984).

Form 1 was directed to patients requesting removable denture and/or fixed bridge treatment presenting to the admissions areas of three public hospitals, two Sydney based hospitals, United Dental Hospital and Westmead Hospital Dental Clinical School and Royal Newcastle, a regional hospital. Form 1A was directed to patients requesting removable denture and/or fixed bridge treatment presenting to private general dental practice.

Form 2 contained variables to assess the attitudes towards dental implants of active private general dental practitioners within New South Wales and their involvement with dental implant treatment modalities and potential explanatory variables were sociodemographic in nature. For Form 2 the sampling frame was the Australian Dental Association membership record of active private general dental practitioners in New South Wales (this was also the primary sampling frame for Form 1A). It was planned to invite 300 of these dentists by a telephone request to participate in the survey.

Forms 3; IA1, IB1 and IC1, IA2, IB2 and IC2, CA1, CB1 and CC1 and CA2, CB2 and CC2 were for the sample of urban edentulous patients receiving implant treatment at the Centre for Osseointegrated Dental Implants (as described by Brånemark et al., 1985; Engquist et al., 1988 and Naert et al., 1988) and their matched control patients receiving conventional complete denture treatment.

Form 3 was designed for use in acquiring pretreatment sociodemographic and dental history data. The remaining forms were for post-treatment evaluation and were to be completed at 1, 3 and 6 month post-insertion time periods by either the patient or the examiner (the dentist).

Data management was committed to a NEC Powermate 1 Plus Personal Computer, utilising mainly the SAS^R system (Saffer 1985).

CHAPTER 3 - RESULTS

RESPONSE TO THE QUESTIONNAIRES

One hundred completed Form 1's were collected from each of United Dental Hospital and Westmead Hospital Dental Clinical School and 89 questionnaires were collected from the Royal Newcastle Hospital. At least one Form 1A was returned by 68.7% of dentists, 54.3% of dentists returned at least one completed Form 1A so that 276 of these questionnaires could be subjected to statistical analysis.

With regard to Form 2, 65.3% of the dentists returned completed questionnaires.

A total of 14 urban edentulous patients receiving implant treatment ad modum Brånemark were able to participate in

the study and were matched to suitable control patients.

DESCRIPTION OF FORMS 1 AND 1A

Unless otherwise stated, the level of significance for the ensuing analyses is considered to be at the $p \leq 0.05$ level.

With regard to the awareness variables, 63.8% (95% CI {confidence interval} $\pm 5.67\%$) of the patients attending private practice had 'heard' of dental implants as compared to 27.3% (95% CI $\pm 5.14\%$) of patients attending public institutions. This difference is highly statistically significant. There was no significant difference between United Dental Hospital (UDH), Westmead Hospital Dental Clinical School (WHDCS) and Royal Newcastle Hospital (RNH) with respect to this issue.

With regard to awareness of the availability of dental implant treatment in New South Wales 84.1% of those patients attending private practice who had 'heard' of dental implant treatment were also aware that dental implant treatment is available in New South Wales as compared to 48.1% for the public group. This difference is highly statistically significant. There was no difference between UDH, WHDCS and RNH with respect to this issue. If the frequency of the 'yes' response is expressed as a percentage of the total number of respondents in the survey then it is apparent that 53.6% of the patients attending private practice are aware that dental implant treatment is available in New South Wales as compared to 13.2% of the patients attending public hospitals.

With regard to self-perceived need for dental implants, of those patients who had 'heard' of dental implants, 30.1% of the private group and 24.1% of the public group responded 'yes' to the question 'do you think that it is likely that you may require a dental implant in the future?' If the frequency of the 'yes' response is expressed as a percentage of the total number of respondents in the survey then it is apparent that 19.2% of the patients attending private practice have a self-perceived need for dental implant treatment as compared to 6.6% of the patients attending public hospitals.

DESCRIPTION OF FORM 2

Dental implants were considered to offer a successful long term treatment outcome by 67.9% (95%CI $\pm 6.5\%$) of the respondents and 14.3% (95% $\pm 4.9\%$) reported that they had completed a stage(s) of work involving dental implants. These outcomes were not significantly associated with age, year of graduation (these factors are probably collinear), gender, location of the institution from which the undergraduate dental qualification was gained or main practice location. However the latter outcome was significantly associated with place of birth. Dentists born outside

Australia were more likely to have completed a stage(s) of dental implant work.

With regard to intent to attend a postgraduate education course on dental implants, 54.1% of the total number of dentists responded 'yes'.

DESCRIPTION OF THE POST-TREATMENT QUESTIONNAIRES

Description and analyses of psychosocial variables

For several variables there were no statistical differences between the implant patients and their control patients at each post-insertion time period (the Binomial Theorem was applied). But, the implant patients considered that their current dentures had improved their psychological status, at 1 month and 6 months post-insertion, $p=0.063$ and $p=0.109$ respectively as compared to the control patients. They also considered that their appearance was significantly better at 1 month post-insertion compared with the control patients ($p=0.031$), that their contact with other people had improved at 3 months post-insertion ($p=0.063$) and that they were not noticing other peoples' teeth as much ($p=0.063$). The control patients reported more general problems associated with the lower denture when compared to the implant patients at 1 month post-insertion ($p=0.063$).

With regard to trends over time (Friedman Two-way Analysis of Variance test was applied) the implant patient group demonstrated improved contact relations with other people ($X_r^2=6.964; p\leq 0.05$), but other trends were not statistically significant.

Description and analyses of functional data

At 1 month post-insertion the control patients exhibited more chewing problems than the implant patients ($p=0.031$) and the implant patients reported more problems with denture cleanliness at a significance level of $p=0.063$ (the Binomial Theorem was applied).

With regard to trends over time in relation to the nature of the post-insertion problems, the control group reported a decrease in chewing problems over time at a significance level of $p=0.052$ (Friedman Two-way Analysis of Variance test was applied).

With regard to the dentist's assessment of post-insertion problems, the implant patients exhibited more unclean prostheses ($p=0.063$) at the 1 month post-insertion assessment (the Binomial Theorem was applied).

Tissue assessment

With regard to the tissue assessments at each post-insertion evaluation period, for both groups of patients the tissues were generally healthy. The 40% incidence of ulceration of the mandibular denture bearing area for the implant group of patients at the 6 month evaluation time period may be considered unfavourable although not significantly greater than for the control patients (the Binomial Theorem was applied).

CHAPTER 4 - DISCUSSION

FORMS 1 AND 1A

Awareness variables

Relatively low percentages of the patients presenting for prosthodontic treatment to the private practices and public hospitals in this study had 'heard' of dental implants and similarly low percentages of these patients were aware that dental implant treatment is available in New South Wales.

Needs variables

With regard to self-perceived need, the result that 19.2% of the patients attending private practice considered that they may require a dental implant in the future may be considered moderately high, although much lower than the approximately 50% figure cited by Akagawa et al. (1988).

Promotional aspects of implant treatment for dental patients

The community of New South Wales could be considered as two distinct groups with regard to increasing the awareness of dental implants:

- a. those patients who attend the dentist regularly.
It is of interest that 71.0% of patients attending private general dental practice and requesting prosthodontic treatment, attend the dentist at least once every 2 years. It could be expected that the dentists would respond to the patients' specific dental status with professional advice regarding implant treatment as appropriate.

Following surveys of the public, van Riel et al. (1988) and O'Neill (1984) reported that the dentist appears to be the most important source of dental information for dental patients. In a concurrent telephone survey of dentists by the latter author however, it was found that only 2 dentists in 5 (39%) considered the dental profession a primary source of information for patients. The dentists overemphasised the contributions of television and newspapers/magazines.

General dental practitioners must recognise their potential as an information source for their patients and the training of dentists and their continuing education should incorporate behavioural science and communication aspects to fully realise this potential.

b. those patients who do not attend the dentist regularly.

These patients could benefit by presenting the indications and advantages of this form of treatment during existing dental health promotional activities, such as Dental Health Week conducted by the Australian Dental Association.

FORM 2

It is apparent that despite the publications describing the very high long term success rates for implant treatment ad modum Brånemark and the Small Transosteal staple, the percentage of general practitioners in New South Wales who consider that dental implant treatment offers a successful long term treatment outcome is relatively low. This could be a result that reflects the documented failures of implant systems other than the Brånemark system.

A relatively low percentage of respondents had completed a stage of work involving dental implants. This possibly reflects the dentists' interests and aspirations regarding the provision of treatment within the practice environment as much as patient demand.

THE LONGITUDINAL STUDY OF PATIENTS RECEIVING IMPLANT TREATMENT

Psychosocial variables

A limited number of studies involving matched control patients has addressed the issue of the social and psychological impact of implant supported prostheses ad modum Brånemark for the treatment of edentulous patients. It is this type of study design that is essential to elucidate whether treatment involving implants is indeed superior to conventional treatment.

In this study, for a limited number of psychological and social variables, the implant patients exhibited significantly improved status in relation to their control patients. Improvements in psychological and social status for both groups of patients were retained over time.

The question of whether implant treatment can be recommended more or less routinely for edentulous patients because of significant improvements in social and psychological functioning has yet to be adequately answered. Although this study makes a positive contribution to this issue, it has a relatively small sample size despite the assessment

of all edentulous patients presenting to the Centre for Osseointegrated Dental Implants over a 2 year period and the data sets for some patients were incomplete. It would be of value to integrate new patient data into the data base of this study and recalculate the statistical results. It would also be of value to collect patient data over longer post-treatment evaluation periods.

Functional variables

Because of the short term nature of this study, it is not possible to apply the criteria for success of implant treatment as described by Albrektsson et al. (1986) directly, however each patient receiving implant treatment (of which 10 of the total of 14 received implant supported overdenture therapy) may, as a general statement be considered to have exhibited a successful functional outcome. Nevertheless, both groups of patients reported a relatively high incidence of post-treatment problems over the 6 month review period emphasising the need for regular maintenance appointments during this time.

CONCLUSIONS

After an examination of the results the following conclusions can be supported:

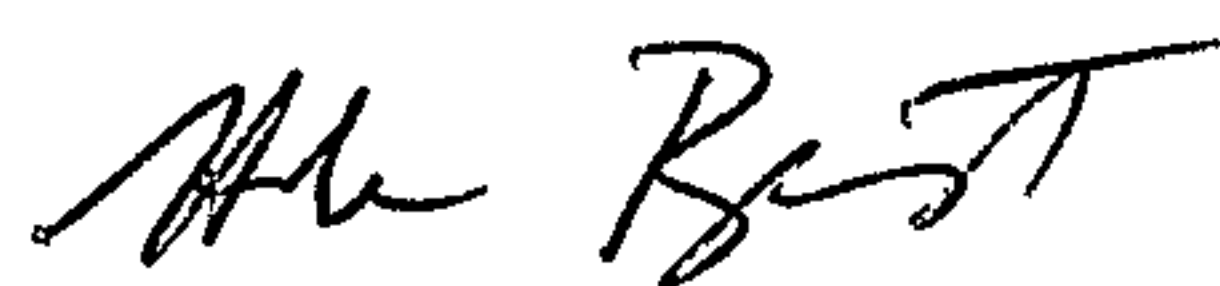
1. a. Relatively low percentages of the patients presenting for prosthodontic treatment to the private practices and public hospitals in this study had 'heard' of dental implants and similarly low percentages of these patients were aware that dental implant treatment is available in New South Wales.

b. A moderately high percentage of the patients attending private practice considered that they may require a dental implant in the future, although much lower than the approximately 50% figure cited by Akagawa et al. (1988).
2. It is apparent that despite the publications describing the very high long term success rates for implant treatment ad modum Brånemark and the Small Transosteal staple, the percentage of general practitioners in New South Wales who consider that dental implant treatment offers a successful long term treatment outcome is relatively low and a relatively low percentage of respondents had completed a stage of work involving dental implants.
- 3 a. For a limited number of psychological and social variables, the implant patients exhibited significantly improved status in relation to their control patients. Improvements in psychological and social status for both groups of patients were retained over time.

b. Each patient receiving implant treatment (of which 10 of the total of 14 received implant supported overdenture therapy) may, as a general statement be considered to have exhibited a successful functional outcome.

DECLARATION

I declare that this thesis contains no material which has been accepted for the award of any other degree or diploma in any University, and to the best of my knowledge and belief, it contains no material previously published by another person except where due reference is made in the text.

A handwritten signature in cursive script, appearing to read "Helen A. Best".

Helen A Best

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DEDICATION

To Ian and Tes

CHAPTER 1 - INTRODUCTION

Tooth loss has several implications for the individual. Partially dentate and edentulous individuals share some similarities but they also exhibit distinctive differences which will be discussed separately.

1.1 THE PARTIALLY DENTATE PATIENT

The implications of missing teeth for the partially dentate patient have been identified as follows (Zarb et al., 1978; Carr, 1988):

1.1.1 Loss of masticatory efficiency

After a review of the literature Bates et al. (1975) concluded that as the dentition deteriorates so does its efficiency and performance, and Helkimo et al. (1978) found that the greater the number of natural teeth remaining the greater the bite force. Although the comminution of most modern foods does not demand vigorous mastication and although effective mastication may not be necessary for adequate nutrition, it has other functions. It is necessary for full appreciation of flavour and for mixing of food with saliva to facilitate swallowing.

1.1.2 Tipping, migration, extrusion and depression of teeth

The loss of any functional tooth from the dental arch will tend to disturb occlusal relations between the remaining teeth. The effect may not be localised but may affect distant areas of the dentition as well. The changes in tooth position may result in:

- a. occlusal interferences and their sequelae, including mandibular deviation,
- b. open tooth contacts and food impaction and
- c. encroachment of a tooth/teeth into the opposing edentulous area thereby compromising replacement of the missing tooth/teeth.

It is rarely possible to predict which teeth will change position but the following factors appear to be prognostically important:

- a. the intercuspatation of teeth adjacent to the space and their antagonists,
- b. patient age,
- c. duration of the partially dentate state and
- d. periodontal status.

1.1.3 Craniomandibular disorders

Cranio-mandibular disorders are a variety of complex

disturbances including organic disorders of articular and non-articular tissues and inorganic disorders of functional origin and those combined with secondary tissue changes (McNeill et al., 1980; McNeill, 1983). Traditional mechanically and morphologically orientated occlusal concepts have associated the occurrence of craniomandibular disorders with loss of posterior jaw (tooth) support (Carlsson et al., 1979; Hansson et al., 1983b) but Roessler (1989) and Kayser (1989) have reported after reviewing the literature, that most studies do not support this association. The association of centric relation and/or centric occlusion discrepancies and/or mediotrusive interferences with craniomandibular disorders is also controversial (Roessler, 1989).

More than ever, the decision to replace missing teeth in the partially dentate patient requires emphasis on individual factors and consideration of the shortened dental arch concept (Kayser, 1989).

1.1.4 Other implications

- a. compromised appearance
- b. loss of occlusal vertical dimension
- c. loss of alveolar bone

1.2 THE EDENTULOUS PATIENT

The implications of missing teeth for the edentulous patient have been identified as follows:

1.2.1 Absence of periodontal ligaments

In simplistic terms, the periodontal ligament allows for the transmission of occlusal forces to the alveolar bone as tension and has a remodelling function. In the absence of natural teeth, alveolar bone changes take place slowly over a period of years and depend on the balance of osteoblastic and osteoclastic activity. The denture bearing area becomes progressively smaller and the reduction of the residual ridges may lead to a reduction in total face height and an increase in mandibular protrusion (Zarb et al., 1990). Tallgren (1972) in a mixed longitudinal study of complete denture wearers covering 25 years, has shown that the mean reduction in height of the mandibular process, as measured in the anterior region, was approximately four times greater than the mean reduction occurring in the maxillary process.

Neurophysiological sensory functions have been ascribed to the periodontal ligament through specialised sensory elements including discrete units and compound receptors which have been identified and described as participating in:

- a. inhibitory response of mandibular elevators that occurs after tooth contact upon jaw closure,
- b. the jaw opening reflex,
- c. direction assessment and proprioception and
- d. dimension discrimination.

The exact role and relative importance of mucosal stimuli in the control of jaw movements need clarification (Zarb et al., 1990).

1.2.2 Parafunctional habits

The initial discomfort associated with wearing new dentures is known to evoke unusual patterns of behaviour in the surrounding musculature. Frequently the complaint of a sore tongue is related to the habit of thrusting it against the denture. Similarly patients tend to occlude the teeth of new dentures frequently at first, perhaps to strengthen confidence in retention until the surrounding muscles become accommodated or because some accommodation in the chewing pattern is required and experimental closure of the teeth is part of the process of adaptation (Thomson, 1971; Zarb et al., 1990).

A strong response of the lower lip and mentalis muscle has been observed electromyographically in long term complete denture wearers with impaired retention and stability of the lower denture. It is possible that the resulting

tentative occlusal contacts may trigger the development of a habitually disturbed occlusion (Zarb et al., 1990).

The prevalence of bruxing for different complete denture populations is unknown but it is a common cause of the complaint of soreness of the denture bearing mucous membranes (Thomson, 1968) and parafunctional habits in complete denture wearers are possibly a significant cause of residual ridge resorption.

1.2.3 Mastication

Mastication is responsible for many different physical stimuli to the sensorimotor systems. The bite force for both sexes has been found to be notably smaller among complete denture wearers compared to dentate persons (Helkimo et al., 1978) and Haraldson et al. (1979) have reported that this difference is five to sixfold. The masticatory efficiency of complete denture wearers has been found to be reduced compared to dentate persons (Bates et al., 1976; Bergman and Carlsson, 1985) and Manly and Vinton (1951) reported the magnitude of this reduction to be approximately 25%.

1.2.4 Compromised appearance

Although not exclusive to the edentulous state Zarb et al. (1990) describe the following cosmetic features that

frequently accompany edentulism:

- a. deepening of nasolabial groove,
- b. loss of labiodental angle,
- c. narrowing of the lips,
- d. increase in columella-philtrum angle and
- e. mandibular prognathism.

1.2.5 Taste

Attempts to measure possible differences in taste sensitivity with and without an upper denture in place have produced contradictory results (Nilsson, 1979). Giddon and Hittelman (1980) have reported the results of Giddon et al. (1954) which demonstrated that the appreciation of flavour differences in solid foods is adversely affected by the presence of complete dentures. Complete denture wearers took more than twice as long as persons with natural dentition to render a less accurate judgement, 15 versus 6 seconds. When restricted to 10 seconds, the maximum time that dentate patients took to render a more accurate judgement, the denture patients were unable to distinguish increasing levels of sucrose in biscuits.

1.2.6 Psychosocial factors

During human development the oral region has functional, social and emotional roles and becomes established as a significant part of body image (Ament and Ament, 1970) and

a psychosexual focus (Albrektsson, 1985). Body image may be defined as an unconscious mental representation of the image and appearance of body and organs. The maintenance of the familiar body image is important for an individual in maintaining a sense of personal security while change in configuration of this image may be experienced as threatening (Miller, 1970). The loss of a tooth or teeth may be considered equivalent to a loss of an organ with associated feelings of deprivation (Moulton, 1946) or equivalent to the loss of a loved person and a process of mourning may occur. The loss of a tooth or teeth may be considered a punishment and have associated feelings of anxiety (Miller, 1970) or symbolise aging (Miller, 1978) and weakness, with subsequent loss of potency and sexual problems (Blomberg, 1988).

Several studies report on success rates and factors influencing success rates of conventional fixed bridgework (Nyman et al., 1975; Nyman and Lindhe, 1976, 1977, 1979; Glantz and Nyman, 1982; Nyman and Ericsson, 1982; Glantz et al., 1984; Randow et al., 1986; Lindhe, 1989), adhesive bridgework (Sykes and Walton, 1983; Barrack, 1985; Flood, 1989; Flood et al., 1989), removable partial dentures (Anderson and Lammie, 1952; Anderson and Bates, 1959; Tomlin and Osborne, 1961; Bergman et al., 1971, 1977, 1982; Addy and Bates, 1977, 1979; Wetherall and Smales, 1980; Lechner, 1985a,b,c) and complete dentures (Langer et al., 1961; Bergman et al., 1964; Yoshizumi, 1964; Carlsson et

al., 1967; Bergman and Carlsson, 1972,1985; Berg, 1984; Berg et al., 1985; Heyink et al., 1986; Heyink and Schaub, 1986; Kalk and de Baat, 1990) for the replacement of missing teeth. Consider however the utilisation of dental implants for this purpose.

1.2.7 Other implications

a. speech

1.3 DENTAL IMPLANTS

1.3.1 Classifications of dental implants

Several different classifications of oral implantations have been suggested and based on:

- a. gross design of the implant (Berger and Baskas, 1970; Cherchève and Berger, 1971; Johns, 1971; Baumhammers, 1975; Potashnik, 1976; Hansson, 1977, Laney, 1988). Laney (1988) categorizes implant types as endosseous (root, blade, ramus frame), subperiosteal (complete, unilateral, circumferential) and transosteal (staple, single and multiple pin) and
- b. anchorage principle (Hansson, 1977; Albrektsson et al., 1981; Albrektsson, 1985).

Unless otherwise stated, in this thesis, the term dental

implant will refer to foreign structures which penetrate the oral mucosa and provide supramucosally positioned supportive and stabilising elements involved with the retention of fixed or removable prostheses (partial or complete) for the provision of artificial teeth.

1.3.2 Indications for dental implants

The following clinical findings singly or collectively are indications for dental implant treatment for the edentulous patient (Lekholm and Zarb, 1988):

- a. severe morphological compromise of denture supporting areas that significantly undermine retention,
- b. poor oral muscular coordination,
- c. low tolerance of mucosal tissues,
- d. parafunctional habits leading to recurrent soreness and instability of prosthesis,
- e. unrealistic prosthodontic expectations,
- f. active or hyperactive gag reflexes, elicited by a removable prosthesis and
- g. psychological inability to wear a removable prosthesis, even if adequate retention or stability have been obtained.

For the partially dentate patient, the aforementioned factors singly or in combinations are indications for dental implant treatment in addition to either or both of

the following (Lekholm and Zarb, 1988):

- a. unfavourable number and/or location and/or poor quality of potential abutments in the residual dentition and
- b. to avoid excessive destruction of dental hard tissues of potential abutments.

1.3.3. Contraindications for dental implants

Contraindications to oral implant treatment may be categorised as general or local and absolute or relative (Adell et al., 1970; Hansson, 1977; Blomberg, 1988; Hobo et al., 1990).

1.3.3.1 General Contraindications

A. Neoplasia:

B. Chronic infections:

- a. tuberculosis and
- b. syphilis.

C. Metabolic and Endocrine disorders:

- a. osteoporosis,
- b. osteo-malacia,
- c. Paget's disease,
- d. hyper- or hypo-parathyroidism,

- e. acromegaly and
- f. Addison's disease.

D. Nutritional disorders:

- a. vitamin C,
- b. vitamin D and
- c. iron deficiencies.

E. Psychiatric disorders:

- a. addiction: alcohol or drug abuse where not diagnosed with great certainty as secondary to the oral problem,
- b. psychotic syndromes: schizophrenia, paranoia,
- c. severe character disorders and neurotic syndromes, hysteroid and borderline personality,
- d. dysmorphophobia and patients with extreme and unrealistic expectations and demands regarding the cosmetic results of the operation and
- e. syndromes of cerebral lesions such as presenile dementia.

F. Irradiation:

Patients who have received therapeutic radiation doses of more than 5000 Rads have a significantly reduced wound healing capacity (Hobo et al., 1990). Albrektsson and Lekholm (1989) reported that previous irradiation in therapeutic doses is not an absolute contraindication for implant insertion but recommend

that some time elapse (at least 1 year) before implant placement.

1.3.3.2 Local Contraindications

A. Abnormalities in the oral mucous membranes and/or jaws:

- a. cysts,
- b. odontogenic tumours and
- c. impacted or retained teeth or roots.

B. Morphological features of the field of operation:

- a. severe atrophy of the alveolar bone,
 - b. a thin bony wall facing the maxillary sinus and
 - c. a mandibular canal near the top of the ridge crest
- may be relative or absolute contraindications to implant therapy.

C. Oral and/or facial neuralgia:

D. Inability of patient to maintain good oral hygiene.

1.3.4 Methods of anchorage

Before considering a review of the success of different implant systems it is worthwhile considering the fundamental difference in the rationale between many of the implant systems, the method of anchorage.

1.3.4.1 Osseointegration

Osseointegration is defined as a direct structural and functional connection between ordered living bone and the surface of a load-carrying implant (Brånemark, 1988). The American Academy of Implant Dentistry (1986) defined osseointegration as 'contact established without interposition of non-bone tissue between normal remodelled bone and an implant entailing a sustained transfer and distribution of load from the implant to and within the bone tissue.' Meffert et al. (1987) have subdivided the term into 'adaptive osseointegration' in which the osseous tissue approximates the surface of the implant without any apparent soft tissue interface (at the light microscope level) and biointegration, used to define a direct biochemical bond to a surface that is significant and confirmed at the electron microscope level of observation. It is probable that the term osseointegration requires redefinition (Brunski, 1988; Albrektsson and Lekholm, 1989) with reference to the exact structural features, the nature and structure of relevant bonds, the minimum total contact area required and the functional connection has to be described in terms other than that of simply long term function.

1.3.4.1.1 Experimental methods utilised to demonstrate osseointegration

A variety of experimental methods have been utilised to

demonstrate osseointegration. Albrektsson et al. (1981) and Hansson et al. (1983a) investigated tissue-implant interfaces for stable pure titanium dental implants manufactured and inserted according to the techniques described by Brånemark et al. (1977) and which were clinically stable but which were required to be removed because of, for example, psychiatric reasons and 'implant fractures'. Albrektsson et al. (1982) and Hansson et al. (1983a) described an experimental technique to analyse the bone-to-titanium interface involving the evaporation of a thin (approximately 1000Å) layer of titanium on the surface of a cylindrical plastic implant. These implants were inserted into rabbit tibias and subsequently removed by trephines after various time periods. The specimens were viewed by light, scanning and transmission electron microscopy.

A general summary of the observations of the tissue-implant interfaces described by these authors together with a report by Albrektsson (1988) is as follows:

- a. the interfaces showed a regular organisation,
- b. the titanium surfaces were immediately surrounded by a proteoglycan layer of a minimal thickness of 200Å. This proteoglycan layer was partly calcified and calcified tissue was observed in direct continuity with the implant surface at a resolution level of the equipment used, that is 30 to 50Å. Bone cells and their processes were separated from the titanium surface by this proteoglycan

layer. The surrounding bone was vital, exhibiting cement lines indicating that it had become actively remodelled in a regular manner, presumably according to the stress forces applied and

c. there was no evidence of the formation of a connective tissue capsule, nor of any fibroblasts and macrophages interposed between the metal and the bone. There were no inflammatory cells in the interface regions. Collagen bundles were seen at a distance of 1 to 3 μ m from the interface. Collagen filaments were observed closer to the interface, but always separated from the titanium surface by the proteoglycan layer.

Albrektsson (1990) has reported the results of Sennerby et al. (1990) who have utilised a new method to study the osseointegrated implant-tissue interface. This method involves electrochemical dissolution of the greater part of titanium implants inserted in the rabbit tibia for twelve months. The surface oxide layer of the implant is left in the tissue and ultra-thin sections of the intact interface of titanium and undecalcified bone can be prepared for transmission electron microscope study. Using this method, an unmineralised zone, 2-10 μ m thick was always present between the fully mineralised bone and the implant surface indicated by the oxide layer. The interfacial tissues had the characteristics of osteoid and contained densely packed collagen fibrils and occasional osteocytes. Forthcoming studies will reveal whether these observations are partly

dependent on a method error, which has given rise to the artefactual decalcification of the bone.

1.3.4.1.2 Mechanism for the development of osseointegration

The mechanism for the development of osseointegration in ideal circumstances with the Brånemark system is similar to primary bone healing (Hobo et al., 1990). Initially, blood is present between the fixture and bone, a blood clot forms and is then transformed by the phagocytic cells polymorphonuclear leucocytes, lymphoid cells and macrophages. The phagocytic activity level peaks between the first and third day after surgery. During this period, formation of the procallus occurs, containing fibroblasts, fibrous tissue and phagocytes. The procallus becomes dense connective tissue and mesenchymal cells differentiate into osteoblasts that appear on the fixture surface. Osteogenic fibres formed by fibroblasts have the potential to calcify and the dense connective tissue then forms a fibrocartilaginous callus, usually between the fixture and the bone. New bone penetrates and the new bone matrix is called the bone callus. This new bone matures, increasing in density and hardness. About this time, the prosthesis is attached to the fixtures and with stimulation, bone remodelling occurs (Brånemark et al., 1984).

1.3.4.1.3 Bonding mechanisms over osseointegrated interfaces

The types of bonds that may exist are currently not known in detail, even though long range (1 to 100Å), weak van der Waal's interaction, that is physical forces, seem to be the most probable (Kasemo, 1983). Parsegian (1983) suggested that the osseointegrated bond may be an example of true chemical forces (1 to 10Å). Hansson et al. (1983a) showed that the bond of bone to the titanium implants was very strong, with fractures in the tissue interface region usually located in the tissue and rarely through the interface between tissue and metal. Brånemark (1983) reported the anchorage capacity of implants in dogs to be 100kg in the lower jaw and 30 to 50kg in the upper jaw.

1.3.4.1.4 Clinical demonstration of osseointegration

Many methods have been tried to clinically demonstrate osseointegration of an implanted alloplastic material. These tests have been used to indicate, not to verify, osseointegration which is a concept involving a histological definition (Albrektsson and Jacobsson, 1987) as follows:

- a. performing a clinical mobility test and finding that the implant is mobile is definite evidence that it is non-integrated, however the presence of clinical sta-

bility cannot be taken as conclusive evidence of osseointegration,

b. radiographs demonstrating a seemingly direct contact between bone and implant have been cited as evidence of osseointegration. Radiolucent zones around an implant are a clear indication of its being anchored in fibrous tissue, whereas the lack of such zones is not evidence for osseointegration. The reason for this is that the optimal resolution capacity of radiography is in the range of 0.1mm whereas the size of a soft tissue cell is in the range of 0.01mm, thus a narrow zone of fibrous tissue may be undetectable by radiography and

c. percussion with a metal instrument and analysing the sound has been used to indicate the degree of osseointegration. However there is no established 'sound diagram' which can be referred to for diagnostic purposes.

1.3.4.1.5 Factors affecting osseointegration

1.3.4.1.5.1 Implant material

Several materials, metals (pure and alloyed) and non-metals (ceramics and glasses) have been tried as implant materials. Commercially pure titanium exhibits the following desirable properties:

a. good corrosion resistance - Clarke and Hickmann (1953) testing metal reactions in equine serum determined the 'Anodic Back emf' (ABE), a parameter bearing a close relation to known corrosion resistance. Titanium was found the least corrosive material in the test, having an ABE-value more than five times higher than, for example vitallium and seven times higher than stainless steel. Solar et al. (1979) presented an in vitro study of titanium in Ringer's solution at 37°C with different measures being taken to imitate the in vivo conditions. The findings showed that titanium should tolerate exposure to physiological chloride solutions at body temperature for an indefinite time without corrosion. No signs of corrosion were noticed on titanium implants manufactured and inserted according to the techniques described by Brånemark et al. (1977) and which were clinically stable but which were required to be removed because of for example, psychiatric reasons and 'implant fractures' (Albrektsson et al., 1981; Hansson et al., 1983a),

b. low toxicity as compared to for example, steel (Laing et al., 1967),

c. appropriate mechanical properties - the Young's modulus is approximately 1.1×10^{11} N/m², in tension, the failure stress of titanium is approximately 3×10^8 N/m²; these values are much greater than those for bone. Titanium also has a low density and

d. formation of an oxide layer - commercially pure

titanium spontaneously oxidizes when exposed to air or a body liquid. Within 1ms a layer of $10\text{\AA}$ is formed which increases to 50 to $100\text{\AA}$ after 1 minute (van Steenberghe, 1988). Titanium forms several oxides such as TiO_2 , TiO and Ti_2O_3 of which TiO_2 is probably the most common. The manufacturing and sterilising procedures influence the composition of the oxides. From the point of view of interfacial tissue response, the most relevant chemical properties of titanium implants are those of the surface titanium oxides (Albrektsson et al., 1983). The oxides have a high dielectric constant (the energy needed to move a charged particle from the aqueous medium into the oxide is inversely proportional to the dielectric constant) and a potential capacity is considered to exist between the connective tissue components and the oxides at the molecular level (Henry et al., 1985). It is to be noted that several differences exist between an oxidised metallic titanium implant and a bulk titanium oxide implant which may be important for osseointegration. While a bulk oxide implant has a quite uniform stoichiometric composition, the oxide layer on the metal is non-stoichiometric and contains concentration gradients and numerous structural defects such as grain boundaries (Albrektsson et al., 1983).

1.3.4.1.5.2 Implant design

In an in vitro comparison between conical, natural tooth

and cylindrico-geometrical implant configurations the latter was shown to minimise the high stresses both in the implant and the mandibular model tested (Atmaram et al., 1979). The screw design provides superior mechanical stability and greater initial resistance to shear in comparison with other surface enlarging designs (Henry et al., 1985). It is advisable to round the outer edge of the thread to relieve stress concentration (Albrektsson et al., 1983).

1.3.4.1.5.3 Implant finish

Surface qualities of an implant may be described in the categories of texture (or roughness), charge (or electric potential) and chemistry (Baier and Meyer, 1988):

a. Texture. Surface roughness of implants will have different roles depending on the different geometric dimensions involved. Kasemo and Lausmaa (1988) concluded that many chemical and physical interactions at the implant/tissue interface occur independently of the surface configuration but the adhesion of large aggregates such as cells and very large biomolecules is expected to be increased by surface roughness. A micro-grooved surface has been empirically found to promote osseointegration (Brånemark et al., 1977).

b. Charge. Baier and Meyer (1988) consider that it is no longer acceptable to consider that selection or even

active control of the surface electrical state of an implant will be sufficient by itself to induce or maintain the desired degree of biological interaction with an implant material.

c. Chemistry. The strong influence of the surface chemistries of various implant materials on the relative bioadhesive events in implant sites is easily demonstrable. Low energy surfaces, referred to as hydrophobic, during even short periods of implantation induce the characteristic 'foreign body response', that is, a non-adhesive scar capsule envelopes the implant, walling it off from the adjacent tissue. High energy surfaces promote osseointegration (Baier and Meyer, 1988).

It is to be noted that the aforementioned surface features can be detrimentally influenced by both inorganic and organic contaminants arising during tooling, cleaning and sterilising processes (Baier and Meyer, 1988; Hartman et al., 1989). The final surface preparation of the implant components described by Brånemark et al. (1977) have not been divulged. Surface coatings of ceramics (bioglass, tricalcium phosphate, hydroxyapatite), carbon and plasma have been suggested as means of improving the tissue response to dental implants (Hench, 1980; Albrektsson et al., 1981; Brunski, 1988; Kasemo and Lausmaa, 1988).

1.3.4.1.5.4 Status of the bone

Healthy bone tissue is essential for proper osseointegration. Whether the implant is inserted into a cortical or a primarily cancellous bed is, however, of less importance for later success as there is a strong tendency for 'corticalisation' of spongy bone around metal implants (Breine and Brånemark, 1980). The significance of medical conditions and irradiation to bone status has been discussed previously.

1.3.4.1.5.5 Surgical technique

A delicate surgical technique is essential and must involve:

- a. prevention of excessive heat generation by adequate cooling and minimal pressure. Bone should not be heated beyond 43°C to maintain its vitality. When temperatures exceed 43°C, alkaline phosphatase begins to breakdown and ideally, heat generation should not exceed 39°C. Brånemark et al. (1969) recommend a maximum drill speed of 2000rpm. For the tapping procedure for threading and fixture installation a drilling speed of 15-20rpm is recommended. The drills should be sharp (Hobo et al., 1990),
- b. adequate implant site geometry. If too much space is made between the surface of the bone and the fixture, soft tissue proliferation is encouraged instead of a direct bone

interface (Brunski et al., 1979). When the procedures are performed correctly for the system described by Brånemark et al. (1977) the screw type fixture fits into the tapped bone site intimately with a sealing effect such that there should not be a problem if a fixture were to perforate into the maxillary sinus (Brånemark et al., 1984). Thread preparation into both the coronal and apical cortex is desirable (van Steenberghe, 1988) and

c. contamination is to be avoided.

The system described by Brånemark et al. (1977) recommends a two stage surgical technique. The first stage is the installation of fixtures into bone, allowing a minimum of 3 months healing time in the mandible and 6 months in the maxilla, the second stage involves connection of abutments to the fixtures. Albrektsson et al. (1981) have reported that if the fixtures are loaded during the interim healing periods, fibrous tissue formation will occur.

1.3.4.1.5.6 Prosthetic techniques

A. Interim prostheses should be well designed because patients prefer to wear their dentures as soon as possible after first stage surgery and this loading causes deformation of the jawbone which can induce micromovements at the implant-tissue interface and disturb osseointegration.

B. Definitive prostheses - the following factors need to be

considered (Skalak, 1983,1988; Henry et al., 1985; Brunski, 1988; Davis et al., 1988a):

- a. the distribution of loads applied to a fixed prosthesis, to the supporting implants or teeth depends on the geometry and stiffness of the supports and the stiffness of the prosthesis. A stiff prosthesis will distribute loads to supporting abutments more effectively. A flexible prosthesis may be adequate if any one fixture can carry the full load applied. Cantilevered ends of a fixed prosthesis increase loading on the screw nearest to the cantilevered end. Moderate extensions may be tolerated if the fixtures are sufficiently strong,
- b. the osseointegrated implant provides direct contact with the surrounding bone and will transmit any stress waves or shocks (large impact forces can occur during chewing if a hard object is inadvertently encountered when the moving lower jaw and muscles are suddenly stopped by impacting on the obstruction),
- c. if a fixed partial denture is to be supported on a combination of osseointegrated implants and natural teeth, a more uniform distribution of load can be achieved by use of a flexible connection of the prosthesis to the implanted screw. Loads otherwise tend to be concentrated on the implant, which is more rigidly anchored than the natural teeth,
- d. mandibular bridge design in the mandible involves considerations different from those of the maxilla

because of differing anatomy and differences in both quality and quantity of bone available for implant anchorage and

e. impeccable fabrication to optimise stress distribution is required.

1.3.4.2 Fibrointegration

Consider the concept of fibrointegration or fibro-osseous integration. The American Academy of Implant Dentistry defines fibro-osseous integration as tissue to implant contact involving interposition of healthy dense collagenous tissue between implant and bone. Proponents of this concept (Linkow and Cherchève, 1970; James et al., 1986; Weiss, 1986,1987a,b) claim that the collagenous tissue is a pseudoperiodontal ligament and can behave as follows:

- a. the fibres connect to bone in a way reminiscent of Sharpey's fibres,
- b. the fibres pull on the bone when the implant is loaded and
- c. this tension on the bone results in a piezoelectric effect necessary for bone growth and remodelling of the lamellae and haversian systems.

James et al. (1986) cite the following clinical studies (Bodine and Mohammed, 1970; Meenaghan et al., 1974; Cranin et al., 1977) as supportive of fibrointegration. However

there are problems with this theory and several of the associated clinical studies are anecdotal (Brunski, 1988). Ten Cate (1988) disputes the analogy between the fibrous tissue and the normal periodontium on the basis of its cellular make-up and biological origin. Hobo et al. (1990) report that the relevant fibres are arranged irregularly, parallel to the implant body. When forces are applied they are not transmitted through the fibres as seen in the natural dentition and no Sharpey's fibres are present between the bone and the implant. Zarb et al. (1987) consider that fibrointegration allows for implant movement which renders clinical success highly dependent on the overlying mucosal response.

1.3.4.3 Osseovariegation

Linkow et al. (1990) have created a new term 'osseovariegation'. They state that like most diametrically opposed conditions, osseointegration or fibro-osseous integration can exist without the presence of the other but more than likely they coexist in various proportions of diversified patches which are known as osseovariegation.

1.3.5 Criteria for the evaluation of dental implants

Kapur and Garrett (1988) stated the following with regard to the research design associated with the evaluation of different implant systems. 'The data in many reports

represent retrospective information gained from chart reviews of patients. Even when authors presented their information as clinical trials, there was evidence that standardisation of methods was absent. Within each of these studies, several different implant designs, surgical techniques and prosthodontic procedures were employed. Further confusion has been created by the efforts of investigators to consolidate and compare data from different developmental periods, practices or clinical institutes. Accumulated data are presented to support claims of high success rates based upon large numbers of inserted implants or treated patients. These reports fail to discuss the steps taken to ensure standardisation and compliance of patient entry, treatment definition, data collection procedures and completeness of data. It is not unusual to find multiple publications reporting the same data in combination with some new data with limited explanation and or information relative to study methodology. Such reports add to the confusion.' However, Laney (1990) reported that retrospective analyses of material derived from good data bases are useful to profit from the learning curves of experience. Laney (1988) reported that for further data on which to base patient treatment decisions and prognosticate success randomised, controlled, prospective multicentre clinical investigations should be initiated and that long term studies that concurrently compare various types of implants are needed to provide information beyond mere survival rates.

Criteria to evaluate the success of dental implants as described by Schnitman and Shulman (1979) (Table 1) are of historical interest because they were recommendations made at the first National Institute of Health Consensus Development Conference on Dental Implants at Harvard University in 1978. Those presented by Cranin et al. (1982) and McKinney et al. (1984) (Table 1) are of comparative interest because they are recommendations of researchers not directly associated with Brånemark teams.

In 1986, Albrektsson et al. proposed 5 criteria for the success of dental implants (Table 2) and presented a major review of the best known implants at the time. This work has sparked considerable controversy (Niznick, 1987a; Smithloff and Fritz, 1987a) and is often cited as a reference. The criteria clearly underscore the basic concept of osseointegration as being the major if not the exclusive, reason for a successful long term implant attachment. Criteria for both mobility and radiographic bone response were included because 'an implant can only be judged as osseointegrated in the context of a continuum of observation, since undermining interfacial changes may be gradual and not evident at the radiographic level of resolution at least in the short term'. These authors did not include conventional gingival and periodontal indices from the dental literature on the basis that clinically it has been observed that various gingival responses can be elicited by different aspects of the implant technique and

Table 1: Criteria for implant success: I.

REFERENCE - CRITERIA	REFERENCE - CRITERIA
Schnitman and Shulman, 1979 1. Mobility less than 1mm in any direction 2. Radiologically observed radiolucency graded but no success criterion defined 3. Bone loss no greater than one third of the vertical height of the bone 4. Gingival inflammation amenable to treatment; absence of symptoms and infection, absence of damage to adjacent teeth, absence of paraesthesia and anaesthesia or violation of the mandibular canal, maxillary sinus, or floor of the nasal passage 5. Functional service for 5 years in 75% of patients	McKinney, Koth and Steflik, 1984 <u>Subjective Criteria</u> 1. Adequate function 2. Absence of discomfort 3. Patient belief that aesthetics and emotional and psychological attitudes are improved <u>Objective Criteria</u> 1. Good occlusal balance and vertical dimension 2. Bone loss no greater than one third of the vertical height of the implant, absence of symptoms and functionally stable after 5 years 3. Gingival inflammation vulnerable to treatment 4. Mobility of less than 1mm buccolingually, mesiodistally and vertically 5. Absence of symptoms and infection associated with the dental implant 6. Absence of damage to adjacent tooth or teeth and their supporting structures 7. Absence of paraesthesia or violation of mandibular canal, maxillary sinus or floor of nasal passage 8. Healthy collagenous tissue without polymorphonuclear infiltration <u>Success Criterion</u> 1. Provides functional service for 5 years in 75% of implant patients
Cranin, Silverbranch, Sher and Salter, 1982 1. In place 60 months or more 2. Lack of significant evidence of cervical saucerization on radiographs 3. Freedom from haemorrhage according to Muhleman's Index 4. Lack of mobility 5. Absence of pain or percussive tenderness 6. No pericervical granulomatosis or gingival hyperplasia 7. No evidence of a widening peri-implant space on radiograph	

Table 2: Criteria for implant success: II.

REFERENCE - CRITERIA	CONDITIONAL STATEMENTS
Albrektsson, Zarb, Worthington and Eriksson, 1986 1. Individual unattached implant that is immobile when tested clinically 2. Radiograph that does not demonstrate evidence of peri-implant radiolucency 3. Bone loss that is less than 0.2mm annually after the implant's first year of service 4. Individual implant performance that is characterised by an absence of persistent and/or irreversible signs and symptoms of pain, infections, necropathies, paraesthesia or violation of the mandibular canal 5. In context of criteria mentioned, a success rate of 85% at the end of a 5 year observation period and 80% at the end of a 10 year observation as a minimum criterion for success	
Smith and Zarb, 1989 6. The implant design does not preclude placement of a crown or prosthesis with an appearance that is satisfactory to the patient and dentist	1. Only osseointegrated implants should be evaluated with these criteria 2. The criteria apply to individual endosseous implants 3. At the time of testing, the implants must have been under a functional load 4. Implants that are beneath the mucosa and in a state of health in relation to the surrounding bone should preferably not be included in the evaluations but reported as complications 5. Complications of an iatrogenic nature that are not attributable to a problem with material or design should be considered separately when computing the percentage of success. This category includes such problems as impingement on the mandibular canal and intrusion into the sinus and nasal cavity

that while a 'nuisance' index of gingival changes can be determined it does not appear to be germane to implant success. Albrektsson et al. (1986) also state that future research may indicate equally good success rates with attachment mechanisms other than osseointegration and that these types of attachment will necessitate changes in the currently proposed criteria.

In 1989, Smith and Zarb proposed a further set of criteria for the success of dental implants. They included the 5 criteria of Albrektsson et al. (1986) and an additional criterion relating to implant design, the implant design should not preclude placement of a crown or prosthesis with an appearance that is satisfactory to the patient and dentist (Table 2). The inclusion of the latter criterion was partly rationalised on the basis of results presented by Blomberg and Lindquist (1983) stating that although satisfaction with dental implant treatment was high, appearance was the most common cause of dissatisfaction. Additionally, these authors proposed 5 conditional statements for the application of their criteria (Table 2), for example that the criteria are only relevant for implant systems designed for osseointegration (because the scientific documentation of these systems is superior to that for other systems).

1.3.6 Review of the success of currently used dental implant systems

The following review of the success of currently used

dental implant systems follows a similar structure to that presented by Albrektsson et al. (1986) for comparative reasons.

1.3.6.1 The International Team for Oral Implantology (ITI) implants

1.3.6.1.1 Implant design and material

The design of all ITI Implants originates from 2 basic forms, a perforated hollow cylinder and a perforated hollow screw both of which were developed in 1974 (Schroeder et al., 1990) and early developments resulted in design types 'C', 'E', 'K', 'H', and 'F' (Babbush, 1986a). In 1985 a new concept involving rotation symmetrical implants was described and using type 'F' as a model new hollow cylinder and hollow screw implants involving both one and two parts were designed. For the two-part system there are essentially 2 surgical options, the closed system (submergible method) and the open system (transmucosal method). The latter method is recommended (Buser et al., 1988; Sutter et al., 1988).

The material used is commercially pure titanium with a plasma sprayed surface.

1.3.6.1.2 Research background

Direct bone to implant contact has been demonstrated in

both animal and human studies involving different research groups (Babbush, 1986a; Schroeder et al., 1990). Albrektsson et al. (1986) consider that Steinemann et al. (1985) have presented excellent scientific data on the bone-to-implant interface with this system.

1.3.6.1.3 Clinical usage

A variety of configurations was developed to accommodate differences in bone quality and quantity between the anterior and posterior aspects of the arches as well as the maxilla and the mandible (Babbush, 1986a). For the new ITI implants the following recommendations have been made (Sutter, 1988a,b; Schroeder, 1990):

- a. one-part hollow cylinders - retentive anchors for bar-type overdentures,
- b. two-part hollow cylinders - single tooth replacement particularly in the anterior maxilla,
- c. one-part hollow screws - retentive anchors for bar-type overdentures and
- d. two-part hollow screws - for abutments for fixed bridges in partially dentate patients.

Some interchange of usage is however possible (Buser et al., 1990; Mericske-Stern, 1990).

1.3.6.1.4 Clinical results

Babbush (1986a) reported on a series of cases from Switzerland, Sweden, Germany and the United States involving 580 hollow cylinders of earlier designs which had been placed for up to 10 years. The overall success rate was reported to be 95.3%, however details of the study design and criteria for success were not stated. Albrektsson et al. (1986) did not refer to this report but stated that there were no appropriate 5 year results published on the outcome of ITI hollow cylinders. These authors also stated however that the ITI hollow cylinder implants appear to have been used in carefully controlled clinical programs and the preliminary results achieved at the time indicated that these implants will probably pass their minimum criteria of 85% success over 5 years.

Clinical results for the implantations of the new one-part ITI implants and two-part ITI hollow cylinder implants (Table 3) were presented by Buser et al. (1988). Criteria for success were considered to be a firm integration (no clinical mobility and no radiolucency between implant surface and bone) and a complication free wound healing. Recent results for two-part hollow screw implants and the mode of prosthetic restoration for the successful implants (Tables 4 and 5 respectively) were presented by Buser et al. (1990). The criteria for success were not provided but it was stated that further details would be provided in a further paper.

Table 3: Outcome of implantations of one-part ITI implants (August 1985 to May 1988) and two-part ITI hollow cylinders (April 1986 to May 1988).

IMPLANT	INDICATION	NUMBER OF PATIENTS	NUMBER OF IMPLANTS	EARLY FAILURES	LATE FAILURES
One part HC [#]	Edentulous MD [*]	19	75	0	3
One part HS ⁺	Edentulous MX [‡]	6	20	0	0
Two part HC	Single tooth MX	23	23	0	0
	DE [@] Base MD	31	47	0	0

[#]Hollow Cylinder; ^{*}Mandible; ⁺Hollow Screw; [‡]Maxilla; [@]Distal Extension.

Table 4: Outcome of two-part ITI hollow screw implants (April 1986 to March 1989).

NUMBER OF PATIENTS	NUMBER OF IMPLANTS	EARLY FAILURES	LATE FAILURES
70	111	1	0

Table 5: Mode of prosthetic restoration of patients receiving two-part ITI hollow screw implants (April 1986 to March 1989).

INDICATIONS	C	I	T-I	TOTAL
DE Base MD	3	20	30	53
DE Base MD	1	5	4	10
Single Tooth MD	8	-	-	8
Extended Spaces MX/MD	-	5	1	6
TOTAL	12	30	35	77

C, Single crown; I, Implant supported or free standing prosthesis;
T-I, Tooth-implant prosthesis.

Mericske-Stern (1990) reported the results of a retrospective study of one and two-part ITI implants used as abutments for overdenture restorations in the mandibles of 62 edentulous patients. The retention devices consisted of a bar connector or single ball-shaped precision attachments. It was stated that after evaluation periods of 6 to 66 months good clinical results had been achieved but it was not possible from this study to discern the precise number of implants lost during each treatment phase, although it appeared relatively small.

Von Wower et al. (1990) measured in vivo changes in the bone mineral content of edentulous mandibles treated with osseointegrated ITI implants supporting overdentures by the method of dual photon absorptiometry. They reported that the increased function of the mandible after this form of implant treatment may counteract the physiological age related bone mineral content loss leading to osteoporosis. D'Hoedt et al. (1989) reported on a comparative study of results with various endosseous implant systems and that when using ITI implants, pathological findings for sulcus depth and peri-implant bone degradation were found significantly more frequently than with the other titanium implants, but only the older types E,K and H were included in the study.

1.3.6.2 Titanium plasma sprayed (TPS) Swiss screw implant system (Institute Straumann, Waldenberg, Switzerland)

1.3.6.2.1 Implant design and material

The screw implant corresponds to the basic design of the Association of Osteosynthesis (associated with the Institute of Straumann) cortical traction screw and has a highly polished neck. Ledermann (1990) has described the following changes to the TPS Swiss screw:

- a. more homogenous, coarse implant surface,
- b. polished supraosseous parts,
- c. the implant head no longer has a longitudinal groove,
- d. precision mechanical gold caps,
- e. sealing hygienic occlusal screws and
- f. hand preparation of the implant bed and has termed the resulting implant, the New Ledermann screw.

Farish and Eichstaedt (1989) proposed several minor modifications to the recommended technique of placement of the TPS Swiss screw implant. The material used is technically pure titanium ASTM standard 265-58T and is coated with a titanium plasma spray (Babbush et al., 1986).

1.3.6.2.2 Research background

Albrektsson et al. (1986) reported that published data related to animal investigation in which the TPS screw has been used are not available. These authors cite the work of Ledermann which indicates that there is combined clinical,

radiographic and histological evidence of the TPS screw becoming osseointegrated.

1.3.6.2.3 Clinical usage

The TPS screw implants were primarily designed to be placed in the mandibular symphysis anterior to the mental foramen (Ledermann, 1981a,b; Babbush, 1986b; Babbush et al., 1986), but cases reported from Switzerland, Germany and Sweden have included TPS screws placed as single tooth replacements or as abutments for fixed or removable prostheses both in the maxilla and the mandible (Babbush et al., 1986).

1.3.6.2.4 Clinical results

Babbush et al. (1986) reported on 484 patients who received TPS Swiss screw implants through the participation of 5 oral and maxillofacial surgery groups in 4 countries (United States, Switzerland, Germany and Sweden). These implants were followed prospectively for a maximum of 8 years, the average duration of implantation for the aforementioned countries being 25.4, 47.7, 40.9 and 18.4 months respectively. Implant success was based on the criteria of Schnitman and Shulman (1979) with regard to gingival indices, periodontal pocket formation, radiographic evidence of bone loss and implant mobility with the superstructure removed. In addition, the patient had to be

asymptomatic and the prosthesis functional. The cumulative success rate for all TPS screws in the study was 88.0% and the cumulative case success rate was 88.3%. El Charkawi (1989) reported a minimum amount of ridge reduction around TPS screw implants associated with complete mandibular denture treatment after a period of 3 years. Specific details of the overall success criteria were not provided in relation to the statement that the TPS implant system is an excellent one although they were possibly the same as those of Babbush et al. (1986). D'Hoedt and Schulte (1989) reported no abnormal findings (ie there was neither a sulcus depth over 3mm, bone breakdown over one fourth of the length of the endosseous implant segment, nor clinical mobility) associated with 83% of TPS implants for similar treatment circumstances as those of El Charkawi (1989). Clinical success rates for the New Ledermann screw have not been published.

1.3.6.3 Tübingen Implant (Frialit R, Friedrichsfeld Ltd, Mannheim, West Germany)

1.3.6.3.1 Implant design and material

The design of the Tübingen implant is basically that of a stepped cone. Both round and oval implants are available. The steps have rounded margins to reduce stress concentration and the surface area of the intra-osseous component of the implant is increased by the microroughness of the

ceramic and by the inclusion of microscopic lacunae which are carved into the surface. External longitudinal grooves are also included in the design. In the cervical region there is a highly polished groove which is the zone of attachment of the gingiva to the implant. An axial hole is already present in the implant to accommodate a post crown. Successful implants become osseointegrated.

The Tübingen implant is manufactured from polycrystalline alumina (Al_2O_3) ceramic which is second hardest only to diamond and is bio-inert (Quayle et al., 1989a).

1.3.6.3.2 Research background

Extensive experimental research has been completed in both animals and man (Schulte, 1984a).

1.3.6.3.3 Clinical usage

The Tübingen implant is recommended for use in the following circumstances:

- a. replacement of single teeth in edentulous spaces delimited by natural teeth,
- b. replacement of single teeth as a tooth row,
- c. increasing the number of abutments for conventional fixed bridges and
- d. telescope abutments for partial removable dentures and

limited edentulous circumstances. They may be utilised in the maxilla or the mandible and as immediate or delayed replacements. It is to be noted that strict guidelines apply for these applications, for example the superstructures should be ground so that they just lack contact in protrusive and laterotrusive movements in comparison to natural teeth (Schulte, 1984b,c,1990; d'Hoedt and Schulte, 1989; Quayle et al., 1989a). Bosker and van Dijk (1986) have termed the Tübingen implant a cosmetic implant as compared to a semifunctional or fully functional implant.

1.3.6.3.4 Clinical results

Utilising criteria involving radiographs, pocket depth, percussion, mobility, gingival attachment and since 1985, the results of Periotest measurements, the 95% confidence limits for the success rate in accordance with the binomial distribution were 85% to 92% for 448 rehabilitations (d'Hoedt and Schulte, 1989). Quayle et al. (1989b) cite a failure rate of 12% over a 2 year period.

1.3.6.4 Intramobile cylinder (IMZ) two-stage osseointegrated implant system with the intramobile element (IME), (Interpore International, Irvine, California)

1.3.6.4.1 Implant design and material

The basic design of the IMZ implant is a cylinder with a highly polished transmucosal implant extension (TIE) for optimal soft tissue adaptation and an intramobile element (IME). The apical end of the cylinder is rounded and the apical third has 4 vertical, rectangular openings that allow bony ingrowth through the apical end. The IME has viscoelastic properties and is designed to simulate the function of the periodontal ligament during loading.

A two stage surgical implantation procedure is recommended to permit a stress free postoperative healing phase during which physical osseointegration of the implant can occur. The IMZ implant cylinder is made from commercially pure titanium and may be coated with a titanium plasma spray or plasma sprayed hydroxyapatite (HA) coated surface. The latter has been in use since 1984. The IME element is polyoxymethylene (Babbush et al., 1987; Kirsch and Ackermann, 1989; Hobo et al., 1990; Kirsch et al., 1990).

1.3.6.4.2 Research background

The IMZ implant system was conceived and developed in the 1970's and gradually evolved over several years as a result of basic laboratory/animal research and clinical trials (Kirsch and Ackermann, 1989; Kirsch et al., 1990). According to Albrektsson et al. (1986) few of the experimental

investigations associated with the IMZ system have been published. M^cGlumphy et al. (1989) compared the difference in the stress patterns generated in photoelastic plastic by an IMZ implant with a rigid or resilient internal element and found no statistical difference between the area of stress pattern generated.

1.3.6.4.3 Clinical usage

The IMZ implant system has been recommended for single tooth replacements, fixed bridges in combination with natural teeth and for overdentures and fixed bridges in edentulous patients (Babbush et al., 1987; Kirsch and Ackermann, 1989; Hobo et al., 1990; Kirsch et al., 1990).

1.3.6.4.4 Clinical results

Kirsch and Ackermann (1989) defined implant failure as involving some or all of the following clinical symptoms, bone loss around the implant, change in the gingival index, bleeding, pain and exudate at or around the implant site. From September 1978 to September 1988, a total of 3088 IMZ implants were placed in 1401 consecutive cases at the clinic of these authors to restore partially or totally edentulous arches. Of the total number of implants placed, 334 implants (10.8%) were lost to follow-up (eg, patient death, relocation). If these implants are excluded from the implant population database, 2754 IMZ implants

continued to be followed up in routine recall examinations. A total of 61 IMZ implants were removed primarily because of soft tissue complications. Therefore, the overall rate of success for the implants placed and routinely followed up over the 10 year period was 97.8%. Babbush has placed 561 implants with only 11 removals over a 3 year period, resulting in a 97% survival rate (Kirsch et al., 1990). Details were not provided on the status of the surviving implants. D'Hoedt and Schulte (1989) reported that following 68 rehabilitations only 1 loss occurred but that associated with 25% of the implants there was a deepening of the sulcus in excess of 3mm. Setz et al. (1989) reported that electrognathographic measurements on 18 patients with IMZ implant-attached mandibular complete dentures showed larger and more stable chewing patterns compared to their former dentures without implants.

1.3.6.5 Core-Vent System, (Core-Vent Corporation, Enico, California)

1.3.6.5.1 Implant design and material

The Core-Vent system offers a variety of implants such as the Core-Vent, Screw-Vent, Swede-Vent, Micro-Vent, Bio-Vent and SUB-Vent Implants. The Core-Vent implant has the apical one-half to one-third hollow basket design with 4 to 8 vents. This design is to permit the interior and exterior growth of bone that will anchor and improve distribution

of the coronal load. The coronal half has some threads on the outer surface and a non-threaded area at the coronal end. The coronal opening is either a hexagonal-shaped hole or threaded internally. Both the Screw-Vent and Swede-Vent Implants are solid screw implants, and match the implant of Brånemark et al. (1977) with regard to material, thread configuration, dimensions and microstructure. The Micro-Vent is also a screw design but provides a series of flutes in the middle section for bone ingrowth and better vertical load capacity. The Bio-Vent is a cylindrical design with a rounded bottom and has been updated to include 3 vertical grooves for antirotation and an apical vent to allow escape of blood trapped in the surgical site during seating of the cylinder. The SUB-Vent implant is a submergible blade implant designed for narrow ridges.

The Core-Vent and Micro-Vent implants are made of titanium alloy (90% titanium, 6% aluminium, 4% vanadium, which is stronger than pure titanium and allows for fabrication of large vents for greater bone ingrowth). The Screw-Vent and Swede-Vent implants are commercially pure titanium. The Micro-Vent and Bio-Vent Implants are both provided with a rough hydroxyapatite coating for greater immediate frictional fit and biologic bond.

The Core-Vent system strives for osseointegration (Niznick, 1986,1989; Hobo et al., 1990).

1.3.6.5.2 Research background

Very little developmental research material is available for review which is also the finding of Albrektsson et al. (1986). Lubar and Katin (1990) consider that the Core-Vent implant was introduced as a prosthetically versatile two stage implant based on the hollow basket concept developed after extensive research principally at the Straumann Institute in Waldenburg, Switzerland by the International team for Oral Implantology. Relatively recently Lum and Beirne (1986) demonstrated that Core-Vent implants do form a bone-implant interface without intervening fibrous tissue. Core-Vent implants were placed in 4 dogs and healing was evaluated histologically 15, 30, 60 and 120 days after insertion. Bone grew through the implant vents to join with the inner bone plug and the implants approximated the bone without an intervening fibrous tissue layer. All samples showed saucerization of the crestal bone around the implant. Lum et al. (1988) considered histological specimens of loaded and unloaded Core-Vent implants in non-human primates and revealed bone in direct contact with more than 50% of the surface of all the implants at the end of a 5 month period. Gores et al. (1989) reported the results of postmortem examination from a single case of 6 maxillary Core-Vent implants completed approximately 9 months after initial insertion of the implants. Light microscope examination revealed osseointegration in all specimens and bone had grown into the core and the vents of

the implants. Unfortunately, however when the pathologist cut the alveolar specimen from the maxilla all 6 of the maxillary implants were inadvertently sectioned in the vent area and therefore it contained only about two thirds of each implant.

Kinni et al. (1987) considered the load distributing characteristics of Core-Vent implants utilising the techniques of quasi three dimensional photoelasticity. Complete osseointegration was assumed. The results indicated that possible problems could be expected in the supporting bone under function because high apical stresses could lead to a large deformation of bone and hence a high concentration of stress at the threads and at the cervical bone-implant interface. Henry (1987) undertook scanning electron microscope studies and spectral surface analyses of 10 Core-Vent implants as supplied by the manufacturer and found that the samples demonstrated a highly variable, inconsistent surface finish and composition. The surfaces appeared to be contaminated which would certainly render the implant more susceptible to corrosion, thereby compromising integration.

1.3.6.5.3 Clinical usage

In general the Core-Vent system is recommended for use in both the maxilla and the mandible. For the edentulous patient a fixed prosthesis which is similar to a 12 to 14

unit conventional fixed partial denture is possible. A fixed/detachable prosthesis which is a combination of acrylic denture teeth and metal framework that is cantilevered off anterior implants or is attached to root and/or blade forms may also be used. An overdenture that is implant supported and retained by attachments or connecting bars may also be used for the edentulous patient. For the partially dentate patient fixed implant supported bridges may be connected to natural teeth. Single tooth replacements may also be considered (Niznick, 1989).

1.3.6.5.4 Clinical results

Golec (1988) reported the results of an extensive review of Core-Vent implant users by English (1987) in which 652 respondents reported on the placement of 15225 implants with an overall success rate of 93.4% in achieving osseointegration. The original material was possibly anecdotal and does not appear to have been published internationally. Hobo et al. (1990) reported on a survey conducted through the Veterans Administration, Augusta, Georgia which, from Core-Vent user responses showed a success rate of 93.5% over a 4 year period. The survey was completed for 15115 Core-Vent implants placed by 672 dentists. These authors considered that the standard for success was not well defined. From their review it is not clear whether the success rate of the original authors referred to individual implants or prostheses.

During a 5 year period (1982 to 1987), 1732 Core-Vent dental implants were consecutively placed in maxillary and mandibular edentulous and partially dentate jaws of male and female patients (Patrick et al., 1989). Of the 1732 implants placed, 1605 were uncovered after the 3-6 month healing time. Any non-osseointegrated implants were removed and the remaining implants put into function. The osseointegrated implants in partially dentate patients were restored with single crowns and fixed bridges, either totally implant supported or in combination with natural teeth, as required. The osseointegrated implants in edentulous jaws were restored with overdentures, bar supported overdentures or fixed detachable dentures. Criteria involving mobility, peri-implant radiolucency and gingival inflammation were used to evaluate the achievement and maintenance of osseointegration and implant success. The median observation period for the entire study was 27 months. All of the investigators' median observation periods were more than 1 year. The longest median observation period was 41 months and the shortest was 15 months. The following conclusions were drawn:

- a. Core-Vent implants achieve and maintain osseointegration on a highly consistent basis,
- b. 96.2% of the maxillary implants and 96.7% of the mandibular implants installed and evaluated achieved and maintained osseointegration throughout the 64 month observation period,

- c. there was no statistically significant difference in Core-Vent implants achieving and maintaining osseointegration between the maxillary and mandibular jaws, between anterior and posterior sites and between maxillary or mandibular jaws,
- d. implants supporting single crowns in this study were successful in 100% of cases in both the maxilla and the mandible,
- e. implants supporting fixed bridges were 97.1% successful in the maxilla and 97.6% successful in the mandible and
- f. most of the implants that failed did so within the first year of installation.

Duncan and Westwood (1987) reported on the outcome of 78 consecutively placed Core-Vent implants. An overall success rate was not specifically cited although qualitative comments were provided for several cases. One implant failed to integrate and was removed at the end of the 3 month healing period. One prosthesis was remade and good gingival health was considered to have been subsequently maintained. Other complications were reversible. It is not possible to cite the precise number of cases treated because of a discrepancy between a table and the text of the article but it was apparent that most cases were edentulous and were restored using a cast bar, magnets and a removable denture and that most of the 3 unit fixed partial dentures were cemented to the implant and the

natural tooth.

Clancy et al. (1991) reported claims by Lubar and Katin (1986) of 98% osseointegration success rate for 100 consecutively placed implants (these implants may have been included in the study of Patrick et al., 1989). Clancy et al. (1991) also reported the results of an assessment of 609 Core-Vent implants from 5 independent dentists by Laskin (1986). Laskin described success rates of 96.5% in the maxillae and 96.7% in the mandible. The main objective of the publication by Clancy et al. (1991) however was to report on the results of a questionnaire used to rate patients' satisfaction, expectations and level of discomfort associated with Core-Vent implant treatment. A list of 262 patients was obtained from a single oral surgeon who had used the same surgical protocol for all the patients. Prosthodontic reconstruction was usually performed by the referring general dentist. The patients were solicited by mail to participate in the study and a response rate of 67% was achieved. Statistical interpretation of the data revealed that the patients were generally satisfied with implant treatment in terms of function, aesthetics, comfort and speech. It is to be noted however that it was not stated at what stage after treatment each patient completed the questionnaire.

Malmqvist and Sennerby (1990) considered that at the time of completing their study no major investigations or

clinical trials had been published describing the clinical outcome of the Core-Vent system. These authors presented the clinical outcome of 47 consecutively placed Core-Vent implants placed in 35 patients over a period of 4 years. The implants were used in mandibles and maxillae to support single crowns, overdentures and fixed prostheses splinted to natural teeth as recommended by the manufacturer. The authors conceded that their study included many variables that should not be present in a controlled study. Relatively few implants were used for a variety of applications but they considered that all the variables reflected the different requirements for the different patients treated and that since their results were in sharp contrast to those claimed by the manufacturer they felt obligated to share their experiences. Of the 47 implants, 43 could be examined. A total of 11 implants were removed, 9 because of progressive vertical bone loss and 2 because of fractures. The vertical bone loss was calculated for the 32 remaining implants. Twenty eight implants demonstrated a bone loss of more than 2mm and 16 showed a loss of more than one third of the implant height. According to the criteria proposed by Schnitman and Shulman in 1979 the total success rate was 37.2%. When using the criteria suggested by Albrektsson et al. in 1986, the total success rate was calculated to be 9.3%. Malmqvist and Sennerby (1990) reported the results of Moy (1987) who used diagnostic criteria such as looseness, radiolucency, mobility and chronic infection in his assessment of Core-Vent implants.

Moy (1987) reported that 13 of 31 maxillary and 22 of 69 mandibular implants were found to be failures, resulting in a total success rate of 58% (maxilla) and 68% (mandible) for a follow-up period of 3 years.

In summary the clinical outcome of the Core-Vent implant system results from different centres appear contradictory.

1.3.6.6 Subperiosteal implants

1.3.6.6.1 Implant design and material

The early design of the casting for implantation was a highly polished continuous casting usually placed on the crest of the resorbed mandible. This concept of course was not adequate and was replaced by the open concept with struts positioned in a variety of locations to maximise support, over the external oblique ridges, the lateral ramal areas, the retromolar areas, the anterior nasal spine and the pterygoid processes of the sphenoid bones. The position and number of transmucosal posts varies between designs. They may be detachable or non-detachable and may be connected by a supragingival bar on which a clip type attachment may be employed or a post may have a micro-ring design (Linkow, 1980; Judy and Misch, 1983; Boyne and James, 1986). The toro-plant is a uniquely designed subperiosteal implant utilising 2 anterior endosteal blade implant posts, the hard palate and the cortical plate of

bone on the anterior side of the maxilla for its support (Linkow, 1973). The material of subperiosteal implants may be an alloy of 65% cobalt, 30% chromium and 5% molybdenum or be aluminium oxide. The implants may be coated with hydroxyapatite, carbon or titanium (Mentag, 1980; Albrektsson et al., 1986; Boyne and James, 1986). Leake et al. (1979) reported the carbon coating of subperiosteal implants by using a catalyst to deposit carbon at a high rate from a carbon-bearing vapour precursor. The coatings are impermeable and the mechanical properties of the implant remain those of the metal and the implant design. Leake et al. (1979) proposed that carbon coatings might reduce epithelial migration along the transmucosal struts. Subperiosteal implants become fibrointegrated (Bodine and Mohammed, 1970; Kay et al., 1987; Stvrtecky et al., 1989).

The use of axial computed tomography can reduce the two stage surgical procedure to a one stage procedure (Boyne and James, 1986; Golec, 1986).

Harris (1990) described a new two stage surgical technique for the subperiosteal implant.

1.3.6.6.2 Research background

Herschfus (1957) reported gross and histological findings for subperiosteal implants (Vitallium) placed in dogs. After periods of up to 16 months postinsertion the implants

were firmly anchored and mechanically efficient. The stratified epithelium of the gingival margin dipped slightly downward immediately adjacent to the abutment. In the immediate vicinity of the implants the submucosa was composed of dense collagenous connective tissue with minimal vascularity and a paucity of chronic inflammatory cells. The osseous structure displayed its usual trabeculae and marrow space, the latter with some fibrous replacement.

In response to criticism that subperiosteal implants would predictably fail as a result of osteomyelitis and lack of permucosal epithelial adhesion, Stvrtecky et al. (1989) described a case involving a chromium/cobalt/molybdenum alloy maxillary subperiosteal implant which had been removed after 2 years of successful function for reasons unrelated to the oral environment. The studies performed on specimens of adherent gingival cuff demonstrated the presence of PAS positive staining material, indicative of glycosaminoglycans (cementing substance) on epithelial surfaces adjacent to the implant.

Bodine and Mohammed (1970) reported the following conclusions in relation to histological studies of a clinically healthy subperiosteal implant denture that had been in place for more than 12 years when the patient died of unrelated causes. Epithelium did not grow downward along the primary abutment struts to encapsulate the peripheral frame. The connective tissue in contact over, around and

under the buried metal was modified into flattened compressed fibres and cells with elongated nuclei. The crevice around an implant abutment somewhat resembled a normal tooth crevice. It had progressed only 2-3mm along the metal strut from the penetration during the 12 year period. Inflammatory cells in the tissue adjacent to the epithelialised implant abutment crevice were comparable to the inflammatory cells generally present around the gingival sulci of natural teeth. No significant bone resorption, 'settling' or loss of vertical dimension occurred. There was a tendency for bone to grow over the implant periphery on the lingual, especially in the mandibular torus area.

Natiella et al. (1972) provided a review of several references for animal experimentation associated with the subperiosteal implant which contradicts the statement by Albrektsson et al. (1986) that little of such material is available.

1.3.6.6.3 Clinical usage

Subperiosteal implants have been utilised in edentulous and partially dentate cases in both the maxilla and the mandible (Linkow, 1980) and in association with skin grafts (Mentag, 1970). The prosthetic appliances may be fixed or removable (Perel, 1977) and have been utilised to splint periodontally involved teeth (Gershkoff, 1970).

1.3.6.6.4 Clinical results

The concept of subperiosteal implants was introduced in the 1940's and many publications have appeared since then dealing with the clinical outcomes of this form of implant treatment. Mentag (1980) reported that the consensus of Harvard University Dental Implant, Benefit and Risk Conference held in 1978 was favourable for subperiosteal implants because they were recommended for use in mature patients in acceptable general and oral health, when conventional methods could not be used successfully and the benefit risk ratio may be improved when the implant is used in the mandible versus the maxilla, on basal bone and against a complete maxillary denture. Certainly the diversity of results presented at this conference is reason for caution, particularly as Mentag cited 5 year success rates for mandibular subperiosteal prostheses of 100% whereas Goldberg (1980) as reported by Albrektsson et al. (1986) reported 10 year success rates of the order of 36%. Albrektsson et al. (1986) also report the study of Bodine and Yanase (1985) which they considered had some favourable design characteristics. These authors achieved 5 year success rates as high as 93%, but the 10 year success rates were of the order of 64% only and the 15 year results were a 54% success rate. Golec (1987) reported that in a recent review of 202 full subperiosteal implants placed before 1976 that a 5 year success rate of 99% and a 13 year success rate of 93% had been achieved. Upon stratification

these results revealed that in the maxilla, a 5 year success rate of 88% and a 13 year success rate of 81% had been achieved. Criteria for success were not presented in this report. Homoly (1990) reviewed the literature in relation to the success rates of the full maxillary subperiosteal implant and concluded that it is successful within a more narrow diagnostic range than the mandibular subperiosteal implant. Kay et al. (1987) presented a qualitative discussion on the outcome of 339 consecutively placed hydroxyapatite coated subperiosteal implants. Of the 339 units placed, 257 involved two stage surgical procedures and 82 involved single stage CT-scan procedures. They concluded that after more than 2½ years of clinical experience hydroxyapatite coatings applied to the struts of subperiosteal implants can positively affect implant performance.

1.3.6.7 Blade implants

1.3.6.7.1 Implant design and material

Several design modifications have occurred in relation to the design of the endosteal blade-vent implant since it was introduced to the profession in 1967. The current basic design features consist of an abutment head, neck, body, vents and a small recessed area in the shoulder or superior aspect of the body. The abutment head is usually etched or demarcated in millimetre measurements to allow for adjust-

ments of the occlusal surface of the opposing dentition and is available with and without a collar. The abutment head is usually designed to simulate the preparation of a natural abutment for full crown coverage. It is tapered to allow for appropriate parallelism of adjacent abutments and for adequate primary retention of the prosthesis as well as distribution of functional loading in a physiological manner. The outer circumference of the vents is bevelled to increase the implant-bone ratio, thus increasing retention (Babbush, 1980a, 1986c). Proponents of blade implants consider that tooth root types require preparation of a sizeable bony socket and are not suitable for patients with moderately resorbed or atrophic residual ridges, whereas blade implants are specifically suitable for ridges with limited height and width (Kapur, 1987). Hahn (1990) has described the 'submergible' two piece blade implant. The abutment head is attached to the body after healing has occurred in relation to the latter. Hahn (1990) considers that having the implant totally immobile during the healing phase will enhance the possibility of achieving osseointegration. The achievement of osseointegration has not been proven for the 'submergible' two piece blades and most proponents of blade implant designs support the fibro-integration concept.

A variety of materials have been used for the construction of blade-vent implants, CrCoMo-alloy, CrNiVa-alloy, titanium alloy, aluminium oxides and vitreous carbon

(Albrektsson et al., 1986). Titanium alloy seems to be the material of choice in most cases and a surface textured coating has been used in many instances to create a more conducive biologic environment and increase the implant-to-bone ratio (Babbush, 1980a,1986c). A two stage surgical technique is used to place these implants and the type of integration is considered to be a fibrous one.

1.3.6.7.2 Research background

Several reports of animal experiments have been published with success rates varying between 56.2% and 90% (Albrektsson et al., 1986) while Kapur (1987) also finds that a range from highly favourable to unfavourable in the histologic findings in animal studies have been reported. Babbush (1972,1977,1980b) demonstrated a well organised type of soft tissue adjacent to blade-vent implants placed in dogs which was surrounded by calcified tissue that resembled bone. The openings of the implants were demonstrated to be occupied by cores of newly formed vital bone and Smithloff and Fritz (1976) concluded that several studies have demonstrated epithelial invaginations into bony tissue around the necks of blade-vent implants. Takeshita et al. (1989) reported on the image analyses of the bone-implant interface of undecalcified histopathologic sections of 2 titanium blade-vent implants which had survived for 5 years in a semi-functional state in a dog. One implant was inserted conventionally in the right

mandible and the other was inserted shallower than usual in the left mandible so that the shoulder was located at the same level as the residual bone ridge. For the deeper implant image analysis demonstrated a 0-56% rate of bony contact around the implant and a 71-84% rate of bone-vent occupancy in the vents. With the shallower implant, a 0-46% rate of bony contact and a 26-60% rate of bone-vent occupancy were observed.

1.3.6.7.3 Clinical usage

Endosteal blade-vent implants have been used in edentulous and partially dentate circumstances. In edentulous circumstances both fixed and removable prostheses have been used while in partially dentate circumstances it is not recommended that these implants be used as abutments for removable prostheses. If they are to be involved in single tooth replacement it is recommended that they be splinted to at least 1 and preferably 2 natural teeth (Babbush, 1980b).

1.3.6.7.4 Clinical results

A great disparity exists in reported success rates for endosteal blade-vent implants. Babbush (1980a) reported on a series of cases with an 85-90% success rate for 5 years but did not provide details on the nature of the cases or the criteria for success. The recommendation of the Harvard

University Dental Implant Benefit and Risk Conference held in 1978 in relation to blade-vent implants was that 'they be used with guidelines'. Babbush (1980a) considers that it is important that the clinician understands that this is an endorsement of and not a limitation on blade-vent implants. Smithloff and Fritz (1982) reported that the data given at the aforementioned conference indicated that blade-vent implants are still experimental and that major criticism was directed at data describing survival rates in retrospective investigations. Smithloff and Fritz (1987b) surveyed a group of 32 patients with 49 implants placed 15 years previously. There were 26 blade-vent implants in 18 patients available for evaluation and 3 basic patterns were observed:

- a. 50% of the implants were clinically and radiographically healthy,
- b. for 50% implants there was a radiolucency 2 to 3mm square around the neck and shoulder of the implants, accompanied by probeable depths from 5 to 8mm on the buccal and lingual surfaces. Bleeding upon probing was routinely observed, and
- c. two implants showed evidence of settling deeper into bone.

The authors suggested that blade-vent implants can be maintained in the mouth for up to 15 years and 50% can be free from periodontal disease. Five year follow-up for this

patient group revealed some degree of bony breakdown at this time for the majority of patients but this was almost exclusively located to the neck of the implant. Albrektsson et al. (1986) estimated the 5 year success rate in this study to be between 42% and 66% and further estimated that the 10 year results described by these authors for this study group did not exceed 50%.

Falomo and Hobkirk (1988) reported on an evaluation of 15 endosseous implants placed by several dentists, 13 were titanium blade-vents and 2 were tantalum pin tripods. The method of evaluation involved the utilisation of a questionnaire developed by the Fédération Dentaire Internationale (FDI). This questionnaire included 10 components, 2 of which were 'status of the tissues around the implants' and 'implant mobility'. Eight of the endosseous implants had to be removed, 7 of which were maxillary blades. Six had failed within 1 year of insertion, the seventh was failing after 6 years. The eighth implant, a tripod type in the mandible had been in place for more than 17 years. The authors considered it remarkable that even in situations where removal of an implant was necessary, most patients requested replacement implant treatment if at all possible.

Kapur (1987,1989,1991) has reported on a multicentre prospective evaluation of fixed bridges supported by blade-vent implants. Treatment failure was related to implant

mobility, vertical bone loss, the need to remove the implant because of unmanageable infection, pain, paraesthesia, loss of an abutment tooth or other reasons. During a 5 year evaluation period treatment failures were considered to have occurred in 19 of the 114 treated patients. Three standardised masticatory tests with peanuts and carrots were made before treatment, repeated at 16 weeks following prosthesis insertion and thereafter at 6, 18, 36 and 60 months. A significantly improved masticatory ability was demonstrated for both Kennedy Class I and Class II partially dentate circumstances but the disturbing feature of the results of this study was that radiographic assessments of implant posts at 5 years post-treatment by a panel of 3 judges demonstrated moderate bone deterioration for 15.9% of the posts, marked deterioration for 27% and severe deterioration for 2.1%.

In summary then, clinical use of the blade-vent implant is not recommended because of documented poor success rates.

1.3.6.8 Transosseous implants

1.3.6.8.1 Mandibular Staple

1.3.6.8.1.1 Implant design and material

The mandibular staple implant involves a bone plate and three possible configurations of pins, the 7, 5 and

modified 7 pin alternatives. The bone plate is anchored to the cortex of the inferior border of the mandible and the pins may be classified as retentive or transosseous (Heflick et al., 1982; Small, 1986). Knapp and Small (1990) reported a modification of the mandibular staple incorporating compression screws in the 2, 4 and 6 positions to additionally secure the bone plate. The surgery is similar to that of an open reduction of a fractured mandible (Heflick et al., 1982; Small, 1986). Small (1990) described the fixed mandibular implant (FMI) an orthopedic bone plate that he considers an improvement of the mandibular staple bone plate. The FMI fastening system provides 2 or 4 transosteal pins and rigidly fixes and compresses the bone plate against the inferior border of the mandible by using self-tapping screws. The main advantages of the FMI cited by Small (1990) were immediate denture placement and function, the versatility for denture construction and the absolutely parallel abutments that make prosthetic adaptation easy.

The staple is constructed of a titanium alloy consisting of 90% titanium, 5% aluminium and 4% vanadium (Small, 1986), although stainless steel, other titanium alloys and ceramic coatings have been tried (Small, 1975; Albrektsson et al., 1986).

1.3.6.8.1.2 Research background

In 1969, Small and Kobernick reported the outcome of the insertion of threaded U-shaped stainless steel pins in 6 mongrel dogs. The dogs were prepared for insertion of the threaded pins by removal of 5 teeth posterior to the left mandibular canine. After placement of the pins, cylindrical nuts were attached to the threaded portion intraorally and the dogs used these steel cylinders as teeth. Examination of the intraosseous portion of the pin tracts at 3 month, 6 month and 12 month intervals revealed, with one exception, that the courses were free of inflammation and epithelial migration. In all instances the pins were surrounded closely by a bland connective tissue and the authors concluded that the pins seemed to be well tolerated by the tissues and despite some loosening of the pins in 2 dogs they were tight enough in all instances to stabilise a denture. A human clinical study was considered justified and Small (1975) reported the results of a 6 year prospective evaluation of 35 patients with atrophic mandibles who received mandibular staple bone plates with removable complete dentures fastened to the superstructures by means of stressbreaking complete dentures. Success was determined on a 4 point scale for clinical and radiographic evaluation and an assessment of patient satisfaction. The total percentage of survival with good function was 86% which included the pilot study of the 3 and 4 pin staples.

Albrektsson et al. (1986) consider that the mandibular staple implant is osseointegrated. Small (1975) provided radiographic and clinical evidence (relating to mobility) and limited microscopic evidence that suggested osseointegration. Small (1986) and Small and Misiek (1986) report that osseointegration has been reported in a number of patients by microscopic examination of the bone-metal interface in specimens obtained during repair and replacement of fractured staples and by postmortem examination. Walker et al. (1987) reported the postmortem findings of a 7 pin mandibular staple which had been in situ for 5½ years and functioning well. Light and electron microscopy and gross and radiographic findings demonstrated bone in intimate adaptation to most of the specimen but the superior half of the right transosteal post demonstrated a soft tissue implant interface. Note that the patient was of advanced age and had a compromising medical condition.

1.3.6.8.1.3 Clinical usage

The mandibular staple implant has been utilised predominantly for removable prostheses in both edentulous and partially dentate circumstances. Bars with a variety of stress broken precision attachments for example the ASC-52 Anterior Regular Attachment (Bell International, Burlingame, California) are recommended, but partial denture designs may involve standard clasps (Small, 1979, 1986; Stines, 1986). Knapp and Small (1990) reported

results for 6 patients where modified staple implants have been utilised to support fixed complete mandibular dentures. Small (1990) has reported treatment with removable overdentures, fixed and fixed removable dentures with the Fixed Mandibular Implant.

Liposky (1982) has reported the successful outcome of two cases when the mandibular staple bone plate was used in conjunction with augmentation bone grafts. Small (1990) reported the use of the FMI with split-thickness skin grafts, with other dental implants and with an onlay iliac crest graft done 6 to 9 months before implant surgery.

1.3.6.8.1.4 Clinical results

Small and Misiek (1986) reported a retrospective study of 1516 patients from 40 practices who had a mandibular staple for jaw reconstruction during the period from 1968 to 1984. The cumulative success rate was 94.6% for 5 to 6 years and 90.9% for 10 to 16 years. In a retrospective multicentre evaluation of 160 patients over a 7 year period Kent et al. (1984) determined a cumulative success rate of 90.9%. and Albrektsson et al. (1986) have concluded that mandibular staple implant treatment is clearly within acceptable standards. For modified staple implants favourable clinical and radiographic responses have also been reported. The time elapsed after surgery for these patients had been 3 years and the average time that the implants had been fully

loaded had been 28 months (Knapp and Small, 1990). Small (1990) has reported that the FMI has been used for 4 years and in 90 patients they are all functioning well without major complications or failures. The criteria for success were not reported but were probably based on this author's previous definitions.

1.3.6.8.2 Transmandibular implants

1.3.6.8.2.1 Implant design and material

The structure of the transmandibular implant is similar to the mandibular staple implant and is inserted in the anterior portion of the mandible between the mental nerves. It consists of a lower border baseplate secured to the mandible by 5 cortical screws. Four threaded transosteal posts pass from the baseplate to the mouth along the alveolar crest. These posts are fixed to the baseplate by means of locking screws and for the most common design, they are connected intraorally by a bar (Bosker and van Dijk, 1986; Arvier et al., 1989). Bosker and van Dijk (1986) consider that the optimum combination of biologic and mechanical properties, including corrosion resistance and bioinertness is provided by an alloy consisting of 70% gold, 5% platinum, 12.8% silver and 12% copper. The intraosseous portion of the implant material has a pore size of 1.68 to 2.10mm so that the surface area of the bone-implant interface can be increased.

1.3.6.8.2.2 Research background

Bosker developed the uniform baseplate of the trans-mandibular implant based on the equality in measurements of the ventrocaudal part of the symphysis of mandibles from human cadavers of varying race, age and sex (Bosker and van Dijk, 1986).

Powers et al. (1989) cited the results of animal studies by Bosker which demonstrated the absence of a fibrous interface at the light microscope level. As part of a multi-centre trial to evaluate the transmandibular implant, the Oral and Maxillofacial Unit at the University of Adelaide conducted experimental studies to develop an animal model to test biocompatibility, various aspects of the implant design, tissue responses to the various components of the implant alloy and to an alloy with a high content of silver (Arvier et al., 1989). The results were as follows:

A. animal model - sheep were found to be satisfactory from a general point of view,

B. implant design - all conventional models of the implant inserted into the sheep resulted in wound breakdown. A simplified implant design of a suprapariosteal baseplate and 4 cortical screws provided better results.

Histologically, 4 types of host-metal interface were found:

- a. direct bone-metal contact,
- b. a thin layer of unmineralised orientated collagen fibres,
- c. a discrete thin capsule of mature fibrous tissue and
- d. a layer of granular acellular material,

C. biocompatibility of various materials - gold alloy, Dentozy1 (Indumed BV, Amsterdam, The Netherlands), gold, platinum and palladium all demonstrated evidence of biotolerance with areas of close apposition but generally with a variable layer of fibrous tissue around the implant. There was no evidence of inflammation. There was fibrous encapsulation with inflammation around the copper and silver implants and these were the only metals to show corrosion on scanning electron microscope examination. Thus both the gold alloy used in the transmandibular implant and the suggested cheaper alternative of the silver alloy, Dentozy1, were bioinert and corrosion resistant when tested in the sheep.

1.3.6.8.2.3 Clinical usage

The transmandibular implant has generally been used with complete removable overdentures for edentulous patients but components are now available for fixed partial denture construction (Bosker and van Dijk, 1989; Powers et al., 1989).

1.3.6.8.2.4 Clinical results

Bosker and van Dijk (1989) reported the results of a 12 year follow-up study of the use of transmandibular implants for reconstruction of severely atrophic mandibles. The study included 368 patients with a mean height of the mandible of 10mm. They were examined clinically (plaque scores, probing depths, bleeding on probing and mobility scores were included), radiographically and by means of a questionnaire. The follow-up period for 185 patients was 5 years or more and 55 were followed for 10 years or more. Removable dentures were made for 350 patients and fixed bridges for 18 patients. The overall success rate was considered to be 97.8% with mobility scores consistently reflecting absolute immobility of the transmandibular implant. It was reported that the radiographs showed a relatively unchanged level of the marginal bone around the implants but the status of the host peri-implant interface was not specifically stated for the successful implants. Maxson et al. (1989) reported the findings for 190 patients who were treated with the transmandibular implant and removable dentures which were designed to load only the bar portion of the implant superstructure. There were 18 patients treated at Aarhus University Hospital, 43 at the University of Adelaide, 31 at the University of Michigan and 98 at Deaconesses Hospital. The postoperative observation period ranged from 3 months to 5 years and the clinical examination included assessment of oral hygiene,

measurement of pocket depth around the transmucosal posts with a periodontal probe, observation of the presence of inflammation or hyperplasia in the gingiva surrounding the posts, testing for mobility of the implant and examination for changes in mental nerve sensation. Panoramic radiographs were taken after 3, 6 and 12 months and after 1 year patients were recalled annually for clinical and radiographic examination. The radiographs were examined for the presence of radiolucency around the posts and screws and resorption at the alveolar crest in association with the transmandibular implant. All preoperative and postoperative complications were recorded. It was considered that 95.8% of 190 transmandibular implants were stable and functional. The 182 implants in function demonstrated no mobility and no infrabony pockets around any of the transmucosal posts. It was stated that a radiolucent space associated with a single transmandibular post was identified in 3 patients but the nature of the host peri-implant interface was not specifically described for other cases.

Powers et al. (1989) reported the results of 13 consecutive patients treated with transmandibular implants and overdentures. Patients were evaluated for pain, paraesthesia, healing of the submental wound, soft tissue response, radiographic change and mobility of the implant for a period of 2 years. An overall success rate was not cited but the authors concluded that the results demonstrated the reliability and reparability of the transmandibular system.

Radiographic examination revealed that except for a single transosseous post in 2 patients, there was complete adaptation of bone along all cortical and transosseous screws. Barber et al. (1990) reported the outcome of 15 edentulous patients who were restored with conventional maxillary dentures opposed by overdentures supported by transmandibular implants. Two to 4 years after surgery these patients were evaluated for vertical and maxillary bone loss with a radiographic analysis developed by the authors. With this technique, attention was focussed on vertical alveolar ridge resorption in the anterior maxilla. It was concluded that the resorption that occurred for this region was not significantly different from that which was recorded for a previous study that evaluated anterior maxillary ridge resorption when complete maxillary dentures opposed natural mandibular anterior teeth and a distal extension removable partial denture. The authors considered however that further studies with a larger sample size and considering gender differences and longer time spans are needed.

1.3.6.9 Integral implants, (Calcitek Inc, Carlsbad, California)

1.3.6.9.1 Implant design and material

The Integral implant is a cylindrical endosseous implant with a pore for tissue ingrowth located in the apical third

and is constructed of titanium with a hydroxyapatite coating. Abutments may be fluted or non-fluted, they may be screwed or cemented to the implant body. Pre-angled 15° abutments are available. The Integral implant involves a two stage surgical implantation technique (Block et al., 1990).

1.3.6.9.2 Research background

Thomas et al. (1987) reported a mechanical and histological evaluation of uncoated and hydroxyapatite-coated titanium implant materials. Cylindrical implants of uncoated commercially pure (CP) titanium and hydroxyapatite-coated Ti-6Al-4V alloy were studied using a transcortical model in 7 mongrel dogs, with implants evaluated after periods of 3, 5, 10 and 32 weeks. Although the implants do not carry physiological loads in this experimental design, they do constitute models for the healing sequelae associated with two stage dental implants where endosseous implant units are inserted and remain unloaded for a specified healing period. All implants had a surface macrotexture consisting of a series of semi-circular annular grooves, approximately 750µm in depth. The characteristics of interface shear strength were determined by mechanical push-out testing. Non-decalcified histologic and microradiographic techniques with implants in situ were used to evaluate the response to the implant materials and the presence of the surface macrotexture. Mechanical testing results indicated that the

hydroxyapatite coated implants exhibited significantly greater values of maximum interface shear strength than the uncoated implants after all time periods. Interface shear stiffness was also significantly greater at all time periods for the hydroxyapatite-coated implants as compared to the uncoated implants. Histological evaluation after 3 weeks revealed an osteoid layer covering all areas coated with the hydroxyapatite material; mineralisation of this layer appeared to be complete after 10 weeks. In all cases, longer term implants demonstrated mineralisation of interface bone directly onto the hydroxyapatite coating and in no case was a fibrous layer observed between the hydroxyapatite coating and interface bone. Sections from the uncoated CP titanium implants revealed a thin fibrous layer present in all areas. Only isolated regions of direct bone-implant apposition were observed for the uncoated implants. The presence of this fibrous tissue layer however, did not adversely affect the development of considerable attachment strength. The results of this study indicate that the hydroxyapatite coating can significantly increase the attachment strength of implants which rely upon bone apposition for fixation. In addition, the hydroxyapatite coating provides an osteophilic surface for bone deposition and allows for a more rapid development of implant-bone attachment. Block et al. (1990) reported that the pullout force required to extract hydroxyapatite coated implants from dog alveolar bone is correlated strongly with implant length but not diameter and cortical bone contri-

buted more to implant retention than cancellous bone and that these results have implications for the design of implants for sites with anatomical restrictions. Cook et al. (1987), de Groot et al. (1987) and Gerner et al. (1988) have confirmed that hydroxyapatite-coated titanium specimens are more firmly attached to bone than uncoated titanium specimens in animal models. Cook et al. (1987) and Gerner et al. (1988) together with Block et al. (1987) have also confirmed the relatively rapid approximation of bone to hydroxyapatite-coated titanium specimens as compared to uncoated specimens in animal models.

It is to be noted that Block et al. (1987) consider that hydroxyapatite-coated surfaces become biointegrated through an apparent direct bonding of bone to the hydroxyapatite surface.

De Groot et al. (1987) reported that the major disadvantage of the application of bulk apatite ceramics to implants is their susceptibility to fatigue failure but that there is no measurable difference in the fatigue strength of hydroxyapatite-coated titanium and uncoated titanium.

1.3.6.9.3 Clinical usage

The Integral implant has been utilised in edentulous patients for maxillary and mandibular overdentures involving a variety of alternative attachments for example, the

ASC52, the Zest attachment system (APM Sterngold, Attleboro, Massachusetts) and also different bar devices, for example the Dolder bar (Cendres Metaux, Biel, Switzerland). Fixed bridges have also been constructed for edentulous patients. For partially dentate patients Integral implants have been utilised for single tooth replacements and for multiple replacements either free standing or connected to natural teeth. Entirely implant retained bridges are the preferred option (Finger and Guerra, 1989; Block et al., 1990) and have been utilised in association with grafted bone (Finger et al., 1989; Kent and Block, 1989a). Kent and Block (1989b) believe the osteoconductivity of hydroxyapatite may make placement into autogenous bone grafts more predictable than when noncoated titanium implants are used. Integral implants have also been placed into fresh extraction sockets (Block and Kent, 1991).

1.3.6.9.4 Clinical results

Block and Kent (1990) reported the clinical experiences of 90 overdenture patients who were followed up to 56 months postrestoration with the majority in the 12 to 36 month range. Of the 243 Integral implants placed to support these restorations 16 required removal, 5 of these were from the mandible and 11 from the maxilla. A success rate was not cited by the authors but it was concluded that with proper patient work-up, failure and morbidity had remained low.

The scale used to define morbidity was probably that devised by Finger et al. (1989). Finger et al. (1989) reported the results of 218 implants placed in 81 patients into posterior mandibular locations. These implants served as the terminal abutment for 75 distal extension or free standing fixed partial dentures, as a pier abutment with natural teeth in 13 prostheses and as the terminal implant for 13 full arch prostheses when suitable bone was present posterior to the mental foramen. Morbidity was graded as 0 = no bone loss, no symptoms; 1 = occasional inflammation which cleared up with oral prophylaxis; 2 = inflammation with purulence and 2-5mm bone loss which responded to treatment; and 3 = severe bone loss and symptoms unresponsive to surgical treatment. It was concluded that 94% of the implants in the study had no significant morbidity. Kent and Block (1989a) reported the results of 54 Integral implants placed in 18 grafted sinuses in 11 patients. Five patients had fixed distal extension prostheses constructed, 4 patients had full arch fixed prostheses and two patients had overdentures. Implants and bone grafts were placed simultaneously and follow-up ranged from 12 months to 4 years. No significant sinus complications occurred. Bone loss around the implants as measured on periapical radiographs was less than 1mm on all but 5 implants.

1.3.6.10 Bioceram Single Crystal Aluminium Oxide Implant,
(Kyocera International, Inc., San Diego,
California)

1.3.6.10.1 Implant design and material

The standard design of the single crystal aluminium oxide implant is the cylindrical design with a screw like radicular portion. These include the S-type, S-collared type and E-type. All 3 designs have a coronal portion which is flattened on one surface to allow keying of copings or crowns. The variation in design occurs in the cervical and radicular portion. In both S-types, the root portion is threaded from the cervical area to the apex while it is partially threaded for the E-type. The S-collared type implants have a 1mm shoulder or collar separating the root and radicular portion. This collar is 2mm greater in diameter than the implant root. The purpose of the S-collar type implant is to provide greater stability in bone as the collar portion is countersunk into the alveolar bone crest. The E-type implants have been designed primarily for insertion into extraction sockets at the time of surgery. The lands and grooves of the E-type radicular portion have the pitch and angle of a self-tapping screw, so the bone does not have to be tapped prior to insertion as does use of the S-type implants. Kyocera International, Inc. also make blade type implants the T and LT and an anchor, the U-type (Yamane et al., 1979; M^cKinney et al., 1982).

The material of these implants is artificially grown single crystalline alpha aluminium oxide. The physical properties of this material are Knoop hardness number 1,750; compres-

sive strength ($\text{kg/cm}^2 \times 10^3$), 30; modulus of elasticity ($\text{kg/cm}^2 \times 10^5$), 40; and modulus of rupture (kg/mm^2), 130 (McKinney and Koth 1982). Although a polycrystalline aluminium oxide crystal can also be grown and cut into desired shapes for dental implants, it does not have appropriate flexural strength or modulus of rupture. One advantage of the polycrystalline alumina material, however is that it allows the dentist to more effectively adjust the length of the implant for occlusal clearance and thickness of crown coverage. When the single crystal implant is reduced in height, the operator must do this by using a diamond disk. The roughened surface is difficult to polish and the grinding by diamonds leaves lattice imperfections on the surface which may cause fracture of the single crystal. In recognition of these problems, the manufacturer has produced an implant with a single crystal radicular portion and a polycrystalline coronal portion, the A-type (McKinney et al., 1982; Howell, 1986). The Bioceram Zestplant (Zest Anchors Inc, San Diego, California) is also available. It is basically a single crystal core with a polycrystalline shaft that incorporates a female receptacle for a Zest attachment.

1.3.6.10.2 Research background

Clinical (gingival health, plaque accumulation, crevicular fluid volume, mobility and rotation, radiographic assessment of the alveolar bone and general health of the

periodontium) and histological evaluation was carried out for a series of single crystal implants inserted into the posterior jaw areas of 18 mongrel dogs. The implants were not in contact with the opposing teeth but did receive occlusal stress when the dog chewed on hard food. At 18 month and 2 year evaluation periods there was close correlation between the health of the implants and control teeth (McKinney and Koth 1982; McKinney et al., 1983; Steflik et al., 1983). Two distinct patterns were reported for the implant-tissue interface, a direct bony interface occurred in 30% of specimens and a periodontal ligament structure in 70% of the specimens (McKinney and Koth 1982). Yamane et al. (1982) also reported favorable tissue responses to Bioceram implants inserted into dogs.

1.3.6.10.3 Clinical usage

These implants are primarily designed for single tooth replacement and in most cases must be stabilised by direct connection to an existing tooth (Howell, 1986). They have also been utilised for additional abutments for fixed prostheses in both bounded and distal free end saddle areas (McKinney et al., 1982).

1.3.6.10.4 Clinical results

One, 3 and 5 year clinical results were reported by Koth et al. (1983), Steflik et al. (1987) and Koth et al. (1988)

for single crystal sapphire implants placed in posterior mandibular areas to serve as fixed bridge abutments. Twenty nine implants were placed in the mandibles of 18 patients. At the end of 1 year the clinical success rate for implants serving as abutments was adjudged to be 91% (Koth et al., 1983). At the end of 5 years 77.7% of all implants placed and 95.5% of implants used as prostheses abutments were providing satisfactory service (Koth et al., 1988). This result does not satisfy the criteria for implant success described by Albrektsson et al. (1986). Howell (1986) reported a success rate of 92% for this system but did not provide details of the nature of the cases or criteria for evaluation.

1.3.6.11 Ramus Frame Implant

1.3.6.11.1 Implant design and material

The basic design of the ramus frame implant is of a one piece monorail type mandibular implant with right and left posterior extensions which are seated in the corresponding right and left ascending rami and an anterior foot which is seated in the bone of the symphysis, that is, the implant is inserted into the 3 areas of the mandible which are most unaffected by normal resorption. The tripodal design is utilised to afford maximum stability and support for the overlying prosthesis. There are 2 notches on the ramal inserts that act as guides at surgery to measure the actual

depth of penetration into the ramal bone required for stability. Design modifications with improved insertion techniques, anterior labial tabs, anterior lingual tabs and tissue support have been proposed to reduce settling and the incidence of paraesthesia. The M1, M2, M20 and M25 series and the RA1, RA2 series represent progressions in design (Collings, 1980,1986; Guernsey et al., 1986; Chamoun and Lemons, 1990; Turner, 1990).

Ramus frame implants have been fabricated from a variety of materials: pure titanium, titanium alloy or stainless steel. Some designs utilised more than 1 alloy within the same implant (Chamoun and Lemons, 1990).

1.3.6.11.2 Research background

The ramus frame implant was conceptualised and developed by Harold D. Roberts and Ralph A. Roberts in 1965 and initial research was conducted in human cadaver specimens. Examination of a large number of dry specimens of edentulous mandibles led H. Roberts to the surprising conclusion that except for small variations all adult mandibles have similar dimensions, the distance in the width between the coronoid notches was shown to range between 80 and 86mm and the distance to the symphysis was shown to range between 50 and 58mm. They concluded that a preformed implant that would fit a wide square mandible could be modified at surgery to fit a narrow tapering one. It was proposed that

a slight differential in the circumferential measurements of these 3 points could be offset in the symphysis with its usually wide 8 to 12mm intercortical table of bone. Therefore, 4 sizes of implants were made available which could conceivably fit all edentulous mandibles. On the basis of these measurements Roberts placed the first ramus frame implant to stabilise a mandibular denture in 1969 (Roberts and Roberts, 1970; Guernsey et al., 1986).

1.3.6.11.3 Clinical usage

Mandibular prostheses for the ramus frame implant may be fixed or removable. Retention or attachment of these prostheses to the implant have been by means of frictional resistance, locking with acrylic resin, cementation, modified Nelson locks and Lew attachments (Turner, 1990). The ramal frame implant has been inserted in circumstances where there has been an opposing natural dentition or complete denture (Guernsey et al., 1986).

1.3.6.11.4 Clinical results

Turner (1990) reported his experiences of ramus frame implants inserted between 1973 and 1985. Of the 417 frames that were placed, 27 were removed during this 12 year period. Of the 27 patients who had their frames removed, all but 10 had them reinserted. Further details of the success criteria were not provided. Chamoun and Lemons

(1990) presented the results of 831 ramus frame cases reported by the Alabama Implant Study Group. More than 75% of the implant devices were in place after 5 years. The incidence of paraesthesia cases was provided but other qualitative data in relation to defining success was not presented. Guernsey et al. (1990) cited the results of Roberts (1980) who reported a 96% success rate for 1656 ramus frame insertions placed for up to 12 years. Details qualifying the definition of success other than the number of implants removed were not provided.

1.3.6.12 Vitredent Tooth Root Replacement System,
(Vitredent Corporation, Los Angeles)

1.3.6.12.1 Implant design and material

The Vitredent Tooth Root Replacement System includes a hollow 303 selenium stainless steel sleeve cemented into a truncated carbon body which accepts a corresponding preformed stainless steel post core. The external carbon surface has a circumferential ridge and groove system that is placed transversely to the long axis of the implant. Depending on the length, either 1 or 2 pairs of major grooves measuring approximately 2mm occlusogingivally and 1mm deep are placed on the mesial and distal surfaces. All of the outside surface except for the occlusal-most 2mm is textured by sand blasting; the balance is left glassy smooth.

The relevant carbon is vitreous (glassy or polymeric). It is a 99.99% pure form of carbon with a modulus of elasticity similar to dentine and the developers of the implant considered this to be a significant factor in reducing shearing forces at the implant/bone interface (Schnitman and Shulman, 1980; Manski, 1982).

1.3.6.12.2 Research background

Biocompatibility of vitreous carbon tooth root implants was demonstrated by Grenoble and Kim (1973) utilising non-functional implants in fresh extraction sockets of adult mongrel dogs. They reported that over a period of 180 days that there was a complete lack of inflammation in the tissues surrounding the implants. The implants appeared to be surrounded by a thin fibrous membrane, and hard tissue deposits conforming to the implant configuration were found regularly. In a second modified study in dogs by these authors the effect of occlusal force upon the outcome of implant placement was assessed. Throughout the study the gingival tissues remained healthy and after 4 to 6 weeks, the sulcus depths, as probed with light pressure, were similar to those of natural teeth. Thirteen of 14 implants were firm, with mobility similar to those of adjacent teeth. The dogs were sacrificed 4 to 15 weeks after the implant had been in function. The results showed bone filling the implant irregularities with a thin fibrous tissue interface. Schnitman and Shulman (1980) provided a

review of additional animal studies by Stallard (1974), Reedy (1974), Samida (1977) and Schnitman et al. (1980) which encouraged clinical use of the Vitredent system.

1.3.6.12.3 Clinical usage

The Vitredent implant has been used for single tooth replacements anteriorly and posteriorly and for pier and free-end abutments for fixed bridges. In some trials splinting of implants has been included (Schnitman and Shulman, 1980).

1.3.6.12.4 Clinical results

At the Harvard NIDR Consensus Development Conference held in 1978 a consensus was reached for a 3 year survival rate of 55% for 133 vitreous carbon single interdental implants (subsequent clarification revealed that the survival of those implants that were splinted was somewhat higher than 55% and that of the freestanding implants was somewhat lower). Other aspects of survival analysis of this implant in other applications for longer periods of time were not considered quotable because of conflicting results. Schnitman and Shulman (1980) reported that low survival rates and low incidence of immobility called a halt to the placement of additional implants for a planned prospective clinical study of the efficacy and safety of Vitredent implants. These authors concluded that the vitreous carbon

tooth root can no longer be recommended as a freestanding implant, that high morbidity contraindicates its use in anterior sites, that the results as a free-end abutment are marginal at best and the prognosis for this application remains guarded. They stated that in view of its extremely low risk and morbidity in posterior sites and measurable survival statistics when used interdentally with splinting, the Vitredent implant may be considered an alternative root replacement for this application. Albrektsson et al. (1986) have concluded that while fairly good results have been achieved in animal models for this system, this implant has not provided an acceptable outcome in clinical trials.

1.3.6.13 Brånemark System (Nobelpharma AB, Sweden)

1.3.6.13.1 Implant design and material

The Brånemark system implant consists of 6 components (Hobo et al., 1990):

- a. the fixture, which is the component which is surgically placed into the jaw-bone. It has a modified cylindrical shape with machined threads on the outer surface as well as on the inner channel. The top of the fixture has a hexagonal design, the apical portion of the fixture is tapered with 4 vertical notches. The notches help to gather bone particles into the transverse access hole during surgery which eventually helps

achieve sound bone anchorage,

b. the cover screw, which is screwed into the threads of the internal channel and over the hexagonal shape at the top of the fixture and is used during the interim period between the 2 surgical procedures. The cover screw has a groove for screwdriver purchase and is rounded on top to help prevent damage to soft tissue. In the centre of the cover screw there is a depression within the groove to accommodate the punch blade. The punch blade is spring loaded and the post fits into the depression of the cover screw; the blade is used for cutting soft tissue located around the circumference of the cover screw,

c. the abutment, which is the transmucosal component which is screwed into the fixture with an abutment screw. It has a modified cylindrical shape and the apical portion is recessed and hexagonal in shape, designed to fit precisely the coronal portion of the fixture,

d. the abutment screw, which inserts through the abutment and threads into the fixture to connect the 2 components. The abutment screw has a silicone ring (optional) that provides a seal to prevent micro-organisms from passing through the abutment to the fixture. The head of the abutment screw has a smaller hexagonal shape with threads machined inside a smaller channel,

e. the gold cylinder, which is machined to fit the coronal portion of the abutment, it becomes an integral

part of the final prosthesis by incorporating it into the laboratory wax-up and investing procedures and f. the gold screw, which inserts through the gold cylinder and threads into the abutment screw to connect the gold cylinder and abutment.

The fixture, cover screw, abutment and abutment screw are made of commercially pure titanium while the gold cylinder and gold screw are made of an alloy of gold, platinum and palladium (Hobo et al., 1990).

A two stage surgical procedure is recommended for the Brånemark system and a substantial body of evidence supports the attainment of osseointegration for this system (Adell, 1981).

1.3.6.13.2 Research background

The initial concept of osseointegration stemmed from vital microscope studies of the bone marrow of the rabbit fibula commenced in 1952. The bone was uncovered for visual inspection in a modified intravital microscope at high resolution in accordance with a very gentle surgical preparation technique. With special instrumentation the marrow could be studied in transillumination in vivo and in situ after the covering bone was ground down to a thickness of only 10 to 20 μ m. Circulation was maintained in this thin layer of bone and with very few signs of microvascular

damage, which is the earliest and most sensitive indication of tissue injury. These intravascular studies also revealed the intimate circulatory connection between marrow, bone and joint tissue compartments. Subsequent studies of the regeneration of bone and marrow emphasised the close functional connection between marrow and bone in the repair of bone defects. A series of in vivo studies on bone, marrow and joint tissue was performed with particular emphasis on tissue reaction to various kinds of injury, mechanical, thermal, chemical and rheological. Various therapeutic possibilities to minimise the effect of such trauma were considered as well as the development of procedures that would promote predictable healing of differentiated tissues. Long term in vivo microscopic studies of bone and marrow response to implanted titanium of a screw-shaped design were also considered and these studies in the early 1960's strongly suggested the possibility of osseointegration since the optical chambers could not be removed from the bone once they had healed, without fracturing the bone, whereas the interface between bone and titanium remained intact. Experimentation continued in relation to the development of procedures for rehabilitation of edentulism. As a consequence of successful experimentation and clinical repair of major defects in the jaw skeleton, resulting in skeletal continuity but without replacement of teeth, a demand was created for a jaw bone anchored substitute for teeth. Accordingly, studies on healing and mechanical stability of jaw bone anchored

prosthetic elements were carried out using anchoring elements of pure titanium of different sizes and designs. It was found that an implant inserted in the marrow space and allowed to heal, without initial loading, became surrounded by a layer of compact bone. There was a positive correlation between the microtopography of the titanium surface, absence of contamination, gentle surgical preparation of implant site and the condition of bone and marrow at radiographical and histological analyses of the interfacial tissues. Osseointegration could be established in different experimental animals even when transcutaneous abutments were connected.

Subsequently, dogs were rendered partially dentate and after bone healing of the extraction sockets the dogs were provided with prosthetic constructions similar to dental bridges attached to osseointegrated screw-shaped titanium fixtures, 4mm in diameter and 10mm long with a particular surface microarchitecture. These fixtures were allowed to heal into the jaw bone during a period of 3 to 4 months under unloaded conditions. Radiological and histological analyses indicated that integration and bridge stability could be maintained for 10 years in dogs without significant adverse reactions in hard or soft tissues despite the fact that oral hygiene procedures were applied only once or twice a year in these dogs. The load bearing capacity of single implants was 100kg for the lower jaw and 30 to 50kg for the upper jaw.

On the basis of these successful long term experimental studies on bone anchorage and soft tissue behaviour in response to titanium devices and additional favourable information on interface integrity in the human skin tube chamber, the first edentulous patient was treated in 1965. A two stage technique was used in accordance with osseointegration principles.

Since this developmental phase many reports have been published dealing with experimental, laboratory and clinical aspects of the Brånemark system; Henry (1989) stated that by January 1st 1988 more than 600 such articles had appeared worldwide. Of particular interest may be articles relating to:

- a. bone augmentation involving autologous grafts and/or involving modified surgical techniques (Keller et al., 1986; Listrom and Symington 1988; Sailer, 1988; Wood and Moore 1988; Kahnberg et al., 1989; Urken et al., 1989; Adell et al., 1990), membrane techniques for guided tissue regeneration (Dahlin et al., 1989; Nyman, 1990) and circumstances involving hyperbaric oxygen (Nilsson et al., 1988),
- b. immediate fixture placement (Parel and Triplett, 1990; Krump and Barnett, 1991),
- c. the application of the Periotest^R method (Siemens AG, Bensheim, Germany, 1991) to the determination of implant success (Olivé and Aparicio, 1990; Teerlinck et al., 1991),