

The Long-Term Efficacy of Currently Used Dental Implants: A Review and Proposed Criteria of Success

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Criteria for the evaluation of dental implant success are proposed. These criteria are applied in an assessment of the long-term efficacy of currently used dental implants including the subperiosteal implant, the vitreous carbon implant, the blade-vent implant, the single-crystal sapphire implant, the Tübingen implant, the TCP-implant, the TPS-screw, the ITI hollow-cylinder implant, the IMZ dental implant, the Core-Vent titanium alloy implant, the transosteal mandibular staple bone plate, and the Brånemark osseointegrated titanium implant. An attempt has been made to standardize the basis for comments on each type of implant.

Dentists and dental specialists employ considerable clinical skills in an effort to cope with the consequences of partial and/or complete edentulism. These consequences are related mainly to partial or total deficits in one or both jaws' complement of periodontal ligaments. As a result, clinical ingenuity has led to many treatment successes, with prostheses supported by varying degrees of residual periodontium and/or alveolar bone. The notion of an analogue for a periodontal ligament attachment with predictable long-term success, has of necessity intrigued clinical researchers for several decades. Regrettably, the many proposed implant prescriptions to fulfill this objective did not survive scientific scrutiny, and the ideal implant (like the ideal dental cement) went on being frequently described, but never encountered. As a result clinical educators on both sides of the Atlantic were prone to regard the prescriptions on use of implants as "human experimentation without informed consent," a departure from the *Primum Non Nocere* commitment of the health professional. In 1978, an NIH-sponsored Consensus Development Conference¹ sought an update of the status of dental implants. This was a brave effort indeed, but one that fell somewhat short of what was really needed. With the obvious advantage of hindsight, several reasons can be advanced for the state-of-the-art, rather than the state-of-the-science report, which the conference produced:

1. A failure to address comprehensively the research literature on the subject. As a result, a significant body of already published European research was

overlooked.

2. A failure to go beyond a retrospective rationalization of implant systems in limited, albeit scientifically untested, use.

Consequently, the consensus statement proposal of minimal criteria for implant success was sadly reminiscent of the early five-year cure rate criteria for cancer therapy—a reflection of the half-way state of biotechnology in the dental implant field as perceived on the North American continent.

In 1982, a conference on Osseointegration in Clinical Dentistry was held in Toronto. Senior academic prosthodontists and oral and maxillofacial surgeons, from all dental schools in North America were invited to listen to, and participate in, a review of the basic science, biomaterials, and clinical research findings, in the area of osseointegrated implants, from the laboratories of P.-I. Brånemark. This was a seminal event that led to the publication of the proceedings from the Toronto conference,² and catalyzed a profound academic interest in dental implants. In the past four years, several universities that were previously very critical of the use of implants, have now started dental implant programs. While this initiative could lead to the perception that the dental implant concept has now been accepted by the academic community, we do not feel this to be a correct conclusion. What has in fact happened, is that one well-controlled dental implant system, the Brånemark osseointegrated screw, has been accepted in academic circles as a recognized treatment for edentulous jaws. This has been further confirmed by the American Dental Association's provisional acceptance of this implant.³ Since the authors have had extensive clinical and research experience with Brånemark's osseointegration system, there may be vulnerability to a certain degree of bias in the preparation of this article. Hopefully, the subsequent analysis will negate such a preconceived notion, should it exist, on the part of any of our readers. The current, independent involvement with osseointegration, is only the result of a collective interpretation of published results, combined with the author's confirmation of the method's clinical safety and longitudinal efficacy. It does not preclude current, or future research/clinical commitment to any other system that matches the yardstick being proposed in this article.

It is imperative that the routine clinical use of any implant system be based entirely on an evaluation of the outcome of that specific system in prescribed scrutiny of long-term follow-up clinical investigations. This review attempts a summary of the current scientific status of dental implants as based on a literature survey. In addition, clinicians and companies in the USA, Europe, and Japan have been contacted to ascertain that this summary will be as up-to-date as possible.

A frequent fault in implant literature has been the failure to recognize the

complex multidimensional problem associated with the insertion of a foreign device into the body and the expectation that it should remain preferably functional, over the life span of the patient. The successful outcome of any implant procedure is surely dependent on the interrelationship of the various components of an equation that includes the following:⁴

1. Biocompatibility of the implant material
2. Macroscopic and microscopic nature of the implant surface⁵⁻⁷
3. The status of the implant bed in both a health (noninfected) and a morphologic (bone quality) context
4. The surgical technique per se^{8,9}
5. The undisturbed healing phase¹⁰⁻¹²
6. The subsequent prosthetic design and long-term loading phase. This reconciles considerations of design, materials used, location of implants, and anticipated loading, together with hygienic and cosmetic considerations.¹³⁻¹⁵

The challenge confronting the clinician is that these several factors must be controlled almost simultaneously, if a predictably successful outcome is to be expected. Clearly, research in this field has outgrown the anecdotal claims of success based upon asseveration. We, therefore, consider it opportune to evaluate the current status of this field by proposing objective criteria for implant success that reflect a rigid scrutiny applied to reported evidence in the field.

Criteria for implant success

The scientific literature does not contain evidence regarding the restoration and maintenance of a proper periodontal ligament around a dental implant in human subjects. Several claims (Linkow¹⁶ and James¹⁷) have been made that a ligament develops around implants, but they are far from compelling. In fact, most reports on the nature of the interfacial response to the vast majority of clinically prescribed implants, suggest anchorage in fibrous connective tissue. Ironically this tissue response has now been renamed "fibro-integration" or even "fibrous osseointegration"¹⁷ and strikes us as a frantic effort to co-opt the term "integration" at all costs! The fact remains that implants anchored in fibrous tissue appear to end up with high clinical failure rates. Previously it was noted that even in those implants where an early interfacial osteogenesis was apparent (at least as judged radiographically) a time-dependent shift to a peri-implant fibrous tissue response was the rule, rather than the exception.¹⁸ Furthermore, it has been observed that the nature of the bone-implant interface appears to determine the vulnerability or otherwise, of the overlying mucosa-implant response. In fact, we are tempted to

conclude, with the current understanding of the entire interfacial phenomenon, that the clinical outcome and performance of any implant, to include the gingival response, is predicated on the nature of the bony response, perhaps even exclusively so.¹⁹

It is clear that the reported method of osseointegration¹⁸ is a viable analogue for the long-term attachment mechanism of a dental implant. Brånemark has pioneered a new system of implant biotechnology, and provided clinicians and researchers alike with a compelling yardstick for determining implant success. This yard-stick, quite logically, dismisses the originally proposed criteria from the 1979 NIH publication,²⁰ and demands stricter expectations from the dental profession prescribing an implant method. Both the NIH minimal criteria (for historical and comparative purposes) and our proposed criteria are graphically listed in [Table 1](#). The criteria proposed herein are relatively easy to apply, and above all ensure a degree of clinical success that is comparable with that experienced in conventional prosthodontic therapy. They are also reconcilable with certain clinical and laboratory observations:

1. Osseointegration is a histological definition, and only partially a clinical and radiographic one. 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 resolution level at least in the short term. Hence the proposal that both clinical evidence of mobility, and radiographic bone response (which like the two sides of a coin, are inseparable, although they *can* be looked at separately), be judged after a substantial period of implant service.
2. Conventional gingival and periodontal indices from the dental literature are not included in those criteria. Clinically it has been observed that various gingival responses can be elicited by several aspects of the implant technique (location, direction, height, design of the prosthesis, patient maintenance, etc.). While a "nuisance" index of gingival changes can be determined,²¹ it does not appear to be germane to implant success.
3. It is impossible to separate the quality of the implant anchorage from its subsequent loaded assignment. Therefore it is presumed that the same surgical skill that ensured a biomechanical anchorage, is matched by the prosthodontic skill that maintains it. Either of the technique interventions, or both, can compromise implant success, and excellence of both should be a common denominator for any implant system.
4. These criteria are profoundly influenced by the compelling nature of the Brånemark results. They clearly underscore the basic concept of osseointegration as being the major, if not the exclusive, reason for a successful long-term dental

implant attachment. However, future research may indicate equally good success rates with differently elicited and resulting attachment mechanisms. For example, an induced analogue for a periodontal ligament could demonstrate variable degrees of mobility of the individual implant. The work of Lindhe and Nyman²² with the natural dentition has confirmed the relative lack of significance of tooth mobility in the presence of a controlled inflammatory environment. It is, therefore, tempting to extrapolate Lindhe's conclusions to the implant attachment situation and suggest that implant immobility not be an essential criterion for success. However, this would imply that a fibrous implant attachment is identical to a widened periodontal ligament in both its mechanical and biological properties. While not appearing to be the case, such a realization should not preclude the possibility that other types of attachment will necessitate changes in the currently proposed criteria.

Review of published evidence

Following is a review of the best known implants in current use. An attempt has been made to standardize the basis for our comments on each method.

Subperiosteal implants

Implant material. The metal framework has been constructed of different materials. Reported examples include Vitallium,²³ aluminum oxide,²⁴ carbon²⁵ or titanium coating.²⁶

Research background. Subperiosteally anchored implants were already introduced by the 1940s.²⁷ Of all currently used devices, it is the type of implant that has had the longest period of clinical trial. No specific animal research programs with subperiosteal implants appear to have been undertaken in the past decade. These implants are not anchored inside the bone as endosseous devices, but are instead shaped to "ride on" the residual bony ridge. They are not claimed to be osseointegrated.²⁸

Indications. Subperiosteal implants have been used in totally edentulous mandibles and maxillae. However, the best results have been achieved in treatment of the edentulous mandible.

Insertion technique and loading time. The subperiosteal implant is inserted with an immediate penetration of the oral soft tissues even if a primary operation has been undertaken for obtaining an impression of bony morphology. The implant is immediately attached to a prosthesis superstructure.

Complications. Complications such as inflammation, postinsertion dysesthesia, swelling, and pain have been reported,²⁹ as well as laceration of the mandibular nerve, or progressive bone resorption. If the subperiosteal implant has to be removed

³⁰ prosthodontic treatment will be complicated.

Clinical results. Varying results have been described in the literature. Köle³¹ found an average success rate of only 6% after, on average, seven years of implantation. At the Harvard NIH conference in 1978, Goldberg³² reported ten-year success figures of 36% ± 6%. A similar description of the outcome of subperiosteal implants was reported by Mercier, Cholewa, and Djokovic,³³ who found a 60% success after an average observation period of 3.3 years.

The optimal outcome of subperiosteal implant therapy is represented by the long-term material of Bodine and Yanase³⁴ whose ten-year report indicated success in the range of 66% ± 8%. In 1985, the same authors published a 30-year report on 28 subperiosteal implants inserted between 1952 and 1959. The patients of this study were followed regularly by recalls, personal contact, telephone, and questionnaires. Not one single patient was lost in the follow-up. One of the patients had his subperiosteal implant in situ without problems for over 26 years of follow-up. The five-year success rate was found to be as high as 93%, but the ten-year results were not better than 64%. This indicates a significant loss of implants with time, further substantiated by the 15-year results that indicated a 54% implant success rate.^{34,35}

Author comments. The work of Bodine and Yanase³⁴ is to be commended for the meticulous approach of the authors as indicated by the lack of patient dropout. Apart from the Brånemark screw implants, and the Small bone staple, the work of Bodine and Yanase represents the only study where a long-term follow-up (>15 years) has been published. However, the long-term outcome of subperiosteal implants is clearly not promising, and the authors concur with Boucher,³⁶ who stated that all subperiosteal implants will eventually be removed if the patient does not die with the implant in place. When first introduced, subperiosteal implants were the only implant system for selected cases. However, in light of the poor long-term data and the existence of alternative methods with much improved results, clinical indications for insertion of subperiosteal implants must surely be regarded as passé.

The vitreous carbon implant

Implant material. These implants have a core of stainless steel that is covered by 99.99% pure carbon.

Research background. The tissue compatibility of vitreous carbon has been demonstrated in many animal studies.^{37,38} Schnitman and Shulman³⁹ reported a five-year baboon study of 48 vitreous carbon implants that gave a positive outcome in 70% of the cases. These implants were inserted into fresh extraction sockets.

Indications. The vitreous carbon implants have been used as single, free-standing units or they have been splinted to adjacent teeth. The implants have been inserted

into the mandible or maxilla in healed sites or fresh extraction sockets.

Insertion technique and loading time. Proponents of the technique recommend the use of a low-speed instrumentation with adequate irrigation.³⁹ After implant insertion, the soft tissues are closed to allow an undisturbed bone healing for a minimum of five months.

Complications. McCoy⁴⁰ described cases with osteomyelitis and paresthesia/anesthesia. Furthermore, the bone loss was substantial, because of the size of the implants.

Clinical results. Meffert⁴¹ reported a zero- to five-year result of 65% (N = 67). McCoy⁴⁰ found a five-year positive result of 31% ± 7% (N = 18). Schnitman and Shulman³⁹ also had discouraging results.

Author comments. While fairly good results have been achieved in animal models, this implant has not provided an acceptable outcome in clinical trials.

Blade-vent implants

Implant material. Various types of blade-vent implants have been used clinically over the last decades. Introduced by Linkow,⁴² the original blade was of a CrNiVa-alloy, but in other cases titanium alloy,⁴³ aluminum oxides,⁴⁴⁻⁴⁶ or vitreous carbon⁴⁷ materials have been utilized.

Research background. Several reports of animal experiments with blade-vent implants have been published, and the following reports serve as examples. Natiella et al.⁴⁸ inserted 149 blades in a monkey model over a follow-up time of 0 to 36 months. Ten percent of the implants failed during the observation period and the authors described soft and hard adverse tissue reactions. Gourley, Richard, and Cordy⁴⁹ placed 44 blades in 11 beagle dogs and followed these for 24 months. Again, 10% of the implants were regarded as failures. All of the implants were surrounded by thick fibrous tissue coats, while other implants were found to be directly bordered by bone in scattered areas. Cranin, Rabkin, and Silverbrand⁵⁰ followed 24 carbon blades inserted in 12 dogs over a time period of 26 weeks. The percentage of success in this study was 54.2%.

Indications. Blade-vent implants have been recommended for use as single replacements, and as treatment for totally edentulous jaws.

Insertion technique and loading times. Generally, direct penetration of the gingiva and a direct connection to a prosthetic superstructure have been allowed.

Complications. Various soft tissue problems and continuous bone deterioration have been reported as complications of blade-vents.⁵¹

Clinical results. Cranin, Rabkin, and Garfinkel⁵² reported the outcome of 952 blades placed in 458 patients. Of the total patient material, 43 were lost to follow-up because of patient death or patient dropout from the study. Implant success or failure was based on clinical examinations and a carefully controlled radiographical analysis. The five-year success rate was determined to be 55%.

Smithloff and Fritz^{53,54} reported the outcome of 33 Linkow blade-vents inserted in 22 patients (5 maxillae and 28 mandibles). Based on clinical and radiological examinations at the five-year follow-up, 14 implants were considered acceptable, eight showed adjacent radiolucent areas of approximately 4 mm² and pocket depths of 4 to 5 mm while the remaining 11 implants (33%) demonstrated large radiolucent areas and pocket depths exceeding 6 mm. The five-year success rate in the study by Smithloff and Fritz can thus be estimated at 42% to 66%. Ten-year results did not exceed a 50% success rate.

Armitage⁵⁵ found a 49% five-year survival in clinical material consisting of 77 blade-vents. At the Harvard Consensus Conference Linkow⁵⁶ reported five-year success rates in the range of 92% (N = 164). However, the patient group presented by Linkow did not seem to include a complete material or represent consecutively inserted implants, nor were criteria for "implant success" properly defined. Recently published papers by Babbush^{57,58} are without precise patient data or result analyses.

Author comments. No matter which implant material has been utilized, the outcome of blade-vent implants has been poor. Despite various types of blades being used for approximately 30 years, not one report with acceptable follow-up results has been published. The authors agree with the statement by Armitage⁵⁵: "In the past 30 years many modifications have been taken to improve blade implants. However, all have proven inadequate to justify such widespread use of this device today. The rapid increase in the use of this implant without documented success is alarming."

The single-crystal sapphire implant

Implant material. Single-crystal aluminum oxide.

Research background. These implants are manufactured in one piece consisting of a threaded screw for anchorage in the jaw bone, a collar, and a smooth gingival top component. Some experimental investigations of the tissue reactions to the single-crystal sapphire have been published.⁵⁹⁻⁶¹ Kawahara⁵⁹ summarized a number of publications on cellular responses to implant materials, and suggested that sapphire implants were well tolerated in the bone and soft tissue implantation bed. McKinney, Steflik, and Koth⁶⁰ performed a scanning electron microscopic study of the soft tissue to sapphire implant interface in a canine experimental study, with a follow-up time of 3 to 24 months. Gingival crevicular epithelial cells were in contact

with the surface of the implant in a manner similar to that seen in the natural tooth interface. This occurrence was seen as an indication of the establishment of a biological soft tissue seal to the sapphire aluminum. Akagawa et al.⁶¹ found sapphire to be well tolerated in the soft tissue as well as in the bone of rats. Fukuyama et al.,⁶² who investigated the interface of bone to sapphire implants, described a bone tissue boundary zone in some situations, whereas in others there was evidence of interposed soft tissue.

Indications. The following indications have been suggested by Sawa et al.⁶³: single replacement with splinting to adjacent natural teeth, or as the last abutment in an extension bridge. The single-crystal implants in the study by Koth et al.^{64,65} were placed only in the posterior region of the mandible, where they served as distal abutments for fixed partial dentures.

Published clinical material that describes single-crystal dental implants in either edentulous jaws or in the partially edentulous maxilla could not be located.

Insertion technique and loading time. Single-crystal sapphire dental implants are inserted with direct penetration of the gingiva. Koth et al.^{64,65} avoid a direct loading of the implants for a minimum of three months following placement. Sawa et al.⁶³ have recommended that single-crystal alumina implants can be placed in fresh extraction sockets without any greater implant loss than that found at later insertion times.

Complications. In the few patient reports published in English there have been no specific complications reported. However, the follow-up time of these reports is limited to less than five years.

Clinical results. A paper by Sawa et al.⁶³ reported the outcome of 443 implants placed into 245 patients and followed for up to three years. Apparently this experience is based upon a random selection of implants inserted by various dentists and, therefore, it cannot be regarded as a study of consecutive patients. Gingival inflammation, pain, as well as bridge mobility were evaluated on the basis of a 4-grade scale one year after implant insertion. The report indicates a positive outcome in between 93.6% and 98.3% of the cases operated. Patient degree of satisfaction was described as "comfortable" in 55.2%, "satisfactory" in 43.8%, and "unsatisfactory" in 1% of the cases. However, these data apply only to the implants that were considered stable enough to provide prosthesis support as does the presented one-year success rate of 98.3% and the three-year success rate of 97.4%. The percentile success of the total experience is not clear from the paper by Sawa et al.,⁶³ but appears to be considerably lower than the reported figures suggest.

Koth et al.^{64,65} inserted 29 single-crystal implants in the mandibles of 18 patients. Their one-year results⁶⁴ indicate a success rate as high as 91%, but again,

this figure reflects only the outcome of those implants that were actually connected to tooth abutments. If all inserted implants are considered, the success rate was in the range of 70%. Nevertheless, the implants inserted by Koth et al. have been meticulously followed up and, so far, only one patient has been lost to the follow-up investigation.⁶⁶ Bleeding index, crevicular fluid volume, mobility, plaque index, alveolar bone status, and patient comfort have been evaluated. Their success criteria included implant mobility of 2 or less on a 4-grade scale, a criterion that may be criticized if true bone integration is to be regarded as a desired state. The five-year outcome of individual implants depends on whether the statistics are based on 27, 28, or 29 of the originally inserted implants. Regardless of the base, the success rate is not higher than 78%. The outcome of 300 sapphire implants inserted at the Scripps Clinic since 1981 is uncertain.⁶⁷

Author comments. The clinical reports by Koth et al.^{64,65} as well as by Sawa et al.⁶³ have often been misinterpreted as indicating success rates of individual implants in the range of 90% or more. However, if all inserted implants are considered, the true success rates appear to be in the 70% to 80% range for a recall period of up to five years, i.e., clearly below the minimal acceptance figures suggested in this article. We, therefore, regard the published results of single-crystal aluminum implants as indicating preliminary stages of development primarily indicated for experimental research and not for routine clinical application.

The Tübingen aluminum ceramic implant

Implant material. This implant is shaped like an irregular conical cylinder with surface lacunae that are claimed to allow for osteocytic ingrowth. The implants are manufactured from aluminum oxide.

Research background. The Tübingen implant was first described by Schulte and Heimke.⁶⁸ Several experimental studies have been published that outline tissue reactions to aluminum oxide. Generally, the aluminum ceramic is well tolerated in the bone and the soft tissues.^{69,70} Büsing et al.⁷¹ found evidence of a bone condensation adjacent to experimental canine dental implants. There is convincing evidence that aluminum oxide Tübingen implants become anchored in bone without intervening soft tissue layers. A biomechanical evaluation of bone-anchored aluminum ceramic implants has been presented by Heimke et al.⁷²

Indications. Tübingen implants are used for the replacement of individual teeth in both the maxilla and the mandible. The implants are not recommended as prosthesis abutments for edentulous patients. Various designs of the Tübingen implant are available depending on the tooth that is to be replaced (Fig. 1).

Insertion technique and loading time. The implants are inserted in a one-stage surgical procedure, and are designed to immediately penetrate the gingival tissues

into the oral cavity. Direct premature loading of the implants is not recommended, and a provisional denture is therefore used to ensure that there is no direct occlusion with the implant. However, this approach does not necessarily preclude force transfer to the implant, minimal as it might be.

Complications. No specific complications other than the occasional loss of an implant have been described. If a Tübingen implant is fractured, it is usually removed easily, and without sequelae for the patient.

Clinical results. From the clinical perspective these implants are well documented. They have been used mainly in Germany, where several teams have participated in a controlled evaluation program. d'Hoedt and Lukas⁷³ and Lukas, d'Hoedt, and Schulte,⁷⁴ reported the outcome of 256 and 451 implants respectively, with follow-up times of 0 to 5 and 6.8 years. According to the authors a clinically positive result was achieved in better than 90% of the cases. However, when these results are compared to the report of d'Hoedt and Lukas,⁷³ it appears that the combined clinical material does not demonstrate such a positive result. In fact, of the 256 inserted implants, no less than 78 were lost, with most losses occurring during the first year after implantation. Thus, an actual clinical result of approximately 69% was realized. While the negative figure for the outcome of the Tübingen implant is, quite correctly, published by d'Hoedt and Lukas,⁷³ unfortunately the abstract of the paper, as well as the short report by Lukas et al.⁷² cite only a 90% to 91% success rate. The reason for this apparent discrepancy is that the authors claim to have changed their clinical routine, which then resulted in improved data. Furthermore, many of the losses reported by d'Hoedt and Lukas⁷³ apparently depended on the use of an unsuitable implant design. If only those implants with the presently used design are considered, the report of d'Hoedt and Lukas⁷³ on 137 implants inserted over zero to five years, indicates that 13 were lost, or a success rate of 90.5%.

Scholz and d'Hoedt⁷⁵ reported on 134 Tübingen implants that had been inserted in the anterior region of the jaws of young persons aged 8 to 17 years. The patients were recalled twice annually for five years; thereafter at least once annually. The average follow-up period was 2.8 years, and 11 implants were observed for more than five years. The success rate in toto was 77% (31 implants were lost). However, at the time of the study five of the implants were not yet connected to a prosthesis and it is uncertain as to how many of the replacements had been functioning for less than one year. If only the outcome of implants inserted in children over 12 years of age is considered, the successful results are 82.4% (N = 117).

Author comments. The Tübingen implant is one of the few devices for which an objective follow-up analysis has been attempted. In addition, these implants are routinely used in the upper jaw. However, no programmed follow-up of at least 100 consecutively inserted implants has been monitored with the outcome reported over

a minimal period of five years. Aluminum implants (but not specifically the Tübingen ones) have been criticized because of a possible long-term toxic effect in the body, and for a presumed increase in brittleness with longer times of implantation. These are, however, speculative objections of unknown practical significance.⁷⁶

The TCP-implant

Implant material. The TCP-implant is a cylindrical, titanium device that is coated with tri- and tetracalciumphosphate.

Research background. The rationale for a surface coating includes the advantage of achieving a direct bone contact with the implant which, based on various experimental reviews⁷⁷⁻⁷⁹ was regarded as impossible with a metallic implant. Riess⁸⁰ hypothesized that the only way to establish such a direct bone-to-implant contact would be to use a biodegradable coating such as tri- and tetracalciumphosphate (TCP), insert the implant and wait for a gradual replacement of the TCP with new, ordered bone. The achievement of a direct bone contact with the TCP-implant was demonstrated through animal experiments.⁸¹

Indications. The TCP-implant has been recommended for various edentulous states in the mandible.⁸⁰

Insertion technique and loading conditions. Lavelle, Wedgwood, and Riess⁸² emphasized the importance of controlling surgical trauma during implant insertion, and recommended a maximal rotational drill speed of 2,000 rpm combined with external and internal cooling. Lavelle et al.^{82,83} described a two-stage surgical procedure for TCP-implant placement that provided for individual loading only when radiological evidence of "ankylosis" of the implant was present.

Complications. No specific complications of TCP-implants have so far been reported.

Clinical results. Single clinical cases have been presented by Riess et al.,⁸¹ but without any controlled long-term data. Lavelle, Wedgwood, and Love⁸³ inserted 30 TCP-implants in 18 patients and followed these up to 20 months. The authors concluded that the implants remained stable, and that the mucoperiosteum remained tight around the cervical margin of the implant without any signs of pocket formation. No evidence of infection or inflammation was reported. Complete five-year reports on the outcome of TCP-implants have not been published.

Author comments. The rationale for TCP-implants—that metallic implants cannot be anchored to bone without a fibrous tissue interface—is misconceived (for a review see Albrektsson⁷⁶). Convincing evidence of any theoretical superiority of TCP-implants over uncoated ones has not been demonstrated. The lack of properly

presented five-year outcome data of TCP-implants prompts the conclusion that this implant cannot be recommended for clinical routine use.

The TPS-screw

Implant material. Commercially pure titanium with a plasma-sprayed surface.

Research background. The TPS-screw (Fig. 2) was originally described by Ledermann.⁸⁴ Published data related to animal investigation in which the TPS-screw has been used are not available. However, the same type of plasma-sprayed titanium surface (Fig. 3) as used with the ITI-hollow cylinder has had desired application, and the latter is well documented in the literature. A clinical situation in which a stable TPS-screw was investigated, revealed a histologically verified direct contact between the bone and the titanium without any interposed soft tissue.⁸⁵ There is combined clinical, radiographical, and histological evidence of the TPS-screw becoming osseointegrated.⁸⁵

Indications. Single replacements: a few reports of single replacements have been published. Edentulous mandible: two to four implants with a bar attachment for overdenture construction or a fixed-prosthesis construction has been recommended. Edentulous maxilla: This implant has not been recommended for use in the maxilla.

Insertion technique and loading time. To avoid overheating of the bone a controlled surgical technique is preferred. The implants are allowed to directly penetrate the gingival tissues, and are used for prosthetic abutment service without any specific unloaded period.⁸⁶

Complications. No serious complications have been reported. The feasibility of implant re-implantation in the healed sites of previous failure has not been reported.

Clinical results. Ledermann⁸⁷ reported the outcome of 415 ITI-screws inserted in 122 edentulous and partially edentulous patients. Four of the patients were lost during follow-up. Clinical parameters similar to those proposed by the NIH consensus¹ were evaluated. Ledermann⁸⁷ reported a success rate of 92.3 % . However, at the time of study completion, 39 of the patients used their implants for less than a year and are, therefore, of limited interest for a proper long-term evaluation. In an unpublished report,⁸⁸ the author reviewed the results of 500 implants inserted over zero to seven years. This series includes the same 415 screws reported in 1983. Of the 500 implants, 41 (8.2%) were failures and 51 (10.2%) were lost during the follow-up period (27 cases because of patient deaths). Again, the number of those implants followed for less than one year is uncertain. While these data suggest a five-year success rate that is clearly below 91.8%, in all probability it is above our proposed criterion of 85%.

Kraekeler⁸⁹ reported 358 implants in service for zero to eight years. In this

experience, 28 were failures, giving a success rate of 92.2%. Five-year success rates are uncertain, but 112 of the 358 implants had been inserted for more than five years. The suggested minimal success criteria of 85% was most probably achieved, since most failures with the TSP-screw have been reported to occur during the first year of implantation.⁸⁸

Babbush⁹⁰ reported the outcome of 456 TPS-screws inserted in 114 patients. The exact mode of evaluation, or the exact number of implant losses is not quite clear, but apparently 28 implants were lost over the follow-up interval of 1 to 42 months. In an unpublished⁹¹ paper, the present authors became acquainted with tabulated results from a worldwide study of the TPS-screw. This report summarizes the outcome of treatment from various centers. Altogether 227 implants had been followed for more than five years, and 113 for more than six years. The five-year success rate was 90.4%, whereas the six-year experience was 87.9%. It may be concluded that 12 implants (5.3%) were lost between five and six years following insertion, which is a surprisingly high figure for a properly bone-anchored implant. Another interesting difference between the TPS-screw, and for example, the material of Brånemark, Zarb, and Albrektsson,⁹² is that most of the failures of the TPS-screw seem to be total failures, i.e., all implants inserted in a patient are lost, rather than individual screws. The criteria for implant failure with the TPS-screw are not entirely clear.

Author comments. Information on use of the TPS-screw appears to be well documented, since 1,739 implants have been inserted in 484 patients.⁹¹ Only some of the clinically reported implants have been actually followed up for five years, and no implants have been followed for ten years or longer. Furthermore, since multiple investigators have been involved, the 1,739 inserted implants have not been consecutively placed. Nevertheless, the five-year data of the TPS-screw appear to be within acceptable standards as defined in this article.

The ITI hollow-cylinder implant

Implant material. Titanium with a plasma-sprayed surface.

Research background. A series of published experimental investigations provide biological as well as a physical background information for these implants. Primate bone tissue reactions to dental implants of the ITI-type were described by Juillerat and Küffer.⁹³ The authors found evidence of fibrous tissue anchorage of some implants, while others became directly anchored in bone. Schroeder et al.⁹⁴ submitted experimental dental implants to masticatory forces, and found clear evidence of a direct bone-to-implant contact. Steinemann et al.^{95,96} have presented excellent scientific papers on the physical characteristics of the bone-to-implant interface.

Indications. The ITI implants exist as single, or double-hollow cylinders, type K and type F. Recommended only for insertion in the mandible, they are used as single replacements or part of a bar (overdenture) or fixed-prosthesis construction.

Insertion technique and loading conditions. A controlled surgical technique that minimizes the risk of tissue trauma during insertion is recommended. The implants are allowed immediate penetration into the oral cavity, and are immediately load-bearing.⁹⁷

Complications. No reports of complications with the ITI hollow-cylinder have been reported in the literature. However, the configuration of the implant makes subsequent removal (should this be necessary) without bone destruction difficult. This is particularly true for the double-cylinder implant.

Clinical results. Ledermann et al.^{98,99} reported the outcome of 18 ITI hollow-cylinders that had been followed for 1 to 36 months. When considering that 11 implants had been followed for more than one year, a one to three year success rate of 90.9% was achieved. This study was performed according to the criteria suggested by the NIH-consensus.¹ Schroeder¹⁰⁰ reported that of 29 type K implants, three failed, indicating a success of 91% over zero to five years. A similar follow-up of 146 type F implants indicated a zero to six year success rate of approximately 95%. Kraekeler,¹⁰¹ reported on 115 dental implants with a success rate of 87.8%. However, these two last cited reports have not yet been published, and it is uncertain which criteria have been used for the evaluation of success/failure. Only 20 of the implants had been followed up for more than five years.

Author comments. There are no appropriate five-year results published on the outcome of ITI hollow-cylinder implants, and because of the small number of implants inserted during the first years of clinical trial, it will be some time before a complete five-year follow-up can be presented. Nevertheless, the ITI hollow-cylinder implants appear to have been used in carefully controlled clinical programs and the preliminary results achieved, so far, indicate that these implants will probably pass the minimal criteria of 85% success over five years.

The IMZ dental implant

Implant material. The IMZ implant is a cylindrical device with or without wings with a plasma-coated titanium surface (Fig. 4).

Research background. Few, if any, experimental investigations of the IMZ implant have been published. However, in a post mortem human specimen, Kirsch¹⁰² investigated the bone-to-implant interface that had been in function for two years. The author found evidence of a direct bone-to-implant contact without any interposed soft tissue. In titanium-plasma coated femoral bone implants, Kirsch and

Donath¹⁰³ found evidence of direct bone attachment of the foreign devices starting as early as seven days after the implantation.

Indications. The IMZ implant has been used for tooth replacement in both partially and completely edentulous mandibles.¹⁰⁴

Insertion technique and loading time. A two-stage surgical technique is recommended, the first being insertion of the implant with internally cooled drills running at approximately 1,000 rpm. Second stage surgery is performed after a postoperative healing phase of three months, at which time the dental bridges are connected.

Complications. No specific reports on complications with the IMZ implant have been reported in the literature. However, should the wing-type implant require removal, the procedure would be difficult without severely damaging the anchoring bone.

Clinical results. The IMZ implant has been mainly used in Germany, although clinical trial studies are being performed in the U.S.¹⁰⁵ The clinical results have been reported in several papers.^{102,106,107} However, in assessing the data it should be noted that the implant and technique of insertion have changed. One must successively evaluate the results of a type I IMZ implant used before 1982 and a type II flame-sprayed implant used thereafter. Kirsch and Ackermann¹⁰⁸ presented the outcome of 206 type I implants that had been inserted over four to seven years. Of those, 11 implants required removal, corresponding to a loosening percentage of 5.4. Of 621 type II implants with an insertion time of zero to four years, 12 had to be removed corresponding to a loosening percentage of 2. It is uncertain how many of the latter implants were in clinical function for less than one year.

Author comments. The data of Kirsch and Ackermann,¹⁰⁸ favorable as they may seem, are very difficult to compare with the success rates reported in other papers. The criteria for implant success were not presented in the short communication by the authors. An implant that remains in situ is not fulfilling the same criteria of implant success as one that is in function. Whether every inserted implant had been clinically evaluated by Kirsch and Ackermann¹⁰⁸ is not known.

The Core-Vent titanium alloy implant

Implant material. Titanium-6 aluminum-4 vanadium alloy.

Research background. No results from animal experiments with the Core-Vent implant have been found in the literature. A histological section from a canine implant published in the booklet from the Core-Vent Company demonstrates a patchy contact between the alloy and bone tissue. However, whether an effective overall osseointegration of these implants occurs or whether they become anchored

mainly in fibrous tissue has not been convincingly demonstrated.

Indications. The manufacturers of the Core-Vent implant recommended its use for both individual and multiple tooth replacements. The manufacturers also claimed that it is possible to attach the implants to remaining teeth for support.

Insertion technique and loading time. To avoid overheating of the bone a careful surgical technique is recommended. The recommended maximal rotational speed of the drilling procedure is 1,500 rpm. It is recommended by Niznick¹⁰⁹ that the Core-Vent implants should not be placed in function for at least three months in the lower and four months in the upper jaw.

Complications. As there are no clinical reports on the outcome of the Core-Vent implants, there are no reports of possible complications associated with this technique.

Clinical results. Clinical experience with the Core-Vent implant system has not been scientifically documented in the literature. In fact, the only report on the Core-Vent implant that has been found is an abstract of 100 consecutively inserted implants that had been followed for up to two years.¹¹⁰ These implants had been inserted in patients for a variety of purposes: splinting with natural teeth, splinting with other implants, and as free-standing posts. Nor were the parameters for implant success properly defined in the paper by Lubar and Katin.¹¹⁰ The true outcome of the Core-Vent implant in various situations is currently not possible to evaluate.

Author comments. The Core-Vent implant is a combination of a screw-porous implant that is manufactured from titanium alloy, and which has particular surface characteristics depending on the mode of manufacturing the implant. Nevertheless, it has been repeatedly claimed^{111,112} that equally good results will be achieved with the Core-Vent implant, as with the Brånemark screw implant of commercially pure titanium. However, this claim is pure anecdote and not supported by any research evidence. Once again, it should be emphasized that the evaluation of any oral implant system must be based on the results of that specific system without any reference to other implants of a presumed similarity. Core-Vent implant manufacturers have, to date, failed to produce even a short-term follow-up investigation that would justify its use. Furthermore, the Core-Vent system, as evidenced by its current overt attempt to copy the Brånemark screw implant, has undergone several consequential design changes and modifications during the past three years. This has been done while continuing the claim of achieving osseointegration. While conceptually unique, this implant system is without long-term investigation on consecutive patient treatment and must be judged by prescribed criteria before it can be considered anything other than experimental.

The transosteal, mandibular staple bone plate

Implant material. Various materials such as stainless steel, ceramic coating, and titanium alloy have been tried in the bone plates.¹¹³

Research background. Small and Kobernick¹¹⁴ inserted stainless steel threaded pins in the mandibles of edentulous dogs, and described tissue reactions over a period up to 12 months. Small¹¹⁵ presented some post mortem evidence of osseointegration of the surgical implant screws, particularly in one case that was examined six years after insertion.

Indications. Mandibular staple implants are indicated for insertion in the edentulous mandible with a minimal alveolar ridge height of 8 to 9 mm.¹¹⁵

Insertion technique and loading time. The staple bone plate is inserted by drilling through the mandible using a specific set of instruments. The procedure involves singly inserted transosteal implants as well as a complete mandibular staple bone plate. However, as the latter seems to give better clinical results, the staple plate is the only approach evaluated in this review.

Complications. Changes in gingival health and saucerization of bone do occur, and they seem to increase with time.¹¹⁶ Small¹¹⁷ reported bone loss of more than half the length of the transosteal pins in three out of ten test patients five years after implant insertion. Only one incidence involving jaw fracture was reported.

Clinical results. Small¹¹⁷ reported on 109 staple bone plates and found a survival of 93% after five years. Kent et al.¹¹⁸ presented a multicenter retrospective review of the outcome of mandibular staple bone plates. In their evaluation the authors followed the protocol suggested by the Harvard consensus meeting.¹ Among the 160 cases followed, 121 were for more than five years. At five years of observation, it was found that the average scores of gingival health were approximately 2, the average mobility was zero in about 90% of the cases, and pocket depth was, generally, between 2 and 3 mm. Implant failures occurred not only within the first year after implantation, but also three and four years afterwards. The cumulative five-year success rate was 90.9%.

Small¹¹⁹ reported on a series of 1,437 staple bone plates in which 93.5% functioned well at five to six years and 86.5% at 10 to 15 years. In a recently published review,¹¹⁷ of 1,516 cases, the cumulative success rate for five to six years was 94.6% and for 8 to 16 years, 90.9%. In total 395 of the 1,516 cases had had the staples five years or longer. Gingival hyperplasia and/or infection about one or both transosteal pins was reported to be a complication in 10% to 15% of the cases. The bone loss in 30 cases in the long-term follow-up (5 to 14 years, mean nine years) averaged only 0.78 mm.

Authors' comments. From an experimental viewpoint the transosteal bone staple

implant has hardly been investigated. However, the clinical papers by Small,^{115,117} Small and Misiak,¹²⁰ and Kent et al.¹¹⁸ appear to document conservative treatments on an impressive number of patients. The five, and 8 to 16 year results, as summarized in the published papers, are clearly within acceptable standards.

The Brånemark osseointegrated titanium implant

Implant material. This implant is screw-shaped and manufactured from commercially pure titanium. The screws have a unique machine-produced surface, with microirregularities (Figs. 5a and 5b).

Research background. The osseointegrated implant has been thoroughly investigated and its use reported in more than 100 published papers based on various animal models in which these implants were used. The use of commercially pure titanium as an implant material has been documented by Brånemark et al.,¹²¹ Albrektsson et al.,¹²² and Albrektsson.⁷⁶ In clinical experiences it has been demonstrated that the implants were anchored in bone without intervening fibrous tissue, while the experimental data point to an osseointegration even at the ultrastructural level. Collagen filaments approaching the titanium oxide surface and separated only by a 20 to 40 nm thick proteoglycan layer¹²⁰ have been observed. Studies on the importance of controlling the surgical technique^{8,124} have demonstrated that bone tissue is much more sensitive to heat than previously believed. Eriksson and Albrektsson⁹ found that subjecting newly inserted titanium implants to a temperature elevation of 47° C significantly disturbed their subsequent integration in the bone bed. Haraldson^{125,126} has measured bite force levels in patients with osseointegrated dental implants and found that these were similar to levels measured in dentate patients with the same extension of the dentition. Brånemark¹²⁷ and Adell et al.¹²⁸ and Lekholm et al.,¹²⁹ have examined soft tissue reactions to the mucosa-penetrating abutments and found a healthy gingival reaction with very few inflammatory cells. The bacteriological investigation revealed only about 3% of the microflora contained potentially dangerous bacteria such as spirochetes. To our knowledge, no other dental implant has been so thoroughly investigated from both an experimental and clinical point of view.

Indications. The majority of osseointegrated implants have been inserted in the totally edentulous mandible or maxilla (Fig. 6). However, about 5% of the total reported number of implants have been used in various partially edentulous situations including those requiring single replacements. The placement of osseointegrated dental implants posterior to the mental foramina must be regarded as experimental, since no five-year results have been published for such implants.

Insertion technique and loading time. The implants are inserted with a delicate surgical technique by using a graded series of drills followed by a tap rotating

maximally at 15 rpm. A recently published paper¹³⁰ has demonstrated that this controlled surgical technique results in a temperature elevation of only a few degrees centigrade. The mucosa is sutured over the newly inserted implants and only after a second stage surgery 3 to 6 months later, abutments are attached and the implants connected to a prosthesis.

Complications. No serious complications have been reported with the use of osseointegrated implants. Implants that have been lost due to failure of bone anchorage, have been replaced with newly re-inserted ones in the same healed socket site.^{121,132}

Clinical Results. Adell¹³² evaluated the outcome of 734 consecutively placed upper jaw fixtures and found a one year result of 88% and a 5 to 12 year positive outcome of 84%. The corresponding figures for a similar number of mandibular implants were 94% and 93%. A consecutive series of sinus-penetrating upper jaw implants showed a five to ten year functioning percentage of between 70 and 72.¹³³ Brånemark and Albrektsson¹³⁴ evaluated the outcome of all implants inserted during one year and then followed up for five years and found an implant success rate of 96.5% in the mandible. This improved success figure compared to the data published by Adell et al.,¹³¹ reflects a true improvement in the outcome, attributed to refined surgical and prosthodontic techniques. The computerized long-term follow-up of more than 350 consecutively inserted mandibular and a similar number of maxillary implants now demonstrate a 15-year implant success of 91% and 81%, i.e., the same figures previously reported by Adell et al.¹³¹ after a follow-up of ten years. These results indicate that any implant losses after the first one to two years of function seem to be unlikely, provided osseointegration has occurred¹³⁵ (Fig. 7). There are, presently, one to six year follow-ups of osseointegrated titanium implants from more than 50 different worldwide centers. The great majority of those have reported a positive outcome of mandibular implants in 90% to 100% of the cases.

Author's comments. To date (March 1986), more than 15,000 osseointegrated implants have been inserted, in various countries around the world. The carefully controlled material of Brånemark suggests a breakthrough in the treatment with dental implants. His strict criteria of implant success include the criterion that any implant mobility is included in the failure statistics, and any such implant is immediately removed. The 15-year success rates in the range of 91% (mandible) have led to this implant's provisional acceptance by the American Dental Association. Recently published figures from the Brånemark group, and in centers outside Sweden indicate that this implant's five-year survival rate in the mandible, may in fact be higher than 95%. This high level of success has been achieved because of a meticulously controlled implantation procedure. The advent of Brånemark's osseointegration heralds a new scientific era for dental implants.

However, untested limitations are bound to become available and the dentist should be warned against the risk of being misled into believing that other implant systems in current use can claim similar excellent clinical results unless these are properly documented in refereed journals.

Discussion

This paper is an attempt to evaluate currently used dental implant systems. We have presented and defined our success criteria as an outgrowth of scientific scrutiny and experience with diverse implant systems. To date, we have found only two dental implant systems that meet our criteria: the Brånemark osseointegrated screw and the Small transosteal staple. Both these systems have presented acceptable long-term (> 10 years) results that have been based on the outcome of each and every inserted implant. Indeed, we would wish and emphasize the desirability, in any clinical trial of implants, of the fate of *all* consecutive implants being faithfully recorded. Lamentably, this has seldom been done. The *Brånemark implantation procedure* has been commended for its versatility and ingenuity, but criticized for being complicated and expensive. However, at the present time it is not known which possible simplifications of the Brånemark approach are possible, without endangering the long-term results. Presently available statistics from several centers enable the dentist to recommend the Brånemark screw for application in the totally edentulous mandible, the maxilla, and in partially edentulous jaws as well. It must be remembered that the use of the Brånemark screw as an individual replacement is, so far, based on anecdotal reporting exclusively. The *Small transosteal staple* is clearly limited in application to the mandible. Nevertheless, the observations of a more than 90% success rate over 8 to 16 years of continuous follow-up, combined with a lack of serious complications makes the Small transosteal staple recommended for implant treatment in the edentulous mandible.

The evaluations and statements in this paper represent our conclusions to date (Spring 1986). Clearly, new ideas and new materials on dental implants will be presented in the future which will make some of our present views inappropriate. However, the time of anecdotal reports on individual successful cases of dental implants (which so far has dominated the literature) is over. We would like to encourage a future in which changes in opinion will be based entirely on the scrutiny of scientifically controlled data. Indeed, the clinical methods advocated by Brånemark and Small must be continuously challenged in order to define possible refinements of their approaches. It is essential that controlled studies of dental implants of various types continue, but that those be done as research projects and not be marketed in a manner to suggest their use as routine clinical procedures when longitudinal data are unavailable. From both legal and humanitarian points of view it is imperative that any patient receiving implant treatment that is not scientifically

backed up, be informed about the investigative character of any such treatment. If these recommendations are combined with a meticulous evaluation technique involving the outcome of each and every inserted implant based on the strict criteria presented in this article, we believe that dental implants may finally become accepted as routine and safe therapeutic methods. Our articulated criteria recognize the practical difficulties implicit in our demands for longitudinal scrutiny and preferably of consecutively treated patients. We are, therefore, reluctant to specify numbers of implants and patients at this stage. But we are strong in our conviction that an implant system that meets our five criteria, will also prove to "anchor" predictably in both short and long span sites in either jaw. Also, such a system can lead to replicable results all over the world and in any patient.

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Table 1 Criteria for implant success

| NIH-Proposal, Schnitman and Shulman, ¹⁸ 1979 | Proposal by Albrektsson, Zarb, Worthington, and Eriksson, 1986 |
|---|---|
| 1. Mobility of less than 1 mm in any direction. | 1. That an individual, unattached implant is immobile when tested clinically. |
| 2. Radiologically observed radiolucency graded but no success criterion defined. | 2. That a radiograph does not demonstrate any evidence of peri-implant radiolucency. |
| 3. Bone loss no greater than a third of the vertical height of the implant. | 3. That vertical bone loss be less than 0.2 mm annually following the implant's first year of service. |
| 4. Gingival inflammation amenable to treatment. Absence of symptoms and infection, absence of damage to adjacent teeth, absence of paresthesia and anesthesia or violation of the mandibular canal, maxillary sinus, or floor of the nasal passage. | 4. That individual implant performance be characterized by an absence of persistent and/or irreversible signs and symptoms such as pain, infections, neuropathies, paresthesia, or violation of the mandibular canal. |
| 5. To be considered successful, the dental implant should provide functional service for five years in 75% of the cases. | 5. That, in the context of the above, a successful rate of 85% at the end of a five-year observation period and 80% at the end of a ten-year period be a minimum criterion for success. |

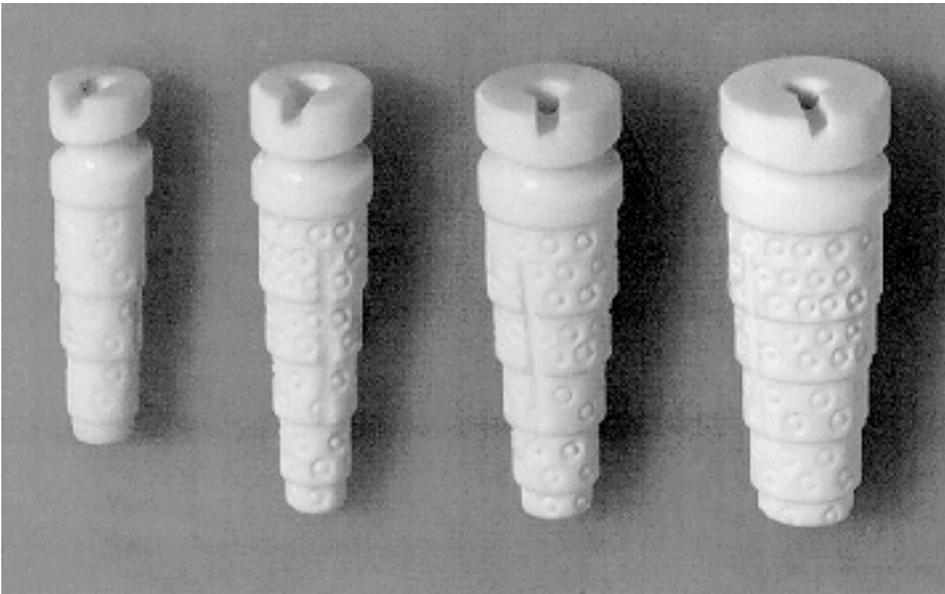


Fig. 1 *The Tübingen implant of aluminum oxide has specific micro-irregularities on the surface, claimed to allow bone ingrowth.*

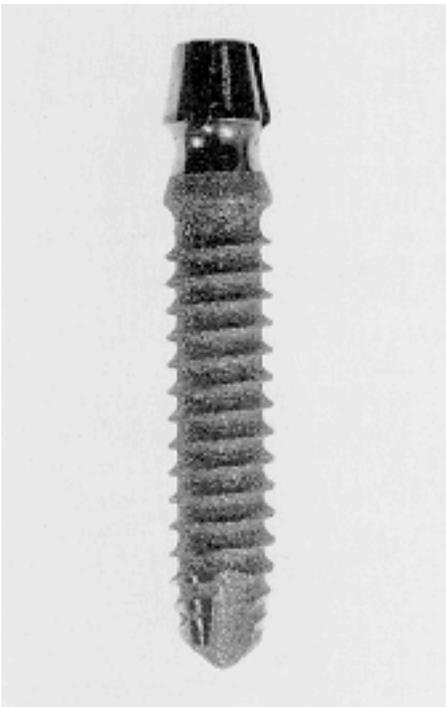


Fig. 2 *The TPS-screw of titanium has been used in the totally or partially edentulous lower jaw.*

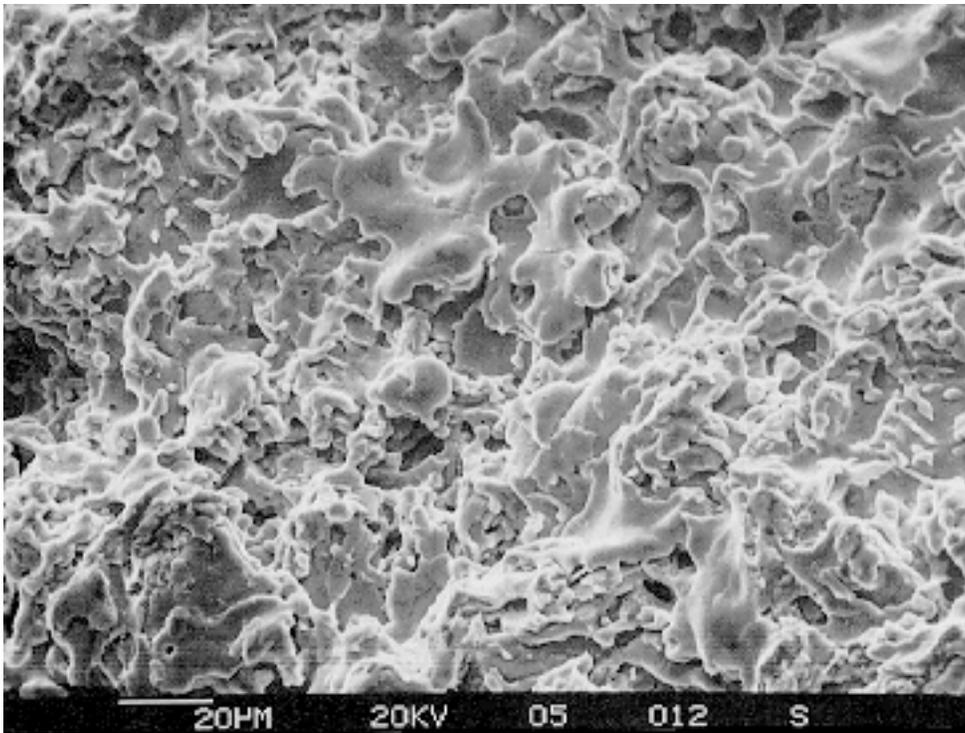


Fig. 3 *The TPS-screw has a flame-sprayed surface, identical to that of the ITI hollow-cylinder implant.*

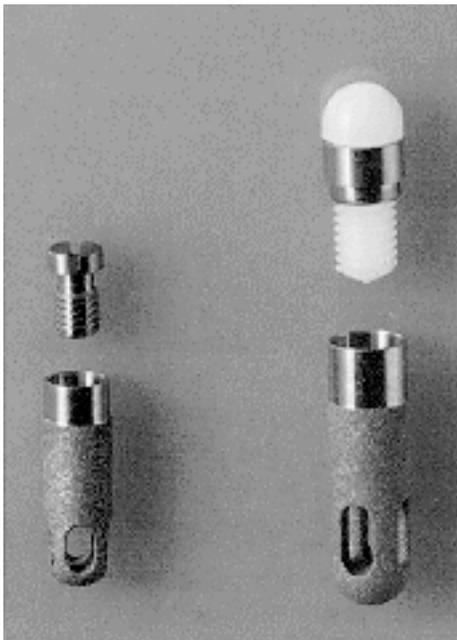


Fig. 4 *The IMZ implant of titanium. There exists another version of this implant with "side-wings."*

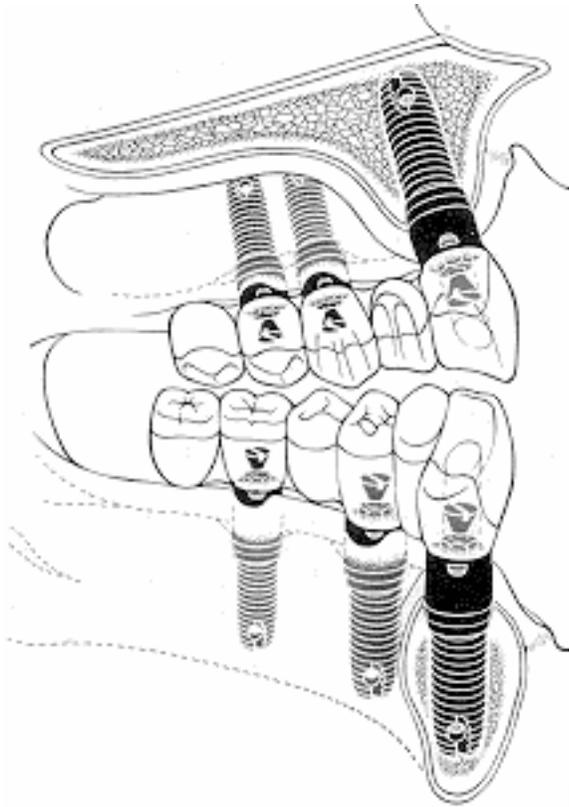


Fig. 5a *The Brånemark osseointegrated screw is inserted in the edentulous mandible or maxilla in a two-stage surgical procedure.*

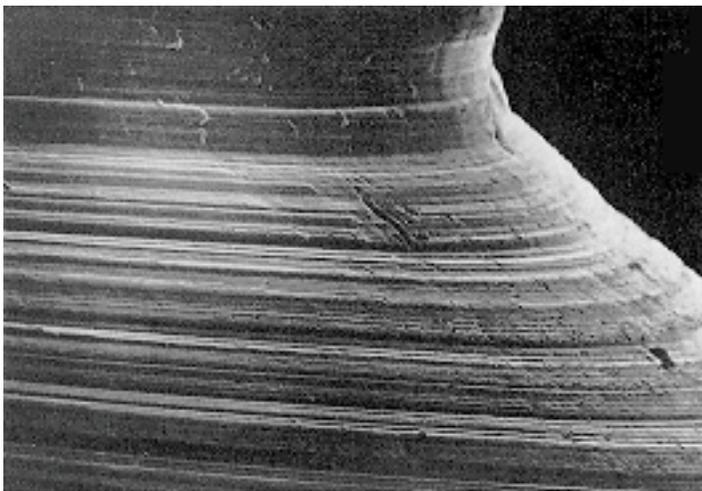


Fig. 5b *The typical surface structure of a Brånemark screw that is manufactured from titanium.*



Fig. 6 *The individual osseointegrated screws are connected to a maxillary dental prosthesis construction.*

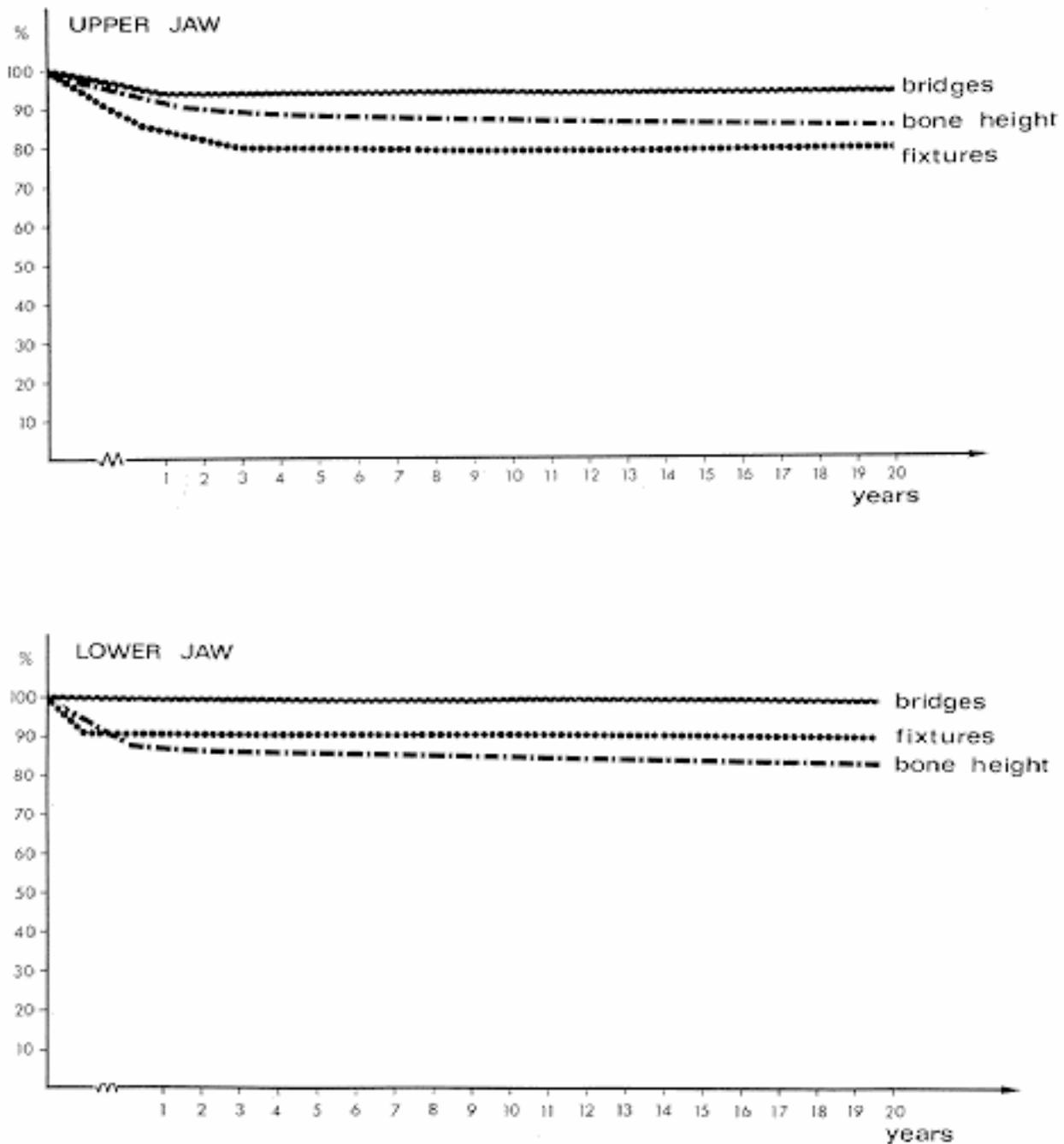


Fig.

7 A unique feature of the osseointegrated screw is the steady state achieved in the mandible after approximately one year and in the maxilla after approximately two years. Provided they are stable at the above cited times, the individual screws remain in the bone without any tendency to later implant loss. The average annual decrease of bone height in the same period has been less than 0.1 mm.