State of the art of oral implants

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In the past, oral implants were regarded as unacceptable by the academic community. This was a sound reaction to the uncontrolled devices of the pre-osseointegration era. There was a dearth of adequate clinical records that prevented any acceptance of the blades, needle-like screws, subperiosteal devices, or other heroic constructions used in those days. The lack of any acceptable historical record of oral implants makes it understandable that even osseointegrated implants (17, 18) were received initially with clear skepticism by the dental authorities. This negative attitude was further fostered by the fact that the early clinical results with osseointegrated implants during the first 5 years were not particularly positive.

In Sweden, osseointegrated implants became acceptable in 1977 (18) and international acceptance followed the Toronto conference held in 1982 (77). Behind this acceptance were positive long-term clinical results, mainly from treatment of totally edentulous patients. Early Swedish research on oral implants was led by Brånemark and his coworkers. However, it is interesting to observe that similar, independent research was carried out elsewhere at about the same time. Schroeder of Switzerland published his first paper on bone-anchored oral implants in 1976 (61) and Schulte of Germany published clinical results for his aluminum oxide implants in the late 1970s (62).

Today, osseointegration is a term regarded as synonymous with clinical success. This is an unfortunate misconception. New implant surfaces and designs are being produced and marketed at a rapid rate. What was once a careful protocol dominated by science and clinical records is today replaced by a ‘car model’ attitude (8) that is not entirely sound. What is overlooked is the risk of secondary failures, which with some designs have been a common, if unwanted, result of challenging the limits of biology. We have learned a lot about osseointegration in the last 25 years, but at the same time we have forgotten the importance of a careful approach to any clinical treatment, an unfortunate attitude that has resulted in the marketing of unsuitable oral implants and unnecessary failures. We must learn to avoid such pitfalls in the future.

Osseointegrated oral implants in clinical practice of the past

Early studies of osseointegration were characterized by a focus on science and clinical scrutiny. Five-year clinical records were regarded as important and were recommended before the marketing of novel designs and surfaces. Clinical records mainly described the treatment of the totally edentulous patient, whereas results from single implants were scarce or non-existent. We described osseointegration in a paper that demonstrated the importance of controlling for hardware, such as biocompatibility, design, and surface conditions of the implant, without omitting other factors that today are seemingly forgotten, such as patient conditions and the importance of the surgical and prosthodontic routines (3). However, at the time we were only aware of one material that was capable of proper osseointegration – commercially pure titanium. The threaded design, as well as the turned surface, was regarded as essential for osseointegration. Today, we know that other metals, such as tantalum, niobium, or titanium alloy, may show osseointegration and we also know of ceramic materials with adequate implant stability (35, 43, 44). Having said this, the great majority of oral implants are still, in 2008, made from commercially pure titanium. The threaded design has likewise survived the scrutiny of time, but cylindrical implants without threads, after demonstrating initial osseointegration, were shown to suffer from unacceptably high secondary loss of bony anchorage and have since disappeared. Turned surfaces are today uncommon and the rough plasma-sprayed surfaces used at one time have been more or less abandoned for the potential benefit of modern, moderately rough surfaces such as the Astra Tioblast (AstraTech Dental, Mölndal, Sweden).
Sweden) (57) (Fig. 1), the SLA (sand-blasted, large-grit, acid-etched; Straumann AG, Waldenburg, Switzerland) (14), and the TiUnite (Nobel Biocare, Göteborg, Sweden) (31).

Initial recommendations for clinical handling included the need to learn the technique of osseointegration by concentrating on surgery of the mandibles only. The team concept was stressed, initial teams consisted of at least five persons with a surgeon, a prosthodontist, and a radiologist and dental nurses included. These many precautions were perhaps sensible to avoid misuse of the new technique, which might have prevented the breakthrough of osseointegrated clinical treatment. Our aim was really to prove that osseointegration also worked outside the University of Göteborg, not to challenge the concept itself.

Admittedly, our early concept had shortcomings, not only with respect to osseointegration, which was not limited precisely to the type of implants for which we had proven it, but also because some of the instructions were inappropriate. For example, we recommended drilling followed by tapping in all types of bone. Clinical analyses soon proved that taps were not at all recommendable in poor maxillary bone, where Jaffin & Berman (41) saw poor clinical results with our recommended approach. Others applied a different surgical routine in this type of bone without taps and avoiding full-size drills (11, 30), and obtained significantly better clinical results. Furthermore, we were adamant in recommending a two-stage surgical technique with loading first occurring 3–6 months after implant placement, whereas others demonstrated the possibility of one-stage techniques and even rapid loading [for review see ref. (7)] with good clinical results. We also learned about the possibility of placing implants in posterior locations in the jaws, which was not in our original concept.

**Definitions of osseointegration**

Osseointegration is a term originally coined by Brånemark (18). It was first defined as a histological concept with direct bone-to-implant contact at the resolution level of the light microscope (3, 16). Obviously, this definition is not clinically applicable, hence a new definition based on implant stability was suggested by Zarb & Albrektsson (78), ‘a process whereby clinically asymptomatic rigid fixation of alloplastic materials is achieved and maintained in bone during functional loading’. The problem of defining ‘rigid fixation’ was solved at the time by the suggestion that the implant should be tested with a pair of surgical forceps, a scientifically disputable approach. However, with the advent of Resonance Frequency Analysis (49) there is now an objective method for stability testing. (Fig. 2).
Experimental and clinical viewpoints on oral implant surfaces

Our old implants all had turned (‘machined’) surfaces. This was not a choice based on scientific scrutiny after comparison of different types of surfaces, but was an empirical choice; our original Brånemark implants were manufactured like that in the workshop of the department of anatomy, where all our implants were made before the industrialization of the project. It was not until the beginning of the 1990s that we had the ability to perform quantifiable characterization of oral implant topography through the work of Ann Wennerberg (67, 69, 71–73, 76). Wennerberg and co-workers (68) had successfully developed a noncontact, optical method for three-dimensional description of the actual bone-contacting surfaces of the implants. Previously applied techniques had either been qualitative, such as scanning electron microscopy, or had been capable only of evaluating the flat surfaces of the implants, e.g., contact profilometers.

Wennerberg and colleagues (70–72, 74) applied the new methodology in a series of experimental investigations followed up for between 4 weeks and 1 year; clear evidence was presented that the bone response to moderately roughened surfaces (Sa around 1.5 \( \mu m \)) (Fig. 3) was significantly stronger than the bone responses to smoother or rougher surfaces. These were interesting findings at a time when commercially available implants were either smoother (turned surfaces) or rougher (plasma-sprayed surfaces) than the surface with the strongest bone response; the Astra Tioblast was the only exception at this time, having a moderately roughened surface. Today, the great majority of commercially available oral implants are indeed moderately roughened. Clinical comparative studies have verified a tendency towards better clinical results with moderately roughened compared to minimally rough surfaces; however, this difference is seldom significant unless grafted, or otherwise compromised, bone is investigated (for review see ref. (8)). Experimental investigations of the importance of surface isotropy/ anisotropy (Fig. 4) did not lead to any obvious preference for surfaces with ordered irregularities (such as the turned surface) over a more irregular, alpine-like structure (such as the blasted surface) (34).

Surface roughness can also be evaluated at the nanometer level of resolution (Fig. 5). However, we

Fig. 3. An image of an experimental surface with optimal roughness, as found in a series of studies to be an Sa of around 1.5 \( \mu m \). Sa, the arithmetic mean of the absolute values of the surface departures from a mean plane within the sampling area.

Fig. 4. (A) Measurements from a turned, anisotropic surface; flank images of the upper threads of an Osseotite (3i) implant. (B) Measurements from an acid-etched, isotropic surface; flank images of the apical threads of an Osseotite (3i) implant. The isotropic surface demonstrates no orientation of surface irregularities that are evenly distributed.
lack in vivo or clinical data verifying that the nano-topography can affect the tissue response. The problem is that changes in nanotopography usually follow alterations in roughness at the micrometer level. Furthermore, modifying the surface chemistry of the implant can also have a nanotopographical influence. Therefore, it often proves difficult to explain clearly a certain tissue response to a surface modification. At present, numerous studies are aimed at investigating the potentials of nanotopography and modified surface chemistry (8), but so far there are no findings to support a change to the current state of the art of oral implants.

Our previously published review papers on the state of the art of oral implants

In the past, our team has participated in several state of the art papers. The first was printed 20 years ago (5), and concluded that there was only one long-term documented oral implant system, the Brånemark turned screw (Nobel Biocare, Göteborg, Sweden), that had sufficient clinical documentation. This paper also presented the first criteria for success for modern oral implants (5). Five years later, Albrektsson & Sennerby (6) published another review warning clinicians about the use of certain osseointegrated designs that were later withdrawn from the market. Various osseointegrated implant systems, apart from the Brånemark screw, had now been documented with good results for follow-up times of about 5 years. Roos et al. (59) presented an update on the clinical documentation of oral implants. The four-field table concept introduced by Albrektsson & Zarb (4) was recommended, i.e., implant outcome was separated into success, survival, unaccounted for, and failure. A common error in the oral implant literature was pointed out; that of identifying failed implants and then assuming all other implant systems were successful.

Albrektsson & Wennerberg (8) concentrated their evaluation on the five most sold oral implant surfaces and reported on 18-month positive clinical results with the TiUnite implant, 3-year positive results of SLA, up to 5-year positive results of 3i implants (Biomet 3i, Palm Beach Gardens, FL), and 7- to 10-year positive outcome of Astra Tioblast implants.

Clinical documentation of modern oral implants of today

Again, concentrating on the most sold oral implant systems, the following findings have been published. The Nobel TiUnite implants have been reported as having good clinical success rates for a full 4 years (31), SLA implants have been documented with good clinical results for 5 years (14), the 3i implants have been documented with good results for more than 5 years (28), and the documentation for Astra Tioblast shows good results for 5–10 years (33, 54, 57).

Recently introduced oral implants from major suppliers

In the last 1 or 2 years even more implant systems have been launched by the major oral implant companies. Nobel Biocare (Göteborg, Sweden) has presented Nobel Groovy, Speedy, and Shorty, none of which has been supported by any clinical documentation known to the present authors. An experimental study demonstrated enhanced bone formation in the grooves of the Nobel Groovy implant and a greater resistance to removal torque compared with control implants without grooves. However, the potential clinical benefits of the grooves are yet to be documented (39).

Straumann AG (Waldenburg, Switzerland) has launched a new SL-Active implant with experimental documentation that it has stronger bone attachment than can be explained solely by surface roughness at the micrometer level (19). This implant system has been treated in isotonic NaCl and is claimed to be chemically modified. To the knowledge of the present authors, none of these implants has been documented on long-term follow-up.
authors, there is currently no clinical documentation pertaining to this novel implant.

Biomet 3i (Palm Beach Gardens, FL) launched the new Prevail system in 2005. There are several ongoing, well-designed studies of the clinical performance of this implant, but no results have been published. Another 3i implant, the Nanotite (Biomet 3i, Palm Beach Gardens, FL), was launched clinically in 2007. This implant, which is supplied with attached nanohydroxyapatite compounds (Fig. 6), is of particular theoretical interest because experimental work has indicated a strong bone response that cannot be explained by surface micro-roughness alone. In this context, the Nanotite implant resembles the SL-Active implant and the Astra Osseospeed implant (AstraTech Dental, Mölndal, Sweden). However, the Nanotite implant lacks clinical documentation.

Astra Osseospeed implant was presented in an experimental study of up to 12 months duration (26). Further experimental studies have indicated that this fluoridated implant has a positive bone response that cannot be explained solely based on its micrometer level roughness (27). However, whether the surface is attractive to bone based on the chemical modification or its nanotopography remains unknown. From a clinical point of view, interesting 2-year results have been published from a prospective, randomized, controlled clinical study of hip arthroplasties in which the test hips had this surface modification (20, 21). For oral implants, there are four published 6- to 12-month clinical studies that indicate good results despite loading after 4–6 weeks and, in some cases, placement in bone of poor quality (12, 53, 60, 65).

Examples of oral implants from small suppliers

Good implant results and positive innovations do not only originate from the major suppliers. We have selected some minor suppliers too, because we realize that progress need not only be coupled to the major international companies.

The Z system (Z Systems AG, Konstanz, Germany) is an implant of particular interest because it is made from zirconia (48), a ceramic material now being investigated by many commercial implant companies. However, the survival rate of 44 zirconia implants was only 93% at the 6-month follow-up, despite only orthopantograms being evaluated and the criteria for radiographic success were very generous. As this first clinical report of zirconia implants gives rise to some concerns, and the number of study implants was small, this clinical investigation merely represents a pioneering effort.

Another implant system of potential interest is produced by the Ospol (Malmö, Sweden). This company introduced a novel, web-based logistic business system that is different from those used by other companies. The Ospol implant is a minimally rough, calcium-reinforced, oxidized screw (Fig. 7). Experimental in vivo results with the Ospol implant indicate improved osseointegration compared to other, rougher oxidized systems (66); however, no clinical studies have been published.

A third example is the Neoss implant (Neoss, Harrogate, UK), which has a ‘positive tolerance’ meaning that the neck part is slightly wider than the apical part, which (according to the manufacturer) results in improved primary stability. The system that was introduced in 2003 consists of a threaded implant with a bimodal surface produced by blasting with two sizes of titanium particles (Fig. 8). At present, no experimental papers or clinical follow-up studies have been published.

What can we learn from oral implant systems that have not worked as expected?

Implants from the pre-osseointegration era, such as blades, various types of threaded needle-like constructions, and subperiosteal devices, present difficulties when trying to draw a reliable conclusion of what actually caused the clinical problems experienced...
with such constructions. The reason for these difficulties is linked to the fact that osseointegration was made possible not only by changes in the hardware, but also because of a number of changes in the clinical handling of the implants (3). It is, of course, difficult to single out, for example, the blade design, inappropriate as it was from a loading point of view, without simultaneously questioning the mode of its insertion, where the imprecise technique of making a slit represented another likely reason for the clinical failures observed with these constructions (46, 64).

The hollow cylinder Core-Vent design [Paragon (Core-Vent) Implant Co.; now Zimmer Dental, Carlsbad, CA] was the first implant system to show some evidence of at least initial osseointegration, albeit followed by unacceptable failure rates because of secondary loss of bony attachment (47). It must be remembered that the Core-Vent was the most sold implant in North America as late as 1990 and was also commonly used internationally. Malmquist & Senneryd (47) demonstrated in 1990 unacceptable clinical results, in the range of 9% success for up to 4 years when evaluated against the strict criteria for success presented by Albrektsson et al. (5). We believe that the most likely reason for the clinical failures with Core-Vent implants was the hollow cylinder design itself. Hollow cylinders have been demonstrated not to maintain osseointegration, presumably because of micro-movements around these devices. Having said this, the Core-Vent cylinder was equipped with a couple of thread-like structures, although these were probably too few to guarantee adequate stability. Core-Vent implants rapidly disappeared from the market around 1991.

Another implant design that demonstrated osseointegration (62), but despite this showed unacceptable clinical outcomes, was the Frialit-1 design (DENTSPLY Friadent, Mannheim, Germany) (22, 50). These implants were made from polycrystalline aluminum oxide and numerous implant fractures occurred (6), a fate that seems to have struck also the single crystal aluminum oxide Kyocera implant (Kyocera, Osaka, Japan) that rapidly disappeared from the market more than 10 years ago.

The next implant system that displayed unusually high secondary failure rates was the IMZ-system (Interpore International Inc., Irvine, CA), a solid cylinder design, that was commonly used in Europe and the USA. Early on, it was demonstrated that these implants, although initially osseointegrated, never
achieved steady state with respect to bone resorption (29). In fact, there was a first-year bone loss in the order of 1.5–2 mm and, thereafter, an average of 0.5 mm annually up to 5 years after implant placement (23). After 5 years, the average bone resorption increased (24), leading to increasing numbers of clinical failures between 5 and 10 years after implant placement. Worst results were, not surprisingly, reported from the maxilla, where Haas et al. (38) found only 13% success for a follow-up period of more than 10 years. Albrektsson (1), in a review paper, came to the conclusion that this implant ought to be withdrawn from clinical use, which is in fact what happened by the late 1990s. The IMZ-implant was a solid cylinder with a titanium plasma-sprayed surface. To the knowledge of the present authors, the solid cylinder is an inappropriate design for osseointegration, presumably as a result of undue micro-movements; however, the rough plasma-sprayed surface may have been another factor for the IMZ-failure. Such surfaces have disappeared from the market, in response to reports of not only a lack of steady-state bone levels but also of an increased incidence of peri-implantitis (10, 13).

The Calcitek (Calcitek; now Zimmer Dental, Carlsbad, CA) and other first-generation hydroxyapatite-coated implants were launched by the mid- to late 1980s despite a lack of clinical documentation. Experimental studies have verified the occurrence of a rapid negative bone response to calcium phosphates such as hydroxyapatite (42). Initially, good clinical results were reported over times less than 5 years with hydroxyapatite-coated implants. However, a number of less reliable clinical studies were also published (for review see ref. (59)). Furthermore, it became evident that long-term results with the hydroxyapatite-coated Calcitek implants were not at all positive (15, 45, 75). A review in 1998 stated that the first-generation of hydroxyapatite-coated implants had no proper 5-year clinical data available (2). Instead, these implants led to unacceptable bone resorption and, with time, high failure rates. The reason for long-term clinical problems with hydroxyapatite-coated implants was related to the cylindrical design of the implant, to loosening of the hydroxyapatite coats, or to the very rough surfaces of plasma-sprayed implants (59). However, it should be noted that a newer generation of hydroxyapatite-coated implants have proved quite successful over 5 years, despite their cylindrical design (43).

The Oraltronics bicortical screw implant (Oraltronics, Bremen, Germany) was a needle-like design with very pointed and narrow threads (Fig. 9) that was clinically introduced in the 1970s. It was never used in great numbers and in Scandinavia, two court litigations led to the disappearance of this implant in the late 1990s. By then, it had been demonstrated to cause severe bone deformation in 150 patients from Denmark and in a similar number of patients from Norway (40). The reasons for the clinical problems with the Oraltronics bicortical screw were, in all probability, a combination of the unsuitable design of the threads, the needle-like design, and the fact that this implant was in one piece, which produced potential alignment problems.

Of some concern was the 5-year documentation of Frialit-2 implants (DENTSPLY Friadent, Mannheim, Germany) that reported not only very high survival rates, but also rates of distinct bone resorption around more than one-third of the implants (58). Others (56) reported about a 90% 5-year cumulative survival rate of tapered, Frialit-2 implants with slightly better results in the maxilla compared to the mandible. In this study only 25 implants were actually followed up for a full of 5 years (56). Wheeler (76)
reported better cumulative survival rates of 802 Frialit-2 implants but only 14 were followed up for a full 5 years and the great majority of implants was actually followed for only 1 year. In cases of direct loading, Wheeler observed only about a 91% cumulative survival rate. Gomez-Roman et al. (32) reported on only a selected number of their originally placed implants and only a small proportion of the implants were reported for a full 5 years. One cannot avoid being concerned about Frialit-2 implants based on the reported clinical outcomes, even if it is uncertain as to whether clinical problems are inevitable or limited to particular clinical indications.

A novel implant design launched by Nobel Biocare (Göteborg, Sweden), the Nobel Direct, seems to cause unacceptable bone loss as well. This implant system is a one-piece design with a rough surface in the soft tissues. It is recommended for placement after a punch procedure through the soft tissues (i.e., surgical flaps are not deemed necessary), followed by grinding down of superior portions of the implant in situ (with potential heat and vibration trauma to the tissues), and then direct loading immediately after implant placement. The combined actions of the implant design and the recommended actions for implant placement are the probable reasons for the problems reported, and the problems are not insignificant. The implant has been recommended to be used by private practitioners who, allegedly, can benefit from the simplicity of this device and the supposed lack of bone resorption around it. Reality differs significantly from the commercial hype. So far, we have analyzed 550 Nobel Direct implants, consecutively placed at 18 different centers in North America, Southern Europe, and Scandinavia. The dentists involved in this treatment were all experienced users of other Nobel Biocare designs, with which they have had substantial clinical success. However, those who followed the directions from the company with respect to the clinical handling of these implants have seen unacceptable problems in the form of bone resorption – about 25% of all implants placed have demonstrated > 3 mm of bone loss at only 1 year of follow-up. An additional 9.9% of all the implants placed have failed (9, 52, 63) (Figs 10A,B and 11A,B). There is no clinically available documentation concerning the maintained bone heights in any of the several publications about this implant (25, 36, 37, 55). One of these publications does report a 97.9% cumulative survival rate at 1 year, but its radiographical analyses concentrate on bone levels, not on bone loss, which can differ considerably (37). The success rate evaluated in a four-field table was only 69% with 27.7% of implants in the survival category, as a result of severe bone loss or lack of proper radiograms (37). However, better results are reported for Nobel Direct if direct loading is avoided (9, 63). We are of the strong opinion that Nobel Direct is an unsuitable implant system if used as prescribed by the company. Our concern is shared by three independent Swedish University experts nominated by the Swedish correspondent of the US Food and Drug Administration (FDA); this has led to a continuing FDA investigation (FDA 2007) of this implant that has so far led to clear restrictions on its use.

Nobel Perfect (Nobel Biocare, Göteborg, Sweden) is an implant system that is similar in design to the Nobel Direct, the only major difference being the scalloped construction in the part of the implant that penetrates the soft tissues. This implant has been claimed to be particularly suitable for use in the
aesthetic zone because, allegedly, the soft tissue will adhere to the scalloped portion of the implant. There is no documentation to support the claim, but one paper described 17 consecutive implants that demonstrated bone loss and lack of aesthetic outcome (51). It seems probable that the Nobel Perfect implant suffers from similar problems of bone resorption as have been reported for the Nobel Direct implant, but we do not yet have a sufficient number of consecutively placed Nobel Perfect implants to verify this hypothesis.

What is happening in the future?

Most osseointegrated oral implants function well clinically. In fact, remarkable successes have been reported with various oral implant systems (14, 31, 57). However, some designs and/or approaches challenge biology too much and clinical problems have followed. We believe that the current state of oral implantology is such that, despite the high success rates obtained with most major oral implant systems, the uncritical challenge of biological limits may lead to clinical failures. Therefore, we recommend that implant companies undertake the initiative of having at least 1 year of clinical documentation to show the maintenance of bone height before the widespread marketing of new implant designs or surfaces. Naturally, minor changes in existing product lines would not necessarily motivate such a documentation strategy. It may be that implant companies will become motivated to form Scientific Advisory Boards if the governmental agencies in Europe and the USA decide to strengthen their demands on the marketing of oral implants. These devices are, after all, placed in humans and are not necessarily without harm to patients in case of unsuitable designs and/or placement strategies.

References


