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## Disclaimer

## Typical contents in ID

- **Evidence Reports** summarize the latest «Hot Topics» from relevant journals putting similar studies «side-by-side». This unique presentation of studies allows you to compare and contrast the patient populations, the treatment interventions, and the quality of the scientific methods. The «evidence-based bottom line» is presented with an overall summary statement at the beginning. Clinical notes by implantologists with special expertise on the topic complete the Evidence Report by providing their expert clinical opinion. **ID** is an implantology publication that provides attention to detail in balancing science with clinical opinion in such a clear, concise, and visually-friendly presentation.

- **Literature Analyses** provide you with an in-depth look at the research on a given topic. A «Literature Analysis» is a critical review of the literature on the epidemiology, treatment methods, and prognosis for implant-related topics or conditions. Literature Analyses are broader than «Evidence Reports» and are written to serve as a reference tool for implantologists to help them make decisions regarding how to manage patients, to assist them in evaluating needs for future research, and to use the material for future presentations.

- **Critical Appraisals** summarize the findings from important papers used for clinical decision making or marketing by implant companies. In addition to the summary, the study's methods and clinical conclusions are critically reviewed in an effort to challenge the implantology community into not accepting everything that is published, while fostering alternative explanations and ideas.

- **Case reports** give implantologists the opportunity to publish on unique patients using innovative or alternative methods for treating challenging patient conditions.

- **Research in Context** is a helpful «what is» section to consult if you've ever read a study and asked «what is a p-value» or any other research method question. It assists clinicians with the critical evaluation of the literature by briefly describing relevant aspects of research methods and statistical analysis that may bias results and lead to erroneous conclusions.

## Scientific classification & evaluation

**Comparison of basal and crestal implants and their modus of application.**

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### 1. Introduction

Crestal and basal implants are endosseous aids to create osseointegrated points of retention for fixed or removable dentures. These two types of implants are not only differentiated by the way they are inserted and by the way forces are transmitted. Rather, the more substantial differences lie in the planning and execution of prosthodontic care and, most of all, in the post-insertion treatment regime. For this reason, the literature on basal implants has introduced the terms "orthopaedic technique" and "orthopaedic implant" to mark a clear distinction between them and the well-known term "dental implant".

According to the well-known implantological rules for dental restorations, crestal implants (i.e. implants inserted from the top of the alveolar crest into the bone: cylinders, blade implants) are indicated in situations with an adequate vertical bone supply is given. Crestal implants function well in patients who provide enough bone when treatment starts, but results are not predictable as soon as augmentations become part of the treatment plan. Augmentation procedures are possible today, but they increase the risks and costs of dental implant treatment as well as the number of necessary operations. Patients providing severely atrophied jaw bones (i.e. those patients who need the implantologists attention most) paradoxically receive little or no treatment, as long as crestal implants are considered the device of first choice.

Basal implants, i.e. BOI®, Diskos®, by contrast, were developed additionally and primarily for immediate use as well as for use in the atrophied jawbone. They can also be applied where very little vertical bone is present, while the supply of horizontal bone is still sufficient (even if these quantities are not contiguous, e.g. in the sinus region): there are no "difficult" or "impossible" cases for implantologists familiar with basal implants, and their treatment leads in all cases straight forward to the desired treatment result. The typical objective of treatments including basal implants is a fixed restoration with 12 teeth per jaw. Optionally, removable dentures may be inserted as well, as long as enough basal implants are splinted by rigid connectors (bars). Single crowns are primarily realized on internal or single-unit BOI implants. They may be loaded immediately only in favourable situations. As the use of BOI implants can help avoid risky and expensive bone augmentation procedures, these implants are the therapy of first choice in moderately or severely atrophied jaws as well as in those cases, where immediate loading or cheaper treatments are desired by the patients.

Whereas crestal (or: axial) implants are inserted vertically from the crest of the alveolar ridge, basal implants are inserted laterally. These lat-

ter implants are synonymously called basal implants, or lateral implants or disk implants . With basal implants, the regions of load transmission and the place of bacterial attack do not coincide: no masticatory forces need to be transmitted to the bone via vertical aspects of the implant; the positive retention in the bone is created in the cortical bone region.

**2. Differences in perioperative status**

An implant bed that is congruent with the implant shape is created for crestal (axial) implants, using burs. Most common crestal implants in use today feature a self-tapping thread, many types feature compression of bone. Once the crestal implant is inserted, the insertion site is obturated by the implant itself. Any infection carried into the implanted bone intraoperatively or any infection that had already been present preoperatively (such as residual ostitis) can endanger the therapeutic result considerably by leading to an early loss ("idiopathic loss") of implants. The mechanism resulting in early loss can be described as follows: To combat any such infection, the flow of blood from and to the bone must be increased. However, this is inherently inconsistent with the existence of bone tissue . The resulting increased oxygen pressure in the bone results in local bone loss, which does not necessarily involve bacteria or purulence. The implant loses its stability and will be lost subsequently. The bone loss associated with this scenario is usually low, since it barely affects any areas beyond the implant bed itself, if the implant is also rapidly exfoliated. If, however, exfoliation does not occur – for example because the implants are kept in place within the bone by the prosthodontic superstructure – an infection may develop in the spongeous region that spreads and causes a significant dissolution of the spongeous and cortical bone substance. In this case, the cortical bone will be replaced by rapidly formed plexiform bone, while the bone marrow spaces remain filled with granulation tissue. The histological findings are typical for an osteomyelitis (Figure 1).

The situation with basal implants is completely different. For basal implants, a T-shaped slot is cut into the bone, which is practically left unobturated by the implant immediately after insertion. Neither intraoperative nor preoperative infection will normally threaten the treatment result, since suppuration from the osteotomy slot is usually uninhibited at all times. In animal studies, no failure of BOI® implants (infection of the implant site, primary implant loss, absence of osseointegration) could be provoked by contamination or infection present preoperatively or introduced intraoperatively. The degradation products of infection are resorbed via the periosteal tissues or removed to the oral cavity through the mucosal access. The necessary pressure is built from inside the bone. This pressure must never be blocked, and the direction of flow must never be inverted by the dentist. Early idiopathic loss thus hardly ever occurs with basal implants.

## 3. Infection around integrated implants

### 3.1 Crestal (axial) implants

Crestal implants are supposed to osseointegrate along the vertical axis of the implant.

The term "osseointegration" describes a state in which there is no more than an ultra-thin layer of connective tissue between the implant surface and the mineralized bone matrix and where this layer contains neither blood vessels or directional fibres or other components characteristic of the periodontal system. This is why osseointegrated crestal implants do not contribute – as opposed to natural teeth or freshly inserted basal implants – to draining the bony implant site.

If peri-implantitis develops around crestal implants, the adducing vessels of the peri-implant mucosa are widened in a pathological way. In addition, the blood is removed by the same route it came, requiring space. The resulting increasing the oxygen pressure in itself causes bone loss. Whether or not the counteracting tendency toward retention of the mineralization or toward remineralization is preserved will depend on functional stimuli. This is why crestal implants (if initially osseointegrated) are often lastingly and stably osseointegrated at their apical end even though their upper enossal portion may be subject to funnel- or crater-shaped areas of bone collapse (Fig. 2 a). Once the crestal bone is lost, macrotrajectorial load transmission is shifted to the basal aspect of the bone, or at least the middle implant region, in almost all areas of the jaw. As the total bone mass is reduced due to the bone collapse, yet the task of transmitting loads is not made easier as masticatory function persists, the remaining basal bone areas have to be more strongly mineralized. This will afford them better protection from further resorption. The surface of crestal implants is usually enlarged in their enossal part today, as they do not have the retentive baseplates that basal implants have. The state of the art is that typical surface enlargements are often created by the manufacturer by adding a TPS layer, by sandblasting, by etching or by a combination of these latter procedures. The surface enlargements are to improve the adhesive properties of the blood and the bone cells, presumably creating a "cell-friendly" environment. Unfortunately, bacteria are also cells, even cells of approximately the same size – and a bone-friendly surface is always at the same time a bacteria-friendly surface. This is why peri-implantitis around crestal implants is difficult to control: As soon as surface-enlarged portions of the implant surface are exposed to the oral cavity, these bacteria may travel more deeply and below the bone level due to the "candle wick" phenomenon, again increasing blood circulation and promoting bone loss. As we have seen, only more highly mineralized bone have better protection against resorption as a result of the predominant trajectorial load. This is why some crestal implants have a hybrid design, where the 1–2 mm of the enossal aspect of the implants located most closely to the mucosa are not surface-enlarged. However, these implants tend to require more vertical bone to achieve sufficient retention. More recently, microsphere-coated surfaces have been introduced in dental implantology, something that has been a familiar concept in endo-

prosthetics for quite some time now: Sintered titanium microspheres 100–150 µm in diameter are completely smooth, offering no microretention for bacteria, even though the surface looks very rough to the naked eye. Fillies et al. (12) have shown that the type and roughness of implant surfaces determines the behaviour of the osteoblasts. Osteogenic cells will settle or be created on smooth, microstructured surfaces more quickly than on SLA surfaces. The latter show more fibroblastic than osteoblastic cells, something that ultimately has considerable influence on implant integration

### 3.2 Basal implants

With basal implants, load transmission is supposed to occur primarily (and initially exclusively) within the basal aspect of the implant, far away from the site of bacterial infection. All aspects of the implant are smoothly polished. Several basal implant systems with different platforms are available today – internal systems that can be secured against rotation and that have an internal screw connection (Figure 3) and external systems that do not have a rotation-protected external thread (Figure 4)[1] . By design, the mucosal penetration areas are considerably smaller with external systems than with internal systems. Whether or not this results in different degrees of resistance to infection (countable as losses / time unit) has not been examined. "Examining" the status of the peri-implant bone with a probe is considered malpractice with basal implants, as no osseointegration is required on the vertical aspect of the implant anyway for permanent function of the implant. The path of insertion of the vertical aspect of the implants can no longer be determined postoperatively, and the positions of the horizontal disk suspensions are unknown. For those two reasons probing may yield false "results". On the other hand, probing may carry pathogens into the depth of the interfacial region that is filled with non-irritant connective tissue at a time when there is little chance of suppuration left. Callus formation and the maturation maturing of the callus in the slot areas are endangered through probing. Facultative pathogens can be transported to an environment that is normally inaccessible to them and cause great damage. In particular, the maxillary sinus area may be contaminated by germs of oral origin by simple probing, if bone height is reduced or if a trans-sinus implant insertion was performed. Probing around basal implants is therefore contraindicated and potentially dangerous . The same considerations show that rinses and any medication down along the threaded pins and under pressure is contraindicated: Ahead of the medication, liquid contaminated with pathogens is pressed into the deep without any control. The direction of flow is deleteriously inverted, resulting in infectious osteolysis (otherwise a rare occurrence). The pressure applied by the "treatment provider" and his syringe is greater by a factor than the internal pressure pf the bone or soft tissues, so that this procedure will almost invariably result in massive adduction of germs

[1] With basal implants, the terms "internal" and "external" thus refer to the thread and not – as with crestal implants – to the type and position of the surfaces that protect against rotation.

and the spread of infection, which may become chronic. A similar effect is observed if dental restorations are seated loosely on individual implants for a protracted time period (months or years) and the continuous relative movement of the abutment and crown creates a chronic submucosal inoculation with debris and pathogens. Here, too, inoculation pressure is higher than internal tissue pressure, resulting in repeated inversion of the direction of flow and increasing osteolysis due to the measures taken by the body to fight infections.

With basal implants, there are normally no funnel- or crater-shaped areas of bone collapse anyway, as the cortical bone closes as part of the healing process and no infection can be transported into the depth of the bone along the smooth threaded pins. Exceptions may occur if there is functionally related massive vertical bone growth along the threaded pin . Surprisingly, bone growth is in some cases unfavourable, but this is explained by the fact that bone growth will cause colonized intraoral areas of the implant to be relocated to submucosal or enossal regions. The proper therapy in these cases consists invariably in creating local drainage around the vertical implant part.

Bicortical screws (BCS®) are also considered as "basal implants", because they transmit masticatory loads deep into the bone, usually into the opposite cortical, while (full) osseointegration along the axis of the implant is not a pre-requisite. BCS provide at least initally some elasticity, they are not at all prone to peri-implantitis (due to their polished surface and their thin mucosal penetration diameter).

## 4. Peculiarities of basal implants

### 4.1 Overload osteolysis and basal implants

It is normally impossible to perform successful recovery treatment for mobile crestal implants, as the mucosal penetration area is too large and infections will recur and descend continuously along the rough interface area.

The situation is different around basal implants: One possible complication of basal implants – although initially reversible – is (functional) overload osteolysis. Successful therapeutic measures are possible. The physiological background should be explained briefly:

- On one hand, the load-transmitting interface areas are located in the cortical bone, which has to perform structural tasks and therefore has a more pronounced self-preservation tendency, and a more favourable prognosis, than spongious bone, which is of minor importance both structurally and with regard to macrotrajectorial tasks and therefore dispensable. It should be noted, however, that large-lumened crestal fixtures (just as teeth) are on the way of the jaws macrotrajectories anyway, so that these bone lines must seek different paths.
- On the other hand, masticatory forces transmitted via the basal implants to an enossal location create local microcracks in the cortical bone. Microcracks are repaired by the formation of secondary osteons, the process is called "remodelling"; this, however, will temporarily increase the porosity of the af-

fected bone region and temporarily reduce the degree of mineralization additionally. If microcracks accumulate at the bone/implant interface, the reduction in mineralization can also be detected on radiographs (Figure 5 a: the osteolytic area initially exhibits only diffuse radiological borders). As long as the bone substance is not torn away from the implant (Fig. 5 b; this is generally accompanied by clear radiological borders) and the area is not superinfected, the loss of mineralization remains diffuse but usually reversible , abd it should be remembered, that the term "osseointegration" describes the close contact between bone and the implant, but it does not describe a high degree of mineralization. Osseointegration at a lowered degree if mineralization is not the same as "fibrointegration". Orthopaedic surgeons describe the equivalent status of orthopaedic implants as "sterile loosening", but they usually have no means of treating this status. Basal implants in this status have a good chance of getting reintegrated at a high degree of mineralization, if loads are reduced to an adequate amount. The measures necessary are discussed below and they are part of the education of a basal implantologist.

Radiological findings should be secured both in the form of overview radiographs (tomographs) and in the form of summary radiographs (small-format radiographs). The implant will now be slightly mobile, which is easily discernible clinically. If areas with mineralization deficiencies are superinfected, granulation tissue is created in the interfacial region that will hardly be replaced by new bone without an added osteotomy stimulus, especially since granulation tissue requires or results in an increase in blood circulation that is maintained from a periosteal direction or enossally and which per se inhibits new bone formation. Nevertheless, even these implants could be re-integrated in isolated cases if the implant site per se exhibits pronounced remineralization tendencies, for functional reasons. Typical examples of such areas with pronounced remineralization are the region of the mandibular second molars, and the maxillary and mandibular canines (the so-called strategic positions) and of course the basal regions of the jawbones as such. These areas must therefore be preferred as implant sites – and other sites outside the strategic regions may even be dispensed with in the case of complete rehabilitation of an entire jaw if the concept of strategic implant positioning is consistently followed. Additional implants may be placed if the preferred regions offer insufficient anchorage.

An equilibrated masticatory pattern is of particular importance for maintaining mineralization in the interfacial region, especially in the first months after implant placement. Unilateral or anterior (like in Class II/2 malocclusions) masticatory patterns result in unilateral or anterior overload (which would seem to be immediately apparent) and also in increased porosity of the crestal aspect of the jawbone on the balancing or distal part of the jaw and thus in atypical patterns of mineralization. , This porosity is a consequence of the increased BMU (bone morphological unit) activity in this region due to a predominance of tensile forces in this region. For

this reason, mobilization of basal implants can be expected also on the non-working side on which the implants are subject to high extrusion forces within the framework of asymmetrical mastication. In case of mobility, it is therefore necessary to make adjustments on the side opposite the mobile side, something that crestal implantologists with their typical mechanist mindset almost invariably get wrong. Alternatively, occlusal areas on the "underload" side should receive an additive occlusal adjustment, leading to an equal loading of both sides of the jaw.

### 4.2. Therapeutic considerations for overload osteolysis

First and foremost, the prognosis of the implant must be determined according to the Consensus on basal implants. As long as implant removal is not indicated, there are several therapeutic strategies that can be followed:

- First of all, it must be determined whether or not the masticatory pattern is evenly balanced and symmetrical. If this is not or no longer the case, the first therapeutic step must be aimed at achieving a bilaterally balanced situation with regard to bone mineralization tendencies.
- In some cases, extensive occlusal adjustment will therefore be required. Deficiencies in vertical dimension must be treated prosthodontically (e.g. by building on the superstructure with composite or by fabricating a new superstructure with changes in vertical dimension). The development of anterior masticatory patterns must be prevented with all means and immediately. Existing anterior masticatory patterns can usually be corrected by increasing the vertical dimension; however, the optimum bite plane must be retained or created and this determines, in which jaw the addition has to be made.
- Furthermore, the question must be evaluated whether or not remineralisation xii by way of self-healing or supported by a suitable therapy can be expected at the existing mobile implants. Possible therapeutic steps are temporary isolation of individual implants from the superstructure, facilitating remineralization of the bone surrounding these implants. It should be noted that not all implants can be detached at the same times some have to perform. The lower bone density caused by function does not lead to reintegration; on the contrary, the result will be implant mobility.
- If excessive parafunctional habits or nocturnal positional deviations of the mandible are suspected, the fixed denture can be replaced, permanently, temporarily or prophylactically, by a bar-supported denture. This type of denture is supposed to be removed by patients at night. This will help avoid peak nocturnal pressure on the bone/implant interface and result in a very stable direct fixation of the implants relative to each other. Masticatory shear forces will also be more favourably distributed between the bar and the denture.
- It is also possible to add basal implants without removing mobile basal implants (Fig. 6a, 6b). Both implants can subsequently be integrated with a high degree of mineralization. The rationale of this procedure is found in

the distribution of the 0- and 1-areas within the bone itself. Mobile implants create 0-areas at the implant/bone interface, that is, areas that cannot perform any macrotrajectorial load transmission tasks. These tasks must then be performed mostly by bone areas in the vicinity, which will mature to form highly mineralized 1-areas. However, implantation into these 1-areas will interrupt the macrotrajectorial load transmission at the new implant site and promote the bone's tendency to once again increase mineralization around the mobile basal implant. Since the masticatory forces will subsequently be distributed to two implants, both implants can stabilize at an even pace. If the dentist intervenes in time, implant removal can be avoided in this manner. Additional implants may be required for the only reason that the masticatory forces can be greatly increased once the removable denture is replaced by fixed bridges. This increase in masticatory forces, however, will be accompanied with an absolute increase in bone mass and an improvement in bone quality (degree of mineralization), something that may have made the insertion of additional basal implants possible in the first place. Often the placement of additions BCS implants is easier than placing more BOI, as BCS implants may be inserted without flap procedure.

- If the fixed denture must or should remain in place as is, the masticatory forces can be temporarily reduced by injecting botulinum toxin (such as Dysport®) into the masseter (and temporal) muscles. This measure also prevents parafunctional loads and has been clinically proven to be extremely effective. Botulinum toxin can be administered prophylactically in cases with a scant bone supply, especially in the maxilla and especially if bar-retained removable superstructures are to be avoided right from the start. Therapeutically, the administration of botulinum toxin is indicated when BOI implant-supported superstructures (bone/implant/restoration systems) have become mobile due to parafunction or due to changes in the bite plane or masticatory pattern that have remained uncontrolled for too long. Note that the cause of overloading or miss-loading must be treated while the medication is acting. Else, after the effect of botulinumtoxin ceases, the mobility of the implants will return of course.
- It will frequently be necessary to perform several of the above measures in combination. At any rate, the correct therapeutic decisions must be made well in time and implemented determinedly, as "self-healing" per se, with all adverse influences remaining present, can be expected only in very isolated cases.

The question as to when or for how long the measures described above may be expected to result in "healing" or restabilization at all cannot be answered summarily. A great deal of clinical experience with basal implants is required to be able to make halfway reliable recommendations in borderline cases. In particular, care must be taken to re-examine the primary healing process after implant insertion and to check what types of basal implants were used. In particular the

thickness of the disks, the surface structure of the enossal aspects and the material properties (titanium graduation) of the implant in question are important factors of treatment planning. Usually, an untrained secondary treatment provider will not have the required familiarity with the aspect of masticatory function and its relation to bone physiology.

This alone is reason enough for complications always to be treated by the primary treatment provider. If that is not possible when complications occur, close consultation is required between the primary and the secondary treatment provider.

BOI implants inserted trans-sinusally without prior augmentation or lefting of the Schneiderian membrane may cause or promote sinusitis if there is vertical mobility (usually cause by overloading). Trans-sinus implant placement with augmentation (e.g. with Nanos®), by contrast, show a rather favourable stabilization potential over the medium term. Primary stabilisation must always be gained in native bone. Placement of a tubero-pterygoid screw distally of the basal implant in area 6 of the upper jaw, reduces the chances of overloading implants in the sinus area dramatically. For this reason this type of basal implant should be placed always in combination with BOIs.

### 4.3 Replacing basal and crestal implants

If an indication for replacing a basal implant really exists, this measure should be taken right away, since mobile implants will invariably cause bone damage. By contrast with screw-type implants, BOI implants will never exfoliate spontaneously. For this reason and because overload trauma may be transferred from one side of the jaw to the other via the denture or via an involuntary change in the preferred working side, there is no point in waiting. The objective of any replacement will be to restore the full function of the fixed restoration and thereby the full range of masticatory movements. This is why the insertion of the new implant must be planned along with the removal of the old implant. In most cases, immediate reimplantation will be possible and indicated.

When replacing defective implants, the osteotomy for the new implant must always be created first (unless the new implant is to be inserted in the same position as the old one), that is, before the existing implant is removed. It has been shown that this procedure is much easier on the bone than the inverse procedure; often only very little bone substance must be removed to remove the old implant. Leaving isolated integrated implant parts (that have no contact with the oral cavity) in situ instead of sacrificing a lot of bone substance to remove them does not usually cause any problems and can be considered lege artis. Four procedures for removal and immediate replacement of basal implants are known today.

While after the removal of formerly integrated crestal implants only rarely new crestal implants can be placed (immediately or at all), the immediate replacement of (crestal and basal) implants by basal implants and their immediate loading is a simple and successful procedure, which is virtually always possible:

### 4.4. Post-insertion treatment of BOI implants seen from the vantage point of crestal implantology

When complications occur, crestal implantologists unfamiliar with BOI implants may occasionally argue that there is not enough bone left for further "implant treatment" once an implant is lost. This is incorrect, since there is always enough available bone in the cranial regions of the facial skull and the basal region of the mandible (see cases of extremely advanced application of basal implants on www.donsimoni.com). This line of argument also negates the fact that there had already been insufficient bone for crestal implants even before the beginning of therapy, which is why the patient had sought treatment from the BOI implantologist and NOT from the crestal implantologist.

In practical crestal implantology, saving a case over time (and beyond the warranty period ...) is an important aspect; ailing crestal implants that are well osseointegrated basally but show unavoidable system-related continuous bone loss near the alveolar ridge (see Fig. 2 b), it is possible to "sell" the patient many years of delaying peri-implantitis therapy until the situation deteriorates to the point that leaving the implant in place becomes inconsistent with any definition of an acceptable oral situation. This kind of approach is clearly wrong in the case of basal implants: Problems must be addressed immediately and professionally, not least in order to prevent the spread of overload-related damage to other implants (which carries a risk of subsequent fracture or overload osteolysis) and thus to prevent bone loss. It is also not necessary to wait with the corrective intervention, because every patient has enough bone for treatment with basal implants. The "waiting-strategy" of crestal implantologists is caused with the fear, that after the removal of the ailing crestal implant no further treatment with crestal implants is possible. This point of view is short sighted.

In crestal implantology, specific aspects of masticatory function play a minor role with regard to bone preservation and the preservation of the masticatory function per se. Certain implantological schools traditionally advocate narrow occlusal surfaces, restricting patients to a primitive chopping masticatory function. Allegedly, this is done to avoid shear forces and fractures in ceramics and implant-parts (implant bodies, screws, abutments); in reality, however, the desirable increased functional stimulation of the jawbone will not occur. That masticatory function can be controlled to positively influence and modulate the bone/implant interface is something that is beyond the experience of the typical crestal implantologist.

Particularly serious damage can be observed when and because a crestal implantologist – or a non-implantologist – does not have the possibility (material, knowledge, experience) to insert additional basal implants, while crestal implants cannot or must not be inserted due to a lack of vertical bone or due to their different biomechanical function. A good example is the extraction of teeth in the opposing jaw or on the contralateral side, which of course would require the insertion of a fixed implant-supported replacement resto-

ration in order to maintain a symmetrical masticatory function. If the patient is not informed of this or if the treatment is not performed, the consequence will be overload-related damage on the working side, either to natural teeth or to implants.

Orthopaedic deformation of the jawbone and the supporting ligaments and locomotor systems of the cranium as a result of changes in loads and function in turn result in changes in the relative position of the restorations in the maxilla and mandible. This will almost always make massive occlusal adjustments of the restorations necessary over time. These adjustments must usually be much more pronounced – orthopaedic deformations of bones being on the order of millimetres rather than of microns – than anything their experience tells dentists working with crestal (axial) implants or on natural teeth.

Special consideration when working with basal implants should always be given to the preservation of a chopping or a lateral masticatory function: anterior masticatory patterns must be corrected, which often requires an elevation of the restoration in the posterior region.

**5. Summary**

Therapeutic options for peri-implantitis around crestal implants are limited: usually the disease stops as soon as it reaches basal (i.e. resorption resistant) bone areals. Peri-implantitis is not found with basal implants.

For sterile loosening of basal implants, numerous therapeutic options exist: functional adjustments or combined surgical/functional treatment of bone/implant/restoration systems are required and in some cases the reduction of muscle forces is part of the therapy plan. Such options are not given for crestal implants.

Even the replacement or addition of basal implants is easily possible, since there is usually sufficient cortical bone available for additive therapy. Corrective actions must be taken in a timely manner. The correct diagnosis and treatment of problems related to basal implants requires specific clinical experience, specific tools and of course basal implants. This is why the work with and on basal implants is and has been restricted by the manufacturer to authorized practioners.

Also with respect to the accepted principle "primum nihil nocere", basal implants are the devices of first choice, whenever (unpredictable) augmentations are part of an alternative treatment plan.

The technique of basal implantology solves all problems connected with conventional (crestal) implantology. It is a customer oriented therapy, which meets the demands of the patients ideally.

## Figures

Figure 1.
Histological section from a dog's mandible, four months postoperatively. The implant was inserted in a non-sterile manner and protected from exfoliation by the superstructure. The cortical bone in its entirety was re-formed as plexiform bone. The implant is not osseointegrated anywhere.

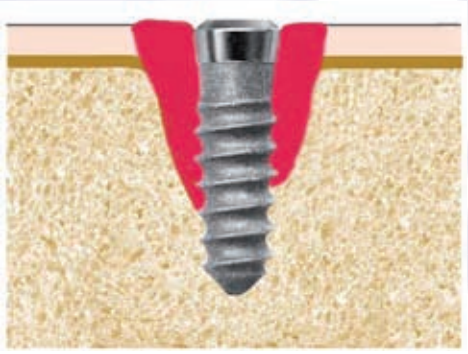

Fig. 2 a.
Funnel- or crater-shaped crestal implants may occur around osseointegrated crestal implants.
The extent of vertical bone loss can be determined by depth probing.

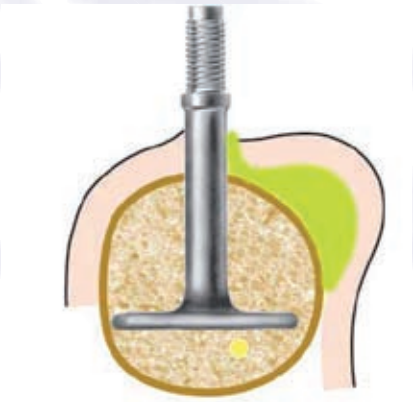

Fig. 2 b:
With integrated basal implants, infection originating in the oral cavity would not normally be expected to spread enossally, for as long as the implants are not mobile to the extent that they can be intruded. Infections can be caused by food retention or impaction or as a consequence of vertical bone growth. However, unlike with crestal implants, they do not spread intraosseously but submucosally. The latter may result in infected vertical parts if the implants are submerged below the mucosal level over time, eliminating the necessary gateway for suppuration as the area of penetration is closed with scar tissue. Any inflammation of this type will spread just like a submucosal abscess (Fig. 3) and is treated in the same way. It is recommended to make generous incisions to open the abscess. The mucosal area immediately adjacent to the threaded pin can be excised by electrosurgery. In rare cases, reduction osteotomies or the replacement of implants will be required if vertical bone growth becomes excessive.

Fig. 3. Internal BOI implants can have different platforms. Left: An ITI-compatible Diskos® implant with octagon. Right: A French "Diskimplant" with an external hex. These implants feature all advantages and disadvantages of screw implants with internal connection.

Fig. 4a, b. One piece basal implants for cortical engagement in vertical or horizontal bone bone morphology.

Fig. 5 a. Diagram showing a diffuse zone of low mineralization around the base plate of a functionally overloaded basal implant.

Fig. 5 b.
A clearly delimited light zone on the radiograph is indicative of an irreversible loosening and detachment of the bone in the interfacial region. In addition, these areas may be superinfected, which additionally stimulated blood circulation. Increased blood circulation as a response to infection is an environmental condition that endangers the presence of bone. Where there is no clinical mobility at all and only a clearly delimited low-density zone is visible radiographically, a pronounced vertical excursive movement of the threaded pin concurrent with sufficient integration of the ring area in the cortical bone may be present at least on one side of the respective jaw.

Fig. 6 a-b: Treating overload-related osteolysis by adding a second lateral implant. Because of the elastic properties of these implants, screw implants must not be included in wide-span bridges. Individual screw implants are mainly indicated for smaller segments or temporarily as accessory implants. It must be tested whether the elasticity of the additional enossal abutment is compatible with the existing bone/implant/restoration system.

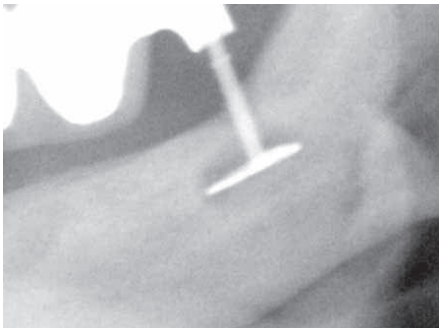

Fig. 6 a

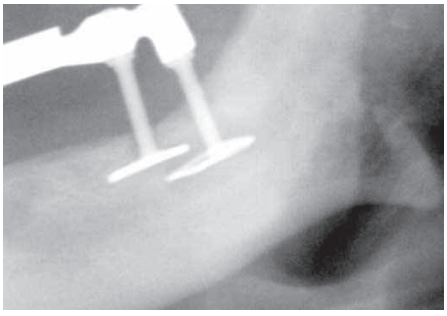

Fig. 6 b

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15. Implantodontie 2005 14:51 - 55

## Implant Directions Critical Appraisal

Reference:

Bornstein MM, Chappuis V, von Arx T, Buser D. Performance of dental implants after staged sinus floor elevation procedures: 5-year results of a prospective study in partially edentulous patients. Clin Oral Implants Res. 2008 Oct;19(10):1034-43.

**Performing Clinic:**

Department of Oral Surgery and Stomatology, School of Dental Medicine, University of Bern, Bern, Switzerland.

## ARTICLE SUMMARY

Authors' Summary:

**Study Objectives:**

The aim of this prospective study was to evaluate the 5-year performance and success rate of titanium screw-type implants with the titanium plasma spray (TPS) or the sand-blasted, large grit, acid-etched (SLA) surface inserted in a two-stage sinus floor elevation (SFE) procedure in the posterior maxilla.

**Study Design:**

- Prospective case series
- All partially edentulous patients scheduled for two-stage SFE between January 1997 and December 2001 were consecutively enrolled in the study, including those with local bone defects requiring local bone augmentation. All patients had a remaining alveolar bone height of <4mm.
- Exclusion criteria included severe systemic problems and smoking.
- 22 men and 34 women (61% female) with a mean age of 53.86 years (range 19-74 years) were enrolled.

**Surgical Methods:**

- A total of 59 delayed SFEs were performed in 56 patients using a composite graft with autogenous bone chips combined with deproteinized bovine bone mineral (DBBM) or synthetic porous beta-tricalcium phosphate (beta-TCP).
- After a healing period averaging 7.75 months, n=111 dental implants were inserted.
- After an additional 8-14-week healing period, all implants were functionally loaded with cemented crowns or fixed partial dentures.

**Outcomes measured:**

- Modified plaque index (mPLI) at four aspects around the implants
- Modified sulcus bleeding index (mSBI) at four aspects around the implants
- Probing depth (PD in mm)
- Distance between implant shoulder and mucosal margin (DIM)
- Clinical attachment level (AL)
- Mobility using Periotest values (PTV)
- All biological complications were also recorded throughout the follow-up period
- Clinical success = absence of persistent subjective complaints, absence of peri-implant infection with suppuration, absence of mobil-

ity, and absence of continuous radiolucency around the implant

**Follow-up:**

- The patients were recalled at 12 and 60 months for clinical and radiographic examination.
- Follow-up rate = 91% (11 implants were lost to follow-up)

**Results:**

- One patient developed an acute infection in the right maxillary sinus after SFE and did not undergo implant therapy.
- Two of the 111 inserted implants had to be removed because of a developing atypical facial pain. Clinical and radiographic findings for the remaining 98 implants are reported in table.
- 5-year success rate = 98%*
- o TPS implants = 89%
- o SLA implants = 100%

*authors state that any comparisons between implant types should be made with caution as the study was not designed from the beginning as a randomized comparative study and the SLA-type implant is overrepresented

Table. Reproduction of table reporting gingival parameters and periotest values.

| Follow-up | mPLI | mSBI | PD (mm) | DIM (mm) | AL (mm) | PTV |
|---|---|---|---|---|---|---|
| 1 year (n=103) | 0.34 ± 0.03 | 0.35 ± 0.04 | 4.43 ± 0.11 | -1.35 ± 0.11 | 3.04 ± 0.06 | -2.71 ± 0.31 |
| 5 years (n=98) | 0.27 ± 0.03 | 0.29 ± 0.04 | 4.14 ± 0.11 | -1.22 ± 0.11 | 2.89 ± 0.08 | -3.00 ± 0.28 |

**Conclusions provided by authors:**

This prospective study assessing the performance of dental implants inserted after SFE demonstrated that titanium implants can achieve and maintain successful tissue integration with high predictability for at least 5 years of follow-up in carefully selected patients.

## Reviewer's Evaluation

| **Methodological Principle** | |
|---|---|
| Randomized design | NO |
| Independent or blind assessment | NO |
| Adequate sample size | NO |
| Appropriate analysis | YES |
| **Appropriate measures** | |
| Radiological analysis | YES |
| Clinical measures | YES |
| Patient report quality of life | NO |

**1. What were the study's methodological strengths?**

- Clearly defined objective.
- Clearly defined inclusion and exclusion criteria.
- The authors report a relatively high follow-up rate over a 5-year period.

**2. What were the study's methodological limitations?**

- Case series provide only descriptive and safety related data. No conclusions can be made on the efficacy of this method or implants versus other implant methods.
- Smokers were not included making these findings non generalizeable to this population.
- The authors attempted to evaluate risk factors for failure (eg, age, gender, time period, grafting material, etc.), however, did not report these findings descriptively or through a stratified analysis so the reader could evaluate their possible effect. With such a small sample size, the p-value can be misleading and not necessarily capture possible differences in outcome based on these factors.
- No patient related quality of life measures were collected. Studies evaluating clinical and radiographic outcomes have been performed for decades with similar results. Studies evaluating the patient's perspective on their implants with respect to various domains including satisfaction, pain, functional ability, timing of implant use, cost, and other factors should be included.
- The authors use a mixture of implants and augmentation materials: TPS-screws are mixed in the same study with SLA-screws and the graft materials are also from different sources. Therefore, this study does not evaluate any specific material or implant, but rather the technique, which is well known to work anyway in about 85-95% of the cases in the hands of other practitioners.

**3. How might the findings from this Critical Appraisal be applied to patient care?**

To improve patient care, specific data about a device is desirable. This article does not provide this information. The discussion lacks appropriate clinical objectivity with respect to the survival rate of the TPS implants (which are considered old fashioned in the view of the Dental school of medicine in Berne). The survival rate was 100%, whereas the "modern" surface SLA rendered a 97.5% success rate. Plausible explanations for this would be helpful to the reader.

It would have been clinically useful if the authors reported long term follow-up up to 9 years since the last patient under control reached the 5 year limit in 2006. The first patients operated

on in 1997 had been equipped with implants for 9 years by that time. We would understand that the drop out rate after this period may be above 15%, but still it would have been interesting to see these long term outcomes as dental implants are a long term solution for patients.

The tendency for the school of medicine to focus on healthy patients limits the generalizeability of these findings. The authors excluded diabetics, smokers and periodontally involved cases. Treating healthy patients is generally occurs without difficulty or complications. The challenge is in these patients with risk factors for a poor outcome who seek implants as well and expect treatment. Further, patients with more than 4 mm vertical bone in the sinus area are not difficult to treat. At the time of the publication, internal sinus lift procedures (instead of the open sinus lifts) have become state of the art and small implants, such as porous coated implants (Osseopore, Endopore), are in use frequently for this purpose.

**4. Were all important assessments performed? If not, what assessments should be considered?**

The authors should have made a comment on why the waiting times before implant placement were so different (4-12 months).

**5. Are there alternative explanations for the findings observed in this study?**

This study demonstrates that various implants work well in combination with various augmentation materials and this contradicts the findings of studies mentioned in the text (Wiltfang 2005, Hallman 2004, Hallman 2005). No explanations are given for this.

**6. How might the findings be applied to patient care?**

The study demonstrates that the surgeons involved in this study are outstanding, and that a good surgeon can achieve perfect results with any kind of implant and any augmentation material. It is astonishing to see that the school of medicine today focuses on augmentation materials from bovine origin (with all its inherent risks), instead of the materials used. It seems that the strong preference for materials from Geistlich Company (Bio Oss) has no scientific foundation.

As far as TPS screws are concerned, unfortunately these devices have not been available since 1999. Reporting on obsolete devices in 2008 makes little sense and is of no help for clinical application today. Mixing their good results with the doubtful results of devices available today (SLA) is questionable. It has to be noted, that SLA-implants have been replaced by SLActive implants, and again, the same group of authors has reported in a doubtful manner on "benefits" of SLActive (see www.implant-directions.info, e.g. the journal issued in April 2008)

## EVIDENCE REPORT

### Title: Effect of diabetes mellitus on dental implants survival and complications


**Evidence Report Purpose**

Diabetes mellitus is a group of metabolic disorders characterized by an increase in plasma glucose levels. The resulting hyperglycemia is caused by a defect in insulin secretion, insulin action, or both. Chronically high levels of plasma glucose may be associated with a wide range of systemic complications such as retinopathy, nephropathy, neuropathy, micro- and macrovascular disease, and altered wound healing. In implantology, microvascular disease may contribute to delayed wound healing, reversed bone turnover, and increased susceptibility to infection.

**Objective**

To critically summarize the recently published literature examining implant survival and other outcomes in studies comparing patients with and without diabetes mellitus.

**Summary**

There was a trend towards lower implant survival rates for subjects with diabetes mellitus compared to nondiabetic subjects. One study found increased implant survival rates in diabetic patients (1) when 0.12% chlorhexidine digluconate was used at the time of implant placement compared to not, (2) when pre-operative antibiotics were used compared to not, and (3) when hydroxyapatite (HA) coated implants were used compared to non-HA implants. Studies found significantly greater levels of peri-implant bone loss in (a) patients with diabetes compared to nondiabetics and (b) patients with poor diabetic control compared to those who were well-controlled. Further, there was a significantly greater prevalence of peri-implantitis in poorly-controlled diabetics compared to well-controlled individuals. Post-operative complications were also greater in poorly-controlled diabetics compared to those with good control, though the prevalences were not significantly different between these two groups. Additional methodologically rigorous comparative studies are needed to better evaluate the treatment outcomes of dental implants in relation to diabetes; however, these findings should be considered when treating patients with diabetes.

**Sampling**

A MEDLINE search was performed to identify recent studies published between January 2000 and September 2008 examining the effect of diabetes mellitus on dental implant treatment outcomes. From a list of 16 articles, 3 included implant treatment outcomes that met our criteria and are included in this report, Table 1.

**Table 1. Medline Search Summary**

| Terms | Hits | Reviewed |
|---|---|---|
| Search **dental implants OR dental implantation, endosseous [MeSH]** | 17,913 | |
| Search **(dental implants OR dental implantation, endosseous [MeSH]) AND [diabetes OR diabetes mellitus]), Limits ENGLISH, Human, Literature containing Abstracts** | 52 | 2 |
| Search **(dental implants OR dental implantation, endosseous [MeSH]) AND [diabetes OR diabetes mellitus] AND comparative studies), Limits ENGLISH, Human, Literature containing Abstracts** | 8 | 1 |
| **Total Reviewed** | **3** | |

### Common Outcome Measures

- Implant survival
- Implant survival, categorized
- Peri-implant bone resorption
- Peri-implantitis
- Post-operative complications

### Interventions

Dental implants were placed in subjects described as follows:

### Tawil (2008)

- Forty-five Type 2 diabetic patients with a glycosylated hemoglobin (HbA1c) value ≤ 7.2% during the perioperative period were matched by age, gender and type of implant to 45 consecutively treated nondiabetic patients. Individuals were followed prospectively for 1 to 12 years.

### Morris (2000)

- In a retrospective study, 255 implants were placed in individuals with Type 2 diabetes, and 2632 implants were placed in patients without diabetes. Implant outcomes were followed for 3 years after implantation.

### Accursi (2000) (within Elsubeihi & Zarb 2002)

- In a retrospective study, 15 medically controlled diabetes mellitus patients were matched to 2 non-diabetic control subjects by age, sex, location of implants, type of prosthetic restoration, opposing dentition, and duration of edentulism. Individuals were followed for 1 to 17 years, and implant survival in diabetic patients (n=59 implants) was compared with that of non-diabetics (n=111 implants).

**Note:** Glycosylated hemoglobin values reflect average blood sugar levels for the 2- to 3- month period before the blood test. Levels from 4% to 7% indicate well-controlled diabetes, and levels above approximately 7% indicate poor control.

Table 1. Comparative studies evaluating dental implant outcomes in patients with and without diabetes mellitus.

| Author (year) | Study Design | Population | Diagnostic Characteristics | Diabetes | | Follow-up (%) | LoE† |
|---|---|---|---|---|---|---|---|
| | | | | Diabetes Mellitus (Group A) | No Diabetes (Group B) | | |
| Tawil (2008) | Prospective cohort | N = 90 female: 37% age: diabetics = 64.7 (43-84) yrs; nondiabetics = 59.6 (29-85) yrs | Indication for dental implant placement | N=45; Ni=255 | n=45; Ni=244 | 1-12 years (mean 42.4 months): NR* | Moderate |
| Morris (2000) | Retrospective cohort | N = 663 female: 5.9% age: NR | Indication for dental implant placement | N=NR; Ni=255 | N=NR; Ni=2632 | 3 years: NR* | Moderate |
| Accursi (2000) | Retrospective cohort | N = 45 female: NR‡ age: NR‡ | Indication for dental implant placement | N=15; Ni=59 | N=30; Ni=111 | 1-17 years: NR* | Moderate |

N = Number; Ni = Number of implants; NR = Not Reported

†Level of Evidence (LoE) is based on study design and methods (Very high, High, Moderate, and Poor)

*NR (not reported) = for follow-up rate either not reported or precise follow-up rate could not be determined since the initial number of eligible patients or number lost to follow-up were not provided.

‡ = Subjects with diabetes were age- and sex-matched to 2 control subjects without diabetes.

Table 2. Evaluation of articles examining implant placement in patients with and without a history of periodontal disease

| Study design and methods | Tawil (2008) | Morris (2000) | Accursi (2000) |
|---|---|---|---|
| 1. What type of study design? | Prospective Cohort | Retrospective Cohort | Retrospective Cohort |
| 2. Statement of concealed allocation?* | N/A | N/A | N/A |
| 3. Intention to treat?* | N/A | N/A | N/A |
| 4. Independent or blind assessment? | NO | NO | NO |
| 5. Complete follow-up of >85%? | NR | NR | NR |
| 6. Adequate sample size? | NO | YES | NO |
| 7. Controlling for possible confounding? | YES | NO | YES |
| LEVEL OF EVIDENCE | Moderate | Moderate | Moderate |

* Applies to randomized controlled trials only
NR = not reported

## Results

**Overall implant survival (Figure 1)**

There was a trend for lower survival rates in those subjects with diabetes.

- Overall implant survival for Type 2 diabetic subjects was 97.6%, while that of nondiabetics was 99.6% (p>.05) in a study in which subjects were followed for 1 to 12 years. [Tawil]
- At 3 years, subjects with Type 2 diabetes demonstrated a survival rate of 92.2% and those without diabetes had a survival rate of 93.2%; p>.05. However, in a multivariate regression, diabetes (p<.05) and health status (p<.02) were significant factors influencing implant survival. [Morris]
- In a retrospective study in which individuals were followed for 1 to 17 years, subjects with diabetes experienced a 93.2% survival rate, while those without diabetes had a survival of 94.6%; p>.05. [Accursi].

**Implant survival, by treatment (Figure 2)**

- When 0.12% chlorhexidine digluconate (CHX) was used at the time of implant placement in Type 2 diabetics, there was a significantly greater implant survival rate at 3 years compared to Type 2 diabetics on whom CHX was not used (95.6% vs. 86.5%; p<.05). In non-diabetic subjects, there was an increased, though non-significant, survival rate in those with CHX compared to those without CHX (94.3% vs. 91.8%, p>.05). [Morris]

- Pre-operative antibiotic usage in Type 2 diabetics provided a significant improvement in implant survival at 3 years (97.1% vs. 86.6%; p<.05). In non-diabetics, there was an increased though non-significant implant survival rate in individuals in whom pre-operative antibiotics were used compared to those without pre-operative antibiotics at 3 years (95.1% vs. 90.6%, p>.05). [Morris]
- The use of hydroxyapatite (HA) coated implants compared to non-HA coated implants significantly improved implant survival in both Type 2 diabetics (97.9% vs. 84.7%; p<.05) and non-diabetics (96.7% vs. 87.2%; p<.05). [Morris]

**Peri-implant bone loss**

- One study reported a significantly greater mean loss of crestal bone height in the first year in subjects with medically controlled diabetes compared to those without diabetes (-0.25 ± 0.07mm vs. -0.06 ± 0.03 mm, respectively; p<.05) [Accursi].
- Another study found significantly greater peri-implant bone loss in Type 2 diabetic patients with poor diabetic control (HbA1c levels ≥ 7%) compared to those with good control (HbA1c levels < 7%) (-0.24 ± 0.28 mm vs. -0.5 ± 0.7 mm, respectively; p=.01). [Tawil]

**Peri-implantitis (Figure 3)**

- In Type 2 diabetics with different levels of diabetic control, there was a significantly greater prevalence of peri-implantitis in patients with HbA1c levels ≥ 7% compared to those with levels < 7% (30.4% vs. 0%, p=.05). [Tawil]

Post-operative complications (Figure 3)

- In Type 2 diabetics with different levels of diabetic control, there was a greater prevalence of post-operative complications in patients with HbA1c levels ≥ 7% compared to those with levels < 7%, though the difference was not statistically significant, likely due to small sample sizes (52.2% vs. 27.3%, p>.05). [Tawil]

Methodological considerations

- All studies reviewed were cohort studies with a rating of moderate (low quality cohort) level of evidence. No very high quality randomized controlled trials or high quality cohort studies were identified in the literature.
- All of the studies had small sample sizes, and two of the studies [Tawil, Accursi] had sample sizes that were likely inadequate to show a difference between the study groups, especially when samples were stratified into subgroups.
- Since multiple implants in the same subject are not statistically independent, either one implant should be chosen per patient or statistical analysis should account for multiple implants per patient. Only one of the studies reviewed [Tawil] accounted for multiple implants in the same subject, but only for com-

plication rates.

- None of the studies reported a follow-up rate or provided data adequate enough to calculate the follow-up rate. A follow-up rate of ≥85% is necessary to ensure valid study results.

## References

### Studies


Study 1

**Tawil G, younan R, Azar P, Sleilati G (2008)**

Conventional and advanced implant treatment in the type II diabetic patient: surgical protocol and long-term clinical results.

Int J Oral Maxillofac Implants 23:744-52.

Study 2

**Morris HF, Ochi S, Winkler S (2000)**

Implant survival in patients with type 2 diabetes: placement to 36 months.

Ann Periodontol 2000;5:157-65.

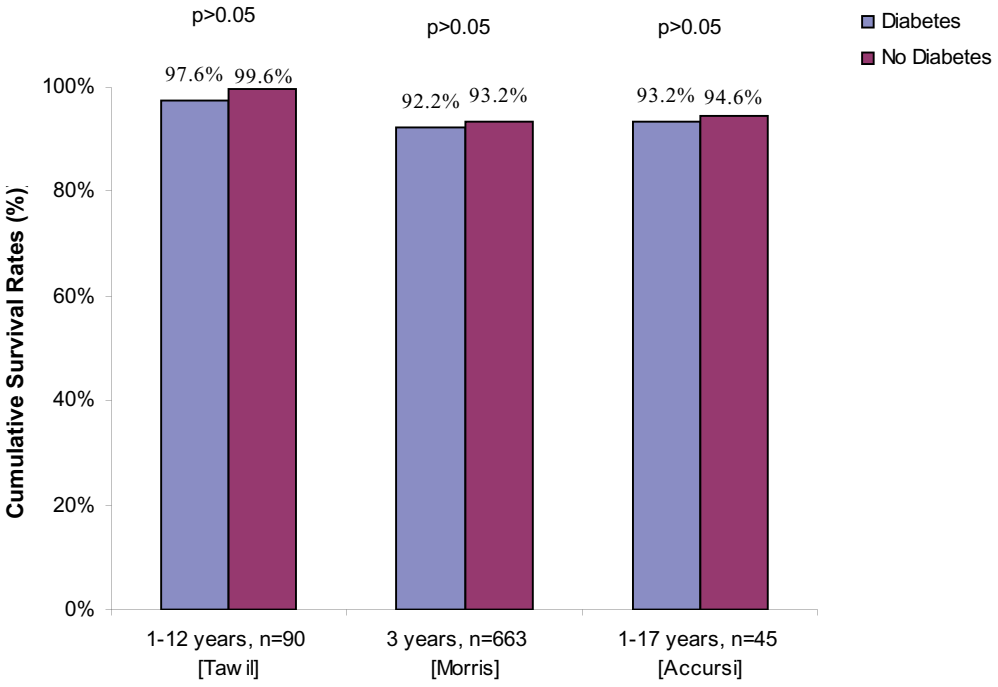
**Study 3**

**Accursi GE (2000)**

Treatment outcomes with osseointegrated Branemark implants in diabetic patients: a retrospective study [thesis]. Toronto (ON): University of Toronto.

In: Elsubeihi ES, Zarb GA. Implant prosthodontics in medically challenged patients: The University of Toronto experience. J Can Dent Assoc 2002;68(2):103-8.

**Figure 1. Cumulative overall survival rates for dental implants by diabetic status.***




Statistical significance noted on graphs if provided by author
* n=number of subjects

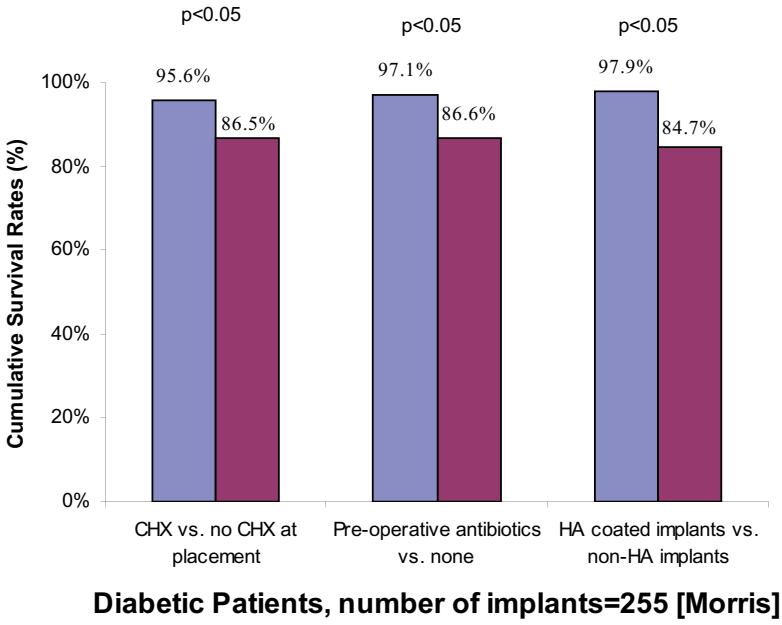
**More interesting references:**

**Dowell S, Oates TW, Robinson M (2007)**
Implant Success in people with Type 2 diabetes mellitus with varying glycaemic control – a pilot study; J Am Dent Assoc , 138: 355-361 (None of the implants places was lost during the observation period)

**Behnke A., Behnke N., Hoedt B., Wagner W. (1998)**
Diabetes mellitus – ein Risikofaktor für enossale Implantate im zahnlosen Unterkiefer?
Dtsch Zahnärztl. Z. 5:332-329 (Controlled clinical study. Article in German: within a 5-year observation period implants placed in the anterior region of the mandible showed higher survival rate in diabetic patients (94,6%), compared to healthy subjects(91,6); the amount of bone resoption along the vertical axis of the implants was slightly higher (1.3mm) in diabetic patients, compared to healthy subjects (1mm), and the amount of resorption depended on duration of the diabetic condition.

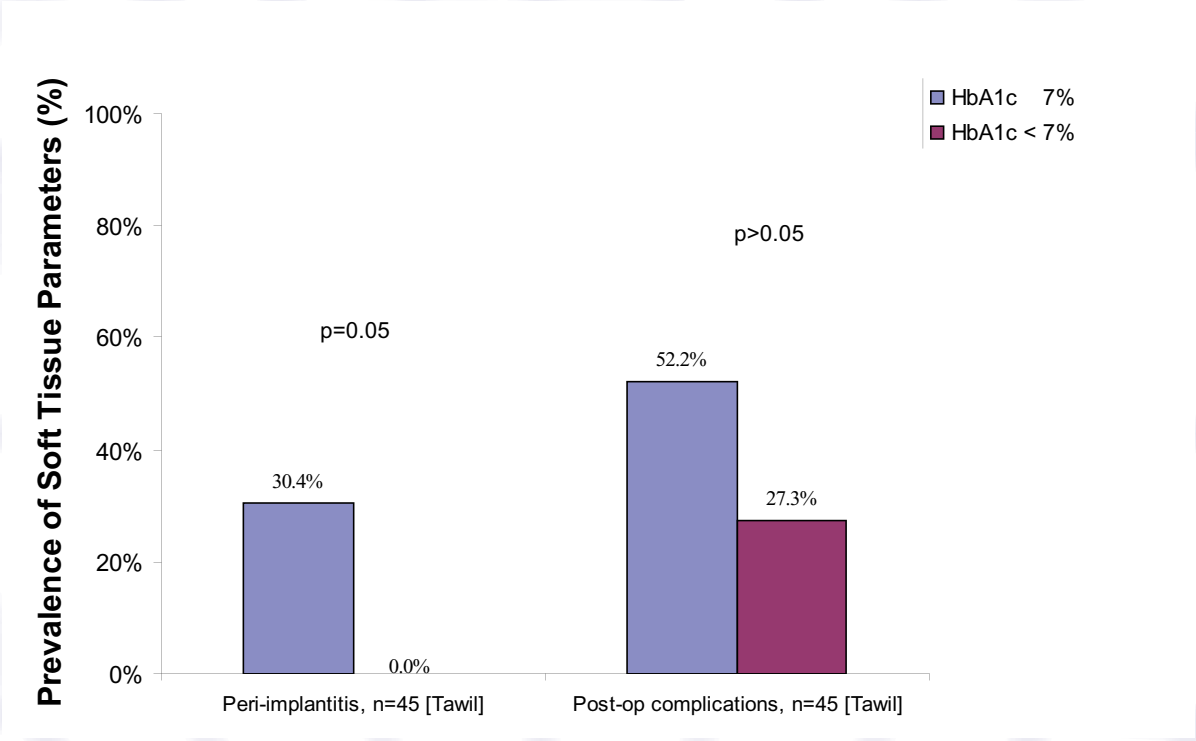
**Tawil G, Younan R et al; (2008)**
A study on diabetic patients (Type II) showed that there is no statistic correlation between the group with well adapted hbA1c < 7%) compared to less well adapted HbA1c (7-9 %). However HbA1c values vorrelated to Plaque-Index and Bleeding Index BOP.
Int. J Oral Maxillofac Implants (2008) 23: 744-752

**Figure 2. Cumulative survival rates for dental implants in diabetic patients by treatment.***




Statistical significance noted on graphs if provided by author
* blue indicates treatment, burgundy indicates no treatment or non-standard treatment

**Figure 3. Post-operative soft tissue parameters of dental implants in diabetic patients by level of diabetic control.***




Statistical significance noted on graphs if provided by author
* n=number of diabetic subjects

## Literature Analysis

**Effects of Radiation Therapy on Craniomaxillofacial and Dental Implants**
**SUMMARY of Findings and Implications**

**Literature Analysis**

A "Literature Analysis" is a critical review of the literature on the epidemiology, treatment methods, and prognosis for implant-related topics or conditions. Literature Analyses are broader than "Evidence Reports" (also published in each issue of Implant Directions) which focus on one specific treatment intervention by comparing and contrasting only 3 to 5 high quality articles in greater depth.

Literature Analyses are written to serve as a reference tool for implantologists:

- To help them make decisions regarding how to manage patients;
- To assist them in evaluating needs for future research;
- To use the material for future presentations.

This literature analysis on the effects of radiation therapy is the second of two parts. Part I evaluated and reported on ANIMAL studies. This analysis (Part II) will be published in the next edition of Implant Directions and will evaluate and report on HUMAN studies.

**Purpose**

The purpose of this Literature Analysis was to systematically search the literature to identify key articles in an effort to evaluate the effects of radiation therapy on craniomaxillofacial and dental implants. Part I of this literature analysis addressed the following objectives:

- 1. Provide an overview of implantology in irradiated craniomaxillofacial bone.
- 2. Summarize dental implant failure from ANIMAL studies with respect to the following:
  - a. Irradiated versus non-irradiated bone
  - b. Dosing of radiation
  - c. Implant types
  - d. Timing of radiation
  - e. Hyperbaric Oxygen Therapy
- 3. Summarize the quality of the literature on ANIMAL studies and recommended future studies.

**This edition (Part II) will address the following objectives:**

1. **Summarize** craniomaxillofacial (CMF) and dental implant failure from HUMAN with respect to the same parameters as reported in ANIMAL STUDIES.
2. **Summarize** complications from HUMAN studies associated with implants in irradiated bone in CMF and dental implants.
3. **Summarize** quality of literature on HUMAN studies and recommended future studies.
4. **Discuss** the role of BOI in the treatment of patients with irradiated bone.

**The search methods and an overview of implants in irradiated bone are reported in the last edition of Implant Directions.**

## Summary of human studies on craniofacial implants in irradiated bone

An attempt was made to address the following categories by relying only on studies that made appropriate comparisons (i.e., cohort studies and case series with historical controls): irradiated versus non-irradiated bone, dosing of radiation, timing of radiation, implant location, implant types, and HBO therapy. Studies were of poor (case series) to moderate (cohort studies) quality so conclusions should be made with caution, Table 1. Rates of failure are reported by implant location in the table so a single study may appear more than once in the table.

### Irradiated versus non-irradiated bone

When comparing rates of implant failure in irradiated versus non-irradiated bone in CF applications, the risk of implant failure in irradiated bone was as high as 12 times greater than that for non-irradiated bone.[1-5] The increased risk was statistically significant in seven comparisons, however, only two were data from cohort studies (i.e., made the comparison in the same study population).[1, 2] Stronger associations were seen in case series compared to historical controls. Survival rates were based on as little as one year and as much as 5 years after implantation.

### Dosing of radiation

Few studies were identified evaluating radiation dose in CF applications. One study reported no difference in failure based on dose (< 50 versus ≥ 50 Gy) in orbital implants, however the sample size was relatively small.[6] Cumulative radiation effect (CRE) as a measure of dose (≤30) was significantly related to implant failure in one prognostic study.[7] Radiation dose (above CRE30) was the only factor associated with implant failure (p=0.05) in this study.

### Timing of radiation

Schoen evaluated failure rates based on whether the implants were placed prior to or after irradiation.[8] The sample sizes were too small to effectively determine the effects of timing or the risks associated with radiation prior to or after implant placement. No other studies were identified.

**Implant location**

Location of CF implants may influence the survival rate. Numbers cited in the literature for implant survival in non-irradiated bone by location are as follows: mastoid region, >95%; orbital implants, 35-91%; nasal implants, 71-81%.[9] No significant differences were seen for implants in other CF locations. Several studies reported a tendency toward higher failure rate in the orbital area due to thin bone in this region,[1, 10, 11] while others did not find any statistical difference between orbital implant success and other craniofacial implants, whether in irradiated or non-irradiated bone.[5-9] A review of patient data over a 25-year period comparing implant success in irradiated and non-irradiated populations indicated that implant location was not a factor in survival, with the possible exception of orbital implants which may show a trend toward lower survival rates (p=0.055), and gingival implants which may have a higher survival rate (p=0.05).[7]

**Implant types**

No studies attempting to compare different types of CF implants in irradiated bone were identified precluding any conclusions regarding superiority of one CF implant type over another.

**HBO therapy**

One study was identified evaluating the effect of HBO therapy in irradiated bone.[4] Failure was significantly less common (RR=0.15; 95% CI 0.7, 0.30) among radiotherapy patients treated with HBO compared with those who had radiotherapy but no HBO. There was no difference in failure rates comparing non-irradiated patients and those who had radiation and HBO.

**Summary of human studies on dental implants in irradiated bone**

An attempt was made to address the same categories of treatment effects reported in the CF section, Table 2.

**Irradiated versus non-irradiated bone**

The proportion of studies that reported statistically significant differences between irradiated bone and non-irradiated bone in the dental implant studies was far less than reported in the CF studies. Further the relative risks were not nearly as high. Of the eight studies that compared rates of implant failure in irradiated and non-irradiated bone, only three reported statistically significant differences. The risk of implant failure in irradiated bone was between 2-3 times greater than that for non-irradiated bone in these studies. In CF studies, the relative risk was as high as 12. Moy reported nearly a 3 times greater risk of implant failure in irradiated versus non-irradiated bone (RR= 2.73; 1.10, 6.81); however, after adjusting for diabetes and smoking status, the RR was still significant but less than two (RR= 1.87; no confidence interval was provided).[12] Raw data was not available so we did not present it in Table 3; however, the author produced the RRs and adjusted RRs that we report here.

**Dosing of radiation**

Visch et al [13]compared survival rates at 10-years in patients receiving a dose either less than or greater than or equal to 50Gy. Lower radiation dose (<50Gy) was significantly associ-

ated with improved implant survival compared with higher doses (≥50 Gy). This difference was greater than two-fold (RR = 0.49; 95% CI 0.29, 0.81). A review article noted that no failures were observed with radiation doses lower than 45Gy. [14]

**Timing of radiation**

Several studies compared failure rates for implants placed at varying intervals post-irradiation. No differences were seen when comparing placement less than or more than one year after radiation in one study. [13] Another study found no differences in timing but the number of subjects and implants was small.[15] One study observed that only the time interval between implant placement and the abutment operation showed significance, where patients receiving implant placement and abutment <4 months apart did significantly worse than those with the abutment procedure >4 months from time of implant (p=0.0001). [16] A second study agreed with this finding, noting that significantly more mandibular reconstruction plates were lost when radiation was administered during the perioperative period, defined as within 12 weeks of implant surgery.[15] A third study did not observe a statistically significant difference in survival rates between implants inserted less than or greater than one year post-irradiation.[13] A review article comparing failure rates for implants placed either pre- or post- irradiation showed that failure rates were similar between the two groups and not statistically significant (5.4% and 3.2%, respectively).[14]

**Implant location**

Implant failure in irradiated maxillary bone was twice that of non-irradiated maxillary bone based on one study where the comparison could be made.[17] Complications based on radiation status were not well reported and generally not separated out in those studies reporting complications, making definitive statements about complications, including osteoradionecrosis difficult. Mandibular implants were significantly less likely to fail compared with maxillary implants. [13] An adjusted RR of 1.79 (p = 0.001, no CI provided) for implant failure in the maxilla compared with that in the mandible was reported (all bone). One study showed a survival rate of 59% in the maxilla, 85% in the mandible. (p=0.001).[13] In a comparison of total implant locations, high implant failures were seen after high dose radiotherapy and a long time after irradiation. All craniofacial regions were affected, but the highest implant failures were seen in frontal bone, zygoma, mandible, and nasal maxilla. Lowest implant failures were seen in oral maxilla.[7] A review article noted that implant location resulted in significant differences in failure rates, with mandibular implants failing less than maxillary implants (4.4% and 17.5%, respectively; OR=4.63; 95% CI: 2.25 to 9.49).[14]

**HBO therapy**

Two studies attempting to evaluate the effect of HBO therapy as an adjunct to irradiation for dental implants in irradiated bone were identified. [18, 19] Based on the criteria that the patient is expected to experience difficulty during osseointegration, Granstrom et al proposed the use of HBO therapy as potentially beneficial.[18] They

reported from a multivariate analysis of 671 irradiated implants that HBO therapy improved implant survival with significance at the p<0.001 level (study in press). Conversely, Donoff et al contend that our understanding of wound healing is incomplete and constantly changing in the light of new research, and that our incomplete knowledge precludes any reliable conclusions regarding the necessity for HBO therapy.[19]

**Summary of complications associated with implants in irradiated bone in human studies**

Complication rates based on radiation status were not well described in any of the comparative studies. Failure to report complications should not be construed as meaning that none were present. Briefly, in the CF studies reviewed, several studies reported no complications,[8, 9] one study reported a low rate of osteoradionecrosis (4.7% (n=5/107)),7 and grade 1-3 tissue reactions were observed in patients receiving radiotherapy (P<0.001 to 0.05).[7, 8]

For the dental implant studies, August et al reported the following early complications in an oral cancer population:[20] soft tissue overgrowth around pins (22.2% (n=4/18)), tongue ulcerations (11.1% (n=2/18)), and intraoral wound dehiscence(11.1% (n=2/18)). Late complications included orocutaneous fistula formation (16.6%(n=3/18)), submental erythema (11.1% (n=2/18)), persistent tissue overgrowth around pins (5.6% (n=1/18)). Soft tissue ulcers have also been noted.[21, 22]

**Radiation scattering**

Implants placed before radiation therapy may cause scattering, resulting in a decreased dose delivered to the tumour and increased exposure to soft tissue and bone adjacent to the implant.[8] Implants of a higher atomic number material cause a greater back-scatter dose factor (BSDF), though the range is small (a few millimetres). Additionally, lower energy photons, i.e. 60Co, caused greater backscatter than higher energy photons.[23, 24] A study of simulated head and neck radiotherapy showed that highest dose enhancement occurs at a distance of 0 mm from the bone-implant interface in all locations and implant materials studied. Transmandibular implants (high gold content, gold-copper-silver alloy) had scatter up to 1mm from the bone-implant interface. No significant difference was noted in buccal, lingual, mesial or distal directions. Hydroxyapatite-coated titanium implants demonstrated the best results.[25] An additional study of titanium implants in mandible confirmed that the risk of radionecrosis from backscatter is slightly but not significantly higher with post-implantation radiotherapay.[24]

A dosimetric evaluation of the effect of previously placed dental implants during radiotherapy concluded that the risk of osteoradionecrosis to the mandible is slightly but not significantly affected by the scattered dose in the radiation field exposed to 3 different radiation beams.[24]Granstrom et al recommend that if irradiation is to be performed post-implantation, all prostheses, frameworks and abutments should be removed prior to irradiation. Fixtures should be left intact but covered with skin or mu-

cosa, as removal of osseointegrated implants is itself a potentially damaging procedure.[3]

**Quality of literature and need for future research**

In general, the quality of studies comparing implant failure/success and complication rates in irradiated versus non-irradiated bone is poor. For animal studies, no studies evaluated all important parameters such as timing, histomorphometric, biomechanical, and histological measurements in the same study using irradiated bone with a non-irradiated control leg. Furthermore, few animal studies were designed to compare implant types in irradiated bone.

For HUMAN studies, most were of poor to moderate quality. The majority of comparisons between irradiated bone and non-irradiated bone were with historical controls. However, a prospective study comparing patients who do and do not get irradiated in the same consecutive patient population may be difficult to perform. No studies were designed to compare implant types in irradiated bone. This may be the focus for future research.

**We recommend the following two studies for future research and publication:**

- **1**. A well-designed animal study with adequate sample size that compares different implant types in irradiated and non-irradiated bone. This study should assess the following important parameters with respect to the implants evaluated:
  - a. Timing of radiation
  - b. Histomorphometric characteristics
  - c. Biomechanical characteristics
  - d. Histological characteristics

- **2**. A well designed HUMAN observational cohort study that follows a group of similar patients during the same time period. This should be a population of patients who do and do not undergo radiation. Furthermore, this should be a large enough population with enough implantologists that more than one implant type is used in both irradiated and non-irradiated bone. This will allow for the comparison of implants in irradiated and non-irradiated bone with respect to the following outcomes:
  - a. Time to loading
  - b. Implant failure
  - c. Complications
  - d. Implant function
  - e. Overall quality of life

**Role of BOI in the treatment of patients with irradiated bone**

**The following key findings from this literature overview make BOI a potential solution for the management of patients with irradiated bone:**

1. **Patients** are at greater risk of implant failure.
2. **Patients** typically undergo multiple procedures and very prolonged waiting times before loading their implants.
3. **No** implants have been identified from the literature superior for treating patients with irradiated bone.
4. **If** animal studies are successful, this may be an area of indication for BOI to market itself and find its way into the US market.
5. **Furthermore,** if BOI appears indicated for patients with irradiated bone then it may also be assumed it is indicated for all indications of "poor" bone quality or quantity.

**Table 1: Summary of studies comparing implantation in irradiated versus non-irradiated bone: Craniofacial applications.**

| Studies | Study Design | Implant Location | Outcome | Irradiated | Non-irradiated | Effect Size RR (CI)* |
|---|---|---|---|---|---|---|
| Roumanas[1] | Cohort | All | Implant Failure | 40% (14/35) | 12% (21/172) | 3.3 (1.9, 5.8)* |
| Albrekteson[2] | Case series | All | Implant Failure | 15% (4/34) | 1.5% (6/389) | 9.5 (3.1, 29.6)* |
| Granstrom[7] | Case series | All | Implant Failure | 23% (147/631) | 12% (76/614) | 1.9 (1.5, 2.4) * |
| Granstrom[4] | Case series | All | Implant Failure | 54% (79/147) | 12%(12/101) | 4.5 (2.6, 7.9)* |
| Wolfaardt[5] | Case series | All | No Osseointegration | 30.5% (44/144) | 2.5 (31/1221) | 12.0 (7.9, 18.4)* |
| Roumanas[1] | Cohort | Various CF | Implant Failure | 30% (3/10) | 27% (9/33) | 1.1 (0.37, 3,3) |
| Wolfaardt[5] | Case series | Nasal | No Osseointegration | 20% (2/10) | 17% (9/53) | 1.18 (0.29, 4.66) |
| Roumanas1 | Cohort | Auricular | Implant Failure | 0%(0/6) | 4.5 % (5/111) | Incalculable |
| Wolfaardt[5] | Case series | Mastoid | No Osseointegration | 0%(0/10) | 1.7% (9/516) | Incalculable |
| Schoen[8] | Cohort | Orbit | Implant Failure | 11% (4/35) | 0% (0/14) | Incalculable |
| Toljanic[6] | Case series | Orbit | Implant Failure | 34% (31/92) | 24% (21/89) | 1.4 (0.89, 2.29) |
| Wolfaardt§[5] | Case series | Orbit | No Osseointegration | 49% (40/81) | 6.1% (7/115) | 8.1 (3.8, 17.2)* |
| Roumanas[1] | Cohort | Orbit | Implant Failure | 59% (11/19) | 25% (7/28) | 2.3 (1.1, 4.9)* |
| | | | | **Rad + HBO** | **Non-Irradiated** | |
| Granstrom [26] | Case series | All | Implant Failure | 8.1% (8/99) | 13.5% (12/89) | 0.60 (0.26, 1.4) |
| | | | | **Rad + HBO** | **RAD only** | |
| Granstrom [26] | Case series | All | Implant Failure | 8.1% (8/99) | 54% (79/147) | 0.15 (0.7, 0.30)* |
| | | | | **Rad after Implant** | **Non-irradiated** | |
| Schoen[8] | Cohort | Orbit | Implant Failure | 14% (2/14) | 0% (0/14) | Incalculable |
| | | | | **Rad prior to Implant** | **Non-irradiated** | |
| Schoen[8] | Cohort | Orbit | Implant Failure | 9.5% (2/21) | 0% (0/14) | Incalculable |
| | | | | **Rad after Implant** | **Rad prior to Implant** | |
| Schoen[8] | Cohort | Orbit | Implant Failure | 14% (2/14) | 9.5% (2/21) | 1.5 (0.23, 9.4) |
| | | | | **< 50 Gy**** | **≥ 50 Gy** | |
| Toljanic[6] | Case series | Orbit | Implant Failure | 17% (2/12) | 16% (10/61) | 1.0 (0.25, 4.1) |

*Indicates statistically significant findings. Cohort studies compare patients in the same treatment population. Case series compared results to historical controls.
**Gy= Grey

## Table 2. Summary of studies comparing implantation in irradiated versus non-irradiated bone: Dental applications.

| Studies | Study Design | Implant Location | Outcome | Irradiation | Non-irradiation | Effect Size RR (CI)* |
|---|---|---|---|---|---|---|
| Weischer[21] | Cohort | Mandible | Implant Failure | 13.7% (10/73) | 5.7% (5/87) | 2.4 (0.85, 6.6) |
| | | | Wound disturbance | 4.8% (4/83) | 0 (0/92) | Incalculable |
| | | | Peri-implant inflammation | 22.2% (4/18) | 9.0% (2/22) | 2.4 (0.50, 11.9) |
| Weischer[22] | Cohort | Mandible | Implant Failure | 7.0% (4/57) | 6.3% (3/48) | 1.1 (0.26, 4.8) |
| Landes[27] | Cohort | Mandible | Implant Failure | 1.4% (1/72) | 0% (0/42) | incalculable |
| Schepers[28] | Cohort | Mandible | Implant Failure | 3.3% (2/61) | 0% (0/78) | incalculable |
| Esser[29] | Case series | | Implant failure | 16.6% (29/221) | 9.9% (7/71) | 1.3 (0.81, 2.02) |
| | | | Osteoradionecrosis | 3.4% (2/58) | NR | Incalculable |
| | | | Soft Tissue Necrosis | 3.4% (2/58) | NR | Incalculable |
| Cao[17] | Cohort | Maxilla | Implant Failure | 51% (27/53) | 22% (17/78) | 2.3 (1.4, 3.8)* |
| | | | Osteoradionecrosis | 0 (0/53) | 0 (0/78) | 1.0 |
| Ryu[15] | Case series | Mandible | Implant Failure | 30.6% (11/36) | 9.1% (1/11) | 3.4 (1.49, 23.2)* |
| | | | Osteomyelitis or necrosis | 11.1% (4/36) | 0 (n=0/11) | Incalculable |
| | | | Chronic Pain | 2.7% (1/36) | 9.1% (n=1/11) | 0.31 (0.02, 4.5) |
| | | | Complications | 30.6% (11/36) | 27% (n=3/11) | 1.1 (0.38, 3.3) |
| Landes[27] | Cohort | Mandible | Peri-implant inflammation | 3.2% (5/155) | 2.2% (3/134) | 1.4 (.35, 5.9) |
| | | | | **< 1yr post IR** | **≥ 1 year post IR** | |
| Visch[13] | Cohort | HA-Titan screw | Implant Failure | 16.5 %(n=29/175) | 12.9% (n=35/271) | 1.3 (0.81, 2.02) |
| | | | | **< 50 Gy* Dose** | **≥50 Gy Dose** | |
| | | | Implant Failure | 9.2% (19/207) | 18.8% (45/239) | 0.49 (0.29, 0.81)* |
| | | | | **10yr post IR** | | |
| | | | | **Mandible** | **Maxilla** | |
| | | | Implant Failure | 9.2% (31/338) | 30.6% (33/108) | 0.30 (0.19, 0.47)* |
| | | | | **IR > 10 mos post implant** | **IR ≤ 12 wks post implant** | |
| | | | Implant Failure | 0% (n=0/10) | 42.3% (n=11/26) | Incalculable |
| | | | Osteomyelitis or necrosis | 0 (n=0/10) | 15.4% (n=4/26) | Incalculable |
| | | | Chronic Pain | 0 (n=0/10) | 3.8% (n=1/26) | Incalculable |
| | | | Complications | 20% (n=2/10) | 35% (n=9/26) | 0.58 (0.15, 2.2) |

Indicates statistically significant findings
**Gy= Grey
NR=not reported

## APPENDIX II

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## Research in Context – Part VII

**Title: Are the differences between two study groups real and applicable clinically or is it possible possibly they are simply due to chance?**

**Research in Context Question**

In the last edition of Implant Directions, we gave an overview of checking for appropriate analyses when critically reviewing a paper and considering the authors conclusions. For example, were there appropriate analyses that included descriptive statistics, analytic statistics using the primary outcome, ample sample size, and adjustment of potential confounding variables?

We listed the following 4 questions that need to be considered when evaluating the statistical analyses used for testing the hypothesis:

(1) Is the primary outcome used for the statistical analysis?

(2) Is any difference between the groups likely due to chance?

(3) Is the sample size large enough to test the hypothesis adequately?

(4) Are potentially confounding variables considered in the analysis?

The first point is self-explanatory – the authors should include the primary outcome outlined by the study question in the statistical analyses and present these data. It is amazing to see how often an author list the study's goal or objective but does not use an appropriate outcome measure to test this hypothesis. In a previous edition of Implant Directions, we discussed in detail the importance of outcomes measures in dental implant research and how to go about choosing the right one.

The second point relates to the role of chance as an explanation for any observed difference between the study groups. When you look at statistical significance (which is the measure of probability that the results you achieved occurred by chance) remember that statistical significance depends on three parameters:

- Sample size (the larger the sample size, the easier to demonstrate statistical significance; the smaller the sample size the possibility that the observed difference is simply due to chance)
- Variability in patient response, either by chance or by non-random factors (the smaller the variability, the easier to demonstrate statistical significance)
- Effect size, or the magnitude of the observed effect between groups (the greater the size of the effect, the easier to demonstrate statistical significance)

A real world example to address this issue is the published Critical Appraisal (CA) in this edition of Implant Directions evaluating an article by Tarnow, et al. The authors compared patients who had less than or equal to 3 millimeters (mm) of distance between implants to patients who had greater than 3 mm of distance

between implants. They reported a mean of 1.04 mm vertical crestal bone loss in patients (n=25) who had less than or equal to 3 mm distance between implants and a mean of 0.45 mm vertical crestal bone loss in patients (n=11) who had greater than 3 mm between implants. This sample size is very small and therefore this mean difference could be due to chance alone. One would want a much larger sample to make a conclusive statement regarding the cause of crestal bone loss.

One way to determine this would be to compare the groups analytically using a t-test which would reveal whether or not this difference is statistically significant ($p<.05$). This would require the mean values and the variability often reported in terms of the standard deviation. The authors failed to report the standard deviation of these findings. If the variability is small, then it is far more likely this difference is real than a result of chance. However, if the variability is high, with such a small sample size, these differences mean little and conclusions regarding the association of one factor (eg, lateral distance between implants) with another (eg, vertical crestal bone loss) are not warranted.

Lastly, if the differences are great, then fewer subjects are needed. For example, if the mean difference in crestal bone loss was 2 mm or more, then the difference is more likely to be real then a result of chance, assuming the variability is not too large.

It is important when reading a paper that one does not trust the author's conclusions without a critical review. Simple considerations such as those mentioned above, will go along way in helping you make informed clinical decisions.

**The effect of confounding on the comparison of two groups will be discussed in the next edition of Implant Directions.....**

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