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For more than 25 years, the TBR group based its development on an ambitious Research & Development policy. Conscious that quality and innovation are very important, the TBR Group has kept investing in people and means to answer to technological demands.

The Research & Development Department is composed of **dental surgeons, biomechanical engineers and biomedical experts**. Built on solid technological background, the TBR group focuses on values of excellence and innovation and considers its customers and collaborators to be partners in the interest of safety, quality and aesthetics.

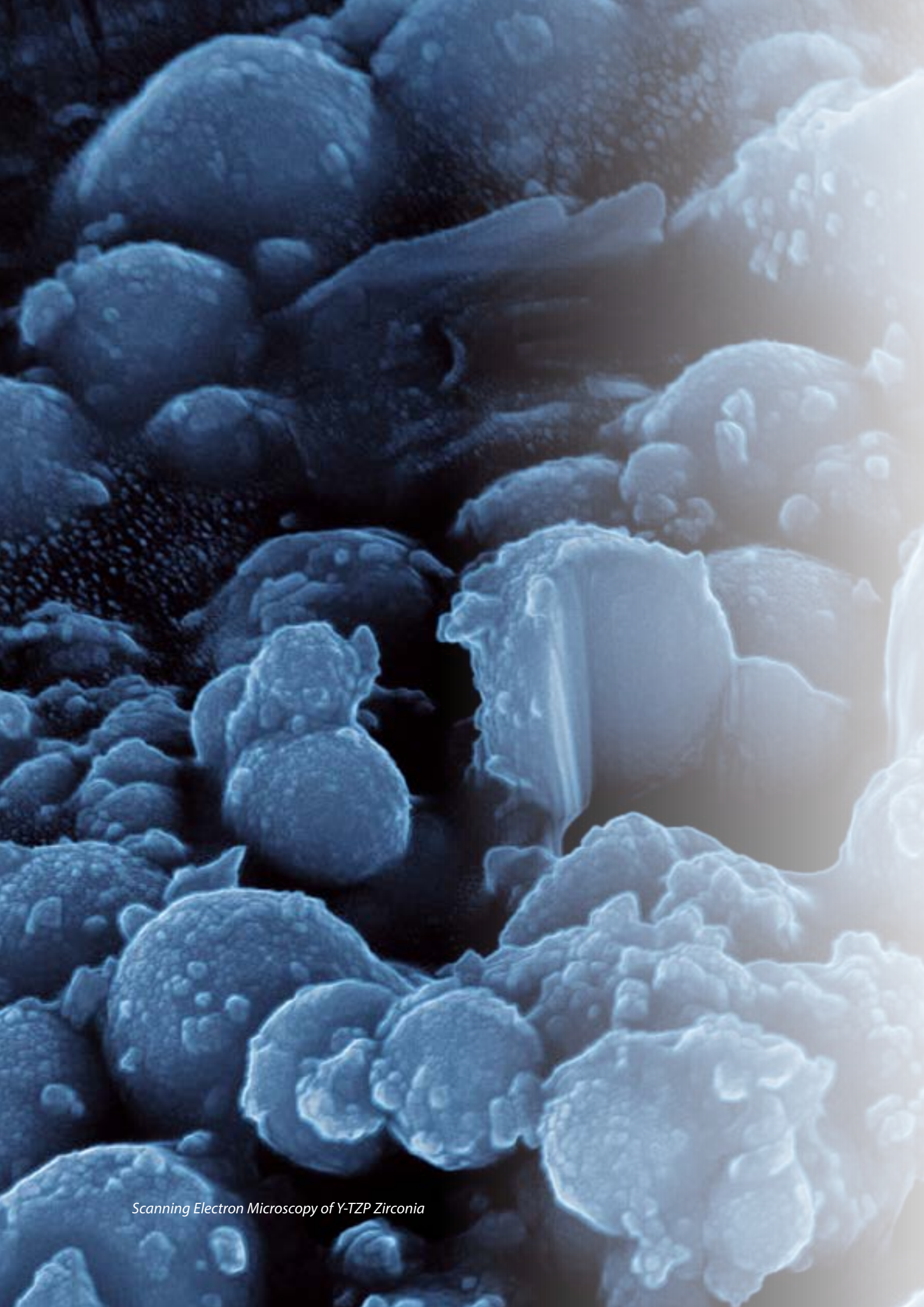
Our mission is to meet the needs of the profession by designing and producing the **most innovative and aesthetic implant system** through the use of the **patented Zirconia Titanium technology**.

You will read in this document our selection of key studies and publications, we hope you really enjoy them."

*TBR Scientific Team*

## SUMMARY

CERAMICS	P	5
SURFACE TREATMENT	P	35
MICROTHREAD	P	63
PROSTHESIS	P	69
TISSUE MANAGEMENT	P	87
SHORT IMPLANTS	P	105
BIOMATERIALS	P	111



*Scanning Electron Microscopy of Y-TZP Zirconia*



# CERAMICS

■	Periosave Z1 implants zirconia-titanium in the subcutaneous tissue of the rat Extract from the report histological	P	6
■	The Zirconia solution: increasing osteoblasts and fibroblasts adhesion and proliferation	P	9
■	The Zirconia solution: favoring peri-implant parameters	P	10
■	Aesthetic benefits of the Zirconia-titanium technology	P	11
■	Periodontal benefits of the zirconia-titanium surface	P	12
■	The Zirconia solution: reducing bacterial proliferation	P	13
■	Collagen Fiber Orientation Around Machined Titanium and Zirconia Dental Implant Necks: An Animal Study	P	14
■	High resistance in a worst-case scenario 3820 N (382kg) Static failure load	P	16
■	TBR Y-TZP zirconia : strategic choice for clinical evidences	P	18
■	Comparative evaluation of the soft tissue response and aesthetics to titanium implants with Zirconia collar and to titanium implants with titanium collar - An In-Vivo Study	P	22
■	Ceramics in implant dentistry (Working Group 1)	P	28
■	Comparison of zirconia and titanium implants after a short healing period. A pilot study in minipigs	P	29
■	Bacterial Adhesion on Commercially Pure Titanium and Zirconium Oxide Disks: An In Vivo Human Study	P	30
■	Zirconia: Established Facts and Perspectives for a Biomaterial in Dental Implantology	P	31
■	Inflammatory Infiltrate, Microvessel Density, Nitric Oxide Synthase Expression, Vascular Endothelial Growth Factor Expression, and Proliferative Activity in Peri-Implant Soft Tissues Around Titanium and Zirconium Oxide Healing Caps	P	32





## SCIENTIFIC STUDIES

# Periosave Z1 implants zirconia-titanium in the subcutaneous tissue of the rat - Extract from the report histological



LEMI (Laboratoire d'études des Matériels Implantables) - France



zirconia-titanium implants, subcutaneous tissue, reducing inflammation phenomena



2011



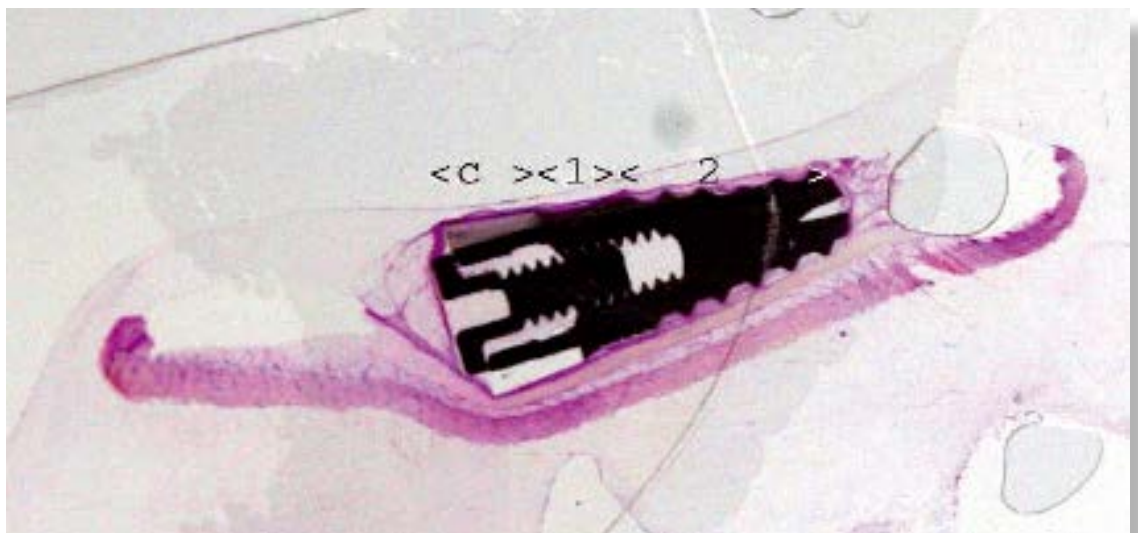
### Materials & method:

10 implants in the subcutaneous tissue of rats in a formalin solution. Washing H2O: 3 weeks in several baths. Dehydration in increasing concentrations of ethanol: 3 weeks. MMA growing suite of solution: 2 weeks. Polymerization of MMA and dibutyl phthalate: 2 weeks. By diamond saw cutting and polishing. Toluidine blue staining. A number of implant (3) were mechanically extracted from the polymer block after cutting to keep one 'intact interface, to be able to thin microtome sections (3μ) and put any foreign objects detected in cells.

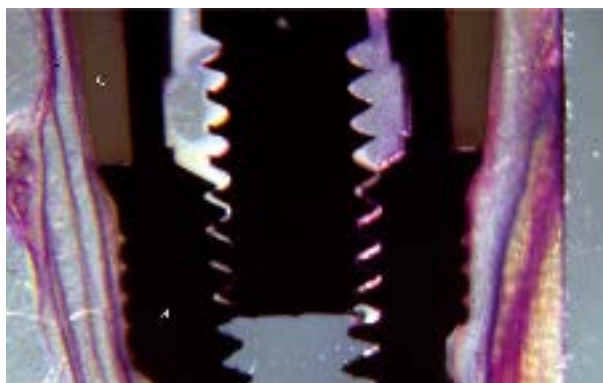
### Macroscopically:

The screws are visible in the subcutaneous tissue. They are firmly attached to the dermis and included in a connective tissue in which they are visible by transparency. The implants were sectioned along their longitudinal axis (FIG. 1).

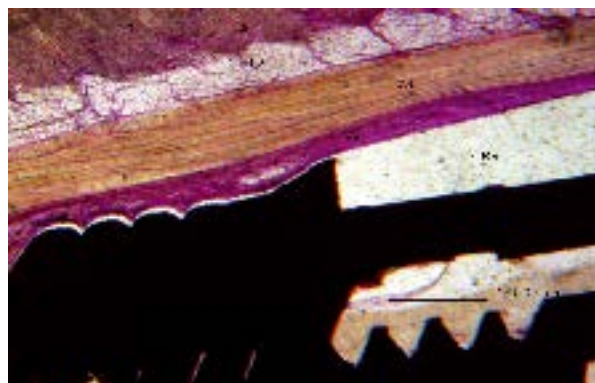
They consist of at least two identifiable to the naked eye different materials. The implant is made of metal and is covered in its proximal portion which appears an amorphous ceramic material. One can thus identify three different areas of interface with the tissue, because of their composition (metal or ceramic) or texture (FIG. 1).



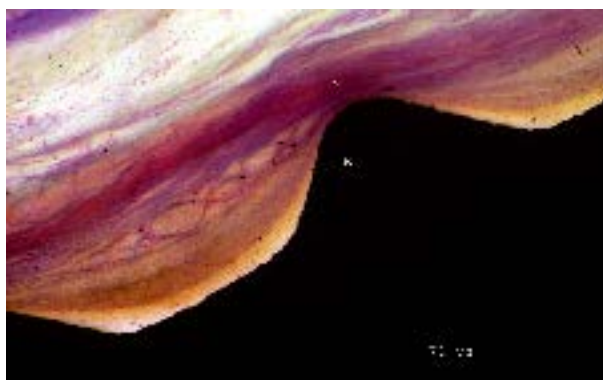
**Figure 1:** Example of a longitudinal section of implant. These are implanted subcutaneously and surrounded by a thin fibrous tissue visible to the naked eye. The black part is probably the lightest metal and ceramic part. There are three different interface areas (C), consisting of the ceramic; (1) and (2) with a machining component of the surface irregularities of different shapes and sizes.



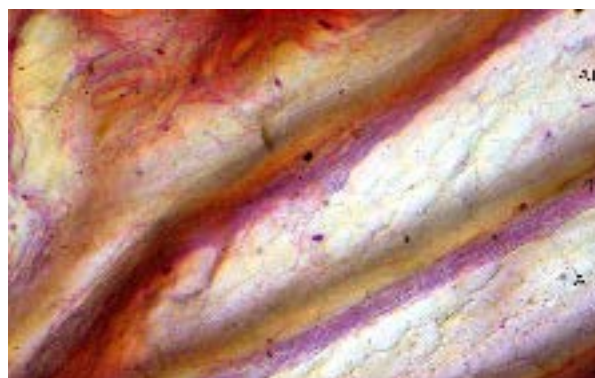
**Figure 2:** Under the microscope, show longitudinal sections, a metallic implant (M) surrounded in its upper part with a ceramic collar C.



**Figure 3:** Under the microscope, the dense fibrous tissue (TF) formed around the implants, which separates it from the facial muscles (FM) is very similar in contact with the ceramic (cer) and metal (black). A low magnification (fig .2, 3) when the cut is perpendicular to the skin, it appears that the implant is separated from the subcutaneous by a plane of muscle fibers (facial muscles) fabric and a plan dense fibrous tissue in contact with different materials constituting the implant creating a tissue encapsulation. There were no differences in the structure of the fibrous web in contact with the different materials at this scale.



**Figure 4:** Cross parallel to the skin surface: the metal (M) has a roughness sanding evoking and is surrounded by a fibrous tissue TF. On parallel cuts in the skin level, the metal is in contact with a connective tissue containing few cells, and formed by successive layers of fibrous tissue layers separated by adipocytes (Figure 4, 5).



**Figure 5:** The connective tissue surrounding the implant is multilaminar alternating fiber layers (TF) and the layers formed of adipocytes (ADP). The ceramic collar is in contact with a fibrous web of less than that in contact with the metal surface thickness.

### Conclusions:

Microtome sections ( $3\mu$ ) after removal of the implant used to better characterize the tissue reaction to the contact of the implant by the wear sections. Wear on the cuts by the tissue reaction appears relatively homogeneous and does not allow to distinguish differences in cell populations in contact with the implant. On thin sections, it can be noted the presence of a large number of macrophages and giant cells in contact with the metal portion of the implant, which indicates a characteristic foreign body reaction. At the ceramic, there is a dense connective tissue membrane but relatively less thick than the metal level present in perfect continuity with the latter. It contains fewer cells and macrophages. Additionally it may be noted the absence of a giant cell reaction signing of lesser intensity.

In conclusion, the presence of the ceramic appears to limit the foreign body reaction induced by the metal. Ceramics thus limit the phenomena of inflammation and thus protects the gum tissue comparable to subcutaneous tissue.





## SCIENTIFIC STUDIES

# The Zirconia solution: increasing osteoblasts and fibroblasts adhesion and proliferation



Drs A.E. BIANCHI, M.BOSETTI, G. DOCI, M.T. SBERNA, F.SANFILIPPO, M. CANNAS



zirconia collar, adhesion, proliferation, osteoblasts, fibroblasts



November 2004



### SUMMARY

#### Aim

In vitro comparative study of human fibroblasts and osteoblasts proliferation and adhesion on implants made of titanium, titanium with a zirconia collar (TBR® Z1) and on a polymeric substrate Thermanox.

#### Materials and Methods

The materials used in this study were tetragonal stabilized with yttrium oxide (Y-TZP) zirconia and titanium disks of 0.4cm diameter sterilized for 2 hours at 160°C. 3-5 mm particles, after treatment were plated in tissue culture at 37°C in 95% air/5% CO<sub>2</sub> in 10 mL Iscove's supplemented with 20% FBS, 50 U/mL penicilin, 15 µg/mL streptomycine and 2 mM glutamine. Cell adhesion and proliferation results were compared to that obtained on a polymeric substrate used as a control (Thermanox slides, Nunc, Milano, Italy) known to induce cell adhesion. Cell morphology and the number on each material were evaluated using a fluorescent microscope Aristoplan (Leitz Leica, Milano, Italy).

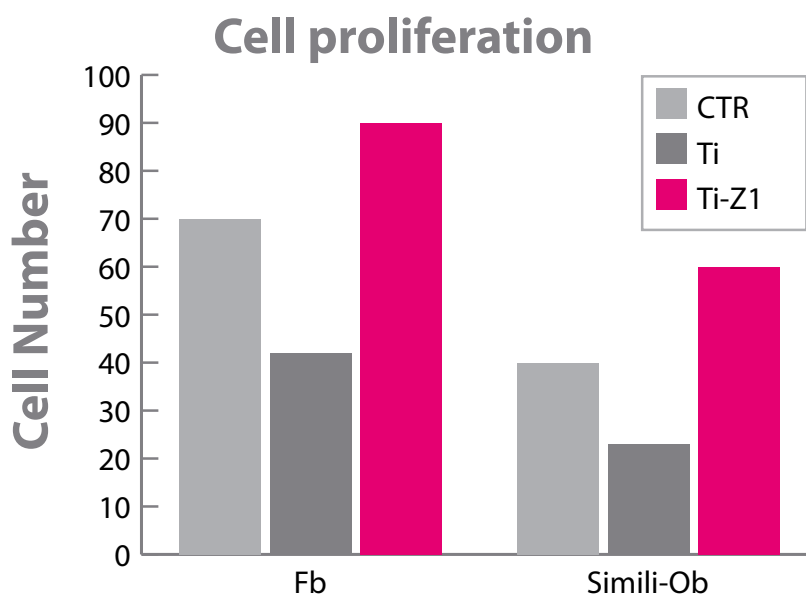
#### Results

As shown in Fig (1), fibroblasts and osteoblast-like cells indicate statistically higher cell adhesion when cultured on zirconia coated titanium compared to the controls (Thermanox slides) and compared to the uncoated titanium material. Results revealed increased cell numbers on the titanium and zirconia coated titanium with respect to the adhesion experiments.

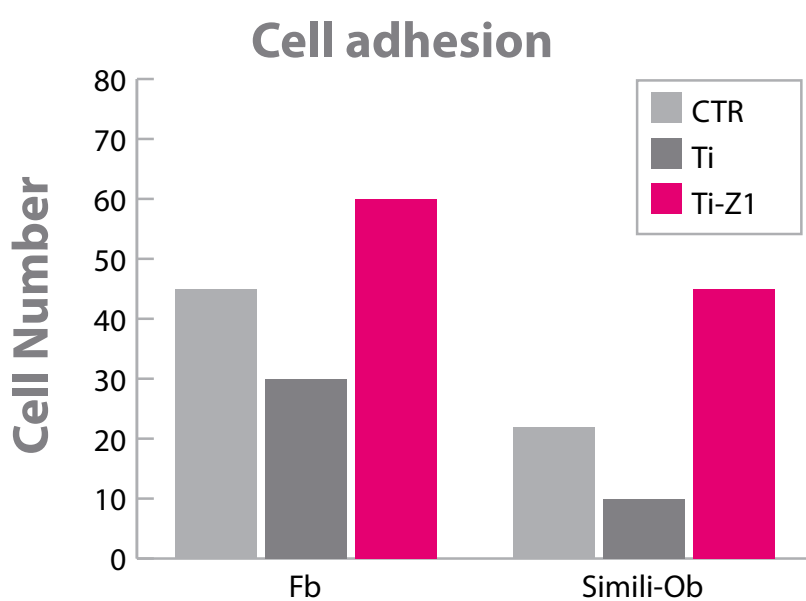
#### Discussion and conclusion

In vitro tests demonstrated that zirconia coated titanium, compared to titanium, enhances fibroblasts and, particularly, osteoblast-like cell adhesion, spreading and proliferation, favoring microscopic tissue/cell in growth and clinical implant fixation improvement (see study in vivo JABB).





**Fig(1)** – Fibroblasts and osteoblast-like cells quantification at 6 hr cell incubation (adhesion test) on titanium (Ti), zirconia coated titanium (Ti-Zi) and on control Thermanox slide (CTR).



**Fig(2)** – Fibroblasts and osteoblast-like cells quantification at 4 days of incubation (adhesion test) on titanium (Ti), zirconia coated titanium (Ti-Zi) and on control Thermanox slide (CTR).





## SCIENTIFIC STUDIES

# The Zirconia solution: favoring peri-implant parameters



Drs A.E. BIANCHI, M. BOSETTI, G. DOCI, M.T. SBERNA, F. SANFILIPPO, M. CANNAS



zirconia collar, plaque index, distance implant-shoulder to bone, probing depth, probing attachment level



November 2004



## SUMMARY

### Aim

In vivo comparative study on the peri-implant parameters of one-stage implants with a zirconia collar (TBR® Z1), in contrast to the same shape implants with a titanium collar.

### Materials and Methods

A 2-yr randomized study was performed from 2000-2002 on 20 patients. A total of 44 implants were placed (24 in the maxilla and 20 in the mandible): 29 implants in 13 patients had zirconia collar TBR® Z1 (treatment) and 15 implants with the same shape in 5 patients had standard titanium collars (control). The remaining two patients were implanted with both implants. The implants were loaded at 3-4 months after their placement.

### Results

- Plaque index (PLI): This index is used to measure the level of the patient's oral hygiene performance; it confirms the quantity of bacterial deposits around the implant emerging from soft tissues. value 0 = no plaque deposit, value 1 = small plaque deposit, value 2 = large plaque deposits.
- Distance Implant-shoulder to Bone (DIB): When the DIB value < 3.5 mm, peri-implant bone is considered stable, > 3.5 mm bone crest resorption has occurred.
- Bleeding on probing (BOP): This index is used to measure inflammation level of the mucosal tissues in response to peri-implant sulcus probing. Value 0 = no bleeding occurred during the probing, value 1 = small mucosal bleeding occurred, value 2 = significant bleeding occurred, value 3 = spontaneous bleeding even if the mucosal sulcus has not been probed.
- Probing Depth (PD): this index measures the mucosal sulcus depth around the implant. When the PD value is < 3 mm, peri-implant tissues are considered healthy, > 3 mm mucosal pathology has occurred.
- Probing Attachment Level (PAL): PAL is related to the implant shoulder. When the PAL is < 2.5 mm, peri-implant tissues are considered healthy, > 2.5mm mucosal pathology and bone resorption have occurred.

### Discussion and conclusion

From clinical analysis (Table I and II), it emerged that the TBR® Z1 treatment group obtained better scores in every peri-implant parameter.

TABLE I - PLI and BOP indexes, Percentage of mean values at last control

	Collar	Value 0	Value 1	Value 2
PLI	Zirconia	72	24	4
	Titanium	50	40	10
BOP	Zirconia	88.9	8.3	2.8
	Titanium	53.3	36.7	10

Mean values of PLI and BOP were significantly lower in treatment group

TABLE II - Peri-implant measures related to observation period (mm)

	Collar	Time period 0 month	Time period 6 month	Time period 12 month	Time period 24 month
PD	Zirconia	2.3	2.8	3	2.5
	Titanium	2.8	3.2	3.4	3.3
PAL	Zirconia	1.8	2	2.1	0.5
	Titanium	2.2	2.2	2.3	2.6
DIB	Zirconia	3	3	3.2	3
	Titanium	3	3.2	3.6	3.4

Mean peri-implant values were lower in treatment group during interval

# Aesthetic benefits of the Zirconia-titanium technology



TBR Research Center



zirconia, aesthetic, peri-implant soft tissue, creeping attachment



October 2005



## SUMMARY

### Aim

There is an abundance of scientific publications that supports the osseointegration of titanium implants in the oral cavity. Greater detail is now on the treatment planning of all dental implant cases with a strong emphasis in the anterior area. The peri-implant gingival shape is essential in obtaining the optimal esthetic results. Zirconia materials are contributing in the efforts of achieving biologic and esthetic success.

### Results

The parameters to take into account in the relationship between the peri-implant soft tissues and the esthetic result are: the smile line, peri-implant tissue thickness, the shape and the similarity of the necks and the cervical limits of the implant supported prosthesis. The smile line and the thickness of the peri-implant tissue are very varied from one patient to another. Two zirconia collar heights are available and are adapted to most of the clinical cases. When using a conventional one-stage titanium implant system in the anterior area, the clinician is often faced with thin gingiva to work with and the grey titanium collar may appear through it. This presents an unacceptable esthetic result for the clinician and patient. If an esthetic result is required, using an implant with a zirconia collar will prevent the appearance of the metal through the soft tissues or even if a recession occurred, the implant looks like a natural root. Furthermore, The coronal repositioning of the gingival margin and the spontaneous reconstruction of the gingival papilla are systematically observed around the zirconia-titanium surface of the Z1-conic implant (see Fig.1 and Fig.2)

### Conclusion

A link exists between the respect of the periodontal demands and successful esthetic results. The zirconia-titanium technology is the solution to all these requirements.



Fig 1: d = 0



Fig 2: d = 6 months / j = 6 mois





## SCIENTIFIC STUDIES

# Periodontal benefits of the zirconia-titanium surface



TBR Research Center



zirconia, soft tissue, peri-implant gingiva junction



Spring 2005



## SUMMARY

### Aim

The peri-implant gingiva junction represents an important aspect in peri-implant tissue integration. It constitutes a barrier between the septic buccal area and the internal area. The aim of this study, is to evaluate the Titanium-Soft tissue relation.

### Evaluation Scheme

- Gingival extraction: palatine slope of the gingiva-implant sulcus
- Implant system: TBR Z1
- Post-implantation time lapse: 6 months
- Extraction coloring: eosin-hematein
- Number of studied histological analysis points : 3
- Analysis tool type: optical microscopy.

### Conclusion

The relationship Titanium-gingiva is a non physiological specific relationship because it is the result of a surgical act a bringing into play an exogenous material. However, with the zirconia, this interface presents a number of histological analogies with the natural dento-tissue gingiva interface. The coronal repositioning of the marginal gingiva and the spontaneous reconstruction of the gingival papilla are systematically observed around the zirconia-titanium surface of the Z1 implant.



### Analysis point 1

Structure of the external part of the gingiva-implant sulcus. Refers to surface epithelial leucokeratine, a classic case in this area.



### Analysis point 2

Internal side of the peri-implant sulcus. The presence of a keratine free sulcate epithelial is observed: there exists a prominent histological analogy between the dento-gingiva sulcus and the gingiva-implant sulcus.



### Analysis point 3

Connective Tissue. Disappearance of the epithelial tissue and presence of a connective protective tube that helps set the cervical area of the implant.



# The Zirconia solution: reducing bacterial proliferation



Drs L. RIMONDINI, L. CERRONI, A. CARASSI, P. TORRICELLI



zirconia, titanium, soft tissue, bacterial adhesion



November 2002



## SUMMARY

### Aim

Assessment of microbial colonization on new ceramics developed for abutment manufacturing.

### Materials and Methods

The materials used in these experiments were «as-fired» and «rectified» ceramic disks made of tetragonal zirconia polycrystals stabilized with yttrium (Y-TZP) and commercially pure grade 2 Titanium (Ti). Discs were tested in vitro and with eluates containing the following bacteria: *Streptococcus mutans*, *S. sanguis*, *Actinomyces viscosus*, *A. naeslundii*, and *Porphyromonas gingivalis*. Proliferation was evaluated on agar containing via observation of inhibitory halos around the shafts. Bacterial adhesion on materials was quantified by spectrophotometric evaluation of exudate production by the same bacteria. Early bacterial adhesion was evaluated in human volunteers and observed using SEM.

### Results

No inhibition of bacterial proliferation using eluates was observed. In vitro examinations on as-fired and rectified Y-TZP ceramics showed poor bacteria accumulation versus Ti, as well as less total number of bacteria and lessened presence of potential putative pathogenic bacteria, such as stick bacteria. We observed no difference between the as-fired ceramic and rectified ceramics.

### Discussion

Y-TZP zirconia accumulates fewer bacteria than Ti.

### Conclusion

Y-TZP zirconia may be considered as a promising material for abutment manufacturing.

**The Zirconia surface shows fewer bacterial accumulation than the Titanium surface.**



**Zirconia (Y-TZP)**

SEM Micrograph of bacteria colonizing a Zirconia surface (magnification X 6000)



**Titanium (Ti)**

SEM Micrograph of bacteria colonizing Titanium surface (magnification X 6000)





## SCIENTIFIC STUDIES

# Collagen Fiber Orientation Around Machined Titanium and Zirconia Dental Implant Necks: An Animal Study



Stefano Tetè, Filiberto Mastrangelo, Andrea Bianchi, Vincenzo Zizzari, Antonio Scarano



collagen fiber orientation, dental implants, machined titanium neck, zirconia neck



2009

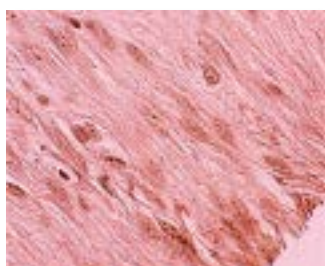
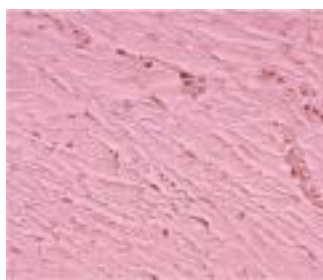
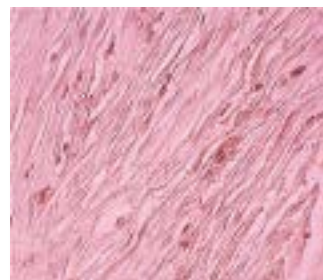
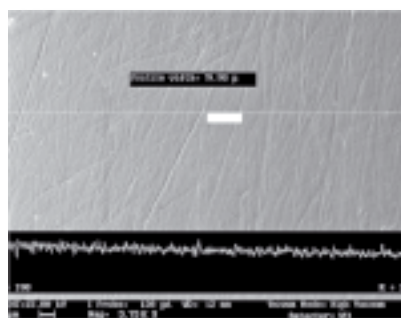
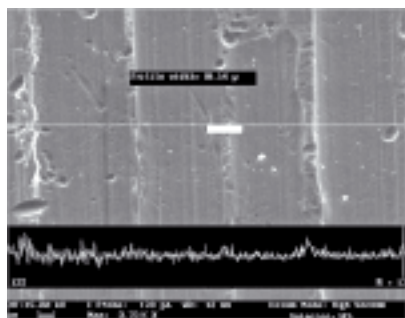


**Purpose:** To evaluate in vivo collagen fiber behavior around two different dental implant necks placed in the mandibular bone of adult pigs.

**Materials and Methods:** Scanning electron microscopic (SEM) and profilometric analyses were performed on both types of implant necks to evaluate the different surface morphology. Ten dental implants with machined titanium necks and 20 implants with zirconia necks were inserted into the mandibles of five adult pigs. Three months later, the animals were sacrificed; samples from the peri-implant mucosa were obtained and prepared for histologic analysis. Evaluation of collagen fiber orientation in the connective tissue surrounding the implant necks was performed by polarized light microscopy. Inflammation in the peri-implant soft tissues was also measured via the Gingival Index.

**Results:** Postoperative healing was uneventful; all implants, except for one of each type, were osseointegrated after 3 months. SEM and profilometric analyses confirmed that zirconia necks showed Ra, Rq, and Rz values that were lower than those seen around the titanium necks. Histologic observation indicated that collagen fiber orientation was similar for both types of implants. The majority of fibers showed a parallel or parallel-oblique orientation to the implant surface for all samples. Implants that were not osseointegrated, as determined by clinical evaluation, showed inflammatory infiltrate, whereas healthy connective tissue was found around all the other implant necks.

**Conclusions:** Collagen fiber orientation was similar, regardless of implant material, demonstrating a predominantly parallel or parallel-oblique pattern. Moreover, zirconia, which is used as a transgingival collar on some implants, showed connective tissue adhesion that was similar to that seen on the machined titanium surface, but demonstrated limited plaque formation and may provide better esthetics.





## SCIENTIFIC STUDIES

# High resistance in a worst-case scenario 3820 N (382kg) Static failure load



French Ministry of Defence CERAH Labs / TBR Research Center



zirconia-titanium implants, mechanical resistance



March 2004 ?



## SUMMARY

### Aim

The maximal occlusal forces are commonly established at around 45 to 68 kg (450 to 680N) for a male adult. (according to Drs Nahmani, and Belilty). To check the resistance of its implants, SUDIMPLANT has performed mechanicals tests following both ISO 14801 and FDA requirements. Tests were run in collaboration with CERAH Laboratories (accredited COFRAH).

### Materials and Methods

NOTE : all tests have been carried out for a worst-case scenario, i.e.:

- Smallest diameter and shortest implant (3,5x8mm, 2.5mm-height Zirconia collar, No ZBC308)
- most angulated abutment (25°, No ZC-MT002)
- 10° additional angulation (total angulation: 35°)
- 3mm simulated bone resorption

This extreme situation suggest the minimal resistance of the system. Any other configuration (wider diameter, longer implant,...) should provide a greater resistance.

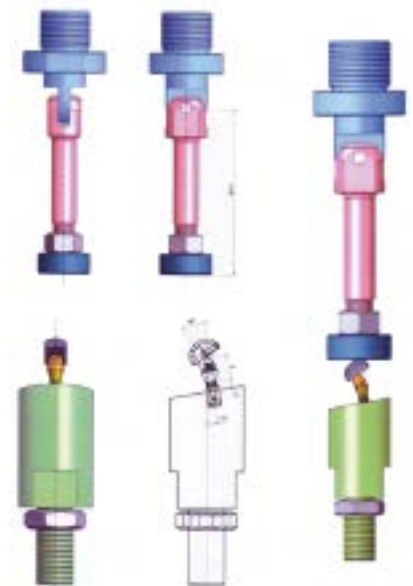
Implants are sealed with an Epoxy resin (tensile modulus of elasticity: 3,5-3,9 GPa). Testing was conducted in air.

5 samples were subject to static break test. Implants were gradually loaded at 50N/s loading speed until the sample break.

### Results

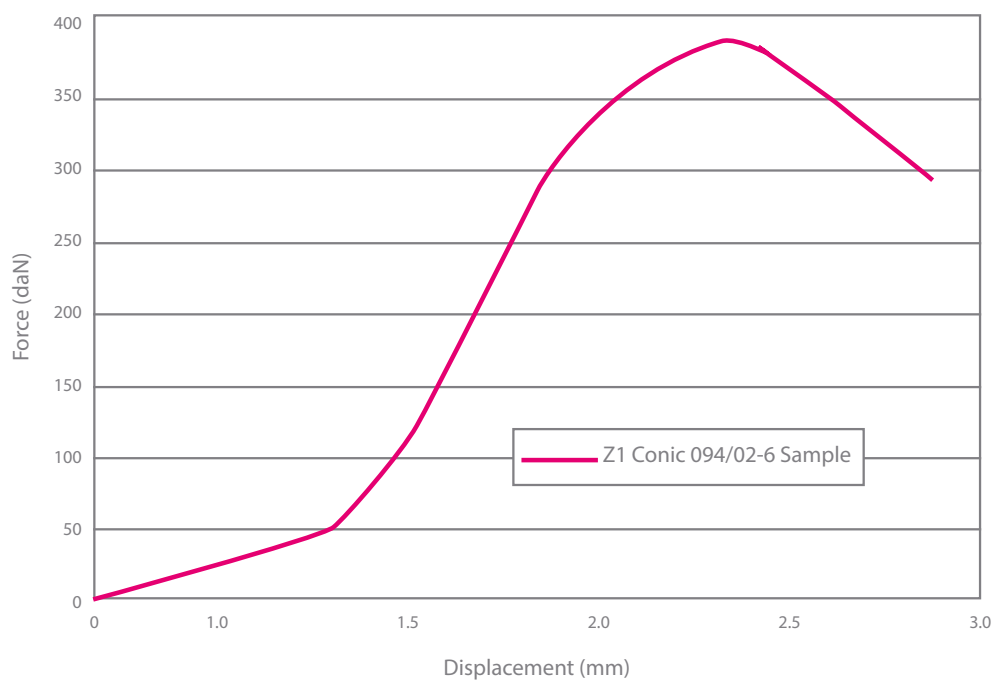
The mean value of the 5 tests was equal to 3820N (382 kg) with a standard deviation of 633N. The maximal value was equal to 4599N and the minima at 3040N.

All breaks appeared at the same place: at the beginning of the intra-osseous thread (as shown on the picture above).



*Schematic of test set-up*





**Load-displacement curve :  
break at 3840N of sample 094/02-6**



**Sample after breaking** – All breaks occurred at the same place on the implant body (at the beginning of intra-osseous thread)





## SCIENTIFIC STUDIES

# TBR Y-TZP Zirconia : Strategic Choice For Clinical Evidences



TBR Research Center



Y-TZP zirconia, features, benefits



June 2010



Odontology is one of the surgical disciplines using the largest panel of biomaterials. However, owing to their different physical and chemical structures and properties, these materials present significant advantages for particular applications. One of these biomaterials is ceramics. Therefore, it is important to distinguish the different types of ceramics available in the dental universe. They are characterized as technical ceramics, mostly oxides : aluminum oxides, zirconium oxides. Y-TZP zirconia used by TBR has properties particularly adapted to the behavior of biological tissues. TBR Y-TZP zirconia is made of 100% metastable tetragonal zirconium oxyde polycrystals. This structure is obtained by adding 2 to 3 mol % of Yttrium oxides ( $Y_2O_3$ ) known for its "stabilizing" action (note : Zirconium as well as Yttrium are transition metals listed on the Mendeliev periodic classification of elements). The addition of a stabilizing agent is essential to obtain a polycrystal with a perfectly stable structure. Indeed, zirconia undergoes a crystallographic evolution depending on its temperature. During its shaping and chilling, between 1000°C and 1100°C, the tetragonal phase transforms into a monoclinic one. This crystallographic transformation includes a 3% volume variation that could damage the material. Due to pure zirconia characteristics, the addition of an additive (doping substances as Yttrium oxides  $Y_2O_3$ ) is therefore important to stabilize the cubic or tetragonal shaped zirconia at room temperature. So yttrium oxide increases zirconia's toughness and prevents possible cracks from spreading. In addition to a high degree of biocompatibility, TBR Y-TZP ceramics possess chemical, physical, mechanical and thermal fundamental properties, which are of high interest for dental implantology. This ceramic received the ISO 13 356 and the American Society for Testing and Materials (ASTM F1873) certifications.

## INNOVATING DISCOVERY : Y-TZP ZIRCONIA'S CHEMICAL STRUCTURES

### ZIRCONIA, ONE SMOOTH MATERIAL

The material roughness, i.e. presents more or less asperities on its surface, is an important property to take into consideration. The more its roughness is small, or the smoother the surface, and the more its periodontal relevance increases : zirconia's smooth surface, combined with its electrical inertness, induces less bacterial plaque anchoring sites and enhances hygiene, important factor for periodontal maintenance especially during prosthetic rehabilitation on implants. Zirconia's roughness depends on various factors : its grain size, its density, as well as its porosity.

### TBR Y-TZP ZIRCONIA MECHANICAL PROPERTIES

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### ZIRCONIA, ONE SMOOTH MATERIAL

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#### - ZIRCONIA'S GRAIN SIZE

The grain size of Y-TZP zirconia is one of the most important factors influencing zirconia's roughness. The size of TBR Group's zirconia grain is  $0.36\text{ }\mu\text{m}$  less than  $0.6\text{ }\mu\text{m}$ . This grading offers a very smooth surface topography, with a significant, favourable impact on the gingival integration of the TBR zirconia.

#### - ZIRCONIA'S DENSITY

Sintering zirconia allows short and strong atomic bonds, hence an elasticity modulus (i.e. Young modulus) in the order of 200 GPa implying high density and toughness of the material. The density of TBR Y-TZP is  $6.07\text{ g/cm}^3$ , real close to the ideal value which is  $6.1\text{ g/cm}^3$ . However, the more the density of zirconia is close to this value, the less space there is between the grains and the smoother the surface/the more the roughness is low.

#### - ZIRCONIA POROSITY

The porous characteristic of zirconia is per se related to its density. It has been proven that the density of this material is very close to its ideal value. Its porosity is therefore close to 0, allowing to obtain the smallest roughness/smoothest surface possible. The perfectly smooth surface topography of zirconia stops bacterial plaque adhesion.

### MECHANICAL BEHAVIOUR EVIDENCES

The knowledge of material science is essential to be able to develop a product designed to integrate a biological organism. The way materials such as Y-TZP zirconia deform must be therefore perfectly predictable. Its high mechanical performance, that is the ability to conserve its shape and dimensions under mechanical solicitation, is chiefly the result of its density, its grain size, and its crystallin structure following the chemical phenomenon of yttrium oxide stabilization. Its characteristics (crystallin structure, density, and grain size) give zirconia a relatively important ductility for a technical ceramic. Indeed, a material which is too hard will not resist cracking propagation and chocks whereas a ductile material will. Plastic distortions of the material will absorb part of the distortion energy and failure will then be delayed. [6] Kohal and al. scientific studies (2006) and those of Andreoitelli and al. (2009) regarding Y-TZP zirconia resistance to failure, have shown that this material resists occlusion forces. More precisely, Zembic and al. proved that no alterations of the implant-carried crown in zirconia occur when placed on Y-TZP zirconia abutments, as opposed to the same type of crown but placed on a titanium abutment (20% alterations).





## SCIENTIFIC STUDIES

Further more, Y-TZP zirconia resists to flexion mechanical phenomenon. Its resistance is in the order of 1000 MPa, i.e. almost 1.5 times higher than some technical ceramics (zirconium oxides) and almost twice as high than alumina oxides. [5] [6] [7] [8] [10] On the other hand, the per se properties of Y-TZP zirconia allow very high resistance to compression, compared to titanium, it is in the order of 4900 Mpa. Its dense submicron crystallin structure enables this material to resist to friction, thus to wear well. [5] [7]

### ZIRCONIA'S SHAPING PROCESSES

Each parameter of TBR® Y-TZP zirconia manufacturing and shaping processes are perfectly controlled in order to give it maximum stability, that is a microstructure, ideal physical-chemical properties and recognized mechanical properties. [7] [8] TBR® Y-TZP zirconia is created using the sintering process, one of the methods that ables to achieve technical ceramics and mechanical piece prototypes. Although, there is no exact definition of the sintering process, it can be simply described as a material strengthening thermal processing technique.

TBR® Y-TZP zirconia grain size and density are dependent on the sentering conditions. Moreover, the use of Hot Isostatic Pressing (HIP) prior to sintering favors considerably the microstructure and properties (wearing, constraint to failure) of bio ceramics currently used in the dental field (alumina and zirconia). [4] [8]

### ZIRCONIA, A MATERIAL FAVORING GINGIVAL INTEGRATION

Thanks to its biocompatiblity, Y-TZP zirconia of the TBR® hybrid zirconia-titanium implant is well tolerated by soft tissues, improving long-terme peri-implant soft tissue stability.

[9] More precisely, TBR Y-TZP zirconia enhances fibroblasts and osteoblasts proliferation compared to titanium. 2 years after implantation, the margin tissue is more stable around zirconia than around titanium. [5] [8] [9] [11] [15]

The physical characteristics of the material also serve to significantly reduce bacterial colonization, plaque formation, and inflammatory risk, compared to titanium. [5] [8] [9] [11] [12] [13] [14] [15]

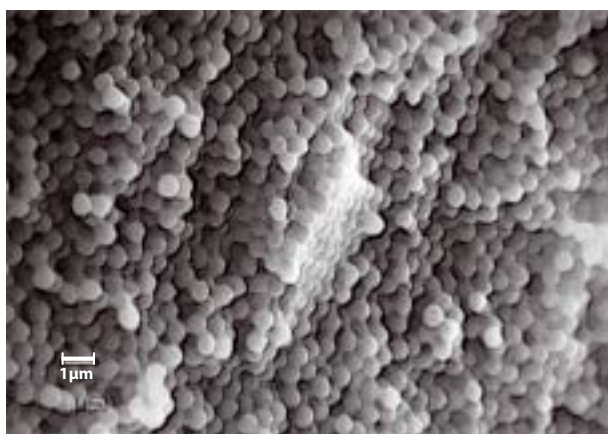
### ZIRCONIA, SYNONYM OF ESTHETIC SUCCESS OF IMPLANT AND PROSTHETIC RESTORATIONS.

Esthetically speaking, the clinical use of TBR 1-stage surgical hybrid implants composed of a zirconia collar or TBR® 2-stage surgical implants with TBR® standard or personalized zirconia abutments, results in an appearance comparable to natural teeth. This esthetic appearance is even more convincing in cases of thin periodont, which are unable to mask the shinning titanium metal of conventional abutments, nor to ensure long-term stability of peri-implant tissue's structures. [6] Generally speaking, non-submerged implantation techniques (1-stage surgical operating technique) are favored because they present significant advantages, from a clinical point of view. However, 1-stage surgical operating procedures using titanium-only implants are unsuitable for esthetic restoration reasons. [16] [17] [18] The development of the TBR® hybrid zirconia-titanium implant fulfils the requirements of each type of tissues: the zirconia for gingival integration and titanium for bone integration. As a result it enables the use of non-submerged techniques will still fulfilling esthetic imperatives. [8]

TBR® Y-TZP zirconia is therefore the archetypal material in implantology, for use in the implant- soft tissue relations because of its esthetic and periodontal qualities.



Zirconia is the ideal matter when used as a transgingival emergence. Following research on zirconia, the TBR Group combined its qualities to titanium and created the first hybrid implant composed of a titanium body designed for osseointegration and a zirconia collar designed for gingival integration. From a clinical point of view, the ideal combination of these two materials, each with their distinct properties, answers the different needs of each tissue composing the periodont. The trend in the technological evolution in the prosthetic field is to a new sort of personalized prosthesis (unique, manufactured according to the clinical case constraint to take into account) entirely made of Y-TZP zirconia. The esthetic and technical optimization of this material is brought out by the launching of the new TBR CAD/CAM line (implant abutments, coppings and customized bridges).



*Scanning Electron Microscope of Yttria-Tetragonal Zirconia Polycrystal*



*Yttria-Tetragonal Zirconia Polycrystal dental block*





## SCIENTIFIC STUDIES

# Comparative evaluation of the soft tissue response and aesthetics to titanium implants with Zirconia collar and to titanium implants with titanium collar - An In-Vivo Study.



DR. SHALINI SURYAVANSHI , Dr. MAHESH VERMA,



zirconia, titanium, soft tissue response, gingival index score, plaque index, MSB index, probing depth, aesthetics



March 2014



The present clinical trial was carried out in the Department of Prosthodontics, Crown and Bridge, Maulana Azad Institute of Dental Sciences, New Delhi, to evaluate the soft tissue response and aesthetics to titanium implants with zirconia collar and to titanium collar.

The sample comprised of 10 subjects of either sex belonging to the age group of 18-55 years. The subjects with two teeth missing within the same arch were included in the study. The patients selected for the present study were examined clinically and radiographically.

In the study a total of 20 two-piece, one-stage implants, i.e. 10 titanium implants with zirconia collar (Periosave, Z1 Conic, TBR Implants Group, France) and 10 titanium implants with titanium collar (Osstem, SSII) were placed. Both types of implants were placed in the same patient and at the same point of time to remove the subjective bias.

The following indices were carried out to analyse the soft tissue response:

1. Gingival index (Loe H and Silness J, 1963)
2. Plaque index (Sillness P and Loe H, 1964)
3. Modified Sulcular Bleeding index (Mombelli A, 1987)
4. Probing Depth

The soft tissue indices were carried out at the following intervals:

- 6 weeks after implant placement.
- 3 months after implant placement.
- 1 month after prosthetic loading.
- 3 months after prosthetic loading.

The aesthetic evaluation was done using the Visual Analog Scale (VAS) 3 months after prosthetic loading.  
Clinical Observation

Twenty implants were placed in ten subjects. All the implants osseointegrated successfully and no implant failed during the course of the study. Soft tissue healing was found to be satisfactory around all the inserted implants.

### Statistical Analysis

Descriptive statistics including mean value and standard deviation were used to compare the gingival index, plaque index, modified sulcular bleeding index, periodontal pocket depth and aesthetics of zirconia and titanium collar implants. All calculations were performed using the SPSS (Version 14) for windows (SPSS Inc., Chicago IL, USA).

#### GINGIVAL INDEX:

Gingival index was measured using the method given by Loe and Silness (1963). The mean values of the gingival index at different intervals of time are arranged in Table 1. The gingival index of the zirconia and titanium collar implants were compared using the INDEPENDENT t-test.

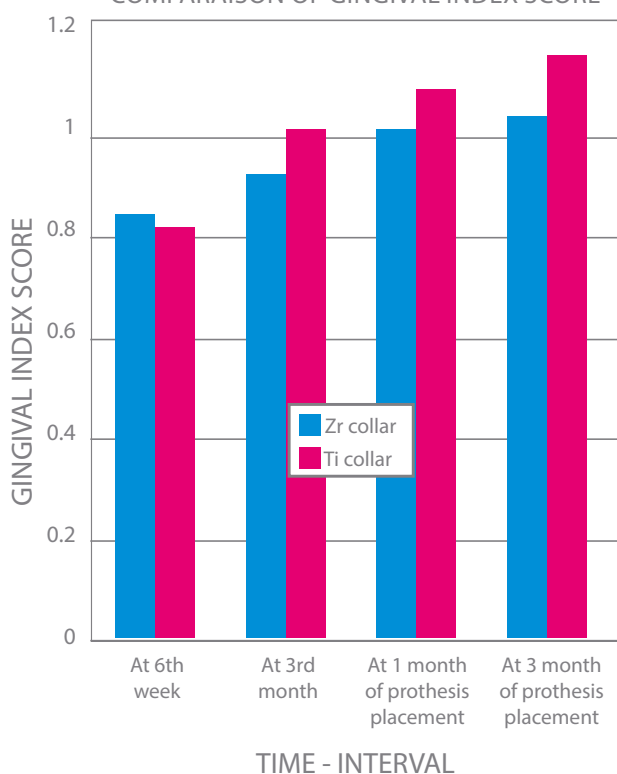
**Table 1: Mean comparison of Gingival index**

Group	Zr collar implant (N = 10)		Ti collar implant (N = 10)		Sig. (p-value)
	Mean	Std. Deviation	Mean	Std. Deviation	
Gingival index (at 6th week of implant placement)	0.875	0.626	0.85	0.556	0.926
Gingival index (at 3rd month of implant placement)	0.95	0.524	1.05	0.705	0.723
Gingival index (after 1 month of prosthesis)	1.025	0.558	1.1	0.592	0.774
Gingival index (after 3 months of prosthesis)	1.05	0.643	1.175	0.602	0.659

(p-value >0.05=insignificant; p-value <0.05= significant)

An increase in the gingival index score amongst both groups, however, was found after each follow-up. The values of this score were comparatively higher in the implants with zirconia collar.

#### COMPARAISON OF GINGIVAL INDEX SCORE



**Graph 1: Comparison of Gingival Index Scores between the implants with zirconia collar and the implants with titanium collar**





## SCIENTIFIC STUDIES

### PLAQUE INDEX:

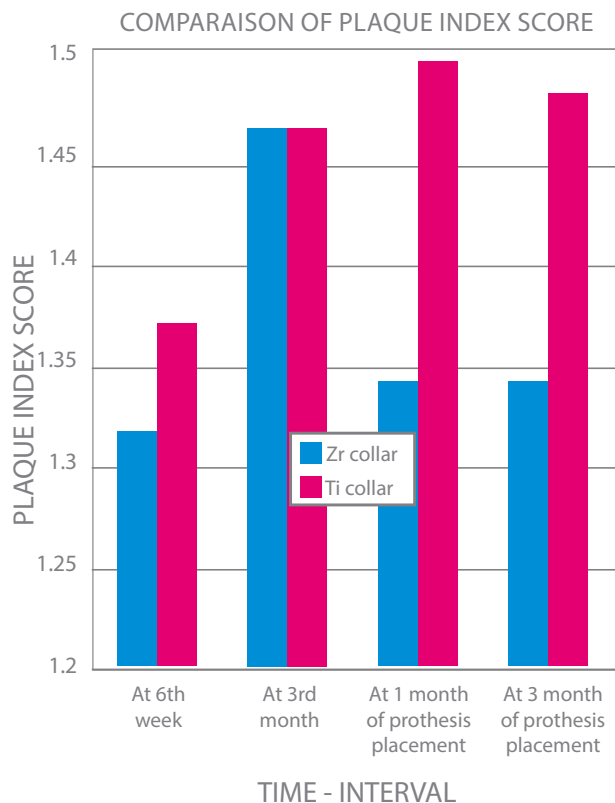
Plaque index was evaluated using the index given by Sillness P. and Loe H.(1964).The mean values of the plaque index at different intervals of time are arranged in Table 2. The plaque index of the zirconia and titanium collar implants were compared using the INDEPENDENT t-test.

**Table 2: Mean comparison of Plaque index**

Group	Zr collar implant (N = 10)		Ti collar implant (N = 10)		Sig. (p-value)
	Mean	Std. Deviation	Mean	Std. Deviation	
Gingival index (at 6th week of implant placement)	1.325	0.834	1.375	0.748	0.889
Gingival index (at 3rd month of implant placement)	1.475	0.731	1.475	0.740	1.000
Gingival index (after 1 month of prosthesis)	1.35	0.719	1.5	0.612	0.622
Gingival index (after 3 months of prosthesis)	1.35	0.592	1.475	0.595	0.643

(p-value >0.05=insignificant; p-value <0.05= significant)

During the follow-up appointments, this index was more or less constant in both groups. Amongst each group, the values of this score increased from 6 weeks to 1 month from implant placement but decreased after the placement of the prosthesis and reinforcement of the oral hygiene instructions. The values were higher for the implants with zirconia collar.



**Graph 2: Comparison of Plaque Index Scores between the implants with zirconia collar and the implants with titanium collar**



**MODIFIED SULCULAR BLEEDING INDEX:**

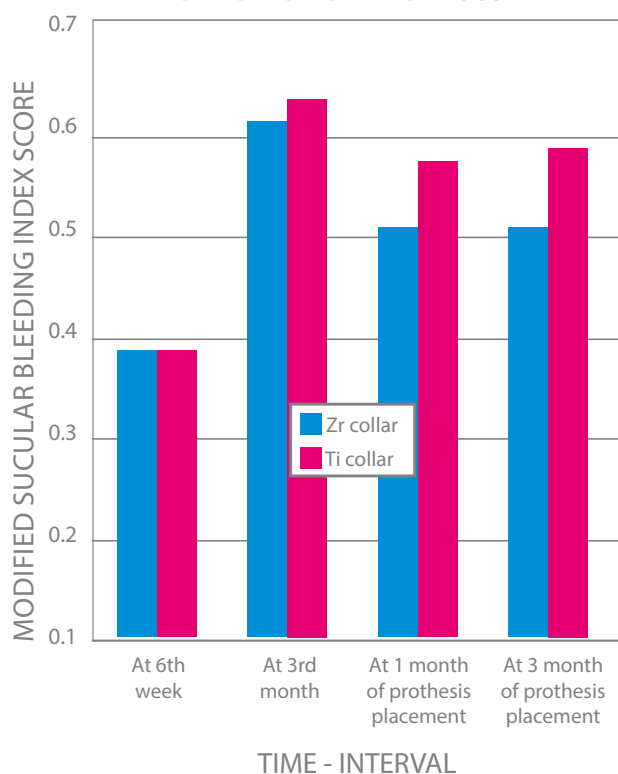
This was evaluated using the index given by Mombelli A (1987). The mean values of the modified sulcular bleeding index at different intervals of time are arranged in Table 3. The modified sulcular bleeding indexes of the zirconia and titanium collar implants were compared using the INDEPENDENT t- test.

**Table 3: Mean comparison of Plaque index**

Group	Zr collar implant (N = 10)		Ti collar implant (N = 10)		Sig. (p-value)
	Mean	Std. Deviation	Mean	Std. Deviation	
Gingival index (at 6th week of implant placement)	0.4	0.316	0.4	0.316	1.000
Gingival index (at 3rd month of implant placement)	0.625	0.377	0.65	0.444	0.894
Gingival index (after 1 month of prosthesis)	0.525	0.381	0.575	0.392	0.776
Gingival index (after 3 months of prosthesis)	0.525	0.381	0.6	0.376	0.663

(p-value >0.05=insignificant; p-value <0.05= significant)

An increase in the modified sulcular bleeding index score was found 3 months from implant placement in both groups and it decreased after prosthesis placement. The mean values of the modified sulcular bleeding scores were higher in the implants with zirconia collar compared to the implants with titanium collar.

**COMPARAISON OF MODIFIED SULCULAR BLEEDING INDEX INDEX SCORE****Graph 3: Comparison of Modified Sulcular Bleeding Index Scores between the implants with zirconia collar and the implants with titanium collar**



## SCIENTIFIC STUDIES

### PROBING DEPTH::

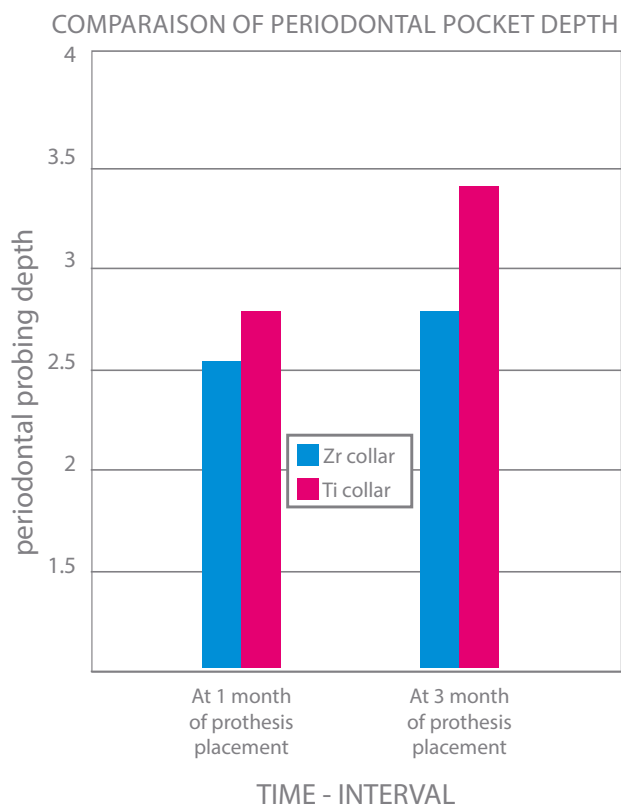
Probing depth around both implants was measured after 1 month and 3 months of prosthesis placement on buccal, lingual, mesial and distal aspect, average value of all the surfaces recorded and compared by using calibrated plastic Periodontal probe (Periowise). The mean and the standard deviation of probing depth for both implants are arranged in Table 4. The comparison of probing depths between the implants was done using INDEPENDENT t- test.

**Table 4: Mean comparison of Periodontal pocket depth**

Group	Zr collar implant (N = 10)		Ti collar implant (N = 10)		Sig. (p-value)
	Mean	Std. Deviation	Mean	Std. Deviation	
Periodontal pocket depth (after 1 month of prosthesis)	2.675	0.472	2.9	0.412	0.271
Periodontal pocket depth (after 3 months of prosthesis)	2.9	0.293	3.525	0.692	0.017* (significant)

(p-value >0.05=insignificant; p-value <0.05= significant)

There was a significant difference ( $p < 0.05$ ) between the probing depth between the two implants after 3 months from prosthesis placement. The increased probing depths were recorded on the implants with titanium collar compared to the implants with zirconia collar. An increase in the mean probing depth was seen in both groups with time. This increase in the probing depth was more important in the case of implants with titanium collar.



**Graph 4: Comparison of Periodontal Probing Depth between the implants with zirconia collar and the implants with titanium collar**

**COMPARISON OF AESTHETICS::**

The mean values of the aesthetic scores were calculated by taking the average of the recordings given both by the trained and the untrained observers together.

The mean values of 'Visual Analogue Scale (VAS)' for both implants are listed in Table 5.

**Table 5: Mean comparison of Aesthetics (VAS)**

Type of collar	Number	Mean	Std. Deviation	Sig. (p-value)
Zr	10	7.63	0.627	0.009
Ti	10	6.85	0.558	

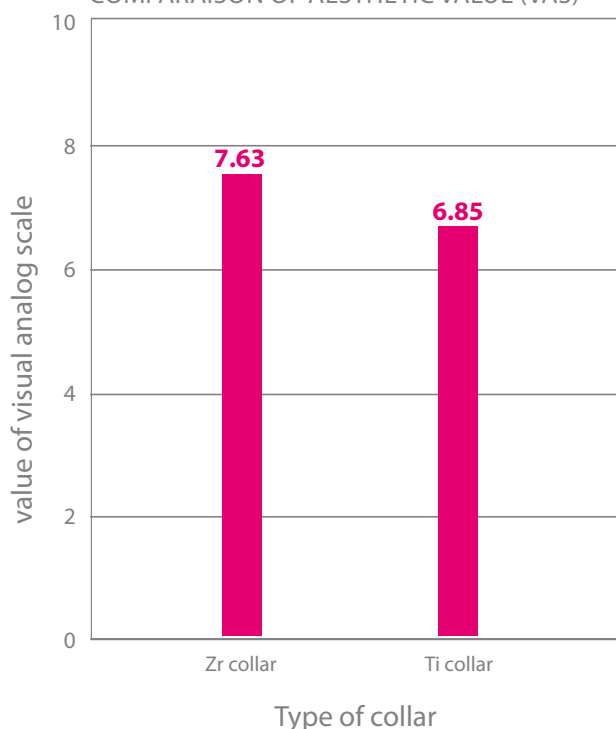
The comparison between the implants was done using INDEPENDENT t-test.  
(p-value >0.05=insignificant; p-value <0.05= significant)

The difference in comparison of aesthetic scores is significant, ( $p < 0.05$ ) with the average score for zirconia collar being 7.63 which is higher than the titanium collar implants having the average score of 6.85. In most cases the gingival hue of the sites which received the titanium collar implants was greyish whereas the sites which received the zirconia collar implants had a gingival hue much similar to the adjacent natural gingiva. The contour and adaptation of the gingiva on the other hand was also better in the implants with zirconia collar.

**CONCLUSION:**

According to the tests performed during this comparative study, there is a difference between the titanium implants with zirconia collar and the titanium implants with titanium collar. This difference shows that the zirconia collar behaves as a true antibacterial shield and thereby improves cellular adhesion and cellular proliferation, more than the titanium collar. This study shows in particular that the zirconia collar provides more aesthetic soft tissue support.

**COMPARAISON OF AESTHETIC VALUE (VAS)**



**Graph 5: Comparison of Aesthetic Scores between the implants with zirconia collar and the implants with titanium collar**





## SCIENTIFIC STUDIES

# Ceramics in implant dentistry (Working Group 1)



J. A. Hobkirk - H. W. A. Wiskott

Members of Working Group: Jens Fischer - Theodoros Kapos - Mathias Kern - Ralph Kohal - Ailsa Nicol - Mutulu O'zcan - Richard Palmer - Michael Payer - Irena Sailer - Van Thompson



biomaterials, bone implant interactions, clinical research, clinical trials, prosthodontics



2009



### ABSTRACT

**Introduction:** The remit of this working group was to update the existing knowledge base in ceramics in implant dentistry. The reviews from working group 1 formed the basis for this update. Moreover, clinical applications as well as suggestions for further research have been formulated.

**Materials and methods:** The papers in the working group critically reviewed the literature on the topic. Manuscripts were produced on:

1. The performance of ceramic and metal implant abutments supporting fixed implant reconstructions.
2. The viability of ceramic implants as alternatives to titanium implants.
3. The survival and complications of CAD-CAM reconstructions as compared with FDPs which have been fabricated using conventional techniques.

**Results:** The results and conclusions of the review process are presented in the following papers, together with the group consensus statements, clinical implications and directions for future research: Sailer I., Philipp A., Zembic A., Pjetursson B. E., Hammerle C. H. F., Zwahlen M. A systematic review of the performance of ceramic and metal implant abutments supporting fixed implant reconstructions. Andreietelli M., Wenz H. J., Kohal R.-J. Are ceramic implants a viable alternative to titanium implants? A systematic literature review. Harder S., Kern M. Survival and complications of CAD-CAM vs. conventionally fabricated reconstructions: a systematic review.

Is the performance of ceramic abutments similar to that of metal abutments?

After a mean estimated observation period of 5 years, high survival rates for ceramic (99.1%) and metal (97.4%) abutments can be expected. All-ceramic crowns supported by ceramic abutments exhibited the same survival rates as metal-ceramic crowns supported by metal abutments. No difference in the technical and biological performance of ceramic and metal abutments could be demonstrated in this review. Because the risk of fracture of a ceramic abutment increases over time, more studies with increased follow-up time of ceramic abutments are needed to verify the conclusion that ceramic and metal abutments have similar failure rates. Finally, a standardization of laboratory tests to evaluate the strength of abutments is needed.

Are ceramic implants a viable alternative to titanium implants?

This systematic review could identify histological animal studies showing similar bone-to-implant contact between alumina, zirconia and titanium. However, only cohort investigations were found making it impossible to answer the posed hypothesis with certainty. Currently, the scientific clinical data for ceramic implants in general and for zirconia implants in particular are not sufficient to recommend ceramic implants for routine clinical use.

Survival and complications of CAD-CAM vs. conventionally fabricated implant-supported reconstructions: a systematic review

Only a small number of clinical studies reporting on implant-supported CAD-CAM fabricated restorations are available which makes a scientifically valid comparison with conventionally fabricated restorations impossible.

# Comparison of zirconia and titanium implants after a short healing period. A pilot study in minipigs



B. Stadlinger, M. Hennig, U. Eckelt, E. Kuhlisch, R. Mai



dental implant; zirconia; titanium; osseointegration; submerged; non-submerged; histology; histomorphometry. Keywords: dental implant; zirconia; titanium; osseointegration; submerged; non-submerged; histology; histomorphometry.



2010



## ABSTRACT

The aim of this animal study was to investigate and compare the osseointegration of zirconia and titanium dental implants. 14 one-piece zirconia implants and 7 titanium implants were inserted into the mandibles of 7 minipigs. The zirconia implants were alternately placed submerged and non-submerged. To enable submerged healing, the supraosseous part was removed, using a diamond saw. The titanium implants were all placed submerged. After a healing period of 4 weeks, a histological analysis of the soft and hard tissue and a histomorphometric analysis of the bone-implant contact (BIC) and relative peri-implant bone-volume density (rBVD; relation to bone-volume density of the host bone) was performed. Two zirconia implants were found to be loose. All other implants were available for evaluation. For submerged zirconia and titanium implants, the implant surface showed an intimate connection to the neighbouring bone, with both types achieving a BIC of 53%. For the non-submerged zirconia implants, some crestal epithelial downgrowth could be detected, with a resultant BIC of 48%. Highest rBVD values were found for submerged zirconia (80%), followed by titanium (74%) and nonsubmerged zirconia (63%). The results suggest that unloaded zirconia and titanium implants osseointegrate comparably, within the healing period studied.



*Measurement of the relative bone-volume density within the grooves (yellow) compared with the region of reference (RoRef; red).*





## SCIENTIFIC STUDIES

# Bacterial Adhesion on Commercially Pure Titanium and Zirconium Oxide Disks: An In Vivo Human Study



Antonio Scarano, Maurizio Piattelli, Sergio Caputi, Gian Antonio Favero, and Adriano Piattelli



bacterial adhesion, dental abutments, dental implants, zirconium oxide



2004



### Background:

Little is known about the mechanisms of bacterial interaction with implant materials in the oral cavity. A correlation between plaque accumulation and progressive bone loss around implants has been reported. Bacterial adhesion shows a direct positive correlation with surface roughness. Other surface characteristics also seem to be extremely important with regard to plaque formation. Different adhesion affinities of bacteria have been reported for different materials. The aim of this study was to characterize the percentage of surface covered by bacteria on commercially pure titanium and zirconium oxide disks.

### Methods:

Ten patients participated in this study. A removable acrylic device was adapted to the molar-premolar region, and commercially pure titanium (control) and zirconium oxide (test) disks were glued to the buccal aspect of each device. The surface roughness of titanium and test specimens was similar. After 24 hours, all disks were removed and processed for scanning electron microscopy, for the evaluation of the portion of surface covered by bacteria.

### Results:

In control specimens, the area covered by bacteria was  $19.3\% \pm 2.9$ ; in test specimens, the area was  $12.1\% \pm 1.96$ . The disk surface covered by bacteria on test specimens was significantly lower than that of control specimens ( $P = 0.0001$ ). Conclusion: Our results demonstrate that zirconium oxide may be a suitable material for manufacturing implant abutments with a low colonization potential.



# Zirconia: Established Facts and Perspectives for a Biomaterial in Dental Implantology



Michael Hisbergues,<sup>1</sup> Sophie Vendeville,<sup>2</sup> Philippe Vendeville<sup>2</sup>



zirconia, biocompatibility, osseointegration, periointegration, bacterial colonization, bacterial adhesion



2009



## ABSTRACT

Currently, zirconia is widely used in biomedical area as a material for prosthetic devices because of its good mechanical and chemical properties. Largely employed in clinical area for total hip replacement, zirconia ceramics (ZrO<sub>2</sub>) are becoming a prevalent biomaterial in dentistry and dental implantology. Although titanium is used in dental implantology currently, there is a trend to develop new ceramic-based implants as an alternative to monolithic titanium. This article reviews the evolution and development of zirconia through data published between 1963 and January 2008 in English language. Articles were identified via a MEDLINE search using the following keywords: zirconia, zirconia/biocompatibility, zirconia/osseointegration, zirconia/periointegration, zirconia/review, and zirconia/bacterial adhesion or colonization. This review of the literature aims at highlighting and discussing zirconia properties in biological systems for their future use in dental implantology. In conclusion, zirconia with its interesting microstructural properties has been confirmed to be a material of choice for the “new generation” of implants, thanks to its biocompatibility, osseoconductivity, tendency to reduce plaque accumulation, and interaction with soft tissues, which leads to periointegration. However, scientific studies are promptly needed to fulfill gaps like long-term clinical evaluations of “all zirconia implants,” currently leading to propose an alternative use of “hybrid systems” (i.e., titanium screw with zirconia collar) and also bacterial colonization of zirconia. Moreover, there is a permanent need for consistent information about topography and chemistry of zirconia allowing easier cross-product comparisons of clinical devices.’





## SCIENTIFIC STUDIES

# Inflammatory Infiltrate, Microvessel Density, Nitric Oxide Synthase Expression, Vascular Endothelial Growth Factor Expression, and Proliferative Activity in Peri-Implant Soft Tissues Around Titanium and Zirconium Oxide Healing Caps



Marco Degidi, Luciano Artese, Antonio Scarano, Vittoria Perrotti, Peter Gehrke, and Adriano Piattelli



nitric oxide synthase; vascular endothelial growth factor



2006



**Background:** The aim of the present study in humans was to conduct a comparative immunohistochemical evaluation of vascular endothelial growth factor (VEGF) and nitric oxide synthase (NOS) expression, inflammatory infiltrate, proliferative activity expression, and microvessel density (MVD) in peri-implant soft tissues of titanium and zirconium oxide healing caps.

**Methods:** Five patients, three men and two women (aged 30 to 66 years; mean: 49 years), participated in this study. All patients received dental implants that were 3.8 mm in diameter and 11 mm in length. All implants were left to heal in a non-submerged (single-stage) mode. Healing caps (3.8 mm in diameter and 3.0 mm in height) were inserted in all implants. Half of the implants were supplied with standard, prefabricated caps of commercially pure titanium, whereas the other half were provided with test zirconium oxide caps. After a 6-month healing period, a gingival biopsy was performed with a circular scalpel (5.5 mm in diameter) around the healing caps of both groups, without unscrewing or removing the healing caps. The dimensions of the gingival biopsies were 1.7 mm (5.5 - 3.8 mm) in thickness and 3 mm in height.

**Results:** Statistically significant differences were found in the microvessel density between titanium and zirconium oxide healing caps and group II (P £0.0001). Statistically significant differences were likewise found in the low and high intensities of NOS1, NOS3, and VEGF (P £0.0001). In conclusion, the high intensity of NOS1, NOS3, and VEGF were mostly expressed in the titanium group, whereas the low intensity of NOS1, NOS3, and VEGF were mostly expressed in the zirconium oxide group.

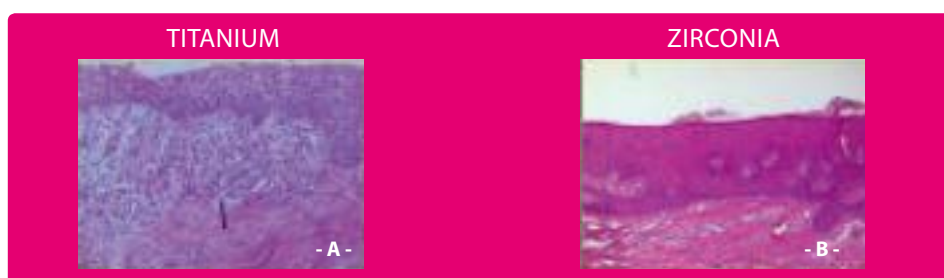
**Conclusions:** In our specimens, the inflammatory infiltrate was mostly present in the titanium specimens. Their extension was much larger than that of the zirconium oxide specimens. Higher values of MVD were observed in the titanium specimens (29.1 versus 15.8). In addition, a higher expression of VEGF intensity was observed in the peri-implant tissues of titanium healing caps, whereas predominantly lower expressions of VEGF intensity were noted around the zirconium oxide healing caps. The Ki-67 expression was higher in the titanium specimens. All these data revealed that the tissues around titanium healing caps underwent a higher rate of inflammation-associated processes, most probably correlated to the higher inflammation processes observed in these tissues. A higher intensity expression of NOS1 and NOS3 was recorded in the tissues around titanium, whereas, on the contrary, a lower intensity of expression was found in the tissues around zirconium oxide specimens. These latter data indicate that the higher expression of these two mediators could be correlated to the higher amount of bacteria present around the titanium samples.



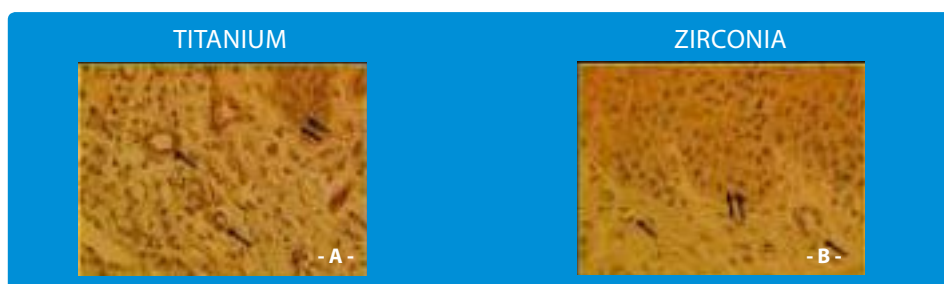
Fig 1 Titanium and zirconium healing caps inserted.



Fig 2 The soft tissues sutured around healing caps.

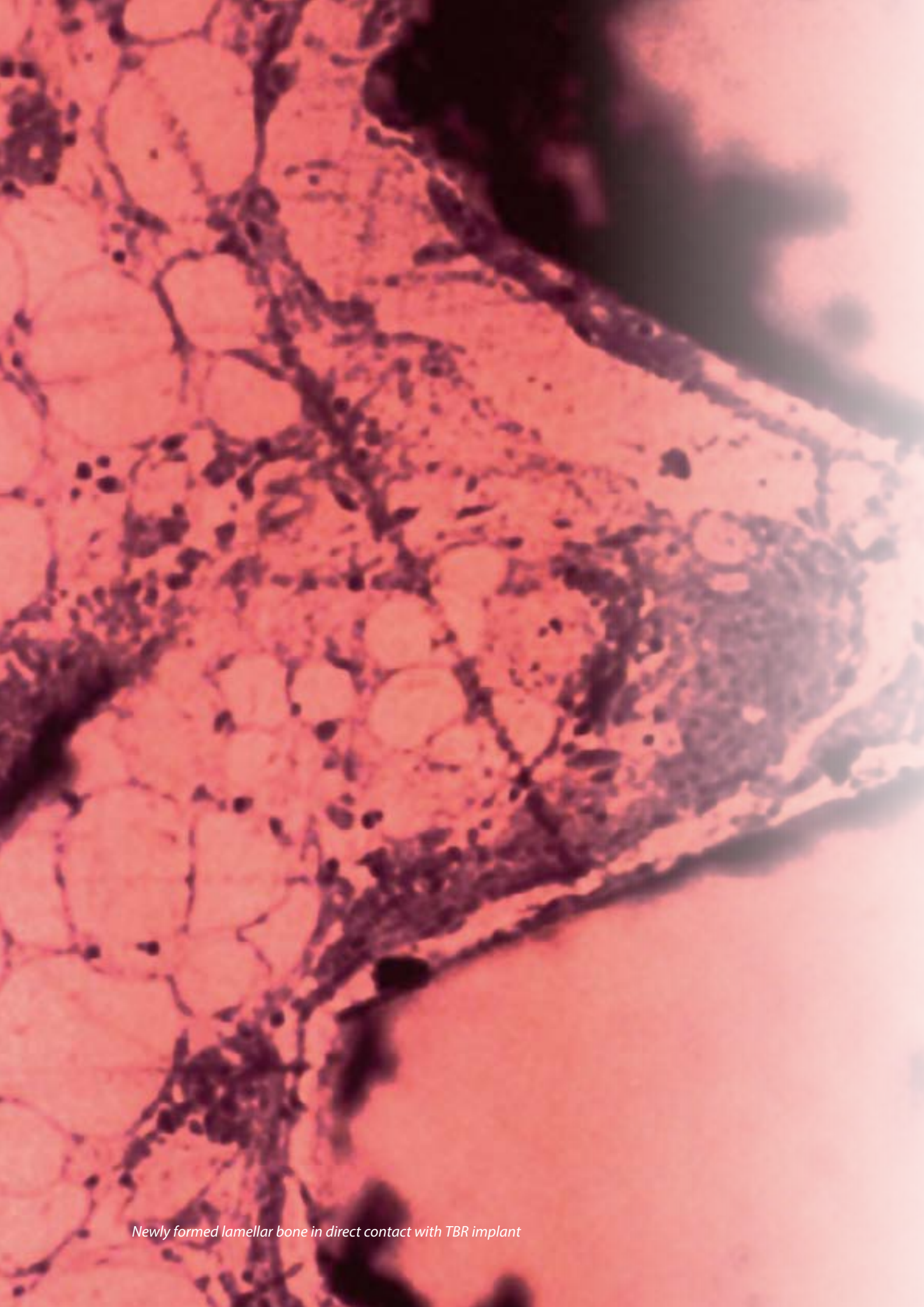


A) A severe inflammatory infiltrate is present in the peri-implant soft tissues around titanium healing caps (arrow). B) Only a small inflammatory infiltrate is observed around zirconium healing caps. (H&E; original magnification  $\times 10$ .)



A) High positivity of NOS 1 expression at the level of superficial epithelium (double arrows) and vascular endothelial cells (single arrows) in the peri-implant tissues around titanium healing caps. B) Low positivity of NOS 1 expression at the level of superficial epithelium (double arrows) and vascular endothelial cells (single arrows) around zirconium healing caps. (Peroxidase-antiperoxidase [PAP]; original magnification  $\times 20$ .)





*Newly formed lamellar bone in direct contact with TBR implant*



# SURFACE TREATMENT

■	TBR surface topography	P	36
■	TBR dental implants success rate and osseointegration	P	40
■	Evaluation of the removal torque of machined implants and sandblasted/acid-etched implants	P	42
■	Study on the Bone - Titanium Implant interface	P	44
■	Peri-implant bone healing - Comparison between sandblasted/acid-etched and machined implants	P	46
■	Biomechanical and histomorphometric analysis of etched and non-etched resorbable blasting media processed implant surfaces: An experimental study in dogs	P	48
■	Bone apposition around two different sandblasted and acid-etched titanium implant surfaces: a histomorphometric study in canine mandibles	P	49
■	Bone healing at implants with a fluoride-modified surface: an experimental study in dogs	P	50
■	Cell Response of Titanium Implant With a Roughened Surface Containing Titanium Hydride: An In Vitro Study	P	51
■	Comparative histomorphometry and resonance frequency analysis of implants with moderately rough surfaces in a loaded animal model	P	52
■	Effect of material characteristics and/or surface topography on biofilm development	P	53
■	Effect of Micrometer-Scale Roughness of the Surface of Ti6Al4V Pedicle Screws in Vitro and in Vivo	P	54
■	Effects of titanium surface topography on bone integration: a systematic review	P	55
■	The Effects of Superficial Roughness and Design on the Primary Stability of Dental Implants	P	56
■	Effect of Titanium Surface Characteristics on the Behavior and Function of Oral Fibroblasts	P	57
■	Sandblasted and Acid-etched Dental Implants: A Histologic Study in Rats	P	58
■	Surface Analysis of Machined Versus Sandblasted and Acid-Etched Titanium Implants	P	59
■	Implants surface and design	P	60





## SCIENTIFIC STUDIES

# TBR Surface topography



TBR Research Center



grade 4 pure titanium, sandblasted / acid-etched surface, macro- and micro-roughness



2010



### SCIENCE SERVING ORAL IMPLANTOLOGY

For over two decades, the number of oral implant acts has continued to rise, today totalling over a million per year worldwide. The clinical success of dental implant placement is dependent on the quality and speed of Osseointegration. In the last 25 years, multiple techniques have progressively been developed in order to improve osseointegration from a physical and chemical point of view. Since the 1980's, the surface topography of the implant has been found to be one of the five principal factors for osseointegration, in addition to the biocompatibility of the implanted material, the implant's shape, the surgical technique applied and the loading conditions. Albrektsson and al. (1981) stated that osseointegration essentially depends on the surface topography of the implant, and more specifically on its chemical composition, its surface energy, its wettability, and its roughness. Studies on titanium and its physical and chemical characteristics as applied to the biological mechanisms of bone healing will permit to determine the surface topography for optimal osseointegration. Titanium was chosen by the dentistry industry for its excellent biocompatibility. This property is further ensured by the coating of a passivating layer of TiO<sub>2</sub> that protects it from corrosion. Dental implants are usually made of two categories of materials: commercially pure titanium (Ti Cp) and titanium alloys. Commercially pure titanium has various degrees of purity, graded from 1 to 4. This purity is characterized by oxygen, carbon and iron content. The lower the grade, the more the material is pure, with negligible oxygen, carbon and iron content. Thus, grade 4 Cp Ti presents greater mechanical characteristics than the grade 2 Cp Ti. The grade 2 Cp Ti is stiff, corrosion-resistant and has a good transformation capacity. Grade 4 Cp Ti allows is remarkably corrosion-resistant and has an extraordinary modulus of elasticity. Titanium alloys, on the other hand, are more rupture-resistant and have a higher wear factor than commercially pure titanium. Because of its oxidized surface, the osseointegration process of the titanium implant begins as soon as the implant is in place. Its oxide layer poses an essential chemical composition, or surface energy, intended for the absorption of specific proteins and for cellular attachment. The layer is responsible for the physiology of the bone/titanium interface. The two structures (bone, titanium) are separated by a proteoglycan layer partially calcified and bundles of collagen fibers a couple hundred Angströms thick. Titanium, recognized for its important wettability, possesses the capacity to be rapidly covered by blood cells ( erythrocytes, thrombocytes, leucocytes, etc) and cells of the initial blood clot. This first stage of study revealed Titanium as the indisputable choice of material for dental implants. After more than 20 years of studying the advantages of titanium alloys and commercially pure titanium, the TBR Group opted to combine both advantages and use grade 4 commercially pure titanium. It is absolutely necessary to be cognizant of the clinical phenomena related to implant procedures in order to develop a surface topography resulting in optimum bone integration.



## TITANIUM, OSSEOINTEGRATION'S ARCHETYPAL MATERIAL

### OSTEOCLASIS

The clinical success of an implant is the result of a series of surgical stages and biological reactions. The initial stability of the implant depending on the bone quantity, quality and distribution must first be ensured. Bone integration the implant integration into the bone begins as a result of an osteoclastic phenomenon (process of local bone necrosis), followed by an osteogenesis process (bone reconstruction). After the implant placement, the surrounding bone undergoes a resorption and bone regeneration process, beginning with the replacement of the lamellar bone by mature compact bone. This osteoclasts phenomenon lasts approximately five days from the date of the surgical act. Subsequently a range of molecular and cellular reactions take place, inducing synthesis and differentiation of new bone cells along the biomaterial's surface : the bone healing stage.

### OSTEOGENESIS

Bone regeneration begins with the development of a blood clot followed by a series of biochemical reactions (fibrin activation, stemming from fibrinogen and activated by thrombin / plasmin activation, enzyme stemming from plasminogen / kinin activation). The regeneration undergoes a second stage, the activation of thrombocytic cells that bind to the fibrin network and at the implant surface. Both Davies's and Lazzara's studies show that the blood and thrombocytic cells are the principal cause of bone cell migration via the fibrin clot that is in direct contact with the implant surface. The thrombocytic cells generate growth factors designated to accelerate bone healing. Macrophage migration follows the thrombocytic cell binding (1st mediator of newly formed tissues) in order to eliminate necrotic fragments resulting from drilling. Yet the macrophages' primary role will be to generate new bone tissue on the implant surface. Macrophages secrete multiple growth factors (FGF-1, FGF-2, FGF-4), as well as proteins for bone genetic development (BMPs). The final result obtained is perfect bone healing including angiogenesis. A subsequent formation of a mineral matrix during osteogenesis and bone regeneration implies the presence of multipotent mesenchymatous stem cells, and their progressive differentiation into osteoblasts. Misaski and al. have shown that human mesenchymatous stem cells in contact with titanium surface specifically increase the expression of alkaline phosphatase, a fundamental enzyme implicated in the control of biomineralization at the implant surface. The revelation of these series of biological reactions implicated in bone healing has enabled the adaptation of TBR implant surface parameters.

### SANDBLASTING-ETCHING, A PROVEN TECHNIQUE.

In the last few years, much effort has been made to improve the success of implant therapeutics. One of these efforts consisted of reducing the length of time of the healing period by using new surface topographies that would improve the osseointegration mechanism, in terms of quality of newly formed tissues, as well as in terms of number of days.





## SCIENTIFIC STUDIES

### THE EVOLUTION OF SURFACE TOPOGRAPHIES

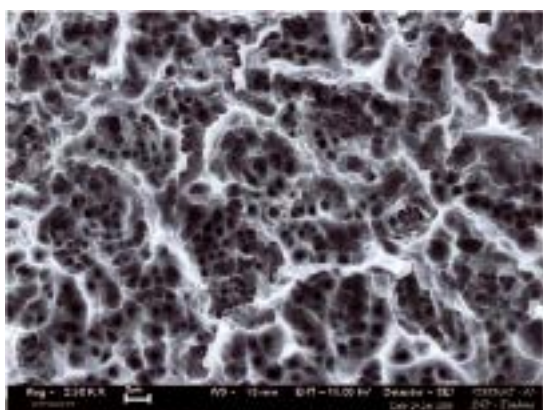
The first osseointegrable surfaces were made of industrial machined titanium. The industrial process results in minimum roughness and micro sulcus all over the implant surface. Machined implants were considered as perfectly adapted to long term osseointegration. According to Ripari and al. (2002), the average percentage of bone-implant contact on machined surfaces, after 8 weeks of healing, is 54,16%, considered a high level of integration success. Albrektsson and al. stated in 1981 that faster and stronger bone development would result in greater implant stability on the one hand, and that an optimized healing process would allow earlier implant loading. Many scientific studies including that by Klokkevold study, proved that roughness of titanium implant surface influences the osseointegration rate and the biomechanic fixation. Martin and al. affirmed that the attraction of certain cells to the fissured surfaces of the machined titanium reinforces the growing notion that the cells have a high sensitivity to surface roughnesses. In fact, an increased degree of surface roughness would increase the total surface area of the implant and the prospective biomechanical fixation of bone. These characteristics would allow to raise the bone/implant interface and increase its stabilization. In 1988 Kasemo and Lausma noticed that micro-roughness has mechanical advantages, promoting good distribution of forces all along the implant, enabling an earlier loading. Today, several techniques are commonly used to modify the smooth surface topography of machined titanium. Some techniques consist of adding matter to the metal, creating a dented surface (convex profile), called additive procedures. Conversely, other techniques consist of eliminating matter from the titanium surface, creating pits (concave profile), are known as subtractive procedures. Generally, sandblasting / acid-etching is one of the multiple surface coatings combining two processes of subtractive modifications. First, the titanium surface undergoes sandblasting with hard ceramic particules, such as alumina, titanium oxyde, or even tricalcium phosphate. Secondly, the surface is soaked in acid, or acid-etched, with HCl, H<sub>2</sub>SO<sub>4</sub>, HNO<sub>3</sub> or HF. TBR Group combines sandblasting and acid-etching for titanium surface modifications, a commonly used and proven technique for more than 30 years. Sandblasting the implant with corundum obtains optimum roughness of the surface favoring mechanical fixation of the bone. Acid-etching with fluorhydric acid softens the sharp angles of the rough surface and adds an energetic component to the implant surface (bioactiv surface) with strong potential for protein binding. The combination of these methods therefore favors primary bone healing.

### FROM A HISTOLOGICAL POINT OF VUE

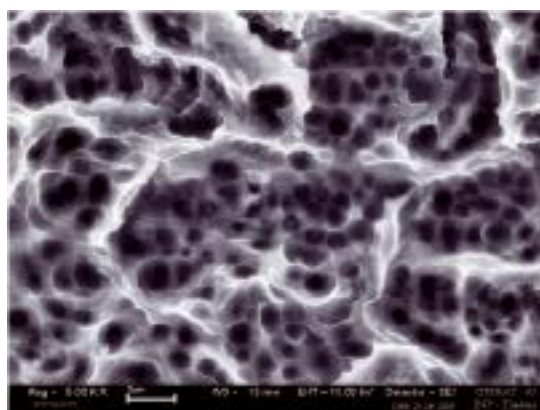
Generally, cells responsible for osseointegration have been shown to be sensitive to microtopography of the implant's titanium surface. It was observed that osteoblasts attach primarily to rough titanium surfaces, versus smooth ones; thus supporting proliferation and differentiation. [25] The results of one of Davies experiments, thrombocytic agglomeration is greater on a rough surface than a smooth one, as is blood clot attachment. In 2006, Standford and al. further proved that the rougher the surface, the thrombocytic activation rate is nearer 100%. Moreover, the experiments of Mendonca et al. as well as Valencia and al. based on the development of human mesenchymatous stem cells showed that these cells develop a specific response to sandblasted/ acid-etched titanium surfaces in 28 days. The geometric properties of TBR sandblasted/ fluorhydric acid-etched titanium implants surfaces affect the cytoskeleton of biological organism responsible for bone cell growth, mobility, and binding. Sandblasted/acid-etched surfaces stimulate cell proliferation and differentiation, thus increasing production of chemical mediators and growth factors. In 2008, Paut et coll. pointed out that macrophages respond to the macroscopic topography of the surface on which they bind to and proliferate. Moreover, the expression of proteins acting on matrix mineralization, such as alkaline phosphatase increases in presence of sandblasted and acid-etched generating bone matrix enhancement. The production of other factors participating in bone growth, for example osteocalcin, is also higher on a rough surface.

The various efforts of implant surface modifications initiated on machined titanium were combined in order to improve the bone healing process following the implant surgical act. Today, one of the most widely used surface modifications is sandblasting associated with acid-etching, with a success rate superior to 95% 5 years later. TBR Group is one of the manufacturers having adopted this surface treatment 25 years ago. These subtractive treatment processes enable optimum post implant bone reaction by favoring reduced physiological osteoclasts and higher osteogenesis. Osteogenesis will ensure perfect primary anchorage and long term preservation of the bone level by developing dense bone around the implant. This strong tissue response is the result of the sandblasted and acid-etched surface

topography of titanium in all of its forms. This specific surface treatment, applied to implant surfaces, improves cellular binding, surface bioactivity, and increases wear resistance, while respecting its biocompatibility. From a clinical point of view, these characteristics favor the osseointegration mechanism, in terms of both the quality of the newly formed tissue, as well as in terms the length of the healing period.



SEM of a TBR sandblasted / acid-etched surface - Magnification x2500



SEM of a TBR sandblasted / acid-etched surface - Magnification x5000





## SCIENTIFIC STUDIES

# TBR dental implants, success rate and osseointegration



TBR Research Center



success rate, osseointegration, sandblasted / acid-etched surface, macro- and micro-roughness



2014



The dental implants have existed for more than 30 years and the use of these implant techniques is considered to be reliable with the success rate superior to 95%.

The dental implants demand the considerable efforts that can be delivered to bone only with organic interface. Hence there are 2 methods used for implant anchoring in the bone: the chemical bonding and mechanical attachment. The research with the aim of creating a sustainable chemical bonding led to use the bioceramics as hydroxyapatite ou alumina to cover the metal implants. Although all the analyses showed the prevalence of mechanical bonding in the appropriate anchoring quality. But the mechanical bonding can be seen both at the macro- and micro- scale.

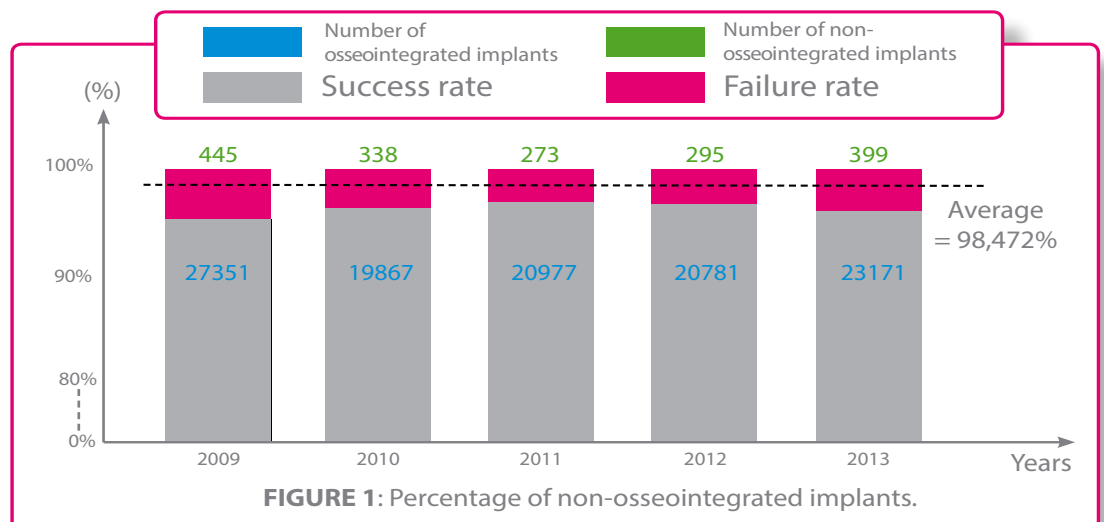
There is a roughness of implant surface at the micro-scale that can be seen as the leading cause of the strength of anchorage. Therefore, the research has concentrated on improving external geometry of these artificial organs, use of new high-tech materials and modification of their surface quality.

A lot of production goals, of quality and of security are to be achieved in order to use surface treatment techniques.

The surface quality of TBR implants (having benefits of both mechanical and chemical processes) accelerates implant osseointegration by stimulating the bone growth and reducing the risk of default during the healing period.

## A CLINICAL MONITORING FOR 5 YEARS PROVES THE EFFICACY OF TBR IMPLANTS SURFACE TREATMENT

The pre-clinical and clinical results over a five-year period prove that the implants with this surface quality bring the certain and predictable results with more than 98% of success rate.

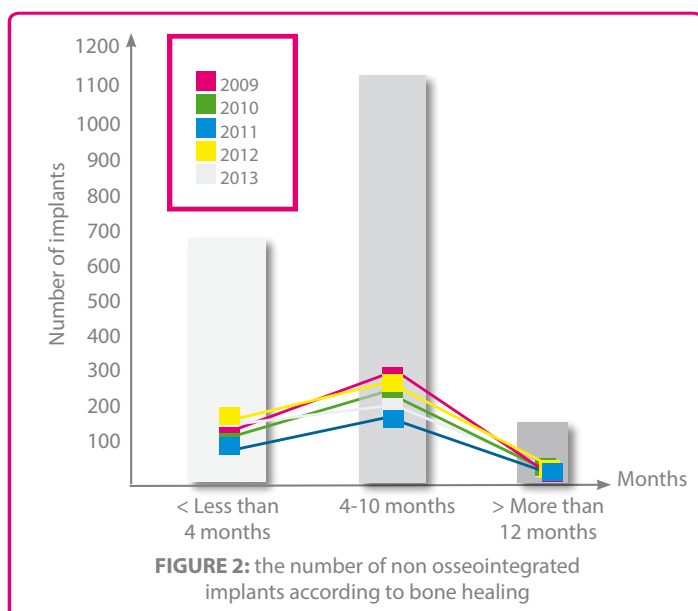


There are slightly less than 1800 non-osseointegrated implants on about 113 897 monitored implant cases.

Study period :	Number of placed implants (for the study) :	Measured success rate :	Total number of failures :
January, 2009 – December, 2013	113897	98,472 %	1750 or 1,528 %

The TBR implants, made of the 4th grade pure Titanium, are manufactured in accordance with the requirements of the international standards ISO 9001 : 2007, ISO 13485 : 2012, ISO 14801 : 2007 and EN 1642: 2013 and with the European Directive 93/42/EEC concerning medical devices.

To go further, this failure rate could be classified according to different bone healing phases and to the periods of implant placements.



At 1896 cases of osseointegration failure (by 113 897 followed up implants over 5 years) there are 695 non-osseointegrated implants at the first 4 months after placement, 1151 – between the 4th and the 10th months and 150 – 12 months later.

These results should be correlated at immediate loading for healing time inferior to 4 months, at loading and at occlusal constraints between the 4th and the 10th months.

#### DISTRIBUTION RANGE OF IMPLANTS

RATIO NOI*/NUMBER OF PLACED IMPLANTS	2009	2010	2011	2012	2013
Conic	1,47%	2,2%	1,11%	1,6%	2,4%
Zirconnect (+Slim)	1,70%	1,50%	1,39%	2,06%	2,47%
M			0,00%	0,44%	1,03%

Through these results, the mechanical and chemical properties of TBR implants confirm the osseointegration success rate of 98.472% over 5 years.

The new surface qualities and the new biomaterials are always under active consideration to optimize the healing rates taking into account the biological aspects and biocompatibility.





## SCIENTIFIC STUDIES

# Evaluation of the removal torque of machined implants and sandblasted/acid-etched implants



Drs M. RIPARI, A. PIATELLI, C. MAGGIORE, F. RIPARI, L. DI ALBERTI, A. SCARANO



titanium implant, state of surface, roughness, osseointegration



August 2002



### Summary

#### Aim

The increased surface roughness may increase torque installation and thus the primary stability of the implant. This study was undertaken to compare removal torque of two different implant surfaces.

#### Materials and Methods

10 machined and 10 sandblasted and acid-etched T.B.R.<sup>®</sup> implants were used in this study. The implants were inserted into the tibia of five New Zealand white rabbits. Each rabbit received 4 implants, two tests (sandblasted and acid-etched) in left tibia and two control (machined) in right tibia. Implants were allowed to integrate for two months. After two months, each implant was surgically exposed via sharp dissection to bone and clinically examined. The coverscrew was removed and an implant removal mount was securely fastened engaging the external hex. The leg was stabilized and the implant was removed under reverse torque rotation with a manual torque meter (Somfy Tec, Milan, Italy).

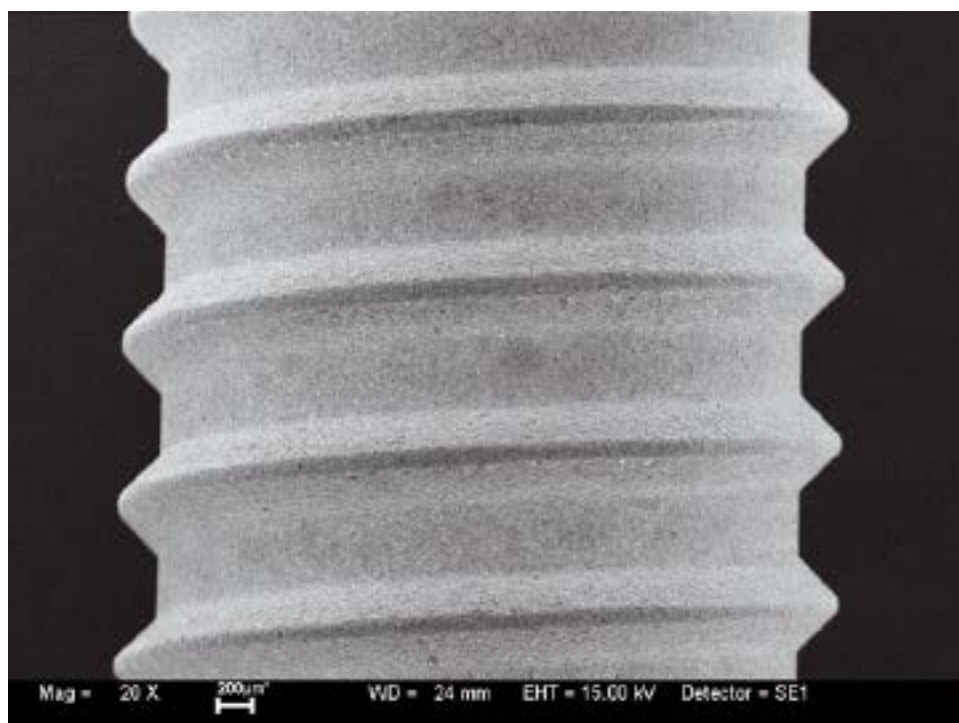
#### Results

Mean torque values for machined and sandblasted acid-etched titanium implants after two months were  $16,6 \pm 2,7$  N.cm,  $31 \pm 2,1$  N.cm respectively. The analysis of removal torque measurements revealed a statistically significant difference ( $P < 0.001$ ) between machined and sandblasted acid-etched titanium.

#### Conclusion

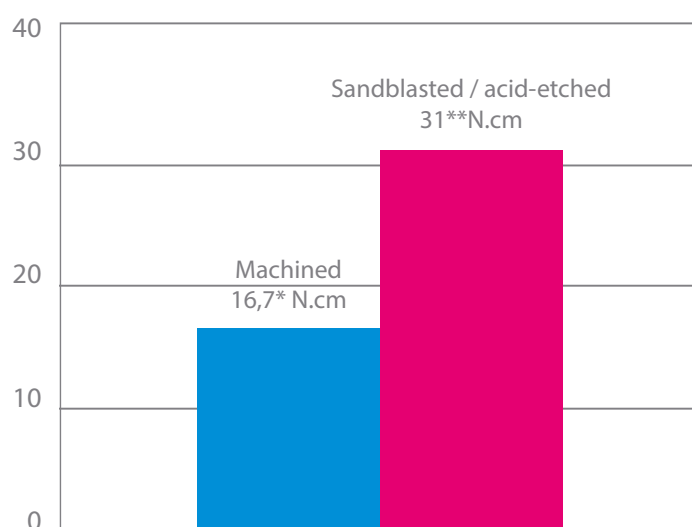
The present study has demonstrated that a relationship exists between surface roughness and removal torque values. Anchorage of implants can probably be influenced by altering the structural surface morphology.





SEM Micrograph of a TBR sandblasted / acid-etched implant

#### REMOVAL TORQUE COMPARISON: HIGHER TORQUE WITH THE ROUGH SURFACE



\* Mean value on 6 samples / Standard deviation =  $\pm 2,66$  N.cm

\*\* Mean value on 6 samples / Standard deviation =  $\pm 2,10$  N.cm





## SCIENTIFIC STUDIES

# Study on the Bone - Titanium Implant interface



Drs J. PIMENTA, M. ROHRER, F. CASTRO, F. PEREZ



bone, implant surface, interface, titanium



Summer 1995



### Summary

#### Aim

Examine bone reconstruction around the TBR® Titanium implant and the bone-implant interface on animal (rabbit) subjects in order to define actual human osteointegration.

#### Materials and Methods

- Animal race: Huila Rabbit
- Animal weight: 3.5kg
- Bone: Tibia
- Anaesthetic: Ketamine, Mepivacaine (implant area)
- Sacrifice medication: Ketamine overdose
- Tibia sectioning procedure (1cm above and below the implant) was followed by alcohol dehydration and Technovit 7200 VLC resin infiltration for preparation.
- Preparation technique used: Cutting/ Grinding allowing sections of 5-15um for better preservation of tissue.
- Staining technique: toluidine blue
- Post implant observation period intervals: 8, 15, 30 & 60 days
- Implants: TBR®
- Surface: sandblasted / acid etched

#### Results

From a clinical point of view no displacement of the implant was observed. Macroscopic data show clear direct bone-implant contact, also identified via optical microscopic shots.

Full osteointegration is achieved in stages: activation- reabsorption- formation.

The extended 60 day observation period (approx. 18 wk loads) allowed a precise definition of these stages and their extrapolation to man.

#### Conclusion

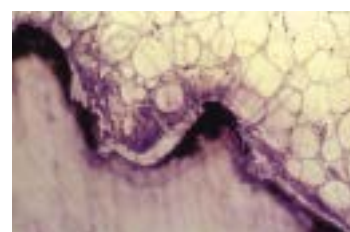
Bone-implant contact is obtained in all threads of the implant. Bone growth is also observed in small surface irregularities of the implant.



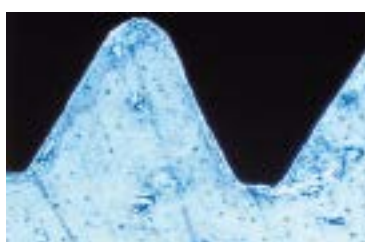
*8 days: TBR implant contact with newly forming bone*



*15 days: Newly formed woven callus bone in the apical region*



*30 days: Newly formed lamellar bone in direct contact with Titanium and intense cellular activity.*



*60 days: Compacta maturation.*





## SCIENTIFIC STUDIES

# Peri-implant bone healing - Comparison between sandblasted/acid-etched and machined implants



Drs M. RIPARI, A. PIATELLI, C. MAGGIORE, F. RIPARI, L. DI ALBERTI, A. SCARANO



sandblasted/acid-etched surface, machined surface, bone healing



August 2002



## SUMMARY

### Aim

Many studies have shown how implant surface characteristics can influence bone healing. Subsequently, some authors have demonstrated, through in vivo studies that by using microrough surfaces they managed to obtain good bone response with regards to both direct bone-implant contact and implant removal strength. The aim of the present study was to compare, through a histomorphometric and histologic analysis, implants with sandblasted acid etched surfaces and machined implants.

### Materials and Methods

T.B.R.® Implant System implants measuring 13x3,5 mm were used. 36 implants were inserted in the articulation of the knee of 9 New Zealand-race rabbits. Each rabbit received 4 implants, two machined in the left articulation and two with sandblasted and acid etched surface in the right articulation.

### Results

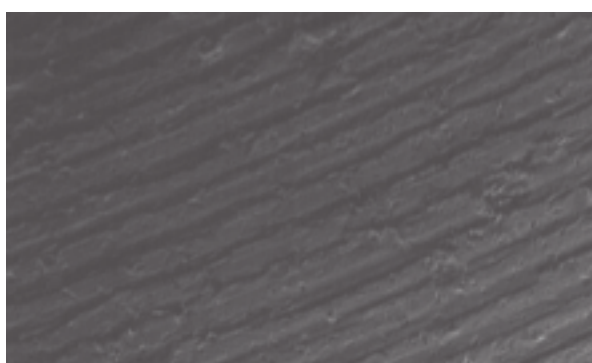
The morphometric analysis showed that a relationship exists between the increase of bone-implant contact and surface roughness.

### Conclusion

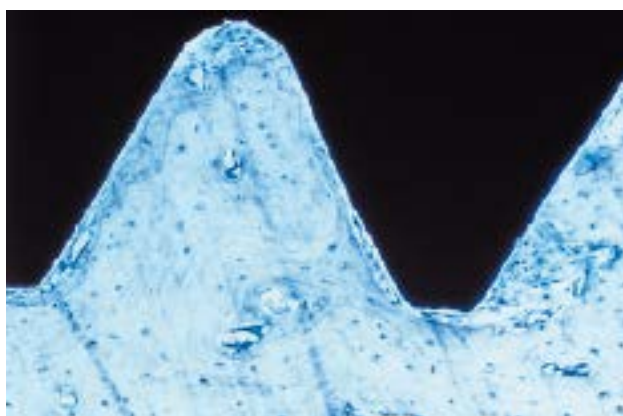
The results of the present study underline that the process of sandblasting and acid etching to which the T.B.R.® implant is submitted promotes excellent for bone healing.

	2 WEEKS		4 WEEKS		8 WEEKS	
	Machined	Sandbl. / Acid-etched	Machined	Sandbl. / Acid-etched	Machined	Sandbl. / Acid-etched
Mean (N=6)	20.3%	27.8%	27.33%	38.16%	54.16%	64.33%

*Percentage of bone-implant contact: contact increased with the sandblasted/acid-etched surface*



SEM Micrographs of machined surface (on the left) and sandblasted/acid-etched surface (on the right) (X221) – The sandblasted/acid-etched roughened surface of T.B.R.<sup>®</sup> implants increases osseointegration capacity in comparison with machined surface.



Histological section on animal at 60 days. New bone in contact with T.B.R.<sup>®</sup> implant





## SCIENTIFIC STUDIES

# Biomechanical and histomorphometric analysis of etched and non-etched resorbable blasting media processed implant surfaces: An experimental study in dogs



Charles Marina, Rodrigo Granatob, Marcelo Suzukic, Malvin N. Janald, Jose N. Gilb, Carlos Nemcovskye, Estevam A. Bonfante, Paulo G. Coelho,



Dental implant, Surface, Resorbable blasting media, Characterization, In vivo



February 2010



### ABSTRACT

This study characterized the interplay between topography/chemistry and early bone response of etched and noetched resorbable blasted media (RBM) processed surfaces. Screwroot form Ti-6Al-4V implants treated with alumina blasting/acidetching (AB/AE), RBM alone (RBM), and RBM + acid-etching (RBMA) were evaluated. The surface was characterized by scanning electron microscopy, atomic force microscopy, and Xray photoelectron spectroscopy. Implants placed in the tibia of dogs remained 3 and 5 weeks in vivo. Following euthanasia, half of the specimens were torqued to interface failure and the remaining subjected to bonetoimplant contact (BIC) and bone area fraction occupied (BAFO) between threads evaluation. The AB/AE surface was rougher than the RBM and RBMA. Higher levels of calcium and phosphorous were observed for the RBM surface compared to the RBMA. No significant differences were observed in torque, BIC, and BAFO between surfaces. Woven bone formation at 3 weeks and its initial replacement by lamellar bone at 5 weeks were observed around all implants surfaces.



# Bone apposition around two different sandblasted and acid-etched titanium implant surfaces: a histomorphometric study in canine mandibles



Michael M. Bornstein, Pilar Valderrama, Archie A. Jones, Thomas G. Wilson, Reinhart Seibl



dental implants, histomorphometric analysis, implant surface chemistry, sandblasted and acid-etched surface, SLA surface, titanium surface



February 2008



## ABSTRACT

**Purpose:** The aim of this study was to evaluate bone apposition to a modified sandblasted and acid-etched (SLA) implant surface (modSLA) in the canine mandible as compared with the standard SLA surface.

**Material and methods:** In this experimental study, all mandibular premolars and first molars were extracted bilaterally in five foxhounds. After a healing period of 6 months, each side of the mandible received six randomly assigned dental implants alternating between the standard SLA and modSLA surface. The dogs were sacrificed at 2 weeks (n¼2) or 4 weeks (n¼3) after implant placement. Histologic and histomorphometric analyses were then performed for each implant.

**Results:** The microscopic healing patterns at weeks 2 and 4 for the two implant types with the standard SLA and modSLA surfaces showed similar qualitative findings. New bone tissue had already established direct contact with implant surfaces after 2 weeks of healing. The mean percentage of newly formed bone in contact with the implant (BIC) was significantly greater for modSLA (28.2 7.9%) than for SLA (22.2 7.3%) (Po0.05). This difference was no longer evident after 4 weeks. An increase in BIC for both implant surface types occurred from weeks 2 to 4. This increase was statistically significant when compared with SLA at 2 weeks (Po0.05), but not when compared with modSLA at 2 weeks.

**Conclusion:** The data from the present study demonstrate significantly more bone apposition for the modSLA surface than the standard SLA surface after 2 weeks of healing. This increased bone apposition may allow a further reduction of the healing period following implant placement for patients undergoing early loading procedures.





## SCIENTIFIC STUDIES

# Bone healing at implants with a fluoride-modified surface: an experimental study in dogs



T. Berglundh, I. Abrahamsson, J.-P. Albouy, J. Lindhe



dental implants, histology, osseointegration, titanium



2007



### ABSTRACT

**Objectives:** The aim of the present experiment was to study early stages of osseointegration to implants with a fluoride-modified surface.

**Material and methods:** Six mongrel dogs, about 1-year old, were used. All mandibular premolars and the first mandibular molars were extracted. Three months later, mucoperiosteal flaps were elevated in one side of the mandible and six sites were identified for implant placement. The control implants (MicroThreadt) had a TiOblast surface, while the test implants (OsseoSpeedt) had a fluoride-modified TiOblast surface. Both types of implants had a similar geometry, a diameter of 3.5mm and were 8mm long. Following installation, cover screws were placed and the flaps were adjusted and sutured to cover all implants. Four weeks after the first implant surgery, the installation procedure was repeated in the opposite side of the mandible. Two weeks later, biopsies were obtained and prepared for histological analysis. The void that occurred between the cut bone wall of the recipient site and the macro-threads of the implant immediately following implant installation was used to study early bone formation.

**Results:** It was demonstrated that the amount of new bone that formed in the voids within the first 2 weeks of healing was larger at fluoride-modified implants (test) than at TiOblast (control) implants. It was further observed that the amount of bone-to-implant contact that had been established after 2 weeks in the macro-threaded portion of the implant was significantly larger at the test implants than at the controls.

**Conclusion:** It is suggested that the fluoride-modified implant surface promotes osseointegration in the early phase of healing following implant installation.

# Cell Response of Titanium Implant With a Roughened Surface Containing Titanium Hydride: An In Vitro Study



Feng Zhang, Gou-li Yang, Fu-ming He, Li-juan Zhang, and Shi-fang Zhao



implant, titanium, sandblasted / acid-etched surface



2010



**Purpose:** The purpose of this study was to investigate the effect of surface chemistry of a sandblasted and acid-etched implant (with and without titanium hydride [TiH<sub>2</sub>]) on cell attachment, proliferation, and differentiation of preosteoblasts (MC3T3-E1).

**Materials and Methods:** Sandblasted and dual acid-etched titanium discs comprised the test group, whereas sandblasted, acid-etched, and heat-treated discs comprised the control group. Both groups' discs were sent for surface characterization. MC3T3-E1 cells were cultured on these 2 groups' discs, and then cell attachment, cell proliferation, and cell differentiation were analyzed.

**Results:** Scanning electron microscope analysis showed that the titanium discs in the 2 groups shared the same surface topography; however, x-ray diffraction examination showed that the TiH<sub>2</sub> diffractions only appeared in the test group. Cell attachment and cell proliferation were much better in the test group than in the control group at all time points investigated ( $P < .05$ ). The expressions of alkaline phosphatase and osteocalcin were significantly higher in the test group than in the control group for both protein and transcription level at every time point ( $P < .05$  or  $P < .01$ ).

**Conclusions:** These results suggested that surface chemistry played a significant role in cell response to the sandblasted and acid-etched surface and the presence of TiH<sub>2</sub> might promote the attachment, proliferation, and differentiation of preosteoblasts.





## SCIENTIFIC STUDIES

# Comparative histomorphometry and resonance frequency analysis of implants with moderately rough surfaces in a loaded animal model



B. Al-Nawas, K. A. Groetz, H. Goetz, H. Duschner, W. Wagner



animal model, dental implant, histology, resonance frequency analysis, surface



2007



### ABSTRACT

**Objectives:** Test of favourable conditions for osseointegration with respect to optimum bone-implant contact (BIC) in a loaded animal model. The varied parameters were surface roughness and surface topography of commercially available dental implants.

**Method:** Thirty-two implants of six types of macro and microstructure were included in the study (total 196). The different types were: minimally rough control: Branemark machined Mk III; oxidized surface: TiUnite MkIII and MkIV; ZL Ticer; blasted and etched surface: Straumann SLA; rough control: titanium plasma sprayed (TPS). Sixteen beagle dogs were implanted with the whole set of the above implants. After a healing period of 8 weeks, implants were loaded for 3 months. For the evaluation of the BIC areas, adequately sectioned biopsies were visualized by subsurface scans with confocal laser scanning microscopy (CLSM).

**Results:** The primary statistical analysis testing BIC of the moderately rough implants (mean 56.1 13.0%) vs. the minimally rough and the rough controls (mean 53.9 11.2%) does not reveal a significant difference ( $P=0.57$ ). Mean values of 50–70% BIC were found for all implant types. Moderately rough oxidized implants show a median BIC, which is 8% higher than their minimally rough turned counterpart. The intraindividual difference between the TPS and the blasted and etched counterparts revealed no significant difference. The turned and the oxidized implants show median values of the resonance frequency [implant stability quotients (ISQ)] over 60; the nonself-tapping blasted and etched and TPS implants show median values below 60.

**Discussion:** In conclusion, the benefit of rough surfaces relative to minimally rough ones in this loaded animal model was confirmed histologically. The comparison of different surface treatment modalities revealed no significant differences between the modern moderately rough surfaces. Resonance frequency analysis seems to be influenced in a major part by the transducer used, thus prohibiting the comparison of different implant systems.

# Effect of material characteristics and/or surface topography on biofilm development



Wim Teughels, Nele Van Assche, Isabelle Sliepen, Marc Quirynen



biofilm, implants, peri-implantitis, periodontal disease, plaque growth, surface characteristics, surface free energy, surface roughness



2009



## ABSTRACT

**Background:** From an ecological viewpoint, the oral cavity, in fact the oro-pharynx, is an 'open growth system'. It undergoes an uninterrupted introduction and removal of both microorganisms and nutrients. In order to survive within the oro-pharyngeal area, bacteria need to adhere either to the soft or hard tissues in order to resist shear forces. The fast turnover of the oral lining epithelia (shedding 3 /day) is an efficient defence mechanism as it prevents the accumulation of large masses of microorganisms. Teeth, dentures, or endosseous implants, however, providing non-shedding surfaces, allow the formation of thick biofilms. In general, the established biofilm maintains an equilibrium with the host. An uncontrolled accumulation and/or metabolism of bacteria on the hard surfaces forms, however, the primary cause of dental caries, gingivitis, periodontitis, peri-implantitis, and stomatitis.

**Objectives:** This systematic review aimed to evaluate critically the impact of surface characteristics (free energy, roughness, chemistry) on the de novo biofilm formation, especially in the supragingival and to a lesser extent in the subgingival areas.

**Methods:** An electronic Medline search (from 1966 until July 2005) was conducted applying the following search items: 'biofilm formation and dental/oral implants/surface characteristics', 'surface characteristics and implants', 'biofilm formation and oral', 'plaque/biofilm and roughness', 'plaque/biofilm and surface free energy', and 'plaque formation and implants'. Only clinical studies within the oro-pharyngeal area were included.

**Results:** From a series of split-mouth studies, it could be concluded that both an increase in surface roughness above the Ra threshold of 0.2 mm and/or of the surface-free energy facilitates biofilm formation on restorative materials. When both surface characteristics interact with each other, surface roughness was found to be predominant. The biofilm formation is also influenced by the type (chemical composition) of biomaterial or the type of coating. Direct comparisons in biofilm formation on different transmucosal implant surfaces are scarce.

**Conclusions:** Extrapolation of data from studies on different restorative materials seems to indicate that transmucosal implant surfaces with a higher surface roughness/surface free energy facilitate biofilm formation.





## SCIENTIFIC STUDIES

# Effect of Micrometer-Scale Roughness of the Surface of Ti6Al4V Pedicle Screws in Vitro and in Vivo



Zvi Schwartz, Perry Raz, Ge Zhao, Yael Barak, Michael Tauber, Hai Yao, and Barbara D. Boyan



titanium alloy, macro- and micro-roughness



2009



**Background:** Titanium implants that have been grit-blasted and acid-etched to produce a rough microtopography support more bone integration than do smooth-surfaced implants. In vitro studies have suggested that this is due to a stimulatory effect on osteoblasts. It is not known if grit-blasted and acid-etched Ti6Al4V implants also stimulate osteoblasts and increase bone formation clinically. In this study, we examined the effects of micrometer-scale-structured Ti6Al4V surfaces on cell responses in vitro and on tissue responses in vivo.

**Methods:** Ti6Al4V disks were either machined to produce smooth surfaces with an average roughness (Ra) of 0.2 mm or grit-blasted, resulting in an Ra of 2.0, 3.0, or 3.3 mm. Human osteoblast-like cells were cultured on the disks and on tissue culture polystyrene. The cell number, markers of osteoblast differentiation, and levels of local factors in the conditioned media were determined at confluence. In addition, Ti6Al4V pedicle screws with smooth or rough surfaces were implanted into the L4 and L5 vertebrae of fifteen two-year-old sheep. Osteointegration was evaluated at twelve weeks with histomorphometry and on the basis of removal torque.

**Results:** The cell numbers on the Ti6Al4V surfaces were lower than those on the tissue culture polystyrene; the effect was greatest on the roughest surface. The alkaline-phosphatase-specific activity of cell lysates was decreased in a surface-dependent manner, whereas osteocalcin, prostaglandin E<sub>2</sub>, transforming growth factor- $\beta$ 1, and osteoprotegerin levels were higher on the rough surfaces. Bone-implant contact was greater around the rough-surfaced Ti6Al4V screws, and the torque needed to remove the rough screws from the bone was more than twice that required to remove the smooth screws.

**Conclusions:** Increased micrometer-scale surface roughness increases osteoblast differentiation and local factor production in vitro, which may contribute to increased bone formation and osseointegration in vivo. There was a correlation between in vitro and in vivo observations, indicating that the use of screws with rough surfaces will result in better bone-implant contact and implant stability.

**Clinical Relevance:** The osseointegration of screws with rough microtopographies is likely to be better than that of screws with smoother surfaces.



# Effects of titanium surface topography on bone integration: a systematic review



Ann Wennerberg, Tomas Albrektsson



bone integration, surface roughness, surface topography, titanium implants



2009



## ABSTRACT

### Aim:

To analyse possible effects of titanium surface topography on bone integration. Materials and methods: Our analyses were centred on a PubMed search that identified 1184 publications of assumed relevance; of those, 1064 had to be disregarded because they did not accurately present in vivo data on bone response to surface topography. The remaining 120 papers were read and analysed, after removal of an additional 20 papers that mainly dealt with CaP-coated and Zr implants; 100 papers remained and formed the basis for this paper. The bone response to differently configured surfaces was mainly evaluated by histomorphometry (bone-to-implant contact), removal torque and pushout/ pullout tests.

### Results and discussion:

A huge number of the experimental investigations have demonstrated that the bone response was influenced by the implant surface topography; smooth ( $Sa 0.5 \mu m$ ) and minimally rough ( $Sa 0.5-1 \mu m$ ) surfaces showed less strong bone responses than rougher surfaces. Moderately rough ( $Sa 1-2 \mu m$ ) surfaces showed stronger bone responses than rough ( $Sa 2 \mu m$ ) in some studies. One limitation was that it was difficult to compare many studies because of the varying quality of surface evaluations; a surface termed 'rough' in one study was not uncommonly referred to as 'smooth' in another; many investigators falsely assumed that surface preparation per se identified the roughness of the implant; and many other studies used only qualitative techniques such as SEM. Furthermore, filtering techniques differed or only height parameters ( $Sa$ ,  $Ra$ ) were reported.

### Conclusions:

Surface topography influences bone response at the micrometre level. Some indications exist that surface topography influences bone response at the nanometre level. The majority of published papers present an inadequate surface characterization. Measurement and evaluation techniques need to be standardized. Not only height descriptive parameters but also spatial and hybrid ones should be used.





## SCIENTIFIC STUDIES

# The Effects of Superficial Roughness and Design on the Primary Stability of Dental Implants



Mychelle Vianna dos Santos, Carlos Nelson Elias, Jose Henrique Cavalcanti Lima



implants, insertion torque, primary stability, resonance frequency analysis



2009



### ABSTRACT

Background: Primary implant stability has been used as an indicator for future osseointegration and whether an immediate/ early loading protocol should be applied. Implant stability is the key to clinical success.

**Purpose:** The aim of this work was to analyze the influence of the design and surface morphology on the primary stability of dental implants. The insertion torque and resonance frequency analysis (RFA) were the parameters used to measure the primary stability of the implants.

**Materials and Methods:** Thirty implants, divided in six groups of five samples were placed in cylinder of high molecular weight polyethylene. The groups were different upon two designs (cylindrical and conic) and three implant surfaces finishing (machined, acid etched, and anodized). The insertion torque was quantified by a digital torque driver (Lutron Electronic Enterprise Co., Taipei, Taiwan) and the resonance frequency was measured by Osstell mentor™ (Integration Diagnostics AB, Göteborg, Sweden). The implant surface morphology was characterized by scanning electron microscopy, roughness measurement, and friction coefficient.

**Results:** The machined implants showed smaller insertion torques than treated implant surfaces. There were no differences between the RFA measurements in all tested surfaces. Statistical analyses demonstrated no correlation between the dental implant insertion torque and primary stability measured by the RFA. The implants with treated surfaces showed greater roughness, a higher friction coefficient, and demanded a larger insertion torque than machined implants. The results of the surface roughness and friction coefficients are in accordance with the results of the insertion torque. The difference, across the insertion torque values, between conical and cylindrical implants, can be explained by the different contact surface area among the thread geometry of these implants.

**Conclusion:** The maximum implant insertion torque depends on the implant geometry, thread form, and implant surface morphology. The placement of conical implants with treated surfaces required the highest insertion torque. There was no correlation between RFA and insertion torque implant.

# Effect of Titanium Surface Characteristics on the Behavior and Function of Oral Fibroblasts



Wael Att, Masahiro Yamada, Takahiro Ogawa



acid etching, collagen, fibroblasts, machined, surface topography, titanium



2009



**Purpose:** The purpose of this study was to evaluate the effect of different titanium surface characteristics on the behavior and function of oral fibroblasts as well as the deposition pattern of collagen within the extracellular matrix.

**Materials and Methods:** Titanium surfaces created by machining, acid etching with sulfuric acid (AE1), or acid etching with hydrofluoric acid (AE2) were analyzed using scanning electron microscopy (SEM) and energy-dispersive x-ray spectroscopy. Rat oral fibroblasts were cultured on different surfaces. Cell spread and morphology of extracellular matrix were evaluated using SEM. Attachment and proliferation of cells were examined by comparing the numbers of attached to detached cells and cell count, respectively. Gene expression was analyzed via reverse transcriptase polymerase chain reaction. Collagen production and deposition were examined via a Sirius red-based stain assay and confocal laser scanning microscopy.

**Results:** The machined surface showed a flat profile with isotropic grooves, the AE1 surface showed a uniformly microscale roughened surface, and the AE2 surface had a grooved profile with intermediate surface roughness. The AE2 surface contained fluoride atoms ( $2.45\% \pm 0.44\%$  as F/Ti atomic ratio). Cell attachment was significantly weaker on the machined surface than on the AE1 and AE2 surfaces, whereas no differences were observed between the AE1 and AE2 surfaces. The cell counts on the machined and AE2 surfaces were higher, with a parallel orientation, whereas the cell count was lower and randomly distributed on the AE1 surface. The expression level of fibroblastic genes was similar among surfaces for all time points tested. Collagen production was highest on the machined surface, followed by AE2 and AE1 surfaces. Collagen deposition displayed a parallel pattern on the machined surface, while it was multidirectional on the AE1 and AE2 surfaces.

**Conclusion:** The surface characteristics of titanium affect attachment, spread, and proliferative activity of oral fibroblasts as well as the deposition pattern of collagen in vitro.





## SCIENTIFIC STUDIES

# Sandblasted and Acid-etched Dental Implants: A Histologic Study in Rats



Vanessa C. Marinho, Renato Celletti, Guido Bracchetti, Giovanna Petrone, Cedric Minkin, Adriano Piattelli



dental acid etching, dental implants, osseointegration, surface properties



2003



**Purpose:** Current literature has revealed that surface etching of endosseous implants can improve bone-implant contact. The aim of this study was to evaluate the differences in bone-implant contact (BIC) between sandblasted/acid-etched and machined-surface implants.

### **Materials and Methods:**

Thirty-two Sprague-Dawley rats were used in this study. Two implant surfaces, Ecotek (sandblasted/acid-etched) and machined, were used with 1 implant placed in each tibia of the animals. A total of 64 implants were placed. BIC was evaluated at 5, 15, 30, and 60 days. Histomorphometry of the BIC was evaluated statistically.

**Results:** The sandblasted/acid-etched surface demonstrated a greater BIC percentage than the machined surface. This difference was statistically significant only at 30 and 60 days after healing. Discussion and Conclusion: The sandblasted/acid-etched surface demonstrated a stronger bone response than the machined one at a later period of healing.

# Surface Analysis of Machined Versus Sandblasted and Acid-Etched Titanium Implants



Giovanna Orsini, Bartolomeo Assenza, Antonio Scarano, Maurizio Piattelli, Adriano Piattelli



acid etching, cellular morphology, dental implants, immunologic cytotoxicity tests, surface properties



2000



Initially, implant surface analyses were performed on 10 machined implants and on 10 sandblasted and acid-etched implants. Subsequently, sandblasted and acid-etched implant cytotoxicity (using L929 mouse fibroblasts), morphologic differences between cells (osteoblast-like cells MG63) adhering to the machined implant surfaces, and cell anchorage to sandblasted and acid-etched implant surfaces were evaluated. Results indicated that acid etching with 1% hydrofluoric acid/30% nitric acid after sandblasting

eliminated residual alumina particles. The average roughness (Ra) of sandblasted and acid-etched surfaces was about 2.15  $\mu\text{m}$ . Cytotoxicity tests showed that sandblasted and acid-etched implants had non-cytotoxic cellular effects and appeared to be biocompatible. Scanning electron microscopic examination showed that the surface roughness produced by sandblasting and acid etching could affect cell adhesion mechanisms. Osteoblast-like cells adhering to the machined implants presented a very flat configuration, while the same cells adhering to the sandblasted and acid-etched surfaces showed an irregular morphology and many pseudopodi. These morphologic irregularities could improve initial cell anchorage, providing better osseointegration for sandblasted and acid-etched implants.





## SCIENTIFIC STUDIES

# Implant surfaces and design



Niklaus P. Lang, Søren Jepsen

Members of Working Group:

Ingemar Abrahamsson, Tomas Albrektsson, Jürgen Becker, Tord Berglund, Daniele Botticelli, Donald M. Brunette, Pedro Bullon, Marco Esposito, Jürgen Geis-Gerstorfer, John A. Jansen, Søren Jepsen, Niklaus P. Lang, David Nisand, Stefan Renvert, Søren Schou, Ann Wennerberg, Library assistants: Adrian Bösch, Caroline Sax



animal model, bone-to-implant contact, decontamination, marginal bone level, oral implants, osseointegration, peri-implantitis, re-osseointegration, surface coatings, surface composition, surface roughness, surface topography



2009



### ABSTRACT

**Introduction:** The remit of this working group (4) was to update existing knowledge on the effects of implant surface topography, composition and design on bone integration and reosseointegration.

### MATERIAL AND METHODS

Based on five narrative reviews that were performed following a defined search strategy, clinical implications as well as suggestions for further research have been formulated.

### RESULTS

The results and conclusions of the review processes in the following papers together with the group consensus, clinical implications and directions for future research are presented:

1. Effects of titanium surface topography on bone integration.
2. Effects of implant surface coatings and composition on bone integration (two reviews).
3. Effects of different implant surfaces and designs on marginal bone level alterations.
4. Re-osseointegration onto previously contaminated implant surfaces.

### Effects of titanium surface topography on bone integration:

- surface topography on a micrometer level influenced bone integration;
- some studies indicated that surface topography on a nanometer level influenced bone integration;
- the majority of published papers presented an inadequate description of surface characteristics or did not characterize them at all.
- The terms 'rough' and 'smooth' were used in different ways among the studies. Consequently, these terms will have to be specified by this consensus conference.
- The measuring and evaluation techniques applied to the characterization of surfaces need standardization.
- When evaluating implant surface topographical characteristics, height, spatial and hybrid parameters should be included.

### Moreover, these parameters should be provided separately for different scale ranges.

With respect to the confusion in terminology, the group accepted the definitions for surface roughness for oral implants specified by Albrektsson & Wennerberg (2004) and Wennerberg & Albrektsson (2009a, 2009b):



- Smooth surfaces: Sa value  $\leq 0.5$   $\mu\text{m}$  (e.g. polished abutment surface).
- Minimally rough surfaces: Sa value  $0.5 - 1$   $\mu\text{m}$  (e.g. turned implants).
- Moderately rough surfaces: Sa value  $1 - 2$   $\mu\text{m}$  (e.g. most commonly used types).
- Rough surfaces: Sa value  $\geq 2$   $\mu\text{m}$  (e.g. plasma-sprayed surfaces). The absolute Sa (average height deviation) values used for the above definitions were determined by optical interferometry using Gaussian filters.

#### **Effects of implant surface coatings and composition on bone integration:**

- Surface modifications that alter the topography of the currently marketed implant types will inevitably also affect the surface composition. Hence, either surface characteristic may have contributed to the observed improved bone integration, and it may be difficult to attribute beneficial effects to either topography or composition alone.
- For four (Osseospeeds, SLActives, TiUnites and Nanotites) of the five most widely marketed implant types in Europe alterations in the surface composition improved bone integration compared with their predecessors. For one implant type (Friadent Pluss) such evidence is lacking. For two (TiUnites, Nanotites) of the five implant types, confirmative human histological data are available.
- Implants with thin calcium phosphate coatings demonstrated improved bone integration compared with uncoated implants. However, confirmative human studies are lacking.
- Coating of implants with peptide sequences (e.g. RGD) has not consistently resulted in improved bone integration.
- Coating of implants with growth factors (e.g. BMP-2) does not enhance bone integration. In fact, BMP-2 coatings may even reduce bone integration.

#### **Effects of different implant surfaces and designs on marginal bone level alterations:**

- Controlled prospective studies evaluating the effect of implant surface and designs on marginal bone level changes  $< 3$  years are few.
- There is no evidence that modified surfaces are superior to non-modified implant surfaces in marginal bone preservation.
- Comparisons between implants of different systems involve evaluations of combinations of surfaces and designs. No one implant system was found to be superior in marginal bone preservation.
- Implants with a conical and microthreaded marginal collar preserved marginal bone levels significantly better than implants with a cylindrical and non-threaded marginal portion after 3 years in function (one study). The clinical relevance of this difference, however, remains unknown.

#### **Re-osseointegration onto previously contaminated implant surfaces**

##### **On the basis of animal studies, re-osseointegration is possible**

- to obtain on a previously contaminated implant surface;
- may occur in experimentally induced peri-implantitis defects following therapy;
- varied considerably within and between studies and is unpredictable;
- may be influenced by implant surface characteristics;
- has not been achieved for the entire previously contaminated implant surface by any of the techniques tested.





*TBR implant with microthreads of 0.2mm*

# MICROTHREAD

■	Comparative Analysis of Peri-Implant Marginal Bone Loss Based on Microthread Location: A 1-Year Prospective Study After Loading	P	64
■	Effect of microthread on the maintenance of marginal bone level: a 3-year prospective study	P	65
■	Effect of Microthreads and Platform Switching on Crestal Bone Stress Levels: A Finite Element Analysis	P	66
■	Tissue Characteristics at Microthreaded Implants: An Experimental Study in Dogs	P	67





## SCIENTIFIC STUDIES

# Comparative Analysis of Peri-Implant Marginal Bone Loss Based on Microthread Location: A 1-Year Prospective Study After Loading



Dong-Wook Song, Dong-Won Lee, Chong-Kwan Kim, Kwang-Ho Park, and Ik-Sang Moon



alveolar bone loss; dental implants; dental radiography; prospective studies.



2009



**Background:** The purpose of the present study was to investigate the short-term effects of microthread location on peri-implant marginal bone levels.

**Methods:** Two types of implants, one with microthreads placed at the implant top (group A) and the other with microthreads placed 0.5 mm below the implant top (group B), were placed adjacent to each other in the partially edentulous areas of 20 patients. In total, 40 implants were placed. Bone loss around each implant was analyzed after 1 year of functional loading, and gingival parameters (modified plaque index and modified sulcus bleeding index) of the peri-implant soft tissue were evaluated. Bone losses after loading and gingival parameters were compared using the paired t test.

**Results:** The average bone loss was 0.16 (SD: 0.19) mm in group A and 0.30 (SD: 0.22) mm in group B after 1-year of functional loading. The paired t test revealed a significant difference in crestal bone loss between groups A and B in individual patients ( $P = 0.004$ ). No significant differences were found between the two groups for the gingival parameters.

**Conclusions:** Less peri-implant bone loss was observed around implants with microthreads placed at the implant top (group A) compared to those in which microthreads were placed below the top (group B). These results indicated that the microthreads acted to stabilize the peri-implant marginal bone, and their locations played an important role in the stabilization process.

# Effect of microthread on the maintenance of marginal bone level: a 3-year prospective study



Dong-Won Lee, Young-Shill Choi, Kwang-Ho Park, Chang-Sung Kim, Ik-Sang Moon



marginal bone level, microthread, prospective study, radiographic image



2006



## ABSTRACT

**Objectives:** The purpose of the present study was to evaluate the long-term effect of the microthread on the maintenance of marginal bone level.

**Material and methods:** Seventeen patients were selected and two types of Astra Tech implants were installed, with the Microthreadt on the coronal portion of the fixture (ST) or without the Microthreadt (TB). ST and TB were installed adjacent to each other within the same partially edentulous sites and marginal bone loss was evaluated by radiographic image. The marginal bone-level alteration of the each fixture after prosthesis insertion was analyzed.

**Results:** The marginal bone loss of ST and TB differed significantly during the observation period ( $P=0.01$ ). Marginal bone levels of both ST and TB were stabilized after 1 year of loading.

**Conclusions:** The Microthreadt might have an effect in maintaining the marginal bone loss against loading.





## SCIENTIFIC STUDIES

# Effect of Microthreads and Platform Switching on Crestal Bone Stress Levels: A Finite Element Analysis



Jason Schrottenboer, Yi-Pin Tsao, Vipul Kinariwala, and Hom-Lay Wang



alveolar bone loss, computer assisted, dental abutment, dental implants, numerical analysis



2008



**Background:** The aims of this study were to investigate the effects of implant microthreads on crestal bone stress compared to a standard smooth implant collar and to analyze how different abutment diameters influenced the crestal bone stress level.

**Methods:** Two-dimensional finite element imaging was used to create a cross-sectional model of an implant (5-mm platform and 13 mm in length) placed in the premolar region of the mandible. The two tapered implant models consisted of one with microthreads at the crestal portion and the other with a smooth neck. The implant model was reverse-engineered to resemble a commercially available microthread implant. Abutments of different diameters (4.0 mm: 20% platform switching; 4.5 mm: 10% platform switching; and 5.0 mm: standard) were loaded with a force of 100 N at 90 vertical and 15 oblique angles. Finite element analysis was used to analyze the stress patterns in bone, especially in the crestal region.

**Results:** Upon loading, the microthread implant model had 29% greater stress (31.61 MPa in oblique and 9.31 MPa in vertical) at the crestal bone adjacent to the implant than the smooth-neck implant (24.51 and 7.20 MPa, respectively). When the abutment diameter decreased from 5.0 to 4.5 mm and then to 4.0 mm, the microthread model showed a reduction of stress at the crestal bone level from 6.3% to 5.4% after vertical loading and from 4.2% to 3.3% after oblique loading. The smooth-neck model showed a reduction of stress from 5.6% to 4.9% after vertical loading and from 3.7% to 2.9% after oblique loading.

**Conclusions:** Microthreads increased crestal stress upon loading. Reduced abutment diameter (i.e., platform switching) resulted in less stress translated to the crestal bone in the microthread and smooth-neck groups.



# Tissue Characteristics at Microthreaded Implants: An Experimental Study in Dogs



Ingemar Abrahamsson, Tord Berglundh



animal, bone level, histology, osseointegration, radiographs, titanium



2006



## ABSTRACT

**Purpose:** The aim of the present study was to analyze bone tissue reactions at implants with and without a microthread configuration.

**Materials and Methods:** In six beagle dogs, one test and two control implants were installed in one side of the mandible. While both implant types had a similar dimension and surface roughness, the test implants were designed with a microthread configuration in the marginal portion. Abutment connection was performed after 3 months. Another 3 months later, fixed partial dentures (FPDs) were cemented to the maxillary canine and premolars and FPDs were connected to the implants in the mandible. Ten months later, the animals were sacrificed and biopsies from each implant region were processed for histological analysis. Radiographs were obtained at implant placement after FPD connection and at the termination of the experiment.

**Results:** The radiographic examination revealed that the marginal bone level was well preserved at both test and control implants during the entire 16-month period. The degree of bone-implant contact within the marginal portion of the implants was significantly higher at the test (microthread) implants (81.8%) than at the control implants (72.8%).

**Conclusions:** It was suggested that the microthread configuration offered improved conditions for osseointegration.





*Customised abutment realised by CAD / CAM*

# PROSTHESIS

■ Sealing implant connections gaseous diffusion test - Permeability of the implant-abutment connection TBR system (An experimental study)	P	70
■ A systematic review of the performance of ceramic and metal implant abutments supporting fixed implant reconstructions	P	78
■ The mucosal attachment at different abutments An experimental study in dogs	P	79
■ The mucosal barrier at implant abutments of different materials	P	80
■ Indications for immediate loading of implants and implant success	P	81
■ Bacterial adhesion and colonization differences between zirconia and titanium implant abutments: an in vivo human study	P	82
■ The effect of material characteristics, of surface topography and of implant components and connections on soft tissue integration: a literature review	P	84
■ Indications for immediate loading of implants and implant success	P	85





## SCIENTIFIC STUDIES

# Sealing implant connections gaseous diffusion test Permeability of the implant-abutment connection TBR system (An experimental study)



Jacques-Henri Torres, Michael Mecahli, Olivier Romieu, Paul Ramini, Sylvie Callas, Frédéric JG Cuisinier, Bernard Levallois



implant-abutment connection, sealing, gaseous diffusion



2014



## ABSTRACT

### Aim

Most dental implant systems are presently made of two pieces: the implant itself and the abutment. The connection tightness between those two pieces is a key point to prevent bacterial proliferation, tissue inflammation and bone loss. Several studies have attempted to examine the tightness of the implant connection for the presence of in vivo or in vitro bacteria, observing the dye diffusion or endotoxins. The present study issue is to adapt to the evaluation of the sealing implant connections, a gas diffusion method developed to test the tightness of seals pulp through diffusion of nitrogen with atmospheric pressure, especially on the dental TBR morse taper implant.

### Methods

A new nitrogen flow technique was developed for implant-abutment connection leakage measurement, adapted from a recent, sensitive, reproducible and quantitative method used to assess endodontic sealing.

### Results

The results show very significant differences between the various conditions and sealing screw. The remaining flow was lower after mechanical tightening to the recommended torque compared to a manual clamp ( $p = 0.03$ ). The reproducibility of the method was very good, with a coefficient of variation of 1.29%.

The TBR M implant appears to have the less permeable connection among all tested systems to date with this technique.

### Conclusions

Therefore, the presented new gas flow method appears to be a simple and robust method to compare different implant systems. It allows successive measures without disconnecting the abutment from the implant and should in particular be used to assess the behavior of the connection before and after mechanical stress.

The good results of TBR M held in part due to the conical nature of the connection. But the very low leakage observed probably shows the quality of the machining of these parts (both implants pillars). Moreover, and this is also a quality variability observed leaks are very low.

## Aim

Dental implant systems presently found on the market are mainly made of two pieces: the implant itself (placed inside the alveolar bone) and the abutment (which goes through the gum and supports the prosthesis). The connection between those two pieces appears to be a key point for implant success. Essentially, besides mechanical considerations, a gap between those two pieces may allow bacterial proliferation, inflammation and peri-implant bone loss [1-6]. It appears an important challenge to assess the tightness of this connection. This has already been tested by:

- showing microbial leakage at the implant-abutment interface in patients [7,8] and in vitro [6,9-15];
- placing a color marker between the implant and the abutment and measuring its leakage by spectrophotometry [16,17];
- and, more recently, studying tightness against endotoxins [18].

These techniques hardly provide a quantitative and reproducible way to measure the leakage, as it was demonstrated in endodontics [19]. Indeed, many techniques have been used to investigate the sealing ability of root filling procedures and materials. Some leakage investigations, like dye spectrometry [20], fluid filtration [21], and electrochemistry [22], are considered to provide pure quantitative data. Other studies using bacteria are essentially qualitative [23,24]. However, the majority of leakage tests are related to linear measurement of tracers like coloring agents and radioisotopes [25], which give semi-quantitative data [26]. Despite the long experience of measuring tightness in this field, in vitro assessment of sealability has lost its credibility [27]. Among the leakage studies, tracer diffusion studies are the more frequent but have been demonstrated to have false conclusions [28] and results to be very driven by presence of air entrapped. These critics could be applied to implants leakage studies using tracers or bacteria entrapped in the inner part of the implant.

Recently, a gas flow test was shown to be a sensitive, reproducible and quantitative method to assess endodontic sealing [29]. The aim of the present engineering contribution was to adapt this gas permeability technique to implant-abutment connection leakage, in order to provide a new quantitative and reproducible tool for further investigations. Such a method has never been used in the field of implantology for assessing implant-abutment microgap before.

## Methods

The experimental set-up used is similar to the set-up used for assessing endodontic leakage [20]. The implants were positioned in an experimental chamber between atmospheric (P1) and negative (P2) nitrogen pressure. Gas flow was assessed measuring the pressure difference between P1 and P2 with a differential pressure gauge (Testo 526, Forbach, France). After vacuum was completed, the needle valve was closed (see Figure 1). Initial pressure difference was about 1010 hPa. Pressure difference versus time was recorded.

Typical pressure curves showed an initial drop followed by a second regimen appearing as a straight line (Figure 2). This latter regimen is due to a pressure difference low enough, compared to atmospheric pressure:

the nitrogen flow is not related any longer to pressure difference, but only to the importance of leakage, and obeys Knudsen's law [30]. The slope of the line was measured by an operator, and recorded. In order to assess the reproducibility of the slope determination by the operator, 10 curves were read twice: another operator drew lots 10 curves from among all the recorded curves. The first operator had to perform again slope determination for these curves, blindly. Reproducibility of the measurements was tested by a Kendall's coefficient of concordance.

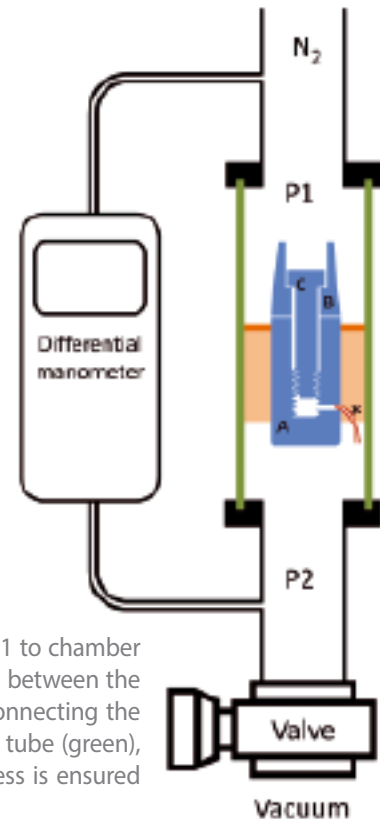




## SCIENTIFIC STUDIES

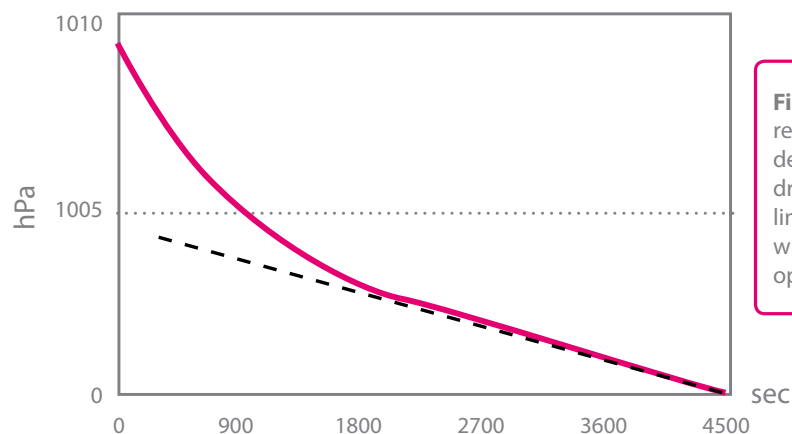
First of all, three types of negative assays were performed to appraise the gas tightness of the employed materials:

- a blind-ended glass test tube was used to assess the gas tightness of the experimental chamber;
- a double-ended opened glass tube sealed on one side with a plug of epoxy glue to assess the gas tightness between the glue and the glass;
- a double-ended opened glass tube sealed on one side with a plug of wax to assess the gas tightness of wax. Under water spray, five One Morse implants (One System Implant, Cannes France), 4.3 mm diameter and 12 mm length, were drilled a hole to the apical part of the screw cavity. A plastic tube was inserted in the hole. The implants were partially embedded in epoxy glue (Araldite 2012, Huntsman Polyurethanes, Everberg, Belgium) and sealed in a glass tube, allowing free spaces around the



**Figure 1:** Experimental set-up. Nitrogen leaks from chamber P1 to chamber P2 through the gap between implant(A) and abutment (B) and between the screw (C) and the abutment, then through a plastic tube (\*) connecting the internal chamber of the implant with chamber P2. In the glass tube (green), the implant is sealed in epoxy adhesive (pink) and the tightness is ensured with wax (brown).

Under water spray, five One Morse implants (One System Implant, Cannes France), 4.3 mm diameter and 12 mm length, were drilled a hole to the apical part of the screw cavity. A plastic tube was inserted in the hole. The implants were partially embedded in epoxy glue (Araldite 2012, Huntsman Polyurethanes, Everberg, Belgium) and sealed in a glass tube, allowing free spaces around the



**Figure 2:** Example of a recorded curve. Progressive decrease in pressure: initial drop is followed by a straight line (black dotted), the slope of which was determined by the operator



abutment connection and around the tube. Wax (Purple wax, GC Europe, Leuven, Belgium) was used to seal implant to glue, and to block the various gaps to be assessed.

Each implant was tested 4 times, respectively after (Figure 3):

Assay 1) abutment manual screwing (by one operator)

Assay 2) abutment manual screwing (by one operator), screw hole blocked with wax

Assay 3) abutment key screwing (35 Ncm), screw hole blocked with wax

Assay 4) abutment key screwing, screw hole and implant connection blocked with wax (as a negative test)

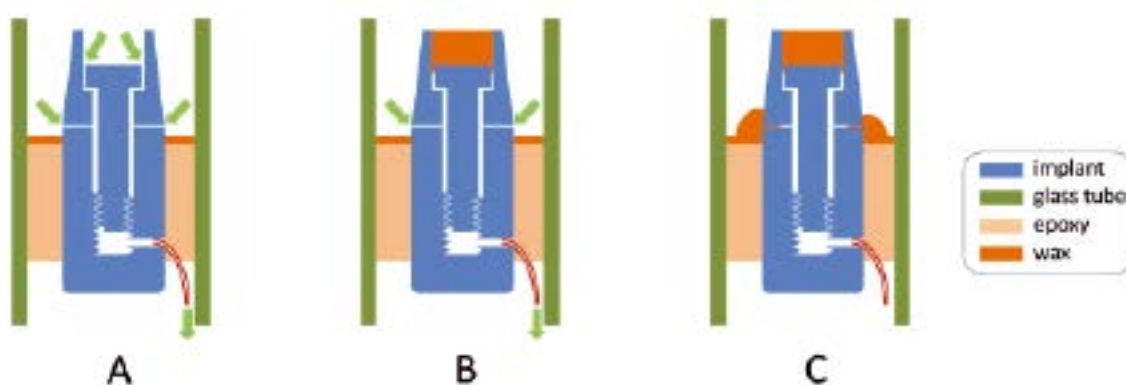
Assay number 3 was performed 10 times for one of the implants to assess the reproducibility of the method.

ANOVA of repeated measures was performed globally to test whether the measured slopes for the 4 assays were globally different. After a logarithmic transformation, data followed a normal repartition. Pairwise comparisons between each assay were tested taking into account Bonferroni correction at  $\alpha = 0.05$  (significance).

## Results

### Negative tests

The negative tests performed proved that the experimental setup and the various materials used to stop nitrogen leaking show convenient gas tightness (Figure 4). The slope of the blind-ended glass tube ( $0.000252 \text{ hPa}\cdot\text{sec}^{-1}$ , or  $e-8.29 \text{ hPa}\cdot\text{sec}^{-1}$ ) gave an idea of the maximal tightness of the experimental setup i.e. the remaining leakage when the system is totally closed. Measures of tightness obtained with the epoxy glue and the blind-ended glass tube were in the same range ( $e-8.02$  and  $e-7.95 \text{ hPa}\cdot\text{sec}^{-1}$  respectively).



**Figure 3:** Test conditions applied. Test conditions applied for each implant (green arrows indicate the possible leakage paths): A) abutment manual screwing. Nitrogen flow may occur at both gaps: between screw and abutment and between abutment and implant collar (assay 1). B) screw hole blocked with wax; manual (assay 2) or key (assay 3) screwing. C) abutment key screwing, screw hole and implant to abutment connection blocked with wax (as a negative test).

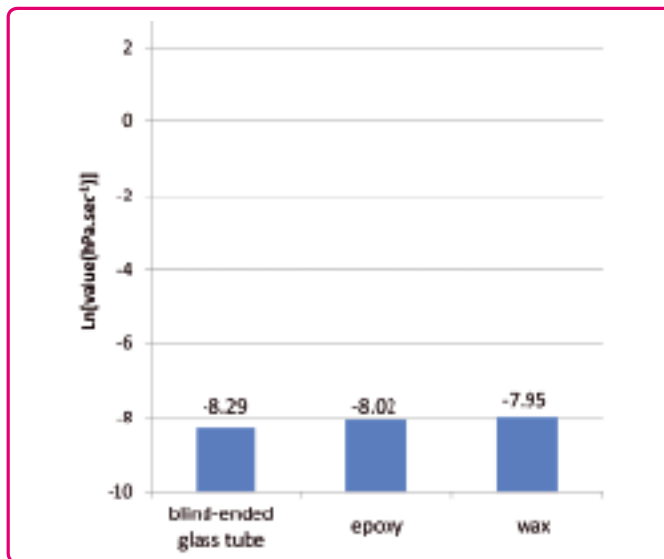


## SCIENTIFIC STUDIES

### Results

#### Negative tests

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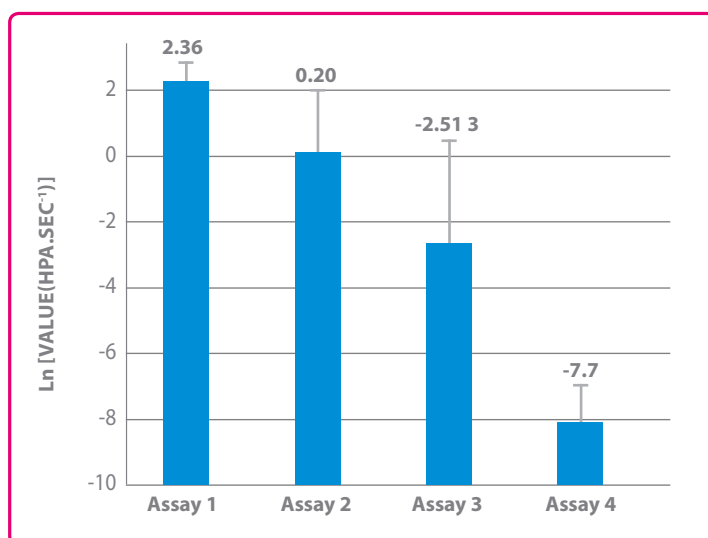
**Figure 4:** Experimental set-up tightness. Three tests were realized to assess experimental set-up tightness: -blind-ended glass tube; - epoxy: a double-ended opened glass tube sealed on one side with a plug of epoxy glue; - wax: a double-ended opened glass tube sealed on one side with a plug of wax.

### Reproducibility

The slope determination reproducibility for 10 curves, given by the Kendall's coefficient (W) of concordance test, was 0.9 (Kendall test),  $p = 0.0004$ . Reproducibility of the method has been calculated by repeating 10 times the measure on one implant and the abutment screwed with a dynamometric key at a torque value of 35 N.cm, and screw hole blocked with wax; the coefficient of variation was 1.29%, which is very low and is usually associated with reproducible methods of measurement.

### Dental implant-abutment assays

The results of the four assays (Figure 5) globally showed a very significant difference between the various sealing conditions. As could be expected, a lower flow was observed after having filled the screw hole with wax (though the difference was not significant between assay 1 and assay 2) (Table 1). Also, the dental implant-abutment remaining flow was lower after key screwing compared to hand screwing ( $p = 0.03$ ). Finally, the implant-abutment flow after key screwing showed to remain different from the negative test ( $p = 0.0004$ ). This observation suggests the persistence of leakage after key screwing in this sort of implant.



**Figure 5:** Gas leaking in four conditions. Gas leaking for the tested implants (values are indicated up bars): Assay 1, abutment manual screwing; Assay 2, abutment manual screwing, screw hole blocked with wax; Assay 3, abutment key screwing, screw hole blocked with wax; Assay 4, negative test with abutment key screwing, both screw hole and implant to abutment connection blocked with wax.

**Table 1: Pairwise comparisons between each assay**

Vs	Assay 4	Assay 3	Assay 2
Assay 1	p = 0.0001*	p = 0.02*	p = 0.06
Assay 1	p = 0.0001*	p = 0.03*	
Assay 1	p = 0.0004*		

#### Example with morse taper TBR implant.

were tested in the laboratory Health Biology and Nanoscience EA 4203 :

##### 5 M TBR implants

Diameter 3,9 mm, length 11,5mm

Screw abutments were tightened torque 30 Ncm

Lot 11/1038

Individual results of the leakage implant neck (natural logarithm of the slopes leakage expressed in millibars per second).

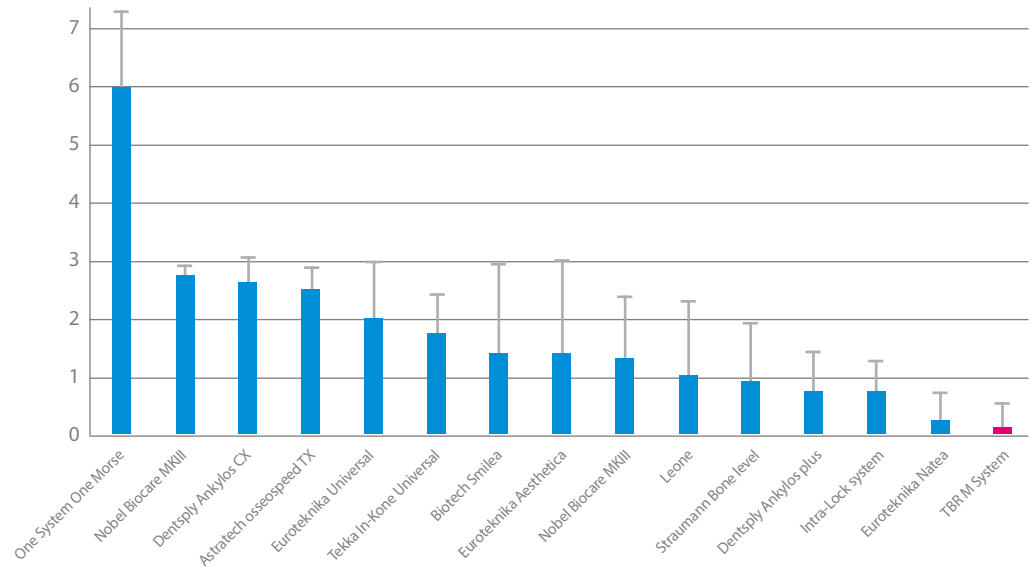
implant # 1	-8,42
implant # 2	-7,62
implant # 3	-8,46
implant # 4	-8,59
implant # 5	-8,77
average	-8,37
standard deviation	0,44





## SCIENTIFIC STUDIES

As a guide, the attached diagram graphically reflects these results, compared with other implants tested in the laboratory.



Compared with the results obtained by all other dental implants, implants TBR M showed a much smaller leak. It appears to have the less permeable connection among all to date tested systems with the technic. For record, the worst result in the graph (on the left) corresponds to Morse One implant (Ferrari) used in the publication which was used to validate the developed model. This reference is available in free text on the web and can be referred to it to have any technical detail about gaseous diffusion technique. Other results on the tightness of the implant connections method of gaseous diffusion have been published internationally and others more numerous in a French indexed review.

The good results of tbr M are partially due to the conical nature of the connection. But the very low leakage observed probably also shows the quality of the machining of these parts (both implants and abutments). Moreover, and this is also a quality, the variability of the observed leakage seems very low in this sample.

### Discussion

Clinically, existence of a gap does not mean necessarily bone loss. In particular, it was shown that micro-movement may have a higher influence than leakage [31]. Furthermore, in this gas permeability model, the size of porosity cannot be assessed precisely. The smaller capillary measurable with gas permeability has an internal diameter of 10  $\mu\text{m}$  (data not shown). This is much bigger than bacteria or even than endotoxin. On the other hand, this assay only assesses the global tightness of the connection. The possible spaces around the implant collar which would not communicate with the inner part of the implant do not influence the result, though they can have a major clinical role. Despite this, leakage can be considered as a good marker of the machining quality.

Unlike in the color marker methods, this technique allows successive measures of the different interfaces (screw hole, collar) without re-opening the connection. This characteristic could be very useful for assessing different treatments of the implant connection such as screwing torque control, chemical stress or mechanical stress. Clinically, tightness could be improved by different ways apart from the quality of machining, for instance by the use of a sealant such as GapSeal® (Hager Werken), though the authors did not find any scientific publication about this product using PubMed.

Using gas leakage allows a precise physical and reproducible value independent of water-wetting properties of the materials tested. The global leak measure obtained can be compared, for simplification and calibration, to an «equivalent capillary» with a length-diameter couple.

### Conclusions

This gas flow method appears to be a simple way to compare different implant systems. It seems to be better than the color marker techniques because it allows successive measures without disconnecting the abutment from the implant and is not subjected to entrapped air bubbles [31]. This new method could be used for instance to assess the behavior of the connection before and after a mechanical stress mimicking the mastication strengths.

Gas permeability appears to be a new, simple, quantitative, reproducible and practical in vitro technique to assess dental implant-abutment leakage.





## SCIENTIFIC STUDIES

# A systematic review of the performance of ceramic and metal implant abutments supporting fixed implant reconstructions



Irena Sailer, Alexander Philipp, Anja Zembic, Bjarni E. Pjetursson, Christoph H. F. Hammerle, Marcel Zwahlen



biological complications, ceramics, complication rates, failures, implant abutments, implant reconstructions, metal, stability, strength, survival, systematic review, technical complications, titanium, zirconia



2009



### ABSTRACT

**Objectives:** The objective of this systematic review was to assess the 5-year survival rates and incidences of complications associated with ceramic abutments and to compare them with those of metal abutments.

**Methods:** An electronic Medline search complemented by manual searching was conducted to identify randomized-controlled clinical trials, and prospective and retrospective studies providing information on ceramic and metal abutments with a mean follow-up time of at least 3 years. Patients had to have been examined clinically at the follow-up visit. Assessment of the identified studies and data abstraction was performed independently by three reviewers. Failure rates were analyzed using standard and random-effects Poisson regression models to obtain summary estimates of 5-year survival proportions.

**Results:** Twenty-nine clinical and 22 laboratory studies were selected from an initial yield of 7136 titles and data were extracted. The estimated 5-year survival rate of ceramic abutments was 99.1% [95% confidence interval (CI): 93.8–99.9%] and 97.4% (95% CI: 96–98.3%) for metal abutments. The estimated cumulative incidence of technical complications after 5 years was 6.9% (95% CI: 3.5–13.4%) for ceramic abutments and 15.9% (95% CI: 11.6–21.5%) for metal abutments. Abutment screw loosening was the most frequent technical problem, occurring at an estimated cumulative incidence after 5 years of 5.1% (95% CI: 3.3–7.7%). All-ceramic crowns supported by ceramic abutments exhibited similar annual fracture rates as metal–ceramic crowns supported by metal abutments. The cumulative incidence of biological complications after 5 years was estimated at 5.2% (95% CI: 0.4–52%) for ceramic and 7.7% (95% CI: 4.7–12.5%) for metal abutments. Esthetic complications tended to be more frequent at metal abutments. A meta-analysis of the laboratory data was impossible due to the non-standardized test methods of the studies included.

**Conclusion:** The 5-year survival rates estimated from annual failure rates appeared to be similar for ceramic and metal abutments. The information included in this review did not provide evidence for differences of the technical and biological outcomes of ceramic and metal abutments. However, the information for ceramic abutments was limited in the number of studies and abutments analyzed as well as the accrued follow-up time. Standardized methods for the analysis of abutment strength are needed.

# The mucosal attachment at different abutments An experimental study in dogs



Abrahamsson I, Berglundh T, Giant: P.-O. Lindhe J.



abutment; biomaterials: dogs; bistometry; Implant; peri-implant mucosa



1998



## ABSTRACT

The present experiment was performed to examine if the material used in the abutment part of an implant system influenced the quality of the mucosal barrier that formed following implant installation. 5 beagle dogs were included in the study. The mandibular premolars and the 1st, 2nd and 3rd maxillary premolars were extracted. Three fixtures of the Branemark System® were installed in each mandibular quadrant (a total of 6 fixtures per animal). Abutment connection was performed after 3 months of healing. In each dog the following types of abutments were used: 2 'control abutments' (c.p. titanium), 2 «ceramic abutments» (highly sintered AUOj), 1 «gold abutment», and 1 «short titanium abutment». This «short titanium abutment» was provided with an outer structure made of dental porcelain fused to gold. Following abutment connection a plaque control program was initiated and maintained for 6 months. The animals were sacrificed and perfused with a fixative. The mandibles were removed and each implant region was dissected, demineralized in EDTA and embedded in EPON\*. Semithin sections representing the mesial, distal, buccal and lingual aspects of the peri-implant tissues were produced and subjected to histological examination. The findings from the analysis demonstrated that the material used in the abutment portion of the implant influenced the location and the quality of the attachment that occurred between the periimplant mucosa and the implant. Abutments made of c.p. titanium or ceramic allowed the formation of a mucosal attachment which included one epithelial and one connective tissue portion that were about 2 mm and 1- 1.5 mm high, respectively. At sites where abutments made of gold alloy or dental porcelain were used, no proper attachment formed at the abutment level, but the soft tissue margin receded and bone resorption occurred. The abutment fixture junction was hereby occasionally exposed and the mucosal barrier became established to the fixture portion of the implant. It was suggested that the observed differences were the result of varying adhesive properties of the materials studied or by variations in their resistance to corrosion.







## SCIENTIFIC STUDIES

# The mucosal barrier at implant abutments of different materials



Maria Welander, Ingemar Abrahamsson, Tord Berglundh



biomaterials, dental implants, gold alloy, histology, peri-implant mucosa, soft tissue, titanium, zirconia



2007



### ABSTRACT

**Objective:** The aim of the present study was to analyze the soft tissue barrier formed to implant abutments made of different materials.

**Material and methods:** Six Labrador dogs, about 1 year old, were used. All mandibular premolars and the first, second and third maxillary premolars were extracted. Three months later four implants (OsseoSpeedt, 4.5–9mm, Astra Tech Dental, Mölndal, Sweden) were placed in the edentulous premolar region on one side of the mandible and healing abutments were connected. One month later, the healing abutments were disconnected and four new abutments were placed in a randomized order. Two of the abutments were made of titanium (Ti), while the remaining abutments were made of ZrO<sub>2</sub> or AuPt-alloy. A 5-months plaque control program was initiated. Three months after implant surgery, the implant installation procedure and the subsequent abutment shift were repeated in the contra-lateral mandibular region. Two months later, the dogs were euthanized and biopsies containing the implant and the surrounding soft and hard peri-implant tissues were collected and prepared for histological analysis.

**Results:** It was demonstrated that the soft tissue dimensions at Ti- and ZrO<sub>2</sub> abutments remained stable between 2 and 5 months of healing. At Au/Pt-alloy abutment sites, however, an apical shift of the barrier epithelium and the marginal bone occurred between 2 and 5 months of healing. In addition, the 80-mm-wide connective tissue zone lateral to the Au/Pt-alloy abutments contained lower amounts of collagen and fibroblasts and larger fractions of leukocytes than the corresponding connective tissue zone of abutments made of Ti and ZrO<sub>2</sub>.

**Conclusion:** It is suggested that the soft tissue healing to abutments made of titanium and ZrO<sub>2</sub> is different to that at abutments made of AuPt-alloy.

# Indications for immediate loading of implants and implant success



Emeka Nkenke, Matthias Fenner



dental implant, edentulism, immediate loading, level of evidence, oral implant, osseointegration, partial edentulism, single-tooth implant



2006



## ABSTRACT

It was the aim of this review to compare the survival and success rates of immediately loaded dental implants with those of conventionally loaded dental implants, based on prospective controlled studies and prospective studies without controls. Studies on immediate loading were identified in the current literature by electronic and hand searches. Only clinical data on root-form or cylindrical threaded oral implants were included. For immediate loading of oral implants in the edentulous and partially dentate, mandible and maxilla controlled studies could be found. All of these studies were based on limited patient numbers. Therefore, definitive conclusions could not be drawn concerning survival and success rates of immediately loaded implants compared with conventionally loaded implants. The compilation of the current literature shows that prospective controlled studies as well as prospective studies without controls using several different approaches to immediate loading have demonstrated high implant survival and success rates. However, more high-level evidence-based studies are needed to demonstrate the relative merits of immediate loading compared with conventional loading in all potential applications.

## Conclusions

The compilation of the current literature shows that several different approaches to immediate loading can lead to survival rates in controlled studies comparable with those of conventionally loaded implants. This is true for edentulous as well as partially dentate situations; however, these studies are only based on small case numbers. At the moment, it is not possible to draw conclusions concerning exclusion and inclusion criteria for immediate loading, threshold values for implant stability that allow immediate loading, bone quality needed for immediate loading and the relevance of immediate functional loading and immediate nonfunctional loading under certain conditions. More controlled studies with larger patient numbers are needed to make immediate loading of oral implants completely evidence based.





## SCIENTIFIC STUDIES

# Bacterial adhesion and colonization differences between zirconia and titanium implant abutments: an in vivo human study



Greison Rabelo de Oliveira, Leandro Pozzer, Lucas Cavalieri-Pereira, Paulo Hemerson de Moraes, Sergio Olate, Jose Ricardo de Albergaria Barbosa



bacterial adhesion, dental abutments.



2012

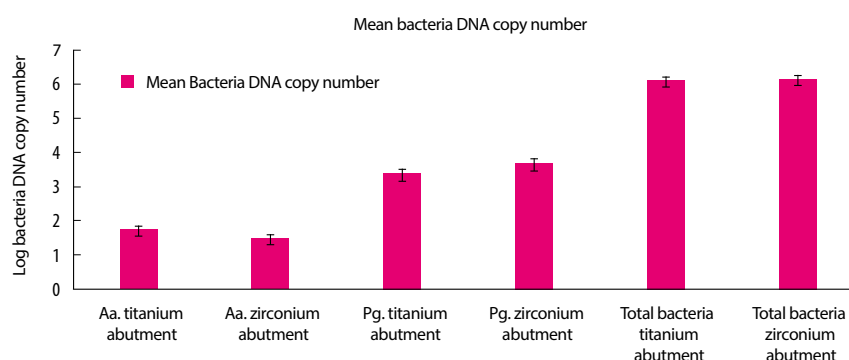


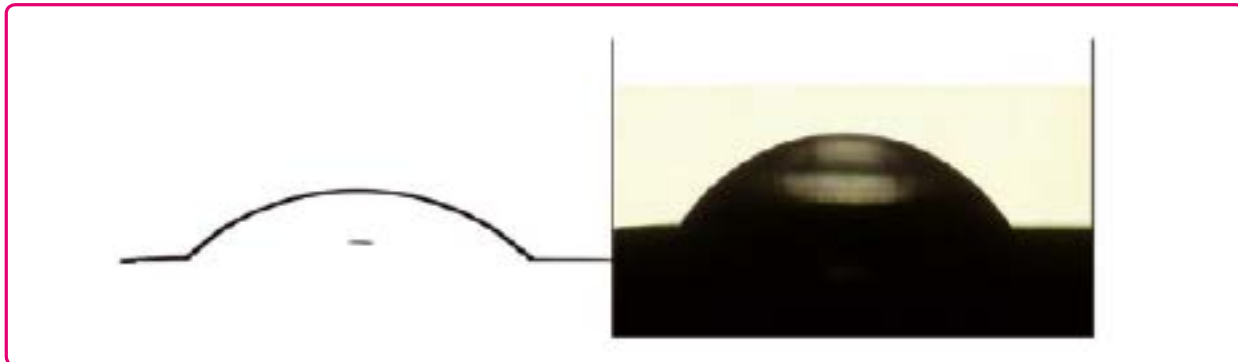
**Purpose:** Several parameters have been described for determining the success or failure of dental implants. The surface properties of transgingival implant components have had a great impact on the long-term success of dental implants. The purpose of this study was to compare the tendency of two periodontal pathogens to adhere to and colonize zirconia abutments and titanium alloys both in hard surfaces and soft tissues.

**Methods:** Twelve patients participated in this study. Three months after implant placement, the abutments were connected. Five weeks following the abutment connections, the abutments were removed, probing depth measurements were recorded, and gingival biopsies were performed. The abutments and gingival biopsies taken from the buccal gingiva were analyzed using real-time polymerase chain reaction to compare the DNA copy numbers of *Aggregatibacter actinomycetemcomitans*, *Porphyromonas gingivalis*, and total bacteria. The surface free energy of the abutments was calculated using the sessile water drop method before replacement. Data analyses used the Mann Whitney U-test, and P-values below 0.05 find statistical significance.

**Results:** The present study showed no statistically significant differences between the DNA copy numbers of *A. actinomycetemcomitans*, *P. gingivalis*, and total bacteria for both the titanium and zirconia abutments and the biopsies taken from their buccal gingiva. The differences between the free surface energy of the abutments had no influence on the microbiological findings.

**Conclusions:** Zirconia surfaces have comparable properties to titanium alloy surfaces and may be suitable and safe materials for the long-term success of dental implants.

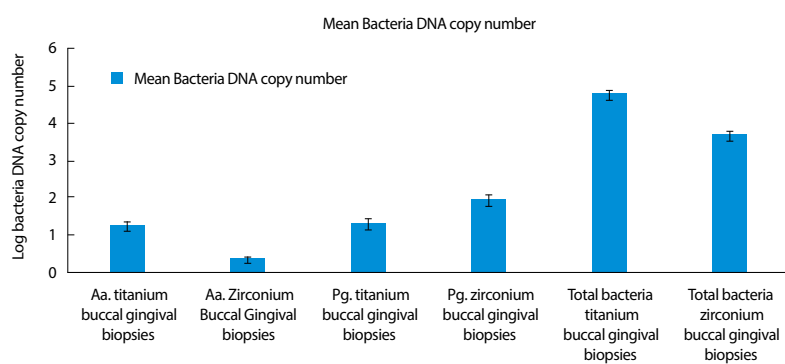




**Figure 1.** The angular value of titanium abutment obtained by sessile water drop: 129.08°.



**Figure 2.** The angular value of zirconium abutment obtained by sessile water drop: 137.99°.





## SCIENTIFIC STUDIES

# The effect of material characteristics, of surface topography and of implant components and connections on soft tissue integration: a literature review



Eric Rompen, Olivier Domken, Marco Degidi, Ana Emilia Farias Pontes, Adriano Piattelli



biomaterials, material science, soft tissue–implant interaction, surface chemistry, wound healing



2006



To be functionally useful, oral implants have to pierce the oral mucosa and enter the oral cavity, thus establishing a transmucosal connection between the external environment and the inner parts of the body. In order to avoid bacterial penetration through this transmucosal piercing, the early formation of a long-standing effective barrier capable of biologically protecting the peri-implant structures is of paramount importance. It is a critical part of tissue integration, and may in part depend on: Material chemistry It is mandatory to place at the transmucosal level a material tissues can adhere to: c.p. titanium is the only material that has proven his biocompatibility towards the soft tissues in long-term clinical studies; some favourable clinical data become available for zirconium and aluminium oxide; animal studies have shown that dental porcelain or gold are less biocompatible and should be avoided. Materials such as resins and composites should not be recommended up to now; the surface of the core material can be contaminated, altering the composition of the interface. Saliva has shown deleterious and hardly reversible effects in vivo. Other contaminations, such as handling in the dental laboratory, could also be detrimental. It should be noted that, with one-piece implants, it is most unlikely to alter the composition of the transmucosal part which will therefore always be biocompatible with currently commercially available one-piece systems.

### Surface topography

No clinical studies are currently available on the effect of altered surface topographies on implant prognosis. Results from in vitro and in vivo studies indicate that surface roughness and surface texture in the micrometer range may have an impact on the early events of healing by influencing attachment, orientation, proliferation and metabolism of epithelial and connective tissue cells. Some roughened titanium surfaces seem to improve the formation of a superficial fibrin network, which could hypothetically be positive for the initial stability of the interface and impair epithelial cells downgrowth. In vitro and in vivo studies tend to indicate that epithelial cells adhesion is lower on rough titanium surfaces than on machined titanium. Animal studies show that micromachined grooved surfaces of appropriate dimensions can improve connective tissue ingrowth and inhibit epithelial downgrowth. Implant components and connections Comparative animal studies have shown equivalent soft tissue integration at one-piece implants and at abutments of two-piece implant systems. These data are confirmed by long-term clinical studies demonstrating the stability of soft tissue integration and comparable marginal bone remodelling at both concepts. It is meanwhile noteworthy that: At two-piece implants systems, animal studies have noticed a discrete inflammatory cell infiltrate at the abutment/ implant interface, the effect of which on marginal bone level being limited and controversial. Unintentional or repeated intentional disconnections of the abutment at two-piece implant systems has been shown to disrupt the soft tissue integration and to induce an increased marginal bone remodelling. As it is also more likely to place transmucosal components with an altered biocompatibility on two-piece implant systems (c.f. supra), effective soft tissue integration at one-piece implants seems easier to reproducibly obtain.

# Indications for immediate loading of implants and implant success



B. Emeka Nkenke, Matthias Fenner



allografts, alveolar ridge augmentation, autografts, dental implants, guided tissue regeneration, sinus floor augmentation, soft-tissue grafts, xenografts  
dental implant, edentulism, immediate loading, level of evidence, oral implant, osseointegration, partial edentulism, single-tooth implant



2006



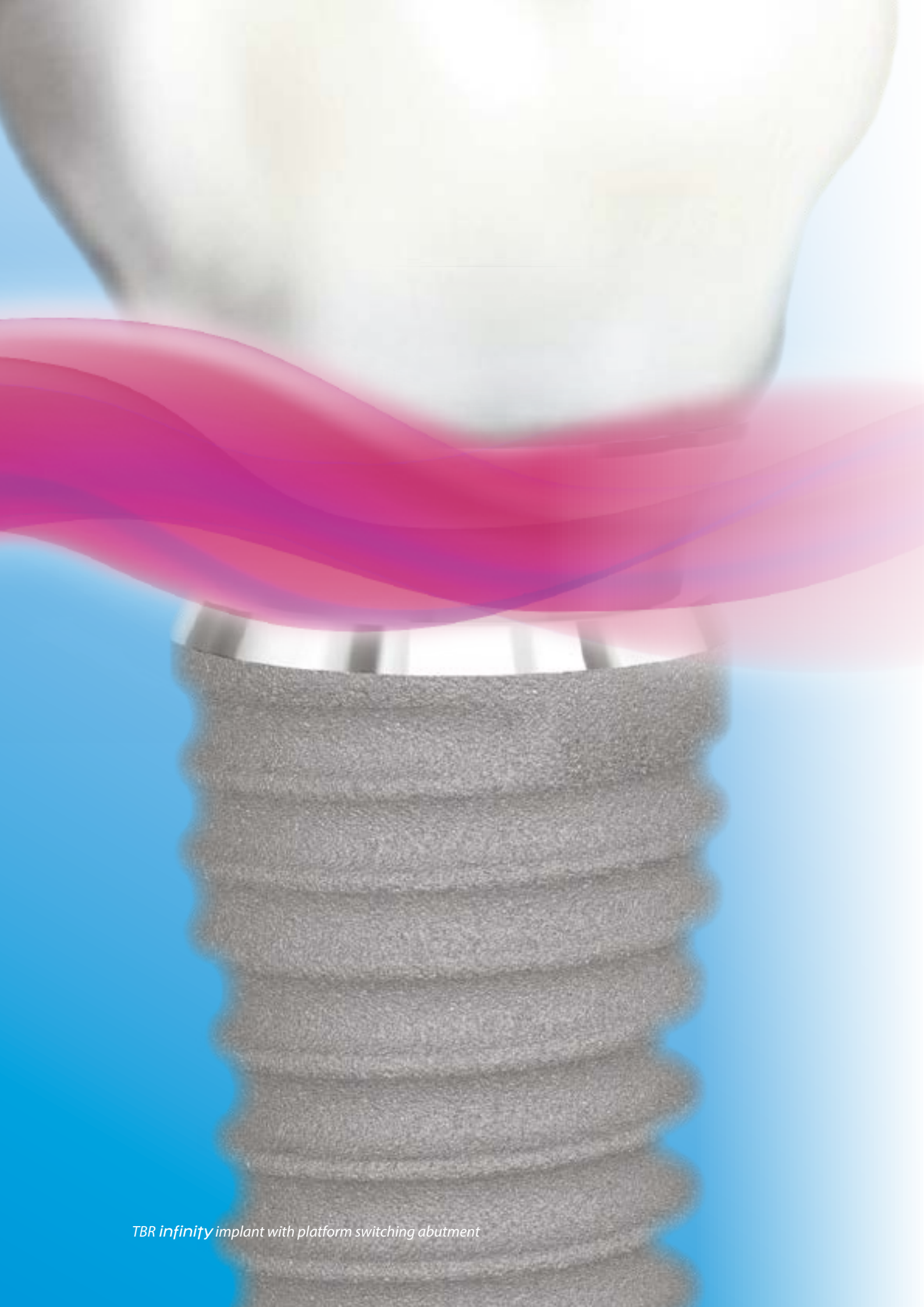
## ABSTRACT

It was the aim of this review to compare the survival and success rates of immediately loaded dental implants with those of conventionally loaded dental implants, based on prospective controlled studies and prospective studies without controls. Studies on immediate loading were identified in the current literature by electronic and hand searches. Only clinical data on root-form or cylindrical threaded oral implants were included. For immediate loading of oral implants in the edentulous and partially dentate, mandible and maxilla controlled studies could be found. All of these studies were based on limited patient numbers. Therefore, definitive conclusions could not be drawn concerning survival and success rates of immediately loaded implants compared with conventionally loaded implants. The compilation of the current literature shows that prospective controlled studies as well as prospective studies without controls using several different approaches to immediate loading have demonstrated high implant survival and success rates. However, more high-level evidence-based studies are needed to demonstrate the relative merits of immediate loading compared with conventional loading in all potential applications.

## Conclusions

The compilation of the current literature shows that several different approaches to immediate loading can lead to survival rates in controlled studies comparable with those of conventionally loaded implants. This is true for edentulous as well as partially dentate situations; however, these studies are only based on small case numbers. At the moment, it is not possible to draw conclusions concerning exclusion and inclusion criteria for immediate loading, threshold values for implant stability that allow immediate loading, bone quality needed for immediate loading and the relevance of immediate functional loading and immediate nonfunctional loading under certain conditions. More controlled studies with larger patient numbers are needed to make immediate loading of oral implants completely evidence based.





*TBR infinity implant with platform switching abutment*



# TISSUE MANAGEMENT

■	Soft tissue level implant solution : from osseo-integration to perio-integration	P	88
■	A success rate higher than 97%	P	90
■	A systematic review assessing soft tissue augmentation techniques	P	92
■	Biological basis for soft tissue management in implant dentistry	P	93
■	Factors affecting soft tissue around dental implants: A review of the literature	P	94
■	Prevalence, extent and severity of peri-implantitis	P	95
■	Long-term stability of surgical bone regenerative procedures of peri-implantitis lesions in a prospective case-control study over three years	P	96
■	Soft-tissue integration of implants Consensus report of Working Group 2	P	97
■	The soft tissue response to osseointegrated dental implants	P	102
■	Tissue augmentation and esthetics (Working Group 3)	P	103





## SCIENTIFIC STUDIES

# Soft tissue level implant solution : from osseo-integration to perio-integration



TBR Research Center



soft tissue level, zirconia-titanium implant, perio-integration



2010



Osseo integration alone of the dental implant is not sufficient to ensure a successful long-term implant restoration and perfect dental aesthetics. The dental implant must integrate into the soft tissues as well. In 1998, experimental animal research carried out by Abrahamson demonstrated that the quality of the peri-implant tissue attachment depended primarily on the implant material that would be in contact with gingival tissue. Gingival tissue heals at the neck of the implant (1-stage surgical system), at the level of the healing screw/implant abutment (2-stage surgical system), or at the level of the rings of MCB abutments (2-part, prosthetic abutment systems, precursor of the hybrid technology, consisting of a zirconium trans gingival and a titanium supra gingival element). The integration is further, more or less significant depending on the surface topography of the material used. The material and its surface topography will determine the nature of the connection of the surrounding implant tissue, the thickness of the tissue and how it will act as a anti- bacterial barrier.

### **ZIRCONIUM, A MATERIAL THAT FAVORS GINGIVAL INTEGRATION**

Clinical results obtained regularly from the use of zirconium as the transgingival material, show : coronary repositioning, papillary reconstruction, scalloped gum.

These results can be interpreted as follows:

#### **REDUCED BACTERIAL ADHESION**

On one hand, microscopic electron scanning and profilometric analysis of zirconium and machined titanium surfaces reveal that the zirconium surface is much smoother than that of machined titanium. On the other hand, histological measurements of the interface of a zirconium and a titanium abutment, at 2 and 5 months of healing were carried out by Welander in 2008. This comparative study based on the Shroeder (1973) / Berglundh and al. (1992) method and on a stereological technique consists in measuring the percentage of leukocytes found in the gingival epithelial and connective tissue. This study is based on the hypothesis that a lower percentage of immune cells (leukocytes, granulocytes, macrophages, etc.) implies a feeble adhesion of bacteria. Yet, the results of this study show that in both types of tissue the percentage of leukocytes present in the tissue surrounding the zirconium surface was less than in that surrounding the titanium surface. Those results reveal that the topography of the zirconium transgingival surface results in a lower level of bacterial adhesion than does that of a titanium surface. Zirconium, when used in a transgingival setting reduces the microbiological challenges thereby resulting in improved conditions for healing and in increased growth of healthy soft tissue. Welander and al. (2008) study was subsequently pursued further. Indeed, the initial objective of the different methods and techniques quoted was to evaluate the epithelial attachment to the implant (abutment, etc.) and study the composition of the connective tissue.

#### **HISTOLOGICAL INPUT OF ZIRCONIUM**

##### **- CHARACTERISTICS OF EPITHELIAL TISSUE**

Welander and al. worked once more on the results obtained above, affirming that the zirconium provides surrounding conditions favoring epithelial attachment, therefore appropriate thick mucus membrane. Once the epithelial cells, which are able proliferate and displace themselves, approach the zirconium surface,

they connect to it via a basal lamina and hemidesmosomes connections. These begin to form as of the 2nd day after the implant. They continue to proliferate up the apical pole (of the basal lamina), along the zirconium surface, until they cover 2 mm. The newly formed epithelium surrounding the transgingival device has all of the histological characteristics of that of a normal tooth. Thus, the epithelial attachment is a dynamic structure allowing coronary migration, a veritable mimicry of the classic creeping attachment described in periodontics.

#### - CHARACTERISTICS OF CONNECTIVE TISSUE

Welander and al (2008) were able to determine the proportion of collagen fibers, fibroblasts, vascular structures, leukocytes and residual tissues (nerves, matrical matter and unidentified structures) in the connective tissue. The result of their experiments reveals that the percentage of collagen fibers around the zirconium was superior to the percentage of fibroblasts. Both values were superior to those found in the tissue surrounding titanium. Tetè and al. histological study (2009) comparing 10 implants with a machines titanium neck and 20 implants with a zirconium ring, all implanted in the mandibular crestal bone of 5 pigs, revealed additional information. In addition to determining leucocytes levels in the connective tissue, the experiment was designed to identify the orientation of the collagen fibers surrounding the zirconium and titanium implants. Collagen fibers are the major components of the extracellular matrix in all mammalian connective tissue. They form an essential framework used by fibroblasts as scaffolding to "crawl" along the zirconium surface. The collagen fiber orientation influences the direction of fibroblasts' growth, their capacity to move towards the transgingival dispositive (implant, abutment) and form an adequate connective seal. It was discovered that the number of 86°-90° oriented fibers in contact with zirconium were superior in number. Therefore, the peri-implant tissue surrounding specifically the zirconium surface (implant, abutment, etc.) is concentrated in collagen fiber. The percentage of fibers oriented perpendicularly to the implant is higher around zirconium than around other biomaterials. This distribution results in ideal conditions for the reconstruction of the mucosa and the formation of quality epithelial attachment. Zirconium in direct contact with the gingival mucosa results in a coronary position of the gingival margin, the shape, colour and contour of the labial gingival tissue and the adequacy of the interdental papillae, in harmony with the surrounding teeth and tissue.

#### A 1-STAGE SURGICAL SYSTEM THAT ENHANCES GINGIVAL INTEGRATION

The different surgical techniques applied will affect the implant's gingival integration. Depending on the type of system used, the surgical and prosthetic acts can be more or less invasive for the soft tissue. In the case of a 2-stage surgical procedure, soft tissue is not in direct contact with the implant, which is buried in the bone. Thus, during the initial procedure, only the Osseo-integration is taken into account. The concern for the gum to heal arises subsequently, months after the osseo-integration. A second surgical act is necessary to place the healing screw or prosthetic abutment. In the case of a 1-stage implant placement, the soft tissues are in direct contact with the non embedded part of the implant. There is only a first intention healing, both at a time : bone healing surrounding titanium, and the gum in contact with the zirconium ring of TBR 1-stage surgical zirconia-titanium implant. The head of the implant is exposed to the oral cavity. The prosthetic abutment can then be placed directly after taking off the cover screw, no additional operation is necessary. After studying clinical cases, Degigi (2009) concluded that the 1-stage implant was favored by practitioners (ease of placement, clinical satisfaction) as well as patients (fewer surgeries, esthetical purposes). By reducing the trauma to the transgingival tissue, the 1-stage surgical procedure reduces the environmental risks inherent surgical and prosthetic acts. Until today, the ideal gingival integration of an implant was one where the various biological components or constraints were controlled and overcome. Thanks to a 1-stage surgical system with a zirconia transgingival ring, this integration becomes highly reproducible. It has been shown that zirconium is a biomaterial of choice and has all of the combined properties necessary for a gingival integration similar to that of nature in terms of histology, biological composition as well as in terms of esthetics " creeping attachment". TBR 1-stage surgical zirconia-titanium implant conforms to these criteria in order to obtain a complete, lasting, and reliable dental restoration with finishings answering to esthetic standards and biocompatibility.





## SCIENTIFIC STUDIES

# A success rate higher than 97%



Dr Carlos MADRID, Dr André BENHAMOU



implants, success rate, osseointegration



Summer 1995



A statistical study was conducted for 1936 T.B.R.<sup>®</sup> implants inserted between 1985 and 1992 on 689 patients, led by Doctor Carlos MADRID of the Faculty of Dental Surgery of Toulouse (France). 5 years after loading, results confirmed the reliability of T.B.R.<sup>®</sup> implants. Global success rate was higher than 97% (98% in mandible, 96% in maxilla).

### Statistical data

Albrektsson's criteria were utilized for this study.

### Patients

Patient distribution according to sex : 397 males, 292 females. Patients age ranged from 17 to 90 years-old with an average age of 45,5.

### Implant type

The 906 maxillary implants were cylindrical implants, 370 of which were coated with Hydroxyapatite. A total of 1030 implants were inserted into the mandible. 479 were cylindrical, 375 screw type and 176 blade-type (T.B.R.2).

### Implant length

Among the 1760 cylindrical and screw type implants, 15% were 8 mm long, 44% 10,5 mm long, 34% 13 mm long and 7% 15,5 mm long.

### Prosthetic distribution

In 57% of cases, prosthetic reconstruction was implant/tooth-supported. The 43% remaining were implant-supported (31,5% single-tooth, 32% bar, 36,5% bridge).

### Failures

52 implants were removed. 65% of failures occurred in the maxilla and 35% in the mandible. On average, failures occurred 9,3 months after implant insertion (standard deviation +/- 2,4 months). The 8 mm-long implants represented 31% of failure whereas they only represented 15% of total implants.

## Mandible



## Maxilla



## TOTAL





## SCIENTIFIC STUDIES

# A systematic review assessing soft tissue augmentation techniques



Daniel S. Thoma, Goran I. Benic, Marcel Zwahlen, Christoph H. F. Hämmerle, Ronald E. Jung



allogenic dermal matrix, free gingival graft, human fibroblast-derived dermal substitute, keratinized tissue, soft tissue augmentation, soft tissue volume, subepithelial connective tissue graft, vestibuloplasty



2009



### ABSTRACT

**Aim:** The aim of the present review was to systematically assess the dental literature in terms of soft tissue grafting techniques. The focused question was: is one method superior over others for augmentation and stability of the augmented soft tissue in terms of increasing the width of keratinized tissue (part 1) and gain in soft tissue volume (part 2).

### METHODS

A Medline search was performed for human studies focusing on augmentation of keratinized tissue and/or soft tissue volume, and complemented by additional hand searching. Relevant studies were identified and statistical results were reported for meta-analyses including the test minus control weighted mean differences with 95% confidence intervals, the I-squared statistic for tests of heterogeneity, and the number of significant studies.

### RESULTS

Twenty-five (part 1) and three (part 2) studies met the inclusion criteria; 14 studies (part 1) were eligible for comparison using meta-analyses. An apically positioned flap/ vestibuloplasty (APF/V) procedure resulted in a statistically significantly greater gain in keratinized tissue than untreated controls. APF/V plus autogenous tissue revealed statistically significantly more attached gingiva compared with untreated controls and a borderline statistical significance compared with APF/V plus allogenic tissue. Statistically significantly more shrinkage was observed for the APF/V plus allogenic graft compared with the APF/V plus autogenous tissue. Patient-centered outcomes did not reveal any of the treatment methods to be superior regarding postoperative complications. The three studies reporting on soft tissue volume augmentation could not be compared due to lack of homogeneity. The use of subepithelial connective tissue grafts (SCTGs) resulted in statistically significantly more soft tissue volume gain compared with free gingival grafts (FGGs).

### CONCLUSIONS

APF/V is a successful treatment concept to increase the width of keratinized tissue or attached gingiva around teeth. The addition of autogenous tissue statistically significantly increases the width of attached gingiva. For soft tissue volume augmentation, only limited data are available favoring SCTGs over FGG.

# Biological basis for soft tissue management in implant dentistry



SCH Yeung



peri-implant soft tissue, biological width, peri-implant keratinized gingiva.



2008



## ABSTRACT

Good aesthetic finish of implant / restorations requires healthy peri-implant soft tissue at the appropriate location. The relevance of the peri-implant soft tissue seal, the biological width, the keratinized gingival zone and the need for effective plaque control in order to maintain peri-implant soft tissue health were discussed. The presence of a soft tissue seal/cuff around dental implants and abutments and its role in defense against infection were convincingly demonstrated in animal studies. In order to achieve long-term stable peri-implant health, it is important to achieve an adequate soft tissue seal around dental implant/restorations. The constant dimension of a biological width (of the soft tissue) often dictates where the final gingival margin will be. It is therefore not surprising that the position and stability of the alveolar bone ridge surrounding dental implants ultimately determines where the gingival margin rests. For dental implant restorations in the aesthetic zone, this is a crucial variable for the clinician to understand and deliver. Available data so far suggest that with good oral hygiene, peri-implant soft tissue health can be maintained irrespective if a keratinized gingival tissue zone surrounding implant/restoration is present. In reality, good oral hygiene is very difficult to achieve around dental restorations without the protection of a band of keratinized gingival tissue. Studies on peri-implantitis and peri-implant mucositis further demonstrated the causal relationship between dental plaque accumulation and peri-implant inflammation. It is therefore imperative that long-term maintenance care of dental implants and implant supported dental restorations should include a strict regime of plaque control and monitoring.

## CONCLUSIONS

Good aesthetic finish in implant dentistry requires appropriate soft tissue management. Satisfactory soft tissue results cannot be achieved without the good foundation of adequate blood supply and hard tissue support. Hence, it is of critical importance that attention is paid during the treatment planning step and the execution of the surgical procedures in implant placement for the preservation and recreation of the loss of alveolar bone. The preservation (or recreation) of the alveolar bone forms the basis of a good aesthetic finish of the final restoration. Without the laying down of these foundations, the manipulation of the soft tissue alone is not sufficient to bring about a satisfactory result.







## SCIENTIFIC STUDIES

# Factors affecting soft tissue around dental implants: A review of the literature



Heidi L. Myshin, a and Jonathan P. Wiens



soft tissue management, dental implants



2005



Much of the focus in the early dental implant literature is on the bone-to-titanium interface because a successful osseointegrated implant requires direct bone contact to the implant surface. The research on soft tissue around dental implants has focused on the partially edentulous patient and, in particular, on the maxillary anterior dentition. Few studies have evaluated soft tissue around dental implants in completely edentulous patients over time. This paper reviews the pertinent literature on soft-tissue healing in both partially and completely edentulous dental implant patients from a Medline search of the English peer-reviewed literature from 1980 to 2004.

### Aim

Healing around dental implants is affected by the patient's health, soft- and hard-tissue contours, and the use and care of the prosthesis, as well as the manufacturer's implant-abutment designs, surgical augmentation and placement, and the design of the definitive prosthesis.

### This literature review revealed:

1. There are no specific guidelines relative to the amount of space or clearance necessary for a patient to clean beneath a fixed implant-supported prosthesis and whether these tissues change predictably over time.
2. Individual variability contributes to the difficulties in assessing soft tissues around dental implants in edentulous patients.
3. Data on trends in soft-tissue shrinkage or hyperplasia should not be pooled to include partially dentulous and edentulous patients.

# Prevalence, extent and severity of peri-implantitis



Christer Fransson



dental implants, peri-implantitis



2009



Department of Periodontology, Institute of Odontology, the Sahlgrenska Academy at University of Gothenburg, Box 450, 405 30 Göteborg, Sweden.

Peri-implantitis is a disorder that affects the tissues surrounding a functional implant. Peri-implantitis can lead to implant loss and impaired function. There is limited information regarding the prevalence of peri-implantitis. In addition the extent of the disease and pattern of bone loss are poorly described. The objective of the present series of studies was to assess the prevalence of subjects exhibiting progressive bone loss at implants supporting fixed prosthesis (Study I) and to examine the clinical characteristics at implants with radiographic evidence of progressive bone loss (Study II). Furthermore, the extent, severity and pattern of periimplantitis-associated bone loss were evaluated (Study III and Study IV). Bone-level assessments were performed in intra-oral radiographs and the clinical conditions of the peri-implant tissues were examined. A multilevel growth curve model was used to analyze the pattern of bone loss. It was demonstrated that 28% of subjects had one or more implants with progressive bone loss. The individuals in this group carried a significantly larger number of implants than the subjects in whom no implants with progressive loss were detected (6.0 vs. 4.8). Out of the total 3413 implants included in the study 12.4 percent demonstrated progressive bone loss (Study I). Clinical signs of pathology were more frequent at implants with than without progressive bone loss. Smokers had larger numbers of affected implants than nonsmokers and the proportion of affected implants that exhibited pus and PPD  $\geq 6$  mm was higher in smokers than in non-smokers. The findings of pus, recession and PPD  $\geq 6$  mm at an implant in a smoking subject had a 69% accuracy in identifying history of progressive bone loss (Study II). About 40% of the implants in each affected subject had peri-implantitis. The proportion of such implants varied between 30 and 52% in different jaw positions. The most common position was the lower front region. (Study III). The average bone loss after the first year of function at the affected implants was 1.65 mm and 32% of the implants demonstrated bone loss  $\geq 2$  mm. The bone loss showed a non-linear pattern and the rate of bone loss increased over time (Study IV). Key words: bone loss, complications, dental implants, implant position, human, multilevel analyses, peri-implantitis, radiographs, smoking.

## Conclusions

This series of studies have demonstrated that:

- (i) prevalence of progressive bone loss at implants assessed from subject-based data is higher than that evaluated from implant-based data,
- (ii) there is an association between clinical signs of pathology and bone loss at implants,
- (iii) peri-implantitis occurs in all jaw positions and that an "end"-abutment position in a fixed reconstruction is not associated with an enhanced risk for peri-implantitis, (iv) peri-implantitis-associated bone loss varies between subjects and is in most cases characterized by non-linear progression with increasing rate over time.





## SCIENTIFIC STUDIES

# Long-term stability of surgical bone regenerative procedures of peri-implantitis lesions in a prospective case-control study over three years



Ann-Marie Roos-Jansåker, Christel Lindahl, G. Rutger Pesson, Stefan Renvert



peri-implantitis, surgery, bone graft, membrane, defect fill, plaque index



2011



### Abstract

**Objectives:** To evaluate the extent of bone fill over three years following surgical treatment of peri-implantitis with bone grafting with or without a membrane. **Material & Methods:** In a non-submerged wound healing mode, 15 subjects with 27 implants were treated with a bone substitute (Algapore) alone, and 17 subjects with 29 implants were treated with the bone substitute and a resorbable membrane (Osseoquest). Implants with radiographic bone loss  $\geq 1.8$  mm following the first year in function, and with bleeding and/or pus on probing were included. Following surgery subjects were given systemic antibiotics (10 days) and rinsed with chlorhexidine. After initial healing the subjects were enrolled in a strict maintenance program.

### Results

Statistical analysis failed to demonstrate changes in bone fill between one and three years both between, and within procedure groups. Mean defect fill at three years was  $1.3 \pm (\text{S.D.})1.3$  mm if treated with bone substitute alone and  $1.6 \pm (\text{S.D.})1.2$  mm if treated with an adjunct resorbable membrane, ( $p=0.40$ ). Plaque index decreased from approximately 40% to 10% remaining stable during the following two years. **Conclusion:** Defect fill using a bone substitute with or without a membrane technique in treatment of peri-implantitis can be maintained over three years.

# Soft-tissue integration of implants

## Consensus report of Working Group 2



Björn Klinge, Joerg Meyle



animal experiments, biomaterials, bone implant interactions, clinical research, clinical trials, material science, microbiology, soft-tissue implant interactions, surface chemistry



2006



Oral implants pierce through the mucosa thus establishing a connection between the oral environment and underlying tissues. The soft-tissue connection to the transmucosal part is of crucial importance as it relates to the stability of the peri-implant tissues and the prevention of peri-implant infection with subsequent destruction of the peri-implant structures.

The adhesion of soft tissue to the material surface is one prerequisite for the longterm success. This adhesion is depending upon the topography and chemical composition of the implanted biomaterial. As regards to surface topography of implants we refer to the definitions proposed by Albrektsson & Wennerberg (2004a, 2004b), where minimally rough surface has been defined in the range of Sa 0.5–1 mm (e.g., turned implants), moderately rough Sa 1–2 mm (e.g., acid etched, sandblasted or anodized) and rough Sa 42 mm (e.g., plasma sprayed).

*Effect of material characteristics and/or surface topography on biofilm development (Teughels et al.)*

1 Does surface roughness have an impact on biofilm formation and composition?

The data show that increased surface roughness has an impact (increased number of bacteria, increased area covered by biofilm and less coccoid species) on biofilm formation.

**Comments:** This review deals with different materials like dental restorations and implant abutments.

There are only four controlled clinical trials (CCTs) with split-mouth design (including 34 patients), which are related to abutments and titanium surfaces. Even though trends toward shifts in the composition of the biofilm have been observed, the bacterial species have not been fully analyzed.

2 Does surface-free energy have an impact on biofilm formation and composition?

The data show that increased surface-free energy has an impact (increased number of bacteria, increased area covered by biofilm and less coccoid species) on supragingival biofilm formation. This review deals with different materials like dental restorations and implant abutments. There are not enough data related to abutments.

3 Does the chemical composition of the material surface have an impact on biofilm formation and composition?

No conclusions can be drawn from the data available.

The materials analyzed are very heterogeneous (different material characteristics, various observation periods).





## SCIENTIFIC STUDIES

### Implications for research

Randomized controlled clinical trial (RCT) studies are needed to examine the relative impact of surface characteristics (identifying properly roughness, surface-free energy and surface chemistry) of the transmucosal part of the implants on the subgingival plaque formation. A systematic review of marginal soft tissue at implants subjected to immediate loading or immediate restoration (Glauser et al.)

#### 1 Does immediate loading/immediate restoration affect marginal soft tissues?

Only two RCTs on overdentures in the mandible and none on fixed restorations on implants have been found, where soft tissue changes have been evaluated comparing immediate loading to the standard protocol (delayed loading). From the available data one can only suggest the following provisional conclusions: When probing depth changes have been used as the outcome measurement to assess soft tissue changes two RCTs and one CCT on patients treated with overdentures have shown comparative changes between the immediate and delayed loading protocols. In fixed restorations there is only one CCT reporting similar outcomes. When gingival inflammation has been assessed as an outcome measurement of soft-tissue health, both clinical protocols have rendered similar results in the previous studies. When papillae were evaluated using the Jemt index, five studies on fixed reconstructions are available (one CCT, four case series (CS)). The results after 1 year show considerable heterogeneity ranging from complete interproximal soft-tissue fill (score 3) to an unsatisfactory outcome (scores 1–2). Facial recessions of the gingival/mucosal margins have been assessed in four studies (all CS) showing as average a mean recession between 0.5 and 1mm after 1 year. These statements are based on findings from non-augmented sites. It should also be noted, that in the majority of the studies (14) a conventional flap procedure was used. However in three additional studies flapless techniques were used. In one study both techniques were used. As there are no comparative data available, the influence of the surgical technique on the outcome on the soft tissues cannot be evaluated.

### Comments

Provided that no changes of the crown contours have been made, the Jemt index can be used for longitudinal evaluation of the papillary stability. Other indices such as the implant crown esthetic index and the pink esthetic score, have been introduced for a composite esthetic appraisal of the final restorative results. However they do not specifically assess the soft-tissue component using objective measurements. The influence on soft tissues of immediate placement/loading (extraction sockets) cannot be assessed with the data available.

### Implications for research

In order to evaluate the soft tissues around implants (RCT) studies should be performed comparing:

- (a) different surgical protocols,
- (b) different implant loading/restoration protocols,
- (c) different implant hardware.

A more detailed approach with regard to early events (within the first 6 months after insertion), long-term changes and parameters used to assess soft-tissue dimensions is recommended. Future research should focus on an independent comprehensive longitudinal approach including periodontal measurements (soft-tissue dimension, soft-tissue margin, papilla) and subjective parameters of the patient also respecting the changes related to the insertion of definitive restorations. Provided that no changes of the crown contours have been made, the Jemt index can be used for longitudinal evaluation of the papilla stability, otherwise other (metric) measurements should be applied. Future studies should investigate the surface of transmucosal abutments in clinical studies. *The effect of material characteristics, of surface topography and of implant components and connections on soft-tissue integration: a literature review (Rompen et al.)*

### **Definition of the biological width around endosseous implants**

The interface between the implant surface and the supracrestal soft tissues consists of junctional epithelium and connective tissue. In a similar manner to dento-gingival tissues this vertical dimension assessed histologically has been termed 'biological width' (Gargiulo et al. 1961; Berglundh & Lindhe 1996). Currently no means exist to precisely assess this dimension clinically, as by probing the depth of the sulcus, the junctional epithelium and probably part of the vertical dimension of the connective tissue is measured.

### **Definition of one-piece and two-piece dental implants**

In a one-piece implant, the transmucosal component facing the soft tissues is part of the implant. In a two-piece implant, the transmucosal component (the abutment) dedicated at soft-tissue integration is a separate part from the implant body. The interface between the transmucosal component and the implant is generally located in the neighborhood of the alveolar bone level. A one-piece implant is, in general, placed according to a one-stage surgery where the implant immediately pierces the soft-tissue's barrier (non-submerged fashion), when a two-piece implant system can either be submerged under the soft tissues for a waiting period (two-stage surgery) or be placed according to a one-stage surgery like one-piece implants.

### **1 What is the dimension of the biological width at implants as compared to teeth?**

Data from two split-mouth animal studies show, based on histomorphometric analysis, that the dimension of the soft-tissue interface around implants is comparable with teeth, but the connective tissue compartment is slightly longer at implants. Two studies in humans reported higher probing depths around implants as compared with natural contralateral teeth. Similar results were obtained in two animal studies where the probe tip penetrated deeper and ended apical to the junctional epithelium close to the bone crest.

### **2 Do the vertical dimensions of the softtissue interface at implants change over time?**

In several prospective studies assessing the dimensions of the marginal peri-implant tissues in well-maintained patients, it has been shown that they remain stable over time (up to 36 months). Data from two long-term (10 years) controlled studies comparing teeth and implants in well-maintained patients demonstrate, that changes in soft tissues occurred in a similar manner around implants as around teeth.

### **3 Do the vertical dimensions of the softtissue interface at implants differ in relation to surgical procedures?**

Because there is little data available from human studies on differences in soft tissues related to surgical techniques, we cannot comment directly on this issue. However, data from several-controlled clinical studies assessing crestal bone level changes did not show any difference regardless of whether the implants were left submerged or not before being placed in function. Based on two animal studies there are no differences in soft-tissue dimensions related to one- or two-stage surgery. In another study a longer junctional epithelium was found related to the two-stage approach.





## SCIENTIFIC STUDIES

### **4 Do the vertical dimensions of the soft tissue interface at implants differ in relation to implant components?**

Although two histological studies on animal models have reported crestal bone level changes in relation to the position of the implant/abutment junction in two-piece implants (Hermann et al. 2000a, 2000b, 2001a, 2001b), other studies using the same experimental model were unable to reproduce these findings (Berglundh et al. 1991, 1994, 1996; Ericsson et al. 1995; Abrahamsson et al. 1996, 1997, 1998a, 1998b, 1999, 2001, 2002, 2003; Lindhe & Berglundh 1998; Hermann et al. 2001a, 2001b).

Several factors have been proposed as a possible cause such as: the dimension of the microgap at this junction, the position of the microgap in relation to the crest of the bone, the possible leakage and bacterial contamination (Quirynen & van Steenberghe 1993) the possible micromovements. In another experiment (Hermann et al. 2001a, 2001b), it was demonstrated, that the size of the microgap between implants and abutments has little influence on marginal bone remodeling, whereas micromovements of the abutments induce a significant bone loss, independent of the microgap's size. This strongly suggests that the mechanical disruption of the soft-tissue interface is of importance.

### **5 Does the surface topography of the transmucosal components affect the soft-tissue interface?**

Only one human experimental study addressed the influence of surface roughness on soft-tissue interface, revealing histologically that the junctional epithelium was shorter on a rough surface. The relevance of this finding for long-term clinical success remains to be evaluated.

Even though animal studies in dogs comparing rough vs. machined transmucosal abutments did not show any difference at the soft-tissue interface, in vitro studies have shown, that epithelial cells do not approximate as closely to acid-etched and sandblasted surfaces as to smooth (polished or optically flat, Sa 0.5 µm) surfaces. In three of four studies it was shown, that fibroblasts adhere as well to rough as machined and even smooth surfaces.

### **6 Does the chemical composition of the transmucosal components affect the soft-tissue interface?**

No clinical studies reporting histological data have been published so far, where this issue was addressed. In animal experiments it was shown, that a normal soft tissue interface was formed with titanium, aluminum oxide, zirconium oxide and HA abutments.

On gold and dental porcelain no effective soft-tissue adhesion was established at the abutment level in animals. In vitro studies have shown excellent results for commercially pure titanium and titanium alloys, however for other materials conflicting reports have been published.

Comments: There is little information from human studies assessing the soft tissue interface using clinical outcome measurements. No studies were found on one-piece implants using different surface characteristics at the transmucosal area. In two-piece implants where different transmucosal abutments with different surface characteristics have been assessed, no significant differences have been encountered.



Therefore we cannot draw valid conclusions on the ideal surface for the soft-tissue interface. The vast majority of articles addressing the issue of the implant – soft-tissue interface are based on in vitro studies. The findings made in such experiments can never be directly transferred to the clinical situation.

It must be noted that, even in vivo, the epithelial tissue is composed of cells in direct contact with each other without an extracellular matrix; they will also be in direct contact with the implant components through hemi-desmosomes and a basal lamina. This is very close from what will be reproduced in vitro.

On the other hand, connective tissue cells are dispersed in a dense extra-cellular matrix. These cells do not normally get in direct touch with each other, but are rather connected to their environment. They can get in direct contact with proteins adhering to implant components. The connection of this tissue to the implant surface is more dependent on the extracellular matrix. In addition, in vivo, the formation of a fibrin network is the first step of connective tissue healing after implant/abutment surgery. In vitro experiments of fibroblasts adhesion to implant materials do not reproduce fibrin polymerization before cell seeding, meaning that in vitro conditions are more artificial and distant from the in vivo situation for fibroblasts than for epithelial cells.

Implications for research: For future studies addressing the biomaterial-tissue interface the characterization of the surface is of outmost importance. The characterization should include the analysis of the surface chemical composition as well as topographic characterizations that can distinguish between feature sizes that may influence biological responses.





## SCIENTIFIC STUDIES

# The soft tissue response to osseointegrated dental implants



Hans-Peter Weber, David L. Cochran



soft tissue management, dental implants



1998



The use of dental implants in the treatment of fully edentulous patients has become an important addition in oral/dental rehabilitation. The fact that these implants penetrate the oral mucosa can lead to the assumption that peri-implant tissues, similar to the periodontal tissues, are fulfilling an important function as a barrier to protect the bony anchorage underneath. It has been shown that insufficient plaque removal may lead to peri-implant tissue disease with bone loss similar to teeth. However, it is unclear how important this cause is as a source of implant failure compared with other factors, such as inadequate bone healing, unfavorable quantity and quality of bone, or (bio)mechanical and functional problems. It is also not understood if peri-implant epithelium and connective tissue are equally needed and/or qualified to slow down or prevent tissue breakdown as their periodontal counterparts. The scientific work focusing on peri-implant soft tissues has dramatically increased in the past few years. Most studies to date have examined and described their structure but little data exist on their true biologic function. This review analyzes the current understanding of morphologic and clinical features of the peri-implant soft tissues. Furthermore, evidence shall be provided that peri-implant soft tissues do not interfere with the current favorable results obtained when treating the edentulous patient with osseointegrated implants. (J Prosthet Dent 1998;79:79-89.)

The supracrestal soft tissues around endosseous dental implants exhibit structures and features of noninflamed soft tissues analogous to noninflamed gingiva around teeth. These include the following:

**1. Structures:** Oral stratified squamous epithelium; sulcular nonkeratinized epithelium; nonkeratinized junctional epithelium; soft connective tissue contact; and vascular components.

**2. Features:** Basement membrane; rete pegs; connective tissue papillae; collagenous stroma; collagen and noncollagen glycoproteins; desmosomes and hemidesmosomes; structural and nonstructural proteins; immune cells.

Titanium, or more properly titanium oxide, does not appear to significantly affect epithelial cell structures or the formation of epithelial structures around transmucosal materials. This suggests that the location of the epithelium (in this case, oral gingival epithelium) is more influential in determining the structure of the epithelial components than is the substrate (implant versus tooth). Evidence also exists that around titanium abutments, or nonsubmerged one-stage implants, the major connective tissue fibers run parallel to the long axis of the implant. The connective tissue forms a nonvascularized, circular, scar-type structure surrounded by a less dense, vascularized connective tissue. Thus the epithelial components around implants appear to be consistent with epithelial components around teeth, whereas the connective tissue, although having a similar composition, has a dramatically different spatial orientation. The factors that influence maintenance of dental implants are similar to those of the natural dentition. However, the value of periodontal parameters for monitoring peri-implant tissue health is not clearly evident, and differences in probing levels around implants are not strongly correlated to peri-implant tissue disease. Peri-implant tissue inflammation and marginal bone loss are associated with the presence of periodontal pathogens in both partially and fully edentulous patients. Whereas, a high correlation between composition of the microbiota in the pockets around teeth and implants exists, periodontal pathogens are generally found in much lower levels in the fully edentulous case. Increased abutment roughness may lead to increased plaque accumulation and colonization with a pathogenic flora in the supracrestal tissues. The design of any prosthetic superstructure must offer sufficient access for plaque removal by the patient.

Clinical studies demonstrate evidence that keratinized, attached mucosa is not a prerequisite for long-term implant maintenance. However, in certain situations, patients may benefit from its presence. The physiologic and functional role of peri-implant soft tissues is not well understood. There is also no current documentation thus far about the role of host resistance in long-term implant maintenance.

## Tissue augmentation and esthetics (Working Group 3)



B. Klinge, Thomas F. Flemmig

Members of working group:

Matteo Chiapasco, Jan-Eirik Ellingsen, Ronald Jung, Friedrich Neukam, Isabella Rocchietta, Paul Stone, Wim Teughels, Daniel Thoma, Maurizio Tonetti, Georg Watzek, Emeka Nkenke



allografts, alveolar ridge augmentation, autografts, dental implants, guided tissue regeneration, sinus floor augmentation, soft-tissue grafts, xenografts



2010

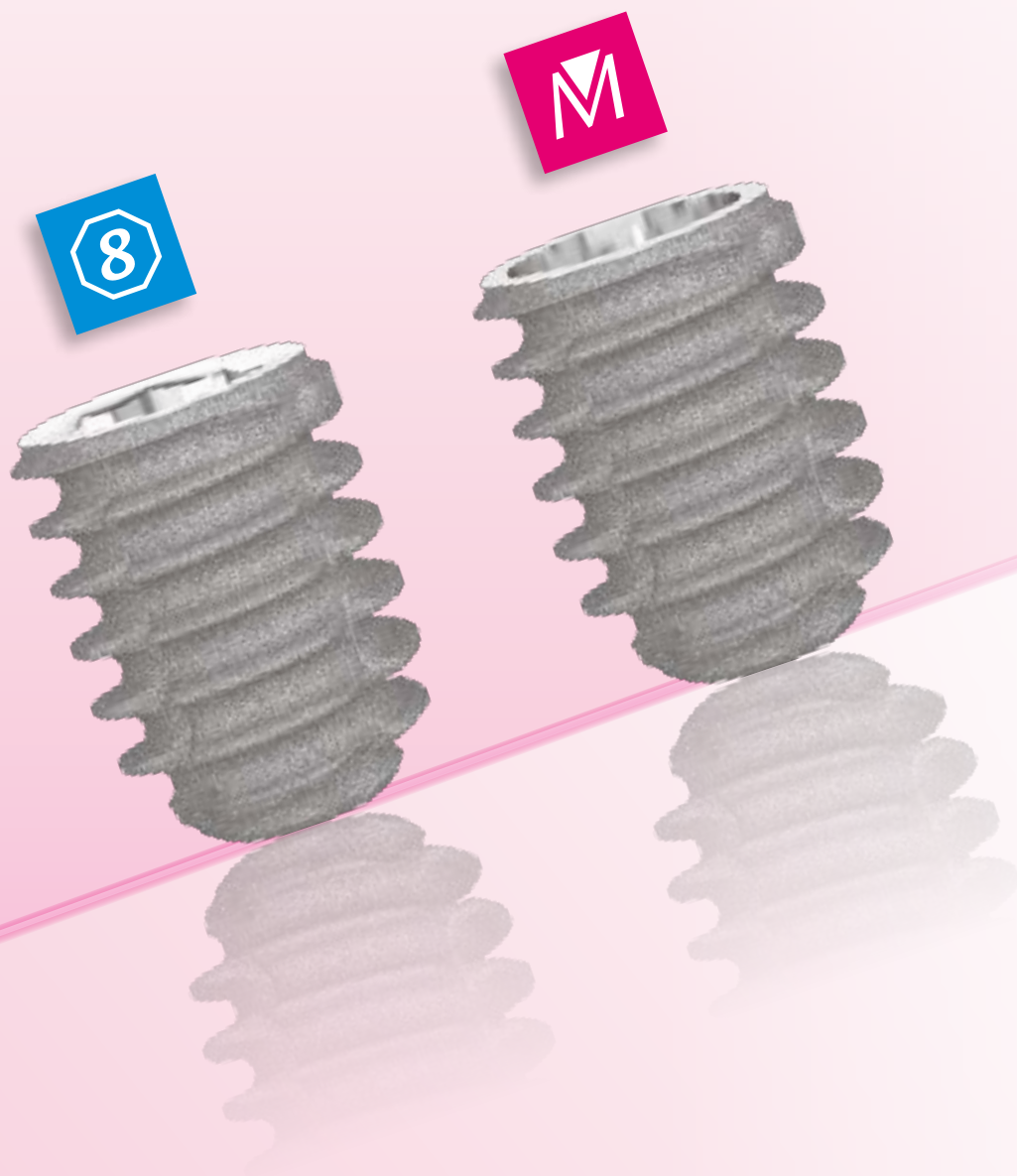


**Introduction:** The remit of this working group was to update the existing knowledge base regarding bone augmentation for implant site development and soft-tissue grafting for esthetic outcomes. Four reviews from the working group formed the basis of this update. Moreover, clinical applications as well as suggestions for further research have been formulated.

**Materials and methods:** The papers in the working group critically reviewed the literature. Four manuscripts were produced assessing (a) the outcomes of correcting dehiscence and fenestration defects at implant sites using various graft materials, (b) the outcomes of sinus floor augmentation at maxillary posterior sites with 6mm or less residual bone height using various graft materials, (c) the association of the horizontal dimensions of buccal and interproximal bone with esthetic outcomes of implant-supported restorations, and (d) the outcomes of soft-tissue augmentations.




**Results:** The results and conclusions of the review process are presented in the following papers. The group's consensus statements, clinical implications, and directions for future research are presented in this article.





*TBR short implants (octagonal and conical connection)*

# SHORT IMPLANTS

	The use of short dental implants in clinical practice: literature review	P	106
	Influence of Diameter and Length of Implant on Early Dental Implant Failure	P	108
	Impact of implant length and diameter on survival rate	P	109





## SCIENTIFIC STUDIES

# The use of short dental implants in clinical practice: literature review



E. ROMEO, A. BIVIO, D. MOSCA, M. SCANFERLA, M. GHISOLFI, S. STORELLI



dental implants, dental implantation, dental prosthesis design, tooth crown.



2010



When anatomic structures and ridge resorption limit the placement of a standard implant, the clinician can apply augmentation techniques or use short implants. A literature review was carried out to evaluate the differences in survival rate and the rational use of short implants. Electronic search (MEDLINE) and manual search have been performed to select papers from 2000 to 2008. Of all the inclusion criteria the most relevant were:

- 1) studies with data on short implants;
- 2) studies on humans;
- 3) prospective, longitudinal,
- 4) no restrictions were applied about study design;
- 5) no implant type selection was applied.

### **Retrospective and multicenter studies;**

#### **Exclusion criteria were:**

- 1) studies concerning treatment of patients with conditions possibly affecting survival or success rates of implant treatment;
- 2) studies concerning treatment of patients with nontreated periodontal disease;
- 3) implants placed in non-healed ridge, such as postextractive short implants.

A total of 13 studies fulfilled the inclusion criteria. Most of the studies have reported different survival rate for short and standard implants. The difference is not significant. The recent literature have demonstrated a similar survival rate for short and standard implants. Older articles have demonstrated a lower survival rate for short implants. The treatment planning is a key factor for success in the use of short implants.

#### **Some of the parameters the clinician should consider are:**

- 1) area to rehabilitate as well as bone quality;
- 2) length of the implant;
- 3) implant diameter;
- 4) type of implant and surface treatment;
- 5) crown to implant ratio of the final prostheses;
- 6) type of prostheses;
- 7) connection to other implants;
- 8) occlusal/ parafunctional load;
- 9) prosthetic complications.

Although in the literature there are no studies that analyze short implant survival from the point of view of each key factors, it can be assumed that a careful treatment planning can lead the clinician to obtain a successful rehabilitation.

### Conclusions

Articles retrieved in the literature demonstrated that short implants have the same survival rate than standard implants in various situations. Compared to ridge augmentation and placement of longer implants,

placing a short implant can be a simpler, less time consuming and more economic treatment with a lower patient morbidity. The higher failure rates reported in older studies may be due to surgical procedures performed independently to the bone quality and with no appropriate surfaced implants. To avoid the complications related to increased crown height and poor quality bone sites, it is important to develop a treatment plan, considering the use of larger diameter implants, splint implant to others, use of surface treated implants and to minimize lateral forces on the implant. What the literature lacks are studies that analyze properly each aspect of such rehabilitations. Therefore, more studies are needed in order to evaluate the prosthetic followup of fixed rehabilitation supported by short implants with an increased crown to implant ratio.







## SCIENTIFIC STUDIES

# Influence of Diameter and Length of Implant on Early Dental Implant Failure



Sergio Olate, Mariana Camilo Negreiros Lyrio, Márcio de Moraes, Renato Mazzonetto, Roger William Fernandes Moreira



biomaterials, dental implants, gold alloy, histology, peri-implant mucosa, soft tissue, titanium, zirconia



2010



**Purpose:** To relate diameter and length of implants with early implant failure. **Patients and Methods:** Implants with a cylindrical design and surface treatment by removal of titanium via acidification from 3 different manufacturers were used in this study. Two surgical procedures for submerged implants were evaluated—the placement of the implants (first surgical phase) and the procedure for reopening (second surgical phase)—before the installation of the prosthetic system. The length of the implants was classified as short (6-9 mm), medium (10-12 mm), or long (13-18 mm), and the diameter was classified as narrow, regular, or wide. The statistics were computed with SAS statistical software (SAS Institute, Cary, NC). Step-wise and 2 analyses were used, in addition to univariate and multivariate logistic regression.

**Results:** In this retrospective study, 1,649 implants (807 maxillary and 821 mandibular) were placed in 650 patients (mean age, 42.7 years) in different areas: anterior maxilla (458), posterior maxilla (349), anterior mandible (270), and posterior mandible (551). The early survival rate for all 1,649 implants was 96.2%. Regarding diameter, the largest loss was observed in narrow implants (5.1%), followed by regular (3.8%) and wide (2.7%) implants. Regarding length, the largest loss was observed in short implants (9.9%), followed by long (3.4%) and medium (3.0%) implants. Early loss occurred in 50 implants, 31 (4.3%) of which were installed in anterior areas and 19 (2.8%) in posterior areas. According to step-wise analyses and the 2 test, short implant ( $P = .0018$ ) and anterior installation of implant ( $P = .0013$ ) showed associations with early loss.

**Conclusion:** A significant relationship of early implant loss was observed with short implants. No relationships between early loss of implants and the osseous quality or diameter of implants were observed. These findings may be attributed to the operator's experience with different implant designs, learning curves, or changes in technique and indications for the use of short implants from 1996 to 2004.

# Impact of implant length and diameter on survival rate



Franck Renouard, David Nisand



biomechanical aspects, dental implants, implant diameter, implant length



2006



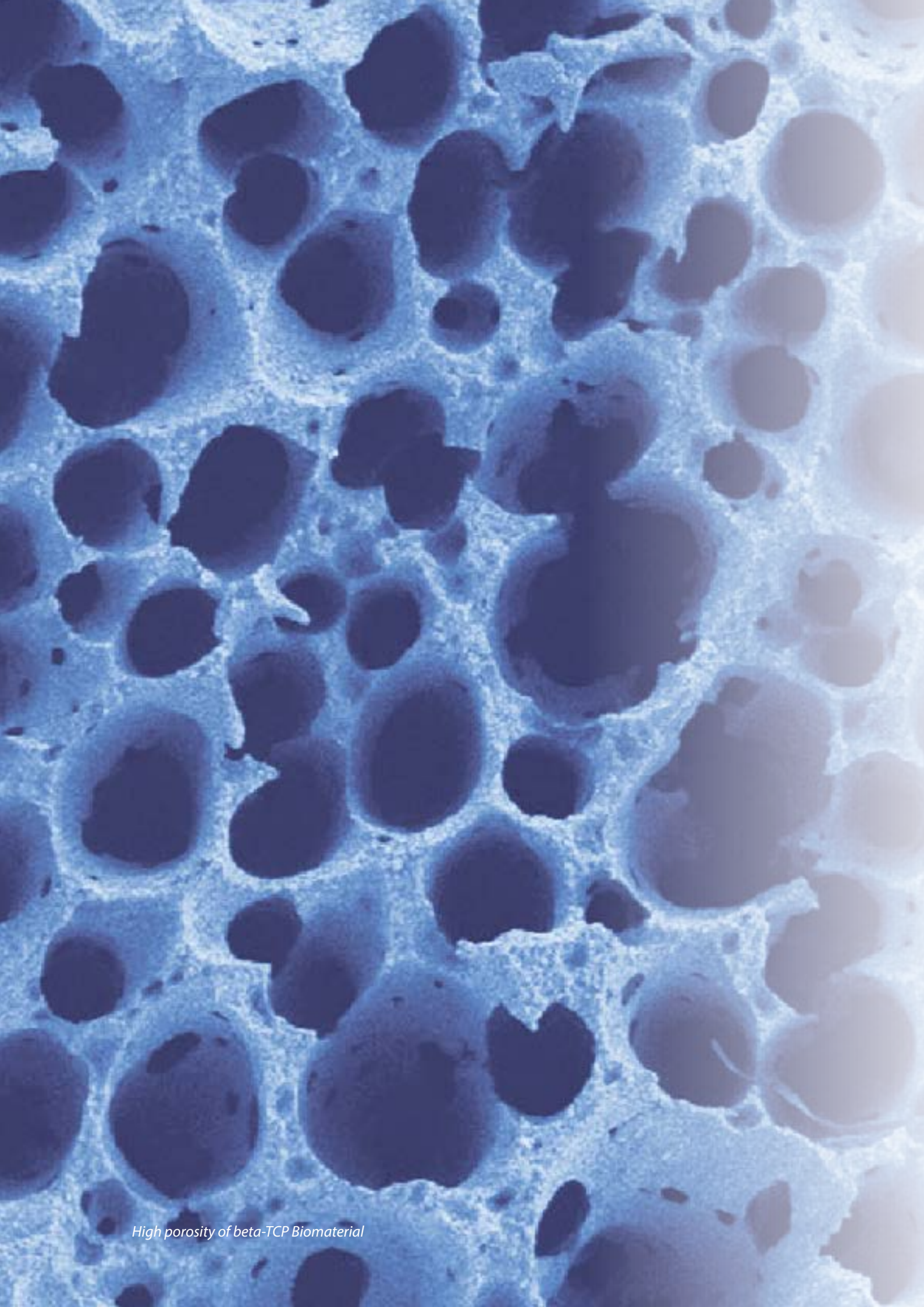
**Introduction:** Despite the high success rates of endosseous oral implants, restrictions have been advocated to their placement with regard to the bone available in height and volume. The use of short or nonstandard-diameter implants could be one way to overcome this limitation. Material and methods: In order to explore the relationship between implant survival rates and their length and diameter, a Medline and a hand search was conducted covering the period 1990–2005. Papers were included which reported: (1) relevant data on implant length and diameter, (2) implant survival rates; either clearly indicated or calculable from data in the paper, (3) clearly defined criteria for implant failure, and in which (4) implants were placed in healed sites and (5) studies were in human subjects.

**Results:** A total of 53 human studies fulfilled the inclusion criteria. Concerning implant length, a relatively high number of published studies (12) indicated an increased failure rate with short implants which was associated with operators' learning curves, a routine surgical preparation (independent of the bone density), the use of machined-surfaced implants, and the placement in sites with poor bone density. Recent publications (22) reporting an adapted surgical preparation and the use of textured-surfaced implants have indicated survival rates of short implants comparable with those obtained with longer ones. Considering implant diameter, a few publications on wide-diameter implants have reported an increased failure rate, which was mainly associated with the operators' learning curves, poor bone density, implant design and site preparation, and the use of a wide implant when primary stability had not been achieved with a standard-diameter implant. More recent publications with an adapted surgical preparation, new implant designs and adequate indications have demonstrated that implant survival rate and diameter have no relationship.

## Discussion:

When surgical preparation is related to bone density, textured-surfaced implants are employed, operators' surgical skills are developed, and indications for implant treatment duly considered, the survival rates for short and for wide-diameter implants has been found to be comparable with those obtained with longer implants and those of a standard diameter. The use of a short or wide implant may be considered in sites thought unfavourable for implant success, such as those associated with bone resorption or previous injury and trauma. While in these situations implant failure rates may be increased, outcomes should be compared with those associated with advanced surgical procedure such as bone grafting, sinus lifting, and the transposition of the alveolar nerve.





*High porosity of beta-TCP Biomaterial*

# BIOMATERIALS

■ A Resorbable, Reconstituted Type I Collagen Membrane for Guided Tissue Regeneration and Soft-Tissue Augmentation	P	112
■ Prediction of In Vivo Stability of Resorbable, Reconstituted Type Collagen Membrane by In Vitro Methods	P	114
■ MicroCT and preparation of BETA-TCP granular material by the polyurethane foam method	P	116
■ A non-steroidal anti-inflammatory drug (ketoprofen) does not delay $\beta$ -TCP bone graft healing	P	118
■ Optimization of sinus filling by blade $\beta$ -TCP	P	120
■ Biomechanical and histomorphometric analysis of etched and non-etched resorbable blasting media processed implant surfaces: An experimental study in dogs	P	121







## SCIENTIFIC STUDIES

# A Resorbable, Reconstituted Type I Collagen Membrane for Guided Tissue Regeneration and Soft-Tissue Augmentation



Debbie Yuen, Claudia Junchaya, Gloria Zuclich, Judith B. Ulreich, Horng-Ban Lin, and Shu-Tung Li



resorbable biomaterial, type I collagen, membrane, soft-tissue augmentation



2000



### Introduction

There are several requirements that a resorbable membrane should meet in order for it to be useful for guided tissue regeneration (GTR) and soft tissue augmentation applications. The membrane should be resorbable, have sufficient mechanical strength to permit suturing of the membrane to the host, be permeable to nutrients and be biocompatible. The particular medical application will define the specifications of each requirement. We present here a new resorbable, reconstituted type I collagen membrane for use in GTR or as a patch for soft tissue augmentation. The results of a comparison between this membrane and a collagen membrane currently marketed for GTR applications are also discussed.

### Methods

**Collagen Membrane:** Two types of collagen membrane were fabricated from purified type I collagen fibers. The collagen fibers were dispersed in an acid solution (pH 2.5), homogenized, filtered, reconstituted, freeze dried, crosslinked, and sterilized by  $\gamma$ -irradiation.

### Characterization:

**Suture pull-out strength:** A size 3-0 silk suture was passed through the membrane, 1.5 cm x 2.0 cm, at about 3 mm from the edge and a loop was tied. The membrane was hydrated in 0.01 M phosphate buffer, pH 7.0, for 10 minutes. The loop was attached to a force gauge (Chatillon, Greensboro, NC) and the sample was secured onto a clamping fixture. The sample was pulled at a rate of 1 inch per minute until the suture was pulled out. The force was recorded.

**Permeability:** The permeability of the membrane was determined by inserting a sample, 2.0 cm x 2.0 cm, into a specially designed chamber, which is separated into two isolated compartments. On one side of the chamber, a fixed volume of phosphate buffered saline (PBS) containing 50  $\mu$ g of carbonic anhydrase (CA) (MW 29,000) per ml was added. The opposite side was filled with the same volume of PBS only. The chamber containing the membrane was allowed to equilibrate for 24 hours and the CA assay was conducted on the side initially without CA by the Coomassie plus assay. (1) **In Vivo Resorption Studies:** A total of 11 rats were used. Each rat received a 1cm<sup>2</sup> membrane implanted subcutaneously. Animals were sacrificed at 4, 8, 12, and 24 weeks after implantation. The explants were evaluated histologically for collagen membrane remaining, tissue reaction and new collagen deposition using standard histologic techniques.

**Biocompatibility:** Biocompatibility testing was conducted on the collagen membrane in accordance with FDA guidelines.

### Results

Table 1 summarizes the characterization studies on the two types of collagen membranes, A and B compared to the commercial product Biomend®. The average suture pull-out strength was 350 g and 290 g, respectively for A and B. This strength is significantly higher than for Biomend®. The total resorption time was obtained through extrapolation via curve fit of the experimental data. The resorption times for the membranes were 27 and 18 weeks respectively for A and B. Both membranes A and B were significantly more stable in vivo than Biomend®. Both membranes A and B were permeable to CA, which has a size similar to the Biomend® pore structure, and biocompatible.

### Discussion

The use of a membrane for GTR in oral surgery often requires the membrane to be permeable for nutrients but not cells so that the membrane can serve as a cell barrier to guide the specific tissue regeneration. Both membranes A and B and Biomend® can serve that function. Very often, the membrane is required to be stabilized with sutures. In this regard, membranes A and B offer advantages over Biomend® in that they have a ' higher suture pull-out strength. In addition, the in vivo, stability of membranes A and B are significantly longer than the Biomend®. Although the significance of this' difference is not known, it would be logical to expect that a longer in vivo stability may provide an additional margin of efficacy in using the membrane as a cell barrier. The characteristics of membranes A and B also offer potential applications as soft tissue augmentation devices such as patch material for hernia and heart surgeries.

**Table 1 Characterization of Collagen Membranes**

Test	Membrane A	Membrane B	Biomend®
Suture pull-out strength (g)	350 80	290 70	74 10*
Pore structure	Permeable to CA	Permeable to CA	0.004 m*
In vivo resorption (weeks)	27	18	4-8*

\* Reported from 510 K (K924408)





## SCIENTIFIC STUDIES

# Prediction of In Vivo Stability of Resorbable, Reconstituted Type Collagen Membrane by In Vitro Methods



Debbie Yuen, Judith B. Ulreich, Gloria Zuclich, Horng-Ban Lin, Shu-Tung Li



resorbable biomaterial, type I collagen, membrane, soft-tissue augmentation



2000



### Introduction:

One of the critical elements in designing a resorbable implant is its in vivo stability. The in vivo stability is generally characterized in an animal model without any guidance. During the design of a resorbable, reconstituted type I collagen membrane for guided tissue regeneration, we developed an in vitro method to predict the in vivo stability of a reconstituted collagen membrane. This study summarizes the development of such a method.

### Method Development:

Three types of membranes were fabricated using an identical procedure and chemically crosslinked with the same crosslinking agent to various extents. These membranes were characterized in vitro to determine the hydrothermal shrinkage temperature and the collagenase digestion characteristics. The membranes were then implanted in a rat subcutaneous model.

### Hydrothermal Shrinkage Temperature Determination:

A collagen membrane, 0.5 cm x 2 cm, was attached to a specially designed fixture and immersed in phosphate buffered saline (PBS) solution, pH 7.4. The solution was heated at a rate of 1°C per minute. The hydrothermal shrinkage temperature ( $T_s$ ) of the membrane was defined as the temperature at which the length started to change.

### Collagenase Digestion:

Approximately 10 mg of membrane material was dried over P2O<sub>5</sub>, weighed and incubated in 2.5 ml bacterial collagenase solution (Sigma, St. Louis, MO) (20 U/ml, 0.025 M PBS, 0.36 M CaCl<sub>2</sub>, pH 7.0) at 37°C. Reactions were terminated at 2, 4, 8, 16, 32, and 48 hrs. Aliquots of the supernatant were sampled at each time point and assayed for hydroxyproline content (1). The hydroxyproline content was converted to the collagen content based on 13% weight of hydroxyproline in collagen. In Vivo Subcutaneous Implantation in Rats: A total of 20 rats were used. Each rat received a 1 cm<sup>2</sup> membrane. The rats were anesthetized and the upper back shaved. A longitudinal dorsal incision was made on the upper/mid back and four pockets were formed. The membranes were inserted into the pockets and the skin was closed. Animals were sacrificed at 4, 8, 12, 16, 20 and 24 weeks after implantation. The explant was evaluated histologically for collagen membrane remaining (area occupied by the residual collagen membrane), tissue reaction and new collagen deposition using standard histologic techniques.

### Results:

Fig. 1 shows the curve fit of the membrane remaining as a function of implantation time for the three membranes. The extrapolated resorption time, defined as <2% membrane remaining, for the membranes were 8, 18, and 27 weeks respectively. Figure 2 shows the correlation between the hydrothermal shrinkage temperature and the time for the complete collagenase digestion of the membrane with extrapolated in vivo resorption time. It was observed that the higher the  $T_s$ , the more stable was the membrane in vivo. The  $T_s$  was linearly correlated with the in vivo stability. Linear regression showed a correlation coefficient of 0.99. The in vivo stability decreased with increasing collagenase susceptibility. However, the enzyme susceptibility was not linearly correlated with to the in vivo stability. There was no adverse tissue response to the membrane implant. The resorption of the membrane was accompanied by new collagen synthesis.



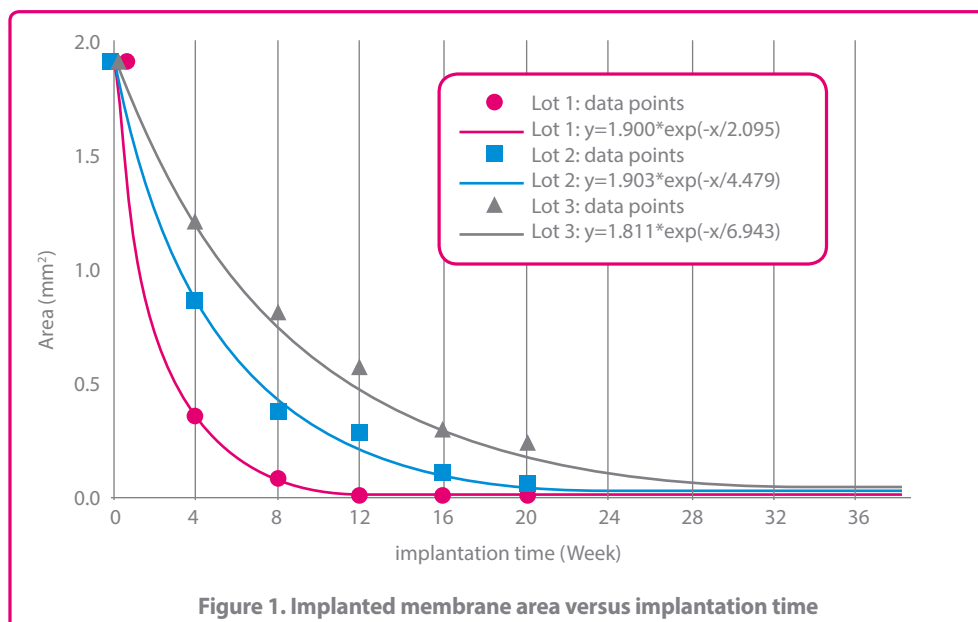


Figure 1. Implanted membrane area versus implantation time

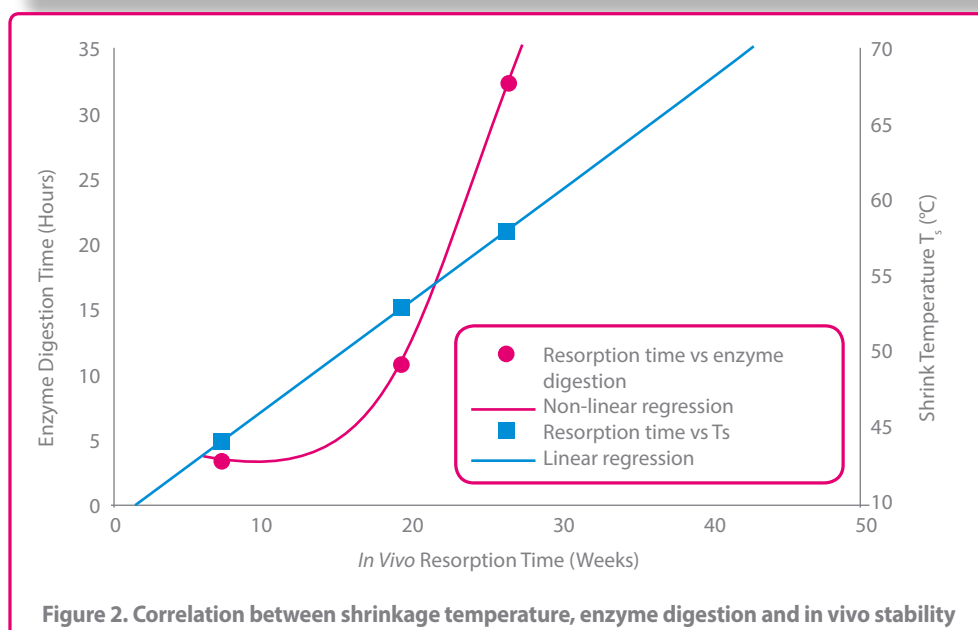


Figure 2. Correlation between shrinkage temperature, enzyme digestion and in vivo stability

#### Discussion:

The method developed here can be used to guide the design of a membrane for a particular tissue repair application. The in vivo stability of a membrane can be predicted by determination of the hydrothermal shrinkage temperature or the collagenase susceptibility of a membrane prototype. For example in this study, if the design of a membrane requires the membrane to be resorbed in vivo for 22 weeks, the membrane should have a  $T_s$  of 53°C and total membrane digestion time of about 15 hours. Since the in vivo stability of an implant is a function of both macro and microstructure of the implant and the nature of the crosslinking, it must be cautioned here that the method is only applicable to membranes which have similar macro and microstructures and are crosslinked with the same crosslinking agent.





## SCIENTIFIC STUDIES

# MicroCT and preparation of BETA-TCP granular material by the polyurethane foam method



Guenaëlle Brossard, Daniel Chappard, Robert Filmon, Florence Grizon-Pascaretti, Michel Félix Baslé, Nadine Retailleau-gaborit



porous resorbable biomaterial, Beta-TCP

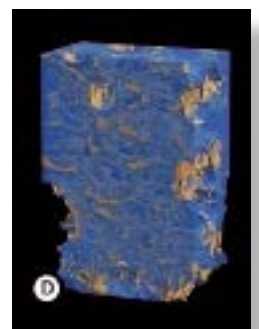
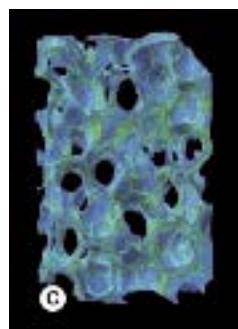
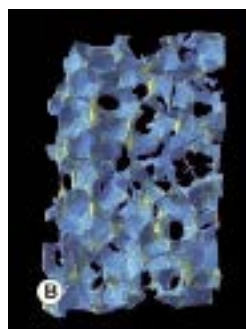
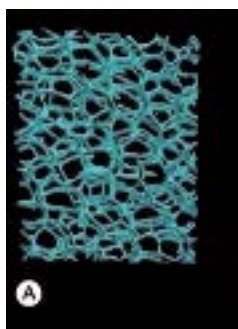


2009



### Introduction

Commercial  $\beta$ -tricalcium phosphate ( $\beta$ -TCP) is commercially available in granules manufactured by sintering of powders.  $\beta$ -TCP has been recognized as a suitable ceramic material with bioactive properties since several decades [1]. TCP is a highly resorbable material that can be prepared in various conditions. Macroporous blocks can be used in orthopedics and granules are preferred in dentistry and maxillofacial surgery for filling small bone defects such as alveolar sockets after tooth extraction or for sinus lift elevation. A large number of papers have been published concerning the fabrication of TCP scaffolds or granules. An interesting method is the use of polyurethane foam to prepare 3D scaffolds that are sintered and crushed in a second time. Several commercial processes are available but the different steps of the full process have not been fully analyzed. The method was originally proposed by Schwartzwalder and Somers and has been used in a number of patents for preparing different types of porous biomaterials [2].

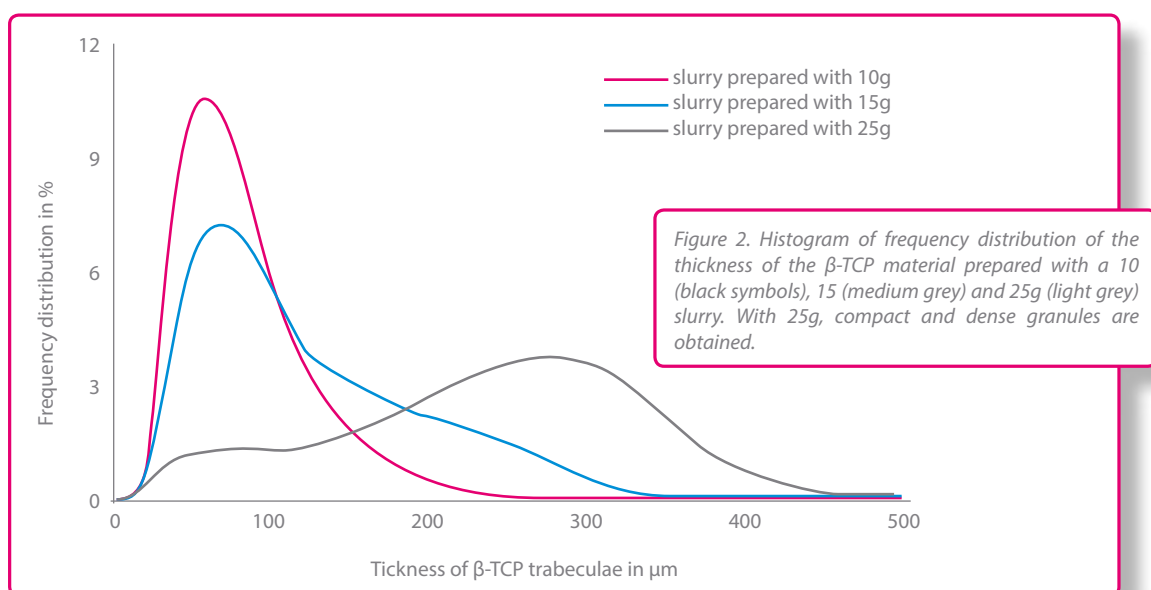


### Method

Briefly, a polymer foam is used as a template and filled with a ceramic slurry; the composite adhere onto the surface of the foam and this creates macroporosity. The composite is then submitted to heat-treatment at an elevated temperature to remove the polymeric template and to sinter the ceramic coating layer. The polymer foam is thus destroyed and leaves small internal voids (microporosity). We have evaluated the different steps of the manufacturing process of  $\beta$ -TCP ceramics granules prepared from blocks obtained with the polyurethane foam technology. 3 types of slurry were prepared with 10, 15 and 25g of  $\beta$ -TCP per gram of polyurethane foam [3]. Analysis was done by scanning electron microscopy, EDX, Raman spectroscopy and microcomputed tomography combined with image analysis. A special algorithm was use to identify the internal microporosity (created by the calcination of the foam) from the internal macroporosity due to the spatial repartition of the material.

### Results and Conclusions

The low  $\beta$ -TCP dosages readily infiltrated the foam and the slurry was deposited along the polymer rods. On the contrary, the highest concentration produced inhomogeneous infiltrated blocks and foam cavities appeared completely filled in some areas. 2D microcomputed sections and reconstructed 3D models evidenced this phenomenon and the frequency distribution of the thickness and separation of material trabeculae confirmed the heterogeneity of the distribution. When crushed, blocks prepared with the 25g slurry provided the largest and irregular granulates.



### References

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## SCIENTIFIC STUDIES

# A non-steroidal anti-inflammatory drug (ketoprofen) does not delay $\beta$ -TCP bone graft healing



Herve Nyangoga a. Eric Aguado a.b. Eric Goyenvallé a.b. Michel Felix Baslé a. Daniel Chappard a.,



$\beta$ -TCP, Bone healing, Non-steroidal anti-inflammatory drugs, Bone graft, MicroCT



February 2010



$\beta$ -Tri calcium phosphate ( $\beta$ -TCP) is a suitable biomaterial in oral and maxillofacial surgery since it can induce a rapid proliferation of woven bone. Granules, prepared by the polyurethane foam method, were implanted in critical size defects performed in the femoral condyles of New Zealand rabbits. Animals were studied after 8 and 28 days. Ketoprofen (a non-steroidal anti-inflammatory drug (NSAID)) was given for 8 and 28 days to evaluate its effects on the healing of the graft. Before euthanasia, the rabbits received an intravenous injection of fluorescent microbeads. Bones were analyzed by microcomputed tomography.  $\beta$ -TCP granules induced metaplastic bone trabeculae as early as 8 days post-surgery. At 28 days, the amount of bone was increased and the biomaterial volume decreased due to simultaneous macrophagic resorption. The amount of macrophages labeled with microbeads was less in the grafted area than in the vicinal intact marrow spaces. Ketoprofen had no effect on the amount of bone formed and on the number of labeled macrophages. The influence of small doses of NSAID, given in a short duration period, did not present deleterious effects on bone graft healing.

The use of porous calcium phosphate granules is recognized as filling or packing biomaterials in an osseous environment. Therefore,  $\beta$ -TCP is used as a bone substitute in oral and maxillofacial surgery for alveolar socket filling after tooth extraction [24] or maxillary sinus floor elevation [25,26]. Although autologous bone is considered as the best material for such techniques, the increased morbidity (due to the harvesting of bone in another surgical location in the same patient) has led to other techniques being developed. In addition, the use of synthetic biomaterials such as  $\beta$ -TCP is reported to be associated with a lower (or the same) risk of failure or complications [5]. In orthopedic surgery,  $\beta$ -TCP granules are seldom used because of the friability of the material in weightbearing areas although interesting results have been presented [27,28]. In the present study, commercially available  $\beta$ -TCP granules were used as a bone filler in a critical size defect performed in the femoral condyle of the rabbit. Ketoprofen was used as an anti-inflammatory drug to evaluate its effects on the bone in growth induced by  $\beta$ -TCP in this model. NSAID and cyclooxygenase-2 (COX-2) inhibitors are commonly prescribed after orthopedic or maxillofacial surgery, and their anti-inflammatory effects are due to their impairment of COX-1 and/or COX-2. These compounds have not the deleterious effects on bone cells and remodeling of glucocorticoids (see review by Bouvard [29]). However, long term use of NSAID has been repeatedly reported to interfere with bone remodeling and to delay bone healing [30-32]. Similar findings have been found in a number of animal studies [33,34]. However, more recent findings have shown that, when given for shorter periods of time (e.g. 2-6 weeks in New Zealand rabbits), the deleterious effects are less pronounced [35,36], allowing the patients to benefit from the analgesic and

anti-inflammatory properties of these compounds. Because the clinical scenario after orthopedic (or oral and maxillofacial surgery) is presently more to prescribe a low dose of NSAID for a short duration, this study was designed with two regimens (8 days and 28 days) during the healing phase of a bone graft. None of the two regimens had influence on the amount of bone deposited or on the microarchitectural quality of the trabeculae formed by osteoconduction induced by  $\beta$ -TCP. Ketoprofen is an NSAID with an antiCOX-1 and antiCOX-2 activity; however, little is known concerning the level of the two isoforms of COX at the grafted site of a bone biomaterial or in a fracture callus [37]. In this study, the onset of metaplastic bone formation occurred rapidly since the first trabeculae could be identified as early as 8 days post-grafting. Similar findings have been reported in the rat grafted with  $\beta$ -TCP in which thin trabeculae were observed as early as 7 days post-surgery [38]. Ketoprofen did not delay the centripetal bone formation starting from the vicinal trabeculae at the periphery of the implantation area. It should also be reminded that selective COX-2 inhibitors have been found to have serious cardio-vascular side effects and some (rofecoxib, Vioxx®) have now been withdrawn over safety concerns [39,40]. Microbeads are a useful tool to study the angiogenesis in tumors and could be used to deliver locally high amounts of angiogenic inhibitors [41]. pHEMA is a well recognized polymer in biomedicine [42] and microbeads can be readily prepared. In this study, microbeads containing Nile red were prepared as a fluorescent tracer for endothelial cells and macrophages. Microbeads can be rapidly trapped by endothelial cells (particularly in the case of rapid angiogenesis) and phagocytosed by macrophages in the stroma of the tissues [19]. This has been recognized as the enhanced permeability retention effect [41, 43, 44]. Methacrylate-based polymers can be easily prepared in the form of microbeads or nanobeads usable as carriers [45]. In addition, we previously showed that macrophages can phagocytose and internalize the pHEMA hydrogel [46]. In this study, the rabbits were euthanized 4 h after injection of the microbeads, a time sufficient to allow their internalization by macrophages at the periphery of the sinusoid capillaries of the bone marrow. The number of fluorescently labeled macrophages was much lower in the grafted zone than in the ungrafted cancellous areas of the epiphysis. Although the number of macrophages has been recognized to be increased in the mesenchymal reaction around  $\beta$ -TCP granules [47-49], this finding may appear intriguing. However, macrophages in the grafted area were filled with  $\beta$ -TCP particles and they are probably less susceptible to internalize a new type of material. NSAIDs can reduce the macrophagic function in inflammatory diseases [50]. Here again, the amount of labeled macrophages did not differ in the ketoprofen-treated groups from the control ones, either in the short or the longer periods of analysis.  $\beta$ -TCP granules, implanted in a critical size defect in the rabbit, induced the rapid and extensive proliferation of bone trabeculae, starting from the margins of the implantation area. Ketoprofen, given for 8 or 28 days, had no effect on osteogenesis or on the uptake of fluorescent microbeads by activated macrophages in the grafted area. Although NSAIDs (given for a long period of time) are known to delay fracture healing, their effect in short time treatment on a biomaterial graft healing appear insignificant.





## SCIENTIFIC STUDIES

# Optimization of sinus filling by blade $\beta$ -TCP



Bernard GUILLAUME



sinus partitioning, sinus lift, sinus augmentation, augmentation material,  $\beta$ -TCP



2009



### ABSTRACT

For the anchoring of implants, surgeons must frequently augment insufficient sinus floor bone volume. Until now, there were two possible courses of action: autologous cranial or iliac grafts, achieving cortical partitioning of the sinus but involving two operative sites. filling with biomaterials to avoid more invasive surgery, but augmentation density varies and there is a risk of mucosal perforation. So as to optimize and facilitate the sinus augmentation technique we are proposing a method featuring the advantages of the two procedures outlined above: creation of a neo sinus floor using a  $\beta$ -TCP strip followed by subjacent augmentation using high porosity  $\beta$ -TCP biomaterial. Further advantages of this technique are: Protection of the sinus membrane. Particles of the biomaterial are prevented from migrating into the sinus should the membrane be perforated. Augmentation material density is optimal.

### Conclusions

Pre-implant surgery, sinus floor elevation today is a reliable technique, but with a risk of perforation of the sinus membrane and the use of large volumes of filling material. The technique of using blade  $\beta$ -TCP optimizes sinus filling technique: protecting the sinus mucosa. allowing to obtain optimum densification of the underlying filler material. achieving savings of filling material and facilitate its distribution by compaction without fear of migration of the material in the sinus by ripping of the membrane. Avoiding taking external plugins, providing additional comfort to the patient while reducing the time and cost of interventions.

# Biomechanical and histomorphometric analysis of etched and non-etched resorbable blasting media processed implant surfaces: An experimental study in dogs



Daniel Chappard a,\* , Bernard Guillaume b, Romain Mallet a, Florence Pascaretti-Grizon a, Michel F. Basle´ a, He´le`ne Libouban a



$\beta$ -TCP, Osteoconduction, Sinus lift augmentation, Tricalcium phosphate, MicroCT



February 2010



## ABSTRACT

Sinus lift elevation is an interesting method to restore bone mass at the maxilla in edentulated patients.

We have investigated the histological effects of beta tricalcium phosphate ( $\beta$ -TCP) combined with autograft bone for sinus lift elevation. A series of 14 patients who were candidate for dental implantation were grafted with  $\beta$ -TCP granules and morcellized autograft bone harvested at the chin.  $\beta$ -TCP was characterized by scanning electron microscopy and optical profilometry. Before implant placement, a small bone biopsy (2 mm in diameter) was done. The amount of residual material and newly formed bone were determined by microcomputed tomography. Histological analysis was done on undecalcified sections stained by Goldner's trichrome and osteoclast identification (TRAcP).  $\beta$ -TCP served as a template for bone apposition by osteoblasts onto the granules' surface. The material was simultaneously resorbed by TRAcP positive osteoclasts and macrophages. Fragments of the material remained buried in bone trabeculae as long as 12 months post-graft but the formed bone onto the granules surface had a lamellar texture.  $\beta$ -TCP combined with autograft bone appears a suitable biomaterial for sinus lift augmentation before the placement of bone implants. The material favors the apposition of lamellar bone by osteoblasts and is simultaneous resorbed by two types of cells.







## IMPLANTS

- soft tissue level
- bone level
- short implant
- one-piece implant



## CAD / CAM

- digital processing of the prosthetic restoration
- custom prosthetic parts: abutments, bridges, bars, etc.
- specific parts for CAD / CAM: Ti-base, scanbody, sandblasted abutment



## PROSTHESES

- parts for fixed cemented restorations
- parts for fixed screw-retained restorations
- parts for removable restorations



## MAXILLOFACIAL SURGERY

- high porosity bone substitute
- bioresorbable membranes
- screw kit for apposition grafting
- screw kit for membrane fixing



TISSUE LEVEL



BONE LEVEL



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