

Reduced healing time of Implantent Implants with bioactive surface

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Dental implantology is a popular and generally recognised part of stomatology. There is no doubt about the long-term functioning and aesthetic benefits of implants. The increasing requirements of medical doctors and their patients are leading to faster and simpler treatment using implants. The greatest efforts are being directed towards attempts to shorten or completely eliminate the healing time of the implant.

Introduction

The length of the healing period, during which the implant is not subjected to loading, has been determined for a number of decades by the Bränemark treatment protocol^{14,18}. In the upper jaw, the implant is left nonfunctional for six months and, in the lower jaw, usually for three months^{1,28}. This unpleasantly long period of time is no longer acceptable in contemporary implantology and is being shortened. If the time reserved for healing the implant is reduced by at least one half, this is termed early loading. If this time is shortened to less than 48 hours, this corresponds to immediate loading.

The difference between early and immediate loading is not only quantitative, but also qualitative. For early loading, the special surface of the implant accelerates the formation of oseointegration, i.e. secondary stability, so that the implant heals sooner^{2,9}. The implantologist is usually able to verify the healing (tapping, torque wrench, Periotest, resonance frequency analysis, etc.) and only then functionally load the implant²⁵. Immediate loading requires not only the same surface quality, but also high primary stability of the implant^{2,4}. It ensures sufficient resistance to loading until primary stability is replaced by secondary stability^{8,30}. Thus, the incompletely healed implant is brought into function. Immediate loading is a promising method; however, not all its disadvantages have been evaluated at the present time.

Both therapeutic approaches are connected with a special implant surface accelerating the occurrence of osteointegration. Various modifications of highly structured surfaces have been developed by practically all leading international manufacturers. The significance of these changes is of key importance in the field and greatly affects the nature of dental implantology.

The surface of the implant is modified macroscopically, i.e. on a scale of hundreds of micrometres and, for some surfaces, also microscopically. Macro-roughness is most frequently created by sand-blasting with an abrasive medium (e.g. the TiOblast surface of the Astra Tech company) or plasma spraying of titanium powder (TPS from the Straumann company)^{5,29}. This increases the surface of the implant and bone trabecules can grow into it in later phases of the healing.

Micro-roughness is created, for example, by anodic oxidation-creating a porous titanium oxide layer on the surface of the implant (TiUnite from the Nobel Biocare company)^{10,13}. In other cases, it is machined, the smooth titanium being etched with mineral acids (e.g. Osseotite from the 3i company)^{6,26,27}. In some cases titanium is sand-blasted prior to acid etching (SLA surface from the Straumann company)^{11,12}. Implantent implants (Lasak) have also been given a new surface, called Bio because of its bioactive properties.

The Bio surface was developed in 1999 and later used for titanium screw implants STI-Bio with a diameter of 3.7mm and later 5.0 mm (Fig. 1).

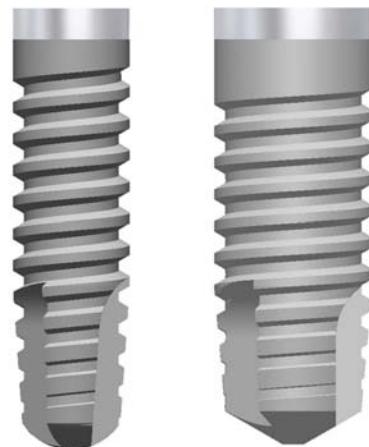


Fig. 1: STI-Bio implants with a diameter of 3.7 and 5.0 mm

The production of the Bio surface occurs in three phases. The titanium is first sand-blasted to obtain macro-roughness; then it is etched with a mineral acid to obtain micro-roughness (Fig. 2). The third phase is most important; here, the implant is exposed to an alkaline medium. A submicroscopic gradient porous surface is formed, giving the implant bioactive properties (Fig. 3). Chemical treatment of the Implantent implant increases its surface many times,²² and simultaneously increases its hydration by an order of magnitude. Thus, the originally hydrophobic acid-etched surface becomes a highly hydrophilic surface that is capable of immediate ionic interaction with the blood⁷. Rapid ion adsorption leads to accelerated formation of apatitic layers, which are a key factor for inducing new bone formation (Fig. 4).

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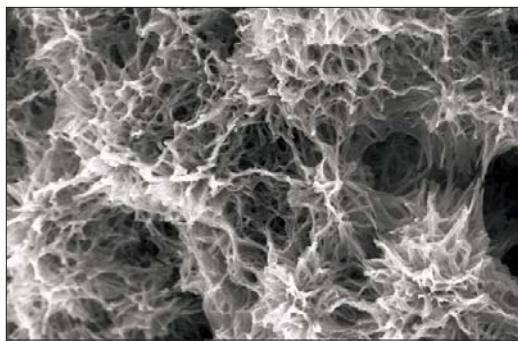


Fig. 2: The porous structure of the Bio surface (SEM magnification 10000x)

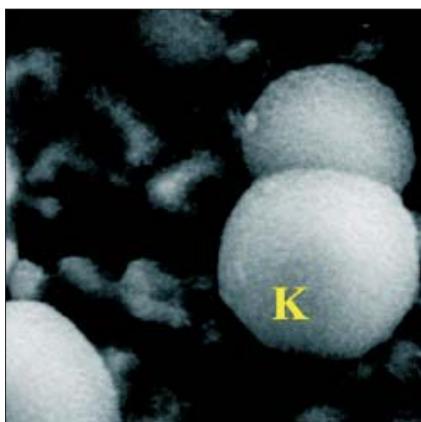


Fig. 4: Induction of bone-like apatite (K) formation. The image shows apatite crystals on the Bio surface following three-day exposure in simulated body fluid (SEM magnification 4000x)

The characteristics of the bio surface have been determined in a series of laboratory tests *in vivo* and *in vitro*^{22,23} (Fig. 5). The results, together with clinical evaluation, have been repeatedly published in the international professional literature^{22,23}.

The Bio surface has similar favourable qualities to those of a hydroxyapatite coating. Especially in less mineralised bones, it increases the quality of osteointegration and tolerates minor incongruencies between the bone bed and the surface of the implant. However, it does not have the disadvantages of hydroxyapatite coating, where the hydroxyapatite surface is considered controversial. The Bio surface is stable in the long term and is highly mechanically resistant, is not endangered by slow disintegration in biological media and can even be used for self-cutting design of the implant, which is a precondition for higher primary stability.

The completed experiments indicate that the bioactive properties of the Bio surface accelerate osteointegration and permit shortening of the healing time. However, clinical verification of this hypothesis has not been published yet.

It is the purpose of the study to evaluate the success of STI-Bio implants, for which the usual healing period was shortened to one half, and to determine how this change in the treatment protocol was manifested in the success rate of the treatment.

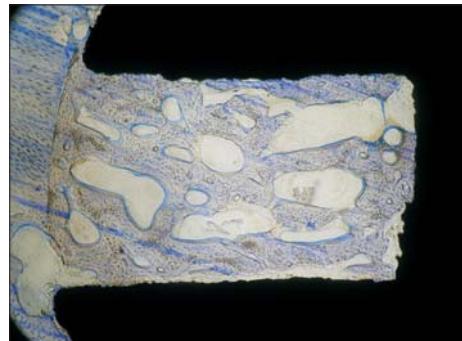


Fig. 3: Demonstration of the bioactivity of the bio surface by an experiment on an animal. Osteointegration (arrows) occurred even at the bottom of a 2 mm deep groove in a cylindrical titanium implant (Ti) with a Bio surface in 4 weeks (magnification 50x)

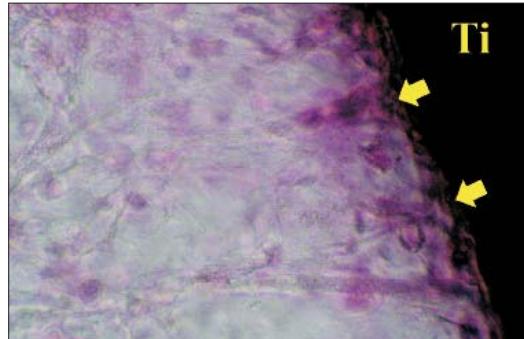


Fig. 5: Proof of the ability of a Bio surface to differentiate cells towards the osteoblastic phenotype. Elevated alkaline phosphatase activity (arrows) in the vicinity of the Bio surface (Ti). (Cells of chicken bone marrow following three-day exposure, magnification 200x)

Material and methods

All STI-Bio implants between March 2002 and December 2003 at the Clinic of Stomatology, Hradec Králové were introduced into natural, i.e. not augmented bone, where the healing period was reduced to one half compared to the Bränemark protocol, were included in a retrospective study.

None of the patients in the study suffered from a disease that would be an absolute "contra-indication" for implantation¹⁸, underwent radiation or cytostatic therapy, or were treated with corticoids or anticoagulants. Eight patients had compensated diabetes mellitus, of which four were treated only by modified diet, three by peroral antidiabetics and one by insulin.

The implantation was carried out by the two-phase technique, a maximum of twelve weeks in the maxilla and six weeks in the mandible expired between the first and second surgical phases of the implantation. With the exception of the healing time, the operation protocol specified by the manufacturer was followed. In the second surgical phase, all the clinically stable implants were tested by a 35 N.cm torque wrench acting in the clockwise direction. If they resisted the torque, they were evaluated as successfully osteointegrated.

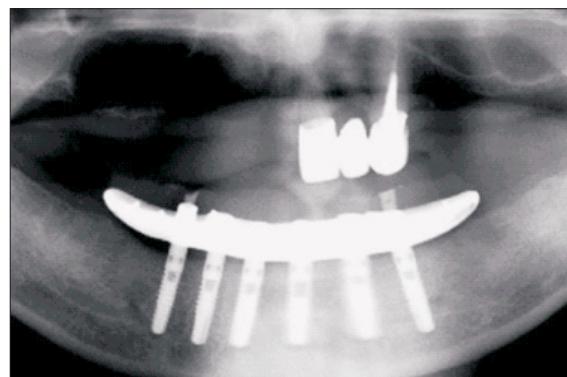


Fig. 6: Clinical use of STI-Bio implants (the Bränemark bridge)

Production of a superstructure was commenced two weeks after the second surgical phase. After this the patients were instructed by a dental hygienist and included in the follow-up care program. They were invited for controls after three months and then after a further nine months (Fig. 6). Following one-year loading, those implants which were; clinically stable, did not cause chronic subjective discomfort, were not the cause of repeated peri-implant infections, did not exhibit progressive loss of marginal bone and tissue, and whose surroundings were not radiolucent, were considered to be successful.

An x-ray was taken immediately after affixing the abutment and then one year later, using a Planmeca ProMax digital orthopantomograph or Gendex Visualix radiovisiographic instrument with XCP-DS grooves ensuring parallel projection, i.e. pathway of the central beam perpendicular to the plane of the implant and the recorder. Resorption of the marginal bone was read off an enlarged radiovisiogram or orthopantomogram with a precision of 0.5 mm, on the mesial and distal sides of the implant.

The statistical treatment included implants that completed the healing period by January 2004. Life-table analysis, the log-rank test and two-choice t-test were employed to evaluate the success of the implantation and resorption of the marginal bone.

Results

During the monitored period a total of 1092 implants with Bio surface, meeting the above criteria, were used with 420 patients; 202 men and 218 women between the ages 15 and- 76 years (average 45.2 years). Of these, 1013 implants, 431 in the maxilla and 582 in the mandible completed the healing period (Tab. 1).

Tab. 1: Dimensions of the implants employed

diameter/length [mm]	8	10	12	14	16	18
3.7	0	29	86	181	235	258
5.0	0	20	77	47	80	0

Osteointegration did not occur for twelve implants, of which seven were in the maxilla and five in the mandible.

Thus 98.8% success was achieved in the healing phase (98.4 % in the maxilla and 99.1% in the mandible, $p>0.05$). A superstructure was fitted on all the healed implants. 176 implants bore a single crown, 663 implants bore a fixed bridge and 162 implants bore a hybrid replacement.

During the first year of functional loading, one implant was explanted because of loss of stability. At the end of the first year, 770 implants were examined; the patients with remaining implants did not accept the follow-up care. 767 implants met the criterion of success. The interval success rate for the first year of loading equalled 99.5%. The cumulative success rate for the entire monitored period was 98.3%. These data, treated in the form of life-table analysis, are summarised in Table 2. Resorption of the marginal bone ($\pm SD$) at the end of the healing period equalled 1.1 ± 0.4 mm and, after the first year of loading, increased by 0.7 ± 0.4 mm.

Discussion

The minimal invasiveness of the operation, the almost hundred-percent probability of osteointegration, a high success rate of the implants in the long term, and almost perfect aesthetic effect of the superstructures are all attributes which have received maximum attention from implantologists. Reducing the interval between introduction of the implant and bringing it into use, or between removing a tooth and introducing an implant into use is a requirement that cannot be met without revision of the Bränemark protocol³. The development of a new generation of titanium implant surfaces¹⁵ is a key precondition for this step to be revealed by evaluation of the success rate for the healing phase, supported by the short-term statistical success rate of the functional phase. It is not probable that early loading of implants would have negative manifestations only in the long-term.

The probability of the formation of osteointegration of 97.6 - 98.8% was found from formerly published values of sand-blasted and hydroxyapatite-coated Implantdent implants with unreduced healing periods^{16,17,19,21,24}. The success of the implantation after one year was from 96.8 to 98.3%^{19,21,24}. The results of the described study (98.8 and 98.3%) correspond with these results.

The loss of marginal bone for sand-blasted and hydroxyapatite-coated Implantent implants measured at the end of the healing period and after the first year of functional loading have already been published and equalled 1.80 and 0.15 mm, resp.²⁰ The values found here (1.10 mm and 0.70 mm) do not indicate faster resorption for implants with Bio surfaces.

Conclusions

It follows from the above statistical findings that STI-Bio Implantent implants can be loaded following twelve months of healing in the upper jaw and after six weeks in the lower jaw without risk of the implant not healing, acceleration of resorption of the marginal bone, or an increase in the

frequency of failure of the implants during the first year of functional loading. In this sense, we recommend changing the treatment protocol laid down by the manufacturer of the implant system.

It is probable that even in shortening the healing time to one half, the potential of the Bio surface is not exhausted. It is not clear though how far the healing time can be shortened. It follows from clinical experience that a six-week interval for implants in the mandible is usually acceptable for patients, while twice this time for the maxilla is not satisfactory. Further studies will be carried out to evaluate the potential for shortening the healing time to six weeks in both jaws and to establish criteria for immediate loading.

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Tab. 2: Life-table analysis

Time interval	Number of implants	Number of failures	Lost from records	Interval success rate (%)	Cumulative success rate (%)
healing period	1013	12	0	98.8	98.8
first year of loading	1001	4	230	99.5	98.3

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