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Clinical and preclinical studies of implants with a Morse-taper implant-abutment connection

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Chapter 1

DENTAL IMPLANTS

1.1 Introduction

Osseointegrated implantology is the branch of dentistry aimed at the placement of dental implants into the bone in order to retain implant-supported prostheses.

Osseointegrated implantology finds its basis in the pioneering works of Prof. Branemark (Brånemark, et al. 2009), who first observed that titanium chambers were able to integrate into the bone tissue, making it difficult to remove them. Since then, new materials have been developed and new techniques evolved, thus endosseous implants represents an excellent therapeutic option to replace lost teeth.

Implantology is based on osseointegration of dental implants, that is the achievement and maintenance of an intimate anatomical and functional connection with healthy bone tissue, when subjected to prosthetic load. Osseointegration depends on a great variety of factors, including anatomical characteristics of the site to be treated, such as bone volume and density, systemic conditions, the experience of the operator, the surgical technique, and the characteristics of the treatment.

A large and continuously growing body of data from scientific research has proven that osseointegrated implantology is a viable and valid therapeutic option.

Implants are considered as an effective treatment option for the restoration of missing teeth. The application of dental implants for the treatment of partial and full edentulism has shown, in several studies, high survival and success rates (Creugers, et al. 2000; Wennstrom, et al. 2005); thus, it has become a common dental treatment. Moreover, it should be considered a viable alternative to teeth-supported fixed partial dentures, mainly due to the benefit of avoiding loss of intact tooth substance in adjacent teeth (Jung, et al. 2008).

In general, the use of osseointegrated implants is necessary in all clinical conditions in which the dental elements have been lost or when, as a result of periodontal disease, caries, trauma, or other pathological conditions, it is not possible to maintain natural dental elements.

Despite the successful clinical results of implant therapy, it should always be remembered that the primary aim of dental treatment is to maintain healthy natural teeth whenever possible and convenient for the patient's health. The evaluation between tooth and implant cannot be separated from a complete diagnostic and prognostic evaluation, not only of the dental element itself but of the subject, his expectations of treatment, and his ability of adhering to the implant treatment and maintenance.

Risk assessment

The assessment of the risk profile of the patient is fundamental in every field of dentistry. Systemic, local, and lifestyle factors of the subject who is candidate to implant surgery must be taken into consideration when evaluating and choosing treatment options, timing and technique.

Systemic risk is represented by the medical and physiological well-being of a patient, while local risk includes dental and anatomic-related issues. An appropriate evaluation and assessment of these indicators is fundamental for the success of implant therapy and to avoid post-treatment complications.

Systemic factors are diseases and conditions that may negatively affect wound healing, bone remodeling, and long-term maintenance of endosseous implants. In general, the systemic conditions of the subject are one of the factors that most significantly influences the treatment plan. Thus, the presurgical evaluation of a patient who will have to undergo implant treatment must include a general systemic evaluation of the state of health.

As a preliminary evaluation, the ASA score may be a useful indicator. The evaluation of the ASA status of the America Society of Anesthetists allows to discriminate simply and immediately the patients who can be subjected to treatment and subjects for which it is contraindicated. From this point of view, surgical treatment for the placement of implants is not indicated in patients with uncontrolled medical conditions or disease, while ASA-1 and ASA-2 subjects (i.e., healthy or with compensated systemic diseases or conditions) can access treatment.

After this general assessment, the clinician must specifically evaluate the presence of pathologies or systemic conditions that may have some influence on surgery or implant treatment in general.

Systemic contraindications for implant surgery have been divided in very high risk and significant risk by Buser et al. (Buser, et al. 2000). Diseases and conditions that determine a high risk are represented by HIV, rheumatoid arthritis, osteomalecia, osteogenesis imperfecta, drug and alcohol abuse, and absence of compliance due to psychological or mental disorders. Significant risk factors are radiation therapy in the head and neck region, uncontrolled diabetes and bleeding disorders. The presence of dysmetabolic diseases such as diabetes, represents a surgical risk factor and an aspect that can affect the onset of biological complications at the level of the implants themselves. For this reason, it is essential to obtain metabolic control in the pre-surgical phase and to maintain a systemic monitoring over time.

As for osteoporosis, there is no solid evidence that this disease can limit the clinical efficacy of endossous implant therapy. However, patients with osteoporosis often assume drugs for bone diseases such as bisphosphonates; therefore, they can only be treated after careful evaluation of the risks and benefits since they can face severe complications following the trauma induced by the surgery itself.

The assumption of specific medications can also influence implant treatment and must be carefully evaluated. The assumption of immunosuppressed medications and the use of intravenous bisphosphonates are considered as high-risk factors, while subjects who take drugs that affect the blood clotting process (anticoagulants including so-called New Oral Anticoagulants, and antiplatelet drugs) are considered at significant risk. Among subjects who are taking drugs or who are undergoing systemic treatments, implant treatment is contraindicated in subjects undergoing anticancer chemotherapy or radiotherapy in the head and neck areas.

In the general population, the increase in the average age has allowed a greater number of elderly subjects to have access to implant treatments. Although it has been reiterated by many scientific studies that age itself does not represent a risk factor for immediate or long-term complications (Heitz-Mayfield, et al. 2018), it must be considered that these subjects can often have comorbidities and are experience more frequently chronic assumption of medications that can affect treatment. For this reason, elder patients with comorbidities must undergo meticulous presurgical evaluation, and the clinical should consult with the patient's specialist doctor when necessary.

The presence or absence of an adequate bone volume for implant placement is a factor of fundamental importance in the pre-surgical and prognostic evaluation of implant treatment. The process of bone atrophy that always follows the extraction or loss of dental elements was first described by Atwood in 1963 (Atwood 1963). This process is particularly intense during the first year and then gradually reduces in the following years. The resorption process has different characteristics in the maxillary jaw and the mandible. The posterior region of the jaws is usually subject to a faster and more extensive resorption.

The most famous classification proposed to describe different resorption degrees, and thus the residual available bone volume, was published by Misch and Judy in 1987 (Misch and Judy 1987)

and is illustrated in Figure 1a. This evaluation is fundamental during presurgical evaluation also for the planning of guided regeneration interventions, which are indicated when insufficient bone volume is available, namely in the situations represented by class C and D.

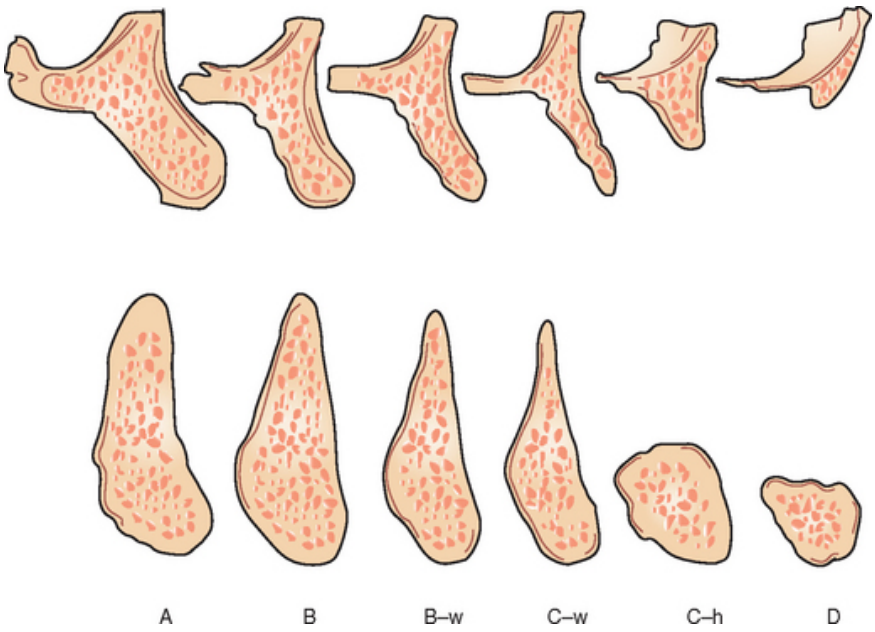

Figure 1a. Classification by Misch and Judy, 1987.

The bone volume must obviously be considered when choosing the diameter and length of the implants. These factors significantly influence the prognosis and the quality of treatment. While choosing the dimension of the implant to be placed, the clinician must take into consideration the following rules for implant positioning, as suggested by the scientific literature:

- in the mesio-distal direction it is necessary that the margin of the implant is positioned at least 1.5 mm from the adjacent tooth and at least 3-4 mm from the adjacent implant, when they are present.
- In the bucco-lingual direction, that is the thickness of the bone, a buccal or lingual bone of at least 1 - 1.5 mm should be available (Chen and Buser 2009). Considering the

diameter of the implant and the minimum requirements for buccal and lingual bone thickness, interventions aimed at increasing the bone volume are frequently necessary.

Together with residual bone volume, bone density is another determining factor for the stability and long-term success of the implant treatment. In general, the maxillary bone has an extremely variable bone density, while the mandible exhibits higher bone density. Following the classification proposed by Misch (Misch 1989), we can distinguish the bone as (Figure 1b):

- D1, widely corticalized and with a compact medulla, typical of the median region of the mandible
- D2, with a well-represented cortical bone and less compact medulla, typical of the anterior and posterior mandible
- D3, with a poorly represented cortical bone and a poorly compacted medulla (anterior and posterior maxilla)
- D4, typical of the posterior maxillary region, with little or no cortical bone, and large gaps in the area of the medulla.

The density of the bone is fundamental for the primary stability of the dental implant, as it affects the percentage of contact between implant and bone and the resistance to mechanical stresses.

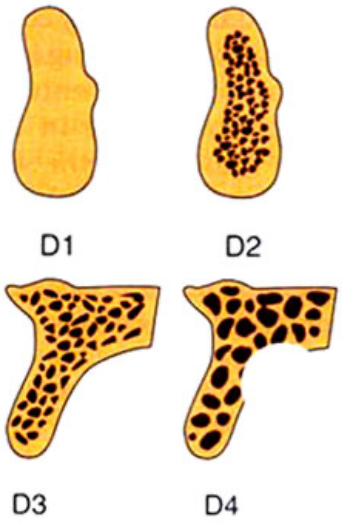

Figure 1b. Classification of bone density by Misch.

Some risk factors are related to lifestyle factors, for example cigarette smoking.

Among the factors most frequently linked to the success of implant treatments, some of them are related to lifestyle and bad habits. Cigarette smoking is one of the factors most closely related to implant failure. On the one hand, cigarette smoking leads to direct trauma to the oral mucosa, which is both chemical and physical (excessive heat). This induces a local inflammatory response that can lead to the development of biological complications. On the other hand, smoking can significantly reduce peripheral vascularization, and, as a consequence, the ability of the peri-implant tissue itself to face an exogenous bacterial insult. The patient must always be informed that smoking leads to increased risk of biological complications such as peri-implantitis and invited to evaluate smoking cessation.

The presence of untreated periodontitis represents an absolute contraindication to implant treatment, since it represents one of the most certain and recognizable risk factors for implant failure and peri-implantitis. In case of active periodontal disease, it is paramount that periodontal treatment is completed in order to achieve periodontal health (on a reduced periodontium, eventually) before implant placement.

Moreover, the level of compliance of the patient must be considered, in terms of oral hygiene and collaboration in following dental therapies, including periodontal and implant maintenance therapy.

Parafunctional habits that could influence the success of implant treatment should also be assessed during the treatment planning. For example, bruxism (a condition in which the patient unknowingly grinds his teeth, especially during the night) determines the transmission of large forces to the implant-prosthetic system. This can lead to a significant increase in the occurrence of prosthetic and mechanical complications in general (Salvi and Bragger 2009).

1.2 Characteristics of dental implants

Morphology

Most dental implants are fabricated from titanium or titanium alloys. Its major advantage is that titanium is virtually chemically inert, it is biocompatible and has a high resistance. Biocompatibility allows titanium implant to integrate into the bone without leading to a foreign-body reaction into the organism.

Basically, the implant consists of a fixture, an abutment, and a prosthetic portion.

The fixture is the endosseous component which is inserted into the bone and undergoes the process of osseointegration. The coronal part of the fixture is called collar or crest module, it is in contact with the abutment through ots most coronal surface (called platform) and it retains the prosthetic component. The body of the implant can be cylindrical or conical/tapered, with an apex of different shapes: the apex can be blunt, sharp for self-cutting ability, or with a rounded apical area to facilitate vertical sinus augmentation. The implant surface is threaded with different thread designs, which can be more aggressive for cutting efficacy or wider and square for stability.

V-thread is considered the standard thread pattern (e.g., Nobel Biocare, Zimmer Dental, Biomet 3); buttress design is optimal for both tensile and compressive forces (e.g. Straumann Standard, Straumann), while reverse buttress exhibits higher resistance to tensile forces (e.g. Nobel Replace, Nobel Biocare); finally, the surface area of the square thread profile is optimal for transmitting compressive load to the bone-implant interface (e.g. Branemark). The number of threads per inch (TPI), the angle and the depth of the threads are other features of the thread design, which can be selected depending on the specific clinical situation, such as the need for greater implant stability in case of low bone density. Some fixtures are also fabricated with vertical grooves or transecting holes, which aim at improving the stabilization of the implant by preventing its rotation after bony ingrowth. Figure 1c shows the shapes and designs of different fixtures.

Figure 1c. Implant fixtures with different designs. From left to right: a standard fixture, a fixture for low-density bone with a thread and apical profile designed to maximize primary stability, a narrow-diameter fixture with a maximum diameter of 2.9 mm, and a short fixture (Leone, Firenze).

The collar or crest module, that is the coronal portion of the fixture, represents the trans-osteal region of the implant at the ridge crest. It has an increasing diameter from the abutment interface downwards to the fixture body. The coronal surface of the fixture, i.e., the platform, represents the interface with the abutment.

The abutment is connected apically to the fixture through the implant-abutment connection, and coronally to the prosthesis through the prosthetic connection. They can be straight or angled at different degrees, depending on the restorative requirements. Dental implant systems where the fixture and the abutment are separate components are known as two-step. On the contrary, one-step implant systems have a single-unit design in which the implant is integrated with the abutment. This single-unit designs exhibits actually some advantages, such as the possibility to restore immediately the edentulous area, and the absence of any micro-gap between the abutment and fixture, which develop predominantly during loading, due to sliding and deformation of both components, and can

lead to bacterial colonization of the implant-abutment interface. However, the clinical applications of one-piece implants are limited since the exposition of the abutment determines an early loading before the achievement of osseointegration. In two-piece implant systems, the fixture can be completely inserted into the bone and protected from early loading, allowing a more predictable bone healing and osseointegration.

In two-piece implant systems, the implant-abutment connection can be internal or external, and exhibit different shape, e.g., hexagonal or conical.

The prosthetic connection can have different designs, namely it can configure as screw retention, cement retention, or attachments for the removable prosthesis. Single, partial, and full-arch prosthesis can be cemented, screw-retained or connected with attachments. Conical connection is also used for prosthetic connection.

Implant surface

The surface of the fixture can be modified to ensure retentive osseointegration. The implant surface can be treated through different methods which provide micro-retention characteristics. These include surface roughening, hydroxyapatite coatings, and acid-etching. According to recent studies, the acid-etched surfaces may provide the optimal degree of surface roughness, which increases the surface for bone contact. Interestingly, it appears that smooth surfaces and acid-etched surfaces are less conducive to bacterial colonization and contamination (Quirynen, et al. 2002).

Some manufacturers use hydroxyapatite coatings in the attempt to enhance osseointegration, particularly to accelerate initial osseointegration. However, a meta-analysis by Lee at al. reported that the survival rates for hydroxyapatite-coated implants were similar to the survival rates reported for uncoated titanium implants (Lee, et al. 2000).

The implant-abutment connection

The implant-abutment connection can be classified as internal or external, having different shapes such as hexagonal, octagonal, or conical. Among internal connections, the conical connection, especially when having a low convergence, relies on frictional retention. This allows to avoid the presence of an implant-abutment screw. Figure 1d illustrates some examples of implant-abutment connections.

Figure 1d. From left to right: coronal and lateral view of an implant with an external hexagonal connection; coronal and lateral view of an implant with an internal hexagonal connection; lateral view of the detail of two conical connections. While internal connection can include the presence of an implant-abutment screw (left), this is not necessary when convergence is low enough to ensure frictional retention if the abutment (right).

When the abutment is anchored to the fixture by an abutment central screw, both the screw and the abutment itself can be subjected to high stresses under loading, which can lead to screw loosening. The polygonal anti-rotational indexing configuration helps in reducing the loosening of the screw, especially for single tooth implants.

External connection, which can have different shapes such as hexagonal or octagonal, were more used in the past and have been superseded by internal connection systems, which ensure higher resistance to lateral forces.

Actually, the internal connection is generally deeper than the external hex, ensuring a greater depth of interlocking of the combined portions of implant and abutment. This guarantees more certain indexing, higher stability and retention. Moreover, internal connection exhibit significantly

decreased incidence of screw loosening. However, the central screw can still loosen, undergo plastic deformation and, particularly under excessive loading.

The conical connection is a particular type of internal connection, which consists of a converging circular surface, whose design may help overcoming potential microleakage and the disadvantages related to the presence of an implant-abutment screw, that range from screw loosening to screw fracture, to the impossibility of reducing the dimension of the fixture to narrow diameters required for implant placement in areas of scarce bone volume availability.

The term Morse-taper connection defines a conical connection with a specific convergence, with a total angle of 3° according to UNI ISO 296 international Standard (Figure 1e). The implant systems available include also conical connections with different degree of convergence, such as an 8° cylindrical taper (16° total convergence) (Strumann, Basel, Switzerland). In these cases, the term Morse-taper is not applicable. The conical design of the connection, and particularly Morse-taper connection with a very small convergence, forms a mechanical locking friction-fit, also known as a cold weld.

The Morse Taper is a method of joining two rotating machine components, which was invented in 1864 by Stephen A. Morse, and is extensively used in other medical fields, such as in orthopedic implants. The underlying principle is that of a cone locked into a cone. In the Morse-taper connection, the “male portion” (trunnion) and the “female portion (bore) have the same taper, thus coming into intimate contact and generating a frictional force that keeps both components fixed together. This

connection is also called “cold-welding”, that is a bonding process that relies on friction, in which two solids are forced together under high pressure to form a single piece.

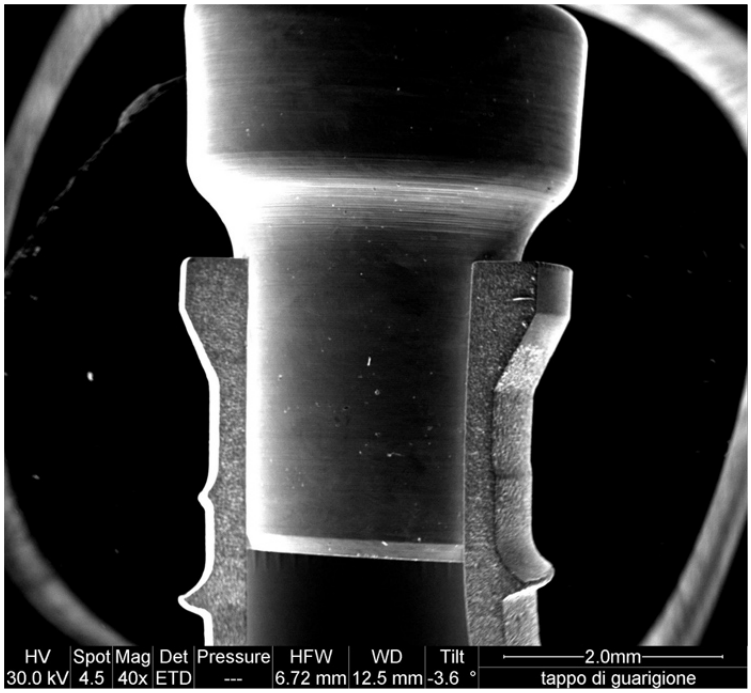

Figure 1e. The Morse-taper connection produces a cold-weld seal between the implant and the abutment, and it minimizes the presence and dimension of microgaps at the implant-abutment interface.

1.3 Timing of implant placement

The standard procedure in implant placement is represented by the placement of implants in native bone or completely healed bone. Thus, when replacing teeth following a dental extraction or trauma, it is recommended to wait a sufficient period for the complete maturation and healing of the bone before proceeding with the implant placement surgery.

The duration of the healing period may vary depending on a series of local and systemic factors, and since now no objective parameters to evaluate the end of the healing process are available. For this reason, this period does not have a defined duration. However, on the basis of histological studies, we can consider this period to be at least two months for the mandible and three months for the upper jaw, because of the anatomical differences of these two districts.

Early in the history of implant dentistry, a waiting period of 6 months following an extraction was recommended prior to the insertion of an endosseous dental implant into the edentulous site (Adell, et al. 1981). However, such waiting period frequently results in a significant resorption of the alveolar process, which can influence the ideal positioning of dental implants (Iasella, et al. 2003).

In recent times, the possibility of placing implants before the complete healing of the bone has increasingly gained attention. Particularly, immediate implants are placed immediately after the extraction of the dental element.

Hämmerle et al. classified the timing of implant placement in three groups, and defined the following times for the placement of an integrated bone implant following the extraction of a dental element (Hammerle, et al. 2004):

1) Immediate implant placement, that is, immediately after extraction
2) Early implant placement, that is, during the healing phase of the alveolus
3) Dilated implant placement, that is, after complete healing of the extraction site.

Immediate implant placement was firstly described in 1976 by Schulte and Heimke (Schulte and Heimke 1976) and reintroduced many years later in a case report by Lazzara (Lazzara 1989) and a case series reporting a 3-year survival rate of 98% (Gelb 1993). After that, a large number of animal, histological and human studies have been performed.

The advantages of this technique include the reduction of the treatment times, also accommodating the patient's requests. However, its main advantage is the possibility to replace teeth immediately after extraction in aesthetic areas, in order to meet the psychological and social patient's needs concerning the aesthetic field. Therefore, the concept of immediate post-extraction implant has found wide application especially in the frontal sectors of the upper jaw.

The main indications of immediate implants are all cases of implant placement in the anterior portion of the upper jaw (that is, from premolar to premolar), if there is an aesthetic need from the patient or if is necessary to significantly reduce treatment times.

As for clinical performance of immediate implants, from the point of view of the existing scientific literature, it is possible to state that, in conditions of integrity of the post-extraction socket, the success rate of immediate implants is about 95%, although they still have a higher failure rate than implants placed in native bone (Cosyn, et al. 2019).

However, it is important to take into consideration the treatment complexities and to perform an accurate clinical and anatomic evaluation. Scientific literature has proven that immediate implants exhibit similar survival and success rate as compared to early and delayed placement protocols, but only under strict observation of the available evidence-supported clinical guidelines (Chen, et al. 2009; Chen, et al. 2004; Wagenberg and Froum 2006). Actually, when applying immediate implant positioning protocol, the site morphology may complicate the optimal placement and anchorage, the lack of keratinized mucosa may complicate the management of the flap, and thin tissue phenotype may negatively affect the soft tissue healing.

Immediate implant placement requires the appropriate anatomical conditions, which are represented mainly by bone characteristics that guarantee an adequate primary mechanical implant stability.

The possibility to achieve primary stability, through engaging bone of the lateral walls of the socket or the bone apical to the original socket, is paramount for the application of the immediate implant placement protocol, but it must be remembered that restorative requirements and guidelines for correct implant positioning need to be accounted for. For example, trying to achieve primary stability through the placement of an implant with a larger diameter platform than desirable for restoration is an error that can lead to various complication, ranging from insufficient aesthetic outcomes to buccal bone plate resorption. Similarly, when replacing multi-rooted teeth, implants should not be placed in the socket of one root with the only aim of obtaining primary stability, neglecting the concept of restoratively driven positioning.

When insufficient bone volume is available, for example in case of marked resorption of the walls of the alveolus itself following an inflammatory process, or in case of fracture of the bone walls of the alveolus, immediate implant placement may not represent a viable option. In general, whenever it is necessary to perform bone regeneration interventions, a delayed and staged approach may be indicated.

A relative contraindication for immediate implant placement is represented by the presence of an infection at the site of the extracted teeth. Actually, this condition has been correlated with a higher rate of implant failure (Lee, et al. 2018).

1.4 Surgical protocol

Together with the presurgical overall assessment of the subject to be treated both from a systemic and a local point of view, the anatomical characteristics of the site should be evaluated both clinically and radiographically. In many cases it is recommended to assess three-dimensional images available, which allow a clear visualization of the anatomical structures and the available bone volume. Usually, these images are obtained through the use of Cone-Beam Computed Tomography (CBCT), a particular type of three-dimensional radiography, specifically designed for the dental field. Through these images it is also possible to produce diagnostic or surgical guides.

The presurgical control of the subject's systemic conditions may include the modification of the systemic therapeutic regimens in place and the administration of antibiotics for infective endocarditis prophylaxis (2 grams of Amoxicillin orally one hour before surgery or, in subjects with allergy or hypersensitivity to beta-lactams 500 mg of clarithromycin one hour before surgery). According to the AHA guidelines, infective endocarditis prophylaxis for dental procedures is only reasonable in patients with underlying cardiac conditions associated with a high risk of adverse outcomes associated with endocarditis, for example heart transplant recipients or with a previous history of bacterial endocarditis (Wilson, et al. 2007).

Once local anesthesia has been performed, a full-thickness muco-periosteal flap in the region of implant insertion is elevated, and the size of available bone volumes is verified through direct visualization and measurement.

The implant site is then prepared through the use of calibrated drills. The precision of the inclination of the implant preparation is then verified whenever necessary through the use of measurment indicators. This procedure must be performed with instruments and movements that are not traumatic to the bone and mucous tissues to reduce the onset of complications. Since the overheating of the site due to inadequate preparation or unsuitable instruments can represent an important cause of peri-implant bone resorption and failure of the procedure, when high speeds are

adopted (higher than 600-800 rpm) it is recommended to ensure the cooling of the site through irrigation with sterile saline solution and an intermittent movement of "up and down" until the desired length is reached.

The positioning inside the prepared site must be carried out limiting stress and with an insertion force that is not excessive, but at the same time adequate to allow sufficient stability to the implant itself. Typically, this procedure is performed at a low number of revolutions (15-20 rpm), under irrigation with saline solution, with a dynamometric device used by hand or mounted on a handpiece. Figure 1f shows the clinical phases of implant insertion.

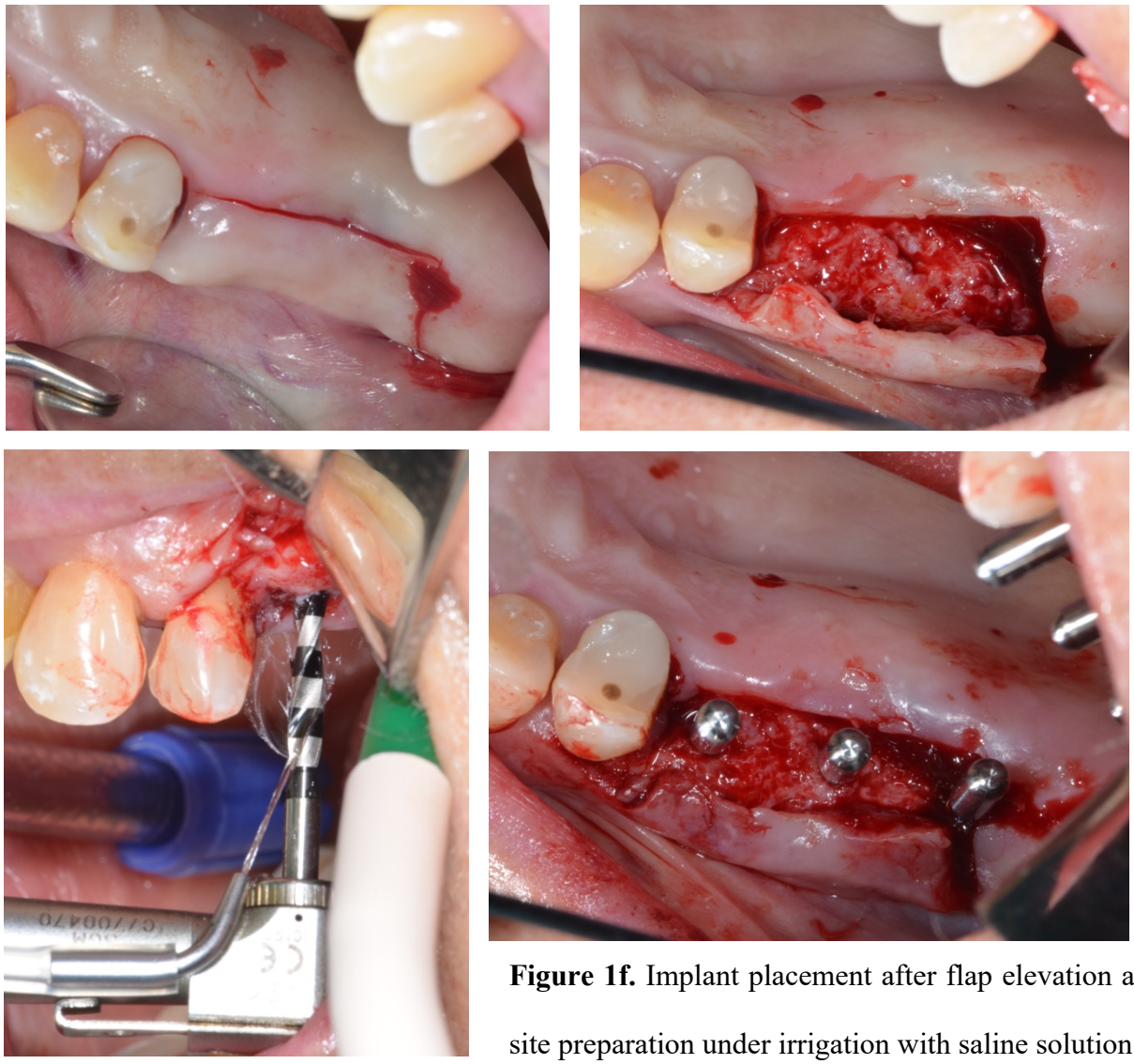

Figure 1f. Implant placement after flap elevation and site preparation under irrigation with saline solution.

Once the implant has been positioned and the surgery has been completed with the placement of the sutures, the patient must be instructed to avoid the intake of foods that are too hot, irritating or capable of damaging wound healing, preferring a semi-solid or liquid, however not hot for at least the first two days after surgery. In addition, the patient must be asked to avoid any trauma to the wound and to moderate the use of cold packs for very limited periods (few minutes) and only during the first 24 hours. The cleansing of the surgical intervention region must be carried out with the aid of topical disinfectant aids (chlorhexidine 1% gel or 0.2% mouthwash) for at least 7 days from the date of the intervention, avoiding trauma induced by normal oral hygiene devices. The administration of systemic drugs should be limited to analgesic or anti-inflammatory drugs, unless antibiotic prescription is indicated for the specific clinical situation.

Surgical protocol for immediate implants

First of all, the surgical procedure for immediate implants involves an atraumatic tooth extraction to preserve the integrity of the socket. Minimizing trauma to the site during the extraction process is one of the keys to successful immediate implant placement, which can be achieved through a variety of methods including, for example, the separation of multi-rooted teeth in order to avoid hard tissue damage.

Then, a careful revision of the post-extraction socket for the removal of all the infected material should be performed, and the implant site should be prepared in the context of the socket itself, after an accurate evaluation of the anatomical conformation of the alveolus. After implant positioning, the gap between the surface of the implant and the internal wall of the socket must be evaluated: if this gap is equal or greater than 2 mm, the contextual positioning of a bone substitute as a filler is recommended, in order to reduce the physiological resorption process of the buccal bone.

1.5 Prosthetic protocol

General characteristics of the prosthesis

Endosseous implants offer a chance to replace lost and missing dental elements through various type of dental prostheses. When planning the implant-prosthetic treatment, it must be considered that implantology should be guided as much as possible by the rehabilitation that we decide to place (prosthetically guided implantology). The advantages of this kind of treatment are both functional and aesthetic.

In general we distinguish removable or non-removable supported implant prostheses.

- Removable implant-supported prosthesis are generally total rehabilitations of entire arches that have an implant anchorage that provides stability during the chewing and phonation, but which can be removed by the patient in order to carry out oral hygiene maneuvers at home. The so-called "overdenture" prostheses belong to this category. Overdentures are total prostheses with both implant anchoring and a mucous support.
- Non-removable implant prostheses offer an adequate solution to partial and total edentulousness of both arches. They can be distinguished in cemented or screw prostheses, according to the method of fixation to the implants. Screwed prosthesis can be easily removed by the clinician in case of complications occur. In case of cemented prostheses supported by implants with a Morse-taper connection, the absence of the implant-abutment screw allows the clinician to remove the abutment (or the superstructure) together with the cemented prosthesis with specific tools.

Timing of prosthetic loading

The first historical approach to implantology provided that the prosthesis was placed after a certain period of healing following the placement of the implant. We can currently distinguish three different prosthetic loading times (Esposito, et al. 2013):

- conventional loading, which occurs at least two months after implant placement
- early loading that occurs in a period between the first week and two months after implant placement
- immediate loading which occurs within the first week after implant treatment, ideally in the first hours.

Immediate prosthetic loading requires the possibility of obtaining primary stability, that is, stability of the implant at the very moment of the intervention, sufficient to guarantee absolute fixity to the structure. This depends on the insertion torque and therefore on all the factors that can influence it, namely the implant morphology, the precision in the site preparation, the bone density at the site of the intervention (with greatest primary stability offered by D1 bone), and the surgical technique (e.g., immediate post-extraction implant placement).

Immediate loading can be indicated in all regions of the jaws but is particularly suitable, where it is possible, in aesthetic regions and in cases of complete edentulism, in which the placement of temporary prostheses could be difficult to practice.

In terms of implant success and survival, in general, immediate loading has slightly lower percentages than conventional loading and this aspect, in the medium and long term, must be considered together with the indications and contraindications to treatment (Chen, et al. 2019).

1.6 Dental implants complications

Implants and, in general, implant-prosthetic rehabilitations are subject to early or late complications, which can be technical or biological.

Biological complications

Biological complications are divided into early and late depending on the timing of onset.

Early complications occur less than 12 months after implant insertion surgery and include all immediate postoperative complications, related to the infection of the implant placement site, which can cause the failure of the implant treatment. Early complications can also arise following the cementation of the prosthesis, due to the dispersion of cement in the peri-implant tissues. This complication can be easily solved through the identification and removal of the cement. Other early complications may be the result of an inadequate and excessive load which can lead to peri-implant bone resorption.

Late biological complications are infectious inflammatory diseases affecting the peri-implant soft tissues (Figure 1g). Unlike periodontal tissues, peri-implant soft tissues lack a real attachment of connective fibers to the implant surface and the tissue is overall weaker against bacterial insults, when compared to the gingival tissues that sorround natural teeth. From a clinical point of view we can distinguish:

- peri-implant mucositis, a reversible inflammation of the peri-implant soft tissues without involvement of the peri-implant bone tissue
- peri-implantitis in which the clinical symptoms of inflammation (edema, redness, bleeding on probing and possibly purulent exudate) are associated with radiological evidence of peri-implant bone resorption.

From the diagnostic point of view, the diagnosis of peri-implantitis is formulated when there is evidence of the following signs (Berglundh, et al. 2018):

- bleeding or suppuration on probing
- increase in probing depth compared to previous measurements
- presence of bone resorption in addition to changes in the crestal bone tissue that results from the initial remodeling.

If no previous findings are available, in order to diagnose peri-implantitis, it is necessary to observe

- a probing depth greater than or equal to 6 mm
- evidence of a bone level of at least 3 mm apical with respect to the intraosseous portion of the implant.

Thanks to these clinical characteristics it is possible to formulate an early diagnosis of peri-implant disease. The programming of an adequate and personalized maintenance protocol according to the characteristics of the patient, together with periodic clinical and radiographic control, is therefore fundamental.

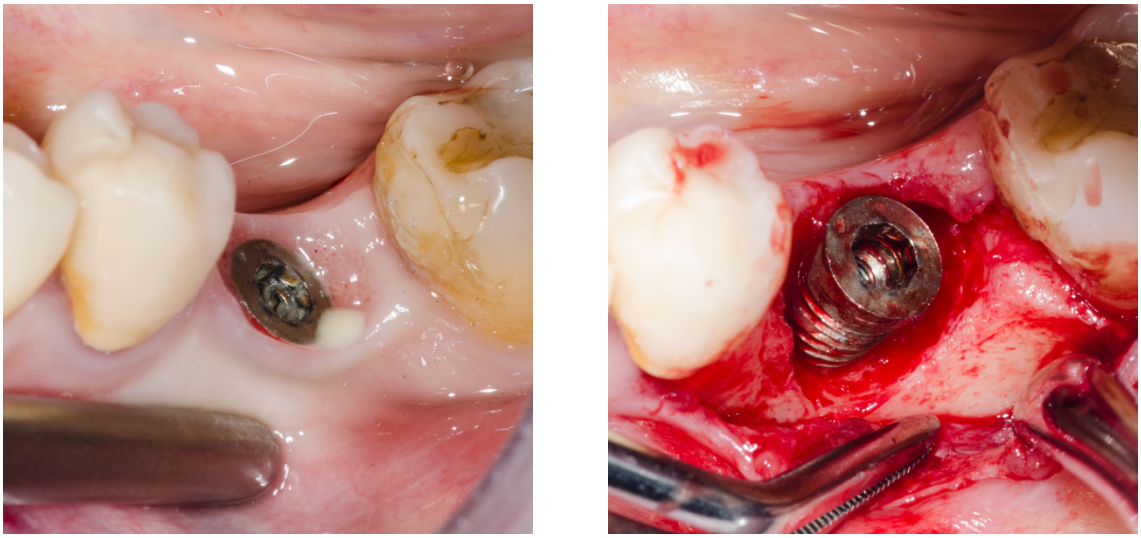

Figure 1g. A case of peri-implantitis with clinical evidence of suppuration. After flap elevation for surgical treatment of peri-implantitis, it is possible to observe directly the extensive peri-implant bony defect.

Peri-implant inflammatory pathology is extremely prevalent in the population. A mean of 22% of implants develops peri-implantitis, and in 43% of implants peri-implant mucositis occurs. This occurs substantially for all types of rehabilitation (Derks and Tomasi 2015). Among the main risk factors of peri-implantitis we can find cigarette smoking and the diagnosis of periodontitis.

Since peri-implant mucositis is an easily treatable and reversible pathology, the approach towards peri-implant diseases must include the prevention and early diagnosis of peri-implant mucositis before it can evolve into peri-implantitis. When peri-implantitis is diagnosed, the therapeutic protocol may include a non-surgical treatment (with the use of local or systemic antibiotics, subgingival instrumentation, and the use of disinfectants). Subsequently, both a regenerative and resective surgical treatment can be associated to non surgical therapy, which is aimed at the removal of the granulation tissue at the level of the peri-implant lesion and the decontamination of the implant surface.

Although the surgical therapeutic strategies against peri-implantitis have shown some efficacy, the disease is to be considered a severe complication and therefore an adequate prevention and management protocol for the reversible phases of the disease is always recommended.

Technical complications

Technical complications relate to the prosthetic and implant device per se and can include fractures of any type of prosthetic coating, fractures of the fixation screw, fractures of the implant, prosthetic abutment, or entire prosthetic structure (Figure 1h, 1i). Some minor problems include the unscrewing or decementation of the prosthesis or partial loss of material that can be easily solved.

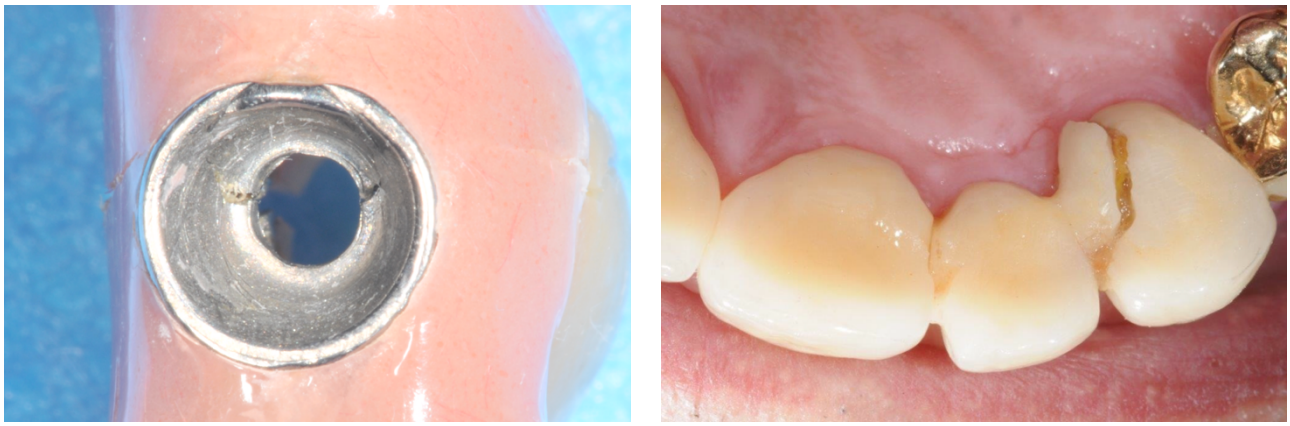

Figure 1h. Fracture of the metallic structure; fracture of the prosthetic coating.

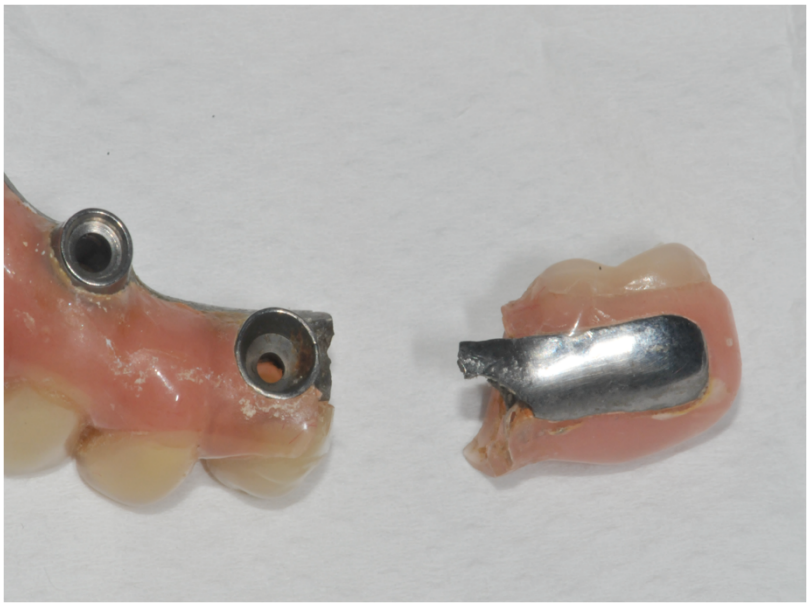

Figure 1i. Fracture of the entire prosthetic structure.

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Chapter 2

LABORATORY STUDIES OF IMPLANTS WITH MORSE-TAPER IMPLANT-ABUTMENT CONNECTION

2.1 Mechanical resistance of a 2.9 mm diameter dental implant with a Morse-taper implant-abutment connection

Abstract

Among the complications that can occur at dental implants, the fracture of any implant component is a relatively infrequent but clinically significant problem. Small diameter implants are at higher risk of such complication. The aim of this laboratory study was to compare the mechanical behavior of a 2.9 mm and a 3.3 mm diameter implant with a conical connection under standard static and dynamic conditions, following the ISO 14801:2017. Finite element analysis was performed to compare the stress distribution on the tested implant systems under a 300 N, 30° inclined force. Static tests were performed with a load cell of 2 kN; force was applied on the experimental samples at 30° with respect to the implant-abutment axis, with an arm of 5.5 mm. Fatigue tests were performed with decreasing loads, at 2 Hz frequency, until three specimens survived without any damage after 2 million cycles. The emergence profile of the abutment resulted the most stressed area in finite element analysis, with a maximum stress of 5829 MPa and 5480 MPa for 2.9 mm and 3.3 mm diameter implant complex respectively. The mean maximum load resulted 360 N for 2.9 mm diameter and 370 N for 3.3 mm diameter implants. The fatigue limit was recorded to be 220 N and 240 N respectively. Despite the

more favorable results of 3.3 mm diameter implants, the difference between the tested implants could be considered clinically negligible. This is probably due to the conical design of the connection, which has been reported to present low stress values in the implant neck region, thus increasing the fracture resistance.

Introduction

Dental implants are a safe and effective treatment option for the resolution of cases of partial or full edentulism of mandibular or maxillary arches. The scientific literature supported the use of dental implants for these purposes, showing high survival rates even over a long-term period (Howe, et al. 2019).

Despite long-term outcomes confirmed the safety and efficacy of implant-supported dental prosthesis, many complications can occur that may compromise partially or totally the functioning of such devices (Papaspyridakos, et al. 2012). Both biological and technical complications could be observed. Biological complications were related to the inflammatory response of peri-implant soft tissues due to bacterial biofilm accumulation at implant-prosthesis level. Peri-implant mucositis could be defined as an inflammatory response which is reversible and limited to the soft tissues, characterized by clear signs of inflammation such as redness, swelling, mild pain, bleeding on probing and, occasionally suppuration (Heitz-Mayfield and Salvi 2018). Peri-implantitis is an inflammatory disease affecting peri-implant tissues, with all signs of inflammation of peri-implant mucositis, that also affects the implant-surrounding bone, determining bone resorption and probing depth increase over time (Schwarz, et al. 2018). In general, biological complications are very prevalent, affecting 1% to 47% of the subjects treated with implant-supported prosthesis (Derks and Tomasi 2015) and 1.1% to 85% of implants (Dreyer, et al. 2018). The risk factors that increase the possibility of development are represented by periodontitis and bacterial plaque accumulation, whilst the effects of other factors (such as smoking) have to be demonstrated (Schwarz, et al. 2018). As for plaque accumulation, various studies reported that a conical design of the implant-abutment connection

could reduce the bacterial colonization of the implant-abutment interface thanks to narrowness of the microgap.

Alongside biological complications, implant-supported restorations could be affected by a number of technical complications. The technical complications may concern both the prosthetic component and the implant itself and the most frequent are represented by abutment screw loosening or fractures, loss of screw access seal, the detachment of an element from a full-arch structure and the loss of esthetic veneer material (Fagbamigbe, et al. 2021; Francetti, et al. 2015; Karlsson, et al. 2020). Most of the technical complications could be resolved easily, quickly, and without particular discomfort for the patient (Francetti, et al. 2015). Among the technical complications, although relatively less frequent than the others, implant body fracture is a significant problem both for the clinician and for the patients, whose resolution requires significant efforts and a substantial discomfort for the patient (Yu and Kim 2020). Moreover, many authors reported that implant extraction after fracture often results in bone defects that could complicate the placement of another implant (Yu and Kim 2020). The authors reported that the causes of implant fractures were mostly related to mechanical failures related to implant design and materials, being metal fatigue the most common occurrence (Patterson and Johns 1992). The results from one large retrospective investigation published by Chrcanovic and coworkers in 2017 found that, among other factors, the 1-mm increase in implant diameter could decrease of almost 100% the risk of incurring in implant fractures, highlighting that implant diameter could be considered as a fundamental factor for estimating the risk of such complication (Chrcanovic, et al. 2018).

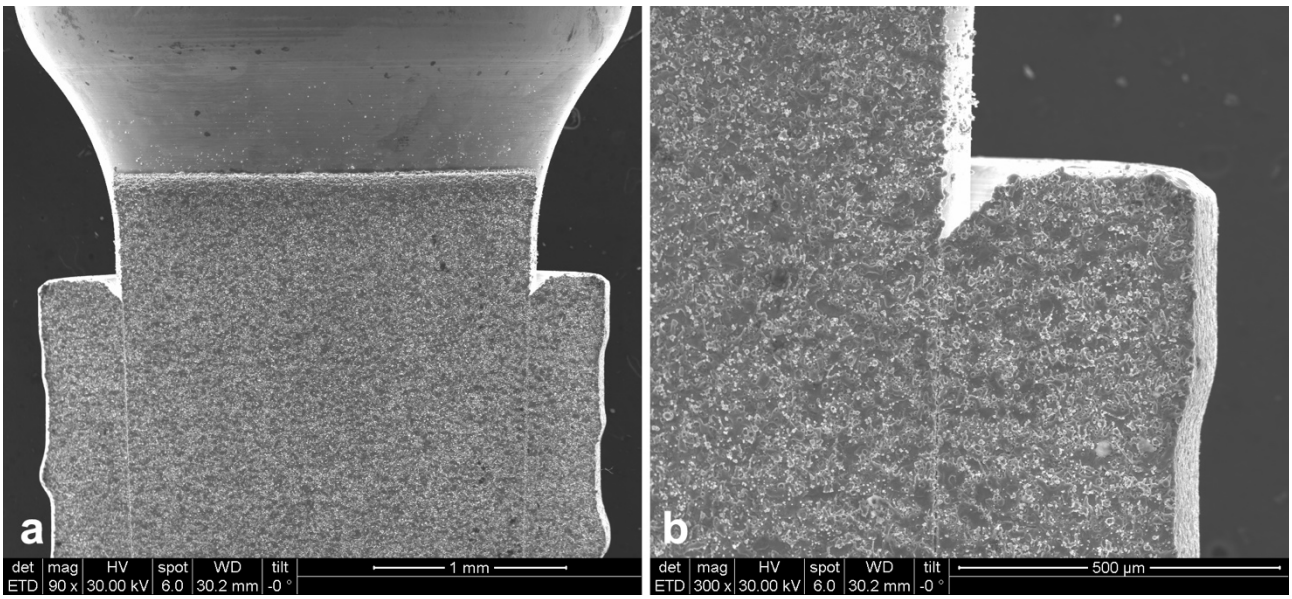
The aim of the present laboratory study was to evaluate the mechanical behavior of one narrow 2.9 mm diameter implant, as compared to one 3.3 mm diameter implant with analogue design, through finite element analysis (FEA) and under standard conditions for testing the dynamic fatigue for endosseous implants (ISO 14801:2017).

Materials and methods

The mechanical behavior of two dental implants with a diameter of 2.9 mm and 3.3 mm respectively and a length of 14 mm (Leone S.p.A, Florence, Italy) was tested through numeric and experimental tests under static and dynamic conditions.

Finite element analysis was performed to investigate the stress distribution on the tested implants: solid models of a 2.9 and a 3.3 mm diameter implants, with a length of 14 mm and cylindric abutments with a hemispherical end, were created using a computer-aided design software (Inventor®). Both 2.9- and 3.3-mm diameter implants were fixed to an abutment with a 3.3 mm diameter, with the same hemispherical extremity. A support of 10x10x20 mm with a hole for the implants was created through solid subtraction. The implants and the abutments were made of titanium grade 5 (Ti 6Al 4V), while the support was designed to simulate the peri-implant bone and it consisted of 2 mm of external cortical bone and internal cancellous bone (Figure 1) (Kadkhodazadeh, et al. 2014).

Figure 1. Scanning electron microscope (SEM) images of a section of a 2.9 mm implant with a Morse-taper connection, obtained with 90X magnification (a) and 300X magnification (b). The connection relies on a broad frictional area.



The elastic characteristics of the material used are reported in Table 1.

Table 1. Mechanical properties of the material used for the FE analysis.

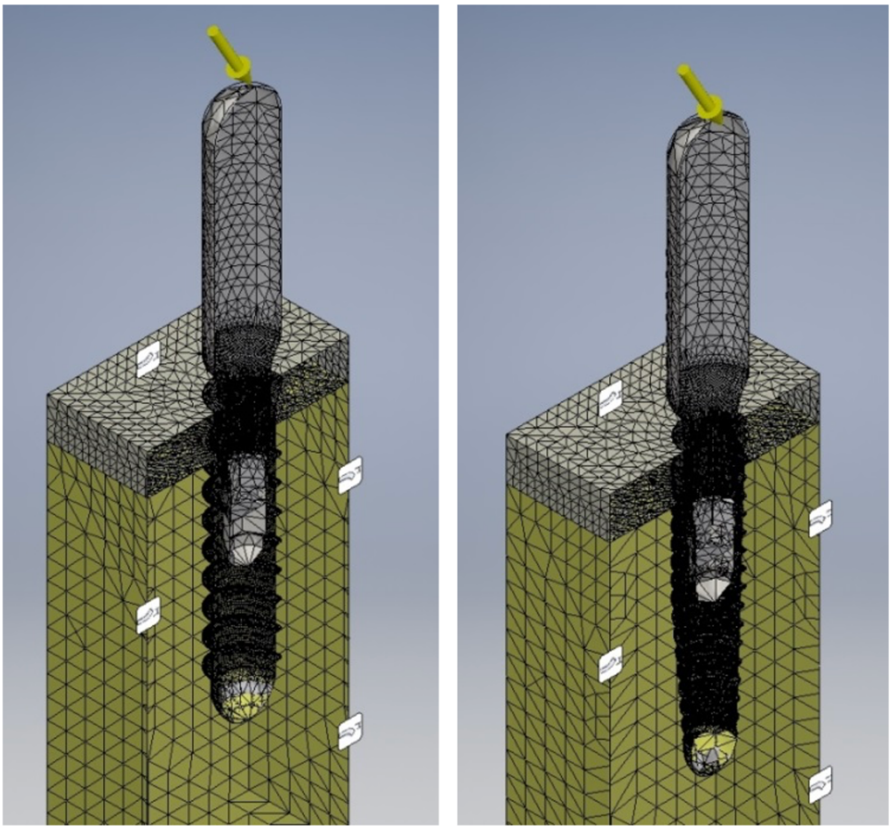
Material	Mechanical behavior	Young's modulus of elasticity (MPa)	Poisson ratio (v)	Density (kg/mm^2)
Implant and abutment (Ti 6Al 4V)	Isotropic	110000	0,30	$4{,}400^{-9}$
Cortical bone	Isotropic	18000	0,30	$1{,}940^{-9}$
Trabecular bone	Isotropic	200	0,30	$1{,}600^{-9}$

The computer-aided design models were transferred into processing software and converted into FE models. A finer mesh was used at the implant-abutment interface in order to guarantee higher accuracy. The lower and lateral surfaces of the bone supports were fixed to the plane of flexion through fixed constraint. The implant and the abutment surfaces were coupled at their interface without relative sliding, gaps or interferences between the contacting areas. Finally, a load of 300 N was applied to the hemispherical cap of the abutment, with a 30 degrees inclination with respect to the implant-abutment axis.

Static and fatigue tests were performed in reference to the ISO 14801:2017 ("Dentistry Implants – Dynamic fatigue test for endosseous dental implants") in the Department of Industrial Engineering of the University of Florence. The following procedures were undertaken to prepare the experimental apparatus: a series of blocks made of polyphenylsulfone plus additive of 40% fiberglass were prepared, with a modulus of elasticity of 14 GPa. The blocks had a hole with a length of 14 mm and a diameter of 2.9, which was instrumented with a tap drill. Dental implants were inserted in the block,

using the dedicated surgical kit, respecting the indications of the manufacturer (Leone S.p.A, Florence, Italy); a standard cylinder abutment (the same for both implants) was fixed to the implant according to the instructions of the producer, beating the abutment twice with a specific instrument (Figure 2).

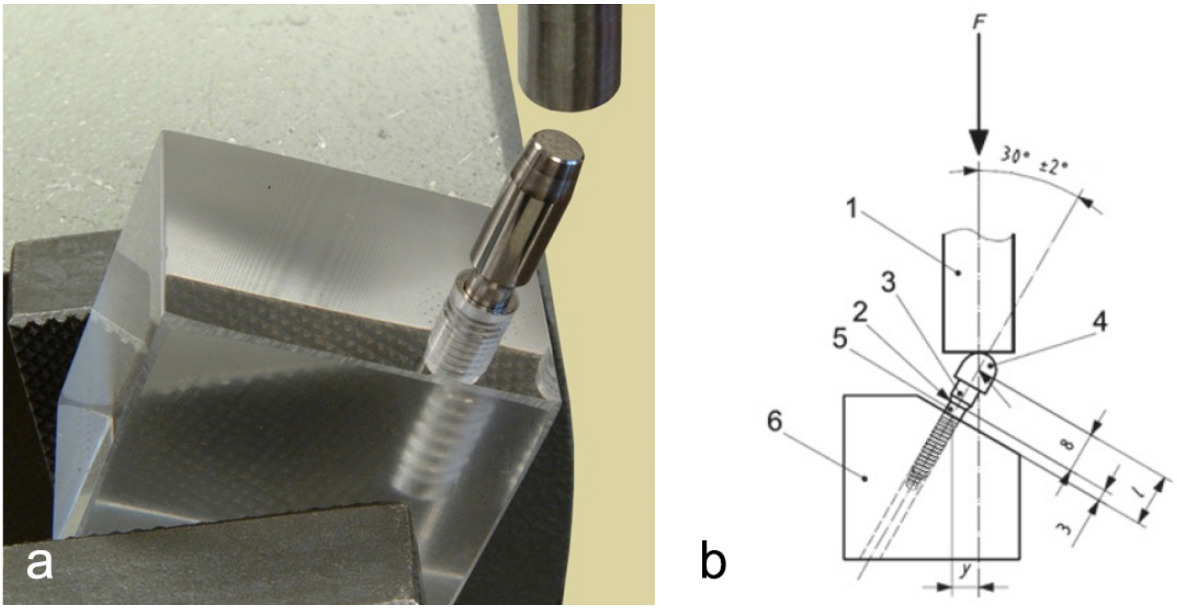
Figure 2. Three-dimensional model of the implant-abutment experimental complex and the support simulating cortical and cancellous bone in its coronal and apical portions respectively.



The standard abutment was made of titanium grade 5 (Ti 6Al 4V). Its head was 11 mm high and had a hemispherical cap at its end, as required by the mentioned ISO standard. The same procedures were repeated to prepare the experimental apparatus for 3.3 mm diameter implants. The tests were performed using an MTS Series 810 universal testing machine (MTS, Eden Prairie, Minnesota), with a load cell of 2 kN. The implant-abutment axis was inclined at 30° with respect to the load axis. Force was applied on the abutment with an arm of 5.5 mm. Figure 3 illustrates the components of the testing apparatus. First, three samples for each implant type were tested statically with a crosshead speed of

1 mm/min, until failure of one of the experimental components. The static bending test was performed in order to determine the failure strength, that is the maximum force to which the system fails or a significant permanent deformation of a component of the system occurs, undermining its functionality.

Figure 3. Testing apparatus (a) and schematic illustration of its design (b), following ISO 14801:2007 (1: loading device, 2: bone crest level, 3: connection part, 4: hemispherical cap, 5: implant, 6: support, y= 5.5 mm, I= 11mm).



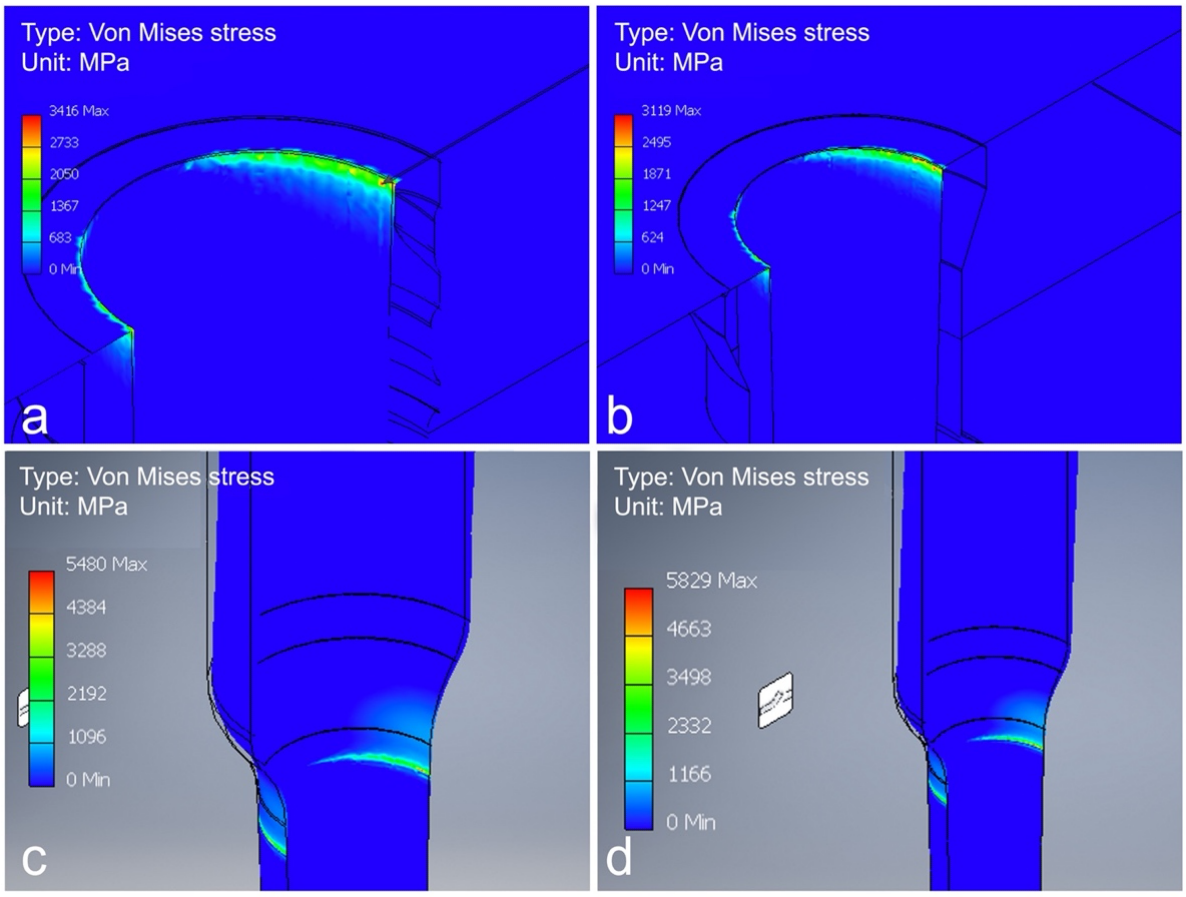
Then, fatigue tests were performed on the remaining samples at different loads. Each load was applied until reaching 2 million cycles or until failure of one of the experimental components. First, a value close to the determined static failure strength was applied, afterwards it was progressively reduced in order to determine the fatigue limit. This value represents the maximum load to which at least three specimens survive without any damage when exposed to 2 million cycles. The load varied sinusoidally between the established peak value and its 10% as described in the ISO standard, and all fatigue tests were performed at a frequency of 2 Hz. At this frequency, testing shall be conducted to

2 x 10^6 cycles, while at higher frequencies 5 x 10^6 cycled must be reached, according to the ISO standard.

Results

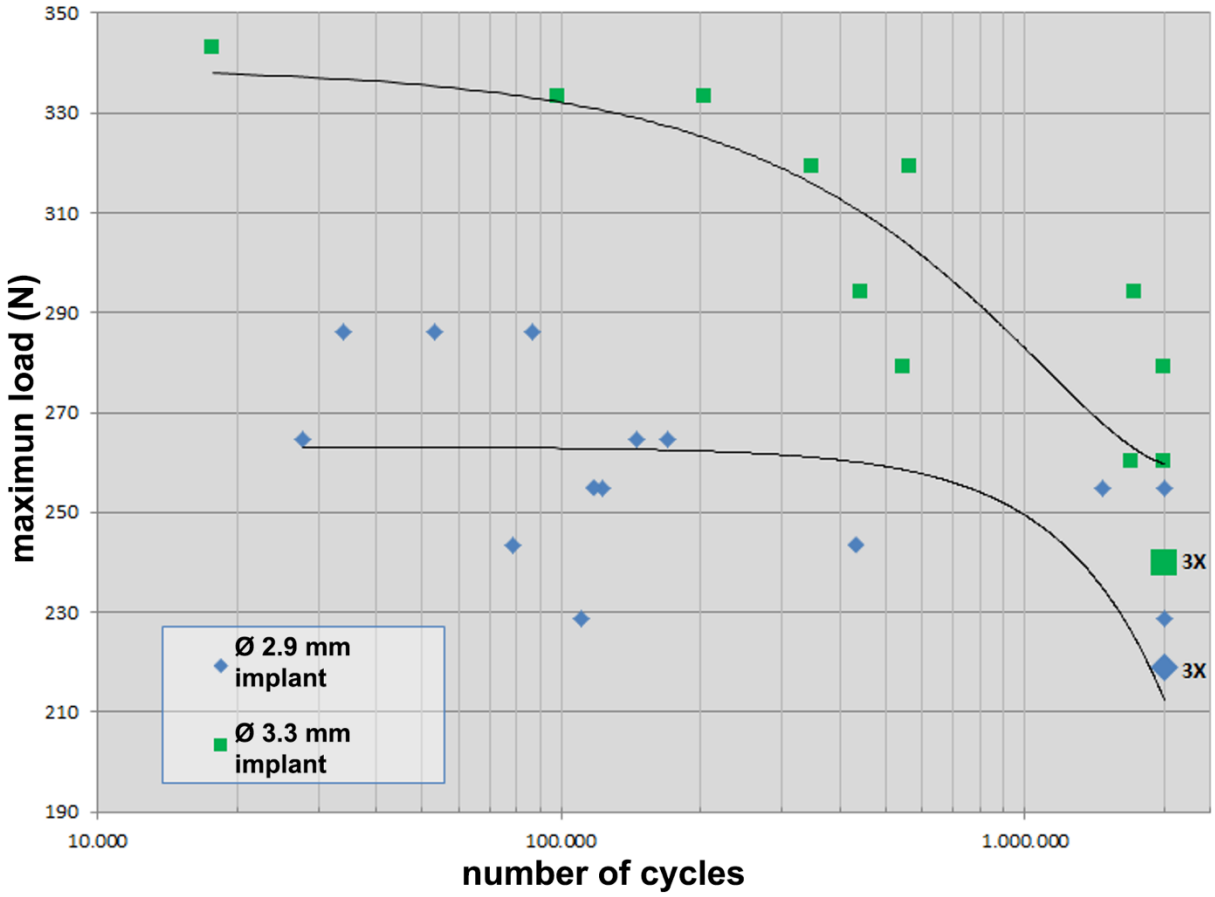
As for the finite element analysis, the greatest Von Mises stresses were registered at the coronal edge of the conical connection and were higher on the abutment than on the implant. Namely, the equivalent stress was 62,3% higher on the abutment than on the implant for the 2.9 mm implant complex, and 53,5% higher in the 3.3 mm implant complex. Maximum tensions of the whole implant-abutment complexes were registered at the emergence profile of the abutments, with an equivalent stress of 5829 MPa and 5480 MPa for the abutments fixed to the 2.9 mm and the 3.3 mm diameter implants, respectively. As for the implant themselves, the most stressed area was located at the internal surface of the implant neck at the compression side, and it registered an equivalent stress of 3416 MPa for the 2.9 mm diameter implant, and of 3119 MPa for the implant with a 3.3 mm diameter.

Figure 4. Distribution of the equivalent Von Mises stresses (MPa) in the implant-abutment complex under 30-degree off-axis loading: a) 2.9 mm diameter implant; b) 3.3 mm diameter implant; c) abutment fixed to 2.9 mm diameter implant; d) abutment fixed to 3.3 mm diameter implant.



During static tests, three specimens of the 2.9 mm diameter implant reached a maximum load of 365 N, 361 N and 354 N respectively, at which the experimental components bended. Hence, the mean maximum load was 360 N. The maximum load of the fatigue test was recorded to be 220 N. For 3.3 mm implants, the mean maximum load was 370 N, while the fatigue limit was determined to be 240 N. Figure 4 shows the Wöhler curves for the tested implants, that is the curve of the fatigue load as a function of the number of cycles. At the end of the test, that is at the reaching of 2 million cycles, three implants survived.

Figure 5. Wöhler curves for the tested 2.9 mm and 3.3 mm diameter implant. Some implants singularly resisted at higher loads during the whole procedure.


maximun load (N)
350
330
310
290
270
250
230
210
190
10.000
100.000
1.000.000
number of cycles
Ø 2.9 mm implant
Ø 3.3 mm implant
3X
3X

Discussion and conclusion

The present laboratory study was conducted with the aim of demonstrating that a Cone Morse implant-abutment connection could have beneficial effects in improving the fatigue resistance of low diameter implants. Moreover, as compared to 3.3 mm diameter implants the differences in maximum static strength values and in the results of the fatigue test, although obviously favoring larger diameter implants, could be considered clinically negligible. Such minor difference in the results of experimental tests can be explained through the structural characteristics of the components and of the connection itself. The Morse-taper connection provides a frictional connection at the implant-abutment interface, which is usually referred to as "cold weld seal". For this reason, the whole implant-abutment complex can be considered as a single unit (Merz, et al. 2000). As proven by the FE analysis, the most stressed area of the entire experimental complex is represented by the narrowing at the coronal edge of the implant abutment interface, which is similar for both experimental complexes, irrespectively of the external coronal diameter of the implant, since both implants are fixed to abutments of equal diameter. In particular, the greatest stresses and the most extended stress area of the whole system was registered coronally to the emergence profile of the abutments, which are actually the first components to fail during resistance and fatigue tests.

From the methodological point of view, the fatigue test was performed in accordance with ISO 14801 norm that described standard methods for such experiment; such test was designed to simulate the conditions of masticatory forces acting to an implant-abutment structure, and it was adopted by many dental implants manufacturers for testing their respective systems.

In general, in the population, maximum masticatory forces could vary significantly and may range from 600N to 1200N, depending on the subjects and on subjective conditions (Shinogaya, et al. 2000). It was found that forces during mastication and swallowing could reach the 40% of the maximum values, with a significant variability between anterior and posterior teeth (Gibbs, et al. 1981; Peck 2016). Moreover, as reported in a study published by van der Bilt and coworkers in 2008, unilateral clenching caused a significantly lower bite force as compared to bilateral force (430N /

429N versus 569) (van der Bilt, et al. 2008). In general, occlusal force could be influenced by a number of factors such as anatomical characteristics of the masticatory muscles, age, sex, and the craniofacial morphology (Peck 2016). Abnormal occlusal forces, as they happen in patients with bruxisms, are, indeed, among the causes of severe mechanical complications of implant-supported rehabilitations (Chochlidakis, et al. 2020), and, more specifically, a recognized risk factor for implant fracture, as it was reported in one retrospective investigation on a total of 9444 implants published in 2017 (Chrcanovic, et al. 2018).

It is known that implants with small diameter were at higher risk of fractures as compared to larger diameters, in particular when positioned in posterior regions of the jaws (Chrcanovic, et al. 2018; Tagger Green, et al. 2002). The implant that was the object of the present study has a 2.9 mm diameter and it has a specific indication, following the instructions of the manufacturer, for the treatment of single tooth edentulism in anterior areas, in presence of bone width deficiencies that could not be treated with horizontal bone augmentation (Froum, et al. 2020). The mechanical behavior of the tested implant-abutment structure could be explained by the characteristics of the connection itself. One study published by Sannino and Barlattani in 2013 performed a mechanical evaluation of the same self-locking taper connection tested in our research (Sannino and Barlattani 2013). The authors reported that the characteristics of the connection allowed a superior stability of the entire structure, in particular in cases of non-axial load, which is the most common condition for implant-supported prosthesis, presenting low stress values in the implant neck region, thus increasing the fracture resistance (Sannino and Barlattani 2013).

In relation to the methodology adopted in the study the ISO 14801 norm allowed to compare our results to the one presented in the scientific literature, obtained in the same conditions. The study by Marchetti and coworkers presented the results of fatigue test performed on 3.8 mm implants (13-mm long), showing a maximum static load before fracturing of 499 ± 50.1N (Marchetti, et al. 2014). Other authors reported the results of fatigue tests on 3.3-mm diameter implants, finding that, considering 1 million cycles with a 5% probability of failure, the predicted load was 185N (95% CI: 98 – 224N)

(Duan, et al. 2018). When compared to implants with similar diameter (namely the so-called 'narrow implants') the Morse Taper connection seems to be related to higher values of both static and fatigue load.

Another interesting point is represented that in the test performed fractures occurred always at the abutment level, near the implant neck, whilst other authors reported that, in narrow implants with screwed abutments, the fracture occurred frequently at the implant level, being much more difficult implant retrieval in the last condition (Shemtov-Yona, et al. 2014).

In order to better evaluate the validity of the results of the present study we should highlight those simulated conditions could differ from the clinical ones, although mechanical tests are widely validated as fundamental for understanding the behaviors of the implant-abutment system under various type of loads (Shemtov-Yona and Rittel 2016).

In conclusion, despite the limitations cited above, the present study found that the mechanical performances of 2.9-mm implants with self-lock morse taper connection were comparable to those of larger implants with the same features. Moreover, the fracture resistance appeared to be increased, if compared to implants with similar diameter and different connections (on the basis of manufacturers data following the same test ISO 14801), also in virtue of the characteristics of the implant-abutment connection itself. Clinical studies with long term follow-up are recommended for confirming the results of the present study.

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2.2 Sealing efficacy of Morse-taper implant-abutment connection: an *in vitro* study using real-time PCR and turbidometry

Abstract

Tissue inflammation around implants could be due to microbial colonization of the implant-abutment interface (IAI). The aim of the present in vitro study was to evaluate bacterial microleakage at the IAI in Morse-taper implant-abutment connections.

A bacterial suspension containing *A. actinomycetemcomitans*, *F. nucleatum*, and *P. gingivalis* was inoculated into the internal cavity of ten implant-abutment samples with a Morse-taper internal connection. The samples were assembled using a calibrated beater, totally immersed individually into culture tubes, and incubated at 37°C. Turbidity analysis, real-Time PCR, and horizontal electrophoresis were performed at 24, 48 and 72 h. Performed tests were negative for every specimen, except two of them because of contamination during the manipulation of the components.

Morse-taper implants rely on a frictional connection, which results in a very narrow implant-abutment space. This can account for the sealing capability of conical connections against bacterial microleakage. Although in literature no connection type was able to provide a complete bacterial seal at the IAI, Morse-taper connection implants showed less microleakage in comparison with other connection types. The present in vitro evaluation confirmed the sealing capability of Morse-taper connections in static conditions.

Introduction

Dental implants are safely and effectively used to treat single, partial and full edentulism (Attard and Zarb 2004). Many scientific papers reported satisfactory long-term outcomes in terms of survival of implant-supported prosthesis and of implants (Attard and Zarb 2004; Chrcanovic, et al. 2018; Francetti, et al. 2019). However, implant failures can occur following inflammatory processes that

lead to peri-implant mucosa tissue inflammation (peri-implant mucositis) and to progressive peri-implant bone loss associated to mucosal tissue inflammation (peri-implantitis) (Berglundh, et al. 2018). Peri-implantitis is a prevalent disease affecting approximately 20% of implants and it is recognized to have a multifactorial pathogenesis with an important role covered by microorganisms that could proliferate over dental implant and prosthesis surfaces (Derks and Tomasi 2015; Dreyer, et al. 2018; Schwarz, et al. 2018).

Microorganisms from the oral cavity may settle at the implant-abutment interface (IAI), thus leading to tissue inflammation around implants (Jansen, et al. 1997; Orsini, et al. 2000). The misfit of the IAI may result in bacterial growth, while the accurate assembly of implant components and the precise fit of the IAI at the level of the bone crest are associated with reduction in the accumulation of inflammatory cells in the peri-implant tissues (Broggini, et al. 2003). Therefore, the accurate assembly of implant components could be an important issue for the long-term survival of dental implants (May, et al. 1997). However, according to Jansen et al. often the presence of a microgap at the IAI is inevitable and the characteristics of one implant system cannot always prevent bacterial microleakage in this area (Jansen, et al. 1997). The supracrestal position of the IAI (Piattelli, et al. 2003), the adaptation torque of the screw to the implant (Gross, et al. 1999) and the system design (Dibart, et al. 2005; Koutouzis, et al. 2011; Lauritano, et al. 2020; Steinebrunner, et al. 2005) could be considered as effective strategies to minimize the clinical relevance of the microgap.

Several studies evaluated the sealing capability of different implant-abutment connections against bacterial microleakage. One review by Schmitt et al. stated that Morse-taper connections have better sealing capability than other systems, although no connection type was able to provide a complete bacterial seal at the IAI. Moreover, Morse-taper connection systems seem more resistant to abutment movement and microgap enlargement under loading (Schmitt, et al. 2014). In another recent review, Passos et al. analyzed the relationship between leakage at the IAI and abutment connection designs and concluded that microleakage seems to occur in at the IAI, irrespective of the type of connection (Passos, et al. 2013). However, the authors underlined the necessity of further studies and

reported that three in vitro studies found no bacterial leakage at the IAI (Dibart, et al. 2005; Larrucea Verdugo, et al. 2014; Scarano, et al. 2016). Such results were confirmed by another review published by Mishra and coworkers that found that Morse-taper implants showed less microleakage in comparison with other connection types including external hexagon implants, which failed to prevent microleakage in both static and dynamic loading conditions of implants (Mishra, et al. 2017). This was also found by both in vitro and in vivo studies in humans (Canullo, et al. 2015; Larrucea Verdugo, et al. 2014; Nascimento, et al. 2015).

The aim of the present in vitro study was to evaluate bacterial microleakage examining with two different methods Morse-taper implant-abutment connections.

Materials and methods

Three bacterial species were selected on the basis of their dimension and pathogenicity in the development of peri-implantitis: *Actinomyces actinomycetemcomitans* (ATCC-33384); *Fusobacterium nucleatum* subsp. *polymorphum* (ATCC-10953); *Porphyromonas gingivalis* (ATCC-33277). Each species was cultured in agar medium; then, an inoculum from single colonies was performed in a liquid medium (trypticase soy broth), in order to obtain a bacterial suspension. Culture was performed using growth conditions described: 37°C, 5% CO_2 for *A. actinomycetemcomitans*, 37°C in anaerobic conditions for *P. gingivalis* and *F. nucleatum*, within 24 h (Figure 1).

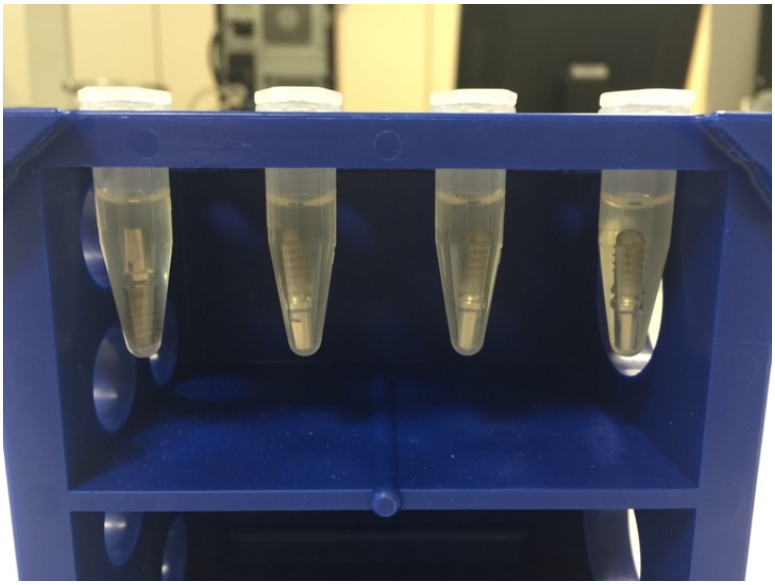
Figure 1. After the inoculum of the bacterial species in a liquid medium, culture was performed in anaerobic conditions at 37° C for 24 h.

Ten implant-abutment samples with a Morse-taper internal connection were used (Exacone® Classix implant 4.1, Leone S.p.a, Florence, Italy). Each experimental sample consisted of one implant with a diameter of 4.1 mm and 10-mm long, and an abutment with a shoulder of 1 mm, without the hexagonal index. The use of an abutment with a removable hexagonal index, which is usually fixed to the abutment by the dental technician in clinical practice, allowed to increase the volume of the internal cavity of the implant-abutment system, without altering structure of the connection, which is guaranteed by the conical portion of the abutment. The volume of the internal cavity such obtained was calculated to be 10.36 mm^3. The ideal volume of the inoculum inside the internal parts of the implant was calculated to be 3 μL. Such amount of bacterial suspension containing a mixture of the three species (1 μL for each species) was inoculated into the internal cavity of the experimental samples, except one of the specimens, which served as negative control. The implant and the abutments were then assembled using a steel support and a calibrated abutment beater (Leone S.p.a., Florence, Italy), in order to apply a standardized force (15 N applied twice), and to avoid the use of excessive force with the forceps close to the implant platform. This could actually distort the implant structure, thus increasing the gap at the IAI, favoring bacterial migration. In one of the specimens

(sample n. 7), the bacterial suspension was inoculated into the implant internal cavity, and the activation of the conical connection using the beater caused the exit of the inoculum from the cavity. For this reason, the remaining samples were treated inoculating the bacterial suspension into the cavity of the abutment, which originated from the absence of the hexagonal index.

Eight samples were placed individually into culture tubes with a volume of 1.5 ml, containing an amount of liquid culture medium (trypticase soy broth) that could completely submerge the sample (1ml). Total immersion of the samples was performed. Actually, the absence of the implant abutment screw and consequently of the screw access, avoided any possible outflow of the bacterial suspension (Figure 2).

Figure 2. The assembled samples were placed into sterile tubes and completely immersed in the bacterial suspension.



One specimen was placed into a growth medium together with the bacterial suspension and served as positive control. The samples were then incubated at 37°C for 24, 48, and 72 hours in an anaerobic atmosphere. All procedures were carried out in sterile conditions.

The occurrence of bacterial outflow via the implant-abutment interface into the surrounding solution was determined through three distinct methods: 1) turbidity analysis of nutritional broth; 2) Real-Time PCR; 3) horizontal electrophoresis on agarose gel. The presence of turbidity was visually assessed at 24 h, 48 h and 72 h. The turbidity test alone is not adequate for microbial leakage assessment. Actually, a positive turbidity test could derive from microbial contamination that is independent of the permeability of the implant-abutment connection; and low entity microbial leakage could not leave to a visible turbidimetric reaction. For this reason, 100 µL from each experimental sample were obtained and analyzed by means of RT-PCR and horizontal electrophoresis at 24 h, 48 h and 72 h.

Results

The negative control did not show bacterial proliferation in turbidity test, RT-PCR and horizontal electrophoresis. The positive control resulted positive to turbidity test; in this case bacterial growth was confirmed by both RT-PCR and horizontal electrophoresis, detecting an amount of bacterial growth of $5.84x10^4$ copies/µL at 24 h, $9.84x10^4$ copies/µL at 48 h, and $2.36x10^5$ copies/µL at 72 h.

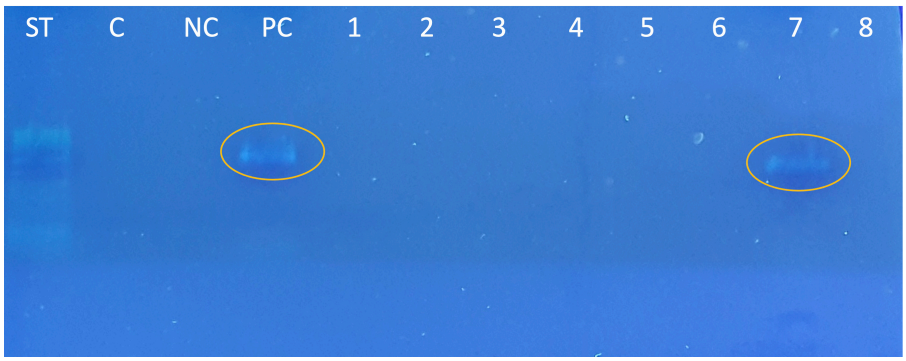
The presence of turbidity was registered at 24h, 48h and 72h in two of the test specimens. RT-PCR and horizontal electrophoresis for the considered bacterial species resulted negative for one of these samples, which was contaminated during the manipulation of the experimental components. As for the other positive sample, RT-PCR confirmed bacterial growth, with a bacterial count of $3.61x10^3$ copies/µL at 24 h, $5.42x10^3$ copies/µL at 48 h, and $6.88x10^3$ copies/µL at 72 h; results were confirmed by horizontal electrophoresis, which was positive at 24 h, 48 h, and 72 h. These results were due to the contamination of the sample surface during the freehand inoculation of the bacterial suspension. All the other specimens resulted negative to turbidity test, RT-PCR and horizontal electrophoresis. Results for all specimens are reported in Table 1, while figure 3 represents the results of horizontal electrophoresis.

Table 1. Results of turbidity test, RT-PCR, and horizontal electrophoresis at 24 h, 48 h and 72 h.

Sample	Turbidity test (24 h; 48 h; 72 h)	RT-PCR (copies/µL) (24 h; 48 h; 72 h)	Horizontal electrophoresis (24 h; 48 h; 72 h)
NC	N; N; N	0; 0; 0	N; N; N
PC	P; P; P	5.84×10^4; 9.84×10^4; 2.36×10^5	P; P; P
1	N; N; N	0; 0; 0	N; N; N
2	N; N; N	0; 0; 0	N; N; N
3	P; P; P	0; 0; 0	N; N; N
4	N; N; N	0; 0; 0	N; N; N
5	N; N; N	0; 0; 0	N; N; N
6	N; N; N	0; 0; 0	N; N; N
7	P; P; P	3.61×10^3; 5.42×10^3; 6.88×10^3	P; P; P
8	N; N; N	0; 0; 0	N; N; N

N: negative; NC: negative control; P: positive; PC: positive control.

Figure 3. Results of horizontal electrophoresis. ST: standard molecular-weight size marker; C: non-template control; NC: negative control implant; PC: positive control implant; numbers from 1 to 8 represents the test specimens.



Discussion and conclusion

The study found that Morse-taper internal connection implies a seal at the level of the IAI, thus limiting the possibility for bacteria to migrate from the oral cavity into the implant cavity. Bacterial proliferation in two of the test specimens was due to contamination of the samples; all the other samples demonstrated the sealing capability of Morse-taper connection against bacterial microleakage. The validity of the results obtained was limited by study design (*in vitro* setting) and by the number of examined samples. However, the size of the examined sample was similar to the one of other published studies on a similar topic (Cavusoglu, et al. 2014; D'Ercole, et al. 2014; Ranieri, et al. 2015; Sahin and Ayyildiz 2014; Tripodi, et al. 2012; Wachtel, et al. 2016). The freehand inoculation of the bacterial suspension into the internal cavity of the samples represent another limitation in the study design, as stated in a review by da Silva-Neto (da Silva-Neto, et al. 2012), since the possible contact with the border of the implant opening can generate false-positive results. Actually, in our study the contamination of one specimen occurred because of the assembly technique: while the direct visualization of the bacterial suspension outflow was possible in this case, the influence of the assembly technique on the occurrence of false-positive results must be taken into consideration for further studies, since procedural errors in this phase may be unnoticed. Also, the

short follow-up period could be considered a limitation of the study; however, the previously mentioned review found that bacterial leakage occurred within the first 3 days in similar microbiological studies (da Silva-Neto, et al. 2012). After this period of time, the limited oxygenation and amount of nutrients lead to a considerable reduction of bacterial motility, reproduction and survival. Since the death of microorganisms within the implant may lead to false-negative results, the authors suggest that the follow-up period should not exceed 7 days. Finally, a limitation of the study is that the connection has been tested in static conditions only. Although similar protocols have been extensively used in literature (Barbosa, et al. 2009; Dibart, et al. 2005; do Nascimento, et al. 2008; do Nascimento, et al. 2009a; do Nascimento, et al. 2009b), an analysis under dynamic loading could provide further information about the microbiological seal of Morse-taper connections in a clinical setting.

Many techniques were adopted to detect bacterial infiltration at the level of IAI in *in vitro* settings. The methods used in the present study were validated by existing literature. Turbidity, which is the amount of cloudiness in the water, was widely used to evaluate the ability of bacteria to surpass the barrier made of implant-abutment connection in the water medium. Such method was used to evaluate microleakage at the level of IAI in other published studies (Khorshidi, et al. 2016; Resende, et al. 2015; Tripodi, et al. 2012). Real-time PCR is one common technique to quantify the presence of bacterial DNA, and it was used in the present study to evaluate bacteria that overpassed the IAI. Such method was used in other papers with the same aim and it appeared more specific than turbidometry (Canullo, et al. 2015; Harder, et al. 2012).

Several studies investigated microleakage at the level of IAI in Morse-taper implants, showing either that microleakage at the IAI is minimal (Assenza, et al. 2012; Canullo, et al. 2015; D'Ercole, et al. 2014; Larrucea Verdugo, et al. 2014; Tripodi, et al. 2015; Tripodi, et al. 2012), or that it does not occur at all (Dibart, et al. 2005; Khorshidi, et al. 2016). Dibart and coworkers demonstrated sealing and absence of bacteria at the IAI both through the scanning electronic microscopy test and through the assessment of bacterial growth in agar nutrient (Dibart, et al. 2005). According to the

authors, the sealing capability of Morse-taper implants was due to the frictional connection, which results in a very narrow implant-abutment space (<0.5 μm) (Dibart, et al. 2005). Various studies actually found a smaller microgap in Morse-taper connection implants, when compared with other implant system designs (Larrucea Verdugo, et al. 2014; Scarano, et al. 2016). Scarano et al. evaluated the implant-abutment microgap through 3D X-ray microtomography, finding only few detectable gaps in Morse-taper connection implants at a resolution of 9.7 μm (mean 0.3 ± 0.1 μm), while numerous gaps were detected at the same resolution (mean 6.3 ± 2.5 μm) in internal-hexagon connection implants (Scarano, et al. 2016). Similarly, Verdugo et al. found a smaller microgap in Morse-taper implants (2-3 μm) when compared with external connection implants (10 μm) (Larrucea Verdugo, et al. 2014). Apart from the geometry of the implant-abutment connection, the size of the gap at the IAI and the consequent microleakage are influenced by the tightening torque. Many studies found that higher tightening torque in Morse-taper connections were related to lower microleakage that any other type of material and of geometry of implant-abutment connection (Baggi, et al. 2013; Larrucea Verdugo, et al. 2014; Nayak, et al. 2014; Smith and Turkyilmaz 2014).

The presence of a gap at the IAI has been suggested as a possible etiology for bone loss around implants (Oh, et al. 2002; Quirynen, et al. 2002), but the influence of the apical-coronal position of the IAI on the bone crest resorption remains controversial (Passos, et al. 2013). While some studies affirmed that the location of the IAI on or below the level of the bone crest could be associated with increased bone resorption (Hanggi, et al. 2005; Hermann, et al. 2000; King, et al. 2002), other studies found no evidence of this correlation (Heydenrijk, et al. 2003; Todescan, et al. 2002). Morse-taper implants seem to produce a lower marginal bone loss (Schmitt, et al. 2014), although it is unclear to what extent microbiological or mechanical factors are involved. Furthermore, in the previously mentioned review, Passos and colleagues concluded that there are no evidences of the relationship between the microbial leakage at the IAI and loss of osseointegration (Passos, et al. 2013).

Within the discussed limitations, the present study demonstrated that Morse-taper connection provides microbiological seal against the considered bacterial species in static conditions. Such

sealing capability of Morse-taper connection may be beneficial to the health of the peri-implant tissues. However, further evaluations are needed, for example in dynamic conditions, and with the use of bacterial toxins or stains, which have a similar molecular size.

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Chapter 3

CLINICAL STUDY WITH IMPLANTS WITH MORSE-TAPER IMPLANT-ABUTMENT CONNECTION

3.1 Clinical evaluation of Morse-taper connection implants: an observational prospective single-cohort study

Introduction

Dental implants are a well-established treatment option for the restoration of missing teeth, and it is considered as an effective viable alternative to teeth-supported fixed partial dentures, mainly due to the benefit of avoiding loss of intact tooth substance in adjacent teeth.

Despite the high success rates of dental implant rehabilitations, treatment failures have been described in literature, both related to technical / mechanical and microbiological factors (Quirynen, et al. 2002). According to the metanalysis published by Pjetursson et al. (Pjetursson, et al. 2012), the most common technical complication in implant-supported fixed dental prostheses after 5 years was the fracture of the veneer material, which was reported to occur in 13.5% of cases for all veneer material (acrylic, ceramic or composite) but it reduced to 7.8% when considering only ceramic. The loss of the screw access hole restoration represents the second most common technical complication over a 5-year follow-up period (5.4%), while the third most common one was the abutment or occlusal screw loosening. This complication was reported in 12 studies with 2800 abutments, resulting in a

cumulative complication rate of 5.3%. Instead, the fracture of abutments and occlusal screws (1.3%), implant fractures (0.5%) and framework fractures (0.5%) were relatively rare complications.

The type and the characteristics of the implant-abutment connection represent an important feature of the implant systems and may play an important role in the implant success from a mechanical and biological point of view. The Morse taper implant-abutment connection has various advantages, which rely for example on the large contact pressure and frictional resistance at the implant-abutment surface. This feature may be fundamental not only for mechanical resistance and stability of the connection, not depending on connection screws, but also for microbiological sealing.

Several studies showed that conical connections provide a significantly higher resistance to bending forces(Chee, et al. 1999; Norton 1999). One review published by Schmitt et al. concluded that Morse-taper connection systems have high resistance to fatigue loading, higher torque-loss resistance than other systems, and lower abutment screw stresses than external hexagonal connection systems but comparable to internal hexagonal systems (Schmitt, et al. 2014). Other studies found that the Morse-taper connection tends to dissipate less stress to the abutment screw when compared with external (Balik, et al. 2012) and internal hexagon (Coppede, et al. 2009), improving fracture resistance.

The high mechanical stability of Morse taper connection could reduce the incidence of prosthetic complications, such as abutment loosening. A lower percentage of implant-abutment loosening was reported when single-tooth Morse taper connection implants were used, compared with external hexagon and butt joint connections (Weigl 2004). Weigl reported an incidence rate of only 1.3% (Weigl 2004); Levine et al. (Levine, et al. 1997) in 1997 reported an incidence of abutment loosening of 3.6% to 5.3% for single-tooth replacements through implants with conical connections. Other studies confirm the relatively low incidence of abutment loosening in Morse-taper connection implants (Doring, et al. 2004; Morgan and Chapman 1999; Muftu and Chapman 1998).

Together with mechanical factors, microbiological factors play an essential role in the long-term implant survival, such as poor oral hygiene, pre-existent periodontal disease and space at the implant-abutment interface (IAI) in two-piece implant systems.

Because of the design of the connection itself, and particularly because of the absence of the connection screw, the coronal portion of the implant is wider when compared to implant with other connection designs. This feature may be particularly useful in some clinical situations, for example when narrow-diameter implants (NDIs) are needed. Missing teeth in certain areas such as the upper lateral incisive region and the anterior lower jaw region may be more difficult to replace. This edentulous area often present narrow mesio-distal space and insufficient bone volume for the placement of regular diameter implants. Actually, the narrow horizontal space may lead to damage of adjacent teeth or loss of interproximal bone, while exposure of implant threads may occur in case of insufficient bucco-lingual space. To achieve long-term success, implant's positioning requires at least 1 mm of residual bone adjacent to the implant platform, and 6 mm width horizontal alveolar crestal space in order to avoid biological complications. Also, 3 mm inter-implant distance and 1.5 to 2 mm between tooth and implant seems to be adequate for papillary fill. For this reason, NDIs are particularly indicated for the above-mentioned areas and demonstrated to exhibit high long-term survival rates comparable to regular diameter implants.

One of the main issues about narrow diameter implants is the higher risk of implant fracture, as showed by Allum et al. in a laboratory study (Allum, et al. 2008). However, Zinsli et al reported only 2 implant fractures among 298 3.3 mm-diameter implants over a period of 6 years. This study also raised a significant concern regarding the importance of appropriate prosthetic restorations for implant survival (Zinsli, et al. 2004). The high mechanical stability of Morse taper connection could reduce the incidence of prosthetic complications.

Primary objective

The main objective of the study was be to evaluate the survival rate and the clinical and radiographic success of Morse taper connection implants, used for single-tooth and partial rehabilitations, after a maximum of two years of functional loading.

Secondary objectives

- to assess the prevalence and incidence of biological complications, such as peri-implant mucositis and peri-implantitis
- to assess the prevalence and incidence of technical complications of the implant or of the prosthesis
- to assess the correlation between the occurrence of any complication and parameters related to the subject and to the prosthesis.

Materials and methods

The present study has been approved by the Institutional Review Board of the IRCCS Istituto Ortopedico Galeazzi in Milan, Italy.

The population included all patients eligible for treatment of single-tooth loss or of partial edentulism of both arches through dental implants in the Dental Clinic of the IRCCS Istituto Ortopedico Galeazzi in Milan, Italy, and in a private practice (Lecco), during the period from June 2019 to September 2020.

Selection criteria

The following inclusion criteria were be adopted:

- subjects requiring single-tooth or partial replacement in the anterior and posterior areas of both arches
- subjects classified as ASA-0 or ASA-1 following the classification proposed by the American Society of Anesthesiologists
- subjects smoking less than 10 cigarettes a day
- subjects with sufficient bone height and width to place an implant of at least 3.3 mm in diameter and 8.0 mm in length.

The following exclusion criteria were be adopted:

- Active periodontal infections
- Uncontrolled systemic disease (e.g., diabetes)
- Poor oral hygiene (Full-mouth plaque score % > 20%)
- Subjects smoking more than 10 cigarettes per day

Definitions

An implant was considered as a *failure* if it presented signs and symptoms that require the extraction. An implant was considered *lost* if, due to loss of osseointegration, it was spontaneously expelled or removed due to unfavorable prognosis.

Among the survived implants, *success* criteria included (Albrektsson, et al. 1986):

- absence of suppuration and clinically detectable implant mobility
- PD (probing depth) < 5.0 mm
- absence of recurrent prosthetic complications at the implant-abutment interface.
- absence of continuous peri-implant radiolucency
- DIB (radiographic distance between the implant shoulder and the first crestal bone-implant contact) < 1.5 mm after 12 months of functional loading and not exceeding 0.2 mm for each following year

A case of *peri-implantitis* was defined with the presence of radiographic bone loss (evaluated through the comparison between baseline and follow-up periapical radiographs) associated to the presence of signs and symptoms of inflammation (swelling, redness, bleeding, and eventually suppuration). If signs and symptoms of inflammation were present without radiographic bone loss the case was classified as *peri-implant mucositis*.

Primary outcome

The primary outcome was be the implant cumulative survival rate %.

Secondary outcomes

The secondary outcomes were:

- cumulative success rate %
- prevalence and incidence of the occurrence of biological complications: presence of suppuration, peri-implant mucositis, peri-implantitis.
- prosthesis survival rate %
- prevalence and incidence of the occurrence of technical / prosthetic complications (implant-abutment loosening, abutment fracture, ceramic-crown fracture)

Data collection

The following data were collected:

- implant-related factors: implant type, length, and diameter
- patient-related factors: age, gender, smoking status, systemic diseases, medications, history of periodontal disease, bruxism
- cause of the initial tooth loss: aplasia, unerupted tooth, traumatic injuries, caries, periapical periodontitis, marginal periodontitis
- site-related factors: implant position, bone quantity / quality following the Lekholm and Zarb classification (Lekholm and Zarb 1985)
- prosthesis-related factors: prosthetic restoration extension (single crown, partial fixed denture), prosthetic restoration material (all-ceramic, metal-ceramic, resin).

To evaluate the clinical and radiographic success of the implants used, the following parameters were recorded during follow-up visits, 3, 6, 18, 12 and 24 months after surgery:

- Full-mouth plaque score % (FMPS%)
- Full-mouth bleeding score % (FMBS%)
- probing depth (PD) on the mesial, distal, buccal and palatal/lingual surfaces of the implants. The higher PD and the mean PD, measured as the average of four measured values, was considered for each implant.

- Bleeding scores, assessed on the basis of this scale: 0) no bleeding; 1) bleeding on probing without redness and swallowing; 2) bleeding on probing with redness and swallowing; 3) spontaneous bleeding.
- Plaque scores, assessed on the basis of this scale: 0) no plaque accumulation; 1) plaque accumulation revealed using a probe; 2) moderate accumulation of visible plaque/calculus; 3) high accumulation of visible plaque/calculus.
- distance from the implant crown margin to the coronal border of the peri-implant mucosa (DIM)
- width of keratinized mucosa (KM)
- radiographic distance between the implant shoulder and the first crestal bone-implant contact (DIB), measured on intraoral peri-apical radiographs taken a Rinn alignment system
- radiographic presence of continuous peri-implant radiolucency, measured on intraoral peri-apical radiographs taken a Rinn alignment system
- Prosthesis function
- Technical complications: implant fracture; abutment fracture; screw fracture; veneer fracture or chipping; metal framework fracture; abutment loosening; screw loosening; loss of access hole restoration.

Statistical analysis

Descriptive statistics was provided by means of mean values and standard deviations.

The Shapiro-Wilk tests served to evaluate the normality of the distribution of the variables considered. The differences between groups were evaluated using Student's t-test or Mann-Whitney test for continuous variables, depending on the normality. Survival analysis were performed through life-table analysis and Kaplan-Meyer method.

Correlation between baseline parameters and outcomes were provided through the use of logistic regression and Cox Regression models for survival function.

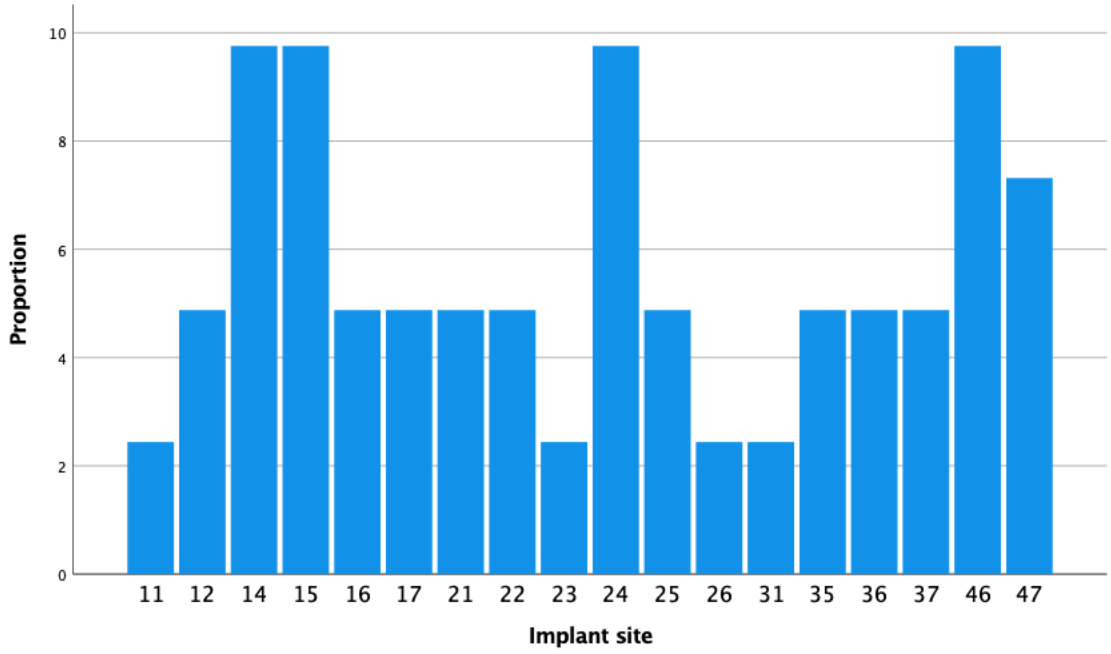
The level of significance was $P<0.05$.

Results

A total of 13 patients were treated with 41 implants (Leone, Firenze). The mean age was 56.6 ±15.0 years (range 38 - 81) at the time of surgery, six were males and seven females. One patient was a smoker, two had diabetes, and three of them were affected by periodontitis (previously treated), at the time of surgery.

The location of dental implants placed is represented in Figure 3a.

Figure 3a. Implant distribution



The insertion torque was 50 Ncm in 50% of cases, 30 - 35 Ncm in 43% of cases and 20 Ncm in 7% of cases. A total of 29 “Classix” implants, seven “2.9 Narrow” implants, two “Max stability”, and

three “6.5 Short” implants were placed. Table 1 showed the distribution of the different implant lengths and diameters in the sample.

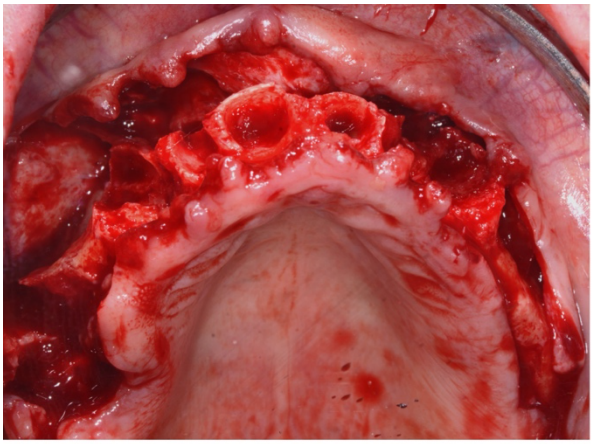
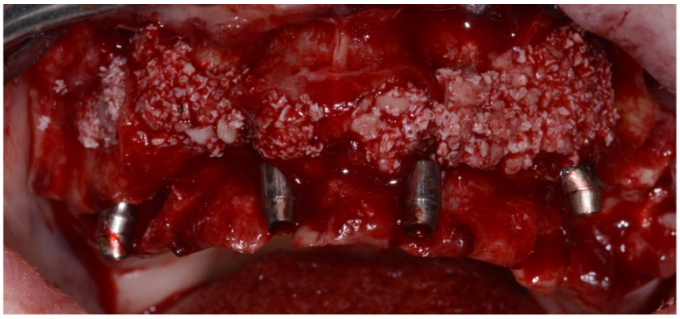
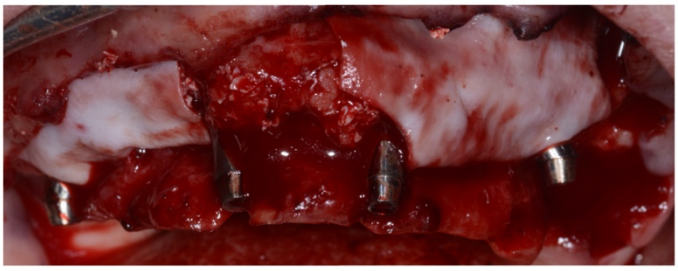
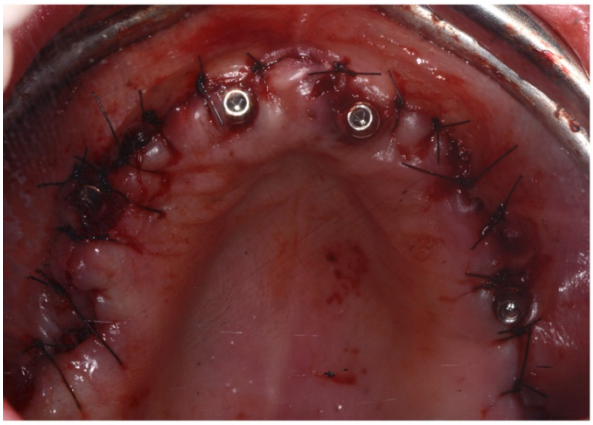
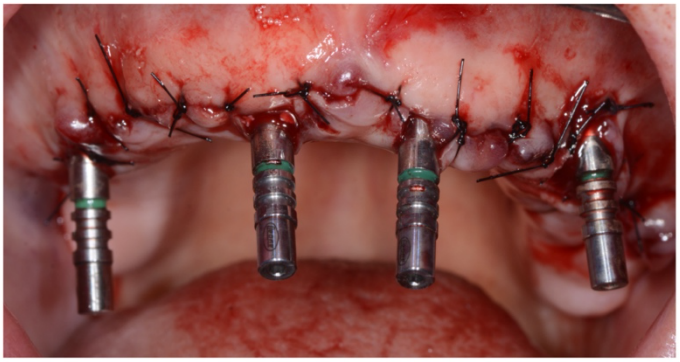
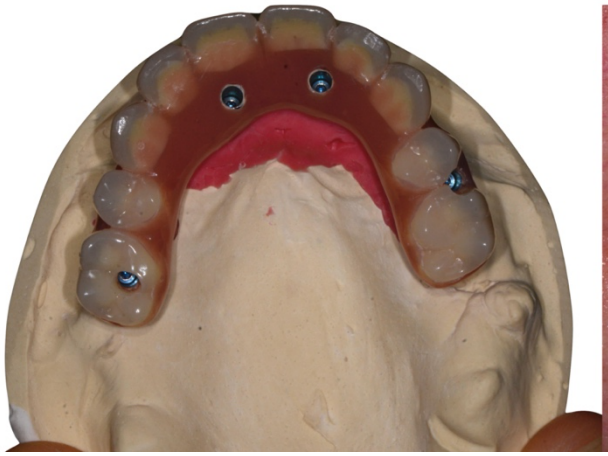
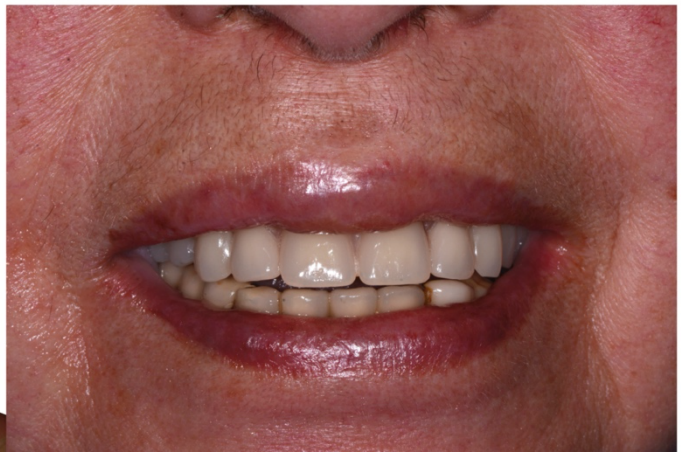
Table 1. Implant characteristics

Diameter (mm)	**N°**	**%**	**Length (mm)**	**N°**	**%**
2.90	7	17.1	***6.5***	4	9.8
3.10	5	12.2	***8.0***	2	4.9
3.30	5	12.2	***10.0***	18	43.9
3,75	6	14.6	***12.0***	11	26.8
4.10	13	31.7	***14.0***	6	14.6
4.30	1	2.4			
4.60	1	2.4			
5.00	3	7.3			

Guided bone regeneration was performed in three cases, by means of the placement of bone substitute and resorbable collagen membrane (Figure 3a).

The mean loading time was 6.3 ± 3.2 months ranging from 0 (in patient who received a full-arch immediately loaded rehabilitation following the All-on-4 protocol) to 12 months (in one patient who suffered severe systemic disease and couldn't proceed with the rehabilitation in the planned period). One patient, as stated before, received a full-arch screw-retained rehabilitation. With regard to prosthesis type, the 71% of the implants supported a fixed partial denture (cement-retained), while 19.2% were cement-retained single crowns.

Figure 3b. The surgical procedure in one case of immediate implant placement for full-arch rehabilitation, where regeneration was performed through bone substitute and collagen membranes.

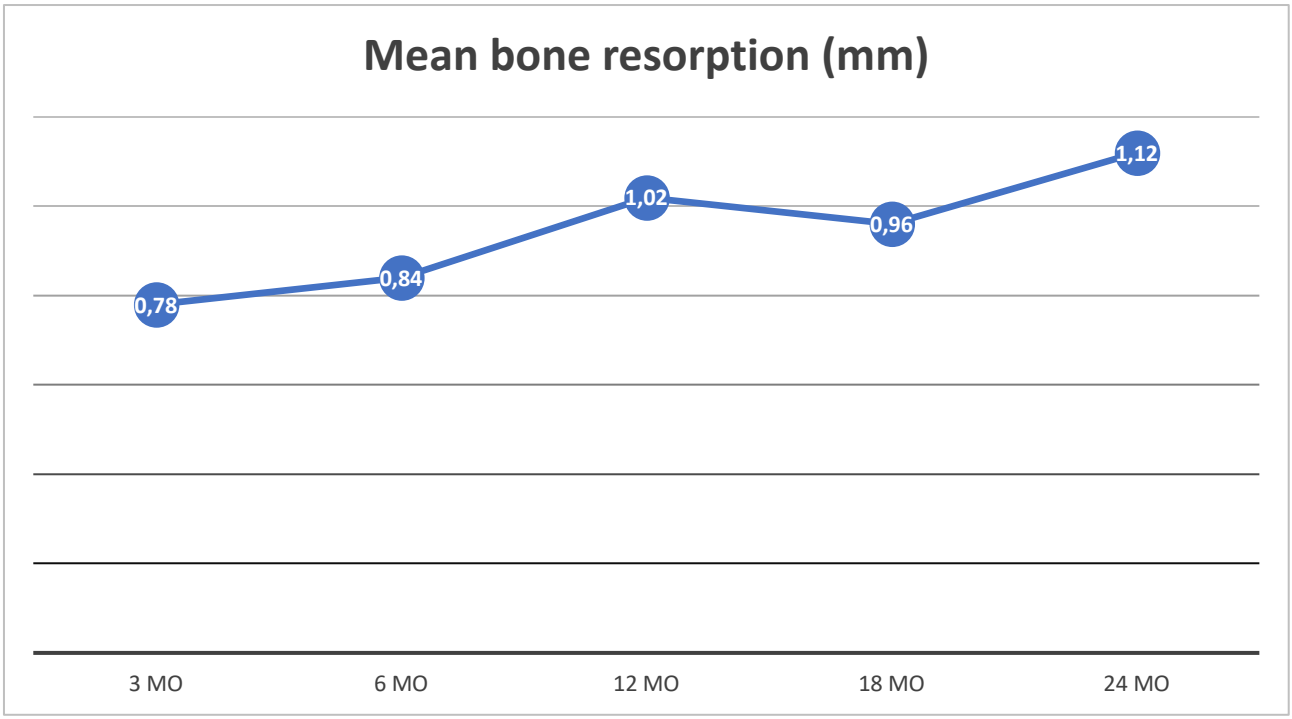
The mean follow-up was 18 months, ranging from 9 to 24 months. At the time of the last evaluation no implants failed, and all were successful. None of the implants presented signs and symptom of peri-implantitis while eight implants in three patients showed signs of peri-implant mucositis. In these cases, the subjects were treated with standard protocol, by performing professional oral hygiene and

air-polishing and placement of chlorhexidine 1% gel for one week, until disappearance of the clinical signs of inflammation.

The trend of bone resorption over time is presented in Figure 3c, without any evidence of statistically significant difference between different time frames and between one timepoint and baseline.

The regression analysis didn't reveal any significant effect of sex, age, and presence of systemic disease over the bone resorption trend. No difference could be found between implants placed in maxilla and in mandible. A small but significant negative effect was found for periodontitis in determining an increase in bone resorption (P = 0.047) but the low number of cases limited the validity of such outcome.

Figure 3c. Bone resorption trend over time



Discussion and conclusion

The present study had the aim of exploring and understanding the behavior and the characteristics of one implant system by examining the results of a clinical examination.

The outcomes obtained, although preliminary and needing further confirmation by longer follow-up studies, allowed to hypothesize that the tested implant system could provide optimal results, in terms of failure / success rate and with regard to bone resorption rate over time. Moreover, as expected, the stability of the implant-abutment connection resulted in no occurrence of technical complications over time.

To understand the relevance of the study, we should examine the results in the light of existing literature. One recent systematic review of the literature aimed at reviewing the published studies investigating the effects of prosthetic characteristics on mechanical behavior of dental implants (Maminskas, et al. 2016). A total of 20 studies were included, performing FEA analysis for the evaluation of different characteristics of the prosthesis, finding that connection-abutment design could influence importantly the stress concentration. There was a consensus in describing a positive effect of platform-switching configuration over the non-platform-switching connections for what regards the stress transmitted to bone (Bouazza-Juanes, et al. 2015). Moreover, the author found that the presence of a misfit, between the implant and the abutment connection, was correlated to an increase in the stress transmitted to implant body and to surrounding tissues, being potentially one of the main causes of technical failure and implant body fracture (Aguirrebeitia, et al. 2013). From the technical aspect, the use of cone morse connection was confirmed and further supported by the laboratory studies, described in detail above.

Considering the clinical outcomes, the results of the research were coherent with those published in literature, with similar follow-up. Two recently published retrospective studies, on different implant-prosthesis configuration, confirmed that the survival rate of dental implants during the

first three years after loading is extremely high and implant failure is a relatively rare occurrence (Corbella, et al. 2021; Francetti, et al. 2019).

The literature showed the results of clinical studies conducted on implants with cone-morse connection. The study by Degidi and coworkers (Degidi, et al. 2016) performed on 65 partially edentulous patients who received 130 implants with cone morse connection, presented the clinical results after 3 years of loading. In two cases, the patients experienced the fracture of the prosthetic failure, that was repaired, no implants failed, and the bone resorption was less than 0.2 mm over the observation period. The same research group published another report in 2017, with similar aims, found a bone resorption after 4 years of 0.42 +- 0.77 mm as compared to baseline values (Degidi, et al. 2017).

Another study by Cassetta et al, published in 2016, prospectively followed for 5 years a cohort of 748 implants placed in 350 patients (Cassetta, et al. 2016).All implants supported cemented crowns and the reported failure rate over the observation period was 8%, while resorption rate was considered substantially stable over time, which appears to be a characteristic of this particular type of connection.

The study by Mangano and colleagues, performed on the same implant system that was the object of the present study, a long-term follow-up study on 1494 implants with morse-taper implant-abutment connection (Mangano, et al. 2015). The cumulative survival rate % of maxillary restorations was 98.3% and for mandibular restoration was 99.1% over a follow-up period of up to 10 years. Interestingly, just three prostheses were removed due to late implant failures and the incidence of biologic complication was 1.4%. Peri-implantitis were relatively rare, occurring in 10 implants. The mean bone resorption was 0.33 ± 0.23 mm after one year, 0.45 ± 0.26 mm after 5 years, and 0.78 +- 0.33 mm after 10 years and the results were substantially similar to those obtained in our study.

The possibility of reducing, on the basis of the clinical experience and of the results of the laboratory studies, the occurrence of the technical and biological complications should be considered of paramount importance for implant treatment. Following this concept, the outcomes revealed that implants presenting this type of implant-abutment connection demonstrated to be a viable treatment option having several advantages over other type of systems. The main advantages were mainly referrable to the higher mechanical stability of the implant-abutment structure and to the absence of microgap at the interface, which reduces significantly the possibility of bacterial proliferation (Scarano, et al. 2015; Tripodi, et al. 2015).

The validity of the results should be considered in the light of the limitations (and strengths) of the study. The major limit is represented by the relatively small sample size and by the non-comparative nature of the study. However, the sample was similar to the one tested in other similar investigations and, although small, it has a significant heterogeneity, since all the patients were treated by the same experienced operator, with similar surgical and prosthetic protocol. These characteristics could increase the validity of the results. Another limitation is represented by the small follow-up which does not allow to make any speculation on medium- and long-term behavior of the implant system we tested.

On the basis of what was said we can conclude:

- the tested implant system allowed to obtain a short-term implant survival rate of 100%, without any implant failure
- none of the implant-prostheses structure experienced a minor or major technical failure
- the occurrence of biological complication is coherent with scientific literature, being 0% the proportion of implants with peri-implantitis and the cases of peri-implant mucositis was extremely low (three patients)
- the bone resorption rate over time was substantially negligible

More studies, with longer follow-up and larger sample size are needed in order to provide more evidence supporting the use of this type of implant system.

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