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Doctoral Thesis

"Healing and remodeling of connective tissue graft around implants with poor keratinized mucosa.

Influence of provisionalization timing (delayed vs immediate) using BOPT abutments.

A clinical observational controlled pilot study"

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INTRODUCTION

The role of keratinized mucosa (KM) around dental implants

There is a lack of strong evidence with regard to risks/benefits of absence/presence of KM at dental implants. However, data suggest that in clinical situations, where proper plaque control is not well performed, the presence of KM around implants may be of importance [1].

The presence of KM mucosa is essential for the maintenance and the predictability of the esthetic result of prosthesis on natural teeth and implants. To date, there is a lack of concordance on the relation between KM mucosa and success of implant therapy. Nevertheless, the presence of KM mucosa plays a key role in prosthetic finalization especially in cases of rehabilitation with implants[2, 3].

The presence of KM mucosa around dental implants is actually determined by the bucco-lingual extension, which is mainly regulated by the following factors[4]:

- the genetic position of the mucogingival line;
- the grade of alveolar process resorption dictated by tooth loss.

The masticatory mucosa is composed of dense connective tissue, rich in collagen and covered with keratinized epithelium. Interestingly, free elastic fibers of the connective layer are absent, that is why the lamina propria is tightly attached to the underlying periosteum.

On the other hand, the lining mucosa encloses a structure that allows for adaptation to tension caused by muscular bundles. In fact, the lamina propria of the alveolar mucosa is poor in collagen, rich in elastic fibers and is covered by non-keratinized epithelium. Notably, submucosa is tightly adherent to the underlying periosteum.

In a study conducted by Wennström and colleagues in which a total of 171 implants were placed in 39 partially or fully-edentulous patients, presence of plaque, bleeding on probing and sulcus depth were investigated in relation to the width of KM around dental implants. Findings revealed that 24% of implants totally lacked KM, and further 13% presented an inadequate amount. Furthermore, there were no major differences in terms of plaque control and bleeding on probing between sites that displayed either “adequate” or “inadequate” width of masticatory mucosa[5].

On the contrary, Roos-Jansa°ker and co-workers in 2006 followed-up 294 patients for 9-14 years, demonstrating a statistically significant result in which the absence of KM was associated with mucositis, defined by a periodontal pocket depth (PPD) of ≥ 4mm with bleeding on probing[6]. In fact, it was documented in a cross-sectional study in 2008 that narrow keratinized zone around dental implants (< 2 mm) resulted in a significantly higher bone loss and bleeding, independent of other factors (plaque control, smoking and thickness of the gingiva)[7]. Other studies emphasized the importance of the presence of KM, since its absence negatively affects patients ability to maintain an effective oral hygiene control, resulting in plaque accumulation, gingival inflammation and gingival recession[8, 9]. In this context, a review was published by Wennström & Derks in 2012[1] in which 19 papers were selected, evaluating the presence and amount of KM in relation to the oral hygiene maintenance, peri-implant soft tissue

health, gingival recession, peri-implant bone resorption and implant loss. Results of this review revealed the presence of poor scientific evidences, which allows for unequivocal conclusions for the tested parameters. Nevertheless, the role of masticatory mucosa is fundamental in patients with poor domiciliary oral hygiene maintenance, suggesting that surgical procedures should be performed to augment it.

Recently, Poli et al. in a observational retrospective cohort study on 421 implants have found that in cases when the patient was not compliant with a professional oral hygiene schedule, there was an increased incidence of peri-implantitis in patients who did not present KM compared with patients presenting with at least 1 mm of KT (OR=3.99; P=0.03)[10].

Beyond functional reasons, the aesthetic necessities on implant rehabilitations often require thickening of soft tissues in order to correct volumetric bone defects to achieve a proper ridge contour. As described in recent studies by Cosyn and colleagues[11-13], alveolar process deficiency may be considered the most frequent aesthetic complication occurring in up to 20% of cases, irrespective of the treatment modality. Moreover, a defect in ridge contour over an implant-supported prosthesis could represent a site for food impaction and a consequent patient discomfort.

Abutment morphology and its influence on peri-implant soft tissues.

Cemented implant restorations are widely used by many clinicians. The traditional abutment design resembles a natural tooth prepared for a crown with a similar taper and a chamfer finishing line. A frequent complication associated with implant restorations in the esthetic zones is the recession of buccal gingiva over time. Abutment morphology, among several other prosthetic factors, may play an important role in the stability of the gingival margin in esthetically sensitive areas, but this has never been thoroughly analyzed.

The abutment morphology traditionally mimics a prepared natural abutment. The intrasulcular part of the abutment emerges from the implant platform, expanding coronally to reach the buccolingual and mesiodistal dimension of the prosthetic tooth to be replaced. The emergence profile of the abutment is continued into the emergence profile of the crown, and a defined finishing line (usually a chamfer) is placed on the abutment and generally positioned subgingivally on the buccal aspect in the esthetic zone. Therefore the buccal gingival contour is shaped by the abutment profile.

Marginal gap and expanded profile may explain the higher incidence of buccal gingival recession in cemented implant restorations in the esthetic zone. Therefore modifications of the morphology of the abutment have been considered.

Recently, a prosthetic technique called biologically oriented preparation technique (BOPT)[14] has been proposed, which utilizes a feather-edge preparation on natural abutments, and it has been claimed that applying the concepts of this technique to implant abutments could improve long-term gingival margin stability.

The BOPT approach suggests modification of the gingival contour by provisional restorations. Once the ideal gingival contour has been achieved, the gingival contour is replicated to the final restorations precisely. The BOPT approach suggests finishing the tooth preparation without a defined shoulder so that the gingival margin can be modified freely. However, for BOPT, the convexity of the final restoration should be similar to that of the natural teeth and could play a role in remodeling.

The clinical problem related to the long term stability of the gingival margin around implant prosthesis is similar to that around crowns on natural teeth in which the risk of gingival recession may cause recurring aesthetic problems. In cemented implant-supported prosthesis, the type of abutment preparation was developed from the same principles of fixed prosthesis on natural teeth. In particular, the design of the margin preparation and its localization were performed in the same way.

Vertical Preparations

On natural teeth, this kind of preparation was adopted in the past in cases with periodontal loss, with a finishing line positioned on the root surface. This has been considered a compromise in order to preserve the dental structure in so called “periodontal prosthesis”.

Actually vertical preparation guarantees, for geometrical reasons, an optimal marginal adaptation even if it provokes an over-contoured prosthetic crown. This kind of preparation, in “traditional prosthesis” has been considered a solution to avoid; in fact, the subgingival position of the crown margin, could be responsible of an inflammatory reaction. Nevertheless this concept has been questioned and Sorensen affirmed that a horizontal over-contour of 45° is well tolerated in the gingival third of the teeth[15].

Biologically Oriented Preparation Technique in natural teeth.

BOPT is a restoration protocol that aims to imitate natural teeth so that convex dental anatomy is transferred to the definitive prosthetic restoration. In this way, a free interaction with the gingiva can take place so that it adapts, shapes, and seats itself around the new shapes and profiles[16].

BOPT technique, as described by Loi et Al., aims to eliminate the existing finishing line (fig.1), by means of a conical diameter diamond rotary instrument. The rotary instrument penetrates the gingival sulcus at an angle of 15° to the long axis of the tooth (so that it cuts with the instrument’s body rather than the tip). Both the tooth and gingiva are prepared at the same time, creating a vertical axial plane. During BOPT, the rotary instrument interacts with the internal wall of the sulcus and the gingival epithelium up to the point where the cementoenamel junction [CEJ] is situated (fig.2). The purpose of the tooth preparation is to eliminate the emergence component of the tooth’s crown anatomy and the preexisting prepared finishing line. This permits the creation of a finished area, within which the crown margin could be displaced coronally. The interim restorations are then relined and adjusted. In this way, a new prosthetic angular component is formed with a new prosthetic CEJ situated in the gingival sulcus at a depth of 0.5 to 1 mm, respecting the available biologic space (controlled invasion of the gingival sulcus) (fig 3-4-5).

This protocol for the dental preparation and fabrication of interim restorations is designed to stabilize the blood clot that is formed in the gingival sulcus during the preparation. The intrasulcular zone of the

interim restoration margin supports the gingival margin circumferentially (fig.6). The healing process determines the reinsertion and thickening of the gingival tissue, which adapts to the new emergence profile. The temporary crowns are then maintained for 3 months (fig.10).

During this time, the emergence profile of the prosthesis is modified to achieve gingival adaptation and promote healing.

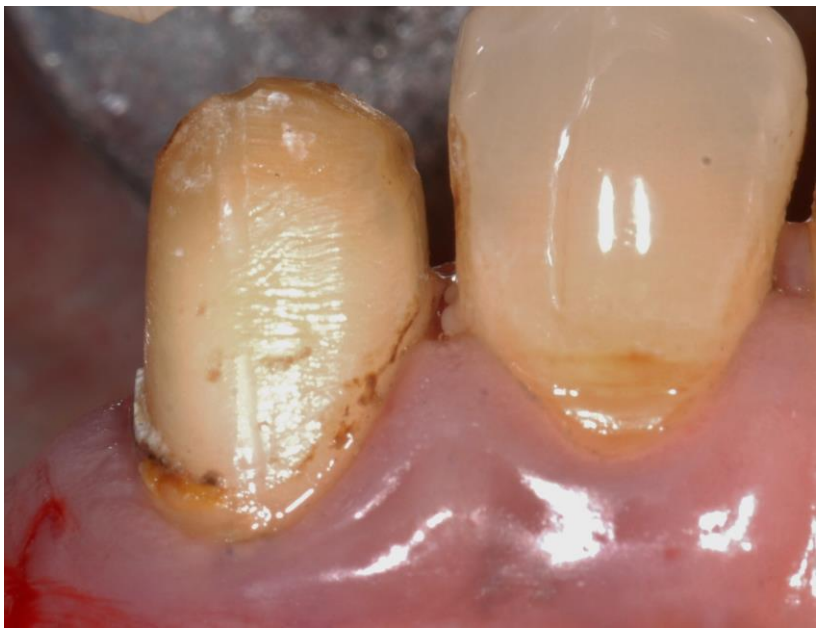


Figure 1: The initial situation with the pre-existing finishing line with a gingival recession respect to the old crown restoration.

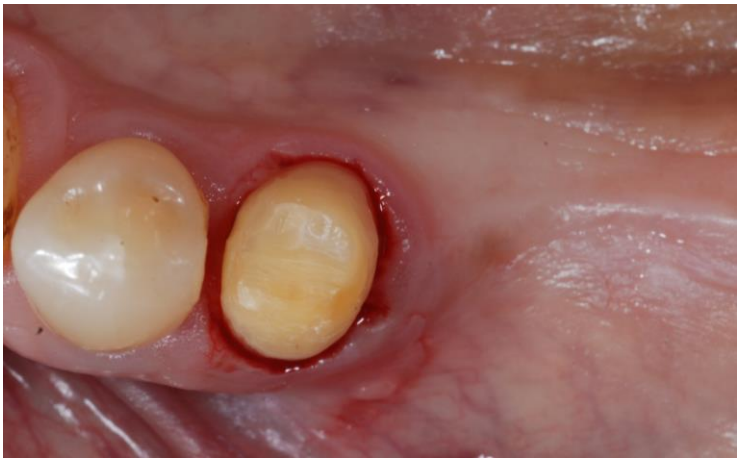


Figure 2: vertical preparation; the existing chamfer preparation is eliminated leaving a margin-free surface. The preparation includes the gingival gingitage.

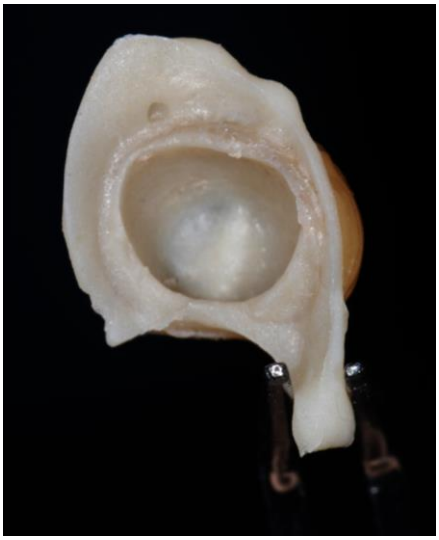


Figure 3: the temporary crown is relined with self-curing methacrilate resin. The thin intrasulcular internal wall and the thicker external one delimit the negative image of the gingival profile.

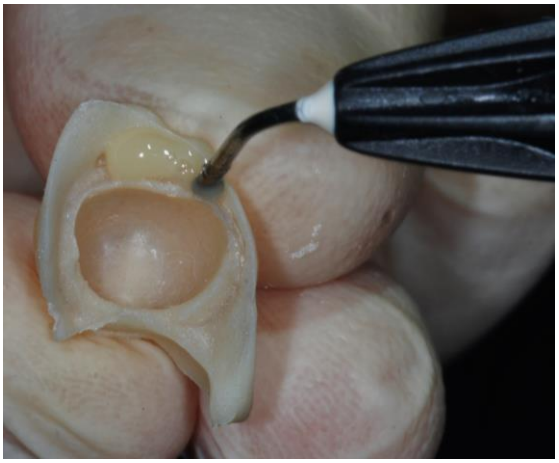


Figure 4: the space between the two walls is filled a light-cure composite.

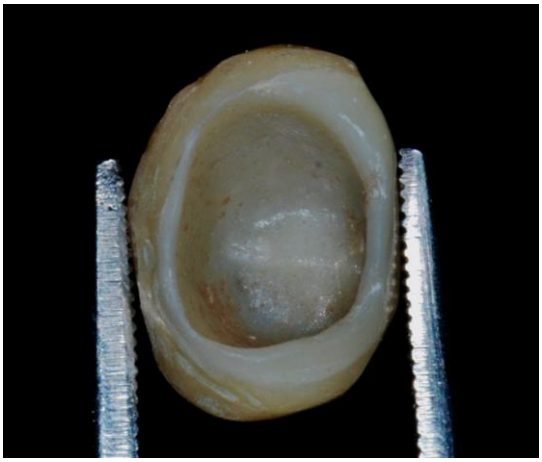


Figure 5: the finished temporary crown that incorporate the new cementoenamel-junction with a new angular component; the excess resin has been trimmed and the emergence profile is shaped in order to support the gingival margin.

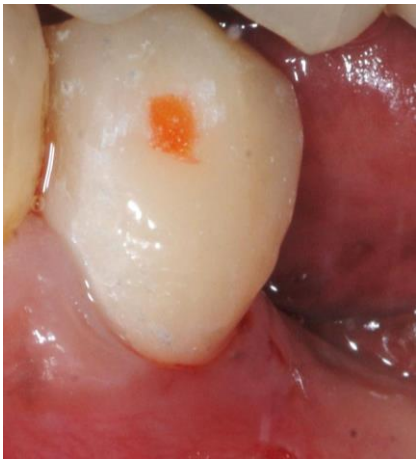


Figure 6: the crown's margin seals the blood clot under the free gingival margin in order to transform it in to a new connective tissue.

Emergence crown profile

The correct emergence crown profile, according to traditional prosthesis theories with horizontal abutment preparation, was dictated by the information recorded at the moment of the dental impression. In this way the technician was able to build a 0° profile which was the natural continuation of the root profile. Contrariwise in the vertical preparation, the prosthetic margins are positioned in the root area, inward the gingival sulcus, respecting the biological width. At the moment of the impression what is revealed will be a surface and not a finishing line. Within this area the technician, according to aesthetic and functional criteria, will determine the anatomical profile of the crown.

Concept of adaptation forms

From the observation on natural teeth prepared with feather edge preparation, the concept for which marginal gingiva is able to adapt to the profile of the prosthetic crown has been developed[14]. Abrams has suggested that emergence profile of the anatomical crown should be specular to the gingival contour[17].

The gingival profile together with the crown profile draw a typical line that form an angle which is more open in the subjects with a thin periodontium and more closed in subjects with a thick periodontium.

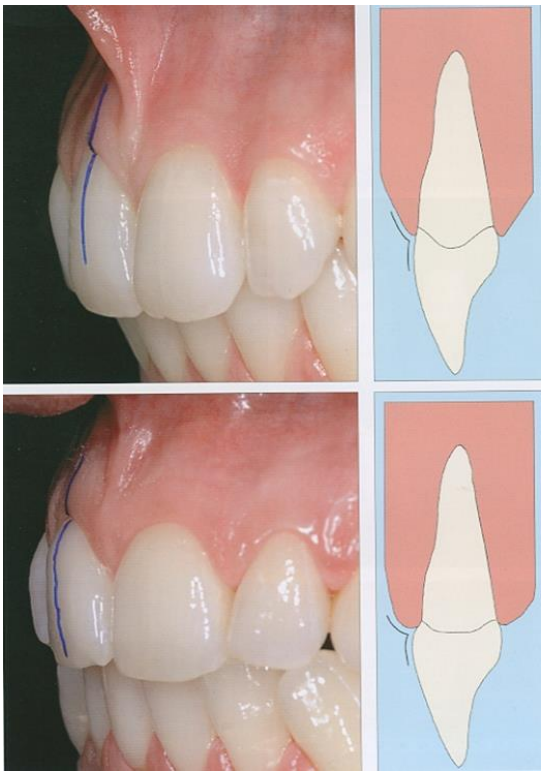


Figure 7: The typical "seagulls wings" line is evident in both pictures. The comparison between thin and thick periodontium is highlighted by the variation of the angle created between gingiva and crown.

Therefore flat emergence crown profiles will determine a flat gingival profiles while in the presence of convex emergence crown profiles the marginal gingiva will tend to increase its volume assuming a thicker and rounder profile. In this way soft tissues will adapt to the crown profiles on the basis of aesthetical parameters.

Implant abutments with vertical preparation

As it has been observed on natural teeth, equally to other parameters responsible for the clinical success, this type of design seems to augment the stability of the soft tissues around prosthetic restoration; especially it reduces the incidence of gingival recession on the buccal aspect.

According to some Authors[18] these results seem only partially depend from the better quality of the marginal closure between crown and abutment after cementation. In fact according to Canullo and Loi, the main reason is that an abutment with horizontal preparation, has the diameter which augment in apico-coronal direction and it joins up the profile of the prosthetic crown. This divergent abutment morphology tends to push tissues in apical direction determining a recession of the soft tissue margin, which could cause the exposition of the abutment margin.Conversely, feather edge abutment has a profile convergent in apico-coronal direction and the soft tissue margin tends to be located more coronally leaving the tissue ingrowing. In particular, the reduction of the abutment obtained by the removal of abutment shoulders or chamfers allowed for the interdental soft tissue to occupy the space previously occupied by the metal.

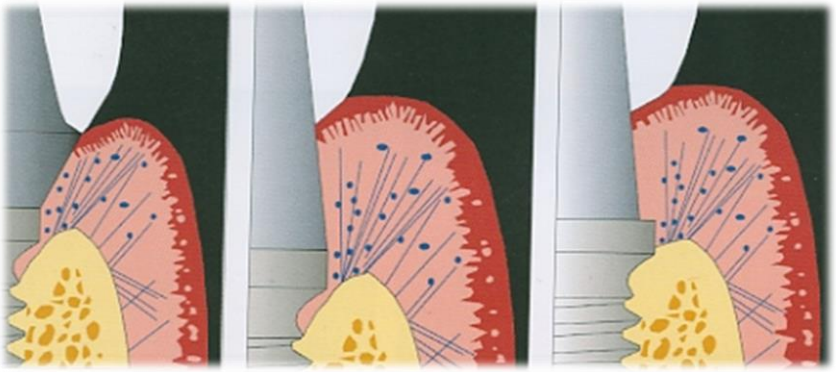


Figure 8: relationship between peri-implant soft tissues and different abutment morphologies; horizontal, vertical and vertical + platform switching respectively. Applying the same concepts expressed for the prosthesis on natural teeth of adaptation profiles, the entire architecture will be supported from crown profiles which will determine its buccal thickness.

Abutment one/two time.

The peri-implant mucosa at titanium implants has been studied in a series of animal experiments[19, 20]. It was observed that the implant-mucosal barrier comprised a junctional epithelium which was about 2 mm long, and a connective tissue compartment that was about 1,5 mm high. Since the junctional epithelium of the mucosa during healing consistently terminated at a certain level, it was suggested that an interaction occurred between the connective tissue and the titanium dioxide of the implant surface and that this zone of "interaction" was not recognized as a wound. Any disturbance of the zone of "connective tissue integration", however, may affect the marginal peri-implant tissues including the peri-implant bone.

An interesting work conducted by Abrahamsson e Berghlundh[21] has demonstrated that dis- and subsequent reconnections of the abutment component may cause an apically positioned of the peri-implant soft tissues associated with 1,49 mm respect to 0,78 mm bone loss in the case in which this component isn't subjected to this processes.

The findings from the test sites of the present study indicate that the dis- and reconnections of the abutment component of the implant compromised the mucosal barrier and its "zone of connective tissue integration". The additional marginal bone resorption observed at the test sites following abutment manipulation may therefore be the result of tissue reactions initiated to establish a proper "biological width" of the mucosal-implant barrier. In summary, it is suggested that the mechanical disruption of the mucosal barrier may be recognized as a wound of the connective tissue and that this damage calls for epithelial proliferation to cover the wound and bone resorption to allow a connective tissue barrier of proper dimension to form.

Other in vitro studies have demonstrated that the interface between abutment and implant consequently to chewing load may be susceptible to bidirectional bacterial leakage[22]. Hence the risk of bacterial toxins pumping in the peri-implant tissue determined by the prosthetic operations which could lead to bone loss[23].

The one abutment one time concept has been applied to the present pilot study and it has been compared with the traditional postponed provisionalization procedure. In this way the immediate conditioning of the soft tissues has been compared with a delayed approach in order to evaluate the role of the prosthetic crown on the soft tissue maturation.

Moreover applying the definitive abutment simultaneously with the soft tissue graft, the healing proceeded undisturbed from the prosthetic phases (connection and re-connection of the abutment, impressions and cementation).

In the recent literature the first studies on the potentialities of "*Biologically Oriented Preparation Technique*"[14, 16] have been published both regarding teeth and implants. To our knowledge there are no studies concerning the relation between this technique and soft tissue augmentation techniques.

The connective tissue enclosed in the graft is a tissue that has a wider conditioning potential if compared to conventional peri-prosthetic tissues. At the same time, the most important aspect for the success in periodontal plastic surgery is the stabilization of the graft to the fixed underlying tissues (periosteum) and the tightly adaptation of the flap to the crown profile in order to entrap the blood clot and to avoid flap collapse. For this reason, the presence of a guide helping the maturation of the graft becomes essential. In this way, a correct convex crown profile could play a key role in supporting the flap and avoiding its collapse and recession.

Moreover it has been split and compared both test and control groups in two different categories depending on the different surgical approaches: bilaminar technique (BT), consisting of an envelope coronally advanced flap covering a subepithelial connective tissue graft ad a free gingival graft (FGG) for the cases in the mandibular site where the KM was lower of 3mm.
Differently from the upper jaw in fact, where the KM is always carried from the palate side the FGG is the only solution to augment the perimplant KM in the atrophic mandible.

Aim of the study

According to the recent literature regarding potentialities of the shoulderless abutment, the aim of the present study was to investigate the most effective timing of the surgical-prosthetic procedure in order to obtain a stable soft tissue augmentation around dental implants.

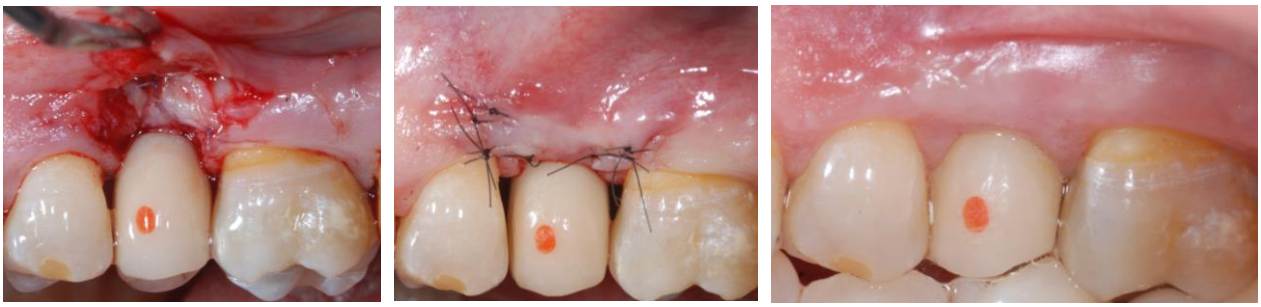


Figure 9: immediate conditioning TEST group. The crown is supporting the soft tissues during the maturation.

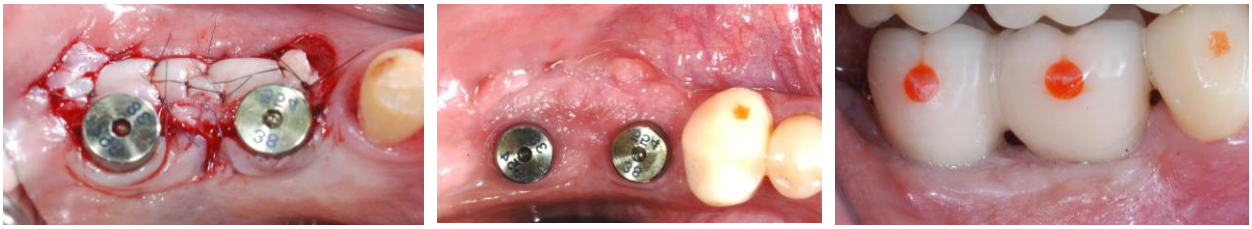


Figure 10: delayed conditioning of the flap: CONTROL group. The influence of the crown takes place only when tissues are already healed.

MATERIALS AND METHODS

Patients recruitment

Overall, 13 patients have been enrolled in the Department of Dental Implants. U.O.C. Maxillofacial Surgery and Odontostomatology, Fondazione Cà Granda IRCCS, University of Milan, Milan, Italy. They were recruited in chronological order from the waiting list.

Patient undersigned an informed consent and the treatment was performed accordingly with the declaration of Helsinki rules.

A total amount of 21 implants have been placed and they have been alternatively assigned to the case or control group on the basis of the waiting list. The total number of implants included in the study was decided empirically, since to our knowledge there are no studies in literature reporting the variance of thickness and apico-coronal migration of soft tissues around implants treated with the present technique. Consequently, it was not possible to calculate the sample size.

The following data obtained from the present study represents the preliminary results that might be used in a wider randomized clinical trial.

Inclusion Criteria

The clinical criteria adopted for the enrollment in the study were the partial edentulism in which the teeth were lost at least 2 months before the date of implant placement with KM lower than 2 mm or inadequate soft tissues volume for a proper ridge contour. Further, only sites with no needs for bone tissue augmentation were included. This evaluation was determined on the basis of cone-beam computed tomography (CBCT) scans performed before implant placement.

Exclusion Criteria

Briefly, each patient underwent initial preparation after receiving personalized oral hygiene instructions to reach full-mouth plaque score (FMPS) <20% and full-mouth bleeding score (FMBS) <20%. All patients unable to have a proper domiciliary oral hygiene control to maintain FMPS and FMBS values were excluded.

Patients affected by imbalanced systemic diseases which could negatively influence the post-surgical healing (diabetes mellitus) were not included in the study.

Patients with smoking habits (> 10 cigarettes/die) were excluded.

Materials

The implants used in the study were (Global, Sweden & Martina, Padua, Italy) ranged from 3.8 to 4.3 mm diameter and from 8.5 to 15mm length. The body of the implants has a first cylindrical section and a progressively tapered apex.

BOPT millable titanium abutments (fig.3) were used in the study with the same diameter suitable for al implants platforms. The morphology of the BOPT millable post has been designed to allow both centric reduction and different options for the angle of the prosthesis without affecting the sturdiness of the supporting walls.

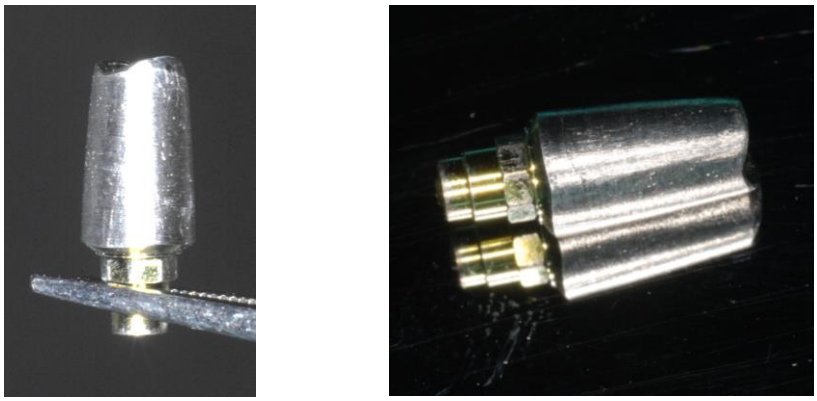


Figure 11: milled abutment and the convex emergence profile.

The decision to simplify the range of BOPT abutments to one size for all implants is also supported by the clinical results of the Platform Switching protocols reported in literature[24]. With BOPT abutments mismatching is made available for larger amount of gingival tissue which is organized and stabilized in keratinized tissue around prosthetic crown.

The gingiva has the capacity to cling to the forms implant prosthesis. The vertically designed BOPT abutments have tapering shape that allows the increase of space available for the thickening of the gingiva around the circumference and a better adaptation to the emerging profile of the prosthetic restoration (fig.11 - 12).

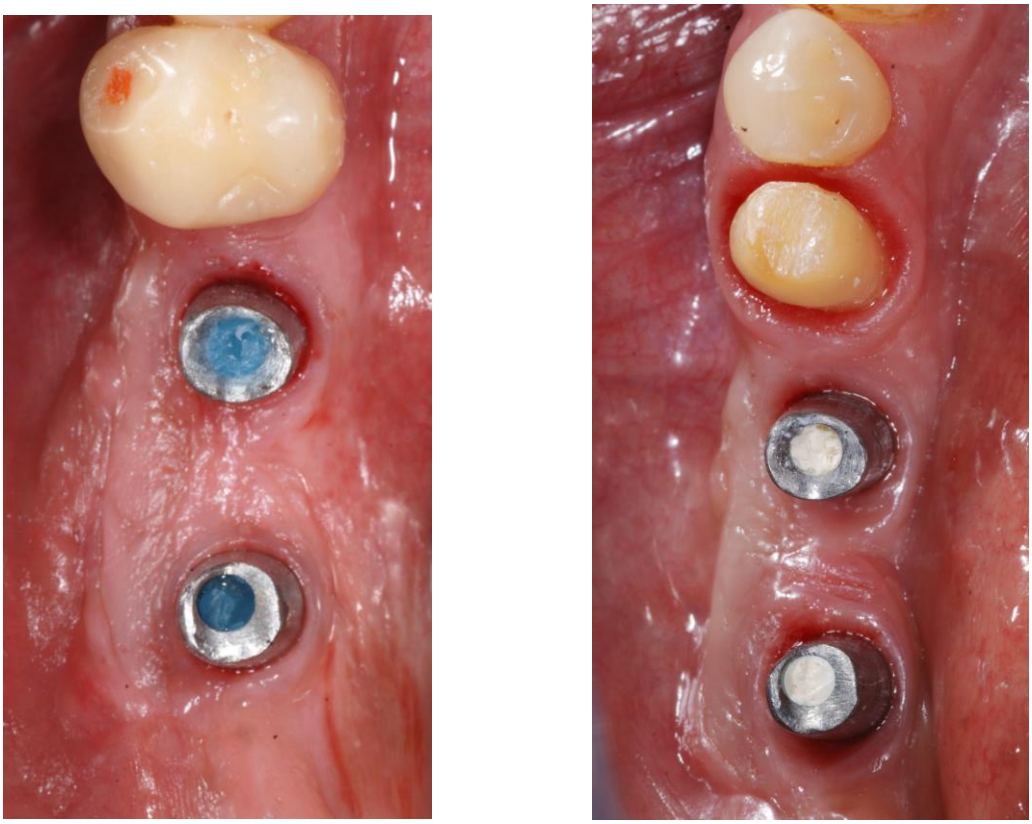


Figure 12: Vertical abutment design both on implants and natural teeth pre and after 3 months conditioning.

SUBGROUPS OF THE STUDY

Both for test and control groups, it has been created two subgroups splitting the patients according to the initial amount of KM. In fact, in all the mandibular cases in which the keratinized tissue was wider than 3 mm it has been opted for a bilaminar technique (fig.13- 24). Conversely if the KM lower than 3 mm the graft was not de-epithelialized opting for a free gingival graft procedure (fig. 25-32).

Surgical and prosthetic phases of the TEST GROUP:

Implant placement and intraoperative impression:

After the initial preparation and the surgical planning using orthopantomographs and CBCT scans the implant surgery was performed (Fig.14); At the end of the surgical phase an intraoperative impression was taken using sterile rubber gum in order to prevent the impression material slipping away under the flaps (fig.15). After the impression the cover screw was positioned and a primary wound closure was obtained.

Once the technician has poured the master cast, the abutments has been milled shoulderless up to the analogue head not considering the relationship with the soft tissues.

The metal framework has been prepared with the finishing line placed 1 mm above the analogue head considering the minimum space for the biological width and leaving the possibility to shorten them after the conditioning period, maintaing the same quality of closure [14].

The resin interim crowns have been positioned with the finishing line at 2 mm from the bone crest. All the resin crowns have been developed with a pre-determined landmark with red resin of 2 mm length (fig.16).

Second stage surgery:

After the osseointegration period the second stage surgery has been performed: a split thickness and apically repositioned flap combined with a subepithelial connective tissue graft has been executed. The definitive abutments were connected with a clamping force of 30 N-cm (fig.17-18). The harvesting site was the palatal fibro mucosa of the molar area. A free gingival graft was harvested and extraorally de-epithelialized(fig.19-21). A subepithelial connective tissue graft of uniform thickness of 1.5 mm was obtained reducing the percentage of fat tissue in the graft and the postoperative morbidity of the patient[25].

The connective tissue graft was fixed with 6.0 suture (*Resorb* or *Polynil* Sweden & Martina,Padua, Italy.) at the periosteum (fig.22).

At this point the resin interim crowns were cemented and the provisional cement accurately removed.

The primary flap has been repositioned and sutured at the prosthetic cementum enamel junction (fig.23). The sutures were generally removed 14 days after the second stage surgery (fig.24).

No modification on the interims crowns were done during the follow-up.

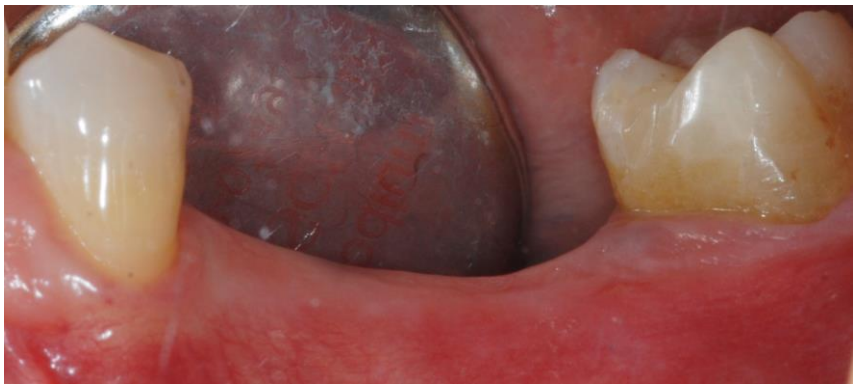


Figure 13: pre-operative view.

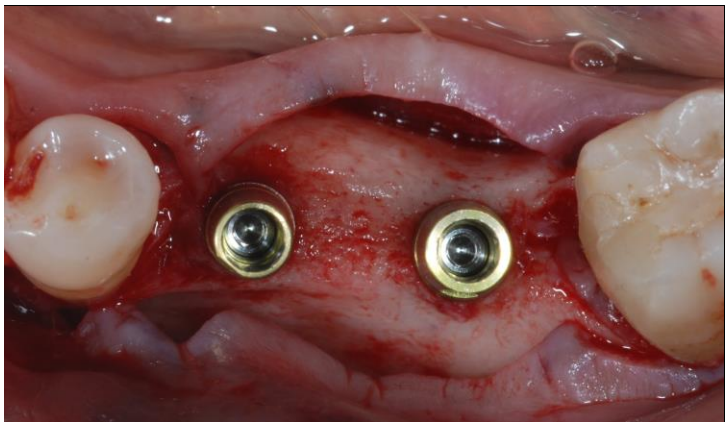


Figure 14: implant placement.

Figure 15: intraoperative impression with dedicated repositiong caps on BOPT abutments.

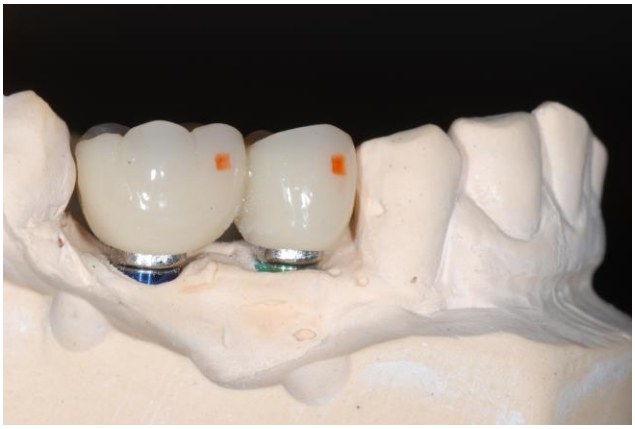


Figure 16: definitive abutments without finishing line and the interim crown with the finishing line at 1.5 - 2 mm from the bone level.

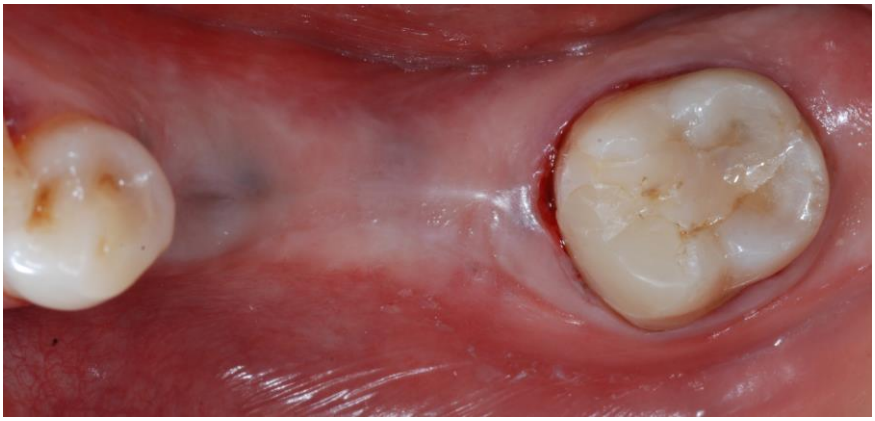


Figure 17: preoperative view before second stage surgery: it is possible to appreciate the vestibular defect of the ridge contour.

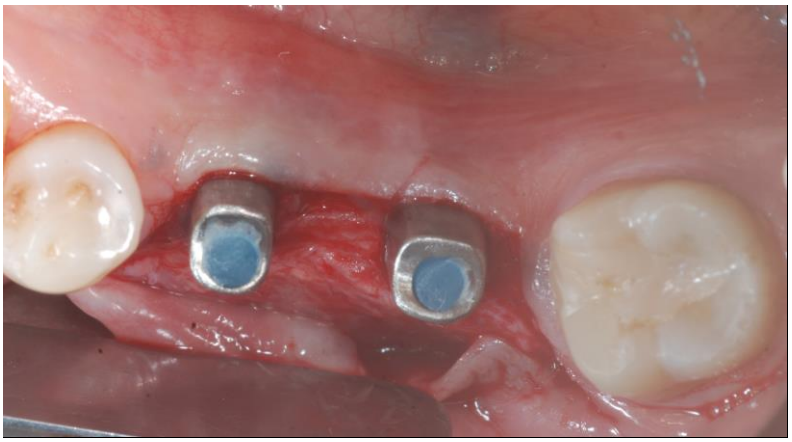


Figure 16: split thickness flap and definitive abutment positioning.

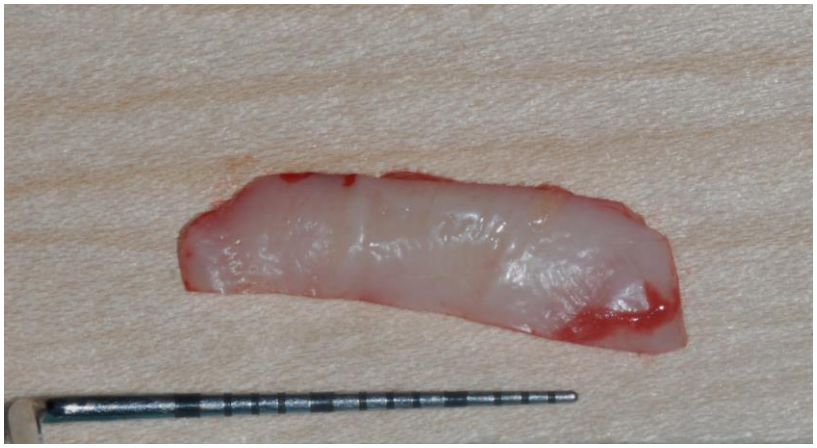


Figure 17: palatal epithelial-connective tissue graft.

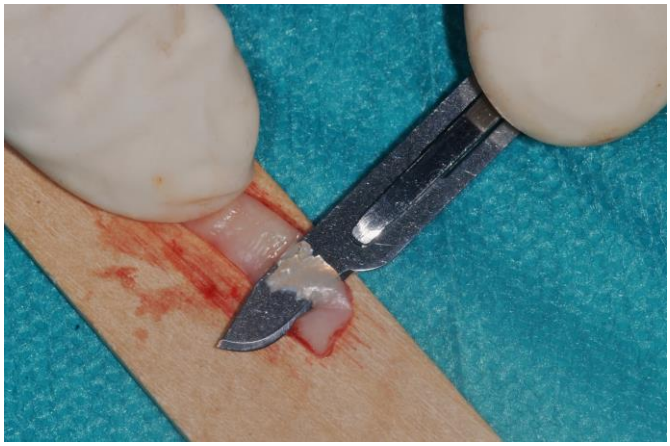


Figure 18: extraoral de-epithelialization

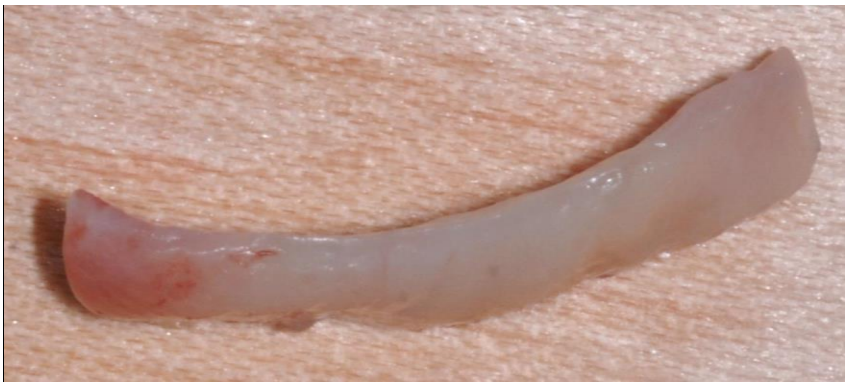


Figure 21:subepithelial connective tissue graft of uniform thickness of approximately 1.5 mm.

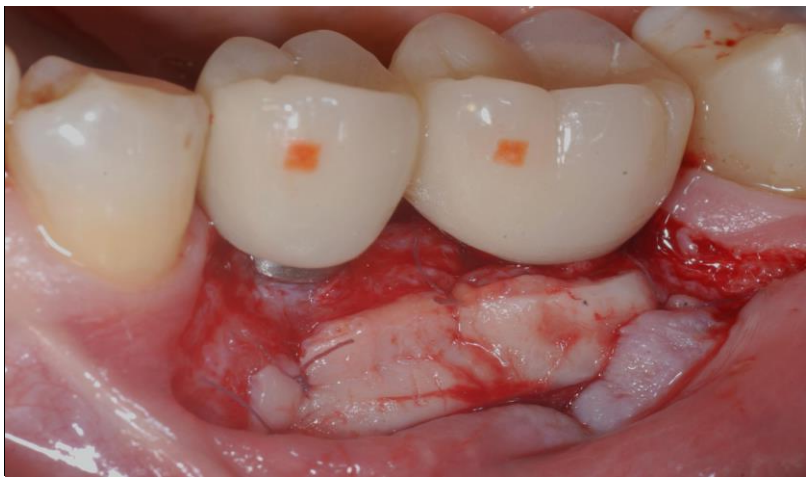


Figure 22: connective tissue graft fixed at the periosteum.

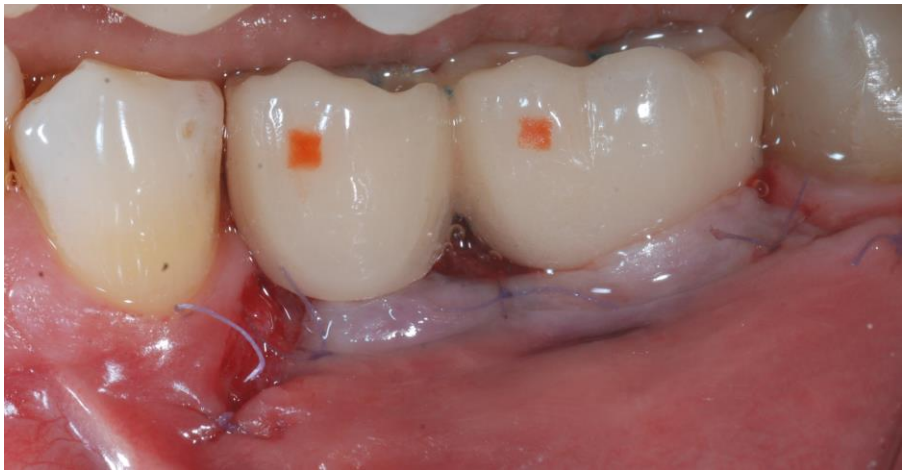


Figure 19: repositioning of the primary flap.

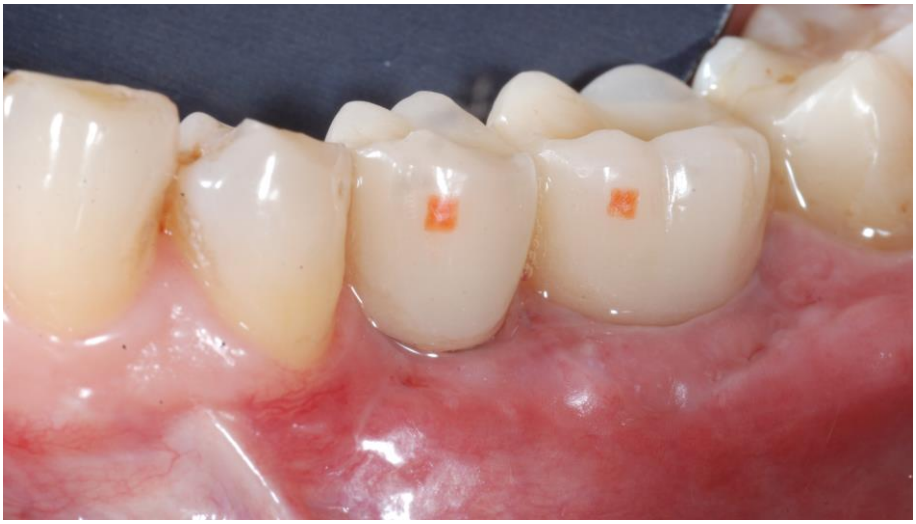


Figure 204: suture removal 15 days later.

Surgical and prosthetic phases of CONTROL GROUP.

Differently from the test group no intraoperative impressions were taken.

At the time of the second stage surgery the healing abutments were connected (fig. 28 – 29).

The impressions were taken one month after the implant surgical connection (fig. 30) and, consequently, the soft tissues conditioning has begun after the healing period on the healing abutment (fig 31-32).

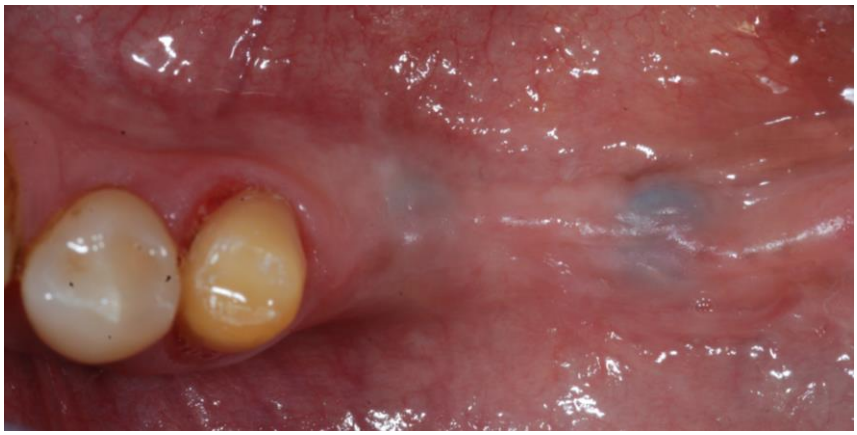


Figure 25: preoperative occlusal view.

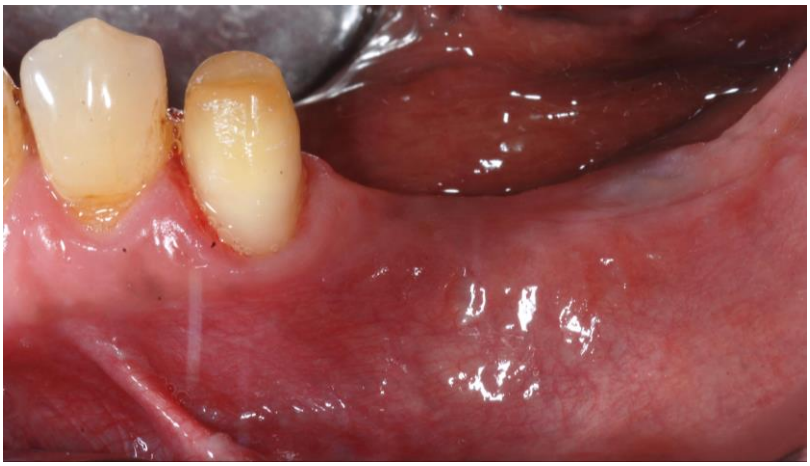


Figure 21: preoperative later view. The lack of vestibular keratinized tissue.

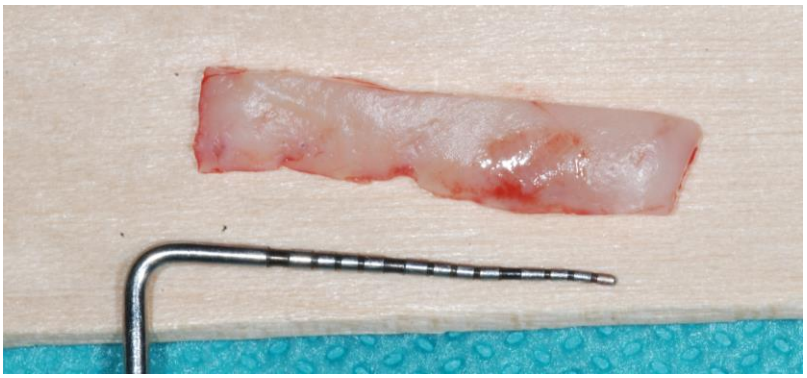


Figure 22:epithelial connective tissue graft.

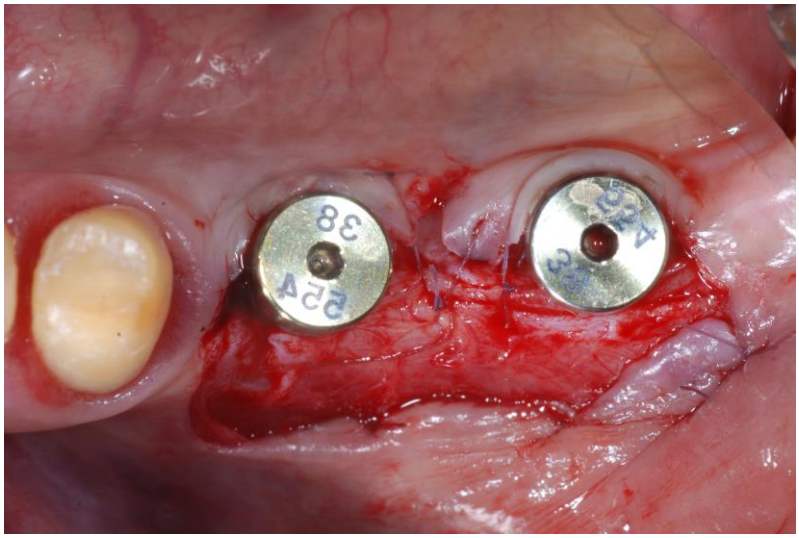


Figure 238: the soft tissue recipient site.

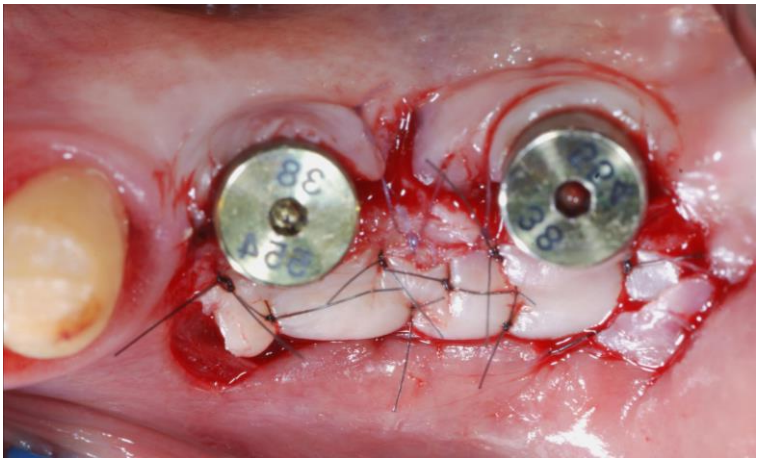


Figure24: the free gingival graft fixed at the peri-implant site.

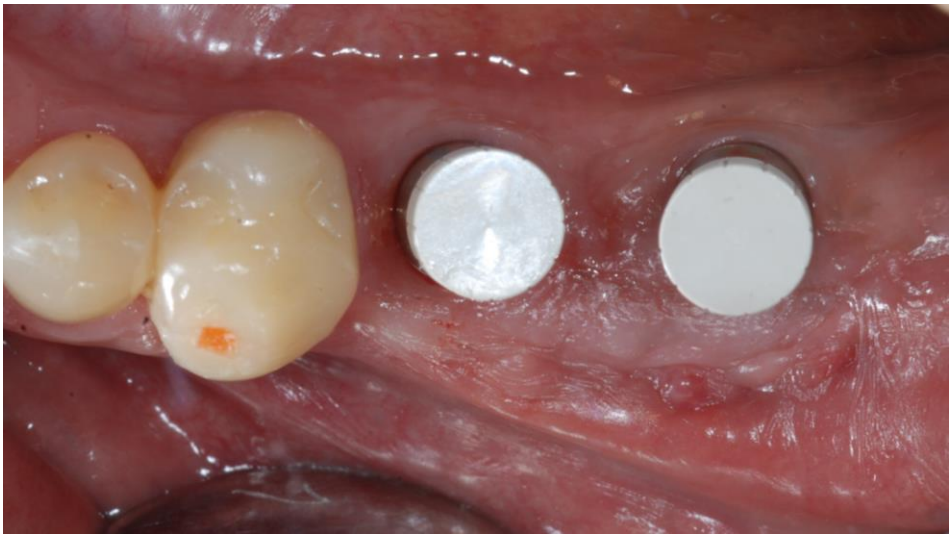


Figure 25: definitive impression using dedicated caps of the BOPT post.

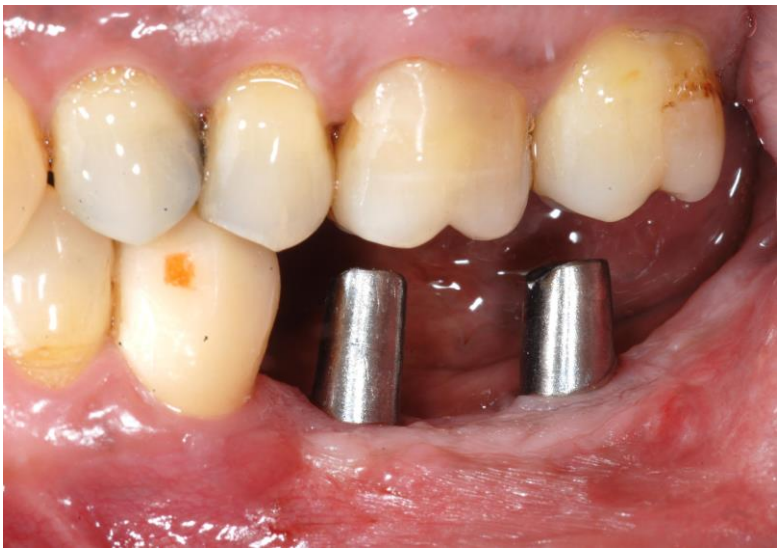


Figure 26: definitive abutments 1 month after second stage surgery.

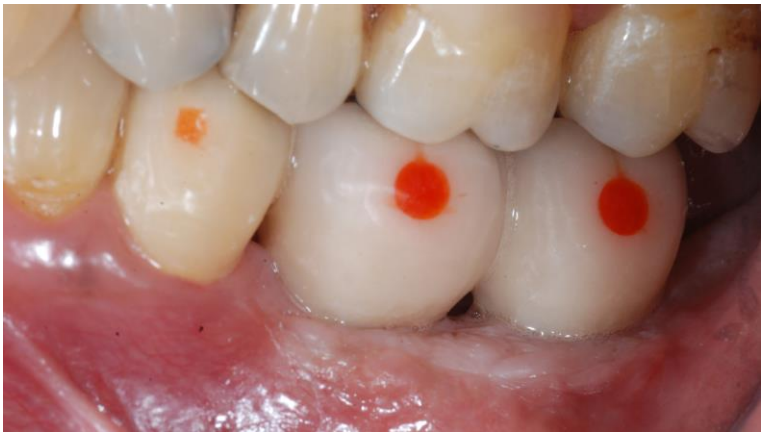


Figure 32: provisional crowns 6 weeks later.

EVALUATION METHODS

The peri-implant soft tissue changes were monitored both vertically and horizontally.

Apico-coronal gingival modification evaluation method.

The free gingival margin migration has been monitored using intraoral photographs combined with dedicated software. The inter-and intra-operative measurement concordance of the following method has been tested before data collection for the study.

Concordance inter-intra operative description.

Thirty-eight measurements on 13 implants in 8 patients were recorded. In every follow-up appointment, an intra-oral photograph was taken for the graft and the provisional crown which enclosed a circular

landmark with a previously determined diameter. The landmark was prepared with a red-resin by the same technician (fig.33).

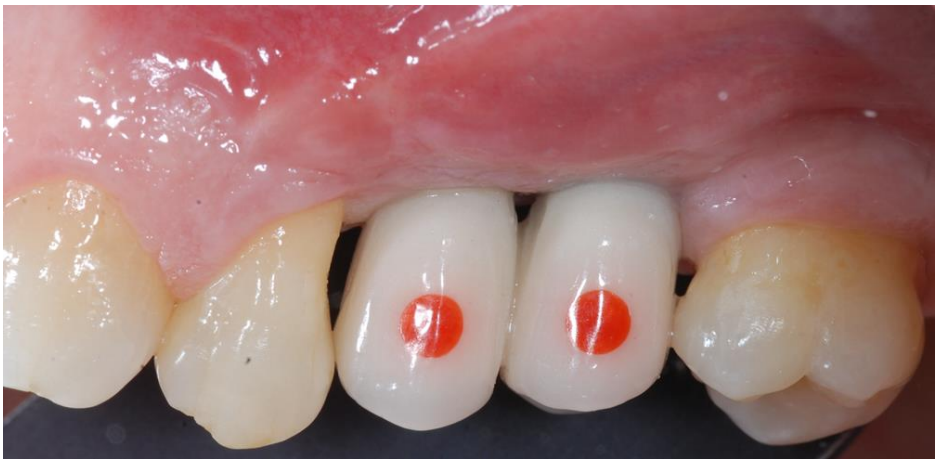


Figure 27: the landmark was centered in the middle of the tooh and of pre-detrmined diamenter.

Before crown cementation, the landmark was calibrated with a digital calibrator by the main investigator, to determine the precise diameter up to two decimal numbers (fig.34).

Figure 28: On-site evalutaion of the evaluation of the landmark with a digital caliber.

On the intra-oral photograph, the distance was measured from the most apical point of the determined landmark to the zenith of the gingiva, using an image processing program designed for scientific multidimensional images (ImageJ).

These measurement were taken by three independent examiners. The independent examiners repeated the same measurements after one month in order to test the reproducibility of this method.

Measurement process using the software:

ImageJ (IMAGEJ 1.43u, NIH, Bethesda, MD, USA) is an open-source software ideal for scientific measurements because it can be freely inspected, modified, and redistributed. Intra-oral photographs were taken with a digital Single Lens Reflex camera (Nikon D90, Nikon Corp, Shinjuku, Japan) at the moment of interim crown cementation (baseline) and 1 to 4 follow-up visits to evaluate the soft tissue changes. At each evaluation the prosthetic landmark has been calibrated with the software in order to transform the pixel of the photograph in millimeters (fig.35).

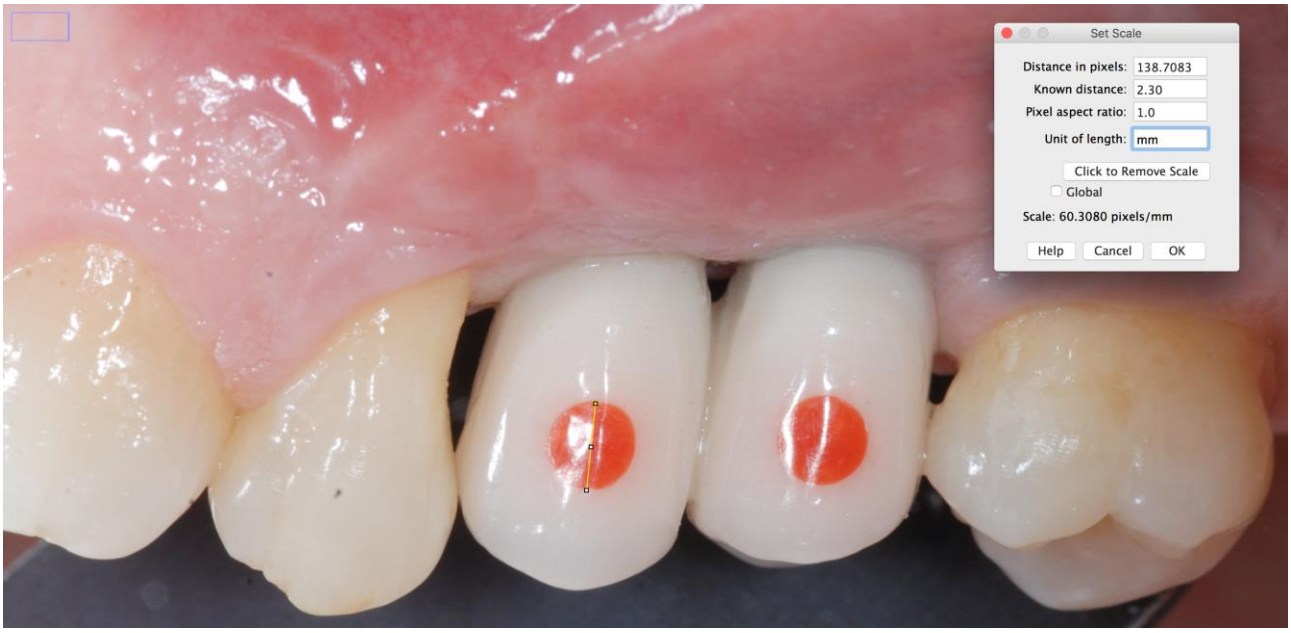


Figure 29: calibration method of the landmark.

The calibration of the landmark allowed to eliminate the error caused by the inclination of the (+/ - 90°) of the intraoral photography. Moreover the calibration of the prosthetic landmark reduced the distortion caused by different plans of position in the space obtained with a periodontal probe. In the end the distance was measured from most apical point of the land mark to the zenith of the gingiva(fig.36).

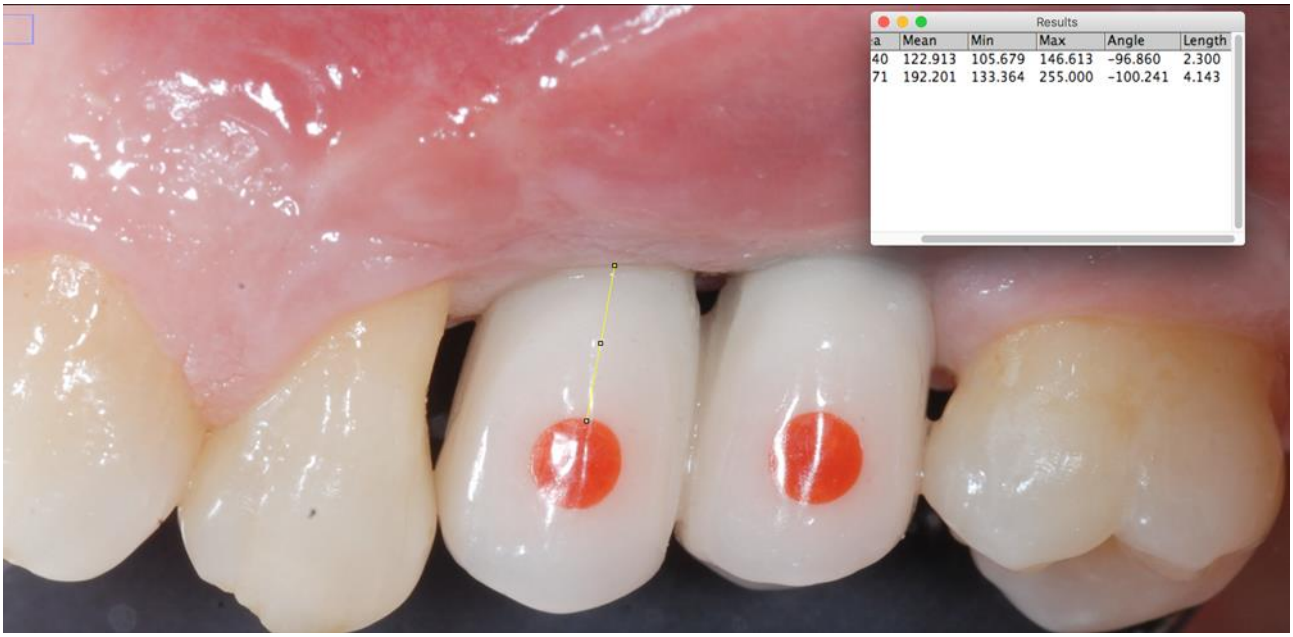


Figure 306: distance measurement from the inferior border of the landmark to the free gingival margin.

Statistical Analysis:

The measurements were entered into an Excel spreadsheet (Microsoft, Redmond, WA, USA) for the statistical analysis. Data were analyzed by the means of SAS 9.4 (SAS Institute, Inc., Cary, NC, USA) for Windows.

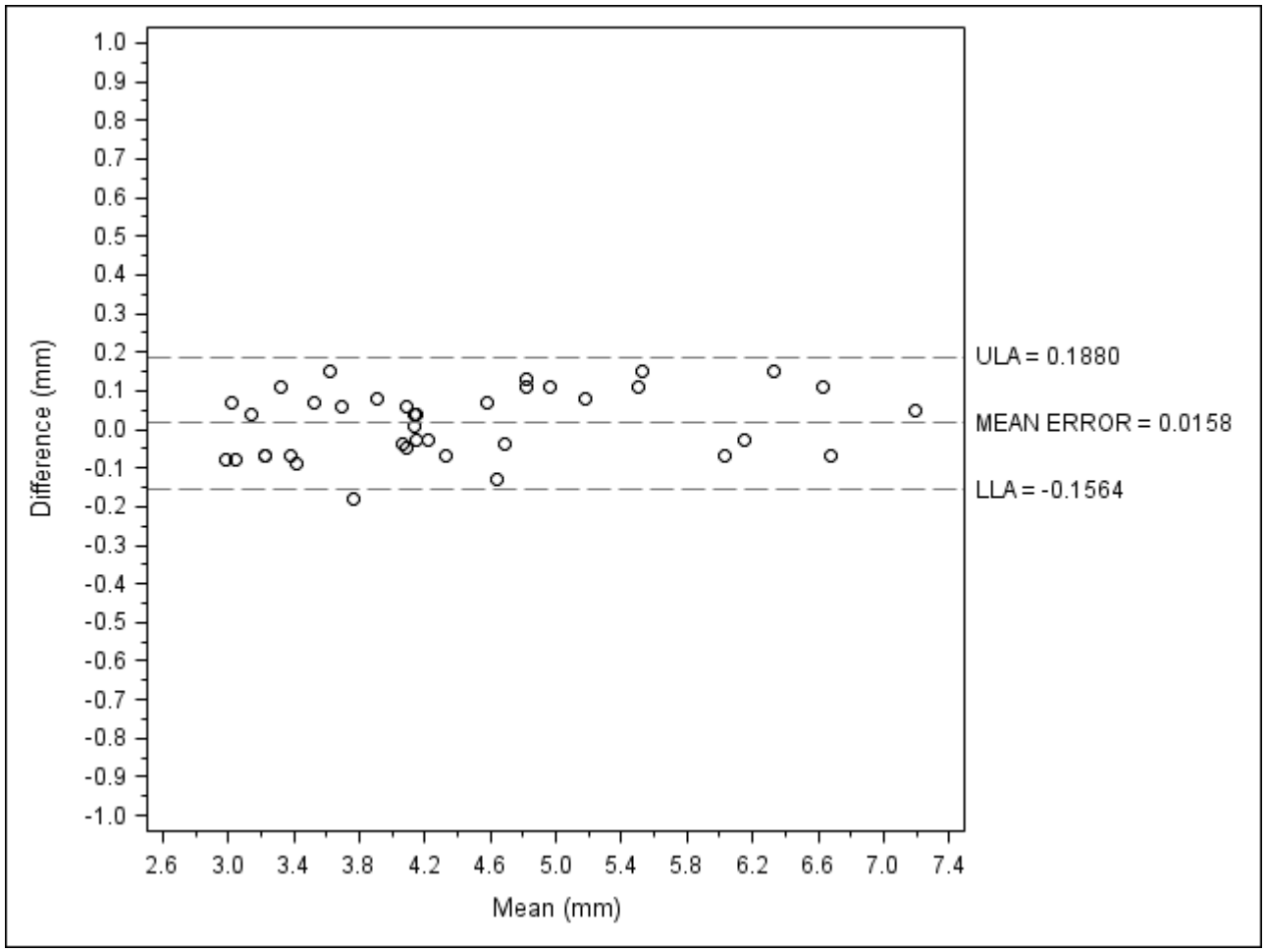
To evaluate the reproducibility of the method inter- and intra-rater concordance was evaluated with Bland and Altman plots and Lin's concordance correlation coefficients[26], and 95% confidence interval (95% CI) calculated with the bootstrap method using 2000 resampling. In estimating inter-rater agreement, the mean of the two readings made in different times was considered.

Results of concordance: results showed that the intra-rater [ICC] was higher than 0.9 for each of the three examiners.

Reader	Lower –upper IC 95% limits	concordance
D.F.	0.9950 – 0.9982	0.9969
F.L.	0.9218 – 0.9711	0.9525
F.A.	0.9348 – 0.9990	0.9888

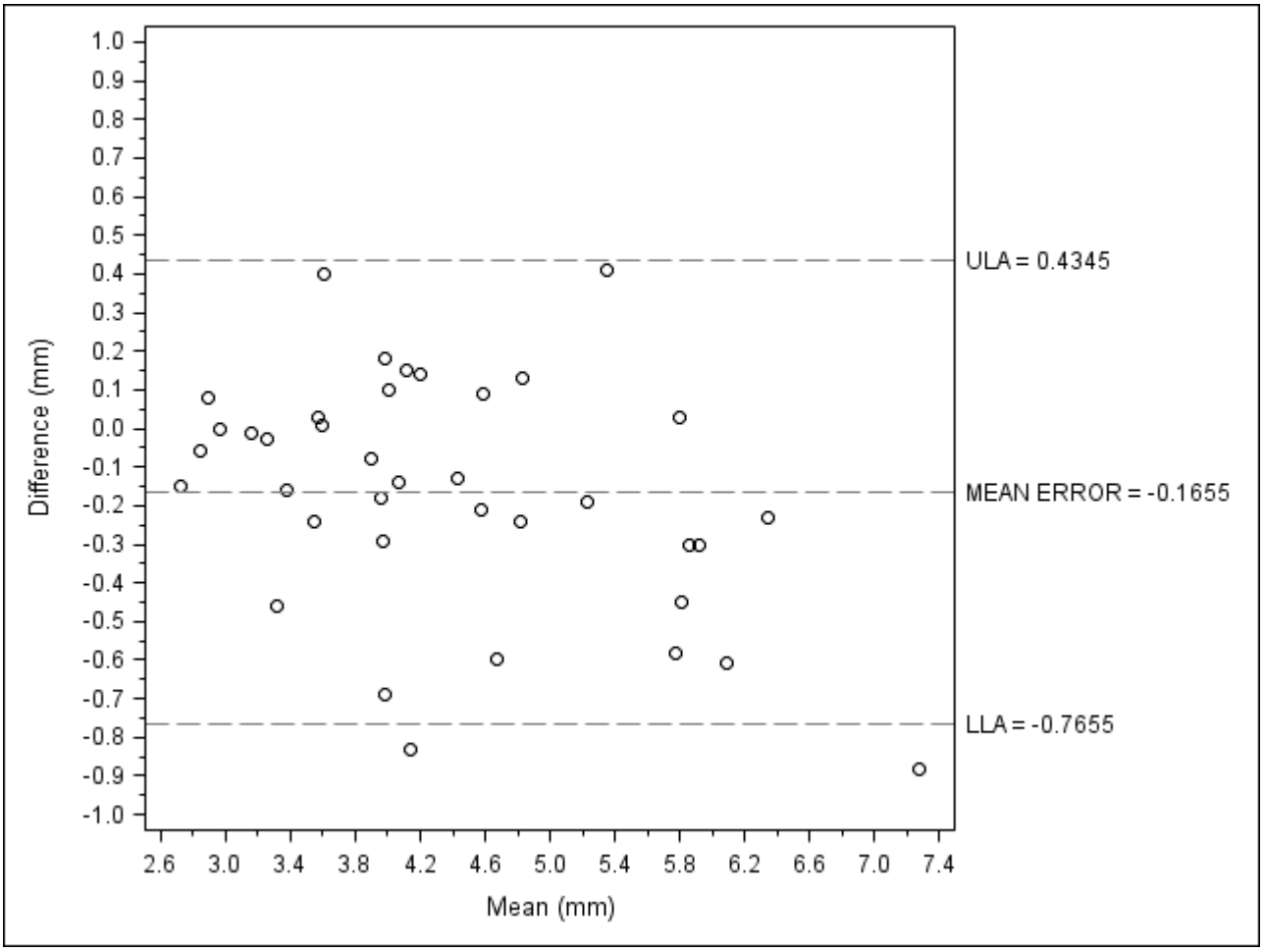
Inter-rater agreement was also high (ICC = 0.964 95% CI: 0.949 - 0.980).

Graphs 1(a, b, c) and 2 (a, b, c) with the Bland-Altman plots illustrates the intra- and inter-rater agreement expressed as mean error and the lower (LLA) and upper (ULA) 95% limits of agreement.



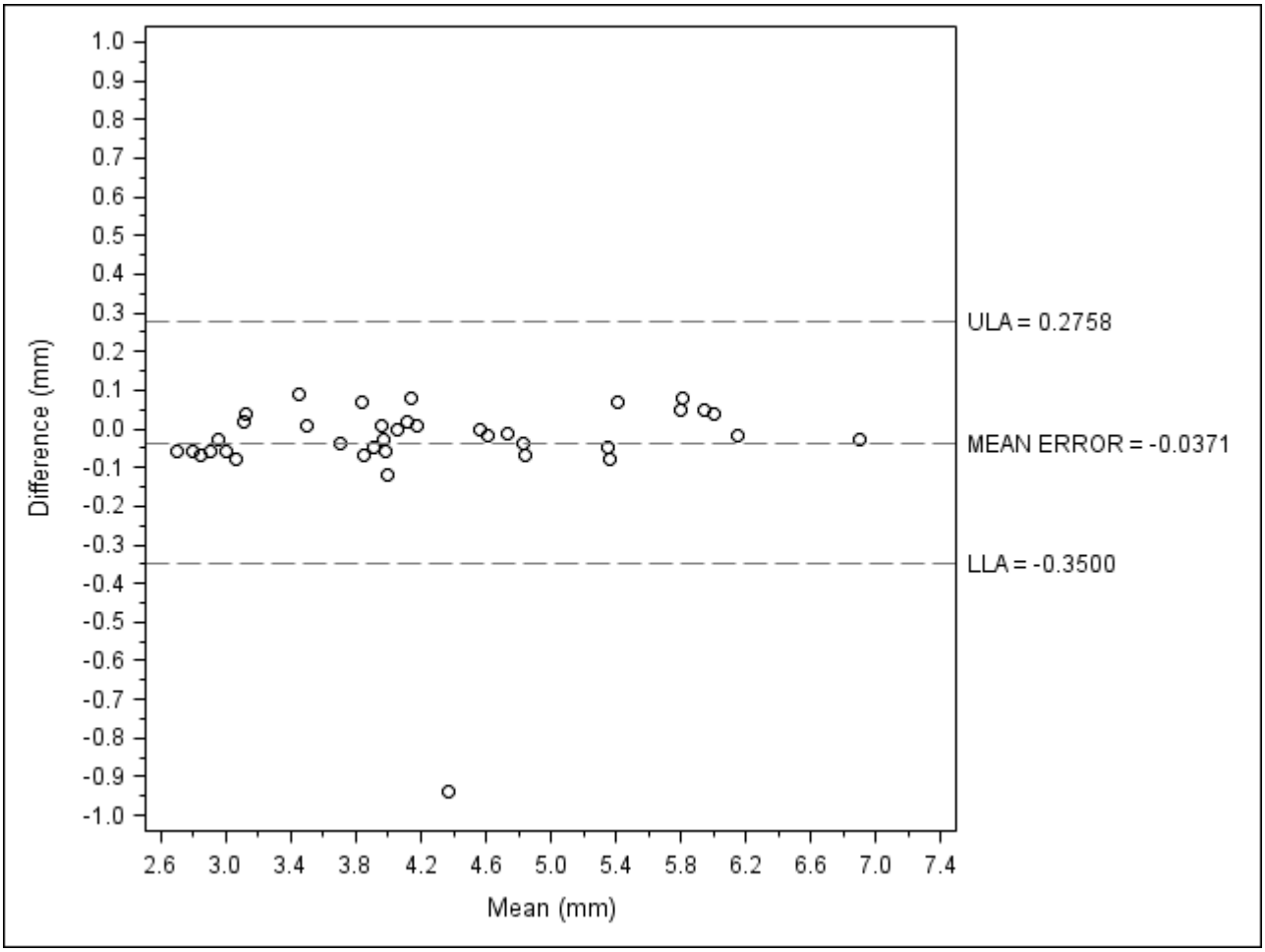
Graph 31a: intra operator concordance correlation Reader (D.F.).

Considering the first examiner (D.F.) the Bland-Altman analysis indicates that the 95% limits of agreement between the two readings ranged from -0.156 to 0.188mm. The medium difference was 0.0158 mm.



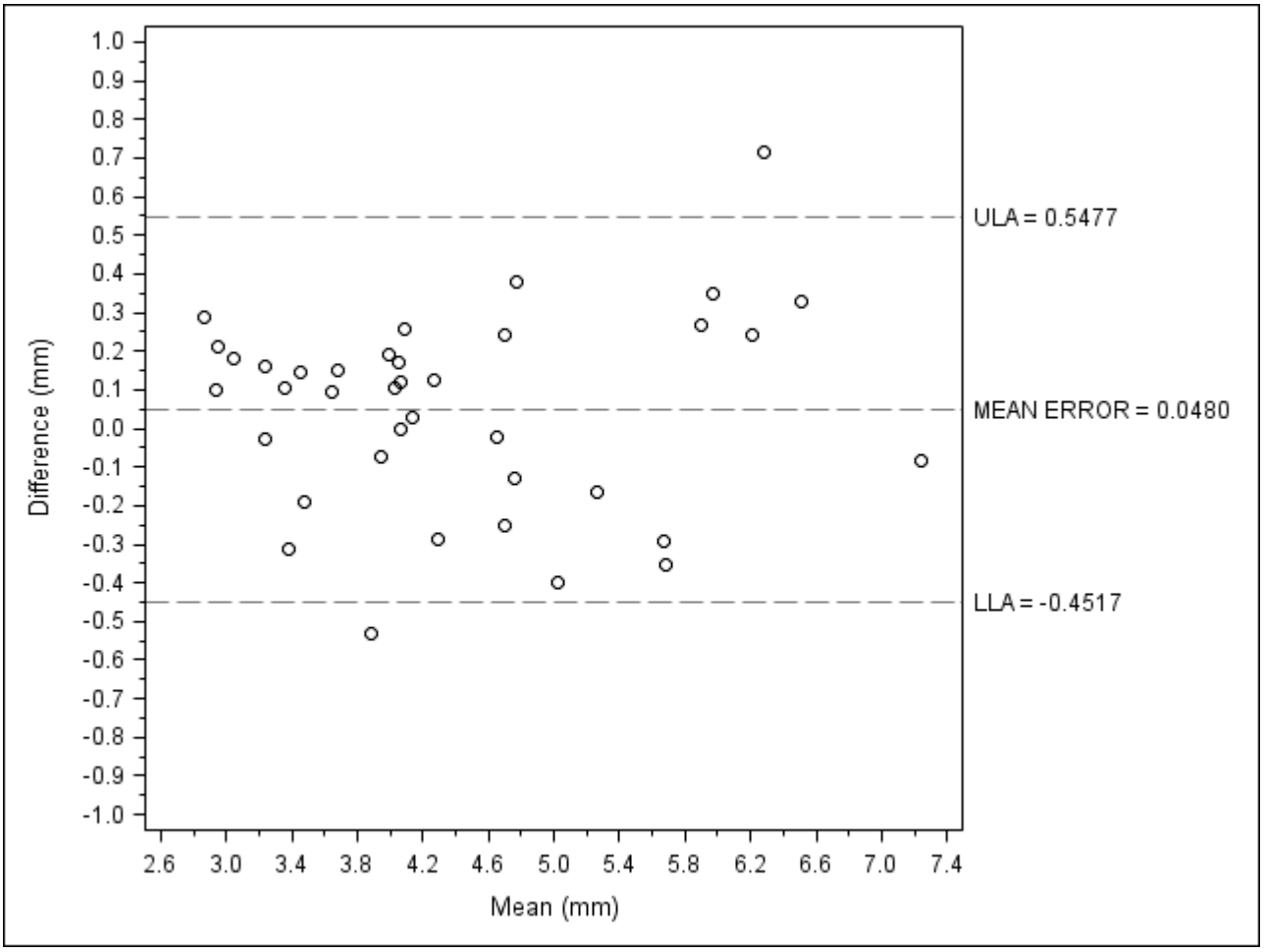
Graph 1b: intra operator concordance correlation Reader (F.L.).

Considering the second examiner (F.L.) the Bland-Altman analysis indicates that the 95% limits of agreement between the mean of the two readings made in different times ranged from -0.76 to 0.43mm. The medium difference was 0.16 mm.



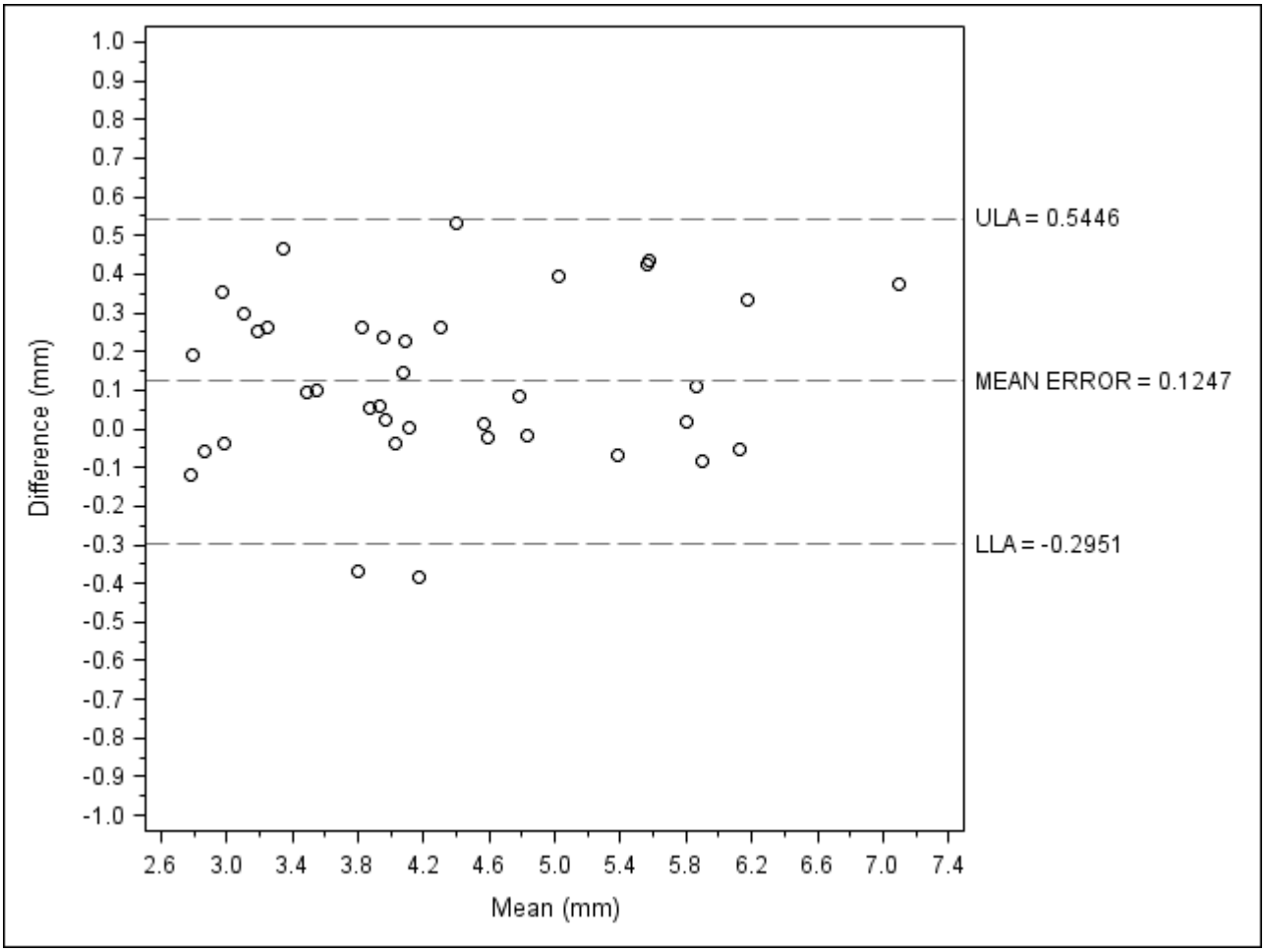
Graph 1c: intra operator concordance correlation Reader (F.A.).

Considering the third examiner the Bland-Altman analysis indicates that the 95% limits of agreement between the two readings ranged from -0.35 to 0.27mm. The medium difference was - 0.037 mm.



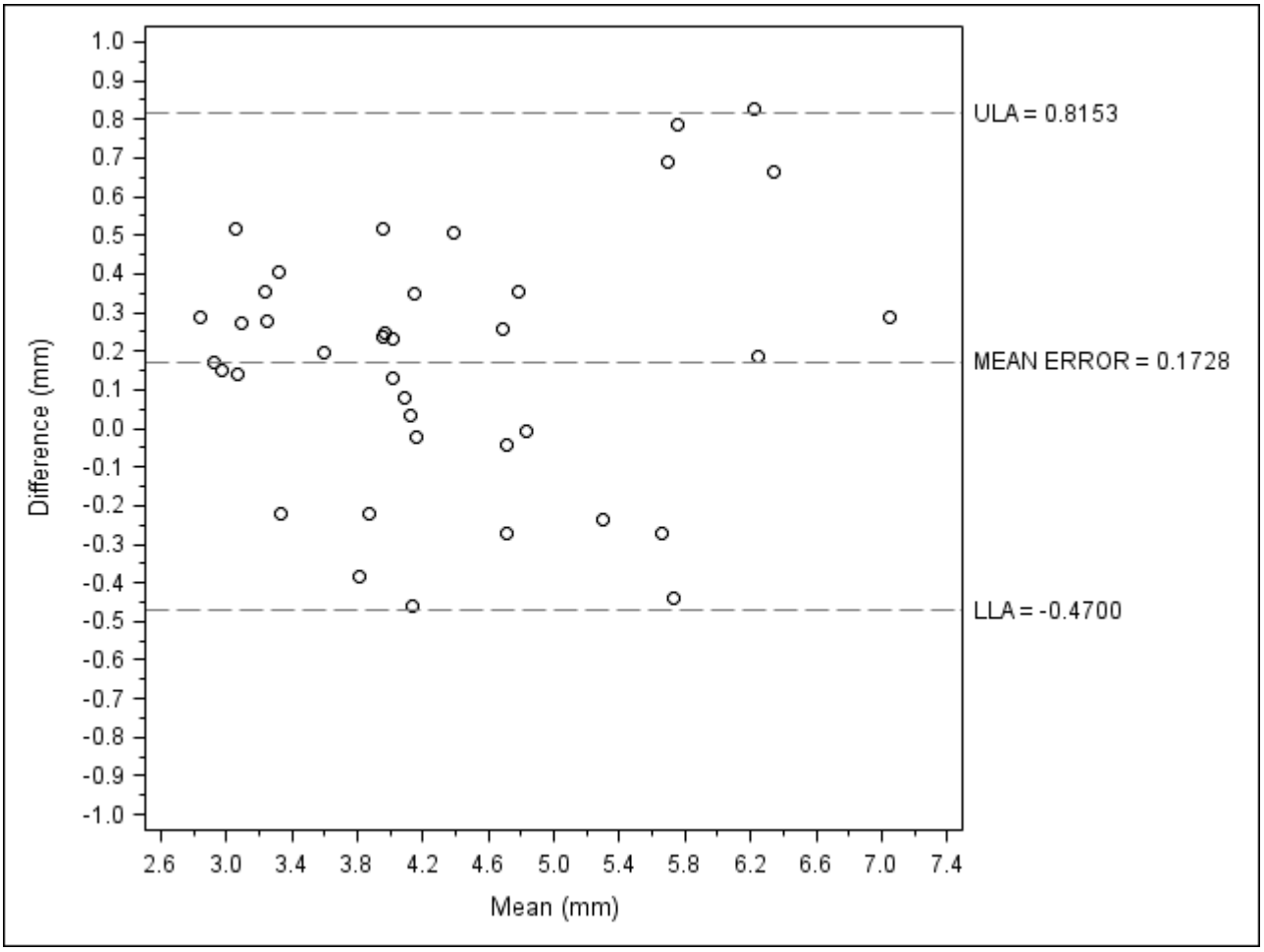
Graph 2a: the inter-operator concordance between D.F. and L.I.

Considering the inter-operators concordance the Bland-Altman analysis indicates that the 95% limits of agreement between the mean two readings ranged from -0.35 to 0.28mm. The medium difference was 0.048mm.



Graph 2b: the inter-operator concordance between L.F. and F.A.

Considering the inter-operators concordance the Bland-Altman analysis indicates that the 95% limits of agreement between the two mean readings ranged from -0.29 to 0.54mm. The medium difference was 0.124mm



Graph 2c: the inter-operator concordance between D.F. and F.A.

Considering the inter-operators concordance the Bland-Altman analysis indicates that the 95% limits of agreement between the two mean readings ranged from -0.47 to 0.81mm. The medium difference was 0.172mm

Tridimensional soft tissue comparison considering a pre-determined area.

The soft tissue graft were compared at different times : pre grafting procedure and 1 up to 4 follow-up.

The soft tissue were scanned using an intraoral scanner TRIOS Pod system (3Shape, Copenhagen,Denmark) and the impressions were matched using a dedicated software *Geomagic* which has permitted to select a specific area at the peri-implant site (both palatal/lingual and vestibular) in which the changes in terms of thickness of the graft has been calculated comparing the initial situation before the grafting procedure and the follow-up recalls (fig.37-38).

The data expressed by the software were the mean and the maximum increase and decrease and the standard deviation of the selected peri-implant area (fig.40).

The software has elaborated a colorimetric map (fig.39) in which the color varied from blue were the gingiva was decreased in thickness to red where the gingiva was augmented. The color green was present when the variation was similar to 0.

The grey were the areas not well read from the scanner and consequently not included in software elaboration's data (fig.41).

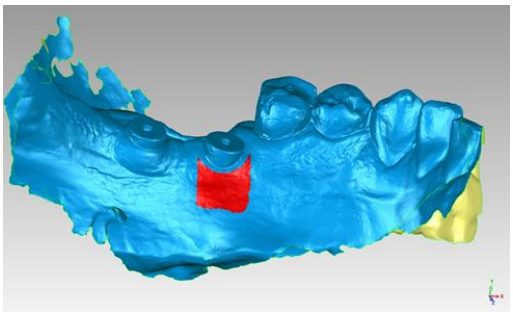


Figure 32: selection of the area on lingual site. control.

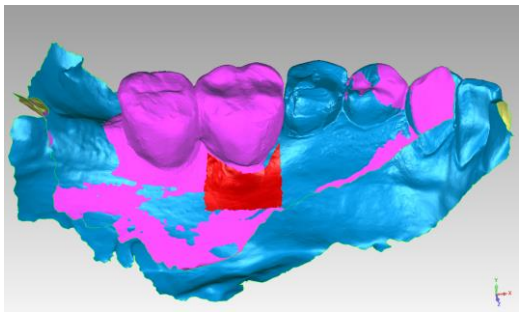


Figure 338: matching of pre-graft and third follow up

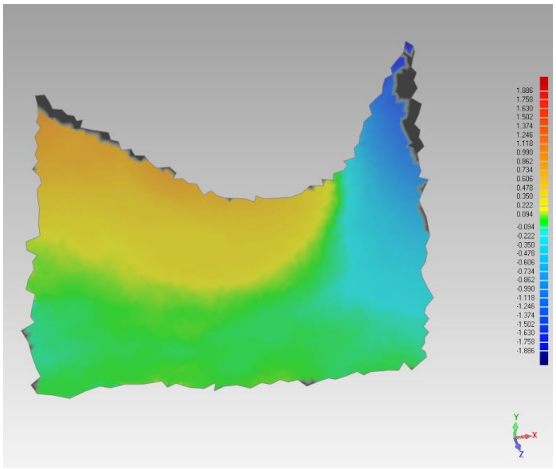


Figure 35: the colorimetric map.

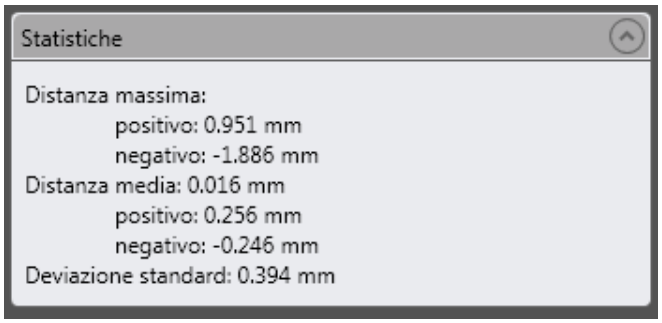


Figure 34: elaboration of the data from the selected area.

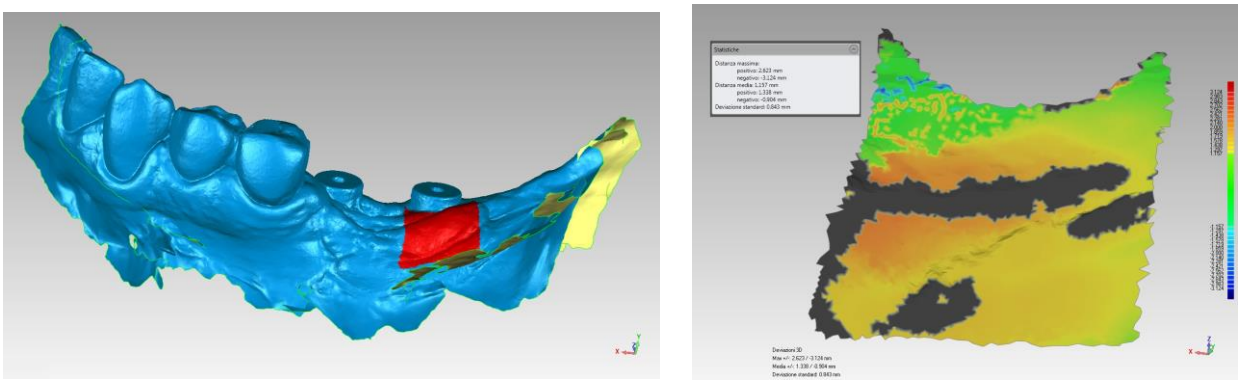


Figure 36:the considered area and colorimetric map of peri-implant site at the first control after the graft.

Statistical methods

Data were collected and subdivided in three groups according to oral site and surgical technique (maxilla bilaminar technique, mandible bilaminar technique, mandible free gingival graft).

The apico-coronal migration was calculated both in mm (absolute value) and as percent variation (relative value).

It is authors opinion that the absolute value does not represent an accurate method of comparison since the initial distance was not equal for all experimental subjects.

The distance between the landmark and the gingiva was calculated as the percent variation between the first and the last survey.

In order to describe the percent variations between the three groups the mean and the standard deviation have been calculated and the values have been reported on the descriptive graphs.

For the comparison between the two groups (test and control) ranks of the original values have been used and Mann – Whitney test[27] has been calculated.

RESULTS

Up to date (15.11.16) the preliminary results of the present study are:

Study design:

Test Group:

- 6 PATIENTS
- 7 GRAFTS
- 9 IMPLANTS

1 patient received 1 graft for 2 adjacent implants.

IMPLANT SITE
- Maxilla: 2 implants (bilaminar technique)
- Mandible: 7 implants
  - Initial KM ≥ 3mm: Bilaminar technique: 4
  - Initial KM ≤ 3mm: Free gingival graft: 3

Control Group:

- 7 PATIENTS
- 7 GRAFTS
- 10 IMPLANTS

1 patients received 1 graft for two adjacent implants.

IMPLANT SITE
- Maxilla: 4 implants
- Mandible: 6 implants
  - Initial KM ≥ 3mm: Bilaminar technique:3
  - Initial KM ≤ 3mm: Free gingival graft: 3

Apical-coronal migration of the peri-implant soft tissues.

Data are presented as mean ± standard deviation (SD) and 95% confidence interval (CI).

For the control group 10 implants were analyzed between first and second evaluation. The mean difference was - 0.011 ± 0.8 mm (95% CI: - 0.3 to 0.27mm).

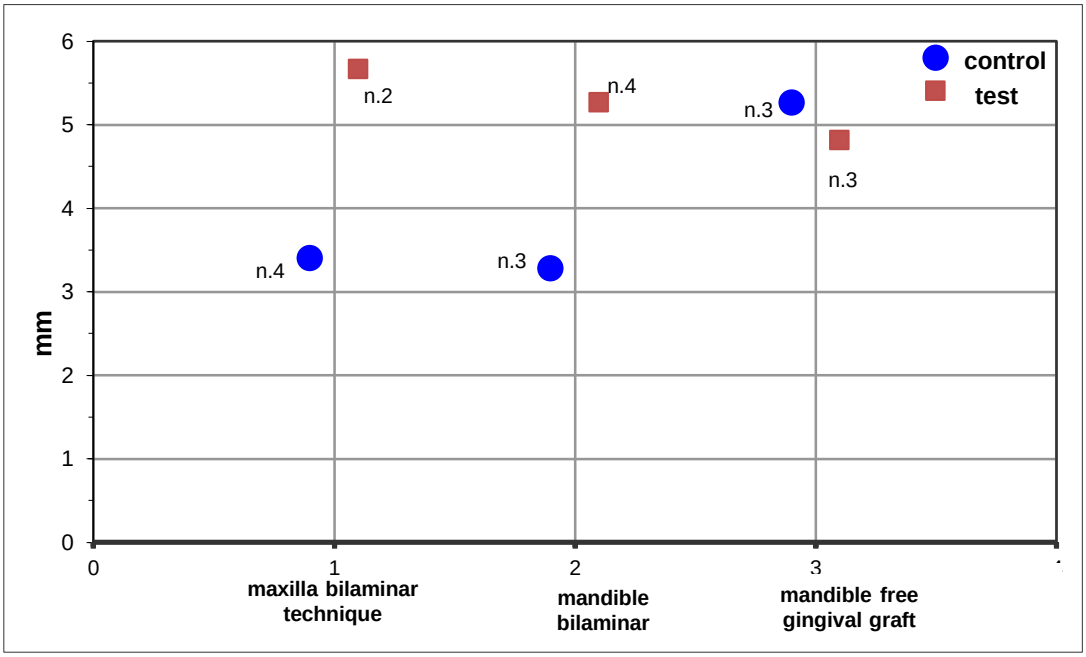
For the test group 9 implants were analyzed between first and second evaluation. The mean difference was 0.0 ± 0.8mm (95% CI: - 0.35 to 0.37mm).

The difference between the control and test groups was not statistically significant.

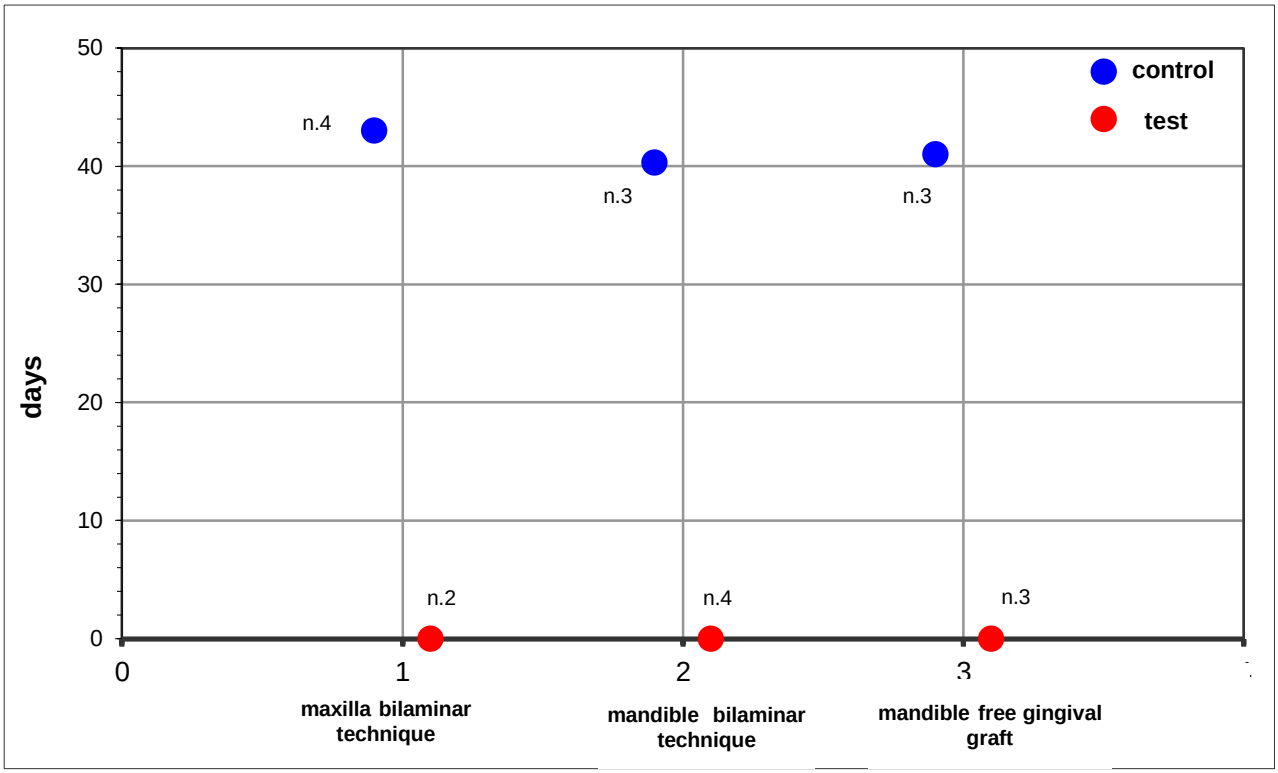
Comparison between test and control considering the three groups according to oral site and surgical technique.

The initial distance between landmark and gingiva was not standardized in the protocol (Graph 3). For this reason it has been opted to express the data regarding the apico-coronal migration of the gingiva in percent values in order to have a more reliable description of the phenomenon. Moreover the evaluation time differences have been taken into account expressing also the daily de-/increase (Δ%/die) and (µm/die) in order to have a more accurate comparison for each group (graphs 4 – 5).

The aim of the present study was to investigate the role of the immediate provisionalization (test) compared with the postponed provisionalization (control) in the conditioning of the perimplant tissue graft. The mean time difference for the provisional crown delivery with respect to the grafting procedure was 41,5 days between the two groups analyzed (graph4).



Graph 3: distance between landmark and the free gingival margin at the time of the first evaluation session.



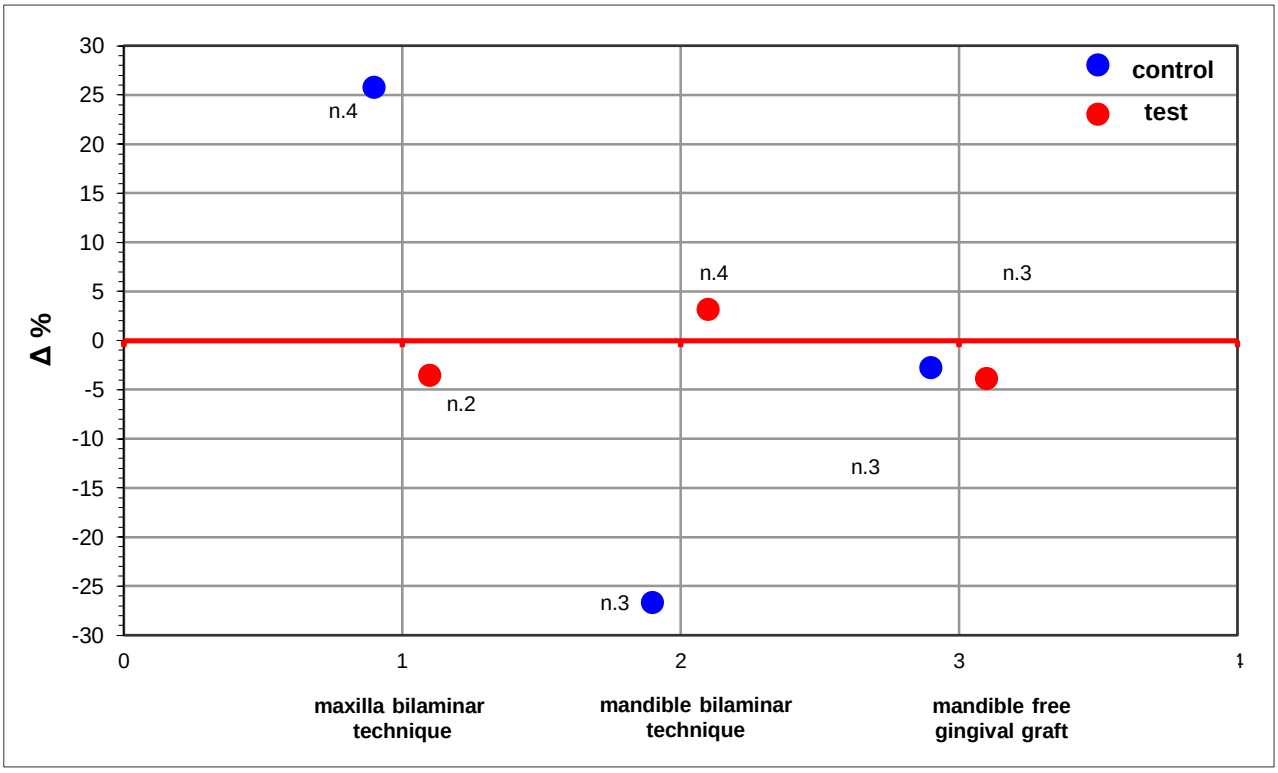
Graph 4: the mean time of the provisional crown delivery for each group.

The percent variation of apico-coronal migration has been analyzed and illustrated in the graph 5.

Considering the maxilla the 4 implants treated in the control group had a distance mean increase of 25.73% (*gingival recession*) while the 2 implants treated in the test group had a distance mean decrease of - 3.59 % (*creeping attachment*).

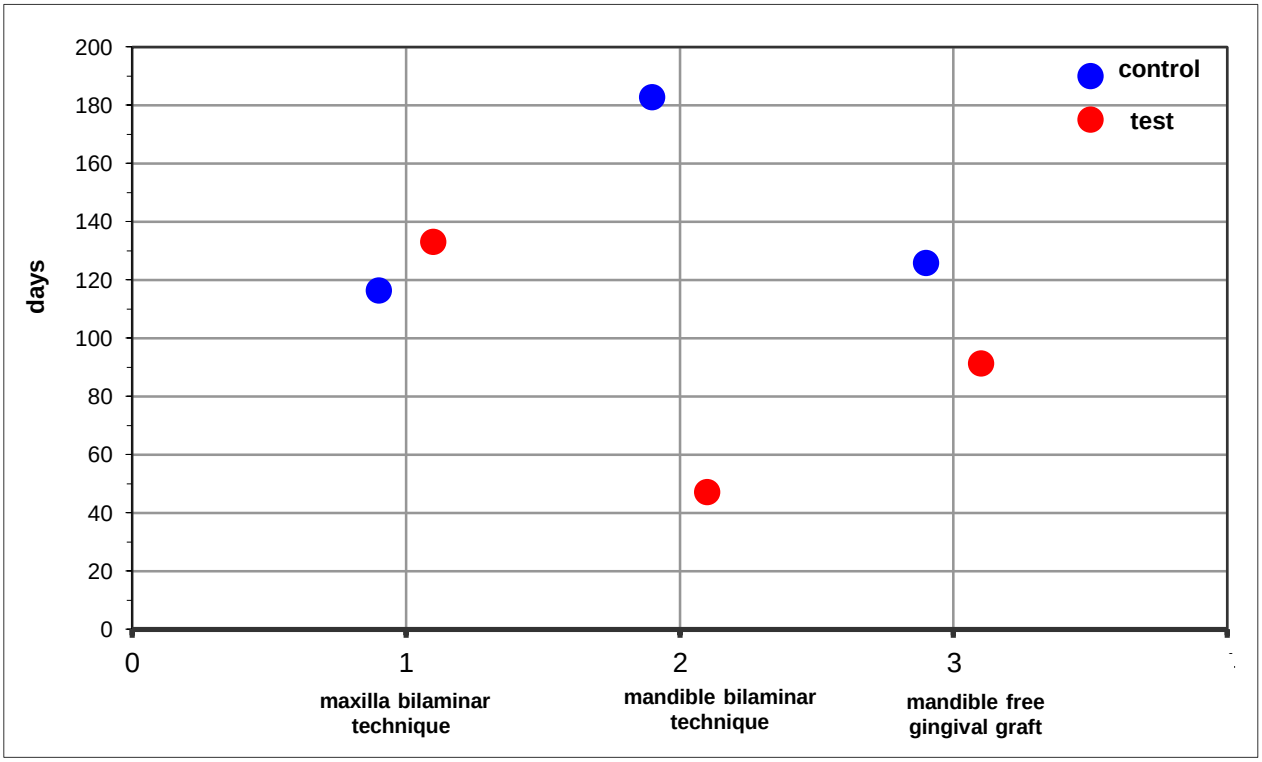
Considering the mandible treated with the bilaminar technique the 3 implants included in the control group had a mean decrease of distance of - 26.71 % (creeping attachment) while the 4 implants included in the test had a distance mean increase of 3.13%. (gingival recession).

Considering the mandible treated with the free gingival grafts both implants included in the control and test groups had a mean distance decrease of - 2.9% and - 3.1% respectively.



Graph5: de-/increase of distance between landmark and free gingival margin for each group.

The mean follow up period was 112, 5 day. At this point of the study, a remarkable difference is present for mandible treated with the bilaminar technique between test and control as observed in the graph 6.



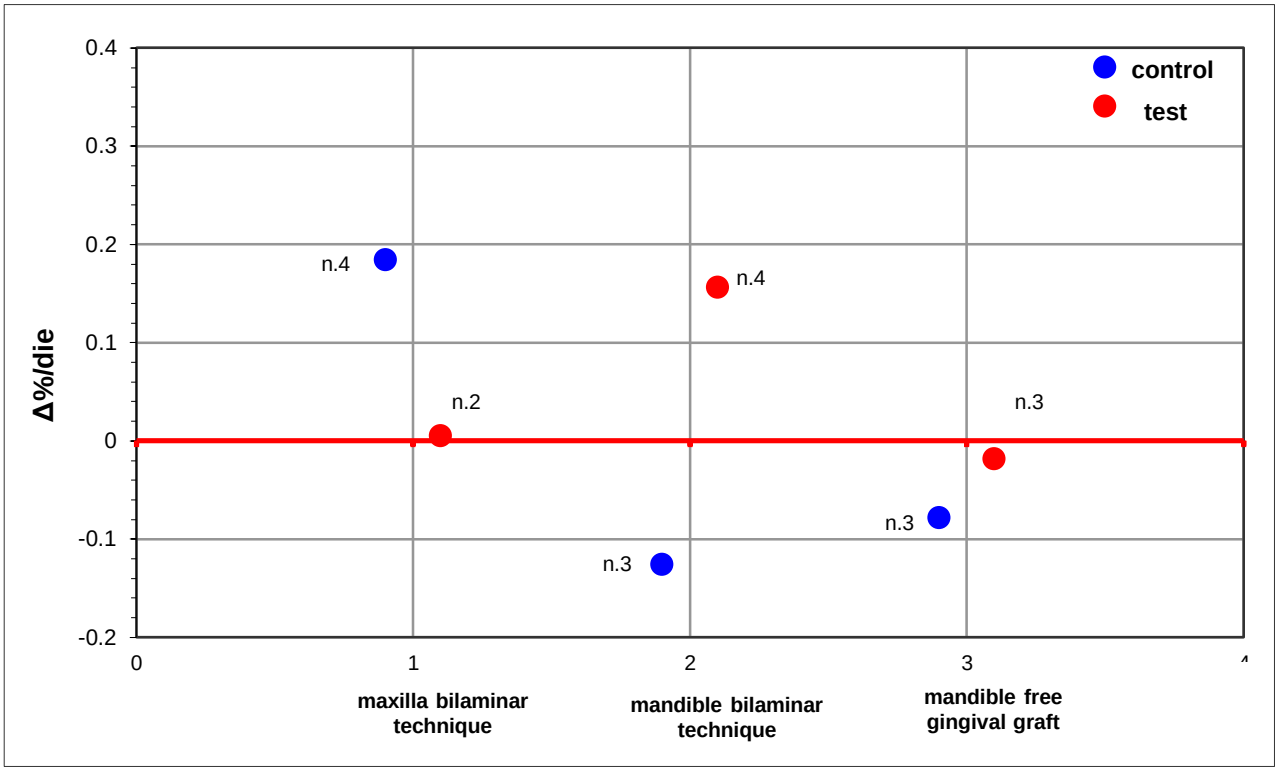
Graph 6: the mean follow-up period (first – last evaluation session) for each group.

It has been caluculated the percent variation of the apico-coronal modification as function of the time interval between the two measurements; consequently it has been expressed a daily de-/increase for each group (graph 7).
In order to simplify the interpretation for each daily percent variation it has been expressed the corrispondent measurment expressed in µm/die.

Considering the maxilla the 4 implants treated in the control group had mean daily increase of 0.18% (6.24 µm/die) while the 2 implants treated in the test group had a mean daily increase of 0.004% (0.23 µm./die).

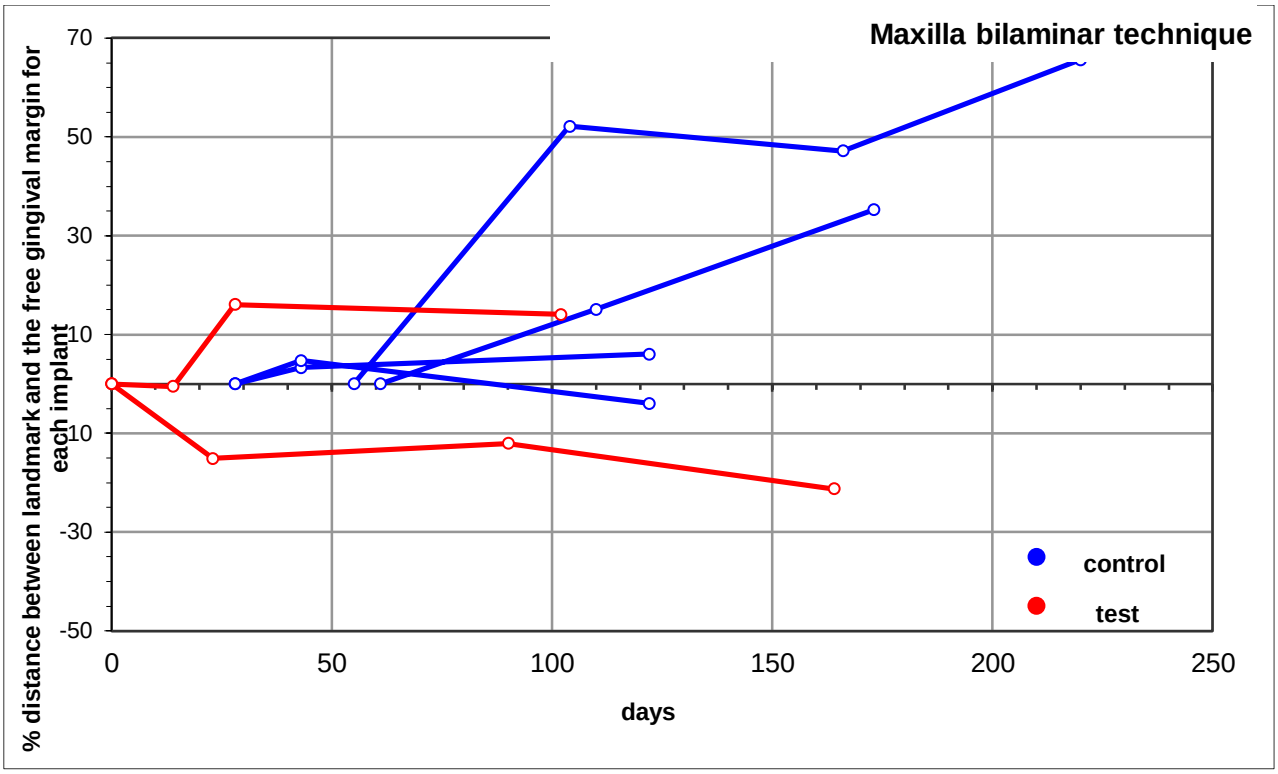
Considering the mandible treated with the bilaminar technique the 3 implants included in the control group had a mean daily decrease of - 0.12% (4,15 µm/die) while the 4 implants included in the test had a daily mean increase of 0.15% (8.17 µm/die).

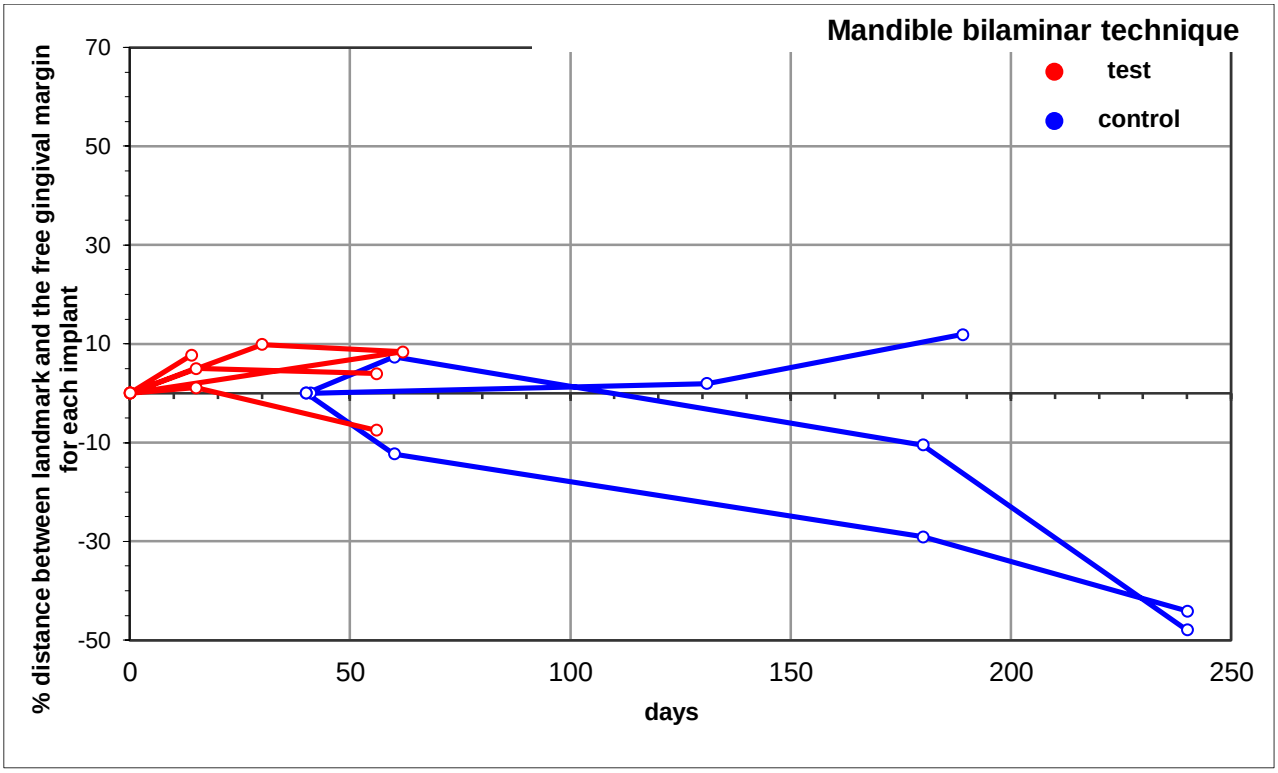
Considering the mandible treated with the free gingival grafts both implants included in the control and test groups had a mean distance decrease of - 0.078% (4.15 µm/die) and - 0.018% (0.91 µm/die) respectively.

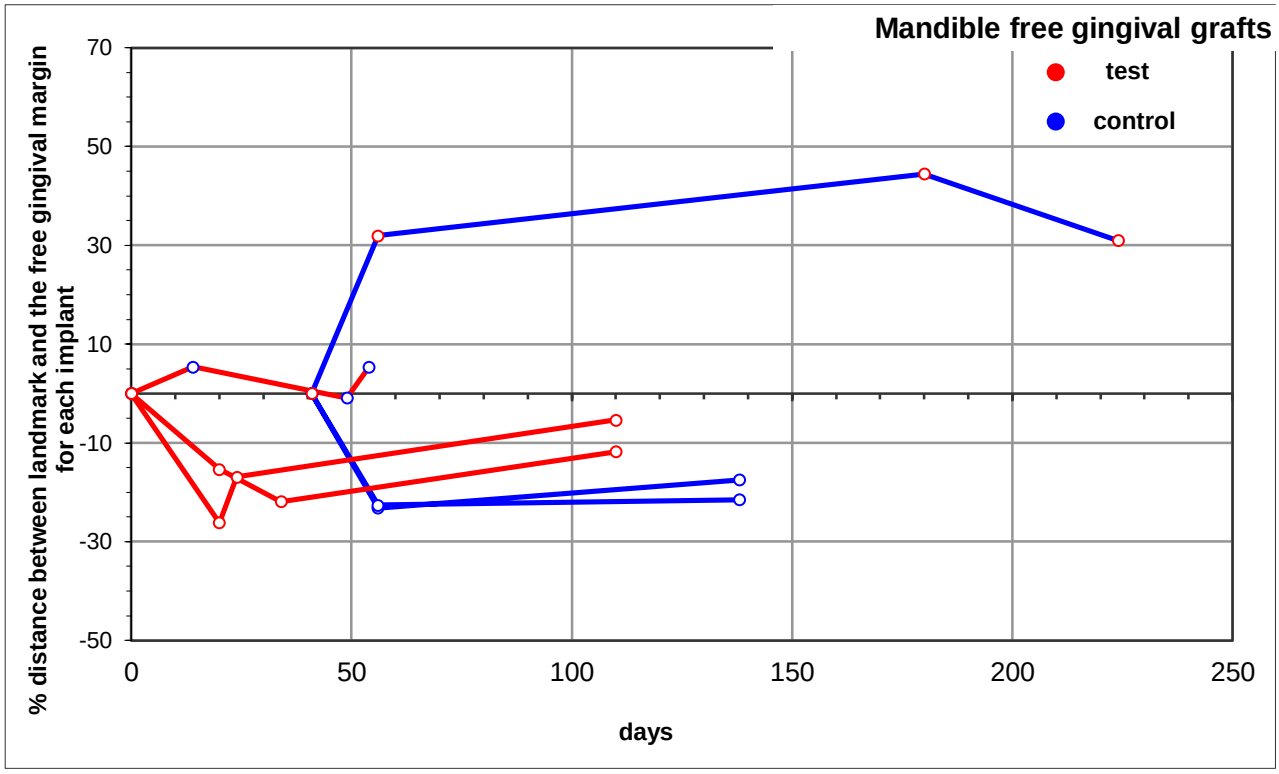


Graph 7: daily percentage de-/increase of distance between the landmark and the free gingival margin.

The following graphs describes the trend for each implant related to the time of follow up. The apical remodeling of the soft tissue margin is a common phenomenon for the bilaminar technique in the maxilla while a slight creeping has been observed in the mandible for the free gingival graft technique.






Mandible free gingival grafts
test
control
% distance between landmark and the free gingival margin for each implant
70
50
30
10
-10
-30
-50
0
50
100
150
200
250
days

Peri-implant soft tissue augmentation.

The soft tissue volume was analyzed both orally and buccally comparing the pre-graft condition with the situation after grafting procedure at first (30 days)and second follow-up (85days).

Vestibular aspect.

For the control group 8 implants were analyzed at the first evaluation. The mean augmentation was 1.17± 0.55 mm (95% CI: 1.12 to 1.45 mm).

For the test group 4 implants were analyzed at the first evaluation. The mean augmentation was 0.82 ± 0.52 mm (95% CI: 0.85 to 0.65 mm).

Comparing test and control groups this difference was statistically significant (p= 0.05).

Lingual/Palatal aspect.

For the control group 8 implants were analyzed at the first evaluation. The mean augmentation was 0.22 ± 0.24 mm (95% CI: 0.04 to 0.35 mm).

For the test group 4 implants were analyzed at the first evaluation. The mean augmentation was 0.33 ± 0.17 mm (95% CI: 0.18 to 0.47 mm).

Comparing test and control groups this difference was not statistically significant (p= 0.35).

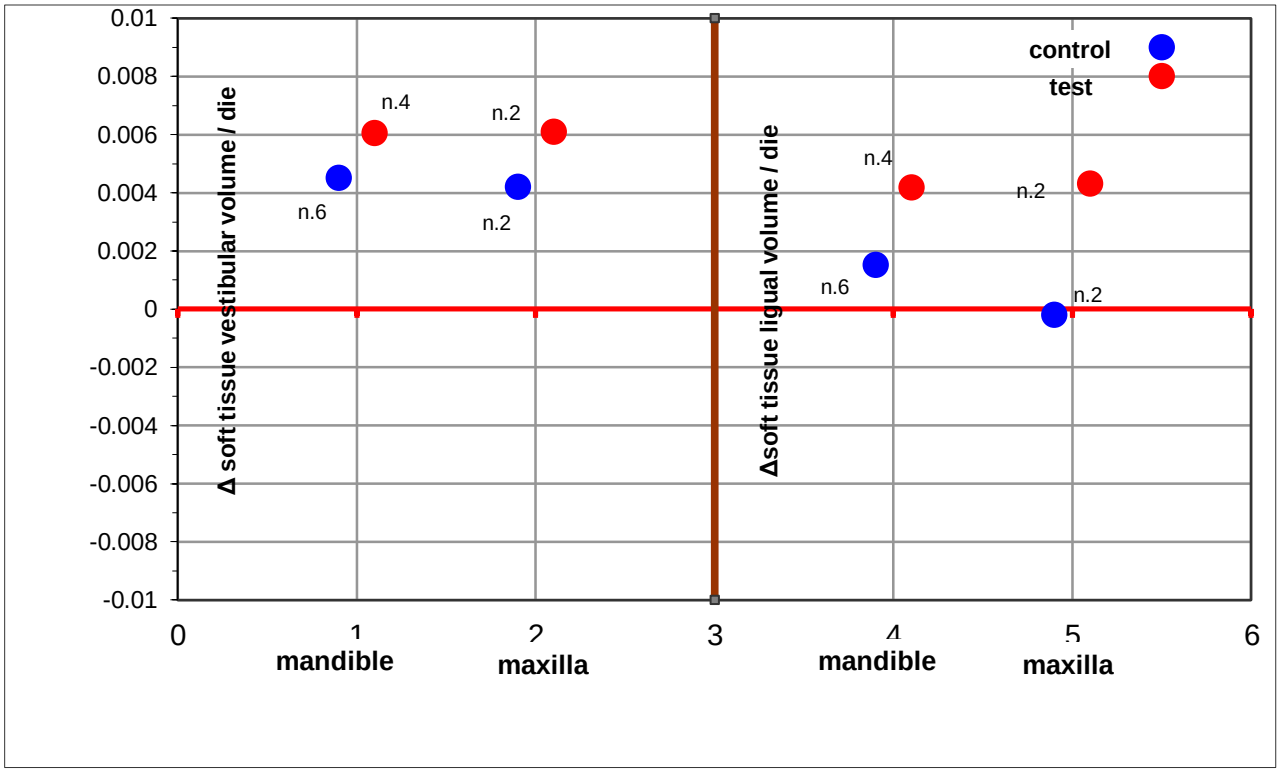
Comparison between test and control considering the two groups according to oral site at the last evaluation session.

For the lack of data available at this point of the study the results have been divided for site (maxilla and mandible) not considering the surgical technique.

In the maxilla the mean augmentation was 1.00 mm (vestibular), – 0. 005mm (palatal) and 0.83 mm (vestibular), 0.59 (palatal) for control and test groups respectively.

In the mandible the mean augmentation was 0.68mm (vestibular), 0.22mm (palatal) and 0.45mm (vestibular), 0.31mm (palatal) for control and test group respectively.

Correlating the mean soft tissue augmentation with the monitoring time for each group it can be observed that the test subjects obtained the highest daily increase both for vestibular and lingual aspect as illustrated in the graph 8.



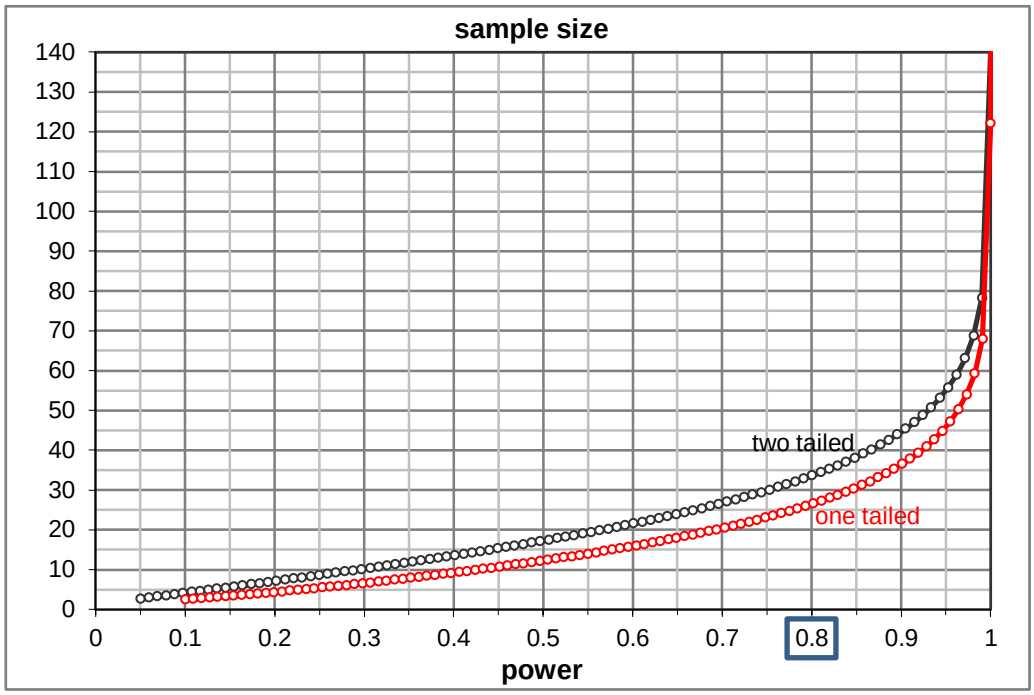
Graph 8: daily soft tissue augmentation on the vestibular and lingual aspect related to oral site (maxilla and mandible).

Considering the percent variation with respect to the apico-coronal migration and the soft tissue volume augmentation the comparison between test and control groups was not statistically significant for each group ($p \geq 0.05$) .

SAMPLE SIZE CALCULATION

The variable adopted to measure the effect of the treatment is the percent variation between the landmark and the gingiva at T0 and the last follow-up. We hypothesize that a 25% variation (1 mm if the initial distance was 4 mm) could represent a clinical success in order to discriminate between the two protocols.

Prior data indicate that the failure rate among controls is 0.25 (25%). In a previous study the response within each subject group was normally distributed with standard deviation 0.36. If the true difference in the experimental and control means is 0.25, we will need to study 34 experimental subjects and 34 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. (two tailed test , presuming a positive and negative difference between tests and controls).
Differently presuming that the test will have a percentage reduction ≥ 25%, the sample size will be 26 (one tailed test).



DISCUSSION

In the present study immediate versus delayed conditioning of the peri-implant soft tissues, associated with submarginal connective tissue graft, for the augmentation/correction of KM and/or soft tissue facial volume has been compared. The two concepts that addressed this investigation were:

1: the insult of prosthetic operation can represent a problem for hard and soft peri-implant tissues [23].

2: the support of the convex profile of the interim crown to the flap which cooperate to stabilize the blood clot and to maintain the space (soft tissue architecture).

The aim of the test treatment was to obtain, in the early period, the maximum sustain of the flap and the grafted area compared with a delayed functionalization at the end of the healing period.

The data obtained in the present pilot study for the mean facial tissue thickening at 1 month from the provisional crown delivery was 1.17 and 0.82 mm for control and test respectively with a statistically significant difference.
The mean lingual soft tissue thickening was 0.22 and 0.33 for control and test respectively but this difference was not statistically significant.
Even if the absolute values obtained at the first evaluation session demonstrated an higher increase of the control group compared with the test, this trend was inverted if we relate these values with the monitoring time. In fact, the maximum daily increase both for maxilla and mandible sites was obtained with the one abutment one time concept applied to the grafting procedure (test group). Another observation from the preliminary data was that the mean increase was generally higher in the maxilla (1 mm controls – 0.83mm tests) compared with the mandible sites (0.68mm controls – 0.45mm tests).
Nevertheless, this differences were not statistically significant among each groups.
In both groups, a trend toward a shrinkage of the graft during follow up periods (3 months) on the facial aspect was observed. This behavior can be also inferred from the colorimetric maps in the example (fig.40 – 44). However, the limited sample has not allowed to draw final conclusions.

Comparing the present data to those present in the literature it is clear that the comparison is really demanding because of the heterogeneity of the data and, most of all, the lack of standardization of the evaluation methods.

In order to compare our preliminary results, the first step was to analyze the most recent systematic review[28] (including articles up to 31 July 2015) concerning the soft tissue augmentation procedures at second-stage surgery. The aim of the review was to evaluate the efficacy of different soft tissue augmentation/correction methods in terms of increasing of the peri-implant width of KM and/or gain of soft tissue volume during second-stage surgery.

The screening of two databases, MEDLINE (PubMed) and EMBASE, and hand search of related articles was performed in the review. The quality assessment of the selected full-text articles was performed according to the Cochrane collaboration's tool to assess the risk of bias. Only eight prospective studies and two case series passed the study selection inclusion criteria, however the risk of bias was high.

Focusing the attention on the parameters analyzed in the eight studies included in the review, it was clear that the only parameter taken into account was the width of KM which ranged from -0.2 to 9.35 mm whereas the increase of the soft tissue volume is discussed only in one cases series report[29] in which no criteria of standardization have been followed.

In this case series, the authors evaluated the height of KM and the mean gain in tissue thickness measuring data preoperatively and 2 weeks and 3, 6 and 12 months after second stage surgery.

In this work three different techniques of stage-two surgery have been compared: apically repositioned flap (n = 14), the roll flap (n = 10) and an apically repositioned flap combined with a connective tissue graft (n = 8). The mean gains after 1 year, were 1.37, 2.41 and d 3.10 mm respectively.

As it can be observed, data obtained from the bilaminar technique are almost 3 times higher than those found in our study.

Nevertheless if we analyze the method adopted for the evaluation by the authors they used a resin stent associated with a periodontal probe (fig.45) which perforated the mucosa always in the same point before and after grafting procedure. It's author's opinion that this method could not be comparable to that adopted in our study for two reasons.

- Firstly this method does not describe the real tridimensional situation of the grafted area but it is only the approximation of one random point into the graft. Conversely, the method that we have adopted, as it can be observed from the map (fig. 42), describes the peri-implant area including partially the papillae and extending the analysis till the mucogingival line. As a matter of fact, this representation of the reality by a digital method is more accurate including the neighboring zones of the grafted area. We opted in this case to express the mean value calculated with the software but for a suitable comparison we should have taken the maximum value of the grafted area which generally coincide with the point taken by Tunkel et Al. with the probe.

- Secondly the evaluation method adopted by Tunkel et Al. is probably inaccurate because of the uncertainty of reaching the hard tissue with the same projection to all the evaluation sessions. The method entrust to hand sensibility of the operator which is generally conditioned by the pain of the patient or probably is invalidated by the soft tissue swelling if the measurement is taken under local anesthesia. Moreover the accuracy of a periodontal probe is generally rounded to the nearest millimeter respect of the elaboration of the software which includes the decimal fraction of the millimeter. In our study in fact we opted to abandon this method for reasons explained and for the high risk to incline the probe in the molar area where the accessibility to the grafted site is surely more challenging.

The second endpoint of the present study was to compare the free gingival margin recession starting from the provisional crown delivery both contextually and delayed to the grafting procedure. The aim of this pilot study was to find a threshold value which could differentiate the investigated protocols.

At this point of the study no differences between the two groups could be found from the preliminary results.

Observing the absolute values expressed in mm the modifications found in both groups were clinically irrelevant. We can notice a slight creeping of the gingiva of 0.28 mm in the control subjects while a irrelevant recession - 0.43 mm was found in the tests. Considering the small sample size of implants reaching the last follow up, no conclusion could be speculated which could address the clinician to choose between the two techniques.

Trying to compare our preliminary data with respect to the gingival shrinkage after provisionalization an important work of Stoupel J. et Al. was published in 2016[30]. The study compared the gingival recession of the immediate implant placement and provisionalization with or without a flapless approach.

At 3 months post-surgery, the mean mesiobuccal peri-implant gingival margin recession from the pre-surgical soft tissue position amounted to 0.11 ± 0.32 mm in the flapless surgery treatment versus 0.43 ± 37 mm in the open flap approach.
The data found in this study are of the same order of magnitude with those found in our study.
Also in this case a reasonable comparison is complex; in fact the mentioned studies do not express an initial standardized value both for graft volume gain and gingival margin recession. As it can been observed in the figures 45a,b extracted from the papers, the initial values are not equal for all the implants included in the studies. Consequently, the absolute values expressed could be considered appropriate only for the comparison between the same implant. This comparison for different implants in the same or different studies is correct if the initial conditions have been previously standardized (for example, the initial distance was 3 mm and the initial soft tissue thickness was 2 mm for all implants included in the protocol). If not standardized, the only method to compare the variation's values remain its expression in percentage.

Indeed, an incremental/ shrinkage or recession/creeping of the peri-implant soft tissue of 1 mm has a different "weight" if the initial distance measured from the landmark was 2 or 5 mm; in the first case the variation is of 50% while in the second of the 20%.

In fact comparing the data of the present study considering the percent values we have found a 26% mean increase of the distance (recession) in the control group for the maxilla while a slight creeping attachment has been found in the test -3.59%. In the mandible this trend was reversed for the bilaminar technique while for the free gingival graft approach a slight creeping has been found in both groups.

Reducing the bias related to the different evaluation times, especially in the mandible, we expressed the same value as the mean daily de-/increase for each group dividing the percent increase for the time of the follow-up. Observing the graphs 5 and 7 in fact it can be noticed how this differences tend to even off and the discrepancies between test and control are less remarkable.

Clinical Considerations:
Considering the lack of available information from the preliminary results it is impossible to assess which is the best therapeutic option, therefore the clinical observations that we have done during this protocol are the following:

- Both the prosthetic-surgical approaches are valid in order to treat limited horizontal defects with the application of connective tissue graft without recurring to costly, invasive and long lasting guided bone regeneration procedures.

- The idea to position the provisional crown contextually to the re-entry surgery in order to guide the peri-implant grafted tissue has given the impression to favor the healing and the maturation. In fact, as observed in figures 47 and 48, where a provisional crown has accidentally decemented 3 weeks after the surgical procedure, the grafted area has revealed an advanced grade of maturation in terms of volume and tissue texture compared to the cases generally observed in the control group. In figure 48, the same case at the initial situation and at the time of the definitive crown delivery, in which the augmented facial volumes enhance aesthetic and function.

- Conversely, the cases treated in the test have shown an higher incidence of intraoperative complications. The simultaneous management of the prosthetic and surgical phase has prolonged the time and increased the difficulties related to cementum removal.

- Moreover, in test group with intraoperative impressions at the time of implant placement, the finishing line of the crown was positioned 2 mm above the bone crest in order to not invade the biological width. This has caused in some implants the partial exposure of the abutment and consequently the lack of the peri-implant graft conditioning. This fact has caused the loss of immediate conditioning as we had planned. Nevertheless the BOPT and the vertical abutment preparation has allowed to change the final finishing line simply shortening the metals without reducing the quality of the closure. This advantage reduces time and cost with respect to an horizontal abutment preparation design.

The clinical considerations expressed are in line with those present in the recent literature concerning the use connective tissue graft for the treatment of facial bone deficiencies and the probable advantages descending from immediate provisionalization. A recent work of Stefanini et Al.[31] reports the short and long term results of the soft tissue stability of a surgical technique combining transmucosal implant placement with submarginal connective tissue graft (CTG) in an area of a shallow buccal bone dehiscence. In the work, a sample of 20 patients have been treated by positioning a transmucosal implant in an intercalated edentulous area. A CTG sutured to the inner aspect of the buccal flap was used to cover the bone dehiscence. Statistically significant increases in buccal soft tissue thickness and improvement of vertical soft tissue level were achieved at the T_1, T_2, and T_3 follow-ups. A significant increase in keratinized tissue height was also found at T_3. No significant marginal bone loss was recorded. The Authors remarked as the submarginal CTG technique was able to provide simultaneous vertical and horizontal soft tissue increases around single implants with shallow buccal bone dehiscence and no buccal mucosal recession or clinical signs of mucositis or peri-implantitis at 1 and 3 years. This work confirm the efficacy of the correction of limited facial deficiencies treated with connective tissue graft without recurring to bone grafting procedures.

Another interesting work comparing immediate implant placement and provisionalization with and without a connective tissue graft in terms of facial gingival tissue thickness was published in 2012[32].

The purpose of this study was to investigate the change in facial gingival tissue thickness (FGTT) after immediate implant placement and provisionalization with and without a connective tissue graft.
The mean FGTT of both groups at prosthesis delivery was significantly higher than that at tooth extraction. The mean change in FGTT in the CT group was also significantly greater than that in the NCT group. Immediate implant placement and provisionalization in conjunction with a connective tissue graft is more likely to result in sufficient peri-implant tissue thickness to conceal underlying implant restorative materials than when performed without a connective tissue graft.

Limits of the study.

The limit of this study is related to the small number of the sample respect to the variables that have been analyzed and its variance. The second limit is related to the bias of statistical unit (implants/patient) analyzed. In fact the grafts that have been considered are related to implants. Two adjacent implants with the same graft on the same patient have a different "weight" with respect to the graft on two different patients. The heterogeneity related to individual variability has not been considered in this pilot study. For this reason the purposes are the subdivision of the data according to patient unit.

An illustrative example of the soft tissue modification in Test Group both in vivo and on the colorimetric maps.

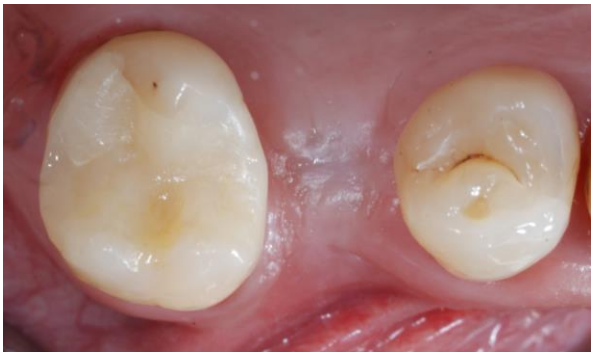


Figure 372: clinical situation before the grating procedure.

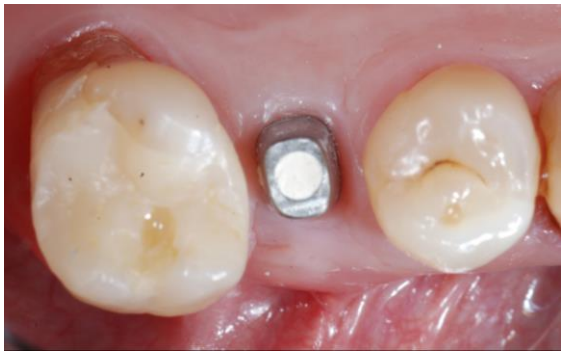


Figure 43: clinical situation at the time of definitive crown delivery.

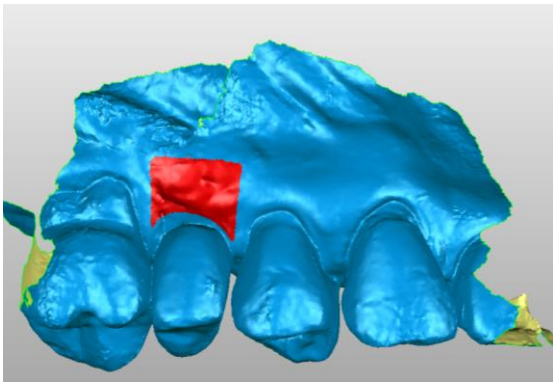
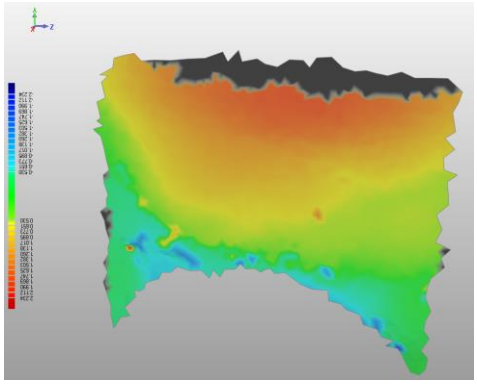


Figure 384: in red color the grafted selected area.



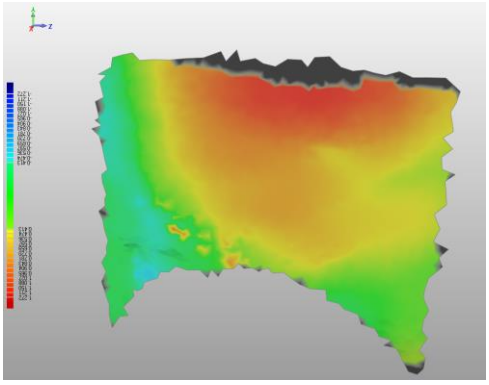


Figure 39a,b : in these maps the soft tissue changes between pre-graft condition and after 1 and 3 months respectively.

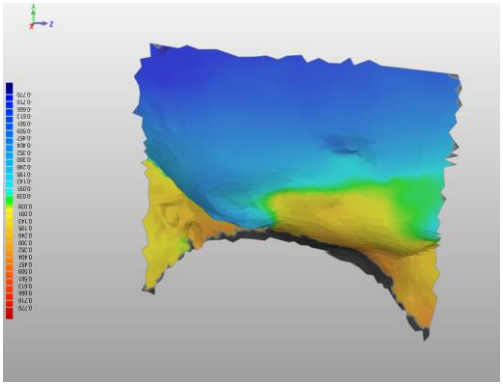


Figure 406: the soft tissue shrinkage between first and second follow up.

Figure 41a: soft tissue evaluation with periodontal probe combined with a resin stent.

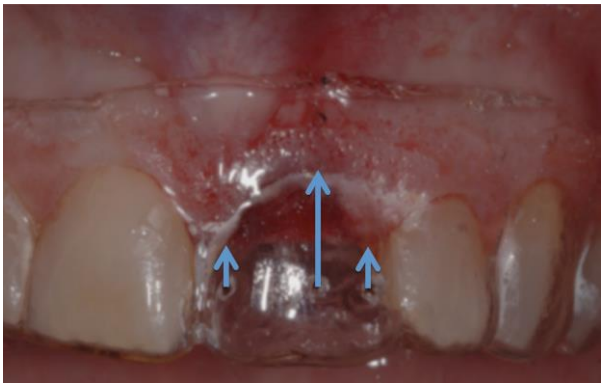


Figure 428: gingival margin recession evaluation with a periodontal probe combined with a resin stent.

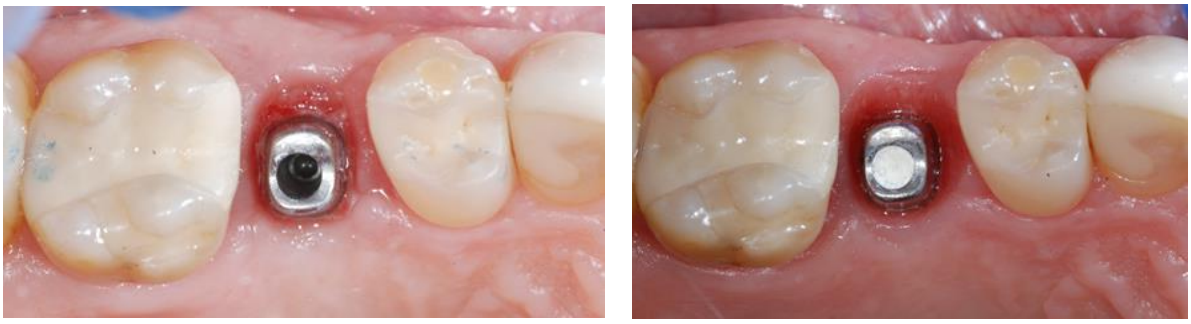


Figure 439a,b: soft tissue maturation after grafting procedure contextually with immediate provisionalization (test group) at 3 weeks and 6 months respectively.

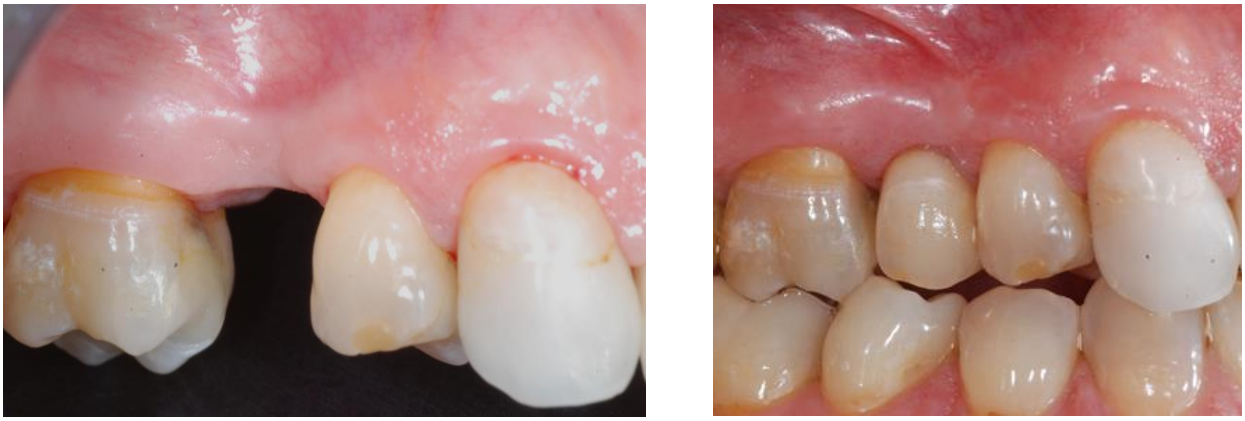


Figure 44: Initial and final lateral view of the case treated in test group.

CONCLUSIONS

From the preliminary results obtained from this study it has been determined the threshold value which could clinically discriminate between the two protocols. The variable adopted to measure the effect of the treatment has been the percent variation between the landmark and the gingiva at T0 and the last follow-up. We have hypothesized that a 25% variation (1 mm if the initial distance was 4 mm) could represent a clinical success in order to discriminate between the two protocols. In this previous study the response within each subject group was normally distributed with standard deviation 0.36. If the true difference in the experimental and control means is 0.25, we will need to study 34 experimental subjects and 34 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. (two tailed test, presuming a positive and negative difference between tests and controls). Differently presuming that the test will have a percent reduction ≥ 25%, the sample size will be 26 (one tailed test).

From a clinical point of view, both surgical –prosthetic approches could be considered efficient to treat limited horizontal bone defects even if for the small size of the sample it is not possible to establish which is the best option. The free gingival graft technique has demostrated a slight creeping of the gingiva both in control and test groups.

The one abutment one time concept combined with BOPT technique on implants reveald an higher daily soft tissue volume increase compared to the delayed conditioning approach even if this difference was not statistically significant.

The preliminary results obtained from this study will be employed for a further randomized clinical trial.

ABSTRACT

Keywords : Implant-Abutment Design, One abutment-One time, Soft tissue augmentation, Dental Implants.

Aim of the study : the aim of the present study was to investigate the most effective timing of the surgical-prosthetic procedure in order to obtain a stable soft tissue augmentation around dental implants using BOPT abutments.

Materials and Methods : Overall, 13 patients have been enrolled. A total amount of 21 implants have been placed and they have been alternatively assigned to the case (immediate provisionalization) or control group (delayed provisionalization) on the basis of the waiting list. The clinical criteria adopted for the enrollment in the study were the partial edentulism in which the teeth were lost at least 2 months before the date of implant placement with KM lower than 2 mm or inadequate soft tissues volume for a proper ridge contour. The two parameters evaluated for test and control groups were the apico-coronal migration and the soft tissue gain after grafting procedure.

Results : gingival recession: for the control group 10 implants were analyzed between first and second evaluation. The mean difference was - 0.011 ± 0.8 mm (95% CI: - 0.3 to 0.27mm). For the test group 9 implants were analyzed between first and second evaluation. The mean difference was 0.0 ± 0.8mm (95% CI: - 0.35 to 0.37mm).

Soft tissue gain: for the control group 8 implants were analyzed at the first evaluation. The mean augmentation was 1.17± 0.55 mm (95% CI: 1.12 to 1.45 mm). For the test group 4 implants were analyzed at the first evaluation. The mean augmentation was 0.82 ± 0.52 mm (95% CI: 0.85 to 0.65 mm).

Conclusions : Both the prosthetic-surgical approaches are valid in order to treat limited horizontal defects with the application of connective tissue graft without recurring to costly, invasive and long lasting guided bone regeneration procedures. Considering the lack of available information from the preliminary results it is impossible to assess which is the best therapeutic option. A total amount of 34 implants will be necessary to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8.

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