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SPECIAL DENTAL ISSUE

Hard and soft tissue changes in the rehabilitation of the anterior maxilla with triangular shape neck implants: A retrospective clinical study with a one-year follow up.

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Running title: hard and soft tissue changes around immediate implants

Conflicts of interest.

The authors declare they have no conflicts of interests.

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Abstract

Aim. Aim of this retrospective study was to evaluate the one-year clinical and radiographic outcomes of implants with a triangular shaped neck inserted immediately after tooth extraction in esthetic zones.

Materials and Methods. Patients in which immediate postextraction implants were placed and restored in the anterior maxilla, who underwent a Cone Beam Computed Tomography (CBCT) at baseline and after 12-16 months were included. The socket was preserved using deproteinized bovine bone to fill the buccal gap, and a resorbable collagen membrane. One-year implant survival and prosthesis success were evaluated. Hard and soft tissue stability was assessed by measuring various parameters on CBCT images. Clinical evaluation was also performed and Pink Esthetic Score (PES) assessed. Data from baseline and one-year follow-up were statistically compared using paired tests and a significance threshold of $p=0.05$.

Results. Twenty patients (13 males, 7 females, mean age 50.42 ± 11.35 years) were included. Each contributed with one implant. No implant was lost. A significant improvement in PES was detected. Excellent hard and soft tissue preservation was observed after one year of function.

Conclusion. Immediate placement of implants with a triangular shaped neck after tooth extraction, can be a suitable solution even for areas with a high aesthetic demand, such as the anterior maxilla.

Key words: alveolar socket preservation; anterior maxilla; CBCT; dental implants; hard tissue changes; immediate implants; soft tissue changes

Introduction

Implant placement is a well-documented procedure, which, when combined with a good case selection and operator's experience, can produce excellent long term outcomes and high predictability for the replacement of a missing tooth or a tooth that needs to be extracted^{1,2}. However, when such tooth is situated in the anterior maxilla, achieving a successful outcome becomes particularly challenging, mainly because of the high aesthetic demand of this region. Several factors have been shown to affect the success rate of implant placement, with timing of implant placement, loading protocol as well as implant design being among the most important ones^{3,4}.

When deciding to rehabilitate a post-extraction site, the operator can choose between four different protocols regarding the timing of implant insertion after extraction: immediate, early placement with soft tissue healing, early placement with initial bone healing, and late placement, which includes a healing time of at least six months after extraction⁵.

Nowadays, for the anterior maxilla, the late implant placement without using a socket preservation technique is almost never an option, not only for aesthetic reasons but also for the unpredictable level of bone change that a prolonged healing time can produce. Actually, immediate implant placement constitutes a treatment of choice in cases showing a good preservation of the socket's walls after the extraction⁶. Nevertheless, Physiological alterations of facial and palatal bone surfaces at the implants should be taken into consideration, so that this approach may be considered at risk for esthetic reasons^{5,6}.

Conventional periapical radiograph does not allow a proper visualization of the socket bony walls as it only provides a bi-dimensional view. In contrast, dental cone beam computed tomography (CBCT) enable clinicians to accurately evaluate the possibility of placing an implant with respect to alveolar bone anatomy. The latter has become widespread among implantologists as it represents an excellent tool for diagnosis and treatment planning. At the same time it allows patients for lower radiation exposure with respect to conventional CT-scan technique⁷.

When it comes to different loading protocols after implant placement, the traditional approach implies a load-free healing time of 3-6 months. However, for aesthetic

demand of this specific region, and because already published studies have reported no difference in terms of implant failure and marginal bone changes between immediate and non-immediate loading protocol^{8,9}, the immediate loading protocol has gained much popularity among operator's and patient's preferences.

On the other hand, implant design has been confirmed to play an important role in the overall success of implant placement¹⁰. Implants with a rough surface neck and platform-switching design, are shown to have a higher success rate and lower marginal bone loss than implants with a standard design^{11,12}. Countless implant types with different micro and macro design have been proposed¹³. However, there is little evidence on whether implants' neck shape can play any role in the overall success rate of an implant, as well as in peri-implant bone preservation.

In the present retrospective study, we aimed to address these three components of an implant treatment protocol of a single tooth post-extraction site in anterior maxilla: immediate implant insertion, immediate loading and triangular neck implant design, and report the a one-year follow up of such combination in terms of function as well as aesthetic outcomes.

Materials and Methods

This clinical study was based on patients treated at two dental offices in Northern Italy, between October 2015 and December 2017, All patients were treated following the principles embedded in the Helsinki Declaration. Two equally experienced surgeons performed the operations. A total of 111 patients received a total of 158 implants, inserted immediately after tooth extraction at the anterior maxilla. All patients were recalled at one year follow up. For the present study a sample was selected from such pool of patients, based on the following inclusion criteria: patients with at least one post-extraction implant in the anterior maxilla showing socket walls with no more than 4 mm of buccal bone dehiscence; patients with a thorough clinical and three-dimensional radiographic examination at baseline (prior to implant insertion and immediately after implant insertion); capability to sign an informed consent; thirty to 70 years of age; ASA I (American Society of Anesthesiologists classification); patients who had undergone a further three-dimensional CBCT

examination for other medical purposes in a period twelve to sixteen months after implant insertion, in which the anterior maxilla region was visible. Applying the above criteria, twenty patients (13 males and seven females, with a mean age of 50.42 ± 11.35 years), were included in this retrospective clinical study. One implant per patient was evaluated. If patients had more than one implant in the anterior maxilla, only one was chosen randomly by coin toss.

Baseline examination

All patients had received a thorough baseline examination prior to implant insertion, which included the evaluation of the following clinical and radiographic parameters. Clinical parameters: Gingival biotype (GB) measured by means of periodontal probe assessment as described by De Rouck et al¹⁴, which was shown to be significantly superior to visual measurements and not significantly different to direct measurements¹⁵; width of keratinized mucosa (KM); mid-facial height of the failing tooth crown (FTCH) if present and intact, defined as the distance from incisal to gingival border of the labial aspect of the crown; the corresponding height of the contra lateral tooth crown (CTCH); the Pink Esthetic Score (PES) of the tooth to be extracted, as reported by Furhauser et al¹⁶. Values for KM, FTCH and CTCH were measured with a periodontal probe to the nearest millimeter.

Surgical procedure

The first step of the surgical procedure consisted of a careful tooth extraction with the intention to minimize the mechanical trauma to the surrounding bone. Then, socket was thoroughly debrided and its apical portion was prepared according to the manufacturer's surgical protocol. A triangular-shaped conical connection bone-level implants with platform switching (V3; MIS Implant Technologies Ltd., Bar-Lev Industrial Park, Israel) was immediately placed in the prepared sites. Care was taken to place the implant shoulder approximately 3 to 4 mm below the ideal buccal gingival margin of the future restoration, leaving one of the sides of the triangular collar on the buccal site. The implant buccal bone gap was filled using a deproteinized bovine bone substitute (Bio-Oss®, Geistlich Pharma, Wolhusen, Switzerland) covered with a resorbable membrane (Bio-Gide®, Geistlich Pharma) in all cases.

Immediate loading with provisional abutments and resin crown was delivered for all cases in the subsequent 24 hours, given an insertion torque value greater than 30 Ncm. Definitive restorations in zirconia were delivered after a minimum of 5 months healing time before the first removal (disconnection) of the provisional restoration.

Follow-up examination

The outcome variables evaluated 12 to 16 months after implant placement were:

1. *Implant survival*, evaluated based on the following criteria: presence of the implant in the patient's mouth, absence of peri-implant radiolucency, no recurrence or persistent peri-implant infection and no complain of pain and of neuropathies or paraesthesia.
2. *Prosthesis success*, defined by the presence of functional prosthesis in patient's mouth with no mechanical complications.
3. *Buccal bone alterations*, evaluated with a radiological examination.
4. *Buccal soft tissue alterations*, evaluated with a radiological examination.

The above parameters were evaluated by the following methods:

Radiographic examination

All CBCTs were taken with the same device (Promax 3D Classic - Planmeca, Helsinki, Finland) before tooth extraction and immediately after implant insertion in order to evaluate bone graft placement. The device had the following specific technical parameters: Field of View of 8 x 8 cm, voxel size of 0.150 mm, an exposure setting of 6.3 mA, 90 kV and a scanning time of 12 seconds. In addition, a further CBCT was taken 12 to 16 months after implant insertion for other medical purposes, was used in all cases where the anterior maxilla region was visible. A dedicated software (Romexis, Planmeca) in combination with a high-resolution screen (5120×2880, 500 nits luminance) was used for measurements, which were recorded in the central-alveolar cross-section slice.

Each CBCT volume was re-oriented according to the long axis of the implant, which was used as a reproducible reference for avoiding image distortion. The central-implant cross section slice served for measurements.

The following parameters were measured on the CBCT.

- *Bone Height (BH)*: The vertical height from the implant platform to the most coronal point of the buccal bone.
- *Bone Contact (BC)*: The vertical height from the implant platform to the first bone-to-implant contact point.
- *Bone Width (BW)*: The horizontal thickness of the buccal bone measured at 0 (BW0) and 2 mm (BW2) apical to the platform, respectively.
- *Mucosal Height (MH)*: The vertical height from the implant platform to the marginal soft tissue level.
- *Mucosal Width (MW)*: The horizontal thickness of the buccal mucosa measured at 0 (MW0) and 2 mm (MW2) apical to the platform, respectively.

All parameters were measured at the CBCT immediately after implant insertion and at the one taken at the 12-16 months follow-up. Positive and negative values of BH, BC and MH indicate bone levels coronal and apical to the implant platform, respectively. All distance recordings were done with 0.01 mm precision.

PES index

In order to evaluate objectively the esthetic outcome of the implant crowns at each of the scheduled stage, the PES index was scored by a single operator and critically controlled by two examiners (ST, TW) via digital images. The PES index consisted of five parameters (Table 1) with a maximum score of 10, representing optimum esthetic outcome with respect to the peri-implant soft tissue conditions. The minimum value for clinical acceptability was set to 6.

Statistical analysis

Descriptive statistical analysis was performed. Data were synthesized using mean value and standard deviation for the quantitative variables. Changes in marginal bone level and soft tissue parameters, were evaluated using paired Student's T-test. Statistical significance was set at $P < 0.05$.

Results

Implant distribution was as follows: central incisors (seven implants), lateral incisors (four implants), canines (two implants), premolars (seven implants).

Patients' clinical and three-dimensional baseline parameters are shown in table 2a,b. Implant survival was 100% as well as prosthesis success at one-year follow-up.

PES index scores are shown in table 3. A statistically significant improvement was registered at the one-year follow-up. Three-dimensional measurements of bone and soft tissue parameters are shown in table 4 a,b. A statistically significant decrease of the vertical height from the implant platform to the first bone to implant contact (BC) was registered at the one-year follow-up.

Two-dimensional measurements of bone parameters for the 6-month and one year follow up are shown in table 5. A statistically significant difference was registered between the 6-month and one-year follow-up for the mesial bone parameter, with the results at one year follow-up displaying a lower bone height.

A clinical case is shown in figures 1-2 as an example. Figure 1a and 1b illustrate the measurements of the hard and soft tissue parameters at baseline and 1-year follow-up, respectively, using CBCT. Figure 2a and 2b show clinical buccal views of the same case, before extraction and at 1-year follow-up, respectively. The probe in Fig. 2a evidences the buccal bone dehiscence.

Discussion

The outcomes of implant treatment in the esthetic areas such as anterior maxilla have dramatically improved in the last fifteen to twenty years, parallel to the knowledge of tissue response and the development of specific techniques and materials. The aim of achieving a functional rehabilitation with the best esthetic outcome possible, has encouraged research in three areas: immediate post-extraction implant insertion, immediate loading, and implant design¹⁷. Most of the studies agreed that there is a higher risk of mucosal recession, in the range of 20-30%, related to immediate implant placement when compared to other protocols¹⁸. However, given that well-defined inclusion criteria were not yet established, an ITI Consensus Conference delivered clear clinical guidelines in which strict inclusion criteria were emphasized as one of the main factors influencing the treatment outcome¹⁹.

On the other hand, providing an initial provisional restoration immediately after implant insertion, introduces significant advantages in terms of reducing bone contour changes²⁰. All patients included in this retrospective study had received a definitive restoration only after five months of provisional loading.

Another aspect that should be considered for the overall success of an implant treatment is implant design. It includes two components: macro-design, referring to implants' body and neck shape, thread design, platform design, diameter and length, and micro-design, referring to its surface properties. Several studies have reported the advantage of the conical body shape and nanoroughness structure of implant surface²¹, but very little evidence is available regarding implant neck properties. Implant neck is crucial for achieving primary stability and is also in direct contact with the coronal portion of bone, which is where loading forces are concentrated²².

In all patients included in this study, a conical implant design with an innovative triangular neck shape was used (V3 implant, MIS). In a recent study on animals, the V3 implant was compared with another implant with exactly the same body and surface characteristics, but with a cylindrical neck shape. The study reported a better peri-implant soft and hard tissues health on the V3 implant, correlating this result to the triangular neck shape of the implant as the only parameter that differed from the other implant involved in the study²³. In another clinical study, which used the same implant design, significantly less bone loss was evidenced in thick biotype cases when compared to thin or medium biotype. However, two-dimensional radiographs were used in that study, introducing an important limitation in terms of accuracy²⁴.

In the present study, in addition to the two-dimensional analysis, we added a three-dimensional CBCT evaluation of the bone and soft tissue parameters, as the literature confirms the reliability of CBCT in such analysis²⁵.

Based on the results of our three-dimensional analysis, no significant difference was registered for Bone Height (BH) and Bone Width (BW) in a one year. A slight vertical and horizontal bone loss in a one year follow-up for an implant treatment protocol is a common clinical finding in everyday practice, but the fact that the difference is not significant when compared to baseline, supports this treatment protocol as suitable even for esthetic areas like the anterior maxilla. On the other hand, a significant

reduction was seen for the Bone Contact (BC) parameter. That can be explained with the fact that, the first bone to implant contact point can be situated in a very apical position due to the irregular shape of the post-extraction site. However, after bone regeneration occurs, the alveolar socket is reshaped and the bone to implant contact is relocated more coronally, as can be seen in Fig. 1b.

Regarding soft tissue parameters, no significant difference was registered for Gingival Height (GH) and Gingival Width (GW) in the one year follow up. This result, combined with a significantly improved PES score, indicates a favorable esthetic outcome of this treatment approach. The extent to which implant neck triangular shape affected this outcome is difficult to quantify. The triangular shape of the neck, with one side of the triangular collar facing the cortical bone, is believed to favor bone regeneration by providing more space between implant and cortical bone for the bone graft material to be placed and for the blood flow accumulation.

Lastly, an attempt was made in order to find a correlation between the vertical mucosal height and the level of bone and soft tissue loss. However, all patients included in our study, except one, had a thick mucosal height (>3 mm), and no such correlation could be done.

Conclusion

In the present retrospective study, the combination of immediate implant placement after tooth extraction and a triangular shaped implant neck resulted in good results in terms of bone and soft tissue preservation as well as aesthetics. Consequently, such treatment protocol could be suitable even for areas with a high aesthetic demand, such as anterior maxilla. Further studies are encouraged with a larger sample size, and with a possible correlation between vertical mucosal height and bone and soft tissue loss.

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Figure legends

Figure 1. Measurements of the hard and soft tissue parameters at baseline (a) and 1-year follow-up (b), using CBCT. BH=Bone Height (yellow vertical line: 1.60 mm in a, 1.05mm in b); BC=Bone Contact (light blue vertical line: 8.60mm in a, 1.05mm (coincident with BC) in b); BW0=Bone Width at platform level (red horizontal line: 3.80mm in a, not detectable in b); BW2= Bone Width 2mm apical to platform level (red horizontal line: 5.00mm in a, 1.65mm in b); MH=Mucosal height (purple vertical line: 5.40mm in a, 6.00mm in b); MW0=Mucosal width at platform level (green diagonal line: 1.72mm in a, 5.44mm in b); MW2=Mucosal Width 2mm apical to platform level (green diagonal line: 1.89mm in a, 5.30mm in b).

Figure 2. Clinical buccal views of the same case, a 49-year old non-smoker male patient. The left upper central incisor was extracted for periodontal reason. (a) before extraction: the probe evidences the buccal bone dehiscence of 8mm; (b) after 1-year follow-up the soft tissue condition appears healthy. The PES was scored at 7.

Table 1. Variables for the Pink Esthetic Score evaluation according to Furhauser et al. (16)

Variables		0	1	2
Mesial papilla	shape vs	Absent	Incomplete	Complete
Distal papilla	shape vs	Absent	Incomplete	Complete
Level of soft-tissue margin	Level vs reference tooth	Discrepancy > 2mm	Discrepancy 1-2mm	Discrepancy < 1mm
Soft tissue contour	Natural, matching reference tooth	Unnatural	Fairly natural	Natural
Alveolar process	Alveolar process deficiency	Obvious	Slight	None

Tab. 2a. Pre-operative intraoral clinical examination.

GB		KM, mm	FTCH, mm	CTCH, mm	PES, mm
12 Thick	8 Thin	4.25±1.50	9.00±1.79	9.23±2.35	6.75±1.75

GB: Gingival Biotype

KM: Width of Keratinized Mucosa

FTCH: Failing Tooth Crown Height

CTCH: Contralateral Tooth Crown Height

PES: Pink Esthetic Score

Tab.2b. Pre-operative three dimensional evaluation of hard and soft tissue parameters

	BT1, mm	BT3, mm	BT5, mm	GW, mm	GH, mm
Failing Tooth	1.13±0.60	1.26±0.93	1.05±0.93	0.95±0.25	3.80±1.83
Contralateral Tooth	0.99±0.50	0.97±0.50	1.15±1.07	0.95±0.41	3.28±0.93

BT: Cortical Bone Thickness

GW: Gingival Width

GH: Gingival Height

Table 3. PES score changes in 1-year follow up

pre-op, mm	1 year, mm	change, mm	p value
6.75±1.75	8.39±1.20	1.29±1.92	0.0005

Table 4a. Evaluation of 3D changes of bone parameters at 1-year follow up

	post-op, mm	1 Year, mm	Change, mm	P value
BH	2.28±3.82	1.25±0.91	1.09±4.10	0.45
BC	7.29±3.95	0.39±0.98	7.78±3.50	<0.01
BW0	2.27±1.35	1.71±1.11	0.81±1.25	0.06
BW2	2.52±1.30	1.94±0.93	0.62±0.97	0.06

BH: Bone Height
 BC: Bone Contact
 BW: Bone Width

Table 4b. Evaluation of 3D changes of soft tissue parameters at 1-year follow up

	Post-op, mm	1 Year, mm	Change, mm	P value
MH	3.78±1.42	3.83±1.06	0.03±1.12	0.93
MW0	1.84±1.29	1.70±1.27	-0.03±1.79	0.95
MW2	1.75±0.65	1.71±1.23	-0.17±1.40	0.74

MH: Mucosal Height
 MW: Mucosal Width

Table 5. Evaluation of 2D changes of bone parameters in 6 months and 1-year follow up

	Post-op (A)	6 Months (B)	1 Year (C)	Change (A vs B)	Change (A vs C)	Change (B vs C)
Mesial , mm	0.53±1.6 4	0.69±1.2 6	0.59±1.0 4	-0.19±0.9 8 (p=0.5)	-0.09±1.1 4 (p=0.88)	-0.16±0.3 4 p=0.04
Distal, mm	0.67±2.0 5	0.52±0.9 0	0.63±1.1 8	-0.04±0.7 9	-0.13±1.0 0	0.08±0.74 p=0.59