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Cover Page Footnote

To Dr Joe El Khoury, MD, MPH, Centre Hospitalier Public d'Hauteville, France, the independent statistician who reviewed the methodology and statistics, for his time and efforts during this study. The authors report no conflict of interest related to this study.

CLINICAL AND RADIOGRAPHIC EVALUATION OF BONE REMODELING AROUND IMPLANTS PLACED IN HORIZONTALLY AUGMENTED BONE: A PILOT STUDY

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Introduction: Marginal bone loss after implant placement is one of the most used criteria to assess the success of osseointegrated implants over time. The type of implant connection and implant surface type are reported to have an influence on bone remodeling around the placed implants. This study aimed to evaluate marginal bone loss around two implant systems with different connections and surfaces in horizontally augmented sites.

Methods: This randomized control pilot study included 8 implants placed in 3 patients who needed implant placement in previously horizontally grafted sites. The placed implants were divided into two groups: group 1 consisting of implants with external connection and a hybrid design, and group 2 including implants with an internal connection and a fully etched surface. Clinical and radiographical measurements were taken at baseline, during the surgery, and up to one year after loading to evaluate marginal bone loss around the two different implants placed in grafted sites.

Results: All implants were retained at all follow-up periods and healing was uneventful. There were similar Marginal Bone Loss (MBL) and soft tissue changes around both types of implants. Group 2 implants had higher MBL, however, the difference was not statistically significant.

Conclusions: Preliminary analysis suggest that full surface etching does not seem to negatively influence marginal bone loss around implants placed in augmented bone.

Keywords: bone remodeling, dental implant, dental implant connection, guided bone regeneration, implant surface, marginal bone loss.

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Conflicts of interest:

The authors declare no conflicts of interest.

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ÉVALUATION CLINIQUE ET RADIOGRAPHIQUE DU REMODELAGE OSSEUX AUTOUR D'IMPLANTS POSÉS DANS UN OS AUGMENTÉ HORIZONTALEMENT: UNE ÉTUDE PILOTE

Introduction: La perte osseuse marginale après la pose d'implants est l'un des critères les plus utilisés pour évaluer le succès des implants ostéointégrés dans le temps. Le type de connexion de l'implant et la nature de la surface de l'implant auraient une influence sur le remodelage osseux autour des implants posés. Cette étude vise à évaluer la perte osseuse marginale autour de deux systèmes d'implants avec des connexions et des surfaces différentes dans des sites augmentés horizontalement.

Méthodes: Cette étude pilote randomisée et contrôlée comprend 8 implants placés chez 3 patients qui avaient besoin de pose d'implants dans des sites préalablement greffés horizontalement. Les implants posés ont été divisés en deux groupes : le groupe 1 composé d'implants à connexion externe et une surface hybride, et le groupe 2 comprenant les implants à connexion interne et une surface entièrement mordancée. Des mesures cliniques et radiographiques ont été prises au départ, pendant l'intervention chirurgicale et jusqu'à un an après la mise en charge pour évaluer la perte osseuse marginale autour des deux implants différents placés dans les sites greffés.

Résultats: Tous les implants ont réussi durant le suivi et la cicatrisation s'est déroulée sans incident. Il y avait une perte osseuse marginale et des modifications des tissus mous similaires autour des deux types d'implants. Les implants du groupe 2 avaient une perte osseuse marginale plus élevée, cependant, la différence n'était pas statistiquement significative.

Conclusions: L'analyse préliminaire suggère que le mordantage sur toute la surface ne semble pas influencer négativement la perte osseuse marginale autour des implants placés dans de l'os augmenté.

Mots-clés: connexion implantaire, implant dentaire, perte osseuse marginale, remodelage osseux, régénération osseuse guidée, surface implantaire.

Introduction

Dental implants have become a standard treatment strategy for partially or completely edentulous patients. Bone grafting techniques are often considered for better implant 3D positioning. Maintaining the marginal bone level around implants is essential as extensive bone loss could lead to aesthetic complications and implant failure. A marginal bone loss (MBL) of 1.5 mm during the first year of function and 0.2 mm after that period is usually accepted [1]. MBL and bone to implant contact (BIC) are mainly affected by implant surface topography/roughness and connection [2]. Studies are controversial regarding the relation between MBL and implant connection, but a recent systematic review and meta-analyses showed no statistical difference between external and internal connections regarding implant survival rate and MBL [3]. Also, surface roughness facilitates the retention of osteogenic cells and allows them to migrate on the implant surface, thus increasing the BIC [2]. Some studies reported that hybrid implants with a machined surface in the coronal part might reduce the risks of peri-implantitis and MBL [4]. A five-year RCT evaluating hybrid and fully etched, placed in a native bone, showed no increased risk of peri-implantitis between the two surfaces [5]. Articles describing MBL around implants placed in previously horizontally regenerated bone are scarce.

The aim of this study, is to evaluate MBL of implants placed in previously horizontally augmented bone crests. Two implant connections (internal and external) and neck surfaces (hybrid and fully etched) were selected for group comparison.

Methods

This was an pilot randomized control study, designed to evaluate MBL around two implant

connections and neck designs (internal/external and hybrid/fully etched, respectively), in horizontally-augmented sites. The methodology was reviewed by an independent statistician.

Three patients (two males and 1 female) were recruited at the department of Periodontics, Faculty of Dental Medicine, Saint-Joseph University of Beirut between 2019 and 2020 (Table 1). Inclusion criteria included adults with recent horizontally-augmented sites. Patients with medical comorbidities were excluded. Horizontal augmentation had been performed 6-9 months before recruitment, by the same experienced surgeon, using the same surgical principles. A mix of autogenous bone graft - Geistlich Bio-Oss® (Geistlich-Pharma, Wolhusen, Switzerland) - and xenograft - Geistlich Bio-Gide® (Geistlich-Pharma, Wolhusen, Switzerland) were used and covered by a well stabilized collagen membrane. Healing was uneventful in all cases. Cone-beam CT was performed, and the patients were recruited for implant placement after obtaining consent. The study protocol was reviewed and approved by the University Institutional Review Board (USJ 2019-96) and registered at *ClinicalTrials.gov* (NCT04343066). The study was conducted in accordance with the Helsinki Declaration 2013.

Surgical phase:

After raising a full-thickness flap and before implant site preparation, a sealed envelope was used to randomly allocate the implant type to be used per site. Two types of implants were used: A Dual Acid Etched implant designed with a machined surface in the coronal region and an external connection (Group 1, Hybrid Osseotite®, BIOMET 3i), and a fully rough internal connection with fine micron features on the implant collar (Group 2, (Full Osseotite® T3, BIOMET 3i™) (Figure 1 and 2). At least 2 implants were placed per patient, one of each type. The implant's platform

was placed 1 mm subcrestally, with at least 2 mm of bone on the buccal and palatal/lingual part, mucosal flaps were closed and the implants were fully submerged during healing. A bone core was taken from the implant site, with a 2 mm trephine bur. Non-decalcified 80 µm sections were obtained and stained with Giemsa-paragon for light microscopic observation and qualitative histological assessment [6] (Fig 3).

Patients were instructed to take antibiotics (2g amoxicillin daily for 7 days), analgesics, and to rinse with chlorhexidine. They were followed to document clinical healing and monitor for complications. Implants were uncovered after 3 months and fixed prostheses, screwed on multi-unit abutments, were delivered 4 months post-implant placement.

The primary outcomes were the survival rate of the implants and the MBL measured as the difference in bone level between baseline and the follow-up (distance between the implant shoulder and the most coronal bone to implant contact) on peri-apical radiographs (using Rinn® XCP Instrument Kit, Dentsply Rinn, Elgin, IL and DBSWIN software). A distortion coefficient was calculated for each implant by considering the implant length as a known value. Other measurements taken are summarized in Table 2.

Results

Results were reviewed by an independent statistician. Several measurements were taken throughout the study and at different stages (Table 2).

Healing was uneventful in all patients. No complications were reported at all follow-up stages. Mesial and distal bone remodeling at peri-apical radiographs were assessed for each implant (at prosthetic crown delivery, 5 to 7 months post-loadings and 10-12 months post-loading) and summarized in Table 3. The average of bone remodeling ranged from

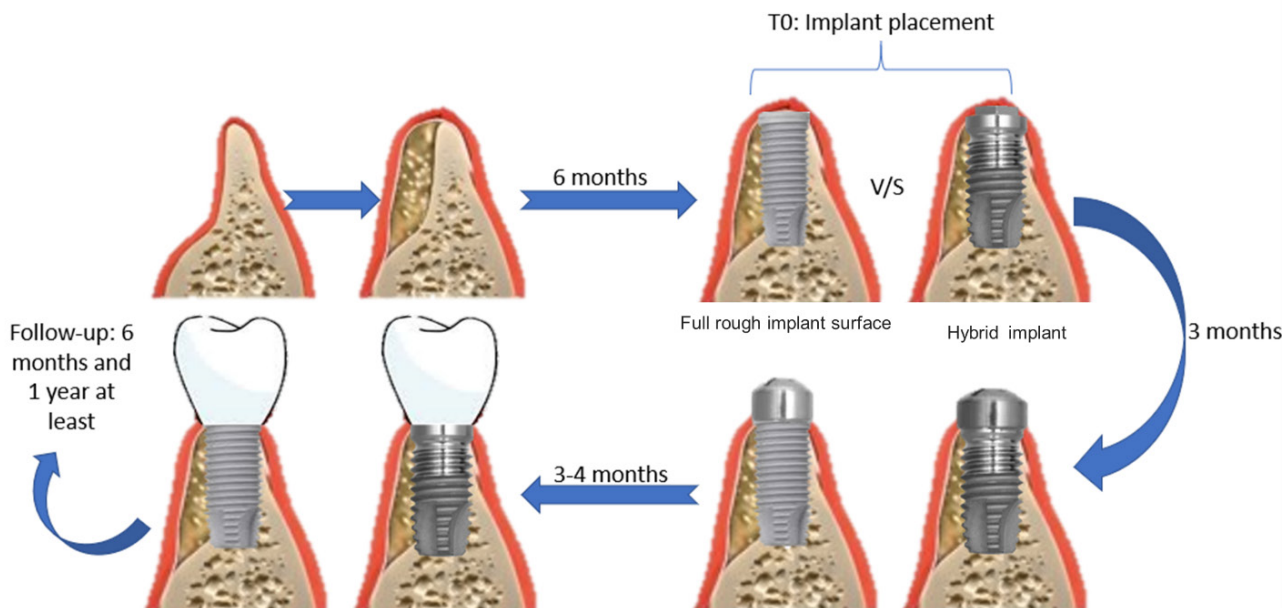


Figure 1: Study Timeline.

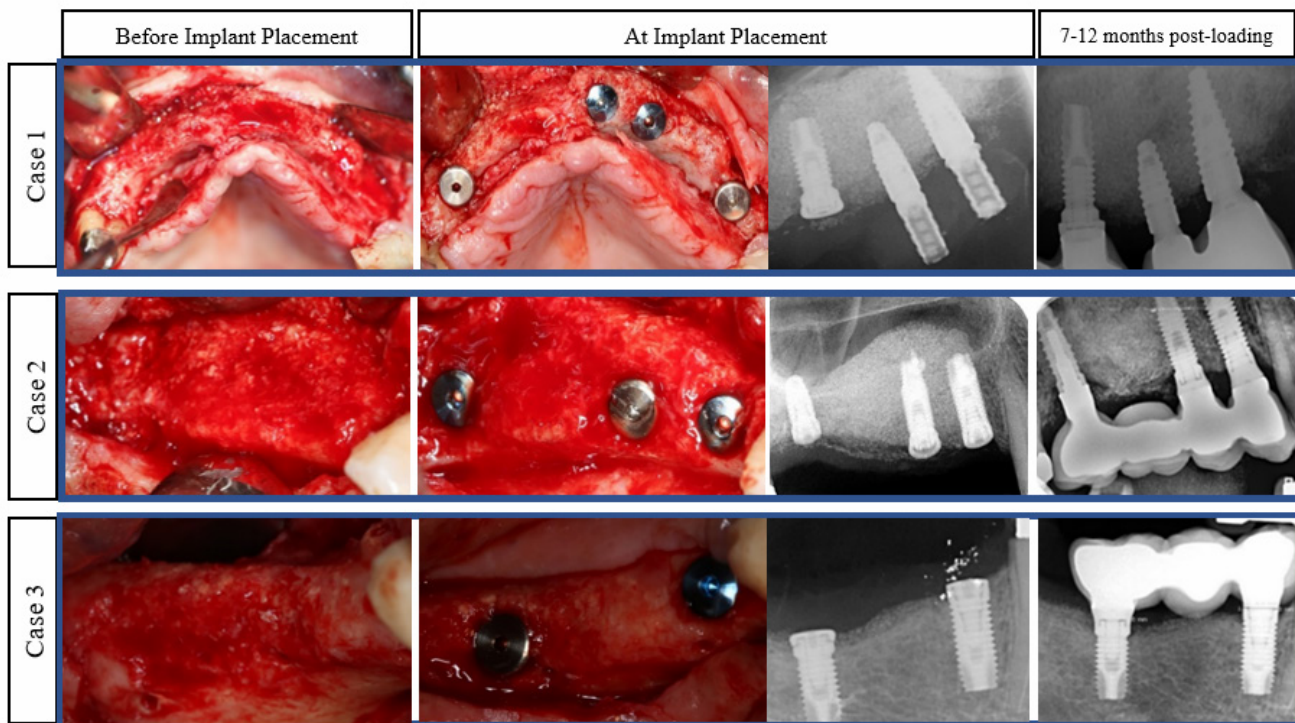


Figure 2: Clinical pictures (before and during implant placement) and radiographic x-rays (at implant placement and 7 to 12 months after crown delivery) of the clinical cases. Note the small bone remodeling around the placed implants after 7 to 12 months of fixed

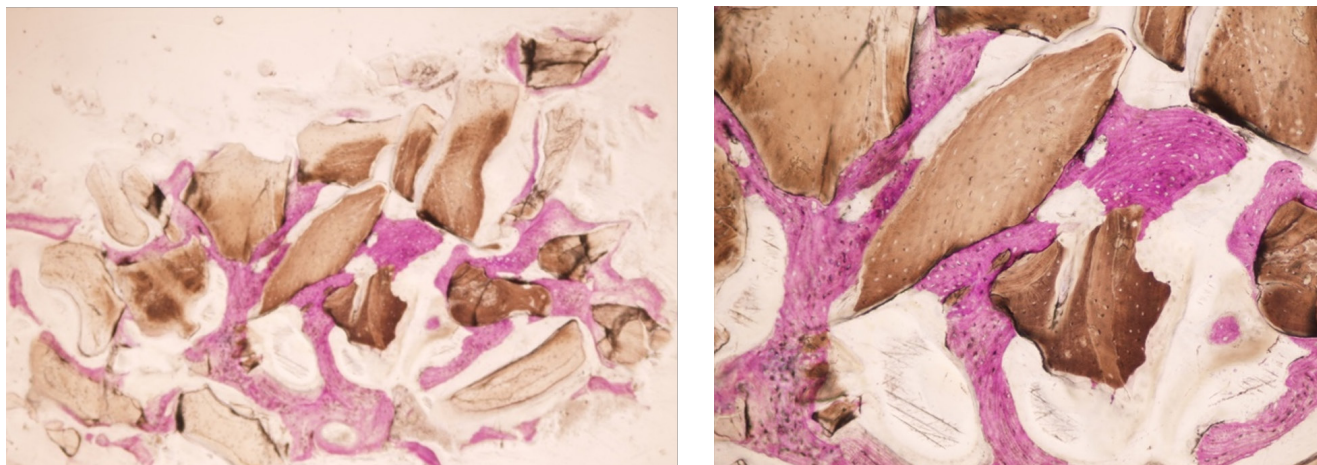


Figure 3: Measurements at prosthetic time delivery, 5 to 7 months post loading and 10 to 12 months post loading (MBR: Mesial Bone Remodeling, DBR: Distal Bone Remodeling).

1mm to 1.25mm for group 1 and 0.9mm to 2.15mm for group 2. However, no statistical association was found between implant surface/connection (BOSS and OSS implant) and mesial/distal marginal bone loss (p-value 0.11 and 0.48, respectively) (Table 4).

Keratinized tissue height (KTH) was also assessed 5 to 7 months post-loading changes for group 1 and group 2. Values ranged between 2mm to 3mm for group 1 and 2.5mm to 4mm for group 2. However no statistical significance was found between both implant type concerning the mean keratinized tissue height (Table 4).

Mann-Whitney test was used to test differences in measures among both groups. Histological analyses of the regenerated sites showed no inflammation. New bone formation was evident in close contact with the DBBM particles. Neither gaps nor connective fibrous tissues were found at the bone-biomaterial interface (Figure 3).

Discussion

In this case series, implant surface and connection type did not affect the MBL in previously horizontally augmented bone. These findings are in agreement with studies reporting on implants placed in native bone [3,7].

While some authors found less MBL when implants with internal connections are used, others stated that an internal connection implant has a higher absolute strain value at the cervical area and is related to an increased MBL [8]. This discrepancy could be explained by confounders affecting the peri-implant marginal bone as occlusal overload, microgap, and micromotion [9].

The insignificant correlation between MBL and implant surface type (rough and turned) seen in our case report and other papers could be due to the MBL not being solely caused by the implant surface characteristics, but also by implant malpositioning and peri-implantitis. Hence, preventing the installation

of peri-implant disease through supportive periodontal therapy and good oral hygiene along with an ideal implant positioning in adequate soft and hard tissue is more relevant for MBL prevention after implant placement [5]. In our study, the average mesial and distal bone loss (1.6 mm) exceeded the loss expected in native bone [10]. One could think that regenerated bone at the implant level does not react and heal the same way as native bone. However, articles studying MBL in native bone v/s regenerated bone, regardless of the bone augmentation technique, found that the clinical and radiographical results around the placed implants are similar [11,12]. The high MBL in our study could be explained by smoking, small sample size, surgical trauma, or by the influence of some biological factors [13]. Studies with larger sample sizes and a longer follow-up period are necessary to conclude which implant type yields better results over time.

KTH did not significantly change

Table 1: Characteristics of the placed implants included in the study.

Patient number	Sex	Age	Number of implants	Implant diameter	Implant length	Implant group	Implant site
1	Female	55	4	3.75	10	1	13
				4	10	2	21
				3.75	8.5	1	24
				4	8.5	2	22
2	Male	49	2	4	11.5	2	14
				4	11.5	1	15
3	Male	76	2	4	8.5	1	46
				4	10	2	44

Table 2: Summary of the measurements taken throughout the study at different stages. (T0: immediately after implant placement, T1: second-stage surgery, T2: prosthetic crown delivery, T3: 7 months post-loading, T4: 12 months post loading, FMBS: Full Mouth Bleeding Score, FMPS: Full Mouth Plaque Score, KTH: Keratinized Tissue Height, CBCT: Cone Beam Computed Tomography)

	Baseline	T0	T1	T2	T3	T4
FMBS	+	+	+	+	+	+
FMPS	+	+	+	+	+	+
KTH	+		+	+	+	+
Peri apical X-ray		+	+	+	+	+
CBCT	+	+				+

Table 3: Measurements at prosthetic time delivery, 5 to 7 months post loading and 10 to 12 months post loading (MBR: Mesial Bone Remodeling, DBR: Distal Bone Remodeling).

Patient	Group	Implant diameter (mm)	Implant length (mm)	Site	Prosthetic crown delivery		5 to 7 Months post loading		10 to 12 Months post loading		Keratinized Gingiva Height 5 to 7 Months post loading (mm)
					Peri apical		Peri apical		Peri apical		
					MBR (mm)	DBR (mm)	MBR (mm)	DBR (mm)	MBR (mm)	DBR (mm)	
1	1	3.75	10	13	-1	-1.5	-1.5	-1.5			2.5
1		3.75	8.5	24	-1	-1	-1	-1			3
2		4	11.5	15	-1	-1.5	-1	-1.5	-1	-1.5	3
3		4	8.5	46	-1	0	-1	-1	-1	-1	2
		Average group 1			-1	-1	-1.12	-1.2	-1	-1.25	
1	2	4	10	21	-3	-3	-3	-3			3
1		4	8.5	22	-3	-3	-3	-3			2.5
2		4	11.5	14	-1.3	-1.3	-1.3	-1.5	-2.5	-1.5	4
3		4	10	44	-1.3	-0.3	-1.3	-0.3	-1.3	-0.3	3
			Average group 2			-2.15	-1.9	-2.15	-1.95	-1.9	-0.9

Table 4: Statistical comparison between both implant groups in relation to the measured variables.

Variable (at 7-month post-loading)	BOSS implant (Group 1)	OSS implant (Group 2)	p-value
Mean Distal Marginal Bone Remodeling on peri-apical x-rays (mm)	-1.25	-1.95	0.48
Mean Mesial Marginal Bone Remodeling on per-apical x-rays (mm)	-1.12	-2.15	0.11
Mean Keratinized Tissue Height (mm)	-0.62	-0.12	0.2

during the follow-up period and was not statistically different between both implant types. This could be explained by the fact that all sites had at least 2 mm of KTH prior to implant placement. Although the amount of keratinized mucosa needed to maintain peri-implant health is still debatable [14], the maintenance of

adequate oral hygiene is the most important aspect for peri-implant tissue health [15].

Conclusion

Within the limitations of this pilot study mainly due to the small sample of enrolled patients due to

the COVID-19 sanitary crisis, both the fully etched implant and the hybrid implant seem viable options in horizontally-augmented ridges. Further studies with larger sample and longer follow up period are needed to be able to draw a solid conclusion.

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