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Comparison between bone height changes around the splinted and non-splinted OT bridge system implants in edentulous mandibles rehabilitated with all-on four full arch prosthesies a randomized clinical trial

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Abstract---Objectives: the aim of this study was to compare the difference in marginal bone loss around the splinted and non-splinted implants supported on OT bridge system in full arch implant mandibular restoration using the All-On -Four concept. Materials and methods: This study was conducted on 12 completely edentulous patients having 48 implants. All patients were treated with a mandibular implant supported fixed restoration. Four implants were placed interforaminally for each patient and restored with immediately loaded restoration following the All-On-Four concept. Comparison was made between the splinted implants and non-splinted implants of immediately loaded temporary conversion prosthesis using OT bridge system regarding the marginal bone loss (MBL) using digital periapical radiograph at base line and after 3 months. Results: The marginal bone loss around both groups splinted and non-splinted implants after 3 months of immediate loading was similar with no statistically significant difference. Conclusion: Both techniques are considered as

reliable methods for immediate loading of a full arch screw retained implant restoration with no preference of one approach regarding marginal bone loss around implants.

Keywords---all-on-four concept, full arch fixed implant restoration, mandibular implant restorations, splinted implants, non-splinted implants, OT bridge system.

Introduction

The state of complete edentulism is the state where the patient loses all his natural teeth. This state has detrimental consequences including loss of function, esthetics, facial support and negative psychological impact (Polzer et al., 2010). Restoration of the completely edentulous mandible is always a challenge due to the small supporting area that renders the removable restoration uncomfortable to the patients. Many options have been proposed to solve this problem starting from placing a single mid line implant to retain the denture up to placing six implants to support a fixed full arch restoration. One of the well-known protocols is the All-On-Four concept. This protocol involves the placement of four interforamenal implants and immediately loading them with a fixed implant supported restoration (Maló et al., 2003; McCord & Grant, 2000).

The “All on 4” concept is known to be a safe, predictable and simple approach to place four mandibular implants and load them immediately within few hours. The idea was based on that the location of the implants enhanced the load distribution where the 4 implants are considered as cornerstones. 2 implants were placed anteriorly, the other 2 were placed distally and all are well spread. Also, distal implants were tilted to allow placement of longer implants by avoiding the inferior alveolar canal and the mental foramen. This concept lessens the cantilever and provides the advantage of force distribution which consequently enhances the prosthetic condition (Krekmanov et al., 2000). Shakhawan et al., (2019) reported a wide range of advantages gained from the “All on four” protocol including the following; it avoids grafting procedures and complex surgery, it is less invasive to the patient, its success rate is predictable. Tilting allows using longer implants that can engage cortical bone, decreases the cantilever and increases the anteroposterior implants spread which enhances biomechanics. It also allows easier surgical and prosthetic procedures as well as allowing immediate loading with good esthetics and an easily cleaned restoration. Finally, it is cost effective due to the use of lesser number of implants.

In Misch (2004) adopted the technique of Balshi he proposed in (1985). They used the patient’s denture for loading by picking it up using self-cure acrylic resin and they named it “conversion denture”. Misch advised the use of such technique due to the fact that the success rate of implants even with immediate loading has been high and many studies reported its predictability. The OT bridge system is a newly introduced abutment system that was introduced in (2020) by Montanari et al. They reported in their case report how they solved the problem of maligned implants using the OT bridge system. The OT bridge system consists of 2 parts; a stud attachment part tightened in the implant that is called “OT equator” and a

titanium sleeve which is the extra grade part that is low in profile, small in diameter with an intermediate elastic piece called “elastic Seeger”.

Splinting or non-splinting step is a controversy issue that no guidelines or consensus have been reported in (Al Amri, 2016). Those who support the idea of splinting their rationale was that splinting provide some extra advantages. These advantages include lessening the deleterious effect of occlusal loads on the implants and the anticipated marginal bone loss. And for those who supports the non-splinted option states that it allows better hygiene maintenance. However, neither of both teams have strong evidence regarding their assumptions (Hasegawa et al., 2017). Different radiographic techniques were used for the evaluation of hard tissue around the implants including marginal bone loss (MBL) which is one of the major criteria for implant success. Intraoral periapical radiographs using the paralleling technique and CBCT is a well-known and predictable techniques to evaluate MBL (Akheshteh et al., 2020). This raises a question that is not answered in the literature yet, whether splinting of implants would provide better prognosis regarding marginal bone loss or it would be similar to non-splinted ones.

Methodology

The present study is a randomized clinical trial. It included 12 patients with a total of 48 implants. Patients’ age was ranging from 40 to 70 (and an average of 56.65 ±9.20). Patients were completely edentulous and all of them received a full arch fixed restoration on 4 mandibular implants following the All-On-Four concept. According to this concept each patient received four interforamenal implants, two anterior axial implants and two tilted posterior ones. They were allocated to one of the following groups; either loading the implants splinted to each other using titanium wire or non-splinted on OT bridge system. In both groups the implants were loaded by a previously fabricated denture.

A thorough preoperative assessment of all patients was carried out including history taking, clinical examination and radiographic examination to confirm that they met the eligibility criteria. Inclusion criteria include placing implants in healed bony sites in patients with no systemic condition that would affect implant healing like immunosuppressed or immunocompromised patients and non-heavy smokers (<10/day). All the steps of conventional complete denture construction were followed to deliver a complete denture for the patients. A CBCT Radiograph was then done with the denture after placing radiopaque markers “Gutta percha” on the occlusal surface of the premolars bilaterally and lingual surface of the 6 anterior teeth. The DICOM files were then analyzed using Blue sky bio software*.

Surgical procedures
Implants placement

The denture was converted into a surgical stent by opening holes at the planned implant sites. Local anesthesia Septocaine† was administrated using bilateral

* Blueskybio software, Liberty Drive, Libertyville, IL, USA.

† Septocaine, Articaine with epinephrine 1:100000, Septodont, Canada.

mental nerve block technique and lingual infiltration prior to the surgical procedure. Incision and flap reflection was then done. Alveoloplasty was done in cases with knife edge ridge using a barrel shaped bur supplied in the implant kit, to enhance bone morphology and increase the bone plateau for easier implant drilling and placement. Sequential drilling was done at the planned implant sites using the implant surgical kit‡ taking into consideration that the two central anterior implants should be parallel to each other while for the posterior implants both were placed with an angle of 30 degrees using Malo metal guide so that the apex of the implant is tilted mesially while the neck is tilted distally, coming out at the position of the first molar of the denture to increase the AP spread and decrease the cantilever length. Anterior implants placed were 10mm in length and posterior implants were 12mm with diameter of 3.5 mm. Implants placed with primary stability of 35 N/cm or more were loaded (Figure 1).

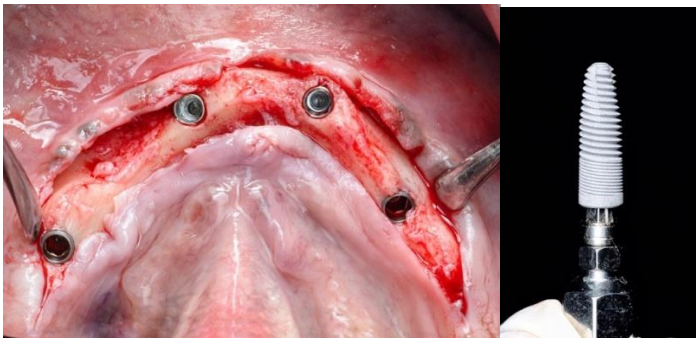

Figure 1. The implants in place

After placing the tilted implants, the bone distal to them was trimmed to make the implant neck all around at the level of the crestal bone this was mandatory to avoid interference when placing the OT abutments. 4 OT abutments§ were selected, their height was decided according to the soft tissue thickness from the 3 available collar heights “1 mm, 2 mm or 3 mm” and then were screwed and tightened in place. Flap closure was done by a continuous with lock suturing technique using a 4-0 polypropylene suture** (Figure 2 a and b). Extra-grade titanium sleeves were screwed in place over the OT abutments using the long screw as it allows better visibility of the interference during denture relief (Figure 3 a and b). a piece of rubber dam was placed around the OT bridge system to avoid escape of any material in the flap or get attached to the suture. In group 1 immediate loading was done directly intraoral by pick up of titanium sleeves in the previously fabricated denture using self-cure acrylic resin††.

‡ B&B Dental Implant Company - Via San Benedetto, San Pietro in Casale (BO) Italy.

§ RHEIN83, Via E. Zago, Bologna, Italy

** Polypropylene 4-0 monofilaments sutures Assut Medical Sarl, Switzerland

†† Bredent, Brimington Road, Chesterfield, UK

Figure 2. (a and b): A. OT abutments tightened in place B: Implants angulation after tightening of the titanium sleeves

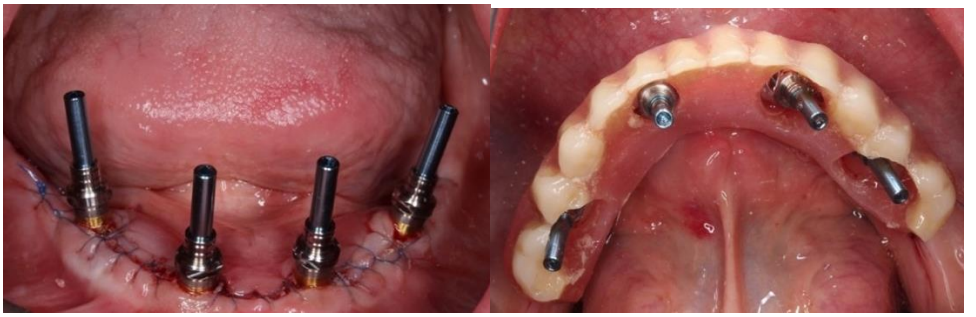

Figure 3. (a and b): A: titanium sleeves with long screws in place – B: denture relieved

In group II an impression was made to splint the sleeves on the cast and relief the denture then an intra-oral pick up of the sleeves was done as the other group (Figure 4 (a and b)).

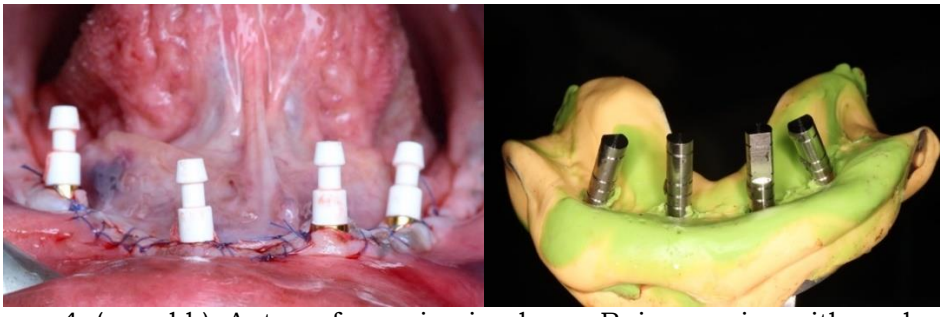

Figure 4. (a and b): A: transfer coping in place – B: impression with analogue attached to transfer

Seeger ring was placed in the fitting surface of the titanium sleeves before final screwing in both groups with its opening directed distally to accommodate the implant angulation (Figure 5 (a and b)).

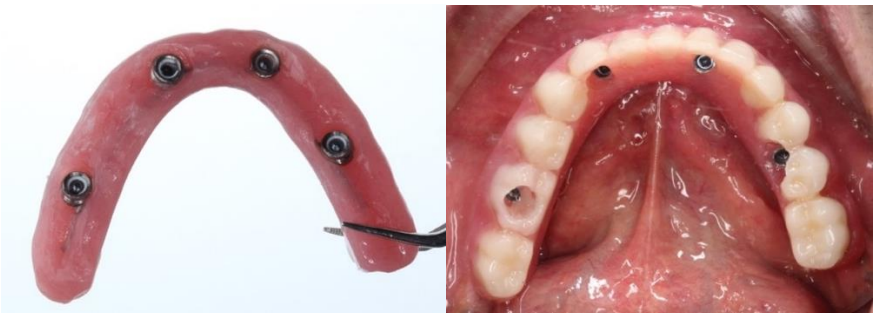

Figure 5. (a and b): A: the removable denture after converting it to a fixed one with Seeger in place – B: denture screwed in place

Marginal Bone loss evaluation

Marginal bone loss was measured using digital periapical radiographs. The radiographs were taken using parallel cone technique and the Digora computerized system[‡‡], the Rinn XCP periapical film holder[§§], and a specially constructed acrylic template. The template was used as a radiographic stent for taking standardized and reproducible serial digital images for the implants using the long cone paralleling technique at the day of loading and 3 months later. This follow-up period was enough to assess the marginal bone loss for immediately loaded temporary prosthesis which will be changed latter on with a permanent one. The digital images were analyzed to evaluate the marginal bone level mesial and distal to the implants as follows:

At first calibration was done to ensure the accuracy of measurements. After the calibration, the bone height changes were measured by drawing 2 lines perpendicular to the line at the top of the implant, one on the mesial and the other on the distal of the implant and both ends at the highest point of bone implant interface (line “4,5”). Then a comparison between both radiographs “baseline and 4 months” was done for the mean of both sides in all implants as there was no statistically significant difference between the mesial and distal marginal bone loss of each implant (Figure 6).

[‡‡] Kavo Kerr, Detroit, Michigan, USA

[§§] Dentsply, Sirona, New York, USA

Figure 6. bone height assessment using the digital periapical radiograph and Digora Software

Sample size calculation

This power analysis used amount of bone loss after three months as the primary outcome. Based upon the results of De Bruyn H et al (2008), the mean and standard deviation (SD) for control group were 0.6 (0.68) mm. The minimal clinically significant difference was 0.5 mm according to expert opinion. Using alpha (α) level of (5%), β level of 0.8 (Power = 80%); the effect size for independent samples t-test (d) was 0.736 and the minimum estimated sample size was 20 implants per group. Sample size was increased to 24 implants per group to compensate for a drop-out rate of 15% after three months. Sample size calculation was performed using PS Power and Sample Size Calculations Version 3.

Statistical Analysis

Data were then explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests. As the data showed non-parametric distribution so Mann Whitney test was used to compare between both groups. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM*** SPSS††† Statistics Version 20 for Windows.

Results

All patients completed the follow up period with no dropouts and no implant failure. More marginal bone loss was found in splinted cases with no statistically significant difference between both groups (p=0.333). There was a statistically significant difference between baseline and after 3 months of follow-up with higher values after 3 months in both groups except for one axially oriented implant (Table 1,2 and figure 7).

*** IBM Corporation, NY, USA.

††† SPSS, Inc., an IBM Company.

Table 1
The mean, standard deviation (SD) values of marginal bone loss in Group I

Variables	Marginal bone							
	Group I							
	Implant 1		Implant 2		Implant 3		Implant 4	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Baseline	0.058	0.065	0.353	0.593	0.125	0.306	0.108	0.265
After 3m	0.245	0.175	0.352	0.450	0.488	0.352	0.440	0.320
p-value	0.027*		0.221ns		0.027*		0.041*	

Table 2
The mean, standard deviation (SD) values of marginal bone in Group II

Variables	Marginal bone							
	Group II							
	Implant 1		Implant 2		Implant 3		Implant 4	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Baseline	0.208	0.246	0.083	0.129	0.067	0.082	0.000	0.000
After 3m	0.849	0.385	0.200	0.245	0.397	0.281	0.792	0.560
p-value	0.027*		0.102ns		0.026*		0.027*	

*; significant (p<0.05) ns; non-significant (p>0.05)

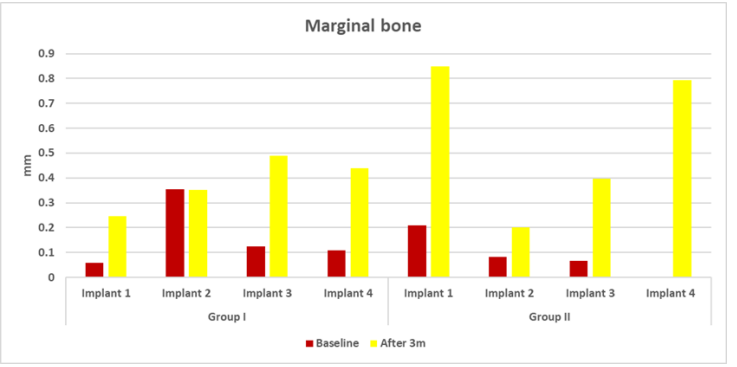

Figure 7. Bar chart representing marginal bone loss for each implant along time in each group

Discussion

The current study was conducted to evaluate the performance of both splinted and non-splinted OT Equator system (Rhein'83) used to support a screw-retained fixed full arch restoration of a completely edentulous mandible. The comparison with such settings was not proposed yet in other studies to the best of the authors' knowledge, however studies comparing splinting was other types of abutments was found in literature. In this study it was witnessed that splinted restoration wouldn't provide better outcome and prognosis regarding marginal bone loss. "All on 4" concept applied the idea of immediate loading with a temporary acrylic prosthesis at the day of surgery. Immediate loading is a double ended weapon that have merits and demerits. One of the great merits is that we can construct a full arch fixed prosthesis on four implants only which is cost

effective but at the same time if failure occurs in one of the implants this will force us to convert the prosthesis into a removable overdenture or otherwise add more implant to construct a new fixed one. Paulo Malo et al, (2003) in their study stated that 3 hours are their timeline for loading, however, it is well-known now that immediate loading can be done up till one week of the surgery. So, in this study the margin of loading was considered as the latest consensus stated regarding loading (Weber et al., 2009).

In this study the conversion denture protocol described by Balshi (1985) and Misch in (2004) was adopted. Both authors reported that this technique is an easy, cost-effective, time-effective technique with predictable success rate. The current study is mainly concerned with the marginal bone loss around dental implants along the follow up period of three months which is the period from immediate loading at the day of surgery till the definite prosthetic phase after 3 months taking into consideration different potentially affecting factors mainly implant splinting (whether splinted or not).

In the comparison between the total bone loss around unsplinted and splinted restorations, no statistically significant difference was found with higher loss values in the splinted group. This insignificance was in accordance to the study conducted by Maló et al. in (2015) in unsplinted cases where they used titanium cylinders and acrylic restorations and the study conducted by Sannino & Barlattani in (2016) in splinted cases. The higher values of bone loss in splinted group may be attributed to loss of passivity in one of the splinted cases as referred by Sahin & Çehreli in their review in (2001). Also, the comparison between baseline and 3 months showed statistical significance in both splinted and non-splinted groups. These results were in accordance to the study conducted by Montanari et al in (2020). Their results showed statistically significant difference with mean and standard deviation of 0.32 ±0.2 mm after one year of follow up.

These findings can be explained by the fact that the maximum amount of bone resorption occurs around the implants in the first year of function, it may be considered a clinically insignificant finding. However, it is still considered an unfavorable condition but inevitable. This fact is supported by several authors as Roos et al. in (1997) and Røynesdal et al. in (2001) since the emergence of the success criteria of Albrektsson et al in (1986) which include this loss in its' aspects. Albrektsson stated that this resorption may be attributed to patient, surgical or prosthetic related factors.

Conclusion

Within the limitation of our current study, it could be concluded that regarding MBL splinting of immediately loaded full arch restorations in conversion denture technique is not crucial without taking into consideration the technical or mechanical complications. It can be also stated that the novel OT bridge system is a promising concept that reduces the problems of passivity in full arch implant restorations of the completely edentulous mandible. This advantage may be due to the Seeger ring concept incorporated in the OT bridge system.

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