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Effect of loading protocol on peri-implant marginal bone loss: randomized clinical trial

Efeito do protocolo de carregamento na perda óssea marginal peri-implantar: ensaio clínico randomizado

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ABSTRACT

Objective: This clinical study was conducted to evaluate the effect of loading protocol using hybrid ceramic resinous material on marginal bone loss. **Material and Methods:** This study was conducted in the fixed prosthodontics department, at Ain Shams University on 30 titanium endosseous tapered threaded implants which were placed in 30 patients in the upper premolar area. Patients were divided randomly according to the loading protocol into 3 groups (10 patients each): Group I (IFLV): patients received CAD/CAM polymer infiltrated ceramic (VITA-ENAMIC) crowns (immediate functional loading), Group II (IFLP): patients received CAD/CAM PMMA crowns (in occlusion for 3 months) followed by CAD/CAM polymer infiltrated ceramic (VITA-ENAMIC) crowns (functional loading), and Group III (INFLP): patients received CAD/CAM PMMA crowns (out of occlusion for 3 months) followed by CAD/CAM VITA-ENAMIC crowns (functional loading). **Results:** After three months; the highest value of marginal bone loss (mm) was found in IFLV, followed by IFLP, while the lowest value was found in INFLP. After six months, the highest value was found in IFLP, followed by IFLV, while the lowest value was found in INFLP. Also, after twelve months, the highest value was found in IFLV, followed by IFLP, while the lowest value was found in INFLP. Marginal bone loss values were within the accepted values for clinical success for all the tested groups. **Conclusion:** Immediate non-functional loading provided more acceptable outcomes than immediate functional loading. Also, immediately functional and non-functional implant loading using hybrid ceramic as permanent material has shown promising results with proper patient selection.

KEYWORDS

Bone loss; CAD/CAM; Ceramic; Hybrid; Loading.

RESUMO

Objetivo: Este estudo clínico foi realizado para avaliar o efeito do protocolo de carregamento utilizando material resinoso cerâmico híbrido na perda óssea marginal. **Material e Métodos:** Este estudo foi realizado no departamento de prótese fixa da Universidade Ain Shams em 30 implantes endósseos cônicos de titânio que foram instalados em 30 pacientes na região de pré-molares superiores. Os pacientes foram divididos aleatoriamente de acordo com o protocolo de carregamento em 3 grupos (10 pacientes cada): Grupo I (IFLV): os pacientes receberam coroas usinadas em CAD/CAM de cerâmica infiltrada com polímero (VITA-ENAMIC) (carga imediata), Grupo II (IFLP): os pacientes receberam coroas usinadas em CAD/CAM de PMMA (em oclusão por 3 meses) seguidas por coroas de cerâmica infiltrada com polímero (VITA-ENAMIC) (carga funcional), e Grupo III (INFLP): os pacientes receberam coroas usinadas em CAD/CAM de PMMA (infraoclusão por 3 meses) seguido de coroas de VITA-ENAMIC (carga funcional). **Resultados:** Após três meses; o maior valor de perda óssea marginal (mm) foi encontrado no IFLV, seguido pelo IFLP, enquanto o menor valor foi encontrado no INFLP. Após seis meses, o maior valor foi encontrado no IFLP, seguido do IFLV, enquanto o menor valor foi encontrado no INFLP. Além disso, após doze meses, o maior valor foi encontrado no IFLV, seguido pelo IFLP, enquanto o menor valor foi encontrado no

INFLP. Os valores de perda óssea marginal estavam todos dentro de valores aceitáveis para sucesso clínico para todos os grupos testados. **Conclusão:** A carga funcional não imediata proporcionou resultados mais aceitáveis do que a carga imediata. Além disso, o carregamento funcional imediato e não imediato de implantes utilizando coroas finais de cerâmica híbrida mostrou resultados promissores com a seleção adequada dos pacientes.

PALAVRAS-CHAVE

Reabsorção óssea; CAD/CAM; Cerâmica; Híbrido; Carregando.

INTRODUCTION

Loss of teeth may affect the quality of patient's life esthetically, functionally, and biologically [1]. Traditionally, these teeth were restored with either a fixed or a removable prosthesis. However, both of these restorative options have some drawbacks related to the health of the oral tissues and reduced patient satisfaction [2]. Therefore, dental implants were introduced to provide an alternative for replacing missing teeth [3]. Implants come in a variety of shapes and sizes to suit the missing teeth and the types of prostheses used. Their surfaces have been improved to enhance the Osseo-integration. Instead of surfaces being smooth or machined, they are roughened by sandblasting and acid etching, which increases the surface area to which bone can attach [4]. The implant design "threaded type implants" are generally recommended due to their mechanical retention properties, which minimize micromotion and improve primary stability [5].

In natural teeth, the impact energy of the masticatory forces is absorbed by the periodontal ligament [6]. Dental implants are not surrounded by a resilient periodontal ligament therefore the forces will be transmitted directly to the bone [7]. The increased amount of stress on the bone can induce resorptive remodeling and mechanical failure of the implant [8]. The desire for fewer surgical interventions and shorter implant treatment times has led to the development of revised placement and loading protocols. A healing period of 4–6 months was proposed to ensure osseointegration of dental implants [9].

With the improvements in oral implantology, the traditional protocol for implant dentistry has been constantly reevaluated. Recent steps include a reduction of the treatment time through the immediate placement of implants into fresh extraction sockets [10] and by loading the implants immediately [11]. Immediate loading protocols have been extensively discussed in the literature and found to be a viable treatment approach in selected cases [11]. This clinical study was conducted to evaluate the effect of loading protocol using hybrid ceramic material on marginal bone loss using three protocols: Immediate functional implant loading - using hybrid ceramic material, Immediate functional implant loading - using PMMA provisional material followed by delayed functional loading using hybrid ceramic material, Immediate non-functional implant loading - using PMMA provisional material followed by delayed functional loading using hybrid ceramic material. The null hypothesis of this research suggested that different immediate functional loading protocols wouldn't have an effect on the marginal bone loss.

MATERIAL & METHODS

This investigation was a randomized double-blinded clinical trial where both the clinician and the patients were blinded during the randomization process . Patients were assigned into three groups using simple allocation sequence concealment by a computer- generated random number sequence . It was conducted in the outpatient clinic of the fixed prosthodontics department, Ain Shams University on a series of 30 titanium endosseous tapered threaded implants (two-piece) which were placed in 30 patients in the upper premolar area. It was approved by the ethics committee of the faculty of dentistry Ain Shams University (FDASU-RECR021805). A total sample size of 30 patients (10 in each group) was sufficient to detect a power of 71%, and a significance level of 5%. It was calculated by G*Power (Version 3.1.9.2).

Patients were selected according to certain inclusion and exclusion criteria. Inclusion criteria involved: patients between the age of 25 and 40, systemically healthy, missing upper premolar not less than 1 year, bounded by natural teeth anteriorly and posteriorly, sufficient bone width and height to receive an implant of minimum diameter of 3.75 mm, bone quality either D2 or D3 as assessed by CBCT (determined using the Hounsfield scale, which is a quantitative scale provides an exact density value for each tissue type. On the Hounsfield scale, the air has a value of −1000 (black on the grayscale), while bone presents values from +700, for spongy bone, to +3000, for dense bone), good oral hygiene with healthy gingiva, canine-guided occlusion, and the implant should be placed in healed bony site with a ridge width of at least 5.5mm. While the exclusion criteria were: patients with metabolic bone disorders, presence of para-functional habits such as bruxism, deep bite, smokers, and and mentally disturbed patients.

Implants were placed in the upper premolar area. The patients were divided randomly (randomized double blinded clinical trial) according to the loading protocol into 3 groups (10 patients each): Group I (IFLV): patients received CAD/CAM polymer infiltrated ceramic VITA-ENAMIC crowns (VITA Zahnfabrik H. Rauter GmbH & Co.KG Spitalgasse Germany) (immediate functional loading), Group II (IFLP): patients received CAD/CAM PMMA crowns (Vipi block, vipi, Brasil) (in occlusion for 3 months) followed by CAD/CAM polymer infiltrated ceramic (VITA-ENAMIC) crowns (functional loading), and Group III (INFLP): patients received CAD/CAM PMMA crowns (out of occlusion for 3 months) followed by CAD/CAM polymer infiltrated ceramic (VITA-ENAMIC) crowns (functional loading).

Precise medical, dental, and family histories were taken from all patients through a direct interview and a questionnaire sheet. Thorough clinical examination including extra and intra-oral examinations. Bone sounding was done to the edentulous area and periodontal probing of adjacent teeth. A diagnostic file of the patient and pre-operative photographs of the patients were performed. Clinical photographs were taken for each patient using a digital camera including the implant site and at least one adjacent tooth on each side, the reference teeth should be visible well enough to ensure comparability.

Cone beam computed tomography (CBCT) was used to evaluate the bone height and width in the area of interest, and also to assess the position of the maxillary sinus and bone quality of the alveolar ridge had been assessed. CBCT was used to select the proper implant diameter and length with a safety margin of intact bone 2 mm between the implant and the floor of the maxillary sinus and 1.5 mm between the implant and the adjacent teeth was left [12].

The planning software (Blue Sky Bio software) was used to simulate implant placement on the 3D model using CBCT data. Two-piece implants (Neo CMI implant, Neo Biotech implant, Korea) were used in the study. Implant Kit: Neobiotech IS Full Kit ver.5 surgical tray kit (Neobiotech Inc., Los Angeles, USA) and Dentis simple guide surgical kit (Dr. Amr EL Khadem, Cairo, Egypt) were used for implant placement. Then drilling was done through the guide using Dentis simple guide kit, as demonstrated in Figure 1. During drilling no lateral movement was done. Only vertical motion is allowed to avoid detachment or fracture of the metal sleeves.

Insertion Torque was checked with the 30N/cm torque wrench, as observed in Figure 2. A post-operative CBCT was made for the patient after implant insertion to ensure the proper positioning of the implant within the bone. On the same day of the surgery, the final impression was taken. Single step impression technique with an Open tray technique using vinyl polysiloxane impression material, Panasil impression material, (Kettenbach LP, Huntington Beach, USA) was used. The Access hole for the impression coping

Figure 1 - Drilling through the guide.

(transfer coping) was prepared in the rigid impression tray. The guide screw was tightened using the hex driver. The putty impression material was mixed according to manufacturer instructions and loaded in the tray at the same time the light body impression material was auto-mixed and applied around the impression post. The loaded tray was seated inside the patient's mouth parallel to the long axis of the teeth and held in place without exerting pressure until the material was set.

The internal hex of the implant was irrigated and the healing cap was screwed inside the implant using the hex driver. The implant-level replicas (laboratory analogs) were screwed into the impression copings with the hex driver. The soft tissue cast (gingival mimic) was used for the proper emergence profile. Abutments were first screwed to the analogs, then occlusal reduction for the abutments was made to create a 2mm occlusal clearance to receive the restoration.

Figure 2 - Checking primary stability with the 30N/cm torque wrench.

Designing of the crowns was done using Exocad 2016 software .

In Group I (IFLV): the occlusal parameters during the CAD procedure were adjusted to establish a light occlusal contact in centric maximum intercuspation. After the milling procedure, final adjustments of the crowns were performed inside the patient's mouth with 200-micron articulating paper to remove any heavy contacts. An additional occlusal checking was performed with 40 micron and 12 micron articulating paper respectively to ensure that a light occlusal marking was achieved on the implant restoration while heavy markings were achieved by the adjacent natural teeth.

The palatal cusps of the restorations occluded in the central cusp or the fossae of their counterparts while the buccal cusps were free from any contact (Figure 3).

Group II (IFLP): patients received CAD/CAM PMMA crown (in occlusion for 3 months) followed by CAD/CAM VITA ENAMIC crown (functional loading).

Group III (INFLP): patients received CAD/CAM PMMA (out of occlusion for 3 months). The occlusal parameters during the CAD procedure were adjusted to have no occlusal contact in centric occlusion or lateral excursive movements. After the milling procedure, final adjustments of the crowns were performed inside the patient's mouth with articulating paper to ensure no contact in centric and eccentric movements. After 3 months the crown was replaced by CAD/CAM VITA ENAMIC crown (functional loading) (Figure 4).

Immediate loading of the implants was done within maximum of 2 days. After the fabrication

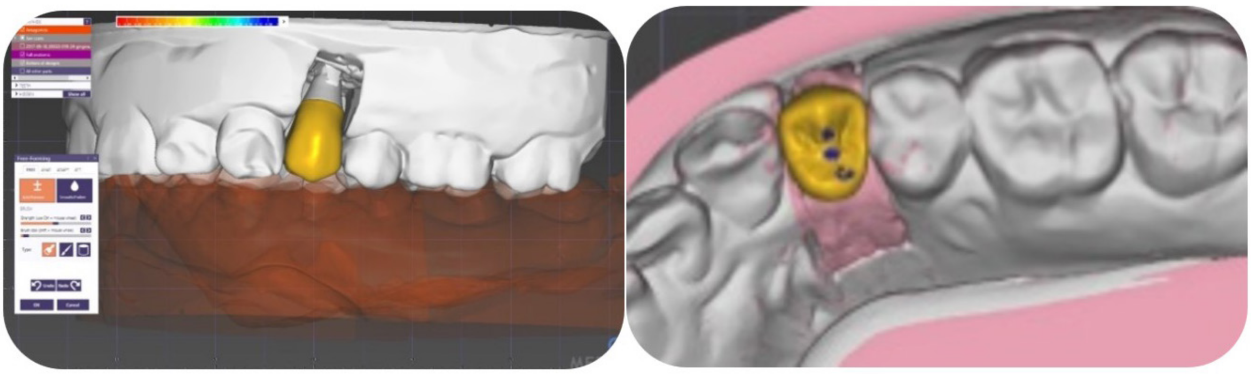

Figure 3 - Functional occlusion design.

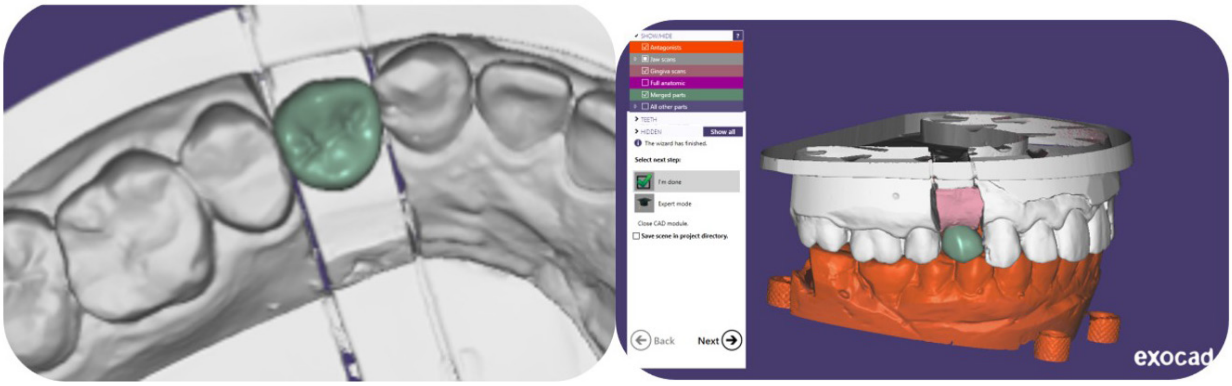

Figure 4 - Non-functional occlusion design.

of the restoration, the healing caps were removed from the patient's mouth and the final abutments were removed from the cast and tightened over the implants with the hex driver, then the restorations were placed over the corresponding abutments and checked for contact, occlusion and shade. PMMA crowns were replaced after 3 months in groups INLP and IFLP by Vita Enamic crowns after taking a new impression and fabrication of the final restoration.

Bone height measurements: An immediate post-operative CBCT was taken after implant placement to serve as a baseline for further investigations. Three CBCTs were taken at three months, six months, and one year. These CBCTs were compared to the baseline CBCT took immediately post-operative to measure the marginal bone loss. A comparison of marginal bone loss was performed by the superimposition of the CBCTs and measuring the amount of bone loss. Surface based registeration method were used which relies on automated superimposition to determine the best surface fit registeration .The measurements were taken from the crest of the ridge until the apex of the implant. The raw DICOM data set obtained from the CBCT scanning was imported to a specialist third party software for secondary reconstruction and the results obtained were compared to each other (Figures 5, 6, 7 and 8).

Statistical methods

Numerical data were presented as mean and standard deviation values and were explored for normality by checking the data distribution and using the Shapiro-Wilk test. Data were normally distributed and were analyzed using one-way ANOVA followed by Tukey's post hoc test for intergroup comparisons and repeated measures ANOVA followed by Bonferroni's post hoc test for intragroup comparisons. The significance level was set at $p<0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.1.3 for Windows R-core Team.

RESULTS

According to Table I and Figure 9, after three months; the highest value of marginal bone loss (mm) was found in group I (IFLV) (0.96±0.03), followed by group II (IFLP) (0.94±0.03), while the lowest value was found in group III (INFLP) (0.57±0.06). Post hoc pairwise comparisons showed group (III) to have a significantly lower value than other groups ($p<0.001$) while there was no significant difference between group I and group II.

While after six months, the highest value was found in group II (IFLP) (1.29±0.02), followed by group I (IFLV) (1.28±0.07), while the lowest value was found in group III (INFLP) (0.74±0.07). Post hoc pairwise comparisons showed group (III) to have a significantly lower value than other groups ($p<0.001$) while no significant difference was detected among group I and group II. Also, after twelve months, the highest value was found in group I (IFLV) (1.62±0.15), followed by group II (IFLP) (1.61±0.15), while the lowest value was found in group III (INFLP) (1.06±0.05). Post hoc pairwise comparisons showed group (III) to have a significantly lower value than other groups ($p<0.001$) while there was no significant difference between group I and group II.

According to Table II and Figure 10, in group (I) (IFLV) there was a significant difference between values measured at different intervals ($p<0.001$).

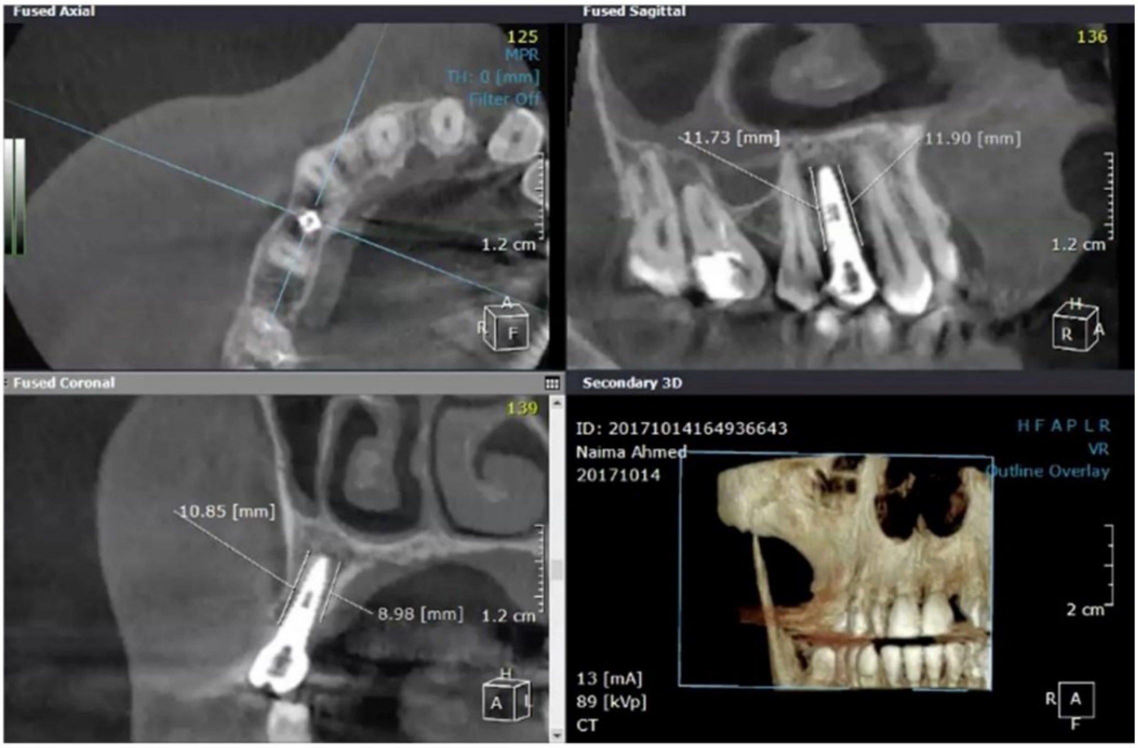

Figure 5 - Buccal, palatal, mesial and distal CBCT measurements at baseline.

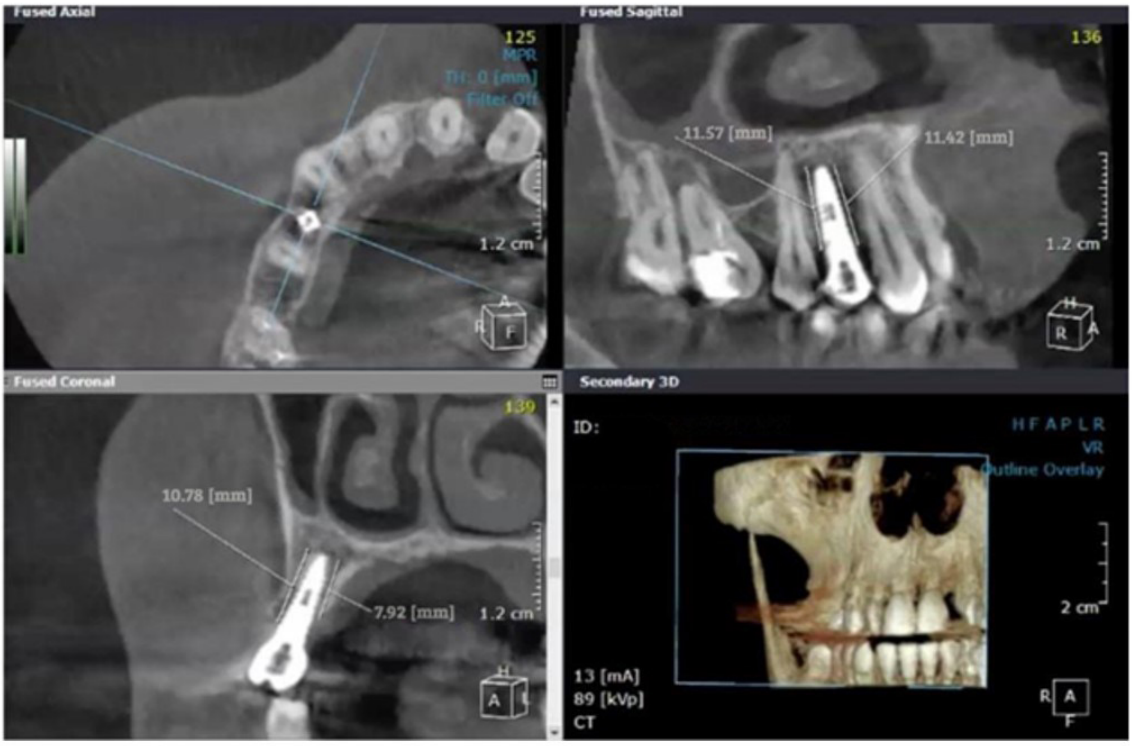

Figure 6 - Buccal, palatal, mesial and distal CBCT measurements at 3 months.

The highest value was measured after 12 months (1.62±0.15), followed by 6 months (1.28±0.07), while the lowest value was found after 3 months (0.96±0.03). Post hoc pairwise comparisons showed values measured at different intervals to be significantly different from each other ($p<0.001$).

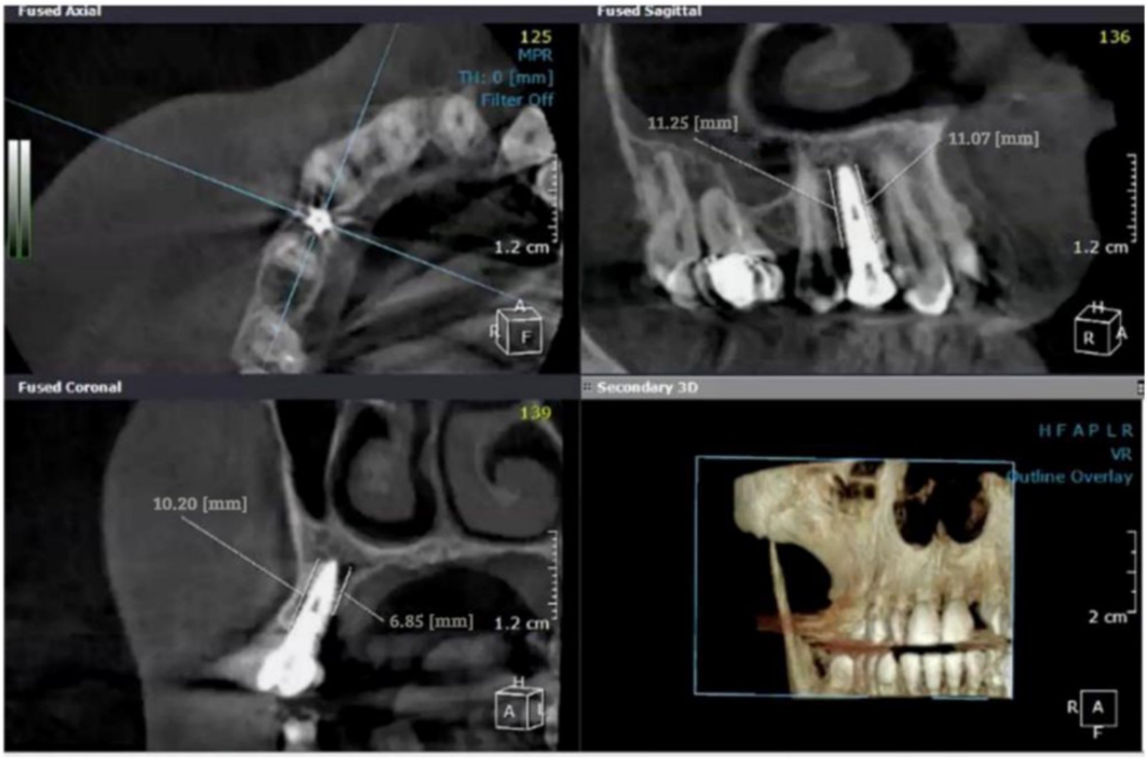

Figure 7 - Buccal, palatal, mesial, and distal CBCT measurements at 6 months.

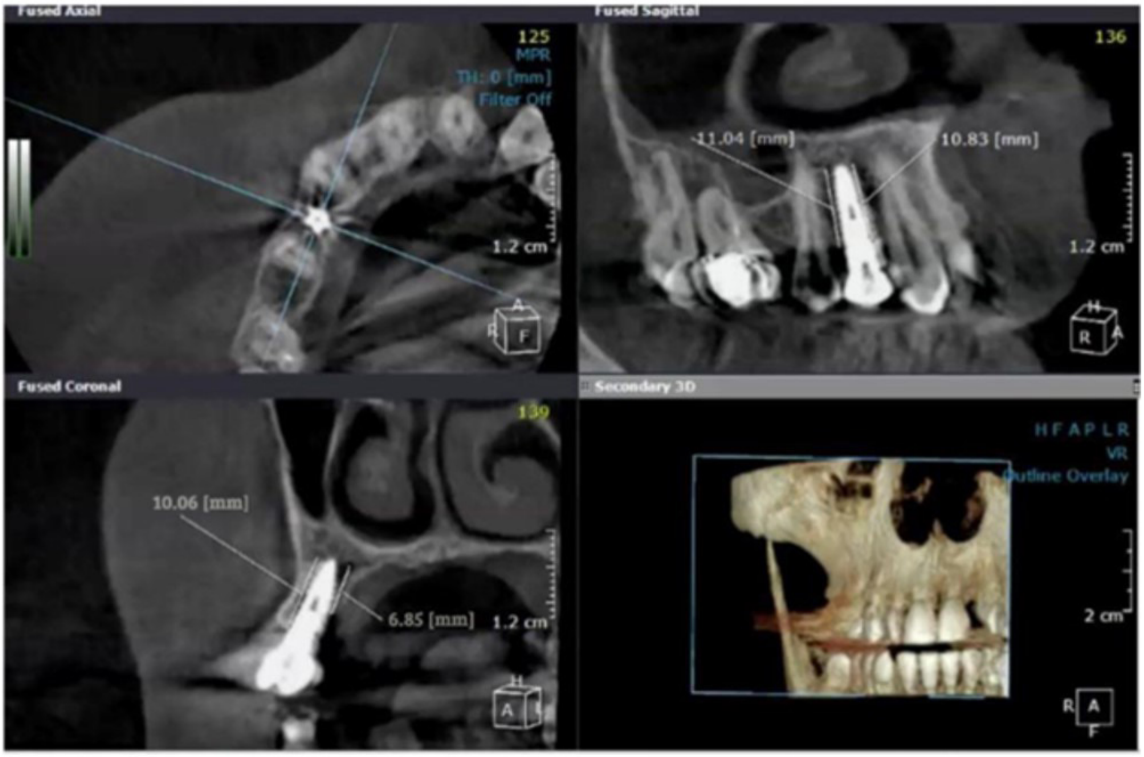

Figure 8 - Buccal, palatal, mesial, and distal CBCT measurements at 12 months.

In group (II) (IFLP) there was a significant difference between values measured at different intervals ($p<0.001$). The highest value was measured after 12 months (1.61±0.15), followed by 6 months (1.29±0.02), while the lowest value was found after 3 months (0.94±0.03).

Table I - Mean, Standard deviation (SD) values for the intergroup comparison of marginal bone loss (mm)

Time	Marginal bone loss (mm) (Mean ± SD)			p-value
	Group (I)	Group (II)	Group (III)	
3 months	0.96±0.03^{A}	0.94±0.03^{A}	0.57±0.06^{B}	<0.001*
6 months	1.28±0.07^{A}	1.29±0.02^{A}	0.74±0.07^{B}	<0.001*
12 momths	1.62±0.15^{A}	1.61±0.15^{A}	1.06±0.05^{B}	<0.001*

Means with different superscript letters within the same row are statistically significantly different *. significant (p ≤ 0.05). ns: non-significant (p>0.05).

Table II - Mean, Standard deviation (SD) values for intragroup comparison of marginal bone loss (mm)

Groups	Marginal bone loss (mm) (Mean ± SD)			p-value
	3 months	6 months	12 months	
Group (I)	0.96±0.03^{C}	1.28±0.07^{B}	1.62±0.15^{A}	<0.001*
Group (II)	0.94±0.03^{C}	1.29±0.02^{B}	1.61±0.15^{A}	<0.001*
Group (III)	0.57±0.06^{C}	0.74±0.07^{B}	1.06±0.05^{A}	<0.001*

Means with different superscript letters within the same row are statistically significantly different*. significant (p ≤ 0.05). ns: non-significant (p>0.05).

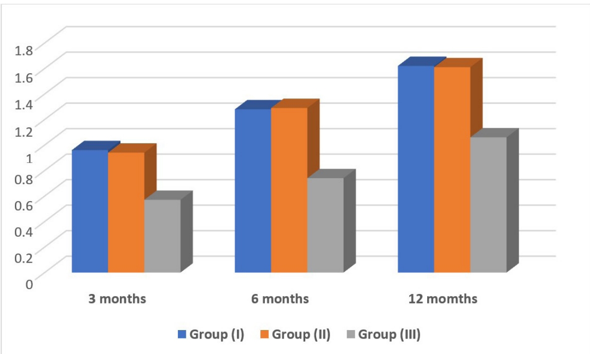

Figure 9 - Bar chart showing average marginal bone loss (mm) in different groups.

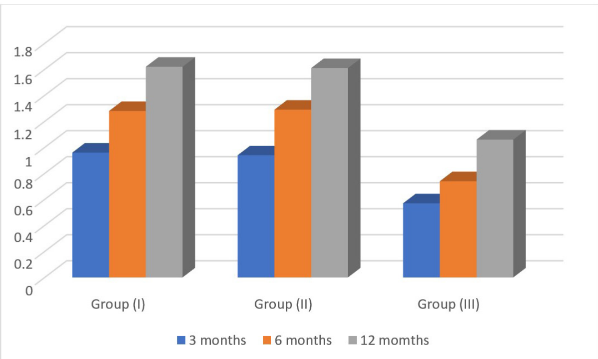

Figure 10 - Bar chart showing average marginal bone loss (mm) in different intervals.

In group (III) (INFLP) there was a significant difference between values measured at different intervals (p<0.001). The highest value was measured after 12 months (1.06±0.05), followed by 6 months (0.74±0.07), while the lowest value was found after 3 months (0.57±0.06).

DISCUSSION

Implants with platform switched design was used in this study in order to switched implants maintain better bone Levels [13]. The maxillary premolar area was chosen as the area of interest in the study as it combines the high concern of both esthetics and function [14]. Flapless technique, surgical stents and guided surgeries based on CBCT images allowed ideal placement of implant according to the the planned restorations to facilitate the establishment of favorable forces on the implant and prosthetic part as well as ensure favorable esthetic outcome [15,16].

All patients received the same treatment protocol performed by a team of implantologist, periodontist and laboratory technician. There was a lack of standardized method in evaluation of the marginal bone loss in the previous literature [17]. However, CBCT software was able to superimpose the different 3D images to provide an accurate measurements of the amount of bone loss during the one year follow up period of the study [15].

Temporary crown materials have routinely been used for immediate restoration and immediate loading of dental implants as they are well known to develop soft tissue contours and maintain the inter dental papilla during the healing period [14]. PMMA is one of the most widely used industrial polymeric materials because of its good biocompatibility, reliability, dimensional stability, absence of taste, odor, tissue irritation and toxicity, insolubility in body fluids, relative ease of manipulation, good aesthetic appearance, and color stability [18,19]. It is supplied in the form of blanks. It has a modulus of elasticity of 3 GPa [20].

The null hypothesis was rejected as the different immediate functional loading protocols have variable effects on the marginal bone loss around dental implants. In this study, groups comparison showed a statistically significant higher amount of bone loss in group I and group II when compared to group III. This is not in agreement with Singh et al. [21]. Chrcanovic et al. [22], Vogl et al. [23], Suito et al. [24], Sato et al. [25], and Donati et al. [26] have found no statistically significant difference in marginal bone loss between functional and non – functional loading.

This study is in agreement with Ramachandran et al. [27] who conducted a study in 2016 to assess the alveolar bone density around immediate functional and immediate non-functional loading. They found that immediate functional loading resulted in a significantly larger amount of bone demineralization at the alveolar crest when compared to immediate non-functional loading as the micromotion caused by immediate functional loading affects the osseointegration by the formation of fibrous tissue between the implant and the bone under functional loading leading to more bone resorption. This study is also in agreement with Margossian et al. [28] who conducted a clinical study on the two-year success rates of immediately functionally and non-functionally loaded implants and concluded that the success rate of immediately loaded implants is comparable to conventional loading if not loaded in occlusion.

Regarding PMMA restorations, our study showed that PMMA crowns had an acceptable amount of marginal bone loss when used in immediate functional implant loading. This is in accordance with Bijjargi et al. [29] who performed a 2D finite element model to investigate the stresses transmitted by various restorative materials through implants in the bone. In the acrylic crown, the forces were more evenly distributed resulting in less stress concentration, especially at the neck of the implant. Thus it can be hypothesized that the lower modulus of elasticity of the acrylic crowns will lead to a more favorable stress distribution and ultimately a more favorable outcome.

Regarding Vita Enamic restorations, our study showed that Enamic crowns had an acceptable amount of marginal bone loss when used in immediate functional implant loading comparable to that of PMMA temporary crowns, this may be attributed to the shock absorbing feature (damping effect) of these materials [30] leading to less load transfer from the restoration to the surrounding bone. This was in agreement with several studies [31-34] which concluded that polymer-based ceramic restorations have a considerably higher capacity to dissipate energy elastically than glass or oxide ceramic restorations. Vita Enamic crowns in group I showed higher values of marginal bone loss than PMMA crowns in group II caused by the higher modulus of elasticity for Vita Enamic crowns than PMMA crowns with no significant difference between both groups.

All of the three groups showed a statistically significant higher value of bone loss from 3 months to one year in accordance with previous studies [15]. Mean marginal bone loss for group I was (1.62) mm and for group II was (1.56) mm and (1.06) mm for group III where all implants showed marginal bone loss within the normal accepted values (lower than 2 mm at the 1 year follow up period) [16],

Neither implants fail nor crowns fractures were noticed during the 1 year follow up period showing a survival rate of 100%.

The limited number of patients, accurate observation of patient inclusion/exclusion criteria, the area of interest limited to the upper premolar area, conservative surgical technique, strict periodontal and prosthetic monitoring, and short observation period, could be considered important limitations and co-factors for a high short-term successful rate observed in the study groups.

CONCLUSION

Within the context and limitations of this study, the following was concluded:

Statistically significant difference was found between immediate functional and non-functional loading protocols. This study might indicate that immediate non-functional loading provides more acceptable outcomes than immediate functional loading. Immediate functional and non-functional implant loading using hybrid ceramic as permanent material has shown promising results with proper patient selection. Marginal bone loss values were all within the accepted values for clinical success for all the tested groups.

Author's Contributions

YSAR: Conceptualization, Methodology, Software, Validation, Formal Analysis, Investigation, Resources. AMH: Visualization, Supervision, Project Administration, Funding Acquisition. MMZ: Writing – Review & Editing. SON: Data Curation, Writing – Original Draft Preparation.

Conflict of Interest

The authors declare that they have no competing interests.

Funding

This study was self-funded.

Regulatory Statement

This research was reviewed and approved by the ethics committee of the faculty of dentistry Ain Shams University (FDASU-RECR021805).

List of Abbreviations

CAD/CAM: Computer Aided Design / Computer Aided Manufacturing

PMMA: Poly Methyle Methacrylate

CBCT: Cone Beam Computed Tomography

IFLV: Immediate Functional Loading by Vita Enamic crown

IFLP: Immediate Functional Loading by PMMA crown

INFLP: Immediate Non-Functional Loading by PMMA crown

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