Original Article

Free-hand Versus Fully guided Monoblock Implant Placement In Full Mouth Rehabilitation Of Edentulous Maxillary Arches: A One-Year Clinical Study

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ABSTRACT

Objectives: Single-piece Monoblock implants promote the utilization of slightly-aggressive surgical maneuvers to restore edentulous spans with the least postoperative pain accompanied by a tremendous implant success rate. Moreover, the monoblock implants could be utilized in cases of several component restorations through Immediately or Progressively- loaded maxillary and/ or mandibular arches.

Purpose of the study: to compare, clinically and radiographically between free-hand and fully-guided placement of monoblock implants in total full mouth rehabilitation of edentulous maxillary arches.

Materials & methods: 16 completely edentulous cases were included based on certain inclusion criteria. Conventional dentures were constructed for all patients followed by, a cone beam radiograph, Patients were randomly divided into 2 groups. Group (A) is the Free-hand implant placement group and Group (Ba is the): fully-guided implant placement group. In both groups, 8 monoblock implants were placed in the central incisor region, canine region, second premolar & first molar region bilaterally. Clinical assessment included: prosthetic fitness, prosthetic maintenance, and prosthesis comfort while radiographic assessment included bone density and bone height measurements. Assessments were carried out 3, 6, 9 & 12 months after implant placement. Patient satisfaction was assisted utilizing a three-point scale patient satisfaction questionnaire.

Results: Regarding Patient satisfaction: a non-significant difference was observed between both groups, on the same line, Regarding bone healing around implants: a non-significant difference was revealed.

Conclusion: Within the limitation of this study, regarding the relatively small sample size, it could be concluded that the clinical and radiographic outcomes revealed that, a non-significant difference was observed between both groups, throughout the whole study period.

Key Words: Monoblock implants, Edentulous Maxilla, Prosthetic maintenance, Patient satisfaction, Progressive Loading.

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INTRODUCTION:

Utilizing two-piece implants as a traditional method for edentulous span rehabilitation sometimes has been unsuitable [1]. To clarify, standard implant designs might be restricted or unsuitable in fixing specific edentulous spans [2,3], an alternative monoblock implant system was recommended for restoring such cases.

Monoblock (sometimes called Monolithic) implants facilitate restoring edentulous spans that formerly couldn't be treated with traditional two-piece implants. Furthermore, they grant slightly-aggressive surgical maneuvers with subsequently increased tissue maintenance [4].

A single-piece implant system is a single-piece system that does not exhibit any other pieces such as abutment screws in-between the implant & abutment [5, 6].

Such a single-piece implant proposes a distinctive one-piece outline incorporating the implant as well as its super-structure, for an immediate, single-stage procedure. Implants were particularly planned to be utilized in knife-edge ridges [7]. Besides, they are time efficient as they eliminate the need for further surgeries or mucosal healing intervals and consequently, reduce patient suffering from any additional discomfort or distress. Monoblock, single-piece implants are considered less aggressive and could be loaded immediately in conditions of appropriate bone characteristics, or furthermore, loaded progressively in cases of inferior bone conditions [8].

Monoblock implant placement affords a modest treatment succession with a minimal budget, also, presenting the possibility to deal with aged patients for instance with tremendously less annoying implantation procedures (Flapless implantation maneuver). [9] Flapless implantation maneuvers might be operated free-handed, utilizing guided surgical approaches or tailor-made stents. Those different flapless maneuvers offered both clinicians & their patients a unique treatment methodology. [10,11] in addition to the technical simplicity that will be It is important to

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mention that, based on previous studies, the mean bone loss in the one-stage technique lies within the clinically acceptable parameters. [14] A fully-guided surgical stent was utilized to direct implant placement in the proper three-dimensional location based on the anatomic, prosthetic as well as aesthetic requirements apparent in each individual patient. [15,16] Regarding fully-guided surgeries, each surgical stent leads the whole procedure. [17] Hence, accuracy is considered the main benefit [18]. Oppositely, the template might hinder the flow of irrigant solution, resulting in elevated temperature, resorption of bone, and injury of the osseointegration process as a whole [19].

The alternative approach is half-guided, incorporating: a guided drilling procedure, utilizing the surgical guide throughout the whole preparation sequence, and finally, the implant is inserted in a free-hand technique, where the template is fabricated from a waxed-up denture or patient,s old prosthesis. [20, 21].

The main research question behind this study was to clarify whether single-piece implant placement utilizing computer-guided stents will give more accurate results than free-hand placement of the single-piece implant or not?..

The null hypothesis was that there will be insignificant differences between free-hand and fully-guided implant placement of monoblock implants as regards the clinical and radiographic outcomes investigated.

MATERIALS AND METHODS:

16 completely edentulous patients from the Prosthodontic department-Cairo university outpatient clinic were selected according to specific inclusion criteria; (Figure1).

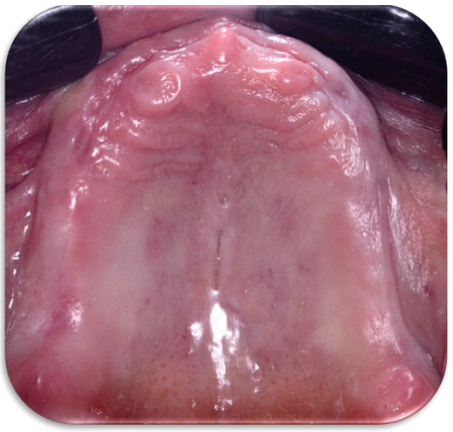
- Male patients with ages ranging between 35- 50 years with completely edentulous maxillary arches.

- patients with sufficient interforaminal bone volume

-Patients with reasonable oral hygiene.

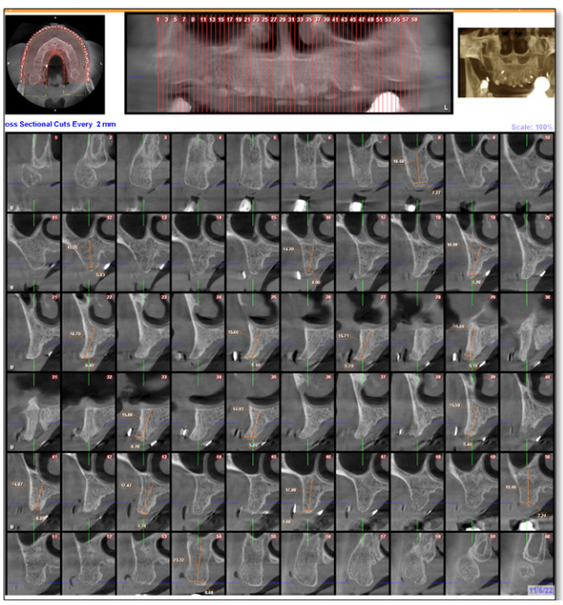
- Patients were free from any systemic or debilitating diseases that might affect the bone quantity or quality. Patients with uncontrolled diabetes (HbA1c >7) were excluded.

- Patients with Angle's class I maxillo-mandibular relationship with normal occlusion.

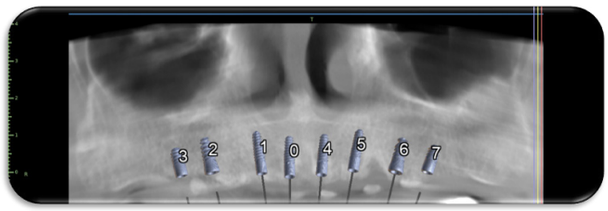


(Figure 1): Patient with completely edentulous maxillary arch.

All patients signed informed consents after taking their approval of conducting the research & being recalled for follow-up appointments. The study was conducted according to principles stated in the Helsinki Declaration and was approved by the Ethical Committee-Cairo University. Conventional dentures were constructed for all patients followed by a cone beam radiograph (CBCT) (Figure 2). The patients were then allocated randomly into two groups using closed opaque envelopes. Group (A): Free-hand implant placement group and Group (B): a fully-guided implant placement group. Eight monoblock implants (GREEN implants, Germany) were planned to be inserted in the central incisor/canine region, second premolar & first molar region bilaterally (Figure 3), using a virtual planning software (Blender for dental software).

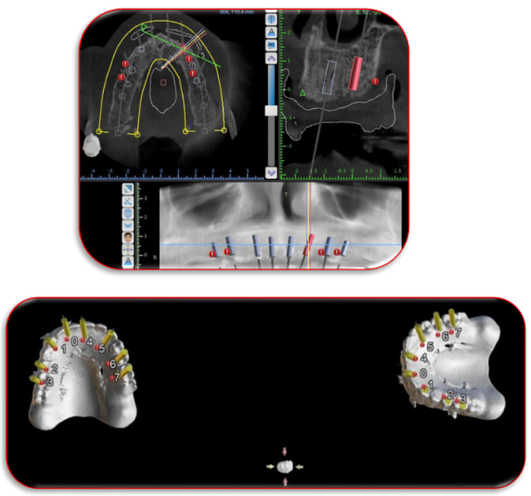


(Figure 2): Diagnostic preoperative cone beam computerized tomography (CBCT).

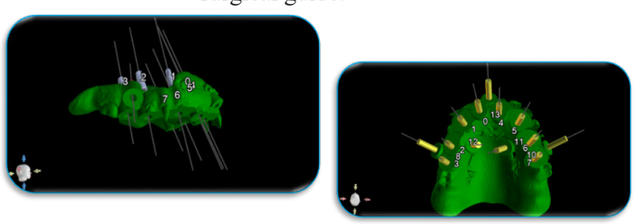


(Figure 3): Virtual planning of Monoblock implants.

For group B: a fully computerized surgical guide was virtually planned (Figure 4), with 5 anchor fixation pins (Two palatally, two buccally & one labially) (Figure 5), It was then 3D printed (Monox 6K 3D printer, China).in a clear transparent acrylic resin stent (Wash and cure 2.0 resin, China). (Figure 6)



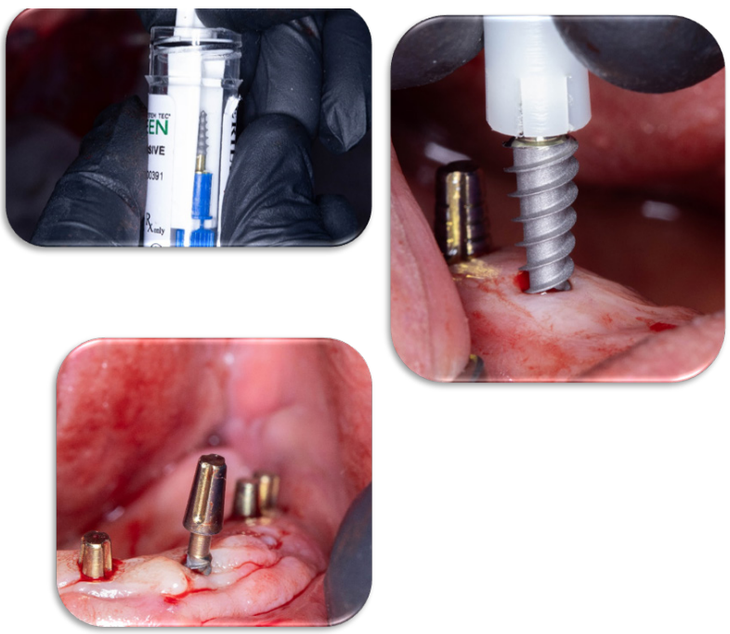
(Figure 4): Virtual planning of a fully computerized surgical guide.



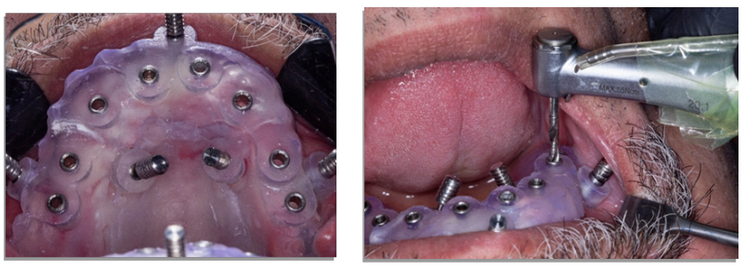
(Figure 5): Surgical guide construction with 5 anchor fixation pins.

(Figure 6): A 3D-printed clear transparent acrylic resin stent.

On the day of the surgery, group (A) patients received the monoblock implants in the planned positions after osteotomy preparation utilizing the free-hand technique (Figure7) while, in group (B), the implants were placed using the printed fully computerized surgical guide after its fixation using 5 anchor fixation pins (Figure8).

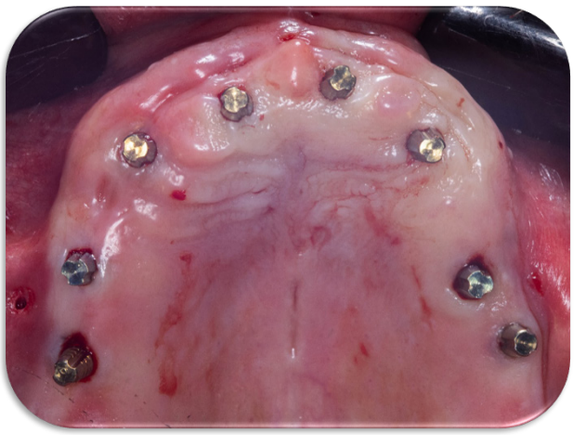


(Figure 7): Proper implant placement after Free-hand osteotomy preparation technique.

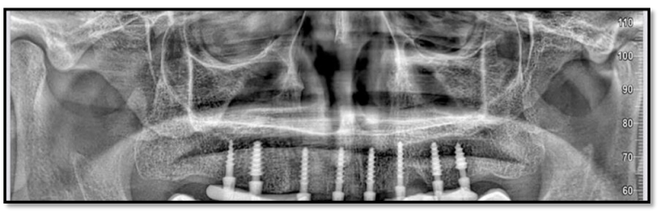


(Figure 8): Proper implant placement after Fully-guided osteotomy preparation technique.

In both groups, monoblock implants were checked intra-orally (Figure 9), as well as by post-operative panoramic x-ray for accurate placement (Figure 10). Next, a direct impression was taken following implant insertion utilizing prefabricated plastic impression caps with One-step Putty & light rubber base impression (Panasil, Katzenbach, Germany) (Figure 11). Afterwards, single-piece transfer copings and implant analogues were installed onto the resultant impression, and finally, an accurate bite registration record. (Figure 12)

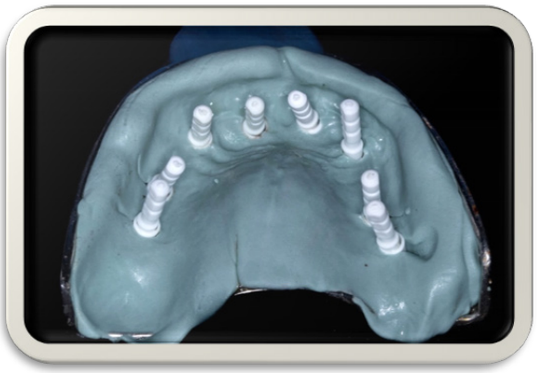


(Figure 9): Confirmation of accurate implant placement in planned positions Intra-orally.



(Figure 10): Post-operative panoramic X-ray for accurate placement.

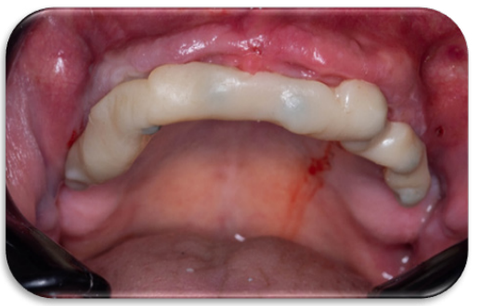
(Figure 11): Positioning of plastic impression caps.



(Figure. 12): Rubber-base, single-step impression enclosing plastic impression caps & Single-piece impression analogues.

It is important to mention that in a few cases of free-hand implant placement, implant position had to be adjusted with the aid of the bending property inherent in monoblock implants.

Splinting of the monoblock single-piece implants was made utilizing a specialized type of light-cured heavy-body composite material (Ivoclar-Vivadent, Germany) (Figure13)



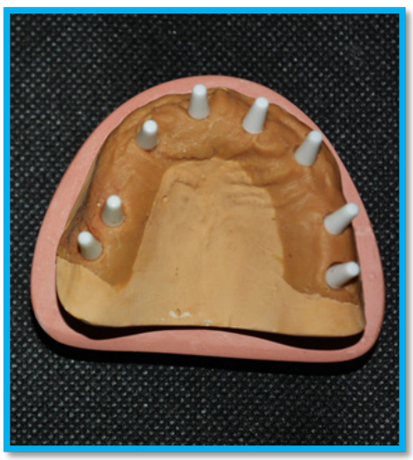
(Figure 13): Splinting of the Monoblock single-piece implants.

Post-surgical instructions

The non-steroidal anti-inflammatory analgesic tablets (Voltaren, 75ml oral, NOVARTIS, Egypt) were prescribed to the patients after surgery to relieve discomfort and swelling, taken as one pill, 3 times per day for three days successively. It was also advised that patients continue taking antibiotics (Augmentin 1g) for 5 days. Patients were instructed to apply cold packs for 10 minutes at intervals of 10 minutes for 3–4 hours. and to follow strict oral hygiene measures

Laboratory procedure (for Both Groups):

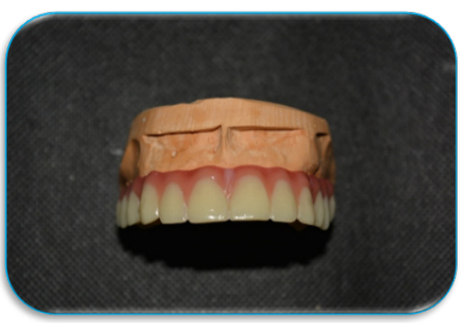
In the laboratory, the impression surface surrounding the single-piece analogues was varnished with vaseline, then a gingival mask (Xilgum, Lascod, Italy), was applied around the analogs .Then the impression was poured using extra-hard stone to gain a master cast that enclosed the implant analogue part with attached abutments analogues were visible from the cast. (Figure 14)



(Figure 14): A master cast obtained from the Direct Impression including the Single-piece analogues.

Final Prosthesis for both groups:

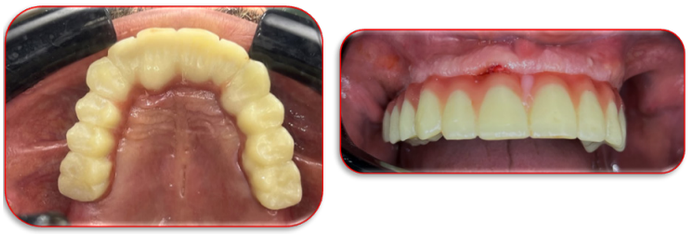
Patients received final acrylic full arch restoration with Visiolign gingiva (Bredent, Germany) being fabricated on the stone master cast, in 57- days only. All Prostheses were fabricated by a single well-experienced dental technician in the same dental laboratory. Patients firmly requested soft dieting for 4 months and strict oral hygiene measures. (Figure 15)



(Figure 15): Maxillary PMMA full arch restoration with Visiolign gingiva being fabricated on the stone master cast.

Final prostheses for patients of both groups were checked intra-orally for accuracy, occlusion (occlusion in centric only & free in any eccentric movements, following guidelines of Progressive loading protocol), and esthetics.

Then, cemented over the implants utilizing a specialized cementing material (low shrinkage acrylic hard recliner-DuraLay- Dentsply; Pattern Resin™, USA). (Figure 16)



(Figure 16): Maxillary PMMA full arch prosthesis intra-orally.

All patients were recalled periodically at 3, 6, 9 & 12 months respectively for clinical outcomes (represented as implant stability using Periotest as well as patient satisfaction questionnaire) as well as radiographic outcomes. It is worth denoting that the opposite mandibular arch was restored in the same manner as the maxillary arch but assisted in another study.

Radiographic evaluation:

The Digora computerized system was utilized for making intra-oral digital radiographic images to evaluate the following:

1- Variations in the mesial and distal marginal bone height around the implants.

2- Variations in bone density around the implants.

- The imaging plate was inserted into a protective bag which was wrapped by the Digora system. The stored images of every single patient were interpreted at the end of the follow-up period.

All the results were calculated, tabulated, and then statistically analyzed.

Sample Size Calculation:

A study of independent cases and controls was planned with 1 control [(s)] per case. Prior data indicate that the probability of exposure among controls is 0.25. If the true probability of exposure among cases is 0.95, we will need to study 6 case patients and 6 control patients to be able to reject the null hypothesis that the exposure rates for cases and controls are equal with probability (power) 0.8. [22]The Type I error probability associated with this test of this null hypothesis is 0.05. An uncorrected chi-squared statistic was used to evaluate this null hypothesis with extra 25% subjects to compensate for dropout cases during follow-up. The total sample size was 16 subjects.

*SPSS, Inc., Chicago, IL, USA.

Statistical Analysis:

Data were revealed as percentages for each clinical output of prosthetic fitness, maintenance, and comfort during twelve months follow-up period. Studying the effect of time on each group was performed using One Way Analysis of Variance (One Way ANOVA) followed by Tukey`s post hoc test for multiple comparisons for each group and comparison between both groups was performed using independent t-test at probability level ≤ 0.05.

The significance level was set at P ≤ 0.05. Statistical analysis was made with SPSS 20* (Statistical Package for Scientific Studies) for Windows.

RESULTS

A. Clinical Outcome:

(i) Effect of time:

For the effect of time on clinical outcomes (Table 1 and Figure 17), prosthetic fitness revealed a higher significant decrease among different follow-up intervals for group II than group I with insignificant differences between (baseline and three months) and between (six months and nine months), as P-value > 0.05.

(ii) Effect of grouping:

Regarding prosthetic maintenance, group I revealed a higher significant increase among different follow-up intervals than group II with an insignificant difference between (six months and nine months), as P-value > 0.05. Finally, for prosthesis comfort, group II revealed a higher significant decrease among different follow-up intervals than group I with an insignificant difference between (six months and nine months), as P-value > 0.05.

B. Radiographic Outcome:

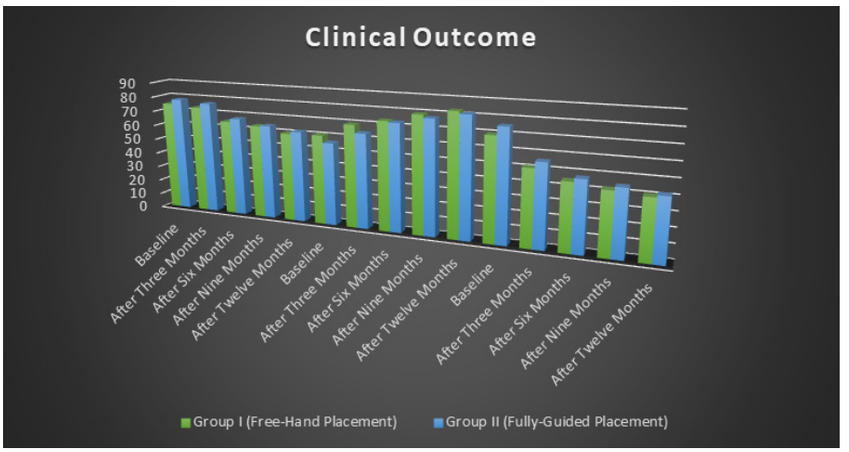
One Way ANOVA followed by Tukey's post hoc test for multiple comparisons revealed a significant increase in bone loss along the twelve-month follow-up for the mesial and distal surfaces with a P-value<0.05 for group I and group II, as listed in Table (2) and showed in Figure (18). There was a substantial increase in bone density for the mesial and distal surfaces throughout the course of the 12-month follow-up for group I and group II, according to One Way ANOVA and Tukey's post hoc test for multiple comparisons, as listed in the Table (3) and showed in Figure (19).

Using Pearson`s coefficient of correlation, revealed a strong positive correlation of implant stability using Periotest with bone loss in height and bone density, as listed in Table (2) and Table (3).

Table (1): Clinical Outcomes Evaluation using Three Point Scale:

		Group I (Free-Hand Placement)	Group II (Fully-Guided Placement)	P-value
Prosthetic Fitness	Baseline	74.87%±3.232a	78.23%±4.255a	0.097 (ns)
	After Three Months	73.52%±4.189a	76.72%±2.176a	0.1071 (ns)
	After Six Months	65.17%±2.654b	67.55%±6.329b	0.3433 (ns)
	After Nine Months	63.74%±5.167b	64.32%±1.725b	0.7677 (ns)
	After Twelve Months	60.14%±3.465b	61.91%±5.324c	0.4438 (ns)
	P-value	<0.0001*	<0.0001*	
Prosthetic Maintenance	Baseline	60.76%±5.846a	56.11%±4.518a	0.0968 (ns)
	After Three Months	69.56%±4.932a	64.29%±6.873b	0.0999 (ns)
	After Six Months	73.63%±4.765b	72.88%±6.193c	0.79 (ns)
	After Nine Months	79.27%±3.194b	77.27%±5.266c	0.3739 (ns)
	After Twelve Months	82.89%±5.247c	81.35%±2.188d	0.4563 (ns)
	P-value	0.0022*	<0.0001*	
Prosthetic Comfort	Baseline	69.62%±5.862a	75.54%±6.126a	0.0683 (ns)
	After Three Months	51.39%±2.211b	55.74%±6.531b	0.163 (ns)
	After Six Months	45.28%±1.358c	47.52%±2.966c	0.3737 (ns)
	After Nine Months	42.34%±4.199c	44.73%±3.264c	0.2244 (ns)
	After Twelve Months	40.63%±3.451c	42.07%±4.138c	0.4622 (ns)
	P-value	<0.0001*	<0.0001*	

M; Mean, SD; Standard Deviation, P; Probability Level
Means with different letters in the same column were significantly different using Tukey`s Post hoc test
Ns; Insignificant Difference
*; Significant Different

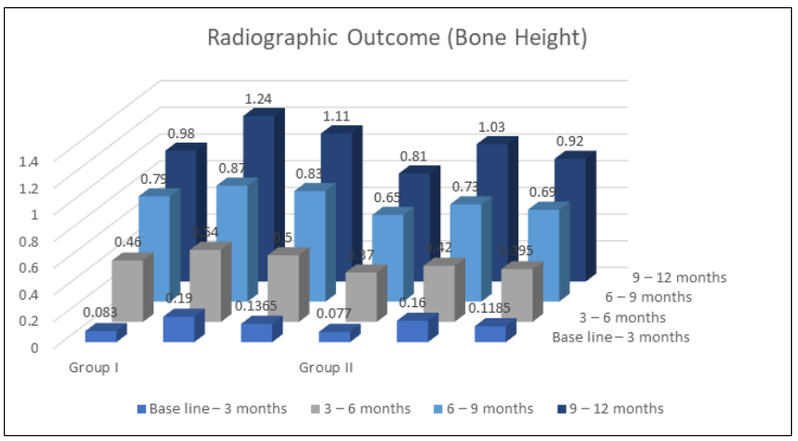


(Figure 17): A histogram representing Clinical Outcomes in both groups.

Table (2): The Means, Standard Deviation (SD) Values, and Results of the One-Way ANOVA Test for Comparison between Bone Height Changes in Group I and Group II:

	Group I (Free-Hand Placement)			**Group II (Fully-Guided Placement)**			**P-value**
	Mesial (M±SD)	Distal (M±SD)	Average (M±SD)	Mesial (M±SD)	Distal (M±SD)	Average (M±SD)	
Baseline – 3 months	0.083±0.0025 a	0.19±0.087 a	0.1365±0.018 a	0.077±0.007 a	0.16±0.002 a	0.1185±0.077 a	0.0001 *
3 – 6 months	0.46±0.06 b	0.54±0.059 b	0.5±0.032 b	0.37±0.09 b	0.42±0.062 b	0.395±0.018 b	0.0001 *
6 – 9 months	0.79±0.014 c	0.87±0.027 c	0.83±0.016 c	0.65±0.011 c	0.73±0.074 c	0.69±0.061 c	<0.0001 *
9 – 12 months	0.98±0.058 d	1.24±0.091 d	1.11±0.057 d	0.81±0.031 d	1.03±0.048 d	0.92±0.034 d	<0.0001 *
P-value	<0.0001 *	<0.0001 *	<0.0001 *	<0.0001 *	<0.0001 *	<0.0001 *	
r with Implant Stability using Periotest		0.998 **			0.948 **		

M; Mean, SD; Standard Deviation, P; Probability Level, r; Pearson`s Correlation Coefficient
Means with different letters in the same column were significantly different using Tukey`s Post hoc test
*; Significant Different
**; Strong Positive Correlation

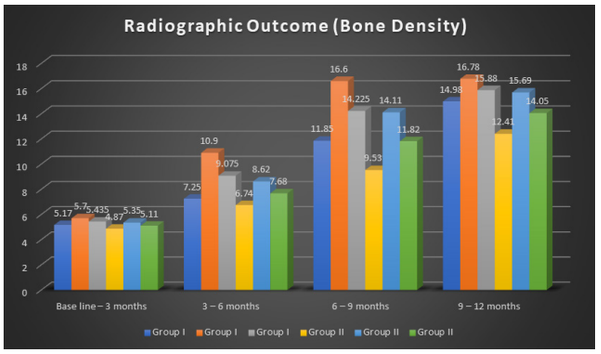


(Figure 18): A histogram representing Radiographic bone height changes in both groups throughout the study period.

Table (3): The Means, Standard Deviation (SD) Values, and Results of the One-Way ANOVA Test for Comparison between Bone Density Changes in Group I and Group II:

	Group I (Free-Hand Placement)			**Group II (Fully-Guided Placement)**			**P-value**
	Mesial (M±SD)	Distal (M±SD)	Average (M±SD)	Mesial (M±SD)	Distal (M±SD)	Average (M±SD)	
Baseline – 3 months	5.17±0.038 a	5.7±0.018 a	5.435±0.096 a	4.87±0.049 a	5.35±0.004 a	5.11±0.047 a	0.0001 *
3 – 6 months	7.25±0.07 b	10.9±0.042 b	9.075±0.028 b	6.74±0.06 b	8.62±0.058 b	7.68±0.006 b	0.0001 *
6 – 9 months	11.85±0.027 c	16.6±0.031 c	14.225±0.004 c	9.53±0.044 c	14.11±0.068 c	11.82±0.057 c	<0.0001 *
9 – 12 months	14.98±0.069 d	16.78±0.004 d	15.88±0.031 d	12.41±0.029 d	15.69±0.037 d	14.05±0.091 d	<0.0001 *
P-value	<0.0001 *	<0.0001 *	<0.0001 *	<0.0001 *	<0.0001 *	<0.0001 *	
r with Implant Stability using Periotest		0.973 **			0.975 **		

M; Mean, SD; Standard Deviation, P; Probability Level, r; Pearson`s Correlation Coefficient
Means with different letters in the same column were significantly different using Tukey`s Post hoc test
*; Significant Different
**; Strong Positive Correlation



(Figure 19): A histogram representing Radiographic bone Density changes in both groups throughout the whole study period.

DISCUSSION:

The current clinical as well as radiographic findings were found to be in the same line with the previously stated null hypothesis.

Discussion of methodology

In the existing study, patient selection was cautiously borne in mind as it may affect the osseointegration of the implants and even after prosthesis delivery. These criteria might be biological or mechanical or both. [23] To prevent any variations in bone changes that would affect the results, patients' ages ranged from 35-50 years. Additionally, the patients selected should be systemically free of any conditions that could affect osseointegration and bone healing surrounding the implants. [24] To guarantee efficient primary stability of the Monoblock implants at the time of installation and to confirm that at least 1 mm thickness of bone remained buccal and lingual to the implant after its placement, bone quality and quantity were examined radiographically. [25]
plant after its placement. [23] Provisional jaw relations have been made for the patients to emphasize adequate interarch space. Additionally, it helped in the determination of ridge relationship where patients only with Angle class I were incorporated in the study to facilitate implant insertion and preclude any possible implant overloading. [24]

To certify the accuracy of Single piece monoblock implant placement three dimensionally plus reducing any human interfering elements that might alter the appropriate implant angulation, an accurate cone beam CT Pre-planned implants positions was performed precisely [26]. Furthermore, the entire implants utilized had a tapered design, multiple aggressive threads as well as self-tapping properties & measuring 10 mm in length and 4 mm in diameter. The former implant design was devoted to improving the osseointegration as well as to ensuring optimum required primary stability for immediately loaded implants through the intimate contact between implants and their surrounding bone. [27]

To guard against possible metallic artifacts which might appear with CBCT, the precise locations of implants were assessed postoperatively, via a panoramic x-ray (owing to the presence of multiple implants) [28]. An acrylic full arch restoration with Visiolign gingiva that is implant-supported and cemented in place for maxillary rehabilitation was made-up from PMMA-reinforced material to defend the implants from overload in addition to, satisfactory aesthetic results. When the superstructure is supported by eight satisfactory-distributed implants, the load distribution over the superstructure (i.e., the prosthesis) became more profitable. [29,30].

During the traditional final impression procedures, the light body PVS impression material should be injected properly around the monoblock implant abutment necks to register all supporting and limiting structures that required for a complete denture construction. [31] The acrylic restoration with Visiolign gingival architecture has to be inspected carefully intra-orally for passivity, occlusion, esthetics, & phonetics. [32]

Although there are several ways to measure implant stability, in this study it was measured using Periotest as it is a reliable and predictable technique that can be used with the configuration of the Monoblock implants. Other techniques like the Osstell can't be used with such types of implants as the smart peg cannot be attached to the implant body itself [33]
The cases were followed up for 12 months to guarantee proper evaluation of patient satisfaction & radiographic parameters throughout an appropriate study period.

Discussion of results

None of the patients had any disturbing issues with the implant during their recall periods, and they all were strictly adherent to the oral hygiene recommendations. [34-36] Numerous experiments assumed that the greater retention and durability of patients' implant-supported fixed prostheses had upgraded their quality of life. The patient satisfaction records in both groups throughout the clinical trial demonstrated how the proper placement & distribution of the implants would affect the quality of the obtained prosthesis, whatever the placement technique utilized in the construction of the progressively loaded prosthesis. [37, 38]

Regarding Prosthetic Fitness as well as Prosthesis comfort (in terms of stability during rest and function without any patient discomfort), it was revealed that both were insignificantly decreased over time in both groups, and this could be attributed to the continuous stabilization process of the tissues underneath the prostheses over time. On the contrary, the prosthetic maintenance was insignificantly increased in both groups over time, due to increased patients' awareness regarding oral hygiene measures thorough out the investigation period. [33, 35]

The frequent remodelling process of the bone surrounding the monoblock implant, especially when employing the immediate loading protocol may describe the considerable rise in mean bone height measures in both groups (which indicates crestal bone resorption from baseline to twelve months [39]. However, the average marginal bone loss from baseline to 12 months in the current study is seen as a small decrease within generally accepted limits for dental implants, due to following guidelines for progressively loaded restorations. [40]

The better bone response revealed in Group (II) over Group (I), might be attributed to Abutment bending performed in certain cases of Group (I) to adjust parallelism, which in turn resulted in force analysis over the corresponding implants & subsequently, increased shear strength with a resultant bone loss observed. [40]The probably distributed implants in both groups antero-posteriorly (AB distance) offered better clinical and radiographic results, as it might decrease or even eliminate the need for any cantilever and increase occlusal scheme in the maxillary fixed implant-supported prosthesis, providing an improved distribution of occlusal forces and hence, enhanced bone density measurements were noticed around the implants by time. [41]

CONCLUSIONS:

Within the limitation of this study, regarding the relatively small sample size, it could be concluded that the clinical and radiographic outcomes revealed that, a non-significant difference was observed between both groups, throughout the whole study period.

CONFLICT OF INTEREST

This clinical study was self-funded by the author, with no conflict of interest.

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