



Original Research Article

Comparative evaluation of success rate of immediate non-functional loaded single tooth implants in Immediate versus delayed implant placement protocol –A randomized controlled clinical trial

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Abstract

Background: Different implant placement and loading protocols have been described for rehabilitation with varying rates of success and survival. This study was designed aimed to compare the success rates of implants placed to substitute maxillary incisors, canines and premolars following immediate or delayed implant placement protocol and subjected to immediate non-functional loaded single tooth.

Materials and Methods: 30 patients (male or female), in the age group of 18-45 years selected based on the inclusion and exclusion criteria. Two treatment protocols were formulated.

Protocol A: Immediately placed implants with immediate non-functional loading

Protocol B: Delayed placement with immediate non-functional loading.

60 implants were placed; 30 following each protocol. Success rates were measured clinically in terms of implant stability (ISQ) using RFA and crestal bone loss radiographically using CBCT at timelines of 02 weeks, 01 month, 06 months and 12 months.

Inter-group statistical comparison was done using Chi-Square test and independent sample t test. The intra-group statistical comparison was done using repeated measures analysis of variance (RMANOVA). P-values less than 0.05 were considered statistically significant. Data was analyzed using SPSS (ver 21.0, IBM Corporation, USA) for MS Windows.

Results: Higher ISQ values and significant bone loss was observed when compared to baseline values in both the groups at 12 months follow up with ($p < 0.05$). Both the protocols presented a survival rate of 100%.

Conclusion: Time dependant and comparable amount of bone loss around implants and gradual improvement in implant stability in both groups suggest immediate implant placement to be an effective option with reduced treatment period.

Keywords: Immediate implant placement, Delayed implant placement, Immediate non-functional loading, Anterior esthetic zone, Implant stability, Crestal bone loss.

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1. Introduction

Loss of dentition has multiple causes but commonly leads to impaired oral function, reduced self-esteem, loss of social status, and poorer quality of life. Successful rehabilitation must address biomechanical needs while maintaining harmony with the stomatognathic system. Dental implants, pioneered by Branemark through the concept of osseointegration, are the preferred rehabilitation option for partially edentulous patients.¹

Both one-stage and two-stage surgical protocols exist for implant placement and loading. The two-stage method involves submerging the implant below the crestal bone and allowing 3–6 months for healing.²⁻⁴ Advances in surgical techniques and improved primary stability have enabled immediate loading of implants, offering benefits like immediate restoration, preservation of peri-implant tissues, and improved esthetics.^{5,6}

Studies report reduced crestal bone loss and enhanced bone-to-implant contact with immediate loading.⁷⁻⁹ In vivo

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studies have confirmed the predictability of immediate loading, especially with implants placed in fresh extraction sockets, resulting in shorter treatment times and better esthetics.¹⁰⁻¹³

However, limited data exists on the success of single tooth implants subjected to immediate loading. Therefore, this study aims to compare success rates of single implants placed to replace maxillary incisors, canines, and premolars, following immediate or delayed placement protocols, with immediate non-functional loading.

2. Materials and Methods

This split-mouth clinical trial was conducted at a tertiary care dental centre in Maharashtra from May 2017 to August 2018, following ethical approval (Project No. 4844/2017) and in accordance with the Declaration of Helsinki (2002).

2.1. Patient selection (*Figure 1*)

Thirty patients aged 18–45 years, with a unilateral edentulous space and a contralateral tooth indicated for extraction in the premolar region, were selected. Inclusion criteria included good oral hygiene, absence of systemic/psychological diseases, and favorable bone conditions for immediate implant placement. Exclusion criteria included heavy smoking, poorly controlled diabetes, radiation therapy, and TMJ or occlusal disorders. After obtaining informed consent, 60 root-form internal hexagon implants (Equinox, Myriad; 11–15 mm length, 3.8–4.5 mm diameter) were used based on individual bone morphology.

2.2. Study design

An in vivo split-mouth clinical trial was employed. Each patient received two implants—one using Protocol A (immediate implant placement with immediate non-functional loading) and the other using Protocol B (delayed implant placement with immediate non-functional loading), with 30 implants in each group.

2.3. Diagnosis and treatment planning

Comprehensive medical and dental histories, clinical investigations (including blood/urine tests, HIV screening) and radiographic evaluation (CBCT using NewTom Giano, Italy) were conducted for treatment planning.

2.4. Protocol A – Immediate placement (*Figure 2*)

Under local anesthesia and aseptic conditions, atraumatic extraction was followed by osteotomy and implant placement at 800–1000 rpm with 35 Ncm torque. Primary stability was assessed using Resonance Frequency Analysis (Penguin™, Bredent) (*Figure 2C*), and gingival formers were placed. Implants achieving ≥ 40 Ncm torque were selected for immediate non-functional loading. After 24 hours, abutments were placed (*Figure 2D*), impressions made with polyvinyl siloxane (Zhermack Elite HD+) (*Figure 2E*), and provisional restorations fabricated using fiber-reinforced BIS-GMA

(DPI, India). Immediate screw-retained provisional restorations were delivered within 48 hours, ensuring no occlusal contacts. Definitive prostheses (PFM) were placed after 3–4 months in the mandible and 6–8 months in the maxilla, per Branemark protocol (*Figure 2F*).

2.5. Protocol B – Delayed placement (*Figure 3*)

Implants were placed in healed extraction sites (*Figure 3A, B*), with RFA used for stability assessment (*Figure 3C*). Abutments were placed (*Figure 3D*), impressions made (*Figure 3E*), and both provisional and definitive prostheses delivered as in Protocol A (*Figure 3F*).

2.6. Postoperative evaluation

Implant stability was clinically measured as ISQ values using RFA, and crestal bone changes were assessed radiographically at baseline, 2 weeks, 1 month, 6 months and 12 months using CBCT. Linear measurements were taken in axial, coronal, and sagittal slices using a standard protocol (*Figure 4, Figure 5*), with bone height changes calculated by comparing measurements over time.

2.7. Data collection and analysis

ISQ values and crestal bone changes were recorded at specified intervals. The data were compiled in Excel and statistically analyzed as detailed in the following section.

2.8. Statistical data analysis

Categorical variables were presented as n (%), and continuous variables as Mean \pm SD. Inter-group comparisons for categorical data used Chi-Square or Fisher's exact test, and continuous data used independent sample t-test. Intra-group comparisons were performed using repeated measures ANOVA (RMANOVA), with normality tested beforehand. A p-value < 0.05 was considered statistically significant. Hypotheses were two-tailed, assuming no treatment difference under the null hypothesis. Analyses were conducted using SPSS version 21.0 (IBM, USA).

3. Results

All patients were followed for a period of 12 months, during which surgical procedures were well tolerated, and no prosthetic failures were observed in either group. The study population ranged in age from 22 to 45 years, with a mean age of 33 years, comprising 53.3% males (n=16) and 46.7% females (n=14).

Inter-group comparisons of mean Implant Stability Quotient (ISQ) values showed no statistically significant differences at the 1-month, 6-month and 12-month follow-ups ($P > 0.05$). However, significant differences were noted at baseline and 1 month, with Group B exhibiting higher ISQ values compared to Group A ($P < 0.05$), as shown in **Graph 1**. Intra-group comparisons revealed that Group A experienced significant increases in ISQ values at 2 weeks, 1 month, 6 months and 12 months when compared to baseline

($P < 0.05$), indicating progressive improvement in implant stability (**Graph 2**). In contrast, Group B showed a significant decrease in ISQ values at 2 weeks and 1 month, followed by a significant increase at 6 and 12 months compared to baseline ($P < 0.05$), as seen in **Graph 2**.

Regarding bone changes, inter-group comparisons at baseline, 2 weeks, 1 month, 6 months and 12 months showed no significant differences between the two groups at any surface ($P > 0.05$), as illustrated in **Graph 3**. Intra-group comparisons for both Group A and Group B demonstrated statistically significant increases in mean bone changes at all post-operative time points compared to baseline across all measured surfaces ($P < 0.001$), as detailed in **Graph 4**. Further, there were no statistically significant differences between the groups in terms of mean bone loss from baseline to 12 months at the mesio-buccal, mesio-lingual, disto-buccal, and disto-lingual surfaces ($P > 0.05$), as shown in **Graph 5**.

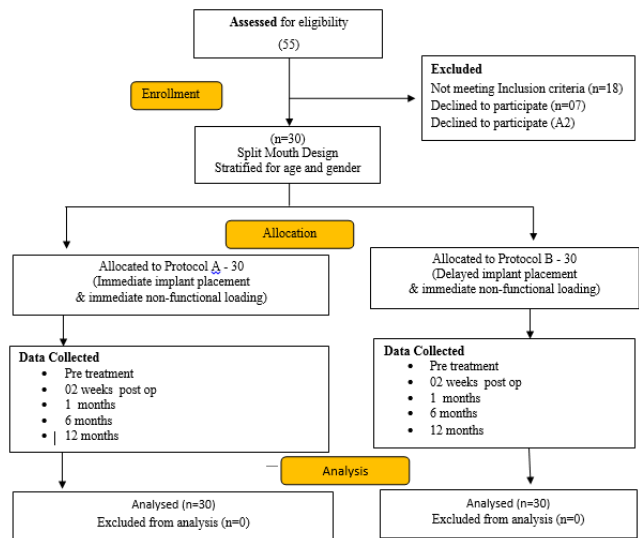


Figure 1: Consort depicting patient selection and allocation

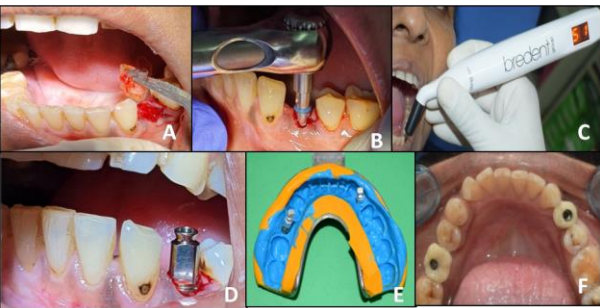


Figure 2: Protocol A (Immediate implant placement and immediate non-functional loading)

At the end of 12 months, ISQ values in both groups were significantly higher than baseline values, confirming improved implant stability. Radiographic evaluations indicated time-dependent bone loss in both groups compared to baseline. Nonetheless, both groups achieved a 100% implant survival rate following immediate or delayed

placement protocols combined with immediate non-functional loading.

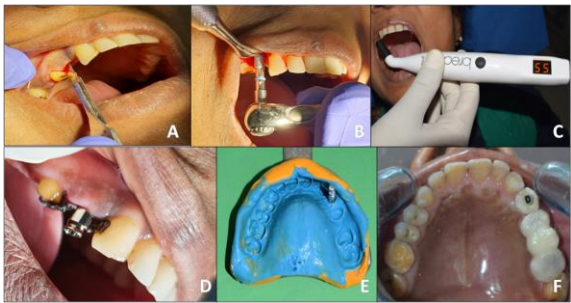


Figure 3: Protocol B (Delayed implant placement and immediate non-functional loading)

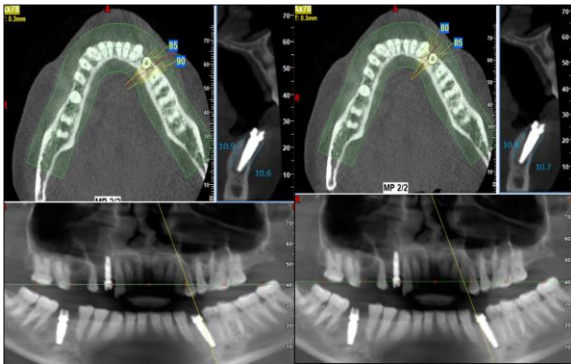


Figure 4: Crestal Bone loss evaluation by CBCT on distal & mesial aspect of 34 (Protocol A)

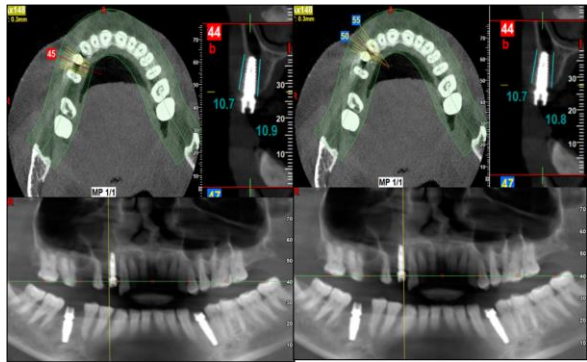
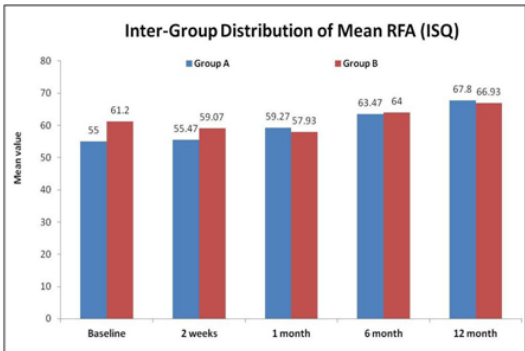
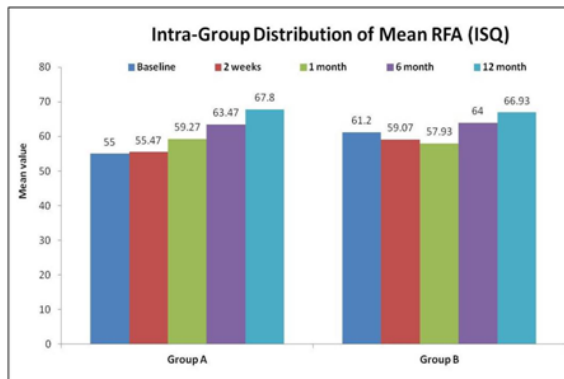


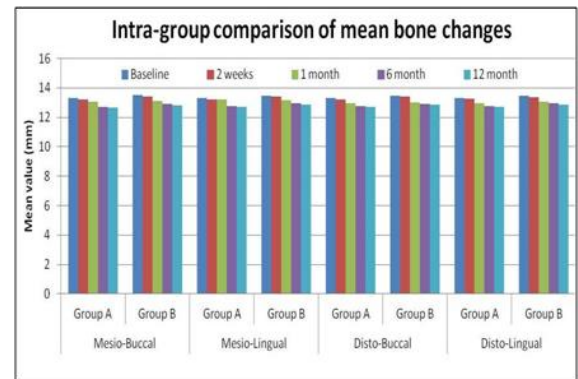
Figure 5: Crestal Bone loss evaluation by CBCT on distal & mesial aspect of 14 (Protocol B)



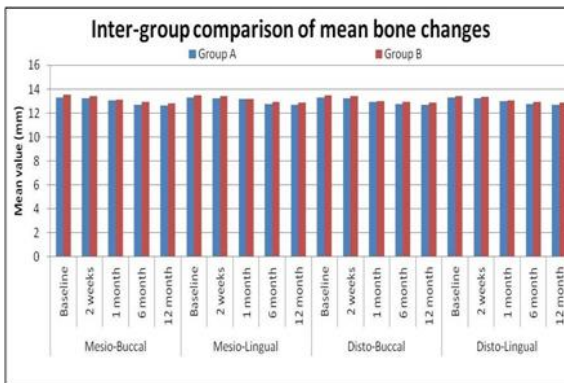
Graph 1: Inter-group comparison of mean ISQ values



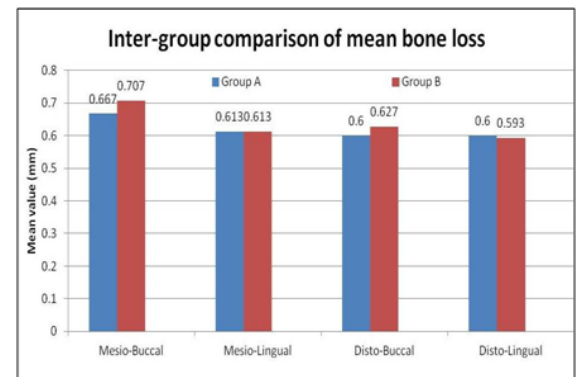
Graph 2: Intra-group comparison of mean ISQ values



Graph 4: Intra--group comparison of mean bone changes at each surface.



Graph 3: Inter-group comparison of mean bone changes



Graph 5: Inter-group comparison of mean bone loss over a period of 12 months at each surface

Table 1: Inter-group and intra-group comparison of mean ISQ values with resonance frequency analyser (RFA)

RFA	Group A (n=30)		Group B (n=30)		P-value (Inter-Group)
	Mean	SD	Mean	SD	
Baseline	55.00	2.78	61.20	1.93	0.001***
2 weeks	55.47	2.87	59.07	1.91	0.001***
1 month	59.27	3.41	57.93	1.94	0.199 ^{NS}
6 month	63.47	3.04	64.00	2.17	0.585 ^{NS}
12 month	67.80	2.96	66.93	2.71	0.410 ^{NS}
P-value (Intra-Group)					
Baseline v 2 weeks	0.004**		0.001***		
Baseline v 1 month	0.001***		0.001***		
Baseline v 6 month	0.001***		0.001***		
Baseline v 12 month	0.001***		0.001***		

Values are mean and SD, P-value (Inter-Group) by independent sample t test. P-value (Intra-Group) by repeated measures analysis of variance (RMANOVA). P-value<0.05 is considered to be statistically significant. **P-value<0.01, ***P-value<0.001, NS-Statistically significant.

Table 2: Inter-group and intra-group comparison of mean bone changes at each surface.

Bone changes (mm)		Group A (n=30)		Group B (n=30)		P-value (Inter-Group)
		Mean	SD	Mean	SD	
Mesio-Buccal	Baseline	13.31	1.02	13.51	1.01	0.607 ^{NS}
	2 weeks	13.23	1.02	13.42	1.00	0.617 ^{NS}
	1 month	13.05	0.98	13.11	0.99	0.855 ^{NS}
	6 month	12.71	1.00	12.91	1.01	0.592 ^{NS}
	12 month	12.65	1.00	12.80	1.00	0.679 ^{NS}
P-value (Intra-Group)		Baseline v 2 weeks		0.001***	0.001***	

	Baseline v 1 month	0.001***		0.001***		
	Baseline v 6 month	0.001***		0.001***		
	Baseline v 12 month	0.001***		0.001***		
Mesio-Lingual	Baseline	13.30	0.99	13.47	1.00	0.652 ^{NS}
	2 weeks	13.23	0.99	13.41	0.99	0.623 ^{NS}
	1 month	13.19	1.13	13.15	0.98	0.918 ^{NS}
	6 month	12.75	1.00	12.96	1.01	0.568 ^{NS}
	12 month	12.69	0.99	12.85	1.01	0.653 ^{NS}
P-value (Intra-Group)	Baseline v 2 weeks	0.001***		0.001***		
	Baseline v 1 month	0.001***		0.001***		
	Baseline v 6 month	0.001***		0.001***		
	Baseline v 12 month	0.001***		0.001***		
Disto-Buccal	Baseline	13.31	0.99	13.47	0.97	0.646 ^{NS}
	2 weeks	13.23	1.00	13.41	0.98	0.612 ^{NS}
	1 month	12.94	0.99	12.99	0.98	0.883 ^{NS}
	6 month	12.76	0.99	12.91	0.97	0.686 ^{NS}
	12 month	12.71	0.99	12.85	0.98	0.700 ^{NS}
P-value (Intra-Group)	Baseline v 2 weeks	0.001***		0.001***		
	Baseline v 1 month	0.001***		0.001***		
	Baseline v 6 month	0.001***		0.001***		
	Baseline v 12 month	0.001***		0.001***		
Disto-Lingual	Baseline	13.30	0.99	13.44	0.98	0.702 ^{NS}
	2 weeks	13.24	0.99	13.36	0.99	0.744 ^{NS}
	1 month	12.97	0.97	13.06	0.97	0.794 ^{NS}
	6 month	12.77	1.05	12.95	0.99	0.645 ^{NS}
	12 month	12.70	1.03	12.85	0.99	0.694 ^{NS}
P-value (Intra-Group)	Baseline v 2 weeks	0.001***		0.001***		
	Baseline v 1 month	0.001***		0.001***		
	Baseline v 6 month	0.001***		0.001***		
	Baseline v 12 month	0.001***		0.001***		
Values are mean and SD, P-value (Inter-Group) by independent sample t test. P-value (Intra-Group) by repeated measures analysis of variance (RMANOVA). P-value<0.05 is considered to be statistically significant. ***P-value<0.001, NS-Statistically significant.						

Table 3: Distribution and success rates of dental implants

	Implant placement protocol	
	Group A [Immediate implant]	Group B [Delayed implant]
Successful implants,n(%)	30 (100%)	30 (100%)
Total, n	30	30

4. Discussion

Criteria for Implant Success was given by Albrektsson specifies: “Success” includes implants with absence of mobility, pain, and peri-implant radiolucency; and marginal bone loss lower than 1.5 mm during the first year after abutment connection followed by 0.2 mm per year evaluated clinically and radiographically. “Survival” includes implants that are still in function, but do not fulfil all success criteria.¹⁴

The implant system selected for this study was Myriad Plus™ implants from Equinox. These are root form implants that have 1mm implant collar with micro and macro groves with roughened surface for osteoconductive action which

increases initial stability. Patients for this study were selected based on a strict inclusion and exclusion criteria. Healthy partially edentulous patients with absence of any systemic condition contraindicating implant surgery and harmonious occlusion were selected

All the surgical procedures were carried out by the same operator under strict aseptic conditions in a standardized manner following manufacturer’s recommendations. In our study, a conservative approach of mid crestal incisions with minimal exposure just adequate for implant placement was followed.

Immediate non-functional loading was achieved with screw cement retained reinforced provisional prosthesis

preventing any centric and eccentric contacts. Provisional restorations fabricated with reinforced BISGMA have their advantages in the initial phase of healing and osseointegration; they minimize the requirements for soft tissue conditioning.¹⁵ Provisional restorations were replaced with definitive restorations (Porcelain fused to metal) after 3-4 months in mandible and 6-8 months in maxilla as per Branemark protocol.¹⁶

The RFA is a non-invasive diagnostic method that measures the stiffness of bone/implant interface and is calculated from a resonance frequency generated as a reaction to the oscillation exerted on the implant/bone system.^{17,18} In our study, Penguin™ (RFA) resonance frequency analyzer was used. The MultiPeg™ mounted on implant has two fundamental resonance frequencies; it vibrates in two directions, perpendicular to each other. One of the vibrations is in direction where the implant is most stable and the other is in direction where the implant is less stable. This equipment provides ISQ value of 1-100. The higher the resonance frequency, the higher the ISQ value and more stable the implant is. The ISQ scale has a non-linear correlation to micro mobility and categorized based on values as following: ISQ value of RFA Stability of implant > 70 High stability, 60 – 69 Medium stability, < 60 Low stability. In our study, approximately consistent RFA values were recorded during repeated measurements indicating implant stability.

Significantly higher ISQ values in Group A at all the timelines when compared to baseline; significantly lower ISQ values in Group B at 2 weeks, 01 month and higher value at 6 & 12 months are in consonance with literature.^{19,20} Significantly higher mean ISQ values at baseline and 1 month follow-up in Group B compared to Group A is in accordance with other studies. The mean ISQ values at 1 month, 6 month and 12 month follow-up did not differ significantly between two study groups. This is in accordance with other studies.^{21,22}

There were time dependant bone level changes around implants at different time-points. Pre-treatment CBCT scan was done to assess quantity and quality of bone and any vital structures around the intended extraction and implantation site. The amount of bone present apico-coronally, mesio-distally, bucco-lingually and apical to the root tips was evaluated.

In Group A & B, the mean bone changes at 2 weeks, 1 month, 6 month and 12 month follow-ups were significantly higher compared to mean baseline bone changes at all surfaces. However the mean bone changes at various timelines did not differ significantly between two study groups at all surfaces (P-value>0.05 for all).^{23,24} Success rate of 100% was observed for single-tooth dental implants submitted to immediate non-functional loading. Implants inserted under delayed placement and immediate non-functional loading conditions presented a success rate of

100%.^{25,26} The provisional prostheses were prevented from any centric and eccentric contacts which is in accordance with other studies.²⁷

The high success rates observed in the clinical trial can be attributed to strict case selection, avoidance of occlusal overloading and frequent use of long and wide implants to the minimum torque level of 40 N, which provided adequate initial stability. The minimum torque value was higher than 32-40 N as reported in other studies.^{28,29}

4.1. Strengths

Being an In-vivo study, it depicted the actual oral environment and standardised the patient related factors thus eliminating bias. Standardization was achieved at various levels by following strict treatment protocols by the same clinician with same clinical set up and utilizing same methodology for rehabilitation and evaluation subsequently.

5. Conclusion

In the clinical trial, no statistically significant differences were found between immediate and delayed implant placement with immediate non-functional loading in the anterior and premolar regions. Both groups showed a 100% success and survival rate at 12 months. Comparable bone loss and gradual improvement in implant stability in both groups support immediate placement and loading as an effective option for faster rehabilitation. However, larger and longer-term studies are recommended to validate these findings.

6. Conflict of Interest

None.

7. Source of Funding

None.

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