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Original Research

Clinical study on effect of implant design on primary stability, hard and soft tissue changes

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***ABSTRACT*:**
Introduction: The optimal achievement of osseointegration is multi-factorial which depends on the density and quality of bone, surgical techniques employed, and the design of the implants. Primary stability is one of the fundamental parameters that determine the success of osseointegration. A multitude of new macro and micro-designs have evolved over the years. However, the true influence of shape on primary stability is still surrounded by controversies. **Materials and methods:** This prospective, double-blind, randomized clinical trial was done among 20 subjects, aged between 25 and 60 years, demonstrating a motivation to receive an implant for replacement of the missing teeth. Systemically healthy subjects demonstrating -adequate height and width of D2 type of bone were included in the study. The study subjects were then randomly allocated to tapered and cylindrical implant groups. Primary stability, crestal bone loss, bleeding on probing, and mucosal thickness were the outcome parameters assessed at baseline, 3 months, and 6 months. Statistical analysis was performed using SPSS version 20 software. **Results:** There was a statistically significant difference in the primary stability between the study groups with higher mean values observed in the tapered implants group (76.2±1.39 vs 61±3.12; p=0.001). While differences in crestal bone loss were observed between the groups at 3 months and 6 months follow-up visits, no differences were noted in the mucosal thickness and bleeding on probing. **Conclusion:** The study results demonstrate that tapered implants exhibit higher primary stability and lesser crestal bone loss compared to cylindrical implants.
Keywords: Cylindrical implants, osseointegration

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INTRODUCTION:

Oral rehabilitation with dental implants has gained prominence over the years for both partially and completely edentulous in light of the improved success rates with these treatment options. The optimal achievement of osseointegration is multi-factorial which depends on the density and quality of bone, surgical techniques employed, and the design of the implants.[1] It is the combination of these factors which influences the primary stability of an implant after implant placement.[2] It has been well established in the literature that primary stability is one of the fundamental parameters that determine the success of osseointegration.[3] Attempts have been made to modify the implant designs in such a manner that contributes towards an improvement in the primary stability by maximizing the contact area of the implant with the bone.[4] The frequently used designs are the cylindrical and tapered implants. Unlike cylindrical implants, the tapered implants demonstrate a consistent reduction in diameter as we proceed towards the apex. When this narrowing starts from the shoulder of the implant and continues till the apex, the implants are categorized as fully-tapered differentiating them from those implants where the taper is restricted to cervical, middle, or apical parts.[5]

Primary stability, length of the implant, diameter, shape, thread design, etc all these factors contribute to osseointegration which promotes implant success.[6] However, the true influence of shape on primary stability is still surrounded by controversies. With this background, the aim of this study was to evaluate the influence of implant design on primary stability and hard, soft tissue changes following implant placement between tapered and cylindrical implants.

MATERIALS AND METHODS:

This prospective, double-blind, randomized clinical trial was done among 20 subjects, aged between 25 and 60 years, demonstrating a motivation to receive an implant for replacement of the missing teeth. The sample size was calculated using G*power 3.1.9.4 software to detect an effect size of 1.4 using the Mann-Whitney U test at 80% power and an alpha error of 5%. The ethical approval for this study was obtained from the institutional ethical committee (Pr.134/IEC/SIBAR/2018). The study was conducted between May 2019 and July 2020. Informed consent was obtained from those participants before conducting the study. Systemically healthy subjects demonstrating adequate height and width of D2 type of bone were included in the study. Pregnant women, lactating mothers, smokers, subjects with uncontrolled diabetes or bleeding disorders, and severe bruxism were excluded. Oral prophylaxis was done for all the study subjects. Clinical evaluation of edentulous sites receiving implants was followed by a radiographic examination by using intraoral periapical radiographs, cone-beam computed tomography (CBCT). Diagnostic casts were made to evaluate the intra-arch space. In order to obtain an ideal position for implant placement, surgical guides were fabricated using acrylic resin. Bleeding on probing was assessed using a pressure-sensitive probe (0.5, 5.5, 8.5, 10.5mm) at baseline, 3rd, and 6th month postoperatively. The probe is passed along the gingival sulcus with the force of 0.25N/cm wait for 30 seconds to score the bleeding index. Mucosal thickness was assessed by using endodontic file no 20 with a rubber stopper The file is inserted at the midpoint of the attached gingiva between the mucogingival junction and an imaginary line from adjacent tooth CEJ.

Prior to implant placement, subjects were advised to perform mouth rinsing with 0.12% chlorhexidine. After administration of 2% lignocaine with 1:80,000 adrenaline, mid crestal and reliving incisions were given and a full-thickness mucoperiosteal flap was reflected and Point of entry was gained through a guiding hole made in the surgical guide using a precision drill. The preparation was done with the conventional drilling method in a sequential manner as instructed by the manufacturer (2.0, 2.4/2.8, 3.2/3.65) with the help of a physio dispenser at a speed of 800-2000 rpm. Preselected implants of 10mm length and 3.75 mm width were threaded into the prepared site at a low speed of 25 rpm at the crestal bone level using a handpiece/rachet with an insertion tool. After placement, the primary stability of the implant was assessed with an osstell peg using a resonance frequency analyzer (Osstell) by attaching a transducer probe to the implant. In both the buccolingual and mesiodistal directions, ISQ measurements were obtained. The mean of the highest measurements in each of the two directions was considered as the ISQ measure for the implant. Soft tissue flaps were approximated using 3-0 silk. The marginal bone level was radiographically assessed at this time. The antibiotic and anti-inflammatory medication was advised for all the study participants along with chlorhexidine mouth rinse for one month. Sutures were removed after 7 days and all the subjects were recalled after 3 months for the prosthesis. During the three-month follow-up visit for prosthesis placement, radiographic assessment of marginal bone loss, evaluation of the mucosal thickness, and bleeding on probing were done. Patients were again recalled three months after the placement of the prosthesis, and crestal bone loss, mucosal thickness, bleeding on probing were assessed. Figure 1 shows the study flow chart.

Statistical analysis was done using IBM SPSS version 20 software (IBM SPSS, IBM, Armonk, NY, USA). The normality of the data was assessed using Kolmogorov Smirnov test and the choice of statistical tests to analyze the study data was made accordingly. Mann-Whitney U tests were used to check the differences in the study parameters between the tapered and cylindrical implant groups at various time points. Repeated Measures Analysis of Variance (ANOVA) tests were used to check the changes in crestal bone loss, bleeding on probing, and mucosal thickness scores within each of the study groups with a change in time.

Figure 1: Primary stability measured with osstel

Figure 2: Measuring bleeding on probing by using pressure sensitive probe at 3 months

Figure 3: Measuring bleeding on probing by using pressure sensitive probe at 6 months

Figure 4: Assessment of mucosal thickness with endodontic k-file at 3 months

Figure 5: Assessment of mucosal thickness with endodontic k-file at 6 months

Figure 6: Evaluation of crestal bone loss at 3 months for tapered implant

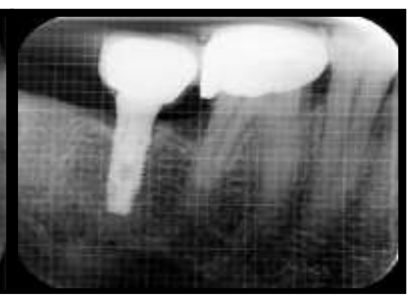

Figure 7: Evaluation of crestal bone loss at 3 months for cylindrical implant

Figure 8: Evaluation of crestal bone loss at 6 months for tapered implant

Figure 7: Evaluation of crestal bone loss at 6 months for cylindrical implant

RESULTS:

The mean age of the study participants was 48.34±9.41 years. There was a statistically significant difference in the primary stability between the study groups with higher mean values observed in the tapered implants group (Table 1). At baseline, there was no crestal bone loss and bleeding on probing in both the study groups. The mean mucosal thickness at baseline in the tapered implants group was 0.92±0.13 mm, while it was 1.03±0.16 mm in the cylindrical implants group (Table 1).

Table 2 gives a comparative account of the crestal bone loss, mucosal thickness, and bleeding on probing at 3 months follow-up between tapered and cylindrical implants groups. Crestal bone loss on the mesial side, distal side, and the overall scores were compared separately between the study groups. None of the study parameters demonstrated significant differences between the study groups at 3 months follow-up. The magnitude of crestal bone loss on the mesial, distal sides and the overall bone loss values were significantly higher in the cylindrical implants group at the 6 months follow-up visit. At 6 months follow-up, though higher mean scores were obtained for bleeding on probing, mucosal thickness in the cylindrical implants group, these differences were not statistically significant (Table 3). Repeated measures ANOVA revealed that there had been significant changes in the parameters of crestal bone loss, bleeding on probing, mucosal thickness during the study period in both the tapered and cylindrical implant groups (Table 4 & Figure 2).

Table 1: Comparison of primary stability between the study groups

Variable	Group	N	Mean±SD	Mean Rank	P Value
Primary Stability (ISQ)	Tapered	10	76.2±1.39	15.5	0.001*
	Cyllindrical	10	61±3.12	5.5	
Mucosal thickness	Tapered	10	.92±0.13	8.65	0.15
	Cyllindrical	10	1.03±0.16	12.35	

Mann Whitney U test; p≤0.05 considered statistically significant; * denotes statistical significance

Table 2: Comparison of study parameters between the groups at 3 months

Variable		Group	N	Mean±SD	Mean Rank	P Value
Crestal bone loss	Mesial	Tapered	10	0.2±0.42	9	0.17
		Cyllindrical	10	0.5±0.52	12	
	Distal	Tapered	10	0.2±0.42	8.5	0.07
		Cyllindrical	10	0.6±0.52	12.5	
	Overall	Tapered	10	0.4±0.69	9	0.03*
		Cyllindrical	10	1.1±0.98	12	
Bleeding on probing		Tapered	10	0.5±0.52	9	0.2
		Cyllindrical	10	0.9±0.73	12	
Mucosal thickness		Tapered	10	0.82±0.16	9.6	0.48
		Cyllindrical	10	0.87±0.13	11.4	

Mann Whitney U test; p≤0.05 considered statistically significant; * denotes statistical significance

Table 3: Comparison of study parameters between the groups at 6 months

Variable		Group	N	Mean±SD	Mean Rank	P Value
Crestal bone loss	Mesial	Tapered	10	0.5±0.52	7.75	0.002*
		Cyllindrical	10	1.2±0.63	13.25	
	Distal	Tapered	10	0.3±0.48	7.05	0.005*
		Cyllindrical	10	1.2±0.63	13.95	
	Overall	Tapered	10	0.8±0.91	7.75	0.021*
		Cyllindrical	10	2.4±1.26	13.25	
Bleeding on probing		Tapered	10	0.5±0.52	9.75	0.52
		Cyllindrical	10	0.7±0.67	11.25	
Mucosal thickness		Tapered	10	0.88±0.16	10.45	0.96
		Cyllindrical	10	0.88±0.13	10.55	

Mann Whitney U test; p≤0.05 considered statistically significant; * denotes statistical significance

Table 4: Changes in study parameters with time in each of the study groups

Variable	Group	Time	Mean±SD	Type III sum of squares	F Value	P Value
Overall crestal bone loss	Tapered	Baseline	0	1.267	5.51	0.014*
		3 Months	0.4±0.69			
		6 Months	0.8±0.91			
	Cylindrical	Baseline	0	7.2	23.14	0.001*
		3 Months	1.1±0.98			
		6 Months	2.4±1.26			
Bleeding on probing	Tapered	Baseline	0	1.67	6.42	0.008*
		3 Months	0.5±0.16			
		6 Months	0.5±0.16			
	Cylindrical	Baseline	0	4.46	8.26	0.003*
		3 Months	0.9±0.23			
		6 Months	0.7±0.21			
Mucosal thickness	Tapered	Baseline	0.92±0.13	0.051	6	0.01*
		3 Months	0.82±0.16			
		6 Months	0.88±0.16			
	Cylindrical	Baseline	1.03±0.16	0.161	74.79	0.001*
		3 Months	0.87±0.13			
		6 Months	0.88±0.13			

Repeated Measures ANOVA; p≤0.05 considered statistically significant; * denotes statistical significance

DISCUSSION:

The study results demonstrate that tapered implants had better primary stability and less crestal bone loss as compared to cylindrical implants. While there were no significant differences between these two groups with regard to bleeding on probing and mucosal thickness, crestal bone loss absolute values were found to be slightly inclined in favor of tapered implants. Primary stability is considered as one of the fundamental parameters in the determination of osseointegration. It has been established in the literature that the incidence of implant failure was higher with lesser primary stability values.[7-10] The rationale for this observation could be found in the reduced micromotion and lesser possibility for fibrous tissue formation at the bone and implant junction among implants with higher primary stability.[11] While primary stability does depend on factors outside implant design such as type of bone and the surgical technique used etc.,[12] the methodology adopted in this study with robust exclusion criteria and randomization ensures that the differences in primary stability between the study groups could be attributed to the differences in implant design. The difference in design between the tapered and cylindrical implants which influences the magnitude of surface area available to be in contact with the bone could be one of the primary reasons for increased ISQ values in the tapered implants group. This double-threaded design also allows for smoother penetration and attributes high bone condensing properties. Furthermore, tapered implants exert an increased compressive force on the surrounding bone that allows for thorough clamping of the bone axially between the threads and the collar. These observations are in congruence with the results from previous literature.[13-16] However, Waechter J et al.[17] and Sakoh J et al.[18]reported comparable ISQ measurements for tapered and cylindrical implants.

The evidence on the influence of implant macro-design on the marginal bone loss around implants is equivocal. Lee et al.[19]reported comparatively lesser marginal bone loss values with tapered implants compared. In the study by Lee et al., the mean difference in the increment of marginal bone loss from baseline to one year between tapered and cylindrical implants was 0.14, with higher increments observed in the cylindrical implants group.[19]Similar observations were made in the present study, with the mean increment in crestal bone loss from baseline to 6 months in the cylindrical implant group being higher compared to the tapered implants group, with a mean difference of 1.6 mm. It could be inferred from these findings that tapered implants fare well in comparison to cylindrical implants demonstrate better integration with the proximal bone. These findings are in accordance with those reported by Kadkhodazadehet al.[20] where the marginal bone loss values at 1-year follow-up were 0.88±0.43 mm and 0.61±0.34 mm for cylindrical and tapered implants, respectively. However, Sargolzaie N et al.[21] reported comparable crestal bone loss for tapered and cylindrical implants at 6-month follow-up, which is in contrast with the findings of the present study. The present study showed no significant differences in the bleeding on probing and mucosal thickness between the tapered and cylindrical implants, which was in accordance with the findings reported by Sargolzaie N et al.[21] and Zafiropoulos GG et al.[22]

CONCLUSION:

Within the limits of this study, it was found that the tapered implants demonstrate better primary stability compared to cylindrical implants. Tapered implants also showed reduced crestal bone loss as compared to cylindrical implants at the follow-up evaluations. However, no significant differences were noted between the two implant designs with regard to soft tissue changes.

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