Original Article

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Dentistry Section

Comparison of Primary Stability of Two Different Implants Designs- A Prospective Clinical Study

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ABSTRACT

Introduction: Any implant treatment must begin with successful implant integration. The effectiveness of implant osseointegration is determined by various factors, including implant design, implant diameter and density, and surgical technique. Osseointegration is dependent on implant design.

Aim: To assess the primary stability of tapered and cylindrical implants by using Resonance Frequency Analysis (RFA) and Insertion Torque Values (ITV).

Materials and Methods: This in-vivo, prospective clinical study was conducted in the Department of Prosthodontics at Sibar Institute of Dental Sciences, Guntur, Andhra Pradesh, India in the month of November 2019. Twenty patients were selected for the study. Tapered Bioline implants (Bioline Dental GmbH & Co. KG-Germany) were spaced in 10 patients (group 1) and cylindrical Bioline implants (Bioline Dental GmbH & Co. KG-Germany) in the other 10 patients (group 2). For both implant designs, primary stability was assessed immediately after implant placement using RFA by Osstell Mentor and ITV by a torque wrench. Kolmogorov-Smirnov test, Shapiro-Wilk test were used for checking normality. Mann Whitney U test, Independent t-tests, Spearman correlation tests were done by using software Statistical Package for Social Sciences (SPSS) Version 23.0.

Results: The mean ISQ (Implant Stability Quotient) for tapered implants was 76.6±2.3, and for cylindrical implants mean ISQ was 59.75±4.2 (p-value <0.001). The mean ITV for tapered implants was 43±2.58 Ncm, and for cylindrical implants, the mean ITV was 33±4.21 Ncm (p-value <0.001). The correlation between ITV and RFA was 0.928 which was highly significant (p<0.001**).

Conclusion: Within the scope of this investigation, tapered implants showed better primary stability than cylindrical-shaped implants as determined by ISQ and insertion torque values. ITV and ISQ values showed a positive correlation in determining the primary stability of implants.

Keywords: Bone density, Osseointegration, Osteotomy, Torque values

INTRODUCTION

Restoration with implants for partially or completely edentulous individuals has proven to be a highly foreseeable and trustworthy treatment option with excellent success and survival rates [1]. Patients local and systemic characteristics, implant design, implant stability, and surgical and sterilisation techniques are some of the factors that determine the outcome of different implant procedures [2].

Mechanical stability achieved with cortical bone determines primary stability. Primary stability is influenced by bone quality and quantity, surgical technique, and implant form (length, diameter, surface characteristics). Secondary stability, produced by bone regeneration and remodelling, provides biological stability [3]. Because primary stability influences secondary stability, the primary stability of implants is seen as a critical aspect in establishing effective osseointegration [4].

Various implants macrodesign available are tapered and cylindrical shape. Tapered, root shape implants make close contact between the osteotomy wall and the implant surface. The close contact offers great primary stability, although localised bone necrosis along the implant surface occurs before bone apposition secures biomechanical fixation [5]. Cylindrical implants with parallel walls had more surface area and quickly gain stability due to the early production of woven bone following the blood-clotted gap between the implant and the osteotomy wall [6]. There are several approaches for determining implant stability. They are divided into two categories: Invasive/destructive procedures and Non invasive/non destructive approaches. Invasive/destructive methods are histologic examination, tensile test, push-out/pull-out test, and removal torque analysis [7].

Non invasive/non destructive methods for assessing implant stability are the surgeon's perception, techniques for radiographic analysis/imaging, Resonance frequency analysis (RFA): Electronic technologies, Resistance to cutting torque (for primary stability), Reverse torque, Seating torque test, Modal analysis and Implatest, Percussion test, Pulsed Oscillation Waveform (POWF) and Magnetic technology [7].

Among the non invasive tests, Insertion torque measurement and RFA are considered effective in determining the implant's primary stability [8].

Insertion torque can be used as a variable that determines implant stability. Insertion torque is a mechanical parameter determined by the surgical procedure, implant design, and bone quality at the implant site. Evidence reveals that insertion torque of 30-60 Ncm is a good indicator of primary stability and indicates implant osseointegration [9].

The RFA evaluates clinical loads and reports on the firmness of the implant-bone interface. In RFA, bone density and implant contact surrounding the implants are assessed by a parameter known as the Implant Stability Quotient (ISQ). The ISQ scales from 1-100, with ISQ values greater than 65 have been regarded as most favourable for implant stability, whereas ISQ values below 45 indicate a poor primary stability. A high primary stability was associated with expectation of good secondary stability, which is essential for implant success and osseointegration. Consequently, poor primary stability was thought to be one of the major causes of implant failure [10].

Implant stabilisation is an important parameter in reducing fibrous tissue formation around implants; according to the literature, maximum acceptable micromovement is between 50 and 150 μm [2].

Previous research has shown that, poor implant stability can lead to early failure, hence, implant primary and secondary stability are important considerations in implant success [11].

Primary stability remains crucial to the success of immediate and early loading protocols. Early failure may be caused by poor implant stability, so implant primary and secondary stability are considered key factors for implant success, hence the purpose of this study was to assess clinical primary stability of tapered and cylindrical implants using RFA and insertion torque to determine whether implant macrodesign had any effect on primary stability and also to evaluate co-relation between RFA and ITV in assessing primary implant stability.

MATERIALS AND METHODS

This in-vivo, prospective clinical study was conducted in the Department of Prosthodontics at Sibar Institute of Dental Sciences, Guntur, Andhra Pradesh, India in the month of November 2019. The ethical clearance was obtained from the Institutional Ethical Committee [166/IEC-SIBAR/CIR/19]. Selected patients were explained about the implant procedure, and written informed consent was obtained from all the patients. Implants were evaluated clinically during and after implant placement.

Sample size calculation: The sample size was calculated using G power version 3.1.9.2. with effect size of 1.5, alpha error of 0.05 and power of study 0.8 with total sample size of 20 with 10 in each group [2].

Twenty patients in the age range of 40-60 years were selected for the study. The patients were selected from the Outpatient Clinic of the Department of Prosthodontics, Sibar Institute of Dental Sciences. The patient selection based on certain inclusion and exclusion criteria.

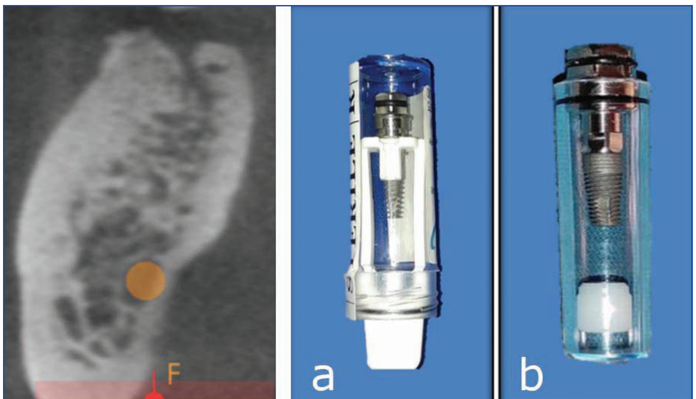
Inclusion criteria: Systemically healthy patients who were partially edentulous in maxilla and mandible due to caries and willing for tooth replacement and patients were included.

Exclusion criteria: Individuals with no periapical infection, pregnant, lactating women, smokers, drug abusers, and individuals with severe bruxism or clenching were excluded.

Implant size of 3.75×10 mm (Bioline Dental GmbH & Co. KG-Germany) and the bone density with D2 bone was standardised for all the patients.

Study Procedure

Preoperative analysis and diagnosis of the patients were made with a thorough history, radiographs, clinical evaluation, and routine blood investigations. Cone Beam Computed Tomography (CBCT) was done before surgery to visualise the available bone and surrounding anatomical structures using CS 3D Imaging software version 3.8 (Carestream Health, Rochester, NY) [Table/Fig-1].

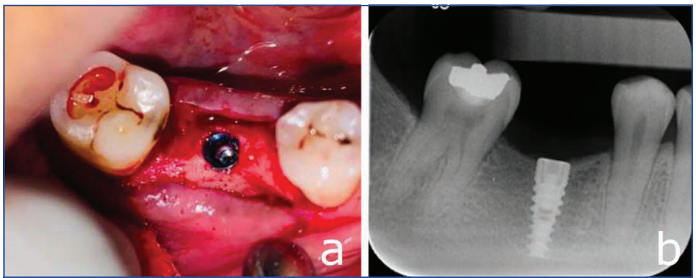


[Table/Fig-1]: CBCT image showing D2 bone. **[Table/Fig-2]:** a) and b) showing tapered and cylindrical implants. (Images from left to right)

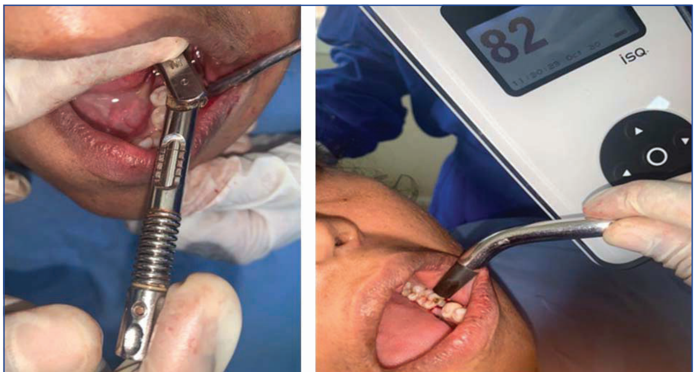
With the patient under local anaesthesia by using Lignox 2% A (lignocaine, Indoco remedies ltd), an incision was made palatal to the crest of the ridge using bard parker blade #15 on the middle of the gingiva attached to the edentulous ridge and extended for several millimetres beyond the osteotomy area. The implants were placed in patients with D2 bone and distributed equally in both groups. Mucoperiosteal flap was elevated exposing implant site. Sequential drilling was done and tapered Bioline implants (group 1) [Table/Fig-2] were placed in 10 patients, and cylindrical Bioline implants (group 2) [Table/Fig-2] were placed in another 10 patients with D2 bone.

Each implant was inserted at the crestal level and the final ITV was evaluated with a manual wrench (Bioline Dental GmbH & Co. KG-Germany) and the Resonance Frequency measurements (ISQ) by osstell Mentor™ (Osstell AB, Gothenburg, Sweden) on each implant by inserting smart peg and the transducer probe was held 2-3 mm distance from the top of smart peg.

The measurements were recorded in buccal, lingual, mesial, and distal directions, and the average values were noted. [Table/Fig-3] Implant placed at the crestal level and radiograph showing implant at crestal level. [Table/Fig-4,5] show the final Insertion Torque Values (ITV) as evaluated with a manual wrench and the Resonance Frequency measurements (ISQ) by osstell Mentor™ respectively.



[Table/Fig-3]: Shows the insertion of insertion of implant at the crestal level; a) clinical image b) radiographic image.



[Table/Fig-4]: Insertion torque value evaluated with torque wrench.
[Table/Fig-5]: Resonance frequency analysis (ISQ) with Osstell's mentor. (Images from left to right)

STATISTICAL ANALYSIS

The results were tabulated using Microsoft excel, and statistical analysis was carried out using SPSS 23 software (IBM SPSS, IBM, Armonk, NY, USA). Test of normality was done by using Kolmogorov-Smirnov test and Shapiro-Wilk test. Non parametric test, Mann Whitney U test was applied for comparison of ITV between cylindrical and tapered implant groups. Parametric test, independent t-test was applied for comparison of ISQ between the two implant groups The insertion torque readings and resonance frequency analyses were compared using Spearman rho test. A p-values less than 0.05 was considered as significant.

RESULTS

There were 10 males and 10 females in the study with 1:1 gender ratio with mean age of 48 years. Ten implants were placed in the maxilla and 10 in the mandible. The ITV and ISQ values for each case are given in [Table/Fig-6].

[Table/Fig-7] shows the findings of the tests of normality. Therefore, non parametric test was applied for comparison of ITV between cylindrical and tapered implant groups. Parametric test was applied for comparison of ISQ between the two implant groups.

S. No.	Gender	Age (years)	Position	Group	Primary stability ITV (Ncm)	Primary stability average ISQ
1.	Male	45	Maxilla	Tapered	40	75
2.	Male	41	Mandible	Tapered	45	77.7
3.	Female	48	Mandible	Tapered	45	78.5
4.	Male	51	Maxilla	Tapered	45	76.5
5.	Female	53	Mandible	Tapered	45	77.5
6.	Female	59	Maxilla	Tapered	45	78
7.	Male	46	Mandible	Tapered	45	79.75
8.	Male	48	Maxilla	Tapered	40	78
9.	Female	49	Mandible	Tapered	40	72.5
10.	Female	52	Maxilla	Tapered	40	73.5
11.	Female	43	Maxilla	Cylindrical	30	56.25
12.	Male	45	Mandible	Cylindrical	40	66.5
13.	Female	46	Maxilla	Cylindrical	30	55.5
14.	Female	58	Mandible	Cylindrical	35	61.5
15.	Male	55	Maxilla	Cylindrical	35	62.75
16.	Male	53	Maxilla	Cylindrical	30	59.75
17.	Female	41	Maxilla	Cylindrical	35	59
18.	Male	45	Mandible	Cylindrical	35	65
19.	Male	50	Mandible	Cylindrical	35	57.75
20.	Female	40	Mandible	Cylindrical	25	53.5

[Table/Fig-6]: Socio-demographic and other implant related variables for all cases.
Ncm: Newton centimetre

Variables	Implant type	Kolmogorov-Smirnova			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
ITV values	Cylindrical	0.282	10	0.023 S	0.890	10	0.172
	Tapered	0.381	10	0.001 HS	0.640	10	0.001 HS
ISQ values	Cylindrical	0.100	10	0.200	0.977	10	0.946
	Tapered	0.236	10	0.122	0.911	10	0.290

[Table/Fig-7]: Tests of Normality of ITV and ISQ values in tapered and cylindrical implants by using Kolmogorov-Smirnov and Shapiro-Wilk tests.
HS: Highly significant at p<0.01; S: Significant at p<0.05

The mean ITV for tapered implants was 43 Ncm, the standard deviation was 2.58, and for cylindrical implants, the mean ITV was 33 Ncm, and the standard deviation was 4.21 (p-value <0.001**) [Table/Fig-8].

Implant type	N	Mean	Std. Deviation	Std. Error Mean	Mean difference	Z value	p-value
Cylindrical	10	33	4.21637	1.33	10.00	-3.74	0.001 HS
Tapered	10	43	2.58199	0.81650			

[Table/Fig-8]: Comparison of ITV values in cylindrical and tapered implants.
Statistical test applied: Mann Whitney U test; HS: Highly significant at p<0.001

The mean ISQ for tapered implants was 76.6, and the standard deviation of 2.3, and for cylindrical implants mean ISQ was 59.75, and the standard deviation of 4.2 (p-value <0.001)** [Table/Fig-9].

Implant type	N	Mean	Std. Deviation	Std. Error mean	Mean difference	t-value	p-value
Cylindrical	10	59.7500	4.20483	1.32968	16.94	-11.16	0.001 HS
Tapered	10	76.6950	2.31834	0.73312			

[Table/Fig-9]: Comparison of ISQ values in cylindrical and tapered implants.
Statistical test applied: Independent t test ; HS: Highly significant at p<0.001

According to ITV and RFA, there were significant variations in primary stability with better primary stability to tapered implants than cylindrical implants.

The Spearman's correlation test yielded a r-value of 0.928 indicating very high correlation which was highly significant, (p-value <0.001**), indicating a positive association between ITV and ISQ values [Table/Fig-10].

Spearman's rho		ISQ
ITV	Correlation coefficient	0.928**
	Sig. (2-tailed)	0.001 HS
	N	20

[Table/Fig-10]: Spearman's rho test to evaluate correlation between ITV and ISQ values.
Statistical test applied: Spearman correlation test (Non Parametric); HS: Highly significant at p<0.01

DISCUSSION

Primary stability is an important factor in achieving osseointegration because it prevents connective tissue formation at the implant/bone interface and allows bone formation, which allows for appropriate distribution of masticatory functional loads [10].

In the present study, more primary stability was achieved for tapered implants than cylindrical implants when evaluated using insertion torque and RFA with p-value <0.001**. Patients with age group 40-60 years were selected because these age range have more edentulous sites than the younger age group [12]. Meniccuci G et al., [9] used an insertion torque device to assess the primary stability of tapered and straight-walled implants and found that tapered implants had ITV of 31.5 Ncm and straight-walled implants (25.5 Ncm) (p=0.05) and concluded that tapered implants had superior primary stability to straight-walled implants. Sakoh J et al., [13] when the primary stability of two implants of different macrodesign, ISQ values of conical implants and the cylindrical implants were in the range of 55-57 with no significant difference. Lozano-Carrascal N et al., [2]. Conducted a study on effect of implant macrodesign on primary stability. The authors compared conical and cylindrical implants with values of ISQ value for tapered implants was 71.67±5.16 and for cylindrical implants 57.15±4.83. (p=0.01). Insertion torque was 46.67±6.85 Ncm for tapered implants and 35.77±6.72 Ncm for cylindrical implants (p=0.01) with a conclusion that conical design implants had superior primary stability, as determined by ISQ and insertion torque values.

A study conducted by Waechter J et al., [14]. compared clinical outcomes of tapered and cylindrical implants and stated that both designs have similar biological behaviour during the healing process. Bone site characteristics can influence insertion torque and implant stability and no significant differences between tapered and cylindrical implants for any outcome measure (p>0.05). Tsutomu Sugiura T et al., [15] investigated the primary stability of cylindrical and tapered implants in different bone types by measuring implant displacement and to examine the relationship between insertion torque value (ITV) and implant displacement. They concluded that implant design had a little impact on primary stability, implant stability was mostly influenced by the type of bone. When crestal cortical bone is present, the use of tapered implants may improve primary stability in individuals with low-density bone.

Ellis R et al., compared the stability of apically tapered and straight implants at the time of immediate placement and to histologically evaluate the healing outcomes after six weeks and stated that apically tapered implants had significantly higher ISQ values at immediate placement compared to straight implants [16].

Simmons DE et al., [17] investigated the stability of two distinct dental implant designs (tapered and cylindrical) and surgical protocols, and their findings revealed a very minimal association between ISQ and ITV during implant placement. In an animal model, Bilhan H et al. [18] compared conical and cylindrical implants; they discovered that the cylindrical implants had much greater insertion torque and ISQ values. These differences might be explained by the fact that the implants were placed in cancellous bone and furthermore, the cylindrical implants were partially tapered. do Vale Souza JP et al.

[8] aimed to assess the relation between the insertion torque and implant stability quotient immediately and six months after implant placement and demonstrated that there is a positive correlation between the insertion torque and the initial ISQ. Therefore, the higher the insertion torque, the higher the initial ISQ.

As invasive procedures are not used due to ethical considerations so non invasive procedures such as the Osstell™ Mentor (Integration Diagnostic Ltd., Goteborg, Sweden) provides information about the stiffness of the implant-bone junction, while insertion torque is a mechanical parameter that measures cutting resistance [7]. In the current study, tapered implants demonstrated clinically higher values of primary stability when evaluated by RFA and IT values than cylindrical implants and there was positive correlation between ITV and RFA.

Limitation(s)

The sample size was small and the study evaluated only primary stability of implants.

CONCLUSION(S)

Within the limits of the study, primary stability measured by RFA and IT was higher with tapered implants than cylindrical implants and there was a positive correlation between RFA and ITV in evaluating primary stability.

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