Original Article

A randomized clinical study to compare implant stability and bone loss using early loading protocol in two implant systems with different design

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Abstract

Aims: The study compared changes in implant stability and bone loss of implants with different designs using early loading at 6 weeks.

Setting and Design: *In vivo*-comparative study.

Materials and Methods: Forty subjects were selected and divided randomly by sealed envelope method in Group X and Group A for early loading for missing single posterior tooth in mandible. Implants in Group X had flared crest module and buttress thread design, whereas implants in Group A had parallel crest module and V-shaped thread design. All subjects were evaluated by Ostell for implant stability at the interval of baseline, 6 weeks, 3 months, and 6 months. ImageJ software was used for measurement of crestal bone loss in intraoral periapical radiographs at the interval of 6 weeks, 3 months, and 6 months.

Statistical Analysis Used: Unpaired t test, repeated ANOVA, Tukey post hoc test.

Results: The mean bone loss values of Group X at predetermined interval were 1.51 ± 0.20 mm, 2.11 ± 0.21 mm and 2.13 ± 0.21 mm. The mean bone loss values of Group A were 1.79 ± 0.16 mm, 2.92 ± 0.23 mm and 2.95 ± 0.23 mm. The mean bone loss was statistical significant ($P < 0.05$) at 6 weeks, 3 months and 6 months. It was highly significant in Group A at 6 months ($P < 0.001$).

Conclusions: It was concluded that Group X implants design showed better implant stability and less bone loss when compared to Group A implants design.

Keywords: Crestal bone loss, design, early loading, resonance frequency analyzer

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INTRODUCTION

Delayed or conventional implant loading protocols were based on the achievement of submerged and prolonged healing duration from 3 to 6 months without loading.[1] The biggest drawbacks of the delayed loading protocol were the length of time required and the resultant patient inconvenience. Moreover, the bone density around the implant after the 6 months was found to be reduced due to the lack of functional stimulation during the healing period.[2]

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Early loading of implants during the healing phase was found to be more favorable to osteogenesis rather than being harmful to bone growth or remodeling. Recent researches have also recommended a shorter healing duration by early loading of the dental implant.[3-7] Nowadays, edentulous areas with good bone quality, early loading of implants are preferred due to their high success rates.[8-14]

The stability of the peri-implant hard tissue was fundamental to success for early loading. Primary stability of the dental implant was achieved through a good mechanical fixation of the dental implant within the bone, whereas secondary stability was achieved due to biological integration.[15]

Various techniques for measuring the primary stability of a dental implant are radiographs, reverse torque analysis, percussion testing, periotest, and implant insertion torque values of a minimum of 35 Ncm and resonance frequency analyzer (RFA).[16,17]

The latest technique for measuring the primary stability by RFA was used in this study. RFA has a metal rod with magnet, which is activated by magnetic impulse from an electronic device. RFA assess implant stability and osseointegration noninvasively.[18-21]

Cochran *et al*., in their prospective human clinical trial, showed International team of implantology implants can be rehabilitated at 6 weeks with a success rate of 99% after 2 years.[11] To further contribute in this field, the present research was designed to compare implant stability and bone loss using early loading protocol in two implant systems with different designs.

MATERIALS AND METHODS

Source of data

The present study was done in the Department of Prosthodontics, Crown and Bridges, Faculty of Dental Sciences, King George's Medical University, Lucknow, U. P., after receiving ethical clearance from the Institutional Ethical Committee of the university (Letter No. 3151/ethics/R. cell-15 Dated 7/1/2015, Ref. Code. 70th ECM II-B/P50).

Sample size

It was calculated using the below formula:

$n = 17\ \sigma^2/\Delta^2 + 1$

For the power of 80% and the significance level of 5%

In the formula, n represents the required sample size per group, which was 20 samples, Δ represents the expected mean difference and σ was half of the confidence interval, which was 0.5.

Study design

This was a randomized, prospective, longitudinal, and *in vivo*-comparative study. Forty subjects out of sixty subjects who were partially edentulous in the posterior mandibular arch, fulfilling the following inclusion and exclusion criteria were enrolled in the research [Flow Chart 1]:

Inclusion criteria

1. Subjects who were having single missing posterior tooth in the mandible
2. Subjects having age between 18 and 65 years
3. Subjects having good general health with no systemic diseases
4. Extraction sites healed for at least 6 months
5. Patients with sufficient bone volume of more than 6.0 mm in width and 11.0 mm in height as evidenced on a pre-operative cone-beam computed tomography (CBCT) scan
6. Implant stability quotient (ISQ) value more than 60 during implant placement.

Exclusion criteria

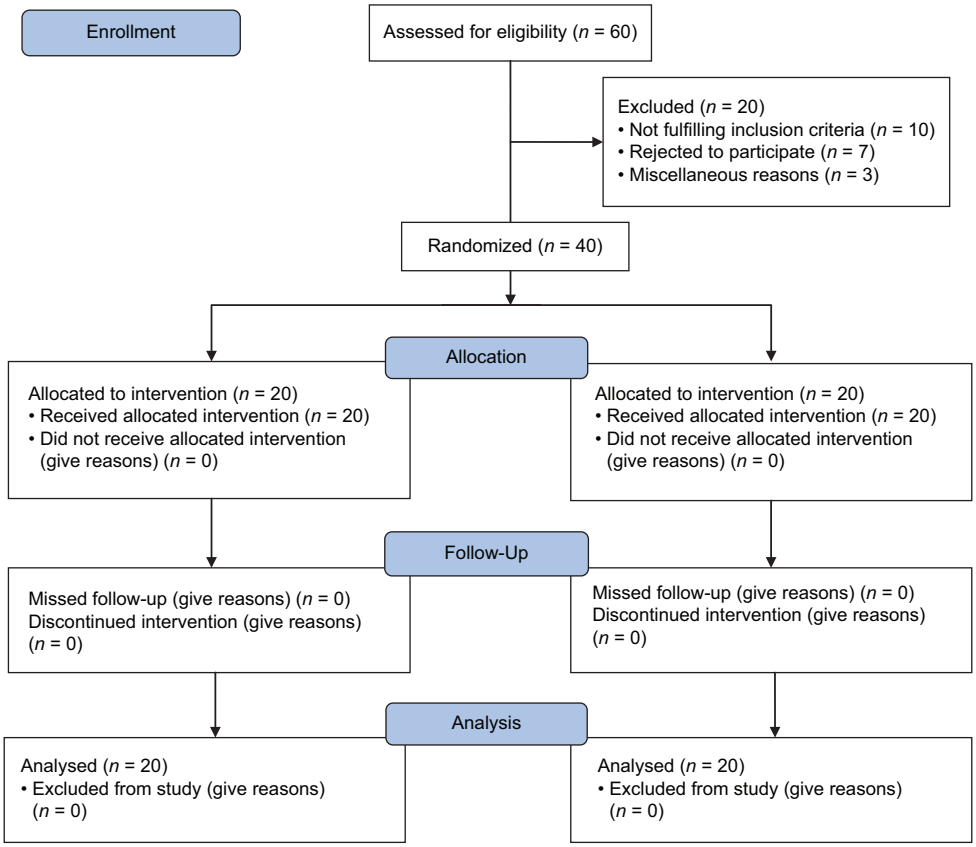
1. Clinical sign of alveolar bone infection at the surgical area
2. Alcohol, drug, and medication dependent subjects
3. Subjects with underlying mental illness
4. Subjects with a previous history of radiotherapy or chemotherapy
5. Subjects with cigarette smoking and paan chewing habit.

The subjects fulfilling study criteria were randomly divided by sealed enveloped method into two groups, each consisting of twenty subjects:

- Group X - Implants with flared crest module, buttress thread design, and 4.5 diameter
- Group A - Implants with parallel crest module, V-shaped thread design, and 4.2 diameter.

Clinical procedure

For each group, dimensions of the edentulous bone to be restored were assessed using CBCT [Figure 1]. During surgery, mid-crestal incision was made and flap elevated, and the implant sequential osteotomy was done with bone drills of increasing diameter. A surgical template guided implant placement was done. The orientation of osteotomy was assessed by paralleling pin of 2 mm diameter and radiovisiography.



Flow Chart 1: CONSORT 2010 flow chart

The implant was inserted at a torque 35 Ncm by a hand ratchet or a high torque low-speed handpiece. Subsequently, measurement of stability and level of crestal bone was determined. Silk suture was used to approximate the flaps, and postoperative instructions to maintain good oral hygiene were given. Postoperatively, oral hygiene instructions, antibiotic (amoxicillin 500 mg TDS for 5 days), and anti-inflammatory drugs (ibroprofen 200–400 mg orally as needed for 5 days) were prescribed. A follow-up appointment after a week was given for suture removal.

Six weeks after surgery, provisional crown was delivered with no occlusal interference in eccentric movement. At 3 months, porcelain fused metal crown was fabricated, which was cemented using noneugenol zinc oxide temporary cement, due to its property of easy removal after follow-up at 6 months [Figures 2-5].

Assessment of implant stability

Implant stability in each subject was assessed using RFA (OSTELL ISQ, Europe). SmartPeg™, a component of the RFA system, attached to the dental implant or abutment using an integrated screw, was activated by magnetic impulses generated by a handheld instrument with a measuring probe. ISQ value ranges from 1 to 100 as displayed on the Ostell instrument [Figure 6]. ISQ was measured, and the mean was recorded for each subject at baseline, 6 weeks, 3 months, and 6 months.

Assessment of crestal bone loss

ImageJ software (National institutes of health, Maryland, USA) was used for measurement of crestal bone in intraoral periapical radiographs taken at an interval of baseline, 6 weeks, 3 months, and 6 months recall. Standardization of radiograph was done with XCP (extension cone paralleling) extension cone. The implant-abutment junction was used as the reference point for all measurements. The linear measurement of the implant from the implant-abutment junction and linear measurement from the implant-abutment junction to crestal bone in IOPA X-ray was used to determine bone value on a computer by ImageJ software [Figure 7]. The crestal bone loss was calculated as the difference between the reading at the time of follow-up examination and the baseline value. The mean of mesial and distal bone value measurements was recorded for each implant at predetermined intervals.[22]

RESULTS

Analyses were performed using SPSS software (PASW Statistics for Windows, Version 18.0. Chicago:SPSS Inc.). The data were analyzed and summarized as

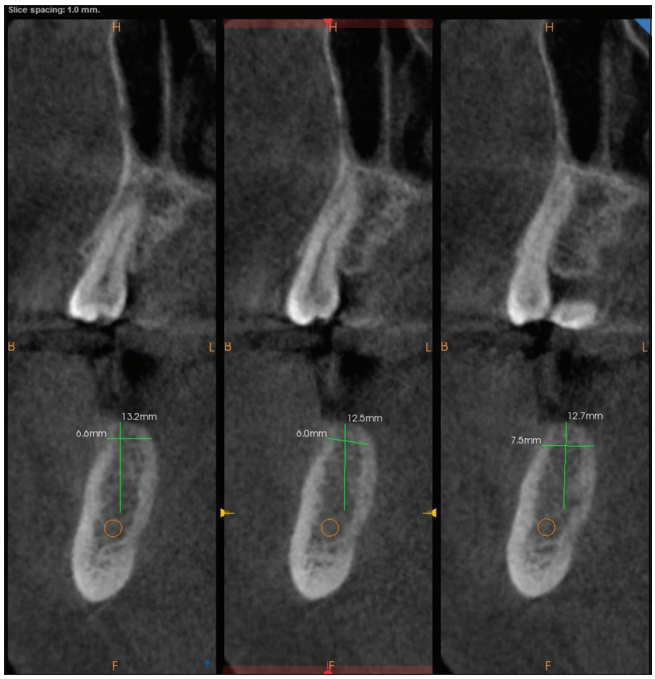


Figure 1: Preoperative assessment of bone by cone beam computed tomography

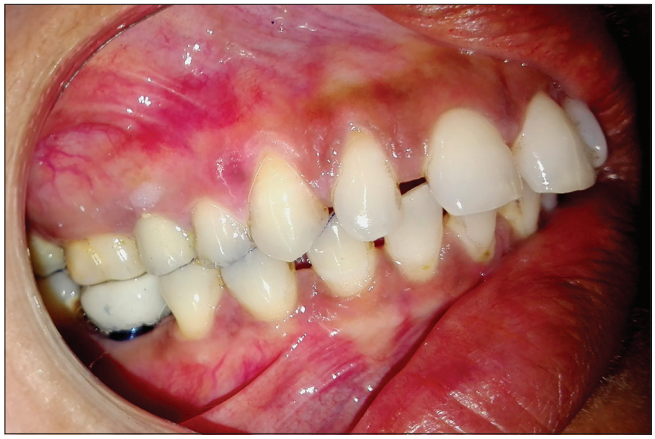


Figure 3: Postoperative of Group X

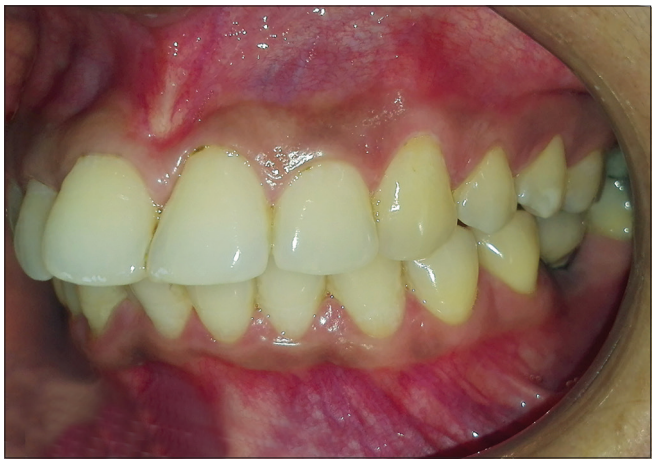


Figure 5: Postoperative of Group A

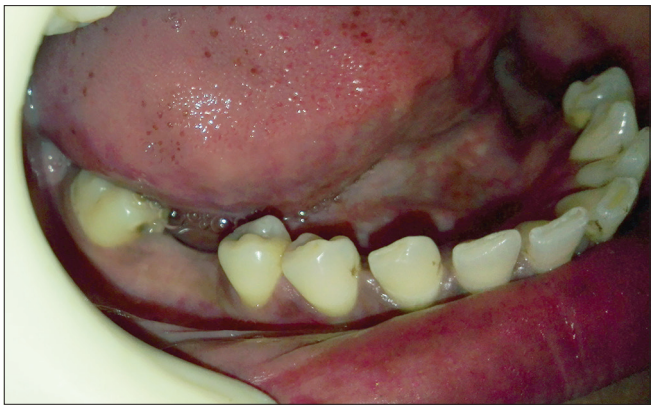


Figure 2: Preoperative of Group X

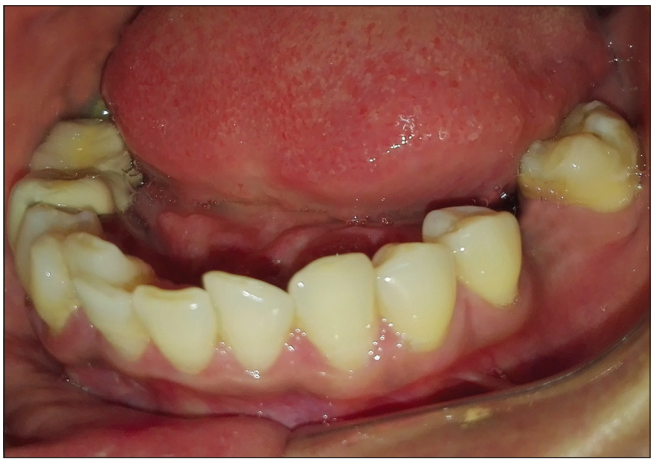


Figure 4: Preoperative of Group A

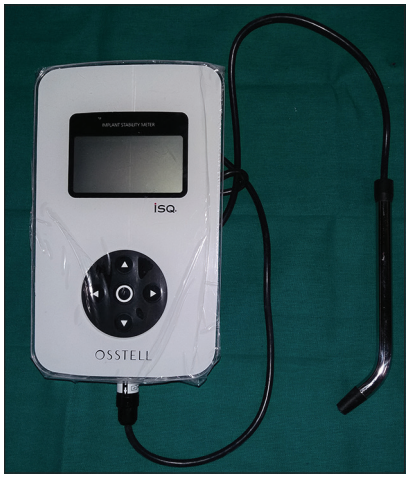


Figure 6: Resonance frequency analyzer

mean ± standard deviation. Table 1 shows the comparison of ISQ at baseline, 6 weeks, 3 months, and 6 months between Group X and Group A. There was a statistically significant ($P \leq 0.05$) ISQ value at each four measured time periods in Group X. The ISQ value was highly significant ($P \leq 0.001$) at 6 weeks in Group X.

Table 2 shows that there was statistically significant ($P \leq 0.05$) bone loss in Group A as compared to Group X at 6 weeks, 3 months, and 6 months. The bone loss value was highly significant ($P \leq 0.001$) at 6 months in Group A.

DISCUSSION

With the recent advancement of implant design, surface modification and better surgical techniques in implant dentistry. The Branemark's protocol of implant of implant loading of 3–6 months has been reevaluated and modified significantly to 6–12 weeks with promising osseointegration and good clinical success rate.[4,5]The present randomized clinical study compared implant stability and crestal bone loss in two implant systems using early loading with the provisional crown at 6 weeks. Implants in Group X had flared crest module, buttress thread design and 4.5 diameter. Implants in Group A had parallel crest module, V-shaped thread design, and 4.2 diameter. The implant surface in both groups was sandblasted and acid-etched surface (SLA), which activates differentiation of bone cell, production of protein and improves bone-implant contact, which are favorable for shorter healing time.[11]

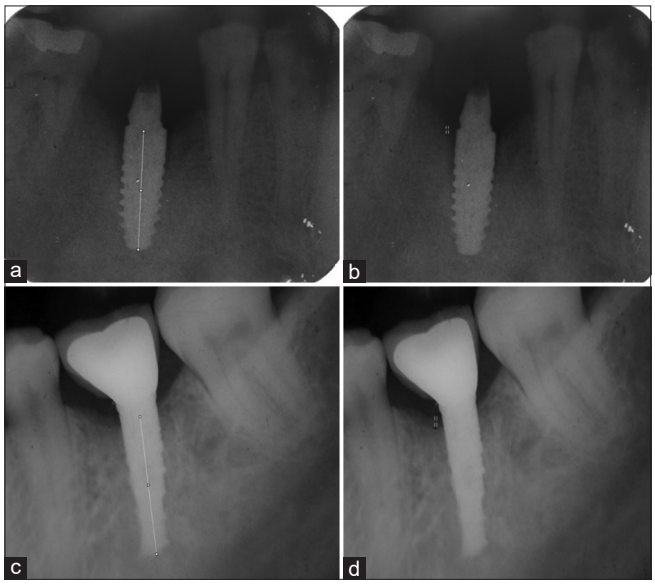


Figure 7: Bone loss calculated by linear measurements of implant and crestal bone from the implant-abutment junction as a reference using ImageJ software. ((a and b) shows bone loss measurement in Group X; (c and d) shows bone loss measurement in Group A)

Table 1: Comparison of implant stability quotient at baseline, 6 weeks, 3 months, and 6 months in early loaded implants between Group X and Group A using unpaired *t*-test

Timeline	Mean±SD		*t*	*P*
	Group X	Group A		
Baseline	85.45±0.55	79±1.49	10.1	0.02
6 weeks	77.20±1.23	74.40±1.76	5.8	0.0001
3 months	79.70±0.31	78.1±1.37	3.68	0.01
6 months	83.20±0.29	81.25±1.37	4.65	0.03

SD: Standard deviation

Table 2: Comparison of bone loss at 6 weeks, 3 months, and 6 months in early loaded implants between Group X and Group A using unpaired *t*-test

Timeline	Mean±SD		*t*	*P*
	Group X	Group A		
6 weeks	1.51±0.20	1.79±0.16	−4.63	0.01
3 months	2.11±0.21	2.92±0.23	−11.66	0.05
6 months	2.13±0.21	2.95±0.23	−11.74	0.001

SD: Standard deviation

For standardization, single missing posterior tooth region in the mandible was chosen as it has bone density of generally D2 with 850–1250 Hounsfield unit, high elastic modulus, 65%–75% bone-implant contact percentage, which not only provides better primary stability but will also permit better stress distribution, lessening the chances of overload, thereby leading to better prognosis and ensuring uniformity among two groups.[9]

Implants with ISQ value above 60 may be suitable for early loading as supported by Meredith *et al*.[18] Other studies by Bornstein *et al*.,[9] Ganeles and Wismeijer,[23] Quinlan *et al*.,[24] Galli *et al*.,[25] and De Smet *et al*.,[26,27] proved that the early loading protocol has implant survival rate of >99%. The key determinant to achieve osseointegration was controlling micromotion at the initial stages of implant healing, which if not controlled leads to fibrous encapsulation formation.[28] In this study, micromotion <100 μm were achieved by removing all eccentric contact in the provisional crown at 6 weeks in both groups.

ISQ comparison of implant stability between Group X and Group A revealed greater stability of Group X at baseline, 6 weeks, 3 months, and 6 months, which was due to buttress thread design of Group X when compared to V thread design of Group A as supported by Rismanchian *et al*.[29] The decrease in the ISQ value from baseline to 6 weeks in both groups was due to the bone remodeling around the dental implant as supported by Huwiler *et al*. and Boronat López *et al*.[30,31]

Diameter of Group X implants used in the study was 4.5 mm, while it was 4.2 mm for Group A implants. As the width increases in increments of 0.5 mm, surface area increases by 10%–15%, and crestal strain decreases as much as a 3.5-fold.[32,33]An increase in diameter from 3.3 mm to 4.1 mm leads to decrease in maximum stress by 29.6% and an increase between 4.1 mm and 4.8 mm, leads to a maximum stress reduction of 34.1% for vertical forces.[34] Moreover, buccolingual forces were reduced with increasing diameter of implant.[35] Hence, the significantly reduced crestal bone loss around Group X implants may

very well be a reflection of the greater reduction in crestal stress concentration attributable to the increased diameter.

Crest module of Group X implants was characterized by a flared crest module by 0.185 mm per side, whereas the Group A implants had a parallel-sided crest module. The flared crest module with smooth collar designs seals the coronal area preventing bacterial invasion; hence, the bone loss was less in Group X implants as supported by Misch *et al*.[36] The heights of the crest modules of the two implants used in this study also differed. Group A implants had a considerably longer collar (1.7 mm) than the Group X implants (1.5 mm). The greater crestal bone loss around Group A implants may also have been influenced by its longer collar length, as supported by Bordin *et al*. in their study.[37]

Thread design modifies the direction of occlusal load applied to the prosthesis at the implant-bone interface. Buttress threads design of Group X transmits compressive stress when compared to V-thread design of Group A, which transmits shear stress to the implant-bone interface.[38] Since bone was 65% weaker under shear stress than under compressive stresses, as supported by Reilly and Burstein and Oswal *et al*.,[39,40] implants with buttress thread design such as those used in Group X may had a beneficial effect in stress reduction at the crestal bone during early loading as compared to Group A.

Limitation

- Interval of the investigation was of short duration
- The sample size of the study was small.
- The outcome of the present research should not be extrapolated to all dental implant systems.

CONCLUSIONS

Within the limitations of the study, we concluded that Group X implants design showed superior results in comparison to Group A implants design with respect to implant stability and crestal bone loss. Hence, early loading at 6 weeks may be considered as a promising option for missing single posterior tooth in the mandible.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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