Original Article

A 3-Year Prospective Clinical Study to Evaluate the Outcome of Single-Piece Implant-Prosthetic Complex after Immediate NonFunctional Loading in the Maxillary Anterior and Mandibular Posterior Areas in Varied Bone Densities

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Abstract

Context: There is limited evidence on the outcome of single-piece implant-prosthetic complex after immediate nonfunctional loading in varied bone densities. **Aim:** The aim of this study was to report the outcome of single-piece implant-prosthetic complex with a novel cervical platform design in the anterior and posterior jaws 3 years after loading. **Setting and Design:** Prospective clinical study. **Materials and Methods:** The present study included placement of 90 single-piece implants in the anterior and the posterior jaws in varied bone densities. After immediate loading, survival and marginal bone loss was recorded at regular intervals. **Statistical Analysis:** Independent sample *t*-test and paired *t*-test were done ($P = 0.05$). **Results:** Group I, annual marginal bone loss at the end of one, 2 and 3 years was 0.21, respectively, in both bone densities. Group II, annual marginal bone loss in D2 regions was 0.75,0.38 and 0.18; 0.64, 0.28 and 0.18 in D3 regions at the end of 1, 2, and 3 years, respectively. Group I showed no statistically significant difference in marginal bone loss between D2 and D3 bone annually in contrast to Group II. Intragroup comparisons of mean between baseline and various time intervals showed statistically significant bone loss in both bone densities. **Conclusion:** Three years after loading, single-piece implants with the novel cervical platform design provided survival rates of 93% in the maxillary anteriors and 91% in the mandibular posteriors. D3 bone showed more marginal bone loss than D2 bone.

Keywords: *Bone densities, cervical platform design, implant-prosthetic complex, indigenous Ti-6AL-4V dental implant, marginal bone loss*

Introduction

The latest modality of treatment of partial and completely edentulous patients is dental implants. Biocompatible dental implants are surgically inserted into the jaw bone primarily as a prosthodontic foundation. An endosteal dental implant is a device placed into the alveolar and/or basal bone of the mandible or maxillae and transecting only one cortical plate.[1] These are either single-piece or two-piece dental implants. Restoration of edentulous sites with single-piece implants is well documented and is considered to be a viable treatment option.[2,3] However, there is limited evidence on the outcome of single-piece implant-prosthetic complex after immediate nonfunctional loading on the surrounding hard tissues such as varied bone densities and soft tissues.[4] And also, pH of peri-implant crevicular fluid is found to be more acidic around two-piece than single-piece dental implants.[5] It shows that the progression of peri-implant mucositis and peri-implantitis is greater around two-piece dental implants resulting in secondary bone loss.[6]

In the present study, a novel and customizable cervical collar for single-piece dental implants has been designed and evaluated in the anterior and posterior jaws, which might enhance the fit of implant and prosthetic margin, overcome marginal discrepancies, which is common with these implants as milling of the abutments cannot be done in the laboratory.

Metals, ceramics, polymers, and a combination of these are used as biological implants. Titanium and titanium alloys are commonly used as a dental implant

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material.[7] Titanium has a modulus of elasticity more closely to the bone than other candidate metals and alloys and unites with living bone without any significant adverse reactions. The process of integration of titanium with bone has been termed as "osseointegration" by Branemark.[8] At present, most of the commercially available implant systems are made of commercially pure titanium or titanium alloy, Ti-6Al-4V.

The objective of the present investigation is to fabricate single-piece dental implants of indigenous titanium alloy, Ti-6Al-4V with a novel and customizable cervical platform design and report the outcome of a single piece implant-prosthetic complex in the anterior and posterior jaws until 3 years after loading. Various parameters are being used to evaluate implant success at the implant level, the prosthetic level, and patient satisfaction level.[9] The mean marginal bone loss and the implant survival rate have been evaluated in the present study. The rationale for choosing the anterior and posterior jaws (two groups) is to evaluate the effect on marginal bone loss as the amount and direction of forces differ in each group with respect to bone densities.

Materials and Methods

A cohort study was done as per the STROBE guidelines, which included both males and females with the age group of 25–50 years individuals, were chosen from the outpatient department of the Department of Prosthodontics, Crown and Bridge and Implantology. Before commencing any procedure, written consent was obtained from patients, and ethical committee clearance was obtained from the institutional board (Lt. MIDS/IEC/2016-11).

Participants with either missing single maxillary anterior/ mandibular posterior teeth, with adequate bone width and height, interocclusal clearance, and adequate mesiodistal space in the edentulous area were included. Participants with smoking habits, immune-compromised state and debilitating diseases, on medication known to interfere with wound and bone healing and para-functional habits were also excluded from the study.

The participants were divided into two groups:

Group I: Patients with single missing maxillary anterior teeth (45); treated with implantation of implants (3.75 mm width and 15 mm length) with single-stage surgical protocol and immediately loaded within 1 week are shown in Table 1.

Group II: Patients with missing single mandibular posterior teeth (45); treated with implantation of implants (4.5 mm width and 10 mm length) with single-stage surgical protocol and immediately loaded within 1 week are shown in Table 2.

All the patients included in the study were motivated toward maintenance care, educating them with oral hygiene instructions, the nature of the provisional prosthesis for 4 months, and the importance of maintenance and the outcome of the permanent implants and their restoration.

The material aspect of indigenous dental implants

The titanium alloy Ti-6Al-4V,[10] for the indigenous dental implants, was obtained from Mishra Dhatu Nigam Ltd. (MIDHANI), Hyderabad, India. This alloy was manufactured by Midhani, Hyderabad, conforming to the American Society for Testing and Material,[11] British Standards Institution, American Dental Association (ADA),[12] and International Standards Organization specifications (ISO: 5832-3; 1996. Implants for Surgery, Metallic Parts– Part 3).[13]

The composition of the indigenous alloy Ti-6Al-4V, as supplied by the manufacturer (MIDHANI) is given in Table 3 and the tensile properties of the alloy, ultimate tensile strength (min) is 860 MPa and yield strength (0.2% offset) is 760 MPa.

Design and fabrication of the indigenous implants

The designed threaded screw is a simple single component and cylindrical with a gradual taper at its apex to facilitate easy insertion [Figure 1].The implant has a body and head.

Table 1: Description of recipient sites for single tooth implant restoration in Group 1

Group I		
Number of edentulous sites	**Edentulous region**	**Bone density**
11	Maxillary central incisors	D2
12	Maxillary central incisors	D3
4	Maxillary lateral incisors	D2
6	Maxillary lateral incisors	D3
6	Maxillary canines	D2
8	Maxillary canines	D3
Total 45		

D2 indicates 750-1250 Hounsfield Units and D3 indicates 375-750 Hounsfield Units in CT reformatted images. CT: Computed tomography

Table 2: Description of recipient sites for single tooth implant restoration in Group II

Number of edentulous sites	Edentulous region-Group II	Bone density
11	Mandibular second premolars	D2
	Mandibularsecond premolars	D3
4	Mandibular first molars	D2
11	Mandibular first molars	D3
10	Mandibular second molars	D2
03	Mandibular second molars	D3
Total=45		

D2 indicates 750-1250 Hounsfield Units and D3 indicates 375-750 Hounsfield Units in CT reformatted images. CT: Computed tomography

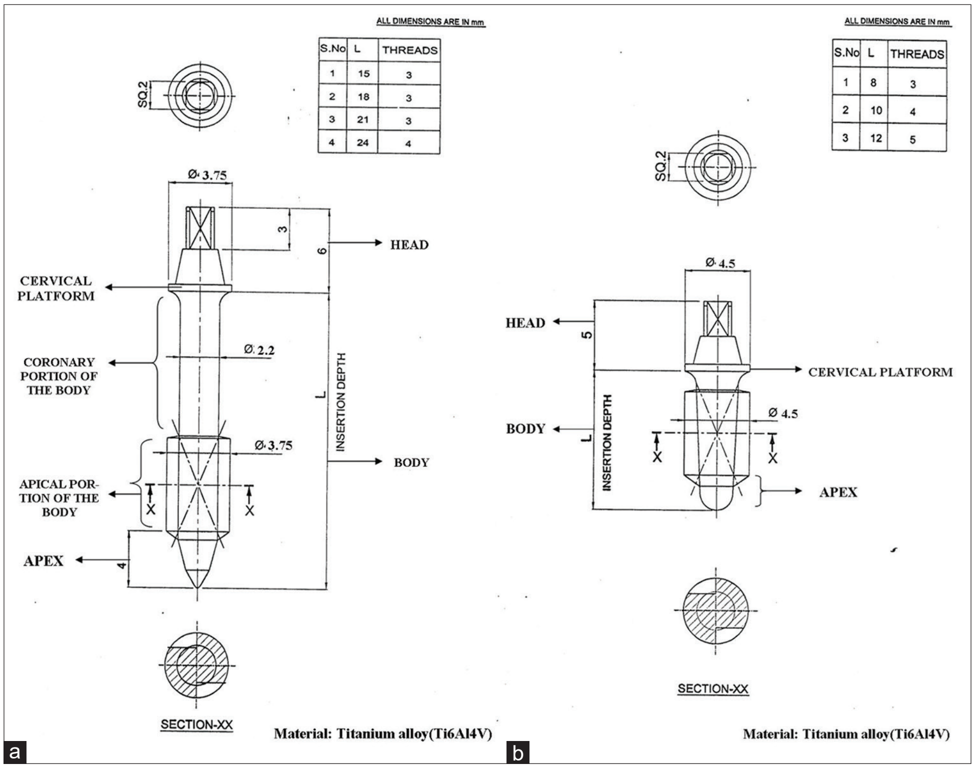

Figure 1: Design of the indigenous single piece dental implants with cervical platform design (a) anterior regions (b) posterior regions

Table 3: Standard chemical composition of the Titanium alloy, Ti-6Al-4V used in the fabrication of the single-piece implants

Element	Compositional limits % (m/m)
Aluminum	5.50-6.75
Vanadium	3.50-4.50
Iron	0.40 max
Oxygen	0.20 max
Carbon	0.08 max
Nitrogen	0.05 max
Hydrogen	0.015 max
Titanium	Balance

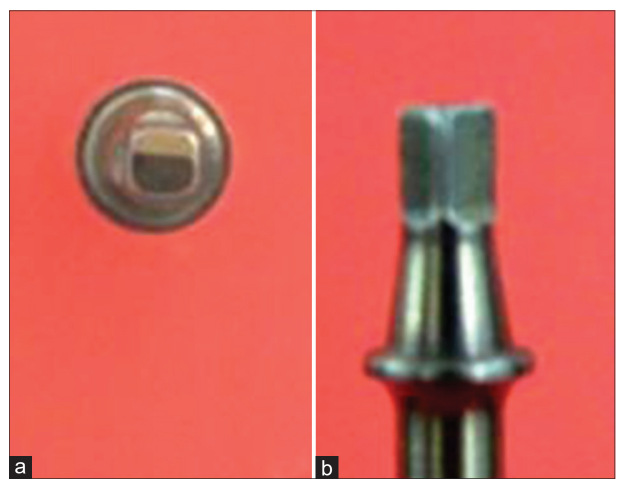

Figure 2: Indigenous single piece dental implants with novel cervical platform design (a) occlusal view (b) frontal view

Body design

A self-tapping threaded screw has:

i. Cervical region: A horizontal platform has been provided on to which margins of the restoration rests. It facilitates better gingival adaptation and a smooth transition to crown fixation [Figure 2]

ii. Coronary portion of the body: Unthreaded shaft facilitates in minimizing thread engagement while the insertion process, thereby reduces stress concentration at the crestal zone. As the diameter is smaller than the outer diameter of the screw thread, osseous healing around the unthreaded regions acts as an anchor preventing secondary failure

iii. Apical portion of the body: Cortical thread profile (buttress thread) which give self-locking feature at bone-implant interface and provides stable initial fixation. The thread design spreads forces evenly to the surrounding bone, preventing stress concentration at the first couple of threads

iv. Apex: Conical apex has been provided to facilitate easier advancement into the bone by nailing action.

Head design

Square head of sufficient length has been provided. The key engages the square head and helps in the insertion of the implant into prepared osteotomy (drilled hole).

Implant surface color

In order to color the implants light golden yellow, anodic oxidation was carried out. The anodization was carried out in an anodizing bath of 1.0 m phosphoric acid under current density 5 $mA.cm^{-2}$ heating to 20° centigrade at 80V. The color defines the thickness of the TiO2 film formed on the surface, being 120 µm.

Implant surface roughness

Smooth and rough surface implants were developed [Figure 3].

Smooth Implants

The R_a (Roughness average) of 0.11 µm (measured using Perthometer, M4P, MAHR, Germany) was achieved after finishing, polishing, and anodization. The initial stabilization of these implants was purely mechanical with threads [Figure 3 a, c-e].

Rough implants

After anodization, the threaded portion of the implants was grit blasted with 180 µm aluminum oxide at 0.25 MPa and achieved a Ra ranging from 2.0 to 2.5 µm [Figure 3b].

The implants were fabricated as per the developed design, using the machines and facilities (CNC turning center, CNS wire – cut machine, EDM machine, precision milling machine, grinding machine, hydraulic presses, blasting machine, and polishing center). Finally, the quality of the fabricated implants was checked using an optical profile projector, tool room microscope, surface roughness measuring instruments, and conventional measuring instruments. Thus, the dental implants with proper implant length, thread profile, and adequate biomechanical properties were developed. The Smooth Implants with Ra 0.11 µm and anodized surface were used in the present study.

Sterilization of implants

After thorough cleaning, all the implants were individually packed in transparent containers and labeled with implant dimensions (implant diameter, length, and date). Later, they were subjected to Gamma radiation sterilization at Gamma Irradiation Plant (^{60}Co isotope being the radioactive source) with a dose of 25kGy, validated to sterilize medical products. In this process, high-energy gamma rays penetrates through the package and destroys all microbes and pathogens present. The packaging maintained the sterilization of the contents until the pack is opened at the operating site. Dosimeters (radiation measuring devices) are kept along with the implants being sterilized to monitor and control the dose for sterilization.

Preparation of patient

It included presurgical treatment planning, blood investigations, premedication and radiographic analysis. On the articulated study model, diagnostic wax-up was done. Cone-beam computed tomography (CT) was done to evaluate jaw bone in vertical, mesiodistal, and labiolingual directions at the future implant site. The bone densities, D2 indicates 750–1250 Hounsfield Units and D3 indicates 375–750 Hounsfield Units in CT reformatted images.[14] Indigenous dental implants with the gingival platform of appropriate dimensions were machined to utilize maximum available bone.

Surgical procedure

Before surgical procedure, sterilization protocol was followed as per the OSHA guidelines. Initial bone preparation to desired depth was done with the pilot drill (diameter 1.25 mm) keeping the angulation checked in the buccal, lingual and mesiodistal directions. The graduated twist drills (diameters 1.8 mm, 2.2 mm, and 3.2 mm) were consecutively used to enlarge the diameter of the osteotomy to the inner diameter of the implants to achieve initial stability and maintaining the same orientation of drills [Figure 4]. The angulation as well as the depth of drilling was checked continuously. Drilling was done gently in straight, deliberate, precise up and down motion

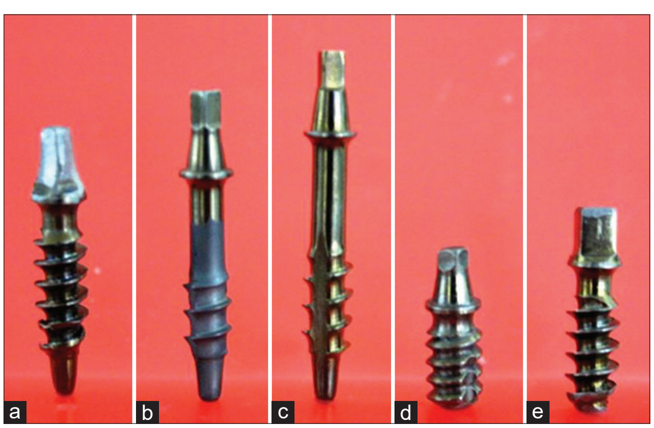

Figure 3: Indigenous single piece dental implants with cervical platform design in assorted sizes (a-c) anterior implants (d and e) posterior implants

Figure 4: Surgical armamentarium: Twist drills 1.8 mm, 2.2 mm, 3.2 mm, finger key

with low pressure, low speed and copious irrigation to avoid overheating, and necrosis of the alveolar bone.

The implant was then placed into the osteotomy, the finger key was engaged to the head of the implant, and it was tightly screwed into bone with gentle pressure till the built-in gingival platform of the implant was 2–3 mm above the crest of bone at the level of the gingiva [Figure 5]. As the implant was of self-tapping type, there was no need to tap osteotomy before insertion of the implant. The implant was never forced with excessive pressure to avoid micro-cracking of the bone.

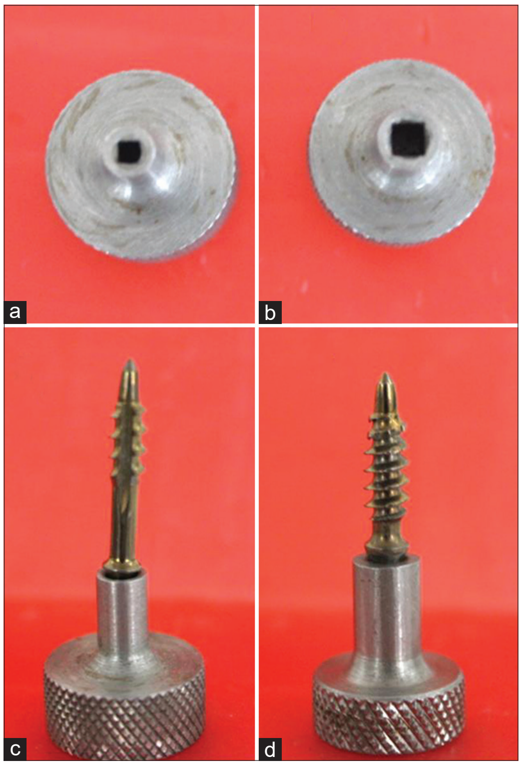

Figure 5: Finger keys for carrying dental implant to the osteotomy site (a and c) narrow head (b and d) wider head

Gingival contouring was appreciable at the end of 1 week. All the implants which achieved an initial torque of 40N and above considered for immediate nonfunctional loading with a long-term provisional. Autopolymerizing resin (Protemp plus Temporization material, 3M ESPE, Standort Seefeld, Bayern D-82229, Germany) was used to fabricate the long-term provisional restoration.

Occlusal adjustments were done before cementation keeping the prosthesis in immediate nonfunctional occlusal loading [Figure 6]. The provisional was cemented with Intermediate Restorative Material Type III, Class I (Dentsply Caulk, 38 West Clarke Avenue, Milford, DE 19963 USA).

After initial placement of long-term provisional prosthesis for 3–4 months, with no occlusal contact, subsequently, it was replaced by permanent restoration and made functional. The final metal-ceramic restorations were cemented with glass-ionomer cement (GC Glass Ionomer, Luting and Lining Cement, GC Corporation, 76-1, Hasunuma-Cho, Itabashi-Ku, Tokyo, Japan) followed by meticulous removal of excess cement.

The patient was examined after 1 week, 3 months, 6 months, 9 months, 1 year, 1.5 years, 2 years, and 3 years after implantation, and implant survival, mean marginal bone loss, and Plaque and Gingival Index were recorded at regular intervals.

Measurement of marginal bone loss

Each implant was assessed by intraoral periapical radiographs recorded using paralleling cone technique (Rinn Xcp Apparatus, Paralleling Cone Technique Device, Manufactured by Sensibles, Universal X-Ray Holder, Flow Dental, and 100West Industry, New York, 11729). To

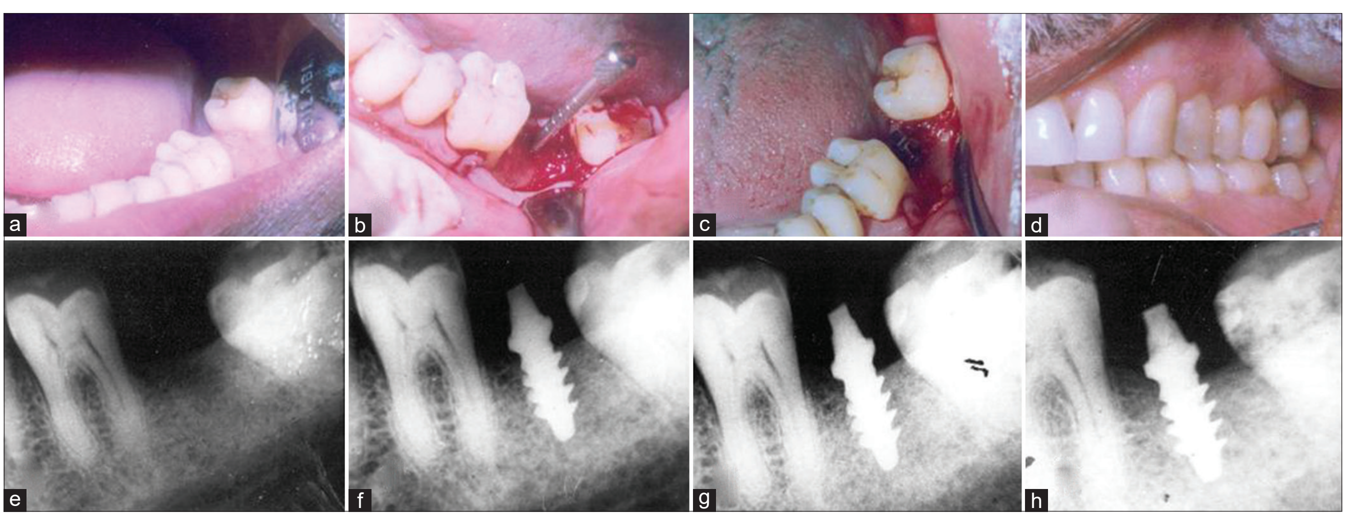

Figure 6: Edentulous site of left second molar implanted with 4.5 width threaded screw implant and restored (a) Preoperative view (b) depth gauge placed in the osteotomy (c) Implantation into osteotomy (d) Temporization with acrylic crown in infra-occlusion. Follow up radiographs (e) Preoperative (f) 1 month postoperative (g) 6 months postoperative (h) 1 year postoperative

calculate the marginal bone loss the intra-oral periapical radiographs (E-Speed, Care Stream Health. Inc., New York, USA, 14608) were scanned with the digital scanner (Epson V700, Dual Lens System), and the images were inverted in vista dent database server (Digital Cephalometric Analyzing Tool, Version-4.2.1 [29]). The inverted images are uploaded in the IMAJE J Analysing tool, version-4.2.1(29) (National Institute of Health, Bethesda, Maryland, USA). Two standard reference lines were used to measure the crestal bone loss.

- Reference 1: Lowest point of marginal bone around the implant as the bone level
- Reference 2: Apical corner of the implant.

After the image was uploaded in the software, “FIND EDGES” tool was applied for the well-defined edges followed by the insertion of GRID on the image to minimize the angulation errors of the implant. With the help of GRID and well-defined margins, the height of the bone adjacent to implant was measured with Image J analysis tool in the software keeping the angulation of the line 90° to standardize the measurements. After the images were uploaded in the software and the distance between two lines were measured with the Image J analysis tool (distance was measured to the nearest 0.01 mm in this software), bone levels were measured on the mesial and distal aspects of the implants. A positive value indicated a level coronal to the first reference line and a negative value indicated a level apical to the first reference line. The readings of the two groups were recorded in pixels and converted into mm; noted at 1 week, 3 months, 6 months, 9 months, 1 year, 1.5 years, 2 years, and 3 years after implantation and analyzed statistically [Figure 4].

Gingival index

The health of soft tissues around implants was assessed at regular intervals as per the grades suggested by Loe and Silness.[15]

Plaque index

Recorded as suggested by Quingley and Hein[16] to assess oral hygiene at regular intervals.

Results

In Group 1, three, one, and zero implants were lost to follow-up after 1, 2, and 3 years, respectively, giving a survival rate of 93% after 1 year of follow-up, 91% after 2 and 3 years of follow-up. The only complication registered was peri-implant radiolucency at three implants. In Group 2, four implants were lost to follow-up after one and zero implants were lost at 2 and 3 years, respectively, giving a survival rate of 91% at patient level after 1 year of follow-up and remained 91% at the end of 2 and 3 years of follow-up. The only complication registered was peri-implant radiolucency for four implants.

Loe and Silness Gingival Index[15] was used to assess the health of soft tissues around implants at regular intervals, i.e., 1 week, 3 months, 6 months, 9 months, 1 year, 1.5 years, 2 years, and 3 years after implantation. The gingival index “0” was observed in most cases which is an indication of healthy peri-implant tissue which may be on account of novel cervical platform design of the single piece implants used in the study. Quigley and Hein Plaque Index[16] was used for oral hygiene at regular intervals, i.e., 1 week, 3 months, 6 months, 9 months, 1 year, 1.5 years, 2 years, and 3 years after implantation. It was observed that in general that plaque index remained 1 at 1-week follow-up has decreased with time and has become “0” in most of the patients. Thus, it is obvious that oral hygiene of all the implanted patients had been quite satisfactory.

The collected marginal bone loss data were entered into Microsoft Excel 2007 and subjected to the statistical analysis using the Statistical Package for the Social Sciences software (IBM SPSS 20.0 , IBM Corp., Armonk, Newyork, USA). This quantitative data were summarized using mean (marginal bone loss of dental implants in millimeters) and standard deviations (SDs) of the maxillary anteriors (Group I) and the mandibular posteriors (Group II) in the present investigation [Table 4]. Independent sample *t*-test was performed for intergroup comparisons of mean between D2 and D3 at one, 2 and 3 year time intervals [Table 5] and paired *t*-test was performed for intragroup comparisons between baseline (3 months) with different time intervals [Table 6], and the results are considered statistically significant at 0.05 level**.**

In Group I, the mean marginal bone loss was found to be greater in D2 than in D3 regions within the 1st year of loading, i.e., on observations at 3, 6, and 9 months follow-ups but were greater by 0.01 mm in D3 at the end of 1, 2, and 3 years of follow-up. In Group I, the mean marginal bone loss after 1, 2, and 3 years of follow-up were 1.01 mm (SD = 0.01 mm), 1.21 mm (SD = 0.01 mm) and 1.41 mm (SD = 0.00 mm) in D2 regions; and 1.01 mm (SD = 0.02 mm), 1.22 mm (SD = 0.01 mm) and 1.42 mm (SD = 0.01 mm) in D3 regions with annual marginal bone loss at the end of 1, 2, and 3 years is 0.21, respectively, in both the bone densities.

In Group II, the mean marginal bone loss was found to be greater in D2 than in D3 regions within the 1st year of loading, i.e., on observations at 3, 6, and 9 months follow-up and at the end of one and two but D3 showed greater bone loss at the end of 3 years of follow-up. In Group II, the mean marginal bone loss after 1, 2, and 3 years of follow-up was 0.99 mm (SD = 0.01 mm), 1.27 mm (SD = 0.01 mm) and 1.45 mm (SD = 0.01 mm) in D2 regions; 0.96 mm (SD = 0.01 mm), 1.24 mm (SD = 0.01 mm) and 1.47 mm (SD = 0.01 mm) in D3 regions. The annual marginal bone loss was 0.75, 0.28, and 0.18 in D2 bone and 0.64, 0.28, and 0.23 in D3 bone at the end of 1, 2, and 3 years, respectively.

Independent sample *t*-test was performed for inter-group comparisons of mean between D2 and D3 at 1-, 2-, and

Table 4: Mean marginal bone loss (mm) and standard deviations of all the clinical variables

Variables	Bone density	Mean±SD							
		3 months	6 months	9 months	1 year	1.5 years	2 years	2.5 years	3 years
Maxillary central incisors	D2	0.20±0.02	0.82±0.14	0.87±0.06	1.00±0.02	1.11±0.02	1.21±0.02	1.26±0.01	1.41±0.01
	D3	0.13±0.01	0.60±0.01	0.90±0.01	0.98±0.04	1.10±0.01	1.20±0.02	1.30±0.02	1.42±0.02
Maxillary lateral incisors	D2	0.16±0.01	0.70±0.02	0.89±0.02	0.97±0.01	1.07±0.01	1.17±0.01	1.24±0.02	1.39±0.01
	D3	0.20±0.01	0.50±0.01	0.80±0.01	1.02±0.02	1.14±0.02	1.23±0.01	1.31±0.02	1.43±0.02
Maxillary canines	D2	0.30±0.01	0.60±0.01	0.91±0.02	1.07±0.01	1.17±0.01	1.26±0.02	1.34±0.02	1.43±0.01
	D3	0.30±0.01	0.50±0.01	0.79±0.02	1.02±0.02	1.16±0.01	1.24±0.01	1.36±0.02	1.43±0.01
Maxillary anteriors (Group I)	D2	0.22±0.01	0.71±0.04	0.89±0.02	1.01±0.01	1.12±0.01	1.21±0.01	1.28±0.01	1.41±0.00
	D3	0.21±0.01	0.53±0.01	0.83±0.01	1.01±0.02	1.13±0.01	1.22±0.01	1.32±0.01	1.42±0.01
Mandibular second premolars	D2	0.20±0.01	0.31±0.01	0.70±0.01	1.00±0.01	1.11±0.04	1.25±0.02	1.34±0.02	1.45±0.01
	D3	0.32±0.01	0.57±0.05	0.70±0.01	0.92±0.02	1.03±0.07	1.22±0.01	1.36±0.01	1.45±0.02
Mandibular first molars	D2	0.21±0.01	0.31±0.01	0.56±0.03	1.00±0.04	1.20±0.02	1.30±0.01	1.38±0.01	1.45±0.01
	D3	0.33±0.02	0.53±0.02	0.72±0.02	1.02±0.01	1.13±0.01	1.25±0.01	1.36±0.02	1.47±0.01
Mandibular second molars	D2	0.33±0.02	0.53±0.02	0.74±0.02	0.98±0.01	1.10±0.02	1.27±0.01	1.34±0.01	1.47±0.01
	D3	0.33±0.01	0.54±0.02	0.73±0.02	0.93±0.02	1.13±0.01	1.26±0.01	1.34±0.02	1.47±0.01
Mandibular posteriors (Group II)	D2	0.24±0.01	0.38±0.01	0.67±0.02	0.99±0.01	1.13±0.02	1.27±0.01	1.35±0.01	1.45±0.01
	D3	0.32±0.01	0.55±0.02	0.72±0.01	0.96±0.01	1.10±0.02	1.24±0.01	1.35±0.02	1.47±0.01

D2 indicates 750-1250 Hounsfield Units and D3 indicates 375-750 Hounsfield Units in CT reformatted images. CT: Computed tomography; SD: Standard deviation

3-year time intervals, as shown in Table 5. Group I showed no statistically significant difference in the mean marginal bone loss at the end of 1 year but significant at the end of 2 and 3 years between D2 and D3 bone densities. In Group II, there was a statistically significant difference in the mean marginal bone loss at the end of 1, 2, and 3 years. Paired *t*-test was performed for intragroup comparisons between baseline (3 months) with different time intervals, as shown in Table 6. A statistically significant bone loss was noted in both bone densities in all the groups with the time periods well appreciated in the graphical representation [Figure 7].

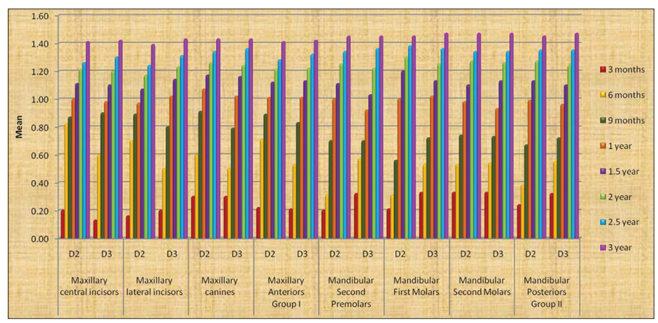

Figure 7: Graph showing mean marginal bone loss of dental implants at different time intervals

Discussion

Several parameters have been suggested in the literature for the evaluation of the implant's success. The oldest concept is whether the implant is physically retained or removed from the mouth.[17] ADA acceptance program for endosseous implants, Council on Scientific Affairs (revised July 1993) have proposed several implant factors such as durability, function, presence of infection; hard tissue factors such as bone loss; soft tissue factors such as gingival health, pocket depth, the effect on adjacent teeth, paresthesia or anesthesia, intrusion on the mandibular canal and also patients emotional and psychological attitude and satisfaction to evaluate the implant success.[18]

Schnitman and Shulman[19] in 1979 suggested that the bone loss up to one third of the height of the implant is acceptable and anterior dental implant should provide functional service for 5 years at least in 75% of the cases. Adell *et al*.[20] determined that after the 1st year an average of 0.1 mm bone loss was observed in each following year. According to Albrektsson *et al*.,[21] bone loss should be <0.2 mm annually following the 1st year of service. A comparative amount of mean bone loss (0.1 mm to 0.13 mm per year) was observed after the 1st year of prosthesis function by Cox and Zarb.[22] Kline *et al*. reported that these are average bone loss measurements and the majority of implants do not loose bone each year.[23] The level of crestal bone is usually measured from the crestal position of the implant at the second-stage surgery for two stage implants. It is noted that when the abutment is attached to the implant body, approximately 0.5-1 mm of connective tissue forms apical to the connection.[24] In the present study, single-piece implants are being used with a cervical platform and a smooth shaft design; a well-adapted connective tissue forms at the neck of the implants apical to the machined finish line.

Under ideal conditions, a tooth or implant loose minimum bone during function. The level of crestal bone around an endosteal implant should be compared to the initial placement position of the implant to find out the marginal bone loss. Early loss of crestal bone beyond 1 mm from the microgap of the abutment after prosthesis delivery

Table 5: Inter group comparisons: Mean comparison between † D2 and ‡ D3 bone densities with different time intervals

Variables	3 months	6 months	9 months	1 year	1.5 years	2 years	2.5 years	3 years
Maxillary central incisors, *P*	0.07, 0.000*	0.22, 0.000*	0.03, 0.208	0.02, 0.169	0.01, 0.163	0.01, 0.247	0.04, 0.000*	0.01, 0.161
Maxillary lateral incisors, *P*	0.04, 0.000*	0.20, 0.000*	0.09, 0.000*	0.05, 0.000*	0.07, 0.000*	0.06, 0.000*	0.07, 0.000*	0.04, 0.000*
Maxillary canines, *P*	0.00 0.859	0.10, 0.000*	0.12, 0.000*	0.05, 0.000*	0.01, 0.318	0.02, 0.014*	0.02, 0.006*	0.00, 0.707
Maxillary anteriors (Group I) , *P*	0.01, 0.019*	0.18, 0.000*	0.06, 0.000*	0.00, 0.229	0.01, 0.000*	0.01, 0.038*	0.04, 0.000*	0.01, 0.000*
Mandibular second premolars, *P*	0.12, 0.000*	0.26, 0.000*	0.00, 0.610	0.08, 0.000*	0.08, 0.007*	0.03, 0.001*	0.02, 0.124	0.00, 0.327
Mandibular first molars, *P*	0.12, 0.000*	0.22, 0.000*	0.16, 0.000*	0.02, 0.122	0.07, 0.000*	0.05, 0.000*	0.02, 0.004*	0.02, 0.001*
Mandibular second molars, *P*	0.00, 0.780	0.01, 0.684	0.01, 0.376	0.05, 0.000*	0.03, 0.000*	0.01, 0.018*	0.00, 0.718	0.00, 0.295
Mandibular posteriors (Group II), *P*	0.08, 0.000*	0.17, 0.000*	0.05, 0.000*	0.03, 0.000*	0.03, 0.000*	0.03, 0.000*	0.00, 0.541	0.02, 0.028*

*Mean difference is significant at 0.05 level ; † D2 indicates 750-1250 Hounsfield Units and ‡ D3 indicates 375-750 Hounsfield Units in CT reformatted images. CT: Computed Tomography

usually results from the excess stress at the per mucosal site or implant crest module design.[25,26] Marginal bone loss may be attributed to surgical trauma, traumatic occlusion, physiological resorption may lead to gingivitis, if left untreated. Secondary bone loss around the implant is usually a compound condition bacteria and increased stress.[6]

It is difficult to exactly determine the extent of bone loss to indicate the success or failure of the implant. In the present study, the mean marginal bone loss after 1, 2, and 3 years of follow-up in Group I were found to be comparable to those reported earlier by Adell *et al*.,[20] Albrektsson *et al*.,[21] and Cox and Zarb.[22]

In Group II, the mean marginal bone loss recorded values were found to be excessive at the end of the 1st year. It can be noted that D2 regions showed 0.11 mm more marginal bone loss than D3 regions in the end of 1st year, whereas D3 regions showed 0.05 mm more marginal bone loss than D2 regions in the mandibular posterior group after 3 years in immediate loading cases. This variable pattern of bone loss can be attributed to the quality of bone, occlusal forces, and peri-implant conditions resulting in secondary bone loss.

In the present study, except in the 1st year follow-up of anterior restorations of Group I, Group I and II showed a statistically significant difference in the mean marginal bone loss at the end of 1, 2, and 3 years in between D2 and D3 bone regions. It can be shown that bone density plays a significant role in mean marginal bone loss in maxillary anteriors and mandibular posterior regions with the novel gingival platform design of the implants.

In 1986, Albrektsson *et al*.[21] redefined the success of implants, in terms of mobility, bone resorption, tissue health, and retention time. The success rate of 85% at the end of 5-year observation period and 80% at the end of 10-year period was considered to be the minimum requirement. Later in 1989, Zarb and Smith[27] put forth different parameters, for the evaluation of long-term effectiveness of osseointegrated dental implants in function, based on the criteria traditionally used in periodontic and prosthodontic clinical evaluation.

In Group 1, three, one, and zero implants were lost to follow-up after 1, 2, and 3 years respectively, giving a survival rate of 93% after 1 year of follow-up, 91% after 2 and 3 years of follow-up. In Group 2, four implants were lost to follow-up after 1 year and zero implants were lost at 2 and 3 years, giving a survival rate of 91% at implant level after 1 year of follow-up and remained 91% at the end of 2 and 3 years of follow-up. The parameters used in the present investigation are as per those suggested by Albrektsson *et al*.,[21] Zarb and Smith,[27] Buser *et al*.[28,29] with regard to submerged as well as nonsubmerged implants and Degidi *et al*.[30] upon comparing the immediate functional and nonfunctional implant loading.

Table 6: Intra-group comparison: Mean comparison between baseline (3 months) with different time intervals

Variables	Bone density	Δ1, *P*	Δ2, *P*	Δ3, *P*	Δ4, *P*	Δ5, *P*	Δ6, *P*	Δ7, *P*
Maxillary central incisors	D2	0.62, 0.000*	0.67, 0.000*	0.80, 0.000*	0.91, 0.000*	1.01, 0.000*	1.06, 0.000*	1.21, 0.000*
	D3	0.47, 0.000*	0.77, 0.000*	0.85, 0.000*	0.97, 0.000*	1.07, 0.000*	1.17, 0.000*	1.29, 0.000*
Maxillary lateral incisors	D2	0.54, 0.000*	0.73, 0.000*	0.81, 0.000*	0.91, 0.000*	1.01, 0.000*	1.08, 0.000*	1.23, 0.000*
	D3	0.30, 0.000*	0.60, 0.000*	0.82, 0.000*	0.94, 0.000*	1.03, 0.000*	1.11, 0.000*	1.23, 0.000*
Maxillary canines	D2	0.30, 0.000*	0.61, 0.000*	0.77, 0.000*	0.87, 0.000*	0.96, 0.000*	1.04, 0.000*	1.13, 0.000*
	D3	0.20, 0.000*	0.49, 0.000*	0.72, 0.000*	0.86, 0.000*	0.94, 0.000*	1.06, 0.000*	1.13, 0.000*
Maxillary anteriors (Group I)	D2	0.49, 0.000*	0.67, 0.000*	0.79, 0.000*	0.90, 0.000*	0.99, 0.000*	1.06, 0.000*	1.19, 0.000*
	D3	0.32, 0.000*	0.62, 0.000*	0.80, 0.000*	0.92, 0.000*	1.01, 0.000*	1.11, 0.000*	1.21, 0.000*
Mandibular second premolars	D2	0.11, 0.000*	0.50, 0.000*	0.80, 0.000*	0.91, 0.000*	1.05, 0.000*	1.14, 0.000*	1.25, 0.000*
	D3	0.25, 0.000*	0.38, 0.000*	0.60, 0.000*	0.71, 0.000*	0.90, 0.000*	1.04, 0.000*	1.13, 0.000*
Mandibular first molars	D2	0.10, 0.000*	0.35, 0.000*	0.79, 0.000*	0.99, 0.000*	1.09, 0.000*	1.17, 0.000*	1.24, 0.000*
	D3	0.20, 0.000*	0.39, 0.000*	0.69, 0.000*	0.80, 0.000*	0.92, 0.000*	1.03, 0.000*	1.14, 0.000*
Mandibular second molars	D2	0.20, 0.000*	0.41, 0.000*	0.65, 0.000*	0.77, 0.000*	0.94, 0.000*	1.01, 0.000*	1.14, 0.000*
	D3	0.21, 0.000*	0.40, 0.000*	0.60, 0.000*	0.80, 0.000*	0.93, 0.000*	1.01, 0.000*	1.14, 0.000*
Mandibular posteriors (Group II)	D2	0.14, 0.000*	0.43, 0.000*	0.75, 0.000*	0.89, 0.000*	1.03, 0.000*	1.11, 0.000*	1.21, 0.000*
	D3	0.23, 0.000*	0.40, 0.000*	0.64, 0.000*	0.78, 0.000*	0.92, 0.000*	1.03, 0.000*	1.15, 0.000*

*Mean difference is significant at 0.05 level; †D2 indicates 750-1250 Hounsfield Units and D3 indicates 375-750 Hounsfield Units in CT reformatted ima.ges; ‡Δ1: Mean difference between baseline (3 months) and 6 months; Δ2: Mean difference between baseline (3 months) and 9 months; Δ3: Mean difference between baseline (3 months) and 1 year; Δ4: Mean difference between baseline (3 months) and 1.5 years, Δ5: Mean difference between baseline (3 months) and 2 years; Δ6: Mean difference between baseline (3 months) and 2.5 years and Δ7: Mean difference between baseline (3 months) and 3 years. CT: Computed tomography

The marginal peri-implant tissues constitute a functional barrier between the oral environment and the host bone by sealing off the osseous fixture site from noxious agents and also thermal and mechanical trauma. The ultimate function of soft-tissue barrier is reflected in the long-term changes of marginal bone height. The inflammation in the soft tissue around the implant is more commonly plaque associated; however, there could also be acute necrotizing, hormonal, drug induced, to those reported by Adell *et al*.,[20] Albrektsson *et al*.,[21] and Cox and Zarb[22] at the end of 2 and 3 years in both the bone densities.

In the present study, Loe and Silness Gingival Index[15] was used to assess the health of soft tissues around implants, and Quigley and Hein Plaque Index[16] was used for the oral hygiene. All the patients in the above study exhibited good to satisfactory oral hygiene and showed no signs of gingival inflammation. This can be attributed to the cervical platform design that facilitated better gingival adaptation and a smooth transition from crown to implant helping the restoration margins to rests on it. It sculpted the peri-implant gingival tissues giving the esthetically pleasing appearance and good peri-implant health.

However, four implants failed in the mandibular posteriors regions. An initial excess load may be the cause of bone loss in this case leading to mobility and pain. Poor oral hygiene maintenance also might have added to the secondary bone loss leading to implant failure. The failure to osseointegrate may be attributed to the traumatic occlusion.[6] The present study could evaluate a long-term primary outcome of single-piece implant-prosthetic complex with a novel gingival collar design. The success criteria can be comprehensive by including the additional factors such as esthetics and patient satisfaction level.[31-35]

Conclusion

Within the limitations of the present clinical study, 3 years after loading, single-piece implants with the novel cervical platform design provided the survival rates of 93% in the maxillary anteriors and 91% in the mandibular posteriors. The wider cervical platform design attributed to good peri-implant health due to smooth transition from crown to implant helping the restoration margins abutting on it. Bone density played a significant role in mean marginal bone loss in both maxillary anteriors and mandibular posterior regions. D3 bone regions showed more marginal bone loss than D2 bone regions in the mandibular posterior dental implants after 3 years in immediate loading cases.

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Conflicts of interest

There are no conflicts of interest.

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