Research

A clinical and radiographic evaluation of immediately loaded fixed full-arch prosthesis supported by implants placed in extraction sockets and healed ridges using All-on-4/All-on-6 protocol: A 2-year follow-up

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Abstract

Aim: The aim of this study was to evaluate immediately loaded implants, both clinically and radiographically, in extraction sites (IPIL) and healed sites (HSIL), rehabilitated using All-on-4/All-on-6 protocol, over a time span of 2 years.

Setting and Design: The study proceeded under following phases of patient selection, placement of implants followed by immediate loading and then statistically analyzing the collected data.

Materials and Methods: A total of 15 patients were evaluated, in 2 years, for study purpose. Among 87 immediately loaded implants, 44 were IPIL and 43 were HSIL. The bone level was measured using Implant abutment junction as reference point, at 0, 6, 12, 18 and 24 months. Bone loss was calculated as difference of mean.

Statistically Analysis: The collected data was statistically analyzed using independent *t*-test ($P < 0.05$).

Results: The average bone loss for 2 years was 1.39 mm and 1.17 mm, in IPIL and HSIL group respectively with 100% implant survival rate and no statistical difference ($P < 0.05$).

Conclusion: Full arch prostheses can be successfully delivered by immediate loading of implants regardless of placement (healed or extraction sites).

Keywords: All-on-Four, All-on-six, full mouth rehabilitation, HSIL, immediate loading, immediate placement immediate loading

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INTRODUCTION

Edentulism being the common state of affair is treated with conventional dentures, removable and fixed partial dentures with implants as the preferred treatment modality. Conventional technique for implant placement has major

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disadvantage of long duration of treatment (8–12 months) involving extraction of hopeless teeth, followed by healing period of 2–4 months, along with surgical and prosthetic period. Thus, immediate placement of the implant is a suggested with promptly loading thereby reducing treatment time and patient trauma significantly.[1]

For full arch prosthesis, Maló *et al.* advertised idea of All-on-4™. Although they were first to disclose this notion in 2003, Brånemark *et al.* had previously outlined comparable techniques.[2] According to this notion, two implants can be place at 30°–45° in the posterior region and two straight in the anterior region, and must have a primary stability (35–45 Ncm.[3-5] The tilt and the use of long implants promote primary stability, increase interimplant space, reduce cantilever length with adequate prosthetic support, and maximize usage of available bone.[6]

It has been found that the dental implants have up to 99% cumulative and up to 95% prosthesis survival rate after 10 years. Conditions that cause prosthesis overload like parafunctional habit of teeth grinding or extended cantilever; prosthesis fracture, porcelain chipping, loosening of abutment, or prosthetic screw may all contribute to lower prosthesis survival rate with All-on-4 concept.[5]

Although "All-on-4" is an appropriate therapy, in situations of poor bone quality and quantity, it may be prudent to convert "All-on-4" protocol to "All-on-6" protocol by putting two extra implants inclined distally with the prosthetic extent at the level of the first molar.[7,8]

Along with the placement of dental implants, time of their loading plays critical role in the success of implant therapy. Esposito *et al.* gave the most widely recognized categorization in their 2007 update to Cochrane systematic review.(a) Within 1 week after implant placement was considered "immediate loading" (b) between 1 week to 2 months was "early loading;" and (c) later than 2 months was "conventional loading." Separate consideration of delayed loading was eliminated since it was superfluous.[9,10] Immediate loading is a viable therapeutic option ensuring high implant survival rate (99%).[5] Immediate loading has several advantages, including immediate function and esthetics, avoiding interim detachable prostheses and second procedures, while preserving soft and hard tissue structures.[8]

Although loading the implants with immediate placement has excellent success rates, there may be few predicaments involved. Even after a successful osseointegration, significant biological problems have the ability to reduce the levels of peri-implant soft/hard tissue or both, as well as alter postinsertion course of implants, which is mostly defined by peri-implant mucositis and peri-implantitis.[11,12] Uninterrupted bone loss may ultimately result in loss of the implant. To address the success of implant and define implant health status, it is critical to determine bone levels and bone loss around the implants as indicators of biological problems.

However, there is relatively limited evidence available comparing clinical and radiological outcomes for immediate functional loading of implants placed in fresh extraction sites versus healed sites supporting fixed full-arch prosthesis.[13]

The purpose of our study was to examine and compare the marginal bone level of implants placed in healed and fresh extraction sites, loaded immediately with fixed full-arch prosthesis, and to assess the implant and prosthesis survival/success rate throughout a 2-year follow-up study.

MATERIALS AND METHODS

The study was done in the following phases:
1. Patient selection
2. Placement of implants followed by immediate loading
3. Collection of data
4. Statistical analysis.

Fifteen patients, either completely or partially edentulous with remaining teeth that were not suitable for a fixed prosthesis, were selected for this clinical study. The selection process followed specific inclusion and exclusion criteria from those visiting the outpatient department of Prosthodontics at HIDS in Paonta Sahib, Himachal Pradesh.

Materials

- Patient record file
- Intra- and extraoral photographs
- Radiographic grid
- Implant kit
- Radiovisiography (RVG), orthopantomogram (OPG), and cone-beam computed tomography (CBCT).

Study population and methodology

This study adhered to revised ethical principles outlined in 2000 in the Declaration of Helsinki (1975) given for medical researches engaging human subjects. Over a term of 2 years, prospective study was conducted on 15 patients, involving total of 87 immediately loaded implants. Amongst these, 44 were placed in extraction sites (IPIL), while 43 in healed sites (HSIL).

Patient selection criteria

Inclusion criteria

- Patient willing and in need for fixed full-arch prosthesis
- Good general health with acceptable oral hygiene
- Adequate bone volume (quality and quantity).

Exclusion criteria

- Uncontrolled diabetes mellitus
- Acute malignant comorbidity including current or recent chemotherapy or radiotherapy
- Bisphosphonate intake
- Presence of active infection or inflammation or peri-apical lesions in areas of the implant site
- Regular follow-ups not possible
- Bleeding disorders
- Uncontrolled periodontal disease
- Smoking
- Unrealistic expectations in terms of esthetic results.

Procedures to be performed were explained to the patient. After presenting various relevant treatment options for missing teeth, restoring with implants was finalized as the choice of treatment, and a written informed consent was attained.

Ethical Committee approval number: EC/NEW/INST/2023/3525.

Implant system used

Osstem TSIII SA Implant with an internal hex and morse taper connection was used.

Presurgical phase

Medical and dental histories of all selected patients were meticulously documented. Comprehensive clinical examination and regular blood testing were carried out to rule out potential medical or blood-related issues that could impact implant surgery or bone healing. Diagnostic impressions were taken to assess both hard and soft tissues, and pre-operative intra- and extraoral images were captured. RVG, OPG, and CBCT scans were utilized to evaluate surgical site, determine bone quantity, location, size, and angulation for implant placement. Oral prophylaxis was performed to reduce microbial load before extraction and minimize infection risk postsurgery. An acrylic custom tray was fabricated to immediately record pick-up impression after surgery. Prophylactic antibiotics and analgesics were given 1 h before surgery.

Surgical procedure

Throughout the procedure, strict adherence to sterilization and disinfection protocols was abetted. The perioral area was cleansed with Povidine iodine solution before surgery, and patients were asked to rinse their mouth for 1 min with a 0.2% chlorhexidine digluconate. Local anesthetic solution of a 2% lidocaine containing 1:80,000 adrenaline was administered. After making midcrestal and buccal relieving incisions, a full-thickness mucoperiosteal flap was carefully elevated. Atraumatic extraction techniques were employed to preserve buccal and lingual cortical bone. Extraction sockets were meticulously cleaned to ensure complete removal of any granulation tissue, and the periodontal probe was used to carefully inspect the socket for any defects or potential perforations of the cortical plate. A pilot drill was used to initiate osteotomy, followed by a sequence of drilling with ample saline irrigation. Implants were then placed in accordance with "all on four" and "all on six concepts", confirming a torque of at least 35 Ncm to ensure adequate primary stability. Multiunit abutments of variable angulations were placed on the implants to facilitate a parallel path for impression copings, which were subsequently screwed in during impression-making process to ensure a passive fit of the final prosthesis. Abutment screws were secured with a minimum torque of 25 Ncm. Healing collars were placed over mutiunit abutments and the flap was approximated. Suturing was done using a 3-0 polyamide suture. Finally, impression copings were securely fastened over abutments. Adjustments were made to the acrylic custom tray to ensure proper seating.

All patients were provided with postoperative instructions.

Prosthetic phase

An open tray impression was made utilizing a customized acrylic tray and monophase PVS material. The material was injected directly around coping and loaded into tray. Following pickup impression removal, it was thoroughly washed and disinfected, and laboratory analogs were attached. Cast was poured, and temporary denture base was created. Fitting of the temporary denture base and the occlusal rim was verified, continuing with adjustments as needed. Bite registration was completed, and the patient was advised to rinse with betadine mouthwash. Healing collars were positioned on multiunit abutments to aid peri-implant mucosa. Screw-retained provisional fixed full-arch prosthesis made of heat-cured acrylic resin, delivered within 72 h postsurgery. After removing the healing collars, the abutments were cleaned, and the provisional prosthesis was secured to the abutments with tightened screws. Centric and lateral contacts were evaluated, and screw access holes were sealed with provisional resin cement. OPG with provisional prosthesis [Figure 1] and intraoral and extraoral photographs were captured. Baseline data was documented, and patients were scheduled for

a follow-up after 7 days. After 3 months, provisional prosthesis was removed, and an open tray impression was made with monophase and putty PVS material. Jig-trial, bite registration, and metal-trial were done to verify each step and ensure a passive fit of the prosthesis. A Porcelain fused to metal prosthesis was then cemented to abutments. Postoperative profile photograph and OPG [Figure 2] were taken, with follow-up appointments set at 6-, 12-, 18-, and 24-month intervals.

Variables assessed

a. Marginal bone level: Periapical radiographs were taken using a paralleling technique and were evaluated to determine bone level in relation to "implant abutment junction " as reference point
b. Implant and Prosthesis survival/success rates: Implants were categorized as failed under the following conditions: peri-implant suppurative infection, fixture mobility, and worsening radiolucency at marginal bone level. Prosthesis; if fractured or needed replacement for any reason was considered to be failed.

Follow-up evaluation

In this study, standardized intraoral digital radiographs, RVGs were obtained by following the long cone technique with a radiographic grid, keeping the central beam perpendicular to the alveolar crest with a X-ray Positioner (XCP holder Rinn™, Dentsply International, York, PA, USA). A total of 5 RVGs were taken for each implant. First, RVG was taken at the time of loading of implants with a provisional denture which served as the baseline (T0) and rest of the RVGs were taken at an interval of 6, 12, 18 and 24 months as T1, T2, T3 and T4, respectively. To account for any variations, a radiographic grid and Image J software was used for precise linear measurements. All measurements were made upto two digits after decimal in millimeters. At each follow-up, RVG and OPG was taken following the standardized technique to evaluate crestal bone level changes around the implant over time.

Measurement of bone loss

On either side of each implant, the highest level of radiologically visible bone-to-implant contact was located and marked with red color. The implant abutment junction was considered as reference point and was marked in green color. From this reference point bone loss was measured using yellow color. Measurements were made, and the mean was calculated [Figure 3]. Three clinicians made measurements with the help of measuring software (Image J), and the mean of all three values was taken into consideration. Final crestal bone loss value was the mean of measurements from the mesial and distal side.

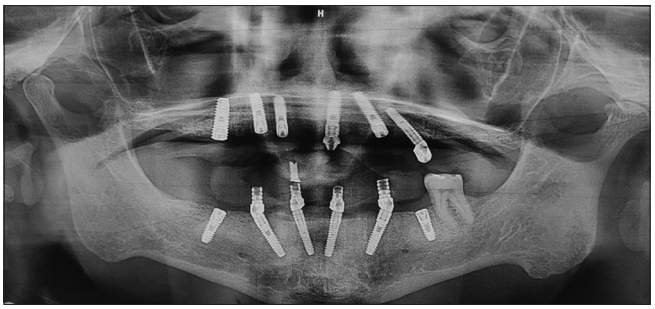

Figure 1: Orthopantomogram showing screw retained provisional restorations

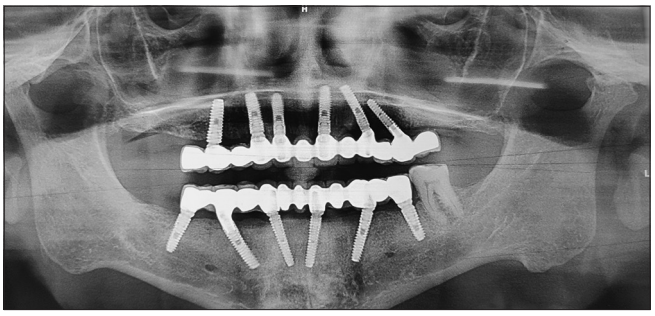

Figure 2: Orthopantomogram with definitive prosthesis

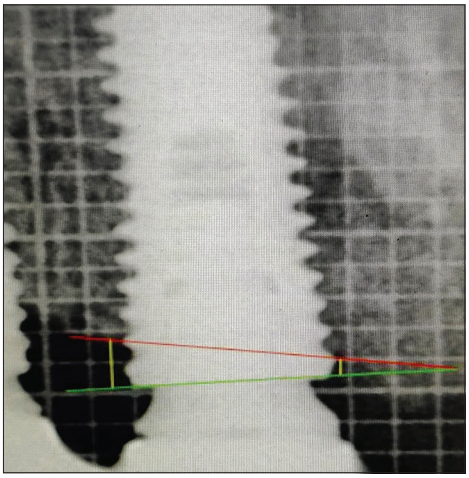

Figure 3: Image showing measurement of bone loss from implant abutment junction on mesial and distal sides

Statistical analysis

The cumulative implant and prosthesis survival rate was assessed statistically using SPSS Software V19. Comparison of bone loss between IPIL and HSIL groups at 6, 12, 18, and 24 months was done using an independent *t*-test with $P < 0.05$.

Null hypothesis

For our study Null hypothesis states that there is no clinical

and radiographic difference in immediately loaded implants in extraction sites and healed ridges rehabilitated using All-on-4/All-on-6 protocol.

RESULTS

Bone loss at 6 months

Mean bone loss in the IPIL group was 0.62 ± 0.70 mm in the HSIL group was 0.46 ± 0.53 mm [Table 1]. No significant difference was found in the mean bone loss among the two groups at 6 months, by independent *t*-test ($P = 0.247$).

Bone loss at 12 months

The mean bone loss in the IPIL group was 0.90 ± 0.72 mm and the mean bone loss in the HSIL group was 0.71 ± 0.60 mm. No significant difference was found in the mean bone loss among the two groups at 12 months, by independent *t*-test ($P = 0.185$) [Table 2].

Bone loss at 18 months

The mean bone loss in the IPIL group was 1.15 ± 0.74 mm and the mean bone loss in the HSIL group was 0.99 ± 0.69 mm. No significant difference was found in the mean bone loss among the two groups at 18 months, by independent *t*-test ($P = 0.302$) [Table 3].

Table 1: Comparison of bone loss at 6 months

Group	*n*	Mean±SD	*P*
IPIL	44	0.6233±0.70902	0.247
HSIL	43	0.4664±0.53369	

HSIL: Healed Site Immediate Loading, SD: Standard deviation, IPIL: Immediate Placement Immediate Loading

Table 2: Comparison of bone loss at 12 months

Group	*n*	Mean±SD	*P*
IPIL	44	0.9057±0.72297	0.185
HSIL	43	0.7140±0.60765	

HSIL: Healed Site Immediate Loading, SD: Standard deviation, IPIL: Immediate Placement Immediate Loading

Table 3: Comparison of bone loss at 18 months

Group	*n*	Mean±SD	*P*
IPIL	44	1.1579±0.74329	0.302
HSIL	43	0.9977±0.69319	

HSIL: Healed Site Immediate Loading, SD: Standard deviation, IPIL: Immediate Placement Immediate Loading

Table 4: Comparison of bone loss at 24 months

Group	*n*	Mean±SD	*P*
IPIL	44	1.3915±0.73625	0.159
HSIL	43	1.1732±0.69421	

HSIL: Healed Site Immediate Loading, SD: Standard deviation, IPIL: Immediate Placement Immediate Loading

Bone loss at 24 months

The mean bone loss in the IPIL group was 1.39 ± 0.73 mm and the mean bone loss in the HSIL group was 1.17 ± 0.69 mm. No significant difference was found in the mean bone loss among the two groups at 24 months, by independent *t*-test ($P = 0.159$) [Table 4].

A bar graph showing mean bone loss for both the groups over 2 years was plotted [Figure 4: X-axis-time span, Y-axis-mean bone loss in mm].

DISCUSSION

Our study aimed to assess clinical and radiographic parameters of immediately loaded implants in fresh extraction sites (IPIL) and healed sites (HSIL) using the All-on-4/All-on-6 protocol over 2-year period. A total of 15 subjects received 87 implants, with 44 in extraction sites and 43 implants placed in healed sites. All implants were planned for immediate loading. Variables such as implant and prosthesis survival rate, and marginal bone loss around the implant supporting fixed full-arch prosthesis at 6-month intervals over 24 months.

Our Primary objective was to utilize radiographic evaluation to examine and compare marginal bone loss around immediately loaded implants placed in extraction sites (IPIL) and healed sites (HSIL) over 24 months.

Bone loss at 6, 12, 18, and 12 months in IPIL was 0.62 ± 0.70 mm, 0.90 ± 0.72 mm, 1.15 ± 0.74 mm, and 1.39 ± 0.73 mm, whereas in HSIL, it was 0.46 ± 0.53 mm, 0.71 ± 0.60 mm, 0.99 ± 0.69 mm, and 1.17 ± 0.69 mm. The comparison of bone loss between two study groups (IPIL and HSIL) revealed no significant difference.

These values also indicate that the maximum amount of bone loss for both the groups (55.39% in IPIL and 60.68% in HSIL) had occurred initially in 6 months, out of total study

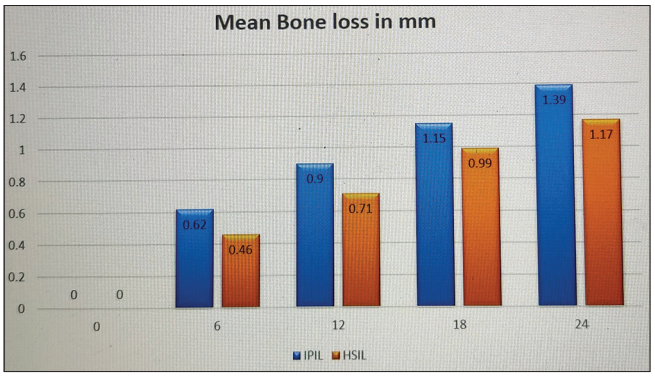

Figure 4: Bar graph comparing bone loss for both the groups over a span of 2 years

period of 2 years. Factors that lead to more early bone loss can be trauma due to surgery, heat generation by drilling, elevation of periosteal flap, overheating of bone, lack of sufficient irrigation, stresses on bone exerted after immediate loading result in microfractures in bone which stimulate bone turnover rate and in turn leads to resorption. Other factors are, less than ideal fit between implant and surrounding bone, insufficient bone density to surround the implant, harmful patient habits such as substance abuse, and impaired healing attributed to overall systemic health of patient. Other factors at the time of loading of prosthesis, like impression making, jig-trial, metal trial, final seating of prosthesis, and presence of excess residual cement require repeated screwing and unscrewing of components which will interrupt homeostasis around implant abutment junction leading to inflammatory cell ingress cause further breakdown of bone.[14-18]

The secondary goal was to evaluate rates of survival and success for Implants and Prostheses within a 2-year timeframe, considering that implants were placed and loaded.

Albrektsson *et al*. established specific criteria for determining the success of dental implants. These criteria include the absence of any long-lasting or irreversible signs and symptoms such as pain, infections, neuropathies, parasthesia, or damage to the mandibular canal. In addition, there should be no radiolucency observed around the implant site, and implant should not exhibit any mobility when tested clinically. These factors collectively contribute to the characterization of individual implant performance according to Albrektsson *et al*.'s guidelines.[19]

In this study, because of the absence of any of conditions stated above, the implant survival rate was 100%.

Influence of various factors on the successful osseointegration of dental implants was highlighted by Albrektsson *et al*. in 1981. There are numerous factors contributing to the failure or success of dental implants. There are patient-related factors such as their age, gender, overall health, smoking habits, and oral hygiene practices. Other factors can be associated with site of implant placement, i.e., its location in the dental arch, the quality, and quantity of surrounding bone. Some factors can be related to surgical procedure itself, including initial stability of implant, angle and angle of placement, and skill of the clinician. Furthermore, the implant fixture's macro and micro geometry features like its surface roughness, length, diameter, etc., has contribution to the prognosis of the therapy. Lastly, there are factors associated with implant prosthesis, including the type of prosthesis used, method of retention (screw or cement), loading conditions, and occlusal scheme.[20-22] Understanding the reasons behind the failure of dental implants has always been a significant concern.[23,24]

CONCLUSION

The average bone loss for 2 years for implants placed in the IPIL group was measured at 1.39 mm, whereas for the HSIL group, it was 1.17 mm. The observed difference of 0.22 mm between the two groups is not significant. In addition, studies mentioned above suggested that high rate of implant and prosthesis survival, with minimal bone loss within acceptable limits, was achieved here. Furthermore, our implant survival rate was 100% as there were no clinical or radiographic indications of failure, such as pain, infection, neuropathies, paresthesia, mobility, peri-implant radiolucency, exudation, or fracture. In addition, none of our prostheses fractured, resulting in a 100% prosthesis survival rate. Therefore, regardless of whether the implants were placed in healed or extraction sites, immediate loading and successful delivery of full arch prostheses to the patient can be achieved.

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Conflicts of interest
There are no conflicts of interest.

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