



Implant Survival and Radiographic Analysis of Proximal Bone Levels Surrounding a Contemporary Dental Implant

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In October, 2006, a new implant system was available (Implant Direct LLC, Calabasas, CA; www.implantdirect.com). However, there are no studies to document the survivability or the amount of bone loss that occurred, after placement of the implants that are available in this system. This implant incorporates design features (Tapered implant body; Anti-rotational internal connection, US Patent No. 4,960,381) and surface biotechnology (SBM, Soluble Blast Media, Paragon Implant Company, 1992–2000) that have been used for many years in other implant systems.¹ The manufacturer of these implants received marketing approval from the FDA (Food & Drug Administration, US Department of Health & Human Services) on October 1, 2006.

In February 2007, information pertaining to this implant system was reviewed online by the author. The company was contacted and additional information pertaining to one of the implant designs (Screwplant; Implant Direct LLC) was evaluated. Scanning electron microscopy assessment at a university (Prof. John Ricci, Biomaterials Lab, NYU Dental College, NY) validated that the used surface tech-

Objective: This study was performed to evaluate the performance of a contemporary dental implant. Assessments were made regarding implant survival and radiographic bone changes from surgical placement to subsequent time points.

Materials and Methods: Seventy-five patients received 204 dental implants. One hundred and seventy-six implants were placed into healed ridges and 28 implants were inserted into fresh extraction sockets. Implant survival percentages and mean data pertaining to radiographic proximal bone loss for 1 randomly selected implant per patient are presented.

Results: The survival rates for implants placed into healed ridges and fresh extraction sockets were 98.6% and 96.4%, respectively. The overall survival rate for all implants in the 75

patients was 99.0%. With respect to proximal bone levels, mesial and distal bone loss from surgical placement to 12 months was 0.96 mm mesially and 0.83 mm distally. From 24 to 36 months follow-up, the mesial and distal bone changes were 0.16 mm and 0.19 mm, respectively. Up to 36 months after implants were placed into fresh extraction sockets, the mean distance from the implant-abutment interface to the first bone to implant contact was 1.01 mm mesially and 1.10 mm distally.

Conclusion: With respect to the time frame of the study, assessed parameters were similar to other implant systems that are currently used. (Implant Dent 2011;20:146–156)

Key Words: implant survivability, proximal bone levels, healed ridges, fresh extraction sockets

nology was similar to other commercially available textured surfaced implants. The vendor (Himed, Old Bethpage, New York, NY), which provided the texturing of the implant surface was contacted by the author for information about its surface biotechnology.

Because many aspects of the implant's design and surface were similar to other well-established implant systems, it was decided to use the implant. To validate its utility, data were collected with respect to its survival and the amount of bone loss that occurred after implant insertion. The purpose of this study, which was con-

ducted in a private office setting, was to determine whether the survival rate of these implants was comparable with other implant systems. In addition, radiographic measurements were taken to analyze the amount of proximal bone loss that occurred from the time of implant insertion to subsequent time points.

MATERIALS AND METHODS

Patient Population

In a private practice setting, conducted by the author, 75 consecutive patients received 204 dental implants in different jaw locations. Patients

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were not excluded on the basis of medical conditions as long as clearance by their physicians for intraoral implant surgery was given. The patients were taking a variety of medications. Smokers (18 patients) and nonsmokers were included. The mean patient age was 61.8 years (range, 28–84 years). There were 33 men and 42 women in this study. All the implants (except one that exists in the author’s mandible) were surgically placed by the author and the majority of restorations were fabricated by the author between May 2007 and December 2009. Twenty patients’ implants were restored by 4 other dentists.

Radiographic Distortion and Measurement Error

Before commencing the study, the author and 1 surgical assistant practiced taking periapical radiographs using the long-cone paralleling technique (Rinn film-holding instruments, Dentsply-Rinn, Elgin, IL). The distortion factor was less than 10%. For any radiograph to be used for measurements, the implant threads had to be discernable.² Before commencing the study, the author calibrated himself with respect to operator measurement error on radiographs and continued this exercise until a mean error on 10 consecutive radiographs was ≤0.1 mm (range, 0.0–0.2 mm).

Surgical Protocol and Maintenance

Clinical data recorded for each patient with respect to implant placement is shown in Table 1. All patients were premedicated with a loading dose of antibiotics (Amoxicillin 2 g or Clindamycin 600 mg for Amoxicillin-allergic patients) before implant surgery.³ Postoperatively, some patients took antibiotics for up to 7 days. Standard surgical procedures were used to achieve access to the osseous crest. The implants were placed in accordance with the manufacturer’s recommendations.⁴ Implants were inserted at, or coronal to, or apical to the osseous crest as dictated by the available interocclusal space and the anticipated prosthetic design.⁵ If 1 or 2 minithreads were exposed on the buccal, no attempt was made to perform a guided bone regeneration procedure to

Table 1. Implant Direct Data

1. Patient code:
2. Site:
3. Bone quality:
4. Length
5. Width
6. Protocol: S, NS
Date:
7. Bm =
Bd =
Date:
8. Integration time
Date:
9. Loaded
Date:
10. Restoration
Date:
11. Bm =
Bd =
Date:
12. E% pa:
13. E op:
14. Healed bone
15. Socket
16. Miscellaneous

1. Patient Code: database entries.
2. Site: location within jaw into which implant was placed, mandible-anterior or posterior; maxilla-anterior or posterior.
3. Bone Quality: Td (type dense), Tm (type medium), and Ts (type soft).
4. Length: implant length in mm.
5. Width: implant width in mm.
6. Protocol and date at surgical placement: S, submerged; NS, nonsubmerged.
7. Bm (bone level mesial), Bd (bone level distal), and date at surgical placement: radiographic (mesial and distal) bone measurement from implant-abutment interface to the first bone to implant (BIC).
8. Integration time (week) and date on which the implant was uncovered and an abutment was placed or the date on which the abutment which was attached to a nonsubmerged implant was changed for the first time.
9. Loaded and date: date on which an implant first received an occlusal load or nonocclusal functional load; could coincide with integration time.
10. Restoration: type of restoration placed; single crown, fixed dental prosthesis, overdenture, or Tisp (tooth-implant supported prosthesis).
11. Same radiographic bone measurements at definitive restoration or follow-up appointment.
12. E pa: periapical radiographic distortion (%).
13. E op: periapical operator error, measurement error (mm).
14. Implant placed into healed bone.
15. Implant placed into fresh extraction socket.
16. Miscellaneous: eg, implant failure.

cover the implant threads. However, in the aesthetic zone, exposed threads were covered with a bone graft and a resorbable barrier.^{6–8} Chromic gut sutures were used to approximate flaps. Patients were instructed to take analgesics as needed.

Patients were seen for postoperative evaluations at 1 or 2 weeks after surgery and again at 4 to 6 weeks. If a

secondary surgery was necessary to uncover the implant, procedures were used to preserve or augment the zone of attached keratinized tissue circumferentially. Healing abutments or prosthetic components were attached to the implants once osseointegration was achieved. After attaching an abutment to the implant at >20 Ncm of torque, osseointegration was verified by tapping the abutment with a metal instrument and listening for a “ringing” sound as opposed to a thud and by testing for any mobility by applying pressure against the abutment using 2 metal instruments in a buccolingual direction.

Patients were instructed in oral hygiene techniques (brushing and flossing) 1 week after implant placement or implant uncovering surgery. The soft tissues were allowed to heal for 6 to 8 weeks after implants were uncovered or longer in the aesthetic zone. Standard prosthodontic protocols were used to fabricate prostheses.

Implant Survival Assessment

Implant survival was assessed in accordance with previously established parameters.⁹ For this assessment, all implants had to be surgically inserted for a minimum of 6 months. Some prostheses were in place for up to 36 months. The percentage of survivability was then calculated. This was done for 3 subsets of patients: (a) 1 randomly selected implant per patient placed into a healed ridge, (b) 1 fresh extraction socket per patient, and (c) the total number of implants placed into healed ridges, which included multiple implants per patient. Data pertaining to changes in proximal bone levels relative to the implant-abutment junction was recorded: 1 implant per patient, healed ridges.

Subset 1: Mean proximal bone changes from surgical placement to 6 months. Proximal bone levels were measured on the radiographs from the implant-abutment junction to the first BIC (bone to implant contact). Radiographs taken at implant insertion served as the baseline reference point. Radiographs were then taken at 6 months to assess proximal bone

Table 2. Number of Inserted Implants Categorized by Implant Length, Width, Jaw Position, Bone Quality, Native Versus Grafted Bone, and Healed Ridge Versus Extraction Socket

Lengths	Widths	Position			Bone Quality*	Restoration
		Maxilla	Mandible			
8 mm (n = 20)	3.7 mm (n = 163)	Anterior (n = 28)	Anterior (n = 22)	Submerged (n = 105)	Dense (n = 22)	Single crown (n = 42)
10 mm (n = 66)	4.7 mm (n = 41)	Posterior (n = 81)	Posterior (n = 73)	Nonsubmerged (n = 99)	Medium (n = 156)	Fixed bridge or splint (n = 49)
11.5 mm (n = 65)					Soft (n = 26)	Removable overdenture (n = 9)
13 mm (n = 52)					Native bone (n = 176)	TISP† (n = 9)
16 mm (n = 1)					Grafted bone (n = 28)	
					Healed ridge (n = 176)	
					Extraction socket (n = 28)	

*For details see Ref. 42.

†Tooth implant-supported fixed bridge.

changes. Therefore, there were 2 radiographs used to make measurements per patient. Bone loss per surface (mesial and distal) was calculated as the net difference between the first and second set of readings. To account for the effect of a patient's biology,¹⁰ 1 implant per patient was randomly selected for these subsets of data. Mean bone change was calculated as the sum of all mesial readings for each implant divided by the total number of patients in the group. The same mathematical procedure was followed for the distal surface calculations.

Subset 2: Proximal bone changes for patients assessed at surgical placement of the implant and at 12 months.

Subset 3: Proximal bone changes for patients assessed at 12 months and again at 24 months.

Subset 4: Proximal bone changes for patients assessed at 24 months and again at 36 months.

Estimated Bone Level in Fresh Extraction Sockets

After implant placement into fresh extraction sockets, a subset of measurements was made for 1 randomly selected socket per patient from the implant-abutment interface to the first BIC on the second set of radiographs. This took place a minimum of 4 months after implant insertion plus a minimum of 2 additional months (prosthetic time to completion). Therefore, the minimum time for socket healing was 6 months before the second radiograph was taken to estimate bone levels. Additionally, radiographs were taken up to 36 months after implant insertion and proximal bone levels were recorded.

Table 3. Number of Patients in Various Time Frames for Monitoring of Implant Survival in Healed Ridges and Fresh Extraction Sockets (One Implant per Patient)

Time Frame: Healed Ridges (mo)	n (Patients)	Time Frame: Extraction Sockets (mo)	n (Patients)
6–12	33	6–12	3
12–24	23	12–24	10
24–36	19	24–36	15

Table 4. Mean Proximal Bone Changes at Delineated Time Frames

No. of Patients (n per Subset)	Time Frame of First Radiograph (mo)	Time Frame of Second Radiograph (mo)	Mean Bone Change (mm)	
			Mesial	Distal
15 (subset 1)	0	6	0.75	0.79
17 (subset 2)	0	12	0.96	0.83
24 (subset 3)	12	24	0.18	0.21
24 (subset 4)	24	36	0.16	0.19
28 sockets	—	6–36	1.01	1.10
9 <i>Post hoc</i> assessment of platform switch	0	12	0.60	0.52

This was done to calculate the distance from the implant-abutment interface (microgap) to the first BIC after initial healing of the sockets and over longer time frames.

RESULTS

Implant lengths, diameters, locations within the jaws, whether submerged or nonsubmerged at insertion, local bone quality, placement into native or grafted bone, healed ridge or fresh extraction sockets and restoration type are presented in Table 2. All patients were available for radiographic analysis at a minimum of 2-time points: surgical insertion (baseline) and at 6 months (n = 15 patients) or 12 months (n = 17 patients) or 12

to 24 months (n = 24 patients) or 24 to 36 months (n = 19 patients).

If an implant was submerged, then the time allotted for osseointegration to occur was computed as to be the number of weeks until the uncovering surgery. If an implant was not submerged, then the integration time was considered to be the number of weeks until the healing abutment was removed for the first time. The mean integration time was 15.2 weeks (range, 9–40 weeks), whereas the most commonly recorded integration time was 12 weeks (41 of 110 entries).

Implant Survivability

Two implants in 2 different patients (1 in a healed ridge and 1 in a

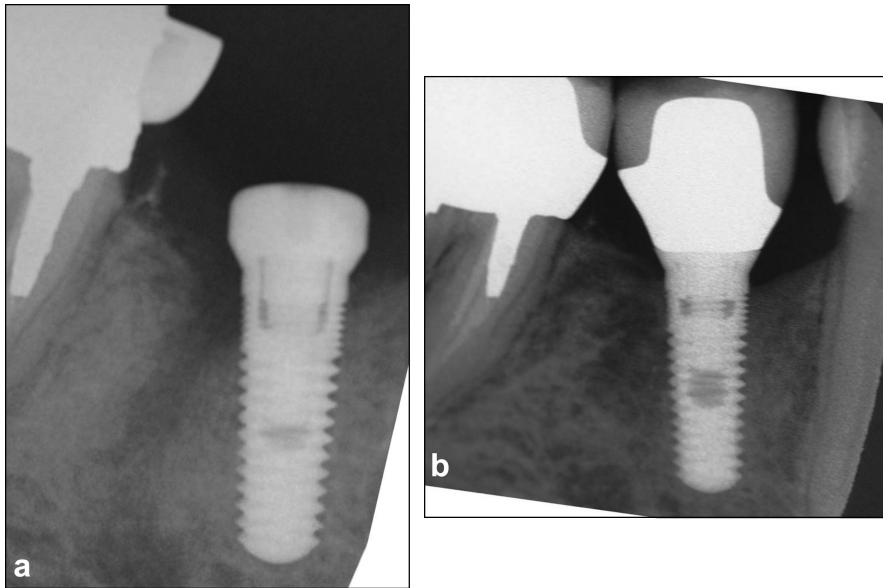


Fig. 1. a, Radiograph taken at implant insertion providing a baseline measurement of proximal bone levels. **b**, Radiograph taken at 12 months after implant insertion which is also 6 months after restoration of the implant. Note that the proximal bone changes are limited to the nonthreaded, blasted portion, or the junction of the nonthreaded portion and the microthreaded portion of the implant.

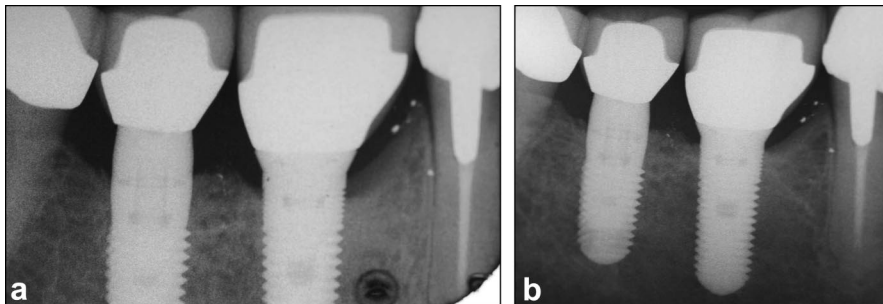


Fig. 2. a, Radiograph of Screwplant at 24 months postrestoration of the implant. **b**, Radiograph of the same implant at 36 months. Minimal additional proximal bone changes have occurred.

fresh extraction socket) failed to achieve osseointegration during the assessment period. These implants were successfully replaced 3 months later, but were included in the data as failures of osseointegration. All the other implants were immobile. Implant survival was 98.6% on a per patient basis when placed into healed ridges (74 of 75 patients) and 96.4% when placed into fresh extraction sockets (27 of 28 sockets). A breakdown of the number of patients available during the various time frames for healed ridges and fresh extraction sockets is provided in Table 3. With respect to all implants placed (includ-

ing multiple implants per patient to the last recorded time point), the survival rate was 99.0% (202 of 204 implants).

Radiographic Assessment of Proximal Bone Changes: Healed Ridges

Mean values (and range) for all subsets of data are summarized in Table 4. Representative examples of the radiographic proximal bone changes from 0 to 12 months and from 24 to 36 months are presented in Figures 1, a and b and 2, a and b, respectively.

Extraction Sockets: 1 Socket per Patient

Estimated bone level in fresh extraction sockets: the mean mesial dis-

tance to the first BIC (after a minimum of 6 months and up to 36 months of healing) from the implant-abutment interface is presented in Table 4. A representative example of this group is presented in Figure 3, a and b.

Post hoc assessment (platform-switching abutment: the placed abutment was smaller than the diameter of the platform of the implant), 9 patients, up to 12 months of follow-up: the mean mesial and distal bone change was 0.60 and 0.52 mm, respectively. A representative example of this group is presented in Figure 4.

Prosthetic Restorations

The design of the definitive restorations is provided in Table 2. To date, no definitive abutments loosened on any restored implants. No other types of prosthetic complications occurred during the 6- to 36-month time frame of the study.

DISCUSSION

The contemporary implant assessed in this study performed well over a 6- to 36-month evaluation period. The primary focus of this discussion pertains to 2 important issues: implant survival and proximal bone changes. In addition, some commentary about the implant's performance is provided.

This study demonstrated a per patient survival rate of 98.6% for implants placed into healed ridges over the time frame of 6 to 36 months. These results are similar to other previously reported implants used to treat fully and partially edentulous patients.¹¹⁻¹⁶ For example, Stanford *et al* reporting on 549 subjects including 1246 implants showed a cumulative implant survival rate of 98.6% 1 year after prosthesis insertion.

With respect to implants placed into fresh extraction sockets, this implant demonstrated a per patient survival rate of 96.4%. This is comparable with other reports assessing implants that were immediately inserted into sockets.^{14,17-19} For example, in a comprehensive review, including meta-analysis, Stafford showed an immediate implant survival rate of 95.5% (95% CI, range, 93.0%-97.1%)

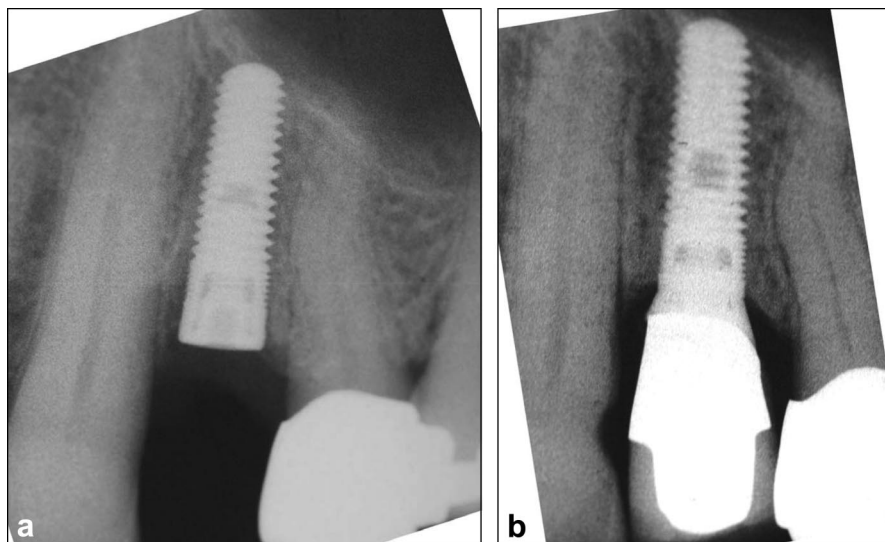


Fig. 3. **a**, Radiograph of Screwplant placed into a fresh extraction socket. **b**, Radiograph of the same implant at 12 months of healing. Note that the first apparent BIC can be found at ~ 1 mm from the implant-abutment interface.



Fig. 4. Radiograph taken 1 year after loading of the implant with a platform-switching abutment in place. There appears to be minimal mesial or distal bone loss measured from the implant-abutment interface.

after 1 year. Therefore, with respect to implant survival in healed ridges and extraction sockets, the contemporary implant design assessed in this study performed well over a 6- to 36-month time frame.

Two implants failed to achieve osseointegration in this study. Similar to other reports that discussed failures of osseointegration, both of these were early failures and occurred before prosthetic loading and prosthesis fabrication. On a per patient basis, this study demonstrated an implant failure rate of 1.33%. Other investigators reported early implant failures (prior to restoration) in the range of 0.7% to 7.4%.²⁰ In this study, minimal time

and resources were needed to rectify these failures; they were replaced with other implants. There were no prostheses that were affected or lost during the assessment period.

In addition to survivability, the stability of osseointegration over time must be incorporated into the assessment of an implant's performance.²¹⁻²³ Historically, the definition of implant success proposed by Albrektsson *et al* was based upon clinical immobility, minimum radiographic bone loss over time, an absence of exudate, persistent inflammation, patient discomfort, bleeding, or periimplant radiolucencies. More recently, a Consensus Conference sponsored by the International

Congress of Oral Implantologists (ICOI) approved 4 clinical categories and certain conditions of implant success, survival and failure. This improved upon historical assessments by offering specific measures of bone loss that may occur during the first year after implant insertion.²⁴ All of the assessed implants in this study fall into the ICOI Early (1-3 years) Success (optimum health) category.

In this study, proximal bone changes were measured at various time points. The first 2 assessment periods, from surgical insertion up to 6 months and 1 year, account for the effects of the surgical procedure,^{25,26} remodeling and formation of biologic width,^{27,28} local factors such as bone quality or quantity,^{29,30} proximity to adjacent teeth³¹ or implants³² and the effects of abutment disconnection and reconnection.^{33,34} It is normal for the biologic width to reform around osseointegrated dental implants.^{27,28} In this regard, Adell *et al*³⁵ found that the mean bone loss for Brånemark implants was 1.5 mm while Cox and Zarb³⁶ showed a mean bone loss of 1.6 mm from surgical placement to the end of the first year. Data in this study provide documentation of the proximal bone changes that can be expected from the time of surgical implant placement into healed ridges to 6 and 12 months for a group of 33 patients. The mean mesial and distal bone changes at the 6-month interval were 0.75 and 0.79 mm, respectively. At 1 year, the corresponding mesial and distal values were 0.96 and 0.83 mm. These bone alterations are less than those reported in the aforementioned studies for the period of up to 1 year.^{21,35-37}

Concerning the second (12-24 months) and third (24-36 months) assessed time frames, radiographic data from 23 patients and 19 patients, respectively, were available. In healed ridges, the mean mesial and distal bone level changes were 0.18 and 0.21 mm for the second time period and 0.16 and 0.19 mm for the third time period. Albrektsson *et al*²² considered an implant "successful" if it did not demonstrate progressive bone loss greater than 0.2 mm annually after the

first year of implant placement. This is a measure of the maintenance of osseointegration over time. The contemporary implant design assessed in this study met these criteria over the assessed time frames subsequent to implant restoration.

With respect to proximal bone levels adjacent to implants placed into fresh extraction sockets, these implants were countersunk relative to the proximal socket walls, so radiographic measurements from those reference points were difficult and less reliable. That is the reason that the first set of radiographs taken at implant insertion was not used for proximal bone measurements for this group of patients. Only the second radiograph, which was taken after a minimum of 6 months of healing, was used to measure the distance from the implant-abutment interface (microgap) to the first BIC. The mean proximal distances from the implant-abutment interface to the first BIC after extraction socket healing reported in this study (1.01 mm mesially and 1.10 mm distally) are similar to other reports over comparable time frames.^{38,39} In this regard, Cardaropoli *et al* showed an early mean proximal bone loss of 0.9 mm at the time of crown insertion and an additional 0.7 mm loss at 1 year measuring on radiographs from the implant-abutment junction to the level of the bone using a 2-piece implant design.

Radiographs are used in private practice for the purpose of monitoring proximal bone levels around implants. Radiographs in this study were done with a Rinn holder to reduce magnification errors. Both rehearsal of the radiographic technique and operator calibration took place before this study, and this resulted in accurate radiographs and reproducible measurements.²⁸ Additionally, all periapical radiographs used for measurements clearly portrayed the implant threads, which indicated that there was minimal radiographic distortion.²

A *post hoc* assessment was performed with respect to platform switching (attaching an abutment which is smaller in diameter than the platform of the implant). Nine patients

received these abutments at surgical placement of the implants or at implant uncovering. Proximal bone changes were assessed radiographically at 1 year. Platform switched implants evaluated in this study demonstrated ~0.3 mm less bone loss than those implants with nonplatform switched abutments in place. A radiograph of 1 such patient is presented in Figure 4. Radiographically, there appears to be minimal proximal bone reduction at the 1-year follow-up. This radiographic effect is probably due to the biologic width reforming on the external bevel of these implants. A future study with larger numbers of platform switched abutments attached to the implants would provide validation of this bone preserving effect.^{40,41}

In recent years, numerous implant systems have become available for use in patient care. Investigators for each system profess certain advantages associated with their system. In this regard, the author observed the following: when procedures are properly performed, it was very easy to achieve primary stability with the studied implant design.^{4,42} Additionally, the internal connection was stable over a 6 to 36 month time frame and no definitive abutments became loose during the assessment period. Prosthetic components (straight, angulated, prefabricated, and custom-cast) were used and functioned well thereby permitting various restorative options (screw-on and cement-on prostheses).

CONCLUSIONS

1. Over the assessed time frame, the contemporary implant evaluated in this study, when inserted into healed ridges and fresh extraction sockets demonstrated survival rates which are favorable when compared with other existing implant systems.
2. After 12 months of healing, and up to the 24 and 36 month time frames, the implant demonstrated minimal alterations of proximal bone levels in healed ridges or extraction sockets.

Further clinical studies will be valuable in monitoring the initial fa-

vorable performance of this dental implant over longer periods of time.

Disclosure

The author claims to have no financial interest in the company mentioned in this article and states that "subsequent to the completion of this study and unrelated to it, I have received and evaluated components for Implant Direct, LLC." He also stated that "No representative of Implant Direct, LLC has seen this manuscript or had any control over its content."

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