ORIGINAL ARTICLE

Clinical and radiographic evaluation of new dental implant system: Results of a 3-year prospective study[☆]

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Abstract *Background/purpose*: The aim of this study was to evaluate implant survival, crestal bone level changes, and clinical parameters of IDcam dental implants over a mean follow-up period of 3 years.
Materials and methods: Seventy-two patients, 32 females and 40 males, received 255 implants. Implant-supported metal—ceramic fixed restorations were inserted. Following completion of restorations, each patient was re-examined at 6-month intervals. Radiographic crestal bone level changes were calculated, as well as soft tissue parameters including pocket probing depth, bleeding on probing, plaque index, and gingival index. Examination results were recorded from 18 months to 42 months. Implant survival was estimated using the Kaplan—Meier method. Associations between implant survival and recorded variables were estimated using Cox proportional regression analysis.
Results: The Kaplan—Meier survival analysis demonstrated a cumulative survival rate of 97.6%. Three implants in three patients failed to osseointegrate at stage 2 surgery, and three implants in three patients were lost after loading. The mean marginal bone losses were 0.35 ± 0.14 mm, 0.47 ± 0.15 mm, and 0.58 ± 0.16 mm, as determined 6 months, 12 months, and 24 months after prosthetic loading, respectively. Cox proportional regression analysis revealed that the variables such as age, sex, type of the restoration, and implant region had no significant influence on implant failure ($P > 0.05$). Coefficients of correlation between implant survival and crestal bone loss, pocket probing depth, bleeding on probing, plaque index, and gingival index were found to be nonsignificant ($P > 0.05$).

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Conclusion: Survival and radiographic and clinical assessments of implants after 2 years of function demonstrated promising results for an IDcam dental implant system.

Introduction

Dental implants are considered one of the most significant scientific breakthroughs in dentistry, and are frequently used in the rehabilitation of total and partial edentulism in most clinical scenarios.[1,2] Branemark et al[3] and Albrektsson et al[4] introduced and presented long-term data on the success of dental implants. They reported 90% implant survival over 10—15 years of follow up.[5,6] Since then the use of dental implants for oral rehabilitation of fully and partially edentulous patients has greatly broadened the scope of clinical dentistry, creating additional treatment options in complex cases in which functional rehabilitation was previously limited or inadequate.[1] Many different implant systems, varying in body shape, material, surface properties, diameter, length, and interface geometry, have been introduced into the dental market.[7,8] At present, far more than 100 different implant systems are avilable.[9] From the clinician's perspective, there is a consensus that long-term scientific evidence is needed to determine the predictability of such a system.

In 2009, IDcam (IDI system, Paris, France) dental implant systems were introduced into the dental market. The implant is made of two phases, Ti6Al4V Grade 4 and 5. Its state of surface is sandblasted, acid etched, and TiO_2 coated. The main features of an implant are that it is threaded, is of cylindro-tapered shape, has a morse taper implant-abutment connection, and has a concave-shaped apex design, namely, concave security osseo wedging apex (Fig. 1). The threads are V-shaped low threads and squared-shaped high threads, which act as self-drilling and condensing threads, respectively. The concave security osseo wedging apex, with its concave shape, was designed to act as a bone reservoir for bone grafting, to limit the risks of damaging the sinus membrane and nerve with its "securit" round-shaped end, and to increase the apical bone retention surface with its peripheral and wedging groove. To the best of the authors' knowledge, there is no published article relating to the predictability and versatility of this system.

The aim of this study was to evaluate the clinical and radiographic outcomes of IDcam implant systems in patients treated with implant-supported fixed full-arch prostheses (FFPs), fixed partial prostheses (FPPs), or single crowns (SCs). Study outcomes are implant survival; radiographic changes in crestal bone levels; clinical parameters of probing depth (PD), gingival index (GI), and plaque index (PI); and bleeding on probing (BOP) over a mean follow-up period of 3 years.

Materials and methods

The study was performed at the Department of Prosthodontics, Faculty of Dentistry, Gazi University. The study protocol was reviewed and approved by the Clinical Research Ethics Board of Faculty. The surgical and prosthetic treatments, and follow-up visits were performed between November 2009 and October 2013. All patients received oral and written information about the study, and those who agreed to participate gave their written consent. The patients that required treatment with implant-supported FFPs, FPPs, or SCs were selected. The following criteria were used for excluding patients from this study:

(1) Need for augmentation of the implant site
(2) Presence of persistent and unresolved infection in the implant site
(3) Having passed at least 2 months after tooth extraction
(4) Heavy smokers (>10 cigarettes/d)
(5) Uncontrolled diabetes
(6) Receiving bisphosphonate therapy at the time of implantation
(7) Active periodontal disease
(8) Severe bruxism or clenching habits
(9) Any medical history that could affect implant surgery
(10) Lost to follow up

Figure 1 Design of the IDcam implants used in the study.

A two-stage surgical procedure was performed under local anesthesia. The patients received implants in the edentulous sites. Midcrestal incisions and vertical releasing incisions were used, and full-thickness flaps were reflected. For implant placement, it was considered to provide minimal 0.5-mm bone thickness around the inserted implants. A cover screw was applied, and the flaps were adapted to achieve primary closure. During the primary healing period, chemical plaque control was recommended via rinsing with a 0.1% chlorhexidine solution twice daily for 1 week. Sutures were removed after 7 days. The implants were allowed to osseointegrate for 3—4 months. During the osseointegration period, complete dentures of edentulous patients were adjusted and provided with a soft relining material (Visco-gel; Dentsply DeTrey GmbH, Konstanz, Germany), provisional layering was not inserted in partially edentulous patients in the posterior sites, and fixed or removable provisional restorations were placed in the esthetically demanding implant sites. At the end of the osseointegration period, gingival removal and healing abutment connection were performed. After a 2-week peri-implant soft tissue healing period, the abutments were connected and tightened with a torque control device, up to 30 Ncm. Implant-supported overdentures for edentulous patients, and metal—ceramic fixed partial dentures or crowns were fabricated in the prosthetic phase. All prosthetic procedures from abutment connection to cementation of the crowns were performed by two experienced prosthodontists.

At baseline, 6 months, 12 months, and 24 months, the reconstructions were examined radiographically and clinically. Standardized periapical radiographs of the implants were taken, and radiographic crestal bone level changes were calculated. Standardized radiographs were obtained with an individualized custom-made bite block using a long-cone parallel technique. The film was placed parallel to the implant long axis to position the film perpendicular to the radiation beam. Radiographs were taken at implant insertion, after 6 months, 12 months, and 24 months from the placement of the implant-supported restorations. For the valuation of marginal bone level, the radiographs were digitized. The most coronal edges of the implant platform, mesially and distally, were chosen as reference points. The length of the implant was used as an internal reference to calibrate the measurements for distortions. Distal and mesial bone distances from the implant shoulder and marginal bony crest were measured and averaged for each implant (Fig. 2). A single examiner who did not participate in the treatment protocol measured crestal bone changes using the ImageJ (NIH Image; National Institute for Health, Bethesda, MD, USA) computer program designed to make measurements from images. The mean bone loss values were calculated from baseline to 6-month, 12-month, and 24-month follow ups.

PD measurements were recorded at mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual, and distolingual surfaces using Williams probes (Hu Friedy, Chicago, USA). PD was assessed as the longest distance between the gingival margin and the base of the gingival sulcus. Full mouth GI[10] and PI[11] were also determined.[10] BOP was recorded as positive if it occurred within 30 seconds of probing. Clinical examinations were conducted by a single, experienced dental examiner who was not involved in the treatment procedures.

Implant survival was estimated using the Kaplan—Meier method (Fig. 3).[12] For each implant, the duration of follow up was calculated from the time of placement to the date of first failure or the date of last follow up. Associations between implant survival and recorded variables were estimated using Cox proportional regression analysis. The
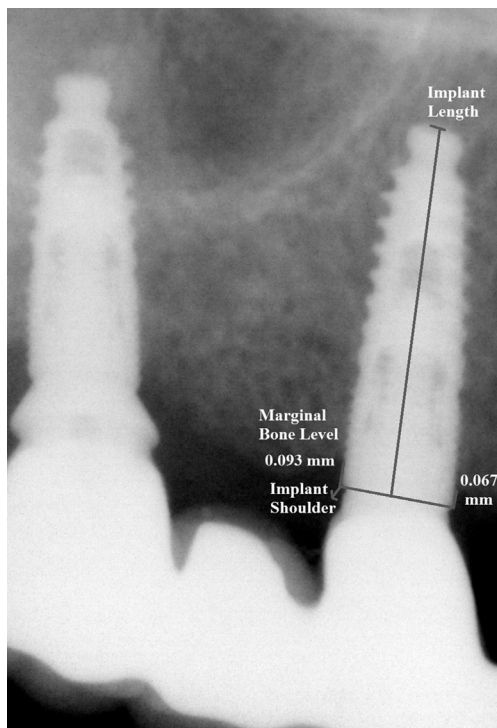

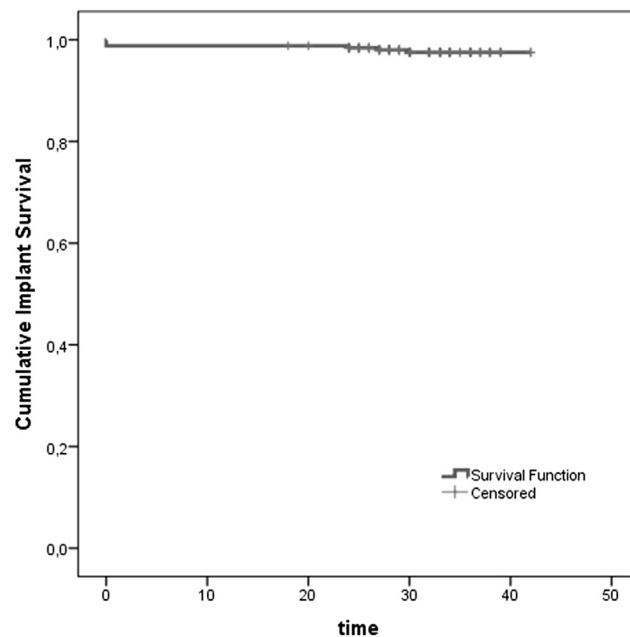
Figure 2 Marginal bone levels of an implant.

Figure 3 Kaplan—Meier survival analysis.

rest of the variables used for data analysis of this report included age, sex, jaw, type of implant-supported restoration (FFPs, FPPs, or SCs), and implant location.

Kendall's tau-b correlation was used to compare the relationship between implant survival and the indices PD, GI, PI, and BOP, as the independent variables, were assumed not to be normally distributed.

Results

A total of 104 patients received 312 implants. Thirty-two of these patients with 57 implants were excluded from the study: 11 patients needed augmentation of the implant site during surgery, 14 patients could not be reached for follow-up examinations, six patients did not agree to attend the study, and one patient died. Data of 72 patients, 32 females and 40 males, with 255 implants were included in the evaluation. The age of these patients ranged from 25 years to 74 years (mean age, 49.1 years). The patients received 255 implants, 104 in the maxilla and 151 in the mandible. A total of 85 implants were inserted in 16 edentulous jaws (13 patients) to support FFPs, 152 implants were inserted in 44 partially edentulous patients to support FPPs, and 18 implants were used to substitute single tooth loss in 15 patients. Patient and implant data are summarized in Table 1.

Six of 255 implants failed, resulting in a cumulative survival rate of 97.6% (with 0.3% standard error and 95% confidence interval) over the follow-up years. Three implants in three patients failed to osseointegrate at stage 2 surgery, and three implants in three patients failed 30 months, 24 months, and 27 months after loading. The implant that failed at 30 months was supporting a single-crown restoration of the maxillary left second premolar tooth. The patient was referred with a complaint of suppuration from the implant site. Clinical examination revealed a mild level of implant mobility, and vertical bone loss was observed in the radiographic examination. The implant was removed. Another implant supporting a three-unit Fixed Partial Denture (FPD) in the left mandibular posterior region failed at 24 months, which showed no signs or symptoms of failure during its function. Extensive peri-implant bone loss from coronal age to apical fourth of the implant was detected from the periapical radiograph taken at the 24-month regular follow-up examination. When the FPD was removed, mobility could be observed and the implant was removed. Another implant supporting an FPD in the maxillary anterior region failed at 27 months of function. The patient was referred with pain and peri-implant infection. Radiographic and clinical examinations revealed extensive bone loss, acute infection of peri-implant soft tissues, and implant mobility. Hence, the implant was removed.

Cox proportional regression analysis revealed that the variables such as age, sex, jaw, type of prosthesis, and implant location had no significant influence on implant failure (P > 0.05). Moreover, the Cox regression model that included all independent variables was not found to be statistically significant (χ^2: 9.019).

The mean marginal bone losses were 0.35 ± 0.14 mm, 0.47 ± 0.15 mm, and 0.58 ± 0.16 mm, as determined 6 months, 12 months, and 24 months after prosthetic loading, respectively. The mean marginal bone losses at 6 months, between 6 months and 1 year, and between 1 year and 2 years are shown in Table 2.

Results of the clinical parameters PD, GI, PI, and BOP at 2 years are shown in Table 3.

Kendall's tau-b correlation showed no significant correlation between implant survival and the indices PD, GI, PI, and BOP (Table 4).

Discussion

The IDcam dental implant system is a new implant system and has been available in the dental market since 2009. It is important that new implant designs are carefully evaluated, preferably in clinical trials.[10] This single-center clinical study aimed to evaluate clinical outcomes of the IDcam dental implant system. To the best of the authors' knowledge, there is no information on this relatively new implant system in the literature; hence, the preliminary results of an ongoing study have been presented here.

Table 1 Summary of patient and implant data.

Age (y)	Range 25–74; mean 49.1 ± 18.3
Sex	40 males, 32 females
Implant region	113 molar
	31 premolar
	61 anterior
Jaw	106 mandible
	149 maxilla
Number of implants placed in each patient	1 implant in 12 patients
	2 implants in 26 patients
	3 implants in 5 patients
	4 implants in 12 patients
	5 implants in 3 patients
	6 implants in 7 patients
	7 implants in 3 patients
	8 implants in 1 patient
	12 implants in 1 patient
	13 implants in 1 patient
	14 implants at 1 patient
	3 replacement implants in 3 patients
Prostheses type	Fixed full-arch prostheses in 13 patients
	Fixed partial prostheses in 44 patients
	Single crowns in 15 patients
Number of implants placed by length	Six implants in 8 mm
	85 implants in 10 mm
	164 implants in 12 mm
Number of implants placed by diameter	208 implants in 4.2 mm
	47 implants in 5.2 mm

Table 2 Mean bone loss around implants.

	Mean	Standard deviation
Baseline to 6 mo	0.35	0.14
6–12 mo	0.47	0.15
12–24 mo	0.58	0.16

Table 3 Mean values of clinical parameters at 24-months follow up.

	Mean	Standard deviation
PPD (mm)	2.6	1.7
PI	0.3	0.5
GI	0.3	0.4
BOP (%)	34.6	28.2

BOP = bleeding on probing; GI = gingival index; PI = plaque index; PPD = pocket probing depth.

The success criteria, which are valid for titanium implants, have to be applied to new implant systems to determine their advantages and disadvantages for clinical use.[13] High survival and success rates for osseointegrated titanium implants have been reported in several studies.[5,14,15] Several factors such as implant design, surgical technique, prosthetic rehabilitation, or patient-related factors have a potential influence on the incidence of implant success.[16] In the present study, IDcam dental implants demonstrated high survival rates (97.6%) over a mean follow-up period of 3 years. A total of six implants failed; three implants were not osseointegrated at stage 2 surgery and three implants failed after loading. This survival rate is compatible with the survival rates previously reported for titanium implants, which were placed according to the two-stage protocol in the healed sites.[2,3,7,8,17,18] In the present study, patients of different age or sex were treated with FFPs, FPPs, or SCs. The implants were inserted in different regions in either the maxilla or the mandible. The results demonstrated that the variables such as age, sex, jaw, type of prosthesis, and implant location had no significant influence on implant failure (P > 0.05). Previous clinical studies reported a variety of results for influences of patient-related factors on implant survival.[19,20] Geckili et al[19] reported a low success rate for short and maxillary implants. Jebreen and Khraisat[21] reported that the survival and success rates of implants placed in male patients and in the maxilla were lower than those of implants placed in female patients and in the mandible. By contrast, the findings of another study indicated that implant survival was independent of the anatomic location of implants.[20] In the present study, influence of patient-related factors should be interpreted with caution due to the failure of a few failed implants. The small number of patients and implants should be considered a limitation of this study as well as a short follow-up period. A 3-year period of function of the implant system described in the present report is short to evaluate the system and draw conclusions on its success. Branemark and

colleagues[3,22] demonstrated the need for long-term follow-up studies for patients receiving dental implants and provided 10-year implant survival data for rehabilitation of fully edentulous patients. Although long-term outcomes are needed to evaluate implant success, in case no data exist on an implant system, short-term data may be useful to provide scientific evidence for clinicians.[20,23] In terms of evidence-based dentistry, clinicians should assess the strength of evidence before choosing an implant system. Therefore, studies reporting short-term outcomes of new implant systems add value to the dental literature.[20,23]

Implant design, which refers to the macro- and microstructure of an implant system, also affected implant success and survival.[24] The implants used in this study have a concave-shaped apex design, acting as a bone reservoir for bone grafting. Further study is needed on clinical outcomes of this type of implant placed in the grafted bone.

Albrektsson et al[4] provided criteria for evaluating patients over time, including survival rates and also changes in crestal bone levels. Preservation of marginal bone height is considered crucial for implant maintenance and often used as an essential success criterion.[25] The loss of 2 mm of bone around the implant neck during the 1st year after functional loading has long been assumed normal by the dental community, and has even been considered a successful outcome in some classifications and consensus statements. However, tissue stability is expected at 1 year after placement, and a loss of >0.2 mm/y is regarded undesirable.[4] Studies have addressed this issue in recent years, clarifying some aspects and leading to improvements in implant design and protocols that have minimized this initial marginal bone loss (MBL).[26] In the present study, radiographic assessments revealed that the mean marginal bone losses were 0.35 ± 0.14 mm, 0.47 ± 0.15 mm, and 0.58 ± 0.16 mm from baseline to 6 months, 6—12 months, and 12—24 months after prosthetic loading, respectively. The results are in accordance with the criteria for marginal bone level change in the 1st year, which should be <1.5 mm.[24]

Recently, clinical parameters have been added to describe implant complications and clinical outcomes.[14] In the present study, implant survival, radiographic changes in crestal bone levels, and the clinical parameters of PD, GI, PI, and BOP were evaluated for IDcam dental implants over a mean follow-up period of 3 years. Periodontal probing is one of the basic diagnostic tools used to measure pocket depth and bleeding.[27] Successful implants generally allow a probe penetration of approximately 3 mm.[25] In the present study, the mean PD and BOP scores were 2.6 ($\pm$1.7) mm and 34 ($\pm$28.2)%. It was observed that PD scores were <3 mm, and there were no sign of peri-implant lesions after 2 years of follow up. The presence or absence of plaque and

Table 4 Correlation coefficients and P values of Kendall's tau-b correlation analysis.

	Mean bone loss from			PPD	PI	GI	BOP
	Baseline to 6 mo	6—12 mo	12—24 mo				
Correlation coefficient	0.085	0.127	0.014	0	−0.011	−0.004	0.041
Sig. (2-tailed)	0.064	0.055	0.764	0.992	0.824	0.933	0.413

BOP = bleeding on probing; GI = gingival index; PI = plaque index; PPD = pocket probing depth.

bleeding tendency are two additional parameters if the pocket depth is not deeper than 3 mm.[25] PI values are directly related to the ability of patients to perform oral hygiene procedures, and poor oral hygiene is associated with peri-implant lesions because dental plaque is one of the main factors of these diseases.[16] In the present study, patients were instructed in performing home-care maintenance twice a day, regularly. PI and GI scores were 0.3 ($\pm$0.5) and 0.3 ($\pm$0.4), respectively. No plaque related peri-implant lesions were observed, and gingival tissues were healthy.

IDcam dental implants showed high implant survival. Radiographic and clinical assessments of the implants after 2 years of function demonstrated promising results for IDcam dental implant systems. However, longer-term clinical studies are needed to evaluate the predictability of this new dental implant system.

Conflicts of interest

The authors have no conflicts of interest relevant to this article.

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