LONG-TERM CLINICAL EVALUATION OF TAPERED MULTI-THREADED IMPLANTS: RESULTS AND INFLUENCES OF POTENTIAL RISK FACTORS

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KEY WORDS

Tapered implants
Risk factors
Survival

This prospective study evaluated the long-term performance of tapered screw implants placed in patients with a variety of potentially compromising clinical variables. Sixty patients were treated with 218 implants; each case included one or more potential risk factors associated with increased rates of implant failure, peri-implant bone loss or clinical complications in the dental literature: short implants (23%), comorbid conditions (25%), maxillary implants (61%), immediate loading (88.5%), placement into extraction sockets (91%), and partial edentulism (97%). The implants were restored with a variety of prostheses. Marginal bone changes were calculated utilizing periapical radiographs taken at placement and at all subsequent appointments utilizing a standardized paralleling device and a 1-mm measurement grid. Mean clinical follow-up was 67.5 (range: 1–94) months for implants and 60 (range: 15–74) months for prostheses. Four implants failed to integrate and were immediately replaced by wide-diameter implants. Eight prostheses sustained porcelain fracture (n = 7) or cement failure (n = 1) and were replaced. No peri-implant marginal bone loss was observed for 98% of the implants; the remaining 2% exhibited 1 mm of bone loss. Cumulative survival rates were 98.2% for implants and 96.3% for prostheses after 5 years of clinical loading. Concerns that tapered implant designs may be more prone to crestal bone loss than cylinder designs are unsupported by the results of this study. Tapered implants maintained integration and marginal bone levels despite the presence of one or more potentially compromising variables.

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Introduction

Evidence-based decision making in implant dentistry requires that clinicians read all available literature on a given subject and then make clinical decisions based on the strengths or weaknesses of the data. Although the currently estimated 1 300 commercially available dental implant designs comprise various forms, materials, dimensions, surface properties, and interface geometries,[1] most lack adequate scientific validation to help clinicians make an informed evaluation.[2]

Implant shape has been one of the most contested variables of implant design among manufacturers because it can directly influence implant biomechanics in bone.[3] Theoretical studies utilizing finite element analysis (FEA), for example, have reported a potential for excessive stress concentrations to occur in the crestal or apical regions of certain tapered, threaded (tapered screw) implant designs, especially in low-density bone.[4–5] Nevertheless, other clinical reports have advocated use of the design for immediate placement into tooth extraction sockets and treatment of dimensionally compromised ridges, although longitudinal clinical research tends to be short-term,[6] retrospective,[7] or unclear as to the actual number of implants followed long-term.[8] If tapered screw implants are more prone to excessive stress concentrations than cylindrical implant designs over long-term use, questions arise as to whether these factors may also synergize with other common clinical variables that can potentially compromise long-term predictability.

In the absence of adequate research data to support evidence-based decision making, a prospective clinical study was undertaken to evaluate the long-term clinical performance of a multi-threaded tapered screw implant in humans, and to assess the influences of common clinical variables generally associated in the dental literature with increased rates of implant failure, crestal bone loss and prosthetic complications. This article reports on the study findings.

Materials and Methods

Patients

Study candidates were consecutive patients in a private dental practice who presented with 1 or more missing or unsalvageable teeth, and adequate bone volume to accommodate a dental implant. Demographic data and treatment data are summarized in Table 1. A total of 60 patients (23 males, 37 females) ranging in age from 22 to 78 years (mean = 55.4 years) were selected as study participants. Within this population, each case included 1 or more potential risk factors that have been associated in the dental literature with increased rates of implant failure, peri-implant bone loss and prosthodontic complications: comorbid conditions (25%),[9–10] short implants (23%),[11] maxillary implants (61%),[12] partial edentulism (97%)[13] and placement into extraction sockets (91%).[14]

Surgical procedures

Each patient was prescribed antibiotic prophylaxis (amoxicillin, 500 mg daily, commenced 2 hours before surgery and continued 4 days postoperatively), and anesthetized via local infiltration (lidocaine hydrochloride 2% and 1:100 000 epinephrine). In partially or completely edentulous cases, full-thickness, midcrestal, and terminal releasing incisions were made, followed by elevation of a mucoperiosteal flap. In cases with nonsalvageable dentition, teeth were extracted utilizing an atraumatic technique. Whenever possible, surgical flaps were kept small or teeth were extracted through the oral mucosa without elevating a surgical flap to preserve as much of the natural periosteal vascular supply as possible. In tooth extraction cases where a soft-tissue flap was necessary, a conservative mucoperiosteal flap designed to provide sufficient accessibility with papillary preservation was used. After tooth extraction, meticulous debridement and curettage of the socket was performed to remove any remaining periodontal ligament and infected or pathologic tissue.

Utilizing a surgical template, the osteotomy or extraction socket was sequentially prepared with copious irrigation according to the implant manufacturer's protocol. A tapered screw implant with triple lead threads and a microtextured surface (Tapered Screw-Vent MTX, Zimmer Dental Inc, Carlsbad, Calif) was placed into the prepared site and the implant mount was removed. In cases where the implant achieved good primary stability and did not require additional augmentation material, provisional prosthetic procedures were immediately commenced before suturing.

In cases where a 2-stage surgical technique was used, a cover screw was attached to the implant. If a gap existed between the cervical portion of the implant and the walls of the extraction socket, the void was augmented with allograft material (Puros cancellous allograft, Zimmer Dental) and covered with a

TABLE 1

Demographic and treatment data

Distribution of patients	By Sex (No.)		By Age (Y)		By Comorbid Conditions	
	Males	Females	Mean	Range	Comorbidity*	Patients (No.)
	23	37	55.4	22–78	Periodontitis Diabetes, Type I	14 1

Distribution of implants	By Jaw Location†		By Time of Loading (No.)†		By Placement with Bone Graft (No.)‡	
	Maxilla	Mandible	Immediate	Delayed	Maxilla	Mandible
	130	88	193	25	10	8

By Implant Diameter, Implant Length and Jaw Location

Placement Location	Implant Diameters	Implant Lengths (No.)			
		8 mm	10 mm	13 mm	16 mm
Maxilla	3.7 mm	—	20	64	23
	4.7 mm	—	3	13	8
Mandible	3.7 mm	2	19	33	14
	4.7 mm	—	6	12	1

By Prosthesis Type

Single Tooth (No.)§		Fixed Partial Denture (No.)§		SRD‖ (No.)§	RPD¶ (No.)§
Maxillary	Mandibular	Maxillary	Mandibular	Mandibular	Maxillary
52	48	74	32	6	2

By Type and Jaw Location

Distribution of prostheses	Single Tooth (No.)#		Fixed Partial Denture (No.)#		SRD‖ (No.)#	SRD‖ (No.)#
	Maxillary	Mandibular	Maxillary	Mandibular	Mandibular	Maxillary
	52	48	26	8	1	2

Distribution of follow-up	Implants Monitored (mo)**			Prostheses Monitored (mo)††		
	Mean	Mode	Range	Mean	Mode	Range
	67.5	65	1–94	60	59	15–74

*Medically controlled conditions.
†Cumulative number of implants placed.
‡Cumulative number of sockets augmented at the time of implant placement.
§Cumulative number of implants used to support this type of restoration.
‖SRD indicates screw-retained denture.
¶RPD indicates removable partial denture.
#Cumulative number of prostheses.
**Baseline, time of implant placement.
††Baseline, time of prosthetic loading.

resorbable barrier membrane (Bio-Mend, Zimmer Dental). The soft tissues were approximated and sutured (4-0 Vicryl sutures, Johnson & Johnson Ethicon, Somerville, NJ) over the top of the implant. Sutures were removed after soft-tissue maturation approximately 1 week later. Following a 3- to 4-month submerged healing period, the implant was surgically exposed and the cover screw was removed from the implant. Clinical osseointegration was evaluated radiographically to verify a lack of radiolucency, and osseointegration was evaluated manually through palpation and the gentle application of torque to verify mechanical stability.

Prosthetic procedures

The mount used to deliver the implant to the osteotomy was prepared as a provisional abutment, reattached to the implant, restored with a nonoccluding, fixed provisional prosthesis, and the soft tissues were sutured (4-0 Vicryl) around it. Sutures were removed after soft-tissue maturation approximately 1 week later, and the implants were allowed to function for 3 to 4 months.

At patient reappointment, the provisional prosthesis was removed. If the implant was placed via a 1-stage technique, osseointegration was evaluated radiographically and manually prior to definitive restoration. Patients were treated with 137 splinted and free-standing restorations (Table 1). Mean clinical follow-up

was 67.5 (range: 1–94) months for implants and 60 (range: 15–74) months for fully functional prostheses.

Assessment of outcome

Crestal Bone Evaluation

Standardized vertical bitewing radiographs utilizing a paralleling technique (Rinn System, Rinn Corp, Elgin, Ill) were taken at implant placement (baseline) and at all follow-up visits. A transparent template with a 1-mm grid pattern enlarged 25% to help compensate for radiologic distortion was placed over each radiograph to evaluate marginal bone change relative to the top of the implant. Bone loss was recorded in 0- to 1-mm, 1- to 2-mm, 2- to 3-mm, 3- to 4-mm and >4-mm increments.

Survival and Influence of Clinical Variables

Implants and prostheses were evaluated for cumulative survival and for the impact of the following clinical variables: sex, implant length, implant diameter, placement location (ie, mandible or maxilla), bone graft use (ie, yes or no), time of placement (ie, immediate or delayed), comorbid conditions (ie, diseases considered relative contraindications), prosthesis type, degree of edentulism (ie, partial or complete), and follow-up time.

Statistical Methods

Statistical Analysis Software (SAS, Inc, Cary, NC) was used to perform the statistical analyses. Each categorical clinical variable was independently tested to identify dependencies of implant or prosthesis failure on variable levels (eg, male vs female). Descriptive statistics were generated using the FREQ procedure in SAS, and crude failure and survival rates were determined for each level. In addition, the MEANS procedure was used to generate average follow-up time for the combined data (ie, independent of failure or survival status). A log-rank test was performed using the LIFETEST procedure in SAS to test for differences in implant survival between levels of each variable. For continuous variables, the UNIVARIATE procedure in SAS was used to generate descriptive statistics by implant failure status (ie, for devices that failed and for devices that survived) for each variable independently, and the Wilcoxon test was used to assess differences in the distribution between failing and surviving implants.

Survival Criteria

Implant survival was used in the present study to describe the cumulative clinical performance of an implant from placement through functional loading over time. To be considered clinically surviving, the implant and prosthesis must have been load-bearing, fully functional, and able to meet the prosthodontic needs of the patient for at least 5 years. In addition, there could be no significant damage to adjacent structures or implant mobility when clinically tested, and no presence of peri-implant radiolucency, persistent or recurrent pain, infection or pathologic crestal bone loss that exceeded the expected bone loss rates previously described by Adell.[15]

Results

Adverse events are summarized in Table 2. A minor peri-implant soft-tissue infection occurred with 1 implant in a single patient; the problem was resolved with antibiotics. Of the 218 implants placed, 4 implants failed to osseointegrate and were removed. The failed implants were placed in maxillary locations and 1 of the patients had a history of periodontitis. The implants were listed as failures in the database, and the patients were successfully re-treated with larger diameter implants and withdrawn from the study. Cumulative implant survival was 98.2% (maxillary 97%, mandibular 100%).

Life-table analysis of implant survival from placement to last clinical follow-up is presented in Table 3. During the long-term follow-up, various patients voluntarily terminated study participation for various reasons (eg, relocation, time constraints, declined interest). These patients were listed in the database and in Table 3 as withdrawals and were removed from the study. Of the 214 functionally loaded implants in the study, 211 implants completed 60 months of clinical follow-up (1 patient with 3 implants withdrew during the 49- to 60-month monitoring interval).

Results from statistical testing for differences in implant failure (crude implant failure rate = 1.8%) across the various categorical variables (eg, length, jaw location, time of placement) were unremarkable. There were no statistically significant results obtained, with the exception of prosthesis type, $P < .0001$, which differed significantly due to the failure of implants precluding the attachment of a prosthesis (Table 4). A comparison of the distributions of continuous variables between failed and successful implants did not suggest dependency of failure on age. As expected, the distribution of follow-up time in failed implants (mean 5.4 months, range 0.5–9 months) significantly differed from surviving implants

TABLE 2
Adverse events*

Patient No.	Prosthesis Type	Implant		Problem	Time† (mo)	Resolution
		Location	Diameter × Length (mm)			
Implant failures						
7	None	Maxillary left central incisor	3.7 × 13	FTI	7	RI
29	None	Maxillary right central incisor	3.7 × 16	FTI	5	RI
44	None	Maxillary right first bicuspid	3.7 × 10	FTI	9	RI
58 (P)	None	Maxillary left lateral incisor	3.7 × 16	FTI	0.5	RI
Prosthesis failures						
4	SRD	Mandibular left first molar	3.7 × 13	PF	51	NP
13	ST	Maxillary left central incisor	3.7 × 13	PF	40	NP
19	RPD	Maxillary left lateral incisor	3.7 × 13	PF	15	NP
30	FPD	Maxillary left cuspid	4.7 × 16	CF	2	NP
31	FPD	Maxillary right second bicuspid	3.7 × 10	PF	3	NP
41	FPD	Maxillary right second bicuspid	3.7 × 13	PF	31	NP
44	FPD	Maxillary left cuspid	3.7 × 10	PF	3	NP
46	FPD	Mandibular left first molar	4.7 × 10	PF	51	NP
Other complications						
13	ST	Maxillary right first bicuspid	3.7 × 13	Imp Inf	13	Antibiotics

*FTI indicates failed to integrate; RI, immediately replaced the failed implant with a new wider diameter implant; (P), patient with history of periodontitis; SRD, screw-retained denture; PF, porcelain fracture; NP, placed new prosthesis; ST, single tooth replacement; RPD, removable partial denture; FPD, fixed partial denture; CF, cement failure; Imp Inf, implant infection resolved by antibiotics.
†Time of occurrence since implant or prosthesis placement.

(mean 68 months, range 13–94 months, $P = .0006$) (Table 4).

Eight prosthesis failures occurred without adversely affecting the supporting implants (Table 2). The patients were successfully provided with new replacement prostheses and the failures were recorded. Cumulative prosthesis survival was 94.2%. Results from statistical testing for differences in prosthesis failure across levels of categorical variables suggested a dependency of prosthesis failure on prosthesis type (crude prosthesis failure rate 3.7%) ($P = .0001$). Failure rates suggest removable partial dentures and screw-retained partial dentures, although infrequently attached, had significantly greater likelihood of failure than either fixed partial denture or single tooth prostheses ($P = .0001$). A comparison of the distributions of continuous variables between failed and successful implants suggested a dependency of failure on age. Prosthesis failures suggested a significant tendency towards older patients (mean age 63 years, range 55–72 years) vs surviving prostheses (mean age 55 years, range 22–78 years). Implant survival for failed prostheses did not significantly differ from surviving prostheses ($P = .50$). However, as expected, follow-up differed significantly for failed prostheses (mean 31.3 months, range 15–51 months) as compared to prostheses that did not fail (mean 60.5 months, range 15–74 months, $P = .0006$).

Crestal bone loss data are presented in Table 5. Of the 214 implants that were restored and placed into functional loading, 209 implants exhibited no measurable crestal bone loss, and 5 implants sustained maximum crestal bone loss of 1.0 mm after 69.8 months of mean functional loading (range: 65–74 months). Four of the 5 patients with crestal bone loss had a history of periodontitis.

DISCUSSION

Tapered dental implant designs have been introduced by a variety of manufacturers over the last decade, but very little data have been published on the long-term clinical functioning of this design. Anecdotal reports of increased crestal bone loss and higher apical stress concentrations were not substantiated by the results of this study. The tapered design enabled an estimated 30% of the implant to be placed before the self-tapping threads engaged the walls of the osteotomy, which facilitated placement in locations with limited vertical access, such as the posterior mandible.[16] This feature, combined with the multi-threaded body design, considerably limited the number of required revolutions to place the implant, and thereby reduced the risk of overheating the bone at the crest of the ridge.[16–17] In contrast, continuous tightening of the crestal bone during placement of

TABLE 3

Life-table analysis of implant survival: baseline* to last clinical follow-up

Time Interval (mo)	Patients (No.)		Implants (No.)			Survival Rates (%)	
	Began Interval	Withdrew During Interval†	Began Interval	Withdrew During Interval†	Interval Failures	Interval	Cumulative‡
All implants							
0–12	60	0	218	0	4	98.2	98.2
13–24	60	0	214	0	0	100	98.2
25–36	60	0	214	0	0	100	98.2
37–48	60	0	214	0	0	100	98.2
49–60	60	1	214	3	0	100	98.2
61–72	59	49	211	179	0	100	98.2
73–84	10	9	32	31	0	100	98.2
85–96	1	1	1	1	0	100	98.2
Maxillary implants							
0–12	36§	0	130	0	4	97.0	97.0
13–24	36	0	126	0	0	100	97.0
25–36	36	0	126	0	0	100	97.0
37–48	36	0	126	0	0	100	97.0
49–60	36	0	126	0	0	100	97.0
61–72	36	33	126	120	0	100	97.0
73–84	3	3	6	6	0	100	97.0
Mandibular implants							
0–12	28§	0	88	0	0	100	100
13–24	28	0	88	0	0	100	100
25–36	28	0	88	0	0	100	100
37–48	28	0	88	0	0	100	100
49–60	28	1	88	3	0	100	100
61–72	27	19	85	59	0	100	100
73–84	8	7	26	25	0	100	100
85–96	1	1	1	1	0	100	100

*Baseline = date of implant placement.
†Withdrawals = patients and implants lost to follow-up because of voluntary termination of study participation by patient.
‡Cumulative = all intervals combined.
§5 patients were treated with both maxillary (n = 25) and mandibular (n = 24) implants.

conventional, straight screw implants has been associated with increased crestal bone loss.[18]

Comorbid conditions in the patient population did not appear to greatly impact implant survival, since 1 variable (ie, periodontitis) was present in only 1 of the 4 patients who sustained single implant failures. The transmission of pathogens from the periodontal pockets of infected teeth to the sulci of dental implants is a reported cause of peri-implantitis[19] and increased implant failure rates.[9] While numerous studies have reported a positive prognosis for implants placed in carefully screened patients with controlled diabetes,[20] histologic and histomorphometric analyses have indicated that the percentage and density of bone apposed to implant surfaces was greatly diminished in diabetic compared to nondiabetic animal models.[21] The single diabetic patient in this study maintained healthy functional implants throughout the duration of the study.

While implant survival rates reported for partially and completely edentulous patients have been comparable, prosthetic complications (eg, loosening of prosthesis screws, porcelain fractures) have been reported to be higher in partially edentulous patients.[22]

TABLE 4

Statistical Summary

Analysis	Statistically Significant Differences	*P* Value
Mean clinical follow-up times	Failed implants vs surviving implants	.0006
	Failed prostheses vs surviving prostheses	.0006
Likelihood of prosthesis failure	Removable partial denture vs fixed partial denture	.0001
	Removable partial denture vs single tooth restoration	.0001
	Screw-retained partial denture vs fixed partial denture	.0001
	Screw-retained partial denture vs single tooth restoration	.0001
Influences on prosthesis failure	Prosthesis failure vs prosthesis type	.0001

TABLE 5
Cumulative crestal bone loss: baseline* to most recent clinical follow-up

Patient (No.)	Implant: Jaw Location	Implant: Diameter (mm)	Implant: Length (mm)	Type of Restoration	Months in Function (No.)	Cumulative Marginal Bone Loss
6	Maxillary left first bicuspid	3.7	16	Single tooth	74	1 mm
48 (P)†	Maxillary left third molar	3.7	13	Single tooth	72	1 mm
53 (P)	Maxillary right second bicuspid	3.7	13	Fixed partial denture	68	1 mm
54 (P)	Maxillary left first bicuspid	3.7	13	Fixed partial denture	65	1 mm
59 (P)	Maxillary right cuspid	4.7	16	Fixed partial denture	70	1 mm

*Baseline = date of implant placement.
†(P) = patient with history of periodontitis.

Of the 8 prosthesis failures in the present study, all but 1 occurred in partially edentulous patients, and the majority of those (n = 6) occurred in fixed partial denture restorations, which is consistent with other reports in the dental literature.[13]

Dental implant designs and surfaces have continued to rapidly evolve over the past decade, often well ahead of the research community's ability to document the long-term clinical response to these changes. More long-term clinical studies are needed to assist clinicians in making informed decisions.

CONCLUSIONS

In the present study, tapered screw implants provided a high degree of predictability with little or no crestal bone loss over long-term clinical functioning, and despite the presence of one or more potentially compromising variables. Concerns that tapered implant designs may be more prone to crestal bone loss than cylinder designs were thus unsupported by these findings.

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