

# Clinical and Patient-Related Outcomes of a Tapered Implant System With Switched Platform Conical Abutments: A Private Practice Field Trial

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The aim of this prospective cohort observational field trial was to examine 1-year survival and success rates of a recently introduced tapered implant system with switched platform conical abutments and to evaluate patient related outcomes of therapy. Partially edentulous patients aged between 18 and 75 years, with available bone height for dental implants  $\geq 10$  mm desiring to restore the missing tooth/teeth with implant supported restoration, were recruited by 7 periodontists in their respective private practices. Dental implants were installed according to standard implant therapy protocol. Three to 6 months postoperatively, after evaluating interim implant success, implants were restored by the referring dentists. Patient, Ramfjord teeth, and implant data, including baseline and 1-year postoperative, were collected. A total of 60 patients were recruited and received 117 implants. Complete 1-year clinical and radiographic data were available for 83 and 65 implants, respectively. Two implants failed during the first year, resulting in a 1-year survival rate of 98.3%. Mean implant probing pocket depth was  $2.29 \pm 0.84$  mm. Mean radiographic bone distance from implant's shoulder at the mesial and distal sites at 1 year was  $0.66 \pm 0.5$  and  $0.79 \pm 0.64$ mm, respectively, resulting in a success rate of 95.4%. Patient subjective evaluation of therapy exhibited a median pain experience of 1 and median esthetics, function, and general satisfaction evaluation of 10 on a scale of 1 to 10. The tapered conical connection dental implant system, used in private dental practices, shows good 1-year survival and success rates that are similar to other implant systems on the market.

**Key Words:** dental implant, private practices, radiology, field study

## INTRODUCTION

There is abundant evidence from numerous prospective clinical trials on the survival and success of many types, shapes, and forms of dental implants.<sup>1</sup> However, almost all of these studies were performed in academic settings that might not be representative of realistic practice conditions. Prospective clinical field trials in private practices, although greatly needed, have seldom been performed. Therefore, although most dental implants are installed in private practice settings, there is a paucity of information regarding their performance in such a situation, let alone

prospective studies that address those issues. As an example, a PubMed search done in July 2017 using the terms [dental implant(Title/Abstract)] AND private practice[Title/Abstract] yielded only 31 articles, most of them retrospective in nature, evaluating specific parameters such as thread design, immediate provisionalization, single implant technical and biological complications, etc.

Ideally, in addition to clinical parameters such as implant survival and success, patient-related outcomes such as pain, the experience of therapy, and satisfaction from therapy should also be evaluated. Some form of oral health-related quality-of-life questionnaire would be the optimal tool to use; however, it may prove time consuming and difficult to obtain in a private practice setting.

We elected to conduct a prospective field study, which would be executed in private practices, aimed at evaluating a recently introduced dental implant design (MIS C1 implants; Implants Technologies Ltd, Shlomi Bar-Lev Industrial Park, Israel). The system combines the properties of surface sandblasting and acid-etching, microrings at the implant's neck, and a 6-degree conical connection of the prosthetic parts.

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Therefore, the aim of the present prospective field study was to evaluate the 1-year survival and success of this implant system and to evaluate parameters related to patients' periodontal condition and patient-reported experience.

## MATERIALS AND METHODS

Patients were recruited by 7 periodontists (JH, EEM, SF, EG, YM, LJ, and OC) in their private dental practices. A competitive recruitment protocol was instituted with 7 clinicians for up to 3 years. The study goal was to include up to 120 implants in those patients. All the implants installed in the surgical area were included in the analysis.

Inclusion criteria were as follows: (1) age between 18 and 75 years; (2) partial edentulism with available bone height for dental implants  $\geq 10$  mm; and (3) patient desire to restore the missing tooth/teeth with implant supported restoration.

Exclusion criteria were as follows: (1) complicating medical conditions such as uncontrolled diabetes, untreated malignancies, pregnancy, and previous/current bisphosphonate therapy; (2) untreated periodontal disease, untreated caries, and periapical pathology in contact with the location of the prospective implant; (3) the need for major bone augmentation in conjunction with implant placement (localized bone augmentation in conjunction with implant placement of up to 3 mm on 1 to 2 aspects of the implant was allowed); and (4) implants were placed using a 1-stage immediate loading/restoration approach.

The study was approved by the Rambam Health Care Campus Institutional Review Board (approval no. 0113-12RMB).

### Study design

An initiation meeting of all participating periodontists preceded study commencement, in which the study design, inclusion and exclusion criteria, and surgical techniques were presented. All participating periodontists received identical implant surgical kits to be used during implant operative procedures of the study patients.

Patients attending the dental offices of the periodontists were screened for the study. Those patients that met the inclusion and exclusion criteria were offered to participate in the study and signed an informed consent. Patients received cause-related therapy to treat caries and periodontal therapy, which included oral hygiene instructions, scaling and root-planing, and periodontal surgery as necessary. Final eligibility was then evaluated, and patients were accepted into the study.

Study models and periapical and/or panoramic and/or computerized tomography (CT) radiographs were used for evaluation and implant planning as deemed necessary by the periodontist.

Antibiotics (500 mg augmentin + 1.5 g amoxicillin or 2 g amoxicillin, or, in cases of penicillin allergy, 600 mg of clindamycin) were prescribed 1 hour before surgery. Implant surgery was performed during which implants were installed, a healing abutment was connected, and flaps were sutured.

Patients were given postoperative instructions and antibiotic therapy, consisting of 875 mg augmentin twice per day or 150 mg clindamycin four times per day for 7 days, and analgesic therapy was given as necessary. Patients were

examined 7 to 10 days after surgery for suture removal and then after 4 weeks and 3, 6, and 12 months after surgery. Maintenance periodontal treatment was prescribed at 1-month after surgery and then every 3 to 6 months. At 3 to 6 months, interim implant success was evaluated, and implants were restored by the patients' referring dentists. First-year implant evaluation was performed at 12 months after surgery.

### Clinical measurements

The following data were collected for each patient/implant: patient data including birthdate, general health parameters, and surgery date; implant length and diameter; insertion torque; bone quality<sup>2</sup>; periapical radiographs (at baseline and 12 months after surgery); postoperative complications and adverse events; 12-month mobility, infection, and complications/failure of the implant; and periodontal data, including plaque<sup>3</sup> (PII) and gingival<sup>4</sup> (GI) indices, probing pocket depth (PPD), and bleeding on probing (BOP) in 6 sites around implants at 12 months and around Ramfjord teeth (16, 21, 24, 36, 41, 44)<sup>5</sup> at baseline and 12 months after surgery. Patient-reported experience was recorded for the following questions: postoperative pain, esthetics of the final prosthetics, function, and general satisfaction from therapy. Patients were asked to mark the most appropriate response for each question using a 1 (least) to 10 (most) scale.

### Data management and analysis

The methodology and results of the present study were reviewed by an independent statistician. Data were collected by the participating periodontists and stored in patient report booklets.

Mean PPD was calculated using PPD from 6 points around implants. Mean PPD (maximal) was calculated using the deepest PPD measurement from each implant.

Periapical radiographs were used for radiographic measurement of the distance in millimeters between implant shoulder and alveolar bone crest at the distal and mesial aspects of the implant. Radiographic measurements were performed by a single operator (JH).

Following the completion of the study, the data were statistically analyzed (using IBM SPSS Ver. 21. for Windows, IBM Corporation, Armonk, NY). Descriptive statistics were used to describe patient and implant outcomes. Wilcoxon paired nonparametric test was used to examine 1-year changes in implant and tooth parameters.

## RESULTS

A total of 60 patients were initially recruited and received 117 implants (Table 1). Fifteen patients (25%) received 1 implant and 44 patients (75%) received 2 or more implants. Bone quality classes 1, 2, and 3 were found in 10 (17%), 32 (53%), and 17 (28%) of the patients, respectively. Data regarding bone quality were missing for 1 implant. Distribution of patients and implants among periodontists is found in Table 2. Compliance among periodontists regarding 1-year data collection and quality varied significantly. Some of them returned incomplete data and periapical X rays that were not acceptable and therefore did not enable radiographic bone level measure-

Data Parameter	No. (%)
Patients	59
Implants	117
Implants per patient	
1	15 (25)
≥2	44 (75)
Bone quality	
1	10 (17)
2	32 (54)
3	17 (29)

ments. We received 1-year clinical data for 83 implants and eligible radiographic baseline and 1-year data for 65 implants. Two implants failed during the first year, resulting in a 1-year survival rate of 98.3%. Prior to enrollment, 16 (27%) subjects were diagnosed with a healthy periodontium, 10 (17%) and 32 (53%) patients with gingivitis and chronic periodontitis, respectively, and 2 were missing a periodontal diagnosis. Patients mean age was 57 ± 11 years (range, 31–79 years). Patients' health status was noncontributory, apart from 5 (8%) patients who reported smoking.

Postsurgical pain medication was provided in some cases; 26 (43%) and 9 (15%) patients received 1 tablet of sodium naproxen 275 and 1 tablet of paracetamol 500, respectively. PII and GI at 1 year around dental implants were 0.45 ± 0.47 and 0.41 ± 0.44, respectively. Mean implant PPD was 2.29 ± 0.84 mm, and mean implant PPD (maximal) was 3.07 ± 1.03 mm (Table 3). Mean radiographic crestal bone distance from implant's shoulder at the mesial and distal sites at 1 year was 0.66 ± 0.5 and 0.79 ± 0.64 mm, respectively; the 1-year mean bone level change was 0.52 ± 0.45 and 0.54 ± 0.55 mm for mesial and distal sites, respectively (Table 3). No postoperative complications and adverse events were reported apart from the failed implants. The remaining implants did not exhibit mobility or signs of infection and complications at 1 year. One implant lost >1.5 mm of bone during the first year, resulting in a success rate<sup>6</sup> of 95.4% in this study population. Patient periodontal conditions, monitored around Ramfjord teeth, did not exhibit clinically significant changes, except a statistically but not clinically significant reduction in mean PPD, from 2.11 ± 0.52 mm at baseline to 1.87 ± 0.36 mm at 1 year (Table 4).

Patient subjective evaluation of therapy exhibited a median

Surgeon	No. Patients	No. Implants	No. Implants With Legible Radiographs
1	14	26	25
2	14	19	11
3	5	12	8
4	5	14	3
5	9	22	0
6	12	21	18
7	1	3	0
Total	60	117	65

Clinical Parameter	Mean ± SD	Median	Significance
PII†	0.45 ± 0.47	0.33	
GI†	0.41 ± 0.44	0.33	
PPD†	2.29 ± 0.84	2.33	
PPD max†	3.07 ± 1.03	3.00	
Mesial bone level T0, mm‡	0.16 ± 0.32	0.0	<.001
Mesial bone level T12, mm‡	0.66 ± 0.5	0.65	
Δbone M, mm‡	0.52 ± 0.45	0.48	
Distal bone level T0, mm‡	0.31 ± 0.48	0.0	<.001
Distal bone level T12, mm‡	0.79 ± 0.64	0.68	
Δbone D, mm	0.54 ± 0.55	0.55	

\*Wilcoxon signed rank test, P = .05. PII indicates plaque index; GI, gingival index; PPD, probing pocket depth.

†Number of implants = 83.

‡Number of implants = 65.

pain experience of 1 and median esthetics, function, and general satisfaction evaluation of 10 on a scale of 1 to 10.

### DISCUSSION

This was a prospective cohort field study evaluating a conical connection dental implant system, conducted at private dental clinics with little supervision, in which first-year survival and success rates were 98.3% and 95.4%, respectively. Dental implant systems with new or modified configurations are constantly introduced into the market, but not necessarily tested for their equivalency or superiority to existing implant systems, let alone their performance in field settings. Therefore, the findings in the present study, in which the survival and success rates of this implant system were similar to other implant systems and to studies performed in more stringent conditions, are significant and valuable.

There are relatively few prospective trials of implant systems performed in less than ideal conditions, such as those found in private dental clinics, on a wide variety of patients, sometimes performed by less experienced clinicians. Zupnik et al,<sup>7</sup> in a retrospective study of dental implants performed by periodontology residents, found a 4-year survival rate of 96.5%. Piek et al<sup>8</sup> reported a 97.4% 1-year survival rate using a recently introduced innovative implant system consisting of a combination of tapered and cylindrical shape, which was tested in a private clinic. Another recently introduced implant system was

Clinical Parameter	Mean ± SD	Median	Significance
PII baseline	0.43 ± 0.32	0.45	.221
PII 1 year	0.46 ± 0.32	0.40	
GI baseline	0.31 ± 0.27	0.28	.078
GI 1 year	0.38 ± 0.31	0.31	
PPD baseline, mm	2.11 ± 0.52	1.93	<.001
PPD 1 year, mm	1.87 ± 0.36	1.79	

\*Wilcoxon signed rank test, P = .05. PII indicates plaque index; GI, gingival index; PPD, probing pocket depth.

tested in 13 Swedish dental clinics and showed a 1-year cumulative survival rate of 97.8%<sup>9</sup> that is similar to the one we report here (98.3%). Similar results were reported in publications of earlier implant systems with variable thread pattern (96.3%–97.6%)<sup>10</sup> and with a sandblasted with large grit followed by acid etch surface (96.9%).<sup>11</sup> In yet another such study conducted in 22 centers in Sweden, Norway, and Finland on Brånemark implants, a cumulative survival rate of 98.9% was reported.<sup>12</sup>

Although field studies such as ours are inherently less controlled than formal clinical trials, it is encouraging to find that their outcomes do not differ significantly. A similar conclusion was reported by Cochrane et al<sup>13</sup> who reported that cumulative survival and success rates from a field study by 86 different investigators (dental surgeons) were similar to formal clinical trials under more controlled conditions. They suggested that variability in patient selection, individual surgical technique, and general clinical settings may have a relatively small effect on the outcome of implant therapy.<sup>13</sup> Finally, Esposito et al,<sup>1</sup> in a review comparing publications regarding 38 implant types with different surface characteristics, shapes, degree of titanium purity, and titanium alloys, reported that early failure rates were small in most of the publications, and no evidence was seen that any particular type of dental implant had superior long-term success. The present study is comparable with these conclusions and further illustrates the general similarity between various implant systems.

The nature of this field study did not allow for a detailed and time-consuming questionnaire regarding patient satisfaction. However, patient perception of therapy was also very good, regarding postoperative pain perception, function, esthetics, and general satisfaction. Patient perception in our study was comparable to a systematic review of implant outcomes, in which patients showed a mean range satisfaction score of 81%–96% for implant restorations.<sup>14</sup>

Despite these encouraging results, some significant limitations in this study should be noted: the moderate sample size (both the number of participating clinicians and overall number of patients) is one of them. Also, the large number of missing data, mostly due to participating clinicians' noncompliance, should be appreciated. A more stringent adherence would enhance and strengthen the results of the present study.

### CONCLUSIONS

The tapered conical connection dental implant system, used in private dental practices, shows good 1-year survival and success rates that are similar to other implant systems on the market. Although the 1-year results in this study do not fall short of the standard in implant survival and success, longer follow-up of larger cohorts is mandatory to verify long-term survival and success rates.

### ABBREVIATIONS

BOP: bleeding on probing  
CT: computerized tomography

GI: gingival index  
PII: plaque index  
PPD: probing pocket depth

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### NOTE

The authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript. The authors state that each of them received one free implant for personal use for every implant installed as part of the study.

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