# **One-Year Survival Rate Outcomes of Innovative Dental Implants: A Prospective Clinical Study**

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- mplant geometry and design is one of the main features for implant success, concerning both implant body and implant collar. Diverse implant designs are available; each one is advocated for improving bone to implant contact and reducing crestal bone resorption by minimizing biomechanical stresses to the bone.<sup>1-5</sup> Implant macro geometry contributes to primary stability at implant insertion phase, whereas thread design and surface condition play a role in secondary healing process. There are 2 major macro design concepts: cylindrical and tapered. At the time of insertion, the tapered root-form implant design generates an intimate contact between the osteotomy wall and the implant surface.<sup>1-3</sup> The tight bond provides excellent primary stability but undergoes localized bone necrosis near the implant surface before bone apposition ensures its biomechanical fixation. The drilling sequence using straight drills

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**Purpose:** The aim of this research was to evaluate an innovative implant design for different placement and loading protocols. The unique implant is a combination of tapered and cylindrical shape, which is aimed to enhance initial stability and long-term osseointegration.

Materials and Methods: Four hundred and sixty implants were placed in 141 patients under different placement and loading protocols in similarity to those encountered in a dental office. Implants were followed and evaluated for 1 year to assert the survival rate of the newly introduced implant.

**Results:** The results showed a total of 97.4% survival rate, ranging from 92% to 98.6% depending on the different protocols. There was no statistical difference between the different protocol groups.

Conclusion: The new implant design showed good results for 1 year of follow-up, comparable with the literature, and could be a good choice for every implant-based procedure. (Implant Dent 2013:0:1–6) Key Words: tapered design, cylindrical design, osseointegration, loading protocols

for the osteotomy after insertion of tapers implant body has a major effect on bone and implant contact ratio. Cylindrical parallel wall implants tend to be less stable at insertion but gain stability rapidly due to early formation of woven bone after the blood-clotted gap between the implant and osteotomy wall.6,7

Immediate placement of implants after extraction is a technique meant for shortening rehabilitation phase from the time of implant insertion to final restoration, sparing both time and surgical procedures.8 The anatomical characteristics of the socket after tooth extraction are different from its environment after proper healing. Implants placed immediately into fresh extraction sites engage to the prepared bony walls only in their apex due to the funnel shape of the socket, whereas the coronal space is filled only by the end of the healing phase.9

The tapered geometry diverts forces from the dense cortical bone to the resilient trabecular bone,<sup>2</sup> leading to higher forces in the apex, a desirable feature when considering immediate placement. In cylindrical implants, the loads are distributed throughout the implant, and because of the parallel wall, the coronal part of the osteotomy is damaged by the preceding implant threads, making a cylindrical implant less suited for immediate placement.<sup>10–13</sup> Immediate placement of an implant requires incorporation of advantages from each macro design, tapered implant's compression ability of the apical portion,

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and the cylindrical implant's lowest stress on the coronal cortical bone.<sup>14,15</sup>

After placement, according to one of the protocols, immediate or delayed placement, loading of an implant is another issue that a clinician has to address. The classic approach of 3 to 6 months of unloaded healing phase is leaning toward shortened sequenceses<sup>16,17</sup>:

- 1. Immediate occlusal loading: loading of an implant up to 48 hours from placement.
- 2. Early occlusal loading: loading of an implant from 48 hours to 12 weeks from placement.

Both protocols require excellent stability throughout the critical weeks of osseointegration, which can be achieved through enhanced implant design.<sup>18–22</sup>

An implant incorporating the advantages of both tapered and parallel wall implants was designed particularly for immediate placement. It consists of a cylindrical body and tapered apical portion. The cylindrical part has an important role as void filler at crestal osteotomy portion. The progressive thread and the tapered part generates bone compression, which contributes to the initial stability<sup>14,23</sup> (Fig. 1). The aim of this study was to report the survival rate of the new innovative implant design in 4 different placement and loading protocols.

### MATERIALS AND METHODS

This nonrandomized prospective study compared the clinical outcomes of innovative implant design (Paltop Advanced Dental Solutions Ltd., Caesarea, Israel). One hundred fortyone patients (58 men, 83 women) with mean age of 57.64 years were treated for 1 or more missing and/or unsalvageable teeth in the upper and lower jaws and met the general inclusion criteria for dental implant treatment (Table 1). Twenty-nine percent of the patients had controlled chronic adult type periodontitis, and 11.3% were smokers. Sixty-five percent of the implants were inserted in the maxilla and 35% in the mandible. The majority of the maxillary implants (55%) replaced anterior teeth and most of the mandibular implants (65%) replaced posterior teeth. Patient charts were reviewed, and data were entered into spreadsheets on a personal computer.

After a careful review of their medical and dental histories, patients were subjected to detailed clinical and radiographic examinations, evaluated for oral hygiene, and assessed for their ability to commit to long-term follow-up. A study cast was fabricated and mounted on a semiadjustable articulator using a face bow transfer and vertical registration to determine jaw relationships, available occlusal dimension, proposed implant position(s), crownroot ratio, and potential complications. A prosthetic wax-up and surgical template were fabricated to allow guided placement of the implants relative to the planned prosthesis. The treatment plan and alternative options were discussed, and signed informed consent was obtained from each patient before treatment. All implants were inserted in the same dental office by 2 surgeons and restored by a single operator. Criteria for immediate placement of implants were initial implant stability and implantalveolar bone gap of no more than 2 mm.<sup>24</sup> When implants were placed into fresh extraction sites, coronal gaps greater than 1 mm were grafted with Osbone (Curasan Regenerative Medicine, Kleinostheim, Germany). The decision to perform immediate loading of implants was made to avoid removable provisional restorations in patients who were reluctant with such a provisional.<sup>25</sup> The implants immediately loaded were tested for reverse torque with a threshold value of 30 N  $\cdot$  cm.<sup>26</sup>

One hundred forty-one patients were subdivided into 4 groups (A–D) according to placement timing and loading:

- A. Immediate placement with immediate loading (n = 73).
- B. Immediate placement with delayed loading (n = 50).
- C. Delayed placement with immediate loading (n = 64).
- D. Delayed placement with delayed loading (n = 273).

Group D is considered the control group, representing the classic Brånemark



Fig. 1. The implant's body consists of a cylindrical body and tapered apical portion with constant tapered length. The macro design assembles of tapered "V" shaped 2 lead threads at the implant body area and 4 lead "microthreads" at the implant neck. The V thread creates 0.8-mm pitch, and the microthread creates 0.4-mm thread. The progressive thread generates bone compression, which contributes to the initial stability and osseointegration. The microthreads on the neck implant decrease bone loss. The implant apex is nonactive reducing the risk for nerve and vessel penetration. The rough implant's surface is formed by sand blasting-acid etching process.

approach for implant placement. Protocols A, B, and C were preformed mainly in the esthetic region, and protocol D was performed in the posterior area of both jaws, where immediate restoration was not needed. Protocol D was established in the first treated patients to evaluate the initial survival rate of the innovative implant.

Chlorhexidine digluconate mouth rinses were prescribed 3 days before surgery and 10 days after surgery. Antibiotic prophylaxis involved daily administration of 2 g amoxicillin and clavulanic acid, beginning 2 hours before surgery and for 5 days thereafter. On the day of surgery, the patient was anesthetized through local infiltration. In some cases, a midcrestal and terminal vertical releasing incisions were made, followed by elevation of a mucoperiosteal flap that was kept small to preserve the periosteal vascular supply. In other cases, drilling was performed directly through the soft tissue without incisions or flap elevation to facilitate healing and minimize invasion, pain, edema, bleeding, and hematoma associated with conventional implant placement, and to preserve the existing vascular network and soft tissue architecture. When extractions were carried out, an atraumatic technique was used to minimally impinge on the surrounding tissues, and the sockets were thoroughly debrided.

### Survival Rate Criteria

Survival meant that an implant was immobile when manually tested, did not exhibit periimplant radiolucency, had no irresolvable clinical symptoms, or mechanical problems. All clinically failed implants were removed from the patients and recorded as failures. Implants were considered successful if they met the implant survival criteria and had no non-failure-related adverse event data that were extracted from patients' files by an independent observer. Time of follow-up was calculated from the time of loading to the patient's last follow-up visit. Due to the short-time follow-up, bone loss was not calculated, as undetectable bone changes could not be measured.

#### Statistical Methods

Study variables were summarized by time of placement of the dental

Table 1. Criteria for Implant Treatment				
Inclusion	At least 18 years of age Adequate available bone to accommodate an implant Systemically and dentally healthy Demonstrated ability to maintain oral hygiene			
Exclusion	Willingness and ability to commit to follow-up Provide signed informed consent Lack of skeletal maturity			
	Ridges that required significant augmentation for implant site development Uncontrolled diseases or conditions that could impede bone healing or			
	soft tissue health Mental, emotional, or lifestyle factors that could adversely impact treatment and follow-up			

Table 2. Distribution of Patients and Implants							
	Sex (No. of Patients)		Health Risks (No. of Patients)		Age, y		
	Males	Females	Periodor	ntitis	Smokers	Mean	Range
Patients	58	83	41		16	57.64	18–85
	Time of Implant Placement		cement	Time of Loading		No. of Implants	
Implants	Immediate			Immediate		73	
				Delayed		50	
	Delayed			Immediate		64	
				Delayed		273	

Table 3. Different Loading Protocols With Immediate Placement				
	Success	Failure		
A. Immediate placement with immediate loading	72	1		
B. Immediate placement with delayed loading	46	4		
Sum	118	5		
Fisher exact test, $P = 0.157$	_	—		

Table 4.	Different	Loading	Protocols	With Delay	ved Placement	
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	Success	Failure
A. Immediate placement with immediate loading	63	1
B. Immediate placement with delayed loading	267	6
Sum	330	7
Fisher exact test, $P = 1.00$	—	—

Table 5. Comparison of Success Rates of All Groups					
	Success	Failure			
Group A: immediate placement with immediate loading	72	1			
Group B: immediate placement with delayed loading	46	4			
Group C: delayed placement with immediate loading	63	1			
Group D: delayed placement with delayed loading	267	6			
Sum	460	12			
Pearson $\chi^2$ , $P = 0.085$	—	—			

implant: immediate or delayed loaded or not loaded. For each analysis group, categorical study end points were summarized as frequencies and percentages at each level of the variable, and continuous variables were summarized using descriptive statistics (N, mean, median, SD, minimum, and maximum). Between-group comparisons of categorical end points were made using either Fisher exact test (dichotomous end points) or the  $\chi^2$  test (polychotomous end points). All analyses were performed using SAS (SAS, Inc., Cary, NC) for the personal computer on the Windows XP operating system.

### RESULTS

A total of 460 implants were placed in the 141 study patients (Table 2). Out of 123 (27%) implants that were placed immediately, 73 (59%) were immediately loaded (group A) and 50 (41%) were delayed (group B).

Out of 337 (73%) implants that were delayed placement, 64 (19%) were immediately loaded (group C) and 273 (81%) were delayed (group D, control group).

Table 3 shows the failure rates within immediately placed implants. In this group, 5 (4%) out of 123 implants failed. In group A, 1 (1.3%) implant failed out of 73. In group B, 4 (8%) implants failed out of 50. No statistical significance was seen between the 2 methods (Fisher exact test, P = 0.157).

Table 4 shows the failure rates within delayed placed implants group. In this group, 7 (2%) out of 337 implants failed. In group C, 1 (1.5%) implant failed out of 64. In group D, 6 (2.2%) implants failed out of 273. No statistical; significance was seen between the 2 methods (Fisher exact test, P = 1.00). When comparing all 4 methods for placement and loading (Table 5), no statistic significance was seen between the 4 methods (Pearson  $\chi^2$  test, P = 0.085).

### DISCUSSION

An innovative endosseous dental implant design has been subjected to conditions similar to those encountered in a dental office for a period of 1 year. All implants placed during this study were included in survival calculation rate. This includes implants placed in patients by means of differences in age, gender, medical and dental conditions, and jaw regions.

Implant survival rate varied from 92% to 98.6%, subjected to different loading and insertion protocols, but with no statistical difference. Total survival rate for 1 year was 97.4% comparable with the published data in the dental literature.<sup>27</sup>

It is clear that implant geometry has some effect on implant success. Although some researchers found that implant design plays a role in success rates,28 others found it less conclusive.<sup>29</sup> Every implant design provokes stress on the crestal bone that might result in alveolar bone loss.1 The aim of any implant design is to provoke less stress to the surrounding bone. Surgical procedures and postoperative osseointegration necessitate an implant design with a lower initial resistance to insertion and a more stable purchase of the bone, a feature attributed to tapered implants. High insertion torque indicates higher primary stability, measured with tapered implants rather than cylindrical,<sup>30,31</sup> due to tighter bony contact at the apical threads. In cylindrical implant designs, the parallel walls of the coronal part of the osteotomy are damaged by the preceding implant threads during insertion.10

Delayed placement with delayed loading is the most long-standing protocol for implant-based restoration, and the survival rates after 20 years of service were 86.76% for implant fixed prostheses.<sup>32</sup> Shortened periods of follow-up show higher percentage of success: 96% for 3 years<sup>33</sup> and 93.2% for 1 year<sup>27</sup> in this research. The results for 1 year of follow-up for the delayed placement and loading were 97.8%.

Although superior implant design enables predictable results, it is inevitable to try and simplify implant-supported procedures for both the patient and the dentist; therefore, immediate placement and immediate loading become commonly executed and studied. Placement of implants into fresh extraction sockets was first reported in the late 1970s.<sup>34–36</sup> This treatment option has been widely reviewed during the last decade<sup>37–40</sup> and shows favorable results. The second method of shortening the treatment time is immediate loading of the recently inserted implants, within 48 hours from the implantation. The current literature<sup>41–46</sup> shows that the survival rates for implants placed immediately, early, delayed, or late are similar in the short term and amounts approximately to 95%.

Placement of an implant immediately after tooth extraction may help to maintain the bone crest and lead to ideal implant positioning from a prosthetic point of view. Shibly et al<sup>47</sup> immediately placed implants in extraction sockets. In the immediately loaded group, the survival rate 96.6% was after 1 year of follow-up and 93.3% for the delayed loading. These findings resemble the results of this article, showing lower survival rates for immediate placement with delayed loading 92% versus 98.6% for immediate loading.

Delayed placement with immediate loading is another protocol for implant-based restoration. One article found no statistical difference between those groups with total survival rate of 96.5%.<sup>48</sup> A second study with a smaller study group showed 93.3% for immediate loading versus 100% survival rate for delayed loading, but the authors emphasized that radiographic bone level change observed after 12 months of loading was significantly less for immediately loaded implants.49 This might be the advantage of this protocol, although it was not considered in this article. As mentioned earlier, it looks that for shorter follow-up periods, similar results are seen, with no statistical difference between different protocols,<sup>41,47</sup> as found in this article with a total survival rate of 97.4% after 1 year of follow-up.

## CONCLUSION

The innovative implant design with cylindrical body and tapered apical portion showed good results for 1-year survival and might be useful for immediate implantation and loading. Additional research and follow-up are warranted.

#### DISCLOSURE

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