Immediate Loading of 190 Endosseous Dental Implants: A Prospective Observational Study of 40 Patient Treatments with up to 2-year Data

Ioannis Nikellis, DDS, PhD[1]/Anna Levi, DDS, MDSc[2]/Costa Nicolopoulos, BDS, FFD(SA)[3]

Purpose: *The present study was undertaken to determine the feasibility of using primary stability as a predictor of implant success in patients whose implants were immediately loaded.* ***Materials and Methods:*** *The study included 40 patients, in whom a total of 190 implants were placed, 102 in maxillary sites and 88 in mandibular sites. All were loaded within 72 hours of placement. Sixteen patients were completely edentulous in the mandible and/or the maxilla. The remaining 24, who were partially edentulous, received fixed partial dentures or single-implant restorations. All of the definitive implant restorations were screw retained. The criterion for loading was clinical judgment of primary stability, verified by a "screw test." Impressions were made after implant placement to facilitate the fabrication of a laboratory-made heat-processed provisional restoration from acrylic resin. Following a 4-month period for osseointegration and soft tissue healing, definitive fixed prostheses were fabricated.* ***Results:*** *There were no surgical complications. After 1 to 2 years, all 190 implants had survived and were considered 100% successful, as determined by independent testing of mobility and radiographic evidence of osseointegration. In 4 patients, fracture of the provisional restoration occurred during the healing period.* ***Discussion:*** *Clinical research has shown that immediate loading is a viable treatment modality. The favorable success rate reported in this study for rough-surfaced implants suggests that adherence to a protocol, an important parameter of which is primary stability above 32 Ncm, can lead to osseointegration.* ***Conclusion:*** *The results of this limited investigation suggest that patients who are partially or completely edentulous may be immediately restored with implants and fixed provisional restorations, provided that the dental implants are adequately stable immediately after their surgical placement. This alternative therapeutic approach did not appear to affect the up-to-2-year survival of the implants in this patient population.* INT J ORAL MAXILLOFAC IMPLANTS 2004;19:116–123

Key words: *dental implants, immediate loading*

The high success rates reported in a number of clinical studies have established dental implants as a predictable treatment modality in oral rehabilitation, provided that a number of parameters are given careful consideration.[1–5] A healing period of 4 to 6 months during which the implant is kept free of functional loads was once considered a prerequisite for the achievement of osseointegration. This healing period is inconvenient to the patient and may necessitate the fabrication of provisional restorations that are not supported by dental implants. The results of studies on immediate loading and early loading (ie, loading after 4 to 6 weeks) appear encouraging.[6] These techniques can assist the clinician in overcoming esthetic and functional problems during the healing period.

Babbush and associates[7] were among the first groups to use an immediate loading protocol with a large study population. They reported that immediate loading could be a viable treatment alternative. After the work of Schnitman and coworkers on immediately loaded fixed interim prostheses supported by implants,[8,9] other clinicians selectively

[1]Assistant Professor, University of Athens Dental School, Department of Prosthodontics, Athens, Greece.
[2]Teaching Assistant, University of Athens Dental School, Department of Prosthodontics, Athens, Greece.
[3]Private Practice, Glyfada, Greece.

Correspondence to: Dr Anna Levi, University of Athens Dental School, 38, Zalokosta St, Halandri 15232, Athens, Greece. Fax: +30 210 6896648. E-mail: levi@lar.forthnet.gr

loaded implants in completely edentulous arches with provisional restorations immediately after placement.[10,11] In 1997 Tarnow and associates[12] proposed a protocol that would allow immediate loading, but only for edentulous arches, to create cross-arch stability. Subsequent clinical trials have reported on immediate loading of implants in completely and partially edentulous mandibles and maxillae.[13–17] Immediate loading of single, free-standing implants has been investigated as well.[18]

The purpose of the present study was to describe immediate loading in both partially and completely edentulous patients, using a protocol with particular emphasis on primary stability of the endosseous implant and provisional restorations that did not include rigid metal reinforcement.

MATERIALS AND METHODS

In this observational study 190 implants (Southern Implants, Irene, South Africa) were placed in 40 patients, ranging in age from 19 to 82 years. Eight patients were completely edentulous in both arches. Six patients were completely edentulous in the maxilla but had natural teeth in the opposing arch; 2 were completely edentulous in the mandible but had natural teeth in the opposing arch (Tables 1a and 1b). All implants were loaded with heat-polymerized provisional restorations within 72 hours of surgical placement and were followed for 1 to 2 years. The 16 patients with 1 or more completely edentulous arches received full-arch prostheses. Eighteen patients received fixed partial dentures (14 mandibular, 4 maxillary) supported by 2 or 3 dental implants (Tables 2a and 2b). Finally, 6 patients received freestanding restorations supported by single implants (4 in the maxilla and 2 in the mandible) (Tables 2a and 2b). The exact location and distribution of the implants placed in each patient is presented in Tables 1 and 2, and the distribution of patients and restorations is shown in Table 3. The criteria for inclusion in the study were: *(1)* the existing bone, examined radiographically, was adequate to allow for the placement of at least 10-mm-long implants; *(2)* medical history revealed no contraindication to implant therapy; and *(3)* the experimental protocol was explained to the patient, who expressed his or her agreement to participate in the study by signing an informed consent form.

Surgical Protocol

Screw-type implants at least 10 mm long and 3.75 mm wide (pure titanium, grade III, sandblasted/acid-etched surface) were used. Bone quality was assessed during implant surgery.[19] The osteotome site was prepared to a diameter 0.75 mm less than the diameter of the implant desired in type 1 or type 2 bone and to a diameter of 1 mm less than the diameter of the implant desired in type 3 or type 4 bone. This compensated for any less than optimal bone and enabled the implant to be tapped in under high torque (at least 32 Ncm) to achieve the required primary stability.

Screw Test

While the implant was still in its sterile case (Fig 1a), the cap was removed, and the square head of the mounting device and the screw, which keeps the implant attached to its mount, were exposed (Fig 1b). A ratchet was placed on the square head, and the screw was tightened to 32 Ncm with a torque-control device (Fig 2). Because the osteotome site was narrower than the implant, a high torque was often required for implant placement. To achieve primary stability, the implant was tapped in manually, without the use of mechanical torque. Following implant placement, the mount was removed without countertorque. If the implant was stable after removal of the implant mount, it was assumed that the implant was torqued into the bone at above 32 Ncm. If the implant rotated (ie, reversed) while its mount was being unscrewed postplacement, then the implant was considered to have inadequate primary stability for immediate loading and was removed and replaced with a wider implant of the same length, which was tapped into place without widening the osteotomy site further. The "screw test" was repeated immediately. When the implant passed the screw test, it was deemed to have adequate primary stability for immediate loading.

A panoramic radiograph was obtained immediately after implant placement. Periapical radiographs were obtained at the time of provisional restoration placement and upon completion of the 4-month healing period to verify osseointegration. They were repeated every 6 months after completion of treatment during follow-up visits.

Prosthetic Protocol

An open-tray polyether or polyvinylsiloxane impression was made immediately after implant placement to facilitate the fabrication of a provisional restoration. This screw-retained restoration (Figs 3a and 3b), which was delivered within 72 hours postsurgery, was made of heat-polymerized acrylic resin on temporary titanium cylinders (UCLA type). Orthodontic wire was utilized for its reinforcement (Fig 4). The occlusion (canine protection or group function) was adjusted carefully,

Table 1a Distribution and Length (mm) of Implants (Maxillary Complete-Arch Restorations)

Patient	Age	Sex	Implant placement site*														Total no.of implants placed
			2 (17)	3 (16)	4 (15)	5 (14)	6 (13)	7 (12)	8 (11)	9 (21)	10 (22)	11 (23)	12 (24)	13 (25)	14 (26)	15 (27)	
1	71	M	15	15	—	18	—	—	20	20	—	—	—	18	15	15	8
2	28	F	—	15	—	13	—	11.5	13	13	11.5	11.5	—	13	—	—	8
3	64	M	—	18	—	—	—	15	—	—	15	—	—	—	18	—	4
4	59	M	—	15	—	13	—	10	—	—	11.5	—	13	—	13	—	6
5	46	M	11.5	—	—	15	—	18	—	—	18	—	15	—	—	13	6
6	53	M	—	15	—	11.5	—	11.5	—	—	11.5	—	11.5	—	15	—	6
7	66	M	13	13	—	18	—	18	—	—	18	—	18	—	15	—	7
8	44	M	—	11.5	—	10	—	—	15	15	—	—	13	—	10	—	6
9	33	F	—	18	—	—	15	—	15	—	15	—	18	—	15	—	6
10	52	F	—	—	18	—	18	—	18	—	18	—	18	—	18	—	6
11	80	F	13	—	—	13	—	—	13	—	13	—	10	—	—	—	5
12	82	F	—	10	—	15	—	—	13	—	13	—	—	13	13	—	6
13	51	F	—	15	—	15	—	15	—	—	15	—	15	—	15	—	6
14	64	F	—	—	15	—	—	15	—	15	—	15	—	15	—	—	5
Total																	85

*The first number is the tooth number according to the US (Universal) tooth numbering system and the number in parentheses is the tooth number according to the European (FDI) tooth numbering system.

Table 1b Distribution and Length (mm) of Implants (Mandibular Complete-Arch Restorations)

Patient	Age	Sex	Implant placement site*													Total no.of implants placed
			31 (47)	30 (46)	29 (45)	28 (44)	27 (43)	26 (42)	25 (41)	24 (31)	23 (32)	22 (33)	21 (34)	20 (35)	19 (36)	
1	71	M	—	11.5	—	—	18	—	—	—	18	—	18	—	11.5	5
2	28	F	—	—	—	—	13	—	13	13	—	13	—	13	—	5
3	64	M	—	—	—	18	—	18	—	—	18	—	15	—	—	4
4	59	M	—	—	—	18	18	—	18	—	18	—	18	—	—	5
5	46	M	13	—	—	18	—	20	—	—	20	—	20	—	13	6
6	53	M	—	—	—	15	—	15	18	—	18	—	15	—	—	5
7	66	M	15	—	—	20	—	18	—	—	20	—	20	20	—	6
8	44	M	—	13	—	18	—	18	—	—	18	—	18	—	13	6
15	54	M	—	—	—	20	—	18	—	—	18	—	20	—	—	4
16	44	F	—	10	—	—	—	18	—	—	18	—	18	—	10	5
Total																51

*The first number is the tooth number according to the US (Universal) tooth numbering system and the number in parentheses is the tooth number according to the European (FDI) tooth numbering system.

Table 2a Distribution and Length (mm) of Implants Placed in the Maxilla: FPDs and Single Freestanding Implants

Patient	Age	Sex	Implant placement site*													Restoration type	Total no.of implants placed
			2 (17)	3 (16)	4 (15)	5 (14)	6 (13)	7 (12)	8 (11)	9 (21)	10 (22)	11 (23)	12 (24)	13 (25)	14 (26)	15 (27)		
17	53	F	—	—	—	—	—	—	—	—	—	—	15	13	—	13	FPD	3
18	51	M	—	—	—	—	—	—	—	—	15	—	—	11.5	—	10	FPD	3
19	62	M	—	—	13	—	—	—	15	—	15	—	—	—	—	—	FPD	3
20	53	F	—	—	15	—	15	—	—	—	—	—	—	—	—	—	FPD	2
21	33	M	—	—	—	—	—	—	—	15	—	—	—	—	—	—	SI	1
22	28	F	—	—	—	—	—	—	15	—	—	—	—	15	—	—	SI	2
23	19	F	—	—	—	—	—	—	—	—	15	—	—	—	—	—	SI	1
24	61	M	—	—	13	—	15	—	—	—	—	—	—	—	—	—	SI	2
Total																		17

*The first number is the tooth number according to the US (Universal) tooth numbering system and the number in parentheses is the tooth number according to the European (FDI) tooth numbering system.
FPD = fixed partial denture; SI = single implant.

Table 2b Distribution and Length (mm) of Implants Placed in the Mandible: FPDs and Single Freestanding Implants

Patient	Age	Sex	Implant placement site*													Restoration type	Total no.of implants placed
			31 (47)	30 (46)	29 (45)	28 (44)	27 (43)	26 (42)	25 (41)	24 (31)	23 (32)	22 (33)	21 (34)	20 (35)	19 (36)	18 (37)		
25	58	M	—	10	—	18	18	—	—	—	—	—	—	—	—	—	FPD	3
26	52	F	—	13	—	—	15	—	—	—	15	—	—	—	13	—	2 FPDs	4
27	55	F	—	—	—	—	—	—	—	—	—	—	15	—	11.5	—	FPD	2
28	54	F	—	11.5	—	15	—	—	—	—	—	—	—	—	—	—	FPD	2
29	57	M	10	—	—	18	—	—	—	—	—	—	18	—	—	11.5	2 FPDs	4
30	53	F	—	—	—	—	—	—	—	—	—	—	—	13	—	11.5	FPD	2
31	54	F	—	—	—	—	—	—	—	—	—	—	15	—	11.5	—	FPD	2
32	55	F	—	—	—	—	—	—	—	—	—	—	—	11.5	—	10	FPD	2
33	58	F	—	—	—	—	—	—	—	—	—	—	10	—	10	—	FPD	2
34	62	M	—	—	—	—	—	—	—	—	—	—	13	—	11.5	—	FPD	2
35	62	M	—	10	13	13	—	—	—	—	—	—	—	—	—	—	FPD	3
36	39	M	—	—	—	—	—	—	—	—	18	—	—	—	—	—	SI	1
37	49	M	15	15	—	—	—	—	—	—	—	—	—	—	—	—	FPD	2
38	50	F	—	—	—	—	—	—	—	—	—	—	15	11.5	13	—	FPD	3
39	57	M	13	—	15	—	—	—	—	—	—	—	—	—	—	—	FPD	2
40	53	F	—	—	—	11.5	—	—	—	—	—	—	—	—	—	—	SI	1
Total																		37

*The first number is the tooth number according to the US (Universal) tooth numbering system and the number in parentheses is the tooth number according to the European (FDI) tooth numbering system.
FPD = fixed partial denture; SI = single implant.

Table 3 Total Number of Implants Placed, Distribution in Patients, and Type of Restoration

Type of restoration	No. of patients	Sex		Total no. of implants	Total no. of restorations
		M	F		
Single implants	6	3	3	8	8
FPDs supported by 2 implants	12	4	8	28	14
FPDs supported by 3 implants	6	4	2	18	6
Complete-arch restorations	16	8	8	136	24
Total	40	19	21	190	52

FPD = fixed partial denture.

FIg 1a Dental implant in its sterile case.

Fig 1b Square head of the implant mount and the screw that connects the implant to the mount.

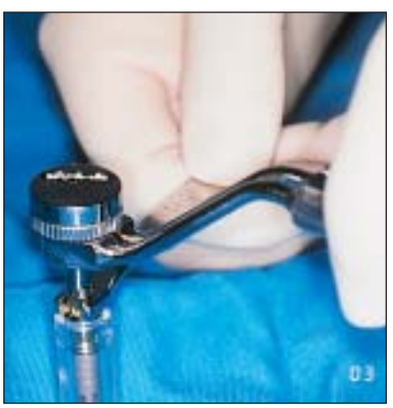

Fig 2 The screw that attaches the dental implant to its mount was tightened to 32 Ncm.

Fig 3a Screw-retained restoration made of heat-polymerized acrylic resin on titanium temporary cylinders (UCLA type).

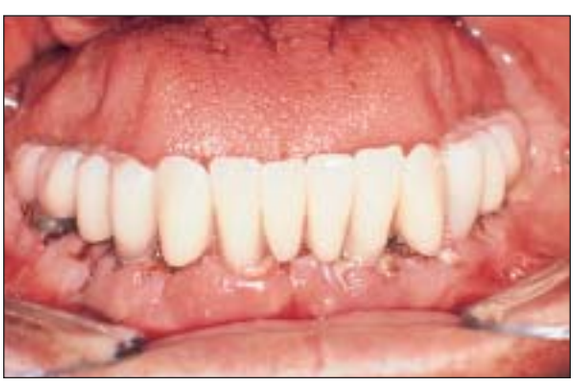

Fig 3b Intraoral view of screw-retained restoration 72 hours postsurgery.

and all contacts were removed from cantilever extensions. Four months later, the provisional restorations were removed, the dental implants were test-torqued to 32 Ncm, and a radiograph was obtained to verify osseointegration. Under no circumstances were the provisional restorations removed before the end of this 4-month period; even when acrylic resin fractures occurred, they were repaired intraorally. Following final impression making, the definitive porcelain-fused-to-metal restoration was fabricated and delivered.

All the restorations were removed after 1 year of function so that the implants could be examined. Criteria for failure[20] were defined as implant mobility, peri-implant radiolucency, or pain, discomfort, altered sensation, or infection attributable to the implants.

RESULTS

In this study, a total of 190 implants were placed in both partially and completely edentulous patients in

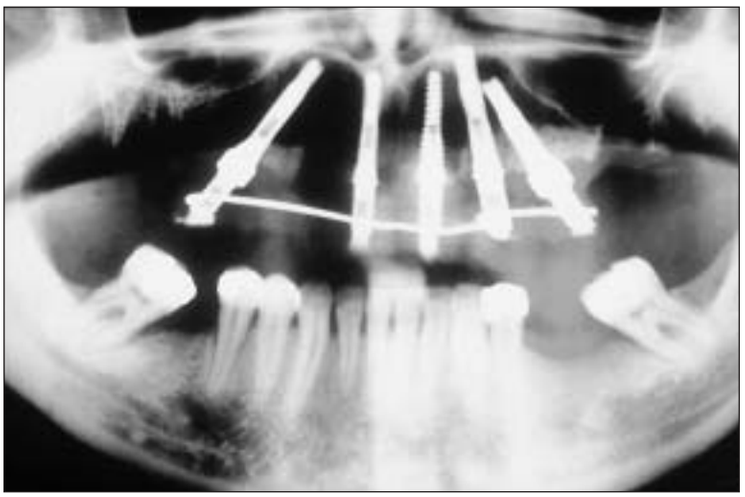

Fig 4 Panoramic radiograph of a screw-retained restoration reinforced by orthodontic wire.

a private practice. All implants were loaded with heat-polymerized acrylic resin provisional restorations within 72 hours of surgical placement and were followed for 1 to 2 years. There were no implant losses during either the healing period (ie, the first 4 months after surgery) or the 2-year follow-up period (ie, there was 100% survival). Radiographic evaluation of bone, which was performed at 6-month intervals postoperatively, revealed that the bone loss did not exceed the first thread of the implant.

Five implants were removed at the time of implant placement and replaced with larger diameter implants because they did not fulfill the primary stability criterion (ie, they failed the screw test). Due to bone stiffness, 3 osteotomy sites had to be enlarged before implants could be tapped in. Four patients had fractures of their acrylic resin provisional restorations during the healing period, but the orthodontic wire held the provisional restorations in place. Those restorations were repaired intraorally with acrylic resin. All of the patients whose provisional dentures fractured had implant restorations in their opposing dentition. There were no hard or soft tissue complications.

DISCUSSION

The early investigations of Brånemark, which eventually led to the application of dental implants, resulted in the establishment of an osseointegration protocol that included a submerged technique and a load-free postoperative healing period of 3 to 4 months for the mandible and 4 to 6 months for the maxilla.[1] The submerged undisturbed healing of the original "ad modum Brånemark" concept has been challenged over the years[21] by the introduction of the nonsubmerged 1-stage technique. Submerged placement of dental implants may no longer be a prerequisite for successful osseointegration. Modifications of implant shape and surface characteristics have encouraged research, the results of which suggest that it is possible to restore implants predictably and safely in considerably shorter healing times.[6] Moreover, several investigators[7–18] have reported promising results with immediately loaded implants.

The 100% survival rate achieved in the present study may be attributed primarily to optimal initial stability and to the surface characteristics of the implants. Preparation of the osteotomy site to a width that was always smaller than the final implant diameter ensured primary stability even in poor quality bone (type 3 or type 4). Furthermore, torque was verified before it was decided that the implant was ready for immediate loading. When the implant, which had been screwed to the mounting device at a minimum of 32 Ncm, remained in place after the removal of the mounting device, the clinicians were reassured that the implant was mechanically stabilized, at least at 32 Ncm.

Rough-surfaced implants at least 10 mm long were used in this study. They were loaded within 72 hours, which is in accordance with other immediate loading protocols.[12–18] Comparisons of polished surfaces with machined surfaces and other roughened surfaces have demonstrated that increasing surface roughness can result in greater initial bone-to-implant contact and greater biomechanical interlocking of the implant with bone.[22,23]

The concept of a rigid framework for the provisional restoration was intended to limit micromovement. In the present study, enhanced implant primary stability, which was achieved by adhering to the aforementioned immediate loading protocol, was thought to be sufficient to retain micromovement within limits. This micromovement appeared to be tolerated by the dental implants without jeopardizing the osseointegration. Therefore it was decided that the provisional restoration did not need to include rigid metal reinforcement. According to the literature,[24–28] early loading per se has not been found to be detrimental to osseointegration. Specifically, only excessive micromotion has been directly implicated in the formation of fibrous encapsulation, ie, implant failure. Although it was once believed that any amount of micromotion could be deleterious at the bone-implant interface, especially if the micromotion occurs soon after implantation, the literature suggests that there is a critical threshold of micromotion above which fibrous encapsulation prevails over osseointegration.[28] This level was found to be somewhere between 50 and 150 μm.[24] In the present study, the provisional restoration was fabricated using heat-polymerized acrylic resin, incorporating orthodontic wire reinforcement. This suprastructure may have prevented some acrylic resin fractures (ie, without it, there might have been more than 4 fractures). However, this metal reinforcement cannot be considered to provide rigid fixation, as it allows for more micromovement than provisional restorations described in other studies[12,15,16] that included a casting for rigid metal reinforcement.

It is noteworthy that the acrylic resin fractures occurred only in completely edentulous patients who had implant restorations in their opposing dentition. Lack of proprioception in peri-implant tissues may have allowed the application of greater masticatory forces by these patients.

The lack of need for rigid metal reinforcement was also proposed by Cooper and colleagues,[14] who used provisional acrylic resin dentures without any metal reinforcement and had no implant losses (100% success rate). Ericsson and coworkers[17] also reported on provisional restorations incorporating nonrigid reinforcement in a 5-year follow-up study on immediate loading of single-tooth implants, with a success rate of 85%. All the provisional restorations in this study incorporated nonrigid reinforcement; therefore, it was impossible to compare provisional restorations with rigid versus nonrigid frameworks. However, the 100% implant survival rate realized in the current population might lead to the conclusion that strict adherence to the other parameters of this clinical protocol was adequate for the achievement of osseointegration, even without rigid metal reinforcement in the provisional restorations. It was not possible to clinically measure whether the amount of micromovement exceeded the threshold of 150 μm, beyond which micromovement has been considered deleterious to osseointegration.

In this study, a favorable survival rate was achieved in the follow-up period. However, there are a number of limitations in this clinical study. Fixed cross-arch stabilized prostheses have been grouped together with unilateral fixed partial dentures and single crowns. Therefore, the number of variables that could impact implant survival is very large. The screw test, which is a simple way to evaluate the torque force required to restore an implant, was used as a criterion of primary stability and determined each implant's capacity for immediate loading. It is unknown whether this test may be used as a true measure of the required primary stability. Further long-term controlled multicenter clinical studies need to be performed before the results of this study can be recommended for more general use.

In summary, it appeared that when the dental implants had a primary stability of at least 32 Ncm, as determined by the screw test, then the functional loads applied through the heat-polymerized acrylic resin provisional restorations without rigid metal reinforcement were transmitted to the bone in a way that allowed osseointegration.

CONCLUSIONS

The results of this limited prospective observational study indicate that immediate loading of implants (both single and multiple) may be a viable treatment option. The 100% survival of the dental implants placed suggests that when the described immediate loading protocol is followed, rough-surfaced dental implants with an initial stability of 32 Ncm or more, immediately loaded by means of fixed provisional restorations placed within 72 hours after surgical implant placement, can be successful in the short term.

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