

Immediate and early implant loading protocols: A literature review of clinical studies

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The purpose of this literature review is to present the outcomes of clinical studies on immediate and early loading protocols, identify shortcomings, and suggest a number of questions that still require exploration. English language clinical studies, limited to peer-reviewed journals between 1975 and 2004, were reviewed to identify treatment outcomes with these loading protocols. The data were tabulated from studies reporting on patients treated with fixed and overdenture prostheses. The former included partially edentulous patients treated with single or multi-unit prostheses. Within the limitations of this review, it can be concluded that these treatment protocols are predictable in the anterior mandible, irrespective of implant type, surface topography, and prosthesis design (success rates 90%-100%). Limited evidence for the edentulous maxilla (success rates 90%-100%) and the partially edentulous patient (success rates 93%-100%) are available, underscoring the need for further research. Studies suggest that to achieve predictable results in extraction sites, implant placement should be restricted to sites without a history of periodontal involvement (success rates 61%-100%). A number of questions require further exploration. There is a need to thoroughly investigate clinical outcomes to measure the economic benefit of these protocols and the impact of treatment on a patient's quality of life. Furthermore, more accurate long-term studies reporting on treatment protocols for separate clinical situations are required to allow meaningful comparisons. (*J Prosthet Dent* 2005;94:242-58.)

One requisite for successful osseointegration is an extended submerged healing phase.^{1,2} This is based on the initial clinical experience of Branemark et al³ in treating a group of patients with severe morphological deficits. Eventually, this 3- to 6-month healing phase was described as empirical,^{4,5} underscoring the need to test it clinically. Clinical and experimental research on other implant systems directly challenged this notion with convincing outcomes.⁶⁻⁹ Clinical evidence supports the notion that Branemark implants can be left exposed during the healing phase without jeopardizing the healing response in completely and partially edentulous patients.¹⁰⁻¹³ A literature review¹⁴ of the experimental research indicated that early loading itself was not a contraindication to successful osseointegration. The latter was dependent on maintenance of a load that precluded extensive micromotion at the bone-implant interface. A conceptual working definition of these loading protocols was suggested^{11,15-17} and comprised immediate loading protocols in which the implants were loaded within 2 days of surgery and early loading protocols wherein a provisional prosthesis was inserted at a subsequent visit prior to osseointegration. Though the implants were not loaded the same day, these protocols directly challenged the healing process by introducing loading during wound healing. The time period suggested for insertion of the prosthesis was between

2 days to 3 months after surgery.¹⁷ This definition of early loading is tenuous, since it includes an extended timeframe during which the bone is allowed to heal. Conventional loading protocols are the original healing periods as envisaged by different implant systems, typically after 12 to 24 weeks. In delayed loading protocols, the healing period was extended due to the compromised host site conditions and, typically, prosthesis connection is later than the conventional healing period.¹⁷ A distinction was made between occlusal and nonocclusal loading, with the former meaning that the immediately or early loaded prosthesis is in contact with the opposing dentition.¹⁶ It should be recognized that in nonocclusal loading, forces on implants could be generated through the oral musculature and food bolus. Surgical protocols that included extraction of residual dentitions and immediate placement of implants in the jawbones were presented.¹⁵ It is acknowledged that the implants can be placed either directly in the extraction sites or in adjacent healed alveolar sites. In certain instances, the surgical preparation of the implant site resulted in the elimination of the extraction sockets. The rationale for the immediate placement of implants in extraction sites was further avoidance of an interim healing phase with a removable prosthesis and a potential reduction in the number of clinical interventions for the patient.

The aim of this literature review is to present these studies under 3 broad categories: patients treated with fixed prostheses (including complete and partially edentulous patients), the single implant-supported prosthesis, and the overdenture approach. This review

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identifies conclusions and shortcomings and presents recommendations for reporting in future studies. Relevant clinical studies written in English between 1975 and 2004 were reviewed to identify the clinical information. The articles were searched with Medline and manually through the references of the peer-reviewed literature. Bone morphology was defined according to the Lekholm and Zarb classification.¹⁸ Implant success or survival rates were as suggested in the Toronto Consensus Conference.¹⁹

IMMEDIATE AND EARLY LOADING PROTOCOLS WITH FIXED PROSTHESES

The edentulous mandible

The initial impetus for this novel approach was the anterior zone of the mandible, a site that provided predictable results with conventional loading protocols. The success rates of immediately loaded implants in this site were high (>90%) in short- to medium-term studies (Tables I through III).^{12,15,20-53} Lower success rates were observed for short implants placed in unfavorable bone morphology and distal positions.^{22,23} A second study by the same authors²⁴ described more favorable results when fewer implants were placed in the anterior mandible, underscoring implant predictability once the surgical and prosthodontic learning phases were completed.

Initial reports described placement of extra implants,^{23,25,30} immediately loaded as interim implants, while the submerged implants healed undisturbed. However, the minimum number of implants required for supporting a fixed prosthesis was investigated in an attempt to reduce treatment costs. Few authors reported using 3 implants per patient.^{20,26,27,48,50,54-56} One system (Branemark Novum; Nobel Biocare, Goteborg, Sweden)^{26,27,48,50} provided high success rates, yet the technique described is not flexible in that the jawbone must either conform or be surgically modified to accommodate the predesigned prosthetic framework. Furthermore, Lekholm⁵⁷ indicated that the technique should be limited to patients with specific jawbone morphology and occlusal relations. Hatano⁵⁶ described a more conservative approach, with success rates of 97.7%. De Bryun et al⁵⁵ indicated that loss of 1 implant led to complete prosthetic failure in 15% of patients that necessitated reoperation. This led to the conclusion that rehabilitation of an edentulous patient with 3 implants was inadvisable and the recommendation that at least 4 implants be placed in an edentulous mandible to support a fixed prosthesis.

The maxilla

The success outcomes for the maxilla, although high (Tables II-III), are limited since the data were

confounded by grouping of completely and partially edentulous patients, including implants placed in both jawbones^{25,30,31,44-47,53,58-68} and extraction sites.^{10,20,36,40,51,64,69-73} Most studies discussing treatment of edentulous maxillae suggested that a high number of implants (8 to 12)^{25,30,31,47,66} were required, yet Olsson et al⁶⁵ presented a case series of 10 patients treated with fixed prostheses supported by 6 to 8 oxidized surface implants. Similar results were presented with a comparable number of implants (5 to 8), but with airborne-particle abraded, large-grit, acid-etched (SLA; sand-blasted, large-grit, acid-etched) surfaces.^{68,72} The authors concluded that this number of implants was adequate for the maxilla and radically reduced treatment costs associated with placement of additional implants. However, long-term data is not available, limiting these conclusions.

It was suggested that in jawbone sites with soft bone conditions, a rough-surface implant would be desirable. Based on implants placed in the edentulous maxilla, this corollary cannot be ascertained. Although comparative short-term case series studies^{25,31} did suggest that rough-surface implants performed better than machined implants, the outcomes were confounded by the use of the variety and number of implants, the limited number of patients, and lack of properly defined success outcomes. On the other hand, a case series³⁰ reported a high success rate (95.5%) for machined implants placed in the anterior zone of the maxilla. The authors discussed modifications in the surgery that may have been sufficient for successful outcomes. This needs to be interpreted within context of the study design, yet it underscores the need for more clinical research to better understand whether a modified implant surface topography plays a clinically significant role in the success of these protocols.⁷⁴

The partially edentulous patient

Tables I through III also present studies of partially edentulous patients,^{12,44-46,53,62,63,66,67,73,75-79} including esthetic zones.^{59,69} The number of treated patients, short follow-ups, and grouping of different types of prostheses limit the conclusions. The implant surface deserves special consideration within context of the partially edentulous patient. Glauser et al⁷¹ reported lower success rates with machined implants in various jawbone sites. In this study, 34% of implants placed in the posterior maxilla failed, and this was attributed to placement of wide-platform implants in patients with poor bone morphology and a history of parafunction. However, the use of an oxidized implant improved the success rate up to 97%, even though 76% of the implants were placed in soft bone.^{44,77} It is not clear whether the improved results were obtained due to the surface only, since longer implants were placed in ideal bone quantities and patients with a history of bruxism were excluded.

Table I. Studies on immediate or early loaded implants with fixed prostheses (mandible only)

Author	Study type	Implant	Patients	Implants	Implant length (mm)
Ericsson ²¹	Pros	Branemark*	11 split-mouth	63	At least 13 mm
Collaert ¹²	Pros	Branemark	85 33 Eden, 17 Par 17 Eden, 18 Par	330 170 I-stage 70 Conv	7-15 mm
Engstrand ^{26,27}	Pros	Branemark Novum*	95	285	11.5-13.5 mm
Ericsson ^{28,29}	Pros	Branemark	16 11	88 Ear 30 Conv	At least 10 mm
De Bryun ⁵⁵	Pros	Branemark	20	98	13-15 mm
Chow ³⁵	Pros	Branemark	27	123	13-18 mm
Hatano ⁵⁶	Pros	Branemark	35	105	13-21 mm
Chow ³⁴	Pros	Branemark	14	56	13-18 mm
Collaert ³⁷	Pros	Astra Tech [†]	25	114	9-17 mm
Engquist ³⁸	Pros	Branemark	82	328	10-21 mm (majority 15-18 mm)
Kronstrom ⁴¹	Pros	Branemark	17	68	13-21 mm
Henry ⁴⁸	Pros	Branemark Novum*	51	153	11.5 mm
Raghoobar ⁴⁹	Pros	Branemark	10	50	10-18 mm
Testori ⁴³	Pros	Osseotite [‡]	15	103	7-18 mm
Testori ⁵²	Pros	Osseotite	62	325	10-18 mm

All patients presented in this table were edentulous in mandible; implants combined in Collaert.¹²

Ran, Randomized trial; Pros, prospective; Ret, retrospective; CS, case series; Imm, immediate loading protocol; Ear, early loading protocol; Conv, conventional loading protocol; NS, not specified; (a), success rate; (b), survival rate; Zone 1, interforaminal area; Zone 2, distal to mental foramina; HA, healing abutment; Eden, edentulous; Par, partially edentulous.

*Nobel Biocare, Goteborg, Sweden.

[†]AstraTech, Molndal, Sweden.

[‡]Implant Innovations Inc, West Palm Beach, Fla.

Implants (machined and modified surfaces) placed in the posterior maxilla integrated when the surgical technique was modified by under-preparation and partial tapping of the osteotomy sites,^{60,63,64,67} implying that if primary stability is obtained, osseointegration is possible irrespective of the surface. However, Rocci et al⁷⁸ randomly assigned 44 patients to receive machined or oxidized-surface implants inserted in the posterior mandible. This short-term study demonstrated a higher success rate (10%) for the modified surface. In bone quality Type 3, the success rate for both machined and oxidized implants was 93% and 96%, respectively, while in Type 4 bone, the success rate was 54% and 92%, respectively. These outcomes are limited due to the restricted number of implant sites with Type 4 bone. Nevertheless, the body of evidence suggests that a modified implant surface may be advisable for clinical situations with Type 4 bone conditions in partially edentulous patients. Additionally, it indicated that clinical trials with more

patients and longer follow-up periods are required to ascertain, conclusively, these clinical findings.

Implants placed in fresh extraction sites

The rationale proposed for implant placement in fresh extraction sites was to preserve soft tissue esthetics and to further reduce the treatment time and associated costs by avoiding an intermediate stage of removable denture wear (Tables III and IV). The conclusions that can be reached from these studies^{10,15,20,22-24,31-33,36,39,40,42,64,69-73} are limited because of the study design, short follow-up times in the majority of reports, and lack of site-specific outcomes. Furthermore, not all extraction sockets were used as implant sites since, in some situations, the extraction site was obliterated due to surgical reduction of the residual ridge. As indicated in Tables III and IV, not all studies stated clearly how the extraction sites were managed, making comparison difficult. Autogenous bone harvested from the implant

Site	Jaw quality	Loading time	Follow-up	Success rate
Zone 1	NS	Left side with HA; right exposed 3 mos	5 yrs	96.82% (b)
Zone 1 and 2 (72/90 in partial were in Zone 2)	Failure in poor bone quality	3-4 mos undisturbed healing	Up to 2 yrs	Edentulous: 96.25% Partial: 95.1% 1-stage 87.8%, 2-stage 89% for Zone 2 (a)
Zone 1	Type 2-3	Same day to 40 days	1-5 yrs	93.3% (b)
Zone 1	NS	20 days	1.5-5 yrs	100% (a)
Zone 1	Type 1-3	Relined denture same day; fixed in 1 mo	Up to 3 yrs	90% (b)
Zone 1	NS	Same day; final 3 weeks	3-30 mos; 15 pts >1 yr	98.3% (b)
Zone 1	NS	Same day restoration	3 yrs	97.7% (b)
Zone 1	NS	Same day; final 3 weeks	1 yr	90% (b)
Zone 1	NS	Loaded 5-32 days	0.5-2 yrs	100% (b)
Zone 1	Type 2-3	No loading first 10 days, then relined during healing; loaded 12 weeks after implant insertion	1 yr	>93% (b)
Zone 1	NS	Relined denture same day; fixed inserted 14 to 78 days	1 yr	93% (b)
Zone 1	Type 1-4	Same day to 2 days	1 yr	90.7% (b)
Zone 1	Type 1-4	Few patients had a relined; final within 6 wks	3 yrs	93% (b)
Zone 1 and 2	Described as normal bone	Same day; final 36 hours to 6 mos	Up to 4 yrs	98.9% (a)
Zone 1 and 2	Type 1-4	Same day; final 6 mos	1-5 yrs	99.4% (a)

osteotomy sites was grafted in the defects surrounding the implants. One used xenografts⁷¹ and three^{36,39,70} did not graft any material in the defects. In addition, not all studies discussed the underlying pathology that led to tooth extraction.

Within these limitations, the studies suggested that success was not compromised by placement in extraction sockets as long as primary stability was achieved. Nevertheless, success was reduced when implants were placed in morphologically compromised jawbone sites.^{23,24,33,36,39} De Bruyn and Collaert³⁹ reported that 39% of machined implants placed in extraction sites failed to osseointegrate and observed that implants placed in extraction sites with a history of previous periodontal disease were more susceptible to failures. To conclude, these short- to medium-term studies suggested that implant placement should be restricted to extraction sites without a history of periodontal disease and limited to the anterior mandible. Further

long-term clinical research is required to support these observations and to determine the efficacy of a similar protocol in other jawbone sites.

SINGLE-IMPLANT STUDIES

The studies of single implant-supported prostheses reported good treatment outcomes (Table IV).^{44-46,53,59,60,63,64,67,69-71,75,76,79-93} Close scrutiny of the studies that reported low success rates^{63,71,80,83} indicated implant placement in fresh extraction sites, which may have been compromised by the presence of infection.⁶⁹ The reasons for tooth extraction included trauma, retained root and root resorption, and nonrestorable crowns. Contraindications discussed were active periodontal and periapical infection,^{69,82,83} suggesting that placement of implants in fresh extraction sites should be avoided in clinical situations with ongoing inflammatory processes. Furthermore, in the

Table II. Studies on immediate or early loaded implants with fixed prostheses in both jawbones

Author	Study Type	Implant	Patients	Implants	Implant length (mm)
Tarnow ²⁵	Pros/CS	Branemark, ITI, ^a Osseotite Astra Tech	10	107	At least 10 mm
Scortecci ⁵⁸	Ret	Diskimplant, Structure implants ^b	72	69 Imm, 38 Conv	NA
Horiuchi ³⁰	Pros/CS	Branemark	14	783	8-12/pt
				140 Imm	7-18 mm
				96 Imm, 9 Conv	
Buchs ⁵⁹	Pros	Altiva ^c	93 Part	44 Imm, 8 Conv	10-18 mm
				91	10-15 mm
Adrianssens ⁶⁰	Pros	Branemark	25 Part ^k	37	13-15 mm
Glauser ⁶¹	Pros	Branemark, TiUnite ^d	24 Part	47	NA
Roccuzzo ⁷⁵	Pros	ITI (SLA and TPS)	32 Part ^k split mouth	68 SLA	8-12 mm
				68 TPS	
Roccuzzo ⁷⁶	Pros	SLA	19	25	8-12 mm
Testori ⁴⁵	Pros	Osseotite	164 ^k	270	7-18 mm
			11	33	
Cochran ⁶²	Pros	SLA	133	383	8-14 mm
Rocci ⁶³	Ret	Branemark	46 Part	70	8.5-18 mm
Rocci ⁷⁸	Ran	Branemark TiUnite	44 Part	121	7-18 mm
Glauser ⁴⁴	Pros	Branemark TiUnite	38 Part ^l	82	8.5-18 mm
Malo ⁶⁴	Pros	Branemark	76 Part	53	10-20 mm
Cannizzaro ⁷⁹	Ran	Spline Twist MTX ^e	28 Part ^m	92	13-18 mm
			14 Imm	46	
			14 Conv	46	
Olsson ⁶⁵	Pros	Branemark TiUnite	10	61	8.5-18 mm
Vanden Bogaerde ⁶⁶	Pros	Branemark	31 ⁿ	124	8.5-18 mm
Calandriello ⁶⁷	Pros	Branemark	26 ⁿ	50	At least 10 mm
Degidi ⁴⁶	Ret	Frialit 2, ^f IMZ, ^f 3i, ^g Frialoc, ^f	39 Mand ^o	241	6.5-18 mm
		Branemark, Restore ^h	14 Max	133	
		Maestro ⁱ	70 Part	214	
Misch ⁴⁷	Pros	Biohorizons ⁱ	30	136	9-12 mm
				108	12 mm
Fischer ⁶⁸	Ran	ITI	24	95 Imm	8-12 mm
				47 Conv	
Gallucci ⁵¹	Pros	ITI	8	78	8-12 mm
Nikellis ⁵³	Pros	Southern Implants ^j	16	85	10-20 mm
			4	51	
			14		

Ran, Randomized trial; Pros, prospective; Ret, retrospective; CS, case series; SLA, sand-blasted, large-grit, acid-etched; TPS, titanium plasma-sprayed; Part, partially edentulous patients; Mand, mandible; Max, maxilla; Imm, immediate loading protocol; Conv, conventional loading protocol; NS, not specified; (a), success rate; (b), survival rate; Zone 1, interforaminal area; Zone 2, distal to mental foramina; FPD, fixed partial denture; Mach, machined surface.

^aStraumann Institute, Waldenburg, Switzerland.

^bVictory SA, Nice, France.

^cAltiva Corp, Minneapolis, Minn.

^dNobel Biocare, Goteborg, Sweden.

^eCenterpulse Dental, Carlsbad, Calif.

^fFriadent, Mannheim, Germany.

^gImplant Innovations Inc, West Palm Beach, Fla.

^hLifecore Biomedical, Chaska, Minn.

Jawbone	Site	Jaw quality	Loading time	Follow-up	Success rate
4 Max 6 Mand	Zone 1	NS	Same day	1-5 yrs	97% (b)
Max	Zone 1 and 2	Type 1-4	Up to 7 days	Up to 4 yrs	98% at 6 mos (a)
12 Mand	Zone 1 and 2	Type 1-4	Same day	Up to 2 yrs	97.2% 97.9% 95.5% (b)
5 Max	Zone 1				
56 Mand	Zone 1 and 2	Type 1-4, majority 2-3	Within 1 day	Up to 2 yrs	93.7%
34 Max					Mand 95% Max 93.4% FPD (b)
Max	Zone 1	Type 1-4	Same day	1 yr	94.6% (b)
Max	Zone 2	Type 3	Same day	0.5 yr	100% (b)
Both	Zone 1 and 2 (majority 2)	NS	6 wks SLA 12 wks TPS	1 yr	100% (b)
Max	Zone 2	Type 4	6 wks	1 yr	97.22% (a)
Both	Zone 2	Type 1-4	2 mos	3 yr	>97% (b)
Both	Zone 2	Type 1-4	6 wks in Type 1-3 bone and 12-15 wks in Type 4 bone	Up to 3 yrs	99.1% (a)
Max	Zone 1 and 2	Type 2-4	Same day	3 yrs	94% (b)
Mand	Zone 2	Type 2-4	Same day	1 yr	95.5% TiUnite 85.5% Mach (a)
Both	Zone 1 and 2	Type 2-4	Same day	1 yr	97.1% (a)
Both	Zone 1	Type 2-3	Same day to 1 week	1 yr	98.1% (b)
Both	Zone 1 and 2	Type 1-3	Imm, same day	2 yrs	98.9% (a) 100% Imm 92% Conv
Max	Zone 1	NS	Same day	1 yr	93.4% (a)
Both	Zone 1 and 2	NS	1 wk to 20 days	1.5 yrs	96.8% (a)
Both	Zone 2	Type 1-4	Same day	1.5 yrs	98% (b)
Both	Zone 1 and 2	Type 3-4	Same day	Up to 5 yrs	100% (b)
12 Max 19 Mand	Zone 1 and 2	Type 1-4	Same day to 2 wks	1-5 yrs	100% (b)
Max	Zone 1	Type 1-3	9-18 days	1 yr	100% (b)
5 Max 6 Mand	Zone 1 and 2	NS	Same day	8-20 mos	97.4% (b)
14 Max 10 Mand 4 Max 16 Mand	Zone 1 and 2	Type 1-4	Within 3 days	1-2 yrs	100% (b)

¹Biohorizons, Maestro Dental Implants, Birmingham, Ala.²Southern Implants, Irene, South Africa.³Single and partial situation not specified.⁴One patient had a complete fixed partial denture in mandible.⁵Included single implant-supported prostheses (11 for immediate group and 10 for conventional group).⁶Complete and partially edentulous patients and included complete fixed partial dentures in maxilla.⁷Included 17 edentulous patients treated with overdentures.

Table III. Studies on implants placed in extraction sites and fixed prostheses

Author	Study type	Implant	Patients	Tooth loss	Jawbone	Loading time
Salama ²⁰	CS	Branemark, Osseotite, IMZ	2	NS	Both, Zone 1	5 days
Becker ¹⁰	Pros	Branemark	63	NS	Both, Zone 1 and 2	>4 mos
Schnitman ²²	Pros/CS	Branemark	10	TD	Mand, Zone 1 and 2	Same day
Balshi and Wolfinger ^{23,24}	Pros	Branemark	10 24 simplified	TD	Mand, Zone 1 and 2	Same day
Jaffin ³¹	CS	TPS/SLA [†] Sterngold-Implamed [‡]	27	NS	Mand, 4 Max Zone 1 and 2	1 to 3 days
Malo ⁶⁹	Ret	Branemark	49	NS	Both, Zone 1 and 2	Same day
Ganales ³³	CS	ITI, Astra Tech Frialit-2	27	P, C	Mand, Zone 1 and 2	Same day
Colomina ³²	Pros	ITI, Astra Tech Klockner [§] Eckermann	13	NS	Mand, Zone 1	1 to 10 days
Grunder ³⁶	Ret/CS	Osseotite	8	P, C, E	Both, Zone 1 and 2	Within 1 day
Jo ⁷⁰	Pros	Sargon [¶]	64	NS	Both, Zone 1 and 2	Same day
Glauser ⁷¹	Pros	Branemark	23	NS	Both, Zone 1 and 2	Same day to 11 days
De Bryun ³⁹	Pros	Branemark	36	P, C, E	Mand, Zone 1	3 wks
Aires ⁴⁰	CS	NS	7	NS	Both, Zone 1 and 2	<3 wks
Cooper ¹⁵	Pros	Astra Tech	10	NS	Mand, Zone 1	Same day
Malo ⁴²	Pros	Branemark	44	TD	Mand, Zone 1	Same day
Malo ⁶⁴	Pros	Branemark	14	TD	Both, Zone 1	Same day to 1 wk
Jaffin ⁷²	Pros	ITI	34	P, C	Max, Zone 1 and 2	2 to 3 days
van Steenberghe ⁵⁰	Pros	Branemark Novum	50 24 Ext pts	NS	Mand, Zone 1	1-3 days
Nordin ⁷³	Pros	ITI	20 Edent 19 Part 15 Part	NS	Max, Zone 1 Max, Zone 2 Mand, Zone 2	4-22 days

Becker,¹⁰ Jo,⁷⁰ Malo,^{64,69} Glauser,⁷¹ and 2 patients in Colomina³² were partially edentulous patients. All other papers include edentulous patients.

Ran, Randomized trial; *Pros*, prospective; *Ret*, retrospective; *CS*, case series; *TPS*, titanium plasma-sprayed; *SLA*, sand-blasted, large-grit, acid-etched; *Edent*, edentulous; *Part*, partially edentulous; *NS*, not specified; *TD*, terminal dentition; *P*, periodontal; *C*, caries; *E*, endodontics failure; *Mand*, mandible; *Max*, maxilla; *Zone 1*, interforaminal area; *Zone 2*, distal to mental foramina; *Imm*, immediate loading protocol; *Ear*, early loading protocol; *Conv*, conventional loading protocol; *(a)*, success rate; *(b)*, survival rate; *Mach*, machined surface; *RS*, rough surface; *Ext*, extraction site; *Heal*, healed site.

*62 additional implants placed as back-up for the first 24 patients treated.

[†]Straumann Institute, Waldenburg, Switzerland.

[‡]Sterngold-Implamed, Attleboro, Mass.

[§]Klockner SA, Barcelona, Spain.

^{||}Eckermann Laboratorium, Orihuela, Spain.

[¶]Sargon Enterprises Inc, Beverly Hills, Calif.

studies^{63,71,80,83} reporting low success rates, the authors reported that the prostheses were in full functional loading^{63,71} or in light occlusal contact.^{80,83} Other studies^{44,67,79,87,88,91} reported that all restorations were in occlusion, and yet high success rates were presented. However, single implant-supported prostheses were also kept out of occlusion with similar success

rates.^{46,59,60,64,69,82,84,86,89,90,92,93} This suggests that studies are required to conclusively determine the role of occlusion in these clinical situations.

Bone quality did not seem to have a major influence on the success rates discussed in these studies. Implants were placed in Type 4 bone with no adverse effect,⁷⁰ yet others suggested higher failure rates in

No implants	Implant length (mm)	Extraction sites	Site management	Follow-up	Success rate
21	13-15 mm	NS	Autogenous bone	3.5 yrs	100% (a)
135	Majority >10 mm	8	NS	7-17 mos	95.6% (a)
28 Imm	7-20 mm	NS	Site obliterated	8-10 yrs	84.7%
35 2-stage	85% \geq 10 mm				100% Conv (b)
130, 40 Imm	At least 7 mm	17	Site obliterated/	5 yrs	80% Imm
144 Imm		Ant 70 Post 12	autogenous bone freeze dried bone	1-4 yrs	96% Conv simplified 97% (b)
149	At least 10 mm	63	NS	12 wks	95% Mach (83%) RS (99%) (a)
94 Imm	10-18 mm	27	NS	1-3 yrs	95.7% (b)
186	At least 10 mm	NS	Autogenous bone	1-3.5 yrs	99% (b)
161 Imm					
61	10-16 mm	32	Site obliterated	8 mos	93.4% (a)
91	8.5-18 mm	66	No augmentation	Up to 2 yrs	87.5% Max 97.6% Mand (a)
213	10-16 mm	57	No augmentation	3.5 yrs	98.9% Ext 93.6% Heal (b)
67	7-15 mm	49	Collagen membranes and xenografts	1yr	82.7% (a)
184	7-18 mm	31	No augmentation	3 yrs	99.3% Heal and 61% Ext (b)
75, 62 Ear	8-15 mm (?)	29	NS	NS	96.7% Imm (b)
54	11-13 mm	34	Site obliterated/ autogenous bone	6 to 18 mos	100% (a)
176 Imm*	10-18 mm	45	NS	1-2 yrs	>95% (b)
116	13-20 mm	22	NS	1 yr	100% Ext 95% Heal (b)
236	At least 10 mm	121	NS	Up to 5 yrs	93% Ext 91.35% Heal (b)
150	11.5-13 mm	NS	NS	1 yr	92.7% (b)
122	8-14 mm	24	NS	1 yr	99.1% (b)
59		22			
53		12			

similar bone conditions.^{59,63} The soft tissue reaction was described as being very favorable due to the presence of a provisional crown during the healing phase. This preserved the gingival and interdental papilla, resulting in highly esthetic outcomes.^{59,81-84,86,89,90,94} The marginal bone loss around single implants was of the same magnitude as described previously with

a conventional approach, at least in the short term,^{69,79,81,82,84,86,89,90-94} though Andersen et al⁸⁴ reported bone gain over a period of 5 years. These short-term clinical studies presented by highly skilled clinicians suggest that immediate loading of a single implant is a viable treatment option when the host site is not an extraction site. However, more long-term research is

Table IV. Studies on single implant-supported prostheses

Author	Study Type	Implant	Patients	No implants
Malo ⁶⁹	Ret	Branemark	49	31
Ericsson ⁸⁰	Pros	Branemark	22	14 Imm, 8 Conv
Adrianssens ⁶⁰	Pros	Branemark	25*	37
Cooper ⁸¹	Pros	Astra Tech	52	58
Jo ⁷⁰	Pros	Sargon	33	73
Buchs ⁵⁹	Pros	Altiva	93	51
Hui ⁸²	Pros	Branemark	24	24, 13 Ext
Chaushu ⁸³	Ret	Sterioss, [†] Alpha Bio [‡]	26	28
Glauser ⁷¹	Pros	Branemark	28	28
Roccuzzo ⁷⁶	Pros	SLA	19	11
Andersen ⁸⁴	Pros	ITI TPS	8	8
Proussaefs ^{85,86}	Pros	Replace [†]	10	10
Kirkterp ⁸⁷	Pros	Replace	35	36 Ext
Testori ⁴⁵	Pros	Osseotite	164*	102
Glauser ⁴⁴	Pros	Branemark TiUnite	38	20
Malo ⁶⁴	Pros	Branemark	76	63
Calandriello ⁶⁷	Pros	Branemark	26	20
Calandriello ⁸⁸	Pros	Branemark TiUnite	44	50
Lorenzoni ⁸⁹	Pros	Frialit-2	9	12, 8 Ext
Rocci ⁶³	Ret	Branemark	46	27
Kan ⁹⁰	Pros	Replace	35	35, all Ext
Degidi ⁴⁶	Pros	Frialit 2, Frialoc, IMZ, Maestro Branemark, 3i, Restore	58	58
Cornellini ⁹¹	Pros	ITI	30	30
Drago ⁹²	Pros	Osseotite	38	77, 15 Ext
Norton ⁹³	Pros	Astra Tech	25	28, 16 Ext
Nikellis ⁵³	Pros	Southern	6	8

Ran, Randomized trial; Pros, prospective; Ret, retrospective; CS, case series; Imm, immediate loading protocol; Conv, conventional loading protocol; Ext, extraction site; Heal, healed site; SLA, sand-blasted, large-grit, acid-etched; TPS, titanium plasma sprayed, (a), success rate; (b), survival rate.

*Single and partial situations not specified.

[†]Nobel Biocare, Yorba Linda, Calif.

[‡]Alpha Bio, Petah-Tikva, Israel.

[§]All implants placed in Type 4 bone.

required to support these conclusions in routine clinical practice.

IMMEDIATE LOADING OF IMPLANTS WITH OVERDENTURE PROSTHESES

Implant-retained overdentures proved to be a predictable and effective method in the management of edentulous patients. Short-term studies limited the treatment to the mandibular interforaminal area, with the resultant high success rates in excess of 90%.^{7,49,71,95-117} The overdenture loading protocols are summarized in Tables V through VII. In early progressive loading (Table V), the dentures were not worn

for 1 to 2 weeks, or else worn, but completely relieved from the healing abutment. Typically, the prosthesis was then relined for 3 to 4 months when the definitive prosthesis and attachments (ball or bar assembly) were connected. In early functional loading (Table VI), the dentures were not worn for 2 weeks or were relined after surgery. The retentive components (ball attachments) were then connected within 3 weeks. Finally, in immediate-early functional loading (Table VII), the retentive attachments were connected within 5 days. In these studies, the retentive components were a bar/clip assembly. It can be appreciated that the loading differences between the 3 groups are rather tenuous, since the time and method of loading overlaps. Nevertheless, studies in

Implant length (mm)	Jawbone	Site	Loading time	Follow-up	Success rate
10-18 mm	Both	Zone 1 and 2	Same day	1 to 3 yrs	95.7% (b)
13-18 mm	Both	Zone 1	Within 24 hrs	1.5 yrs	85.7% (a)
13-15 mm	Max	Zone1	Same day	1 yr	94.6% (a)
11-17 mm	Max	Zone1	3 wks	1 yr	96.2% (b)
10-16 mm	Both	Zone 1 and 2	Same day	3.5 yrs	98.9% Ext
					93.9% Heal (b)
10-15 mm	Both	Zone 1 and 2	Within 24 hrs	Up to 2 yrs	93.7% (b)
13-18 mm	Max	Zone 1	Same day	Up to 1.5 yrs	100% (a)
12-16 mm	Both	Zone 1 and 2	Same day	Up to 2 yrs	82.4% Ext
					100% Heal (b)
7-15 mm	Both	Zone 1 and 2	Same day-11 days	1 yr	79% (a)
8-12 mm	Max	Zone 2	6 wks	1 yr	97.22% (a)
12-14 mm	Max	Zone 1	1 wk	5 yrs	100% (a)
13 mm	Max	Zone 2	Same day	3 yrs	100% (a)
13-16 mm	Max	Zone 1	Same day	1 yr	97.2% (b)
7-18 mm	Both	Zone 2	2 mos	3 yrs	>97% (b)
8.5-18 mm	Both	Zone 1 and 2 ^s	Same day	1 yr	97.1% (a)
13-20 mm	Both	Zone 1	Same day-1 wk	1 yr	93.7% (b)
At least 10 mm	Both	Zone 2	Same day	1.5 yrs	98% (b)
At least 10 mm	Mand	Zone 2	Same day	1 yr	100% (a)
13-15 mm	Max	Zone 1	Same day	1 yr	100% (a)
8.5-18 mm	Max	Zone 1 and 2	Same day	1 yr	81% (b)
At least 13 mm	Max	Zone 1	Same day	1 to 3.5 yrs	100% (a)
6.5-18 mm	Both	Zone 1 and 2	Same day	Up to 5yrs	96.6% (b)
10-12 mm	Max	Zone 2	Within 24 hours	1 yr	96.7% (b)
At least 10 mm	Both	Zone 1 and 2	Same day	At least 1.5 yrs	97.4% (b)
11-17 mm	Max	Zone 1	Same day	1.5 to 2.25 yrs	96.4% (b)
11.5-18 mm	Both	Zone 1 and 2	Within 3 days	1 to 2 yrs	100% (b)

Tables VI and VII directly challenged the osseointegration process, since direct loading occurred within a month, in contrast to the first group in which full functional loading was at 3 to 4 months. In effect, studies in Table V can be viewed as a single-stage protocol.

Comparable high success rates were reported in 4 studies^{100,102,105,106} that included control patients treated with a 2-stage technique, suggesting that these novel protocols with overdentures were an attractive methodology. Research is necessary for the maxilla since only 1 patient has been reported.⁷¹ The majority of the opposing dentitions were complete dentures.^{96,97,99,102-104,110,115,117} However, in a few studies, the opposing dentition was restored and

included implant-supported prostheses.^{7,97,105,107,115} This would suggest that the impact of the opposing dentition was limited, but obviously, a comparative study is required to clearly ascertain this issue.

Studies have suggested that implants should be splinted together with a bar within a short period of time to prevent axial rotation and implant micromotion (Table VII).^{95,97,101,106,115} However, other studies (Tables V and VI) have used fewer implants (minimum of 2) that were left exposed and unsplinted after an initial healing phase of 2 to 3 weeks. Therefore, it could be argued that splinting of implants is not a definite requirement for osseointegration with these protocols in the anterior mandible. However, it should

Table V. Overdenture articles classified by loading protocols: early-progressive loading

Author	Study type	Implant	Patients	Implants	Implant length (mm)	Loading time (wk)*	Prosthesis connection	Attachment mechanism	Follow-up time (y)	Success rate
Bernard ⁹⁶	Pros	Branemark	5	2/pt	10-20 mm	1	3 mos	Ball	1	100% (a)
Cooper ⁹⁹	Pros	AstraTech	58	2/pt	At least 11 mm	1 [†]	3 mos	Ball	2	95.7% (b)
Packer ¹⁰⁰	Ret	Branemark	10 Ear	3/pt	NA	2	4 mos	Bar	1	90%
			14 Conv	2 Ear 4/pt, Conv						96.4% (b)
Tawse-Smith ¹⁰⁴	Pros	Sterioss Southern Implants	24	2/pt	10-18 mm	2	3 mos	Ball	1	>95% (a)
Tawse-Smith ¹⁰⁸	Pros	Sterioss (Steri) Southern Implants (SI)	48 24 Ear (T) 24 Conv (C)	2/pt	10-18 mm	2	1.5 mos	Ball	2	Steri: (C) 88%, (T) 71%; SI: (C) 83%, (T) 100% (b)
Heydenrijk ¹⁰⁹	Pros	IMZ ITI	40	2/pt	At least 10 mm	2	3 mos	Bar	1	97.5% (a)
Fenlon ¹¹⁰	Pros	Branemark	16	2/pt	8.5-15 mm	2	3 mos	Ball	2	81.25% (b)
Payne ¹¹²	Pros	ITI	12 Ear 12 Conv	2/pt	10-16 mm	2	6 and 12 wks in Ear and Conv, respectively	ITI retentive anchors	2	Ear 100%, Conv 91.6% (a)
Raghoobar ⁴⁹	Pros	Branemark	30	4/pt	10-18 mm	(16/40 pts) had a relined time not specified	Within 1.5 mos	Bar	3	93% (b)

Ran, Randomized trial; Pros, prospective; Ret, retrospective; CS, case series; Ear, early loading protocol; Conv, conventional loading protocol; NS, not specified; (C), control group; (T), test group; (a), success rate; (b), survival rate.

*During early healing phase, denture was not worn during specified weeks. Afterward the denture was relined and intaglio surface was in contact with patric component in all studies except for studies by Bernard et al,⁹⁶ Tawse-Smith et al,^{104,108} and Fenlon et al.¹¹⁰ In latter studies,^{96,104,108,110} the denture was relieved from implant-supported components.

[†]Denture worn from day of surgery but intaglio surface completely relieved.

be noted that healing was unobstructed for the first couple of weeks and led to a high success rate with such protocols (Tables V and VI). In most of these studies, the loading was progressive, with the next stage involving relining for a few weeks. Final attachment and, presumably, full functional loading typically progressed within 3 to 4 months (Table V), while others constructed the frameworks within 2 to 3 weeks (Table VI).

The peri-implant soft tissues appeared to be comparable to conventional protocols and did not compromise implant outcomes.^{96,99,104,109,111,117} However, others observed a change in the mucosa, mainly describing it as soft-tissue shrinkage.^{100,103,104,116} This suggests that a period of soft tissue healing, along with a change, is to be expected following surgery. It is, therefore, safe to assume that time should be allowed for optimal soft tissue health. If not, it could be hypothesized that the dentures would require relining to maintain the best possible adaptation of the prosthesis to the tissue. Peri-implant bone behavior was observed with intraoral

radiographs^{103,104,109,111,116} or panoramic radiographs corrected for magnification.^{49,97,101,105,106,115,117} The observed bone loss suggested that bone loss was within 0.2 mm/year,^{97,101,105,106,117} and immediate loading was not a higher risk factor for early or late marginal bone loss when compared to the conventional loading protocols.

CONCLUSIONS ON IMMEDIATE AND EARLY LOADING PROTOCOLS

The majority of the authors^{7,10,12,15,21-25,27-33,35,37-41,43-53,55,58-73,75,76,78-84,86,88,90-93,96-99,101-112,114-117} discussed the medical status of the patients included in the studies. The authors included patients who were healthy or had a controlled medical condition (endocrine, bone metabolic disorders) that did not preclude a minor oral surgical procedure. Some authors^{10,43,52,85,93,98} viewed patients with a history of diabetes as a contraindication for these loading protocols, although the diabetic status was not stated. Others⁹⁹ specifically excluded diabetic patients only

Table VI. Overdenture articles classified by loading protocols: early-functional loading

Author	Study	Implant	Patients	Implants	Implant length (mm)	Loading time	Prosthesis connection	Attachment mechanism	Follow-up time (y)	Success rate
Røynesdal ¹⁰²	Pros	ITI	21	2/pt	10-16 mm	Denture not worn for 2-3 wks	3 wks	Ball	2 (15 pts)	100% (b)
			11 Ear 10 Conv							
Payne ¹⁰³	Pros	Branemark	10	2/pt	13-18 mm	Relined denture same day	2 wks added matrix	Ball	1	100% (a)
Glauser ⁷¹	Pros	Branemark	4	4/pt Mand 1 6/pt Max	7-15 mm	NS	2-11 days	Bar	1	82.7% (a)*
Payne ¹¹⁶	Pros	ITI, Southern Implants	12	2/pt	8.5-15 mm	Relined denture same day	2 wks added matrix	ITI retentive anchors and ball	1	91.6% SLA, 100% Southern (a)
			12							
Stricker ¹¹⁷	Pros	ITI	10	2/pt	10-12 mm	Denture not worn for 1 wk	1 wk	Bar	2-3	100% (a)

Abbreviations are explained in first footnote to Table II.

*Global success rate, not specific for overdentures.

if the condition was not controlled. Cigarette smoking^{59,66,80,81,83,86,89,103-105,107,108,111,112,116} was considered as a contraindication for immediate/early loading protocols; however, other authors^{32,38,46,62,67-69,73,82,92,97,101,106,110,115} viewed only heavy smoking as an exclusion criterion. It is interesting to note that others^{23,27,33,35-37,39,45,48,50,52,55,58,63,70,72,78,79,81,84,88,93} reported that patients who smoked were included in the studies. Of the latter, only 1 author^{63,78} found a significant association between smoking and implant loss, although it should be emphasized that the number of failures was small and clustered in patients. As such, the role of cigarette smoking on implant success in immediate/early loading protocols is inconclusive, and the need for properly designed studies to thoroughly investigate the role of smoking is required.

The literature discussed in this paper and recent reviews^{118,119,120} underscored the fact that primary stability of the implant was the underlying requisite for predictable results. Various methods for measuring implant stability have been suggested; however, it is impossible to compare results and reach definite conclusions on the preferred method of measuring this parameter.¹¹⁸ Primary implant stability was virtually guaranteed with a screw-shaped implant in the anterior mandible, and in other jawbone sites, a modified surgical protocol appeared to improve success. It seems that no further surgical-prosthetic modifications beyond those tenets proposed for the delayed loading protocol were necessary. Modifications of the surgical protocol were described in an attempt to improve the treatment outcomes. However, the introduction of variables and lack of proper discussion of the surgical techniques

precluded comparison between studies and prevented any conclusion of the potential benefits of modifying the surgical protocol. Nonetheless, the following modifications were presented: avoiding/reducing bone tapping of the osteotomy site^{20,22,30,33,93,103} or tapping osteotomy sites in dense bone only^{59,60,67,72}; avoiding countersinking or limiting it to cancellous bone conditions^{15,36,42-44,55,60,64-67,69,71,83,103}; engaging both cortices where available to provide bicortical stabilization^{22,28,30,56,64,69,82,84,97,104,103}; performing under-preparation of the osteotomy site using narrower twist drills^{20,30,35,53,54,59,60,63-65,69,78,93} or the osteotome technique,^{36,67,76} and, in a few papers,^{30,39,53,99} using a wider implant when primary stability was not obtained with the initial implant. It appears that the influence of bone tapping, bicortical stabilization, and countersinking were not clear-cut, which may be due to jawbone site-specific considerations, lack of comparison of these parameters, or because these factors were not relevant. However, it is tempting to propose that in the anterior mandible, the traditional protocol may suffice, whereas a modified surgery may be advisable for other sites.

Although implant length was presented by the majority of clinical studies, its role on implant success was limited. Few authors did describe failures for shorter implants,^{22-24,30,31,36,51,97} especially when placed in sites where limited bone was available.²²⁻²⁴ Authors have suggested that a minimal implant length of 10 mm is necessary for immediate and early loading protocols.^{25,97} However, as noted in a review,¹²¹ these data should be interpreted cautiously, owing to small sample sizes and implant placement in compromised host sites—conditions that were previously described with

Table VII. Overdenture articles classified by loading protocols: immediate- functional loading

Author	Study type	Implant	Patients	Implants	Implant length (mm)	Loading time prosthesis connection	Attachment mechanism	Follow-up time (y)	Success rate
Babbush ⁷	Ret	TPS	129	4/pt	At least 10 mm	Prosthesis relined on bar after 2-3 days; matrix added 2-3 wks	Bar	Up to 5.5	96.1% (b)
Spierkerman ⁹⁵	Ret	TPS IMZ	11 Ear 125 Conv	2-3/pt	NA	<1-2 days	Bar	Up to 11	97.3% (b)
Chiapasco ⁹⁷	Ret	NLS*, ITI, TPS HA-Ti [†]	226	4/pt	10-20 mm	1 day	Bar	Average 6.4	96.9% (a)
Vassos ⁹⁸	Ret	Sterioss	58	240 4/pt	8-18 mm	1-5 days	Bar	Average 2	99.2% (b)
Gatti ¹⁰¹	Pros	ITI	21	4/pt	10-14 mm	1 day	Bar	2-5	96% (a)
Chiapasco ¹⁰⁵	Pros	Branemark	10 Ear 10 Conv	4/pt	13-18 mm	3 days	Bar	2	97.5% (a)
Romeo ¹⁰⁶	Pros	ITI	10 Ear 10 Conv	4/pt	>10 mm	2 days	Bar	2	100% Imm 97.5% (a)
Gatti ¹⁰⁷	Pros	Branemark	10	4/pt	11.5-18 mm	1 day	Bar	2	100%
Rungcharassaeng ¹¹¹	Pros	Sterioss	5	4/pt	12-16 mm	<1 day; matrix added 1-2 wks	Bar	1	100% (a)
Mau ¹¹⁴	Ran	TPS	360	652 TPS	At least 13 mm	<2 days for TPS; matrix added 2 wks	Bar	Up to 5	91%
Lorenzoni ¹¹³	Pros	IMZ Frialit-2	7	354 IMZ 42 14 Imm 2/pt 28 Conv 4/pt	10-15 mm	2-4 days	Bar	0.5 [‡]	95% (a) 100% (a)
Chiapasco ¹¹⁵	Pros	HA-Ti, ITI, Branemark, Frialoc*	82	4/pt	10-20 mm	1 day	Bar	Average 5	96.1% (b)

Abbreviations are explained in first footnote to Table II.

*Friadent, Mannheim, Germany.

[†]Mathys Dental Implants, Bettlach, Switzerland.

[‡]Prosthesis was converted to fixed partial denture.

delayed loading protocols.¹²²⁻¹²⁵ This signifies the need for further clinical studies to investigate the influence of length on the treatment outcomes with immediate and early loading protocols.

Within the limitations of this review, the following observations were made. Short- to medium-term studies suggest that treatment with fixed prostheses in the anterior mandible is predictable,¹¹⁹ irrespective of implant type, surface topography, and prosthesis design. At least 4 implants should be placed in the edentulous anterior mandible to support a fixed prosthesis. Caution is required with a fewer number of implants due to potential complete prosthodontic failure if 1 implant fails to osseointegrate. Limited evidence for the maxilla suggests that reasonable success rates of immediately loaded implants are limited to the anterior region only.

Early loading protocols with overdentures were an attractive treatment methodology. Short- to medium-term studies suggest high success rates in the mandible,

irrespective of implant splinting and surface topography, yet these results cannot be extrapolated to the edentulous maxilla due to the lack of evidence available to support such a protocol. Immediate or early loading with the single implant-supported prostheses provided predictable results. Nonetheless, in the partially edentulous patient, including single implant-supported prostheses, definite conclusions are limited by the study designs and the fact that data were presented by highly skilled clinicians on a limited number of patients and implants.¹²⁰ The role of occlusion in these clinical situations is yet to be determined with properly designed studies. The notion that a rough surface is always necessary to improve the implant success outcomes with immediate loading protocols cannot be supported entirely, since a combination of a modified surgical technique and a machined implant yielded comparable results in edentulous patients with favorable bone quantity and quality. Studies suggest that to achieve

predictable results in extraction sites, implant placement should be restricted to sites without a history of periodontal involvement. Finally, the marginal bone loss measured, irrespective of prosthesis design, was of the same magnitude as presented for the conventional loading approach.

Although numerous articles were published on these novel protocols, a number of questions still require exploration in the context of recognized treatment outcomes¹²⁶ and properly designed studies.¹²⁷ Recent reviews^{119,120,127} observed a paucity of properly designed studies to allow definite conclusions on this topic. A common claim was that treatment with immediate loading improved patient satisfaction and was cost effective. However, no scientific evidence was presented to support these claims. It is clear that this treatment protocol should be investigated thoroughly, including maintenance and complication issues, to measure the economic benefit of these protocols and the impact on a patient's quality of life.¹⁷ Furthermore, more accurate long-term studies reporting on treatment protocols for separate clinical situations are required to allow meaningful comparison.

SUMMARY

This literature review examined clinical outcomes of studies on immediate and early loading protocols. Within the limitations of the studies, it can be concluded that only treatment protocols in the anterior mandible can result in predictable results. Limited studies on the edentulous maxilla and partially edentulous patients precluded definite conclusions. More accurate long-term studies with stronger research design and reporting on treatment protocols for separate clinical situations are required to allow meaningful comparisons and conclusions. Furthermore, there is a need for research to evaluate the implications of these protocols on patient-mediated outcomes.

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