Immediate Functional Loading of Brånemark System Implants in Edentulous Mandibles: Clinical Report of the Results of Developmental and Simplified Protocols

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Purpose: *This report evaluates the 5-year results of 9 of 10 patients in a clinical investigation of immediate functional loading of Brånemark System implants in edentulous mandibles, and of 24 patients treated with a simplified protocol for the same indication. The purpose of the paper is to suggest a simple, reliable, and documented method for immediate implant loading of complete-arch mandibular prostheses.* ***Materials and Methods:*** *Ten healthy patients in need of full-arch mandibular implant reconstruction (development group) were treated between December 1993 and December 1994 with 130 Brånemark System standard implants, placed in fresh extraction and healed sites. Four implants per patient were immediately loaded with acrylic resin fixed prostheses. The prostheses were replaced by metal-framework conversion prostheses approximately 6 weeks later, and definitive metal-reinforced prostheses incorporating all implants were placed after second-stage surgery. An additional 24 patients were treated with a simplified protocol using a total of 144 implants placed between March 1997 and October 2000. In these patients, the acrylic resin prostheses were not disturbed for 3 months, and fewer implants were used with an increasing ratio of implants loaded. Eventually, all implants were loaded immediately for the last patients treated.* ***Results:*** *The prosthesis survival rate was 100% for the total material. In the developmental group, the implant cumulative survival rate was 80% for the immediately loaded implants after 5 years, while the 2-stage implants reached 96%. Bone level measurements showed no differences between immediate and 2-stage protocols for this group. The implant cumulative survival rate was 97% for the simplified treatment group.* ***Discussion and Conclusion:*** *A predictable and simple concept for loading of immediate implant prostheses in edentulous mandibles was demonstrated. Results from the development of this technique suggest that it may be essential to maintain the initial implant splinting over a healing period of about 3 months and that implant placement between the mental foramina provides optimal support.* (Int J Oral Maxillofac Implants 2003;18:250–257)

Key words: *dental implants, denture, immediate loading, mandible*

While the protocol for direct bone-to-implant contact was originally described by Brånemark and associates[1–3] using submerged, unloaded implants, many researchers,[4–11] including Brånemark,[11] have demonstrated comparable results for integration of implants placed under immediate functional load. Previous investigations of immediate and early loading of implants with fixed[4–8,11–15] and removable[9,10,16–19] interim prostheses have been reported, indicating that placement of a few implants between the mental foramina in the mandible allows for simplified immediate loading protocols.

The preliminary results of a study involving 10 patients utilizing unique surgical and prosthodontic techniques for the immediate functional loading of Brånemark System implants (Nobel Biocare, Göteborg, Sweden) in edentulous mandibles have been reported previously.[14] The present report evaluates the 5-year results of 9 of these patients and the

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results of 24 patients treated with a revised and simplified protocol for the same indication with up to 4 years of function. The purpose of this report was to present the method used for immediate implant loading of complete-arch prostheses in the mandibles of patients involved in these 2 protocols.

MATERIALS AND METHODS

Developmental Protocol

Originally 10 patients, ranging in age from 45 to 70 years (average 55 years), were treated between December 1993 and December 1994.[14] These patients have now been followed at least 5 years since definitive prosthesis placement. The patients were required to be healthy and in need of full-arch mandibular implant reconstruction, and to have adequate bone for the placement of implants at least 7 mm long in the posterior mandible. Presence of parafunctional habits did not exclude patients from the investigation. The previous dental conditions of these patients included 9 with missing teeth, 8 with moderate to advanced periodontal disease, 1 with a severe Class II malocclusion, and 1 with failing overdenture abutments. Eight of the 10 subjects had noncontributory past medical histories. One patient had hypertension, an aortic aneurysm, and angina, and another had diabetes and arthritis. These patients were being treated by their physicians for these conditions. Nine of the 10 patients in this initial study were followed for 5 years and 1 patient was lost to follow-up after the 1-year examination.

Surgical Procedure. Any natural teeth with a poor or hopeless prognosis were extracted in all patients. One hundred thirty Brånemark System standard implants were then placed in immediate extraction sites, as well as in healed sites, with a minimum of 10 implants in each mandible (range 10 to 15; mean 13). Bone quality and quantity were registered according to Lekholm and Zarb.[3] Abutments were connected to 4 implants per patient immediately after surgery, 2 on each side of the mandible (2 between the mental foramina and 2 distally above the mandibular canal). The remaining 90 implants were submerged, allowed to heal in the conventional manner, and uncovered 3 months after first-stage surgery. The implants were spread as far apart as possible, with unloaded implants both anterior and posterior to each loaded implant (Fig 1). Implants placed anterior and posterior to the foramina are in the following referred to as anterior and posterior, respectively.

Prosthetic Procedure. The 4 implants with abutments connected at first-stage surgery were immediately loaded with all–acrylic resin fixed prostheses or conversion prostheses.[20] All patients were instructed to maintain a soft diet for the next 3 months. The acrylic resin provisional restorations were removed after 7 to 10 days to facilitate removal of the sutures. At that time, final plaster impressions were made of the 4 immediately loaded implants for fabrication of master casts. Titanium frameworks (Procera, Nobel Biocare USA, Yorba Linda, CA) were fabricated on each of the master casts. These metal frameworks replaced the acrylic resin conversion prostheses approximately 6 weeks later, because at that time the authors thought that the metal-reinforced prostheses would provide better load distribution to the implants.

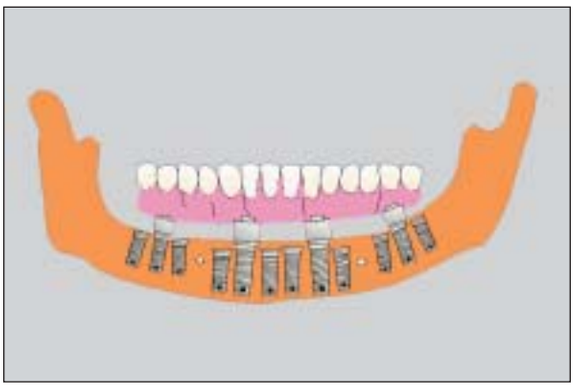
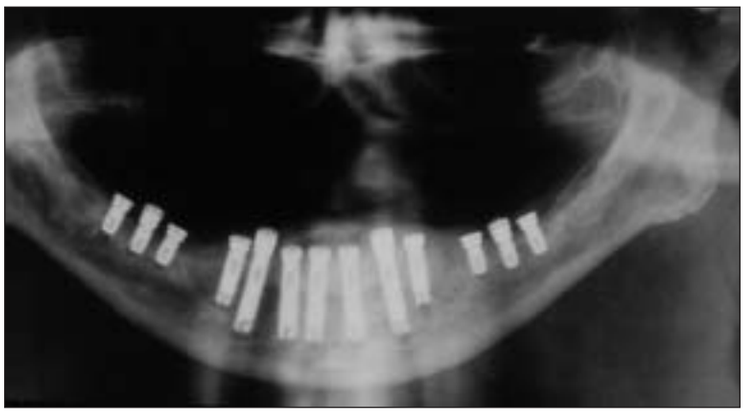
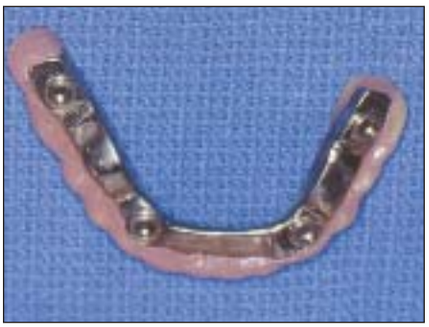


Fig 1 The implants in the developmental group were spread as far as possible with unloaded implants both anterior and posterior to each loaded implant.

Follow-up. If mobility of an immediately loaded implant had been noted before second-stage surgery, the implant was retained as long as it did not appear to jeopardize any additional adjacent implants. If a lesion were developing around that mobile implant and approached an adjacent implant, the mobile implant was removed before the adjacent implant would be affected. At second-stage surgery, implant stability was individually evaluated, mobile implants were removed, and marginal bone levels were registered. Abutments were connected to all clinically immobile implants and plaster final impressions were made. The original conversion prostheses were modified to include all implants, and the patients wore these prostheses until the definitive metal-reinforced prostheses were fabricated and placed approximately 6 weeks later (Figs 2a and 2b).

After placement of the definitive prostheses, the patients were followed for oral hygiene recall on at least a 6-month basis, at which time security of the prosthetic screws was checked. Radiographic evaluations were made at the 1-year, 3-year, and 5-year appointments. Radiographic analysis was performed





Figs 2a and 2b The definitive mandibular metal-reinforced implant prostheses for the developmental group were placed 6 weeks after second-stage surgery.

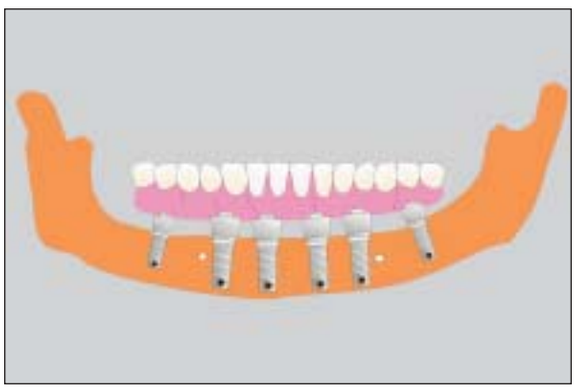


Fig 3 Eventually all implants were loaded immediately for the simplified protocol.

by a single examiner on non-standardized periapical and panoramic radiographs, using the thread width of the implant as a guide to measurement standardization. At the 5-year examination, all fixed implant prostheses were removed, and each individual implant was evaluated for clinical stability and absence of pain.

Simplified Protocol

Based on the experience of the developmental group, an additional 24 patients with edentulous mandibles were treated with a simplified protocol for immediate loading. A total of 144 implants were placed in these patients between March 1997 and October 2000. The major change in the new protocol was to not disturb the acrylic resin prostheses for 3 months. Three to 9 implants (average 6) were placed and spread throughout the entire mandibular arch in both healed and fresh extraction sites (Figs 3 and 4). The protocol was modified over time, with an increasing number of the implants loaded immediately and using fewer overall implants per arch. Eventually all implants were loaded immediately for the last patients in the group (Figs 4a and 4b).

The inclusion criteria were the same as for the developmental group, except that posterior implant placement was not considered essential. Of the 144 implants, 104 were placed in the anterior region and 40 were placed in the posterior. The surgical procedure and the follow-up were the same as for the developmental group.

Prosthetic Procedure. The temporary all–acrylic resin prostheses placed at the time of surgery remained fastened to the implants during the entire 3-month healing period. All patients were instructed to maintain a soft diet during this time. At 3 months, examination for stability of individual implants was done and final impressions were made for fabrication of the definitive metal-reinforced prostheses. The impressions were made by picking up the all–acrylic resin fixed provisionals (conversion prostheses) in a wash impression. The definitive prostheses were placed within a 2-week period.

Figures 4a and 4b show an overview of the numbers of immediately loaded and 2-stage implants and their positions in the jaws for all study participants.

Survival Criteria

All mobile implants were recorded as failures. All implants without signs of mobility, without pain or discomfort on pressure, and exhibiting radiographic evidence of osseointegration were considered survivals. The results are presented as cumulative survival rates.

Bone Level Registration

For the developmental group, panoramic and/or periapical radiographs were taken the day of

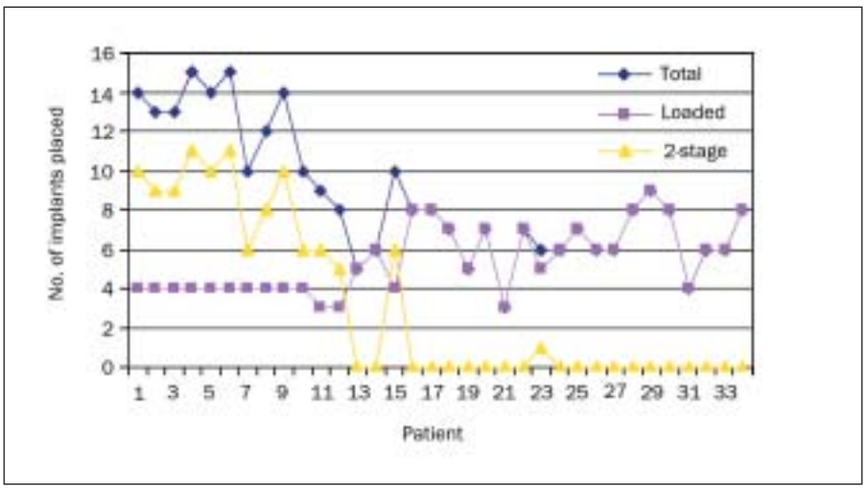


Fig 4a The total number of implants per patient decreased from 10 to 14 for the developmental group (patients 1 to 10) to an average of 6 for the simplified group (patients 11 to 34). The number of 2-stage implants decreased from 6 to 10 for the developmental group to none for the simplified group.

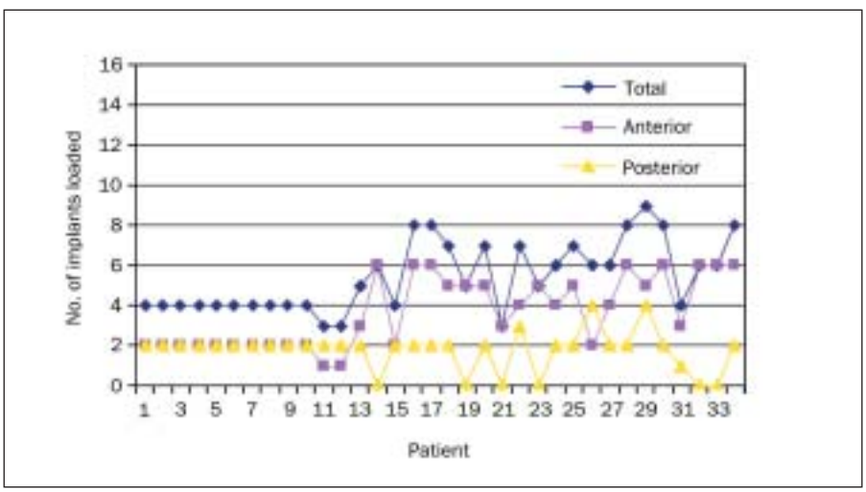


Fig 4b The number of anterior immediately loaded implants increased from 2 for the developmental group to 6 for the simplified group, while the number of immediately loaded posterior implants remained the same (2 implants).

implant placement and at 1 week, 1 month, 3 months, 1 year, 3 years, and 5 years. For the simplified protocol patients, panoramic and/or periapical radiographs were taken at the day of implant placement, at the 3-month recall, and on a yearly basis. Bone level measurements were performed on the non-standardized radiographs by a single examiner.

RESULTS

Developmental Protocol

All 10 patients reached second-stage surgery, experiencing a prosthesis survival rate of 100%, which was maintained over the 5-year study period (Table 1). The total number of failures for both immediately loaded and submerged implants is shown in Table 1. Thirty-two of the 40 immediately loaded implants were stable at second-stage surgery, giving a survival rate of 80% after 5 years. The survival rate for the unloaded implants at second-stage surgery was 98% (2 failures of 90 implants). Two additional unloaded implants failed after second-stage surgery—one at 4.5 months and one at 10 months—giving a survival rate of 96%, which was maintained during the 5-year study period. The details of the patients who lost implants are presented in the 1-year follow-up report.[12]

Table 1 Life Table Analysis of Implant/Prosthesis Survival (CSR) in Developmental Group

Time period	No. in function	No. failed	No. withdrawn	Survival rate (%)	CSR (%)
Immediately loaded implants					
Loading to 6 mo	40	8	0	80	80
6 mo to 1 y	32	0	0	100	80
1 y to 2 y	32	0	0	100	80
2 y to 3 y	28	0	4	100	80
3 y to 4 y	28	0	4	100	80
4 y to 5 y	28	0	4	100	80
5 y to 6 y	28	0	4	100	80
6 y to 7 y	28	0	4	100	80
7 y to 8 y	28	0	4	100	80
Standard protocol implants					
Loading to 6 mo	90	3	0	96.7	96.7
6 mo to 1 y	87	1	0	98.9	95.6
1 y to 2 y	86	0	0	100	95.6
2 y to 3 y	77	0	9	100	95.6
3 y to 4 y	77	0	9	100	95.6
4 y to 5 y	77	0	9	100	95.6
5 y to 6 y	77	0	9	100	95.6
6 y to 7 y	77	0	9	100	95.6
7 y to 8 y	77	0	9	100	95.6
Restorations					
Loading to 6 mo	10	0	0	—	100
6 mo to 1 y	10	0	0	—	100
1 y to 2 y	10	0	0	—	100
2 y to 3 y	9	0	1	—	100
3 y to 4 y	9	0	1	—	100
4 y to 5 y	9	0	1	—	100
5 y to 6 y	9	0	1	—	100
6 y to 7 y	9	0	1	—	100
7 y to 8 y	9	0	1	—	100

Table 2 Marginal Bone Level Changes (in mm) in Developmental Group

Time	Immediately loaded implants	Two-stage implants (SD)
0 to 6 mo	0.21	0.10
0 to 5 y	0.46	0.53

One patient was lost to follow-up after the 1-year recall, and the remaining 9 patients were followed over the 5-year period. The prostheses in the 9 patients were removed at the 5-year examination, and each implant was checked for clinical stability and absence of pain. None of the patients experienced discomfort with any of the implants, and no implants showed any signs of instability. Periapical radiographs were taken at the 5-year examination to compare the bone levels between the implants that were placed in immediate functional loading at stage 1 surgery versus those that followed the standard 2-stage protocol. Mean bone level measurements did not indicate any differences between the groups (Table 2).

Simplified Protocol

All prostheses were successful in the simplified group, and 139 of the 144 implants placed were considered survivals, resulting in a 97% implant survival rate within the first year (Table 3). Of the 5 implants that failed, 4 were posterior and 1 was anterior. Only 1 of the 104 implants in the anterior region failed to integrate, while 4 of the 40 (10%) posterior implants that were immediately loaded failed. The failures all occurred in 4 of 24 patients: 1 anterior failure in 1 patient, 1 posterior failure each in 2 patients, and 2 posterior failures in 1

Table 3 Life Table Analysis of Implant/Prosthesis Survival in Simplified Protocol Group

Time period	No. in function	No. failed	No. withdrawn	Survival rate (%)	CSR (%)
Immediately loaded implants					
Loading to 6 mo	144	5	0	96.5	96.5
6 mo to 1 y	139	0	0	100	96.5
1 y to 2 y	76	0	0	100	96.5
2 y to 3 y	6	0	0	100	96.5
3 y to 4 y	6	0	0	100	96.5
4 y +	3	0	0	100	96.5
Standard protocol implants					
Loading to 6 mo	18	0	0	100	100
6 mo to 1 y	18	0	0	100	100
1 y to 2 y	17	0	0	100	100
2 y to 3 y	11	0	0	100	100
3 y to 4 y	11	0	0	100	100
4 y +	6	0	0	100	100
Restorations					
Loading to 6 mo	24	0	0	—	100
6 mo to 1 y	24	0	0	—	100
1 y to 2 y	14	0	0	—	100
2 y to 3 y	2	0	0	—	100
3 y to 4 y	2	0	0	—	100
4 y +	1	0	0	—	100

patient. The 1 anterior failure was in an immediate extraction socket, the 2 patients with single failures of posterior implants had had implants placed in healed bone, and the 1 patient with 2 posterior failures had 1 failure in native bone and 1 in an immediate extraction socket.

Of the 104 anterior implants, 70 were placed in immediate extraction sockets and 34 in healed sites. Of the 40 posterior implants, 12 were placed in immediate extraction sockets and 28 were placed in healed sites. In the healed anterior sites there were no failures (0/34), while 1 anterior implant in an immediate extraction socket failed to integrate (1/70 = 13%). In the healed extraction sites there were 3 failures (3/28 = 11%), while 1 posterior implant in an immediate extraction socket failed to integrate (1/12 = 8%).

The higher survival rate of the immediately loaded implants for the simplified protocol (97%) versus that of the developmental group (80%) was statistically significant (log-rank test, $P = .0003$), while there was no statistically significant difference between the 2 groups for submerged implants (standard protocol) ($P = .366$). Further, there was no statistically significant difference between the immediately loaded and submerged implants in the simplified protocol ($P = .423$), while the results within the developmental group differed significantly ($P = .005$). This indicated that a simplified protocol, based on immediately loaded implants only, appears to be a reliable protocol, with predictability close to that of a standard protocol. The prosthesis survival was 100% for both protocols.

DISCUSSION

One difference of importance between the protocols might be that in the simplified treatment, there was no change of provisional prosthesis during the initial healing period, while for the developmental group there was a shift after 5 to 6 weeks. This shift could have led to a change in loading of the implants at a critical phase in the bone remodeling process. While the authors' original intention of replacing the acrylic resin prostheses with stiffer metal-reinforced prostheses at 5 to 6 weeks was to reduce micromotion[21] at the bone-to-implant interface, this may have actually been counterproductive. Removal of the all–acrylic resin prostheses at 1 week for suture removal and final impressions, and again at 5 to 6 weeks for placement of the metal-reinforced prostheses, may have created excessive micromotion at the bone-to-implant interface during the primary healing period and may have caused some early losses of the immediate functionally loaded implants.

In the developmental group, all the initial implant losses (ie, the first implant lost in a patient) were always distal implants; 3 of the 4 bruxers and 1 of the 6 non-bruxers lost implants, and all the losses were in bone quality 3 or 4.[12] These observations indicate that the reason for failures of the immediately loaded implants was likely a combination of high load (distal implants and bruxing patients) and insufficient bone support (bone quality 3 or 4). In the simplified protocol, there was also an overrepresentation of failures for the immediately loaded implants in the posterior region. That the majority of implant losses were at the unicortically anchored posterior implants in both groups indicated that the anchorage capacity of these implants may be more critical and that the implants placed between the mental foramina are probably the most important implants in completely edentulous mandibles.

The widely spread arrangement of 4 implants to provide a full complement of teeth without cantilevers implied that long spans were created between the implants. However, an in vitro study involving 3 sets of prostheses from this patient group showed that there were no differences in the force distribution to the implants with the all–acrylic resin versus metal-reinforced prostheses.[22] Recent in vivo load measurements with different prosthesis materials support this conclusion for non-cantilevered restorations.[23] In vivo measurements with different numbers of supporting implants between the most posterior and anterior, respectively, have shown that 4 implants can provide equally good support as 5 or more.[24] Therefore, the low number and the large spread of the implants supporting the provisional prostheses may not necessarily be seen as causative for the implant failures.

Comparison of the developmental protocol—in which 10 to 14 implants were placed which, only 4 were loaded immediately, and 2 were in posterior positions—versus a protocol in which only 6 implants were placed but all were loaded and at least 4 were in an anterior position seems to support these findings. This would appear to favor the placement of fewer implants in optimal positions and in good bone quality and quantity.

Mandibular flexion may have played a role in implant losses, especially when the most distal implants were distant from the foramina. Mandibular flexure has been demonstrated and measured clinically in patients with osseointegrated implants.[25] While mandibular flexion may not be as significant with implants that are already osseointegrated, its effects may be more detrimental during the healing phase for osseointegration. Furthermore, increased occlusal loads in the posterior quadrants may also be an important factor during the early healing period.

A large number of implants were placed in immediate extraction sockets: 58 of 130 (45%) for the developmental group and 82 of 144 (57%) for the simplified protocol group. However, there was no statistically significant overrepresentation of failures in these sites. This may be related to the fact that extraction sites after alveoloplasty become much like previously edentulous sites, especially in the anterior mandible, because the extraction sockets are smaller and there is adequate native bone for anchorage beneath the sockets. Mechanical stability was achieved in all patients in this investigation population.

The bone level was similar between the immediately loaded and the submerged implants. These results correspond to the findings of Schnitman and coworkers, who observed the same positive response up to 10 years.[6]

The diabetic patient in the developmental group lost 3 of 4 immediately loaded implants and 1 of 11 submerged implants. In a recently published retrospective study of 214 implants in diabetic patients, an implant survival rate of 94.3% at second-stage surgery was reported.[26] Another retrospective study of 215 implants in diabetic patients has shown that the survival rate of dental implants in controlled diabetic patients is lower than documented for the general population (85.7% cumulative success rate after 6.5 years of function). This study found that the increase in failure rate occurred during the first year following prosthetic loading.[27] The present study supports this finding and suggests that diabetes could be a risk factor for immediate implant loading.

In the simplified protocol, the acrylic resin prosthesis provided adequate splinting of the implant positions, which apparently was maintained during the healing period. In fact, the authors believe that this could possibly be the most accurate method for impression making for an implant-supported prosthesis, since bone remodeling and healing take place over 3 months to adapt and conform to this prosthesis. With this newer method, the second-stage procedure is also quicker, more accurate, and more cost effective.

CONCLUSION

Within the limits of this investigation involving a single implant system, a predictable and simple concept for immediate implant prosthesis loading in completely edentulous mandibles is proposed. The results from the development of this technique indicated that it could be essential to maintain the initial implant splinting over a healing period of approximately 3 months and that implant placement

between the mental foramina provides optimal support. No specific exclusion criteria were used for patients in the study. However, the result in this investigation population suggested that diabetics and bruxers may be at increased risk of implant failure in the immediate loading situation.

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