A Prospective Multicenter Study Using Two Different Surgical Approaches in the Mandible with Turned Brånemark Implants: Conventional Loading Using Fixed Prostheses

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ABSTRACT

Background: The use of a submerged implant system in a nonsubmerged surgical procedure has been reported to have promising results. At the time this study was initiated, no prospective, comparative studies with randomization between submerged and nonsubmerged surgical techniques had been published.

Purpose: To evaluate the submerged and nonsubmerged surgical techniques when treating mandibular edentulism using a submerged implant system, with regard to implant survival and complications.

Materials and Methods: A total of 77 patients were included and treated at nine clinics in Sweden and Norway. In total, 404 Brånemark System implants (standard and MkII implants) were inserted in the edentulous mandible; 198 implants according to the nonsubmerged protocol and 206 implants according to the traditional submerged procedure. The follow-up period was up to 36 months after prosthesis insertion.

Results: In the nonsubmerged group, 17 implants out of 198 implants (8.6%) were lost and in the submerged group, 5 out of 206 implants (2.4%) were lost. All implant failures occurred before the delivery of the final prosthesis. No major complications were reported during the implant surgery. However, at the clinical check-up postoperatively and at the abutment connection surgery, 6 patients in the nonsubmerged group complained of pain at the implant sites, whereas there were no complaints of pain in the submerged group.

Conclusions: The results of this study suggest that a turned Brånemark implant designed for a submerged implant placement procedure can be used in a nonsubmerged procedure and may be as predictable as the conventional submerged approach.

KEY WORDS: dental implants, edentulous mandible, endosseous implants, submerged, nonsubmerged

A variety of endosseous implant systems are being used. There is the submerged, two-stage implant installation procedure or the nonsubmerged, one-stage implant installation procedure. The implants in the Brånemark System® (Nobel Biocare AB, Göteborg, Sweden) and other implant systems consist of two parts: the implant itself, which is in bone contact and submerged after the first surgical procedure, and the abutment, the transmucosal part, which is connected to the implant after the second surgical procedure. The latter system is collectively referred to as submerged or two-stage systems. Implants in nonsubmerged or one-stage systems are inserted during a single surgical procedure. The transmucosal part of these implants is integrated with the implant. Well-documented, long-term clinical studies have revealed that both implant types have good and predictable outcomes.[1–4]

The nonsubmerged implant installation has several advantages,[4] for example, only one surgical intervention is required resulting in a considerable cost-benefit advantage. The prosthetic phase can often start earlier because

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TABLE 1 Distribution of Patients in Treatment Groups with Regard to Gender, Age, and Follow-Up Period

Treatment Group	Number	Male/Female	Mean Age (SD) (years)	Age Range (years)	Mean Follow-Up Period (SD) (months)	Follow-Up Period Range (months)
Nonsubmerged group	39	18/21	63.5 (9.1)	47–89	34.6 (14.6)	0–50
Submerged group	41	16/25	65.5 (9.4)	44–84	35.6 (12.4)	5–53

no healing period is involved related to a second surgical procedure. However, the submerged technique is preferable in combination with bone augmentation, because it prevents overloading of the implants and secures an infection-free environment during the healing period. It also gives a possibility to alter the pink aesthetics, at the second surgery procedure, where it is demanded.

To use a two-stage/submerged implant system in a one-stage/nonsubmerged, surgical procedure has been reported to have promising results.[5–8] At the time this study was initiated, no prospective, comparative studies with randomization between submerged and nonsubmerged surgical techniques had been published.

The objective of this prospective clinical multicenter study was to verify earlier reported results regarding implant survival and prosthetic function at the nonsubmerged surgical procedure with Brånemark System® (Nobel Biocare AB, Göteborg, Sweden).[8,9] Furthermore, the nonsubmerged and submerged surgical techniques were compared with regard to procedure and follow up with special attention to occurring associated complications. In accordance to the objectives, the study was also to evaluate, in a large group of experienced clinicians, the nonsubmerged surgery procedure when treating mandibular edentulism with Brånemark System implants.

MATERIALS AND METHODS

Patients

A total of consecutive 80 patients (34 males, 46 females; mean age: 64.5 years; range: 44–89) with totally edentulous mandibles were included at nine clinics. Presurgical examinations were performed by a surgeon and a prosthodontist. The radiographic examination comprised panoramic and lateral radiographs, and if required, intraoral radiographs. The inclusion criteria were: (1) totally edentulous mandible and (2) possibility to place four to six implants for a fixed bridge. The exclusion criteria were: (1) general contraindications for implant surgery and (2) age less than 20 years. The patients were informed of the design of the study and randomized into one of two groups through an envelope system: Nonsubmerged group: implants and abutments were placed at the time of implants surgery. Prosthetics were made 3 to 4 months later. Submerged group: implants were left to heal submerged during 3 to 4 months when abutment connections were performed and the prosthetic treatment was started (Table 1).

Surgery

A total of 404 implants (Brånemark System, Nobel Biocare AB) were inserted; 198 implants according to the nonsubmerged protocol and 206 implants according to the traditional submerged procedure. The surgical procedures were performed under local anesthesia, according to the standard protocol used in each clinic. All implants in the nonsubmerged and submerged groups were inserted between the mental foramina after crestal incisions. Standard abutments and healing caps (Brånemark System, Nobel Biocare AB) were immediately connected to the nonsubmerged implants, and at a separate surgical procedure for the submerged implants 3 to 4 months later. Postoperatively, systemic antibiotics, analgesics, and chlorhexidine 0.2% mouth rinse were prescribed.

Prosthodontics

The dentures were relined 1 to 3 weeks after implant surgery and at/after abutment connection surgery. For the patients treated according to the nonsubmerged protocol, the prosthetic treatment procedure commenced 3 to 4 months following implant/abutment insertion. In the submerged group, the prosthetic treatment started following abutment connection surgery; 3 to 4 months after implant insertion. Fabrication of fixed prostheses followed the standard procedures for the Brånemark System.[10]

TABLE 2 Life Table Analysis for the Nonsubmerged Group

Time	Number of Successful Implants	Number of Failed Implants	Withdrawn	Cumulative Survival Rate (%)
Insertion – loading	198	17	6	91.4
Loading – 6 months	175	0	8	91.4
6 Months–1 year	167	0	11	91.4
1–3 Years	156	0	10	91.4
3 Years	146	—	—	—

Radiographic Examination

Preoperatively, panoramic, lateral, and periapical radiographs were used for the surgical planning and classification of the bone quantity, according to Lekholm and Zarb.[11] Radiographic examinations with periapical radiographs were made at the time of the abutment connection surgery or at the impression taking appointment (baseline) and at the follow up II (12 months after prosthesis insertion) and follow up III (36 months after prosthesis insertion).

Follow Up

Data were collected from the time of pretreatment examination, at the insertion of the implant/abutment, during the healing periods, at the prosthesis insertion, at the follow up I (6 months after prosthesis insertion), follow up II (12 months after prosthesis insertion), and follow up III (36 months after prosthesis insertion). Out of 80 patients, 59 patients were followed for 3 years after receiving the prosthesis, and 66 patients were followed for at least 1 year after receiving the prosthesis.

The following parameters were recorded: age, gender, medical history, oral status, nonsubmerged or submerged surgical procedure, type and number of implants placed and lost, bone quality and quantity,[11] prosthetic outcome, and complications. Data were analyzed using descriptive statistics and life table analysis.

RESULTS

Patients included in the two groups were similar in number, age, and gender and had a mean follow-up period of 34.6 months for the nonsubmerged group and 35.6 months for the submerged group (Table 1).

Of the 404 Brånemark implants placed in the two groups, 241 were of the standard design and 163 of the MkII design. During the healing phase and up to the delivery of the final prosthesis, a total of 22 implants (5.4%) were lost. After delivery of the final prosthesis, no implant failures occurred.

In the nonsubmerged group, 17 (8.6%) of 198 implants were lost, all before delivery of the final prosthesis, resulting in a cumulative survival rate of 91.4% (Table 2). The failed implants represented 6 patients.

Four patients in the submerged group experienced implant failures. Five (2.4%) implants out of 206 failed, all before the delivery of the final prosthesis, resulting in a cumulative survival rate of 97.6% (Table 3).

Thus, the patients in the submerged group showed a higher survival rate than the patients in the nonsubmerged group.

TABLE 3 Life Table Analysis for the Submerged Group

Time	Number of Successful Implants	Number of Failed Implants	Withdrawn	Cumulative Survival Rate (%)
Insertion – loading	206	5	0	97.6
Loading – 6 months	201	0	5	97.6
6 Months–1 year	196	0	15	97.6
1–3 Years	181	0	19	97.6
3 Years	162	—	—	—

TABLE 4 Bone Quality and Implant Failures

Bone Quality Nonsubmerged	Inserted Implants	Failed Implants
1	6	0
2	126	9
3	60	7
4	6	1
Total	198	17
Bone Quality Submerged	**Inserted Implants**	**Failed Implants**
1	32	1
2	101	3
3	62	1
4	11	0
Total	206	5

Classification according to Lekholm and Zarb.[11]

The implant failures in relation to bone quality and quantity (Tables 4 and 5) and to implant type and length (Table 6) were evaluated and no clinical differences between the two groups could be stated. The reported complications during the study period indicate slightly more reactions for the patients in the nonsubmerged group (Table 7). During the implant surgery, no major complications were reported for either group. At the clinical check-up postoperatively 6 patients complained about pain in the nonsubmerged group compared to none in the submerged group. Besides implant failure, reported pain and soft tissue reactions reported at the clinical check-up/abutment connection visit, the complication pattern during the study period was similar in the two groups.

TABLE 5 Bone Quantity and Implant Failures

Bone Quantity Nonsubmerged	Inserted Implants	Failed Implants
A	15	0
B	118	11
C	50	6
D	15	0
E	0	0
Total	198	17
Bone Quantity Submerged	**Inserted Implants**	**Failed Implants**
A	17	1
B	78	1
C	65	2
D	46	1
E	0	0
Total	206	5

Classification according to Lekholm and Zarb.[11]

TABLE 6 Distribution of Placed Implants with Regard to Number, Type, and Length

Nonsubmerged Implant Length (mm)	Standard	Mk II	Failed Implants
10	22	2	2
11.5	0	4	0
13	19	10	1
15	59	26	11
18	26	30	3
Total	126	72	17
Submerged Implant Length (mm)	**Standard**	**Mk II**	**Failed Implants**
8.5	4	0	0
10	17	21	3
11.5	0	0	0
13	41	21	0
15	44	27	2
18	9	22	0
Total	115	91	5

The proposed radiographic examinations had not been consistently performed at the different examinations and could therefore not be taken in consideration for an analysis.

DISCUSSION

The present study compared the clinical outcome of implant treatment in 39 patients with edentulous mandibles using a nonsubmerged surgical procedure and 41 patients using a submerged surgical procedure. There was no clinical difference demonstrated in CSR for the nonsubmerged and submerged groups after a follow up of 2 to 3 years. In the nonsubmerged group, the CSR was 91.4%, and in the submerged group, the CSR was 97.6%. Out of 77 patients followed, included the prosthesis insertion visit, all (100%) received a fixed prosthesis.

The survival rate of 91.4% with the nonsubmerged versus 97.6% with the submerged procedure could be considered a tendency toward greater implant losses with the nonsubmerged technique. Other similar

TABLE 7 Complications Reported (Number of Events)

At Implant Insertion	Nonsubmerged	Submerged
Exposed threads	18	16
Unstable implant	2	2
Excessive bleeding	0	5
Other	5	1
Non-device related	2	4
At Clinical Checkup/Abutment Connection		
Implant loss (five patients)	14	2
Paresthesia	3	6
Soft tissue reaction	13	2
Pain (six patients)	18	0
Abutment screw loosening	4	0
Other	13	3
Fracture of relined denture	0	1
At Prosthesis Insertion		
Implant loss	3	3
Soft tissue reaction	1	1
Pain	2	3
Fracture of relined denture	4	0
Other	2	2
Non-device related	2	1
At 6-Month Follow Up		
Soft tissue reaction	1	4
Abutment screw loosening	0	2
Fracture of prosthesis veneer	0	1
Pain	0	1
Other	1	3
Non-device related	3	6
At 1-Year Follow Up		
Fracture of prosthesis veneer	14	0
Other	1	9
Non-device related	2	2
Soft tissue reaction	3	0
At 3-Year Follow Up		
Fracture of prosthesis veneer	2	1
Paresthesia	2	0
Soft tissue reaction	1	0
Fracture of prosthetic framework	0	1
Other	0	9

studies[9,12] comparing the nonsubmerged and submerged procedures reveal a similar result with no significant difference in survival rate. However, like the report by Ericsson and colleagues,[9] where a split-mouth design was used, the survival rate among the nonsubmerged implants was lower (93.9%) compared with the submerged implants (100%); there is an indication that there might be a greater risk of implant failures with a nonsubmerged technique compared with a submerged technique.

All implant failures were early losses, occurring before loading. One causative factor for the early failures could have been occlusal overload during the healing period, which resulted in inadequate tissue response, and thereby, impaired osseointegration. Factors of significant importance for overload are denture stability and fit, occlusion, bite force, and opposing dentition.[13] Another factor could be the abutment surgery and conveyed rotational forces to the implant/bone interface associated with tightening of the abutment screws.

The care of the provisional denture during the healing phase was maybe not as optimal in the nonsubmerged group as it was in the submerged group, and using standard abutments including healing caps instead of healing abutments during the healing phase could be another reason to overload. The centers participating in this study had a tradition and more experience of working with the submerged procedure, which also could be one causative factor to the better survival rate of this group.

The adjusted and relined denture causes an indirect load through the oral mucosa causing more or less trauma to the implants installed, according to the submerged procedure. In the nonsubmerged procedure, the implants are most likely more traumatized because of early loading conditions. The extent of load of the implants, during the healing phase, might be the reason of an impaired and failed osseointegration. There are studies though, reporting that trauma, to some extent, could be favorable to the osseointegration and by stimulating the bone healing.[14] The optimal loading conditions to the implants during the healing phase, in a clinical point of view, are yet to be investigated. Thus, the true reason for the failure to osseointegration largely remains obscure.

Early or immediate loading, where the loading of splinted implants starts 0 to 3 weeks after implant

installation and therefore before osseointegration has taken place, is currently well tried and has been presented in several reports.[15,16] Friberg and colleagues[14] reported a resonance frequency analysis in patients with a good primary stability of the implants in the mandible, where little or no further stability was gained after 3 months of healing. Therefore, the risk with early loading of splinted mandibular implants should be small. In a second part of this study, the results of early loading will be investigated.

The denture is normally used during the healing period after it has been relieved and relined with tissue conditioner. However, different approaches to these procedures could cause unfavorable loading conditions and thereby establish trauma to the implant region and implant failures.[17,18]

The space between the implant and the abutment has, in some experimental studies, been demonstrated to give an inflammatory infiltrate in the connective tissue adjacent to the implant.[19] The advantages of a one-piece implant have for that reason been discussed.[20] On the other hand, other reports suggest that the space between the implant and the abutment is of negligible importance to the clinical outcome.[21] The peri-implant sulcus can and does harbor potential periodontal pathogens without significant signs of tissue breakdown.

The results of this study suggest that dental implants designed for a submerged implantation procedure can be used in a nonsubmerged procedure and may be as predictable as the conventional submerged approach.

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