Outcome of Brånemark Novum® Implant Treatment in Edentulous Mandibles: A Retrospective 5-Year Follow-Up Study

Federico Gualini, MD, DDS, Odont. Lic.;* GianLuigi Gualini, MD, DDS;† Roberto Cominelli, DDS;‡ Ulf Lekholm, DDS, Odont. Dr.§

ABSTRACT

Background: A gradual progression from a two-stage surgical technique to a one-stage and even immediate surgical protocol has occurred during the last decade with most oral implant systems. However, every new approach must obviously be reported individually, with long-term results, in order to assess whether the changes have any real patient value.

Purpose: The aim of the present report was to retrospectively review the 5-year outcome of patients treated with the Brånemark Novum® (Nobel Biocare AB, Göteborg, Sweden) protocol.

Methods: The first 15 patients treated according to the Novum procedure in a private specialist clinic in Lovere, Italy, were followed-up with clinical, radiographic, and resonance frequency analyses. All the patients' fixed constructions had been in function for an average of 5 years. Parameters recorded were implant survival, prosthesis success, oral hygiene and mucosal health, marginal bone remodeling, type and frequency of complications, and patient's opinion of the treatment outcome.

Results: After 5 years, the cumulative survival rate for implants was 91%, and for inserted bridge constructions it was 87%. Very small changes in implant stability occurred during implant loading from 1 to 5 years. Oral health conditions were good; 87% of mucosal quadrants around the implants were free from signs of inflammation. Very small marginal bone height changes were observed at the implants during the examination period, and except for four implant losses reported, severe complications were few. All patients were satisfied with the functional outcome of their constructions, but two patients were not completely happy with the aesthetics of their bridgework as supplied.

Conclusion: This report shows 5-year evidence of acceptably good results with the Brånemark Novum implant technique in edentulous mandibles, when using only three implants to support the fixed bridge construction, and as long as inserted implants become and remain osseointegrated.

KEY WORDS: Brånemark Novum implants, edentulous mandibles, retrospective, 5-year follow-up study

INTRODUCTION

The original Brånemark oral implant protocol[1] was a two-stage surgical procedure, using a gentle surgical technique and allowing 3 to 6 months of healing between placement and loading of implants. With time and certain anatomical conditions of the jaws, this implant was also used with a one-stage technique, which now is frequently used.[2–4] The obvious advantages are no second surgical intervention and reduced discomfort for the patient. Outcomes of the one-stage technique equivalent to those of the original protocol have been reported,[4,5] but mainly when some time of healing was allowed before actively loading the implants.[3,4]

More recently, a further development of the Brånemark procedure was described,[6] in which the implants were loaded shortly after insertion, that is, *early loading* within days or weeks after placement. Such an approach has been used with overdentures and full fixed

*Partner, The Gualini Specialist Clinic, Lovere, Italy; †partner, The Gualini Specialist Clinic, Lovere, Italy; ‡associate, The Gualini Specialist Clinic, Lovere, Italy; §professor and chairman, The Specialist Clinic of Oral and Maxillofacial Surgery, Public Dental Health Service of Västra Götaland and the Sahlgrenska Academy, University of Göteborg, Göteborg, Sweden

Reprint requests: Dott Federico Gualini, Studio Associato Gualini Maironi, via Oprandi, 4; 24065 Lovere (Bergamo) Italy; e-mail: fguali@tin.it

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bridges,[7–10] as well as with partially edentulous jaws and single-tooth replacement.[11,12]

Immediate loading most commonly refers to implants being in function within 24 hours of placement.[13,14] Follow-up results of such direct loading protocols using various levels of prefabricated components have been reported.[15,16] Procedures are even available today for placement of the implants using computer-aided techniques. This facilitates insertion in the most favorable position and direction and allows the immediate loading of the implants with provisional constructions.[17] However, long-term follow-up reports of these new immediate loading protocols are scarce.

The Brånemark Novum® (Nobel Biocare AB, Göteborg, Sweden) technique[13] is based on inserted implants being loaded within hours of insertion. To enable treatment completion in such a short time, the implants must be inserted in preset positions, using a preformed surgical stent for the positioning. Prosthesis manufacture also relies on prefabricated components, the lower bar attaching to the implants at placement, and the upper bar on which the prosthesis is built before attachment to the substructure.[18] Since the introduction of the Novum protocol in 1999,[13] relatively few follow-up reports on the technique have been published, most with short follow-up times, but still indicating the potentials of the procedure.[19–21] However, whenever new clinical protocols gain general acceptance, longer follow-up results must be sought so that clinicians may learn from the experience of others, whatever the outcome.

The aim of the present investigation was to review the outcome of early Novum implant treatments in 15 patients after an average of 5 years in clinical function.

MATERIALS AND METHODS

Patients and Preoperative Examinations

This study comprised patients consecutively treated using a team approach in a private specialist clinic in Lovere, Italy, between December 2000 and June 2003. Fifteen patients (4 women and 11 men), aged 63.5 years old (range: 55–78 years), were provided with implant-supported constructions in the lower jaw (Table 1). The treatment was performed according to the Novum technique described by Brånemark and colleagues.[13] The indications for selecting this protocol were (1) that the treatment was cheaper than the conventional two-stage implant treatment and/or (2) was a one-day clinical procedure.

TABLE 1 Distribution of Patient Characteristics

Patient Number	Sex	Age (years)	Preoperative Condition*	Opposing Dentition†
1	F	59	Edent	Nat dent
2	M	75	Part edent	Dent
3	M	60	Part edent	Nat dent
4	F	55	Part edent	Nat dent
5	F	63	Edent	Dent
6	M	67	Part edent	Part dent
7	M	67	Part edent	Dent
8	M	64	Part edent	Impl
9	M	56	Edent	Dent
10	M	62	Part edent	Impl
11	F	62	Edent	Dent
12	M	78	Part edent	Dent
13	M	61	Part edent	Part dent
14	M	65	Edent	Impl
15	M	58	Edent	Nat dent

*Preoperative dental condition in treated jaw.
†Preoperative dental condition in opposing jaw.
M = male; F = female; Edent = edentulous; Part edent = partially edentulous; Nat dent = natural dentition/crowns and bridges; Dent = removable complete denture; Part dent = removable partial denture; Impl = implant-supported construction.

Six patients were edentulous and nine were partially edentulous in the treated mandible on the day of surgery (see Table 1). Partially edentulous individuals had their remaining lower jaw teeth extracted, mainly because of severe periodontitis, the day the implants were inserted. Most patients (60%) were also edentulous in their upper jaw on the day of surgery, using either maxillary full dentures ($n = 6$) or implant supported constructions ($n = 3$). The remaining six patients were dentate ($n = 4$) or used removable partial dentures ($n = 2$) in the opposing jaw (see Table 1).

Prior to Novum implant insertion, the patients and their jaws were clinically assessed for medical and oral health conditions and inter-jaw relation, according to the techniques described by Brånemark and colleagues.[13] The jaws were also radiographically examined according to the Novum protocol[13] and in accordance with Gröndahl and colleagues,[22] with panoramic, lateral, and axial projections obtained to identify anatomical conditions and pathology within the areas to be treated. Jaw shape and bone quality were assessed in accordance with Lekholm and Zarb[23]; the majority of mandibles

TABLE 2 Distribution of Jaw Shape and Bone Quality in Treated Jaws Judged according to Lekholm and Zarb[23]

Patient Number	Shape/ Quality	Implant Lengths (mm)	Follow-Up Time (months)
1	C/2	3 × 11.5	62
2	A/4	3 × 13.5	2‡
3	†	3 × 11.5	65
4	B/3	3 × 11.5	57
5	D/2	3 × 11.5	65
6	B/2	C* × 11.5 + 2 × 13.5	4‡
7	C/2	3 × 11.5	64
8	B/3	3 × 11.5	69
9	B/3	3 × 11.5	72
10	B/3	3 × 11.5	63
11	A/3	3 × 13.5	68
12	B/4	3 × 11.5	59
13	B/2	3 × 11.5	60
14	D/3	3 × 11.5	52
15	C/2	C* × 13.5 + 2 × 11.5	42

*Central implant.
†Missing data.
‡Failed patient.

conforming to shape group B and quality groups 2 or 3 (Table 2).

Treatment Protocols

In principle, the surgical and prosthetic procedures followed the original Novum protocol described by Brånemark and colleagues.[13] In all, 45 Novum implants, having a machined surface and being of 5 mm in diameter and 11.5- ($n = 36$) or 13.5 mm in length ($n = 9$), were placed (see Table 2). In some patients, the insertion of the Novum prefabricated upper bar would have interfered with the opposing jaw and/or teeth/constructions, a surgical stent was thus produced to guide the surgeon on the amount of alveolar bone to be removed from the mandible prior to applying the surgical guide in the correct relation to the prosthetic mounting.

Once implants were inserted, a prefabricated Novum lower bar was attached ($n = 15$), and onto this a fixed construction fabricated on a Novum upper bar was connected. The prostheses were finalized and inserted on the day of surgery, or the morning after if surgery had taken place in the afternoon of the previous day. The fixed prostheses were designed as 12 unit constructions, extending from first molar to first molar.[18] Some minor adjustments of the prosthetic protocol were performed as follows. The vertical occlusal dimension was established and the intermaxillary relation determined via the McGrane technique, modified according to Gerber.[24] Thereafter, extra- and intraoral jaw registrations were performed. In the extraoral phase, the dynamic facial arc enabled the characterization of the relation between the mandible and the skull, together with a graphic registration of the sagittal condylar route, in order to optimize the orientation of the occlusal plane. In the intraoral phase, the mandibular excursions in protrusion, retraction, and lateral motion were traced in the horizontal plane. Hence, it was possible to determine the basic therapeutic position of the jaws in order to optimize the aesthetic and functional outcomes of the treatment.

In some patients, treatment or modification of existing prostheses in the upper jaw was required to facilitate the lower jaw treatment. In one patient, for example, an upper temporary full-arch implant-supported prosthesis was attached simultaneously with the lower jaw treatment. In a further five patients, adjustments were also required, whereas 9 of the 15 patients (60%) required no such handling.

Baseline Registrations

At implant placement, the 15 patients were radiographically assessed using panoramic imaging[22] to obtain *baseline registrations* for follow-up assessments of the osseointegration of – and marginal bone level at – implants inserted. The initial marginal bone-implant contact level was located on the first implant thread level at the mesial and distal surfaces of all implants; confirming adherence to the surgical protocol.[13] Furthermore, clinical photographs were taken throughout the treatment steps.

Follow-Up Registrations

All patients were clinically followed regularly after 3, 6, 9, and 12 months postoperatively and, thereafter, annually. The treatment outcome and any problems with the Novum protocol were then noted and documented clinically and, when applicable, radiographically.

At *final assessment* during the last quarter of 2006, clinical and radiographic registrations were carried out, meaning that the last treated patient (number 15) was followed-up in all 42 months (3.5 years). The first patient (number 9) had then been followed for 72

TABLE 3 Resonance Frequency Analyses (Implant Stability Quotient Values*) Recorded during the First Year of Loading (First Control), after 42 months (Intermediate Control), and 62 months (Final Control) of Implant Function

Patient Number	First Control (12 months)	Intermediate Control (42 months)	Final Control (62 months)
1	R58C51L53	R65C71L63	R61C68L769
3	R47C64L60	R54C65L64	R58C72L67
5	R69C67L65	R69C67L67	R70C69L73
7	R56C62L54	R57C64L67	R72C67L70
10	R69C68L92	R71C70L91	R93C92L93
11	R78C70L70	R78C70L74	R79C70L74
14	R54C65L64	R65C71L74	R64C70L68

*Meredith and colleagues.[25]
Implant position: R = right; C = central; L = left.

months, giving a study average of 5 years. The following parameters at each implant were examined:

1. survival rate – this was assessed clinically after the removal of the lower jaw construction and/or by panoramic or intraoral radiographs;
2. resonance frequency analysis (RFA) – this was assessed during follow-up as described further;
3. prosthesis success – this was extracted from patient records;
4. mucosal health – this was assessed subjectively by an examining clinician (F.G.) in four quadrants around each implant, and the number of affected quadrants was noted;
5. marginal bone remodeling – as studied by two of the authors (F.G. and R.C.) from panoramic radiographs, being taken at implant placement and from intraoral radiographs taken at the final checkup, and using the first thread as the reference point for measurements;
6. treatment complications – these were extracted from patient notes; and
7. patient satisfaction – this was rated from a self-administered questionnaire.

During the follow-up period, every second patient ($n = 7$) was also assessed with RFAs for implant stability quotient (ISQ) as described by Meredith and colleagues[25] using Osstell equipment (Integration Diagnostics AB, Göteborg, Sweden). The first measurement was performed (Table 3) when the implants had been in function on an average of 12 months (first control). A second examination was carried out after about 42 months (intermediate control), and the final measurement after a mean of 62 months of loading (final control).

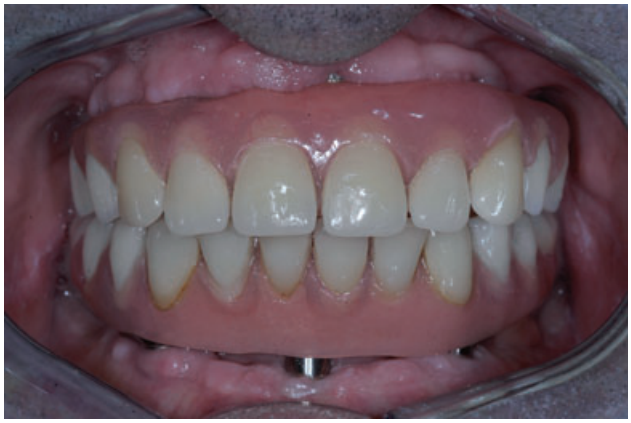
RESULTS

Of the 45 Novum implants originally placed, four failed because of the absence of bone to implant integration: two in one patient after 2 months of loading, and two in another patient after 4 months of function (see Table 2). All implants lost had been placed in distal sites. Both patients affected were men having periodontally compromised mandibular teeth extracted at the time of implant insertion. Their mandibles were categorized as shape and quality A/4 and B/2, respectively. The two patients were reoperated directly after removing the loose Novum implants, using conventional Brånemark implant components (Nobel Biocare AB) and were subsequently provided with new conventional implant-supported fixed bridge constructions.[26] The patients were considered as total failures with the Novum protocol. However, their surviving central Novum implants continued to be followed throughout the study.

The remaining 39 implants, supporting 13 fixed Novum constructions (Figure 1) in as many patients, and the two central implants still in function within the two failed patients (in total $n = 41$ implants), functioned well during the entire follow-up period, being on average 62 months (range: 42–72 months; see Table 2). Consequently, the cumulative implant survival rate was 91.1% after 5 years of clinical function (Table 4). The corresponding prosthesis success rate was 86.7% (13/15).

The RFAs of 21 Novum implants in seven patients reported mean stabilities for each patient of 64 ISQ units (range: 54–76) at the first control. A modest increase was observed thereafter (mean increase of +4.4 ISQ units; range: +1 to +12) from the first to the intermediate control. A further increase of +3.0 ISQ units was observed up to the final control performed 20 months later (range increase from 0 to +7 ISQ units, respectively). The two distal implants demonstrated stability almost identical to the central implant at the three control occasions (64/64 ISQ units at 12 months distal/central, 68/68 at 42 months, and 72/73 at 62 months). A similar pattern in stability increase was also observed for implants inserted in jaw shapes A and B versus C and D from the first to the final control. The corresponding changes for jaw bone quality were also similar.

A



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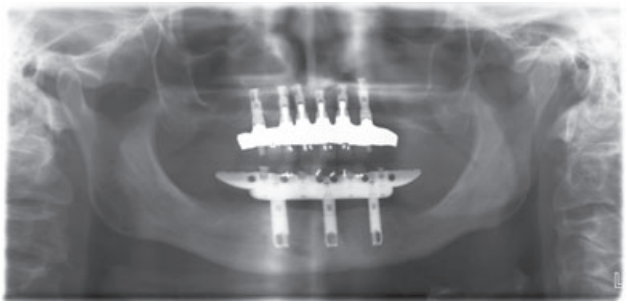

Figure 1 Clinical (A) and radiographic (B) appearances of a Brånemark Novum lower bridge construction 5 years after insertion.

The oral mucosa health around the implants was good in most patients at the final follow-up examination (Figure 2); only 20 of the 156 sites examined registered swelling, redness, and/or bleeding on probing (87% healthy quadrants). No suppuration was seen from any of the peri-implant mucosa sulcuses. However, some

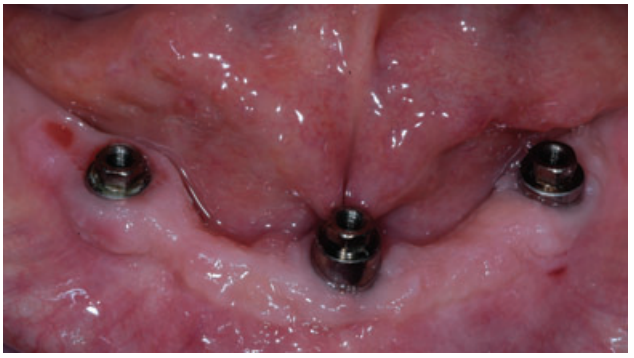

Figure 2 Clinical appearance of mucosa surrounding implants in function for 5 years; healthy soft tissues.

patients still exhibited plaque and/or calculus on their lower bar, or even on the exposed parts of the abutments (Figure 3), when constructions were removed to check the implant stability.

Marginal bone remodeling mesially and distally at implants was minute. After an average follow-up of 62 months (42–72 months), 11 patients showed no bone loss below the reference point, that is, the first thread level (Figure 4). One patient averaged 0.1-mm loss over the 6 sites, and in the 13th patient, the remodeling was as a mean 0.5 mm for the three implants (Figure 5). In the remaining two patients, no measurements were performed at their surviving central implants. Radiographic registrations were possible at all of the 78 mesial and distal implant surfaces present for the final assessment.

During the follow-up period, some treatment complications other than fixture losses were seen (Table 5).

TABLE 4 Life Table Analysis of Brånemark Novum Implants Placed during the Period from December 2000 to June 2003 and Followed-Up during the Autumn of 2006

Months after Implant Placement	Total Number of Implants at the Start of the Period	Number of Failures within the Period	Number of Implants Lost to Follow-Up Because of Death	Number of Implants Lost to Follow-Up within the Period	Cumulative Success Rates (%)
Placement–3 months	45	2	0	0	95.6
3–6 months	43	2	0	0	91.1
6–12 months	41	0	0	0	91.1
12–24 months	41	0	0	0	91.1
24–36 months	41	0	0	0	91.1
36–48 months	41	0	0	0	91.1
48–60 months	41	0	0	17*	91.1
60–72 months	24	0	0	24	91.1
72 months	0				

*Including the two still-functioning implants remaining in the two failed patients (patient numbers 2 and 6 in Table 1).

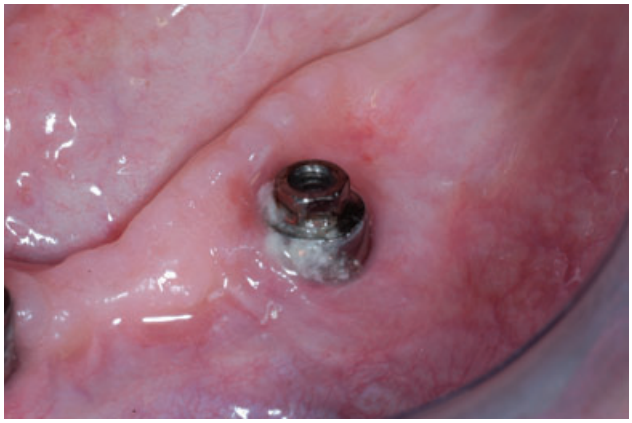

Figure 3 Clinical appearance of a Brånemark Novum implant, protruding above the mucosa level and covered with copious plaque.

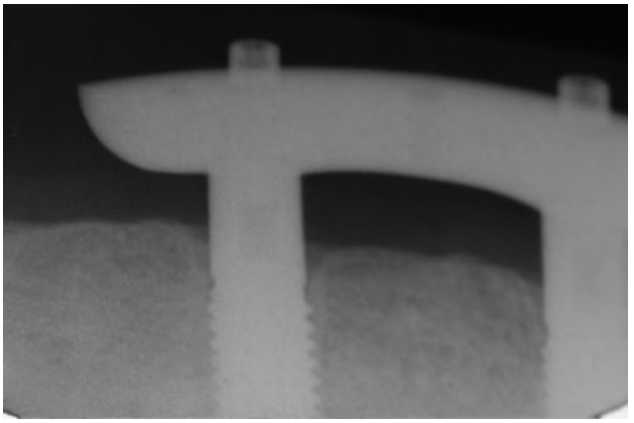

Figure 5 Radiographic appearance of a Brånemark Novum implant where marginal bone loss has extended below the first thread level mesially and distally; as seen after 5 years of loading.

The most commonly occurring problems were resin or teeth fractures ($n = 12$), followed by screw loosening ($n = 6$), and the need for upper bar modification ($n = 6$). It is interesting to notice that 90% of the resin/teeth fractures occurred in 3 of the 13 patients being continuously followed.

All patients were satisfied with the function of their implant-supported fixed Novum prosthesis when questioned at the final follow-up control. However, 2 of the 13 patients interviewed were not totally satisfied with the aesthetics of their Novum construction and rated its appearance as just acceptable.

DISCUSSION

This investigation of the Brånemark Novum protocol showed implant survival (91%) and prosthesis stability (87%) that was considered acceptable, in the view of using three implants to support full bridge constructions in immediately loaded situations, and after 5 years of clinical function. Similar outcomes have also previously been reported for shorter observation periods.[13,19,20] However, compared with the outcome, when the original two-stage Brånemark protocol is used,[27] the results seem to be somewhat inferior. The most probable reason for the failures in the two patients losing four implants in the present study was that those implants failed to achieve sufficient initial stability to become integrated. Their jaws were classed as shapes A and B, so even using the longest implants available (13.5-mm

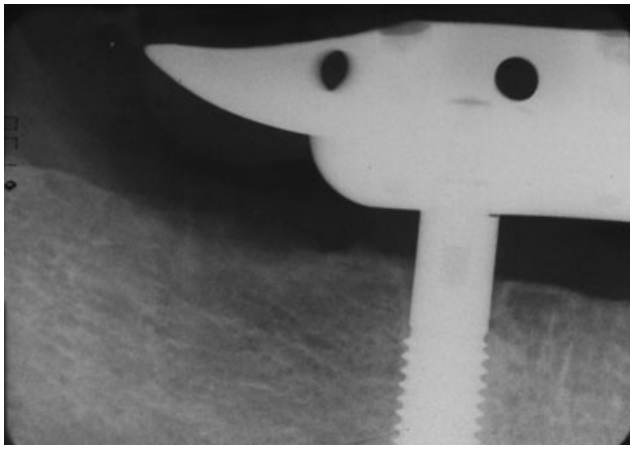

Figure 4 Radiographic appearance of a Brånemark Novum implant, surrounded by marginal bone well above the first thread level; as seen after 5 years of loading.

TABLE 5 Complications in Brånemark Novum-treated Patients during the 5-Year Follow-Up Period

Type of Complication	Number of Complications
Upper bar modifications	6
Soft tissue pathologies needing treatment	0
Screw loosening of either upper bar screws and/or lower bar screws	6
Bridge resin fractures (including resin teeth fractures)	12*
Upper bar anchorage unit fractures	3
Problems related to vertical occlusal dimension	3
Abrasion	3
Lip paresthesia after surgery	0

*Ninety percent in three patients.

long) did not reach sufficient dense bone at the tip. Having only two implant lengths (11.3 and 13.3 mm) is of course a limitation of the Novum technique when treating jaws with much alveolar bone still present. The use of implants having a "smooth" machined surface could, of course, have been another reason for the current failures of implants being placed in immediate extraction sites.

It has been suggested[10] that implants should display a stability of 60 ISQ units or better to be immediately loaded. Therefore, it would have been interesting if assessments of initial implant stability had been performed in all patients before attachment of the lower Novum bar. However, no resonance frequency measurements were carried out from the commencement of this study. Instead, assessments were only obtained for alternate patients during the first year of function, and thereafter at 3.5 and 5 years. However, these registrations showed very small increases in stability of the implants examined. No differences were detected between distal sites and central implants, and no differences were seen between implants inserted in different bone quality or jaw shape either. Consequently, the most interesting period to be observed would have been from installation to the first monthly test, as has previously been shown by Friberg and colleagues.[28]

In general, the oral mucosa was healthy (87% of the quadrants around the implants showed no signs of inflammation). Radiographic assessment of marginal bone loss supported this observation; only very small losses below the first thread were observed, and those in just two patients. Similar good results have previously been reported for Novum patients,[13] but for shorter observation periods, and for patients treated according to the conventional Brånemark protocol.[29]

The marginal bone levels were measured relative to the first thread. Because of the surgical technique and the dimensions of the implants, the highest bone-implant contact on the mesial and distal surfaces of the implants, consequently, was initially on that level. Bone could, of course, have integrated higher on the implants during the early stages of healing, had they been inserted deeper. However, because of the examination technique currently used, changes within the bone above the first thread level could not be detected. Besides, the radiographic examinations of the marginal bone level were performed in panoramic radiographs from start except in intraoral pictures at the final examination because the current assessments followed the original Novum protocol[13] for radiographic examinations.

The complications experienced during the follow-up period (see Table 5), apart from the implant losses, were mainly related to the prosthetic part of the treatment, that is, resin teeth fractures and screw loosening. Similar outcomes have also been reported for the conventional Brånemark protocol.[30] The Novum technique often also required upper bar adjustments and extensive mandibular alveolar bone remodeling (six patients; Table 5), not generally needed with the original technique. However, when the Novum protocol was introduced, clear indications for its use were described,[31] suggesting that patients with too high alveolar crests were not suitable for this procedure.

The questionnaire showed that all treated patients were satisfied with the function of their constructions, although two patients had concerns about the appearance of their fixed bridges. However, the inclusion criteria used (ie, a 1-day protocol and/or the fixed construction to be at a low-cost level) are possible reasons not to allow for sophisticated aesthetics.

In conclusion, the Brånemark Novum implant protocol seems to be a useful oral implant procedure for immediate loading in edentulous mandibles, as long as careful patient selection is enforced and patients are properly informed preoperatively about the limitations and potentials of the protocol.

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