Brånemark Novum Immediate Loading Rehabilitation of Edentulous Mandibles: Case Series with a 16-Year Follow-up

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The aim of the present report was to evaluate the clinical outcomes of edentulous jaws rehabilitated with the Brånemark Novum protocol over a 16-year period. Between April and November 2001, four patients (three males, one female) were rehabilitated with fixed full-arch rehabilitations supported by three immediately loaded implants following the Brånemark Novum protocol. Cumulative survival rates (CSRs) of the implants and prosthesis, bleeding on probing (BOP), Plaque Index (PI), probing depth (PD), implant stability quotient (ISQ; as measured through resonance frequency analysis [RFA]), and peri-implant bone resorption were evaluated over time, up to the 16-year follow-up. At 16 years of follow-up, no implant failed (CSR 100%) and no prosthesis needed to be substituted (CSR 100%). During the period between the 11th and 16th year of follow-up, bone level (mean: 2.2 mm at 16 years) and RFA values remained stable. At the 16-year follow-up, the implants presented high PI (79.2%) but low BOP (10.4%) values. Mean PD was 3.30 mm (range: 2 to 6 mm). One biologic complication was detected on a central implant (crater-form bone destruction), and several prosthodontic complications occurred during the 16 years (fractures of resin or teeth), the majority of which were registered on the same parafunctional patient. This is the first description of the Brånemark Novum protocol rehabilitation with a 16-year follow-up. The outcomes demonstrated very good long-term outcomes for this protocol. Int J Periodontics Restorative Dent 2019;39:729–735. doi: 10.11607/prd.4340

In order to reduce treatment time and improve patient comfort and satisfaction, at the beginning of the 2000s, full-arch immediate loading rehabilitations were proposed as an alternative to the traditional delayed loading protocol introduced by Brånemark. Using immediate loading, patients did not need to wear provisional complete dentures and their satisfaction was found to be significantly higher than with the traditional delayed loading.¹

Immediate full-arch rehabilitation of totally edentulous patients allows the restoration of patients’ esthetic and phonetic function within 24 to 48 hours,² allowing patients to return immediately to their normal social and working life.

To date, numerous studies have demonstrated the high predictability of immediate loading rehabilitations over the medium-term follow-up and when using a reduced number of implants.³,⁴ A review of the literature reported that even though immediate-loading rehabilitation presents greater possibilities for failure, the percentage of success is high and comparable to the delayed load method.⁵ However, long-term studies are lacking.³,⁴

The first codified immediate-loading rehabilitation proposed at the beginning of 2000 was the Brånemark Novum protocol (Nobel Biocare). It consisted of the place-
ment of three implants in the inter
foraminal zone and the delivery of
the prosthesis within the same day.2

The Brånemark Novum proto-
col sought a reduction in implant
prosthodontic treatment time, plus
improvement in patient comfort
and satisfaction. It offered an al-
ternative to the traditional delayed
loading protocol that introduced the
osseointegration technique to the
dental profession. It also pro-
vided the genesis for subsequent variations of versatile and diverse
clinical protocols that facilitated
high predictability of immediately
loaded rehabilitations over varying
time periods when a reduced num-
ber of implants are used and imme-
diately loaded.

One of the main disadvantages
of the Novum protocol was the ri-
gidity of the procedure, providing
the use of drilling templates for im-
plant insertion and prefabricated
prosthetic bars that were not cus-
tomized. This protocol could be ap-
plied only in patients with specific
anatomical characteristics of the
mandibular arch. It is for this reason
that the protocol was abandoned.6

However, this protocol demon-
strated favorable clinical outcomes7
and had the merit of indicating some
key factors for successful outcomes
of full-arch immediate-loading reha-
bilitations, namely standardized sur-
gical and prosthesis protocol, rigid
splitting of the implants, passive-
fitting and screw-retained prosth-
esis, a reduced number of implants,
and occlusal material with shock-
absorption capacity.

The authors’ prior publication6
provided 11-year data on treatment
outcomes for a selected group of
patients while the present report
provides clinical outcome details
following 16 years of experience
with the Novum approach.

Materials and Methods

Between April and November 2001,
four patients (one woman and three
men) with edentulous mandibles
(n = 2) or seriously unfavorable prog-
noses of their mandibular dentition
(n = 2) were treated following the
Brånemark System Novum protocol
at the Division of Implant and Pros-
thetic Dentistry of Genoa University.

The present report was conduct-
ed in accordance with the Helsinki
Declaration and was approved by the
local Scientific Ethical Commit-
tee of the University of Genoa.

Patients were in good general
medical conditions. Inclusion and
exclusion criteria are reported in a
previously published report.6 In par-
ticular, patients needed sufficient
bone volume to accommodate a
minimum of three implants (5 mm in
diameter, 11.5/6 mm or 13.5/7 mm
in length), and a sufficient mouth
opening (minimum 50 mm) was
needed to obtain complete access
with instruments and components.
Mandibles conforming to V shape
or group E of the Lekholm and Zarb
atrophy classification8 were consid-
ered exclusion criteria.

All patients were rehabilitated
with fixed full-arch rehabilitations
supported by three immediately
loaded implants. The implants
placed (Fixture Novum, Nobel Bio-
care) had a machined surface, 5-mm
diameter, and 11.5/6-mm (six im-
plants in two patients) or 13.5/7-mm
(six implants in two patients) length.
Before implant insertion, crestal
bone remodeling was performed to
create a 7-mm–wide bone platform
to accommodate the prefabricated
templates.

Four surgical templates were
used during implant site prepara-
tion. The first one (“guide template”) was
used to mark the positions for implant insertion. The second guide
(“evaluation template”) was used to
control the final position, angula-
tion, and parallelism of the implants.
Then, special drill guides of gradu-
ally increasing dimensions were
placed on top of the third template
(“positioning template”), and the
central fixture site was completely
prepared.

After placing the central im-
plant, a last template (V template)
was attached to the central implant
and used for the preparation of
distal implant sites.

When all three implants had
been inserted, the prefabricated
titanium lower bar was connected
to the transmucosal portion of the
implants.

All prostheses contained 12
units. Each was endowed with the
prefabricated titanium upper bar
and was attached at the lower bar
with four retaining screws, using an
electric torque device with preset
values (20 Ncm).

All patients were visited at 3, 6,
9, and 12 months postoperatively
and annually thereafter for dental
hygiene reinforcement, up to the
16-year follow-up appointment (Figs
1 and 2).
Fig 1  Panoramic radiograph at one patient's (a) 10-year and (b) 16-year follow-ups. Occlusal view of (c) the prosthesis, which is attached to the lower bar with four retaining screws, and (d) the implants at the 16-year follow-up. (e) Frontal view of the lower bar at the 16-year follow-up.

Fig 2  Clinical views of a patient's crater-like defect on the central implant at the 16-year follow-up visit. (a) The vestibular position of the implant is visible. (b) Frontal view of the three implants.
Outcome Measures

Primary
The first outcome measures were (1) cumulative survival rates (CSRs) of the implants and prosthesis and (2) peri-implant bone resorption, measured using intraoral periapical radiographs and the parallel long-cone technique, at the following time points: at prosthesis delivery immediately after implant insertion (t0) and at 5 (t5), 11 (t11), and 16 years (t16) after implant insertion. The implant-abutment interface was used as the reference point for bone resorption measurements. Interproximal bone levels were assessed from these reference points to the most coronal bone levels at the mesial and distal surfaces of each implant. Two examiners (P.P. and F.B.) performed the clinical measurements after a calibration exercise demonstrating 95.7% concordance within ± 0.5 mm for measurements.

Secondary
Implant stability, expressed through implant stability quotient (ISQ) as assessed by the resonance frequency analyzer (RFA; Osstell Integration Diagnostics), was analyzed at five time points: t0, t1 (12 months after surgery), t5, t11, and t16.

The periodontal parameters bleeding on probing (BOP), probing depth (PD), and Plaque Index (PI) were recorded at the 11- and 16-year follow-up appointments.

PD, BOP, and PI were recorded at four points for each implant (mesial, distal, buccal, and lingual) using a nonmetallic probe. BOP and PI values ranged from 0 to 4 for each implant, and PI was measured using an erythrosine gel.

Prostheses were unscrewed to evaluate periodontal parameters and RFA. Technical and biologic complications were also recorded.

Results

There were no dropouts during the follow-up period, and all patients attended the 16-year recall appointment. No implant failures occurred, resulting in an implant CSR of 100%. One biologic complication was detected: As described in the previous paper reporting the 11-year follow-up,6 one central implant exhibited a crater-form bone resorption, but it was in function and clinically stable at the 16-year follow-up.

Two prosthetic complications occurred between the 11th and the 16th year of follow-up. These complications (little chips in the prosthesis) occurred in one parafunctional patient and were solved in the same day (polishing the prosthesis in one case, and sending the prosthesis back to the dental technician in the other case). No prostheses needed to be substituted during the 16-year follow-up; consequently, the prosthesis CSR was considered 100%.

Bone level over time is reported in Table 1 and Fig 3 (mean: 2.2 mm at 16 years). Greater peri-implant bone loss was detected on central implants (median: 4.5 mm on both the right and left sides at 16 years).

At 16 years of follow-up, PI was 79.2% (38 of 48 implant surfaces); BOP was 10.4% (5 of 48 implant surfaces), with BOP present at the level of three implants in the same patient; and mean PD was 3.30 mm (range: 2 to 6 mm), slightly reduced compared to the 11-year follow-up control.

RFA values expressed by ISQ remained generally stable during the entire 16-year period (Table 2).

Discussion

At the 16-year follow-up appointment, the implant and prosthesis survival rates were both 100%. Similar

Table 1 Median Interproximal Bone Level (mm) over 16 Years of Follow-up

<table>
<thead>
<tr>
<th>Implant measurement</th>
<th>t0</th>
<th>t5</th>
<th>t11</th>
<th>t16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right, D</td>
<td>0.00</td>
<td>0.00</td>
<td>0.50</td>
<td>0.50</td>
</tr>
<tr>
<td>Right, M</td>
<td>0.00</td>
<td>0.50</td>
<td>1.50</td>
<td>1.50</td>
</tr>
<tr>
<td>Central, L</td>
<td>0.00</td>
<td>1.50</td>
<td>4.50</td>
<td>4.50</td>
</tr>
<tr>
<td>Central, R</td>
<td>0.00</td>
<td>1.25</td>
<td>4.25</td>
<td>4.50</td>
</tr>
<tr>
<td>Left, D</td>
<td>0.00</td>
<td>0.25</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Left, M</td>
<td>0.00</td>
<td>0.25</td>
<td>0.75</td>
<td>1.25</td>
</tr>
</tbody>
</table>

M = mesial; D = distal; L = left; R = right; t0 = time of implant placement; t5 = 5 years after implant placement; t11 = 11 years after implant placement; t16 = 16 years after implant placement.
outcomes were registered in previous studies reporting shorter follow-up periods for this protocol.\(^2,7,9–11\)

The Brånemark Novum protocol was the first standardized procedure for the immediately loaded rehabilitation of the mandible using a reduced number of implants. With this protocol, Brånemark defined key points to be respected for long-term success of immediate-loading rehabilitations, which are: a reduced number of implants, well-spread implants, rigid framework, and passivity of the prosthetic structure.

In addition, the Novum protocol involved the use of templates for implant placement and anticipated the modern guided surgery with bone support, the main difference being that the Novum protocol guides were not customized for each individual patient.

The use of a reduced number of implants provides some advantages, such as simplification of surgical and prostodontic procedures, simplification of home and professional oral hygiene, and easier maintenance of enough circumferential bone volume around the implants to respect the vascular network. A reduced number of implants is sufficient to support a full-arch immediate loading prosthesis as long as they have sufficient primary stability and they are well spread.

Implant disposition is a key factor to correctly distribute occlusal forces on the supporting bone. An in vitro study by Ogawa et al evaluated the distribution of axial forces and bending moments (BMs) in rehabilitations that included the mandibular placement of three, four, or five implants with different implant distributions and prosthesis materials under static loading conditions.\(^12\)

BMs were significantly influenced by implant distribution: the smallest distribution induced the highest BMs. Implant number and distribution appeared to have an interacting effect on implant loading. A favorable spread of the implants reduces peak BMs, and this is particularly important when a reduced number of implants is used. The study by Ogawa et al demonstrates that implant distribution becomes a more-important determinant for implant loading when the implant number decreases.\(^12\)

Moreover, maximum BMs were lowest with the rigid titanium prosthesis compared to acrylic and fiber-reinforced acrylic prostheses.\(^12\) The greater stiffness of a metal framework leads to a smaller deformation.

Table 2 Median (Min–Max) Resonance Frequency Analysis (ISQ units) over 16 Years of Follow-up

<table>
<thead>
<tr>
<th>Implant</th>
<th>t0</th>
<th>t1</th>
<th>t5</th>
<th>t11</th>
<th>t16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right</td>
<td>63.00 (57.00–66.00)</td>
<td>63.00 (57.00–66.00)</td>
<td>63.50 (58.25–68.00)</td>
<td>62.00 (58.75–6.75)</td>
<td>64.00 (62.00–74.00)</td>
</tr>
<tr>
<td>Left</td>
<td>60.50 (57.25–63.75)</td>
<td>60.50 (57.25–63.00)</td>
<td>60.50 (60.75–66.00)</td>
<td>62.50 (62.00–7.50)</td>
<td>65.00 (58.00–70.00)</td>
</tr>
<tr>
<td>Central</td>
<td>57.00 (52.25–62.50)</td>
<td>57.00 (52.25–62.50)</td>
<td>59.00 (53.25–64.75)</td>
<td>57.50 (47.75–5.75)</td>
<td>59.00 (42.00–69.00)</td>
</tr>
</tbody>
</table>

\(t0 = \) time of implant placement; \(t1 = 1\) year after implant placement; \(t5 = 5\) years after implant placement; \(t11 = 11\) years after implant placement; \(t16 = 16\) years after implant placement.

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of the prosthesis at the site of load application, thereby resulting in a better distribution of occlusal forces among all supporting implants.13 The lower deformation for stiffer materials may also reduce risk of fatigue and eventual failures related to overloading of the components.12,13

An additional requirement of the Novum protocol was the use of acrylic-resin occlusal surfaces. Acrylic resin is an elastic shock-absorbing material, which might dampen occlusal loads.14,15

Through such prosthodontic requirements, the Novum protocol aimed to control occlusal loads as much as possible, reducing the risk of overloading the implants.

Despite a high success rate, the Novum protocol has been abandoned due to the rigidity of the conditions necessary for the application. In fact, prefabricated surgical templates and prosthodontic bars limited its application to patients with specific mandibular anatomical characteristics.

However, the long-term predictability of this original treatment protocol has led to developments aimed at simplifying the technique and making it available for a greater number of patients with different anatomic conditions. Besides modern All-on-Four rehabilitations, Nobel Biocare recently developed and publicized a new immediate loading protocol, the so-called Trefoil, which is a direct evolution of the Novum protocol. In fact, it provides full-arch immediate loading of three implants in the mandible using surgical guides and a prefabricated prosthesis.

The main difference is the presence of a double metal structure in the Novum protocol: a first metallic framework (lower bar) splitting the three intraforaminal implants, above which a metal structure (upper bar) covered by the resin prosthesis is screwed. In contrast, only one unique metal framework is present in the Trefoil system, with the aim of simplifying prosthodontic procedures and reducing the necessary prosthodontic space. Moreover, the prefabricated milled titanium bar in the Trefoil system is specifically designed to compensate for small deviations from the planned implant position. In fact, it is equipped with adaptable joints, which adjust to compensate for horizontal (± 0.4 mm), vertical (± 0.5 mm), and angular (± 4.0 degrees) deviations. Further research is needed to evaluate the efficacy and effectiveness of this new protocol.

Between the 11th and 16th year of follow-up, there were no drop-outs, implant failures, or newly occurring biologic complications. Few prosthetic complications (chippings) were present in one parafunctional patient and were solved by repairing the prosthesis in the same day.

Gingival inflammation, as recorded by BOP, was present only in one patient and was associated with high PI in all patients (global PI: 79.2%).

As reported in the 11-year follow-up article,4 the only biologic complication was a wide crater-form bone destruction in one central implant that presented great bone reabsorption and probing depth but not mobility. Given the small sample size, this implant affected the results. Excluding this implant from the calculation resulted in 1.7-mm (median: 1 mm) bone resorption for all implants. This complication was probably due to the use of the prefabricated template, which induced the placement of the central implant in a site located too vestibularly. The low bone thickness on the vestibular side of the implant probably induced bone resorption. In fact, the implant volume overwhelmed that of the bone site, engaged the buccal bone plate, and caused dramatic and predictable marginal and vertical bone loss.16–19

The main limit of this case series is the reduced sample of patients included in the research (four patients), limiting the generalizability of the outcomes. The positive results reported in such a small group of patients should be taken with caution. However, to the authors’ knowledge, this is the longest follow-up period (16 years) reported for the Brånemark Novum protocol.

Conclusions

Recorded 16-year clinical outcomes underscored the efficacy of the Novum protocol, even if the protocol’s rigidity led to its being eclipsed by more readily accessible ones. Nonetheless, and in spite of this report’s limitations, the cited protocol was the first codified immediate functional loading one for edentulous mandibles. This report endorses the merits of this standardized surgical and prosthesis protocol, including
employment of a rigid metal framework for splinting the implants via a passive and screwed prosthetic structure and selection of a reduced number of implants, while offering the additional possibility of using an occlusal material with a high capacity for shock absorption.

Acknowledgments

The authors declare no conflicts of interest.

References