JO JOURNAL OF OSSEOINTEGRATION periodontics and prosthodontics

Rehabilitation of edentulous mandibles following the Brånemark Novum immediate loading protocol. A 21-Year Case Series Follow-up.

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TO CITE THIS ARTICLE
Delucchi F, Bagnasco F, Pera F, Tealdo T, Pera P, Pesce P, Menini M. BRehabilitation of edentulous mandibles following the Brånemark Novum immediate loading protocol. A 21-Year Case Series Follow-up. J Osseointegr 2023; 15

DOI 10.23805/JO.2023.609

ABSTRACT

Aim The purpose of the present research was to evaluate the clinical outcomes of edentulous mandibles rehabilitated using the Brånemark Novum protocol with 21-year follow-up.

Material and Methods Between April and November 2001, four patients (3 men, 1 woman) were rehabilitated with fixed full-arch prostheses supported by three immediately loaded implants following the Brånemark Novum protocol. The main clinical outcomes evaluated were: peri-implant bone resorption (BR), cumulative implant survival rate (iCSR), and cumulative prosthetic survival rate (pCSR). The following parametres were also evaluated: probing depth (PD), bleeding on probing (BOP), plaque index (PI), and implant stability (expressed through implant stability quotient (ISQ) assessed by resonance frequency analysis (RFA)), and were evaluated over time, up to the 21-year follow-up.

Results At the 21- year follow-up, one drop-out occurred as one patient died. Over the 21 years, no implant failed (iCSR 100%) and no prosthesis was replaced (pCSR 100%). In the period between the 16- and 21-year follow-up, bone level (mean BR: 2.45 mm at 21 years) and RFA values remained stable. At the 21-year follow-up, the implants had high PI values (83.3%) but low BOP values (13.9%). Mean PD was 3.30 mm (range: 2.5 to 4.5 mm). A biological complication was detected on a central implant (bone resorption with crateriform defect) but did not worsen between the 16th and 21st year of follow-up. Numerous prosthodontic complications (resin or tooth fractures) occurred over the 21 years; however, they were mostly recorded in the same parafunctional patient.

Conclusion This is the first study reporting the outcomes of the Brånemark Novum protocol with a 21-year follow-up and shows excellent clinical results in the long term. The protocol has now been abandoned for his rigidity and difficulty in application, but it had the merit of indicating the key factors that can lead to predictability of the success in full-arch immediate loading rehabilitations.

KEYWORDS: Dental implants, immediate loading, full-arch, mandible, case series, Brånemark Novum

INTRODUCTION

Rehabilitation of completely edentulous patients or those with severely compromised dentition using fixed prostheses supported by immediately loaded implants is considered a valid and effective treatment today for restoring aesthetics and masticatory function, with a good predictability of success (1,2). Especially in cases of complete edentulism, this can bring a significant improvement in the patient's quality of life (3).

Although immediate implant loading protocols had been proposed before the Brånemark era, these were based on empirical evaluations lacking strong scientific support and often led to rehabilitation failures.

Modern implantology, grounded in scientific principles and clinical evidence, was introduced in the 1960s by Per-Ingvar Brånemark, who placed his first implants as part of a full fixed rehabilitation in the completely edentulous mandible of a patient.

The protocol initially proposed by Brånemark involved delayed loading and a so-called "two-stage" surgical approach (4). The implants, after placement, healed submerged in the mucosa, which was considered a fundamental prerequisite for osseointegration. After 3-6 months, the implants were uncovered through a second surgical access for prosthetic restoration.

This type of protocol demonstrated a high predictability of long-term success and was based on the adherence to fundamental biological principles of osseointegration studied by Brånemark and his team of researchers. Among these principles, delayed loading ensured the need to avoid implant micromovements. In fact, it was established that implant body movements exceeding 100-150 µm could lead to osseointegration failure with fibrointegration and implant failure (5, 6, 7).

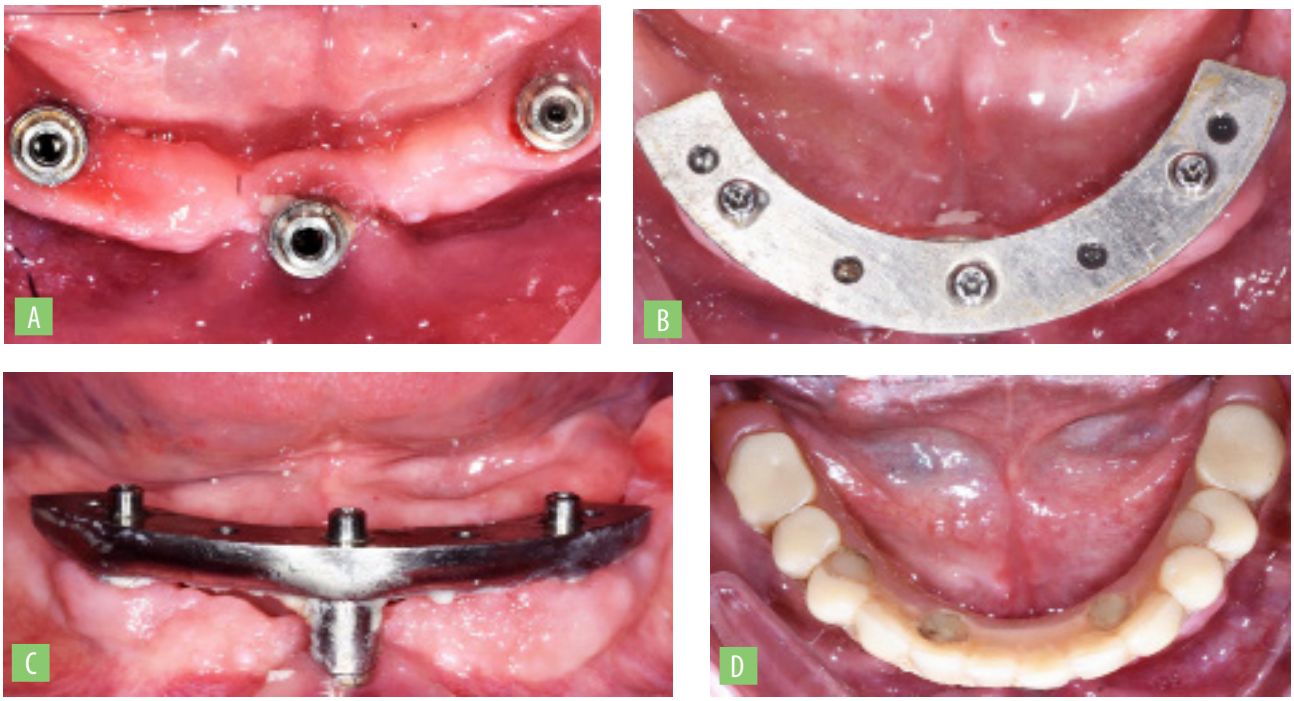


FIG. 1: A) Occlusal view of implants at the 21st year of follow-up (T21) in a patient with a crateriform bone defect around the central implant; B) Occlusal view and C) Frontal view of the lower bar screwed onto the implants; D) Occlusal view of the prosthesis (T21), which incorporates the upper bar screwed to the lower one

One of the challenges of immediate loading protocols is, therefore, to reduce the risk of implant micromovements, and this can be achieved through two fundamental prerequisites: primary implant stability and control of occlusal loads.

Today, several studies in the literature on immediate loading with fixed full-arch prostheses report positive and comparable results to those obtained with traditional delayed loading, provided that appropriate patient selection and correct surgical and prosthetic requirements are met (1, 2, 8, 9, 10, 11, 12).

Several systematic reviews have also shown that implant-supported rehabilitations with immediate loading, both in the mandible and maxilla, can be as effective as traditional delayed loading rehabilitations, with similar implant survival rates, failures, and complications (13, 14, 15).

The first codified immediate loading protocol introduced in the early 2000s was the Brånemark Novum protocol (Nobel Biocare, Kloten, Switzerland) (16).

It involved the placement of three implants in the anterior mandibular region, which were then restored on the same day. The prosthetic structure consisted of two bars, one lower bar screwed to the transmucosal portion of the implants and one upper bar screwed to the first and embedded in the acrylic resin of the prosthesis. In addition to providing clear guidelines for predictable immediate loading with a reduced number of implants, this protocol also offered all the advantages of immediate loading from the patient's perspective. Shortened return to function times, the possibility of immediate definitive esthetic restoration following the procedure, avoiding removable temporary prostheses and secondary interventions, resulting in pa-

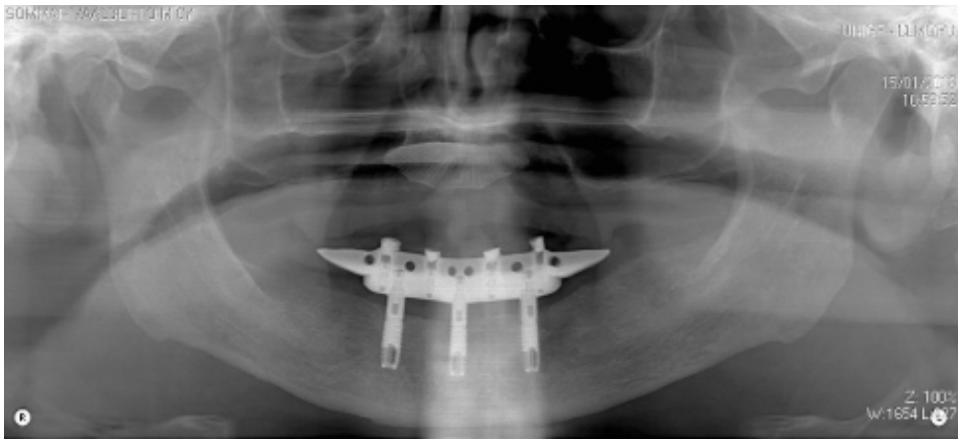


FIG. 2
X-ray of one of the patients included in the research

tient comfort and satisfaction.
Among the main disadvantages of the Novum protocol, however, was the excessive rigidity of the procedure, which required specific templates for implant site preparation and non-customizable prefabricated prosthetic bars for each patient. Therefore, this protocol could only be applied to mandibular arches with specific anatomical characteristics. Despite the above-mentioned reasons leading to the abandonment of the protocol, it showed excellent long-term clinical results and helped identify key factors for long-term success in immediate loading rehabilitation: a reduced number of implants, well-distributed implants, a rigid substructure, and passive fit of the prosthetic structure. In the scientific literature, since the introduction of the Novum protocol in 1999, studies on this protocol have been few and of short duration (16, 17, 18, 19, 20, 21, 22, 23).
In our previous studies, we reported results at 11 and 16 years of follow-up for this protocol (24, 25). The purpose of this research is to present the clinical results at the 21-year follow-up of the same sample of patients rehabilitated using the Brånemark Novum protocol.

MATERIALS AND METHODS

In this study, four patients (1 woman and 3 men) with good systemic health conditions and either edentulous mandibles (n = 2) or mandibular arches containing residual teeth with poor prognoses (n = 2) were included.
Between April and November 2001, the patients were rehabilitated according to the Brånemark Novum protocol at the Department of Prosthodontics and Dental Implantology at the University of Genoa.
The study was conducted in accordance with the Helsinki Declaration and was approved by the local ethics committee of the University of Genoa.
Detailed inclusion and exclusion criteria are reported in a previously published study (23). The volume of residual bone present had to be sufficient to accommodate at least 3 implants (5 mm in diameter; 11.5/6 mm or 13.5/7 mm in length). Patients were required to have a mouth opening of at least 50 mm to ensure adequate access to the surgical site with all the necessary tools for the procedure.
Mandibular anatomical morphologies classified as "V-shaped" or categorized as Group E in the Lekholm and Zarb atrophy scale (24) were excluded as they were not compatible with the shape of the prefabricated mask required for the protocol.
On the day of the surgery, after full-thickness flap elevation, the bone crest at the implant site was remodeled and reduced in height to create a 7 mm-wide platform.
The central implant was the first to be placed with the assistance of a "guide mask," used to mark the implant positions, followed by a special surgical template for site preparation using a series of specially designed drills. The preparation of the sites for the two distal implants was done by attaching the "V-shaped mask" to the central implant. An "evaluation mask" was also used to verify the final position, angle, and parallelism of the implants. After suturing the flaps, a prefabricated titanium bar ("lower bar") was screwed with titanium screws to the transmucosal portion of the implants.
All prostheses, delivered on the same day of surgery, contained 12 masticatory units and had an upper prefabricated titanium bar screwed to the lower bar with 4 retention screws at a torque of 20 Ncm.
Patients were recalled for suture removal after one week and for follow-up checks at 3, 6, 9, and 12 months post-surgery, followed by annual check-ups and oral hygiene sessions. The primary outcomes evaluated were cumulative implant survival rate (iCSR), cumulative prosthetic survival rate (pCSR), and biological and prosthetic complications. Peri-implant bone resorption (BR) was also calculated using intraoral radiographs taken with parallel beam technique.
Interproximal bone level was measured by two operators (F.B. and F.D.) after calibration exercises demonstrated 95.8% agreement, with a margin of error within 0.5 mm, between measurements. The bone resorption level was calculated as the distance from the implant-abutment interface, used as a reference point, to the most coronal bone level on the distal and mesial surfaces of each implant.
Intraoral radiographs were taken at T0 (immediately after implant placement) and subsequently at T5, T11, T16, and T21, corresponding to 5, 11, 16, and 21 years after implant placement, respectively.
The implant stability quotient (ISQ), an expression of implant stability, was recorded using a resonance frequency analysis (RFA, Osstell Integration) at five different time points: T0, T1 (12 months after implant placement), T5, T11, and T16, as reported in a previous article (25).
At T11, T16, and T21, soft tissue health indices for peri-implant tissues were recorded: probing depth (PD), bleeding on probing (BOP), and plaque index (PI). These measurements were taken on 4 surfaces for each implant (mesial, distal, buccal, lingual).
PD was measured in millimeters using a non-metallic implant probe.
BOP and PI (the latter recorded using an erythrosine-based plaque disclosing gel) were recorded with a value from 0 to 4 for each implant, depending on the number of surfaces showing bleeding or plaque.

RESULTS

Up to the 16-year follow-up recall, all four included patients attended their appointments. At T21, there was a drop-out as the only female patient passed away. The 3 patients who attended the appointments were 73, 87, and 83 years old.
At the 21-year follow-up, none of the evaluated implants (n = 9) had failed (iCSR 100%): all implants were stable (evaluated after the removal of the lower bar) and func-

Implant	T0	T5	T11	T16	T21
Right, D	0.00	0.00	0.50	0.50	0.75
Right, M	0.00	0.50	1.50	1.50	1.50
Central, R	0.00	1.25	4.25	4.50	4.75
Central, L	0.00	1.50	4.50	4.50	4.75
Left, D	0.00	0.25	1.00	1.00	1.25
Left, M	0.00	0.25	0.75	1.25	1.75

M = mesial; D = distal; R= right; L=left; T0 = time of implant insertion; T1 = 1 year after implant insertion; T5 = 5 years after implant insertion; T11 = 11 years after implant insertion; T16 = 16 years after implant insertion; T21 = 21 years after implant insertion.

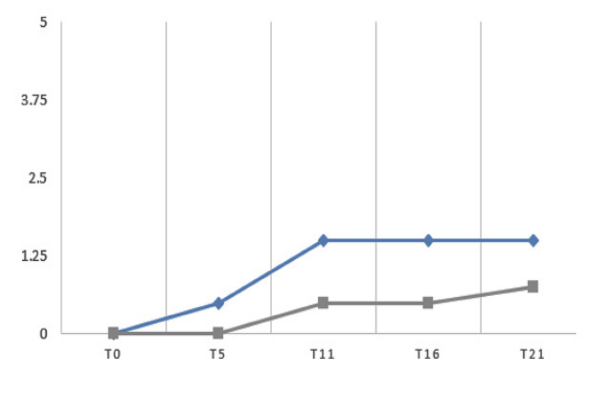
TABLE 1 Medians of interproximal bone level (mm) over the 21 years of follow-up

tioning.
Between the 16-year and 21-year follow-up, no prosthetic complications occurred. Furthermore, over the course of 21 years, there was no need for the replacement of any prosthesis (pCSR 100%), despite two prosthetic complications (minor chipping of the aesthetic coating material) occurring between T11 and T16, both in the same parafunctional patient. Both complications were managed promptly by polishing the prosthesis chairside in one case and sending the prosthesis to the dental laboratory for same-day return in the other case.
Table 1 shows the BR values over time from T0 to T21 (average: 2.9 mm at 21 years). The highest rate of peri-implant bone loss was observed in the central implants. In fact, as reported in a previous article about the eleventh year of follow-up, increased bone resorption with a crater-shaped defect morphology was recorded at a central implant. However, this implant is still stable and functional 21 years later.
At T21, a PI of 83.3% was calculated (30 surfaces out of 36 showed plaque presence), which is slightly higher than at T16 (79.2%).
The BOP was 13.9% (5 surfaces out of 36 showed bleeding on probing) at T21, a value higher than at T16 (10.4%).
The average PD was 3.30 mm (range: 2.5 to 4.5 mm), so the mean value of probing depth remained unchanged compared to T16, although the range narrowed, with the maximum value reported being lower than that recorded at the 16-year follow-up (6 mm). The RFA values recorded remained generally stable during the entire 21 years in which the implants remained in function (Table 3).

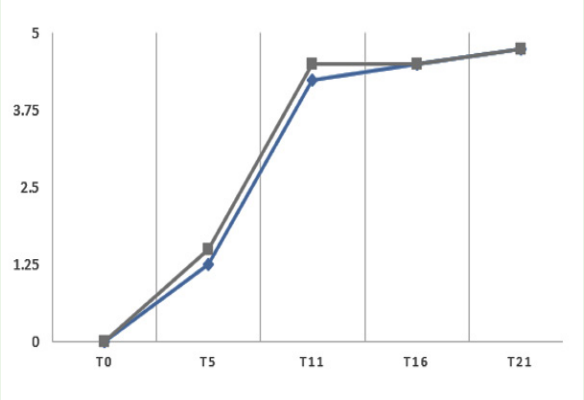
DISCUSSION

This is the first clinical study to describe the 21-year results of complete rehabilitation of edentulous mandibles using implant-supported prostheses following the immediate loading protocol of Brånemark Novum.
The main limitation of the research is the small number of patients (n = 4). However, the positive results collected after long-term follow-up, during which the inserted implants remained functional, allow us to highlight the clinical success of this protocol.
Over the entire 21-year period, the cumulative survival rate of the implants (iCSR) remained at 100%. No im-

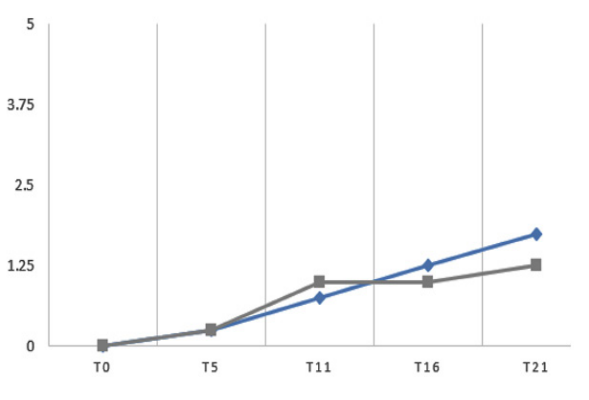
GRAPH 1
Comparison between the medians of bone levels at the time of insertion (T0) and at the 5-year (T5), 11-year (T11), 16-year (T16), and 21-year (T21) follow-ups for the right (a), central (b), and left (c) implants.



A - Blue line (mesial right) Grey line (distal right)



B - Blue line (central right) Grey line (central left)



C - Blue line (mesial left) Grey line (distal left)

Implant	PD (mm)	BOP (%)	PI (%)
Right	3.41	8.33	83.33
Central	3.83	16.66	100
Left	2.66	16.66	66.66
Total	3.30	13.88	83.33

TABLE 2 Average values of peri-implant soft tissue health indices (PD, BOP, and PI) at the 21-year follow-up

plants failed, and there was never a need to replace any prostheses (pCSR of 100%). Previous studies by other author groups with shorter follow-up periods reported similar results for this protocol.

Within the 11th year of follow-up, there was a single biological complication related to a central implant in one of the rehabilitations. This implant exhibited a large area of perimplant bone destruction with a crater-like morphology, recession of vestibular perimplant mucosa, low ISQ values, and increased probing depth, although implant mobility was never recorded. In the first 16 years of follow-up, several prosthetic complications occurred, mainly chipping of the esthetic veneer of the prosthesis. However, these mostly occurred in a single bruxing patient and were resolved on the same day. In contrast, no new biological complications occurred after the 11th year, and from the 11th to the 16th year, only two prosthetic complications occurred. From the 16th to the 21st year, no new complications, either biological or prosthetic, were recorded, with overall satisfaction reported by all patients.

Over the 21-year follow-up period, perimplant bone resorption showed stable values, with an average bone resorption (BR) of 2.9 mm at 21 years. This value reduced to 2.2 mm when excluding the single implant with significant resorption. Small variations in ISQ values recorded over the 21 years were considered clinically insignificant.

Regarding soft tissue health indices, the mean probing depth (PD) was 3.30 mm, while the mean PD for central implants was 3.83 mm. Excluding the central implant affected by crateriform bone resorption, the mean PD for central implants was 3.50 mm. The overall mean PD, including all implants (PD = 3.30 mm) at 21 years, was still lower than the value recorded at the 16-year follow-up.

The mean bleeding on probing (BOP) value slightly increased to 13.9%, accompanied by an increase in the plaque index (PI) to 83.3% at 21 years. These data indicate a slight increase in inflammation of the perimplant mucosa, likely attributed to challenges in maintaining oral hygiene at home and ensuring patient compliance with recall visits as they aged. However, this did not seem to have negative repercussions on the interproximal perimplant bone level or implant stability.

The Brånemark System® Novum™ was the first protocol to provide standardized surgical and prosthetic procedures for the immediate loading of completely edentulous mandibles. Nowadays, it has been demonstrated that full-arch implant-supported rehabilitations with immediate loading yield results comparable to those with traditional delayed loading protocols (1).

The Brånemark Novum immediate loading protocol involves the placement of three implants in the intraforaminal area, using prefabricated surgical templates. Subsequently, a fixed prosthesis made of titanium-acrylic on prefabricated components is delivered immediately after the surgical procedure.

Key factors for the success of immediate loading include immediate prosthetic delivery within a single day, restoring masticatory function and aesthetics rapidly. Proper management of immediate loading involves careful planning of the number and position of implants, aiming to minimize implant micromovements and ensure an even distribution of occlusal forces that could negatively impact implant stability. The mandatory placement of implants in the Novum protocol creates a stable triangular support polygon, allowing for control and reduction of extra-axial masticatory forces. Thanks to the non-alignment of the three implants, rotational forces are counteracted by axial forces in the implants rather than bending moments. Conversely, when implants are positioned in a straight line, they are subject to greater bending mo-

Implant	T0*	T1*	T5*	T11*	T16*	T21**
Right	63.00 (57.00-66.00)	63.00 (57.00-66.00)	63.50 (58.25-68.00)	62.00 (58.75-66.75)	64.00 (62.00-74.00)	69.00 (64.00-74.00)
Central	57.00 (52.25-62.50)	57.00 (52.25-62.50)	59.00 (53.25-64.75)	57.50 (47.75-65.75)	59.00 (42.00-69.00)	55.50 (42.00-69.00)
Left	60.50 (57.25-63.75)	60.50 (57.25-63.00)	60.50 (60.75-66.00)	62.50 (62.00-67.50)	65.00 (58.00-70.00)	67.50 (65.00-70.00)

*T0 = at implant insertion; T1 = 1 year after implant insertion; T5 = 5 years after implant insertion; T11 = 11 years after implant insertion; T16 = 16 years after implant insertion; T21 = 21 years after implant insertion *Values recorded for 4 patients **Values recorded for 3 patients*

TABLE 3 Median (Min-Max) related to the values of resonance frequency analysis (ISQ units) during the 21-year follow-up

ments (26,27).
These concepts have laid the foundation for the key principles underlying modern All-on-Four type rehabilitations. To achieve full-arch immediate loading rehabilitation, most studies consider 4-6 implants as the minimum number necessary to achieve predictable results, provided that the implants are stable and well-distributed within the arch to form as broad and symmetrical a support polygon as possible (28, 29, 30). The Novum system was also the first to propose immediate loading through a bar system for rigid splinting of the implants. Early splinting of the implants with a rigid and passive (stress-free) metal structure, unlike fully acrylic prostheses, allows for less deformation of the prosthesis at the load application site, resulting in a better distribution of forces among all supporting implants (31, 32, 33). The reduced deformation of more rigid materials can also reduce the risk of fatigue and technical complications related to overloading of the implant-prosthetic components (28).
Acrilyc resin, on the other hand, was used in the Novum system for the occlusal and esthetic veneer of the rehabilitation because its elasticity allows for the absorption and dissipation of occlusal loads (shock absorption capability) (34).
To minimize the risk of failure, we now know that these surgical-prosthetic concepts should be accompanied by a patient's oral hygiene and dietary education protocol, especially in the first few weeks after implant insertion and subsequent loading (35).
The Novum system used templates for implant placement and prefabricated bars for the prosthesis, representing a precursor of modern guided surgery. However, the procedure employed did not use customized guide templates for individual patients as is done today but rather identical templates for each subject. This led to the excessive rigidity of the system, which could only be employed on patients with a specific anatomical conformation of the lower jaw.
As pointed out by Gualini (23), another limitation was the use of only two implant diameters (4.5 mm and 5 mm) and two lengths (13.5/7 mm and 11.5/6 mm). Therefore, the Novum system could not be applied to very narrow mandibles (V-shaped), low alveolar ridges, or atrophic mandibles (19). This is the main reason why the protocol was abandoned. Another disadvantage of this system was the difficulty in resolving potential implant-related complications, especially in cases of implant loss. In fact, the prefabricated prosthetic structure required that implants be placed in predetermined positions using a preformed template. Therefore, this technique ensured the passive fit of the prosthesis but did not allow for modification of the predetermined implant position.
A "rescue set" consisting of drills and templates was proposed to immediately replace a failed implant with a larger diameter implant (6 mm), allowing the immediate use of the original bar structures during the same appointment (36). Alternatively, in case of implant loss, a new implant had to be placed, and a new prosthesis had to be created. The implant position that often led to complications was that of the central implant, which was often forcefully placed in a too vestibular site without respecting the minimum thickness requirement of the perimplant bone on that side. This could explain why, in this study, higher values of bone resorption and lower ISQ values were detected on central implants compared to distal ones, as well as the fact that the only biological complication occurred on a central implant.
More recently, Nobel Biocare introduced a new system, the so-called Trefoil (37, 38), which represents an evolution of the Novum protocol but, unlike the Novum, uses a single metal framework rather than a double metal structure to simplify prosthetic procedures and reduce the necessary prosthetic space. The Trefoil system also allows for compensation of minimal deviations in implant position from the originally established one. However, studies on Trefoil available in the literature to date have too short follow-ups to draw long-term conclusions about its effectiveness and predictability.

CONCLUSIONS

In conclusion, despite the limited number of patients, the data recorded at the 21-year mark in this study highlight the clinical success and long-term predictability of the Brånemark Novum protocol. This protocol, although abandoned due to its excessive rigidity and limited applicability, was the first to standardize a surgical and prosthetic procedure for immediate loading of edentulous mandibles.

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