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Purpose: To clinically evaluate a recently developed, standardized, three-implant–supported full-arch treatment concept for fully edentulous mandibles. Materials and Methods: This ongoing multinational prospective cohort study is evaluating the performance of the treatment concept over 5 years in patients who were fully edentulous or had failing dentition of the mandible. The primary outcome was the cumulative survival rate of implants (CSRI). Secondary outcomes included the cumulative survival rate of the prostheses (CSRP), marginal bone level change, soft tissue outcomes, impact on quality of life, and patient and clinician satisfaction. The 1-year report is presented here. Results: In total, 110 patients (330 implants) were included. Prostheses underwent immediate loading in 76.4% of cases and early loading in 23.6% of cases. The mean surgical time was 1.60 ± 0.78 hours, and the mean laboratory time was 3.99 ± 1.74 hours. At 1 year, eight implants and three prostheses failed, yielding an implant-level CSRI of 97.5% and a CSRP of 97.3%. All prosthetic failures were due to loss of two implants in the patient. The mean marginal bone level change at 1 year was –0.62 ± 1.39 mm. Among soft tissue outcomes, the Bleeding Index improved significantly between the 6-month and 1-year follow-up, and 242 implants (75%) were surrounded by keratinized mucosa by the 6-month follow-up. Patients reported a significant improvement in quality of life between prosthesis placement and the 6-month follow-up based on the Oral Health Impact Profile for Edentulous 21 questionnaire. Both patient and clinician satisfaction with function and esthetics were high throughout treatment. Conclusion: This novel treatment concept using a passively fitting standardized framework with simplified surgical and prosthetic workflow demonstrated high survival and excellent outcomes at 1 year while reducing chair and fabrication time. This concept may offer patients a safe and efficient option for full-arch mandibular prostheses. INT J ORAL MAXILLOFAC IMPLANTS 2020;35:150–159. doi: 10.11607/jomi.7650

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Despite worldwide declines in recent decades, edentulism continues to be a global public health problem that predominantly affects aging and lower-income populations.¹,² In 2015, 276 million people suffered from total tooth loss,³ and prevalence projections estimate that in 2050, there will still be 8.6 million edentulous individuals in the United States alone.⁴ Based on these data, it is reasonable to assume that a significant percentage of the population also suffer from debilitating partial edentulism or failing dentition.

In addition to affecting masticatory function, edentulism has been correlated with numerous systemic diseases. These comorbidities include obesity,
atherosclerotic plaque formation, hypertension, diabetes, rheumatoid arthritis, chronic obstructive pulmonary disease, cancer, and cognitive impairment. There is also strong psychosocial impact to severe tooth loss. In older adults, edentulism is associated with significant decreases in quality of life and life satisfaction, leading to reductions in subjective well-being.

Currently, edentulous patients have two broad treatment options: removable conventional dentures and implant-supported prostheses (fixed or removable). Conventional dentures are typically the first-line treatment, but long-term outcomes are often better for implant-supported prostheses. A recent systematic review showed that oral health–related quality of life (OHRQoL) was typically higher in patients with dental implants compared with conventional dentures.

Mandibular edentulism is particularly debilitating because the alveolar ridge of the mandible has less surface area for stabilizing a conventional denture. This minimal surface area combined with the high degree of mobility in the musculature around the ridge frequently dislodges dentures and affects function. The mandibular alveolar ridge is also four times more likely to undergo bone loss, making denture retention increasingly difficult over time. Mandibular denture retention is one of the most common complaints of conventional denture users. Individuals with mandibular implant-assisted dentures were consistently more satisfied and had higher OHRQoL than those with conventional dentures, even when accounting for confounders, such as number of implants, anatomy, sociodemographic factors, and prosthetic superstructure. When comparing fixed vs removable implant-supported prostheses, several studies have shown favorable outcomes for both systems. However, fixed dental prostheses had superior improvements in chewing ability, esthetics, general satisfaction, and better OHRQoL.

Even though implant-supported prostheses yield better long-term outcomes than conventional dentures, less than 4% of edentulous adults who received treatment in the United States and Europe had implant-supported prostheses. There are numerous reasons for patients to refuse implant-supported prostheses, such as anxiety about surgical procedures and fear of pain, but by far the most common reason is cost. When considering the cost of a full-arch prosthesis, a large portion of the population, including middle-class patients, find current treatment options out of reach.

Reducing the number of implants placed can reduce overall costs because the number of implants concomitantly affects costs for hardware as well as laboratory and chair time. In 1977, Branemark et al developed the first full-arch implant-supported prosthesis using four to six implants. Since then, full-arch prostheses secured with fewer implants have been shown to have a high survival rate in a clinical setting.

Another way to potentially reduce costs is to treat edentulous patients with a standardized prosthesis. One of the earliest attempts to create a standardized fixed prosthesis was the Branemark System Novum (Nobel Biocare) introduced by P.I. Brånemark in 1999. The Novum system comprised three machined-surface implants and a two-piece bar. While an early study yielded favorable implant and prosthesis survival rates, later studies showed cumulative failure rates of 9% and 13% for implants and suprastructures, respectively. The high incidence of prosthetic complications, including prosthesis resin fractures, screw loosening, upper-bar modifications, anchorage fractures, and abrasion eventually led to the discontinuation of the Novum system. However, those studies created a roadmap for designing a standardized prosthesis concept with a passive fit comparable to customized computer-aided design/computer-assisted manufacturing (CAD/CAM) solutions.

One concern for fixed implant-supported prostheses, including custom restorations, is that they are sensitive to deviations from planned implant placement. Even when using a digitally developed surgical guide, slight deviations in implant placement can occur. These deviations can exert undue mechanical stress on the prosthesis and components, which may result in prosthetic complications, such as screw loosening and screw fracture. To address this issue, the Trefoil system (Nobel Biocare) was developed. The system consists of three anodized parallel-walled implants with a machined tissue-level collar and a conical-connection abutment interface for optimal hard and soft tissue compatibility, a standardized single-piece titanium framework, and three adaptive fixation mechanisms that compensate for implant placement deviations (Fig 1). The innovative adaptive mechanisms involve a specially designed series of articulating disks that allow for limited shift in the vertical (±0.5 mm) and horizontal (±0.4 mm) dimensions and multiaxial rotation (±4 degrees) to achieve passive fit of the prosthesis despite implants that are not perfectly parallel or level.

This adaptive, three-implant–supported standardized treatment concept combines a time-efficient clinical workflow using standardized analog guide templates and straightforward laboratory protocol to deliver a definitive full-arch mandibular prosthesis on the day of surgery or within several days postoperatively. This workflow reduces the number of clinical visits and laboratory time required to deliver the definitive restoration, which has the potential to ultimately reduce costs for both patients and clinicians compared
with treatments where a provisional prosthesis is placed before delivery of the definitive restoration.

This ongoing multinational multicenter prospective cohort study was designed to evaluate the outcomes of this new three-implant–supported treatment concept in edentulous mandibles. The primary objective was to evaluate the cumulative survival rate of implants (CSRI) over a period of 5 years. Secondary objectives included evaluating the cumulative survival rate of the prostheses (CSRP), the cumulative success rate of both implants and prostheses, marginal bone level change (ΔMBL), soft tissue parameters, safety, the impact of the treatment concept on OHRQoL, and patient and clinician satisfaction. The 1-year results of this study are presented here.

MATERIALS AND METHODS

Study Design
The study was designed in accordance with STROBE guidelines and performed according to the Declaration of Helsinki. All protocols and amendments were approved by the Ethics Committees of the study sites, and all patients provided written informed consent. The study included five clinics, both academic institutions and private practices, located in the United States (22 patients), Spain (15 patients), Australia (23 patients), Italy (14 patients), and Chile (36 patients).

The CSRI after 1- and 5-year follow-ups was expected to be in the range of 94% and 90%, respectively.14–17 The number of implants required for the study was determined using the 90% CSRI. A total of 217 implants were needed based on a two-sided 95% confidence interval for a single proportion using the large-sample normal approximation that extends 0.04 from the observed proportion for an expected proportion of 0.90 (calculated with nQuery Advisor 7.0). Thus, 90 or more patients were required when accounting for a 25% dropout rate. This number would also allow the results to be verified with a nonparametric approach that has a 5% lower efficiency in case of non-normally distributed data.

Subjects were included if they were at least 18 years of age; were physically and mentally capable of completing the 5-year follow-up; had a harmonic, stable occlusal relationship with opposing dentition; were willing and able to comply with study-related procedures; had good oral hygiene; had an edentulous mandible or failing mandibular dentition with sufficient bone in the interforaminal area for a fixed restoration on three implants; had sufficient osseous architecture to receive three implants at least 11.5 mm in length and 5 mm in diameter (eg, jaw volume B, C, or D, interforamina distance at least 20 mm, buccal/lingual width of at least 7 mm, vertical height after bone leveling sufficient to receive an 11.5-mm-length implant); had a jaw curvature that fits the prefabricated framework design; had healed or extraction sites available for implant placement that were free from infection and extraction remnants as well as fulfilling early-loading criteria. Patients with Class II and Class III interarch relationships were included on a case-by-case basis based on the judgment of the clinician. Subjects were excluded if they had health conditions that did not permit surgical or restorative procedures (including anesthesia); the clinician thought treatment might have a negative effect on the subject's overall situation (eg, psychiatric problems) based on patient history; they had any disorders in the planned implant area (eg, previous tumors, chronic bone disease, or previous irradiation); they had a history of alcohol or drug abuse; they smoked more than one pack of cigarettes per day (> 20 cigarettes or equivalent); they had uncontrolled diabetes; they were taking bisphosphonate therapy; they had pathologic occlusion, eg, severe bruxism or other parafunctional habits; they lacked opposing dentition or had unstable occlusion; they had ongoing infections or endodontic or periodontal problems in opposing teeth or implants; they had poor oral hygiene; or they had allergic or adverse reactions to the restorative material.

Surgical and Prosthetic Protocols
The surgical and prosthetic protocols were performed by experienced clinicians (K.H., R.R. R.D., M.A., G.L.) in accordance with the manufacturer’s recommendations, as described in detail previously.21 The anterior mandible was surgically exposed. Any remaining compromised teeth were removed either before or after flap elevation based on the surgeon’s preference. The bony
The International Journal of Oral & Maxillofacial Implants

Higuchi et al

platform of the residual mandible was surgically leveled parallel to the maxillary occlusal plane to create 21 to 22 mm of space for the restoration and soft tissue. Analog drill guides and templates were used to ensure precise placement of implants in the correct location while accommodating the position of the maxillary dentition (Figs 2a to 2d).

Implant positioning was determined by first preparing the site with guide and evaluation templates (Figs 2a and 2b). Using the positioning template stabilized with guide pins (Fig 2c), the center implant was placed and assessed with a manual torque wrench to an insertion torque of at least 35 Ncm. The right and left posterior implants were placed using the V-template and drill guides (Fig 2d). Confirmation of primary stability of the posterior implants was determined with a manual torque wrench with care taken to avoid altering the vertical level of the posterior implants. A try-in framework was secured to the implants to verify fit and spacing under the distal framework cantilever. A verification index was obtained using specific transfer abutments and used to fabricate a master cast with the exact position and angulation of the implants.

The jaw relation needed to construct the prosthesis was recorded either at the time of surgery using a prefabricated surgical guide, such as a duplicate or trial denture with the correct vertical dimension and cutouts to record implant positions, or by constructing a wax rim and tooth setup on the superstructure.

The master cast was constructed with an accurate die stone, and implant replicas were embedded to ensure the framework fit. The framework was seated to the master cast model and tightened to 35 Ncm (Fig 2e). Visual magnification of the complete circumference of the framework interface was used to verify precise fit. The compensation mechanisms were secured by luting with resin or laser welding, followed by silanating and opaquing the substructure. Following clinical assessment of centric occlusion and fit in the patient’s mouth, conventional wrap-around prosthesis technology was used to process the teeth and acrylic prior to final trimming and polishing.21

At delivery, the clinical and radiographic fit was confirmed, and the prosthesis was attached with clinical screws torqued to 35 Ncm. Occlusion was confirmed to exhibit balanced group function with no premature contacts or interferences during lateral excursions. Patients were asked to follow dietary and oral hygiene recommendations. Peri-implant bone and soft tissue, oral health, patient and clinician satisfaction, and implant and prosthetic survival and success were evaluated at regular follow-ups, as described below (Figs 2f and 2g).

**Outcomes**

Baseline radiographs and an evaluation of fit, pain, patient satisfaction, and adverse events were performed at the 1-month post-prosthesis delivery follow-up. At the 6-month and 1-year follow-ups, patients underwent the same radiographic and clinical measurements.
as those at the 1-month follow-up as well as evaluations of implant stability, implant survival and success, prosthesis survival and success, Gingival Index, and Bleeding Index. Keratinized mucosa was assessed at 6 months, and patients completed the Oral Health Impact Profile (OHIP EDENT-21) pretreatment and at the 6-month and 1-year follow-ups.

Implant survival was based on whether the implant remained in the jaw and whether the implant was damaged to the extent that it could not be restored. Implant success was defined according to the criteria proposed by van Steenberghhe.23 Prosthesis success was defined as the restoration remaining in function and satisfactory esthetics as assessed by the clinician and patient. Prosthesis survival was defined as the restoration remaining in function regardless of fulfilling all success criteria. Prosthesis failure was defined as a prosthesis that required removal or was fractured beyond repair. The cumulative survival rates were calculated using an actuarial life-table method.24 The statistical evaluation considered all collected data from surgery and follow-up procedures.

Marginal bone levels were assessed using intraoral periapical radiographs at prosthesis placement (baseline) and at 6 months and 1 year. Radiographic examination was performed using a standardized long-cone parallel technique. Images were collected perpendicular to the implant and had to have a clear thread profile with at least 2 mm of surrounding bone visible. Radiographic images were collected either digitally or conventionally. All bone-height measurements were made by an independent radiologist (University of Gothenburg, Sweden). The distance between the implant platform and the most coronal level of the bone was measured, and the collar length was subtracted. The distance was calibrated to the implant diameter, and measurements were accurate to 0.1 mm. Mesial and distal bone levels were recorded. Marginal bone levels are presented as averages, (mesial + distal)/2. Negative numbers indicate bone levels below the reference point, and positive numbers indicate bone levels above the reference point. ΔMBL was calculated for the mesial and distal sides of the implant separately, and the average of mesial and distal remodeling was calculated for each implant site. Negative numbers indicate bone loss.

The Gingival Index was assessed according to a modified version of Löe and Silness25 and scored as: 0 = normal mucosa, 1 = bleeding with superficial probing, or 2 = spontaneous bleeding. The bleeding tendency was assessed using a modified Sulcus Bleeding Index (mBI) according to Mombelli et al26 and scored as: 0 = no bleeding when a periodontal probe is passed along the gingival margin adjacent to the implant, 1 = isolated bleeding spots visible, 2 = blood forms a confluent red line on the margin, or 3 = heavy or profuse bleeding. The status of the keratinized mucosa surrounding the implant was evaluated as: 0 = no keratinized mucosa around the implant, 1 = mucosa surrounding the implant is partially keratinized, or 2 = the entire mucosa surrounding the implant is keratinized.

The changes in quality of life were assessed by an OHIP EDENT-21 questionnaire. The OHIP EDENT-21 questionnaire resembles an excerpt of the original OHIP-49 defined by Slade and Spencer27 with a focus on edentulous patients according to Zani et al.28 Changes in the patient’s quality of life were assessed using a five-point Likert scale ranging from 0 to 4. Patients could respond with: 0 = never, 1 = hardly ever, 2 = occasionally, 3 = fairly often, and 4 = very often. Therefore, the total score for the entire questionnaire could be between 0 and 84, with lower scores indicating higher quality of life. In cases of failing dentition, some of the included questions were not relevant to the patients, and patients were permitted to skip those questions.

Patient satisfaction was a subjective measure evaluated using a visual analog scale.29 Patient satisfaction in function and esthetics was assessed separately using a scale with ratings of 0 to 10 where 10 = fully satisfied and 0 = not satisfied. The clinicians’ assessment was based on their impression of the treatment concept. The clinician scored function and esthetics separately from 1 to 10, with 10 = excellent, 5 = average, and 1 = poor.

Descriptive statistics, including frequency tables, mean values, and standard deviations, were used to present the results. Statistical analyses were performed using SPSS Statistics Desktop software version 24.0 (SPSS).

RESULTS

Patient Demographics
In total, 330 implants were placed in 110 patients. All 110 patients received the prosthesis. Twelve patients (26 implants) were not included in the investigation because they were identified as screening failures (9 patients) or the surgery deviated from the investigation plan (3 patients). A study flow chart is provided in Fig 3. Patient demographics are provided in Table 1. Most patients (78 patients, 70.9%) had an Angle Class I interarch relationship,30 18 (16.4%) had a Class II relationship, and 14 (12.7%) had a Class III relationship. Jaw curvature was registered according to Lekholm.30 Most patients (105 patients, 95.5%) had a U-shape jaw, 4 (3.6%) had a V-shape jaw, and 1 (0.9%) had an N-shape jaw. Of the 330 implants placed, 152 (46.1%) were in sites that were edentulous, and 178 (53.9%)
were in sites with failing dentition. Bone quality was primarily 2 or 3 (299 sites, 90.6%) and quantity A (79 sites, 23.9%), B (156 sites, 47.3%), or C (76 sites, 23.0%).

**Surgical Outcomes**
The method of anesthesia varied on a case-by-case basis. The most common method was local anesthesia with intravenous sedation (57 patients, 51.8%), followed by a combination of local and general anesthesia (24 patients, 21.8%), local anesthesia alone (22 patients, 20.0%), general anesthesia alone (4 patients, 3.6%), and intravenous sedation alone (3 patients, 2.7%). Of the 330 implant sites, 4 did not require bone leveling, 54 required minimal leveling (1 to 3 mm), 222 required moderate leveling (4 to 9 mm), and 50 required significant leveling (> 10 mm). Among the 330 implants placed, 81 were 11.5 mm in length and had a 4.5-mm transmucosal collar, 21 were 11.5 mm in length and had a 6.0-mm transmucosal collar, 194 were 13.0 mm in length and had a 4.5-mm transmucosal collar, and 34 were 13.0 mm in length and had a 6-mm transmucosal collar. The mean insertion torque of placed implants was 60.38 ± 13.39 Ncm (range, 30 to 90 Ncm); insertion torque was not recorded for 62 implants. No adjustment in verification index was needed at 322 implant sites (97.6%). The mean surgical time was 1.60 ± 0.78 hours (range, 0.5 to 4.5), the mean laboratory time for fabricating the prosthesis was 3.99 ± 1.74 hours (range, 1.2 to 8.0), and the mean time to place the prosthesis was 0.43 ± 0.41 hours (range, 0.15 to 3.0) (Table 2). The cantilever was reduced in 21 frameworks, and 9 frameworks required adjustment in the horizontal direction. Among the 110 prostheses delivered, 107 (97.3%) had an uneventful delivery, and 109 (99.1%) had the framework fit with the three implant positions. Among the three eventful deliveries, one patient felt discomfort and asked to delay loading until definitive prosthesis delivery, one prosthesis had a screw break during the laboratory procedure, and one framework did not fit the central implant because the cementation procedure of
the compensation mechanism was modified. With respect to occlusion, 56 prostheses (50.9%) did not require adjustment, 49 (44.5%) required minor adjustments, 3 (2.7%) required major adjustments, and 2 (1.8%) required adjustments to opposing dentition of prostheses. Ten percent of patients received their prostheses on the day of surgery. The choice of immediate or early loading was based upon patient and clinician preferences, clinic and laboratory locations. The longest time to deliver the prosthesis from implant insertion was 10 days (1 patient). On average, it took 2.47 ± 2.39 days for definitive prosthesis delivery (Table 2). Immediate loading (1 to 2 days postsurgery) took place in 76.4% of cases, and early loading (3 to 10 days postsurgery) in 23.6% of cases. For 82 patients (74.5%), only one visit to the surgeon was required. With respect to the prosthodontist or restorative dentist, 80 patients (72.7%) required two or more visits, though this was due to the preference and schedules of the restorative dentists and laboratories.

**Secondary Outcomes**

The mean marginal bone level was –0.58 ± 1.32 mm (n = 278) from baseline to 6 months and –0.62 ± 1.39 mm (n = 283) from baseline to 1 year. Based on the Gingival Index, spontaneous bleeding was observed at three implants at the 6-month follow-up and at six implants at the 1-year follow-up. Most patients had normal mucosa at both visits. There was no significant difference in the Gingival Index between the 6-month and 1-year follow-ups. Based on the mBL, no implants had heavy or profuse bleeding at 6 months, but three implants (1.0%) had heavy or profuse bleeding at 1 year. Most implants (264 implants [83.8%] at 6 months and 279 implants [89.4%] at 1 year) showed no bleeding when a periodontal probe was passed along the gingival margin. There was a significant improvement in bleeding between the 6-month and the 1-year follow-ups (P < .05). With respect to keratinized mucosa, at 6 months, 242 implants (76.8%) had keratinized mucosa surrounding the entire implant, 60 (19.0%) had partially keratinized mucosa, and 11 (3.5%) had no keratinized mucosa. Oral hygiene maintenance was provided at the 6- and 12-month follow-up appointments, and most patients exhibited a tendency for calculus formation on the lingual surface of the prosthesis and center implant adjacent to the orifices of the submandibular salivary gland.

Of the 104 patients who attended the 1-year follow-up visit, 102 completed all three OHIP questionnaires. The mean OHIP score was 44.58 ± 6.10 at prosthesis placement, 6.10 ± 6.72 at the 6-month follow-up, and 5.61 ± 9.83 at the 1-year follow-up (Fig 4). There was a significant improvement between prosthesis placement and the 6-month follow-up and prosthesis placement and the 1-year follow-up (both P < .05). All 104 patients who completed the 1-year follow-up submitted patient satisfaction surveys. With respect to function, the mean patient satisfaction was 9.30 ± 1.50 at prosthesis placement, 9.56 ± 0.84 at the 6-month follow-up, and 9.59 ± 1.18 at the 1-year follow-up. There was a significant difference in patient functional score between prosthesis placement and the 1-year follow-up (P < .05). With respect to esthetics, patient satisfaction scores were 9.66 ± 0.98 at prosthesis placement, 9.78 ± 0.54 at the 6-month follow-up, and 9.61 ± 1.22 at the 1-year follow-up. There were no significant differences in patient esthetic satisfaction. Clinicians submitted satisfaction surveys for all 104 prostheses that completed the 1-year follow-up. With respect to function, the mean score was 9.51 ± 1.09 at prosthesis placement, 9.67 ± 0.72 at the 6-month follow-up, and 9.68 ± 0.61 at the 1-year follow-up. Regarding esthetics, the clinical satisfaction score was 9.64 ± 0.98 at prosthesis placement, 9.66 ± 0.69 at the 6-month follow-up, and 9.65 ± 0.72 at the 1-year follow-up. There were no significant differences in clinician satisfaction scores for either function or esthetics.
Complications
In total, 42 adverse events were reported, 5 of which were considered serious adverse events. All serious adverse events were due to hospitalization or death from causes unrelated to the device. Among the nonserious adverse events, 27 were device-related and 10 were non-device-related. The primary device-related adverse events were implant failure (8 events) and temporary paresthesia (8 events), followed by abnormal or prolonged pain after insertion (5 events) and submandibular swelling on the right side with mild discomfort (2 events). Single events included bone exposure on the distal aspect of the implant, infection related to implant placement, fracture of prosthesis teeth due to patient fall, and twisting of the hexagon of the implant mount. Events not related to implant failure were resolved to the satisfaction of the patient and of the providing clinician. There were relatively few complications related to technical or prosthetic issues. Twenty-two patients received reline of the inferior region of the prosthesis to address complaints of food catching (8 patients) or to satisfy the esthetic concerns of the patient or clinician. The considerable drop in OHIP scores at 1 year, particularly pertaining to questions relevant to these concerns, strongly indicates that these concerns were resolved (Fig 4). Nine individual denture teeth were repaired or replaced due to detachment or fracture during the first year of follow-up. One minor fracture involving the acrylic wrap-around portion of the prosthesis was reported and repaired. Screw loosening was rare, with three clinical screws exhibiting minor movement at the 6-month visit and six at the 1-year visit. One center reported minimal clinical screw loosening of six screws of approximately 25 Ncm to 30 Ncm requiring retightening to 35 Ncm.

DISCUSSION
In this study, the outcomes compare favorably with other successful full-arch implant solutions using different concepts,14,18,31 as shown by the > 97% 1-year CSRI and CSRP and minimal bone remodeling (~0.62 ± 0.39 mm). Of the eight implant failures, most were due to biologic factors, such as postoperative pain related to proximity to interfacing neural structures or infection; only two implants failed to osseointegrate (0.6%). The marginal bone level change below 1 mm is typical of remodeling that occurs around implants within the first year.32 Additionally, soft tissue parameters at the 6-month and 1-year follow-up visits were considered ideal in more than 80% of patients and stable after 1 year. These results indicate that this adaptive, three-implant–supported standardized treatment protocol can be an effective and predictable treatment option for the edentulous or soon-to-be-edentulous mandible.

Although financial cost is often reported as the primary barrier to implant-supported rehabilitation, the lack of time, fear of surgery or pain, health conditions, and provider choice have also potentially restricted patients’ access to the benefits of this treatment modality.2,33 The aim of this 5-year prospective multicenter study was to examine if some of these obstacles could be surmounted by providing a time-efficient highly performing fixed implant-supported prosthesis with limited clinical visits. Fewer implant and abutment components together with reduced chair time may potentially lower the financial burden for treatment while improving OHRQoL.

The efficiency of this standardized treatment system is also improved by eliminating the need of a provisional appliance, which is often used in most full-arch fixed implant-supported treatment solutions using immediate loading (including the All-on-4 treatment concept [Nobel Biocare] and similar imitation concepts). In this study, the definitive prosthesis was placed either on the day of surgery or within several days postoperatively. This approach circumvents the cost, time, and maintenance involved with a provisional prosthesis. Consequently, this improves time- and cost-efficiency due to the limited number of treatment visits and clinical chair time. In this study, the mean surgical time was 1 hour and 36 minutes, which is similar to values reported for two-implant overdentures (1 hour and 44 minutes),34 and the mean time of the prosthetic delivery visit was 25 minutes. A definitive fixed full-arch prosthesis was delivered on the day of surgery in 10% of participants. The mean time from implant placement to prosthetic delivery was 2 days and 11.5 hours with 76.4% of patients having their prosthesis immediately loaded within 1 to 2 days after surgery. The only other treatment concept that directly delivered a definitive prosthesis within 24 hours of implant
placement was the Novum protocol, and the delivery times in those studies were similar to or less than those reported for this system.\textsuperscript{16,17,35}

One notable feature of the current methodology is that the three adaptive fixation mechanisms facilitate a precise passive fit between the framework and implants, which lowers the risk of mechanical misfit complications, such as screw fracture or loosening. Novum lacked design features that could eliminate mechanical misfit between the lower bar and implants. The passivity of fit of the adaptive, three-implant–supported standard framework has been shown in vitro to be comparable to the fit of a CAD/CAM superstructure and exhibits greater passivity than cast restorations.\textsuperscript{19,36}

The literature on the Novum concept, the predecessor to the current concept, is varied. The initial prospective study of Novum demonstrated both a 1-year implant and prosthesis survival of 98.0\% (n = 50 patients; 150 implants),\textsuperscript{14} but a subsequent prospective multicenter trial had a 1-year cumulative implant and prosthesis survival rate of 90.7\% and 94.0\%, respectively (n = 51 patients; 153 implants).\textsuperscript{17} A retrospective analysis of the Novum concept in 15 patients over 5 years showed a CSR of 91.1\% and a prosthesis success rate of 86.7\% at 5 years. Common complications in that study were prosthesis-related and included resin prosthesis fractures, screw loosening, upper-bar modifications, and upper-bar resin and tooth fractures.\textsuperscript{16} The survival rates with the present treatment concept are similar to the initial prospective study but better than the subsequent studies. Importantly, very few of the mechanical and prosthetic problems were reported in this study. At the 1-year follow-up, no screw fractures occurred, a 1.9\% screw-loosening rate was observed, and no major prosthetic complications were reported except for six detached and three fractured teeth. Additionally, there were no reports of fractures of the framework or large sections of acrylic resin. Key differences between the Novum and Trefoil designs could explain the improved outcomes with the new adaptive protocol. Notably, the Novum 2-piece bar was bulky and occupied a significant volume of the available interarch space. This resulted in greater vertical bone reduction, and the framework often required extensive modification. Consequently, the limited space available reduced room for securing resin and teeth, weakening the prosthesis. The new single-piece adaptive framework height is 50\% less (5.5 mm) than that of the two-bar Novum design and allows more space for wrap-around processing, providing greater bulk, strength, and retention.

One time-saving aspect of the concept in this study is the simplified template-guided surgery that does not require complex digital planning beyond confirming if there is sufficient bone for implant placement. The standardized templates circumvent the need to produce additional customized surgical guides. The standardized components, including the definitive framework, eliminate the additional time needed for the clinician to obtain a customized bar. Similarly, the active working time required for the laboratory and restorative protocols is streamlined for efficiency. For conventional treatment protocols, delivery of the definitive prosthesis involves the fabrication of a customized CAD/CAM framework. This process relies on technical support and manufacturing capabilities available to the clinician. The Novum approach was estimated to reduce the time for the prosthetic and laboratory work by two-thirds and one-half, respectively, compared with conventional implant treatments.\textsuperscript{17}

The present study protocol is comparable to Novum, indicating that the Trefoil concept could similarly reduce costs and time, all while improving outcomes.\textsuperscript{18}

In this report, two important metrics examined patients' responses to treatment. Using a visual analog scale to assess functional and esthetic satisfaction, both patients and clinicians reported a mean satisfaction greater than 9.5 out of 10 after 1 year of function. Supporting this positive patient feedback was a corresponding marked improvement in quality of life as measured by the OHIP-EDENT 21 questionnaire. The authors believe these positive responses are in part related to the short time to deliver a high-quality definitive prosthesis involving few appointments. These results are similar to those of the Novum concept\textsuperscript{16,17} and with reviews reporting higher satisfaction and quality of life in patients treated with implant-supported dentures compared with conventional dentures.\textsuperscript{7,8}

While the adaptive, three-implant–supported standardized treatment system has the potential to serve a much broader patient population who find current treatment options out of financial reach, it does have some limitations. Patient selection is important, as the mandibular anatomy must be able to accommodate the position and geometry of the three planned implants. The standardized surgical procedure is more demanding than other concepts and requires precise execution. The extent of bone leveling can be greater with this protocol compared with options using customized CAD/CAM frameworks due to the standardized bar and tissue-level implants with polished collars. Further, depending on patient preference, the undersurface of the acrylic wrap-around may need to be relined following reduction of soft tissue swelling or tissue shrinkage.

**CONCLUSIONS**

High implant and prosthesis survival outcomes with excellent marginal bone and soft tissue responses indicate that the protocol in this study is a successful treatment
option for patients with edentulous mandibles or those with failing mandibular dentition. These 1-year results suggest that this adaptive, three-implant–supported standardized treatment concept can improve function and patient quality of life. Based on the available data, this approach may significantly reduce chair time for providers and is intended to reduce cost for patients compared with currently available treatment concepts, mainly due to the reduced number of visits and elimination of a provisional prosthesis.

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