Short-term report of an ongoing prospective cohort study evaluating the outcome of full-arch implant-supported fixed hybrid polyetheretherketone-acrylic resin prostheses and the All-on-Four concept

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Abstract

Background: More research is needed on the study of new materials for fixed prosthetic implant-supported rehabilitations.

Purpose: The purpose of this study was to report the short-term outcome of full-arch implant-supported fixed hybrid polyetheretherketone (PEEK)-acrylic resin prostheses and the all-on-four concept.

Materials and Methods: This prospective cohort clinical study included 37 patients (29 women, eight men) with an average age of 60 years (range: 38-78 years) with 49 full-arch hybrid PEEK-acrylic resin prosthesis supported by implants through the all-on-four concept. Primary outcome measures were prosthetic survival.

Results: Two patients with two maxillary prostheses were lost to follow-up. One patient with a double full-arch rehabilitation fractured the mandibular PEEK framework, rendering a 98% prosthetic survival rate. No implants were lost. The average (SD) marginal bone remodeling after 1 year of follow-up was 0.37 mm (0.58 mm). Technical complications concerning the veneer adhesion occurred in six patients and were resolved in all patients (with exception of the patient with prosthetic failure) through the creation of mechanical retentions and changing the bonding primer. Mechanical complications occurred in three patients and five prostheses consisting in prosthetic screw loosening (n = 2 patients) and fracture of the acrylic resin teeth (the patient with a prosthetic failure).

Conclusions: Within the limitations of this study, the results suggest that hybrid polymer (PEEK)-acrylic resin prostheses supported by implants for full-arch rehabilitation may represent a valid treatment option, still requiring longer-term validation.

KEYWORDS
all-on-four, immediate implants, polyetheretherketone, prostheses and implants

1 | INTRODUCTION

The rehabilitation of edentulous jaws through fixed implant-supported prosthesis with immediate function protocols allows the restoration of aesthetics, phonetics, and mastication, providing a psychological benefit for the patient. The all-on-four concept (Nobel Biocare AB, Göteborg, Sweden) is one of such immediate function protocols involving the insertion of four implants for full-arch rehabilitation of edentulous jaws with a minimum bone volume and avoiding bone augmentation procedures. Provided the implants are placed strategically—two posterior implants tilted up to 45° and two anterior axial implants—and they are well anchored (achieving a high primary
stability of at least 30 Ncm), the treatment success rate is high (98% for the maxilla and 98.1% for the mandible after 5-10 years of follow-up). Under these specific principles in implant arrangement, a large anterior/posterior spread between implants can be obtained consistently, aiming for prostodontic stability.

Full-arch fixed implant hybrid prostheses, in function for over 40 years, require frameworks to splint the implants together for support, an assembly considered as one of the keys to long-term clinical success. The historical perspective of framework materials includes the evolution from cast noble (gold, silver, etc) or base metal alloys (nickel and chromium) to the modern milled titanium and zirconium frameworks, the latter providing high biocompatibility, corrosion resistance, and the possibility of computer assisted-design/computed assisted-manufacture (CAD/CAM), an important improvement to achieve a better fit between framework and dental implants. Nevertheless, the high stiffness of these frameworks measured by the flexural strength (titanium: 434 MPa; zirconia: 900-1100 MPa) can be considered a potential disadvantage in shock absorption behavior of the prosthesis.

Polyletheretherketone (PEEK) consists in a high-performance polymer from the polyaryletherketone (PAEK) family. PEEK is a thermoplastic polymer that is typically used as a metal replacement, owing to its strength to weight ratio and corrosion resistance.

PEEK was originally developed in the United Kingdom in 1978 (ICI—now as Victrex plc) and requires a particular polymerization process, which enables the control of the length of the resulting polymer chains. This polymer versatility allows the offering of a range of processing options and an array of formulations, ranging from unfilled grades with varying molecular weights, to image contrast, colored and carbon fiber-reinforced grades.

Implantable PEEK polymer displays a number of properties including biocompatibility, biostability, and compatibility with medical diagnostic imaging. In addition, PEEK provides superior chemical stability, mechanical behavior, creep, and wear resistance and is therefore well suited to the demanding environment encountered by medical devices.

Over the last decades, PEEK has seen extensive use in highly demanding industrial (aerospace, automotive, oil and gas, electronic) and medical applications including implantable medical devices such as orthopedic, spinal and cranial implants. PEEK (Thornton Cleveleys, United Kingdom: PEEK-OPTIMA Invibio Ltd.) has been used clinically for more than 15 years and in over 5 000 000 implanted devices across a wide range of medical applications, including spinal fusion, where it has become an industry standard implant material. Specifically in the field of dentistry, PEEK has been used over the last decade in healing caps and temporary abutments. Due to its proven biocompatible nature and its shock absorbing characteristics, while maintaining the possibility of CAD/CAM manufacture, such a material could be interesting for use in full-arch restorations as a nonmetal alternative. Nevertheless, proof on its long-term outcome in implant-supported fixed rehabilitations is lacking, making it necessary to evaluate the outcome of implant-supported fixed prosthetic rehabilitations using PEEK material.

The aim of this ongoing prospective study was to report on the short-term outcome (1 year) of full-arch rehabilitations using the all-on-four concept (Nobel Biocare AB) and a full-arch hybrid PEEK-acrylic resin prosthesis (PEEK infrastructure and acrylic resin artificial gingiva and acrylic resin teeth).

2 | MATERIALS AND METHODS

This prospective cohort clinical study was performed in a private practice (Lisbon, Portugal) and is estimated to last for 5 years. The present report concerns the 1-year evaluation (short-term outcome). The patients were rehabilitated between May 2015 and October 2016. This study was approved by an independent ethical committee (Ethical Committee for Health, authorization no. 008/2013). All patients signed a written informed consent to participate in the present study. Thirty-seven full-arch edentulous patients (29 females and 8 males) with an average age (SD) of 59.8 years (10.6 years) and 49 edentulous arches (double full-arch: 12 patients; single full-arch maxillae: 12 patients; single full-arch mandible: 13 patients) were included and treated in a private practice (Maló Clinic, Lisbon, Portugal). The patients who met the inclusion criteria were identified at the treatment planning phase.

2.1 | Inclusion and exclusion criteria

Inclusion criteria were patients submitted to full-arch fixed prosthetic rehabilitation supported by implants in immediate function inserted through the all-on-four concept (Nobel Biocare AB). Patients were excluded from this study if they presented the following criteria: insufficient bone volume, active radiotherapy or active chemotherapy, or hindrance to provide written informed consent.

2.2 | Surgical protocol

The surgical and prosthetic procedures are described in a previous published manuscript.

In brief, surgery was performed with the patient under local anesthesia using articaine clorhidrate (72 mg/1.8 ml) with epinephrine (0.018 mg/1.8 ml) 1:100.000 (Artinibsa 2%; Iniba Laboratory, Barcelona, Spain). Prior to the surgical procedure the patients were administered with diazepam (Valium 10 mg, Roche, Amadora, Portugal). The administration of antibiotics was performed 1 hour before surgery and thereafter on a daily basis for 6 days (amoxicillin 875 mg and clavulanic acid 125 mg; Labsal, Campo de Besteiros, Portugal). Corticosteroids were given daily in a regression mode (15 mg on the day of surgery to 5 mg on the fourth day) (prednisone 5 mg [Meticorten Schering-Plow Farma, Lda, Agualva-Cacém, Portugal]). Anti-inflammatories (ibuprofen, 600 mg; Ratiopharm, Lda, Carnaxide, Portugal) were given for 4 days postoperatively starting on the fourth day. Analgesic medication [clonixine (300 mg, Clonix, Janssen-Cilag Farmaceutica, Lda, Barcarena, Portugal)] was administered to the patients on the day of surgery and only used postoperatively in case of experiencing pain. Antacid medication (omeprazole, 20 mg; Lisboa, Portugal) were administered to the patients on the day of surgery and from thereafter on a daily basis for 6 days.
Implant insertion (Nobelspeedy; Nobel Biocare AB) followed standard procedures with the exception of the use of under-preparation, employed to guarantee a final torque of over 32 N/cm before the final implant seating. Implant length ranged between 10 and 18 mm.

The two most anterior implants were inserted following the direction determined by anatomy of the jaw. The two posterior implants were inserted (one implant on each quadrant) anterior to the mental foramina (in the mandible) and the anterior wall of the maxillary sinus (in the maxilla) with a distal tilting between 30° and 45° relative to the occlusal plane, aiming for good implant anchorage, large inter-implant distance and short cantilevers.

The implants were positioned at bone level. Whenever possible, bicortical anchorage was established. Soft tissue was readapted and sutured back into position on each patient using 3-0 nonresorbable sutures (Silkam, B. Braun Surgical SA, Rubi, Spain). The abutment choice was made based on the use of straight multiunit abutments (Nobel Biocare AB) for the anterior implants and 30° angled abutments for the posterior implants. Whenever was needed a further compensation of the angulation in the anterior implants due to jaw anatomy, 17° abutments were used. The specific choice of abutments was made with the objectives of allowing the prosthesis to have passive fit, maintaining the prosthesis with an acceptable thickness, and having the prosthetic screw-access holes emerging on the occlusal or lingual aspects of the prosthesis.

Patients were informed that the surgical area should be kept cool and under minimal pressure for the first 48 hours after the surgery; only soft and cold foods were to be ingested during that period.

2.3 | Immediate provisional prosthetic protocol

High-density acrylic resin (PalaXpress Ultra; Heraeus Kulzer GmbH) prostheses with titanium cylinders (Nobel Biocare AB) were manufactured at the dental laboratory and inserted on the same day (n = 49). The occlusion scheme adopted in the provisional prosthesis privileged anterior occlusal contacts and canine guidance during lateral movements. On the provisional prostheses, the emergence positions of the screw-access holes were normally at the second premolar level for the posterior implants. The prostheses exhibited a minimum of 10 teeth.

2.4 | Pilot study

The CAD/CAM guidelines as related to cross-sectional material dimensions below which fabrication is not advised were a minimum occlusocervical height of 4 mm, a buccolingual width of minimum 3 mm and a maximum of one cantilever unit according to the manufacturer (Figure 1). A pilot study was performed with four patients and five full-arch prostheses in the period between May 2014 and May 2015. The results of the pilot study determined that a titanium sleeve had to be inserted within the PEEK infrastructure at the CAM phase in order to avoid PEEK strangulation provoked by the titanium prosthetic screws’ torque tightening (Figures 2 and 3). The special retention mechanism was not necessary for the titanium sleeves that were inserted on the PEEK infrastructure in its coronal aspect, surrounded by PEEK and acrylic-resin.

2.5 | Definitive prosthetic protocol

The final full-arch hybrid prostheses were assembled of polymeric-acrylic resin implant-supported fixed prostheses with a PEEK substructure, reinforcing titanium sleeves, acrylic resin prosthetic teeth and pink acrylic resin gingiva (patent pending; United Kingdom Patent Application No. GB1711004.0). The final full-arch hybrid prostheses determination was based on the all-on-four concept (Nobel Biocare AB), aiming to achieve the area of the first molar in a prosthesis with 12 functional teeth, which is based on the exploratory nature of the present study implied the inclusion of more than one cantilever unit in nine patients and nine prostheses.

The dental laboratory used the tooth arrangement on the interim implant-supported fixed prostheses as a starting point to manufacture the definitive prostheses.
A silicone mask index (Zetalabor; Heraeus Kulzer GmbH, Hanau, Germany) was made with the maxillary and/or mandibular interim prostheses removed from the patient and screwed onto the master casts to serve as a guide for the final restoration. The setup (wax pattern and acrylic teeth) was assembled and a try-in was performed in mouth with the patient. A new silicone mask index (Zetalabor) was made over the try-in. The try-in and the stone model were scanned and CAD designed (DentalCAD software, version 6.0.0.446; Cara DS Scan scanner, version 3.2.1A 360). A screw-retained framework was manufactured from a PEEK disk (Juvora Ltd, Lancashire, United Kingdom) after CAM processing adapting to the multiunit abutments. The reinforcing titanium sleeves comprising a generally tubular wall and an annular shoulder portion were introduced at the CAM processing step and shaped to receive the terminal end of the multiunit abutments. The PEEK substructure (Juvora Ltd, Lancashire, United Kingdom) surface was prepared according to the following protocol: the framework was uniformly sand-blasted with silica (Rocatec plus, 3 M; Maplewood, Minnesota) at a 3 bar pressure and a distance of 1 cm in a $45^\circ$ angle. The primer (metal-bond 1 and 2 on all cases; Signum Connector on the cases identified with veneer adhesion issues; Heraeus Kulzer GmbH) was applied over the framework, followed by a light-curing pink opaque (Opaque F, Heraeus Kulzer GmbH). The prosthetic teeth (anterior teeth: Premium; posterior teeth: Mondial; Heraeus Kulzer GmbH) were sand-blasted with aluminum oxide (Corundum, Heraeus Kulzer GmbH) at a 3 bar pressure-1 cm distance and placed on the silicon mask from the try-in. The pink acrylic resin was poured on the framework (PalaXpress Ultra, Heraeus Kulzer GmbH) and polymerized using a pressure pot (Palamat, Heraeus Kulzer GmbH) for 25 minutes at 55°C.

The final full-arch hybrid prostheses was a polymer-acrylic resin implant-supported fixed prostheses with a PEEK framework (Juvora Ltd.), reinforcing titanium sleeves, acrylic resin prosthetic teeth (Premium and Mondial crowns, Heraeus Kulzer GmbH), and pink acrylic resin gingiva (PalaXpress Ultra, Heraeus Kulzer GmbH). The average time manufacture process until the connection of the final prostheses was 6 months.

The occlusion for the final prosthesis was adjusted to a mutually protected occlusion scheme respecting the patients’ centric relations. Figures 5–14 illustrate the definitive prosthetic protocols of a full-arch mandibular rehabilitation through the all-on-four concept (Nobel Biocare AB) with a polymer-acrylic resin hybrid prosthesis.

2.6 | Postoperative and maintenance protocols

The patients were instructed to have a soft food diet for the first 4 months postsurgery. Ten days after surgery, the sutures were removed, and hygiene and implant stability (clinical mobility and suppurvation by finger pressure) were checked. The occlusion was rechecked according to the initial protocol, a procedure that was repeated after 2 and 4 months. Usually, at around 4 months, the prostheses were again removed, jet-cleaned (using Air-Flow Powder, EMS, Nyon, Switzerland), and disinfected (using 0.2% chlorhexidine; Elugel, Pierre Fabre Dermo-Cosmetique), and the implants were checked for anchorage (clinical mobility), suppurvation, and pain.

The connection of the definitive prosthesis was considered the baseline for clinical and radiographic evaluations. After the connection of the full-arch definitive prostheses, the patients were evaluated after 6-months (clinically) and 1 year of function (clinical and radiographically).

2.7 | Primary outcome measure

Primary outcome measure was prosthetic survival (need to be replaced) including fracture of framework.

2.8 | Secondary outcome measures

Secondary outcome measures were implant survival, marginal bone remodeling, modified plaque index, modified bleeding index, technical
evaluation concerning manufacture issues, the incidence of mechanical complications, the incidence of biological complications, and patient subjective evaluation.

Implant survival was evaluated based on function and using the patient as unit of analysis (first implant failure in a patient considered as censoring event irrespective of the remaining implants maintaining function).³

Marginal bone remodeling was evaluated using a conventional radiographic holder (super-bite; Hawe Neos, Bioggio, Switzerland) was used, and its position was manually adjusted for an estimated orthognatic position of the digital film. An outcome assessor examined all implant radiographs. The marginal bone remodeling was assessed with image analysis software (rayMage, version 2.3; MyRay, Imola, Italy). The reference point for the reading was the implant platform (the horizontal interface between the implant and the abutment), and the marginal bone level was assessed and defined as the most apical contact between bone and implant. The difference in marginal bone level between the 1-year and baseline assessments was defined as the marginal bone remodeling. The measurements were performed on...
the mesial and distal sites, and average values were calculated. The radiographs were accepted or rejected for evaluation based on the clarity of the implant threads; a clear thread guaranteed both sharpness and an orthogonal direction of the radiographic beam toward the implant axis. The radiographs were calibrated using the implant threads.

Modified plaque index (mPLI),\(^{35}\) evaluated by inserting a periodontal plastic probe 1 mm into the peri-implant sulcus, running a circular movement all around the implant and measured in a scale between 0 and 3 (0: no detection of plaque; 1: plaque only recognized by running a probe across the smooth marginal surface of the implant; 2: plaque can be seen by the naked eye; and 3: abundance of soft matter).

Modified bleeding index (mBI)\(^{35}\) evaluated on the same moment as mPLI and measured in a scale between 0 and 3 (0: no bleeding when a periodontal probe is passed along the mucosal margin adjacent to the implant; 1: isolated bleeding spots visible; 2: blood forms a confluent red line on mucosal margin; and 3: heavy or profuse bleeding);

The technical evaluation of concerning manufacture issues was evaluated comprising the infrastructure manufacture issues (presence or absence), framework integrity issues (present/absent), and veneer adhesion issues (present or absent).

Biological complications assessed were as follows: probing pocket depth > 4 mm, evaluated using a plastic periodontal probe calibrated to 0.25 N; abscess (presence or absence); fistulae formation (presence or absence); suppuration (presence or absence); and patient adverse soft tissue reaction (presence or absence).

Mechanical complications assessed were loosening or fracture of prosthetic screws, abutments, or prosthesis.

The patients’ evaluation comprised the “in mouth comfort”, defined as the comfort felt by the patient with the prosthesis in function regarding an overall fulfillment of expectations, measured in a visual analogue scale between 0 (poor) and 10 (excellent) and “overall chewing feeling”, defined as the patients’ feeling when chewing food in their daily food intake routines related to the ability to chew any type of food and measured in a visual analogue scale between 0 (poor) and 10 (excellent).

2.9 | Statistical analysis

Survival was estimated using life table analysis (actuarial method) and using the implant and prosthesis as unit of analysis. Descriptive statistics (average with 95% confidence intervals, SD) were computed for the variables of interest: age, marginal bone loss, and the patient evaluation variables “in mouth comfort” and “overall chewing feeling”; the mode was computed for the variables mPLI and mBI; and frequencies were computed for the technical evaluation concerning manufacturing issues and for the incidence of biological and mechanical complications. Inferential analysis was computed for the evaluation of the correlation between mPLI and mBI through the Spearman’s correlation coefficient.

The significance level was set at 5%. The data were analyzed using the software SPSS for Windows version 17 (IBM SPSS, New York).

3 | RESULTS

3.1 | Sample

A total of 37 patients were rehabilitated with 49 full-arch prostheses. The average cantilever length in a prosthesis was 0.7 units (SD: 0.6 units; range: 0-2 units). Two patients (5.4%) with two single full-arch maxillary prostheses (4.1%) were lost to follow-up during the first 6 months of follow-up, becoming unreachable.

3.2 | Primary outcome measure

One patient (male, 55 years of age, heavy bruxer) with a double full-arch rehabilitation needed to replace the mandibular prosthesis due to fracture of the PEEK framework, rendering 98% prosthetic survival rate (Table 1).

<table>
<thead>
<tr>
<th>Time</th>
<th>Total number of patients</th>
<th>Prostheses</th>
<th>Prosthetic failures</th>
<th>Lost to follow-up</th>
<th>Survival rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prosthesis connection–1 year</td>
<td>37</td>
<td>49</td>
<td>1</td>
<td>2(^{a})</td>
<td>98.0</td>
</tr>
</tbody>
</table>

PEEK, polyetheretherketone.

\(^{a}\) Two prostheses in two patients.
3.3 | Secondary outcome measures

A total of 196 implants were inserted for rehabilitation of 49 edentulous arches. No implant failures were registered, rendering a 100% implant survival rate after 1 year.

The average (SD) marginal bone remodeling after 1 year of follow-up was 0.37 mm (0.58 mm), with 0.33 mm (0.52 mm) for maxillary implants and 0.40 (0.63 mm) for mandibular implants. The marginal bone remodeling distribution considering the type of rehabilitation per patient is illustrated in Figure 15, with a nonsignificant lower average registered for double full-arch rehabilitated patients compared to single full-arch rehabilitations evaluating the significant overlap in the 95% confidence intervals.

The mode for the mPLI was two (plaque visible by the naked eye) at 1 year of follow-up. The mode for the mBI was one (one isolated bleeding spot visible when tested) at 1 year. The correlation between mPLI and mBI was a nonsignificant, weak positive linear relationship \( R = 0.321; P = 0.068; \) Spearman’s correlation coefficient.

Concerning the technical evaluation, no issues were registered during the manufacture phase of the prosthesis in both infrastructure manufacture and integrity. The incidence of veneer adhesion issues with avulsion of the acrylic resin from the PEEK infrastructure was 15.8% \( (n = 6 \) patients) at patient level and 14.3% \( (n = 7 \) prostheses) at prosthesis level: One male patient with mandibular full-arch rehabilitation occluding with a mucosal-retained full-arch prosthesis after 2 months of follow-up in position #35 (last cylinder); one female patient with mandibular full-arch rehabilitation occluding with natural teeth and implant-supported prosthesis after 4 months of follow-up in position #46 (last cylinder); one female patient with mandibular full-arch rehabilitation occluding with a mucosal-retained full-arch prosthesis after 10 months of follow-up in position #35 (last cylinder); one female patient with mandibular full-arch rehabilitation occluding with a mucosal-retained full-arch prosthesis after 12 months of follow-up in position #35 (last cylinder); one female patient with a double full-arch rehabilitation after 12 months in positions #15 and #22. The issues with veneer adhesion were resolved in five patients and five prostheses by increasing the amount of exposed PEEK in the cylinder areas to increase flexion resistance, creating retentions in the PEEK infrastructure with a tungsten bur to increase mechanical retention, and changing the bonding primer used to improve the tensile bond strength (Figures 16–20). In one male patient (55 years of age, heavy bruxer) with a double full-arch rehabilitation with the avulsion occurring after 5 months in positions #12, #22, #25, and #35, the issue was not resolved as the patient accumulated this event with a fracture of the acrylic teeth in both restorations and fracture of the PEEK infrastructure in the lower restoration (position #35), forcing the manufacture of a new prostheses (considered a failure).

During the follow-up of the study, no biological complications were registered, with absence of peri-implant pockets >4 mm, abscess, fistulae, formation, suppuration, or soft tissue adverse reactions. Mechanical complications occurred in three patients (7.9%) and five prostheses (10.2%) consisting of fractures of the acrylic resin teeth and PEEK framework in one patient (2.6%) and two prostheses (4.1%) and loosening of prosthetic screws in two patients (5.3%) and three prostheses (6.1%). Prosthetic screw loosening occurred in one female patient with PEEK-acrylic resin maxillary rehabilitation occluding with a full-arch acrylic resin implant-supported prosthesis after 4 months of follow-up and one female patient with double full-arch PEEK-acrylic resin rehabilitation after 8 months of follow-up.

The prosthetic screw loosening events were resolved by torque controlled retightening the prosthetic screws and adjusting the occlusion. No further mechanical complications occurred.

Concerning the patients’ evaluation, the registered averages (SD) were 88% (16%) satisfaction for “in mouth comfort”, and 84% (19%) satisfaction for “overall chewing feeling”.

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**FIGURE 15** Error bar chart illustrating the marginal bone loss distribution according to the type of rehabilitation. Note the overlapping 95% confidence intervals (bars) of the average (circles) indicating a non-significant difference between single full-arch and double full-arch rehabilitations.
DISCUSSION

This study reports the short-term follow-up of a new proposal for full-arch fixed prosthetic rehabilitations using an implant-supported hybrid polymer-acrylic resin prosthesis. Considering the outcomes of prosthetic survival, implant survival, marginal bone loss, complications and patients' subjective evaluation, this new proposal for full-arch implant-supported rehabilitation may be a viable treatment option but still requiring further follow-up evaluation to validate its use in implant dentistry.

PEEK, a thermoplastic polymer with excellent thermal and chemical stability, especially used in a wide range of applications for automotive and aerospace industries, was proposed as a metal replacement. The PEEK properties include biostability, biocompatibility, and shock-absorbing characteristics. Rosentritt et al. made an in vitro study to investigate the force absorption capacity of implant-supported molar crowns made of polymethyl methacrylate, PEEK, composite, lithium disilicate, titanium and zirconia, and connected to abutments with different luting agents registered that materials with a higher moduli of elasticity (ceramics and titanium) exhibited lower shock-absorbing capacity than resin-based materials. In a study, Sarot et al. compared carbon fiber-reinforced PEEK components (implants and abutments) with titanium using finite element analysis, registered a higher stress, and higher load concentration in the cervical portion and on the cortical bone for carbon fiber-reinforced PEEK implants when submitted to load, whereas the carbon fiber-reinforced PEEK abutment exhibited a similar performance to the titanium abutments. This increase in stress was attributed to the higher displacement capacity of the carbon fiber-reinforced PEEK. Nevertheless, the stress distribution of carbon fiber-reinforced PEEK abutments was similar to titanium when connected to a titanium implant. In a study, Stawarczyk et al. evaluated the surface properties and fracture load of three-unit PEEK fixed dental prosthesis determined the cut-off point of 1200 N for plastic deformation and 1383 N for mean fracture load, concluded that PEEK might be a suitable material for fixed dental prostheses, especially in load-bearing areas. Therefore, PEEK was chosen for further investigation in this study, as part of a full-arch hybrid prosthesis supported by dental implants.

The prosthetic survival registered in this study was 98% due to one prosthetic failure in a double full-arch rehabilitated heavy bruxer, presenting a line of fracture on the mandibular PEEK framework suggesting occlusal overload. According to a systematic review, occlusal overload, associated with parafunctional habits such as bruxism, was considered the primary etiologic factor in biomechanical implant treatment complications. The association of maximum bite force with bruxing/clenching habits can impact significantly on the outcome of prosthetic materials. Previous studies investigated the influence of gender and bruxism on the human maximum bite force registered peaks between 978-1000 N of bite force in a heavy bruxer males. Forces of this magnitude or stronger, constantly applied to prosthetic materials through daily use will impact negatively the prosthetic outcome even in a material with a deformation point module at 1200 N of force.

The present study recommends the following CAD/CAM guidelines for a clinically successful framework as related to cross-sectional material dimensions: a minimum occlusocervical height of 5 mm and an anterior buccolingual width of 4 mm. The fact that PEEK material is less stiff and flexes more implied the increase of width in the areas of the titanium sleeve for a minimum of 6 mm buccolingual width to compensate flexion as it represented a weak point. Moreover, a 1-2 mm acrylic resin to increase the adhesion while considering the previously mentioned dimensions together with a maximum of one cantilever unit (following the manufacturer's instructions) are also recommended.

The inclusion of cantilevers in the full-arch prostheses is directly related to the degree of maxillary or mandibular crest resorption when considering the all-on-the concept given the need of a minimum 12 functional teeth. A previous study evaluating the outcome of all-on-four concept rehabilitations and proposing an edentulism classification reported different implant distributions according to available bone in volume and density. The presence of bone available up to

FIGURE 18 Applying the bonding primer

FIGURE 19 Prosthesis vestibular view after resolving veneer adhesion issue

FIGURE 20 Prosthesis lingual view after resolving veneer adhesion issue. Note the increased amount of exposed PEEK in the cylinder area to increase flexion resistance
second premolar determined the anterior implant exits in the canine area and the posterior tilted implants exits on the molar without including cantilevers; the presence of bone available up to the first premolar determined the anterior implant exits in the lateral incisor area and the posterior tilted implants exits on the second premolar with inclusion of a one unit cantilever; the presence of bone available up to the canine determined the anterior implant exits in the central incisor area and the posterior tilted implants exits on the first premolar with inclusion of a two units cantilever. Significant differences were reported with the absence of cantilever units in the prosthesis as a protective effect (odds ratio = 0.22) and bruxism (odds ratio = 60.95) as a risk factor for the occurrence of mechanical complications in a logistic regression model. A similar result was reported in this study, with bruxism significantly influencing the occurrence of mechanical complications (framework and prosthetic fracture in one patient). Given the exploratory nature of this study, nine patients with nine prosthesis with more than a one unit cantilever were included. In this study, the use of cantilever units did not imply neither a decrease in implant or prosthetic survival nor an increase in mechanical complications (three prosthetic screw loosening events in one prosthesis with one cantilever unit and two prostheses without cantilever units) but was reflected on the technical complications (the veneer adhesion issues) with an increased trend for prosthesis with longer cantilever lengths implying the flexing of the distal cantilever are of the PEEK framework as potential cause. Nevertheless, it is important to reinforce that the veneer adhesion issues were resolved for all patients independently of the prosthesis cantilever length, suggesting that the correct bonding agent between acrylic resin and PEEK could be of increased importance.

Considering implant survival, the 100% survival rate registered in this study compares favorably with previous investigations. A study evaluating the short-term outcome of All-on-4 (Nobel Biocare AB) full-arch rehabilitations using the same implant design as the present study registered a cumulative survival rate of 98.9% at 1 year of follow-up. Patzelt et al.37 in a systematic review to evaluate the all-on-four treatment concept registered a mean (SD) combined cumulative survival rate of 98.6% (1.3%) at 1 year of follow-up and another systematic review42 on the same topic reported a 99.8% survival rate for rehabilitations with 2 years or more of follow-up.

The average marginal bone remodeling after 1 year of function was low and within the accepted standards, comparing favorably with previous reported short-term ranges for full-arch restorations. In a systematic review44 comparing marginal bone remodeling around axially versus tilted implants supporting fixed prosthetic reconstructions of partially and fully edentulous jaws after 1 year of function, the authors registered a range between 0.51-1.13 mm and 0.43-1.14 mm for axial and tilted implants of full-arch restorations, respectively.

The mode for mPLI was high, with patients scoring a level 2 of the mPLI scale (the second worst level of the scale with plaque visible by the naked eye) corresponding to low levels of oral hygiene habits. The mBI level was mild (corresponding to the second best level with only one isolated bleeding spot visible around the implant). The causal relation between plaque and mucositis was previously explored: Pontoriero et al.45 explored the conditions of an experimental gingivitis model in their study of 20 partially edentulous patients who were treated with implants and subsequently refrained from oral hygiene for a period of 3 weeks. The authors observed an increase in mucositis severity, including inflammation of the soft tissues and an increase of ±1 mm in peri-implant pockets. Salvi et al.46 used the same 3-week period of undisturbed plaque accumulation followed by a period of optimal plaque control to monitor clinical, microbiological, and host-derived alterations on experimental mucositis/gingivitis models of 15 patients. The authors registered median mPLI scores of 1.17, 1.33, and 1.33 and mBI scores of 1.33, 1.33, and 1.5 after 1-, 2-, and 3-weeks, respectively, suggesting a positive linear relationship; while after resuming optimal plaque control, the median values for weeks 6, 7, and 8 were always 0 for mPLI and 0.75, 0.5, and 0.5 for mBI, suggesting a negative linear relationship. These findings confirmed the causal relation between plaque accumulation and peri-implant health.

In this study, the issues with veneer adhesion occurred were related to the mechanical and chemical retentions used between PEEK and acrylic resin. After applying the remedies to the complications, no re-incidences occurred with the exception of the patient that fractured the PEEK infrastructure. The change of bonding primer in the present study was supported by previous investigations: Both Stawarczyk et al. and Keul et al.24,50 made an investigations using an in vitro model with 9624 and 68050 specimens to evaluate the tensile bond strength of veneering resins to PEEK, reported a higher tensile bond strength of the bonding primer used to resolve the complications in this study. Furthermore, the increased amount of exposed PEEK in the cylinder area was performed to reinforce the structure to have an area of less flexion and also avoid a direct transition line between acrylic-resin and PEEK as it represented a point of rupture and infiltration.

Concerning the mechanical complications, the 7.9% and 10% incidence of mechanical complications at the patient and prosthetic level, respectively. The mechanical complications occurred in double full-arch rehabilitated patients (two patients with PEEK-acrylic resin prostheses and one patient with acrylic resin implant-supported prostheses as opposing dentition). This tendency was previously described in a study investigating the 5-years outcome of double full-arch versus single full-arch all-on-four (Nobel Biocare AB) implant-supported rehabilitations, with the authors reporting an increased incidence rate of mechanical complications (statistically significant) for double full-arch when compared to single arch.51

The patients’ evaluation of the restorations were high in both “in mouth comfort” (88%) and “overall chewing feeling” (84%) reflecting the overall satisfaction in important subjects to be evaluated at the first year of follow-up. Similar evaluations were reported by Kennedy et al.52 for metal-acrylic resin mandibular full-arch implant-supported
fixed prostheses with the patients evaluating at a 79% satisfaction both the improvement in the ability to chew and that the fulfillment of expectations. The limitations of this study were related with a single center, the short sample, the short follow-up, and the lack of a control group. The strengths of this study were related with the low dropout rate, accounting for increased internal validity and the prospective design. Future research should focus on the outcome at 3 years of follow-up and in the evaluation of a routine group.

5 | CONCLUSIONS

Within the limitations of this study and considering the high prosthetic/implant survival and patient satisfaction, the low marginal bone loss and the low incidence of biological and mechanical complications, it is possible to conclude that full-arch hybrid PEEK-acrylic resin implant-supported prostheses may be a valid treatment option, nevertheless, requiring a longer follow-up to fully attest its validity in implant dentistry.

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CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest with the contents of this article. Doctor Moura Guedes, Mister Miguel de Araújo Nobre and Mister António Silva received previous educational fees from Juvora.

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