

Bite Force Evaluation for Patients Wearing Mandibular Screw Retained Hybrid Complete Denture (All on Four Implant Concept) supported with Polyetheretherketone (PEEK) CAD \ CAM Milled Framework Material

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Abstract— Purpose: The aim of this study was to evaluate the bite force value between patients wearing PEEK frameworks fabricated by CAD-CAM in mandibular hybrid screw retained implant-supported prosthesis with all on four concepts. Materials and Methods: This study was a comparative clinical trial. It was conducted on six completely edentulous patients, according to the calculated sample size each patient received hybrid prostheses reinforced with PEEK framework. Biting force was assessed by a bite force transducer. All assessments were carried out three months after hybrid denture insertion as follows: - 1 week, 1 month, 3 months follow-up periods Results: The mean \pm SD of bite force for peek group is 91.50 ± 2.38 at 1 week ranging from 88.48 to 93.51, 88.43 ± 4.37 at 1 month ranging from 80.22 to 92.4, 90.69 ± 2.61 at 3 months ranging from 85.93 to 93.08. The repeated Measures test was used to assess change in bite force during follow-up from 1 week to 1 month to 3 months and demonstrates statistically non-significant difference between different follow up periods.

Conclusion: Within the limitation of this study, the bite force value increases over time. The use of PEEK is very important in improving the bite force value and has proven highly effective in these cases.

Keywords— PEEK, All-On-Four.

1. Introduction

The functionality and integrity of the masticatory system significantly influence an individual's quality of life [1]. Numerous factors impact masticatory performance, including age, bite force, gender, the loss and type of restoration of post-canine teeth, malocclusion, total occlusal contact area, oral motor function, and salivary gland function. Bite force has been identified as a primary determinant of masticatory function and performance [2].

Edentulism is considered a disability, negatively affecting both oral function and the psychological well-being of patients. Complete dentures gained widespread popularity several decades ago with the introduction of acrylic polymers in dentistry. While dental implants are extensively used as a treatment option for completely edentulous patients, financial constraints, anatomical limitations, and systemic conditions often contraindicate this approach for many individuals [3].

The "All-on-4" treatment concept for edentulous patients has gained considerable popularity over the last two decades [4, 5]. This concept involves the rehabilitation of patients with significantly

resorbed ridges using four implants to support fixed restoration (FR). For the edentulous mandible, two implants are vertically inserted in the canine regions, and two implants are distally tilted 30 degrees posteriorly towards the mental foramina. This implant tilting strategy reduces the need for invasive surgical procedures (such as bone grafting and nerve displacement), enhances prosthetic support, increases the interimplant distance, provides superior implant anchorage in the bone using longer implants, and allows for a reduction in the cantilever length of the prosthesis [6].

Furthermore, immediate functional loading of the implants can be achieved with a screw-retained fixed provisional restoration, which promptly restores mastication and esthetics, while simultaneously reducing cost and treatment time [7]. The final restoration typically consists of a short-arch fixed prosthesis (10 to 12 teeth) [8]. Recently, the author reported the use of milled bar overdentures (MO) as a definitive prosthetic rehabilitation for implants placed according to the All-on-4 concept [9-11].

The clinical success of dental implants is primarily dependent on biomechanical considerations and the appropriate distribution of occlusal forces. Accurate diagnosis and meticulous treatment planning are crucial for successful dental implant outcomes. Strategies to reduce strain on the crestal bone include increasing the anteroposterior spread of dental implants, placing longer and wider implants, increasing the number of implants, and utilizing stress-breaking or stress-releasing materials such as PEEK [12].

Polyetheretherketone (PEEK) represents an innovative material for fabricating CAD/CAM fixed and removable prostheses due to its ease of milling compared to titanium and its polishability. Milling with PEEK is highly recommended as the resulting non-allergenic prostheses are lighter in color than those constructed from other materials, such as cobalt-chromium (Co-Cr) or titanium, and the milling process does not adversely influence the mechanical properties of the PEEK material [13].

Evaluations of bite force have proven to be constructive and are widely utilized in dentistry. The measurement of bite force aims to determine muscular activity and jaw movements during the chewing process, and these measurements are also valuable for assessing masticatory efficiency [14]. A decline in the masticatory ability of elderly individuals has been identified as a potential long-term risk factor for mortality [14]. Limited research has investigated the bite force efficiency of PEEK when utilized as a framework. Therefore, the present investigation was designed to evaluate the bite force values in patients wearing PEEK frameworks fabricated via CAD/CAM in hybrid screw-retained implant-supported prostheses.

2 . Materials and Methods

2.1 Participant selection

This investigation comprised a comparative clinical trial involving six completely edentulous patients (three males, three females; age range: 55-65 years). The sample size was determined prior to patient recruitment. Each participant received hybrid prostheses reinforced with a PEEK framework.

Inclusion Criteria:

1. Complete edentulism with healthy residual alveolar ridge mucosa.
2. Documented reduction in retention and stability of conventional dentures attributed to alveolar ridge atrophy, coupled with patient preference for implant-supported hybrid rehabilitation.
3. Adequate bone volume within the mandibular interforaminal region to accommodate standard implants (minimum 11 mm length, 3.75 mm diameter). Bone quantity and quality were confirmed via preoperative cone-beam computed tomography.

Exclusion Criteria:

1. General contraindications for surgical intervention, including a history of head and neck radiotherapy, bleeding disorders, or hepatic dysfunction.
2. Metabolic disorders known to impair osseointegration, such as diabetes mellitus, hepatic disorders, or osteoporosis.
3. Long-term immunosuppressive or Corticosteroid pharmacotherapy.
4. Presence of parafunctional habits, such as bruxism or clenching.

All participants received comprehensive information regarding the treatment protocol and the necessity for routine follow-up appointments. Written informed consent was obtained from all subjects. The study adhered to the ethical principles approved by the institutional ethics committee of the Faculty of Dentistry and conformed to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for clinical trials.

Initially, all selected patients received new maxillary and mandibular complete dentures (CD). Subsequently, four implants were placed in each patient according to the "All-on-four" concept, with immediate loading of the mandibular denture. Following a 3-month healing period, each patient received a definitive mandibular fixed hybrid prosthesis.

2.2 Surgical and prosthetic interventions

The newly fabricated mandibular denture was utilized as an acrylic resin radiographic template, into which gutta-percha radiopaque markers were integrated on the polished surface. Patients subsequently underwent computed tomography (CT) scans to precisely determine bone volume for prosthetically driven implant placement [15]. A dual-scan protocol was employed using Cone Beam Computed Tomography (CBCT) in accordance with the All-on-4 protocol. The initial scan was acquired with the radiographic stent positioned extraorally, while the second scan was performed with the patient in occlusion on the radiographic stent.

Virtual surgical planning was conducted for each patient using 3-D image treatment planning software (OnDemand), which facilitated the generation of an individualized surgical template. All planning procedures were executed and verified by a prosthodontist. Within the guide software, the four implants were virtually positioned: anterior implants were placed in the canine/lateral incisor regions, parallel to each other and perpendicular to the occlusal plane. Posterior implants were

inserted in the premolar areas, anterior to the mental foramina, maintaining a safety margin from these structures, and were distally tilted to achieve a 30-degree angle relative to the occlusal plane.

Virtual model planning software was also used to delineate the precise implant placement sites and the anchorage pin locations for the surgical guide. A mucosal-supported, 3D-printed, fully guided surgical template was designed using the software. This template incorporated four sleeves precisely aligned over the proposed implant sites to guide drilling at the planned angulation and position within the bone. The template was subsequently fabricated using rapid prototyping technology.

Four Neobio Tec (Korea) implants were inserted into the interforaminal region of the mandible using a single-stage flapless surgical protocol. This procedure was performed by the same oral and maxillofacial surgeon [15]. A minimum insertion torque of 40 Ncm was achieved to ensure sufficient primary stability for immediate implant loading. In instances of compromised bone quality, the final drilling step was omitted to further enhance primary stability. Abutment angulations were carefully chosen to compensate for the divergence between anterior and posterior implants, thereby positioning the prosthetic screw access holes in either occlusal or lingual locations. A post-operative panoramic radiograph was acquired to confirm accurate implant placement and the passive seating of the abutments (Fig. 1).

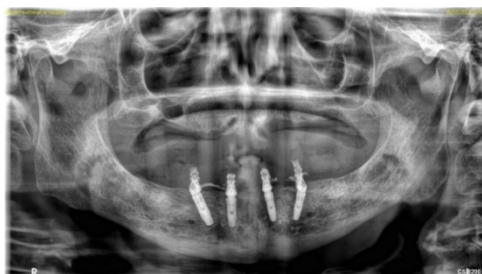


Figure 1: Post-operative panoramic radiograph

Implants underwent immediate loading with provisional acrylic dentures. The existing mandibular denture was modified by excising all denture flanges and removing the second molar artificial teeth. Titanium cylinders were then secured to the multi-unit abutments. The corresponding area of the lower denture base opposite the cylinders was hollowed out. These cylinders were subsequently integrated into the modified denture using autopolymerizing acrylic resin. Following polymerization, the cylinders were unscrewed, the denture was removed, and excess acrylic resin was finished and polished. To mitigate pressure on the inclined posterior implants, occlusal contact between the first molar and the opposing denture was eliminated. An acrylic temporary prosthesis (Fig. 2) with 12 teeth was delivered on the same day as the surgery, with centric and lateral contacts restricted to the intercanine zone.

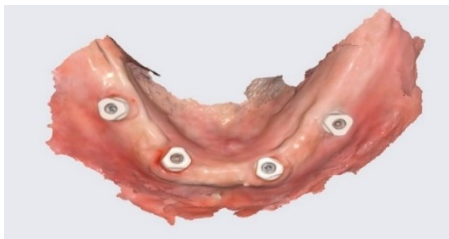


Figure 2: A modified denture insitue

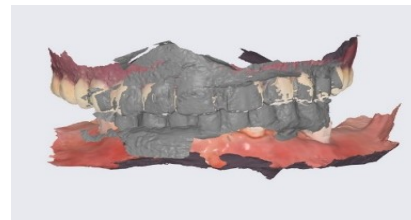
Following a 3-month osseointegration period, the digital impression procedure was initiated. An extraoral desktop scanner (SHERA eco-scan 7, Shera Werkstoff-Technologie, Germany) was used to scan the provisional lower acrylic denture and the upper conventional complete denture separately, and then with the patient in occlusion. The provisional acrylic denture was unscrewed from the multi-unit abutments, and scan bodies were attached to the multi-unit abutments of the lower arch for subsequent scanning of the lower arch (Fig. 3).

The scanned data was converted into an STL (Standard Tessellation Language) file format and uploaded to an Exocad design program. The framework, incorporating a distal molar cantilever, was then designed. A full-contour mock-up of the definitive prosthesis was created using definitive PMMA composite veneers (Novolign, Bredent GmbH & Co. KG, Senden, Germany) to verify both aesthetic and occlusal parameters. The acrylic resin interim framework was designed with increased buccal/lingual and vertical thickness (minimum 5 mm), incorporating specific retentive elements as integral parts, and a calix shape was applied.

The acrylic resin interim framework was scanned and transferred using system-specific software. Glass fiber-reinforced composite resin blanks (Italian) were directly inserted into a 5-axis milling machine (SHERA eco-mill 5-axis machine, Shera Werkstoff-Technologie, Germany). Upon completion of the milling process, the blank was removed, and the discs were retrieved, finished, and polished according to the manufacturer's instructions. Passive fit was verified using the Sheffield Test.



A



B

Figure 3: A. Scanning of upper arch with scanner, B. Digital impression of upper complete denture, g. bite registration

The framework was subsequently returned to the cast and prepared for the application of denture veneers, which were fabricated from composite teeth and pink gingiva (Novo-lign A2, Bredent,

Germany). An adhesive was then applied to both the framework and the internal surfaces of the veneers, followed by light curing for 90 seconds.

The final prosthesis was torqued into place at 15 Ncm, and both phonetics and adequate tissue pressure were verified. After torquing, any necessary occlusal adjustments were performed. The screw access holes were sealed with light-cure composite or acrylic to prevent bacterial accumulation. All centric and eccentric contacts were meticulously assessed using 40 μ m articulating paper (Bausch Articulating Paper, Köln, Germany) until light, uniformly distributed occlusal contacts across the entire prosthetic arch were achieved (Fig. 4).

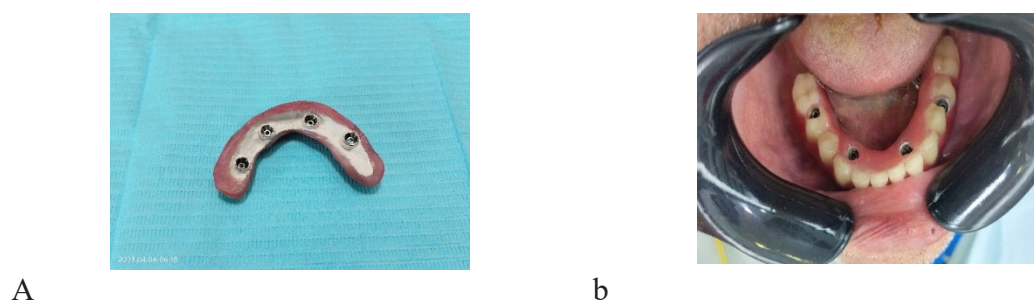
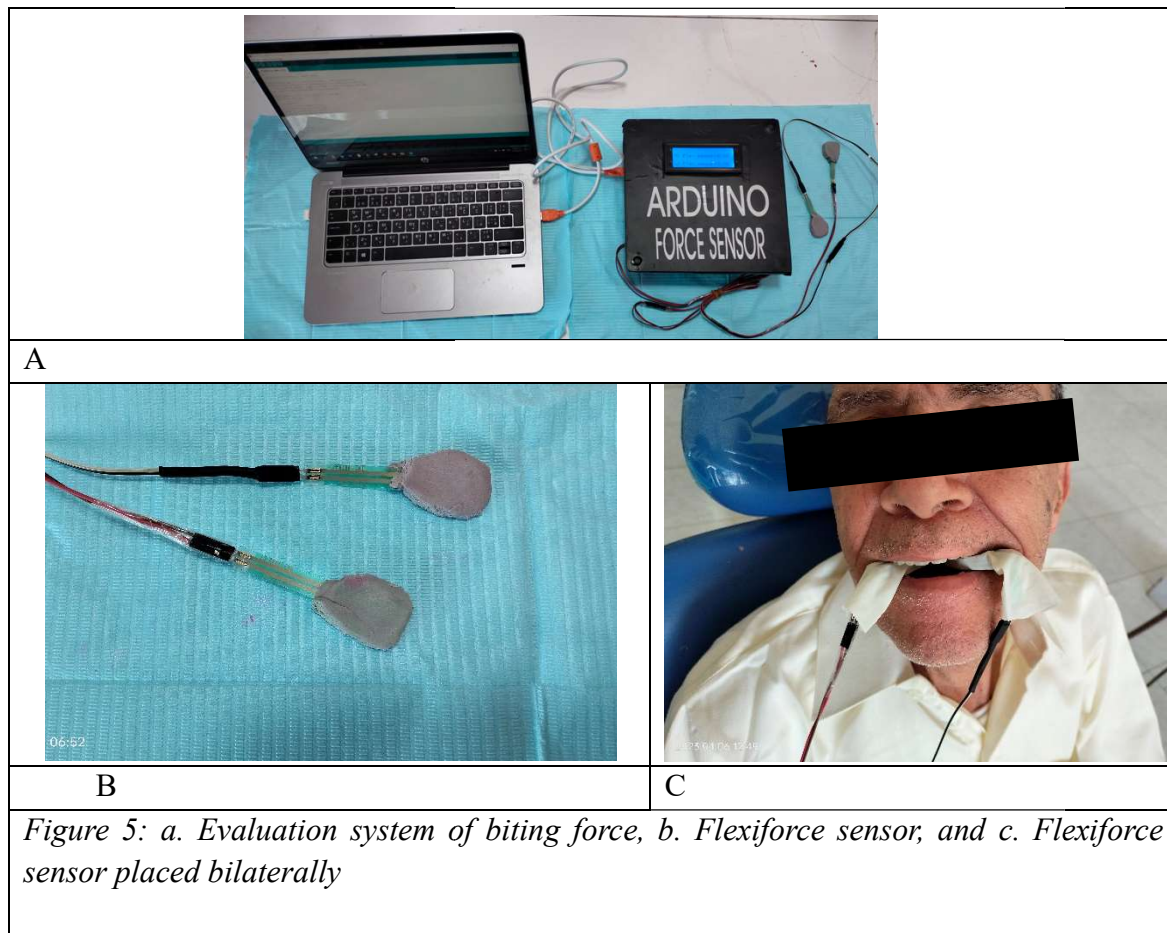


Figure 4: A. Fitting surface of definitive prosthesis with titanium slaves. B. Definitive prosthesis insitue

2.3 Evaluation of Biting Force:

Interocclusal vertical biting force was assessed bilaterally using an FSR 151 sensor (Tekscan, South Boston, MA, United States) integrated with an Arduino microcontroller and a crystal display, which presented force units in kilogram-force (kgf). Sensor calibration was performed multiple times using an object of known weight. A 3 mm thick layer of putty rubber base impression material (Zetaplus C-silicone putty, Zhermack, Italy) was applied to cover the sensor [16, 17].

The sensor was then positioned inter-occlusally between the denture teeth in the region of the upper and lower first molars. Patients were instructed to exert maximal biting force for a duration of 3 seconds. Three measurements were recorded, with a 20-second resting period between each bite. The highest biting force value among the three measurements was selected, and the average biting force between the right and left sides was calculated and subjected to statistical analysis. All assessments were conducted nine months post-hybrid denture insertion, with follow-up periods at 1 week, 1 month, and 3 months (Fig. 5).



2.4 Statistical Analysis

All collected data were calculated, tabulated, and statistically analyzed using appropriate tests. A Kolmogorov-Smirnov test was performed to verify the normal distribution of the samples. Statistical analysis was conducted using SPSS software for Windows version 26.0 (Statistical Package for Social Science, Armonk, NY: IBM Corp), with a significance level set at $p < 0.05$. Descriptive statistics are presented as Mean \pm Standard Deviation (SD) and range (Max-Min). One-way ANOVA (Analysis of Variance) was employed to compare the groups under investigation.

Financial and Resource Allocation

This research was entirely funded by the primary investigator.

Results

This clinical trial aimed to evaluate the biting force (in Newtons, N) in patients wearing PEEK frameworks fabricated by CAD/CAM technology in hybrid screw-retained implant-supported prostheses. Six cases were included in each of the studied groups. All patients exhibited osseointegrated implants, and no implant loss occurred throughout the study period. Furthermore, all patients attended their scheduled follow-up visits, with no dropouts, likely attributed to the study's relatively short duration.

Biting force

There was not a statistically significant in the biting force at 1w, 1m and 3m follow-up periods, where ($p > 0.005$) as shown in (Table 1, Figure 6).

Table 1: Descriptive statistics of Bite force value between patients wearing PEEK

		Mean	Standard deviation	Minimum	Maximum
Peek	1week	91.50	2.38	88.48	93.51
	1month	88.43	4.37	80.22	92.4
	3 months	90.69	2.61	85.93	93.08

Table (1) and figure (6) demonstrates that mean \pm SD of bite force for peek group is 91.50 ± 2.38 at 1 week ranging from 88.48 to 93.51 , 88.43 ± 4.37 at 1 month ranging from 80.22 to 92.4, 90.69 ± 2.61 at 3 months ranging from 85.93 to 93.08. Repeated Measures ANOVA test was used to assess change in bite force during follow up from 1 week to 1 month to 3 months within peek group and demonstrates no statistically significant difference between different follow up periods.

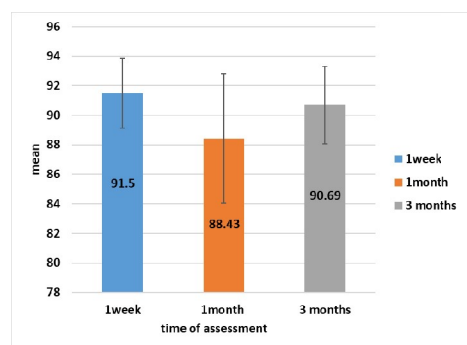


Figure 6: Comparison of Bite force value between patients wearing PEEK

Discussion

This in vivo study aimed to evaluate the biting force generated by patients utilizing a PEEK framework fabricated via CAD/CAM in a hybrid screw-retained implant-supported prosthesis. To ensure the integrity of the study, stringent inclusion and exclusion criteria were applied. The within-patient study design facilitated the standardization of patient-specific factors such as gender, age, ridge morphology and relation, and muscle power/tone. This standardization enhanced the reliability of chewing efficiency and bite force measurements [18, 19]. A 3-month period was considered sufficient for adequate neuromuscular adaptation to complete dentures, as previous research indicates that masticatory muscle activity approaches original levels after this adaptation period following new denture insertion [20]. While some controversy exists regarding the optimal timeframe for neuromuscular adaptation after implant-supported overdenture and fixed restoration rehabilitation, Gartner et al. [21] reported one month as sufficient for well-coordinated muscle

activity. Feine et al. [22] assessed masticatory function with fixed and removable implant-supported mandibular prostheses after a 2-month adaptation period, and Van Kampen et al. [23] demonstrated that 3 months post-implant overdenture rehabilitation was adequate for achieving good neuromuscular control, with maximum bite force approaching that of dentate individuals.

A study indicated that the stress distribution within the components of the system was not significantly influenced by the framework's material. Conversely, another investigation observed that PEEK frameworks demonstrated reduced stress compared to cobalt-chromium (Cr Co) and titanium (Ti), a phenomenon attributed to the minimal strains resulting from PEEK's viscoelastic properties. This observation corroborates findings from a previous study [24]. The unique characteristics of PEEK, which provide maximum strength with flexibility similar to that of human bone, may explain the reduced crestal bone resorption observed in PEEK cases [25]. Furthermore, the tensile properties of PEEK closely resemble those of enamel and dentin, making it a suitable restorative material in terms of mechanical properties [26].

Patients with metabolic diseases known to affect bone metabolism, such as osteoporosis, hyperparathyroidism, or diabetes, were excluded. This decision was based on the potential for these conditions to interfere with osteoprogenitor cell migration, woven bone formation, and lamellar bone deposition, thereby compromising the osseointegration process [27].

To mitigate detrimental stresses on the implants, only patients exhibiting Class I maxilla-mandibular relations were selected. Furthermore, individuals with parafunctional habits like clenching or bruxism were excluded to prevent excessive forces on the implants. Literature indicates that parafunctional habits can generate forces up to 15 times greater than those exerted during mastication, a particularly critical consideration in immediate loading protocols [28]. All smokers were excluded due to the reported association between smoking and higher implant failure rates, increased complications, and altered peri-implant tissue conditions. A minimum restorative space of 12 mm at the canine region was a prerequisite to ensure adequate room for implant abutment and superstructure placement. This aligns with Misch et al.'s observation that 15 mm of restorative space between the soft tissue ridge and the occlusal plane is sufficient for unmodified denture tooth arrangement and restoration accommodation [29].

The implant-supported screw-retained full-arch prosthesis was employed for mandibular rehabilitation in this study, presenting a viable option for completely edentulous patients. This prosthesis type is suitable for those requiring advanced implant prosthetic rehabilitation and addresses the need for the shortest possible treatment time without compromising esthetic and functional outcomes [30]. The All-on-four concept was utilized for patient restoration to address challenges associated with insufficient bone volume and to avoid critical anatomical structures in the posterior mandible, such as the mandibular nerve. Posterior implant tilting was implemented to reduce cantilever lengths, broaden the prosthetic base, and enhance the implant-to-bone surface area due to the use of longer implants [31].

This *in vivo* study utilized flapless-guided surgery, which offers several advantages, including reduced surgical time, decreased intraoperative bleeding, and minimized postoperative discomfort, pain, and edema. Given the critical role of primary stability in osseointegration, a higher insertion torque is generally preferred. Splinting implants through a full-arch immediate loading restoration has demonstrated better outcomes compared to single crowns, where immediate loading can be more precarious for implant survival. However, one study comparing flapless and conventional surgery reported no significant differences in bone loss between the two techniques [32].

Digital impression techniques were employed in this study, providing enhanced accuracy for the All-on-four implant concept. Full-arch digital implant impressions using a True Definition scanner demonstrated significantly higher accuracy when compared to conventional impressions using a splinted open-tray technique. Digital impressions also proved more efficient in terms of total treatment time, requiring less preparation and allowing for rescans without complete repetition, thereby shortening the impression phase. Additionally, digital impressions were reported to have a lower level of difficulty for less experienced clinicians [33]. Implant-retained prostheses can be screw-retained, cement-retained, or a combination. The European Association of Osseointegration recommends screw-retained frameworks for extensive implant-supported reconstructions [34].

Consistent with the classic All-on-four concept, immediate loading was implemented in this study. This aligns with the findings of Esposito et al. [35], who reported high success rates for all loading strategies (immediate, early, and conventional), with no significant differences in implant survival and complications, provided an insertion torque exceeding 40 N is achieved for early or immediate loading. They favored immediate and early loading due to patient demand for rapid prosthetic rehabilitation. This contrasts with Schimmel et al. [36], who concluded that while all loading protocols exhibit high survival rates, early and conventional loading are better documented and appear to result in fewer implant failures during the first year in implant-supported overdentures.

The provisional denture comprised 10 teeth, and cantilevers distal to the last implant were avoided to minimize fracture risk. Cantilever length was reduced by distally tilting the posterior implants to emerge in the second premolar/first molar region, thereby increasing the anteroposterior (A-P) prosthetic spread [37]. Clinical studies have indicated that distal implant tilting can reduce cantilever length by approximately 6.5 mm in the mandible and 9.3 mm in the maxilla. For the final restoration in this study, the cantilever length was less than 1.5 times the anteroposterior spread, as suggested by Mericske-Stern [38].

Bite force exhibits intraoral variation, with the maximum force typically recorded in the first molar region, representing approximately 80% of the maximum bite force (MBF) [39,40]. Consequently, multiple recordings were performed in this area to enhance measurement reliability [41]. Previous studies have indicated no significant difference in maximum bite force between males and females [42]; therefore, both genders were included in this study. Moreover, bite force has been utilized to evaluate prosthetic devices in adults and to establish reference values for biomechanical research in prosthodontics [43]. Lepley et al. [44] highlighted occlusion and maximum bite force as the most critical factors influencing masticatory performance in their study of 30 adults [45].

The FSR 151 sensor, characterized by high sensitivity, rapid dynamic response, high measurement accuracy, good stability, a wide operating temperature range, small dimensions, and ease of mass production, has been widely adopted. It overcomes limitations associated with strain gauge transducers by integrating resistance, compensation circuits, and signal conversion circuits on silicon chips, and can even incorporate calculation processing circuits and sensors [46].

Overall, the null hypothesis was rejected. The limitations of the present study include its small sample size and short follow-up period. Further clinical studies with longer-term follow-up and a larger number of participants are recommended for a comprehensive evaluation of bite force. Additional studies are needed to assess whether other factors, such as tooth material and bonding strength between teeth and different denture base materials, may affect biting force. Patient-reported outcomes and prosthetic complications can also be assessed in future investigations.

Conclusion

Within the limitations of this study, the bite force value demonstrated an increase over time. The utilization of PEEK as a framework material proved highly effective in enhancing bite force.

Clinical Implication

PEEK as a framework material for the construction of screw-retained hybrid complete dentures represents an effective treatment option for the rehabilitation of completely edentulous patients, particularly when the primary patient concern is their ability to bite and chew.

Ethical Considerations for Clinical Studies (In-vivo Studies)

This research was conducted following the approval of the Research Ethics Committee (REC) of the Faculty of Dentistry, Suez Canal University. It involved six patients undergoing removable prosthodontic treatment at the out-patient clinic of the Removable Prosthodontic Department, Faculty of Dentistry, Suez Canal University. The researcher upheld ethical considerations concerning patient well-being and confidentiality. All patients provided informed written consent prior to study commencement, which detailed all clinical examinations, procedures, and follow-up protocols.

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