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Prosthesis and implant survival in immediately loaded full arch restorations using fiber-reinforced versus non-reinforced temporary frameworks: a randomized clinical trial

Sobrevivência de próteses e implantes em restaurações de arcada completa com carga imediata usando estruturas temporárias reforçadas com fibra versus estruturas temporárias não reforçadas: um ensaio clínico randomizado

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ABSTRACT

Objective: To evaluate and compare prosthesis and implant survival in case of interim fixed complete dentures reinforced with fiber resin frameworks versus those that were not reinforced with any framework in case of immediately loaded full arch restorations in completely edentulous patients. **Material and Methods:** Thirty completely edentulous patients were randomly allocated into two parallel arm groups. Non-reinforced control group in which patients received non-reinforced all-on-four immediately loaded fixed complete denture and Fiber reinforced group in which patients received all-on-four fixed complete denture supported with glass-fiber reinforced resin framework. Prosthesis and implant survival were clinically evaluated after 4 months follow up period. **Results:** A statistically significant difference for prosthesis (p=0.032) and implant survival (p= 0.031) was found between both groups. The fiber-reinforced group showed 100% prosthesis survival and 95% implant survival. On the other hand, the non-reinforced group showed 73.3% prosthesis survival and 81.1% implant survival. **Conclusion:** Based on the findings of this study, it can be concluded that strengthening the fixed full arch restorations with fiber reinforced frameworks can help overcoming the problem of interim prosthesis fracture during the osseointegration period when used for immediate loading in completely edentulous patients. It can also improve the survival of the immediately loaded implants.

KEYWORDS

Dental implants; Dental prosthesis; Implant-supported; Prosthesis survival.

RESUMO

Objetivo: Avaliar e comparar a sobrevivência de próteses e implantes no caso de próteses totais fixas provisórias reforçadas com estruturas de resina de fibra versus aquelas que não foram reforçadas com nenhuma estrutura no caso de restaurações de arcada completa com carga imediata em pacientes completamente desdentados. **Material e Métodos**: Trinta pacientes completamente desdentados foram alocados aleatoriamente em dois grupos de braços paralelos. Grupo controle não reforçado, no qual os pacientes receberam prótese total fixa (all-on-four) não reforçada, com carga imediata e grupo reforçado com fibra, no qual os pacientes receberam prótese total fixa (all-on-four), suportada com estrutura de resina reforçada com fibra de vidro. A sobrevivência da prótese e do implante foi avaliada clinicamente após 4 meses de acompanhamento. **Resultados**: Foi encontrada diferença estatisticamente significante para prótese (p=0,032) e sobrevivência do implante (p=0,031) entre os dois grupos. O grupo reforçado com fibra apresentou 100% de sobrevivência da prótese e 95% de sobrevivência do implante. Por outro lado, o grupo não reforçado apresentou 73,3% de sobrevivência da prótese e 81,1% de sobrevivência do implante. **Conclusão**: Com base nos achados deste estudo, pode-se concluir que o fortalecimento das restaurações fixas de arcada completa com estruturas reforçadas com fibras pode ajudar a superar o problema da fratura da prótese provisória durante o período de osteointegração quando usada para carga imediata em pacientes

completamente desdentados. Também pode melhorar a sobrevivência dos implantes carregados imediatamente.

PALAVRAS-CHAVE

Implantes dentários; Prótese dentária; Implanto-suportada; Sobrevivência da prótese.

INTRODUCTION

When a condition of complete edentulism occurs, there are many available rehabilitative options that can be selected according to the patient condition. The available options may be removable complete denture, implant-retained removable complete denture or implant-supported fixed complete denture [1]. Unfortunately, the main disadvantage of the removable options is related to the patient's desire as many patients refuse to wear a "removable" prosthesis. The majority of patients prefer to use a fixed restoration because it is perceived as an actual body part of the patient [2]. Furthermore, as the functional demand and social confidence rise, an increasing number of patients are gravitating toward fixed implant-supported options [3].

In order to maximize the use of the remaining jawbone, the "all-on-four" concept was developed for completely edentulous patients, enabling the immediate function and avoiding regenerative procedures that increase patient morbidity and treatment costs. [4] The "all-on-four" concept in the mandible involves the placement of four implant inter-foraminally; two axially placed implants in the anterior region and two distally tilted implants in the premolar region to support a provisional fixed immediately loaded prosthesis [5].

A conversion prosthesis can be used in such conditions which is made from the patient's removable complete denture and converted into a fixed provisional prosthesis at the stage of implant placement [6]. The presence of such interim prosthesis offers psychological benefit and convenience for the patient. Moreover, the clinician has control over the amount of soft tissue pressure exerted as the patient does not need to wear a removable restoration during initial bone healing [7].

An ideal interim restoration should be strong, durable, and esthetically pleasing. It should not apply excessive pressure to the underlying soft tissue [8]. Otherwise, interruption of healing at the grafted sites could occur and implant osseointegration may be jeopardized [7].

Control of micromovement at the bone/implant interface during the first healing period is critical for integration of dental implants and host tissue, and this could be crucial in terms of immediate implant loading [9]. The control of micromovement could be achieved by ensuring that the implants have adequate primary stability at the time of placement and controlling the amount of applied occlusal force as much as possible during the osseointegration period [10]. In addition, splinting of the implants can help to stabilize the newly placed dental implants by improving stress distribution through cross-arch stabilization during the osseointegration process [11].

Unfortunately, full arch fixed provisional restorations may fracture during function due to several reasons. It may be due to acrylic porosities and/or foreign materials embedded in the acrylic as "Air pockets" were noted in the cracked acrylic bases of many restorations [12]. Porosity in acrylic denture base resins is well documented in dental literature with up to 11% porosity associated with certain processing conditions [13]. Acrylic porosities are typically caused by volatilization of the monomer, polymerization shrinkage, inadequate pressure during acrylic/monomer mixing and/or residual monomer [12]. Porosity in acrylic resins weakens the provisional restoration due to accumulation of internal stresses and may lead to distortion, warpage, and fracture of the acrylic base [12]. Such fractures during the healing period eliminate cross-arch stabilization and disrupt stress distribution patterns. Flexural fatigue, which occurs after repeated flexing of the PMMA prosthesis, can also cause fractures [14]. The development of microscopic cracks in areas of stress concentration can explain this type of failure [15].

Over the past decades, a number of attempts have been made to strengthen and improve the fracture resistance of polymethylmethacrylate

(PMMA) prosthesis using different reinforcement materials such as glass fibers, polyethylene fibers, nylon and metal [16]. Glass fiber reinforced frameworks (GFRF) were introduced recently into the market. The GFRF material is a combination of glass fibers and a resinous matrix. It has an elastic modulus of about 26 GPa which is seven times higher than that of conventional PMMA. It also has greater hardness and impact strength than PMMA material. It was found that using glass fiber reinforced framework in maxillary complete dentures can readily provide mechanical reinforcement for the dentures and reduce denture deformation during occlusal loading [15,17].

Therefore, it was suggested that the glass fiber reinforced frameworks can strengthen the provisional prosthesis and might decrease the risk of fractures in case of immediately loaded 'all-on-four" cases. Nevertheless, the clinical effect of such frameworks on the durability of the conversion prosthesis and on the survival of the implants supporting them, has not been fully elucidated. Accordingly, the aim of the present clinical study was to evaluate the effect of using fiber reinforced framework on the prosthesis and implant survival of the immediately loaded full arch provisional prosthesis.

MATERIALS AND METHODS

The CONSORT guidelines for improving the quality of randomized trials were followed in this trial. Written informed consent was applied for all patients enrolled in the trial. The study protocol was approved by the ethics committee of the university. The protocol was registered in clinicaltrials.gov (ID: NCT03814070).

Participant selection and study design

The study was conducted in the prosthodontic department where completely edentulous patients fulfilling the inclusion criteria were recruited from the outpatient clinic of the department. The patients' age ranged from 45 y to 69 years old. Thirty participants were selected based on strict inclusion and exclusion criteria that included the following:

Inclusion criteria:

i. Completely edentulous patients with Angle's Class I maxillomandibular relationship.

ii. Mandibular ridge, with no history of recent extraction.

iii. Adequate zone of keratinized attached mucosa (≥ 2mm) over the mandibular crest.

Exclusion criteria:

i. Cancer patients receiving chemotherapy and/or radiotherapy.

ii. Patients with uncontrolled diabetes, assessed by measuring glycosylated hemoglobin (HbA1c ≥ 7%)

iii. Potentially uncooperative patients who are not willing to go through the proposed interventions.

iv. Moderate-to-heavy daily smokers.

The selected study design was set to be randomized controlled trial with two parallel arm groups. Computer-generated random numbers was used for simple randomization of the subjects. Therefore, the participants were randomly allocated into two groups: fiber reinforced framework (FR) group and non-reinforced (NR) group. The allocation ration was set to be 1:1. Allocation concealment was done using opaque sealed envelopes. The trial was single blinded as only the statistician was blinded. The investigator and the patients could not be blinded because the technique in both groups was different from each other.

Construction of complete dentures and preparation of a scan appliance

The pre-surgical preparation required the construction of conventional maxillary and mandibular complete dentures so that the mandibular denture would be used as a conversion prosthesis. The patient's denture was also used as a scan appliance by the addition of 6-8 gutta percha cones to act as radiopaque markers over the polished surfaces of the prosthesis on both facial and lingual surfaces. Double scan protocol was used in our study in which two cone beam conventional tomography (CBCT) images was produced for each case. One was taken for the modified mandibular denture alone outside the patient mouth using denture exposure module and the other one was for the mandible while the patient was wearing the mandibular denture with the gutta percha cones.

Virtual planning and surgical guide fabrication

The implant planning was done using the *BlueSky Bio 4* software. The CBCT of the mandibular denture was superimposed over that

of the mandible using points over the gutta purcha cones as alignment points for proper orientation of the stent over the mandible. The "all-on-four" concept was followed and four implants were planned to be placed inter-foraminally. Two straight implants planned to be placed in the lateral incisor/canine region and two distally tilted implants planned to be placed in the second premolar region. Endosseous implants (*DENTIS Co., Headquarters, USA*) were used in this study. The implants' diameters used were 3.7 mm for the anterior implants and 4.2 mm for the posterior ones. The length ranged from 8 to 10 mm based on the available bone height.

A surgical guide was planned and then the 3D virtual guide was exported as STL file to the 3D printing machine (*Phrozen shuffle XL™, Hsinchu, Taiwan).*

Implant insertion

The surgical guide was fixed in place using three fixation screws; two screws placed in the buccal shelf area on both sides and one screw in the midline. The osteotomies were drilled and implants were inserted with 35 Ncm torque. The multiunit abutments were screwed to the implants and pick-up titanium cylinders were attached to the abutments (Figure 1).

Adjustment of the conversion prosthesis and immediate loading

It should be highlighted that all the pick-up procedures were done in the same session of implant installation for both groups.

1) For the fiber-reinforced group:

Fiber reinforced frameworks (Trilor arch Bioloren™, Saronno, Italy) with 5.5mm thickness were used in this group. The mechanical properties of the framework, according to the manufacturer, are described in (Table I).

A soft sheet of wax was applied on the surface of the framework then this side was applied over the titanium cylinders so that the cylinders could make indentations in the wax surface. These indentations were used to mark

Table I - Mechanical properties of the fiber reinforced framework

Mechanical properties	Values
Tensile strength	**380 MPa**
Flexural Strength	540 MPa
Tensile Elongation	2%
Flexural Modulus	26 GPa
Tensile Modulus	26 GPa
Compressive Strength (perpendicular)	530 MPa
Charpy Impact Strength	300 KJ/cm^2

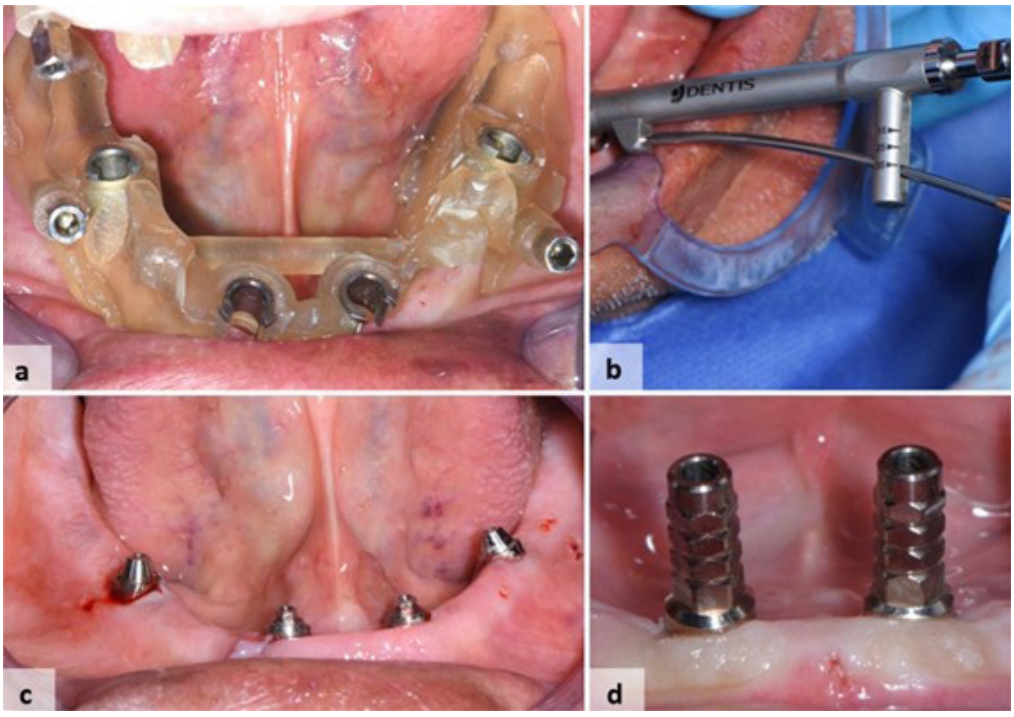

Figure 1 - A) Fixing the surgical guide intraorally using pins, B) torquing the implant at 35 N.cm, C) Multiunit abutments after being inserted and tightened over the implants, and D) titanium cylinders inserted and tightened over the multiunit abutments.

the areas to be perforated in the framework. Then, the framework was seated intraorally over the titanium cylinders and checked for presence of any further interferences and pick-up of the cylinders into the framework was done by injecting flowable composite (Voco, GmbH, Cuxhaven, Germany) around the titanium cylinders. After that, the desired outline was drawn on the fiber reinforced framework (FRF) using a pencil and it was trimmed and finished to that outline. The trimmed framework was seated intraorally, and the titanium cylinders were retightened to the multiunit abutments (Figure 2).

A window was opened in the denture over the crestal area to create space for the framework. In addition, the lingual flange in the area of the framework was removed in some cases to facilitate denture seating over the bulky framework. The lingual flange distal to the framework was not removed to facilitate and guide the seating of the denture over the framework in the correct position. The window area included all areas of the placed implants and slightly distal to it (Figure 3a).

Finally, rubber dam sheet was applied over the mucosa through the titanium cylinders to protect the mucosa against any possible irritation during the pick-up procedure. The denture was seated over the framework and tooth shade self-cure acrylic resin (*Acrostone; Acrostone Dental Manufacturer, Egypt*) was injected in the window area and denture remained in place until complete hardening of the pick-up material. This was followed by unscrewing of the pick-up titanium cylinders and any deficient areas were adjusted by addition of more self-cure acrylic resin (Figure 3bcd). Finally, the prosthesis was retightened intraorally, and the occlusion was checked and refined (Figure 4).

2) For the Non- reinforced group:

Four separate holes were opened in the denture opposite to each titanium cylinder. The denture was checked for proper seating over the cylinders without interference or rocking. Rubber dam sheet was applied over the to prevent tissue irritation. Self-cure acrylic resin was injected in the window around the pick-up cylinders. The denture remained in place until complete hardening of the pick-up material. This was followed by unscrewing of the pick-up Ti cylinders and any deficient areas were adjusted by addition of more self-cure acrylic resin.

For both groups, all flanges of the prostheses and all sharp areas were removed. The prostheses were finished, polished and re-screwed to the

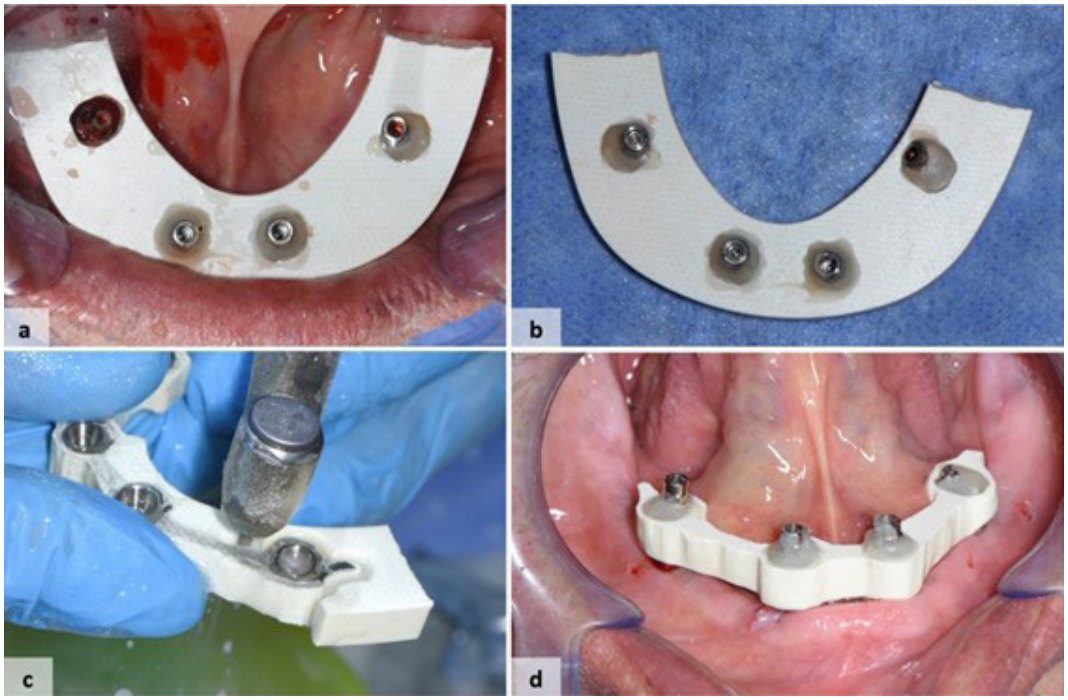

Figure 2 - A) Intraoral pick up of the framework by injecting flowable composite around the titanium cylinders, B) Removing the Trilor arch framework after picking up the titanium cylinders to start the trimming procedure, C) trimming the fiber reinforced framework to accommodate the buccolingual width of the ridge, and D) the trimmed fiber reinforced framework after seating and tightening intraorally.

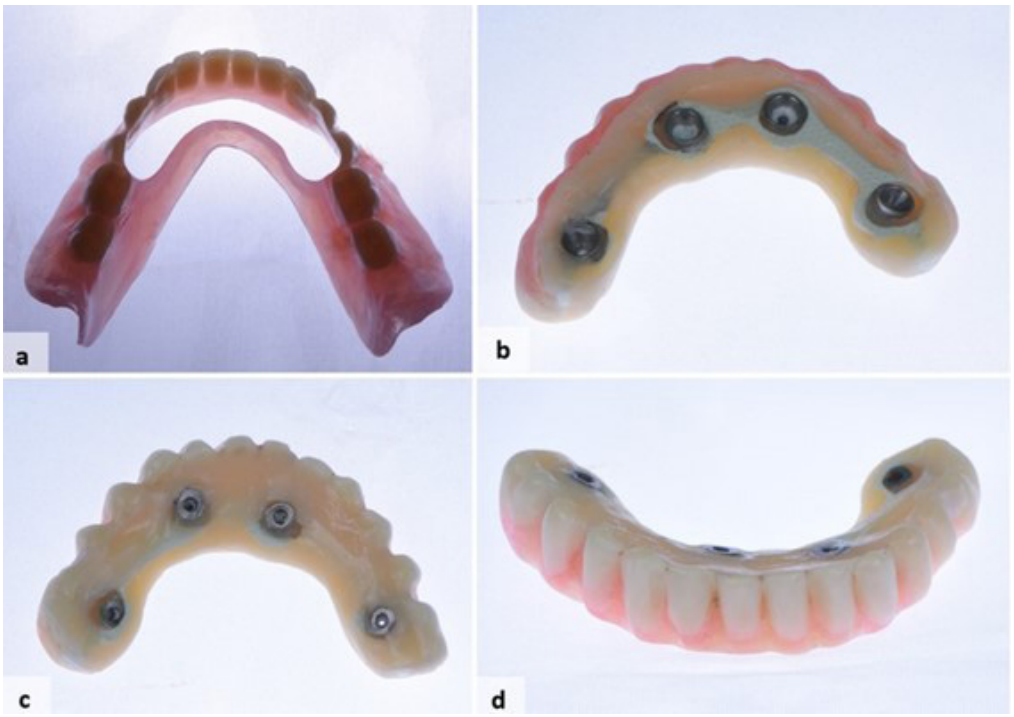

Figure 3 - A) Cutting a window in the mandibular denture for the pick-up procedure, B) finished fiber reinforced framework prosthesis after removal of flanges and polishing from fitting surface, C) occlusal view of the prosthesis, and D) facial view of the prosthesis.

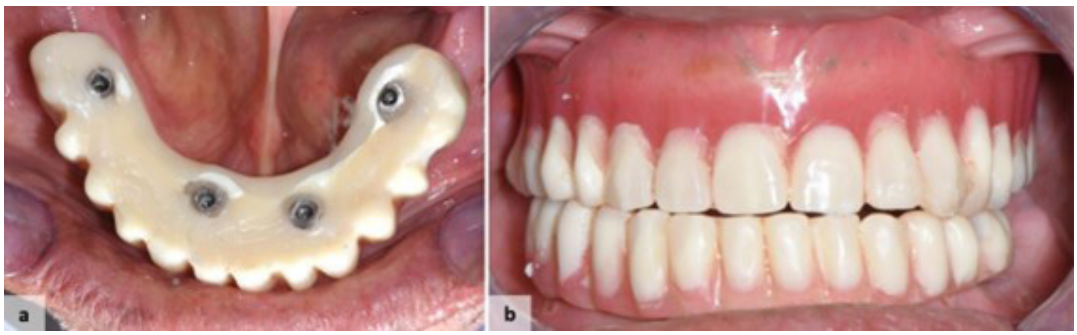

Figure 4 - A) Tightening of the fiber reinforced framework prosthesis intraorally, and B) patient occlusion from front view.

multiunit abutments using the prosthetic screws. The access holes were partially plugged with rubber pieces and then the access holes were completely closed with light-cured composite resin. The occlusion was checked in both centric and eccentric positions to eliminate any occlusal interferences in order to establish a balanced occlusion with the opposing maxillary removable complete denture.

Outcome measures

Patients were followed up for 4 months, and data were collected at the end of the four-month follow up period. *As regards to prosthesis survival*, the prosthesis was considered *"Surviving",* when it remained sound in place without any major fractures that affect function or require total removal of the prosthesis. *On the other hand, for implant survival,* implant was considered "surviving" when there was no implant mobility, no pain during function, no exudates, no signs of peri-implantitis and no radiographic peri-implant radiolucency.

Statistical analysis

Owing to lack of RCT studies on short-term prosthesis survival for immediately loaded interim acrylic prostheses, clinical and practical aspects were considered to determine the design and sample size of this study. The required minimal number of 30 participants was selected based on a previous study comparing interim

acrylic bases with and without cast metal base, which was more sensible approach than sample size calculation [18].

Data were analyzed using IBM SPSS advanced statistics (version 25, SPSS Inc., Chicago, IL, USA). A binary logistic model was used to analyze the results. In this model, survived implant or prosthesis was coded as 1 while failed implant/prosthesis was coded as 0. Variables that had p-values lower than 0.05 were considered as significant predictors in this model. The statistical test used for analysis was the Chi-square test.

RESULTS

Prosthesis survival

For the Fiber reinforced (FR) group, clinical examination of prostheses showed 100% survival for the prostheses of this group. All prostheses were perfectly functioning in place without major fractures.

Two cases exhibited detachment of the veneering acrylic teeth; one in the anterior region and one in the premolar region after 2 months of function but these detachments did not affect neither the function nor the seating of the prosthesis intraorally. These cases were managed by bonding the detached part to the denture using flowable composite and since then no separation reoccurred (Figure 5).

For the non-reinforced (NR) group, clinical examination of the prostheses showed 73.3% survival for this group after four months of function. This indicated less survival than the FR group by 26.7%. Four cases exhibited major fractures and detachment of the whole part of the prosthesis. The fractures in those cases did affect the function as large areas were separated and could not be re-attached since it was not in the veneering part but rather in the main bulk. Moreover, two other cases exhibited fractures of the acrylic part around titanium cylinders in the distal part of the prosthesis. However, the prostheses were still functioning in place, so they were considered surviving prostheses. Those cases were managed by removing the fractured part and the posterior end of the prosthesis was smoothened and all sharp areas were removed (Table II).

Implant survival

Clinical examination of implants of both groups revealed 95% implant survival for the FR group and 81.1% for the NR group. Using the fiber reinforced frameworks improved the survival of implants by 13.9%. For the NR group, the four cases that exhibited failed prostheses were excluded from the analysis as they were not functionally loaded for the whole 4 months follow up period. The posterior tilted implants were the most frequently failed implants in both groups. On the other hand, failure of the anterior implant

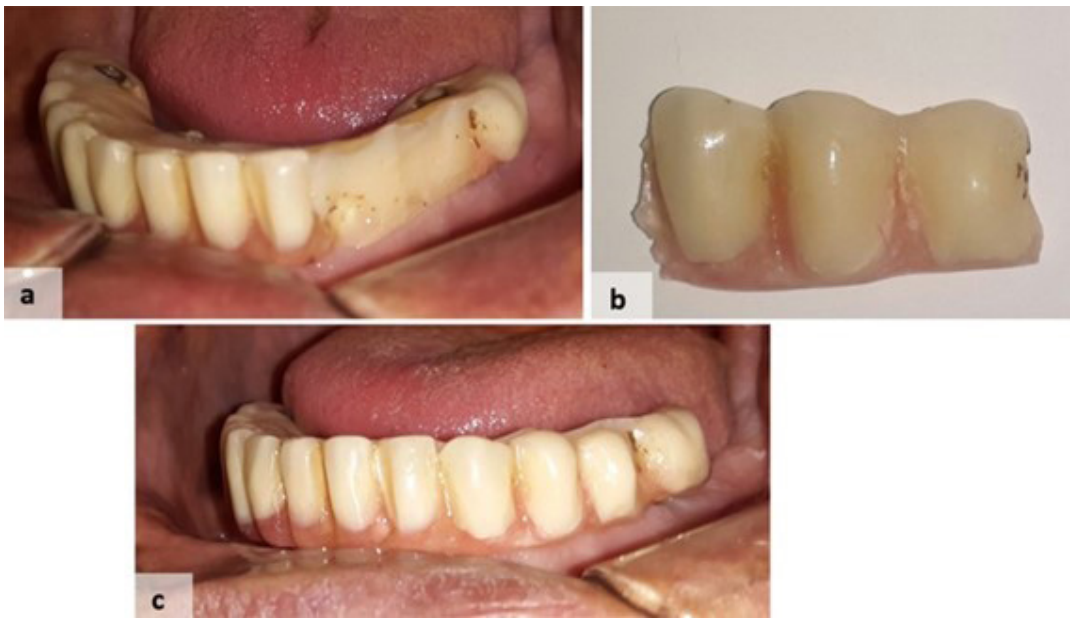

Figure 5 - A) Intraoral prosthesis after detachment of the veneering part in the premolar region, B) the detached part, and C) the prosthesis after bonding of the detached part.

Table II - Prosthesis Survival after 4 months

	Failure		Survival		*p-value* (p)
	N	*(%)*	*N*	*(%)*	
Fiber reinforced group ***(n = 15)***	0	(0)	15	(100)	0.032 *
Non reinforced group ***(n = 15)***	4	(26.7)	11	(73.3)	

* Statistically significant difference between groups (p<0.05)

Table III - Implants Survival after 4 months

	Failure		Survival		*p-value* (p)
	N	*(%)*	*N*	*(%)*	
Fiber reinforced group ***(n = 60)***	3	(5)	57	(95)	0.031 *
Non reinforced group ***(n = 44)***	8	(18.9)	36	(81.1)	

*Statistically significant difference between groups (p<0.05)

solely was uncommon. They usually occurred as part of multiple implant failures of the same case rather than occurring solely unlike the posterior ones (Table III).

DISCUSSION

The aim of the current study was to evaluate the prosthesis and implant survival in case of immediately loaded full arch provisional restorations reinforced with fiber frameworks versus those that are non-reinforced. Based on the findings of this study, the use of fiber reinforced framework in fabrication of interim Implant supported fixed complete dentures caused 100% survival of the provisional prosthesis, unlike the non-reinforced group in which the survival rate was 73.3%. These results are in accordance with the results of *Collaert et al.* study, which displayed 100% prosthesis survival after three years in edentulous cases with immediate functional loading of implants using glass fiber reinforced prostheses[19]. Furthermore, an in vitro study performed by *Goldberg et al.*, could provide reasonable explanations of these findings. *Goldberg et al.* evaluated the ultimate force-to-failure distal to the terminal implant of a simulated implant-supported complete fixed prosthesis reinforced with glass fiber compared with that of a conventionally fabricated prosthesis [20]. They found that the mean fracture load of the non-reinforced group was much lower than that of the fiber reinforced group. Moreover, their study revealed that fractures in the non-reinforced group were initiated by excessive load application propagating through the cross-section of the prosthesis, causing a complete fracture of the material. On the other hand, they found that the presence of the glass fiber in the reinforced group has prevented the complete separation of the fractured segments [20]. Their findings can assure the results of the present study that using glass fiber frameworks could reinforce the interim prosthesis, thus reducing the risk of prosthesis fracture.

Furthermore, the results agreed with the opinion of *Gary Steen* [21] who recommended the use of acrylic resin denture reinforced with a glass fiber composite resin impregnated mesh as a long-term, durable restoration on the day of surgery. He focused on that the chemical bonding of the fiber to PMMA results in a homogeneous mass with high flexural strength and elasticity.

The results of this study also revealed fractures of the distal cantilevered part of the NR prostheses. This might be explained by the emergence of the titanium cylinders from the occlusal surface of the prosthesis causing inevitable thinning and weakening of the denture at these areas. As the acrylic resin (PMMA) lacks sufficient strength and rigidity in thin sections, fractures can easily occur in these areas which represent weak points of the denture. This problem was not evident in the FR group as the presence of the framework in the areas surrounding the titanium cylinders help in keeping these areas thick, thus resist fractures.

Moreover, the presence of the framework in the cantilevered part allows for a minimal thickness of 5.5 mm in the distal areas which seem to provide more resistance to bending and deformation. This works together with the inherent rigidity and strength of the framework

material (compared to the non-reinforced resin) caused by the incorporation of glass fibers. Such reasons might explain the absence of distal fractures in the FR group.

The results of our study also showed that the implant survival in the FR group was higher than that in the NF group. This can be explained by the investigations of early failures done by *Tarnow* and his coworkers. They stated that rigid splinting and minimal lateral force application were critical factors for success [22]. Implants stabilized at initial placement by splinting and utilizing the widest anteroposterior distribution of the implants are able to resist the critical degree of micromovement at the bone-implant interface [22,23]. Apparently, the reinforced provisional restoration used in this study seems to prevent macromovement and significant micromovement. In addition, it appears that it provides resistance to forces in all directions.

Failure of the posterior implant was the most common type of failures especially in the NR group. This might be attributed to the loading of the cantilevered part of the prosthesis which cause a hinging effect that induces considerable stresses on the implants closest to the load application which is the distal one. When forces are applied on the distal cantilever parts, stiffness of the prosthesis material affects the amount of bending of the prosthesis which subsequently affects the amount of stress generated on the terminal implants. The more bending and deformation of the cantilever part, the greater the stresses in the prosthesis and supporting terminal implants [24]. Therefore, failure of the most posterior implant was more evident in the NR group as the prosthesis was less rigid than that of the FR group.

CONCLUSION

Based on the findings of this study, it can be concluded that strengthening the fixed full arch restorations with fiber reinforced frameworks can help overcoming the problem of interim prosthesis fracture during the osseointegration period when used for immediate loading in completely edentulous patients. It can also improve the survival of the immediately loaded implants.

Authors' Contributions

NAH: Conceptualization, methodology, validation, formal analysis, data curation and writing-original draft preparation.

AHE: Conceptualization, resources, supervision and project administration.

NS: Conceptualization, software, data curation, supervision and project administration.

AK: Conceptualization, validation, investigation, writing-review and editing, supervision and project administration. All authors have read and agreed to the published version of the manuscript.

Conflict of Interest

None of the authors reports any conflict of interest.

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Regulatory Statement

The study was conducted in accordance with all the provisions of the local human subject's oversight committee guidelines and was approved by the Ethics Committee of Scientific Research - Faculty of Dentistry – Cairo University.

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