Prosthetic maintenance assessment for implant fixed complete dentures and implant overdentures: a randomized clinical trial

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ABSTRACT

Objective: The rehabilitation choice for the edentulous patients usually lies between the fixed and removable prosthetic options. The treatment decisions are affected by many factors where complications and maintenance needs are both considered crucial factors, in addition to the cost effectiveness of the chosen treatment.

Material and Methods: This study was applied on 44 edentulous patients, where 22 patient for each group were enrolled in the outpatient clinic of prostodontics, Cairo University as per a set of eligibility criteria. Four inter-foraminal implants were installed for all eligible participants. Three months later, healing abutments were used for soft tissue preparation prior to the fabrication of the final prosthesis. A prosthetic treatment option was then randomly allocated to obtain two equal groups via computer generated randomization program; Group A received telescopic implant overdentures, and Group B received screw retained dentures. All Complications (Screw loosening or fracture, tooth or denture base fracture and mucositis) were reported after overdenture insertion along the follow up period (1, 6, 9 and 12 months respectively).

Results: The frequency of the screw loosening for hybrid overdentures where (59.1%) compared to (27.3%) of telescopic prosthesis at 12 months follow up period (p=0.035), mucositis reporting at 6m interval had shown the highest frequency in both groups (Group A (54.5%), Group B (81.8%), (p=0.045), all other reported complications that lack statistical significance either within the same group or between both groups at different time intervals.

Conclusion: Both treatment modalities; telescopic implant overdenture and hybrid fixed screw-retained are reliable for restoring the completely edentulous arches, the decision whether to make a fixed or removable implant denture shall be guided with the patient preference together with the dentist assessment in relation to the patient’s state of general and oral health.

KEYWORDS
Dental prosthesis; Implant-supported, Denture; Overlay; Dental prosthesis design; Maintenance/standards.

RESUMO

Objetivo: A escolha da reabilitação para pacientes edêntulos geralmente recai entre próteses fixas e removíveis. As decisões de tratamento são afetadas por muitos fatores onde as complicações e as necessidades de manutenção são consideradas critérios cruciais, além do custo-efetividade do tratamento escolhido. Material e Métodos: Este estudo foi aplicado em 44 pacientes edêntulos, onde 22 pacientes para cada grupo foram matriculados no ambulatório de prótese dentária da Universidade do Cairo de acordo com um conjunto de critérios de elegibilidade. Quatro implantes interforaminais foram instalados para todos os participantes elegíveis. Três meses depois, pilares de cicatrização foram utilizados para preparação dos tecidos moles antes da fabricação da prótese final. Uma opção de tratamento protético foi então alocada aleatoriamente para obter dois grupos iguais por meio de
randomização gerada através programa de computador. O Grupo A recebeu overdentures de implantes telescópicos e o Grupo B recebeu dentaduras fixas parafusadas sobre os implantes. Todas as complicações (afrouxamento ou fratura do parafuso, fratura da base do dente ou da prótese e mucosite) foram relatadas após a inserção da overdentures ao longo do período de acompanhamento (1, 6, 9 e 12 meses, respectivamente). Resultados: A frequência do afrouxamento do parafuso para overdentures híbridas (59,1%) em comparação com (27,3%) da prótese telescópica no período de acompanhamento de 12 meses (p=0,035), o relato de mucosite no intervalo de 6 meses mostrou a maior frequência em ambos os grupos (Grupo A (54,5%), Grupo B (81,8%), p=0,045, todas as outras complicações relatadas foram sem significância estatística dentro do mesmo grupo ou entre os dois grupos em intervalos de tempo diferentes. Conclusão: Ambas as modalidades de tratamento; overdentures sobre implantes telescópicos e próteses híbridas fixas parafusadas são confiáveis para reabilitar as arcadas completamente edêntulas. A decisão de fazer uma prótese fixa ou removível sobre implantes deve ser guiada pela preferência do paciente juntamente com a avaliação do dentista em relação ao estado geral do paciente e sua saúde bucal.

PALAVRAS-CHAVE
Prótese dental; Prótese suportada por implante; Overlay; Desenho de prótese dentária; Manutenção/padrão.

INTRODUCTION

The implant-supported overdentures provided a long-term successful and satisfying restoration when used to rehabilitate an edentulous jaw [1,2]. Other patients with similar oral conditions would prefer fixed treatment modality aiming to increase their self-esteem and decrease their anxiety.

The clinical decision among different prosthetic options commonly relied on the available bone quantity and quality, the number, location and implant distribution, the available inter-arch distance and maxilla-mandibular relationship in addition to the nature of the opposing occlusion [3,4].

Different attachments as bar, ball, and magnetic attachments together with telescopic crowns were suggested to connect the overdentures to the dental implants [5].

The usage of the telescopic retainers were expanded to include the implant retained prostheses. These retainers provided an excellent retention arising from the frictional fit between the abutment and the sleeve. They also reported better force distribution and axial transfer for the occlusal loads that minimize the rotational torque on the abutment thus preserving the underlying alveolar bone [6].

When compared to other attachments, the studies showed more favorable gingival conditions of the telescopic overdentures above the bar-blocked implants resulting from the better cleansing abilities of the telescopic over-denture that in turn lead to less plaque accumulation [7,8]. Regarding maintaining requirement, the telescopic attachments showed less prosthetic maintaining than the bar attachment [9].

On the other hand, “All-on four concept” which was developed by Paulo Malo using the straight and angled multi-unit abutments, to retain an immediately loaded full arch restoration with only four implants was encouraged by many studies for the rehabilitation of both arches. However, the main descriptions were limited to the survival rates, implant failures and technical complications [10].

All-on-four treatment concept offers a predictable way for treating the edentulous jaw especially the atrophic cases where patients refuse the regenerative procedures, however, the current evidence is limited due the scarcity of the information referred to methodological quality, a lack of adequate follow-up [11].

There are two types of complications in implant prosthesis; biologic and prosthetic. The biologic complications refer to the disorders in the implant function that disturb the supporting peri-implant tissues resulting in the mucositis or peri-implantitis in severe conditions, the technical complications refer to subjecting the implant, implant parts and/or the superstructures to a damage such as the screw loosening, attachment wear, fracture to part of the prosthesis or some of its teeth [12]. The prosthetic complications after the insertion of the final prosthesis may or may not lead to the implant loss, but may lead to an increase demand for the repair and maintenance [13].

This study aimed to assess whether the telescopic overdenture as a removable prosthesis
would necessitate performing maintaining work at a frequency similar to that with a screw retained hybrid overdenture as a fixed prosthesis.

**MATERIAL AND METHODS**

**Ethical approval**

This study was approved by the ethical committee; faculty of dentistry, Cairo University with the approval No. 31922.

**Sample size calculation**

This power analysis utilized the frequency of implant complications as the primary outcome. Based upon the results of Ragheb et al. [14]; the proportions of the complications were 0.407 and 0.037 in the two groups, respectively. Using alpha (α) level of (5%) and Beta (β) level of (20%) i.e., power = 80%; the minimum estimated sample size was 19 implants per group. The sample size was increased to twenty-two implants per group to compensate for a drop-out rate of 30% after two years. The sample size calculation was performed using G*Power Version No. 3.1.9.2.

**Patients’ enrollment**

Only male Patients were engaged in the study from the Outpatient Clinic of the Prosthodontics Department, Faculty of Dentistry, Cairo University. All of which were dissatisfied with their previous denture experience and are seeking better retention to their mandibular denture. The patients received verbal and written information about the study procedures and a written informed consent was signed prior their participation in the study.

During their involvement in the study, the patients passed through a thorough history and clinical examination. Factors that might interfere with tissue healing and implant Osseointegration were excluded among which were systemic diseases that interfere with the bone quality, normal healing mechanism, osseointegration of the implants or proper bone response to the applied forces [15].

The irradiated patients were also excluded from the study as the implants placed in the irradiated bone showed significantly lower survival rates, risk of osteoradionecrosis, obliteration of fine vasculature and progressive fibrosis [16].

Heavy smoker (more than 20 cigarette/day) were excluded, as smoking is a significant factor that may lead to the implant failure due to its adverse impact on the immune cells and tissue reparative capacity along with the significant increased risk of failure [17].

Also, the patients with the parafunctional habits as the bruxism and clenching were excluded in order to avoid undue stresses that might affect the implant’s success. Those with TMJ disorders were excluded to avoid any degree of muscular incoordination which might overload the implant and the prosthesis [18]. The male patients were selected to avoid the female hormonal changes such as the calcium insufficiency and osteoporosis which have a high prevalence among the females and might affect the Osseointegration of the placed implants [19].

The patients selected had completely edentulous maxillary and mandibular arches with normal maxilla-mandibular relationship to facilitate the implant insertion and avoid the implants overloading [20].

Each patient was evaluated for a proper restorative space not less than 15 mm to allow a proper space for the attachment and the over-denture [21].

The patients were selected with the adequate buccolingual width of the keratinized mucosa equal to or greater than 5 mm over the crest of the lower ridge; its presence was correlated with less plaque accumulation and mucosal inflammation [22]. All the patients were selected with a good physical and psychological condition to tolerate the conventional implant surgical protocol and commit to the follow-up schedule.

The panoramic radiograph was taken for each patient to assess the bone height and location of the nearby vital structure in the areas planned to receive the implants followed by CBCT imaging for the accurate Implant planning.

**Study design**

This study is a randomized clinical trial, which was approved by the Ethics Committee of Scientific Research of Cairo University.

In this study, all the participants had to install four interforaminal implants to receive either the telescopic over-denture or screw retained denture.

Before the prosthetic phase, both groups were randomly assigned as per a computerized random allocation program where the data of
randomization were entered by the secretary of the department who neither participated in recruitment nor in examination procedures. The randomization and allocation concealment were guaranteed as the randomization table was locked with the study coordinator who wasn’t involved in any clinical intervention. The operator was informed about the treatment modality in a sealed enveloped delivered by the secretary of the department before the impression procedures.

The data collection was performed by the study coordinator, blinding of the operator or data collector was not applicable due to the clear difference between the two prostheses, but collected data was coded prior to sending to the statistician (Blinded statistician).

**Surgical and prosthetic procedure**

A preoperative CBCT scan was taken for the participant’s mandibular arch with a scan appliance (Duplicated from his previous denture) with (PLANMECA Pro max 3D mid CBCT machine). The resultant image was obtained as DICOM file (Digital imaging and communications in medicine) on a compact disc. The virtual planning was made using blue-sky software (Blue sky Bio, LLC. planning software).

The surgical steps were explained for all the participants and an informed consent was signed before the surgery. All the patients were instructed to rinse their mouth with an antimicrobial mouth wash (Chlorohexidine, Kahira pharma and chem. Ind. Co. Cairo, Egypt) three times daily starting two days before the surgery and one hour before surgery. The patient was also pre-medicated by a prophylactic antibiotic (2 gm amoxicillin-clavulanic) 1 hour before surgery.

The mental and lingual nerve block (Artinibsa, Spain) were given bilaterally adjacent to the dental implant installation sites. Surgical stent was used to mark the bleeding points by using a periodontal probe opposing to the proposed implants sites.

The mid-crestal incision was made slightly behind the location of the implant placement via blade 15 (Swan Morton England) with the buccal realizing incisions for an easy release of the flap without laceration. A complete flap retraction was made by using a suitable size mucoperiosteal elevator (Martin Germany). The sequential drilling with copious irrigation guided by the path initially created by the pilot drill was made. A parallel pin was then used to guide the next site drilling.

The root form tapered threaded dental implants (Neo Biotech Co. Ltd, Seoul, Korea) were installed with 3.5/11.5 mm for the anterior and 3.5/10 mm for posterior sites after which primary stability was checked. The interrupted sutures were done using 000 silk sutures (0 silk braided Shandong Weigao Co. LTD) for the flap closure. The analgesics drugs (Ibuprofen 600 mg, Knoll AG, Ludwigshafen, Germany) was prescribed every 8 hours for the next three days to control post-operative pain and reduce the inflammation.

Participants were instructed to rinse with 0.2% chlorohexidine antimicrobial mouthwash three times daily starting the day after the surgery. The sutures were removed 7 days later, and the dentures were relieved adjusted with soft liner opposite the previous surgical site. (Dura Base Worth, Illinois 60482)

Three months later, the surgical stent was used to relocate the implants position for uncovering. The infiltration anesthesia was given to the patient and small crestal incision was made for each implant sites then slightly widened by a small mucoperiosteal elevator till the covering screw was seen, unscrewing was made using the screwdriver and the healing abutment was screwed with the collar height 5 mm to allow a proper gingival healing around the implants prior making the impression as shown in Figure 1.

**Prosthetic fabrication stage**

The impression was made with an open tray splinted implant level impression technique. The healing abutments were removed, and impression copings were inserted and screwed in position. After splinting, the impression was taken using putty and light consistency silicon impression material (Zeta plus Zhermack, Italy) on a modified stock tray.

The impression was checked, and analogues were screwed in place over the copings before pouring the impression. A verification Jig was prepared over the resulted cast and used to check implant’s positions inside the patient mouth. The lack of the passivity during the insertion of the impression copings were dealt with via copings separation and reseating over the implants. They were then reattached using Duralay (Duralay GC AMERICA INC.3737, ALSIP...
IL 60803 USA), and impression was repeated. According to randomization, either a telescopic implant supported overdenture (Group A), or a screw retained denture (Group B) was fabricated for each case as shown in Figures 2 and 3.

After the prosthetic insertion, participants were recalled according to a follow-up schedule (1, 6, 9 and 12 months respectively).

During the follow-up period, prosthetic complications were grouped and their frequency was documented as per the type of prosthesis. Both the prosthetic and biological aspects were included.

Group A: For telescopic overdenture (screw loosening, screw fracture, tooth wear, teeth fracture and/or separation, acrylic fracture and/or separation, mucositis, relining need for the denture and coping retention loss was seen for this group)

Group B: For screw retained denture (screw loosening, screw fracture, tooth wear, teeth fracture and/or separation, acrylic fracture and/or separation, mucositis) patients were recalled each month for the first 6 months and every 3 months the rest of the study period unless the patient complained, he was then seen immediately. Each complication was documented with stating the frequency of its occurrence, any complication was managed and repaired. Figures 4 and 5, Table I.
Table I - Frequency of maintenance in different groups

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<th>Group B (Screw retained)</th>
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*; significant (p<0.05), ns; non-significant
RESULTS

The mean and standard deviation values were calculated for each group in each test. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests, data showed non-parametric distribution.

Mann Whitney test was used to compare between the two groups in non-related samples.

Table I - Continued...

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*; significant (p<0.05), ns; non-significant

The significance level was set at P ≤ 0.05. The statistical analysis was performed with IBM® SPSS® Statistics Version No. 20 for Windows.

Prosthetic maintenance assessment

1- Screw looseness:

During the first month, 6 months and 9 months there was no statistically significant difference
between (Group A) and (Group B) where \((p=0.152)\), 
\((p=0.055)\), and \((p=1)\) respectively where the 
highest frequency was found in (Group B), and the 
least frequency was found in (Group A).

At 12 months, there was a statistically 
significant difference between (Group A) and 
(Group B), where \((p=0.035)\), where the highest 
frequency was found in (Group B),

Through the follow up period, the 
screw looseness revealed a non-statistically 
significant difference between (Group A) and 
(Group B), where \((p=0.181)\). With the highest 
frequency was found in (Group B), while the least 
frequency was found in (Group A).

II- Screw fracture:

Throughout the whole follow up records 
(1, 6, 9 and 12 m), there were no statistically 
significant difference between (Group A) and 
(Group B) \((p=1)\). \((p=0.317)\). \((p=1)\). \((p=1)\) 
respectively). This resulted in an overall non-
statistically significant difference between the 
two groups \((p=0.317)\) with relatively higher 
frequency in (Group B).

II- Tooth fracture:

No statistically significant difference was 
reported between (Group A) and (Group B), after 
1, 6, 9 and 12 months \((p=1)\). \((p=0.554)\). \((p=1)\) 
and \((p=1)\) respectively). Both groups showed the 
same frequency, except after 6 months where the 
higher frequency was found in (Group B). Total 
values showed non-statistically significant 
difference between the two groups \((p=0.554)\) 
despite (Group B) showed more incidence of 
occurrence.

III- Acrylic Base Fracture:

There was no statistically significant difference 
between (Group A) and (Group B) in 1, 6, 9, and 
12 months \((p=1)\). \((p=0.317)\). \((p=1)\) and \((p=1)\) 
respectively). Both groups exhibited no fracture 
in the acrylic base at all time periods except 
after 6 months when (Group B) reported single 
incidence of occurrence.

At the end of the follow up period, there 
was no statistically significant difference between 
(Group A) and (Group B) \((p=0.317)\).

IV- Mucositis:

A month after insertion, there was no 
statistically significant difference between 
(Group A) and (Group B) \((p=1)\). Both groups 
showed the same frequency.

After 6 months, there was a statistically 
significant difference between (Group A) and 
(Group B) \((p=0.045)\) with higher incidence in (Group B). after 9 and 12 months, there was no statistically significant difference between (Group A) and (Group B) \((p=0.371)\) and \((p=0.522)\) respectively, where the higher 
frequency was found in (Group B), with a total 
result of non-statistically significant difference 
between both groups \((p=0.082)\).

In all complications for all time periods, there 
were no statistically significant difference between 
(Group A) and (Group B). Group B reported 
relatively a higher incidence over Group A, and 
significantly higher incidence for screw loosing at 
(12 m) and mucositis at (6 m).

DISCUSSION

The difference in the tissue response 
between the fixed screw retained denture and 
telescopic removable overdenture is due to the 
nature of each type and accessibility for the oral 
hygiene measures, where the removable type is 
much more accessible by the patient to a proper 
massage and clean the underneath mucosa even 
if it is compared to the hygienic type of the screw 
retained denture which requires a dentist visit 
to perform a deep cleaning of the underneath 
mucosa [23]. Therefore, the patient is only 
able to rinse and use the dental floss, which 
reflects the results of this study considering 
the biological complication as mucositis where 
it was significantly higher for Group B than in 
Group A with statistically significant difference 
in the first 6 months due to the mucosal covering 
with less accessibility to the oral hygiene which 
increases the mucositis unless the patient was 
meticulously care about his oral hygiene.

Although the screw retained prosthesis, 
including the hybrid prostheses, have the 
advantages of easy retrievability, but screw 
hole affecting the esthetics and bulkiness of the 
overlying restoration and the patient still needs 
the dentist to remove the prosthesis [24], but 
when comparing with the removable prosthesis 
removal and insertion is much easier for both the 
patient and dentist.

Considering the mechanical complication 
in terms of the screw loosening, screw fracture,
teeth fracture and acrylic fracture in the fixed screw retained denture; are usually occurred because of the prosthesis and tissue response to the applied forces [25].

Abutment screw looseness frequency was more in Group B than in Group A, but with the statistically non-significant difference, which can be due to the transmission of chewing forces to the implant-abutment interface where the energy in turns transmitted to the screws which may lead to its loosening in addition to the passivity which cannot be totally obtained in any prosthesis. The superstructure of the implant retained prosthesis misfit is a result of the accumulative distortions that occurred during the whole procedure of the final prosthesis fabrication, which is known as the distortion equation, Theoretically, the total passive fit can be achieved if the summation of this distortion equation was zero [26]. Also the deficient preload on the screws, over tightening of the screws may cause stripping, screw distortion and/or excessive occlusal load from parafunction, occlusal interferences, or exceedingly long cantilevers [27].

Other studies showed that the prosthetic maintenance/complication were more in removable types of the implants retained overdentures than the fixed ones [14]. As for the prosthetic maintenance requirement found in the telescopic implant retained overdentures especially after 12 months was the loss of the retention between the primary & secondary copings resulting from the wear happened between both copings due to the loss in the retentive mechanism of the removable overdenture’s attachments as prosthetic complication [28,29].

Recently Secondary coping of the telescopic crowns can be fabricated by one of these generation of polymers as Poly Ether Ketone-Ketone (PEKKTON) and Poly Ether-Ether Ketone (PEEK), these are the two most well-known of the family Pol aryl ether ketone PEEK which overcomes the wear happens between similar coping materials [30].

Relining required for the overdentures happens in four cases; two cases needed relining after 9 months, other two cases at 12 months due to the undesirable forces transmitted to the denture bearing area, which led to the bone resorption atrophy of the denture bearing area overtime [31]. Rigid telescopic abutments and the height of the telescopic attachments in the implant overdentures had a marked impact on the lateral force on the implants and the transmitted force to the denture bearing area, which may be attributed to the need for relining in some patients depending on the type of both the supporting structure and its quality together with the masticatory forces which differ from a patient to another [32].

Acrylic base Fracture of the prosthesis was found with the fixed screw retained type more when found with the removable telescopic implant overdentures, which can be due to the attachment mechanism of the acrylic resin with the metallic framework, which may be related to the poor chemical bonding of the acrylic resin to base metal alloys, which can results in the microleakage and bond failure [33]. In this study resin fracture occurred due to the improper usage of the prosthesis with 1 patient who stated that he used the denture to cut a hard object.

Tooth fracture in Group B with a higher frequency than Group A, but with non-statistically significant difference, which may be due to the improper utilization of the denture by the patient for putting hard objects inside his mouth which was revealed by taking the history from the patients. Some studies reported fracture of anterior acrylic teeth more than posterior ones. Incidence of the tooth fracture varies in the studies from low incidence to a frequent ones that may be due to the different follow-up periods or patient’s behaviors [34].

**CONCLUSION**

Both treatment modalities; telescopic implant overdenture and hybrid fixed screw-retained are reliable for restoring the completely edentulous arches. Regarding to the prosthetic complications and maintenance; screw retained showed a higher incidence than telescopic overdenture in abutment screw loosening and fracture. Also, screw retained showed a higher incidence of mucositis, while relining was more evidenced in the telescopic overdentures. Therefore, the decision whether to make a fixed or removable implant denture shall be guided with the patient preference together with the dentist opinion in relation to the patient’s general and oral health state.
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Author’s Contributions

NMA: Conceptualization, data curation.
MAE: Writing – Original Draft Preparation
DME: Methodology, Writing – Review & Editing

Conflict of Interest

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subject’s oversight committee’s guidelines and policies of the ethical committee; Faculty of Dentistry, Cairo University.

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Prosthetic maintenance assessment for implant fixed complete dentures and implant overdentures: a randomized clinical trial


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