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ORIGINAL RESEARCH

ASSESSMENT OF ORAL-HEALTH RELATED QUALITY OF LIFE AND PATIENT SATISFACTION IN PATIENTS RECEIVING FIXED HYBRID PROSTHESIS VERSUS REMOVABLE IMPLANT-SUPPORTED OVERDENTURES (A RANDOMIZED CLINICAL TRIAL)

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ABSTRACT

The aim of this study is to evaluate oral health-related quality of life and patient satisfaction in completely edentulous patients, when restored with fixed hybrid or removable telescopic implant supported prosthesis in maxillary and mandibular arches simultaneously.

60 patients were randomized to receive either a fixed-hybrid (group H) or a removable implant-supported prosthesis (group T). They were then asked to answer the oral health related quality of life (OHIP-14) questionnaire and a patient satisfaction questionnaire at 2 weeks, 3, 6 and 12months post-prosthetic insertion.

Twelve months following prosthetic insertion, all domains of OHIP-14 and patient satisfaction improved for both prosthetic groups. No statistically significant difference was found between both groups in all domains of OHIP-14. At 12 months, the total OHIP-14 scores of Group H and group T were **5 ± 7.151 and 2.63 ± 2.973, respectively** (mean ± SD) **p = 1**. There was also no statistically significant difference in total patient satisfaction scores between the 2 groups with H and groups T scoring **43.38 ± 10.487 and 39.75 ± 10.236 (**mean ± SD), respectively, with **p-value equals 0.246.** The only exception was the domain of satisfaction with esthetics at **p≤.05**, favoring the fixed-hybrid group.

***Keywords*:** Implant overdentures, hybrid prosthesis, implant fixed prosthesis, Removable implant prosthesis, Implant-supported prosthesis, patient satisfaction, patient-related outcomes, oral-health related quality of life, OHIP-14

INTRODUCTION

The use of dental implants in the rehabilitation of edentulous patients, whether by fixed or removable prosthesis, has become a well-established line of treatment providing significant improvements when compared to conventional dentures. [1, 2,] Several attachment systems have been developed to provide retention of the prosthesis to the implant abutments. [3,4] A key difference between them is how they are retrieved. **Fixed implant prosthesis can't be removed** by the patient **and require a** dental professional using specialized tools. They are either screw-retained or cement-retained to the implant abutments.[5] Removable implant prostheses are designed to be easily removed by the patient, for hygiene and comfort. They use many attachment systems for retention like locator abutments, bars, telescopes or magnets allowing for repeated placement and removal without professional intervention.[3]

When it comes to making a clinical decision for either fixed or removable implant supported prostheses, it was found that the choice still largely depends on the clinician's professional opinion which doesn't necessarily take into account the patient's preferences [6] A few studies concluded that evaluations of treatment outcomes by dentists do not necessarily correspond to the patients' own perception of the prosthesis. This mandates that the decision-making process of which type of prosthesis to use should take into consideration the needs and attitudes of individual patients as well as the clinical judgement of the dentist. [6, 7,8]

Studies comparing patient-reported outcomes in patients rehabilitated with fixed and removable implant –supported prostheses failed to reach a satisfactory agreement regarding the patient preference.[9,10]
Hence, this randomized clinical trial was conducted to compare the oral-health related quality of life and patient satisfaction of completely edentulous patients, when restored with fixed hybrid and removable implant-supported prostheses.

MATERIAL AND METHODS

This parallel group randomized controlled trial (RCT) was reported following the Consolidated Standards of Reporting Trials (CONSORT) statement. [11] It was approved by the ethical committee, Faculty of Dentistry, Cairo University. A protocol of this study was published on clinicaltrials.gov with a registration number NCT04694209. Recruitment, surgical and prosthetic procedures were conducted in the Research Clinic of the Prosthodontic Department, Faculty of Dentistry, Cairo University.

60 patients were recruited and randomly allocated into 2 groups, fixed-hybrid (H group) and removable (T group) implant supported prostheses with an allocation ratio 1:1. Simple randomization was done by using opaque, sealed envelopes, that contained two-times folded cards with the treatment group written inside to be matched to each patient accordingly. The recruited patients fulfilled the following selection criteria; completely edentulous male patients that were dissatisfied with their complete dentures, a glycosylated haemoglobin (HbA1c) ≤7 [12] and available interarch space ≥22 mm. [13] Patients smoking> 10 cigarettes were all excluded. [14]

Sample Size

The sample size for this study was determined in reference to the methodology used by Oh et al.,[15] who conducted a comparative analysis of patient satisfaction and oral health-related quality of life among fully edentulous patients treated with fixed implant-supported prostheses, removable implant-supported prostheses, or complete dentures. In their study, the minimum sample size was calculated using standard statistical criteria ($\alpha = 0.05$, power = 0.80) and based on the primary outcome oral health-related quality of life from prior literature. They determined that **26 patients per group** were required to achieve sufficient statistical power. Aligning with this methodology, the minimum required sample size per group was calculated as 26 patients, using an alpha of 0.05 and a power of 80%, with the primary outcome being Oral health-related quality of life as measured by the OHIP-14 questionnaire. Therefore, a total sample size of 52 patients (26 per group) will be required to detect a statistically significant difference between the two groups. This number has been increased to 60 patients (30 per group) to allow for an approximate 15% dropout rate. Sample size calculation was performed using G*Power (Version 3.1.9.4, Universität Düsseldorf, Düsseldorf, Germany)

Statistical methods

Data were statistically described in terms of mean ± standard deviation (± SD), median and range. Comparison of ordinal variables between the study groups was done using Mann Whitney *U* test for independent samples. Within group comparison of the ordinal data was done using Friedmann test to detect significant differences between time in periods. This was followed by Wilcoxon signed rank test for paired comparisons. Two-sided *p* values less than 0.05 was considered statistically significant. Additionally, a correlation between relevant domains of the OHIP-14 and the patient satisfaction questionnaires was done using Spearman rank correlation test. All statistical calculations were done using computer program IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows

For all eligible patients, new complete maxillary and mandibular dentures were fabricated. The maxillary and mandibular dentures were used for the construction of radiographic scan appliances using radiopaque resin (Major.Base.20, Self-cure acrylic resin, Major- Italy). Patients were scanned, while wearing the appliance using cone beam computed tomography (CBCT, Carestream Health, USA). The DICOM file was imported into a planning software (Blue sky Bio, LLC. Blue Sky Bio, LLC, Grayslake, IL-USA) to design the surgical guide through a process called segmentation. The final virtual surgical guide was then exported as STL file and processed with a special software at the rapid prototyping unit (Zenith 3D Printer- Dentis Daegu- Korea). Using selective laser sintering technology the guide was built from poly-amide material (ZMD-1000B Zenith 3D printing material-Dentis, Daegu- Korea). This guide was used in the computer-assisted, flapless surgery. A simplified universal, computer guided surgical kit (Simple Guide Kit, Dentis, Daegu –Korea) was used to insert four root form implants (S-clean tapered dental Implant fixtures - Dentis- Korea), 3.7×10mm parallel to each other in the lateral incisors and second premolars regions in the maxillary arch and in the interforaminal region in the mandibular arch. Drilling through the surgical guide was done with the pilot and inter- mediate drills only. The final drilling and implant insertion were done after removing the surgical guide using the conventional final drills.

After 6-8 weeks of submerged healing, the surgical guide was used to relocate the position of the implants and healing caps were attached to the implants for 1 week. They were then replaced by transmucosal abutments (TMA, Transmucosal Octa abutment, Dentis, Daegu -Korea) that were torqued at 35 Ncm. Abutment level splinted open tray impression technique was used

for recording the implant positions. Pick-up impression copings (Titanium, Dentis Implant System, Daegu -Korea) were screwed to the TMA. The non-hex model was used for the fixed-hybrid prosthesis impression, and the hexed model was used for the telescopic one. They were splinted intra-orally using resin (Duralay GC AMERICA INC.3737, ALSIP IL 60803 USA) on a dental floss scaffold (Oral B floss Satin Dental Tape, Ireland). Putty silicone rubber base (Zetaplus. C-silicone putty. Zhermack company – Italy) was used for border molding, while medium body addition silicone (medium consistency addition silicone, elite HD, Zhermack, Italy) was used for final impression recording. Compatible implant lab analogues (Lab analog, Subocta System, Dentis Company, Daegu - Korea) were screwed to the transfer copings. Tissue mimic (Pentron, Correct Plus™, light body, KaVo Kerr, CA-USA) was injected around the analogues, and the impression was poured using extra-hard stone (Ventura Extra Hard Stone, Madespa, S.A Toledo– Spain). The impression was later verified using a resin verification jig (Duralay GC AMERICA INC.3737, ALSIP IL 60803 USA). If the jig wasn't properly seated, it's sectioned and re-united intra-orally and the impression procedure is repeated again for the fabrication of a new cast that would later be re-verified using a new jig.

Fabrication of fixed-hybrid prosthesis

The non-engaging (non-hex) cylindrical, plastic sleeve patterns (N-octa plastic cylinder, multiunit abutment, white, Dentis, Daegu –Korea) were screwed to the lab analogues in the cast. Height of the plastic patterns was adjusted using the putty index. A wax pattern corresponding to the cobalt-chromium alloy framework joining the cylindrical patterns is made and is later sprued and cast using the lost- wax technique. After ensuring the passivity of the framework during metal framework try-in ***(figure 1)***, using the single screw test and radiographic imaging, wax occlusion rims were added on the top of the framework to be used for the jaw relation record. Try in of the waxed-up dentures was then performed after setting up of the teeth. The wax up of the trial denture was processed into heat-cured acrylic resin (heat-polymerized polymethyl methacrylate (PMMA) (Acrostone, Anglo-Egyptian Company. Hegaz, Cairo, Egypt,) using conventional processing techniques.

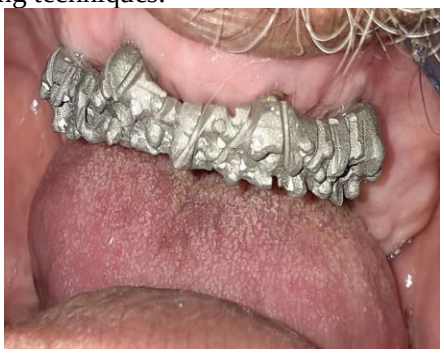

Figure 1. Fixed hybrid prothesis framework

Fabrication of removable telescopic prosthesis

Engaging (Internal hex) cylindrical, plastic patterns (Octa plastic cylinder, multiunit abutment, Red, Dentis, Daegu –Korea) were used to construct the primary copings of the telescopic prosthesis. The height of the plastic patterns is adjusted according to the putty index ***(figure 2)*** and the contours of the coping's pattern were adjusted by adding milling wax all around, then developing a 2° taper proximally by the aid of a milling bur mounted on the milling surveyor (Milling unit BF 2, Bredent © GmbH & Co.KG, Germany)

Patterns of the primary copings were then cast, finished and polished. The metal primary copings were scanned using a laboratory scanner (Shera Echo-scan 7. Dental Wings, Montreal-Canada). Using CAD/CAM technology (Dental Wings Software, Dental Wings, Montreal -Canada). The secondary copings were digitally designed and the wax patterns milled. The milled wax patterns were cast into secondary copings, then placed on the cast and were scanned together with the relevant primary copings to start designing the framework using CAD/CAM technology. The wax pattern of the framework was then milled, cast, finished and polished. Proper intra-oral seating of the primary and secondary copings was ensured by the aid of an acrylic seating jig. The framework was then tried in the patient's mouth followed by bite registration. After waxing up of the trial denture base, the denture is processed into acrylic the conventional way.

Patients were instructed to use their denture all day upon delivery. Oral hygiene procedures involved removing the telescopic denture (group T) for cleaning of both the mucosa, the primary copings and the fitting and polished surfaces of the prosthesis. For the fixed-hybrid group (group H), regular intra-oral brushing was strongly recommended. Patients were recalled for an inspection visit after one week, in order to check for any sore spot or pressure area and to adjust the occlusion, if necessary.

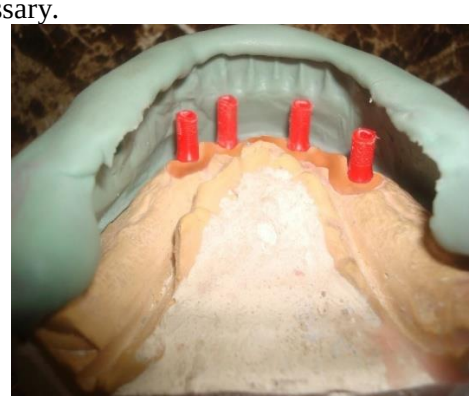

Figure. *2* using putty index to adjust occlusal height of

Outcomes

The primary outcome was oral health related quality of life using OHIP-14 questionnaire [16] while the secondary outcome was patient satisfaction. [17]

Both outcomes were measured using previously validated questionnaires. A validated Arabic translation of the 0HIP-14 questionnaire found in literature was used. [18]

For the cross-cultural translation of the patient satisfaction questionnaire forward and backward translation from English to Arabic and again from Arabic to English by a dentist and an independent translator was performed to ensure the validation of the cross-translated version.

The questionnaires were administered to the patients by a dentist, who was not involved in the clinical procedures to decrease the risk of assessment bias. The patient was allowed to sit comfortably in a quiet well-lit room to avoid his distraction and to provide a suitable environment for answering the questions. The outcomes were measured 2 weeks post-prosthetic insertion (2w) then 3, 6, 9 and 12 months.

1- Oral health related quality of life

The questionnaire of choice was OHIP-14. *appendix (1).* This tool consists of seven domains; 2 questions each studying functional limitation, physical pain, psychological discomfort, and handicap as well as physical, psychological and social disabilities. For each domain a value was given based on the mean of the 2 questions. Values of all categories were added to obtain a total global score. Answers were given according to a five-point Likert scale, never [score 0], hardly ever [score 1], occasionally [score 2], fairly often [score 3], and very often [score 4]). The highest score was given to the most adverse effect inflicted on the patient's quality of life.

2-Patient satisfaction

The questionnaire had items evaluating esthetics both initially and today, chewing, speaking, ease of cleaning, costs and if the patient is willing to repeat the same procedure again. *appendix (2).* Some modifications were made to the original questionnaire: the 2 questions regarding esthetics were combined into one question, the questionnaire was answered and the score was calculated according to the five-point Likert scale instead of the original VAS. Although VAS is **highly sensitive** to small differences and changes in perception, for our studied population a Five-point Likert scale was deemed as easier to administer and interpret.[19] the highest score (5) denoted the best satisfaction score. The questions regarding satisfaction with the cost of the prosthesis weren't included as they didn't apply to our study.

RESULTS

Baseline characteristics:

The 60 male patients included in this RCT had an average age of 60.13±3.80 and 58.50±5.01 for group H and T respectively.

Baseline characteristics of both groups were compared regarding the occupation, marital status and gender. As shown in *table 1*, none of these variables showed a significant difference in the distribution between both groups, which provided an equal baseline for the studied groups.

Table 1. Baseline characteristics of both groups

Variables		Hybrid		Telescope		p-value
Character		N	%	N	%	
Occupation	Employed	19	63.3%	17	56.7%	0.157ns
	Retired	11	36.7%	13	43.3%	
Marital status	Married	30	100%	20	66.7%	0.400ns
	Single	0	0%	6	20%	
	Widowed	0	0%	4	2%	
Age (By years): Mean ± SD		60.13±3.80		58.50±5.01		0.537ns

Primary Outcome: Oral Health-related quality of life

By studying the effect of prosthesis on the OHIP-14, no significant differences were found between the studied groups at different time periods. Significance level was set at ≤0.05. This holds true to all seven domains and total OHIP-14 score. All the scores of the 14 items of the questionnaire (2 in each domain) were summed up to calculate the total OHIP-14 score. ***(Figure 3)*** Each item is given a score from 0 to 4 on a 5-point Likert scale and adding up all items yields a maximum total of score of 56 and a minimum of 0, showing the maximum and minimum impairment on the quality of life, respectively. At 12 months, the mean Total OHIP-14 score among Group H was **5 ± 7.151 (**mean ± SD) with scores ranging from **0 to 28**, while for Group T was **2.63 ± 2.973 (**mean ± SD) with scores ranging from **0 to 14.** There was no statistically significant difference in OHIP-14 scores between both groups with p-value equals 1. *Table 2* shows different scores for all seven domains for both groups.

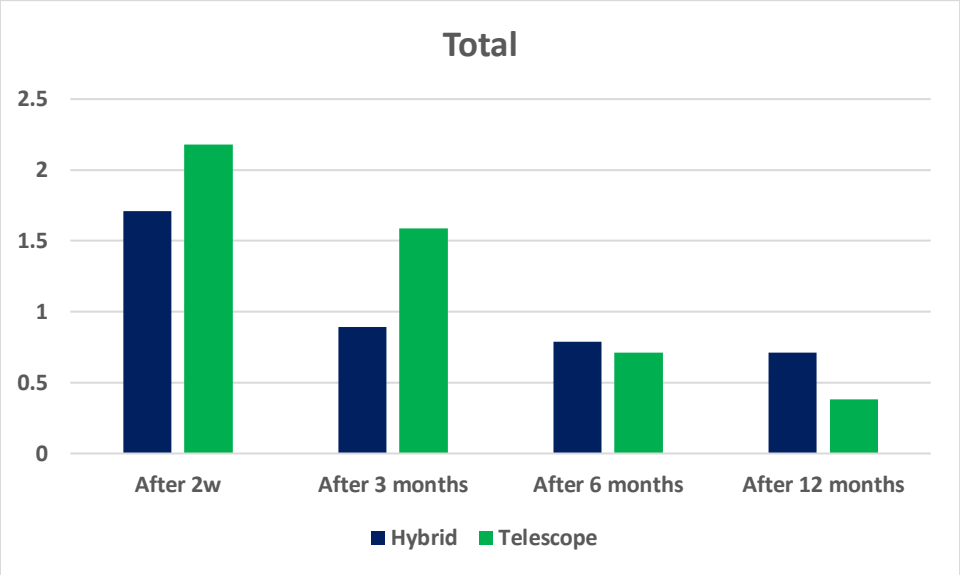

Figure 3. Bar chart representing Total OHIP-14 scores for both groups

Table 2. OHIP-scores (H=fixed Hybrid, T= Removable telescopic)

		Group H		Group T		**P -value**
		mean	SD	**P value**	SD	
Functional limitation	2w	2.88	2.031	3.38	1.188	0.545
	3m	2.13	1.727	3.38	1.598	0.106
	6m	1.75	2.435	1.13	0.991	0.956
	12m	1.50	2.507	0.63	0.916	0.809
Physical pain	2w	2.88	2.167	3.38	1.506	0.667
	3m	1.38	1.685	1.63	1.847	0.821
	6m	1.13	1.458	0.25	0.707	0.124
	12m	1.13	1.458	0.13	0.354	0.084
Psychological discomfort	2w	1.75	2.188	2.00	1.414	0.518
	3m	0.50	1.414	1.00	1.414	0.179
	6m	0.38	0.744	0.50	0.756	0.653
	12m	0.13	0.354	0.50	0.756	0.239
Physical disability	2w	2.38	2.066	3.63	2.504	0.218
	3m	1.88	2.031	3.13	2.475	0.282
	6m	1.75	2.188	1.75	1.581	0.824
	12m	1.63	2.387	0.88	1.246	0.629
Psychological disability	2w	1.00	1.309	1.50	1.690	0.651
	3m	0.38	0.744	1.63	2.066	0.205
	6m	0.25	0.707	0.63	0.744	0.178
	12m	0.38	0.744	0.50	0.535	0.460
Social disability	2w	0.50	0.756	0.88	1.126	0.520
	3m	0.00	0.000	0.38	0.744	0.144
	6m	0.00	0.000	0.25	0.707	0.317
	12m	0.00	0.000	0.00	0.000	1.000
Handicap	2w	0.63	0.744	0.50	0.756	0.680
	3m	0.00	0.000	0.00	0.000	1.000
	6m	0.25	0.707	0.50	1.414	0.927
	12m	0.25	0.707	0.00	0.000	0.317

Secondary Outcome: Patient Satisfaction:

To calculate total patient satisfaction score, each item is given a score from 0 to 4 on a 5-point Likert scale and adding up all items yields a maximum total of score of 20 and a minimum of 0. The larger the number, the more the patient is satisfied. At 12 months, the total patient satisfaction score for group H score was 43.38 ± 10.487 **(**mean ± SD) with scores ranging from 13 **to 20**, while for Group T was 39.75 ± 10.236 **(**mean ± SD) with scores ranging from **10 to 20.** There was no statistically significant difference in total patient satisfaction scores between both groups with **p-value equals** 0.246 (Figure 2).

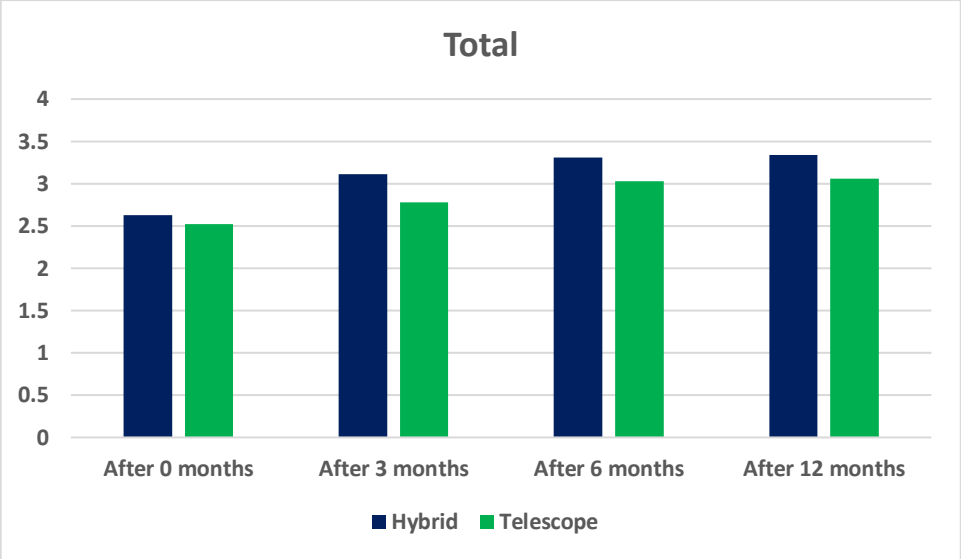

Figure 4. Bar chart representing Total patients' satisfaction for different groups (B)

When analyzing each domain independently no statistically significant difference was found between group H and T across 4 out of 5 question categories: namely speech, mastication, hygienic procedures and cleaning, and the possibility of repeating the procedure. The question category about the cost of the procedure was not included in our questionnaire as it was not applicable to the study settings.

A statistically significant difference was found only for the esthetics question category at 6 and 12 months, favoring group H (table 3).

Table 3. **Scores for esthetics domain for both groups**

	Esthetics		
	Hybrid	**Telescope**	**p-value**
After 0 months	3.38	2.38	**0.161ns**
After 3 months	3.75	2.25	**0.065ns**
After 6 months	3.88	2.25	**0.021***
After 12 months	3.88	2.25	**0.021***
p-value	**0.066ns**	**0.845ns**	

Correlation between OHIP-14 and Patient Satisfaction:

The correlation between the OHIP-14 and the patient satisfaction questionnaire revealed a significant negative relation between the functional limitation and speech only at r = -0.628 and p-value= 0.009. *(Table 4)*

Table 4. Spearman's correlation

Variables	Correlation coefficient	p-value
Functional limitation and speech	-0.628	0.009
Physical pain and repeating the procedure	-0.29	0.276
Physical disability and chewing	-0.248	0.354
Psychological disability and repeating the procedure	-0.224	0.405
Social disability and repeating the procedure	0.383	0.143

DISCUSSION

Studies comparing oral health -related quality of life and patient satisfaction of edentulous patients rehabilitated with fixed and removable implant prostheses failed to reach a satisfactory agreement about the type of prostheses the patient prefers. [9,15, 20-22] This RCT was carried out to shed light on patient preferences regarding the type of implant prosthesis.

The patient-related confounders were controlled through implementing restrictions on the selection criteria, as well as randomization of the study subjects. Balance between the groups was statistically checked regarding the following domains; occupation, marital status and age. Only male patients were selected for this study, to exclude the effect of post-menopausal osteoporosis in women and subsequent higher risk for ridge resorption and implant failure. [23] This also abides with a study by Awad et al [3] that demonstrated that patient gender contributed significantly to the expression of general satisfaction.

This study intended to include a wide age range for the patients, but ended up with an age rannge from 40 to 70 years old with a median of 60.13±3.80 and 58.50±5.01 for group H and T respectively due to the available edentulous patient pool at the hospital. In 2003, Awad and coworkers [3,24]carried out 2 studies comparing mandibular implant overdentures and conventional dentures in two patient populations: middle aged (35 to 65 years old) and senior (65 to 75 years old). In the younger group, they found that OHIP scores were significantly better in the implant group compared to the group restored with conventional complete dentures. However, in the senior group, the OHIP scores were significantly better for Implant treatment only in the physical domain. The authors concluded that the differences between these two studies were probably a result of the fact that subjects in the senior study were less likely to be engaging in the activities assessed in the OHIP. This was also confirmed by another study by Allen et al[25]. Smokers and nonsmokers were included in this study with a maximum limit of 10 daily cigarettes for smokers to minimize the risk of postoperative infections and marginal bone loss in smokers.[14]

In our study, we chose to report two important outcomes; Oral Health-related quality of life and patient satisfaction.

The oral health related quality of life was compared using Oral Health Impact Profile (OHIP-14). It's well-validated, widely used and much shorter than the original OHIP-49 questionnaire that the patient may find time consuming and burdensome. Among the shortcomings of the OHIP-14 questionnaire are lack of questions directly assessing the costs, ease of cleaning the prosthesis as well as insuffucuent focus on esthetics and appearances. [26] To cover these key shortcomings, the patient satisfaction questionnaire was also used as an adjuctive questionnaire.

The correlation between the relevant domains of these two outcomes were studied to further clarify the importance and inter-relationship between both outcomes and the different aspects measured.

When studying the OHIP-14 across both groups, a consistent trend of decreasing OHIP-14 scores over time was observed, reflecting improved quality of life post-rehabilitation. Despite some numerical differences between groups over time, no statistically significant differences ($p > 0.05$) were observed in any domain at any time point.significant differences between the two groups across all seven OHIP-14 domains and the total score suggests that both prosthetic modalities were similarly effective in enhancing patient-reported outcomes. These findings are in accordance with similar studies studying Oral-Health related quality of life between fixed and removable prosthesis. [15,26,27]

Functional limitation and physical disability showed delayed improvements, with significant changes detected predominantly at the 12-month follow-up. This late improvement may reflect the extended adaptation period required for both prosthesis types, particularly as patients learn to accommodate changes in speech, chewing, and prosthetic handling.

In contrast, social disability and handicap domains showed early and stable improvement from the 2-week follow-up onward. This suggests that even early in the prosthetic adaptation process, patients perceived a marked psychosocial benefit—possibly due to the restoration of facial esthetics and reestablishment of social confidence. Interestingly, the social disability domain improved earlier in Group H, while the handicap

domain improved earlier in Group T, possibly reflecting the faster esthetic adaptation with fixed prostheses versus the immediate comfort and retrievability offered by removable options.

Further domain-specific trends revealed that physical pain and psychological discomfort improved earlier in Group H (3 months) compared to Group T (6 months). These results are clinically significant, as fixed prostheses may offer more immediate stability and reduced mucosal loading, minimizing discomfort. Additionally, the psychological reassurance of a non-removable prosthesis could explain the earlier improvement in mental well-being observed in this group.

In both groups, psychological disability improved early and significantly—already observable by the 2-week follow-up—demonstrating the profound psychological impact of transitioning from complete dentures to implant-supported restorations. This finding aligns with previous literature emphasizing the emotional and confidence-related benefits of implant therapy. [24, 25]

Upon inspection of the patient satisfaction results , no statistically significant differences between the two groups across a broad range of functional and experiential categories. However, esthetic satisfaction was significantly higher in the hybrid group at both 6 and 12 months, indicating a potential advantage of hybrid prostheses in meeting patients' aesthetic expectations.

Despite this difference, total patient satisfaction did not differ significantly between the groups suggesting that overall satisfaction is multifactorial and not determined solely by esthetics. Our findings relevant to esthetics are opposite to those of two other studies that found a significant difference in the esthetics of fixed and removable prostheses, favoring the removable option. They explained their findings by the more natural appearance of the flanges of the removable implant overdentures that extended to the depth of the vestibule when compared to the fixed prosthesis. [26,28] Neverthesless, the difference between the attachments used in our study and the relevant studies could have accounted for the difference in the esthetic results of our study and the 2 other studies. It is worthy to mention that patient's preference amd choice of prosthtic option, when made possible, might affect his satisfaction scores, regradless of being removable or fixed as suggested by Feine and her colleagues.[29]

A key finding was the significant negative correlation between functional limitation and speech satisfaction ($r = –0.628$, $p = 0.009$). This indicates that as patients perceived fewer functional limitations—such as improved clarity in speech—their satisfaction with prosthetic speech-related performance increased. [21] This finding is in line with Heydecke et al[30,21] who investigated speech from an objective dental opinion and found that subjects produced a significantly higher percentage of correct sounds with overdentures than with fixed prostheses. He justified his results by the sub-prosthetic space present in the fixed prosthesis that allowed air escape in the maxilla and impaired phonation. Surprisingly, patient satisfaction with speech in the same study did not show any significant difference between the two prosthetic options, similar to our findings. [15] Other studies ;demonstrated improved speech satisfaction in the fixed group and explained it by the decreased bulk of the prosthesis and the absence of any palatal coverage. [30,31] However, they still concluded that there was no significant preference for one type of prosthesis over the other , owing to the fact that other aspects of denture satisfaction, like ease of performing hygienic procedures played an important role in the patient's choice.

Few studies showed increased patient satisfaction with the ease of hygienic procedures for the removable prosthesis in comparison to the fixed, despite of being of no statistical significance. [26,33] Previous studies reported that patients prefer the removable prosthetic option, especially in elderly, when there is limited manual dexterity or vision impairement that complicated the cleaning and made patients deprioritize other domains like chewing efficiency or esthetics. [26,29,32] In our study, group H reported faster satisfaction in the hygienic procedures, with no significant difference between the groups. The results are in accordance with the conclusion of Quirynen et al,[33] who found no significant difference between fixed and removable prostheses in a 10-year study, regarding plaque index, bleeding index, marginal bone level and peri-implant micro-flora. However, the patients' findings contradict the operator's clinical observations in this study, where plaque formation, gingival inflammation, irritation and sometimes hyperplasia beneath the prosthesis in group H was more evident, especially in the first 3 months, despite of the reported increased levels of patient satisfaction. This necessitates a need for re-evaluationg the relationship between the patient- and the dentist-reported outcomes to reach a conclusive evidence about the debate between both.[34,35]

Limitations of the study

Restricting this RCT to male participants only, has eliminated the confounding effect of the gender but affected its generalizability. The results of this study are only applicable to male subjects. It is worthy to mention that the unique clutural and linguistic background of the Egyptian population limited the applicability of the study results to Egyptian elderly male subjects.

Blinding of the operator and the patient were not possible, which puts the results under the risks of performance and assessment bias.

Since in this study patients received both maxillary and mandibular implant prostheses, the recorded satisfaction and OHIP-14 scores could not be correlated

to the arch that was restored and were, hence, reported combined rather than separately. This made the authors unable to investigate the effect of each prosthetic option in each arch on the studied outcomes.

Many studies, reported that the cost of the prosthesis played a major role in the patient's choice for a prosthetic option, regardless of the remaining satisfaction domains. Unfortunately, in this study the financial domain was left unanswered, since the patient did not pay for the delivered prosthesis. [36]

SUMMARY

When it comes to choosing between fixed and removable implant supported prosthesis for completely edentulous patients, much research covered the technical aspects and not enough studied the patient-reported outcomes. This parallel-group RCT adopts a patient-oriented approach and compares patient satisfaction and OHIP-14 in completely edentulous patients receiving hybrid prosthesis (group H) or removable telescopic retained overdentures (group T).

60 patients were randomized to receive either a fixed or a removable maxillary and mandibular full arch implant prosthesis. They were then asked to answer the patient satisfaction and OHIP-14 questionnaires at 2 weeks, 3, 6 and 12months post-prosthetic insertion.

No statistically significant differences were found between the two groups in all domains of the OHIP-14 and the patient satisfaction except esthetics at $p \leq .05$, favoring group H. Twelve months following prosthetic insertion The total OHIP-14 scores of Group H and group T were 5 ± 7.151 and 2.63 ± 2.973, respectively (mean ± SD) $p = 1$. While total patient satisfaction scores were 43.38 ± 10.487 and 39.75 ± 10.236 (mean ± SD) for H and T respectively. Both types of prosthesis seem to offer an improved quality of life and patient satisfaction for edentulous patients.

CONCLUSIONS

Within the limitations of this study it can be concluded that:

1. Maxillary and mandibular fixed hybrid implant prosthesis provide comparable patient satisfaction to telescopic retained ones in all domains except esthetics, where hybrid prosthesis showed better statistical results. In the clinical setting, both groups were esthetically satisfied with their prostheses.
2. Both prosthetic options improve oral health related quality of life and patient satisfaction.

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APPENDICES

Appendix 1 : OHIP-14 Questionnaire

Functional limitation

OHI, have you had trouble pronouncing any words
because of problems with your implant prosthesis?
OH2, have you felt that your sense of taste has worsened because of problems with your implant prosthesis?

Physical pain

OH3, have you had painful aching in your mouth?
OH4, have you found it uncomfortable to eat any foods because of problems with your implant prosthesis?

Psychological discomfort

OH5, have you felt self-conscious because of problems
with your implant prosthesis?
OH6, have you felt tense because of problems with your
implant prosthesis?

Physical Disability

OH8, has your diet been unsatisfactory because of
problems with your implant prosthesis?
OH8, have you had to interrupt meals because of problems with your implant prosthesis?

Psychological Disability

OH9, have you found it difficult to relax because of
problems with your implant prosthesis?
OH10, have you been a bit embarrassed because of problems with your implant prosthesis?

Social Disability

OH11, have you been a bit irritable because of problems
with your implant prosthesis?
OH12, have you had difficulty doing your usual job because of problems with your implant prosthesis?

Handicap

OH13, have you felt that life in general was less
satisfying because of problems with your implant prosthesis?
OH14, have you been totally unable to function because of problems with your implant prosthesis?

Appendix 2: Patient Satisfaction Questionnaire

1. How would you rate the appearance of your teeth?
2. How would you rate your present capacity to chew?
3. How would you rate your present capacity to speak?
4. How easy do you find it to clean your teeth and gums?
5. In hindsight would you undergo the treatment you had for your mouth and teeth again?