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Original Article

Comparative Assessment of Two Filling Materials as Restorative Options for Tooth-Tissue Supported Overdentures: A Split-Mouth Randomized Clinical Trial

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Abstract

Aim: The idea of tooth tissue supported overdentures is considered as an alternative to extraction of remaining teeth. The difference in clinical outcome between amalgam and nanohybrid composite as filling material for the overdenture abutments, yet has not been emphasized, thus further research is required to confirm the ideal filling material in prepared endodontically treated abutment teeth.

Subjects and methods: 28 patients with bilateral remaining canines or premolars in the maxillary or mandibular arch were enrolled in the study. Dome shaped preparations of the abutments were performed. The amalgam and composite restorations were randomly assigned to either the right or left remaining abutments, then conventional steps of overdenture fabrication and insertion were accomplished. Patients were followed up for 3 years. Wear depth and survival rate of restorations were evaluated.

Results: A non -statistically significant difference was revealed in the wear depth of the two restorations (P value <0.001). However, A statistically significant higher survival rate of nanohybrid composite was revealed (P value= 0.387).

Conclusion: Nanohybrid composite can be used successfully as filling material for overdenture abutments.

Keywords: Overdenture, Tooth-Tissue supported, Amalgam, Nano-hybrid composite, Wear

Introduction

The idea of using complete dentures over retained teeth was first proposed by **Miller in 1958**, but it wasn't until then that it truly caught on as a realistic alternative to extracting the remaining teeth. Since the 1960s, on examination of numerous long-term studies, which has demonstrated advantages of overdentures, including the prevention of increasing residual ridge reduction, improved denture stability, and better load transmission of the prosthesis (***Toolson and Smith 1982; Davis et al. 1981; Ettinger and Jakobsen 1996; Rissin et al. 1978; Ettinger and Jakobsen 1997; Van Waas et al. 1996)*** **.** There have also been reports of people experiencing psychological advantages as a result of not feeling toothless. This might play a significant role in upholding a more optimistic self-esteem ***(Toolson and Smith 1983).*** According to some research, these people may still have some sensory feedback from the periodontal receptors of the residual roots, which would give them the ability to discriminate oral textures more precisely than people who wear complete dentures ***(Kay and Abes 1976; Mushimoto 1981; Sposetti et al. 1986).*** The teeth are retained to preserve residual bone around the overdenture abutments, thereby improving denture function ***(Morrow et al. 1969; Ralph and Murray 1976; Kalk et al. 1990).***

Total extraction now takes a more cautious approach as a result of the expanding emphasis on prevention in prosthodontic practice ***(Budtz-Jorgensen 1995).*** In contrast to traditional complete dentures, the preservation of natural tooth roots as abutments for complete overdentures is now more widely regarded as a better treatment choice ***(Ettinger 1988).*** According to studies, the least number of teeth needed for tooth supported overdentures is two abutment teeth ***(Keltjens et al. 1990).*** Nevertheless, abutment teeth are reduced to a level that is 1-2 mm above the gingival margin as part of the treatment process, and then any caries that is already present is eliminated ***(Keltjens et al. 1994).*** Cavities are prepared up to a depth of 2 mm while being maintained as tiny as possible ***(Toolson and Taylor 1989).*** The easiest and least expensive technique to make an overdenture is to seal the endodontically treated teeth with a filling material, as amalgam or composite resin. Amalgam, resin composite, and glass ionomer are the proposed restorative materials for sealing the root canal orifices ***(Toolson and Taylor 1989).***

Special requirements for the restorative material are necessary due to the cariogenic environment that is likely to be present under an overdenture. In this regard, factors like fluoride release and microleakage may have an impact on the longevity of the treatment. Another issue is that patients frequently are not aware of restorative loss or leakage in endodontically treated abutment teeth, which can hasten the teeth's deterioration. According to ***(Ettinger 1988)*** standard glass ionomer cement restorations have a lower survival rate than amalgam and resin composites because of their reduced solubility, which is also the cause for their failure ***(Ettinger and Qian 2019)***. A previous clinical study suggested that there were no statistical differences between the performance and survival rate of amalgam versus resin composite ***(Keltjens et al 1999).***

No doubt that dental amalgam as a filling material has been characterized by high compressive strength and longevity if put under ideal conditions and following strict oral hygiene instructions ***(Ettinger and Qian 2019).*** However, the immense difference in the thermal expansion coefficients of the amalgam and tooth structure, dimensional changes during setting, and other considerations hasten the sequalae of microleakage and subsequent tooth loss.

With the new advances in resin composite and nanotechnology, nano-filled and nanohybrid composites have been developed.

That development gave a huge advantage of higher wear resistance due to less filler particle dislodgement ***(Angerame and De Biasi 2018).*** The shift to nanosized fillers has significantly improved the physical and mechanical properties of composite resin enabling it to provide optimal performance in cavity size and position in the oral cavity ***(Alzraikat et al. 2018).***

Therefore, the aim of this study was to compare the wear depth and survival rate of amalgam and nanohybrid composite as filling materials in tooth tissue supported overdenture. The null hypothesis was that there is no difference in wear depth and survival rate of nanohybrid composite when compared to amalgam after 3 years, and the null hypothesis was tested against the alternative hypothesis of a difference.

Subjects and Methods

Sample size calculation

The sample size was calculated using the software PS: Power and Sample Size Calculation Software Version 3.1.2 (Vanderbilt University, Nashville, TN, USA). The sample size for this investigation was determined by power estimation based on data from previous clinical trials ***(Hickel et al 2010).*** Using a mean of 0.5 and a standard deviation of 0.6, with a significance level of 0.05, and a power of 0.80; the predicted minimum sample size was 24 patients. To mitigate possible dropout effects, 28 patients were ultimately included

Trial Design and Participant Selection:

This RCT has been described according to the CONSORT checklist for case report writing and publishing guidelines (***Riley et al. 2017).*** A split mouth randomized clinical trial (RCT) was designed. Twenty-eight participants were selected from the pool of patients attending the outpatient clinic Delta University for Science and Technology, patients were seeking the replacement of their missing teeth. To be eligible for the inclusion in the trial, the participant should be medically free and presented with partially edentulous maxillary and mandibular arches particularly with bilaterally remaining any of these teeth; 33 #34 #35 #43 #44 #45 #13 # 14#15 #23 # 24 #25; besides, good periodontal support and grade I mobility. Medically compromised patients and teeth with grade II or grade III mobility were excluded. The main complaint was that they couldn't eat properly because they only had few teeth. The study protocol was registered and posted on the ClinicalTrials.gov public website.

For all cases, clinical and radiographic assessments were performed. Primary impressions were made for upper and lower arches using a stock tray and alginate impression (Cavex, Netherlands) material to obtain a study cast and a diagnostic bite. Panoramic and periapical radiographs were used to reassess the remaining dentition in terms of the prognosis of remaining teeth to reassure the absence of any bony lesions and to assess the bone support of the abutments. All necessary mouth preparations; surgical preparations like extraction of hopeless teeth and periodontal preparations as scaling or root planning were performed for all patients.

The amalgam restoration (group I) and nanohybrid composite (group II) were randomly assigned to either the right or the left abutment. Randomization was performed using computer generated random numbers. Allocation concealment was performed by using sealed opaque envelopes.

Stage 1 pre-prosthetic phase

Root planning and supra- and subgingival scaling were carried out utilizing an ultrasonic scaler. The second step was to educate patients about the need of maintaining good oral hygiene practices, including cleaning their teeth three times per day. The patient's oral hygiene was then reevaluated after two weeks to make sure they were being followed by the patients.

For all cases thereafter, intentional endodontic treatment of abutments was accomplished. Treatment with single cone technique with bioceramic sealer (Ceraseal, META BIOMED) was performed. *Fig1a-1e*

All teeth were cleaned, shaped, and then obturated during the first visit. Local anesthesia was achieved with local infiltration of 4% articaine plus 1:100,000 epinephrine (Inibsa Laboratories, Barcelona, Spain). After anesthesia, endodontic access cavities were created using round 014 carbide burs and Endo Z burs (Dentsplysirona). The root canals were prepared using the crown-down technique, and glide paths were created using No. 10 stainless steel hand instruments. Patency was confirmed and the determination of ultimate working length was performed by means of an electronic apex locator (Dentaport Z X, Morita, Tokyo, Japan) and periapical radiograph. The canals were cleaned and shaped using Pepsi Gold rotary system (PepsiGold, China). The final instrument size was established as three sizes greater than the first file which binds at the working length. Master apical file ranged from #25 to #50, depending on both the anatomy of the root and initial diameter of the canal. Irrigation was performed using Ultra-sonic activation; it involved an oscillating tip placed in the root canal, which is activated by an ultrasonic device, resulting in mechanical agitation of the irrigant, with no contact between the instrument and the root canal wall. Using Acteon® IrriSafeTM Passive Ultrasonic Irrigation Files size K25/21mm with a frequency of 30kHz using Newtron P5 SATELEC US device. Obturation was performed using single cone technique with gutta-percha (Aceone-Endo, Aceonedent. Co. Geonggi-Do, Korea), the master gutta-percha cone was coated with bioceramic sealer (Ceraseal, META BIOMED) and obturation was carried out utilizing the lateral compaction technique.

Afterwards, for group I, the amalgam, high copper non gamma 2 spherical and lathe-cut amalgam (Permite Regular set®; SDI, Melbourne, Australia) was used. Amalgam was mixed in the amalgamator according to the manufacturer's instructions. Then the well triturated amalgam was placed in the cavities using the amalgam carrier and then each increment was forcefully condensed using the suitable sized condenser till the cavity was overfilled. That was followed by precarving burnishing then carving of the restoration with a hollenback carver and finally post carving burnishing was done. Polishing of the amalgam restorations was done after 24h using amalgam polishing kit (SHOFU, Japan). For group II selective etching of enamel for 30 seconds then rinsing and dryness were done followed by application of universal bonding agent (Bisco, USA) with agitation action and then light cured for about 20 seconds. It was then followed by composite buildup with light cured Nanohybrid composite body (3M Filtek Z350, Germany) which was applied increment by increment obliquely where every increment was 2 mm maximum and cured for 40 seconds. The composite restorations were finished using yellow coded diamond finishing stones (GZ, Austria) followed by polishing using composite polishers (Kenda, Switzerland) and polish paste (EZ -PAC, Egypt). Restorations were placed with Rubber dam isolation for both groups. Then shaping abutment teeth into a dome shape and preparing them 2-3 mm above mucosal tissue with a reduction of 30 degrees from the buccal and 15 degrees from the lingual was performed. *Fig2*

Stage 2 Definitive Prosthetic Phase

For all patients, fabrication of new dentures was employed. Using medium rubber base impression material (Zhermack SpA, Italy) and a special tray, secondary impressions of the upper and lower arches were made. Then, occlusal wax rims were used to register the bite, with the vertical dimension and centric relation being recorded. Denture stability, extension, retention, occlusal plane, vertical relation, centric relation, even bearing, speech, and tooth color and shape were assessed during the try-in stage. Heat cured polymethyl methacrylate material (Beginor, China) has been used to fabricate the final prosthesis.

Outcome measure

Wear depth

For each patient, a scan of the abutments was performed using intra-oral scanner (Trios 3;3 shape, Copenhagen, Denmark) in the day of overdenture insertion and another scan was performed after 36m follow up periods. The scans were acquired by a single, experienced operator and the resultant data were exported to modeling analysis software (Ortho Analyzer, 3Shape, Copenhagen, Denmark) and converted into Standard Tessellation Language (STL) file format serving as test models. For each case two scans were then imported and super-imposed on each other on the Exocad software (DentalCAD3.2 Elefsina) and the wear depth of each restoration on the right and left abutments was calculated. *Fig 3*

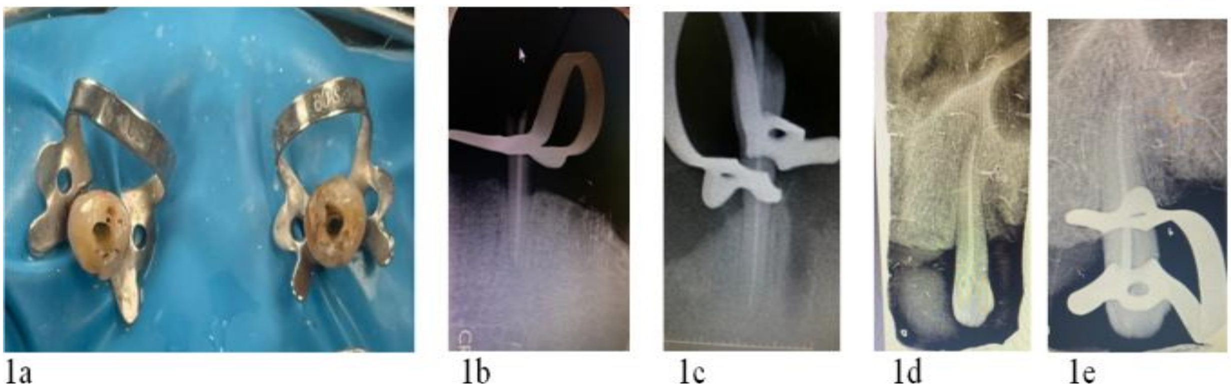
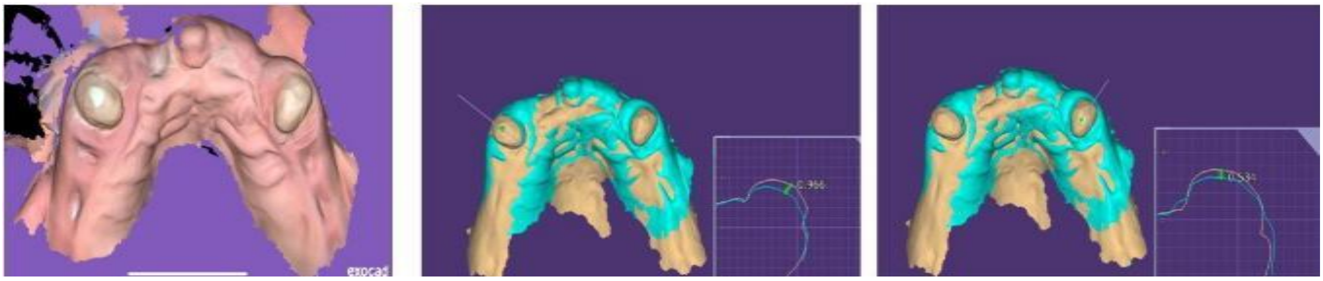


Figure (1): 1a to 1e Endodontic treatment of abutments

Figure (2): Dome shaped preparation and restoration of abutment teeth



a. **b.** **c.**

Figure (3): Wear depth measurement (3a scan of the abutments, 3b wear depth measurement of amalgam, 3c wear depth measurement of composite)

The data were determined statistically in terms of mean ± standard deviation (± SD), 95% confidence interval, range, and median. Normality assumption testing was performed using the Kolmogorov-Smirnov test.

To compare the study groups, the student t-test for independent samples was used. Statistical significance was set at a two-sided p-value less than 0.05. IBM SPSS (Statistical Package for the Social Sciences; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows was employed for the statistical analysis.

Survival rate of restoration

Restoration survival was assessed according to the criteria approved by the FDI World Dental Federation (FDI) Scientific Committee in 2007 and the General Assembly in 2008 as criteria specifically developed for use in clinical trials. (***Hickel et al 2023)*** Survival analysis was performed using the Kaplan Maier statistic, and the median survival time and its 95% CI and the corresponding survival graph were calculated for each group. Comparisons between different factors were performed by the log-rank method using the Cox-Mantel equation. Two-sided p values less than 0.05 were considered statistically significant. Statistical analyses were performed using IBM SPSS Release 22 for Microsoft Windows (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA).

Results

All 28 patients completed the follow-up period for 3 years. The age range of the patients was from 40-80 years. A non-statistically significant difference was revealed in the wear depth of the two restoration (P-value <0.001) Table 1, *Fig 4*. However, a statistically significant higher survival rate of Nanohybrid composite was revealed compared to the amalgam restorations (P value= 0.387). *Fig 5 and table 2*

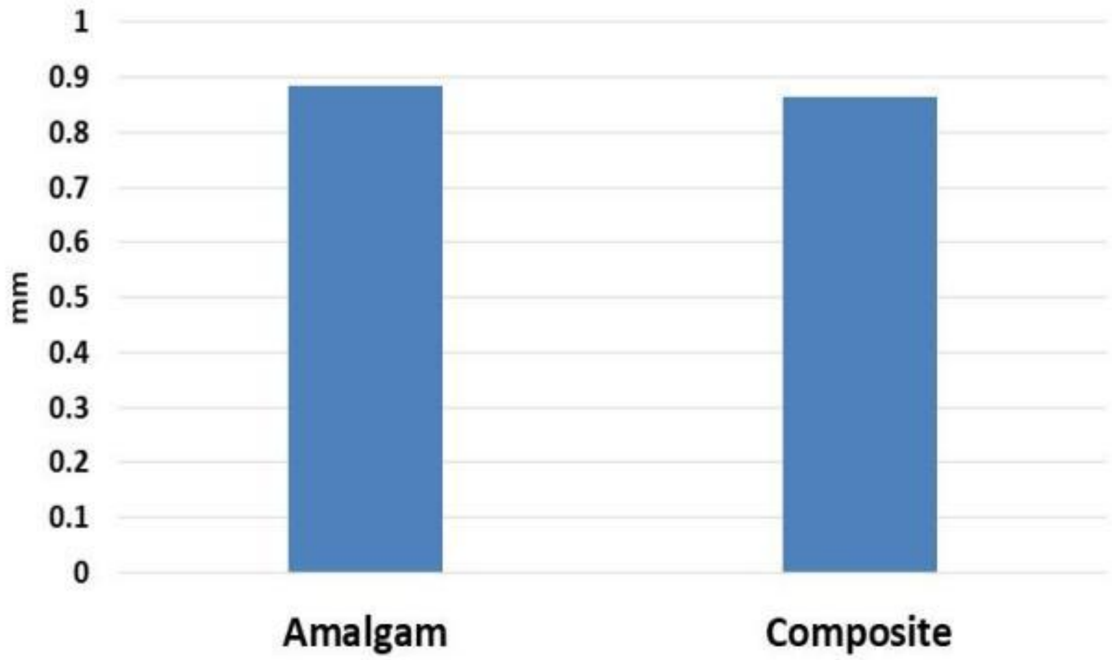


Figure (4): Mean wear depth (mm) in amalgam and composite group

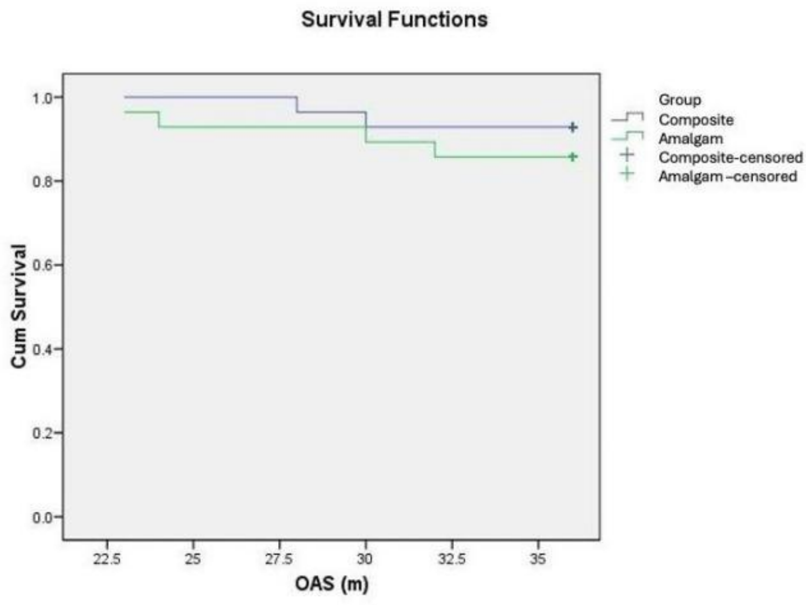


Figure (5): Kaplan -Meier analysis of survival time

Table (1): Comparison of maximum wear depth between amalgam and composite materials.(mm)

Material	Median Min.-Max.	Mean ± SD 95% CI
Amalgam (n = 28)	0.890	0.885 ± 0.056
	0.8 - 1.0	0.864 - 0.907
Composite (n = 28)	0.665	0.674 ± 0.043
	0.6 - 0.8	0.658 - 0.691
p value	< 0.001	

Table (2): Kaplan -Meier analysis of the survival time

Case Processing Summary

Group	Total N	N of Events	Censored N	Censored Percent
Composite	28	2	26	92.9%
Amalgam	28	4	24	85.7%
Overall	56	6	50	89.3%

Means and Medians for Survival Time

Group	Mean(a) Estimate	Mean(a) Std. Error	Mean(a) 95% Confidence Interval Lower Bound	Mean(a) 95% Confidence Interval Upper Bound	Median Estimate	Median Std. Error	Median 95% Confidence Interval Lower Bound	Median 95% Confidence Interval Upper Bound
Composite	35.500	0.344	34.825	36.175	.	.	.	.
Amalgam	34.750	0.640	33.495	36.005	.	.	.	.
Overall	35.125	0.367	34.406	35.844	.	.	.	.

a. Estimation is limited to the largest survival time if it is censored.

Overall Comparisons

	Chi-Square	df	p value
Log Rank (Mantel-Cox)	0.749	1	0.387

Test of equality of survival distributions for the different levels of Group.

Discussion

Studies proved that tooth tissue supported overdenture is a smart treatment modality, particularly with patients having few remaining teeth in the arch ***(Al-Jallad 2020).*** Patients must keep regular recall appointments for maintenance, practice daily hygiene, and apply topical fluoride gel daily. Overdenture patients require regular recalls because they have ongoing maintenance follow ups that necessitate evaluation and long denture serviceability. Numerous studies have shown that if patients are part of a frequent recall system and given sufficient maintenance instructions, such abutment teeth can be kept for a long amount of time. However, few studies have documented overdenture-related issues, but even fewer have reported longitudinal data.

Three materials were suggested to deal with sealing the orifice of endo treated teeth, which are glass ionomer, amalgam, and resin composite. But no definite guideline is crystally clear reviewed as the ultimate material to implement with sealing endodontically treated orifice together with tooth tissue supported overdenture. There has been a paradigm shift recently towards materials that closely resemble natural teeth in both function and esthetics due to the emergence of biomimetic approach **(*Rao et al. 2022).*** In contrast to amalgam restoration, resin composite encourages conservative cavity preparation, hence lowering the risk of creating cracks or fracture related to the restored tooth ***(Duncalf and Wilson 2001).***

It must be noted that mechanical resistance and retention forms inside the tooth structure must be included in the design of amalgam cavities. The primary goal is to correctly seal the opening of the endodontically treated tooth. Consequently, this is not immediately accomplished with newly amalgam filled tooth due to the variations in the thermal expansion coefficients of the amalgam and tooth structure, dimensional changes during setting. Accordingly, the issue of microleakage jeopardizes the amalgam in terms of restoration's durability ***(Ben-Amar 1989).*** Another issue is that patients frequently do not notice restorative leakage in endodontically treated abutment teeth, which can hasten tooth decay and affect the apical periodontal health after root canal therapy. Coronal seal is crucial to the success of the tooth tissue supported overdenture. Unfortunately, failure to obtain ultimate coronal seal may result in tooth loss and extraction ***(Shetty 2015).*** Hyflex EDM files were used in this study to preserve the integrity of the teeth as much as possible and to preserve the pericervical dentin in an attempt to obtain ultimate coronal seal ***(Shyma et al 2023).***

Recent advances in nanotechnology have led to a gross leap in the resin matrix's characteristics as a result of the employment of nanoparticles. Mechanical, physical, and optical qualities were improved using nanoparticles. The compressive strength of resin composite was increased by nanoparticles (ZrO2, TiO2, and SiO2), which in turn made it possible to restore posterior teeth with resin composite ***(Azmy et al. 2022).*** Thanks to nanoparticles, resin material has owned greater strength, wear resistance, flexural strength, and surface hardness, low abrasion resistance, biocompatibility and desired optical properties. Resin composite is bonded to enamel and dentin surfaces of teeth through micromechanical retention, which aids a biomimetic method for creating conservative cavities, which is bonded to tooth structure ***(Antony et al 2008)***. Moreover, nanofillers have enhanced the resin composite's mechanical qualities in terms of polymerization shrinkage, resulting in minimal or no leakage along the interfaces of tooth and restoration. Resin composite restoration repair is significantly more feasible than amalgam restoration repair. Beside that resin composite, depending on the degree of defectiveness, may not require complete removal of the old composite restoration ***(Popoff et al 2011).***

Wear is the result of a dynamic process that primarily affects the occlusal and proximal surfaces of restorations and can be influenced by factors such as individual occlusion, bruxism, personal habits, and various nutritional, chemical, and mechanical related challenges. Assessment of wear through clinical observation alone is difficult; therefore, objective monitoring techniques are needed. These methods allow for direct comparison of follow-up data with baseline data, for example through the use of 3D scanning ***(Carvalho et al. 2015).*** Therefore, to obtain accurate quantitative wear data, it was recommended to consider intraoral 3D scanning or impression-post-duplicate scanning as the preferred method ***(Ning et al. 2021; O'Toole et al. 2020; F Esquivel-Upshaw et al 2020).***

The present study reported no significant difference in wear between amalgam and nanohybrid composite which is in agreement with **Lazaridou et al. (2014) and Yılmaz and Sadeler (2018).** Wear is not directly related to the material's hardness alone as wear is a multifactorial process where several factors can have an effect. Friction force and oral environment are among the factors that can affect wear resistance. The change in surface characteristics that can happen due to loss of material components as fillers can affect the materials' wear resistance ***(Yılmaz and Sadeler 2018; Zafar 2019; Maier et al. 2022).***

Kaplan–Meier curve was used as it is commonly applied to demonstrate the success or survival probability over time ***(Matthews and Farewell 2017).*** According to the results of the present study, a statistically significant difference in the survival rate of restorations was revealed between filling materials with composite showing better results. In the FDI criteria for evaluation of direct restorations, a score of 5 is clinically unacceptable and requires replacement due to inaccessible deep staining at the margins. This is common to occur in Amalgam restorations especially those with wide and deep ditching which is a predisposing factor for recurrent caries ***(Kidd et al 1995).*** The black corrosive products of Amalgam have been found to be correlated with dentin demineralization which is considered the first step of secondary caries ***(Scholtanus et al 2013).*** While the higher survival rates of nanohybrid composites can be attributed to their higher wear resistance and less polymerization shrinkage which decreases the chance of microleakage and subsequent recurrent caries ***(van Dijken and Pallesen 2013).*** The ability of nanohybrid composite to maintain high polishability in addition to proper polishing procedures decrease biofilm formation on the surface of restorations and subsequent recurrent caries ***(Motevasselian et al 2017).*** This is in contrary to a 4-year clinical study, which suggested that there were no statistical differences between the performance and survival rate of amalgam versus resin composite ***(Keltjens et al 1999).*** More RCTs are recommended with larger sample size and longer follow up period to establish an evidence-based recommendation.

Conclusion:

1)This RCT represents a stepping-stone and proof of concept that supports the routine clinical use of nanohybrid composite together with tooth tissue supported overdenture treatment modality.

2)Further randomized clinical trials with an increased number of participants and longer follow up -period are still needed to evaluate the different clinical aspects of Nanohybrid composite as a filling material implemented within abutment tooth.

Conflict of Interest:

The authors declare no conflict of interest.

Funding:

The research study was self- funded by the authors.

Ethics:

The trial was approved by Ethics Committee of Delta University for Science and Technology, approval number FODMRC-202100102.

Data Availability:

Data will be available upon request.

Clinical trial registration:

The protocol for this study was registered on clinicaltrials.gov, under ID: NCT06580483

CRediT statement:

Dina Mohamed Elawady: Research idea, Data curation, Writing original draft - review & editing, Methodology, Conceptualization, resources and supervision.

Eyad Ahmed El-Batawi: Methodology and writing.

Ahmed Wagdy Hashem: Methodology and data curation.

Mona Tarek Balbaa: Methodology, Writing - original draft, Investigation, and Data curation.

Wafaa Ibrahim Ibrahim: Data curation, Writing - review & editing, Writing - original draft, Methodology, Conceptualization, Resources.

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