

MECHANICAL COMPLICATIONS AND PATIENT SATISFACTION IN FULL ARCH MONOLITHIC ZIRCONIA AND HYBRID CERAMICS ON TITANIUM BAR IMPLANT RESTORATIONS FOR THE REHABILITATION OF EDENTULOUS MANDIBLE: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Aim: To evaluate the difference of mechanical complications and patient satisfaction in monolithic zirconia and hybrid ceramics on titanium bar mandibular full arch implant restorations supported on 5 implants.

Materials and methods: Complete, mandibular, edentulous patients were treated with an implant-supported fixed restoration. Five implants for each patient were placed. After 3 months, patients randomly received monolithic zirconia or hybrid ceramic on titanium bar implant-supported restorations. Mechanical complications were monitored after restoration placement at 6 months and 12 months later and patient questionnaire was done at the same intervals using OHIP-14 questionnaire.

Results: This study was conducted on 20 completely edentulous patients that received 100 implants. Mechanical complications and patient OHIP were monitored six months and one year after implant loading. It was similar with no statistically significant difference.

Conclusions: Both techniques are considered as reliable methods for restoring of completely edentulous mandible, with preference to hybrid ceramics on titanium bar regarding mechanical complications.

KEYWORDS : full arch implant restoration, All on X, completely edentulous patients, monolithic zirconia, hybrid ceramics.

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INTRODUCTION

Once the dental implant was introduced for restoring missing teeth, restoring completely edentulous patients with implants became the gold standard treatment option. Full arch implant restoration can be fabricated using different restoration materials. Every material would be more favorable in a specific scenario. However, some decisions are still controversy and no solid evidence to support some situations¹.

Using monolithic zirconia have been widely used after the improvements occurred in the computer aided designing and computer aided manufacturing technologies and the digital workflows. It has several advantages including esthetics, strength, less chipping and adequately durable. However, its prone to some complications which is caused due to the main problem of zirconia which is being brittle. Also, its liability to develops cracks and fracture with overload easily².

These complications include screw loosening either for abutment or suprastructure, implant fracture, zirconia chipping. Most probably these complications can be controlled or avoided by achieving passivity. Although there is no specific definition for passivity, however the most suitable one is defined as the clinical passive fit level that does not produce any long-term complications³.

Recently hybrid ceramics were introduced to the market and research was done to examine its mechanical properties, esthetics and biocompatibility⁴. Still to the author's knowledge not enough research was done to confirm its long term durability especially in full arch restorations. However, it was suggested that it can overcome some of the zirconia drawbacks⁵.

As much research is concerned with evaluating the long-term success of implants and restorations. A lot of factors play a part in the success of this therapy, but the most important reference to the

success is avoiding different complications by following protocols confirmed in the literature. Complications that may occur in the restorations can either be biological or mechanical complications. These complications have several causes including occlusal overload, implant design, connection, framework passivity and restoration material⁶.

Technical or mechanical complications were classified by Pjetursson et al into 3 categories; minor, medium and major. The minor complications are screw looseing, loss of screw hole sealing. The medium ones are abutment fracture and framework fracture. The major complications are implant fracture and loss of suprastructure⁷.

Oral health impact profile is a questionnaire for patient's satisfaction. It is a type of Oral Health-Related Quality of Life (OHRQOL). This questionnaire aims to evaluate how prosthetic treatment affected patient's life on daily basis. A modified form was introduced for edentulous patients and also a short form was introduced. The questionnaire is composed of 14 questions with multiple domains⁸.

These domains include: functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. Each domain measures a certain level of functionality regarding patients quality of life⁹.

The aim of the present randomized controlled trial is to evaluate whether a restoration of a titanium bar veneered with hybrid ceramic as a full arch implant restoration would provide better prognosis regarding mechanical complications or it would be similar to monolithic zirconia to rehabilitate a full arch implant restoration. The null hypothesis is that there is no difference between the two options. The null hypothesis has been tested against the hypothesis of difference. The present manuscript is written according to the CONSORT guidelines.

MATERIALS AND METHODS

The present study was designed as a randomized controlled trial. Patients were recruited and treated at the Faculty of Dentistry, Cairo University, between April 7th 2023 and March 30th 2024. The study was conducted in accordance with Helsinki Declaration guidelines and all participants provided written informed consent prior to be enrolled. The study was approved by the Ethics Committee of Scientific Research, Faculty of Dentistry, Cairo University in April 2024 (Protocol number 1, April 2023). Sample size was calculated based upon the results of De Bruyn H et al (2008). Using alpha (α) level of (5%), β level of 0.8 (Power = 80%); the effect size for independent samples t-test (d) was 0.736 and the minimum estimated sample size was 50 implants per group. Sample size calculation was performed using PS Power and Sample Size Calculations Version 3¹⁰.

20 Patients presenting with a completely edentulous mandible requiring an implant-supported restoration, aged 40 years or older, was considered eligible for this study. Implant sites must allow the placement of five implants. In case of post-extractive sites, they must have been healed for at least 3-month before being treated in the study. Patients were excluded if they presented at least one of the following condition: poor oral hygiene and motivation; heavy smokers (up to 10 cigarettes/day); systemic condition that may interfere with implant placement (e.g., immunosuppressed or immunocompromised patients, patients under treatment of intravenous amino-bisphosphonates); patients with signs of hyperactive muscles; pregnancy or nursing; drug abusers; psychiatric problems or unrealistic expectations; patients with infection and or inflammation in the area intended for implant placement; patients participating in

other studies, if the present protocol cannot be properly adhered to.

A thorough preoperative assessment of all the enrolled patients was carried out including medical history taking, clinical and radiographic examination to confirm that they met the eligibility criteria.

Before planning the implants, all the patients undergo a cone beam computer tomography (CBCT) scan. The DICOM files were then analyzed using Blue Sky Plan software*.

On the day of surgery, local anesthesia using articaine with epinephrine 1:100000 (Septocaine, Septodont, Canada) was administrated prior to the surgical procedure. Crestal incision and flap reflection was done.

Bone was flattened in cases of knife edge crest, by using a barrel shaped bur supplied in the implant kit, to enhance bone morphology and increase the bone plateau for easier implant drilling and placement. According to the study protocol each patient received five implants widely distributed in teeth positions. First the point drill was used to locate implant position. Then, sequential drilling was done at the planned implant sites according to the manufacture's instruction. The implants were placed parallel to each other as much as possible and this was confirmed by the paralleling pins (Dual implants)**. Anterior implants were 12 mm in length, with a diameter of 3.5 mm, and posterior implants were 10 mm length, with the same diameter. Implants were placed with an insertion torque ranging between 35 and 45 N/cm.

The cover screws were placed and tightened onto the implants, according to the manufacturer's instruction. Flap closure was done by a continuous suture using a 4-0 polypropylene (Polypropylene 4-0 monofilaments sutures, Assut)***.

* BlueSkyBio, Version, Grayslake, Illinois

** 815 industrial zone , Third settlement , New Cairo – Egypt.

*** Assut Medical Sarl, Switzerland

3 months later after implant healing, it was the time to start the second stage part. Before implant exposure, the patients were randomly allocated to one of the following groups: either monolithic zirconia restoration (group 1) or hybrid ceramics on titanium bar (group 2).

Randomization was done using computer generated randomization. The patient picks up a number this number indicates a certain treatment option that was previously listed.

Exposure was done and 5 multi-units were screwed in place. The collar height of the multi-unit was chosen according to the soft tissue height available (Fig. 1). Regarding the multi-unit angle, it was also decided according to the implant

angulation if there is any discrepancy regarding the implant parallelism.

2 weeks later after soft tissue healing (Fig. 2), digital intra oral scan was done using Aoralscan 3 shining 3D*. Screwing 5 scan bodies to the implant followed by scanning the mandibular arch then the maxillary arch and recording the jaw relation (Fig. 3).

At this step a decision which workflow would be followed is done according to the randomization by picking a number that indicates a specific group. Then the restoration was designed using exocad** software (Fig. 4).

In group 1, a milled copper verification jig is screwed to ensure passivity (Fig. 5) and try-in for



Fig. (1) Exposure and placement of MUA



Fig. (2) Soft tissue healing

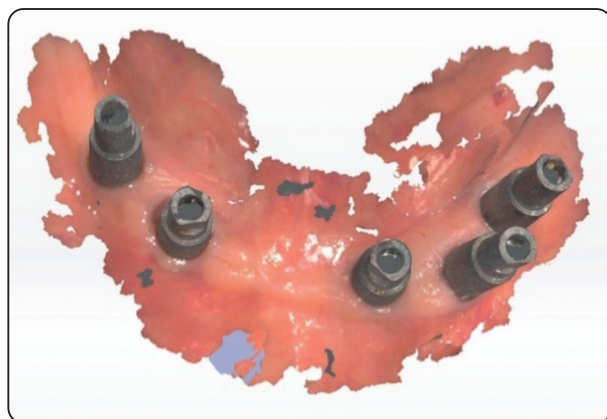


Fig. (3) Scan on 3D shining software

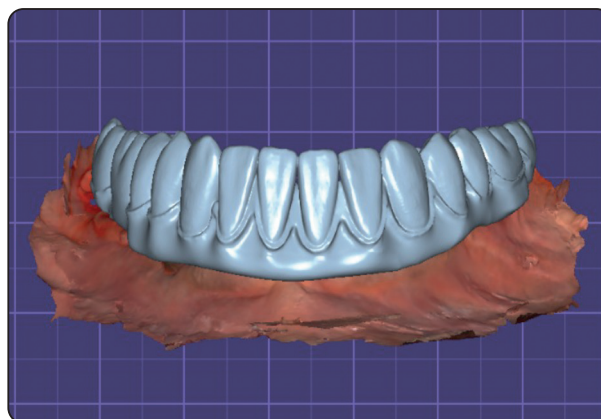


Fig. (4) Design of restoration on exocad software

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teeth was done using PMMA restoration (Fig. 6). It was used to confirm seating, esthetics, occlusion and soft tissue surface configuration. Then after that the final restoration was milled to be a monolithic full arch zirconia restoration (Katana YML)* (Fig 7). In group 2, after designing the bar it was milled in copper then a try-in was done with PMMA restoration over the bar to ensure the design.

After confirming both passivity and design, the final restoration was fabricated either a full milled monolithic zirconia restoration or the titanium bar with the printed using anycubic 3D printer** (Fig. 8) hybrid resin ceramics (Flexera)*** on it (Fig 9).

The titanium bar was cemented in the hybrid ceramics using a printed model (Fig 10). After that, the both restorations were screwed in placed using prosthetic screws (Fig 11). The tightening torque would be 25 N/cm with no resistance. One screw test was used to confirm passivity and radiographs were taken. Monolithic zirconia full arch restoration (Fig 12) was screwed in place following the same pattern (Fig 13).

The outcome measures were mechanical and technical complications that occurred during the follow-up period. Any of the following complications

were recorded at 6 months and 12 months follow-up. Losing of screw hole sealing material, prosthetic screw loosening, zirconia chipping, abutment screw loosening, screw fracture, implant fracture. The complications were listed from the less risky to the major ones. Also, the patients answered the OHIP-14 questionnaire after 6 months and 12 months (Fig 14).

OHIP-14 questionnaire was answered by 1 of the 5 following answers; never which is scored with a (1), hardly ever scored as (2), occasionally as (3), fairly often (4) and very often is scored as (5). The less the score the higher the satisfaction¹¹.

Categorical data are presented as frequency and percentage values and were analyzed using Fisher's exact test. Numerical data were presented as mean, standard deviation, median, and interquartile range (IQR) values. They were explored for normality by viewing the distribution and using the Shapiro-Wilk test. Age data were normally distributed and analyzed using an independent t-test. However, the satisfaction score data were non-parametric and analyzed using the Mann-Whitney U test. The significance level was set at $p < 0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.5.0 for Windows.^{****}



Fig. (5) Verification using milled copper bar in place



Fig. (6) PMMA for teeth try-in

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**** R Core Team (2025). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL <https://www.R-project.org/>.



Fig. (7) Katana Zirconia Block

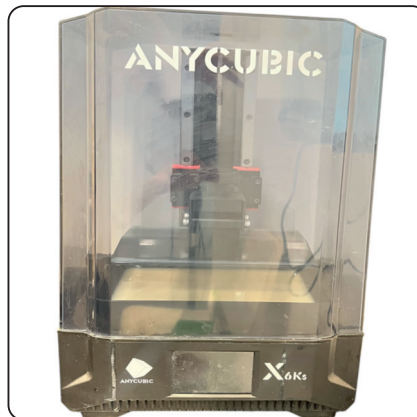


Fig. (8) 3D printer



Fig. (9) Flexcera resin



Fig. (10) hybrid ceramics on milled titanium bar extraorally



Fig. (11): hybrid ceramics on milled titanium bar in place



Fig. (12): monolithic zirconia full arch restoration extra orally



Fig. (13) Monolithic zirconia full arch restoration in place

RESULTS

A total of 30 patients were screened for eligibility. Of these, 20 patients with a total of 100 implants (5 implants for each patient) were included and randomly allocated to tested groups (i.e., 10 cases each). 10 patients were excluded (4 for not meeting the inclusion criteria, 6 refused to get enrolled). There were 6 males and 4 females in the monolithic zirconia group with a mean age of (53.20 ± 8.51) years. In the hybrid ceramic group, there were 7 males and 3 females with a mean age of (54.50 ± 6.11) years. There was no significant difference between both groups regarding gender ($p=1$) and age ($p=0.699$). All patients completed the follow-up period, with no drop-out. No implants and no prosthesis failed.

After 6 months, all cases in both groups were free of complications. After 12 months, a single case in the monolithic zirconia group had a cantilever fracture, while another case in the hybrid ceramic group had a chipped veneer material (Table 1), and the difference was not statistically significant ($p=1$). Within both groups, there was no significant difference in the incidence of complications in both intervals ($p=1$) (Fig 15).

Regarding the OHIP-14 questionnaire, The majority of cases in both groups answered “Never” to the different quality of life questionnaire questions (Table 2). Also, there was no significant difference between satisfaction scores measured in both groups after 12 months of follow-up ($p=0.845$) (Fig 16).

1. Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?
2. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?
3. Have you had painful aching in your mouth?
4. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?
5. Have you been self conscious because of your teeth, mouth or dentures?
6. Have you felt tense because of problems with your teeth, mouth or dentures?
7. Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?
8. Have you had to interrupt meals because of problems with your teeth, mouth or dentures?
9. Have you found it difficult to relax because of problems with your teeth, mouth or dentures?
10. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?
11. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?
12. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?
13. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?
14. Have you been totally unable to function because of problems with your teeth, mouth or dentures?

Fig. (14) List of questions of OHIP-14 questionnaire.

TABLE (1) Compilations.

Time	Complications	n (%)		p-value
		Monolithic Zirconia	Hybrid ceramic	
6 months	No	10 (100%)	10 (100%)	NA
	Cantilever fracture	0 (0%)	0 (0%)	
	Chipping of veneering material	0 (0%)	0 (0%)	
12 months	No	9 (90%)	9 (90%)	1
	Cantilever fracture	1 (10%)	0 (0%)	
	Chipping of veneering material	0 (0%)	1 (10%)	
p-value		1	1	

NA Not Applicable

TABLE (2) Satisfaction score.

Measurement	Monolithic Zirconia	Hybrid ceramic	p-value
Mean±SD	15.50±1.78	15.70±1.89	0.845
Median (IQR)	15.00 (1.75)	15.00 (2.50)	

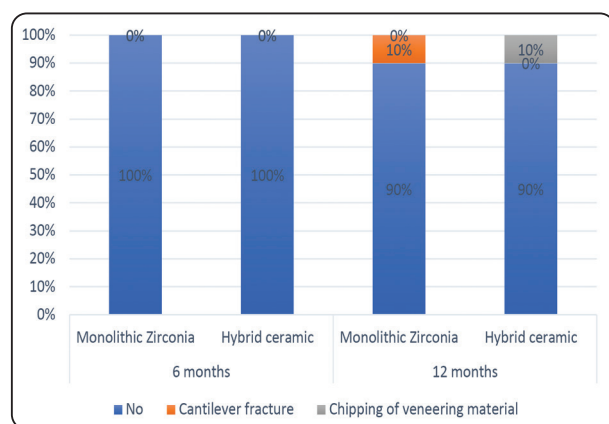


Fig. (15) Stacked bar chart showing complications' distribution.

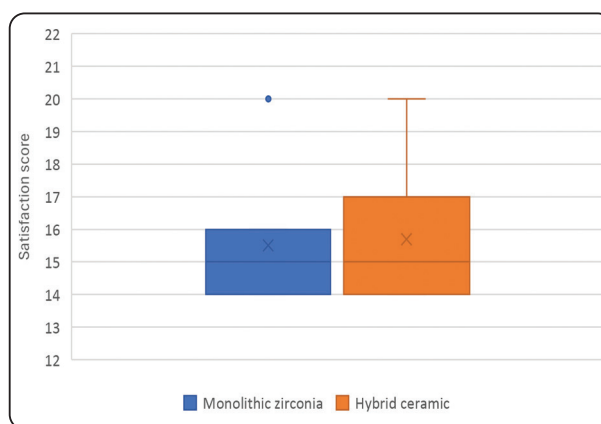


Fig. (16) Box plot for satisfaction score values.

DISCUSSION

The aim of this randomized control trial is to evaluate the results of using monolithic zirconia compared to the outcomes of those hybrid resin veneering material on titanium bar. Comparison was done for mechanical complications and patient satisfaction reported through the OHIP questionnaire for 20 patients and 100 implants. Comparison was done after 6 months of loading and 12 months. Monolithic zirconia is widely used restorative

material for restoring full arch implant restorations, they have been accepted by several authors^{12, 13, 14}. However, to the authors' knowledge using the hybrid resin for restoration is an innovative material that has no sufficient evidence in restoring full arch cases.

As no implant failures occurred, and no prosthesis failure occurred too. This indicates and attributes to the efficiency of both materials as a long-term final restoration in completely edentulous patients on

adequate number of implants. These results are in accordance with the systematic review published by vozzo et al 2023 regarding the performance of full arch monolithic zirconia. As long as both materials have matching outcomes, predictability of the hybrid resin can be assumed to be as zirconia¹⁵.

The positive and successful results of zirconia can be attributed to its several advantages and characteristics such as biocompatibility, good wear resistance, less bacterial colonization, high strength even in those of less strength to increase translucency¹⁶.

The success of hybrid ceramic resin can be attributed to its properties which are high levels of flexural strength, and high flexural resistance and good optical properties¹⁷.

On comparing mechanical complications of both groups along the year complications reported were scarce. However, the common complications occurred in hybrid ceramic resin was the wear and chipping of the material. This outcome is in accordance with the properties of the material and is an expected complication. As the strength of the material is way less than that of zirconia. However, it is within the acceptable range and the outcome of such restorations is convenient to the patients.

Another complication of hybrid ceramics is the discoloration that occurs compared to that of zirconia. It usually occurs due to different factors including water sorption, incomplete polymerization, external stains, surface roughness and oral hygiene. The better handling of the material the less discoloration occurs. This outcome is similar to these reported by other authors previously on comparing both materials; hybrid ceramics and zirconia¹⁸.

Regarding monolithic zirconia fracture is the common complication that occurred, and this is attributed to the material brittleness. These results are in accordance with Limmer et al who reported monolithic zirconia fracture in their study¹⁹.

For patient satisfaction and OHIP-14 questionnaire, it showed that both materials shown a little adverse effect on the patients' quality of life. Huge positive impact was detected in both groups with comparable results. The results were comparable to the zirconia results reported by Lim et al in 2017²⁰. These outcomes is predictable as converting a completely edentulous patient to a dentate patient using either materials will definitely enhance patient's quality of life and patient perception to different external factors.

CONCLUSION

Within the limitation of the present study, it could be concluded that full arch fixed restoration to rehabilitate a complete edentulous mandible fabricated of hybrid ceramics over titanium bar, can be a favorable and provide fewer mechanical complications over monolithic full arch zirconia restorations. However, it is crucial to confirm restoration passivity as its mandatory over any other factor. Nevertheless, due to the short follow-up period, this data should be carefully interpreted. Longer follow-up is needed to confirm these preliminary results.

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