



Patient Satisfaction and Debonding of Monolithic Translucent Zirconia Crowns Using two Compositions of Self-Adhesive Resin Cements (Randomized Clinical Trial)

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KEYWORDS

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ABSTRACT:

objectives: The aim of the present study was to evaluate the effect of TheraCem (MDP containing, ca and fluoride releasing) self-adhesive resin cement and Multilink (non MDP containing) self-adhesive resin cement on the patient satisfaction and debonding of monolithic translucent zirconia crowns. Twenty single monolithic translucent zirconia crowns were constructed to restore premolar teeth using two types of Self-adhesive resin cements

Methods: First, Scaling and polishing were performed for all enrolled patients two weeks before the preparation. The patients were divided into two groups according to the type of the self-adhesive resin cement after randomization. Group1: Multilink (non MDP containing cement) and Group 2: TheraCem (MDP-containing, Ca and fluoride releasing cement). The teeth were prepared to receive single monolithic zirconia crown. Then, the try-in crowns were fabricated from resin (YAMAHACHI PMMA) and the final crowns were constructed from super translucent multilayered monolithic zirconia (STML Katana, Kuraray) using CAD/CAM technology in which (DWX-50) machine was used for milling and (exoCad) software for designing. The restoration surfaces were treated using sandblasting and the cementation was using the cement selected for each group. Debonding and patient satisfaction were assessed at base line using the modified United States Public Health Service for restoration clinical assessments and repeated at three, six, and twelve months respectively.

Results No statistical significant difference in the debonding of zirconia crowns was found in both groups. Finally there was significant decrease in patient satisfaction with multilink cement by time.

Conclusion: Patient satisfaction was improved by time using TheraCem self-adhesive resin cement. Besides, both TheraCem and Multilink resin cements produced comparable results in terms of debonding of the restorations

1. Introduction

Current ceramic materials can produce esthetically pleasing restorations that accurately reproduce tooth color. The newer ceramic materials as zirconia, have improved strength and physical properties that can be equal and even surpass metal alloys. Therefore, their use has increased measurably and have been used extensively for both anterior and posterior tooth

restorations because of their long term color stability and wear resistance.^{1,2}

Translucent veneering porcelains are typically applied to zirconia core materials to enhance esthetics. However, layered zirconia restorations have a higher risk of failure, often due to fractures starting at weak points, such as the veneer or the core/veneer interface.³ Monolithic zirconia is one of the newly developed



materials. It is basically core zirconia without the veneering porcelain. 3

The generations of zirconia have been introduced to the market and classified according to their yttria content (mol. %) which largely defines its mechanical and optical properties. The first generation (3 mol. % yttria) of monolithic zirconia is characterized by its high flexural strength (1000 - 1500 MPa), biocompatibility, good integrity to soft tissues, high sintering temperature (1600 °C) and must be veneered by feldspathic ceramic to enhance the aesthetics.^{4,5} The second-generation zirconia was developed to enhance the translucency of the first generation without compromising its mechanical properties by reducing the alumina content and eliminating porosity. In 2015, the third generation was introduced to further reduce opacity and achieve better aesthetics, it includes up to 53% cubic phase zirconia. When the cubic phase is less than 50%, it's called partially stabilized zirconia (PSZ); when it's more than 50%, it's known as fully stabilized zirconia (FSZ). Cubic crystals are larger than tetragonal ones, which reduces light scattering at crystal boundaries and porosities, making the material more translucent but also significantly lowering its flexural strength (400 - 1000 MPa).⁴

Super translucent multi-layered zirconia is a high-translucency multilayer zirconia could be precolored, and has gradient shade with incisal layer least stained 6 . Unfortunately, unlike glass ceramics, zirconia cannot be etched, making it impossible to perform traditional adhesive procedures. Proper bonding between the zirconia restoration and the tooth is crucial for the longevity of the prosthetic restoration. Resin bonding not only ensures the adhesion of indirect ceramic restorations to teeth but also enhances their flexural strength.⁷

The rationale for the selection of the luting material is essential to give the restoration reliable strength, optimal esthetic, providing retention at both interfaces to withstand occlusal chewing forces, and marginal sealing to prevent secondary caries. 8 Besides, the adhesive bond can furthermore stabilize brittle ceramic restorations, resulting in a greater resistance to external forces. 9,10

Self-adhesive became the most widely used adhesives, as they offer the mechanical, esthetic, and adhesive

advantages of typical resin cements. 11,12 The type of acidic monomer used in the adhesive cement is crucial for creating a stable chemical bond for both enamel and dentin structure. Adhesives containing methacryloxydecyl dihydrogen phosphate (MDP) are particularly effective in forming a stable bond. MDP bonds with hydroxyapatite, creating an intermediate layer where two MDP molecules align with their methacrylate groups facing each other and their phosphate groups facing outward. Calcium salts are then deposited between the layers of these phosphate groups.¹²

TheraCem, as newly introduced calcium silicate cement, showed an ability to form crystalline calcium hydroxide, which may improve the mechanical bond between these cements and dentin. It has the ability to release fluoride and calcium ions, contributing to the remineralization of the tooth mineral structures.¹³ Null hypothesis that there is no difference in the patient satisfaction and debonding of translucent zirconia crowns cemented either with TheraCem or Multilink self-adhesive cements.

2. Material and methods

Super Translucent Multi-Layered (STML) (Kuraray Noritake Dental Inc. Japan) that had translucency similar to natural tooth enamel was used for the fabrications of single crowns restoring the premolars. Multilink Speed cement (Ivoclar Vivadent Inc. Schaan, Liechtenstein) was used to meet the demand among dentists for luting materials that offer easy, quick, universal application and doesn't require conditioning or bonding agents for the dental hard tissues. TheraCem (Bisco, Inc. Schaumburg, Chicago, USA) is a dual cured self-adhesive, (MDP-containing, Ca and fluoride releasing) resin luting cement was used as intervention. The PICO elements were detected as the following:

PICOS:

P: Patients requiring single zirconia crowns

I: TheraCem self-adhesive resin cement (MDP, calcium and fluoride releasing cement)

C: Multilink adhesive resin cements (non MDP, non-calcium and fluoride releasing cement)

Os: Primary outcome: patient satisfaction - Secondary outcome: debonding and USPHS for 12 months



Sample size calculation: A power analysis was designed to have adequate power to apply a statistical test of the null hypothesis. By adopting an alpha (α) level of 0.05 (5%), a beta (β) level of 0.20 (20%) i.e. power=80%, and effect sizes of (1.076) and (1.204) that were calculated based on the results of Konstantinidis, Ioannis, et al. and on expert's opinion respectively; the predicted sample size (n) was a total of (16) cases (8) cases per group. Sample size was increased by (25%) to compensate for possible drop-outs during follow-up periods to be (20) cases i.e. (10) cases per group. Sample size calculation was performed using G Power version 3.1.9.4.14

Research ethics approval the present study and the template of the informed consent form was reviewed by the Ethics Committee of Scientific Research - Faculty of oral and dental medicine – Cairo University and approved in September 2020.

The complete study design (RCT) and protocol were previously published in details and was registered in ClinicalTrials.gov (Identifier NCT04875468). The patients were selected by the main researcher from among those who attended the dental clinic in Faculty of dentistry Cairo University) from January 2019 to 2022, who required at least one total coverage restoration in the posterior maxillary or mandibular regions according to Inclusion criteria: From 18-50 years old, be able to read and sign the informed consent document, have no active periodontal or pulpal diseases, have teeth with good restorations, psychologically and physically able to withstand conventional dental procedures and patients with teeth problems indicated for single crowns; badly decayed teeth, teeth restored with large filling restorations, endodontically treated teeth, malformed teeth, malposed teeth (tilted, over-erupted, rotated, etc.) and spacing between teeth while exclusion criteria included ; patient less than 18 or more than 50 years, patient with active resistant periodontal disease , patients with poor oral hygiene and uncooperative patients and pregnant women. The patients who were enrolled in the present study signed an informed consent of the detailed treatment plan.

Randomization; the randomization unit was the cement used per tooth restoration. A sequence number from 1 to 20 was created, and intervention was assigned

randomly to each number through the randomization function in randomization.com website. The allocation sequence was kept with the contributor (ANOVA research solutions) concealed from the primary investigator. In our clinical trial, more than one group was blinded as trial participants and outcome examiners. Two examiners had been responsible for the assessment of clinical outcomes, any conflict in assessment between the two examiners, was solved by the main investigators.

Diagnosis: an extraoral and intraoral examination was conducted for accurate diagnosis, followed by a preoperative radiographic analysis using periapical x-rays to assess endodontic treatment, periapical pathology, and root conditions. Initially, a full mouth scaling and polishing were performed to remove all calculus deposits from the teeth. Primary impressions were taken using irreversible hydrocolloid impression material and poured with type IV stone and mounted on an articulator to produce diagnostic casts. The tooth shade was visually recorded using the VITA 3D master shade guide under natural daylight. Vital Teeth received a composite build up if needed, while non-vital teeth were restored using either a direct composite build up or a prefabricated titanium or fiberglass root post.

Tooth preparation phase: One investigator prepared all the teeth to receive single crowns according to specific design criteria. A putty index was first constructed. The teeth were prepared following guidelines, with preparation margins created as 0.5 mm an equi-gingival circumferential chamfer finish line and extended subgingivally if needed as in pre-existing conditions like caries, restorations, or previous preparation margins dictated. The amount of occlusal reduction was 1.0-1.5 mm and the axial taper was a 6-8 degree without any sharp angles. The remaining prepared tooth height had to be at least 4 mm. **Fig. (1)** After completing the preparation, gingival retraction was achieved using a retraction cord **Fig. (2)** And a final impression was made using normal set addition silicone impression material (Panasil Putty, panasil initial contact light) with a perforated stock tray, employing a double mix two step impression technique.



Figure (1): Preparation (lateral view)

The Inter-occlusal records were obtained using Zhermack Occlusfast Rock and temporary crowns were made from Charm Temp (Ludwigshafen, Germany) to protect the tooth preparation and dental pulp and were secured with non-eugenol temporary cement (Any Temp NE, Kerr Corporation, Korea). The final impressions were then poured using type IV stone with vacuum mixing. The resulting casts were mounted on an articulator using the interocclusal record (Polyvinyl siloxane bite registration material) crown fabrication: First, the dental casts were scanned to create an STL file for analyzing the preparation and designing the restoration using ExoCad software. **Fig (3)** the milling process was carried out with a Roland VHF milling machine and SumD3 software. A try in resin crown was first made using PMMA, which was then tried intraorally to check for proper seating, marginal integrity, stability, and occlusion The final crowns were



Figure (2): Occlusal view preparation

made from monolithic zirconia (MZCs) using partially sintered, super translucent, multilayered zirconia blanks (KATANA Zirconia STML; Kuraray Noritake, Miyoshi, Japan). All restorations were sintered at 1,550°C for 2 hours in a furnace (Programat CS4; Ivoclar Vivadent). The crowns were received from the laboratory with a polished surface, and the Vita Akzent Plus staining kit was used to stain the crowns. This was done in a ceramic furnace (Programat CS32) at 850°C during the firing cycle. The sintered restorations were glazed with Cerabien ZR (Kuraray Noritake) at 750°C. All the steps from the try-in stage were repeated for the final restorations, including checking the seating, marginal integrity, retention, stability, and occlusion. Radiographic evaluation was performed using peri-apical radiographs to ensure the marginal fit of the final restorations.



Figure (3): A) Scanning upper arch



B) Scanning upper arch



Cementation of crowns: after the crowns were checked, they were rinsed with water and dried with air. The bonded areas were covered with a layer of ZirClean (Bisco, Inc. Schaumburg, Chicago, USA) for 20 seconds the rinsed with water. The fitting surfaces of the single crowns were sandblasted with Al₂O₃ particles (50µm, 2.8 bar, 1 cm) Augusti et al (2014) then washed with water spray for 60 seconds and ultrasonically cleaned with 95% ethyl alcohol for 10 minutes. According to the randomization protocol, crowns were cemented using either TheraCem cement or Multilink Speed resin cement. The cement was applied to the fitting surfaces of the restorations, which were then seated, then cured for 2-3 seconds and any excess cement was removed. The final curing was 20 seconds for each surface. Two evaluators independently assessed the crowns for patient satisfaction and debonding using the MUSPH criteria. They used a

mirror and a sharp explorer to evaluate the crown during recall appointments at three, six and twelve months. Fig (4) Statistical Analysis: qualitative data were reported as frequencies and percentages. To compare the two groups, Chi-square and Fisher's Exact tests were used. Changes over time within each group were analyzed using Friedman's test. Patient satisfaction scores, which are non-parametric data, were presented as median, range, mean, and standard deviation (SD). The Mann-Whitney U test was employed to compare the two groups, and Friedman's test was used to assess changes over time within each group. When Friedman's test indicated significant results, Dunn's test was used for pair-wise comparisons. The significance level was set at $P \leq 0.05$, and statistical analysis was conducted using IBM SPSS Statistics for Windows, Version 23.0 (Armonk, NY: IBM Corp.).



Figure (4): Post-operative follow up of upper first premolar at a) 3 months, b) 6 months, c) 12 months

3. Results

a- Results of the patient satisfaction testing

The effect of cement type (TheraCem versus Multilink) on patient satisfaction with zirconia crowns at different time intervals showed that at base line, after three, six as well as twelve months, there was no statistically significant difference between the two groups at (P-value = 1, Effect size = 0), (P-value = 1, Effect size = 0), (P-value = 0.107, Effect size = 0.695) and (P-value = 0.052, Effect size = 0.998). The effect of time interval on the patient satisfaction with each cement type showed that in TheraCem group, there was no statistically significant change in patient satisfaction scores by time at (P-value = 0.468, Effect size = 0.106). In Multilink group, there was a statistically significant change in patient satisfaction scores by time at (P-value

= 0.016, Effect size = 0.433). Pair-wise comparisons between time periods revealed that there was no statistically significant change in patient satisfaction scores after three months. This was followed by a statistically significant decrease in patient satisfaction scores from three to six months. From six to twelve months, there was no statistically significant change in patient satisfaction scores as shown **table (I)**.

Table (I): Results of the effect of cement type (TheraCem versus Multilink) and time intervals on patient satisfaction with zirconia crowns.

Time	TheraCem (n = 8)		Multilink (n = 8)		P-value	Effect size (d)
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
Base line	10 (9, 10)	9.63 (0.52)	10 (9, 10) ^A	9.63 (0.52)	1	0



3 months	10 (9, 10)	9.88 (0.35)	10 (9,10) ^A	9.88 (0.35)	1	0
6months	10 (8, 10)	9.75 (0.71)	9 (6,10) ^B	8.75 (1.49)	0.107	0.695
12 months	10 (8, 10)	9.63 (0.74)	8.5 (8, 10) ^B	8.75 (0.89)	0.052	0.998
P-value	0.468		0.016*			
Effect size (w)	0.106		0.433			

b- Debonding Comparison between groups

At base line as well as after three months, none of the restorations in both groups had debonding, so no statistical comparisons were performed. After six months, no restorations (0%) in TheraCem group and three restorations (37.5%) in Multilink group showed debonding. There was no statistically significant difference between the two groups (P-value = 0.200, Effect size = 2.6). After twelve months, no restorations (0%) in TheraCem group and two restorations (25%) in Multilink group showed debonding. There was no statistically significant difference between the two groups (P-value = 0.467, Effect size = 2.333) Changes by time within each group; in TheraCem group, none of the restorations showed debonding through all follow up times, so no statistical comparison was performed. In Multilink group, there was no statistically significant change in debonding by time (P-value = 0.101, Effect size = 0.26) as seen in table (II).

4. Discussion

The use of monolithic zirconia restoration is highly advocated nowadays because of their superior esthetic and mechanical properties which increase their use in the clinical dentistry. Besides, multilayered super translucent zirconia was introduced to mimic the natural color of the teeth that allow gradient transition of color from the incisal area to the cervical which greatly enhance the esthetics. However, bonding of zirconia restorations to tooth structures is still challenging.

Table (II): Results of the effect of cement type (TheraCem versus Multilink) on the debonding of zirconia crowns (Frequencies (n) and percentages (%) at different time interval.

Debonding	TheraCem	Multilink	P-	Effect
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	(n = 8)		(n = 8)		value	size (OR)
	n	%	n	%		
Base line						
Debonding	0	0	0	0	Not computed	
No debonding	8	100	8	100		
3 months						
Debonding	0	0	0	0	Not computed	
No debonding	8	100	8	100		
6 months						
Debonding	0	0	3	37.5	0.200	2.6
No debonding	8	100	5	62.5		
12 months						
Debonding	0	0	2	25	0.467	2.333
No debonding	8	100	6	75		

The aim of the present study was to assess the patient satisfaction and debonding of fourth-generation monolithic translucent zirconia crowns over one year using two compositions of self-adhesive cement – MDP containing (TheraCem) and Non MDP containing.

A randomized clinical trial was selected for the present study as it is considered feasible and generally the strongest study design for evaluating an intervention’s effectiveness and eliminates bias by randomization. Any diseases with related psychiatric problems were excluded from the current study as these patients had “poor periodontal status with high treatment needs Shah, Patel, and Jain (2012). Pregnant female patients were excluded from the present study to avoid fetus deformities from x-rays exposure Pirih et al. (2021). Miura et al. (2018).

For all patients, full mouth scaling was performed to remove the biofilm, periodontal bacteria, toxins, calculus, and debris that improve the gingival and periodontal conditions which have direct effect on the outcomes of the present study as reported by Reynolds (2018). The Tooth preparation guidelines were 1 mm must be provided for interocclusal space to prevent prosthetic crown fracture and 0.5 mm round chamfer finish line as it resulted in the least marginal opening



and gives restoration a correct geometry that reduces occlusal stress.

For the final cementation, the restorations were cemented either by TheraCem (the intervention) or Multilink (comparison) according to the randomization. Both cements are self-adhesive resin cements as they allow chemical adhesion which is the most critical factor for bonding of zirconia. Besides, both cements are dual cured cements that allow a better degree of conversion for adequate polymerization providing optimal mechanical properties of the cement. Turp, Turkoglu, and Sen (2018)

The patient satisfaction was also evaluated using visual analogue scale (VAS) which is a type of psychometric response scale that is commonly used in surveys and questionnaires. Debonding was evaluated by the presence or absence of the restoration using the terms of (yes or no). The present study assessed the debonding which reflects aspects used for assessment of the success of the cement and cementation procedure in the term of the retention of restoration intra-orally and the bond strength. The clinical outcomes were evaluated at base line, three months; six months and twelve months as this increases the trial efficiency in evaluating the clinical outcomes of the restoration. Longer observation periods, are better for checking the functionality and esthetics of the restoration. Hickel et al. (2023)

Regarding the effect of the cement type on the patient satisfaction score, the results of the current study showed that at base line, after three, six as well as twelve months, there was no statistically significant difference between the two groups which could be attributed to the good clinical performance of the monolithic single crowns. As they are associated with enhanced patient satisfaction due to good esthetic, marginal color and no excessive periodontal inflammation, bleeding or other adverse effects such as gingival margin migration Mikeli, Walter, and Rau, n.d.(2022).This is in agreement with Mai et al. (2022) who evaluated the patient satisfaction of monolithic zirconia crowns cemented with self-adhesive resin cement with VAS scale and found successful clinical performance in terms of patient satisfaction of zirconia full coverage restorations. Tammam, Abuzinadah, and Alhaddad, n.d.(2021).

Regarding the effect of time interval on the patient satisfaction in TheraCem group, there was no statistically significant change in patient satisfaction scores by time this could be explained by good clinical outcomes of the TheraCem group in terms of marginal adaptation and gingival parameters. Regarding the effect of time interval on the patient satisfaction in Multilink group, there was a statistically significant change in patient satisfaction scores by time this could be explained by debonding of three and two restorations at six and twelve months respectively. Besides, the Multilink group showed statistically significant increase in the marginal discoloration by time, decrease in marginal adaptation and increase in the gingival index (GI).

Regarding the results of the effect of the cement type (TheraCem versus Multilink) on the debonding of the restorations there was no statistically significant difference between the two groups. This may indicate that both cements could be recommended to be used for zirconia crowns as no statistically difference was recorded. This may be because of the preparation principles used as 6-8 degree of tapering and a full converge retentive preparation so the effect of bonding is minimal as the retention is mainly mechanical as it depends on complete encircling of the tooth. Another explanation could be that both are self-adhesive cement with good bond strength. A self- adhesive system was developed to be used to eliminate the need for a separate priming and conditioning steps that simplify the treatment procedures, and prevent the collapse of the collagen fibers in the dentin through acid-etching. The use of sandblasting with Al_2O_3 , which increases irregularities as well as the roughness, surface energy, and wettability of the zirconia that improve adhesion. The curing parameters were precisely followed in the present study as time of the curing, distance, depth of curing together with a small thickness and translucency of the zirconia restoration used as recommended by manufacturer

The results of the present study are in agreement with Abd Alraheem et al. (2023) who studied the clinical outcomes of adhesively resin-bonded monolithic zirconia and the examiner used the (MUSPHS). The crowns were either glass ionomer cemented zirconia (GIC-Zr), resin-bonded zirconia (Adh-Zr). The



retention of all crowns was rated as alpha regardless the both types of cement.

Regarding The effect of the time interval on the debonding of the restoration in each group in TheraCem group, none of the restorations showed debonding through all follow up times, while in Multilink group there was debonding in three and two restorations at six and twelve months respectively with no statistically significant change in debonding. It could be clarified that there may be a prevalence to the TheraCem cement as there was a clinical significance difference as the debonding was 0 % in comparison to multilink 37% at six months this may be related to its MDP containing property. MDP-based cements showed higher and more stable adhesion to zirconia. MDP is a comparatively hydrophobic monomer because it has a 10-carbon chain. MDP has a bifunctional adhesive monomer that can bond to zirconia, metal, or silica.

The long term stability of the TheraCem bond strength could be because it contains hydrophobic long carbon chains that do not attract water and have superior hydrolytic stability after long-term-aging micro-tensile bond strength tests. Berkman et al. (2021). Some previous studies have clarified that the remineralization effect of TheraCem due to presence of Ca ions may explain its better SBS to caries affected dentin (CAD) as compared to other cements that also contain MDP. Ranjkesh et al. (2016) Meraji et al. (2018)

Debonding of three and two restorations at six and twelve months respectively in multilink group may be because Multilink has Flexural strength slightly lower due to its low filler contents, the water molecules that resulted from the chemical reaction and neutralization between resin cement and dental enamel that interfere with the polymerization of the cement and high viscosity which compromises infiltration of resin particles, leading to short resin tags formation and deficient chemo-mechanical interaction on dental enamel results in a less durable adhesive interface increasing the probability of adhesive failure Pisani-Proença et al. (2011)

The results in contrast with study by Jamel RS et al, showed TheraCem has decrease bond strength, he claimed that this was due to increase Biphenyl glycidyl methacrylate (Bis-GMA) which is a high-molecular-weight monomer that decreases the DC and (MDP)

functional group has negative effects on the polymerization reaction because it chemically interacts with the tertiary amine (co-initiator) and Camphorquinone. However, this could be overcome by increase the time of curing, use of more translucent zirconia and keep the thickness of the zirconia within minimal thickness recommended which was done in our study

The results were in contrast with study done by Mohamed Elsayd Shokry et al, who found that multilink show the highest bond strength. He justified that as Multilink Speed contains an adhesive monomer that consists of a long-chain methacrylate with a phosphoric acid group. However, the difference from our present study could be because Multilink Group in his study involve the use Monobond N that contains MDP molecule, that can create a very stable bond Shokry, Al-zordk, and Ghazy (2021)

5. Conclusions

1. Both TheraCem and Multilink self-adhesive cements showed comparable results regarding the debonding of the bonded monolithic zirconia crowns.
2. Patient satisfaction results were comparable with both tested cements. However Multilink showed a decrease in the patient satisfaction at 6 and 12 months' time intervals as compared to base line.
3. TheraCem and Multilink cements could be used for cementation of zirconia crowns with successful clinical outcomes at 12 months' time interval.

Data availability: Datasets related to this article will be available upon request to the corresponding author.

Conflict of interest

The authors have no potential conflicts of interest to declare.

Author Contributions

The author confirm that this article content has no conflicts of interest Authors' contributions

DM: Conceptualization; Data curation; Formal Analysis; Writing – review & editing.

GE: Supervision; Validation; Visualization; Writing – original draft.



AM: Investigation; Supervision; Writing – review & editing.

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