Original Article

Clinical Performance of Zirconia Reinforced versus Conventional Viscous Glass Ionomer in Class I Cavities of Geriatric Patients: A 1-year Randomized Controlled Clinical Trial

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Abstract

Background: For the elderly population, efforts are made to simplify the restorative procedure while maintaining good clinical performance. Glass ionomer (GI) cements are showing signs to fulfill many of these qualities. With their new properties and ease of use, they can be developed further to become a useful group of materials to overcome the problems of elderly patients. **Aim:** The aim of the study was to evaluate the clinical performance of zirconia-reinforced versus conventional viscous GI restorations in Class I cavities of geriatric patients. **Setting and Design:** The study design was *in vivo* randomized clinical trial, parallel-arms, allocation ratio: 1:1. **Subjects and Methods:** A total of 28 Class I carious lesions in 21 geriatric patients were restored randomly either by zirconomer-improved or Ketac Molar Quick Aplicap (n = 14) each. Restorations were evaluated for 1 year by modified USPHS criteria. **Statistical Analysis:** Data were analyzed with the Chi-square test and Cochran's Q-test. Survival rate was analyzed using the Kaplan–Meier and log-rank test. **Results:** Twenty-four restorations were evaluated in 19 patients with a recall rate of 85.7% at 12 months. Significant differences were found in marginal integrity and marginal discoloration within both restorative materials between different time intervals ($P < 0.05$). However, none of the materials were superior to another regarding all assessed criteria. **Conclusions:** Both zirconia-reinforced GI and conventional highly viscous GI have acceptable clinical performance.

Keywords: *Class I, clinical assessment, elderly, geriatric, glass ionomer, high-viscosity glass-ionomer cement, Ketac molar, occlusal caries, permanent teeth, USPHS criteria, zirconomer*

Introduction

Dental awareness in the elderly population has increased worldwide as a result of the increasing implementation of preventive dentistry together with higher life expectance.[1] For the elderly, many efforts are made to simplify the restorative procedure while maintaining good clinical performance.[2] Glass ionomers (GIs) are used in many dental practices, restoring both deciduous and permanent teeth, as GIs can form a chemical and micromechanical bond with tooth substances.[3]

However, it is frequently questionable to use the conventional GI restorative materials as a permanent restorative material due to their inferior mechanical properties and susceptibility to fractures more than other restorative materials available.[4] Modifications in GI restorations were established to achieve a good long-term performance with minimal restorative procedure.[5,6] The demand for a more durable material has elicited the development of a novel material that adds zirconia filler particles to the composition of GI restorative materials[7] to convey superior mechanical properties for the restoration in stress-bearing areas and enhance esthetic properties.[8]

In view of the advanced properties and ease of use of zirconomer-improved GI, it could be an increasingly useful group of materials to overcome the problems of dental management in such groups as elderly patients. Due to the lack of clinical trials testing the performance of zirconomer-improved GI in stress peering posterior areas in the geriatric population, it was found beneficial to evaluate the newly introduced material using a randomized controlled trial to test the null hypothesis that this new material will have the same clinical performance as the conventional viscous GI in such situation.

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Subjects and Methods

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the Research Ethics Committee (REC) of the Faculty of Dentistry, Cairo University, (Ref. 20/3/16), approval date (March 31, 2020), and with World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects (2013) (http://www.wma. net/en/30publications/10policies/b3/).

Protocol registration

The protocol was registered in (www.clinicaltrials.gov) database, with the unique identification number NCT04298151.

Informed consent

Informed Consent Model of REC Faculty of Dentistry, Cairo University was used in this study. All participants received detailed information regarding the study aim, procedures, safety, benefits, and the expected duration of participation. After which, the informed consent was given to be signed, before the initiation of the trial.

Sample size estimation

A power analysis was designed to have adequate power to apply statistical tests of the research hypothesis. The estimated probability of zirconia reinforced GI restoration for score A in terms of filling integrity was 0.65, probability of score B was 0.30, probability of score C 0.04, and score D was 0.01 with effect size w = 1.02 (n = 11). By adopting an alpha (α) level of 0.05 (5%), power = 80, the predicted sample size (n) was a total of 22. The sample size was increased by 20% to account for possible dropouts during follow-up intervals to be a total of 28 (14) for each group. Sample size calculation was performed using G*Power 3.1.9.2 using the Chi-square test.

Trial design

The trial design is a randomized, double-blind, two-parallel arms clinical trial with 1:1 allocation ratio. A total of 28 teeth in 21 patients with occlusal caries in the posterior teeth were randomly assigned into two groups (n = 14) each. The intervention group received zirconia-reinforced GI, while the control group received conventional viscous GI. The clinical performance of the restoration was evaluated immediately after placement, after 3, 6, 9, and 12 months using the modified USPHS criteria.

Recruitment

Participants were recruited from the outpatient clinic of the Conservative Dentistry Department, in Faculty of Dentistry, Cairo-University, to fulfill the eligibility criteria.

Eligibility criteria

Inclusion criteria were geriatric patients (1) age range 60-74 years, (2) males or females, (3) Co-operative patients approved to participate in the trial, (4) good likelihood of recall availability, (5) vital posterior teeth with no symptoms of pulp pathosis, (6) healthy periodontium, and (7) class I posterior carious lesions of ICDAS code 3 or 4.

Exclusion criteria were (1) lack of compliance, (2) extremely poor oral hygiene, (3) heavy smoking, (4) severe medically compromised patients, (5) teeth with irreversible pulpitis or pulp necrosis, (6) endodontically treated teeth, and (7) nonfunctioning teeth.

Randomization

Sequence generation

In accordance with the principles of randomized trials, simple randomization for teeth was performed by a third party using (www. randomization. com), to generate numbers from 1:28 that were randomly assigned to either intervention or comparator group.

Allocation

Allocation was done in the order of patients' presentation to the clinic, where eligible participants were examined for eligible teeth. In case, the patient has more than one-maximum two teeth eligible for the trial, the allocation was done according to the tooth position in the mouth in accordance with the FDI numbering system.

Allocation concealment

For each participant, a sequentially numbered opaque sealed envelope containing the treatment group code (A or B) generated previously was randomly assigned for every eligible tooth. The randomization list was kept secured by a third party to ensure the allocation concealment and avoid any tampering with the random list. The chosen number on the envelope was recorded in the patient chart with the corresponding tooth.

Treatment protocol

The oral examination of the enrolled participants was done under a standard dental operating light. The teeth were cleaned, dried, and then examined using a mirror and explorer. Out of 35 teeth examined, a total of 28 teeth in accordance with the eligibility criteria were recorded. A simple occlusal Class I conservative cavity design was applied by following the minimally invasive dentistry principles, by one operator. The preparation was performed by rotary instrumentation; a #245 bur (0.8 mm in diameter and 3 mm in length) (MANI, INC, Japan) through a water-cooled high-speed hand piece (RC-98, W and H, Austria). The cavity preparation was performed without any bevel and did not involve any cusps, with round-shaped cavity walls. The cavity width was limited to no more than one-half the distance of the cusp tips on the occlusal surface of the prepared tooth, whereas the cavity depth was about 2–4 mm according to the caries and tooth anatomy of each case. The cavity to be restored was isolated with cotton rolls in addition to a saliva ejector to absorb saliva.

Restoration

Materials specifications are listed [Table 1].

For zirconomer improved

The material was prepared according to the manufacturer's instruction by dispensing two separate full scoops of powder and one drop of liquid. The first portion of the dispensed powder was mixed with the liquid for 5–10 s. Then, the remaining powder portion was added and mixed until reached a thick putty-like consistency. Mixing was completed within a total of 30 s. Cavities were then filled by the bulk placement of the GI and restored according to the tooth anatomy form, while the excess material was removed completely using a flat plastic instrument (Hu-Friedy Mfg. Co., Chicago, Ill, USA). When the material was set approximately 7 min, restoration was finished by fine-grain yellow-coded diamond stones (MANI, INC, Japan), whereas polishing was done using silicone dental polishers (KENDA®, Vaduz, Liechtenstein).

For Ketac Molar Quick Aplicap

The cavities were rinsed with water and dried with air using a triple-way syringe. Then, pretreated with Ketac conditioner "poly-acrylic-acid" using a disposable brush (fine yellow disposable microapplicator, Unipack medical, Dukal LLC) for 10 s, then rinsed followed by gentle dryness. Ketac Molar Quick Aplicap capsule prepared according to the manufacturer instruction and mixed for 10 s using high power amalgamator (Softly8, de Götzen S. r. l., Olgiate Olona (VA), Italy, mixing frequency 4000/min ± 50/min). Followed by application into the cavity in one layer using 3 m Aplicap™ Applier (3M ESPE, St. Paul MN, USA), then adapted to the cavity walls, and any excess material was removed using the flat plastic instrument (Hu-Friedy Mfg. Co., Chicago, Ill, USA). Finishing and polishing were done in the same pervious manner after the initial setting (about 3.5 min).

Calibration for clinical evaluation

To achieve interexaminer's reliability, at the beginning of the study, the examiners went through profound assessment training program by performing repeated assessments of twenty posterior restorations using modified USPHS criteria.

Blinding

The study was a double-blinded clinical trial where both the patients and assessors were blinded to the material assignment. Therefore, assessors were not included in the preclinical assessment. Regarding the operator, although the envelope was opened after the cavity preparation, the operator was not completely blinded due to the difference in restorative material presentation. While for intraexaminer reliability, it was not done in the trial as the Modified USPHS criteria were used which present high intraexaminer reliability.[9]

Clinical examination

Outcomes were evaluated and documented by two trained assessors at baseline, after 3, 6, 9, and 12 months. All evaluations were conducted under a dental operating light, using mirrors and dental explorers in terms of anatomic contour, marginal discoloration, secondary caries, marginal integrity, surface texture, and gross fracture [Table 2].

Statistical analysis

Data were analyzed using Medcalc software, version 19 for windows (MedCalc-Software Ltd, Ostend, Belgium). Categorical data were described as frequency and percentage, intragroup comparisons between interventions were performed using the Chi-Squared test, and intragroup comparison within each intervention was performed using Cochran's Q-test with a statistical significance level set at $P \leq 0.05$. Relative risk was used to assess the clinical significance. Survival rate was analyzed using Kaplan–Meier and log-rank test. The confidence limit was set at 95% with 80% power, and all tests were two tailed.

Results

After 1 year, 24 restorations out of 28 were evaluated with an overall 85.7% retention rate. There was no statistically significant difference between both zirconia-reinforced GI and conventional highly viscous GI after 1 year of clinical service.

Table 3 shows the inter- and intragroup comparison between both materials within different time intervals "baseline, 6 months, and 1-year." Both GI restorations showed no failures during the 12-month period. Only one restoration in Ketac Molar Quick Aplicap scored "C" in marginal integrity. Intergroup comparison between both materials has

Table 1: Materials manufacturer, lot number, specification, and composition

Materials	Material specification	Powder composition	Liquid composition
Zirconomer improved®. (Shofu INC. Kyoto, Japan) lot# 05191382	Zirconia reinforced GI	Fluoro-alumina-silicate glass, zirconium oxide, pigments	Polyacrylic acid solution, tartaric acid
Ketac™ Molar Quick Aplicap. (3M ESPE, St. Paul, Minnesota, USA.) lot# 7295885	Conventional GI with high viscosity	Calcium-lanthanum-alumina-fluoro- silicate glass, pigments	Polycarboxylic acid, tartaric acid, water
Ketac™ conditioner. (3M ESPE, St. Paul, Minnesota, USA.) lot# 7716498	Liquid, mild polyacrylic solution	-	25% wt. polyacrylic acid, 75% wt. water

GI: Glass ionomer

Table 2: Modified USPHS criteria selected for assessment

Criteria/score	Alpha	Bravo	Charlie	Delta
Anatomic contour (integrity filling) (visual inspection and explorer)	The restoration is a continuation of the existing anatomic form or is slightly flattened. It may be overcontoured. When the side of the explorer is placed tangentially across the restoration, it does not touch two opposing Cavo surface line angles at the same time	A surface concavity is evident. When the side of the explorer is placed tangentially across the restoration, it does not touch two opposing Cavo surface line angles at the same time, but the dentin or base is not exposed	There is a loss of restorative substance such that a surface concavity is evident and the base and/or dentin is exposed	Total loss of the restoration
Cavo surface marginal discoloration (visual inspection)	There is no visual evidence of marginal discoloration different from the color of the restorative material and from the color of the adjacent tooth structure	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration, but the discoloration has not penetrated along the restoration in a pulpal direction	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration that has penetrated along the restoration in a pulpal direction	Strong discoloration in major parts of the margins, not removable
Secondary caries (visual inspection)	The restoration is a continuation of the existing anatomic form adjacent to the restoration	There is visual evidence of dark keep discoloration adjacent to the restoration (but not directly associated with Cavo surface margins)		
Marginal integrity (visual inspection and explorer)	The explorer does not catch when drawn across the surface of the restoration toward the tooth, or, if the explorer does not catch, there is no visible crevice along the periphery of the restoration	The explorer catches and there is visible evidence of a crevice, which the explorer penetrates, indicating that the edge of the restoration does not adapt closely to the tooth structure. The dentin and/or the base is not exposed, and the restoration is not mobile	The explorer penetrates the crevice defect extended to the dentine-enamel junction. (localized)	Strong negative step in major parts of the margin not removable
Surface texture (explorer)	Surface texture similar to polished enamel as determined by means of a sharp explorer	Surface texture gritty or similar to a surface subject to a white stone or similar to a composite containing supramicron-sized particles	Surface pitting is sufficiently coarse to inhibit the continuous movement of an explorer across the surface	
Gross fracture	Restoration is intact and fully retained	Restoration is partially retained with a portion of the restoration still intact	Restoration is completely missing	

USPHS: United States Public Health Service

shown no statistically significant difference within different follow-up periods in all assessed criteria ($P \geq 1$). However, intragroup comparison for marginal discoloration within zirconomer improved has shown a statistically significant difference between different follow-up periods ($P = 0.001$), as well as intragroup comparison within Ketac Molar Quick Aplicap have shown a statistically significant difference between different follow-up periods ($P = 0.037$).

Likewise, for marginal integrity, Intragroup comparison within both zirconomer improved and Ketac Molar Quick Aplicap have shown a statistically significant difference between different follow-up periods ($P = 0.017$) ($P = 0.020$), respectively.

Regarding anatomic contour, an increase was observed in score B for Ketac Molar Quick Aplicap (18.2%) than zirconomer improved after 1-year follow-up with no statistically significant difference between them within different follow-up periods ($P \geqslant 1$).

On the other hand, regarding surface texture, an increase was observed in score B for zirconomer improved (23.1%) than Ketac Molar Quick Aplicap (9.1%) after 1-year follow-up with no statistically significant difference between them within different follow-up periods ($P \geqslant 1$).

Overall survival of zirconomer improved and Ketac Molar Quick Aplicap for posterior restorations in geriatric patients was assessed after 12 months, one restoration in Ketac Molar Quick Aplicap group failed after 12 months due to scoring C in marginal integrity. However, there was no statistically significant difference between both materials ($P = 0.317311$).

Discussion

As a result of the increasing numbers of elderly in population, many efforts are made to manage elderly adults having carious lesions as early as possible; therefore, less invasive procedures would only be needed.[10] Since elderly

Table 3: Frequency (*n*) and percentage of outcomes assessed according to USPHS criteria for assessment of dental restorations

Criteria	Time	Intervention (Zirconomer improved)			Control (Ketac molar quick aplicap)			*P*
		Alpha	Bravo	Charlie	Alpha	Bravo	Charlie	
Anatomic contour	Baseline	14 (100)	0	0	14 (100)	0	0	1.0000 (NS)
	6 months	13 (100)	0	0	13 (100)	0	0	1.0000 (NS)
	1 year	13 (100)	0	0	9 (81.8)	2 (18.2)	0	0.1160 (NS)
	P		1.0000 (NS)			0.171 (NS)		
Marginal discoloration	Baseline	14 (100)	0	0	14 (100)	0	0	1.0000 (NS)
	6 months	11 (84.6)	2 (15.4)	0	11 (84.6)	2 (15.4)	0	1.0000 (NS)
	1 year	6 (46.2)	7 (53.8)	0	7 (63.6)	4 (36.4)	0	0.4018 (NS)
	P		0.001*			0.037*		
Secondary caries	Baseline	14 (100)	0	0	14 (100)	0	0	1.0000 (NS)
	6 months	13 (100)	0	0	13 (100)	0	0	1.0000 (NS)
	1 year	13 (100)	0	0	11 (100)	0	0	1.0000 (NS)
	P		1.0000 (NS)			1.0000 (NS)		
Marginal integrity	Baseline	14 (100)	0	0	14 (100)	0	0	0.3173 (NS)
	6 months	12 (92.3)	1 (7.7)	0	11 (84.6)	2 (15.4)	0	0.5472 (NS)
	1 year	9 (69.2)	4 (30.8)	0	7 (63.6)	3 (27.3)	1 (9.1)	0.5394 (NS)
	P		0.017*			0.020*		
Surface texture	Baseline	14 (100)	0	0	14 (100)	0	0	0.3173 (NS)
	6 months	12 (92.3)	1 (7.7)	0	13 (100)	0	0	0.3173 (NS)
	1 year	10 (76.9)	3 (23.1)	0	10 (90.9)	1 (9.1)	0	0.3698 (NS)
	P		0.115 (NS)			0.406 (NS)		
Gross fracture	Baseline	14 (100)	0	0	14 (100)	0	0	1.0000 (NS)
	6 months	13 (100)	0	0	13 (100)	0	0	1.0000 (NS)
	1 year	13 (100)	0	0	11 (100)	0	0	1.0000 (NS)
	P		1.0000 (NS)			1.0000 (NS)		

*Statistically significant. NS: Nonsignificant; USPHS: United States Public Health Service

patients cannot tolerate extensive treatment times on the dental chair, short appointments, and simplified treatment are required.[11]

It is well known that the success and longevity of dental restorations depend on their sealing ability as well as the retention on the tooth surface. GI provides low technique sensitivity as it provides a chemical bond to the tooth structure, can be used under humid circumstances, and short operating time which is useful in the treatment of the elder population.[10]

Despite their advantages, the GI restorative materials are not widely used in stress-bearing areas as permanent restorations due to their poor mechanical properties, as they tend to fail during high masticatory forces or stresses due to their poor fracture toughness, wear resistance, tensile strength, and hardness.[5] One of the methods to improve their mechanical properties was through increased powder-to-liquid ratio by incorporating more controlled sizes of glass particles, this tactic resulted in high-viscosity GI cements (GICs) (HVGIC) with superior properties compared to conventional GICs.[12] Ketac Molar is a HVGIC that has been tested clinically several times and showed sufficiently good performance as a permanent restoration in the posterior region.[13] Ketac Molar Quick Aplicap has short mixing and setting time, with adequate working time which makes it ideal for pediatric and geriatric restorations. On the other hand, zirconomer improved has been reinforced with zirconia fillers that pass on outstanding mechanical properties to the restoration of posterior load-bearing areas.[14] However, few studies have evaluated the clinical performance of such restorative materials, especially in the elderly.[15]

This study was conducted to assess the clinical performance of two types of GI restorations; based on different material categories used as occlusal restorations. The first was zirconomer-improved GI, a self-adhesive, tooth-colored zirconia reinforced posterior bulk fill restorative material, the second was Ketac Molar Quick Aplicap, bulk-fill, packable, and fast-setting conventional viscous GI.

In the current study, marginal integrity and discoloration and intergroup comparison between both materials have shown no statistically significant difference within different follow-up periods, but intragroup comparison within both materials showed a statistically significant difference with a higher risk of marginal discoloration for zirconomer restorations. Marginal discoloration is usually linked to marginal integrity, and both are linked to the marginal adaptation or seal, which is a major concern in the performance of any restorative material. The search for an ideal restorative material that would be able to form a

permanent but perfect seal between the restoration margin and tooth substance shows the constant establishments of new products in the market.[16] Attained results could be explained by the chemical structure of zirconomer which encompasses zirconia-ceramic particles as fillers. It is likely that the zirconia fillers could affect the chelating reaction by meddling between the carboxylic group of polyacrylic acid and the calcium ions of tooth structure which could negatively affect the bonding of the material and consequently the marginal seal and adaptation.[17] Another factor that could have influenced the marginal adaptation is the conditioning agent applied on the dental substrate before Ketac Molar Quick Aplicap GI application. Dentin conditioner provides a cleaning effect by which the smear layer is removed without removing the smear plugs minimizing the dentinal wetness, conditioning also improves the ion exchange with the cement, thus increases the bonding efficiency of GIC by the chemical interaction of polyalkenoic acid with residual hydroxyapatite.[18]

The surface texture, which is one of the characteristics of any restorative material that helps maintaining the cleanliness of the restoration surface and inhibits bacterial growth.[19] The surface texture of different restorative materials could be affected by interior factors, as alterations in the inorganic fillers' shape, size, distribution, and volume, in addition to external factors, such as material exposure to different liquids or medications. As the materials' filler size increases, the surface roughness would increase. The result obtained in this study showed that the surface roughness of Ketac Molar Quick Aplicap was less compared to zirconomer-improved GI which could be due to the heterogeneous phases present within the zirconomer-improved GI.[20] The presence of zirconia-silica fillers and glass fillers made the material to be more susceptible to dislodgment of the particles by hydrous attack and hence surface roughness.[21] This could also be a result of the hand mixing which may evolve somewhat human error that could influence the mechanical and physical properties, such as the presence of air bubbles in the matrix that would cause surface hydrolytic instability as well as surface softening and consequently surface roughness.[22]

Concerning the survival rate when comparing both materials, there was no statistical significance after 12-month follow-up and only one restoration in Ketac Molar Quick Aplicap failed after 12 months scoring C in marginal integrity. This could be attributed to the operator learning curve starting from the restorative phase till the final application of restoration. Hence, the results of this study suggest the acceptance of the null hypothesis and confirm the similarity in the clinical performance of zirconomer-improved and Ketac Molar Quick Aplicap in restoring Class I cavities in geriatric patients over 12-month follow-up period.

There were very limited data available in the literature regarding the clinical performance of zirconia-reinforced GI restorations. The study results were in agreement with Prabhakar *et al*. in 2015,[23] Walia *et al*. in 2016,[24] Asafarlal in 2017,[25] Naidu and Tambakad in 2018,[26] and Nanavati *et al*. in 2021,[27] who stated that zirconomer and Ketac Molar both showed similar results regarding the assessed criteria.

The study results were in disagreement with Melody *et al*. in 2016[28] who reported that Ketac Molar Qquick showed lower shear strength than zirconomer which could be attributed to the difference in materials presentation in that study, as the Ketac Molar Quick tested in that study was used in a powder and liquid "noncapsulated" form. Another disagreement was with Albeshti and Shahid in 2018[17] who reported that the highly viscous GI restorations showed less marginal adaptation than zirconia-reinforced GI, which could be due to the difference in the type of materials tested as they used Ketac silver which is a another type of high viscous GI. Moreover, a disagreement with Mohamed *et al*. in 2022[29] who reported that zirconia-reinforced GI showed a significantly lower success rate after 12 months compared to HVGICs, this could be attributed to the difference in the study design as the materials were tested in Class II cavities, also could be due to the difference in materials' types as they used resin protected conventional high-viscous GI as the comparator.

The technological advances that have occurred in the past few years in GI restorations would make them a great candidate for expanded use with reliable performance in different situations. The use of newer materials such as zirconomer-improved GI can be helpful in reducing the impact of subtle and widespread oral disease in the elder population and thus enhance their quality of life.

Limitations and future study prospects

However, the current clinical trial has some limitations, such as the eligibility criteria and the follow-up period. Moreover, the results of the present study cannot be generalized as only one type of highly viscous GI was tested.

Thus, trials with longer follow-up periods are advised to confirm the current results and monitor the clinical performance over a longer period of clinical service. Moreover, trials comparing the performance of zirconia-reinforced GI versus other types of restorative materials in different clinical situations are recommended.

Conclusions

- Both zirconia-reinforced GI and conventional highly viscous GI have acceptable clinical performance
- Simple Class I cavities in geriatric patients could be restored by either zirconia reinforced or highly viscous GI.

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Conflicts of interest

There are no conflicts of interest.

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