Original Article

Biological Assessment and Patient Satisfaction of PEKK versus CoCr Framework in Mandibular Fixed Hybrid Prosthesis

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Abstract

Background: Patient's satisfaction is one of the most important aspects of any successful prosthodontic treatment. The biological qualities of the materials used in implant prosthetics are as important as the mechanical qualities and have an important role in the acceptance of the prosthesis. Factors like the microbiotic population can affect the progression of mucositis and peri-implantitis. **Aim:** The primary outcome of the current study is to compare oral microbiotic colonization count on Polyetherketoneketone (PEKK) framework versus Cobalt Chromium (CoCr) framework in full arch fixed hybrid prostheses. The secondary outcome was to evaluate patient's satisfaction based on a questionnaire. **Subjects and Methods:** This clinical study was carried out on fourteen patients exhibiting edentulous mandible who were rehabilitated with implant supported fixed hybrid prostheses. Five delayed loaded implants were inserted. Group I: frameworks were fabricated using CoCr alloy. Group II: frameworks were fabricated using PEKK. Implant supported fixed hybrid prostheses were screwed to the implants in the mandible. Sterile swabs were used to collect the samples from the fitting surface of the prosthesis at the junction between the implant and the framework. The samples were then cultivated. The microbiotic count (CFU) on PEKK frameworks versus CoCr frameworks was evaluated to identify any changes in bacterial and fungal colonization. Patient satisfaction was evaluated using a questionnaire to determine the efficacy of treatment based on the patient's subjective point of view on delivery and after 2 months. **Results:** This study showed a statistically significant increase in colonization (CFU) of Streptococcus and Neisseria at 2 and 4 weeks, and Candida at week 4 on PEKK frameworks versus CoCr frameworks. There was no difference in the patient satisfaction in all aspects except for bad smell and change in taste which was in favor of the CoCr group.**Conclusion:** Although PEKK is known for its esthetic advantage for the construction of full arch implant hybrid prosthesis, its biological characteristics are not ideal which contributed to micro-organismal invasion, and dependently affected the level of patient satisfaction in terms of taste and smell.

I. INTRODUCTION

The revolution of modern implant dentistry has led to the development of a safe and predictable alternative for the replacement of missing teeth. The advances in treatment protocols for implant placement along with change in design and prosthetic properties have dramatically led to a reduction in the initially observed failures related to osseointegration. Late implant complications include microbiological and biomechanical factors. Peri-implant mucositis is the inflammation of the peri-implant mucosa without signs of bone loss and is the first step in the process of development of peri-implantitis. [1]

Both physiochemical and morphological factors of the implant and the prosthesis play a drastic role in the formation of the bio-film on their surface, subsequently increasing the risk of biological complications. The formation of a bio-film is directly related to the chemical and physical characteristics of the materials.[2]

One of the main objectives of oral implantology is to reduce the risk of infection by using biocompatible materials that alter the local environment to hinder bio-film formation and growth of unwanted microbiota. Properties of materials used in the manufacturing of abutments and prostheses are as important as the properties of implants to achieve the best conditions and maximize biocompatibility and resistance to microbial colonization.[3,4]

Faot et al,[5] stated that CoCr alloy is a favorable material for the manufacturing of implant supra-structures. The first trials of implant supported fixed prostheses was made from a cast CoCr alloy framework veneered with heat cured acrylic resin. The aim was to achieve high core strength and at the same time use a material that accepts modifications later on. Afterwards the development of ceramics led to the shifting of their use as veneers due to their better esthetic properties.[6]

Polyaryletherketones are considered high performance thermoplastic polymers which may be polyetheretherketone (PEEK), or polyetherketoneketone (PEKK).PEKK has 80% higher compressive strength and shows better fatigue properties on the long term than reinforced PEEK. PEKK has been gaining popularity due to its light weight and its compatibility with a wide range of veneering materials as well as its manufacturing versatility. Despite all this a few reports have evaluated its clinical use and its biological qualities. [7,8,9]

A lot of elderly population lack the visual acuity and manual dexterity to properly perform the oral hygiene methods which are crucial to remove dental plaque and calculus on the tissue surface of the prosthesis and on the implants as they emerge from the mucosa, leading to many soft tissue problems in the form of tissue hypertrophy, chronic infections of the soft tissue with the formation of granulation tissue. [10]

In modern dental science the impact of treatment on the patient's social and psychological wellbeing in terms of esthetics and function has become of utmost importance. [11] The impact of dental treatments on quality of life and the patient satisfaction which reflects the individual's perception of how oral disorders affect the patient's life in many aspects has become an essential part of evidence based dentistry. With the rise of multiple new materials for the construction of implant frameworks, it is essential that we correlate patient satisfaction with the different material options to reach satisfactory levels. [12]

Research on relationship between materials used in the manufacturing of implants is numerous on the other hand research on prosthetic materials and abutments is scarce. Therefore the purpose of the current study is to compare oral microbiotic colonization count around two different framework materials as a primary outcome and patient satisfaction as a secondary outcome. The null hypothesis was adopted that there is no significant difference between microbial colonization and patient satisfaction regarding the two different materials.

II. SUBJECTS AND METHODS

Sample size calculation was performed using G*Power version 3.1.9.7 based on the results of a previous study (Mansour et al., 2020). A power analysis was designed to have adequate power to apply a two-sided statistical test to reject the null hypothesis that there is no difference between groups. By adopting an alpha level of (0.05) and a beta of (0.2), i.e. power = 80% and an effect size (d) of (0.625) calculated based on the results of a previous study. The predicted sample size (n) was found to be a total of (14), i.e., Group I: CoCr (n=7) and Group II: PEKK (n=7). This was calculated to detect for difference between groups in regard to CFU. [13]

a. Patient selection & study design

Eighteen patients (as we took into consideration failure and drop out cases) for this study were selected from the department of removable prosthodontics Ain-Shams University. The inclusion criteria were healthy male patients aged 45-65 years old having completely edentulous maxillary and mandibular arches. Patients were chosen with adequate restorative space for the mandibular prosthesis of minimum 12 mm from bone level to occlusal plane to permit the fixed hybrid prosthesis.

Patients were free from any systemic disease e.g uncontrolled diabetes, cardiovascular diseases and bone diseases, hyperparathyroidism and impaired physiological conditions that might affect the oral tissues or the bone metabolic rate and may interfere with implant placement and\or osseointegration.

Patients who had bone metabolic disorders and diseases that may complicate surgical procedures as liver, heart, autoimmune diseases and radiation to head and neck were excluded. Patients with parafunctional habits and heavy smokers were also excluded.

All participants were informed about the surgical and prosthetic steps for this treatment modality. They were also informed about the importance of properly following the instructions and signed an informed consent.

Visual and digital intra-oral examinations were carried out. Examination of the temporomandibular joint (TMJ) was carried out to detect any disorders as clicking, pain or dislocation. Provisional jaw relation was taken and diagnostic casts were mounted to assess the ridge relationship and the restorative space.

b. Construction of the 3D surgical guide:

New upper and lower complete dentures for all patients were constructed following the conventional steps. Blue Sky Plan® software was used to select the most suitable implant location, diameter and length. The produced stereolithographic surgical guide with a rapid prototyping machine was provided with five metallic sleeves matching the precise depth, angulation, mesiodistal and buccolingual positioning of each implant at the virtually planned sites with three fixation pins.

c. Surgical phase

On the day of the surgery, the 3D surgical guide was stabilized and secured in place on the mandibular ridge through the fixation pins. Sequential drilling was done for each implant (V plus implant, Vitronix, Italy) following flapless surgical approach. The five implants were inserted with insertion torque ranged from 35-45 N.

d. Prosthetic phase

After four months, the implants were exposed using a punch and their sites were determined by the surgical guide. Healing abutments were attached to implants for two weeks. Patients were recalled and open tray impression copings were attached to the implants and then splinted with a low shrinkage autopolymerizing resin. An open tray impression was done using heavy and light bodied impression material (Elite HD+ Putty Soft Fast; Zhermack SpA) to record the positions of the implants and the soft tissues. Then a verification jig was fabricated on the master cast to ensure accuracy of

the impression and then transferred back to the patient's mouth to verify passivity. Mandibular cold-cured acrylic denture base was constructed on the final stone cast. It was connected to two implant abutments posteriorly to be totally implant supported. Therefore, the mucosal resiliency effect was excluded. A face-bow record was taken to mount the maxillary cast. The centric relation was recorded using bite registration material to mount the mandibular cast. The patients were randomly divided into two groups using a numbered excel sheet and closed envelope method to allocate them into the perspective group according to the material used in the definitive prosthesis.

Group I: patients were rehabilitated with mandibular fixed hybrid CoCr frameworks.

Group II: patients were rehabilitated with mandibular fixed hybrid PEKK frameworks.

Try in of the metal framework CoCr alloy or PEKK framework was done intraorally to ensure proper seating and passivity of the framework. Fig (1&2) Passive fit was checked using one screw test and by taking peri-apical radiographs to check misfits.

The ceramic veneers were attached either to the CoCr framework or PEKK framework then delivered to patients. Screws were tightened according to manufacturer instructions (20 Ncm) screw access holes were sealed with flowable composite and occlusal adjustment was done.

Figure (1): CoCr frame-work

e. Microbiological sampling

Figure (2): PEKK frame-work

The clinician collecting the samples was blinded from the study design and was asked to take the samples and number them to be analyzed anonymously.

The patients were instructed to use brush only without tooth paste and the instructed to refrain from eating for an hour before the visit. Clinical sites were isolated. A total of eighty four oral swab specimens were collected. Three oral sterile swabs were used to collect the sample from each patient within each group on delivery, week two and week four.

The swab specimen was taken in a zigzag motion to cover the entire oral surface in contact with the implant at the junction of the implant and framework, in a rolling manner to cover all the swab surface, then, the swab was suspended in 2 ml sterile saline Fig (3). Swab specimens were transported at 4 °C (using an ice-box) as soon as possible within 2 hours to the Main Microbiology laboratory at Ain Shams University Hospital for processing, in case of delayed transport, the sample was kept at 4 °C, maximum for 24 hours. Upon reaching the Microbiology laboratory, the specimen was vortexed then cultured on suitable culture media. One microliter was inoculated on Blood and MacConkey agar plates and was incubated aerobically at 35-37 °C for 24-48 hours. Colony count was reported as CFU/ml Fig (4).

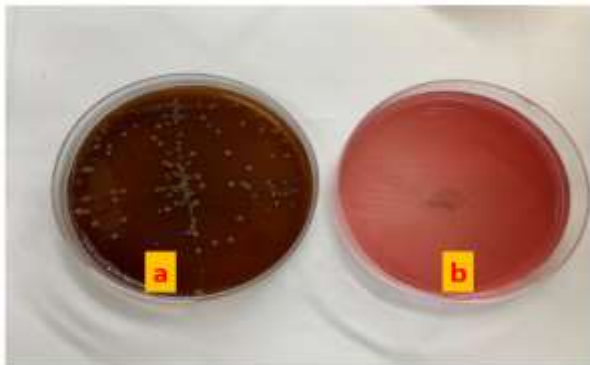**Figure (3):** Cultivation of sample using sterile swab

Figure (4): A Blood agar plate showing growth of Neisseria species (round convex yellow colonies), b. MacConkey agar plate showing no growth

A questionnaire was used to evaluate the patient's satisfaction. The questionnaire was derived from a previous study taking into consideration that only the second part was included as the first part was irrelevant to our study as the patient gender was already determined.[14] A blinded personal that was not aware of the study design was responsible for this step. All patients were asked to complete questionnaires including several items related to their overall satisfaction with the offered prosthesis. The questionnaires were given to the patients after being translated into Arabic. This process was done after 2 months. The questionnaire consisted of 5 dichotomous questions and the individual patient responses were then marked and recorded on proforma. Questions also aimed to assess various problems related to prosthesis and to assess overall satisfaction level of patient on a scale from 1 to 10 where 1 was highly dissatisfied and 10 was highly satisfied. Six factors were evaluated including (mastication difficulty, pain, esthetics, bad smell, food taste and speech difficulty).

III. RESULTS

First outcome

Numerical data were explored for normality by checking the data distribution, calculating the mean and median values and using Kolmogorov-Smirnov and Shapiro-Wilk tests. Data showed parametric distribution so; it was represented by mean and standard deviation (SD) values. Three-way ANOVA was used to study the effect of different tested variables and their interaction. Comparison of main and simple effects was done utilizing pairwise t-tests with Bonferroni correction. The significance level was set at $p \leq 0.05$ within all tests. Statistical analysis was performed with IBM® SPSS® Statistics Version 26 for Windows.

Table (1): Comparison between swabs from the two groups during follow up time

Bacterial	Time	Group I:CoCr		Group II: PEKK		p-value
		Mean	±SD	Mean	±SD	
Streptococci	Baseline	3.27C	0.26	3.27B	0.26	*1.000*
	After 2 week	4.43B	0.23	5.70A	0.10	*<0.001**
	After 4 week	4.70A	0.10	5.75A	0.13	*<0.001**
	p-value	*<0.001**		*<0.001**		
Candida	Baseline	0.00A	0.00	0.00B	0.00	*1.000*
	After 2 week	0.00A	0.00	0.00B	0.00	*1.000*
	After 4 week	0.00A	0.00	4.82A	0.19	*<0.001**
	p-value	*1.000*		*<0.001**		
Neisseria	Baseline	3.41A	0.23	3.41C	0.23	*1.000*
	After 2 week	0.00B	0.00	4.60B	0.19	*<0.001**
	After 4 week	0.00B	0.00	5.78A	0.08	*<0.001**
	p-value	*<0.001**		*<0.001**		

*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

Different capital letters indicate significant difference at (p<0.05) among means in the same column in each bacterial

Three types of microorganisms were detected as for Streptococci There was a highly statistically significant higher mean value in group II than group I after 2 week and after 4 week, with p-value (p<0.001) while baseline insignificant difference, with p-value (p>0.05). For *Candida,* There was a highly statistically significant higher mean value in group II than group 1 after 4 week, with p-value (p<0.001) while baseline and after 2 week insignificant difference, with p-value (p>0.05).

As for Neisseria it was observed to have a highly statistically significant higher mean value in group II than group I after 2 week and after 4 week, with p-value (p<0.001) while baseline insignificant difference, with p-value (p>0.05).
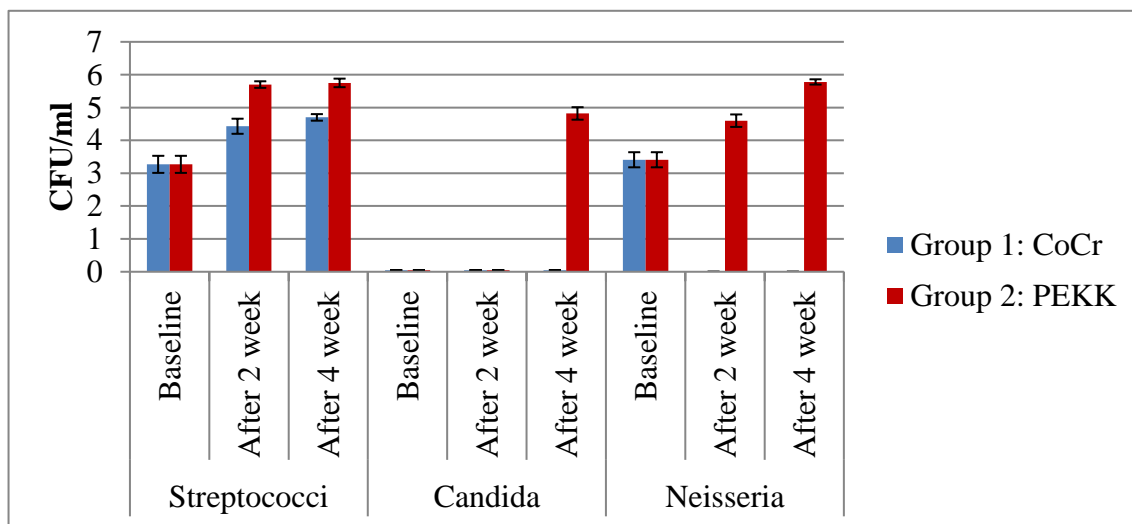

Figure (5): Comparison between Group I and Group II according to CFU/ml.

Second outcome

Ordinal data was represented as mean, standard deviation (SD), median and interquartile range (IQR) values. They were analyzed for intergroup comparisons using 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 4.3.0 for Windows[1].

Results of intergroup comparisons and summary statistics for satisfaction score values are presented in table (2) and in figure (2). For "Bad smell" and "Food taste change" parameters, Group II PEKK group had significantly higher scores than Group I Co-Cr group (p<0.001). For other parameters, the difference was not statistically significant (p>0.05).

Table (2): Intergroup comparisons of satisfaction score

Parameter		Satisfaction score		Test statistic	p-value
		PEKK	Co-Cr		
Mastication difficulty	Mean±SD	5.43±1.40	6.14±0.90	32.00	0.383
	Median (IQR)	6.00 (2.50)	6.00 (1.50)		
Pain with prosthesis	Mean±SD	2.57±0.53	2.14±0.90	18.00	0.456
	Median (IQR)	3.00 (1.00)	2.00 (1.50)		
Esthetics	Mean±SD	8.29±0.49	8.57±0.79	32.50	0.318
	Median (IQR)	8.00 (0.50)	9.00 (0.50)		
Bad smell	Mean±SD	8.00±0.00	0.86±0.90	0.00	<0.001*
	Median (IQR)	8.00 (0.00)	1.00 (1.50)		
Food taste change	Mean±SD	2.00±0.00	1.00±0.00	0.00	<0.001*
	Median (IQR)	2.00 (0.00)	1.00 (0.00)		
Speech difficulty	Mean±SD	1.57±0.53	1.71±0.49	21.00	0.645
	Median (IQR)	2.00 (1.00)	2.00 (0.50)		

*significant (p<0.05)

[1]R Core Team (2023). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.
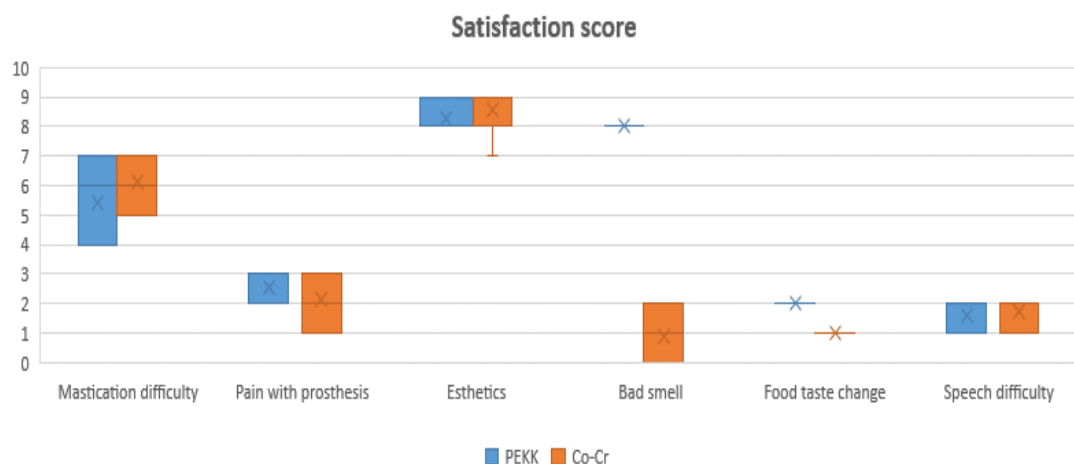
Figure (6): Box plot showing satisfaction score values

IV. DISCUSSION

Introduction of new esthetic materials to restorative and prosthetic dentistry in the last decade has had a great impact on implant dentistry so the current study was designed to investigate the biological criteria and level of patient satisfaction of two different widely used materials taking into consideration that the CoCr is the control material.

There is direct contact between abutments and prostheses with soft tissue at the area where peri-implant inflammatory disease is initiated and later on spreads to the bone.[1] Microscopic and macroscopic morphological and physiochemical characteristics of the first 2-3mm above the implant prosthesis connection are the most important areas for the success of the implant. [15]This key area is directly in contact with connective tissue and epithelium, near to the bone depending on the implant prosthesis design. For this reason the material selected for this area along with the manufacturing and polishing procedures are critical to preclude infection and ensure biocompatibility.[16]

This study aimed at evaluating the microbial count on two different materials at 2 and 4 week postinsertion.

The null hypothesis was rejected due to the significant difference between the cfu/ml in

streptocoocus and neisseria at week 2 and 4 and candida at week 4 between the two groups.

It has been proved that microbial colonization of the bio-fims follow a similar pattern on dental implants and teeth. Streptococci bacteria are considered the initial colonizers as they have the ability to bind to the surface. They play an important role in the early stages of colonization moreover they act as a bridge helping more virulent periodontal pathogenic organisms to colonize the mature biofilm.[17] Factors affecting the nature of biofilm on artificial materials are the surface properties, roughness and topography. This can explain the results of our study that observed an increase in Streptococcus, Neisseria and Candida albicans in the Group II PEKK versus the Group I CoCr group. [18]

The degree of surface roughness of all dental materials contributes to bacterial plaque adhesion and accumulation. There is an increase bacterial adhesion on rough surfaces due to increased surface area. Therefore, choosing materials with low surface roughness is essential to reduce bioadhesion. A Ra threshold of 0.2 mm has been previously reported as the clinical acceptability threshold for dental prostheses. Above this level, biofilm formation increases, and below this level, surface roughness has no significant impact on biofilm formation. [19,20] Therefore, one of the main goals of surface finishing is to achieve a surface roughness of

below 0.2 mm. Burcu Batak et al, stated that PEKK had a surface roughness of 0.613 before polishing and 0.502 after polishing which is much higher than the acceptable level. Whereas Kyung-Soo Jang et al, reported the surface roughness of Co-Cr to be 0.104 before polishing and 0.133 after polishing this is well below the accepted levels.[21, 22]

This is why resins in general have a low resistance to the formation of biofilms compared to other materials.[8] The recommended clinical application is to limit their use when designing hybrid prosthesis to patients who have metal allergies and to those who can comply with good oral hygiene methods. Multispecies biofilm formations on new materials such as PEEK and PEKK have shown promising results but the results are still inferior to those obtained from CoCr.[23]

Another reason for our findings is Cross – kingdom interactions that occur between the oral streptococci and candida albicans opportunistic fungus, which are predominant microorganisms naturally occurring in the oral cavity, which have recently become of growing interest.[24-27] This is due to the fact that they play some very important roles in pathogenesis of dental carious lesions and mucosal infections. Some commensal microorganisms like Neisseria and Streptococcal species have the ability to increase the virulence of oral bio-films and create multispecies bio-films in areas where they reside.[28]

Although inter-individual variability is observed, some species are abundant in all patients. Some of the abundant species common to peri-implantitis as well as periodontitis, i.e., Fusobacterium nucleatum, Neisseria, Streptococcus, and red complex, play important roles in bio-film formation.[29]

Some results suggest that Streptococcus and Candida albicans are both commensal micro-organisms that grow separately but can synergistically affect each other's pathogenic potential. Moreover, despite the common belief that commensal streptococci protect the host against Candida- related infections, it has been reported widely that Candida albicans has the ability to synergize with certain streptococcal species leading to an exacerbated pro-inflammatory local host response which promotes epithelial damage, increases the severity of oral mucosal infection and leads to breach of the mucosal barrier.[30]

This study demonstrated that factors related to complications after delivery of the prosthesis, had a direct effect on the patients satisfaction. The decrease in patient satisfaction in terms of bad smell and change of taste in the PEKK framework can be attributed to the wide finding of candida and other microorganisms on the PEKK frame work due to its inherent roughness. On the other hand there was no difference in satisfaction in the other items as the same treatment modality was used. For example both groups were rehabilitated with 5 implants supporting fixed hybrid prosthesis.[12]

V.   CONCLUSION

Although PEKK is known for its esthetic advantage for the construction of full arch implant hybrid prosthesis, its biological characteristics are not ideal which contributes to micro-organismsal invasion, and dependently affected the level of patient satisfaction in terms of taste and smell.

Conflict of Interest:

The authors declare no conflict of interest.

Funding:

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors

Ethics:

This study was approved by the ethical committee of the faculty of dentistry Ain Shams University on 16.11.22, approval number (FDASU-RecIR 112214)

VI.   REFERENCES

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