3M[™] ESPE[™] Clinpro[™]

Prophy Paste with Fluoride

3M[™] ESPE[™] Clinpro[™]

Disposable Prophy Angles





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Introduction

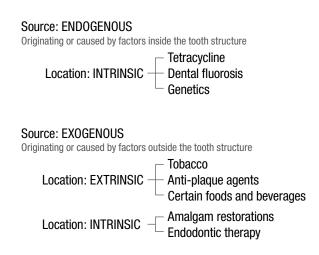
Dental prophylaxis is one of the most widely administered procedures in the dental office. A dental prophylaxis treatment consists of cleaning and polishing the teeth with a paste applied with a prophy angle, or with a powder applied with an air-polishing device. The ultimate goal of dental prophylaxis is the removal of stain from the teeth. Dental prophylaxis also serves an important role in the prevention of gingivitis and periodontal disease. While infrequent prophylaxis treatments alone are not sufficient to provide an anti-caries benefit, dental prophylaxis as part of a professionally-administered oral hygiene program has been shown to reduce the risk of caries. 4,5,6,7,8,9,10

Overview of Dental Prophylaxis

Cleaning and polishing teeth is a part of preventive oral health care. The aim of dental prophylaxis is to minimize and inhibit re-accumulation of stains, pellicle and debris.¹

Stains and other dental deposits accumulate on the teeth over time. Certain factors are known to predispose a person to the accumulation of both dental deposits and stains. These factors include enamel roughness, decreased salivary flow, and poor oral hygiene.¹¹

Staining or discoloration of teeth occurs in two ways. The stain is either adhered directly to the tooth surface through bonding to the acquired pellicle, calculus and soft deposits, or is incorporated in the tooth structure. Thus stains can be classified as either endogenous or exogenous. Endogenous stains originate within the tooth structure. Exogenous stains originate outside the tooth structure. Stains can be further categorized as extrinsic or intrinsic. Extrinsic stains are on the exterior of the tooth and can be removed by the patient or dental professional. Intrinsic stains become incorporated into the tooth structure and cannot be removed by dental prophylaxis.



Historically, both clinicians and patients have considered cleaning and polishing to be an innocuous procedure that benefited teeth by removing stains and dental plaque. However, research has revealed both positive and negative effects of polishing.¹²

On the positive side, cleaning and polishing has been shown to:

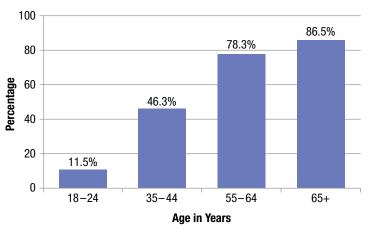
- improve the esthetic appearance of teeth by removing extrinsic stains
- reduce oral microorganisms
- serve an important role in the prevention of gingivitis and periodontal disease

Negative effects caused by cleaning and polishing include:

- removal of tooth structure
- roughening surfaces of restorative materials
- removal of outer fluoride-rich enamel layer

With the increased life expectancy of permanent teeth and the resulting extended frequency of professional cleaning, abrasion of hard tissue is becoming a major clinical concern. Several studies have demonstrated that an abrasive prophylaxis agent can remove significant amounts of enamel. One such study utilizing a water and pumice slurry showed 3–4µm (microns) of enamel removed when polishing for 30 seconds.¹³ This problem is compounded when polishing dentin and cementum because these surfaces abrade 20 times more rapidly than enamel.^{14,15} As the population ages, the chance of dentin and cementum becoming exposed, and therefore subjected to polishing, increases. Gingival recession of 1 millimeter or more is seen in 11.5% of 18 to 24 year olds, 46.3% of 35 to 44 year olds, 78.3% of 55 to 64 year olds, and 86.5% of people 65 and older.¹⁶

Gingival Recession of 1mm or More



In addition to abrasion on dentin and enamel, some prophy pastes roughen the surface of dental restorations.^{17,18} The optimal degree of abrasion required to clean tooth surfaces while not removing excessive amounts of tooth structure or restoration is difficult to calculate. To combat the negative effects that polishing may impose, some dental professionals incorporate "selective polishing" into their dental hygiene practice. In selective polishing, the dental professional may elect to polish only selected tooth surfaces. Another option is the use of a prophylaxis product with "variable abrasion", or the ability to convert from coarse particles for stain removal to fine particles for polishing.

Product Description

Clinpro[™] Prophy Paste with Fluoride is a cleaning and polishing paste containing perlite, a unique abrasive particle. The perlite abrasive converts from coarse to fine grains during use, changing the cleaning paste into a polishing paste. Clinpro Prophy Paste provides the dental professional with a product offering the benefits of variable abrasion.

Clinpro[™] Disposable Prophy Angle is used for the delivery of prophy paste. Clinpro Disposable Prophy Angles combine reliable performance with the convenience of single-patient use. The non-latex prophy cup on Clinpro Disposable Prophy Angles is available in soft or firm to allow the dental professional to tailor the prophy treatment to the individual patient's situation.

Indication

Clinpro Prophy Paste with Fluoride and Clinpro Disposable Prophy Angles are indicated for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment.

Composition

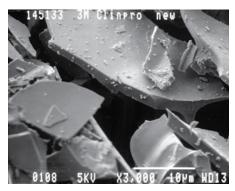
Clinpro[™] Prophy Paste with Fluoride

Clinpro Prophy Paste contains sodium fluoride at a concentration of 1.23% fluoride ion. The product is supplied in two flavors — mint and bubble gum.

Clinpro Prophy Paste contains **perlite**, a unique abrasive particle. The perlite in Clinpro Prophy Paste converts from coarse to fine grains when applied to a tooth surface during a prophylaxis. This self-adjusting abrasive property allows the paste to be used in both the cleaning and polishing of tooth surfaces.

The perlite in Clinpro Prophy Paste is a volcanic glass which differs from other prophy paste abrasives. Perlite has a sheet-like geometry initially aligned in angles for effective tooth cleaning. The angled orientation of the particles changes to a parallel alignment within 5–10 seconds of cleaning. This smooth change in movement rounds and softens the edges of the perlite particles, reducing abrasion to the tooth surface and transforming Clinpro Prophy Paste into a polishing paste.¹⁹

Figure XX.
Scanning Electron Microscopy images of perlite prophy paste. (magnification 3000x)



Perlite particles prior to polishing enamel, showing the cutting edges necessary to remove tooth stain.



Perlite particles after 10 seconds of polishing on enamel, showing edges becoming more rounded.



Perlite particles after 15 seconds of polishing on enamel, showing a reduction in particle size as the product converts from a cleaning paste to a polishing paste.

Clinpro Prophy Paste offers gentle, yet highly effective cleaning and polishing in one product. The integrated abrasion variability makes Clinpro Prophy Paste a universal paste. There is no longer a need to stock various grits of prophy paste.

Clinpro[™] Disposable Prophy Angles

Clinpro Disposable Prophy Angles are composed of a flexible prophy cup attached to an angled housing which contains gears to rotate the cup. The gears within the body of Clinpro Disposable Prophy Angle provide reliable performance for the duration of the prophy treatment. The long gear is manufactured to fit all doriat style slow speed handpieces. The internal mechanism is pre-lubricated, lowering the risk of overheating, noise, and stalling. The prophy cup is both ribbed and webbed, with webs recessed from the edge to gain maximum access to tooth surfaces subgingivally and interproximally. Clinpro Disposable Prophy Angles are available in two choices of flexibility — soft (gray) and firm (white). The prophy cup is made of synthetic rubber and does not contain latex.

Evaluations

Clinpro Prophy Paste with Fluoride

Stain Removal

Tooth enamel is the hardest and most highly mineralized substance in the human body.²⁰ Using the Mohs scale of hardness for minerals (where 1 is the "hardness" of talc and 10 is the hardness of diamond), tooth enamel has a Mohs hardness value of 5.5–8. To clean tooth enamel most effectively, abrasive particles should have a Mohs hardness value similar to or higher than that of tooth enamel. The perlite in Clinpro Prophy paste has a Mohs hardness value of 5.5–7; the product will effectively remove stains from tooth enamel.¹⁹

Methodology: Samples of bovine enamel were prepared and stained by cycling for one week in mixtures of tea and 2% chlorhexidine digluconate. The enamel samples were divided into groups for cleaning and polishing. One of the groups was cleaned with 3M ESPE Clinpro Prophy Paste (n=10); another group was cleaned with the coarse grit of Dentsply NuPro Prophy Paste (n=10). Other groups were cleaned with pumice prophy paste or water. Cleaning consisted of applying the prophy paste in a prophy cup run at a speed of 1500–2000 rpm with a load force of 150 grams as outlined by Christensen et al. ¹² All enamel samples were cleaned in this manner for 5 seconds. The cleaned samples were evaluated using computer image analysis. ²¹

Results: Clinpro Prophy Paste removes stain as well as the coarse grit of Dentsply NuPro Prophy Paste.

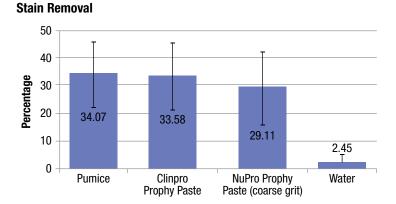


Figure XX.

The amount of stain removed with

Clinpro Prophy Paste and the coarse
grit of NuPro Prophy Paste are
statistically the same.

Abrasion

Clinpro[™] Prophy paste contains abrasive ingredients to remove all types of accumulation from the tooth surface. Abrasive particle-size distribution within the dental prophylaxis paste or powder can markedly influence the cleaning, polishing, and abrasion properties.²² If the particles are too abrasive, they can remove excessive tooth enamel and dull the tooth surface. The ideal prophy product provides effective cleaning without removal of the luster from the tooth surface.

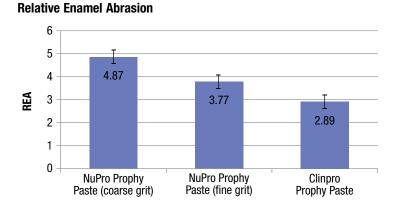
Relative Enamel Abrasion

Methodology: Eight human enamel incisor specimens were prepared for prophylaxis treatment with either 3M[™] ESPE[™] Clinpro[™] Prophy paste, the coarse grit of Dentsply NuPro Prophy Paste, or the fine grit of Dentsply NuPro Prophy Paste. The teeth were irradiated and cleaned for 30 seconds at a prophy cup speed of 2100 rpm with a load force of 250 grams. After each treatment, the amount of enamel that had been abraded was measured using a scintillation counter for radiation detection.

Results: Clinpro Prophy Paste was less abrasive on enamel than the fine grit of Dentsply NuPro Prophy Paste.

Figure XX. Clinnro Prophy Paste is less abrasive.

Clinpro Prophy Paste is less abrasive on enamel compared to both grits of NuPro Prophy Paste.



Relative Dentin Abrasion

Methodology: The dentin of eight bovine teeth was exposed, irradiated, and cleaned with either 3M[™] ESPE[™] Clinpro[™] Prophy Paste, the coarse grit of Dentsply NuPro Prophy Paste, or the fine grit of Dentsply NuPro Prophy Paste. The prophylaxis treatment consisted of 15 seconds of cleaning at a prophy cup speed of 2100 rpm at a load force of 250 grams. After each cleaning, the amount of abraded dentin was measured using a scintillation counter for radiation detection.

Results: Clinpro Prophy Paste was significantly less abrasive on dentin than the fine grit of Dentsply NuPro Prophy Paste.

Relative Dentin Abrasion

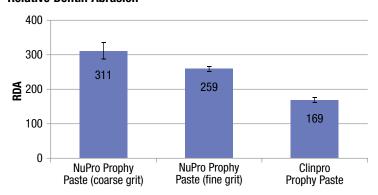


Figure XX.Clinpro Prophy Paste is less abrasive on dentin compared to both grits of NuPro Prophy Paste.

Surface Roughness

A coarse prophy paste will remove or cut substance such as stain from a surface. Unfortunately, it may also create a rough surface by making large scratches on the tooth. A rough surface will appear dull. A fine prophy paste will produce small scratches which are less likely to roughen the surface. The smoother surface will appear more shiny.

The influence of prophy pastes and prophy cups on surface roughness can be determined with a profilometer. This instrument measures the "mean surface roughness" by a mechanical scanner. Roughness is expressed in Ra units. The higher the Ra number, the rougher the surface.

Methodology: Acrylic block samples were prepared, with each sample divided into two sections. One section of each sample was polished with a soft prophy cup filled with either 3M[™] ESPE[™] Clinpro[™] Prophy Paste, the coarse grit of Dentsply NuPro Prophy Paste, or the fine grit of Dentsply NuPro Prophy Paste using a predetermined speed and load.¹² The other section of the sample was unpolished to serve as a control. Five samples were polished per paste. Roughness measurements were taken from the polished sections at 10 seconds for both grits of NuPro Prophy paste and at 5, 10 and 15 seconds for Clinpro Prophy Paste. Measurements were compared to the unpolished sections and to each other.

Results: The surface treated for 5 seconds with Clinpro Prophy Paste had a comparable roughness to that treated for 10 seconds with the coarse grit of Dentsply NuPro Prophy Paste. However, after continued cleaning with Clinpro Prophy Paste, the surface roughness decreased to be comparable to that achieved with 10 seconds of polishing with a fine grit of Dentsply NuPro Prophy Paste. The use of Clinpro Prophy Paste resulted in an excellent polish without the need for two grits of prophy paste.

Surface Roughness

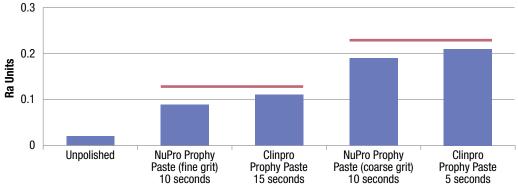


Figure XX.

Clinpro Prophy Paste has variable abrasion, resulting in an initial surface roughness value equivalent to that with the coarse grit of NuPro Prophy Paste and ending with a value equivalent to that with the fine grit of NuPro Prophy Paste.

рH

The pH value of oral health products can affect the demineralization of teeth.²³ A critical pH for enamel is between 4.5 and 5.5; below this level the enamel can begin to demineralize. A critical pH for root surface demineralization is between 6 and 6.7. The amount of demineralization of enamel or dentin depends on the length of time and the frequency with which the tooth is exposed to the lower pH. However, it is desirable to use oral health products with a pH above the value at which demineralization can occur.

Methodology: Samples of various brands of prophy pastes were suspended in deionized water. Triplicate measurements were taken of the pH for each sample.

Results: Clinpro[™] Prophy Paste has a pH value of 8.4, well above the level at which dentin or enamel demineralization occurs.

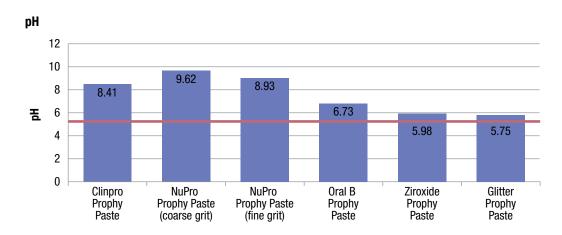


Figure XX.

Dollesequo torae et odisciet etum sit voluptas dolor am sequi tem. Tibus mossinus est, omnimusamus.

Ania volupis mo quide optus id utae praestion cus, acepel minctet porest qui dissi ut latur, a qui dolores sitinve

Patient Preference

Most patients expect that their teeth will be cleaned and polished during a traditional dental hygiene appointment.²⁴ Satisfaction with any dental treatment is important to the patient as well as to the dental professional.

Methodology: 130 patients had their teeth cleaned and polished with the mint flavor of Clinpro Prophy Paste. Following the treatment, each patient completed an evaluation regarding his or her perception of the paste compared to previous pastes used to clean the teeth.

Results: Patients preferred the lack of residual grit following a cleaning with Clinpro Prophy Paste. 87% of the patients reported that they did not feel the grittiness normally left in the mouth after their cleaning appointment. The mint flavor of Clinpro Prophy Paste was described as pleasant. The majority of patients were satisfied with the cleaning and polishing that they received following a prophylaxis with Clinpro Prophy Paste.

Clinpro[™] Disposable Prophy Angle

Infection Control

The Centers for Disease Control and Prevention classify dental handpieces as "semi-critical" instruments.²⁵ Prophy angles attached to dental handpieces have the same classification. Infection control procedures for multi-use metal prophy angles can involve cleaning, disinfection, and autoclaving. An alternative to multi-use prophy angles is single-use disposable angles.

Clinpro Disposable Prophy Angles are designed to meet infection control guidelines. Each Clinpro Disposable Prophy Angle is packaged in a sealed packet with printed instructions for use. The prophy angle is to be used for one patient, and then discarded after use. Clinpro Disposable Prophy Angles save time by eliminating the need to clean, disinfect and autoclave prophy angles.

Design

Dental hygienists, who perform the majority of prophylaxis procedures, often make the decision about the type of prophy angle used in the dental practice. In a recent survey, 77% of dental hygienists stated that they were involved in selecting the prophy angle used in their office.²⁶

Methodology: Dental hygienists attending a national meeting were asked to evaluate features of various prophy angles, including Clinpro Disposable Prophy Angles. In addition, dental hygienists were asked to evaluate Clinpro Disposable Prophy Angles in the office, using the product with patients during a prophy treatment. 187 patients were involved in the evaluation.

Results: 95% of the hygienists rated the overall performance of Clinpro Disposable Prophy Angles to be above average. During the in-office evaluation, no failures were reported with the angle mechanism or housing of Clinpro Disposable Prophy Angles.

Clinpro Disposable Prophy Angles provide quality construction with reliable performance.

Weight

Dental professionals may perform prophylaxis treatments several times a day. A recent survey found that the typical dental hygienist performs 32 prophy treatments per week.²⁷ The repeated motions involved in a dental prophylaxis combined with the weight of the prophy angle used in these procedures can have a cumulative effect over time. This combination may lead to musculoskeletal disorders.²⁸

Methodology: Clinpro Disposable Prophy Angles were weighed and compared to the weight of metal prophy angles.

Results: Each Clinpro Disposable Prophy Angle weighs less than 3 grams. A typical metal prophy angle weighs over 15 grams.²⁸ Clinpro Disposable Prophy Angles offer greater than an 80% weight reduction of a device typically used several times a day by dental professionals.

Instructions for Use

For instructions on the use of Clinpro Prophy Paste or Clinpro[™] Disposable Prophy Angles, refer to the instructions provided with the product — also available online at www.3MESPE.com.

Storage

Clinpro[™] Prophy Paste with Fluoride is designed to be used at room temperature. If stored in cooler, allow product to reach room temperature prior to use. Shelf life at room temperature is 24 months. Ambient temperatures routinely higher than 27°C (80°F) may reduce shelf life. See outer package for expiration date.

Clinpro Disposable Prophy Angles should be stored at room temperature.

Questions and Answers Clinpro Prophy Paste with Fluoride

1. Does the prophy treatment procedure need to be changed for Clinpro Prophy Paste?

To optimize the characteristics of Clinpro Prophy Paste, the procedure for polishing may need to be adjusted. It is important to keep in mind that when Clinpro Prophy Paste is first applied to the tooth surface, it will behave like a coarse paste. Within seconds it will change to a fine paste. For normal dentition, treat a limited number of teeth (2–3) with one portion of paste in the prophy cup. Work from the incisal/occlusal surface toward the gingival area of the tooth. Avoid starting with fresh paste on areas such as cementum, dentin, or restorations where a coarse paste could abrade the surface.

2. After cleaning with a prophy paste containing fluoride, is it necessary to apply more topical fluoride to teeth?

Prophy pastes cannot be considered a substitute for topical application of fluoride. Although some studies have shown a reduction in caries following professional prophylaxis applied at various frequencies, these studies were complicated by the use of other prevention treatments.^{29,30} The infrequent application of prophy paste (with fluoride) alone does not appear to have a significant impact on caries.

3. Do the teeth need to be cleaned with a prophy paste before an in-office fluoride treatment?

A number of studies have shown that neither the type of cleaning nor the degree of cleaning has an effect on the efficacy of the professional fluoride treatment.³¹

4. How much tooth surface is lost with polishing, and can this be minimized?

Studies have estimated that up to 4µm of enamel can be lost during a 30 second treatment with a pumice-containing prophy paste. ¹³ Use of a specialized abrasive such as the perlite in Clinpro™ Prophy Paste provides effective tooth cleaning without excessive tooth wear. ^{32, 33, 34}

5. Can Clinpro Prophy Paste be applied with a bristle brush instead of a rubber prophy cup?

Yes, however with any prophy paste and brush, this combination should be limited to use on the occlusal surfaces.

Clinpro[™] Disposable Prophy Angles

1. How should a Clinpro Disposable Prophy Angle be attached to the handpiece?

Align the notch on the disposable angle with the guide pin on the handpiece. Tighten the retention mechanism to lock Clinpro Disposable Prophy Angle onto the handpiece.

2. What is the recommended speed for use of Clinpro Disposable Prophy Angles?

Use the lowest possible speed to move the cup against the tooth without stalling. Do not use Clinpro Disposable Prophy Angles at speeds above 3,000 rpm.

3. Can Clinpro Disposable Prophy Angles be sterilized?

No, Clinpro Disposable Prophy Angles are designed for single use only. They should not be sterilized or used on more than one patient. Each Clinpro Disposable Prophy Angle is packaged in a sealed packet for cleanliness.

4. Should the dental professional be concerned about the presence of latex in a prophy angle?

The Centers for Disease Control and Prevention recommend that dental patients and dental health care professionals with latex allergy avoid direct contact with latex-containing materials. All latex-containing products should be removed from the treatment area.²⁵ People with a history of latex allergy can be at risk from procedures involving dental products that contain latex. These products include prophylaxis cups.²⁵ Latex allergy represents a serious systemic allergic reaction. Dental health care professionals may have repeated exposure to latex because of the presence of latex-containing dental products. 4.3% of dental professionals tested at an annual meeting of the American Dental Association were positive for Type 1 latex hypersensitivity.²⁵

5. Do Clinpro Disposable Prophy Angles contain latex?

No, 3M ESPE Clinpro Disposable Prophy Angles do not contain latex. The prophy cups are composed of non-latex synthetic rubber.

6. Troubleshooting with the Clinpro™ Disposable Prophy Angle

- The rotating prophy cup stalls or stops during a procedure
- Prophy angles require a low rpm and high torque. Handpieces may offer a choice of different speed range settings. Be sure to set the handpiece to the low range speeds.
- The prophy cup is rotating in the opposite direction than usual
- On most handpieces there is an option to reverse the rotation direction. Check the handpiece manufacturer's instructions for use.
- . The entire angle, not just the prophy cup, is rotating
- This usually indicates a problem with the collet, or locking mechanism, in the handpiece. When placing the angle on the nose cone, leave a space of no more than 1/4" (7mm) between the bottom of the nose cone and the base of the angle. When the collet locks the angle in place, it may pull the angle back to eliminate this gap. If this fails to correct the problem, check the instructions for use of the handpiece for possible service issues.

Summary

3M ESPE Clinpro™ Prophy Paste with Fluoride

- · Indicated for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment
- Contains perlite, a unique particle with integrated variable abrasion
- Converts from coarse to fine grains to minimize abrasion to enamel and dentin
- Removes stains as well as a coarse prophy paste
- · Less abrasive than a fine prophy paste on enamel and dentin
- Virtually eliminates the grittiness left in the mouth after a dental prophylaxis
- Has a pH above the value at which demineralization occurs
- · Contains fluoride
- Available in two flavors mint and bubble gum
- Supplied in unit-dose cups with an autoclavable prophy ring
- 24-month shelf life

Clinpro Disposable Prophy Angles

- Indicated for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment
- Developed with input from dental hygienists
- Provides reliable performance and quality construction
- Provides effective infection control through disposable single-use features
- Available with either a soft or firm non-latex prophy cup

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Use is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

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