



Welcome to the World of DreamLens™

Bausch + Lomb Vision Shaping Treatment™ for overnight orthokeratology using Boston® Equalens® II



Training and Resource Guide



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Bausch+Lomb Vision Shaping Treatment is not a lens design, but instead is an *umbrella term* used to describe methods and designs for the practice of overnight orthokeratology.



FDA Approved

In June 2004 Bausch + Lomb acquired a premarket approval for the Boston® Orthokeratology Lens, marketed as Bausch + Lomb Vision Shaping Treatment™ (VST) for overnight orthokeratology using Boston® Equalens® II. DreamLens™ is an approved VST lens design.

Additionally, in December of 2004 a supplemental fitting approval that encompasses the use of corneal topography and/or software based designs was also received from the FDA.

Modern Ortho-k with DreamLens

Modern orthokeratology with DreamLens uses specially designed reverse geometry gas permeable (GP) ortho-k shaping lenses worn during sleep.

Using Boston materials, you fit custom-designed orthokeratology lenses to reshape your patients' corneas overnight, so they're able to enjoy clear vision throughout the day—without glasses, contact lenses, or surgery.

The Boston® Equalens® II Material

Distinctive colors allow patients to easily discern which lens belongs in which eye.

Boston Equalens II provides a significant amount of oxygen exchange with a Dk of 85 as measured by the ISO/Fatt polarographic method. Importantly, Boston Equalens II provides excellent on-eye wetting resulting in a decrease of debris and surface deposit buildup.

Uniquely, Boston Equalens II materials for overnight orthokeratology are available in distinctive colors to allow patients to easily discern which lens belongs in which eye.



Left Lens is yellow.



Right Lens is red.

A RED lens is used for the right eye and a YELLOW lens for the left. This allows the wearer to easily determine the proper lens for each eye and also ensures the prescriber is receiving the Boston lens material they expect.

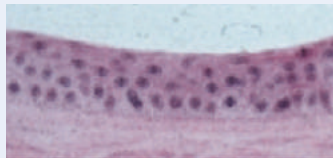


Corneal Shape Change Through Redistribution of Tissue

In orthokeratology with DreamLens, the change in corneal shape results from forces exerted on the tear film between the back surface of the lens and the cornea, causing a gradual and steady compression and possibly a redistribution of fluids and epithelial cells under the lens from the center toward the periphery.



Before Ortho-k



After Ortho-k

Specifically, the central corneal epithelium becomes thinner as a result of positive pressure under a flat central curve of the shaping lens, while the mid periphery becomes thicker due to the negative created by the annular tear pool under a steeper second or reverse curve.

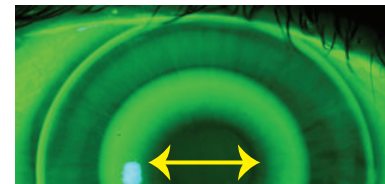


Anatomy of the DreamLens

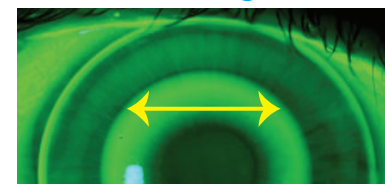
The DreamLens is composed of four zones. Each zone has a precisely designed width and curvature, which has been specifically calculated for each cornea.

+ Fitting Zones

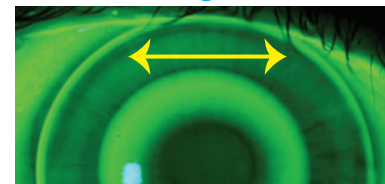
Zone 1 Central Zone



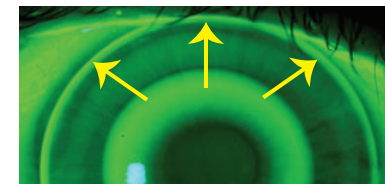
Zone 2 Fitting Zone



Zone 3 Alignment Zone



Zone 4 Peripheral Zone



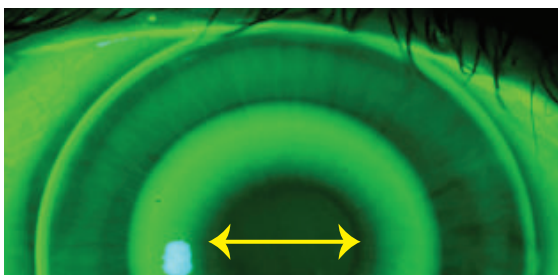
+ DreamLens

An in-depth look at the four fitting zones of DreamLens

Understanding Each Zone

- Central Zone
- Fitting Zone
- Alignment Zone
- Peripheral Zone

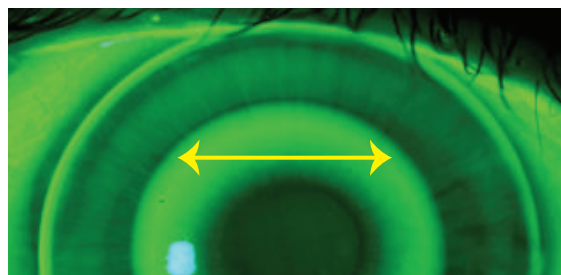
The Central Zone



The Central Zone, commonly referred to as the base curve, is a radius of curvature calculated from the flat K, minus the desired amount of myopic correction, minus the compression factor of 0.75D.

The diameter of this zone is 6.0mm, which has proven to be the most effective diameter. A change in this zone can have a negative effect on treatment results and is not recommended. The NaFl pattern will show a dark area indicating minimal clearance.

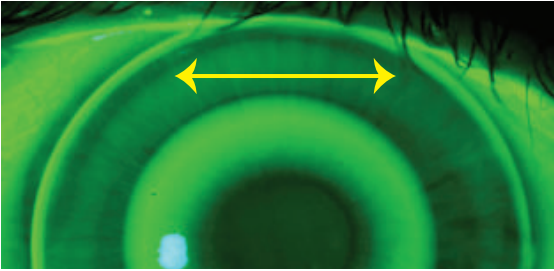
The Fitting Zone



The Fitting Zone is a very steep reverse curve, specifically calculated to bring the back surface of the lens into proper alignment with the cornea.

The width of this zone is 0.6mm, allowing for the displaced cornea tissue from the central zone to be redistributed in this area. A wider fitting zone tends to reduce the Ortho-k effect and is not recommended. Any change in this zone will also affect the fitting characteristics of all zones peripheral to the fitting zone. The NaFl pattern under this zone will be a thin dark green ring indicating lens clearance in this area.

The Alignment Zone

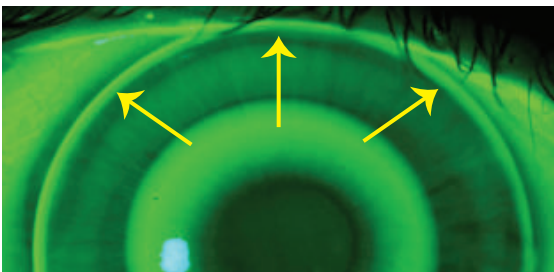


The Alignment Zone has a dual-purpose. The first function is alignment to keep the lens centered on the cornea. The second function is enhancement of the orthokeratological effect.

The Alignment Zone has a standard width of 1.0mm and is designed to compress the cornea. A 10.6mm diameter variation of the standard design increases this width to 1.3mm, which is then divided into two curves.

Since the alignment zone compresses the cornea, the NaFl pattern will show a dark annular area indicating a lack of NaFl. Changes can be made in this zone to improve centration, however changes are only recommended if the standard lens needs to be modified.

The Peripheral Zone



The last zone is the Peripheral Zone. The sole purpose of this zone is to give the lens edge lift to aid with lens removal and tear exchange. This zone is 0.4mm wide with an 11.0 radius.

Based on a dual compression concept.

The DreamLens is based on a dual compression concept. The Base Curve provides the template to mold the central cornea. The Alignment Zone area provides the support. The Fitting Zone acts to control the amount of compression each area provides. The junction between the Fitting Zone and the Alignment Curve acts as a fulcrum to control the tightness of the Alignment Curve, which controls centration.

Each parameter of the DreamLens has been clinically and theoretically validated to give the best results.

In the majority of cases, the *standard* DreamLens design will provide excellent results; therefore, modifications from the standard design should be made with caution.

NaFl patterns should only be used for gross observations, as many fluorescein patterns may look similar but the lenses will produce different results. Utilizing a corneal topographer is recommended.



The DreamLens™ Design Program

Bausch + Lomb Vision Shaping Treatment™ for overnight orthokeratology using Boston® Equalens® II

A Straightforward Process

Fitting the DreamLens does not incorporate diagnostic fitting and only requires K's and spectacle Rx for use with the DreamLens proprietary Design Program.

Fitting the DreamLens is straightforward and has been found to have a success rate over 90%. Typically, the standard DreamLens design will successfully fit 80% of patients.

Trial lens fitting can be used, however this approach will not yield better results than empirical fitting. The reason is that differences in the lens design that are too small to change the NaFl pattern will give significantly different clinical results. In troubleshooting, trial lens fitting can be helpful but generally is of little use.

To design and order DreamLens, follow the DreamLens Design Program explanation guide on the following pages. Your TruForm consultant can also assist you in designing your lens order.

Call your TruForm Optics consultant for guidance with the DreamLens Design Program

800-792-1095



DreamLens Design Page

The DreamLens design program allows complete flexibility in designing DreamLens for your patient.

Basic Design: The DreamLens design program utilizes the patient's topographical data to calculate the elevation of the cornea at specific distances and uses this data to design the lens. All that is required to design the basic DreamLens is the patient's Spherical correction at the spectacle plane, amount of myopia reduction needed and the Flat K reading from your topographer. These fields are highlighted in yellow. With the basic design you can expect over an 80% success rate with the first lens.

Advanced Design: When modifications to the basic design are required, the DreamLens Design Program provides the tools required. The "e" value can be added to further refine the elevation calculations, the steep K allows for toric designs and the adjust column modifies the individual zones. Over a 90% success rate can be achieved when these tools are utilized.

General Ordering Procedure: Enter the patient's name or ID number, Rx at the corneal plane, amount of myopia you like reduced, K readings from your topographer and "e" value if available. Select the desired material, color and the lab, TruForm Optics, from the drop-down lists. Make any modifications in the basic design and press the "Calculate" button. The lens will be designed with the parameters shown. Review the data, add any comments in the fields located at the bottom of the form, and if correct, press the "Order" button. The design data will be sent to TruForm Optics and the database. A confirmation message will appear when the order has been sent. Your account information provided at registration is also included with the order.

Design Modification: The DreamLens Design Program allows unsurpassed freedom in the design of the DreamLens. Modifications can be made to suit your patient's specific requirements.

Target Power: Normally the target power is the same as the sphere power to correct the full amount of myopia. If a patient is over corrected or under corrected, the target power can be modified to compensate for this. Monovision is another situation that requires the target power to be changed. If you want a +2.00 add, just reduce the amount of target power by +2.00. This will reduce the amount of correction by +2.00 and allow the patient to read with this eye. If the patient likes to read in bed before falling asleep, the lens power can be increased by +2.00 also to allow monovision with the lenses on the eye. If an increase in myopia is noticed during their annual visits, often the sphere power should be changed along with the target power when the increase is determined to be from an axial length increase.

Diameter: The default diameter is 10.6mm. This works for most patients. If your patient has small eyes and a smaller diameter is needed, check the diameter required. If the diameter is not listed, check the closest size and modify the zone widths in the widths column. It is suggested that the AC1 width not be changed and all changes are made in the AC2 width.

Zone Widths: Manually change the zone widths in the widths column. This will also change the diameter of the lens. The optical zone can be changed here. It is recommended that the optical zone remain between 5.8mm and 6.2mm.

Zone Adjustments: The adjustment column is where changes in the elevation of the lens are made. Changes are in mm so a 10um change would be 0.010mm. A plus will increase the elevation of the lens thereby tightening the fit of the lens. A minus value will loosen the lens. The AC2 is different. Here enter the amount flatter in diopters you would like the AC2 than AC1. The entered "e" value changes this value to loosen the lens for corneas that flatten more than normal.

DreamLens Design Page (continued)

Toric: Check the toric option to design a DreamLens with a toric fitting curve, AC1 and AC2. Toric lenses greatly increase the centering properties of the DreamLens and can also reduce greater amounts of astigmatism.

Power Adjustment: This is where you can change the power of the lens. Normally this is not needed because the patient is only wearing the lens during sleep.

Trouble Shooting: These buttons allow the most common problems to be corrected with a simple press of the button. Press the button for the problem encountered and the appropriate change will be made. Press the button again for additional correction. When you have the changes needed in the adjustment column, press the "Calculate" button to redesign the lens. Pressing the troubleshooting button only shows the amount that will be changed; it does not recalculate the lens design.

Custom Design: The custom design overrides the calculate button changes and allows you to enter specific values. To activate this function, check the Custom Design box and press the "Calculate" button. You can now enter values for the lens independent of the design algorithms. Design changes are overridden in this mode. Please use this mode with caution!

Comment Box: Enter changes for the lens design not included in the fields. An example would be changes in the center thickness of the lens.

E-Mail Comments: Comments here will be in the body of the e-mail. Use this comment box for patient shipping instructions or questions on the order.

DreamLens Design Calculators

mm to Diopter: In the design program, the "K" readings must be entered in diopters. This calculator converts mm to diopters and diopters to mm.

Vertex Converter: Simply enter the spectacle power in Diopters and the vertex distance and this calculator will convert the spectacle power to the power at the corneal plane. The default vertex distance is 12mm but can be changed when required.

Aspheric/Sphere: This calculator allows the conversion of an aspheric lens segment to a spherical segment with the same sag change.

SAG converter: The sag converter converts a change in curve segment from radius change to sag change. This is just the opposite of what the design program does.



DreamLens Design Page (continued)

The History Page

The history page tracks all orders placed using the design page. When the “Order” button is pressed on the design page, the parameters of the lens are recorded in the database and displayed on the history page. Your last order will appear first.

To search for a patient, enter the patients name or a portion of the name, select the appropriate search function from the drop down list. The search function can be used for all fields. An example would be to see how many patients have an Rx over -4.00D or have cylinder over -2.00D. You can then see how successful these patients are and track the number of orders.

At the bottom of the page are the “Print” and “Troubleshoot/Re-Order” buttons. Press the “Print” button to print a hard copy of the design. Pressing the “Troubleshoot/Re-Order” button transfers the displayed lens parameters to the design page. Now you can reorder the lens if no changes are required or modify the design before reordering. When a pair of lenses is required and only one lens is displayed, press the “Troubleshoot/Re-Order” button to transfer the lens displayed and then go back to the history page and display the other lens.

You might have to do a search for the other eye. You now have a split screen where you can manually enter the Rx parameters from the second lens into the order page. Make sure any changes from the standard design are included when the parameters are manually transferred.

Call your TruForm
Optics consultant
for guidance with
the DreamLens
Design Program

800-792-1095





DreamLens™ Initial Fitting and Follow-Up Visit

Initial Fitting Process

Once you have verified the DreamLens parameters, you are ready to dispense the lenses. Place the lenses on the patients eye and after 5-to-15 minutes, check the visual acuity, evaluate the fluorescein pattern and over-refraction with the lenses on the eye. The over-refraction should be Plano.

Call your TruForm Optics consultant for guidance with the initial fitting process.

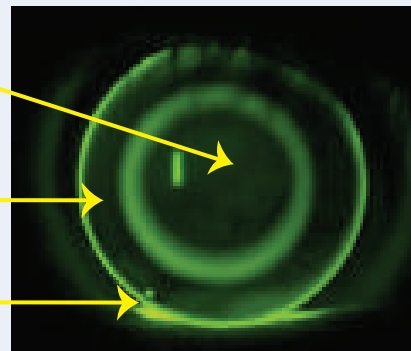
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The lens should be centered over the Central Zone (base curve treatment area).

Adequate tear film touch in the Alignment Zone (periphery) should be apparent.

Ensure there is proper edge lift.



Occasionally, an air bubble will form under the lens and, at times, can be rather large. If the bubble covers more than 30 degrees, have the patient remove the lens, fill the concave surface of the lens with rewetting solution and reapply the lens.

If the Fluorescein Pattern Is Normal

If the NaFl pattern appears normal, instruct the patient to remove the lens and reapply it for the rest of the day. Have the patient put two drops of the rewetting solution in the eye before insertion which will help reduce lens adhesion. Stress that lens removal should not be attempted if the lens is adhered to the eye. It may be necessary to gently digitally massage the eye to break any lens adhesion. It is important to instruct the patient not to remove the lens via suction cup if the lens is not moving upon blinking. Continue to add re-wetting drops and digitally massage the eye through the eyelid until the lens is moving.

Schedule the patient to return to your office the next day, preferably in the morning, wearing the lenses.

Lens Application and Removal Training

Before the patient leaves your office, have the staff instruct lens application and removal. Consider dispensing a DMV® to remove the lenses, as the DreamLens will be larger than a standard GP lens and can be more difficult to remove with traditional removal techniques. Advise the patient to apply a drop of lubrication solution before the lens is applied to provide a thicker film for the lens to rest on, thus decreasing the chance for lens adhesion.



Lens Care Solutions

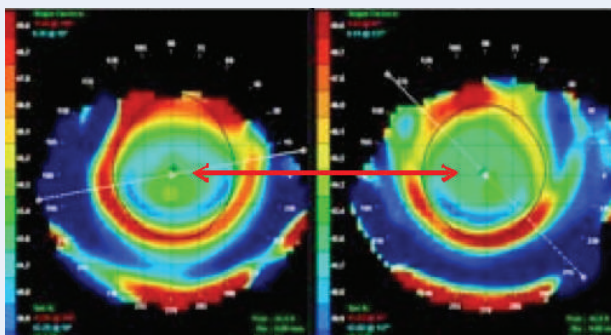
The DreamLens is made from high dK Boston® materials and Boston® solutions are recommended for the care of the DreamLens. Instruct the patient to use the Boston® Simplus for the routine cleaning and storage of the DreamLens. Once a week use the Boston® cleaner with a 100% cotton swab to clean the back surface of the lens. Before lens application and removal, put one to two drops of Boston® rewetting drops in the eye. This will give the eye a thicker tear layer for the lens to rest upon and prevent lens adhesion in the morning. If deposits start to pose a problem, add an enzymatic cleaner to the regimen.

First Morning Follow-Up

Check the vision and with the slit lamp determine if the lenses are moving. If the lenses appear to be adhered, have the patient blink a few times and add rewetting drops. Gently take the lower lid and push against the edge of the lens until it moves. Have the patient blink a few times and then remove the lens.

With the lenses removed, check the patient's unaided visual acuity. Consider checking both eyes together by first showing the 20/200 line and then going down one line at a time. This will provide positive reinforcement to the patient on their vision improvement. Next, check the acuity of each eye separately and perform a subjective refraction. Do not use an auto refractor, as the readings will not be accurate.

Perform a corneal topography. The maps should reflect a centered lens position over the treatment area.





Subsequent Follow-Up Visits and Troubleshooting Tips

Call your TruForm Optics consultant for guidance with follow-up visits or troubleshooting questions.

800-792-1095



Subsequent Follow-Up Visits

At the conclusion of the first morning follow-up, answer any patient questions and schedule the next appointment in one week, at the end of the day. While the one-day visit is in the morning, on future progress checks it is best to evaluate the patient later in the day to test how the vision treatment is holding throughout the day.

At the one-week visit, check the topography and uncorrected acuity, perform a refraction and then evaluate the eye with the slit lamp. At this point the uncorrected vision should be in the 20/20 to 20/25 range and holding during all waking hours. The treatment will be complete in most cases at this point. During upcoming office visits you will be looking for consistency in visual acuity and topographical findings.

If a problem is present, call your TruForm Optics consultant to discuss, and schedule another visit in a week to see if the problem is still present. Unless the patient presents with acute discomfort or pain, only make a change if the same problem is present during two consecutive visits.

Have the patient bring their lenses with them at every visit.

+ Troubleshooting Tips

Possible Adverse Effects

Patients should be advised to discontinue lens wear and call your office if they experience any of the following:

- pain
- discomfort
- excessive tearing
- decreased vision
- foggy vision
- halos
- photophobia
- redness

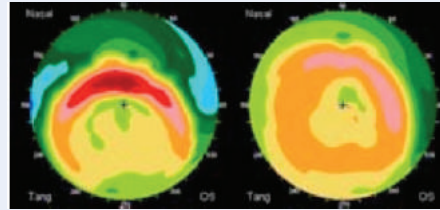
Orthokeratology with DreamLens should also be discontinued if you observe any corneal hypoxia or staining greater than Grade 2.

Notes

Common Problems

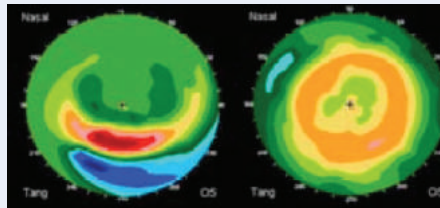
If there is an inadequate amount of myopic reduction, flattening the base curve would be appropriate. Also, too small of a treatment zone can be helped by increasing the optical zone.

Inferior Positioning = Loosen Fit



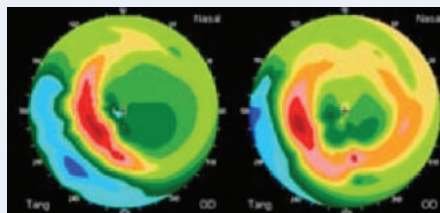
The most common change is to loosen the lens when it is positioning inferiorly. This will give the upper lid more grab to raise the lens.

Superior Positioning = Tighten Fit



A high riding or superior fit is just the opposite. In this case the lens needs to be tightened.

Lateral Decentration = Increase OAD



Lateral riders need more surface area in the alignment curve so this area is widened, primarily by increasing the overall diameter.



+ Candidates

Proper patient selection is critical to achieve success

DreamLens Candidates

With DreamLens, candidates can correct their eyesight and reduce dependence on glasses or contact lenses — without having to undergo eye surgery.

Proper patient selection, along with utilizing consultation from TruForm Optics, are among the most important aspects of having a successful patient.



Important Tips to Keep in Mind

There are no age restrictions in prescribing the DreamLens for the temporary correction of myopia. The DreamLens works best for myopia of -4.00 Diopters and below.

Powers from $-4.00D$ to $-5.00D$ are often successful, but might require more lens changes with the results more difficult to obtain. Myopia above $-5.00D$ is not recommended.

With the rule astigmatism up to $-1.50D$ and against the rule astigmatism of $-0.75D$ will yield good results. Above these limits, the amount of residual astigmatism will decrease the patients unaided acuity.



+ Patient Expectation



Identifying Good Candidates

DreamLens is suitable for people with lifestyles where glasses and contact lenses can be problematic, such as:

- Children and young adults who want to be glasses-free
- Athletes, and people who participate in contact sports
- People with active lifestyles
- A profession which requires hassle-free visual freedom
- People who work in dusty environments
- People who are
 - too young for LASIK surgery
 - not ready for LASIK surgery
 - not candidates for LASIK surgery



Identifying Poor Candidates

DreamLens *may not* be suitable for:

- Flat corneas below 39.00D
- Steep corneas above 46.00D
- Previous hard or gas permeable contact wearers
- A diagnosis of keratoconus
- Previous ortho-k wearer with corneal scarring
- A diagnosis of dry eye*.

**Note: A patient with dry eye (by itself) does not preclude from being fit with DreamLens, but caution needs to be taken to make sure that rewetting drops are used before lens insertion.*

Communication is key.

Managing the patients expectations throughout the entire orthokeratology process is key in achieving clinical success and patient satisfaction with DreamLens.

Patients should be informed what they should expect during every step of the process. Failure to fully communicate may result in less than desirable results for you, and the patient. Key items to communicate include:

- What is Ortho-k
- The use of gas permeable (gp) lenses with ortho-k
- FDA approval
 - Bausch+Lomb Vision Shaping Treatment (VST)
 - DreamLens is approved under VST
- Professional certification required to prescribe ortho-k using DreamLens
- Vision problems DreamLens can correct
- What makes someone a good candidate
- No age restrictions
- How long the effect of ortho-k with DreamLens lasts on day-one, day-three, day-seven, etc.
- Results to expect from ortho-k
- In-office training for lens application and removal
- What to expect when overnight lens wear begins
- Length of time to achieve maximum results
- Managing vision during the 7-to-14 day treatment period
- The cost of ortho-k with DreamLens
- CareCredit®, or alternate payment plans, if available
- The fitting process and necessary follow-up visits
- The importance of having a spare pair of lenses
- The cost of a spare pair, and replacement lens cost
- Lens care solutions
- Yearly visits, what is included, and the cost





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