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Analysis of Accommodation Gain of Presbyopia Eye After Laser Ablation (or Shrinkage) of Sclera Via Lens Reshaping and Lens Anterior Shift

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Authors' contributions

The sole author designed, analysed, interpreted and prepared the manuscript.

Article Information

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Original Research Article

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ABSTRACT

Purpose: To derive and provide analytic formulas for an accommodative gain of presbyopia eyes. via sclera ablation and/or thermal shrinkage such that the lens is reshaped and/or its position is shifted. New mechanisms are also proposed.

Study Design: To increase the accommodation of presbyopia.

Place and Duration of Study: New Taipei City, Taiwan, between June 2021 and July 2021.

Methodology: Accommodation gain is calculated by a 4-component theory, in which the rate functions are derived by an effective eye model for the change of anterior curvature of the lens and its anterior shift. The measured data of accommodative response of the lens versus the lens curvature change and anterior shift are analyzed. The measured net change of the posterior vitreal zonules (PVZ) length and the space between the ciliary body and lens (CLS) during the accommodation are also analyzed.

Results: The accommodative gain (AG) is mainly due to the change of lens anterior curvature and its anterior shift. The AG per diopter change of the reshaped lens is 0.62 to 0.68 by our formulas, comparing to the measured average value M'=0.69. The efficacy of LASA (or AG) is proportional to the amount of scleral tissue removed (or shrinkaged), such that more space is produced for the change of PVZ and CLS from a UCS to AS for accommodation.

Conclusion: The AG is proportional to the amount of scleral tissue removed (or shrinkaged), such that more space is produced for the change of PVZ and CLS from a UCS to AS for accommodation.

Keywords: Presbyopia; accommodation; scleral ablation; ciliary body; lens reshaping; lens anterior shift.

1. INTRODUCTION

Presbyopia affects over 1.3 billion populations worldwide, for those aged over 50. The principles of presbyopia were given by the classical hypothesis of von Helmholtz [1] and Schachar [2-4] and the modern theory of Lin [5-9]. Non-traditional methods [2-9] for presbyopia correction, including Schachar using scleral band expansion [2-4] and scleral tissue ablation via IR laser of Er: YAG (at 2.94 um) and UV laser (at 266 nm) [5-7].The prior art of US patent, Lin and Martin [10], proposed a non-invasive method using a gonio lens guided infrared laser to heat the zonules fiber of the eye for the treatment of presbyopia.

The present author also proposed various methods for presbyopia correctionscombining laser surgery and pharmacologic means [11]. However, these prior arts are not patentable due to their lack of merits. By the same reasons, there are few prior US Publications having proposed various methods for presbyopia treatment, but not yet patented. Most of the prior arts of non-patented-publications are due to their similarity to the methods patented by the present for presbyopia Technology author [10]. corrections include [2,5-10]; SEB (scleral expansion band), SRI (scleral radial incision by knife), SEP (silicon expansion plugs), BIC (band implanted in ciliary body), LPR (laser presbyopia reversal using scleral ablation), CK (conductive keratoplasty), DTK (diode laser thermal keratoplasty), LASIK (presbyopia LASIK using monovision). AIOL (accommodative IOL). The accommodative theory postulated by Helmholtz (in 1855) [1] remains the most widely supported and cited despite alternative theories proposed subsequently by Schachar et al. [2-4]. As traditionally accepted Helmholtz hypothesis, presbyopia is due to progressive weakening or atrophy of the ciliary muscles [1]. Consequently, the ciliary muscle is left with no space to contract. Thus, with a view to give the muscle "more room" for contraction. Helmholtz [1]

proposed that (as shown in Fig. 1) the ciliary muscles contract which relaxes the zonules causing the lens capsule to become relax. The jelly-like lens material hence bulges in the center. There is a decrease in the equatorial diameter in the process. Schachar et al. [2], on the other hand, postulates that when the ciliary muscles contract the "equatorial" zonules tighten while the non-equatorial zonules relax. Comments on Schachar's theory, the concept of scleral expansion is under hot debate. Many studies have actually discounted the Schachar hypothesis.

Accommodation is the ability to focus on near objects through controlled changes in the shape and thickness of the crystalline lens and mediated by ciliary muscle contraction. To correct presbyopia, it is a fundamental necessity to understand how accommodation occurs and how it changes the optical and tissue parameters of an agedeve. The effectiveness of ciliary body lens contraction for relaxation (or accommodation) may be influenced by the combined aging factors, including lens property changes (index, size, thickness, and curvature), elastic tissue changes (in the sclera and ciliary), and the zonular tension change [8]. We note that methods using mechanical sclera expansion techniques such as the scleral band expansion (SEB) suffer from major regression due to tissue healing, whereas the laser method showed less regression.

In the present article, we will first review the prior arts and the classical accommodation theory of Helmholtz [1]. An effective eye model is presented to derive the accommodative gain (AG), which is given by a 4-component theory. The measured data of accommodative response of the lens versus the lens curvature change and anterior shift are analyzed. Finally, the measured net change of the posterior vitreal zonules (PVZ) length and the space between the ciliary body and lens (CLS) during the accommodation are also analyzed.



Helmholtz's theory

Fig. 1. Schematic depiction of the accommodative theories of Helmholtz [1] left-half is for unaccommodated-state, and right-half is for accommodated-state, showing the relax of the zonular fibers

2. MATERIALS AND METHODS

2.1 The Aging Effects of Human Eyes

Many theories have been proposed for the agerelated loss of accommodation, including(a) lensbased theories, (b) geometric theories, (c) lenticular theories, and (d) multi-factor theory [12,13]. The factors, which may contribute to changes in overall refractive power, include the corneal shape and thickness, lens shape and thickness, anterior and vitreous chamber depth, and globe axial length. A change in the refractive index gradient of the lens cortex has been suggested to be a substantial factor contributing to the progression of presbyopia [13] and also proposed that because of the increased thickness of the lens and the anterior shift of the zonular attachments, presbyopia is a failure of the lens to be maintained in a flattened state. Cross-sectional studies of age-related changes in resting refraction show a drift towards hyperopia from about age 30 to 65 yeas and then a drift towards myopia after age 65 year attributed to growth and the forward movement of the lens [13]. It should be noted that the "lens paradox" showing "myopic shift with ageing (due to lens curvature changes) may be counterbalanced by all those factors which may cause a hyper-shift including the decreases of lens equivalent index and globe axial length with age. We shall also note that the increase of lens power due to radii decrease is a weaker agedependence that the of the equivalent refractive index change; therefore, the "net effects" cause a "hyper-shift" by aging [13,14].

2.2 The Effective Eye Model

By Gaussian optics theory (or paraxial ray approximation along the axial axis), the refractive error (De) is given by [15,16]

$$De = 1000 [n1/(L-L2) - n/F],$$
(1)

where n is the refractive index of the aqueous humor, L is the axial length, L_2 is the position of the system second principal plane, and F is the system effective focal length (EFL). The total system power is given by D=1000n/F (D in diopter, F in mm),which is determined by the corneal power (D') and lens power (D) as follows [15]

$$D_T = D' + D - S(DD')/(1000n1),$$
 (2.a)

D' = 1000 [(n3-1)/r - (n3-n1)/r'] + bt, (2.b)

$$D = 1000 [(n4-n1)/R - (n4-n2)/R'] - aT,$$
 (2.c)

where nj (j=1, 2, 3, 4) are the refractive index for the aqueous, vitreous, cornea, and lens, respectively, the anterior and posterior radius of curvatures (in the unit of mm) of the cornea and lens are given by (r. r') and (R. R'), respectively. noting that R'<0 for a concave surface. Finally, S is the effective anterior chamber depth. related to the anterior chamber depth (ACD), S1, by $S=S_1+P11+0.05$ (in mm), where P11 is the distance between the lens anterior surface and its first principal plane, and 0.05 mm is a correction amount to include the effect of corneal thickness (assumed to be 0.55 mm) [17,18]. The thickness terms in Eq.(2.b) and (2.c) are given by b=11.3/(r1r2), $a=[(n4-n1)^2/n4]=(4.97/(RR'))$, for refractive indexes of n1 = n2 = 1.336. n3 = 1.377and n4 = 1.42; and t and T are the thickness of the cornea and lens, respectively. For T=3.7, R=11.6, R'=6.3, we obtain aT=0.25. Lens power D=84(1/R - 1/R') - aT=20.3D.

As shown in Fig. 2 for an effective eye model, using $L-L_2=X+$ SF/f, with X=L-S-aT+0.05, and aT and 0.05 are the correction factors for the lens and cornea thickness, Eq. (1) may be rewritten in an effective eye model equation [15,16]

 $De = Z^{2} [1336/X - D'/Z - D]$ (3.a)

$$Z=1-S/f=1-S(D'/1336)$$
 (3.b)

where f (in mm) is the EFL of the cornea given by f=1336/D', and the nonlinear term k is about 0.003 calculated from the second-order approximation of SF/(1336f). The nonlinear term may also be derived from the IOL power formula [2]. We note that in Eq. (3), X, Z, S, and f are in the unit of mm; D, D' and De are in the unit of diopter; and 1336 is from 1000x1.366 in our converted units.

2.3 The Rate Functions

To find the change of refractive error (De) due to the change of Qj, we further define Qj=(r, r', R, R',S1,S2) with j=(1 to 6), respectively. The ACD (S₁) and vitreous length (S₂) are related to the axial length by L=S₁+S₂+T. The derivative of the refractive error (De) with respect to these ocular parameter change (Qj) given by Mj=dDe/dQj, defines the rate function, or the change of De per unit amount change of Qj, where the standard notation "d" for "derivative" is used in this study.

In general, under the second-order approximation including the contributions from both n1/(L-L2) and (n1/F) in Eq.(1), one shall rigorously calculate the derivative dDe=Mj(dQj)

based on Eq.(1). The complexity of this method is due to the nonlinear dependence of L2 on the ocular parameters.

Using Eq. (2) and (3) analytic formulas for the rate function for the surface curvatures and thickness of the cornea and lens may be derived (to be presented else where) by Mj=dDe/dQj, with Qj (j= 1 to 6), for (r, r', R, R', S1, S2) respectively, as follows [15,16]

$$M1 = +378/r^2$$
, (4.a)

$$M2 = -41/r'^2,$$
 (4.b)

M3= +82.75 C_F/R^2 , (4.c)

M4=+82.75 C_F / R^2 , (4.d)

M5= 1336
$$(1/F^2 - 1/f^2)$$
, (4.e)

$$M6 = -1336/F^2$$
, (4.f)

where C_F is a conversion function, from lens power translated to eye power, given by $C_F =$ $(dDe/dD)=Z^2$; f and F (both in mm) are the corneal and system EFL given by f=1336/D' and F=1336/D.We had used the refractive indexes nj=(1.336, 1.336, 1.3371,1.42) for the aqueous, vitreous, cornea and lens, respectively.



Fig. 2. An effective eye model is defined by the power of the cornea and lens. Also shown are the parameters of S and X which is related to the axial length by L=S+X+aT - 0.05 (mm) [15,16]

2.4 Accommodative Eye Model

As shown in Fig. 3, a 4-component theory for the accommodative gain (AG) is proposed [19,20]

$$AG = m dR + m' dR' + M dS_1 + M' dS_2$$
 (5)

where the AG is attributed by 4 components: front (dR) and anterior (dR') lens curvature change, anterior chamber depth (ACD) change, dS₁ and vitreous length change (dS₂). The rate functions are defined in Eq. (4), with renamed notations: m=M5, m'=M6, M'=M3, and M'=M4.

2.5 The Accommodative Lens Reshaping

It was known that accommodation might be improved by: (i) thermal shrinkage (with a temperature range of 50° C to 70° C) of the scleral stroma such that the space between the ciliary body and lens (CLS), or ciliary apex ring diameter increases; or (ii) softening of the scleral stroma (with a temperature range of 70° C to 90° C), and (iii) laser ablation (tissue removal) of scleral stoma, such that the net change of the posterior vitreal zonules (PVZ) length and CLS increase during the accommodation.

As shown in Fig. 4, a lens reshaping model for AG due to decrease of CLS (with relaxed zonular fiber), and decrease of PVZ, where the left figure shows relaxed zonular fiber with CLS space from A to B, increasing lens anterior radius of curvature (dc) such that the focused image ismyopic-shifted to see near (for dR>0) at the accommodative-mode, or a positive AG. Defining the CLS decrease (dc) given by the distance dc=AB, and dR given by the distance DE, and under a balance condition of AD=BE, we obtain dR is related to dc by the solution of (using a simple geometry shown in Fig. 4)

$$dR^{2}+2(dR)(DC) - (dc)^{2} - 2(dc)(BC)=0$$
 (6)

Because dc<<BC and dR<<DC, Eq. (6) reduces to dR=(BC/DC)(dc). We note that combining Eq. (5) and (6) allows us to estimate the AG and dR as a function of dc, to be shown later.



Fig. 3. Schematics of an accommodating eye showing the anterior shift of the lens (with decreasing distance, S), and its surface curvatures, R and R' (becoming more curved)





Fig. 4. The lens reshaping model for AG due to increase of CLS (dc) with relaxed zonular fiber and decrease of PVZ, where the left figure shows CLS decrease (from A to B), resulting in the increase of lens anterior radius of curvature (dR, from D to E)

3. RESULTS AND DISCUSSIONS

3.1 The Formulas for Accommodative Gain (AG)

By using a set of typical ocular parameters: corneal radius of curvature (r', r2)=(7.8, 6.5) mm, lens radius of curvature (R, R')=(10.2, 6.0) mm, corneal and lens thickness (t, T)=(0.55, 4.0) mm; and S=6.0, S_1 =3.5 and S_2 =16.0 mm, or an axial length of L=3.5 + 16 + 4 = 23.5 mm, we calculate the corneal power D'=42 diopter, and lens power D=21.9 diopter, and total eye power, from Eq.(2.a), D=D'+0.81D=59.8 diopter. The rate function Mj (j=1 to 6) are calculated for each 1.0 mm change, M1=+6.2, M2=-0.97, M3==0.53, M4=1.48,M5=+1.35, and M6=-2.67 diopter/mm. Furthermore, for each 1.0 diopter increase of corneal and lens power, the rate functions are 1.0 and 0.66 diopter, respectively, for a typical value of effective ACD, S=6.0 mm and corneal power of 43 diopters. We shall note that the above values of Mj depend on the choices of the ocular parameters and may vary 10% - 15% from the typical values chosen. The conversion function translates the change of the lens power to the whole eye power, having a typical value of C_F=0.62 to 0.68.

One may also calculate the reported pseudoaccommodation caused by a myopic shift -2.6 diopter for an axial length increase 0.89 mm (with a steady-state axial length of L=22.94 mm). However, Uozato (Uozato, ARVO Meeting, 2003, Abstract) measured a very small axial length elongation (mean of 0.06mm) in true accommodation. It was known that change of the rear surface of the lens is about one-third of the front surface during accommodation: our formula shows that the AG contribution from posterior radius change (dR') is about the same as that of anterior change (dR), because of R' (6.0 mm) <R (10.2 mm), and rate function m'=2.9 m. We note that for older (or hard lenses), the AG is mainly attributed to the lens translation (or dS_1 and dS_2), whereas lens shaping dominates the power change in young or soft lenses.

Given typical rate functions of m=M5=0.53, m'=M6=1.48, M=M3=1.35 and M'=M4=-2.67 (D/mm), we may calculate the AG given by Eq. (5). However, the change of dR, dR', dS₁, dS₂, are correlated by: dR also induces dS₁=dR, and dR' also induces dS₂=dR', therefore, Eq. (5) becomes

AG = (m + M) dR(7)

Due to lens anterior curvature change (dR) and the associated anterior shift (dS₁=dR), For typical value of m=0.53, and M=1.35, we obtain AG=1.88 dR, that is the rate function of AG due to lens anterior curvature increase (or myopic shift) defined by R_A =-dR/d(AG)=11/1.88=-0.53 (mm/D), which is comparable to the measured data of 0.6 by Martinez-Enriquez et al [21].

Similarly, the change of dR' also induces $dS_2=dR'$, therefore, the AG of Eq. (5) becomes

$$AG' = (m' + M') dR'$$
 (8)

For typical value of m'=1.48, and M'=-2.67 (D/mm), AG'=4.15dR', we obtain another rate function AG'= dR'/d(AG')=1/4.15=-0.24, which is comparable to the measured data of 0.22 by Martinez-Enriquez et al [21]. we not that AG is more sensitive to dR' and dR, because typical value of R'=6.0 mm, much smaller than R=10.2 mm. These theoretically predicted values (for dR and dR') are very close to (within 10%) the measured data of Martinez-Enriquez et al. [21]. However, our theory did not calculate the rate functions due to ACD change or lens thickness change (dT), which needs many complex calculations, while the actual measured data are not well defined. Fig. 5 shows the measured average rate functions (or slopes) (shown in bars and dashed curves), and theoretical curves (in solid red curves).

Fig. 5 shows the measured data of Martinez-Enriquez et al. [21] for the rate function R_c defined as the AG per diopter change of the reshaped lens, or R_c =dDe/dD=C_F=0.62 to 0.68, comparing to the measured average value M'=0.69.

3.2 Analysis of Measured Accommodative Gain

Combining Eq. (5) and (6) allows us to calculate the AG (or dR) for a given ((measured) value of CLS increase (dc) as follows. It was reported that in non-presbyopic eyes, the length of PVZ changes from 4.6 mm in the un-accommodative state (UAS) to 3.6 mm in the accommodative state (AS) for a net change of 1.0 mm. In comparison, PVZ mobility is substantially reduced in presbyopic eyes: the PVZ length changes from 4.6 mm in the UAS to 4.45 mm in AS. for a net change of only 0.15mm. Furthermore, the CLS is significantly smaller in presbyopic eyes compared to non-presbyopic eyes: with measured values of 0.68mm and 0.35mm (in UAS) and 0.68mm and 0.2 mm (in AS), respectively. They also reported that the mid-stroma of the sclera can be heated to approximately 60°C to increase scleral elasticity and shrink the mid-stroma within a range of 100 um to 250 um of

shrinkage, and thereby increase the CLS within a rage from 200 to 500 um. The inward mobility of the ciliary body can be enhanced post-treatment by approximately 250 um.



Fig. 5. Measured data of accommodative response of the lens vs. various ocular parameters of Martinez-Enriquez et al.[21], shown in bars and dashed curves; and theoretical curves (in solid red curves); for the change of lens curvatures (dR and dR'), top figures; and anterior shift, d(ACD) and corneal thickness change, d(LT), low figures



Fig. 6. The measured data of Martinez-Enriquez et al. [21] for the rate function (or slope) shown by bars and dashed curve having an average value M'=0.69, comparing to the theoretical curves (solid curves) with M'=0.62 to 0.68

Based on above-reported data and the reduced formula of Eq (6), dR=(BC/DC)(dc). For example, for dc=0.3 mm, we obtain dR= 0.9 mm, if BC/DC=3. These data may be related to our formula, Eq. (7), AG=(m+M)dR=1.88x0.9=1.69 D. Another example is that McDonald et al. reported an eye at age 53 administered by pilocarpine-induced an accommodation of 4.25 diopter after scleral buckling. Lens thickness increase (dt) 0.18 mm and anterior shift (dS) 0.57 mm were measured associated with the total accommodation AG= M(dS) + m(dR)=A1+A2, calculated by our theory to be A1=0.53D and A2=3.78D, where a net anterior shift dS=-0.57+0.18=-0.39mm and change rate m=1.36 (D/mm) are used.

3.3 Effects of S₁ and S₂

The increase of S₁ results in a hyperopia shift (HS), whereas S_2 results in a myopia shift (MS), where M6 is about two times of M5, which has two competing terms as shown by Eq.(6). The rather high change rate M6=-2.67 (D/mm) has a significant impact on the onset of emmetropization and myopia, which are governed by the correlation among the growth of axial length $(L=S_1+S_2+T)$ and the power decrease of the cornea and lens when an eye grows [18]. The change rate M7 having a lower value than M8 can be analyzed as follows. The competing between the MS (due to the increase of ACD, S₁) and the HS (due to the associate decrease of S2 for a fixed axial length (L=S1+S2+T) results in a net hyperopic-shift, because the hyperopic component is always the dominant one, since the corneal power (D) is always less than the total system power (D) in Eq.(3.a). This new finding based on the analytic formula of Eq.(5) has not been explored before. The hyperopic shift due to the increase of S_1 is equivalent to a myopic-shift when S_1 decreases, or a forward movement of the lens. This feature is important for presbyopia accommodation which is contributed by two components: the lens curvature decrease and the lens forward movement [18,1]. The lens forward movement is also the main feature in an accommodative IOL, and our formulas, Eq. (5) provides the amount of accommodation

3.4. Laser Sclera Ablation

Lin and Mallo [23] reported the laser sclera ablation (LASA) procedures for presbyopia patients (age 42-60, mean 53.2) to cause a mean true accommodation of 1.96 diopters, without myopic-shift induced pseudoaccommodation. This was justified by no change of the far vision or corneal topography in treated eyes or comparing the pre-operative and postoperative keratometer (K) readings. Lin propose a two-component theory [19], A=A1+A2=aA + bA, with a=(0.1-0.4) for old eyes (age 50-60) and a=(0.5-0.7) for young eye (age 40-49) where lens capsules are less rigid. For extremely rigid eyes, lens anterior shift, A2=-mdS, becomes the only contribution, but it is limited to about (1.0-1.5) diopters. Based on our theory, accommodation is easier to achieve (for a given amount of ciliary body contraction, or the change of PVZ and CLS) under the following initial ocular parameters: smaller radius of curvature of the lens or the cornea; shallower anterior chamber depth or shorter globe axial length; less rigid lens capsule and larger spacing between the lens edge and ciliary muscle. Furthermore, any power changes due to corneal surface change or axial length elongation should be excluded from the true accommodation amplitude, which may be further justified by the amount of lens anterior shift and the lens radius of curvature (or thickness) changes.

The efficacy of LASA (or AG) is proposed to be proportional to the amount of scleral tissue (AST) removed (or shrinkaged), such that more space is produced for the change of PVZ and CLS from a UCS to AS for accommodation. As reported [22] that a net change of 1.0 mm of the PVZ length (from 4.6 mm in the UAS to 3.6 mm in the AS), for a non-presbyopia eye versus only 0.15 mm for a presbyopia eye, which also has a small UAS space of CLS about 0.35 mm (vs. 0.68 mm of non-presbyopia). Therefore, LASA produces increased PVZ and CLS at UAS, such that larger AG is achieved when the the zonular fibers are relaxed from UAS to its AS. We have derived the formula, Eq. (6), relating dR (or AG) and dc of CLS. However, the actual value of dR (and AG) requires accurate data for the distance of BC and CD in Fig. 3; and the relation of the amount of sclera tissue (AST) removed (or shrinkage) and dc (or dR). Based on the reported clinical outcomes of Lin et al. [23,24], Xu et al. [25]. Kaiti et al [26] and Hipsley et al. [27,28], we found out that the efficacy of LASA (or AG) is mainly governed by AST, and insensitive to the ablation patterns (either lines or dots).

4. CONCLUSION

The principles of accommodation and the key factors influencing the outcomes are discussed, where the amount of accommodation

gain (AG) after the laser scleral ablation is predicted by analytic formulas based on a 4component theory that AG is mainly due the lens anterior curvature change and its anterior shift. The AG per diopter change of the reshaped lensis 0.62 to 0.68 by our formulas, comparing to the measured average value M'=0.69.The measured data of OCT-based lens shape change during accommodationare analyzed by analytic formulas. Net change of 1.0 mm of the PVZ length (from 4.6 mm in the UAS to 3.6 mm in the AS), for a non-presbyopia eye versus only 0.15 mm for a presbyopia eye, which also has a small UAS space of CLS about 0.35 mm (vs. 0.68 mm of non-presbyopia). The efficacy of LASA (or AG) is proportional to the amount of scleral tissue removed (or shrinkaged), such that more space is produced for the change of PVZ and CLS from a UCS to AS for accommodation.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company; rather, it was funded by the personal efforts of the author.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Author has declared that no competing interests exist.

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