

Visual Performance Results after Tetraflex Accommodating Intraocular Lens Implantation

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Purpose: To present the clinical results that demonstrate the efficacy of the Tetraflex accommodative intraocular lens (IOL) in providing both enhanced distance and near acuity.

Design: Single-center prospective data collection performed in Manchester, United Kingdom.

Participants: A series of 95 eyes of 59 patients implanted with the Tetraflex lens was performed by a single surgeon. Thirty-six of these cases were implanted bilaterally.

Intervention: Implantation of the Tetraflex accommodative IOL.

Main Outcome Measures: Prospective data collection included both uncorrected distance visual acuity (UCDVA) and uncorrected near visual acuity (UCNVA) testing, manifest refraction, best-corrected distance visual acuity (BCDVA), distance corrected near visual acuity (DCNVA), and the amplitude of accommodation. Intraoperative and postoperative complications also were reported.

Results: At 6 months after surgery, 63% of all cases achieved a DCNVA of 20/40 or better. Virtually all of the patients had at least 1 diopter (D) of accommodative amplitude (98% at 1 month; 100% at 3 and 6 months); 75.7% had at least 2 D at 6 months after surgery. At 6 months or later, 92.2% had 20/40 or better UCDVA. The proportion of cases achieving a UCNVA of 20/40 or better remained relatively constant at 45% to 47%. At 6 months and later, 98.7% had a BCDVA of 20/40 or better. In the bilaterally implanted series, at 1 month after surgery, all patients had at least 1 D of accommodative ability; 96% had at least 2 D at 6 months. One hundred percent achieved a BCDVA, 89.3% achieved a DCNVA, and 74.1% achieved a UCNVA of 20/40 or better at 6 months after surgery.

Conclusions: The Tetraflex accommodating IOL provides enhanced near vision with good distance vision 6 months after surgery. *Ophthalmology* 2007;114:1679–1684 © 2007 by the American Academy of Ophthalmology.

Many of the obstacles of modern cataract surgery have been resolved by continuously evolving surgical techniques such as small-incision phacoemulsification and intraocular lens (IOL) implantation. Although the ultimate goal of cataract surgery is to restore uncorrected distance and near vision, standard monofocal IOLs allow patients clear vision only at a fixed distance, requiring spectacles to provide functional vision at other distances.^{1–5} Postoperative presbyopia remains an unsolved challenge in the ophthalmic field. Presbyopia can be managed in a number of ways. Traditionally, it has been treated with the use of spectacles with distance or near correction, or both, or contact lenses using monovision techniques. Other options can include zonal photorefractive keratectomy,⁶ implantation of corneal inlays, and the implantation of multifocal or accommodative IOLs.

Multifocal IOLs allow multiple object distances to be focused on by various parts of the eye. Although these lenses have been satisfactory for some patients, non-acuity-related

visual problems have been intolerable to other patients.⁷ Despite the excellent restoration of near vision, the quality of vision obtained with multifocal lenses is compromised with problems of decreased contrast sensitivity, halos, and night glare.^{8–10} Further efforts to address the presbyopic challenge in cataract surgery have resulted in the alternate approach of using an accommodating IOL. A monofocal IOL with accommodative abilities may lead to superior vision quality without the inherent optic problems of the multifocal IOLs.

The Tetraflex IOL (Lenstec, Inc., St. Petersburg, FL) is currently CE marked in Europe, where this data was collected, and also is under clinical trial with the United States Food and Drug Administration as an accommodative IOL. The United States trial will complete enrollment of 350 primary eye cases in early 2007 and will have completed 1 year of follow-up data on at least 300 cases available in early 2008. In the present international data collection, we evaluated our clinical experience (both safety and efficacy end points) with the Tetraflex accommodative IOL and assessed the visual and accommodative changes within 6 months after implantation.

Patients and Methods

Patient Characteristics

In this single-center prospective data collection performed in Manchester, United Kingdom, a population of 95 eyes of 59

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subjects received the Tetraflex accommodative lens, with 36 of the patients having the lens implanted bilaterally. All patients who underwent implantation of the Tetraflex lens had prior informed consent, and all data were collected prospectively on standardized case report forms in a consecutive series of cases meeting the inclusion criteria. Because the data collection was performed in the United Kingdom, where the IOL was CE marked and thus approved for use, and no testing that put the patient at extra risk was performed, Ethics Committee approval was not obtained; however, the prospective data collection was performed in conformance to the World Medical Association Declaration of Helsinki.

Subjects included in the prospective data collection were required to have implantation of the Lenstec Tetraflex intraocular implant and have potential for good visual acuity (20/40 or better best-corrected visual acuity). Exclusion criteria included any subject with a preoperative cylinder of 2.5 diopters (D) or more (astigmatism) or who required corneal relaxing incisions for the treatment of astigmatism and any subject diagnosed with amblyopia before surgery. The mean age \pm standard deviation was 53.9 ± 11.77 years. In this patient series, 33.3% were male and 66.7% were female.

Tetraflex Accommodating Intraocular Lens

The Tetraflex accommodating posterior chamber IOL is a single-piece IOL (Model KH3500) with extremely flexible 10° anteriorly angulated closed-loop haptics. The Tetraflex IOL can be inserted through a small (2.5–3.0-mm) clear corneal incision and is manufactured completely from medical grade hydroxyethyl methacrylate (26% water content) and a polymerizable ultraviolet blocker. The Tetraflex 1-piece hydrophilic acrylic lens has a 5.75-mm optic with square edges.

Surgical Technique

The power of the lens used in surgery was calculated using a postoperative refractive target of 0 to -0.5 D in all eyes using the Holladay 2 formula. Surgery was performed using a topical anesthesia consisting of 1 drop of tetracaine 5 minutes before surgery and 1 drop immediately before surgery commenced. Lidocaine (0.3 ml of 1%) for intraocular injection was used immediately after paracentesis. The surgical method was standard phacoemulsification cataract surgery with clear corneal incision. The lens was inserted through commercially available 2.2- or 2.8-mm cartridges using standard posterior chamber IOL insertion techniques. Gentamicin (5 mg) and 0.5 ml epinephrine (1:1000) were added to the 500 ml balanced salt solution infusion fluid bottle used for phacoemulsification and an intracameral injection of cefuroxime (0.1 ml at concentration of 1 mg/ml) was injected at the end of surgery. Postoperative drops of both prednisolone sodium phosphate 1%

and ofloxacin 4 times daily for 10 days were used for all patients. All operations were performed by the same surgeon.

Outcome Measures

The preoperative assessment included any preoperative conditions, manifest refraction, and best-corrected distance visual acuity (BCDVA). Postoperative assessments were performed and recorded at 1 day, 1 week, 1 month, 3 months, and 6 months. Follow-up rates were more than 90% at 1 week, 1 month, and 3 months after surgery and 81% at 6 months or more after surgery.

The follow-up on day 1 included a slit-lamp examination along with uncorrected distance visual acuity (UCDVA) testing. At the 1-week, 1-month, and 3-month examinations, patients were tested additionally for manifest refraction, BCDVA, distance-corrected near visual acuity (DCNVA), and the amplitude of accommodation. The final visit occurred at 6 months after surgery. Distance visual acuity (both uncorrected and distance corrected) was measured using the Snellen chart at a standard distance in a well-lit room. Near visual acuity, measured both monocularly and binocularly, was determined using a Jaeger reading chart held 40 cm from the eye in good lighting conditions. Accommodation was determined subjectively using the Royal Air Force accommodation and vergence measurement rule while using a push-up method to determine the accommodative amplitude. The patient was asked to fixate on a movable target of a minimum angle (5° arc) of resolution determined with best distance spectacle correction. Best spectacle distance correction was used to eliminate potential pseudoaccommodative effects of residual myopia and corneal cylinder. A standard 100% contrast acuity test card mounted on a movable scale was moved toward the eye until the patient reported it to be blurred. The distance to the eye was recorded and the inverse distance in meters was the amplitude of accommodation. No anatomical studies to demonstrate movement of the IOL with accommodative effort were performed.

Results

Safety Assessment

Best Spectacle-Corrected Visual Acuity. From a safety standpoint, 75 of 76 eyes (98.7%; 95% confidence interval, 96.1%–100%) had a best spectacle-corrected distance vision acuity of 20/40 or better and all patients had 20/50 visual acuity or better at the 6-month follow-up.

Intraoperative and Postoperative Complications. No intraoperative complications were observed. Fibrin was noted in the anterior chamber in 1 patient at 1 day and 5 patients at 1 week after surgery. All cleared with topical antiinflammatory drops. The

Table 1. Distance-Corrected Near Vision with Time

	1 Week	1 Month	3 Months	6 Months or Later
20/20 or better	2/85 (2.4%)	1/85 (1.2%)	1/87 (1.1%)	1/76 (1.3%)
20/25 or better	18/85 (21.2%)	7/85 (8.2%)	5/87 (5.7%)	9/76 (11.8%)
20/32 or better	32/85 (37.6%)	16/85 (18.8%)	22/87 (25.3%)	20/76 (26.3%)
20/40 or better	50/85 (58.8%)	39/85 (45.9%)	45/87 (51.7%)	48/76 (63.2%)
20/50 or better	50/85 (58.8%)	39/85 (45.9%)	45/87 (51.7%)	48/76 (63.2%)
20/63 or better	68/85 (80%)	57/85 (67.1%)	66/87 (75.9%)	67/76 (88.2%)
20/80 or better	68/85 (80%)	57/85 (67.1%)	66/87 (75.9%)	67/76 (88.2%)
20/200 or better	77/85 (90.6%)	71/85 (83.5%)	75/87 (86.2%)	75/76 (98.7%)
Worse than 20/200	8/85 (9.4%)	14/85 (16.5%)	12/87 (13.8%)	1/76 (1.3%)
Not reported	9	5	0	1
Total	94	90	87	77

Table 2. Accommodative Amplitude with Time

	1 Week	1 Month	3 Months	6 Months or Later
>0.0	82/82 (100%)	80/80 (100%)	86/86 (100%)	74/74 (100%)
>1.0	82/82 (100%)	78/80 (97.5%)	86/86 (100%)	74/74 (100%)
>2.0	59/82 (72%)	56/80 (70%)	63/86 (73.3%)	56/74 (75.7%)
≥2.5	56/82 (68.3%)	50/80 (62.5%)	56/86 (65.1%)	53/74 (71.6%)
>3.0	25/82 (30.5%)	21/80 (26.3%)	21/86 (24.4%)	14/74 (18.9%)
>4.0	9/82 (11%)	8/80 (10%)	5/86 (5.8%)	1/74 (1.4%)
>5.0	6/82 (7.3%)	4/80 (5%)	0/86 (0%)	0/74 (0%)
>6.0	5/82 (6.1%)	3/80 (3.8%)	0/86 (0%)	0/74 (0%)
>7.0	1/82 (1.2%)	2/80 (2.5%)	0/86 (0%)	0/74 (0%)
Mean	3.09	3.03	2.79	2.77
Standard deviation	1.37	1.52	0.80	0.64
90% confidence interval	2.85 to 3.36	2.77 to 3.35	2.65 to 2.96	2.65 to 2.92
Not reported	12	10	1	3
Total	94	90	87	77

BCDVA was 20/25 at the last visit in 1 case and 20/20 or better in the remainder of these cases. Both eyes of 1 patient were reported to have mild uveitis at 1 month that cleared with topical medication. The BCDVA in both eyes at 6 month after surgery was 20/15. One case required a neodymium:yttrium–aluminum–garnet posterior capsulotomy for posterior capsular opacification at 3 months after surgery. At the 6-month follow-up, 3 months after the neodymium:yttrium–aluminum–garnet capsulotomy, this case demonstrated 2 D of accommodative amplitude and had a DCNVA of 20/25. One eye at 3 months underwent LASIK to treat residual refractive error. No other postoperative complications were reported in this series.

Efficacy Assessment

Uncorrected Visual Acuity. At 6 months or later, 71 of the 77 reported eyes (92.2%) had 20/40 or better UCDVA, 72.7% had 20/25 or better UCDVA, and 50.6% achieved 20/20 or better UCDVA. With regard to uncorrected near vision, at 6 months or later, 37 of the 77 reported cases (48.1%) had 20/40 or better uncorrected near visual acuity and 88.3% had 20/80 or better uncorrected near visual acuity.

Distance-Corrected Near Vision. Table 1 demonstrates the DCNVA over time. At 1 month after surgery, 45.9% of cases had achieved 20/40 or better DCNVA, and by 6 months after surgery, 63.2% (48 of the 76 reported cases) had achieved 20/40 or better DCNVA. Additionally, 88.2% of reported cases could see 20/63 or better.

Manifest Refraction. A total of 71 of the 77 cases (92.2%) examined at 6 months after surgery were within ±1.0 D of

emmetropia (manifest refraction spherical equivalent), and 72.7% were within ±0.5 D of emmetropia at 6 months or later.

Accommodative Amplitude. Table 2 demonstrates that 100% of the 74 reported cases at 6 months or more after surgery had an accommodative amplitude of more than 1.0 D, 75.7% could accommodate more than 2.0 D, 71.6% could accommodate 2.5 D or more, and 18.9% could accommodate more than 3.0 D. We also examined the relationship (correlation) between accommodative amplitude at 6 months after surgery and patient age and found a correlation coefficient and the slope of the best fit line both to be 0, indicating no relationship between the 2 variables.

Bilateral Series Cohort: Efficacy Assessment

Separate data analysis was carried out for those patients who underwent bilateral implantations with the Tetraflex lens and were tested bilaterally (examinations performed with both eyes open).

Best Spectacle-Corrected Visual Acuity. Six months or later after Tetraflex IOL implantation, all examined patients had a BSCVA of 20/32 or better; additionally, 96.4% had 20/25 or better visual acuity. All patients (27 reported) had 20/25 or better best-corrected near visual acuity at 6 months.

Uncorrected Visual Acuity. With regard to unaided distance vision (UCDVA), there was no degradation in visual performance over time; 92.6% of the cases achieved 20/25 and 20/32 or better UCDVA, and 96.3% achieved 20/40 or better in UCDVA at 6 months after surgery. By 6 months after surgery, the unaided near visual acuity of the series was 20/40 or better in 74.1% of the cases and 20/32 or better in 63% of the cases.

Table 3. Distance-Corrected Near Vision with Time in Bilaterally Implanted Patients Examined Binocularly

	1 Week	1 Month	3 Months	6 Months or Later
20/20 or better	5/32 (15.6%)	1/32 (3.1%)	1/32 (3.1%)	1/28 (3.6%)
20/25 or better	15/32 (46.9%)	3/32 (9.4%)	6/32 (18.8%)	8/28 (28.6%)
20/32 or better	19/32 (59.4%)	9/32 (28.1%)	14/32 (43.8%)	19/28 (67.9%)
20/40 or better	24/32 (75%)	20/32 (62.5%)	22/32 (68.8%)	25/28 (89.3%)
20/50 or better	24/32 (75%)	20/32 (62.5%)	22/32 (68.8%)	25/28 (89.3%)
20/63 or better	28/32 (87.5%)	26/32 (81.3%)	27/32 (84.4%)	27/28 (96.4%)
20/80 or better	28/32 (87.5%)	26/32 (81.3%)	27/32 (84.4%)	27/28 (96.4%)
20/200 or better	30/32 (93.8%)	29/32 (90.6%)	31/32 (96.9%)	28/28 (100%)
Worse than 20/200	2/32 (6.3%)	3/32 (9.4%)	1/32 (3.1%)	0/28 (0%)
Not reported	3	2	0	0
Total	35	34	32	28

Table 4. Accommodative Amplitude with Time in Bilaterally Implanted Patients Examined Binocularly

	1 Week	1 Month	3 Months	6 Months or Later
>0.0	32/32 (100%)	29/29 (100%)	32/32 (100%)	26/26 (100%)
>1.0	32/32 (100%)	29/29 (100%)	32/32 (100%)	26/26 (100%)
>2.0	27/32 (84.4%)	25/29 (86.2%)	30/32 (93.8%)	25/26 (96.2%)
≥2.5	25/32 (78.1%)	24/29 (82.8%)	28/32 (87.5%)	25/26 (96.2%)
>3.0	16/32 (50%)	11/29 (37.9%)	13/32 (40.6%)	12/26 (46.2%)
>4.0	11/32 (34.4%)	5/29 (17.2%)	6/32 (18.8%)	1/26 (3.8%)
>5.0	5/32 (15.6%)	2/29 (6.9%)	1/32 (3.1%)	1/26 (3.8%)
>6.0	5/32 (15.6%)	2/29 (6.9%)	0/32 (0%)	0/26 (0%)
>7.0	1/32 (3.1%)	2/29 (6.9%)	0/32 (0%)	0/26 (0%)
Mean	3.95	3.84	3.28	3.17
Standard deviation	1.95	3.13	0.98	0.71
90% Confidence interval	3.41 to 4.6	2.96 to 4.9	3 to 3.62	2.95 to 3.44
Not reported	3	5	0	2
Total	35	34	32	28

Distance-Corrected Near Vision. With the best distance correction in place, the results show that near vision significantly improved over time (Table 3). Sixty-two percent of bilaterally implanted patients had a DCNVA of 20/40 or better at 1 month after surgery. Of the 28 examined patients at 6 months or later, 89.3% (25 cases) had 20/40 (and 20/50) visual acuity or better. Twenty-seven of the 28 examined cases (96.4%), had a DCNVA of 20/63 or better.

Accommodative Amplitude. As early as 1 month after surgery, all of the patients had at least 1 D of accommodative ability. At 6 months, 96% had at least 2 D of accommodative amplitude, and 46% demonstrated at least 3 D of accommodation (Table 4).

Discussion

Monovision and multifocal lenses have not been the solution to the objective of providing patients with both functional distance and near vision.¹¹ Despite excellent restoration of visual acuity in cataract surgery, most patients remain presbyopic using standard monofocal IOLs because of the lack of accommodation in pseudophakic eyes. Multifocal IOLs, although addressing the issue of accommodation by demonstrating excellent reading vision under conditions of good illumination, show evidence of compromised vision with photic occurrences such as glare, halos, and contrast sensitivity.^{8,9,12,13} Additionally, intermediate visual acuity with multifocal IOLs may be significantly worse than that obtained with monofocal IOLs.¹⁴ An accommodative IOL may restore functional near vision while also giving the patient high-quality intermediate and distance vision.¹⁵

This clinical data collection evaluated the safety of the Tetraflex accommodating IOL in patients undergoing crystalline lens removal and confirmed the efficacy of the lens in correcting refractive errors. The primary safety end points were a loss of BSCVA to below 20/40 and any incidence of adverse events and complications. The threshold standard for loss of BSCVA below 20/40 for best-case cataract cases by the International Standards Organization (ISO Standard 11979-7:2006(E)) is 93.6%. Even with our relatively modest sample size of 75 cases examined at 6 months after surgery, this threshold was met because the lower limit of

the 95% confidence interval for this value was 96.1%. Although there were very few complications and none were serious, our small sample size allows detection of threshold event rates only on the order of 4%.

The primary efficacy end points were the level of accommodative ability measured by DCNVA and accommodative amplitude. Uncorrected near visual acuity is of lesser value in assessing accommodative ability because it is sensitive to patients' residual refractive error, therefore permitting variance owing to additional factors other than solely the IOL's ability to produce accommodation. With the best distance correction in place, near vision improved consistently over time. With the patient's best-corrected distance in place, 63% could see 20/40 or better and 89% could see 20/63 or better. One hundred percent of the 78 reported cases at 6 months or more after surgery had accommodative amplitude of more than 1.0 D and 75.6% could accommodate more than 2.0 D. These results demonstrate the lens' ability to provide enhanced, functional near vision while allowing the patient quality distance vision as well.

The Tetraflex lens seems to perform at its best in patients who have the lens implanted bilaterally. As can be seen in Table 5 regarding all efficacy variables, the cases with both eyes implanted with the Tetraflex IOL exceeded the performance of the monocular cohort as a whole. Patients have a variety of preferences and needs regarding their daily lives.

Table 5. Safety and Efficacy Variables of the 2 Study Cohorts

Parameter at 6 Months or Later after Intraocular Lens implantation	All Eyes	Bilateral Cohort Examined Binocularly
Best-corrected visual acuity 20/40 or better	98.7%	100%
Uncorrected visual acuity 20/40 or better	92.2%	96.3%
Uncorrected near vision 20/40 or better	48.1%	74.1%
Distance-corrected near vision 20/40 or better	63%	89.3%
Distance-corrected near vision 20/63 or better	88.2%	96.4%
Accommodative amplitude >2.0 D	75.7%	96.2%
Accommodative amplitude >3.0 D	18.9%	46.2%

D = diopters.

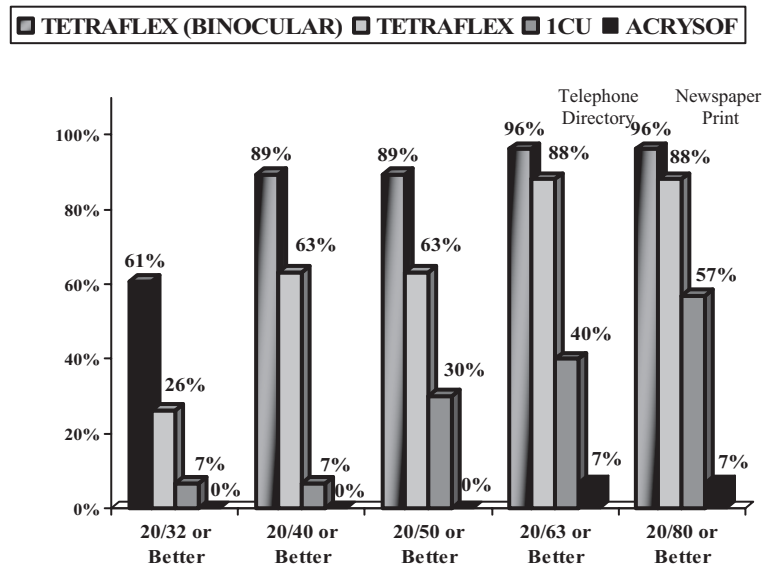


Figure 1. Bar graph comparing distance-corrected near visual acuity of the Tetraflex intraocular lens (IOL; binocular and monocular), 1CU accommodative IOL, and AcrySof MA30 monofocal control IOL.⁵

Emphasizing the importance of reading for personal convenience is crucial to understanding patients' needs in terms of IOLs. The results of the Tetraflex IOL's near vision capabilities need to be put into perspective. To correlate the IOL's ability to meet patients' functional needs, Sanders (unpublished data) determined the levels of functional near vision acuity measurements or print sizes that would help patients with social reading and activities. A variety of commonly read print objects (want ads, stock quotes, standard newspaper, nutrition labels, etc.) were measured and correlated to the DCNVA measurements of the IOL using computer-generated font size equivalencies of a logarithmic visual acuity near chart (Early Treatment of Diabetic Retinopathy Study). The smallest print objects studied were nutritional information on sweetener packets where the type was between 20/40 (J5) and 20/50 (J6). Standard newspaper print, stock quotations, and want ads were identical in numerous national and local publications; want ads, pocket bibles, and stock quotations were 20/50 (J6). Telephone directory listings were 20/63 (J8), and standard newspaper print and journal and magazine articles were 20/80 (J9).

The DCNVA, tested monocularly using another accommodative IOL (1CU, Human Optics, Erlangen, Germany) and a monofocal control IOL (AcrySof MA30, Alcon, Fort Worth, TX) at 6 months after surgery, recently was reported.⁵ Tested monocularly, 88% of Tetraflex, 40% of 1CU, and 7% of MA30 eyes had DCNVA sufficient to read newspaper and telephone directory print, and 63% of Tetraflex, 30% of 1CU, and 0% of MA30 monofocal IOL eyes could read want ads, stock quotations, and pocket bibles (Fig 1). Tested binocularly after bilateral implantation, 96% of Tetraflex patients could read telephone directory print, and 89% could read ads, stock quotations, and pocket bibles. The Tetraflex data presented here was dramatically better than the reported monofocal control data and that of another accommodative IOL.

It is a common belief that an IOL to treat presbyopia must provide crisp, clear, 20/20 near vision that can be attained more readily with multifocal IOLs. A review of the print sizes of commonly read print objects demonstrates that this level of vision is not necessary for patients to read functionally in their daily lives. With the Tetraflex lens, it has been shown that a large percentage of patients possess the near visual acuity necessary to read virtually all social (daily) reading materials without the use of spectacles.

In summary, effectiveness of the Tetraflex accommodative IOL has been demonstrated in this clinical data collection, and no major safety events were observed in this relatively small series. This IOL provides enhanced near vision with good distance vision 6 months after surgery.

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