# **ORIGINAL ARTICLE**

# Contact Lens Methods for Clinical Myopia Control

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#### **ABSTRACT**

**Purpose.** A number of optical methods for slowing myopia progression have been tested and are now available. However, data on real-world use in clinical use is scarce. Here, we present a review of the clinical outcomes for patients attending a specialist myopia control clinic at The University of Auckland Optometry School, NZ.

Case Series. We report a comparative case series of 110 patients (aged 4–33 years, mean:  $12.13 \pm 4.58$  years, 62% female) who attended the clinic between 2010 and 2014. Fifty-six were prescribed orthokeratology, 32 dual focus soft contact lenses, and 22 received advice only. Initial myopia, vitreous and axial eye length, previous myopia progression, age, number of myopic parents, and gender were not significantly different between orthokeratology and dual focus soft contact lens groups. Mean follow-up time for the orthokeratology and dual focus lens groups was the same (orthokeratology:  $1.30 \pm 0.88$  years; dual focus lens:  $1.33 \pm 0.80$  years (p = 0.989)). There was a significant reduction in the annualized myopia progression in both groups (orthokeratology:  $-1.17 \pm 0.55$  to  $-0.09 \pm 017$  D/yr, p < 0.001; dual focus soft contact lens:  $-1.15 \pm 0.46$  to  $-0.10 \pm 0.23$  D/yr, p < 0.001). There was no difference between orthokeratology and dual focus lens treatment efficacy (p = 0.763), nor in axial or vitreous chamber length changes after treatment (p = 0.184). One adverse event was reported over the 4-year period.

**Conclusions.** Both orthokeratology and dual focus soft contact lenses are effective strategies for targeting myopia progression in the clinic. We saw no significant difference in the efficacy of the two methods in this regard, and so we believe there are very few barriers for any contact lens practitioner to be actively promoting myopia control treatment to at-risk patients.

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Key Words: myopia control, orthokeratology, multifocal contact lens, dual focus contact lens

he high prevalence of myopia worldwide is well documented, and the sight-threatening conditions associated with high degree of myopia have long been recognized. More recently, it has become apparent that low to moderate degrees of myopia also increase the risk of myopic maculopathy, retinal detachment, glaucoma, and cataract, providing further motivation for public health initiatives to reduce myopia incidence. However, until those initiatives are widely implemented, morbidity associated with myopia is best reduced by controlling myopia progression in those affected. A Cochrane review in 2011 concluded that the most effective treatment for slowing myopia progression was the use of antimuscarinic topical medications. Although atropine eye drops are often prescribed in parts of Asia, the side effects of light sensitivity and near blur, unknown

mode of action, unknown long-term side effects, and limited availability have restricted their use elsewhere. Controlled studies of orthokeratology, 10-12 multifocal and dual focus contact lenses, 13-15 low-concentration atropine, 16 progressive addition spectacle lenses, 17 and prismatic bifocals<sup>18</sup> suggest that these methods can also slow myopia progression to varying degrees, and a recent meta-analysis of orthokeratology studies<sup>19</sup> indicated that useful reductions in eye elongation and myopia progression can reliably be achieved with orthokeratology. However, the underlying mechanisms of all of these methods remain poorly understood.<sup>20</sup> Childhood is the preferred time to initiate myopia control, as early-onset myopia is associated with higher progression rate and therefore increased risk of continuing to high myopia.<sup>21</sup> In an effort to increase awareness and adoption of myopia control methods by both clinicians and the public, a specialized Myopia Control Clinic opened for 1 day per week, seeing fee-paying public patients in The University of Auckland Optometry Clinic in 2010. Here, we report the efficacy of contact lens treatments used in the clinic.

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## **CASE REPORTS**

We present a consecutive case-series study of data from all 114 patients that had full eye examinations in our Myopia Control Clinic across 652 appointments between 2010 and 2014: this includes all patients seen during that time. The study adhered to the tenants of the Declaration of Helsinki, and procedures for deidentifying clinical data were approved by The University of Auckland Human Participants Ethics Committee (Ref. 014505). The clinician who managed all the patients de-identified the patient data by removing the name, date of birth, all contact details, and medical record numbers, and then assigned an unrelated identification number that was used to link subsequent visits of individual patients. The clinician also coded ethnicity, sex, and treatment so that the analyst was masked to the treatments. The analyst, who was independent of the clinic, performed statistical analyses on the de-identified data set. Thus, the treatment a patient received was determined clinically: it was neither predetermined nor allocated and there were no control treatments. Consistent with standard clinical practice, patients consented verbally to all procedures and could refuse or discontinue treatment or any individual test at any time.

## **Clinical Assessments**

Patients were seen in the clinic if they or their referring optometrist reported, at the time of making the initial appointment, a myopic refraction that had progressed more than -0.25 D over the last year. Clinical management of all patients and all optometric procedures were carried out by the same optometrist. Optometric measures included subjective refraction, objective refraction by retinoscopy and autorefraction (NVision-K 5001, Osaka, Shin Nippon, Japan), ocular biometry (Lenstar LS900, Köniz, Haag-Streit, Switzerland) for measurement of vitreous chamber depth (VCD) and axial eye length (AXL), and corneal topography (E300, Medmont, Nunawading, Australia). Visual acuity (AT20P; Medmont, Nunawading, Australia) was recorded while wearing dual focus contact lenses or habitual correction (for advice), and without the orthokeratology lens on the eye once the lens had been finalized. Disassociated phorias (Cover Test and Von Graefe), stereopsis (Wirt rings, Prevision Vision, USA), and anterior and posterior ocular health examinations were performed on every patient. In patients with suspected pseudomyopia, or with myopic shifts greater than 1.50 D per year, refraction with cycloplegia (one drop of 1% cyclopentolate) was performed at an ancillary appointment. Rates of myopia progression were computed regularly throughout treatment for the benefit of the patient and for the clinician to track efficacy of treatment.

## **Management Options**

Patients were initially offered the choice of treatment versus no treatment, then conventional glasses or contact lenses, and then specific interventions such as orthokeratology, dual focus contact lenses, or low-concentration atropine eye drops. The practitioner explained that there was no evidence that conventional spectacles or contact lenses slowed the progression of myopia. The benefits and risks associated with orthokeratology, dual focus contact lenses, and low-concentration atropine were explained and discussed with

the patients and parents. No preferential recommendations were made regarding the relative efficacy of the treatments, though it was made clear that none of the interventions could guarantee to completely prevent progression. Almost all patients chose contact lens treatments, specifically orthokeratology (Paragon CRT, Arizona, USA, or custom-made Falco, Tägerwilin, Switzerland), and dual focus soft contact lenses (daily disposable MiSight, CooperVision, Pleasanton, USA, or custom-made dual focus lenses with concentric +2.00 D add zones<sup>14</sup>). However, no attempt was made to analyze the complex factors influencing patient choice of one treatment over another, nor to randomize treatment allocations. Some patients opted to not start treatment for various reasons (not progressing, not myopic, or resource constrained), so they received advice only. Such advice included increasing time spent outdoors,4 taking frequent breaks to look out of a window during near tasks,<sup>3</sup> and ensuring that their near working distance was at least forearm length.<sup>22</sup> Few patients considered spectacle options despite them being offered. This may have been due to the public perception of regular glasses being ineffective, or even causative of myopia, the availability of other options, or the cost involved in updating spectacles compared to changing a contact lens prescription. Three patients commenced low-concentration atropine (0.01%) eye drops and one patient wore alternating monovision spectacles.<sup>23</sup> Follow-up appointments were dependent on the clinical indication, but once established, review appointments were scheduled approximately every 6 to 12 months.

# Assessing Efficacy of Treatments

Measures of efficacy were based on changes in myopia progression and rate of eye elongation. Both eyes received treatment and were refracted at every visit, but for the purposes of this report, myopia progression during treatment was calculated based on change in the right eye only. Differences between pretreatment measures and measures made during treatment were pooled into orthokeratology and dual focus contact lens groups. Measures of clinic occupancy, such as chair time and number of visits, were also collected. Myopia progression was determined as the annualized dioptric progression (D/yr) in the right eye, based on mean sphere (sphere + cylinder) over-refraction in the spectacle plane. For both dual focus and orthokeratology lens wearers, overrefractions were performed with the lenses on the eye. The purpose was to reduce refractive variability due to time of day or difference in lens wear time, particularly for orthokeratology wearers. Rate of eye elongation was determined as the annualized change in VCD and AXL (mm/yr) in the right eye measured by ocular biometry. Computation of pretreatment myopia progression was based on historical data. The clinic predominantly operated as a referral clinic, and so previous refractions and dates were available to calculate myopia progression for the year before the first clinic visit. Previous progression rate was annualized on a pro rata basis using the time period in days between the previous refraction and the first visit to our clinic. During treatment, refractive changes were only considered relevant if the difference from presenting refraction was greater than ±0.25, to allow for refractive variability. Progression rates during treatment were calculated by taking the most recent refraction, subtracting it from the presenting refraction at the initial clinic visit, and annualizing

**TABLE 1.**Distribution of patient details at first visit to our myopia control clinic, who either received orthokeratology, dual focus contact lenses, or advice only

	Ethnicity		Myopic parents			Sex		Mean sphere (D)		Age (yrs)	
	East Asian	Other	0	1	2	Female	Male	Mean	SD	Mean	SD
Advice	13	9	3	4	14	14	8	-2.71	2.41	14.02	7.27
	59%	41%	14%	19%	66%	64%	36%				
Orthokeratology	33	23	9	13	33	32	24	-2.89	2.74	11.69	2.61
	59%	41%	16%	24%	60%	57%	43%				
Dual focus contact lenses	18	14	4	10	18	22	10	-2.98	2.39	11.41	2.39
	56%	44%	13%	31%	56%	69%	31%				
Total	64	46	16	27	65	68	42	-2.88	2.55	12.07	4.03
	58%	42%	15%	25%	60%	62%	38%				

There was no significant difference in ethnicity, number of myopic parents, sex, and initial mean sphere refraction between children receiving different treatments, except for age: the children who ultimately received advice were older than those who received a contact lens—based treatment (p = 0.037).

by dividing the time between appointments in days by 365. Changes in VCD and AXL were calculated from biometry measures and annualized for progression (mm/yr) in the same manner as for refractions. Follow-up time in the clinic was calculated using the difference in days between the most recent appointment and the first clinic visit. Patients with a follow-up period of less than 3 months were not included in posttreatment data analysis to prevent improper extrapolation of progression rates. The "advice only" group was not included in progression comparisons because only a few patients in this group were followed for longer than 3 months.

## **Statistical Analysis**

Pretreatment patient parameters including age, presenting refraction, and myopia progression rate were compared between the orthokeratology, dual focus contact lens, and advice groups by one-way ANOVA, with Turkey HSD post hoc testing. Non-parametric variables such as ethnicity and number of myopic parents were compared with Kruskal-Wallis one-way ANOVA for ordinal variables and chi-squared tests for nominal data. General linear models were constructed to compare myopia progression rates between the three treatment groups with age, sex, number of myopic parents, and ethnicity as covariates. Pairwise comparisons for nonparametric data show the adjusted significance for multiple comparisons. Correlations were investigated with Pearson R ( $r_{(df)}$ ) for parametric data and Spearman's Rho ( $\rho_{(df)}$ ) for nonparametric data. P values <0.05 were taken as significant.

## **RESULTS**

#### **Initial Visit**

From a total of 114 patients seen, the 4 patients who commenced low-concentration atropine eye drops or alternating monovision spectacles were excluded from further analysis because of low numbers. Of the 110 patients who were included in the following analysis, 22 received advice and no treatment (advice), 56 were treated with orthokeratology, and 32 wore dual focus contact lenses (Table 1). At the initial visit, there was a significant difference in age between the groups (ANOVA,  $F_{(2,107)} = 3.400$ , p = 0.037), with the advice group being older (14.0  $\pm$  7.23 years)

than the dual focus group (11.4  $\pm$  2.39 years, p = 0.049), but not the orthokeratology group (11.7  $\pm$  2.61 years, p = 0.053). Presenting ages for orthokeratology and dual focus groups were not different (p = 0.948). There was also a difference in the previous year's progression rate (ANOVA,  $F_{(2,106)} = 7.089$ , p = 0.001), with the advice group having significantly less progression  $(-0.65 \pm 0.73 \text{ D/yr})$  than both the dual focus  $(-1.15 \pm 0.46 \text{ D/yr})$ , p = 0.005) and the orthokeratology (-1.17 ± 0.55 D/yr, p = 0.001) groups, which were not different from each other (p = 0.995, Fig. 1A). There was no difference in initial mean sphere (ANOVA,  $F_{(2,106)} = 0.074$ , p = 0.929), VCD (ANOVA,  $F_{(2,101)} = 0.098$ , p = 0.0980.907), AXL (ANOVA,  $F_{(2,101)} = 0.511$ , p = 0.602), number of myopic parents (KW, n = 108, p = 0.837), sex ( $\chi^2$  = 1.19, df = 2, p = 0.552), or ethnicity ( $\chi^2 = 0.069$ , df = 2, p = 0.966) between all three groups. A younger presenting age was correlated with a higher presenting progression rate ( $r_{(107)} = 0.294$ , p = 0.002), shorter VCD  $(r_{(102)} = 0.334, p = 0.001)$ , and a shorter AXL  $(r_{(102)} = 0.354, p =$ 0.0002). There was no correlation between previous progression rate and presenting refraction ( $r_{(106)} = 0.078$ , p = 0.424), and correlations between previous progression rate and ethnicity ( $\rho_{(102)} = 0.184$ , p = 0.056), sex ( $\rho_{(107)} = 0.149$ , p = 0.056), and number of myopic parents ( $\rho_{(106)} = 0.178$ , p = 0.065) fell just short of significance.

# Treatment Efficacy

Myopia progression rates during treatment were significantly lower than pretreatment rates in both the orthokeratology group ( $-0.09\pm0.17$  D/yr vs. pre:  $-1.17\pm0.55$  D/yr, n = 52, p < 0.001) and in the dual focus contact lens group ( $-0.10\pm0.23$  D/yr vs. pre:  $-1.15\pm0.46$  D/yr, n = 32, p < 0.001, Fig. 1A). Despite the wide range of patient age and refractive error within our case series (Fig. 2), the progression rates during treatment were not significantly different between the orthokeratology and dual focus groups ( $F_{(1,82)}=0.092$ , p = 0.763), and mean follow-up time was not different between groups (orthokeratology:  $1.30\pm0.88$  years, dual focus contact lens:  $1.33\pm0.80$  years,  $F_{(1,86)}=0.018$ , p = 0.894). There was no difference between orthokeratology and dual focus groups in the annual change in AXL (orthokeratology:  $0.08\pm0.31$  mm, dual focus contact lens:  $0.18\pm0.29$  mm, p = 0.230) or VCD (orthokeratology:  $0.09\pm0.33$  mm, dual focus

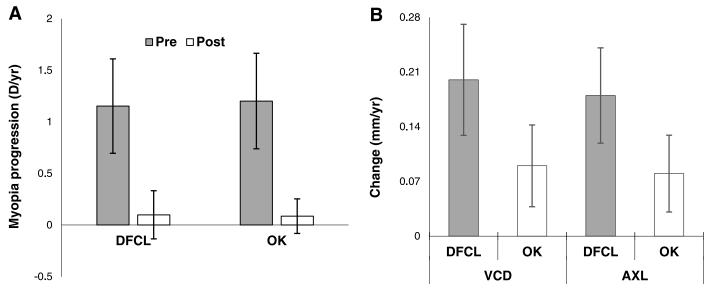


FIGURE 1.

(A) Annualized myopia progression between orthokeratology (OK) and dual focus contact lenses (DFCL) wearers in the year before admission, compared to myopia progression while at our myopia control clinic. Both OK and DFCL groups had similar myopia progression rates pre- (p = 0.995) and posttreatment (p = 0.763), and both groups had a significant reduction in myopia progression after treatment (p < 0.001). (B) There was no significant difference in the annualized change in vitreous chamber depth (VCD, p = 0.184) nor axial length (AXL, p = 0.230) between the OK and DFCL groups. Error bars are SEM.

contact lens:  $0.20 \pm 0.34$  mm, p = 0.184, Fig. 1B). Visual acuity over the treatment period was not significantly different between orthokeratology (0.08 ± 0.11 logMAR), dual focus contact lens  $(0.07 \pm 0.11 \text{ logMAR})$ , nor the advice groups  $(0.05 \pm 0.05)$ logMAR,  $F_{(2,181)} = 0.338$ , p = 0.713).

Although the retrospective study design and maximum follow-up period of 3 years makes it difficult to determine factors influencing treatment efficacy, there was no correlation between the posttreatment progression rates with the length of follow-up (r = -0.099, n = 88, p = 0.372), presenting refraction (r = -0.78, p = 0.372)n = 108, p = 0.424), nor previous progression rate (r = 0.138, n = 91, p = 0.193).

## **Clinical Metrics**

There was a significant difference in the mean number of appointments between orthokeratology and dual focus contact lens groups (KW,  $\chi^2 = 7.338$ , df = 1, p = 0.007), with each orthokeratology patient being seen  $7.29 \pm 4.33$  times, compared to  $4.72 \pm 2.00$  times for dual focus contact lens patients. This translated to a difference in total chair time in clinic ( $\chi^2 = 55.381$ , df = 1, p < 0.0001), with orthokeratology patients spending an average of  $8.64 \pm 2.1$  hours in clinic compared to  $4.36 \pm 1.00$  hours for those in the dual focus contact lens group. Longer chair time was correlated with higher progression rate during treatment in the orthokeratology group (r = -0.423, n = 52, p = 0.002), but not in the dual focus group (r = 0.72, n = 32, p = 0.697).

One adverse event was seen over the 4-year period. A small (<1 mm) central corneal epithelial defect was seen in an experienced orthokeratology patient after they presented with a painful red eye. After treatment with a topical antibiotic, there was no loss of acuity and they were confident in resuming lens wear 1 week later. In addition, five orthokeratology patients experienced lens adherence on waking, with pain on lens removal. In each case, this was resolved by modifying the edge profile of new lenses. In contrast, there

were no reports of adverse events from patients in soft dual focus contact lenses and most children claimed that they wore their lenses 7 days a week.

## **CONCLUSIONS**

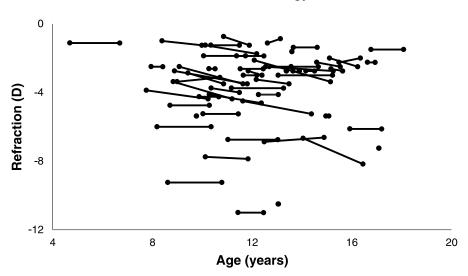
Our comparative case series indicates that meaningful reductions in myopia progression can be achieved in a clinical setting, using either orthokeratology or dual focus contact lenses with a +2.00 treatment defocus. Progression rates during treatment in orthokeratology and dual focus contact lens patients were reduced by 92 and 91%, respectively, when compared to pretreatment progression rates. The similarity in these values is notable, although they cannot be interpreted as indicating absolute efficacy in slowing progression because of the lack of a control group which would indicate the natural degree of slowing that would be expected over the treatment period. Moreover, due to the lack of randomization into each treatment group, the lack of masking techniques, and the self-selected population base, the reduction in myopia progression may not be directly comparable between dual focus contact lenses and orthokeratology.

The clinical nature of the case series also resulted in a wide range of patient ages and patient refractive errors (Fig. 2). The majority of patients represented the transition from pre- to post-puberty, a period when significant variation in myopia progression is expected.

During treatment, most patients in both groups experienced a clinically negligible change in their myopic refraction for a mean period of about 18 months. This relatively short mean follow-up period reflects the large number of patients with stable refractions who were either returned to their referring optometrist or were scheduled for an annual review beyond the date of this audit.

Although both orthokeratology and dual focus contact lenses seemed to achieve similar success in slowing myopia progression, from a clinical perspective, other factors deserve consideration.

## Orthokeratology



## **Dual Focus Contact Lenses**

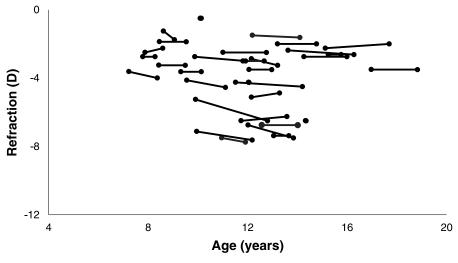


FIGURE 2.
Individual data plots of patient age versus refraction of patients in our clinic wearing either orthokeratology (top) or dual focus contact lenses (bottom). The two points mark an individual's initial and most recent appointment, so that the x-length of the line indicates period of follow-up, the y-height indicates

Orthokeratology treatment required familiarity with rigid contact lens design, access to a corneal topographer, and significantly more chair time (almost double over 18 months) compared to dual focus contact lens treatment. Our finding of a correlation between chair time and posttreatment myopia progression in patients treated with orthokeratology suggests that our more challenging orthokeratology fits provided diminishing returns with regards to myopia control. Furthermore, as the degree of myopia increases, it becomes increasingly difficult to achieve a satisfactory visual outcome with orthokeratology and only partial myopic correction may be achieved. In this study, only dual focus contact lenses with +2.00 annuli were used, without consideration of optimal treatment power. This introduced a fixed amount of ghosting/blur, which was regularly noted at the initial fitting appointment, but was tolerated or adapted to by the 1- to 2-week follow-up. Traditionally, hard contact lenses have been less prone to adverse events than soft lenses. However, the

change in refraction, and the gradient of the line indicates myopia progression while in the clinic.

majority of dual focus contact lenses used in the clinic were MiSight lenses, which are daily disposable soft lenses: these typically have a very low complication rate.<sup>24</sup> Nonetheless, orthokeratology was the more popular choice in our sample, likely due to the additional benefits of orthokeratology over daily lenses, such as freedom from optical appliances during activities such as water sports. Moreover, orthokeratology lens handling and management, important factors in managing the risk of serious adverse outcomes,<sup>25</sup> can be done with support at home, which made parents feel more comfortable with younger children wearing contact lenses. In addition, many new patients heard of the clinic by word of mouth, and the seemingly "magical" orthokeratology lenses were occasionally presented by current wearers at classroom show-and-tell presentations.

Both VCD and AXL were reported in this study despite their high correlation (r = 0.964). Although VCD may represent a more accurate method for comparing progression between orthokeratology

and dual focus contact lens groups, AXL is more easily obtainable in primary practice and perhaps as valid for monitoring ocular elongation.<sup>26</sup> The mean VCD and AXL of all patients presenting to the clinic was  $17.65 \pm 1.01$  mm and  $24.90 \pm 1.05$  mm, respectively, despite the average age being  $12.07 \pm 4.03$  years. These values are at the high end of the range reported in other studies of myopic children,<sup>27</sup> and are similar to adult eye sizes,<sup>28</sup> which may suggest a non-representative patient group: something that might be expected for a specialist myopia clinic. Although there were no significant differences between the changes in AXL or VCD between the orthokeratology and dual focus contact lens groups, there was an indication that the dual focus contact lens group may have had a greater increase in biometry given a longer follow-up period. When viewed alongside the negligible difference in refractive changes between the groups, this could suggest that dual focus contact lenses and orthokeratology are enacting their anti-myopiagenic effects through different mechanisms.

Our patients were a self-selected group who were screened for current myopia progression before admission to the clinic, and although these patients can likely be found in the demographics of any optometric clinic, they are not representative of all children with myopia. Most of the patients who attended the clinic had two myopic parents (Table 1), who were sufficiently concerned to choose treatment in a specialist university-based clinic. This may have increased patient expectation and motivation because of the interest being shown in them,<sup>29</sup> especially as the number of appointments was likely higher than it would have been in mainstream practice. These effects may have increased compliance with the contact lens based treatments and increased efficacy. Our anecdotal observations were of very high compliance, with parents remembering and reporting specific days and dates when the contact lenses were not worn. While it is possible that patients who experienced a poor response to treatment simply dropped out, only 22 patients did not meet the eligibility criteria for minimum follow-up period: 15 were from the "advice" group and only 7 were from the treatment groups (3 dual focus contact lens, 4 orthokeratology). In addition, three patients discontinued treatment after their refraction had remained stable over at least 18 months.

Our results confirm that significant reductions in myopia progression can be made with currently available orthokeratology and dual focus contact lenses, which require minimal upskilling of a clinician to implement. Therefore, it does indeed seem that the control of myopia has come of age,30 and on the balance of risk and benefit, we suggest that the default position of a clinician should be to justify why they should not begin anti-myopia treatment in children with progressing myopia.

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