

CTL TINTED HYDROGELS  
AND  
CORNEO - REFRACTIVE CHANGES

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## CTL Tinted Hydrogels and Corneo-Refractive Changes

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Abstract: The purpose of this study is to evaluate the extent of corneal and refractive changes in normals due to the daily wear of hydrophilic contact lenses tinted by the CTL Permatint Process (TM). Sporadic cases of keratoconoid<sup>like</sup> changes have been associated with these clear pupil tinted lenses. ONE such case is included. Refitting this patient with a clear hydrogel contact lens after a short period of mandatory spectacle wear reversed this corneal abnormality adequately and efficiently.

Key Words: clear pupil zone, CTL Permatint Process (TM), polymer change, survey, keratoconoid

## INTRODUCTION

It has been well documented that contact lenses can indirectly or directly alter corneal shape. These alterations have ranged in spectrum from the permanent, severe *Pseudomonas aeruginosa* corneal ulcer to the beneficial yet temporary effect of orthokeratological lens therapy. Hydrophilic daily wear contact lenses are not particularly notorious for directly changing corneal shape when fit, worn, and cared for properly. However, sporadic cases of such changes have been rumored with the tinted variety of these lenses. The U4 and CTL 38-L lenses tinted by the CTL Permatint Process (TM) are particularly suspect in this study. This process leaves a 4.5mm clear central pupillary zone while incorporating the pigment into the lens polymer to an 11mm diameter. A corresponding keratoconoid distortion appears in normals after a few months of daily wear. This patient reports a slowly progressive blur which is not amenable to refraction yet responds with an improvement with the pinhole test. This distortion resolves after a week of mandatory spectacle correction and does not seem to reappear if the patient is fit with a similar clear lens. The purpose of this study is to describe a case of corneo-refractive change associated with CTL Permatint(TM) hydrogel daily wear lens as well as its probable incidence in normals.

## CASE REPORT

L.B., a 19 year old optometric technician student, was seen at the FSCO Contact Lens Clinic in late October with a chief complaint of a gradual onset of blurred vision since the end of August, 1986. She was fit with a pair of B&L U4 lenses tinted blue by the CTL Permatint Process(TM) only a couple of weeks before. She is essentially a -4.50 spherical myope and has ~~successfully~~ worn clear B&L U4 lenses successfully for two years on a daily wear regimen. No significant ocular, visual, or medical histories were elicited. Pertinent examination findings are as follows:

Habitual Visual Acuity: 20/30 OD, OS, and OU; with spectacle or contact lens correction. Pinhole acuity was 20/25 as above.

Best Visual Acuity. 20/30 was elicited at the -4.50 and the -7.00 DS level OD, OS, and OU.

Retinoscopy: Same as Best Visual Acuity due to a central reflex of approximately 4mm demonstrating three diopters of myopia in addition to the four and one half diopters of myopia found in the peripheral reflex. The pupil was 7mm in the dark during retinoscopy.

Keratometry and Photokeratoscopy: The lower right quadrant OU 2.5mm away from the pupillary center revealed an apparent mild depressed area causing a distortion of the mires.

Slit Lamp Biomicroscopy: The only abnormal finding was a 4.5mm diameter ring of pooled fluorescein located in the same place as the central distortion observed during retinoscopy.

No other signs indicating keratoconus were observed.

Dilated Fundus Examination: All structures appeared free of disease or abnormality.

She was taken off of these lenses and was required to wear her spectacles until the next visit in ten days. She returned for this visit with 20/15 spectacle acuity and no apparent corneal distortion even during retinoscopic and biomicroscopic examination. She was refit with clear B&L U-4 lenses and is encountering no corneal or refractive changes since.

Upon comparison to other CTL Permatint Process(TM) lenses, the tinted annulus was found to be distinctly less flexible than other comparable lenses. Further investigation revealed that sporadic incidences of this occur regardless of disinfection method. In this case, hydrogen peroxide was used and strictly adhered to and not contraindicated.

## METHOD

Optometrists involved with contact lenses were contacted and asked if they fit lenses tinted by the CTL Permatint Process(TM). They were then asked if they had ready access to collect files of these patients without going through all of their files individually and if they were willing to participate in this research. Also asked was if they had any patients with any corneal distortion associated with these lenses. If they were willing to participate, they were asked to schedule time to discuss their cases and let me possibly observe the examination of these patients. A paper briefly outlining this project and several data collection forms were then given to the practitioner and further concerns were discussed. A copy of each of these forms are included as the next two pages of this report. The data was then reviewed by the optometrist and myself and was then correlated and changes in the measured parameters that may be directly or indirectly due to these lenses.

Robert T. Kocembo, Jr.  
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OPT 699 - F.S.C.O.  
Advisor: Dr. Lowther

The Effect of Tinted Hydrogel Lenses on Corneal Curvature - Abstract

This study will involve at least 25 random patients who wear U series B&L hydrogel lenses tinted by the B&L or CTL processes. These patients will not have histories of gross refractive change or corneal abnormalities, particularly keratoconus. A comparison of keratometric, retinoscopic, and refractive data taken before exposure to the lens and after full time wear will be conducted. A brief, pertinent history will accompany each patient report. The amount and frequency of corneal distortion associated with this lens will summarize the report.

  
clear per  
2000

Sincerely,  
Robert T. Kocembo, Jr.  
x 5 4 Lowther

PATIENT:

DATE:

H/O/V HX:

CL HX (to include experiences with other types and tints worn to present):

VA & CL:

OR & VA:

ORIGINAL K (date and any distortion):

K TODAY (note any distortion):

RET (note any distortion):

BASELINE REFRACTION:

REFRACTION TODAY:



## RESULTS

30 offices were contacted. Only 5 had heard of these lenses and 3 of these five had adequate record collection abilities and the will to participate in this study. Of these offices, sporadic incidences of this type of distortion were not recalled in enough detail to find the particular file.

Therefore, most all of my data includes data indicating no change due to the wear of these lenses. No significant overrefractive, retinoscopic, or biomicroscopic changes were evident in resembling the described distortion. Some minor refractive and keratometric changes were evident, however. None of these patients have significant health, ocular, or visual histories that would predispose a corneorefractive change though one case involved a cycloplegic refraction.

CT	DATE	VA	K	CL
19.55	12/86	-3.00 + 0.75 x 085	25	44.75 44.62 -2.75
Hx) → -		-3.00 + 0.75 x 082	25	44.62 47.12 -2.75
	1/87	"	"	-3.00
		0	0	-3.50
		0	0	-0.25 -0.75
SA 1/10/69	1/4/86	-2.25 DS	20	43.75 44.00 -2.25
-		-2.50 DS	20	43.75 -5PH -2.50
	1/18/86	"	"	"
		0	0	0
MB 7/28/69	5/86	-2.00 + 0.50 010	20	N/A -6.50
PMMA-78		-6.25 + 0.50 175	20	-5.75
SCL-81				
FINF-85				
B-LU4 ADUT	5/87	"	"	"
		0	0	0
SC 3/17/70	12/85	-5.50 + 0.50 x 060	20	44.62 46.25 w -5.00 GRN
		-5.50 + 0.50 x 070	20	44.62 46.12 w -5.00 GRN
	12/86	"	20	
			25+	

+ 1/2 LINE  
- 1/2 LINE

\* No Pin VA by OR unless indicated.

AMB 1961 6/84 -1 + 2 15 20 41.25 42 W HCV 45 -1.75 circ

1/86 -1.75 S " " " " circ 20 -1.75  
 -1.75 S " " " " -1.75

3/86 " " " " 41.50 42.00 HCV 45 space -1.75  
 41.12 41.87 -1.75

(-0.50)  
 -0.50

4.12	-1.12
------	-------

6 MC 9/11/83 9/11/85 -2.00 +0.25 100 25 43.50 42.75 A -2.00 circ 35-38  
 -1.75 +0.50 175 25 43.87 43.25 A -1.75

10/85 " " " " 20

+1 line

7 DJ - 10/20/86 -5.00 DS 20 46<sup>50</sup> 46-A -5.00 39-42  
 -7.75 DS 20 46<sup>62</sup> 46-A -7.75

(do ~ 0.25 0.37) 11/86 " " " " " " " " " "

8 EF 9/66 9/86 -4.25 DS 20 44 44<sup>37</sup> -4.25 DS 38-40  
 10/76 " " " " 43<sup>12</sup> H

2/76

KM	9/27/85	12/85	-1.50 +0.50	107	20	42.25	43	-1.75 35.5 BCL
Polycan 2. min			-1.50 +0.50	075	20	43	42.57	-1.50

	1/87		-1.75 +0.25	135	20	42.37	43	Plus Ser
			-1.75 +0.25	045	20	42.75	43.25	

-0.25	-0.25	+2.8
-0.25	-0.25	+2.00

1.17	
-1.4	+3/8

MK	10/84	10/84	-4.50 ns		20	43-	43.50	0.3
			-4.25 ns		20	43.75	43.97	

	10/86					43.37	44	-4.2505 B to CFL
						43.25	43.37	-4.2505

	11/86							
						+3.7	+5.0	
						0	-0.10	

OGM	-	9/85	+1.75 +0.75	180	20	44.37	87	+2.50 B to
			+1.25 +0.50	180	20	44-	25	+1.50

	10/86							
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2 KP 72 1/25 -2 + 1/2 106  
 -2 2) 103

20 44.87 45.61  
 20 44.87 45.25

80 B3 1/25 (20)  
 -2  
 STD OF 9.0  
 -2.25  
 03 AGO CTA  
 -2.25  
 2.07 8°

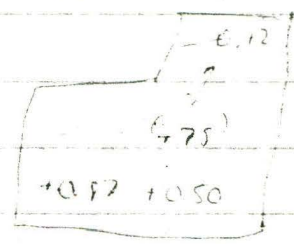
1/26 -2 + 1/2 190  
 -2.00 193

45.12 44.75  
 45.25

1/07

45.12 45.50  
 -15.75

-2  
 2.21



5.5  
 5.5  
 1.5

14 JP 63 1/25 -0.50 103  
 -0.50 103

20 43.5 44  
 20 43.75 44

-0.25  
 0.25  
 -0.25

2/81

15 7/28/38 9/30/35 +2.25  
 +2.25

20 43.67 44.62  
 20 43.62 44.17

0.25  
 0.25

+2 add

19/25 +3.00 25+  
 +3.00 25+

OK

~~1/25~~  
~~1/25~~

+0.75

- 1/2 LINE

0

44.50 43.87  
 44.62 44-

but

11/26 +2.5  
 +2.5

+3  
 OR PL

12/26

+0.87 -0.50  
 +1.00 -0.87

(16) BK 77 5/9/84 -5.25 25+ -4.75 -55 B+L 04 clr -45 AA

1/77 " " " " " " " "

1/77 " " " " " " " " -55 CFC BLUE -115

2/87

(17) RD 1/5/85 # 1196 +2.25 20+ 41.4 41.37 +2 CFC WLN  
 cyclopleged. +3.15 30+ 43.62 44.22 +35

cyclopleg. 8/86 +2.00 30+ 40 20 20 ~~43.62~~ 44 +1.00 20  
 +4.00 30/40 +2.00  
 due to over +

(18) BK 1/63 #196 -1.25 10 41.75 42. #85 -1.25 COCOA  
 15 41.50 42 #85

12/86

(19) AS 1/65 1/86 -4.00 20 42.25 42.75 W -3.75 blue  
 -4.25 20 42.50 42.00 -3.75

1/87

No Δ

20 DJ 1/63 10/86 -1.25 125 25 44 445  
 -1.25 125 25 44 447

-1.25  
 etc ~~34~~  
 -125

11/86

ff. Des  
 like cal  
 out to cl

21 BD 4/62 10/86 -0.50 15 43.30 44.00  
 -0.75 15 43.25 43.75

-0.50  
 34 etc 800  
 0.75

22 RU 5/53 5/86 -3.50 15 42.87 42.88  
 -4.50 15 42.50 43.00

-3.50  
 34 etc 800  
 -4.75

6/86

1/87 -3.50 -0.25 x 105 42.00 42.50

23 LK 7/37 1/87 -1.50 -0.50 x 0.85 43.25 44  
 -2.25 -0.25 x 0.85 43.12 45.62  
 2/87

-2.00  
 etc 345 800  
 -2.25

like spec  
 better

24 LK 7/67 pl +0.50 x 0.90 44.00 -  
 +0.25 +0.50 x 0.90 44.50 -

+0.25 8/12 44 800  
 +0.50

11 Hassle

No Δ

## DISCUSSION

Changed parameters with supporting cases are individually presented. An attempt to explain why this change occurred is attempted. The following parameters are as follows:

### Change in Visual Acuity Only:

Case 4: An increase OD and decrease OS of  $\frac{1}{2}$  line. This patient had no change in prescription or keratometry readings. The possibility of a cylindrical change may have occurred due to an effect only when the lens is actually worn. This patient wore a CTL 38-L green lens. The only parameter this "custom eyes" lens comes in is 8.7 / 14.0. Theoretically, this lens should adequately fit corneas between 42.75 (7.9) and 44.50 (7.6). This patient has 44.62 by 46.12 OD/ 46.25 OS with the rule keratometry (K) readings. This lens most possibly be flat though well fit with good movement but may be compressing the steep meridian slightly despite no observed overrefractive change. This patient only has  $\frac{1}{2}$ DC in the best correction. Internal cylinder may be a factor.

Case 6: An increase of one line OU was noted. This patient wears a CTL 38-L cocoa pair. K readings indicate about  $\frac{3}{4}$  D of corneal cylinder which is only slight in the overall correction. Theoretically, these lenses are a little steep but this was not indicated.



Changes in K readings only:

In all three of these cases, no observable changes in visual acuity, refraction, or any other parameter was noted.

Case 5: A 0.62 D flattening OD was noted. This is unusual because the 38-L aqua lens should theoretically be steep but this is not indicated. This change was noted over a two month period and no further change has been observed since.

Case 11: This patient had a  $\frac{1}{2}$ DS steepening OD / flattening OS after switching from a B&L U-3 (Para-Apical Radius = 8.6, spin cast aspheric) to a 38-L (lathe cut 8.7 B.C.). Both of these lenses fall within the range of theoretic and clinical proper fit parameters. The U-3 was not tinted. This change occurred over the span of a year. One year afterward, no keratometric or other change was noted.

Case 13: This patient is an adolescent but did not have any other ocular change during the past two years. Theoretically, the B&L B-3 (P.A.R. 9.0, spin cast, aspheric) is quite flat for this patient whereas the B&L U-3 would more likely be on K. However, spun cast lenses tend not to move much. Both of these lenses were aqua. The switch from the B to the U series correlates with a 0.87 D flattening of the steep meridian of the right eye only. After one year of U-3 wear, the left eye steepened by 0.87 in the flat and 0.50 in the steep meridian. It is quite unusual that no refractive changes of any type have been found.

Change in Refraction and Visual Acuity:

Case 15: This patient wears a pair of CTL 38-L sapphire lenses OU. This change occurred between 9 and 10/85 and has remained stable until presently. Theoretically and clinically, these lenses were noted to be properly fit. The change was noted as a +0.75DS change on overrefraction and manifest refraction without lenses. K readings changed by +0.87 / -0.50 OD which changed the corneal cylinder from one WTR diopter to 0.62 ATR cylinder. The left eye went from  $\frac{1}{2}$ D WTR to 0.62 ATR; a change of +1.00 on the flat and -0.87 on the steep meridian. It is again interesting that no refractive change was noted and that both corneas have 0.62 ATR. This patient is proceeding through presbyopia and was given a pair of +2.00 readers. This is rumored to decrease accommodative effort, therefore increase presbyopia and the tendency for ATR lenticular cylinder, which increases the mystique that this patient did not have a noticeable refractive change. The contacts might be altering corneal curvature only while the contacts are on.

Change in K and Refraction:

Case 10: This patient wears a CTL 38-L blue and had a very mild refractive change of -0.25 DC shifting 28 degrees OD and 20 degrees OS resulting in a 0.25 DC oblique component. The K reading OS changed by -0.25/+0.62 to reduce corneal cyl to  $\frac{1}{2}$ D. The Ks are more symmetrical after lens wear.

## CONCLUSIONS

This study did not prove that keratoconoid <sup>like</sup> distortion associated with lenses tinted by the CTL Permatint Process(TM) is even remotely a common clinical entity. However, this condition must be considered in the differential diagnosis of anomalies of corneal shape. Granted, this study could have been more extensive, but it is a safe assumption that since most contact lens practitioners have little awareness of this problem and that contact lens wearers are almost always advised not to wear their lenses during periods of visual and ocular abnormality, this problem may already be well controlled. This is reinforced by the fact that lens types are often switched after such problems occur.

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