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A clinical investigation of the Bausch and Lomb and American Hydron toric soft contact lenses

Abstract

A clinical evaluation was made comparing two soft toric lenses currently available. Both lenses are front surface toric lenses utilizing lenticular design to reduce edge thickness, and employing prism ballast for stabilization. In addition, the Hydron lens has an aspheric back surface and uses a truncation for increased stabilization. Eighteen eyes were fit with the Bausch and Lomb lens of which 62.5 percent achieved success. Of those successful, 70 percent were wearing the lenses first fit. After one refit or reorder all patients achieved success. Of the 21 eyes fit with the Hydron lens, 80 percent were considered successful. The first fit success rate was 75 percent and after one refit or reorder, all patients achieved success. Pachometry findings revealed that the Hydron lens induced greater corneal thickness increase than the Bausch and Lomb lens.

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A CLINICAL INVESTIGATION OF THE BAUSCH AND
LOMB AND AMERICAN HYDRON TORIC
SOFT CONTACT LENSES

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Spring 1983

TABLE OF CONTENTS

Acknowledgements	ii
Abstract	iii
Preface.	iv
Introduction	1
Table 1: Manufacturers' Lens Specifications.	3
Methods.	7
Table 2: Recommended Fitting Parameters.	8
Bausch and Lomb Lenses	10
Hydron Lenses.	12
Pachometry	13
Table 3: Patient Statistics and Data Summary	14
Table 4: Student T-Test Results.	18
Discussion	20
Table 5: Graph of Corneal Thickness Changes.	21
Recommendations.	24
Appendix	
Bausch and Lomb Subject Baseline Data	27
Bausch and Lomb Follow-Up Data.	28
Hydron Subject Baseline Data.	29
Hydron Follow-Up Data	30
Bibliography	31

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ABSTRACT

A clinical evaluation was made comparing two soft toric lenses currently available. Both lenses are front surface toric lenses utilizing lenticular design to reduce edge thickness, and employing prism ballast for stabilization. In addition, the Hydron lens has an aspheric back surface and uses a truncation for increased stabilization. Eighteen eyes were fit with the Bausch and Lomb lens of which 62.5 percent achieved success. Of those successful, 70 percent were wearing the lenses first fit. After one refit or reorder all patients achieved success. Of the 21 eyes fit with the Hydron lens, 80 percent were considered successful. The first fit success rate was 75 percent and after one refit or reorder, all patients achieved success. Pachometry findings revealed that the Hydron lens induced greater corneal thickness increase than the Bausch and Lomb lens.

PREFACE

Part of this study was intended to follow-up those patients in the previous study by Schnider et. al. However, a large portion of these patients were unable to be contacted. A long term study would have been invalid without a full patient pool. Of the patients that were contacted, some had discontinued wear, some needed to be refitted, while others were wearing their lenses without problems.

INTRODUCTION

The most common refractive error present today is astigmatism. Spherical soft lenses have been found to provide acceptable visual acuity in most eyes up to 0.75 D of astigmatism. A toric lens is needed for those eyes showing greater than 0.75 D of residual astigmatism. According to many sources, the incidence of astigmatism greater than 0.75 D is between 25 to 45 percent.^{1,2} Therefore, a significant proportion of the population are potential candidates for toric soft lenses.

At the present time in the fitting of soft contact lenses, the lens of first fit is often rejected. If expressed as a ratio comparing the number of people successfully fit with the first lens versus with subsequent lenses, this ratio seems to vary from manufacturer to manufacturer. This variability seems to be due to alterations in fitting characteristics over time caused by changes occurring to the eye or to the lens leading to a number of patients requiring new lenses. Complications resulting from soft contact lens wear include variable acuity, edema, neovascularization, abrasions, superficial punctate keratitis, circumcorneal injection, and giant papillary conjunctivitis. This study examined the clinical success and problems encountered in fitting two toric soft contact lens designs, the American Hydron and Bausch & Lomb (B & L).

The lenses used in this study are of front surface toric design. The American Hydron toric has an aspheric back surface

with an eccentricity of 0.7.³ This lens utilizes prism ballast and inferior truncation for axis stabilization. The B & L toric has a single curve spherical back surface and utilizes only a prism ballast for axis stabilization. Both lenses are of lenticular design to reduce weight and edge thickness. Table 1 lists the available parameters for these lenses.

A major problem associated with toric soft lenses is axis stabilization. These lenses have to be properly oriented and stabilized to ensure accurate correction resulting in good visual acuity. Prism ballast is the major lens design currently used for stabilizing rotation and providing proper axis orientation. Both lens designs examined in this study utilize about one prism diopter base down for axis stabilization. It is likely that the thinner upper edge helps stability although the main factor involved is the differential weight distribution between the top and bottom edges of the lens.⁴ This variability of edge thickness may affect the flexing characteristics causing a compromised pumping mechanism leading to a greater hypoxic condition. Due to the thicker bottom edge, it has been found that prism ballast lenses cause a significant increase in corneal thickness compared to non-prism ballast lenses.⁵ Other problems include axis instability due to tight lids, low errors of astigmatism, and high plus and minus spherical refractive errors. Also, prism ballast lenses may require a binocular fit to prevent induced vertical imbalance.⁶ Truncation of the lower edge does enhance axis stability by allowing the lens to conform to the lower lid margin or for larger diameters, to "lock" into the lower conjunctiva.¹ With minus lenses, truncation of the inferior lens edge reduces

Table 1

	AMERICAN HYDRON TORIC (Polymacon)	BAUSCH & LOMB TORIC (Hefilcon B)
Manufacturer	American Hydron Division of Nat'l. Pat. Dev. Corp. Woodbury, New York	Bausch & Lomb, Incorporated Rochester, New York
Hydration	38.6%	45%
Diameters (mm)	13.5, 14.0, 14.5	14.0
Base Curves (mm)	7.7 to 8.7 in 0.2 steps	8.3 and 8.6
Sphere Power Range	-20.00 DS to +20.00 DS 0.25 D steps from -9.00 to +6.00 0.50 D steps outside this range	-6.00 DS to +4.00 DS 0.25 D steps
Cylinder Power Range	-0.50 DC to -6.00 DC (0.25 D steps)	-0.75 DC, -1.25 DC and -1.75 DC
Axis Availability	0 to 180 degrees	90 or 180 degrees, \pm 20 in 10 degree increments
Center Thickness	averages 0.18 mm	averages 0.12 mm
Other Features	1 prism diopter base down ballast 1 mm inferior truncation	1 prism diopter base down ballast

the amount of ballast which may change the weight distribution enough to cause lens instability.⁷ The use of an aspheric back surface lens design allows a closer conformity to the natural corneal surface. This contour increases lens adhesion, thus increasing resistance to rotation.⁸

Various investigators have reported on the success in fitting American Hydron toric soft lenses. Hodd, in his study of toric lenses, found the first fit success rate to be 72 percent. Of this group, 42 percent reported good visual acuity and no subjective complaints with all day wear and 30 percent with some subjective complaints at the end of the day. Of those people who were unsuccessful, 14 percent failed due to poor visual acuity and 14 percent developed severe edema due to physiologically intolerant conditions after one to two hours of wear.⁹ Wauwe reported a 75 percent first fit success rate with 81.25 percent after the first exchange. Some of the failures include stabilization problems due to a steep fitting lens, incorrect conformation of the lens to the cornea, and incorrect prism ballast causing gravity and lid forces to rotate the lens.¹⁰ In a study by Muckenhirn on the fitting of Hydron toric lenses, a 67 percent first lens success rate was achieved. Of those who were unsuccessful, failure was due to poor visual acuity, misty vision after wear, foreign body sensation, and light sensitivity.¹¹

Presently, there are only a few studies investigating the success of the B & L toric lens. Remba found that the B & L Miracon contributed to a first fit success rate of 48 percent. The ultimate success rate for up to three lenses was 79.8 percent.¹²

Other practicing optometrists have reported on the clinical utility of the B & L toric lens. Levenson found the lens to be good physiologically as well as refractively but somewhat limited due to the number of lens parameters available.¹³ Solomon found the B & L lens good for the correction of astigmatism oriented vertically and horizontally and reported consistent quality.¹⁴

Complications associated with soft contact lens wear is well documented in the literature. Variable acuity can occur secondary to unstable axis orientation or lens flexure due to blinking. Edema can result if the cornea is under physiological distress. This swelling, whether due to hypoxia or a change in tear tonicity, leads to an increase in corneal thickness. Kame has reported that a change in thickness of 4 to 6 percent leads to vertical striae formation visible with a slit lamp.¹⁵ According to DeDonato, peripheral corneal edema, limbal injection, and leukocyte infiltration may precede corneal vascularization.¹⁶ McMonnies has pointed out that observed increases in limbal vasculature could be the result of neovascularization or merely the engorgement of vessels already present.¹⁷ Mandell has studied "tight" fitting hydrogel lenses and found that they cause circumcorneal injection.¹⁸ Limbal and corneal irritation due to lathe cut lenses has been reported by Josephson. He states that it may appear as a small circular epithelial abrasion or as an arc-line abrasion.¹⁹ Poor insertion and removal techniques can also lead to an arc-line abrasion on the inferior cornea.

Due to their hydrophilic nature, soft lenses are more prone to contamination from various coatings and deposits. Calcium and protein deposits have been demonstrated to be the main cause of

surface deterioration. Mucoid coatings, which can develop on both surfaces, consist of mucopolysaccharides, mucinous substances from the conjunctival secretions, and other proteins.²⁰ Other substances which may adhere include mercurial deposits from preservatives, pigment deposits, and fungal and bacterial organisms.²¹

With a greater number of eye practitioners recommending cold storage systems for lens sterilization, there has been increased interest in the incidence and cause of allergic reactions to preservatives in contact lens solutions. Rahi and Garner²² described the types of ocular allergic reactions as (1) acute anaphylaxis (immediate, humoral, or IgE mediated), (2) cell-mediated (delayed hypersensitivity), and (3) autogenous (autoimmune). These reactions may be seen as itchiness, watery discharge, conjunctival injection, edema, subepithelial infiltrates, or giant papillary conjunctivitis. Chemicals implicated in these reactions include chlorhexidine, thimerosal, and papain which is used in enzymatic cleaners. Cioletti,²³ in his study of thimerosal uptake by HEMA materials found that the lens takes on an amount equal to the water content of the lens. Fichman²⁴ et. al., in his study of enzyme cleaners, found by biochemical assays that a measurable amount of papain remained enzymatically active despite repeated cleaning and washing. Kleist²⁵ reports that mercurial deposits are fairly common in lenses thermally disinfected in thimerosal preserved saline. There seems to be great variability as far as the accepted incidence of allergic reactions in contact lens patients. Roth et. al.,²⁶ in a study of sterilization systems, found the incidence of allergic reactions to be 5.7 percent for a multiple solution system and 7.1 percent for a single solution

system. Stein,²⁷ in a study of lens care systems using three different sterilization techniques, found the incidence of reactions to be 23 percent for chlorhexidine, 14 percent for heat with preserved saline, and 3 percent for a quaternium-16 based solution. Fichman,²⁴ in his study reported that when patients employed a chemical system alone (chlorhexidine based), 8 percent showed ocular symptoms, but when an enzymatic cleaner was also used, 28 percent showed ocular irritation. In the study done by Kline²⁸ et. al., examining different care regimens, it was found that the quaternium-16 based regimen had an allergic reactions rate of 7 percent. For the chlorhexidine based system, it was found to be 52 percent and for the unpreserved saline heat regimen, no reactions.

METHODS

Subjects were selected from the Pacific University College of Optometry clinic population and attempts were made to divide the two groups by age, sex, refractive error, and astigmatism. Previous contact lens wearers, hard or soft, were included only if their refractive error had been stable for a period of three weeks verified by a weekly exam. Subjects excluded from the study included those with active pathology, or any other conditions that contraindicated soft contact lens wear.

Parameters selected for the initial lens were based on the manufacturer's fitting guide. Table 2 lists recommended fitting procedures.

Table 2

<u>HYDRON TORIC</u> ²³	
Overall diameter	Horizontal visible iris diameter + 2 mm
Base curve radius	Mean keratometer reading + 0.5 mm for ballasted, truncated trial lenses
<u>BAUSCH & LOMB TORIC</u> ²⁴	
Overall diameter	14.0 mm (only diameter available)
Base curve radius	8.30 mm initially - if too tight, try 8.60 mm

Diagnostic lenses were used to determine base curve relationships and rotational characteristics. For American Hydron, the following information was needed: spectacle correction, vertex distance, keratometer readings and axis, horizontal visible iris diameter, parameters of diagnostic lens used, and overrefraction. By means of a computer, a custom made lens was designed and returned according to the data submitted.²³ During the course of this study, Hydron changed its policy regarding the use of a computer to determine lens design. Originally, sphere power, cylinder power, and axis were usually figured from the patient's spectacle correction. Later on, specifications were determined by the overrefraction obtained through diagnostic lenses.

B & L recommends using their diagnostic set when fitting the patient. After determining the properly fitting diagnostic lens an overrefraction was done to find final sphere power, cylinder power and cylinder axis. Final cylinder axis is determined by using a fitting lens which has front surface cylinder power and

axis closely matching the patient's refractive error. The inclusion of front surface cylinder may effect lens position so final lens orientation was found and adjustment of axis orientation made.

At the time of dispensing the investigators assessed optical fit by means of visual acuity and overrefraction. If the visual acuity was poor or the overrefraction questionable, lens parameters were verified. Retinoscope reflex clarity, slit lamp evaluation (including movement, rotation, lid interaction and centering) and Fluorexon helped determine physical fit. A Dicon II RK digital computer pachometer was used to get baseline pachometry reading. Patients were taught proper lens care which included handling, cleaning and sterilization and were put on a wearing schedule. Progress evaluations were performed one week later following achievement of eight hours daily wear. Subsequent evaluations after the accomplishment of daily wear were done at two week, one month and two month intervals. At these progress exams we checked visual acuity, performed an overrefraction, assessed lens fit, took pachometry readings and evaluated eye health (conjunctival, lid and corneal physiology) with a biomicroscope. In addition, patient subjective symptoms were noted and we reviewed patient handling, cleaning and disinfecting regimens to obtain optimal care of the lenses. For those lenses which did not provide full time wear, a change in lens parameters, reordering of lenses or changing cleaning regimens were attempted to alleviate the problem.

The chemical disinfecting regimen originally used was the Allergan system. The regimen was later modified with the addition of LC-65^R (Allergan) as the surfactant cleaner. This system has

been found to be effective in removing most deposits commonly found on lenses. For those patients showing sensitivity to preservatives, the regimen was changed to heat. This regimen consisted of a low temperature heating unit, salt tablets, and Pliagel^R (Cooper), a thimerosal-free surfactant cleaner. In both systems enzymatic tablets were used weekly for protein removal.

BAUSCH AND LOMB

During the course of this study, 18 eyes were fit with B & L toric lenses. At the close of the study, 5 subjects (62.5 percent, 10/16 eyes) were still wearing their lenses and considered successful fits. The criteria for a successful fit was no physiological upset, visual acuity within one line of spectacle acuity, and achievement of full-time daily wear (8 hours). Of the subjects that were not successful, 3 of them failed because of poor lens fit. One subject was dropped because of failure to return for progress exams.

All of the successful patients achieved 20/20 vision through their contact lenses. Of these patients, 70 percent (7/10 eyes) were wearing their originally dispensed lens. The ones that needed to be refit were successful after one refit/reorder. Two lenses were reordered with base curve changes to obtain a better fit, while one lens was replaced because the patient tore it.

Of the 10 eyes successfully fit, 60 percent had refractive cylinder of one diopter or less. Thirty percent had refractive cylinder of 1.12-1.50 diopter. Most of the patients (80 percent) had axis orientation ATR (60-120 degrees). Also, 80 percent had corneal cylinder (K) from 0 to 1.0 diopter.

In terms of fitting characteristics, the base curve minus mean K relationship (expressed in mm), was on the average 0.905 mm for the successful patients with a range of 0.67 to 1.10 mm. The unsuccessful patients were fit on the average, 0.855 mm over mean K with a range of 0.52 to 1.15 mm.

Eighty percent used the cold disinfection system without problems during the study. The remaining 20 percent were put on heat disinfection because of possible allergic reactions to preservatives.

Several physiological changes were noted during the course of the study. Dimple veiling was seen on several of the patients. The majority of bubbles were seen centrally or under the prism ballast area of the lens. These bubbles were stationary despite good lens movement and often resulted in no corneal dye retention. Peripheral seal-off, as determined by the use of Fluorexon, was seen in conjunction with dimple veiling. Conjunctival injection was frequently seen initially, but often decreased with lens wear. Baseline circumcorneal injection was noted at dispensing. Increases in circumcorneal injection were seen in a majority of the unsuccessful lens fits but only in a few of the successful lens fits. One patient developed superior-nasal neovascularization which led to discontinuation of lens wear. A majority of the patients had lens deposits which prompted the use of additional surfactant cleaners. This proved effective in reducing deposit formation in most of the lenses. No corneal subepithelial infiltrates or changes in lid physiology were seen.

HYDRON

Out of the subject pool, 21 eyes were fit with the Hydron toric soft lens. Three patients (6 eyes) were not included in the data collection because of incorrect lens parameters being sent and long delays in lens delivery. Of the remaining 15 eyes, 80 percent (12/15 eyes) were successful in wearing the Hydron toric lens. The same criteria for successful lens wear used for the B & L group was applied on the Hydron group. Of those that failed, one patient (2 eyes) suffered from cloudy vision after 4 to 5 hours of wear. One lens failed due to excessive rotation causing lid irritation and fluctuating acuity. Of those patients successfully fit, 75 percent (9/12) did not need to be refit and after one refit/reorder, all patients in this group achieved good vision, a properly fitting lens, and full-time wear. Seventy-five percent (9/12) of the patients in this group had 20/20 or better vision through their contact lenses, the remaining 25 percent had acuities of 20/25. The profile of these successful patients includes a majority (58 percent) having refractive cylinder in the range of 1.12-1.50 D. Thirty-three percent having an amount in the 1.62-2.00 D range. There was about an equal amount (6 versus 5) of WTR and ATR cylinder axis respectively. Fifty percent had an amount of corneal cylinder (K) in the range of 0-1.00 D. In terms of the base curve minus average K relationship (expressed in mm), the range of values run from 0.51-1.12 mm, the average amount being 0.93 mm. Of the 7 eyes initially started on the cold disinfection system, 2 were switched to heat following the appearance on the lids of an allergic-type reaction. Because of a history of allergic reactions, 5 eyes were initially started on the heat

system and did not develop any problems. At the close of the study, 12 eyes achieved full-time daily wear. Dimple veiling was seen in a majority of the patients. Circumcorneal injection was also noted in many of the patients. Truncation lift-off with occasional lower lid irritation was seen in half of the patients. Lens deposits were noticed in some of the patients necessitating the need for additional surfactant cleaners. Lid irritation seen as papillae and hyperemia of the palpebral conjunctiva was seen in a few of the patients prompting the switch from chemical to heat disinfection.

PACHOMETRY

Corneal thickness was measured on every patient with a Dicon digital computer model II RK. We found that this pachometer hampered our study in that instrument delivery was slow and breakdown frequent. The instrument delivery was 6 months behind schedule and the pachometer broke down 3 times during our study over the course of 6 months.

The corneal thickness was measured by one of three clinicians. The pachometer was calibrated before each set of measurements for a given patient. Five measurements were taken along the horizontal meridian in each eye. The two most peripheral measurements were not included in the data analysis due to a larger variability in these readings. The central three measurements covered a corneal area of 6.2 mm. The standard deviation was kept below 0.01 mm in 96 percent of the readings for these measurements. An average was taken of the three central measurements and this value was used to compute corneal thickness changes over time.

Table 3		
	B & L	Hydron
Sex:		
Male	5	6
Female	4	5
Number eyes fit	18	21
Number eyes at end of study	16	15
% successfully fit	62.5% (10/16)	80% (12/15)
Number refit/reorder	3	3
% first fit successful	70% (7/10)	75% (9/12)
% success after 1st refit	100% (10/10)	100% (12/12)
VA spectacles 20/20 or better	100%	100%
VA best with lens 20/20 or better	100%	75% (9/12)
20/25 or better		25% (3/12)
Spectacle correction (sph. equivalent)		
myopes	100%	100%
hyperopes	0%	0%
emmetropes	0%	0%
Refractive Cyl		
0 - 1.00 D	60% (6/10)	0%
1.12 - 1.50 D	30% (3/10)	58% (7/12)
1.62 - 2.00 D	0%	33% (4/12)
2.00 D	10% (1/10)	8% (1/12)
Cyl Axis		
WTR	20% (2/10)	50% (6/12)
ATR	80% (8/10)	42% (5/12)
OBL	0%	8% (1/12)
K		
0 - 1.00 D	80% (8/10)	50% (6/12)
1.12 - 1.50 D	0%	17% (2/12)
1.62 - 2.00 D	10% (1/10)	8% (1/12)
2.00 D	10% (1/10)	25% #/12)
BC-K Range		
successful patients	0.67 - 1.10 mm	0.51 - 1.12 mm
mean	0.912 mm	0.93 mm
	(S.D. = +0.11)	(S.D. = +.18)

Table 3 (continued)			
	B & L		Hydron
Disinfection			
chemical	80%	(8/10)	42% (5/12)
heat	20%	(2/10)	42% (5/12)
switched (chemical to heat)	0%		16% (2/12)
% achieving full-time wear	100%		100%

Pachometry readings were compared at three different time intervals that were common to all patients included in the analysis. Patients whose data did not fall into these time intervals were not included in the data analysis. This reduced the number of eyes in the B & L group to 8 and the number of eyes in the Hydron group to 7. Time interval one was one week after dispensing. Time interval two was two to three weeks. Time interval three was five weeks or longer after dispensing.

The pachometry readings from the patients wearing B & L lenses were analyzed separately from those wearing Hydron lenses. A single factor analysis of variance for repeated measures was performed for each group. The F value for B & L group was significant at the 20 percent level while the F value for the Hydron group was significant at the 1 percent level. This analysis revealed a significant change in the corneal thickness for those patients wearing Hydron lenses. Significance here is defined as the 5 percent level or below. The change in corneal thickness for those wearing B & L lenses would be considered insignificant with this analysis.

A t-test was also used to determine if there was any significant thickness changes between time intervals. This test revealed significant changes in thickness for the Hydron group between dispensing and time interval one (one week). However, there was an insignificant change in thickness between time intervals one and two, two and three, and one and three. The t-test showed insignificant changes in thickness for the B & L group between all time intervals. One could conclude from both analyses that there was a significant increase in corneal thickness for those patients

wearing Hydron lenses but not for those wearing B & L lenses.

Refer to Table 4 for the results of the t-test. In both the B & L group and the Hydron group, the greatest average corneal thickness increase was between dispensing and time interval one. This increase was found to be significant for those wearing Hydron lenses but not for those wearing B & L lenses. Both groups showed on the average, an insignificant decrease in corneal thickness between time intervals one and two. Both groups showed an insignificant increase between time intervals two and three. The average overall increase in corneal thickness for the Hydron group was 4.28 percent with a 4 percent increase occurring between dispensing and the first week. The B & L group had an average increase in corneal thickness of 1.43 percent with a 1.48 percent increase occurring between dispensing and one week later. Refer to Table 5 for a graphic representation of corneal thickness changes.

The difference in pachometry findings between the Hydron and B & L group could be explained by the different physical characteristics of the two lenses. The Hydron lens is on the average 50 percent thicker than the B & L lens. The Hydron lens also has a lower water content than the B & L lens. These values are 38.6 percent versus 45 percent respectively. The greater thickness and lower water content of the Hydron lens may lead to a lower oxygen transmissibility than the B & L lens. Another factor is that the average OAD for the Hydron lens was 14.3 mm versus 14.0 for the B & L lens.

In summary, the greater thickness, lower water content, and larger diameter of the Hydron lens reduces oxygen availability to

Table 4

t-values using different time intervals
 minus values represent increases in corneal thickness
 positive values represent decreases in corneal thickness

HYDRON

	Dispensing	T1	T2	T3
Significance Values		one week	two to three weeks	five weeks or longer
.1 level	1.943			
.05 level	2.447			
.02 level	3.143	$T = -3.07$		
.01 level	3.707	.05 level of sig.		
		$T = -2.56$		
		.05 level of sig.		
		$T = -2.56$		
		.05 level of sig.		
		$T = .34$		
		less than .1 level of sig.		
		$T = -.435$		
		< .1 level of sig.		
		$T = -.196$		
		< .1 level of sig.		

Table 4
(continued)

<u>BAUSCH AND LOMB</u>					
	Dispensing	T1	T2	T3	
Significance Values		$T = -1.152$			
		$< .1$ level of sig.			
.1 level	1.895				
.05 level	2.365				
.01 level	3.499	$T = -1.105$			
		$< .1$ level of sig.			
			$T = -.877$		
			$< .1$ level of sig.		
		$T = .514$			
		$< .1$ level of sig.			
			$T = -.441$		
			$< .1$ level of sig.		
				$T = -.08$	
				$< .1$ level of sig.	

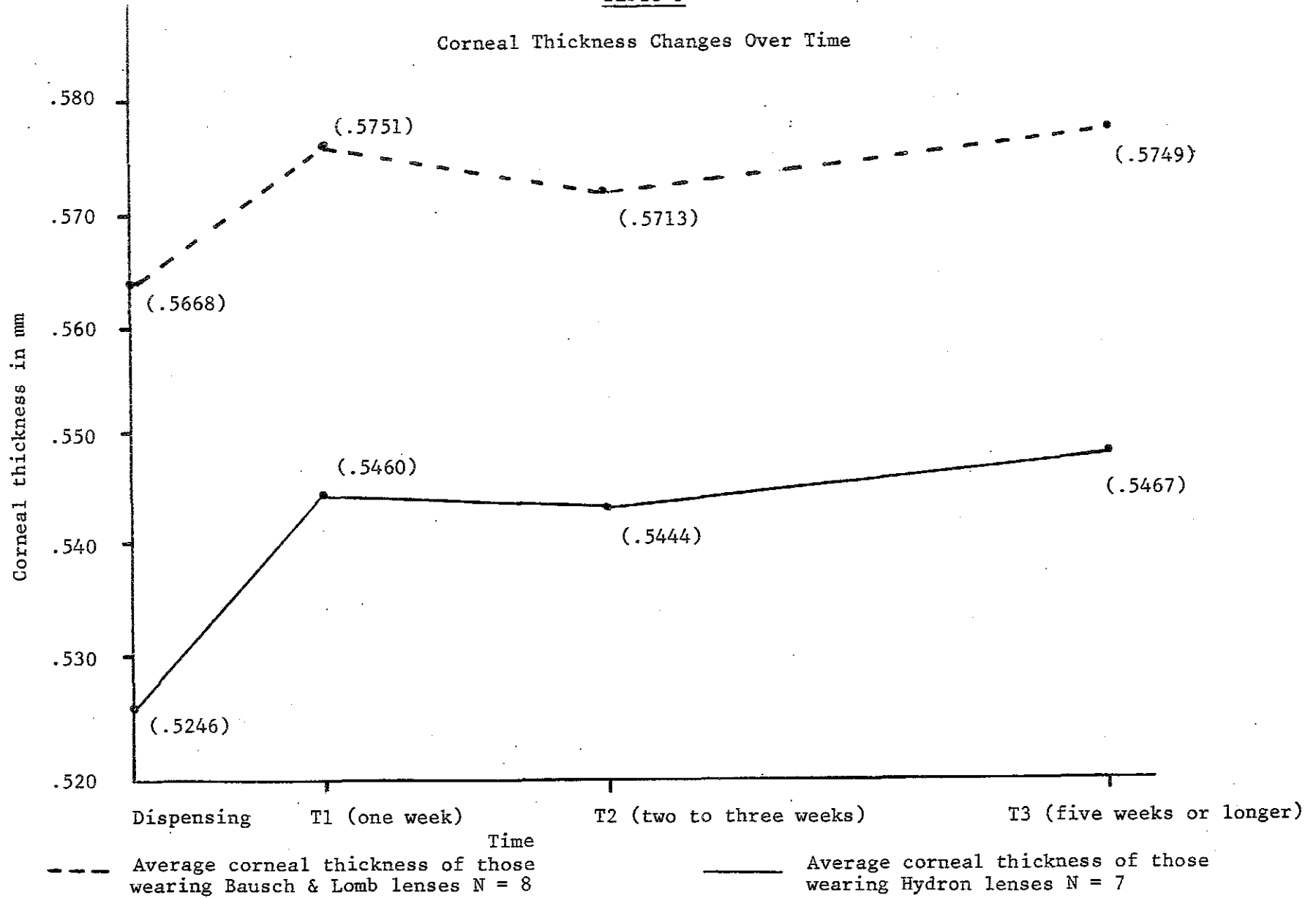
the cornea resulting in a potential for corneal edema. A previous study by Schnider et. al. did not use a pachometer and failed to detect these subtle changes in corneal thickness. The use of this pachometer enabled us to objectively determine changes in corneal thickness that would have been undetected otherwise.

DISCUSSION

Fitting toric soft lenses requires more time and expertise in problem solving than with spherical soft lens designs. There were several problems encountered in obtaining a satisfactory fit during the course of this study. In fitting these lenses, it was often found that the dispensed lens did not fit like the diagnostic lens. The rotational characteristics of the dispensed lens tended to be more unstable than the diagnostic lens. This axis instability usually settled within two weeks. The dispensed lens often appeared to have less movement than the diagnostic lens. In most instances, lens movement was adequate at dispensing but with the B & L lenses, two eyes needed to be refit with flatter base curves. One Hydron lens needed to be reordered due to poor optics. With the Hydron lens, lens parameters were custom designed by utilizing a computer. We found this system resulted in improper lenses being sent in the case of five eyes. These mistakes along with lengthy delivery times resulted in three patients (6 eyes) being dropped from the patient pool. Hydron delivery times were found to be five to ten weeks. For B & L, the delivery time was two to three weeks. Reasons for Hydron's long delivery time include orders having to be sent in by mail

Table 5

Corneal Thickness Changes Over Time



and because they're manufactured in England, a two week quarantine is required by the FDA.

Physiological problems often encountered with spherical soft lenses were also noted with the toric lenses in this study. These include lid irritation, edema, staining, neovascularization, and circumcorneal injection. These physiological changes seemed to appear sooner than in spherical soft lenses with most of these changes occurring within the first few weeks. These lenses are thicker than most spherical soft lenses. For B & L, the average thickness is 0.13 mm and for Hydron, the average is 0.18 mm. The thicker nature of these lenses is probably the reason for these problems appearing sooner.

Physical problems were also often noted. Fluctuating visual acuity due to lens rotation was a common problem. Axis orientation usually stabilized over time resulting in improved visual acuity. Despite increased axis stability, some patients still reported fluctuating visual acuity with prolonged nearpoint activities such as reading. A possible explanation is increased lid interaction on the lens with convergence. There is also a tendency for these lenses to tighten over time. This problem was serious enough to reorder new lenses in four of the eyes wearing B & L lenses and in two of the eyes wearing Hydron lenses. One patient developed cloudy vision due to edema despite adequate lens movement. These eyes appeared to be edema prone and were therefore refit with a thinner toric soft lens. With the Hydron lens, truncation lift-off was frequently noted. This lift-off, however, did not appear to cause any physiological problems.

Dimple veiling due to bubbles under the lens was a frequent finding. This problem appears to be due to trapped air bubbles causing depressions in the anterior epithelium. These depressions or pits fill with fluorescein although the epithelium is intact. Dimple veiling may signify trapped or inadequate tear flow resulting in metabolic waste build-up under the lens. The use of Fluorexon shows that it is possible to have peripheral seal-off with good lens movement. Therefore, dimple veiling with good lens movement may signify peripheral seal-off and a need to go to a flatter base curve.

Fluorexon was found to be helpful but not definitive in determining lens-cornea relationships. This study found that Fluorexon was useful in evaluating alignment or flat lens fits but for a steep fitting lens, the dye pattern may be misinterpreted. With a steep fitting lens, central pooling may be decreased with blinking and may not reestablish itself due to poor tear flow producing an apparent alignment fit. It was found that Fluorexon was absorbed into the lens matrix, but the dye seemed to leach out with soaking or boiling in a saline solution. Fluorexon can be instilled in the eye either by dropping it in the lower fornix or by putting a drop in the concave surface of the lens and then placing it on the eye. However, to get the most information from the dye patterns, Fluorexon should be placed in the concave surface of the lens. In this way, a steep fitting lens will show central pooling momentarily, then revert to an alignment-like fit.

RECOMMENDATIONS

Patient selection is very important for toric soft contact lens success. Patients have to be screened with a complete case history and thorough slit lamp evaluation to assess eligibility for soft contact lenses. In addition, more careful assessment of lids, corneal cylinder, and refractive cylinder should be done. All patients should be checked for axis sensitivity to determine whether the patient can tolerate minor axis fluctuation inherent in toric soft lens designs. In this study, some patients were very sensitive to axis orientation with as little as 1.25 D cylinder power. Therefore, all patients should be counseled to expect possible minor acuity fluctuations at both far and near distances while wearing these lenses. This is an important point to discuss with the patient during the initial workup to avoid future problems with high patient expectations.

When choosing between these lens designs, several factors need to be considered. If a patient has less than 2.00 D refractive cylinder power orienting along the major meridians (WTR, ATR) and a horizontal visible iris diameter (HVID) of less than 12.0 mm, try the B & L lens first. A disadvantage with this lens, however, is its limited available parameters. For those patients with greater than 2.00 D refractive cylinder or oblique axis orientation, try the Hydron lens. Hydron's main advantage is that its a custom lens with a wide range of parameters. However, one must consider the long delivery time a disadvantage.

When determining the lens of first choice, Hydron recommends the base curve to be 0.4-0.5 mm flatter than average K. In a

study conducted by Schnider et. al. the lens of first choice was recommended to be 0.6-0.7 mm flatter than average K. This study found in those patients successfully fitted, the base curve minus mean K value to be 0.9 mm (S.D. \pm 0.18 mm). Therefore, we recommend that the lens of first choice be 0.8-1.0 mm over mean K with a 14.0 mm OAD.

Bausch and Lomb recommends trying the 8.3 mm lens first, if too steep or axis orientation unstable, switch to the 8.6 mm. The previous study by Schnider et. al. and this study recommend the 8.6 mm as the initial lens, if there is excessive movement or unstable axis orientation, try the 8.3 mm.

Axis orientation should be scrutinized for location and variability with eye movements. Axis orientation should be within 5 degrees variability with blinks. There should be no conjunctival impingement (tugging and blanching of blood vessels) by the lens. In all diagnostic findings, lenses should be left on the eye at least 20 to 30 minutes to insure proper evaluation. A properly fitting lens should exhibit at least 1 mm movement on blinks with the eye in the primary, upward, and lateral positions of gaze. A lens that moves less than 1 mm should be evaluated carefully because with continued daily wear, lenses will often tighten causing corneal physiological upset.

At dispensing, maintenance of proper soft lens hygiene needs to be emphasized to the patient to insure long term success. When choosing a lens care system, special attention needs to be given to those patients who have a history of allergies. Those patients may require a preservative-free lens care system. In this study, heat, salt tablets, and Pliagel^R (Cooper) surfactant cleaner was

found to be an effective thimerosal-free regimen. For most patients, the Allergan cold disinfection system proved adequate with the addition of a good surfactant cleaner (LC 65^R Allergan). Enzymatic tablets should be given to minimize protein build-up.

Progress examinations should be done at one week, three weeks, two months, and six months after dispensing. A thorough case history, slit lamp evaluation, and review of lens hygiene should be performed.

These lenses have been found to be effective in correcting the refractive error in a majority of patients fit in this study. However, these lenses are not without their problems. Further technological advances in this field will help the clinician in the fitting of toric lenses with greater success in the future.

APPENDIX

B & L Toric Subject Data								
Subject	Age	Sex	Eye	Low K	Corneal Cyl	Spectacle Rx	Refractive Cyl	
DH	25	M	OD	46.25	0	-0.50-0.62x85	ATR	
			OS	45.87	-0.37x105	-0.75-0.87x95	ATR	
CJ	27	F	OD	44.25	-0.50x60	-2.00-1.00x78	ATR	
			OS	44.00	-0.50x138	-1.75-1.25x103	ATR	
CO	20	F	OD	43.00	-1.75x170	-5.00-1.25x172	WTR	
			OS	42.75	-2.37x170	-5.00-2.25x177	WTR	
RP	32	M	OD	40.87	-1.87x180	+0.75-1.25x007	WTR	
			OS	40.75	-2.12x008	+0.75-1.50x175	WTR	
JP	41	F	OD	42.00	-1.50x170	-1.75-1.25x180	WTR	
			OS	41.50	-2.50x10	-1.75-1.75x180	WTR	
DS	25	M	OD	45.12	-0.12x90	-0.50-1.00x105	ATR	
			OS	44.75	-0.50x80	-0.25-1.50x65	ATR	
CS	30	F	OD	46.00	-2.37x165	-1.50-1.00x170	WTR	
			OS	45.75	-2.00x005	-1.00-2.00x25	WTR	
CS	25	M	OD	43.75	0	-3.50-1.00x78	ATR	
			OS	43.25	-0.75x145	-3.25-1.00x120	ATR	
HW	26	M	OD	43.00	-1.87x173	-5.25-1.25x005	WTR	
			OS	43.12	-1.62x173	-5.25-1.50x005	WTR	

APPENDIX

B & L Toric Subject Follow-Up Exam					
Subject	Dispensed Base Curve	Total Time Lenses Worn	Reorder Information	Notes	
DH	OD 8.3	12.5 wks			
	OS 8.3	12.5 wks			
CJ	OD 8.6	16.5 wks			
	OS 8.3	16.5 wks			
CO	OD 8.3	11 wks	8.6		
	OS 8.3	11 wks	8.6		
RP	OD 8.6	12 wks		D/C physiological	
	OS 8.6	12 wks		D/C problems	
JP	OD 8.6	1 wk		D/C patient	
	OS 8.6	1 wk		D/C didn't return	
DS	OD 8.3	16 wks			
	OS 8.6	16 wks			
CS	OD 8.3	17 wks		D/C poor lens	
	OS 8.3	17 wks		D/C fit	
CS	OD 8.6	6 wks	replace lens		
	OS 8.6	6 wks	patient tore lens (OS)		
HW	OD 8.6	2 wks		D/C physiological	
	OS 8.6	2 wks		D/C problems	

D/C - discontinued

APPENDIX

Hydron Toric Subject Data							
Subject	Age	Sex	Eye	Low K	Corneal Cyl	Spectacle Rx	Refractive Cyl
AA	34	M	OD	40.75	-3.87x007	+2.00-3.25x005	WTR
			OS	41.50	-2.62x173	+1.75-2.00x175	WTR
TG	25	M	OD	44.50	-1.25x108	-3.75-1.25x118	ATR
			OS	45.62	-0.37x102	-3.75-1.25x122	OBL
LK	25	F	OD	44.00	-0.75x90	-0.50-1.50x90	ATR
TK	19	F	OD	49.25	-3.00x180	-0.25-2.00x005	WTR
			OS	49.00	-3.50x170	-2.00-3.50x170	WTR
JM	24	M	OD	44.37	-2.62x23	-1.75-2.25x35	OBL
			OS	44.25	-2.00x155	-1.75-2.50x155	WTR
CN	25	M	OD	43.50	-0.50x150	+4.25-0.75x180	WTR
			OS	43.75	-0.50x115	+5.00-1.25x112	ATR
EP	29	M	OD	43.25	0	p1 -1.25x95	ATR
			OS	42.25	-0.37x85	p1 -1.25x85	ATR
RP	27	M	OD	42.50	-1.50x10	-1.75-1.50x25	WTR
			OS	42.12	-1.87x175	-1.75-1.75x175	WTR
BS	29	F	OD	44.50	-2.50x168	-4.25-1.50x155	WTR
			OS	44.50	-2.50x160	-5.75-1.25x003	WTR
TT	25	F	OD	45.00	-1.00x160	-0.75-1.25x150	WTR
			OS	45.00	-0.50x42	-1.00-1.75x30	WTR
BT	37	F	OD	43.87	-1.25x110	+0.25-1.75x97	ATR
			OS	44.00	-0.62x80	+0.25-1.62x73	ATR

APPENDIX

Hydron Toric Subject Follow-Up Exam					
Subject	Dispensed Base Curve		Total Time Lenses Worn	Reorder Information	Notes
AA	OD	8.7	2 wks	sph, cyl, axis changed	D/C poor VA
	OS	8.9	2 wks		D/C delays on delivery
TG	OD	8.3	10 wks		D/C corneal
	OS	8.3	10 wks		D/C edema
LK	OD	8.3	8 wks		
TK	OD	8.7	0	parameters changed	D/C delays on
	OS	8.7	0		D/C delivery
JM	OD	7.9	4 wks		D/C lens rotation
	OS	7.9	4 wks		
CN	OD	8.5	0	8.7	D/C delays on
	OS	8.5	0	8.7	D/C delivery
EP	OD	8.9	6 wks	replace lens poor optics	
	OS	8.9	6 wks		
RP	OD	8.9	4 wks		
	OS	8.7	4 wks		
BS	OD	8.3	12 wks	8.5	
	OS	8.3	12 wks	8.5	
TT	OD	8.5	5 wks		
	OS	8.5	5 wks		
BT	OD	8.7	8 wks		
	OS	8.7	8 wks		

D/C - discontinued

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