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A clinical evaluation of the hydron toric and bausch and lomb toric self contact lenses

Abstract

A clinical evaluation of two currently available toric hydrogel lens was made. The Hydron Tor ic and the Bausch and lomb Toric lenses are both front surface torics with prism ball aststahilization features. The Hydron lens also employs an inferior truncation and an aspheric back surface. First fit success rate for the Hydron lenses on 27 eyes was 40%. An increase to 72% success was achieved after one lens reorder and 76% were fit after a total of two reorders. Len::es had been worn for periods ranging from one week to six months. Of 27 eyes fit with the Bausch and Lomb lens, 71% were still wearing the initial lens fit after one to four weeks. Further data on these lenses i s forthcoming in Part II of this study. Physiological difficulties with the Hyd.rons were the primary reasons for failures, this resulted in l ens reorders, most frequently due to lens tightening, or to edema caused by the thick lenses. Stabilization was excellent for all types and magnitudes of astigmatism in the study. Bausch & Lomb offers limited parameters and some stabilization difficulties were encountered with all types of astigmatism but more frequently with against the rule types .

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A CLINICAL EVALUATION OF THE HYDRON TORIC AND BAUSCH & LOMB TORIC SOFT CONTACT LENSES

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ABSTRACT

A clinical evaluation of two currently available toric hydrogel lens was made. The Hydron Toric and the Bausch and Lomb Toric lenses are both front surface torics with prism ballast stabilization features. The Hydron lens also employs an inferior truncation and an aspheric back surface. First fit success rate for the Hydron lenses on 27 eyes was 40%. An increase to 72% success was achieved after one lens reorder and 76% were fit after a total of two reorders. Lenses had been worn for periods ranging from one week to six months. Of 27 eyes fit with the Bausch and Lomb lens, 71% were still wearing the initial lens fit after one to four weeks. Further data on these lenses is forthcoming in Part II of this study. Physiological difficulties with the Hydrons were the primary reasons for failures, this resulted in lens reorders, most frequently due to lens tightening, or to edema caused by the thick lenses. Stabilization was excellent for all types and magnitudes of astigmatism in the study. Bausch & Lomb offers limited parameters and some stabilization difficulties were encountered with all types of astigmatism but more frequently with against the rule types.

PREFACE

This represents preliminary results of a continuing study of short and long term effects and effectiveness of toric hydrogel lens wear. The time lags and data collection disparities evident in this paper are due to a later acquistion of one type of lens. Part II of this study will present further data on both lens designs and will include long term evaluations of physiological, refractive and physical changes occurring after wearing periods of one year or more for both lens designs.

INTRODUCTION

The incidence of astigmatic refractive errors in the population has been reported to be between 25 and 30%[1]. If it is assumed that the soft contact lens seeking public is representative of the population at large, the need and demand for soft contact lens correction of astigmatism is evident. The development of designs for toric hydrophilic lenses was slow due to several factors including the inability to apply techniques used in rigid lens fabrication to that of the soft lens process, the effects of lid dynamics, limbal and scleral topography and their effects on the rotational behavior of the larger lenses, and costly FDA requirements[1].

The currently available hydrophilic lenses are thinner and conform closely to the corneal topography and tend not to mask significant amount of corneal astigmatism as do rigid lens designs. Therefore, the toricity must be incorporated into the soft lens, either on the front or back surface. A means of stabilizing the cylinder axis must also be incorporated into the design. The toric lens will tend to stabilize with the meridian of longest radius (thinnest edge) vertically due to decreased lid resistance. If, as in with the rule or oblique astigmatism, the long axis is not oriented vertically, other features are necessary for stabilization[2]. This can be accomplished by two means: dynamic stabilization by thinning of the edges to decrease lid resistance or stabilization by prism ballast which causes a difference in weight of the top and bottom of the lens and also creates less lid interactions with the superior edge. Truncation is often used to prevent rotation of the lens and the combination of this and the prism

ballast is the most commonly used in current lens designs. Double truncation was found to be prone to rotation so a single inferior truncation is preferred. Lens rotation is influenced by upper lid tension, the looseness of the bulbar conjunctiva, and the rigidity of the lens material. Studies have indicated that the aphakic and against the rule astigmats are more likely to be successfully fit with the combination of truncation and ballast. Patients with high amounts of with the rule astigmatism may be better fit with a round, ballasted lens[3].

The lenses used in this study were of the front surface toric design. They were the Hydron Toric and Bausch & Lomb Toric lenses. Hydron employs prism ballast and inferior truncation for axis stabilization while the Bausch & Lomb (B & L) lens utilizes only prism ballast. The lenses are lenticular designs to reduce weight and edge thickness. The Hydron Toric lens has an aspheric back surface with a constant eccentricity value of 0.7 and the B & L Toric lens has a spherical back surface with a 1 millimeter posterior bevel. Table 1 lists the available parameters for these lenses.

Table 1 - Manufacturers' Lens Specifications

	HYDRON TORIC (Polymacon)	BAUSCH & LOMB TORIC (Hefilcon B)
Manufacturer	American Hydron Division of Nat'l. Pat. Dev. Corp. Woodbury, N.Y.	Bausch & Lomb, Incorporated Rochester, N.Y.
Hydration	38.6%	45%
Diameters (m.m.)	13.5, 14.0, 14.5	14.0
Base Curves (m.m.)	7.7 to 8.7 in 0.2 mm steps	8.3 and 8.6 m.m.
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)	-1.25 DC and -1.75 DC
Axis availability	0 to 180 degrees	90 or 180 degrees, ±20 degrees in 10 degree increments
Center thickness	averages 0.18 m.m.	averages 0.12 m.m.
Other features	1 prism diopter base down ballast 1 m.m. inferior truncation	1 prism diopter base down ballast

Table 1 - Manufacturers' Lens Specifications

A review of the literature yields various reports of problems associated with the use of any hydrophilic lens and some associated strictly with toric lens wear. Forms of physiological embarrassment include arc line abrasions from lathe cut lenses located near the superior limbus with associated limbal vessel engorgement. This was seen mostly in Orientals and other patients with tight or low positioning upper lids[4]. Vertical striae have become the hallmark of hydrogel induced corneal edema reports Polse[5]. Japanese studies by Kamiya have more recently cited the appearance of horizontal striae as a precursor of vertical striae in soft lens wearers[6]. He maintains that the horizontal striae become evident after about two hours of wear and/or 4.6% increases in corneal thickness and vertical striae are not visible until the swelling reaches over 7%, or after 6 or more hours of lens wear. The lens thickness seems to be the single most important factor in the control of edema but other research have shown relationships to base curve[7], lens diameter[8], and prism ballast[9]. Ballast has been shown to cause a selective swelling in the lower cornea, where the lens is thicker. Other corneal changes reported include endothelial blebs[10], arcuate, punctate, inferior closure, mechanical and physiological staining[11]. DeDonato reported limbal injection and leukocyte infiltration preceding corneal vascularization due to decreased oxygen transmission to the cornea[12].

Various coatings and deposits on the lenses can cause a decrease in patient comfort and optical performance so an assessment of lens cleanliness must be made during the evaluation of the lenses. The deposits develop on both sides and consist of mucopolysaccharides, mucin and proteins. Calcium and urea may also adhere as well as mercurial deposits, pigment deposits and fungal and bacterial organisms[13, 14, 15].

Patient reports of variable visual acuity with blinking and head tilt,

reduced wearing time, sensation in the lower limbal area and discomfort with prolonged near visual tasks are often accompanied by problems with the physical, optical or physiological fit of the lens[16].

Various studies have been cited in the literature as to the success of practitioners with the Hydron Toric lenses. The first fit success rate for Hodd in his study of Hydron Toric lenses was 72%, which he further divided into 42% with all day wear, good visual acuity and no subjective complaints; 30% with all day wear with some subjective complaints at the end of the day; 14% failure due to poor visual acuity and 14% who were physiologically intolerant with severe edema after one to two hours of wear[17]. Wauwe reported a 75% first fit rate with 81.25% success after the first exchange[18]. His failures were due to stabilization problems due to too steep a lens, incorrect conformation of the lens to corneal toricity or incorrect prism ballast causing gravity and lid forces to rotate the lens.

At the time of this writing, actual studies relating success or failure rates on the Bausch & Lomb Toric lenses could not be located. However, a number of practitioners have given overall impressions of these lenses in letters published in Collected Letters of the International Correspondence Society of Optometrists over the past year. Solomon found the B & L lenses good for the correction of with the rule (WTR) and against the rule (ATR) astigmatism and reported consistent quality. Levenson also found the lenses good refractively as well as physiologically but found the parameters somewhat limited. Wesson confirmed the utility of the B & L torics with the ATR cylinders but Koetting discouraged their use in cases of exophthalmos, flat cornea and refractive errors over three diopters. Increased success is possible with a large fitting set because the rotation of the actual lens is difficult to predict before seeing the final prescription on the eye[19-23].

METHODS

SUBJECTS - Subjects were selected from the clinic population at Pacific University College of Optometry and range in age from 20 to 55 years. An effort was made to select a sampling of various refractive errors and types of astigmatism: myopes, hyperopes and simple astigmats exhibiting with the rule, against the rule or oblique cylinders. Initial efforts were made to match the groups wearing Hydron Toric and Bausch & Lomb Toric lenses but available parameters made this impossible. Subjects were free of detectable pathology of ocular structures and were judged to be acceptable contact lens candidates at the onset of the study. Previous contact lens wearers were accepted only if their refraction had stabilized after the discontinuation of lens wear.

METHODS AND MATERIALS - The lenses were fit according to the manufacturer's recommendations as outlined in the fitting guides supplied with the lenses. See table 2 for recommended fitting parameters.

HYDRON TORIC[24]

Overall Diameter	Horizontal Visible Iris Diameter + 2 m.m.
Base Curve Radius	Mean Keratometer reading + 0.4 to 0.5 m.m. for ballasted, truncated trial lenses

BAUSCH & LOMB TORIC[25]

Overall Diameter	14.0 m.m. (Only diameter available)
Base Curve Radius	8.30 m.m. initially - if too tight, try 8.60 m.m.

Table 2 - Recommended Fitting Parameters

For Hydron lens ordering, the following information is sent to the laboratory and a custom made lens is computer designed and returned according to the data given: spectacle correction, vertex distance, horizontal visible iris diameter, power, base curve and diameter of optimum fitting trial lens,

over-refraction and vertex distance with any remarks as to lens rotation, lid configuration peculiarities, etc.

Bausch & Lomb orders are made based on an over refraction using a spherical diagnostic lens combined with a trial lens fit of a toric lens close to the subject's correction to assess rotation. If a trial fitting set is not available, the sphere power and cylinder power and axis are determined and the closest available lens is ordered. Because the cylinder is available in only two powers and twelve axes, bracketing should be used to determine the subject's tolerance for power and axis when over refracting. Orientation and rotation are assessed using the marking on the inferior lens edge and compensation made in axis ordered if necessary.

Lens delivery time was recorded and parameters verified at the time of receipt. Lens performance was rated at dispensing, one week later or following 8 hours of wear, after acccomplishment of full time wear and at one, three and six months, as directed by the manufacturers. Assessments were made of the physical fit as determined by clarity of the retinoscopic reflex and keratometer mires, movement (0.5 to 1.0 mm desired in the vertical meridian without torsional movement) and centering, and over refraction and visual acuity for indications of optical fit. Biocompatibility was monitored with the biomicroscope to check for lid, corneal, limbal and conjunctival integrity and subjective reports of comfort and wearing time. Attempts were made to monitor corneal thickness changes with the Electronic Digital Pachometer but computer malfunctions prevented collection of accurate readings so it was discontinued in this portion of the study.

Lenses not satisfying the necessary criteria for full time wear were reordered by specifying the appropriate parameters to correct the inadequacies of the initial lens. In some cases, subjects were switched to the other manufacturer's lens if performance could be improved by doing so. Subjects who were unable to wear either lens were discontinued from the study.

RESULTS - HYDRON TORIC LENSES

Twenty seven eyes (fourteen subjects) were initially fit with the Hydron Toric lenses. All lenses received were verified and accepted based on parameters which could be determined by standard verification techniques. Due to the aspheric back surface of these contact lenses, base curves and prism ballast parameters were best assessed by judging the performance of the contact lens prescription in relation to the trial lens.

Of the twenty seven lenses, two were returned to the manufacturer for reverification of base curve due to excessive movement not seen with the trial lens of similar base curve. Because these lenses were not returned in time for further data collection, only 25 lenses are included in data analysis. Of these lenses, nineteen or 76% were still being worn after periods ranging from one week to six months at the close of this portion of the study. However, only eleven lenses (40%) are the first lenses dispensed. Seven additional lenses were correct after one reorder (18/25 or 72%) and one lens was reordered twice to achieve an optimum fit. At the close of data collection for Part I, there was indication that as many as 19% of the lenses may require a second reorder within six months of fitting.

SUBJECTS - There appeared to be no obvious trend as to what types of subjects were likely to succeed with these lenses. Of the 6 eyes discontinued, due primarily to physiological problems, two were hyperopic and four were myopic. Two of the myopic eyes were of a previous hard contact lens wearer. There were 2 with the rule, 2 against the rule and 2 oblique astigmatic corrections in the failures. Corneal curvatures were also equally dispersed throughout the range - two near 42.75, two near 43.75 and two near 45.75 diopters (low keratometer reading) with corneal cylinders between 1.50 and 2.50 diopters. The lenses reordered due to tight signs and symptoms

were largely in female subjects but both plus and minus powers and all axes were included in the group.

The data does suggest that if a proper physiological fit can be attained through precise fitting or monitoring of the lens, virtually any type patient can be successfully fit. Profiles of the subjects are listed in Table 3.

Sex		Age	
Male	5 (10 eyes)	Range	22-54 years
Female	9 (17 eyes)	Mean	29.8
Keratometer Readings (low K)		Corneal Cylinder	
Range	40.50 - 45.75 D	Range	0.00 - 3.00 D
Mean	42.82 D	Mean	1.79 D
Refractive Sphere	Hyperopic (10)		Myopic (17)
Range	0.00 to +6.75 D		-0.50 to -5.75 D
Mean	+1.78 D		-3.41 D
Refractive Cylinder			
Range	-0.75 to -3.50 D		-1.00 to -3.50 D
Mean	-2.40 D		-1.96 D
Astigmatism Type			
WTR	6		11
ATR	4		0
OBL	0		6

Table 3 - Subject Summary - Hydron Toric Lenses

FITTING/ORDERING - Hydron offers both a spherical trial lens set with prism ballst and truncation and a spherical set with no ballast or truncation. A variety of base curves and diameter combinations are available. The parameters of the diagnostic set used in this study are listed in Table 4.

Base Curve (m.m.)	Diameter (m.m.)	Power (D.)	Prism Ballast (p.d.)	Truncation (m.m.)
7.9	13.5	-3.50	1 BD	1.0
7.9	14.0	-3.50	1 BD	1.0
8.1	14.0	-3.50	1 BD	1.0
8.3	14.0	-3.50	1 BD	1.0
8.5	14.5	-3.50	1 BD	1.0
8.7	14.5	-3.50	1 BD	1.0

Table 4 - Diagnostic Lens parameters for Hydron Toric Lenses

Following Hydron's recommendation for selecting the optimum diagnostic lens, a base curve of 0.4 to 0.5 mm longer than the mean keratometer reading and a diameter of 2.0 to 2.5 mm larger than the largest iris diameter was selected when available. The lens was allowed to equilibrate on the eye for 20 to 30 minutes before further assessments were made.

An ideal fit, according to the manufacturer's fitting guide had four characteristics: 1) slight (1.0 mm or less) vertical post-blink movement, 2) almost perfect centering during normal eye position and when lids are held apart, 3) rapid recentration after decentering, and 4) a 1.0 mm lens lag on upward gaze. If the lens fulfilled three of these guidelines, the fit was judged to be acceptable. If a lens was too tight or too loose, Hydron recommended a change in base curve and/or diameter. Choosing a suitable diameter at first and making further changes in base curve only, gave more predictable results. Good limbal coverage was achieved with the initial lens and effective alterations in movement were gained by only the base curve manipulations.

The first lens chosen was an average of 0.59 mm flatter than the mean keratometric readings for all subjects, slightly flatter than the fitting guidelines. The mean radius of the subjects' corneas was 7.70 and the most frequently ordered base curves were 8.3 mm (33%) and 8.5 (39%).

DELIVERY AND VERIFICATION - Delivery time for the Hydron lens was not less than four weeks and was as long as six weeks, even when the order was made by telephone to avoid the 3 to 5 day cross country mail delay. Part of the delay can be attributed to an FDA requirement for a ten day quarantine of the lenses after manufacturing and before shipment.

Verification of sphere power and cylinder power and axis is readily accomplished using a standard lensometer and correct positioning of the

truncation. However, due to the asphericity of the ocular surface of the lens, base curve verification was difficult and not reliable. Prism power was also difficult to assess with the lens off the eye. Two lenses were returned for verification of base curve and prism ballast.

PHYSICAL FIT - At dispensing, 100% of the lenses centered well with 0.75 to 1.0 mm limbal overlap. One lens showing excessive movement was suspected to be of incorrect base curve and returned. After three months, 21 lenses were still being worn. Eight of the lenses were reordered, however, due to the development of tight signs and symptoms (38%). Signs signifying a tight lens include inadequate movement, circumcorneal injection, limbal vascular changes, bubbles under the apex of the lens, and irregular keratometer mires or retinoscopic reflex. Symptoms include blurred vision which clears briefly after the blink and discomfort. Because lens hygiene can affect lens fit, patients showing tight lens characteristics were switched from a heat disinfecting regimen to a chemical one before a reorder was made. This change did not usually alleviate the problems. After the first reorder, the optimum base curve was recalculated to be 0.64 mm flatter than the mean K reading (6 eyes were discontinued and not tabulated).

At the close of this part of the study, there was an estimated 67% of the 21 eyes remaining which would eventually need a change in base curve due to tight fitting lenses. This reordering will probably be necessary within the first six months of lens wear. The first 8 lenses reordered were within the first month. Anticipating a further lens change in some of these subjects, the optimum base curve will be 0.7mm flatter than the average K value in millimeters radius.

Rotation of the lens can also be a result of poor fit. At the time of ordering, rotation of the truncation was measured on the slit lamp with a protractor in the eyepiece. Rotation of the trial lens must be reported on

order form with the TRUNCATION as reference for nasal versus temporal. Due to a misunderstanding in terminology, one lens was fabricated with an incorrect axis so all future orders were accompanied by a drawing of lens orientation.

At dispensing, 81% of the lenses received showed identical orientation characteristics as noted on trial lens evaluation. Lid interactions with the front toric surface accounted for the increased rotation of some lenses. The combination of the aspheric back surface, prism ballast and truncation provided excellent stability. For corneas with less than 1.25 D toricity, no rotation was seen, regardless of axis. For toricities greater than 1.50D, the rotation tended to align the ballasted/truncated portion toward the flattest corneal meridian due to lid interactions with the alternating thick and thin portions of the lens.

In with the rule corneal astigmats, the lenses showed a predominantly nasal rotation of 2 to 7 degrees. This nasalward movement is predicted on the basis of lid dynamics. Only two of the lenses showed temporal rotation and one eventually stabilized at 180 degrees after a few weeks of wear.

At the first and second progress exams, 20% of the lenses showed rotations of greater than 5 degrees from the initial fit. Greater deviations became evident in later progress exams which corresponded to lens tightening. The prism ballast tended to lock itself into position with the base-apex meridian wrapping itself around the flattest corneal meridian. This rotation and stabilization proved to be a good prognostic indicator for lens tightening.

One lens which rotated 45 to 90 degrees after several blinks was returned for prism verification. Hydron suggests that a lens that rotates 30 to 90 degrees, locks in place and has little or no movement is too tight or too large. However, this lens was freely moving so the lack of ballast was suspected.

OPTICAL FIT - During the trial lens fitting, 100% of the subjects were able to attain visual acuities equal to or better than their best spectacle correction. At dispensing, 92.6% achieved 20/20 or their best spectacle acuity. Reduced acuity was due to clinician ordering error in one case and vision fluctuations due to hard contact lens wear in another. The latter subject had stable vision, K readings and refractions for three months prior to fitting with these lenses but returned to hard contact lenses for a period during lens ordering and delivery. The subject was subsequently dismissed from the study.

After one week of wear (approximately 8 hours), stable visual acuity (VA) was found in 82.6% of subjects (20/23 eyes). One subject exhibited vertical striae and spectacle blur in both eyes in spite of a good physical fit. The other decrease in acuity was in the case of a presbyope fit in one eye for near work (monovision fit). More plus was required in that eye.

At one month, most subjects were up to full time wear (10 - 12 hours per day). Twenty two eyes were examined because the lens reordered with more plus had not arrived. Nineteen or 86% still showed stable VA. The two eyes being monitored for edema still showed striae and decreased acuity after only a few hours of lens wear so was discontinued. Vision returned to normal and the striae cleared after the lenses were not worn. This subject was deemed edema sensitive and was judged unsuitable for soft lens wear. One other lens was tight, causing unsatisfactory vision.

At the close of part I of this study, 19 eyes remained. Two more eyes (one subject) were changed to the other brand of lenses when bubbles began to accumulate centrally despite a well moving lens and one eye was again participating because a reordered lens was received. All eyes showed stable V.A.

Inability to achieve adequate visual acuity due to optical factors was never a reason for lack of success with the Hydron Toric lenses. They were

excellent for the correction of oblique astigmatism and in cases where corneal and refractive cylinder axes did not coincide. The three stabilization features made the lens fit almost too well, making physiological insult more of a problem than decreased acuity due to misorientation. The prism feature could also potentially cause binocular instabilities when fit monocularly in a subject with a vertical imbalance. This was not encountered in this study but should be considered in monocular fits.

Over refraction of the spherical diagnostic lens gave approximately the same spherical component as the spectacle prescription. In the case of the cylindrical component, some incomplete draping of the lens or perhaps flexure caused some masking of corneal cylinder. Nine of 27 subjects had essentially the same cylinder on over refraction as with spectacles. This was predominantly for low to moderate amounts of cylinder. The over refractions showed as little as 0.25 D less minus for 1.50 to 2.50 D spectacle cylinders to 1.25 D less for a 3.50 D spectacle cylinder. When differences existed between the over refraction prescription and the spectacle value, lenses were manufactured closer to the spectacle prescription.

On progress examinations, over refraction can indicate both optical and physiological fit. Sphere values in excess of ± 0.75 D may indicate a poorly fitting lens and/or associated physiological problems such as edema. Cylinder differences of greater than 25% of the prescribed cylinder (the amount lost due to masking) may indicate rotational or physiological instabilities.

Overall, refractive changes due to lens wear were negligible. An average increase in myopia of 0.08 D and 0.09 D less cylinder occured over the course of this investigation for the remaining subjects.

BIOCOMPATIBILITY - Initial attempts to monitor changes in corneal thickness due to edema was curtailed due to computer malfunctions associated

with the electronic digital pachometer. Therefore, assessments of the eye's physiological response to the lens was made with biomicroscopy, keratometry and refraction.

The primary difficulties encountered with these lenses were physiological. The thickness of the lenses, primarily due to the prism ballast, along with the previously mentioned tendency for close conformity to corneal topography contribute to physiological insult. The center thickness averaging 0.14 mm makes oxygen transmissibility significantly lower than with the super thin hydrogels conventionally fit and creates a need for an active tear pump. This is accomplished by fitting the flattest lens which will remain centered and meridionally stable on the cornea. In spite of a good fit, some individuals may be extremely sensitive to even minute amounts of oxygen deprivation and develop severe edema. Polse maintains that the tear pumping mechanism in hydrogels is minimal, 0.022 values versus 0.1 to 0.2 as found in hard lenses[26]. But with thick hydrogels, the oxygen diffusion route is not as efficient so more pumping action must be provided by the lens fit.

Keratometric findings did not indicate a change in corneal curvature as a cause for needing flatter base curves after lens wear. The changes causing the lens tightening appear to be related to dehydration of the lens and changes in the lens matrix or in the peripheral cornea outside the range of the keratometer. Although the fitting guide states that the aspheric design allows a successful fit even if the lens appears tight, signs other than movement indicated a need for a looser lens in many cases. Because, as Hydron mentions, movement is not the ideal indicator of lens fit, the use of high molecular weight fluorescein is suggested and may be used in part II of this study to assess tear dynamics under the lens.

One of the problems encountered, not always as a result of tight fitting

lenses, was microedema of the epithelium (gross generalized edema associated with soft lens wear specifically). This was predominantly in female patients (8 of 9 cases) and seemed to be related to periodic fluctuations in water balance and water retention. Of those nine eyes, three did eventually require a lens 0.2 mm flatter as indicated by other signs and symptoms. It is important that edema due to oxygen deprivation intolerance caused by thick lenses be differentially diagnosed from problems due to tight or large lenses, dirty lenses, patients' tear quality or quantity or poor blinking habits.

Circumcorneal injection was noted in 16 eyes, 4 of which were apparently sensitive to preserved saline. These subjects were switched to the salt tablet and distilled water regimen.

Involvement of the limbal vessels was observed in 3 eyes. Neovascularization was nasal inferior and superior temporal. Two lenses were re-ordered in flatter base curves and all three subjects are being closely monitored.

Eleven cases of conjunctival pulling occurred, primarily nasally and temporally. Tight lenses and/or loose bulbar conjunctiva were the causes.

One subject exhibited vertical striae, as previously noted. This was attributed to a severe intolerance to oxygen deprivation. Edematous corneal formations (ECF) were noted in another subject but disappeared when wearing time was decreased.

In three cases where bubbles were trapped under the lens apex, fluorescein instillation upon removal of the lens showed dimpled staining in the central corneal region. A flatter lens solved this problem which is attributed to central clearance with peripheral bearing of a steep lens, causing a 360 degree seal off. Interestingly, both overrefraction and movement characteristics were normal. A fluorescein assessment with the lens in place would be helpful in detecting this condition.

No mechanical insult or desiccation was evident in the inferior region of the cornea, even when the lens impinged on the limbus. The continual hydration of this area by the marginal tear meniscus and the thinning of the anterior edge of the truncation may have been factors in preventing such problems.

COMFORT AND WEARING TIME - All subjects tolerated the Hydron lenses well. Only minor lens awareness was reported by subjects whose lenses did not ride below the lower lid margin. A dry eye sensation in some wearers, most notably in partial blinkers, was relieved with the use of Adapettes ocular lubricant. In the case of tight fitting lenses, a sensation of heat and discomfort occurred after four hours of wear. A looser lens eliminated the discomfort.

RESULTS - BAUSCH & LOMB TORIC LENSES

Twenty seven eyes (16 subjects) were fit with Bausch & Lomb (B & L) Toric lenses. All lenses were accepted as optically correct based on verification of parameters and physical inspection. At dispensing, 22 lenses satisfied performance and acuity requirements (81.6%). Of these lenses, one was on a subject who discontinued wear in both eyes due to unsatisfactory vision in only one eye, leaving only 21 lenses to be further evaluated. At the first progress exam (after attainment of 8 hours of wear), 15 of the 21 lenses (71%) were still being worn without difficulty. Data collection beyond the first progress exam was incomplete due to reordered lenses and will be continued and discussed in the subsequent part of the investigation. As of this writing, 8 eyes (39.6%) had been discontinued and 4 lenses (19.8%) had been reordered but not received.

SUBJECTS - Available parameters limit the range of subjects potentially

able to wear these lenses. Stabilization characteristics are variable as well according to magnitude of spherical refractive error and astigmatism type.

Subjects exhibiting with the rule (WTR) or oblique astigmatism (within the range of lenses made) may experience lens rotation but it is often predictable and can be compensated for when writing the final prescription by assessing diagnostic lens rotation. The trend is for the thicker ballasted portion of the lens to move towards the steeper meridian to "fill in" the space. Lid interactions would predict just the opposite based on edge thickness but cylinder powers were fairly low with these lenses. The rotation was found more frequently in high minus lenses, perhaps initiated by the thick minus edge with final orientation based on corneal toricity. Against the rule (ATR) astigmats showed less predictable rotational characteristics. Subject profiles are summarized in table 5.

Sex		**Age**	
Male	12 (21 eyes)	Range	21-38 years
Female	4 (6 eyes)	Mean	26.4
Keratometer Readings (Low K)		**Corneal Cylinder**	
Range	40.50 - 44.87	Range	0.12 - 2.50 D
Mean	42.15 D	Mean	1.49 D

Refractive Sphere	**Hyperopic (3)**	**Myopic (24)**
Range	-0.50 to +0.75 D	-0.75 to -5.75 D
Mean	+0.67 D	-2.92 D
Refractive Cylinder		
Range	-1.25 to -1.50 D	-1.00 to -2.00 D
Mean	-0.67 D	-1.41 D
Astigmatism Type		
WTR	3	12
ATR	0	7
OBL	0	5

Table 5 - Subject Summary - Bausch & Lomb Toric Lenses

FITTING/ORDERING - Bausch & Lomb's diagnostic lenses are available in 8.3 and 8.6 millimeter base curves with one prism diopter prism ballast incorporated into the lens. Orientation marks are present on the inferior edge of the lens and denote the base apex line and 30 degrees on either side (5 and 7 o'clock) to aid in quantifying rotation. A fitting set is suggested to verify final rotational characteristics of a toric lens before ordering. A trail set can be accumulated from failures of previous subjects or a predesigned set of 24 to 100 lenses can be purchased from the manufacturer. No trial lenses were purchased for the fitting set in this study but it is anticipated that a few will be available due to reorders for the second phase of this study. Diagnostic lens parameters are noted in Table 6.

Base curve (m.m.)	Diameter (m.m.)	Power (D.)	Prism Ballast (p.d.)
8.3	14.0	+1.00	1 BD
8.3	14.0	-1.25	1 BD
8.3	14.0	-2.75	1 BD
8.6	14.0	+1.00	1 BD
8.6	14.0	-1.25	1 BD
8.6	14.0	-2.75	1 BD

Table 6 - Diagnostic Lens Parameters, Bausch & Lomb Lenses

The fitting guide recommends starting with the 8.3 mm base curve in a sphere power as close as possible to the subject's spectacle prescription. The 8.6mm base curve is suggested in cases of steep signs with the 8.3 lens. In this study, we chose to evaluate both base curves on every subject. After a minimum of 15 minute equilibration period, evaluation of the lens was performed according to manufacturer's guidelines. Movement was to be at least 0.5mm with the blink in primary position and in upward gaze and with the eye in upgaze, the vertical orientation guide should stabilize with the 90 degree guide near the 6 o'clock position, and reorientation and stabilization

should occur after manual rotation. Further assessments were made of retinoscopic and keratometric reflex clarity over the lens, centration, comfort and acuity. If both base curves appeared satisfactory, the 8.6 mm lens was chosen as experience has shown that soft lenses tighten with wear. It was the optimum lens chosen in 67% of all eyes fit.

DELIVERY AND VERIFICATION - Because these lenses are stocked in standard powers, delivery time is comparable to spherical soft lenses. Verification of base curve can be accomplished using standard equipment and techniques.

PHYSICAL FIT - Limbal coverage was adequate with the 14.0 mm diameter in all cases, even though five of the lenses showed superior or superior temporal riding characteristics. These lenses all showed increased magnitudes of rotations, indicative of greater lens/lid interactions. In such cases, an alternate base curve should be considered to improve centering.

Steep fitting lenses tended to stabilize off axis and should be avoided even when acceptable acuity can be attained initially. Later tendencies of these lenses are for misorientation causing decreased acuity. Contrary to recommendations in the fitting guide, we found that the 8.6 mm base curve was a good starting lens, unless keratometer readings (flat K) were steeper than 43.75 D. The ballast is more effective with a freely moving lens and tightening of hydrogels can be expected to occur in as few as three months of wear. Although no eyes exhibited a need for a lens steeper than 8.3 mm, five could have benefited from a radius longer than 8.6 mm.

Because only spherical diagnostic lenses were used in fitting, some uncompensated rotations did occur in the prescription lenses. Diagnostic lens rotations were from 0 to 20 degrees but 77% were under 5 degrees. Lid forces and corneal topography account for this movement. Rotation of dispensed lenses averaged 7.9 degrees. Seven lenses showed less rotation, 11

showed more and 9 had rotation identical to the diagnostic lens. Changes of five degrees or more occurred in 52% of the lenses as compared with that seen on initial fitting. Rotations of less than 10 degrees did not generally affect acuity significantly. Such magnitudes were seen in 2 of the 19 lenses at the first progress exam.

OPTICAL FIT - Acuities, even when good, tended to fluctuate with the B & L lenses due to rotation and rocking. When the axis was stable, optics were found to be excellent. An optic zone of 7.0 mm proved adequate for all patients due to the good centering capabilities.

Decreased acuity after dispensing was due to lens rotation as evidenced by improvement occuring after manual repositioning of the axis.

These lenses tended to mask about 0.53 of cylinder in 47% of the eyes. Six eyes (19%) showed a need for more cylinder on overrefraction of a spherical lens and 34% (11 eyes) showed identical spectacle and overrefraction cylinders. Greater masking effects (0.75 D or more) should lead to suspicion of a steep fitting lens.

BIOCOMPATIBILITY - No major problems were noted physiologically with these lenses when properly fit. Long term data is still not available for any of the subjects, however, so close attention is still prudent. One subject had injection of the inferior conjunctiva thought to be due to the ballast. Several subjects experienced conjunctival injection and dry symptoms after all day wear. Careful monitoring of these subjects for limbal or corneal changes indicative of a tight lens is continuing. No major edema related conditions were detected during the preliminary followup exams of any patients wearing the B & L torics.

COMFORT AND WEARING TIME - Slight lens awareness was frequently noted with fitting but subsided in most subjects within one week. When rotation was greater than 20 degrees, pain was reported and subjects with low lids

reported some discomfort associated with bumping of the prism area on the lower lid margin. Some dry eye sensation was experience by subjects wearing the lenses for ten or more hours per day.

DISCUSSION

Fitting a toric hydrogel lens successfully requires more time and effort than fitting a spherical soft lens or conventional hard contact lens. Because of the cylinder incorporated into the lens, several additional difficulties ensue. The cylinder must remain properly oriented on the eye, resisting lid dynamics and interactions with corneal topography. The cylinder, coupled with additional features such as ballast add thickness to the lens, inducing physiological consequences. Such were the difficulties encountered in working with the two lens designs in this study.

On inspection of the data available at this writing, it appears that both the Hydron and the Bausch & Lomb Toric lenses offer the eye care practitioner and the astigmatic patient a promising alternative to rigid contact lenses or spectacles. Both lenses provided successes in a number of patients previously unable to be fit with contact lenses.

The two lens designs did show characteristic differences in various aspects related to fitting, however. The Hydron lenses offer an exceptionally wide variety of parameters, sufficient to accommodate almost any request. However, it may not be the lens of first choice in patients with low to moderate amounts of astigmatism with axes near the primary (90/180th) meridians. Although successful with virtually any type of amount of astigmatism optically, the cost of these lenses is double or more than of other non-custom toric lenses. Long delivery times also are a major inconvenience. The Bausch & Lomb lenses have proven acceptable in cases of with the rule astigmatism under 2.00 to 2.50 diopters. Against the rule fits were more

variable but still economically more prudent than a Hydron fit.

When economics are not a factor or when physical factors rule out other lens designs, the Hydron lens can prove invaluable. In cases of high spherical or astigmatic refractive errors, oblique astigmatism or continued failures with other lens designs due to stabilization problems, Hydron can often be the only alternative to spectacles.

The Hydron lens is not the panacea of the astigmatic "affliction", however. With its superior stabilization features, it can compromise oxygen transmissibility to the cornea. Its closely conforming aspheric posterior surface, large center thickness and tendency to tighten can easily cause corneal "suffocation". Even properly fitting lenses can trigger oxygen deprivation signs in sensitive individuals.

While virtually all Hydron lens failures were due to physiological complication, the B & L lenses showed few early indications of similar problems. It is too soon to make any hard and fast predictions, given the limited time course of data collection in this case. It can be proposed, though, that higher success rates with this lens can be anticipated if a toric fitting set is used to supplement and refine data collected with the spherical diagnostic set. High molecular weight fluorescein has potential to be a valuable tool in assessing the fit of both lenses.

Patient acceptance with both lenses can be expected to be good provided adequate motivation exists and the practitioner communicates the minor difficulties associated with using any soft contact lenses. These include the cleaning/disinfecting regimens, possible minor acuity fluctuations, the possibility of allergy or sensitization to chemical preservatives, and perhaps most importantly, the need for close and continued supervision of lens fit and ocular health. A three to four month recall routine should not

be dismissed as overzealous. Drastic and serious changes can occur without significant patient awareness.

Perhaps with further technological advances in the contact lens field, the problems associated with these lenses can be overcome and the vision care profession can look forward to greater ease of fitting combined with decreasing costs and fewer physiological complications.

APPENDIX

HYDRON TORIC SUBJECT DATA

Subject	Age	Sex	Eye	Low K	Corneal Cyl	Spectacle RX	Refr. Cyl
C.C.	37	F	OD	45.75	1.00 D OBL	+2.25 - 2.25 X 082	ATR
			OS	45.50	1.25 D OBL	+1.75 - 2.50 X 103	ATR
J.C.	26	F	OD	41.87	2.75 D WTR	-2.00 - 2.25 X 168	WTR
			OS	41.75	2.87 D WTR	-2.50 - 3.50 X 003	WTR
B.D.	38	F	OD	43.37	2.12 D WTR	-4.50 - 1.75 X 175	WTR
			OS	43.25	2.50 D WTR	-4.50 - 1.50 X 015	WTR
S.D.	24	F	OD	40.50	3.00 D WTR	-1.75 - 3.00 X 002	WTR
J.G.	30	M	OD	41.75	1.12 D WTR	-5.25 - 1.75 X 011	WTR
			OS	41.75	1.25 D OBL	-5.25 - 1.50 X 160	WTR
P.L.	23	M	OD	42.50	1.87 D WTR	-5.75 - 1.25 X 006	WTR
			OS	42.50	1.62 D WTR	-4.50 - 1.00 X 165	WTR
J.M.	22	F	OD	41.50	2.00 D WTR	+0.25 - 3.50 X 020	WTR
			OS	41.62	1.87 D WTR	+0.25 - 3.00 X 165	WTR
D.N.	22	M	OD	43.87	1.62 D WTR	-5.50 - 1.50 X 040	OBL
			OS	43.75	2.62 D OBL	-5.50 - 1.75 X 130	OBL
C.N.	54	M	OD	44.12	0.00 D	+3.75 - 0.75 X 090	ATR
			OS	43.00	0.50 D ATR	+6.75 - 1.00 X 105	ATR
L.P.	24	F	OD	44.25	0.75 D OBL	-3.50 - 1.25 X 120	OBL
			OS	44.25	0.87 D OBL	-3.75 - 1.75 X 045	OBL
D.S.	33	M	OD	42.25	2.62 D WTR	+1.00 - 2.00 X 015	WTR
			OS	42.87	2.50 D WTR	+1.25 - 2.50 X 165	WTR
T.T.	24	F	OD	45.00	1.00 D WTR	-0.75 - 2.00 X 150	OBL
			OS	45.00	0.50 D OBL	-1.00 - 1.75 X 030	OBL
J.W.	27	F	OD	41.87	2.00 D WTR	-1.50 - 2.50 X 175	WTR
			OS	42.00	3.00 D WTR	-0.50 - 3.25 X 175	WTR
L.Y.	34	F	OD	41.12	2.87 D WTR	+0.50 - 3.50 X 020	WTR
			OS	41.12	2.75 D WTR	+0.00 - 3.00 X 165	WTR

APPENDIX

HYDRON TORIC SUBJECT FOLLOWUP DATA

Subject	Dispensed Base Curve	Total Time Lenses Worn	Reorder Information	Notes
C.C.	OD - 8.3 OS - 8.3	1 mo 1 mo		D/c - vertical striae D/C - vertical striae
J.C.	OD - 7.9 OS - 7.9	3 mo 3 mo		
B.D.	OD - 8.1 OS - 8.1	5 wks 5 wks	1 mo - 8.3	
S.D.	OD - 8.5	3 mo	3 mo - 8.7	
J.G.	OD - 8.5 OS - 8.7	1 mo 1 mo	*Subject changed to B & L lenses*	D/c - apical seal-off D/C - apical seal-off
P.L.	OD - 8.5 OD - 8.5	0 0	*rejected at disp for B.C. verif*	Lenses not returned by mfgr for data collection
J.M.	OD - 8.7 OS - 8.7	6 mo 6 mo	3 mo - 8.9 3 mo - 8.9	
D.N.	OD - 8.3 OS - 8.3	1 wk 1 wk		D/C - Hard CL wearer with vision fluctuations
C.N.	OD - 8.1 OS - 8.1	3 wk 3 wk	R/O X2 - 8.3, 8.5 R/O more plus	Monovision fit - distance Monovision fit - near
L.P.	OD - 8.3 OS - 8.3	3 mo 3 mo		
D.S.	OD - 8.3 OS - 8.3	6 mo 6 mo		
T.T.	OD - 8.3 OS - 8.1	6 mo 6 mo		
J.W.	OD - 8.5 OS - 8.5	1 mo 1 mo		
C.Y.	OD - 8.3 OS - 8.3	6 mo 6 mo	4 mo - 8.5 4 mo - 8.5	

APPENDIX

B & L TORIC SUBJECT BASE LINE DATA

Subject	Age	Sex	Eye	Low K	Corneal Cyl	Spectacle RX	Refr. Cyl
J.C.	37	M	OD	40.87	0.50 D ATR	-1.50 - 1.12 X 88	ATR
			OS	40.87	0.75 D ATR	-0.87 - 1.50 X 85	ATR
R.C.	21	M	OS	41.87	1.67 D WTR	+0.50 - 1.50 X 165	WTR
B.D.	38	F	OD	43.37	2.12 D WTR	-4.50 - 1.75 X 175	WTR
			OS	43.25	2.50 D WTR	-4.50 - 1.50 X 015	WTR
S.D.	24	F	OD	41.25	1.75 D WTR	-2.25 - 1.75 X 180	WTR
L.E.	29	M	OD	40.75	1.25 D WTR	-5.50 - 1.25 X 030	OBL
			OS	41.00	1.50 D OBL	-4.00 - 2.00 X 145	OBL
T.G.	24	M	OD	44.00	0.50 D ATR	-3.25 - 1.00 X 116	ATR
			OS	43.87	0.62 D ATR	-3.25 - 1.00 X 057	ATR
J.G.	30	M	OD	41.75	1.12 D WTR	-5.25 - 1.75 X 011	WTR
			OS	41.75	1.25 D OBL	-5.25 - 1.50 X 160	WTR
R.G.	24	M	OD	41.50	1.75 D WTR	-3.50 - 2.00 X 180	WTR
			OS	41.50	2.00 D WTR	-3.50 - 1.75 X 180	WTR
L.K.	24	F	OD	44.50	0.12 D ATR	-0.75 - 1.50 X 095	ATR
P.L.	23	M	OD	42.50	1.87 D WTR	-5.75 - 1.25 X 006	WTR
			OS	42.50	1.62 D WTR	-4.50 - 1.00 X 165	WTR
G.M.	24	M	OS	42.37	0.12 D ATR	-1.50 - 1.25 X 080	ATR
R.N.	24	M	OD	42.62	2.50 D WTR	-1.25 - 1.25 X 003	WTR
			OS	42.50	2.50 D WTR	-1.25 - 1.25 X 005	WTR
J.P.	22	M	OD	40.50	1.87 D WTR	-1.75 - 1.00 X 173	WTR
			OS	40.50	1.87 D WTR	-1.75 - 1.00 X 018	WTR
R.P.	31	M	OD	40.62	1.62 D WTR	+0.75 - 1.25 X 007	WTR
			OS	40.50	2.00 D WTR	+0.75 - 1.50 X 175	WTR
T.S.	23	M	OS	42.25	2.50 D OBL	-2.50 - 1.75 X 145	OBL
T.T.	24	F	OD	44.37	1.62 D WTR	-0.75 - 1.25 X 145	OBL
			OS	44.87	0.87 D OBL	-1.25 - 1.75 X 035	OBL

APPENDIX

B & L TORIC SUBJECT FOLLOWUP DATA

Subject	Dispensed Base Curve	Total Time Lenses Worn	Reorder Information	Notes
J.C.	OD - 8.6	2+ wks		
	OS - 8.6	2+ wks		
R.C.	OS - 8.6	2+ wks		
B.D.	OD - 8.6	2+ wks		
	OS - 8.6	2+ wks		
S.D.	OD - 8.6	2+ wks		
L.E.	OD - 8.6	1 wk		Discontinued - Rotation
	OS - 8.6	1 wk		D/C - Rotation, discomfort
T.G.	OD - 8.3	1 wk		D/C - unstable orientation
	OS - 8.3	1 wk		D/C - unstable orientation
J.G.	OD - 8.6	2+ wks		
	OS - 8.6	2+ wks		
R.G.	OD - 8.3	2 wks	Reordered	Rotation, decr. VA
	OS - 8.3	2 wks	Reordered	Rotation, decr. VA
L.K.	OD - 8.3	1 wk	Reordered	VA fluctuations
P.L.	OD - 8.6	1 wk	Reordered	Axis instability
	OS - 8.6	1 wk	Reordered	Axis instability
G.M.	OS - 8.6	2+ wks		Minor VA fluctuation
R.N.	OD - 8.6	2+ wks		
	OS - 8.6	2+ wks		
J.P.	OD - 8.3	2+ wks		Minor VA fluctuations
	OS - 8.3	2+ wks		Minor VA fluctuations
R.P.	OD - 8.6	1 day		D/C - unstable
	OS - 8.6	1 day		D/C - unstable
T.S.	OS - 8.3	2+ wks		
T.T.	OD - 8.6	1 wk	Reordered	rotation
	OS - 8.3	2+ wks		

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