# W TO CHOOSE A. JUTRA-THIN LI

Today's thin HEMA extended wear contact lenses are not created equally. Each one of the currently available lenses has its own unique strengths and weaknesses, making each lens suitable for some patients, unsuitable for oth-

That's the finding of a threemonth, 30-patient study I conducted on five different thin

HEMA lenses.

I tested all lenses which met three criteria: Each of the lenses had to be made of standard daily wear materials, each had to have very thin center thicknessesaround .035 to .040mm—and each had to have capability—though not necessarily FDA approvalfor extended wear.

The lenses that fit these criteria included Ciba's Cibathin, Syntex's C.S.I. "T," Cooper Vision's Permathin, Bausch & Lomb Soflens 03/04, and Hydron's Zero 4.

To make comparison easier, I prescribed these lenses so that each patient involved in the study wore two brands of lenses at once, one on either eye.

I compared these lenses on the

following points:

 Which lens offers the best fit? I evaluated centration, lens movement after the blink, subjective and objective acuity, and center and edge thickness. I also looked at the reproducibility of each type of lens.

• Which lens appeals most to patients? I collected patients subjective comments on comfort and ease of handling, and also tracked frequency of removal and frequency of lens replacement.

• Which lens is healthiest for the eye? I followed patients for de-

Dr. Hanks, a graduate of both the New England College of Optome-try and of the University of New South Wales in Australia, has served on the research and development staffs of Bausch & Lomb and Ciba Vision Care. He is now a consultant on vision and contact lenses and is in part-time practice.

bris under the lens, edema, corneal infiltrates, epithelial microcysts, giant papillary conjunctivitis, and staining.

#### Lens dimensions

For patient and practitioner comfort, thin extended wear lenses must be thin enough to allow good oxygen permeability, and reproducible enough to allow easy replacement.

To test lenses on both counts, I used five study lenses of each lens type, each within 0.50D of -3.00D. Using a Heidenhahn gauge and the Holden-Payor technique, I measured each lens three times independently. Then I figured in the standard deviations on these measurements to determine manufacturing consistency.
The 03/04, Cibathin and

Permathin lenses were around the expected 35 microns, while the C.S.I. 'T' and Zero 4 lenses were a little thicker.

Using similar methodology, I also measured edge thicknesses. Permathin and Zero 4 lenses had the thickest peripheries, Soflens 03/04 the thinnest.

Not surprisingly, the spin cast manufacturing of Soflens 03/04 was most consistent. Amongst the other lenses, Cibathin and Permathin were best, while the cast molded Zero 4 lenses had the highest variability.

Fitting characteristics

Another concern with thin lenses is that they move less than standard thickness soft lenses.1,2 A lens that moves on the eye produces less debris accumulation,<sup>3</sup> "red eye" responses<sup>4</sup> and polymegathism.<sup>4,5</sup>

I observed the average amount of lens movement on the biomicroscope during primary

gaze and up gaze.
All of the thin lenses moved less than other types of extended wear lenses. But among the lenses, the only appreciable clinical difference was between the Soflens 03/ 04 lenses and all other types. On average, each of the other types of



TABLE 1: FREQUENCY OF LENS REMOVAL				
	Removals per Week			
Scheduled	1.0			
Actual				
Soflens 03/04	1,4			
C.S.I, 'T'	1.7			
Cibathin	1,1			
Permathin	1.2			
Zero 4	1.8			

Anthony J. Hanks, O.D. Port Macquarie, Australia

# ULTRA-THIN

Each of today's thin extended wear lenses has its own strengths and weaknesses, making it suitable for some patients, unsuitable for others.

thin lenses moved almost twice as much as the Soflens 03/04 lenses. However, later portions of the study indicated that even this minimal movement was adequate.

Another key concern is centration. Here again, every lens except for the Soflens 03/04 showed good centration on all patients. The 03/04 lenses decentered 0.67mm (+/-0.45) on average.

Amongst the twelve 03/04 lenses dispensed, nine were 04, while the remainder were 03. As the study progressed, the decentration of these three 03 lenses often became excessive. I finally decided to change all Soflens patients over to 04 lenses.

One lens, the Hydron Zero 4, frequently caused limbal indentation. I noted this indentation in five of the 12 Zero 4 eyes, often as early as the 24-hour visit. No other lens caused limbal indentation.

Patient satisfaction

After fitting the lenses, I evaluated another important concern: Patient satisfaction. Which lenses provided the best vision? Which were most comfortable? Which were easiest to handle? Which were most convenient?

To determine visual acuities, I asked patients to rate the subjective quality of their vision. I compared their response to over-refraction findings and measurements of corrected vision on a Snellen chart.

All patients maintained stable over-refractions and normal visu-

al acuity throughout the threemonth study. I found no clinical difference in these responses.

There was also little difference in perceived comfort of the lenses. After three weeks, I asked patients to rate their lenses in terms of comfort. Patients felt all the lenses were "very comfortable," with no statistically significant differences or clinically noticeable differences between any of the lenses.

In other categories, however, there were differences.

Removal. One of these was frequency of removal. I asked patients to remove their lenses for cleaning and disinfection once each week. I also told them to remove the lenses as often as they felt necessary, provided they recorded each removal.

Among all the lenses, the Zero 4, the CSI 'T,' and the Soflens 03/04 got removed most frequently (Table 1).

The Zero 4 usually got removed due to tight lens symptoms and limbal indentation; the CSI lens got removed due to discomfort and staining, and the Soflens removal occurred with discomfort from excessive decentration.

It is relevant to note that circumstances which led a patient to remove an offending lens usually also resulted in him removing the other lens at the same time. Thus, the overall removal frequencies found were somewhat inflated by the study design.

Handling. After patients had used their lenses for five weeks, I

	Soflens 03/04	C.S.I. T	Ciba- thin	Perma- thin	Zero 4
Parameter Changes	3	1	1		1
Deposits	<u>==</u>	-	<del>-</del>	2 <u></u>	
Damaged Lens	2	1	2	1	-
Lost Lens		- <u>187</u>	-	1	1
Avg. Lenses per Eye *	1.42	1.16	1.25	1.16	1.16

### ULTRATHIN

On the eye, thin lenses move less than standard soft lenses, possibly resulting in more debris accumulation, "red eye" responses and polymegathism.

asked them to compare and then rate the ease of handling of each of their lenses. This was an easy task for patients, since each one was wearing a different lens on each eye.

While these differences were not statistically significant, I considered some to be clinically rele-

vant.

The three patients using lenses from both the easiest and hardest to handle groups on this scale (Soflens 03/04 and Hydron Zero 4) did report a noticeable handling difference between the two lenses. Soflens 03/04 are clinically more difficult, while Zero 4 lenses provide superior handling. The most important reason probably is the variance in edge thicknesses for each lens.

In general, the C.S.I. 'T,' Cibathin and Permathin all rated

average in handling.

Replacement. Because extended wear lenses are expensive, another important concern is frequency

of replacement.

I had to replace the Soflenses most frequently, mostly due to refits. Cibathin lenses came in second, with all other lenses about equal (Table 2).

By the way, these results can be a little misleading, because the lenses with the most discontinued eyes were not exposed to as much wear as were the other lenses.

Physiological response

I didn't encounter any serious complications of extended contact lens wear during the course of this study.

One reason probably was conservative management. I allowed patients to wear their lenses for no more than seven days at a time, and I prescribed a non-allergenic care regimen.

Too, the study lasted for just three months. I would expect that patients proceeding on for extended wear longer than three months would benefit from the regular replacement of lenses.<sup>4</sup>

But I did see relatively common less serious complications<sup>6,7</sup> in my

study, such as edema, debris under the lens, corneal infiltrates, epithelial microcysts, giant papillary conjunctivitis, and staining.

lary conjunctivitis, and staining. Edema. To manage the edema in the study, I monitored striae, rating the lens satisfactory if striae cleared during each day. I converted patients with unsatisfactory edema responses to daily

Most of the patients whom I did discontinue probably required more oxygen than the ones who weren't discontinued. However, lens thickness may have also played a part. It's interesting to note that the thicker Zero 4 lenses had the highest incidence of discontinuation due to edema.

Debris. Mucous and epithelial cells accumulate under extended wear lenses during sleep, when the lens movement is inadequate to clear the debris. This trapped debris can be seen at the moment of eye opening. The debris is small, usually less than 0.1mm,

pale grey in color.

Normally, the debris clears during the day. But if the lens does not move adequately, the patches of trapped debris become larger and remain throughout the day, despite the fact that the eyes are open. Later, this collection of debris may lead to an inflammatory reaction and the so-called "red eye response." 3,4,8

During the course of the study, I scheduled visits to collect observations early in the day as well as

later in the day.

Many patients had debris under their lenses, with most debris for Soflens 03/04 lenses, which move the least.

However, when I reviewed these patients again later in the day, the debris had all cleared. There were consequently no "red eye responses" recorded for any of the lens types.

So how much, or how little, movement is enough? Zantos<sup>9</sup> believes that in the case of very thin lenses, the movement should be enough to be discernable at low magnification. This was the case

#### TABLE 3: INCIDENCE OF EPITHELIAL MICROCYSTS

A State of the Sta	Incidence	Completing
Soflens 03/04	33%	9
C.S.I. `T'	50%	6
Cibathin	33%	9 .
Permathin	22%	9
Zero 4	50%	4

## ULTRA-THIN

with the lenses which moved the least during testing, and these lenses did clear the debris during the three months of study.

Corneal infiltrates. The most common of extended wear adverse responses, infiltrates are an accumulation of inflammatory cells in the cornea and indicate white blood cell penetration of the cornea.<sup>10</sup>

Zantos<sup>1</sup> describes them as occuring in peripheral areas of the anterior stroma and having a

dull grainy appearance.

To find infiltrates, he suggests looking for localized redness. Infiltrates are often adjacent. Staining is not a good indicator. The usual signs and symptoms include monocular occurrence, onset during sleep, secretions on the lid, photophobia, lacrimation, lens movement lacking and posterior lens debris.

I saw clinically significant corneal infiltrates in only three eyes during the course of this study. Two were wearing Zero 4 lenses, while the other lens was a Permathin. These lens types also had the greatest peripheral thicknesses.

I discontinued these three patients from contact lens wear for one week, then returned the unaffected eye to extended wear and the affected eye to daily wear.

Epithelial microcysts. I noticed these small, irregular, high index, bubble formations in the corneal epithelium<sup>11</sup> only towards the end of the study, between two and three months of extended wear

(Table 3).

Zantos<sup>10</sup> has reported a 41 percent incidence rate for extended wear patients and also noted their onset after approximately two months of wear. They are usualy less than 50 per eye and generally cause no problems while they remain in small enough numbers. They have a fluctuating course, are slow to resolve and may also follow abrupt cessation of extended wear.

I discontinued no patients because of microcysts.

Corneal infections. I encountered no serious infections, undoubtedly because of the short, three-month life of lenses used in the study. This effectively models a "frequent replacement" situation.

Giant papillary conjunctivitis. I encountered only one case of GPC during the study. The affected patient wore a Soflens 04 lens on one eye, and a Cibathin lens on the other. Earlier in the study, I had changed the patient from an 03 to the 04. After one month with the new 04 lens, the patient developed a thin protein coating which then produced an episode of GPC. The patient experienced discomfort with large papillae and severe injection of the palpebral conjunctiva.

The other eye exhibited no reaction, and the Cibathin lens remained clean and free of the pro-

tein deposits.

I used Allergan enzyme tablets to clean the 04 lens, with little success. I got better results by using Oxycare, which appears to break up combined coatings of calcium and protein. Subsequent Allergan enzyme treatment then removed the majority of deposits and lens wear was resumed. I added Oxycare to this patient's weekly regimen.

Staining. Most of the patients in the study exhibited some corneal staining. However, staining was most problematic for eyes wearing C.S.I. 'T' lenses. (Table 4).

The patterns of corneal staining fall into two distinct groupings. The staining produced by lenses other than the C.S.I. 'T' had a diffuse corneal and conjunctival "dry eye" pattern. For some of these patients, the "dry eye" pattern was less pronounced than when previously fitted with standard thickness daily wear lenes.

CSI 'T' lenses, on the other hand, produced a moderate arcuate punctate pattern, apparently around the line of the lens junction. Based on the consistent pattern of staining, there appears to be a problem with the optic zone I discontinued a fourth of the 60 eyes beginning the study, due to physiological problems such as staining, edema, corneal infiltrates and limbal indentation.

	Incidence	Eyes Evaluat
Soflens 03/04	17%	12
C.S.I. 'T'	70%	10
Cibathin	17%	12
Permathin	18%	11
Zero 4	20%	10

# UTTRATHIN

All lenses rated well in visual acuity and comfort. But some rated less well in ease of handling, frequency of removal and replacement, and physiological response.

junction in the CSI material.

I discontinued three patients due to clinically unacceptable staining. These paitents also complained of "dryness" and excessive lens awareness.

**Drop-outs**Of the 60 eyes beginning this study, 23 had to be discontinued (Table 5). Fifteen eyes had physiological problems, with 10 eyes wearing either Zero 4 or C.S.I. 'T'

In summary, the C.S.I. 'T' problems (four eyes) were largely staining and the Zero 4 difficulties (six eyes) seemed to arise from excessive thickness evidenced by edema, corneal infiltrates and limbal indentation.

Four patients simply chose to discontinue participation in the study. These drop-out incidents were probably more related to patient personality rather than specific lens types.

Conclusion

Thin design soft contact lenses can provide good results for cosmetic extended wear. But doctors must match patients to lens type, manage the patients conservatively, and stay on the watch for adverse signs.

Acknowledgement

Thanks Rick Payor, O.D., of Sydney, Australia, for confirming clinical evaluations.

- Zantos, S., Davies, G. and W. Reule: "Extended Wear With the Bausch and Lomb 03/04 Polymacon Contact Lens," The Optician, Nov. 5, 1982.
- Solomon, O.D., et al: "Bausch and Lomb 'O' Lenses for Extended Wear," CLAO Journ., 1983, 9(2):137-40.
- Mertz, G.W. and B.A. Holden: "Clinical Implications of Extended Wear Research," Can. J. Optom., 1981, 43(4):2-3.
- 4. Holden, B.A., et al: "The C.C.L.R.U. Gote-borg Extended Wear Studies," to be pub-lished. Reported by Holden, Ellerbrook Cont.
- Ed. Courses, Houston, Tex., Dec. 9, 1983.

  5. Schoessler, J.P.: "Endothelial Effects of Extended Wear," 10th Nat'l. Res. Symp. on Con. Lenses, New York, N.Y., Aug. 13, 1983.
- 6. Holden, B.A. and S.G. Zantos: "The Ocular Response to Continuous Wear of Contact
- Lenses," The Optician, Apr. 6, 1979.

  Holden, B.A.: "Long Term Effects of Contact Lenses on the Cornea," 10th Nat'l. Res. Symp. on Con. Lenses, New York, N.Y., Aug. 13, 1983.
- 8. Holden, B.A., Mertz, G.W. and J.J. McNally: "Corneal Swelling Response to Contact Lenses Worn Under Extended Wear Conditions," Invest. Ophthalmol. Vis. Sci., 1983, 24(2):218-
- Zantos, S.G.: "Thin Design Lenses for Extended Wear," presented at 5th Int'l. Con. Lens Congress, August 1984.
- Coon, L.J., Miller, J.P. and Meier, R.F.: Overview of Extended Wear Contact Lenses," J. Am. Opto. Assoc., 1979, 50 (6):745-749.
- 11. Zantos, S.G.: "Cystic Formations in the Corneal Epithelium During Extended Wear of Contact Lenses," Int. C.L. Clinic, 1983, 1-

TABLE 5: EY	Soflens 03/04		Ciba- thin	Perma- thin	Zero 4
Lost Motivation (4 pts)	Market Sparing		2		2
Physiological Problem —Edema	1 <u>22</u>	1	1	1	2
—Red eye response	1 (1990) A 1990 1 (1990) <del>-</del>	<u></u>			r: ''
-Corneal infiltrates	and the second		. <del></del>	1	2
—Epithelial microcysts	an en <del>e</del>	energy (see		Cally Co.	enter <del>tree</del> ,
—Corneal Infections	<u>-</u> -		i i i i i i i i i i i i i i i i i i i		
-G.P.C.	1			- 10 <u></u>	
—Corneal staining	1	- 3	-		es marco
—Limbal indentation		-	Seethern Court		2
TOTAL EYES DISCONTINUED:	3	6	3		8
(* primary reasons)	erang Philosophia (	of the second second		alan e	