## A VISUAL COMPARISON AND PATIENT PREFERENCE OF SILICONE HYDROGEL AND CORNEO-SCLERAL RIGID GAS PERMEABLE CONTACT LENSES

by

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#### ABSTRACT

*Background:* Currently there are a number of options available for vision correction, with one of the most successful options being prescription contact lenses. To date, many studies have been conducted investigating the advantages and disadvantages of the many different lens modalities. This raises the question as to whether there is a lens modality that can combine both the short adaptation period of a soft contact lens with the superior optical clarity and physiological advantages of a RGP contact lens. Regarding RGP's, experience has shown that comfort levels improve with adaptation, but it is still quite unclear as to the role of the cornea and lids in the adaptation process.<sup>4,5</sup> Therefore, it is proposed that a large diameter RGP, which provides much less contact lens/lid and corneal interaction, could combine the advantages of both the RGP and soft contact lens into a single contact lens design.

*Methods:* In order to assess visual performance and subjective patient preference, we fit 20 patients with both soft contact lenses and a corneo-scleral RGP's. *Results:* This study revealed a very mild difference in objective acuity between the two contact lenses with Air Optix being superior in each of the six means calculated. The Air Optix was the preferred lens by the majority of the subjects, although certainly not a unanimous choice. *Conclusions:* Based on a limited number of subjects and very few statistically significant numbers we feel that both lenses have approximately equal potential for good acuity. We propose that given an adequate adaptation period and proper settling of each respective lens, the difference in visual clarity of these two lenses would be insignificant.

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#### INTRODUCTION

The responsibilities of eye care practitioners are many, and as the field of health care continues to progress, so does the eye care practitioner's role in providing improved ocular healthcare. That being said, providing patients with optimal vision should always be of the utmost importance. Currently there are a number of options available for vision correction, with one of the most successful options being prescription contact lenses. To date, many studies have shown that soft contact lenses are initially more comfortable than rigid gas permeable (RGP) lenses.<sup>1,2</sup> This is likely due to the fact that the hydrogel material of soft lenses is more forgiving and flexible, allowing a shorter adaptation period as compared to RGPs.<sup>3</sup> On the other hand, it is important to remember that many patients do successfully adapt to RGPs and therefore benefit from many significant longterm physiological advantages as compared to soft lenses.<sup>4</sup> This prompts the question as to whether there is a lens modality that can combine both the short adaptation period of a soft contact lens with the superior optical clarity and physiological advantages of a RGP contact lens. Regarding RGPs, experience has shown that comfort levels improve with adaptation, but it is still quite unclear as to the role of the cornea and lids in the adaptation process.<sup>4,5</sup> Therefore, it is proposed that a large diameter RGP, which provides much less contact lens/lid and corneal interaction, could combine the advantages of both the RGP and soft contact lens into a single contact lens design.

In order to assess visual performance and subjective patient preference, we fit 20 patients with both soft contact lenses and corneo-scleral RGP's.

#### MATERIALS AND METHODS

#### Study Design

Subjects were scheduled for a one time visual and subjective comfort comparison of soft contact lenses and corneo-scleral RGPs. Informed consent was obtained as required by the Michigan College of Optometry. Also, a Human subjects form was completed and permission obtained from the Ferris State University Human Subjects Resource Committee (HSRC). The study was described as a one-time trial involving the CIBA Air Optix and the Art Optical SO2Clear corneo-scleral RGP. The subjects presented for an initial visit at which time they were fit first with the CIBA Air Optix soft contact lens, and second with the Art Optical SO2Clear corneo-scleral RGP. After the lenses were received and verified, the subjects returned in order to confirm a proper fit of both lenses. In the case of a less-than-adequate fit the lenses were reordered with the proper change in lens parameters. Once a suitable fit was achieved regarding both the soft and RGP lenses, the subjects returned for a final visit, at which time visual performance was assessed and subjective patient preference was recorded.

#### Subjects

This study consists of twenty subjects without any known current or previous history of ocular disease. The inclusion criteria for this study were all inclusive of those

without any known current or previous history of ocular disease, in addition to expressing a desiring to participate.

Lenses

The CIBA Air Optix silicone hydrogel was used under the following parameters: base curve: 8.7 mm; diameter: 14.5 mm; sphere powers: plano to -6.00 in (0.25D steps); cylinder powers: -0.75D, -1.25D; axes: around the clock in 10° increments. Dk=108.

Art Optical SO2Clear corneo-scleral RGP produced in Boston XO material was used under the following parameters: base curve 7.11-10.55 (0.01 mm steps); diameter: 14.00mm; powers:+20.00 to -25.00 in 0.25D steps; optic zone: 9.60 mm; Dk=130.

Visual Performance

Distance visual acuity was measured, on each eye individually, using the Bailey-Lovie visual acuity chart at ten feet. Contrast sensitivity was measured, on each eye individually, using the Pelli-Robson contrast sensitivity chart at ten feet. Brightness acuity testing was performed using the Bailey-Lovie visual acuity chart and the Marco brightness acuity test instrument. Brightness acuity testing was performed by first occluding the patient's left eye and measuring visual acuity of the right eye under "high" illumination as established by the Marco brightness acuity test instrument. This procedure was then repeated in likewise manner with the right eye occluded and the Marco brightness acuity test instrument over the left eye. Each patient was afforded 20 seconds of total time in order to subjectively convey their best possible visual acuity under "high" illumination with each eye. All measurements were taken through both the CIBA Air Optix soft contact lens and the Art Optical SO2Clear corneo-scleral RGP, in

that order. All visual acuity measurements were taken under similar and consistent lighting environment and circumstances.

#### Subjective Response

Succeeding visual assessment all subjects were asked for a subjective response regarding the comfort and adaptability of both the CIBA Air Optix soft contact lens and the Art Optical SO2Clear corneo-scleral RGP. The questions were presented to the subjects in the form of a one page survey consisting of three parts. Part one asked the subject to rate the comfort of each lens in the study on a scale of 1 to 7 with 1 being extremely uncomfortable and 7 being extremely comfortable. Part two asked the subject to rate the vision of each lens in the study on a scale of 1 to 7 with 1 being extremely poor and 7 being extremely good. Part three of the subjective patient response form asked for additional patient comments for those subjects who desired to add further information.

#### RESULTS

Twenty subjects were successfully fit with both the CIBA Air Optix soft contact lens and the Art Optical SO2Clear corneo-scleral RGP. Data was successfully collected from 19 of the 20 subjects.

#### **Objective Response**

Distance visual acuity was measured, on each eye individually, using the Bailey-Lovie visual acuity chart at ten feet. The CIBA Air Optix soft contact lens showed a mean OD visual acuity of -0.0658 Log Mar. The Art Optical SO2Clear corneo-scleral RGP showed a mean OD visual acuity of -0.0068 logMAR. When comparing the obtained mean visual acuity of the two lenses using a paired samples T-test, a P value of 0.074 was calculated. This indicates that there is no significant difference between mean acuity values. The CIBA Air Optix soft contact lens showed a mean OS visual acuity of -0.0479 logMAR. The Art Optical SO2Clear corneo-scleral RGP showed a mean OS visual acuity of visual acuity of -0.0068 logMAR. When comparing the obtained mean visual acuity of the two lenses using a paired samples T-test, a P value of 0.043 was calculated. This indicates significant difference between mean acuity values.

# logMAR Visual Acuity

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	SoClear	Ciba	
Mean OU	-0.00684	-0.05684	
Standard Deviation	0.095602	0.063997	
Equivalent Snellen Mean	20/19.69	20/17.55	

Contrast sensitivity was measured, on each eye individually, using the Pelli-Robson contrast sensitivity chart at ten feet. The CIBA Air Optix soft contact lens showed a mean OD visual acuity of 1.658 log units. The Art Optical SO2Clear corneoscleral RGP showed a mean OD visual acuity of 1.682 log units. When comparing the obtained mean visual acuity of the two lenses using a paired samples T-test, a P value of 0.525 was calculated. This indicates there is no significant difference between mean acuity values. The CIBA Air Optix soft contact lens showed a mean OS visual acuity of 1.629 log units. The Art Optical SO2Clear corneo-scleral RGP showed a mean OS visual acuity of 1.713 log units. When comparing the obtained mean visual acuity of the two lenses using a paired samples T-test, a P value of 0.008 was calculated. This indicates there is a highly significant difference between mean acuity values.

## **Contrast Sensitivity**

(Pelli-Robson)

	SoClear	Ciba
Mean OU	1.697369	1.643421
Standard Deviation	0.122479	0.131388

Brightness acuity testing showed mean visual acuity of: CIBA Air Optix soft contact lens: 0.1095 logMAR OD and 0.1032 logMAR OS; Art Optical SO2Clear corneo-scleral RGP: 0.1384 logMAR OD and 0.1384 logMAR OS. When comparing the obtained mean visual acuity of the two lenses using a paired samples T-test, a P value of 0.398 OD and 0.298 OS was calculated. This indicates there is no significant difference between mean acuity values.

# logMAR Brightness Acuity

(Bailey-Lovie, "high" illumination)

	SoClear	Ciba	
Mean OU	0.138421	0.106341	
Standard Deviation	0.148259	0.092598	
Equivalent Snellen Mean	20/27.51	20/25.55	

Comparison of Ciba Air Optix silicone hydrogel lenses to the large diameter RGP SO2Clear

# **Paired Samples T-Test**

Paired Differences								
			95% Confidence Interval Std. of the Difference					
	Mean	Std. Deviation	Error Mean	Lower	Upper	t	df	Sig. (2- tailed)
Pair 1 BL OD SC - BL OD Ciba	.05895	.13523	.03102	00623	.12413	1.900	18	.074
Pair 2 BL OS SC - BL OS Ciba	.04105	.08205	.01882	.00151	.08060	2.181	18	.043
Pair 3 BAT OD SC - BAT OD Ciba	.03526	.17765	.04076	05036	.12089	.865	18	.398
Pair 4 BAT OS SC - BAT OS Ciba	.03526	.14331	.03288	03381	.10434	1.073	18	.298
Pair 5 Contrast OD SC - Contrast OD Ciba	.02368	.15931	.03655	05310	.10047	.648	18	.525
Pair 6 Contrast OS SC - Contrast OS Ciba	.08421	.12366	.02837	.02461	.14381	2.968	18	.008

#### Subjective Response

The mean subjective response as pertaining to the comfort of each lens on a scale of 1 to 7 with 1 being extremely uncomfortable and 7 being extremely comfortable was as follows. CIBA Air Optix soft contact lens: 6.263. Art Optical SO2Clear corneoscleral RGP: 4.737. When comparing the obtained mean values of the two lenses using an unpaired samples T-test, a P value of <0.0001 was calculated. This indicates there is a highly significant difference between mean values. The mean subjective response as pertaining to the vision of each lens on a scale of 1 to 7 with 1 being extremely poor and 7 being extremely good was as follows. CIBA Air Optix soft contact lens: 5.684. Art Optical SO2Clear corneo-scleral RGP: 5.105. When comparing the obtained mean values of the two lenses using an unpaired samples T-test, a P value of 0.074 was calculated. This indicates there is not a significant difference between mean values.

# **Subjective Responses**

	SoClear	Ciba	SoClear	Ciba
	Comfort	Comfort	Vision	Vision
Mean (out of 7 possible)	4.736842	6.263158	5.105263	5.684211
Standard Deviation	1.045738	1.045738	0.994135	0.945905
P Value		<0.0001		0.0742
Statistical Significance		YES		NO

#### DISCUSSION

This study revealed a very mild difference in objective acuity between the two contact lenses, with Air Optix being superior in each of the six means calculated. Only the OS acuity and OS contrast sensitivity were of statistical significance. Interestingly, both lenses recorded mean acuities of better than 20/20 equivalent. It is of note that 82% of the all subjects had superior visual acuity through the Air Optix lens. It was our hypothesis prior to this study that the SO2Clear would provide superior vision. One possible explanation for not obtaining this result is that a number of patients reported inconsistent visual clarity while wearing the SO2Clear. This fluctuating level of vision appeared to correlate with movement of the lens upon blinking. Another possible cause was thought to be an increase in tearing which may be a result of increased contact lens awareness.

When comparing the results of brightness acuity testing the Air Optix again showed superior visual clarity, although at a level that is not statistically significant. Surprisingly though, when comparing the decrease in visual acuity as relating to the nonbrightness acuity, the SO2Clear exhibited a less significant loss of perceivable vision.

The comfort of the Air Optix lens was preferred at a highly statistically significant level. Only one of twenty subjects preferred the comfort of the SO2Clear lens and three of the subjects rated the comfort as being equal. We found it very interesting that nearly all 20 subjects found the SO2Clear lens more comfortable than they had anticipated.

Four of the subjects reported superior vision and six subjects reported equal vision through the SO2Clear lens.

It is our conclusion that regarding both vision and comfort, the Air Optix was the preferred lens by the majority of the subjects, although certainly not a unanimous choice. Based on a limited number of subjects and very few statistically significant numbers we feel that both lenses have approximately equal potential for good acuity. We propose that given an adequate adaptation period and proper settling of each respective lens, the difference in visual clarity of these two lenses would be insignificant, if not in favor of the SO2Clear.

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