

A New Method for Examining the Anterior Segment by UBM

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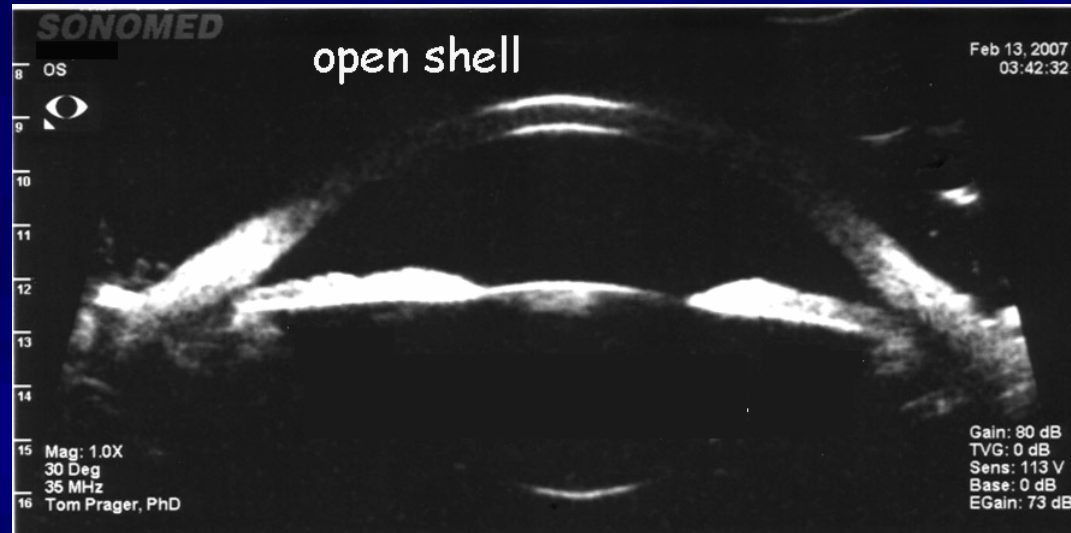
INTRODUCTION

The limitation of examining the angle or other eye structures by ultrasonic biomicroscopy (UBM) is that an open shell with gel/saline is required. Corneal abrasions may result if either the probe or the edge of the open shell makes contact with the corneal epithelium.

The ClearScan™ is a sterile, water-filled bag which covers the end of the UBM probe. A rigid collar at the base of the bag creates a tight seal around the UBM probe. As the examiner pushes on the eye, positive pressure results within the bag, minimizing the potential of the probe coming into contact with the cornea. Gel is not required for the exam. Only a drop of BSS is used as an interface. The ClearScan™ and the traditional open shell are compared for comfort and structural measurement correlation (anterior chamber & sulcus-to-sulcus).



Equivalent Images



Study Questions

- Which method do patients prefer?
 - Quantification of comfort level

- Are measurements equivalent?

METHODS

In this prospective investigation a cohort of 20 subjects was evaluated by both the open shell and ClearScan TM techniques. Presentation order was randomized. The anterior chamber and sulcus-to-sulcus measurements were taken 3 times, and the average used as datum.

Subsequent to measurement by both techniques, each subject was asked which method was preferable and to rate comfort on a 1 to 5 validated pain scale modified for this study.

The main outcome variables were statistically evaluated by paired t-tests and correlations. P-value <0.05 was considered statistically significant.

β (1-power) Anterior Chamber comparison = 0.89

β (1-power) Sulcus-to-Sulcus comparison = 0.96

RESULTS

Comfort Scale

ClearScan™ = 0.40



0

not uncomfortable
at all



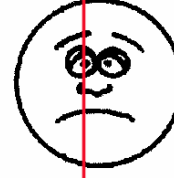
1

uncomfortable
Little Bit



2

uncomfortable
Little More



3

uncomfortable
Even More



4

uncomfortable
Whole Lot

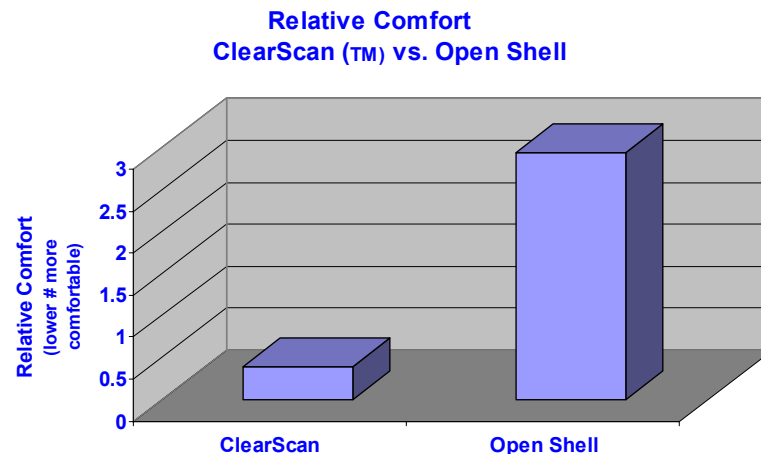


5

uncomfortable
Worst

Open Shell = 2.95

100% of the cohort (20 out of 20) preferred the ClearScan™ over the shell



Results

Paired Samples Summary Statistics

		Mean	N	Std. Deviation
Pair 1	<u>Comfort</u>			
	ClearScan™	.40	20	.52
	Shell	2.95	20	.90
Pair 2	<u>AC avg</u>			
	ClearScan™	2.88 mm	20	.24
	Shell	2.94 mm	20	.23
Pair 3	<u>S to S avg</u>			
	ClearScan™	11.24 mm	20	.56
	Shell	11.20 mm	20	.60

Results

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	<u>Comfort</u> ClearScan™ & Shell	20	.072	.763 NS
Pair 2	<u>AC avg</u> ClearScan™ & Shell	20	.948	<.0001
Pair 3	<u>S to S avg</u> ClearScan™ & Shell	20	.912	<.0001

Results

Paired Samples t- test

				95% Confidence Interval of the Difference		T	df	sign (2-tailed)
		Mean	Std. Deviation	Lower	Upper			
Pair 1	<u>Comfort</u> <u>ClearScan™</u> & Shell	-2.550 difference	1.012	-3.024	-2.076	-11.27	19	<.0001
Pair 2	<u>AC avg</u> <u>ClearScan™</u> & Shell	-0.056 mm difference	.07875	-.09327	-.01956	-3.20	19	.005 Not clinically significant
Pair 3	<u>S to S avg</u> <u>ClearScan™</u> & Shell	0.039 mm difference	.24597	-.07595	.15428	.71	19	.485 NS

Results

- Results show a preference for the ClearScan™ methodology.
- Anatomical comparisons between ClearScan™ and open shell are:
 - r= 0.94 AC (0.056 mm difference)
 - r= 0.91 sulcus-to sulcus (0.039 mm difference)

Conclusions

- The ClearScan™ technique was preferred by 100% of the cohort over the open shell technique and the comfort rating difference was statistically significant.
- Anatomical measurement differences were clinically negligible and the correlations between methodologies were high.
- Given improvements in comfort, sterility and safety, the ClearScan™ technique removes many of the barriers to anterior segment UBM examinations.