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

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

Comfort Scale

ClearScan™ = 0.40
Open Shell = 2.95

not uncomfortable at all
uncomfortable
uncomfortable
uncomfortable
uncomfortable
uncomfortable

Little Bit
Little More
Even More
Whole Lot
Worst

Relative Comfort
ClearScan (™) vs. Open Shell

Relative Comfort (lower # more comfortable)
## Results

### Paired Samples Summary Statistics

<table>
<thead>
<tr>
<th>Pair</th>
<th>Type</th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pair 1</td>
<td>Comfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ClearScan™</td>
<td>.40</td>
<td>20</td>
<td>.52</td>
</tr>
<tr>
<td></td>
<td>Shell</td>
<td>2.95</td>
<td>20</td>
<td>.90</td>
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<tr>
<td>Pair 2</td>
<td>AC avg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ClearScan™</td>
<td>2.88 mm</td>
<td>20</td>
<td>.24</td>
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<tr>
<td></td>
<td>Shell</td>
<td>2.94 mm</td>
<td>20</td>
<td>.23</td>
</tr>
<tr>
<td>Pair 3</td>
<td>S to S avg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ClearScan™</td>
<td>11.24 mm</td>
<td>20</td>
<td>.56</td>
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<tr>
<td></td>
<td>Shell</td>
<td>11.20 mm</td>
<td>20</td>
<td>.60</td>
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</table>
## Results

### Paired Samples Correlations

<table>
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<tr>
<th>Pair</th>
<th>Sample Description</th>
<th>N</th>
<th>Correlation</th>
<th>Sig.</th>
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</thead>
<tbody>
<tr>
<td>Pair 1</td>
<td>Comfort ClearScan™ &amp; Shell</td>
<td>20</td>
<td>.072</td>
<td>.763 NS</td>
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<td>Pair 2</td>
<td>AC avg ClearScan™ &amp; Shell</td>
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<tr>
<td>Pair 3</td>
<td>S to S avg ClearScan™ &amp; Shell</td>
<td>20</td>
<td>.912</td>
<td>&lt;.0001</td>
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</tbody>
</table>
## Results

### Paired Samples t-test

<table>
<thead>
<tr>
<th>Pair</th>
<th>Groups</th>
<th>Mean Difference</th>
<th>Std. Deviation</th>
<th>95% Confidence Interval of the Difference</th>
<th>T</th>
<th>df</th>
<th>Sign (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pair 1</td>
<td>Comfort ClearScan™ &amp; Shell</td>
<td>-2.550</td>
<td>1.012</td>
<td>-3.024, -2.076</td>
<td>-11.27</td>
<td>19</td>
<td>&lt;.0001</td>
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<td></td>
<td></td>
<td>-0.056</td>
<td>.0785</td>
<td>-.09327, -.01956</td>
<td>-3.20</td>
<td>19</td>
<td>.005 Not clinically significant</td>
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<tr>
<td>Pair 2</td>
<td>AC avg ClearScan™ &amp; Shell</td>
<td>0.039</td>
<td>.24597</td>
<td>-.07595, .15428</td>
<td>.71</td>
<td>19</td>
<td>.485 NS</td>
</tr>
</tbody>
</table>
Results

Results show a preference for the ClearScan™ methodology.

Anatomical comparisons between ClearScanTM 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.