Clinical performance and patient preferences for hydrogel versus rigid gas permeable lenses: A crossover study

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Abstract
A clinical trial was conducted with twenty subjects to compare patient preference and corneal physiology for hydrogel (soft) contact lenses to that with rigid gas permeable (RGP) contact lenses. Each subject wore each type of lens for six weeks and then switched materials for the remaining six weeks. Initially, half of the subjects wore RGP contact lenses while the other half wore soft contacts lenses. Subjects were monitored after one week, three weeks, and six weeks of wear with each lens type. At the completion of the study eight of the subjects preferred the RGP contact lenses while twelve of the subjects preferred the soft contact lenses. Excluding foreign body staining, every subject demonstrated corneal fluorescein staining with soft contact lenses equal to or greater than that found with the RGP contact lenses. Although five subjects could not fully adapt to the RGP lenses, seven of the twelve subjects who preferred the soft contacts lenses were also "successful" RGP lens wearers. "Successful" was defined as that the lenses provided clear vision and good comfort without interrupting corneal physiology. The results of this study indicate that 75% of subjects traditionally deemed more suitable for soft lenses could successfully wear RGP lenses, and 40% of the subjects may actually prefer them.

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Thesis

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CLINICAL PERFORMANCE AND PATIENT PREFERENCES FOR HYDROGEL VERSUS RIGID GAS PERMEABLE LENSES: A CROSSOVER STUDY

By

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ABSTRACT

A clinical trial was conducted with twenty subjects to compare patient preference and corneal physiology for hydrogel (soft) contact lenses to that with rigid gas permeable (RGP) contact lenses. Each subject wore each type of lens for six weeks and then switched materials for the remaining six weeks. Initially, half of the subjects wore RGP contact lenses while the other half wore soft contacts lenses. Subjects were monitored after one week, three weeks, and six weeks of wear with each lens type. At the completion of the study eight of the subjects preferred the RGP contact lenses while twelve of the subjects preferred the soft contact lenses. Excluding foreign body staining, every subject demonstrated corneal fluorescein staining with soft contact lenses equal to or greater than that found with the RGP contact lenses. Although five subjects could not fully adapt to the RGP lenses, seven of the twelve subjects who preferred the soft contacts lenses were also “successful” RGP lens wearers. “Successful” was defined as that the lenses provided clear vision and good comfort without interrupting corneal physiology. The results of this study indicate that 75% of subjects traditionally deemed more suitable for soft lenses could successfully wear RGP lenses, and 40% of the subjects may actually prefer them.

Key Words: contact lenses, rigid gas permeable, hydrogel, patient preference, lens performance, staining.
INTRODUCTION

In today's fast-changing contact lens practice the clinician is often presented with the dilemma of fitting a patient with a soft daily wear spherical contact lens or a rigid gas permeable (RGP) spherical lens. Typically, if the patient has minimal corneal and refractive cylinder, the clinician may opt to fit a patient with the soft lens. Many clinicians prefer the ease of fitting the soft lens over the RGP lens and expect the soft lens to be readily accepted because of the initial comfort. However, it is well documented in the literature that RGPs provide increased oxygen to the cornea, equivalent or improved vision, are more durable, and deposit less than soft lenses. Further, RGP lenses are easier to care for, rarely have toxic or allergic reactions, and provide a physiologically superior environment compared to soft lenses.¹

Recent studies have shown that RGP lenses do offer a viable alternative to soft lenses, both in terms of on-eye performance and patient satisfaction. Studies by Fonn and Holden ² and Weiss ³ compared the performance of rigid and soft lenses worn simultaneously for extended and daily wear, respectively. Weiss found that 9 of her 10 subjects preferred the rigid lens after a 3 month wearing period. Fonn and Holden reported similar results with their longer term extended wear study, indicating that lens performance and patient satisfaction is superior with RGP lenses in the long term. However, wearing a rigid lens in one eye and a hydrogel in the other hardly constitutes normal conditions in practice. In this study, a cross-over design was utilized such that each patient wore a pair of the same type of lenses for a 6 week period, then switched to the other type for another 6 week period. The order was randomized so that one half began with rigid, the other half with soft lenses, thus controlling for order effects. This significant alteration in the design of the study was projected to provide a more realistic clinical scenario for making appropriate comparisons between the two types of lenses.
METHODS

SUBJECTS

Twenty subjects, 10 female and 10 male, with ages ranging from 16 to 39 years, participated in the study. Corneal and/or refractive cylinder of less than 0.750D with no other accepted contraindications of contact lens wear were criteria for patient selection. A written informed consent was obtained from each subject prior to the study. Only one subject had previous contact lens experience. That subject had worn soft daily wear contact lenses seven years before the study and discontinued wear due to solution allergies after 1.5 years of full-time wear.

One group of subjects (group A; n=10) started the study wearing soft lenses in both eyes for six weeks and then changed to RGP lenses. The second group (group B; n=10) initially wore RGP lenses for six weeks while changing to soft lenses for the concluding six weeks of the study.

LENSES

The RGP lenses used in the study were of a silicone-acrylate composite (silafcon A; Polycon II; Sola/ Barnes-Hind). The soft lenses used were crofilcon A (CSI-T; Sola/ Barnes-Hind) that contained 38.5% water. The oxygen transmissibility (Dk) of the lens materials were 12.0 and 13.0, respectively.

PROCEDURES

Subjects were fitted with RGP and soft contact lenses to obtain optimal centration, movement, and bearing characteristics. The lens to be worn initially was selected from a random drawing, ensuring equal numbers of subjects in groups A and B. All subjects were monitored after one week, three weeks, and six weeks of wear with each type of lens. A complete biomicroscopic evaluation of the cornea, including fluorescein staining, was performed at each visit as well as an assessment of refractive and/or keratometric changes at the first and last visit for each lens type.
A questionnaire was completed by the subjects at each visit. They were asked to assess clarity of vision, comfort, ease of insertion and removal, and frequency of comfort drop use at each visit. Overall lens preference was assessed only for the final visits.

Sola/Barnes-Hind RGP and Softmate Concept systems were the solutions used during the study with minor modifications, as noted below. Subjects were instructed to clean their rigid lenses using the RGP daily cleaner and digital massage and store the lenses in the wetting and soaking solution. Due to the short duration of the study none of the patients used the protein removing solution for the care of the RGP lenses. A daily cleaner in addition to the Softmate Concept solutions were use in soft lens care instead of the Hydramat "hands off" cleaning method advocated by Sola/Barnes-Hind. Sola/Barnes-Hind weekly cleaning solutions and/or tablets were used for enzymatic cleaning in the care of soft lenses.

DATA ANALYSIS

Data were analyzed using standard and single group Chi-square (observed versus expected), as indicated by the data. For the single group $X^2$, it was assumed that each answer had an equal chance of being selected. An alpha level of 5% was used for determining significance.
RESULTS

PHYSIOLOGICAL CONSIDERATIONS

Fluorescein staining of the cornea was the chief physiological variable investigated. Staining was graded according to the scale described in Table 1. Thirty-five percent of the RGP wearers and eighty percent of the soft lens wearers exhibited observable corneal fluorescein staining (Figure 1). The staining seen with rigid lenses was typically mild foreign body and 3 & 9 o'clock peripheral desiccation, while the soft lens staining resembled the classical CSI "smile" pattern described by other authors. Figures 2 and 3 present unusual staining patterns observed in one wearer of CSI-T lenses.

There were no significant observable changes to the subjects' palpebral conjunctiva and corneal endothelium associated with either type of lens wear over the course of the study.

TABLE 1
GRADING SCALE USED FOR ASSESSMENT OF CORNEAL STAINING

<table>
<thead>
<tr>
<th>GRADE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>NONE</td>
</tr>
<tr>
<td>1</td>
<td>1-20 DISCRETE DOTS</td>
</tr>
<tr>
<td>2</td>
<td>20-50 DOTS AND/OR MILD COALESCEENCE</td>
</tr>
<tr>
<td>3</td>
<td>&gt;50 DOTS AND/OR MODERATE COALESCEENCE</td>
</tr>
<tr>
<td>4</td>
<td>CONFLUENT STAINING (DELEN, EROSION)</td>
</tr>
</tbody>
</table>
FIGURE 1  Distribution of staining grades by lens type.
FIGURES 2 and 3  Atypical staining patterns seen in a subject wearing CSI-T lenses.
RESULTS OF SUBJECT QUESTIONNAIRES

Table 2 contains the results of the statistical analysis of the subjective data gathered in the questionnaires. At the final visit of the study, forty percent of all subjects preferred the RGP lenses overall while sixty percent preferred soft lenses when forced to select one lens type. Lens preference was not significantly affected by the order of the lens presentation, (e.g. rigid first). It was interesting to note, however, seventy-five percent of all subjects could successfully wear both types of lenses (Figure 4).

As might be expected, when surveyed at the final week visit, subjects reported that soft lenses were more comfortable than RGP lenses, but vision with RGP lenses was more clear than with soft lenses. Also noted was that RGP lenses were easier to insert and care for than soft lenses. In fact, 100% of subjects said RGP lenses were easier than soft lenses to care for.

![Graph](image)

FIGURE 4 The black faced columns represent the response to the forced choice preference question posed at the final visit. The grey faced bar indicates the percentage of subjects who could have successfully worn either lens type, based on subjective and objective findings.
### TABLE 2 - QUESTIONNAIRE RESPONSES
**RGP VS SOFT (VISIT 6)**
(Chi-squared Analysis)

<table>
<thead>
<tr>
<th>Comparisons Asked</th>
<th>P value (alpha = 0.05)</th>
<th>If not statistically significant, trends observed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Comfort</td>
<td>$p = 0.0042$</td>
<td>Statistically significant. Soft lenses were more comfortable than RGP lenses.</td>
</tr>
<tr>
<td>2. Clarity of Vision</td>
<td>$p = 0.0295$</td>
<td>Statistically significant. Vision with the RGP lenses more clear than with soft lenses.</td>
</tr>
<tr>
<td>3. Ease of Insertion</td>
<td>$p = 0.0442$</td>
<td>Statistically significant. RGP lenses were easier to insert than soft lenses.</td>
</tr>
<tr>
<td>4. Ease of Removal</td>
<td>$p = 0.1710$</td>
<td>Not significant.</td>
</tr>
<tr>
<td>5. Ease of Care</td>
<td>$p &lt; 0.00001$</td>
<td>RGP lenses were easier to care for than soft lenses.</td>
</tr>
<tr>
<td>6. Light sensitivity</td>
<td>$p = 0.0719$</td>
<td>Appears that RGP lenses cause at least as much or more light sensitivity than soft lenses.</td>
</tr>
</tbody>
</table>
DISCUSSION

The results of this study suggest that many of the patients who traditionally would be fitted with soft lenses as a first choice, would be equally or better suited to rigid lens wear. This data confirms that of Fonn and Holden as well as Weiss, but utilized a paradigm more applicable to standard clinical practice.

Although vision was better with the RGP lens at the final visit, there was no significant difference in clarity of vision when using the data for all visits combined. This may be explained by the fact that the CSI-T lens has excellent optical properties and has been reported to be more resistant to deposits. RGP lenses may provide even more noticeable improvements compared to "optically average" soft lenses. The more important contributions to these results, however, might have been the restrictions on corneal and refractive cylinder for subjects to be included in this study, imposed so as not to "sabotage" the soft lens case, in terms of attainable visual acuity. While patients with as much as 2 diopters of corneal and refractive cylinder are commonly fitted with spherical RGP lenses, this would cause moderate to severe reductions in the vision with spherical soft lenses, and his study was designed to specifically evaluate a population which is considered ideal for soft lenses.

In terms of objective measures of lens performance, the corneal staining results were very interesting. Very few reports of corneal staining with soft lenses are seen in the literature, yet we observed significant staining in 80% of our patients wearing soft lenses, and only 35% of rigid lens patients. Given that these are the same patients and observers, and that order was randomized and balanced, it is unlikely that the data is spurious. While specific patterns of staining have been reported with the CSI lens\(^4\), it is likely that staining occurs with all soft lenses for similar reasons. Dittoe hypothesizes that it is due to poor tear exchange and Holden and Mertz have also shown that a soft lens restricts the tear exchange such that debris cannot be removed from under the lens\(^5\), thus setting up conditions for staining to occur.
Few practitioners bother to stain patients wearing soft lenses. Reasons given are that it will ruin the lens, that these lenses are "soft" and therefore not likely to cause staining, and that staining can be observed in white light, among others. In our study, we did not replace a single lens due to discoloration, nor did we receive any complaints from patients about discoloration or fluorescence of their lenses. Our technique was to remove the lenses following white light evaluation, instill fluorescein, and observe the cornea, lids and conjunctiva with Cobalt blue light and a yellow Wratten #12 filter over the objective. This barrier filter enhances the appearance of fluorescein. Following this observation, the eyes were rinsed by squirting non-preserved saline in the upper and lower fornices, having the patient roll their eyes, and repeating. The patient was supplied with a tissue “dam” to collect the excess saline.

The other findings in the study were not unexpected, and are consistent with previous studies, as well as commonly held beliefs about rigid and soft lenses. The soft lenses are initially more comfortable and a period of adaptation time is required with rigid lenses. We hypothesize that if the study had been for a longer duration, the comfort with the rigid lenses for subjects who completed the study would have continued to improve. However, this would not have affected the subjects who were unable to complete the study. It has been demonstrated in the past that large majority of drop outs from rigid lens studies occur in the first month, and a plateau is then reached. However, with soft lenses, the discontinuations tend to remain constant for a time, and then increase with longer term wear.

The overwhelming preference for the care and handling of the rigid lenses is not surprising either. The firmness of the material and the smaller overall diameter compared to the soft lens make the RGP lens easier to place on the cornea. As often discussed in the literature, RGP lenses are more durable and are not prone to accidental tearing or ripping. Figure 5 shows a crack noted in a CSI-T lens as received from the manufacture. Additionally, four CSI-T lenses had to be reordered during the course of the study due to poor optics.
In the final analysis, comfort levels with rigid lenses are of concern to all practitioners and patients. Despite the fact that the soft lenses were found to be more comfortable than RGP lenses throughout the study, at the completion of the study, forty percent of all subjects still preferred the RGP lens. That seventy-five percent of the subjects could wear both lenses successfully may prove surprising to some. It is the authors' opinion that if the length of the study could have been extended, more of the subjects would have preferred the RGP lens.

As with comfort, one has to consider the long term performance of a given lens wear modality. Long term problems with soft lens wear include neovascularization, epithelial cell loss, giant papillary conjunctivitis, and lens deposits. Particularly in the case of extended wear, there are more serious complications which can occur including corneal ulceration and infection, which are seen less commonly with rigid lenses.

Conversely, effects of RGP long term wear are usually limited to 3 and 9 o'clock staining, and mild changes in corneal curvature and refractive error, all which often can usually be eliminated by lens design and fitting manipulations. Infection, scarring and corneal vascularization are very rare with RGP lens wear.
In summary, not everyone can wear rigid lenses, but the recent advancements in the materials and designs make RGP lenses a viable alternative for the next "soft lens" patient that sits down in your chair. Once the hurdle of adaptation is cleared, the RGP lens becomes the obvious choice. Is it better to have an unhappy soft lens patient after two years or a happy RGP patient for a lifetime?
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REFERENCES


