Are Disposable and Standard Gonioscopy Lenses Comparable?

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Purpose: Gonioscopy is important in the evaluation and treatment of glaucoma. With increased scrutiny of acceptable sterilization processes for health care instruments, disposable gonioscopy lenses have recently been introduced. Single-time use lenses are theorized to decrease infection risk and eliminate the issue of wear and tear seen on standard, reusable lenses. However, patient care would be compromised if the quality of images produced by the disposable lens were inferior to those produced by the reusable lens. The purpose of this study was to compare the quality of images produced by disposable versus standard gonioscopy lenses.

Materials and Methods: A disposable single mirror lens (Sensor Medical Technology) and a standard Volk G-1 gonioscopy lens were used to image 21 volunteers who were prospectively recruited for the study. Images of the inferior and temporal angles of each subject's left eye were acquired using a slit-lamp camera through the disposable and standard gonioscopy lens. In total, 74 images were graded using the Spaeth gonioscopic system and for clarity and quality. Clarity was scored as 1 or 2 and defined as either (1) all structures perceived or (2) all structures not perceived. Quality was scored as 1, 2, or 3, and defined as (1) all angle landmarks clear and well focused, (2) some angle landmarks clear, others blurred, or (3) angle landmarks could not be ascertained. The 74 images were divided into images taken with the disposable single mirror lens and images taken with the standard Volk G-1 gonioscopy lens. The clarity and quality scores for each of these 2 image groups were averaged and *P*-values were calculated.

Results: Average quality of images produced with the standard lens was 1.46 ± 0.56 compared with 1.54 ± 0.61 for those produced with the disposable lens ($P = 0.55$). Average clarity of images produced with the standard lens was 1.47 ± 0.51 compared with 1.49 ± 0.51 ($P = 0.90$) with the disposable lens.

Conclusions: We conclude that there is no significant difference in quality of images produced with standard versus disposable gonioscopy lenses. Disposable gonioscopy lenses may be an acceptable alternative to standard reusable lenses, especially in conditions where sterilization is difficult.

Key Words: gonioscopy, lens, disposable, glaucoma

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Gonioscopy is an important part of the standard ophthalmic examination when evaluating for glaucoma and allows the ophthalmologist to visualize the iridocorneal angle, thus differentiating between open-angle and narrow or angle-closure glaucoma. It also helps in diagnosing secondary glaucomas and is used for treatment in procedures such as selective laser trabeculoplasty.[1]

The use of gonioscopy lenses is necessary to visualize the angle structures and deliver laser treatment during trabeculoplasty.[2] The lens utilizes a mirror to allow light from the iridocorneal angle to overcome the critical angle of defraction at the air-corneal interface and be viewed by the observer.[3] Most health care institutions currently use standard, reusable lenses for these procedures. As there are no uniformly adopted standardized guidelines on how to clean these lenses, they can undergo steam sterilization or chemical sterilization, both of which have relatively lengthy time requirements and can wear down the coating on the lens and produce scratches. In addition, due to increasingly strict regulations regarding infection prevention and hygiene maintenance, disposable lenses for ophthalmic laser therapy have recently become available. Possible benefits are decreased cost depending on use and theoretically decreased infection rates. However, clinicians question whether these benefits could be outweighed by potentially inferior image quality produced by the disposable lens compared with the reusable lens. The purpose of this study was to compare the quality of the images provided by a disposable versus a standard gonioscopy lens.

MATERIALS AND METHODS

In total, 21 volunteers were prospectively enrolled. Complete ocular histories were taken and consent was obtained from each individual for the gonioscopy and imaging process. The room lights were turned off for the duration of data collection. An experienced ophthalmologist, specialized in glaucoma, performed the gonioscopy and image acquisition. The procedure began by instilling topical anesthesia (Akorn proparacaine hydrochloride ophthalmic solution, 0.5%) to the subject's left eye. Goniovisc Eye Lubricant Hypromellose Ophthalmic Solution was then placed on the gonioscopy lens, which was placed against the patient's left eye to visualize the iridocorneal angle. Multiple images of the inferior and temporal angles were acquired using a Haag-Streit slit-lamp camera, first using the standard lens (Volk G-1; Mentor) and then using the disposable lens (Sensor Medical Technology, Maple Valley). The slit-lamp settings were standardized for all images ($\times 40$ magnification, an aperture of step 6, slit width 5 mm, fill light of 0 at 2/3 intensity, and slit angled at 30 degrees). No actual laser procedure was performed.

The images were sorted by patient and by lens type, selecting for the best inferior and nasal image available for each lens for each patient. These images were then

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randomized for the purpose of grading. In total, 37 images were graded for the disposable lens and 37 images were graded for the standard lens in random order with the grader masked to which lens was used. The images were graded according to the Spaeth gonioscopic grading system. There is a paucity of literature on quality scoring of gonioscopic images. For that purpose, and to obtain an objective measure of image quality, we identified and used a quality gonioscopic grading system set forth in a published paper by Azad et al[4] comparing quality of images obtained by gonioscopy and Retcam images. Clarity grades (1 to 2) and quality grades (1 to 3) were summed and averaged separately for the 2 image groups. We then used the unpaired *t* test to determine if there were any significant differences in image quality score.

(1) Clarity of trabecular meshwork:

Grade 1: all structures perceived.
Grade 2: all structures not perceived.

(2) Quality of details seen:

Grade 1: all angle landmarks clear and well focused.
Grade 2: some angle structures clear, others blurred.
Grade 3: angle landmarks could not be ascertained.

RESULTS

All components of the Spaeth gonioscopy assessment were possible with both lenses. When looking at the clarity of the trabecular meshwork as perceived through the disposable lens, the images were scored either 1 or 2. The mean image score produced by the disposable lens was 1.49 ± 0.51 while the mean grade received by the standard glass lens was 1.47 ± 0.51, with a *P*-value of 0.90 ($\alpha < 0.05$). For overall image quality, the images were scored 1, 2, or 3 and the mean grade received by the images taken with the disposable lens was 1.54 ± 0.61 and the mean grade received by the standard glass lens was 1.46 ± 0.56, with a *P*-value of 0.55 ($\alpha < 0.05$). For both of these factors, the difference in image grade was insignificant, leading us to conclude that image quality is comparable between the standard lens and the disposable lens (Figs. 1, 2).

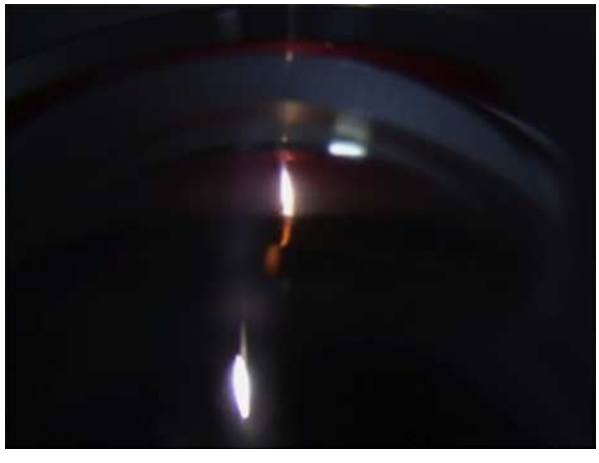

FIGURE 1. Image of the inferior iridocorneal angle via standard gonioscopy lens. Figure 1 can be viewed in color online at www.glaucomajournal.com.

FIGURE 2. Image of the inferior iridocorneal angle via disposable gonioscopy lens. Figure 2 can be viewed in color online at www.glaucomajournal.com.

DISCUSSION

There are now reusable and disposable lenses available for gonioscopy. Although there are no strict, universal rules on how to clean ophthalmic equipment and specifically gonioscopy lenses, it is recommended by the Center for Disease Control (CDC), Joint Commission, Centers for Medicare & Medicaid Services (CMS), and American Academy of Ophthalmology (AAO) that reusable health care products be disinfected and sterilized, and cleaned according to the manufacturer's guidelines.[5,6] On the highest end of sterilization procedures, recommendations for intraocular surgical equipment include manual removal of debris, rinsing, steam sterilization in a decontaminated environment, and sterile packaging before use. Steam sterilization must meet time, pressure, and temperature requirements to be considered adequate.[7] Volk manufacture disinfecting guidelines for the G series gonioscopy lenses include soaking the lens in glutaraldehyde or dilute sodium hypochlorite for 10 to 26 minutes.[8] Alternatively, gonioscopy lenses are commonly cleaned with running water, soaked in a disinfectant solution, such as 70% ethanol or 3% hydrogen peroxide, for 10 minutes followed by rinsing with sterile saline and air dry.[9] Chemical disinfectants must be used with caution because improper rinsing could lead to damage of the eye from contact with the chemical disinfectant. All of these processes require a significant amount of time and wear and tear can occur during any of these cleaning processes with scratches of the lens surfaces that then compromise optical qualities.[6] And while there is no national database of eye infections or publications documenting infections arising from gonioscopy lens use, there is theoretically a higher risk of infection with reusable lenses like there would be with other reusable health care equipment.[10]

Another aspect of the reusable versus disposable gonioscopy comparison worth further exploration is the cost. The Volk G-1 lens used in our study is retailed at $458 on the Volk website, whereas the Sensor Medical Technology single mirror disposable lens is sold in packs of 10 for $100, equaling $10 per lens. Depending on an institution's use and subsequent wear and tear, the time and cost of the sterilization technique used to cleanse the

lens between each patient, and the time and cost of repackaging and transportation of reusable lenses, it may be more financially efficient to use disposable lenses in certain circumstances.

Our literature search indicated that no studies have been published thus far to compare the quality of the images produced by the standard lenses versus disposable lenses. In our study, the quality and clarity of the details were comparable for images acquired through a disposable lens compared with the standard lens. This indicates that disposable lenses are a plausible substitute for standard gonioscopy lens when performing procedures.

A limitation of the study is the small study population size with normal angles. However, we graded 2 images from each lens per subject to increase yield, which supported the findings that image clarity of both lenses was comparable. More studies in eyes with gonioscopic pathology can be done to further confirm our findings.

Health care policies and institutions continue to adopt patient safety measures that include single use disposable equipment. It is imperative that as clinicians we support those measures after confirming that best clinical outcomes are preserved for patients. In this work we were able to confirm that the use of disposable gonioscopy lenses may be a suitable alternative to standard glass lenses and that quality of imaging and angle structure visibility through disposable lenses were not compromised.

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