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Clinical Performance of Novel Single-Use Lenses in Vitreoretinal Surgery

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Abstract

Purpose: To conduct a premarket study of 3 new single-use lenses for the RESIGHT ophthalmoscopy system during routine vitrectomy surgery. **Methods:** In this investigator-initiated prospective, academic, interventional case study from a single center, 3 new single-use lenses (a wide-angle lens, ultra wide-angle lens, and macula lens) were compared head-to-head with reusable lenses in 181 patients who had retinal detachment surgery (n = 89) or macular surgery (n = 92). After each surgery, participating surgeons completed a survey grading the performance of the new single-use lenses compared with the reusable lenses. **Results:** For all 3 single-use lenses in the RESIGHT system, condensation was significantly reduced compared with that of the reusable lenses, and the image quality was clearly better. The telescopic design of the ultrawide-angle lens allowed a better view of the retinal periphery, enabling complete shaving of the vitreous base without indentation in the majority of phacovitrectomy cases. The macula lens offered a wider field of view with similar image quality to that of a flat contact lens, allowing better visualization of the surgical instruments without sacrificing detail in the image, thus facilitating safer surgery. The improved resolution of the wide-angle lens allowed sufficient magnification for use in macular surgery. **Conclusions:** Compared with their reusable counterparts, the newly designed single-use lenses for the RESIGHT system offer significant improvements during routine vitrectomy surgery.

Keywords

RESIGHT, vitrectomy, microscope, visualization, noncontact wide-angle viewing system, disposable lenses

Introduction

Vitrectomy requires an additional optical system mounted below the operating microscope to visualize the posterior segment of the eye. These optical systems can be divided into 2 categories: contact lens systems and indirect ophthalmoscopy systems. Indirect systems offer an advantage in that the surgeon is not dependent on the surgical assistant to correctly position a contact lens on the eye, and there is less chance of iatrogenic corneal damage since the indirect lens is not in contact with the eye surface. However, the field of view can be somewhat limited compared with that of a convex contact lens in combination with a well-dilated pupil, often necessitating scleral indentation to obtain a complete view of the retinal periphery. Moreover, the surgical view using a flat contact lens for macular surgery tends to outperform indirect systems, because it provides better stereopsis.[1,2] Choosing between the 2 systems largely depends on surgeons' preference and training, as limited data comparing the two systems are available.[3]

Several indirect ophthalmoscopy systems are available for retinal surgery, such as the Eibos system (Haag-Streit), the BIOM system (Oculus Surgical), and the RESIGHT system (Zeiss).[4] In the RESIGHT and Eibos systems, an internal moving lens is used to adjust the focus, keeping the distance between the lens and the cornea unchanged, which further reduces the likelihood of iatrogenic corneal damage. In contrast, in the BIOM system the lens height is altered during focusing. The RESIGHT system features a lens turret that holds 2 aspheric lenses, which are visibly enclosed in a rotating mechanism. This turret is positioned centrally below the microscope's objective lens. When activated, the RESIGHT system swings into place underneath the microscope, aligning the selected lens for optimal retinal imaging (Figure 1D).

Currently, 2 types of reusable lenses are commercially available for mounting on the RESIGHT system: a 128-diopter yellow wide-angle lens and a 60-diopter green lens for macular surgery. Both lenses can be alternately dialed in front of the eye, depending on the surgeon's needs. These lenses float only a few millimeters above the cornea during their use and are manufactured from glass, which is highly effective at conducting heat. As a

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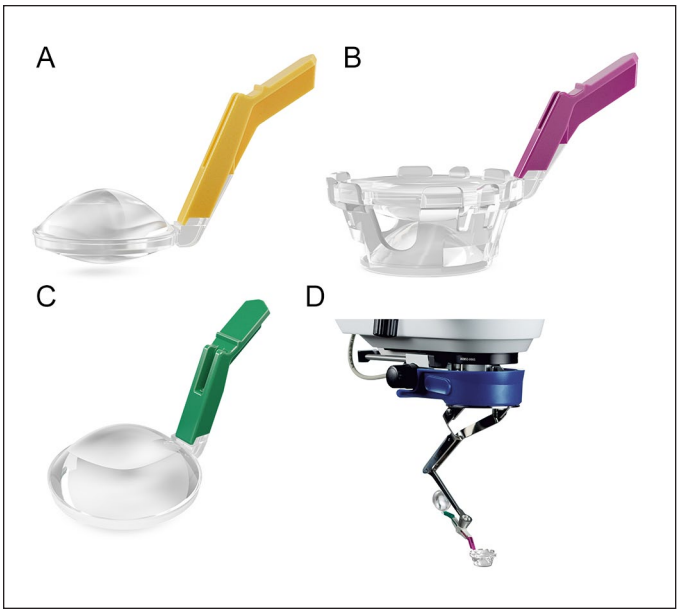

Figure 1. Single-use lenses mounted on the RESIGHT system. (A) Wide-angle lens. (B) Ultrawide-angle lens. (C) Macula lens. (D) Single-use macula lens and ultrawide-angle lens.

result, condensation on the lens may occur because of moist air evaporating from the cornea and the patient's breath under local anesthesia. This is a common problem with all noncontact viewing systems, for which various solutions have been proposed, and yet none are universally accepted.[5]

The RESIGHT system is cleaned and sterilized together with the lenses after each surgery. These reusable lenses are validated by the manufacturer for 200 reprocessing cycles. However, at our institution, when hydrogen peroxide is used for sterilization (Sterrad, Advanced Sterilization Products), wear and tear of the optical surface of the reusable lenses can occur, even after a few dozen cycles. This has resulted in the following issues:

- The lens surface shows scratches from the cleaning process, which obscures the surgeon's view.
- The lens surface shows stains created by the residue of the cleaning agents used. These stains become permanently baked into the lens surface due to the heat from the sterilization process.
- Condensation occurs more easily on the lower surface of the lens (closest to the eye surface), again hindering the surgeon's view.
- At our institution, most lenses have to be replaced after fewer than 100 reprocessing cycles because the image quality becomes too degraded, despite the system having been validated for 200 reprocessing cycles.

To overcome these issues induced by reprocessing of the lenses, Zeiss designed a new series of single-use lenses compatible with the RESIGHT system: the wide-angle lens, the completely novel ultrawide-angle lens, and the macula lens. In addition to being designed for single use, the optical performance of these lenses is improved over that of their reusable counterparts. The diameter of the wide-angle lens is similar to that of the yellow wide-angle lens, but because there is no plastic mounting ring around the optical part of the lens, the overall diameter is smaller, offering better compatibility in adults with narrow orbits or in children (Figure 1A). The ultrawide-angle lens has a telescopic design whereby 2 individual lenses are mounted in a single lens design (Figure 1B). The diameter of the single-use macula lens is larger than that of the reusable green macula lens, providing a wider field of view (Figure 1C). The telescopic design of the ultrawide-angle lens should allow a better peripheral view due to its 150-degree field of view. The optical part of the single-use lenses is composed of polymethyl methacrylate, which has a much lower heat conductance than the glass of its reusable counterparts. Consequently, less fogging of these lenses is expected to occur during their use.

The present investigation was a premarket study designed to test the efficacy of these 3 new single-use lenses during routine vitrectomy surgery.

Methods

This study was an investigator-initiated prospective, academic, interventional case study conducted at a single center and involving a total of 181 patients, of whom 89 had retinal detachment (RD) surgery and 92 had macular surgery (for macular pucker, macular holes, or vitreomacular traction). Three vitreoretinal surgeons operating at the University Hospitals Leuven participated in the trial.

All surgeries were performed using an Eva Nexus surgical device (Dutch Ophthalmic Research Center) and a Zeiss Artevo 800 microscope.[6] For each participant, the single-use RESIGHT lenses were directly compared with their reusable counterparts by placing each lens in the RESIGHT system and alternating between the single-use and reusable lens. To provide a real-world comparison, the single-use lenses were compared with reusable RESIGHT lenses that are routinely used in daily practice in our hospital. In addition, a single-use flat contact lens (VL00. D01, Vitreq/BVI) was used as a comparator for the macula lens. Use of antifog spray was not allowed on any of the lenses.

To reduce potential bias, the surgical assistant alternately dialed the lenses into place while the surgeon graded the view provided by each lens. However, when comparing the single-use macula lens with the flat contact lens, potential bias could not be mitigated, as these lenses differ greatly, and it is impossible to rapidly switch between them. Immediately upon completion of surgery, each surgeon completed a survey subjectively evaluating and grading the performance and features of each lens according to the following parameters:

For macular surgery:

- Performance (resolution and field of view) of the macula lens compared with the green lens

- Performance (resolution) of the macula lens compared with the flat contact lens
- Amount of condensation on the wide-angle lens compared with the yellow wide-angle lens
- Feasibility of using the wide-angle lens for both peripheral vitrectomy and macular surgery (combined use)
- Quality of intraoperative optical coherence tomography with the macula lens compared with the green lens mounted on a Zeiss Artevo 800 microscope
- Specific features (recorded for only the final 23 cases), including:
  - Occurrence of splatter on the macula lens
  - Occurrence of corneal touch with the macula lens
  - Occurrence of condensation on the macula lens

For RD surgery:

- Amount of condensation occurring on the ultrawide-angle lens compared with the yellow wide-angle lens
- Amount of indentation necessary to remove all vitreous material with the ultrawide-angle lens compared with the yellow wide-angle lens
- Number of cases in which no more vitreous material could be found upon indentation after unindented shaving using the ultrawide-angle lens with triamcinolone staining.
- Specific features (recorded only for the final 24 cases), including:
  - Number of cases in which it was possible to visualize up to the ora serrata without indentation in a fluid-filled eye
  - Number of cases in which the design of the ultrawide-angle lens interfered with the instruments
  - Number of cases in which splatter occurred on the interior of the ultrawide-angle lens
  - Number of cases in which splatter occurred on the exterior of the ultrawide-angle lens

For both types of surgery:

- Amount of endoillumination needed when using any of the single-use lenses compared with the reusable versions
- Color appearance
- Ability to easily distinguish different single-use lens types in a dark operating room (recorded only for the final 47 cases)

In comparing continuous data between groups, we tested the assumptions of the *t* test: we determined whether groups had comparable variances with Bartlett's test for homogeneity of variance, and whether the residuals of the *t* test were normally distributed. When one of the underlying hypotheses was not met, a nonparametric approach with the Wilcoxon signed-rank test was used. Categorical variables were analyzed with the chi-square test. Mean (SD) or median (interquartile range) values are used for continuous data, as appropriate, and numbers and percentages are reported for count data. R software (R Core Team 2021, version 4.2.0) was used to calculate the results.

Table 1. Participating Surgeon Survey Grading Performance of Single-Use Lenses Compared With a Reusable Lens in the Retinal Detachment Surgery Group.

Condensation, UWAL vs. YL	**Count (%)**
Far more condensation	0/86 (0)
More condensation	1/86 (1.2)
Similar condensation	7/86 (8.1)
Less condensation	56/86 (65.1)
Far less condensation	22/86 (25.6)
Indentation, UWAL vs. YL	**Count (%)**
Far more indentation	1/83 (1.2)
More indentation	0/83 (0)
Similar indentation	10/83 (12.1)
Less indentation	28/83 (33.7)
Far less indentation	44/83 (53.0)
Illumination intensity, WAL or UWAL vs. YL	**Count (%)**
Significantly higher	0/83 (0)
Higher	0/83 (0)
Similar	13/83 (15.7)
Lower	60/83 (72.3)
Significantly lower	10/83 (12.1)
Color appearance, WAL or UWAL vs. YL	**Count (%)**
Far less natural colors	0/84 (0)
Less natural colors	0/84 (0)
Similar natural colors	18/84 (21.4)
Better natural colors	49/84 (58.3)
Far better natural colors	17/84 (20.2)
True/False questions	**Count (%)**
No more vitreous material after UWAL shaving	33/80 (41.3)
Phacovitrectomy	31/43 (72.1)
Vitrectomy	2/37 (5.4)
Visualization of the ora serrata with UWAL	13/24 (54.2)
Interference of UWAL with instruments	6/24 (25.0)
Splatters on interior of UWAL	0/24 (0)
Splatters on exterior of UWAL	10/24 (41.7)

Abbreviations: UWAL, ultrawide-angle lens; WAL, wide-angle lens; YL, yellow wide-angle lens.

Results

In total, 181 patients were included in the study, of whom 89 had RD surgery and 92 had macular surgery. In the macular surgery group, 67% of the patients had combined lens surgery (phacoemulsification with implantation of an intraocular lens), and in the RD group, 56% of the patients had combined surgery.[7] The results of the participating surgeon survey are shown by surgery type in Tables 1 and 2.

In the RD group, the surgeons' ratings (Table 1) clearly showed better performance of the ultrawide-angle lens compared with the yellow wide-angle lens: in 90.7% of cases, the ultrawide-angle lens had less condensation, and 86.7% of cases

Table 2. Results of survey in macular surgery group.

Performance of ML compared to GL	**Count (%)**
Far less performant compared to GL	1/92 (1.1)
Less performant compared to GL	0/92 (0)
Similar performant compared to GL	11/92 (12)
More performant compared to GL	49/92 (53.2)
Far more performant compared to GL	31/92 (33.7)
Performance of ML compared to CL	**Count (%)**
Macula lens better than contact lens	3/56 (5.4)
Macula lens similar to contact lens	32/56 (57.1)
Contact lens better than macula lens	19/56 (33.9)
Contact lens far better than macula lens	2/56 (3.6)
WAL condensation	**Count (%)**
Far more condensation compared to YL	0/86 (0)
More condensation compared to YL	0/86 (0)
Similar condensation compared to YL	12/86 (14)
Less condensation compared to YL	56/86 (65.1)
Far less condensation compared to YL	18/86 (20.9)
WAL combined use possible	**Count (%)**
Strongly disagree	1/71 (1.4)
Disagree	0/71 (0)
Neither agree nor disagree	2/71 (4.2)
Agree	44/71 (62)
Strongly agree	23/71 (32.4)
iOCT quality of ML	**Count (%)**
iOCT quality far less compared to GL	0/77 (0)
iOCT quality less compared to GL	0/77 (0)
iOCT quality similar compared to GL	17/77 (22.1)
iOCT quality better compared to GL	42/77 (54.6)
iOCT quality far better compared to GL	18/77 (23.4)
True/False questions	**Count (%)**
Splatters on ML	0/23 (0)
Corneal touch with ML	0/23 (0)
Condensation on ML	0/23 (0)
Sufficient overview of intra-ocular instruments with ML	47/47 (100)

Abbreviations: ML, macula lens ; GL, green lens; iOCT, intraoperative optical coherence tomography; WAL, wide-angle lens; YL, yellow wide-angle lens.

needed less indentation to perform vitreous base shaving. Moreover, 41.3% of cases had no more vitreous material with scleral indentation after unindented shaving using the ultrawide-angle lens. Notably, this result with the ultrawide-angle lens was significantly different in the combined surgery group compared with the vitrectomy only group: while 72% of combined surgery cases had sufficient visualization to remove all vitreous material without indenting, this was only the case for 5% of the vitrectomy without phacoemulsification group ($P < .001$). In 84.4% of the cases, these results with the ultrawide-angle lens could be obtained with less illumination compared with that required using the yellow wide-angle lens, and the ultrawide-angle lens had a better subjective color appearance (78.5% of cases).

Because of its bulkier design, there was some degree of interference from the ultrawide-angle lens design with surgical instruments (25% of cases). However, this interference never reached a level that would require use of another lens to finish a case. The ora serrata was visible without indentation using the ultrawide-angle lens in 54.2% of cases, which aligns with the fact that vitreous base shaving without indentation was completed in 41.3% of the RD subgroup.

Compared with the green lens, the single-use macula lens had better performance in the macular surgery group (Table 2). In 86.9% of cases, the performance of the macula lens was deemed superior to that of the green lens because of its better resolution and wider field of view, which was also reflected in better intraoperative optical coherence tomography quality in 78% of cases. The image quality of the macula lens was deemed similar to that of the flat contact lens in 57% of cases, yet the flat contact lens outperformed the macula lens in 37.5% of cases because of better stereopsis. However, the wider field of view of the macula lens did allow a good overview of the intraocular instruments in all cases, a feature that is a known weakness of a flat contact lens for macular surgery. No condensation, splatter, or corneal touch occurred on the macula lens.

The single-use wide-angle lens also clearly had less condensation (86% of cases) than did the yellow wide-angle lens when used for core and peripheral vitrectomy. Due to its improved resolution compared with that of the yellow wide-angle lens, the combined use of the wide-angle lens for both vitrectomy and macular peeling was deemed possible in 94.4% of cases if no macula lens or flat contact lens was available.

Conclusions

The results of this premarket study indicate that the new single-use lenses for the RESIGHT system offer several advantages over their reusable predecessors. The design of all lens types using polymethyl methacrylate causes significantly less condensation on the lens, and the image quality is clearly improved, as seen in the online Supplementary Videos 1 to 3. Wear and tear of the lens surface due to reprocessing, which deteriorates retinal visualization quality when the reusable yellow and green lenses are used, is a feature that is, by definition, absent when a single-use lens is used.

Although it is difficult to obtain the optical quality of a contact lens with an indirect system, the flat contact lens outperformed the macula lens in only 37.5% of cases. In our opinion, the minor compromise in image quality is compensated for by the advantages of the macula lens. The new design is larger than that of the previous green lens, offering a wider field of view than the green lens, especially when compared with the contact lens. This enables safer surgery because the instruments are always highly visible, and fewer microscope adjustments are necessary. In addition, the surgeon does not need to rely on an assistant to keep the lens well positioned, and the cornea is not touched. The wider field of view also allows for more peripheral peeling to be performed with the macula lens in patients

with proliferative membranes outside of the vascular arcades, for example. Combining the benefits of this new lens with heads-up viewing systems could further improve macular surgery by enhancing depth perception, field of view, and image resolution.[8,9]

Interestingly, the quality of the new wide-angle lens image was so good that, in nearly all cases, the surgeons believed that it could also be used for macular surgery because even at high magnification, the image remained sufficiently sharp. In those few cases where more detail is needed, the surgeon would then ask for a macula lens or a contact lens. The fogging that occurred frequently with the yellow lens was far less common with the wide-angle lens.

Despite the short working distance of the telescopic ultrawide-angle lens, we did not encounter problematic condensation, as one might expect. In contrast, condensation occurred even less often than with the yellow lens, which is held further from the eye. This short working distance did lead to frequent splatters on the inferior surface of the lens; yet these are easily wiped off. The potential concern about splatters on the interior of the ultrawide-angle lens, which would require disassembling the lens to remove the droplets, proved unfounded, as this never occurred. Compared with the yellow lens, the ultrawide-angle lens allows for complete vitrectomy with less manipulation of the eye. One caveat is that this mainly occurred in combined cases where the capsular bag was freshly polished and thus transparent or in phakic patients. This advantage diminished significantly in pseudophakic patients with an opacified capsular bag surrounding the optic. However, we encountered a few patients with RD with extremely small pupils, in which the ultrawide-angle lens offered us a clearly wider field of view than did the yellow lens but still necessitated indentation for complete removal of the vitreous humor (for details, see online Supplementary Video 4).

While the new single-use lenses for mounting in the RESIGHT system offer numerous advantages, there are certain limitations to consider, such as cost and environmental impact. To compare the actual cost difference between reusable and single-use lenses, multiple parameters must be considered, as these can vary significantly between surgery centers. Using the following formulas, the cost per surgery for each lens type can be calculated. For single-use lenses, the calculation of the disposable cost per surgery is straightforward, encompassing only the purchase cost of the disposable lens. For reusable lenses, additional factors come into play. To calculate the reusable cost per surgery, the purchase cost of the lens is divided by the number of reprocessing cycles. The number of cycles depends on factors such as the sterilization method (steam, peroxide, or gas) and handling practices. Additionally, the sterilization cost, cleaning cost, and repackaging cost must be factored in, as these are influenced by regional variables, including personnel and material costs. Thus, the reusable cost per surgery is calculated as follows: reusable cost per surgery = (cost of reusable lens ÷ number of reprocessing cycles) + cleaning cost + repackaging cost + sterilization cost.

In our high-volume surgery center in Belgium, the calculated cost per surgery with reusable RESIGHT lenses is only marginally lower than that of their single-use counterparts. However, in some healthcare settings, this could be a significant factor to consider. Additionally, while the environmental impact of using single-use lenses is an important consideration, this study was mainly focused on the clinical benefits and performance of the lenses. It is important to note that the cost and environmental impact are factors that need to be weighed when considering the broader adoption of new technologies.

In summary, this study shows that these new single-use lenses designed for RESIGHT significantly outperform their reusable counterparts, particularly in terms of reduced fogging, enhanced field of view, and consistent, superior image quality. The macula lens stands out for offering a broader field of view while maintaining image quality comparable to that of a flat contact lens, thereby facilitating safer surgery with better visibility of surgical instruments. The novel telescopic design of the ultrawide-angle lens brings a fresh approach to retinal surgery, offering a unique advantage with its extremely wide field of view, especially in challenging cases such as those involving very small pupils. Together, the findings suggest that these novel single-use lenses could offer significant improvements in the outcomes of routine vitrectomy surgery.

Ethical Approval

The study adhered to the tenets of the Declaration of Helsinki. Ethics committee approval was obtained from the board of the University Hospitals Leuven (Study S67415).

Statement of Informed Consent

Written informed consent was obtained from all participants prior to inclusion. Approval from the Belgian Competitive Authorities (FAMHP – Federal Agency for Medicines and Health Products) was obtained to use the single-use lenses in this trial prior to their CE-mark (authorization # CIV-23-02-042213).

Declaration of Conflicting Interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article:
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Supplemental Material

Supplemental material is available online with this article.

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