Challenges with foldable intraocular lenses with hollow haptics or eyelets in scleral fixation

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Problems are not stop signs, they are guidelines.
—Robert H. Schuller

There has been great interest on new surgical techniques for secondary intraocular lens (IOL) implantation in the absence of capsular support in the past several years. Between January 2020 and February 2021, at least 15 publications on this subject have appeared in this journal alone, featured within the different article types (eg, full-length article and correspondence). Off-label, scleral fixation of posterior chamber, foldable IOLs with hollow haptics or eyelets seemed to be among the techniques proposed that gained considerable popularity. Primary functions of such design features incorporated into some IOLs include even transmission of forces, enhancement of rotational stability, and facilitation of intraoperative lens manipulation during in-the-bag implantation.

A foldable lens initially considered ideal for scleral fixation was the Akreos AO60 IOL (Bausch & Lomb, Inc.), a single-piece, plate-type lens with 4 closed loops, manufactured from a hydrophilic acrylic material. The possibility for a 4-point fixation was considered one of the main advantages of this lens design, minimizing the risk of IOL tilt inherent to methods using a 2-point fixation. Different studies described scleral suture fixation of the AO60 IOL using Prolene (polypropylene) or Gore-Tex (polytetrafluoroethylene) sutures. This latter has greater tensile strength than polypropylene, and although it has gained popularity among ophthalmic surgeons, its use in the eye is considered off-label. Sutureless, intrascleral fixation of the AO60 IOL has also been described using the 4-flanged technique proposed by Canabrava et al.

However, some surgeons who were initially enthusiastic about using this and other hydrophilic acrylic IOLs with similar design characteristics for scleral fixation moved away from it owing to concerns about postoperative IOL opacification, related to calcification. Indeed, a specific pattern of calcification after scleral fixation, the higher susceptibility of hydrophilic IOLs to postoperative opacification of these designs after scleral fixation, the higher susceptibility of hydrophilic IOLs to postoperative calcification in comparison with other IOL materials warrants vigilance.

Considering the aforementioned concern related to hydrophilic acrylic materials, another foldable IOL that also started to be considered an ideal candidate for scleral suture fixation was the enVista IOL (model MX60, Bausch & Lomb, Inc.). This is a hydrophobic acrylic IOL with water content of approximately 4%, which was U.S. Food and Drug Administration (FDA) approved in 2012. It is noteworthy that 2 new innovative foldable IOL designs have been recently developed specifically to be used for sutureless scleral fixation. One of them is the Carlevale (Soleko), and the other is the CM-T Flex (Appasamy Associates). Both IOLs have an overall plate-type design, with transscleral T-shaped haptics or plugs, which are exteriorized through sclerotomies locking the IOL in position using the horizontal limbs. They are both manufactured from hydrophilic acrylic materials. Although there is, to date, no reports of postoperative opacification of these designs after scleral fixation, the higher susceptibility of hydrophilic IOLs to postoperative calcification in comparison with other IOL materials warrants vigilance.

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Considering the aforementioned concern related to hydrophilic acrylic materials, another foldable IOL that also started to be considered an ideal candidate for scleral suture fixation was the enVista IOL (model MX60, Bausch & Lomb, Inc.). This is a hydrophobic acrylic IOL with water content of approximately 4%, which was U.S. Food and Drug Administration (FDA) approved in 2012. It is a single-piece design with open loops, with 2 eyelets located at the optic–haptic junctions. This foldable IOL allows scleral suture fixation through a 1.80 mm corneal incision, with reportedly great stability likely because of 4 points of support, namely, the 2 sutures fixed to the eyelets and the 2 haptics placed in the ciliary sulcus. Although this IOL has an excellent safety profile when implanted in the capsular...
but the intact suture passed through the fracture. Twenty fractures occurred postoperatively, whereas 5 fractures were observed intraoperatively, during IOL fixation. The suture used was Gore-Tex in most cases (N = 24) and Prolene in only 1 case. Two different knot configurations were used to secure the suture to the eyelet: simple pass method and modified cow-hitch method. Postoperative eyelet fracture occurred at 96 ± 125 days after IOL scleral suture fixation in this series. Another MX60 IOL was sutured in 10 cases, with 2 of them experiencing a repeat dislocation due to new eyelet fractures.

In this issue, the same group of authors, Watane et al., described their study (page 677) investigating the force required to fracture the eyelet of the MX60 IOL using a benchtop model. Two knot configurations were evaluated, using Gore-Tex sutures. Their results showed that the mean force required to fracture the eyelet in the simple pass suture configuration was 2.42 ± 0.11 N. The force was, however, significantly lower in the cow-hitch suture configuration, 1.40 ± 0.26 N (P < .001). This was the same benchtop model that had been used by Pollmann et al. to investigate Gore-Tex suture tension force leading to eyelet fracture with different knot configurations and different IOLs. Two enVista IOL models were included in the study by Pollmann et al., MX60 and MX60E IOLs. This latter is a second generation enVista IOL, which was U.S. FDA approved in 2018, and features enhanced material properties that produce controlled unfolding with improved optical recovery. The study found that eyelets of the first-generation MX60 IOL had greater strength than those of the second-generation MX60E IOL. Suture orientation (radial compared with nonradial) had no effect on the tension force required for MX60E IOL eyelet fracture. Therefore, it seems that use of the MX60E IOL for scleral suture fixation using Gore-Tex sutures in the cow-hitch configuration represents the most susceptible combination to eyelet fractures.

The quest for simplified surgical techniques to be used in the absence of adequate capsular support will certainly continue and will likely be influenced by the availability of new IOLs. However, surgeons must be aware of potential material and design limitations of IOLs when used in off-label procedures.

**REFERENCES**


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