Surgical Technique

A novel device for safe exteriorization of haptic in scleral fixation intraocular lens surgery

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The aim of this study was to describe a novel device that has been designed to facilitate anterior segment and novice surgeons to perform extraocular needle-guided haptic insertion technique (X-NIT) for scleral fixation intraocular lens surgery (SFIOL). We performed SFIOL surgery using X-NIT device in 21 eyes of 21 patients. The mean preoperative best-corrected visual acuity (BCVA) was 0.5 ± 0.2 logarithm of minimum angle of resolution (log MAR), which improved by one or more lines postoperatively in all eyes. There were no intraoperative complications. Postoperatively, we noted minimal corneal edema in one patient and dispersed vitreous hemorrhage in one patient. The sharpness and angulation of the needle and the haptic holding ability of silicone stopper were found to be satisfactory. The X-NIT device may potentially improve the safety of SFIOL procedures by minimizing intraocular maneuvers.

Key words: Aphakia, SFIOL device, silicone stopper, XNIT device

Although there are various techniques of scleral fixation of an intraocular lens (SFIOL), every technique invariably has a steep learning curve.[1-3] The two most crucial steps in SFIOL surgery are exteriorization of the haptic of a three-piece intraocular lens and fixation of the exteriorized haptic. Our SFIOL technique called extraocular needle-guided haptic insertion technique (X-NIT) has reduced the difficulties in haptic exteriorization by shifting the haptic transfer site from an intraocular location to a much safer extraocular site.[4] To further simplify the technique and make it ready-to-do, we have developed a new instrument called the X-NIT device.

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X-NIT device

In conventional X-NIT procedure, a standard 26-gauge (G) needle is bent to 60° close to its hub and connected to 1-cc syringe. A small 2.5 mm × 3 mm silicone stopper fashioned out of no. 240 silicone band is pierced by tip of the bent needle before making sclerotomy.[4] However, procuring no. 240 silicone band, cutting it into pieces, making and loading silicone stoppers, and bending the needle to recommended angle are all preparatory steps that can be avoided by using X-NIT device [Video 1].

Components of X-NIT device

X-NIT device is an assembly of bent 26-G needle preloaded with round silicone stopper that is connected to a handle [Fig. 1] and [Video 2].

The handle

The handle is made up of plastic polypropylene measuring 87 mm × 7 mm. It has two scleral markers at one end (1.5 and 4 mm). The 1.5 mm mark guides to mark the sclerotomy site. The 4 mm mark can be used to measure the length of scleral grooves needed for haptic fixation. The other end has a groove measuring 0.5 mm × 5 mm, into which the needle is fixed. Side ridges provide better finger grip.

The 26-G needle

The needle is made up of surgical grade stainless steel. The external and internal diameters are 0.46 and 0.26 mm, respectively. The overall length of the needle is 22 mm. The needle is bent to 60° close to its hub with 14 mm shaft length and fixed 5 mm deep into the handle with bevel up position.

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The silicone stopper

The stopper is designed like a three-dimensional circle with central foramen. Outer and inner diameters are 2.5 and 1.5 mm, respectively. It has two preformed holes (180° apart) to snugly fit the needle that is inserted through and through. It is kept close to distal end of needle shaft [Fig. 2]. It has been thoughtfully made to give dual protection for leading haptic when trailing haptic is maneuvered.

It can simply be slid over needle shaft and on to leading haptic. It is recommended to hold the leading haptic using a forceps inside the circle of the stopper before the needle is disengaged from the haptic. It can then be adjusted to the tip of haptic.

Compared to conventional silicone band which was used in X-NIT technique,[4] the dual silicone stopper holds the exteriorized haptic more firmly with more stability. We tested the haptic holding capacity of dual stopper in cadaveric human eye. The cadaveric eye collapsed when we attempted to explant the partially exteriorized IOL, but the haptic was safe and did not rebound into anterior chamber [Video 3].

This has been exclusively designed to perform SFIOL using large 5.5 mm sclero corneal incision.

Results

We conducted a prospective study using X-NIT device on 21 eyes of 21 patients. All surgeries were performed by single surgeon (PB). The study was approved by the institutional ethics committee (Protocol no. IRB2018012CLI). Table 1 shows the demographic and preoperative details. All patients completed 3-month follow-up. The mean preoperative best-corrected visual acuity (BCVA) was 0.5 ± 0.2 logarithm of minimum angle of resolution (log MAR), which improved by one or more lines post operatively in all eyes at 3-month postoperative period [Table 2]. None of them showed deterioration in BCVA at the final visit. There were no intraoperative complications such as haptic break, haptic slips, or posterior dislocation of IOL. There were no vision threatening postoperative complications such as bullous keratopathy, retinal detachment, choroidal detachment, and hypotony. There was minimal corneal edema in one patient and dispersed vitreous hemorrhage in one patient, both of which resolved within 2 weeks after surgery. We assessed different features of the device namely sharpness of the needle, length of the needle, gliding smoothness, ease of docking, ability of silicone stopper, utility of sclerotomy marker by giving numerical scores (poor: 1–3, satisfactory: 4–6, good: 7–8, excellent: 9–10). Table 3 gives the details of the assessment scoring. All the devices used were found to be over all good.

Discussion

Scharioth et al.[1] reported a novel sutureless technique of intrasceral fixation of IOL in the year 2007. Agarwal et al.[2] described the glued IOL technique for gluing the scleral flaps down over the exteriorized haptics. Yamane et al.[3] described a double-needle-based haptic exteriorization with transconjunctival flanging of haptic tips to fix the IOL. Although all three methods have different ways of haptic fixation, the

Table 1: Patient demographics and preoperative assessment data

| Parameter                        | Distribution     |
|----------------------------------|------------------|
| Mean age (years)                 | 58.33±15.82      |
| Sex: males/females               | 14/7             |
| Eyes: right/left                 | 12/9             |
| Cause for Aphakia                |                  |
| Post-cataract complication       |                  |
| PCR                              | 7 eyes (33.3%)   |
| Intraoperative dislocation of nucleus | 11 eyes (52.4%) |
| Post-traumatic                   |                  |
| Dislocation of nucleus           | 1 eye (4.8%)     |
| Dislocation of IOL               | 2 eyes (9.5%)    |
| Preoperative mean IOP (mm Hg)    | 18.05±6.13       |

PCR=Posterior capsular rupture, IOL=Intraocular lens, IOP=Intraocular pressure

Table 2: Visual outcome at 3-month postoperative follow-up

| Parameter               | Preoperative | Postoperative |
|-------------------------|--------------|---------------|
| BCVA (logMAR)           | 0.5±0.2      | 0.4±0.2       |
| Change in BCVA          |              |               |
| Gained two lines or more| -            | 5 eyes (23.81%)|
| Gained 1-2 lines        | -            | 16 eyes (76.19%)|
| Lost 1 line or more     | -            | Nil           |

log MAR=Logarithm of minimum angle of resolution, BCVA=Best-corrected visual acuity
common factor is the intraocular maneuver in order to exteriorize the IOL haptics. The X-NIT technique simplified this step by shifting the haptic transfer site to an extraocular location.\textsuperscript{[4]}

Here we report a novel device, first of its kind and exclusively designed for SFIOL surgeries. The device draws its inspiration from the previously reported X-NIT technique. Although the X-NIT technique simplifies haptic exteriorization, especially for novice, we analyzed that certain steps could probably be further simplified to enhance the surgical performance. Reliable and reproducible bending of the 26-G needle with proper angulation, need to procure a no. 240 silicone band for preparing the silicone stopper and preloading it into the needle were key steps which we envisioned to expedite with our device. Also the needle shaft length of the commercial available 26-G needle is 13 mm, which after bending may become marginally insufficient. In X-NIT device, we have increased the overall length of the needle to 17 mm with an available shaft length of 14 mm after bending. In the process of crafting the device, we have also added few additional features like an ergonomic handle, an inbuilt sclerotomy marker, and a dual protection stopper that augment the safety and simplicity of the X-NIT technique. Table 4 summarizes the differences between the X-NIT technique and X-NIT device. The incidence of a few minor complications noted with X-NIT device is comparable with that of the X-NIT technique.\textsuperscript{[4]} Hence, we believe that the device has not resulted in any additional complications.

### Conclusion

Our early experience suggests that the X-NIT device may serve as an economical, safe, all-in-one device that can potentially simplify the performance of SFIOL surgeries especially for novice and anterior segment surgeons.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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