Microincision vitrectomy surgery (MIVS) was first introduced in 1996 by Chen and associates using 20 gauge (G) tunnel-based sclerotomies.¹ In 1990, de Juan and Hickingbotham described a series of 25-gauge vitrectomy instruments but these were never commercialized.² In 2002, Fuji et al.³,⁴ introduced the first commercially available, sutureless, transconjunctival 25 Gauge (0.5mm) vitrectomy (TSV, Transconjunctival Sutureless Vitrectomy) system. Eckardt in 2005 described a 23-gauge two-step transconjunctival sutureless system. Subsequently, other manufacturers have released competing 23- and 25-gauge systems. There are several distinct advantages of transconjunctival MIVS over traditional pars plana vitrectomy surgery including a quicker surgery, lack of sutures, less postoperative discomfort, and shorter recovery time and is becoming increasingly acceptable as the default system for almost all Vitrectomies.

Correct construction of the sclerotomy tunnel configuration is the key step in achieving a self-sealing wound in MIVS. Two types of wound constructions have been described, 1) One-step and b) Two-step incision techniques. One-step Incision involves entry with the sharp trocar with the overlying cannula on it; following entry, the trocar is removed and the cannula stays behind. Two-step Incision: Initial entry is made with a sharp blade and then a cannula is inserted with the help of a blunt ended trocar. The two-step technique has a steeper learning curve and there may be difficulty in locating the trocar insertion point.⁴ Hence the single step insertion technique is more popular.

Though India is in the forefront of ophthalmology, the reimbursements from Vitreoretina surgery are almost 10-20% of similar procedures done in developed countries. This, unfortunately makes surgeons cut corners by reusing “single use” instruments after re-sterilization by Ethylene Oxide (ETO). Sometimes these instruments are reused on the same day without resterilization, if multiple surgical cases are scheduled. This exposes patients to risk of infections and blunts the entry trocar with repeated use.

The purpose of the current study was to assess a newly developed Needle Trocar system (henceforth called the ANT, Aurora Needle Trocar) that uses an...
ordinary sterile disposable hypodermic needle as the trocar and to compare it with four proprietary Trocar cannula (PTC) by: Penetration Analysis (PA), Scanning Electron Microscopy (SEM) and wound integrity.

**MATERIALS AND METHODS**

Aurora Needle Trocar (ANT) (Fig 1,2) consists of a handle, a cap and a needle adapter. A Silicon washer /O-ring is loaded on the knob at the front end of the handle. The Hypodermic needle is loaded into the needle adapter by “railroad technique” (similar to one used for catheterization). This is done to prevent blunting of the tip of the needle if it comes in contact with the walls of the adapter. The adapter with the needle is placed within the ANT cap and the handle is screwed in. The silicon washer closes the hub of the needle, making the needle lumen a cul de sac. The cannula is now loaded on the needle (trocar) projecting from the needle adapter and the ANT system is ready for use as a single step trocar cannula system.

Needles used in this study are commercially available disposable hypodermic needles of 23 Gauge (0.6mm dia), 25 mm length with triple beveled tip manufactured by Hindustan Syringes and Medical Devices, Faridabad, India and marketed as “Dispovan” single use needle and “BD” single use needles. The Alcon Trocars used in this study are 23 GA Entry System, Enhanced, 3-CT manufactured by Alcon Laboratories Inc., Fort Worth, Texas, USA. Midlabs Inc, San Leandro, CA,USA; Fritz Ruck GmbH, Germany and Ovation International, Jaipur, India.

The Aurora Needle Trocar and the Proprietary Trocar Cannula systems have been tested and compared by:

1. Penetration Analysis
2. Scanning Electron Microscopy
3. Micro Incision Vitreous Surgery Incision Analysis (ANT and AT) Midlabs and Ovation trocar cannula system were tested in five eyes each and Fritz-Ruck Trocar cannula system in four eyes.

**Penetration Analysis**

The penetration analysis test was performed on the DEKA station of the melab penetration analyzer (melab GmbH, Mollenbachstrasse 19-DE-71229, Leonberg Germany) using 0.4mm Polyurethane membrane 6 as the substrate at the Quality Control Laboratory of Hindustan Syringes and Medical Devices, Faridabad, India. This is a standard method used by Hindustan Syringes and Medical Devices to needles randomly quality check their during their automated manufacturing process.

The Hypodermic Dispovan 23 Gauge Needle is mounted on the load cell,
which is fixed. The 0.4mm Polyurethane film (PU) is mounted on a slider (that moves at a speed of 100mm/min). The penetration test is carried out for a fixed length of the test object (needle/trocar) set at the start of the test. The load cell records the force necessary to penetrate the PU film. When the needle touches the PU film the recording starts and the slider moves the PU film to the `set testing length' of the test object. In this study we recorded the changes in penetration force and resistance for 8mm length of both the ANT (Dispovan and BD needle) and Proprietary Trocar Cannula (Alcon, Midlabs, Fritz Ruck and Ovation). The set testing length was 8 mm with all the PTC.

Penetration analysis was done with cannulas loaded on new 23 Gauge needles to simulate the real-life situation. For PTC also the Trocar Cannula was tested simultaneously mounted on the load cell.

The initial point of entry by the needle/trocar gave the Initial Penetration Force (IPF), subsequent entry by the cannula gave the Final Penetration Force (FPF) and the overall friction of the system generated the third reading.

**Scanning Electron Microscopy**

Tests were carried out on Zeiss EVO 50 Scanning Electron Microscope at the Indian Institute of Technology, New Delhi. The samples tested were:

1. Dispovan 23 Gauge hypodermic needle
2. BD 23G Hypodermic Needle
3. Dispovan 23G Needle with Alcon Cannula
4. BD 23G Needle with Alcon Cannula
5. Alcon Trocar and Cannula
6. Midlabs Trocar and Cannula
7. Ovation Trocar and Cannula
8. Fritz Ruck Trocar and Cannula

Dispovan needle and new PTC were cut along their shaft. These and the cannula were mounted on the Specimen holder (specimen stub), coated with a thin film of gold to obtain uniform conductivity. These were then put into the SEM chamber for analysis.

**Micro Incision Vitreous Surgery Incision Analysis**

The ANT loaded with Alcon cannula was used in 250 human eyes and the Alcon Trocar system in 220 human eyes. Additionally Midlabs Trocar Cannula was tested in 5 human eyes, Ovation trocar cannula in five human eyes and Fritz-Ruck Trocar Cannula in 2 human eyes. The Alcon Cannula underwent resterilization with Ethylene Oxide (ETO) after every use and it could be used 8 to 10 times before being discarded. A fresh hypodermic needle was used in every case.
The procedure of trocar-cannula insertion is essentially a single step technique. The loaded ANT with 23 Gauge needle and Alcon cannula or 23 Gauge Alcon trocar cannula were held tangentially to the sclera with the bevel of the needle up. Conjunctiva is slightly displaced, to one side and the needle inserted till the cannula; direction of insertion is now changed to about 30° and the cannula inserted in the eye with minimal 0-90° rotatory movement. Once in, the cannula is held with Lim’s forceps and the needle Trocar or the Alcon trocar removed. The variables recorded was: leaking sclerotomy and the need to put a suture; postoperative hypotony. Eyes with long surgery or excessive manipulations for vitreous base dissection, invariably needed a suture on the active port (upper temporal for right eye and upper nasal for left eye).

**RESULTS**

*Penetration Analysis*

Following are the results of the penetration analysis carried out on 0.4mm polyurethane film on Deka station.

Scanning Electron Micrographs suggests that Alcon, Midlabs, Fritz Ruck and Ovation Trocars have a smoother edge and surface as compared to both 23G needle. The Proprietary Trocar blades shows pits on their surface. SEM photomicrograph of the needle at magnification shows different zones of the triple beveled needle. First bevel is adjacent to the tip, second bevel is as labeled and the heel is the third bevel.

MIVS Incision Analysis Eighteen percent of sclerotomies made with ANT required suturing compared to sixteen percent of the Sclerotomies made with Alcon Trocar cannula system. No eye in either group developed hypotony. The wound at the completion of surgery with Enhanced Alcon Trocar Blade is Linear. Comparable linear wound was achieved with ANT with bevel up incisions.

**DISCUSSION**

Single Step Trocar cannula systems worldwide are preferred MIVS entry system for 23 gauge vitrectomy. The Alcon Trocar Cannula system, a single step system, has become a popular MIVS entry system. It is supplied as part of the Alcon Accurus Vitrectomy 23G Total Plus Pak and is not available as stand alone item in India. Ideally the entire Total Plus Pak is disposable and should be used in a single case only. However in India and many Developing countries due to economic constraints this ideal situation is not adhered to. Various components of the Total plus Pak are reused multiple times after resterilization by different methods till discarded. This obviously results in less than ideal instrumentation available for every case with the added risk of infection.
The Aurora Needle Trocar system uses disposable hypodermic needle costing only Rs two per needle and rest of the instrument can be repeatedly autoclaved. A new disposable needle can be used as trocar in every case (and may be for every sclerotomy). This would allow the surgeons to obtain acceptable quality and yet not compromise on sterility. Another advantage of the ANT is its all gauge adaptability. One can use 20,23,25 or 27 Gauge hypodermic needles of 25mm length with appropriate cannula.

Dispovan and BD 23G needles, despite having surface and edge irregularities on SEM have better penetration curves as compared to the Proprietary Trocars and with Alcon cannula penetrate the eye with ease. This may be because all hypodermic needles are siliconised. This coating probably coats the edge and surface irregularities and improves the needle’s tissue penetration performance. Considering the cost saving and the possibility of reducing the risk of infection, it appears that ANT will fill a major gap in the armamentarium of the available entry systems in India and developing countries. If separate needle is used with every sclerotomy, the entry could become smoother as it is possible that with every entry the silicon coating on the hypodermic needle is affected.

Limitations of the ANT include blunting of the needle tip. This typically happens when the needle tip touches the wall of the adapter. This problem was addressed by railroading the needle through a 20 Gauge cannula introduced through the needle adapter. Another point where the needle may get blunted is when the cannula is being loaded on the needle trocar. This can be avoided by loading the cannula carefully under the microscope at the start of surgery. Other limitation of the ANT system at present is non-availability of good cannulas as stand alone items. An ideal reusable cannula should have following characteristics.

a) Should be Metallic and reautoclavable
b) Snuggly fitting the needle (appears to be a significant Factor)
c) Tapered edge to allow easy entry
d) Supplied with a device (wire) to clean the internal lumen (to clean protein deposits on repeated use)

Limitation of this study include

1) Small sample size for penetration analysis.
2) Reuse of Alcon cannulas after reautoclaving for both Alcon Trocars and Needle Trocars.
3) Inability to test Midlabs, Fritz Ruck and Ovation Trocar Cannulas in larger numbers clinically.
4) Lack of histological data to compare the tissue trauma caused by the Alcon Trocar and the needle trocar.

**Conclusions**

The Aurora Needle Trocar system is an efficient, cost-effective, all Gauge device for making Micro Incision Vitrectomy Surgery entry incisions. It will enhance surgical outcomes as a new disposable hypodermic needle will be used in every case and hence will also reduce the risk of infection.

**REFERENCES**