PHILIPPINE JOURNAL OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY VOL. 32 NO. 1 JANUARY – JUNE 2017

Optical Myringotomy Knife

Rozelle O. De Leon, MD
Jay Pee M. Amable, MD

Department of Otorhinolaryngology
Head and Neck Surgery
UERM-Memorial Medical Center, Inc.

ABSTRACT

Objective: To describe an improvised optical myringotomy knife essential in creation of an incision in a myringotomy simulator.

Methods:

Design: Instrumental Innovation
Setting: Tertiary Private Hospital
Subject: None

Results: The optical myringotomy knife was able to create incisions on mock membranes made up of polyethylene film (Cling Wrap) in a myringotomy simulator. The incisions measured approximately 2mm with sharp edges indicating that the myringotomy knife was able to penetrate the mock membrane with ease. It provided good control in performing myringotomy incisions under endoscopic visualization of the tympanic membrane.

Conclusion: Our initial experience with this optical myringotomy knife for tympanostomy tube insertion suggests that it may greatly improve the performance of myringotomy especially among less experienced surgeons. Further studies may establish its accuracy and replicability *in vitro*, after which formal *in vivo* trials can be attempted.

Keywords: *tympanostomy, middle ear ventilation, endoscopy, instrumentation*

Otitis Media with Effusion (OME) is the presence of fluid in the middle ear with no signs of infection or tympanic membrane perforation.[1] OME is a very common disease affecting people of all ages worldwide though more commonly encountered in children. Myringotomy with or without tympanostomy tube insertion has become the standard of care for patients with OME lasting more than three months with associated significant hearing loss and unresponsive to conservative management.[2]

Through the years, approaches to myringotomy have evolved, recently involving microscopic, endoscopic and even laser-assisted procedures.[3] With the advent of endoscopes, endoscopic myringotomy under topical anesthesia has been proven to be safe and practical.[4] Endoscopic myringotomy provides better visualization of the tympanic membrane and some of the middle ear structures. We describe a simple optical myringotomy knife with accuracy and precision in placement of myringotomy incisions.

Correspondence: Dr. Jay Pee M. Amable
Department of Otorhinolaryngology
Head & Neck Surgery
Rm. 463, Hospital Service Bldg., UERMMMC, Inc.
64 Aurora Blvd., Quezon City 1113
Philippines
Phone: (632) 715 0861 local 257
Fax: (632) 7161789
E-mail: orlhns_uerm@yahoo.com

The authors declared that this represents original material that is not being considered for publication or has not been published or accepted for publication elsewhere, in full or in part, in print or electronic media; that the manuscript has been read and approved by the authors, that the requirements for authorship have been met by the authors, and that the authors believe that the manuscript represent honest work.

Disclosures: The authors signed a disclosure that there are no financial or other (including personal) relationships, intellectual passion, political views or beliefs, and institutional affiliations that might lead to conflict of interest.

Philipp J Otolaryngol Head Neck Surg 2017; 32 (1): 51-54

METHODS

A. Endosheath Fabrication

A 3/10cc insulin syringe was used to create the endosheath for a 0 degree 2.7mm x 110mm rigid endoscope. *(Figure 1)* The attached needle and flange were removed using a cutter creating a 55mm hollow tube with inner diameter of 3mm and outer diameter of 6mm with smooth edges. *(Figure 2)* Two insulin syringes were utilized in the construction to form a 110mm endosheath. *(Figure 3)*

Figure 1. 3/10cc Insulin syringe

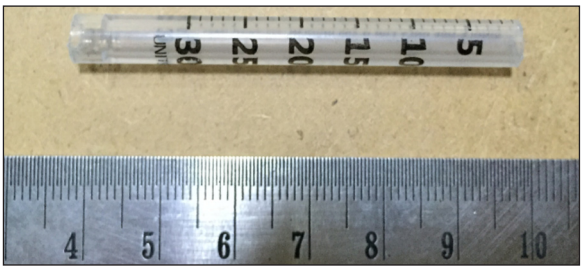

Figure 2. Trimmed insulin syringe

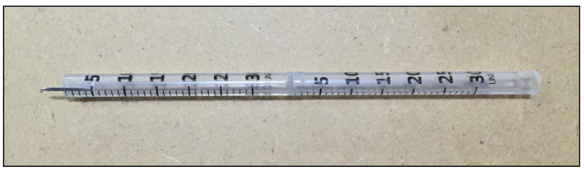

Figure 3. Two insulin syringes connected with attached needle at one end

B. Improvised Myringotomy Knife

A gauge 19 needle was flattened to create a 2mm improvised knife using pliers without violating the sharp edge of the needle. *(Figure 4)* The pinpoint sharpness of the needle was maintained to facilitate puncturing of the tympanic membrane. The needle was then attached to the distal end of the insulin syringe using 100% Ethyl Cyanoacrylate exposing 5mm of the tip. This ensured that only 5mm of the needle would penetrate the tympanic membrane and the middle ear cavity. *(Figure 5)*

Figure 4. Gauge 19 needle

Figure 5. Attachment of needle to insulin syringe

C. Technique

The optical myringotomy knife was fitted into the endoscope with just enough length to visualize the tip of the needle from the scope. The needle tip was designed to create a stab incision of 2mm in length with sharp edges. *(Figure 6)*

Figure 6. Optical myringotomy knife with endoscope

In a myringotomy simulator measuring 2.5 cm long x 0.7 cm wide to more or less replicate the average length and diameter of the Filipino adult ear canal, polyethylene film (Cling Wrap) was used to create the mock membrane. *(Figure 7)* The optical myringotomy knife with the

Figure 7. Myringotomy simulator (anterior, lateral and posterior view)

endoscope was advanced into the model ear canal using a one-hand technique. *(Figure 8)* The endoscope had an advantage of allowing visualization of the entire tympanic membrane, allowing the surgeon to determine where to perform the stab incision and to direct the needle tip to that particular quadrant. Once the quadrant of choice was identified and visualized, the device could be advanced using the index and middle fingers without moving the endoscope. As the needle tip punctured the mock membrane, an incision was created. *(Figure 9)* The endoscope also allowed immediate evaluation of incision placement. Several myringotomy trials using the optical myringotomy knife were conducted to verify the technique.

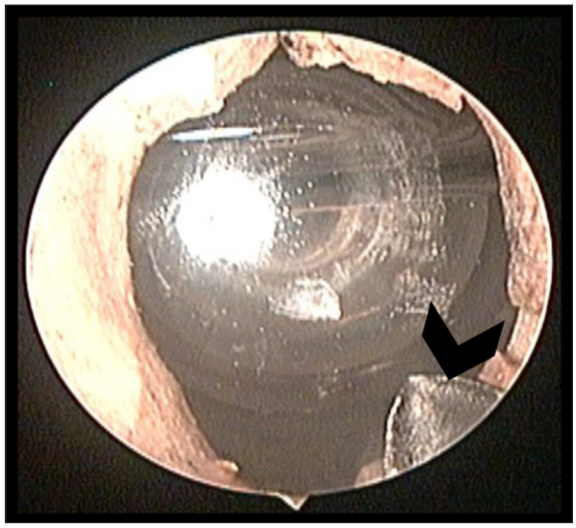

Figure 8. Endoscopic view of tympanic membrane with optical myringotomy knife at the 5 o'clock position (arrowhead)

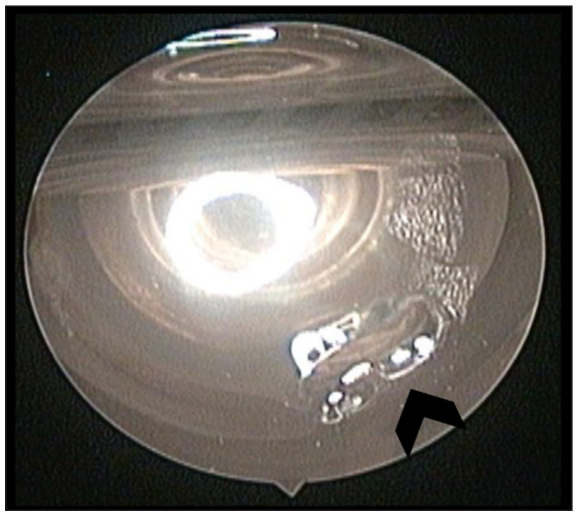

Figure 9. Endoscopic view of tympanic membrane with incision at the antero-inferior quadrant (arrowhead)

DISCUSSION

Myringotomy with or without tympanostomy tube insertion is one of the most common procedures in Otolaryngology. It is a relatively rapid procedure which can be performed under local or general anesthesia. Generally, myringotomy entails at least two maneuvers to achieve the end result. First, myringotomy is performed using a myringotome to create a stab incision which is usually at the antero-inferior (sometimes postero-inferior) quadrant. Afterwards, insertion of tympanostomy tubes can be done using applicators or alligator forceps. Commercial devices like the Hummingbird™ TTS (Tympanostomy Tube System) claim to lessen maneuvers and facilitate myringotomy and tympanostomy tube insertion in one pass.[5] In our setting, a novel low-cost tympanostomy tube with applicator was conceptualized which also perforated the tympanic membrane and inserted the tympanostomy tube at the same time.[8] With the aid of endoscopy, one is able to perform myringotomy with better visualization and a closer view of the tympanic membrane.[4]

The EndoSheath® Technology is a sterile, disposable protective barrier between the scope and the patient which works like a condom. This technology also incorporates a channel for suction, irrigation and tool passage.[6] This was the inspiration for the development of this device. The insulin syringe served as the "EndoSheath" which snugly fits the endoscope. Optical forceps have been also part of ENT instrumentation ideal for foreign body removal and biopsy procedures.[9] The telescope joined with the forceps provides a close-up view and allow control and visualization in biopsy or foreign body removal. This resulted in the idea for the improvised optical myringotomy knife wherein a Gauge 19 needle was attached to the distal end of the syringe. The endoscope and optical myringotomy knife provided a close-up view of the tympanic membrane and allowed precise control and accurate placement of the myringotomy incision. The endoscope provides better resolution and depth perception in performing myringotomy. It has been reported that the most frequent human errors during myringotomy are failure to perform a unidirectional myringotomy incision and multiple attempts to complete the myringotomy.[10] This can be eliminated with the use of an optical myringotomy knife that provides excellent visualization of the tympanic membrane and allows creation of a 2mm single stab incision sufficient for inserting tympanostomy tubes.

The dimensions of the adult external auditory canal and tympanic membrane were taken into account in conceptualizing the design of this optical myringotomy knife. During the procedure, instruments would have to be maneuvered in the external auditory canal and visualize the tympanic membrane. The average length of an adult ear canal is approximately 25mm with an average diameter of 7

PHILIPPINE JOURNAL OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY VOL. 32 NO. 1 JANUARY – JUNE 2017

to 10mm.[4,7] With this in mind, we utilized a rigid endoscope with a diameter of 2.7mm to fit inside an insulin syringe with an inner diameter of 3mm and outer diameter of 6mm. This would have enough room for manipulation inside the ear canal although its shape and cross sectional dimensions change along its length.[4,7] The tympanic membrane dimensions along its two major perpendicular axes are 9 to 10 mm and 8 to 9 mm with an average thickness of approximately 70 μm but can vary from approximately 30 to 120 μm[7] The exposed needle tip used to puncture the tympanic membrane is approximately 5mm which would safely penetrate the usual middle ear cavity without injuring middle ear structures.

This exploratory study has several limitations. Due to the lack of appropriate equipment for fabrication, the ideal size and shape of the myringotomy knife was not achieved since we utilized a flattened gauge 19 needle as the knife. A customized medical grade stainless steel myringotomy knife can be fabricated to ensure sharp instrumentation, but it would definitely cost more than our fabricated instrument. Difficulties in the one-hand technique were also identified such as a good hand-eye coordination, ease of advancing the endoshealth and handling the endoscope at the same time and the finesse in puncturing the tympanic membrane. The lack of formal trials by multiple operators is another limitation of our study.

Our initial experience with this optical myringotomy knife for tympanostomy tube insertion suggests that it may greatly improve the performance of myringotomy especially among less experienced surgeons. Further studies may establish its accuracy and replicability *in vitro*, after which formal *in vivo* trials can be attempted.

REFERENCES

1. Chiong CM, Yang NW, Almazan-Aguilar NA, Cabungcal AC, Diaz JGP, Perez AB, et al. Otitis Media with Effusion in Children. In: Magiba-Caro R, Acuin JM, Jose EM, Chiong CM, Villafuerte CV, Pontejos AQY, et al (editors). PSO-HNS Clinical Practice Guidelines. 2006:23-30.
2. Rosenfeld RM, Culpepper L, Doyle KJ, Grundfast KM, Hoberman A, Kenna MA, et al. Clinical practice guidelines: Otitis media with effusion. *Otolaryngol Head Neck Surg*. 2004 May:130(5Suppl):595-118. DOI: 10.1016/j.otohns.2004.02.002; PMID: 15138413.
3. Tan KK, Liang W, Pham LP, Huang S, Gan CW, Lim HY. Design of a Surgical Device for Office-Based Myringotomy and Grommet Insertion for Patients with Otitis Media with Effusion. *J Med Devices* 2014 Jul 21: 8(3). DOI: 10.1115/1.4027247.
4. Fernando AF, Calavera KZ. Endoscopic Myringotomy and Ventilation Tube Placement: A Valuable Otolaryngologic Procedure under Topical Anesthesia. *Philipp J Otolaryngol Head Neck Surg* 2012: 27(1):41-43.
5. Hummingbird TTS (Tympanostomy Tube System). [cited 2014 Sep 26]. Available from http://www.preceptismedical.com/product/.
6. EndoSheath Technology. [cited 2014 Sep 26]. Available from http://www.visionsciences.com/HealthcareProfessionals/ProductsCatalog/EndoSheath-Technology.
7. Maroonroge S, Emanuel DC, Letowski TR. Chapter 8: Basic Anatomy of the Hearing System. [cited 2014 Sep 26]. Available http://www.usaarl.army.mil/publications/HMD_Book09/files/Section%2015%20-%20Chapter%208%20Ear%20Anatomy.pdf.
8. Aguila KP. Self-Retaining Harpoon Tympanostomy Tube with Applicator. *Philipp J Otolaryngol Head Neck Surg*. 2007: 22(1-2):27-30.
9. Optical Forceps. [cited 2014 Sep 26]. Available from: : http://www.teleflex.com/en/usa/pdf/Optical%20Forceps%20sell%20sheet.pdf.
10. Montague ML, Lee MS, Hussain SS. Human error identification: an analysis of myringotomy and ventilation tube insertion. *Arch. Otolaryngol Head Neck Surg*. 2004 Oct 1; 130 (10): 1153-7. DOI: 10.1001/archotol.130.10.1153; PMID: 15492160.