

The Triune, A New Silicone Tympanostomy Tube

A Review of 1,500 Insertions

By Frank Hill, MD

Clinical Assistant Professor, School of Medicine of the University of South Carolina

CENTA Medical Group



Abstract

- 1589 Triune tubes were inserted in a two year period and followed every six months to determine the rate of extrusion and the complication rate.
- 73% of patients followed up and the average extrusion was at 30 months.
- Perforation rate was 2.2%, tube granulomas formed in 2.8%, and 6.2% of tubes became plugged.
- 32% of the tubes developed otorrhea.
- The conclusion is that the Triune is a medium term tube with a low complication rate.

Introduction

The premise of the Triune's design is that the T-tube causes a high percentage of perforations due to the "tenting" of the tympanic membrane by the perpendicular arms. The Triune tube was intended to conform closely to the convex shape of the tympanic membrane and to stabilize the tube perpendicular to the plane of the TM by using three soft arms that are angled down 15 degrees from perpendicular. The arms are .2mm in thickness, soft, flat, and therefore relatively atraumatic to the TM. See figures below.

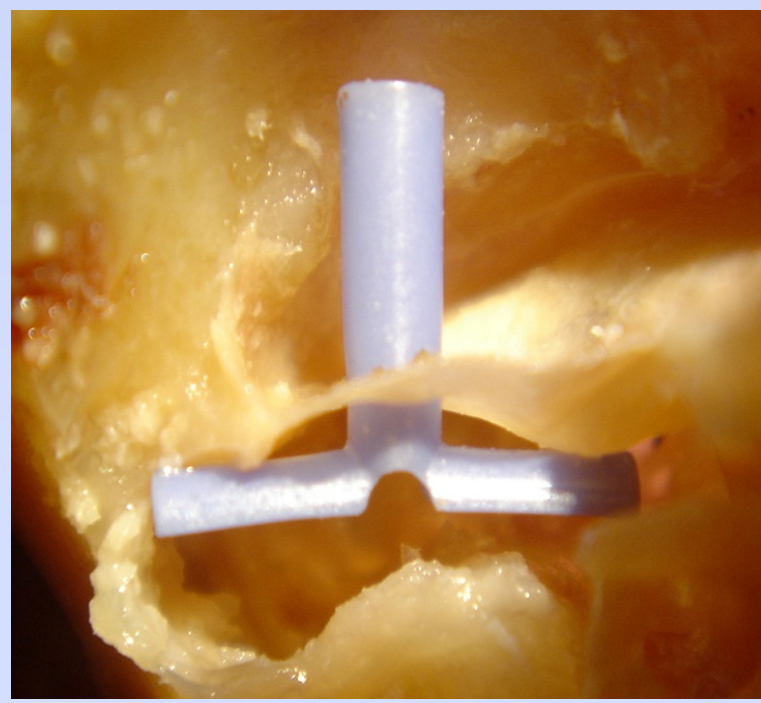
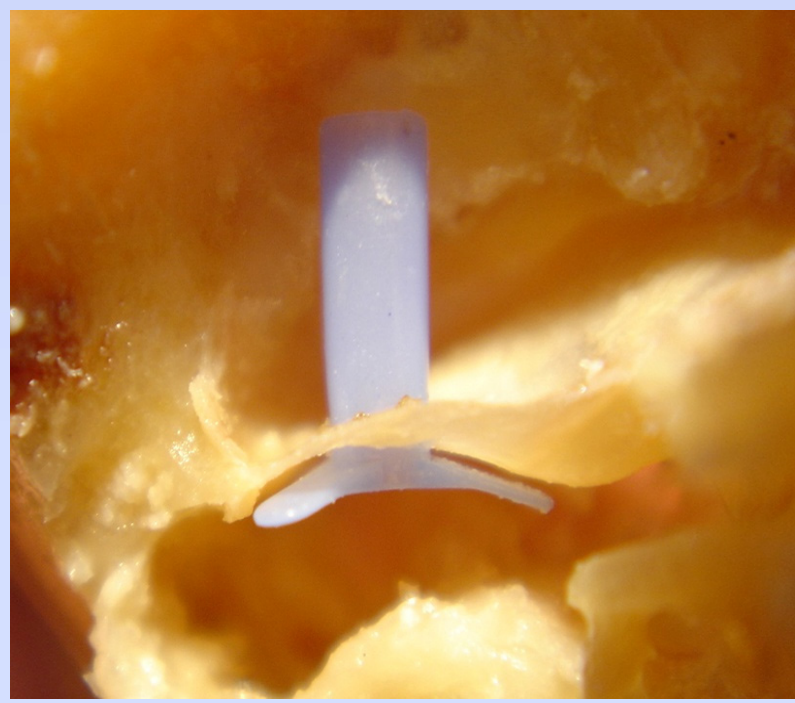


Figure 1-The Triune vs a T-tube in a temporal bone TM

Methods and Materials

- Triune tubes were inserted into all the author's patients needing more than brief middle ear ventilation in a private otolaryngology group practice.
- Over a two year period from March, 2004 to March of 2006, 1,589 tubes were inserted, 1132 under general anesthesia and 458 under local anesthesia.
- Patients were instructed to return in one month and every six months thereafter for microscopic examination. 1158 tubes or 73% were seen in follow up.
- Complications were documented in a spreadsheet at every return visit with a mean follow up of 12.3 months.
- Tubes were manufactured using a cold extrusion process by Grace Medical in Memphis, Tenn.
- Tubes were inserted using micro alligator forceps with the lower jaw in the lumen of the tube. See figure 2 below.

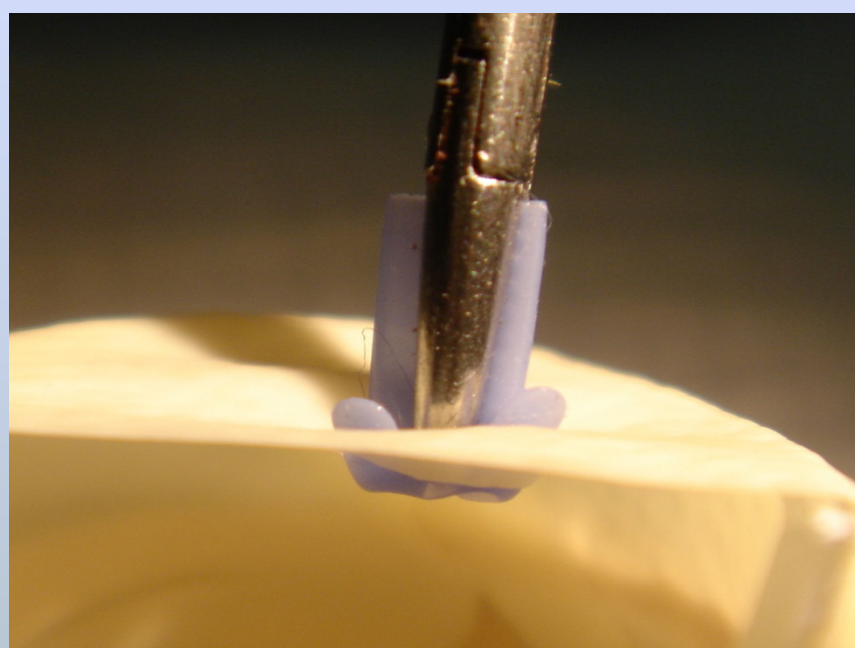
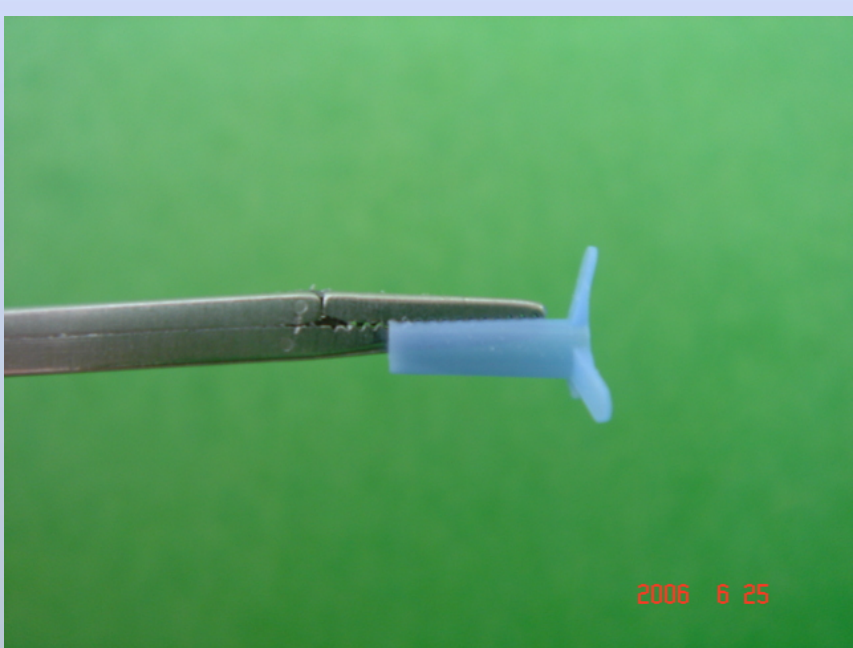


Figure 2-Grasping and Inserting the Triune

Results

- Graphing the extrusion of 1158 tubes seen in follow up, it is evident that the average extrusion is at approximately 30 months, see below.
- 26 of 1158 intubated ears seen in follow up developed perforations, which represents 2.2%.
- 32 of 1158 tubes or 2.8% developed granulomas averaging 1.4 mm in size. All resolved with topical antibiotic/steroid drops.
- Serous or blood clot plugs developed in 72 tubes or 6.2%.
- Otorrhea occurred in 264 ears out of 818 questioned regarding drainage. This represents 32.3%.

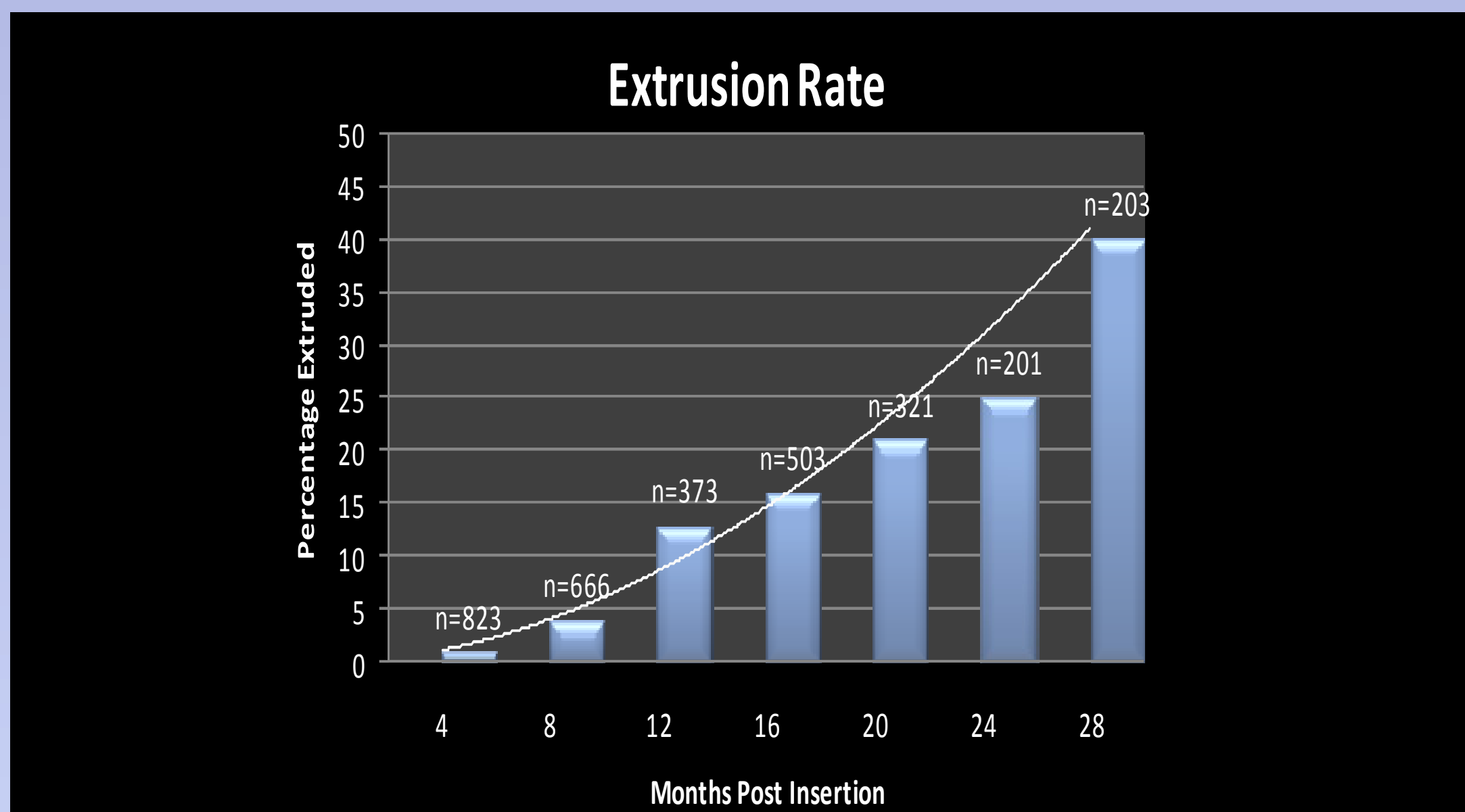


Figure 3-Extrusion Rate

Discussion

- Kay et al report a 4.8% perforation rate in a meta-analysis of 20,222 intubated ears and T-tubes are reported to cause perforations in 10-20% of cases, therefore the Triune compares favorably with a 2.2% perforation rate.
- 4.2% of 887 ears developed granulomas in Kay's meta-analysis while 2.8% of the Triune tubes developed granulomas.
- 50% of patients in Mandel's study of 246 children developed otorrhea, compared to 32% of the Triune tubes.

Conclusions

- The Triune tube ventilates the middle ear an average of 30 months.
- The Triune Tube has a low perforation rate, particularly considering the 30 months to extrusion.
- Most likely the low perforation rate is related to the tube's conformity to the convex shape of the TM.

Bibliography

1. Kay DJ, Nelson M, Rosenfield R. Meta-analysis of tympanostomy tube sequelae. Otolaryngol Head Neck Surg 2001;124:374-80.
2. Goode RL. Long-term middle ear ventilation with T tubes: the perforation problem (editorial). Otolaryngol Head Neck Surg 1996;115:500-1.
3. Mandel EM, Casselbrant ML, Kurs-Lasky M. Acute otorrhea: bacteriology of a common complication of tympanostomy tubes. Ann Otol Rhinol Laryngol 1994; 103:713-718.