

# BIOINTEGRATED VENTILATION TUBE: CURRENT STATUS AND NEW DEVELOPMENTS

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## ABSTRACT

The biointegrated (HydroxylVent) ventilation tube has been used over the past 3 years in a variety of clinical cases. The chief indication for its use is unresolving eustachian tube dysfunction and failure of more conventional medical and surgical therapy. The surgical technique and a postoperative management are described. New directions in clinical research include a larger lumen prosthesis and a compound prosthesis of hydroxylapatite with Teflon lining.

In 1990 the biointegrated (HydroxylVent) tube was presented to the American Academy of Otolaryngology—Head and Neck Surgery.<sup>1</sup> This device, manufactured by Smith and Nephew Richards (Memphis, Tennessee) combines the biomaterial properties of hydroxylapatite with a specific method of insertion to yield a prosthesis that resists extrusion through biointegration. At the 1991 Academy meeting, the first clinical series of 30 implantations was presented and the indications, clinical results, and management of the tube were discussed.<sup>2</sup> Hydroxylapatite has been shown to be highly biocompatible. The mineral, which is the inorganic component of bone, is accepted by host tissues and shows excellent integration into osseous and soft tissues.<sup>3</sup> The HydroxylVent tube is a long, flanged ventilation tube made of dense hydroxylapatite. The tube has an eccentric flange at its medial end. It is designed to be placed into a groove in the bony annulus and to lie between the bony and fibrous annulus under a short tympanomeatal flap.

## CLINICAL APPLICATION OF THE HYDROXYLVENT TUBE

### Indications

The chief indication for this long-term ventilation prosthesis is unresolving eustachian tube dysfunction. In adults, the tube has been used in patients with persistently blocked eustachian tubes and recurrent collapse of the tympanic membrane. The tube has also been used in patients with a long history of intermittent eustachian tube dysfunction who have

failed to retain conventional ventilation tubes and in one patient with unresolving patulous eustachian tube.

An emerging indication for long-term ventilation is in patients with tympanic membrane perforations and incompetent eustachian tubes. Some of these patients have failed previous tympanoplasties or have failed tympanoplasties with simultaneous short-term ventilation tubes.

In children the indications are more specific. Since in most cases eustachian tube dysfunction is temporary, conventional ventilation tubes and T-tubes are the prostheses of choice. The HydroxylVent tube has been placed in children who have extruded numerous (5 to 10) conventional tubes, in children in whom conventional tubes have failed and who have developed structural damage to the tympanic membrane, and in older teenagers who have not outgrown their eustachian tube dysfunction despite having completed their growth spurt. Children with cleft palates and head and neck syndromes form a distinct group in whom maturation of eustachian tube function is not normally expected.

A small group of patients (both pediatric and adult) seems to rapidly extrude ventilation tubes made of conventional materials. These patients, who typically extrude ventilation tubes within 3 to 6 months, are also potential candidates for a prosthesis made of this highly biocompatible material.

### Contraindications

The HydroxylVent tube is contraindicated in patients who can be adequately managed with conven-

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tional medical and surgical measures. These measures include antibiotics, decongestants, and steroids, as well as the more customary plastic and metallic myringotomy tubes. The HydroxylVent tube should not be used in patients with primary mucosal disease of the middle ear or in patients in whom scarring and inflammation have destroyed the integrity of the middle ear's mucosal lining. Because of the high biocompatibility of this material, the tube may become incorporated into the soft tissues of the middle ear and lose its patency. Two illustrative cases were a 5-year-old child with congenital atelectasis of the middle ear and a 10-year-old child with Kartagener syndrome and cholesterol granulomas of the middle ear. In both of these cases, although the tube resisted extrusion, its medial end became incorporated into the mucosal disease of the middle ear.

### Surgical Technique

The HydroxylVent tube is placed posteroinferiorly. A short tympanomeatal flap is elevated and the middle ear is entered. A thorough exploration of the middle ear is undertaken to ascertain mucosal integrity and to rule out an inflammatory process that may be irreversible. Adhesions in the middle ear are lysed and the ossicular chain is examined. If the middle ear mucosa is intact and any inflammation is judged to be reversible on ventilation, the tube is placed.

A groove is created in the posteroinferior canal wall with a Shea microdrill. The groove must be deep enough to accommodate at least one half of the width of the tube. The tube is placed into the groove and the flange is rotated posteriorly into the facial recess. If there is inadequate space the tube is rotated 180 degrees, so that the larger portion of the flange lies under the tympanic membrane. The flap is replaced in its anatomic position and the canal wall skin is split along the shaft of the tube and wrapped around the neck of the tube. A 2-0 nylon stylet may be placed into the lumen of the tube.

One week following surgery the patient begins to use ear drops and continues the drops for 1 week. The ear is debrided 2 weeks following surgery.

### Long-Term Results

The first HydroxylVent tube, placed 3.5 years ago, continues to be patent and functional. Since that time, 35 tubes have been inserted; 33 of the 35 have shown good biointegration; and 20 of the 35 tubes have shown rigid bony fixation. Two tubes extruded within 2 months of placement; and one tube, with its flange buried subcutaneously, migrated to the lateral canal.

### Removal

The HydroxylVent prosthesis cannot simply be pulled out. Its removal requires local anesthesia. A small slit along the superior surface of the tube re-

leases the tube and it can be dislodged. Three tubes have been removed, and the small dehiscence left following removal has closed spontaneously.

### Prevention and Management of Complications

The chief complications, as with any ventilation tube, are extrusion and occlusion. It has been determined that the three tubes that moved from their position had not been properly placed. To anchor the tube and maximize bony fixation, it now appears important that the groove drilled in the bony annulus should accommodate a large portion of the tube. In some of the procedures this groove was too shallow, and designed merely to provide a point of fresh bony contact.

Occlusion of this biocompatible prosthesis was a possible complication that had been anticipated from the beginning and has been actively addressed. The following techniques minimize occlusion of the prosthesis: (1) removal of all bony and mucosal debris from the undersurface of the bony annulus at the time of tube placement, (2) use of a stylet or the injection of ointment into the lumen of the tube at the time of surgery, and (3) use of antibiotic ear drops in the postoperative period.

Long-term maintenance of patency is achieved by having the patient flush the tube once a week with ear drops. Drops are instilled into the ear and by means of tragal pressure the patient massages the solution through the tube and into the middle ear. This appears to minimize crusting and possible occlusion.

Crusting along the outside of the tube is unpredictable. The junction of canal wall skin and prosthesis is normally smooth and intact. In some cases an accumulation of keratin in this area may lead to an inflammatory reaction, causing seepage and even a small amount of granulation tissue. This is minimized by proper tube placement, weekly ear drops, and regular office follow-up. There has been no instance of cholesteatoma attributable to ingrowth of squamous epithelium, either adjacent to or through the tube.

The patients are followed every 3 months. The ear is examined with the microscope and carefully debrided using hydrogen peroxide and suction.

### NEW DEVELOPMENTS

Following the introduction of the initial tube (internal diameter 1 mm), a larger caliber tube was developed. This tube, with an internal diameter of 1.27 mm, is similar in internal dimension to the modified T-tube. Initial results indicate that the tube with the larger internal diameter further facilitates ventilation and maintenance.

Preliminary results of a study using a HydroxylVent tube with Teflon lining indicate that this composite tube retains the advantages of tissue compati-

bility and may further facilitate cleaning. The first composite tube was placed 8 months ago and will be the subject of a future report. This device is the subject of a current multicenter study the results of which will be reported at a future meeting.

### CONCLUSIONS

The hydroxylapatite ventilation tube, Hydroxyl-Vent, offers unique advantages of biocompatibility and long-term ventilation to selected patients. Although the initial patient population has been drawn from those end-stage cases that have failed other methods of management, the indications for this device continue to develop. Initial results have been

encouraging and the prosthesis is undergoing further modifications to enhance its success.

### REFERENCES

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