



**Australian Government**  
**Department of Health and Ageing**

# **National Horizon Scanning Unit**

## **Horizon scanning prioritising summary**

**Volume 11, Number 4:**

**EarPopper™ for the treatment of otitis  
media with effusion in children.**

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# PRIORITISING SUMMARY

**REGISTER ID:** 000178

**NAME OF TECHNOLOGY:** EARPOPPER™

**PURPOSE AND TARGET GROUP:** TREATMENT OF OTITIS MEDIA WITH EFFUSION IN CHILDREN

## STAGE OF DEVELOPMENT (IN AUSTRALIA):

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental             | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational          | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established       |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- |   |             |
|---|-------------|
| <input type="checkbox"/> Yes            | ARTG number |
| <input checked="" type="checkbox"/> No  |             |
| <input type="checkbox"/> Not applicable |             |

## INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		

## IMPACT SUMMARY:

Micromedics provides the EarPopper™ with the aim of treating otitis media with effusion (OME) in children.

## BACKGROUND

OME or 'glue ear' is defined as the presence of fluid in the middle ear without signs or symptoms of acute ear infection (Rosenfeld et al 2004). OME is considered distinct from acute otitis media (AOM), which is defined as a history of acute onset of signs and symptoms. OME may occur spontaneously because of poor eustachian tube function, or as an inflammatory response following AOM.

The EarPopper™ is a non-invasive device for treating conditions such as otitis media with effusion, middle ear effusion, aerotitis/barotitis and eustachian tube dysfunction, without the need for surgery or antibiotics (Micromedics 2005).

The EarPopper™ device delivers a constant, regulated stream of air pressure and flow into the nasal cavity through the nostril with a 1-oz infant nasal syringe equipped with a plastic tip. During the moment of swallowing the air is diverted up the Eustachian tube clearing and ventilating the middle ear. The EarPopper™ relieves the negative ear pressure allowing any accumulated fluids to drain.



The device has two settings. Setting 1 delivers an air pressure of 5.2 psi at a volume velocity of 1,524 ml/min; setting 2 delivers an air pressure of 2.5 psi at a volume velocity of 1,690 ml/min (Arick and Silman 2005).

Figure 1. The EarPopper™ (Micromedics 2005)

### **CLINICAL NEED AND BURDEN OF DISEASE**

OME is a very common condition in children, occurring mostly between the ages of one and three years with a prevalence of 10% to 30%, and a cumulative incidence of 80% at the age of four years (Burton et al 2005). Approximately 90% of children (80% of individual ears) have OME at some time before school age, most often between ages 6 months and 4 years (Rosenfeld et al 2004). In the first year of life, more than 50% of children will experience OME, increasing to more than 60% by age 2 years. Many episodes resolve spontaneously within 3 months, but about 30% to 40% of children have recurrent OME and 5% to 10% of episodes last 1 year or longer. Some children with OME may go on to develop chronic otitis media with structural changes (tympanic membrane retraction pockets, erosion of portions of the ossicular chain and cholesteatoma), language delays and behavioural problems.

### **DIFFUSION**

The EarPopper™ is not currently available in Australia.

### **COMPARATORS**

Alternative methods of managing persistent OME include observation, medical or surgical approaches. Medical approaches include administration of decongestants, antihistamines, corticosteroids, and antimicrobial agents. Surgical approaches may include myringotomy, a surgical incision into the eardrum (to relieve pressure or release pus from the middle ear) with or without tympanostomy tube placement, adenoidectomy with or without tonsillectomy; and insufflation of the middle ear using the Valsalva manoeuvre or the Politzer method.<sup>1</sup>

The efficacy of some of these methods has been questioned partly because OME resolves spontaneously in 80% to 90% of children within three months (Rosenfeld et al 2004). The benefits of antihistamines and antibiotics have also been questioned and/or not recommended

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<sup>1</sup> The two most common methods of insufflation of the eustachian tube are the Valsalva manoeuvre and the Politzer method. The Valsalva manoeuvre involves performing forced nasal expiration with the nose and lips closed. The Politzer method involves inserting the tip of a rubber air bulb into a patient's nostril, simultaneously compressing the other nostril with a finger, and having the patient swallow as the rubber bulb is compressed (Arick and Silman 2005).

for treatment (Williams et al 1993, Rosenfeld et al 2004). Potential complications of tympanostomy tube placement include tympanic membrane retraction, foreign body reaction, granulation, hyalinisation, tympanosclerosis, and hearing loss. Tympanostomy tubes often fall out prematurely and there is a risk of otorrhea (discharge from external ear).

## **EFFECTIVENESS AND SAFETY ISSUES**

In a recent study (level II intervention evidence) 94 children aged four to eleven years (174 ears) were randomised to treatment with the EarPopper™ in the home setting for a seven-week period or to the control group (Arick and Silman 2005). Study criteria included a minimum two-month history of middle ear effusion (MEE) and associated hearing loss, pure tone air-conduction deficits, tympanometric peak pressures (TPP) of -100 decapascals (daPa) or less, absence of large adenoids and other ear abnormalities.

Children in the control group (n=47; 86 ears) received no treatment during the seven weeks and 47 patients (88 ears) were assigned to treatment with the EarPopper™ device for seven weeks. Treatment with the EarPopper™ device was administered twice daily by the parent (morning and evening) for seven weeks and compliance was monitored with a daily log. The study group had a compliance rate of 98%. Children in the control group who had not spontaneously recovered by the post-test were given the option of receiving treatment with the study device upon the conclusion of their involvement in the study. Results for these children were yet to be published at the time of writing this summary.

Audiometry (air- and bone-conduction threshold testing and tympanometry), otolaryngoscopic examinations and otoscopy were performed at baseline and at four weeks post study termination by investigators blinded to treatment. Treatment was temporarily discontinued during respiratory tract infections and completed after recovery. There were no reported difficulties in using the device.

The study reports significant improvements in mean air-conduction thresholds in the study but not in the control group. There was a significant improvement in the TPP for the treatment group compared to the control group ( $p < 0.001$ ). In the treatment group, comparisons of pre- and post-test measures in each ear demonstrated a statistically significant improvement ( $p < 0.001$ ) in mean air-conduction thresholds across 4 frequency ranges in both ears. There was no statistically significant improvement in mean air-conduction thresholds at any frequency or in either ear in the control group ( $p > 0.05$ ). The treatment group experienced a statistically significant improvement ( $p < 0.001$ ) in mean TPPs in both ears, while no improvement was observed in the control group ( $p > 0.05$ ).

Hearing sensitivity returned to at least one ear in 40/47 (85%) patients in the treatment group compared to 15/47 (32%) patients in the control group. Recovery of hearing sensitivity was observed in 74% of treatment and 27% of control ears. At baseline, bilateral hearing loss was present in 41/47 (87%) patients in the treatment group. Hearing was restored to normal in 37(90%) of these patients. Of these 37 patients, hearing was restored to both ears in 68% and in one ear in 32%. Of those who achieved normal hearing sensitivity after treatment, normal tympanic membrane mobility was seen in 75%, moderate mobility in 19%, and no mobility in 6%. The authors suggest the lack of hearing improvement in 7/47 (15%) of the treatment group may be attributed to a deterioration developing over the four week gap between ending treatment and audiologic evaluations (Arick and Silman 2005). These children were offered an additional three weeks treatment with the EarPopper™. The results are yet to be published at the time of preparing this summary.

Although the study ceased at four weeks post treatment, the authors report on 6 children who experienced recurrent episodes of OME at different time points (three, seven, nine and 12 months) following treatment with the EarPopper™. For two of the three children who were

seen post study (one at three months and the second at seven months) a repeat treatment with the device improved hearing while the third child seen at nine months was found to have hearing within normal limits. All three children who had contact at  $\geq 12$  months reported surgical treatment for OME: two children received tympanostomy tubes (one with an adenoidectomy) and one child underwent an adenoidectomy alone. Repeat treatment with the EarPopper™ appeared to improve hearing in one child's hearing post tube insertion (who was still experiencing OME with hearing loss). The authors do not report on the second child who received a tympanostomy tube. The child who received an adenoidectomy alone improved.

The EarPopper™ has been tested in young children and in the short-term only. The authors note that further studies of safety and effectiveness are required in children younger than four years, adolescents and adults.

### **COST IMPACT**

The current cost of tube insertion including myringotomy (MBS item number 41632) is \$202.65 (Medicare Benefits Schedule 2005). In 2004-05 Medicare Australia reported a total of 39,577 services for unilateral and bilateral tube insertions performed in Australia at a total cost of \$4,404,000 (Medicare Australia 2005). Of the total number of procedures 31,542 (80%) were performed in children aged 0-14 years (Medicare Australia 2005).

The cost of the EarPopper™ is \$AUD400. At the time of preparing this summary there was no available data on the cost impact of the use of the EarPopper™.

### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified/raised in the sources examined.

### **OTHER ISSUES**

The authors of the above study developed the EarPopper™ device.

### **CONCLUSION:**

Recurrent OME in children is a common condition with considerable burden on families in treating the condition. The evidence date suggests that the EarPopper™ may provide a safe and effective treatment option in the short term with minimal clinical impact on health practitioners as it can be used at home.

### **HEALTHPACT ACTION:**

HealthPACT recommended that this technology be monitored.

### **SOURCES OF FURTHER INFORMATION:**

Agency for Healthcare Research and Quality (2004). 'Otitis media with effusion', *Pediatrics*, 113 (5), 1412-1429.

Arick, D. S. & Silman, S. (2000). 'Treatment of otitis media with effusion based on politizerization with an automated device', *Ear Nose Throat J*, 79 (4), 290-292, 294, 296 passim.

Lous, J., Burton, M. J. et al (2005). 'Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children', *Cochrane Database Syst Rev*, (1), CD001801.

Medicare Australia (2005). *Medicare Australia - Statistics - Medicare Benefits Schedule (MBS) Item Statistics*: [Internet]. Medicare Australia. Available from:

[http://www.medicareaustralia.gov.au/statistics/dyn\\_mbs/forms/mbs\\_tab4.shtml](http://www.medicareaustralia.gov.au/statistics/dyn_mbs/forms/mbs_tab4.shtml) [Accessed 13<sup>th</sup> October 2005].

Medicare Benefits Schedule (2005). *Medicare Benefits Schedule Book. 1 November 2004*. [Internet]. Australian Government Department of Health and Ageing. Available from: [http://www7.health.gov.au/pubs/mbs/mbsnov04/MBSNov2004\\_PDF/MBS\\_Book\\_1\\_Nov\\_2004.pdf](http://www7.health.gov.au/pubs/mbs/mbsnov04/MBSNov2004_PDF/MBS_Book_1_Nov_2004.pdf) [Accessed 13<sup>th</sup> October 2005].

Micromedics (2005). EarPopper<sup>TM</sup> [Internet.] Micromedics. Available from: <http://www.micromedics-usa.com/products/earpopper/> [Accessed 6<sup>th</sup> October 2005].

Rosenfeld, R. M., Culpepper, L. et al (2004). 'Clinical practice guideline: Otitis media with effusion', *Otolaryngol Head Neck Surg*, 130 (5 Suppl), S95-118.

Silman, S. & Arick, D. (1999). 'Efficacy of a modified politzer apparatus in management of eustachian tube dysfunction in adults', *J Am Acad Audiol*, 10 (9), 496-501.

Williams, R. L., Chalmers, T. C. et al (1993). 'Use of antibiotics in preventing recurrent acute otitis media and in treating otitis media with effusion. A meta-analytic attempt to resolve the brouhaha', *Jama*, 270 (11), 1344-1351.

### **LIST OF STUDIES INCLUDED**

Total number of studies	
Level II intervention evidence	1

### **SEARCH CRITERIA TO BE USED:**

Eustachian Tube/ physiopathology  
Hearing Tests  
Middle Ear Ventilation  
Nasal Decongestants/therapeutic use  
Otitis Media with Effusion/ diagnosis/ therapy  
Otitis Media with Effusion/physiopathology/prevention & control/ therapy  
Otoscopy  
Politzer Maneuver  
Tympanic Membrane/physiopathology  
Valsalva Maneuver