Diode laser myringotomy for short-term middle-ear ventilation: a pilot study on children

Hassan M. Hegazy

Department of Otolaryngology, Tanta University, Tanta, Egypt

Correspondence to Hassan M. Hegazy, MD, Department of Otolaryngology, Ear, Nose and Throat Hospital, Tanta University, Tanta, Gharbia, Egypt
Tel: +20 40 3341000; fax: +20 40 3407734; e-mail: hmhegazy@hotmail.com

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Objective
The aim of the study was to evaluate diode laser myringotomy (DLM) in children for the management of Eustachian tube and middle-ear disorders that require myringotomy for short-term treatment.

Study design
This is a prospective clinical study.

Patients and methods
The study comprised 20 children selected to undergo DLM for middle-ear ventilation as a mode of treatment for recurrent acute serous otitis media; these children suffered from persistent middle-ear effusion and had experienced failure of medical treatment for at least 8 weeks. Postoperative weekly visits to evaluate the myringotomy opening (MO) were carried out until healing was recorded. The Eustachian tube and hearing ability were evaluated preoperatively and postoperatively 4 weeks after healing of the tympanic membrane. Cases were deemed to be failed when the MO closed early within the second week postoperatively without improvement in hearing, or the myringotomy persisted until the end of the third month postoperatively. Outcome measures were the state of the MO and of the ear drum, the patency time of the myringotomy, improvement in hearing and Eustachian tube function and incidence of operative and postoperative complications.

Results
The mean operative time was 5 min. No operative complications occurred. Procedural success was achieved in 16/20 ears (80%). Two ears showed postoperative persistent perforations, and two recorded early closure of the MO. The mean improvement in the air/bone gap was 12 dB for the successful cases. Twelve ears with healed MOs showed type A curve (75%). Four ears showed type C curve (25%) and needed further management.

Conclusion
DLM is useful in children for the management of Eustachian tube and middle-ear disorders needing myringotomy for short-term treatment.

Keywords:
diode laser, eustachian tube dysfunction, middle ear effusion, middle ear ventilation, myringotomy

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Introduction

Myringotomy with or without pressure equalizing (PE) tube insertion is a common procedure for treatment of Eustachian tube dysfunction associated with middle-ear disorders and pathologies [1]. The patency time (PT) needed for the myringotomy opening (MO) differs on the basis of the cause of the Eustachian dysfunction. Chronic Eustachian tube dysfunction, which causes chronic serous otitis media with effusion, needs longer PT for MO. Also, a PE tube is needed in the MO to prolong the PT for 6–12 months [2,3]. In contrast, acute Eustachian tube dysfunction, causing acute serous or suppurative otitis media, may need very short PT for MO. This is achieved by means of surgical cold-knife myringotomy without the PE tube, resulting in a PT of 24–72 h [1,4].

Some Eustachian tube and middle-ear disorders such as recurrent acute serous otitis media with persistent middle-ear effusion and failure of medical treatment for 8–10 weeks need neither the long duration of the MO with a PE tube nor the very short duration of cold-knife surgical MO without a PE tube [3,5,6]. Recurrent acute serous otitis media with persistent middle-ear effusion is a clinical condition in which the patient suffers from persistent recurrent earache with deafness after acute attacks of acute otitis media unilaterally or bilaterally. Despite thorough medical treatment for weeks, the ear shows signs of acute serous otitis media with effusion [3]. Those disorders need a PT for MO of 1–7 weeks for a useful therapeutic effect [5,6].

According to the literature, laser is an accepted method for myringotomy to create a MO without a PE tube that gives a PT of 1–7 weeks for certain indications [3,5]. Carbon dioxide (CO_2) and diode are common types of lasers used for this purpose [2–6]. The diode laser has

wave lengths of 810–980 nm and its energy is delivered by hand-held fibro-optic cables [6]. Diode laser myringotomy (DLM) is a procedure that can be applied in outpatient clinics or in operating theatres to create an MO without a PE tube for a short term [6].

The aim of this pilot study was to evaluate the efficacy of DLM and highlight the importance of its PT in the management of Eustachian tube and middle-ear disorders needing short-term MO for treatment in children with acute serous otitis media with persistent middle-ear effusion.

Patients and methods

The patients in this prospective clinical study were selected, operated upon and followed up from November 2010 to March 2012. The study included 20 children (20 ears) with recurrent acute serous otitis media with persistent middle-ear effusion and experiencing failure of medical treatment for at least 8 weeks. Among the 20 patients included, 12 (60%) were male and eight (40%) were female and were aged between 5 and 12 years (mean 8 years) (Table 1).

Any patient who had undergone prior middle-ear surgery, PE tube insertion, was suffering from Down's syndrome, other head and neck syndromes, or cleft palate, or gave indications for tonsillectomy or adenoidectomy was excluded from the study. All patients and their parents were informed about the purpose and method of the operation. Informed consent was taken after discussion of the alternatives between watchful waiting and medical treatment, cold-knife myringotomy without PE tube or myringotomy with PE tube insertion. Consent of the institutional review board was obtained.

All patients had suffered unilateral recurrent acute serous otitis media with persistent middle-ear effusion and complained of hearing loss, earache and sense of ear pressure and reported failure of medical treatment in the form of antibiotics, analgesic anti-inflammatory drugs, oral nasal decongestants and nasal drops for at least 8 weeks. All ears underwent a thorough clinical examination, which revealed a congested, dull, retracted, opaque tympanic membrane. Pure tone audiometry and tympanometry with full laboratory preoperative testing were performed.

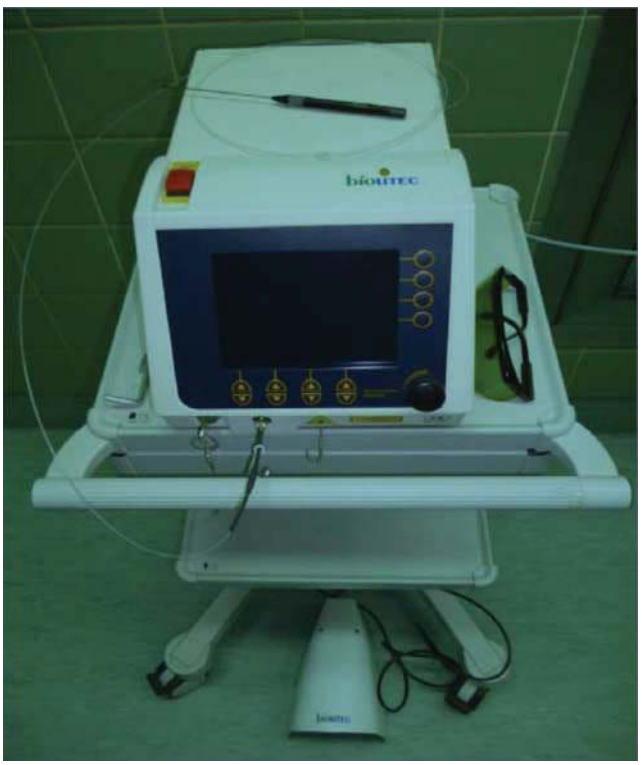
Technique

All procedures were performed under general anaesthesia using laryngeal masks. With the help of an operating microscope, a diode laser of 980-nm wavelength with a fibro-optic delivery system (Ceralas D25, 980 ± 30 nm, 25 W, model 003; CeramOptec GmbH, a company of Biolitec Group, Bonn, Germany) (Fig. 1) was used to perform the MO, using a 0.6-mm Ceralas bare fibre of a new design with a fibro-optic hand piece and the fibre tip projecting 3 mm from the hand-piece edge (Fig. 2). The myringotomy was performed by establishing contact between the laser fibre and the surface of the anteroinferior quarter of the tympanic membrane midway between the annulus and the umbo of the malleus handle. The laser energy was delivered by 4–5 shots in a circular manner beginning from 2 to 5 W in 0.5-s single-pulse mode. The achieved MO was 2–2.5 mm in

Table 1 Age of patients and operative time

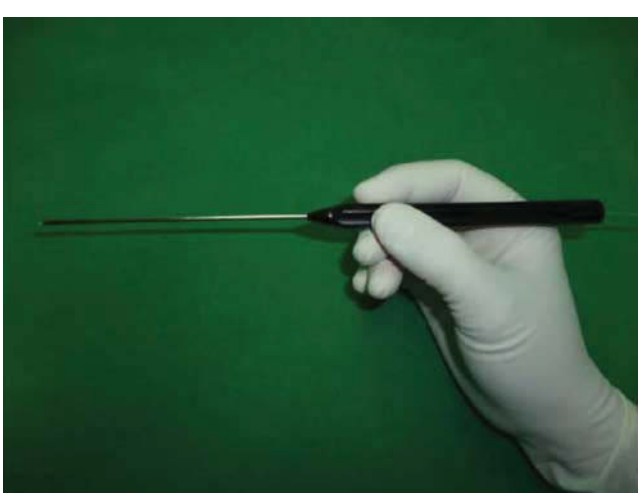
	N	Minimum	Maximum	Mean	SD
Age	20	5	11	8.00	1.974
Operative time (min)	20	3	7	5.00	1.451

Figure 1



Diode laser of 980-nm wavelength with a fibro-optic delivery system (Ceralas D25, 980 ± 30 nm, 25 W, model 003; CeramOptec GmbH, a company of Biolitec Group).

Figure 2



Diode laser hand piece with fibre in place.

diameter. During the laser procedure, all appropriate precautions were taken to protect the safety of the theatre personnel. Suction of the middle-ear fluids was carried out. Ototopical antibiotic drops (Ofloxacin 0.3% otic solution, Bausch & Lomb Incorporated, Tampa, USA) were applied in the ear.

After recovery from anaesthesia, the patient was discharged on the same day after being prescribed the following medications: antibiotics, analgesics, ototopical antibiotic drops and oral nasal decongestant spray for 1 week. The patient was instructed to keep the ear dry.

Weekly postoperative follow-up visits for the evaluation of the MO under the otomicroscope were made until complete healing of the MO was recorded. The evaluation of the Eustachian tube and hearing was done 4 weeks after complete healing of the tympanic membrane. The amount of closure of the air bone gap at 0.5, 1, 2 and 4 kHz and the improvement in middle-ear pressure were the parameters of improvement.

Cases were deemed to have failed when the MO closed early within the second week postoperatively without improvement in hearing, or the myringotomy persisted until the end of the third month postoperatively.

The outcome measures of this study are the postoperative state of the MO and the ear drum, the PT of the MO, improvement in hearing and Eustachian tube function and incidence of operative and postoperative complications.

Statistical analysis

Qualitative variables were presented as frequency and percentage. Quantitative variables were presented as mean and SD. The Kolmogorov–Smirnov test was performed to test normality. Parametric variables were compared between the studied groups using the independent sample *t*-test and were compared within groups using the paired *t*-test. Nonparametric variables were compared between the studied groups using the Mann–Whitney *U*-test and were compared within groups using the Wilcoxon signed-rank test. Comparison between the studied groups regarding qualitative variables was made using the χ^2-test and Fisher's exact test. The recorded significance level was 0.05. SPSS statistical package version 20 (IBM Corporation, Armonk, USA) was used in data analysis.

Results

Twenty children were included in this study. All patients had unilateral recurrent acute serous otitis media with persistent middle-ear effusion and failure of medical treatment for at least 8 weeks.

There were no side effects or complications at the time of the procedure. The mean operative time for the procedure, determined as the time from application of the aural speculum to its removal from the external ear canal, was 5 min (Table 1).

Out of 20 ears, 16 had a PT of 4–6 weeks (80%) for MOs. Two cases (10%) recorded persistent perforation for more than 6 weeks. The first case was due to postoperative infection, which led to chronic perforation. The second case was due to failure of complete closure of MO with a residual perforation of 1.5 mm diameter. This ear had an MO of about 3 mm in diameter in the laser procedure. Both ears were managed later by fat graft myringoplasty 3 months after the laser procedure and without otorrhoea. Two cases (10%) showed very early healing and closure of the MOs (after 2 weeks). Those two ears constituted the early cases of the study and the MOs in both were less than 2 mm at that time (Table 2).

There was statistically significant improvement in the patients' air/bone gap postoperatively as seen in the pure tone audiometry (PTA) results (Table 3).

Preoperatively, the tympanometry curve for the whole patient group was B type. The two ears with very early closure of the MO sustained a type B curve postoperatively and had to undergo myringotomy with a PE tube. Twelve out of 16 ears that healed in 4–6 weeks showed a type A curve (75%). The remaining four ears showed a type C curve (25%) and needed further medical treatment, Eustachian tube exercises and further follow-up. Tympanometry was not performed in the two ears with persistent perforation (= O tympanometry). There was statistically significant improvement in the postoperative tympanometry results, indicating improved Eustachian tube functions after the laser myringotomy procedure (Table 4).

Discussion

Ventilation disorders of the middle-ear cavity are the main cause of many acute and chronic middle-ear diseases. In children, these disorders are frequent because of recurrent upper respiratory tract infections and lymphoepithelial hyperplasia of adenoids and palatine tonsils [1].

Some Eustachian tube dysfunctions and/or middle-ear clinical disorders need neither the long duration of the MO with a PE tube nor the very short duration of surgical

Table 2 Myringotomy patency time

	Frequency (%)
Improved	
PT 4–6 W	16 (80.0)
Failed	
PT > 6 W	2 (10.0)
PT < 4 W	2 (10.0)
Total	20 (100.0)

PT, patency time.

Table 3 Comparison between preoperative and postoperative PTA

	Mean	*N*	SD	*P*-value
PTA preoperatively	20.00	20	4.942	0.000 (significant)
PTA postoperatively	8.10	20	4.303	

PTA, pure tone audiometry.

Table 4 Comparison between preoperative and postoperative tympanometry

	Frequency (%)	
	Preoperative	Postoperative
Valid		
A	0 (0.0)	12/20 (60.0)
C	0 (0.0)	4/20 (20.0)
B	20 (100.0)	2 (10.0)
O	0 (0.0)	2 (10.0)
Total	20 (100.0)	20 (100.0)
Wilcoxon signed-rank test	*P* (0.000)	Significant

MO without a PE tube. Those disorders need a PT for MO of between 1 and 7 weeks to give a useful therapeutic effect. Acute serous otitis media with persistent middle-ear effusion and failure of repeated courses of medical treatment is one of those clinical disorders [3,5,6].

The principal aim of laser myringotomy is to restore the middle-ear ventilation by means of a small tympanic membrane perforation with a short-term PT (a few weeks) to decrease the air/bone gap and improve Eustachian tube functions after the MO has healed. The size of the laser MO is the main factor for the period of PT. Other factors include the power setting applied, number of pulsed shots and thickness of the tympanic membrane [3,6].

In CO_2 laser studies [2,6–8], the average PT was around 2.5 weeks. Silverstein *et al.* [5] recorded an average PT of 4.04 weeks with 2 mm MOs and 4.17 weeks with 2.5 mm MOs or larger. They stated that, with each 0.5 mm increase in size, a myringotomy will remain patent an average of one additional week in their CO_2 laser group. Sedlmaier *et al.* [9] recorded a PT of 8–34 days (mean 16.35 days) for MOs of 2 mm in their paediatric group of CO_2 laser myringotomy patients.

In the study by D'Eredit and Shah [4] on chronic middle-ear effusion in children, a PT of 3.5 months (= 16 weeks) was recorded for DLM and the MO was 2.5 mm. Zanetti *et al.* [6] recorded a PE of 7–25 days (average 15.6 ± 4.8 days) in their adult patients and the MO was 0.8–3.5 mm (mean 1.8 mm). In this study, on acute recurrent cases, the average PT was recorded as 2–6 weeks (average 4.67 weeks), including for the two MOs that closed early after 2 weeks (18 ears) with MO 2.5 mm.

It seems that the duration of time needed for middle-ear ventilation varies according to the nature of the Eustachian tube disorder: if it is an acute disorder causing salpingitis and severe pain, it can be resolved by a very short duration of MO with medical treatment; if it is a chronic mechanical or functional disorder causing chronic effusion, it will resolved by long duration of MO with a PE tube; if it is a temporal oedema of the Eustachian tube, osteal and luminal mucosa caused by infection or allergy with failure of medical treatment, a longer duration than that required for acute disorders but shorter duration than that for chronic disorders is needed [3].

The average time of the DLM procedure was 5 min, which concurs with the studies by D'Eredit and Shah [4] and Zanetti *et al.* [6]. This short operative time adds to the advantages of using a diode laser device over a CO_2 laser, being small sized, light weight and easily transported. Also, by use of the contact modality, the diode laser gives the surgeon more control on the place, size and power of the energy applied on the ear drum as the penetration power of the contact mode is less than 2 mm, thus avoiding injury to the surrounding structures – for example, the middle-ear promontory. Silverstein *et al.* [5] recorded 8 dB as the mean improvement in air/bone gap in their CO_2 laser myringotomy postoperatively, whereas Zanetti *et al.* [6] recorded improvement in the air/bone gap in their DLM within 10 dB in 28 of their 39 patients in the first week postoperatively. In this study, the mean improvement in the air/bone gap was 12 dB for the ears after healing of the MOs. Also, there was a statistically significant improvement in the patients' air/bone gap postoperatively, as seen in the pure tone audiometry results.

In the postoperative tympanometry, there was a statistically significant improvement in the postoperative tympanometry results, indicating improved Eustachian tube functions after the laser myringotomy procedure.

Local anaesthesia was used in most of the studies in the literature as the procedure is easy, simple, fast and minimally invasive. In this study, it has been noticed that general anaesthesia with a laryngeal mask is more useful for avoidance of patient discomfort in children, especially in the case of unsteady anxious patients, as well as for avoidance of vasovagal responses and the long time needed for the sedatives and local anaesthetic cream to take effect. General anaesthesia with a laryngeal mask gives smooth induction and recovery, better visibility, accessibility, accuracy and stability to the procedure.

The failure rate of this study was four out of 20 ears (20%). The causes of failure were very early closure of the MOs (10%), postoperative infection (5%) and very large MOs (5%). Zanetti *et al.* [6] reported focal myringitis for 5 days in one ear and burning sensation in two patients at the time of laser shots who were given local anaesthesia. D'Eredit and Shah [4] reported otorrhoea in two ears 8 weeks after the procedure.

Although the costs of the laser procedure are higher than that of the conventional ones, the benefits of the laser procedure are much more valuable regarding the avoidance of the too short duration of patency provided by the cold-knife procedure and the much longer duration of patency with water restriction demands and possibility of infection and/or persistent perforation resulting from myringotomy with ventilation tube insertion in this specific type of otitis media.

Conclusion

DLM is a useful procedure for the management of the Eustachian tube and middle-ear disorders that need short-term MO for their treatment (weeks), such as in children with acute serous otitis media associated with persistent middle-ear effusion. It is a safe, simple, short-timed, nearly bloodless, precise procedure, less

traumatic to the ear drum and external auditory canal and has fewer complications, with favourable hearing results. Study of larger patient groups and comparison between different myringotomy techniques are recommended to allow more accurate statistical analysis.

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Conflicts of interest

There are no conflicts of interest.

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