Underlay tympanoplasty with laser tissue welding

David Foyt, MD; William H. Slattery III, MD; Matthew J. Carfrae, MD

Abstract
We investigated the feasibility of using laser tissue welding techniques to perform transcanal underlay tympanoplasty. We used 10 temporal bones obtained from human cadavers. After creating a subtotal tympanic membrane perforation, we introduced harvested periosteum through the perforation and used laser tissue welding to secure the periosteum graft in place in an underlay fashion. The procedure was performed via a transcanal approach and did not require middle ear packing. Immediately after the graft had been placed, we qualitatively tested its integrity with a blunt probe. The graft was as strong as the native cadaver tympanic membrane in all 10 cases. We conclude that laser transcanal underlay tympanoplasty is a feasible and effective method of repairing a tympanic membrane. The ultimate goal is to develop a technique that will allow physicians to routinely perform underlay tympanoplasty on moderately sized perforations in an office setting.

Introduction
The two basic procedures used to repair large perforations of the tympanic membrane are the overlay technique and the underlay technique. The overlay technique requires removal of the skin of the anterior canal wall and the skin of the tympanic membrane; it is often reserved for large perforations involving the anterior aspect of the tympanic membrane. The underlay technique requires the creation of a tympanomeatal flap for placement of the graft under the native tympanic membrane; it is often used for smaller, posteriorly based perforations. The overall success rate of these procedures is the same.1

However, both procedures have their drawbacks:

• Both require canal and/or postauricular incisions to access the perforation.

• Middle ear packing is often used to support the fascia graft, and it sometimes contributes to hearing loss during the immediate postoperative period.

• Because the procedure is performed in an operating room with the patient under general anesthesia, it is expensive and it carries the morbidity of general anesthesia.

Although small perforations can be treated in the office with paper patches or fat grafts, these techniques are not suitable for perforations of even moderate size. A technique that would allow transcanal tympanoplasty for moderately sized perforations to be done in an office setting under local anesthesia would greatly reduce patient morbidity and the cost of this common otologic procedure.

Laser tissue soldering technique
Laser soldering is a new technique for bonding tissue together. A solid-state diode laser (808 nm) is used to activate an albumin-based solder, which has been combined with a laser-energy–absorbing dye (indocyanine green). The dye color is chosen specifically to absorb the laser's output wavelength. The solder is preferentially heated and activated while the surrounding tissue remains unaltered (figure 1).2,4 This technique has been applied both experimentally and clinically in anastomosis of blood vessels, the bowel, the urethra and ureter, and the trachea with excellent results.5-9

Laser welding has been used by one of the authors (D.F.) to repair dural incisions in cadaver dura and in the live rat.10 Dura closure with the laser was found to have a significantly higher leak pressure than that seen with conventional suture closure. Histologic studies of underlying rat brain showed very little heat dissipation to surrounding tissues. Long-term histologic study of laser-welded dura revealed a well-healed incision.11 This experience paved the way for an ongoing clinical trial of intraoperative dural closure with laser tissue welding in humans. The purpose of the present study was to explore the feasibility of performing a transcanal underlay tympanoplasty with the laser soldering technique.
Methods
Laser soldering was performed with a diode laser module (Iris Medical Instruments; Mountain View, Calif.) coupled to a quartz silica fiberoptic cable (600-μm core diameter). The laser parameters were as follows: power, 0.5 W; pulse duration, 0.5 sec; and pulse interval, 0.1 sec. The power density was 15.9 W/cm$^2$ and fluency was 8.0 J/cm$^2$ per pulse. The major wavelength output of the diode laser is 808 ± 1 nm. Additional bands of laser energy occur in the visible spectrum so that the operator can visualize the spot size of the laser during activation.

The laser solder was prepared fresh prior to each experimental run. A pasteurized 25% human albumin solution (Melville Biologics Division, New York Blood Center; New York City) was lyophilized (dehydrated) under sterile conditions to powder form (2.5 g of albumin) and reconstituted in 6.0 ml of sterile water (42% albumin solution). After sterile filtration through a 0.2-μm pore filter, 200-μl aliquots of this solution were mixed with 100 μl of sterile indocyanine green dye (CardioGreen, 2.5 mg/ml; Becton, Dickinson and Co.; Cockeysville, Md.) and stored at –20°C. Twenty-four hours before use, the solution was thawed and combined with 200 UL of sodium hyaluronate (Healon, 10 mg/ml; Kabi Pharmacia Ophthalmics; Monrovia, Calif.) to make a total volume of 0.5 ml/aliquot. The final solution was vortexed for 30 sec and stored in conical tubes overnight.

Ten human cadaver temporal bones were clamped to a House-Urban temporal bone holder (House Ear Institute; Los Angeles). The tympanic membrane was visualized with a Wild operating microscope. A subtotal perforation of at least 50% of the pars tensa was created with an otologic sickle knife. Care was taken to ensure that some tympanic membrane remained surrounding the perforation. The intervening tympanic membrane was completely excised. Periosteum was harvested from the mastoid cortex and prepared to approximate 125% of the area of tympanic perforation. The periosteum was introduced through the perforation so that half of the graft protruded under the residual membrane.

The solder was applied with a 1-ml syringe and a 16-gauge Angiocath (figure 2, A). The laser was then used to activate the solder. This fixed the first half of the graft to the undersurface of the tympanic membrane. The remainder of the graft was then placed under the residual perforation and soldered into place. This created a structurally firm bond between the graft and the undersurface of the tympanic membrane (figure 2, B).

The integrity of the weld was tested qualitatively by placing progressively increasing pressure on the lateral aspect of the graft until the graft completely separated from the tympanic membrane.

Results
Transcanal underlay tympanoplasty was easily performed with the laser tissue solder technique. Graft adhesion to the native tympanic membrane was very firm. A significant amount of lateral pressure with the blunt probe was required in order to break through the graft. In 8 instances, the surrounding tympanic membrane broke under pres-
sure before the laser-weld seal broke. No obvious thermal injury was noted to the underlying middle ear structures or surrounding tympanic membrane.

Discussion
This study confirms the technical feasibility of performing underlay tympanoplasty with the laser tissue soldering technique. The ultimate goal is to develop a technique that will allow physicians to perform underlay tympanoplasty on moderately sized perforations in an office setting. Further studies will be required before this can become a reality, including long-term animal studies to test the effects of the laser and solder on tympanic membrane healing.

Laser welding already has a proven clinical safety record. In vivo bonding of dura has been accomplished with no damage to the underlying cerebral cortex. It is assumed, therefore, that laser soldering will be similarly safe in the middle ear. No thermal effects on the middle ear structures were noted in our study. All of the components of the laser solder mixture have a proven clinical safety record. The albumin is routinely used as an intravenous volume expander.

Indocyanine green is used clinically as an ophthalmologic angiographic dye. Other tissue bonding techniques carry much greater risks. For example, cyanoacrylate (e.g., Krazy Glue) may produce an intense soft-tissue reaction, and therefore it is not suitable for this procedure. Also, fibrin glue has a much lower tensile strength than does the laser solder mixture, and it carries a potential for allergic reaction.

For our study, we used mastoid cortical periosteum as the donor graft material. This, of course, would not be an appropriate or desirable donor material in a clinical office setting. Superficial temporalis fascia could be used, but this would require a separate incision and dissection, which would increase the complexity of the procedure, as well as patient discomfort and general morbidity. Other possible graft materials include homograft, xenograft (animal fascia), and man-made substances.

Laser weld tympanoplasty would ideally be performed with local anesthesia in the form of an application of phenol to the tympanic membrane. If additional anesthesia were to be required, lidocaine 1% could be placed into the middle ear to anesthetize the middle ear mucosa. For cases that might require extended manipulation, external canal infiltration with lidocaine could easily be administered. Extra anesthesia would be necessary if the edges of the perforation required local debridement.

All told, this procedure takes little more time than a routine myringotomy and tube insertion in the office. Contraindications to the procedure include suspected cholesteatoma, ear discharge, ossicular problems, or a marginal perforation. In these cases, a formal open procedure is still indicated.

References