Fenestration operation in middle ear bone with pulsed infrared lasers: an *in-vivo* study

Xianzeng Zhang (张先增)¹, Xiaoyan Wang (王晓燕)^{2,3}, Zhenlin Zhan (詹振林)¹, Qing Ye (叶 青)^{2,3*}, and Shusen Xie (谢树森)¹

¹Institute of Laser and Optoelectronics Technology, Fujian Provincial Key Laboratory for Photonics Technology,

Key Laboratory of Optoelectronic Science and Technology for Medicine of Ministry of Education,

Fujian Normal University, Fuzhou 350007, China

²Department of Otolaryngology, Fujian Provincial Hospital, Fuzhou 350001, China

³Provincial Clinical College of Fujian Medical University, Fuzhou 350001, China

*E-mail: yeqing180302@yahoo.com.cn

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The feasibility of fenestration operation in middle ear bone with pulsed infrared laser is evaluated. Healthy male New Zealand rabbits *in vivo* are used in the experiment. Middle ear mastoid bone of animal model is completely exposed with conventional methods, and then a pulsed CO₂ laser (10.6 μ m) and an Er:YAG laser (2.94 μ m) are used to perform the fenestration operation. Diamond drill is also used as a control group. The total operation time and light irradiation time are recorded and the opening efficiency is assessed. The morphological changes and thermal damage around the opening window on the middle ear bone are examined. It is shown that both laser systems are suitable for the fenestration operation in middle ear bone, and this no-touch technique has a lot of benefits compared with traditional methods. The bleeding during operation has an important effect on operation time and thermal injury and needs to be controlled efficiently in further study.

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Many ear diseases in otolaryngology, such as tympanitis and deafness induced by sclerosis and neuroma, have to be treated by surgical operation. The microscopic opening surgery of middle ear requires the minimal trauma to the involved tissue to preserve hearing and to avoid damage to the vestibular organ and facial nerve. The conventional or standard instruments for ear opening surgery in today's medical practice are mechanical tools such as handheld perforators or diamond drill. Unfortunately, the traditional method always brings mechanical defects and serious damage produced by mechanical friction, which may induce hearing damage or even hearing loss and noticeably delay the healing of incision. Precise perforation required in ear surgery may be best accomplished by no-touch technique, and modern laser technology may be a good candidate thanks to its unique advantages compared with conventional tools. The noncontact application of a focused beam offers free and arbitrary complicated cut geometry. The beam position on the target can be very precisely and easily controlled with electronic device, especially combined with advanced computers and robots. There is no traumatic vibration, bone dust, or metal abrasion in the incision during laser ablation. Aseptic and haemostatic effects can be expected by using some laser systems^[1-6]. Thus,</sup> lasers have been introduced to ear surgery. The most successful application of lasers in ear surgery may be stapedotomy, which has been proven to be beneficial in terms of hearing outcome compared with mechanical drilling in primary surgery and even more in revision surgery, as the diseased ear is even more vulnerable to mechanical stress induced by the conventional surgery. In some cases, revision surgery has been made possible only with a laser that otherwise would have been contraindicated.

Various lasers such as argon, CO₂, KTP, and Er:YAG lasers have been evaluated in in vitro and in vivo experiments. The most promising wavelength is 2.94 μ m which coincides with a very strong water absorption peak. Previous studies suggest that the Er:YAG (2.94 μ m) laser is capable of producing very high ablation rates with a thermal damage zone of $5-15 \ \mu m^{[7,8]}$, but it is limited to operate at low pulse repetition rates. CO_2 lasers at 9.6 and 10.6 μ m are another promising candidate for bone tissue removal due to the high optical absorption by water and hydroxyapatite. Although the early attempts to cut bones with continuous wave (CW) and long-pulse CO_2 lasers have failed because of strong thermal injury, good results have been reported recently by relatively long CO_2 laser pulses combined with a fast multi-pass beam scanning and using water $\operatorname{spray}^{[4,5,9-11]}$.

So far, the reported studies on laser surgery in ear mainly focus on ear opening with a relatively small window. Massive ablation of ear mastoid bone or opening of middle ear bone with a large size which is necessary in some cases has not yet been reported. Furthermore, the influence of bleeding during operation on operation time and thermal injury has not been assessed. In this letter, pulsed CO₂ and Er:YAG lasers are used to ablate rabbit ear mastoid bone *in vivo* to open a window with a size of 10×5 (mm) to provide an passageway to inner ear. The availability of these two different laser systems for massive bone ablation in ear surgery is evaluated by comparison with the more conventional method of using

a diamond drill. The total operation time and light irradiation time are recorded and the opening efficiency is assessed. The morphological changes and thermal damage around the opening window on the middle ear bone are also examined.

All animal experiments were approved by the Committee of Animal Experimentation of Fujian Province, China. 24 New Zealand white rabbits, all 1-2 years old, male, weight from 2.0 to 2.5 kg, were kept in individual metal cages at room temperature, with 12 h of light per day and 50% relative humidity. They received a standard pelleted laboratory diet and water ad libitum. Before the experiments, middle ear infections were excluded by otoscopic inspection of the eardrum, and hearing reactions were tested by the Preyer reflex. All animals were labeled by number and divided randomly into 3 groups named Group A , Group B, and Group C corresponding to diamond drill, pulsed CO₂ laser, and pulsed Er:YAG laser, respectively. Only right ears for all experimental animals were used for study.

Before the opening surgery of middle ear bone, experimental animals were conducted under an intramuscular injection of atropine with a dose of 0.2 ml (0.5 mg/ml), followed by anesthetization with intravenously administered 2% sodium pentobarbital given slowly at a dose of 1.5 mg/kg. And 0.5% lidocaine hydrochloride was also used for site anesthetization during surgery. A 3-cm-long incision was cut along the place of 0.5 cm behind auricle by traditional surgery method under surgical microscope (Leica M520, Germany), and the middle ear mastoid bone was completely exposed, as shown in Fig. 1(a). After that, the middle ear mastoid bone was ablated with two different laser systems respectively or perforated by diamond drill to produce a window (as shown in Fig. 1(b)) with a size of about 10×5 (mm) at outside part and $5 \times 3 \text{ (mm)}$ at inside part. The total operation time and multi-light irradiation time were recorded. The whole surgery process was conducted by the same surgeon under surgical microscope and monitored with a three-color charge-coupled device (CCD) camera (Hitachi HV-D30, Japan). The details of this opening surgery by different methods are shown as following.

In Group A, the opening surgery was performed with an electrically driven diamond drill (Nouvag MD20, Switzerland) with a diameter of 2 or 1.5 mm. The drill was set with gentle pressure against the bony wall turning at 2000 to 4000 revolutions per minute.

In Group B, the pulsed CO₂ laser (Sharplan 30C, Israel) with a wavelength of 10.6 μ m and a pulse duration of about 10 ms was used to carry out the opening surgery. The laser light was delivered through an articulatedmirror-arm system and coupled to the surgery microscope with a micromanipulator (Sharplan 712 Acuspot, Israel) mounted directly onto the operating microscope. Thus it is possible to control the beam position precisely and safely. The laser fluence was 8.3 J/cm² with a repetition rate of 60 Hz, and the beam diameter was 1.0 mm. The exact radiant exposure was determined by reading the laser pulse energy with a pyroelectric detector and relating it to the beam area.

In Group C, the pulsed Er:YAG laser system (Contour Profile 2940, America) with a wavelength of 2.94 μ m and a pulse duration of about 1 ms was used to carry out



Fig. 1. (a) Rabbit middle ear mastoid bone exposed by traditional methods; (b) the opening window on middle ear bone.





Fig. 2. Morphology changes can be observed during the opening surgery with three different methods. (a) Diamond drill; (b) pulsed CO₂laser; and (c) pulsed Er:YAG laser.

the experiment. The laser light was delivered through an articulated arm system and coupled to a 2-mm handpiece and controlled by freehand to perform the opening surgery. The laser fluence was 3.7 J/cm^2 with a repetition rate of 20 Hz, and the beam diameter was 2.0 mm.

After the opening surgery, the incision was sutured zone-by-zone. Six hours later, the experimental animal was euthanatized and the whole middle ear mastoid bone was obtained and fixed in 10% neutral buffered formalin, decalcified in ethylene diaminetetraacetic acid (EDTA) solution, and then embedded in paraffin. 5- μ mthick serial sections were cut transversely to the laser cuts from the embedded sample, mounted on 1×3 (inch) glass slides, and stained with hematoxylin and eosin-Y (H&E). Then the prepared samples were examined by light microscope, and the thickness of the thermal damage along the opening window was also measured.

Different morphology changes can be observed during the opening surgery with three different methods. Figure 2 presents the opening windows on middle ear bone by using diamond drill, pulsed CO_2 laser, and pulsed Er:YAG laser, respectively. As a standard tool in today's ear surgery, diamond drill can perforate or open the middle ear bone easily, and clear and regular surface of incision (as shown in Fig. 2(a)) can be obtained by skilled surgeon. However, the outcome largely depends on the surgeon's skill and experience, and blood loss is still a problem. As for laser systems, both the pulsed CO_2 laser and Er:YAG laser are able to ablate bone tissue efficiently and can be used for ear fenestration operation. As shown in Figs. 2(b) and (c), the pulsed CO_2 laser and Er:YAG laser can obtain the similar outcome as the



Fig. 3. Total average operation time and light irradiation time consumed in opening surgery for three different methods. The error bars are standard deviation of the data (n = 8).



Fig. 4. Optical microscopy images of typical histological sections of the bone tissue around the opening windows created by (a) diamond drill, (b) pulsed CO₂ laser, and (c) pulsed Er:YAG laser. The arrows indicate the thermal damage.



Fig. 5. Average thickness of the thermal damage zone along the cut created with three different methods. The error bars are standard deviation of the data (n = 8).

traditional method. Although char formation can be

found around the opening window, these kinds of notouch technique shows a lot of benefits such as less blood loss, easy control or operation, and clear visual field. Less blood loss means more benefit to the healing of the incision, and less operation time will reduce the patient's risk.

The average total consumed operation time and light irradiation time for three different methods are presented in Fig. 3. The total operation time is varies with different methods. The average consumed operation time by using pulsed CO_2 is the shortest one, the next is the Er:YAG laser, and the longest is the diamond drill. However, the difference among the groups is not obviously statistically significant (P > 0.05); even in the same group, the operation time varies for different animals. The average irradiation time is 105.04 s for the pulsed CO₂ laser and 121.72 s for the Er:YAG laser (Fig. 3), also, this difference is not statistically significant (P>0.05). However, we find that a large portion of the consumed time during the opening surgery with these two laser systems is used to remove the char formation around the incision. The char was mainly produced by the blood which absorbed the incident light. If we can control the char formation, the opening surgery time may be shortened greatly, especially for the Er:YAG laser. While the time consumed by the diamond drill mainly depends on surgeon's skill.

Figure 4 presents the optical microscopy images of typical histological sections of the bone tissue around the opening windows created by the diamond drill, pulsed CO_2 laser, and pulsed Er:YAG lasers, respectively. The thermal damage zone can be found clearly along the cut created by both laser systems (as shown in Figs. 4(b)and (C)), while the thermal damage induced by the diamond drill is the minimum (see Fig. 4(a)). The average thicknesses of the thermal damage zone at the sides of the opening windows are shown in Fig. 5. Both groups of laser systems present almost equal-thickness injury, and there does not exist statistical significance (P > 0.05). The thermal damage produced by the diamond drill is significantly thinner than both of laser systems. These unexpected results may be explained that the absorption of incident light by blood during the procedure will induce char formation which will absorb the incident light dramatically and prevent the process of ablation, resulting in the strong thermal injury around the opening window. In other words, it is the char formation or bleeding that plays a key role on thermal injury instead of wavelength or pulse duration as reported in other *in-vitro* studies^[3,4]. As for diamond drill, although the friction of the drilling during the procedure will produce thermal effect, the bleeding almost has not effect on thermal injury. So the thermal injury induced by the diamond drill is the minimum compared with both laser systems.

In conclusion, a pulsed CO_2 laser and an Er:YAG laser are capable of ablating massive middle ear bone and can be used as new tools to perform the fenestration operation in ear. This no-touch technique can not only obtain the similar outcome as traditional methods, but also present a lot of advantages compared with the traditional methods, such as less blood, easy control operation, and clear vision field. Excessive heat deposited in ear may damage the vestibular organ and facial nerve, or even induce hearing loss, so it must be controlled carefully. It seems that if the bleeding during the opening procedure can be controlled efficiently, the operation time will be shortened and the thermal injury will be minimized.

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