

Lumenis CO₂ Solutions for Otology

Bibliography of Published Studies
& Peer Reviewed Papers

The use of CO₂ Laser in surgical procedures in otology is clinically based, and is used successfully in various surgical approaches. CO₂ Laser is a valuable tool in the treatment of several pathologies, as stapedotomy, myringotomy and cholesteatoma.

The following list presents selected publications from the last years, pointing out the advantages of using CO₂ Laser for various applications in otology.

In order to provide additional data from the user's perspective, 'white paper' publications and technique guides written by experienced surgeons are attached.

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Energy to Healthcare

1990

- Introduced
 - › UltraPulse® CO₂ and VersaPulse® Holmium laser systems
 - › patented WaveGuide delivery system for CO₂ laser

1996

Introduced VersaPulse® C

2000

Introduced VersaPulse® PowerSuite™, world's first 100W Holmium laser for BPH

2009

Introduced AcuPulse™ with SurgiTouch

2010

Introduced VersaPulse P20

2012

Introduced AcuPulse WaveGuide

2012

Introduced

- › AcuPulse DUO
- › FiberLase Robotic DIG
- › MicroLase Fiber
- › FiberLase GYN Handpieces

2014

Introduced

- › Lumenis Pulse 120H
- › Xpeeda Fiber
- › SlimLine 200 D/F/L Fiber

2015

Introduced

- › UltraPulse DUO
- › Lumenis Pulse 100H
- › Lumenis Pulse 50H

2016

Introduced

- › Lumenis Pulse 30H
- › Suction hand-piece
- › Otolase Fiber Delivery System



A Heritage of Innovation

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Stapedotomy

| Title | Publication | Authors | Year | Short summary of study and conclusion | Laser system |
|---|---|---|------|---|----------------------|
| Laser versus conventional fenestration in stapedotomy for otosclerosis: a systematic review | Laryngoscope. 124(7):1687-93 | Wegner I, Kamalski DM, Tange RA, Vincent R, Stegeman I, van der Heijden GJ, Grolman W | 2014 | <ul style="list-style-type: none"> › Review of hearing results and complications following primary stapedotomy in patients with otosclerosis, comparing the use of laser and conventional techniques for fenestration › Both footplate fractures and sensorineural hearing loss appear to occur more frequently in the conventional group than in the laser group › The authors prefer CO₂ laser above conventional methods for footplate fenestration in primary stapedotomy | N/A |
| Classic and reversal steps stapedotomy performed with CO ₂ laser: a comparative analysis | Eur Arch Otorhinolaryngol. 271(5):981-6 | Freni F, Mannella VK, Cammaroto G, Azielli C, Cappuccio C, Galletti F | 2013 | <ul style="list-style-type: none"> › Evaluation and comparison of hearing outcomes and complications following CO₂ laser stapedectomy in 84 patients with otosclerosis in 2 groups: classical stapedotomy and reversal stapedotomy › No significant differences were found between groups in air-bone gap (ABG), air conduction, bone conduction, and tinnitus handicap inventory (THI) score. Complications in both groups were not significant › Both reversal and classic stapedotomies performed with CO₂ laser can be considered efficient, safe and reliable techniques considering the hearing outcomes and complications | Lumenis laser system |

Stapedotomy

| Title | Publication | Authors | Year | Short summary of study and conclusion | Laser system |
|--|-----------------------------|---|------|--|----------------------|
| First experience with the fiber-enabled CO ₂ laser in stapes surgery and a comparison with the "one-shot" technique | Otol Neurotol. 34(9):1581-5 | Brase C, Schwitulla J, Künzel J, Meusel T, Iro H, Hornung J | 2013 | <ul style="list-style-type: none"> › Retrospective comparison of bone conduction after fiber-enabled CO₂ laser perforation of the stapes footplate with conduction after the "one-shot" technique during stapedotomy in 178 patients with otosclerosis in 2 groups › The postoperative bone conduction threshold at 0.5 and 2 kHz improved within a month, and was significantly different from the preoperative value. Direct comparison of the fiber-enabled CO₂ laser and the "one-shot" technique showed no significant difference › Compared with the "one-shot" technique, the fiber-enabled CO₂ laser can be used safely in stapes surgery, without great risk to the patient. This technique has practical advantages, especially in difficult anatomic conditions | Lumenis laser system |
| Bone conduction after stapes surgery: comparison of CO ₂ laser and manual perforation | Otol Neurotol 34(5):821-6 | Brase C, Keil I, Schwitulla J, Mantsopoulos K, Schmid M, Iro H, Hornung J | 2013 | <ul style="list-style-type: none"> › Retrospective comparison of bone conduction after CO₂ laser and manual perforation of the stapes footplate during stapedotomy in 302 patients with otosclerosis › The bone conduction threshold was improved to baseline within the first 4 days in lower frequencies (0.5 and 1 kHz). A direct comparison with classic stapedotomy showed a trend in favor of the laser technique › Both laser and classic techniques can be used successfully in stapes surgery without causing long-term damage to the inner ear | Lumenis laser system |

Stapedotomy

| Title | Publication | Authors | Year | Short summary of study and conclusion | Laser system |
|--|------------------------------|--|------|---|----------------------|
| KTP versus CO ₂ laser fiber stapedotomy for primary otosclerosis: results of a new comparative series with the otology-neurotology database | Otol Neurotol. 33(6):928-33 | Vincent R, Bittermann AJ, Oates J, Sperling N, Grolman W | 2012 | <ul style="list-style-type: none"> › Comparing 3-month postoperative hearing results after laser stapedotomy using a KTP or CO₂ laser fiber in 818 patients with primary otosclerosis in 2 groups › Postoperative air-bone gap (ABG) was 4.3 dB in the KTP group compared with 3.1 dB in the CO₂ group. In 90.4% of the patients of the KTP group, the postoperative ABG was 10 dB or lower, as compared with 96.5% in the CO₂ group. Sensorineural hearing loss was reported by 1 patient with KTP laser (0.3%) and by none with CO₂ laser › The use of the CO₂ laser fiber may be associated with better hearing results than the KTP laser fiber, regarding the ABG closure within 10 dB | Lumenis laser system |
| Microdrill, CO ₂ laser, and piezoelectric stapedotomy: a comparative study | Otol Neurotol. ;30(8):1111-5 | Cuda D, Murri A, Mochi P, Solenghi T, Tinelli N | 2009 | <ul style="list-style-type: none"> › Comparing 3 different devices: a microdrill, a piezosurgery bone device a CO₂ laser to perforate the stapes footplate in 90 patients with otosclerosis › CO₂ laser shows a trend toward less residual air-bone gap and more functional gain at low frequencies. Bone-conduction pure-tone averages did not worsen in the microdrill and CO₂ groups. A higher rate of postoperative vertigo was found in patients after piezosurgery › The use of the CO₂ laser was associated with the best functional results, although not significant | Lumenis laser system |

Stapedotomy

| Title | Publication | Authors | Year | Short summary of study and conclusion | Laser system |
|---|--|-------------------------------------|------|---|----------------------|
| Early and late hearing outcomes after CO ₂ laser stapedotomy | J Med Assoc Thai 90(8):1647-53 | Boonchoo R, Puapermpoonsiri P | 2007 | <ul style="list-style-type: none"> › Retrospective comparison of hearing outcomes between early (1-3 months) and late (> 1 year) postoperative periods in 26 otosclerotic patients following CO₂ laser stapedotomy › Closure of air-bone gaps at pure-tone average and individual frequencies began in the early postoperative period, and continued to improve through the late postoperative period. Bone conduction hearing thresholds were stable even in the early postoperative follow-up, and the improvement in bone conduction hearing thresholds at 1 and 2 kHz and worsening at 4 kHz were seen. › Following a CO₂ laser stapedotomy, the early postoperative hearing outcomes reflect a side effect of postsurgical sensorineural hearing loss, and the long-term postoperative hearing outcomes determine the efficacy of this procedure | Lumenis laser system |
| CO ₂ laser stapedotomy with the “one-shot” technique- clinical results | Otolaryngol Head Neck Surg. 131(5):750-7 | Jovanovic S, Schönfeld U, Scherer H | 2004 | <ul style="list-style-type: none"> › Optimizing the surgical technique with the CO₂ laser in stapes surgery using the Lumenis SurgiTouch™ scanner to obtain a footplate perforation with only 1 laser application (“one-shot” stapedotomy) in 188 patients with otosclerosis › In 68% of the patients, an adequately large perforation diameter could be achieved with a single shot. In 11% of the patients, a second laser application at the same site was necessary. In 21% of the patients, the perforation had to be enlarged by several slightly overlapping laser applications without scanner. › The CO₂ laser combined with modern scanner systems is well suited for application in stapes surgery | Lumenis laser system |

Myringotomy

| Title | Publication | Authors | Year | Short summary of study and conclusion | Laser system |
|---|--|--------------------------------|------|--|----------------------|
| Paper-patch myringoplasty with CO ₂ laser for chronic tympanic membrane (TM) perforation | Eur Arch Otorhinolaryngol .265(10):1161-4 | Lee SH, Jin SM, Lee KC, Kim MG | 2008 | <ul style="list-style-type: none"> › Successful management of timpanic membrane perforation with paper patch after trimming the perforated tympanic membrane (TM) margin with the CO₂ laser in 90 patients › Successful closure of the timpanic membrane was achieved in 52.2% of cases (47/90) without any severe complication. The procedure was successful in 16 of 19 (84.2%) cases in perforation smaller than 2 mm, 19 of 29 (63.0%) cases when the size was 2–4 mm, 10 of 25 (40.0%) cases when the size was 4–6 mm, and 2 of 17 (11.8%) cases when the size was 6 mm › Paper-patch myringoplasty after CO₂ laser trimming is simple and safe to perform, and suitable as an outpatient procedure | Lumenis laser system |
| Intractable chronic myringitis treated with carbon dioxide laser microsurgery | Arch Otolaryngol Head Neck Surg.134(2):152-6 | Cheng YF, Shiao AS | 2008 | <ul style="list-style-type: none"> › Retrospective 10-year review of the effect of CO₂ laser microsurgery in the treatment of intractable chronic myringitis in 29 patients › Of 30 affected ears, 22 demonstrated total resolution of chronic myringitis, 7 demonstrated partial resolution, and the status of 1 ear remained unchanged at the end of follow-up. Revision laser therapy was performed in 3 ears, resulting in total resolution of disease in 1 ear. Time to total resolution of disease ranged from 1 to 16 months › CO₂ laser microsurgery to treat intractable primary chronic myringitis has the advantages of less invasiveness and higher applicability compared with aggressive surgical treatment | Lumenis laser system |

Myringotomy

| Title | Publication | Authors | Year | Short summary of study and conclusion | Laser system |
|---|---|--------------------------|------|---|----------------------|
| CO ₂ laser myringotomy in children with otitis media with effusion | J Laryngol Otol. 120(3):188-92 | Lin SH, Lai CC, Shiao AS | 2005 | <ul style="list-style-type: none"> › Evaluation of the clinical application of CO₂ laser myringotomy in 54 children with otitis media with effusion under topical anaesthesia in an office setting › The mean healing time was 2.51 weeks (range 1–5 weeks). The otitis media with effusion resolution rate was 73% › Laser myringotomy provides intermediate duration middle-ear ventilation. It could be beneficial in selected children with otitis media with effusion | Lumenis laser system |
| The efficacy of CO ₂ laser myringotomy in serous otitis media | Kulak Burun Bogaz Ihtis Derg. 12 (3-4):55-9 | Bozkurt MK, Calgüner M | 2004 | <ul style="list-style-type: none"> › Evaluation of the efficacy of CO₂ laser myringotomy combined with adenoidectomy compared with adenoidectomy and ventilation tube (VT) insertion in 35 children with serous otitis media › The mean healing time was 13 (SD +/- 2.16) days in 4 ears with myringotomies less than 2 mm in diameter, and 25 (+/-2.34) days in 46 ears with myringotomies with 2 mm in diameter. During the 6-month follow-up period, there were 11 recurrences (22%) in the CO₂ laser group and 4 recurrences (20%) in the control group. However, this was not statistically significant (p>0.05) › CO₂ laser myringotomy is preferred in serous otitis media cases who do not need long-time middle ear ventilation | Lumenis laser system |

Myringotomy

| Title | Publication | Authors | Year | Short summary of study and conclusion | Laser system |
|---|------------------------------|-------------------------------|------|---|-------------------------|
| Atypical indications for OtoScan laser-assisted myringotomy | Laryngoscope. 111(1):87-9 | Bent JP, April MM, Ward RF | 2001 | <ul style="list-style-type: none">› Describing the role of OtoScan laser-assisted myringotomy for indications other than chronic otitis media or recurrent acute otitis media in 21 patients› Middle ear disease resolved with closure of the laser-assisted myringotomy. At a later date, 2 patients (10%) underwent another laser-assisted myringotomy in the opposite ear, and 4 patients (20%) required repeated laser-assisted myringotomy in the same or both ears. 3 patients (15%) ultimately underwent myringotomy tube placement because of recurrent middle ear dysfunction› OtoScan laser-assisted myringotomy may provide an additional option in the care of certain patients who have previously been treated with myringotomy tubes | Lumenis laser system |

Cholesteatoma

| Title | Publication | Authors | Year | Short summary of study and conclusion | Laser system |
|---|--|--|------|---|----------------------|
| Transcanal CO ₂ laser-enabled ablation and resection (CLEAR) for intratympanic membrane congenital cholesteatoma | Int J Pediatr Otorhinolaryngol; 79(12):2316-20 | Lee CH, Kim JY, Kim YJ, Yoo CK, Kim HM, Ahn JC | 2015 | <ul style="list-style-type: none"> › Review of a case series of 10 cases with pediatric intratympanic membrane congenital cholesteatoma › Almost 90% of the cases were found abutting the umbo of malleus. The cases were treated with minimally invasive transcanal CO₂ laser-enabled ablation and resection (CLEAR) alleviating any ossicle vibration trauma, incision or graft harvest. All patients retained normal hearing without complications and recurrence › CO₂ laser-enabled ablation and resection surgery can be a good treatment option for intratympanic membrane lesions | Lumenis laser system |
| Surgical technique of minimal incision approach with CO ₂ laser for congenital cholesteatoma | Korean J Otorhinolaryngol-Head Neck Surg ;55:422-8 | Lym DK, Lee CH, Hong JE, Kong WK | 2012 | <ul style="list-style-type: none"> › Retrospective evaluation of the use of minimally invasive CO₂ laser in removing pediatric congenital cholesteatoma (CC) through transcanal antrotomy approach (TCA) in 37 patients › CO₂ Laser surgery was effective in surgical exposure and reducing the chance of residual CC. It could satisfactorily avoid postauricular tympanomastoidectomy, which allowed preservation of healthy mastoid air cells for almost all Potts III CC, including posterior CC (14 patients). CO₂ laser was also useful for 6 cases of Potts IV CC that extended beyond the incus posterosuperiorly to the auditus ad antrum. Finally, children were not committed to second look operation because the attic was exteriorized without the cavity problem and the complete removal of CC from the stapes was facilitated with the CO₂ laser | Lumenis laser system |

Cholesteatoma

| Title | Publication | Authors | Year | Short summary of study and conclusion | Laser system |
|--|-----------------------------|-------------|------|--|--------------|
| Systematic preservation of the ossicular chain in cholesteatoma surgery using a fiber-guided laser | Otol Neurotol; 31(7):1104-8 | Hamilton JW | 2010 | <ul style="list-style-type: none"> › Investigating the different outcomes of hearing in people who underwent CO₂ laser-assisted cholesteatoma surgery in 2 groups: resulting in an intact ossicular chain (80 ears) and resulting in a disrupted chain and an ossiculoplasty onto an intact stapes superstructure (69 ears) › Median hearing loss was 11.44 (group A) and 15.63 dB HL (group B), p = 0.001. In Group A, 70/80 ears, and in group B 46/69 ears fulfilled the Belfast Rule of Thumb (p = 0.002). The two groups did not significantly differ in respect of conductive hearing loss, change in bone conduction threshold, residual cholesteatoma rate and rate of facial palsy › The CO₂ fibre-guided laser allows the cholesteatoma surgeon to preserve the ossicular chain in a systematic manner which is both safe and of benefit to the patient | N/A |

White Papers and Technique Guides

| Title | Publication | Authors | Year | Short summary of study and conclusion | Laser system |
|---|----------------------------|------------|------|--|----------------------|
| Left primary stapedotomy for otosclerosis using the Lumenis OtoLase™ flexible CO ₂ fiber delivery system | ENT Technique guide series | Babu S | 2017 | <ul style="list-style-type: none"> › Using OtoLase fiber delivery system for CO₂ laser stapedotomy with fascia graft in a 42-year old male with otosclerosis › The OtoLase Fiber delivery system seemed easy to set up and use › The CO₂ laser allows near complete perforation of the footplate with little risk of damage to the saccule or utricle as the fluid should dissipate the energy | Lumenis laser system |
| First experience using the Lumenis OtoLase™ CO ₂ fiber delivery system for primary laser stapedotomy | ENT Technique guide series | McElveen J | 2017 | <ul style="list-style-type: none"> › Using Otolase fiber delivery system for CO₂ laser stapedotomy in a 43-year old male with otosclerosis › The CO₂ laser was utilized on the stapedius tendon and the posterior crus, and to thin the footplate prior to the fenestration being made with the microdrill. Only one pulse was needed to thin the footplate in this patient, and minimal pressure was needed to make the fenestra › At the end of procedure, the patient had a positive rinne and could hear whispered speech. A major benefit of using the CO₂ laser with the OtoLase fiber is that it minimizes the potential for creation of a floating footplate | Lumenis laser system |

White Papers and Technique Guides

| Title | Publication | Authors | Year | Short summary of study and conclusion | Laser system |
|--|----------------------------|-------------------|------|--|----------------------|
| Use of lumenis OtoLase™ flexible CO ₂ fiber delivery system to remove small cholesteatoma during left medial graft tympanoplasty with cartilage graft | ENT Technique guide series | McElveen J | 2017 | <ul style="list-style-type: none"> › Using the Otolase fiber in a 19-year old female to remove a cholesteatoma limited to the left middle ear stapedius tendon and remove middle ear adhesions › The cholesteatoma and adhesions were fully removed using the CO₂ laser. The tympanic membrane was grafted with fascia and reinforced with cartilage › The OtoLase Fiber Delivery System is very useful in removing cholesteatoma, particularly when the cholesteatoma is very adherent to the stapedius tendon or the stapes footplate. No mechanical force is imparted to the stapes footplate, so the likelihood of displacing the footplate is minimized | Lumenis laser system |
| Functional orthogonal cholesteatoma surgery, or why cholesteatoma surgery with laser is the logical choice | ENT White paper series | Blom HM, Natte RN | 2017 | <ul style="list-style-type: none"> › An ex-vivo cadaveric histological examination to determine the thermal effect when using the Otolase fiber › The histologic results showed that the penetration depth never exceeds 0.2 mm, which provides low thermal effect and safe procedure. For delicate work around the ossicles and the facial nerve the distal bend tip was selected. For sanitization of larger surfaces such as the mastoid cavity a straight tip and defocusing of the handpiece was used to speed up the process › The OtoLase fiber is a safe instrument to use by skilled ear surgeons. The handpiece is narrow, making it usable in small spaces such as the oval recess, the stapes arc and the medial side of the ossicles | Lumenis laser system |

Risk information: CO₂ lasers (10.6 μm wavelength) are intended solely for use by trained physicians. Incorrect treatment settings or misuse of the technology can present risk of serious injury to patient and operating personnel. The use of Lumenis CO₂ laser is contraindicated where a clinical procedure is limited by anesthesia requirements, site access, or other general operative considerations. The use of Lumenis CO₂ laser is contraindicated for patients who are not candidates for general surgery, or when local or spinal epidural anesthesia is inappropriate, laparoscopic applications where laparoscopy is contraindicated. Risks may include excessive thermal injury and infection. Read and understand the CO₂ systems and accessories operator manuals for a complete list of intended use, contraindications and risks.

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