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A Clinical Evaluation of the Safety and Efficacy of 980 nm Laser with Bare Fiber Tips in the Treatment of ENT Disorders

Minocha Dr. Pramod Kumar[1], Kothwala Dr. Deveshkumar Mahendralal[2], Shah Khusboo[3], Modi Darshita[4], Durani Ovesh[5], Thakor Aakash[6]

[1,2,3,4,5,6]Meril Medical Innovations Private Limited, Bilakhia House, Survey no.879, Muktanand marg, Chala, Vapi, Dist-Valsad, Gujarat, 396191, India.

Abstract

In otolaryngologic procedures, improvements in laser technology have significantly increased accuracy, safety, and recuperation time after surgery. The 980 nm diode laser has become well-known among these advancements due to its capacity to be minimally intrusive, its excellent coagulative control, and its decreased intraoperative haemorrhage. It is a flexible choice for a range of soft tissue application because to its small size, adjustable energy settings, and compatibility with common ENT equipment. To evaluate the clinical performance and user safety of the *Mesic™ Laser Ablation System* (Meril Medical Innovations Pvt. Ltd., Vapi, Gujarat, India) in the minimally invasive management of selected ENT pathologies, in accordance with ISO 13485:2016 and IEC 60825-1 performance and safety standards. This was a prospective, non-randomized clinical study conducted at a tertiary care centre in India with institutional ethical approval. The MesicTM 980nm diode laser system with a bare-tip optical fiber was used to perform laser ablation on three adult patients (ages 28 to 45) who had been diagnosed with ranula, pharyngeal papilloma, and cholesteatoma cyst. The device was purchased with a test certificate conforming the 980nm wavelength specification and a manufacture-validated calibration to guarantee compliance to IEC 60825-1 criteria. Depending on the kind of tissue and the features of the lesion, the laser's strength varied from 0.4 W to 4 W. The day-care procedures were performed under local or general anaesthesia and included normal postoperative treatment and surveillance at three and six months after the procedure. Clinical outcomes were assessed according to intraoperative visibility, recurrence, bleeding problems, and symptoms relief.

All three patients (mean age =36.3±8.5 years) had no intraoperative or postoperative problem, including hematoma of infection, and all their symptoms were completely resolved (100%) after the procedure. A clean operating field and shorter treatment duration were the outcomes of the 980nm diode lasers' superior hemostasis.

Sustained symptoms reduction, no recurrence, and a successful functional and cosmetic recovery were all confirmed by follow-up evaluations conducted three to six months later. The system functioned in full accordance with ISO 13485:2016 quality management and IEC 60825-1 user safety rules.

High precision, safety, and therapeutic efficacy were established using the MesicTM 980 nm diode laser during minimally invasive ENT surgery. Its reliability for clinical application is demonstrated by the system's confirmed wavelength calibration and compliance with international safety and quality standards. These encouraging first findings encourage further through assessment through research involving bigger sample numbers and longer follow-up periods.

Keywords: 980 nm Diode Laser; Bare-tip fiber, Minimally Invasive Surgery, Ranula, Pharyngeal Papilloma, Cholesteatoma Cyst, ISO 13485

1. Introduction

A laser ablation system is a medical device that uses concentrate light energy to evaporate, incise, coagulate, or eliminate biological tissue in a targeted manner. The effectiveness of these systems is influenced by laser parameters such as wavelength, pulse duration, power, and energy density, as well as tissue properties such as composition, water content, absorption, and thermal conductivity (Diam & Wajeha, 2019; Azadgolo & Baker, 2016; Ravi-Kumar et al., 2019). Numerous medical specialities have found it easier to employ laser technology due to its accuracy, speed, and little invasiveness. It speeds up recovery, decreases the chance of infection, and lessens bleeding as compared to standard surgery.

An ENT Laser system is a specialized medical laser platform designed for use in otolaryngology, or surgery of the ears, nose, and throat. With the least amount of thermal harm to nearby healthy tissues, these systems provide concentrated light energy to carry out precise tissue interactions such incision, excision, ablation, vaporization, coagulation, and photocoagulation (Paiva et al.,2019; Karkos et al.,2021)

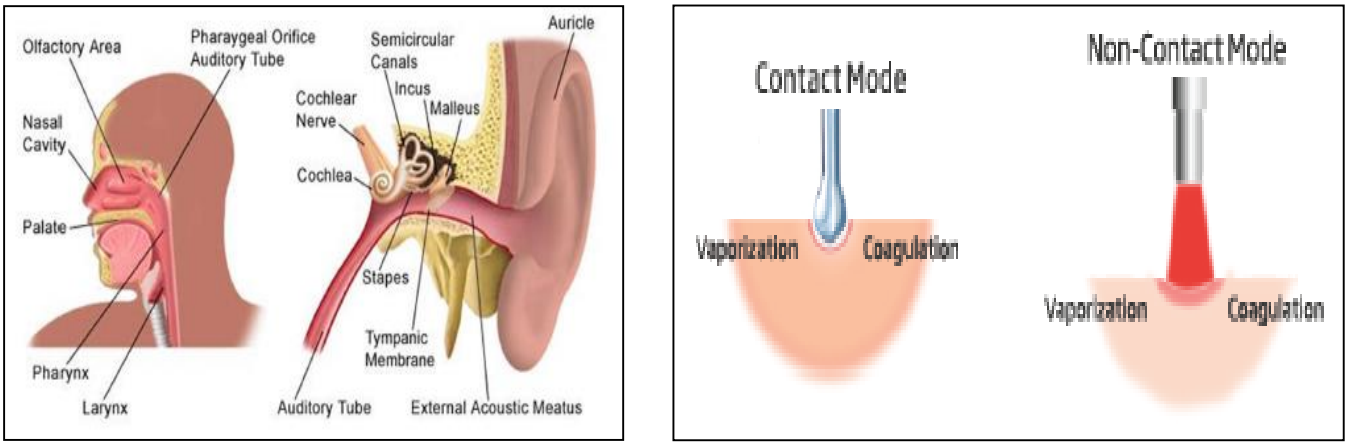

Fig.1 ENT laser system

EAR/OTOLOGY	NOSE	THROAT
Stapes Surgery	Nasal Sinus Surgery	Tonsillotomy
Removal of cholesteatoma Cysts	Nasal Polyp, Rhinitis	Laryngeal carcinoma
Accessory auricle	Turbinate reduction	Cysts, mucous cysts
Tumors of the inner ear	Turbinate treatment	Synechia, stenosis in endonasal structures
Hemangioma	Septum spur	Tumor, Granuloma resection
Myringotomy	Septum deformation	Congenital larynx stenosis
Tympanitis	Cysts & Mucoceles	Hemangiomas
	Epistaxis	Morbus Osler
	Stenosis & Synechia	Uvulopalatoplasty (LAUP
	Surgery for Sinus	
	Dacryocystorhinostomy (DCR)	
	Epistaxis treatment	
	Lacrimal surgery	
	Removal of stenosis in lacrimalis	

Table: 1 Applications for Laser Ablation in ENT

In otolaryngology, lasers have been employed for the management of tumors, cysts, vocal cord lesions, epistaxis, and sinus disorders, with the aim of minimizing damage to healthy tissue (Newman & Anand, 2002; Orgain et al., 2018). The 980 nm diode laser has demonstrated particular utility due to its compact design, reliable coagulative properties, precise tissue interaction, and compatibility with routine surgical instruments.

Both contact and non-contact modes of the 980 nm diode laser system have been approved for ENT surgery. Contact mode is primarily used for tissue vaporization and coagulation, while non-contact mode enhances photocoagulation and facilitates hemostasis through selective absorption by melanin and haemoglobin (Karkos et al., 2021). Based on the established concepts of monochromaticity, coherence, and directionality, the laser's operation improves its reproducibility and clinical dependability (Paiva et al., 2019).

In accordance with ISO 13485: 2016 for medical device quality and IEC 60601-2-22 and IEC 60825-1 (laser safety standards), medical lasers, particularly ENT laser systems, must adhere to safety rules.

Consistent tissue interaction at predetermined Power settings, minimal thermal spread to neighboring tissues, and predictable coagulative and ablation depth are all requirements for surgical laser systems to be accepted. These requirements are confirmed by analytical accuracy standards and performance testing in accordance with ISO guidelines (ISO 13485;IEC 60601-2-22:2019;IEC 60825-1:2014).

The objective of this study was to evaluate the safety, effectiveness, and short-term surgical outcomes of a 980 nm diode laser system with bare-tip fiber in the management of selected ENT conditions, under conditions that comply with ISO-approved user performance and analytical accuracy standards.

Material and Method:

This prospective, single-center case series was carried out from December 2023 to February 2024 in a third-level concern hospital in India. Composed Knowledgeable permission was acquired from each participant before to enrolment, and the study protocol was authorized.

Materials

A portable 980nm diode laser system was powered by a rechargeable lithium battery and a high-resolution touch screen. The system had programmable repetition rates, pulse duration, operation modes, and power settings. Accessories included cannulas of various diameters (18G×30, 18G×80) and hand pieces designed for precise energy distribution during ENT procedures such laryngeal surgeries and stapendotomies. Accurate tissue ablation, vaporization, and coagulation were possible by the 980nm wavelength, which huranteed efficient absorption in water haemoglobin.

Technical Details of the Generator:
The laser diode was procured with the given specifications and testing report for 980nm wavelength verification.

Specifications	
Wavelength	980nm
Maximum Power	10W
Operation Mode	Consistent(C) or Repeat Pulse(R)
Pulse Duration	10μs - 3s
Rate of Repetition	1Hz - 20KHz
Beam Pilot	Red Diode Laser of 650nm, Power <5mw
Control Mode	True Color Touch Screen (7 Inches, Resolution 600*1024)
Transmission System	Medical Fibers with SMA905 Connector
Dimensions	160(W)*180(L)*235(H)mm
Weight	2.1 Kg

Table: 2 Generator Configuration and Parameters

Patient Selection

Included were patients of either sex who were at least eighteen years old and had been clinically and/or radiologically diagnosed with ENT disease that could be treated with minimally invasive laser ablation therapy. The following conditions were excluded: (1) bleeding disorders or coagulopathies; (2) an active infection or skin disease at the surgical site; and (3) any condition that the investigator believed would put the patient or study at unnecessary danger.

Laser Tools and Methods

It made use of portable 980 nm diode laser system that included a high-resolution touch screen, sophisticated preset protocols, and an integrated rechargeable lithium battery. The system featured wavelength power adjustments and technical specifications including continuous mode operation, adjustable pulse duration, repetition rate, pilot beam, control mode, and fiber-optic transmission. A 400 µm bare-tip fiber was used in conjunction with compatible surgical cannulas (18G×30, 18G×80) and handpieces.

Laser parameters were customized based on the pathology treated:

- Ranula: 0.4 W, 20 J, continuous mode
- Pharyngeal papilloma: 2–4 W, 36 J, continuous mode
- Cholesteatoma cyst: 1.5–2 W, 25 J, continuous mode

Method was carried out under endoscopic or microscopic direction to make sure accuracy and reduce collateral tissue damage.

Monitoring and anesthesia during surgery

Adrenaline (1:100,000) infused at the surgical site was mixed with 12% lignocaine to supply local anesthetic. Midazolam (1-2mg) was conducted intravenously too selectively induce aware Sedation. The standard intraoperative observing inclined non-invasive blood pressure (NIBP) Measurements, pulse oximerty, and ongoing electrocardiography (ECG). To maintain the oxygen saturation level above 95%, additional oxygen was using a nasal cannula. No patient needed airway intervention or conversion to general anesthesia.

Laser Equipment and Surgical Technique

A portable 980 nm diode laser ablation system (comprising a generator, 400 nm bare fiber, handpiece, and 18G×30 and 18G×80 cannulas) was employed for all procedures. Laser settings and procedural details were as follows:

Case 1: A 32-year-old woman with mucoceles causing ranulas beneath the throat wall presented with swallowing difficulty, airflow obstruction, speech disturbance, and mild pain. Laser ablation was performed at 0.4 W power, 20 J total energy in continuous mode. The cystic tissue was effectively cauterized.

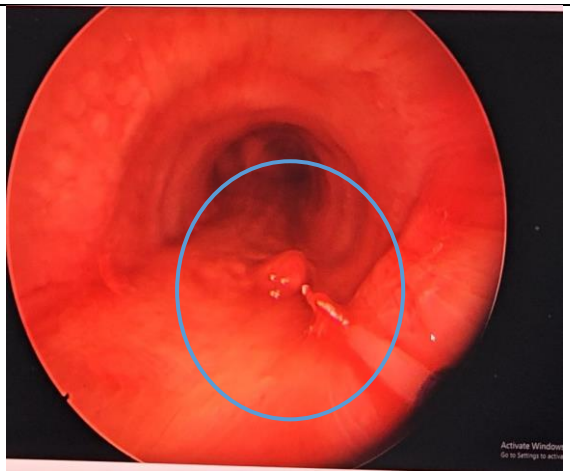

Figure :2 Image presenting Mucocele cyst before the treatment by laser ablation diode

Fig: 3 Image presenting Mucocele cyst after treatment by Laser ablation diode

Case 2: A 33-year-old man with pharyngeal papilloma secondary to HPV infection, presenting with chronic cough, hoarseness, airway obstruction, dysphagia, and globus sensation, was treated using 2–4 W power, 36 J total energy in continuous mode. The papillomatous tissue was successfully ablated.

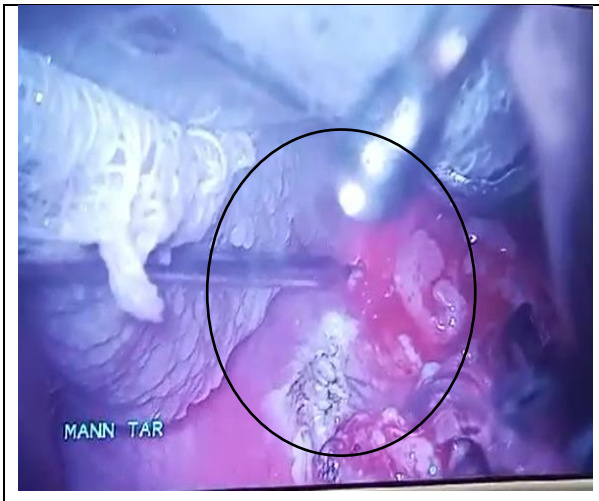

Fig:4 Image presenting treatment of Papillomatous growths by laser ablation system during clinical trial

Fig:5 Image of post clinical trial

Case 3: A 35-year-old woman with a cholesteatoma cyst, presenting with hearing loss, minor ear pain, and malodorous discharge, underwent laser ablation at 1.5–2 W power, 25 J total energy in continuous mode, effectively removing the lesion.

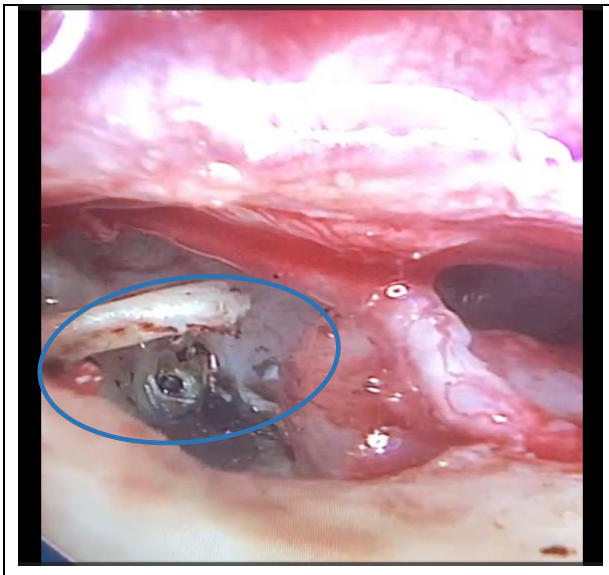

Fig:6 Pre-procedure image

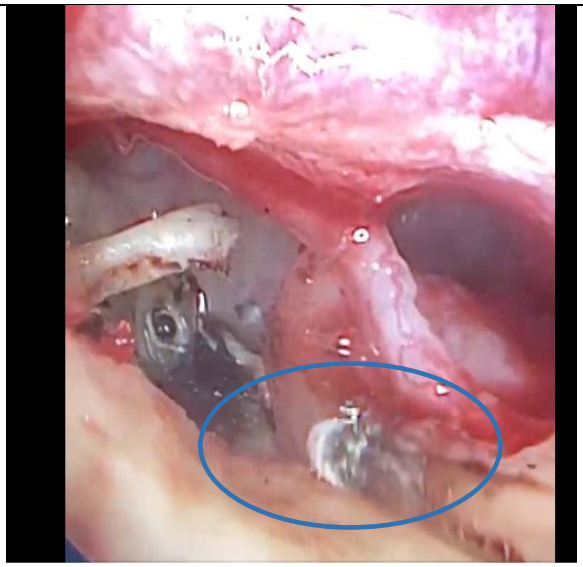

Fig:7 Blue circle indicating diode of laser ablation system during clinical procedure

All methods were carried out under endoscopic or microscopic direction to make sure precision and minimize collateral tissue damage.

Sr No.	Sex	Age	Medical History	Diseases
1	Female	32yrs	Tobacco addiction and Hypertension	Ranulas or Mucous Retention cysts
2	Male	33yrs	Tobacco and smoking	Pharyngeal Papilloma
3	Female	35yrs	-	Cholesteatoma cyst

Table: 3 Patient`s Details

Postoperative Management and Aftercare

Routine postoperative care involved analgesics and antibiotics. Patients were afterward at 3 months and 6 months post-process to assess symptom resolution, functional recovery, and recurrence.

Patient Feedback and Questionnaire

After treatment, patients completed a structured questionnaire designed in accordance with ISO 15197:2013(E) performance evaluation guidelines. The questionnaire assessed:

- Ease of use of the laser system.
- Clarity of instructions provided.
- Visibility of the treatment site during the procedure.
- Ease of understanding post-treatment care instructions.
- Clarity on managing potential complications.

Reaction were capture using a 3-point Likert scale (0 = strongly disagree, 3 = strongly agree).

Statistical Analysis

Descriptive statistics were used for data analysis. Continuous variables were presented as mean ± standard deviation, and categorical variables as frequencies and percentages. The analyses were performed using a Microsoft Excel™ VBA macro program (Microsoft Corporation, Redmond, WA, USA). We also performed SEG analyses, a novel error grid system introduced recently by several medical societies and authorities

Result

Three Patients in all were part in this clinical assessment. The patients were 33.3± 1.5 years old on averages (range: 32-35 years; median 33 years). The demographic and clinical characteristics of the patients are presented in [Table: 3&4].

All patients underwent laser ablation using a 980 nm diode laser system equipped with a bare-tip fiber. On a day care basis, the treatments were carried out under aesthetic. No airway interventions or conversions to general aesthetic were necessary, and intraoperative or postoperative problems were noted.

In the case of the mucous retention cyst (ranula), laser ablation was performed using a 400 nm bare fiber at 0.4 W powers, delivering a total of 20 J in continuous mode. Approximately fifty seconds were needed for the operation. At the 3-month mark, all symptoms, including Uncomfortable, speech a barrier, and problem swallowing, had completely vanished. No recurrence was determined.

For the pharyngeal papilloma associated with Human Papilloma Virus (HPV), laser excision was conducted using a 400 nm bare fiber at 2–4 W power, delivering a total of 36 J in continuous mode. The operative duration was approximately 50 seconds. During the 6-month follow-up, there was a sustained improvement in the preoperative symptoms, which included intermitted breathing difficulties, hoarseness, chronic cough, dysphagia, and limp sensation. Recurrence was not found.

In the case of the cholesteatoma cyst, laser ablation was carried out using a 400 nm bare fiber at 0.4 W power, with a total of 20 J delivered in continuous mode. The procedure duration was approximately 50 seconds. The ear discharge stopped, hearing got better, and there condition no recurrence after a 6-month follow-up.

In summary, the use of laser ablation for all cases has been successful in achieving removal of lesions, symptom resolution, as well as no recurrences throughout the observation period. Safety was also fully guaranteed since no adverse events or complications were reported.

Case	Pre-op Symptoms	Laser Parameters	Operative Time	Hospital Stay	Complications	Follow-up Duration	Recurrence
Female (Mucous Retention Cyst)	Difficulty swallowing, speech impairment, pain	400 nm bare fiber, 0.4 W, 20 J, continuous mode	50 Secs	Day-care, same-day discharge	None	6 Months	No Recurrence
Male(Pharyngeal Papilloma, HPV)	Cough, hoarseness, dysphagia, lump sensation, dyspnea	980 nm, 2-4 W, 36 J, continuous mode	50 Secs	Day-care	None	6 Months	No Recurrence
Female (Cholesteatoma Cyst)	Hearing loss, ear discomfort, purulent discharge	400 nm bare fiber, 0.4 W, 20 J, continuous mode	50 Secs	Day-care	None	6 Months	No Recurrence

Table: 4 Clinical Outcomes following treatment of ENT disorders using a 980 nm diode laser with bare-tip fiber.

Pathology Type	Frequency	Percentage
Ranula	1	33.3%
Pharyngeal papilloma	1	33.3%
Cholesteatoma cyst	1	33.3%

Table:5 Pathology Frequency

Variable	Mean	Standard Deviation
Laser Power (W)	1.3	1.2
Total Energy (J)	27	8.2

Table:6 Laser Settings Summary

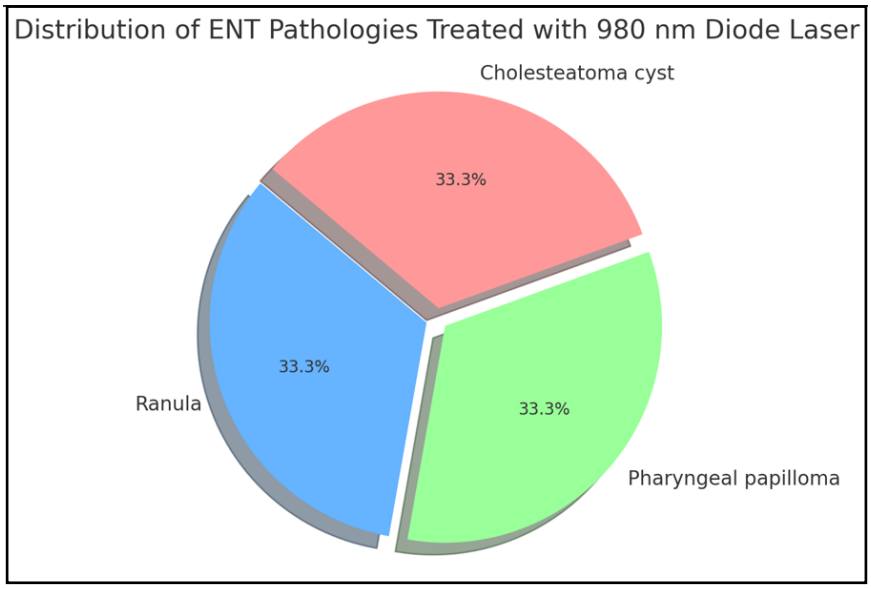

Fig: 8 Operative Time Distribution by Case

Subject questionnaires: More than 95% of participants either strongly agreed or agreed with the questionnaire items regarding ease of use of the laser system, clarity of display and controls, precision, and confidence in safety features. Most of the users also recognized that the directions to the task as well as the error messages were very simple. Nearly 90% of the participants were content with the instructions given for adjusting and with the handpiece fitting. [Table -7] depicts the results of the ease-of-use subject questionnaires.

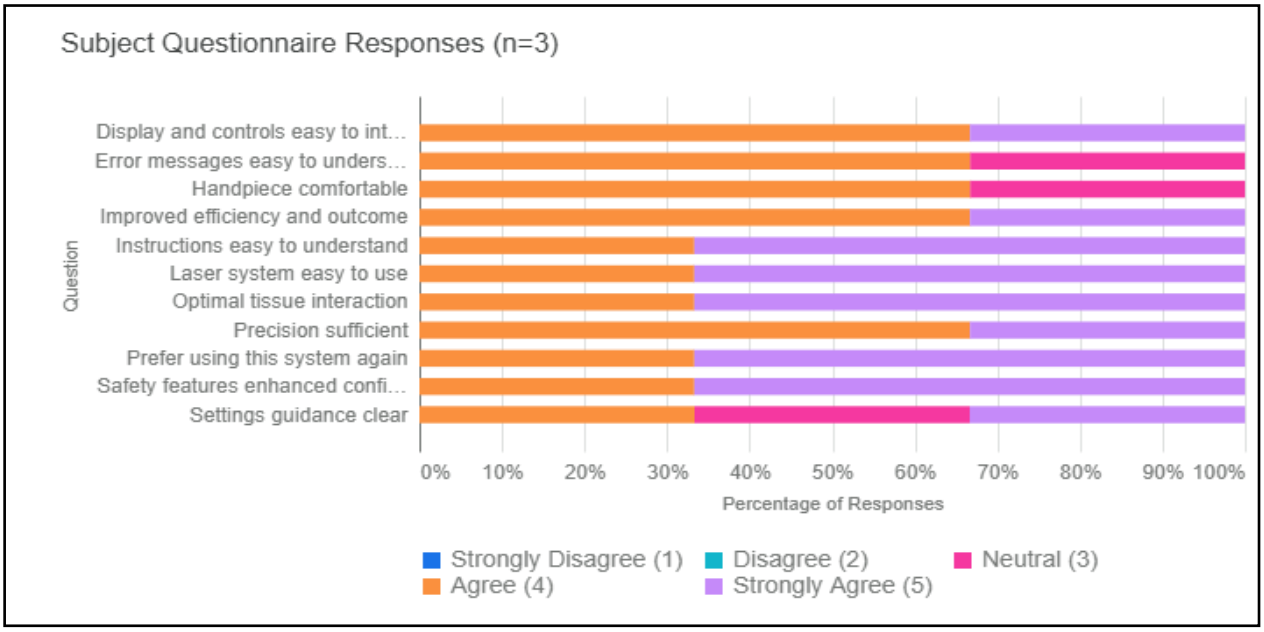

Table: 7 Ease of use questionnaire for the use of 980 nm diode laser with bare-tip fiber.

Discussion

Through thermal evaporation brought on by laser energy, laser ablation is a minimally invasive therapeutic technique that makes it possible to precisely remove tumors, cysts, or aberrant tissues. When compared to traditional open surgical techniques, this procedure is linked to diminished collateral tissue damage and increased precision. The problematic tissue is heated specifically as part of the mechanism of action; at greater energy densities, plasma tissue contact requires careful consideration of the laser's wavelength. For example, hemoglobin-rich tissues preferentially absorb wavelengths of 450 nm, vascular lesions can effectively coagulate at 980 nm, and water-rich tissues are targeted by wavelength of 1470 nm. Excellent hemostatic qualities were shown by the 980nm diode laser used in this test, which reduced intraoperative bleeding allowed for clear operational fields. In this investigation, no intraoperative or postoperative problems, including excessive bleeding, thermal injury, or infection, occurred, and all patients tolerated laser ablation well. Effective operations were carried out, and positive short-term results included full lesion ablation, the cessation of preoperative symptoms, and the absence of recurrence during the follow-up period. Because diode laser are quick, easy, and minimally invasive, these results are consistent with previous research that supports their use in ENT treatments. Laser ablation has a number of benefits over traditional surgical methods, such as less blood loss during surgery, quicker recovery periods, and a decreased requirement for suturing or lengthy wound closure. The 980nm wavelength's coaqulative qualities improve intraoperative vision and accuracy even further.

Limitations

Some limitations have to be recognized although the results are encouraging. Without a control group, one cannot compare these outcomes directly with those of established surgical methods, while the small sample size limits the extent to which these results can be generalized. Despite the fact that this series showed no concerns, laser broadly these findings may be applied. Although the series exhibited no alarming signs, a cautious operating procedure is still mandatory to prevent thermal injuries to adjacent tissues, thus the importance of the operator's expertise. Also, the follow-up duration was short, and the long-term outcomes including relapse and functionality improvement in relation to standard surgery remain uncertain. The present study was only allowed to adult patients to ensure patient safety and procedural standardization. Following the proper ethical and safety assessments, future research will try to extend the use to additional patient categories, such as expectant mothers, as well as pediatric populations within specified age ranges. To confirm these first results and clarify the function of laser ablation in ENT surgery, larger, multicentric trials with longer follow-up times are necessary.

Conclusion:

The current analysis has demonstrated that the 980nm diode laser ablation is a minimally invasive, safe, and effective method of treatment for such ENT disorders as Cholesteatoma cyst, pharyngeal papillomas, and mucus retention cysts, a few of the laser technology enabled precise tissue removal and good hemostasis, minimal damage to the surrounding area, and satisfactory short-term results. The control did not detect any relapses, and all the cases were resolved without any complications both during and after surgery. Future research on the same devices will be conducted to assess its long-term effectiveness, functional outcomes,, and recurrence rate, even if the study's finding demonstrate the therapeutic relevance of diode laser ablation in ENT procedures. The current study is limited to adults

for preliminary studies because of patient safety. The future study will extend to the children belonging to a particular age group and other category of patients such as pregnant women, geriatric patients etc.

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