Intraoral Dual Wavelength Laser Diode Therapy for Chronic Maxillary Sinusitis.

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Background: Chronic sinusitis is one of the most common chronic diseases involving different age groups. The different etiological factors and difficult diagnostic procedures contribute to misdiagnosis and chronicity of sinusitis. There is no standard treatment for sinusitis. Long term use of corticosteroids and antibiotics may lead to numerous adverse side effects. Laser therapy has been suggested as a non-invasive treatment for sinusitis. It has anti-inflammatory and antibacterial effects. When considering maxillary sinusitis, discharge tends to collect in the sinus base due to its anatomy and altered physiology. To improve penetration of laser into the maxillary sinus, intraoral laser at the vestibule depth of the maxilla may be more effective.

Material and Subject: Thirty-four patients with chronic maxillary sinusitis were assigned into two groups. All were assessed before and after treatment. Group A received laser radiation plus standard medical treatment and group B received medical treatment only. The treatment plan was performed in 12 sessions using a Diode laser with a wavelength of 810 nm and 980nm. The SNOT-22 questionnaire and Computed Tomography were used to evaluate patients. A p-value < 0.05 was considered statistically significant.

Results: Both groups showed a significant improvement in symptoms following treatment ($p < .001$), however, the laser therapy group demonstrated greater improvements for all variables in response to treatment as compared to the traditional treatment group ($p < .001$).

Conclusions: Using high intensity intra-oral laser therapy with medical treatment is more effective than using medical treatment only for treatment of chronic maxillary sinusitis.

Key words: Maxillary Sinusitis • High Intensity Laser Therapy (HILT) • Sino Nasal Outcome Test (SNOT22)¡

Introduction

Sinusitis, or rhinosinusitis (RS), is an inflammation of the nasal cavity and paranasal sinuses. Rhinosinusitis is the more preferred term because it encompasses the inflammation of both the nasal cavity and the paranasal sinuses [1]. It may be acute or chronic and is common in different age groups, with the highest prevalence in patients in the age range of 44 to 64 years old [2]. The overall consensus is that inflammation from infectious and non-infectious factors plays a key role in chronic rhinosinusitis pathogenesis [3] and is usually associated with anatomical and environmental factors. Sinusitis is also associated with high medical treatment costs. Many people do not respond to medical treatment and with additional treatment, may develop an increased drug resistance and sinusitis becomes a chronic problem that affects a patient's productivity and quality of life [4, 5]. A broad spectrum of disease processes can involve the maxillary sinus, arising

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either from within the lining of the sinus, the adjacent paranasal sinuses, nasal space or dental and oral tissues. Since the floor of the maxillary sinus is in a close proximity to the posterior maxillary teeth, maxillary sinusitis of odontogenic origin is highly recognized. Opacification of the maxillary sinus and sinusitis involving a unilateral anterior sinus group have a dental etiology in 75% and 25–40% of cases, respectively [6].

Diagnosis of chronic sinusitis is based on the presence of two symptoms which last for 12 consecutive weeks, including facial pressure, fullness or pain, nasal obstruction, headache, clear or mucopurulent nasal discharge and hyposmia or anosmia [7]. Numerous medical treatments have been used to address the symptoms, as well as the inflammatory process. These often include corticosteroids, antimicrobials and immune modulating medications. However, a percentage of the population does not respond to traditional treatments. Long-term use of corticosteroids and antibiotics may lead to adverse effects, drug interactions, and antimicrobial resistance in addition to the high cost of medication for these patients [8].

Laser therapy is a form of non-invasive alternative therapy which uses equipment to transmit a wavelength between 600 and1000 nm. It promotes tissue healing and reduces inflammation and pain. Diode laser ranges from about 800nm to 980nm wavelength with 1-10W power output. The light energy is placed at the start of the near-infrared portion of the invisible non-ionizing spectrum [9]. Near infrared laser irradiation (NILI) has a modulating role in cells involved in tissue repair and a significant effect on slowing or inhibiting bacterial growth. The amount of irradiance received from NILI and its effects are dependent on time and radiant exposure [10]. High intensity laser therapy is a newly developed treatment option in physical therapy practice. The devices that are used for this therapy are termed high power lasers or Class IV lasers. High intensity laser can deliver high energy which stimulates a photochemical effect within the tissue, increasing tissue metabolism and promoting oxidation in the mitochondria and increasing ATP production. In addition this physiological change enhances edema absorption and removal of inflammatory exudate. The advantage of HILT over low level laser therapy (LLLT) is that, it is able to reach and stimulate larger and deeper tissues and areas that are difficult to reach with LLLT in lesser time [11]. Two issues with typical laser treatment studies are that previous studies tried to treat the maxillary sinus externally with only low level laser with an intensity not more than 500 mW [12, 13, 14]. Only one study used high intensity laser therapy with an internal delivery method, however it was through the nasal cavity [10]. As noted earlier, the anatomical relationship of the maxillary sinus makes it easier to reach through the internal oral cavity. Thus, treatment may be more effective if done intraorally with high intensity laser. Our review of the literature showed limited studies which used intraoral laser therapy for treatment of maxillary sinusitis. One study used low level laser therapy with one wavelength and no control group. They showed a significant improvement in individual symptoms of the SNOT [15]. A recent publication compared low level laser therapy applied intraorally to extra orally. The study showed better efficiency for intraoral therapy as compared to the extra oral therapy [16]. However, there are currently no studies that examine the use of HILT when used intraorally. Thus, the aim of our study was to examine the efficiency of high intensity intraoral laser therapy using dual wavelengths (810 and 980 nm) for treatment of chronic maxillary sinusitis.

Material and methods

This study was experimental. Thirty four patients with chronic maxillary sinusitis participated in this study. The patients were assigned into two different groups. The participants were affected by a chronic inflammatory process of the maxillary paranasal sinuses, lasting at least 12 weeks and with either two major clinical symptoms or one major and two minor clinical symptoms. Further, patients with previous sino nasal surgery, presence of a tumor of the maxillary or oral region, traumatic surgery, and an abnormal sinus endoscopy were excluded from this study. Objectives of the study and treatment procedures were explained to patients and written consent was obtained from each of them. This study was registered with the Research Ethical Committee of Cairo University (No: P.T.REC/012/002065). Physical examinations of all patients were performed by an otolaryngologist at Badr Hospital. A licensed physical therapist conducted the research assessments and treatments.

Patients were evaluated using two methods. The subjective component of the evaluation was based on the patients' answers to the Sino Nasal Outcome Test 22 (SNOT-22). The SNOT-22 contains 22 items reflecting various elements of sinusitis symptoms, ear and facial symptoms, sleep functioning and psychological factors that may be associated with nasal and paranasal diseases. All these symptoms were assessed in six grades ranging from no problem (0) to severe problems (5). Thus, the total score can range from 0 to110, with lower scores reflecting less symptoms. The SNOT 22 was validated in many languages, including Arabic [17]. The Arabic one was used to assess the efficiency of intraoral laser therapy for chronic maxillary sinusitis in this study. The objective component included Computed Tomography (CT) of the paranasal sinuses [18] to reveal any diffuse mucosal thickening, bone changes, or air-fluid levels. The air-fluid levels were obtained using the geometric calculation method [19], which considering the pyramidal shape of the sinus to calculate the volume of the sinus cavity, by calculating the anteroposterior (width) × craniocaudal (length) × me-

diolateral (height) / 3. The same method was also used to calculate the volume of the existing fluid. Then, From the resultant values, the air volume was obtained. The air-fluid level for each sinus was recorded as a ratio. The lower the ratio, the less fluid and inflammation is present within the sinus.

Specific procedures were followed to ensure subject safety. Sensory assessment testing was done for all patients before enrolment in the study. Prior to the initial treatment, a thermal threshold test was done for each subject. This test protocol is recommended by the manufacturers (Zimmer) to enable selection of the appropriate power output and prevent use of too high an intensity and potential tissue damage in people with a wide range of skin types and photosensitive patients.

During each treatment session, both the therapist and patient wore safety eye goggles to protect the retina from laser beams. After the treatment procedure, oral gel which contains Lidocaine HCL10% and Jojoba Oil was used to control any anticipated inflammation of the oral mucosa at the area of radiation. The tip of the laser probe was sterilized using an antiseptic solution and autoclaved after each session.

A Zimmer Opton Pro, Integrated High-Power Class IV Laser device (serial N: 1520001370 & REF: 9160), was used for treatment **(figure 1)**. A single laser probe was utilized to provide laser radiation at dual wavelengths of 810 nm and 980 nm simultaneously, and a power density of 1 W/cm^2 [20]. The energy density delivered for each point was 50 J/cm^2 with pulsed laser at a duty cycle of 1:1 at three adjacent points. The total energy delivered for each sinus was 150 J within the 3 minutes of radiation. Treatment was given every other day (3 sessions / week) for 12 consecutive sessions. The intra-oral laser radiation was applied at the vestibule depth of the maxilla from the canine apical zone to the first molar apical zone, which represents the floor of the maxillary sinus. It was performed at an angle of 45 degree, without pressure, at 3 separate adjacent points. Treatment was performed by a physiotherapist at Outpatient Physical Therapy Clinic, Badr University in Cairo and under the supervision of an oral surgery specialist for better determination of the proper radiation area and angle.

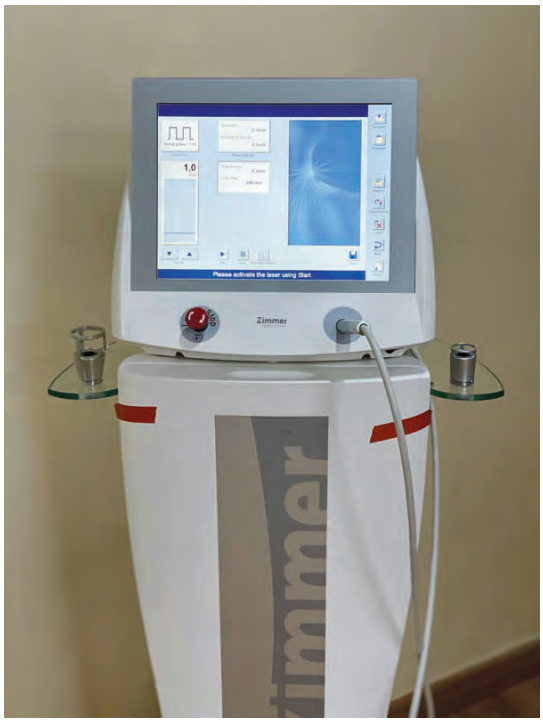

Figure 1: Zimmer Opton Pro Laser Device.

Data analysis

Data were analyzed using SPSS software (version 24). Descriptive statistics for all variables were defined by means and standard deviation. Repeated measures ANOVAs were used to measure differences in response to treatment between the two groups. Differences were considered significant if less than or equal to the .05 level of probability.

Results

This study included 34 patients (14 females and 20 males) with chronic maxillary sinusitis. The distribution of the genders between the two groups was not significantly different. The average age of the patients was 31 ± 9 years - see **Table 1**. Values for the SNOT, pre and post treatment by group are presented in **Table 2**. The average value prior to treatment for the entire group was 81.9±11.7, while the average value following treatment was 31.6 ± 21.4.

The values from the CT scans for all group showed air-fluid level on the right side (RT) averaged of 62.4±23.3, and 52.1 ± 28.3 for the left side (LT) prior to treatment. Air-fluid levels after treatment averaged 20.3 ± 19.6 for RT side and 18.01 ± 19.4 for LT side presented in **Table 3**. Repeated measures ANOVAs showed significant

Table 1: Descriptive statistics for age (years) and gender (M = Male; F = Female).

Group	Mean	Std. Deviation	Minimum	Maximum
Control (9 M, 8 F =17)	30.6	8.6	18.0	43.0
Experimental (11 M, 6 F=17)	30.1	10.1	18.0	56.0
Total (20 M, 14 F=34)	30.4	9.2	18.0	56.0

improvements for both groups following treatment ($p < .001$), however, the laser therapy group demonstrated greater improvements in all variables in response to treatment ($p < .001$ for all measures). These changes are demonstrated in **Tables 2 and 3**. The SNOT showed the greatest effect size, with a partial eta squared of .695. The right side air/fluid level had an effect size of .507, while the left side had an effect size of .354. These effect sizes are identified as large and moderate, respectively [21]. Changes in the air/fluid level are illustrated in **Figures 2 and 3**.

Discussion

As noted, sinusitis has multiple etiologies and it is difficult to accurately diagnose. Furthermore, there is no "gold" standard for treatment. This can lead to chronicity and a high patient cost. The use of laser therapy provides a potential treatment that may reduce treatment time and improve symptoms. However, research with laser therapy treatment of chronic sinusitis is limited. Thus, this study examined the use of high intensity laser therapy, applied through the oral cavity, for maxillary sinusitis.

Our study was limited by the number of participants. The number had to be lowered due to the high cost of using CT for assessment of all patients' pre and post-treatment. Moreover, the narrow inclusion and wide exclusion criteria for this study further reduced the poten-

Figure 2: CT of maxillary sinuses prior to treatment.

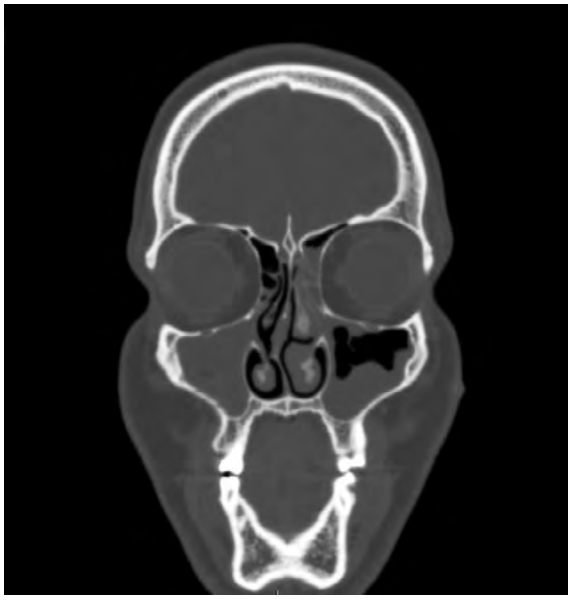

Figure 3: CT of maxillary sinuses following treatment.

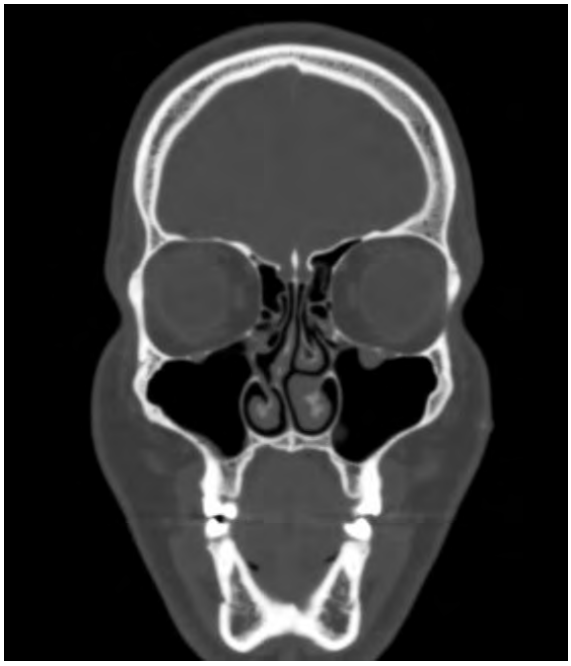

Table 2: SNOT values, pre and post treatment by group.

Group		Pre SNOT	Post SNOT
Control (N= 17)	Mean	79.8	47.3
	Std. Deviation	11.7	18.1
Experimental (N= 17)	Mean	84.05	15.9
	Std. Deviation	11.5	9.4
Total (N= 34)	Mean	81.9	31.647
	Std. Deviation	11.7	21.4

Table 3: Means and standard deviations of pre and post treatment values for the air/fluid (A/F) level.

		Pre A/F Right	Post A/F Right	Pre A/F Left	Post A/F Left
Control (N=17)	Mean	56.9	33.09	48.2	30.1
	Std. Deviation	21.6	19.7	23.1	20.8
Experimental (N=17)	Mean	67.9	7.5	56.03	5.9
	Std. Deviation	24.3	7.4	33.03	5.5
Total (N=34)	Mean	62.4	20.3	52.1	18.01
	Std. Deviation	23.3	19.6	28.3	19.4

tial number of subjects. The infection control procedures, as well as the safety procedures, also limited the number of sessions that could be held per day. In our study, we were unable to determine the effect of laser radiation on bacterial growth as it requires endoscopy to biopsy for a culture analysis. Thus, we recommend future studies include bacterial assessments, as this may help identify the potential for recurrence of the sinusitis.

This study was conducted to investigate the effectiveness of using high intensity intraoral laser therapy with two different wavelengths as an adjunct to medical treatment in sinusitis management. The laser therapy combined with the standard medical treatment was compared with the medical treatment only in treating maxillary sinusitis. The large effect sizes that were obtained for the SNOT for the intraoral laser group suggests that this was a very effective adjunct to traditional treatment. We think this could alleviate the symptoms of chronic sinusitis and decrease prolonged treatment times. The severity of symptoms in terms of the objective CT finding and the subjective individual symptoms of SNOT were significantly improved.

Laser therapy was used in treatment of chronic and acute sinusitis during the last few decades with different categories of patients and in terms of the type of laser therapy used and the application techniques. But, the design for this study was relatively different from previous studies with similar cases, thus the results are difficult to compare. Some of the previous studies treated sinusitis using low intensity laser therapy applied either externally or intraorally. One previous study used high intensity laser energy intra-nasally while, our study used high intensity laser therapy intraorally.

The result of this study was similar with the result of the study for post-surgical CRS patients with positive cultures by Krespi et al. [10] in which a high energy of 500 J per side was delivered internally to the maxillary sinus through the nasal cavity. They found a significant decrease in modified SNOT scores. However, they reported that the high intensity with continuous laser caused pain associated with high heat. In this study, we applied high laser energy of 150 J per affected sinus with pulsed laser at each session and no side effects were noted. We believe that the thermal threshold test was helpful to avoid potential issues by identifying the maximal power output that would be tolerated.

Although the results of the study by Isser et al. [13] and the pilot study conducted by Naghdi et al. [12] were consistent with the results of this study, they used low level laser and directed it to the sinus externally. The amount of energy they were able to deliver to the sinus was relatively very low with more time needed for laser exposure during each session in comparison to this study. Referring to previous studies, Naghdi et al noted the higher incidence of low penetration depth value (PDV) for laser light. The epidermal melanin absorbs a percentage of light in a wide range of different wavelengths before it reaches the targeted deeper tissue. We tried to avoid the issue of absorption in our study through the intraoral application. Further comparison with Naghdi et al. was difficult, as they used the total symptoms score rather than SNOT. Additionally, our study overcomes the limitation of their pilot study through the inclusion of a medical treatment control group. Comparison with Isser et al. [13] is also challenging, as they did not use standardized assessment of symptoms such as the SNOT and they used conventional plain-film for evaluation, However, CT scanning is the study of choice for the imaging evaluation of acute and chronic inflammatory diseases of sinonasal cavities [22]. Our results also were supported by the recently punished study by Mortazavi et al. [16] which compared the effect of external versus intraoral laser for treatment of sinusitis. They showed a significant improvement in the symptoms with both application methods however, they noted that the intraoral laser application was able to reduce the symptoms earlier and control the symptoms within the following 6 months compared with the extraoral application.

There was only one other previous study that used laser intraorally to treat maxillary sinus [15] however, they used low level laser therapy instead of the high power laser used in this study. While they reported a significant improvement, they had lower SNOT scores prior to treatment than subjects within this study ($\bar{x}$ = 44, $\bar{x}$ = 82, respectively). In addition, the laser device used in this study was emitting two different laser beams with different wavelengths (810, 980) at the same time. The dual wavelengths were used to allow for treatment of patients with different skin colors since different melanin concentrations will absorb light differently and have a different mechanism of action. The Photo-biomodulation effect, as 810nm largely affects mitochondrial cytochrome c oxidase, while 980nm affects temperature-gated calcium ion channels [23]. Both wavelengths are in the accepted therapeutic window and have different depth of penetration. This suggests that, the patient might benefit from receiving two wavelengths of laser. The improvement in the previous intraoral laser study was demonstrated by the improvement of clinical symptoms and the amount of resistance to air flow in the nose. In our study we not only confirmed the results with clinical symptoms, but also with a CT scan of the sinus. Changes in the sinus fluid levels reflected decreased inflammation.

As noted before, several studies have been used LLLT to treat sinusitis. Only one study by Moustsen et al. [14] found no changes in outcomes when compared to a placebo group. The rest of the studies which have been identified, using either LLLT or HILT, showed these types of therapies to be effective. These finding are similar to the finding of our study. As discussed, we believe the

large effect sizes for the SNOT and the significant changes with air fluid levels demonstrate better results and address some of the limitations identified in the other studies.

Conclusion

The results of this study showed a meaningful difference in all outcomes measures of the treatment that integrates high intensity intraoral laser therapy with the medical treatment, when compared to medical treatment alone. Both symptoms and evidence of sinus inflammation were significantly improved, while there were no adverse effects of the intraoral therapy. Thus, we found that intraoral laser therapy is a complementary treatment choice for chronic maxillary sinusitis.

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Conflict of Interest
None of the authors reported any conflict of interest.