

Comparison of Alvogyl, SaliCept Patch, and Low-Level Laser Therapy in the Management of Alveolar Osteitis

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Purpose: The aim of the present randomized prospective clinical trial was to compare the effects of alvogyl, the SaliCept patch, and low-level laser therapy in the management of alveolar osteitis.

Patients and Methods: The study population included 104 patients who had been referred to our clinic with a complaint of alveolar osteitis. The patients were randomly assigned to 1 of 4 groups: group 1, curettage and irrigation alone; group 2, curettage and irrigation followed by alvogyl applied directly to the socket; group 3, curettage and irrigation followed by a SaliCept patch applied directly to the socket; and group 4, curettage and irrigation followed by continuous-mode diode laser irradiation (808 nm, 100 mW, 60 seconds, 7.64 J/cm²). The treatment procedures were repeated after 3 days. The clinical signs and symptoms for each patient were recorded at diagnosis, at 3 days after the diagnosis, and at 7 days after the diagnosis. In addition, the pain intensity levels for each patient were recorded at diagnosis and daily for 7 days after the initial treatment.

Results: No statistically significant differences in the management of alveolar osteitis were observed between groups 2 and 3. However, the management of alveolar osteitis was significantly better in group 4 than in the other 3 groups.

Conclusion: Within the limitations of the present study, it can be concluded that acemannan in the form of the SaliCept patch is an acceptable alternative to alvogyl as a dressing for the management of alveolar osteitis. However, low-level laser therapy treatment at 7.64 J/cm² (0.1 W × 60 seconds = 6 J) performed superiorly to both SaliCept and alvogyl in managing alveolar osteitis in our study population.

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Alveolar osteitis (AO), also known as dry socket, is the most common complication occurring after the extraction of a permanent tooth.¹⁻⁶ The condition has generally been characterized by degraded or delayed healing associated with clot degradation^{2,5} and is usually accompanied by persistent, radiating postoperative pain in and around the extraction site that is not easily relieved by analgesics, occurs

within 2 to 4 days after extraction, and accompanied by premature loss or necrosis of the blood clot and exposure of the underlying bone. AO can also be accompanied by halitosis.²⁻⁸ Factors such as a difficult or traumatic extraction,^{1,3-6,9} pre-existing infection,^{1,4-6,8,10} gender,^{1,3,8} smoking,^{1,3-6,8,9} oral contraceptive use,^{1,3-6,8,9} menstruation,^{1,10} and an inadequate blood supply³ might play important roles in the formation of AO. AO has a reported incidence of 3% to 4% after routine dental extractions and 1% to 45% after extraction of the mandibular third molars.⁵

AO can be a burden for both patients and surgeons. This painful condition can result in a loss of productivity, because at least 45% of patients require multiple visits to the surgeon's office. AO can also be costly in terms of the clinic time required to manage the patient's symptoms.^{1-3,6,7,9}

The management of AO is customarily directed toward reassurance of the patient and the prompt relief of pain until normal healing commences.^{1,5-7,9} Alvogyl is a widely used palliative treatment that in-

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cludes eugenol (analgesic, anti-inflammatory), iodoform (antimicrobial), and butamen (anesthetic).^{1,11,12} A more recent form of treatment is the SaliCept patch (Carrington Laboratory, Irving, TX), a freeze-dried preparation of acemannan hydrogel, a mixture of naturally occurring substances whose primary component is acemannan, a β -(1,4)-acetylated mannan obtained from the clear inner gel of *Aloe vera* L.² Preclinical studies have suggested that this extract promotes wound healing, augments reticuloendothelial function, regulates the immune response, and acts as an anti-inflammatory and antibacterial agent.^{2,13-16} Recently, low-level laser therapy (LLLT) has gained considerable recognition among treatment modalities for various medical problems, including wound repair, musculoskeletal complications, and pain control.¹⁷ LLLT has been found to increase the speed and quality of wound healing and to show an overall positive effect on the inflammatory processes.¹⁷⁻²¹ It has also exhibited antimicrobial potential when applied to oral tissue.²² This study aimed to compare the effectiveness of alvogyl, the SaliCept patch, and LLLT in the management of AO.

Patients and Methods

STUDY DESIGN

The present randomized prospective controlled clinical study was designed to compare the clinical outcomes of alvogyl, SaliCept patch, and LLLT in the management of AO. The study was conducted in line with the principles of the Helsinki Declaration, and the ethics committee of the Atatürk University Faculty of Dentistry provided ethical approval. All participants provided informed consent. All surgical procedures were performed by the same 3 oral and maxillofacial surgeons, and all post-treatment follow-up examinations were performed by the same independent examiner unrelated to the present study.

STUDY POPULATION AND CLINICAL PARAMETERS

The study population included 104 adult patients (53 women and 51 men, mean age 32.9 ± 0.9 and 32.8 ± 0.9 years, respectively) who had presented with a complaint of AO at the Department of Oral and Maxillofacial Surgery (Atatürk University Faculty of Dentistry) during an 18-month period from January 2008 to July 2009.

INCLUSION CRITERIA

The criteria for selection included age 18 years or older, the ability to understand verbal and written instructions, and previously diagnosed, but untreated AO in the mandibular permanent first molar extraction socket. In line with Blum's 2002 definition,⁹ a

diagnosis of AO was made according to the presence of postoperative pain in and around the lower permanent first molar extraction site that had increased in severity at any point 1 to 3 days after the extraction and was accompanied by a partially or totally disintegrated blood clot within the alveolar socket, with or without halitosis.

EXCLUSION CRITERIA

The exclusion criteria were previous radiotherapy, any medical condition that could affect AO treatment (eg, bone pathologic features, vascular or hematologic disorders, diabetes mellitus), the use of antibiotics, pregnancy or lactation, and an allergy to iodine, eugenol, or paracetamol. In addition, patients who smoked, used oral contraceptives, were menstruating, or would require a surgical flap to remove the tooth were excluded.

ALVEOLAR CURETTAGE

Before alveolar curettage, articaine HCl 2.5% plus 1:100,000 epinephrine (Ultracaine D-S Forte Ampul; Aventis, Istanbul, Turkey) was applied as a local anesthesia. Curettage of the extraction sockets was performed, followed by thorough irrigation with a sterile saline solution (0.09% NaCl). All debris was removed, taking care to avoid dislodging any normal clot found in the socket. Curettage and saline irrigation were repeated again 3 days later.

TREATMENT GROUPS

The patients were randomly assigned to 4 groups of 26 patients each: group 1 (control group; 15 women and 11 men), curettage and irrigation alone; group 2 (12 women and 14 men), curettage and irrigation followed by alvogyl (Septodont, Cambridge, ON, Canada) applied directly to the socket; group 3 (15 women and 11 men), curettage and irrigation followed by SaliCept patch (Carrington Laboratory, Irving, TX) applied directly to the socket; and group 4 (11 women and 14 men), curettage and irrigation followed by LLLT irradiation (808 nm, 100-mW continuous mode gallium aluminum arsenide diode laser; "Doctor Smile," Lambda Laser Products, Vicenza, Italy). The laser was applied for 60 seconds (6 J at 7.64 J/cm^2) perpendicular to a single point on the wound surface at a distance of approximately 1 cm, resulting in a 0.7854-cm^2 circular beam spot (irradiance 127.3 mW/cm^2). The treatment procedures for all groups were repeated 3 days later.

OUTCOME ASSESSMENT

The pain levels were assessed each morning for 1 week after initial debridement using a visual analog scale (VAS). The patients were asked to rate the maximal level of pain experienced from 0 (the absence of

Table 1. DEMOGRAPHIC CHARACTERISTICS

Characteristic	Control	Alvogyl	SaliCept	LLLT
Age (yr)	31.2* ± 1.3	30.5* ± 1.3	33.2* [†] ± 1.3	36.5 [†] ± 1.3
Symptoms and signs (n)	1.9 [‡] ± 0.102	2.5* ± 0.102	2.4* ± 0.102	3.4 [†] ± 0.102

Data presented as mean ± standard error.

*†‡Significantly different statistically from data in same column with different superscript symbol ($P < .05$).

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pain) to 10 (the greatest pain imaginable). Clinical examinations for the signs and symptoms of AO were performed on the first day of treatment (T0) and again on the third and seventh days of treatment for comparison. During the 7-day postoperative period, the patients were allowed 500 mg of acetaminophen (Minoset; Roche, Istanbul, Turkey) as a rescue medication, as required, and were instructed to record how many times daily the medication was used. Additional follow-up visits were organized through the department, as necessary.

STATISTICAL ANALYSIS

Statistical analysis was performed using the Statistical Package for Social Sciences, version 13.0, for Windows (SPSS, Chicago, IL). The Kruskal-Wallis and χ^2 tests were used to assess the differences within and among groups, with $P < .05$ considered statistically significant.

Results

No difference was present in the distribution of men and women among the 4 groups ($P > .05$), and

the age was similar for the men and women ($P > .05$). No differences were found in the number of symptoms when stratified by gender ($P > .05$; Table 1).

The baseline clinical examinations revealed severe pain in all patients ($n = 104$; 100%). Other signs and symptoms included halitosis ($n = 78$, 75%), debris ($n = 62$, 60%), an empty socket ($n = 60$, 58%), redness around the socket ($n = 50$, 48.1%), exposed bone ($n = 50$, 48.1%), and an unpleasant taste in the mouth ($n = 29$, 28%; Table 2).

The differences in the changes in the clinical signs and symptoms between the control group and all 3 treatment groups were statistically significant ($P < .05$) on the third day after treatment. Statistically significant differences were also observed between the LLLT group (group 4) and the alvogyl and SaliCept groups (groups 2 and 3) on the third and seventh days after treatment ($P < .05$; Fig 1). Differences were also observed between the alvogyl (group 2) and the SaliCept (group 3) groups, but they were not statistically significant ($P > .05$).

Regardless of the treatment, the VAS scores changed during the follow-up period ($P < .0001$); however, the intensity of pain decreased more rapidly

Table 2. CLINICAL SYMPTOMS AND SIGNS OF STUDY GROUPS DURING FOLLOW-UP

Group	Signs and Symptoms (n)	Quality of Life Outcomes (n)			Signs of Healing (n)			
		Pain	Unpleasant Taste	Halitosis	Empty Socket	Exposed Bone	Redness Around Socket	Debris
At diagnosis								
1	4.00	26	8	20	13	13	14	13
2	4.23	26	7	20	14	15	8	12
3	4.62	26	5	16	18	9	16	18
4	4.69	26	9	22	15	13	12	19
3-d after treatment								
1	3.65	26	8	20	5	4	13	5
2	2.62	21	5	15	6	9	8	5
3	2.23	25	0	8	4	0	11	8
4	1.04	8	0	6	0	1	3	6
7-d after treatment								
1	1.62	23	2	3	0	1	12	2
2	0.62	6	0	2	2	1	1	2
3	0.36	3	0	2	1	0	0	0
4	0.08	1	0	0	0	0	0	1

Abbreviations: 1, control group; 2, alvogyl group; 3, SaliCept group; 4, low-level laser therapy group.

Standard error = 0.117.

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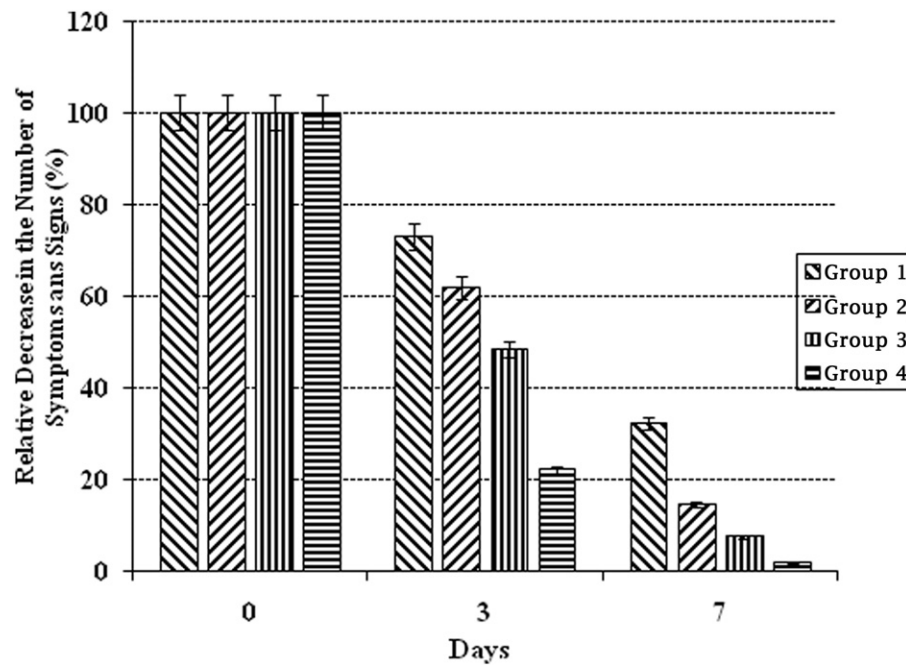


FIGURE 1. Change in number of symptoms and signs during follow-up. Group 1, control group; group 2, alvogyl group; group 3, SaliCept group; and group 4; LLLT group.

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in all 3 treatment groups than in the control group ($P < .05$). This decrease was significantly greater for the LLLT group than for the alvogyl, SaliCept, and control groups ($P < .05$; Fig 2). In line with the other clinical parameters, the VAS scores of the alvogyl group and the SaliCept group did not vary significantly at any point during the 7 days of treatment ($P > .05$). The greater level of pain intensity in the control group was reflected by a greater need for rescue medication, particularly within the first 72 hours. Although all patients in the control group required acetaminophen within the first 3 days after debridement surgery, in the alvogyl, SaliCept and LLLT groups, 10, 12, and 2 patients, respectively, required acetaminophen. Moreover, the LLLT group required the least amount of rescue medication ($P < .05$). Although the SaliCept group required more rescue medication than the alvogyl group, the difference in amounts between the 2 groups was not statistically significant ($P > .05$). On the third day of treatment, the pain symptoms had completely disappeared in 19 patients in the LLLT group, 5 patients in the alvogyl group, and 2 patients in the SaliCept group; however, none of the patients in the control group reported an absence of pain. On the seventh day of treatment, the pain symptoms had disappeared in all the patients in the LLLT group, 22 patients in the alvogyl group, 19 patients in the SaliCept group, and 3 patients in the control group.

Discussion

The treatment of AO is palliative, given that healing occurs eventually within 1 to 4 weeks postoperatively.^{1,2,4-6,9} Regardless of the method used, cleaning and irrigation of the extraction socket is important to remove any debris and bacteria from the denuded bone.⁴ The importance of this procedure has been highlighted by the finding that even the patients in our study who received no treatment other than curettage and irrigation improved symptomatically, albeit slowly. However, the statistically significant differences between the control group and all 3 treatment groups in every parameter examined have shown that curettage and irrigation alone will be insufficient. Equally important was the application of a dressing to the extraction socket to fill the gap in the socket, prevent the accumulation of debris, relieve the pain, disinfect the alveoli, promote healing as quickly as possible, and prevent malodor emanating from the empty socket.⁸ The active components of the dressings cited in published studies have possessed antibacterial properties, analgesic properties, or a topical anesthetic, or a combination of these characteristics.⁹ Most dressing techniques have been adopted over generations. Although no reliable clinical evidence is available to suggest that any 1 method has a therapeutic advantage over another, individual

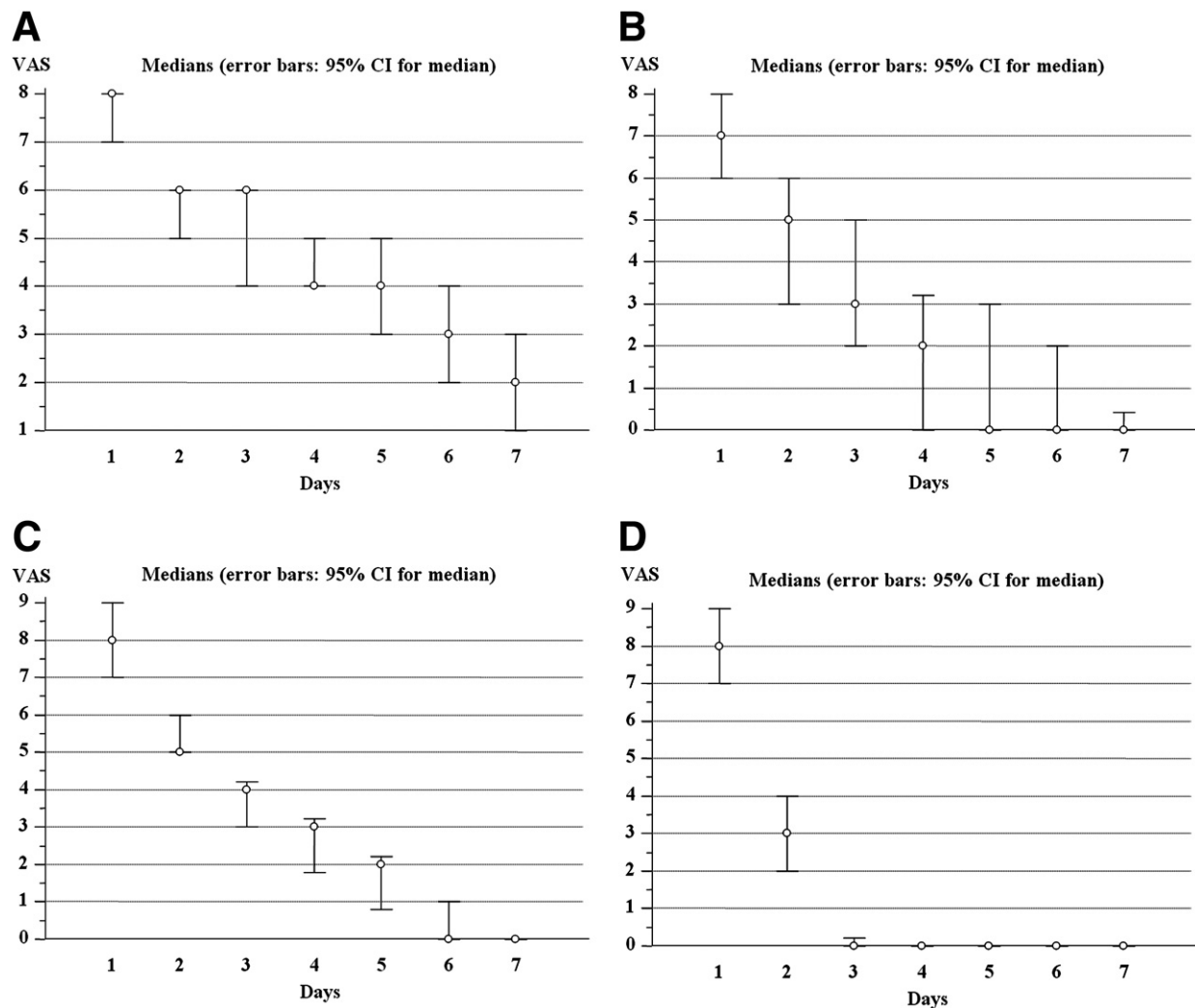


FIGURE 2. Change in VAS scores for A, control group, B, alvogyl group, C, SaliCept group, and D, LLLT group during follow-up.

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clinicians have their own preferences, with only anecdotal evidence available regarding their efficacy.⁸

Given the severe pain and subsequent anxiety of patients with AO,⁵ pain relief is the primary goal of treatment.²³ Acemannan inhibits the inflammatory process and relieves pain by interfering with the arachidonic acid pathway by way of cyclooxygenase.¹³ Alvogyl, which contains eugenol, can also inhibit the inflammatory process and provide analgesic effects by inhibiting the action of prostaglandins.⁸ LLLT has been used for pain treatment for 20 years.¹⁸ The mechanism of pain relief is not well understood, although some studies have suggested that LLLT helps to reduce inflammation by inhibiting the production of cyclooxygenase-2 and prostoglandin-2, potent mediators of inflammation.^{20,21} LLLT's effect on wound healing has been attributed to an increased mobility of keratinocytes, the pro-

motion of early epithelization, increased fibroblast proliferation, matrix synthesis, and the enhancement of neovascularization.²⁴

A clinical study by Choonhakarn et al¹³ investigating the efficacy of aloe vera gel in the management of oral lichen planus found that after 8 weeks of treatment, the pain symptoms had completely disappeared or had considerably decreased in 33% and 63% of patients administered aloe vera gel twice daily, respectively, compared with only 4% (n = 1) and 7% of patients administered a placebo.

Another clinical study by Jorkjend and Skoglund,²⁵ comparing the effects of 2 periodontal dressings containing eugenol and 1 dressing without eugenol on postoperative pain after gingivectomy, found that eugenol had a significant effect in the control of postoperative pain.

Venancio et al²⁶ reported that LLLT had a positive effect in overcoming pain among a group of 30 pa-

tients with temporomandibular joint pain and dysfunction, one half of whom underwent 6.3 J/cm² (30 mW) LLLT using a 780-nm wavelength diode laser, with the other half receiving only simulated laser therapy as a placebo.

In our study, no statistically significant differences were observed in the pain scores among the patients treated with alvogyl (eugenol) and SaliCept (acemannan) during the 7-day treatment course, indicating that acemannan is an effective palliative treatment of AO. However, LLLT resulted in the quickest decrease in the VAS scores after treatment. Although the patients in the alvogyl and SaliCept groups reported total pain relief by the sixth day after treatment, the patients in the LLLT group had reported no pain by the third day after treatment.

Although the aim of AO treatment has generally been palliative, because pain is subjective and can vary in degree from person to person,¹⁸ it is important to evaluate other clinical parameters to provide a more objective comparison of the treatment methods. Acute pain is a symptom of injury, with the severity of pain reaching its peak during the inflammatory phase. Because eradicating inflammation contributes to tissue repair, and because acute pain generally subsides after tissue repair,¹⁸ it has been understood that eradicating inflammation will substantially decrease the severity of pain. Clearly, promoting wound healing will provide faster pain relief, and a treatment method that combines a strong anti-inflammatory effect with pain relief and contributes to early tissue repair would be considered a successful method.

In terms of redness around the socket, a slight improvement ($P > .05$) was observed in the SaliCept group on the third day, and the redness had completely disappeared in the SaliCept and alvogyl groups by the seventh day. This finding suggests that despite the lack of statistically significant differences between the SaliCept and alvogyl groups and the control group with regard to the other clinical signs and symptoms, both SaliCept and alvogyl have a positive effect on the wound healing process. Moreover, the effect of both these dressings on inflammation appeared to increase after the third day. In contrast to our findings, in a study of dogs, Summers and Matz¹¹ reported delayed healing and extensive inflammation when alvogyl was applied to an extraction socket and recommended not using this dressing on any wound.

Viegas et al¹⁹ compared the effects of a 685-nm wavelength gallium aluminum arsenide diode laser (35 mW, 4 J/cm²), an 830-nm wavelength indium gallium aluminum phosphide (InGaAlP) laser (35 mW, 4 J/cm²), and meloxicam on the inflammatory response during scarring. The investigators reported that treatment with 830-nm wavelength (35 mW, 4 J/cm²) laser irradiation resulted in the best organization and maturation of col-

lagen, with more intense vascular activation observable during the first 36 hours of tissue repair. They concluded that the application of laser light shortens the acute inflammatory phase, hastens the initiation of the proliferative phase, and accelerates the healing course. Our finding that redness around the socket had disappeared by the third day after treatment in 10 of 13 patients in the LLLT group was in line with the findings from that earlier study and has reinforced the use of LLLT as an effective method of treating inflammation ($P < .05$). In addition to alleviating the inflammation and pain, LLLT also performed better than alvogyl and SaliCept in terms of the other clinical parameters ($P < .05$; Table 2).

Bjordan et al¹⁸ suggested that obtaining the optimal anti-inflammatory effect from laser irradiation in the 810- to 830-nm wavelength range requires a minimal energy density of 6 J/cm² for small wounds and 10 J/cm² for large wounds. Our study was designed according to these recommendations¹⁸; however, additional research is needed to definitively establish the optimal irradiation densities.

In conclusion, our study findings have shown that acemannan in the form of the SaliCept patch is an acceptable alternative to alvogyl as a dressing for the management of AO. However, LLLT with an 808-nm, 100-mW, continuous-mode diode laser using a beam spot of 0.7854 cm² (irradiance 127.3 mW/cm²) at 7.64 J/cm² (0.1 W × 60 seconds = 6 J) performed superiorly to both SaliCept and alvogyl in managing AO in this study population.

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