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Research Article A Clinical Study on the Efficacy of Vitamin B Supplements in the Treatment of Traumatic Ulceration

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Abstract

Background and Objective: Traumatic ulceration is a type of mouth ulcer caused by the accidental biting of the cheek or tongue, harsh brushing or poorly fitting dentures. Symptoms include pain, redness, swelling and soreness in the affected area. Vitamin B serves as a microelement necessary for its treatment. This study aims to evaluate the beneficial efficacy of vitamin B supplements in the treatment of traumatic ulceration. **Materials and Methods:** A total of 290 patients aged between 18-75 with traumatic ulceration were enrolled at Tongling People's Hospital, Anhui Province, China which were randomly categorized into three groups' viz. Vitamin B (N = 97) was given with oral vitamin B supplements and apply vitamin B12 solution topically on the oral mucosa, antibiotic group (N = 96) was given cefdinir capsule and the control (N = 97) was a placebo. The participants were evaluated for pain using a visual analog scale (VAS) and assessed for their efficacy. **Results:** The vitamin B group showed a significant reduction in ulcer size with 0.22±0.01 mm on day-8 and 100% healing rate by day-12. The vitamin B group also experienced a significant decrease in pain intensity score with 0.33±0.50 by day-8 and the pain intensity score was zero by day-12. The antibiotic group showed a limited and moderate improvement in pain intensity, indicating the superior effectiveness of vitamin B supplements in pain management. Whereas, the outcomes for the control group indicate a comparatively slower response in both ulcer size reduction and pain intensity compared to the vitamin B group and antibiotic group. **Conclusion:** The findings of this study conclude that vitamin B supplements is a viable and effective choice for managing pain and reducing ulcer size caused by traumatic ulceration.

Key words: Vitamin B supplements B12, ulcer, traumatic ulceration, mouth ulcer, antibiotic

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Competing Interest: The authors have declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.

INTRODUCTION

Traumatic ulceration is a type of ulcer that is caused by biting the cheek or tongue or by sharp teeth in the mouth¹. Traumatic ulcerations can occur due to accidental biting, harsh brushing or flossing, ill-fitting dental appliances or other sources of irritation. Symptoms of traumatic ulceration may include pain, redness, swelling and a raised bump or sore in the affected area². Treatment for traumatic ulceration typically involves managing pain and discomfort with over-the-counter pain relievers, applying topical creams or gels to the affected area and avoiding further irritation to the area by practicing good oral hygiene habits or adjusting dental appliances as necessary³. While most cases of traumatic ulceration will heal on their own within a few days to a week, it is important to monitor the affected area for signs of infection or other complications and to seek medical attention if symptoms persist or worsen⁴. Vitamin B, which serves as a microelement necessary in a general body of a person may be increased via nutritional alteration or treatment with medication. Vitamin B is widely used in the treatment of mouth ulcers because of its low cost and it is mostly recommended by the clinic⁵. Vitamin B, an essential nutrient crucial for the human body, plays a beneficial role in the process of wound healing. Vitamin B supplements, a compound comprising vitamin B1, B2, B6, B12, nicotinamide and pantothenic acid is commonly utilized in the treatment of mouth ulcers. Traumatic ulceration is mainly caused by traumatic injury or accidents, thermal injury, chemical injury, infective ulcers or due to neoplastic conditions^{6,7}. To understand symptoms, patients are required to enquire about pain, systemic illness, previous medical illness, frequent medication, smoking and alcohol consumption. Proper examination and investigation are necessary for traumatic ulceration control. Machine-driven trauma or thermal burn ulceration can be resolved within 10-14 days⁸. Ulceration can be acute or chronic. In dental medicine, ulceration of the mouth is a distress with painful mucosal lesions, which can be frequently found in the gustatory sensation, gingiva, buccal pouch or lips⁹. Therefore, the present study aims to investigate a randomized, double-blind, placebo-controlled study to evaluate the effectiveness of vitamin B12 for ulcer pain management and ulcer size reduction.

MATERIALS AND METHODS

Eligibility criteria: The study took place from January, 2021 to June, 2023 in the Department of Stomatology, Tongling People's Hospital, Anhui Province, China. The study evaluated

adult patients aged 18-75 years with traumatic ulcers attending the hospital's outpatient clinic. Written and verbal consent about the study and its potential side effects were obtained from the participants.

The inclusion criteria include the following:

- Patients with age 18-75 years
- Chinese population or Chinese ethnicity
- Mouth ulcer size >2 mm

The exclusion criteria include the following:

- Patients with vitamin B12 deficiency
- Patients with systemic mouth lesions diseases, aphthous ulcers, lupus and acquired immune deficiency syndrome
- Patients with chronic diseases such as liver diseases, rheumatoid arthritis, diabetes, cancer and renal diseases
- Pregnant or nursing

Procedures: After obtaining consent, the doctors recorded the medical history, demographic data, baseline information and clinical measurements. A total of 290 patients were enrolled in the study who had experienced traumatic ulceration within 48 hrs duration. Participants were then randomly made into three group's viz. Vitamin B group (N = 97), an antibiotic group (N = 96) and a control group (N = 97) using system-generated patient identification numbers (ID): The group assignments were blinded to both physicians and participants until the end of the study. The dental physician carried out the medical history assessment and questionnaire which included the measurement of ulcer size, location and traumatic incident.

The vitamin B group was given vitamin supplements which comprised of the following:

- Vitamin B12 solution applied topically 0.5 mg/bottle lasts for 7-10 days
- Vitamin B complex tablets, taken orally, three times a day, one tablet at a time

The antibiotic group was given the following:

• Cefdinir capsule 0.1 mg for 3-5 days

The control group was given the following:

• Placebo solution has the same in appearance, color and same flavor as vitamin B12 injection which does not have vitamin B12

The participants were evaluated for pain using a Visual Analog Scale (VAS), a widely used self-reporting device for pain measurement. A VAS score of "0" was taken as 'no pain' on one end and a score of "10" was taken as 'unbearable pain' on the other end.

Statistical analysis: The IBM SPSS version 21 statistical software package (SPSS, Inc., Chicago, Illinois, USA) was used to conduct statistical analyses. Descriptive statistics were utilized to summarize the data, with continuous variables presented as mean SE. Categorical data were compared using the chi-square for comparing normally distributed data. The Mann-Whitney test, a nonparametric test, was used to compare treatment effectiveness measurements between the groups. Statistical significance was set at p<0.05.

RESULTS

Patient recruitment and baseline characteristics: A total of 290 patients with traumatic ulceration who convene the inclusion criteria were included in the study. The 97 patients each were assigned to the vitamin B group and control group whereas the antibiotic group was assigned with 96 patients. Table 1 displays the characteristics of the patients of the three groups viz. Vitamin B, antibiotic and control. The mean age of the participants was 45.66 ± 0.91 years (range = 18-75). The

total number of males was 142 and the total number of females was 147. All the subjects had an ulcer size ranging from 4 to 7 mm. The gradual reduction in the ulcer size and VAS pain score was measured after treatment on 4, 8 and day-12. There were no statistically significant differences between the three groups based on the baseline characteristics.

Ulcer size reduction: The study showed that the patients in the vitamin B group experienced a significant decrease in ulcer size compared to the antibiotic group and the control group (Table 2). The mean changes in the ulcer size reduction were shown in Table 2. The vitamin B group showed a significant reduction in ulcer size on day-4 (1.75±0.46 mm) and day-8 (0.22±0.01 mm) compared to baseline data on day-1 (5.66 \pm 0.92 mm). The vitamin B group also experienced a total recovery by day-12. Whereas the antibiotic group and the control group observed a slight change in the ulcer size reduction compared to day-1. The ulcer size reduction in cases of antibiotic was 2.63 ± 0.46 mm on day-4, 0.74±0.03 on day-8 and 0.45±0.01 on day-12 compared to 5.63 ± 0.93 on day-1. However, the ulcer size reduction in cases of the control group was comparatively slower with a mean size of 2.71 ±0.45 mm on day-4, 1.43 ±0.54 mm on day-8 and 0.79±0.35 mm on day-12 compared to 5.45±0.08 at day-1. Out of the 97 patients in vitamin B group, 63.92% (n = 62) of the patients showed a gradual improvement at day-4 with

Characteristics	Vitamin B (97)	Antibiotic (96)	Control group (97	
Age (Years)				
Mean	46.25 ±1.51	46.46±1.60	44.29±1.61	
Range	18-75	20-74	19-75	
Age group (Years)				
18-35	31 (31.96%)	28 (29.17%)	42 (43.30%)	
36-55	27 (27.84%)	33 (34.38%)	19 (19.59%)	
56-75	39 (40.21%)	35 (36.46%)	36 (37.11%)	
Sex				
Female	54 (55.7%)	41 (42.7%)	52 (53.6%)	
Male	43 (44.3%)	54 (56.3%)	45 (46.4%)	
Ulceration cause				
Injury	39 (40.2%)	(47.9%)	45 (46.4%)	
Other causes	58 (59.8%)	(52.1%)	52 (53.6%)	
ВМІ				
Underweight	5 (5.2%)	2 (2.1%)	4 (4.1%)	
Normal	38 (39.2%)	50 (52.1%)	54 (55.7%)	
Overweight	47 (48.5%)	42 (43.8%)	33 (34.0%)	
Obesity	7 (7.2%)	2 (2.1%)	6 (6.2%)	
Smoking status				
No	53 (54.6%)	50 (52.1%)	49 (50.5%)	
Yes	44 (45.4%)	46 (47.9%)	48 (49.5%)	
Drinking status				
No	57 (58.8%)	42 (43.8%)	51 (52.6%)	
Yes	40 (41.2%)	54 (56.3%)	46 (47.4%)	

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Table 2: Comprehensive overview o	f ulcer reduction, percentage improvement and Visual Analog Scale (VAS) scores for the vitamin B, antibiotic and control groups
over the course of the study	,

aracteristics Vitamin B (97)		Antibiotic (96)	Control group (97)	
Ulcer reduction				
Day-1	5.66±0.92	5.63±0.93	5.45 ± 0.08	
Day-4	1.75±0.46	2.63±0.46	2.71±0.45	
Day-8 0.22±0.01		0.74±0.03	1.43±0.54	
Day-12	0.0 (full recovery)	0.45±0.01	0.79±0.35	
Percent of improvement				
Day-4 (>2 mm) 62 (63.92%)		7 (7.29%)	5 (5.15%)	
Day-8 (>0.50 mm)	97 (100%)	28 (29.17%)	2 (2.06%)	
Day-12 (>0.0 mm)	97 (100%)	75 (78.13%)	13 (13.40%)	
VAS scale				
Day-1	5.68±0.16	6.11±0.17	5.37±0.17	
Day-4	1.72±0.10	2.56±0.11	3.08±0.12	
Day-8	0.33±0.50	1.12±0.07	1.40±0.08	
Day-12	0.0 (no pain)	0.11±0.03	0.27±0.05	

Table 3: Logistic regression analysis with patient characteristics

Characteristics	Vitamin E		Antibiot		Control	
	Odds ratio (95 CI)	p-value	Odds ratio (95 CI)	p-value	Odds ratio (95 CI)	p-value
Age	1.54 (1.06-1.76)	0.919	1.02 (0.99-1.05)	0.141	1.23 (0.87-1.32)	0.839
VAS scale pre	1.29 (0.97-1.85)	0.946	1.13 (0.81-1.61)	0.491	1.42 (1.14-2.07)	0.919
VAS scale post	1.34 (1.12-1.86)	0.820	1.21 (0.71-2.05)	0.496	1.64 (1.23-2.47)	0.819
Ulcer size reduction						
Day-1	1.69 (1.21-1.96)	0.947	3.93 (1.55-9.98)	0.004	2.42 (1.45-2.76)	0.947
Day-4	1.12 (0.94-2.12)	0.827	0.61 (0.11-3.57)	0.584	0.74 (0.53-1.56)	0.827
Day-8	0.85 (0.56-1.64)	0.794	0.03 (0.01-0.04)	0.001	0.53 (0.31-1.43)	0.796
Sex	1.45 (1.18-2.12)	0.998	0.99 (0.40-2.44)	0.976	1.34 (1.02-3.21)	0.794
BMI						
Normal	1.23 (1.17-2.14)	0.989	1.05 (0.67-2.15)	0.120	1.12 (0.84-1.74)	0.561
Overweight	2.53 (2.04-3.12)	0.981	0.04 (0.02-1.90)	0.103	0.63 (0.42-1.54)	0.994
Obesity	0.93 (0.63-1.83)	0.998	0.57 (0.33-1.63)	0.030	0.94 (0.83-1.32)	0.983
Smoking	1.23 (0.94-1.93)	0.912	1.07 (0.45-2.54)	0.874	1.34 (1.05-2.83)	0.912
Alcohol	1.18 (0.54-2.01)	0.958	0.61 (0.25-1.47)	0.268	1.42 (1.05-2.34)	0.960
Cause	1.43 (1.14-2.03)	0.868	0.59 (0.24-1.43)	0.242	1.53 (1.04-2.53)	0.866

ulcer size >2 mm. However, the antibiotic group and the control group showed only 7.29% (n = 7) and 5.15% (n = 5) of the patients, respectively ulcer size >2 mm on day-4 (Table 2). By day-12, all the 97 patients in the vitamin B group showed full recovery with ulcer size >0.0 mm. The antibiotic group showed a healing rate of 78.13% (n = 75) at day-12 with ulcer size >0.0 mm. Whereas, the control group showed a lesser sign of healing on day-12 with 13.40% (n = 13) of the patients with ulcer size >0.0 mm (Table 2). Since no other medication that could impact mouth ulcer evolution was allowed during the study, the observed efficacy is solely related only to vitamin B supplements for mouth traumatic ulceration application in the vitamin B group.

Comparison of pain in the treatment groups: In general, the study observed that the patients in the vitamin B group experienced a significant decrease in pain intensity score (VAS) compared to their initial baseline levels based on the VAS score, as shown in Table 2. The mean VAS score for

vitamin B group at day-4 and day-8 was 1.72±0.10 and 0.33 ± 0.50 compared to 5.68 ± 0.16 of the initial baseline at day-1 (Table 2). By day-12, the pain intensity score was zero or no pain among the patients of the vitamin B group. Whereas the antibiotic group and the control group observed little change in the pain intensity score (VAS) compared to day-1. The pain intensity score (VAS) of the antibiotic group was 2.56±0.11 mm on day-4, 1.12±0.07 at day-8 and 0.11±0.03 at day-12 compared to 6.11 ± 0.17 at day-1. However, the pain intensity score in cases of the control group was comparatively slower with a mean VAS score of 3.08 ± 0.12 at day-4, 1.40 ± 0.08 at day-8 and 0.27 ± 0.05 on day-12 on compared to 5.37±0.17 at day-1. The logistic regression analysis also observed that the vitamin B group demonstrated notable effectiveness in reducing ulcer size on both day-1 and day-8 compared to the other groups (Table 3). Factors such as age, sex, smoking, alcohol consumption and the cause of the condition did not appear to significantly influence treatment outcomes across the groups (Table 3).

DISCUSSION

The findings of this study, conducted on patients with traumatic ulceration using a double-blind, placebo-controlled design, suggest that vitamin B supplementation proved to be a useful adjunctive treatment for reducing pain caused by traumatic ulcers and for reducing pain intensity during the healing process. Traumatic injuries such as an injury due to sharp edged eatable items, bites by self accidentally or while speaking or during sleep cause traumatic injuries to the mucosal layer of the mouth leading to traumatic ulcers¹⁰. It may be caused by heat or chemical burns. Traumatic ulcers mostly happen in the lips, tongue and buccal mucosal layer. Mechanical trauma serves as a maximum collective source for mouth ulceration¹¹. This trauma is usually triggered via dentures, braces or broken teeth. They might likewise be caused by bitten fingernails or via the chewing of hard foods. Traumatic ulcers happen as a wound inside the gums, mouth or tongue¹². The traumatic ulcers are caused by biting inside the cheeks and burning of the mouth by eating heated foods, hot drinks or cold drinks. Traumatic ulcers usually heal by themselves within 15 days¹³. Acidic food or spicy food also prompts mouth ulcers. Wearing false teeth and anxious chewing also leads to traumatic ulcers. In a separate study, patients given 50-500 mg of vitamin B12 solution for topical application on the buccal side of a tooth and exposed to saliva for 15 days showed a considerable improvement with a decrease in VAS pain level without any reported adverse reactions or complications¹⁴. In fact, oral vitamin B supplementation has also been found to be an effective treatment for traumatic ulcers, as indicated by studies conducted¹⁵. Deficiency of some vitamins and minerals can also be the cause of mouth ulcers. Mouth usually mimics gut, bad gut and digestive tract inflammation can mimic bad breath and breadth oral condition. Certain ailments can also trigger mouth ulcers; ailments include infections like herpes simplex, cold sore virus, chicken pox, foot and mouth diseases¹⁶. So as to attain a decisive diagnosis, it is important to study difference diagnoses. It is the mental procedure of combining knowledge and logic into a sequence of stepwise judgments. Entire lesions that can't be omitted at first must be involved to undergo the difference identification, trailed through research lab investigations followed by further research in constricting the conclusion¹⁷.

Another study observed that the use of nebulized vitamin B12 solution as a treatment for oral ulcers induced by surface corticosteroid inhalation resulted in an improvement in pain level and ulcer size compared to the placebo group¹⁸. The results of the present study were also consistent with previous findings of decreased ulcer size reduction and pain levels associated with vitamin B12 treatment. However, despite these previous studies, the efficacy of vitamin B12 for treating traumatic ulceration is not yet fully established. Nevertheless, vitamin B12 happens to be a promising therapy for managing oral pain caused by mouth ulcers¹⁹. Numerous reports of vitamin B supplements is available, however, no data on the comparison of antibiotic administration is reported, this study report for the first time, the comparison and effectiveness of vitamin B supply with respect to antibiotic use and control. The study also observed that the use of vitamin B is more effective compared to antibiotics and the control. Moreover, it is obvious that the joint, supplementation of vitamin B has an elevated clinical significance in the treatment of submissive people living with traumatic ulcerations of the mouth²⁰. Abrasions of mouth ulcers were characterized such as solitary severe, multiple severe, solitary long-lasting, multiple long-lasting and repeated injuries. In most cases, severe mouth ulcers and traumatic ulceration arise from shocking invectives, virus-related or bacteriological contagions, allergenic hyperactivity or chemotherapy of cancer disease²¹. However, vitamin B12 deficiency normally occurs amongst circumstances of recurrent oral ulceration, therefore it is recommended to increase levels and consumes vitamins B supplements. In addition to vitamins, iron also plays role in cure of recurrent oral ulcers. People with recurring oral ulcers were found to have a low iron levels as compared to people without mouth ulcers. Food rich in iron or intake of iron supplements will help increase the level²². Zinc, a trace element also helps avoid mouth ulcer. Supplementation with zinc helped avoid the occurrence of mouth ulcers. The occurrence of hematinic shortages together with ferritin and deficiency of vitamin B12 with the part in the management and expansion of recurrent aphthous ulcers has been unknown completely²³.

Certain revisions had conveyed that there is no linkage between mouth ulceration and iron. Vitamin B supplements inadequacy is occasional and typically happens in later part of old age. Shortage or anemia, mainly iron insufficiency, vitamin B12 insufficiency effects the incidence of recurring aphthous stomatitis. In another study, it was observed that deficient in vitamin B12 overpowers the cell-mediated immunity and it serves the commonly prevalent hematinic insufficiency, creating variations in the epithelium of the cavity of mouth²⁴. The treatment with vitamin B12 is both simple and inexpensive. Previous studies have investigated different dosages, administration routes and treatment durations for vitamin B12^{25,26}. In present study, clinical nurses were used to administer a specific dosage, delivery method and treatment duration that can be easily applied by patients with oral ulcers to reduce pain levels. This can help improve the quality of life for patients. Current study findings provide evidence-based nursing interventions and can be used to educate nurses on oral health and how to enhance their impact on patient care. On the other hand, six comparative investigations between the ulcer soothing time and treatment time. While comparing them using control, the duration taken for soothing the ulceration comes down by two and 0.15 days and the curative time comes down by 2.32 days in the treating group²⁷. These results are owing to the capability of vitamin B in defending oleaginous gland; mucous membrane tissue, also encourages mucous membrane reparation and redevelopment, hence restricting the soothing time. In the meantime, vitamin B hinders the growth of soreness, hence restricting duration taken for treating the ulceration²⁷. Either vitamin B only or vitamins B mixed with pantothenic acid are operative in the treatment of mouth ulcers. Besides its efficiency, it also contributes hugely to reducing the likelihood of reappearance, hastens ulcer soothing and minimizes the duration of management. Together, vitamin B showed great medical significance for curing a person with ulceration of mouth. The TUGSE which stands for Traumatic-Ulcerative-Granuloma by-Stromal-Eosinophilia is an uncommon, generous and identityrestrictive abrasion in the mucosal tissue of mouth²⁸. The TUGSE could be exist without symptomatic or are linked through slight to intense pain. The lesion typically reverts instinctively or after removing the probable activator of microtrauma (e.g., dental plate), within one week to a month. Checking aphthous ulcer persons computing serum ferritin and vitamin B12 levels is compulsory so that recurrent aphthous ulceration can be stopped. A study where some cases were considered in which the duration taken to restoration course from ulcer may perhaps proceeds till one vear²⁹.

The TUGSE is an uncommon self-limiting ailment occurring inside the mucous layer of mouth. The abrasion is demonstrated as an inaccessible abscess which may remain either one non symptomatic or supplementary having slight to serious discomfort and in most cases, it distresses the gustatory perception³⁰. Aphthous ulceration in the interior side of the mouth recurrently comes across in overall preparation. Although, a well detail pathophysiological study has been in an incomprehensible state, various conditions are contributing to the process of pathogen origination in the ulcerative lesions. Conditions such as immunological, native trauma, consumption of smoke, tension, imbalance of hormone, having a familial history of the disease, over sensitivity to food as well as infection. Aphthous ulceration in the mouth is usually associated with pain, low ulceration is regularly enclosed with a grey-white secretion and enclosed with an erythematous boundary³¹. There is an inclination to

persist in uneven intermissions with solo or manifold abrasions. Contrary to the recurring intraoral viral herpes simplex, persistent aphthous ulcerations (or recurring aphthous stomatitis) occur on non-keratinized mucosal layer for example the pharyngeal and mucosal layer of labia and the adjacent boundary of the taste perceptive organ³². In a meta-analysis study, six different investigations were involved which included one thousand five hundred thirty-four submissive people³³. Patients by whom the treatment was not given had been served as the control group whereas those patients who had undergone treatment with giving vitamin B supplements only or those who had given combine treatment of vitamin B combining vitamin B5 were kept in the treatment group³⁴. While comparing the control and the treatment group, the rate of effectiveness was higher which have an occurrence rate. Supplements of vitamin B facilitates a more degree of effectiveness as well as a low rate of recurrence, also facilitates therapeutic efficacy of ulceration and reduces the duration of taking the treatment.

Therefore, the findings of the study put forward that healthcare providers can consider using vitamin B supplements as an adjunctive therapy for traumatic ulceration to improve pain management and reduce ulcer size. However, further research involving a multi-ethnic sample size is necessary to verify these results. (I) The study considered only Chinese population and did not consider other ethnicity and (ii) The study did not measure dose-dependent analysis and concentration of vitamin B12 supplements.

CONCLUSION

This study investigated the efficacy of vitamin B12 supplements in the management of traumatic ulceration in the oral cavity. The results demonstrated that vitamin B supplements, specifically vitamin B12 significantly contributed to the reduction in ulcer size and alleviation of pain compared to both antibiotic treatment and a control group receiving a placebo. The study highlighted the potential of vitamin B12 supplementation as a cost-effective and clinically relevant approach for managing traumatic ulceration in the oral cavity. The observed outcomes emphasize the importance of considering vitamin B supplementation, as a valuable adjunctive therapy for enhancing pain management and promoting the healing process in patients with traumatic oral ulcers.

SIGNIFICANCE STATEMENT

The findings of the study suggest that vitamin B12 serves as a promising adjunctive therapy. The study's controlled design, randomization and blinded assessments provide valuable insights into the benefits of vitamin B12, offering a potential cost-effective and accessible approach to enhance the quality of life for individuals suffering from traumatic ulceration. Overall, the study contributes valuable evidence for healthcare providers considering vitamin B12 supplementation as part of the treatment regimen for traumatic ulceration, opening avenues for improved pain management and accelerated healing.

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