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A Randomized Controlled Trial Assessing the Effect of Preoperative Ibuprofen Administration on Postoperative Pain Reduction Following Miniscrew Insertion

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Abstract

Objective To evaluate the impact of preoperative oral ibuprofen premedication as a preemptive analgesia protocol on postoperative pain following the insertion of a single miniscrew insert.

Methods A randomized, single-blind, placebo-controlled parallel-group trial design was adopted. A total of 68 patients seeking miniscrew insert placement were recruited based on inclusion and exclusion criteria. Patients were randomly assigned in a 1:1 ratio to either the ibuprofen group or the control group, with 34 patients in each group. The ibuprofen group and the control group received 300 mg of ibuprofen sustained-release capsules and a placebo, respectively, 30 min before surgery. Postoperative analgesics were administered as needed. Pain scores at 2, 4, 6, 8, 12, and 24 h postoperatively were recorded using the Numerical Rating Scale (NRS), and the postoperative analgesic consumption was documented.

Results A total of 68 patients (34 in the control group and 34 in the preemptive analgesia group) completed the trial. No adverse events such as nausea or vomiting occurred in any of the patients. The preemptive analgesia group exhibited significantly lower pain scores at 2, 4, 6, and 8 h postoperatively [2 (0,3), 0 (0,2), 0 (0,0), 0 (0,0.25), respectively] compared to the control group [3 (2,5), 3 (2,4), 2 (0.75,4), 1 (0,3), respectively] ($P=0.0396$, $P=0.0067$, $P=0.0111$, $P=0.0299$). The proportions of patients requiring additional analgesics within 2–24 h postoperatively were 17.6% (6/34) in the preemptive analgesia group and 64.7% (22/34) in the control group, with a statistically significant difference between the two groups ($P=0.013$).

Conclusion Preemptive analgesia with ibuprofen can effectively reduce postoperative pain following miniscrew insert placement and represents a safe and effective perioperative pain management strategy.

Trial Registration The UK's Clinical Study Registry; ISRCTN68332234 (Retrospectively registered); 20/12/2024.

Keywords Miniscrew Insert, Preemptive Analgesia, Pain Management, Oral Treatment

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Introduction

Malocclusion stands as one of the most pervasive oral and maxillofacial conditions, earning recognition from the World Health Organization (WHO) as the third most common oral health concern trailing dental caries and periodontal disease [1, 2]. This condition exacts both physiological and psychological tolls on patients, thereby constituting a substantial public health burden. Anchorage preparation is a pivotal aspect in the therapeutic intervention for malocclusion [3]. However, the prospect of pain associated with miniscrew insertion can evoke aversion in patients, potentially undermining the therapeutic efficacy for malocclusion [4].

Postoperative pain intensifies patients' distress and anxiety, potentially disrupting the homeostatic balance of the circulatory and endocrine systems [5]. Noxious stimuli can elicit hypersensitivity reactions, hyperalgesia, allodynia, and dysesthesia, ultimately leading to non-noxious stimuli provoking pain. The integration of peripheral sensitization linked to a lowered nociceptor threshold and central sensitization associated with heightened excitability within the central nervous system is purported to ultimately mediate the genesis and perpetuation of postoperative intractable pain [6]. Furthermore, once central sensitization is entrenched, patients may exhibit a suboptimal response to pain mitigation measures [7]. Hence, there is a pressing need for more efficacious pain relief interventions to augment clinical care for individuals with malocclusion.

Non-steroidal anti-inflammatory drugs (NSAIDs) are the most frequently utilized analgesics for managing postoperative pain subsequent to miniscrew insertion [8]. However, in the event of severe pain, the efficacy of NSAIDs remains questionable. Moreover, acidic NSAIDs may induce severe adverse effects in certain patients, necessitating meticulous selection of NSAID dosage and administration [9]. Preemptive analgesia is an analgesic approach aimed at minimizing postoperative pain by forestalling central sensitization prior to surgical trauma [7, 10]. Once central sensitization is established due to surgical tissue damage, postoperative hyperalgesia persists for an extended duration [11]. However, if preemptive analgesia is administered preoperatively, central sensitization is inhibited, thereby effectively controlling the occurrence of postoperative hyperalgesia. Furthermore, it is worth noting that miniscrew insertion may sometimes require removal due to loosening or re-implantation due to changes in orthodontic treatment plans. For patients, especially younger ones, improvements in post-operative pain management after the first miniscrew insertion can significantly impact their willingness to undergo re-implantation and even improve patient compliance throughout the entire orthodontic treatment process.

Preemptive analgesia has been reported in applications such as third molar extraction, implant placement, endodontic treatment, and periodontal flap surgery, yielding favorable outcomes [12, 13]. However, to date, no research has focused on preemptive analgesia for orthodontic miniscrew insertion, highlighting a significant gap in the current understanding and management of postoperative pain in this context. The present study aims to investigate the clinical efficacy of orally administered ibuprofen sustained-release capsules in providing preemptive analgesia during orthodontic miniscrew insertion. The objective was to evaluate the impact of preoperative ibuprofen administration on postoperative pain following the insertion of a single posterior orthodontic miniscrew. This study endeavors to contribute to the body of knowledge regarding optimal pain management strategies for such procedures, aiming to enhance patient comfort and satisfaction during orthodontic treatment.

Materials and Methods

Study design and setting

The prospective, randomized, single-masked, and controlled clinical study population was recruited from patients seeking miniscrew insert at Hospital of Stomatology, Wuhan University.

Ethical consideration

The research protocol was rigorously reviewed and approved by the Ethics Committee of the Stomatological Hospital of Wuhan University (Approval Number: [WDKQ2024]LUNSHEN(B46)). All patients who completed the questionnaires provided their informed consent and surgical consent voluntarily.

Sample size determination

The number of patients included in this study was based on previous studies that found a significant effect of administration of ibuprofen for over-the-counter analgesia in minor oral surgery. [14] Based on the findings of this studie, it was hypothesized that the mean pain scores at 72 h postoperatively would be (2.95 ± 2.08) in the control group and (4.40 ± 1.78) in the ibuprofen group. A sample size of at least 30 participants in each group was calculated using StatBox (https://www.trialstats.com) to achieve the estimated power higher than 80.0% and a significance level of 10%. Each group consisted of 34 participants, taking into account the possibility of participants dropping out.

Randomization and participants allocation

The trial employed a single-blind design. The experimenters used SAS software (9.4, USA) to generate a random number for each patient, and then the generated random numbers were sorted, and based on the sorting results, patients in the first half of the sorting were assigned to the trial group, and patients in the second half of the sorting were assigned to the control group, ensuring that the number of patients in each group was equal, and the results of the randomization were recorded. According to the randomization results, different drugs were packaged and distributed to the patients in each group before the operation, and the drugs in both groups were in the same capsule form with the same appearance.

Eligibility criteria

Inclusion criteria were as follows:

1. Age range: 18 to 50 years inclusive; 2. Absence of cardiopulmonary diseases, normal liver and kidney function, no history of abnormal bleeding or coagulation disorders; 3. Requirement for the insertion of a miniscrew bilaterally for orthodontic treatment, with no need for other oral surgeries apart from orthodontic interventions; 4. Normal bone density at the insertion site confirmed by cone-beam computed tomography (CBCT); 5. Voluntary participation in the study and completion of the survey questionnaire.

Exclusion criteria encompassed:

1. Pregnant or lactating women; 2. Presence of systemic diseases such as coagulation disorders, cardiovascular and cerebrovascular diseases, or endocrine disorders; 3. Allergic to the medication ibuprofen and the intraoperative medication articaine hydrochloride used in this study; 4. Untreated dental pain conditions such as pulpitis, apical periodontitis, or trigeminal neuralgia requiring long-term analgesic use; 5. Concurrent acute oral infections or tumors; 6. Alcohol consumption within one week prior to surgery; 7. Active or past history of peptic ulcer, gastrointestinal bleeding, or perforation; 8. Current use of ibuprofen, selective cyclooxygenase-2 (COX-2) inhibitors, or other NSAIDs; 9. Prior history of miniscrew insertion surgery.

Intervention

Experimental group was received 300 mg of ibuprofen sustained-release capsules (Tianjin Smith Kline & French Laboratorles Ltd, China & UK) orally 30 min prior to surgery. And control group was received a placebo capsule (300 mg/capsule, filled with starch) orally before surgery. All procedures were performed by the same experienced oral surgeon under local anesthesia, following standardized surgical protocols. Local anesthesia was administered with 4% Articaine hydrochloride with 1:100,000 epinephrine (Produits Dentaires Pierre Rolland, Frence). Anesthesia was administered by local soft tissue infiltration injection to ensure complete anesthesia of the operative area. The miniscrew insertion process requires precise control of direction and depth. A miniscrew with a size of 8 mm*1.4 mm is used for the anterior region, while a size of 10 mm*2 mm is selected for the posterior region. The miniscrew is slowly inserted into the bone using a specialized insertion driver, with an insertion angle of approximately 30° to 60° relative to the long axis of the adjacent teeth to enhance mechanical stability at the bone-screw interface. During insertion, the torque should be controlled within a range of approximately 5–10 N·cm. (Fig. 1) Postoperatively, the stability of the miniscrew should be assessed immediately, and patients should be instructed to maintain proper oral hygiene and avoid direct mastication in the insertion area. Pain Relief Medication: Following surgery, subjects could self-administer ibuprofen sustained-release capsules 300 mg based on their pain levels (reaching an Numerical Rating Scale (NRS) score of 3), while documenting the frequency and timing of administration. NRS provide simplicity and ease of use by asking patients to express pain levels directly using numbers. This makes them particularly suitable for fast-paced clinical environments and a wide range of patient populations. [15] Adverse events (AEs) were systematically monitored throughout the study period. Patients were instructed to report any unexpected symptoms or complications. The predefined criteria for AEs included severe postoperative pain unresponsive to analgesics, persistent swelling beyond the expected inflammatory response, localized or systemic infection requiring additional treatment, and any signs of allergic reactions. All reported events were recorded, assessed by the clinical investigators, and managed according to standard clinical protocols. [16]

Validity and reliability

All clinical procedures were performed by one trained and calibrated operator to reduce the bias. Another operator was responsible for collecting pain scales.

Outcome indicators,data collection and study variables

1. Baseline Information: Collected patients' basic information, including gender and age. 2. Insertion Site: Documented the site of miniscrew insertion (maxilla or mandible). 3. Primary outcome: Provided subjects with a diary to record their pain intensity at 2, 4, 6, 8, 12, and 24 h postoperatively. Pain intensity was assessed using the NRS score, where 0 indicates no pain, 1–3 mild pain, 4–6 moderate pain, and 7–10 severe pain. 4. Secondary outcome 1: Provided subjects with a diary to record

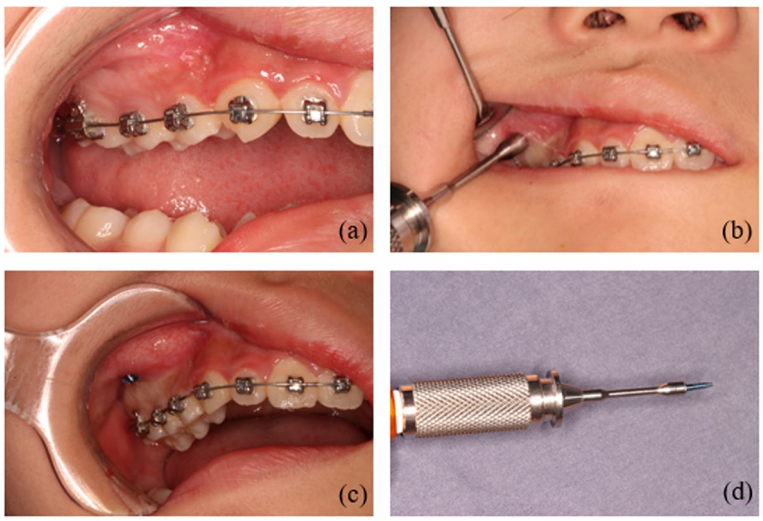

Fig. 1 (**a**)-(**c**) Miniscrew insertion preoperative, intraoperative, and postoperative; (**d**) Insertion instrument and miniscrew

the number of analgesic tablets consumed within 24 h. 5. Secondary outcomes 2: Recorded the incidence of adverse events, such as nausea, vomiting, and allergies [16].

Statistical analysis

Independent statisticians conducted the analysis based on the per-protocol set using GraphPad Prism 9.5.0. The Shapiro–Wilk test was employed to assess the normality of continuous variables. Given the non-normal distribution of data in this study, results were presented as "Median (Q1, Q3)", and comparisons between groups were made using the Mann–Whitney U test. Categorical variables were expressed as frequencies and percentages, with comparisons between groups performed using the χ^2 test. All statistical tests were two-sided, and a $P<0.05$ was considered statistically significant.

Results

General Information

During the study period, all inserted miniscrews remained stable and were not lost. A total of 68 patients were assessed and deemed eligible for the study, completing the trial successfully (34 in the experimental group and 34 in the control group). The experimental group had an age range of 21.00 (20.75, 24.00), with 10 males and 24 females; 23 cases involved the maxilla and 11 involved the mandible. The control group had an age range of 22.00 (20.00, 26.25), with 14 males and 20 females; 26 cases involved the maxilla and 8 involved the mandible. There were no statistically significant differences between the two groups in terms of gender ($P=0.310$), age ($P=0.267$), or insert site (maxilla or mandible, $P=0.883$). All participants completed the questionnaire (Table 1).

NRS Pain Scores

The NRS pain scores of the preemptive analgesia group were significantly lower than those of the control group at 2, 4, 6, and 8 h postoperatively (2 h-$P=0.40$, 4 h-$P=0.07$, 6 h-$P=0.11$, 8 h-$P=0.30$); however, there were no statistically significant differences in NRS pain scores between the two groups at 12 and 24 h postoperatively (12 h-$P=0.235$, 24 h-$P=0.250$). Additionally, there were no statistically significant differences in NRS pain

Table 1 Comparison of baseline between the two groups of patients with miniscrew insert [M (Q1, Q3)]

Groups	cases	Genders		Insertion sites		Age (years)
		Male	Female	Maxilla	Mandible	
Control group	34	12	20	26	8	22.00 (20.00,26.25)
Preemptive analgesia group	34	10	24	23	11	21.00 (20.75,24.00)
P		0.447		0.587		0.366

scores between different insert sites within each group ($P > 0.05$) (Tables 2 and 3).

Postoperative Medication Usage

Within 8 h postoperatively, there was a statistically significant difference in the proportion of patients taking analgesics between the control group [64.7% (22/34)] and the preemptive analgesia group [17.6% (6/34)] ($P = 0.013$). All patients who took postoperative medication consumed only one tablet of analgesic, and all self-administered medication records occurred within 12 h postoperatively (Fig. 2).

Adverse Reactions

No adverse reactions such as postoperative pain unresponsive to analgesics, persistent swelling beyond the expected inflammatory response, and any localized or systemic infection requiring additional treatment.

Discussion

As the paradigm of comfortable treatment evolves, pain management has garnered heightened attention among clinicians [17]. Roughly 80% of patients undergoing oral and maxillofacial surgery experience acute postoperative pain [18, 19], with 10% progressing to chronic pain [20]. Preemptive analgesia holds paramount significance in mitigating or preventing postoperative pain by diminishing the risk of neural sensitization [21]. An integrated approach encompassing preemptive analgesia, routine intraoperative anesthesia, and postoperative pain management yields superior analgesic outcomes, reducing opioid consumption and associated adverse reactions [22].

Table 2 Comparison of postoperative pain scores at different time points in two groups of patients with miniscrew insert [Score, M (Q1, Q3)]

Groups	Cases	2 h	4 h	6 h	8 h	12 h	24 h
Control group	34	2 (1,4)	2 (0.75,2.25)	0 (0,2)	0 (0,2)	0 (0,1.25)	0 (0,1)
Preemptive analgesia group	34	2 (0,3)	0 (0,2)	0 (0,0)	0 (0,0.25)	0 (0,0.25)	0 (0,0.25)
P		0.040	0.007	0.011	0.030	0.235	0.254

Table 3 Comparison of postoperative pain scores at different loci in two groups of patients with miniscrew insert [Score, M (Q1, Q3)]

Groups	cases	2 h	4 h	6 h	8 h	12 h	24 h
Control group							
Maxilla	28	3 (1.5,4)	3 (2,4)	1 (0,3)	1 (0,2,25)	0 (0,0.75)	0 (0,0.5)
Mandible	6	4 (1.5,4.25)	3.5 (3,4)	3.5 (2.25,4.75)	2.5 (0.5,3)	1 (0.25,1.75)	1 (0.25,1)
Preemptive analgesia group							
Maxilla	23	1 (3,0)	0 (0,1)	0 (0,0)	0 (0,1)	0 (0,2)	0 (0,3)
Mandible	11	2 (0,2)	2 (0,3)	0 (0,1)	0(0,1)	0 (0,1)	0 (0,1)
P(a)	0.096	0.071	0.108	0.108	0.053	0.066	0.072
P(b)	0.525	0.083	0.638	0.638	0.793	0.978	0.978

Note: **a** refers to the comparison within the control group between different insertion sites at the same time point; **b** refers to the comparison within the preemptive analgesia group between different insertion sites at the same time point

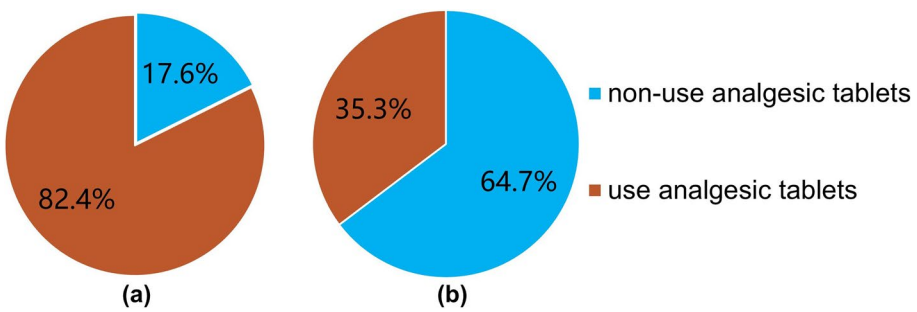

Fig. 2 Medication administration in the control group(**a**) and preemptive analgesia group(**b**) in the 12 h postoperative period

In our study, the surgical site did not significantly influence pain perception and discomfort. When assessing the severity of pain and discomfort, the preemptive analgesia group exhibited the lowest NRS score at 6 h, followed by a slight elevation at 8 h. This observation aligns with previous research findings [23–25]. The underlying rationale may be attributed to the peak plasma concentration of ibuprofen, achieved within 0.5 to 2.0 h after oral ingestion of sustained-release capsules, coinciding with the waning effect of local anesthetics, which typically lasts 1 to 2 h postoperatively. Consequently, as postoperative pain emerges, ibuprofen's peak plasma concentration provides maximal pain relief. Within the first 6 h postoperatively, preemptive analgesics continuously suppress the production of cyclooxygenase-2 enzyme through sustained release. However, between 6 and 8 h postoperatively, the efficacy of ibuprofen wanes, resulting in a mild increase in pain intensity. Beyond 8 h, as preemptive analgesics gradually lose their effectiveness and tissue damage and inflammatory responses persist, no significant difference in pain scores was observed between the experimental and control groups at 12 and 24 h.

Preemptive analgesia studies for surgeries encompassing extensive nociceptive fields, such as tumor resection, maxillary sinus surgery, and orthognathic procedures, have reported scant findings regarding the inhibition of central sensitization. Furthermore, scholars have highlighted the persistent stimulation of local nociceptors by various inflammatory mediators associated with surgical trauma, inducing peripheral sensitization [26]. Additionally, inflammatory reactions may serve as sensory signal sources, thereby precipitating central sensitization. For surgeries with intense postoperative inflammatory responses, severe pain is often anticipated. Conversely, in miniscrew insertion, which involves minimal trauma primarily consisting of bone compression and perforation of mucosa or gingiva, and with most procedures completed within 5 min, the degree of peripheral neural sensitization is relatively low [27]. Consequently, preoperative administration of lower doses of analgesics can achieve satisfactory analgesic effects. In this context, the preemptive analgesia strategy may exert an even more potent impact.

Kissin summarized three preemptive analgesic approaches currently employed in clinical trials: preoperative oral medication, preoperative, intraoperative, and early postoperative intravenous administration, as well as regional nerve block anesthesia for preemptive analgesia [28]. To achieve superior analgesic efficacy, multimodal analgesia is frequently adopted in clinical practice for perioperative pain management [29]. By integrating preemptive analgesia, routine intraoperative anesthesia, and postoperative pain management, improved analgesia can be achieved, with reduced opioid consumption and associated adverse reactions. For pain management following miniscrew insertion, oral analgesics are typically prescribed to alleviate postoperative pain. In this study, ibuprofen was selected as the test drug, as NSAIDs such as ibuprofen are recommended as first-line medications in pain management guidelines [30]. Compared to other NSAIDs (e.g., diclofenac, aspirin), low-dose ibuprofen exhibits favorable safety profiles with lower risks of gastrointestinal, hepatic, renal, and other adverse reactions [31].

To control variables, patients in the experimental group were all undergoing their first anchorage screw insertion surgery. Preliminary experimental results indicated a slight increase in pain perception after the second insert surgery. Similar conclusions have been reported in previous literature for surgeries involving local anesthesia, where, despite remaining relatively painless under monitored anesthesia care with topical anesthesia, a subtle increase in pain was observed during the second surgery compared to the first. This appears to be associated with reduced preoperative anxiety [32].

The limitation of this study stems from ethical considerations, as the timing and dosage of postoperative analgesic use were determined based on patients' subjective feelings. This could have influenced pain scores at different postoperative time points to some extent. Based on preliminary experimental results, patients receiving the preemptive analgesia protocol typically experienced pain scores not exceeding 3, negating the need for postoperative analgesic use. In contrast, patients without preemptive analgesia reported pain levels ranging from 0 to 5 within eight hours postoperatively. Given that acidic NSAID analgesics should be used at the minimum effective dose to meet clinical needs, ethical considerations precluded requiring all patients to take analgesics at fixed times and doses for standardized variable control. Despite potential biases introduced by this experimental design, results indicated that, under conditions allowing patients to self-administer analgesics postoperatively, the experimental group exhibited superior analgesia compared to the control group, with significantly lower analgesic use frequencies. Therefore, a general trend can be inferred: preemptive analgesia demonstrates a significant positive effect on pain relief following miniscrew insertion. In this research endeavor, despite the absence of statistical analysis on the disparities in preemptive analgesia outcomes between the anterior and posterior dental zones, we clinically noted that there was insignificant variation in pain intensity between these two zones approximately 24 h after the surgical procedure. Nonetheless, during the interval spanning from 24 to 72 h postoperatively, a slight inclination towards heightened pain was observed in the

anterior dental zone compared to the posterior zone. It is pertinent to mention that this preliminary observation necessitates rigorous further investigation for definitive analysis. However, it does not undermine the conclusions presented in this study and will indeed serve as a pivotal direction for our ongoing and future research endeavors.

Another limitation of this study is the reliance on participants' self-reported postoperative analgesic use, which may introduce variability in the assessment of pain management efficacy. Although patients were instructed to record their analgesic intake accurately, subjective reporting inherently lacks the standardization that objective monitoring methods could provide. Future studies incorporating electronic medication tracking or direct supervision may help enhance the accuracy of analgesic usage data.

Additionally, the study was conducted at a single center with a relatively small sample size (34 participants per group). While the sample size was determined based on power analysis and previous studies, the findings may not be fully generalizable to broader populations. Larger, multicenter trials are necessary to validate these results and further assess the effectiveness of preoperative ibuprofen administration in different clinical settings.

In contrast to surgical procedures involving significant trauma, clinicians often overlook the necessity of adequate analgesia in minimally invasive surgeries [33]. We endeavor to argue that pain, regardless of its severity, should be meticulously avoided in any clinical intervention. Even mild pain can elicit localized inflammation and impart discomfort upon patients, prompting them to avoid wound irritation, which may subsequently lead to inadequate wound cleansing, reduced oral intake, and compromised mood states. These consequences collectively contribute to suboptimal recovery outcomes.

While some studies on preemptive sedation for tooth extraction have suggested that NSAID administration post-extraction is more effective than pre-extraction [31–33], possibly due to extended inhibition of reactive inflammation, these studies involved postoperative analgesic use initiated before pain onset. In a broader sense, preventing peripheral sensitization is considered a preemptive analgesic effect. However, there is no conflict between preemptive analgesia and postoperative analgesic use. For pain management following miniscrew insertion, preoperative administration of analgesics to inhibit central sensitization induced by tissue damage is considered a more successful postoperative analgesic approach.

Conclusion

Preemptive analgesia with ibuprofen effectively reduces postoperative pain intensity following miniscrew insertion, significantly improving patient comfort and enhancing their overall acceptance of orthodontic treatment. The results of this study support the use of preoperative ibuprofen administration as a safe and effective perioperative pain management strategy, providing a more controlled pain experience for patients during the early postoperative period. This approach not only minimizes the need for additional analgesic medications but also contributes to better treatment compliance and a smoother overall orthodontic experience. However, further studies with larger sample sizes and multicenter designs are needed to confirm these findings and explore the long-term benefits of preemptive analgesia in orthodontic and oral surgical procedures.

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Not applicable.

CONSORT statement
This study adheres to CONSORT guidelines.

Authors' contributions
Hong-Yu Zhang: Conceptualization, Methodology, Investigation, Writing—Original Draft, Writing—Review & Editing, Visualization. Chao-Chen Rui: Methodology, Investigation, Writing—Original Draft. Li-Wen Su: Methodology, Formal analysis, Visualization. Yu-Jie Xiao and Meng-Di Nie: Methodology and Writing—Original Draft. Huan Sun and Yang Wu: Conceptualization, Methodology, Writing—Review & Editing, Project administration, Funding acquisition. All authors reviewed and approved the final manuscript.

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Data availability
Data will be made available on request.

Declarations

Ethics approval and consent to participate
The review board of the Wuhan University Medical Ethics Committee approved this retrospective study. Reference Number: [WDKQ2024] LUNSHEN(B46). Informed consent to participate was obtained from all participants and the parents or legal guardians of all participants under the age of 18. All experiments were performed in accordance with relevant guidelines and regulations.

Consent for publication
Written informed consent for publication of identifying images or other personal or clinical details was obtained from all participants and the parents or legal guardians of all participants under the age of 18.

Competing Interests
The authors declare no competing interests.

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