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Comparison of Ora-Aid Mucoadhesive Patch and Suture Techniques on Pain Following Tooth Extraction: A Randomized Controlled Clinical Trial

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Abstract

Background and objectives: Pain is a common issue following tooth extraction. Various methods, such as sutures or mucosal adhesives, alleviate post-extraction pain. This study aimed to compare the effectiveness of Ora-Aid mucosal adhesive patches and suturing in reducing postoperative pain after tooth extraction.

Materials and methods: This clinical trial involved 18 volunteer patients undergoing the extraction of their maxillary first premolar tooth. Each patient had two premolar teeth extracted during two visits, one on each side of the maxilla. Sutures and Ora-Aid were used to cover the extraction site during each visit. The severity of pain was assessed using a visual analog scale (VAS) at 5, 12, 24, and 48 hours post-extraction. Data was analyzed using One-way ANOVA and Wilcoxon rank tests with a significance level of $P < 0.05$.

Results: The study included 18 participants with a mean (SD) age of 18.27 (2.72) and 44.5% (8) of them were men. At the baseline measurement (5 hours post-surgery), there was no difference in pain levels between the two groups ($P > 0.05$). The results indicated no significant difference in pain scores between the two groups ($P = 0.445$). However, pain decreased over time in both groups ($P < 0.001$).

Conclusion: Both techniques effectively reduced post-extraction pain, and there was no significant difference between the two in terms of pain reduction. Therefore, dentists can use either sutures or Ora-Aid based on patient preference.

Keywords: Ora-Aid mucosal adhesive; Suture technique; Pain; Tooth extraction.

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1. Introduction

Tooth extraction is one of the most common dental treatments, involving a combination of surgical principles and physical mechanisms (1). However, tooth extraction is associated with several potential complications, such as bleeding, pain, and infection, both during and after the procedure (2). Therefore, the proper closure and maintenance of the extraction site is crucial for adequate wound healing (3). Surgical wound closure techniques can decrease dead space, minimize the risk of infection, and ensure the proper proximity of wound edges for acceptable aesthetic and functional results (4). Various wound closure techniques include non-absorbable sutures, synthetic absorbable sutures, surgical staples, and surgical adhesives (4). Mucosal adhesives in dentistry have become more common in recent years. One such mucosal adhesive is Ora-Aid (TBM, Gwangju, Korea). Ora-Aid is a new type of intra-oral patch used to protect affected areas such as post-implant sites, extraction sites, orthodontic sites, and ulcers. This intra-oral wound dressing protects the affected area and aids in natural healing. It is a non-eugenol protective dressing made of high-density hydrophilic polymers encapsulated in

hydrophobic synthetic mucoadhesive cellulose containing vitamin E, which can enhance homeostasis and wound healing. Ora-Aid is available in 25 mm × 15mm or 50 mm × 20 mm (5).

Compared to the suture technique, the use of tissue adhesives like Ora-Aid is less time-consuming and reduces patient discomfort. Sutures can cause issues such as leakage, flap detachment, bone exposure, necrosis, and pain, as well as tissue incompatibility which may lead to foreign body reactions and fistula formation (4,6,7). Sutures also have disadvantages such as challenges in controlling plaque, increased tissue response and secondary infection due to the potential for bacterial colonies to form (8,9).

In a study by Suthar et al. in 2020 that compared intraoral wound healing using 3-0 silk sutures and n-butyl-2-cyanoacrylate mucosal adhesive, the results showed that tissue adhesive leads to immediate hemostasis, reduced operation time, reduced postoperative pain, and better wound healing compared to 3-0 silk sutures (4). In a study by Jamdar et al. in 2020, they compared the clinical outcomes of intraoral mucosal incisions closed using n-butyl-2-cyanoacrylate. The study found that the use of cyanoacrylate and sutures had similar effects on pain, swelling, wound healing, and scar formation after intraoral surgery (10).

Since there is no consensus on the effectiveness of sutures versus mucosal adhesives in reducing pain, the current study aimed to assess the impact of two techniques: sutures and Ora-Aid mucosal adhesive, as a new method for applying intra-oral patches, on postoperative pain following tooth extraction.

2. Materials and methods

2.1. Design and Setting

This study was conducted at the Oral Medicine Department of the School of Dentistry, Yazd University of Medical Sciences between 2020 and 2021. The study was carried out following the Declaration of Helsinki guidance from the World Medical Association and Good Clinical Practice recommendations.

2.2. Study Population and Trial Design

A randomized clinical trial was conducted in which all participants volunteered for the extraction of their first maxillary premolar tooth for orthodontic purposes. The results were reported according to the Consolidated Standards of Reporting Trials.

Inclusion criteria were people with no systemic disease, no history of allergies to specific medications, and good oral hygiene. Teeth with abnormal anatomy after extraction were not included in the study.

Exclusion criteria included patients who did not show up on the designated follow-up treatment days. Patients were also excluded from the study if they needed to use painkillers for pain relief or antibiotics for secondary infection after the procedure. Furthermore, patients with systemic diseases that affect wound healing and post- operative pain were also excluded from this study.

The sample consisted of 18 eligible patients who visited the Oral and Maxillofacial Surgery Department of Yazd Shahid Sadoughi University of Medical Sciences in 2020-2021.

2.3. Procedure

Following a thorough clinical examination and an accurate medical history review, eligible patients who were confirmed for maxillary first tooth extraction for orthodontic purposes were enrolled. After written informed consent was obtained from the patients, their left and right premolars were coded with random numbers. The random sequence is created using simple random allocation. To determine the intervention group for each eligible individual, numbers from 1 to 18 are considered and assigned to intervention A or B. The first eligible individual is assigned the number 1, the second individual is assigned the number 2, and so on up to 18 patients in the groups. To blind the random allocation of participants, we seek help from the third person who is unaware of the interventions, and this table is given to them. When an eligible individual visits, based on their assigned number, the intervention group is verbally asked to the third person by phone. The individual is then assigned to one of the groups. For this purpose, lidocaine 2% with epinephrine 1.80000 was injected and after creating deep anesthesia based on a random number table, one of the teeth on the left or right maxillary first premolar was extracted (closed technique) by Oral and Maxillofacial Surgery resident and sutured by 0.3 Supasil silk thread (Supa Company, made in Iran) (Figure 1). To assess the extent of post-operative pain, each patient was given a visual analogue scale (VAS) form and was instructed on how to complete it. The visual analogue scale (VAS) is a 10 mm line representing pain intensity. It has endpoints that indicate 'no pain Following a thorough clinical examination and detailed medical history, we enrolled eligible patients with a confirmed diagnosis of needing to have their maxillary first premolar extracted for orthodontic reasons. We randomly coded patients' left and right premolars with numbers. We used 2% lidocaine with epinephrine for anesthesia and randomly selected one of the teeth for extraction using a closed technique performed by Oral and Maxillofacial Surgery resident. The extracted area was then sutured using 0.3 Supasil silk thread made by Supa Company in Iran. To assess post-operative pain, we gave each patient a visual analogue scale (VAS) form and explained how to use it. The VAS is a 10 mm line representing pain intensity, with endpoints indicating 'no pain at all' and 'pain as bad as it could be.' Patients used the line to indicate their perceived level of pain intensity (11,12). They recorded their pain levels on the chart 5, 12, 24, and 48 hours after the tooth extraction. After

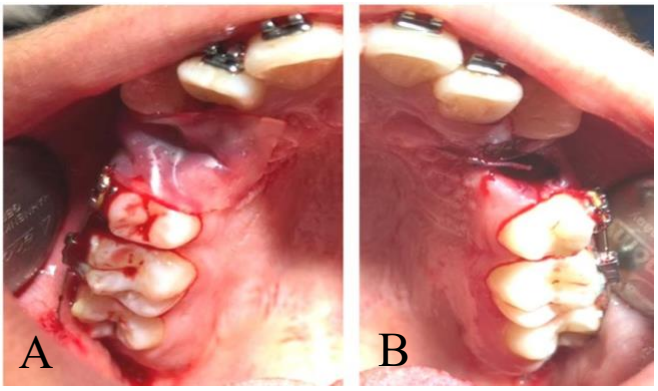

Figure 1. (A) Polymer-based non-eugenol wound dressing material (Ora-Aid, TBM Corporation, Gwangju, South Korea). (B) Suture technique used after first premolar extraction, utilized after first premolar extraction.

a two-week recovery period, another premolar tooth was extracted using the same method, and the area was covered with Ora-Aid mucosal adhesive made by TBM company in Gwangju, South Korea. To use the mucosal adhesive, we cleansed the wound area with saline solution, cut the Ora-Aid to the correct shape and size, removed it from the release film, and applied it to the wound. The dressing was gently pressed for 5-10 seconds to ensure it adhered. It is important to note that the dressing typically falls off within 6-12 hours, eliminating the need for a separate visit to remove it. It was explained to the patient that there is no need for re-covering the area after the adhesive falls off. The VAS form was given back to the patients to record pain levels 5, 12, 24, and 48 hours later. Patients were advised to avoid hot and hard foods and not to touch the wound area. Patients mark the line to show their perceived level of pain intensity. The distance between 'no pain at all' and the mark represents the patient's pain level (11,12). The patients recorded their pain on a chart 5, 12, 24, and 48 hours after tooth extraction. After the recovery period (two weeks), another premolar tooth was extracted by the same resident last year and the area was covered with Ora-Aid mucosal adhesive (TBM company, Gwangju, made in South Korea) (Figure 1). The method through which the mucosal adhesive was used is as follows: as the first step, the wound area was rinsed with saline solution, and the Ora-Aid was trimmed to the correct shape and size. Using forceps, it was removed from the transparent release film and placed on the wound. The dressing was then gently pressed for 5-10 seconds to ensure it adhered to the wound. The Visual Analogue Scale (VAS) form was returned to the patients so that they could record pain 5, 12, 24, and 48 hours later. Patients were prescribed not to consume hard and hot foods and not to retouch the wound area.

2.4. Outcomes (Primary and Secondary)

The main objective of this study was to compare the effects of the suture technique and Ora-Aid mucoadhesive patch on reducing pain after tooth extraction. Therefore, the severity of pain was the primary outcome. There were no secondary outcomes in this study.

2.5. Randomization

Based on the block simple allocation method, an Oral and Maxillofacial Surgery resident extracted one of the premolars from the left or right maxillary and then sutured it using 0.3 Supasil silk thread (Supa Company, made in Iran) or covered it with Ora-Aid mucoadhesive paste (TBM company, made in South Korea). After a two-week recovery period, another premolar tooth was extracted, and a different method was used to cover the wound area. To determine the intervention group for each eligible individual, numbers from 1 to 18 are considered and assigned to intervention A or B. The first eligible individual is assigned the number 1, the second individual is assigned the number 2, and so on up to 18 patients in the groups. To blind the random allocation of participants, we seek help from the third person who is unaware of the interventions, and this table is given to them. When an eligible individual visits, based on their assigned number, the intervention group is verbally asked to the third person by phone. The individual is then assigned to one of the groups. It's important to note the expert statisticians were also unaware of the method used while analyzing the data.

2.6. Sample Size Calculation

The sample size was determined to be 18 based on a previous study (4), with a significance level (alpha) of 5% and a study power of 80%.

2.7. Statistical Analysis

In terms of statistical analysis, since pain is an ordinal measure, non-parametric tests were used to compare it between the two groups. The data required for analysis included frequency and percentage, mean, and standard deviation. Since the data for each patient was paired, the Wilcoxon rank test was used to compare the pain experienced with each intervention. The Friedman test was used to analyze the VAS score in two groups. Additionally, the time variable in the repeated measures analysis of variance (RM-ANOVA) was significant, and a post hoc test (Greenhouse- Geisser test) was used. All the statistical analyses were performed using SPSS version 24 (SPSS Inc., IL, USA) with a significance level 0.05.

3. Results

In this study, 18 patients took part, with 10 (55.6%) were fem-

ale and 8 patients were male. The average age was 18.27 years with a standard deviation of 2.72. The findings indicated that the error distribution in the study's quantitative variables, such as age and repeated pain scores, followed a normal distribution ($P > 0.05$).

Table 1 shows that both groups' pain scores varied over time ($P < 0.001$). The results of the Wilcoxon test indicated no significant difference between the two groups at each measured time ($P > 0.05$). Overall, the pain experienced in the mucosal adhesive group was less than that in the suture group; however, this difference was not statistically significant.

Analysis of the Friedman test trend in pain scores over time revealed a significant linear trend ($P < 0.001$). This indicates that the average pain score in one group (tissue adhesive) has been lower than that in the other group (suture) throughout the study period (Figure 2).

Table 1. Comparing pain scores in two groups.

Method		Time 5 H	12 H	24 H	48 H	P-value*
Tissue Adhesive	Mean	5.57	5.12	4.45	3.95	< 0.001
	Std. Deviation	1.54	1.713	1.60	1.64	
Suture	Mean	6.14	5.81	4.98	4.26	< 0.001
	Std. Deviation	1.44	1.53	1.44	1.46	
P-value*		0.14	0.07	0.07	0.273	

*Wilcoxon Rank test

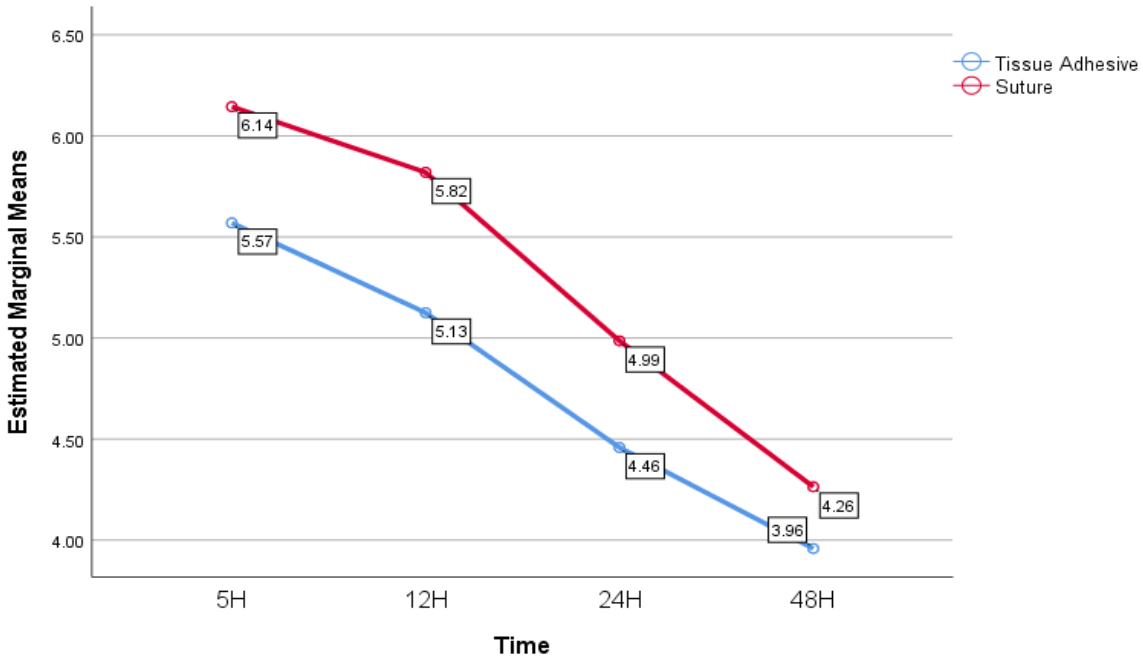

Figure 2. Pain score trend during four times.

4. Discussion

One of the crucial subjects in dentistry is the impact of using different types of mucosal adhesives. To the best of our knowledge, there has been little published research in Iran and worldwide on the Ora-Aid mucosal adhesive as a new concept for applying intra-oral patches in the field of dentistry so the study compared the effects of suture and Ora-Aid mucosal adhesive on postoperative pain following tooth extraction.

Given that the pain and bleeding are common after tooth extraction. Proper wound closure is crucial for the healing process, and various techniques like suturing and mucosal adhesives can help control bleeding and pain (3). The study involved healthy volunteers who had their first maxillary premolars extracted for orthodontic reasons. This is different from previous studies such as Ghoreishian et al. (13), and Joshi AD et al. (14), who focused on damaged lower third mandibular teeth, which generally have a higher risk of injury

and pain due to the greater strength of the mandibular bone and the need for deeper anesthetics. In the current study, both techniques were performed on one patient, which made the gender, oral health status, systemic condition, and nutrition the same in both methods. However, in most studies, such as Rewaing et al. (15) and Gogulanathan et al. (16), two techniques were studied in different individuals. Given that pain thresholds vary from person to person, comparing pain scores will provide more accurate results when the affective characteristics are matched. Also, the Visual Analogue Scale was used to evaluate pain intensity. The visual analog scale (VAS) score is a common and reliable assessment used for measuring postoperative pain during dental treatments. It provides a useful and straightforward method for assessing pain intensity among dental patients (11,17).

The findings showed that both techniques resulted in a decreasing trend in pain scores over time, and the mean pain score was slightly lower in the mucosal adhesive group compared to the suture group. However, this difference was not statistically significant. These results are consistent with other studies such as Suthar et al. (4), Rewainy et al. (9), Phani Himaha Devi Vaaka et al. (18), and Abdeshahi SK et al. (19) emphasized the advantages of mucosal adhesives over sutures. Notably, the study used Ora-Aid mucosal adhesive, while previous research typically used cyanoacrylate adhesives (4,9,18,20). The adhesive wound covering material used in this study was Ora-Aid (TBM, Gwangju, Korea) that mix Containing Polymers and Vitamin E. Ora-Aid mucosal adhesive was used as a new technique which made the present study as one of the first studies to make use of this adhesive in Iran. Ora-Aid is composed of high-density hydrophilic polymers encapsulated in hydrophobic synthetic mucoadhesive cellulose containing vitamin E, which can enhance homeostasis and wound healing (5). In Iran, only one study has compared the use of the Ora-Aid mucoadhesive patch with Trident for the treatment of recurrent aphthous stomatitis. The study found that Ora-Aid was significantly more effective in reducing pain and burning sensation (21).

5. Limitations

It's essential to acknowledge the limitations of our research. The small sample size was a significant limitation, which was unavoidable due to the COVID-19 pandemic, resulting in an insufficient number of patients and frequent closure of medical centers. This emphasizes the necessity for further research involving a larger number of participants in this field. Additionally, pain perception is subjective and varies based on individual traits. Establishing a standardized pain baseline is crucial for consistency in research, which was identified as a limitation of this study. Another limitation of the study is that the extractions for a patient at each site did not take place at the same time, which can result in bias. It is suggested that further research be conducted to assess additional outcomes, such as wound healing, patient comfort, and application time, to gain a more comprehensive understanding of the benefits and drawbacks of each method.

6. Conclusion

The study's findings suggest no statistically significant difference between the pain perceptions in both groups. Both techniques effectively reduce post-extraction pain so, dentists can use either sutures or Ora-Aid based on patient preference. Further research in this area is recommended to build upon these findings.

Ethics

The data was collected after obtaining written informed consent from all participants. All methods were conducted by the relevant guidelines and ethical standards of the Declaration of Helsinki. The study protocol was approved by the ethics committee of the Yazd Shahid Sadoughi University of Medical Science (IR.SSU.REC.1399.066) and registered in the Iranian Registry of Clinical Trials (IRCT20210306050604N1).

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Using artificial intelligence (AI)

None.

Author contributions

Adele Pouyafard: Conceptualization, Methodology, Writing - Review & editing
Ali Karbalaeaian: Data curation, Formal analysis
Mohsen Barzegar: Conceptualization, Methodology, Writing - Original draft, Writing - Review & editing

Conflict of interest

The authors declare no conflict of interest.

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