EVALUATION OF SATISFACTION AND ACCEPTABILITY OF A CENTELLA ASIATICA-BASED ORAL ULCER PATCH AMONG HEALTHY VOLUNTEERS

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ARTICLE HISTORY
Received: 1 September 2025 **Revised:** 22 September 2025 **Published:** 7 October 2025

ABSTRACT
This study evaluated the satisfaction with a standardized *Centella asiatica*-infused oral ulcer patch among healthy volunteers. A non-randomized, uncontrolled clinical trial was conducted at the Faculty of Dentistry, Prince of Songkla University, with 20 participants aged 18-65 years who applied a 1.40 cm patch to the inner lower lip for three hours. Satisfaction was assessed using patient-reported outcome measures (PROMs), covering ease of use, removal, adhesion, comfort, taste, texture, odor, overall satisfaction, and willingness for future use and recommendation. Most participants reported that the patch was easy or very easy to apply (75%) and remove (75%). Adhesion at the intended site was maintained throughout in 35% of cases, while 65% reported partial displacement without complete detachment. Odor received the highest satisfaction rating (90%), followed by taste (65%) and texture (70%). Overall satisfaction was reported by 70% of participants, and willingness to recommend the product to others was noted by 75%. Additionally, 65% expressed an intention to use it in the future. No serious adverse events occurred, with only mild and transient issues, such as temporary taste alteration or adhesion to adjacent teeth, reported. In conclusion, the *C. asiatica*-infused oral ulcer patch demonstrated favorable user satisfaction, ease of handling, and acceptability among healthy volunteers. Refinements in sensory attributes and adhesion may further improve the user experience.
Keywords: Oral Ulcer Patch, Centella asiatica, Satisfactory, Acceptability

CITATION INFORMATION: Pomnum, P., Puttarak, P., & Teerakanok, S. (2025). Evaluation of Satisfaction and Acceptability of a *Centella asiatica*-Based Oral Ulcer Patch among Healthy Volunteers. *Procedia of Multidisciplinary Research, 3*(10), 30.

INTRODUCTION

Aphthous ulcers are common lesions found in the oral cavity, associated with various factors such as immune system disorders, gastrointestinal diseases, iron deficiency anemia, and physical trauma. Common symptoms include severe pain or burning sensations in the affected area, which can significantly impact daily life. Treatment typically focuses on symptom management. If the underlying cause is identified, addressing that cause is crucial. Treatment often involves the use of topical medications, commonly steroids and anesthetics. In recent years, medicated oral patches have been introduced to help the medication adhere to the lesion for a longer duration, thereby reducing pain. Additionally, herbal remedies with wound-healing and pain-relieving properties (Vaillant & Samimi, 2016), such as *C. asiatica* and *Aloe vera*, have been incorporated into treatment approaches.

C. asiatica (L.) Urb., commonly known as gotu kola, is a perennial plant in the family Apiaceae. Its leaves are green with slight hair, and it has long green petioles. The leaves contain key chemical components, primarily pentacyclic triterpenes such as asiatic acid, madecassic acid, asiaticoside, and madecassoside. These compounds exhibit wound-healing properties, promote tissue regeneration, inhibit the growth of pus-forming bacteria, and reduce inflammation. Traditionally, fresh *C. asiatica* is used by taking one handful of the plant, thoroughly washing it, pounding it into a fine paste, and extracting its juice. The juice is generously applied to the affected area every hour for the first hour and subsequently 3-4 times daily until the wound heals. There are reports of using wound patches containing *C. asiatica* extract for treating wounds in animal studies. It was found that the group treated with *C. asiatica*-infused oral ulcer patches presented wound healing comparable to the group treated with commercially available standard wound patches (Chokevivat et al., 2005).

A. vera (L.) Burm is short, segmented stems and succulent, water-retentive leaves. The leaves are arranged in a spiral around the stem, thick, elongated, and tapering to a pointed tip. The edges of the leaves are serrated with small spines. The leaves retain moisture well and contain a translucent, light green gel inside. The gel from *A. vera* leaves contains key chemical components, primarily polysaccharides, which have properties that promote wound healing, reduce pain, alleviate inflammation, and eliminate bacteria (Boudreau & Beland, 2006).

The present study's oral ulcer patch is an oral ulcer patch containing a mixture of *C. asiatica*, *A. vera*, *Ocimum basilicum* (sweet basil), sodium alginate, and glycerin. The patch has undergone analysis to determine the quantities of its active compounds, including pentacyclic triterpenes such as asiatic acid, madecassic acid, asiaticoside, and madecassoside (Mingkwan, 2020). Furthermore, the oral ulcer patch, which has a *C. asiatica* extract concentration of 0.99% w/w, has been subjected to irritation tests in animal models. The findings showed no indications of irritation in the subjects tested. Consequently, the investigator aims to assess user satisfaction with oral ulcer patches featuring standardized *C. asiatica* extract in healthy volunteers. This research aims to provide preliminary evidence on the acceptability and user experience of the *C. asiatica*-infused oral ulcer patch, supporting future studies in patients with active oral ulcers.

LITERATURE REVIEWS

Oral ulcerations

Oral ulcerations are common lesions in the oral cavity with various etiologies. The most frequent causes include infections, immune-mediated conditions, and traumatic injuries. Among the immune-related causes, Recurrent Aphthous Stomatitis (RAS) is the most prevalent type of oral ulceration. Although the exact etiology remains unclear, RAS is believed to be multifactorial in origin, with associated risk factors such as psychological stress, vitamin deficiencies, and systemic diseases. RAS is classified into three clinical forms: minor, major, and herpetiform. All forms of RAS are typically painful and exhibit a characteristic appearance consisting of a central necrotic yellow area surrounded by a prominent erythematous halo.

Diagnosis is generally made based on clinical evaluation. The first-line treatment commonly involves the use of topical corticosteroids to alleviate symptoms (Fitzpatrick et al., 2019).

C. asiatica-infused oral ulcer patch

C. asiatica-infused oral ulcer patch (manufactured by HerbaciaTex Co., Ltd.) is prepared by first dispersing sodium alginate (43.68%), *O. americanum* seed extract (8.74%), and *A. vera* gel powder (17.47%) in glycerin (29.12%). Distilled water is then added, and the mixture is stirred until a clear solution forms. Afterward, 0.99% concentrated *C. asiatica* extract is added and mixed thoroughly. The resulting solution is cast onto a backing layer of aluminum foil, then dried in a hot air oven at 55°C for 8 hours. The thickness of the *C. asiatica*-infused oral ulcer patch is controlled by measuring the weight of the solution before casting to achieve a final thickness of 15 ± 0.5 micrometers. After drying, the patches are cut into specified sizes, resulting in the *C. asiatica*-infused oral ulcer patch. The patches are then analyzed to determine the content of pentacyclic triterpenes (asiatic acid, madecassic acid, asiaticoside, and madecassoside) (Mingkwan, 2020).

Analysis of the active compounds in the *C. asiatica*-infused oral ulcer patch indicated the presence of asiatic acid at 26.24 mg/g, madecassic acid at 106.85 mg/g, asiaticoside at 383.43 mg/g, and madecassoside at 108.57 mg/g, totaling 625.09 mg/g of pentacyclic triterpenes. This value corresponds to 99.74% of the labeled amount for the 0.99% w/w concentrated *C. asiatica* extract.

Safety of the _C. asiatica_-infused oral ulcer patch

All ingredients in the *C. asiatica*-infused oral ulcer patch is classified as a food-grade substance, approved for human and animal consumption. The amounts of each ingredient used in the ulcer patch are as follows:

Table 1 Ingredients of the *C. asiatica*-infused oral ulcer patch

No.	Ingredient	Amount (g, %)
1	Sodium alginate	0.359 (23.9)
2	Glycerin	0.359 (23.9)
3	*A. vera* powder	0.216 (14.4)
4	Tamarind extract powder	0.537 (35.8)
5	*C. asiatica (L).* urban extract	0.03 (2)
	(45% Pentacyclic triterpenes)	(0.013)

Based on the ingredient content per patch (weighing 1.5 grams), none of the components exceed the daily intake limits set forth by the Thai Food and Drug Administration (FDA) according to its announcement on the use of key ingredients in dietary supplements. Thus, the composition of *C. asiatica*-infused is within the safety limits recommended by the authority.

Advantages of the _C. asiatica_-infused oral ulcer patch

1) Stronger adhesion compared to paste or gel formulations.
2) Stable in the oral cavity, resistant to saliva and slightly alkaline pH, for up to 3 hours.
3) Protects the ulcer from contact with oral structures such as teeth, tongue, and even orthodontic appliances like braces.

Satisfaction and Acceptability

Patient satisfaction and acceptance are crucial factors in determining the effectiveness of mucoadhesive oral patches, since adherence by customers is heavily influenced by how pleasant, easy to use, and handy the patches are. Studies on recurrent aphthous stomatitis (RAS) showed that patients frequently prefer mucoadhesive patches to conventional therapies. For example, Shemer et al. found that a citrus oil-magnesium salt patch enhanced clinical results while also being preferred by patients because of its simplicity of use, fewer adverse effects, and greater willingness to reuse compared to oral rinses (Shemer et al., 2008). Similarly, a

randomized controlled study by Molania et al. demonstrated that cinnamaldehyde-based patches minimized ulcer size and pain while receiving favorable ratings for usability and patient participation. This points to the importance of satisfaction as both an outcome and a driver of treatment adherence (Molania et al., 2022).

Several reviews reported formulation-related factors that directly impact satisfaction. Flexibility and comfort are often cited as significant characteristics because inflexible or bulky dose forms can cause irritation or discomfort in the oral cavity. Gilhotra observed that mucoadhesive films are more comfortable than tablets because they adapt well to mucosal surfaces and resist premature detachment by saliva (Gilhotra et al., 2014). Jacob et al. (2021) also indicated that lightweight, flexible patches that are resistant to oral mechanical stress improved overall satisfaction (Jacob et al., 2021).

In addition to mechanical features, sensory aspects such as taste, odor, and texture play a crucial role in determining consumer satisfaction. A review of buccal delivery systems found that unpleasant taste or gritty texture is a key obstacle to compliance, while neutral or pleasant sensory qualities promote appreciation and encourage reuse. (Jain et al., 2024).

Adherence and retention time of the oral patch are also essential factors in determining satisfaction. Strong but non-irritating mucoadhesive properties enhance confidence in the product's efficacy and ease of use. A study of polymer features reveals that physicochemical parameters, such as swelling, chain interpenetration, and hydration capacity, impact adhesion strength and durability, thereby influencing the perceived reliability of the patch (Zhang, 2020).

Finally, ease of application and removal is crucial to acceptance. Studies show that patients who have trouble applying or removing the patch are less likely to continue using it. Conversely, patches that can be applied quickly and removed without discomfort are more likely to be accepted and suggested to others (Molania et al., 2022; Shemer et al., 2008).

RESEARCH METHODOLOGY

Study Design and Setting

This was a non-randomized, uncontrolled clinical trial conducted at the Faculty of Dentistry, Prince of Songkla University, Thailand. The study was approved by the Human Research Ethics Committee of the Faculty of Dentistry, Prince of Songkla University, prior to initiation (project number EC6804-018).

Participants

Healthy volunteers aged 18-65 years were recruited between June and July 2025 through posted announcements at the faculty. Inclusion criteria were: age 18-65 years, good general health, and non-smokers. Exclusion criteria included orthodontic appliances or dentures, oral lesions, recent use of medications (antihistamines, steroidal anti-inflammatory drugs, or NSAIDs), oral wound dressings, mouthwash, or alcohol within two weeks; recent dental procedures or toothpaste change; allergy to *C. asiatica*, *Aloe vera*, tamarind, sodium alginate, glycerin, coriander, or celery; xerostomia; pregnancy or breastfeeding; inability to read and write Thai; and concurrent participation in other studies. Written informed consent was obtained from all participants.

Sample Size

Sample size was calculated using G*Power version 3.1.9.7, which indicated 14 participants. Allowing for a 20% dropout rate, 20 participants were enrolled.

Procedures

Baseline data, medical history, and vital signs were recorded. Each participant underwent an oral examination by a specialist dentist, and intraoral photographs were obtained using a standardized digital camera. Participants rinsed with 15 mL sterile saline, washed their hands according to the seven-step technique, and received video instructions on patch application and self-photography.

Each participant applied a 1.40 cm *C. asiatica*-infused oral patch to the inner lower lip adjacent to the left lateral incisor, pressing for three seconds. Adhesion and adverse events were self-assessing every 30 minutes for 3 hours, with six assessments in total. During the first hour, participants refrained from eating, drinking, or manipulating the patch under investigator supervision; in the following two hours, they resumed normal activities but minimized tongue contact and consumed water only through a straw. If detachment occurred, participants reapplied the patch within one minute or used a replacement patch. At 3 hours, any remaining material was removed, followed by a final intraoral examination and photograph.

Outcomes

The primary outcomes were patient-reported outcome measures (PROMs) evaluating comfort, tolerability, and satisfaction.

Data Analysis

Demographic characteristics were summarized using descriptive statistics. PROMs were analyzed as percentages to describe adhesion performance and participant-reported tolerability.

RESEARCH RESULTS

Participant Characteristics

A total of 20 participants completed the study without exclusions or withdrawals. Detailed demographic data, including sex and age distribution, are presented in Table 2. The mean age was 36.05± 10.37 years.

Table 2 Demographic data of the subject

Demographics data	Description	Number	Percentage
Gender	Male	4	20
	Female	16	80
	Total	20	100.0
Age (Years)	Less than 20	0	
	20-30	9	45
	31-40	4	20
	41-50	5	25
	More than 50	2	10
	Total	20	100.0

Patient-Reported Outcome

Patient-reported outcomes regarding comfort, retention, satisfaction, and future use are summarized in Table 4. Overall, ratings indicated favorable ease of use, satisfactory retention at the intended site, and high satisfaction across most evaluated attributes. No participants reported difficulty with application, and complete detachment of the patch was not observed.

Participants provided qualitative feedback to support their ratings. Those who described patch removal as “medium” noted occasional adhesion to both the inner lip and an adjacent tooth, requiring gauze for detachment from the tooth surface, whereas removal from the lip could be accomplished using fingertips. One participant reporting dissatisfaction with taste described a transient abnormal flavor perception during application. Suggested improvements included enhancing flavor and odor to increase product appeal, simplifying packaging for easier opening, providing clearer side identification and usage instructions, and addressing unintended adhesion to teeth. For potential use in individuals with orthodontic appliances, some participants recommended increasing patch thickness to prevent perforation and reduce irritation. Willingness to recommend the product was generally favorable; however, some participants expressed hesitation due to the absence of personal experience using the patch during an active ulcer episode, creating uncertainty about its effectiveness in that context.

Table 3 Patient-Reported Outcome Measures (PROMs) (n = 20)

Parameter	Criteria	Participants response (%)
Part I. Comfortable		
1) Ease of use of the oral ulcer patch	Very easy	10 (50)
	Easy	5 (25)
	Medium	5 (25)
	Somewhat difficult	–
	Very difficult	–
2) Ease of removal of the oral ulcer patch	Very easy	7 (35)
	Easy	8 (40)
	Medium	5 (25)
	Somewhat difficult	–
	Very difficult	–
3) The oral ulcer patch's ability to stay in the desired location	Did not adhere to the desired location at all	–
	Partially displaced but remained near the desired location	13 (65)
	Adhered and stayed at the desired location throughout	7 (35)
Part II. Satisfactory		
1) Duration of retention of the oral ulcer patch	Very dissatisfied	–
	Slightly satisfied	–
	Moderately satisfied	8 (40)
	Very satisfied	8 (40)
	Extremely satisfied	3 (15)
2) Texture of the oral ulcer patch	Very dissatisfied	–
	Slightly satisfied	–
	Moderately satisfied	10 (50)
	Very satisfied	7 (35)
	Extremely satisfied	4 (20)
3) Taste of the oral ulcer patch	Very dissatisfied	–
	Slightly satisfied	–
	Moderately satisfied	7 (35)
	Very satisfied	9 (45)
	Extremely satisfied	4 (20)
4) Odor of the oral ulcer patch	Very dissatisfied	–
	Slightly satisfied	–
	Moderately satisfied	4 (20)
	Very satisfied	11(55)
	Extremely satisfied	7 (35)
5) Overall participant satisfaction	Very dissatisfied	–
	Slightly satisfied	–
	Moderately satisfied	7 (35)
	Very satisfied	9 (45)
	Extremely satisfied	5 (25)
Part III. Willingness to use and recommend		
1) Intention to use the oral ulcer patch in the future	Wound not use	1 (5)
	Not sure	6 (30)
	Would use	13 (65)
2) Willingness to recommend the oral ulcer patch to others	Wound not recommend	1 (5)
	Not sure	4 (20)
	Would recommend	15 (75)

DISCUSSION & CONCLUSION

The present study investigated the usability, safety, and user perceptions of the *C. asiatica*-infused oral ulcer patch in healthy volunteers. The results showed a high level of overall satisfaction, favorable ease-of-use ratings, and few adverse events, with no serious adverse events reported throughout the study period.

In terms of usability, the majority of participants said the patch was easy or very easy to apply and remove, though some participants experienced moderate difficulty due to adhesion to tooth surfaces. Similar problems have been reported in other studies, where contact with non-target surfaces can affect the comfort and acceptability of the user (Colley et al., 2018).

Patient satisfaction with the *C. asiatica*-infused oral ulcer patch was investigated across various aspects, namely retention duration, sensory properties (taste and odor), texture, and overall acceptability. Most participants pointed to the average retention time of 96 minutes to be adequate, with those achieving prolonged adhesion expressing a higher level of satisfaction. Duration of adhesion is one of the key factors of perceived effectiveness, as users frequently prefer longer retention with better therapeutic benefits and convenience (Hearnden et al., 2012; Madhav et al., 2009). However, early detachment within 30 minutes with dissatisfaction, which was caused by mechanical interference during speech or oral movements, suggests the importance of improving stability in dynamic oral environments.

Taste and odor were important factors in levels of satisfaction. Although the majority of participants rated both as pleasant or acceptable, a small percentage dissatisfaction with the taste, mentioning transient abnormalities during patch use. Odor was consistently well received, aligning with previous evidence that a neutral or pleasant odor improves product acceptability and promotes favorable user perceptions (Colley et al., 2018). These findings indicate that, while the *C. asiatica*-infused oral ulcer patch achieved high odor acceptability, taste improvement is still an area for further study.

Texture had an impact on participant satisfaction as well. While the majority reported moderate to high satisfaction, some noted a preference for smoother or less adhesive textures, similar to previous findings that mucoadhesive strength should balance retention and comfort (Nautiyal, 2023).

Overall, satisfaction levels were high, with the majority of participants indicating that they were very or extremely satisfied. The majority of participants stated they would use the patch again and recommend it to others; however, some of them were hesitant because they were unsure about its performance during active ulcer periods. This emphasizes the importance of testing the patch under symptomatic conditions in order to confirm therapeutic efficacy and user perceptions in practical situations. Participants' feedback suggested specific areas for product improvement, including taste enhancement, more user-friendly packaging with clearer placement indicators, prevention of unintended tooth adhesion, and increased thickness for patients with orthodontic appliances to prevent perforation and reduce irritation.

Once the therapeutic benefits of the *C. asiatica*-infused oral ulcer patch have been validated in symptomatic patients, it may be a viable option for managing oral ulcers. Clinicians should be aware of its favorable safety and usability aspect, as well as minor issues with taste and adhesion that may affect patient satisfaction. Implementing patient-centered improvements, particularly in flavor, odor, and application design, might increase usage and acceptance. Future clinical trials in patients with active oral ulcers are required to confirm efficacy, assess healing outcomes, and determine its role in comprehensive oral ulcer management strategies.

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Data Availability Statement: The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Conflicts of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.