



Comparative evaluation of use of face ice pack wrap and Romo-Vac drain in post-operative oedema and pain of mandibular fractures: a randomized controlled trial

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Abstract (J Korean Assoc Oral Maxillofac Surg 2025;51:294-301)

Objectives: This study aimed to compare the effectiveness of cryotherapy using a facial ice pack wrap and Romo-Vac drainage in postoperative management of patients undergoing open reduction and internal fixation (ORIF) for mandibular fractures, with a focus on reduction of oedema, pain relief, mobility limitation, and patient satisfaction.

Materials and Methods: A prospective, randomized, open-label, monocentric clinical trial was conducted on 30 patients with mandibular fractures requiring ORIF. Participants were randomly assigned to receive either a facial ice pack wrap (Group I) or Romo-Vac drainage (Group II) postoperatively. Standardized surgical and pharmacological protocols were followed. Oedema was assessed using linear facial measurements on Days 0, 1, 3, 7, and 21. Pain was measured using a visual analogue scale, and subjective parameters—comfort, mobility, and satisfaction—were evaluated via structured patient questionnaires.

Results: Group I demonstrated significantly reduced postoperative swelling compared to Group II ($P=0.001$), with the largest difference on Day 3. Pain scores were consistently lower in Group I, though not statistically significant. Group I participants reported significantly less discomfort ($P=0.001$), fewer mobility limitations ($P=0.001$), and greater overall satisfaction ($P=0.001$) than those in Group II. The Romo-Vac drain was associated with more postoperative inconvenience and movement restrictions.

Conclusion: Cryotherapy using a facial ice pack wrap is more effective than Romo-Vac drainage in minimizing postoperative oedema and discomfort following ORIF in mandibular fracture cases. It also improves patient satisfaction and facilitates early mobility, supporting its use as a preferred post-operative care strategy.

Key words: Oedema, Drain, Mandibular fractures, Cryotherapy

[paper submitted 2025. 5. 8 / accepted 2025. 8. 8]

I. Introduction

Facial oedema, pain, and ecchymosis characterize the post-operative sequelae of a range of craniomaxillofacial treatments, including facial fracture management, orthognathic surgery, and cosmetic facial surgery¹.

The body's inflammatory reaction to surgical trauma is the main cause of post-operative oedema. Increased vascular permeability results from the release of inflammatory mediators during surgery for mandibular fractures, which is caused by the manipulation of soft tissues and bone. Fluids, particularly inflammatory exudates, can build up in the tissues surrounding the surgical site as a result of this process. White blood cells, proteins, and other mediators are abundant in inflammatory exudates, which aid in the development of pain and oedema. Serum, fibrinogen, and leukocytes make up the majority of the exudate; these substances cooperate to promote the healing process but also increase the amount of fluid in the interstitial space, which causes discomfort and oedema².

The use of topical ice at the site of injury to reduce regional pain and oedema is known as cryotherapy³. Cryotherapy lowers the temperature of the soft tissues and causes local vaso-

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constriction of the arterioles in the anatomical area. This leads to a decrease in tissue perfusion, a reduction in metabolic responses, and a reduction in the inflammatory process^{1,3-5}. Cryotherapy lowers oedema and offers an analgesic treatment option. However, cryotherapy treatment plans differ in the published literature, and the craniomaxillofacial community has not embraced standard practice. There are several ways to apply cold therapy to the face, including chemical packs, gel packs, rubber ice bags, a hilotherm cooling system⁶⁻⁸, and makeshift tools like plastic bags and ice-filled gloves.

Suction drains can be used to collect biological fluids, such as blood or pus. They are constant drains that maintain a low pressure gradient. The collecting reservoir of an active drain uses negative pressure to exchange fluid; if the vacuum is removed, the drain may malfunction.

This study aims to examine the extent of oedema reduction, pain alleviation, and patient-reported outcomes linked to these two therapies. This study offers a thorough evaluation of both treatment techniques by examining characteristics like visual analogue pain levels, postoperative swelling measurements at various time intervals, and subjective satisfaction ratings. The results can provide significant insights into enhancing postoperative care practices for better patient outcomes.

The researchers made the hypothesis that using face ice pack wrap would be superior to Romo-Vac drain. Measurements of facial oedema, pain scale, an evaluation of comfort, an analysis of how ice pack wrap affected mobility were particular objectives of the study.

II. Materials and Methods

A prospective *in vivo* study was conducted in the Department of Oral and Maxillofacial Surgery between July 2024 and March 2025. The study population included patients aged 18 to 45 years who presented with a history of facial trauma and were diagnosed with isolated mandibular fractures requiring open reduction and internal fixation (ORIF) under general anaesthesia. All participants were thoroughly informed about the study procedures and potential risks, and written informed consent was obtained from each patient prior to inclusion. A detailed case history was obtained.

The study protocol adhered to institutional guidelines and applicable laws, with ethical clearance obtained from the Institutional Ethics Committee (Reg. No. DYPDCH/DPU/EC/583/190/2023). Clinical trial reporting followed the Consolidated Standards of Reporting Trials (CONSORT) and the

Declaration of Helsinki on ethical principles.

A total of 30 patients meeting the inclusion criteria were enrolled. Exclusion criteria included patients with systemic illnesses or comorbid conditions, a history of abnormal cold responses including cold intolerance or Raynaud's phenomenon, renal or hepatic impairment, blood dyscrasias, current or previous peptic ulcers, cardiovascular disease, or known hypersensitivity, allergy, or idiosyncratic reaction to standard medications used in the perioperative period.

Over the 9-month study duration, participants were prospectively and randomly allocated to one of the two treatment groups. Randomization ensured balanced distribution of demographic and clinical variables such as age, sex, weight, race, preoperative pain levels, anaesthetist, surgeon, and surgical complexity across the groups. All surgeries were performed under general anaesthesia by specialist maxillofacial surgeons (B.M.R., P.P.W., and K.B.) with board certification following a set protocol⁹.

Under general anaesthesia with nasal intubation, ORIF of mandibular fractures under sterile conditions, was performed following a standardized protocol. Temporary intermaxillary fixation^{10,11} was achieved using fixation screws. At each fracture site, at least two Pitkar mini plates (2 mm titanium plate; Pitkar) were placed to prevent displacement due to rotational forces. Mucosal closure was done using resorbable Vicryl sutures (Ethicon). Patients received a single intraoperative dose of cefotaxime sodium (1,000 mg), and postoperatively, diclofenac (75 mg three times a day) and dexamethasone (8 mg twice a day) for three days. All patients remained hospitalized for at least 72 hours with standard postoperative care.

1. Application of face ice pack wrap

A facial ice pack wrap (Face Ice Pack; LotFancy) as shown (Fig. 1. A-1. C), maintained at a temperature of 2°C, was utilized for cold compression therapy. The same ice pack wrap was also used to provide regular compression without ice at room temperature. The ice pack wrap was applied immediately after the surgery (within 15 minutes). The cold gel ice pack was positioned within the wrap to shield the patient's skin. Following the manufacturer's instructions, the wrap was firmly placed over the patients' heads with the cold gel ice pack pouches touching their cheeks. Patients were advised to replace the ice pack every 8 hours for two days post-operatively, since it would thaw and become ineffective after 20 minutes, leaving only compression for the remainder of the time at room temperature. The bilateral facial ice

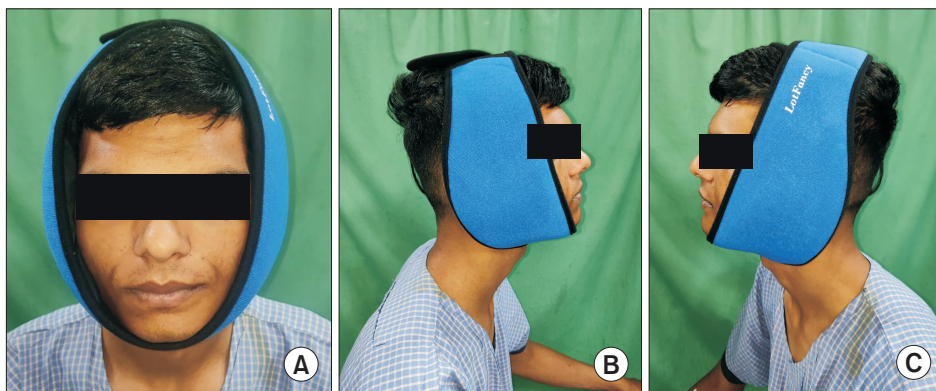


Fig. 1. A. Showing application of face ice pack wrap (Face Ice Pack; LotFancy): central profile. B. Showing application of face ice pack wrap: right lateral profile. C. Showing application of face ice pack wrap: left lateral profile.

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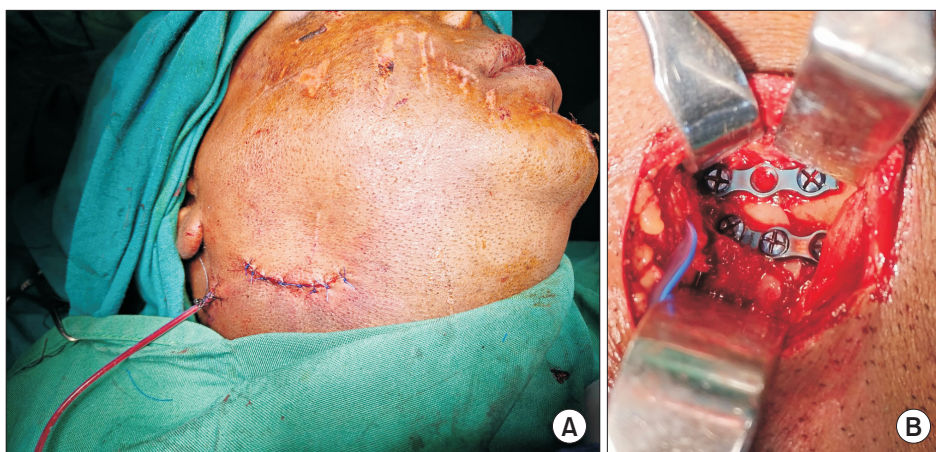


Fig. 2. A, B. Showing insertion of Romo-Vac (Romsons Romo-Vac set No. 14; Romsons) drain.

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pack featured two gel ice packs that were securely positioned inside built-in compartments. The wrap is designed with a hook-and-loop closure that easily fits around the head and is fastened with a velcro strap. The gel ice packs were reusable, flexible, and impervious to tearing and splitting because they are made of premium vinyl. Long-term durability is ensured by the sturdy nylon liner, which stops leaks. The latex-free, non-toxic, environmentally friendly carboxymethylcellulose and glycerin-filled packs are designed to absorb and wick away condensation to keep the pack dry as well as to insulate and maintain optimal cold transfer. When frozen, the gel pack maintained its pliability, which helped to conform to the face.

2. Placement of Romo-Vac drain

The Romo-Vac drain (Romsons Romo-Vac set No. 14; Romsons) as shown (Fig. 2. A, 2. B) was inserted subcutaneously using a trocar, ensuring careful placement to avoid nerves and vessels. After insertion, the trocar was removed and a safety rubber was placed over its sharp tip. The catheter was trimmed so that the drainage holes remained beneath the skin. A hanging knot was tied near the exit point, followed by

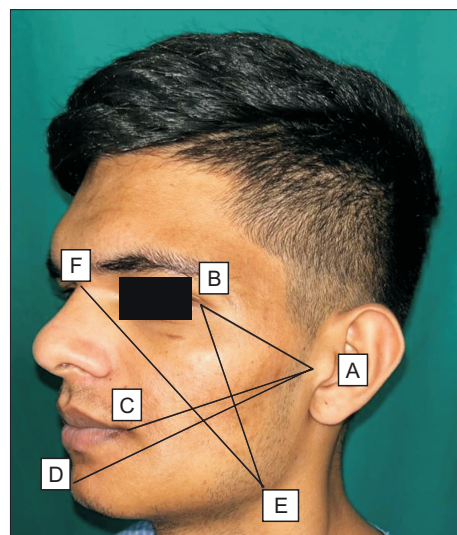


Fig. 3. Showing oedema measurement.

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multiple securing double knots to keep the drain in place.

Lines A through F were measured and added together to determine the swelling at various times.(Fig. 3) Lines are

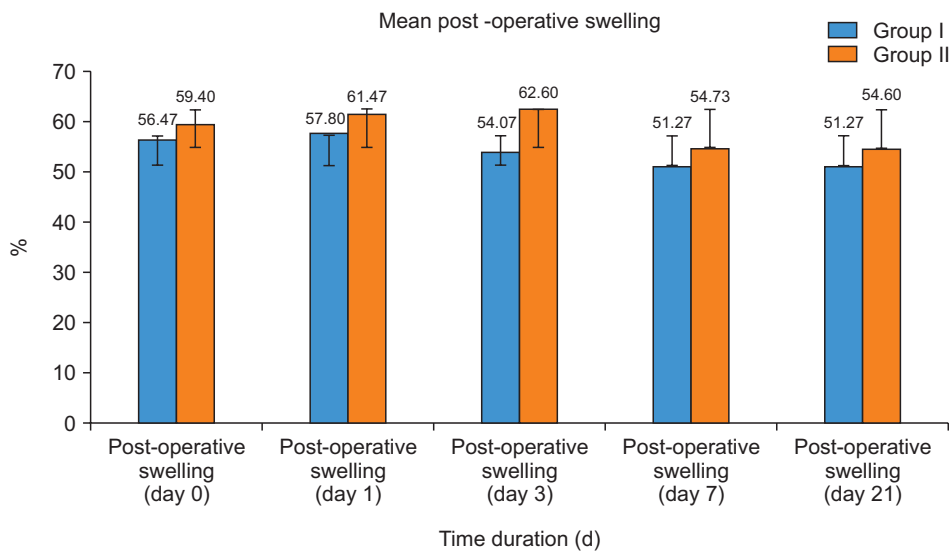


Fig. 4. Mean post-operative swelling in the study groups at different time periods.

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Table 1. Comparison of sex distribution, mean age, and fracture type between Group I and Group II

Variable	Group I (n=15)	Group II (n=15)	Total (n=30)
Sex			
Male	10 (66.7)	7 (46.7)	17 (56.7)
Female	5 (33.3)	8 (53.3)	13 (43.3)
Age (yr)	32.01±5.20	33.00±4.78	-
Type of mandibular fracture (unilateral)			
Condylar	2	2	4
Parasymphysis	5	5	10
Angle	5	5	10
Ramus	1	1	2
Symphysis	2	2	4

(-:not available)

Values are presented as number only, number (%), or mean±standard deviation.

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defined by oedema measurements. Secondary endpoints were to: (1) determine the extent of oedema on Days 0, 1, 3, 7, and 21 after surgery; (2) determine the extent of maximal swelling; and (3) use a visual analogue scale (VAS) to gauge subjective pain on Days 1,3 and 7; and (4) evaluate the subjective results of ice pack wrap comfort (as determined by the patient questionnaire), movement limitations (as determined by the patient questionnaire), and patient satisfaction in order to illustrate differences between study arms (as determined by the patient questionnaire).

In order to ensure group comparability, demographics and baseline information were also acquired.

Table 2. Mean Ranks of Pain score at various time intervals for both study groups

	Group	Mean rank	Sum of ranks
Post-operative day 0	I	13.37	200.50
	II	17.63	264.50
Post-operative day 1	I	13.90	208.50
	II	17.10	256.50
Post-operative day 3	I	13.63	204.50
	II	17.37	260.50
Post-operative day 7	I	13.50	202.50
	II	17.50	262.50

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III. Results

Utilizing IBM SPSS Statistics software ver. 22.0 (IBM), the data was statistically analyzed and a *P*-value of less than 0.05 was deemed statistically significant.

The demographic distribution and baseline characteristics of the 30 patients enrolled in the trial are detailed in Table 1. The sex and age distribution of participants in both study groups along with type of fracture are summarized in Table 1. Group I had a higher proportion of male participants (10 male, 66.7%) compared to Group II (7 male, 46.7%), whereas females were more prevalent in Group II (8 female, 53.3%). This difference in gender distribution was not statistically significant ($X^2=1.22$, $P=0.46$).

Pre-operative swelling ranged from 42 to 60 cm in Group I and from 44 to 61 cm in Group II. The mean pre-operative swelling was higher in Group II (56.07 cm) than in Group I (53.27 cm). Both groups demonstrated slight variability in pre-operative swelling.

Table 3. Comparison of ice pack (Group I) vs. Romo-Vac (Group II) in terms of drain disturbance, mobility impact, and patient satisfaction

Parameter	Score description	Group I	Group II	χ^2 -value	P-value
Disturbing drain	1: Not disturbing	11 (100.0)	0 (0.0)	19.81	0.001
	2: Slightly disturbing	4 (36.4)	7 (63.6)		
	3: Very disturbing	0 (0.0)	8 (100.0)		
Affected mobility	1: No affect	3 (100.0)	0 (0.0)	14.00	0.001
	2: Slight affect	12 (66.7)	6 (33.3)		
	3: Strong affect	0 (0.0)	9 (100.0)		
Satisfaction and convenience	1: Very satisfied	11 (68.7)	5 (31.3)	0.06	0.001
	2: Dissatisfied	4 (28.6)	10 (71.4)		

Values are presented as number (%).

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1. Post-operative swelling at various time points

In Group I, the mean maximum post-operative swelling occurred on Day 1 (57.80 cm) and Day 0 (56.47 cm). By Day 3, swelling had decreased to 54.07 cm, and by Day 7, it stabilized at 51.27 cm. Swelling remained unchanged at 51.27 cm on Day 21. Maximum variation was observed on Day 3.

In Group II, swelling increased from Day 0 (56.47 cm) to Day 1 (59.40 cm) and Day 3 (61.47 cm), reaching its peak on Day 3 (62.60 cm). Swelling then decreased to 54.73 cm on Day 7 and 54.60 cm on Day 21. The greatest variation in swelling also occurred on Day 3.(Fig. 4)

Intra-group comparisons revealed a statistically significant difference ($P=0.001$) in Group I across time points. However, no significant difference was observed in Group II ($P=0.08$). Moreover, the inter-group comparison showed a highly significant difference ($P=0.001$) between the two groups.

2. Pain scores at different time intervals

Group II participants consistently reported higher mean ranks for pain, with values of 17.63, 17.10, and 17.37 compared to Group I (13.37, 13.90, and 13.63). This suggests that Group I provided superior pain relief, with lower pain scores across the time intervals, reflecting better long-term cumulative pain management.(Table 2)

3. Drain disturbance

In Group I, all participants (100%) rated the drain as “not disturbing,” with 36.4% rating it as “slightly disturbing” and none indicating it was “very disturbing.”

In Group, eight participants (100%) found the drain to be “very disturbing,” while 63.6% rated it as “slightly disturbing.”

This demonstrates a highly significant difference ($P=0.001$)

between the groups, with Group II participants experiencing significantly more discomfort during the recovery process. (Table 3)

4. Mobility impact

In Group I, all participants (100%) reported no effect on mobility.

In Group II, a total of 66.7% reported a slight effect on mobility, while 33.3% reported a strong effect. There was a highly statistically significant difference ($P=0.001$) in mobility impairment between the two groups, with Group II participants experiencing a more substantial impact on mobility. (Table 3)

5. Satisfaction and convenience

In Group I, 68.7% of participants expressed being “very satisfied,” while 28.6% were “dissatisfied.”

In Group II, 31.3% were “very satisfied,” and 71.4% were “dissatisfied.”

A highly significant difference ($P=0.001$) was found between the two groups, indicating that Group I was significantly more satisfying and convenient, while Group II was less well-received in terms of convenience and overall satisfaction.(Table 3)

IV. Discussion

A typical surgical technique for stabilizing and aligning fractured bone segments using plates and screws is called ORIF of mandibular fractures. Despite being a useful technique for ensuring appropriate healing, ORIF is linked to a number of postoperative side effects, such as discomfort, oedema, infection, and restricted mandibular motion. These results can be greatly impacted by the application of various

postoperative care techniques, such as Romo-Vac drain and ice packs.

According to the study's sex distribution, Group I had a larger proportion of men (66.7%) than Group II (46.7%), whereas Group II had a higher proportion of women (53.3%). Nevertheless, the difference ($P=0.46$) was not statistically significant. Patel et al.¹², reported similar results, indicating that post-operative outcomes were not significantly impacted by gender distribution. The majority of participants were between the ages of 26 and 35, which is consistent with studies by Yilmaz et al.¹³, who found that younger patients recovered more quickly because of their greater metabolic rates and ability for tissue regeneration.

The results show that whereas pre-operative swelling was similar in both groups, Group I had noticeably decreased swelling at various time intervals ($P=0.001$). The oedema in Group I reached its maximum on Day 1 (57.80 cm) and then diminished, stabilizing on Day 7 (51.27 cm). Conversely, swelling in Group II escalated from Day 0 to Day 3 and subsequently diminished, suggesting that the administration of an ice pack facilitated a more rapid decrease in post-operative oedema. This is consistent with the results of a systematic review and meta-analysis conducted by Bleakley et al.¹⁴, which showed that cryotherapy is effective in alleviating swelling and pain after musculoskeletal injuries. Although a statistically significant difference was observed between the two groups in favour of the ice pack wrap, clinical observations indicated that the use of a Romo-Vac drain in condylar fractures resulted in a more effective reduction in swelling compared to the ice pack wrap, particularly among the two patients out of four in whom the drain was used. Group I continuously displayed lower pain scores than Group II at all time periods, although the difference was not statistically significant. The pain levels were measured using the VAS. This finding was corroborated by the mean ranks of pain scores, which showed that Group II continuously had higher mean ranks, which indicated a higher pain perception. According to research by Hubbard and Denegar¹⁵, cryotherapy can effectively reduce post-operative pain by reducing nerve conduction velocity and minimizing inflammatory reactions. Patients in Group II reported higher levels of discomfort ($P=0.001$), indicating a substantial difference in the disruption caused by drainage and its impact on mobility. Drainage was generally considered non-upsetting by Group I patients, but it was often considered quite disturbing by Group II patients. Additionally, Group II had a considerably larger mobility impairment, which may indicate that the Romo-Vac system played

a role in the pain and movement restriction. These results are consistent with those of Cina-Tschumi¹⁶, who discovered that external drainage devices may restrict early mobilization and increase post-operative discomfort. Furthermore, excessive drainage device use has been linked to prolonged hospital stays and delayed rehabilitation, according to Gausden et al.¹⁷.

While 71.4% of participants in Group II expressed dissatisfaction with the Romo-Vac approach, Group I had substantially higher satisfaction rates (68.7% very satisfied). This suggests that patients found the ice pack approach to be more practical and acceptable. The significance of patient comfort in the healing process was also highlighted by earlier research by Thienpont¹⁸, which shown that non-invasive cooling therapies increased post-operative care compliance and satisfaction. Similarly, he also discovered that the simplicity of post-operative recovery treatments had a substantial impact on patient satisfaction, favouring less intrusive methods like cryotherapy. Additionally, even while Romo-Vac drain is effective in draining, prolonged use and movement issues can occasionally result in increased discomfort. Romo-Vac drain users frequently complained of drain site irritation and a higher risk of infection as a result of extended wound exposure. On the other hand, ice packs offer a non-invasive way to lessen discomfort and swelling without raising the risk of infection. Ice packs are a more practical and patient-friendly solution for postoperative treatment because of their simplicity of use and decreased reliance on external devices. Furthermore, in situations of ORIF, oedema and inflammation may be a factor in the delayed healing of bones. Ice packs may accelerate tissue healing and improve the stability of fractured bone segments by successfully lowering postoperative oedema^{19,20}. This benefit is especially important for ORIF patients, whose long-term swelling may jeopardize the fixation's effectiveness.

The small sample size in this study might have affected how broadly the findings can be applied. Further large-scale randomized controlled trials are needed to confirm these results and explore additional benefits or drawbacks of the ice pack and Romo-Vac methods.

V. Conclusion

The results indicate that the ice pack approach is superior at reducing oedema, pain and discomfort, while simultaneously increasing patient mobility and satisfaction. In line with other research, these findings lend credence to the use of cryo-

therapy as a common post-operative care method. In future it can be utilized in the post-operative period for patients who underwent Orthognathic surgery apart from facial traumas.

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Authors' Contributions

All authors contributed to the study conception and design. All authors read and approved the final manuscript.

Funding

No funding to declare.

Acknowledgments

The authors would like to thank Dr. Pushkar P. Waknis and Dr. Kalyani Bhate for their valuable contributions as operating surgeons, along with the author.

Ethics Approval and Consent to Participate

This study was reviewed and approved by Institutional Ethics Committee (Reg. No. DYPDCH/DPU/EC/583/190/2023). The patients were enrolled and signed the informed consent form.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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How to cite this article: Borghate P, Rudagi BM, Setiya S, Sakhariya S, Shah S. Comparative evaluation of use of face ice pack wrap and Romo-Vac drain in post-operative oedema and pain of mandibular fractures: a randomized controlled trial. *J Korean Assoc Oral Maxillofac Surg* 2025;51:294-301. <https://doi.org/10.5125/jkaoms.2025.51.5.294>