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Meta-Analysis
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# Systematic review and meta-analysis of the efficacy of hilotherapy following oral and maxillofacial surgery

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*Abstract.* Craniofacial surgery causes immediate postoperative pain, oedema, and functional limitations. Hilotherapy delivers cooled water to the face at 15 °C and may reduce the postoperative recovery time. This work presents a meta-analysis of short-term postoperative outcomes after hilotherapy. Following a systematic literature search, comparative trials of patients undergoing surgical interventions in the maxillofacial region and receiving either hilotherapy or ice-cooling therapy were included for meta-analysis. Demographics and surgical outcomes were extracted. Data were analysed using Comprehensive Meta-Analysis software. Mean (SEM) data were calculated for demographic variables and standardized mean differences with the 95% confidence interval for surgical outcomes. Five trials were analysed, providing 206 patients for evaluation; mean patient age was 29.4 (9.4) years. Hilotherapy reduced pain (10-point visual analogue scale) at 48 h ($P < 0.010$) and 72 h ($P < 0.050$), as well as postoperative facial oedema ($P < 0.010$), compared to ice-cooling treatment. Trismus and facial neurological scores were also improved ($P = 0.08$). Patients preferred hilotherapy to other cooling methods ($P < 0.010$). Hilotherapy appears to be effective in reducing postoperative facial pain, oedema, and trismus, and in improving patient-reported outcomes. Well-designed randomized controlled clinical trials are required to clarify the procedure-specific efficacy of postoperative hilotherapy and optimal durations of treatment.

Key words: cryotherapy; hypothermia; induced; hilotherapy; hilotherm; meta-analysis; review; surgery; face.

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Cryotherapy describes the application of topical ice at the site of injury, as a means to ameliorate localized oedema and pain.[1] Cryotherapy induces local vasoconstriction of arterioles in the anatomical region and reduces the temperature of the soft tissues.[1–3] As a consequence, tissue perfusion falls, metabolic reactions are diminished, and the inflammatory process is abated.[4] Cryotherapy provides a mode of analgesic therapy and reduces oedema. Nevertheless, cryotherapy treatment regimens vary throughout the published literature, and standard practice has not been adopted by the craniomaxillofacial

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community.[1–3] Cryotherapy is, however, used widely in the management of orthopaedic injuries and sports medicine.[5,6]

This study examined the potential future role of hilotherapy, an alternative to cryotherapy, for use following postoperative oral and maxillofacial surgery. Hilotherapy (Hilotherm GmbH, Argenbühl-Eisenharz, Germany) delivers cooled water through a contoured facemask to the site of pathological or surgical injury.[7] The hilotherapy facemask is anatomically designed, and provides water at a controlled temperature through a network of tubes that run adjacent to the skin. Hilotherapy provides a means of cooling therapy at a constant controlled temperature of 15 °C, well above freezing point, which circumvents the risks associated with cryotherapy such as iatrogenic cold injury, patient-reported discomfort, and suboptimal complicance.[8–12]

Facial pain, oedema, and ecchymosis characterize the postoperative sequelae of a range of craniomaxillofacial procedures, including oral surgery, orthognathic surgery, facial fracture management, and aesthetic facial surgery.[8–12] Given the increasing importance of enhanced recovery after surgery (ERAS) and emphasis on patient-reported outcome measures (PROMs),[13] hilotherapy may provide a means to reduce the postoperative convalescent period by reducing pain and swelling, whilst avoiding the side effects of conventional analgesia. The purpose of this systematic review and meta-analysis was to examine the published outcome data for hilotherapy.

## Methods

A systematic review of the literature was performed to seek published articles describing the use of hilotherapy following oral and maxillofacial surgery. Medical databases were searched from 1966 to May 2014, using the following key words: oral and maxillofacial surgery, facial surgery, cryotherapy, hilotherapy, facial cooling, ice-cooling, swelling, oedema, pain. The resources searched included Medline, Embase (Excerpta Medica), PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), CAB Abstracts, The Cochrane Library, and Google Scholar.

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed to complete the searches.[14] Papers were extracted according to strict inclusion criteria. These criteria were decided by a consultant oral and maxillofacial surgeon at the study institution (GJK) and a chartered medical statistician. Inclusion criteria stated that reviewed articles must be in the English language and include patients using hilotherapy after oral and maxillofacial surgery. Papers not written in English, not including ice therapy or hilotherapy, and those describing laboratory-based non-human studies were excluded. Extracted papers were also hand-searched for additional references. Two authors (ASB and GJK) independently judged articles for suitability before a final decision was made for inclusion. All papers were evaluated for study design, perioperative data, ethical suitability, follow-up data, and surgical outcome reporting. All surgical procedures in the maxillofacial region were included in the quantitative analysis.

Relevant demographic and outcome data were extracted from the papers, including the total number of patients and number of patients receiving hilotherapy and control treatments, mean patient age, and surgical outcomes of the comparison groups (postoperative pain, facial oedema, trismus, neurological scores, and patient-reported outcome), as well as the mean follow-up and a description of the data collection for each study. A kappa statistic was calculated to measure concordance in the authors' final decisions to include studies. This was calculated as 'moderate', at 83.3% concordance of agreement and $\kappa = 0.571$ (0.353) (95% confidence interval −0.121 to 1.000).

Following data extraction, a meta-analysis of outcome data from the patient groups was conducted using the statistical software Comprehensive Meta-Analysis version 3 (Biostat Inc., Englewood, NJ, USA). Outcome data for patient groups receiving either postoperative hilotherapy or ice pack cooling were compared using the random effects meta-analysis model, to account for potential heterogeneity between studies due to the number of surgical maxillofacial procedures used within the extracted cohorts, variable peri/postoperative analgesic protocols, patient age range, duration of device application, and the differing methods of postoperative outcome parameter measurement. Standardized mean differences (SMD) with the 95% confidence interval (95% CI) were calculated for the continuous measure variables recorded in each trial. As defined by the Cochrane Collaboration, ''The SMD is the difference in means divided by a standard deviation''.[15] The SMD is therefore the pooled standard deviation of the participants' outcomes across the trials analysed. The SMD provides a measure of the treatment effect of an intervention on an outcome and is unit-less, yet can indicate a positive or negative directionality. The $I^2$ value was used to quantify heterogeneity.[15] Forest plots were constructed for postoperative outcome variables. Mean values with standard error of the mean (SEM) and 95% CI were calculated for demographic and surgical outcome data.

## Results

### Literature search results

The full search strategy is detailed in the PRISMA flow diagram in Fig. 1. After the removal of duplicates, 533 articles were screened for further analysis. Six studies were identified describing prospective trials of hilotherapy. One of the six studies contained insufficient data for meta-analysis. Summary demographics were extracted and are provided in Table 1. The papers analysed were published between 2011 and 2013. None of the trials was multi-centre, and four of the five trials were performed by the same research group.

### General description of studies included and study design

A description of the studies included in the meta-analysis is presented in Table 2. The studies analysed were prospective comparative studies of patients undergoing oral and maxillofacial surgery. All studies were rated as '2b' according to the Oxford Centre for Evidence-Based Medicine—Levels of Evidence criteria.[16] There were no randomized trials suitable for inclusion that followed the Consolidated Standards of Reporting Trials (CONSORT) statement.[17] Furthermore, the evaluation of patients often did not include standardized pain scales, or use validated patient-reported satisfaction measures, such as those used to quantify patient satisfaction following facial surgery.[18] The measurement of facial oedema also varied across the trials. The analgesic protocol differed between the studies analysed, however each postoperative analgesic regimen was standardized within studies.[8–12]

Four trials examining the effect of ice pack therapy following facial surgery but not including hilotherapy were also retrieved from the search strategy and are included for the purpose of discussion alongside hilotherapy cooling; however these studies were not quantitatively analysed as comparators to hilotherapy and were analysed separately as part of the PRISMA systematic review process.[19–22]

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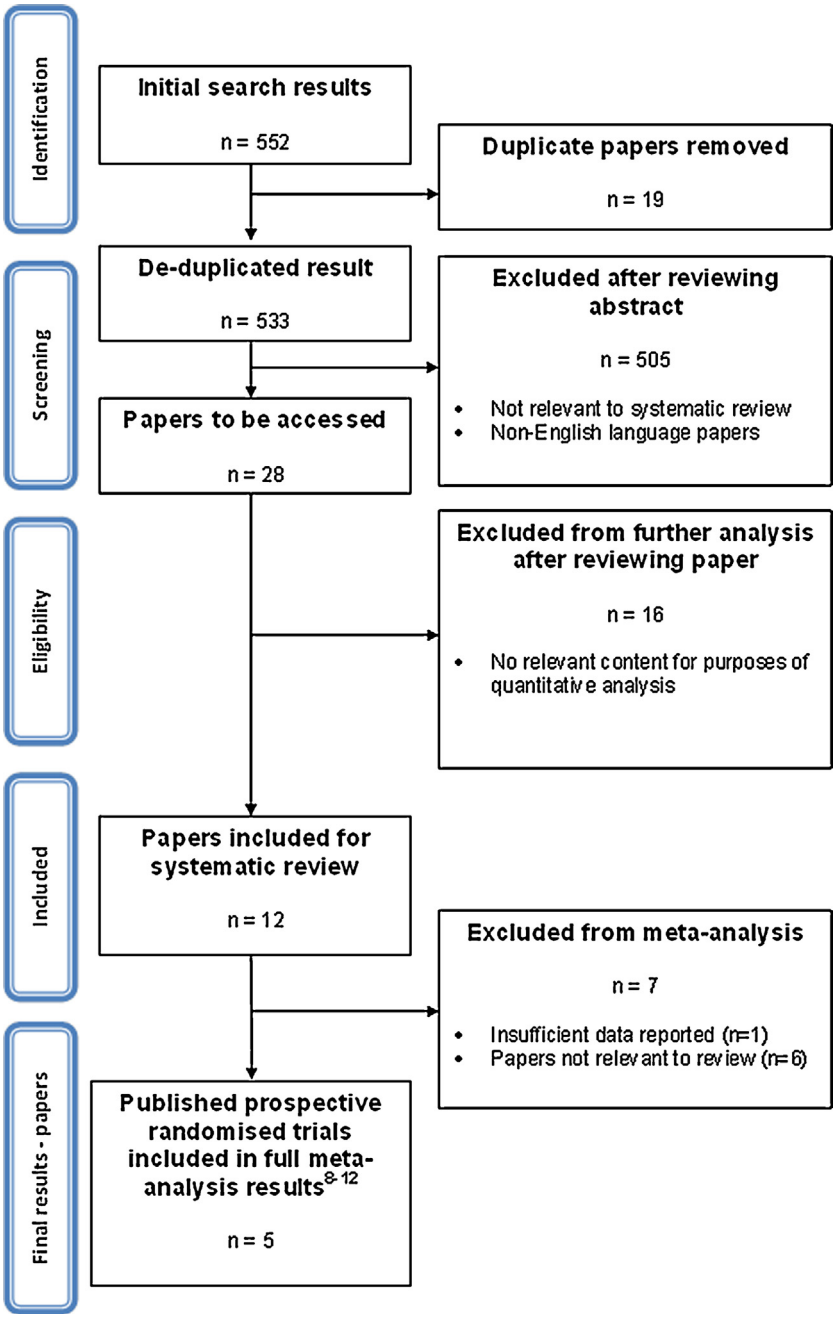


*Fig. 1.* Systematic PRISMA search strategy—extraction and exclusion protocol applied to the available literature.

### Meta-analysis of the outcomes of the prospective randomized trials

The five studies analysed provided 206 patients for analysis: 103 patients underwent conventional ice-cooling therapy and 103 received the hilotherapy device as postoperative treatment (Table 1). The percentage of patients receiving hilotherapy in each study was either 33.3% (one study)[8] or 50% (four studies).[9–12] The mean patient age was 29.3 (2.0) years and the mean number of patients per study was 47.2 (7.4) (95% CI 16.7–77.0). Follow-up ended at day 10 postoperative in all studies.

Postoperative pain, assessed using a 10-point visual analogue scale (VAS), was reduced by hilotherapy on day 2, with SMD −2.43 (0.85) (95% CI −4.10 to −0.77, $P = 0.004$) (Table 3 and Fig. 2); it was also reduced on day 4, with SMD −1.33 (0.19) (95% CI −2.64 to −0.02, $P = 0.046$) (Table 3). It was not possible to compare postoperative pain scores after the fourth postoperative day due to the lack of data in the literature analysed.[8–12]

Postoperative facial oedema was reduced by hilotherapy on day 2, with SMD −1.74 (0.17) (95% CI −2.49 to −1.00, $P < 0.001$) (Table 3 and Fig. 3). Oedema on day 3 was also reduced by hilotherapy: SMD −2.08 (0.20) (95% CI −3.40 to −0.76, $P = 0.002$) (Table 3). Data were not available for postoperative ecchymosis at any point, or for facial oedema following the third postoperative day. In four studies, facial oedema was quantified using a three-dimensional (3D) optical face scanner (FaceSCAN3D; 3D-Shape GmbH, Erlangen, Germany), with 200-μm accuracy in the '*z*' dimension. The camera had a 430 ms shutter time and was linked to software specifically designed to volume-render the facial structure of participants.[9–12] Moro et al.[8] took measurements from facial landmarks using a tape measure.

In all studies quantitatively analysed, trismus measurements were taken on postoperative day 3 using calipers, recording the inter-incisal distance at maximal opening. Hilotherapy improved trismus between the first and third postoperative days by 5.53 (0.31) (95% CI −0.66 to 11.73, $P = 0.08$), reaching the cusp of significance; however it was only possible to extract data from three of five surgical trials for this analysis (Table 3).

Postoperative neurological scores quantified sensitivity to light touch, pinprick sensation, pressure, and two-point discrimination at facial nerves around the site of surgery. These parameters were improved by hilotherapy, with SMD −0.76 (0.17) (95% CI −1.19 to −0.32, $P < 0.001$) (Table 3). A neurological score of 13/13 was deemed the poorest outcome.[8–12] Patient-reported satisfaction with the cooling intervention undergone was in favour of hilotherapy: SMD −3.71 (0.25) (95% CI −5.71 to −1.70, $P < 0.001$) (Table 3), where a higher score indicated a poorer rating. The four studies measuring patient satisfaction used the same four-point scale.

Publication bias was assessed using the 'classic fail-safe test', for all parameters examined. For all outcomes, publication bias was not detected with the fail-safe test, with $P$ at <0.001.

## Discussion

The purpose of this systematic review and meta-analysis was to compare the published outcomes of maxillofacial surgery following postoperative facial cooling by

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*Table 1*. Summary demographic data from all studies included.

| Study | Number of patients, *n* | Mean age, years | Males ice, *n* | Males hilotherapy, *n* | Procedures undertaken in each study | Randomization (hilotherapy/ice-cooling) |
|---|---|---|---|---|---|---|
| Moro et al.[8] | 90 | 29 | NA | NA | Correction of progenic syndrome ($n = 58$), prognathism ($n = 30$), maxillomandibular asymmetry ($n = 14$) | 30/30 (30 patients also received no cooling treatment) |
| Rana et al.[9] | 30 | 24 | 8 | 12 | Third molar extraction (mandibular) with osteotomy | 15/15 |
| Rana et al.[10] | 42 | 27.5 | 7 | 4 | Mandibular retrognathia ($n = 26$), mandibular prognathism ($n = 16$) | 21/21 |
| Modabber et al.[11] | 42 | 36 | 18 | 17 | Treatment of unilateral zygomatic bone fracture (open reduction, internal fixation using a three point technique) | 21/21 |
| Rana et al.[12] | 32 | 30 | 14 | 13 | Treatment of bilateral mandibular fracture requiring reduction and osteosynthesis | 16/16 |
| Pooled data | | | | | | $N = 206$ (total) |
| Mean (SEM) | | 29.3 (2.0) | 11.8 (2.6) | 11.5 (2.7) | | |
| 95% CI | | 23.8–34.7 | 3.5–20.1 | 2.8–20.1 | | |

NA, data not available; SEM, standard error of the mean; CI, confidence interval.

*Table 2*. Description of studies included in the present meta-analysis.

| Study | Duration of hilotherapy and ice-cooling applied in each study | Study description and limitations |
|---|---|---|
| Moro et al.[8] | 48 h of hilotherapy postoperatively vs. ice packs applied for 30 min every 90 min in the immediate postoperative period | Prospective, randomized trial. Unclear if outcome assessors were blinded. Patients were not blinded to therapy. No power calculation mentioned. |
| Rana et al.[9] | 45 min of hilotherapy vs. ice pack cooling in the immediate postoperative period | Prospective, randomized trial. Patients were not blinded to therapy. No power calculation mentioned. |
| Rana et al.[10] | 16 h of hilotherapy applied over a 24-h period for 3 days postoperatively vs. cool compress therapy applied every 2 h, derived from melted ice water | Prospective, randomized trial. Not clear if clinicians or assessors were blinded. Patients were not blinded. No power calculation mentioned. |
| Modabber et al.[11] | 12 h of hilotherapy applied over a 24-h period for 3 days postoperatively vs. cool compress therapy derived from melted ice water | Prospective, randomized trial. Clinicians were blinded, however patients were not blinded. No power calculation mentioned. |
| Rana et al.[12] | 12 h of hilotherapy applied over a 24-h period for 3 days postoperatively vs. cool compress therapy derived from melted ice water | Prospective randomized trial. Patients were not blinded to therapy, however surgeons and assessors were blinded. No power calculation mentioned. |

conventional means (cool compress or ice packs) versus the hilotherapy device. Surgical outcomes were compared using statistical software, with the SMD between groups calculated for a number of outcome measures, including postoperative pain, facial oedema, trismus, postoperative neurological score, and patient-reported satisfaction. This analysis suggests that hilotherapy reduces postoperative facial pain and oedema, whilst trismus, neurological scores, and patient-reported satisfaction are improved by hilotherapy, in comparison to standard ice-cooling therapies. Four papers describing the postoperative topical application of ice were also retrieved during the systematic review search strategy and these are included for the purpose of discussion.

It is purported that cooling therapies limit pain and swelling through multiple pathways, including slowed cellular metabolism, vascular constriction, and impaired neural impulse conduction.[23] Cold therapy directly causes vasoconstriction and reduces vascular permeability, preventing the egression of plasma into the extracellular space, which reduces oedema.[23] Cooling may also reduce the risk of haematoma formation.[4,24,25] Vasoconstriction reaches a maximum at 15 °C, due to the blockade of alpha adrenergic vascular innervation,[24] and thus the analgesic effect of cold therapy is hypothesized to be through a reduction in conduction velocity of nerve impulses along c-fibres, thereby inhibiting nociceptor–thalamic neural pathways.[26,27]

Cryotherapy is supported by evidence obtained through meta-analyses for use in sporting injuries and orthopaedic surgery.[1,6] It is possible to administer cryotherapy using a variety of means,[1] however there is no clear evidence regarding the most effective method of cryotherapy or the optimal period of cooling that should be undertaken.[6] Furthermore, clinician–patient compliance is difficult with cryotherapy, due to the transient nature of ice and repetition involved for frequent application in the postoperative period.

In this quantitative analysis, a published randomized controlled trial conducted by Jones et al.[4] was excluded due to insufficient demographic and outcome data in the trial. In the trial led by Jones,[4] outcomes following superficial muscular aponeurotic system (SMAS) face lift surgery were compared after postoperative treatment with hilotherapy, contralateral hilotherapy applied to the opposite side, or no cooling therapy at all. Surgical data were collected for patient-reported postoperative facial oedema in the postoperative period, ecchymosis, and patient satisfaction. Patients and clinicians were

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*Table 3*. Standardized mean difference recorded between hilotherapy and the conventional cooling method used—postoperative outcome variables.

| Study | Pain day 2 SMD (95% CI) | Pain day 4 SMD (95% CI) | Oedema day 2 SMD (95% CI) | Oedema day 3 SMD (95% CI) |
|---|---|---|---|---|
| Moro et al.[8] | Not performed | Not performed | −2.00 (−2.62 to −1.38) | Not performed |
| Rana et al.[9] | −0.90 (−1.65 to −0.15) | −0.53 (−1.26 to 0.20) | −1.34 (−2.14 to −0.55) | −2.35 (−3.28 to −1.42) |
| Rana et al.[10] | −6.84 (−8.43 to −5.26) | −3.96 (−5.00 to −2.92) | −3.40 (−4.36 to −2.46) | −4.22 (−5.31 to −3.13) |
| Modabber et al.[11] | −1.45 (−2.13 to −0.77) | −0.49 (−1.10 to 0.93) | −1.20 (−1.86 to −0.55) | −1.01 (−1.65 to −0.37) |
| Rana et al.[12] | −1.24 (−1.99 to −0.48) | −0.57 (−1.29 to 0.14) | −0.95 (−1.68 to −0.24) | −0.95 (−1.68 to −0.22) |
| Pooled data (SE) | −2.43 (0.85) | −1.33 (0.19) | −1.74 (0.17) | −2.08 (0.20) |
| | In favour of hilotherapy | In favour of hilotherapy | In favour of hilotherapy | In favour of hilotherapy |
| Meta-analysis 95% CI | −4.10 to −0.77 | −2.64 to −0.02 | −2.49 to −1.00 | −3.40 to −0.76 |
| *P*-value | 0.004 | 0.046 | <0.001 | 0.002 |
| Heterogeneity $I^2$ (%) | 60.50% | 36.51% | 20.10% | 20.82% |

| Study | Trismus SMD (95% CI) | Postop. neurological score SMD (95% CI) | Patient-reported satisfaction SMD (95% CI) |
|---|---|---|---|
| Rana et al.[9] | 8.14 (5.96 to 10.32) | −0.90 (−1.65 to −0.15) | −4.70 (−6.10 to −3.32) |
| Rana et al.[10] | 8.33 (6.45 to 10.21) | −1.13 (−1.78 to −0.48) | −4.31 (−5.41 to −3.21) |
| Modabber et al.[11] | Not performed | −0.86 (−1.49 to −0.23) | −1.30 (−1.96 to −0.63) |
| Rana et al.[12] | 0.30 (−0.39 to 1.00) | −0.10 (−0.79 to 0.59) | −4.70 (−6.05 to −3.36) |
| Pooled data (SE) | 5.53 (0.31) | −0.76 (0.17) | −3.71 (0.25) |
| | In favour of hilotherapy | In favour of hilotherapy | In favour of hilotherapy |
| Meta-analysis 95% CI | −0.66 to 11.73 | −1.19 to −0.32 | −5.71 to −1.70 |
| *P*-value | 0.08 | <0.001 | <0.001 |
| Heterogeneity $I^2$ (%) | 0.00% | 0.35% | 0.00% |

SMD, standardized mean difference; CI, confidence interval; SE, standard error.

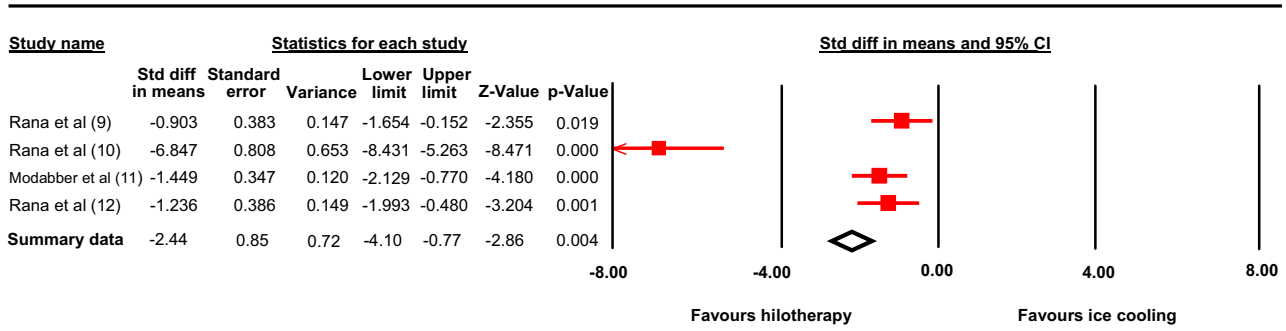


*Fig. 2*. Forest plot demonstrating the efficacy of the hilotherapy device in reducing postoperative pain at 48 h, assessed using a 10-point visual analogue scale. Box size reflects study size. The diamond at the bottom of the figure represents the pooled effects analysis.

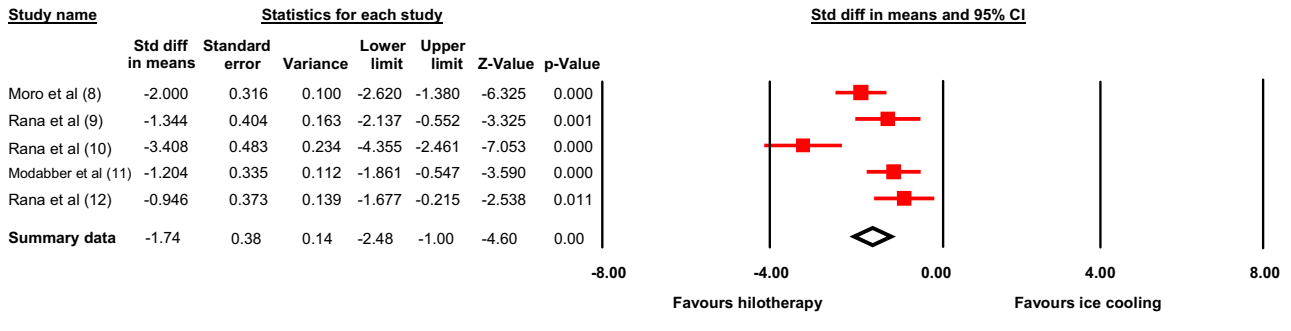


*Fig. 3*. Forest plot demonstrating the efficacy of the hilotherapy device in reducing postoperative swelling at 48 h compared to ice pack therapy. Box size reflects study size. The diamond at the bottom of the figure represents the pooled effects analysis.

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blinded to therapy. In contrast to the reported outcomes of other studies,[8–12] Jones et al.[4] reported that patients receiving hilotherapy experienced greater postoperative oedema on postoperative days 6–8, with no statistical benefit in ecchymosis, haematoma, or analgesic effect. These findings are at odds with the results of the trials included in this review and the pooled effects analysis. In the study by Jones and colleagues,[4] hilotherapy was removed on the first postoperative day, which might account for the failure to reach statistically significant differences between the outcomes observed. The small study size was acknowledged by the authors as a potential cause of the greater oedema reported in the hilotherapy group.[4] Future trials of hilotherapy should report data in a framework that is amenable to direct comparison and further meta-analysis, including the evaluation of subgroups.

The data extraction phase in this review retrieved four studies examining ice pack therapy following a number of procedures, including third molar extraction and blepharoplasty. In 2005, van der Westhuijzen et al.[19] conducted a study using ice packs to treat the mandibular region following mandibular third molar extraction. Patients were randomized equally to receive either an ice pack to personally refill or no cold therapy. Measurement of facial swelling was performed using modified Vernier calipers and pain was recorded using a five-point scale. The study found that pain, swelling, and trismus were improved; however these improvements were not significant at the level of $P < 0.05$. Swelling on the side contralateral to cooling was not compared directly between patients as a result of the experimental methodology used, which weakened the study design significantly. Pain between groups did not differ, yet the raw data were not reported. There was a 1.8-mm mean increase in mouth opening ability (decrease in trismus) in the ice treatment group, yet this was not significant. Patients reported significantly improved subjective perceptions of pain control if receiving ice. Patient compliance with ice therapy varied hugely in the trial, ranging from 2 to 21 h postoperatively.

Laureano Filho et al.[20] removed lower third molars from 14 patients bilaterally, at different time points. At one of the time points, the patient received postoperative cryotherapy in the form of a topical ice pack. Ice therapy was found to improve swelling significantly ($P < 0.050$). Pain was also improved significantly, however trismus was not improved using topical ice. The study was limited by the small sample size and preliminary nature of the work.

Forouzanfar et al.[21] randomized groups of 30 patients following third molar extraction to cold compress, control compress, or no therapy at all. The measurement of pain was conducted using a 10-point VAS, whilst patient-reported outcomes were collected using a global perceived effect score for pain management and also a dedicated quality of life instrument, which was a Dutch version of a validated English third molar quality of life questionnaire. In the study by Forouzanfar et al., pain was improved on day 3 postoperatively, however on day 1, pain did not differ between the patient groups. As reported on the VAS, pain on day 3 in the ice group was $16.5 \pm 14.9$ mm and in the compress group was $24.2 \pm 20.3$ mm. Patient quality of life was not significantly improved in the ice-cooling group. The results obtained by Forouzanfar and colleagues are in partial agreement with those of van der Westhuijzen et al.,[19] yet are limited by the small study size and lack of measurement of swelling and trismus. Of note, these studies were limited to third molar extraction and the results cannot be extrapolated to other oral and maxillofacial procedures.

Pool et al.[22] conducted a study in 2015 using topical ice following blepharoplasty in a randomized, observer-blinded study. Thirty-eight patients underwent blepharoplasty consecutively and received ice applied to only one eyelid postoperatively. The subjects were given a 10-point VAS to complete on the postoperative days and also scored their perceived oedema, erythema, and haematoma on a four-point non-validated scale. Only pain on day 1 was improved. The authors concluded that topical ice plays no part in the management of patients following blepharoplasty. However, that study was potentially confounded by the concurrent bilateral nature of the procedure, absence of objective assessment of swelling, and lack of standardized equipment to accurately measure ecchymosis.

It is proposed that hilotherapy offers an alternative to ice packs and may be more efficacious, as demonstrated in this analysis, due to a more physiological operating temperature compared to ice packs. It avoids the unnecessary cold-induced pain experienced on the application of ice. Ice itself may cause pain, aside from the cooling effect on local tissues. Of note, ice in water is used experimentally to compare pain thresholds in individuals in the widely acknowledged 'cold pressor test', which is described in the literature. Indeed, the prolonged application of ice to a skin surface might logically be expected to cause some degree of secondary pain.[27] Hilotherapy clearly avoids this feature of extreme ice-cooling and enables tissue to experience physiological cooling minus ice-induced pain, operating at a higher temperature of around 15 °C. Besides this, hilotherapy enables a greater element of clinician/patient control and may improve compliance compared to ice, avoiding the requirement to replenish ice continually, as described in previous work.[8–10,12]

It may be the case that hilotherapy is effective for a shorter dose duration for procedures of a low–medium invasive nature. However, the evidence for procedure-specific hilotherapy regimens remains to be ascertained through evidence-based trial outcome reporting and subgroup analyses. Indeed, the duration of postoperative hilotherapy in the study examining third molar extraction lasted only 45 min postoperatively,[9] whilst the duration of hilotherapy ranged from 12 to 16 h per day for three postoperative days in the remaining studies examined.[8,10–12]

The absence of power calculations was noted in all trials included in this meta-analysis. It is suggested that future prospective studies be adequately powered, with a longer follow-up. Randomization should be minimized on the surgical procedure undertaken. Clinicians and patients should be blinded wherever possible. Furthermore, patient sex should be controlled for, and strict exclusion criteria should be applied, for example, minimising the inclusion of patients with chronic pain conditions in trials. It is also suggested that facial oedema be quantified using accurate equipment such as an optical face scanner (FaceSCAN3D),[9–12] or through repeatable facial measurements, such as those described by Moro et al.[8] The group to which the present authors belong will be conducting a trial of facial cooling in orthognathic surgery (the Facial Cooling in Orthognathic Surgery Trial), which will seek to address postoperative pain and nausea following facial surgery. The trial will use objective qualitative and quantitative measures to clarify the efficacy of hilotherapy.[28] In particular, the Facial Cooling in Orthognathic Surgery Trial will explore the suggested analgesic and anti-oedemogenic properties of hilotherapy in comparison to no cooling therapy by way of pain score recording for up to 28 days postoperatively. The study will also include a prospectively designed cost–benefit analysis.

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The present meta-analysis is limited by the low number of studies included for numerical analysis. From the pooling of data extracted from surgical series, the measurement of the true treatment effects of the hilotherapy technology is expected to be affected by variations in cohort treatment protocols and surgical procedures undertaken. Heterogeneity between cohorts was quantified as modest using the $I^2$ value. For all parameters, heterogeneity was measured as either mild or moderate, and therefore it is suggested that the analysis was not affected significantly by the various methods of measurement of continuous variables collected. The minimal heterogeneity may be attributed to similar patient demographics throughout the studies and the standard hilotherapy system utilized. However, subgroup analyses, such as male and female pain reporting outcomes, outcomes stratified by age, and the surgical procedure undergone, were not performed. Although significant results are demonstrated by this meta-analysis, the external statistical validity of the numerical data generated is insufficient to direct treatment guidelines at present. Indeed, four of the five trials included in the meta-analysis were from the same study authors. This was accounted for by performing an analysis for publication bias, which did not detect any bias in publication of the results. It is hoped that this analysis will stimulate further well-designed scientific trials seeking to build a reliable evidence base.

In conclusion, the present analysis suggests hilotherapy might provide patients with a significant reduction in postoperative facial pain and oedema. Outcomes for trismus, neurological score, and patient-reported satisfaction were also found to be beneficial in comparison to conventional ice-cooling therapy. This systematic review and meta-analysis of hilotherapy has relevance to postoperative recovery regimens, in that clinicians and patients might elect to use this cooling device in efforts to improve the postoperative recovery period. Well-designed, prospective, multi-centre randomized controlled trials are necessary to confirm or refute the analgesic and anti-oedemogenic effects of hilotherapy over standard cryotherapy techniques, before routine clinical use is established following oral and maxillofacial surgery.

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## Competing interests

None declared, financial or otherwise.

## Ethical approval

This study is a meta-analysis of existing data which had ethical approval. Additional ethical approval to perform statistical analyses was not sought as per international medical publishing guidelines.

## Patient consent

Not required.

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