Systematic Review and/or Meta-analysis

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Efficacy and safety of phototherapies for upper lip scars in cleft lip patients: a systematic review and meta-analysis

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Objective: Cleft lip is a prevalent congenital developmental defect, and its surgical repair often results in scarring that adversely impacts facial esthetics, function, and mental health. Numerous studies have examined the efficacy and safety of phototherapy for scar treatment. However, definitive evidence is lacking. This study aims to evaluate the effectiveness and safety of phototherapies for treating upper lip scars in cleft lip patients.

Methods: The authors searched PubMed, Cochrane Library, Embase, and Web of Science databases using specific search terms. The authors collected clinical trials on laser or other phototherapy treatments for upper lip scars after cleft lip surgery published up to the end of March 2024. Two researchers independently screened the literature, extracted data, and assessed quality based on inclusion and exclusion criteria. The data were analyzed by using RevMan 5.4 statistical software.

Results: A total of nine studies were included. 1 Analysis of the clinical efficacy rate between the control group (routine care) and the intervention group (phototherapy) showed that laser or intense pulsed light (IPL) treatment significantly reduced total VSS scores ($P < 0.0001$). 2 Analysis of the Pretest-Post-test cohort showed that total VSS scores were significantly reduced after phototherapy ($P < 0.00001$). 3 Timing of phototherapy intervention analysis: early postoperative phototherapy intervention had a better effect. None of the literature reported permanent complications, nor were there any serious adverse events, only localized temporary erythema or blisters.

Conclusion: Phototherapy can effectively improve the total VSS scores of upper lip scars after cleft lip surgery (including skin color, vascular distribution, softness, and thickness) with no apparent adverse reactions or serious complications. Early phototherapy intervention for upper lip scars has a better effect.

Keywords: cicatrix, cleft lip, meta-analysis, phototherapy, plastic surgery procedures

Introduction

Cleft lip is a common congenital developmental defect, and surgical repair of the cleft is currently the only effective treatment[1]. Despite advancements in surgical techniques, the formation of postoperative scars remains an inevitable outcome.

Recent studies have identified the primary factors influencing scar formation, which encompass complex physiological reactions during wound healing. These include extensive infiltration of inflammatory cells, abnormal proliferation of fibroblasts, and notably, local tension has been found to play a crucial role in scar formation and hypertrophy[2]. Local tension at the surgical incision site can directly lead to scar widening through mechanical stretching and activate a series of cellular activities via mechanotransduction mechanisms. These activities exacerbate chronic inflammation in the reticular dermis, promote fibrosis, and accelerate angiogenesis and collagen deposition, ultimately fostering scar hypertrophy[3]. This phenomenon is particularly notable in the upper lip, where the complex distribution of muscle fibers and varied movement patterns make hypertrophic scarring more pronounced compared to other relatively static facial areas. Simply stated, upper lip scars in cleft lip patients, which arise directly from surgical intervention, are exacerbated by the continual facial movements essential for expressions and daily functions. Consequently, scar contracture and hypertrophy frequently develop, substantially hindering the healing process and

HIGHLIGHTS

- This comprehensive meta-analysis is the first to demonstrate the efficacy of phototherapy in treating upper lip scars following cleft lip surgery.
- Early postoperative phototherapy intervention is significantly more effective for managing upper lip scars compared to mid-to-late postoperative intervention.
- Phototherapy is a safe and effective treatment modality for upper lip scars after cleft lip surgery.

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adversely affecting both the patient's psychological well-being and the functional integrity of the upper lip[4–7]. Thus, the imperative for effective scar management is underscored.

As medical research advances, the exploration of scar prevention and treatment continues to evolve. Commonly used clinical methods include local drug treatment, phototherapy, and massage[8–11]. With the rapid development of laser and light technologies, phototherapy has gradually become the preferred option for treating upper lip scars[12–15]. Although existing studies have indicated that laser or intense pulsed light (IPL) technology can improve the color, texture, and morphology of scars, comprehensive evidence of its treatment effect and safety for upper lip scars after cleft lip repair surgery is lacking.

To address this gap, in this study, we conducted a meta-analysis and systematic evaluation to comprehensively assess the efficacy and safety of phototherapy in treating upper lip scars among cleft lip patients. Our objective is to provide an unbiased appraisal of its clinical effectiveness and safety profile, thereby addressing critical knowledge deficits and informing future treatment protocols.

Methodology

Data sources and searches

The search database includes PubMed, Cochrane Library, Embase, and Web of Science. The literature on laser or other phototherapy for the treatment of upper lip scars after cleft lip surgery, which was publicly published by April 2024, was retrieved. Search terms were as follows: (((((((((((((((laser[MeSH Terms]) OR (laser)) OR (lasers)) OR (masers)) OR (maser)) OR (phototherapy[MeSH Terms])) OR (Phototherapies)) OR (Therapy, Photoradiation)) OR (Photoradiation Therapies)) OR (Therapies, Photoradiation)) OR (Light Therapy)) OR (Light Therapies)) OR (Therapies, Light)) OR (Therapy, Light)) OR (Photoradiation Therapy)) AND (((((lip[MeSH Terms]) OR (lip)) OR (lips)) OR (Philtrum)) OR (Upper Lip))) AND ((((((Cicatrix [MeSH Terms]) OR (Cicatrix)) OR (scar)) OR (scars)) OR (Cicatrization)) OR (Scarring)). References cited in the literature were also searched to avoid omissions. The work has been reported in line with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)[16] and AMSTAR (Assessing the methodological quality of systematic reviews) Guidelines[17]. This work has been registered in PROSPERO system.

Inclusion and exclusion criteria

Inclusion criteria: (1) Patients diagnosed with unilateral or bilateral cleft lip; (2) Patients with upper lip scars remaining after cleft lip repair surgery; (3) Intervention measures are various laser and intense pulsed light treatments using light as the energy source; (4) At least one of the following outcome evaluation indicators are included: Vancouver Scar Scale (VSS) (a widely used scale in clinical practice and research to document change in scar appearance)[18], Visual Analog Scale (VAS) (a commonly used scale in pain assessment)[19], Patient Scar Assessment Questionnaire (PSAQ) (a reliable and valid measure of the patient's perception of scarring)[20], and other indicators that can evaluate clinical efficacy.

Exclusion criteria: (1) Upper lip scars left after non-cleft lip surgery; (2) Scars on other parts of the face; (3) Review, comments, expert opinions, letters to editors, conference abstracts, animal and in vitro experiments, and other literature; (4) Unable to obtain full-text; (5) The data description is unclear, there are anomalies in the data, or the data cannot be merged and analyzed with other studies.

Data extraction

Two researchers independently screened the retrieved studies, strictly following the inclusion and exclusion criteria. In the event of disagreement, discussion, or the involvement of the third researcher was used to resolve issues. Incomplete data were obtained by contacting the authors via e-mail or phone. The following information was extracted from the included studies: trial name, author, year of publication, type of experimental design, number of patients included, intervention measures, outcomes, follow-up time, and adverse events.

Quality of the studies

Cochrane risk of bias tool was used to assess the risk of bias in each study. Two researchers independently evaluated the following items: Selection bias (including random sequence generation and allocation concealment); Performance bias (blinding of participants and personnel); Detection bias (blinding of outcome assessment); Attrition bias (incomplete outcome data); Bias caused by selective outcome reporting; Other bias.

Statistical analysis

Review Manager 5.4 software was used for statistical analysis of the included studies. Treatment efficacy was evaluated using the total VSS score. Since the VSS score was a continuous variable, MD and 95% CI were used to merge the effect size of each study. The value of I^2 was used to determine the heterogeneity between studies. Sensitivity analysis (excluding one study at a time) was performed to determine the stability of the conclusion.

Results

Literature search

A preliminary search yielded 732 articles, of which 179 duplicates were removed. After reading the titles and abstracts, 25 articles were initially selected, and upon full-text review, 9 articles were ultimately included (Fig. 1).

Characteristics and quality of included studies

Nine studies were included[21–29], Table 1 shows the basic information and details of the included studies. Five RCTs were evaluated for quality using the criteria of the Cochrane Handbook for Systematic Reviews, as shown in Figure 2. Four N-RCTs were evaluated for quality using MINORS scales, as shown in Table 2.

Meta-analysis results

Among the nine included studies, Nocini PF[21] used the Patient Satisfaction Questionnaire (PSAQ) for outcome evaluation; Jahanbin A[22] used a four-level scale, PSAQ, and electromyography for outcome evaluation; Li YY[27] used a three-level

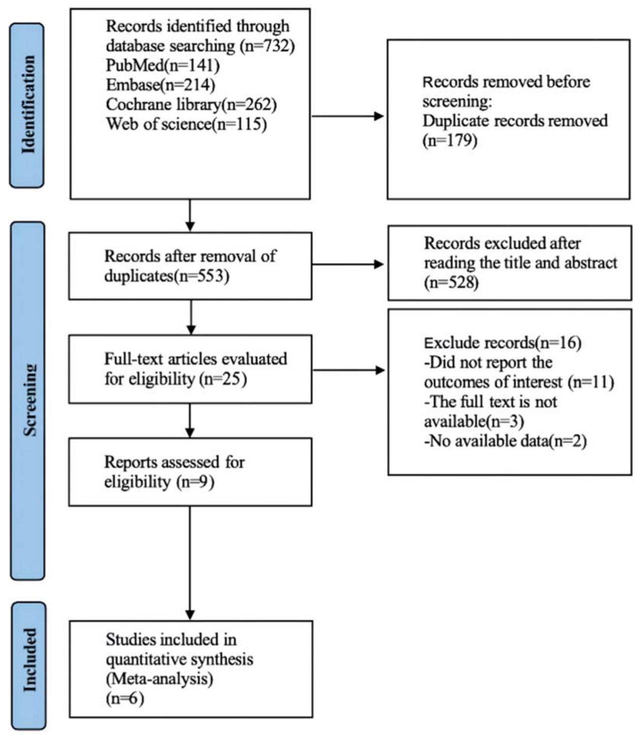

Figure 1. Literature search-This figure depicts the search and selection process.

scale for outcome evaluation. The remaining six articles used the Vancouver Scar Scale (VSS) for outcome evaluation. Due to the different efficacy evaluation methods of the studies, only six articles that used the VSS to evaluate scars were included in the meta-analysis (Fig. 3). Among these six articles, some reported comparative data between the phototherapy group and the control group. Some reported pre-phototherapy and post-phototherapy self-comparison data.

Phototherapy group VS control group

There are a total of five articles that can obtain raw data from the phototherapy group and the control group. Due to significant heterogeneity among the studies, a random effects model was used for meta-analysis. The results (Fig. 3A) showed that the overall improvement in VSS score of phototherapies for upper lip scars after cleft lip surgery was better than routine care (MD = – 1.44, 95% CI [– 2.13 to – 0.76], $P < 0.0001$), with a statistically significant difference between the two groups.

Of the five articles mentioned above, two provided subgroup data regarding phototherapy intervention at different time points in the original text. Further evaluation of each subgroup data in the forest plot (Fig. 3B) showed that the VSS scores could be significantly reduced by using phototherapies (MD = – 1.29, 95% CI [– 2.12 to – 0.46], $P = 0.002$).

However, the forest plot showed that the sub-groups that started phototherapy at 3 months and 6 months postsurgery in the article by Chi *et al.*[28], as well as the subgroup that started phototherapy at 3 months postsurgery in the article by Shadad *et al.*[23], had no statistically significant difference compared with the control group, suggesting that started phototherapy 3 months postsurgery and later may obtain a poor therapeutic effect.

We further analyzed the two studies mentioned above regarding the intervention of phototherapy at different times and compared the data of early postoperative (within 1 month after surgery) with mid-to-late postoperative (3 months and later after surgery). In this subgroup meta-analysis, an I^2 value of 0 indicates minimal heterogeneity between these two studies, suggesting high homogeneity of findings. The results showed (Fig. 3C) that early phototherapy is significantly better than mid-to-late intervention, with a statistically significant difference (MD = – 1.87, 95% CI [– 2.23 to – 1.52], $P < 0.0001$).

Before treatment vs after treatment

Three articles provided data for self-comparison before and after treatment, and due to significant heterogeneity among the studies, a random effects model was used for meta-analysis. The result (Fig. 3D) showed that phototherapy significantly improved VSS scores for upper lip scars after cleft lip surgery compared to before treatment (MD = 4.33, 95% CI [2.66–6.00], $P < 0.00001$), with a statistically significant difference.

In the article published by Chi *et al.* in 2023[28], subgroup data for phototherapy intervention at different times were listed, and further evaluation of each subgroup data in the forest plot (Fig. 3E) was conducted. The results showed that whenever treatment is given, it is more effective than routine scar care, and the difference is statistically significant.

Table 1

Characteristics of included studies.

Study	Experimental design	Sample size (intervention Group: Control Group)	Intervention measures	Outcome evaluation indicators
Nocini PF (2003)[16]	Pretest-Post-test cohort	10	Er:YAG Laser	Patient satisfaction questionnaire
Jahanbin A (2019)[17]	Pretest-Post-test cohort	12	Fractional CO_2 laser	Quartile grading scale, PSAQ, EMG
Shadad M (2021)[18]	RCT	80:40	Fractional CO_2 Laser	VSS
Mossaad A (2018)[19]	Pretest-Post-test cohort	6	Fractional CO_2 Laser	VSS, VAS
Abdul Mohsen M (2023)[20]	RCT	60:20	Diode laser	VSS, Ultrasound examination
Peng L (2018)[21]	Retrospective Study	25:25	Intense Pulsed Light + Fractional CO2 Laser	VSS
Li YY (2020)[22]	RCT	43:70	Fractional CO_2 Laser	Grade evaluation
Chi H (2023)[23]	RCT	30:12	Fractional CO_2 Laser	VSS
Chi H (2024)[24]	RCT	18:18	595 nm pulsed dye laser	VSS

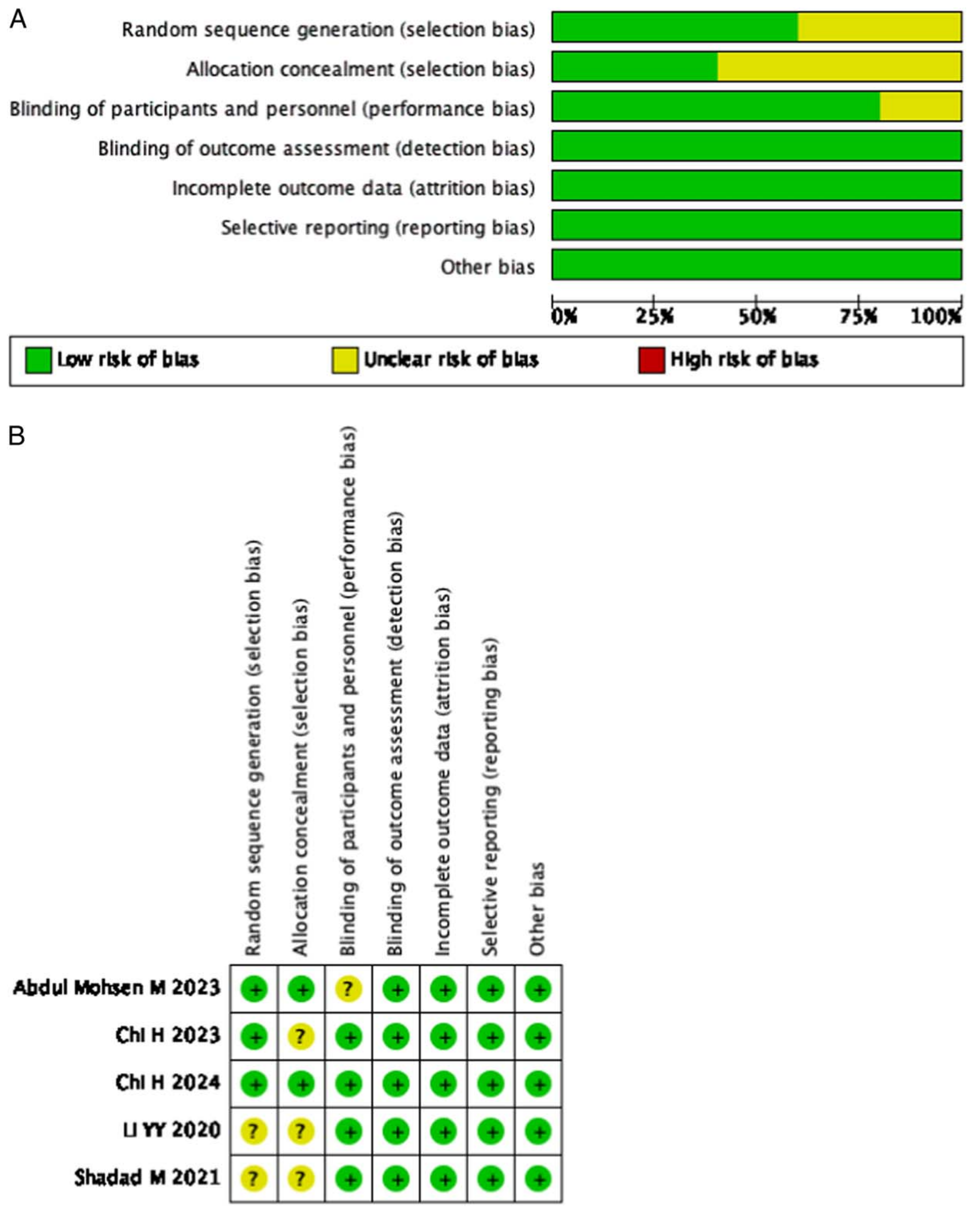

Figure 2. A Risk of bias graph. B Risk of bias summary.

Complications and adverse events

None of the studies reported permanent complications or serious adverse events.

Publication bias analysis

Due to the limited number of studies included in this meta-analysis, funnel graphs were not used to analyze publication bias.

sensitivity analysis

A sensitivity analysis (reanalyzing the data after excluding one study at a time) was conducted to determine the robustness of the conclusions of this meta-analysis. The results showed that the study published by Chi in 2023[28] had the greatest impact on heterogeneity, both in the meta-analysis of controlled trials between two groups and in the pretest-post-test meta-analysis. The I^2 dropped from 58 to 46%, MD = − 1.70, 95% CI [− 2.41 to − 0.99], $P < 0.00001$, in the meta-analysis between the phototherapy group and the control group. The I^2 statistic dropped from 91 to 0%, MD = 4.92, 95% CI [4.34–5.50], $P < 0.00001$, in the pretest-post-test meta-analysis.

Discussion

The residual scars after lip surgery have always been a difficult problem for doctors and patients, which not only involves esthetic issues but may also affect the daily lives of patients. Although traditional scar treatment methods such as silicone gel and silicone sheeting have certain effects, they need patients to use

Table 2

Methodological index for non-randomized studies (MINORS) scores for the included studies.

Item	Nocini PF (2003)[21]	Jahanbin A (2019)[22]	Mossaad A (2018)[24]	Peng L (2018)[26]
Clear aims	2	2	2	2
Inclusion of consecutive patients	1	1	1	2
Prospective	1	2	2	2
Appropriate endpoints	2	2	2	2
Unbiased estimate of endpoint	2	2	2	2
Appropriate follow-up	1	2	2	2
Lost to follow-up <5%	2	2	2	2
Prospective sample size	0	0	0	0
Additional criteria in the case of comparative studies				
An adequate control group	0	0	0	2
Contemporary groups	0	0	0	2
Baseline equivalence of groups	0	0	0	2
Adequate statistical analyses	0	0	0	2
Final score	11	13	13	22

them continuously every day, and their effects are highly dependent on patients' compliance[30,31]. Additionally, these treatment methods may cause discomfort in the local skin during use and may lead to rashes in severe cases.

With the rapid development of phototherapy, various lasers and light treatments have been increasingly applied in scar management[32,33]. The theoretical basis for using phototherapy to treat scars includes the theory of selective photothermolysis and photomodulation, etc.[34–37]. The application of these technologies has brought breakthroughs in scar treatment.

The most commonly used laser for scar treatment in clinical practice is CO_2 laser, which uses laser lattice technology to decompose a beam of light into several small beams, creating several small treatment areas on the surface of the scar, causing scar gasification and peeling, stimulating local collagen regeneration, promoting collagen rearrangement, and ultimately achieving scar remodeling. Its therapeutic effect is remarkable and has a high safety[38–40].

Similar to the CO_2 laser, Er: YAG laser also causes local thermal damage and tissue evaporation, but unlike the CO_2 laser, dual-mode Er: YAG laser causes linear evaporation of tissue without accompanying changes in tissue color[21,41–43].

Low-level laser therapy (LLLT) is a low-power light that can improve microcirculation through vasodilation, angiogenesis, and proliferation, thereby promoting many processes including metabolism, regeneration, and epithelialization. Photomodulation promotes collagen deposition and protein synthesis, improving the tensile strength of scars[25,44].

The principle of intense pulsed light (IPL) is the same as that of laser[45,46]. During treatment, IPL can selectively act on hemoglobin and pigment in scar tissue, thus achieving the purpose of improving scars[47]. Although this treatment method is not as high-energy as laser treatment, it causes less damage to the tissue and has fewer side effects. With IPL treatment, the color, texture and shape of the scar can be effectively improved, bringing it closer to normal skin.

Our meta-analysis results show the great potential of laser or intense pulsed light in scar treatment. These minimally invasive or noninvasive treatment methods can effectively improve the color, texture, and shape of scars, enhancing skin elasticity and function. More importantly, early treatment is more significant, helping patients return to normal life faster and improve their quality of life.

Although the existing research results reveal the positive effects of laser and intense pulsed light in the treatment of scars to some extent, we must carefully examine the limitations and challenges of these studies. The primary problem is that there is still a lack of literature on the treatment of upper lip scars with laser or intense pulsed light. From the forest plot, we can find that the overall I^2 value is greater than 50%, which indicates that there is great heterogeneity among different studies. This heterogeneity may be due to the significant differences in the setting of laser or intense pulsed light parameters, the arrangement of treatment cycle, and the start time of treatment among the studies. Due to the delicate distribution of muscles in the upper lip region and the complexity of its motion mode, the local stress of the scar in this region is quite different from that in other facial regions. Therefore, to understand the pathophysiological mechanism of upper lip scars more comprehensively, future research needs to be more in-depth and systematic. More high-quality, large sample randomized clinical controlled trials should be promoted. This kind of research design will help us more accurately evaluate the effect of laser or intense pulsed light in scar treatment, and then determine the optimal treatment scheme and parameter settings.

In addition, it is equally important to delve into the specific mechanisms of action of laser and intense pulsed light treatment for scars. A deeper understanding of its mechanisms will help us grasp the key elements in the treatment process, thereby optimizing the treatment plan. At the same time, deeper research into the mechanisms also helps us discover new treatment targets, opening up new ideas and methods for future scar treatment.

Furthermore, we should focus on the most appropriate time for treatment. At present, most studies focus on the evaluation of the effect after treatment, and the discussion on the timing of treatment initiation is relatively rare. In the studies included in this meta-analysis, Chi *et al.*[28] listed the data of CO_2 laser treatment of upper lip scar at three different times: 1 month, 3 months, and 6 months after surgery. In the overall meta-analysis, we combined the data of each subgroup. Therefore, we assumed that this is the reason why this article has the greatest impact on heterogeneity. Identifying the best timing of treatment will help patients achieve the best results and avoid treatment delays.

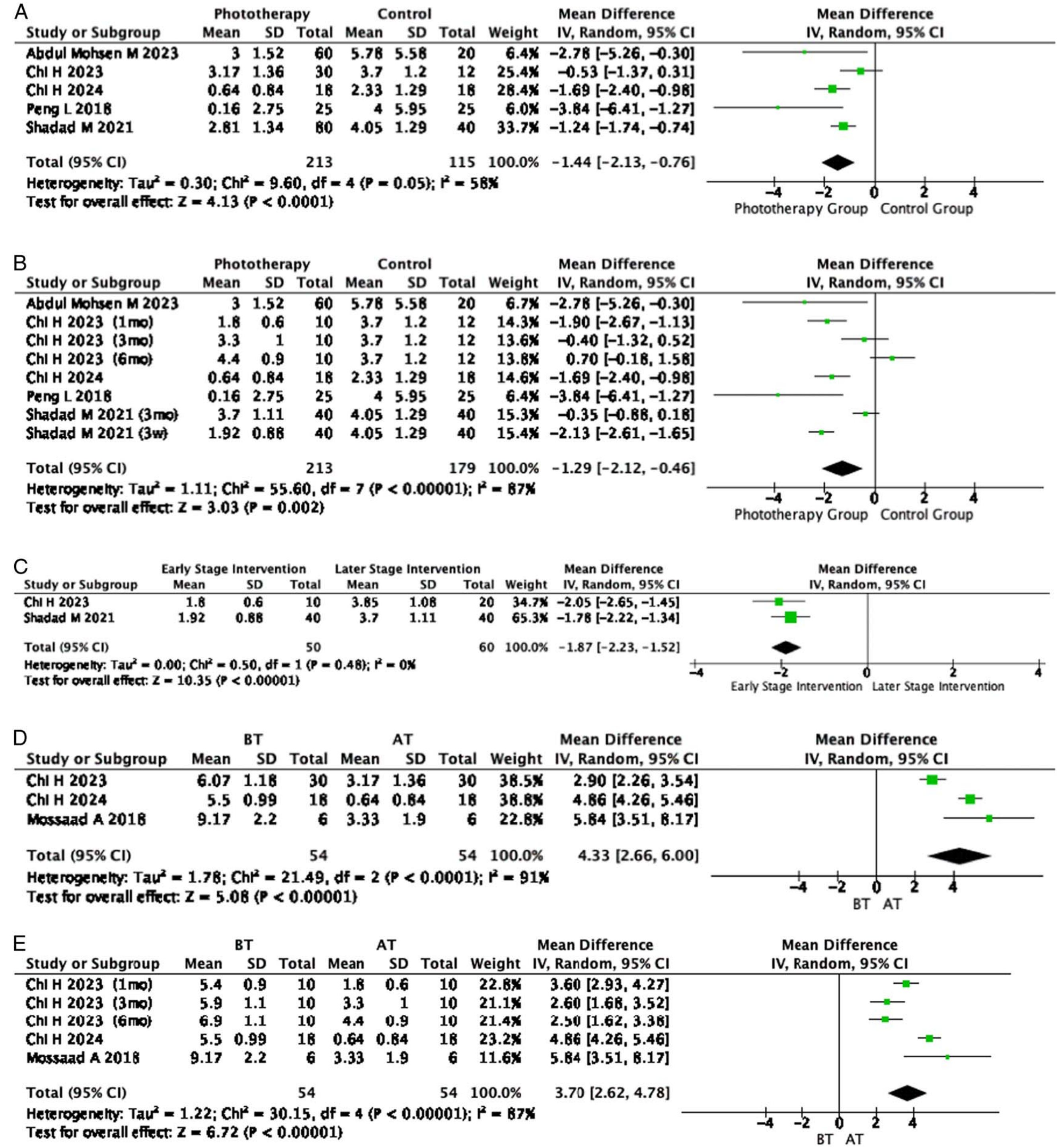

Figure 3. A This forest plot shows the meta-analysis for VSS score differences in five studies that compared phototherapy with routine care (Control Group). B This forest plot shows the meta-analysis for subgroup VSS score differences in five studies that compared phototherapy with routine care (Control Group). C This forest plot shows the meta-analysis for VSS score differences in two studies that compared the data of early postoperative (Early Stage Intervention) with mid-to-late postoperative (Later Stage Intervention). D This forest plot shows the meta-analysis for VSS score differences in three studies that compared before-treatment (BT) with after-treatment (AT). E This forest plot shows the meta-analysis for subgroup VSS score differences in three studies that compared before-treatment (BT) with after-treatment (AT).

Finally, the safety and long-term stability of laser and IPL in the treatment of scars should not be ignored. Future studies should focus on the long-term follow-up results, comprehensively evaluate the safety and stability of treatment, and explore whether long-term maintenance and treatment are necessary.

In conclusion, laser and IPL show great potential in the field of scar treatment. However, further research and exploration are still needed. We look forward to future studies that will provide us with consummate treatment strategies to provide safer and more effective personalized treatment options for patients with upper lip scars after cleft lip surgery.

Conclusion

Compared with routine care, the total VSS score after laser or IPL treatment was significantly decreased. Phototherapy is a safe and effective method for the treatment of scars after cleft lip surgery. The clinical effect of laser or IPL treatment in the early postoperative period is significantly better than that in the mid-to-late postoperative period.

To achieve more solid research conclusions and provide better guidance for the treatment of upper lip scars after cleft lip surgery, more comprehensive, large-amount randomized controlled trials and more reliable and unified evaluation criteria are required, given the limitation of the quantity and quality of included studies.

Ethical approval

Not applicable.

Consent

Not applicable.

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Author contribution

S.W. and Y.W.: conceptualization; S.W., G.Z., and Q.W.: data curation; Y.W.: funding acquisition; T.S., N.Y., and Y.W.: project administration; S.W. and G.Z.: software; N.Y. and Y.W.: supervision; S.W.: writing – original draft; S.W. and Y.W.: writing – review and editing.

Conflicts of interest disclosure

The authors declare no conflicts of interest.

Research registration unique identifying number (UIN)

PROSPERO CRD42023482170. This work has been registered in PROSPERO system.

Guarantor

Yongqian Wang.

Data availability statement

Data are available upon from the corresponding author on reasonable request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Assistance with the study

Not applicable.

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