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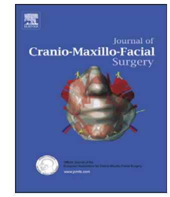

Red-blue light irradiation in the prevention of surgical wound infection after mandibular distraction using internal distractors in hemifacial microsomia: A randomized trial

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A R T I C L E I N F O

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A B S T R A C T

Background: Postoperative infection is a complication of mandibular distraction osteogenesis (DO) in patients with hemifacial microsomia (HFM). The risk of surgical wound infection in DO is reported to be high due to the long duration of the distraction process. Treatment during the perioperative period is critical in combating infection.

Aim: This study aimed to evaluate the effectiveness of red-blue irradiation in the prevention of surgical wound infection after mandibular distraction.

Methods: In our single-centered, randomized clinical study, 118 patients diagnosed with HFM who had undergone DO between April 2016 and April 2018 were included. The patients were randomly divided into two groups: the experimental group received red-blue irradiation treatment and the control group received white-light irradiation.

Results: None of the infections occurring in this study resulted in serious complications. The post-operative infection rate during the 4 weeks after DO in the experimental group was 1.7%, whereas that in the control group was 13.6% ($p = 0.016$) (based on a modified NHSN wound infection criterion). The total social cost during the active period for the experimental group was 3386840 RMB, 5.12% higher than for the control group (3221882 RMB).

Conclusions: Red-blue irradiation is recommended as adjunctive therapy after mandibular distraction osteogeneis in HFM.

1. Introduction

In 1992 distraction osteogenesis (DO) was successfully applied to mandibular lengthening in patients with hemifacial microsomia (HFM). Since then it has become a reliable procedure in the management of craniofacial anomalies (Nouri and Farzan, 2015). This technique is complex and time consuming, and uses internal distractors composed of two components: one on the mandibular ramus and the other outside the skin (Fig. 1). DO consists of three phases: latency, activation, and consolidation. The latency phase (the period between the osteotomy and the commencement of distraction) can range from 5 to 7 days. The activation phase progresses with a usual distraction speed of 1 mm per day, until the desired length of the distracted mandible is achieved. The consolidation phase can take from 6 to 8 weeks. Due to the long period required for healing, the risk of infection of the surgical wound in DO is high.

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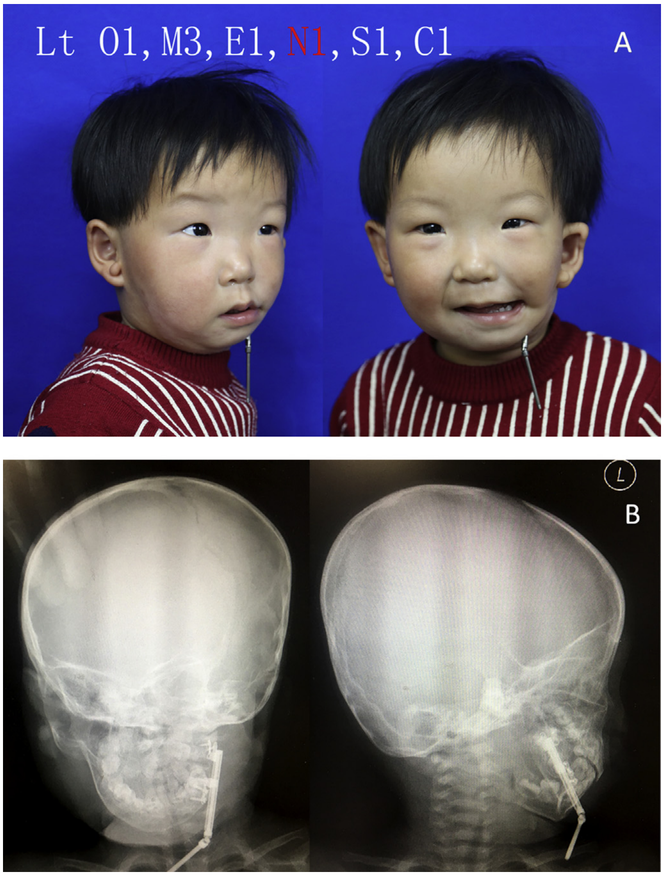

Fig. 1. Distraction osteogenesis of HFM patients using internal mandibular distractor. A,B. Patient wearing the internal distractor, composed of two components — one on the mandibular ramus and the other outside the skin; C,D. Patient X-ray demonstrating the location of the distractor.

Some studies have reported that infection from the external adjustable pin can lead to inflammation of the deep tissues. This can require removal of the distractor, adding a further mental and economic burden on the patient (Mofid et al., 2001; Diner et al., 1996). Most HFM patients start their treatment at a young age. Compared with adult patients, it is difficult for them to maintain their oral hygiene. Moreover, the treatment needs continuous regulation of the distractor for about 25 days (25 ± 3.72). According to Mofid et al., a worldwide questionnaire survey on mandibular traction (3278 cases) showed that infections, premature healing, and other problems were prevalent, with a postoperative infection rate of 9.5% (Mofid et al., 2002). Hence, treatment during the perioperative period is very important in combating infection.

Red-blue light has been used in the treatment of acne. It has also been shown that visible blue light (470 nm) leads to photo-excitation of bacterial porphyrins, production of singlet oxygen, and eventually bacterial destruction (Waldeck et al., 2012). Red light may have anti-inflammatory properties by influencing the release of cytokines from macrophages or other cells. However, its exact mode of action in the treatment of acne vulgaris is not yet fully understood (Papageorgiou et al., 2000). With red-blue light equipment it is easy irradiate the whole face of the child. However, there are no reports in the literature on using red-blue irradiation to control postoperative infection. This study aimed to determine whether red-blue light is effective in preventing infections during mandibular DO procedures and thus can be recommended as adjunctive therapy after mandibular distraction osteogenesis in HFM.

2. Material and methods

2.1. Ethical approval

This study was approved by the Ethics Committee of Shanghai Ninth People's Hospital, affiliated to Shanghai Jiao Tong University (SH9H-2018-T49-1), and complies with the principles stated in the declaration of Helsinki.

2.2. Study design and sample

This prospective, single-blind, randomized study was conducted in the Department of Plastic and Reconstructive Surgery, Shanghai Ninth People's hospital with the involvement of one chief consultant, two surgeons, two residents, one laser physician, and one data administrator. The team had over 10 years' experience in the treatment of HFM.

We conducted a pre-experimental, single-center, small-sample study with 16 patients: eight received red-blue light irradiation and eight received white light irradiation. The results of this study showed that one patient in the red-blue light group and three patients in the white light group had infection. Based on this result, we calculated using PASS software that 118 patients were needed for the study: 59 in the red-blue group and 59 in the white group.

The study was conducted between April 2016 and April 2018, and 118 patients were included. The inclusion criteria were: age between 4 and 8 years; Pruzansky-Kaban Type II; patients who underwent mandibular distraction; and patients who gave informed consent. Patients who did not meet these criteria were excluded from the study.

2.3. Surgical and routine postoperative procedures

Professor Chai Gang, with over 15 years' experience in treating HFM, was the operator in the experimental and control groups. All the patients were treated with intraoral distraction osteogenesis. The same vertical distraction was used in both groups (Xi'An Zhongbang Titanium Biological Materials Co., China). The activating rod protruded into the lower vestibule and broke through the epidermis, keeping it outside the skin. Distraction started on the 4th to 7th postoperative day, by turning the rod 0.35 mm each time, 2–4 times per day.

2.4. Irradiation equipment

The irradiation sources were high-energy, solid-semiconductor, cold light emitting diodes (Carnation-88c; Lifotronic, Shenzhen, China) (Fig. 2). The red lamps had asymmetrical peak wavelengths of 625 nm. The blue lamps had asymmetric peak wavelengths of 465 nm. If the light came from a distance of 25 cm, the duration required for one irradiation for the treatment of acne was 30 min (Papageorgiou et al., 2000).

2.5. Randomization and masking

The patients were randomly divided into two groups: the experimental and control groups to receive red-blue light and white light irradiation, respectively, for 4 weeks during the preoperative period. In order to blind the study, patients in the control group were given white light irradiation. The pragmatic placebo white light irradiation does not have a bacteriostatic effect (Bitter, 2016).

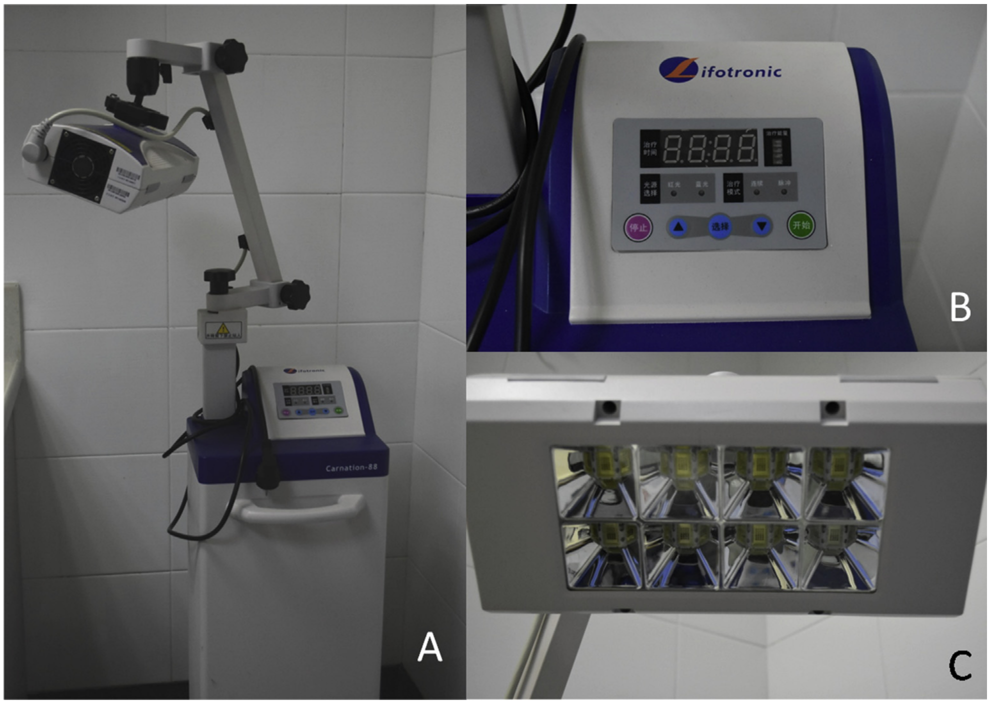

Fig. 2. Red-blue light machine (Carnation-88c, Lifotronic, Shenzhen, China). A. Overall view; B. Operating interface; C. Red-blue light tube.

2.6. Red-blue irradiation and routine wound care procedures

During the preoperative period (4 weeks), the patients in the experimental group received red-blue irradiation for the whole face once every 2 days (Fig. 3). The red lamps had a symmetrical peak wavelength of 660 ± 10 nm. The blue lamps had an asymmetric peak wavelength of 415 ± 10 nm. When the light source was 25 cm away from the patient, the total irradiance received was 4.23 J/cm^2 for the blue light and 2.67 J/cm^2 for the red light. Each treatment duration was 30 min, applied twice a week for a total of 4 weeks. The UV content in the red-blue light tube was 7%, and was well within the Health and Safety Executive guidelines for occupational exposure of the unprotected eyes and skin (Alexiades, 2017; McGinley et al., 1980; Kjeldstad, 1984).

The patients in the control group received cool white light irradiation for a duration of 30 min per time, twice weekly for 4 weeks after mandibular distraction. Prophylactic antibiotic was used for a duration of 3 days in all patients. An intravenous drip of 1 g of ceftriaxone sodium was administered once daily. If the patient was allergic to cephalosporin, an intravenous drip of 0.15 g of clindamycin hydrochloride was administered twice daily.

The dressing protocol was the same in both groups. Each patient used chlorhexidine mouthwash twice daily under the guidance of a nurse, beginning on the day before surgery. The parents of the patients were taught by the resident to change the dressing of the intraoral incision and the external surgical wound. Then, the resident rechecked whether the parents changed the dressing correctly. A gastric tube was inserted immediately after the operation for nutrition and was removed after the intraoral incision had healed. All the patients followed this dressing protocol. Patients were not allowed to take other antiseptic therapy without our permission during the study.

2.7. Evaluation methods

The primary outcome measure was the rate of surgical site infection (SSI) within the preoperative period (4 weeks). SSI was determined by recording a body temperature greater than 38 °C and by observing the condition of the wound (Ding et al., 2015; Horan et al., 2008; Malanchuk and Kopchak, 2007) (Fig. 4). According to Ding et al., we used strict criteria for wound evaluation, which were modified from NHSN criteria (Horan et al., 2008) (Table 4). We considered slightly exudative wounds with no obvious swelling, and requiring additional antibiotics after surgery, as infection cases (corresponding to wound level II in our study). The wound condition was graded in five levels (modified NHSN criteria): level I, the wound had no exudation, redness, or swelling; level II, the wound was slightly exudative with no obvious swelling; level III, the wound was red and swollen; level IV, the wound had pus and blood, and was fluctuant; and level V, a part of the wound was split. Level II, III, and IV wounds were defined as infected wounds (Sanger et al., 2016).

There were four secondary outcome measures. The first was the SSI rate at the end of the consolidation period (6 months after the end of the activation phase). It was evaluated using telephone follow-up and photo images of the wound. The second was the satisfaction of the patient, which was evaluated using an aesthetic numerical analog scale (ANA scale) and a paper survey questionnaire after 4 weeks of irradiation (Funk et al., 2012). The third was the total distracted length of the mandibular ramus at the end of the consolidation phase. The fourth was the total expenditure during the whole treatment.

2.8. Statistics

Statistical analyses were performed using SPSS version 22.0, and data were expressed as averages ± standard deviations ($X \pm s$). The t-test was used to compare means between the two groups. The χ^2 test was used to compare count data, which were expressed as rates (%). p-values of <0.05 were considered statistically significant.

3. Results

118 patients were included in this study, which was conducted between April 2016 and April 2018. They were randomized into the

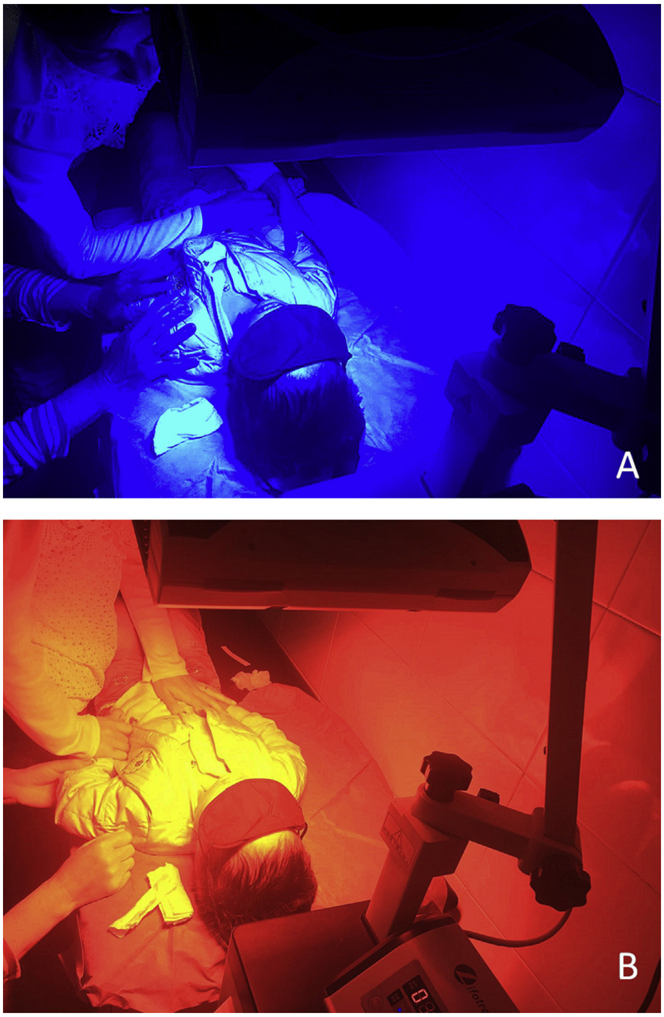

Fig. 3. Patients who received red-blue light irradiation. A. Blue light irradiation; B. Red light irradiation.

experimental and control groups, each with 59 patients. There were no exclusions or losses to follow-up after randomization. There were no statistically significant differences in the baseline characteristics between the two groups (Table 1). The average time needed to achieve the desired bone traction was 25 ± 3.72 days (4 weeks). The consolidation phase took approximately 4 months. There were no statistical differences in the type of antibiotic use during the duration of treatment between the two groups (Tables 2 and 3).

3.1. Primary outcome

One case in the experimental group and eight cases in the control group developed infection of the wound after 4 weeks of irradiation. In five patients, high body temperatures were recorded (>38 °C). Four patients required the dressing to be changed due to the leakage of blood from the wound (Table 5). The infection rate was 1.7% in the experimental group and 13.6% in the control group after 4 weeks of irradiation, $p = 0.016$. The difference in the infection rate was statistically significant in 95% CI.

3.2. Secondary outcomes

One case in the experimental group and three cases in the control group had wound infections at the end of the consolidation phase (Table 6). The infection ratio during this phase in experimental group was 1.7% and that in control group was 6.3%. The difference showed a p-value of 0.531, and was not statistically significant in 95% CI.

The ANA-scale scores represented the following: 0, ‘insufficient’; 1, ‘poor’; 2, ‘unsatisfied’; 3, ‘sufficient’; 4, ‘neutral’; 5, ‘agreed’; 6, ‘satisfied’; 7, ‘as requested’; 8, ‘harmonic’; 9, ‘highly satisfied’; and 10, ‘perfect’. A paper questionnaire was used to collect these data after 4 weeks of irradiation (Table 7). The average score in the experimental group was 4.610 ± 1.0034 and that in the control group was 3.542 ± 1.179; $p = 0.001$. The difference in patient satisfaction between the groups, represented by the ANA-scale, was statistically significant in 99% CI. The ANA-scale score for the experimental group was higher than that for the control group.

Fig. 4. Wound condition was graded into five levels. A. Level I, the wound had no exudation, redness, or swelling; B. Level II, the wound was slightly exudative with no obvious swelling; C. Level III, the wound was red and swollen; D. Level IV, the wound had pus and blood, and was fluctuant.

Table 1
Baseline characteristics between the two groups.

Characteristics	Red-blue light group	White light group	*p*
Mean age	6.076	5.949	0.816
Parents' education level			
Primary education or less	15	17	0.694
Secondary education	17	13	
Tertiary education	27	29	
Mean days of hospitalization	6.492	6.763	0.485
Mean family income	21.259million	20.329million	0.522
Selection of antibiotic schemes			
Hypersensitivity to cephalosporin	6.778%	8.475%	0.729
Days of using antibiotics	3.576	3.848	0.183
Missing patients	0	0	
Mean length of mandibular increase	21.134	20.672	0.658

Table 2
Statistical table for time using antibiotics.

	Red-blue light group	White light group	*p*
Time using antibiotics using (days)	3.576 ± 0.770	3.848 ± 1.350	0.183

Table 3
Type of antibiotic use during treatment between the two groups.

	Cefxi sodium	Clindamycin hydrochloride	Total	Allergic rate[a]	*p*
Red-blue light group	55	4	59	6.778%	0.729
White light group	54	5	59	8.475%	

[a] Cefoxitin was used routinely after the operation. If the patient was allergic to cefoxitin, clindamycin hydrochloride was used instead. Allergic rate = number of cases using clindamycin hydrochloride/total.

Table 4
Wound condition was graded into five levels*.

Wound level	Wound picture	Wound grade
I: the wound had no exudation, redness, or swelling	Fig. 4A	1
II: the wound was slightly exudative, with no obvious swelling	Fig. 4B	2
III: the wound was red and swollen	Fig. 4C	3
IV: the wound had pus and blood, and was fluctuant	Fig. 4D	4
V: part of the wound was split	No patients with such a serious infection	5

*The wound infection criteria in our study were stricter than the NHSN criteria.
NHSN criteria defined the level III and above as infected wounds, but the modified NHSN criteria in our study defined level II as infected.

The mean total distracted length of the mandibular ramus on the affected side from the end of the activation phase to the end of the consolidation phase (6 months) in the experimental group was 21.13 ± 5.49 mm and that in the control group was 20.67 ± 5.82 mm (Table 8). The difference was not statistically significant, with a *p*-value of 0.658. The total distracted length of the mandibular ramus in the infected patients was 15.098 ± 2.003 mm, and that in the uninfected patients was 21.359 ± 5.583 mm; $p = 0.001$. Thus, the total distracted length of the mandibular ramus in the infected patients was shorter than that in the uninfected patients. This was statistically different in 99% CI (Table 9).

According to the hospital's standard unified charging system, the operation-related fee was 54200 RMB per patient and the irradiation-related fee was 3200 RMB per patient. The total infected wounds treatment fee for the experimental group was 240 RMB and for the control group 24082 RMB. Thus, the total social cost in the experimental group was 3386840 RMB $((54200 \times 59) + (3200 \times 59) + 240)$; the total social cost in control

Table 5
Postoperative infection rate for the two groups during the light irradiation period (4 weeks).

Wound level	Red-blue light group	White light group
I	58	51
II	0	3
III	1	3
IV	0	2
V	0	0
Total	59	59
Infection rate	0.017	0.136
p	0.016	

Table 6
Postoperative infection rate for the two groups during the consolidation phase (6 months).

Wound level	Red-blue light group	White light group
I	0	0
II	0	1
III	1	2
IV	0	0
V	0	0
Total	1	3
Infection rate	0.017	0.051
p	0.531	

Table 7
Patients' satisfaction following irradiation treatment (ANA-scale).

Score	Red-blue light group	White light group
0	0	0
1	0	4
2	1	8
3	2	10
4	32	28
5	11	7
6	10	2
7	3	0
8	0	0
9	0	0
10	0	0
Average score	4.610 ± 1.034	3.542 ± 1.179
p	0.001	

Table 8
Mean total distracted length of the mandibular ramus on the affected side from the end of the activation phase to the end of the consolidation phase (6 months).

	Red-blue light group	White light group
Average extended length (mm)	21.134 ± 5.491	20.672 ± 5.823
p	0.658	

Table 9
Total distracted length of the mandibular ramus in infected patients and uninfected patients.

	Infected patients	Uninfected patients
Average extended length (mm)	15.098 ± 2.003	21.359 ± 5.583
p	0.001	

group was 3221882 RMB ((54200 × 59) + 24082). The total social cost for the experimental group was therefore 5.12% higher than that for the control group.

4. Discussion

The oral cavity, which is important for the entry of food into the digestive tract, is also an optimum environment for microbial habitation and breeding (Paulsson et al., 1999). Patients who undergo mandibular distraction have operative trauma, wear distractors for long durations, are young, and have wounds inside the oral cavity as well as on the skin. Due to the abundant blood supply in the facial area, experiments have shown that the peak blood flow in the traction area can increase to up to seven times the normal level (Aronson, 1994). The infection rate for DO in the craniofacial region is reported to be relatively low when compared with that for the lower limb regions, due to the rich blood supply in the craniofacial region (Velazquez et al., 1993). However, once superficial infection has evolved into deep tissue infection, it can lead to serious results, such as suture loosening or bone deterioration. Therefore, effective prevention of postoperative infection is important to increase the success rate of mandibular distraction. The postoperative use of antibiotics is still the most effective method to prevent infection after surgery. However, with the development of drug resistance the necessity for new methods that can prevent infection has become significant.

The infection rates for DO surgery for HFM have been reported as 7.14% (Carls and Sailer, 1998), 14.28% (Lu et al., 2016), and 18.3% (Hollier, 2018). The criteria for infected wounds in these articles were based on the NHSN criteria (Horan et al., 2008). We used modified NHSN criteria (Ding et al., 2015) in our study. Modified NHSN wound infection criteria were more strict than NHSN criteria (Table 4). If we had used NHSN criteria, wound infection rates in our study would have been 8.47% for the control group and 1.69% for the experimental group.

Red-blue light generates large amounts of reactive oxygen species (ROS), which are very small molecules that are highly reactive due to the presence of unpaired valence shell electrons (Lavi et al., 2004). It is already known that high amounts of ROS are lethal to cells as well as bacteria (Sellera et al., 2019; Chen et al., 2018). After blue light irradiation, the photodynamic substances stored in the bacteria are stimulated and singlet oxygen is generated, which kills the bacteria (Arakane et al., 1996).

There are several reports on the bactericidal effects of visible light that claim that blue light (400–500 nm) can inhibit bacteria, including Gram-positive bacteria, such as *S. aureus*-MRSA, *S. epidermidis*, *S. pyogenes*, and *C. perfringens*, and Gram-negative bacteria, such as *A. baumannii*, *P. aeruginosa*, *E. coli*, *P. vulgaris*, and *K. pneumonia* (Maclean et al., 2009).

It has been mentioned in the literature that singlet oxygen (reactive oxygen species) produced by low-dose phototherapy stimulates the production of TGF-beta 1 subtype. TGF-beta 1 can regulate the roles of various cells in wound healing, such as keratinocyte migration, fibroblast collagen synthesis and remodeling, wound contraction through myofibroblast transformation, angiogenesis, and neurogenesis. However, TGF-beta 1 is involved in various aspects of wound healing. Recent theoretical studies on the promotion of wound healing by phototherapy report different or even contrary effects (Arany, 2016).

In this study, we conducted bacterial cultures using facial secretions from all the infected patients, and counted the bacterial strains grown in the two groups of patients. The constituent ratios of pathogens in the infected patients are shown in Table 10.

Table 10
Constituent ratios of pathogens in the infected patients (4 weeks).

Pathogens	Red-blue light group		White light group	
	Infected cases	Pathogens ratio[a]	Infected case	Pathogens ratio
Gram-positive bacteria	0	0	0	0
Staphylococcus aureus	0	0	6	0.667
Enterococcus	0	0	1	0.111
Coagulase negative Staphylococcus	0	0	0	0
Streptococcus	0	0	0	0
Gram-negative bacteria	0	0	0	0
Escherichia coli	0	0	0	0
Pseudomonas aeruginosa	0	0	0	0
Klebsiella pneumoniae	0	0	1	0.111
Acinetobacter baumannii	1	0.111	0	0
Total	1	0.111	8	0.889

[a] Pathogens ratio = infected cases/9 (total number of infected patients).

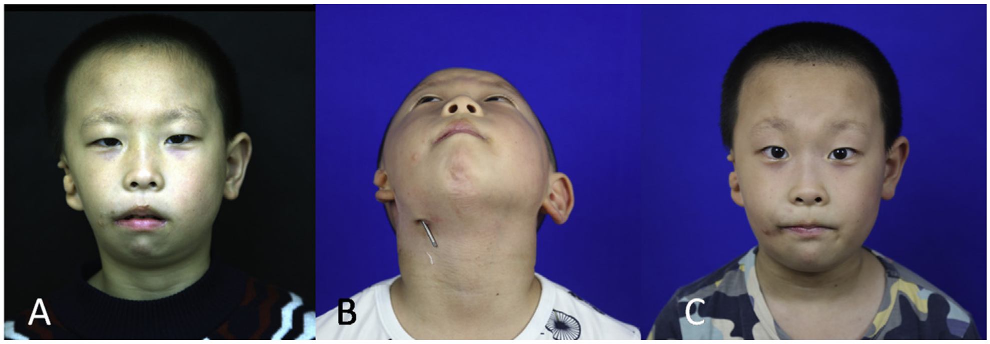

Fig. 5. Experimental group patient, HFM Pruzansky Type II. A. Preoperative view; B. Wound condition level I, distraction for 3 weeks; C. Postoperative view.

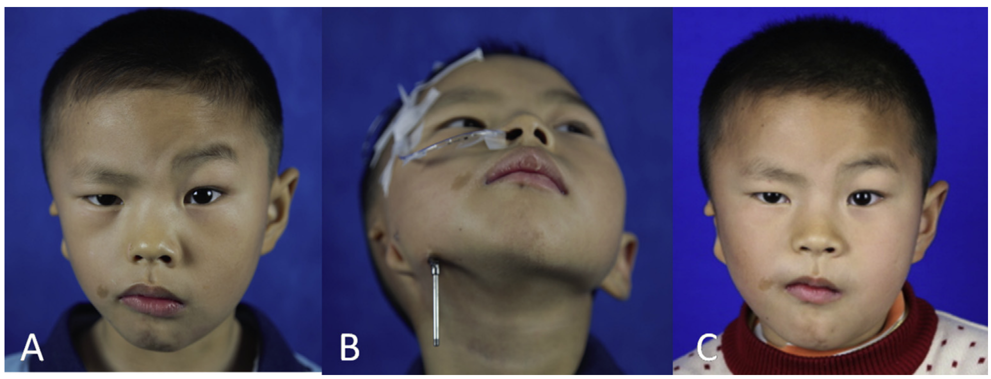

Fig. 6. Controlling group patient, HFM Pruzansky Type II. A. Preoperative view; B. Wound condition level III, distraction for 3 weeks; C. Postoperative view.

Red light has not been explored adequately. Exposure to light of low wavelengths, such as 600–660 nm, could stimulate fibroblast proliferation and the production of growth factors. It could thereby influence healing and wound repair (Abergel et al., 1987).

During treatment with red-blue irradiation, damage caused to the human body by ultraviolet light is a problem that cannot be ignored. However, the lamp used in this study had a low UV content and did not constitute a risk to the patients on whom it was used. We proposed that blue light and red light may act synergistically in reducing the postoperative infection rate by combining antibacterial and anti-inflammatory actions.

The cost of treating an infected patient after orthopedic surgery is reported to be twice the cost of treating an uninfected patient (Thakore et al., 2015). The average extra treatment fee (anti-infection-related fee) for all infected patients is 2702.44 ± 593.51 RMB, which is 84.45% of the irradiation-related cost. In our study we found that in cases where the wound developed an infection, swelled, and secreted pus or blood, we needed to stop the rotation adjustment, use chlorhexidine mouthwash to flush the wound, perform debridement of the wound, and leave a rubber latex tube to drain it. Following this, antibiotics had to be used until the wound infection was controlled. If the wound became better, mandibular traction was continued. However, if the wound became worse, traction had to be stopped and the bone distractor removed. If the wound developed an infection, the treatment fee and number of days hospitalized increased markedly and the final orthodontic result could have been affected. Preoperative and postoperative pictures of the experimental and control groups are shown in Figs. 5 and 6. Hence, irradiation treatment is worth trying. In this study all irradiation treatment was conducted in the Dermatology Department of our hospital. A red-blue light machine is not expensive, and its parameter settings are very simple, so even community hospitals can afford and operate it. So it is possible for irradiation treatment to be promoted as a routine anti-infective treatment method, thereby reducing social costs.

There are some limitations to this study. First, the total social cost in the experimental group was higher than in the control group. Detailed expenditures for the treatment process were as follows. Each red-blue light treatment was charged at 200 RMB (according to the standard charges of the Shanghai Ninth People's Hospital). The lodging cost and the travelling cost for one irradiation treatment is 200 RMB. Therefore, the four-week red blue irradiation will cost the patient an average of 3200 RMB. According to the hospital's standard unified charges, the operation-related fee was 54200 RMB. The total infected wounds treatment fee for the experimental group was 240 RMB and for the control group was 24082 RMB. Thus, the total social cost for the experimental group was 3386840 RMB ($(54200 \times 59) + (3200 \times 59) + 240$). The total social cost for the control group was 3221882 RMB ($(54200 \times 59) + 24082$). The total social cost for the experimental group was therefore 5.12% higher than that for the control group.

Second, there were some areas of bias that could not be avoided. The care given by the parents to the children could not be standardized because parents spend different amounts of time and energy on caring for their children. Moreover, the patients came from different parts of China, and the varied temperatures of these places could have affected wound healing.

Patients diagnosed as Pruzansky-Kaban Type II who underwent mandibular distraction with external distracters and who were treated with red-blue irradiation had a lower postoperative infection rate after 4 weeks of irradiation than those who were not treated with red-blue irradiation. Therefore, we have reason to believe that red-blue light irradiation can reduce postoperative infection and promote wound healing.

5. Conclusion

Red-blue irradiation is recommended as adjunctive therapy after mandibular distraction osteogeneis in HFM. Further studies with larger sample sizes need to be conducted to establish the long-term effects and the explicit mechanism of action of red-blue irradiation in the prevention of postoperative wound infections.

Financial disclosure statement

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Conflicts of interest

None.

Authors' contributions

Xiaohui Qiu, MD, Trial implementation, data analysis, and drafting the article.

Yanchun Zhou, Patient collection and trial implementation.

Huifang Zhou, Patient collection and trial implementation.

Xiaojun Chen, MD, Clinical data collection.

Haisong Xu, MD, Participation in the operation.

Weijun Mooi, MD, Acquisition of data.

Wei Chen, MD, Clinical data collection.

Wenqing Han, MD, Data collection and analysis.

Gang Chai, MD, Trial design and arrangement.

Xianxian Yang, MD, Guidance of the task and revision of the article.

Yan Zhang, MD, The overall arrangement and revision of the article.

Patient consent

All patients provided written informed consent.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jcms.2019.07.004.

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