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Development of swelling following orthognathic surgery at various cooling temperatures by means of hilotherapy—a clinical, prospective, monocentric, single-blinded, randomised study

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ABSTRACT

Purpose: An alternative cooling method in oral and maxillofacial surgery is post-operative cooling with hilotherapy. It has not yet been clarified how the development of pain and swelling progresses post-operatively at different cooling temperatures. The aim of this study was the post-operative comparison of cooling temperatures of 18 °C and 22 °C. The parameters of this trial were swelling and the post-operative development of pain levels. In addition, the need for analgesics and patient satisfaction were documented.

Materials and methods: This study included 36 patients, divided into two groups among whom a mono- one or bignathic osteotomy or genioplasty in orthognathic surgery was indicated. After the intervention, hilotherapy was employed directly instead of the conventional cooling method with moist compresses. The post-operative check of swelling during and after hilotherapy was performed using a 3D optical scanner (FaceSCAN3D®). This examination was repeated on post-operative days 1, 2, 3, 7, 14, 30 and 90. In this process, the final examination on day 90 served as a reference value in respect of swelling and pain.

Results: Group 1 (18 °C, 18 patients) showed an increase in post-operative swelling on the 1st post-operative day of 62.22 ± 36.29 ml. The maximum was reached on the 3rd post-operative day with 81.85 ± 40.23 ml. On the 30th post-operative day, residual swelling measured 7.39 ± 15.77 ml ($p = 0.016$). Group 2 (22 °C, 18 patients) showed an increase in postoperative swelling on the 1st post-operative day of 61.69 ± 34.7 ml. The maximum was reached on the 2nd post-operative day with 92.83 ± 48.03 ml. On the 30th post-operative day, residual swelling measured 28.09 ± 19.04 ml ($p = 0.016$).

Discussion: The study results indicate slightly less residual swelling in group 1 (18 °C) on the 30th post-operative day. One possible reason for this, based on the design of the study, could be the lower cooling temperature. The post-operative pain development exhibits a comparable level of pain intensity between the two groups. In overall terms, a subjectively more agreeable treatment was observed in group 1 (18 °C).

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1. Introduction

Clinical data from the maxillofacial area show that a thermo-healing process that promotes natural healing action in the damaged tissue offers advantages over the conventional cooling methods (e.g. cooling compresses), in terms of reduction of swelling, mitigation of pain and patient satisfaction, which can in turn speed up the convalescence process (Belli et al., 2009; Moro et al., 2011; Rana et al., 2011a, 2011b, 2011c, 2013; Modabber et al., 2013).

In most patient cases, secondary effects such as post-operative swelling, pain, facial oedema, inflammation and restricted mouth opening were found to occur after orthognathic surgery (Phillips et al., 2008). Postoperative pain usually occurs shortly after the operative intervention. However, the swelling and restriction on opening of the mouth reach their maximum extent after 48–72 h (Seymour et al., 1985). Consequences of this nature, which substantially impair the quality of life post-operatively and slow down the convalescence process, can be mitigated by the use of

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corticosteroids (Grossi et al., 2007), nonsteroidal anti-inflammatory drugs (NSAIDs) (Benetello et al., 2007), enzyme preparations (Al-Khateeb and Nusair, 2008) or manual lymph drainage (Szolnoky et al., 2007). Another low-impact alternative method is cryotherapy. Cryotherapy involves the local or systematic application of cold for therapeutic purposes, and was already in use successfully at the time of Hippocrates (Stangel, 1975). As tissue temperature drops, the sensitivity to nociceptive systems also drops, continuously to about 15 °C until complete analgesia is achieved (Gerold et al., 1998). At tissue temperatures of less than 10 °C, tissue damage can occur (Denny-Brown et al., 1945; Schaumburg et al., 1967; Zemke et al., 1998). Cold also affects the refractory time that increases as the temperature drops (Douglas and Malcolm, 1955). The speed of nerve conductivity declines in a linear fashion as skin temperature is cooled to between 23 °C and 36 °C. Below 20 °C the excitability threshold rises rapidly (De Jong et al., 1966), then at 4 °C the excitation line is blocked (Li, 1958). By influencing the membrane properties of the nerve fibres responsible, it is possible to reduce the nerve-induced impulse frequency, leading in turn to a reduction in the intensity of pain experienced (Olson and Stravino, 1972; Senn, 1985). Further benefits of the postoperative use of cryotherapy include delayed bacterial growth, the prevention of oedema through reduction of the accumulation of fluids in body tissues, the reduced release of inflammation mediators and a reduction in the level of enzymatic activity as well as the formation of haematomas (van der Westhuijzen et al., 2005). An alternative and innovative cooling method after an adjustment osteotomy in orthognathic surgery is postoperative cooling with the device Hilotherm Clinic (Hilotherm® GmbH). This involves a process of continuous, controlled cold therapy with the help of a water-circulating and anatomically shaped facial sleeve. This device, an approved medical product, is used on patients in the temperature range of +10 °C to +35 °C. It has not yet been clarified how the development of pain and swelling, and of patient satisfaction, progresses postoperatively at different approved cooling temperatures.

The aim of this study is the post-operative comparison of hilotherapy at cooling temperatures of 18 °C and 22 °C. The parameters of this trial are swelling and the post-operative development of pain levels. Through this comparison of cooling temperatures, the intention is, in the future, to enable patients to convalesce more quickly, to achieve immediate analgesic impact, and to experience reduced swelling and less damage to skin tissue.

2. Materials and methods

This study was examined and approved by the Ethics Committee at the medical faculty of the Westfälische Wilhelms-Universität in Münster, Germany (file reference: 2013-239-f-S). First of all, all patients were advised of the content of the study (clinical trial), and a declaration of their written consent was obtained.

2.1. Patients

This study included 36 patients, divided into two randomised groups (cooling temperature of 18 °C versus 22 °C) among whom a one- or two-sided adjustment osteotomy or genioplasty in orthognathic surgery was required. The operations were carried out at the department of oral and maxillofacial surgery at Klinikum Dortmund gGmbH on the basis of standardised operating methods, and always by the same surgeon. As a standard procedure for adjustment of the position of the mandible the sagittal split method developed by Obwegeser and Trauner was employed. The osteotomy and adjustment of the maxilla was performed on the Le Fort I level (Reuther, 2000). Age, gender, length of operation, need for analgesics and patient satisfaction levels were all documented.

2.2. Hilotherapy

Hilotherapy comprises a Hilotherm® Clinic device (Hilotherm® GmbH, Argenbühl Eisenharz, Germany), that enables water, temperature-controlled to within 1 °C, flows through an anatomically adapted, specially developed and very lightweight facial sleeve (Latex-free thermoplastic polyurethane). This device, an approved medical product, is used on patients in the temperature range of +10 °C to +35 °C (Fig. 1A–B).

2.3. Inclusion, exclusion and study parameters

Table 1 provides a summary of the inclusion and exclusion criteria. In accordance with the study protocol, all patients received Solu-Decortin 500 mg and a dose of antibiotics (3 g Unacid intravenously prior to the operation, or, if not compatible, clindamycin 600 mg) was administered. Post-operatively during the hospital

A

B

Fig. 1. (A) Hilotherm®: clinical device with adjustable temperature range of +10 °C to +35 °C. (B) Face sleeve applied to patient (Hilotherm® GmbH).

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Table 1
Study inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Therapy of bi- or monomaxillary orthognathic surgery, genioplasty	Drug ingestion of glucocorticoids or NSAIDs
Written informed consent	Cooling therapy under 16 h/day
	Inability to acceptance
	Intolerance of cooling therapy

NSAIDs, nonsteroidal anti-inflammatory drugs.

stay, the antibiotics therapy was continued intravenously with 3 × 3 g Unacid per day (3 × 600 mg clindamycin per day). As therapy against pain, instead of a rigid analgesia regimen, paracetamol 1 g/Novalgin 1 g was simply administered intravenously as and when required. On the 1st post-operative day, a routine laboratory check was conducted, together with an X-ray examination. Patients were dismissed on the 3rd postoperative day and received antibiotic therapy orally with 3 doses of amoxicillin comp 875/125 mg (3 × 600 mg clindamycin) per day for another 7 days. For pain therapy, ibuprofen 600 mg was advised up to 3x daily on demand and subject to compatibility. During the entire investigation period, swelling and pain levels were examined and documented on the basis of a visual analogue scale (VAS), together with the need for analgesia.

2.4. Clinical trial procedure

Hilotherapy was started immediately after the surgical intervention. The patients were not aware of whether they were being subjected to a cooling temperature of 18 °C or 22 °C. The daily application of cold lasted for at least 16 h. To examine the need for analgesics, following surgical intervention, no prophylactic analgesics were administered. Medication was provided on an as-needed basis, i.e. in response to pain occurring. A post-operative comparison and investigation of the development of swelling was conducted using a 3D optical scanner (FaceSCAN3D®), a 10-point pain visual analogue scale (VAS) was administered, and a patient satisfaction survey form was also distributed. This examination was repeated on post-operative days 1, 2 and 3 during the inpatient stage of this treatment. While being treated as in-patients, as well as a check on progress, a daily mouth and tooth cleaning procedure was followed. During the out-patient stage, the investigation times were post-operative days 7, 14, 30 and 90 (reference value, without swelling and with no reports of pain or discomfort) (Fig. 2).

2.5. Three-dimensional recording of facial swelling

The examination of post-operative swelling development during and after hilotherapy involved the use of a 3D optical scanner (FaceSCAN3D®). This is used to create a 3D image of facial areas using a strip light projection process. The FaceSCAN3D® sensor was developed specifically for the measurement of faces. It measures the entire face quickly and precisely. FaceSCAN3D® delivers 3D images of body parts for 3D visualisation and for the comparison of pre-operative and post-operative conditions for study purposes, and for the provision of advice to individual patients. Both sensors are based on the principle of strip projection. Through a mirror unit, a single image of the face can be taken in 0.8 s. This measurement process not only generates a 3D set of data but also records the texture of the soft tissue surface. The measuring process is performed by projecting strips of light on the investigation object. The distortion of these reflected strips of light, recorded by two cameras, provides the topographical information (FaceSCAN3D®, 3D-Shape GmbH, Erlangen, Germany).

2.6. Volumetric determination

Measurement and quantitative evaluation of 3D image data Rhinceros® Version 5 software (McNeel Europe SL, Barcelona, Spain) was used to evaluate the 3D photographs. This is a program that is capable, among other attributes, of calculating volumes from 3D data. The volumetric proportion of the face with the largest increase in swelling should be recorded. By inserting two planes (intersecting faces) oriented on four fixed-location anatomical landmarks (nasion, tragus on both sides, zone of hyoid bone) on the face that remain virtually unchanged in the post-operative swollen condition, it is possible to determine volumes in a reproducible manner (Fig. 3).

2.7. Statistical analysis

The descriptive analysis of data and the graphic presentation of measuring results was evaluated using the statistical program R Development Core Team (2015). R: A language and environment for

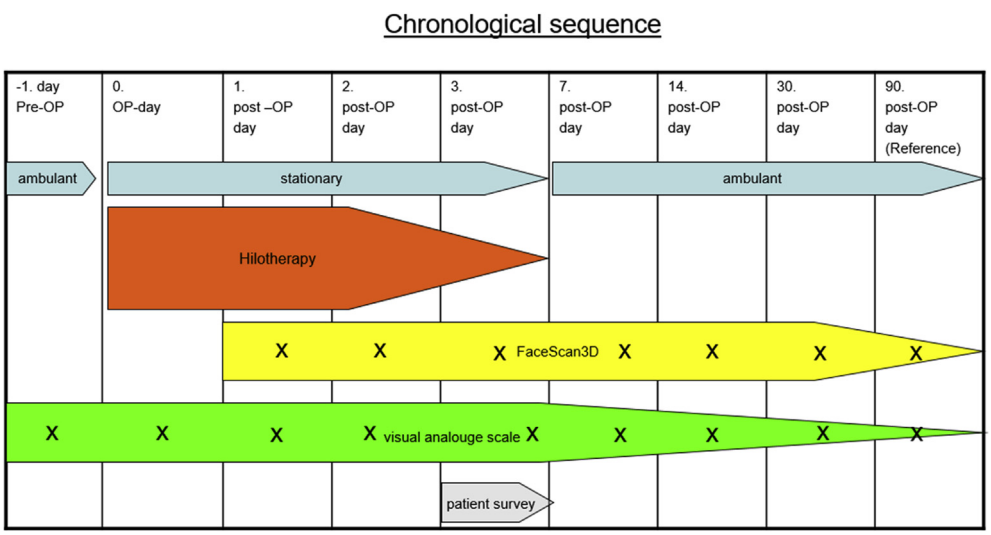

Fig. 2. Chronological sequence.

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statistical computing (Version 3.2.0; R Foundation for Statistical Computing, Vienna, Austria). Using the non-parametric Wilcoxon-Mann-Whitney test (group comparison), the data were examined for signs of significant differences. A value of $p < 0.05$ was regarded as statistically significant.

3. Results

3.1. Study patients and characteristics

This study examined 36 patients. On the basis of various different diagnoses, they all received orthognathic surgery at the

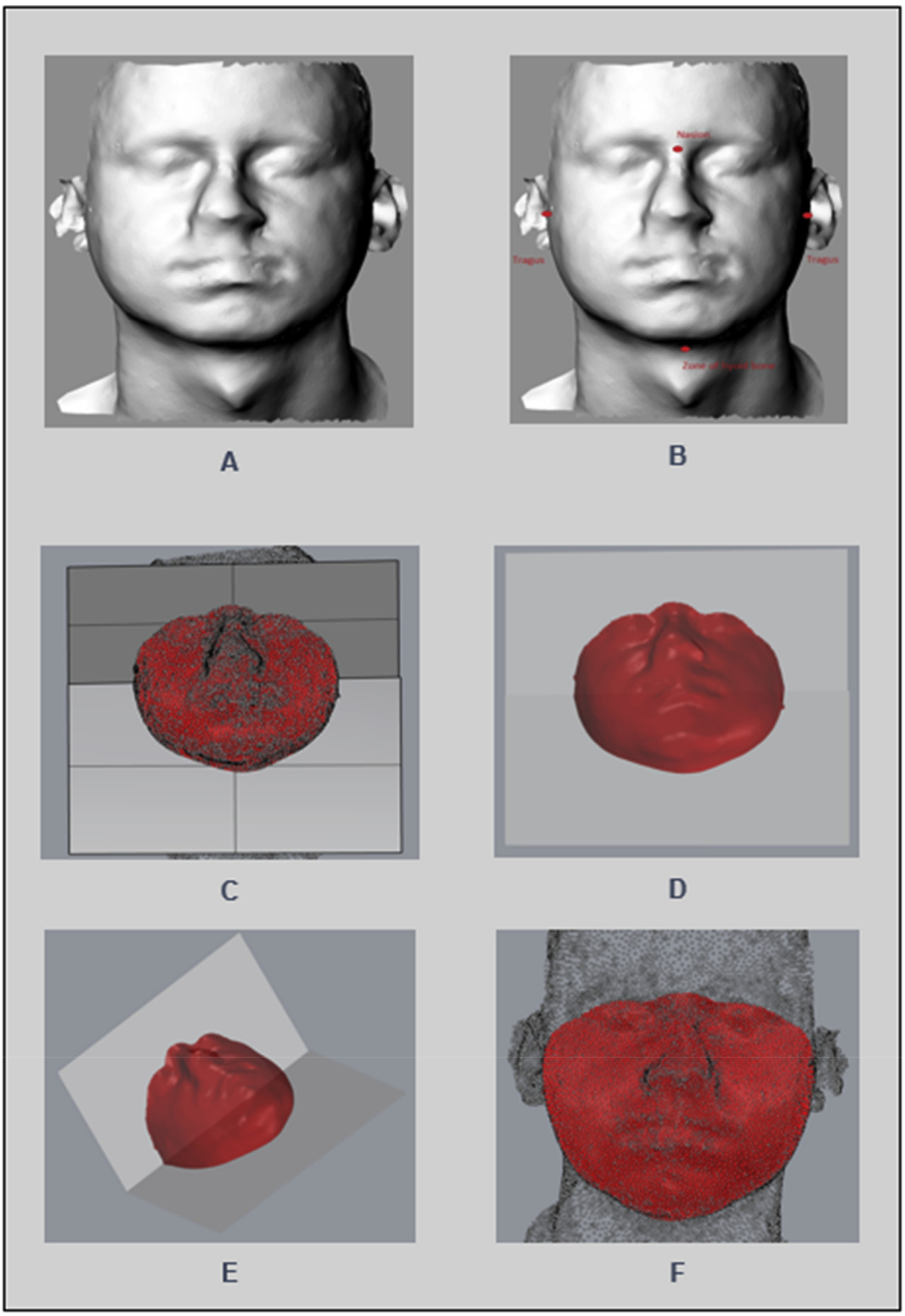

Fig. 3. Illustration of measurement and volume determination process (in milliliters).

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department of oral and maxillofacial surgery at Klinikum Dortmund gGmbH. The following illustration shows the results, comparing group 1 (18 °C) to group 2 (22 °C). Both randomised groups were treated in a standardised manner by means of hilotherapy. The characteristics of these investigation groups are summarised in Table 2.

3.2. Volumes of swelling

Both groups showed a broadly similar set of characteristics in terms of comparative swelling (median ± standard deviation). On the 1st post-operative day, group 1 (18 °C) exhibited an increase to 62.22 ± 36.29 ml. The maximum level of swelling was reached on the 3rd post-operative day with 81.85 ± 40.23 ml. From this time onwards, swelling reduced successively over the following observation days. On the 30th post-operative day, residual swelling measured 7.39 ± 15.77 ml ($p = 0.016$).

On the 1st post-operative day, group 2 (22 °C) exhibited an increase to 61.69 ± 34.7 ml. The maximum level of swelling was reached on the 2nd post-operative day with 92.83 ± 48.03 ml. Here too, the characteristic curve values declined continuously. On the 30th post-operative day, verifiable residual swelling measured 28.09 ± 19.04 ml ($p = 0.016$), which is significantly higher than that measured in group 1 (Fig. 4).

3.3. Need for analgesia: Number of doses per day

When considering the average post-operative need for analgesia, this diagram shows that there are differences between the groups up to and including the 2nd post-operative day. In group 1 (18 °C) fewer analgesics were needed than in group 2 (22 °C). On the 3rd post-operative day, group 1 needed a higher level of analgesics (Fig. 5).

3.4. Intensity of pain

Post-operative pain was documented using the 10-point pain VAS up to the 90th post-operative day (mean ± standard deviation). Patients in both groups gave no pre-operative indications of being in pain. Those in group 1 (18 °C) reached their maximum levels of pain on the 1st post-operative day (3.17 ± 1.42). After that, values dropped successively until the 14th post-operative day (1 ± 1.57). After the 14th post-operative day, no patient in this Group reported any further experience of pain.

Patients in group 2 (22 °C) reached their maximum levels of pain on the 2nd post-operative day (3.61 ± 1.91). After that, values dropped successively until the 30th post-operative day (0.11 ± 0.32). In overall terms, both groups manifested a similar characteristics curve without any variations of statistical significance (Fig. 6). It was interesting to note that, in this study, 10% of patients did not require any postoperative analgesia at all.

Table 2
Patient groups and characteristics.

	Group I 18 °C	Group II 22 °C
Bimax: Monomax: Genioplasty	11:5:2	11:6:1
Patients (n)	18	18
Gender (F 69.5%/M 30.5%)	12/6	13/5
Age ± SD (yr)	24.9 ± 7.1	24.9 ± 5.9
Duration of operation ± SD (min)	201.3 ± 71.7	193.5 ± 92.19
Hospital length of stay (days)	4	4

F, female; M, male; SD, standard deviation.

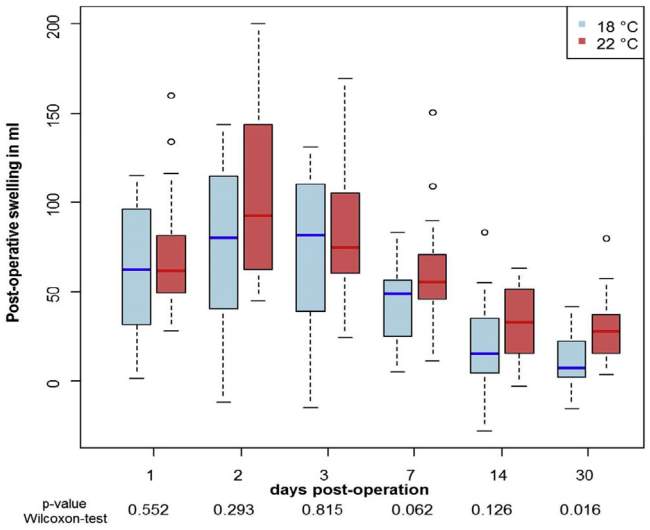

Fig. 4. Study results: swelling characteristic curve.

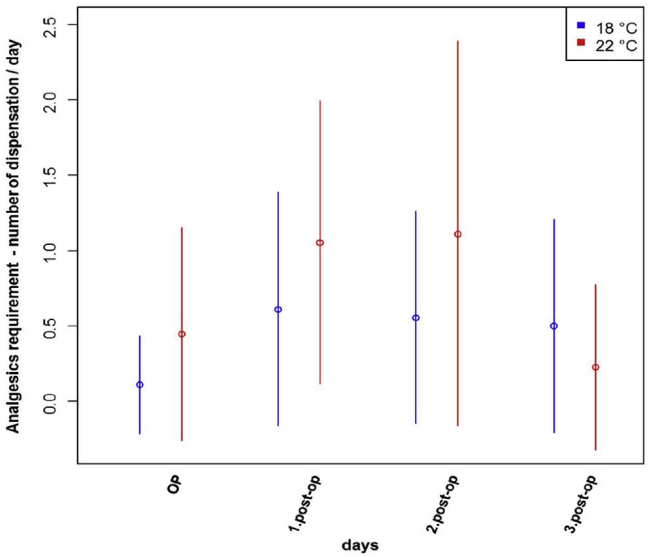

Fig. 5. Study results: intake of analgesia. OP, operation; post-op, post-operatively.

3.5. Patient survey

On the 3rd post-operative day, a patient survey was carried out in relation to various subjective features and sensations. They reported on the sensation of cooling temperature on their facial skin, on discolourations (haematoma), pain and swelling of the face and of total satisfaction levels after hilotherapy. The survey was based on the German school grade system (1 = excellent to 6 = very poor). Both groups demonstrated a similar and positive set of results. In overall terms, group 1 (18 °C) found the treatment more agreeable/less unpleasant than group 2 (22 °C). However, in response to the question relating to overall satisfaction, there was no discernible difference in the replies from the two groups (Fig. 7).

4. Discussion

This was the first clinical trial to conduct a post-operative comparison of two cooling temperatures during hilotherapy on the face after orthognathic surgery. The main criterion of this trial

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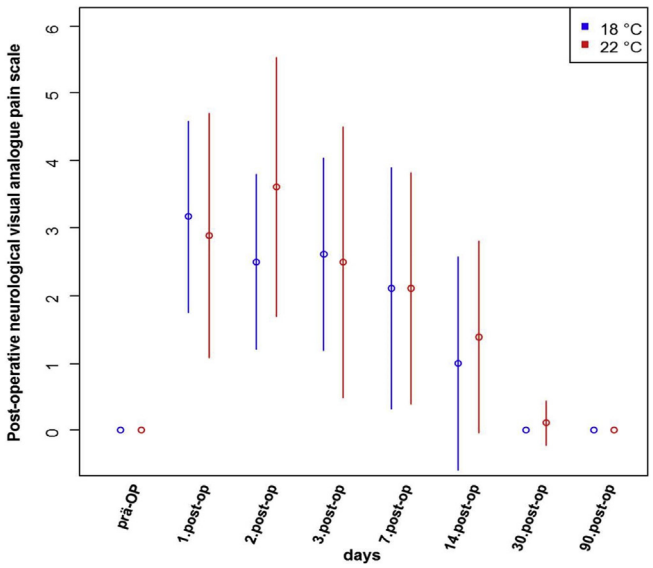

Fig. 6. Study results: pain scale. Pre-op, pre-operatively; post-op, post-operatively.

was the post-operative swelling characteristics curve and the development of pain levels. In addition, patient satisfaction was examined. The results of this study show that hilotherapy, subject to compatibility, led to an effective reduction in swelling and pain with minimal side effects. Post-operative cooling of the face, as a function of skin temperature, exerts an autonomous form of vasoconstrictorial effect that, in theory, minimises oedemas and ecchymosis (Ho et al., 1994; Pergola et al., 1996). At a low skin temperature, the activity of the neutrophile granulocytes is reduced. This also reduces the proinflammatory cytokines responsible for the transmission of pain and swelling. When temperature drops below 14° Celsius, action potentials are transmitted to the sensory and vegetative nervous system to a reduced extent, in a similar manner to cold-induced neuropraxia resulting in paradoxical vasodilation and paraesthesia. Other undesirable impacts of facial cooling can take the form of bradycardia, raised blood pressure and an increase in the cerebral blood supply (Brown et al., 2003; Hall, 2010). We were not able to observe any of this with any of our patients.

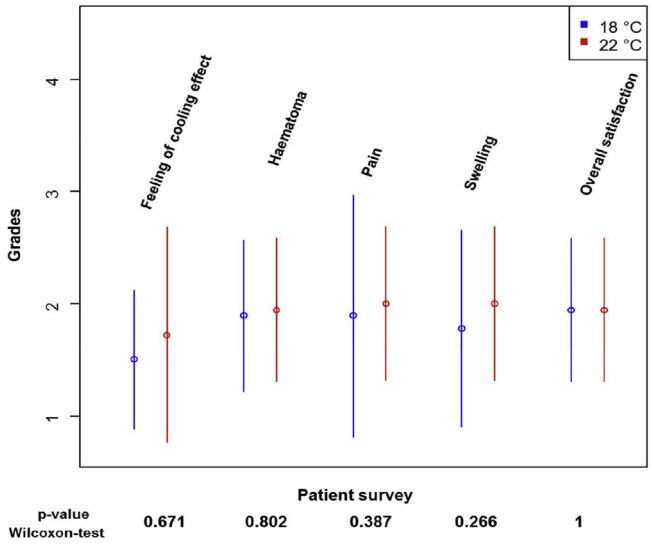

Fig. 7. Study results: patient survey.

4.1. Volume of swelling

In this trial, both groups manifested a post-operative increase in the volume of swelling. Group 1 (18 °C) reached its maximum level of swelling on the 3rd post-operative day. In contrast, group 2 (22 °C) reached its maximum level of swelling on the 2nd post-operative day, with comparably higher figures. On the basis of this data, it was possible to show that the maximum level of post-operative swelling occurred between 48 and 72 h after the procedure. This is supported by the results from the working group of Rana et al., by whom maximum swelling was also observed on the 2nd post-operative day, after which the extent of swelling diminished (Rana et al., 2011b). In working group of Modabber et al., the swelling characteristic curve of Hilotherapie® (15 °C) versus conventional therapy with moist compresses was examined. In both groups, the maximum level of swelling was detected on the 3rd post-operative day (Modabber et al., 2013). In this study, residual swelling in both groups exhibited a statistically significant difference.Group 1 (18 °C) 7.39 ± 15.77 ml ($p = 0.016$) exhibited on the 30th post-operative day a substantial reduction in residual swelling that was much greater than that exhibited by group 2 (22 °C) 28.09 ± 19.04 ml ($p = 0.016$). It was also observed that group 1 (18 °C), swelling declined faster and more sharply than group 2 (22 °C). This may be due to a higher and more sustained impact caused by the lower cooling temperature. The anti-oedematic effect of cryotherapy is also caused by a damping of the metabolism of inflammation, sustained vascular constriction and potentially the activation of the lymphatic system (Gerold et al., 1998).

4.2. Postoperative pain and need for analgesia

In this study, the post-operative pain levels and the need for analgesia was examined and documented in both groups. In overall terms, group 1 (18 °C) manifested slightly less intensity of pain and less consumption of analgesia than group 2 (22 °C). This may be related to the lower cooling temperature. In the study of Rana et al., hilotherapy was compared to the conventional therapy involving the use of moist compresses. It was possible to observe here that the patients who received hilotherapy had a significantly lower sensation of post-operative pain (Rana et al., 2011b). It was interesting to note that, in our clinical trial, 10% of patients did not require any post-operative analgesia at all.

4.3. Patient satisfaction

After hilotherapy, the patients were issued an evaluation form. In terms of the experience of cooling temperature on the facial skin, discolourations (haematomas), pain and swelling on the face was found in the comparison to be subjectively more agreeable with milder levels of response in group 1 (18 °C). In terms of total satisfaction levels, no difference could be detected between the groups. The slight, statistically insignificant difference may be based upon the different cooling temperatures. To date, two different cooling temperatures have never been compared against one another in a patient clinical trial. In a review conducted by Bates et al., it was established that hilotherapy, when compared to conventional cooling methods, generated a higher level of patient satisfaction (Bates and Knepil, 2016).

5. Conclusion

Hilotherapy is an effective form of cryotherapy that is comfortable for patients. To date, the comparative studies conducted only compared hilotherapy to the conventional therapy employing the use of moist compresses. The results of this study

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have demonstrated the presence of a difference in terms of the amount of swelling recorded at the different cooling temperatures. Thus can be established in daily routine a more accurately targeted and faster convalescence period with immediate analgesic impact and reduced levels of damage to skin tissue. The extent to which further differences may arise in the context of other cooling temperatures cannot be answered within the scope of this study. This would require a trial in the form of further follow-up studies.

Conflicts of interest

The authors declare that they have no conflict of interest.

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