3D evaluation of postoperative swelling in treatment of zygomatic bone fractures using 2 different cooling therapy methods: - A randomized observer blind prospective study –

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Short title: Cooling therapy in treatment of zygomatic fractures

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Abstract

Background: Surgical treatment and complications of patients with zygomatic bone fractures can lead to a significant degree of tissue trauma resulting in common postoperative symptoms and types of pain, facial swelling and functional impairment. Beneficial effects of local cold treatment on postoperative swelling, edema, pain, inflammation, haemorrhage as well as the reduction of metabolism, bleeding and hematomas have been described.

The aim of this study was to compare post-operative cooling therapy applied through the use of cooling compresses with the water-circulating cooling face mask by Hilotherm® in terms of beneficial impact on postoperative facial swelling, pain, eye motility, diplopia, neurological complaints and patient satisfaction.

Methods: 42 patients were selected for treatment of unilateral zygomatic bone fractures and were divided randomly to one of two treatments either a Hilotherm® cooling face mask or conventional cooling compresses. Cooling was initiated as soon as possible after surgery until postoperative day 3 and was applied continuously for 12 hours daily. Facial swelling was quantified through a 3D optical scanning technique. Furthermore, pain, neurological complaints, eye motility, diplopia and patient satisfaction were observed from each patient.

Results: Patients receiving a cooling therapy by Hilotherm® demonstrated significantly less facial swelling, less pain, reduced limitation of eye motility and diplopia, fewer neurological complaints and were more satisfied compared to patients receiving conventional cooling therapy.

Conclusions: Hilotherapy is more efficient in managing postoperative swelling and pain after treatment of unilateral zygomatic bone fractures compared to conventional cooling.

Trial Registration Number: DRKS00004846

Introduction

The face represents the most prominent position in the human body and is often involved in trauma injuries. The zygomatic bone it is particularly prone to facial injuries due to its prominence [1] and is the second most common mid-facial bone affected. The fracture of the zygomatic bone can pose considerable functional complications such as restricted mouth opening. Disruption of the zygomatic position can also carry psychological, aesthetic and functional significance, causing impairment of ocular and mandibular functions. Therefore, a prompt diagnosis of fracture and soft tissue injuries for both cosmetic and functional reasons [2].

In most cases the treatment of unilateral zygomatic bone fractures leads to a significant degree of tissue trauma that again causes an inflammatory reaction [3]. As a result, patients display common postoperative symptoms and types of pain, facial swelling and functional impairment [4]. Pain is typically brief and peaks in intensity in the early postoperative period. In contrast to that, facial swelling reaches the characteristical maximum 48-72 hours after surgery [5]. These symptoms can affect the patient's quality of life and well-being. To increase patient satisfaction after treatment of uni- and bilateral zygomatic bone fractures it is a necessary goal to minimize side effects as much as possible [6]. One way do so is to prescribe medication such as corticosteroids [7], non-steroidal anti-inflammatory drugs (NSAID) [8], a combination of corticosteroids and NSAID [9] or enzyme preparations like serratiopeptidase [10]. Furthermore, there are also non-medication methods to treat the above named side effects. These can include manual lymph drainage [11], soft laser [12, 13] and cryotherapy [14]. Historically, the therapeutic use of local or systemic cryotherapy was first described by Hippocrates [15]. Beneficial effects of cold treatment on postoperative swelling have been described previously [16, 17, 18, 19, 20] as well as positive impact on edema, pain and inflammation [21, 22, 23]. The activity of inflammatory enzymes rises with increasing of temperatures [21]. On reviewing the literature, there is a lack of scientific evidence and trials in oral and maxillofacial surgery which show positive as well as no effect of cold therapy [24]. Cooling therapy vary from conventional, such as ice packs, gel packs or cold compresses to mechanically supported continuous cooling with face masks. Both, positive and negative side effects are previously discussed such as tissue injuries, disturbances of lymph drainage and microcirculation or chilblains. The aim of this study was to examine the effect of hilotherapy in comparison with conventional cooling method using cold compresses, on swelling, pain, eye motility, diplopia, neurological complaints and overall patient satisfaction following treatment of unilateral zygomatic bone fractures.

Materials and Methods

The study was approved by the local ethics committee at the University Aachen, Germany (EK 142/2008). Before the beginning of the study, written informed consent was obtained from each patient.

Patients

42 healthy patients were scheduled for treatment of unilateral zygomatic bone fractures (Figure 1). Only patients who required open reduction and internal fixation using 3 point fixation technique were divided randomly into 2 treatment groups. 21 patients were treated with conventional cooling and 21 patients received continuous cooling using hilotherapy after reposition of unilateral zygomatic bone fractures. The observer was not aware of the kind of therapy that was applied at the time of the patient examinations and during analysis of the data. The patients were not blinded and were informed that the study was designed to compare the effect of Hilotherm® cooling face mask and conventional cooling compress on swelling, pain, eye motility, diplopia, neurological complaints and patient satisfaction.

Fixation Methods

The approach to expose the fracture sites was achieved using different standard incisions. Frontozygomatic suture was approached using an eyebrow incision, zygomatico maxillary buttress was exposed using an intraoral buccal sulcus incision and additional exposure of infraorbital rim was accomplished using infraorbital approach. In all cases, plating was attempted along frontozygomatic suture, infraorbital margin and zygomatico maxillary buttress (Figure 2). The osteosynthesis was done with 2.0 mm or 1.5 mm plates (Stryker®, Duisburg, Germany) per fracture line.

Cooling methods

Hilotherapy refers to the water-circulating external cooling device Hilotherm® Clinic (Hilotherm® GmbH, Germany) that consists of a preshaped thermoplastic polyurethane (TPU) mask and the Hilotherm cooling device control unit (Figure 3A,B). The temperature setting is adjustable from +10°C to +30°C and was set to 15 °C immediately after surgery. Conventional cooling was performed through cool compresses. Cooling was initiated as soon as possible after surgery until postoperative day 3 continuously for 12 hours daily.

Study protocol and inclusion criteria

Only patients with an unilateral zygomatic bone fracture were included in this study. Potential participants were excluded from the study because of missing operability, foreseeable missing opportunity for follow-up examination, pregnancy, nursing, drug addiction, recent operations, and diseases of heart, metabolism, CNS, infectious, circulation, systemic, malignant and immune system affecting diseases as well as blood coagulation disorders and allergic reactions to pharmaceuticals and antibiotics. The clinical inclusion and exclusion criteria's are shown in Table 1. All patients were examined and scanned on fixed dates using standardized methods and techniques. Thus, every patient received the same postoperative analgetic drug therapy which included 1000 mg Paracetamol (Perfalgan®) intravenously for 2 times per day for 3 days; per os: 600 mg Ibuprofen (Ibu-ratiopharm®) (1st day: Ibuprofen 600mg 3 times per day, 2nd day: Ibuprofen 600mg 2 times per day, 3rd day: Ibuprofen 600mg 1 time per day, 4th day: Ibuprofen 600mg 1 time per day) Antibiotic prophylaxis consisted of 600 mg Clindamycin (Clindamycin-Actavis®) intravenously for 3 times per day for 3 days. Perioperative only a single dose of 250 mg steroids (Solu Decortin ®) was administered to every patient. During a first visit, the physician collected information about past illnesses and diseases and conducted a standard blood test. The operation took place using general anaesthesia and oral intubation.

During the study the following parameters were assessed: pain, swelling, eye motility, diplopia, neurological complaints and patient satisfaction. To minimize bias through patient contact, the patients were examined and hospitalized in separate rooms.

Measurement of facial swelling

This study used a 3D optical scanner named FaceScan3D (3D Shape® GmbH, Erlangen, Germany) to measure facial swelling in volume (ml) as described previously [18, 19, 25]. The 3D optical scanner consists of an optical range sensor, two digital cameras, a mirror construction and a commercial personal computer. The sensor is based on a phase-measuring triangulation method [26]. There is no need for special safety precautions for the patient, since the advantage of this optical sensor is its contactless data acquisition accompanied by its high accuracy in the z-direction with 200 μm and a short measurement time of 430 ms. The mirror construction permits the capture of over 180° of the patient's face. The computer program Slim 3D (3D Shape®, Erlangen, Germany) automatically triangulates, merges and post processes the data [27]. The final output is a triangulated polygon mesh that is visualized as a synthetically-shaded or wire-mesh representation [28]. For the volume calculation all patients were photographed with a standard technique for frontal views of the face. Adjustment occurred on the Frankfurt horizontal line, parallel to the floor. Patients sat on a self-adjustable stool and were asked to look into a mirror with standard horizontal and vertical lines simulating a red cross marked on it. The horizontal line was adjusted to subnasale and the vertical line was aligned the midline of the face. Patients were instructed to swallow hard and to keep their jaws in a relaxed position for the scan. 3D optical scans were recorded at 6 points in time: on the 1st day after surgery (T1), on the

2nd (T2), the 3rd (T3), the 7th (T4) and the 28th (T5) and the 90th (T6) postoperative day. For each patient we chose time point T6 as reference, because at this time point swelling of soft tissue could be excluded which otherwise could influence the measurements. Annotations of T1-T6 were prepared by an error minimization algorithm which applied modified ICP (Iterative Closest Point) using simulated annealing by Levenberg-Marquardt algorithm [29, 30]. To minimize disturbance of soft tissue during the registration process only facial areas that were not influenced by the swellings were used for surface matching: forehead, ears and root of the nose. The geometrical models were aligned with the forehead and the ears. After the aligned shell deviation panels were created for cut off to create an individual mask of the face (Figure 4).

Pain analysis

Post-operative pain analysis was conducted with the help of a 10-point visual analogue scale (VAS) based on measurements before surgery (T0), on the 1st (T1), 2nd (T2) and 7th (T3) day after operation, where the patients had to rate their pain on a score from 0 to 10, with 0 describing a situation without pain and 10 denoting a maximum intensity of pain.

Neurological analysis

The neurological analysis was utilized in order to enable the evaluation of nerve dysfunctions. The skin of the upper lip was checked using a cotton test for touch sensation, a pinprick test using a needle for sharp pain and a blunt instrument for testing pressure. Additionally, a two-point discrimination test was executed on the lip. The results were recorded on a score that ranges between 0 and 9, with 9 being the worst neurological score. The neurological score was assessed at 5 points in time:

before surgery (T0), on the 1st (T1), the 7nd (T2), the 28th (T3), and the 90th (T4) postoperative day.

Eye motility and diplopia

For the analysis of eye motility and diplopia the patient was required to fix a light source at a distance of 30 cm. While the head was fixed, the light source was guided in different directions of view. The relative displacement of the reflected images to each other and the movement of the eye were analyzed. Meanwhile, the patient was asked about diplopia. The data were collected at 4 points in time: before surgery (T0), on the 1st (T1), the 7th (T2) and the 28th (T3) postoperative day.

Patient satisfaction

Each patient was asked to complete a questionnaire on the 10th postoperative day subjectively rating their comfort and satisfaction with the applied postoperative cooling therapy. The grading scale ranged from 1 to 4, where 1 denoted "very satisfied" and 4 for "not satisfied".

Statistical analysis

To check for statistical significance of quantitative variables the Student t-test for unrelated samples was used. All data are expressed as mean values ±1 SEM, denoting a p-value of ≤ 0.05 as significant. For analyzing gender, eye motility and diplopia statistically χ^2-test was utilized, and a p-value of ≤ 0.05 as level of significance was defined. The statistical analysis was conducted using SPSS for Windows version 14.0 (SPSS Inc., Chicago, IL, USA).

Results

Baseline characteristics

42 patients were randomly enrolled in the study. After reposition and osteosynthesis of unilateral zygomatic bone fractures 21 patients were assigned to conventional cooling therapy and 21 patients were treated with hilotherapy. The clinical and demographic characteristics of patients in both groups are shown in Table 2. Both groups showed no statistical significances regarding gender, age, body mass index (BMI), surgery duration, hospitalization duration, preoperative pain and neurological score as well as preoperative limited eye motility and diplopia..

Postoperative swelling

Swelling was measured in terms of volume in milliliters as described in the methodology section. On the 1st day following surgery a statistically significant reduction of swelling could be noticed by applying the Hilotherm cooling device compared to conventional cooling therapy (Hilotherm: 9.45±4.42 ml, conventional: 20.69±9.05 ml, p = 0.00002) (Figure 5). Maintaining this tendency on the 2nd day following surgery a statistically significant reduction of swelling could be documented (Hilotherm: 13.20±7.71 ml, conventional: 22.97±8.50 ml, p = 0.00036). After the 3rd day (Hilotherm: 14.44±8.21 ml, conventional: 23.52±9.69 ml, p = 0.00217) and on the 7th day (Hilotherm: 7.06±4.97 ml, conventional: 11.51±6.70 ml, p = 0.01907) the measured swelling was also significant. On the 28th postoperative postoperative day the measured swelling was almost equal in both groups (Hilotherm: 3.62±4.02 ml, conventional: 4.80±4.43 ml, p = 0.36980). Maximal swelling was noticed at the 3rd postoperative day with 14.44±8.21 ml by hilotherapy and with 23.52±9.69 ml for conventional cooling (Figure 5).

Postoperative pain score

Pain was quantified in terms of a 10-point visual analogue scale ranging from 0 to 10, based on subjective analysis. At 1st and 2nd postoperative day a significant reduced pain score was obtained by hilotherapy compared to conventional cooling (1st day: Hilotherm: 2.38 ±1.36, conventional: 4.10±1.76, p = 0.00105) (2nd day: Hilotherm: 2.34±1.49, conventional: 4.38±1.32, p = 0.00003). No statistically significant difference could be observed at 7th postoperative day (Hilotherm: 1,43±0.68, conventional: 1.90±1.18, p = 0.11627) (Figure 6).

Postoperative neurological score

Hilotherapy obtained a significantly reduced neurological score at 1st day obtained by Hilotherapy compared to conventional cooling (Hilotherm: 2.57 ±1.29, conventional: 3.90±1.76, p = 0.00775). There were no statistically significant differences between both groups concerning the neurological score 7, 28 and 90 days after surgery (7th day: Hilotherm: 2.05±0.80, conventional: 2.90±1.97, p = 0.07642; 28th day: Hilotherm: 1.76±1.81, conventional: 2.06±1.79, p = 0.55187; 90th day: Hilotherm: 0.48±0.87, conventional: 0.67±1.02, p = 0.51947) (Figure 7).

Eye motility and diplopia

Using χ^2-test no statistically significant differences were found preoperative between both with respect to eye motility (preoperative: Hilotherm: 9 patients without and 12 patients with limited eye motility, conventional: 8 patients without and 13 patients with limited eye motility: p = 0.753) and diplopia (preoperative: Hilotherm: 11 patients without and 10 patients with diplopia, conventional: 11 patients without and 10 patients with diplopia: p = 1.000). At 1st postoperative day a significant reduction in eye motility limitation (1st day: Hilotherm: 17 patients without and 4 patients with limited eye motility, conventional: 11 patients without and 10 patients with limited eye motility: $p = 0.050$) and diplopia (1st day: Hilotherm: 18 patients without and 3 patients with diplopia, conventional: 11 patients without and 10 patients with diplopia: $p = 0.019$) was obtained through hilotherapy compared to conventional cooling. There were no statistically significant differences found between both groups concerning the limitation of eye motility and diplopia 7 and 28 days after surgery (7st day: Hilotherm: 18 patients without and 3 patients with limited eye motility, conventional: 15 patients without and 6 patients with limited eye motility: $p = 0.259$; Hilotherm: 19 patients without and 2 patients with diplopia, conventional: 16 patients without and 5 patients with diplopia : $p = 0.214$); (28st day: 19 patients without and 2 patients with limited eye motility in both groups: $p = 1.000$; 20 patients without and 1 patient with diplopia in both groups : $p = 1.000$).

Patient satisfaction

Regarding the patient´s satisfaction, which was assessed at 10th day after surgery, a statistically significant difference between hilotherapy and conventional cool packs could be detected. Patients treated with hilotherapy had a significantly greater satisfaction (Hilotherm: 1.43±0.60, conventional: 2.29±0.72, $p = 0.00014$) (Figure 8).

Discussion

This study demonstrates that continuous cooling with the hilotherapy device reduces post-operative swelling and pain in the treatment of unilateral zygomatic fractures compared to conventional cooling with cold packs. Furthermore, satisfaction of patients treated with hilotherapy was greater compared to patients who received conventional cooling. However, eye motility limitation, diplopia and neurological score revealed significant differences only at 1st postoperative day. Wound healing was uneventful. Malfunctioning of the cooling device by Hilotherm® did not occur.

The healing process and possible complaints regarding the treatment of facial trauma can be influenced by patient related factors such as age and gender, compliance and health status as well as patient independent factors such as surgeon experience, duration of surgery time, extent of trauma and fragment dislocation as well as use of antibiotics [3, 18, 19, 31]. Since in this study, the use of antibiotics and the duration of surgery time were not significantly different among both groups, and since health compromised patients were excluded from the study, these factors are considered not to have influenced the observed results.

Although the effects of different cooling methods were investigated for a number of maxillofacial and plastic surgery treatment procedures, there is so far no study comparing conventional cooling versus hilotherapy following treatment of zygomatic bone fractures [18, 19, 32, 33, 34].

Consistent with our results, Belli et al. [32] reported of a safe use of hilotherapy as well as a postoperative decrease in pain and swelling intensity and duration after Le-Fort-I osteotomy and bilateral sagittal osteotomy of lower jaw. While Belli et al. [32] investigated only 10 patients without the comparison to other cooling techniques, Jones et al. [33] recorded differences in hilotherapy and conventional group of a greater cohort of 50 patients following face-lift surgery procedures. In contrast to our results, Jones et al. [33] described a statistically significant increase of patient reported postoperative swelling with no significant differences regarding ecchymosis, haematoma or pain in both groups. However, subjectively the majority of patients found the cooling masks to be comforting. In order to overcome the lack of significance of subjective assessments versus objective evaluation methods, Moro et al. [34] measured the distance of multiple anatomic landmarks for swelling purposes. In so doing, 90 patients operated for maxillomandibular malformations were divided in 3 groups and treated solely with hilotherapy, conventional cooling or left untreated with cryotherapy as control group. Expectedly, no cryotherapy treatment led to the worst results whereas cooling with the hilotherapy method showed the least degree of swelling.

With the aim of improving measurement accuracy of different swelling stages our study group used 3-dimensional evaluation by the means of an optical face scanner [18, 19, 20]. Hence, 3-dimensional volumes could be measured instead of 2-dimensional lines.

Although cryotherapy is a relatively safe way to treat complications after oral or maxillofacial surgeries, cold therapy should only be employed with caution. Above all very young or very old patients can react with intolerances on external cooling [35].

Topographical considerations make it difficult to quantify facial volume of swelling. However, there are some limitations of this measurement technique which have to be discussed. The volume measurement with this technique is limited to localized facial swelling, since facial areas which have not been affected by the swelling are necessary for surface matching [18, 19]. Some methods are described to predict soft tissue via cephalograms, which are able to create 3D images. Ethically, the benefit of cephalograms might not justify the patient’s exposure to ionizing radiation [36].

In summary, use of the cooling device by Hilotherm reduces post-operative swelling and pain compared to conventional cooling. As biological effect of cooling therapy vascular, neural, metabolic and muscular effects are known. Cryotherapy decelerates cell metabolism, because according to Van’t Hoff law, it slows down biochemical reactions. Regarding vascular effects, cold therapy constricts blood vessels. The intensity of vasoconstriction reaches the highest value at a temperature of 15°C. Furthermore, a decrease in body temperature slows down peripheral nerve conduction. For temperatures below 15°C, nerve conduction is completely disabled and the vasoconstriction turns into a vasodilatation. These biological effects influence postoperative symptoms. Meanwhile, the anti-edema effect is caused by the vasoconstriction and the pain reducing effect of cold is related to a blocking of nerve endings. This blocking decelerates nerve conduction, and consequently, inflammation phenomena. Ice packs or similar conventional cooling methods use a temperature of around 0°C. Such a low temperature constrains lymph drainage and cell metabolism [37]. The effects of a treatment with overly low temperatures have already been mentioned before. The inference is that a system is needed that maintains the desired temperature over a fixed period of time. To fulfill this requirement, this study worked with the cooling device Hilotherm ® Clinic (Hilotherm® GmbH, Germany) [25]. Further studies are needed to investigate the benefits of this technique in other clinical research areas.

Conclusions

Hilotherm is easy in use for both, patients and medical staff. Constant cooling with the possibility of adjusting temperature are important advantages. This is why hilotherapy is expected to play a greater role in oral and maxillofacial surgery as well as other clinical fields in future.

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None.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

AM and MR were responsible for the study concept and design. AM was responsible for data acquisition and writing the paper. AM and MAR carried out the statistical analysis. All authors were responsible for data analysis and interpretation. AM and MR drafted the manuscript. MR, FH, NCG, AG and MG were involved in revising the manuscript. All authors reviewed the manuscript. All authors read and approved the final manuscript.

Ethical approval

Approval for the study was obtained from the relevant ethics committee at the University of Aachen, Germany (EK 142/2008). Before the beginning of the study, written informed consent was obtained from each patient.

The study was registered with the **Trial Registration Number:** DRKS00004846

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TABLE 1. Study inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Unilateral zygomatic fracture	Complex midfacial fracture
Combination of infraorbital approach, eyebrow and	Panfacial fracture
Buccal sulcus incision	Polytrauma
Osteosynthesis using 2.0 mm and 1.5 mm plates	Infected fractures
(Stryker®)	Pathological fractures
Plating along frontozygomatic suture, infraorbital	Missing operability
margin and zygomatico maxillary buttress	Foreseeable missing opportunity of
Age between 18 and 79	follow-up examination
Written informed consent	Pregnancy
	Heart-, pulmonal-, liver- and kidney disease
	chronic pain syndrom
	Drug addiction
	Recent operations,
	Metabolism, CNS, infectious, circulation,
	systemic, malignant and immune system
	affecting diseases
	Blood coagulation disorders
	Allergic reactions to pharmaceuticals and
	antibiotics
	Dermatological diseases of the face
	Raynaud´s phenomenon

TABLE 2. Baseline characteristics of patients

	Hilotherm®	Conventional	*p*-value
Gender female – no./total no. (%)	4/21 (19)	3/21 (14)	0.68
Age (years) ± SD	36.5 ±16.1	35.6 ± 21.9	0.89
BMI (kg/m^2) ± SD	23.8 ± 3.6	24.4 ± 3.8	0.56
Surgery duration (minutes) ± SD	70.2 ± 33.4	73.9 ± 38.7	0.74
Hospitalization duration (days) ± SD	4.6 ± 1.9	4.4 ± 1.1	0.69
Preoperative pain score (VAS) ± SD	3.1 ± 0.7	3.2 ± 0.8	0.55
Preoperative neurological score (NS) ± SD	3.4 ± 1.7	3.5 ± 1.7	0.86
Preoperative limited eye motility – no./total no. (%)	12/21 (57)	13/21 (62)	0.75
Preoperative diplopia – no./total no. (%)	10/21 (48)	10/21 (48)	1.00

Figure Legends

Figure 1

The coronal view of a 24-year-old patient shows an isolated zygomatical fracture on the right side. Red arrows demonstrate the fracture lines.

Figure 2

3D Reconstruction of postoperative Cone Beam CT after ostheosynthesis of a right side zygomatical fracture, along frontozygomatic suture, infraorbital margin and zygomatico maxillary buttress.

Figure 3

(A) Front view of a patient wearing the Hilotherm® mask. **(B)** Lateral view of the same patient.

Figure 4

The final 3D output of the Slim3D software is a triangulated polygon mesh, visualized as a synthetically shaded representation. 3D optical scans were recorded during six time points: T1 (1^{st} day after surgery, mask not shown), T2 (2^{nd} day postoperatively, yellow mask), T3 (3^{rd} day postoperatively, red mask), T4 (7^{th} day postoperatively, green mask), T5 (28 days after operation, mask not shown) and T6 (90^{th} day postoperatively, blue mask). The reference 3D model of each patient was T6. An individual mask of the midface of each patient was created and aligned to all captures and the difference of volume was calculated thereby.

Figure 5

The amount of swelling in ml of both groups at different time points is shown. At 1^{st}, 2^{nd} and 3^{rd} post-operative day a significant down-regulation of swelling could be achieved by cooling with Hilotherm® compared to conventional cooling. This trend could be maintained on 7^{th} post-operative day. After 28 days no differences with respect to swelling could be documented in both groups.

Figure 6

Pain was calculated in terms of a visual analogue scale from subjective analysis ranging from 0 to 10. A significant increase of pain was reported in the conventional group compared to Hilotherm® group during 1^{st} and 2^{nd} post-operative days. The pain intensity remained significantly unchanged during 7^{th} postoperative day in both groups.

Figure 7

Changes were found concerning the neurological score at 1^{st} postoperative day but no differences were detected after 7, 28 and 90 days in both groups.

Figure 8

The overall satisfaction was significantly lower of patients receiving conventional therapy compared to patients receiving cooling therapy by Hilotherm®.

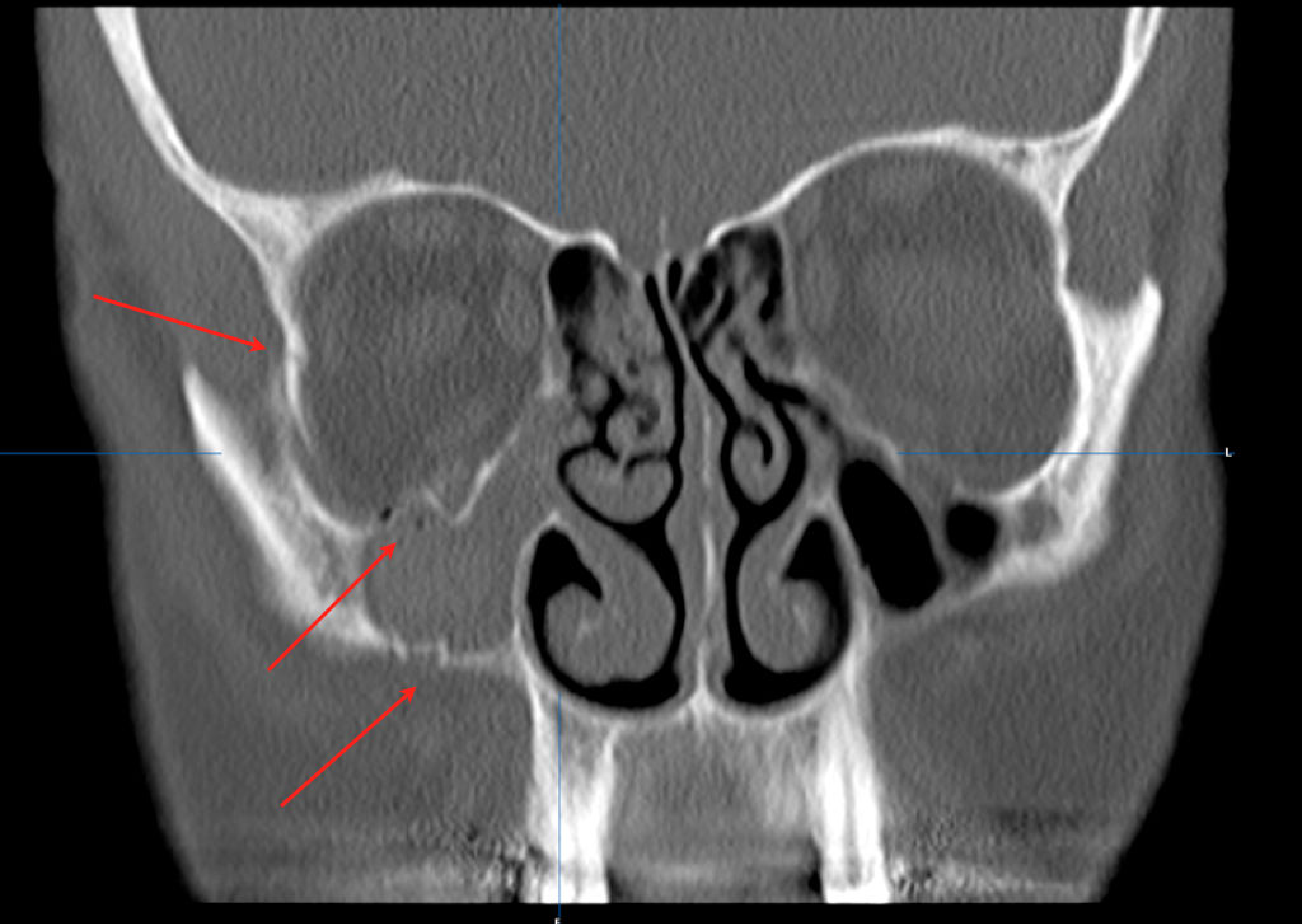


Figure 1

Figure 2

Figure 3

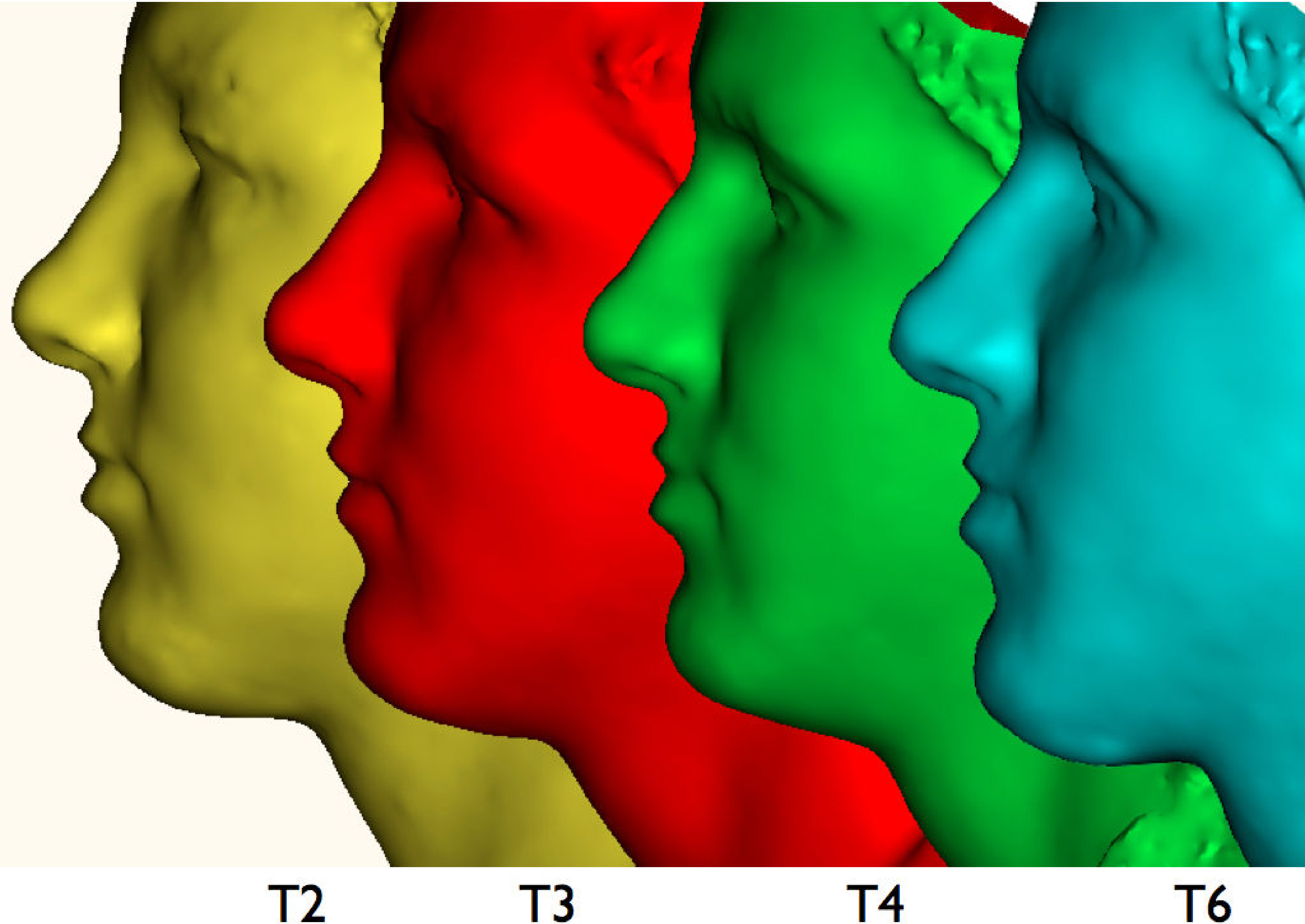


Figure 4

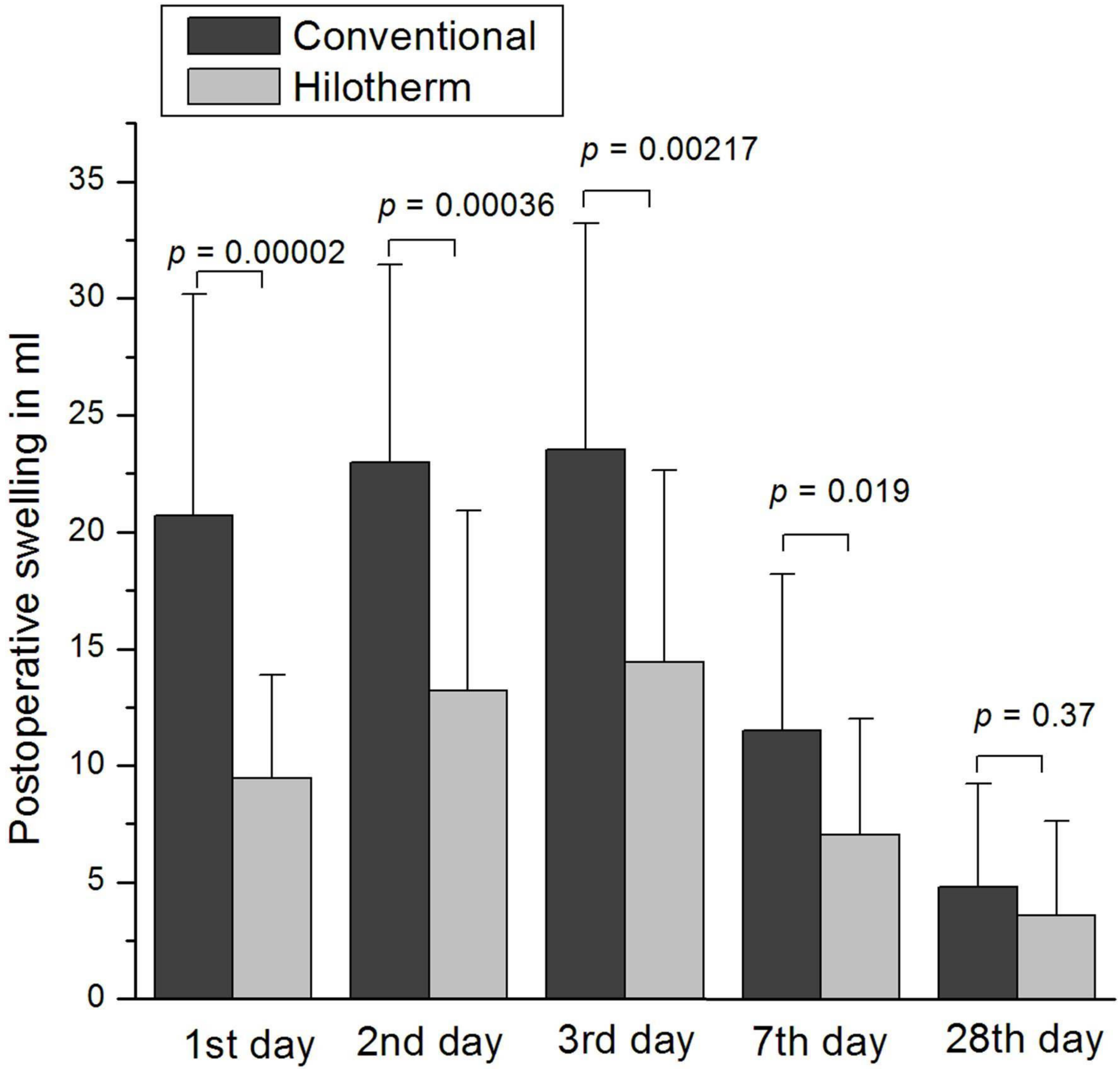

Conventional
Hilotherm
Postoperative swelling in ml
0
5
10
15
20
25
30
35
p = 0.00002
p = 0.00036
p = 0.00217
p = 0.019
p = 0.37
1st day
2nd day
3rd day
7th day
28th day

Figure 5

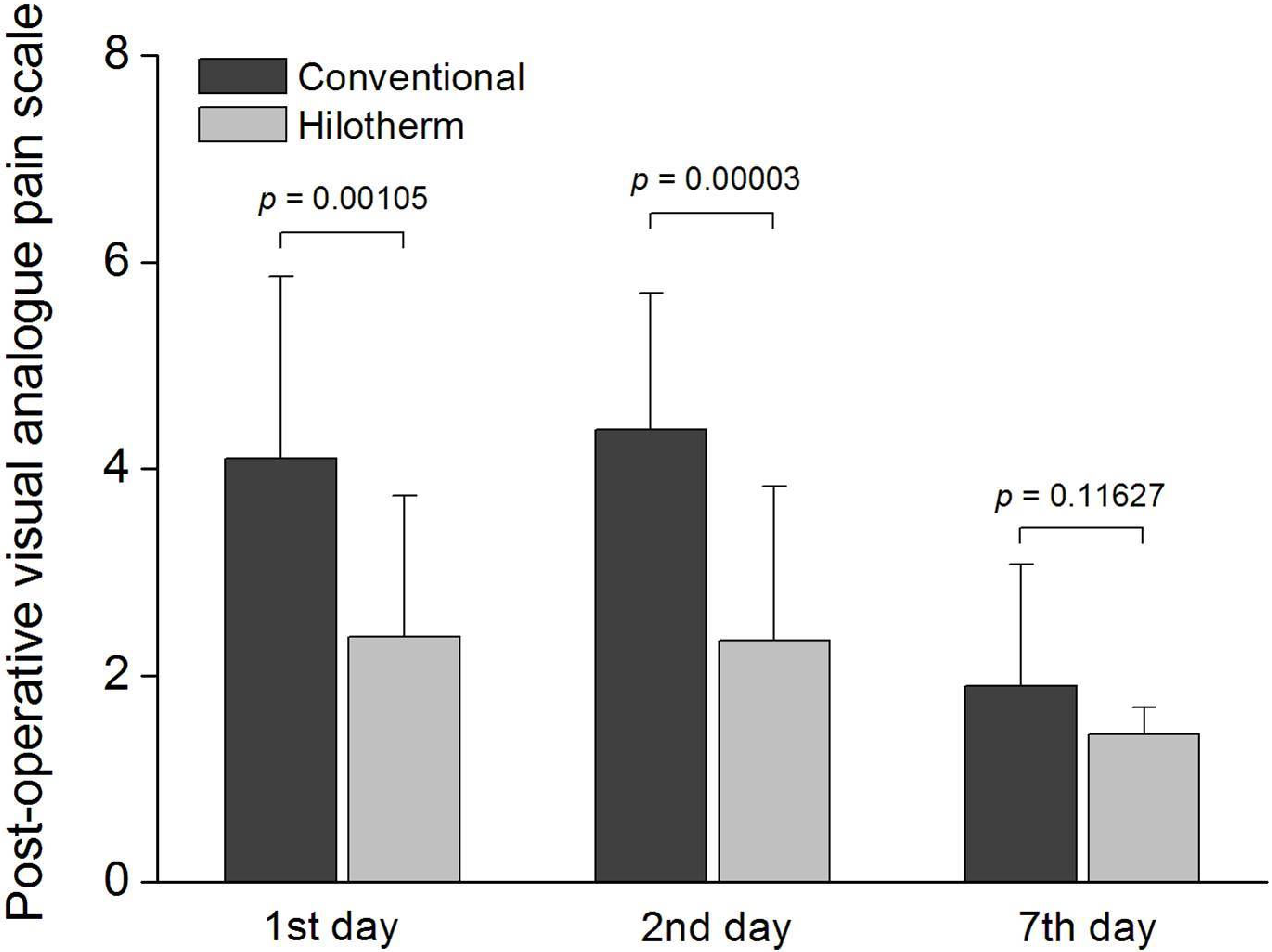
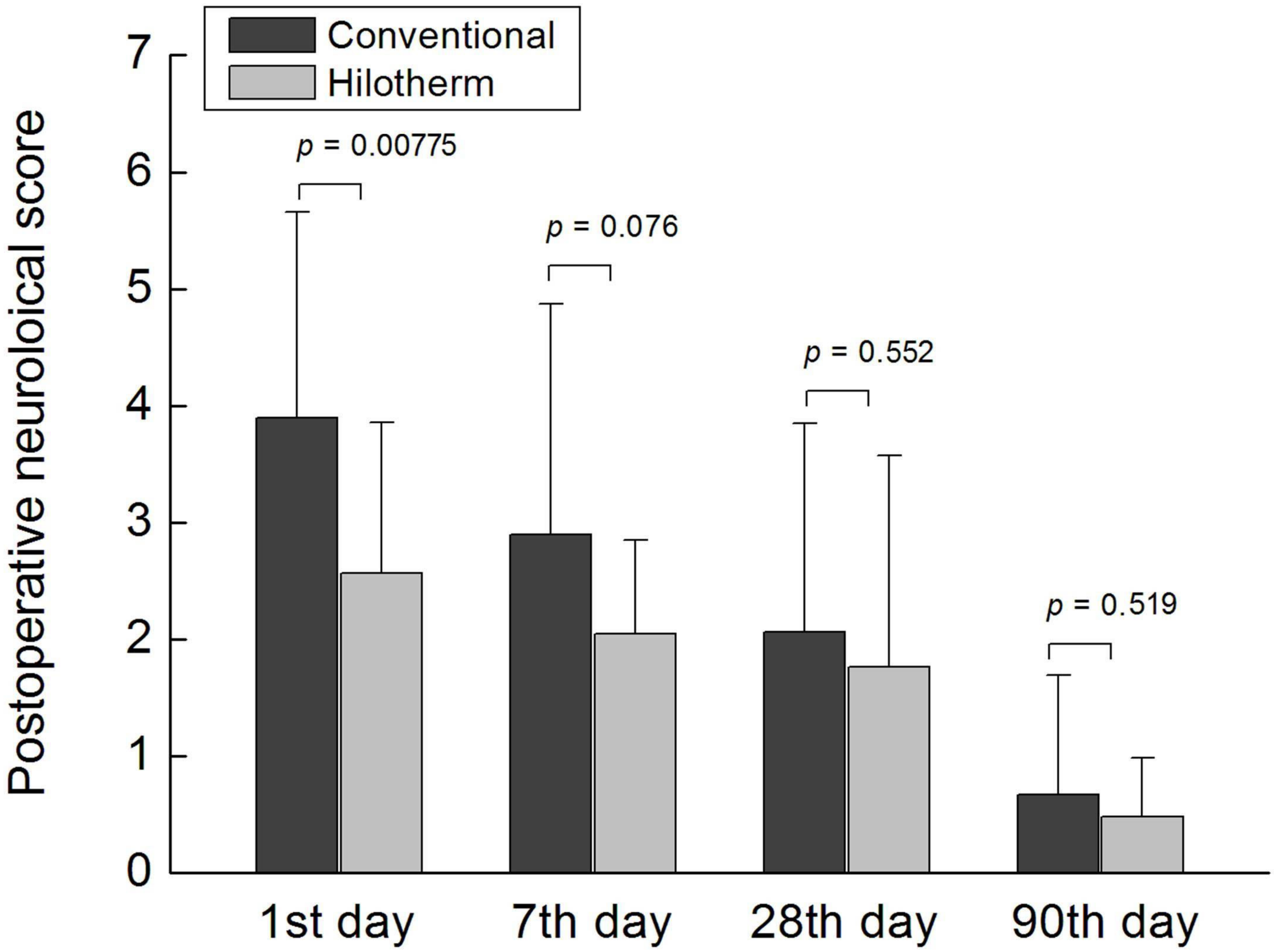

Post-operative visual analogue pain scale
0
2
4
6
8
Conventional
Hilotherm
p = 0.00105
p = 0.00003
p = 0.11627
1st day
2nd day
7th day

Figure 6


Conventional
Hilotherm
Postoperative neuroloical score
p = 0.00775
p = 0.076
p = 0.552
p = 0.519
0
1
2
3
4
5
6
7
1st day
7th day
28th day
90th day
Figure 7

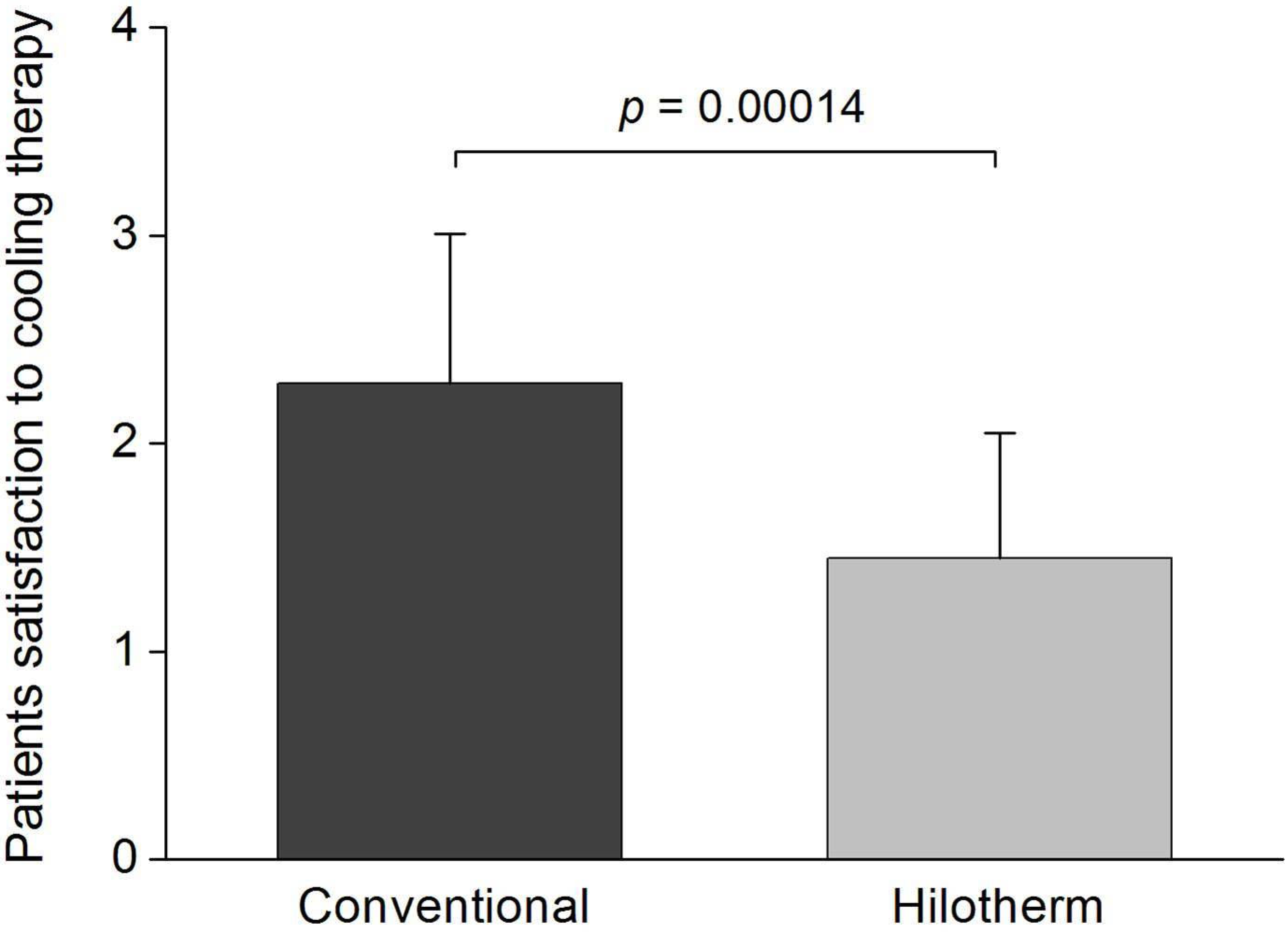

Patients satisfaction to cooling therapy
4
3
2
1
0
p = 0.00014
Conventional
Hilotherm

Figure 8

Additional files provided with this submission:

Additional file 1: Statement of Agreement-Patients_Foto.pdf, 1000K
http://www.trialsjournal.com/imedia/3222323849536000/supp1.pdf
Additional file 2: Trial-Registration_DRKS00004846_de.pdf, 48K
http://www.trialsjournal.com/imedia/5082826499535995/supp2.pdf