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Title: 3D evaluation of postoperative swelling following third molar surgery using 2 different cooling therapy methods: a randomised observer blind prospective study

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Abstract: Abstract

Purpose:

In most cases the removal of third molars leads to a significant degree of tissue trauma resulting in common postoperative symptoms and signs of pain, facial swelling, dysfunction and limited mouth opening (trismus). Beneficial effects of cold treatment on postoperative swelling, edema, pain, inflammation as well as the reduction of bleeding and hematomas have been described. The aim of this study was to compare post-operative cooling therapy by cooling compresses with the water-circulating cooling face mask by Hilotherm® in terms of beneficial effects on postoperative facial swelling, pain, trismus and neurological complaints.

Patients and Methods:

30 patients were assigned for third molar surgery and were divided randomly into treatment either with Hilotherm or with conventional cooling with cooling compresses. Cooling was performed for 45 minutes after surgery. Facial swelling was quantified by a 3D optical scanning technique. Furthermore, pain and neurological score and the degree of mouth opening were observed from each patient.

Results

Patients receiving a cooling therapy by Hilotherm® demonstrated less facial swelling, less pain, a tendency to less neurological complaints and were more satisfied than with conventional cooling.

Conclusions

Hilotherm® is more efficient to manage postoperative swelling and pain after removal of third molars compared to conventional cooling.

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Dear Dr. Leon A. Assael,

enclosed please find our manuscript entitled “3D evaluation of postoperative swelling following third molar surgery using 2 different cooling therapy methods” which is submitted to be considered for publication as an original contribution in Journal of Oral and Maxillofacial Surgery. Neither the entire paper nor any part of its content has been published previously or is under consideration for publication elsewhere.

In most cases the removal of third molars leads to a significant degree of tissue trauma resulting in common postoperative symptoms and signs of pain, facial swelling, dysfunction and limited mouth opening (trismus). Beneficial effects of cold treatment on postoperative swelling, edema, pain, inflammation as well as the reduction of bleeding and hematomas have been described. Therefore, this study aimed to evaluate the post-operative cooling therapy by cooling compresses with the water-circulating cooling face mask by Hilotherm® in terms of beneficial effects on postoperative facial swelling, pain, trismus and neurological complaints. Facial swelling was quantified by a new 3D optical scanning technique.

In accordance with the instructions for authors, the manuscript has been approved by all authors and all of them have taken due care to ensure the integrity of their work. We assure that none of the authors disclose any association that poses a conflict of interest. The authors declare that they agree to pay for the cost of printing.

Thank you very much.

Sincerely yours,

Majeed Rana, M.D. D.D.S

3D evaluation of postoperative swelling following third molar surgery using 2 different cooling therapy methods

A randomised observer blind prospective study

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Abstract

Purpose:

In most cases the removal of third molars leads to a significant degree of tissue trauma resulting in common postoperative symptoms and signs of pain, facial swelling, dysfunction and limited mouth opening (trismus). Beneficial effects of cold treatment on postoperative swelling, edema, pain, inflammation as well as the reduction of bleeding and hematomas have been described. The aim of this study was to compare postoperative cooling therapy by cooling compresses with the water-circulating cooling face mask by Hilotherm® in terms of beneficial effects on postoperative facial swelling, pain, trismus and neurological complaints.

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30 patients were assigned for third molar surgery and were divided randomly into treatment either with Hilotherm or with conventional cooling with cooling compresses. Cooling was performed for 45 minutes after surgery. Facial swelling was quantified by a 3D optical scanning technique. Furthermore, pain and neurological score and the degree of mouth opening were observed from each patient.

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Patients receiving a cooling therapy by Hilotherm® demonstrated less facial swelling, less pain, a tendency to less neurological complaints and were more satisfied than with conventional cooling.

Conclusions

Hilotherm® is more efficient to manage postoperative swelling and pain after removal of third molars compared to conventional cooling.

Introduction

In most cases the removal of third molars leads to a significant degree of tissue trauma that again causes an inflammatory reaction (1). As a result the patient suffers from the common postoperative symptoms and signs of pain, facial swelling, dysfunction and limited mouth opening (trismus) (2). Pain is typically brief and peaks in intensity in the early postoperative period; meanwhile facial swelling and trismus reach their characteristic maximum 48-72 hours after surgery (3). Those symptoms are a major disadvantage and affect the patient's quality of life. To increase patient satisfaction after third molar surgery it is a necessary goal to avoid the inconvenience associated with the tooth extraction and to minimize the occurring side effects. One way to reduce side effects is to prescribe medication like corticosteroids (4), non-steroidal anti-inflammatory drugs (NSAID) (5), a combination of corticosteroids and NSAID (6) or enzyme preparations like serratiopeptidase (7). Besides that, there are as well non-medication methods to treat the above named side effects, such as manual lymph drainage (8), soft laser (9,10) and cryotherapy (11). Cryotherapy has been used since the times of Hippocrates, who described the use of local or systemic application of cold for therapeutic reasons (12). Beneficial effects of cold treatment on postoperative swelling have been described previously (13), (14), (15) as well as positive consequences on edema, pain and inflammation (16), (17), (18) and the reduction of bleeding and hematomas. Low temperatures lead to a reduction of the activity of inflammatory enzymes (16). The pain relieving effect of cold therapy is well documented. Considering literature in oral and maxillofacial surgery there is an insufficiency of scientific evidence and trials that show positive as well as no effect of cold therapy (19). There are different cooling procedures known, such as ice packs, gel packs or cold compresses. Both, positive and negative side effects are previously discussed such as tissue injuries, disturbances of lymph drainage and microcirculation or chilblains. As an alternative to

those conventional cooling methods this study works with a procedure that permits continuous cooling via face mask by a water-circulating cooling device named Hilotherapy (Hilotherm®, Germany).

The aim of this study was to examine the effect of Hilotherapy in comparison with conventional cooling method with cold compresses on swelling, pain, trismus, neurological complaints and patient satisfaction after third molar surgery.

Materials and Methods

The study was approved by the local 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.

Patients

30 healthy patients were scheduled for extraction of all four wisdom teeth, were divided randomly into 2 treatment groups. 15 patients were treated with conventional cooling and 15 patients received continuous cooling using Hilotherapy after extraction of all four third molars. The observer did not know about the kind of therapy applied at the time of the patient examinations.

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 1A). The temperature setting is adjustable from +10°C to +30°C and was set to 15 °C after surgery.

The cool compressive were usual cool packs. The patients were recommended to use the cool compressive for 45 minutes after surgery (Figure 1B).

Study including criteria's and protocol

Only patients with a Pell & Gregory level B and C were included in this study. Patients who need extraction of wisdom teeth of the mandible were not included in this study. Further inclusion criterions for the participation were misaligned teeth, tooth anomalies, retained and impacted third molars. Potential participants would have been excluded from the study because of missing operability, foreseeable missing opportunity of follow-up examination, pregnancy, nursing, drug addiction, recent operations, and diseases like 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. All patients were examined and scanned on fixed dates using standardized methods and techniques. Thus every patient received the same postoperative analgetic (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) and no antibiotic prophylaxis therapy. 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. During the study the following parameters were assessed: pain, swelling, neurological complaints, patient satisfaction and mouth opening.

Post-operative pain analysis

Post-operative pain analysis was conducted with the help of a visual analogue scale (VAS) on a daily base from 2nd to 10th day, where the patients should 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.

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). 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 (20). 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 Slim3D (3D-Shape®, Erlangen, Germany) automatically triangulates, merges and post processes the data (21). Final output is a triangulated polygon mesh that is visualized as a synthetically-shaded or wire-mesh

representation (22). 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 midline of the face was aligned to the vertical line. Patients were instructed to swallow hard and to keep their jaws in a relaxed position for the scan. 3D optical scans were recorded at 5 points in time: before surgery (T0), directly after surgery (T1), on the 2nd (T2), the 10th (T3) and the 28th (T4) postoperative day. The reference 3D model for each patient was the scan from T0. The resulting difference of volume was calculated as described swelling, using the computer software Comparison (3D-Shape®, Erlangen, Germany)

Neurological analysis

The neurological analysis was performed bilaterally. It was used to be able to evaluate nerve dysfunctions. The skin of the infraorbital, mental region, upper and lower lip were 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 these regions. The same procedure was accomplished for the lower lip and the mental nerve skin region. The results were recorded on a score that ranges between 0 and 13, with 13 being the worst neurological score. The neurological score was assessed at 3 points in time: before surgery (T0), on the 2nd (T1) and the 28th (T2) postoperative day.

Patients satisfactory

Each patient was asked to complete a questionnaire on the 10th postoperative day. The question was how they evaluated satisfaction and convenience of the applied postoperative cooling therapy on a subjective base. The grading scale ranged from 1 to 4, where 1 stands for very satisfied and 4 for not satisfied.

Measurement of mouth opening

Trismus was calculated with interincisal mouth opening and was measured with a caliper. The result was quoted in millimetres and observed at 5 days: before surgery (T0), directly after surgery (T1), on the 2nd (T2), the 10th (T3) and the 28th (T4) postoperative day.

Statistical analysis

Regarding the statistical analysis, all data is expressed as mean values ± 1 SEM. For repeating measures a one-way analysis of variance (ANOVA) with post hoc Bonferroni's test for multiple comparisons of means was applied. Since the observed parameters consist above all of dichotomous variables, a χ^2 -test and a Wilcoxon-test were conducted to detect differences between conventional cooling and hilotherapy. To check for statistical significance of quantitative variables the Student t-test was used, denoting a p-value of < 0.05 as significant. The statistical analysis was conducted using SPSS for Windows version 14.0 (SPSS Inc., Chicago, IL, USA).

Results

Baseline characteristics

30 patients were randomly enrolled in the study. After third molar surgery 15 patients were assigned to conventional cooling therapy and 15 patients were treated with Hilotherapy. The clinical and demographic characteristics of patients in both groups are shown in Table 1. Both groups showed no statistical significances regarding gender, age, body mass index (BMI) and surgery duration.

Postoperative swelling

Swelling was measured in terms of volume in milliliters as described in the method section. On 2nd day after surgery a statistical significant down-regulation of swelling could be achieved by applying the Hilotherm cooling device compared to conventional cooling therapy (Hilotherm: 72.2±14.9 ml, conventional: 96.6±20.9 ml, $p = 0.005$) (Figure 2). This tendency was maintained on the 10th postoperative day (Hilotherm: 23.3±6.1 ml, conventional: 46.7±12.7 ml, $p < 0.001$). After 28 days no statistical significant differences with respect to swelling could be documented in both groups (Hilotherm: 5.1±3.4 ml, conventional: 5.8±3.7 ml, $p = 0.57$). Maximal swelling was noticed at 2nd day after surgery with 72.2±14.9 ml by Hilotherapy and with 96.6±20.9 ml for conventional cooling.

Postoperative pain

Pain was calculated in terms of a visual analogue scale from subjective analysis ranging from 0 to 10. At 2nd and 3rd postoperative day a significant down-regulated pain score was assessed by Hilotherapy compared to conventional cooling (2nd day: Hilotherm: 3.4±1.5, conventional: 4.8±1.6, $p < 0.05$) (3rd day: Hilotherm: 2.9±1.1, conventional: 3.7±1.2, $p < 0.05$) (Figure 3). Although not statistically significant, at 4th postoperative day we could achieve lower pain scores compared to conventional cooling (Hilotherm: 1.7±0.7, conventional: 2.1±0.8, $p = 0.06$). At 28th postoperative day

no differences were obtained comparing the pain score in both groups (Hilotherm: 0.3 ± 0.1 , conventional: 0.3 ± 0.1 , $p = 0.67$).

Postoperative neurological score

There were no statistical significant differences found between both groups concerning the neurological score 2 and 10 days after third molar extraction (2nd day: Hilotherm: 1.2 ± 0.6 , conventional: 1.1 ± 0.6 , $p = 0.8$) (10th day: Hilotherm: 0.07 ± 0.3 , conventional: 0.1 ± 0.4 , $p = 0.6$) (Figure 4). However, a highly significant decrease of the neurological score can be observed after 10 days compared to the results of the 2nd postoperative day in both groups (Hilotherm: 2nd day: 1.2 ± 0.6 vs. 10th day: 0.07 ± 0.3 , $p < 0.001$; conventional: 2nd day: 1.1 ± 0.6 vs. 10th day: 0.1 ± 0.4 , $p < 0.001$).

Trismus

Post-operatively and at 2nd postoperative day mouth opening was significantly higher in the Hilotherapy group compared to conventional cooling (post-operatively: Hilotherm: 22.8 ± 0.7 , conventional: 17.1 ± 0.7 , $p = 0.01$) (2nd day: Hilotherm: 25.1 ± 2.4 , conventional: 22.0 ± 1.9 , $p = 0.002$) (Figure 5). Mouth opening returned to normal values 28 days after surgery without statistically differences in both groups.

Patient satisfaction

Regarding the patient's satisfaction, which was assessed at 2nd day after surgery, a statistically significant difference between Hilotherapy and conventional cool packs could be detected (Hilotherm: 1.9 ± 0.2 , conventional: 3.1 ± 0.3 , $p = 0.003$).

Discussion

This study demonstrates that continuous cooling with the Hilotherapy devices reduces post-operative swelling, pain, trismus after third molar surgery compared to conventional cooling with cold packs. Furthermore, patients satisfaction treated with Hilotherapy was greater compared to patients receiving conventional cooling. However, post-operative neurological score was unchanged in both groups.

It has been shown that the healing process and the possible complaints after removal of third molars can be influenced by various factors such as surgeon experience, age and gender of the patient, necessity of tooth sectioning or of bone removal (1), (23), (24), (25), (26). Another variable that can have an influence on the degree of facial swelling is the duration of operating time that again is related to surgical difficulties in extraction (27). Since operating time was not significant different in both groups this factor does not have any impact on the results.

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 (28). However, since the region that is affected by swelling after third molar surgery, exhibits superior blood supply, the probability of these contra-indications is very low for oral and maxillofacial surgery (19).

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. Those biological effects hold influence on the postoperative symptoms. Meanwhile the anti-

edema effect is caused by the vasoconstriction; the pain reducing effect of cold is related to a blocking of nerve endings. This blocking decelerates nerve conduction and consequently as well 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 (29). The effects of a treatment with too 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 fulfil this requirement this study worked with the cooling device Hilotherm® Clinic (Hilotherm® GmbH, Germany). In comparison to cool compresses there is no need to change ice packs regularly. It represents a simple, easy-to-use and cost-effective treatment alternative to conventional cooling.

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None

Financial Interests

None

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TABLE 1. Baseline characteristics of patients

	Hilotherm [®]	Conventional	<i>P</i> value
Gender female – no./total no. (%)	5/17 (29)	7/15 (47)	0.5
Age (years) ± SD	23.5 ± 4.7	24.7 ± 5.5	0.499
BMI (kg/m ²) ± SD	23.6 ± 3.8	23.9 ± 3.6	0.281
Operation duration (minutes) ± SD	70.2 ± 20.8	67.6 ± 19	0.784

Figure Legends

Figure 1A

Figure 1A demonstrates the Hilotherm® device connected with 2 masks. A maximum of 2 masks can be connected to 1 Hilotherm® device. The temperature can be adjusted from 10 to 30 degrees Celsius.

Figure 1B

Figure 1B demonstrates the front view of a patient wearing the mask.

Figure 2

Figure 2 demonstrates the amount of swelling in ml of both groups at different time points. At 2nd 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 at 10th post-operative day. After 28 days no differences with respect to swelling could be documented in both groups.

Figure 3

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 2nd and 3rd post-operative days. The pain intensity remained significantly unchanged during 4th and 28th post-operative day in both groups.

Figure 4

No changes were found concerning the neurological score at 2nd and 10th post-operative days in both groups. However, a highly significant decrease of the neurological score was observed at 10th compared to 2nd post-operative day in each group.

Figure 5

Pre-operative mouth opening values did not differ significantly in both groups. Post-operatively, a significant reduction of mouth opening could be revealed in both groups. The reduction of mouth opening was significantly lower in the Hilotherm group compared to conventional group. At 2nd post-operative day a significant increase of mouth opening could be achieved in both groups compared to post-operative. The reduction of mouth opening remained significantly lower in the Hilotherm group compared to conventional group at 2nd post-operative day. 28 days after removal of third molars mouth opening climbed to pre-operative values and no differences were observed comparing both groups and in comparing to baseline. * $p < 0.05$.

Figure 6

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

Figure 1A
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Figure 1B
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Figure 2
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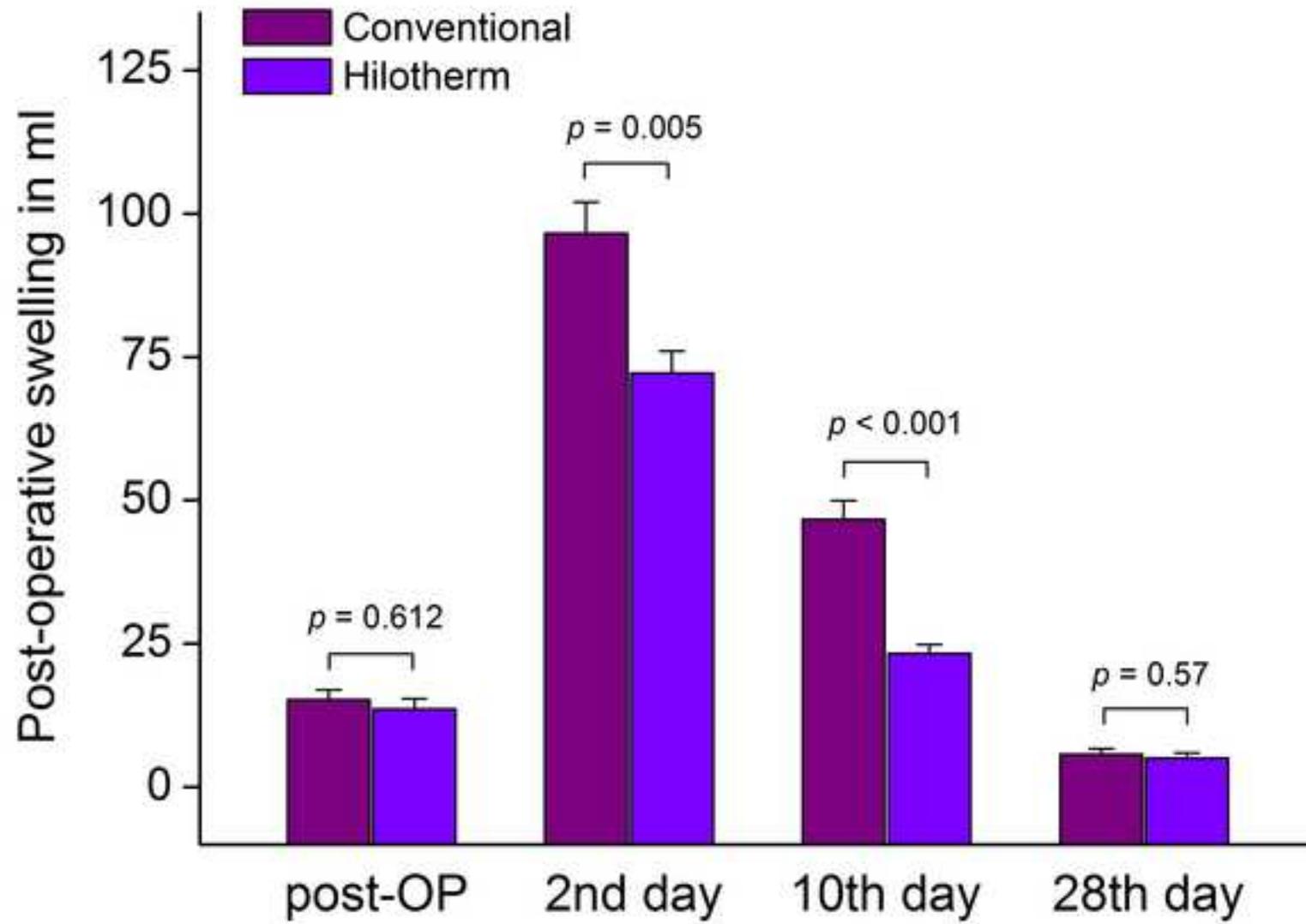


Figure 3
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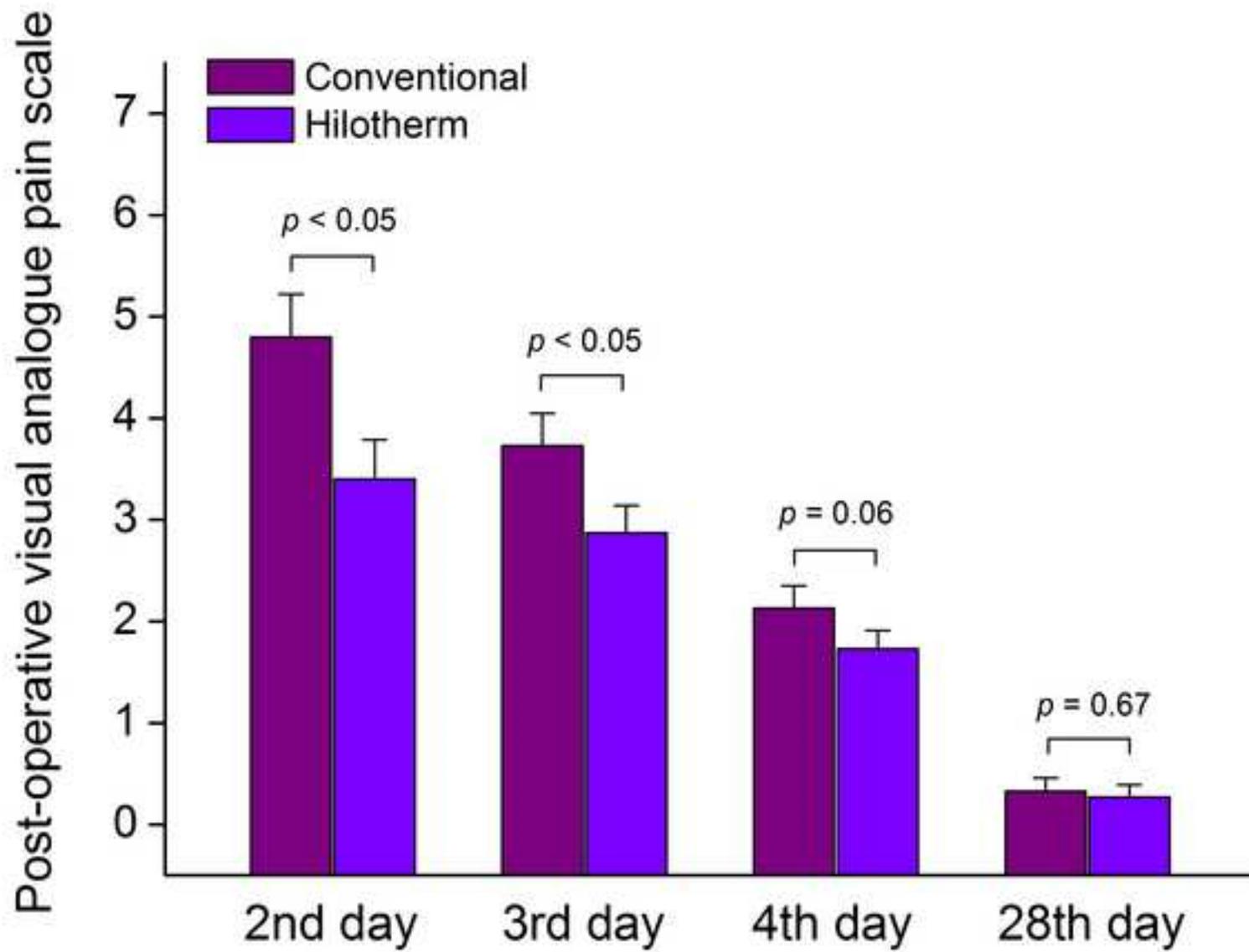


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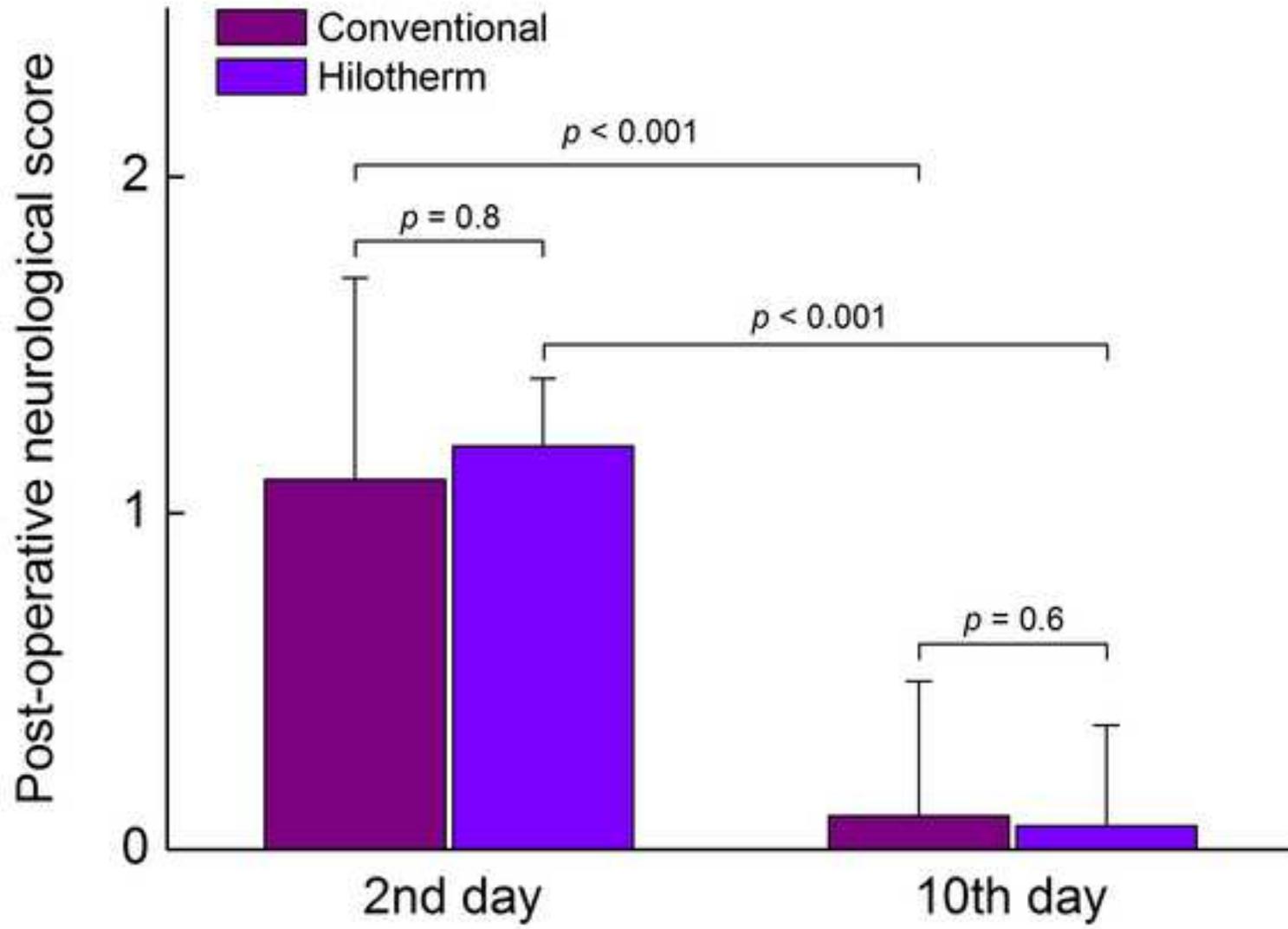


Figure 5
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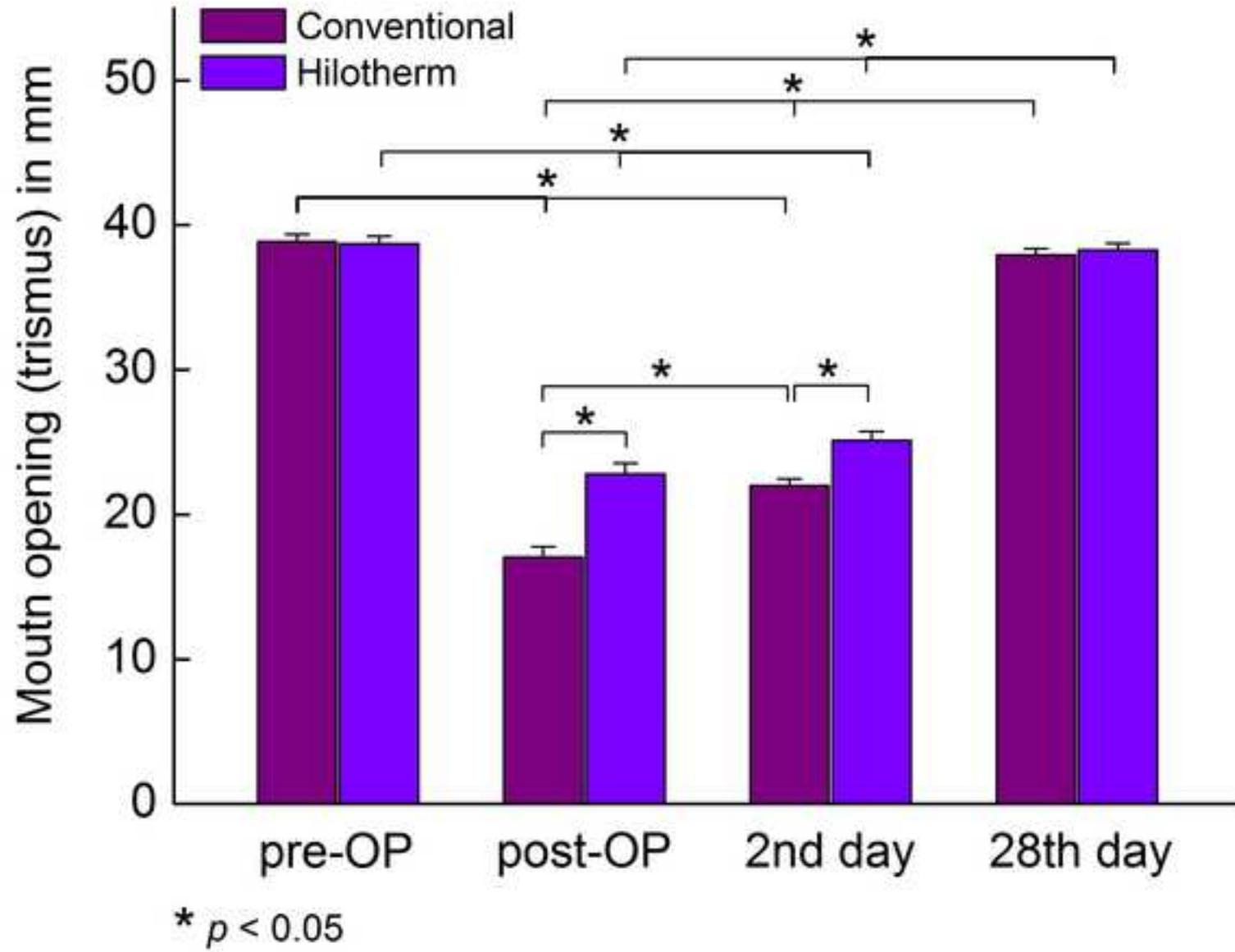
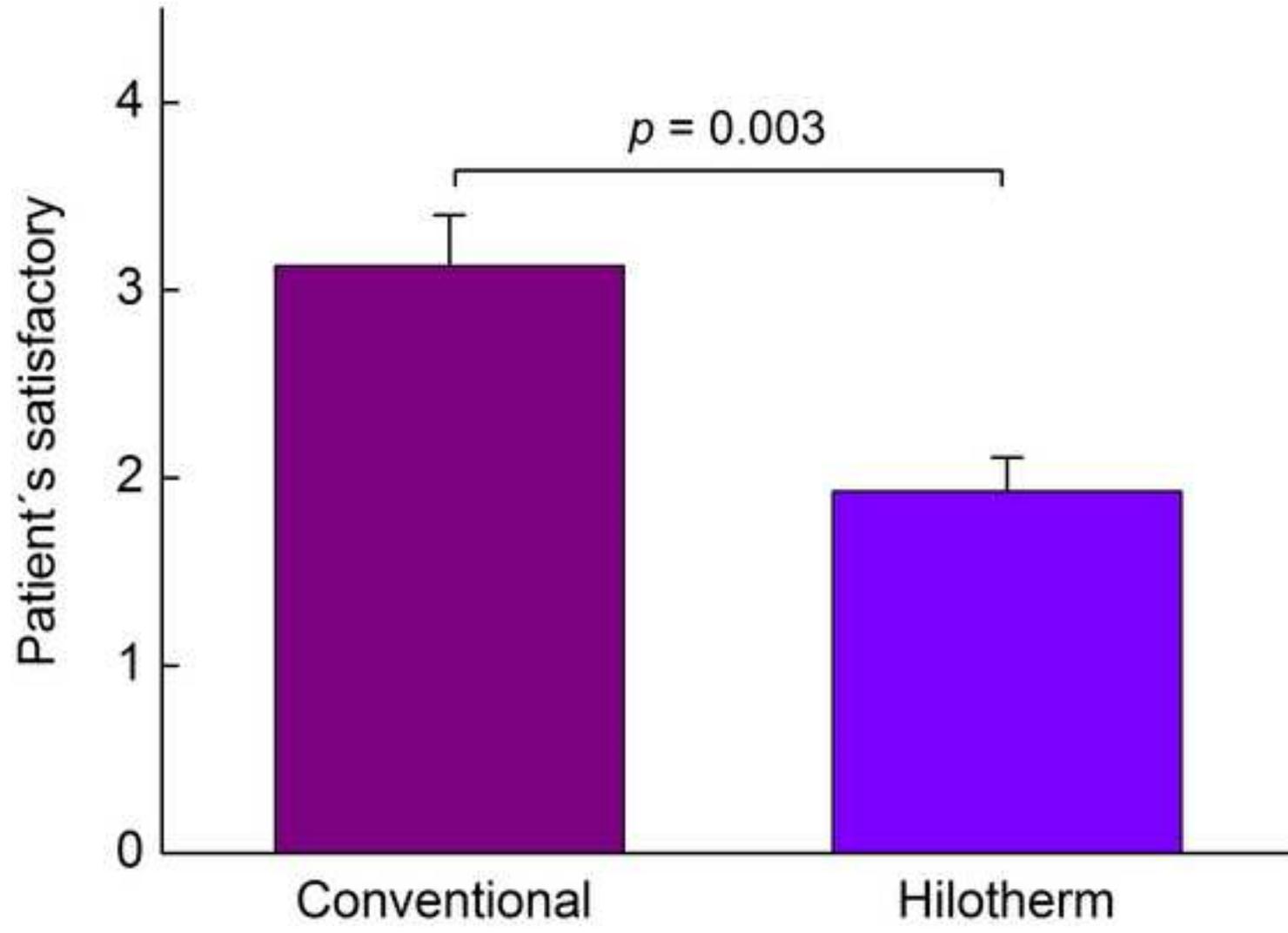


Figure 6
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SUMMARY OF OPERATING PRINCIPLES GOVERNING DISCLOSURE OF DUAL COMMITMENT

1. The expression “dual commitment” describes the dilemma faced by authors when their responsibility to remain unbiased may be compromised, or perceived to be compromised, by a simultaneous commitment to commercial interests related to the subject of a specific scientific/educational activity. “Conflict of Interest” refers to a degree of dual commitment that may be strong enough to produce reservations regarding potential loss of objectivity.
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**American Association of Oral and Maxillofacial Surgeons
Disclosure Statement**

Publication: Journal of Oral and Maxillofacial Surgery
 Author: Rana, Majeed, M.D. D.D.S.
 Article Title: 3D evaluation of postoperative swelling following third molar surgery using 2 different cooling therapy methods: a randomised observer blind prospective study

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