Knee Temperatures Measured In Vivo After Arthroscopic ACL Reconstruction Followed by Cryotherapy with Gel-Packs or Computer Controlled Heat Extraction

Cryotherapy After ACL Surgery

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Abstract

Purpose

To obtain in vivo data about intra and extra articular knee temperatures to assess the effectiveness of two cryotherapeutic methods - conventional cooling with gel-packs and computer controlled cryotherapy following Anterior Cruciate Ligament (ACL) reconstructive surgery.

Methods

Twenty patients were arbitrary assigned for cryotherapy after ACL reconstruction: 8 patients with frozen gel-packs and 12 patients with computer controlled cryotherapy with constant temperatures of the cooling liquid in the knee pads. The treatment was performed for 12 hours. Temperatures were measured with two thermo sensors in catheters placed intraarticularly and subcutaneously, four sensors on the skin and one sensor under protective bandage, every second for 16 hours after surgery.

Results

In the first two hours of treatment there were no significant differences (n.s.) between the groups in temperatures in the intracondylar notch. After four hours of cryotherapy, the temperatures were significantly lower on the skin (24.6 ± 2.8 °C and 31.4 ± 1.3 °C, $p < 0.01$) and in the subcutaneous tissue (28.6 ± 5.7 °C and 34.6 ± 1.4 °C, $p = 0.01$), and the difference between the temperature in the intracondylar notch and the subcutaneous tissue was significantly greater (4.0 ± 3.0 °C and 0.8 ± 0.6 °C, $p = 0.01$) in the computer controlled cryotherapy group compared to the gel-pack group.

Conclusions

The cooling effect of the arthroscopy irrigation fluid on the knee temperature is evident in the first two hours of treatment. The energy extraction is significantly more effective and controllable by computer controlled cryotherapy than with frozen gel-packs.

Key Words: arthroscopy; Anterior Cruciate Ligament; cryotherapy; temperature.

Level of Evidence

Prospective comparative study, Level II.

Introduction

It has been known for many years, mostly from empirical evidence, that cryotherapy following anterior cruciate ligament (ACL) reconstruction contributes to reduced tissue edema, inflammation, hematoma formation and pain, reducing the need for pain medication and enabling faster rehabilitation [16]. Cryotherapy is routinely used in postoperative treatment in orthopedics, traumatology, facial surgery, pain prevention in sport, etc [8]. Topical cooling is often performed using either ice chips or refrigerated gel-packs, or a cryotherapeutic cuff cooled by a liquid at a constant temperature maintained by an external cooling device or by a container with ice water [9].

The empirical properties of cryotherapy have been investigated, applying different means of cooling. Some authors have reported that cryotherapy decreases the need for medications and improves rehabilitation after ACL reconstruction [3, 7, 18], while others failed to confirm such beneficial effects [5, 10]. The relative importance of compression or the application of cold itself during cryotherapy has not been established [1, 17]. Previous studies [5, 6] have shown that neither cooling nor compression influences the clinical effects of cryotherapy.

A few studies related to knee temperatures, after ACL reconstruction [4, 7, 14] or arthroscopy [11, 12, 15, 21], followed by postoperative therapeutic cooling, have been reported. We have taken into account all previous experience and results in an attempt to gain a deeper insight into the effects of cryotherapy. The purpose of our study was to perform long-term in vivo measurements with high accuracy of the temperature distribution on the skin, in the subcutaneous tissue and in the knee joint after ACL reconstruction followed by cryotherapy. The obtained data are significantly more detailed compared to previous studies and available in full resolution for further research. We use an innovative approach for in vivo temperature measurements, replacing the standard drainage catheters with ones equipped with thermistors.

In this study, the effectiveness of two modalities of cryotherapy – the standard cooling with refrigerated gel-pack changed after some predefined time intervals, and computer controlled cryotherapy with pre-programmed protocols in terms of heat extraction intensity and treatment time, was assessed. It was

hypothesized that extracting energy by computer controlled cryotherapy is more effective and controllable than cooling with gel-pack. Further, the important impact of the irrigation fluid on the temperature field inside the knee was investigated.

The results of our study can contribute to a better understanding of cryo effects, the evaluation of various cryo methods, and further development and standardization of cryotherapy.

Materials and methods

The study protocol was explained in details to patients regularly scheduled for ACL reconstruction. The patients were informed that the study will not have any impact on their rehabilitation. All patients, as they appeared in the waiting queue, have been invited to participate in the study; there were no exclusion criteria. Written consent to take part in the study was signed by 20 patients. After surgery, the patients were assigned interchangeably to receive postoperative knee cooling, with either cold gel-packs (Group A, 8 patients) or computer controlled cryotherapy using a cryotherapeutic pad (Group B, 8 patients). The remaining 4 patients were assigned to Group B to increase the statistical power of the measured temperatures. The allocation of patients in groups did not depend on any patient characteristic or any other criteria. The cooling was performed over 12 hours and temperatures were measured for 16 hours after surgery. The patient and environmental data before surgery: age, gender, weight, height, body mass index (BMI = weight/height^2), and knee circumference are given in Table 1.

Surgical technique

All operations were performed by the same three surgeons. The technique used was arthroscopic single bundle reconstruction with Quadriceps bone-tendon graft. For joint distension, an arthropump (Arthrex Continuous Wave III arthroscopic pump; Arthrex Medizinische Instrumente GmbH, Karlsfeld, Germany) was used with lactate solution at room temperature. After fixation of the graft, the joint was washed-out with irrigation fluid at 27 °C. During surgery a tourniquet with a pressure at 300 mm Hg was always used. Patients were operated under subarachnoid anesthesia or general anesthesia. The decision about the type of anesthesia was determined by the patient and the anesthesiologist.

Temperature measurements

Temperatures were measured electronically with eight miniature thermo sensors (thermistors) connected to a small 8-channel measuring device for automatic recording. The measuring device was powered by a battery and had a memory for 18 hours of continuous operation.

After the ACL reconstruction, two thermo sensors, placed in sterile drainage catheters (sterile silicon Foley catheter, Degania Silicone Ltd., Emek Hayarden, Israel), were implanted - one in the central part of the knee and the other in the subcutaneous tissue. Under arthroscopic control, the first catheter with thermo sensor #1-ICN was introduced through the anterolateral portal to the intercondylar notch, between the graft and the posterior cruciate ligament. The catheter was fixed to the anterolateral portal suture. Through the anteromedial portal, the subcutaneous layer was bluntly tunneled along the medial border of the patella and the second catheter with thermo sensor #2-SC introduced into the tunnel. The catheter was placed subcutaneously, 2 cm medially and in the level of the superomedial corner of the patella. The catheter was fixed to the anteromedial portal suture. The wounds were covered by minimal sterile adhesive tapes.

Four thermo sensors were fixed on four locations on the knee skin at the level of the joint line: sensor #3-SK12 (anterior), sensor #4-SK3 (medial), sensor #5-SK6 (posterior), and sensor #6-SK9 (lateral). The positions of sensors are shown schematically in Fig. 1.

Three layers of sterile cotton bandage were wrapped around the knee. Thermo sensor #7-BA was fixed to the upper bandage (BA) layer below the cooling pack or pad, just above the sensor #3-SK12, on the same side as the sensor #2-SC. Sensor #8-DE was mounted in the measuring device (DE) to monitor the temperature inside the device. The measuring device was fixed with a few turns of bandage to the lower part of the patient's leg. The tourniquet was removed 5 minutes after the start of the measurements.

Temperatures were measured every second for 16 hours, starting after surgery (placement of sensors), then during the whole cooling treatment, and continuing after the treatment. The thermistors were previously calibrated to assure resolution of 0.02°C and accuracy $\pm$ 0.05 °C, except for the thermistors placed in catheters, where the accuracy was $\pm$ 0.1 °C.

Treatment

After surgery the patients were transported to the recovery room with controlled temperature. The initial ICN temperature after the surgery was not significantly different (n.s.) between the groups (27.3 ± 1.3 °C for Group A and 27.2 ± 1.6 °C for Group B). The cooling procedure was started approximately half an hour after the start of temperature recording. The ICN temperature before the start of the cooling was also not significantly different (n.s.) between the groups (33.8 ± 2.0 °C for Group A and 33.5 ± 1.7 °C for Group B).

Group A: Conventional cooling with gel-packs

Group A patients were administered the standard gel-packs (dimensions 370 x 290 mm, covered area 0.11 m^2, weight 1.5 kg, specific heat capacity cp = 4.5 kJ/(kg K)) cooled in a refrigerator at temperature -12.2 ± 1.5 °C (a thermometer was placed in the refrigerator to measure the temperature of the gel-packs.). They were wrapped around the anterior part of the knee, with a single-layer cotton sac, covering 2/3 of the total circumference of the knee and fixed by protective bandage with the same compression as routinely applied with protective bandages after knee surgery. The gel-packs were changed according to the standard rehabilitation protocol [6] used routinely at the University Medical Centre Ljubljana: six two-hour intervals of treatment each consisted of 20 minutes of cooling with gel-pack followed by 100 minutes period without gel-pack.

Group B: Computer controlled cryotherapy

Patients in Group B were administered Cryoceutical Treatment (cTreatment®), using the Cryoceutical Treatment Server (CTS100, Waegener, Beerse, Belgium) equipped with a knee Cryoceutical Pad (cPad, Waegener, Beerse, Belgium) with effective covering area of 0.10 m^2. The cPad could be shaped to the knee by fastening it with fixing straps and covering the same amount of the knee as gel-packs. The cPad allows a uniform flow of the cooling liquid. The circulating liquid in the cPad, cooled to a specified temperature, efficiently extracts the heat energy from the deep parts of the knee. The filled cPad produces approximately the same compression to the treated body part as in the case of gel-packs because the medical personnel were instructed to apply the same tension to the fixing straps (cPad) as to the protective bandage (gel-packs).

Cooling was carried out over 12 hours in six two-hour intervals. Temperatures of the cooling liquid were as determined by the protocol previously applied in several rehabilitation cases in the Department of Orthopedic Surgery, Ghent, Belgium [20]. In the first and second two-hour intervals the cooling liquid was set to 9 °C and circulated for 90 minutes, followed by a 30 minute pause with no circulation, but with the cPad remaining around the knee. During the next four hours the cooling liquid was set to 13 °C, with continuous circulation. In the last four hours, the temperature of the circulating liquid was again set to 9 °C, with continuous circulation.

The protocol during cooling was controlled by a trained nurse who also recorded the ambient temperature of the recovery room and the tympanic temperature (TT) of the patients before and after every cooling interval. Patient's pain was recorded against the VAS scale. Basic postoperative analgesia consisted of 3ml/h continuous intravenous (IV) Dipidolor (1.5 mg/h) administered via a PCA pump (CADD-Legacy PCA pump, Sims Deltec Inc., Saint Paul, Minnesota, United States). In the case of a VAS score > 3, additional boluses of IV analgesics were administered. The next day the wounds were re-dressed, sensors were removed and the temperature measuring device removed for data download and prepared for a new measurement.

The study was approved by the Medical Ethics Committee of the Republic of Slovenia and conducted at the University Medical Centre Ljubljana.

Statistical analysis

The unpaired two-tailed t-test was used to assess the statistical significance of the differences between the groups at a significance level of $p < 0.05$. The measured temperatures were analyzed for both groups in the first two intervals of cooling (Interval 1, Interval 2), since these intervals are comparable in terms of the cooling protocols. Both methods of cooling have one part of the interval with cooling and the other part without cooling. Statistical power analysis was also performed with the alpha error at 5% (CI 95%) and the level of significance $p < 0.05$. The statistical power evaluation was done using IBM SPSS Sample Power for Microsoft Windows 3.0.

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Following the approval of the Ethics Committee, which restricts the number of in-vivo measurements, the number of participating patients was kept to the minimum required for relevant study results. After 8 measured patients in each group, a preliminary statistical analysis of the measured data was performed and was recognized that the patients' response to cooling with gel-pack was similar in all 8 patients, while the patients' response to cooling with cPad showed more diversity. Therefore, to increase the statistical power of cPad measurements, the remaining 4 patients were assigned to cooling with cPad. Nevertheless, this study conducted more patients compared to other similar studies related to knee temperatures after ACL reconstruction [4, 11, 12, 14, 15, 21].

The measurements obtained in this study, presented with additional details in supplementary material, are available in electronic form for further research and non-commercial use from the authors.

Results

The average temperatures during the cooling treatment for the gel-pack and cPad groups are shown in Fig. 2. A visual inspection of Fig. 2 indicates that most temperatures are lower for the cPad than for the gel-pack group, e.g., the ICN temperature remains higher than the tympanic temperature for the gel-pack group, and is lower than the tympanic temperature for the cPad group. The initial effect of the gel-packs on the knee was similar to the cPad, although the gel-packs were kept in the refrigerator with temperature -12.2 ± 1.5 °C while the knee pads operate with the cooling liquid set to 9 °C; however, the gel-packs started warming immediately after application and became less effective in time.

We could further see that the ICN is warming up until the end of Interval 1 in the case of gel-packs and for the first 30 minutes after the start of the treatment with cPad, which distinguishes Interval 1 of gel-pack and cPad groups. In Interval 2 all the temperatures decrease during the cooling for both protocols, but significantly more pronounced in the case of treatment with cPad.

A more complete list of temperatures with statistical evaluation is given in Table 2. Statistically significant differences between groups with high statistical power of the tests are detected in most effects in both intervals. Note that the temperature difference between the ICN and the subcutaneous tissue temperature

is greater in the case of treatment with cPad, implying more effective energy extraction. Moreover, in the case of treatment with cPad, the SC and SK temperatures are lower, again indicating that this method is more efficacious in the heat transfer from the knee to the pad.

There were no statistically significant differences (n.s.) between groups in the minimal temperatures under the bandage, which implies that the energy flow of both methods is similar when the cold is applied. The mean differences between the ICN and tympanic temperature, Mean (ICN – TT), and between subcutaneous tissue and average skin temperature, Mean (SC – mean average SK), are not significantly different (n.s.) between groups.

Clinical effects of the cooling treatments and environmental data are given in Table 3. The differences in knee circumference and tympanic temperature between groups are not statistically significant (n.s.). The difference in the number of analgesic boluses used in the two groups is statistically significant with high statistical power of the test. However, the type of anesthesia could significantly influence the consumption of analgesics. A greater number of patients were operated under subarachnoid anesthesia in Group B (9) than in Group A (4).

In Group A, the first bolus was applied, on average, after 4.7 hours and in Group B after 7.0 hours postoperatively, which would be expected, because the subarachnoid anesthesia should delay the pain and consequently the application of the first bolus. The extra bolus needed after the first bolus could indicate the decreasing effect of subarachnoid anesthesia. No patients in Group B were given a second bolus of analgesics, unlike the patients in Group A. The average number of additional boluses of analgesics per hour after the first bolus is statistically significantly different between the groups with high statistical power of the test, which could indicate higher pain reduction by the treatment with cPad.

Discussion

The most important finding of the present study was that extracting energy by computer controlled cryotherapy is more effective and controllable than cooling with gel-pack. The finding was confirmed with the analysis of the in-vivo data about intra-articular, subcutaneous and skin temperatures of the knee during the cryotherapeutic methods.

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A greater difference in temperatures between the intracondylar notch and subcutaneous tissue was found in the group with computer controlled cryotherapy, indicating more effective energy extraction. Moreover, this difference was also greater compared to previous studies, confirming the better effectiveness of the used equipment for computer controlled cryotherapy. Further, Fig. 2 shows that a constant temperature of 17 °C should be maintained on the protective bandage under the cooling gel-pack/cPad for an adequate cooling efficacy. While by cPad this can be easily controlled, similar effects by gel-packs could be achieved by replacing them more frequently. Previous computer simulations showed that a period of 30 minutes would provide such conditions, but with additional risk of frostbite and nerve damage [13].

Next, the difference in minimal ICN temperature between groups in Interval 1 is not statistically significant, implying that the topical cooling effect is less important in the first two hours after surgery. This result is a consequence of the wash-out by irrigation fluid at 27 °C. After surgery, such a knee possesses significant stored self-cooling energy that masks the differences in the effects of the two topical cooling methods, especially in the center of the knee. In Interval 2 this energy is consumed and the effects of topical cooling are therefore more pronounced. The cooling impact of irrigation liquid at room temperature was neglected in previous studies, even its evident influence on the deep tissue temperature, particularly if applied for longer periods. A significant cooling effect of the irrigation liquid was confirmed by computer simulation [19] and also by measurement [4]. This effect also confirms and explains the surprising result published in [21] where the difference in the intra-articular temperature after one hour between two groups with cooled and non-cooled knee was not statistically significant.

Results show that patients' responses to cooling differ considerably. Most of the patients respond as shown in Fig. 2; however, Patient 12 (female, 53 years old, with body mass index 22.0 kg/m2 and knee circumference before surgery 37.3 cm, operated under general anesthesia) is a significant exception, as is evident from Fig. 3. The recorded temperatures are shown for the whole period of the treatment with cPad. ICN temperatures decreased significantly by 13 °C. This is the first time such a significant change of ICN temperatures has been reported.

The result indicates that the cooling procedure preferably has to be controlled by feedback information from the cooled region.

The groups are different with respect to age and BMI, but the statistical analysis failed to confirm the statistical power of the tests. Moreover, the age difference is not likely to be decisive, because the temperature variations seem to be minimally dependent on them. The thickness of the subcutaneous fat layer of each patient was not determined. The difference in the patients' thickness of the subcutaneous fat layer could have caused the patients' responses to cooling to differ considerably. Even though BMI was larger in Group B, statistically significant greater cooling efficiency was confirmed for Group B, indicating that the results were not crucially influenced by the BMI.

The study has several limitations that should be considered. The cooling protocols were different with respect to the dosage and are not generally accepted as standard, but we selected two approaches currently used in medical praxis [6]. The amount of compression of gel-pack and cPad was not measured and was set to common and approximately equal values by all patients. The occurrence and amount of intra-articular bleeding was not exactly quantified in each patient. Theoretically, the intra-articular bleeding could have influenced the results. Also, the use of different types of anesthesia, subarachnoid and general, could bias the results. Subarachnoid anesthesia can have peripheral vasodilatation effect lasting 4-6 hours after induction, i.e. approximately 3-4 hours after surgery. The impact of anesthesia on postoperative pain cannot be distinguished from the impact of cooling. Although patient's pain was recorded against the VAS scale, these results were excluded from our study because of uncompleted reports from several patients. Furthermore, the statistical power of some tests was very low; nevertheless, we draw conclusion only from the results with adequate statistical power.

For applications beyond the classical cryotherapy, much more sophisticated cryotherapy devices are needed, with the ability to control cooling in terms of intensity and locality. The cooling pad could have more inputs in order to maintain specified temperatures in different regions of the cooled part of the body. Such a "smart" cooling device would be able to perform cooling adapted to the individual patient's response. Different patients need different cooling protocols, depending on their constitution, regulatory systems and on environmental

conditions such as room temperature, air movement, blankets used. To achieve these goals, the smart cryotherapeutic devices should incorporate thermal sensors placed on the body surface to provide personal feedback of the body temperature regulation.

Conclusions

In the group with computer controlled cryotherapy greater differences in temperatures between intracondylar notch and subcutaneous tissue was found, compared to previous studies. The cooling effect of the arthroscopy irrigation fluid on the knee temperature was clearly demonstrated in the first two hours of treatment. Despite higher temperatures of the cooling liquid, the computer controlled cryotherapy is significantly more effective than the classical method of cooling with frozen gel-packs, both in deep and superficial tissues of the knee.

Acknowledgements

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Figure Legends

Fig. 1 A horizontal cross-section in the level of sensors . The positions of the temperature sensors are marked with crosses. Different tissues (bone, muscles, SC, SK, bandage) are shown with gray levels. The outer layer represents the cooling pack/pad. ICN intercondylar notch, SC subcutaneous, SK skin (12 anterior, 3 medial, 6 posterior, 9 lateral), BA bandage

Fig. 2 Average temperatures of all patients during cooling treatment. **a** Group A with the gel-pack. **b** Group B with the cPad. ICN intercondylar notch, SC subcutaneous, SK skin (12 anterior, 3 medial, 6 posterior, 9 lateral), BA bandage

Fig. 3 Measured temperatures on Patient 12 from all sensors and for the complete duration of treatment with cPad. ICN intercondylar notch, SC subcutaneous, SK skin (12 anterior, 3 medial, 6 posterior, 9 lateral), BA bandage
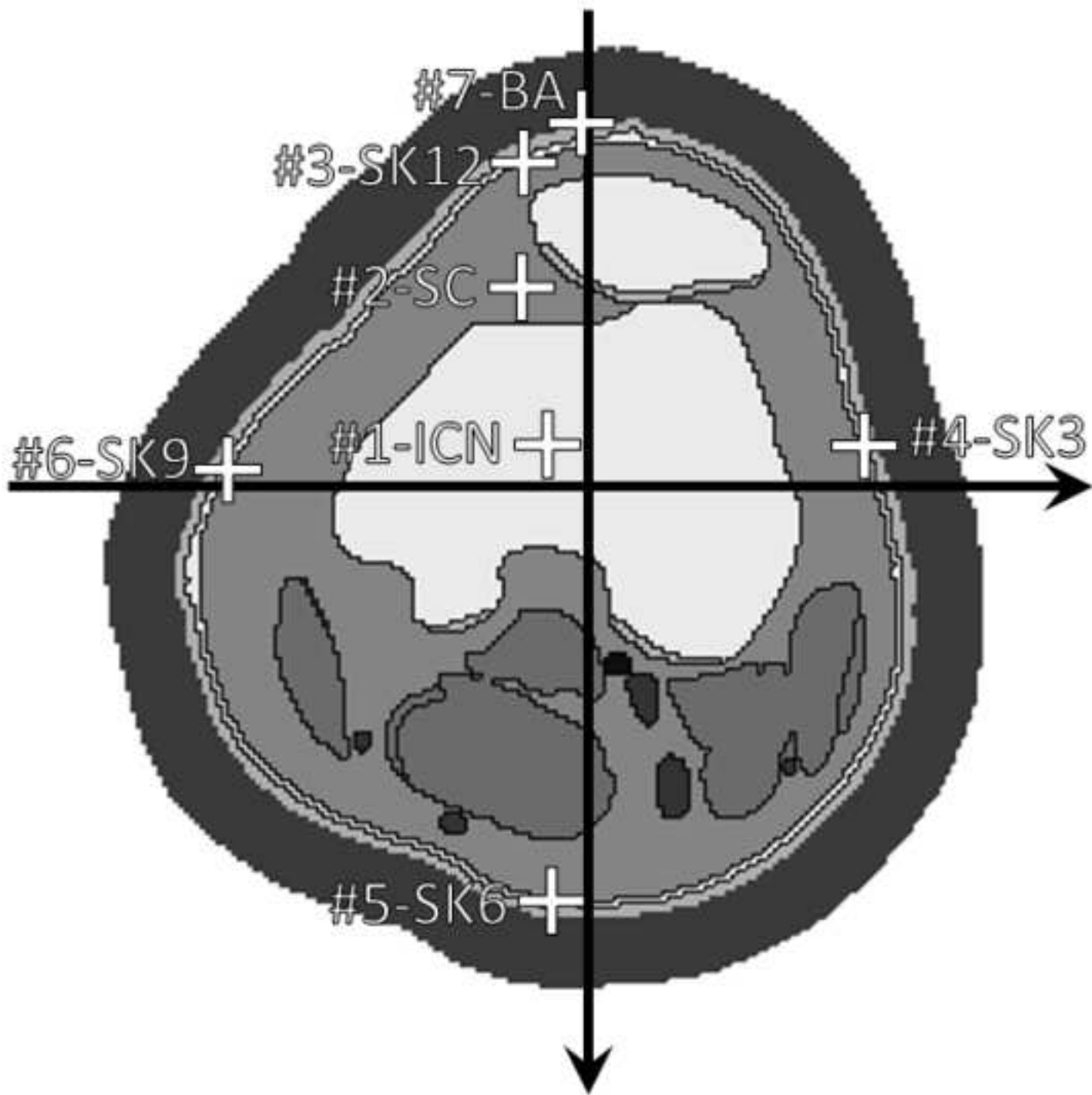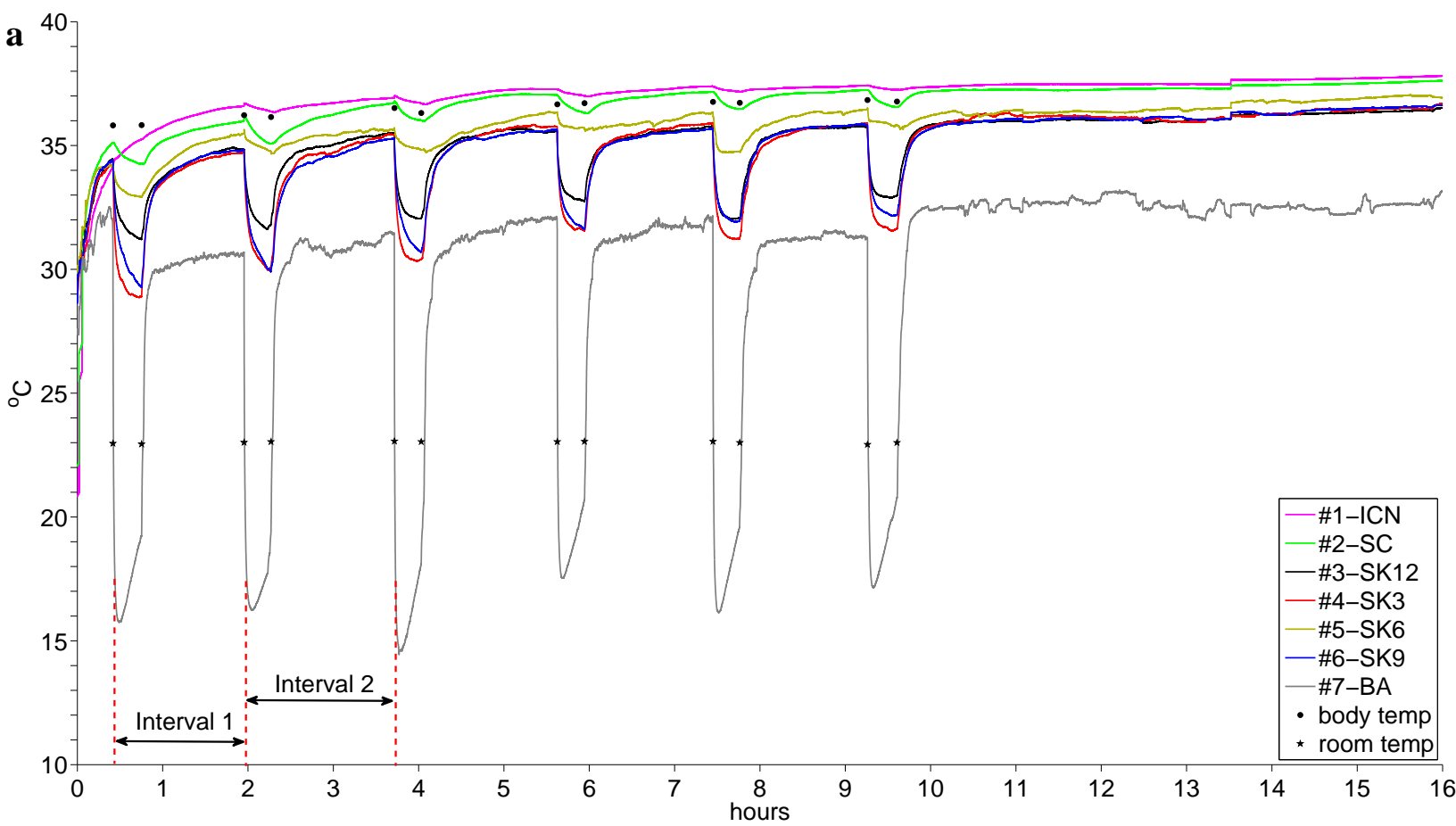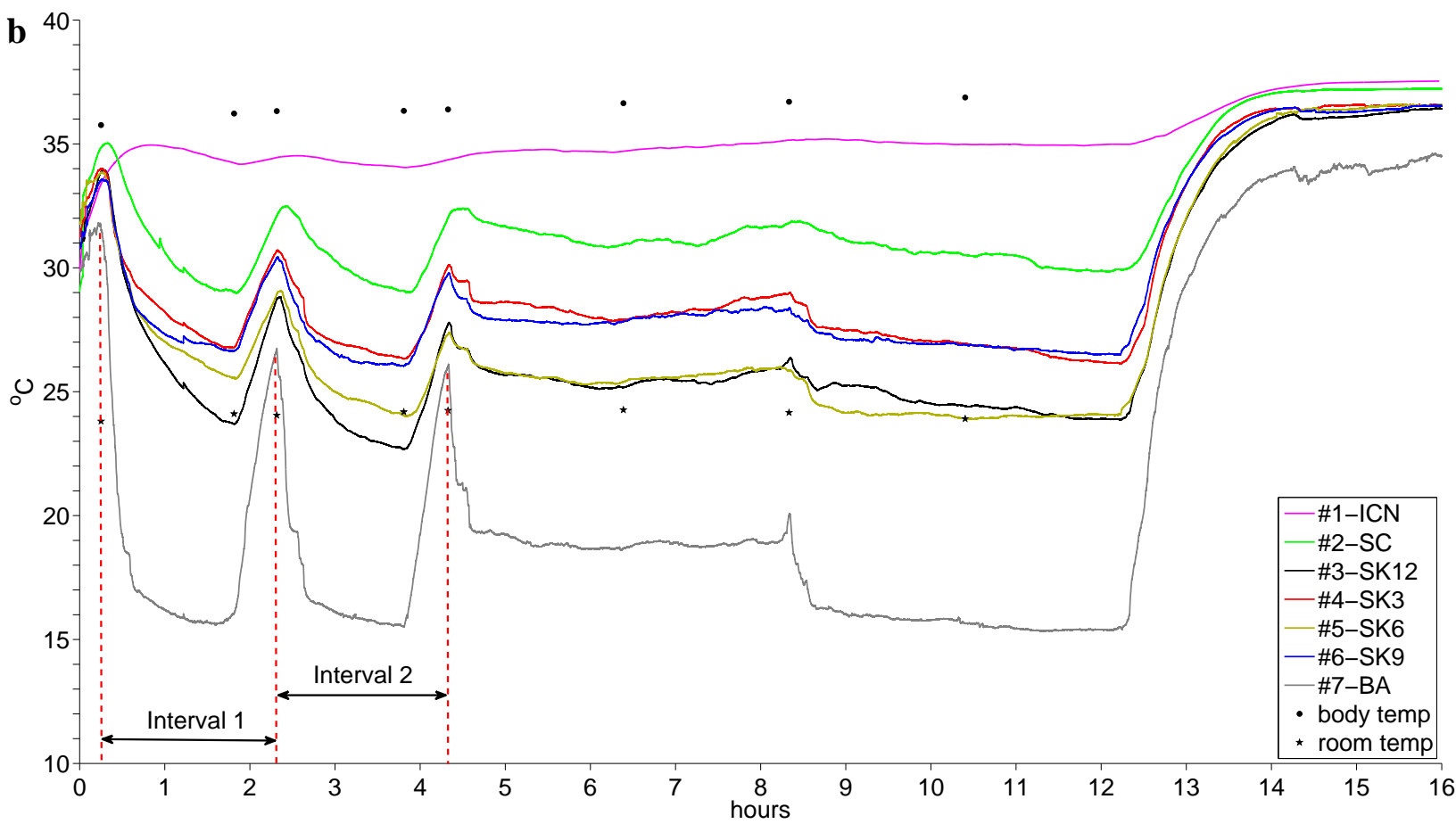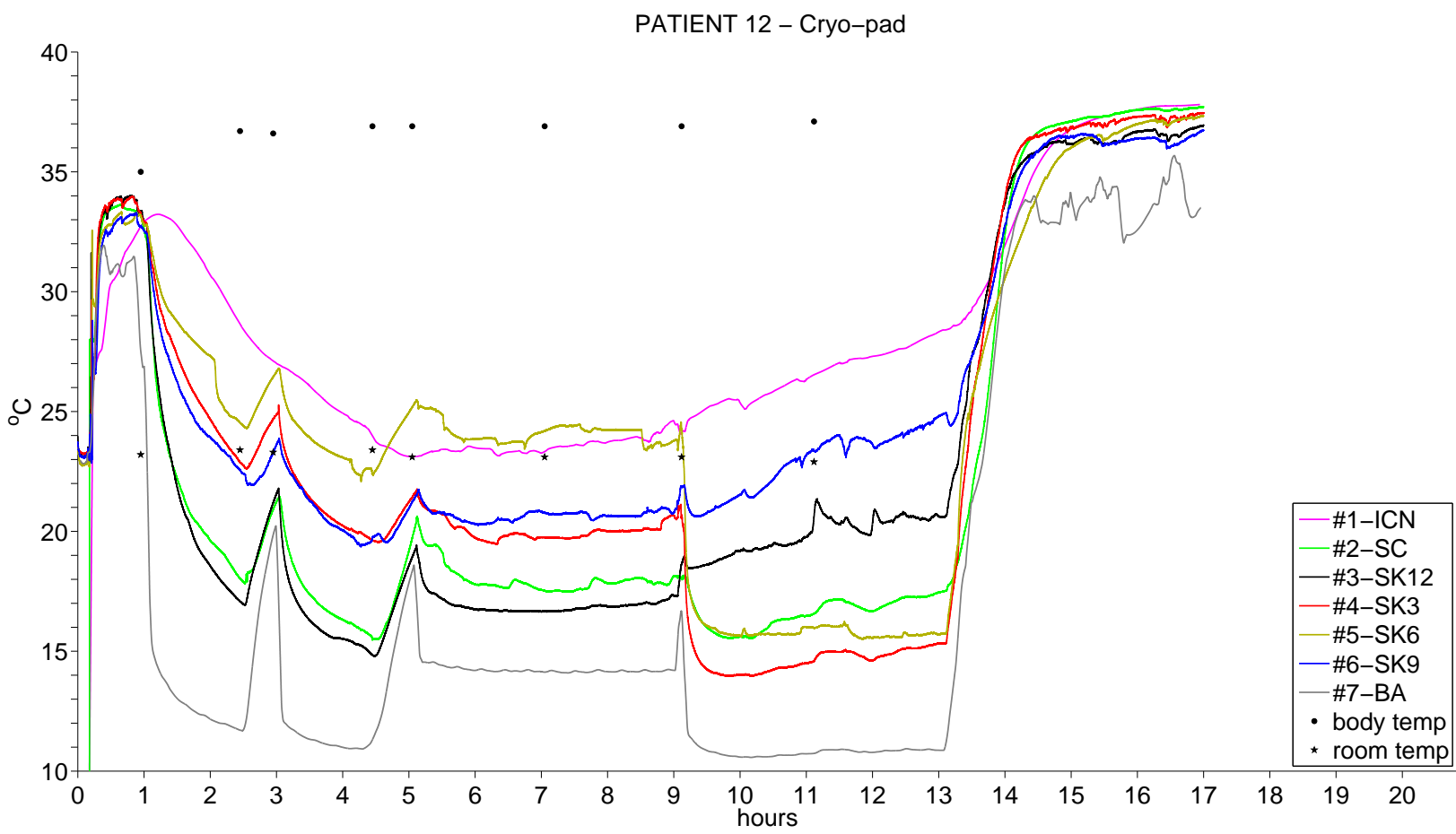
Figure 1

Figure 2a

Figure 2b

Figure 2b

Figure 3

PATIENT 12 – Cryo-pad

Table 1

Table 1 Patients and environmental data before surgery for Group A with the gel-pack and Group B with the cPad

PATIENT DATA	Group A [*]	Group A 95% CI	Group B [*]	Group B 95% CI	P Value	Statistical Power
Number of patients	8	NA	12	NA	NA	NA
Gender [Male/Female]	3/5	NA	9/3	NA	NA	NA
Age [years] [†]	25.8 ± 11.1	18.1 - 33.4	35.8 ± 9.4	30.5 - 41.2	0.04	0.5
Body mass index (BMI) [kg/m2] [†]	23.7 ± 2.2	22.2 - 25.2	26.3 ± 2.4	25.0 - 27.6	0.02	0.6
Knee circumference before surgery [cm]	38.6 ± 2.7	36.7 - 40.4	41.2 ± 3.2	39.4 - 43.0	n.s.	0.4

CI, confidence interval; NA, Not Applicable; n.s., non-significant

[*] Values are means ± SD, except where otherwise indicated

[†] Statistically significant differences at a significance level of $p < 0.05$

Table 2

Table 2 Temperatures at different knee locations in °C for group A with the gel-pack and Group B with the cPad

TEMPERATURES	Interval 1						Interval 2					
	Group A[*]	Group A 95% CI	Group B[*]	Group B 95% CI	P Value	Statistical Power	Group A[*]	Group A 95% CI	Group B[*]	Group B 95% CI	P Value	Statistical Power
Mean ICN after surgery	27.3 ± 1.3	26.4 - 28.2	27.2 ± 1.6	26.3 - 28.1	n.s.	0.1	NA	NA	NA	NA	NA	NA
Mean ICN before cooling	33.8 ± 2.0	32.4 - 35.2	33.5 ± 1.7	32.5 - 34.5	n.s.	0.1	NA	NA	NA	NA	NA	NA
Mean ICN [‡]	36.0 ± 0.5	35.6 - 36.4	34.6 ± 1.9	33.5 - 35.7	n.s.	0.5	36.8 ± 0.1	36.7 - 36.9	34.3 ± 3.2	32.5 - 36.1	0.04	0.5
Minimal ICN [‡]	33.8 ± 2.0	32.5 - 35.2	33.0 ± 2.4	31.6 - 34.4	n.s.	0.1	36.6 ± 0.1	36.5 - 36.7	33.4 ± 3.9	31.2 - 35.6	0.03	0.6
Minimal SC [†‡]	34.2 ± 1.7	33.0 - 35.3	28.4 ± 5.1	25.4 - 31.4	0.01	0.8	34.6 ± 1.4	33.6 - 35.6	28.6 ± 5.7	25.3 - 32.0	0.01	0.8
Minimal average SK [†‡]	30.5 ± 1.5	29.4 - 31.5	25.4 ± 2.2	24.2 - 26.6	< 0.01	1.0	31.4 ± 1.3	30.5 - 32.3	24.6 ± 2.8	23.1 - 26.2	< 0.01	1.0
Mean average SK [†‡]	33.9 ± 0.9	33.3 - 34.5	27.7 ± 1.7	26.8 - 28.7	< 0.01	1.0	34.5 ± 0.4	34.2 - 34.7	26.1 ± 2.6	24.6 - 27.6	< 0.01	1.0
Minimal BA	15.3 ± 3.4	12.9 - 17.7	15.1 ± 3.3	13.3 - 17.0	n.s.	0.1	16.0 ± 4.9	12.6 - 19.5	15.3 ± 3.3	13.4 - 17.1	n.s.	0.1
Mean (ICN – TT)	0.2 ± 0.5	-0.1 - 0.5	-1.8 ± 2.9	-3.5 - -0.2	n.s.	0.4	0.4 ± 0.4	0.1 - 0.7	-1.9 ± 3.4	-3.9 - -0.0	n.s.	0.4
Mean (ICN – SC) [†‡]	0.5 ± 1.2	-0.3 - 1.3	3.8 ± 2.8	2.1 - 5.5	< 0.01	0.8	0.8 ± 0.6	0.3 - 1.2	4.0 ± 3.0	2.2 - 5.7	0.01	0.8
Maximal (ICN – SC) [†‡]	1.3 ± 1.4	0.3 - 2.2	6.0 ± 3.9	3.8 - 8.3	< 0.01	0.9	2.1 ± 1.4	1.1 - 3.1	5.4 ± 3.6	3.3 - 7.6	0.02	0.6
Mean (SC – mean average SK)	1.6 ± 0.7	1.1 - 2.1	3.1 ± 3.4	1.1 - 5.1	n.s.	0.2	1.6 ± 0.5	1.2 - 1.9	4.2 ± 3.9	1.9 - 6.5	n.s.	0.4
Mean (mean SK – BA) [†‡]	5.8 ± 1.3	4.9 - 6.7	9.1 ± 2.7	7.6 - 10.7	< 0.01	0.9	5.9 ± 1.6	4.8 - 7.0	8.2 ± 2.5	6.8 - 9.6	0.03	0.6

CI, confidence interval; ICN, intercondylar notch; SC, subcutaneous tissue; SK, skin; BA, bandage; TT, tympanic temperature; NA, Not Applicable; n.s., non-significant

[*] Values are means ± SD

[†] Statistically significant differences between groups at a significance level of P < 0.05 for Interval 1

[‡] Statistically significant differences between groups at a significance level of P < 0.05 for Interval 2

Table 3

Table 3 Clinical effects and environmental data during the cooling treatment

CLINICAL EFFECTS	Group A[*]	Group A 95% CI	Group B[*]	Group B 95% CI	P Value	Statistical Power
Knee circumference (after cooling /before surgery) [%]	5.4 ± 2.7	3.5 - 7.3	4.9 ± 3.3	3.0 - 6.7	n.s.	0.1
Number of IV analgesic boluses/patient [†]	1.6 ± 0.7	1.1 - 2.1	0.8 ± 0.4	0.6 - 1.1	< 0.01	0.8
Time to first bolus of IV analgesic [h]	4.7 ± 1.4	3.7 - 5.7	7.0 ± 3.0	5.1 - 8.8	n.s.	0.4
Number of IV analgesic boluses per hour after the first bolus [†]	0.12 ± 0.06	0.1 - 0.2	0.0 ± 0.0	0.0 - 0.0	< 0.01	1.0
Tympanic temperature during 12h treatment [°C]	36.5 ± 0.3	36.7 - 36.7	36.5 ± 0.4	36.3 - 36.7	n.s.	0.1
ENVIRONMENTAL DATA						
Type of anesthesia [subarachnoid:general]	4:4	NA	9:3	NA	NA	NA
Recovery room temperature [°C]	23.0 ± 0.4	22.7 - 23.3	24.0 ± 1.6	23.1 - 25.0	n.s.	0.4

CI, confidence interval; IV, Intravenous; NA, Not Applicable; n.s., non-significant

[*] Values are means ± SD, except where otherwise indicated

[†] Statistically significant differences at a significance level of p < 0.05