HILOTHERAPY

The thermo-technique that can be controlled precisely to the degree

Local heat application
for body tightening interventions
and tissue transfers

HILOTHERM® GmbH

What does heat application using HILOTHERAPY mean?

Hilotherapy enables the local application of heat for pre- or postconditioning of tissue that potentially or actually experiences a critically low blood supply. This condition particularly occurs with surgical interventions on the surface of the body, such as extensive dissections or tissue transfers. The heat is applied by placing pliable silicone water-flow cuffs on the target tissue and the temperature can be set to a precise degree from +35 °C to +43 °C.

The risk for extensive tissue dissections and tissue transfers:

Especially for extensive tissue dissections and tissue transfers, the tissue away from the pedicle can be exposed to lasting, critical ischemia due to its randomized blood flow. If left untreated, this can result in delayed or disrupted wound healing and tissue necrosis.

The risk for planar tissue dissections and tissue transfers:

For extensive tissue dissections and tissue transfers, the tissue away from the vascular pedicle can be subjected to randomized blood flow (i.e. the **tissue is supplied with blood using a purely haphazard, randomly arranged and non-axially arranged vascular network**). Acutely lasting ischemia that is critical for the tissue occurs. If left untreated, the consequences can be diverse and manifest themselves from delayed or disrupted wound healing through to tissue necrosis. Even with standardized interventions such as skin-sparing mastectomy (SSM) and tummy tucks, ischemia-related skin necrosis and other skin necrosis occur in 54 % or 39 % of cases.[1,2]

'Surgical delay' is a surgical measure that can be applied prior to tissue transfers to prepare the tissue for the upcoming ischemia. Here, the flap is lifted in stages over a period of around 14 days.[3] The hypoxia (lack of oxygen) in the tissue leads to a release of growth factors (including vascular endothelial growth factor, VEGF), and thus to increased blood vessel growth in tissue with potentially critical blood flow. This procedure means greater security for the patient during tissue transfer (fewer ischemia-related complications), although it is invasive and time consuming due to the additional surgical interventions.

The role of vascular alteration (increase in vascular diameter and number of blood vessels)

Tissue preconditioning (prior to tissue dissection) using local heat leads to

1. Vascular dilatation immediately after heat application (maintenance of blood flow in areas with critical ischemia) and
2. Increase in ischemia tolerance (improved tissue survival despite tissue blood flow remaining the same)

Tissue postconditioning (following tissue dissection) using local heat leads to better maintenance of perfusion, especially at a capillary level in areas at risk

In both cases, it must be guaranteed that the desired temperature is kept constant. Ideally, the physically stressor (in this case, the local heat) must be applied in the supraphysiological or sublethal range, which is guaranteed for local heat at around 43 °C.[4]

The experimental concept:

The difficult clinical implementation of 'surgical delay' has led many researchers to investigate alternative forms of conditioning for tissue and organs. Murry et al. have performed pioneering work here by researching the concept of ischemic preconditioning on the heart. They were able to demonstrate that the repeated, short-term occlusion (ischemia) of the supplying coronary blood vessels, followed by a temporally defined reperfusion phase, was able to significantly reduce the extent of a subsequent heart attack compared with unconditioned animals. [5] This concept of ischemic tissue preconditioning found imitators that achieved similar effects through alternative physical (including local heat, cold, shockwaves) and non-physical stressors (including Monophosphoryl Lipid A, erythropoietin, ghrelin). As local heating of the skin to 43 °C is not only effective but also pleasant for the patient, this concept of tissue conditioning was pursued and implemented in the hospital.

References:

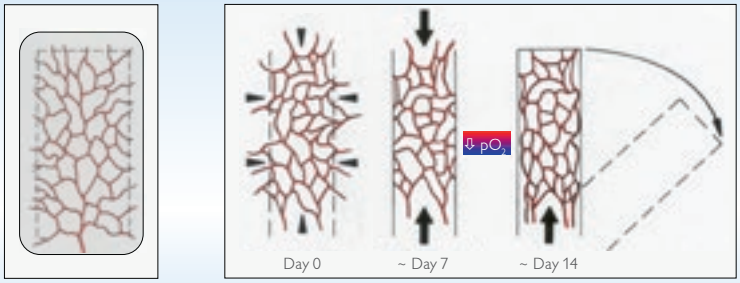
1. Sotheran W, Rainsbury RM. Skin-sparing mastectomy in the UK - a review of current practice. Ann R Coll Surg Engl. 2004; 86(2):82-86.
2. Zoumaras, Lawrence J. Inverted-T versus vertical scar breast reduction: one surgeon's 5-year experience with consecutive patients. Aesthet Surg J. 2008; 28(5): 521-6; discussion 526-527.
3. Reinisch JF. The pathophysiology of skin flap circulation. The delay phenomenon. Plast Reconstr Surg. 1974; 54(5): 585-598.
4. Harder Y, Amon M, Schramm R, Georgi M, Banic A, Erni D, Menger MD. Heat shock preconditioning reduces ischemic tissue necrosis by heat shock protein (HSP)-32-mediated improvement of the microcirculation rather than induction of ischemic tolerance. Ann Surg. 2005; 242(6): 869-878, discussion 878-9.
5. Murry CE, Jennings RB, Reimer KA. Preconditioning with ischemia: A delay of lethal cell injury in ischemic myocardium. Circulation. 1986; 74(5): 1124-1136.

+35 °C to +43 °C

Local heat application on the skin

Experiments from animal testing and clinical research have been able to show that tissue preconditioning with local heat at around 43 °C leads to a significant improvement in wound healing and the survival of the skin flap, and thus can replicate the effects of repeated skin flap circumcision ('surgical delay').

Surgical delay



Invasive, time-consuming and expensive

The solution: Heat application using HILOTHERAPY

Thermo-therapy enables the local and controlled application of heat, both before an intervention **(tissue preconditioning)** and after an intervention **(tissue postconditioning)**. This local heat application on the skin appears to be particularly helpful in plastic and reconstructive surgery, as extensive tissue dissections often occur here. Hilotherapy with local heat is a very effective alternative to 'surgical delay'.

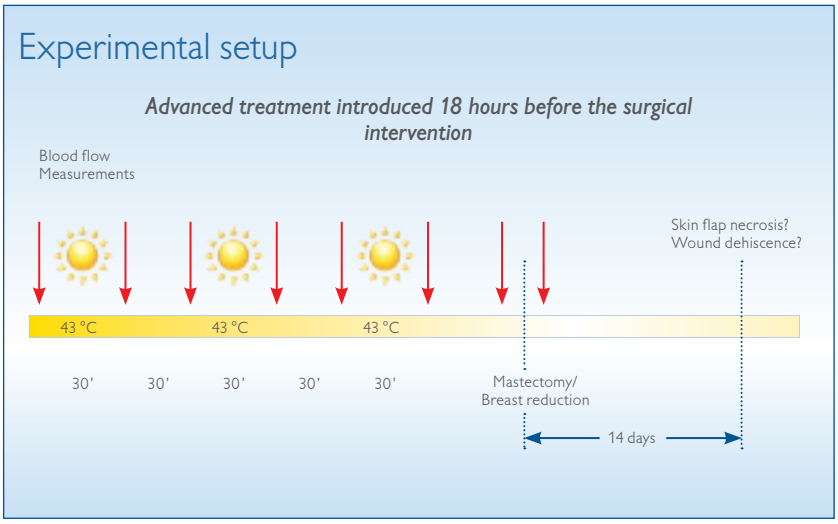
The application

As a comparative study has shown, tissue protection is especially pronounced when the heat application is applied repeatedly around 18 hours before the operation - i.e. on the evening before.

Three heat cycles of 30 minutes each at a temperature of 43 °C, each interrupted by a passive cooling phase at room temperature, have proven to be especially effective.

(For details of the study, see page 4)

Experimental setup



In the postoperative phase, the heat can be applied on the day of the intervention and then on a daily basis afterwards. It is recommended to also apply the heat repeatedly here. The aim it to achieve through vascular dilatation both an improved arterial inflow and an improved venous outflow. The heat application should above all be performed during the first 3-5 days following the intervention, the time in which necrosis usually occurs.

Results of two clinical pilot studies in which two fields of application were investigated:

1. Skin-sparing mastectomy with immediate breast reconstruction for breast cancer. [6]

2. Breast reduction for breast hypertrophy (enlargement of the breast). [7]

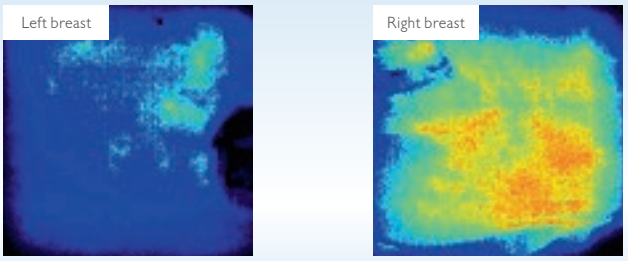
The first study included 50 patients, 25 patients each with and without heat preconditioning.

The second study involved 20 patients with one breast pretreated with heat and one breast that was not pretreated.

The patients or breasts pretreated with heat showed improved tissue survival in comparison with the untreated patients (12 % partial necrosis vs. 36 % in the control group) for mastectomy skin flaps and faster healing of surgical wounds following breast reduction. The improved tissue survival involved permanently improved blood flow. As a positive side effect of the reduced surgery-related morbidity, it was found that the pretreated patients were able to leave the hospital following breast reconstruction on average after a stay of just 4 days (9 days in the case of untreated patients).

Skin-sparing mastectomy

Skin perfusion

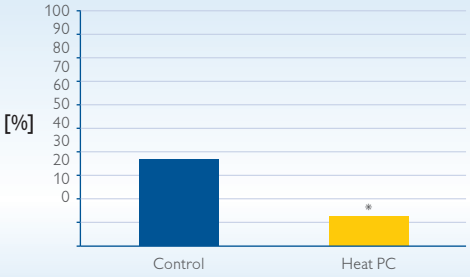


1 hour after mastectomy not pretreated

1 hour after mastectomy pretreated

Skin-sparing mastectomy

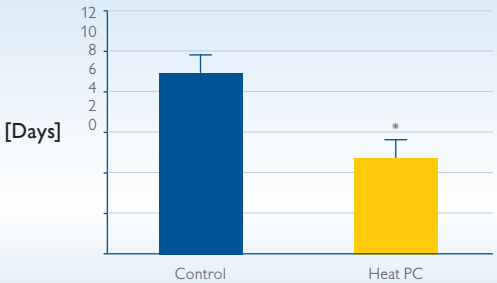
Skin flap necrosis



Mean *$p < 0.05$ *vs.* control group

Skin-sparing mastectomy

Duration of the hospital stay



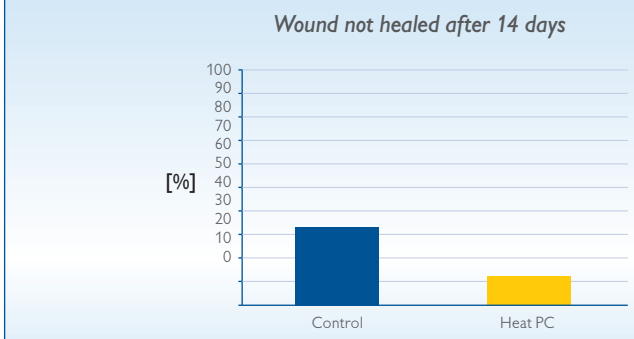
Mean ± SD *$p < 0.05$ *vs.* control group

[6] Mehta S, Rolph R, Cornelius V, Harder Y, Farhadi J. Local heat preconditioning in skin sparing mastectomy: a pilot study. J Plast Reconstr Aesthet Surg. 2013; 66(12): 1676-1682.

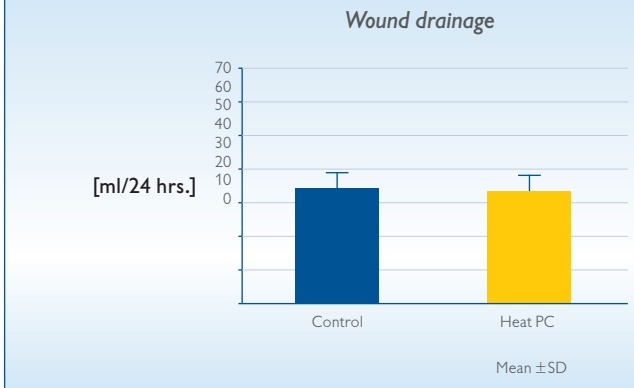
[7] Schmauss D, Finck T, Mehta S, Farhadi J, Egana JT, Machens HG, Harder Y. Local heat preconditioning to prevent wound breakdown and skin necrosis: A translational study. Br J Surg. 2014; 101: Suppl. 5: 19.

Following breast reduction, it was shown that in the case of heat preconditioning on the evening before, 92 % of all surgical wounds were healed just 14 days after the intervention (67 % in the case of breasts that were not pretreated). Furthermore, it was observed that patients treated with local heat did not display any increased tendency toward postoperative bleeding.

Breast reduction



Breast reduction



Conclusion

Heat preconditioning leads locally in the skin tissue to

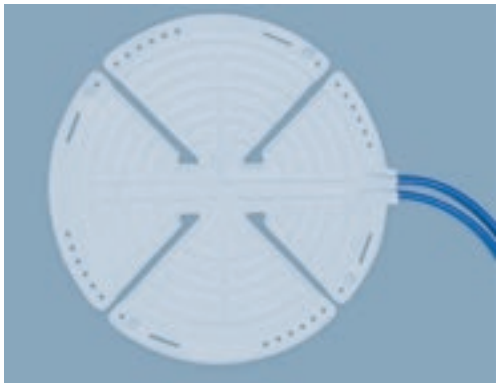
1. lasting maintenance of blood flow, especially in tissue that is potentially at risk of ischemia, without the increased risk of postoperative bleeding
2. rapid increase in the ischemia tolerance of the tissue (better survival despite poorer tissue blood flow)
3. significant reduction in the skin necrosis and wound-healing disorder rates and
4. faster healing of surgical wounds.

The heat application

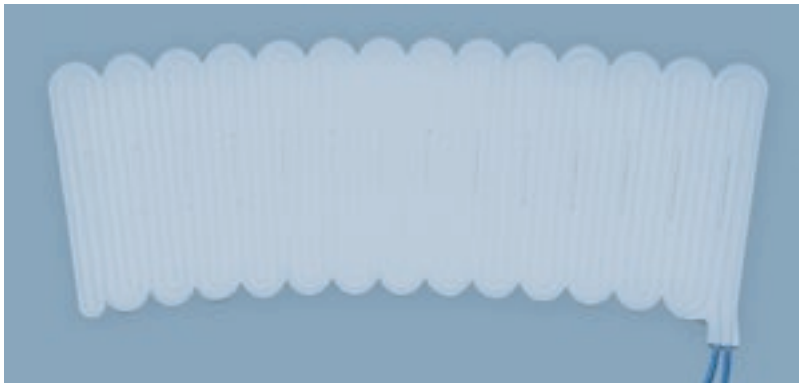
The heat effect is produced using water as a medium. This is set to the desired temperature, which is precise to the degree, in the specially designed treatment equipment and kept constantly at this level.

This ensures the temperature is kept constant, as required medically, regardless of whether the application is needed over the short, medium or long term. Multi-hour or even multi-day applications are also possible by applying a constant temperature.

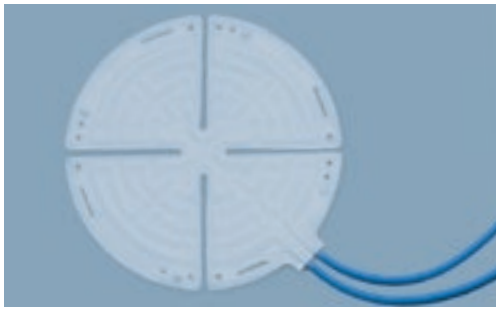
The water heated to the desired temperature (application range 35 °C to 43 °C) flows through pliable water-flow cuffs made from silicone, which are available in various shapes and sizes, and thus can be applied to various areas of the body.



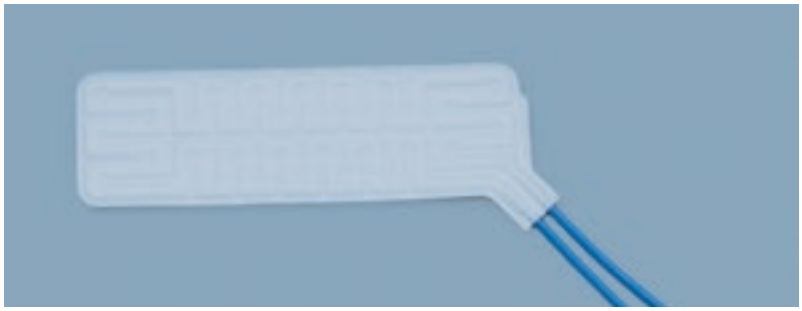
Round cuff, large



Flat cuff, large



Round cuff, small



Flat cuff, small

The treatment equipment

The HILOTHERM *Calido* device was specially developed for local heat application as part of HILOTHERAPY.

HILOTHERM *Calido*

- Particularly suitable for the clinical field of application, both pre- and postoperatively
- Designed for the connection of 1 cuff (using a Y-piece, 2 cuffs can also be used at the same time).
- Constant-temperature permanent operation (through sensors).
- Cooling medium: distilled water (2 liters of distilled water every 6 months).
- Temperature range +35 °C to +43 °C (can be selected in 1 °C increments)
- Dimensions 430 x 275 x 268 mm
- Weight: Empty weight: 10 kg
  Ready for operation: 12 kg
- Transport:
  Indoors: Where possible on a *Hiloroll* equipment trolley.
  Outdoors: In the original box or in a suitable carry bag.
- Power supply (230 V)

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