17thThermological Symposium of the Austrian Society of Thermology

K. Ammer

Ludwig Boltzmann Research Institute for Physical Diagnostics, Vienna, Austria

This years symposium of the Austrian Society of Thermology jointly organised by the Ludwig Boltzmann Research Institute for Physical Diagnostics discussed the use of thermal imaging as outcome measure in clinical trials.

Is Thermal Imaging a Proper Outcome Measure

K. Ammer defined outcome measure as the systematic collection (usually prior to and following an intervention) and analysis of information that is used to evaluate the efficacy of an intervention. Various types of outcome measures exist such as patient-completed self-report questionnaires, clinician-completed observation scales, task-specific activities -tests e.g. sit to stand, tests to assess body structure and tests to assess body function. Thermal imaging must be understood as a technique that images function, but not body structure e.g. anatomy.

Table 1 lists the features of outcome measures. For each feature examples related to thermal imaging were discussed. The fact, that the technique of the intended outcome measure should be published in a peer-reviewed journal was well supported by recent publications, with a mean impact factor of 2,3 (range 0.42 to4.5). Standardised procedures for thermal imaging have been repeatedly published from as early as 1979 (1). Thermal imaging is an appro- priate outcome measure in all cases where changes of the surface temperature are significant signs of a disease associated with inflammation, nerve blocks, nerve entrapment, muscle spasm or reduced blood flow.

As thermal imaging is regarded as a technique for temperature measurement, all requirements for measurements must be met particularly validity (accuracy) and reliability (accuracy). Factors affecting accuracy and precision of measurements from thermal images were discussed based on available publications (2,3,4). Both, accuracy and precision, have an impact on the sensitivity to change of outcome measures. Validity is needed to define correctly the symptom to be measured. Precision will affect the responsiveness also, because a change of the symptom can only detected if this change is bigger than the variation of repeated measurements. Evaluation of exercise treatment for mild pseudo-neurogenic thoracic outlet syndrome has shown that thermal imaging can detect sufficiently changes in finger temperatures induced by therapy (5).

Table 1
Requirements for outcome measures

Published in a peer-reviewed journal
Standardised procedure
Written scoring procedure
Appropriateness
Reliability
Validity
Responsiveness (sensitivity to change)
Interpretability
Acceptability
Feasibility

Thermal imaging is very well accepted by patients because it is an non-invasive, remote method for temperature measurement that can easily be repeated. The technique is yet not fully accepted by medical science (6). This is mainly caused by poor studies in the past, based on clusions from interpretations of thermal images instead of quantified analysis of temperature readings.

With respect to feasibility, thermal images must be recorded under controlled conditions and therefore this technique is not feasible as a bedside test. Also transient changes of the surface temperature, elicited outside the thermal imaging laboratory, may be missed inside the examination room.

Costs for thermal imaging compared to x-ray examination, magnetic resonance imaging, CT-scans or bone scans are low for both installation and maintenance.

Thermal imaging have been already used as an outcome measure in trials of acupuncture for facial paralysis, physical therapy and drug treatment of Complex Regional Pain Syndrome, physical therapy of tennis elbow, exercise treatment of Thoracic Outlet Syndrome, lymphatic drainage of lymphedema, surgery for osteoarthritis of the knee, exercise treatment of low blood pressure in children and drug treatment of occlusive arterial disease.

Thermal imaging provides all necessary requirements to be used as an outcome measure in clinical trials.

Thermal imaging as an outcome in drug trials

Prof Ring, University of Glamorgan, reported the application of thermal imaging as outcome measure in drug trials. The author has long lasting personal experience in this field (7). He was able show already in the nineteen seventies, that a clear relationship exists between the anti-flammatory power of antirheumatic drugs and their ability to reduce radiant heat from inflamed joints (8,9). This was found in a number of non- steroidals (10,11), steroids (12,13,14) and disease modifying drugs (15).

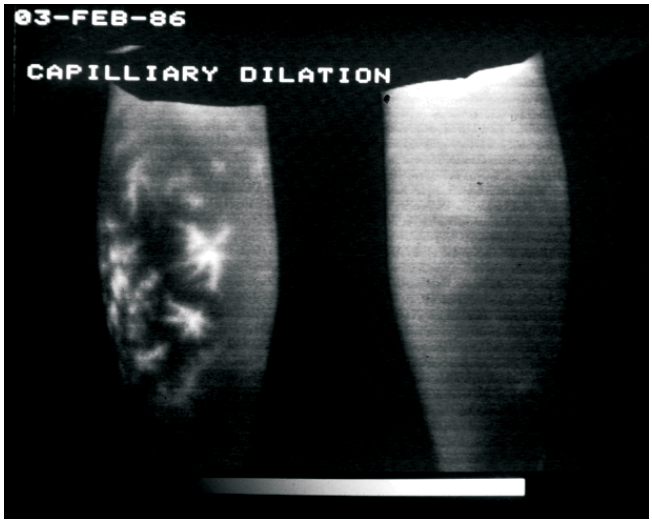

Figure 1
Effect of nicotinic acid on the skin

Treating Paget´s disease of bone with either calcitonin or biphosphanates confirmed the relationship between temperature, pain, activity of alkaline phosphatase. Effects of therapy and flares of the disease could be predicted by infrared thermal images of the affected sites (16,17)..

The effects of vasoactive compounds, given systemically or locally, can be visualized by thermography (18,19,20), major changes follow the local application of nicotinic acid (21, Figure 1).

In conclusion, quantitative thermal imaging performed under a strict protocol in a constant ambient temperature can provide reliable objective evidence of treatment when the disease condition affects temperature.

Temperature Measurements as Outcome Measure in Trials for Raynauds´s Phenomenon

In his second talk, K Ammer presented an overview on temperature related outcome measures in trials for Raynaud´s phenomenon. He started with the fact, that the diagnostic criteria for Raynaud´s phenomenon differ for the primary (22) and the secondary form of the disease. If the diagnosis is based on triphasic colour changes of the fingers, a number of patients with vasospastic disease might be misdiagnosed as only 4 – 65% will present with triphasic colour changes (23). 14 – 40% appear to be biphasic and 10 – 44% will have pallor or cyanosis only.

A cold challange is used to study the skin temperature dynamically. F Ring has suggested immersion of both hands in 20°C water for 1 minute (wearing plastic gloves) after acclimatization for 15 minutes with bare arms to a room temperature 24°C. However, other water temperatures, ranging from 0 to 20° C have been proposed (24), An alternative method is that the participants placed their right hand into a thermostatically controlled cooling chamber with a temperature of 4 , -5(25) or-20°C.. The hand was kept in the chamber either for 10, or 15 min or until the skin temperature reached 18 (26) or 12.5°C. Thereafter, the hand was returned to the 21 or 25°C ambient temperature, and the time course of skin temperature 50 and 100% recovery was recorded at 1 min intervals.

Table 1 lists the variety of techniques for temperature measurements used in published trials for Raynauds disease. Unfortunately the thermal gradient index (27), which summarises s the temperature gradients prior and post cold challenge is not predominantely applied, although this index combines both temperature difference along fingers and temperature recovery. In this index thermal gradient is defined as the mean temperature difference between the fingers and the wrist before and 10 minutes after a cold challenge in waterbath of 20°C for 1 minute. A "+"index indicates (normal) reactive hyperemia, values between + 5 and - 3 normality, -4 to -10 Raynaud´s phenomenon and -10 to -15 secondary Raynaud in suspected connective tissue disease.

The relationship between skin temperature and colour changes is not yet established (28). Cold finger tips prior to a cold challenge predict only in 58.5 percent a prolonged delay in rewarming after cold exposure.Warm finger tips predict in 87% a normal temperature recovery after cold challenge (29).

Table 2
Temperature measurements used in trials

SPOT TEMPERATURES	AREA MEASUREMENTS
ONE SINGLE FINGER **at the distal pad,** **metacarpophalangeal joint,** **metacarpal bone,** **wrist joint,** **on palmar or dorsal side**	**From total or part of fingers and hands; only possible from thermal images** **TEMPERATURE GRADIENT** **Difference between spot or area temperatures** **TEMPERATURE RECOVERY** **(Total or partial) recover of temperature after a defined cold challenge**

MEAN VALUE OF SEVERAL FINGERS
MEASURED BY

Thermocouples
Thermistors
Infrared radiometer
From infrared images

In a trial, investigating the effect of ceramic-impregnated gloves, skin temperature measurements were done over the fingertips and the finger dorsum (between the nail bed and the distal interphalangeal joint) of the 2nd to 5th digits with an infrared radiometer (30). The distal-dorsal difference was calculated based on previous findings suggesting that a difference > 1°C is specific for Raynaud´s phenomenon. However, the gradient prior to treatment was 0.74°C in the treated group and 0.48 in the placebo treated patients. The active treatment decreased the gradient by 0,25°C and placebo by 0.40°C.

In a trial using triiodothyronin (31), the temperature outcomes were studied, as follows. At least 1 h after arrival at the hospital, the patients' blood pressures and pulse rates were recorded in a room at a temperature of 24°C.

After 30 min temperatures were measured in the left hand using a TP 252 temperature probe (Beckman Industrial, Scotland). For these measurements, the patients were seated semi-erect, with arms placed flat on the arm rests of a chair, hands open and palms upwards with fingers relaxed.

The thermographic index (TI) was defined as the mean temperature over the skin creases of the middle 3 fingers minus 24°C.

The longitudinal thermal gradient (LTG)was defined as the temperature of the palmar crease overlying the metacarpophalangeal (MCP,) joint minus the temperature of the finger crease overlying the distal interphalangeal (DIP,) joint.

Subsequently, skin temperature recovery times (STRT) were measured: both hands were immersed in an ice water mixture (0°C) for 20 s, patted dry and the pulp temperatures of the middle 3 fingers recorded every 5 min until recovery to baseline temperatures or for 45 min.

The acute effect of topical minoxidil (25) was studied as follows: Each subject was studied on 2 separate occasions while in an environmental chamber (25°C, 50% relative humidity).

Subjects were required to refrain from caffeine ingestion, smoking cigarettes, and taking any vasoactive drugs for at least 24 h before the study sessions.

All subjects assumed a supine position with the right arm placed in a neutral position level with the heart. The distal pad of the right first, 2nd, and 3rd fingers (2nd, 3rd, and 4th digits of the hand) were used to measure finger surface skin temperature.

Initial baseline measures of surface skin temperature were made and subsequently measured continuously, with a surface temperature thermistor (Yellow Springs Instruments, Yellow Springs, OH, #408).

Drying the drug solution with hot air, resulted in a localized increase of skin temperature, which complicated the interpretation of temperature effects of the drug.

The experimental procedure in a study applying misoprostol therapy (26), required the subjects to take no caffeine or cigarettes, and to stop any vasoactive drugs for 24 h prior to the study. Subjects were asked to lie in a dimly lit thermostatically controlled laboratory for at least 30 min to obtain stable baseline readings of digital hemodynamics.

The participant then ingested a capsule containing either 400 μg misoprostol or an identical placebo. Thereafter, at 10 min intervals for 1 h, measurements were taken of digital skin temperature, laser Doppler digital skin blood flow, and finger systolic pressure.

Finger skin temperature was recorded with a surface temperature thermistor secured to the distal pad of the right ring finger.

Other studies with low level laser treatment (32) or nitroglcerin tape (33) in patients with systemic sclerosis, used temperature measurements from thermal images and used the re-warming of defined areas in the image.

In conclusion, a variety of temperature measures have been used as outcome in published trials of Raynaud´s phenomenon. The thermal gradient index is the only temperature measure that considers persistent coldness of the distal part of the limbs.

Temperature measurements for the evaluation of therapy with Low Level Laser and Magnetic fields in Raynaud´s patients

M. Al-Awami from the Department of Angiology at the Viennese University Hospital reported the results of trials using low level laser (LLL) and magnetic field treatment in patients suffering from Raynaud´s phenomenon (RP).

The laser study was designed as prospective, randomised, placebo controlled trial in 47 patients with RP (31). 24 subjects (16 f, 8 m, median age 45 years) have allocated to the laser irradiation group and 23 (21 f, 2 m, median age 46 years) to the placebo(sham laser irradiation group).

Continuous temperature recordings were made by means of infrared thermal imaging at the following time intervals: a:. basal finger tip skin temperature after being adapted to room temperature for about 20 minutes,

Figure 2
Setup for low level treatment

b. immediately after 1 minute warm challenge (immersion of gloved hands in water at 39°C) ,

c. immediately after 1 minute cold challenge (immersion of gloved hands in water at 20°C).

d. recovery temperatures were measured 10 and 20 minutes later. The room temperature was 22.0 ± 0.5°C.

Overall a significant reduction of the frequency and the severity of RP in patients with either LLL (frequency $p<0.0001$, severity $p<0.0001$) or placebo treatment (frequency $p<0.0001$, severity $p=0.02$) was found, but patients in the LLL group exhibited statistically a more significant improvement of the frequency $p=0.007$ at 6 weeks and 3 months $p=0.02$ and the severity ($p=0.02$, $p=0.04$) of RP .

A significant improvement in the thermographic response to cold challenge was only seen in patients treated with LLL but not in those treated with placebo.

In conclusion, LLL significantly lowers the frequency and severity of Raynaud's attacks in patients with primary and secondary RP. Since this therapeutic modality is a safe, and non-invasive treatment, it might be considered as an alternative to existing therapeutic regimes.

The treatment of Raynaud's phenomenon with pulsed electromagnetic fields was recently investigated in another randomised, placebo controlled study . The study design was comparable to the LLL-trial. However, treatment was applied as home therapy for 12 weeks in 24 patients (7 male, 17 female) 15 with primary and 9 with secondary RP.

No significant changes of frequency or severity of Raynaud's attacks was observed, and the temperature outcome measures did not show a significant change.

Conclusion

The presentations of the symposium showed clearly that thermal imaging is a useful, but underused outcome measure in trials in which changes of the surface temperature are significant symptoms of the underlying disease. However, this is only true, when quantitative thermal imaging is per formed under a strict protocol in a constant ambient temperature.

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News in Thermology

8th Congress of the PoIish Association of Thermology

The conference will take place in Zakopane, Poland (2 hours from Krakow International Airport)from March 19-20, 2004. Zakopane is a beautiful ski resort in the Tatra Mountains in South Poland. The hotel HYRNY has been the location for this con- ference for a number of years. The costs are low and this is a good opportunity to meet with European colleagues.

Abstract deadline 20th.]anuary 2005

Registration deadline st March 2005

Congress fee 100.- Euros, paid on arrival includes accommodation (based on double room with Bathroom & TV) from Dinner Friday 19th March to Breakfast Monday 21st March. Attendance at sessions and congress materials, participation in the social programme.

Abstracts to ajung©wim.mil.pl

Apply to Prof. A Jung

Klinika Pediatrii 1 Nefrologii Dzieciece]

W.I.M. 00909 WARSAW ul. Szaserow 128

Tel +48 22 6817 2316, Fax +48 22 6816 763

Romanian Society of Thermography

The Romanian Society of Thermography (Societatea Romana de Termografie, SRT) was founded on 13 April 2003, by the decision of 87 founding members.The members of the Society are medical doctors and specialists involved in thermographical research. Current president of SRT is the gynaecologist and endocrinologist Dr. Bogdan Cupceancu and treasurer and general secretary is Dr. Calin Tiu-

Postal address of this new thermograpic society is Societatea Romana de Termografie, str. Sergent Major Erou Grigore Nicolae nr.5, Campina, judetul Prahova, Romania, tel/fax 0040244373108, 0040722452576, email office@srt.ro. Further information is available at www.srt.ro

The aims of the SRT are the development of medical expertise in thermography, the harmonisation of concepts for thermography specialists in Romania, alignment of the thermographic activity in Romania to the international standards of thermal imaging. For that purpose contacts with other National Thermography Societies and affiliation to the European Association of Thermology are intended. Regular National Conferences have been organised in the past and will be continued in the future.

The Second National Conference of Thermography was held on10-11 October 2003 in Campina. The town of Campina is located near the well known tourist area, Prahova Valley, 90 km north from Bucharest.

The Third National Conference of Thermography, was organised on 8-9 October in Campina, Romania. Topics included a themed session on multidisciplinary approach to the imaging of breast pathology. .

50th Anniversary of the German Society of Thermography & Regulation Medicine

The longest existing society for medical temperature measurements celebrates its 50th anniversary. Founded by the first president E.Schwamm on 1st February 1954, changes of temperature over time and their predictive value for health conditions became the major focus of interest for this society. Infrared radiometers were the original tools for measurement. A. Rost developed the method further and used fast reacting contact thermometers for the recording of temperatures. Under his presidency the society attracted more than 600 members.

The current president R.Berz started in 1985 a journal dedicated to the scope of regulation thermography. Originally named "Thermodiagnostik", the journal 1988 renamed to ThermoMed and served as the combined publication organ of both German Socities, the German Society of Thermography and the Society of Thermology. The dermatologist R.Stüttgen was the mentor, who put much effort into the liaison of these groups. But the German Society of Thermology left Thermomed in 1998, and since ThermoMed has returned to being the journal of regulation thermography.

However, use of infrared equipment has returned into the practice of regulation thermography and differences in the approach of temperature measurements between the German Society of Thermography and the standards promoted by the European Association of Thermology, to which the German Society of Thermography is affiliated for more than 10 years, are less pronounced than previously.

14thth International Conference on Thermal Engineering and Thermogrammetry (THERMO)

The International Conference on Thermal Engineering and Thermogrammetry (THERMO), which started in 1977 from annual national symposia and became an international conference in 1987 running in a three year circle, is now a series of biennial meetings. The next conference is announced for 22-24th June, 2005 in Budapest, Hungary. This congress is intended to be an event of the interest to all engineers, scientists, physicians and re searchers who are involved in the solution of thermal or energy related problems, and in the applications of thermal imaging.

The conference will cover topics both the field of theory and application including new measurement concepts; transducer technique; thermal mapping; contact, optical

and IR imaging; biomedical and biotechnological applications; thermal informatics, automatic methods and systems for industrial energy management and process control; heat loss detection and analysis; heat and mass transfer; utilization of alternative energy; thermophysical properties, common practice of thermal engineering, protection of the human environment, medical and veterinary applications and remote control through infrared sensors.

The conference is hosted by the House of Technology in Budapest (Bp.V., Kossuth Lajos tér 6-8) located near the House of Parliament and the River Danube. More information about the conference venue and hotel accommodation will be sent after the arrival of the Registration Form.

The language of conference and abstracts is English. Oral presentation of papers and also a poster session will be organized.

The preliminary programme (until September 2004) includes more than 50 papers from 29 countries (Algeria, Austria, Bahrein, Belgium, Canada, Croatia, Rep. of China, Czech Republic, France, Germany, Greece, Hungary, India, Iran, Italy, Japan, Jordan, Korea, Poland, Portugal, Romania, Russia, Slovakia, Spain, Tajikistan, Turkey, United Kingdom, Ukraine, USA). . Duration of each presentation will be limited to 15 minutes and additional time for discussion will also be provided. The English translation of lectures not read in English should be submitted at the registration desk on arrival LCD projector and computer with Windows OS for Microsoft Power Point format presentations is available. (Please note, that the use of your own computer is not allowed.)

Those intending to attend the conference are kindly invited to send a registration form (page 156) to:

Dr. Imre BENKÕ,
MATE Secretariat, House of Technology, III. 318., H-1372 Budapest, POB. 451., Hungary, Fax: +361-353-1406,
Phone: +361-332-9571., E-mail: mate@mtesz.hu

For any further information and personal inquiries please contact the following address:

Dr. Imre BENKÕ,
H-1112 Budapest, Cirmos u. 1, 6/38, Hungary,
Phone/fax: +361-310-0999, E-mail: ibenko@freestart.hu