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Study Protocol
Predictors of skin temperature, barefoot plantar pressure and ulceration in diabetic foot patients

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Thermology international consider now study protocols for publication

Kurt Ammer

Editor in chief, Thermology international, European Association of Thermology, Vienna, Austria

When the journal Physical Therapy introduced study-protocols as a new publication format, the following arguments in favour of this new publication type were provided [1].

In advance publication of study protocols

1.increases research quality and transparency

2.informs the scientific community as to what studies are being done, which helps to avoid duplication and to better coordinate research efforts

3.allows the scientific community to evaluate whether the eventual analysis and results are consistent with the investigators' original intent.

4.has the benefit of disseminating the most contemporary ideas with respect to study design and data-analysis.

Similar reasonings can be found in other journals which included study protocols in their publication spectrum. Common requirements for the publication of study protocol are

- Proof of ethics approval
- Registration of clinical trials in a public trials registry at or before the time of first patient enrolment as a condition of consideration for publication as defined in the guidelines of the International Committee of Medical Journal Editors (ICMJE)[2].
- In proposed or ongoing trials, participant recruitment must not be completed at the time of submission.

In general, publishing study protocols can be understood as a contribution to the quality assurance of scientific publications. Quality assurance is an important strategy to increase acceptance and reputation of research in thermology. Following previous recommendations to use guidelines, collected at the EQUATOR-network [3], and apply the TISEM-checklist for reporting conditions during infrared thermal imaging [4], authors are invited to submit their thermology study protocols to Thermology international. The first paper of that kind can be read on pages S5 to S11 in this issue[5].

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Predictors of Skin Temperature, Barefoot Plantar Pressure and Ulceration in Diabetic Foot Patients: protocol for a prospective cohort study

Adérito Seixas[1,2], K. Ammer[3,] R. Carvalho[4], J. P. Vilas-Boas[5], J.Mendes[6] R.Vardasca[3,6]

1 Escola Superior de Saúde, Universidade Fernando Pessoa, Porto, Portugal
2 LABIOMEP, INEGI-LAETA, Faculdade de Desporto, Universidade do Porto, Porto, Portugal
3 Medical Imaging Research Unit, University of South Wales, Pontypridd, United Kingdom
4 Hospital Santo António, Centro Hospitalar do Porto, E.P.E., Porto, Portugal
5 LABIOMEP, CIFI2D, Faculty of Sports, University of Porto, Porto, Portugal
6 LABIOMEP, INEGI-LAETA, Faculdade de Engenharia, Universidade do Porto, Porto, Portual

SUMMARY

AIM: Diabetes can damage several organs and systems and may result in impaired blood flow and nerve damage, increasing the risk of foot ulcers and amputation. Foot ulcers have also been linked to changes in skin temperature and increased plantar pressure. This study aims to investigate the skin temperature characteristics of patients with diabetic foot, which factors can predict skin temperature, barefoot plantar pressure and ulceration, the relationship between skin temperature and plantar pressure in patients with diabetic foot and the value of a conductive cooling test applied to the feet of patients at risk.

METHOD: Patients with established diagnosis of diabetic foot will be recruited from a specialized centre for diabetic foot care. Primary outcome measures will be skin temperature, barefoot plantar pressure, and the percentage of patients developing a foot ulcer during a period of one year after the assessment. Secondary outcome measures will include multiple clinical measures: ankle and hallux mobility, soft tissue hardness, in-shoe plantar pressure and time to ulceration. Other outcome measures related to the disease and the patient will also be assessed.

CONCLUSION: Our study will increase the understanding of the determinants of skin temperature and plantar pressure, the association between skin temperature, soft tissue hardness and plantar pressure, and the role of skin temperature and plantar pressure as predictors of ulceration.

STUDY REGISTRATION: Thermal and Biomechanical Characterization of Diabetic Foot Patients, Predictors of Skin Temperature, Barefoot Plantar Pressure and Ulceration. ClinicalTrials.gov, NCT03254095.

KEYWORDS: Diabetic foot; Foot ulcer; Skin Temperature; Plantar pressure

PRÄDIKTOREN FÜR HAUTTEMPERATUR, BARFUSS-SOHLENDRUCK UND GESCHWÜRBILDUNG BEI PATIENTEN MIT DIABETISCHEM FUSS: PROTOKOLL EINER PROSPEKTIVEN KOHORTEN STUDIE

ZIEL: Diabetes kann viele Organe und Systeme beschädigen, zu Beeinträchtigungen der Durchblutung und Nervenschäden führen, was das Risiko von Fußgeschwüren und Amputationen erhöht. Fußgeschwüre wurden auch mit Veränderungen in der Hauttemperatur und erhöhtem Sohlendruck verbunden. Diese Studie zielt darauf ab, die Hauttemperaturcharakteristik von Patienten mit diabetischem Fuß zu untersuchen, welche Faktoren die Hauttemperatur, den Barfuß-Sohlendruck und Geschwürbildung vorhersagen können, die Beziehung zwischen Hauttemperatur und Sohlendruck bei Patienten mit diabetischem Fuß zu beschreiben und den Wert einer konduktiven Kühlung der Füße von Risikopatienten für Fußgeschwüre zu ergründen.

METHODE: Patienten mit bestätigter Diagnose eines diabetischen Fußes werden von einem spezialisierten Zentrum für Patienten mit diabetischem Fuß rekrutiert werden. Hauttemperatur, Barfuß-Sohlendruck, und der Anteil der Patienten, die innerhalb eines Jahres nach Studienbeginn ein Fußgeschwür entwickeln, werden als primäre Studienergebnisse definiert. Die klinischen Befunde wie die Gelenkbeweglichkeit des Sprunggelenks und der Großzehe, die Härte von Haut und Fuß-Bindegewebe, der Sohlendruck im Schuh gemessen, und die Zeit bis zum Auftreten eines Geschwürs dienen gemeinsam mit anderen klinischen Parametern als Nebenergebnisse.

FAZIT: Unsere Studie wird das Verständnis für die Determinanten von Hauttemperatur und Sohlendruck, für die Zusammenhänge zwischen Hauttemperatur, Verhärtung der Weichgewebe und Sohlendruck verbessern, sowie die Rolle der Hauttemperatur und Sohlendruck in der Vorhersage von Geschwüren klären

STUDIEN REGISTRIERUNG: Thermal and Biomechanical Characterization of Diabetic Foot Patients, Predictors of Skin Temperature, Barefoot Plantar Pressure and Ulceration. ClinicalTrials.gov, NCT03254095.

Schlüsselwörter: Diabetischer Fuß; Fuß-Geschwür; Hauttemperatur; Sohlendruck

Thermology international 2018, 28(Supplement) S5-S11

Introduction

The burden of diabetes in the world is unquestionable. If the actual trend continues, in 2045 the estimated number of people, aged 18-99 years, with diabetes will rise to 693 million [1]. Diabetes is estimated to be the seventh leading cause of death in 2030 [2]. Foot problems are common among patients with diabetes. The International Working Group on the Diabetic Foot (IWGDF) defines "Diabetic Foot" as infection, ulceration or destruction of tissues of

NOVELTY STATEMENT

The determinants of skin temperature, the relationship between skin temperature and other parameters and the role of skin temperature as a predictor of ulceration still need discussion.

This study will investigate the association between skin temperature, soft tissue hardness and plantar pressure.

The determinants of skin temperature and plantar pressure in patients at risk to develop foot ulcers will be explored.

The role of skin temperature as a predictor of ulceration, independently and in combination with plantar pressure will be studied.

the foot associated with neuropathy and/or peripheral artery disease in the lower extremity of people with diabetes [3] and lower limb amputation is one of the many complications related to the disease.

The potential to result in reduced blood flow and nerve damage increases the risk of foot ulcers in diabetic patients [4]. The yearly incidence of foot ulcers is around 2-4% [3, 5] and the lifetime incidence may reach 25% [6] with recurrence rates that may be more than 40% [7, 8], evidencing the high burden placed on patients, healthcare systems and society. Recent evidence from a metanalysis highlights the inability to sense a 10-g monofilament, the absence of palpable foot pulses, a history of previous foot ulcer and a lower extremity amputation as key factors to predict ulcer formation [9].

Foot temperature and plantar pressure have also been recognized as important factors related to increased risk of foot complications [10]. Strong evidence from systematic reviews suggests that peak plantar pressure is associated with ulcer development [11] and that an increase in skin temperature, when compared to the contralateral limb, predicts foot ulceration [12]. Regarding plantar pressure, the studies included in the systematic review [11] showed that subjects with high peak plantar pressure had an increased risk for ulcer development. However, the impact of peak plantar pressure in ulcer recurrence is not consensual, with evidence suggesting that plantar pressure is not associated with ulcer recurrence [13] and evidence suggesting the opposite [14], with barefoot and in-shoe plantar pressure acting as significant independent predictors for ulcer recurrence. Concerning skin temperature, a recent narrative review [15] has not identified skin temperature as an independent predictor of ulcer recurrence, however, the IWGDF systematically reviewed the literature [16] on interventions for the prevention of ulcer recurrence and pointed that monitoring skin temperature can effectively reduce the incidence of recurrent plantar ulcers. From the studies included in the cited reviews [12, 16] it is easily noted that none of the included studies used an infrared thermo- graphic camera to collect data, 2 studies [17, 18] used liquid crystal thermography in the assessment and the others used dermal thermometry [e.g. 19]. These findings highlight the need for more research on the predictive factors of ulcer development in patients at risk, particularly using infrared thermography.

Despite the recognized value of both variables in ulcer development, their determinants are poorly understood, limiting researchers in the ability to predict which patients may develop increased skin temperature and plantar pressure.

Previous research has identified key factors related to barefoot plantar pressure measurements such as body mass [20], foot deformities [20, 21], callus [21], joint mobility at the ankle and metatarso-phalangeal joints [22], presence of neuropathy [22] and soft tissue thickness [23]. Predictors of skin temperature have not received so much attention from the scientific community, but neuropathy [24] and the presence of infection [25] have been shown to increase skin temperature and the presence of peripheral artery disease in neuropathic feet has been associated with lower skin temperature values [26]. Considering the existing evidence, especially regarding skin temperature, the patients included in those studies are very heterogeneous in terms of risk level to develop foot ulcers, and few studies investigated patients with confirmed diagnosis of diabetic foot, even though the expression "diabetic foot" is used in the title or to describe the research [e.g.27]. Moreover, the relation between skin temperature and plantar pressure has not yet been explored in the literature.

It is believed that most ulcers are preventable and a topical review [28] suggests several approaches to achieve this goal, one of which focuses on the analysis of predictive factors of foot ulcer recurrence, including biomedical, biomechanical and behavioural factors. Detailed information about the factors related to skin temperature and plantar pressure changes, and ulcer development in patients with diabetic foot may provide useful evidence related to the early identification of patients at risk. Furthermore, despite the research already published, whether the measurements of skin temperature and plantar pressure, and ulcer occurrence can be predicted by standard clinical measures remains a question to be answered. As stated in a recent review [15], new studies on innovative approaches and on the efficacy of technological support to prevent ulcer recurrence are needed.

This protocol details the proposed methodology for a study aiming to establish the skin temperature characteristics of patients with diabetic foot, which factors can predict skin temperature, barefoot plantar pressure and ulceration and the relationship between skin temperature and plantar pressure in patients with diabetic foot.

Materials and Methods

Study design and participants

A prospective cohort study was planned. The study will be carried out in Porto, Portugal, in a specialized diabetic foot centre. Diabetic foot patients will be recruited for this study and all primary outcomes will be carried out by the principal investigator (AS).

Outcome measures
Primary outcome measures will include skin temperature, barefoot plantar pressure and the percentage of patients developing a foot ulcer. Secondary outcomes will include ankle mobility, hallux active extension range of movement, soft tissue hardness, in-shoe plantar pressure and time to ulceration. Other outcome measures will include disease duration, type of diabetes, foot deformities, amputation, neuropathy assessment, peripheral artery disease, generic health status, age, height, weight and body mass index.

Sample selection
Diabetic foot patients will be recruited from a specialized diabetic foot centre in Porto, in the Northern region of Portugal. The study is approved by the Centro Hospitalar do Porto ethical committee (approval number: 2015.248 (208-DEFI/188-CES)). Following the recommendation of the Declaration of Helsinki, written informed consent will be obtained from all participants at the time of screening for eligibility after a clear explanation of the experimental procedure.

Inclusion criteria
Inclusion criteria include: males and females older than 18 years, able to walk at least 10 metres without assistance and with established criteria of diabetic foot (history of ulceration or destruction of tissues of the foot in association with the presence of neuropathy and/or peripheral artery disease in the lower extremity of people with diabetes).

Exclusion criteria
Exclusion criteria include: (1) the decision not to cooperate; (2) the presence of major amputations; (3) the presence of active ulcers or infection in the previous month, at the time of assessment and (4) the presence of cognitive impairment.

Sample size requirements
Austin and Steyerberg [29] have established that, in the context of linear regression a minimum of two subjects per variable in the model are required for adequate estimation of regression coefficients. In the context of logistic regression and Cox proportional hazards models a minimum of ten events per variable are required [30, 31]. Considering a recurrence rate of 40% [7, 8], 50 feet with history of previous ulcer would be required to include two variables (skin temperature and plantar pressure) in the Cox proportional hazards regression model and in the logistic regression model to predict foot ulceration. G*Power (version 3.1.9.2) [32] was used to calculate the required sample size for a logistic regression model, considering the odds ratio for plantar pressure and the squared multiple correlation coefficient between skin temperature and plantar pressure reported in previous research [33, 34]. A total of 96 feet are required considering a significance level of 0.05 and statistical power of 0.8.

Baseline data collection

Clinical history, demographics and anthropometry
Clinical history will be obtained from participants via structured interview and clinical record consultation performed by a single researcher (AS). Information such as age, gender, type and duration of diabetes, glycated haemoglobin (HbA1c), height, body mass, absence of foot pulses, presence of claudication, pain at rest and night pain will be recorded. Medical conditions such as hypertension, dyslipidaemia, retinopathy, nephropathy, heart disease and stroke will be recorded as present or absent based on the clinical record of the patient. Current medication will also be noted.

Foot assessment
The presence of neuropathy and peripheral artery disease will be recorded as present or absent based on the individual clinical record and clinical history. The specialized diabetic foot centre uses the IWGDF criteria as standard procedure to diagnose neuropathy (10-g monofilament, tuning fork and/or cotton wool) [3] and peripheral artery disease [35]. The absence of foot pulses (dorsal pedal and tibial posterior), the presence of night or rest pain and claudication will be used as minimum criteria to diagnose peripheral artery disease. The following foot deformities will be recorded as present or absent: hammer toes, claw toes, hallux valgus, Charcot midfoot deformity, pes planus and pes cavus [36]. Hammer toes will be defined as hyperflexion of the proximal interphalangeal joints and claw toes will be defined as hyperextension of the metatarso- phalangeal joints with hyperflexion of the interphalangeal joints of the lesser toes. Hallux valgus will be defined as lateral deviation of the hallux relative to the first metatarsal. Charcot midfoot deformity will be assessed visually, as visible dislocation of the midfoot joints and rocker bottom deformity and verified in the medical records. Pes cavus will be defined as a high medial-longitudinal arch and pes planus as a lower medial-longitudinal arch and both will be assessed weight-bearing. The presence and location of prior ulceration, hyperkeratosis and minor amputation will be recorded and the IWGDF risk classification system [3] will be used to identify the risk category of each foot.

General health assessment
General health status will be assessed with the EQ-5D-5L instrument [37]. The EQ-5D-5L assesses 5 dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and each of the dimensions has 5 levels of perceived problems (level 1 indicates no problem, level 2 indicates slight problems, level 3 indicates moderate problems, level 4 indicates severe problems and level 5 indicates extreme problems). It also assesses the perceived health on a 20 cm vertical, visual analogue scale with endpoints labelled 'the best health you can imagine' and 'the worth health you can imagine'. This information can be analysed as a quantitative measure of perceived health, perceived by the individual respondents.

Skin temperature
Skin temperature measurements will be conducted in the morning, away from airflow and infrared radiation sources. Patients will be asked to remove the shoes and socks and after a 10-minute acclimation period, images of the plantar and dorsal aspects of the feet will be obtained using an in-

frared camera (FLIR Systems, E60, Wilsonville, OR, USA), with a focal plane sensor array size of 320x240, noise equivalent temperature difference (NETD) of 50mK at 30°C and ±2% of repeatability of the overall reading. Camera emissivity settings will be set to 0.98 and will always be turned on at least 40 minutes before the first assessment of the day to allow sensor stabilization. Images will be recorded with the camera positioned 1 metre away, perpendicular to the feet, before and after a 2-minute conductive cold stress test using a 0.8 cm thick aluminium surface. During the cold stress test, images of the dorsal surface of the feet will be recorded every 10 seconds. Room temperature and relative humidity will be continuously monitored during data acquisition. The patients will be seated, with knees extended and legs supported by a chair, while acquiring plantar thermograms. When acquiring dorsal thermograms and during the cold stress test, patients will be seated with knees flexed.

Thermograms will be analysed with FLIR ResearchIR Max software (FLIR Systems, version 4.30.0.69). Regions of interest will be drawn in the plantar and dorsal surfaces of the foot and mean temperature values will be extracted and analysed.

Barefoot plantar pressure

Barefoot plantar pressures will be assessed using an EMED-a50 pressure platform (Novel GmbH, Munich, Germany) in two conditions: static and normal walking. The platform has 1760 sensors in a sensor area of 389x226 mm (resolution of two sensors/cm^2) and will be sampled at 5Hz in the static measurement and at 50Hz in the dynamic measurement. In the static assessment patients will be asked to stand with one foot in the platform at a time, relaxed, with the upper limbs pending lateral to the body, looking straight ahead and data will be acquired for 30 seconds. Dynamic assessment during normal gait will be performed using the two-step protocol [38]. The subject will be asked to stand away from the platform and step into the platform with their second foot strike, continuing to walk over and past the platform for approximately 2 metres. After several familiarization trials, three trials will be conducted with each foot in both static and dynamic assessments.

In-shoe plantar pressure

In-shoe plantar pressure data will be acquired with the F-Scan resistive sensor system (Tekscan inc., SB, USA) [39]. The system samples at a frequency of 100Hz and has a resolution of 3.9 sensors/cm2 in a thin insole (0.15 mm) that can be trimmed to fit every shoe size. After the insole placement in the shoes and calibration has been performed according to the manufacturer's instructions, patients will be asked to walk 10 metres in a straight line at the preferred speed. Three trials will be recorded for each patient.

Range of motion

Ankle and hallux range of motion will be assessed via goniometry in a supine position. Ankle range of motion will be calculated from the values of dorsiflexion and plantarflexion. The amplitude of extension of the hallux will be recorded relative to the first metatarsal shaft. Bisection lines will be drawn medially along the shaft of the first metatarsal and the proximal phalanx of the hallux and the range of motion of extension will be measured [36, 40].

Soft tissue hardness

Soft tissue hardness will be assessed using a durometer [41, 42]. A Shore-A PCE-DDA 10 durometer (PCE Instruments, Meschede, Germany) will be used to assess the soft tissue hardness in eight locations, at the calcaneum (medial and lateral), midfoot (medial and lateral), first metatarsal head, between the second and third metatarsal heads, between the fourth and fifth metatarsal heads and the hallux. The durometer consists of a spring-loaded truncated cone-tipped indenter. For this assessment the patients will be seated, with the knees extended and toes pointing upwards. The durometer will be pressed against the surface of the foot of both feet [42]. Three measurements will be recorded at each location and averaged.

Follow-up data collection

Percentage of patients developing a foot ulcer and time to ulceration

Foot ulcer will be defined as a full thickness skin break below the level of the malleoli and will be recorded if the ulcer causes the patient to seek assistance from a healthcare professional [43]. The clinical records of the patients assessed at the baseline will be consulted after 12 months of the baseline assessment to assess if the outcome (foot ulcer) has occurred. The percentage of patients developing a foot ulcer will be calculated and the time to ulceration, in days, since baseline data collection will be noted.

Statistical analysis

The Statistical package for the Social Sciences (SPSS) version 25.0 for Windows (SPSS Statistics, IBM, Chicago, IL, USA) will be used for statistical analysis. Continuous variables will be reported as mean ± standard deviation or median and interquartile range based on the results of the data distribution assessment with the Shapiro-Wilk test. Additional graphical assessment will be used to complement the data distribution assessment. If data follows a normal distribution, parametric tests will be used, if not, non-parametric alternatives or data transformation will be conducted. Differences in skin temperature and peak plantar pressure between presence and absence of dichotomous predictor variables will be assessed via student t-tests or Mann-Whitney U tests. Relationship between skin temperature and peak plantar pressure and continuous predictor variables will be assessed using Pearson or Spearman correlation coefficients. Data will be pooled for both right and left limbs to increase statistical power and since most independent predictors are at the limb and not at the patient level, the analysis will be performed at the foot level. Skin temperature and pressure variables with skewed data will be log transformed and univariate regression analysis will be used to explore the relationship between predictor variables and skin temperature and peak plantar pressure. Statistical assumptions will be verified. Significant factors

($p<0.20$) will be included in multivariate linear regression models. Univariate analyses of potential risk factors in relation to time to ulceration will be performed using Cox regression analysis. Continuous variables will be entered in the analyses as linear terms. Stepwise Cox proportional hazards regression will be used to identify independent risk factors for ulcer occurrence while controlling for potential confounding variables. Variables with $p<0.20$ in univariate analyses will be considered for inclusion in the Cox model. Logistic regression will be used to identify independent risk factors (skin temperature and plantar pressure) for ulcer occurrence. Statistical significance in all analysis will be considered if $p\leq0.05$ and confidence intervals will be reported.

Discussion

The novelty of the proposed approach resides in the methodology and in the variables that will be assessed, which will provide evidence in domains that are currently lacking information such as the relation between skin temperature and tissue hardness and plantar pressure, the determinants of skin temperature in diabetic patients at risk to develop foot ulcers, the value of skin temperature assessment as a predictor of ulcer development, both independently and in combination with plantar pressure and skin temperature changes caused by a conductive cooling test.

Although minimal, soft tissue hardness has a significant influence on the ability to perceive light touch in healthy subjects [44]. Patients with diabetic neuropathy have higher soft tissue hardness than patients with diabetes but without neuropathy and healthy controls [41], and this increase in hardness is strongly correlated with the severity of neuropathy. In a similar study [42], patients with diabetes and neuropathic foot had significantly reduced joint mobility and increased foot sole hardness, which appear to be important determinants of foot sole ulceration. Despite the potential interest of soft tissue hardness [45], more studies are needed to establish the value of this parameter in the ulceration process. Moreover, the relationship between skin temperature and soft tissue hardness and joint mobility in diabetic patients has yet to be assessed.

The relation between skin temperature and plantar pressure is poorly explored in the literature. A research group has explored the importance of shear forces as an emerging predictive factor for foot ulceration [46-48] and its relationship with skin temperature [34] and reported that skin temperature changes after walking in healthy subjects were significantly correlated with peak shear stress values. However, the association between skin temperature and plantar pressure at rest remains to be studied.

When compared with the contralateral foot, a skin temperature increase has been shown to indicate foot ulceration [12]. However, most of the studies included in the systematic review that led to such conclusion [e.g. 19, 49, 50] were conducted by the same research group, measuring skin temperature at six specific sites in the foot with dermal thermometry. These findings require validation from other research groups in other regions of the world [16] to increase the validity of the findings. Two other studies have used liquid crystal thermography, one published in 1986 [18] and the other in 1994 [17], a technology that lacks the quality of modern infrared camera technology. The use of infrared thermography to detect foot complication has been rarely reported [e.g. 51] and more studies are required to assess the efficacy of this technological support to prevent ulcer recurrence as suggested in a recent review [15]. Moreover, to date, no study as assessed a predictive model of foot ulceration based in skin temperature and plantar pressure assessment and the determinants of skin temperature in diabetic foot patients are not fully understood.

The response of the thermoregulation system after the application of external stress, thermic or mechanical in nature, in diabetics has been assessed in several studies. Studies assessing plantar skin temperature after cold stress are the most common [e.g. 52, 53] but the effect of mechanical stress has also been studied [e.g. 54]. Regarding studies based in cold stress, the approach has been the immersion of the foot in cold water and the assessment of the rewarming pattern, which is a simple test but requires the access to cold water and monitoring its temperature to ensure it is kept within the desired values. Studies assessing the effect of conductive cooling and its potential value in the study of patients with diabetic foot are still lacking.

We report the methodology for a prospective cohort study that aims to investigate the predictors of skin temperature, plantar pressure and ulceration in patients with diabetic foot. As previously discussed, few studies investigate the determinants of plantar pressure in this population and fewer assess the role of soft tissue hardness or skin temperature in disease development. The determinants of skin temperature in this population have not been addressed extensively and the relationship between skin temperature and plantar pressure remains to be explored. Research assessing the role of skin temperature in the ulceration process is also scarce and thus, the need to better document these relationships is evident. It is believed that this study will provide important evidence related to the early identification of patients at risk to develop foot ulcers.

Conflicts of interest

The authors have no conflict of interest to declare.

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Address for Correspondence:
Adérito Seixas
Escola Superior de Saúde, Universidade Fernando Pessoa
Rua Delfim Maia, 334
4200-253 Porto, Portugal
Email: aderito@ufp.edu.pt

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22th National Congress of the Polish Association of Thermology

Kurt Ammer

European Association of Thermology, Vienna, Austria

Once in a year, the thermology community is heading to the mountain region in South Poland and exchange their ideas, research on temperature related applications in medicine and biology. This movement started in 1998 [1] and with 2 exceptions all conferences of the Polish Association of Thermology took place in the Zakopane-Krakow region. The proceedings of all conferences have been published in Thermology international, and last year a supplement of Thermology international was dedicated to the Abstracts of the 20th Congress, held in Gdansk [2].

This year, the 22nd Congress attracted experts from 7 countries including Austria, Czech Republic, Poland, Portugal, Russia, Slovakia and United Kingdom resulting in an increased number of presentations. Figure 1 show attendants of the conferences. All abstracts, some of them as an extended version appear in this 2018 supplement of the journal.

In addition, the Polish Association elected a new board. Prof Anna Jung passed the presidentship to Prof Armand Cholewka, who promised to continue with the tradition of organising a conference in Zakopane. The next meeting is already scheduled for 12 - 14th April, 2019.

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Participants of the 22th National Congress of the Polish Association of Thermology (image courtsy to Dr.Jozef Gabrhel)

22th National Congress of the Polish Association of Thermology in Cooperation with the European Association of Thermology

Extended Abstracts

SHOULD INFRARED THERMAL IMAGING BE CLASSIFIED AS QIB (QUANTITATIVE IMAGING BIOMARKER)?

Kurt Ammer [1,2]

[1] European Association of Thermology, Vienna, Austria

[2] Medical Imaging Research Unit, University of South Wales, Pontypridd, UK

The Quantitative Imaging Biomarkers Alliance (QIBA) was organized by the Radiological Society of North America (RSNA) in 2007 to unite researchers, healthcare professionals, and industry stakeholders in the advancement of quantitative imaging and the use of biomarkers in clinical trials and practice. Quantitative imaging is defined as the acquisition, extraction and characterization of relevant quantifiable features from medical images for use in research and patient care [1]. According to the Food and Drug Administration (FDA), a biomarker is defined as "a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or biological responses to a therapeutic intervention." Standardisation of the use of imaging biomarkers in clinical trials will reduce the variance inherent across different hardware and software platforms.

Medical Infrared thermography captures the infrared radiation from humans and displays it as an image of skin temperature distribution. The interval scaled temperature can be extracted from thermal images and can be regarded as quantitative imaging biomarker at least as indicator of biological responses to heat gain or heat removal. The value of skin temperature as a marker of normal biological processes or pathogenic processes is under ongoing discussion. Currently, Infrared thermography is not recognised by QIBA as quantitative imaging biomarker.

QIBA has established an organisation structure that supports the development, promotion and implementation of QIBs in clinical medicine. Carefully defined metrology standards include definitions of terms such accuracy, uncertainty, bias, agreement, precision, repeatability and reproducibility [2]. Statistical methods for technical performance assessment, for computer algorithm comparisons and for meta-analysis of the technical performance of an imaging procedure are also described [3].

Some standards have been met in recent thermal imaging studies, others were addressed in parts and other are neglected. Howell et al reported the performance of 6 thermal imagers in multi-centre study using the proposed measures of agreement and bias determination [4]. The TISEM-checklist addresses conditions that may affect the precision of temperature readings extracted from thermal images [5]. Variation in body posture and placement of regions of interest are underestimated sources of error in repeated measurements.

However, the greatest challenge for thermal imaging is to be accepted as a valid surrogate endpoint. Collins & Ring showed in the nineteen seventies that the change in temperature measured over an experimental arthritis in rats, is a valid surrogate endpoint for the evaluation of anti-inflammatory drugs [6]. However, this does not mean that infrared imaging is an accepted diagnostic test for inflammatory arthritis or an evaluated outcome measure for the evaluation of anti-inflammatory treatment of joint diseases.

Detection of perforator vessels by thermal imaging is a very successful procedure but cannot be classified as QIP since the evaluation of the images is purely qualitative [7]. The duration of the vasoconstrictive response in fingers after exposure to a cold stimulus might be accepted as QIP if more data on the variation of temperature recovery time in healthy subjects are available [8].

An article from 2015 showed good agreement between the area of skin response and the area of increased skin temperature in thermal images from cutaneous tuberkulin tests. The areas of redness and of intracutaneous reaction to the tubeculin protein could be clearly separated by temperature levels [9].

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THE IMPORTANCE OF THERMOGRAPHY IN THE DIFFERENTIAL DIAGNOSIS OF GROWING PAINS

Gabrhel J.1, Popracová Z.2, Tauchmannová H3 .

1. Private Medical Practice of Treatment Rehabilitation and Acupuncture, Thermal Imaging Diagnostics, Trencin

2. University of St. Cyril and Methodius, Trnava

3. National Institute of Rheumatic Diseases, Pieštany

Introduction

Growing pains were first described by the French physician Marcel Duchamp in 1823 [1]. They appear at the age of 2-19; however, their most frequent clinical presentation occurs at the age of 3-5 and 8-12 years. Their clinical manifestation primarily includes deep muscle pain. Most often the pain appears in the thigh, shin, calf, and popliteal fossa. Pain attacks occur in the late afternoon and night hours, lasting from several minutes to hours [1,2]. Etiology and pathogenesis of growing pains remain unknown. As a result, the diagnosis "growing pains" is confirmed in patients with suspicious symptoms "per exclusionem" i.e. diagnosis is made after exclusion of other pain causes such as inflammatory rheumatic diseases, orthopedic disorders, unrecognized

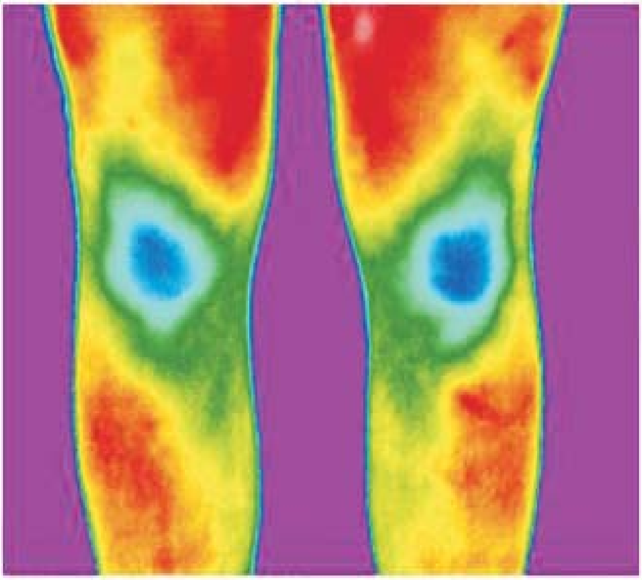

Figure 1
.Normal thermal pattern in an adult knee.

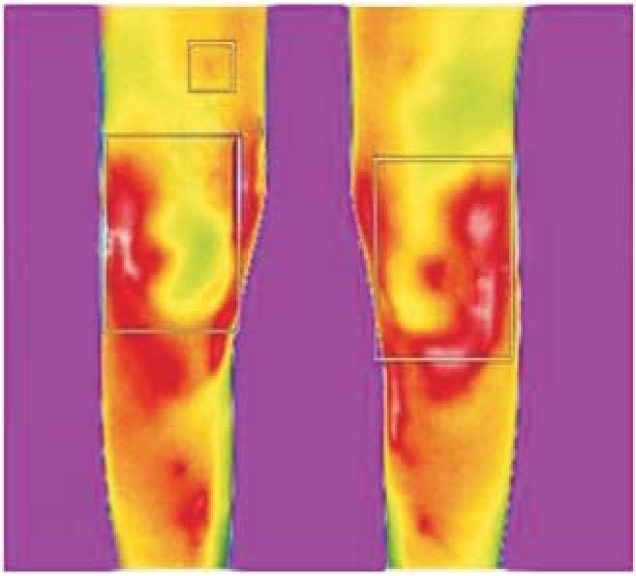

Figure 2.
Thermal pattern in growing pains or in accelerated growth

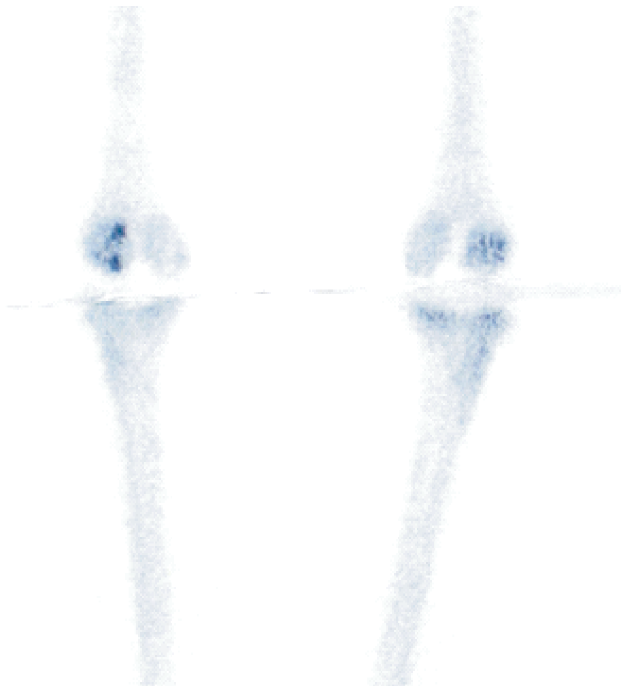

Figure 3
Normal scintigraphic findings in an adult knee

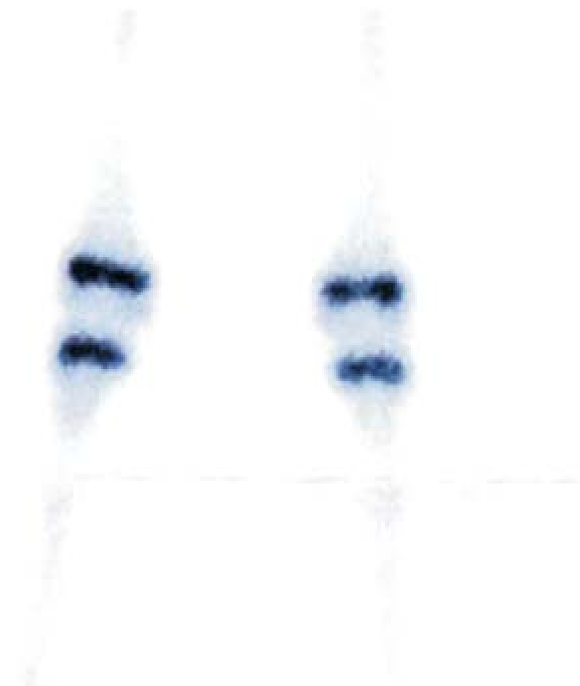

Fig.ure 4
Scintigraphic findings in growing pains or in accelerated growth

trauma, neuromuscular disturbance, endocrine malfunction, malignant diseases, or sympathetically mediated pain [3]. Recently, a possible association with the restless leg syndrome was discussed [4].

We found in our analysis that temperature patterns from children with "growing pains" in the lower limb differed significantly from the normal temperature distribution seen in adults, especially in the knee region. In the long-term continuous observations of the temperature patterns in adolescent athletes engaged in various sports disciplines, which was performed at our workplace for three decades, we noticed that this pattern is no longer present in the monitored individuals after their growth has been terminated. Therefore, we do not consider it pathological, but we assume it is caused by the temperature increase in the epiphysodiaphyseal plate regions due to their increased metabolic activity during growth acceleration.

Since 1992, we have reported our findings at several national and international symposia on thermography, sports medicine or rehabilitation. The results of our research were published as book chapters [5,6] or as articles in national and [7,8,9] international journals[10,11,12]. Since the last presentation of our results at the XXth Conference of the Polish Association of Thermology in Gdansk 2016 [13], we have continued to monitor painful symptoms in the lower limbs of children. We re-analysed our findings and compared infrared thermal images, ultrasonography, radiography, computer tomography (CT), magnetic resonance (MR) images from symptomatic children with the findings from asymptomatic juvenile athletes. We aimed to detect typical imaging findings that can differentiate growing pains from other painful conditions and from healthy adolescents.

Cohort and methodology

Between January 8, 2013 and October 25, 2016, 44 pediatric patients with lower extremity pain underwent differential diagnostic testing at our clinic. Of these, 10 were females and 34 males with an age of 12.5 years on average (range: 3-19 years).All patients underwent clinical, laboratory, myo-skeletal, thermographic and sonographic examinations. Some particularly painful conditions required an X-ray, CT, MR or scintigraphy examination as well. We then compared the thermal patterns of patients with 15 asymptomatic athletes. This included 12 males and 3 females aged 11-18 years, (13.8 years on average), who were divided into two groups according to the intensity of growth acceleration. The first group included 6 subjects with the growth acceleration of 0-2 cm in 6 months. The other group included 9 subjects with growth acceleration of 3-15 cm in 6 months.

Results

The overall number of diagnostic findings was 52. In 6 patients, the pathological finding was detected in 2 locations, and in another patient diagnostic signs were present in 3 body regions. 37 of 52 diagnostic findings in the symptomatic athletes were identified in the knees, in 11 other patients the lower leg was affected and the region of the hip joints in 4 patients. 43 lesions presented with increased thermal activity. In 17 thermal images the increased temperature was detected over the growth plates and other body regions were affected in the 26 remaining patients. Reduced thermal activity was found in 2 cases and normal temperature was recorded in 7 cases. 35 of 52 pediatric pain problems could be explained by a specific structural cause, or some sort of pathophysiology behind the cause. A diagnosis of growing pains made in 17 patients, because no other explanatory cause for pain was detected.

In the thermal images recorded from the knees of 15 asymptomatic athletes, there was no significant temperature increase over the growth plates in the group of 6 athletes with a growth acceleration of 0-2 cm in 6 months. In the group of 9 athletes with the growth acceleration of 3-15 cm in 6 months, a significantly elevated temperature over the growth plates was noted. Children with growing pains and pain free children with high growth acceleration show increased temperatures over growth plate, and their temperature distribution differs significantly from the normal temperature pattern of adults. An increase in temperature over the growth plates coincides with an increase in radio- pharmaceutical uptake in the region of the growth plates in bone scintigraphy. X-ray, CT, and MR findings of children with growing pains are the same as in asymptomatic children.

Conclusion

Based on typical thermal patterns, thermal imaging of painful regions of the lower extremity of children may help at the one hand to differentiate standard findings from findings that are suggestive of growing pains, and on the other hand to facilitate the differential diagnosis of other serious diseases or injuries at the lower extremity.

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A FUNCTIONAL IMAGING MULTIMODALITY APPROACH TO MONITOR A CASE STUDY ON HIGHLY VASCULARIZED THYROID NODULE

R. Vardasca[1,2], C. Magalhaes[3], C. Rio[4], C. Freitas[4], A. Carvalho[4], R. Carvalho[4], J. Mendes[1]

1 LABIOMEP, INEGI-LAETA, Faculdade de Engenharia, Universidade do Porto, Porto, Portugal

2 Medical Imaging Research Unit, University of South Wales, Pontypridd, Wales, United Kingdom

3 Faculdade de Engenharia, Universidade do Porto, Porto, Portugal

4 Clinica Carlos Rio, Braga, Portugal

5 Serviço de Endocrinologia, Centro Hospital e Universitário do Porto, Porto, Portugal

Introduction

A male patient with 40 years old and a BMI of 29.7 kg/m2, was identified to have a thyroid nodule at the left side of the gland in an occasional ultrasound scan. The thyroid gland is a large endocrine gland located on the neck above the trachea. It is responsible for the control and regulation of the speed that body uses energy and of the degree of sensitivity of other hormones to the human body. Thus, regulates the body metabolic rate contributing to the human homeostasis and thermoregulation. The thyroid nodules can be benign or malignant. In case of carcinoma, it is one type of cancer that has grown in incidence over the last decade, especially in women and at an early age. It has a relatively low mortality rate but has a high number of recurrences. The most common method of diagnosis is through biopsy and nuclear medicine. The common treatments available today are surgery and radiation, the surgery can be total (thyroidectomy) or partial (ablation), the radiation can be through iodine I131 or chemotherapy. This type of neoplasm not having a high mortality rate has associated with the treatments high costs. The total surgery in addition to the costs of the procedure has associate the dependency of drugs and additional costs for the lifetime. Infrared thermal (IRT) imaging has already been used for designing with success a prototype of a model to aid the diagnose of thyroid gland disease, however advanced image processing methods and the use of dynamic thermography could improve it.

Methods

A thermal camera FLIR E60 with a focal plane sensor array size of 320x240, NETD of <50 mK and measurement uncertainty of ±2% of the used temperature range, was used to collect the images in an acclimatized room at mean temperature 22º C and 45% of relative humidity. A static thermal image was taken from the anterior view of the throat, it was followed by a contact thermal stimulus provided by two aluminum medals with 5cm diameter and 1cm thick during 1 minute, 5 images were taken at 1 minute interval. Two squared regions of interest (ROI) were drawn at the left and right side of the thyroid skin region at the software package FLIR ThermaCAM Researcher Pro 2.10 for assessing the thermal data. In a posterior medical appointment, active Doppler imaging was recorded by two experienced endocrinologists.

Results

In the initial static image an asymmetry value of 0.5ºC was measured between the left and right ROI. After cooling the thyroid area, at the recovery, the affected area presented a hotspot, which recovered faster and during the thermal resumption process the bilateral asymmetry was more evident reaching the value of 1.6ºC at the 3 minutes after the cold stimuli. The recorded Doppler scan showed a nodule of 11x6 mm highly vascularized in a form of halo surrounding it.

Discussion

This case study showed evidence of the utility on using dynamic IRT imaging when assessing thyroid nodules, which was confirmed by Doppler imaging to be highly vascularized, however for diagnostic purposes the traditional expensive methods such as biopsy and nuclear medicine are still required. Although the application of IRT imaging should be further researched in monitoring and documenting the treatments applied to thyroid cancer.

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DYNAMICS OF LOCAL TEMPERATURE IN THE INDEX FINGERTIP AFTER CONTACT WITH THE RIFLE TRIGGER IN FROSTY WEATHER

A.L.Urakov; V.B.Dement'ev; A.A.Gadelshina

Udmurt Federal Research Center of Ural branch of RAS, Izhevsk, Russia

Introduction

We hypothesized that the use of the thermal imager can help in the modernization of small arms to enhance shooting accuracy in the frost. Modern sporting and sniper rifles are not ready for accurate shooting in frosty weather. It seems to us that for effective, accurate and safe shooting, athletes and soldiers need special rifles when the air temperature is below 0° C, and heavy snowfall and cold wind are present. To make an accurate shot with a modern rifle, you must remove gloves from the hand or uncover the index finger at least. Thereafter, the bare index finger should be placed in the inner space of the iron trigger guard, where it should be placed in contact with the trigger. Then the shooter is forced to wait some time and to press the trigger in the "right" moment. Professional shooters know very well that rifle shots are more successful in warm than in cold weather. It is hypothesized that in the cold, with snow or cold rain, the rate of accurate shots is reduced because of the rapid and excessive cooling of the index finger in cold ambient conditions. Moreover, the cold rifle and its cold trigger can further cool the fingers, because the cold trigger function as refrigerating device for the bare finger. However, a study of the effect of the trigger on the dynamics of the local temperature in the index finger when shooting a rifle in the cold was not yet conducted.

Methods

The dynamics of local temperature in bare fingers was studied in 10 healthy adult volunteers (male, aged 22 - 63 years) under open field conditions in January and February 2018 near Izhevsk in Russia. Finger temperature was recorded for several minutes after removing the mittens from the right hand. Two series of observations were conducted. In the first series of observations, we investigated the temperature dynamics of the fingers of the hand that was surrounded by cold air. In the second series we observed finger temperatures during contact with the trigger of the cold rifle, while a piece of fur was wrapped around the weapon in region of the trigger guard. Instead of real military rifles were used a toy rifle, in which the trigger mechanism was made of metal. We recorded finger temperatures with a Thermo-Tracer TH9100XX (NEC, USA) when the fingers of the volunteers were in contact with the rifle. The air temperature during the study was -3, -13 or -23°C, it was snowing, and a moderate wind was blowing. In addition to this, one volunteer agreed to conduct a study at an air temperature of -30°C. The temperature window of the thermal camera was set to the range from +30 to -30°C on days when the air temperature was -23°C; to the range from +20 to -20°C on days when the air temperature was -13°C; and to the range from +20 to -5°C on days when the air temperature was -3°C.

We investigated the trigger mechanisms of modern sniper rifles and other small arms from different countries and confirmed that they are still not designed to protect the index finger from exposure to outdoor temperatures. In fact, the trigger pull of sniper rifles are traditionally made of metal. When the air temperature is below 0° C, a cold trigger increases the risk of cold injuries at the index finger, since prolonged contact may cause frostbites. In addition, the space around the trigger is not sheltered against forced air convection. When snow and rain is present, wind blows snowflakes and water droplets on the index finger, which is placed in a "working state".

Results

When air temperature is below 0° C, high wind and snowfall cool the bare palm and fingers with or without holding a rifle. When holding a cold rifle ready to fire with bare hands under conditions of cold and snowy weather, the hand temperature will decrease fast and strongly. We observed at an air temperature of -3° C combined with heavy snow and strong wind a decrease of the index finger temperature to +12 ± 1.0º ? after 1.5 minutes cold exposure. After 3 minutes the volunteers experienced severe pain in the finger and one volunteer had to wear a warm fur glove. At the same time, they released the rifle from the hands, thus made continuing with aiming impossible.

In air temperature of -13° C and absent snow, the fingertip temperature of the index of the 10 volunteers decreased after 1, 2 and 3 minutes contact with the trigger from baseline values of 23 ± 1.2°C to 17.0 ± 0.8°C, 13.0± 0.5°C 12.0 ± 0.4°C respectively. 30 seconds after aiming, the temperature at the contact of the index with the trigger was 4.5°C less than the fingertip temperature. The finger increased quickly in temperature. The fingertip reached the baseline temperature 3 minutes after contact with the rifle trigger. 10 minutes after start of the experiment the final temperature was 30°C. Protecting the trigger and the index finger with a fur, resulted in a smaller decrease of temperature at the fingertip and contact site, but the overshooting re-warming was similar in magnitude.

In air temperature of -23°C, a 3 minutes contact of the index finger with the trigger can cool the fingertip to 2° C (Fig.1).

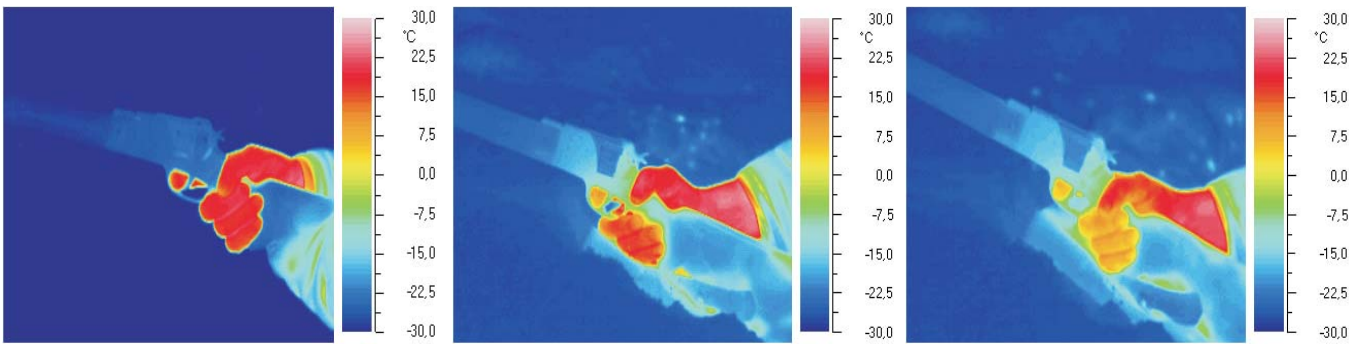

Figure 1.
Infrared image of a hand (male at age of 63 years) at baseline (A), after 1.5 min (B) and after 2.5 min (C) contact of the right index finger with the trigger at an air temperature of -23º C.

The cold weather with snowfall and a strong wind caused very severe pain in the fingers, which significantly worsened the mood of the volunteers. Severe pain and a bad mood motivated the volunteers to wear warm fur gloves. At the same time, they released the rifles from the hands, thus longer aiming became impossible. It was previously shown that the cooling of the fingers reduces their functional activity, impairs mobility, reduces the threshold of tactile receptors, causes spasms of blood vessels, which is accompanied by pain sensation and reduction of blood flow [1]. All these factors contribute to a reduced rate of accurate shooting with modern sniper or sporting rifles in the cold. When air temperature drops to -30° C or less and the contact with the trigger lasts for 3 minutes, accurate rifle shooting becomes impossible due to the loss in dexterity and the high risk of finger frostbites.

Conclusion

Shooting with modern rifles employs the contact of bare index finger with a trigger, made of metal. When shooting in the cold with snowfall and strong wind, the fingertip of index gets cold very quickly. Infrared thermography allows the monitoring of local temperature at the tip of index finger of the working hand in rifle shooting, even in cold and wet weather. Therefore, thermal images may be suitable for designers when upgrading the trigger of a sniper and sporting rifles.

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A CASE STUDY OF THIGH ELECTRONIC CIGAR BURN ASSESSMENT WITH INFRARED THERMAL IMAGING

R. Vardasca[1,2,] D. Marques[3], S. Teixeira[4], A. Silva[4,] J. Mendes[1]

1 LABIOMEP, INEGI-LAETA, Faculdade de Engenharia, Universidade do Porto, Porto, Portugal

2 Medical Imaging Research Unit, University of South Wales, Pontypridd, Wales, United Kingdom

3 Faculdade de Engenharia, Universidade do Porto, Porto, Portugal

4 Serviço de Cirurgia Plástica, Reconstrutiva, Estética e Maxilo-Facial, Centro Hospital S. João, Porto, Portugal

Introduction

A male patient with 31 years old and a BMI of 23.38 kg/m2, victim of an electronic cigarette explosion in his pocket and resulted in a thigh burn in left side. He was admitted to the burn unit of the Hospital S. João in Porto. Infrared Thermal (IRT) imaging has been previously proposed as an effective remote and innocuous tool for assessing burns depth and degree of large areas of skin. It was aim of this research to verify the correct estimation of burn depth and degree with IRT imaging.

Methods

A thermal camera FLIR E60 with a focal plane sensor array size of 320x240, NETD of <50 mK and measurement uncertainty of ±2% of the used temperature range, was used to collect the images in an acclimatized room at mean temperature 24º C and relative humidity of 48%. Images were taken having into account the "Glamorgan protocol" using the anterior thigh view 36 hours after the injury. The images were analyzed using the software package FLIR ThermaCAM Researcher Pro 2.10. Two circular ROIs were drawn over the upper area of the burn in the affected side and in the contralateral side, to obtain ROI mean temperatures and calculate thermal asymmetries. Clinical assessment was made by an experienced plastic surgeon.

Results

The lateral side ROI (grade IIa burn) showed a contralateral difference of 1.6ºC and the medial ROI (grade IIb burn) presented a bilateral asymmetry of -0.8ºC.

Discussion

For burns it is important to refer that the time of IRT image collection cannot exceeded 48 hours after injury. To assess whether IRT is an effective method for burn depth assessment, it was compared the outcome of clinical evaluation with the difference of mean temperatures between burned area and contralateral unburned area. The obtained bilateral difference for the lateral ROIs is in agreement with the previously documented studies, Zhu and Xin, which reported that for superficial partial skin thickness (grade IIa) the skin temperature was in general higher than that of the contralateral unburned skin, and according to Medina-Preciado et al., for superficial dermal (grade IIa), an average ΔT of 1.7°C was presented with an increased temperature when compared to their contralateral healthy region. The medial ROIs demonstrated that the burned tissue is colder than the unaffected contralateral respective area. Through this observation, it is possible to conclude that this zone has a depth greater than the lateral ROI, as a result of damaged blood vessels and therefore it showed a lower temperature. This result is supported by literature and according to Hardwicke et al. deep partial thickness burns (grade IIb) were 1.2 °C cooler that unburned contralateral skin area (ΔT=-1.2°C). The value obtained in this case study is close, being possible to state that IRT determined correctly the burn depth. Despite being only a single case result, the IRT imaging method proved to be a valid complementary technique for burn depth and grade assessment.

Acknowledgments

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DYNAMICS OF PLANTAR FOOT TEMPERATURE AFTER CONDUCTIVE COLD STRESS IN PATIENTS WITH DIABETIC FOOT

A.Seixas, [1,2], K. Ammer [3], R. Carvalho [4], J.P.Vilas-Boas [5], J.Mendes [6], R. Vardasca [3,6]

1 Escola Superior de Saúde, Universidade Fernando Pessoa, Porto, Portugal
2 LABIOMEP, INEGI-LAETA, Faculdade de Desporto, Universidade do Porto, Portugal
3 Medical Imaging Research Unit, University of South Wales, Pontypridd, UK
4 Centro Hospitalar do Porto, Porto, Portugal
5 LABIOMEP, CIFI2D, Faculdade de Desporto, Universidade do Porto, Porto, Portugal
6 LABIOMEP, INEGI-LAETA, Faculdade de Engenharia, Universidade do Porto, Porto, Portugal

Introduction

Foot problems are common in patients with Diabetes as a consequence of related neuropathy and/or peripheral artery disease in the lower extremity [1]. Lifetime diabetes self-management is essential to achieve glycaemic control and is associated with long term prognosis of patients with diabetes and guidelines often recommend reference values to reduce the incidence of foot complications [2]. Patients with poor glycaemic control, neuropathy, peripheral artery disease, and other risk factors, are at high risk to develop foot ulcers, which would increase the risk of amputation.

The relevance of thermal imaging to diabetes has been established [3] and in recent years research on this topic has increased. Studies assessing plantar skin temperature response after exposure to a cold stress have been published [e.g. 4] but the influence of glycaemic control and peripheral artery disease in such assessment is not fully understood. Therefore, the aim of this study was to assess the dynamics of foot skin temperature after a conductive cold challenge in patients with diabetic foot (DF).

Methods

Twelve patients with DF (10 males), aged 42-76 were recruited from a specialized foot care centre. All patients had established diagnosis of neuropathy and 6 had clinical signs of peripheral artery disease. Poor glycaemic control (HbA1c > 7%) was identified in 6 patients. The analysis was done at the foot level; therefore 24 feet were assessed. Ambient temperature, humidity and air flow were controlled to avoid experimental bias.

All participants followed a 10-minute acclimatization period before thermograms were acquired. Thermograms were obtained with a FLIR E60 camera with an array size of 320x240, noise equivalent temperature difference (NETD) of 50mK at 30ºC and ±2% of repeatability of the overall reading.

Images from the plantar surface of the foot were collected before, immediately after and 5 minutes after a 2-minute conductive cold challenge test using a 0.8 cm thick aluminium surface. Thermograms were analysed with FLIR ResearchIR Max software.

Regions of interest were drawn in the angiosome areas of the peroneal and medial calcaneal artery [5], which have been shown not to be influenced by peripheral artery disease [6].

A repeated measures ANOVA was used to analyse the data with skin temperature as within subject factor and glycaemic control and peripheral artery disease as between subject factors.

Results

There was a statistically significant effect of time in skin temperature, $F(2, 19)=75.877$, $p<0.001$, $=0.889$, but not of glycaemic control, $F(1, 20)=2.734$, $p=0.114$, $=0.120$, nor peripheral artery disease, $F(1, 20)=0.147$, $p=0.705$, $=0.007$.

Discussion

The conductive cold challenge test was easy to apply and was able to induce skin temperature changes in the feet of DF patients. However, skin temperature dynamics during recovery were not significantly different in patients with and without peripheral vascular disease and inadequate glycaemic control. The small sample size may have been a key factor to these results and further studies exploring the usefulness of such test in patients with DF, with a larger sample size, are required.

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DEPARTMENT OF BIOPHYSICS, MEDICAL FACULTY, BRNO: OVERVIEW OF RECENT INFRARED THERMOGRAPHIC STUDIES IN HUMAN AND VETERINARY MEDICINE

V. Bernard, E. Staffa, J. Pokorna, A. Bourek, V. Mornstein

Department of Biophysics, Medical Faculty, Masaryk University, Brno, Czech Republic

In the last decade, the Department of Biophysics (Faculty of Medicine, Masaryk University) was strongly focused on infrared thermal imaging (IRT) The cameras AGA and Fluke were used at first. The Flir B200 and Workswell cameras are used at the department in recent time. The camera Flir i7 is used for educational purposes. Both staff and postgraduate students are very interested in infrared thermal measurements and experiments. The department cooperates with several clinics in diagnostic thermography research.

The IRT experiments are focused on the human and veterinary medicine in context of the measurement of surface temperatures in biological objects (1).

A study focused on the lower limb ischemia was performed in large cohort of monitored patients. Patients were monitored for percutaneous transluminal angioplasty and arterial bypass surgery in this project. The IRT served as a tool for evaluating the restoration of blood circulation in the affected limb. The study was also focused on predicting the development of lower limb lesions in the early stages of the disease (2, 3).

The evaluation of the thermal changes of the tissues during surgical interventions was another chapter of the research. The modern techniques of radiofrequency ablation and irreversible electroporation were studied by means of IRT (4, 5). The aim of the studies was to optimize the procedure and the innovation of the method or instrumentation in both cases.

The cooperation with surgery clinic was established in recent times. The intestine resection surgery is monitored by IRT for determination of the best positioning of resection lines (6). The observations are performed in both human and animal surgery.

The pareses of nerves are observed at the department of neurology. The paresis of ulnar nerve and its influence on the surface temperature of the patient's upper limb were observed. The paresis of limbs and thermal effects of immobility were observed in animal models too.

Purely experimental research is focused on effect of capsaicin and associated temperature changes in human face. Other realized experiments are oriented on physical factors influencing thermography measurement.

IRT seems to be appropriate tool for observing temperature changes in all presented studies. The authors tried to compare IRT with other commonly available and used diagnostic methods in most cases.

There are a few physicians in private practice who use IRT as a general diagnostic methods in Czechia. The authors do not know whether the IRT is used routinely in clinical practice in hospitals although it is known that some hospitals own IRT systems.

Acknowledgement

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EFFECTIVENESS OF A CONTACT THERMAL IMAGING SYSTEM IN DETECTION OF BREAST PATHOLOGY

A. Jung[1], M. Trzyna[2], A. Pypkowska[2], J. Biernat[2,3], A. Byszek[2,4], M. Biernat[2], A. Szczesniak[2], M. Polak[2], H. Jaremek[2]

1 Military Institute of Medicine, Szaserów 128, 04-141 Warsaw, Poland
2 Braster S.A., Cichy Ogród 7, 05-580 Ozarów Mazowiecki, Poland
3 Faculty of Mechatronics, Warsaw University of Technology, Boboli 8, 02-525 Warsaw, Poland
4 Centre of Oncology, Maria Sklodowska-Curie Memorial Institute, Warsaw, Poland

Introduction

Breast cancer is the most common malignancy amongst women (25%) and the most common cause of death related to cancer (14%). However, these mild changes in the gland constitute 80% of all pathologies detected during breast self-examination.

In the 80's, the usefulness of thermography was observed in the diagnosis of breast lesions. Two main phenomena in thermovision could be observed: heightened overall body temperature and neoangiogenesis. Based on the biological characteristics (i.e. proliferation and neonagiogenesis) of malignant neoplasms, by using contact thermography we can detect new lesions of increased temperature, associated with carcinogenesis. Mild lesions usually do not manifest by heightened temperature, so they cannot be differentiated using contact thermography.

Material and method

The study was conducted on woman with a confirmed pathological change in the breast (from ultrasound, histopathological examination). The patients performed an examination using contact thermography (BRASTER System), and the whole procedure was executed in accordance with the study protocol.

Results and Discussion

Three cases of benign lesions and one case of malignancy- invasive ductal carcinoma, were presented; all cases were confirmed by histopathology. Among the benign lesions, we observed, a cyst with dense content, fibroadenoma and a mild phylloides tumor. All cases, either benign or malignant, were classified as BI-RADS 4-4b under USG, which qualifies changes for histopathological verification, by means of a biopsy due to the possibility of neoplastic change (in 4A, the risk is up to 3%, and in the case of 4b, up to 50%). In the thermographic examination, benign changes were invisible, BTS-1, and in the case of the malignant lesion, an outbreak of hyperthermia was observed corresponding to the verified neoplastic change, BTS-3.

Case 1. Cyst with dense content confirmed by histopathology, classified as BI-RADS 4 on ultrasound. In thermography, the change was not observed, BTS-1.

Case 2. Fibroadenoma classified as BI-RADS 4A on ultrasound. In thermography, the change was not observed, BTS-1.

Case 3. Phyllodes tumor, palpated, confirmed by histopathology, BI-RADS 4b on ultrasound. In thermography, the change was not observed, BTS-1.

Case 4. Invasive ductal cancer. Changes felt on palpation. BI-RADS 4b on ultrasound, mammography did not reveal suspicious focal lesions or microcalcifications, BI-RADS 1. In thermography, visible hyperthermia corresponding to the verified neoplastic lesion, BTS-3.

Conclusions

Contact thermography enables imaging of breast changes, which are manifested by increased metabolic rate, which causes a local increase in temperature on the surface of the skin - changes are consistent with neoplastic processes. Using contact thermography, is not possible to differentiate benign lesions.

INFRARED THERMOGRAPHY AND INDOCYANINE GREEN ANGIOGRAPHY AS IMAGING METHODS IN COLON SURGERY - CASE STUDY

E. Staffa[1], V. Bernard[1], V. Can[2], J. Pokorna[1], A. Zetelova[2], M. Farkasova[2], V. Mornstein[1], Z. Kala[2]

1 Department of Biophysics, Medical Faculty, Masaryk University, Brno, Czech Republic
2 Department of Surgery, Faculty Hospital Brno, Czech Republic

Introduction

The right-sided hemicolectomy is the methods of choice in colon cancer treatment. After resecting part of the colon with tumour, both ends of the colon must be connected through an anastomosis. Anastomotic leakage is a very serious postoperative complication. It is mainly caused by poor blood supply of the anastomosis. The evaluation of good blood perfusion after resection can be performed by indocyanine green angiography (ICG). Infrared thermography (IRT) is another option for indirect estimation of adequate blood perfusion. This case study describes both techniques during surgery in a single patient.

Methods

A 81-year patient was admitted for abdominal pain and signs of partial gastrointestinal tract obstruction. He was diagnosed with stenotizing tumor of transverse colon. After preparation patient underwent the right-sided hemicolectomy. To determine the quality of blood perfusion during the surgery, the ICG angiography and IRT were used. The infrared camera used was a Workswell WIC 640 with resolution of 640x512px. To determine the best location for the anastomosis, the resection margins were assessed macroscopically by the surgeon, by ICG angiography and IRT as well.

Results

No signs of colon ischemia were present during the surgery. Surgical aspection and both ICG angiography and IRT showed adequate blood supply for the margins of resection. The postoperative course of the patient, however, was complicated on the 7th day by sepsis cause from anastomotic leakage which was confirmed by a CT scan. Surgery confirmed a major defect of anastomosis which had to be resected and terminal ileostomy was performed The following post-operative course was without any other complications.

Discussion

Based on the both imaging methods and surgeons aspection of colon the resection margins were clearly well perfused. Despite the use of special imaging methods, anastomotic leakage occured on 7th postopeative day. Reason why the leakage occurred remains unclear. . Obviously, peroperative asessment of blood supply may not reveal or prevent blood supply alteration in the days following surgery.

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COMPARISON OF INFRARED AND LIQUID CRYSTAL CONTACT THERMOGRAPHY AFTER MASTECTOMY OR BREAST CONSERVING SURGERY

A.Cholewka[1], A. Jung[2], A. Szczesniak[3], M. Trzyna[3,] A. Maciejewski[3,6],A. Pypkowska[3], J. Biernat[3,4], A. Byszek[3,5], M. Bierna[t3,] M. Polak[3], H. Jaremek[3],

1 Afiliacja Profesora
2 Military Institute of Medicine, Szaserów 128, 04-141 Warsaw, Poland
3 Braster S.A., Cichy Ogród 7, 05-580 Ozarów Mazowiecki, Poland
4 Faculty of Mechatronics, Warsaw University of Technology, Boboli 8, 02-525 Warsaw, Poland
5 Centre of Oncology, Maria Sklodowska-Curie Memorial Institute, Warsaw, Poland

Introduction

Breast cancer is the most frequent cancer diagnosed in over 1.5 million women each year. In the past, the standard treatment for breast cancer has been a modified radical mastectomy. In recent years, many patients have been opting for breast-conserving surgery, rather than the traditional mastectomy. Up to two thirds of women diagnosed with invasive tumors are electing to have their breast preserved with lumpectomy and radiation therapy. This involves removing the cancer while leaving as much of the healthy breast tissue as possible. Thermography is a non-invasive study that can assess the earliest possible changes in breast tissue by providing an accurate and reproducible high-resolution image based on changes in skin temperature. This abstract compares two methods of thermography: infrared and liquid-crystal contact thermography for the possibility of performing the examination in women after cancer treatment.

Materials and Methods

The study was an observational, single center, non-interventional study aimed at assessing the use of thermography in 16 females after cancer treatment. The age of the participants ranged from 36 to 69 years (average 52.8 years) who finished oncological therapy; surgical or radiotherapy, more than 2 years ago. Half the group (8 females), performed 8 procedures using both contact and infrared thermography. The other half only performed contact thermography. The number of procedures was dependent on the type of treatment is shown in Table 1. Thermography examinations using a wireless infrared camera and contact thermography was performed according to the instructions for each method.

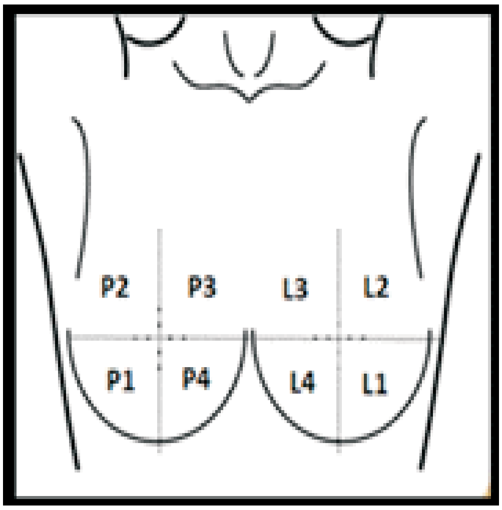

Figure 1
Scheme of the division of the breast surface into quadrants.

Each female, upon removing clothes from the waist up, was asked to remain in a calm, sitting, position for 6 minutes with her arms by her side. Room temperature throughout the examination was consistent and between 20-25°C. Thermography examination using a thermovision camera on the breast surface was performed shortly after the female undressed and again after two, four and six minutes. The examination registered images in each quadrant in both breasts, and noted the average temperature of both breasts using the FLIR system. The examined surface was divide into 4 symmetric quadrants for each breast, analogous to the predefined quadrants used in mammography (figure 1). Contact thermography was performed only after 6 minutes, immediately after the last examination using the thermovision camera. Patients examined only using contact thermography were required to have 6 minutes of acclimatization prior to commencing the examination. During contact thermography, 3 or 5 applications of the thermographic matrices are required on each breast using 3 different matrices with different margins of temperature detection. Matrix temperature detection margins in Celsius include:
no 1: 31,5-32,8; no2: 32,8-34,2; no3: 34,2-35,7.

On the basis of the thermographic images of every patient it was possible to choose the appropriate matrix for each individual.

Results and Discussion

For the thermograms obtained using the thermovision camera, the average temperature of each breast was calculated and segregated according to the groups (Table 2). In the group of women examined only using contact thermography, a suitable matrix was selected for each breast (Table 3). Infrared thermography results revealed that the body surface post mastectomy had a temperature of 1.75°C higher compared to the healthy breast. This difference is also observed in contact thermography where the matrix was different for each breast, meaning a high thermal

Table 1
The characteristics of the number of procedures in examined women according to type of treatment.

	Number of procedures	Liqiud-crystal contact thermography	Liquid-crystal contact and infrared thermography	Age [average]	Radiotherapy treatment
Mastectomy	6	3	3	52	6
Breast reconstruction	2	1	1	47	1
Breast-conserving surgery	8	4	4	53,8	7
Total	16	8	8	52,8	14

Table 2:
Average temperature of eachbreast according to the type of treatment.

Women after mastectomy											
Procedure:	t – 0 min		t – 2 min		t – 4 min		t – 6min		Difference between breasts after 6 min	Breast after tumour removal	Breast recon-struction
	Right	Left	Right	Left	Right	Left	Right	Left			
1	35,07	33,24	34,37	32,71	34,09	32,55	33,98	32,48	1,5	Right	no
2	35,79	33,4	35,38	33,22	35,1	33,03	34,67	32,19	2,48	Right	no
3	35,94	34,02	35,39	34,05	34,95	33,63	34,57	33,29	1,28	Right	no
Average temperature									1,75		
Women after breast-conserving surgery or breast reconstruction											
1	34,4	33,6	33,59	33,46	33,53	33,25	33,5	33,03	0,47	Left	no
2	34,42	34,08	34,22	33,88	34,19	33,81	34,12	33,75	0,37	Right	no
3	33,9	34,45	33,69	34,25	33,56	34,09	33,47	33,93	0,46	Left	no
4	33,74	34,61	33,54	34,21	33,26	34,02	32,87	33,75	0,88	Right	no
5	33,26	33,26	33,28	33,23	33,13	33,24	32,96	32,98	0,02	Left	yes
Average temperature:									0,54		

Table 3: Optimal Liqiud-crystal Matrix for every breast according to type of treatment.

Procedure Number	ID	Type of treatment	Optimal Matrix	Breast after re-move tumor	Reconstruction	
			Right	Left		
1	0010	Mastectomy	2	1	Right	-
2	0014	Mastectomy	1	2	Left	-
3	0015	Mastectomy	1	2	Left	-
4	0003	Mastectomy	2	1	Right	-
5	0004	Mastectomy	2	1	Right	-
6	0008	Mastectomy	2	1	Right	-
7	0012	Mastectomy	1	1	Left	Yes
8	0005	Mastectomy	2	2	Left	Yes
9	0002	Breast-Conserving	2	2	Left	-
n010	0006	Breast-Conserving	2	2	Right	-
11	0007	Breast-Conserving	2	2	Left	-
12	0009	Breast-Conserving	2	2	Right	-
13	0013	Breast-Conserving	2	2	Right	-

asymmetry when comparing both breasts. The results for contact thermography in females after mastectomy without reconstruction reveal incomplete thermal images in the region of the mastectomy, the cause of which is uneven adherence of the matrix to the examined surface. In the group of women after breast-conserving therapy or post breast reconstruction, the average temperature difference between the healthy breast and the cancerous breast is about 0.5 °C. This non-significant tem- perature difference allows us to select one matrix to conduct the examination on both breasts.

Conclusions

The thermal images obtained from thermovision camera and contact thermography show no significant difference in females post breast-conserving surgery or radical mastectomy with reconstruction. Both modalities can be used according to the standard instruction scheme for each examination. Females post cancer treatment using contact thermography pose no technical barriers in performing the examination erroneously, for example, inappropriate application of the matrix or a temperature difference exceeding the margins between both breasts.

Contact thermography in the group of patients after a radical mastectomy without reconstruction is difficult because of incomplete adherence of the liquid crystal matrix to the examined surface as well as high temperature difference between the healthy breast and the breast with scar tissue. Based on this, the goal would be to design a matrix with a wider temperature range and adapting the procedure to improve adherence of the matrix to the skin surface at the site of mastectomy.

Infrared thermography examination could be performed without any hindrance in both groups.

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DIFFERENCES IN SKIN TEMPERATURE BEFORE AND AFTER BRACHYTHERAPY TREATMENT ON BASAL CELL CARCINOMA

Lukasz Kapek[1,2], Agnieszka Cholewka[3], Marta Szlag[3], Piotr Wojcieszek[4], Sylwia Kellas-Sleczka[4], Krzysztof Slosarek[3], Armand Cholewka[1]

[1]A. Chelkowski Institute of Physics, Department of Medical Physics, University of Silesia, 75 Pu?ku Piechoty 1, 41-500 Chorzów, Poland

[2]Department of Medical Physics, Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Wybrzeze Armii Krajowej 15, Gliwice, Poland

[3]Department of Radiotherapy and Brachytherapy Planning, Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Wybrzeze Armii Krajowej 15, Gliwice, Poland

[4]Brachytherapy Department, Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Wybrzeze Armii Krajowej 15, Gliwice, Poland

The goal of this study was to determine temperature changes of the skin lesions and surrounding tissues after high-dose rate brachytherapy. Studied group consisted of 32 patients with confirmed basal cell carcinoma localized on the head area with exception of ears and the corner of the eye. Patients were treated in Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology in Gliwice. The whole treatment cycle consisted of 9 fractions of irradiation where each one delivered 5Gy into tumor area. Patients were treated with the use of either H.A.M. applicator or an individual mold applicator.

Thermal imaging was performed for every patient before starting treatment and one month after the last fraction of treatment. All studies were performed with thermal camera E60 Flir Systems. The localization of lesion for each patient was confirmed taken into account digital picture as well as thermal image. Additional thermal images were taken on the symmetrical healthy side of the head.

Obtained results showed that the difference between mean temperature of lesion and its surrounding before treatment is relevantly higher than one month after the last fraction of treatment. Similar effects were obtained in analyzing data of thermal parameters acquired from area affected by BCC and the symmetrically healthy side.

Such temperature changes suggest that HDR treatment leads to cancer cells necrosis, which might cause slower metabolism. This could be a reason of lower temperature in treated region. Such effects may prove proper radiotherapy effects on tissue and may also point that thermal imaging could be used in brachytherapy effects evaluation.

THE APPLICATIONS OF ACTIVE DYNAMIC THERMOGRAPHY IN TISSUE-LIKE SYSTEMS - SEARCHING FOR MEDICAL APPLICATIONS

Teresa Kasprzyk[1], Blazej Mleczko[1], Tomasz Winiarz[1], Agata Stanek[2], Armand Cholewka[1]

1 A. Chlkowski Institute of Physics, Department of Medical Physics, University of Silesia, Uniwersytecka 4, 40-007 Katowice, Poland

2 School of Medicine with the Division of Dentistry in Zabrze, Department and Clinic of Internal Diseases, Angiology and Physical Medicine in Bytom, Medical University of Silesia, Batorego Street 15, 41-902 Bytom, Poland

3 School of Health Sciences in Katowice, Department of Physical Medicine, Chair of Physiotherapy, Medical University of Silesia, Medyków Street 12, 40-752 Katowice, Poland

The Active Dynamic Thermography (ADT) can be defined as a measurement of infrared body irradiation after some thermal or energetic stimulus application. ADT may be useful in analyzing of inner body structure. Interior material layers and defects changes influence the heat transport inside. In fact, mentioned inhomogeneities can be captured on the surface as a resulting thermal map (in fact it is parameter's image) due to thermal response of the object.

The aim of this study was to use Active Dynamic Thermography in tissue-like systems to check the possibility of non-invasive defects detection. Measurements were made on various sizes at different depths plasticine cubes embedded in silicone or gelatin form.

There were three platicine "defects" arranged side by side, at a different depths: 1mm, 5mm, 10mm in the phantom. All dimensions of the defects were measured. For measurement ten phantoms were used. A halogen lamp was used as a excitation source. Time of excitation was set at different periods of time to find the best accuracy of the method.

Performed study have shown that generally the accuracy ADT decreases with the depth of the defects in the phantom. However, the highest accuracy can be obtained in the study of defects submerged in phantoms up to 5mm and the sharpest images were captured simultaneously the dimensions obtained from the ADT were closest to the defects dimensions.

The results suggests that ADT may be useful in medicine to detect only subcutaneous lesions. However, further measurements are necessary to check and confirm the obtained results.

COMPARISON OF THERMAL EFFECTS OF HOT STONE, RUBBER CUP, AND CLASSICAL MASSAGE

Dariusz Boguszewski, Jakub Grzegorz Adamczyk, Dariusz Bialoszewski

Rehabilitation Department, Medical University of Warsaw, Poland

INTRODUCTION. Dynamic development of manual treatments make the necessity to look for indicators to achieve information about therapies, because empirical evidences of effects of new methods (like hot stone and rubber cup massages) are insufficient.

AIM. The aim of the study was to determine the thermal effects of three types of massages (hot stone, rubber cup and classical).

MATERIAL AND METHODS. 89 women and men, aged 19-23 (randomly divided into three groups) participated of the research. Volunteers from the first group were subjected to hot stone massage, from second groups - rubber cup massage, and from third group classical (Swedish) massage of back. All treatments lasts 20 minutes. Prior to performing the massage, a Flir A325 thermographic camera was for thermal imagining of back surface on all subjects. Furthermore heart rate, arterial blood pressure was measured (with a medical sphygmomanometer Omrom M6 Comfort), and a Thomayer test (to determine the flexibility of back muscles) was performed. All measurements were repeated after the massage. The thermal imagining were also repeated 5, 10 and 20 minutes after treatment. The significance of differences between the results of measurements were determined with the Wilcoxon signed-rank test. The minimal level of significance was assumed at p?0.05.

RESULTS. Directly after the massage temperature of surface was significant higher ($p<0.001$) in all groups. The highest temperature was noted after hot stone massage. The thermal effect lasted the longest in the group massaged by stones. After 20 minutes the temperature was significant higher than in the first measurement ($p<0.01$). There were not significant differences between the temperature of back surface after rubber cup and classical massages. Cardiac parameters were similar in all groups. Classical massage was the most effective in improving flexibility of back muscles ($p<0.001$)

CONCLUSIONS. After all massages, higher temperature was recorded up to 20 minutes after the procedure, which may indicate an extended massage effect. Hot stone massage caused the highest temperature increase. It may be the result of the specific properties of basalt stones used in massage.

EVALUATION OF RECOVERY EFFECT OF FOAM ROLLING MASSAGE WITH TWO DIFFERENT TYPES OF ROLLER

Jakub Grzegorz Adamczyk[1,2], Dariusz Boguszewski[1], Dariusz Bialoszewski[1]

1.Rehabilitation Department, Physiotherapy Division, Madical University of Warsaw

2. Department of The-ory of Sport, Józef Pilsudski University of Physical Education in Poland

INTRODUCTION: Foam rolling aims to enhance the recovery through mechanical impact on muscle and skin. However potential differences of treatment between different types of roller are not well known.

Aim. This study was designer to evaluate the effectiveness of foam roller massage with smooth or ribbed surface in supporting post exercise recovery, skin temperature and potential benefit to preventing DOMS.

MATERIAL AND METHODS. The research encompassed 33 male subjects divided into three groups of eleven depending on the form of recovery: foam rolling by smooth (STH) or ribbed (RBD) roller or passive recovery (PAS). All the participants were asked to jump as high as possible from a full squat for one minute. Blood lactate level (LA) was measured and thermal imaging (Tsk) was conducted at rest, immediately following the exercise, following the recovery treatment (only IR), and after 30min of rest. Participants pain levels were assessed using the Visual Analogue Scale (VAS).

RESULTS. After applying the selected method for supporting recovery, the LA level decreased by 4.71 mmol/L in the STH group, and by 4.55 mmol/L in the RBD group (STH vs.RBD $p>0.05$). The 2.32 mmol/L decrease in LA concentration in the PAS group was significantly lower than in the other groups (STHvs.PAS $p<0.01$ / RBDvs.PAS $p<0.01$). In all groups, Tsk after 30min return to resting values (?Tsk<0.15 °C $p>0.05$). Time of 96 h after the trial was only moment when occurred significant differences in VAS between PAS and groups with foam rolling treatment.

CONCLUSION. Foam rolling massage has a positive effect on regeneration after anaerobic exercise but the type of the roller doesn't improve recovery rate.

CAPSAICIN EFFECTS MEASURED BY INFRARED THERMOGRAPHY

J. Pokorna, E. Staffa, V. Bernard, V. Mornstein

Department of Biophysics, Medical Faculty, Masaryk University, Brno, Czech Republic

INTRODUCTION: Capsaicin is the main irritant component in chilli peppers. Chemically, it is considered to be an alkylamide. There are proofs of the capsaicin analgesic properties, as well as other properties such as the adjuvant healing effect in control of peripheral nerve pain and to help to reduce side effects of chemotherapy and radiotherapy. Because of the irritant effects of the capsaicin, it affects body temperature. Our research is aimed to specify what is its specific effect to facial and neck temperature.

METHODS: For the measurement, Workswell WIC 640 infrared camera was used to obtain temperature distribution images. It is a LWIR camera with uncooled VOx microbolometer.

Facial and neck temperatures were measured before and after ingestion of about teaspoonful of Jalapeño chilli pepper extract (1.17 grams) of 6.000 - 8.000 SHU, which is a quite slightly irritant form. Measurement was performed for 2 minutes 30 seconds for 12 people (4 males and 8 females) aged 20-30 years.

RESULTS: It is possible to conclude, that individual physiology and psychology of volunteers participating in the study has great influence on the obtained results. The temperature increase of different parts of the face depends on many factors that are influenced by the individualities of the volunteers. Normally, the temperature change is observable almost immediately after ingestion of the Jalapeño chilli pepper extract. Temperature rise was observed between 1 - 2°C in oral region, between 0 - 1,5°C in frontal region, between 0 - 1°C in canthi, and 1 - 0,9°C in the neck region after 2 minutes.

Based on the study, it was confirmed there is an obvious relation between the temperature rise and subjective perception of the hot taste. It can be said, that subjective affection to the hot taste correlates with the slower and moderate growth of the facial temperature.

CONCLUSION: To summarise our results, capsaicin affects surface body temperature but in very individual way. The temperature rise is probably caused by a psychosomatic reaction - brain gives a signal for vasodilatation in the specific body region. Using the appropriate amount of capsaicin can be helpful in medicine but we must consider individual variability of physiological reactions to this irritant substance.

EVALUATION OF HYPERBARIC OXYGEN THERAPY EFFECTS IN HARD-TO-HEAL WOUNDS STUDIED BY THERMAL IMAGING AND PLANIMETRY

Beata Englisz [1], Armand Cholewka[1], Ewa Firganek [1], Grzegorz Knefel [2], Grzegorz Liszka [1], Marek Kawecki [2], Mariusz Nowak [2], Siern Karolina[3], Agata Stanek [4]

[1] A. Chelkowski Institute of Physics, University of Silesia, Uniwersytecka 4, 40-007 Katowice

2. Burn Treatment Center Siemianowice Slaskie, Chair and Clinic of General Vascular and Transplanting Surgery, Silesian Medical University, Poland

3School of Health Sciences in Katowice, Department of Physical Medicine, Chair of Physiotherapy, Medical University of Silesia, Medyków Street 12, 40-752 Katowice, Poland

4 School of Medicine with the Division of Dentistry in Zabrze, Department and Clinic of Internal Diseases, Angiology and Physical Medicine in Bytom, Medical University of Silesia, Batorego Street 15, 41-902 Bytom, Poland

The aim of the study was to compare the planimetry parameters obtained from Ecare device and thermal parameters derived from thermal images in patients with hard-to-heal wounds treated by hyperbaric oxygen therapy.

The studies were carried out at the Burn Treatment Center in Siemianowice Slaskie. The research group consisted of 60 patients (28 women and 32 men) in the age of 65 ± 17, suffering from hard to heal wounds placed in the lower extremities (cruras). Each patient underwent 30 treatments in a hyperbaric chamber, where a single session lasted 86 minutes.

Thermal imaging was performed each time before and immediately after a single session of oxygen therapy.

Otained results were analyzed both taking into account individual sessions in the hyperbaric chamber as well as the full course of treatment, grouping the results of patients in individual periods of the whole cycle: first part of treatment (0-10 treatments) - period I, second part (11-20) - II and the third part of treatment (21-30) - period III.

The results showed differences between parameters obtained from planimetric and thermal measurements. Studies confirmed that structural changes of the skin surface seen in planimetric analysis correlated with functional/thermal parameters may be can give important information not only in the assessment of treatment effects, but perhaps in the patients qualification for this type of therapy.

This study is a further approximation towards the description of a new diagnostic device that uses and correlates several imaging techniques that could be used in evaluation of wounds diagnosis as well as therapy effects, giving the physician not only qualitative but also objective, quantitative information in the form of planimetric and thermal parameters.

THE APPLICATIONS OF THERMAL IMAGING IN THIRD MOLAR TEETH SURGICAL EXTRACTION

Teresa Kasprzyk[1,] Karolina Balamut[1], Agata Stanek[2], Karolina Sieron[3], Michal Kaszuba[4], Ewelina Kopczynska[4], Armand Cholewka[1], Tadeusz Morawiec[4]

1 A. Chelkowski Institute of Physics, Department of Medical Physics, University of Silesia, Uniwersytecka 4, 40-007 Katowice, Poland

2 School of Medicine with the Division of Dentistry in Zabrze, Department and Clinic of Internal Diseases, Angiology and Physical Medicine in Bytom, Medical University of Silesia, Batorego Street 15, 41-902 Bytom

3 School of Health Sciences in Katowice, Department of Physical Medicine, Chair of Physiotherapy, Medical University of Silesia, Medyków Street 12, 40-752 Katowice, Poland

4 Institute of Stomatology in Katowice,Labedzia 2, 40-534 Katowice, Poland

5 Department of Oral Surgery, School of Medicine with the Division of Dentistry in Zabrze, Medical University of Silesia in Katowice,Plac Akademicki 17, 41-902 Bytom, Poland

The changes of given body surface temperature observed in a short period of time or occurrence of a large thermal asymmetry in relation to the opposite area may indicate irregularities in the production and emission of heat, and thus the disease of a given organ. Therefore, thermal imaging can carry a lot of information related to the metabolic activity of subcutaneous tissues and can be used not only in diagnostics but also in the study of therapeutic effects in some treatment techniques.

The aim of the study was to determine the possibility of using thermovision in dentistry. An attempt was made to use thermal imaging in assessing inflammation in dentistry as well as in observation of tissue repair processes after surgical tooth extraction.

Twenty-five patients participated in the study. They underwent surgical ablation of the third molar teeth. Thermal imaging was performed before and after the treatment, on the first, fourth and seventh day after the procedure. It should also be noted that the healthy side of the face has been imaged as the control area.

Obtained results shown differences in temperature changes during healing time. It was connected with changes in metabolically activity of tissues what occurred during the regeneration processes.

Performed studies suggest that thermal imaging may be useful in some dentistry procedures by giving the dentists additional information about functional/metabolically changes in the tissues.

THERMOGRAPHIC ASSESSMENT OF THE FLOW RUNNING OF TREATMENTS IN INVASIVE AESTHETIC MEDICINE WITH INTERRUPTION OF SKIN COATINGS

Karwowski W. [1]

[1].Departments of Mea-surement and Electronics.of Faculty of Electrical Engineering, Automatics, Computer Science and Biomedical Engineering AGH in Krakow, Poland.

INTRODUCTION: A large part of the services provided by the so-called Aesthetic medicine are treatments that result in the break of the skin's continuity. Each such event is accompanied by the induction of inflammation. There are often various complications. Treatments are often combined.

On the other hand, skin products are used to prepare the skin and cache the course of inflammation and prevent complications.

Combining one and the other is often accidental and more driven by the marketing pressure of the market and the style of being than the real needs of the patient.

It is also difficult to determine how much number of imaging will have to be done in order to be able to determine repeating trends, although the results of some cases have proved surprising.

AIM: The aim of the work is to use thermographic imaging to show efficacy or lack of it when applying the most annoying solutions from the side of invasive surgery or combining these treatments with other, most often exfoliants. Also demonstrating the effectiveness or lack thereof regarding the use of the most popular buffering substances in combining them after skin pricking procedures.

METHOD: Thermographic imaging was performed in several basic types of treatments related to skin pricking. The Flir One Pro portable cameras were used for this purpose due to easy manipulation (access to the surgical site in a short time) and mobility.

Imaging was performed before the beginning of the procedure, after the execution, and after the application of various types of substances. Also before and after the initial use of various exfoliants (acids and alkalis).

RESULTS:Imaging demonstrated high invasiveness of the treatments - inflammation was extensive and often led to complications in the form of temperature changes in places that were not directly the treatment area.

On the other hand, it showed the absolute necessity of using buffering preparations, which manifested itself in the faster return of temperature areas to the norm.

It is also difficult to determine how many images will have to be made to be able to determine trends, although the results of some cases, as mentioned, have been surprising, demonstrating the usefulness of this imaging technique.