THERMOELECTRIC PRODUCTS

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THERMOMETRIC INDICATORS IN PATIENTS WITH CHRONIC LOWER BACK PAIN

The paper presents the results of the development of a thermoelectric device for the diagnosis of inflammatory processes and pain syndrome in degenerative-dystrophic diseases of the lumbosacral spine. Such a device makes it possible to store, process and visualize measurement results in real time. The results of preliminary clinical trials are presented, in particular, the determination of thermometric indicators in the lumbosacral region of the spine in persons with chronic pain syndrome against the background of degenerative-dystrophic pathology of the spine in the presence of hernias and protrusions of intervertebral discs. The effectiveness of using the proposed thermoelectric device in medical practice has been confirmed. Bibl. 33, Fig. 2, Tabl. 3.

Key words: heat flux density, temperature, thermometric indicators, spinal osteochondrosis, thermoelectric device.

Introduction

General characterization of the problem. Degenerative-dystrophic pathologies of the spine and their neurological manifestations are one of the urgent problems of modern medicine. This is due to the wide prevalence of pathology in the active working age, the frequent predisposition of the disease to a stable and prolonged course, the steady progression of the number of such patients with age. An important place in this list is occupied by neurological manifestations of osteochondrosis of the lumbar spine, which account for 60-70 % of all diseases of the peripheral nervous system and are the cause of more than 70 % of cases of temporary disability. The prevalence of this pathology in Ukraine is 10 thousand people per 100 thousand population. It should be noted that many aspects of this pathology

have not yet been studied, modern methods of diagnosis and treatment of this disease need further improvement [1-5].

The Institute of Traumatology and Orthopedics of the National Academy of Medical Sciences of Ukraine has established [6-10] that determining the pathophysiological mechanisms of back pain based on clinical and paraclinical methods of examination of the patient is the main step towards prescribing the most effective and safe therapy and predicting the disease. The most common cause of low back pain is a herniated disc – a disease of the musculoskeletal system which occurs due to rupture of the fibrous ring (upper disc) and squeezing out the pulpal ring (inner part of the disc). The main clinical signs of intervertebral disc herniation can be manifested alone or in combination with the following syndromes: local pain (lumbar pain), reflected pain (lumbosciatica), radicular syndrome (radiculopathy), spinal cord injury syndrome (myelopathy).

The development of modern diagnostic methods, such as magnetic resonance imaging, computed tomography, makes it possible to determine the level, localization of hernia or protrusion of the intervertebral disc. Today there are already many works [11-13], which showed the absence of a direct relationship between the presence or severity of degenerative-dystrophic changes in the spine and the presence or intensity of pain in the back. That is, there is an urgent problem of studying other peripheral mechanisms that cause back pain. The mechanisms of back pain in the first hours/days of its occurrence in degenerative-dystrophic pathology of the spine, especially in its lumbosacral region, which is most common in the clinical practice of neurologist and orthopedist, have not been studied at all. Medical practice also requires the introduction of new highly informative, portable devices for functional diagnostics, which would allow in the first hours/days to reveal the nature of neurological damage in degenerative-dystrophic pathology of the spine and assess the degree of pain in this pathology [14-17].

Semiconductor thermoelectric heat flux sensors [18-27], which combine miniature size, high sensitivity, stability of parameters in a wide range of operating temperatures and are consistent with modern recording equipment [28-31], are promising for the study of local human heat release. Use of such sensors allows one to achieve high locality and accuracy of thermometric measurements. This, in turn, makes it possible to obtain information about the characteristics of objects under study and analyze them in detail in order to identify in the early stages the inflammatory processes in the human body.

Therefore, *the purpose of this work* is to study the thermometric indicators in patients with chronic low back pain using a thermoelectric device for the diagnosis of inflammatory processes and pain in degenerative-dystrophic diseases of the lumbosacral spine.

Design and technical characteristics of the device

The Institute of Thermoelectricity of the National Academy of Sciences and the Ministry of Education and Science of Ukraine has developed a thermoelectric device for diagnosing inflammatory processes and pain in degenerative-dystrophic diseases of the lumbosacral spine [32, 33] (Fig. 1). Technical characteristics of the device are given in Table 1.

The device comprises control unit 1 and thermoelectric temperature and heat flux sensors 2. Temperature and heat flux density are measured simultaneously by two thermoelectric sensors with recording of measurement results on a MicroSD memory card and computer display on a personal computer (PC). Special computer program "TermoMonitor" was also developed to process measurement results, their accumulation and reproduction in a given form on a PC.



Fig. 1. Thermoelectric device for diagnosing inflammatory processes and pain degenerative-dystrophic diseases of human lumbosacral spine: 1-control unit, 2-thermoelectric temperature and heat flux sensor

Technical characteristics of the device

<u>Table</u>	1

No	Technical characteristics	Parameter values
1.	Heat flux density measurement range	$(1 \div 100) \text{ mW/cm}^2$
2.	Maximum error in measuring heat flux density	5 %
3.	Operating temperature range of thermoelectric sensor	(0 ÷ +50) °C
4.	Temperature measurement accuracy	± 0.1 °C
5.	Number of thermoelectric sensors	2
6.	Overall dimensions of thermoelectric sensor	$(14 \times 14 \times 3)$ mm
7.	Thermoelectric sensor weight	0.020 kg
8.	Overall dimensions of control unit	$(90 \times 55 \times 25) \text{ mm}$
9.	Device weight	0.150 kg
10.	Time of continuous operation of the device	48 hours

The operating principle of the device consists in converting the heat flux and temperature of the human body using two thermoelectric heat flux density and temperature sensors into equivalent electrical signals, which are shown on the digital display of the control unit in units of heat flux density (mW/cm^2) and temperature $(^{\circ}C)$.

On the upper wall there are two connectors for thermoelectric temperature and heat flux sensors and a power button. On the right side wall there is a slot for a microSD memory card and a miniUSB-connector for connecting the device to a PC. The device battery is also powered via the miniUSB connector.

Mounted on the front wall of the case is a liquid crystal display, which displays the values of the heat flux density of the relevant parts of the human body and the temperature values in the form of graphs. Thus, the obtained measurement results can be analyzed directly from the graphs shown on the display. The presence of two thermoelectric sensors in the device at the same time allows one to compare the results of measuring the sick and healthy parts of the human body surface.

In addition, on the front wall of the device there are 6 buttons to control the operation of the device – "LEFT", "RIGHT", "UP", "DOWN", "OK", "MENU". The purpose of the "MENU" items of the device is as follows:

- "START RECORDING" / "STOP RECORDING" the device starts recording the measurement results in a new file, stops the corresponding recording and saves the information on the memory card:
- "MODE SELECTION" calls the sub-menu to select one of 9 modes of displaying information in the form of real-time graphs;
- "RECORDING PERIOD" is used to select the period of time after which the measured results will be recorded in a file on a memory card and shown on the display of the device;
- "TIME/DATE" switch to time and date setting mode;
- "BATTERY" displays the voltage on the battery of the device;
- "HELP" displays information about the device.

The block-diagram of the device (Fig. 2) consists of the following functional units: thermoelectric heat flux sensor with built-in temperature sensor, analog-to-digital converter (ADC) for converting analog sensor signals to digital, multiplexer for switching digital signals from ADC and their alternate transmission to microcontroller. It is used for processing digital signals, their storage on a memory card, graphical visualization of information on the display and PC.

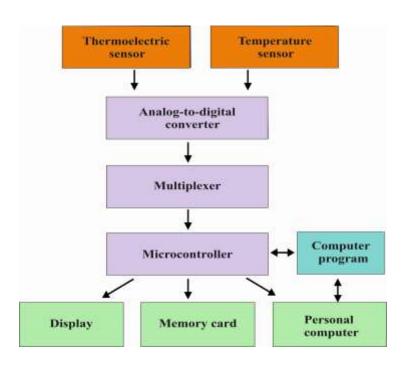


Fig. 2. Block-diagram of thermoelectric device

The main functional unit of the control unit is a microcontroller that operates at a frequency of up to 20 MHz and provides a high speed of processing signals from thermoelectric temperature and heat flux

sensor. Personal computer helps to program the microcontroller, which, in turn, controls the work of other functional units of the device.

The device contains its own power supply in order to be able to use it offline with a patient. This, in turn, allows one to expand the functionality of the device. The device is powered by a lithium-ion battery with a capacity of 1200mA/h, which provides 48 hours of continuous operation of the device.

Methods of clinical trials

The purpose of preliminary clinical trials was to investigate thermometric parameters in patients with chronic low back pain using a thermoelectric device to diagnose inflammation and pain in degenerative-dystrophic diseases of the lumbosacral spine, and to confirm the effectiveness of such a device in medical practice. Clinical trials were conducted in the laboratory of neuro-orthopedics and pain problems and in the rehabilitation department of the Institute of Traumatology and Orthopedics of the National Academy of Medical Sciences of Ukraine.

This study included 55 patients with chronic lumbosacral pain. The pain was constant, radiated to one of the lower extremities, significantly limited their daily activities and intensified at night. Along with the use of nonsteroidal anti-inflammatory drugs, patients were forced to use anticonvulsants and antidepressants. The duration of the disease was 1-5 years. Age of patients: 49 ± 3.5 years. All patients were divided into two clinical groups.

Clinical group I included 39 people with unilateral lumbosciatica in the presence of hernias and protrusions of intervertebral discs with signs of linear instability of the lumbosacral spine, which were subject to conservative treatment (main group).

Clinical group II included 16 patients with unilateral lumbosciatica with hernias and protrusions of intervertebral discs without signs of linear instability of the lumbosacral spine, which were also subject to conservative treatment (comparison group).

The control group consisted of 10 people with no pain, in the presence of hernias and protrusions of the intervertebral discs, without signs of linear instability of the lumbosacral spine.

In all patients, the level of pain intensity was assessed using a verbal-analog scale (VAS). We used a scale of 100 mm length with millimeter divisions, which additionally every 20 mm contains words that characterize the intensity of pain: 0 – means no pain (starting point of the line), 20 mm – corresponds to the descriptor "weak", 40 mm – "moderate", 60 mm – "strong", 80 mm – "extremely strong", 100 mm – "intolerable" (end point of the line). The intensity of pain was estimated in millimeters [10].

In the room where the examination was carried out, the temperature was constantly maintained in the range of 20 - 22 °C and the relative humidity of 50 - 60 %. On the eve of the examination, the patients were canceled all physiotherapeutic and warming procedures, as well as anti-inflammatory, antipyretic, sudinosilicidal or vasoconstrictive medications. Patients had to stop smoking 3 - 4 hours before the examination, patients were removed from various ointment applications and the skin surface was degreased with a mixture of 40 % ethyl alcohol and ether (in a ratio of 4:1). Immediately before the examination, patients underwent temperature adaptation for 15 - 20 minutes. At this time, they were at rest, without static and dynamic muscle tension. The measurement of thermometric parameters from the patient's skin surface was carried out in real time for 3 min. using the above thermoelectric device. During the measurements, the time of thermal adaptation (in seconds) was recorded – t (the time from the beginning of the examination until the main parameters of the device reached "saturation"), the temperature and heat flux density at "saturation". Thermoelectric sensors were applied in the spine region symmetrically on both sides paravertebrally at the level of the spinous processes of the $L_4 - L_5$ vertebrae. In addition to measuring thermometric parameters, heart rate variability was

determined simultaneously, as both of these parameters are regulated by the autonomic nervous system, and the main centres of regulation of heat exchange and vascular tone are located nearby in the brain stem.

Spectral analysis of the heart rhythm made it possible to identify high-frequency respiratory waves (HF – high frequency), reflecting the tone of the parasympathetic nervous system, low-frequency waves (LF – low frequency), reflecting the state of segmental baroreflex regulatory sympathetic mechanisms and very low-frequency slow waves (VLF), reflecting the degree of activation of cerebral ergotropic systems. Additionally, time characteristics were also analyzed: for the parasympathetic nervous system (RMSSD and Pnn 50 %), sympathetic nervous system (SDNN), cerebral metabolic fluctuations (SDANN), and the ratio of autonomic balance was determined by the formula of this ratio LF/HF. The obtained results were processed using the computer software package STATISTIKA 6.0.

Results of preliminary clinical trials

Patients of clinical group I complained of heartburn and pain in the lower back, lower extremities, trophic disorders. Their backs were fixed in a bent position. Unilateral tension symptoms were positive, and 23 % of patients had the overlapping Lasegue sign. There was also a decrease in the volume of movements in the lumbar spine, lumbar muscle tension, pain on palpation and percussion of the paravertebral points, a sharp restriction of inclinations towards the lesion. In the supine position and with bent lower limbs in the hip joints, the pain decreased. The pain was pulling in nature, accompanied by numbness and running creeps in the lower extremities. The skin was pale, cold to the touch, dry with signs of hyperkeratosis. White dermographism was noted. The severity of the pain syndrome on the VAS scale was 76.2 ± 4.1 mm.

In persons of clinical group II, the pain was also unilateral, sometimes at night it tended to be bilateral, increased with flexion or extension of the spine and prolonged sitting, decreased at rest. Movements in the lumbar spine were not limited, but painful, especially when bending. At a symptom of a tension there was a back pain. Pale skin, burning sensation, distension, asymmetry of white and red dermographism in the lower extremities were noted. Cyanosis, "marbling" of skin, mainly in feet was noted. Concomitant diseases were detected: varicose veins of the lower extremities and hemorrhoidal veins, which indicated systemic weakness of the venous apparatus. The intensity of the pain syndrome on the VAS scale was 49.4 ± 3.9 mm.

In the control group (10 persons), uniform indicators of temperature and heat flux density were recorded on both sides within the range: $T_0 = 33.2 \pm 0.5$ °C, $q_0 = 171.3 \pm 0.6$ mW/cm².

In the main group I (39 people) there was a symptom of "scissors" on the pain side (intersecting temperature and heat flux density on the pain side), with a significant decrease in heat flux density and a moderate increase in temperature on the injured side. Indicators of temperature in the paravertebral region on the pain side were $T_I = 34.2 \pm 1.7$ °C, and heat flux density $q_I = 26.8 \pm 4.9$ mW/cm² (Table 2). In our opinion, the appearance of the scissors symptom in the examined individuals can be explained based on the well-known experimental studies of P. Veselovsky (1982), who found that when the peripheral nerve fiber is damaged, cold receptors, which are 2-2.5 times more numerous than thermal, are the first to suffer.

In comparison group II (16 people), a moderate decrease in the heat flux density and a slight increase in temperature on the pain side were revealed. The main thermometric parameters are as follows: $T_2 = 39.8 \pm 6.3$ °C, $q_2 = 120.6 \pm 99.2$ mW/cm² (Table 3).

The analysis of the obtained results showed that in persons of the main and clinical group the severity of long-term chronic pain process is due to the high degree of activity of metabolic processes both at the cellular level and at the level of cerebral ergotropic systems; there is a relative activation of both sympathetic and parasympathetic autonomic nervous system. In addition, a balanced combination of drugs helped to maintain a balanced autonomic balance between the sympathetic and parasympathetic nervous systems.

 $\underline{\textit{Table 2}}$ Parameters of spectral and time characteristics of vegetovascular reactions in group I

N = 39	$M\pm m$	$T_1 = 34.2 \pm 1.7 ^{\circ}\text{C}$	$q_1 = 26.8 \pm 4.9$ mW/cm^2
		Correlation ratio, r	
Indicators (spectral characteristics)			
VLF, ms ²	13768.07±7361.08	0.65	0.28
LF, ms ²	23417.68±14962.65	0.76	0.37
HF, ms ²	32919.18±21321.92	0.84	0.44
LF/HF, conventional units	2.01±0.55	- 0.15	0
LFn, %	54.86±4.37	- 0.2	- 0.3
HFn, %	45.14±4.37	0.2	0.3
Indicators (time characteristics)			
SDNN, ms	156.11±61.38	0.76	0.41
Pnn 50, %	18.35±7.01	0.65	0.57
RMSSD, ms	186.58±86.67	0.81	0.46

<u>Table 3</u>
Parameters of spectral and time characteristics of vegetovascular reactions in group II

N = 16	$M\pm m$	$T_2 = 39.8 \pm 6.3 ^{\circ}\text{C}$	$q_2 = 120.6 \pm 99.2$ mW/cm ²
		Correlation ratio, r	
Indicators (spectral characteristics)			
VLF, ms ²	21608.2±11315.41	- 0.09	- 0.10
LF, ms ²	60093.9±31361.08	- 0.06	- 0.11
HF, ms ²	114969.2±60523.87	- 0.07	- 0.10
LF/HF,	1.0±0.37	- 0.13	- 0.14
conventional units	1.0±0.57	0.13	0.11
LFn, %	37.4±3.57	- 0.17	- 0.28
HFn, %	60.5±3.72	0.21	0.30
Indicators (time characteristics)			
SDNN, ms	287.5±108.02	- 0.02	- 0.06
Pnn 50, %	54.0±22.07	0.08	- 0.08
RMSSD, ms	383.7±153.47	- 0.02	- 0.04

According to correlation analysis, in patients of clinical group I a high degree of correlation with the indicators of skin temperature fluctuations in the superficial paravertebral areas in the lumbar region was recorded. A high degree of correlation was also observed when measuring the heat flux density. However, these correlative changes indicated that patients undergo more significant changes in the deep nervous processes with a tendency to predominant activity of the parasympathetic part of the nervous system.

This was indicated by the ratio of the LF/HF coefficient, when a high correlation was found between this indicator and the heat flux density; the reliability was p < 0.05.

In the comparison group (clinical group II), all negative weak correlations between the heat flux density and heart rate variability were found, except for the HFn indicator, which also indicated the role of parasympathetic reactions in the formation of heat flux density indicators in patients with signs of lumboischialgia in the absence of linear instability in lumbar spine.

Thus, preliminary clinical trials provide an opportunity to diagnose inflammatory processes, in particular in the neurological manifestations of spinal osteochondrosis, and to monitor the effectiveness of conservative treatment in degenerative-dystrophic diseases of the lumbosacral spine.

Thus, the statistical set of clinical material will improve the method of automatic processing of the results, which in the future will introduce the proposed thermoelectric device in the primary care at the level of family doctor's office and automatically diagnose people with neurological vertebrogenic disorders without costly diagnostics.

Conclusions

- 1. A thermoelectric device for the diagnosis of inflammatory processes and pain syndrome in degenerative-dystrophic diseases of the lumbosacral spine has been developed and manufactured. Such a device makes it possible to store, process and visualize measurement results in real time.
- 2. On the basis of preliminary clinical trials it was established that determination of thermometric parameters in the lumbosacral region of the spine in persons with chronic pain syndrome against the background of degenerative-dystrophic pathology of the spine in the presence of hernias and protrusions of intervertebral discs makes it possible to improve the diagnosis of neurological manifestations of this pathology, to predict the course of this disease and choose an effective method of treatment.
- 3. The efficiency of using the proposed thermoelectric device in medical practice has been confirmed, which, in the future, at the level of a family doctor's office, will automatically make a diagnosis for persons with neurological vertebrogenic disorders without the use of expensive radiation diagnostic devices.

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ТЕПЛОМЕТРИЧНІ ПОКАЗНИКИ У ПАЦІЄНТІВ З ХРОНІЧНИМ БОЛЕМ У ПОПЕРЕКУ

У роботі наведено результати розробки термоелектричного приладу для діагностики запальних процесів та больового синдрому при дегенеративно-дистрофічних захворюваннях поперековокрижового відділу хребта. Такий прилад дає можливість збереження, обробки і візуалізації результатів вимірювань у режимі реального часу. Наведено результати попередніх клінічних досліджень, зокрема визначення теплометричних показників у попереково-крижовій ділянці хребта у осіб з хронічним больовим синдромом на фоні дегенеративно-дистрофічної патології хребта за наявності гриж і протрузій міжхребцевих дисків. Підтверджено ефективність застосування запропонованого термоелектричного приладу у медичній практиці. Бібл. 33, рис. 2, табл. 3.

Ключові слова: густина теплового потоку, температура, теплометричні показники, остеохондроз хребта, термоелектричний прилад.

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ТЕПЛОМЕТРИЧЕСКИЕ ПОКАЗАТЕЛИ У ПАЦИЕНТОВ С ХРОНИЧЕСКОЙ БОЛЬЮ В ПОЯСНИЦЕ

В работе приведены результаты разработки термоэлектрического прибора для диагностики воспалительных процессов и болевого синдрома при дегенеративно-дистрофических заболеваниях пояснично-крестцового отдела позвоночника. Такой прибор дает возможность хранения, обработки и визуализации результатов измерений в режиме реального времени. Приведены результаты предыдущих клинических исследований, в частности определение теплометрических показателей в пояснично-крестцовой области позвоночника у лиц с хроническим болевым синдромом на фоне дегенеративно-дистрофических патологий позвоночника при наличии грыж и протрузий межпозвонковых дисков. Подтверждена эффективность применения предложенного термоэлектрического устройства в медицинской практике. Библ. 33, рис. 2, табл. 3.

Ключевые слова: плотность теплового потока, температура, теплометрические показатели, остеохондроз позвоночника, термоэлектрический прибор.

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