IMPEDANCE THERAPY
IN THE REHABILITATION OF DEGENERATIVE SPINE DISEASE

Randomised clinical trial

The right way to a healthy spine

- method of intervertebral disc growth using impedance therapy
- method of treating degenerative spine disease

A new strategy for treating degenerative spine disease is based on the application of electrical impulses: SEI in combination with dry needle therapy.

MUDr. Pavol Kostka

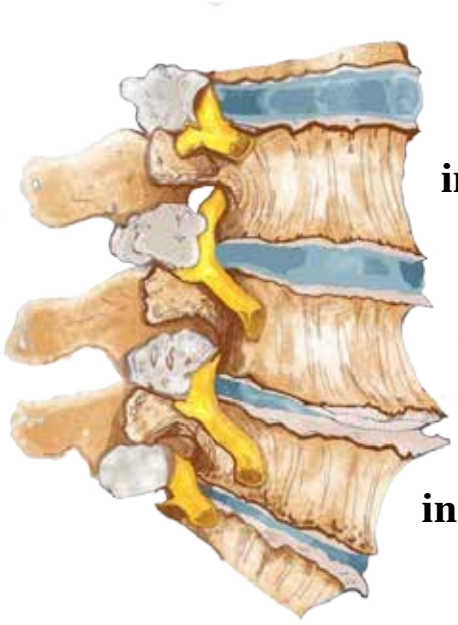
Impedance Therapy is a revolutionary method, unique throughout the world, of treating Degenerative Disc Disease (DDD), which gives patients chronic neck pain or pain in the small of the back, a feeling of numbness, weakness and pulsating pain in the arms and feet (radicular pain).

The wear of the axial skeleton often begins with a non-infectious disease of the intervertebral discs. Because of various internal or external factors, they lose their function – they lose the ability to bind water and so dry out, changing their shape, strength and flexibility, which negatively affects the health and physiological processes of the whole body. Such changes cause nerve end irritation, acute pain and even immobility.

Impedance therapy heals damaged discs, increasing their volume and restoring their structure.

The added value is regeneration of the whole body. Cured patients prove that only impedance therapy cures patients with DDD as a disease of modern civilisation. In fact, standard medical or non-medical procedures are not able to eliminate degenerative changes in the intervertebral discs.

The uniqueness of our treatment process has been confirmed by controlled results of imaging examinations (MRI) and the objective conclusions of radiologists.



healthy intervertebral disc

damaged intervertebral disc

Patients affected by DDD represent a significant health, economic and social problem in all countries of the world. Diagnosis and treatment of the spine require a team approach involving a general practitioner, neurologist, neuroradiologist, neurosurgeon, algesiologist and physiotherapist. Rapid identification of the source of pain is important. However, its severity and dynamics are often misrepresented by the difference between the findings obtained using imaging methods (MRI, CT) and clinical findings, and structural changes are not always causally related to clinical symptomatology.

Diagnostic errors are a common cause of conservative or surgical treatment failure. This may result in patient disability.

When applying impedance therapy, you will be impressed by its unambiguous parameterisation model and the process of active control of the electrotherapy process. Based on the amount of experience and the underlying DDD, we are able to offer the patient a response to the therapy's success as early as during the actual process. After successful impedance therapy, the patient's body can deliver an optimal performance that matches their physical age.

If you are interested in receiving treatment or would like more information, please contact: Klinika impedančnej terapie s.r.o., www.liecbaplatniciek.sk

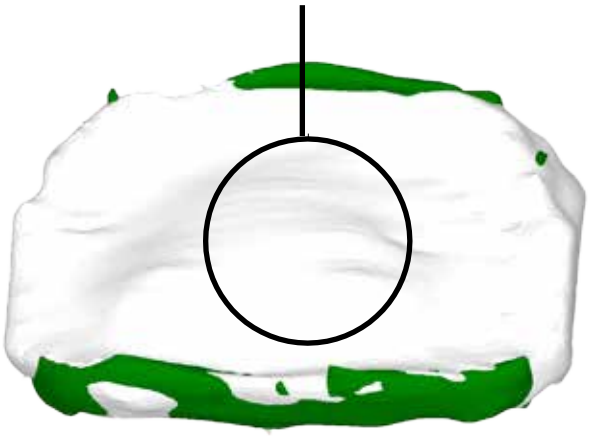
Damaged intervertebral disc before impedance therapy versus healthy intervertebral disc after drug-free and non-surgical impedance therapy.

Damaged intervertebral disc before treatment

Regenerated intervertebral disc after treatment

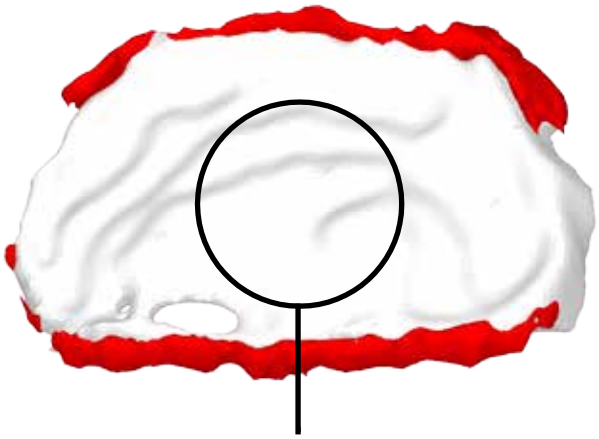
Volume increase by +16% (+ 3.641 cm^3)

Characteristics: oval, healthy core of the intervertebral disc, optimal height of the intervertebral disc



herniated structures before treatment

disc volume
23,135 cm^3



herniated structures after treatment

disc volume
26,776 cm^3

Characteristics: damaged core of the intervertebral disc, reduced height of the intervertebral disc

Source: patient of Impedance Therapy Clinic, 60 years old, male, L4/L5 segment - 3D visualisation

Pavol Kostka
Impedance Therapy in Rehabilitation of Degenerative Spine Disease (Impedance Therapy)

Print: Poptlač, Poprad 2019 Issue
First issue, number of pages 14

ISBN 978-80-89613-27-4

Pavol Kostka and others

Impedance Therapy in Rehabilitation of Degenerative Spine Disease (Impedance Therapy)

Randomized clinical trial

Bratislava/2019

Summary

Introduction
Degenerative spine diseases are the most common cause of sickness absence for people under the age of 45 and the fifth most common cause of hospitalisation in the adult working-age population. Patients suffering from chronic back pain and/or lower limb pain due to degenerative spine disease represent not only a significant health problem but also a significant economic and social problem in all countries of the world. Treatment of degenerative spine disease requires a multidisciplinary approach. The diagnosis of the source of pain is often hampered by the discrepancy between structural changes found by imaging (CT, MRI) and clinical findings. Impedance therapy offers new approaches to the treatment of degenerative spine issues with objective control of structural/degenerative spine changes.

Aim of the work
The aim of the work is to investigate the impact of innovative impedance therapy (IT) on changes in the health condition in rehabilitation care for patients with degenerative spine disease (DDD); to verify the effects of IT in the treatment of degenerative spine disease by confirming the presence of the "disc grow-up" (DGU) phenomenon.

Patient data set and methodology
The clinical randomised trial (RCT) set comprised 55 patients with an average age of 51.3 years. The set was divided into two groups. Both the observed groups (experimental group and control group) of patients underwent a magnetic resonance imaging (MRI) examination before and after a series of electrotherapy sessions. The images were processed in the Digital Imaging and Communications in Medicine (DICOM) format and a 3D visualisation was performed to clearly determine the volume of the intervertebral disc using the program InVesalius. Defining the volume of the intervertebral disc is important for assessing its growth and thus confirming the presence of the DGU phenomenon. The DGU phenomenon is considered a clear manifestation of the regeneration and recovery of the intervertebral disc. Both observed groups underwent rehabilitation at a frequency of three times every two weeks (29 to 48 therapies). The experimental group of patients underwent IT rehabilitation; the second (control) group underwent the same rehabilitation plan with the exception that a classical electrotherapy impulse was applied instead of a specific electrotherapy impulse (SEI) in the set of 10 cyclic recurring therapies throughout the rehabilitation plan.

Results
In the experimental group of patients with DDD, who received IT, the DGU phenomenon with a success rate of 76% was observed, with an average statistically significant increase in the volume of the intervertebral disc of 31% ($p < 0.00$). In the control group of patients receiving standard electrotherapy, the DGU phenomenon was not proven – the DDD progressed normally with a mean volume reduction of 15% ($p < 0.00$).

Conclusion
Degenerative spine disease as a disease of modern civilisation is treatable. The evidence is the presence of the DGU phenomenon – the restoration of the original size and function of the intervertebral disc. It can be concluded that the theory that degenerative spine changes are irreversible has been overcome by the impact of impedance therapy.

Keywords
Impedance Therapy – IT, Specific Electrotherapy Impulse – SEI, DGU phenomenon – "Disc grow-up", Degenerative Spine Disease – DDD.

Introduction

The rapid development of civilisation, which is evident especially in recent decades, has had extremely negative effects represented by qualitatively new types of public health problems. The main causes of modern civilisation diseases currently include the polluted environment, poor diet, bad habits of the population and low health literacy of the population. Civilisation diseases include: 1. cancer, 2. AIDS, 3. addiction – narcotism, smoking and alcoholism, 4. vertebrogenic diseases manifested by spine pain caused by degenerative spine disease.

The category of civilisation diseases involving spine changes due to degenerative spine disease is now considered to be the second most common cause of incapacity for work in industrialised countries and is the most common cause of disability in working-age people. Epidemiological studies have shown that up to 80% of people need medical assistance to treat vertebrogenic pain at least once during their lives (Rubin, 2007). In 5% to 10%, acute pain syndrome evolves into a chronic condition (Deyo, 2002). Chronic back pain has serious social and economic consequences. Approximately 75% of the total financial cost spent on back pain treatment (Martin, 2008) is used to treat chronic pain. Financial costs are increasing every year and it can now be clearly said that vertebrogenic diseases are the most expensive diseases in the world.

Theoretical background

In the clinical investigation of the method of joining and healing small vessels in the past, we focused also on the histological analysis of the site of vascular junction. We found that under the influence of cauterisation currents, the healing of the observed vessels proceeded differently from without these currents. Consequently, we focused on the effect of current and voltage on the regenerating part of the tissue. The results of the study were more than satisfactory and therefore we began to focus on the more general possibility of using this mechanism to regenerate the human body. In the following investigation, we examined the effect of electrical impulses on back pain caused by degenerative changes in the spine. For this purpose, we built a pulse generator. Then, we tested the therapeutic effect of generated impulses in painful conditions of the lumbar spine caused by degenerative spine disease. We currently own the 7th generation generator.

The result of the testing was that the painful spine condition was alleviated by the impulse which changes the properties of the skin by making it more conductive. The neurophysiological basis of the impulse-induced change in skin resistance is called the psychogalvanic reflex (PGR). The skin galvanic reaction leads to an increase in the electrical conductivity (resistance reduction) of the skin. The mechanism of the PGR reflex is associated with the activation of sweat glands via postganglionic sympathetic fibres. Thus, sweat becomes an electrolytic conductor and indirectly changes the electrical properties of the skin cover (Choroš, 2011; Trávničková, 2012).

Specific Electrical Impulse – SEI

Based on sweat conductivity measurements, we created a specific electrical impulse, SEI, to stimulate people with vertebrogenic pain caused by degenerative spine disease. In the set of patients, we analysed the organism's responses to the applied SEI.

Conditions of SEI application:

1. there are time pauses and amplitude changes during the impulse application,
2. the chemical composition of the sweat changes during the application,
3. combination with dry needle therapy (effect on skin resistance change).

Based on the above-mentioned conditions for SEI application, we defined the impulse sequence, which, while maintaining PGR reflex induction, can have a beneficial effect on pain in degenerative spine disease. The analysis and subsequent synthesis of stimulation results enabled the creation of a new treatment method, so-called impedance therapy, which leads to the most effective removal of vertebrogenic pain in a patient with DDD.

"Disc grow-up" (DGU)

In 2009 (after 10 years of SEI application) we started to investigate, monitor and evaluate structural changes of the spine based on CT and MRI examinations. After evaluating the findings in more than 1000 patients, radiologists have confirmed that structural changes occur in the spine

of treated patients. These changes mainly concerned the size of the intervertebral disc, namely the volume and size of the herniated structures of the disc. By converting DICOM images into 3D visualisation, it was confirmed that the change in the volume of intervertebral discs is dependent on the SEI composition in combination with dry needle therapy. Following this method, we introduced the term "disc grow-up" (DGU) phenomenon as a manifestation of regeneration and healing of the intervertebral disc. The DGU phenomenon was confirmed in 1078 patients based on 3D visualisation (Kostka, 2017).

Methodology

A randomised clinical trial took place from October 2016 to May 2018. The aim of the study was to investigate the impact of innovative IT on improving the health condition during the rehabilitation of DDD patients; to verify impedance therapy for the treatment of degenerative spine disease as a civilisation disease. The aim of the study was to monitor the effect of IT as a drug-free therapy of degenerative spine disease through objective MRI spine findings and neurological examinations, and subjective patient experience before and after completion of a given treatment course. Patients were included in the long-term rehabilitation plan anonymously for approximately 5 to 10 months.

The rehabilitation plan had a common pattern for both groups, while one (experimental) group received electrotherapy with SEI and the second (control) group received standard electrotherapy. Patients were registered in an information system in an anonymised mode and were not informed which group they belonged to. To this end, they were assigned personalised RFID chips (providing an anonymised process and protected access to patient data in the patient information system).

Methods for assessing the effectiveness of the applied electrotherapy

1. McGill-Melzack Pain Questionnaire (Melzack,1985)

Numeric Rating Scale (NRS)			
Mild Pain	1	2	3
Severe Pain	4	5	6
Very Servere Pain		7	8
Worst Pain Possible	9	10	

2. MRI examination – to assess and compare the effect of therapy, MR images in DICOM format were processed to realise 3D visualisation. Then, the DGU phenomenon was evaluated as a manifestation of the regeneration, recovery and growth of the intervertebral disc. The acquired MR images were processed in InVesalius (Paulo, 2014). MRI was performed on a 1.5T (Siemens) device. The protocol consisted of the following sequences: 1. transversal T2 weighted images; 2. sagittal T2 weighted images; and 3D data. The sequences were always at the same level with a cut thickness of 1 mm. The standard number of sections was 19 ± 3 per sequence. Subsequent processing of DICOM images in the InVesalius program converted the images into the STL (stereolithography) format, thus subtracting the volume of the displayed part by MRI examination (3D visualisation of selected patients can be found on the YouTube channel of Pavol Kostka). The examination was evaluated by a neurologist, radiologist and neurosurgeon. Standardised volume measurements were performed on each of the magnetic resonance devices prior to the start of the study. The reference volume created by us was recorded on a magnetic resonance device and a 3D reconstruction was created. Thus, proof of the accuracy of the magnetic resonance device was obtained. The standard deviation of the magnetic resonance device was about ± 10%. For our purposes, a tolerance of ± 0.68% at the precision level was accepted.

3. Neurological examination of periosteal and tendon reflexes (PTR) – 7-point scale, where: 0 – reflexes not manifested, 3 - average reflexes, 6 - strong reflexes.

Classification of periosteal and tendon reflexes (PTR)	
absent reflex	0
trace, or seen only with reinforcement	1
less than normal	2
normal reflex	3
brisk reflex	4
irritative phenomena	5
sustained clonus	6

4. Blood lactate level – supplemental measurement. One of the factors of fatigue is the level of lactate in the blood, the increased concentration of which is the cause of the metabolic acidification of the internal environment of the body, which is also manifested by a decrease in performance. During our study, lactate levels in the blood were measured at rest and during exercise. The measurement results form part of the CRF of the study and control group of patients. Mean blood lactate levels are for exercise of 10 to 30 min. – column N (before and after inclusion in the study). Blood lactate levels at rest are from 0.7 to 1.8 mmol/L. A 4 mmol/L level of lactate in the blood during exercise is generally considered to be the limit of the body's effectiveness during exercise. Measuring the level of blood lactate provides us with information on the impact of this innovative method on improving body condition. In the experimental group, the optimisation of blood lactate levels was on average 30% better than in the control group. In the experimental group, blood lactate returned to physiological values in all patients in the study group in which the DGU phenomenon was proven.

The outcome of the treatment was considered successful when, at the same time:

1. conversion of DICOM images from MRI examinations before and after completion of the rehabilitation plan confirmed morphological changes of the intervertebral discs – the DGU phenomenon
2. comparative neurological examination showed improvement
3. the patient considered their subjective condition to have improved after losing or significantly reducing algic complications, allowing them to return to their original activities, not only self-care activities.

Rehabilitation plan

The long-term rehabilitation plan was based on a retrospective analysis of 9,831 patients who underwent a total of 248,643 impedance therapies (Cube, 2019).
It consists of blocks and their associated phases:

1st block – aimed at reducing pain - according to a rehabilitation plan – applying standard physiotherapy procedures in combination with electrotherapy
Phase 1 – classification, Phase 2 – RT symptom (retrospective symptom), Phase 3 – inclusion of individual exercise

2nd block – aimed at increasing physical performance
Phase 4 – inclusion of training, Phase 5 – metabolism analysis, Phase 6 – regeneration fixation

3rd block – non-medical process (repeated exercise measurements with defining blood lactate levels in the context of heart rate, maintaining proper exercise, maintaining the right weight)

The observed patients underwent rehabilitation three times in two weeks in a total number of therapies ranging from 29 to 48. The experimental group of patients underwent rehabilitation with IT and the control group underwent the same rehabilitation plan with the exception that a classical electrotherapy impulse in form of 10 therapies was applied instead of SEI:

1. Low-frequency currents therapy – 5 times			
1x	diadynamik	DF	8-10 mins
2x	diadynamik	LP	17-19 mins
3x	TENS	2-8 Hz	12-15 mins
2. Medium frequency and interference currents therapy– 5 times			

Each implemented therapy was recorded in the information system; it lasted from 90 to 120 min. and consisted of:

1. examination of the patient, recording their medical condition
2. application of electrotherapy – SEI or classic electrotherapy
3. application of thermal and light therapy, application of dry needle therapy
4. manual therapy
5. patient examination after electrotherapy

All data obtained from enrolment to termination of participation in the study were recorded in a summarised anonymised case report (CRF) for the patient. The anonymised summary of results of patients in the experimental and control group before and after inclusion in the rehabilitation plan at the level of the first block of impedance therapy forms an annex to this document.

Characteristics of the patient set

The set consisted of 55 patients with established diagnosis according to the International Classification of Diseases G54.0, 1, 2, 4 and M54, 2, 4, 5, 12, 16, 17 with an average age of 51.3 years. The set was divided into two groups – the experimental group and control group. A total of 61 patients were enrolled in the clinical trial, 6 of whom were excluded (4 on the basis of exclusion criteria and 2 decided to terminate the study). The first group, i.e., the experimental group, consisted of 29 patients with an average age of 56.7 years, of which 22 were men with an average age of 57.2 and 7 were women with an average age of 55.2 (Annex 1 – Summary of results of the experimental group). The second group, i.e., the control group, consisted of 26 patients with an average age of 45.8 years, of which 10 were women with an average age of 45.8 years and 16 were men with an average age of 45.9 years (Annex 2 – Summary of results of the control group).

Inclusion criteria

1. Age 18 to 80, regardless of sex.
2. The patient understands and voluntarily signs the informed consent with medical observation prior to any medical observation procedure and after explaining its nature and the purpose of observation.
3. The patient accepts the conditions, scope and nature of the medical observation with their signature.
4. The patient has been treated for pain syndrome for 6 months or longer and differentially diagnosed with a degenerative spine disease, where degenerative spine disease was proven, without further questioning, to be the evident cause of the pain.
5. The patient is willing and able to cooperate and has agreed to all conditions of their participation in medical observation.

Exclusion criteria

1. Age under 18 years and over 80 years at the time of inclusion in the medical observation.
2. Presence of recurrent upper respiratory tract diseases (hereinafter referred to as HDC), i.e., repeated treatment of upper respiratory tract infections with antibiotics with a minimum interval of 6 months prior to inclusion in the medical observation.
3. Has undergone tissue or organ transplantation.

4. An unspecified fever condition with no known cause at least 3 months prior to the start of medical observation.
5. Deterioration of health with a proven sequestrum.
6. Diagnosed discitis.
7. Newly discovered paroxysmal supraventricular tachycardia with extrasystoles.
8. Poorly compensated arrhythmias and arrhythmia attacks lasting longer than 2 days.
9. Long bone fracture.
10. Newly discovered, medically treated blood clotting disorder.
11. Hypertensive crisis.
12. Sudden diabetes mellitus.
13. Sudden psychiatric illness or recurrence of psychosis.
14. Epileptic seizure in last 3 months.
15. Implanted osteosynthetic material that has been rejected.
16. Implanted pacemaker.
17. History of anaphylactic reactions or severe reactions to certain blood derivatives.
18. Previously diagnosed with hepatitis B or C.
19. Pregnant or nursing mothers.
20. History of chronic alcoholism or illicit drug abuse at least 12 months prior to inclusion in this study.
21. Cancer.

Reasons for interrupting participation in the clinical trial

1. The patient withdraws informed consent to participate in medical observation.
2. It has been additionally discovered that the patient does not meet all inclusion criteria for inclusion in the medical observation.
3. It has been additionally discovered that the patient meets one of the exclusion criteria for exclusion from the medical observation.
4. The patient is unable to adhere to the main medical observation conditions.
    - they do not adhere to the specified therapy interval
    - they do not adhere to the individual treatment regimen for acute recurrence of pain
    - they do not adhere to the individual treatment regimen for acute febrile illness
    - they do not adhere to the individual treatment regimen for other non-infectious diseases/difficulties (injury, car crash, mental illness)
    - they do not adhere to the individual treatment regimen for newly diagnosed skin disease
    - they do not adhere to an individual treatment regimen for infectious disease
5. The investigator additionally finds any reason in the context of simulation or dissimulation of the painful condition.
6. Any information, fact, belief, and so on prevent the individual from taking part in the medical observation.

Methods of safety monitoring

Local and systemic tolerance of patients to medical procedures was observed individually using the adverse event monitoring protocols. The patient was under the direct control of medical personnel during therapy. They were exposed to physical stress during electrotherapy. Physical stress is the basis of the therapeutic effects of electrotherapy and is approved by the state regulatory authority.

Statistical analysis
Comparison of results in individual patients was based on anonymised patient data, to which the final CRF composition was subordinated. We verified the intervertebral disc volume evaluation by the accuracy of the magnetic resonance device based on sample calibration volume measured in each magnetic resonance device.

The deviation of the data thus obtained was about 0.68% of that sensed and thus displayed data versus the defined mathematical and weight basis. None of the patients in the comparison group knew which of the two groups they belonged to. This information was included in the Minutes of the Ethics Committee meeting created for the purpose of this monitoring and was not accessible to any of the personnel included in the executive staff matrix administering the physiotherapeutic rehabilitation therapeutic doses to selected patients in the anonymised set.

The data obtained were processed using descriptive statistics and the Kolmogorov-Smirnov and Shapiro-Wilk tests were used to evaluate normal data distribution. If the significance of the alpha level test was less than 0.05, this was a selection with a disrupted normal data distribution and therefore, nonparametric statistics tools were used for evaluation – the Wilcoxon pair test. To obtain the standard size measure, the Effect size was calculated, which, together with the significance value, gave us information about the magnitude and significance of the effect.

Financial analysis of the study
In the preparatory phase of the clinical study, the composition of personnel matrix, ethics committee, synopsis, inclusion and exclusion criteria, analysis of structured data that will form the case report form was processed. In the implementation phase, patients were informed via a questionnaire about the progress and conditions of inclusion in the clinical study, reimbursement of eligible costs for patients enrolled in the study, etc. The cost of the preparatory phase was €750,000. The cost of the implementation phase was set at €11,500 per patient. Operating costs were around €14/m^2/month. The clinical study was carried out on an area of 450 m^2. Clinical study insurance was €43,000. The total cost of the study was €1,557,500 and was covered by the business activities of MUDr. Pavol Kostka.

Ethical approval of the biomedical study
Ethical approval took place in 2012, when a methodological process for the implementation of a clinical study was prepared in cooperation with the Faculty of Pharmacy of Comenius University in Bratislava under the supervision of Professor PharmDr. Ján Kyselovič, CSc. The implementation of the study was in line with the guidelines set out in the Helsinki Declaration (2000). All patients agreed to be enrolled in the study and with the anonymised data processing. They were allowed to terminate participation in the clinical trial at any time.

Results
The anonymised final summary of CRF of patients comparing MRI results before and after inclusion in the rehabilitation plan at the level of the first block of impedance therapy of the first and second group of patients form annexes to this document. IT in the patient group caused changes in health that copied the course of changes in the rehabilitation plan. Patients enrolled in the experimental group had a period of RT symptoms (retrospective symptoms) – occurrence of past difficulties with a lower intensity. The presence of RT symptoms is a manifestation of regeneration of the intervertebral disc – the DGU phenomenon. The control group with classic electrotherapy procedures experienced a transient improvement in health during the first 3-4 weeks. Then, the health condition changed harmoniously from the image of a painful condition before inclusion in the therapeutic block with periods of subjective good health. **In the first (experimental) group, growth of the intervertebral disc was observed in 76% of the patients**, i.e., the DGU phenomenon was proven in 22 patients (**volume of the intervertebral disc increased by more than 10%),** in 24% (7) of the patients, the DGU phenomenon was proven after impedance therapy, with the intervertebral disc volume not decreasing and DDD not progressing (**0-5% increase in intervertebral disc volume**). In patients with a proven DGU phenomenon, not only the spine but also the large joints improved significantly. Overall, the statistically significant increase in intervertebral disc volume was reported to be 31%, $p < 0.000$, reduction in perception of pain after IT $p < 0.000$, and the final neurological examination, i.e., the examination of the periosteal and tendon reflexes, showed statistically significant changes in the manifestation of PTR $p < 0.00$ (Table 1).

Table 1 - Statistical analysis of the experimental group

Experimental group								
	N	Mean	Std. Deviation	Min	Max	Z	p	r
cm3_before	29	8,0394	6,23834	0,84	23,14	-4,703	0,000	-0,873
cm3_after	29	10,530	7,74621	1,11	26,78			
pain_input	29	6,41	0,983	5	8	-4,739	0,000	-0,880
pain_output	29	1,45	0,47	1	2			
PTR_input	29	1,86	1,187	1	5	-2,886	0,004	-0,536
PTR_output	29	2,59	0,501	2	3			

Z – Wilcoxon test calculation; p – value of statistical significance; r – effect size

In the second (control) group, patients received a standard electrotherapy. Each of the treated patients had a reduced intervertebral disc volume after long-term treatment according to a rehabilitation plan. DDD progressed according to Kirkaldy-Willis degeneration (Bertilson, 2006). **Overall, a statistically significant reduction in intervertebral disc volume of 15%, $p < 0.000$, was observed, and the final neurological examination did not specifically show statistically significant changes in PTR, $p > 0.005$.** In the control group only a reduction in pain perception, $p < 0.00$, after standard therapy was noted (Table 2).

Table 2 - Statistical analysis of the control group

Control group								
	N	Mean	Std. Deviation	Min	Max	Z	P	r
cm3_before	26	10,9145	7,70878	1,61	27,12	-4,45735	0,000	-0,874
cm3_after	26	9,2905	6,51451	1,45	23,24			
pain_input	26	5,69	0,884	4	7	-4,542	0,000	-0,891
pain_output	26	3,77	0,652	2	5			
PTR_input	26	2,77	1,608	0	6	0,000	1,000	0,000
PTR_output	26	2,77	1,478	0	5			

Z – Wilcoxon test calculation; p – value of statistical significance; r – effect size

In the obtained structured data, there was a correlation between regeneration induction and blood lactate levels at rest and during aerobic activity (Table 3 and Table 4).

Table 3 - Statistical calculation for lactate measurements in the experimental group

Experimental group - lactate									
		Paired Differences					t	df	p
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	aero_in - aero_out	2,4172	1,3472	0,2502	1,9048	2,9297	9,662	28	0,000
Pair 2	rest_in - rest_out	1,6690	0,5813	0,1079	1,4478	1,8901	15,461	28	0,000

Table 4 - Statistical calculation of lactate in control group

Control group - lactate									
		Paired Differences					t	df	p
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	aero_in - aero_out	0,9885	1,1782	0,2311	0,5126	1,4644	4,278	25	0,000
Pair 2	rest_in - rest_out	-0,0231	0,2747	0,0539	-0,1340	0,0879	-0,428	25	0,672

Discussion

The aim of the randomised clinical trial was to determine the impact of innovative IT on improving health in the rehabilitation of DDD patients. The impact of IT on the growth of the intervertebral disc was investigated. Our results showed a positive impact of IT on increasing the volume of the intervertebral disc in the observed file, where the "disc grow-up" phenomenon (DGU) was confirmed by MRI – proof of the growth of the intervertebral disc based on the effect of impedance therapy. In the control group, no DGU phenomenon was observed. Conservative treatment including a resting regimen and adequate medical treatment and rehabilitation is effective in 85-90% of patients at the level of subjective symptoms. Surgical treatment is indicated in 10% of patients in whom radicular irritation persists or neurological deficit progresses during conservative treatment. Rare syndromes and progressive motor radicular deficiency require urgent surgical treatment. Despite the available treatment, the remaining 5-10% of patients remain chronically affected, especially patients with back pain. Surgical treatment in patients with chronic back pain is usually of little success. It is indicated for significant functional disability or pain not responding to multidisciplinary conservative treatment. The prognosis of patients is influenced by the severity of the clinical manifestation, the possibility of providing rapid adequate treatment and psycho-socio-economic factors. Degenerative changes in the spine as a disease of modern civilisation have so far been treated with medication or non-drug treatment, but have never been eliminated (Wheeler, 2016; McCulloch, 1998).

Based on our findings, we make the following conclusions:

1. It can be considered that the theory that degenerative spine changes are irreversible has been overcome on the basis of the proven impact of impedance therapy.
2. The basis of impedance therapy itself is the ability to influence the lost regenerative abilities of the organism. We called this phenomenon the DGU phenomenon and it has been proven in 1123 patients (06/2018) (Kostka, 2017, Kostka 2019).
3. Impedance therapy as a drug-free therapy for degenerative spine disease is becoming a medical procedure with an objectively measurable outcome of patient recovery.

Conclusion

In a randomised clinical trial, the effect of IT with SEI on the growth of the intervertebral disc in the experimental group of patients with DDD was observed. In the control group with standard electrotherapy, the manifestation of regeneration of the intervertebral disc, DGU, was not observed. The presented IT method opens a new perspective for the treatment and prognosis of degenerative changes in the spine. The results of impedance therapy in patients with degenerative spine diseases are the reason why we offer this innovative treatment process to other health care facilities with an objective measurable outcome.

Pavol Kostka, MUDr. – profile
He was born in 1973 in Slovakia. He finished his studies at the Faculty of Medicine of Comenius University in Bratislava in 1999. He has carried out his medical practice in the field of neurology in the Poprad region since 2001. Since 2000 he has dealt with the application of specific electrical impulse (SEI) with the aim of reversing degenerative spine disease in a non-invasive way. In 2009, he introduced the term "DGU phenomenon" as clear evidence of the growth of the intervertebral disc based on the impact of SEI in combination with dry needle therapy.

Literature

1. ANDERSSON, GB. 1999.Epidemiological features of chronic low-back pain. Lancet 1999; 354:581–585.
2. DEYO, RA. – WEINSTEIN, JN. Primary care: Low back pain. N Engl J Med 2001; 344:363–370.
3. DEYO, RA. – MIRZA, SK. – MARTIN, BI. Back pain prevalence and visit rates: estimates from U.S. national surveys, 2002. Spine (Phila Pa 1976) 2006; 31:2724–2727
4. FREBURGER, J.K. - HOLMES, G.M., AGANS,R.P. et al. The Rising Prevalence of Chronic Low Back Pain. Arch Intern Med. 2009 ; 169 (3): 251–258.
5. KATZ, JN. Lumbar disc disorders and low-back pain: socioeconomic factors and consequences. J Bone Joint Surg Am. 2006;88(Suppl 2):21–24.
6. SOON, SL. – WASHINGTON, CV. Electrosurgery, electrocoagulation, electrodesiccation, electrofulguration, electrosection, electrocautery. In ROBINSON, JK. – HANKE, CW. – SIEGEL, DM. et al. Surgery of the Skin. 2nd edition. Elsevier; 2010. Ch 9.
7. ALBORNOZ - CABELLO, M. et al. Effect of interferential current therapy on pain perception and disability level in subjects with chronic low back pain: a randomized controlled trial. Clin Rehabil. 2017;31(2):242-249
8. WMA. 2000. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, WMA. In 52nd WMA General Assembly, Edinburgh, Scotland, October 2000. [cit. 2017-01-15]. Dostupné nainternete: www.samawomenshealth.in/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
9. RUBIN, DI. 2007 Epidemiology and risk factors for spine pain. Neurol Clin. 2007;25(2):353–371
10. FREBURGER, J.K., - HOLMES, G.M., - AGANS, R.P. et al. The Rising Prevalence of Chronic Low Back Pain. Arch Intern Med. 2009 ; 169 (3): 251–258.
11. MARTIN, BI. - DEYO, RA. - MIRZA, SK. et al. Expenditures and health status among adults with back and neck problems. JAMA 2008; 299:656–664.
12. MELZACK, R. - KATZ, J. - JEANS, M.E. 1985. The role of compensation in chronic pain: analysis using a new method of scoring the McGill Pain Questionnaire In Pain, ISSN 1872-6623, 1985, roč. 23, č. 2, s. 101-112. [cit. 2016-10-15]. Dostupné na internete: https://yorkspace.library.yorku.ca/xmlui/bitstream/handle/10315/7921/KAT005.pdf?sequence=1
13. PAULO H. J. AMORIM, THIAGO F. DE MORAES, FÁBIO DE S. AZEVEDO, JORGE V. L. DA SILVA.2014:InVesalius: Software Livre de Imagens M´edicas www.researchgate.net/publication/260322057_InVesalius_Software_Livre_de_Imagens_Medics
14. BERTILSON, BO. C., BRING JOHAN, SJOBLOM ANNELI, SUNDELL KARIN, LARS – ERIK STRENDER. 2006: (Inter-examiner reliability in the assessement of low back pain using the Kirkaldy Willis classification, Eur Spine J (2006) 15: 1695-1703, DOI 10/1007/s00856-005-0050-3)
15. WHEELER, A.H. (Feb 03. 2016) Low Back Pain and Sciatica. eMedicine [on line]. In: Berman, S.A. Medscape, (cit 20.12.2016), dostupne na internete: http://emedicine. medscape.com/article/1144130-overview#a3
16. MCCULLOCH JA, YOUNG PH. Essentials of spinal microsurgery. Philadelphia, Lippincott-Raven 1998
17. CHOROŠ, R. – Integrovaný mikroelektródový systém, 2011, 50str.
18. TRÁVNIČKOVÁ, H. – Kožní odpor a psychogalvanický reflex, 2012, 40str.
19. KOSTKA, P. - Impedančná terapia, 2017, 180 str, ISBN 978-80-89613-17-3
20. KOSTKA, P. et al. Impedančná terapia II - aplikácia v medicínskej praxi, 2019, 204 str, ISBN 978-80-89613-24-3

Annex 1 - Summary of results of the monitored group

number of patient	sex	age	spinal segment	number of treatments	V cm3 before	V cm3 after	cm3/% increase	PTR input	PTR output	Range of motion	Scale of pain before	Scale of pain after	Lactate during aerobic exercise 10 to 30 min – input/output		Average lactate during relax – input/output	
1	man	59	C5/C6	38	1,62	2,786	1,17/71,98%	1	2	0	5	1	6,3	4	3,4	1,6
2	woman	45	C5/C6	29	1,187	1,731	0,54/45,83%	4	3	1	7	1	7,3	5,1	3,6	1,8
3	man	62	C5/C6	37	2,601	3,611	1,01/38,83%	2	3	0	6	2	10,1	4	2,8	1,4
4	woman	75	C5/C6	36	0,985	1,366	0,38/38,68%	4	3	1	5	2	7,2	4,2	3,2	1,6
5	woman	45	C5/C6	32	0,976	1,114	0,14/14,14%	1	2	0	5	2	8,5	4,4	4,1	1,7
6	man	65	C6/C7	47	2,941	3,285	0,344/11,7%	1	3	1	6	1	8,2	6,2	2,9	1,7
7	man	49	C6/C7	36	1,626	1,905	0,279/17,16%	2	3	1	7	2	6,2	4,5	3,2	2,1
8	man	55	C6/C7	40	1,884	2,818	0,934/49,58%	2	3	0	7	1	6,8	4,9	3,7	1,4
9	man	71	C6/C7	29	0,838	1,9	1,062/126,73%	1	2	1	6	2	8,7	5	3,9	1,9
10	man	48	L2/L3	31	5,238	12,949	7,711/147,21%	1	3	1	7	1	7,2	5,8	4,2	2,2
11	man	57	L2/L3	35	10,837	16,817	5,980/55,18%	1	2	0	7	1	9,1	5,2	3,8	2,4
12	woman	48	L2/L3	29	11,073	12,273	1,2/10,84%	5	3	1	5	1	5,5	5,5	4,4	2,6
13	man	75	L4/L5	32	8,374	16,522	8,148/97,30%	1	2	1	6	2	8,3	4,5	3,5	0,9
14	man	34	L4/L5	29	12,044	15,26	3,216/26,7%	2	3	1	5	1	8,1	4,1	3,8	1,2
15	woman	48	L4/L5	32	12,137	16,441	4,30/35,46%	1	2	1	6	2	6,1	5,7	3,9	2,4
16	man	79	L4/L5	36	13,974	20,906	6,93/49,61%	1	2	1	7	2	6,1	5,5	3,1	1,8
17	man	62	L4/L5	32	23,135	26,776	3,641/15,74%	1	3	1	7	1	5,6	4,2	3,2	2,1
18	man	34	L5/S1	29	10,391	13,698	3,307/31,83%	4	2	0	8	1	7,2	4,2	4,5	1,9
19	man	60	L5/S1	35	16,599	21,775	5,176/31,18%	1	2	1	7	1	10,1	6,3	3,7	2
20	man	67	L5/S1	36	5,729	12,663	6,934/121,03%	1	3	1	8	2	7,2	4,9	3,2	1,1
21	man	56	L5/S1	48	17,413	23,155	5,74/32,98%	1	2	1	7	1	6,5	4,9	3,9	2,4
22	man	54	L5/S1	35	10,7	12,429	1,73/16,16%	2	3	1	6	2	7,1	4,5	3,6	2,2
23	man	54	C4/C5	32	2,143	2,227	0,084/3,92%	1	2	1	6	2	9,1	6,4	4	1,9
24	man	58	L4/L5	39	15,041	15,563	0,522/3,47%	2	3	1	7	2	7,2	6,2	3,4	2,2
25	woman	54	L5/S1	34	11,904	12,321	0,417/3,5%	4	3	0	5	1	8,3	6,2	3	1,9
26	woman	72	L4/L5	41	12,537	13,121	0,58/4,66%	2	3	1	8	2	8,5	7,2	4,1	1,6
27	man	62	C6/C7	30	2,848	2,981	0,13/4,67%	2	2	1	6	2	8,2	6,2	3,6	2,4
28	man	46	L5/S1	29	14,077	14,605	0,53/3,75%	2	3	0	8	2	8,3	4,5	2,4	1,7
29	man	52	C6/C7	41	2,29	2,386	0,10/4,19%	1	3	1	6	1	7,4	6	2,8	2,4

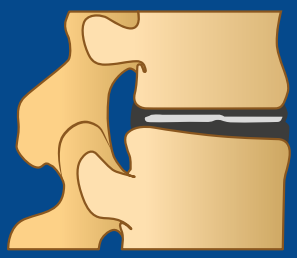
Annex 2 - Summary of results of the control group

number of patient	sex	age	spinal segment	number of treatments	V cm3 before	V cm3 after	cm3/% increase	PTR input	PTR output	Range of motion	Scale of pain before	Scale of pain after	Lactate during aerobic exercise 10 to 30 min – input/output		Average lactate during relax – input/output	
1	woman	52	C3/C4	29	1,623	1,445	-0,178/-10,97%	2	2	0	6	4	14,1	11,6	3,9	3,7
2	woman	38	C5/C6	36	1,988	1,536	-0,452/-22,74%	4	4	0	7	5	9,2	9,1	3	3,1
3	man	51	C6/C7	45	2,562	2,353	-0,209/-8,16%	6	3	0	5	3	11,2	9,4	4,2	4,1
4	woman	44	L4/L5	47	17,532	15,953	-1,579/-9,01%	4	2	1	6	4	7,3	7,5	3,3	3,1
5	woman	42	L4/L5	32	7,113	5,14	-1,973/-27,74%	4	5	1	6	4	11,8	9,6	4,1	4,1
6	woman	55	L4/L5	48	15,831	14,613	-1,218/-7,69%	2	4	0	5	4	5,6	5,6	2,5	2,3
7	man	46	L4/L5	45	18	16,47	-1,53/-8,50%	5	5	0	5	4	7,5	7,5	3,7	3,8
8	man	52	L3/L4	29	18,608	16,249	-2,359/-12,68%	2	2	1	6	4	6,3	5,9	4	3,5
9	woman	46	L4/L5	32	13,366	11,12	-2,246/-16,80%	2	3	0	5	4	12,4	10,1	4,2	4,4
10	woman	31	L5/S1	37	11,281	10,233	-1,048/-9,29%	2	4	1	4	3	9,5	7,9	3,1	3,2
11	man	49	L4/L5	41	16,591	14,167	-2,424/-14,61%	1	2	1	4	3	7,2	7,5	2,9	2,9
12	man	34	L5/S1	33	12,433	9,99	-2,443/-19,65%	2	2	1	6	4	11,9	9,8	4,1	4,2
13	man	62	L4/L5	48	22,68	15,588	-7,092/-31,27%	1	1	0	7	5	8,1	7,8	3,5	3,5
14	man	67	L5/S1	49	12,636	11,173	-1,463/-11,58%	4	4	0	6	4	6,2	6,2	3,7	3,8
15	man	47	L5/S1	45	27,116	23,244	-3,872/-14,28%	4	2	1	6	4	7,9	7,6	3,1	3,1
16	man	59	L5/S1	29	19,205	14,575	-4,63/-24,11%	1	1	1	7	4	13,7	12,7	4	3,9
17	man	35	L5/S1	44	15,932	14,604	-1,33/-9,09%	1	1	0	5	4	10,9	9	3,7	4,1
18	man	53	C6/C7	37	2,934	2,514	-0,420/-16,71%	5	5	1	5	3	12	8,9	2,9	2,8
19	man	32	C3/C4	38	1,809	1,633	-0,176/-10,78%	5	5	1	6	3	6,2	6,4	2,5	2,2
20	man	57	C3/C4	31	2,227	1,724	-0,50/-29,18%	4	4	0	5	4	7,8	6,8	3,6	3,5
21	woman	63	C6/C7	33	1,765	1,525	-0,24/-15,74%	4	3	0	6	4	11,2	8,8	2,8	3,5
22	woman	45	L5/S1	42	6,366	5,909	-0,457/-7,73%	2	3	0	5	4	14,9	12,1	3,6	3,9
23	man	23	C5/C6	31	2,552	2,011	-0,541/-26,90%	2	3	1	7	4	10,9	9,2	4,1	3,7
24	man	41	L3/L4	46	16,231	13,728	-2,503/-18,23%	0	0	0	7	3	8,6	9,7	4,9	5,1
25	man	26	C3/C4	29	1,606	1,451	-0,155/-10,68%	1	1	1	5	2	8,1	7,9	3,2	3,1
26	woman	42	L3/L4	48	13,79	12,606	-1,18/-9,39%	2	1	0	6	4	13,4	13,6	4,2	4,8

One-way degenerative cascade described by Kirkaldy-Willis, which characterises the physiological ageing of the spine over time.

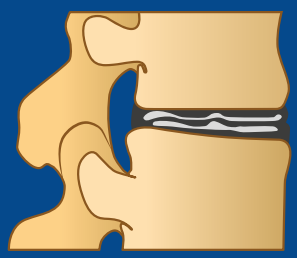
Phase I: Dysfunctional

Dysfunctional initial changes to the disc
- dehydration of the disc
- cracks and weakening of the disc
- disc slides out



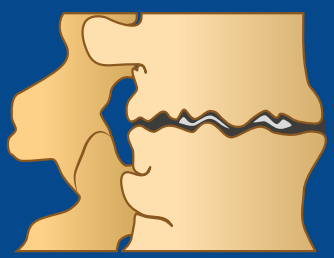
Phase II: Unstable

Spine stability disorder
- disc height reduction
- more cracks and micromo-vements of the disc
- disc herniations

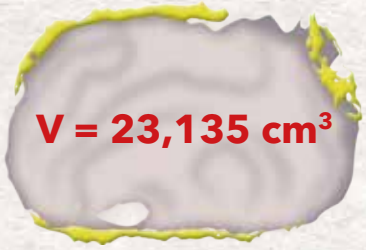


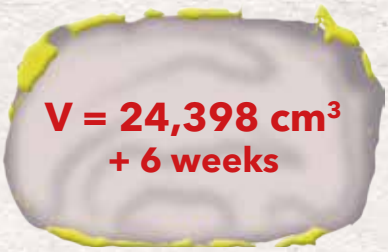
Phase III: Stabilising

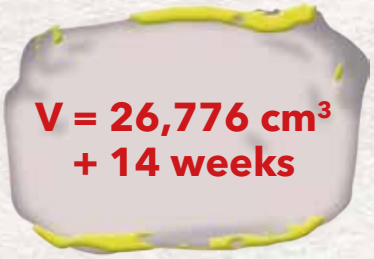
Stiffening of the spine
- significant reduction in disc height
- disruption of the intervertebral disc nutrition
- possible disc resorption



IMPEDANCE THERAPY regenerates damaged parts of the spine and restores its lost function







DGU phenomenon – evidence of growth of damaged intervertebral disc

ISBN 978-80-89613-27-4

www.kitclinic.sk www.liecbaplatniciek.sk