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Research and contributions on the application of quality management to the preservation of exoskeletons

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Motto:

„If you can't describe what you are doing as a process, you don't know what you're doing"

W.Edwards Deming

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1. BACKGROUND

Exoskeletons are used in the process of rehabilitation of various pathologies, such as: cerebrovascular attack, complete or incomplete spinal lesions, diabetic foot, neuromuscular diseases (e.g. neuro-muscular dystrophy, spastic tetraparesis). Medical exoskeletons have been most widely used for the recovery of patients who have suffered spinal injury. Epidemiological data suggest a number of patients with spinal lesions of 60-80 patients to 10^6 in the general population. This report is due to advances made in the medical field, where survival has increased to 88% for paraplegic patients and 70% for tetraplegics after a spinal injury, whether post-traumatic or not.

The life expectancy and quality of life of these patients has increased with the innovative research brought by the military industry as well as the civil, medical industry. The use of medical robots is an important adjuvant therapy in the rehabilitation process. Medical exoskeletons are not just a medical device intended for patients with neuromusculoskeletal sequences, they have the potential value of becoming costumes used to acquire autonomy. The main problem, despite the increased number of published studies, is the absence of standardization, i.e. recommendations highlighting the type of exoskeleton, the number of sessions to be performed and the duration of the rehabilitation process.

Medical robotics has provided solutions to various medical problems. Robotic technology has been appreciated but also challenged by society. Exoskeletons, military engineering products and more recently players in the field of medical rehabilitation have not been exempt from the scepticism of civil society.

According to the stages of the rehabilitation plan, there are 3 types of exoskeletons: exoskeletons used in rehabilitation strictly in specialized units such as hospitals or rehabilitation clinics, which impose dependency on a third person (e.g. physiokinetotherapist), exoskeletons used outpatiently, which give a greater independence to the patient and exoskeletons used for personal purposes; the patient has the chance to improve his daily physical performance (daily activities), inserted in the medical texts with the abbreviation ADL (activities of daily living) and thus also the quality of life. The last type of exoskeleton is also affected by the highest degree of both physical and moral wear. If the degree of moral wear cannot be ameliorated, instead the level of physical wear being defined by the use of the good, by the phenomenon of physical aging, as well as by the conditions of storage and storage, it is susceptible to improvement.

Involved in medical rehabilitation with the help of robotic medical devices and in the absence of their validation by the FDA (Federal Drug Administration), respectively EMA (European Medical Agency) based on the lack of studies on cohort-type populations and lack of customized norms and standards for medical exoskeletons, the main objective of our research of 52 Liviu Cristian CHIȘ was to develop quality standards for the exploitation of the exoskeleton of the type Phoenix MK1 which by the study of the degree of wear extend the life of exosckeleton.

Working hypothesis:

1. Virtual simulations of the use of a piece from the exoskeleton composition proven vulnerable vs laboratory testing of the strength/life of the replacement part could bring added value through substantial savings of physical means;
2. A mathematical model of prediction of the life of the original piece could anticipate the lifetime of the entire exoskeleton.

Far from seeking to raise awareness of the FDA and EMA in order to contribute to the validation of a robotic medical device like the Phoenix MK1 exoskeleton, we have set as secondary objectives the following:

1. Constructive optimization of the Phoenix MK1 exoskeleton based on observational and interventional study;
2. Development of a mathematical model for predicting the reliability of the Phoenix MK1 exoskeleton based on data collected from current exploitation.

By thus shaping the objectives of our research, we can report in the future to the serious undesirable events that may occur due to the wear of the exoskeleton.

2.RESEARCH METHODOLOGY

After setting the general objective and specific objectives, we conducted a series of theoretical and experimental research.

1. **STUDY 1 -** the ESCI (Exoskeletons can Improve the Spinal Cord Injury's Patients Life) study

The main aim of our study is to outline the role of different exoskeletons in the improvement of quality of life of patients with spinal cord injuries as an active part of their process of rehabilitation as well as part of their future autonomy. Thus, projecting in the future what kind of exoskeleton can be used in different steps of the process of social reinsertion of those with spinal cord injury. The robotic exoskeletons are emerging not as only as an option in the rehabilitation of patients with spinal cord injuries and the affection consequences of long terms but as future "suit" to be wear by those with lost autonomy. The main problem, despite the large number of the studies published is the heterogeneity of their design, different targets studied and as well different exoskeletons used. No recommendations are published aiming when, what kind and for how long can the patients use the robotic exoskeletons. In order to have a background to be used as a future prospective research, a meta-analysis of aiming for the use of different exoskeletons (ReWalk, Indego and Ekso) as tools for rehabilitation or personal used was performed. A number of 456 studies targeting patients with spinal cord injury using exoskeletons in their rehabilitation and regaining autonomy was found after an electronic search of the PubMed, PlosOne and clinicaltrials.gov research data bases. After applying the inclusion and exclusion criteria a number of 11 studies were selected. The statistical analysis was performed using MedCalc software. Success in using exoskeletons rehabilitation or social reinsertion was obtained at an RR/OR <1. Success was defined, in clinical terms, as an improvement of 6 time minutes walking test. Overall, the exoskeletons were an accepted and successful method in the rehabilitation of patients with spinal cord injuries (p: 0.0021, I2: 63.81). An unexpected surprise came as results showed the less adherence of the patients An unexpected surprise came as results showed the less adherence of the patients for the type Ekso exoskeleton (less autonomy) versus Rewalk and Indego that provided more autonomy (p: 0.0145, I2: 76,39).

2. STUDY 2 - the UZEXO 1 study

International standards provide a number of requirements for a medical device to be recognized in a particular class and promoted as such. They are: safety, quality and efficiency.

Any robotic device that involves the use of energy (consumption and generation) in tandem with research and contributions on the application of quality management to the preservation of exoskeletons the human being can have as side effects, expressed by the development of musculoskeletal diseases (e.g. muscle elongations / ruptures, fractures). Consequently, the safety offered by the exoskeletons corroborates with the quality of the parts from which it is made, improving the efficiency of it.

While industrial robots have lifetimes between 5 and 15 years, the exoskeleton industry does not provide studies and information on the lifetime or physical wear accumulated by these medical devices. Both duration and physical wear depends on several characteristics: the type of material used, the storage mode or the mode of use. By abstaining from the moral wear of the device, which cannot be disabled and/or improved, the beneficiaries (patients) as well as private users want the longest operating life of the exoskeletons.

There are currently no generalized or specific rules on exoskeleton types that specify how medical devices can be operated to the longest possible operating life.

The components in the composition of exoskeletons are subject to the conditions of storage and use, and over time they can deteriorate, which can lead to accidents with injury to users. That is why it is extremely important to know the working life of exoskeletons in good condition. As a rule, manufacturers secret the data, and the most accurate knowledge of operating times requires the use of predictive methods.

The main objective of this study is to determine the physical wear of exoskeletons (UZEXO) used for medical recovery activities in outpatient conditions. The secondary objectives are to provide measures to increase the strength and durability of the exoskeleton in extreme conditions of use.

In the period 2019-2023 we tracked in operation 10 exoskeletons type Phoenix MK1 and one Exoskelet type ReWalk. The locations where these medical devices are located are the ProWalk Centre in Târgu Mureș (11 exoskeletons). Currently in the country are registered active exoskeletons at the Robănescu Recovery Clinic in Bucharest (an exoskeleton) and one in Iași at the Arcadia Clinic. All exoskeletons outside the ProWalk centre in Târgu Mureș are Indego type.Their use was done according to the manufacturer's recommendations, from which we concluded that the operation of medical devices was carried out under identical conditions, according to the recommendations of the manufacturer.

We collected the data of the 10 Phoenix exoskeletons that we used during their exploitation, recording the operating times from the start of the entry into operation until the occurrence of the first malfunction. Following this observational experiment we found that the part that constitutes the hip joint of the Phoenix exoskeleton is most affected and it is necessary to replace it in each of the 4 exoskeletons used, successively, before the end of the warranty period.

Using the ANSYS R15.0 software, we modeled and simulated the accumulation process of hip joint wear in real working conditions of the Phoenix MK1 exoskeleton. We did not shape the exoskeleton as a whole system, which would present some difficulties due to the complexity of the structure, only the piece that shapes the hip joint, which we found to show the highest degree of wear. The track yielded during use after a number of 468 sessions, 56160 minutes, 234 days.

The studied piece was modeled in 3D mode and subsequently a realistic playback program was applied – ANSYS 15.0. Initially there was a problem with the modeling of the piece due to its design (multiple facets), then the quotas were measured so that it could be reproduced in pf 3D format and imported into the ANSYS 15.0 program.

The tensions generated in static conditions were tracked in order to anticipate the moment of rupture of the piece and to assess the degree of deformation of the analyzed piece. The conditions of use of the exoskeleton were optimal (the ones recommended by the manufacturer) and did not produce unexpected events for the user, respectively the patient.

To the objectives proposed in this study we scanned the studied part of the hip joint that showed wear. Bias data (error data) were excluded due to the use of the exoskeleton by the same patient, with similar biomecanic data. The only variable in the use of the exoskeleton was a change in the patient's center of gravity due to an increase in the body mass index.

The material of the play was studied to fatigue. This analysis is based on finding out the number of cycles the piece can withstand. The steps followed were to establish the maximum duration of use of the hip joint by the number of cycles performed until the appearance of cracks of the material from which the piece is made. The fatigue demand of the material is measured in cycles, and the most durable materials withstand a number of cycles > 10^5.

The strength of the piece was studied through the Young module, the bulk module (Bulk), the Poisson ratio and the forging module after application of 700N, 1000 N, 2000 N, 2250 N and 6500 N Compression resistance was 250 MPa (megapascals) with a traction resistance of 250 MPa at the strength values of 700 N with an increase to a constant value of 1387 MPa. The maximum traction resistance was 460 MPa at a force of 700 N with a value of 1414 which remains constant after the application of the forces of 1000 N, 2000 N, 2250 N and 6500 N respectively. A resistance coefficient of 920 and 0.213 was recorded for ductility/elasticity at a cyclic strength factor of 1000 MPa. The number of operating cycles obtained in a virtual simulation of the hip joint with the help of the ANSYS program reveals that its operating time increases if the loading forces act on the x and y axis directions.

The piece has an extremely good traction/compression resistance on the vertical axis (y axis) reaching flow limits at forces above 4000 N (real spatial constraints).

At forces equivalent to 700 N, 1000 N, 2000 N, 2250 N and 6500 N respectively, the piece withstood the x and y axes, yielding to a charge of 700 N on the z axis. Biomechanical studies have shown that the femur is the longest and strongest bone in the human body, having an average length of 48 cm and a diameter of 2.39 cm in a male whose equivalent weight in newtons is 872 N.

The femur can bear a load of approximately 30 times the weight of the subject. In our study, the number of cycles was limited when a force of 700 N was applied to the z axis, despite the fact that the piece was able to withstand loads of 2250 N on the x and y axis. In a study that tracked the properties of exoskeletons, even in the industrial field, it was found that an exoskeleton can be overloaded by 64% of the subject's weight.

We used the JSM-5200 Electronic Scanning Microscope (SEM) for the ultramorphological study of the surface of the piece. Three-dimensional images obtained at an acceleration voltage of 25 kV and an image amplification of 500 x did not show the appearance of cracks/cracks of the centripet type, the surface being unaltered.

3. **STUDY 3 -** The study of the reliability and lifespam of the MK1 exoskeletons

The exoskeleton is a complex mecatronic system and this study aims to study the reliability of this medical device through numerical simulation. For this we started from the mathematical definition of reliability, after which we estimated reliability by the average time left of operation, analysing the components of the structural system through the systems in series and the parallel systems. The reliability of a complex mechatronic system, respectively of a medical device, can be estimated by mathematical calculation methods by referring to the time variable respectively at the number of cycles performed.

In the case of complex mechatronic equipment, the predictive and operational reliability of its components and the entire equipment is studied. The lifetime of an element coincides with the period from the first use to the occurrence of the failure.

In view of the extremely small number (ten) of exoskeletons evaluated/in research to which the operating times (cycles) are known, in order to be able to make predictions on the characteristics of the average operating time (cycle) we used the bootstrap re-sampling method.

In the period 2019-2023 we tracked in operation 10 exoskeletons type Phoenix MK1. Their use was done in accordance with the manufacturer's recommendations, from which we concluded that the operation of medical devices was carried out in approximately identical conditions. The data collection was achieved by recording the operating times from the start of the operation and until the occurrence of the first malfunction. These data were recorded in the medical records of each patient who benefited from the rehabilitation program using the Phoenix MK1 exoskeleton.

From the analysis of the collected data it is found that the main and only recorded defect is that of the hip joint.

Using the MathCad program we generated, using the bootstrap algorithm, 2000 replicas of the average running times.

We have not found statistically significant differences between the value of the average life of exoskeletons in current operation, compared to the value for this indicator obtained by simulation.

The average duration of good operation of exoskeleton type Phoenix MK1 which has in its structure titanium alloy hip joint parts is 285.031 operating cycles.

Based on the results of this study, a review of the exoskeletal hip joint parts is recommended at 250,000 cycles of use.

4. STUDY UZEXO 2 - Experimental Study of the Fatigue Behavior for a Medical Rehabilitation Exoskeleton Device Using the Resonance Method

The development of materials or structural components requires fatigue tests that simulate operating conditions.

Fatigue tests can be performed by two main methods: Demanding fatigue by applying on specialized stands a large number of cyclical loads (forces or moments) to deformations (voltages) of the tested element, especially in the elastic field Requesting fatigue by using the resonance phenomenon of the tested structure's response to cyclical displacements (linear or circular), imposed in certain areas to excite certain modes of its vibrations, predictable by calculation.

In this research using the resonance method we studied the behavior to fatigue of the hip joint part of an exoskeleton used in the medical field. Research and contributions on the application of quality management to the preservation of exoskeleton fatigue of different parts of the exoschelet is very important to improve their quality and lifespam.

The first natural frequency of the hip joint part is predicted theoretically using the finite element method. The first approximation stage consists of rewriting the elasto-dynamic equation with boundary and initial conditions from the classical approach to the variation form. It has an advantage in that it contains the limit conditions and the degree of the derivation operator is reduced to half (the Gauss formula and the space of permissible functions). In the next stage we approximated the spatial variable, from the variational form, using the finite element method, obtaining an ordinary second-degree differential system with initial conditions. The final approximation stage consists of approximating the temporal variable using the finite differences method, resulting in nodal displacements, nodal speeds, and nodal accelerations at each time increment. After obtaining the first natural way by numerical study, we conducted the experimental test by keeping the oscillations close to the resonance frequency. In this way, only a relatively small amount of energy is needed to maintain large response amplitudes, which can produce significant demands in the tested structure.

The load voltage of the tested component can also be elevated by the inertial effect of light masses mounted on the test sample, which has as effect a certain decrease in the resonance frequency. They must be located near antinodes of the excited vibration mode.

Due to the structural degradation of the tested parts of the hip joint, the resonance frequency decreases as the number of test cycles increases, resulting in a gradual decrease in the amplitude of the response of the structure and, by default, of the tensions to which it is subjected. By monitoring this phenomenon, the excitation frequency can be modified in a controlled way to find a new resonance regime and re-adjust the response amplitude to its original level. This procedure can be repeated as many times as is necessary for the resonance frequency to fall below a certain imposed limit, until the test part fails. This test mode can be automatically controlled and can reduce about 10 times the time required for breaking, compared to classic testing on the universal test machine.

The fatigue tests, performed successively on the same piece, with two different additional masses (0.06 kg and 0.620 kg respectively), revealed a significant difference in the evolution of the macroscopic damage variable: 1% for about 1.380.000 cycles in the first case and 84% for about 1.060.000 cycle (until the test piece is broken).

The appearance of the rupture surfaces highlights the ductile rupture of the part and the propagation of the cracks from the areas of the voltage concentrators located right at the connections to the line of the two holes existing near the castration area, as predicted in the calculation by the finite element method.

5. STUDY - Development of new quality standards for the use of phoenix MK1 exoscheleton

The ultimate objective of our study was to provide information on safe use, maintenance process and requirements for conducting clinical practices in good condition with the ultimate aim of improving the quality of life of patients undergoing locomotor recovery treatments.

The secondary objective of these standards is to highlight the limitations of the exoskeleton in its use in operation.

A prospective study was realized in order to achieve our main goal - standardization of the medical exoskeletons, in the lack of international and national standardization of its.

The real-life assessment of exoskeletons after replacing the hip joint with another alloy, highlights its reliability.

Due to the small number of rehabilitation centers using robotics, respectively exoskeletons, and the lack of quality standards in the operation of these medical devices, we concluded that a model of standards of strictly empirical regressive type with general valences cannot be achieved.

Using the results obtained as a beneficiary/user of the Phoenix exoskeleton at the ProWalk recovery center and following observations derived from the adverse events associated with the use of the exo-skeleton in order to benefit as much time as possible in the safe conditions of the Exoskeleton, but also in conjunction with the standards developed in the last two years, we have developed new quality standards for using the Exo-skeleton Phoenix.

The quality standard for the use of the PHOENIX MK1 exoskeleton developed in this research includes the following chapters: 1. Purpose/relation with the quality standards of exoskeletons 2. Reference documents 3. Definitions/terminology 4. Description of the medical device/exoskeleton 5. Direct and indirect beneficiaries of the exoskeleton 6. Manufacturer's obligations and rights 7. User's duties and rights 8. Specific recommendations for the use of the Phoenix exo-skeleton

8.1.Recommendations relating to the pre-use of the exoskeleton 8.2. Recomendations concerning the use and post-usage of the external skeleton 9. Recomendations regarding the use of the Exoskelets Phoenix in extreme conditions 10. Maintenance of the medical device/exoskeleton

3. CONTRIBUTIONS

The 21st century has proved to be the century that has challenged our imagination through economic, political, social and medical dilemmas. In recent years the degree of socialization has been limited for the purpose of survival (e.g. application of epidemiological rules to stop the COVID 19 pandemic), society increasingly relying on robotic partners equipped or not with artificial intelligence.

Thus, the society has expanded its fields and exposed virgin beaches in the legislative and economic fields, touching sensitive topics of ethics and morality with the use of robots in various fields as a central point, especially the medical one.

The beginnings of our research preceded the onset of the pandemic of COVID 19 by about 5 months.

Working in the field of medical rehabilitation of patients with neuro-musculoskeletal sequences after complete or incomplete spinal injury or post stroke with the help of exoskeletons, and meeting special situations unspeculated by the recommendations of exo-skeleton manufacturers in conjunction with the limitation of studies and the use in the civil society on a large scale of medical exoscheletons, I intended to explore this field.

The research has focused from the outset on the medical exoskeleton of the Phoenix MK1 type, used in the rehabilitation of patients at the PROWALK center. When we started our research, we started from the premise of the effectiveness of the use of medical exoskelets in neuro-musculoskeletal rehabilitation.

The lack of international standards (with the exception of Japan) for the validation of medical exoskelets in the field of rehabilitation is a consequence of the limited use of exoschelets due to limited data on the benefits of exo-skelets to the direct recipients and patients respectively. We conducted a meta-analysis, the ESCI study, which included the most used exoskeletons in rehabilitation centres. The main objective was to highlight the effectiveness of exoskelets in improving the quality of life of patients with neuro-musculoskeletal sequences as well as their preferences according to the type of exo-skeleton. The meta-analysis revealed an improvement in the clinical status of patients after the use of exoskelets. The limitations of the study consisted in the small number of published studies as well as the heterogeneity of their design. However, the main premises of the research, i.e. the use of a robotic medical device that in the future being equipped with software and capable of incorporating artificial intelligence, to become an active partner of the medical rehabilitation team were reinforced by this meta-analysis.

In establishing the usefulness of exoskelets in the medical field, we focused on the lack of validated quality standards on the use of medical exoschelets. Their lack is explained by the vacuum of economic interest, the exoskelets being consumers of resources (financiare, umane). Moreover, profit-making in the robotic medical device industry tends to contract time, rushing into the heterogeneous landscape of exoskeleton design and the limited number of items used in rehabilitation centres.

Starting from an unexpected incident, damage to the hip part of the Phoenix MK1 exoskeleton during a rehabilitation session with the possibility of injury to the patient, we conducted the study UZEXO (physical wear of the exo-skeleton). The incident was a solitary one in compliance with the criteria for the use of the exoskeleton developed by the manufacturer.

The study UZEXO 1 followed the behavior of the initial part of the hip in virtual conditions with the help of the program ANSYS 15.0. The wear of the original hip joint of the exoskeleton was tracked. It was found that the piece yields to a force applied laterally of 700 N on the Z axis, exceeding the flow limit and reaching the break limit, despite the large number of cycles performed on the x and y axes at forces up to 2500 N.

This incident was reported to the Phoenix MK1 exoskeleton manufacturer, who modified the original titanium-steel alloy of the piece with a stainless steel alloy. Thus, we assume ourselves as the main factor in changing the design of the Phoenix MK1 exoskeleton.

Subsequently, the study UZEXO 2 followed the behavior of the new piece, the hip of the exoskeleton, respectively the demand to fatigue, in vitro conditions. This could be achieved by two methods.

Research and contributions on the application of quality management to the preservation of the respective exoskelets: demand for fatigue by application on specialized stands or demand for fatigue by using the resonance phenomenon of the tested structure's response to cyclical displacements. In achieving our objective, we have chosen the second method.

The tests were carried out on a universal hydropuls test machine Schenck PSA 100KN, on the piston of which the rigid castration system of the part was mounted, mounting which allows a significant cyclical load at the bending of the tested part in resonance mode, by controlling the frequency of movement of the piston of the machine to be tested.

The piece yielded to 114.8 Hz after approximately 735400 cycles, the appearance of the rupture surfaces highlighting the ductile rupture of the piece and the propagation of the cracks from the areas of the voltage concentrators located right at the connections to the line of the two holes applied near the castration area.

Subsequently, a mathematical projection was made using the finite element method (through the use of a dedicated software) in establishing the life of the exoskeleton.

The purpose was to develop standards for the use of the Phoenix MK 1 exoskeleton.

The originality of the thesis is given by the interdisciplinary approach (medical, engineering, mathematics and management) of the study of wear of medical exoskelets Phoenix MK1 with the aim of establishing quality standards in the absence of international ones, with the purpose in modifying the material design of the hip joint piece of the robotic medical device, the exoschelet Phoenix Mk 1. The study starts from a general approach with the location of exoskelets and arrives at the customization of the application of the standards of the Phoenix Medical Exoskelet MK 1 as well as the establishment of a mathematical model capable of predicting the life of the exo-skeleton.

These researches are unprecedented in Romania and benefit from the translation of the resonance method from engineering into the therapeutic landscape, with immediate impact / consequences in favour of the recovery of some neuro-motor lesions with solutions to this disappointing point, of which I can highlight a number of original contributions in the field of theoretical research and applied research.

a. Original contributions in the field of theoretical research:

We virtually simulated the wear of exoskelets PHOENIX MK1 used for medical recovery activities in outpatient conditions and set the maximum duration of use of the hip joint by the number of cycles performed until the appearance of cracks of the material from which the piece is made.

We have formulated measures to increase the strength and durability of the exoskeleton in extreme conditions of use.

We conducted a meta-analysis study to highlight the contribution of medical exoskelets in improving the quality of life of patients with complete and incomplete spinal lesions.

Through the meta-analysis study we highlighting the preference of patients for exoskeletons ReWalk or Indego compared to Exoskelets Ekso.

We have designed a method for performing the fatigue tests of the hip joint using the resonance method which reduces about 10 times the time required for breaking the studied piece compared to the classic testing on the universal test machine.

We have classically and variationally formulated the elasto-dynamic problem required in the modeling of the hip joint of the exoskeleton.

We have approximated with finite elements the elasto-dynamic problem required in the modeling of the hip joint of the exoskeleton.

We determined by the finite element method the frequency of the first vibration mode for the experimental test mounting to fatigue by resonance method, in two configurations: the hip joint piece to which a required acceleration transducer is attached at the resonant rate of approx. 195 Hz, which we subsequently loaded it with an additional mass to simulate the current operating conditions for which the Resonant Frequency was about 120 Hz.

We have developed a theoretical model for estimating the average working life of exoskelets Phoenix MK1, which with the help of a limited number of operating data achieves a good prediction of the reliability of these medical devices;

We have determined the average working life of 285.031 cycles of the Phoenix MK1 exoskeleton which has in its structure titanium alloy hip joint parts.

We have shown that the recent introduction of exoskelets into medical rehabilitation practice requires the development of new standards that provide information on safe use, maintenance process and requirements for conducting clinical practices in good condition with the ultimate aim of improving the quality of life of patients undergoing locomotor rehabilitation treatments.

We have developed the quality standard for the use of the PhoeniX MK1 exoskeleton, which leverages the results of the experimental study on patients and integrates international standards for use of medical devices: ASTM F339-20 - Standard Practices for Exoskeleton Wearing, Care and Maintenance; ASTM F3444/F3444M-20. Standard of practices for training exoskeleton users; ISO 14155:2020 Good Practices for Clinical Investigations with Medical Devices on Human Subjects.

The quality standard for the use of the exoskeleton PHOENIX MK1, has provisions regarding the exploitation of exoschelets in normal clinical conditions and in extreme conditions, but also provisions concerning its maintenance with regard to the periodicity of the reviews.

b. Original contributions in the field of experimental research:

We have compiled the experimental configuration of the plant and equipped with the necessary equipment for the fatigue tests of the hip joint using the resonance method;

We tested the fatigue by the pisa resonance method of the hip joint in two stages, firstly with a small additional mass (0,060 Kg) due to an acceleration transducer mounted on the tested piece, followed by the second row of tests in which we attached to the piece a cylindrical body, which together with the accelerator had a mass close to the mass of the exoskeleton drive engine (0,620 Kg) and which simulated operating conditions in a more realistic way;

The first natural frequency of the sample, which is initially used as the demanded tiredness rate for a given test configuration, has been predicted theoretically using the finite element method according to which it was experimentally validated;

We have experimentally demonstrated that the decrease in the resonance frequency of the tested piece with the increase in the number of fatigue cycles constitutes a measure of the degradation of the rigidity of the material;

We conducted an experimental study on 10 Phoenix MK1 exoskelets in operation at the ProWalk rehabilitation centre, by which we determined the actual operating times, which can be used as input elements in the theoretical model of estimating the average operating time of exoschelets;

Based on the results of this study, we recommended a review of the exoskeletal hip joint parts at 250,000 cycles of use;

We conducted a prospective clinical experimental study of the use of Phoenix exoskelets on a group of 19 patients, from which we extracted the specific recommendations for the operation of the medical device, which constitutes entry elements in the quality standard for using the Phoenix Exoskelet MK1;

By applying the provisions of the quality standard for the use of the exoskeleton Phoenix MK1 in a prospective clinical trial we have demonstrated the increased reliability of exoschelets at which the hip joint was replaced manufactured after the new composition presented in this research.

The valorization of the results of scientific research contributes to increasing the prestige of IOSUD by the presence in the main scientific current of published articles: seven articles, of which six articles as the first author. Of these, one article is indexed Clarivate Q1- red area IF 3,748 and two articles are indexed clarivate, proceedings paper.

4. SELECTIVE REFERENCES

1. Mitu AM, Sireteanu T, Pop N, Chiș LC, Maxim V.M, Apsan M.R. Numerical and Experimental Study of the Fatigue Behavior for a Medical Rehabilitation Exoskeleton Device Using the Resonance Method. Materials 2023;16:1316. DOI:10.3390/ma16031316, https://www.mdpi.com/1996-1944/16/3/1316,WOS:000930159600001, Q1 - zona roșie, IF 3,748.
2. Chiș LC, Copotoiu M, Moldovan L. Different Types of Exoskeletons can Improve the Life of Spinal Cord Injury's Patients – a Meta-Analysis, Procedia Manufacturing 2020;46:844-849, DOI: 10.1016/j.promfg.2020.04.014, https://www.sciencedirect.com/science/article/pii/S2351978920310015, WOS:000582466200119.
3. Chiș LC, Moldovan L., Chiș, M. (2022). Particular Life Span of a Medical Rehabilitation Exoskeleton Device – The First Step in Implementing a Quality Management Norm in Real Life. In: Moldovan, L., Gligor, A. (eds) The 15th International Conference Interdisciplinarity in Engineering. Inter-Eng 2021. Springer, Cham, Lecture Notes in Networks and Systems 2022;386:382-391, DOI: 10.1007/978-3-030-93817-8_36, https://link.springe.com/book/10.1007/978-3-030-938178?page=2#toc, https://www.springerprofessional.de/en/particular-life-span-of-a-medical-rehabilitation-exoskeleton-dev/20094604 WOS:000773080200036.
4. Chiș LC, Chis M, Moldovan L. New Requirements for the Development of Quality Standards of Medical Exoskeletons as a Result of the Unexpected Near Miss Events. In: Moldovan, L., Gligor, A. (eds) The 16th International Conference Interdisciplinarity in Engineering. Inter-Eng 2022. Springer, Cham, Lecture Notes in Networks and Systems 2023;605:516-528, DOI: 10.1007/978-3-031-22375-4_41, https://link.springer.com/chapter/10.1007/978-3-031-22375-4_41

5. Chiș LC, Chis M, Moldovan L. Study on the Lifespan of the Exoskeleton. Scientific Session of University Academic Staff International Conference of PhD Students and Young Doctors. Book of Abstracts 2021;4:192. https://sscd.umfst.ro/page/past-editions.

6. Chiș LC, Chis M, Moldovan F, Moldovan L. Study of the Exoskeletons Lifespan in the Intensive Care Units. Acta Marisiensis. Seria Technologica 2023;2020 XXXVII (1):10-16, DOI: https://doi.org/10.2478/amset-2023-0002,

7. Chiș LC, Chis M, Moldovan F, Moldovan L. A New Quality Assurance Standard for the Explotation of the PHOENIX MK1 Exoskeleton. Articol prezentat la „The 17th International Conference Inter-Eng 2023 Interdisciplinarity in Engineering", Târgu Mureș, Romania, secțiunea Innovative Technologies, Advanced Manufacturing and Materials, October 5th 2023, https://inter-eng.umfst.ro/2023/technical-program.html, conferință indexată ISI Web of Science. Articol în curs de publicare - Springer Lecture Notes in Networks and Systems, 2023.

8. Pesenti M, Antonietti A, Gandolla M, Pedrochchi A. Towards a Functional Performance Validation Standard for Industrial Low-Back Exoskeletons: State of the Art Review. Sensors, 2021, 21, 808.

9. Rodríguez-Fernández A, Lobo-Prat J, Font-Llagunes, JM. Systematic review on wearableV lower-limb exoskeletons for gait training in neuromuscular impairments. J Neuro Engineering Rehabil18, 2021, 22. (2021). doi:10.1186/s12984-021-00815-5.

10. Cresswell K, Cunningham-Burley S, Sheikh A. Health Care Robotics: Qualitative Exploration of Key Challenges and Future Directions. J Med Internet Res. 2018, 20(7), e10410. doi: 10.2196/10410.

11. Kermavnar T, de Vries AW, de Looze MP, O'Sullivan LW. Effects of industrial backsupport exoskeletons on body loading and user experience: An updated systematic review. Ergonomics, 2021, 64(6), 685–711. doi:10.1080/00140139.2020.1870162.

12. Turja T, Saurio R, Katila J, Hennala L, Pekkarinen S, Melkas H. Intention to Use Exoskeletons in Geriatric Care Work: Need for Ergonomic and Social Design. Ergonomics in Design, 2022, 30(2), 13-16. doi:10.1177/1064804620961577

13. Schwartz M, Theurel J, Desbrosses K. Effectiveness of Soft versus Rigid Back-Support Exoskeletons during a Lifting Task. International Journal of Environmental Research and Public Health. 2021, 18(15), 8062. doi:10.3390/ijerph18158062

14. O'Connor S. Exoskeletons in Nursing and Healthcare: A Bionic Future, Clinical Nursing Research 2021, 30(8), 1123–1126. doi:10.1177/10547738211038365.