Principles of Efficiency and Safety Assessment in Using Exoskeletons for Patients with Lower Limb Paralyses (Review)

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In rehabilitation of patients who have lost their ability to move independently due to the paralysis of lower limbs, using exoskeletons is a perspective direction. In recent years a great number of robotic devices improving walking of people with lower paraparesis have been developed. However, their comparison is hindered since there are no standardized approaches to the assessment of their efficiency and safety. In this review, general principles of evaluating external robotic devices have been presented, and methods of determining safety and convenience of exoskeleton usage have been analyzed. Assessment of qualitative and quantitative parameters of exoskeleton-assisted walking has also been considered. The characteristic of the questionnaires, standard tests and biochemical investigations, which are used in approbation of exoskeletal devices in people with paraplegia has been presented. Possible ways of evaluating energy expenditure when moving in exoskeletons are shown. The need of elaborating a unified evaluation strategy of walking in exoskeletons has been substantiated.

Key words: exoskeleton; assessment of walking; approbation of exoskeleton devices; paralysis of the lower limbs.

Introduction. Bioengineering devices, enhancing functional capabilities of patients with pathology of the musculoskeletal apparatus, include, among others, exoskeletons, which are special constructions that are put on a man in the form of an external frame, reproduce the biomechanics of his movements, improve muscular power, and reduce metabolic expenditure for walking [1–7]. In rehabilitation medicine, the development of exoskeletons for patients who have lost the ability to ambulate due to paralyzation of the lower limbs, is the most grounded and perspective [8–15]. A sufficient number of models of robotic orthoses and exoskeletons enabling patients with lower paraplegia and paraparesis to stand up and sit down, walk along an even surface and ascend stairs [16–27]. Creation and improvement of such systems require assessment of their efficiency and safety. Nevertheless there are not so many publications on this topic. The majority of these works touch upon more simple robotic devices compared to skeletons [28–31] often using different metrical sets [32–34]. Assessing the efficiency of a new robotic device with functional electrostimulation for patients with lower limb paraparesis, Goldfarb et al. analyzed an average walking speed, heart rate (HR), arterial pressure (AP), gas exchange, variability of the angles in the pelvic and knee joints [30, 35]. An average walking speed and HR normalized relative to the walking speed served as criteria of evaluation of orthoses for people with paraplegia in the works of Nene, Harvey, Winchester et al. [36–39]. Ohta et al. assessed a robotic orthosis designed for patients with vertebral-cerebrospinal trauma (VCST) using walking speed, step length, amplitude of vertical and lateral displacement of the head in walking [16]. In some cases, in addition to the walking speed, the authors took into consideration the maximal distance the patient could travel without rest using the device [40–42], or the kinematics of motions in the knee or pelvic joints [43]. Kobetic et al. studied the efficiency of a robotic orthosis intended for restoration of the capacity of persons with paraparesis to standing, walking and ascending stairs by analyzing the kinematics of motions in the knee joint [9]. A short analysis of biomechanical parameters was presented also in the work of Jung et al.: the investigators performed a comparative analysis of gaits of patients with spinal cord traumas using robotic devices and without their assistance [44]. In order to evaluate the efficiency of using exoskeletons for rehabilitation of stroke patients Fan et al. analyzed indices of surface electromyogram [45].

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Quantitative characteristic of the efficiency of an active lower limb exoskeleton in the work of Neuhaus et al. was given on the basis of walking speed, and an extent of efforts expended on the exoskeleton control was evaluated by registration of the HR, respiration rate, color of the skin; the authors assessed also the stability of standing (ability of the patient to catch a ball), and cognitive efforts (ability to maintain a visual contact) [22]. Apart from walking, of patient's capacity to sit down and stand up in the exoskeleton was estimated in some cases; for this purpose angles in the pelvic and knee joints [46], as well as pressure of the arms on the wheel-chair handles during these maneuvers were used [20, 21].

On the whole, it should be noted that a generally accepted methodology of exoskeleton assessment has not been worked out so far [47–50]. But the analysis of the literature showed, that a great deal of investigations are devoted to the elaboration of the general principles of approbation of novel robotic device, exoskeletons for lower limbs in particular. Approbation of exoskeletons usually includes testing of the walk in the exoskeleton and determination of such indices as energy expenditure, safety, convenience and simplicity of using the external device [24, 51]. These approaches to approbation are valid for all types of lower limb exoskeletons, making it possible to compare different variants of exoskeleton devices [52, 53].

General principles of exoskeleton approbation

The protocol of investigation should be approved by the local ethic committee in accordance with the requirements of the Declaration of Helsinki of the World Medical Association [54]. Criteria of patient selection for the investigation depend on the designation and technical characteristics of the device. Usually, only one patient [47, 48] or a small group of patients [24] participate in the test. Prior to the clinical trials full information about the work of the exoskeleton, its performance capabilities and limitations is presented to the patients, and they also sign the informed consent for participation in the study. Then the device is individually adjusted to every patient considering the length and circumference of his leg segments, and participants are instructed how to use the exoskeleton. Thus, according to Zeilig et al., informing the patient and individual adjustment of the exoprosthesis takes about 30 min, and training to walk in the exoskeleton is performed with the help of kinesotherapist during several sessions (initially the patient in the exoskeleton is trained to walk with bars, then to move with walkers and only thereafter with crutches) [24]. A physician should always be near the patient to ensure security during exoskeleton testing.

Concurrently with training the exoskeleton is adjusted to provide stability of the leg in the knee joint in the supporting phase and a sufficient lifting of the foot from the floor in the transferring phase [48]. Part of the patients, according to the authors' observations doubt their ability to learn to use a new device or worry about possible traumatization; to help overcome doubts and fears patients are demonstrated how a trained person after VCST is walking in the exoskeleton. Exoskeletons are tested only if a patient can walk in it a distance not less than 100 m with the help of crutches (according to the data of Zeilig et al.). On average, six patients with VCST required 13.7 training sessions to learn to use exoskeletons [24].

Statistical processing of the results with a small number of observations is usually performed using nonparametric criteria.

Assessing safety and convenience of using exoskeletons

Safety is a first priority requirement to any innovative device of medical designation. Safety of using robotic devices for patients survived VCST is suggested to be evaluated according to the following parameters: occurrence and the number of falls; skin condition (a grazed or reddened skin); joint condition; AP; HR; electrocardiogram (ECG) [24]. Visual examination of the skin in the sites contacting with the exoskeleton, measurements of AP, HR and ECG recording are recommended to perform before and after testing. Pain and fatigability are self-assessed by a patient using visual-analog scale.

In some cases questionnaires are used for safety monitoring. Zeilig et al. [24] elaborated a questionnaire, which contained some statements concerning the assessment of the training process, comfort and safety of wearing an exoskeleton, medical aspects of using an external device: "I felt comfortable in doing exercises in exoskeleton"; "exoskeleton caused no pain"; "I did not get overtired using exoskeleton"; "after a training period it was convenient for me to use exoskeleton"; "a training session in exoskeleton reduced spasticity in the legs"; "I did not feel difficulties in breathing while training in exoskeleton"; "my bowel worked better when I was training to walk in exoskeleton"; "after the training course I feel sure and safe in using exoskeleton". The examined patient evaluated the degree of his agreement or disagreement with each statement using a 5-point Likert scale (strongly disagree (1); disagree (2); neither agree nor disagree (3); agree (4); strongly agree (5)). The sum of assessments of each separate judgment allows for revealing general opinion of a concrete patient, while a mean assessment of the group of examined people can give a characteristic of various aspects of using the exoskeleton.

Safety criteria for using a robotic device depend to some extent on the pathology, which caused paraplegia (VCST, stroke, myelitis, etc.). Thus, in VCST, rentgenography of the vertebra fracture area (or the area of the spinal column fixation) is supposed to be performed before and after the exoskeleton testing for safety monitoring [24].

Assessment of exoskeleton-assisted walking

Assessment of qualitative and quantitative parameters of walking is fulfilled using questionnaires, standardized tests and findings of biomechanical investigations [55, 56]. The analysis of the gait biomechanics in exoskeletal devices is usually performed by the comparison of similar characteristics of other robotic devices or with standard data [24, 43, 51].

Questionnaires for mobility assessment. Evaluating the mobility of patients using exoskeletons, sections of FIM, SCI-FAI and other scales are usually applied [47]. Section "Walking" of the FIM scale (Functional Independence Measure), developed in the 80s of the XX century by the American Academy of Physical Therapy and Rehabilitation as a standard method of measuring vital function impairment in rehabilitation settings of the USA, assesses ambulation of a patient by a 7-point system. According to this scale point "7" corresponds to the ability to walk without any assistance to the distance of more than 17 m [57–59]. Such an assessment, though suitable for patients with any disease, is categorical and rather tentative.

SCI-FAI questionnaire (Spinal Cord Injury Functional Ambulation Inventory) was developed especially for patients with a spinal cord injury in connection with the necessity to evaluate the efficiency of novel devices to restore locomotor functions [60] (Table 1). The test combines categorical (score) and qualitative assessments of walking and includes three sections ("Gait parameters", "Assistive devices", "Temporal/distance characteristics"). In the first two sections evaluation is performed for the right and left leg separately. Section "Parameters" includes 6 indices, which are considered to be most significant in the assessment of the sufferers' gait: support ability, step width, step rhythm, step height, foot contact, step length. The score evaluation was determined empirically: the higher scores were assigned to those indices, which were recognized to be more important for walking. The indices are arranged in a certain sequence requiring examination of the patient first in the frontal and then in the sagittal plane. Equal score for the right and left limb denotes a symmetrical gait. "Assistive devices" section characterizes the efficiency of using orthotics for lower limbs and devices for upper limbs allowing the patient to maintain the balance and to support the body. The score assessment of each device reflects the degree of the assistance, which a given device provides. The "Temporal/distance characteristics" comprises a score evaluation of the walking mode, which is recommended by the authors to be specified with the help of "Walking mobility" scale (Table 2). This scale was worked out by Perry et al. [61] for stroke patients and modified to patients after VCST. Additionally, the results of 2-minute walk test (the distance walked by the patient in 2 min, a walking speed in steps and meters per minute) are recorded in the investigation protocol. The score is summed for each section; a higher score obtained by the patient indicates a higher level of function. The maximal score for the first section is 20, for the second 14, and for the third one 5. It is not valid to calculate a total score for the whole test, as its sections reflect absolutely different aspects of walking. Reliability, validity and sensitivity of the given measuring tool — SCI-FAI questionnaire — have been confirmed, which enables its use for the assessment of the efficiency of robotic devices intended for improving the ability of sick people to walk independently [60].

Biomechanical investigations. The average walking speed and maximal distance, which an examined patient can go without rest and assistance, are the most universal and accessible for measuring indices, which are evaluated in approbation of innovative robotic devices for lower extremities [36, 62, 63]. For example, approbation of a ReWalk exoskeleton by 12 patients with lower paraplegia showed, that after training sessions all of them could go independently and without rest during 5–10 min, cover the distance about 50–100 m with the speed ranging from 0.03 to 0.45 m/s (0.25 m/s on average) [51]. A more detailed study includes determination of podographic walking parameters (step length, duration of a double step, duration and ratio of leg support/transfer periods) [16, 64–66], as well as kinematic indices (alteration of the angles in the hip and knee joints in movements) [9, 20, 21, 30]. Sensors can be built in the exoskeleton construction [51, 67], or portative systems of movement registration with active markers, e.g. CODA CX1, can be used [24].

In recent years video analysis of movements has become available for a comprehensive analysis of the gait and quantitative evaluation of gait parameters [68, 69]. It enables a detailed study of kinematics, and, in combination with tensodynamometric platforms and electromyography, movement kinetics as well. Patterns of pathological walking can also be determined using this method [70]. Video analysis is being widely used to assess the walking function of patients using lower limb exoskeletons, since an explicit analysis of the obtained data allows for optimization of exoprosthesis design [71, 72]. Application of walking video analysis is of current importance in approbation of exoskeletons as well, since the application of external robotic devices can result in impairment of the normal walking pattern even in healthy people [63, 73–75]. It should be noted, that video analysis of movements in using exoskeletons is connected with some difficulties and requires the development of special investigation models.

Standardized tests. These tests can give quantitative assessment of walking in the exoskeleton, thus minimizing subjective distortion of the results. In accordance with the review devoted to the method of estimation of functional outcomes in patients with paraparesis of lower extremities, three tests are believed to be optimal tools of the assessment: Timed Up and Go (TUG), Six-Minute Walk Test (6 MWT), Ten-Meter Walk Test (10 MWT) [73, 76].

TUG test measures the time needed for a patient to stand up from a sitting position, walk a 3 m distance up to

Table 1

Spinal cord injury functional ambulation inventory SCI-FAI (according to Field-Fote et al., 2001)

Gait parameters	Criteria	Right limb	Left limb
Support ability	Lower limb support ability (successive transfer of the body mass to the leg) is preserved in walking	1	1
	The leg is not able to support or support ability is achieved by some assistive devices	0	0
Step width	While walking, the leg making a step does not touch the supporting leg	1	1
	While walking, the leg making a step touches the supporting leg	0	0
	Foot position, when it rests on the floor during walking, does not hinder the next walking movement by this leg	1	1
	Foot position, when it rests on the floor during walking, hinders the next walking movement by this leg	0	0
Step rhythm	When one leg touches the floor with its heel, the other leg starts to perform a walking movement:		
	in less than 1 s	2	2
	in 1–3 s	1	1
	in more than 3 s	0	0
Step height	The great toe of the foot does not touch the floor, when performing a walking movement	2	2
	The great toe of the foot touches the floor at the beginning of making a step by a leg	1	1
	The great toe of the foot is touching the floor during the whole time of making a step	0	0
Foot contact	The heel comes in contact with the floor prior to the forefoot	1	1
	The forefoot or the sole comes in contact with the floor prior to the heel	0	0
Step length	The heel of the leg, which made a step, appears to be in front of the first toe of the support leg	2	2
	The first toe of the leg, which made a step, appears to be in front of the first toe of the support leg	1	1
	The first toe of the leg, which made a step, appears to be behind the first toe of the support leg	0	0
			Overall score__/20
	Assistive devices	**Right side**	**LEFT side**
For upper limbs (devices for maintaining balance/support)	No	4	4
	Cane(s)	3	3
	Crutch(es)	2	2
	Walkers	2	
	Parallel bars	0	
For lower limbs	No	3	3
	Orthosis for ankle joint /foot	2	2
	Orthosis for knee/ankle joint/foot	1	1
	Orthosis for the whole lower limb	0	0
			Overall score__/14
	Speed/distance of walking		
Mobility (walking not assisted by a wheel-chair is implied)	Walks regularly in community (never or rarely uses a wheel-chair for the travel)	5	5
	Regularly at home/rarely in community	4	4
	Sometimes at home/rarely in community	3	3
	Rarely at home/never in community	2	2
	For exercises only	1	1
	Does not walk	0	0
			Overall score__/5
2-min walk test	Distance, which the patient walks in two minutes_______	Steps/min	Speed/min

Table 2

Walking mobility: criteria of ambulation status definition (according to Perry et al., 1995; Field-Fote et al., 2001)

Walking	Criteria of ambulation status definition
Walking as an exercise	Endurance, muscular strength or the degree of assistance are such that make walking nonfunctional. Aid in standing may be needed (walking is used only for exercise)
A restricted walking around the house	Is able to walk within the house, but movement is limited by low endurance, muscular strength or demands of safety (rarely walks at home/never in community)
Independent walk around the house	Constantly walks the required distances at home. May need assistance in going upstairs within the house. Outside the house a wheelchair may be required (sometimes walks at home/rarely in community)
A limited movement outside the house	Walks outside the house and can manage independently doors, low obstacles and curbs. For long distances a wheelchair may be needed (walks regularly at home/never in community)
Independent movement outside the house	Can travel the distance approximately equal to 400 m (1/4 mile) with a speed not less than 50% of the normal one. Can provide the safety himself, can manage the stairs, doors, curbs (walks regularly in community (never or rarely uses a wheelchair for travelling)

a rear guiding line (e.g. a mark on the floor), turn around, go back to the chair and sit down again [77]. An initial position of the examined person is sitting on the chair, with HR corresponding to its value at rest. The patient is given a verbal command to stand up, go to the mark, turn, go to the chair, turn and sit down. The time from the verbal command till reaching the sitting position is fixed. 30 s after the test has been completed, HR is registered again. The patient is given the opportunity to train; once a patient has learnt to fulfill the task, he performs the test three times, the time of its performance and HR being registered [47].

A high test-retest reliability of the TUG test was confirmed in patients with various pathologies (stroke, Parkinson's disease, amputation of the limb, cerebellar ataxia etc.) [78–80]. The benefit of this test is a composite evaluation of the main movements (standing, walking, turns, returning to the sitting position) which underlie the mobility and show the person's functional capabilities, therefore its application is justified in the assessment of exoskeleton efficiency [43, 47, 51].

MWT test measures the time, which is necessary for the examined patient to walk a 10-meter distance, not considering the phase of acceleration and slowdown. A ten-meter walkway is marked on the floor along a straight line, designating the start and finish. The patient is instructed to go with a normal comfortable speed. Walking should start several meters before the first mark (acceleration). The time of crossing the first and last mark is fixed. HR is registered before the beginning of the test and 30 s after crossing the second mark. The test is repeated three times, each repetition starts only when HR level reaches the HR values at rest. Like a TUG test, the given test has demonstrated a high degree of validity and reliability in persons with neurological pathology [81–83].

6 MWT test measures a distance, an individual is able to walk over a total of 6 min. Ideally, a person walks straight 30 m (e.g. in the hospital hall), turns around, goes back 30 m more, and does so several times. The patient is instructed to stand up from the chair and go as far as possible for 6 min. HR is measured in a sitting position before and after completion of the 6-minute walk. The test is repeated three times [47]. Initially this test was intended for assessing the function of cardiovascular and respiratory systems in patients with heart and lung pathology [84], but later it started to be applied for patients with the limited mobility caused by neurological diseases [85–87].

Both 6 MWT and 10 MWT tests allow for evaluation of the walking speed, but both tests are usually used in the investigations, as their scope differs: if the 10 MWT makes it possible to characterize the velocity of movement over a straight short distance, the results of the 6 MWT demonstrate to a more extent the degree of patient endurance and ability to maintain balance when he turns.

On the whole, the effect of the auxiliary robotic device is suggested to assess proceeding from the results of the three above mentioned tests, which complement each other: mean time to accomplish the test (TUG), mean time of 10-min walk (10 MWT) and mean distance walked over 6 min (6 MWT) [47].

Assessment of energy consumption

The efficiency of using exoskeletons requires obligatory evaluation of the efforts, spent by a patient using these devices. The assessment of energy consumption during walking, including the walk in the exoskeleton, can be done by registering oxygen consumed during walking, and the content of carbon dioxide in the expired air, and measuring HR as well [88, 89].

Gas analysis. The most important physiological index, reflecting the level of metabolic processes, is the value of oxygen uptake. With the increase of a physical load, oxygen consumption and the amount of energy spent become greater. Therefore, the most accurate way of defining energy consumption is a method of full gas analysis based on the amount of oxygen consumed and carbon dioxide released, on calculation of respiration coefficient and respective calorific equivalent of oxygen [90, 91]. The method of gas exchange investigation is rather labor consuming and requires special equipment (e.g. an automated gas analyser). Nevertheless, the analysis of the gas content in the expired air is one of the most widely used methods of evaluating energy consumption in using robotic prostheses; with the help of this method investigators prove the advantages of novel prostheses over mechanical in terms of decreasing energy consumption during their application [91–94]. Though it should be taken into consideration, that, as a rule, patients needing exoskeletons (VCSI, stroke etc.) considerably differ by their physiological reserves from persons requiring limb prosthesis; bulky equipment necessary for investigations does not suite them [47].

Measuring HR. An indirect (surrogate) method of energy expenditure evaluation is registration of HR, which changes proportionally to the intensity of oxygen uptake by the organism, and therefore can indirectly show the level of physical activity and energy expenditure of an individual.

The method of energy expenditure by registering HR is applicable, when comparative data are more important than absolute, in particular, in comparison of energy consumption in walking with an exoskeleton and without it. Two indices are used most frequently: total heart beat index (THBI) [95] and physiological cost index (PCI) [36, 96]. Both these indices are shown to have a high correlation with oxygen uptake, though THBI calculation requires continuous HR monitoring, that is not only a labor and time consuming process, but prevents standartization of this index as well [47]. That is why, PCI is usually calculated as the relation of HR alteration under load (in comparison with HR at rest) to the speed of ambulation [36, 97]:

PCI=(HR under load – HR at rest)/speed of ambulation.

This estimate indicator is shown to be informative in monitoring the load intensity when walking with lower limb orthosis [98] to assess external devices, which improve ambulation in patients with VCSI [37, 38, 99]. In the study of Farris et al., PCI was calculated for all three walking tests (TUG, 10 MWT, 6 MWT), HR being registered before and 30 s after the test [47].

Conclusion. The analysis of publications shows, that exoskeletons are referred to perspective tools of rehabilitating patients with lower limb paralysis, though evidence of their efficiency and safety is necessary. There are no unified approaches to quantitative and comparative assessment of exoskeletons so far, therefore the development of a unified methodology for evaluation of walking in exoskeletons continues to be the task of vital importance.

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