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STUDY OF THE EXOSKELETONS LIFESPANIN THE INTENSIVE CARE UNITS

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Abstract

The exoskeletons surface as useful devices in alleviating the Intensive Care Units (ICU) medical stuff's quality of life. A goal of manufacturers and users of exoskeletons is to determine the probability of proper functioning and increase their lifespan. Considering the extremely small number of exoskeletons for which the durations (cycles) of operation are known, in order to be able to make predictions on the characteristics of the average durations of operation, we used the bootstrap method. Through this method, starting from a small number of data collected from the exploitation of exoskeletons, a desired number of data "similar" to real data is obtained. We used the data of 10 exoskeletons of the same type and their operating times with which 2000 replicates were generated. The data were processed using the EasyFit program and the functional probabilities of the exoskeletons were deduced. A pilot study was performed in order to find the usefulness of using a passive or active torso support exoskeleton in the ICU for prone positioning. It demonstrated a lower degree of fatigue in the subjects who used the exoskeletons.

Key words: exoskeletons, lifespan, intensive care unit, low back pain, fatigue, prone position

1. Introduction

Robotics, a domain merged from science, technology and engineering starts to be a constant presence in health care facilities. Robotics is a science that involves not only the design, the construction, the operation but also the use of robots. Nowadays, robotics gathers specialists from military, industry, science and medical fields. Robots can be categorized according with the domain are to be used [1].

Medical robots are defined by diversity, having multiple destinations, such as [2-4]: *Telepresence* – monitoring the patients in the absence of the physician or in an environment that is not considered safe for the human being; *Sanitation*; *Transport* – delivering prescriptions or medical supplies; *Clinical management* – keeping accountability of the medication, updating the medical files; *Rehabilitation* – aiding patients in performing different tasks. *Supporting* – helping nurses and physicians to perform.

According to the design and mechanism of action, robots can be classified as: *pre-programmed robots* (a simple mechanical mechanism that performs one task); *humanoid robots* (that mimic human behavior), *autonomous robots* (independent machines, not linked with a human operator), *teleoperated robots* (dependent machines, operated by humans – prosthesis controlled by mind), *augmenting robots* (replace or enhance the lost capabilities of the patient or the health caregivers – exoskeletons or robotic prosthetic limbs) [5].

The objective of this study is to model the operational duration of exoskeletons and demonstrate their applicability in Intensive Care Units.

2. The employment of exoskeletons in medical rehabilitation

The exoskeletons surface as useful devices in alleviating the Intensive Care Units (ICU) medical stuff's quality of life. The increased number of different maneuvers – the most common one being the proning the patients for a better respiratory outcome, impeded on the nurses who performed the task. Quality of life is defined in different studies involving the ICU nurses and physicians, as lack of or not increased pain on a visual analogue scale of low back pain, neck and lumbar muscle contractures, fatigue and the presence of burn out syndrome [6].

Low back pain (LBP) is the most common musculoskeletal condition affecting the globe population. It is also the main health issue driving to absenteeism and years lived with disabilitiesin the medical field. Chronic LBP is linked with somatization and depression. The main health care providers affected by the LBP are: nurses, surgeons (orthopedic surgeons and neurosurgeons), internal medicine physicians and dentists. The risk factors identified as associated with LBP are: unusual positions, stress, lack of physical activity, lack of training in executing certain tasks and lack of assistive devices for handling the patients [7−10].

Exoskeletons known as portable devices that generate forces on one or multiple joints in order to sustain the physical activity, already proved their benefits in the rehabilitation of patients with neuromusculoskeletal disabilities. Adherence of using the exoskeletons in order to regain autonomy, the benefits of the exoskeletons and preferences according with the design of the exo-suit have been demonstrated for the patients undergoing neuro-rehabilitation [5,11].

Exoskeletons were first used in the army as helping devices for transporting overloads. The industry soon absorbed them for different heavy tasks, spearing human effort and saving time and money. During the last decades, the medical facilities took the relay (e.g. geriatric hospices) mainly for rehabilitation and then used the upgraded exoskeletons in the operating theaters and in the ICUs [5,11].

Exoskeletons are classified by different characteristics, such as: the presence of power supply – active (quasi-active) or passive (quasi-passive) or static or dynamic, body parts – upper limbs (arms, torso), lower limbs (hip, knee, ankle), mobility–fixed, supported and mobile, materials – flexible (exo-suit, soft exoskeletons) and rigid (carbon fibers, metals) and origin (industry, research lab, home build, government research) [2,5].

In the ICUs, the most common used exoskeletons are the back-support exoskeletons. In the published studies, the exoskeletons proved their active role in improving the gait, the balance, the muscle atrophy, the muscle contracture, the spasticity, the presence of sores, the osteoporosis and the overload in patients, but there are limited data on real life situations concerning the nurses and physicians that are involved in manipulating patients [6, 11-14].

At the present, nineteen active and seventeen passive exoskeletons are used for holding and lifting loads with the benefit or decreasing the back-muscle activity by ten up to forty percent. From those ones, only two were designated for the medical system [13, 14].

A couple of studies have been published having the main objectives to prove the benefits provided to the health caregivers by the exoskeletons. Thus, a Japanese research team succeeded in demonstrating a decrease of spinal overload by using a lower limb exoskeleton by the nurses in a geriatric hospice. The tasks performed by the assistive device were the transfer of the patient from the bed to a wheelchair and from the wheelchair to a toilet. The exoskeleton provided four basics functions: it was lightweight, didn't interfere with the nurse's squat motion, sustained the weight of the caregiver during the transfer and blocked the possibility of falling backward of the nurse [12].

Exoskeletons serve well the patients, to say nothing of the caregivers. But their future is to some extent, subject of inclusion. Their evolution road was paved with hope, they were welcomed as hype, but at the end of the day, if anything goes wrong, they may become subjects of Hospital Inpatient Inquiry (HIPE).

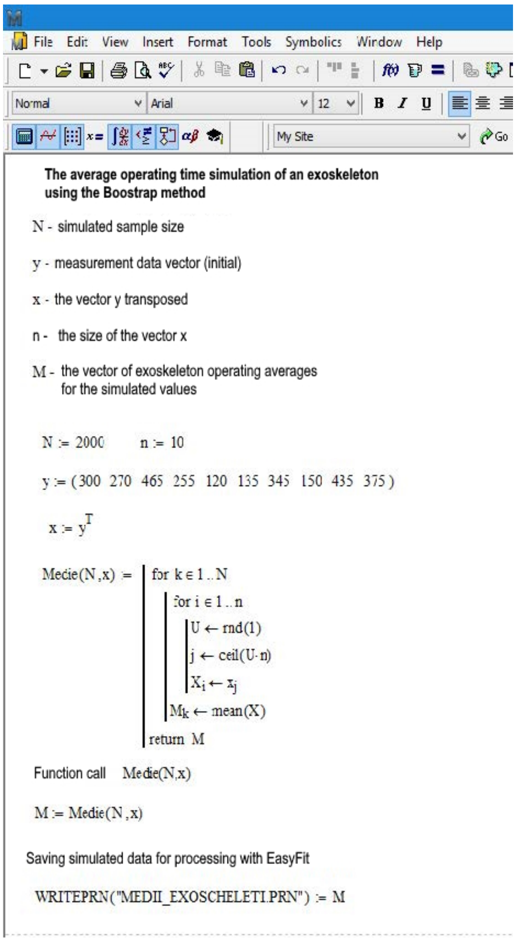
One of the most common problems in real life studies of using by the exoskeletons in the medical field, was the acceptance of both the health caregiver and the patient the symbiosis formed by the exoskeleton and the human being. A study conducted in Finland provided useful information concerning the adherence of the team to the exoskeleton as well as the future intention to use it by the nurses. The main targets were the geriatric patients. The study was subdivided in 2 parts. The first sub-studyaimed to show the improvements added to the nurses by using in a controlled environment an exoskeleton in order to transfer a patient from bed to a wheel chair. The second sub-study was aiming for the same objectives but the scene was established in an uncontrolled environment – the home of the patients. The results showed that the intention to use in the future of an exo-suit was linked with the convictions of the nurses about the utility and the easy to use assisted devices properties and was limited to the perceivenessof the colleagues and the patients formed by the image robot and the human being as a unit. In the study, Laevo a passive, back support exoskeleton was used. The limitations for the future intention to use were linked with the anxiety of the image created – a cyborg that might lack empathy and as well as to the limitations induced by the robot concerning the certain movements. Overall, the subjects were willing of an invisibility characteristic of the exoskeleton [15]

3. Modeling the working life of exoskeletons

Considering the extremely small number of exoskeletons for which the durations (cycles) of operation are known, in order to be able to make predictions on the characteristics of the average duration (cycles) of operation, we used the bootstrap method (resampling).

The Bootstrap method (Re-sampling) - allows, starting from a small number of measurement data, to obtain a desired number of data "similar" to the real data that we do not have at our disposal.

The Bootstrap method consists in resampling a selection on a random variable or random vector. Given $x=(x_1,x_2,...,x_n)$ a selection on the random variable X that has the distribution function F(x) and which is supposed to have a parameter $\theta(F)$ to be estimated.



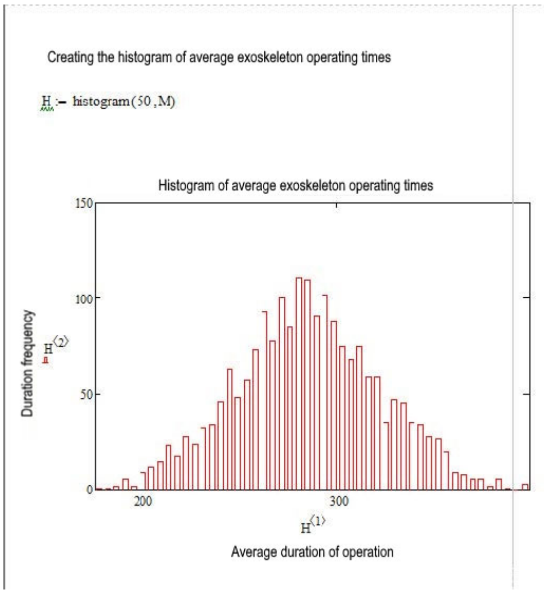


Fig. 1: Histogram of average running times using MathCad.

The bootstrap technique consists in resampling the initial selection, that is, if $\hat{F}(x)$ is the empirical distribution function of X, o obtained with the given sample, a bootstrap sample is $x^*=(x_1^*,x_2^*,...,x_n^*)$ obtained by simulating with $\hat{F}(x)$. Bootstrap sampling is obtained with the following algorithm:

AlgBootstrap

P0. Entry: $x=(x_1,x_2,...,x_n)$ - the initial selection, N - the volume of the final selection;

P1. For $k=\overline{1,N}$

For $i=\overline{1,n}$

Generate $U \rightarrow \mathcal{U}(0,1)$; {generates a uniform number distributed over (0, 1)}

$j=[n \cdot U]+1$; {with [nU] it is noted "whole part" = the largest whole number less than nU}

$x_i^*=x_j$;

Keep $\boldsymbol{x}_k^*=(x_1^*,...,x_n^*)$

P2. Stop!

3.1. Experimental study

We have examined 10 exoskeletons of the same type and their operational duration under identical conditions, expressed in hours, are given by the vector: $x=(x_1,x_2,\ldots,x_{10})=$ (330, 270, 465, 255, 120, 135, 345, 150, 435, 375).

We generated 2000 replicas and represent the histogram of average operational durations using MathCad (Figure 1).

Fig. 2: 3-parameter Weinbull distribution.

The data obtained we used in the EasyFit program and deduced the distribution function that best describes, in the sense of the Kolmogorov-Smirnov statistics (concordance tests) (K-S=0.011751) and Anderson-Darling (A-D=0.3708), [on position 1 - the best "adjustment"] Hi square (χ^2 =23.327) [on position 8 out of 60] the behavior of the average operational duration of the exoskeleton, as the Weibull distribution (3P) can be seen from Figure 2.

The Weibull (3P) distribution has the probability density:

$$f(x;\alpha,\beta,\gamma) = \frac{\alpha}{\beta}\left(\frac{x-\gamma}{\beta}\right)^{\alpha-1} \exp\left(-\left(\frac{x-\gamma}{\beta}\right)^{\alpha}\right)$$

and the distribution function is shown in Figure 3.

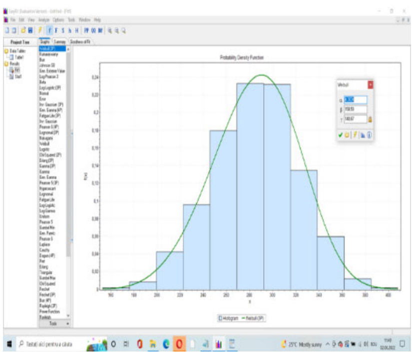


Fig. 3: Distribution function.

$$F(x;\alpha,\beta,\gamma) = 1-\exp\left(-\left(\frac{x-\gamma}{\beta}\right)^{\alpha}\right)$$

having parameters $\alpha = 4.3834$, $\beta = 158.59$ $\gamma = 140.67$, where: $\alpha > 0$ is the shape parameter, $\beta > 0$ is a scale parameter, and γ is location parameter, which checks $\gamma \le x < \infty$.

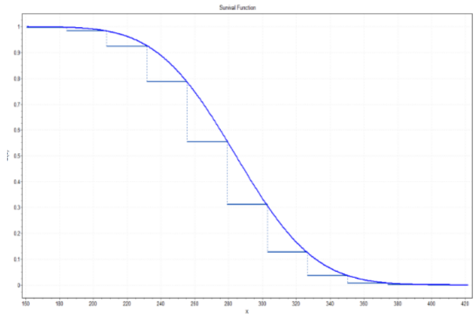


Fig. 4: The reliability function of the average operating time.

The reliability function of the average operating time is (Figure 4):

$$\overline{F}(t;\alpha,\beta,\gamma) = 1-F(t;\alpha,\beta,\gamma) = \exp\left(-\left(\frac{t-\gamma}{\beta}\right)^{\alpha}\right)$$

Table 1 lists the operating probabilities corresponding to the Weibull distribution (3P).

Table 1: Duration and probability of operation.

Duration	Probability of operation
150	1
255	0.788
300	0.36
345	0.048
375	0.0039

3.2. Estimation of mean squared error

We assume that the parameter $\theta(F)$ can be estimated by $g(x_1, x_2, ..., x_n)$. If the parameter $\theta(F)$ is estimated by $\theta(\hat{F})$ we say that the plug-in estimation principle was used. The mean squared error of the estimate is $MSE_{F(g)} = M_{\hat{F}}[(g(x_1, x_2,...,x_n) - \theta(\hat{F}))^2]$.

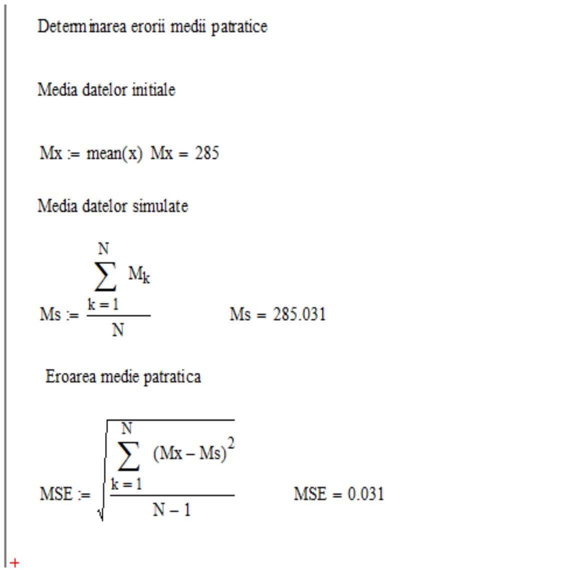


Fig. 5: Mean squared error.

For estimation of $MSE_{F(g)}$ we can use the EstMSE algorithm:

P0. Entry: $\boldsymbol{x} = (x_1, ..., x_n)$, N – volume of the final selection (generated with bootstrap);

P1. For $k = \overline{1, N}$ run

Generate with the bootstrap technique $\boldsymbol{x}_k^* = (x_1^*, ..., x_n^*)$;

Calculate $\hat{\theta}^*(k) = g(\boldsymbol{x}_k^*)$;

P2. Calculate

$$\bar{\theta}^* = \frac{\sum_{k=1}^{N} \hat{\theta}^*(k)}{N}, \quad MS\hat{E}_{\hat{F}(g)} = \sqrt{\frac{\sum_{k=1}^{N} \left(\hat{\theta}^*(k) - \bar{\theta}^* \right)^2}{N-1}}$$

;

P2. Stop!

The above algorithm is programmed in MathCad considering that it is the average operating time of the exoskeleton. We used the same initial data as in the AlgBootstrap algorithm (Figure 5).

3.3. Confidence intervals

A confidence interval for $\theta(F)$ can be obtained with the following procedure:

CuantBootsrap

P0. Entry: $\boldsymbol{x} = (x_1, ..., x_n)$, N – the volume of the final selection;

P1. For $k = \overline{1, N}$ run

Generate with the bootstrap technique $\boldsymbol{x}_k^* = (x_1^*, ..., x_n^*)$;

Compute $\hat{\theta}^*(k) = g(\boldsymbol{x}_k^*)$;

Construct histogram of $\hat{\theta}^*(k)$;

For a confidence level $\delta = 1 - 2\alpha$, determine $\hat{\theta}_\alpha$, $\hat{\theta}_{1-\alpha}$, α- the lower and upper quantiles, as follows: $\hat{\theta}_\alpha = \hat{G}^{-1}(\alpha)$, $\hat{\theta}_{1-\alpha} = \hat{G}^{-1}(1-\alpha)$; {G is the distribution function of $\hat{\theta}$, and G^{-1} is its inverse.

P2. Stop!

In the practical case analyzed, G^{-1} is the inverse function of the Weibull distribution function (3P). Figure 6 shows the expressions of the probability density and distribution functions obtained in EasyFit.

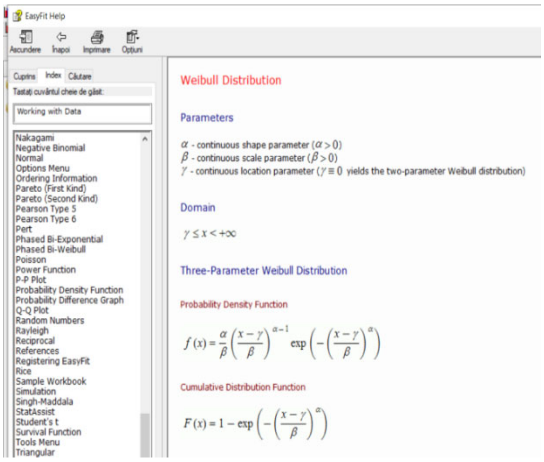


Fig. 6: Probability density and distribution functions.

Using MathCad, the values presented in figure 7 are obtained for the most used quantiles.

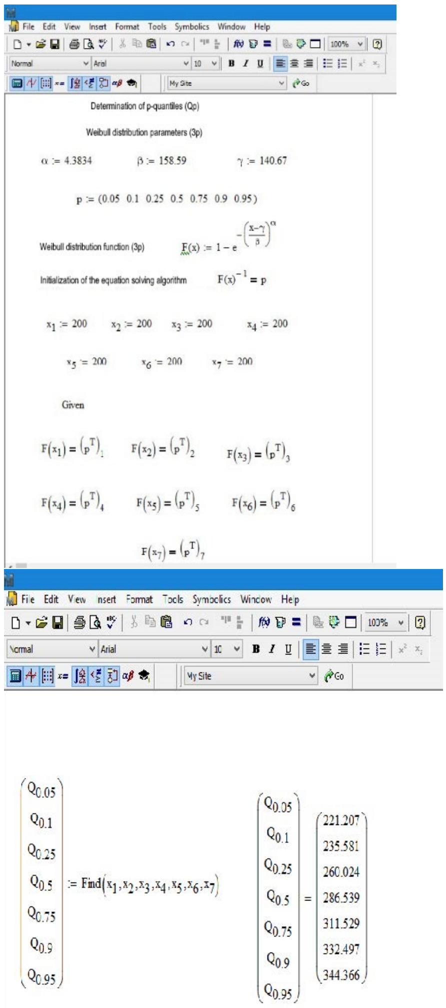


Fig. 7. Quantile values.

It can be seen that for a large N, the arithmetic mean of the bootstrap estimator $\hat{\theta}^*(k)$, $1 \le k \le N$, is asymptotically normal. This implies a confidence interval for $\theta(F)$ using the quantiles of the standard normal distribution, thus:

$$\overline{\theta}^* - \hat{MSE}_{Z_{\frac{\alpha}{2}}} \le \theta(F) \le \overline{\theta}^* + \hat{MSE}_{Z_{\frac{\alpha}{2}}} \; ,$$

$$\text{where} \quad \frac{1}{2\pi}\int_{-Z_{\frac{\alpha}{2}}}^{Z_{\frac{\alpha}{2}}} e^{-\frac{x^2}{2}} dx = 1-\alpha \; .$$

4. The use of exoskeletons for prone positioning tasks

A pilot study was performed in order to find the usefulness of using a passive or active torso support exoskeleton in the ICU for prone positioning. Burn out syndrome, fatigue, depression associated with low back pain and stress of the medicalstuff were one of the multiple obstacles that influenced the management of the ICU patients and as well the quality of life of the ICU's nurses.

It was recorded that the number of maneuvers performed by the nurses in the first ten days of the onset of pandemics was equivalent with those realized in a whole year per patient. Initially, the research teamtried to discriminate between four different back support passive and active exoskeletons [16–20]. Finally, Laevo, a passive back support exoskeleton was chosen to be used by the ICU team to perform the prone positioning of the ventilated patients (Table 1).

Table 1. The patterns of the exoskeletons used in a simulation ICU facility by the medical staff.

Device	Company	Type	Aim	Pros	Cons
Corfor	CORFOR, France	passive, soft	decreases the lumbar forces	safety comfort decreases the physical effort	overall, not very helpful
Laevo	LAEVO, Netherlands	passive, rigid	protects the spine during lifting and moving	safety comfort decreases the physical effort future intention to use did not change the movements/postures during the manipulation	should pay attention when correlating movements with walking
BackX	SuitX, USA	passive, rigid	decreases the forces on the wearer's back at L5/S1 location	safety comfort decreases the physical effort	limits certain movements due to the design
CrayX	German Bionics,Germany	active, rigid	lifting and walking	safety comfort decreases the physical effort	heavy, difficult to manipulate

The Laevo exoskeleton was used by the team members positioned at the sides of the patient (seven times by the same member) as well as at the head of the patients (three times by the same member). The number of hours spent by shift with the exoskeleton was three hours for every team member. Each nurse performed 10 maneuvers on an ICU patient [6].

At the ending of the pilot study, the subjects felt less fatigue and scored better on physical exhaustion. They expressed their willingness to further on using the exoskeleton during shifts.

5. Conclusion

This pilot study showed a solution for the improvement of the burn out syndrome of the health care providers from the ICU units [6]. We think that using robots able to really perform at the bedside and support the nurses in their tasks is the next challenge for the ICU managers who are offered an opportunity to improve strategic efficacy and effectiveness to say nothing of LBP and burn-out.

There is a need for more studies to emphasize on the essential role of the exoskeletons in the improvement of care of the patients and as well of the medical staff and to determine their lifespan.

The limitations of initiating protocols of using the exoskeletons in ICU are linked to the lack of common and validated standards for exoskeletons and exo-suits, lack of specific protocols for medical exoskeletons as to when, why and by whom to be used and the last but not the least, they need the validation of medical device certification bodies [21].

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