

Robot-mediated arm rehabilitation in Virtual Environments for chronic stroke patients: a clinical study

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Abstract—This paper presents the results of a clinical trial employing the PERCRO L-Exos (Light-Exoskeleton) system, which is a 5-DoF force-feedback exoskeleton for the right arm, for robotic-assisted rehabilitation. The device has demonstrated itself suitable for robotic arm rehabilitation therapy when integrated with a Virtual Reality (VR) system. Three different schemes of therapy in VR have been tested in the clinical evaluation trial, which was conducted at the Santa Chiara Hospital in Pisa with nine chronic stroke patients. The results of this clinical trial, both in terms of patients performance improvements in the proposed exercises and in terms of improvements in the standard clinical scales which have been used to monitor patients progresses will be reported and discussed throughout the paper. It is to be noted that statistically significant improvements have been demonstrated in terms of Fugl-Meyer scores, Ashworth scale and increments of active and passive ROMs on shoulder, elbow and wrist joints of the impaired limb.

I. INTRODUCTION

Several research studies have recently focused both on the development of novel robotic interfaces and on the use of Virtual Reality technologies for neurorehabilitation. The former may overcome some of the major limitations manual assisted movement training suffers from, i.e. lack of repeatability, lack of objective estimation of rehabilitation progress, and the high dependence on specialized personnel availability. As a matter of fact, thorough and constant exercise has revealed itself essential to produce a significant therapy outcome [1]. On the other hand, VR-based rehabilitation protocols may significantly improve the quality of rehabilitation by offering strong functional motivations to the patient, who can therefore be more attentive to the movement to be performed.

Several arm rehabilitation robotic devices, both cartesian and exoskeleton-based, have been developed in the last 10 years. Some examples include MIT Manus [2], [3], ARM-guide [4], MIME (Mirror Image Movement Enabler) [5], 1-DoF and 2-DoF devices developed at Saga University [6], [7], ARMin-II [8] and Salford Exoskeleton [9]. A recent survey [10] outlines that robotic-aided therapy allows a higher level of improvement of motor control if compared

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to conventional therapy. Nevertheless, no consistent influence on functional abilities has yet been found.

On the other hand, several studies (e.g.: [11]) have demonstrated positive effects of Virtual Reality on rehabilitation, which enhances cognitive and executive functions of stroke patients [12] by allowing them to receive enhanced feedback on the outcome of the rehabilitation tasks he/she is performing. Moreover, VR can provide an even more stimulating videogame-like rehabilitation environment when integrated with force feedback devices, thus enhancing the quality of the rehabilitation [13].

This paper presents the results of an extended clinical trial employing the L-Exos system [14], a 5-DoF arm exoskeleton, to upper limb rehabilitation. L-Exos is installed at the Neurorehabilitation Unit of the University of Pisa, where it has been used in schemes of robotic assisted VR-based rehabilitation with 9 chronic stroke patients. This work is intended to extend previous works concerning a pilot study with the L-Exos system ([15], [16]) by providing significant therapy and clinical data from a much larger set of patients.

Section II presents a general description of the L-Exos system, underlining the main features which make the device useful for rehabilitation purposes, and a description of the developed VR applications may be found in Section III. Section IV and Section V discuss the main results which have been obtained with the L-Exos both in terms of improvements in the metrics used to assess patient performance in the therapy exercises and in terms of improvements in the standard clinical scales which have been used to monitor patients progresses. Conclusions and perspectives opened by this pilot study are briefly reported in Section VI.

II. L-EXOS SYSTEM

L-Exos (Light Exoskeleton) is a force feedback exoskeleton for the right human arm. The exoskeleton is designed to apply a controllable force of up to 100N at the center of the user's hand palm, oriented along any spatial direction and it can provide active and tunable arm weight compensation. The device mechanical structure has been extensively described in [17], whereas a description of the model of its novel tendon transmission may be found in [18]. For a sake of clarity, a brief review of the device kinematics will be provided in this section.

L-Exos has 5 DoFs, 4 of which are actuated and are used to define the position of the end-effector in space (see Figure 1). The system is therefore redundant, allowing

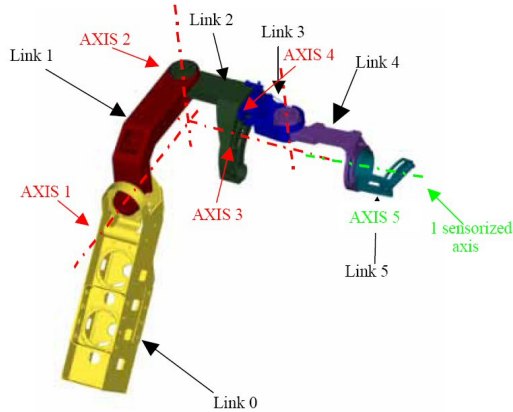


Fig. 1. L-Exos kinematics

different joint configurations corresponding to the same end-effector position, which is fundamental for chronic stroke patients. Such subjects are likely to implement compensatory strategies in order to overcome force and Range of Motion (ROM) limitations remaining after stroke rehabilitation [19]. The 5th DoF is passive and allows free wrist pronation and supination movements. Moreover, design optimizations allow total arm mobility to a healthy subject wearing the device.

The structure of the L-Exos is open, the wrist being the only closed joint, and can therefore be easily wearable by post-stroke patients with the help of a therapist. In order to use the L-Exos system for rehabilitation purposes, an adjustable height support has been created, and a chair has been placed in front of the device support, in order to enable patients to be comfortably seated while performing the tasks. The final handle length is also tuneable, according to the patient's arm length.

After wearing the robotic device, the subject's elbow is kept attached to the robotic structure by means of a belt. If necessary, the wrist may also be tightly attached to the device end-effector by means of a second belt, which has been used for patients who are not able to fully control hand movements. A third belt can easily be employed in order to block the patient's trunk when necessary.

The L-Exos device has been integrated with a projector used to display on a wide screen placed in front of the patient different virtual scenarios in which to perform rehabilitation exercises. The VR display is therefore a mono screen in which a 3D scene is rendered. Three Virtual Rehabilitation scenarios have been developed using the XVR Development Studio [20]. The photo shown in Figure 2 has been taken during a therapy session, while one of the admitted patients was performing the required exercises, and is useful to visualize the final clinical setup.

III. CLINICAL PROTOCOL

An extended clinical study involving 9 subjects pilot study with the main objective of validating the implemented therapeutic schemes and generally of evaluating the robot-aided therapy with the L-Exos system has been carried out

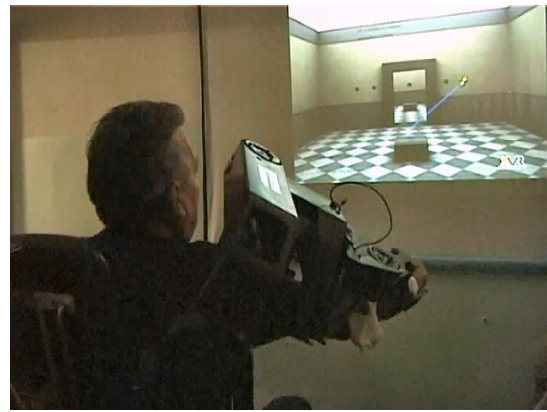


Fig. 2. Admitted patient performing the robotic-aided therapy exercises

at the Santa Chiara Hospital in Pisa, Italy, between March and August 2007. Potential subjects to be enrolled in the clinical protocol were contacted by clinicians in order to ask for a possible interest in robotic-therapy and to take part in a preliminary test session used to evaluate patients acceptance of the device. Most of the patients gave an enthusiastic positive feedback about the opportunity.

Patients who were declared fit for the protocol and agreed to sign an informed consent form concerning the novel therapy scheme were admitted to the clinical trials. The protocol consisted of 3 one-hour rehabilitation sessions per week for a total of six weeks (i.e., 18 therapy sessions). Each rehabilitation session consisted in three different VR-mediated exercises. A brief description of the goal of each exercise will be provided in the next paragraphs, whereas a more detailed description of the VR scenarios developed may be found in previous works [15], [16]. Some relevant control issues concerning the proposed exercises will be reported as well.

A. Exercise description

1) Reaching task (see Figure 3(a)): seven spheres in a horizontal row are positioned in a virtual room and represent targets to be reached during the therapy. Subjects are required to move their hands towards each target and then back to the initial position following a yellow marker which moves according to a minimum jerk model [4], i.e. a sigmoid-like shape which is approximated by a 5th degree polynomial with a bell-shaped displacement profile. Variable height and maximum speed levels are employed during each therapy sessions, patients being required to perform 126 forward and backwards movements. The typical duration of this exercise is of about 30 minutes.

2) Path following (see Figure 3(b)): subjects are required to move along a circular trajectory, both clockwise and counterclockwise, where they are constrained by means of an impedance controller provided by the exoskeleton. Position, orientation and scale of the circular trajectory can be changed online, thus allowing the patient to move within different workspaces. Patients are then asked to follow the same trajectory without the robotic constraint, while the robot

compensates for part of their arm weight. The typical total duration of this exercise is of about 10 minutes.

3) Object manipulation (see Figure 3(c)): subjects are asked to displace some cubes in order to re-compose a given image which appears on the background. In this task the therapist can decide to help the patient making the L-Exos apply an active compensation of the weight of the arm in a consistent way with patients' motor arm-lifting capabilities. Patients are required to reconstruct the puzzle as fast as they can, and with the minimum number of movements. Arm weight is compensated during the exercise. The typical total duration of this exercise is of about 10 minutes.

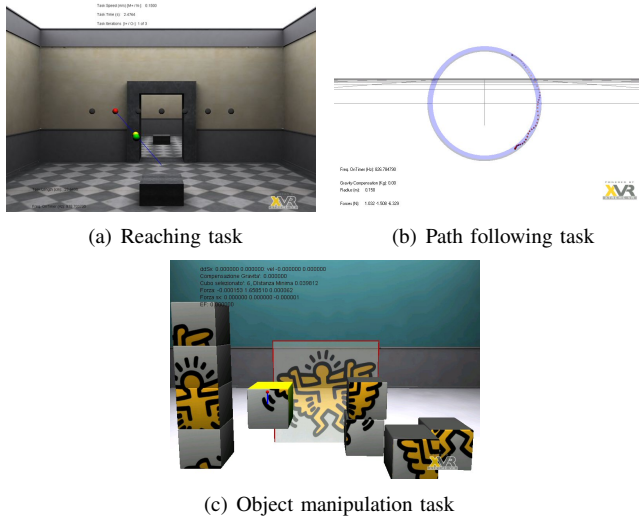


Fig. 3. VR scenarios

B. Control issues

Two different impedance control algorithms are applied to the L-Exos during the first and during the last two therapy exercises. In particular, the reaching task control algorithm always guarantees that the device is gravity compensated and realizes two virtual springs of different stiffness along the direction of the task and on the plane normal to that direction (see Figure 4). In particular, stiffness values of 500N/m and of 1200N/m have been used along the trajectory and on the plane perpendicular to the trajectory respectively. The patient is thus constrained inside the virtual cylinder created by the two springs, and can move more (although not completely) freely along the trajectory. Damping terms are added to the control in order to increase the overall system stability. Patient-specific stiffness parameters could be employed in future studies. Figure 6 shows a typical path followed by a patient during the reaching task, whereas a block diagram of the control system is shown in Figure 5.

For the last two tasks, an integrated physics module based on the Ageia PhysX physics engine [21] computes interaction forces and communicates them to the Control Unit, which is only in charge of dealing with the low-level motor actuation. The physics engine is able to compute interaction forces during collisions and to haptically render inertias along with

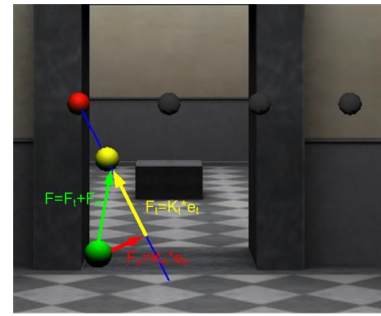


Fig. 4. Impedance control used for the reaching task

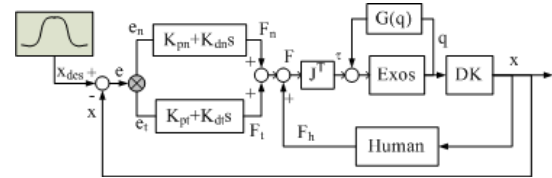


Fig. 5. Control block diagram for the reaching task - x_{des} is the desired end point position; e , e_n and e_t are the total error, the error normal to the trajectory and the error along the trajectory; K_{pn} , K_{dn} , K_{pt} and K_{dt} are the proportional and derivative control coefficients normal to and along the trajectory; F is the control force deriving from the impedance control; $G(q)$ is the gravity model to compute the gravity compensation torque; $Human$ represents the model of the weight of the human arm to compensate (part of) its weight and DK is the direct kinematics block.

friction forces. The same engine is used to provide a haptic constraint on the desired path in the circle drawing task.

IV. THERAPY RESULTS

The following paragraphs will describe the metrics used in order to quantitatively evaluate patients' performance in the reaching task and in the path following task exercises. It is to be noted that no quantitative data has been computed for the last proposed task. A first obvious possible quantitative measure, such as task completion time, was thought as being not significant to evaluate patient performance improvements. This was due to the high variability in the task difficulty among different therapy sessions (initial cube disposition was randomly chosen by the control PC), and to the high variability in patient's attitude to consider the exercise as completed, i.e. the accepted amount of cube misalignment and hence the amount of time spent in trying to perform fine movements to reduce such misalignment.

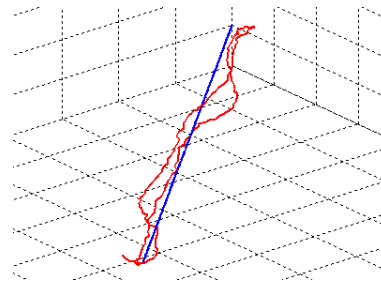


Fig. 6. Typical path followed during a reaching task - Blue: ideal trajectory, Red: actual trajectory

A. Reaching task

The cumulative error for each task has been chosen as being the most significant metric to analyse reaching data. After the definition of a target position and of a nominal task speed, the cumulative error in the reaching task is computed for iterations corresponding to the given target position and speed. The cumulative error curves are then fitted in a least-square sense by a sigmoid-like 3-parameter curve:

$$s(t) = \frac{a}{1 + e^{(t-b)/c}} \quad (1)$$

s being the cumulative error at time t , whereas a , b and c are fitting parameters.

Fitting curves are then grouped and averaged on a therapy session basis, each set containing the fitting curves computed for a single rehabilitation session. Sample data resulting from this kind of analysis are shown in Figure 7 and Figure 8, where a greater dash step indicates a later day when a given target was required to be reached with a given peak speed.

It is to be said that statistically significant improvements in the average fitting curves from Week 1 to Week 6 are recognizable for more than half targets in only 4 out of 9 patients enrolled in the protocol. A typical improvement pattern for a sample target is shown in Figure 7 for Patient 6. This patient is constantly improving his performance in the exercise, leading to a significant decrease in the final cumulative error for a given target. A reducing of the mean slope of the central segment of the fitting curve is therefore present, thus indicating a higher ability to maintain a constant average error throughout the task.

Figure 8 reveals an interesting aspect of the application of the belt used to avoid undesired back movements. During the first therapy sessions, no belt was present, and each therapy session registered a comparable value of the cumulative error. As soon as the trunk belt is introduced, the error increases dramatically, as formerly employed compensatory strategies are not allowed. However, due to the fact that active patient's movements become much more stimulated, the cumulative error fitting curve improves significantly. It is to be noted that, by the end of the therapy, values which are nearly comparable to the ones obtained in the no-belt condition are reached.

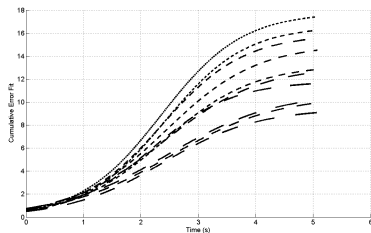


Fig. 7. Sample reaching results for Patient 6

B. Path following task

Total time required to complete a full circular path was the quantitative parameter used to assess patient improvement

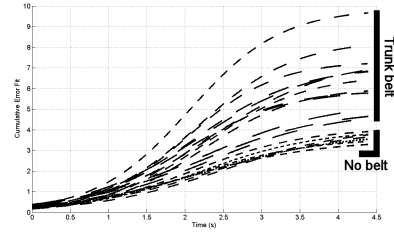


Fig. 8. Sample reaching results for Patient 3

for the constrained motion task. 3D position data have been projected onto a best fitting plane (in the sense of least squares), and the best fit circle has been computed for the projected points. Time to complete a turn was then evaluated with regard to trajectory. Curvature along the trajectory, which is irregular for the three patients, was not evaluated. In particular, due to the deliberately low value of the stiffness which realizes the motion constraint, patients sometimes move in an unstable way, bouncing from the internal side to the external side of the trajectory and vice versa, requiring some time to gain the control of their movements again. This behaviour has detrimental effects on curvature computation.

Although three of the patients report no significant decrease of the completion time from Week 1 to Week 6, three patients report a decrease of about 50% in the task completion time, whereas other three patients report a decrease of about 70% of the same performance indicator. Such results are significant from a statistical point of view ($p < 0.001$ for the t-Student test for each patient showing improvements).

Sample data from Patient 3 are shown in Figure 9, in order to visualize a typical trend which has been found in the patients reporting improvements in the motion constrained exercise. It is interesting to note that, along with the significant reduction in the mean time required to complete a circle, a significant reduction of the associated standard deviation is recognizable, hence suggesting an acquired ability of performing the exercise with a much higher regularity level.

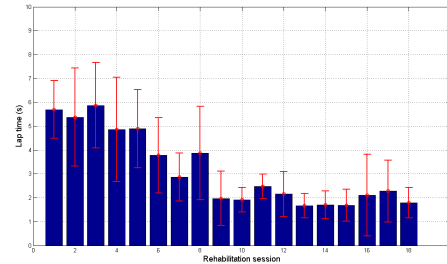


Fig. 9. Sample constrained motion task results - Patient 3

V. CLINICAL RESULTS

All patients have been evaluated by means of standard clinical evaluation scales: - Fugl-Meyer scale: this scale [22] is used for the evaluation of motor function, of balance, and of some sensation qualities and joint function in hemiplegic

patients. The Fugl-Meyer assessment method applies a cumulative numerical score. The whole scale consists of 50 items, for a total of 100 points, each item being evaluated in a range from 0 to 2. 33 items concern upper limb functions (for a total of 66 points) and are used for the clinical evaluations.

- Modified Ashworth scale: it is the most widely used method for assessing muscle spasticity in clinical practice and research. Its items are marked with a score ranging from 0 to 5, the greater the score, the greater being the spasticity level. Only patients with modified Ashworth scale values ≤ 2 were admitted to this study.

- Range Of Motion: it is the most classical and evident parameter used to assess motor capabilities of impaired patients.

Clinical improvements in each scale have been observed by the end of the therapy protocol for *every* patient, and they will now be discussed.

A. Fugl-Meyer assessment

Table I outlines the results obtained by a Fugl-Meyer assessment carried out before and after robotic therapy. Every patient reported an increment ranging from 1 to 8 points, 4 points (out of 66) being the average increment. Such results is absolutely comparable with the results which may be found in the scientific literature [10].

A paired t-Student test on the significance of the increments in the Fugl-Meyer scale leads to a result of $p = 0.003$. The increments are therefore significant from a statistical point of view.

TABLE I
FUGL-MEYER TOTAL SCORES

Patient ID	Pre-therapy	Post-therapy	Difference
1	36	41	+5
2	52	58	+6
3	12	20	+8
4	56	57	+1
5	57	60	+3
6	12	13	+1
7	43	46	+3
8	37	44	+7
9	17	18	+1

B. Ashworth scale assessment

Slight decrements of some values of the Modified Ashworth scale may be found examining detailed clinician assessments. The following improvement index has been defined for each value of the Ashworth scale:

- +1: decrement of one step (e.g. from 1 to 0/1)
- +2: decrement of two steps (e.g. from 1+ to 0/1)
- +3: decrement of three steps (e.g. from 1+ to 0)
- -1: increment of one step (e.g. from 1 to 1+)

The total improvement index has been computed for each patient, as reported in Table II. A mean improvement of 6.2 points in the overall improvement index has been found, with a standard deviation of 4.2 points. It can therefore be asserted that the robotic therapy with the L-Exos device leads to improvements in patients' spasticity levels.

TABLE II
ASHWORTH SCALE IMPROVEMENTS

Patient ID	+1	+2	+3	-1	Total score
1	9	0	0	0	+9
2	3	0	0	0	+3
3	4	1	0	0	+6
4	5	0	0	1	+4
5	2	2	0	0	+6
6	0	0	0	0	0
7	4	2	0	0	+8
8	3	1	0	0	+5
9	6	3	1	0	+15

C. ROM evaluation

Many ROM measurements have been performed by the clinicians collaborating in the protocol. Statistical significance data elaborations on total ranges have been performed by means of the paired t-Student test. Statistically significant improvements ($p < 0.05$) have been demonstrated for many ROMs, whereas many other ROM improvements reached marginal significance ($0.05 < p < 0.10$). Only 1 ROM increment has been found as not statistically significant.

Statistically significant improvements have been found for the following ROMs:

- Wrist - active flexion/extension ($p = 0.004$)
- Elbow - active flexion/extension ($p = 0.005$)
- Shoulder - active inward/outward rotation ($p = 0.008$)
- Shoulder - passive flexion/extension ($p = 0.013$)
- Wrist - passive radial/ulnar ($p = 0.017$)
- Forearm - active pronation/supination ($p = 0.021$)
- Shoulder - active abduction ($p = 0.021$)
- Wrist - passive flexion/extension ($p = 0.030$)
- Wrist - active radial/ulnar ($p = 0.038$)
- Shoulder - active flexion/extension ($p = 0.043$)

Marginally statistical significance has been found for the following ROMs:

- Shoulder - passive abduction ($p = 0.056$)
- Shoulder - passive inward-outward rotation ($p = 0.086$)
- Forearm - passive pronation/supination ($p = 0.088$)

Non-statistical significance has been found for the following ROMs:

- Elbow - passive flexion-extension ($p = 0.111$)

It is to be noted that marginally significant or non-significant improvements have been found for *passive* ROMs, whereas each *active* ROM improvement is at statistically significant. This observation confirms that the therapy with the L-Exos has beneficial effects on the maximum range of motion both for joints directly employed when performing the therapy exercises and for joints not directly exercised by the rehabilitation exercises (e.g. wrist) and blocked in a fixed position during the therapy. This evidence supports the theory stating that a dedicated shoulder or elbow therapy and the resulting neural repair of cerebral areas involved in proximal segments motor control may lead to a natural neural repair of cerebral areas involved in distal segments motor control.

Further evidence supporting such theory is provided by a single patient who reports unexpected significant improve-

ments in hand movements. In particular, he is now able to control finger opening and closing motions at a slow speed, whereas he had not been able to perform any hand movement after the Cerebrovascular Accident. It is to be noted that no hand movements are employed in any exercise performed with the L-Exos system, due to the fact that hand and wrist are blocked in a fixed position with respect to the forearm throughout the therapy.

VI. CONCLUSIONS

The L-Exos system, which is a 5-DoF haptic exoskeleton for the right arm, has been successfully clinically tested in a study involving nine chronic stroke patients with upper limb motor impairments. In particular, the extended clinical trial presented in this paper consisted in a 6-week protocol involving three one-hour robotic-mediated rehabilitation sessions per week.

Despite most of the patients enthusiastically report major subjective benefits in Activities of Daily Life after robotic treatment, it is to be said that no general correlation has been found yet between such reported benefits and performance improvements in the proposed studies. In other words, patients who improve on the reaching task exercise may fail to present a corresponding performance improvement in the path following task and vice versa, and this does not seem to be correlated to the generalized extremely positive qualitative feedback. This observation may be caused by a variety of factors and requires further studies to be conducted.

Nevertheless, qualitative subject feedback is strongly supported by the clinical analyses which definitely underline significant improvements in clinical metrics deriving from robotic-mediated rehabilitation therapy, thus suggesting the possible need for more complex metrics to be used in order to analyze exercise performance. In particular, significant ROM increments for joints which are not actively exercised by the robotic therapy is considered an extremely important result. As a matter of fact, global cortical reorganization involving upper limb can be positively stimulated by exoskeleton devices like the L-Exos, even though some limitations in terms of number of DoFs are present. Further differentiated clinical studies will be conducted in order to evaluate which kind of robotic-assisted therapy is able to provide the best possible rehabilitation outcome.

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