Abstract—This paper addresses the development of an apparatus designed to evaluate clinically the presence of spasticity affecting the elbow. The biomechanical contributions due to the lever-arm muscles and to the gravity force are accounted for using software algorithms that express gravity force and lever arm as functions of the elbow angle and are able to provide information on the force exerted by the muscles at a known speed. The preliminary data indicate that the device can be applied easily in the clinical setting. Further studies are required to demonstrate conclusively the validity and reliability of this device in quantifying spasticity at the elbow.

Key words: elbow, muscular force, spasticity, stretch reflex.

INTRODUCTION

Spasticity, properly defined by Lance (1) as a “motor disorder characterized by a velocity dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyper excitability of the stretch reflex, as one component of the upper motor neuron syndrome,” is normally evaluated through semi-qualitative scales like, among others, the Ashworth scale. Its clinical assessment is hampered by the dependence of the disorder upon numerous factors (e.g., initial muscle tone, length of responding muscles, posture, state of relaxation, et cetera) that must be taken into account to obtain a reliable clinical assessment of the pathology (2).

Although many attempts have been provided for quantifying spasticity with the help of motorized and sensorized devices for elbow (3), knee, and ankle (4), their use is still very limited—probably because of the difficulty in using such apparatuses in clinical practice. In addition, accurate measurement is prevented by the fact that skeletal muscles are length- and velocity-dependent force generators (5) and the distance between their line of action and the center of bone rotation changes greatly within the allowed range of motion (ROM; reference 6).

The first evidence of the relationship between speed and stretch reflex has been given by Wartemberg in 1951 with the pendulum test for the leg (7) and quantified many years later (1984), by Bajd and Vodovnik (8). The test is performed by elevating the leg of the patient at the maximum extension and then permitting the free oscillation of the knee joint while electromyography (EMG) and angular position against time are recorded.
In normal subjects the behavior of the knee angle is similar to a second order viscous damped mechanical system in response to a unit step input (see Figure 1).

The EMG activity is not usually present on normal subjects. When testing subjects with spasticity, a stretch reflex is evoked that causes a decrease of the amplitude of the oscillations and, in some cases, an inversion of motion. Such a stretch reflex can be evidenced by EMG activity. The test is quantified by the Relaxation Index—the ratio between the angle relative to the maximum oscillation and the angle necessary to reach only the rest position.

Puglisi demonstrated that in some subjects with spasticity, such an index is not determined because the spastic reaction is not sufficient to invert the motion of the leg, but only to modify the trajectory of the angle (9).

In cases of spasticity at the upper arms, it is extremely difficult to quantify the extent of the disorder by applying the pendulum test. This is because of the practical difficulty in having a patient achieve a comfortable position that can still permit the action of gravity against the forearm. Furthermore, some patients showing severe spasticity are not able to freely move their limbs.

Wolf (1996), by using a motorized device, tried to establish a threshold angle, defined as the angle at which a change in muscle response is elicited during passive stretch (10), as a method for measuring spastic hypertonia. He concluded that, in general, there is great intra-subject variability because the trial is affected by starting angle, speed, and session. Finally, Sehgal has pointed out the lack of reliability of the Ashworth scale, suggesting a clinical protocol for a better clinical assessment of the disorder through electrophysiological techniques (11).

Despite the numerous methods proposed for assessment of spasticity, very few are used in clinical practice, perhaps due to the complexity in clinical use of the associated apparatuses. Nevertheless, the clinical evaluation of spasticity and tone is crucial for the clinical assessment of new interventions aimed at reducing the effect of such a disabling condition (e.g., Botulinum toxin, Baclofen injection) as well as for the optimal reorganization of the altered capabilities of the patient.

The purpose of the present work is, therefore, to demonstrate the effectiveness and user-friendliness of a simpler apparatus aimed at providing clinicians with an accurate measurement of spasticity at the elbow level.

**Objectives**

The objectives of the present study are to provide clinicians with a simple device able to evaluate the presence of spasticity at the elbow and to quantify how the influence of velocity, gravity, and the moment arm can affect clinical assessment. In fact, as shown in Figures 2a, 2b, 2c and 3, the great variation of the moment arm of the main flexors and extensor of the arm, plotted against the elbow angle, acts as a biomechanical artifact in the evaluation of the presence of the disorder. If it is assumed to maintain a constant muscular force at the triceps and to apply a measurable torque at the elbow joint sufficient to maintain equilibrium conditions, a decrease of the applied torque is noticed because the lever arm variation changes approximately from −25 mm to −15 mm (Figure 3) within the elbow ROM. The same decrease should be noticed if the test is performed during elbow extension because the moment arms of all the flexor muscles decrease their magnitude (Figures 2a, 2b, 2c).

Another biomechanical contribution is given by the variation of the gravity force acting on the center of mass (G) of elbow plus hand, because the distance between G and the elbow joint rotation axis changes within the elbow ROM. As a result, the clinical evaluation of the passive resistance offered by the subject during the assessment of spasticity at the elbow level is unavoidably affected by the above contributions.

Since the lever arm of the flexors and extensors can be expressed as a polynomial function of the elbow angle (6), the mass of elbow plus hand segments as a percentage
of body weight, and the distance between their centers of mass and their elbow rotation axes as a percentage of the height of the subject, it is possible to account for all these factors using algorithms that provide accurate information on the muscular force exerted within the allowed ROM.

METHODS

Materials

A clear definition of the main system requirements was obtained by imposing strict functional specifications concerning the suitability of the device to different positions of the patients, as well as to abnormal postures. To this end, the apparatus has been equipped with additional, adjustable passive degrees of freedom (dof) allowing an easier interface with patients. It was decided to conduct the test with the patient seated or stretched out and to avoid locating passive or active markers on the skin of the patient as much as possible. The above considerations, together with the additional, technically feasible constraints of the apparatus, have led to a mechanical design where the device is located in front of the side to be examined (Figure 4).

With reference to Figures 4, 5, and 6, the system is equipped with a torque sensor (strain gage full bridge configuration; accuracy 0.1 N-cm, maximum load 20 N-m) purposely conceived to measure the resistance of the patient and a miniaturized angular sensor—Hall effect-based (accuracy 0.5°; range 0–180°; sensitivity 7 mV/°; power supply: 5 V; output range: 1.6–3 V)—able to measure elbow angular motion. The above sensors are embedded in the electromechanical subsystem, and are comprised of: 1) an adaptable cast for the elbow; 2) two linear slides, for making the necessary adjustments along the vertical axis; and, 3) an angular passive dof, permitting the correct alignment between the anatomical elbow axis of the patient and the rotational axis of the system. The device can, therefore, be adjusted for the patient, and allows maintenance of a comfortable posture (see Figures 5 and 7).
Two EMG sensors (amplification gain 8.600; power supply 5 V; output floating at 2.5 V) are used to measure EMG activity during the trials, in order to account for hyper-excitability of the stretch reflex at different speeds. An external, battery-powered, opto-isolated acquisition unit, connected via a serial port to a host computer, allows real-time acquisition and processing of data that can be stored, analyzed, and compared offline through a purposely developed software. The only sensors to be physically positioned on the patient are the EMGs (see Figure 5).

Test Methodology
The test is performed with the patient seated or laying in the most comfortable position with the machine located in front of the side to be examined. The equip-
The goodness of fit of the above polynomial expressions are estimated by the coefficient of determination, $R^2$ (correlation coefficient squared), which is $R^2 \geq 0.9904$.

By applying an equilibrium equation and assuming one can neglect the inertial forces, it is possible to obtain information on the muscular force exerted. In fact, with reference to Figure 8, we have:

$$C_{ext} + W \cdot l \cdot \cos \alpha = F_m \cdot d_m \Rightarrow F_m = \frac{C_{ext} + W \cdot l \cdot \cos \alpha}{d_m} \quad [1]$$

where: $C_{ext}$ = applied torque (measurable), $W$ = gravity force, $l$ = distance of the center of mass (G) from the rotation axis, $\alpha$ = elbow angle, $F_m$ = muscular force.

Since $W$ can be expressed as a percentage of body weight and $l$ as a percentage of body length, we can plot the muscular force against time within the elbow ROM.

Finally, since the terms used in Equation 1 do not account for the contributions from the spastic reaction, which is a function (according to the definition given by Lance in reference 1) of the angular velocity $(d\alpha/dt)$ (see Figure 8), curve segments executed at different constant speeds are extracted via software, compared, and the differences between them analyzed.

From a clinical perspective, by quantifying the contributions due to the gravity force and the lever arm, we hope to answer the following questions: Does the weight of forearm and hand affect clinical assessment? Is such a
contribution significant? Is it possible to establish a clinical protocol to help clinicians avoid the artifacts caused by the lever arm variation in the assessment of spasticity at the elbow? Such information would be of great clinical relevance, particularly in the accurate evaluation of new interventions aimed at reducing the presence of the disorder (e.g., Botulinum toxin, Baclofen injection, et cetera).

Validation Studies

The development phase of the system, together with the procedures necessary to characterize the “quality” of the new measurement device, has been carried out.

As far as accuracy, resolution, and repeatability of the sensor readings are concerned, they have been quantified using a liquid goniometer and a known weight. In order to verify to what extent the system can quantify the contribution of the gravity force, the following experiment was designed. A known weight with a well-defined geometry was positioned at a known distance from the rotational axis of the system. By using only the information obtained by the angular sensor, a simulation of the torque generated by the weight was performed (the distance of its center of mass being a function of the angle $\alpha$). Therefore, the information acquired by the angular sensor (Figure 9a) has been compared with that acquired by the torque sensor.

The comparison between the two curves is given in Figure 9b, where the maximum error of approximately 10 N-cm is due to the inertial forces acting during the inversion of movement (flexion-extension).

An additional trial was then carried out using a sample of 11 healthy subjects (mean age, 35 y; variance, 15 y). By introducing their anthropometrical data (height and weight), data on the position of the center of mass and the weight of the elbow plus hand could be and were extracted (12). Assuming zero to be the muscular force exerted by the patient ($F_m=0$), it was possible to again perform the test, comparing the information acquired by the angular sensor and the torque sensor, respectively (see Equation 6).

In order to assess any possible voluntary resistance exerted by the subjects, EMG activity has been recorded during the test over the same time intervals (Figure 10a).

A difference in system accuracy was noticed when performing the test in elbow flexion or in extension, for almost all the frequencies examined. With reference to Figure 10b, an example of a test performed at a frequen-
The irregular curve represents the torque read by the torque sensor (real torque); the second curve is the simulation of gravity, introduced using angular sensor information (see Figure 10c), plus data relative to the patients’ anthropometrics. With reference to Figure 10b, during elbow flexion (descendant curves) the two curves are well correlated, while during elbow extension an inversion of motion, together with a considerable error, are noticed. Such error increases when the operator performs the inversion of motion (elbow fully extended).

The mean errors obtained on the examined sample are: for elbow flexion, 30 N·cm; for elbow extension, 70 N·cm.

Such preliminary results have indicated that the system is more accurate if the test is carried out in flexion. Further studies are in progress to identify the reasons for the differences in the system.

In order to have information on the suitability of the system for patients with abnormal posture, a preliminary test on 14 subjects affected by stroke (mean age, 65 y; variance, 10 y) was performed. Preliminary data have shown the suitability of the system to 85 percent of the examined cases.

The main difficulties were encountered with patients with severe spasticity at the shoulder joint. In particular, if the disorder also involved the shoulder abduction-adduction and internal-external rotation movements, it was impossible to find a comfortable patient posture that would permit alignment of the machine axis to the anatomical elbow axis.

DISCUSSION

The clinical use of any new measurement system requires validation through a set of experiments aimed at determining accuracy, precision, repeatability, and reproducibility of the test parameters assessed with the apparatus. To this purpose, technical and clinical tests must be performed in order to quantify all the sources of error affecting the readings. Particular attention must be paid to establishing inter- and intra-operator errors, through the application of a standard statistical analysis aimed at determining mean value and confidence interval of the variable under examination.

The preliminary tests carried out have shown an easy use of the apparatus in the clinical setting. The suitability of the machine to the posture of a patient, combined with the possibility of treating the patient either in bed or in a wheelchair, has allowed its use on 85 percent of the cases, although difficulties have been encountered with some patients showing spasticity at the shoulder joint.

A clinical test can be performed in approximately 15 min and limited training of clinical personnel is necessary. The results obtained have shown sufficient robustness in mechanical structure and sufficient accuracy of the sensors used.

In summary, the preliminary data have indicated that:
• it seems possible to assess the influence of gravity, although the system seems more accurate when the test is executed in flexion (mean error, 30 N-cm); and,
• operators are capable of carrying out part of the test at a constant speed, required by the software for data processing, analysis, and comparison.

A considerable number of clinical tests are in progress in order to analyze data from patients with different motor disorders. In particular, we hope to learn how the shape of the resistance curve is modified because of the influence of the lever arm and gravity in patients affected by spasticity. Tests performed at different speeds will be compared in order to quantify the velocity-dependent behavior of the phenomenon.

CONCLUSIONS

The development and preliminary validation phases of the apparatus have been completed. Their use for the quantification of spasticity evaluated at the elbow level seems, therefore, feasible in clinical practice. An extensive number of tests are in progress on patients affected by stroke, in order to evaluate the effective application of the device in patients showing spasticity at the elbow.

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REFERENCES


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