Portable low-cost smart brace for elbow rehabilitation

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PORTABLE LOW-COST SMART BRACE FOR ELBOW REHABILITATION

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ABSTRACT

This article deals with the development and experimentation of an elbow static progressive brace equipped with special sensors, aimed at objective evaluation of the physiological response of the articulation during treatments for recovery of the functional range of motion. The device is able to acquire and record the moment which is applied to the joint and the flexion angle of the latter. The first part of the article describes the general design of the brace, which takes into account the several specifications of such a device. The design considers both the mechanical and electronic requirements of the application. The device, after acceptance tests, was employed in an experimental phase where two different patients were analyzed. Ultimately, the device proved to be an useful instrument for the classification of the patients and the definition of the treatment protocol; further experience may allow to define criteria for an objective monitoring during the rehabilitation treatment.

Keywords: elbow brace, elbow splint, static progressive brace

1 INTRODUCTION

The elbow joint rigidity can have several causes and is very invalidating: the 50% reduction of elbow range of motion (ROM) induces a decrease of 80% of arm functionality, while the altered movements of the limb generate failure and overload on bones and muscles [1].
The causes of elbow rigidity are various, i.e fractures, burns, surgeries, cranial trauma and degenerative diseases[2], but all of them bring to joint immobilization. Depending on the cause, the rigidity is called ‘intrinsic’, when the overall geometry of the joint is altered, or ‘extrinsic’, when soft tissue or heterotopic ossification are involved. Sometimes the rigidity affects only the flexion-extension movement, but more often the prono-supination is involved too [3].
The joint immobilization causes various chemical, physical and mechanical changes in the tissues and these bring to rigidity.

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Indeed, any biological tissue suffers a remodelling when subjected to physical, mechanical or chemical stimuli. The first affected tissue is the periarticular connective tissue, in which there is an increase of intermolecular links due to water and collagen losses, which limit the elasticity [4]. Another consequence of the immobilization, hence a cause of rigidity, is the growth of adhesions: scar tissue formations between tissues that normally move relative to one another. In addition, the muscles undergo some changes caused by the immobilization in a shortened position: they themselves result to be shortened, losing sarcomeres [5].
According to the specific need of the patient, the clinician decides the therapy. If there is an internal cause or a change in joint structure, the doctor usually chooses a surgical treatment depending on the specific characteristics of the disease. Otherwise, the doctor can decide to opt for a non-invasive method: physiotherapy, use of continuous passive motion machines, braces and drugs. Braces keep the joint in the extreme position of ROM for several hours a day, resulting in a very slow recovery. Therefore, the therapy should provide active motion as well [6] in order to enhance the effectiveness of the therapeutic treatment.
There are several types of braces that can be differently classified. For example, according to their general functioning, the elbow braces can be classified as [3]: *immobilization braces*, which prevent any movement of the joint; *restriction braces*, which allow passive and active

movements in a restricted range; *mobilization braces*, which apply a certain force to the joint to maintain or increase ROM. The mobilization braces can be classified in two categories, according to the way the force is applied to joint: *dynamic braces* (Figure 1a), which use elastic elements or metallic springs; *static progressive braces* (Figure 1b), which use inelastic components such as static line, progressive hinge, gears, hook-and-loop tape and screws.

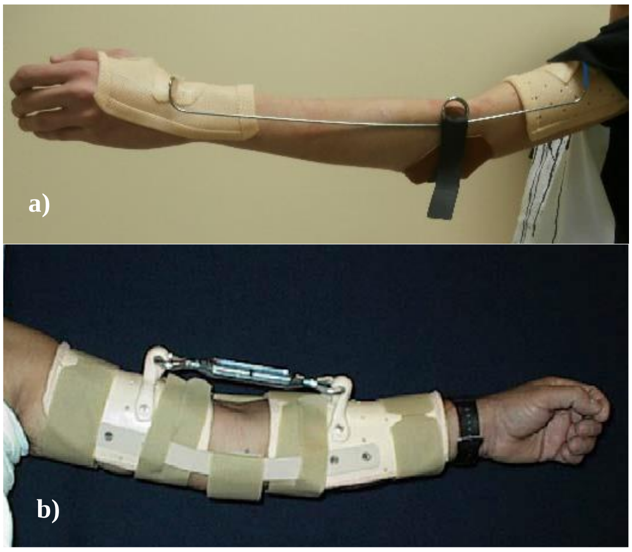

Figure 1 (a) Dynamic brace with coil springs. (b) Static progressive brace [7].

A further type of brace exists, called *static serial brace*, in which the element does not allow a change in position as ROM increases. A second classification can be done according to loading condition [8]: *creep-based loading*, when the moment is held as constant while the ROM is increasing; *stress-relaxation loading*, when the applied moment varies over time against a stable ROM. With the first loading case the effectiveness of the treatment significantly depends on the characteristics of the specific patient, since in some cases there is no plastic change in the tissue during the 12 hours a day the brace is worn. In the second loading case, instead, the plastic changes in the viscoelastic tissues occur significantly faster. The static progressive braces apply this kind of loading.
When the clinicians have to choose the most suitable type of brace for the patient, they must take into account various considerations: diagnosis, surgery, patient inclination to accept the brace, general patient conditions and scar evolution stage. Many algorithms have been developed to help the therapists in this choice but all of them have subjective components or failures. Flowers [9] designed such an algorithm, based on the criterion of the joint compliance, which is evaluated with a test called "modified Weeks test". According to the gain of ROM obtained after a thermal treatment, the therapist chooses the best type of brace: if the gain is approximately 20°, the patient is not splinted; if the gain is about 15°, a static brace is used; if the gain is 10°, a dynamic brace is recommended; if the gain is 5° or less, a static progressive brace is required. However, this algorithm shows two main failures: the use of goniometer for ROM evaluation generates errors, in addiction there is no indication about the applied moment and for this reason only pain criterion is used, which is very subjective.
Schultz-Johnson proposed another algorithm based on scar healing stage [10]: if scars are in acute stage, static and serial static braces are recommended; during proliferative stage, instead, the therapists choose serial static, progressive static or dynamic braces; at last, if scars are chronic the option is between serial static and progressive static braces. However, the main limitation is that this algorithm can be adopted only in presence of scars, which are instead absent when rigidity is caused by other tissues problems. In addition, this algorithm has subjective components as the valuation of scars, which have not certain healing timing.
After choosing the kind of brace to be used, the clinicians can be helped in the use by another algorithm [11]. It requires to set the level of force applied to the joint, but this cannot be objectively determined with current instrumentation. For this reason, the therapist bases his decision on his experience, while defining intensity, frequency and duration. The intensity is often limited by patient pain, while frequency and duration are combined into another parameter, TERT (total end-range time), obtained by their product.
In conclusion, the elbow rigidity is still a disease extremely difficult to tackle in a systematic way and currently no specific instrumentation is available to give objective and quantitative data to personalize the therapy. Indeed the rehabilitation strategy is still defined only by means of the therapist experience and sensibility, based on the inaccurate measurements of a goniometer. Therefore, in order to overcome these limits, this work is aimed to the development of a mechatronic instrument able to give quantitative and objective data, supporting the therapist in a more appropriate definition of the rehabilitation treatment protocol.

2 THE INSTRUMENTED BRACE

The device presented in this work is based on a three-point static progressive brace (TPSPB) for elbow extension recovery, whose architecture allows a precise regulation of the flexion angle and of the applied moment at the same time. This original brace has been equipped with load and angular position sensors and a data acquisition system. In this way, when the brace is worn by the patient, the data acquisition system gives to an operator the information about voluntary or involuntary variation of force and angle.
The original structure is a TPSPB with turnbuckle, as shown in Figure 2, which has been modified for sensor's insertion as described below.
The original turnbuckle has been replaced by a custom-made jackscrew, provided with a load cell for the measurement of the force applied to the brace and proper spherical joints for a precise connection to the device. The features of the load cell (DACELL UMM-K20) are: rated capacity 200 N; nonlinearity and hysteresis less than 0,1% of rated capacity.

In order to measure the angular displacement, a rotary potentiometer has been inserted in the joint axis of the brace (CERMET): rated capacity 270 deg, nonlinearity and hysteresis less than 0,5% of rated capacity.

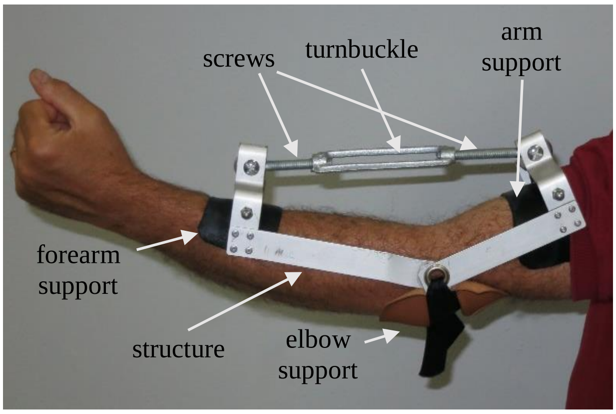

Figure 2 The original brace with its components.

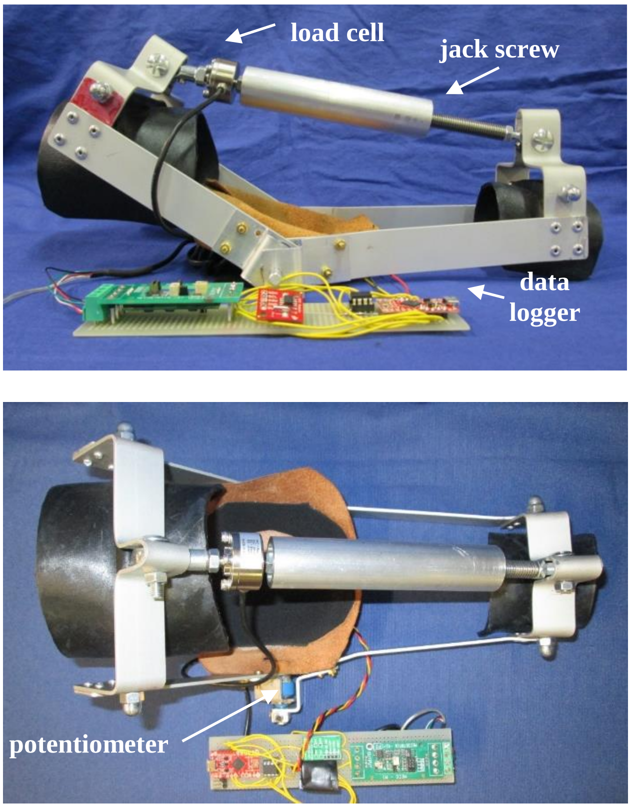

Figure 3 The instrumented brace with its components.

To record and elaborate the signals produced by the sensors, a miniaturized data logger has been realized. It features:

- Two analogue inputs for sensors acquisition (sampling rate 1 Hz);
- Sensor signals conditioning;
- Data storage in memory;
- Data export through USB standard communication.

To fulfill all requests, the following basic components have been integrated:

- A ProMicro® electronic board (SparkFun, Italy), provided with microcontroller ATmega32U4 and programmable with Arduino® software;
- A MecoStrain® instrumentation amplifier (DSPM Industria, Italy), i.e. a miniaturized conditioning module for full bridge strain gauge;
- A DC-DC voltage converter (boost), for proper supplying of the amplifier;
- An EEPROM rewriteable memory (24LC256, Microchip, Italy), for direct interface with microcontrollers;
- An RTC DS1307 module with timer function (SparkFun, Italy), for real time tracking even if the device is turned off.

The Figure 3 shows the brace equipped with all the components previously described

3 EXPERIMENTAL TESTS

The experimental tests were aimed at verifying the correct functioning of the instrumented brace and its effectiveness in the characterization of the patients, thus providing quantitative data to the clinicians in order to improve their subjective evaluations.

Two experimental sessions on two different patients, named A and B, were performed. The main data of the patients are reported in Table I. Informed consent for treatment interventions, photographs, and videos were obtained from the patients.

Table I. - Main data of the patients

	sex	**age**	**pathology cause**	**injured arm**	**cold PROM**	**after thermal treatment PROM**
A	m	19	accident trauma	left	ϑ=150°	ϑ=158°
B	m	46	accident trauma	left	ϑ=138°	ϑ=138°

The protocol of the session is summarized in the following steps:

1. The operator measures patient’s cold initial passive ROM by a goniometer;
2. The operator applies the brace and checks its correct positioning;
3. The operator commands a signal acquisition in zero condition (no load on patient limb);
4. The brace is progressively forced to the maximum extension position tolerated by the patient, maintained for 3 minutes;

5. The patient undergoes thermotherapy (by hot packs) for 20 minutes;
6. The points 1 and 2 are repeated;
7. The brace is brought to the maximum extension position tolerated by the patient; if the patient feels reduction of tension, asks for restoring of maximal tolerable force;
8. Eventually, the load application is repeated.

The various steps of the protocol are aimed at extracting different information on the patient and its response to the brace application, according to the following criteria:

- Step 4 allows a direct measurement of the maximum tolerable moment in the articulation;
- In steps 4, 7 and 8, one should expect an increase of articular moment when the extension angle is contemporarily increased, that can lead to the calculation of the Torque Angle Curve (TAC) and of the articulation stiffness.
- Steps 7 and 8 should provide information about the effectiveness of the therapy: referring to an hypothetical mechanical model, after a while, because of a first relaxation of the tissues, the force moment on the articulation should decrease and the patient should be willing to restore the maximum force by increasing the brace angle.

4 RESULTS

Despite the same protocol was applied to the two patients, the results were very different, not only in the level of the recorded signals, but mainly in the subjective patients' response and the overall trend of the force-position behavior. By way of example, Figure 4 shows the variation of the extension angle and the corresponding articular moment versus time of patient B, recorded in the step 7 of the protocol. The red bars correspond to the request of the patient to increase the angle. The moment is calculated multiplying the force measured with the load cell by the force arm, calculated as the distance between the center of the hinge and the line representing the axis of the load cell, as a function of measured extension angle and geometry of the brace.
Considering only the section of the curve related to the initial application of the load (step 4, 7 or 8), by filtering and post processing the data, it is possible to obtain the Torque Angle Curve (TAC) of the patient. As an example, Figure 5 shows the TAC of the patient A, obtained in three different load applications: cold load application (TAC1), load application after thermal treatment (TAC2), further load application after the interruption of test 2 following the onset of a hand tingling (TAC3). The third test has been immediately interrupted due to scar pain, and it is therefore not very significant.
As can be seen, the TAC obtained in the three subsequent tests still show a good overlap. In particular it can be affirmed that the slope of the curve is characteristic of the patient in the current conditions, as evident from the comparison between TAC of patients A and B shown in figure 6.
Finally, starting from the TAC, it is possible to evaluate the articular stiffness of the patient, defined as the ratio between the moment and the rotation angle. Figure 7 depicts the angular stiffness of the elbow of the patient A, obtained from TAC1 and TAC2.

5 CONCLUSIONS

The device here described has been conceived as a tool to support the therapist in profiling a patient with post-traumatic elbow stiffness and defining the most appropriate rehabilitation protocol.
Although rather limited and with no statistical base, the preliminary tests evidenced that the information provided by the device are strictly related to the patient's condition and representative of its evolution during a rehabilitation process.
In particular, analyzing the time history of the test, it is possible to quantify the maximum tolerable moment (MTM, Figure 4) in the articulation. This value is extremely subjective and could vary according to different personal factors, such as stress and mood. However, a change in MTM is above all due to joint stiffness variation. For instance, an increase in MTM during a recovery process may be an evidence of the effectiveness of the rehabilitative therapy, together with an increase of ROM.
Besides, the measure of patient's MTM in a preliminary application of the device would also be useful in case of therapy provided by dynamic brace: in fact, this parameter could be used to size the elastic elements of the brace so as to tailor it to the specific patient needs.
In addition, a proper application protocol of the device could be used in a preliminary evaluation phase to verify if the patient is suited for this kind of therapy or otherwise it is more appropriate to orientate towards a different method, for example dynamic splinting.
The instrumented device has also proved to be suitable for tracing of both the Torque Angular Curve and the angular stiffness of the patient's elbow.
The experimental tests have also highlighted some weaknesses of the device, that must be taken into account and corrected when the brace is applied to the patient. In particular, it is appropriate to consider the complexity in aligning the anatomical axes with those of the brace, and, in any case, in the evaluation of the angular deviation between the two axes with good repeatability. When the brace is worn, it could be advisable to identify some anatomical references and take photographs so as to be able to calculate the deviation between the two axes in case of a second application.

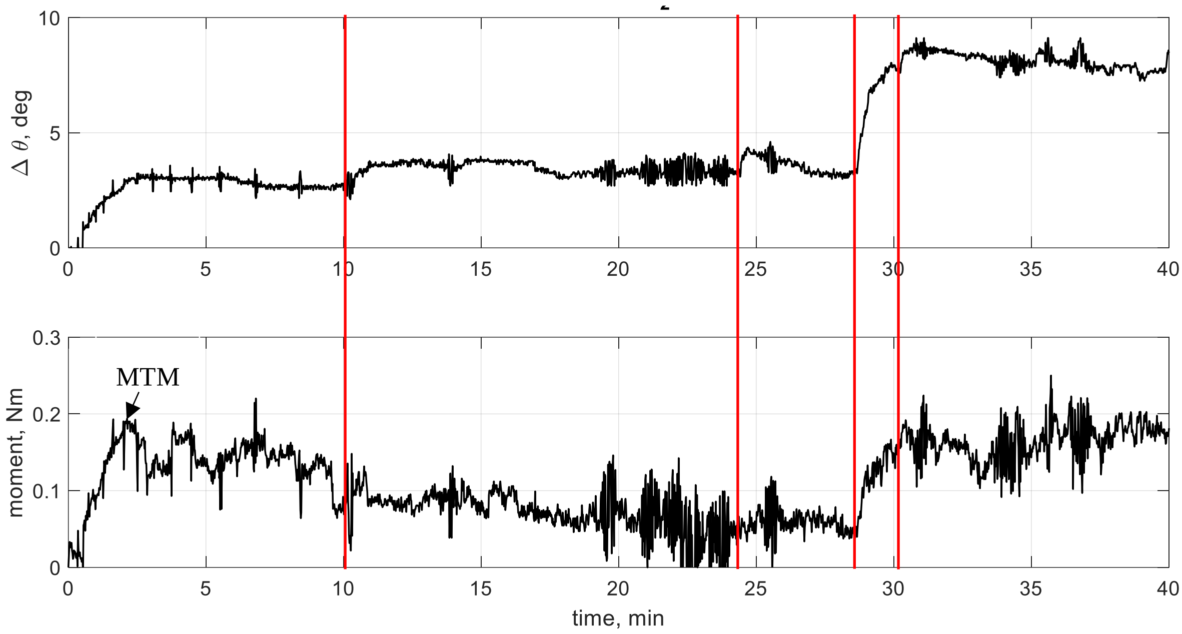

Figure 4. The values of articulation moment and variation of extension angle during application of the brace (patient B, step 7 of protocol). Red bars indicate the instants at which the patient asked to increase the force. MTM: maximum tolerable moment.

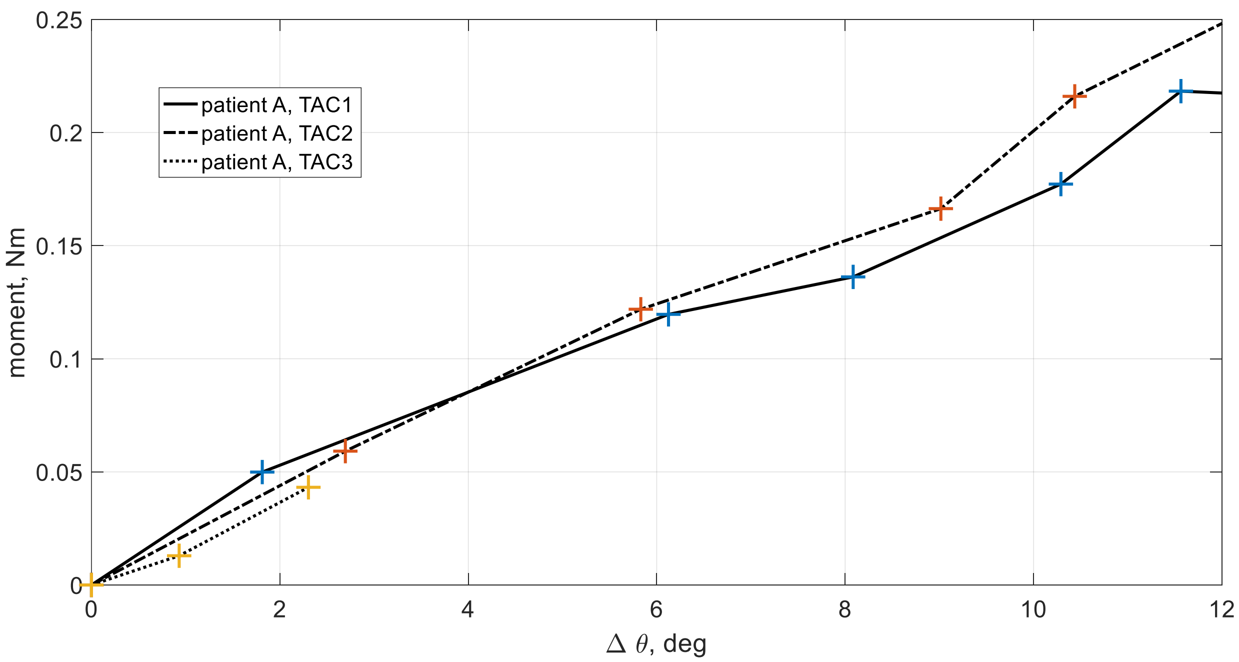

Figure 5. Torque angle curve (TAC) obtained in three different application loads to the patient A elbow.

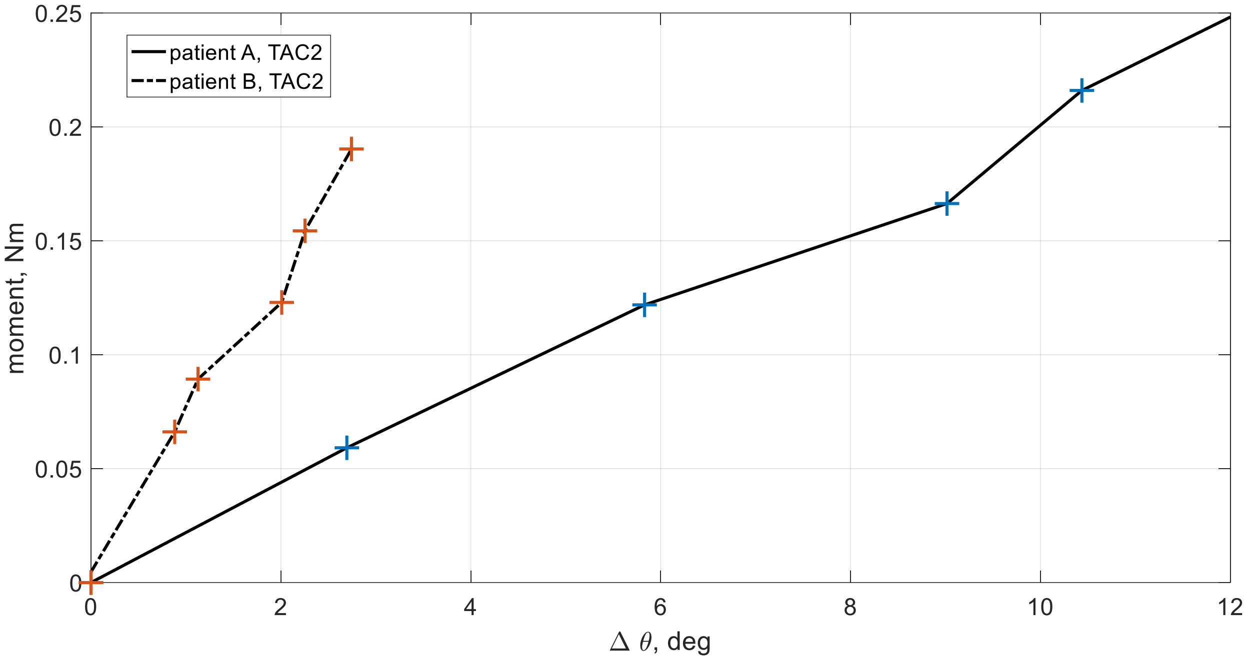

Figure 6**.** Comparison of torque angle curve (TAC) obtained in two different patients.

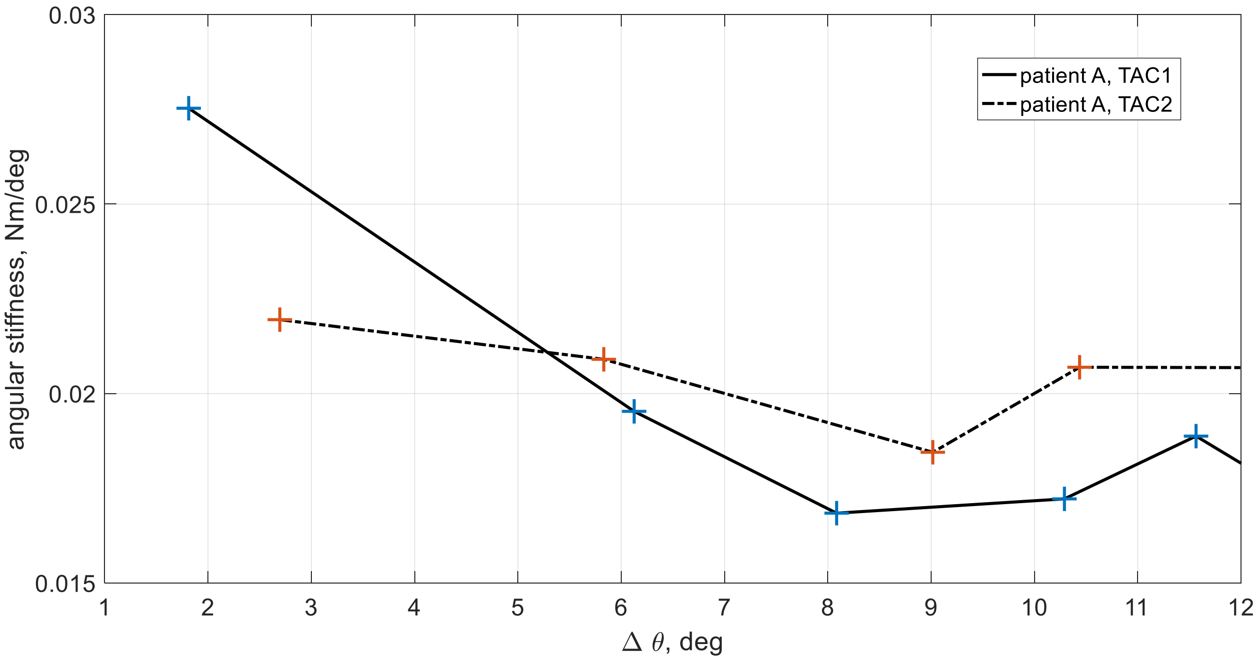

Figure 7. Angular stiffness versus the variation of extension angle of the patient A.

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