Technical Evaluation of the SCRIPT Passive Orthosis

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***Abstract*— Rehabilitation robots are useful tools to objectively quantify and treat post-stroke impairments. The SCRIPT Passive Orthosis (SPO) is an passively actuated hand orthosis that can be used for interactive therapy at home. In the last year the SPO was used independently by 24 patients in three EU countries. In this paper we report on the technical challenges this has presented and the, mostly positive, feedback we were given by the patients. This includes the range-of-motion of the device, the assistive characteristics, and the user acceptance. The evaluations reported here have already been used to improve the design of the upcoming SCRIPT Active Othosis (SAO).**

I. Introduction

Impairments in the hand are often the most debilitating for stroke survivors. Patients struggle with simple activities such as buttoning shirts, tying shoelaces, opening bottles, and eating with knife and fork. The movement impairments are caused by muscular weakness, overactive reflexes, muscle control imbalances, and loss of sensory information, and require intensive physical therapy to overcome.

In recent years, more and more rehabilitation devices have facilitated therapy in the clinic. These devices have reduced the workload for the therapists and have made physical therapy more efficient [1]–[5]. As therapy intensity has a strong correlation with functional recovery [6], [7], the most recent trend is to move the therapy from the clinic to the home, where patients can practice longer and at more convenient moments in their day.

Advanced rehabilitation devices for home use allow patients to perform controlled exercises at the right intensity and duration, while therapists can monitor progress remotely. In the SCRIPT project (EU-FP7), we have developed such a system. It consists of the SCRIPT Passive Orthosis (SPO, [8]), interactive games, and a clinical monitoring back-end.

The SPO is a wrist, hand and finger orthosis (see Fig. 1) that compensates for impairments caused by spasticity and abnormal synergies. These impairments are characterized by excessive involuntary flexion torques that severely inhibit hand function. The SPO offsets these undesired torques with passive springs. The SPO cannot actively generated or control movements, thus the user needs to use voluntary muscle activation to perform movements and is therefore always actively involved.

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Fig. 1. The SCRIPT Passive Orthosis (SPO).

The SPO physically interfaces with the forearm, hand and fingers of the users. It offsets the undesired flexion after stroke by applying external extension torque to the wrist and extension forces to the fingers via passive leaf springs and elastic tension cords. The amount of support can be adjusted. The SPO is equipped with sensors to measure the joint rotations and applied forces, and interact with the computer system. It also provides information on the users forearm posture and movements.

In 2013 the system was used independently by 24 patients in three EU countries. In this paper we report on the technical challenges this presented for the SPO and the feedback we were given by the patients. The information has helped us to improve the design of the upcoming SCRIPT Active Othosis (SAO), but should be of value to any designers of interactive rehabilitation systems.

II. Technical Evaluation

A. Hardware Components

The hardware components of SPO are (also see Fig. 2):

- Physical interfaces: forearm shells, hand plates, and digit caps, all available in multiple sizes.
- Finger mechanisms: digit leaf springs and adjustable tension cords.

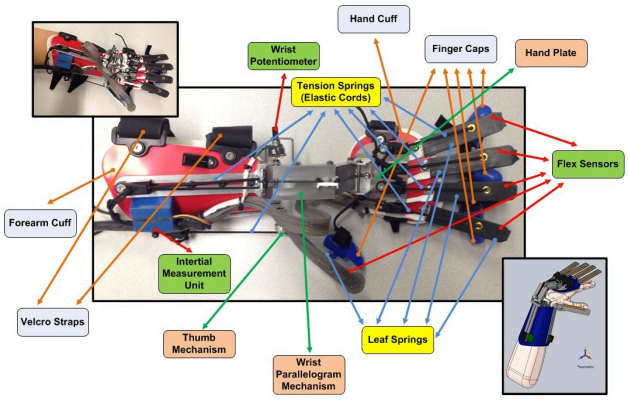
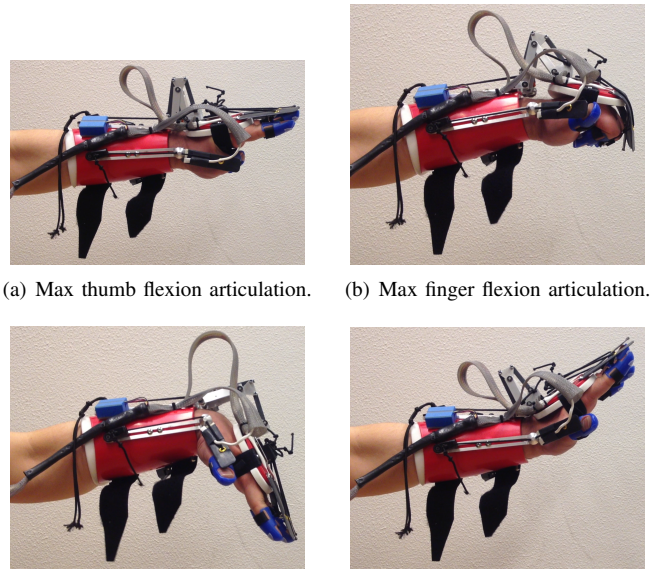


Fig. 2. The hardware components in the SPO.



(a) Max thumb flexion articulation. (b) Max finger flexion articulation.

(c) Max wrist flexion articulation. (d) Max wrist extension articulation.

Fig. 3. SPO flexion and extension of the thumb, fingers and wrist.

- Wrist mechanism: double parallelogram between forearm shell and hand plate.
- Device controller: microcontroller board for sensor readings and conversions.
- State sensors: integrated measurements units (IMUs) for forearm posture estimation.

B. Range of Motion

The most important requirements relate to the desired Ranges of Motion (ROMs). Tab. I details the desired (in brackets) and achieved ROMs as measured from video stills (see Fig. 3). (The first item listed in the DoF column is defined as the positive direction for the angles in the Max/Min columns.)

The achievable maximum angles strongly dependent on the physical characteristics of the hand of the individual user. Healthy users could achieve most the desired ROMs without difficulty, as indicated with +'s in the table. There are a few exceptions. One, rotations of the thump IP and finger DIP joints are blocked due to the usage of the digit caps that cover these distal joint axes. Two, the extension of the MCP joints is intentionally blocked by the hand plate to prevent overextension. Three, the achievable wrist extension was restricted for some, though not all, users. These limitations are discussed per mechanism below.

C. Finger Mechanism

The finger actuation mechanism consists of leaf spring and an elastic cord. The elastic cord is attached to digit cap on the finger. The digits are actuated in extension only, as per the requirements for the device. The elastic cord both provides the desired extension cord (together with the leaf spring), but it also allows the mechanism to be compliant enough to not interfere with the natural movements of the fingers, such as for variations of flexion/extension per digit axis or with ab/adduction of the finger. It is a light structure that has minimal impact on moment of inertia on the hand. The mechanism is inexpensive and through the use of changeable finger caps can be fully customized for each patient.

TABLE I

SPO ROM FOR HAND AND WRIST JOINTS.

Segment	Joint	Degree of Freedom	Max [deg]	Min [deg]
Forearm	Wrist	Flexion/Extension	40+ (40)	-20 (-40)
Thumb	CMC	Palmar Abduction	50+ (50)	0 (0)
	CMC	Radial Abduction	20+ (20)	0 (0)
	MCP	Flexion/Extension	60+ (60)	0 (-5)
	IP	Flexion/Extension	15 (80)	0 (0)
Index, Middle, Ring, Pinky	MCP	Flexion/Extension	60+ (60)	0 (-5)
	PIP	Flexion/Extension	80+ (80)	0 (0)
	DIP	Flexion/Extension	15 (80)	0 (0)

The mechanism includes a bending sensor (Spectra Symbol, SEN-10264, 55 [mm]) in the leaf spring to measure both the finger movement and the applied force (see [8]). The leaf springs are covered with the plastic shrink tubes that protects both these sensors from the environmental conditions such as liquids, mechanical impacts, etc, but also the user from possible sharp edges.

As the digit caps block the PIP joint rotation (see Tab. I), the two distal digit segments rotate as one, which reduces the complexity of movement. The combined segment is better suited as the application point for the extension forces as it prevents overextension of the most distal joint. Even so, it is still possible to make a full grasp while wearing the orthosis (see Fig. 3).

Measured perpendicular to the fully extended finger, the maximum exerted force on the tip of the finger is 10 [N]. The actual exerted torque on the finger is highly non-linear depends on the bending of the leaf spring, the extension of the elastic cord, and on the angle between the cord and the digit cap. The latter deviates from perpendicular with greater joint angles, although the 'following'-behavior of the leaf spring compensates for these partially.

The clinical partners and the patients report that the assistance force achieved was satisfactory, and that the flexibility of the leaf spring both facilitated don/doffing and improved

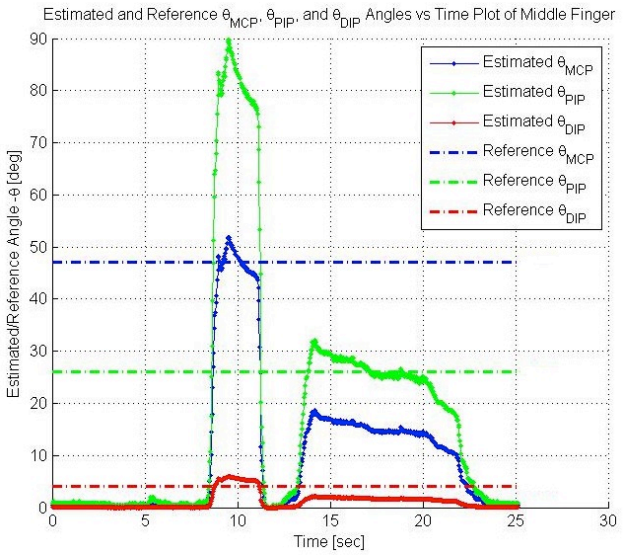


Fig. 4. Grasping an object consists of three different phase. In the first phase (0-5 sec), the hand is held flat. In the second phase (8-12 sec), the hand is making a full grasp without any object present. These two phases are used to calibration the bending sensors. In the third phase (16-19 sec) an 84mm wide cylinder is grasped. Estimation of MCP, PIP and DIP rotations is given in blue, in green, and in red, respectively. The reference angles are measured during grasping of the cylinder in the third phase. There is a lack of DIP rotation due to it being blocked by the digit cap.

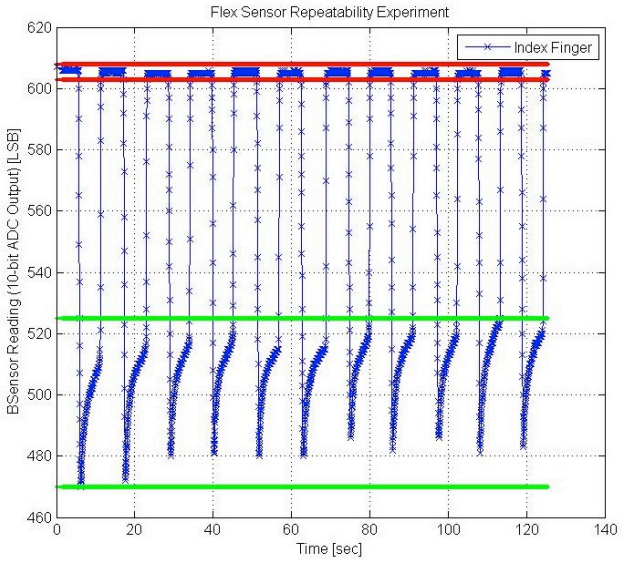


Fig. 5. Reproducibility of flat to flexed angles of the fingers. The hand was flexed and extended repeatedly and kept constant at the extremes for 5s at a time. The figure demonstrates the repeatability of the maximum values, but the accuracy is poor and suffers from natural decay in the step response during maximum flexion.

the experienced force interaction.

Measuring the joint rotations directly is impossible with the compliant mechanism created with the leaf springs and elastic cords. There are no rigid mechanical links for angle measurements with potentiometers. The angle measurements thus have to be estimated using bending sensors. During use, the bending sensors proved to be much less reliable, accurate and precise than expected.

To validate this, we tested the reproducibility of segment angles using the angle estimation algorithm [8] with grasping of objects of different diameters. Still frames from a video recorded at 60 [Hz] were used to measure the joint angles and then compared to the estimated angles.

The estimation of the angles of the MCP, PIP and DIP joints (θ_{MCP}, θ_{PIP} and θ_{DIP}, respectively) during the grasping of a 84 [mm] wide cylinder can be seen in Fig. 4. The algorithm estimates maximum angles of 32 [deg], 19 [deg] and 2 [deg], respectively. The video analysis resulted in corresponding measured maximum angles of 52 [deg], 90 [deg] and 6 [deg]. The two sets of angles clearly do not match. This is because the algorithm is calibrated using free-air movements using outstretched hands and clasped fists, but the grasping of an object forces the joints of a single digit into a fixed positional pattern. The single measurement DOF in the leaf spring cannot resolve the multiple joint angles of a single digit. Furthermore, in subsequent experiments, we were not able to distinguish between three cylinders with diameters 84 [mm], 60 [mm] and 50 [mm].

The second experiment (see Fig. 5) demonstrated the (lack of) repeatability of the sensor recordings. Here, the hand was flexed and extended repeatedly for 5[s] at a time time. With the hand fully extended (the sections between the red bars), the sensor repeatability was much higher than with the hand fully flexed (green bars). For the flexed situation, the sensors clearly demonstrate a time-decaying step response: the value reaches a maximum and then decays slowly. The repeatability of the base position (fully extended) and the initial response to maximum flexion, is high.

We concluded that the sensors are able to detect small relative movements (change detection) and differentiate between three to four different flexion angles (absolute measurement) for each finger, from the fully flat position to the full grasp, but they cannot estimate the joint angle with greater (absolute) accuracy or distinguish between intra-digit angles when holding objects. Yet we were still able to identify the different grasp articulations with these bending sensors (see Sec. III-D. The accuracy is also sufficient to interact with the video games developed in the SCRIPT project.

D. Thumb Mechanism

The actuation mechanism for the thumb is similar to the one for the fingers and assists the extension of the thumb's MCP and IP joints. It has one additional free DOF that allows the thumb to freely ab/adduct, independently from MCP and IP flexion and extension (see Fig. 3). The ab/adduction joint does not need to be aligned to the human thumb, as the elastic cord in the thumb mechanisms allows for slight misalignments to occur. The abduction/adduction movement is not measured.

E. Wrist Mechanism

The wrist mechanism uses a double parallelogram between forearm shell and hand plate (see Figs. 1 and 2) that allows

wrist flexion-extension but blocks all other wrist rotations. The double parallelogram is needed to prevent misalignment between human and device axes and make the device comfortable to use. Through the parallelograms, the rotation of the hand around the wrist flexion-extension axis of the wrist is transferred to the parallelogram clamp at the forearm. Interference in the double parallelogram mechanism limited the wrist extension to 20 deg for some subjects.

The wrist extension is actuated using an elastic tension cord at the base of the parallelograms at the forearm. The tension in the cord can be adjusted using the cord stops at the elbow end of the forearm shell, but was deemed not strong enough to provide the required assistance force at the wrist. The stopgap solution was to change the moment arm by attaching the elastic cord to a link higher on the double parallelogram mechanism. The wrist elastic cords were less durable then desired and occasionally broke under intensive use.

A potentiometer is attached to the wrist double parallelogram mechanism in order to measure the wrist flexion/extension movement. Furthermore, an inertial measurement unit (IMU) measured the pronation/supination at the wrist and translational movement of the forearm. The performance depended strongly on the calibration and processing of the IMU data, and outside factors (such as nearby metal objects) can disrupt the correct functioning. During the clinical trials, the IMU solution proved to be sufficient to control the games, but calibration of the device was occasionally a frustrating experience for the users.

F. Physical Interfaces

For the SPO, we chose to use the commercially available off-the-shelf parts (Saebo Inc., Charlotte, USA) for the physical interfaces between device and subject: the forearm cuff, hand plate, and finger caps. These parts have been in used by thousands of patients over the last 10 years, and have proven to be reliable and reasonably comfortable. They are available in a selection of sizes and allow our device to be adjusted for a large number of subjects.

The hand plate has been the most problematic of all the Saebo parts. If it does not not perfectly align itself with the hand of the subject, it tends to angle away from the back of the hand. This affects the delivery of the assistance forces but also the measuring of wrist rotations. An additional Velcro straps should solve this problem, but we expect to get much better results if and when custom-made hand plates become available.

III. Performance Evaluation

A. Formative Evaluation

Observations from the clinical partners have provided valuable insights into the performance and usability of the device. During the formative evaluation (D1.3), several characteristics as discussed in the System Specifications (D1.2) were discussed with the users. The results are summarized in Tab. II.

B. Clinical Observations

The SPO is intended to be used independently by patients at home. It should therefore be possible to putting it on and removing it without additional support using the unaffected hand. Subjects need to follow a well-defined procedure for donning and doffing, which includes, in order, donning forearm shell, hand cuff, finger caps and vice versa for doffing. Healthy subjects need only a few minutes to start using the device using this approach, but the observations have showed that not all patients are able to do so. Many need the extra help from a caregiver (see Tab. III, from D8.2), such as from their partners.

The most difficult parts of putting on the orthosis were to slide the forearm shell over the arm and to fasten the Velcro straps of the physical interfaces. Familiarity with the orthosis does improves the donning/doffing process of the subjects. A stable table stand on which the device can rest was suggested as a way to make the process easier, and better positioning of the straps should also improve the fastening procedure.

The primary technical problems experienced have been discussed in the earlier sections of this report. The clinicians reported that the extension springs (elastic cords) for the wrist are damaged due to intensive use. We provide spare elastic cords in case of failure for immediate change without any use of specific tools. In addition, while grasping the hand cuff is not perfectly fixed and may lead some misreadings in finger sensors and to exerting less the desired extension forces. Another solution to fix this problem should be suggested such as using additional and diagonal Velcro straps instead of the single one. We also noticed that the force/torque provided by the wrist orthosis should be improved by increasing the stiffness of this elastic cord.

Pronation/supination movements of the wrist are notably restricted. Adding pronation/ supination DoF to the system makes the orthosis really complicated in terms of mechanical

TABLE II

Reported user experience.

Specification	Description
Safety	Generally the hand device was perceived safe.
Size	The generic size of the hand device was problematic in the FE1 but the size of the device was more convenient when it was customized for individual participants in SE1+FE2.
Weight	The hand device felt heavy after using it for a while. This is compensated by supporting the weight of the device using Saebo arm support during SE1+FE2.
Appearance	The general positive impression was that the hand device looked like a mechanical robot which could be used effectively for training and therapeutic purposes.
Noise distractions	This attribute was not explored specifically but based on researchers observation the flexion and extension of wrist creates a clapping noise.
Comfort	Generally speaking, when the hand device is tailored to the size of the hand of an individual user it feels comfortable.
Ease of use	Users found it difficult to put on and off the hand device due to difficulty with fastening the Velcro straps especially the ones designed to secure the finger caps.

engineering and heavy since this joint is spread between wrist and elbow. If the need for pronation/supination outways these engineering challenges, is currently being discussed with the clinical partners.

An additional challenge will be when the SPO is used for patients with severe spasticity, as it is expected that they will not be accommodated with the forces currently provided by the device.

Compared to the Saebo Flex, with which the SPO shares clinical purpose but few of its mechanisms, the SPO has and advantage because it does not fix their wrist in extension. This makes it easier to put the device on and off, as a relaxed, flexed wrist allows for much great finger extension in these patients. After the digit caps are attached, the wrist can be put in extension, which tensions up both the wrist and fingers for these patients.

We would like to emphasize the fact that since the SPO is a passive device, it does not pose critical danger to the users wellbeing. The SPO is a device with only springs and no actuators (electrical motors etc.), so it does not transfer external energy to the hand or wrist. All movement performed while wearing the device needs active movement by the person him/herself. Furthermore, the physical interfaces of the SPO are composed largely of the SaeboFlex components (forearm cuff, hand cuff and finger-end caps) that comply with clinical safety requirements. They have been in safe use for over 10 years across the US and Europe, in similar purposes as those pursued by us.

C. Technical Support

The effort it took to support the clinical trials with the SPO was recorded. When no extraneous modifications were needed on an orthosis, it took approximately ten hours to customize it for a new patient and approximately another two hours to complete the calibration procedure. Tab. IV details which parts needed replacing and how often and why this occurred. Here, RC refers to Replacement Count, RF to Replacement Frequency, and PP to per patient customization.

D. Grasp Recognition

The SPO has been used for grasp recognition. In our technical evaluation, we have noted that the SPO can detect small movement changes, but has problems with the estimation of absolute, static angles. UH have taken the lead to use this limited information to comparing different recognition methods to identify different types of grasps for hand rehabilitation.

In their feasibility study, conducted with healthy subjects, they developed and tested methods for recognizing the hand posture. Participants wore the SPO during grasping of several objects. They then repeated their procedure in absence of the real objects. The three methods were based respectively on the statistics of the produced postures, on neural networks or on support vector machines. The three postures considered were lateral prehension (e.g. using a key), cylindrical grasp (e.g. holding a bottle) and palmar prehension (e.g. grasping a small ball).

UH compared the methods in terms of accuracy and robustness with respect to size of the training sample, inter-individual subjects variability and differences between dif-

TABLE III

ASSISTANCE NEEDED BY PATIENTS IN PUTTING ON THE ORTHOSIS.

Pat.	Gender	Age	ARAT	FM	Severity	Helped
A10	Male	34	47	56	Mild	No
A60	Male	52	5	17	Severe	Yes
A80	Male	43	4	11	Severe	Yes
A95	Male	48	31	44	Moderate	Yes
A11	Female	62	3	9	Severe	Yes
A20	Male	69	53	49	Mild	No
A14	Female	51	9	26	Sev./Mod.	Yes
A94	Female	68	35	47	Moderate	No
A56	Male	62	3	12	Severe	Yes
A08	Male	58	54	53	Mild	No

TABLE IV

SERVICE NEED ON SPO COMPONENTS DURING SE1.

Component	RC	RF	Description
Wiring	0	None	
Leaf springs	0	None	No need to replace leaf springs, but modifications to them were done during this stage due to hole size and location.
Finger elastics	80	Once PP	With the best quality elastics usually every three patients, and usually because the elastic had to be shortened. However, the crimps used to fix the elastic to the finger caps had to be changed every single customization or every time an elastic broke.
Wrist elastics	35	Twice PP	With best quality elastic only one elastic had to be provided and replaced every customization, however, with the other elastics 2 or three had to be provided per patient.
Finger caps	0	None	
Liners	25	Once PP	Some got dirty, others worn down due to rubbing with the Velcro. Due to appearance they had to be replaced.
Splints	0	None	
IMUs	0	None	
Bending sensors	0	None	No sensor broke or malfunctioned, however, they should not be separated from the leaf springs.
Potmeter	6	Incidental	The location of the potmeter left it open for accidental collisions. These, and malfunctions of unknown cause, required incidental replacement.
Velcro	3	Incidental	Since the Velcro became saggy it was difficult to guide them through the loops, also due to appearance. Only for the strap from the hand splint.
Arduino board	0	None	No replacements necessary but resoldering of a pin had to be realized on every board after a bug was discovered. The soldering was done only one time and never had to be redone.
USB cables	2	Incidental	Unknown causes.

ferent postures. Their results show that the support vector machine approach allows to recognize with an accuracy above 90% among three different types of grasping posture, even with a small training sample. This is possible also when subjects are not grasping the actual object, but rather aiming at repeating the same movements imagining these postures.

The difference with the detection of the object dimension (see Fig. 4) is that the grasp posture detection uses the inter-digit differences as apposed to the intra-digit absolute measurements. The inter-digit approach relies more on the recognized patterns, which explains the much better results when recognizing grasps compared to absolute intra-digit angles.

IV. Discussion and Conclusions

The SCRIPT Passive Orthosis (SPO) is the passively actuated orthosis which was designed during the first year of the SCRIPT project and clinically and technically evaluated during the second year of the project.

The SPO is intended to be used independently by patients at home. It should be a lightweight, functional and relatively simple to use hand and wrist orthosis. The SPO is able to deal with misalignment problem of the joints with the help of its wrist and finger mechanisms. Its weights about 0.650 kg with electric cables connected and about 0.400 kg without them. It is also possible to use the SPO with the integrated of forearm supports. In our tests, we used SaeboMAS forearm support without any heavy structural modification.

The SPO uses the physical interfaces (forearm shell, hand cuff and finger caps) from the Saebo Flex (Saebo Inc.) to reduce development risk. All other components and mechanisms are completely of our own design to use the orthosis for rehabilitation at home with integrated gaming, support, and therapeutic software modules.

The finger mechanisms is an affordable, light-weight solution to apply adjustable extension forces to each finger. The integrated bending sensors are good enough to differentiate between different grasps, can detect small changes of motion, but are only able to resolve between large absolute angle deviations. These limitation are caused not by mechanism itself, but by the type of bending sensor used: these flex sensors suffer from natural decay in step response that makes it hard to get accurate absolute values from the sensors. Despite this, this mechanism has been used successfully in the clinical trials and for gesture recognition. If a better absolute accuracy is required, different, more expensive sensors need to be used, for instance based on the distortion of light in bended glass fibers.

The wrist mechanisms allows for self-aligned flexion/extension of the wrist, but has a few limitations. One, the range of motion, especially in the extension direction, is limited for some of the patients. This is due to the large variability of segment dimensions between subjects that could not be completely accounted for in the design. Having multiple lengths for the parallelogram links available for per-patient customization should improve this. Two, the potmeter measured the angular deflection correctly, but was bulky and suffered from backlash. A smaller, more integrated design should solve this. Three, the elastic cords were not strong enough to provide sufficient wrist extension torque and also occasionally broke. And four, the IMU provided the software with usable movement measurements, but these can be further improved by a better selection of IMU hardware and algorithms.

The technical evaluation and clinical usage showed that the SPO meets it primary requirements, but that it can also be improved in several ways. Primarily, the sensors and elastic cords need to be made more reliable and the wrist mechanism and hand plate better adapted to the individual user.

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