Development and Evaluation of a Soft Wearable Knee Rehabilitation Apparatus

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October 3, 2022

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***Abstract*—In this paper, the design, construction and preliminary evaluation of a knee joint flexion rehabilitation device capable of restoring knee joint range of motion is detailed. To compensate for the movement of the knee joint's center of rotation, the design consists of an array of air-filled, inflatable pouches with varying spacing between them. The device is intended to achieve knee flexion of 90 degrees and provide 10 Nm of torque. A torque evaluation test bed was constructed and utilized to measure the actuator's exerted torque at fixed angles. Torque exerted by the device is examined to ensure it satisfies design specifications and can exert even more torque if utilized appropriately. The device was further assessed in a standing posture on three healthy individuals in order to establish the effect of lower limb form and weight on the device's functionality, which demonstrates an adequate response time for usage on patients with knee flexion impairments. Also, a considerable transient reaction shift was seen during a response test that was done on a fixed 30-degree device to assess the impacts of regulator pressure change.**

***Index Terms*—Soft; Rehabilitation; Knee; Lower-limb; Design; Fabrication; Validation**

I. Introduction

Loss of complete knee flexion can have harmful effects on the function of the lower extremity of the body. Several reasons may cause functional loss of the knee which is to be unable to perform normal working movements of the knee joint. Injuries such as anterior cruciate ligament (ACL) reconstruction, total knee arthroplasties, arthrofibrosis of the knee joint and other musculoskeletal injuries can cause the knee joint to lose its full flexion ROM [1]. This loss of ROM may lead to problems such as altered gait patterns, limited squatting, and difficulties using stairs and sitting.

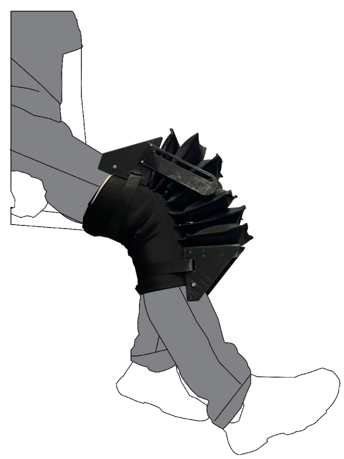

Fig. 1. An illustration of a patient wearing the knee rehabilitation equipment while seated.

Due to the aforementioned complications caused by various injuries, regaining full knee flexion is necessary for normal behavior of the lower extremity and so knee rehabilitation is needed. Continuous passive motion (CPM) is mostly used for knee rehabilitation, using assisting robots. Compared with physical methods, CPM therapies only lead to short-term effects and no further advantages are seen [2]. In addition, the knee only experiences 68% to 76% of the programmed arc and this is highly influenced by the patient's body position

[3]. Furthermore, there is a misalignment between the knee joint and the CPM joint that may be caused by the difficulties in fitting the device to each patient [4], and the flexing knee generates a migrating medial-lateral axis of rotation [5]. These devices are also bulky and heavy.

Bulky devices are not easy to use and as mentioned before there can be problems fitting the device correctly to different patients and there will also be a misalignment in the center of rotation causing a difference between the desired and reached angle of rotation. Therefore, there is a need for a lightweight, easy-to-fit device that is compliant with the human lower limb and does not have a fixed center of rotation. Using soft rehabilitation devices can minimize and eliminate most of the aforementioned issues. Soft robots have several advantages, for example, high power-to-torque ratio, compliance with the human body, and low fabrication costs [6].

Numerous devices have been created and manufactured for knee rehabilitation purposes. Commonly designed for gait assistance, these devices include the reconfigurable multi-joint actuation platform by Ding et al. [7], which is cable driven and uses a bulky mechanical actuation box, and the lightweight soft exosuit for gait assistance using MC kibben muscles developed by Wehner et al. [8], which is difficult to wear and does not provide useful assistance if actuated incorrectly. Sridar et al. created a soft-inflatable exosuit [6]with an inflatable bladder design that is positioned behind the knee and generates small torque for gait assistance. Fang et al. created a foldable pneumatic knee actuator inspired by accordions [9]that is ideal for knee extension exercises.

To augment bicep lifting ability, Thalman et al. created a soft elbow exosuit [10]. This design consists of a collection of pneumatically pressurized soft actuators that provide a high joint torque. Although the device generates a high torque, it is constructed with a single center of rotation, and its proportions are not ideal for other joints; hence, it cannot be used on the knee joint. In addition, there is no component to prevent the bladders from slipping, which can result in a loss of device functionality.

In this paper, a knee rehabilitation device, illustrated in Fig. 1, constructed from a TPU-coated nylon fabric is demonstrated and fabricated. This device is meant to alleviate the knee joint misalignment issue and to be easy to fit. In addition, the device can produce 10 Nm of torque for rehabilitation of knee joint flexion in patients with a variety of conditions, such as ACL reconstruction, arthrofibrosis, etc.

II. Materials and methods

A. Design requirements

Depending on the type of surgery, rehabilitation stage, and other circumstances, different patients require varying knee torques. When the knee is fully extended, the flexion angle is zero, and the knee joint is in flexion when the tibia slides posteriorly relative to the femur. Due to the wide variety of elements influencing the stiffness torque, the target is to achieve 10 Nm of torque between 0 and 90 degrees, while the patient is seated. The apparatus must also be simple to install on the knee and eliminate misalignment with the knee's center of rotation.

B. Design of the device

Each actuation cell's main bladder is composed of two layers of nylon coated with thermoplastic polyurethane (TPU). The items are sealed using a heat sealer and placed within a nylon fabric pouch. Next, the cells are placed sequentially in a configuration that fits the knee, and two retainers are affixed at the ends to transfer force to the desired point (Fig. 2).

Two retainers were created with curved bottom surfaces to match the front surface of the tight and the front of the lower leg, based on estimates of the measurements of the average human lower limb. A rod was subsequently placed to the retainer's back bottom to transmit the applied force. The concept behind the construction of the retainer was to transfer the imposed force from the pouches to the limb utilizing the lever principle (Fig. 2), from the contact surface between the retainer's flat surface to the rod on the retainer's back bottom. On the retainer, a strap secures the rotation of the lever.

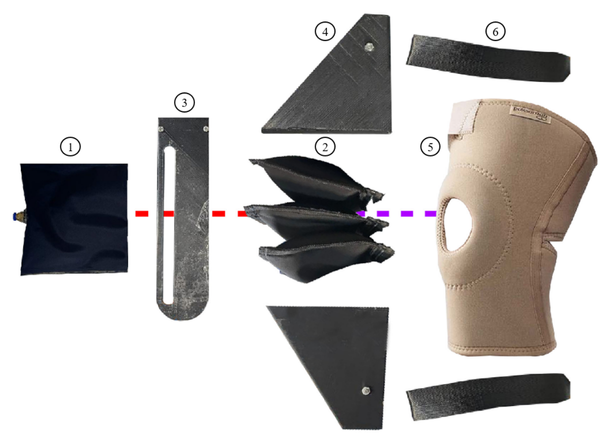

Fig. 2. Device components: (1) Inner bladder made of TPU-coated nylon fabric for inflating (2) Pouch made of nylon fabric for helping the bladders resistance (3) Restricting component for keeping the pouches inline (4) Retainers for transferring the force onto the limb (5) Flexible knee brace to attach the device on the user's knee (6) Straps to tighten the device. The bladder (1) is situated inside the pouch (3), illustrated by red dash-line. The pouch (3) and the retainers (4) are sewn onto the knee brace (6), shown by the purple dash-line.

The transferred force from the device to the limb is proportional to the retainer's vertical surface dimensions and the mounting position of the rod. The equation depicts the relationship between the force of the array of pouches and the force exerted on the limb. F and d represent the force exerted by the array and the distance from the hypothetical point where its point force is applied, which is considered to be half the height of the retainers, to the center of rotation, respectively. F_e and d_e represent the force exerted to the limb and the distance between the rod and the retainer's center of rotation, where the strap is secured. The relationships are depicted by equation (1).

$$Fd = F_e d_e \quad (1)$$

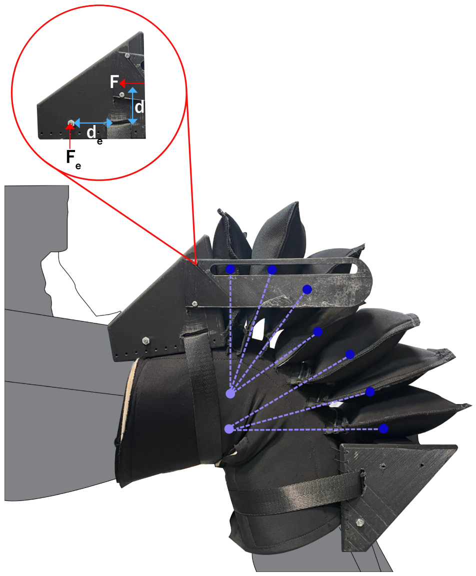

Fig. 3. (1) Different location of the centers of rotation. (2) The lever principle of the retainers

For estimating the actuator's exerted torque, each pouch is modeled as a sphere with two parallel flat surfaces on each side. The flat surface is a good representation of the surface from which force is applied to the subsequent pouch. If each pouch is considered to be square prior to inflation, the surface area is equal to w^2. Therefore, the force exerted by each pouch is determined as the effective percentage of each pouch's surface, denoted by $EA\%$, multiplied by the pouch's area and internal pressure, denoted by P. The torque is then computed by multiplying the length of the moment arm, denoted by L in the force calculation. The equation for calculating torque is denoted by equation (2).

$$T = P.EA\%.w^2.L \quad (2)$$

According to the aforementioned calculations, the desired actuator torque is 10 Nm. Based on the usual dimensions of a human leg, each pouch is designed to be 12 cm by 12 cm. If it is assumed that only 10 percent of each pouches surface will be in contact with the next, and if the arm moment, which is the distance between the center of a pouch and the center of rotation of the knee, which is assumed to be 14 centimeters, then the calculated exerted torque is as shown in equation (3) , which is the maximum amount of torque the actuator is designed to exert.

$$0.1 \times (0.12 \times 0.12) \times 50 \times 10^3 \times 0.14 = 10.08Nm \quad (3)$$

The aim was to arrange the pouches in a different order with varied lengths in order to allow the actuator to have several centers of rotation (Fig. 3) to fix the knee center of rotation misalignment problem. It was determined to design the device with two centers of rotation, for which a number of pouches should be located with a distance of 13 cm from the center of a pouch to the first center of rotation, denoted by dc_1, and some should be located in a distance of 15 cm from the second center of rotation, denoted by dc_2. Additionally, it was anticipated while determining the number of required pouches that they would not form a perfect sphere while the device was under pressure; hence, roughly estimating, only 50% of their calculated diameter, shown by D, will be used (Eq. (4)-(5)). By visualizing a right triangle with the short leg being half the effective diameter and the hypotenuse being the distance between the pouch center and the center of rotation, equations (6) and (7) illustrate the angle each pouch forms with θ_1 and θ_2, respectively. Then, it was determined that group 1 needed four pouches, each of which added up to 16.9 degrees, and group 2 needed three pouches, each of which added up to 14.6 degrees. Equation (8) demonstrates that the device should, in theory, accomplish more than a 90-degree rotation by adding up the rotation angles.

$$\pi D = 24cm \quad (4)$$

$$D = 7.64cm \quad (5)$$

$$\theta_1/2 = sin^{-1}(50\%D/2/dc_1) \quad (6)$$

$$\theta_2/2 = sin^{-1}(50\%D/2/dc_2) \quad (7)$$

$$Total\ Flexion\ Angle = 4\theta_1 + 3\theta_2 = 111.4^\circ \quad (8)$$

C. Fabrication

One piece of TPU-coated nylon fabric (WUXI XIANGLONG POLYMER FABRIC COMPANY LTD., Jiangsu, China) measuring 24 cm by 12 cm is used to create a bladder. As the pouch air inlet, a pneumatic push-in fitting was then fitted and sealed with O-rings. The fabric was then folded from the middle to create a square, and its perimeter was sealed using a 50-watt, 3-mm-wide heat sealer. The bladder was then placed within a nylon fabric pouch that had been sewn into the same square shape, and the remaining side was likewise sewn.

After creating seven pouches, these pouches were sewed onto a flexible knee brace, with the first four pouches above the knee joint separated by 1.5 cm and the last three by 3 cm. A retainer is affixed to either end of the actuator, 1 cm away from the end pouch.

If the pouches disperse, the function of the actuator will be severely compromised. A restricting component is constructed and connected to the side of the retainer, which is situated above the knee, in order to prevent the pouches from slipping during inflation. This limiting component ensures that the pouches remain aligned and do not escape their prescribed confines.

A pneumatic 5/2 proportional valve (FESTO MPYE-5-1/8-LF-010-B) was employed because the device has a large volume and must be filled with air at an acceptable rate.

Concerning the device's rapid discharges, a quick exhaust valve (BLCH QE-04) was utilized to eliminate the issue. With the use of a pneumatic pressure regulator, the maximum available pressure was adjusted and set.

III. Experimental Validation

Torque output, patient functionality, and device reaction are the most important properties of the actuator. To analyze these properties, three distinct methods are provided, with each method evaluating the actuator separately.

In order to evaluate the output torque, a test bed was constructed using a hinged knee support to represent the knee. The force exerted at a point 14 cm from the joint was measured using a load cell (ZEMIC H3-C3-50kg-3B-D55) which was connected to an amplifier (RED LION PXS000) and a pressure sensor (FESTO SPAU) measured the pressure inside the actuator. The actuator was then mounted to the brace and fixed from its side on a flat horizontal surface so that the effects of gravity can be ignored ((Fig. 4)). The test bed was then fixed at 0 degrees, 30 degrees, 60 degrees, and 90 degrees, and the exerted torque was determined after inserting a 50 KPa step pressure, by multiplying the force in the moment arm.

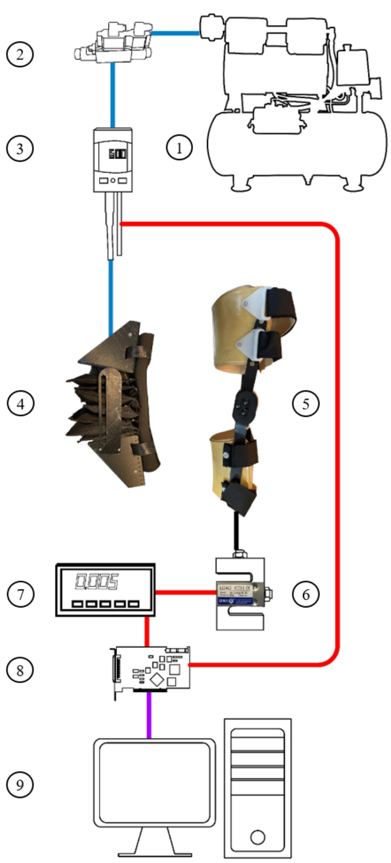

Fig. 4. This diagram illustrates the relationships between the torque test bed's components. The blue lines are pneumatic relations, the red lines are analog voltage relations, the black line is a mechanical connection and the purple line is a serial communication. The components are: (1) Air compressor (2) Proportional pressure valve (3) Pressure sensor (4) Rehabilitation device (5) Knee support (6) Load cell (7) Amplifier (8) DAQ card (9) PC.

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Due to the inability to test the device on patients, the output was measured while the device was worn by three healthy persons with the details provided in table I, in order to evaluate the response time of the actuator. The participants were instructed to stand on a platform while the leg on which the device was affixed was loose, and they were not to contract their leg muscles. In this test, a 1 bar step input was introduced for 10 seconds into the device, and the angle was measured using an IMU (MPU6050) linked to an Arduino nano (CH340); the origin was set to zero when the leg was perfectly straight. To offer more accurate data based on observation, the angle measuring unit was aligned with a hypothetical line drawn from the knee joint to the ankle joint and placed above the ankle.

TABLE I
Test individuals

	Individual Characteristics			
Individual	***Gender***	***Age***	***Height***	***Weight***
1	Male	24	182	67
2	Male	25	186	87
3	Male	24	180	69

The test bed of the output test was utilized for evaluating the device's response. The device was angled at 30 degrees, and the previously mentioned pressure sensor was used to monitor the pressure inside the pouches. The objective was to investigate the impact of various regulator pressures on the actuator's response. This was accomplished by setting the regulator pressure to various pressures and then using the 5/2 pneumatic valve to introduce air to the device. This procedure is identical to introducing a step input to the system, and the control system was set to maintain the actuator pressure at a constant 0.5 bar. The pressure of the regulator was set on 1 bar, 2 bars and 3 bars during the test.

Using a DAQ card (National Instruments 6024E), all of the measured data were uploaded to a PC. The data was then captured and filtered with Simulink before being submitted to MATLAB R2018b for the elimination of unnecessary data.

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IV. Results

As seen in Fig. 5, the findings of torque evaluation indicate that the change in torque is linear with regard to the internal pressure of the device. Torque exerted at each angle is close to 10 Nm and nearly identical. Variations from the theoretical calculations may be attributable to the fact that the effective contact surface of the pouches varies at each angle, as well as the changing shape of the contact surface of the end pouches and retainers. In addition, undesirable environmental alterations, such as an unintended twist of the knee support utilized as an example of the lower limb or the slide of the flexible brace on the knee support, may also be a possibility. At 30 degrees, when the pouches were entirely aligned and a significant contact area was seen between them, the greatest torque, 14.9 Nm, was observed. In contrast, the lowest torque, 8.9 Nm, was observed at an angle of 90 degrees in which the pouches had a small contact area and the pouches at each end were bowed and had little contact with the retainer. This experiment also demonstrated that the time it takes the actuator to achieve a constant pressure at various fixed angles varies only slightly.

Various settling times emerge in different individuals, as revealed by the response evaluation. Also, the angle obtained varies between individuals, with the maximum angle recorded under a constant pressure of 1 bar being 50 degrees for individual 1 and 40 degrees for individual 2 (Fig. 6). This variation in response time may be caused by differences in the weight of each individual's lower leg, which alters the required torque for achieving a greater range of motion. Another factor may be the shape of the lower limb and how the retainers and flexible knee brace fit the leg. Although there is slight variation in the output angle, it was clear during testing that individual 2's retainer did not fit entirely on his leg. At the beginning of the inflation, the upper retainer began to rotate before the device was able to move the lower leg.

Based on the findings of the device response test, shown in Fig. 7, it is evident that adjusting the regulator to higher pressures will result in a quicker transient reaction. However, the settling period will not be greatly altered. This may occur for various causes, including the increased airflow through the pressure regulator when set to higher pressures. The minor leakage from the connectors and fittings may also contribute to variances in settling time, and improved control may have a considerable effect on response time.

V. Conclusion and Future work

Inflatable actuators were used to construct and fabricate a soft knee flexion rehabilitation device to assist patients with knee flexion stiffness in regaining their range of motion. A device with an inline pouch design was presented that did not restrict the knee joint to a single center of rotation. The device's torque output was evaluated on a setup, along with its response time and maximum flexion angle under constant pressure.

The torque of the device was evaluated using a setup that fixed the device at various angles, and the force was measured after the device was inflated. It was determined that the output torque was adequate, around 10 Nm, and its variation was about as anticipated. The output torque at various angles also shown that the effective contact surface between succeeding pouches has a substantial effect on the output torque.

The step response assessment of the flexion rotation was performed on three healthy individuals who were constructed to have no lower limb muscle contraction. All of the findings fell between 40 and 50 degrees. The discrepancies may have resulted from various causes, such as differences in lower leg weight and shape, which considerably impact the device's

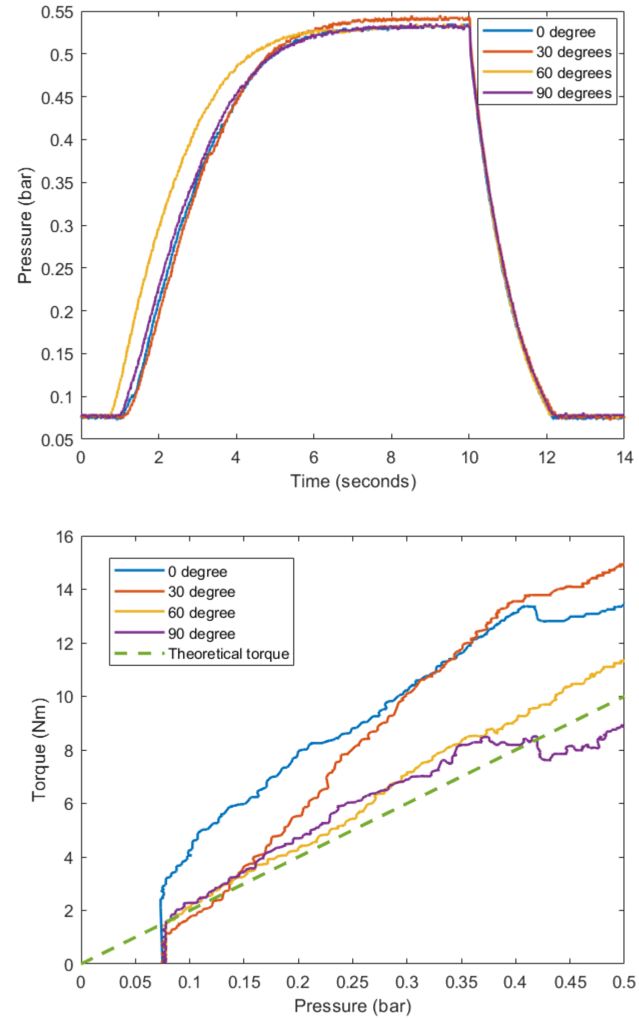

Fig. 5. Results of the torque output and pressure measurement of the apparatus at fixed angles. The amount of time needed to obtain a set pressure is not considerably impacted. The torque increased linearly and peaked at 14.9 Nm in a 30-degree angle.

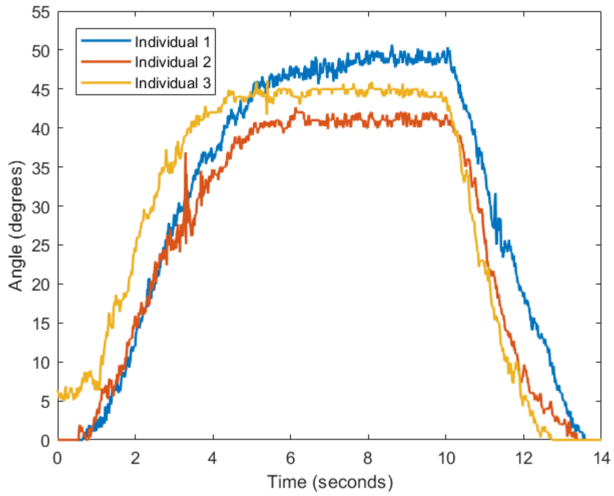

Fig. 6. Outcomes of healthy subjects' standing posture tests. At least 40 degrees of flexion were achieved by all three subjects. Results are significantly influenced by the weight and form of the lower leg.

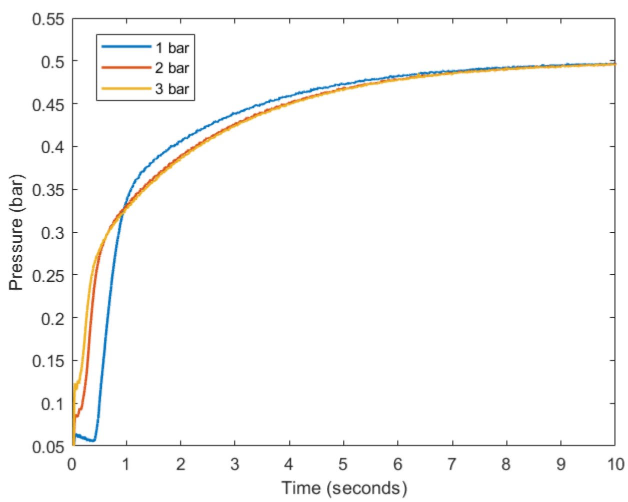

Fig. 7. data from the regulator input pressure change test. Higher regulator pressure causes a faster transient reaction, but the settling time is about the same.

performance.

The constant pressure test demonstrated that altering the input regulator pressure will speed up the device's transient response. The settling time won't be considerably impacted by this alteration. That might be the result of slight connection leakages in addition to the device's basic feedback system.

Future research on soft inflatable pouch designs and its effectiveness will involve altering the used material, shapes, and sizes, as well as employing computer modeling. Several modifications can be made to the device in order to increase its endurance, allowing it to accommodate a larger variety of lower limb shapes and further minimizing slippage between the pouches.

It is planned to test the device such that a stiff knee joint can be modeled in a seated position, so that more accurate data can be gathered regarding the performance of the actuators on a seated patient, for whom the device is meant to be utilized. In addition, a parameter estimation can provide enough information about the performance and functionality of the device to create a mathematical model of the device.

Obviously, such a device that interacts with patients should be properly regulated. Therefore, a sophisticated control system is required to adapt to the lower limb anatomy of different patients and achieve the appropriate angle with a predetermined trajectory. A future application of the system would be appropriate for a control strategy that can overcome the majority of the previously specified requirements.

Additionally, future work will be performed on the device to make it appropriate for various rehabilitation applications. These applications include the use of the device in gait training, both passively and actively, for patients with knee joint impairments. Utilizing the device on the posterior side of the knee to aid in knee extension. Moreover, adapting the device's architecture for hip joint therapy.

Acknowledgment

We thank the New Technologies Research Center Soft Robotics Lab members for helping with every step of the project presented in this paper.

References

[1] N. Shah, "Increasing knee range of motion using a unique sustained method," North American journal of sports physical therapy : NAJSPT, vol. 3, no. 2, pp. 110–3, 2008, [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2953321/

[2] K. Kim, M. Kang, Y. Choi, H. Jang, J. Han, and C. Han, "Development of the exoskeleton knee rehabilitation robot using the linear actuator," International Journal of Precision Engineering and Manufacturing, vol. 13, no. 10, pp. 1889–1895, Sep. 2012, doi: 10.1007/s12541-012-0248-3.

[3] J. E. Bible, A. K. Simpson, D. Biswas, R. R. Pelker, and J. N. Grauer, "Actual Knee Motion during Continuous Passive Motion Protocols is Less Than Expected," Clinical Orthopaedics and Related Research, vol. 467, no. 10, pp. 2656–2661, Oct. 2009, doi: 10.1007/s11999-009-0766-1.

[4] A. Golgouneh, A. Bamshad, B. Tarvirdizadeh, and F. Tajdari, "Design of a new, light and portable mechanism for knee CPM machine with a user-friendly interface," 2016 Artificial Intelligence and Robotics (IRANOPEN), Apr. 2016, doi: 10.1109/rios.2016.7529498.

[5] D. A. Neumann, Elisabeth Roen Kelly, C. L. Kiefer, K. Martens, and C. M. Grosz, Kinesiology of the musculoskeletal system foundations for rehabilitation. St. Louis Mosby, 2017.

[6] S. Sridar, P. H. Nguyen, M. Zhu, Q. P. Lam, and P. Polygerinos, "Development of a soft-inflatable exosuit for knee rehabilitation," IEEE Xplore, Sep. 01, 2017. https://ieeexplore.ieee.org/document/8206220 (accessed Jul. 15, 2022).

[7] Y. Ding et al., "Biomechanical and Physiological Evaluation of Multi-Joint Assistance With Soft Exosuits," IEEE Transactions on Neural Systems and Rehabilitation Engineering, vol. 25, no. 2, pp. 119–130, Feb. 2017, doi: 10.1109/tnsre.2016.2523250.

[8] M. Wehner et al., "A lightweight soft exosuit for gait assistance," 2013 IEEE International Conference on Robotics and Automation, May 2013, doi: 10.1109/icra.2013.6631046.

[9] J. Fang et al., "Novel Accordion-Inspired Foldable Pneumatic Actuators for Knee Assistive Devices," Soft Robotics, vol. 7, no. 1, pp. 95–108, Feb. 2020, doi: 10.1089/soro.2018.0155.

[10] C. M. Thalman, Q. P. Lam, P. H. Nguyen, S. Sridar, and P. Polygerinos, "A Novel Soft Elbow Exosuit to Supplement Bicep Lifting Capacity," 2018 IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS), Oct. 2018, doi: 10.1109/iros.2018.8594403.