



Development and Evaluation of a Sliding Type Continuous Passive Motion Automation Device for Diagnosis and Rehabilitation of Frozen Shoulder

유착성관절낭염 (Frozen Shoulder) 진단과 재활운동 자동화를 위한 Continuous Passive Motion 기기

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Abstract

The shoulder joint is crucial for daily activities, but disruptions in its components can result in pain and instability, as seen in frozen shoulder (FS). While several treatment options are available, rehabilitation exercise is essential for maintaining or achieving shoulder functionality. Continuous passive motion (CPM) exercise is considered one of the most effective methods, but it requires active participation from physical therapists or patients. Robotic rehabilitation devices have gained interest as a new alternative to reduce cost burdens and enable self-monitoring of rehabilitation progress. However, current devices have limited accessibility, complicated control methods, and hinder monitoring functions. This research developed a sliding-type CPM automation device to cover a wide range of motion with precise monitoring functions, making it suitable for motivating self-exercise patients and can still be manufactured at a reasonable cost. The device offers both diagnosis and rehabilitation exercise for frozen shoulder with a simple mechanism and control methods, ultimately increasing accessibility of robotic therapies. Clinical trials with 7 FS patients were conducted to verify the therapeutic effect of the device, and the results were compared with 7 healthy subjects. The device can be set up within 5 minutes, making it easy to use and deploy in a clinical or home setting.

Keyword : Rehabilitation device, Frozen Shoulder, Cable-driven actuator, Clinical trials **Student Number** : 2021-27899

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Chapter 1. Introduction

1. Introduction

The shoulder is a ball-and-socket joint, which enables the widest range of motion (ROM) and highest degrees of freedom (DOF) among the other joints. Due to the versatility, the shoulder joint is crucial for activities of daily living (ADL) such as lifting, reaching and throwing. Four joints (glenohumeral, acromioclavicular, sternoclavicular and scapulothoracic) with corresponding tendons, ligaments and muscles provide static and dynamic stability during the complex shoulder movements [1]. Any single disruption on the components of shoulder structure can result in pain and instability of shoulder.

Adhesive capsulitis, also known as frozen shoulder (FS), is a condition that causes pain and stiffness in the shoulder joint, resulting in a loss of ROM [2]. FS can be characterized by the thickened tissues surrounding shoulder joints, or the shoulder capsules. FS is estimated to affect 2% of the general population at minimum, with the incidence peak at the age of mid-50s [3], [4]. Although the exact cause which thickens the shoulder capsules and reduces the joint volume is not clarified, FS is linked with various comorbidities, including stroke [5] and diabetes [6].

Despite the belief that FS is a self-healing disease, 20~50% of patients suffer from persistent shoulder stiffness and pain as a chronic condition [4]. Several treatment options including physical

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therapy, medications, heat and cold therapy, injections or surgeries are offered to the patients to improve such symptoms and increase the chances of a full recovery. Among the various options, rehabilitation exercise should always be included in the postoperative care, in order to achieve or maintain the shoulder functionality [2].

Among various exercises, continuous passive motion (CPM) is considered to be one of the most effective methods [7], [8]. Without the participants active control of limbs, CPM moves the shoulder joint to the end range, so that collagen fibers comprising the shoulder joint are elongated and help improving ROM [9]. CPM exercise can be conducted either by physical therapists or self-exercise [10], [11]. Although exercise with physical therapists can have higher satisfaction ratio than self-exercise method [12], intrarater and interrater reliability of diagnosis are significantly low according to therapists [13]. On the other hand, self-exercise has advantages on cost-effectiveness [14]. However, patients conducting selfexercise are not easy to verify effects of the exercise and need to be motivating themselves to continue on, which often leads to failure. Tanaka et al. [11] compared effectiveness of physical therapists on self-exercise, where 47% of patients in the self-exercise group were eventually classified as not-treated.

Robotic rehabilitation devices are gaining interests as a new alternative, to reduce the cost burdens imposed on patients and help monitoring the rehabilitation progress themselves. To deal with the wide ROM of the shoulder joint and misalignment issues, rigid type rehabilitation robots apply multiple actuators [11]. With torque and

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force sensors applied on the actuator and the limbs of the robots, rigid type robots offer precise status measuring functions. However, due to the high costs and bulky size, accessibility to the device is largely limited to ordinary patients [6], [12]. Moreover, due to complicated control methods, rigid robots are currently constrained to in-clinic usage [15]. Soft type robots solve these problems by using cable-driven or pneumatic actuators [15], and improving wearing conformity. But non-linear behaviors of the soft materials hinder monitoring functions and cannot provide kinetic measurements which is critical for joint stiffness calculation in FS diagnosis stage.

In this research, sliding type CPM automation device was developed to fill the gap between current robotic devices, by covering wide ROM with precise monitoring function for motivating self– exercise patients and still can be manufactured with reasonable costs. The device offers both diagnosis and rehabilitation exercise of frozen shoulder with a rather simple mechanism and control methods, ultimately increasing accessibility of robotic therapies. The device can be set up within 5 minutes, which is sufficient enough for usability [16]. Cable–driven actuator covers wide ROM of shoulder in three directions: flexion, abduction and external rotation. With position and force sensor data acquired during the exercise, shoulder status was diagnosed and the progress report could be provided to the patient. Clinical trials with 14 FS patients were conducted to verify the therapeutic effect of the device and the results were compared with 7 healthy subjects.

2. Methods

2.1. Physical Therapist Analysis

Exercise methods of human therapists in CPM exercise were analyzed in prior to the design of the device. The exercise sessions were observed at a university hospital, after which discussions with the human therapists (n = 3) were conducted. The session usually took about 45 minutes, including 15 minutes of heat-pack treatment prior to the session.

Exercise principles of human therapists could be classified into three stages; sensing, actuation and decision. First, sensing stages are conducted by putting hands on the patients. As can be seen from the Fig. 1, human therapists put their hands on two spots of the patient, one on the trapezius muscle and the other on the arm being elevated. The hand on the trapezium detects whether the patient has proper scapulohumeral rhythm (reference about glenohumeral rhythm), while the hand on the arm checks the stiffness of shoulder. Second, actuation stage is mainly carried out by the hand on the moving arm with rotating the shoulder joint. Human therapists have



Fig. 1. Hand positions of the physical therapist on the patient. Red: sensing, green: actuation and yellow: decision

ability to move their hand freely to rotate shoulder joints in three main direction: forward flexion (FF), abduction (Abd) and external rotation (ER) (reference about direction). The hand on the trapezium acts as preventing excessive movements of scapula and maintaining the scapulohumeral rhythm. Third, in the decision stage, the therapist decides whether to move the joint further or not by integrating whole senses acquired from the patient.

Based on the human-therapist analysis, requirements for developing a robotic CPM device could be derived in both hardware and software point of view. For the hardware, the device should provide passive motion in three different motion with the full ROM. For the software, the device should detect the end-range of the shoulder joint in each direction and determine when to release the passive motion.



Fig. 2. Hardware design

2.2. Hardware Design

The device (Fig. 2) is an aluminum-frame based, cable-driven system with a handle attached on a linear guide on which the arm of the patient is held using wrist brace (Formfit®, Össur, Reykjavik, Iceland). The geared motor (9DCW24, DKM Motors Co. Ltd., Incheon, Korea) is mounted at the bottom of the device and moves the handle via cable-pulley system. Position of the handle is measured using a rotary encoder attached at the device. The rotary encoder and the motor were detached in order to measure the movement of the handle when the motor is not moving, which enabled easier position calibration.

When using the device, patients sit on a chair where a shoulder pad is attached. The pad covers the shoulder being lifted, and prevents excessive elevation of the scapula. When conducting external rotation exercise (Fig. 3), additional module is added on the device in order to fix the elbow of the patient and make linear up-and-down motion of the handle into the rotating motion of shoulder joint.



Fig. 3. Exercise direction: shoulder abduction, flexion and external rotation

2.3. Sensing and Control

The device utilizes two load cells (333FDX, Ktoyo Co. Ltd., Gyeonggi-do, South Korea) to mimic the sensing part of human therapists. The load cell embedded in the handle measures the vertical force during the CPM exercise, and further used on calculating torque applied on the shoulder joint. The other load cell attached on the shoulder pad measures the force exerted by the scapula and calculates the muscle synergy during shoulder movements.

The device is operated using a controller with a Teensy 3.2 board inside. Load cell data is accumulated using an Arduino board and transmitted to the controller through serial communication. Overall operation is monitored with a computer program developed with Processing, on which control parameters including force threshold, motor speed and number of repetitions can be adjusted.

2.4. Inverse Kinematics

During the rehabilitation exercises with the device, IMU data of the patients were collected for the reference data of the shoulder joint angle. We attached 5 IMU sensors (MTw Awinda, Xsens Inc., Culver City, USA) onto the limbs of the patient and 1 IMU sensor on the



Fig. 4. Calibration posture using IMU sensors

motor pulley to synchronize the movement of human joint with the motor actuation.

To calculate the shoulder angle with the IMU data, the patient takes the initial calibration posture (Fig. 4) with one IMU attached on the back, two IMUs on the upper arm and two IMUs on the lower arm. Directional vector of each segment is estimated using the rotation matrices. Shoulder angle during flexion and abduction exercise is calculated based on the rotation angle of upper arm vector from the chest vector, while the rotation angle of lower arm vector from the chest vector is used for the external rotation exercise.

Torque applied on the shoulder joint is calculated using the shoulder angle acquired from the IMU data, force measured by the device, statistically estimated anthropometric values and additional distance measured on-site. In case of flexion and abduction, estimated torque is as following:

$$\tau = F_{load \ cell} * \bar{l} - m_{eg} * g * \bar{r} \tag{1}$$

where \bar{l} is the horizontal distance of the shoulder joint from the device, m_{eq} is the equivalent mass of the whole arm, \bar{r} is the horizontal distance of m_{eq} from the shoulder joint and g is the gravitational acceleration constant.

Torque during the external rotation movement is estimated as following. As elbow support module is applied for the external rotation movement, elements used in the formula was modified. m_{eq} is the equivalent mass of only lower arm and hand, \hat{r} is the distance of m_{eq} in lower arm direction, l is the distance from the elbow the strap, θ is the angle between the strap of the wrist brace and the device and ϕ is the angle of the lower arm from horizontal axis calculated from the IMU data.

$$\tau = \frac{F_{load cell}}{\cos(\theta)} * \hat{l} * \cos(\theta - \phi) - \hat{m}_{eq} * g * \hat{r}$$
(2)

Anthropometric values including limb lengths and weights are estimated using statistical data of Korean male and female [17], while the distance from the shoulder joint to the device is measured onsite.

3. Experimental Setup

3.1. Participants

14 frozen shoulder patients from the Seoul National University Hospital were recruited. Patients who had been diagnosed of adhesive capsulitis of shoulder or suffering from shoulder pain with decreased ROM for more than 3 months were invited. Exclusion criteria were those who has rotator cuff tear, glenohumeral osteoarthritis, systematic rheumatic disease, neurological diseases including strokes which affect shoulder ROM or those who had any kind of surgery on the affected side shoulder. In addition, 7 controls without history of adhesive capsulitis were recruited for comparison between the affected and unaffected shoulder. All subjects provided informed consent to a protocol approved by Seoul National University Hospital Institutional Review Board (IRB No. 2206–161–1335).

3.2. Clinical Trial Design

A 3-armed clinical trial was conducted where the participants were randomly allocated to (1) heat-pack treatment: control group 1, (2) exercise with human therapists: control group 2 and (3) exercise with the CPM device: experimental group. Hypothesis of this research was first, result from the experimental group would yield comparable therapeutic effects with the control group 2. Secondarily, result from the experimental group would provide greater benefits than the control group 1. Primary outcome was ROM measured in three different direction with goniometer. The secondary outcomes measured pain and functionality of the affected shoulder with Visual Analogue Scale (VAS) and Shoulder Pain and Disability Index (SPADI).

After allocating each patient into one of the three arms, baseline measurements were completed followed by 6-week intervention. Second and the third assessment was conducted immediately and 6-week after the intervention. Variations of outcome measures were utilized as the quantitative comparison between the three arms.

3.3. Experiment Procedure

Participants allocated in the control group 1 received heat-pack treatment for 20 minutes once a week. Control group 1 was designed based on the current therapeutic protocol conducted by general university hospitals. Control group 2 participants received both the heat-pack treatment and rehabilitation exercise therapy with human therapists for 20 minutes a week. The exercise was comprised of



Fig. 5. Measurement and evaluation protocol

flexion, abduction and external rotation, 20 times each.

Participants in the experimental group received the heat-pack treatment and robotic exercise therapy twice a week, which reflects easier accessibility to the robotic device compared with human therapists. For the patients in the experimental group, the overview of the measurement protocol is shown in Fig. 5. The robotic device was positioned on a square grid sheet, so that the sitting position of a participant is fixed for every visit. After fixing the participant's wrist on the wrist brace of the device, the handle was elevated with the controller until the patient felt high enough stretching strength, while measuring the corresponding force with the robotic device so that the force threshold was set. After setting the force threshold, the handle was lowered to the initial position where shoulder angles were set to 60°, 45° and 100° for flexion, abduction and external rotation direction. During the exercise, motor speed was fixed to manipulate the handle to move 0.15 m/s. While elevating the handle, once the force value on the handle exceeds the force threshold, the motor stopped for 10 seconds to ensure enough stretch time, and then lowered to the initial position.

On the first visit, the patients in all groups were handed out with self-exercise manuals and encouraged to follow the guidelines but were not checked from then on.

3.4. Data Analysis

Age, height, weight, ROM in flexion, abduction and external rotation, VAS and SPADI results of the patients were collected on the first

 $1 \ 2$

visit. During the whole exercise session in experimental group, including flexion, abduction and external rotation, ROM, maximum passive resistive torque and stiffness indices were estimated from the data acquired by the robotic device and IMU sensors.

ROM during the exercise was measured using the IMU sensors. In case of flexion and external rotation, due to the distance between the device and the chair on which the participants sit, rotating motion of shoulders were limited. To solve this limitation, a cushion was laid on the knee of the participants so that the torso could be slightly leaned on and enlarge the rotating range.

Passive resistive torque is calculated using the inverse kinematics as introduced in the section II. The maximum passive resistive torque is applied on the force threshold level which varies every session, and can be estimated to measure the pain. Irritability, meaning the level of pain [4] is one of the most common indices collected during the shoulder rehabilitation therapies. However, measure of pain was only available with analog scales such as VAS or SPADI, which can often be not objective. Tracking how the force threshold level changes according to each session offers an objective approximation to the pain level.

Among the 20 repetitions for every session, the last five times were collected for the data analysis, considering the adapting time required at the beginning of the repetitions. Reference data from the healthy subjects were analyzed in 5th, median and 95th percentile. For statistical significance identification, analysis of variance (ANOVA) was used for comparison between each group.

	Gender	Age (yr)	Time post-FS (m.)	Group
Patient 1	F	61	9	PT
Patient 2	F	60	10	PT
Patient 3	F	47	5	Robot
Patient 4	М	81	3	Robot
Patient 5	F	48	29	PT
Patient 6	F	70	48	Robot
Patient 7	М	76	7	PT

TABLE I. Patients information

TABLE II. Rehabilitation result comparison between the PT group and the Robot group

Measure		PT Group			Robot Group				
		IA	2 nd	3 rd	IA	2^{nd}	3 rd		
ROM [deg]	FF	127.50	150.00	145.00	136.67	156.67	163.33		
	Abd	100.00	122.50	127.50	106.67	126.67	140.00		
	ER	37.50	57.50	62.50	43.33	66.67	76.67		
SPADI	Pain	43.00	43.50	25.00	58.00	29.33	26.67		
	Disability	40.32	32.50	23.44	48.33	22.50	22.08		
	Total	41.34	36.73	24.29	52.05	25.12	23.84		
IA: initial assessment									

2nd: right after intervention 3rd: 6 weeks after intervention

4. Results

4.1. Participants

14 FS patients completed the clinical trial between November 2022 and March 2023 (TABLE I). Average (standard deviation) ages of the PT group and the Robot group were 61.25 (11.47) and 66.00 (17.35) respectively, with average time after-symptoms of 13.75 (10.24) months, 18.67 (25.42) months each. The control group without FS history was consist of 7 people with an average age of 32.43 (7.25).



Fig. 6. Stiffness profile of the patient's first visit, last visit and the healthy subject

4.2. Rehabilitation Effects

Of the three exercise directions, ROM improvements of 19.51%, 31.25% and 76.94% occurred respectively. On the SPADI test, the result showed that pain and disability decreased by 54.02% and 54.31% respectively, in total decrease of 54.20%. ANOVA analysis result (TABLE II) shows that there is no statistical significance between the PT group and the robot group

4.3. Diagnosis Functions

Stiffness profile comparison between the Robot group patients and the healthy subjects are shown on Fig. 6. Higher stiffnesses of postintervention and the control group compared with pre-intervention seems to be counter-intuitive but can be explained with increased stretch tolerance [18], [19]. As the therapy session progresses, ROM increases along with accompanying torque, which increases in a greater magnitude hence drives the stiffness grows as well.

While ROM and torque tolerance of the initial assessment results are 63.84% and 21.45% of healthy subjects, they recovered 85.47% and 74.34% respectively on the 12th visit.

5. Discussion and Conclusion

3-armed clinical trial investigating effectiveness of the developed robotic CPM device was conducted with ## patients randomly allocated to each group. In comparison with the heat-pack only treatment, the developed device showed greater ROM increases and SPADI decreases with statistical significance than heat-pack group. There was no statistical significance in the comparison between the robot group and the therapist group.

During FF and Abd direction exercise, human therapists rotate their actuating hand in arc shape, so that the upper arm of affected side can naturally move around the shoulder socket as the center of the trajectory. On the other hand, the developed device fixes the wrist of affected side while drawing linear trajectory, relying on the elbow flexion for making rotating motion of upper arm. As tensile force is applied by the wrist brace, participants who were sensitive in skin deformation addressed discomfort on the wrist. In order to address with the tensile force problem for easier usage of the device, brace fixing whole lower arm would be appropriate rather than utilizing commercial wrist brace.

The developed device showed possibility of improving accessibility

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for robotic rehabilitation of FS, with automated CPM exercise monitoring function. As the current study is limited on the hospital environment, future works are needed for the situation of the device supplied to homes of the patients. Whether the device could be used by the patients alone and monitoring function could affect motivation of exercise should be validated in further researches.

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Abstract

어깨 관절은 일상 생활의 다양한 활동에 필수적이며, 작은 부상만으로 도 유착성관절낭염(오십견)과 같은 통증과 불안정성이 초래된다. 회복을 위한 여러 가지 치료 옵션 중에서도, 재활 운동은 어깨 기능을 유지하거 나 회복하기 위해 필수적이다. 재활 운동 중에서도 Continuous Passive Motion (CPM) 운동은 가장 효과적인 방법 중 하나이며, 이는 물리치료 사나 환자의 적극적인 참여를 필요로 한다. 이 때, 로봇 재활 기기를 통 해 비용 부담을 줄이고 재활 진행 상황을 자체 모니터링할 수 있다. 그 러나 시중의 로봇 재활 기기는 제한된 접근성, 복잡한 제어 방법 등의 문제로 인해 모니터링 기능을 온전히 이용하지 못한다. 본 연구에서는 넓은 범위에서 동작하고 정밀한 모니터링 기능을 갖춘 슬라이딩형 CPM 자동화 장치를 개발했다. 해당 기기를 통해 자가 운동을 진행하는 환자 에게 동기부여를 제공할 수 있을 것으로 기대된다. 본 기기는 간단한 메 커니즘과 제어 방법으로 오십견 진단과 재활 운동 기능을 제공하며, 궁 극적으로 로봇 치료의 접근성을 높일 수 있다. 임상시험을 통해 14명의 오십견 환자를 대상으로 장치의 치료 효과를 검증하고, 그 결과를 7명의 건강한 피험자와 비교했다.