

The Efficacy of Sheanut Oil Extract and Influence of Ultrasound Imaging of Vastus Medialis Oblique in Knee Osteoarthritis Patients

San-Pei Chen

Department of Physical Therapy
China Medical University
Taichung, Taiwan
sanpeichen@gmail.com

Sui-Foon Lo

Department of Physical Medicine and Rehabilitation
China Medical University Hospital
Taichung, Taiwan
d4659@mail.cmuh.org.tw

Li-Wei Chou

Department of Physical Medicine and Rehabilitation
China Medical University Hospital
Taichung, Taiwan
chouliwei@mail.cmu.edu.tw

Kang-Ming Chang

Department of Photonics and Communication Engineering
Asia University
Taichung, Taiwan
changkm@asia.edu.tw

Objectives: To examine the influence of Sheanut Oil Extract (SheaFlex75TM) on patients with knee osteoarthritis (OA). **Methods:** 33 patients, of average age 63.6 ± 5.8 , with knee OA were recruited from the China Medical University Hospital, Taichung, Taiwan. Real-time ultrasound imaging and surface electromyography were used to objectively assess the morphological changes and the muscle activity of Vastus Medialis Oblique (VMO) during the 16-weeks intervention of SheaFlex75TM. The intraclass correlation coefficient (ICC) was calculated to examine the reliability of the inter-scans. A paired-sample *t* test was used to assess the difference between the percentage of thickness changes and muscle activity. The Spearman's rank correlation coefficient was used to examine the relations among the variables of OA severity, pain duration, pain scale and percentage of thickness changes of VMO at different contraction status. **Results:** The baseline findings showed no significant differences among those variables. The reliability of inter-scans at pre-test day was high (ICC= 0.92-0.99) to prove the stability of the skills. The ability to contract muscles of knee at 30% contraction level was showed significant changes between the baseline and post-16 weeks, both on morphological changes ($p=0.04$) and muscle activities ($p=0.03$). Pain scale reported significant decrease ($p=0.02$) at the 16th week. **Conclusion:** The results suggest that the intervention of SheaFlex75TM relieve the symptoms of knee OA and cause the alteration of muscles control of knee.

Keywords—Knee; muscle contraction; osteoarthritis; real-time ultrasound imaging; sheanut oil; vastus medialis oblique

I. INTRODUCTION

Osteoarthritis (OA) also known as degenerative arthritis or degenerative joint disease or osteoarthrosis, is a group of mechanical abnormalities involving degradation of joints,

including articular cartilage and subchondral bone. Knee is the most common degenerative joint affected, and has an impact on health-related quality of life for the aging population [1].

Symptoms may include joint pain, tenderness over the inside of knee, stiffness, locking, less mobility, atrophy of lower extremity and decreased walking speed. These signs have caused the functional impairments and may result in some possible risks such as fall in the daily life.

The existing conservative intervention includes medication (such as Non-steroidal anti-inflammatory drug and steroid joint injection), physical therapy, knee braces and injections of hyaluronic acid. If disability is significant and the conservative managements are ineffective, the surgical knee arthroplasty may be recommended [2].

Recently, another alternative supplement is applied and proven to be effective, sheanut oil extract. In 1998, US Food and Drug Administration (FDA) approved that sheanut oil is a safe food additives. The traditional Africans used the Sheanut oil extracts to treat arthritis, but the mechanism was not approved. Cheras et al. [3] carried out a 15 weeks random, double-blind osteoarthritis biomarkers study to compare the effectiveness of SheaFlex75TM (a triterpene-rich extract of *Vitellaria paradoxa*) intervention and placebo groups. They found the osteoarthritis biomarkers were significant decreased in comparison with the placebo group.

Few studies proposed the possible mechanism of Sheanut oil extracts on knee osteoarthritis, but only on the symptoms improvement or the inflammatory changes within blood. The influences of Sheanut oil on patients' functional activity, ability to control or modulate knee functions are not explored so far.

The objectives of the study are to investigate the influence of SheaFlex75TM on (1) the functional activities and (2) the neuromuscular control of knee OA.

II. PARTICIPANTS RECRUITMENT

Patients aged over 50 years old with knee OA were recruited from the outpatient departments of Physical and Rehabilitation Department, China Medical University Hospital, Taichung, Taiwan. Each participant was informed and understood the purposes and protocol of the study, and the signed consent form was obtained.

A. Inclusion criteria

- Each patient was diagnosed as knee OA according to American College of Rheumatology criteria.
- Inner side knee pain.
- X-ray findings: spur formation and joint space narrowing.
- Morning stiffness over half hour.
- Knee clicking during activities.

B. Exclusion criteria

- Unable to independent walking or walking with any assistive devices.
- Neurological systematic diseases, such as Parkinson's disease, Alzheimer's disease, Multiple Sclerosis et al.
- Traumatic injuries or fractures of lower extremity (Hip, knee or ankle joint).
- Rheumatoid Arthritis or relevant arthritis such as metabolic arthritis (Gout).
- Any surgical intervention for lower extremity such as arthroplasty, amputation or ligament reconstruction.
- Radiological findings of degenerative knee under the 2nd degree according to Kellgren and Lawrence grading system (1963)
- Restricted Range of motion of lower extremity joints (Hip, knee and ankle) over 10°.
- Have experienced and continue accept physical therapy during the experimental period.
- Unable to understand the whole experimental protocol.

III. METHODOLOGY

This section describes the methodology used in this study to detect the morphological changes of muscles around knees and the ability to control muscles in different tasks. The two equipments, ultrasonography and surface electromyography (sEMG), were used in this study to provide the objective assessment of the changes on muscle after taking Sheanut Oil Extract (SheaFlex75TM) for 16 weeks. The subjective findings were assessed by subjective pain intensity and Modified Lequesne index [4] to assess the pain and functional impairment.

A. Outcome measures

To avoid the intra-examiners difference, the questionnaires and real-time ultrasound applications were assessed by the same examiner. The EMG applications and instructions were performed by the other two examiners.

B. Subjective measures

- Subjective pain intensity, visual analog scales (VAS)

Participants were requested to scale the subjective intensity of pain using the VAS. VAS is a type of assessment tool to request patient describe the pain intensity. This tool was widely applied in the clinical to assess the improvement of pain in patients with musculoskeletal dysfunction. The questionnaire is composed with a 10-cm continuous line between two end-points, one end is 0 and the other end is 10. The "0" indicates no symptom and the "10" indicates the most severely pain (intolerable pain). Each patient specifies his/her level of agreement to a statement by indicating a scale along this line.

- Modified Lequesne index in knee OA

Modified Lequesne index in knee osteoarthritis which was developed in France in 1970 and was published in 1980 is an assessment tool for the functions of knee OA. There are 11 questions to evaluate the functional of knee including knee pain, stiffness, walking, squatting and stair climbing. The scores are between 0 and 24. Marc et al (2003) reported high reliability and validity of the questionnaire on symptoms changes and functions assessment of knee OA [4].

C. Objective measures: Ultrasonography and sEMG

In this study, ultrasound images were taking using a linear transducer (>7.5 MHz). Images of vastus medial (VM) were captured both at rest and in contracted states at two different knee positions. All images were downloaded to a computer to be measured offline using Image J software 1.4.

During scanning of the knees, each participant was positioned in an erect sitting on a device of N-K table to standardize the position of knee. The site for scanning was at the height of distal one third of distance between ASIS and medial tibial plateau in a standing posture. The asymptomatic or less-symptomatic side was examined first, and each task was performed three times. Rest images were taken bilaterally at the position of knee flexion at 90 degrees. Subsequently, subjects were requested to activate knee extensors maximums by extending the knee against the pad at the same posture. The examiner then adjusted the torque arm of NK table to 60 degrees. The maximal voluntary effort (MVE) and 30% of MVE were performed at this position separately. The same protocol was replicated at the other leg.

As expected, muscle thickness increased with level of effort. Since the actual thickness of muscle was different, percentage changes were useful for comparing the general changes within three sections. The equation is bellowed:

$$\left(\frac{\text{thickness at different contraction status}}{\text{thickness at rest}} \right) \times 100\%$$

The EMG signals from eight muscles of bilateral vastus medial (VM), vastus lateralis (VL), medial hamstring (MH) and gastrocnemius (GM) were collected (bandpass filter: 2-400 Hz; sample rate 1000 Hz). Following the SENIAM procedure of skin preparation, the alcohol swabs were used to wipe skin and then the electrodes were placed. Reusable electrodes were used to detect the signals from muscles.

The examination protocol was listed below: The electrodes over VM and VL were placed at the 90-90 sitting posture on the NK table, and then the MVE of these two muscles were collected with ultrasound synchronically. Each participant was request to extend the tested leg against the pad of NK table and continuously hold the efforts for 5 seconds. The MVE and the 30% of MVE of VM and VL were collected at 60 degrees of knees separately. The electrodes over the right and left MH were placed in a prone position. Each participant was requested to extend the knee maximally against the resistance from the examiner. The electrodes over the bilateral calf muscle were placed in standing posture. The MVE of GM was collected on tiptoe of the measured side while flexed the opposite leg. The signals of middle 3 seconds of 5 seconds were average to be reference. The foot-switch was applied to record the gait cycle during the task of even bold-feet walking for 5 meters 5 times. Walking speed was recorded by a timer.

D. Data analysis strategy

The demographic features of age, body mass, height and body mass index (BMI) are presented in the descriptive statistics. The data analysis of ultrasound imaging was conducted using the statistical methods listed below. The descriptive findings of the measurements taken were displayed. The intraclass correlation coefficient (ICC) was considered as the appropriate statistical methods for repeated measurement of muscle thicknesses [5,6,7]. The ICC was calculated to examine the reliability of the inter-scans. The Spearman's rank correlation coefficient was used to examine the relations among the variables of OA severity level, pain duration, pain scale and percentage of thickness changes of VMO at different contraction status. A paired-sample t test was used to assess the difference between the percentage of thickness changes and muscle activity. The p value less than 0.05 indicate the significant difference.

IV. RESULTS AND DISCUSSION

In this study, there were 33 patients completed the three sections of the experimental protocol. The demographic data of participants are listed in Table 1. The descriptive findings of the percentage of thickness changes among rest and different contraction status in VM are listed in Table2.

TABLE I. DEMOGRAPHIC DATA OF PARTICIPANTS FOR COMPLETING THE THREE STUDIES

	N=33	
	Mean	SD
Age (y/o)	63.6	5.8
BW (kg)	66.8	11.8
Height (m)	1.6	0.1
BMI (kg/m ²)	26.5	4.5

Inter-scans reliability at the baseline secession was reported moderately reliability (ICC> 0.85) to approve the stability of skills. The Spearman's rank correlation coefficient was used to assess the correlations and other possible variables, which may affect the muscle contractions. The OA severity level, pain duration and pain scale (p>0.05) were

showed no significant difference with the percentage of muscle contractions.

TABLE II. DESCRIPTIVE FINDINGS OF THE PERCENTAGE OF THICKNESS CHANGES AMONG REST AND DIFFERENT CONTRACTION STATUS IN VM

	Percentage of thickness changes	
	Mean (%)	SD (%)
Rt 90 dif	19.5	14
Lt 90 dif	17.5	12.9
Rt 60 dif	16.5	11.8
Lt 60 dif	18.3	13.5
Rt 60 sub dif	15.5	12.3
Lt 60 sub dif	15.6	12.6

The Paired-sample t test was used to compare the findings among baseline, post-8-weeks and post-16-weeks. The significant findings at the percentage of thickness changes at sub-maximal efforts between the baseline and post-16-weeks were reported (p=0.024). The Modified Lequesne index includes 4 sections of pain, stiffness, mobility and total work. The paired-sample t test was used to compare individually among the three sessions. The pain section was reported significant difference (p=0.026) between the baseline and post-16-weeks sessions. The average amplitude of VM was compared among the three sessions as well, and the significant findings were reported between the baseline and post-16-weeks section (p=0.042).

In this study, ultrasonography is primarily for viewing both static and dynamic muscle performances to define neuromuscular control of normal and specific alteration underlying dysfunction. After 16 weeks intervention, real-time ultrasound and EMG findings showed that the contractile function was changed at the sub-maximal effort in compared with the baseline finding. It indicates that the ability to control and coordinate the contractile components was improved. The preliminary results suggest that the intervention of Sheaflex75TM relieve the symptoms of knee OA and cause the alteration of muscles control of knee.

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