BIOMECHANICAL EFFECTS OF DIFFERENT KNEE SLEEVES ON EARLY UNILATERAL KNEE OSTEOARTHRITIS IN 6 WEEKS INTERVENTION

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DESSERTATION SUBMITTED IN FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS IN ENGINEERING SCIENCE

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BIOMECHANICAL EFFECTS OF DIFFERENT KNEE SLEEVES ON EARLY UNILATERAL KNEE OSTEOARTHRITIS IN 6 WEEKS INTERVENTION

ABSTRACT

Knee osteoarthritis (OA) is a common joint disorder that affects balance, knee joint proprioception and gait. Many treatment approaches have been used to improve the conditions of people with this disease. Knee sleeves are often prescribed to alleviate pain. However, the biomechanics underlying their pain-relieving effect is still not well understood. This pre-post study is aimed at evaluating and comparing the effects of two different types of knee sleeves on gait biomechanics and postural stability of people with early knee OA, and to determine the relationship of these changes to patient-reported pain outcomes following a six-week application. Six-week is generally longer than immediate term and often used in clinical trials. Patients with clinically diagnosed knee OA were recruited from the University of Malaya Medical Centre (UMMC), and were randomly assigned to two test groups comprising those using: 1) a simple sleeve, and 2) a simple sleeve with patella cutout. The walking motion and the ground reaction forces of participants were measured using Vicon Nexus motion analysis system (with five cameras) and two Kistler force plates, with sampling rates of 100Hz (kinematics) and 1,000Hz (kinetics), respectively for two walking speeds – controlled and self-selected. The postural stability was measured using Biodex Stability System (BSS) – with seven protocols – to obtain the Overall Stability Index (OSI): Postural Stability Test (PST), and Athlete Single Leg Test (ASL) – static and dynamic conditions – and Fall Risk Test (FRT). Pain, stiffness and physical functions were recorded using the Western Ontario and McMaster Universities Arthritis Index (WOMAC). SPSS v22 was used for statistical analyses, with two-way repeated measures Analysis of Variance (ANOVA) with mixed approaches were used to compare knee sleeve designs (between-subject effects) against all dependent variables (within-subject effect), with additional Bonferroni corrections for multiple tests and confidence interval. All measurements were made before, immediately after, and following six weeks of knee sleeve application (primary time point). Seventeen participants (aged 47.7 ± 9.7 years) with early unilateral knee OA completed the study. Overall results show significant reduction in pain, early stance and late stance knee adduction moment, and increased walking speed after six weeks of sleeve application. However, there are no significant differences between the groups in all parameters at all points of measurements. The results indicate that there is improvement in overall stability index (OSI) but no significant changes are detected for static and dynamic PST for both types of sleeves immediately after application. The findings show that early knee OA patients could experience improved balance ability in both static and dynamic conditions, and less pain after six weeks of knee sleeve application. This study results suggest that knee sleeves can reduce knee adduction moments in early unilateral knee OA by 14.0% and 12.1% using the simple sleeve and the sleeve with patella cutout, respectively, and possibly delay disease progression. Additionally, knee sleeve with patella cutout does not provide additional benefits when compared to the simple knee sleeve.

479 words

Keywords: Knee osteoarthritis, knee sleeve, gait, postural stability, WOMAC.

KESAN BIOMEKANIK LENGAN LUTUT YANG BERBEZA PADA OSTEOARTRITIS LUTUT UNILATERAL AWAL DALAM 6 MINGGU INTERVENSI

ABSTRAK

Osteoartritis (OA) lutut adalah masalah sendi yang kerap dihadapi. Ia berpotensi menganggu prestasi keseimbangan badan, keupayaan relatif lutut dan gaya berjalan. Beberapa langkah telah diambil untuk meningkatkan keupayaan fizikal dalam kalangan individu yang menghadapi masalah ini. Lengan lutut kerap diberi kepada mereka yang mengalami OA lutut bagi mengurangkan kesakitan. Walaubagaimanapun kesan biomekanik yang bertanggungjawab dalam membantu mengurangkan kesakitan masih belum difahami sepenuhnya kerana kurangnya kajian yang dijalankan. Kajian *pre-post* ini bertujuan untuk menilai dan membuat perbandingan diantara kesan keseimbangan badan, kinematik dan kinetik gaya berjalan yang dialami oleh pesakit OA peringkat awal apabila mereka memakai dua jenis lengan lutut yang berlainan selama enam minggu. Enam minggu dipilih kerana tempoh itu lebih lama daripada kesan segera, dan sering digunakan dalam ujian klinikal. Kaitan diantara perubahan-perubahan biomekanik ini dengan perubahan kesakitan yang dilaporkan oleh pesakit juga akan dikaji. Pesakit OA lutut yang memenuhi syarat telah dibahagikan secara rawak kepada dua kumpulan: 1) kumpulan lengan lutut asas dan 2) kumpulan lengan lutut dengan *patella cutout*. Kestabilan keseluruhan indeks (OSI) telah diukur menggunakan *Biodex Statibility System*. Tujuh ujian telah dijalankan bagi setiap sesi: *Postural Stability Test* (PST), *Fall Risk Test* (FRT) and *Athlete Single Leg Test* (ASL). Analisis *gait* telah diperiksa menggunakan perisian Vicon Nexus dengan lima kamera dan dua *force plate Kistler*, masing-masing dengan kadar pensampelan 100 Hz dan 1,000 Hz. Kesakitan lutut, kekakuan lutut dan kesukaran melakukan aktiviti harian telah direkodkan menggunakan WOMAC. Untuk analisis statistik, ANOVA dengan ukuran berulang dua hala dengan pendekatan campuran digunakan untuk membandingkan jenis lengan lutut (antara kesan subjek) dan pembolehubah bersandar (*within-subject effect*) dengan tambahan *confidence adjustment* menggunakan Bonferroni. Ukuran-ukuran ini diperolehi sebanyak tiga kali sepanjang kajian: sebelum lengan dipakai, sejurus selepas ia dipakai serta enam minggu kemudian (titik masa primer). Tujuh belas peserta (47.7 ± 9.7 tahun) berjaya menjalani semua ujian. Keputusan keseluruhan menunjukkan pengurangan yang ketara dalam tahap kesakitan, *adduction moment* lutut yang pertama dan kedua, dan kelajuan berjalan selepas enam minggu dari penggunaan pertama. Walau bagaimanapun, tiada perbezaan yang signifikan dikesan antara kedua-dua jenis lengan lutut dalam semua parameter pada mana-mana titik ukuran. Keputusan kajian menunjukkan *Overall Stability Index* (OSI) telah bertambah baik tetapi tiada perbezaan yang signifikan dapat dikesan untuk PST, statik dan dinamik, untuk kedua-dua kumpulan lengan lutut selepas penggunaan serta-merta untuk kedua-dua lengan lutut. Keputusan ini menunjukkan bahawa pesakit lutut OA peringkat awal boleh mengalami peningkatan keupayaan keseimbangan dalam kedua-dua keadaan statik dan dinamik dan juga pengurangan kesakitan selepas enam minggu penggunaan. Kajian ini juga membuktikan bahawa memakai lengan lutut semasa berjalan boleh mengurangkan *adduction moment* lutut pada peserta dengan OA lutut. *Adduction moment* lutut yang lebih tinggi sebelum ini telah dikenal pasti sebagai faktor risiko untuk perkembangan penyakit pada pesakit dengan OA lutut medial, kesimpulan dapat dibuat bahawa memakai lengan lutut boleh memberi manfaat kepada kumpulan ini. Selain itu, lengan lutut dengan *patella cutout* kelihatan tidak memberi manfaat tambahan berbanding dengan lengan lutut biasa apabila digunakan di peringkat awal OA lutut.

482 patah perkataan

Kata kunci: Osteoarthritis lutut, lengan lutut, analisa berjalan, kestabilan, WOMAC.

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Nahdatul Aishah Mohd Sharif

University of Malaya, December 2017

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LIST OF SYMBOLS AND ABBREVIATIONS

OA	**:**	**Osteoarthritis**
KOA	:	**Knee Osteoarthritis**
BMI	:	**Body Mass Index**
ACL	:	**Anterior Cruciate Ligament**
KAM	:	**Knee Adduction Moment**
ACR	:	**American College of Rheumatology**
UMMC	:	**University of Malaya Medical Centre**
APSI	:	**Anterior-Posterior Stability Index**
MLSI	:	**Medial-Lateral Stability Index**
COP	:	**Center of Pressure**
vGRF	:	**Vertical Ground Reaction Force**
ROM	:	**Range of Motion**
WOMAC	:	**Western Ontario McMaster Universities Osteoarthritis Index**
K&L	:	**Kellgren-Lawrence**
CI	:	**Confidence Interval**
CONSORT	:	**Consolidated Standards of Reporting Trials**
SD	:	**Standard Deviation**

LIST OF APPENDICES

CHAPTER 1: INTRODUCTION

1.1 Overview

Knee osteoarthritis (OA) is a multifactorial disease, in which the joint mechanics play a pivotal role in its initiation, progression and treatment (Felson, 2013; Wilson, McWalter, & Johnston, 2013). In Malaysia, the knee OA is one of the most debilitating musculoskeletal diseases, and is responsible for of all complaints pertaining to the joints by 64.8% of respondents, recorded by COPCORD 2007, and more than half of that percentage were examined with knee pain had clinical evidence of knee osteoarthritis (OA) (Veerapen, Wigley, & Valkenburg, 2007). The disease has been gradually attacked Malaysians since 1990 and causing disability such as pain, postural balance impairment and difficulty in performing daily routines. The statistics raise major concern from the Ministry of Health Malaysia, as the disabilities increases as the OA progresses (Health Grove, n.d.; Ministry of Health Malaysia, 2013) (Figure 1.1). Very few researches on the management of OA in Malaysia, whereby, less scientific evidences to verify what are the strategies that can be pursued in delaying knee OA progression (Khalaj, Abu Osman, Mokhtar, George, & Abas, 2014; Khalaj, Abu Osman, Mokhtar, Mehdikhani, & Wan Abas, 2014b; Khan, Khan, Usman, Mokhtar, & Osman, 2016).

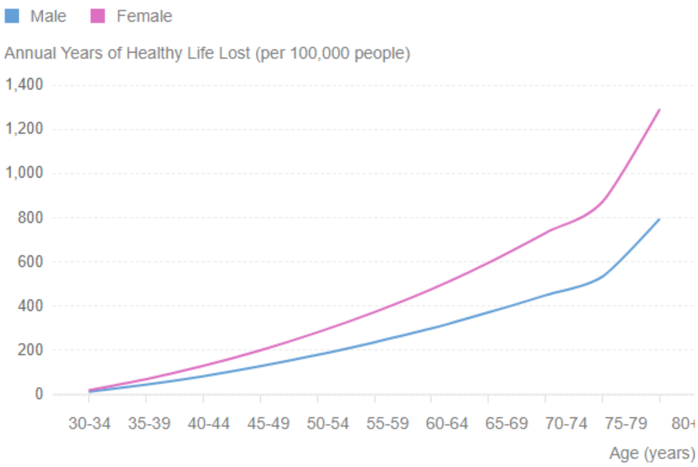

Figure 1.1 The prevalence of knee OA in Malaysia has been gradually increase since 1990, with an average of 2.4% per year (Health Grove, n.d.)

Knee OA also known as a disease of mechanics but not many studies have been conducted on the biomechanical characteristics of OA. Interestingly, patients with the disease have abnormal gait parameters such as reduced knee flexion (Al-Zahrani & Bakheit, 2002; Andriacchi & Mündermann, 2006), increased knee adduction moment (KAM) (Landry, McKean, Hubley-Kozey, Stanish, & Deluzio, 2007), and greater impulsive forces (Liikavainio et al., 2016). These abnormalities are believed to have adverse effects on knee joint loading (Lewek, Rudolph, & Snyder-Mackler, 2004). However, correction or rectification of these abnormal biomechanics has been successful in mitigating the disease progression and alleviating pain – the most common and disabling symptom in knee OA (Bennell et al., 2011).

Many treatment approaches have been used to help improve functionality in knee OA patients, including the use of orthoses (Johann Beaudreuil et al., 2009). Orthoses such as knee braces, foot insoles and knee sleeves are widely used – especially for joint support and compression (Wilson, Mazahery, Koh, & Zhang, 2010). Knee sleeves are often used to assist and stabilize movements leading to pain reduction in the joints. Besides, knee sleeves provide better biomechanical balance between the joint structures, and consequently help in reducing pain (Bryk et al., 2011).

The effects of knee sleeves are mainly functional and neuromuscular in nature because they do not usually offer rigid support and therefore their physical restraining effects on the skeletal system are minimal. Knee sleeves are made from sock-like elastic material which provides compression and warmth to the targeted area to improve functional performances (Sasek, 2015). It is relatively cheaper, lighter and less rigid than knee brace, thus, making it a popular option for patients with knee problems. Moreover, there has been no report on serious side effects attributed to knee sleeves, which indicates that they are relatively safe.

Knee sleeves have been shown to have various clinical effects such as pain relief, improved proprioception, functional performances of the knee, and stability (Bryk et al., 2011; Chuang et al., 2007; Collins et al., 2012). However, the benefits of knee sleeves from the biomechanical aspects are less clear. Some researchers believed that the compression exerted by knee sleeves stimulates the mechanoreceptors around the knee joint, leading to improvement in proprioception and balance (Bottoni, Herten, Kofler, Hasler, & Nachbauer, 2013; Ramsey, Briem, Axe, & Synder-Mackler, 2011; Wilson et al., 2010). Although knee sleeves are generally found to be beneficial for knee OA, it is unclear which type of sleeves confer the best clinical and biomechanical benefits.

There have not been many studies on the effects of knee sleeves pertaining to knee forces and loading in knee OA, probably because of the elastic nature of the sleeves (Collins et al., 2014; Collins, Blackburn, Olcott, Yu, & Weinhold, 2011; Giotis et al., 2011; Schween, Gehring, & Gollhofer, 2015). In their study, Schween et al. used knee adduction moment (KAM) to represent medial joint loading, and found that knee sleeves can significantly reduce joint loading by 10.1%, immediately after application. Since most of these studies investigated only the immediate effects of the sleeve use, the long-term benefits of knee sleeve use is still unclear. Practically, it is important to establish if the effect of knee sleeve persist beyond immediate application in order to justify its extended use in patients with knee OA.

1.2 Problem Statement

Many treatment approaches that have been introduced to alleviate the pain have not proven to be satisfactory. Knee sleeves have been widely prescribed to alleviate the pain, but with limited evidences. Pain management is vital for knee OA individuals as pain causes difficulty doing daily routines. The studies that have been conducted on knee sleeves use have thus far focused on the immediate effects and without comparing different designs of knee sleeve.

The research intends to answer the following questions: 1) Can knee sleeves help to reduce pain in people with early unilateral knee OA in six weeks? 2) Can knee sleeves improve postural stability in people with early unilateral knee OA in six weeks? 3) Do knee sleeves change the knee joint mechanics in people with early unilateral knee OA in six weeks? And 4) Do the different types of knee sleeves produce different effects?

1.3 Objective

This study is undertaken: 1) to determine the biomechanical effects of knee sleeves on early unilateral knee OA following six weeks of application, and 2) to determine the difference in the effects for two different types of knee sleeves. To achieve the objectives, our primary outcome is the patient-centered parameter – pain, stiffness, and difficulty performing daily activities. Our secondary outcome - the biomechanical effect comprises of: 1) Gait parameters – knee adduction moment (KAM), ground reaction force (GRF), knee sagittal plane kinematics, and walking speed; and 2) Postural stability – Single-stance standing balance and dual-limb standing balance.

This study will investigate whether knee sleeves could modify any of the biomechanical parameters to achieve the following aims: 1) to help clinicians comprehend the indications and properties of the knee sleeves, and 2) to help fill the gap on information pertaining to the biomechanical aspects of knee sleeves. If proven to be effective, knee sleeves could be used in patients with early knee OA to alleviate pain.

We chose a six-week testing duration as this is the generally accepted duration for any academic study and is generally longer than immediate duration (Birmingham et al., 2008; Hunter et al., 2011). Besides, we are considering the logistics of the project: short duration for project, and no administrative assistance in managing the patient's affairs.

1.4 Hypothesis Statement

In this study, we aim to determine the effects of knee sleeves of two different designs on the knees of people with early knee OA based on three aspects – pain, gait, and postural stability. In this context, we have formulated the following hypotheses to guide us in answering questions pertaining to the efficiency of knee sleeves used in knee osteoarthritis:

Hypothesis 1 – pertaining to pain in knee OA:

H_0: The application of the knee sleeves would not alleviate pain, reduce knee stiffness and improve knee functional performance;

H_1: The application of the knee sleeves would alleviate pain, reduce knee stiffness and improve knee functional performance.

Hypothesis 2 – pertaining to gait in knee OA:

H_0: The application of the knee sleeves would not increase walking speed, decrease ground reaction force (GRF) loading rates and KAM in people with knee OA;

H_1: The application of the knee sleeves would increase walking speed, decrease ground reaction force (GRF) loading rates and KAM in people with knee OA.

Hypothesis 3 – pertaining to postural stability:

H_0: The application of the knee sleeves would not improve postural stability in people with knee OA;

H_1: The application of the knee sleeves would improve postural stability in people with knee OA.

1.5 Dissertation Structure

This dissertation consists of six chapters.

Chapter 1 provides a general overview of this dissertation and discusses the background of the study, objectives, problem statement and the hypotheses formulated for the study. **Chapter 2** presents the literature review pertaining to knee sleeves use in treatment of knee osteoarthritis, their limitations, and findings. **Chapter 3** is the methodology used in the study, which include discussion on the recruitment of participants for the study, and the various processes involved. **Chapter 4** presents the results and discusses the findings vis-à-vis the hypotheses. **Chapter 5** discusses the study findings presented in Chapter 4 and focuses on the core aspects of the study that include the kinetics and kinematics parameters, postural stability, knee pain, knee stiffness, and knee functional performance. **Chapter 6** presents the conclusion to the study, and highlights the problems encountered in the study, the contribution of the study, and suggestions for future researches.

1.6 Summary

This chapter introduced the reader to the main message, aim, and objectives of this dissertation.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter discusses various findings from the literature review on the topics relevant to this research. It includes background on knee osteoarthritis (OA) and the management strategies in dealing with the pain and other symptoms associated with the disease. Subsection 2.2 discusses the definitions of OA; subsection 2.3 discusses the management and treatment of knee OA; subsection 2.4 discusses the orthoses for knee OA; subsection 2.5 discusses the studies on knee sleeves use; and subsection 2.6 summarizes the whole chapter.

2.2 Osteoarthritis: Definition

Osteoarthritis (OA) is a multifactorial disease in which the joints of the body become damaged and painful. The prevalence of knee OA in Malaysia was estimated to be 10% to 20% of the elderly population and is said to affect mainly female, with a male to female ratio of 2:3 among Malays, 1:1 among Chinese, and 3:6 among Indians, respectively and the ratio increases gradually every year (Foo et al., 2017; Fransen et al., 2011). Knee OA results from the breakdown of the tissues of the knee joint (UK Arthritis Research, 2013). Joint abnormalities such as cartilage degradation, muscle weakening, inappropriate mechanical stress and ligament tear are some of the risk factors which initiate the disease (Figure 2.1) (Egloff, Hügle, & Valderrabano, 2012). Besides, there are several other factors that could affect the progress of the disease.

There are some non-modifiable risk factors such as advancing age, gender and genetic influence. The female has a higher likelihood of having arthritis due to the wider range of motion of the pelvis and the hip (Kaufman, Hughes, Morrey, Morrey, & An, 2001; McKean et al., 2007). As for age, there is higher prevalence of knee OA in the older population due to the decrease in bone strength and density (Bagge, Bjelle, Edén, &

Svanborg, 1991). Genetic influences that lead to abnormal joint morphology, and obesity or injuries can amplify the effect of abnormal mechanical stress (Guilak, 2011).

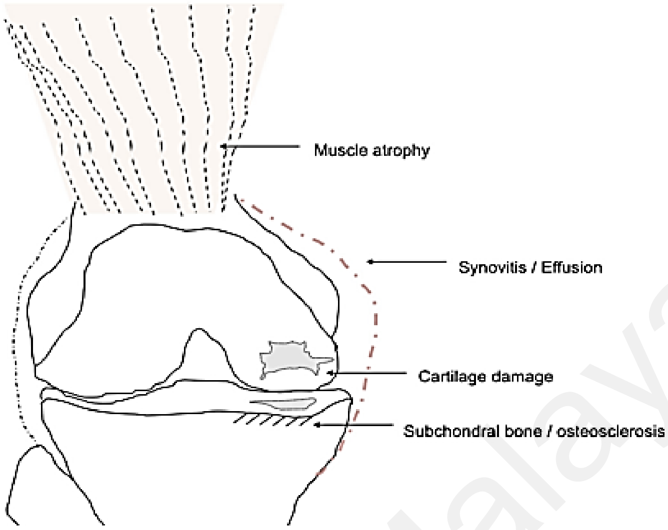

Figure 2.1: Characteristics of knee OA which include muscle atrophy, synovitis (cause radiological progression and pain), osteosclerosis and cartilage damage (Egloff et al., 2012)

The modifiable risk factors include previous knee injury, obesity (BMI >30 kg/m^2), overweight BMI (BMI 25 – 30 kg/m^2), and malalignment of the knee (Ministry of Health Malaysia, 2013).

Patients are diagnosed to have clinical knee OA if they fulfill the American College of Rheumatology (ACR) 1986 Criteria that include both clinical and radiographic criteria and a myriad of symptoms that include knee pain; osteophytes seen on x-ray; at least 50 years old; and knee stiffness of less than 30 minutes, or crepitus (Table 2.1). Kellgren-Lawrence (K&L) Grading System is a commonly-used radiographic classification to identify and grade the severity of radiographic OA (Kellgren & Lawrence, 1957) (Table 2.2). The World Health Organization (WHO) adopted the grading as the standard for epidemiological studies of OA. The reliability of K&L grading system showed good to very good reliability (K between 0.6 and 0.8 and above 0.8) (Schiphof, de Klerk, Koes, & Bierma-Zeinstra, 2008).

Pain and stiffness of the knee joint are the primary indicators of the presence of knee OA and are usually very mild at the beginning and progresses as the disease increases in severity (Foxworth, 2007). The pain and stiffness are often much worse when the patient rises from a seated position. Patients with knee OA also often present with inflammation and swelling on the knee joint. Besides, the other minor symptoms include gait disturbance, clicking or grinding sensation on the arthritic joint, and also instability (Ministry of Health Malaysia, 2013).

Table 2.1: Knee OA grading based on ACR classification (Table is adapted from the Ministry of Health Malaysia, 2013).

Criteria \ Diagnosis	Clinical and laboratory	Clinical and radiographic	Clinical only	
Must have	Knee pain + At least 5 of 9 of the following	Knee pain + Osteophytes on x-ray + At least 1 of 3 of the following	Knee pain + At least 3 of 6 of the following	
1	Age >50 years	Age >50 years	Age >50 years	
2	Stiffness <30 min	Stiffness <30 min	Stiffness <30 min	
3	Crepitus	Crepitus	Crepitus	
4	Bony tenderness		Bony tenderness	
5	Bony enlargement		Bony enlargement	
6	No palpable warmth		No palpable warmth	
7	ESR <40			
8	RF <1: 40			
9	SF OA			
Sensitivity **Specificity**	92% 75%	91% 86%	95% 69% (if 3/6)	84% 89% (if 4/6)

ESR=erythrocyte sedimentation rate RF=rheumatoid factor
SF OA=synovial fluid signs of OA (clear, viscous, or white blood cell count <2,000/mm³)

Table 2.2: Knee OA grading based on Kellgren-Lawrence classification (Kirkley et al., 1999).

Grade	Narrowing of Joint Space	Osteophytes	Sclerosis	Deformation of Joint Contour
I	Doubtful	Possible lipping	None	None
II	Possible	Definite	None	None
III	Definite	Moderate, multiple	Some	Possible
IV	Marked	Large	Severe	Definite

2.3 Management on Knee OA and the Challenges

Owing to the irreversible nature of knee OA, physicians focus their efforts on arresting the functional decline of the osteoarthritic knee, reducing pain, and thus, giving quality of life to their patients. The treatment approaches include both pharmacological and non-pharmacological interventions, and surgery in severe cases (Egloff et al., 2012; Sasek, 2015). Today, surgical intervention is recommended in severe cases.

The most common approach to manage knee OA is to combine pharmacological therapy and non-pharmacological approaches (Foxworth, 2007). Pharmacological treatment involves oral treatment which consists of simple analgesics such as paracetamol, and also nutraceuticals such as glucosamine and chondroitin. Chondroitin sulphate and glucosamine sulphate may be beneficial as modifying agents while analgesics are mainly used to control pain (Bijlsma & Knahr, 2007).

Non-pharmacological treatment involves education of knee OA patients regarding the disease itself, self-management and on how to cope with the pain and disabilities. Obese patients are also advised to reduce their weight as this helps to minimize joint loading, especially on the knee (Christensen, Bartels, Astrup, & Bliddal, 2006; Guilak, 2011; M Henriksen et al., 2013). Khalaj et al. (2014) recommended exercise as an effective way in reducing pain, reducing body weight, improving mobility, and improving muscle strength.

Other than exercises, the European League Against Rheumatism (EULAR) recommends that patients with knee OA should use external assistive devices such as knee brace, knee sleeve and also orthosis when indicated (Jordan et al., 2003). Beaudreuil et al. (2009) systematically reviewed the clinical guidelines on OA management and found that one-quarter to one-third of the physicians are likely to prescribe knee sleeves, while 65% to 74% are unlikely to do so.

2.4 Orthosis for Knee OA

Orthotic devices are used to give external strength and support the joint, align deformities or improve function of movable parts of the body. The main purpose of prescribing these devices in OA is primarily to reduce pain, improve physical function and, hopefully, delay disease progression. Insoles, elastic knee brace, rigid knee brace, knee sleeve, and knee orthosis are often been prescribed by health professionals as a management of knee OA (Beaudreuil et al., 2016; Beaudreuil et al., 2009; Jones et al., 2013). Knee brace is effective in altering the deformities of the knee, depending on the varus or valgus alignment of the device, by getting the knee back to its neutral position – in a way, to unload the excessive forces on the knee. For insoles, it reduced KAM but no lessening in pain (Jones, Chapman, Forsythe, Parkes, & Felson, 2014). But, an extended usage of laterally-wedged insoles for one-month is effective in reducing pain (Turpin et al., 2012). Knee brace and foot insoles have been extensively experimented for a longer term – from eight-week to 12-month longitudinal studies (Hinman et al., 2008; Hurley, Murdock, Stanish, & Hubley-Kozey, 2012; Knoop et al., 2013; Toda & Tsukimura, 2004; Turpin et al., 2012).

While there are good quality evidence to support the positive clinical outcomes of knee braces, the laboratory evidence that demonstrates beneficial biomechanical outcomes of knee sleeves is still not fully explored and unconvincing (Johann Beaudreuil et al., 2009; Moyer et al., 2015). Beaudreuil et al. also stated that clinicians and consumers tend to use the knee sleeves indiscriminately, hence, it is important to assess the effects of knee sleeves more objectively.

Knee braces have been well investigated in high quality randomized controlled studies, while knee sleeves or rest orthosis have not been much researched (Johann Beaudreuil et al., 2009). This could be due to the assumption that the more rigid knee brace would be more likely to alter abnormal joint mechanics than the flexible knee sleeve (Mohd Sharif, Goh, Usman, & Wan Safwani, 2017). However, the bulkiness of the brace can cause discomfort and inconvenience to the user and from a review, in longer follow-up studies (1 to 2 years) many patients stopped their brace or insole treatment (Bottoni et al., 2013; Brouwer et al., 2009). For some, the simple and flexible knee sleeves then become the more practical and more acceptable treatment option.

However, it is difficult to conclude whether knee sleeves have beneficial effects because of the limited research evidences. Based on current evidence, knee sleeves are effective in relieving pain in knee osteoarthritis, and they have been generally associated with effecting subjective improvement to the disease (Johann Beaudreuil et al., 2009). They also effect improvement in gait parameters and balance control, but no improvement in knee alignment alteration. Therefore, Beaudreuil et al. suggested more comprehensive investigations on the knee sleeves and their effects on knee OA.

2.5 Past Studies on Knee Sleeves

From the literature review covering the period 2005 until 2015, it was found that seven studies had reported the use of knee sleeves for knee OA (Bryk et al., 2011; Chuang et al., 2007; Collins et al., 2010, 2011, 2012, 2014; Schween et al., 2015). In these studies, various assessment parameters were used and duration of the tests were generally or immediate.

2.5.1 Clinical Assessment on Knee Sleeves

Apart from the biomechanical parameters, pain experienced by patients is used to determine the efficacy and effectiveness of knee sleeves. This subsection will also discuss some of the adverse effects of knee sleeves reported in past studies.

2.5.1.1 Pain

Pain is one of the primary patient-centered outcomes considered in many studies to assess the efficacy of knee OA intervention methods. Pain is a protective mechanism which allows us to perceive harm. However, chronic pain may adversely affect the independence and physical functions of patients (Hurwitz, Sharma, & Andriacchi, 1999). Hence, the primary objective of any proposed intervention for knee OA should be to decrease pain experienced by the patients.

Pain reduction following the use of a knee orthosis was reported in a number of studies (R. K. Jones et al., 2013; Laroche et al., 2014). For knee brace and foot insoles, pain is consistently reduced, immediately and after a long-term usage (Jones et al., 2014; Pagani, Böhle, Potthast, & Brüggemann, 2010; Toda & Tsukimura, 2004). Meanwhile, Schween et al. (2015) reported a slight reduction in pain – measured using the Visual Analog Scale (VAS) (Figure 2.2) – following the immediate use of the knee sleeve. This observation indicates that knee sleeves can effect immediate pain reduction following their application. Another study by Bryk et al. (2011) supported the findings of Schween et al. These finding answers Bockrath et al. (1993) query on the duration for knee sleeves to take effect in reducing pain. However, there is no longer term study on knee sleeves, which investigating on knee pain.

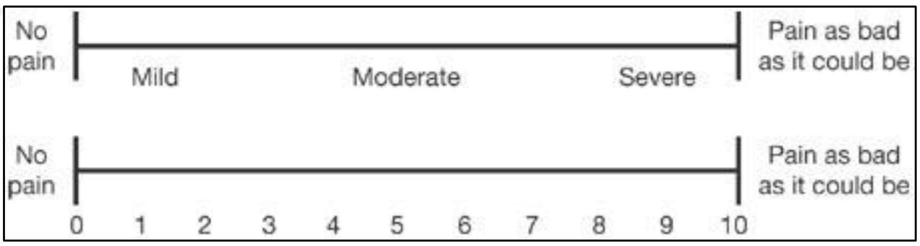

Figure 2.2: Visual Analog Scale (VAS) that is used for rating pain (Mannion, Balagué, Pellisé, & Cedraschi, 2007)

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a scoring system that has been widely used to assess knee pain and knee functional performance in OA (Jones et al., 2013; Laroche et al., 2014; Pagani et al., 2010). Higher WOMAC score indicates more severe knee pain, stiffness, and other physical dysfunctions (Turpin et al., 2012). The WOMAC score is derived from the VAS scale (Figure 2.2), in which in a 10-cm line (scale), the initial number 0, positioned at the left end of the line, indicates 'no pain' and a final number 10, positioned at the right end of the line, indicates the 'worst pain possible' (Bryk et al., 2011; Laroche et al., 2014).

Although WOMAC is a self-reported measure with poor inter-rater reliability, it has good intra-rater reliability. The use of a subjective tool in an intervention study will introduce reporting bias because not app patients will grade pain in the same manner. The participants' perception of pain may not reflect their real pain level. The same painful stimuli could be graded as severe by those with low pain threshold but may be perceived by mild by those who are more tolerant to pain. Nevertheless, the WOMAC score is a measure of function, pain or stiffness (Wolfe, 1999). Basically, the WOMAC score is a way of assessing a patient's degree of pain.

The above discussion shows that knee sleeves are able to reduce pain very shortly after application. However, the actual mechanism on how this works is not fully understood. The temporal changes in pain pattern at various periods of sleeve use is poorly covered in the literature. Hence, it would be useful to reconfirm the pain relief benefits of knee sleeves and to investigate how their effects change on the short-term and long-term usage, as well as with the designs of the knee sleeves.

2.5.1.2 Adverse Effects

Many studies reported that knee sleeves are well tolerated by participants. Only a few studies have mentioned about local adverse effects such as swelling, muscle weakness, and spasms (Asl, Kahrizi, Ebrahimi, & Faghihzadeh, 2008; Chuang et al., 2007).

Moreover, there has been no report that knee sleeve has caused any serious discomfort to participants.

2.5.2 Gait

Studies have also been conducted on the biomechanical effects of knee sleeves. Excessive loading on the knee has been acknowledged as the main cause for the onset of knee OA. By enhancing the proprioceptive ability and also decreasing the loading rate on the knee, knee sleeves could aid in altering gait and delaying disease progression (Collins et al., 2011; Van Tiggelen, Coorevits, & Witvrouw, 2008). In this section, we focused on walking gait and Figure 2.3 below illustrates the terms that are commonly used.

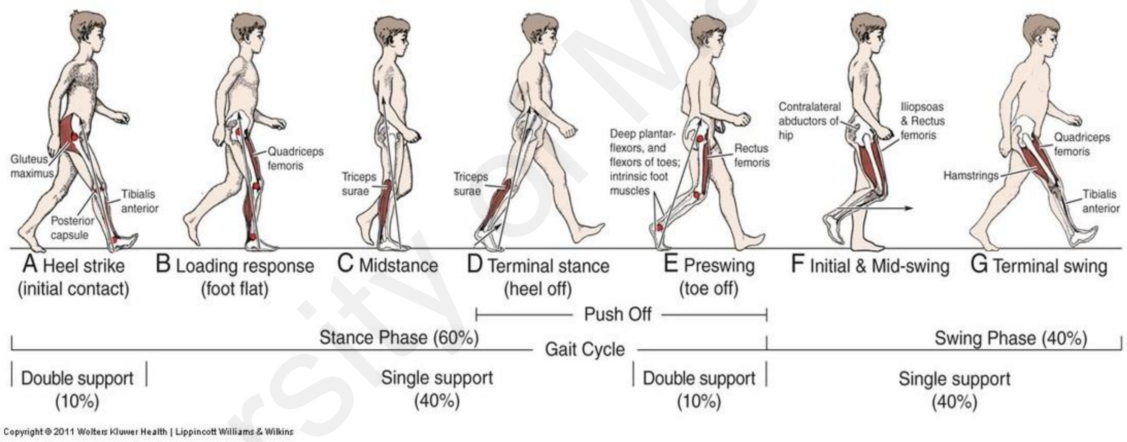

Figure 2.3: The phases of walking gait. Figure is adopted from http://advancedhealth.ca/clients/516/images/Chiro_gait_cycle.jpg

2.5.2.1 Knee Adduction Moment (KAM) and Ground Reaction Force (GRF)

Particularly, dynamic knee joint loading during walking is of interest, because walking is the most common way of human locomotion and causes repetitive joint loads. To measure the mechanical loads internally – from the joint area – would be difficult. Therefore, from a biomechanical view, we often linked knee adduction moment (KAM) to indicate the degree of loading (Figure 2.4) (Marius Henriksen, Aaboe, & Bliddal, 2012). KAM is a reliable measure of loading on the medial compartment of the joint, hence, it is a reliable predictor of disease progression, best characterized knee OA, and closely related to pain, walking speed and body mass OA (Baert et al., 2013; Creaby, Bennell, & Hunt, 2012; Khalaj et al., 2014b; Levinger et al., 2012).

Reducing KAM has become the objective of early and conservative treatment approaches in attempting to reduce pain, maintaining function and arresting disease progression (Heiden, Lloyd, & Ackland, 2009; R. K. Jones et al., 2013). Often, increased KAM is the cause of pain in patients with knee OA (Thorp et al., 2003). In another study, Heiden et al. suggested that pain is a protective mechanism that leads to a self-selected reduction in KAM during gait and is inversely correlated with KAM. As such, some treatment approaches involve modifying gait in order to minimize KAM and to alleviate pain in knee OA. These include reducing gait speed and applying toe-out gait (Farrokhi, O'Connell, Gil, & Kelley Fitzgerald, 2013; Jenkyn, Erhart, & Andriacchi, 2011). As well as orthosis, the devices – knee brace, knee supporters, foot insoles – are meant to unload the medial joint loading (Deshaies, 2002). Number of studies identified the positive effects of knee braces and foot insoles, and two studies compared the effects between these two orthoses and found that foot insole is more effective in reducing knee moments and is comfortable to be used by knee OA individuals (Dessery, Belzile, Turmel, & Corbeil, 2014; Jones et al., 2013; Lamberg, Streb, Werner, Kremenic, & Penna, 2015; Maleki et al., 2014; Shelburne, Torry, Steadman, & Pandy, 2008).

For knee sleeve, from our literature search, only two studies were investigated the effects on gait – focusing on frontal and sagittal plane kinematics and kinetics. The studies reported the positive effect of knee sleeves on KAM and frontal plane kinematics during walking following the immediate use of knee sleeves (Collins et al., 2014; Schween et al., 2015). Schween et al. reported that KAM is significantly reduced by 10.1%, while Collins et al. found that KAM is reduced, but not significantly. They also reported improvements on knee adduction angle and found significant reduction during terminal stance while Schween et al. obtained similar result during walking while wearing the knee sleeves.

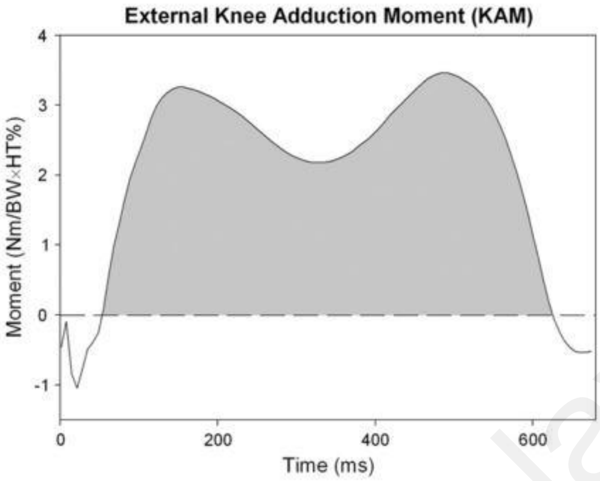

Figure 2.4: Graphical illustration for KAM during stance phase (Henriksen et al., 2013)

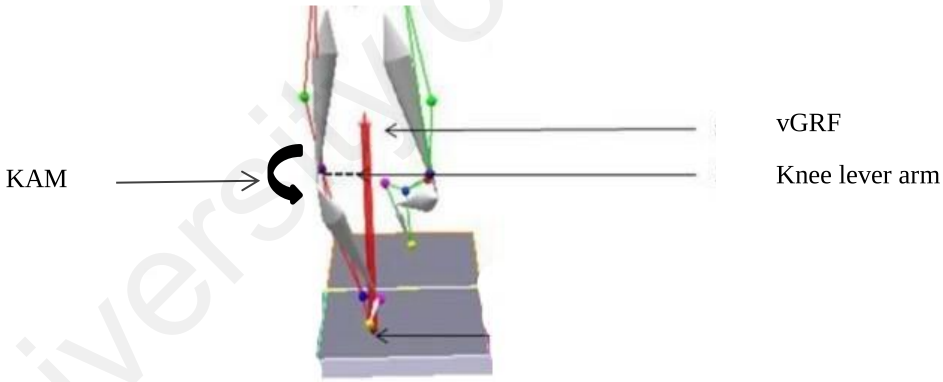

Figure 2.5: Illustration for lever arm, and vGRF, resulting in KAM. Figure is adapted from Turpin et al., (2012)

In addition, KAM was also reported to be closely correlated with the loading rate or the ground reaction force (GRF). However, the projection of GRF may deviate from the center of the body due to malalignment. Therefore, when there is an increase in the GRF, combined with an increased lever-arm distance between the knee joint center and the GRF vector, they will result in higher KAM (Figure 2.5) (Duffell, Southgate, Gulati, & McGregor, 2014; Turpin et al., 2012). Hence, reducing KAM is aimed at reducing pain, maintaining function and arresting disease progression, and similarly, reducing GRF would also bring the same benefits to knee OA patients (Jones et al., 2013).

Collins et al. (2011) applied additional stochastic electrical stimulation to the knee sleeve, and found significant reduction in the GRF. This finding shows that electrical stimulation applied to the knee sleeves can change the GRF. However, in all these studies, only the immediate effects of the knee sleeve use were observed. To date, there has been no study on the effects of long-term use of knee sleeves on gait biomechanics.

2.5.2.2 Knee Extension and Walking Speed

GRF is correspondingly highly affected by the initial contact of the heel. Greater flexion angle could also be an attempt to stabilize the joint to lessen knee pain. This additional knee flexion serves as a shock absorption mechanism as the body weight is transferred from the opposite limb (Foxworth, 2007). However, this claim is controversial. Another study reported that high knee flexion during heel strike may create larger GRF projection. The study suggested that to reduce knee medial loading, knee flexion during heel strike must be smaller to generate smaller GRF (Paquette, 2012). Therefore, heel repositioning during heel strike must be carefully considered in defining knee flexion at contact and also the GRF.

The conflicting findings can be resolved by considering them from the biomechanical aspect. When the knee flexes within a certain range, it will immediately transfer the load. Schipplein and Andriacchi (1991) found that knee flexion ranging from 35^{o} to 40^{o} would reduce the impact of GRF due to the gradual deceleration of the vertical velocity. Riskowski, Mikesky, Bahamonde, Alvey, and Burr (2005) also stated that large GRF may cause faster degradation of the cartilage, and this will quicken the thinning of the meniscus over time.

Knee sagittal kinematics – knee flexion and extension – plays a role in knee disease progression and is also associated with knee pain (Astephen, Deluzio, Caldwell, Dunbar, & Hubley-Kozey, 2008; Creaby, Hunt, Hinman, & Bennell, 2013; Kaufman et al., 2001) (Figure 2.6). People with knee OA have reduced range of motion particularly in the sagittal plane, because of the impact of the stiffened knee (Kaufman et al., 2001; Schmitt & Rudolph, 2007). Thus, greater flexion angle could be an attempt at reducing the GRF, and lessening pain. Besides, additional knee flexion serves as a shock absorption mechanism as the body weight is transferred from the affected knee to the unaffected knee (Foxworth, 2007).

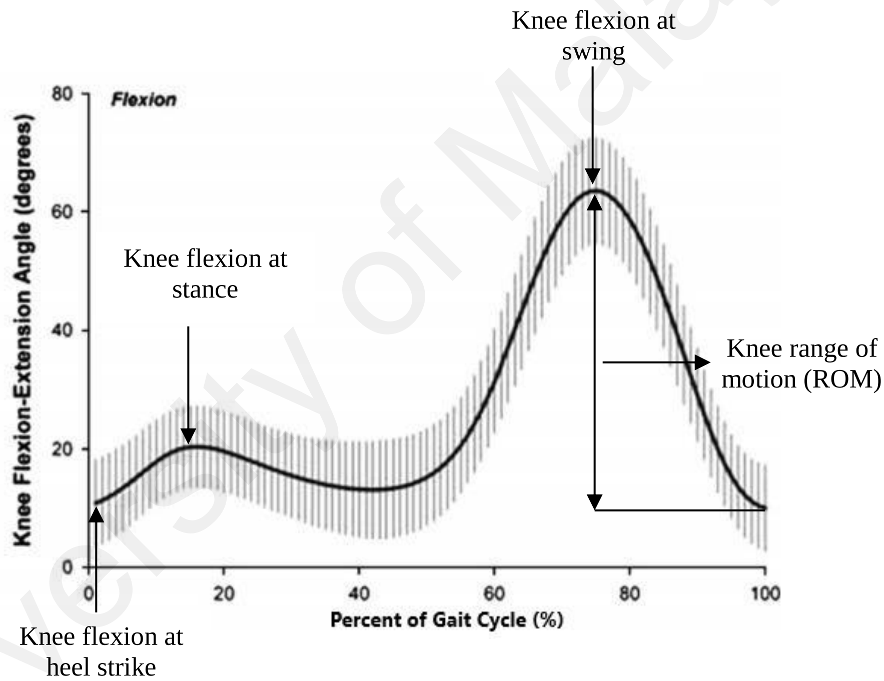

Figure 2.6: Sagittal kinematics that often investigated in knee OA researches (Maly, Costigan, & Olney, 2008)

Two studies assessed knee flexion and knee extension by varying the additional stochastic electrical stimulation applied to the sleeve, and reported significant reduction in pain and this finding concurs with the results of Collins et al. (2014) and Collins et al. (2011). These studies explored additional stochastic resonance electrical stimulation on the knee sleeves. If there is no significant difference in the effects with or without the additional electrical stimulation, we can infer that knee sleeve alone – without the additional stochastic electrical stimulation – is beneficial to those with knee OA or knee-related problems.

It was found that test subjects exhibit slower walking speed during the pain adaptation stage (da Silva, Cliquet Junior, Zorzi, & Batista de Miranda, 2012). Walking speed clearly represents the health level of a person and it is inversely correlated with the pain levels (Astephen Wilson, Deluzio, Dunbar, Caldwell, & Hubley-Kozey, 2011). In fact, walking at a reduced speed has been found to be the best method for reducing adduction moment (Mündermann, Dyrby, Hurwitz, Sharma, & Andriacchi, 2004). Also, from walking speed, we should also assess the pain level. Since pain is a protective mechanism, people tend to walk slower in a painful condition. However, in the only study that assessed gait velocity in conjunction with the usage of knee sleeve, Collins et al. (2011) found that there is no significant difference in the mean forward velocity between the treatment group (with stochastic electrical stimulation) and the control group (no stochastic electrical stimulation). If knee sleeves can help people to improve their gait speed, then it can be inferred that they can also help to improve knee functions and postural stability. Therefore, further studies on the long-term use of knee sleeves would give clearer and more substantive findings of their benefits.

2.5.2.3 The Gait Analysis

Many of the studies on motion analysis used the universally recommended Helen Hayes (Davis model) marker placement protocol (Davis, 1988; Giotis et al., 2011; Schween et al., 2015). However, other studies did not specify their markings (Collins et al., 2014; Collins et al., 2011). The optimum sampling rates ranged from 100Hz to 200Hz for kinematics, and 1,000Hz to 1,440Hz for kinetics. The parameters used are presented in Table 2.3.

It is advisable to adopt the Davis model for marker placement and at the same time provide more cameras for motion capture. If there are too few cameras, the distance between cameras may lead to lower image resolution and inaccuracy in detecting the markers in some frames (Kirtley, 2006). These studies, however, involved only one design of knee sleeve, thus, further research using different knee sleeve designs would be useful.

Table 2.3: Kinematics and kinetics parameters used in the studies

Author, Year	Motion Capture System	Procedure/Protocol	Results
Collins et al. (2013)	MotionStar electromagnetic tracking system	Walking speed is controlled. Walking, 5 trials, barefooted Test duration: Immediate	Knee adduction moment: 0.84% reduced to 0.80% (with 75% electrical stimulation applied), no significant difference Knee adduction angle: Reduced from 3.9^o ±5.6 to 2.9^o ±6.4 (weight acceptance) Reduced from 5.0^o ±5.7 to 4.6^o ±6.3 (mid-stance), no significant difference Knee flexion angle: Significantly increased from 25.4^o ±10.0 to 26.8^o ±9.1 (weight acceptance) and from 5.0^o ±5.7 to 4.6^o ±6.3 (mid-stance)
Schween et al. (2015)	Vicon V-mx	Walking speed is controlled. Walking, 10 trials, using special shoe Test duration: Immediate	Knee adduction moment: Significantly reduced ($p < 0.05$) from 0.854 to 0.780 Nm•kg^{-1} (10.1% reduction) Knee adduction impulse: Significantly reduced ($p < 0.05$) from 0.243 to 0.219Nm•s•kg^{-1} (12.9% reduction) Knee adduction angle: Significantly reduced ($p < 0.05$) from 11.5^o to 9.6^o
Collins et al. (2011)	Flock of Birds electromagnetic tracking system	Walking speed is controlled. Walking, 5 trials, barefooted Test duration: Immediate	Knee flexion angle*:* E75:S increased from 12.40^o ±8.28 to 14.67^o ±8.13 (Significant improvement in NE:S and E75:S ($p < 0.05$))
Giotis et al. (2011)	Vicon	No reported walking speed. Doing activities: jumping and landing Test duration: Immediate	Tibial rotation: Descending: Reduced from 17.1^o ±7.7 to 16.1^o ±4.5. Ascending: Reduced from 14.0^o ±3.3 to 12.2^o ±3.5 (No significant difference)

NE:S : no electrical stimulation applied to knee sleeve; E75:S: 75% electrical stimulation applied to knee sleeve

2.5.3 Balance and Postural Stability

Aside from gait parameters, intervention study on knee OA patients also often assesses their postural stability. This is because these patients often experience balancing impairment and knee instability probably due to the decreased sensitivity of the proprioception and somatosensory receptors resulting in limited functional independence (Elbaz et al., 2010; Khalaj, Abu Osman, Mokhtar, Mehdikhani, & Wan Abas, 2014a; O'Connell, Farrokhi, & Kelley Fitzgerald, 2015). This dysfunctional condition could lead to injuries following a fall and aggravate any existing balancing problem of these patients. Besides, knee OA patients often have impairment of proprioceptive acuity or weakness in the quadriceps muscles when compared with those without knee OA. These are the consequences of instability in those with knee OA (Park, Ko, Hong, Ok, & Lee, 2013).

As equally important as pain, knee instability also causes significant disability for people with knee OA in performing their daily activities such as climbing stairs, bending and reaching for things, and walking. In Malaysia, people tend to do outdoor activities such as outdoor exercises, playing tennis and badminton (Eng Hoe, 2009). Therefore, knee support is highly needed to overcome the difficulty. To date, however, there has not been much attention on the sensorimotor control parameters of patients with early knee OA. For knee brace, significant improvement in proprioception has been reported, but no significant changes in postural control in flat surface, after an immediate use of knee brace (Birmingham et al., 2001). Another study found In the literature search, there were four studies on knee sleeve use in knee OA, which specifically focused on knee proprioception and balance (Bryk et al., 2011; Chuang et al., 2007; Collins et al., 2010; Collins et al., 2012) (Table 2.4).

Chuang et al. (2007) reported significant reduction in the stability index in both static and dynamic balance tests after patients wore the sleeves. Reduction in the stability index denotes improvement in postural stability. They recorded 28% and 7% to 8% improvement in static balance and dynamic balance, respectively. Their findings were supported by Schween et al. (2015) who measured instability using self-stability approach, and reported significant immediate improvement in postural stability following the use of knee sleeve. Only one study used sway velocity and reported no significant difference in the sagittal and coronal planes despite using five different levels of stochastic electrical stimulation (Collins et al., 2012).

Sanchez-Ramirez et al. (2013) reported that postural stability index can help physicians in assessing the muscle strength of the lower extremities as they represent the balance ability. Thus, instrumented balance systems have been widely used in hospitals and rehabilitation centers to monitor the progress of the patients' balancing ability. An instrumented balance system can be set to several test protocols and to several dynamic levels. The system also provides visual feedback to ensure that patients control their balance in the same way they control their balance on the real surface. Measuring balance using a balance system is relatively easy and produces reliable results (Karimi, Ebrahimi, Kahrizi, & Torkaman, 2008).

Postural stability can be tested dynamically and statically. Dynamic tests assess balance control during voluntary movement, such as walking or rising from a chair. Static tests assess the ability to maintain an upright position under varied situations, such as with the eyes closed, or with expected or unexpected disturbance in motion (Hassan, Mockett, & Doherty, 2001). Many past studies considered these two conditions in balance assessment in order to obtain more cogent findings for these two conditions, and to have a better understanding of the postural stability of the patients (Giuliamarta Bottoni, Kofler, Hasler, Giger, & Nachbauer, 2014; Chuang et al., 2007; Khalaj, Abu Osman, Mokhtar, Mehdikhani, et al., 2014a).

2.5.3.1 Functional Tests

Besides assessing postural stability, functional tests are often conducted on people with knee OA to evaluate their sensorimotor control and to assess their ability to perform daily activities such as walking, sitting down and standing up to walk, stair climbing, and jumping (Bryk et al., 2011). These activities are relatively easy to carry out and the performance of these activities is assessed based on the total time taken to complete each task or activity. Physicians deem the reduction in total time to complete an activity as an improvement in the patients' sensorimotor control. These functional tests are relevant to knee OA as they assess the performance of daily activities, and the test outcomes largely reflect a person's physical ability and current health condition (Bryk et al., 2011).

For people with knee OA, the functional tests used include Timed-up and Go (TUG) test and Stair Climb Power Test (SCPT) (Bryk et al., 2011). Bryk et al. found significant improvement in TUG test, but no significant improvement in SCPT. However, other studies that involved healthy subjects, found significant improvement in both TUG test and SCPT, suggesting that knee sleeves improve proprioception of healthy knees (Kwon et al., 2014). Van Tiggelen et al. (2008) also found significant improvement in proprioception in healthy knees, both in fatigued state and in non-fatigued state. In conclusion, knee sleeves can effect improvement in the functions of osteoarthritic knee because they improve proprioception, and give additional strength and stabilizing effect to the knees (Bryk et al., 2011).

Table 2.4: Studies' characteristics for proprioception and balance

Author, Year	Output Parameters and Procedure/protocol	Findings
Chuang et al. (2007)	Parameter: Balance score (static and dynamic). Protocol: Dual-leg stance, Eyes open. Test Duration: Immediate	Significant improvement in balance ability for both static and dynamic condition. Improvement 28% static, 7%-8% dynamic condition.
Collins et al. (2009)	Parameter: Mean repositioning error. Protocol: Lying supine (PWB), Sitting (NWB), Eyes closed, ears with headphones. Test Duration: Immediate	Joint position sense improved when electrical stimulation is combined with knee sleeve. For PWB, the error reduced from 3.35° (1.63) to NE/S: 2.87° (1.41), and with electrical stimulation; reduced to E/S: 2.48° (1.32) (significant). For NWB, 5.86° (3.80) reduced to 4.96° (3.52) and with additional electrical stimulation, reduced to 5.69° (3.73) (no significance).
Collins et al. (2010)	Parameter: Mean repositioning error. Protocol: Lying supine for knee extension, Lying prone for knee flexion, Eyes closed, ears with headphones. Test Duration: Immediate	For PWB: Sleeve alone NE/S: 2.9°±2.6° and with 75 µA-RMS stimulation/sleeve E75/S, 3.0°±2.3° conditions significantly decreased compared to the control condition (NE/NS, 3.7°±2.5°). For NWB: No significant difference between the treatment conditions.
Bryk et al. (2011)	Parameters: VAS pain score. Protocol: Stair Climb Power Test (SCPT), Timed-Up and Go (TUG) test, 8-meter walk (8MW) test. Eyes open, Dual-leg stance. Test Duration: Immediate	Significant difference was observed for the 8MW and TUG tests ($P < 0.05$); better performance in the group with knee sleeves. However, that same difference was not observed in the SCPT test ($p > 0.05$).
Collins et al. (2012)	Parameter: Center of pressure (COP) variation. Protocol: Single stance, Eyes closed, Static standing. Test Duration: Immediate	No significant different in COP path length, COP sway velocity, range of COP displacement. No added benefit using heat stimulation on balance.

PWB: Partial weight bearing; NWB: No weight bearing; NE/S: No electrical stimulation of knee sleeve; E/S: Electrical stimulation of knee sleeve.

2.5.4 Relationship between Gait and Balance

Gait and balance are two functions that are derived from sensorimotor control and they are affected by the strength of the lower extremities of an individual. Farrokhi et al. (2013) investigated the relationship between instability and joint moments, and suggested that in order to increase stability, knee OA patients tend to add more compressive forces on the knee which lead to an increase in knee extension moment. Mechanically, the forces will undoubtedly create additional forces on the knee, resulting in a better balance but causing further damage to the knee. With the aid of knee sleeves, Collins et al. (2014) found that individuals with the poorest proprioceptive acuity will have the greatest improvement in knee flexion kinematics.

The above discussion on the relationship between gait and balance, and the effects of knee sleeves with regard to both parameters, show that knowledge on these issues is still at the preliminary stage. Wolfson (2001) believed, that there is correlation between gait and balance. He suggested that diseases such as knee OA – which involves motor association cortex and subcortical white matter – are often associated with gait disturbance and significantly influence the balance ability of an individual. Similarly, Jones et al. (2014) suggested that any structural changes within the knee would also affect a person's balance control.

2.5.5 Types of Knee Sleeves

The mixed clinical and biomechanical conclusions in the past studies could be caused by the use of non-standardized or different knee sleeve designs. Although knee sleeves are generally beneficial for knee OA, it is unclear which type or design of sleeve is more effective for each of the parameters mentioned above. Some of the studies used only simple knee sleeves, while other studies used semi-rigid knee sleeves such as those with patella reinforcement, as well as those with thin metal bars at the side (Asl et al., 2008;

Baltaci et al., 2011; Bryk et al., 2011; Chuang et al., 2007; Schween et al., 2015). These differences in knee sleeve designs could change the joint mechanics, such as exerting more force on the patella, and more compression on the knee.

Different sleeve designs, materials, and the constriction characteristics might produce different changes and stimulation on the knee, and have different influences on knee proprioception as the compression could improve coordination by restricting the range of motion (Baltaci et al., 2011; Bottoni et al., 2013). Sleeves with patella cutout could restrict and stabilize the movement of the patella which is useful for knee problems that is caused by abnormal patella tracking (movement). The thin metal bars, if present, may help in lateral stabilization for knees that has collateral ligament laxities. The results from the studies suggest that the additional restriction imposed by the compressive design of knee sleeves might help in minimizing proprioception deficits, thereby, enhancing the level of stability (Bottoni et al., 2014).

Giotis et al. (2011) studied two different sleeve designs: 1) a knee sleeve with a thin reinforced metal on the medial and lateral sides, and 2) a simple knee sleeve with patella cutout. The reinforced knee sleeve helps in limiting the range of tibial rotation that typically occurs in anterior cruciate ligament (ACL)-deficient knee. Excessive tibial rotation could degrade the soft tissues of the knee (Kanamori et al., 2002). Asl et al. (2008) also showed that the use of a reinforced knee sleeve effects more improvements in replicating target angles as compared to the use of a simple knee sleeve. The use of knee sleeves with reinforcements at the sides to support the knee and also the patella could minimize soft tissues damage caused by excessive tibial rotation in those with ACL injuries.

Bottoni et al. (2014) also reported the use of a simple knee sleeve – without fixation straps or rigid side bars – but is still able to reduce the stability index, significantly. This shows that a simple knee sleeve also gives a slight compression to the joint area, and does not affect the range of knee motion. Bottoni et al. believed that the fixation straps or rigid side bars, in fact, cause discomfort around the knee and may also disturb the signal generation of the skin receptors, and thus, affect balance control, adversely.

Collins et al. (2010, 2011, 2012, 2014) studied additional stochastic resonance electrical stimulation on the sleeve, and found only minimal improvement in gait and proprioception but no additional improvement in balance. Thus, stochastic electrical stimulation on the knee sleeve does not help in improving stability.

The use of different types of knee sleeves seems to effect varied improvements to gait and balance control. Although sleeves with patella cutout might restrict the movement of the patella, they do help in patella stabilization and reinforcement. It appears that knee sleeve can act through different mechanisms to improve knee proprioception. This is because knee sleeves – irrespective of designs – have all demonstrated evidence of benefits on knee pain, gait and postural stability (Baltaci et al., 2011; Bottoni et al., 2013).

On the materials of knee sleeve, manufacturer often used either Neoprene or Drytex. To make a good choice, the user should consider the activities he might dealing with, and his perspiration rate. Neoprene are ideal in giving uniform compression and mostly used in OA to reduce the pain. Nevertheless, it is also durable and suitable in colder climates (Shapiro, 2010). However, Neoprene does not work well in perspiration, which Drytex would be a better choice since Drytex allows breathability and not allergenic as Neoprene (DonJoy USA, 2016; Shapiro, 2010).

2.5.6 Limitations

Most studies on knee sleeve investigated only the immediate effects and the long term effect is largely unknown. It would be useful to bridge this gap in understanding and to establish if the effects of knee sleeve could be sustained and improved with time. Besides, the immediate effects are not necessarily an accurate reflection of the potential benefits of knee sleeves. This is because the immediate measurements do not consider the effect of neuromuscular adaptation in knee sleeve use. The initial beneficial effect such as found by Bottoni et al. (2013) following 30-minute of knee sleeve use may only represent the partial effects of knee sleeves. Due to the lack of past research, it is unclear if any benefits that is observed with following short term use can continue to increase or remain the same if knee sleeve is worn for longer period of time such as for weeks or months. Hence, it is useful to conduct serial measurements of biomechanical or clinical effect a longer duration of knee sleeve use. The type of knee sleeve used in any study, as mentioned in Subsection 2.5.5, could be one of the factors that could lead to difference in the study results. The different types of knee sleeves used, make it difficult to decide which type of knee sleeves effect greater improvement on the target population.

Another factor that hampers definitive conclusion on the effects of knee sleeves is due to different designs of knee sleeve used. Knee sleeves can be of different rigidities. A simple knee sleeve is more likely to give partial functional improvement when compared to a complex and more rigid knee sleeve which could change the joint mechanics. Until more studies are done to directly compare different types of knee sleeves, the relative efficacy of different knee sleeves is unknown.

The use of different experimental protocols – each with its own method of measuring – makes it difficult to generalize any findings pertaining to knee sleeve effects on balancing. Some studies used the balance scores or index, and one study used the center of pressure (COP) parameter to identify postural sway using force plates, and only focuses on static condition. On the other hand, Chuang et al. (2007) obtained more specific information because they used a balance machine which can measure the stability index directly, and can assess the postural stability on the dynamic condition as well. This shows that it is more reliable to evaluate postural stability using a balance machine, compared to force plates (Arnold & Schmitz, 1998).

2.6 Summary

The beneficial effects of knee sleeves were observed immediately in some studies - on pain; on the joint kinetics and kinematics – KAM and knee flexion angle (Bryk et al., 2011; Collins et al., 2014; Collins et al., 2011; Schween et al., 2015).

However, the efficacy of knee sleeves from their biomechanical aspect is still unclear. Although knee sleeves have proven to be effective in improving the functional parameters, there is still a gap in understanding the biomechanical mechanism involved because many of the study protocols are not standardized. Moreover, there is no serial measurement of each parameter over long-term testing. Thus, it is difficult to generalize the results due to lack of homogeneity in the study designs, protocols, participants population, comparator groups, type of knee sleeves used, and the parameters. However, further work is needed to confirm this hypothesis, due to the lack of homogeneity and rigor of existing studies. Nevertheless, from the studies reviewed, it can be concluded that knee sleeves effect positive changes on the knee movement, can effect functional improvements to knee problems, thereby, helping people to have a better walking pattern. Based on the findings, more rigorous experimental design should be adopted to obtain more reliable results. More longitudinal studies with randomization on the testing conditions would provide more reliable outcomes pertaining to the benefits and understanding of knee sleeves use from the biomechanical aspect.

CHAPTER 3: METHODOLOGY

3.1 Introduction

This chapter discusses the experimental procedures in more detail. It begins by discussing the study design and ends with procedure on data collection for gait kinetics and kinematics, postural stability and pain, as well as the statistical tests that are applied on the collected data.

3.2 Study Design

A comparative study was performed. It was calculated that samples of 17 participants in total would provide 80% statistical power. In this study, participants do not know there is a comparator group. The participants were handed the knee sleeve by quasi-randomization, which means each participant received only one knee sleeve and the randomization sequence is alternate. Then, the sizes of the knee sleeve were then set according to the knee circumference of the participants, whenever possible (Refer to Section 3.4). All participants gave written informed consent before the trial began. This study adopts a parallel-group randomized clinical trial design, which involves three different measurements over six weeks. Each group receives knee sleeves of two different designs. This study was approved by the Medical Ethics Committee of the University of Malaya Medical Centre (UMMC) (MECID No 201410-626). This study also adheres to the principles of the Declaration of Helsinki of the World Medical Association. The testing duration was set to six weeks because it is generally longer, and considering the logistic factors of the project, including the administration of patients and short duration of project. The testing duration was confirmed via consultation from a specialist from Sports Medicine Unit, UMMC.

3.3 Participants

Participants (patients) with early unilateral knee OA who are registered in UMMC were selected. The participants had been diagnosed based on the American College of Rheumatology (ACR) criteria. These diagnoses were also confirmed radiographically. Participants were included if they were aged between 30 and 60, and had suffered from unilateral knee pain. Other inclusion criteria include: 1) Kellgren–Lawrence (K&L) scale of disease severity of grade 1 or 2; 2) functionally independent people; and 3) no known allergy to knee sleeves. Both male and female participants were recruited for the trial. The limb considered in the study was decided based on the radiography results. Radiographic severity of the OA was categorized – based on the K&L scale – by a specialist from Sports Medicine Unit, UMMC. In the K&L scale, disease severity is rated from 0 to 4; where 0 = none, 1 = doubtful, 2 = mild, 3 = moderate, and 4 = severe; by observing the bony changes such as narrowing of joint space, and presence of osteophytes (Altman et al., 1986). In this study, a participant is selected if his/her rating is 1 or 2.

Exclusion criteria include participants: 1) receiving any intra-articular injection within the last six months; 2) who had prior knee surgery e.g., total knee replacement or fracture fixation; 3) with other balance problems e.g., neurological conditions, inner ear problem; and 4) with back, hip or ankle injuries that could affect the physical testing outcomes.

3.4 Intervention

This study is aimed to evaluating and comparing the biomechanical effects of two different knee sleeves – simple knee sleeve (without patella cutout), and knee sleeve with patella cutout (Drytex Basic Knee Support, DonJoy, USA) (Figure 3.2). The simple knee sleeve exerts even compression throughout the knee area, while the sleeve with patella cutout provides slight reinforcement on the patella, aimed at controlling the movement of the patella. These two types of sleeves were chosen because the material is suitable in a warmer climate and for rigorous activity usage due to its breathability. Both are elastic knee sleeves made from Drytex® - an alternative material to neoprene (Shapiro, 2010). Drytex is a combination of nylon core and polyester lycra fabric that allows breathability and good airflow (DonJoy USA, 2016).

The suitable size of the sleeve for a user is based on the measurement of the circumference at six inches above the middle of the knee cap of the user in a seated position (Figure 3.1). The knee sleeve sizes were individualized for each participant. Randomization of intervention was implemented based on quasi-randomization. Each individual is alternately randomized to one treatment group. As the study only involved two male participants, we handed the first male participant the simple knee sleeve and the second male participant the knee sleeve with patella cutout.

To ensure that the knee sleeves are used correctly, participants were taught the way to apply the knee sleeve – to grasp the edges of the sleeves at the larger opening and roll the sleeve to cover the knee. Participants were instructed to wear the sleeve daily for as long as it could be tolerated, since past studies mentioned the compliance for knee bracing and orthosis were ranged from 3-12 hours per day (Johann Beaudreuil et al., 2009; Bennell, Kean, Wrigley, & Hinman, 2013; Toda & Tsukimura, 2004). They were then asked to register in a log book the number of hours of usage per day. Participants were told they could put on or take the knee sleeve off according to their needs and schedule, but it has to be worn daily for six weeks. The log book was given to each participant on their first lab visit.

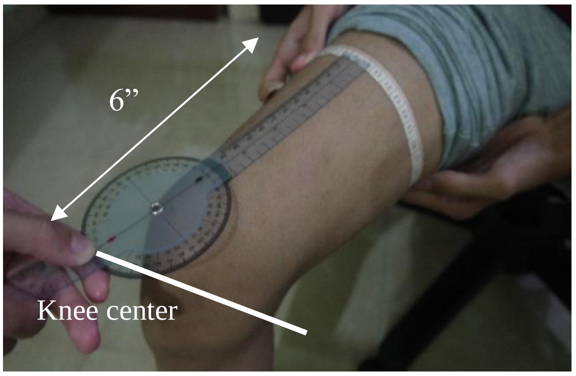

Figure 3.1: The method of measuring the knee circumference for the sizes of knee sleeves

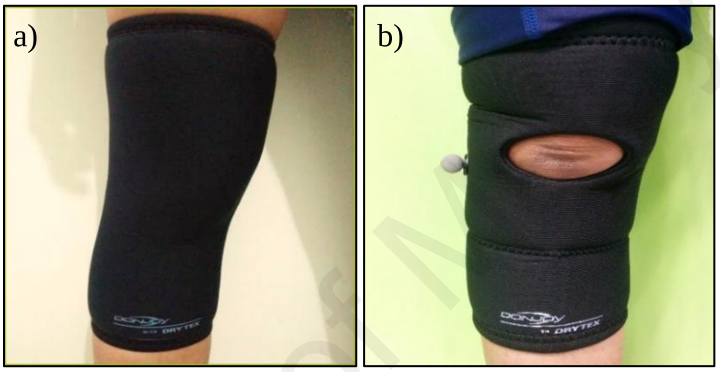

Figure 3.2: Knee sleeves used in the study; a) Simple knee Sleeve (Knee Sleeve A), and b) Knee sleeve with patella cutout (Knee Sleeve B) (Drytex Basic Knee Sleeve, Donjoy, USA)

3.5 Adherence

The participants were regularly monitored to ensure that they strictly follow the instructions on how to wearing of the knee sleeves. Compliance was confirmed via the recorded daily usage in their log book during the second visit.

3.5.1 Log Book

Along with the knee sleeve, participants were given a log book (Appendix C) each – on their first lab visit – to record their total hours of usage for the entire six weeks. They were also advised to record any adverse effects attributed to the knee sleeve usage. All participants were also asked to report on the overall knee sleeve usage experiences.

3.6 Instrumentations

During each visit, gait analysis was conducted, while walking on a flat surface, on a self-selected speed and on a controlled speed (Refer Section 3.6.2); and the Western Ontario and McMaster Universities Arthritis Index (WOMAC) was used to assess the pain levels of the participants.

3.6.1 WOMAC® Score

Clinical outcomes were assessed using the WOMAC scores at each stage of the trial. WOMAC is a pain score to assess level of pain, stiffness, and physical functions in patients with knee OA. The participants may choose the WOMAC either in English or Malay (Bellamy, 2014) (See Appendix D).

WOMAC consists of 24 items divided into three subscales: 1) Pain (5 items): during walking, using stairs, in bed, sitting or lying, and standing; 2) Stiffness (2 items): after waking and later in the day; 3) Physical Functions (17 items): stair use, rising from sitting, standing, bending, walking, getting in / out of a car, shopping, putting on / taking off socks, rising from bed, lying in bed, getting in / out of bath, sitting, getting on / off toilet bowl, heavy household duties, light household duties (Bellamy, 2014). Total score for WOMAC would be 2,400 mm (based on VAS 100 mm scores for each question). Participants have to answer the questions before, immediately after, and after six weeks of the knee sleeve usage. Participants were also given a VAS score ruler to guide them on answering the WOMAC questionnaire.

3.6.2 Gait Analysis

Kinetics data were collected at 1,000Hz using two Kistler force plates (Kistler Instruments, Winterthur, Switzerland) to measure the ground reaction forces and joint moments. The kinematics data were collected at 100Hz using the Vicon motion analysis system with five infrared cameras (Vicon, Oxford, UK). The system was calibrated at every session to ensure that the output from the cameras and force plates are appropriately synchronized and accurate. The standard Vicon Plug-in-Gait model for measuring the lower extremity was used. Sixteen (16) markers were placed on the lower extremity following the Helen Hayes standard marker set (Davis, 1997). The markers were placed on the lateral side of both legs, anterior superior iliac spines, posterior superior iliac spines, femur, lateral epicondyles, tibia, lateral malleoli, distal head of the second metatarsals, and on the heels (Laroche et al., 2014). Figure 3.3 illustrates the marker placement for this study.

Each participant performed twelve complete walking trials and the mean scores were used for analysis. Each gait assessment consisted of six trials at the self-selected speed and six trials at the controlled speed. All participants performed barefoot walking trials. At their self-selected walking speed, the participants were asked to walk leisurely at their own comfortable walking speed. The controlled walking speed was monitored using a timer to ensure that the speed reflects the average walking speed of a normal person, which is estimated at 1.3 ± 0.2 m/s (Wikipedia, n.d.). The participants were asked to practise walking within a 3-meter walking range and within 2 seconds to obtain the controlled speed. After the practice session, the speeds in the actual trials were monitored. Trial speeds that exceeded the set speed range were ignored. The speed was controlled to obtain an optimum value on moments and forces for all participants. Meanwhile, the self-selected speed trials are done to obtain the walking speed parameter. Following the baseline data collection, the participants were given a knee sleeve to be worn on the studied limb. The immediate-effects were measured after a 10-minute adaptation period, during which participants practised walking.

Figure 3.3: Marker placement for this study, following Davis model (Henriksen et al., 2012)

All parameters were normalized using the Vicon Nexus motion capture system and output as graphs generated using the Vicon Polygon report module (Vicon, Oxford, UK). The early stance and late stance peak for KAM data (in Nm/kg) were normalized for body mass. The vertical ground reaction forces (vGRF) (in N/kg) were normalized for body mass. The relevant kinematics data recorded included knee flexion at heel strike, peak knee flexion during stance, peak knee flexion during swing, and knee flexion excursion. The diagrammatic representation of gait events is shown in Figure 2.3, and graphical representation of sagittal plane kinematics is shown in Figure 2.6. The walking speed was obtained from the self-selected walking speed trials using the Vicon Polygon software.

PlugInGait model (Oxford Metrics, Oxford, UK) of the driving software VICON Nexus was used to perform inverse dynamics analyses, obtaining joint moments calculated about an orthogonal axis system located in the distal segment of the joint (Refer Appendix T). The data were smoothed with a third-order, 6Hz Butterworth low-pass filter. All KAM values were normalized to the percentage of the stance phase. The first peak KAM was taken as the maximum value during the initial 50% of the stance phase, while the second peak was taken as the maximum value during the latter 50% of the stance phase.

3.6.3 Postural Stability Tests

Postural stability and fall risks were assessed using the Biodex Stability System (BSS) – a balance device for evaluating, measuring and recording postural stability and neuromuscular control under static and dynamic stress conditions (Arnold & Schmitz, 1998) (Figure 3.4). The BSS consists of a circular platform that can either be set to move or to remain static about the anterior-posterior (AP) and medial-lateral (ML) axes, depending on the level of instability chosen by the user (Arnold & Schmitz, 1998). The BSS provides 12 levels for assessing balance and risk of fall. Level 12 is the most stable and level 1 is the most unstable (difficult). Besides, the device allows three parameters as the outputs which include: 1) overall stability index (OSI); 2) anterior-posterior stability index (APSI); and 3) medial-lateral stability index (MLSI) (Cachupe, Shifflett, Kahanov, & Wughalter, 2001). Low overall scores denote better stability, while high overall scores indicate instability.

The measurements were repeated before, immediately after, and after six weeks of usage of the knee sleeves. There were three major protocols for each session: Postural Stability Test (PST), Fall Risk Test (FRT), and Athlete Single-Leg Test (ASL). These tests were selected in order to assess the both-limb standing postural stability, single-leg standing postural stability, and fall risk on individuals with knee OA. The assessments follows the suggested protocols in the BSS manual (Biodex Medical Systems, 1999). The dynamic bilateral stance was assessed by setting the platform at level 8, while for PST, the platform was set to remain static. For FRT, the platform was set from level 12 to level 8. For ASL test, the participants were asked to flex their knees approximately 10^o and with both their hands on their waist. The same procedures were repeated for both left and right legs.

Figure 3.4: Biodex Stability System used in the study to assess postural ability (Biodex Medical Systems, 1999)

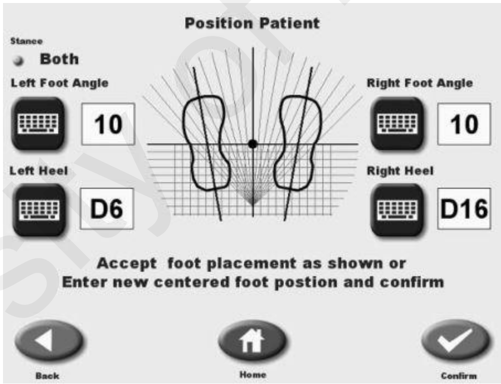

Figure 3.5: The foot placement of participants that needs to be set by the investigator before starting any trial using BSS (Biodex Medical Systems, 1999)

The participants performed the test barefooted and were asked to stand comfortably on the surface. They were asked to stand on both legs, and on one leg, depending on the test, and with eyes open, looking forward at the monitor of the device (Khalaj et al., 2014a). The participants can choose their preferred standing position before any test begins. Each participant was given a 5-minute adaptation period to familiarize himself/herself with the BSS. In case participants feel unstable, they are allowed to hold onto a brief support or grasp at the handrail temporarily, to regain balance. However, the test is considered invalid if the participant is unable to remain stable, and holds on to a support longer than three seconds.

In the static balance test, the participants were asked to maintain the point at the center of the screen as level as possible. Balance and risk of fall were assessed using three trials for a period of 20 seconds with 5 seconds rest in between. Participants were given 2 minutes rest in between two testing positions to avoid the effect of fatigue and pain from affecting the scores. Similar procedures were repeated for dynamic balance test and fall risk test. Our study included single-leg standing tests for both affected knee and unaffected knee to make necessary adjustment in view of the theory of leg dominance (Duffell et al., 2014). The standing position during postural stability tests was self-selected (Figure 3.5).

3.7 Procedures

The trial consists of two visits. In the first visit, participants' baseline measurements were recorded. After immediate application of the knee sleeve, the measurements were repeated. In the second visit, which was scheduled six weeks after sleeve application, the post six-week effects were recorded. The same procedures were repeated for immediate and post six-week effects (Figure 3.6). Standardized instructions were given to the participants before the trial begins. Participants were asked to fill in the consent form, responded to the WOMAC score for the baseline measurement, and their anthropometrics data were collected – height, weight, and age. The instructions of knee sleeve usage and using the log book were also explained before the trial begins. Next, they were instructed to run a gait analysis, followed by postural stability tests (Figure 3.6).

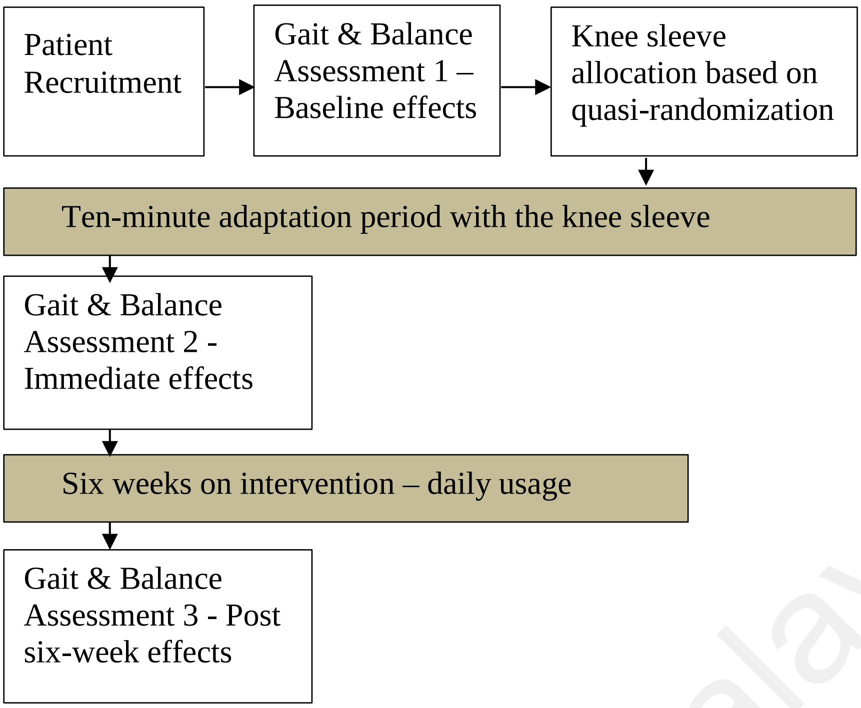

Figure 3.6: Study protocol

3.8 Statistical Analysis

Analyses were performed using SPSS Version 22 (IBM Corporation, Armonk, NY, USA). A priori alpha level of 0.05 was used to determine statistical significance. Our study design wan repeated measures, thus, we use a classical approach to analyze the data. All dependent variables were measured at continuous levels, the independent variables were matched pairs, the dependent variables were assumed to be approximately normally distributed since the study was a repeated measures – the measurements are obtained from the same entities (Field, 2012). Thus, analysis of variance for repeated measures (RM ANOVA) with mixed approaches was used to compare between knee sleeve designs (between subject effects) and all dependent variables/outcome measurements (within subject effect) with additional Bonferroni correction for multiple tests and confidence interval. Bonferroni correction is a conservative test that protects from Type 1 Error and is necessary for data with multiple comparison. The utmost assumption that should be taken into account, for this analysis is sphericity test. Sphericity is the measure pf homogeneity of variance of difference between levels and is known as Mauchly's sphericity test (W). The violation of this assumption can impact the results drawn from the analysis – loss of statistical power. If W>0.05, the sphericity assumption is satisfied and no correction should be made. But if the W<0.05, the assumption is violated and correction is necessary – the Geisser-Greenhouse (G-G) or Huynh-Feldt epsilon (€) correction is used (Field, 2012). Descriptive statistics were used to analyze the demographics of the participants. The data were considered missing if the participants did not managed to complete all trials and the data were not included in the final results of this study.

3.9 Summary

In summary, all the procedures stated above were conducted to obtain the outcomes. The procedures started with participant recruitment, ethical approval, followed by participants' selection, intervention allocation, followed by data collection which consists of the experiment and the intervention period, and lastly, data analysis. The next chapter will present the results from all the trials that were conducted.

CHAPTER 4: RESULTS

4.1 Introduction

This chapter presents the results of all the tests for knee pain, knee stiffness, knee function, gait, and postural stability. It also presents the quantitative data collected using procedures mentioned in the previous chapter. All measurements are quantified in mean ± standard deviation (SD) format, if not stated otherwise. A few often-used terms pertaining to when the test measurement is taken are defined as follows: 1) T_0 or pre – indicates the measurement taken at baseline, 2) T_1 or immediate – indicates the measurement taken after the immediate use of knee sleeve, 3) T_2 or post – indicates the measurement taken following six weeks of knee sleeve use, 4) T_0 - T_2 or pre-post – indicates the measurement taken at baseline compared to measurement taken after six weeks of knee sleeve use, 5) T_0 - T_1 or pre-immediate – indicates the measurement taken at baseline compared to the immediate reading after immediate use of knee sleeve, and 6) T_1 - T_2 or immediate-post – indicates the measurement taken after the immediate use of knee sleeve compared to the measurement made after six weeks. The assumption of Mauchly's test of sphericity is met for all dependent variables ($W > 0.05$) (Refer Appendix G to Appendix S).

4.2 Participants

Nineteen participants (including two male participants) with unilateral knee OA (of K&L grade 1 and grade 2) were recruited from UMMC for this study. Figure 4.1 shows that two participants dropped out from the trial - one had to stop wearing the sleeve after seven days due to severe pain which aggravated the participant's condition, and another dropped out due to work commitment. Those who remain (17 participants) have managed to perform all required tests. All participants have the same baseline characteristics and the two groups are treated in the same manner. Table 4.1 shows the summary profiles of the participants that include their age, gender, height, weight, and BMI. All values obtained from the various tests are reported as mean ± standard deviation (SD), unless stated otherwise.

4.2.1 Lifestyle of Participants

Six participants (31.6%) out of the 19 participants had previous injuries due to one of the following reasons: accidents and falls (10.6%); ligament tear (10.5%); and muscle tear (10.5%). Their injuries were not caused by any sports activities. Other information on the participants include: none are smokers; 11 participants never consumed nor had been prescribed analgesics for the knee pain; six of them are undergoing a rehabilitation program; 16 participants are planning to lose weight to alleviate their knee pain; 17 participants reported that the knee pain had disrupted their daily routines; eight participants fear that exercise will aggravate their knee pain; 14 participants are working; none of them are sportsmen; and all participants have gone through tertiary education – diploma or degree holders.

From the log book given to each participant (Appendix C), the hours of knee sleeve use and the adverse effects were tabulated and averaged. From Appendix G, the knee sleeves were used an average of 3.7 ± 2.4 hours per day, calculated based on an average of 3.7 ± 2.7 hours for simple knee sleeve and 3.7 ± 2.3 hours for knee sleeve with patella cutout. Overall, 82.4% (14 out of 17 participants) stated that the sleeve is helpful. Meanwhile, the adverse effects reported include poor fitting (47.1%), skin irritation (47.1%), and discomfort (41.2%).

Table 4.1: Brief participants' profiles (n = 17).

Group	All (n = 17)	Simple knee sleeve (n = 9)	Knee sleeve with patella cutout (n = 8)	p-values (between groups)
Age (year)	47.2 (10.2)	46.9 (11.3)	47.6 (9.6)	0.888
Gender	15 F, 2 M	8 F, 1 M	7 F, 1 M	-
Height (m)	1.58 (0.1)	1.59 (0.1)	1.58 (0.1)	0.860
Weight (kg)	66.82 (13.7)	72.44 (15.7)	60.50 (7.8)	0.081
BMI (kg/m^2)	26.69 (6.1)	28.90 (7.1)	24.23 (3.7)	0.134

Data presented as Mean (SD). BMI = Body-mass index, F = Female, M = Male. $p > 0.05$ denotes no significant difference among participants at baseline.

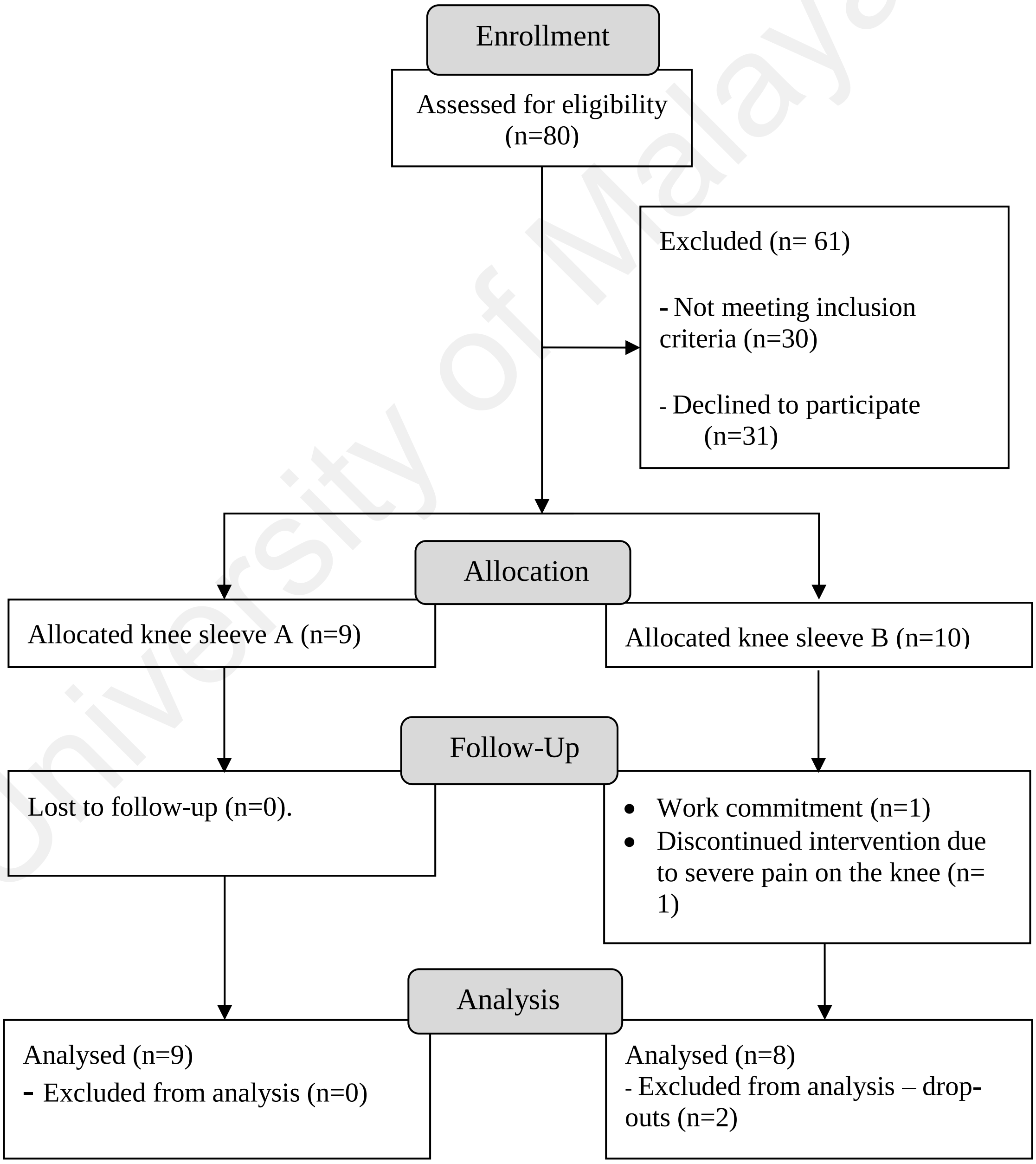

Figure 4.1: Participants involved in the study (following CONSORT Flow Diagram)

4.3 WOMAC® Scores

We used WOMAC to measure pain level. All participants (17) have completed the WOMAC questionnaire. Table 4.2 shows the WOMAC scores for T_0, T_1 and T_2 measurements. Appendix K shows the SPSS results for descriptive statistics and pairwise comparison on points of measurement and different types of knee sleeves. The table shows that the WOMAC scores at $T_0 – T_1$ were significantly reduced; mean difference = 17.958, p = 0.034, 95% CI (1.233, 34.684) (Refer Appendix K). Significant decrease in overall WOMAC scores was observed for T_0 - T_2; mean difference = 28.888, p = 0.012, 95% CI (5.914, 51.862) and for T_1 - T_2; mean difference = 10.930, p = 0.048, 95% CI (0.097, 21.762) for both sleeves. There was no significant difference in all points of measure between the two interventions ($p > 0.05$). Following six-week of use, there is marked reduction of 49% in the WOMAC scores after simple knee sleeve application when compared to reduction of 26% in the scores after knee sleeve with patella cutout application, compared to baseline. Overall, 26.0% reduction in WOMAC scores for pre-immediate effects, and 42.9% for pre-post effects of knee sleeve use.

Appendix H shows the tables of results on WOMAC score – pain. From the tables, the mean difference for $T_0 – T_1$ readings is 3.29, p = 0.155, 95% CI (-0.900, 7.481). For T_0 - T_2 measurement, the mean difference is 5.414, p = 0.055, 95% CI (-0.089, 10.917). Between simple knee sleeve and knee sleeve with patella cutout, there is no significant differences at all points of measure (p = 0.122). Figure 4.2 shows the graphs for both types of knee sleeves. We partially reject the null hypothesis, and partially accept the alternative hypothesis (H_1), that, the application of the knee sleeves would alleviate knee pain for pre-post measurement.

Table 4.2: WOMAC overall scores (n = 17)

	All	Simple knee sleeve	Knee sleeve with patella cutout
T_0	697.4 (50.96)	936.8 (52.11)	428.1 (35.60)
T_1	514.4 (46.15)*	699.1 (40.38)	306.6 (45.52)
T_2	398.2 (42.31)*,†	471.9 (45.04)	315.3 (40.32)

* indicates significant difference compared to baseline ($p<0.05$). † indicates significant reduction compared to immediate effects ($p<0.05$). WOMAC pain score is measured in 100mm. Total score is 2,400mm. Data presented as mean ± SD (standard deviation).

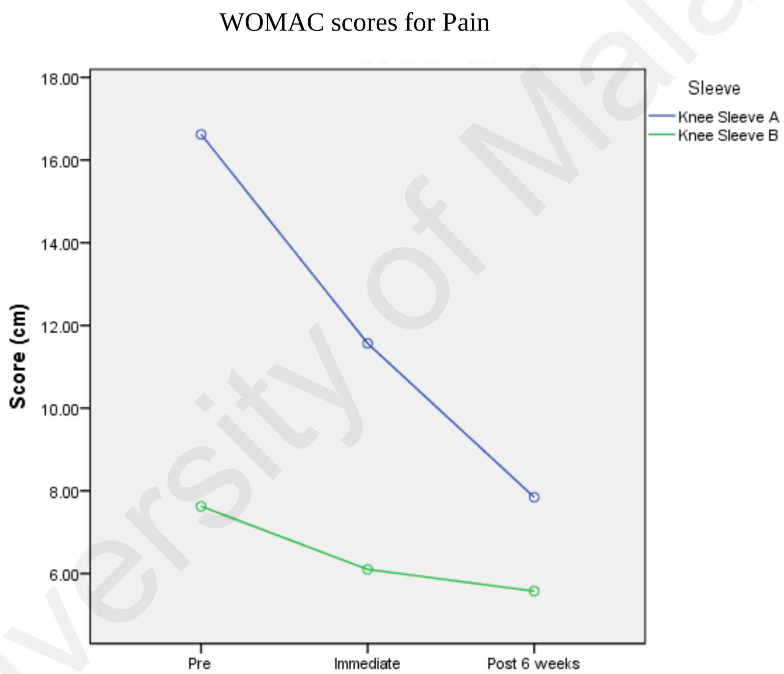

Figure 4.2: WOMAC scores for knee pain of 17 participants, for simple knee sleeve (Knee Sleeve A) and knee sleeve with patella cutout (Knee Sleeve B), respectively.

WOMAC scores for Stiffness

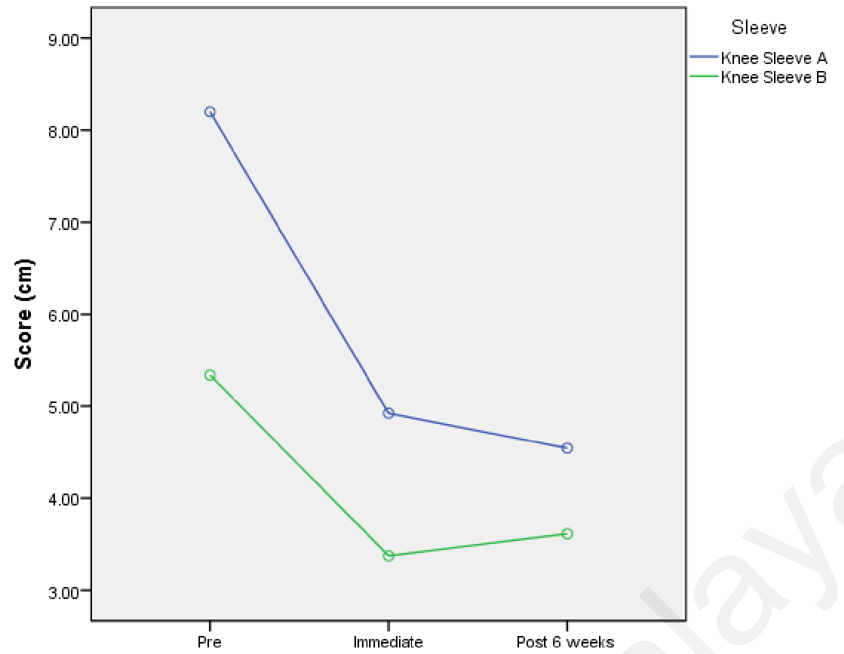

Figure 4.3: WOMAC scores for knee stiffness of 17 participants, for simple knee sleeve (Knee Sleeve A) and knee sleeve with patella cutout (Knee Sleeve B), respectively.

WOMAC scores for Difficulty Performing Daily Activities

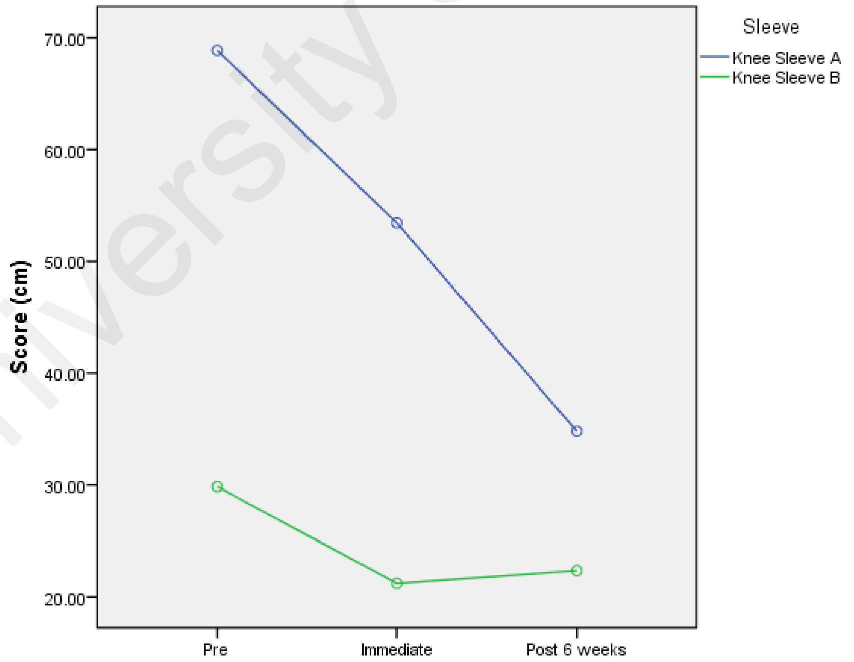

Figure 4.4: WOMAC scores for functional performance of 17 participants, respectively, for simple knee sleeve (Knee Sleeve A) and knee sleeve with patella cutout (Knee Sleeve B)

Appendix I shows the WOMAC scores on knee stiffness and Figure 4.3 shows the graphs for both types of knee sleeves. In the measurement of knee stiffness, the mean difference of the T_0 - T_1 scores is 2.62, p = 0.022, 95% CI (0.347, 4.894). For T_0 - T_2 measurement, the mean difference is 2.690, p = 0.018, 95% CI (0.421, 4.959). For the intervention groups – simple knee sleeve and knee sleeve with patella cutout – no significant differences was found (p = 0.443). Figure 4.3 shows the graphs for the different types of knee sleeves on knee stiffness. We reject the null hypothesis, and accept the alternative hypothesis (H_1), that, the application of the knee sleeves would alleviate knee stiffness for pre-immediate and pre-post measurements.

Appendix J shows the WOMAC scores on functional performance and Figure 4.4 shows the graphs for both types of knee sleeves. In measuring the knee functional performance, the mean difference for T_0 - T_1 is 12.048, p = 0.061, 95% CI (-0.477, -24.573). For $T_0 – T_2$, the mean difference is 20.784, p = 0.014, 95% CI (3.834, 37.734). At all points of measurement, there is no significant difference was found for simple knee sleeve and knee sleeve with patella cutout (mean difference = 27.901, p = 0.079). We reject the null hypothesis, and accept the alternative hypothesis (H_1) for knee functional parameters – indicating that there are benefits from using the knee sleeves after six weeks.

4.4 Gait Analysis

All reported values in this subsection are shown in Appendix S.

4.4.1 Knee Adduction Moment (KAM)

Table 4.3 shows the results for KAM measurement. There is no significant difference in the KAM during early stance; mean difference = 0.107; p = 0.744, 95% CI (-0.133, 0.347) or late stance; mean difference = 0.04; p = 1.00; 95% CI (-0.182, 0.191) for T_0 - T_1 effects. There is reduction between $T_0 – T_2$ effects on first peak KAM; mean difference = 0.273; p = 0.061, 95% CI (-0.011, 0.557), and significant reduction on second peak

KAM; mean difference = 0.240; p = 0.008, 95% CI (0.059, 0.422). There is no significant difference between knee sleeves at any time of measurement, for early stance KAM (first peak), p = 0.305; and for late stance KAM (second peak), p = 0.467. Both knee sleeves significantly reduce late stance KAM for $T_0 - T_2$ effects (p = 0.008). There is 47% reduction in KAM with simple knee sleeve compared to 24% reduction in KAM with knee sleeve with patella cutout for $T_0 - T_1$ readings. Figure 4.5 is a graphical representation of KAM measurement for T_0, T_1, and T_2. For both sleeves, the percentage of reduction for first peak KAM, for pre-immediate effects compared to pre-post effects are 13.9% and 39.0%, respectively.

Table 4.3: Knee adduction moment (KAM) measurement of the participants for pre, immediate, and post effects scores

	All		**Simple knee sleeve**		**Knee sleeve with patella cutout**	
	Early Stance	**Late Stance**	**Early Stance**	**Late Stance**	**Early Stance**	**Late Stance**
T_0	0.71 (0.56)	0.49 (0.29)	0.83 (0.55)	0.55 (0.37)	0.59 (0.53)	0.44 (0.20)
T_1	0.65 (0.65)	0.57 (0.47)	0.89 (0.52)	0.67 (0.56)	0.46 (0.57)	0.48 (0.17)
T_2	0.45 (0.26)*	0.27 (0.16)*†	0.44 (0.17)	0.25 (0.15)	0.45 (0.33)	0.29 (0.18)

† indicates significant difference between pre-post scores (p<0.05), * indicates significant difference between immediate-post scores (p<0.05). Data presented as Mean (SD). All results above in Nm/kg.

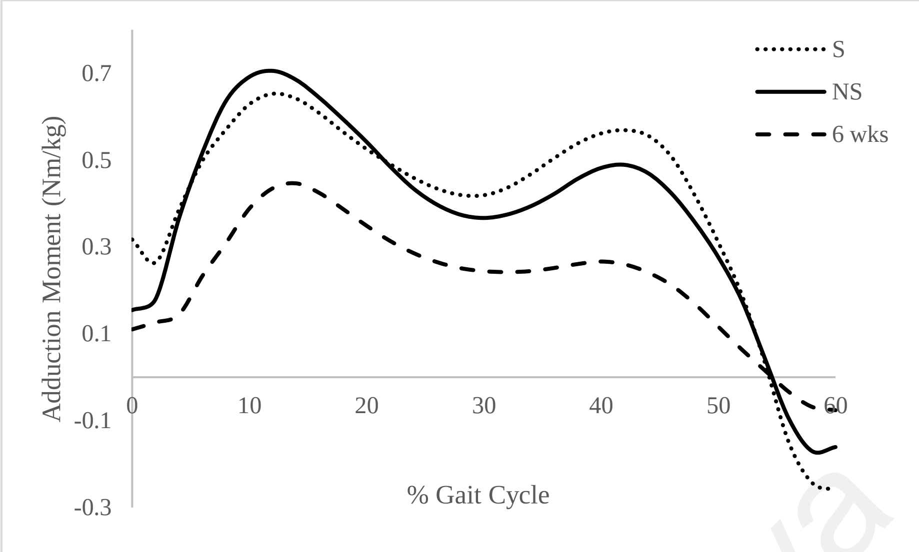

Figure 4.5: Knee adduction moment (KAM) during stance phase for all the participants. (NS is the measurement at baseline; S is measurement immediately after knee sleeve use; 6 wks is measurement at six weeks effects)

Table 4.4: Vertical Ground Reaction Force (vGRF) summary

	All		**Simple knee sleeve**		**Knee sleeve with patella cutout**	
	1st Peak	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**
T_0	13.45 (5.33)	12.41 (5.04)	12.86 (5.48)	12.05 (5.51)	11.96 (4.82)	11.00 (3.93)
T_1	13.91 (5.70)	12.97 (4.91)	14.80 (6.09)	13.92 (4.91)	13.30 (5.24)	12.21 (4.59)
T_2	9.95 (2.26)*	9.36 (1.98)*	9.79 (2.60)	9.42 (2.70)	10.20 (2.12)	9.29 (1.31)

* indicates significant difference between immediate-post values ($p<0.05$). Data presented as Mean (SD), 1^{st} Peak indicates the maximum loading rate during early stance, and 2^{nd} Peak indicates the maximum loading rate during late stance.

4.4.2 Vertical Ground Reaction Forces (vGRF)

Appendix S and Table 4.4 show the results of vertical ground reaction force (vGRF) which measures loading rate. There is significant reduction between $T_1 – T_2$ effects in early stance (first vGRF peak); mean difference = 4.673; p = 0.038, 95% CI (0.233, 9.112) and in late stance (second vGRF peak); mean difference = 3.840; p = 0.041, 95% CI (0.138, 7.542) in vGRF for both sleeves. No significant difference between $T_0 – T_2$ scores for first peak loading rate; mean difference = 3.622; p = 0.092, 95% CI (-0.471, 7.714) and second peak loading rate; mean difference = 2.889; p = 0.148, 95% CI (-0.751, 6.528). No difference in using knee sleeves of different designs in first peak and second peak, at any point of measure (p = 0.306, p = 0.207).

4.4.3 Knee Flexion and Walking Speed

Table 4.5 shows the results of kinematics of knee flexion and walking speed. Significant difference for knee flexion at heel strike; mean difference = 4.834, p = 0.012, 95% CI (1.000, 8.668) and knee flexion during stance; mean difference = 5.119, p = 0.020, 95% CI (0.735, 9.502) observed between $T_0 – T_2$ assessments. No significant findings in the flexion range of motion; mean difference = 5.841, p = 0.094, 95% CI (-0.784, 12.465) and knee flexion during swing; mean difference = 1.154, p = 1.000, 95% CI (-5.321, 7.630) between pre-post six-week effects. There is no significant difference in knee flexion at contact, during stance phase, and during swing phase between $T_0 – T_1$ effect (p = 0.457, p = 0.426, p = 0.460). There is no significant difference between both sleeves in all sagittal plane parameters, at all points of measurements ($p > 0.05$) (Appendix S).

The results in Appendix S also show that there is no significant difference in walking speed between $T_0 – T_1$ effects of knee sleeve usage; mean difference = -0.011, p = 1.000, 95% CI (-0.081, 0.060). However, walking speed increased significantly after six weeks of knee sleeve usage ($T_0 – T_2$); mean difference = -0.090, p = 0.026, 95% CI (-0.170, -0.010). There is no significant difference in walking speed when using either simple knee sleeve or knee sleeve with patella cutout; mean difference = 0.044, p = 0.542, 95% CI (-0.107, 0.196). Based on the results discussed above, on gait, alternative Hypothesis 2 (H_1) is accepted – the application of the knee sleeves would increase walking speed, decrease ground reaction force (GRF) loading rates and KAM in people with knee OA. Overall, there is increment of 1.2% after the immediate use of knee sleeve, and 7.9% increment following six weeks of knee sleeves use, in walking speed.

Table 4.5: Kinematics parameters and walking speed results of the participants (n = 17)

	All			Simple knee sleeve			Knee sleeve with patella cutout		
	T_0	**T_1**	**T_2**	**T_0**	**T_1**	**T_2**	**T_0**	**T_1**	**T_2**
Walking Speed (m/s)	1.05 (0.18)	1.05 (0.16)	1.15 (0.16)†	1.08 (0.17)	1.12 (0.16)	1.17 (0.14)	1.12 (0.20)	0.98 (0.14)	1.13 (0.18)
Flexion ROM (º)	55.8 (11.76)	54.4 (9.41)	54.5 (10.79)	57.4 (13.96)	53.9 (7.35)	54.07 (13.79)	53.9 (9.26)	54.9 (11.83)	54.9 (6.96)
Knee Flexion at heel strike (º)	18.8 (6.30)	15.9 (9.03)	14.0 (8.06)†	18.3 (6.29)	13.2 (8.69)	14.4 (7.64)	19.4 (6.68)	19.1 (8.89)	13.6 (9.01)
Peak knee flexion during stance (º)	27.2 (7.78)	22.3 (10.00)	22.2 (10.01)†	26.1 (7.09)	18.9 (8.79)	22.0 (9.02)	28.4 (8.83)	26.0 (10.48)	22.3 (11.67)
Peak knee flexion during swing (º)	69.5 (14.32)	65.3 (11.75)	63.6 (15.47)	71.3 (18.22)	64.0 (12.02)	64.5 (18.93)	67.4 (8.95)	66.9 (12.06)	62.5 (11.61)

† indicates significant difference between pre-post scores ($p<0.05$), * indicates significant difference between immediate-post scores ($p<0.05$). Data presented as Mean (SD). T_0 = baseline measurement, T_1 = immediate measurement, and T_2 = post six-week effects of knee sleeve usage.

4.5 Balance Tests

From Biodex Stability System (BSS), three parameters for each protocol will be obtained – Overall Stability Index (OSI), Medial-lateral Stability Index (MLSI), and Anterior-posterior Stability Index (APSI). Only the OSI is included in this current study.

4.5.1 Postural Stability Test (PST)

Postural stability test (PST) protocol used in this study assessed both-leg standing balance, for static and dynamic conditions. In Appendix L and Appendix M, the results show that there is no significant difference between static and dynamic PST for $T_0 – T_1$ of both sleeves (Static: mean difference = 0.014, p = 1.000, 95% CI (-0.105, 0.133); Dynamic: mean difference = 0.160, p = 0.605, 95% CI (-0.163, 0.482)). Also, for $T_0 – T_2$, no improvement in PST was observed (Static: mean difference = 0.008, p = 1.000, 95% CI (-0.120, 0.136); Dynamic: mean difference = 0.191, p = 0.486, 95% CI (-0.159, 0.541)). Figure 4.6 illustrates OSI for static PST for both sleeves for every points of measurements, while Figure 4.7 illustrates OSI for dynamic PST.

With regard to the difference between knee sleeve designs, no significant difference was observed in the PST, static condition (p = 0.616) and also in the dynamic PST (p = 0.370). We fail to reject the null Hypothesis 3. Overall, for dynamic PST, there is reduction in OSI from 17.2% during $T_0 – T_1$ to 20.9% during $T_0 – T_2$.

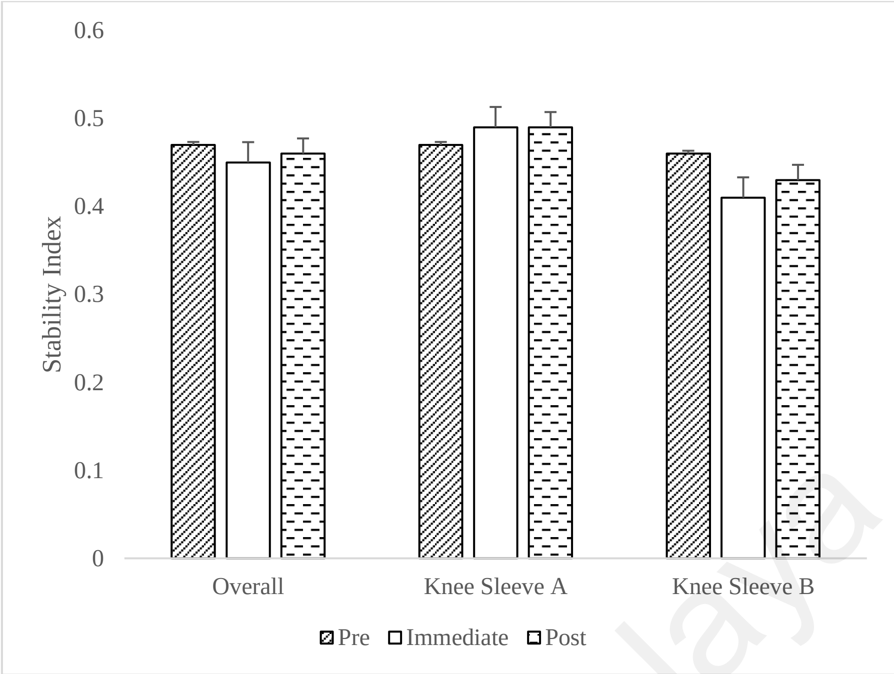

Figure 4.6: OSI for PST (Static) for pre, immediate and post effects according to treatment groups. Overall [n=17], Simple knee sleeve (Knee Sleeve A) [n=9], Knee sleeve with patella cutout (Knee Sleeve B) [n=8].

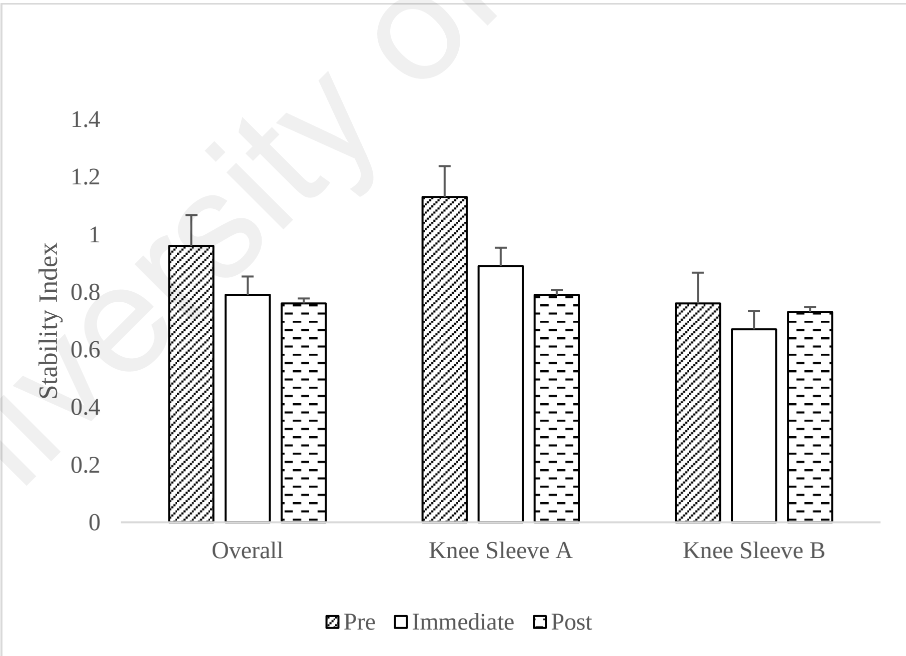

Figure 4.7: OSI for PST (Dynamic) for pre, immediate and post effects according to treatment groups. Overall [n=17], Simple knee sleeve (Knee Sleeve A) [n=9], Knee sleeve with patella cutout (Knee Sleeve B) [n=8].

4.5.2 Athlete Single Leg (ASL) Test

The ASL test was used to test the single-leg standing – for the affected knee and the unaffected knee. For the affected knee, the results from our study show that there is no significant difference between the static and the dynamic ASL tests on both sleeves for $T_0 – T_1$ effects (Static: mean difference = -0.080, p = 1.000, 95% CI (-0.893, 0.734); Dynamic: mean difference = 0.248, p = 1.000, 95% CI (-0.462, 0.958)) after the immediate usage of both sleeves (refer Appendix N and Appendix O). After six weeks of knee sleeve application, no improvement was observed (Static: mean difference = 0.392, p = 0.167, 95% CI (-0.117, 0.900); Dynamic: mean difference = 0.276, p = 1.000, 95% CI (-0.690, 1.243)). Based on the p-values, we fail to reject the null Hypothesis 3 (H_0).

Figure 4.8 illustrates the OSI for ASL static test for the affected knee, for each knee sleeve for every point of measurements. From the figure, no significant difference is observed between the interventions for static test; mean difference = 0.200, p = 0.392, 95% CI (-0.284, 0.685). Figure 4.9 shows the graphical illustration for ASL dynamic test for the affected knee. From Appendix O, there are 14.1% and 15.8% reduction in OSI, for pre-immediate and pre-post effects, respectively.

Appendix P and Appendix Q show the results of the ASL test on the unaffected knee, for the static and the dynamic tests, respectively. The results reveal no significant difference in the static and the dynamic ASL tests for both types of sleeves for pre and immediate effects on the affected knee (Static: mean difference = 0.106, p = 1.000, 95% CI (-0.372, 0.584); Dynamic: mean difference = 0.219, p = 1.000, 95% CI (-0.434, 0.872)) after the immediate usage of both types of sleeves. For $T_0 – T_2$ effects, no improvement was observed during the static test but a significant reduction in the OSI during the dynamic ASL test (Static: mean difference = 0.300, p = 0.209, 95% CI (-0.268, 0.898); Dynamic: mean difference = 0.744, p = 0.047, 95% CI (0.009, 1.479)).

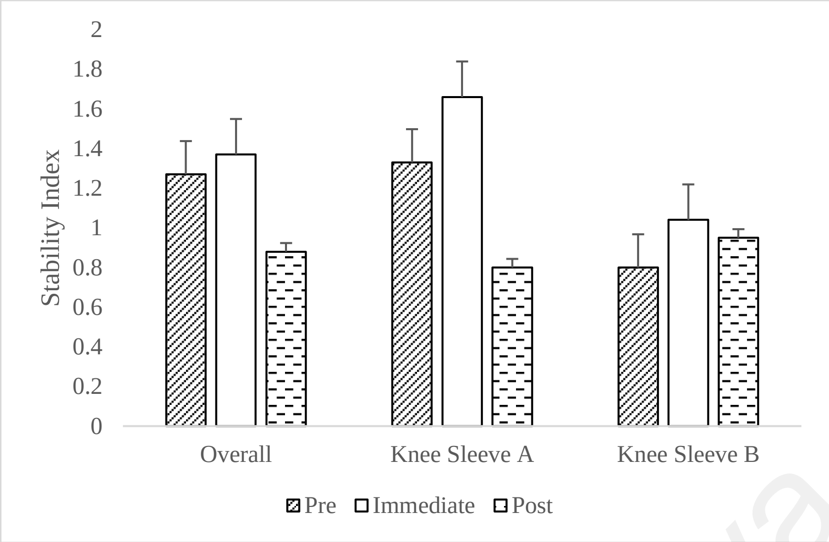

Figure 4.8: OSI for ASL (Affected Knee - Static) for pre, immediate and post effects according to treatment groups. Overall [n=17], Simple knee sleeve (Knee Sleeve A) [n=9], Knee sleeve with patella cutout (Knee Sleeve B) [n=8].

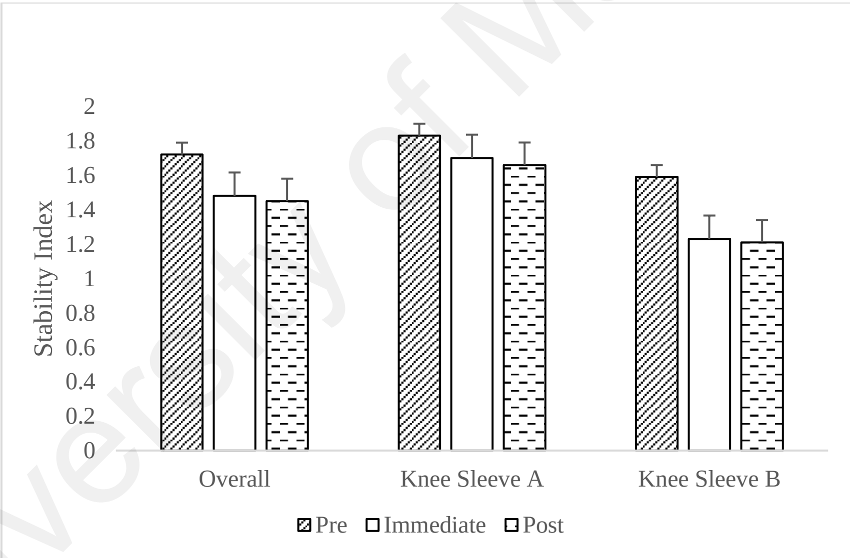

Figure 4.9: OSI for ASL (Affected Knee - Dynamic) for pre, immediate and post effects according to treatment groups. Overall [n=17], Simple knee sleeve (Knee Sleeve A) [n=9], Knee sleeve with patella cutout (Knee Sleeve B) [n=8].

In comparing the types of knee sleeves, no significant difference is observed in the static test in the mean difference ($p = 0.480$) (Figure 4.10) and also for the dynamic test; mean difference = -0.171, $p = 0.527$. Figure 4.10 and Figure 4.11 show the graphical illustration of the ASL test on the unaffected knee, for the static and the dynamic tests, respectively.

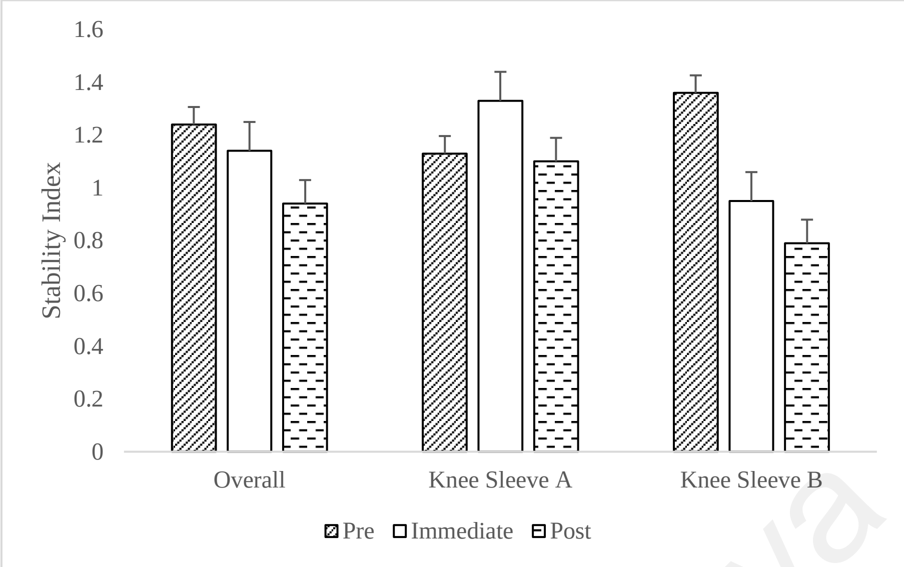

Figure 4.10: OSI for ASL (Unaffected Knee - Static) for pre, immediate and post effects according to treatment groups. Overall [n=17], Simple knee sleeve (Knee Sleeve A) [n=9], Knee sleeve with patella cutout (Knee Sleeve B) [n=8].

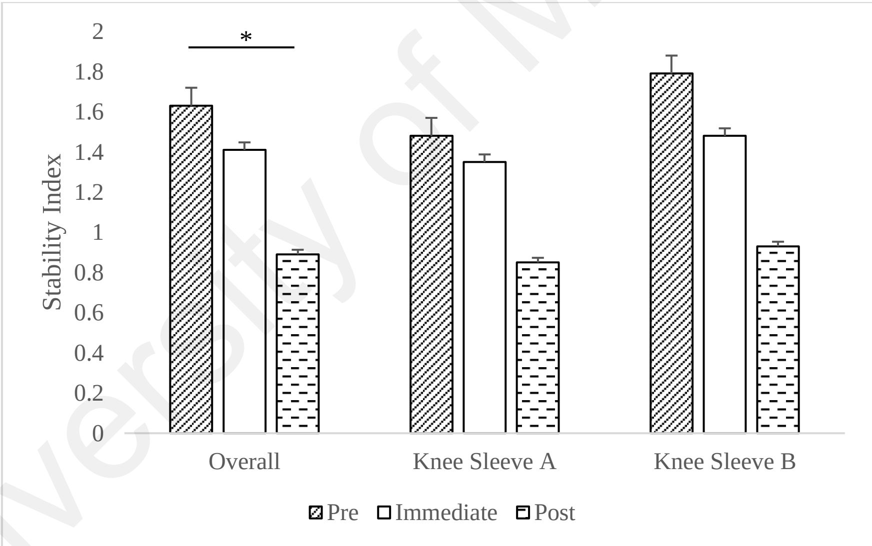

Figure 4.11: OSI for ASL (Unaffected Knee - Dynamic) for pre, immediate and post effects according to treatment groups. Overall [n=17], Simple knee sleeve (Knee Sleeve A) [n=9], Knee sleeve with patella cutout (Knee Sleeve B) [n=8]. The asterisk (*) denotes significant reduction between $T_0 – T_1$ effects.

4.5.3 Fall Risk Test (FRT)

Figure 4.12 shows the graphs that represent OSI for FRT at all points of measurement for both types of knee sleeves. From Appendix R, the results show no significant difference in the OSI between the two knee sleeves of different designs, regardless of when the measurement were made; mean difference = 0.146, p = 0.398, 95% CI (-0.211, 0.503). For $T_0 - T_1$ scores, no significant reduction in OSI was observed; mean difference = 0.131, p = 0.142, 95% CI (-0.032, 0.293 and similar changes were observed for $T_0 - T_2$; mean difference = 0.067, p = 1.000, 95% CI (-0.177, 0.311).

As a summary for postural stability, from all the p-values, we fail to reject the null hypothesis pertaining to postural stability (Hypothesis 3). Thus, the application of the knee sleeves would not improve postural stability in our study participants.

Figure 4.12: OSI for FRT (Level 12 to Level 8) for pre, immediate and post effects according to treatment groups. Overall [n=17], Simple knee sleeve (Knee Sleeve A) [n=9], Knee sleeve with patella cutout (Knee Sleeve B) [n=8]

4.6 Summary

The results from all the measurements show significant improvements on our targeted parameters: 1) pain level is reduced after the six weeks of knee sleeve application, 2) significant increase in walking speed, 3) reduction in knee joint loading rates and KAM, and 4) no significant reduction in postural stability assessment – except on single-leg standing task. Between the intervention groups, there is no significant difference between any of the targeted parameters, regardless of when the measurement were made.

CHAPTER 5: DISCUSSION

5.1 Introduction

This chapter discusses the study findings presented in the previous chapter, interprets the results, and compares the findings with that of past studies. This chapter also discusses the core aspects of the study under appropriate subsections as follows: 1) kinetics and kinematics parameters; 2) postural stability; and 3) knee pain, stiffness, and functions. This chapter also states the limitations of this current study, and the clinical implications of the knee sleeves application in knee OA. A few often-used terms pertaining to when the test measurement is taken are defined as follows: 1) pre – indicates the measurement taken at baseline, 2) immediate – indicates the measurement taken after the immediate use of knee sleeve, and 3) post – indicates the measurement taken following six weeks of knee sleeve use.

5.2 Significance Findings

Overall, knee sleeves used in the current study have been effective in reducing pain (based on WOMAC score) (42.9%), early stance peak KAM (38.9%), late stance peak KAM (47.0%), GRF loading rates (first peak (27.1%), second peak (23.8%)), and increased walking speed (9.5%) after six weeks of sleeve application. This study found a significant reduction in WOMAC scores – on pain (44.7%), on stiffness (39.8%), and on difficulty performing daily activities (42.1%). Significant differences in single-leg postural stability test for unaffected leg (45.6%). No significant differences between the knee sleeves in all tested parameters ($p>0.05$).

5.3 Effects of Knee Sleeve on Pain, Stiffness, and Physical Functions of the Knee

This present study also assessed the effects of knee sleeves on knee pain, stiffness and dysfunctions associated with knee OA. In particular, it was aimed at determining how pain in knee OA can be alleviated following six weeks of knee sleeve use. Pain has been the most patient-reported parameter in knee OA, therefore, it is important to explore the patient-centered outcome pertaining to the beneficial effects of the knee sleeve.

To confirm the findings from the previous studies, WOMAC was used to evaluate pain, stiffness and knee functions among the participants. WOMAC has been used extensively in knee OA studies and has proven to be a reliable health instrument (Wolfe, 1999). From the scores, we would be able to assess the level of pain, stiffness and difficulty in performing daily activities. Also, we tested using the knee sleeve alone – without external stochastic stimulation or additional reinforcing features applied to the sleeve – in order to generalize the effects of knee sleeves on the clinical symptoms of knee OA.

5.3.1 Knee Pain

The findings from this study show that pain is significantly reduced following immediate and post six-week of knee sleeve application. Statistically, the results from the study show that a knee sleeve can reduce knee pain significantly immediately in 26.2% of participants after the application of the sleeve, and can reduce knee pain significantly in 42.9% of participants after six weeks of application of the sleeve. No significant difference in knee pain reduction was observed between using knee sleeves of different designs. This level of pain relief was larger than that observed by Hassan et al. (6–11%) in a study that used a common elastic bandage, and observed in Mazzuca et al. (16%) in a study that used knee sleeve (with heat retention properties) and simple knee sleeve, following a four-week treatment period, in patients with knee OA (Hassan, Mockett, & Doherty, 2002; Mazzuca, Page, Meldrum, Brandt, & Petty-Saphon, 2004). This reduction is lower than a study which assessed the effects of Cingal Hyaluronic Acid on patients with stage I-III knee OA, with a 70% reduction after 12 weeks (Hangody et al., 2017).

Although knee sleeves have been claimed to have antalgic effects on people with knee OA, there have not been many studies that assess the effects in more details (Bryk et al., 2011). Previous studies suggested that knee sleeves might improve heat retention and blood flow in knee OA, and this has been consistently supported by many studies (Bryk et al., 2011; Mazzuca et al., 2004; Schween et al., 2015). Taping – which works in the same way as the knee sleeve – relieves pain by improving blood circulation in the target joint (Kwon et al., 2014).

With regard to the additional stochastic stimulation on the knee sleeves, we compared our findings with the study of Collins et al. (2011). They found reduction in the pain, denotes a presence of pain-relieving effect due to the additional stochastic stimulation on the sleeves. This suggests that the additional warmth or external heat stimulus might give additional benefit to the sleeve in reducing pain.

5.3.2 Knee Stiffness

Our findings show that most participants have a stiffed knee upon waking up. In the average baseline measurement, high rate of knee stiffness was recorded, but the rate reduced significantly after using the knee sleeve for six weeks (39.8%) – indicating the benefits of the knee sleeve. This findings agreed with a previous study, Collins et al. (2011) which found improvement in knee stiffness, using Knee Injury and Osteoarthritis Outcome Score (KOOS) score. Our study found no significant difference in the effects attributed to knee sleeve of different designs used in our study.

5.3.3 Functional Performance of the Knee

There are 14 questions in WOMAC pertaining to knee functions. These questions attempt to determine a participant's difficulty in performing these functions because of the pain (Appendix D). It is well-known that knee pain can adversely affect the functional activities of the knee (Foxworth, 2007). Our study found significant reduction in

WOMAC scores – pertaining to difficulty in performing daily activities – following the use of knee sleeves for six weeks (42.1%). This indicates an improvement in our participants' knee functions for them to perform the daily activities, following six weeks of knee sleeves use.

Our findings are consistent with the findings of Bryk et al. (2011), who also found statistically significant reduction of knee pain ($p < 0.001$), following the use of knee sleeves. The other studies discussed above, only assessed the immediate effects of knee sleeve use, but there has been no study that assesses their long-term effects. In our study, we also assessed the effects of knee sleeve use over a six-week period, and found that the knee sleeves reduce pain and stiffness, as well as improve functional activities of the osteoarthritic knee.

We took precautions to prevent external factors such as fatigue and depression of participants from influencing the outcomes of the trials by ensuring that they have adequate rest and that they only rate the knee pain of the affected limb.

5.4 Effects of Knee Sleeve on Gait

The present study shows that the use of knee sleeves of two different designs: 1) simple knee sleeve, and 2) simple knee sleeve with a patella cutout, for six weeks could improve the knee mechanics in people with knee OA. Based on our findings, we advocate extended usage of the knee sleeves to improve symptoms associated with knee OA especially knee joint loading.

5.4.1 Knee Adduction Moment (KAM) and Ground Reaction Force (GRF)

The knee joint loading in knee OA individuals are said to be altered due to proprioceptive deficits and mechanical alteration due to breakdown of cartilage (A. Collins et al., 2014). Besides, KAM is considered a reliable parameter for identifying knee OA progression (Sharma et al., 1998). Our study shows further reduction in first peak KAM after prolonged use of the knee sleeves – 39.0% reduction after six weeks of use, and 13.9% reduction after immediate use compared to 10.1% reduction in first peak KAM after immediate use (Schween et al., 2015). This clearly shows that prolonged knee sleeves usage effects greater improvement to symptoms of knee OA, evident after the treatment period.

Moreover, our findings highlight the efficacy of knee sleeve – without any stochastic resonance electrical stimulation – in which Collins et al. (2011, 2014) have found no significant in KAM. This adds the current configuration that stochastic resonance stimulation did not enhance any effects on knee loading. Our study has established a similar findings, in which we used the same population of knee OA individuals, with a mild to moderate level of severity.

However, our study found a higher peak for late stance KAM, after the immediate usage of knee sleeve, compared to the baseline. This finding denotes a higher loading during the late stance of gait, after wearing the knee sleeve. We advocate the results due to the adaptation of our participants with the knee sleeve while walking. After six weeks of usage, there is a significant reduction in late stance KAM, denotes the treatment effect, with a 44.9% reduction ($p<0.005$).

KAM is also positively correlated to GRF (Duffell et al., 2014; Jenkyn et al., 2011). Our study shows that GRF loading rate during gait decreases significantly when using both types of knee sleeves over a six-week period, together with KAM reduction. These findings are similar to the findings of Collins et al. (2011). The authors explained that the higher loading rate in people with knee OA causes faster cartilage degradation, but following the use of knee sleeves, the loading rate is reduced. However, the actual association between knee sleeve use and any mechanical change in joint loading is still not clearly understood. Some studies suggested that the change could be due to reduced pain or improved proprioceptive ability brought about by the knee sleeves (Perlau, Frank, & Fick, 1995; Van Tiggelen, Coorevits, & Witvrouw, 2008).

A study investigated on peak pressure and contact area of knee bracing when applied to the knee (Wilson et al., 2010). They found a significant decrease in peak pressure and significant increase contact area on the patellofemoral, when knee bracing is applied – suggest to improve the abnormal patella tracking which lead to patellofemoral contact pressure. Though, knee sleeve did not significantly reduce the peak pressure, but only has a significant increment on the contact area. These finding suggests that while the compression applied by sleeve-type braces increases contact area, it also increases contact force, leading to no decrease in patellofemoral contact pressure.

Knee sleeves could also improve proprioceptive ability which will lead to more normal gait pattern. It was previously suggested that the compression exerted by the knee sleeve improves sensory stimulation and joint position sense (Schween et al., 2015; Van Tiggelen et al., 2008). Thus, the improvements observed in our study could be due to the extra support provided by the sleeve, which in turn, facilitates movement of the pained knee or diseased knee. As a result, the knee gains more strength as those with knee OA feel more confident in moving their knees.

5.4.2 Knee Range of Motion – Knee Flexion Angle

With regard to the knee range of motion, however, we did not found any significant changes in the current study (55.8^{o} to 54.5^{o}). People with knee OA usually walks slower with a reduced range of motion (Foroughi, Smith, & Vanwanseele, 2009). These impairments could be troublesome to knee OA individuals as their movement is restricted (Fitzgerald, Piva, & Irrgang, 2004). Knee range of motion is said to decrease with increasing OA severity (Nagano et al., 2012). Therefore, since our findings did not found any significant observations, we suggest that simple knee sleeve could not improve nor impede the range of motion of our participants.

A lower knee flexion angle at heel strike was recorded in this study and is significantly reduced (18.8^o to 14.0^o). This finding contrasts the results obtained by Collins et al. (2011) and the statement that knee OA individuals have a greater knee flexion at heel strike to effectively reducing the GRF. However, the range of knee flexion is still within the normal range for early knee OA (Nagano et al., 2012). In addition, no significant changes is found in the range of knee extension, indicating that the range of motion neither degrade nor improve after a six-week trial. This could be because our participants comprised those diagnosed with early knee OA – their knees are not yet stiff and still have good flexion range or our method in calculating knee kinematics is insufficiently accurate. Our study also found negative results comparing to other similar studies – on peak knee flexion during stance (Collins et al., 2011; Nagano et al., 2012). It is possible that avoidance gait to pain or decreased knee stability induced by decreased knee extension strength negatively affects the knee flexion angle (Nagano et al., 2012).

5.4.3 Walking Speed

In terms of walking speed, the findings indicate increase in walking speed following the treatment period. Walking speed may decrease as the severity levels of knee OA is increases (Pagani et al., 2010). Previous studies mentioned that in order to compensate for pain, knee OA sufferers often reduce their walking speed to reduce the impact on the joint (Amin et al., 2004; Foxworth, 2007). But our study found a significant reduction in pain, together with the significant increase in walking speed. These suggest the positive effects of the knee sleeves.

There is no studies investigated on the change in walking speed after the application of knee sleeve. Thus, we compare our results with other bracing. Pagani et al. found no significant improvement in walking speed in their study's participants after an immediate use of flexible knee brace and knee brace with 4^{o} valgus alignment – but, this could be due their participants were among those with a grade IV knee OA (severe). Another study uses grade II and grade III knee OA, and found significant increment in the walking speed (4.4%), after four-week use of lateral-wedged foot insoles and knee brace. The study found no significant difference in both types of intervention (Jones et al., 2013). Supported with another study which found 10.2% increment in gait speed after five-week usage of knee brace on knee OA with grade II and above (Laroche et al., 2014). While, we found 9.5% increment in walking speed for grade I and grade II knee OA – with the six-week intervention period. From these findings, it is agreeable that every level of severity has to be managed appropriately i.e. knee brace is appropriate to moderate level of severity; knee sleeve is appropriate for mild level of severity.

5.5 Effect of Knee Sleeve on Postural Stability

Biomechanically, whenever the movement of the knee is restricted, it would lead to instability (Fitzgerald et al., 2004). Thus, our study was also aimed at determining whether there is any improvement in postural stability of participants with early knee OA after six weeks of knee sleeve application. It is believed that the knee sleeves can improve proprioceptive ability (Herrington, Simmonds, & Hatcher, 2005). The results of our study revealed that the use of knee sleeves of two different designs on a longer-term basis could improve postural stability in participants with knee OA – a reduction, albeit not significantly, in the overall stability index (OSI) in all tests. Also, there was no significant difference in the effects when knee sleeves of two different designs were used. Knee sleeves used in the current study effect reduction in the OSI following the stability tests, and this indicates better stability.

In our study, we used Biodex Stability System (BSS) to assess postural stability. Arnold & Schmitz (1998) also used BSS and deemed it a good postural stability measuring device that produces highly reliable measure of OSI. In addition, BSS is a user-friendly machine and is easy to handle. It provides a screen monitor to display visual input to the users to aid them in controlling their posture. The series of tests available in BSS are also reliable and provide accurate scores to represent balance (Cachupe et al., 2001).

In the trial, we only considered the OSI. The OSI is a composite of the medial-lateral stability index (MLSI) and anterior-posterior stability index (APSI), and is sensitive enough to detect changes in any direction of the postural sway, and represents the overall score for stability (Arnold & Schmitz, 1998). High stability index indicates higher sway of motion, which means that the participant has problem in balancing.

In this study, different protocols on postural stability were assessed which involve both static and dynamic tests (single-leg standing – using the Athlete Single-Leg (ASL) Test and both-leg standing), and also the fall risk test. Findings from this study showed that there is no significant changes on postural stability except the unaffected limb during a single-leg standing dynamic test. There is no significant effect observed in other tests on postural stability after six weeks of knee sleeve usage. However, we believe that even a small reduction in OSI is indicative of the positive effects of the interventions.

5.5.1 Both-Leg Standing of Postural Stability

Standing balance is often part of the physical evaluation of lower-limb neuromuscular function. In comparing our findings with that from previous studies, we note that Chuang et al. (2007) found significant immediate improvement upon application of the knee sleeve – 28% reduction in the stability index for the static test, and 7% - 8% reduction in the stability index for the dynamic tests. Hassan et al. (2002) found significant improvement in postural sway after applying L-bandage. Although our study did not produce similar findings, the single-leg test results also show reduction in the stability index. The discrepancy between our findings and other studies could be due to the different methods and tests used, as well as the different severity levels of the disease among the participants or study subjects.

As discussed above, our test results show reduction in the stability index and this indicates better balance ability after six weeks of knee sleeve usage. The full effects of knee sleeve were not observed during the intervention period, probably because our sample size was too small to be able to detect occurrence of type-2 error.

The results of previous studies to determine the underlying mechanism of knee sleeve in postural stability suggest that the compression exerted by the knee sleeve improves both proprioceptive ability and joint position sense, as well as postural stability (Birmingham et al., 1998; McNair, Stanley, & Strauss, 1996). Our study outcomes also suggest that our participants gain increased confidence regarding their postural stability following the use of the knee sleeve. Many knee OA patients experience postural instability, caused mainly by impaired proprioception of the knee. This, in turn, could lead to alteration in gait patterns, which could usually be reversed by improvement in postural stability (Schween et al., 2015). Kirkley et al. (1999) found that a neoprene knee sleeve used by knee OA patients – regardless of their disease severity – can lead to a modest decrease in the symptoms. This supports our findings that prolonged usage of the knee sleeve could improve postural stability on our study participants.

With regard to pain associated with postural stability in knee OA, our study shows that there is a reduction in the WOMAC scores in the tests, which indicates alleviation or decrease in pain levels following the use of the knee sleeves for six weeks. However, over the same period, we did not observe any significant change in postural stability. Pain is seemingly related to balance, because we often observed that increased pain can lead to instability. To cope with pain associated with knee OA, people adapt in various ways such as adopting certain standing styles, and walking patterns (Kim et al., 2011). It is well-known that people with knee OA have impairment in position sense (static) proprioception (Walker, Amstutz, & Rubinfeld, 1976). In this context, it is clear that there is close correlation between postural stability and pain. In our study, however, we found no significant reduction in the stability index, or in other words, no significant change in postural stability. Hence, our study outcome is not able to reaffirm the aforementioned correlation between postural stability and pain.

Owing to the limitations of our study, the results of the postural stability tests were not sufficiently comprehensive. One limitation is the absence of functional tests. BSS is a reliable tool but if it is complemented by relevant functional tests, it would provide a more comprehensive understanding of postural stability. Besides, more levels of dynamic testing should be applied. This study used a few levels of dynamic tests – level 8 (both-leg standing) and level 4 (single-leg standing), guided by the proposed protocol in the BSS manual. Besides, BSS produces relatively reliable values with only one decimal point for the stability index, therefore, there is little difference between pre and post measurements.

In addition, our measurements did not consider the brief loss of balance which was allowed during the trials. It was obvious that all the participants have different degrees of postural stability. Also, we did not take into consideration other parameters such as APSI and MLSI. In our study, the choice of foot position was a self-made decision, hence, there was no balance constraint. We suggest that balance should be controlled by the participants depending on their own comfortable standing style.

This is the first study to assess the use of knee sleeves of different designs on both leg testing and single-leg testing over a six-week period by using a balance machine. The findings from this study would be beneficial to clinicians who are always exploring ways of managing pain in knee OA patients, and improving their quality of life. People with balance problems inevitably lose confidence in their postural stability because balance control indicates good physical functioning of the lower limbs to prevent incidence of falling (Hunt, McManus, Hinman, & Bennell, 2010).

5.5.2 Single-Leg Standing Test of Postural Stability

Single-leg testing is conducted to evaluate balance as a whole and is related to the modifiable factors, such as, lower extremity alignment, knee pain, and quadriceps strength in people with knee OA (Hunt et al., 2010). Logically, falls may occur in situations where only one foot is in contact with the surface. For example, people who loses stability may trip while stepping over an obstacle. As people with knee OA often experience instability, single-leg balance retraining is often part of many rehabilitation programs and is crucial for them. Single-leg testing also allows us to evaluate the effects on the affected limb without any help from the unaffected limb (Hunt et al., 2010). The results in the current study show statistically significant changes to the unaffected limb in the dynamic test after six weeks use of the knee sleeve. Unaffected limb in this context represents the non-pained knee. The findings, however, could suggest that there would be a significant compensatory stabilizing effect on both sides of the limb (Duffell et al., 2014).

From the single-leg test that we conducted, the results show no significant reduction in the stability index after six weeks of knee sleeves application. A possible explanation is that the participants were at the early stage of knee OA, hence, most of them were able to balance themselves properly – the disease has not affected their balance yet (Duffell et al., 2014). The single-leg standing balance test, however, may not provide information that assists clinicians in determining clinical change or functional level for knee OA patients, therefore, the need to evaluate both-leg standing in this individuals is necessary (Harrison, Duenkel, Dunlop, & Russell, 1994).

5.5.3 Fall Risk

The risk of falls in people with knee OA is less well studied (Levinger et al., 2011). In our study, however, we did not find any significant difference in all the three preset schedules to take measurement: pre (baseline), immediate, and post 6-week of knee sleeve use. We believe that it is possible for a type-2 error to occur under such circumstance because at the early stages of our statistical analysis for pre and immediate effects of knee sleeve use – with 15 participants – we observed significant reduction in the OSI. Fall risk is one of the major concerns of people with knee OA because it could further aggravate symptoms of the disease. Since people with knee OA have an impaired postural stability, they need a device that can strengthen their weakened knee besides making them more aware of the risk of falling. The risk of falling in people with knee OA can emanate from many factors, such as, muscle weakness, poor proprioceptive acuity, and postural imbalance (Sturnieks et al., 2004). Therefore, we should constantly strive to drastically reduce the risk of falling among people with knee OA to avert more serious consequences.

No study related to knee sleeve identifying on fall risk. However, a study investigated the effects of hyaluronic acid injection on mild-to-moderate level of knee OA. They found significant reduction in the stability index after five dosage of injection (within six weeks) (Khalaj et al., 2014). Comparing to our study, we did not found significant reduction in the OSI. This can relate to the type of treatment. Hyaluronic acid injections are effective in preserving knee pain, which consecutively help improving postural balance (Ministry of Health Malaysia, 2013).

5.6 Participants' Lifestyle

Feedback to the questionnaire from our participants indicate that most of their lifestyle requires them to be active. Such lifestyle may lead to faster degradation of the cartilage of their knee joints. However, active people are less likely to develop knee OA at an early age. Moreover, knee tissues and cartilage are more likely to remain in good condition if people – of any lifestyle – learn to adapt impact loads (Nyland et al., 2015). None of our participants are athletes which suggests that most of them lead sedentary lifestyle which could be the reasons for the different responses to our targeted parameters. Besides, none of them are smokers, thus, we believe that their knee OA is not attributed to smoking.

Only six participants had undergone a rehabilitation program. Six participants (31.6%) out of 19 participants, had previous injuries, which might have involved the need for various kinematics and kinetics treatments, and these injuries could have initiated the knee OA, as mentioned earlier in Chapter 2. Other injuries reported included ligament tear, falls and dislocation of patella, which could also have initiated their knee OA.

5.7 Participants' Compliance and Adverse Effects of Knee Sleeve

The validity of the trial results and outcomes depends also on participants' compliance with the study protocols. Based on the data in the log book (subsection 4.3), the total daily compliance for both knee sleeves application is 3.7 ± 2.4 hours.

The most reported problem regarding the knee sleeves is the poor fitting. The participants were urged to adapt to the sleeves as best as they could as individually customized sleeves were not available. There were also reports on skin irritation and discomfort.

5.8 Clinical Implications

Our results have important clinical implications on early knee OA. The use of knee sleeves in people with early knee OA, can improve the functional performance of the knee in their daily activities and delay disease progression. Using the knee sleeves for six weeks can bring about pain reduction, improvement in joint moments and loading rates. Our study also shows that there is no significant difference in the effects between the use of simple knee sleeve and knee sleeve with patella cutout – both of different designs. Our study is the first to evaluate and compare the biomechanical efficacy of the two different designs of knee sleeves in a six-week trial on patients with early knee OA.

Any improvement in postural stability is crucial in preventing people from falling and also to enable them to carry out their daily activities. This is because falls could lead to serious health consequences and further aggravate the loading problems of the knee joint. Any balance deficits people may have, are likely to affect their overall bodily functions and inevitably their quality of life (Hsieh et al., 2013). For such people, any form of treatment or intervention – such as the use of knee sleeves – would be of invaluable benefits in their daily life.

The extensive use of knee sleeve today is largely attributed to the intense promotion by the manufacturers. Its lower cost, compared to other orthotic aids, makes it affordable to most knee OA sufferers. It is a simple aid and relatively easy to use. Other than effecting physical functions improvement, knee sleeves are now a source of emotional and therapeutic support to knee OA sufferers because of their beneficial properties.

Overall, the results from this study suggest that different designs of knee sleeves are not significantly different in their effect on osteoarthritic knees.

5.9 Summary

It can be said that patients' perception of pain can result in altered knee mechanics and postural stability. Knee sleeves could be working in this way to relieve pain and reduce stiffness in the knee of people with knee OA. They help to reduce medial loading and also the GRF. They also improve joint position sense, resulting in improved postural stability, and knee functional performance. In summary, this chapter has highlighted new findings from our study and compared them to that from previous studies – highlighting both similarities and differences. This chapter also discusses the principles and relationships of the parameters considered in this study. The clinical implications are also discussed. The next chapter concludes the present study and suggests further researches on this same topic.

CHAPTER 6: CONCLUSION

6.1 Introduction

This study was undertaken to evaluate and compare the biomechanical effects of knee sleeves of different designs on early unilateral knee OA. Our trials involved observing the immediate effects of knee sleeves, and the effects after six weeks application. We aim to determine whether knee sleeves can modify any of the biomechanical parameters for the following reasons: 1) Help clinicians to comprehend the indications and properties of the knee sleeves, and 2) Help fill the gap on information pertaining to the biomechanical aspects of knee sleeves. The outcomes from this study and achievement of the objectives would encourage wider use of knee sleeves as an affordable and non-invasive intervention to relieve symptoms, especially pain, in early knee OA.

The results from the trial show that application of the knee sleeves over six weeks has many positive effects such as reduction in pain level, improvement in knee joint moments and loading rates. This is the first study to focus on evaluating and comparing the biomechanical mechanism of knee sleeves of two different designs used in a six-week trial.

6.2 Limitations

Although the current study provides new information on the beneficial effects of knee sleeves for our participants, this study has its limitations. We only compared the immediate effects and the effects after six weeks of knee sleeve use with the baseline, and within the same group of participants. The difference or similarity in the effects would have been clearer if there had been a control group to compare. Besides, we had focused on only one stage of knee OA – early knee OA – thus, our findings are only relevant to early knee OA. With regard to knee sleeve application, we did not consider slippage of the knee sleeves during the trials. The slippage rate must be considered to ensure minimal deviation errors and to confirm that the sleeve remains intact throughout the trial. The grip of the knee sleeve might change after the walking trial, and this could affect the results as well. Besides, feedback from our participants indicate some problems with the sleeves such as the sleeves slipping downwards after using them for some time. Owing to time constraint and other participant-related factors, we were unable to recruit more participants for each intervention. However, to reduce the error, we added three point of measurements for each participant – pre, immediate, and post six-week effects.

6.3 Contribution of Research

From our findings, we can conclude that the two types of knee sleeves used in this study are able to decrease pain and to improve knee functions in people with early knee OA following six weeks of use. The knee sleeves also help in reducing joint loading and increasing walking speed. The positive effects observed are attributed to the reduction in pain and the extra support brought about by the sleeves during the six-week treatment period. The knee sleeves could be used by people with early knee OA on a longer term to bring about better improvement to their condition. Our findings also indicate that the reduction in loading rates is probably due to the decreased KAM during early stance and late stance, as well as marked reduction in pain levels which is probably due to the increased feeling of stability from improvement in proprioception following six weeks of knee sleeve application. The findings further indicate that knee sleeves can improve postural stability and reduce risk of falling, based on the reduction in the stability index.

The improvements on the immediate effects agreed with similar previous studies, which had investigated the immediate effects of knee sleeve – such as KAM, pain and vGRF. These findings give additional merits to the knee sleeve as one of the treatment approach to people with early knee OA. We also tested the postural stability on single-leg standing, which has insufficient findings from past studies. Though our results did not find any significant findings on the parameter, the idea to investigate the shingle-leg standing balance should lead to future works that could focus on the importance of the assessment. Our study also justifies the improvements that can be addressed to the people with knee OA to have an easy intervention to easing their knee pain.

6.4 Future Research

Although the results of our study seem promising, future studies should evaluate various designs of knee sleeves, and also include participants with different levels of severities in knee OA. This is because knee sleeves are relatively easy and convenient to use, besides being a cost-effective treatment option for early knee OA.

More researches should be undertaken on other pertinent aspects of knee sleeves use in knee OA, such as: the experimental protocol; different designs of knee sleeves; other gait parameters; different stages of knee OA; the underlying mechanism of knee sleeves; and knee braces and knee sleeves with reinforcements. Further, the materials and mechanical aspects of other knee supports, and the functional tests to give better understanding of proprioception, balance and stability, use of other gait parameters such as tibial rotation and knee flexion moment, to provide more information from different aspects of gait, other gait studies such as ankle, knee and hip kinematics and kinetics in all planes, and tests for high-speed walking, and wearing shoes as the intervention method for outdoor tests.

Future studies should explore the relationships between gait parameters of sagittal plane with pain and knee functional performance, and also disease progression (Chang et al., 2015). They mentioned that from sagittal biomechanics, it appears more relevant to characterize the disease progression of knee OA. Besides, future studies should also consider investigating the transverse plane biomechanics, as the past studies have put more focus on the frontal and sagittal biomechanical parameters.

Future studies should also consider the role of quadriceps muscle strength in people with knee OA, and whether increased muscle contraction leads to higher risk of muscle stiffness or more joint loading. The correlation between these parameters will provide further insights on knee OA. Besides, research should be conducted to understand the long-term effect of altered muscle activity on the onset and progression of knee OA.

To have a better understanding of the study population, more functional tests such as Timed-up and Go (TUG), 8-metre Walking Test (8MW) and Stair Climb Power Test (SCPT) should also be conducted (Bryk et al., 2011).

Because of our study limitations, further testing should involve the gender factor because of the anthropometric difference and the influence of gender on the efficacy of knee sleeves. Also, other factors such as BMI and participants' lifestyle should be explored, as those factors, combined, might provide different effects when using the knee sleeve. These efforts will provide a more comprehensive understanding of the effects of knee sleeves.

In terms of experimental protocols, future studies should control the foot position during standing and more dynamic levels should be included. Besides, postural stability can also be improved with functional tests to fully comprehend balance ability of knee OA population. Studies should also be undertaken on the adaptation periods during trials, and provision for rest in between the tests, are advisable to prevent fatigue among participants. The measurement of APSI and MLSI should be further explored to obtain a better understanding of postural stability, besides the OSI. The standard deviation obtained together with the OSI results should also be taken into consideration. The BSS should be used to conduct a thorough and more accurate evaluation of postural stability.

Further investigations should consider the BMI of the participants because a person's BMI can influence the level of loading (Runhaar, Koes, Clockaerts, & Bierma-Zeinstra, 2011). In addition, specific parts of an osteoarthritic knee should be considered in the inclusion criteria during recruitment of participants – such as the medial part or lateral part of the knee. This is because Weidow et al. (2005) reported that the pelvic and hip anatomy and biomechanical measurements of the medial and lateral parts of the osteoarthritic knee are different.

6.5 Conclusion

Our study also indicates the need to further explore the use of knee sleeves of different designs to evaluate their true effects. We conclude that knee sleeves effect both biomechanical and clinical improvements to the symptoms of early knee OA following knee sleeve use over a six-week trial. The study outcomes have met the research objectives in helping clinicians to comprehend the indications and properties of the knee sleeves, and helping researchers to have better insight on the biomechanical action of knee sleeves.

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LIST OF PUBLICATIONS AND PAPERS PRESENTED

Mohd Sharif, N. A., Wan Safwani, W. K. Z., Usman, J., Goh, S. L., Abdul Karim, S., Mohamed, N. A., & Khan, S. J. (2017). *Biomechanical effects of different knee sleeves in OA following a 6-week application*. Manuscript submitted for publication.

Mohd Sharif, N. A., Goh, S. L., Usman, J., & Wan Safwani, W. K. Z. (2017). Biomechanical and functional efficacy of knee sleeves: A literature review. *Physical Therapy in Sport, 28,* 44–52. http://doi.org/10.1016/j.ptsp.2017.05.001

Mohd Sharif, N. A., (2016, September). *Effect of different knee sleeves on balance and risk of fall in early knee osteoarthritis (OA): Preliminary results of a randomized trial*. Paper presented at the Annual Meeting of 3rd International Conference on Movement, Health & Exercise, 28th – 30th September 2016, Melaka, Malaysia.

APPENDIX

Appendix A – Medical Ethics

UNIVERSITY OF MALAYA MEDICAL CENTRE

MEDICAL ETHICS COMMITTEE
UNIVERSITY MALAYA MEDICAL CENTER
ADDRESS : LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE : 03-79493209/2251 FAXIMILE : 03-79492030

NAME OF ETHICS COMMITTEE/IRB Medical Ethics Committee, University Malaya Medical Center	**MECID.NO: 201410-626**
ADDRESS : LEMBAH PANTAI, 59100 KUALA LUMPUR	
PROTOCOL.NO(if applicable) :	
TITLE: Effects of simple knee sleeves and padded knee sleeves on pain and function of individuals with symptomatic knee osteoarthritis (OA) in 6 weeks.	
PRINCIPAL INVESTIGATOR : DR GOH SIEW LI	**SPONSOR** -

The following item [✓] have been received and reviewed in connection with the above study to conducted by the above investigator.

[✓]	Application to Conduct Research Project(form)	Ver.No :	Ver.Date : 03-10-2014
[✓]	Study Protocol	Ver.No :	Ver.Date :
[✓]		Ver.No :	Ver.Date :
[✓]		Ver.No :	Ver.Date :
[✓]	Questionnaire	Ver.No :	Ver.Date :
[✓]	Investigator's CV / GCP (DR GOH SIEW LI,Nahdatul Aishah Mohd Sharif, Dr Juliana Usman, Dr Wan Safwani Wan Kamarulzaman,)	Ver.No :	Ver.Date :
[ ]	Insurance certificate	Ver.No :	Ver.Date :
[✓]	Other Attachments		

and the decision is [✓]

[✓] Approved

[ ] Rejected(reasons specified below or in accompanying letter)

Comments:

This intervention study does not involve invasive procedures.

Investigator are required to:

1) *follow instructions, guidelines and requirements of the Medical Ethics Committee.*
2) *report any protocol deviations/violations to Medical Ethics Committee.*
3) *provide annual and closure report to the Medical Ethics Committee.*
4) *comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.*
5) *obtain a permission from the Director of UMMC to start research that involves recruitment of UMMC patient.*
6) *ensure that if the research is sponsored, the usage of consumable items and laboratory tests from UMMC services are not charged in the patient's hospital bills but are borne by research grant.*
7) *note that he/she can appeal to the Chairman of MEC for studies that are rejected.*
8) *note that Medical Ethics Committee may audit the approved study.*
9) *ensure that the study does not take precedence over the safety of subjects.*

Date of approval : 26-10-2014

Appendix B - Participant Consent Form

Patient Name:

Intervention Risks

The nature and purpose of the procedure necessary for my condition has been explained to me. I am aware that the practice of medicine is not exact science and no guarantee about the outcome. I have been given explanation on the medical risks and consequences of these interventions. I understand that there are general risks associated with these non-invasive procedures which may include discomfort and pain.

Intervention Benefits

I also know the benefits which may include:

- Less pain on the knee.
- Improving my balance.
- Reducing load on my knee.

Consent for Intervention

I consent to participate in the 6 weeks intervention period. I also consent to come to the Motion Analysis Lab and Body Performance Lab in Biomedical Engineering Department two times during the intervention. I also consent to participate to record the daily usage of knee sleeve in the log book and pain score.

I understand the intervention protocol and agree to adhere to it during my daily routines.

I consent to the taking of photographs for the purpose of medical study or research and the initial reproduction or publication of the photographs in any manner, providing my identity is not revealed. I also consent to the presence of observers, technical representatives and participants in the laboratory.

Consent for use of body part

I allow the researchers to use my knee for the procedures and I consent to take part in this research.

Signatures

My signature below means that:

- I have read and understood this consent form.
- I have been given all the information I asked about the procedures, risks and other options.
- All my questions were satisfactorily answered.

I agree to everything explained above.

Sincerely,

____

Appendix C – Participant's Log Book on Daily Usage

INSTRUCTIONS FOR PARTICIPANT

ARAHAN KEPADA PESERTA

- The data provided in this log book is very important for this research. Please fill in the data very carefully and honestly.
  Buku log ini sangat penting untuk mendapatkan satu set data untuk projek ini. Sila isi dengan baik dan jujur.

- The log book needs to be filled **daily**. Please do not fill in after gaps of one or more days. If you forget to fill in the data on that day, please leave the page blank.
  Buku log ini perlu diisi ***setiap hari*** *selama projek berjalan. Jika anda terlupa untuk mengisi data untuk satu hari, sila teruskan ke hari yang berikutnya.*

Guidelines for Using Knee Sleeve

Garis Panduan Menggunakan Knee Sleeve

- Please wear the sleeve carefully as demonstrated to you during your first lab visit.
  Sila pakai knee sleeve ini dengan cara yang betul sebagaimana yang telah ditunjukkan kepada anda.

- The sleeve must be worn *at least 4 hours* per day. Please use the sleeve during the hours in which you are most active (daytime/ work/ doing home chores) or as much as needed. The more you use it, the more beneficial it will be to you and the study.
  Knee sleeve ini perlu dipakai dengan kadar minimum selama 4 jam sehari. Sila pakai knee sleeve ini ketika anda sedang melakukan aktiviti yang memerlukan pergerakan (seperti semasa kerja ataupun ketika melakukan kerja-kerja rumah) atau selama mana yang anda mahu. Lebih lama anda memakai knee sleeve ini, lebih banyak ia dapat membantu anda dan projek ini.

- Please do not use the sleeve while sleeping or when bathing.
  Anda tidak dinasihatkan untuk memakai ketika tidur atau ketika mandi.

- Only air dry the sleeve. If you wish to wash it, reduce the amount of detergent as it can cause irritation due to the residuals.
  Hanya angin keringkan knee sleeve ini. Tetapi jika anda mahu membasuh, sila pastikan tiada saki-baki sabun kerana ia akan menyebabkan iritasi pada kulit.
- **Week 1, Day 1** will be your first visit. **Week 6, Day 7** will be your final visit.
  Minggu 1, Hari 1 *ialah temujanji pertama.* ***Minggu 6, Hari 7*** *ialah temujanji terakhir.*

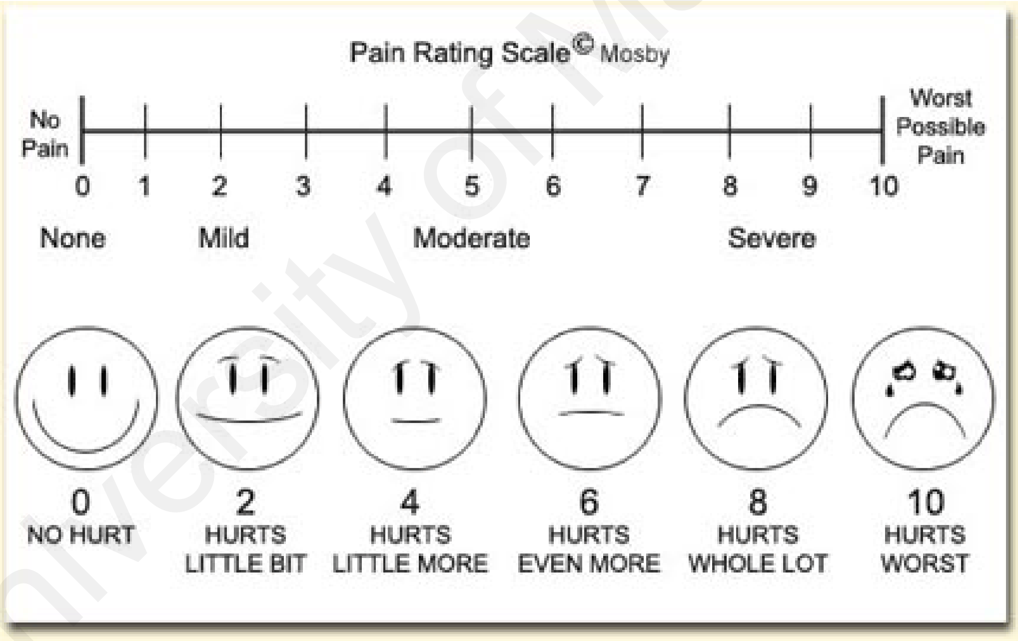
Guidelines to Use the Log Book

Garis Panduan Menggunakan Buku Log

- Please report any discomfort or any pain that you have felt/experienced while wearing the sleeve.
  Sila laporkan sebarang ketidakselesaan ataupun kesakitan yang anda alami semasa memakai knee sleeve.

- You may write in Malay or English, whichever you prefer.
  Anda boleh menulis buku log ini dalam Bahasa Melayu atau Bahasa Inggeris, mengikut kesesuaian anda.

- This is how you answer the questions for the pain section. Just state the average pain on that day while using the knee sleeve.
  Berikut ialah contoh jawapan yang boleh anda isi dalam bahagian "kesakitan".



		Date *Tarikh*	Hours of usage for today *Jumlah jam anda menggunakan knee sleeve hari ini*	Average pain score for today? *Purata kesakitan anda alami hari ini?*	Notes / Problems / Others *Nota / Masalah / Lain-lain*
Week 1 / *Minggu 1*	**Day 1**				
	Day 2				
	Day 3				
	Day 4				
	Day 5				
	Day 6				
	Day 7				
Week 2 / *Minggu 2*	**Day 1**				
	Day 2				
	Day 3				
	Day 4				
	Day 5				
	Day 6				
	Day 7				
Week 3 / *Minggu 3*	**Day 1**				
	Day 2				
	Day 3				
	Day 4				
	Day 5				
	Day 6				
	Day 7				
Week 4 /	**Day 1**				
	Day 2				
	Day 3				
	Day 4				

	Day 5				
	Day 6				
	Day 7				
Week 5 / *Minggu 5*	**Day 1**				
	Day 2				
	Day 3				
	Day 4				
	Day 5				
	Day 6				
	Day 7				
Week 6 / *Minggu 6*	**Day 1**				
	Day 2				
	Day 3				
	Day 4				
	Day 5				
	Day 6				
	Day 7				

Overall Knee Sleeve Usage Experiences /

Pengalaman Keseluruhan dengan Pengunaan Knee Sleeve

1. Do you think the knee sleeve helps you in your daily routines during these 6 weeks? *Adakah anda rasa knee sleeve tersebut membantu anda menjalani hidupan harian selama 6 minggu ini?*

☐ Yes / *Ya*
☐ No / *Tidak*

2. Adverse Effects: Please tick the appropriate box for any adverse effects you feel while wearing the knee sleeve. *Sila tandakan mana-mana kotak yang bersesuaian dengan sebarang kesan sampingan ketika memakai knee sleeve.*

☐ Too tight / *Terlalu ketat*
☐ Not fitting properly / *Tidak mengikut saiz lutut saya*
☐ Pain in knee joint / *Sakit di bahagian lutut*
☐ Skin irritation and redness / *Gatal-gatal dan kemerahan di bahagian kulit*
☐ Discomfort / *Kurang selesa*
☐ Joint swelling / *Sendi membengkak*
☐ None / *Tiada*
☐ Others / *Lain-lain* :

____

Thank you for your participation and high cooperation to complete this study. The findings from this study will help other patients with knee osteoarthritis to deal with their pain.

Thank you very much.

Terima kasih atas segala kerjasama tuan/puan untuk projek ini. Hasil daripada projek ini akan dapat membantu pesakit osteoarthritis lain untuk menangani kesakitan mereka.

Terima kasih.

Appendix D – WOMAC® Score (Malay version)

WOMAC OSTEOARTHRITIS INDEX VERSION VA3.1

ARAHAN KEPADA PESAKIT

Dalam Bahagian A, B dan C, setiap soalan akan ditanyakan dengan cara yang berikut. Sila jawab dengan menulis tanda "X" di garisan melintang.

CONTOH:

1. Sekiranya anda meletakkan tanda "X" di sebelah kiri garisan seperti yang ditunjukkan di bawah ini, bererti anda **tidak** berasa sakit.

2. Sekiranya anda meletakkan tanda "X" di sebelah kanan garisan seperti yang ditunjukkan di bawah ini, bererti anda berasa **amat** sakit.

3. Sila perhatikan:
   a) semakin ke kanan tanda "X" itu bererti semakin **teruk** sakitnya.
   b) semakin ke kiri tanda "X" itu bererti semakin **kurang** sakitnya.
   c) **jangan** letakkan tanda "X" **di luar penghujung garisan.**

Anda akan diminta menunjukkan pada skala seperti ini setakat mana anda berasa sakit, kejang atau hilang upaya dalam masa 48 jam (2 hari) yang lalu.

Cuba fikirkan __________ (sendi dalam kajian) anda semasa menjawab soal-selidik ini. Tandakan setakat mana rasa sakit, kejang atau hilang upaya yang anda fikir disebabkan oleh penyakit sendi (artritis) di __________ (sendi dalam kajian) anda.

Sendi dalam kajian telah pun ditunjukkan kepada anda oleh pegawai kesihatan.

Jika tidak pasti sendi mana yang dikaji, sila bertanya sebelum menjawab soal-selidik ini.

Malaysia (Malay) - V5

WOMAC VA3.1 QUESTIONNAIRE **WOMA**

Bahagian A

KESAKITAN

Cuba fikirkan sakit yang anda rasakan di _______________ (sendi dalam kajian) akibat penyakit sendi (artritis) dalam masa 48 jam (2 hari) yang lalu.

(Sila tandakan jawapan anda dengan "X")

SOALAN: **Setakat mana anda berasa sakit?**	**Untuk kegunaan Penyelaras Kajian sahaja**
1. Berjalan di permukaan rata. Tidak sakit |———————————————| Amat sakit	PAIN1 _______
2. Naik atau turun tangga. Tidak sakit |———————————————| Amat sakit	PAIN2 _______
3. Di waktu malam semasa tidur, iaitu sakit yang mengganggu tidur. Tidak sakit |———————————————| Amat sakit	PAIN3 _______
4. Semasa duduk atau berbaring. Tidak sakit |———————————————| Amat sakit	PAIN4 _______
5. Berdiri tegak. Tidak sakit |———————————————| Amat sakit	PAIN5 _______

Malaysia (Malay) - V5

WOMAC VA3.1 QUESTIONNAIRE **WOMB**

Bahagian B

KEKEJANGAN

Cuba fikirkan kekejangan (bukan sakit) yang anda rasakan di _______________ (sendi dalam kajian) akibat penyakit sendi (artritis) dalam masa 48 jam (2 hari) yang lalu.

Kekejangan ertinya berasa lebih **payah** menggerakkan sendi.

(Sila tandakan jawapan anda dengan " X ")

	Untuk kegunaan Penyelaras Kajian sahaja
6. **Setakat mana** anda rasa kejang **sebaik saja bangun tidur waktu** pagi? Tidak kejang |————————————————| Amat kejang	STIFF6 _______
7. **Sepanjang hari, setelah kali pertama bangun dari tidur, setakat mana** anda rasa kejang selepas duduk, baring atau berehat sebentar? Tidak kejang |————————————————| Amat kejang	STIFF7 _______

Malaysia (Malay) - V5

WOMAC VA3.1 QUESTIONNAIRE **WOMC1-3**

Bahagian C

KESUKARAN MENGERJAKAN KEGIATAN HARIAN

Cuba fikirkan sukarnya anda mengerjakan kegiatan harian akibat penyakit sendi (artritis) di ______________ (sendi dalam kajian) dalam masa 48 jam (2 hari) yang lalu. Maksud kami ialah sukarnya **bergerak dan mengurus diri sendiri**.

(Sila tandakan jawapan anda dengan "X")

SOALAN: **Setakat mana anda berasa sukar bergerak?**	**Untuk kegunaan Penyelaras Kajian sahaja**
8. Turun tangga. Tidak sukar |————————————| Amat sukar	**PFTN8** ______
9. Naik tangga. Tidak sukar |————————————| Amat sukar	**PFTN9** ______
10. Bangkit daripada duduk. Tidak sukar |————————————| Amat sukar	**PFTN10** ______
11. Berdiri. Tidak sukar |————————————| Amat sukar	**PFTN11** ______
12. Membongkok ke lantai. Tidak sukar |————————————| Amat sukar	**PFTN12** ______
13. Berjalan di permukaan rata. Tidak sukar |————————————| Amat sukar	**PFTN13** ______

Malaysia (Malay) - V5

Bahagian C

KESUKARAN MENGERJAKAN KEGIATAN HARIAN

Cuba fikirkan sukarnya anda mengerjakan kegiatan harian akibat penyakit sendi (artritis) di ______________ (sendi dalam kajian) dalam masa 48 jam (2 hari) yang lalu. Maksud kami ialah sukarnya **bergerak dan mengurus diri sendiri**.

(Sila tandakan jawapan anda dengan "X")

SOALAN: **Setakat mana anda berasa sukar bergerak?**

Untuk kegunaan Penyelaras Kajian sahaja

14. Keluar atau memasuki kereta, atau naik atau turun dari bas.

Tidak sukar |————————————| Amat sukar — **PFTN14** ______

15. Membeli belah.

Tidak sukar |————————————| Amat sukar — **PFTN15** ______

16. Memakai sarung kaki atau stoking.

Tidak sukar |————————————| Amat sukar — **PFTN16** ______

17. Bangun dari katil.

Tidak sukar |————————————| Amat sukar — **PFTN17** ______

18. Membuka sarung kaki atau stoking.

Tidak sukar |————————————| Amat sukar — **PFTN18** ______

19. Berbaring di katil.

Tidak sukar |————————————| Amat sukar — **PFTN19** ______

Malaysia (Malay) - V5

WOMAC VA3.1 QUESTIONNAIRE **WOMC3-3**

Bahagian C

KESUKARAN MENGERJAKAN KEGIATAN HARIAN

Cuba fikirkan sukarnya anda mengerjakan kegiatan harian akibat penyakit sendi (artritis) di _______________ (sendi dalam kajian) dalam masa 48 jam (2 hari) yang lalu. Maksud kami ialah sukarnya **bergerak dan mengurus diri sendiri.**

(Sila tandakan jawapan anda dengan "X")

SOALAN: **Setakat mana anda berasa sukar bergerak?**

SOALAN	Untuk kegunaan Penyelaras Kajian sahaja
20. Masuk atau keluar dari tab mandi. Tidak sukar |————————| Amat sukar	PFTN20 ______
21. Duduk. Tidak sukar |————————| Amat sukar	PFTN21 ______
22. Duduk dan bangun dari tempat membuang air. Tidak sukar |————————| Amat sukar	PFTN22 ______
23. Melakukan kerja-kerja rumah yang berat. Tidak sukar |————————| Amat sukar	PFTN23 ______
24. Melakukan kerja-kerja rumah yang ringan. Tidak sukar |————————| Amat sukar	PFTN24 ______

I have reviewed this information.	Staff's initials:	Date:

Malaysia (Malay) - V5

Appendix E – Patient Information Sheet

<u>Patient Information Sheet / *Maklumat Untuk Pesakit*</u>

You are invited to participate in our research study. However, before you decide whether you want to take part or not, it is important that you completely understand the whole idea of this research. It is important that you read the following information in order to make an informed decision. If you have any questions on this study, never hesitate to ask our team members. Please make sure that you are satisfied before you decide to take part or not. Thank you for your time and consideration of this invitation.

Anda telah dijemput untuk melibatkan diri dalam projek kami. Sebelum anda bersetuju untuk mengambil bahagian, anda dinasihatkan agar memahami protokol eksperimen untuk kajian ini dengan membaca kertas kerja ini. Jika anda mempunyai sebaran pertanyaan tentang projek ini, jangan takut untuk bertanya kepada para penyelidik. Sila pastikan anda berpuas hati dengan keterangan yang diberikan sebelum anda bersetuju. Terima kasih atas masa dan kerjasama anda dengan jemputan ini.

Research Title / *Tajuk Kajian*: Do individuals with symptomatic early osteoarthritis demonstrate functional improvement and reduced pain after 6 weeks of knee sleeve usage?

Adakah individu yang mempunyai osteoarthritis (OA) lutut di peringkat awal menunjukkan penambahbaikan dan kurang rasa sakit selepas 6 minggu menggunakan knee sleeve?

A Brief Introduction about the Research / *Pengenalan Ringkas tentang Kajian*:

Knee osteoarthritis (OA) is one common joint disease that most occurred among people. One of the common approach used to improve the symptoms is knee sleeves. However, the benefit of these sleeves, both early and delayed, have not been convincingly demonstrated.

Osteoarthritis (OA) lutut merupakan sakit sendi yang selalu dialami oleh kebanyakan orang. Salah satu cara untuk mengurangkan kesakitan ialah dengan penggunaan sarung tangan. Walaubagaimanapun, kebaikan knee sleeve ini masih belum dikenalpasti sehabis-habisnya.

Some Q&A's and Facts about this study / *Soal Jawab tentang OA lutut*:

Q: What is the purpose of this study? *Apakah tujuan kajian ini?*

A: The purpose of the study is to establish if / *Tujuan kajian ini adalah untuk memaparkan jika*: Knee sleeves can help improve symptoms, function and gait of patients with knee OA after 6 weeks. / *Knee sleeve mampu mengurangkan symptom dan menambahbaik fungsi harian dan tahap sakit pesakit OA lutut selepas 6 minggu penggunaan.*

1. Any difference on the functional improvement of using different designs of knee sleeves. / *Ada sebarang perbezaan yang positif terhadap memperbaiki kualiti aktiviti harian menggunakan dua knee sleeve yang berbeza.*

Q: What are the procedures to be followed? / *Apakah yang patut saya lakukan?*

A: If you are agreeable, you will be expected to go through the following steps / *Jika anda bersetuju, kami perlukan bantuan anda untuk mengikuti beberapa langkah di bawah*:

1. You will be asked / *Anda akan disuruh*:

a. Day 1 / *Hari Pertama*: To participate without wearing any knee sleeve in order to collect a baseline data. You have to come to the lab on this day. / *Untuk mengambil bahagian tanpa memakai sebarang sarung lutut untuk mengumpul data asas. Anda perlu untuk datang ke makmal pada hari ini.*

b. Day 1 to Week 6 / *Hari pertama hingga minggu keenam*: To wear a knee sleeve on your knee. Knee sleeves will be provided for you, which you have to consent to wear it daily for 6 weeks' time (as long as you can). / *Memakai sarung lutut pada lutut anda yang sakit. Sarung lutut akan disediakan untuk anda. Anda dikehendaki memakai setiap hari untuk jangka masa 6 minggu (selama mana yang anda selesa).*

c. Day 7 (of Week 6) / *Hari ketujuh*: Data collection for post-intervention effect. You have to come to the lab on this day. / *Pengumpulan data untuk kesan selepas pemakaian sarung lutut. Anda perlu untuk datang ke makmal pada hari ini*.

2. Within the research period, you will be required to / Dalam tempoh kajian, anda diperlukan untuk:

a. Attend two lab experiments for two times. On Day 1, and Day 7, Week 6 at the Faculty of Engineering, University of Malaya. Transportation will be provided. / *Menghadiri dua eksperimen makmal untuk dua kali. Pada hari pertama, dan Hari ke-7, Minggu ke-6 di Fakulti Kejuruteraan, Universiti Malaya. Pengangkutan akan disediakan.*

b. Participate to jot down a log book on your condition (daily) and record a pain score (every lab visit). The pain score and log book will be provided. / *Mengambil bahagian untuk mencatat buku log tentang jumlah jam pemakaian (harian) dan merekodkan skor kesakitan (setiap lawatan makmal). Buku log dan 'pain score' akan disediakan.*

3. In the Motion Analysis Laboratory, you will be assessed on your gait. The analysis is about how you walk, which tells how your joints worked (quantitatively). For that purpose, your weight and height will be recorded and you will be fitted in dark and fit attire especially on your lower limbs. The attire is provided. But you may bring your own attire if you want. Loose fitting attire is not recommended. Then, few reflective markers will be attached on your attire (leg area) using adhesive tapes. You will have to perform 3 meters walking at your self-selected speed. You will need to repeat the activity for 5 valid trials. Rest interval between 5 to 10 minutes will be given after each trial or activity, and upon request. The lab will be repeated during your next lab visit.

Di Makmal Analisa Gerakan, kami akan membuat analisa gaya berjalan anda. Analisa ini adalah tentang bagaimana anda berjalan, dan bagaimana sendi anda bekerja (secara kuantitatif). Untuk tujuan itu, berat badan dan ketinggian anda akan direkodkan dan anda akan memakai pakaian gelap dan ketat. Pakaian akan disediakan. Tetapi anda boleh menggunakan pakaian anda jika ada. Pakaian longgar tidak digalakkan. Kemudian, beberapa penanda reflektif akan dilekatkan pada pakaian anda (kawasan kaki) menggunakan pita pelekat. Anda perlu berjalan sepanjang 3 meter menggunakan kelajuan yang anda suka dan juga kelajuan yang dikawal. Anda perlu untuk mengulangi aktiviti selama 5 ujian sah. Selang rehat antara 5 hingga 10 minit akan diberikan selepas setiap percubaan atau aktiviti, dan atas permintaan. Protokol makmal ini akan diulang semasa lawatan makmal anda yang seterusnya.

4. In the Body Performance Laboratory, you will be assessed on your balance. For this experiment, you just have to stand on a platform to perform several test which will define your balance. There will be 3 tests which either one-leg stand or both legs stand, open or closed eyes and we will set the platform to be stable or unstable. Each trial will take 10 seconds with a 5 seconds rest. If you feel imbalance, there are handrails which you can hold on to. The lab will be repeated during your next lab visit.
Di makmal Prestasi Tubuh, anda akan dinilai dengan kestabilan anda. Untuk tujuan ini, anda hanya perlu untuk berdiri di atas platform untuk melakukan beberapa ujian yang akan menentukan kestabilan anda. Akan ada 3 ujian yang menggunakan pendirian satu kaki dan kedua-dua kaki berdiri, mata terbuka dan tertutup dan juga platform yang stabil dan tidak stabil. Setiap percubaan akan mengambil masa 10 saat dengan rehat 5 saat. Jika anda rasa tidak seimbang, terdapat susur tangan yang anda boleh berpegang kepada. Protokol makmal ini akan diulang semasa lawatan makmal anda yang seterusnya.

Q: What are the benefits of this study to the investigator? / *Apakah kebaikan yang dapat diperoleh oleh para penyelidik melalui kajian ini?*

A: For healthcare providers to decide if there is any benefit in prescribing knee sleeves. / *Bagi penyedia penjagaan kesihatan untuk menentukan jika terdapat apa-apa faedah dalam menetapkan lengan lutut.*

Q: What are the benefits of this study to the patient? / *Apakah kebaikan yang dapat diperoleh oleh pesakit melalui kajian ini?*

A: The intervention might help you find a way to ease your daily routines especially on balance and pain. Besides, we can help to see whether the intervention help you as much as possible. Apart from that, from the tests, you are able to know and improve your gait and balance. Besides, the outcomes from the intervention may also assist your healthcare provider in identifying a possible way to help in managing your OA progression. / *Pemakaian sarung lutut ini mungkin akan membantu anda mencari jalan untuk mengurangkan kesakitan dan menambah kestabilan anda. Selain itu, kami boleh membantu untuk melihat sama ada sarung lutut ini dapat membantu anda sebanyak yang mungkin. Selain itu, anda dapat mengetahui cara anda berjalan dan juga kestabilan anda. Selain itu, hasil daripada sarung lutut ini boleh membantu pembekal penjagaan kesihatan anda dalam mengenal pasti cara yang mungkin untuk membantu dalam menguruskan perkembangan OA anda.*

Q: Is there any possible drawbacks to the patient during this study? / *Adakah terdapat apa-apa kesan sampingan terhadap pesakit semasa kajian ini?*

A: Since you are expected to perform only movements of daily routine, your injury risk in this study will not be much different from your daily predisposition. There is no invasive method used in this study, so there should be no concern about procedure related complications. However, there may be possibility of skin irritation for patients who have sensitive skin. If you do, please stop using the sleeve and contact the investigators. / *Oleh kerana anda melakukan pergerakan biasa dan rutin harian sahaja, risiko kecederaan anda dalam kajian ini tidak akan banyak berbeza daripada kecenderungan harian anda. Tidak ada kaedah berbahaya yang digunakan dalam kajian ini, jadi tidak perlu bimbang tentang komplikasi prosedur. Walau bagaimanapun, mungkin ada kemungkinan untuk pesakit mengalami gatal-gatal pada lutut jika kulit sensitif. Jika anda mengalaminya, sila berhenti menggunakan sarung lutut dan segera menghubungi kami.*

Appendix F – Lifestyle Questionnaire

LIFESTYLE QUESTIONNAIRE

This questionnaire (2 pages) is designed to help the project investigators understand your lifestyle. Answer the questions without thinking about them too much because your first response is the most accurate. Circle the answer that best reflects your current lifestyle.

Patient's Name: ____________________________

Gender: Male / Female

Age: ________________________

		Eating Habits			
1	How many meals you eat a day?	3 - 5 meals per day	2 meals per day	1 meal per day	Inconstant
2	Do you want to lose weight?	Yes	Planning to	No	Don't know
3	Do you try to eat a healthy balanced diet every day?	Yes	Planning to	No	Don't know
		Physical Activity Section			
1	Do you exercise regularly?	Yes		No	
2	How often do you take the stairs?	Always	Often	Seldom	Never
3	How many times a week do you exercise for at least 30 minutes?	Always	Often	Seldom	Never
4	Do you organize your time so as to include exercise?	Always	Often	Seldom	Never
5	Does the following statement apply to you? - "I don't exercise because I'm afraid of my knee getting hurt."	Always	Often	Seldom	Never
6	When you have joint problems, do you find alternatives for adapting your exercise program and staying active?	Always	Often	Seldom	Never
7	How often do you get around on foot?	Always	Often	Seldom	Never
		Medication Section			
1	Do you take any medicine or drugs (on medication) such as acetaminophen or glucosamine to reduce the pain on your knee?	Always	Often	Seldom	Never

2	Do you take your drugs as prescribed by your doctor?	Always	Often	Seldom	Never
			Smoking Section		
1	Do you smoke? (*If **No**, ignore the following questions.)*	Yes		No	
2	How often do you smoke?	Every day	Smoke but not every day	Smoke occasionally	
3	If you smoke every day, how many cigarettes per day?	More than 10	5 – 10	Less than 5	
			Career Section		
1	Are you working?	Yes		No	
2	Please name your occupation:				
3	Your highest level of education:				
4	How is your working lifestyle?	Office	At site	At home	
5	Do your work require you to be active (go here and there?)	Yes		No	
6	When you are having joint pain, does it restrict your work?	Yes		No	
			Rehabilitation Section		
1	Do you go for rehabilitation?	Yes	Planning to go	No	Don't know
2	If yes, how frequent?	Every 2 weeks	Once a month	Once in three months	Whenever necessary
3	Do you think it helps for people with knee pain?	Very helpful	Helpful	Not helpful	Don't know
			Previous Injury Section		
1	Do you have any previous injury?	Yes	No		
2	If yes, please describe the injury:				

Thank you for your participation.

Appendix G: Results – Participants' Feedback on Log Book

Table 1: Hours of Knee Sleeve Usage

Sleeve		Hours of Usage
Simple knee sleeve	Mean	3.700
	N	9
	Std. Deviation	2.7295
Knee sleeve with patella cutout	Mean	3.713
	N	8
	Std. Deviation	2.2618
Total	Mean	3.706
	N	17
	Std. Deviation	2.4419

Table 2: Knee sleeve is helpful (Yes) / not helpful (No)

Yes/No

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	14	73.7	82.4	82.4
	No	3	15.8	17.6	100.0
	Total	17	89.5	100.0	
Missing	System	2	10.5		
Total		19	100.0		

Appendix H: Results – WOMAC on knee pain

Knee Sleeve * Point of Measurement

Mauchly's W = 0.555; The assumption for sphericity is met.

Measure: Pain

				95% Confidence Interval	
Sleeve	factor1	Mean	Std. Error	Lower Bound	Upper Bound
Simple knee sleeve	Pre	16.622	2.867	10.512	22.733
	Immediate	11.567	2.627	5.967	17.166
	Post	7.844	2.470	2.579	13.110
Knee sleeve with patella cutout	Pre	7.625	3.041	1.144	14.106
	Immediate	6.100	2.786	.161	12.039
	Post	5.575	2.620	-.010	11.160

Estimates

Measure: Pain

			95% Confidence Interval	
ALL	Mean	Std. Error	Lower Bound	Upper Bound
Pre	12.124	2.090	7.670	16.577
Immediate	8.833	1.915	4.752	12.914
Post	6.710	1.801	2.872	10.548

Pairwise Comparisons on Points of Measurement

Measure: Pain

					95% Confidence Interval for Difference[a]	
(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[a]	Lower Bound	Upper Bound
Pre	Immediate	3.290	1.556	.155	-.900	7.481
	Post	5.414	2.043	.055	-.089	10.917
Immediate	Pre	-3.290	1.556	.155	-7.481	.900
	Post	2.124	1.091	.212	-.816	5.063
Post	Pre	-5.414	2.043	.055	-10.917	.089
	Immediate	-2.124	1.091	.212	-5.063	.816

Pairwise Comparisons on Knee Sleeve Types

Measure: Pain

					95% Confidence Interval for Difference[a]	
(I) Sleeve	(J) Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	5.578	3.402	.122	-1.673	12.829
Knee Sleeve B	Knee Sleeve A	-5.578	3.402	.122	-12.829	1.673

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Appendix I: Results – WOMAC on knee stiffness

Knee Sleeve * Point of Measurement

Mauchly's W = 0.622; The assumption for sphericity is met.

Measure: Stiffness

Sleeve	factor1	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
Simple knee sleeve	Pre	8.200	1.798	4.368	12.032
	Immediate	4.922	1.539	1.642	8.202
	Post	4.544	1.627	1.076	8.013
Knee sleeve with patella cutout	Pre	5.338	1.907	1.273	9.402
	Immediate	3.375	1.632	-.104	6.854
	Post	3.613	1.726	-.067	7.292

Estimates

Measure: Stiffness

ALL	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Pre	6.769	1.310	3.976	9.562
Immediate	4.149	1.122	1.758	6.539
Post	4.078	1.186	1.550	6.607

Pairwise Comparisons on Points of Measurement

Measure: Stiffness

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Pre	Immediate	2.620*	.844	.022	.347	4.894
	Post	2.690*	.842	.018	.421	4.959
Immediate	Pre	-2.620*	.844	.022	-4.894	-.347
	Post	.070	.480	1.000	-1.223	1.363
Post	Pre	-2.690*	.842	.018	-4.959	-.421
	Immediate	-.070	.480	1.000	-1.363	1.223

Pairwise Comparisons on Knee Sleeves Types

Measure: Stiffness

(I) Sleeve	(J) Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	1.781	2.260	.443	-3.037	6.598
Knee Sleeve B	Knee Sleeve A	-1.781	2.260	.443	-6.598	3.037

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

Appendix J: Results – WOMAC on knee functional performance

Knee Sleeve * Point of Measurement

Mauchly's W = 0.384; The assumption for sphericity is met.

Measure: Difficulty Performing Daily Activities

Sleeve	factor1	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
Simple knee sleeve	Pre	68.856	11.316	44.736	92.975
	Immediate	53.422	10.463	31.120	75.724
	Post	34.800	10.692	12.010	57.590
Knee sleeve with patella cutout	Pre	29.850	12.003	4.267	55.433
	Immediate	21.188	11.098	-2.467	44.842
	Post	22.338	11.341	-1.835	46.510

Estimates

Measure: Difficulty

ALL	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Pre	49.353	8.248	31.773	66.933
Immediate	37.305	7.626	21.050	53.560
Post	28.569	7.793	11.958	45.180

Pairwise Comparisons on Points of Measurement

Measure: Difficulty Performing Daily Activities

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Pre	Immediate	12.048	4.650	.061	-.477	24.573
	Post	20.784*	6.292	.014	3.834	37.734
Immediate	Pre	-12.048	4.650	.061	-24.573	.477
	Post	8.736*	2.870	.025	1.006	16.466
Post	Pre	-20.784*	6.292	.014	-37.734	-3.834
	Immediate	-8.736*	2.870	.025	-16.466	-1.006

Pairwise Comparisons on Knee Sleeves Types

Measure: Difficulty Performing Daily Activities

(I) Sleeve	(J) Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	27.901	14.777	.079	-3.596	59.398
Knee Sleeve B	Knee Sleeve A	-27.901	14.777	.079	-59.398	3.596

Based on estimated marginal means

*. The mean difference is significant at the .05 level, b. Adjustment for multiple comparisons: Bonferroni.

Appendix K: Results – WOMAC Overall Score

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
WOMAC ALL Pre	Simple knee sleeve	93.6778	52.11487	9
	Knee sleeve with patella cutout	42.8125	35.59942	8
	Total	69.7412	50.96370	17
WOMAC ALL Immediate	Simple knee sleeve	69.9111	40.38290	9
	Knee sleeve with patella cutout	30.6625	45.51800	8
	Total	51.4412	46.14767	17
WOMAC ALL Post	Simple knee sleeve	47.1889	45.03500	9
	Knee sleeve with patella cutout	31.5250	40.31730	8
	Total	39.8176	42.31043	17

Mauchly's W = 0.401; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: WOMAC Overall

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Pre	Immediate	17.958*	6.209	.034	1.233	34.684
	Post	28.888*	8.529	.012	5.914	51.862
Immediate	Pre	-17.958*	6.209	.034	-34.684	-1.233
	Post	10.930*	4.021	.048	.097	21.762
Post	Pre	-28.888*	8.529	.012	-51.862	-5.914
	Immediate	-10.930*	4.021	.048	-21.762	-.097

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: WOMAC Overall

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	35.259	19.831	.096	-7.010	77.529
Knee Sleeve B	Knee Sleeve A	-35.259	19.831	.096	-77.529	7.010

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Appendix L: Results – Postural Stability Test (PST) Static

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
PST Static Pre	Simple knee sleeve	.467	.2291	9
	Knee sleeve with patella cutout	.463	.2722	8
	Total	.465	.2422	17
PST Static Immediate	Simple knee sleeve	.489	.2667	9
	Knee sleeve with patella cutout	.413	.1458	8
	Total	.453	.2154	17
PST Static Post	Simple knee sleeve	.489	.2205	9
	Knee sleeve with patella cutout	.425	.1282	8
	Total	.459	.1805	17

Mauchly's W = 0.922; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: PST Static

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Pre	Immediate	.014	.044	1.000	-.105	.133
	Post	.008	.048	1.000	-.120	.136
Immediate	Pre	-.014	.044	1.000	-.133	.105
	Post	-.006	.037	1.000	-.106	.094
Post	Pre	-.008	.048	1.000	-.136	.120
	Immediate	.006	.037	1.000	-.094	.106

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: PST Dynamic

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	.048	.094	.616	-.152	.249
Knee Sleeve B	Knee Sleeve A	-.048	.094	.616	-.249	.152

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Appendix M: Results – Postural Stability Test (PST) Dynamic

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
PST Dynamic Pre	Simple knee sleeve	1.133	.9552	9
	Knee sleeve with patella cutout	.763	.2925	8
	Total	.959	.7281	17
PST Dynamic Immediate	Simple knee sleeve	.889	.4567	9
	Knee sleeve with patella cutout	.688	.2100	8
	Total	.794	.3665	17
PST Dynamic Post	Simple knee sleeve	.789	.6153	9
	Knee sleeve with patella cutout	.725	.1669	8
	Total	.759	.4501	17

Mauchly's W = 0.639; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: PST Dynamic

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Pre	Immediate	.160	.120	.605	-.163	.482
	Post	.191	.130	.486	-.159	.541
Immediate	Pre	-.160	.120	.605	-.482	.163
	Post	.031	.070	1.000	-.158	.221
Post	Pre	-.191	.130	.486	-.541	.159
	Immediate	-.031	.070	1.000	-.221	.158

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: PST Dynamic

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	.212	.230	.370	-.277	.701
Knee Sleeve B	Knee Sleeve A	-.212	.230	.370	-.701	.277

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Appendix N: Results – Athlete Single Leg Test (ASL) Static – Affected Knee

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
ASL Static Affected Knee Pre	Simple knee sleeve	1.333	.7665	9
	Knee sleeve with patella cutout	1.200	.5155	8
	Total	1.271	.6440	17
ASL Static Affected Knee Immediate	Simple knee sleeve	1.656	1.4475	9
	Knee sleeve with patella cutout	1.038	.3159	8
	Total	1.365	1.0920	17
ASL Static Affected Knee Post	Simple knee sleeve	.800	.3317	9
	Knee sleeve with patella cutout	.950	.1604	8
	Total	.871	.2687	17

Mauchly's W = 0.700; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: ASL Static Affected Knee

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Pre	Immediate	-.080	.302	1.000	-.893	.734
	Post	.392	.189	.167	-.117	.900
Immediate	Pre	.080	.302	1.000	-.734	.893
	Post	.472	.230	.175	-.149	1.092
Post	Pre	-.392	.189	.167	-.900	.117
	Immediate	-.472	.230	.175	-1.092	.149

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: ASL Static Affected Knee

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	.200	.227	.392	-.284	.685
Knee Sleeve B	Knee Sleeve A	-.200	.227	.392	-.685	.284

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Appendix O: Results – Athlete Single Leg Test (ASL) Dynamic – Affected Knee

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
ASL Dynamic Affected Knee Pre	Simple knee sleeve	1.833	1.1435	9
	Knee sleeve with patella cutout	1.588	.6244	8
	Total	1.718	.9167	17
ASL Dynamic Affected Knee Immediate	Simple knee sleeve	1.700	1.0747	9
	Knee sleeve with patella cutout	1.225	.4950	8
	Total	1.476	.8628	17
ASL Dynamic Affected Knee Post	Simple knee sleeve	1.656	1.2953	9
	Knee sleeve with patella cutout	1.213	.5194	8
	Total	1.447	1.0044	17

Mauchly's W = 0.892; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: ASL Dynamic Affected Knee

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Pre	Immediate	.248	.263	1.000	-.462	.958
	Post	.276	.359	1.000	-.690	1.243
Immediate	Pre	-.248	.263	1.000	-.958	.462
	Post	.028	.275	1.000	-.711	.768
Post	Pre	-.276	.359	1.000	-1.243	.690
	Immediate	-.028	.275	1.000	-.768	.711

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: ASL Dynamic Affected Knee

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	.388	.292	.204	-.235	1.011
Knee Sleeve B	Knee Sleeve A	-.388	.292	.204	-1.011	.235

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Appendix P: Results – Athlete Single Leg Test (ASL) Static – Unaffected Knee

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
ASL Static Unaffected Knee Pre	Simple knee sleeve	1.125	.3495	8
	Knee sleeve with patella cutout	1.362	1.0941	8
	Total	1.244	.7941	16
ASL Static Unaffected Knee Immediate	Simple knee sleeve	1.325	.4432	8
	Knee sleeve with patella cutout	.950	.3071	8
	Total	1.138	.4161	16
ASL Static Unaffected Knee Post	Simple knee sleeve	1.100	.4811	8
	Knee sleeve with patella cutout	.788	.2295	8
	Total	.944	.3983	16

Mauchly's W = 0.394; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: ASL Static Unaffected Knee

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a] Lower Bound	Upper Bound
Pre	Immediate	.106	.176	1.000	-.372	.584
	Post	.300	.209	.519	-.268	.868
Immediate	Pre	-.106	.176	1.000	-.584	.372
	Post	.194	.082	.101	-.030	.417
Post	Pre	-.300	.209	.519	-.868	.268
	Immediate	-.194	.082	.101	-.417	.030

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: ASL Static Unaffected Knee

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a] Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	.150	.207	.480	-.294	.594
Knee Sleeve B	Knee Sleeve A	-.150	.207	.480	-.594	.294

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Appendix Q: Results – Athlete Single Leg Test (ASL) Dynamic – Unaffected Knee

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
ASL Dynamic Unaffected Knee Pre	Simple knee sleeve	1.475	.7960	8
	Knee sleeve with patella cutout	1.788	1.1192	8
	Total	1.631	.9520	16
ASL Dynamic Unaffected Knee Immediate	Simple knee sleeve	1.350	.7091	8
	Knee sleeve with patella cutout	1.475	.8828	8
	Total	1.413	.7762	16
ASL Dynamic Unaffected Knee Post	Simple knee sleeve	.850	.3338	8
	Knee sleeve with patella cutout	.925	.4652	8
	Total	.888	.3931	16

Mauchly's W = 0.894; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: ASL Dynamic Unaffected Knee

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Pre	Immediate	.219	.240	1.000	-.434	.872
	Post	.744*	.270	.047	.009	1.479
Immediate	Pre	-.219	.240	1.000	-.872	.434
	Post	.525	.202	.063	-.025	1.075
Post	Pre	-.744*	.270	.047	-1.479	-.009
	Immediate	-.525	.202	.063	-1.075	.025

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: ASL Dynamic Unaffected Knee

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	-.171	.263	.527	-.736	.394
Knee Sleeve B	Knee Sleeve A	.171	.263	.527	-.394	.736

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Appendix R: Results – Fall Risk Test (FRT)

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
FRT Pre	Simple knee sleeve	.844	.4275	9
	Knee sleeve with patella cutout	.675	.2375	8
	Total	.765	.3517	17
FRT Immediate	Simple knee sleeve	.733	.3708	9
	Knee sleeve with patella cutout	.525	.1832	8
	Total	.635	.3081	17
FRT Post	Simple knee sleeve	.722	.6180	9
	Knee sleeve with patella cutout	.663	.2825	8
	Total	.694	.4763	17

Mauchly's W = 0.787; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: FRT

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a] Lower Bound	Upper Bound
Pre	Immediate	.131	.060	.142	-.032	.293
	Post	.067	.091	1.000	-.177	.311
Immediate	Pre	-.131	.060	.142	-.293	.032
	Post	-.063	.073	1.000	-.261	.134
Post	Pre	-.067	.091	1.000	-.311	.177
	Immediate	.063	.073	1.000	-.134	.261

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: FRT

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a] Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	.146	.167	.398	-.211	.503
Knee Sleeve B	Knee Sleeve A	-.146	.167	.398	-.503	.211

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Appendix S: Results – Gait Parameters

a) Knee Adduction Moment

i) First Peak KAM

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
Pre 1st Peak KAM (Nmm/kg)	Simple knee sleeve	.8283	.55787	9
	Knee sleeve with patella cutout	.6023	.49374	8
	Total	.7219	.52515	17
Imm 1st Peak KAM (Nmm/kg)	Simple knee sleeve	.8396	.54267	9
	Knee sleeve with patella cutout	.3767	.54922	8
	Total	.6218	.57961	17
Post 1st Peak KAM (Nmm/kg)	Simple knee sleeve	.4070	.16813	9
	Knee sleeve with patella cutout	.4776	.31548	8
	Total	.4402	.24289	17

Mauchly's W = 0.964; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: FirstKAM

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a] Lower Bound	Upper Bound
Pre	Immediate	.107	.089	.744	-.133	.347
	Post	.273	.105	.061	-.011	.557
Immediate	Pre	-.107	.089	.744	-.347	.133
	Post	.166	.097	.326	-.096	.428
Post	Pre	-.273	.105	.061	-.557	.011
	Immediate	-.166	.097	.326	-.428	.096

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: FirstKAM

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a] Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	.206	.194	.305	-.207	.620
Knee Sleeve B	Knee Sleeve A	-.206	.194	.305	-.620	.207

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

ii) Second Peak KAM

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
Pre 2nd Peak KAM (Nmm/kg)	Simple knee sleeve	.5486	.37766	9
	Knee sleeve with patella cutout	.4627	.18316	8
	Total	.5082	.29656	17
Imm 2nd Peak KAM (Nmm/kg)	Simple knee sleeve	.6462	.53494	9
	Knee sleeve with patella cutout	.3569	.20588	8
	Total	.5101	.42870	17
Post 2nd Peak KAM (Nmm/kg)	Simple knee sleeve	.2193	.17749	9
	Knee sleeve with patella cutout	.3110	.17854	8
	Total	.2625	.17867	17

Mauchly's W = 0.922; The assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: SecondKAM

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Pre	Immediate	.004	.069	1.000	-.182	.191
	Post	.240*	.067	.008	.059	.422
Immediate	Pre	-.004	.069	1.000	-.191	.182
	Post	.236*	.083	.037	.012	.460
Post	Pre	-.240*	.067	.008	-.422	-.059
	Immediate	-.236*	.083	.037	-.460	-.012

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: SecondKAM

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	.095	.127	.467	-.176	.365
Knee Sleeve B	Knee Sleeve A	-.095	.127	.467	-.365	.176

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

b) Vertical Ground Reaction Force (vGRF)

i) First Peak vGRF

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
Pre 1st Peak GRF (N/kg)	Simple knee sleeve	15.2543	6.00736	9
	Knee sleeve with patella cutout	12.0588	4.46837	8
	Total	13.7505	5.42979	17
Imm 1st Peak GRF (N/kg)	Simple knee sleeve	15.9436	6.54020	9
	Knee sleeve with patella cutout	13.4713	4.89704	8
	Total	14.7801	5.78764	17
Post 1st Peak GRF (N/kg)	Simple knee sleeve	9.8267	2.06286	9
	Knee sleeve with patella cutout	10.2428	1.96175	8
	Total	10.0225	1.96398	17

Mauchly's W = 0.550; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: FirstGRF

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b] Lower Bound	95% Confidence Interval for Difference[b] Upper Bound
Pre	Immediate	-1.051	.802	.630	-3.212	1.110
	Post	3.622	1.519	.092	-.471	7.714
Immediate	Pre	1.051	.802	.630	-1.110	3.212
	Post	4.673*	1.648	.038	.233	9.112
Post	Pre	-3.622	1.519	.092	-7.714	.471
	Immediate	-4.673*	1.648	.038	-9.112	-.233

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: FirstGRF

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a] Lower Bound	95% Confidence Interval for Difference[a] Upper Bound
Knee Sleeve A	Knee Sleeve B	1.751	1.651	.306	-1.768	5.269
Knee Sleeve B	Knee Sleeve A	-1.751	1.651	.306	-5.269	1.768

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

ii) Second Peak vGRF

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
Pre 2nd Peak GRF (N/kg)	Simple knee sleeve	14.0204	5.54424	9
	Knee sleeve with patella cutout	10.8409	3.69442	8
	Total	12.5242	4.90068	17
Imm 2nd Peak GRF (N/kg)	Simple knee sleeve	14.5728	5.31582	9
	Knee sleeve with patella cutout	12.1910	4.25707	8
	Total	13.4519	4.85380	17
Post 2nd Peak GRF (N/kg)	Simple knee sleeve	9.5746	2.16850	9
	Knee sleeve with patella cutout	9.5094	1.32949	8
	Total	9.5439	1.76794	17

Mauchly's W = 0.603; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: SecondGRF

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Pre	Immediate	-.951	.723	.625	-2.900	.998
	Post	2.889	1.351	.148	-.751	6.528
Immediate	Pre	.951	.723	.625	-.998	2.900
	Post	3.840*	1.374	.041	.138	7.542
Post	Pre	-2.889	1.351	.148	-6.528	.751
	Immediate	-3.840*	1.374	.041	-7.542	-.138

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: SecondGRF

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	1.876	1.422	.207	-1.156	4.907
Knee Sleeve B	Knee Sleeve A	-1.876	1.422	.207	-4.907	1.156

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

c) Walking Speed

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
Pre Walking Speed (m/s)	Simple knee sleeve	1.0640	.15545	9
	Knee sleeve with patella cutout	1.0483	.20264	8
	Total	1.0566	.17353	17
Imm Walking Speed (m/s)	Simple knee sleeve	1.1148	.13980	9
	Knee sleeve with patella cutout	1.0193	.17735	8
	Total	1.0698	.16108	17
Post Walking Speed (m/s)	Simple knee sleeve	1.1574	.12800	9
	Knee sleeve with patella cutout	1.1351	.16701	8
	Total	1.1469	.14327	17

Mauchly's W = 0.958; the assumption of sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: WalkingSpeed

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Pre	Immediate	-.011	.026	1.000	-.081	.060
	Post	-.090*	.030	.026	-.170	-.010
Immediate	Pre	.011	.026	1.000	-.060	.081
	Post	-.079	.031	.070	-.164	.005
Post	Pre	.090*	.030	.026	.010	.170
	Immediate	.079	.031	.070	-.005	.164

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: WalkingSpeed

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	.044	.071	.542	-.107	.196
Knee Sleeve B	Knee Sleeve A	-.044	.071	.542	-.196	.107

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

d) Knee Flexion

i) Knee Flexion at Heel Strike

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
Pre Knee Flexion at Heelstrike (deg)	Simple knee sleeve	18.285	6.2932	9
	Knee sleeve with patella cutout	19.387	6.6844	8
	Total	18.803	6.2986	17
Imm Knee Flexion at Heelstrike (deg)	Simple knee sleeve	13.174	8.6864	9
	Knee sleeve with patella cutout	19.062	8.8888	8
	Total	15.945	9.0261	17
Post Knee Flexion at Heelstrike (deg)	Simple knee sleeve	14.431	7.6412	9
	Knee sleeve with patella cutout	13.573	9.0104	8
	Total	14.027	8.0565	17

Mauchly's W = 0.721; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: FlexionHST

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a] Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	-2.044	3.187	.531	-8.836	4.748
Knee Sleeve B	Knee Sleeve A	2.044	3.187	.531	-4.748	8.836

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: FlexionHST

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b] Lower Bound	Upper Bound
Pre	Immediate	2.718	1.802	.457	-2.136	7.571
	Post	4.834*	1.423	.012	1.000	8.668
Immediate	Pre	-2.718	1.802	.457	-7.571	2.136
	Post	2.116	2.279	1.000	-4.021	8.254
Post	Pre	-4.834*	1.423	.012	-8.668	-1.000
	Immediate	-2.116	2.279	1.000	-8.254	4.021

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

ii) Knee Flexion at Stance Phase

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
Pre Max Knee Flexion during Stance (deg)	Simple knee sleeve	26.144	7.0920	9
	Knee sleeve with patella cutout	28.361	8.8259	8
	Total	27.188	7.7800	17
Imm Max Knee Flexion during Stance (deg)	Simple knee sleeve	18.904	8.7874	9
	Knee sleeve with patella cutout	26.041	10.4774	8
	Total	22.263	10.0059	17
Post Max Knee Flexion during Stance (deg)	Simple knee sleeve	22.004	9.0159	9
	Knee sleeve with patella cutout	22.264	11.6675	8
	Total	22.126	10.0109	17

Mauchly's W = 0.791; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: FlexionStance

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Pre	Immediate	4.780	1.902	.072	-.344	9.904
	Post	5.119*	1.627	.020	.735	9.502
Immediate	Pre	-4.780	1.902	.072	-9.904	.344
	Post	.339	2.398	1.000	-6.121	6.798
Post	Pre	-5.119*	1.627	.020	-9.502	-.735
	Immediate	-.339	2.398	1.000	-6.798	6.121

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: FlexionStance

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	-3.205	3.914	.426	-11.546	5.137
Knee Sleeve B	Knee Sleeve A	3.205	3.914	.426	-5.137	11.546

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

iii) Knee Flexion at Swing Phase

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
Pre Max Knee Flexion during Swing (deg)	Simple knee sleeve	71.335	18.2152	9
	Knee sleeve with patella cutout	67.438	8.9467	8
	Total	69.501	14.3156	17
Imm Max Knee Flexion during Swing (deg)	Simple knee sleeve	63.994	12.0178	9
	Knee sleeve with patella cutout	66.850	12.0596	8
	Total	65.338	11.7474	17
Post Max Knee Flexion during Swing (deg)	Simple knee sleeve	64.548	18.9321	9
	Knee sleeve with patella cutout	62.544	11.6082	8
	Total	63.605	15.4670	17

Mauchly's W = 0.919; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: FlexionSwing

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Pre	Immediate	3.965	2.665	.473	-3.214	11.143
	Post	5.841	2.459	.094	-.784	12.465
Immediate	Pre	-3.965	2.665	.473	-11.143	3.214
	Post	1.876	3.114	1.000	-6.513	10.265
Post	Pre	-5.841	2.459	.094	-12.465	.784
	Immediate	-1.876	3.114	1.000	-10.265	6.513

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: FlexionSwing

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	1.015	6.173	.872	-12.143	14.173
Knee Sleeve B	Knee Sleeve A	-1.015	6.173	.872	-14.173	12.143

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

iv) Knee Flexion Range of Motion (ROM)

Descriptive Statistics

	Knee Sleeve	Mean	Std. Deviation	N
Pre Range of Flexion/Extension (deg)	Simple knee sleeve	57.4041	13.95964	9
	Knee sleeve with patella cutout	53.9039	9.26122	8
	Total	55.7569	11.75598	17
Imm Range of Flexion/Extension (deg)	Simple knee sleeve	53.8600	7.35028	9
	Knee sleeve with patella cutout	54.9349	11.82905	8
	Total	54.3658	9.40941	17
Post Range of Flexion/Extension (deg)	Simple knee sleeve	54.0705	13.79135	9
	Knee sleeve with patella cutout	54.9287	6.96343	8
	Total	54.4744	10.79396	17

Mauchly's W = 0.990; the assumption for sphericity is met.

Pairwise Comparisons on Points of Measurement

Measure: FlexionROM

(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Pre	Immediate	1.257	2.242	1.000	-4.784	7.297
	Post	1.154	2.404	1.000	-5.321	7.630
Immediate	Pre	-1.257	2.242	1.000	-7.297	4.784
	Post	-.102	2.442	1.000	-6.680	6.475
Post	Pre	-1.154	2.404	1.000	-7.630	5.321
	Immediate	.102	2.442	1.000	-6.475	6.680

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Pairwise Comparisons on Knee Sleeves Types

Measure: FlexionROM

(I) Knee Sleeve	(J) Knee Sleeve	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Knee Sleeve A	Knee Sleeve B	.522	4.588	.911	-9.256	10.301
Knee Sleeve B	Knee Sleeve A	-.522	4.588	.911	-10.301	9.256

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

Appendix T: Method – Plug-In-Gait Modelling (using Vicon Nexus 2.5.1)

This section contains the computation formulae of parameters which are related with this study. Retrieved from: https://docs.vicon.com/display/Nexus25

Terms (in Vicon)	**Definition**
GroundReactionForce	The force exchanged between the foot and the ground while walking. Note: **Ground Reaction force Z will look similar to Ankle Force X** **Ground Reaction Force Y will look similar to Ankle Force Z** **Ground Reaction Force X will look similar to Ankle Force Y**
NormalizedGRF	The ground reaction force expressed as a percentage of the body weight.
KneeMoment	The moment between the thigh and the shank.
KneeForce	The force between the thigh and the shank.
KneeAngles	Relative. The angles between the thigh and the shank.

In Plug-in Gait, we use an external moment and force description. That means that:

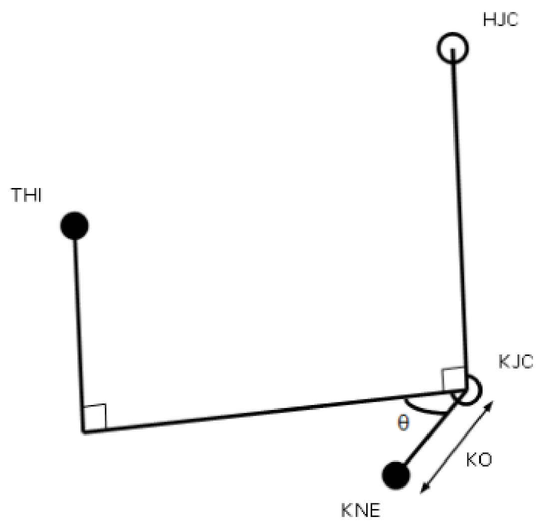
- For the Z axis, a negative force is compression and a positive force, tension
- For the Y axis, a positive force for the right side is medial and negative lateral
- For the X axis, a positive force is anterior and negative posterior

Formulae:

$$\boldsymbol{Walking\ speed\ (m\ s^{-1}) = \frac{Stride\ length\ (m)}{Stride\ time\ (s)}} \quad \textbf{(1)}$$

$$\boldsymbol{Ground\ reaction\ force\ (N) = Body\ mass\ (kg) x\ Gravity\ (\frac{N}{kg})} \quad \textbf{(2)}$$

$$\boldsymbol{Knee\ adduction\ moment\ (N\ m) = GRF\ (n)\ x\ Distance\ of\ knee\ center\ from\ the\ midline\ to\ the\ knee\ marker\ (m) = same\ as\ the\ thigh\ wand\ offset\ angle\ (Refer\ figure\ below).} \quad \textbf{(3)}$$



In the dynamic model, the KJC is determined using the modified chord function, from the global position of the HJC, the thigh wand marker (THI), and the knee marker (KNE), together with the knee offset (KO), and thigh wand angle offset (θ) from the subject measurements. KJC is found such that the KNE marker is at a distance of KO from the KJC, in a direction perpendicular to the line from the HJC to KJC. It is also found such that the angle between the KJC-KNE line and the KJC-THI line, projected onto a plane perpendicular to the HJC-KJC line, is the same as the thigh wand offset angle.