A. Study Title:

Can proprioceptive knee brace improve functional outcome following total knee arthroplasty?

B. Introduction:

Osteoarthritis is among the most prevalent form of degenerative joint disease in arthritis (1). The World Health Organisation identified osteoarthritis as one of the top ten most disabling cause of disease in developed countries (2), and the single most common cause of disability for elderly persons (3). In fact, worldwide statistics for men and women over 60 years of age with signs of symptomatic osteoarthritis are estimated to be at 9.6% and 18.0% respectively (2). In Hong Kong, the latest census revealed that 514,000 people suffer from degenerative arthritis, representing 0.7% of the population (4). Although these values are much lower than the international figures reported by the WHO, it is inevitable that the prevalence of osteoarthritis will continue to rise with an increasing trend of obesity and an aging population in Hong Kong (5, 6). Similar to any other chronic disease with wide prevalence, the impact of osteoarthritis translates to a substantial socioeconomic burden on a societal level.

Total knee arthroplasty has become the gold standard to manage the pain and disability associated with end-stage arthritis who have exhausted all conservative measures. Although contemporary advances in prosthesis design, surgical techniques, postoperative rehabilitation regimes have hasten patient's recovery, the restoration of proprioception and neuromuscular control is often prolonged despite solid rehabilitation regimes(7, 8) .

Knee bracing is one of the non-pharmacological modalities designed to evenly distribute load and provide proprioceptive feedbacks for those with knee injuries or knee pain (9-11). There are four categories of knee braces for the purpose of prophylactic, functional, rehabilitative and unloader/off-load. This study will mainly be focusing on the effects of the unloader/off-loader brace. Previous studies have demonstrated the effects on alteration of kinematic variables, including range of movement ($p=0.002$), speed of walking ($p<0.001$) and knee adduction moment ($p=0.001$) for knee injuries and osteoarthritis (12, 13) as a part of the conservative management protocol. However, there have few studies (14) that investigated whether proprioceptive knee bracing has any role in functional recovery post total knee arthroplasty.

C. Aims and Hypotheses to be tested:

This proposed research study aims to conduct a randomised control trial to evaluate the functional outcomes of the utilisation of proprioceptive knee brace following total knee arthroplasty.

D. Description of the knee unloader brace:

For the intervention group that randomly consisted of 15 subjects will be using a design of knee brace (Reaction Web®; DonJoy, Vista, CA). The elastomeric web design helps to reduce pain by dispersing load across the knee. The web acts like a spring to absorb shock and shifts the peak loads away from the painful area of the knee. Elastomeric web acts to dynamically stabilise the patella on all sides, bringing the patella into proper tracking position to reduce pain for patients with general patellofemoral instabilities. Reaction Web® has dual-axis hinges that are flexible, creating synergy with the elastomeric web for optimal fit and support, and providing energy dispersion to the knee.

(The above information was retrieved from DonJoy website)

E. Plan of Investigation:

30 patients with end stage knee OA who are schedule for TKA will be recruited via face to face promotion from the Li Ka Shing Orthopaedics Specialist clinic at the Department of Orthopaedics and Traumatology at Prince of Wales Hospital (PWH) Hong Kong. 15 patients will be randomly allocated to each of the treatment (proprioceptive knee brace + routine post-operative procedures) and control (routine post-operative procedures) groups.

Part 1a. Preliminary assessment on patients from Prince of Wales Hospital Orthopaedics specialist clinic based on inclusion and exclusion criteria

Part 1b. Preliminary assessment on patients [i.e. Basic demographics, Knee Function Assessment, Outcome Measurement Questionnaires]

Part 1c. Randomise allocation between treatment and control group

Part 2. Peri-operative assessment [i.e. Length of Hospital Stay]

Part 3. Distribution of knee brace (available to treatment arm) post-operative 2 to 4 week recovery

Part 4a. Post-operative 6 weeks Assessment

Part 4b. Post-operative 6 months Assessment

Part 4c. Post-operative 12 months Assessment

F. Methods:

(1) Post recruitment assessment
After recruitment, oral and written consents will be obtained from individuals who agree to participate in the study. The recruitment period will last for 12 months and the whole project period is 2 years in total. Basic Demographics, Knee Function Assessment and Physical Activity Questionnaires will be carried out.

Inclusion criteria - Patients are included in the experiment if

(1) Adult (age over 18 years old) underwent Total Knee Arthroplasty within 2 to 4 weeks;
(2) Adult who is able to provide written consent and compliance with treatment and assessment regime

Exclusion criteria - Patients are excluded from the experiment if

(3) Patients with disabilities, wheelchair dependence for mobility;
(4) Underwent revision Total Knee Arthroplasty;
(5) Found with complication wounds following surgery;
(6) Diagnosed with comorbidities e.g. inflammatory arthritis, obesity, dermatological disorders that might affect their compliance to treatment;
(7) Do not fit to the sizes of knee braces;
(8) Not to given written consent and be non-compliance with the treatment and assessment regime

Sample Size Estimation

The sample size estimation was calculated using GPower 3.1 based on the yearly admission total knee replacement cases at Prince of Wales hospital. Effect size was calculated at 0.5. With 95% power and an alpha value of 0.05, 12 participants are required for each of the study control and intervention groups. An additional 25% will be added to account for possible attrition. Total 30 (15x2) subjects will be recruited for this study.

Basic Demographics

Pre-operation baseline demographics will be collected for inter-patient comparisons:
1. Gender
2. Age
3. Height, Weight and Body Mass Index
4. Duration of Symptomatic Knee OA
5. Ethnicity

Knee Function Assessment

1. Speed of motion

The 10-meter timed walking test is a well-established and documented test for assessment for gait speed in patients. However, due to space limitations and the exhaustive nature of the test for patients with OA, the **6-meter test timed walking gait test** has been documented to be a valid and reliable substitute. Patients will be asked to walk a straight line of 6 meters where the time taken to complete the distance will be measured. (<7.5 seconds is normal).

The **Time up and go test (TUG)** is to determine fall risk and measure the progress of balance, sit to stand and walking. Patients will be asked to stand up from a chair, walk as quickly as possible in their a safe and most comfortable gait until they pass to 3 meters (10 feet) end of marked course with both feet. Turn around and walk back to the chair, time will be counted to the moment until the back of patients touches the back of the chair. (≤ 10 seconds = normal; ≤ 20 seconds = good mobility, can go out alone, mobile without gait aid; ≤ 30 seconds = problems, cannot go outside alone, requires gait aid; ≥ 14seconds indicates high risk of falls)

2. Range of motion

The **active range of motion test** predicts the mobility of the joint by measuring the amount of active knee extension and flexion. “For measurement using the goniometer, 1 arm of the goniometer is placed parallel to the shaft of the femur lining up with the greater trochanter, and the other arm is placed parallel to the shaft of the lower leg lining up with the lateral malleolus of the fibula. The axis of the goniometer is placed over the lateral femoral epicondyle. Knee extension: The patient is supine. The heel of the limb of interest is propped on a bolster, assuring the back of the knee and calf are not touching the support surface. The patient is asked to actively contract the quadriceps. The amount of knee extension is recorded with the goniometer. Knee flexion: The patient is prone. The patient flexes the knee as far as possible. The amount of knee flexion is recorded with the goniometer.”(15)

3. Knee Stability test

KT-1000 will be used at the assessing of knee laxity as it provides an objective evaluation of knee stability resulting from the automated anterior drawer test it performs.

4. Knee extensor/flexor strength
Muscle strength on the quadriceps is measured by instructing the patient to perform an active knee extension movement in a sitting position with both feet free from ground, and the hip and knee joint flexed at 90%. The optimal isometric force of the knee extension/flexion movement is measured by the dynamometer attached at the malleoli level with a strap.
The measurements will be taken at maximum force for three times.

Physical Activity Questionnaires

Patient's health related quality of life (HRQoL) will be assessed through three validated and reliable questionnaires (i.e. SF-12, WOMAC).

1. Short-Form 12 (SF-12)
The SF-12 health survey uses 12 questions to measure patient's functional health and well-being from a patient's point of view. It is reliable and validated measure that summaries the patients' physical and mental health.

2. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)
The WOMAC questionnaire is a questionnaire that measures patient's pain, stiffness and physical function and can be summed up into a score out of 96. A high score indicates a more disabled participant.

3. The Forgotten Joint Score-12
The FJS-12 comprise measures for the assessment of joint-specific patient-reported outcome in their ability to forget about a joint as a result of successful treatment. Join awareness can be simply defined as any unintended perception of a joint. This may include strong sensation sensations like pain, but also includes more subtle feelings like mild stiffness, subjective dysfunction, or any discomfort.

4. Knee Society Score (KSS), Knee Society Function Score (KFS)
The KSS is an instrument assessing patient's pain and functionality based on a series of questions interviewed by a clinician. The validated questionnaire combines the objective physician derived component with a subjective patient derived component which evaluates pain, functionality, satisfaction and fulfillment of expectations. The results will be calculating the total score with 100 being the highest and 0 the lowest.

Physical Assessments	**Prep-op**	**6 weeks**	**6 months**	**12 months**

6m gait	✓	✓	✓	✓
TUG	✓	✓	✓	✓
Active ROM	✓	✓	✓	✓
KT-1000	✓	✓	✓	✓
Knee extensor/flexor	✓	✓	✓	✓
SF12	✓	✓	✓	✓
WOMAC	✓	✓	✓	✓
KSS & KFS	✓	✓	✓	✓
Compliance assessment	✓	✓	✓	✓
Satisfaction Survey	✓	✓	✓	✓

Clinical Research Compliance assessment will be conducted to measures the period and amount of time designated knee brace has been put on as interventional means. It is also recorded to the attendance of routine post-operative procedures of physiotherapy training one might receive.

Patients satisfaction Survey is to be recorded in terms not only how well to the quality of care patient was being treated, but to also the content a patient is with the care they received.

Data Processing and Statistical Analysis:

Demographic characteristics will be demonstrated using Student t-test or Chi-square test for continuous data and categorical data respectively where appropriate. The accuracy of primary measurements between the treatment (proprioceptive knee brace + routine post-operative procedures) and control (routine post-operative procedures) groups at the 4 time points (Pre-operative, 6 weeks, 6 months, 12 months) will be compared using ANOVA. Secondary outcomes and different types of patient-oriented quality of life questionnaires collected at the 4 time points will be compared using ANOVA likewise. All statistical analysis will be carried out using IBM SPSS version 25 (Armonk, NY:IBM Corp).

Primary outcome:

- ***Speed/range of motions of the knee.***

Secondary outcome:

- ***Patient's clinical outcome (knee stability and function), HRQoL and satisfaction. Complications and adverse events.***

This study is stated in compliance with Declaration of Helsinki and ICH-GCP.

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