Department of Orthopaedics & Traumatology
The Chinese University of Hong Kong
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Clinical Research Study –Can proprioceptive knee brace improve functional outcome following total knee arthroplasty? **– Inform Consent Form**

Information Sheet

The Department of Orthopedics and Traumatology in the Chinese University of Hong Kong is conducting a research project to evaluate the effectiveness and efficacy of knee bracing on patients that have undergone total knee arthroplasty in recovery state. The aim of this study is to investigate whether the combination of the treatment (proprioceptive knee brace + routine post-operative procedures) would demonstrate a superiority over + routine post-operative procedures alone in the management of knee functional recovery post-operatively.

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.

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. 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 as a part of the conservative management protocol. However, there have few studies that investigated whether proprioceptive knee bracing has any role in functional recovery post total knee arthroplasty.

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 Group 1 (proprioceptive knee brace + routine post-operative procedures) and control Group 2 (routine post-operative procedures).

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 brace to treatment group at day 1 following total knee arthroplasty

Part 4. Use of knee brace when ambulating from post-operation day 1 to week 6

Part 5a. Post-operative 6 weeks Assessment

Part 5b. Post-operative 6 months Assessment

Part 5c. Post-operative 12 months Assessment

We would like to invite you to participate in this randomized control study. It is entirely voluntary. This study will recruit patients that have recently undergone total knee arthroplasty who are able to comply with the research inclusion and exclusion criteria. You will be randomly assigned to two different groups. Group 1 patients will receive proprioceptive knee brace along with routine post-operative procedures care, whereas patients in group 2 will routine post-operative procedures care alone. Both groups would be scheduled with routine knee functional assessments for out-patient clinic at Prince of Wales Hospital, Hong Kong. All patients will be given standard medical treatment for pain relief and physiotherapy referral.

Group 1 subjects will be assigned with a set of Reaction Web® proprioceptive knee brace (DonJoy, Vista, CA). The elastomeric knee web design is to help reduce pain by dispersing energy across the knee by acting as a spring to absorb shock and shifts the peak loads away from the painful area of the knee. Elastomeric web functions to dynamically stabilise the patella on all sides, bring 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.

Inclusion criteria - Patients are included in the experiment if

(1) Adult (age over 18 years old) underwent Total Knee Arthroplasty within 2 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

(1) Underwent revision Total Knee Arthroplasty;
(2) Found with complication wounds following surgery;
(3) Diagnosed with comorbidities e.g. inflammatory arthritis, obesity, dermatological disorders that might affect their compliance to treatment;

A total of 30 subjects are needed for this study. If you are willing to participate in this study, you will be undergoing three extra non-invasive knee functional assessment sessions including measures of:

1. Speed of motion **2.** Range of motion **3.** Knee Stability test **4.** Knee extensor strength **5.** Physical activity questionnaire assessment.

Those assessments will be conducted at baseline enrolment, 6 weeks, 6 months and 12 months post-surgery. Questionnaire on quality of life and treatment satisfaction will be done at the last assessment. Each assessment will last for 20 -30mins.

Assessment types	**Measurements**	**Method**
Active range of motion test	Range of motion	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.
6-meter walking test / Time up and go test	Speed of motion	Walk at normal speed for 6 meters / stand up from a chair, walk as quickly as possible for 3 meters (10 feet) end of marked course with both feet.
KT 1000	Knee Stability test	Assessment of knee laxity from the automated anterior drawer test it performs.
Knee extensor/flexor	Muscle strength	The optimal isometric force of the knee extension/flexion movement is measured by the dynamometer attached at the malleoli level with a strap.
Physical activity questionnaire	Quality of life	1) Forgotten Joint Score – 12 2) WOMAC Osteoarthritis Index 3) 12-Item Short Form Survey 4) Knee Society and function Score

Benefits to the Participants and society:

This study will help explore the effectiveness and efficacy of knee bracing on patients that have undergone total knee arthroplasty in recovery state, and help better understanding the treatment in the management of post-TKA care and provide evidence for its use. It will reduce the individual and societal burdens caused by osteoarthritis knee pain in the long run.

Potential Risks:

This project has no potential risk of threat to health and life. Skin allergy (i.e uneasiness of wear, poor fit of size, skin irritation, and excessive sweating) may occur to individual subjects with knee bracing whom would be monitored closely.

Treatment Charge:

All assessments and measurements in this study are free of charge. Participants will not receive any financial benefits. You have the right to terminate at any stage within the study. Your participation or not will not affect the medical service provided in this hospital.

Management of Data:

All the information collected will be coded and analyzed for this research study. They will be kept strictly confidential. Personal data will be kept for 5 years after the study for future reference and journal submission. Information could only be accessed by related research staff, regulatory authorities and ethics committee.

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1. I hereby declare that I am willing to participate in a research project called “Can proprioceptive knee brace improve functional outcome following total knee arthroplasty?" and follow the research guidelines.

2. I have read the Participant Notice and the "Informed Consent Form - Study Description". The researcher has also explained in detail the nature of the project, the time of participation and all possible side effects, and informed me of the matters that need to be involved.

3. I understand the purpose and risks of this research project and understand that the treatments involved do not guarantee complete recovery.

4. The doctors participating in this research project have explained and explained to me in detail the risks they may face in receiving vibration therapy. I understand that I will not face any health potential risks other than potential skin allergy (i.e uneasiness of wear, poor fit of size, skin irritation, and excessive sweating) may occur to individual subjects with knee bracing.

5. I am willing to work with the healthcare professional responsible for this research project and report any unpredictable or unusual symptoms to them as soon as possible.

6. I understand that this research project is covered by the insurance of the Chinese University of Hong Kong.

7. I understand that this research project has been approved by the Joint Committee on Clinical Research Ethics.

8. I understand that participation in this research as a volunteer is purely voluntary and does not require any penalty if I participate in the suspension of cooperation.

9. I agree that the results of the research will be disclosed to the competent authorities, and personal information such as my name and address will be kept strictly confidential.

10. Once this document has been signed, I agree that I will be able to review my clinical report by a qualified appointee.

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(Patient Full Name)	(Patient HKID)
(Patient Signature)	(Date)

(Doctor's name - the name of the consenter’s interpreter)		(Doctor’s Number)

(Doctor's Name - Signature of the Consent Interpreter)		(Date)