Research proposal

Prospective randomized study on the effects of valgus knee brace for knee osteoarthritis in Chinese patients

Principal Investigator: Dr WAN Keith Hay-Man, Resident Specialist

List of Co-investigators: Dr CHOI Siu Tong, Associate Consultant
Dr WONG Kam Kwong, Consultant

Department of Orthopaedics and Traumatology, Kwong Wah Hospital

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Aim of study

Osteoarthritis of the knee is the commonest type of arthritis affecting both the middle age and geriatric population, which poses a huge burden to our in-patient and out-patient orthopaedic services. Conservative treatment like physiotherapy and analgesic provide temporary symptomatic relief. Surgical treatment like high tibial osteotomy and knee arthroplasty are not without major potential surgical risks and implant-related complications.

Orthotic treatment can theoretically alter the loading to the knee joint and help to reduce the symptoms and disease progression. Small scale biomechanical studies have demonstrated such effects with the use of valgus knee brace (2-4). Though prospective clinical outcome studies on Chinese patients in our locality are lacking.

Valgus knee brace is a non-pharmaceutical, non-invasive option for knee pain. Using a three-point leverage the unloader brace is to shift the stress away from the arthritic area to the normal portion of the knee, maintains good alignment and stability and thus provides significant pain relief during daily activities. It has been commonly used as a first line management option in other countries.

Our aim is to perform a prospective randomized study to look at the difference in outcome measures in osteoarthritic patients with the use of valgus knee brace, on top of the usual regime of conservative treatment.

Materials and Methods

The present study protocol will be submitted to the Research Ethics Committee (Kowloon Central/Kowloon East) for review. It would be a multi-disciplinary project with the

contribution from the physiotherapy department and occupational therapy department.

We aim to recruit 45 consecutive patients with symptomatic isolated medial knee osteoarthritis, who are referred to our knee arthritis clinic as new cases. We expect a drop-out rate of 10%. Upon randomization into a 1:1 ratio using sequentially numbered sealed envelopes, patients will be assigned to either a knee brace group, or a control group. Patients in control group will receive conservative treatment of physiotherapy with a standardized, protocol-driven knee osteoarthritis programme. Patients in the knee brace group will receive the same treatment, with the additional use of valgus off-load knee brace (OA corrector). They are advised to wear the knee brace for a minimum of four hours a day, excluding the time when they are sleeping. To ensure proper usage of the knee brace patients in the knee brace group will have a demonstration session by occupational therapists. They will be asked to put on the knee braces in front of the therapists at the beginning of the study period. Patient will be followed up at 8 weeks and 16 weeks. The time frame for study will be 16 weeks.

At the end of the study, upon request, we may consider giving the knee braces to the patients if they find them useful.

Inclusion criteria:

- Age between 40-80
- History of symptomatic medial unicompartmental knee osteoarthritis > 6 months
- Willingness to wear the knee brace for a minimum of 4 hours per day during daily activities
- Understanding of the Chinese language
- Ethnic Chinese patients

Exclusion criteria:

- Symptomatic knee osteoarthritis affecting more than one compartment
- Clinical and radiological signs of osteoarthritis over the lateral compartment or patello-femoral joint
- Significant knee effusion or soft tissue compromise preventing long-term knee brace use
- Obesity (BMI>30)
- Previous surgery on the affected knee other than diagnostic arthroscopy with debridement, soft tissue reconstruction, menisectomy
- Peripheral vascular disease of the lower limb

Outcome measures would include assessment of **pain**, including visual analogue scale (VAS), analgesic use (number of times required per week); **stability** in terms of improvement of limping gait assessed by orthopaedic surgeons; and **functioning** by the Western Ontario and McMaster Arthritis Index (WOMAC). ANOVA test will be used for statistical analysis. Outcome assessors will be blinded.

Implication

Osteoarthritis of the knee is not only a common and debilitating problem affecting the geriatric population, it is also not uncommonly seen in the middle age patient group with significant hindrance to their quality of life.

The current literature recommendations for the use of orthotic treatment for medial compartment knee osteoarthritis are still varied (5,6). Valgus off-load knee bracing is a non-invasive, non-pharmaceutical option for medial knee osteoarthritis.

By performing this prospective study we would be able to tell if there is any additional benefits with the use of bracing in patients with medial compartment knee osteoarthritis.

Time-frame for the research

1/9/2019 - 31/12/2020	Recruit 45 consecutive patients with medial compartment knee osteoarthritis
1/1/2021 – 31/3/2021	Data analysis for the study
1/4/2020– 30/6/2020	Progress report and result publication of the study
30/6/2021	Final report submission date to REC(KC/KE)

Ethical Concern

Personal data is kept anonymous with identifiable code on study document and will follow the HA policy on handling of patient data privacy. They would be locked in cabinets where the department or ward keeps patients' confidential information. Electronic data should be saved in secured computer of the hospital with restricted access.

Reference:

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2. Pollo FE, Otis JC, Backus SI, Warren RF, Wickiewicz TL. Reduction of medial compartment loads with valgus bracing of the osteoarthritic knee. Am J Sports Med 2002;30:414-21.
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6. Jevsevar DS, Brown GA, Jones DL, et al. The American Academy of Orthopaedic Surgeons evidence-based guideline on: treatment of osteoarthritis of the knee, 2nd edition. J Bone Joint Surg Am 2013;95:1885-6.