Utility gain in orthotic treatment for osteoarthritis knee - preliminary results of a prospective randomized control study

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Introduction
In Hong Kong, prevalence of osteoarthritis (OA) knee is 7%-13% in aged men and women ≥50 years, respectively. OA knee causes pain, disability, and quality of life (QOL) impact to patients, and social and emotional burden on their caretakers. Unloading the symptomatic knee compartment using orthosis may help in pain reduction and QOL improvement.

Objectives
To measure the desirable health outcome, termed utility gained, and pain reduction for OA knee with orthotic treatment in a prospective randomized controlled study (RCT)

Methodology
Subjects with painful & moderately degenerated medial knee OA (i.e. Kellgren and Lawrence stage 2 or 3) were recruited. Subjects were randomized into intervention (Hardgp) and sham group (Softgp) by a sealed envelope. An innovative orthosis using ankle brace with lateral-wedged insole (hard insole for Hardgp and soft insole for Softgp) were fitted. No subjects had other treatment within previous 3 months or plan for knee surgery. SF-36 and knee pain (VAS), were documented at baseline, 1-month, 3-month and 6-month. SF-6D utility score (Utility) were converted from SF-36 and computed by area under the Utility-duration graph. Higher utility represent greater QOL.

Result
In this preliminary report, Utility during the 6-months orthotic treatment period was 0.287 and 0.335 in the Hardgp (N=7) and Softgp (N=6), respectively. Mean age 64 years. Non-parametric test showed that Softgp imparted an expected utility gain of 0.049 with statistical significant, compared with the Hardgp. (Mann-Whitney U-test, p≤0.05, Z-score=-2.07). In 6-months, pain reduction (VAS/10) was reported from 6.7 to 3.6 (i.e. 49%) and 4.1 to 2.4 (i.e. 41%) in Hardgp and Softgp, respectively. Averaged pain reduction is 45%. According to Walters and Brazier (2005), minimal important difference (MID) of utility for effective OA knee treatment is 0.035. Subjects managed with ankle brace and soft insole imparted an superior utility gain of 0.049 in 6-months, which satisfy the MID threshold. Based on the results of the first 13 subjects, orthotic treatment is effective in improvement of QOL for moderate deformed medial knee OA and reduction of pain by 45% in 6-months. The study is on-going with larger sample size in QEH.