# Knee Pain, Structure and Function after One Year of Unloader® Bracing For Medial Knee Osteoarthritis

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## INTRODUCTION

Medial knee osteoarthritis (OA) is commonly associated with a genu varum deformity. Surgical realignment of genu varum is aimed to shift the **mechanical axis of the lower limb** (Figure 1) towards the knee center, and thus, distribute the joint stresses more laterally, and off-load the medial compartment. The *"unloading"* type braces are intended to achieve the same objective conservatively.

## BACKGROUND & SIGNIFICANCE

- Unloading knee braces are designed to apply a corrective moment *via* a three-point bending mechanism (Figure 1).
- The mechanical effects of unloading braces are not well understood.
- The effectiveness of the newer light-weight Unloader® One brace with dual dynamic straps has not been adequately evaluated beyond six months.

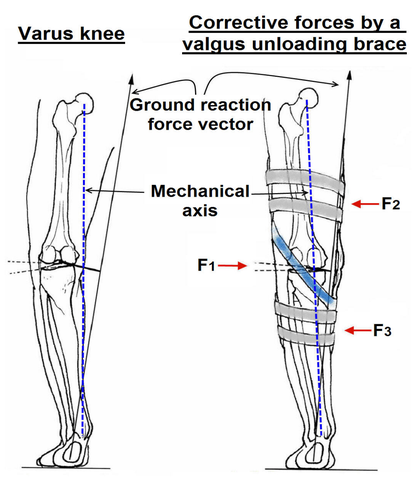


**Figure 1: Three point bending mechanism of unloading knee braces**

**Purpose:**

To assess the effect of a 12 month course of unloading brace therapy on knee pain, structure and subjective function in medial knee OA.

**Hypothesis:**

***There will be significant reduction of knee pain, and improvement of subjective knee function and structure at successive visits as compared to baseline.***

## METHODS

- Six unilaterally symptomatic medial knee OA subjects (4 males, 2 females, 66 ± 8 yrs, 79.1 ± 8.2 kg, 1.7 ± 0.1 m)
- Custom Össur Unloader® One brace (Figure 2) therapy for subject's symptomatic knee for 6 hours/day and 5 days a week for 12 months
- Standardized neutral walking shoes (New Balance 576)

**Figure 2: Unloader® One Brace**

- **Patients' Self-reported Questionnaires:**
  - Visual-Analog-Scale (VAS) knee pain (Figure 3a) recorded following:
    - stair ascent/ descent
    - 50 feet comfortable speed walking
    - 50 feet fast speed walking
  - Knee Injury and Osteoarthritis Outcome Score: (KOOS; Figure 3b)
    - knee pain
    - other symptoms
    - function during activities of daily living
    - function during sports & recreational activities
    - overall quality of life
- **Radiographic assessment:**
  - Kellgren-Lawrence (K-L) grade
  - tibio-femoral angle
  - joint space
- **Statistical analysis:**
  - Repeated-measures ANOVA followed by *post-hoc* LSD test for between-visit comparisons
  - Significance at $\alpha < 0.1$ (since this is a preliminary study)

## RESULTS

**As compared to baseline:**

- **The mean VAS values (Figure 3) for knee pain following:**
  - **stair climbing** (ANOVA p value = 0.06) were significantly reduced at 1 week (p = 0.09), 4 months (p = 0.03) and 12 months (p = 0.08)
  - **comfortable speed walking** (ANOVA p value = 0.01) were reduced at 1 week (p = 0.04), 4 months (p = 0.03) and 12 months (p = 0.05)
  - **fast walking** (ANOVA p value = 0.07) were reduced only at 1 week (p = .051)

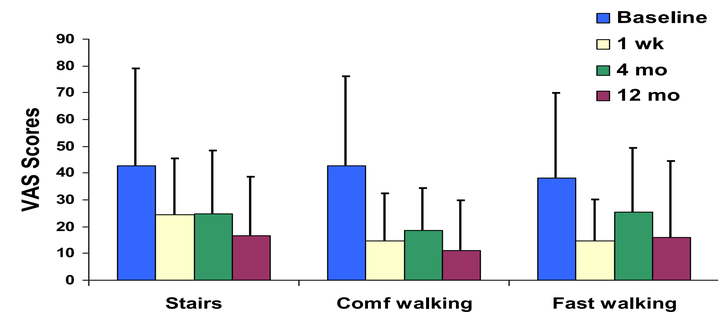


**Figure 3: VAS scores over time (n=6)**
*Smaller VAS values imply functional improvement*

- **The mean KOOS values (Figure 4) for:**
  - **knee pain** (ANOVA p value = 0.06) were improved at 4 months (p = 0.06)
  - **other knee symptoms** were not improved (ANOVA p value = 0.45)
  - **function during activities of daily living** were not improved (ANOVA p value = 0.36 ) improved at subsequent visits
  - **function during sports and recreation** (ANOVA p value = 0.46) were not improved at subsequent visits
  - **quality of life** (ANOVA p value = 0.04) were improved at 12 months (p = 0.066).

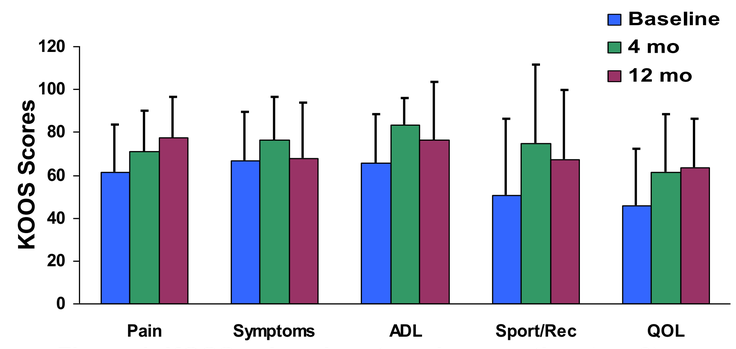


**Figure 4: KOOS subscale categories over time (n = 6)**
Increased KOOS values imply functional improvement

- **Radiographic Measurements (Figure 5):**
  - **The K-L grade, tibio-femoral angle** and **knee joint space** were not statistically different between the baseline and 12 month follow-up visits.

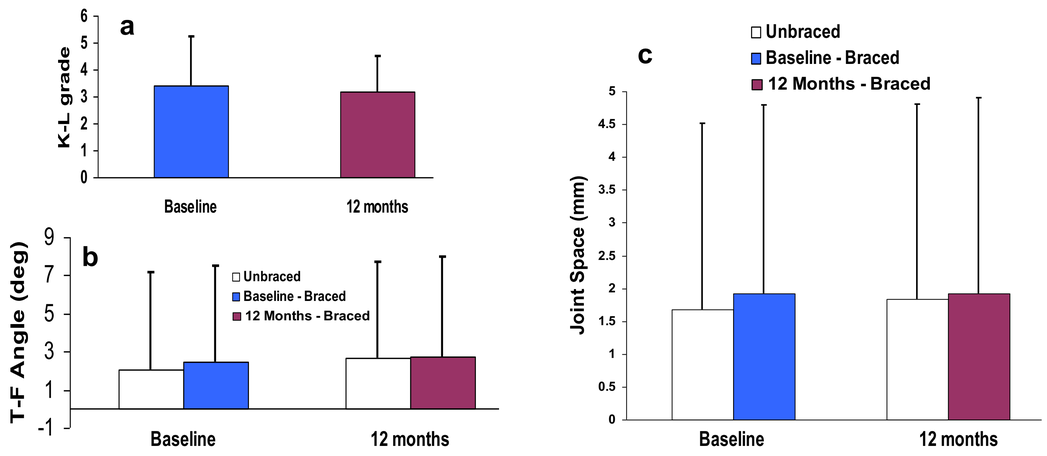


**Figure 5: Radiographic measurements a) K-L grade b) Tibio-femoral angle c) Joint space**

## CONCLUSIONS

- We observed **significant knee pain reduction** and subjective **functional improvement** with Unloader® One brace therapy for varus knee OA at 4 and 12 months, based on VAS and several KOOS subcategories. These findings corroborate with several previous studies[1-3].
- **No significant radiographic changes** in our study, albeit limited sample size, may also be indicative of favorable outcome of brace therapy.
- Radiographic changes have been observed as early as 18 months in past studies[4]. Therefore, longer-term data from additional subjects will be helpful to derive definitive conclusions regarding the effects of Unloader® brace therapy on progression of knee OA.

## REFERENCES

[1] Kirkley et al., JBJS, 81(4):539-47, 1999
[2] Briggs et al., AAOS, New Orleans, LA, March 2010
[3] Ingvarsson et al. AAOS, New Orleans, LA, March 2010
[4] Sharma et al., *JAMA*;286(2):188-195, 2001

## ACKNOWLEDGEMENTS

Össur Americas and New Balance - for providing braces and shoes resp.