Biomechanical and clinical outcomes with shock absorbing insoles in patients with knee osteoarthritis: Immediate effects and changes following one month of wear

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Agenda:

1) Introduction to OA
2) Previous interventions
3) Study Rationale
4) Methods
5) Results
6) Discussion
7) Conclusions/Future considerations
Osteoarthritis Facts:

- degenerative joint disease affecting hands and weight bearing joints

  - knee most commonly affected

  - affecting 1 in 10 Canadians

- no cure for OA

Characteristics of OA:

- degradation of articular cartilage, menisci & subchondral bone
- progressive
- joint pain, stiffness, localized swelling
- ↓ physical function
OA and Walking:

- walking implicated in progression of OA due to repetitive nature\textsuperscript{3,4}

- higher loads in medial compartment cause ↑ breakdown of articular cartilage and more severe disease\textsuperscript{5,6}

How is load measured?

- Knee adduction moment (KAM) → indirect measure of medial tibiofemoral loading\(^7,8\)

- \( \text{KAM} = \text{ground reaction force (GRF)} \times \text{lever arm} \)\(^9\)

- Increased KAM at stance → changes in joint structure and more severe disease\(^{10,11}\)

Valgus bracing: improves pain, function\textsuperscript{12,13} and reduces KAM\textsuperscript{14,15}, but expensive and cumbersome\textsuperscript{16}

Variable stiffness footwear: uses varying material properties to make shoe stiffer on lateral side\textsuperscript{17}

Lateral wedged insoles: unload medial compartment by shifting load laterally\textsuperscript{18}; can be off the shelf or custom made\textsuperscript{19,20}

High tibial osteotomy: redistributes weight bearing forces, reduces pain, improves function\textsuperscript{21,22}

\textsuperscript{21} Birmingham et al, 2009, \textsuperscript{22} Marti et al, 2001
Rationale:

A) Shock Absorbing Insoles:

✓ inexpensive
✓ no known contraindications
✓ ↓ impact forces and loading rates in healthy runners and military populations
✓ never been tried before in this population
B) it is proposed that by ↓ the rate of tibial acceleration and magnitude of loading at foot strike during gait, the load transmitted to knee will be reduced\textsuperscript{23}

\textsuperscript{23}Nigg et al, 1988
Purpose:

To examine the effectiveness of SAIs in:

1) the immediate reduction of knee joint load

2) the reduction in knee joint load, pain, and dysfunction after one month of wear

* in individuals with knee OA *
Ethics...

Ethical approval was obtained from the Institutional Clinical Research Ethics Board and all participants provided written informed consent.
Research Design:

Pre-post design with participants exposed to

2 conditions: - normal footwear
- SAIs

with a one month follow-up
Inclusion Criteria:

- radiographic evidence of tibio-femoral OA
- varus malalignment
- knee pain during walking > 3/10 most days of the previous month
- grade ≥ 2 knee OA based on Kellgren and Lawrence criteria by an independent radiologist
Kellgren and Lawrence Radiographic Criteria for Assessment of OA*

<table>
<thead>
<tr>
<th>Radiographic grade</th>
<th>0</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification</td>
<td>Normal</td>
<td>Doubtful</td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
</tr>
<tr>
<td>Description</td>
<td>No features of OA</td>
<td>Minute osteophyte; doubtful significance</td>
<td>Definite osteophyte; normal joint space</td>
<td>Moderate joint-space reduction</td>
<td>Joint space greatly reduced; subchondral sclerosis</td>
</tr>
</tbody>
</table>

*Radiography does not reliably correlate with symptoms.

Exclusion Criteria:

- Knee injury, surgery or corticosteroid use within 6 months (oral use= 1 month)
- MSK or neurological condition affecting lower limb function
- Ankle/foot pathology that precludes the use of insoles
- Current use of foot orthotics
- Primary footwear unable to accommodate an insole
- Walk with a gait aid
- Inflammatory arthritic condition
Recruitment strategy:

Participants were recruited from the community via advertisements in local papers.
Participants:

- 16 in total (10 F, 6 M)
- mean age: 66.9 years
- mean BMI: 27.7
- mean lower limb alignment of: 178.0°
- 10 participants had mild OA, 2 had moderate, 4 had severe
- all had OA in medial compartment
- 14 returned for follow-up testing
Procedure:

- baseline and follow-up testing over one month
- measured gait, physical function and pain
- participants given 2 pairs of insoles to take home
- completion of daily log
Insole:

- 3/4 length Spenco® insoles
- Non-customized, triple density gel
- Heel thickness of 8.35mm and forefoot thickness 4.31mm
Gait Analysis:

- 3 dimensional gait analysis
- 2 synchronized force platforms
- modified Helen Hayes 22-marker set
- walk at self-selected speed
Outcome Measures:

1) Primary:
   - $KAM_1$, $KAM_2$, $KAM_p$
   - KAM impulse
   - peak vertical tibial acceleration

2) Secondary:
   - walking pain
   - WOMAC
   - timed stair climb
Statistics:

- **biomechanical**: 2 factor repeated measures ANOVA

- **clinical**: paired t-test
Results:

1) **Biomechanical**: no significant ↓ in knee joint loading were observed*

2) **Pain and Function**: significant differences found for all measures after **one month**
   - average pain during walking
   - WOMAC pain
   - WOMAC total
   - time to ascend 12 stairs

* One exception
Discussion:

1) improvements in joint pain & function found; unlikely due to changes in the loading environment

2) SAIs may not have a protective role against disease progression
Discussion cont...

3) SAIs effective in ↓ impact forces and loading rates using tibial accelerometry; not found in this study (findings may be due to relatively smaller GRF’s that occur during walking)
4) Improvements in pain and function found: WHY?

- Treatment effect for pain?
- Placebo?
- Reflection of natural history of disease?
Furthermore...

-these findings highlight the disconnect between measures of pain and function and objective measures of knee joint loading as quantified indirectly using 3-D motion analysis.
Limitations:

A) KAM is not a direct measure of knee joint loading

B) 16 individuals: possible that much smaller ↓ in joint load may have gone undetected

C) no control group
Future Considerations:

- more research is required to:
  - optimize the clinical benefits of SAIs
  - improve uptake of this treatment strategy
Conclusions:

1) SAIs can significantly improve measures of knee joint pain and physical dysfunction after 1 month of wear

2) evidence for the role of SAIs in the clinical self management of the disease

3) SAIs represent an intervention that is inexpensive, non-invasive and has minimal side effects
References:


