DonJoy OA Bracing

Scientific Studies Overview
**COMPARTMENT UNLOADING with DONJOY OA BRACING**

### In Vivo Three-Dimensional Determination of the Effectiveness of the Osteoarthritis Knee Brace: A Multiple Brace Analysis

<table>
<thead>
<tr>
<th>Authors</th>
<th>Nadaud MC, Komistek RD, Mahfouz MR, Dennis DA, Anderle MR.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>2005</td>
</tr>
<tr>
<td>Place of origin</td>
<td>The University of Tennessee, Knoxville, TN, USA.</td>
</tr>
</tbody>
</table>

#### Objective
To analyse the effectiveness of 5 commercially available OA braces in providing separation of the femoral condyle from the tibial plateau in subjects with symptomatic unicompartmental osteoarthritis under in vivo, dynamic, weightbearing conditions using video fluoroscopy.

#### Tested products
- DonJoy OAdjuster
- Bledsoe Thruster 2 (not commercially available - taken off the market in 2005 - patent infringement issue)
- Breg Tradition X2K
- Innovation Sports Oasys
- Generation II Unloader Spirit

#### Study design & methods
**In vivo laboratory study using video fluoroscopy.**

**Subjects:** 5 patients with substantial unicompartmental osteoarthritis

**Methods:** subjects were studied under fluoroscopic surveillance in the frontal plane while performing treadmill gait.
- Each subject had to walk without brace, with the 5 different OA braces and with an ACL brace (placebo/control).
- Each subject performed normal gait under fluoroscopic surveillance and in addition, each subject was asked to undergo a CT scan in order to reconstruct the 3D femoral and tibial bones.
- This study is the first study to analyze the OA knee in 3 dimensions.
- Images were captured at 5 instances during stance-phase of gait : heel strike, 33% of stance phase, midstance, 66% of stance-phase and toe-off.

**Outcome:** the amount of medial condylar separation was assessed for each subject and compared for all 5 subjects while wearing the 5 different braces to determine which brace is the most effective.

#### Results
- The largest medial condyle separation was observed for all braces at heel-strike.
- **Greatest amount of condylar separation** was obtained with Bledsoe and DonJoy brace (average separation for the five patients resp. 1.3mm and 1.2mm at heel strike).
- The average amount of separation throughout stance phase was calculated by summatng the amount of separation for all five instances during stance phase of gait (heel-strike, 33% of stance phase, midstance, 66% of stance phase, and toe-off) and then dividing this amount by five for each subject. Bledsoe (0.8mm) produced the best average, followed by OAdjuster (0.5mm). OAsys and Gen II were the least effective.

#### Conclusion
OA bracing is an effective mode of treating unicompartmental degeneration; articular seperation of a degenerated knee compartment can be achieved consistently with 2 braces : Bledsoe Thruster 2 and DonJoy OAdjuster.

#### Key message
OAdjuster was the best performing commercially available brace for achieving condylar separation of the narrowed and degenerated knee compartment.

#### Pubmed ID
16326730
Is valgus unloader bracing effective in normally aligned individuals: implications for post-surgical protocols following cartilage restoration procedures.

Authors  
Orishimo KF, Kremenic IJ, Lee SJ, McHugh MP, Nicholas SJ.

Published  

Date  
Aug 2012

Place of origin  
Nicholas Institute of Sports Medicine and Athletic Trauma, New York, NY, USA.

Background  
Utilizing valgus unloader braces to reduce medial compartment loading in patients undergoing cartilage restoration procedures may be an alternative to non-weightbearing post-operative protocols in these patients.

Objective  
To evaluate the effect of a valgus unloader brace on knee adduction moment during gait in normally aligned healthy individuals.

Tested product  
DonJoy OAAdjuster

Study design & methods  
Biomechanical Gait Analysis study - repeated measures design.

Subjects: 12 healthy individuals with no history of knee pathology

Methods: subjects were tested in 5 bracing conditions

1. no brace
2. OAAdjuster - neutral valgus position (screws loosest position)
3. OAAdjuster - screws one half-turn valgus
4. OAAdjuster - screws one full-turn valgus
5. OAAdjuster - screws tensioned maximally

Outcomes: Frontal (adduction/abduction) and sagittal plane (flexion/extension) knee angles and external moments were calculated during stance phase of gait using specialized computer software.

Results  
- With increasing tension in the brace, peak frontal plane knee angle during stance shifted from 1.6° (± 4.2°) varus without the brace to 4.1° (± 3.6°) valgus with maximum brace tension (P = 0.02).
- Peak knee adduction moment and knee adduction impulse decreased with increasing brace tension.
  - The first peak in adduction moment was significantly reduced in the full-turn (p=0.02) and the maximal tension conditions (p=0.002) compared with the no brace condition.
  - The second peak in adduction moment was significantly reduced in the half-turn (p=0.041), full-turn (p=0.021) and the maximal tension conditions (p=0.007) compared with the no brace condition.
  - Knee adduction impulse over the stance phase was significantly reduced in the full-turn (p=0.049) and the maximal tension conditions (p=0.021) compared with the no brace condition.

Results table:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Knee Adduction Moment (N.m/kg)</th>
<th>1st Peak</th>
<th>2nd Peak</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Brace</td>
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<tr>
<td>Neutral Valgus</td>
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<td>Half-turn Valgus</td>
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<tr>
<td>Full-turn Valgus</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Max. Tension</td>
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</table>

- Gait velocity and sagittal plane knee biomechanics were minimally affected.

Conclusion  
- Valgus unloader braces effectively shift the knee into a more valgus position and decrease knee adduction moment during gait in healthy subjects with normal alignment.
- The use of these braces following a cartilage restoration procedure may provide adequate protection of the repair site without limiting the patient's mobility.

Key message  
The OAAdjuster brace effectively shifts the knee into a more valgus position and decreases knee adduction moment during gait and may therefore provide adequate protection of the repair site.

Pubmed ID  
22898913
### Clinical and Biomechanical Evaluation of the Unloading Brace.

**Authors** Finger S, Paulos LE.  
**Date** 2002  
**Place of origin** The Orthopedic Specialty Clinic, Murray, Utah

#### Background
As people with OA continue to desire a more active lifestyle, mechanical bracing may be a more appropriate choice of treatment because of its low cost, compatibility, and effectiveness. Shifting the load to the unaffected compartment reduces the load in the affected compartment. This load-shift is achieved through a "three-point force" system applied by the knee brace. The 3-point force system applies a bending movement, or torque, to the knee in the medial-lateral plane. In medial compartment OA the brace applies a valgus bending movement to the knee.

#### Objective
1) Biomechanical evaluation and comparison of commercially available load-shifting braces.  
2) Clinical evaluation of the use of the OAdjuster in the treatment of knee pain due to osteoarthritis.

#### Tested products
Donjoy OAdjuster

#### Study design & methods
Clinical study.  
- 28 patients participated in this study.  
- The mechanical axis of the knees ranged from 10° valgus to 15° varus.  
- Pain levels were assessed using a questionnaire and visual analog scales (1-10) at baseline and after 3 months of brace use.  
- Bone scans were obtained, before brace use and after 3 months of brace use.

#### Results
Of the 28 patients involved in the clinical study with the OAdjuster, 23 were available for evaluation at 3 months.  
- average resting pain decreased from 4.2 to 1.9: **54.8% decrease**  
- average night pain decreased from 3.9 to 2.4: **38.4% decrease**  
- average pain with activity decreased from 7.2 to 3.9: **45.8% decrease**  
- Bone scan changes were insignificant.  
- 5 patients were wearing the braces all times for daily activities, 15 patients were using the brace only for strenuous activities, the remaining patients stopped brace use due to discomfort.

#### Conclusion
- Load shifting braces are effective in reducing pain in patients with medial or lateral knee OA.  
- The use of load shifting braces in the treatment of unicompartmental osteoarthritis, osteochondral lesions, ligament instabilities, and meniscal repairs or transplants should be considered as part of their treatment regime by orthopaedic surgeons.

#### Key message
**The OAdjuster is effective in reducing pain in medial and lateral knee OA.**

**Pubmed ID** 12152976
The Effectiveness of Self-Adjustable Custom and Off-the-Shelf Bracing in the Treatment of Varus Gonarthrosis

<table>
<thead>
<tr>
<th>Authors</th>
<th>Draganich L, Reider B, Rimington T, Piotrowski G, Mallik K, Nasson S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>December 2006</td>
</tr>
<tr>
<td>Place of origin</td>
<td>University of Chicago, Chicago, Illinois</td>
</tr>
<tr>
<td>Background</td>
<td>A recent development in valgus-producing knee braces has been the adjustable &quot;unloader&quot; brace.</td>
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<tr>
<td>Objective</td>
<td>To compare the effectiveness of off-the-shelf patient-adjustable valgus-producing brace with a custom-made patient-adjustable, valgus-producing brace in decreasing pain and stiffness, improving function and in reducing the peak varus moments about the knee during gait and stair-stepping in patients with painful varus gonarthrosis.</td>
</tr>
<tr>
<td>Tested products</td>
<td>OAdjuster (off-the-shelf brace)</td>
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<td></td>
<td>OA Defiance (custom brace)</td>
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**Study design & methods**
- **Cross-over study**
  - 10 adult patients served as their own controls for the measurement of baseline values and then wore each of the two braces, one after the other, for 4 to 5 weeks in a random order.
  - Pain, stiffness, and function were assessed with the Western Ontario and McMaster Universities Osteoarthritis index (WOMAC).
  - Gait and stair-stepping were evaluated with a 3-dimensional motion analysis system and multicomponent force platform.
  - Full-length (hip-knee-ankle) standing anteroposterior radiographs were used to determine knee alignment of the knee.

**Results**
- Both braces significantly reduced pain and stiffness, with the custom OA Defiance reducing stiffness significantly more than the off-the-shelf OAdjuster brace.
- The custom OA Defiance significantly improved function and reduced the peak knee adduction moments during gait and stair-stepping compared with baseline values and compared with the off-the-shelf brace.
- The average varus angle was significantly reduced with the custom OA Defiance brace, while the off-the-shelf brace did not significantly change the varus alignment.
- The better results with the custom brace were assumed to be the result of a better fitting to the limb, which allowed the custom brace to maintain higher levels of valgus loading of the knee in the patients during activities of daily living.

**Conclusion**
Patients with varus gonarthrosis of the knee may benefit significantly with respect to pain relief and reduced stiffness from use of either brace. However, such patients may experience additional significant benefit in improved function and reduced stiffness, varus angulation, and medial compartment loading of the knee from use of the custom-made patient-adjustable brace, due to the close fit of the brace on the limb.

**Key message**
The OA Adjuster and OA Defiance offer significant pain relief and reduced stiffness. OA Defiance moreover offers improved function, improved knee alignment and reduced knee adduction moment thanks to its close fit.

**Pubmed ID**
17142415
Load-shifting brace treatment for osteoarthritis of the knee: a minimum 2 1/2-year follow-up study.

**Authors**
Giori NJ.

**Published**

**Date**
2004

**Place of origin**
Surgical Service, VA Palo Alto Health Care System, Palo Alto, CA, USA.

**Background**
Objectives in treating primarily unicompartmental knee arthritis with a load-shifting brace are pain relief, compliance, brace durability, and complication-free treatment over multiple years. At present, no published information exists on the success of load-shifting brace use in meeting these objectives. The high cost of the brace and concern about early failures limit enthusiasm for this treatment strategy.

**Objective**
This study describes the minimum 2 1/2-year results of bracing for osteoarthritis of the knee involving primarily one compartment at one institution and makes recommendations for improving outcomes.

**Tested products**
- 33 DonJoy Defiance OA brace
- 9 DonJoy Monarch brace
- 6 Bauerfeind MOS Genu brace

**Study design & methods**
**Retrospective + survey study.**

**Subjects:** 55 patients fitted with a custom OA brace from 1997 to 1999 - 46 patients were available for follow-up - 49 braced legs were analysed.

**Methods:**
- retrospective chart review, radiograph review, and telephone survey of patients treated from 1997 to 1999 with a load-shifting knee brace.
- minimum 2 1/2-year follow-up (average 3.3 years)

**Outcomes:**
- Knee society pain and function score
- Brace use (compliance)
- Brace satisfaction
- Complications
- age and radiographic grade of OA

**Results**
- Load-shifting brace use had a survival of 76% at 1 year, 69% at 2 years, and 61% at 3 years.
- Brace use was discontinued within 6 months in 10 of 49 knees (20%).
- Younger patients had a higher likelihood of longer brace use than older patients.
- Among the 22 patients (25 knees) who were found still to be using the brace when they were contacted, only 6 reported using the brace full time. The remaining 16 patients reported using the brace only as needed, particularly when they were being active or at work.
- In patients still using the brace, Knee Society pain scores improved an average of 26 points with use of the brace, from 13 to 39 points.
- Knee Society function scores did rise, but not dramatically, from an average of 61 points to 72 points.
- 6 patients (from the 22 still using the brace) reported problems with skin irritation, 2 reported some mechanical problem with the brace, 1 reported a problem with the fit of the brace, and 12 reported no problems with the brace.
- One patient had ipsilateral leg swelling and a pulmonary embolus after initiating bracing.
- Among the 46 patients surveyed, 17 reported being very satisfied with the brace, 19 reported being satisfied, 4 were unsatisfied, and 6 were very unsatisfied with the brace.

**Conclusion**
- A majority of patients who were issued a load-shifting brace for osteoarthritis involving primarily one compartment of the knee were found still to be using their brace and deriving some benefit of pain relief and functional improvement 3 years later.
- A large proportion of the discontinuations occur early in treatment: how can this be prevented?
- Though load-shifting brace use seems to be a treatment modality with minimal risk, one should be aware of the potential complication of venous thrombosis and thromboembolism.

**Key message**
Load-shifting brace use for unicompartmental knee OA was found to be successful in a majority of patients 3 years after brace issue, with patients reporting pain relief and functional improvement.

**Pubmed ID**
15558372
The Effectiveness of Off-Loading Knee Orthoses in the Reduction of Pain in Medial Compartment Knee Osteoarthritis: A Systematic Review

### Authors
Feehan NL, Trexler GS, Barringer WJ.

### Published

### Date
Jan 2012

### Place of origin
University of Oklahoma Orthotics and Prosthetics, Oklahoma City, Oklahoma.

### Background
Many treatments have been developed for OA, including the unloader knee orthosis. With the growth and acceptance of the market for these orthoses, there have been multiple articles and studies published on the topic. Although some articles focus on the biomechanical aspects of the knee and its varus and valgus moments, others consider whether or not function is increased by the use of knee orthoses. Other articles reveal the long-term effects of the orthosis; still others investigate pain reduction of the participant with the orthosis. Some articles include various combinations of these aspects of study.

### Objective
The purpose of this review is to determine the effectiveness of knee orthoses in the treatment of pain in unilateral compartment osteoarthritis (OA).

### Tested products

**Systematic Review.**
- Using the keywords “knee osteoarthritis” and “orthosis” or “brace,” the PubMed, CINAHL, RECAL, and ISI Web of Knowledge electronic databases were searched for randomized control trials with “orthoses” or “braces” for the knee between January 1980 and December 2010.
- Only studies that dealt with medial unilateral compartment knee OA and the use of a knee orthosis were selected.
- Of these articles, only experimental trials were selected based on the American Academy of Orthotists and Prosthetists State-of-the-Science Evidence Report Guidelines.
- A comparative analysis of the articles was used to determine the effectiveness of the orthoses in reducing pain.

### Results
- **15 studies** were included and reviewed based on the inclusion guidelines.
- Most of these articles were either single-subject research or before-and-after studies. 3 studies were RCTs. The majority were of moderate quality. There were no studies of low quality reviewed.
- **All studies showed that there was pain reduction in the patients.** This pain reduction was statistically significant in 73% of the studies reviewed.
- 8 of the studies in some way investigated function. All of them noted **significant increases in the function** of participants.
- The rate of pain relief was further investigated and revealed that **pain relief was almost immediate.**
- A “carryover” effect has been documented in one study, with the **effects of the orthosis continuing after discontinuation of the orthosis.**
- Although the numbers are small, there is an interesting trend showing **decreased incidence of surgery** in patients treated with orthosis versus controls.

### Conclusion
On the basis of the articles reviewed, an **OA or unloading knee orthosis is an effective way to relieve pain in the osteoarthritic knee.** Pain relief was documented to help in **98.6% of patients fitted with unloading orthoses** for medial compartment OA of the knee. With decreased pain comes **increased function and quality of life.** When compared with surgery, these orthoses are a **cost effective** means of treating OA.

### Key message
OA knee orthoses are a cost-effective way to reduce pain in patients with medial compartment OA.

### Pubmed
PMH0046552
### OARSI RECOMMENDATIONS

#### OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines.

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<tbody>
<tr>
<td>Published</td>
<td>Osteoarthritis &amp; Cartilage, Volume 16, nr. 2, pp. 137-162</td>
</tr>
<tr>
<td>Date</td>
<td>2008</td>
</tr>
<tr>
<td>Place of origin</td>
<td>University of Edinburgh, UK</td>
</tr>
<tr>
<td>Background</td>
<td>OARSI = Osteoarthritis Research Society International</td>
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</tbody>
</table>

#### Objective
To develop concise, patient-focused, up to date, evidence-based, expert consensus recommendations for the management of hip and knee osteoarthritis (OA), which are adaptable and designed to assist physicians and allied health care professionals in general and specialist practice throughout the world.

#### Study design & methods
- Systematic review of existing guidelines for the management of hip and knee OA published between 1945 and January 2006.
- 16 experts from four medical disciplines (primary care, rheumatology, orthopaedics and evidence-based medicine), two continents and six countries (USA, UK, France, Netherlands, Sweden and Canada) formed the guidelines development team.
- A core set of management modalities was generated based on the agreement between guidelines.
- Evidence before 2002 was based on a systematic review conducted by European League Against Rheumatism and evidence after 2002 was updated using MEDLINE, EMBASE, CINAHL, AMED, the Cochrane Library and HTA reports.
- The quality of evidence was evaluated, and where possible, effect size (ES), number needed to treat, relative risk or odds ratio and cost per quality-adjusted life years gained were estimated.
- Consensus recommendations were produced following a Delphi exercise and the strength of recommendation (SOR) for propositions relating to each modality was determined using a visual analogue scale.

#### Results
- Overall there was no statistically significant difference between non-pharmacological therapies and pharmacological therapies with regard to effect size.
- Consensus was reached on 25 carefully worded recommendations.

#### Optimal management of patients with OA hip or knee requires a combination of non-pharmacological and pharmacological modalities of therapy.

- **12 recommendations cover non-pharmacological modalities:** education and self-management, regular telephone contact, referral to a physical therapist, aerobic, muscle strengthening and water-based exercises, weight reduction, walking aids, knee braces, footwear and insoles, thermal modalities, TENS and acupuncture.
  
  **In patients with knee OA and mild/moderate varus or valgus instability, a knee brace can reduce pain, improve stability and diminish the risk of falling."** SOR: 76%

- **8 recommendations cover pharmacological modalities** of treatment including acetaminophen, cyclooxygenase-2 (COX-2) non-selective and selective oral NSAIDs, topical NSAIDs and capsaicin, intraarticular injections of corticosteroids and hyaluronates, glucosamine and/or chondroitin sulphate for symptom relief; glucosamine sulphate, chondroitin sulphate and diacerein for possible structure-modifying effects and the use of opioid analgesics for the treatment of refractory pain.

- **5 recommendations cover surgical modalities:** total joint replacements, unicompartmental knee replacement, osteotomy and joint preserving surgical procedures; joint lavage and arthroscopic debridement in knee OA, and joint fusion as a salvage procedure when joint replacement had failed.

Strengths of recommendation and 95% CIs are provided.

#### Conclusion
25 carefully worded recommendations (12 non-pharmacological) have been generated based on a critical appraisal of existing guidelines, a systematic review of research evidence and the consensus opinions of an international, multidisciplinary group of experts. The recommendations may be adapted for use in different countries or regions according to the availability of treatment modalities and SOR for each modality of therapy. These recommendations will be revised regularly following systematic review of new research evidence as this becomes available.

#### Key message
Amongst the 12 recommended non-pharmacological treatment modalities for knee and hip OA are knee bracing, TENS, muscle strengthening and thermal modalities.

#### Pubmed ID
18279766
# THE TREATMENT GAP IN KNEE OA MANAGEMENT

## Clinical and economic consequences of the treatment gap in knee osteoarthritis management.

<table>
<thead>
<tr>
<th>Authors</th>
<th>London NJ, Miller LE, Block JE.</th>
</tr>
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<tbody>
<tr>
<td>Date</td>
<td>Jun 2011</td>
</tr>
<tr>
<td>Origin</td>
<td>Department of Orthopaedic Surgery, Harrogate District Foundation Trust, Harrogate, United Kingdom.</td>
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</tbody>
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## Background
Osteoarthritis affects 27 million American adults of all ages and is a leading cause of disability in middle-aged and older adults. Initial management of knee osteoarthritis symptoms utilizes conservative care although long-term efficacy is poor. Arthroplasty and high tibial osteotomy may be considered for patients with severe pain or disability.

## Objective
To evaluate the hypothesis that a distinct treatment gap exists for the patient with symptomatic knee osteoarthritis who is unresponsive to conservative care (including simple surgical treatments) yet refuses to undergo or is not an appropriate candidate for more invasive surgical procedures.

## Results
- The treatment gap is defined as the time from unsuccessful exhaustion of conservative treatment to surgical intervention.
- This treatment gap represents a protracted period in which the patient experiences debilitating pain, reduced quality of life, and a significant financial burden.
- The typical duration of the treatment gap in patients who undergo arthroplasty is 10 years. However it extends to 20 years in patients refusing arthroplasty. The younger osteoarthritis patient is faced with the treatment gap throughout the majority of their adult life.
- Approximately 3.6 million Americans linger in the knee osteoarthritis treatment gap and this number will grow to about 5 million people by 2025. The total annual costs associated with the treatment gap is calculated to be 17 billion dollars each year and may rise to 24 billion dollars by 2025.
- Patient willingness to pay for treatment is $5700 per QALY (quality-adjusted life year).
- Cost effectiveness of bracing is estimated at $6000 per QALY versus $15,000 per QALY for NSAID.

## Conclusion
The treatment gap in knee OA management is an underappreciated period of 10 to 20 years or more in many cases that results in enormous clinical and economic consequences for millions of Americans. There is great need for a safe, effective, and cost effective treatment option for patients with moderate to severe osteoarthritis that enjoys high patient acceptance.

## Key message
The "treatment gap", a period during which the patient endures chronic pain and disability and where substantial economic resources are depleted, highlights the great need for a safe, effective, less invasive, and more cost effective treatment option for patients with moderate to severe OA that enjoys high patient acceptance.
Questions?
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