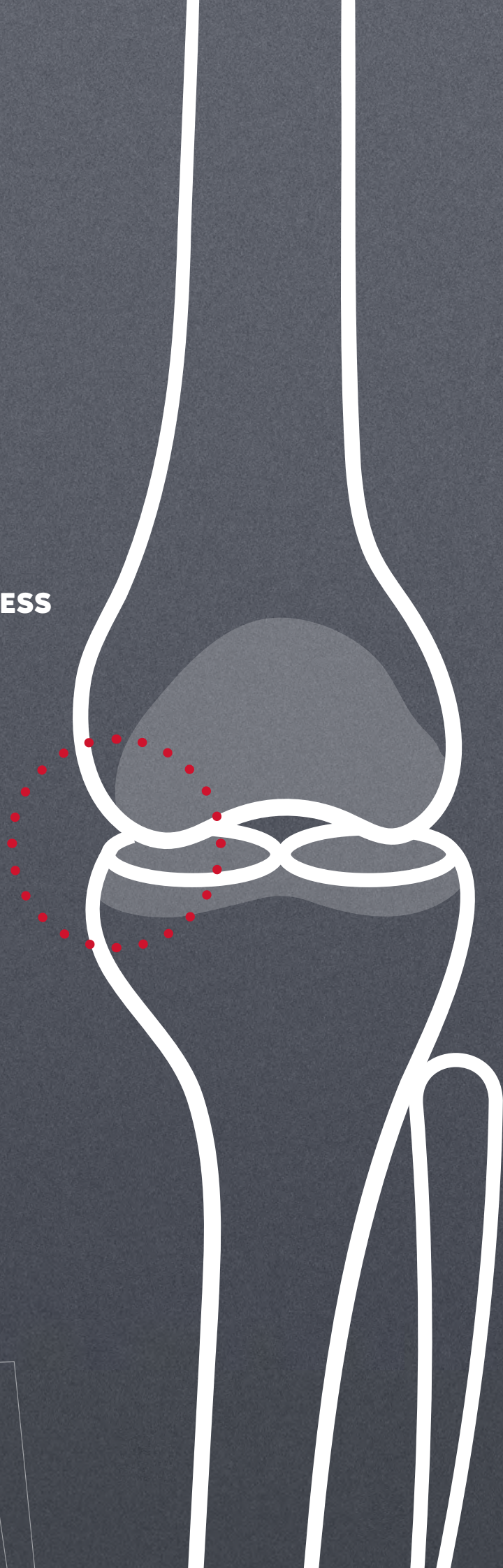


enovis™

DONJOY® OA BRACES

**CLINICALLY-PROVEN EFFECTIVENESS
OF KNEE OA BRACING**

THE EVIDENCE



FACTS & FIGURES

Global prevalence of knee OA⁹



22.9%

of people \geq 40 years
suffer from knee OA



= 654 MILLION
OA PATIENTS

in 40+ age group

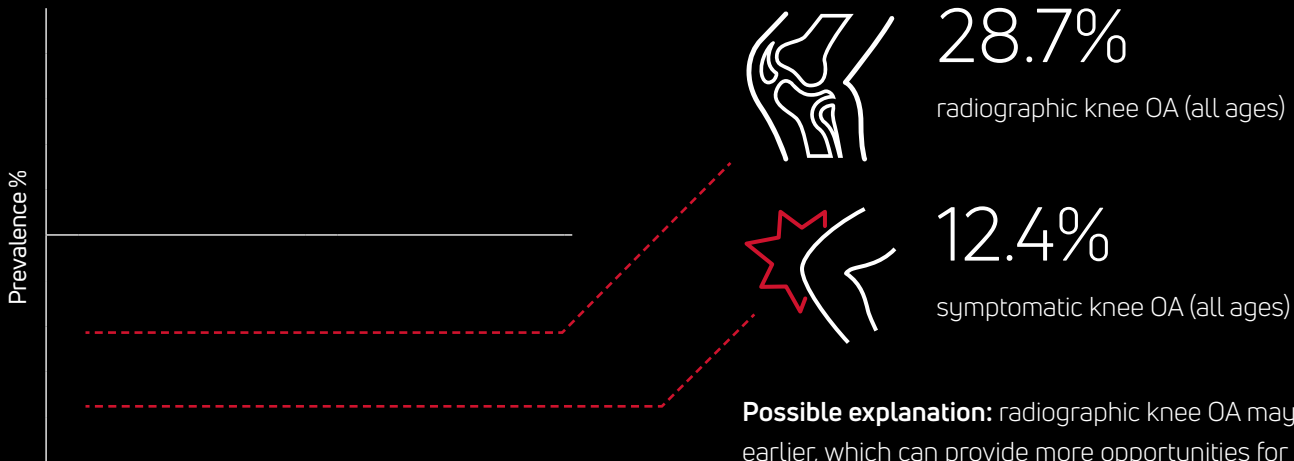


HIGHEST
PREVALENCE
IN ASIA

1.69 times more knee OA in Asia than
in Europe and North America



LOWEST
PREVALENCE
IN LATIN
AMERICA



Possible explanation: radiographic knee OA may be detected earlier, which can provide more opportunities for prevention.



344 MILLION

people living with osteoarthritis (all
joints) experience severity levels
(moderate or severe) that could
benefit from rehabilitation (WHO
2023 facts sheet⁴⁸)



BRACES

and other assistive technologies can
help people with osteoarthritis to **stay
independent** when movement becomes
more difficult (WHO 2023 facts sheet⁴⁸)

RISK FACTORS

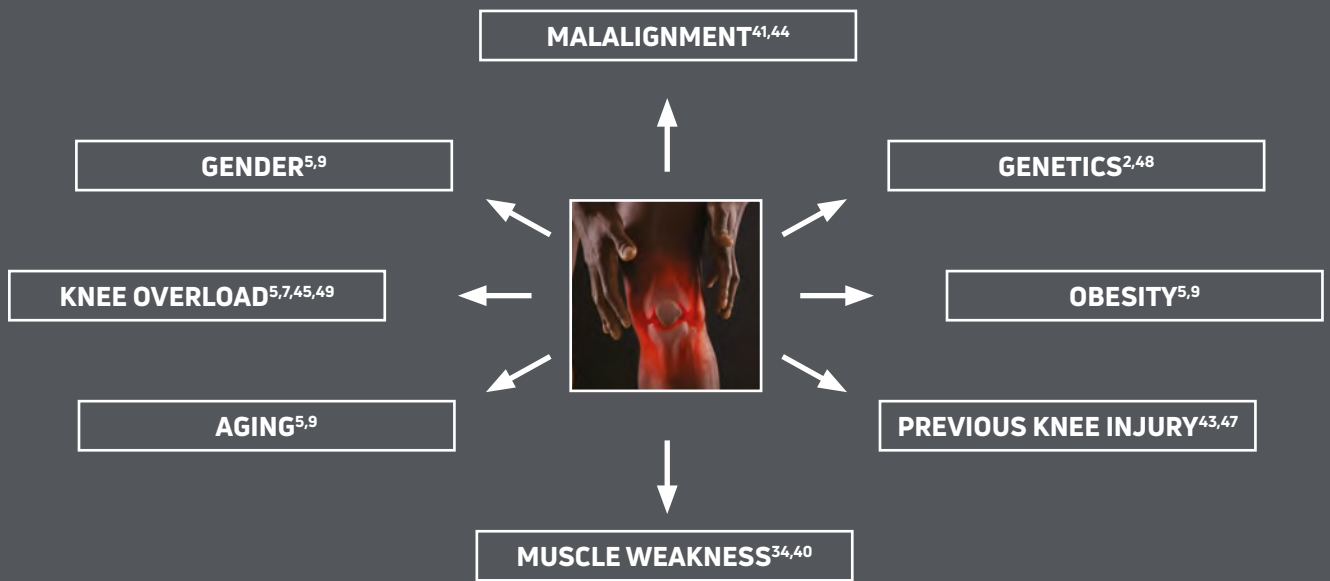
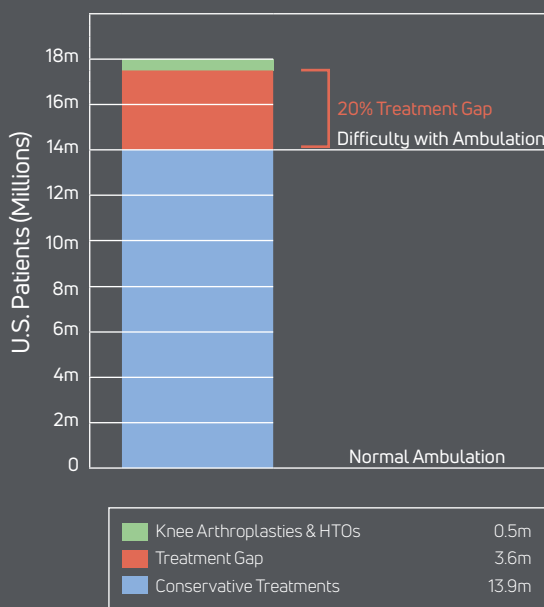


Fig. 1: Risk factors for knee OA

TREATMENT GAP



- The treatment gap is the time from unsuccessful exhaustion of conservative treatment to surgical intervention. During this treatment gap chronic pain and disability are endured by the patients and substantial economic resources are depleted^{27,28}.
- London et al. calculated that approximately 20% of American patients with symptomatic knee OA linger in this treatment gap for 10 years. For younger patients, this can extend to 20 years²⁸, and the clinical scenario can be challenging because they often seek to remain involved in sporting activities.²¹
- The off-loading knee brace is a cost-effective method as a bridging therapy and its long-term use can delay and reduce surgical intervention^{26,29}.
- A study by Lee et al. (2017) showed that patients who wore an off-loading knee brace for 2 years or more did not require surgery at 8 years follow-up²⁶.

Fig. 2: The Treatment Gap²⁸

PROGRESSION OF KNEE OA AND HOW A DONJOY® OA BRACE CAN HELP

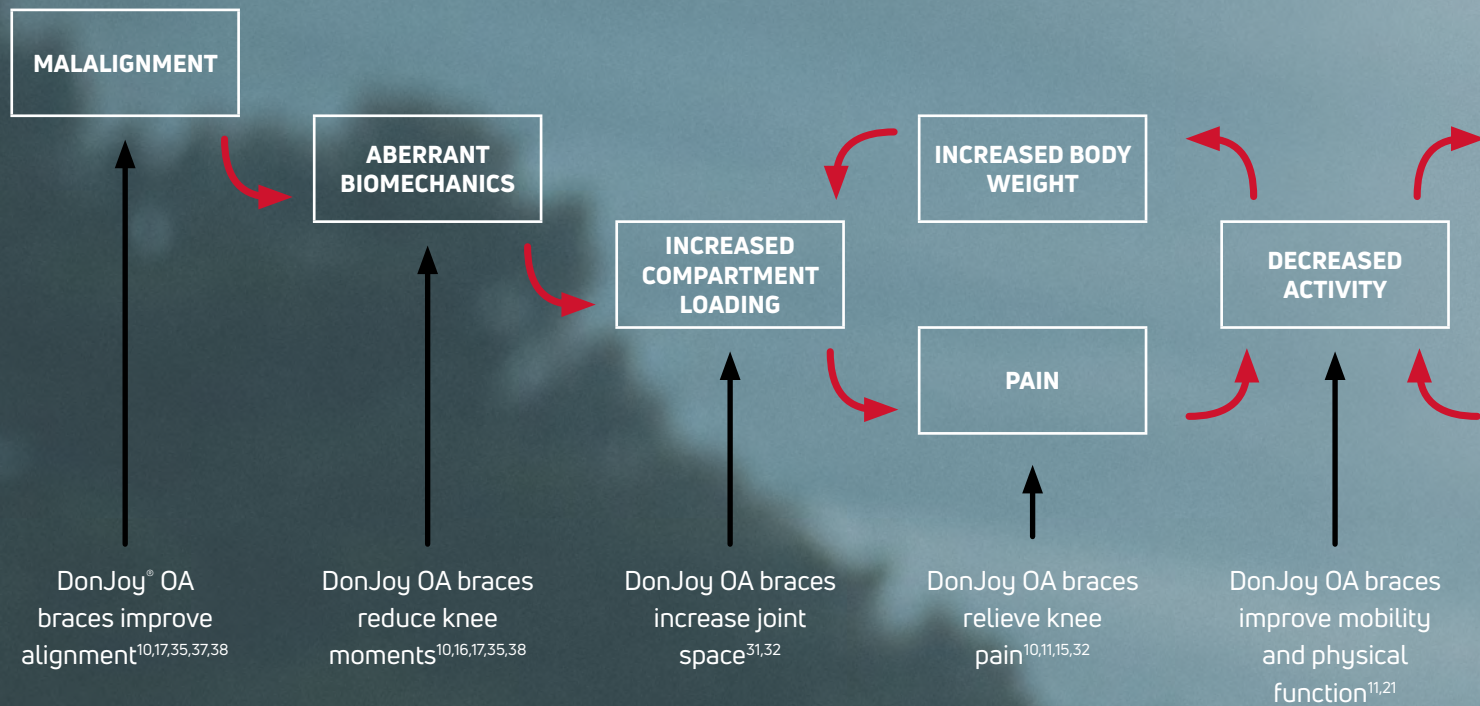


Fig. 3: The progression of knee OA

In the conservative treatment modalities, analgesia and non-steroidal anti-inflammatory (NSAIDs) drugs provide reductions in pain, increased quality of life and increased activity levels. However, they don't address the underlying biomechanical causes and consequences of the OA disease process. There are reports of increased joint loading³⁹ and accelerated disease progression¹⁸ probably due to increased pain free activity or walking speed. Off-loading braces allow for a more active lifestyle while protecting the knee joint from excessive loading.

A DONJOY OFF-LOADING BRACE CAN HELP KEEP THE PATIENT IN MOTION WHILE PROTECTING THE KNEE JOINT FROM EXCESSIVE LOADING

MUSCLE
WEAKNESS

DECREASED
CONFIDENCE

DECREASED
STABILITY

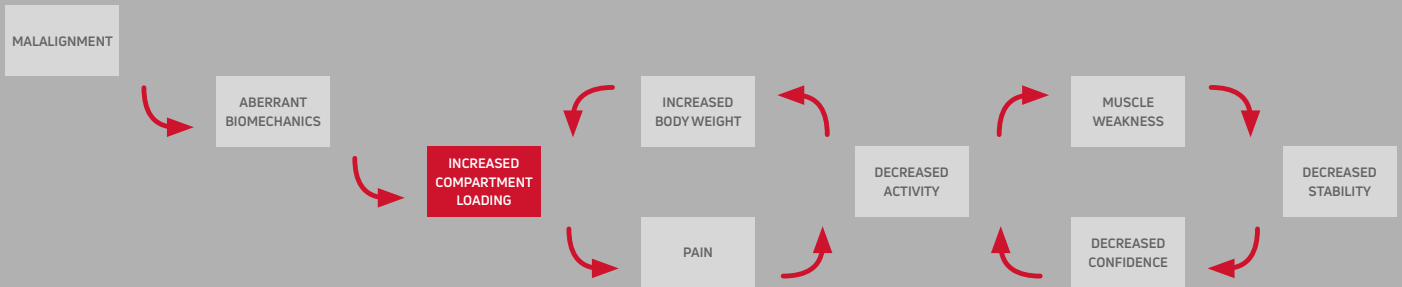
DonJoy® OA
braces improve
confidence¹⁶

DonJoy OA braces
improve knee
stability^{16,17,25}



EFFECTIVENESS OF DONJOY® OA BRACES

Increased joint space



- DonJoy OA Defiance® brace can induce a significant increase (0.3 mm) in medial compartment dynamic joint space during gait in medial compartment knee OA patients³². This corresponds to roughly 10% increase in joint space during the impact phase of gait.
- The study measured the dynamic joint space in the medial compartment continuously over the stance phase of the gait using highly accurate biplane radiography system with three-dimensional sub-millimeter accuracy. The increase of medial compartment joint space when wearing the brace was consistent from heel strike to terminal stance in this study. (fig. 4)

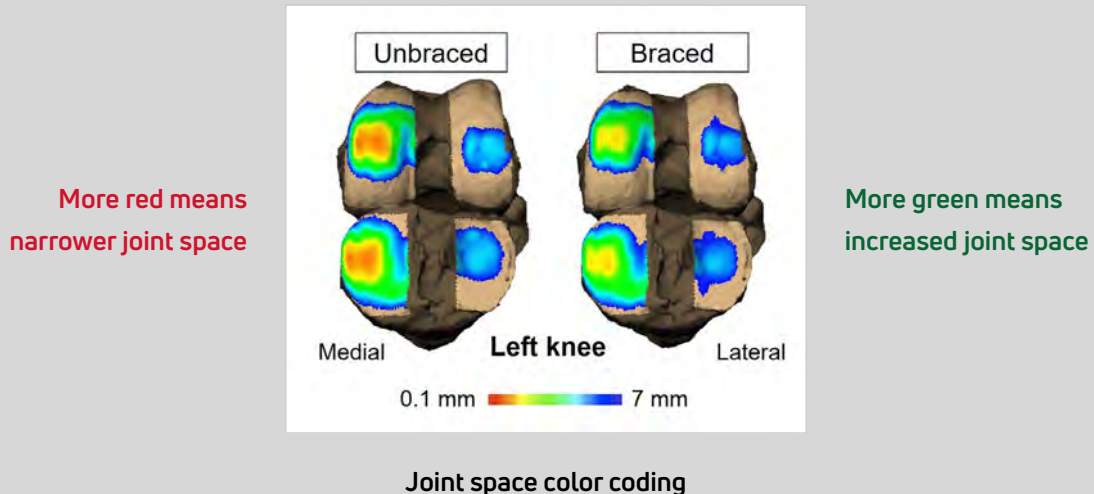
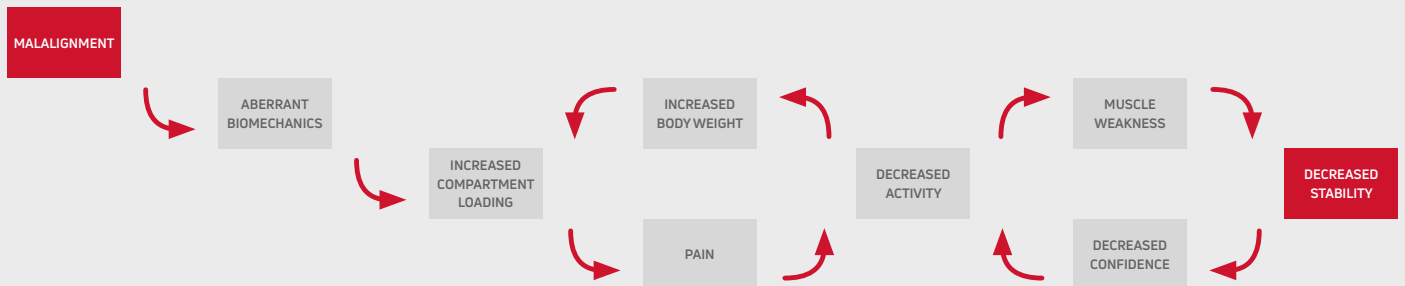


Fig 4: The instantaneous dynamic joint space during gait at 15% of the gait cycle for one subject. Subchondral bone surfaces are color coded according to minimum distance from the opposing bone surface. The figure demonstrates increased medial compartment joint space in the braced condition (red color disappeared, yellow surface decreased, green surface increased)³².

Increased dynamic joint space during gait with DonJoy® braces offloads the OA compartment³²

Improved alignment and stability



- DonJoy® OA braces effectively improve alignment by shifting the knee into a more valgus position in subjects with varus knees^{10,37} as well as in normally aligned subjects³⁵.
- At approximately 10% of the gait, the point of greatest loading, the OA Adjuster brace produced the greatest corrective effect^{37,38} (fig. 5).
- In ACL reconstructed subjects with valgus malalignment and lateral compartment OA, a DonJoy OA brace not only reduces the knee abduction angle (fig. 6), but also tibial internal rotation angles during high dynamic loading activities¹⁷.

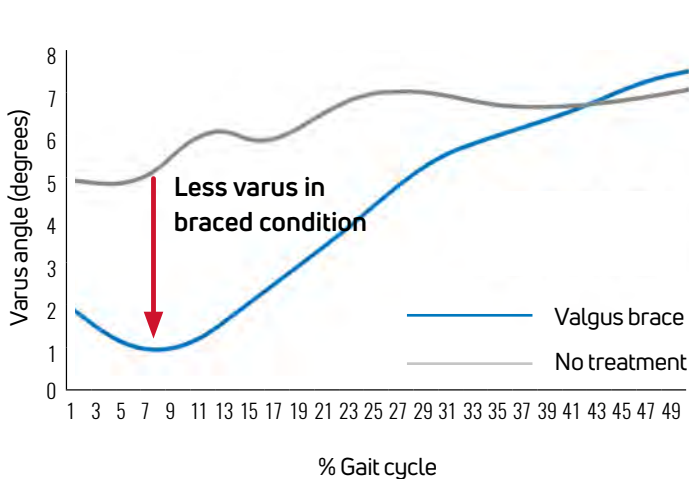


Fig. 5 : Varus angle from 0 to 50% of the gait cycle in **subjects with varus malalignment**. The greatest effect in the varus angle is during loading response from 0 to 20% of the gait cycle.

At approximately 10% of the gait cycle, the difference between the braced and unbraced conditions was 4°. This was with a 5° dial-in of the OA Adjuster brace³¹. (Figure with courtesy of Jim Richards³⁸).

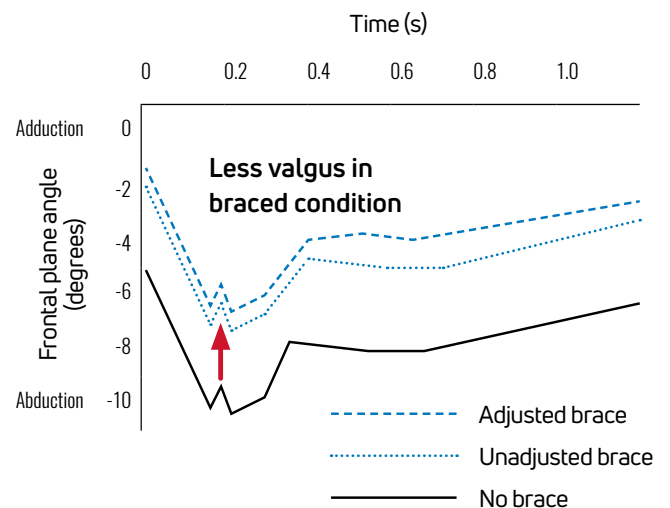
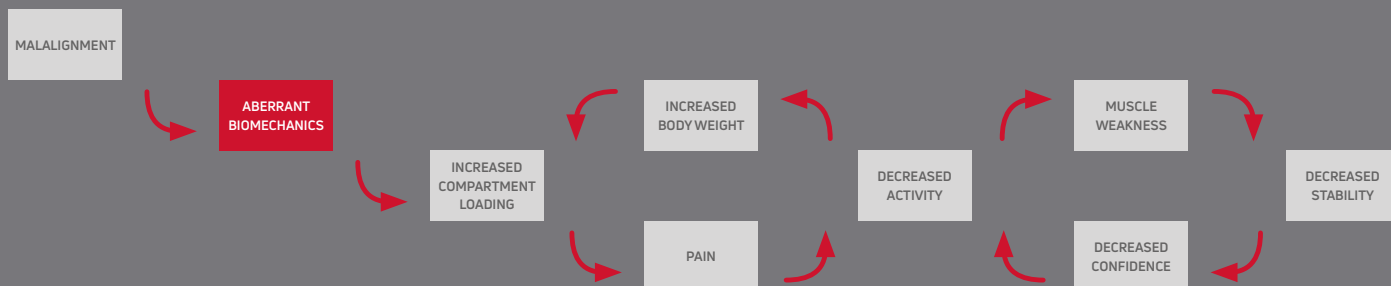


Fig. 6 : Frontal plane kinematics for no brace, unadjusted and adjusted brace conditions during hopping in **subjects with valgus malalignment**¹⁷.

EFFECTIVENESS OF DONJOY® OA BRACES

Reduced knee adduction moment and adduction impulse



- The knee adduction moment during walking forces the knee outwards (varus) and creates compression on the medial side of the knee joint. The first peak adduction moment happens during loading, the second peak adduction moment happens during push off.
- DonJoy® OA braces reduce peak knee adduction moment up to 32% during gait^{10,35,38} and stair stepping³⁰.
- The more the hinge is dialed in, the greater the reduction of the knee adduction moment³⁵.

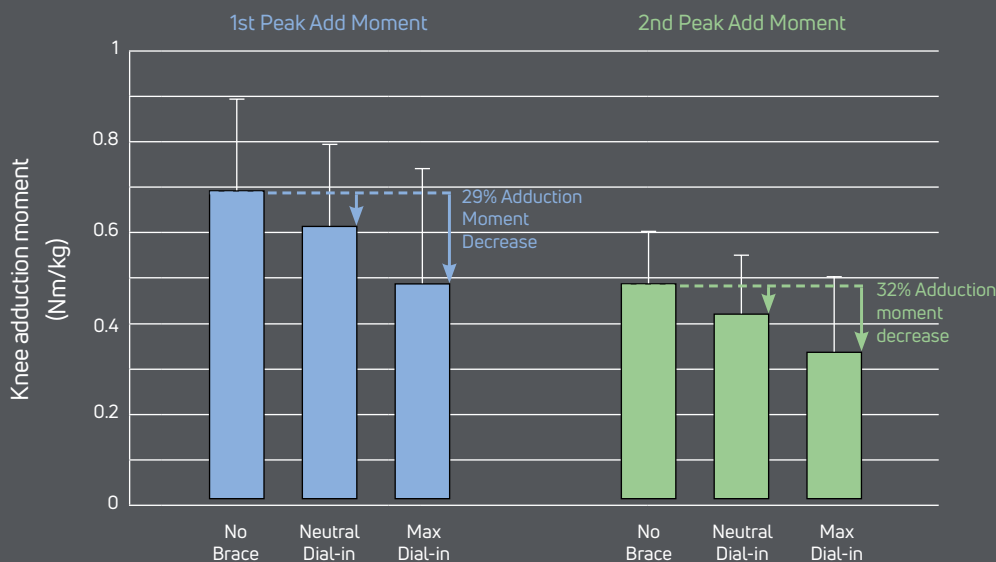


Fig. 7: Changes in first (blue bars) and second (green bars) peak knee adduction moments during gait in normally aligned subjects wearing the OA Adjuster brace with multiple hinge dial-in conditions³⁵. Dial-in of the hinge produced reduction of the peak knee adduction moments.

- The adduction angular impulse is a complimentary measure of knee joint loading and accounts for both the load as well as the loading time. If a person walks more slowly, the peak adduction moment may be lower but the adduction impulse may be higher as the loading time will be longer.
- The DonJoy OA Adjuster™ reduces the adduction impulse up to 37%³⁵.
- The more the hinge is dialed in, the greater the reduction of the knee adduction impulse³⁵.

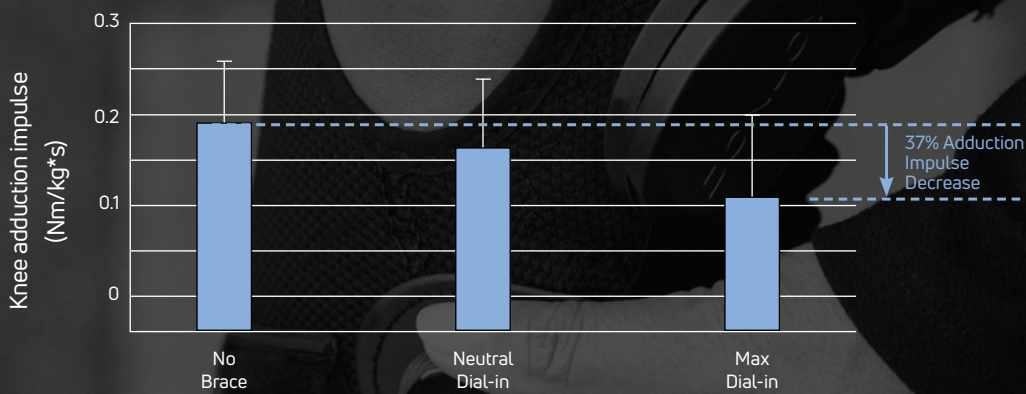


Fig. 8: Changes in knee adduction impulse by brace status. Knee adduction impulse was significantly decreased by 37% when wearing the OA Adjuster in the maximal tension condition compared with the no brace condition³⁵.

Pain relief



- The DonJoy OA Adjuster™ and OA Defiance® lead to significant pain relief at rest and during activity and improve symptoms of stiffness and function^{10,15,11,32,16}.
- In a systematic review by Feehan et al.¹² including 15 clinical studies, 98.6% of 567 patients with medial knee OA experienced pain relief when fitted with an off-loading brace.

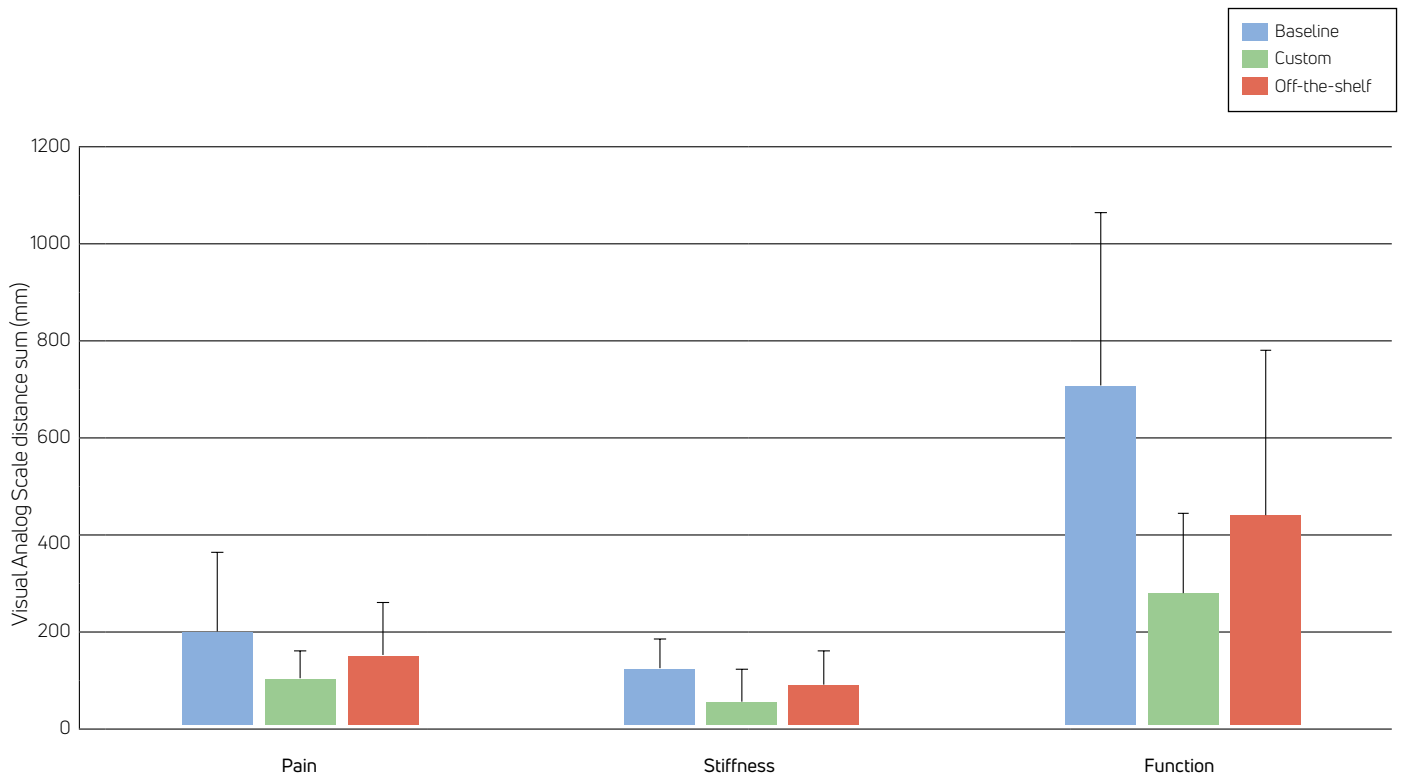
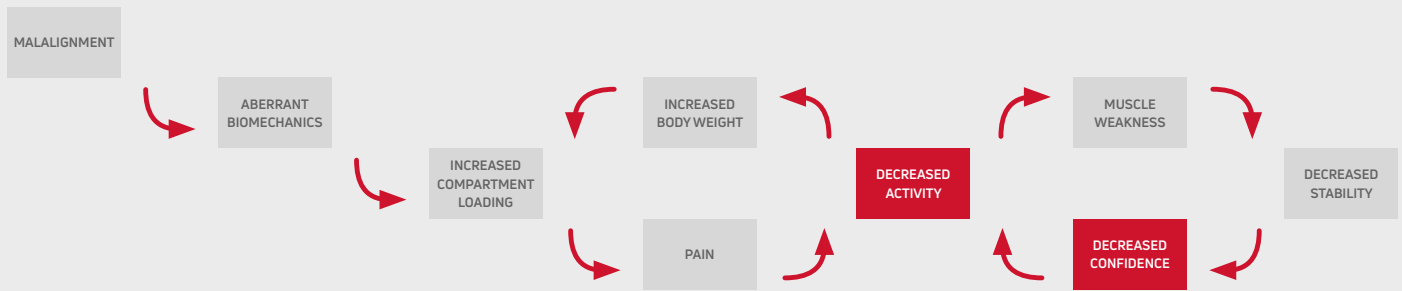


Fig. 9: Graph showing the pain, stiffness and function components of the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) in patients with varus gonarthrosis wearing *no brace*, the (custom) *DonJoy OA Defiance* and *DonJoy OA Adjuster* brace. The values are given as the mean, and the bars indicate the standard deviation. Lower values indicate improvement. Both braces significantly reduced pain and stiffness. OA Defiance also significantly improved function¹⁰.

A DonJoy® off-loading brace can significantly improve pain, resulting in a more active life and increased quality of life.¹¹

Increased confidence and activity



- The DonJoy OA Adjuster™ improves knee confidence and perceived stability in patients with post-traumatic knee OA after ACL reconstruction¹⁶.
- A recent patient feedback study showed that a DonJoy OA Defiance® brace increases the possibility to perform daily activities and also enables increased mobility away from the home environment, including going to a local shop, resulting in a more active life and increased quality of life¹¹.

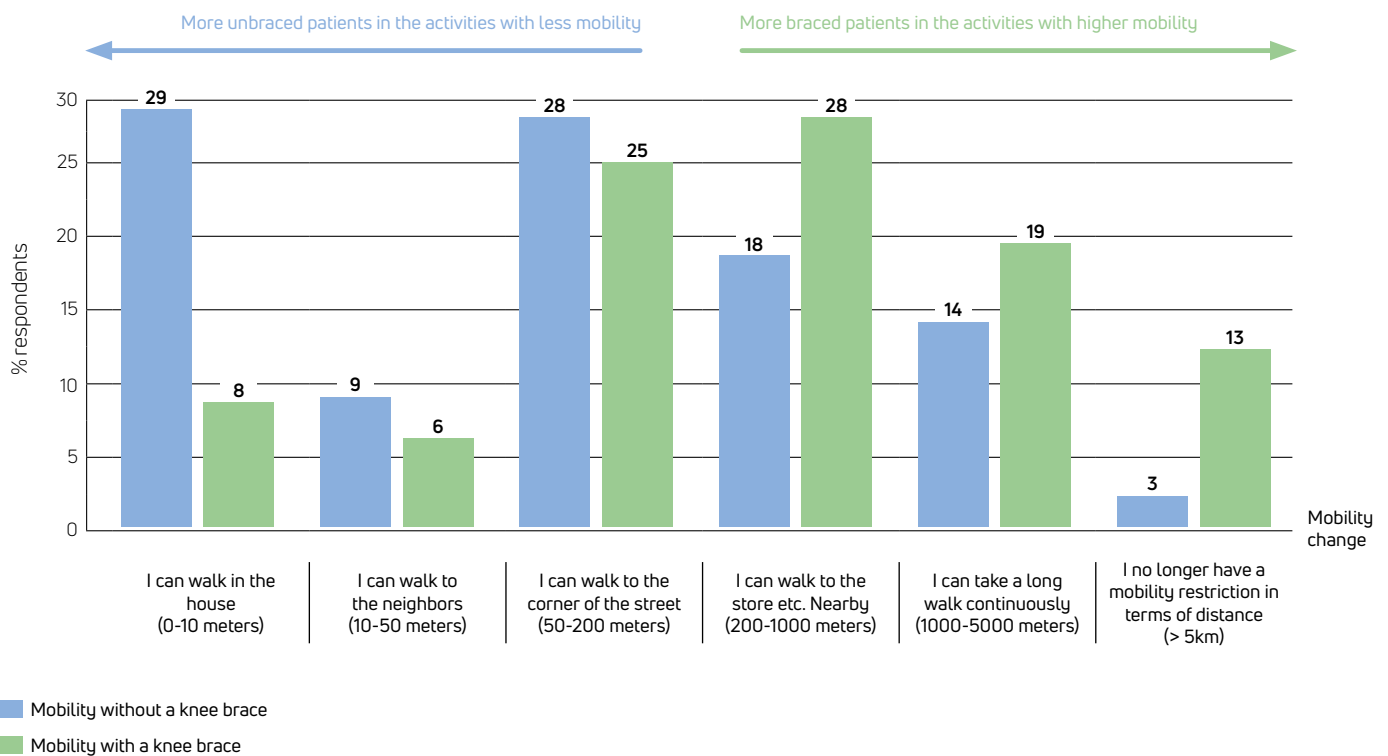


Fig. 10: Results for the question: "Please indicate how mobile you are with/without the knee brace?"¹¹.

This figure shows the results regarding the change in mobility for all respondents. Mobility while using a knee brace improved considerably in different mobility groups. The mobility of respondents who were limited to their home environment reduced by 74%. The mobility of the respondents who were able to walk to a nearby shop increased by 50%, and the group experiencing no mobility restrictions increased from 3% without using a knee brace to 13% while using a knee brace. A total of 42% of respondents using a knee brace indicated that they could take a long walk again (18%) or go to the local shop (24%).

A DonJoy® off-loading brace can bring back freedom of movement to knee OA patients¹¹

GUIDELINES AND RECOMMENDATIONS



- This evidence based practice guideline⁶ is based on a systematic review of published studies for the non-arthroplasty treatment of osteoarthritis of the knee in adults (ages 17 years and older). The purpose of this clinical practice guideline is to evaluate current best evidence associated with treatment.
- The strength of recommendation is assigned based on the quality of the supporting evidence, and also takes into account the quality, quantity, trade-offs between the benefits and harms of a treatment, and magnitude of a treatment's effect.

"Brace treatment could be used to improve function, pain, and quality of life in patients with knee osteoarthritis."

STRENGTH OF RECOMMENDATION: MODERATE

- *Moderate means: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention. Also requires no or only minor concerns addressed in the EtD (Evidence to Decision) framework.*

NON-PHARMACOLOGICAL	PHARMACOLOGICAL	INTRA-ARTICULAR	SURGICAL
Supervised exercise ●●●●○	Topical NSAID ●●●●●	Intra-articular corticosteroids ●●●●○	Partial Meniscectomy ●●●●○
Self-management ●●●●●	Oral NSAID ●●●●●	Platelet-rich plasma	Tibial Osteotomy ●●○●○
Patient education ●●●●●	Oral Acetaminophen ●●●●●	Hyaluronic Acid ●●●●○	Free Floating Interpositional Devices ●○●●○
BRACES ●●●●○	Dietary suppl ●●○●○	-	Arthroscopic Lavage/Debridement ●●●●○
Canes ●●●●○	Oral Narcotics ●●●●●	-	-
Neuromuscular training ●●●●○	-	-	-
Weight loss ●●●●○	-	-	-
Manual Therapy ●●○●○	-	-	-
Massage ●●○●○	-	-	-
Laser Treatment ●●○●○	-	-	-
Acupuncture ●●○●○	-	-	-
TENS ●●○●○	-	-	-
PENS ●●○●○	-	-	-
Shock Wave Therapy ●●○●○	-	-	-
Denervation Therapy ●●○●○	-	-	-
Dry Needling ●○●●○	-	-	-
Lat. wedge insoles ●●●●●	-	-	-

Fig. 11: AAOS Recommendations for the management of knee OA⁶.

- RECOMMENDATION FOR THE INTERVENTION
- RECOMMENDATION AGAINST THE INTERVENTION

These 2019 ACR/AF recommendations²² for the management of OA are based on the best available evidence of benefit, safety, and tolerability of physical, educational, behavioral, psychosocial, mind-body, and pharmacologic interventions, as well as the consensus judgment of clinical experts. Either strong or conditional recommendations were made for or against the approaches evaluated.

- **Tibiofemoral knee braces are strongly recommended** for patients with knee OA in whom disease in 1 or both knees is causing a sufficiently large impact on ambulation, joint stability, or pain to warrant use of an assistive device, and who are able to tolerate the associated inconvenience and burden associated with bracing.
- **Patellofemoral braces are conditionally recommended** for patients with patellofemoral knee OA in whom disease in 1 or both knees is causing a sufficiently large impact on ambulation, joint stability, or pain to warrant use of an assistive device. The recommendation is conditional due to the variability in results across published trials and the difficulty some patients will have in tolerating the inconvenience and burden of these braces.

NICE National Institute for Health and Care Excellence

NICE³³ does not recommend the routine use of braces, however they do recommend braces in specific conditions which are often present in knee OA patients:

"Do not routinely offer insoles, braces, tape, splints or supports to people with osteoarthritis unless:

- there is joint instability or abnormal biomechanical loading and
- therapeutic exercise is ineffective or unsuitable without the addition of an aid or device and
- the addition of an aid or device is likely to improve movement and function".

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INTRODUCING ROAM™ OA BY DONJOY®

ROAM™ OA is the newest innovation in offloader braces from DonJoy®. Indicated for patients with symptoms, physical findings or radiographic evidence of moderate to severe unicompartmental knee osteoarthritis, ROAM helps improve mobility and provides relief by offloading the pressure of unicompartmental osteoarthritis or other knee pain.

Biomechanical testing* showed an improved biomechanical gait pattern in patients with moderate-to-severe knee OA (KL grade 3-4) wearing a ROAM OA brace.

* Multicenter biomechanical study including 14 patients (St. Luke's University Health Network, Pennsylvania and Rush University, Chicago, USA).

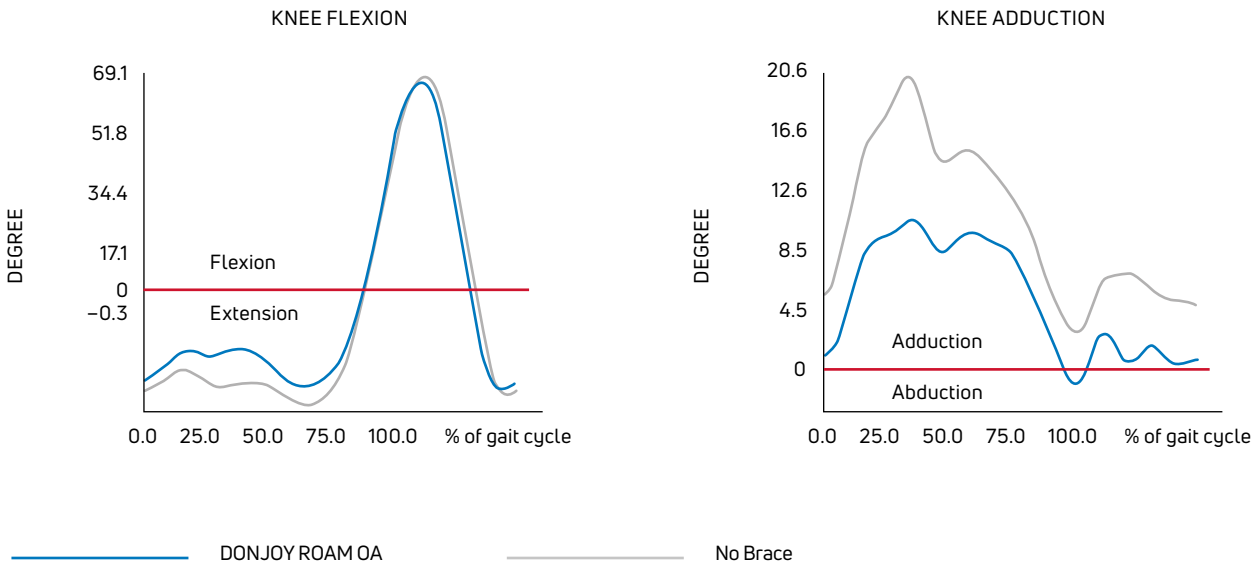


ROAM™ OA REDUCED KNEE ADDUCTION ANGLES IN MAJORITY OF PATIENTS.

Lower knee adduction angle led to a more balanced mediolateral load distribution.

The blue line shows joint movement and joint angle changes during gait when ROAM is worn versus the gray line representing when no brace is applied. As indicated in the blue line, ROAM reduced knee adduction angles in majority of patients. Lower knee adduction angle led to a more balanced mediolateral distribution.

JOINT ANGLES

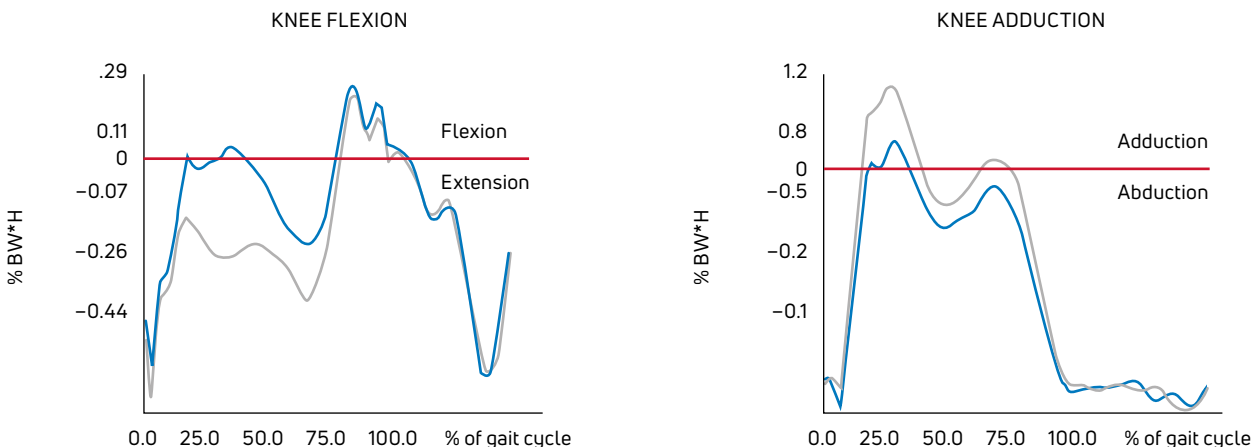


ROAM OA IMPROVED LOAD ACCEPTANCE AFTER HEEL STRIKE WHICH IMPROVED THE FLEXION-EXTENSION PATTERN FROM EARLY TO MIDSTANCE PHASES.

Healthier quadriceps use was suggested based on the increased flexion movements during stance phase of gait.

The blue lines in the knee flexion graphs show that ROAM improved load acceptance after heel strike which improved the flexion-extension pattern from early to midstance.

JOINT MOMENT (EXTERNAL)



DONJOY® OA BRACES

Depending on the osteoarthritis severity, and the activity level of the patient, DonJoy® offers a wide choice of off-loading braces.

Please consult your healthcare professional prior to use.



Fig. 12: Positioning of DonJoy OA braces



**ROAM™
OA**

NEW



**OA
FULLFORCE®**



**OA
NANO®**



**OA
ADJUSTER™ 3**



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DEFIANCE®**

MODERATE

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