



Clinically-proven
ACL protection & Injury prevention



CLINICAL RESEARCH
ACL Functional Knee Bracing



ACL Protection & Injury Prevention

ACL INJURY: FACTS & FIGURES

Incidence

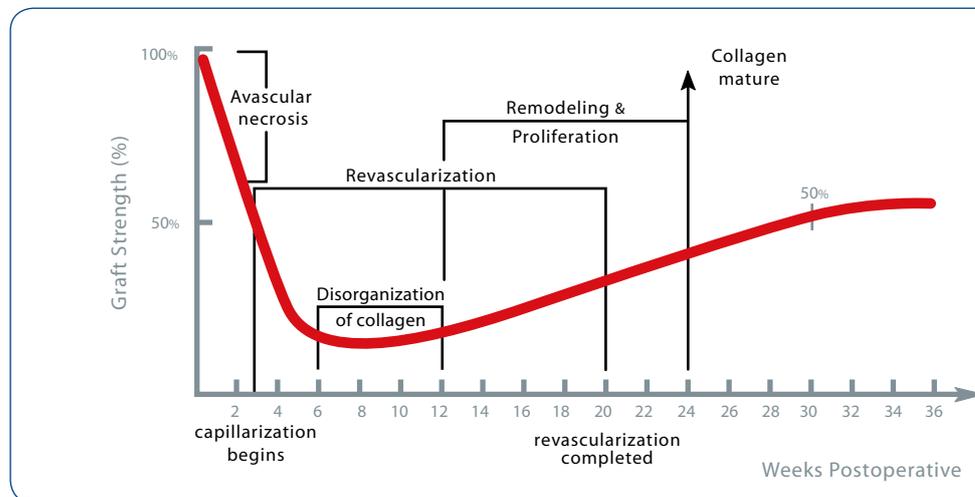
- Over two million ACL injuries occur worldwide annually.¹
- **50%** of ACL injuries occur in **15-25** year olds²
- **60-80%** of ACL injuries are **non-contact** related³
- **Women** are **2-10x** more likely to injure ACL⁴

Risk of ACL injury to contralateral knee is **2 TIMES** that of the reconstructed knee.

Re-injury

- The re-injury rate for the ACL reconstructed knee is 5%-10%⁵
- Risk of **ACL injury** to the **contralateral knee** is **double** that of the reconstructed knee⁵
- Only **1/3** of reconstructed athletes **attempt** to play competitive sports at their **pre-injury level** within **one year** following reconstruction⁶
- **1 in 5** active reconstructive athletes develop **new** injuries⁶
- **Fear of re-injury** prevented competitive college and high school football players from returning to play⁷

Biology of graft healing



Final ACL graft strength is 67% of a normal ACL

Use of a brace until 24 weeks post-op is recommended

Fig. 1: Revascularisation of an ACL graft

- Immediately following ACL surgery the graft is at its strongest, graft strength quickly declines due to avascular necrosis.
- Graft healing research indicates that the graft is most vulnerable to injury around 6 to 8 weeks postop. Between the third and the 20th week after operation the revascularisation process takes place. Proliferation and remodelling of collagen only occurs as from 12 weeks post-operative.
- **Protection of the ACL graft with a brace is recommended until 24 weeks post-op to ensure maximum healing.** ^{8,9,10,11,12,13}

ACL GRAFT PROTECTION DURING HEALING

PROTECT the ACL graft and avoid reinjury



WEAR a DONJOY 4-point-of-leverage brace

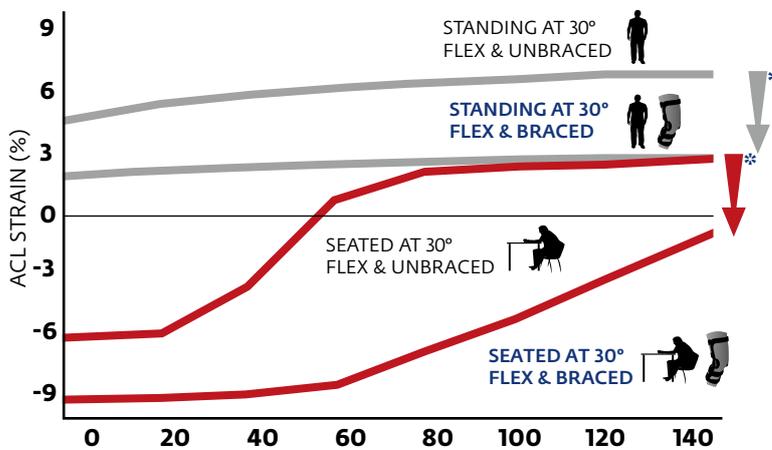


- Decreases ACL strain by 50% for anteriorly directed loads during weight bearing and non-weight bearing activities^{14,15,16,17}
- Improves proprioception and neuromuscular control^{18,19} and increases patient confidence after ACL reconstruction²⁰
- Improves bilateral gait symmetry²¹

DonJoy's 4-Point-of-Leverage brace will decrease ACL strain BY AT LEAST 50%.

THE EVIDENCE

In-vivo ACL strain study¹⁵ - with and without brace



*Decreases ACL Strain by 50% for anteriorly directed loads during weightbearing and non-weightbearing

Fig. 2: This graphic shows the mean ACL strain values produced by anterior shear loads applied to the tibia of the unbraced and braced knee with the subjects in standing (weightbearing) and seated (nonweightbearing) positions. In both loading situations, the subject's knee was flexed at 30°. ACL strain was measured through transducers implanted into the ACL. Calculation of ACL strain was referenced to the slack-taut transition point of the ligament.



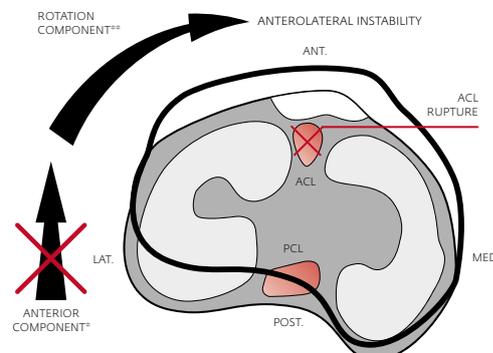
The DonJoy 4-point-of-leverage technology effectively reduces ACL strain which could be particularly important during rehabilitation while the graft is remodeling^{14,15,16,17}

The DonJoy Brace Design

4-POINT-OF-LEVERAGE™

How the DonJoy 4-Point Brace Protects the ACL Deficient Knee

- Patients with an ACL deficient knee have an anterolateral instability.
- A brace can help to stabilize the knee and prevent further injury but controlling rotation instability in a direct way is very difficult.
- By avoiding an anterior tibial translation*, the subsequent rotation component (***) can be reduced or potentially completely avoided.
- The DonJoy® biomechanical 4-point design is clinically proven to be the most effective way to prevent anterior translation of the tibia and will provide a high level of stability for the ACL deficient knee.



The DONJOY 4-point-brace = the best brace to control rotation instability by limiting anterior tibia translation



The 4-Point-of-Leverage™ Design Explained

Point of Leverage #1

The rigid calf cuff is secured at the bottom of the calf providing the distal anchor point to the leverage system.

Point of Leverage #2

The rigid thigh cuff is secured at the top of the anterior thigh providing the proximal anchor point to the leverage system.

Point of Leverage #3

The strap across the back of the lower thigh pushes the femur anteriorly.

Point of Leverage #4

The strap placed on the anterior tibia applies an active constant load to prevent anterior tibial translation.

- The ground reaction forces (GRF) acting during functional activities play an important role in ACL loading.
- The horizontal component of the GRF imposes an anterior translation on the tibia which causes strain to the ACL.
- The DONJOY 4-Point braces with OPPOSING rigid cuffs are designed to reduce the ACL strain.
- An anteriorly directed force on the femur (3) and a posteriorly directed force on the tibia (4), both close to the knee, are biomechanically the best system to control the anterior tibial translation.
- In order to make these two dynamic forces work, two additional static anchor points are needed (1) (2).
- The combination of these two dynamic "strap" forces and two static "rigid cuff" forces produce the '4-Point-of-Leverage system'.
- The 4-Point-of-Leverage system requires a correct configuration of the straps and a brace design with opposing cuffs.

FOURCEPOINT™ HINGE

How the FourcePoint™ Hinge keeps the knee out of the “at risk” position

Aggressive eccentric contractions of the quadriceps produce significant anterior tibial translation and can injure the ACL or permanently stretch out an ACL graft²².

Quadriceps-intensive activities should be avoided at joint angles where strains are at a maximum, particularly the last 30 degrees of extension. DJO has developed a hinge to address maximising ACL and ACL graft protection in these “at risk” positions.

Small knee flexion angles at initial contact during landing tasks may contribute to ACL injuries. The FourcePoint Hinge can be used to control joint range-of-motion by increasing the knee flexion angle during landing, resulting in a decrease of anterior shear force on the ACL by 9-13%²³.

Flexion



Extension



The DonJoy FourcePoint™ utilises a leaf spring mechanism in the hinge to apply gradually increasing resistance during knee extension. The resistance engages in the last 25 degrees of extension (relative to the extension stop).

The hinge has three levels of resistance with the option to turn off resistance if appropriate.

**The DonJoy
Fourcepoint™
utilises a leaf
spring system
in the hinge**

The resistance serves three critical roles:

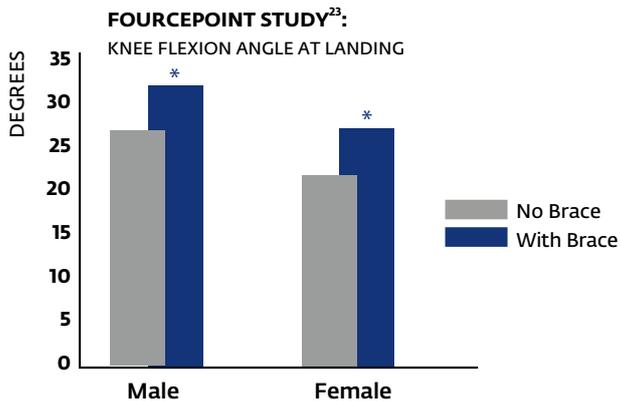
- First, it reduces the time spent near full extension or in the “at risk” position.
- Second, it gradually adds posterior load to the tibia complementing the 4-Point-of-Leverage in preventing anterior tibial translation.
- Third, it eliminates the extension shock felt when a patient extends into a 10 degree standard rigid stop.

FourcePoint Hinge Technology works to enhance DonJoy's 4-Point-of-Leverage design by damping knee joint extension, which improves the mechanical performance of the brace and reduces shear forces at the knee.

The FourcePoint hinge combined with the 4-Point-of-Leverage cuff and strapping design provides a more comfortable brace that reduces anterior shear forces at the knee, providing protection to the healing graft in ACL reconstructed patients, stability to an unstable knee in ACL deficient persons, and prophylaxis during sports activities.

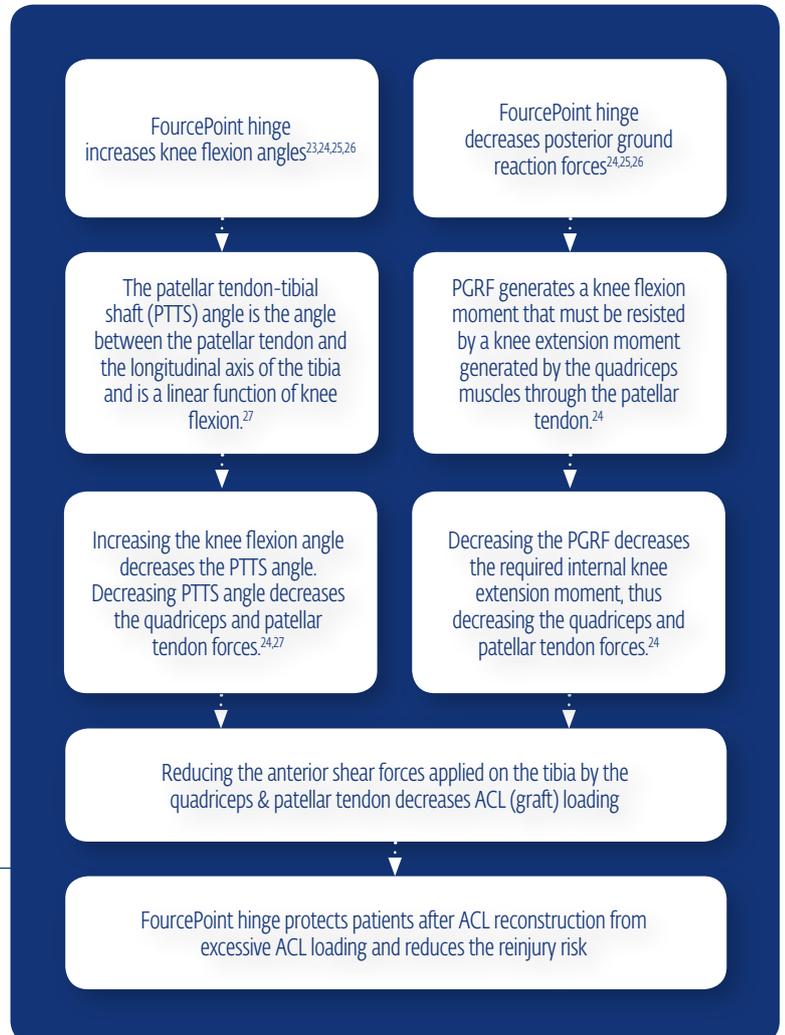
ACL (GRAFT) PROTECTION

Reducing the risk of ACL reinjury to the reconstructed knee



Wearing a fourcepoint brace significantly increased knee flexion angle at landing in a stop-jump task with an average of 5.1° in males and 5.3° in females.

* Significant: $p = 0.001$



Using a brace with FourcePoint™ hinge technology in conjunction with a 4-Point-of-Leverage™ frame design:

- Significantly increases knee flexion angle by up to 9° at landing in a stop-jump task in healthy subjects^{23,25,26} and at initial foot contact during walking, jogging and stair descent in ACL reconstructed patients²⁴, when compared to standard braced and non-braced condition.
- Significantly reduces the anterior shear force applied on the tibia during landing in a stop-jump task, by an average of 9% for females and 13% for males.²³
- Significantly decreases peak posterior ground reaction force (PPGRF) during walking, stop jump task landing and side-cutting activities^{24,25,26}
- Does not impede performance^{23,25}

ACL INJURY PREVENTION

Training effect of the FourcePoint hinge

Improved lower leg biomechanics are retained for 4 weeks, suggesting a positive transfer in protective movement patterns

The evidence: Controlled laboratory study on 24 athletes²⁶

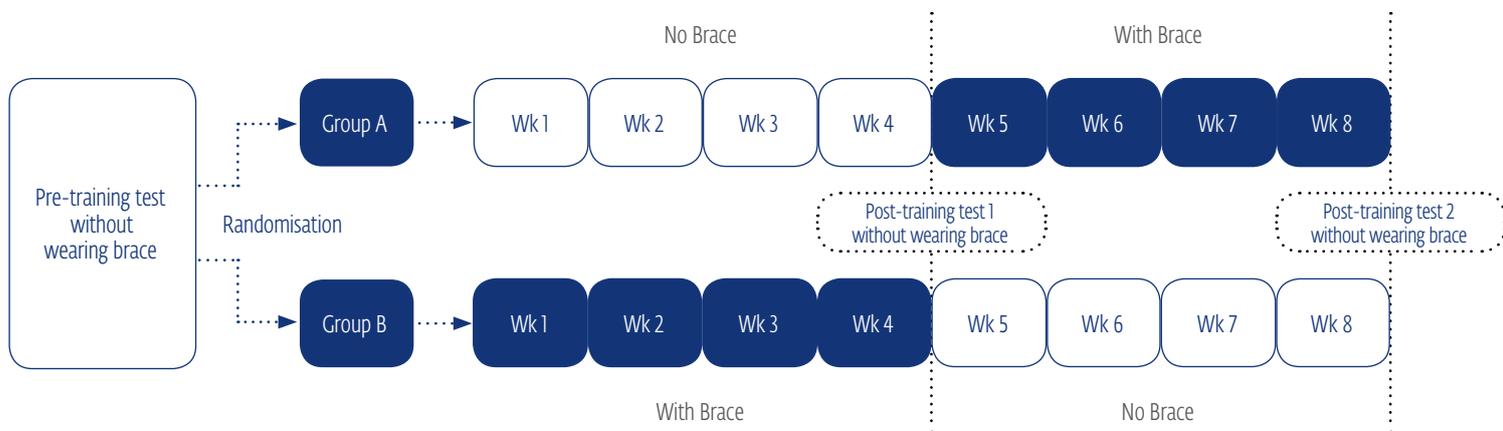


Fig. 1: Study design. Group A trained without brace from week 1 to week 4, and with brace from week 5 to week 8. Group B trained with brace from week 1 to week 4, and without brace from week 5 to week 8. Braces were worn for a minimum of two hours per week on both legs. Tests were performed without braces.

- Training with a FourcePoint brace significantly improves motion patterns during ACL challenging tasks. Figure 2 shows increased knee flexion angles during landing after 4 weeks of training with a FourcePoint brace.
- About 50% of the training effects were retained 4 weeks after the end of the training using the brace (figure 2, group B), suggesting a positive transfer in the skill learning related to increased knee flexion.
- The authors suggest 4-week FourcePoint brace training should reduce the risk for noncontact ACL injuries at least during the 4 weeks immediately after the training.

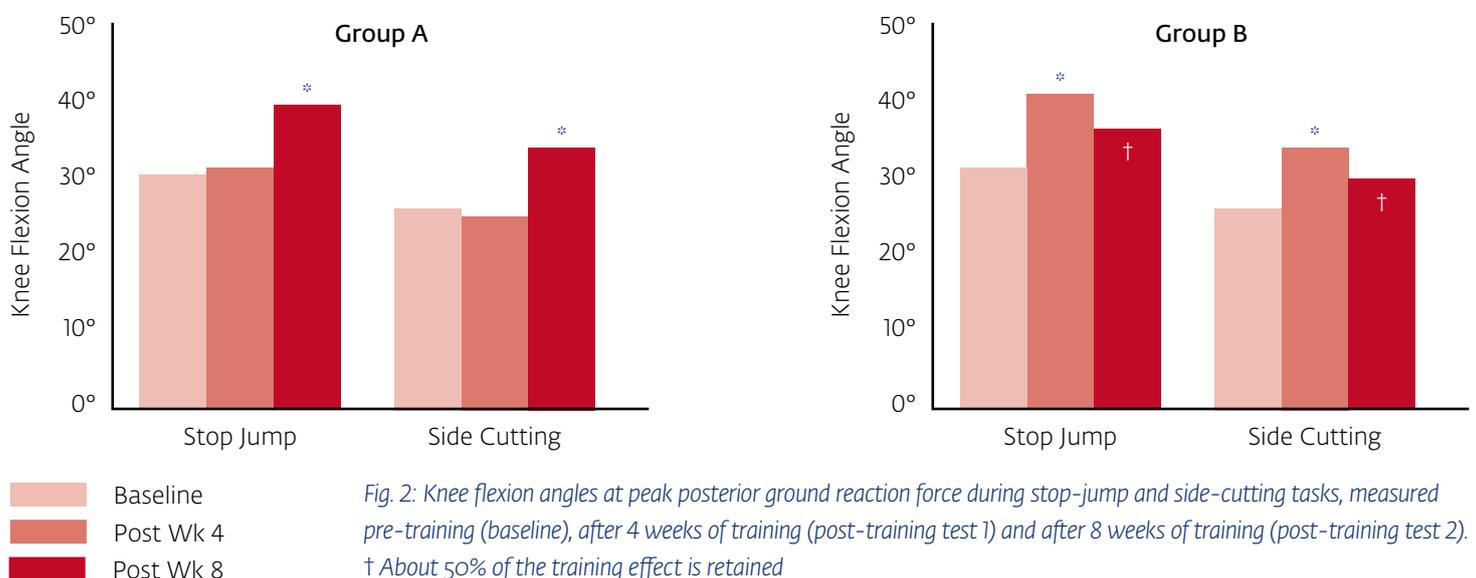


Fig. 2: Knee flexion angles at peak posterior ground reaction force during stop-jump and side-cutting tasks, measured pre-training (baseline), after 4 weeks of training (post-training test 1) and after 8 weeks of training (post-training test 2). † About 50% of the training effect is retained

* Significant: $p = 0.001$

Supporting Studies

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