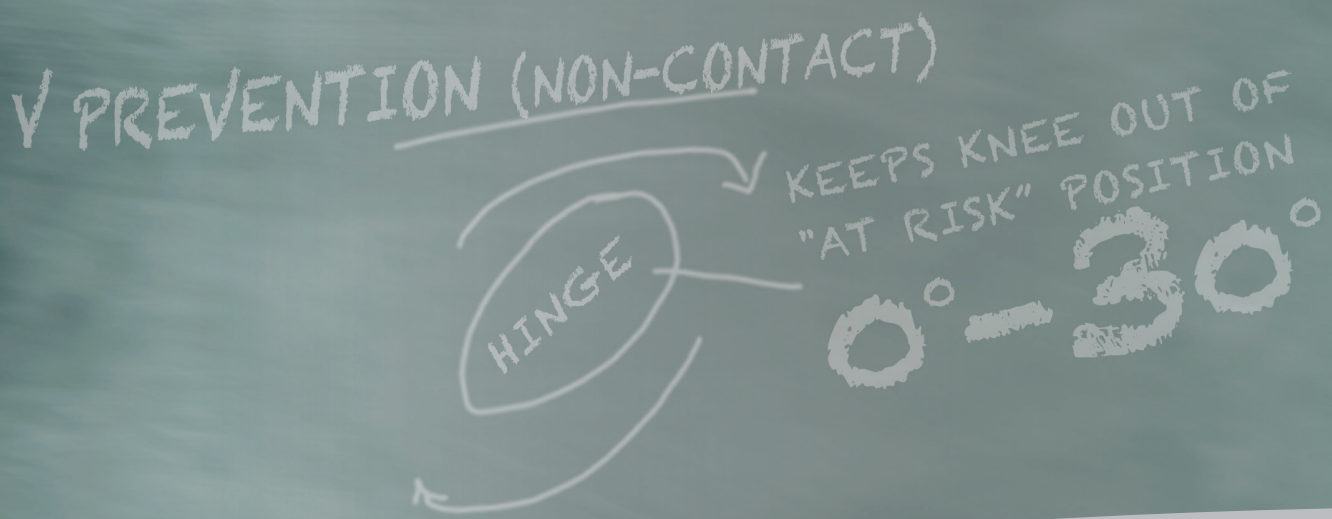
DONJOY

ACL Functional Knee Bracing
CLINICAL RESEARCH

4 POINTS-OF-LEVERAGE + FOURCEPOINT TECHNOLOGY = CLINICALLY-PROVEN ACL PROTECTION & INJURY PREVENTION



DJO GLOBAL

ACL INJURY: FACTS & FIGURES

Contributing Factors

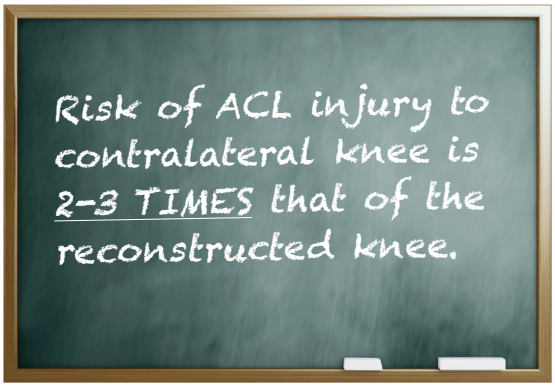
- Decreased knee flexion angle[1]
- Anterior tibial shear forces[2]
- Combined valgus and knee internal rotation moments[2]
- Combined valgus and knee external rotation[2]

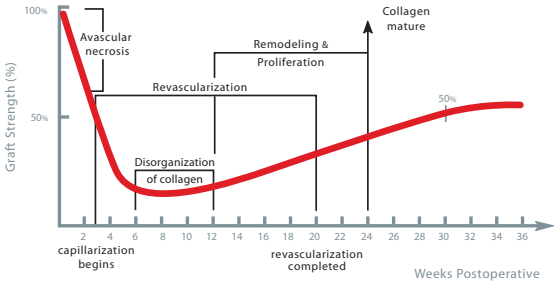
Incidence

- Approximately **200,000** ACL injuries per year occur in the U.S.[3]
- **50%** of ACL injuries occur in **15-25** year olds[3]
- **60-80%** of ACL injuries are **non-contact** related[4]
- **Women** are **2-10x** more likely to injure ACL[5]

Re-injury

- The **re- injury** rate for the ACL reconstructed knee is **5%-10%**[6]
- Risk of **ACL injury** to the **contralateral knee** is **double** that of the reconstructed knee[6]
- Only **1/3** of reconstructed athletes **attempt** to play competitive sports at their **pre-injury level** within **one year** following reconstruction[7]
- **1 in 5** active reconstructive athletes develop **new** injuries[7]
- **Fear** of **re-injury** prevented competitive college and high school football players from returning to play[8]





Immediately following ACL surgery, graft strength quickly declines. Graft healing research indicates that the graft is most vulnerable to injury around post-op weeks 6-12. [9, 10, 11, 12, 13, 14]

References

1. Markolf KL, Gorek JF, Kabo JM, et al. Direct measurement of resultant forces in the anterior cruciate ligament. Journal of Bone & Joint Surgery, Am. 1990 72:557-567.
2. Shimokochi Y, Shultz SJ. Mechanisms of Noncontact Anterior Cruciate Ligament Injury. Journal of Athletic Training. 2008 43:4. 396-408.
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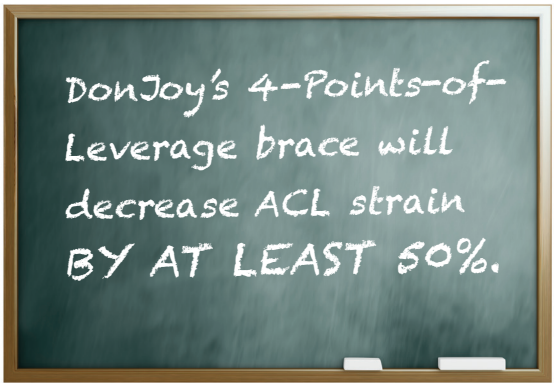
PROTECTION

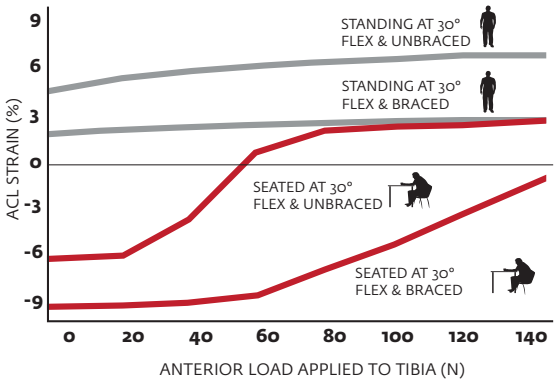
Reducing the risk of ACL reinjury to the reconstructed knee



Wearing a 4-Points-of-Leverage brace:

- Decreases ACL strain by 50% for anteriorly directed loads during weight bearing and non-weight bearing activities[1, 2, 3]
- Significantly reduces tibial rotation vs. unbraced and sleeved groups[5]
- May improve both proprioception and postural control[6]
- Increases patient confidence after ACL reconstruction[7]

4-POINTS-OF-LEVERAGE STUDY



ACL strain values produced by anterior tibial loading.[2]
Braces utilizing 4-Points-of-Leverage technology effectively reduce ACL strain which could be particularly important during rehabilitation while the graft is remodeling.[1,2,3,4]

Supporting Studies

1. Beynnon BD, Pope MH, Wertheimer CM, Johnson RJ, Fleming BC, Nichols CE, Howe JG. Journal of Bone & Joint Surgery, Am. 1992; 74:1298-1312.
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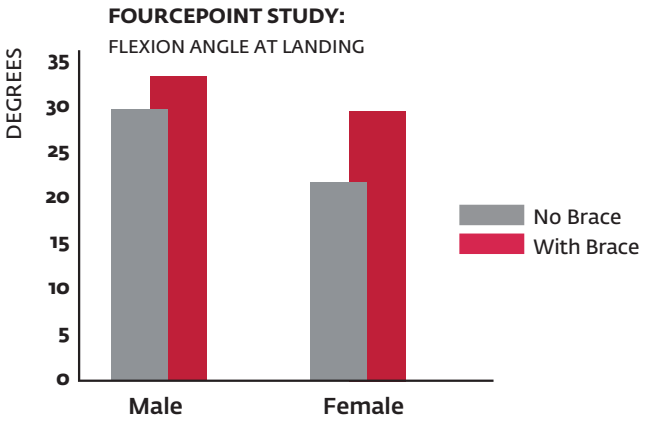
PROTECTION

Reducing the risk of ACL reinjury to the reconstructed knee

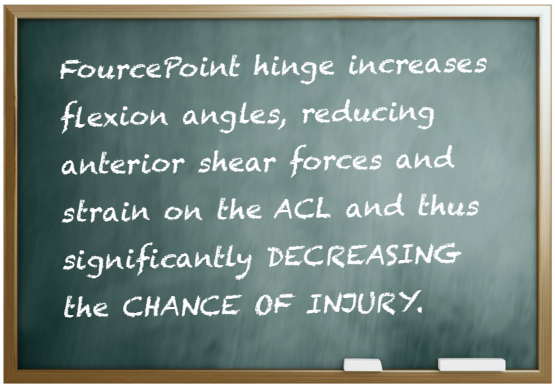


The anterior shear force applied on the tibia was reduced by 9% for females & 13% for males.[5]

The decrease in anterior shear force on the tibia should substantially reduce the load on the ACL.[2, 4]

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

- Significantly increases knee flexion angle at peak posterior ground reaction force (PPGRF) by 9° vs. a standard braced knee and a non-braced knee[1, 3]
- Significantly decreases PPGRF during stop jump task landing and side-cutting activities[1]
- No significant performance limitations were associated with the knee brace with FourcePoint hinge technology[1]



Supporting Studies

1. Lin CH, Liu H, Garrett WE, Yu B. Effects of Knee Extension Constraint Brace on Selected Lower Extremity Motion Patterns During a Stop-Jump Task. Journal of Applied Biomechanics.2008;4:158-165.

2. Markolf KL, Gorek JF, Kabo JM, et al. Direct measurement of resultant forces in the anterior cruciate ligament. Journal of Bone & Joint Surgery, Am. 1990; 72:557-567.

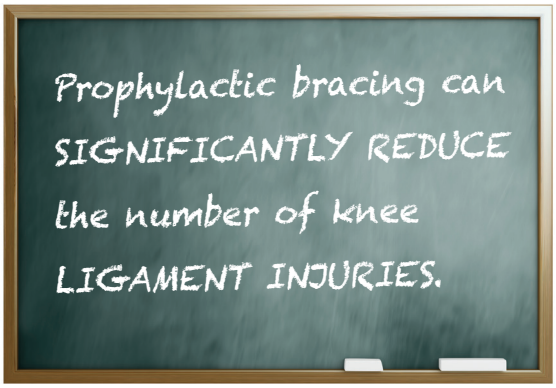
3. Stanley C, Creighton R, Gross M, Garrett W, Yu B. Effects of a Knee Extension Constraint Brace on Lower Extremity Movements after ACL Reconstruction. Clinical Orthopaedics and Related Research. 2011; 469(6):1774-1780.

4. Yu B, Herman D, Preston J, Lu W, Kirkendall DT, Garrett WE. Immediate Effects of a Knee Brace with a Constraint to Knee Extension on Knee Kinematics and Ground Reaction Forces in a Stop-Jump Task. American Journal of Sports Medicine. 2004;32:1136-1143. Nunley et al. 2003

5. Nunley RM, Wright DW, Renner JB, Yu B, Garrett WE. Gender Comparison of Patella-Tendon Tibial Shift Angle with Weight-Bearing. Res Sports Med. 2003; 11:173-185.

PREVENTION (CONTACT)

Reducing the risk of contact/high impact knee ligament injuries



Football

Prophylactic brace use:

- May be effective in reducing the risk of incurring an MCL sprain in football, and generally provide 20-30% greater MCL resistance to a lateral blow[3]
- Reduces injury rates among college football players, linemen, linebackers and tight ends when worn in both practices and games vs. unbraced players[1, 5]
- During one season at a Division I University, football players who wore braces missed only 43 practices and 3 games vs. 258 and 43 respectively for unbraced players[2]
- Of the 12 knee surgeries of the season, only one occurred in a player who was wearing a brace at the time of injury[2]
- In a 2 year study at a major Division I university football program, the number of days lost due to knee injury (and related associated healthcare costs) was reduced by 99% from year 1 to year 2 through the use of a custom fitted prophylactic knee brace in the 2nd year[7]

Off-road Motorcycling

Prophylactic brace use:

- Reduces ACL injury rates by 50% with a 7-fold decrease in MCL injury rates[4]

Skiing

Prophylactic brace use:

- Reduces ACL reinjury by 3-times[6]

Supporting Studies

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2. Jones C. Prophylactic Knee Bracing. DonJoy ATC Seminar, University of Richmond, July 2006.

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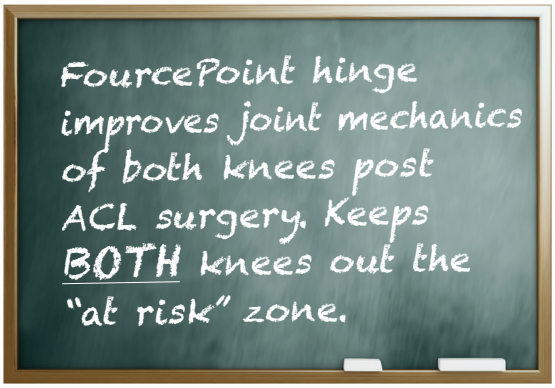
PREVENTION (NON-CONTACT)

Reducing the risk of injury to the contralateral knee



Wearing NO brace or a knee brace without FourcePoint hinge technology (results at 6-12 months post-op):

- 30% deficit in joint mechanics
- Asymmetry of mechanics in both knees[1]

Wearing a knee brace with FourcePoint hinge technology:

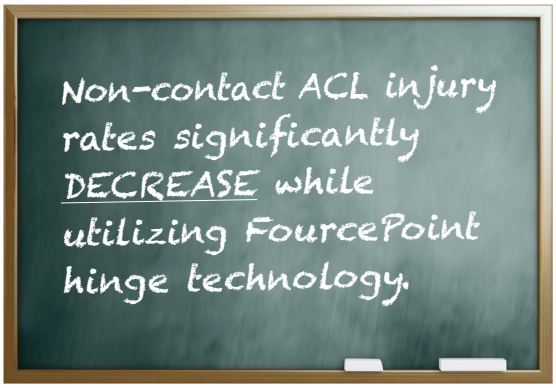
- Improved joint mechanics on **BOTH** the surgical and non-surgical knees for enhanced symmetry[1]
- Improved mechanics caused **BOTH** knees to act more symmetrical[1]
- Increased peak knee flexion velocity of **BOTH** knees[1]
- Helped keep **BOTH** knees out of the *"at risk"* position (0°- 30° flexion)[1, 2]

Supporting Studies

1. *Queen R, Butler RJ, Dai B, Garrett WE. Effects of Knee Extension Constraint Bracing on Lower Extremity Motion Patterns in Post-ACL Reconstruction Patients. Interim report of six and twelve month data from the ongoing study, 2012.*
2. *Yu B, Herman D, Preston J, Lu W, Kirkendall DT, Garrett WE. Immediate Effects of a Knee Brace with a Constraint to Knee Extension on Knee Kinematics and Ground Reaction Forces in a Stop-Jump Task. American Journal of Sports Medicine. 2004;32:1136-1143.*

PREVENTION (NON-CONTACT)

Reducing the risk of non-contact ACL Injury

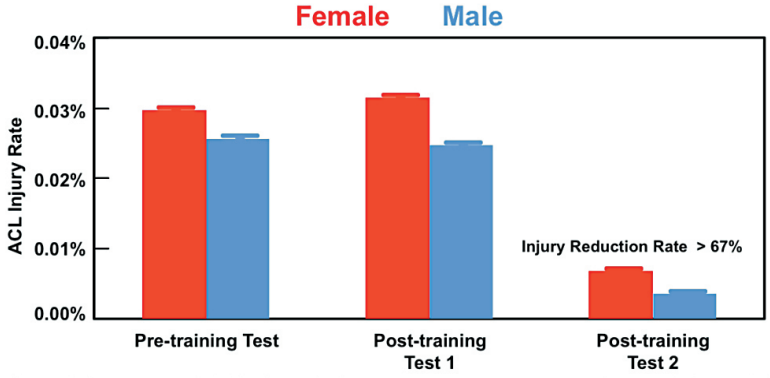


Significant reduction in ACL injury rate

- > 80% while wearing brace with FourcePoint hinge[1]
- > 50% after training in brace with FourcePoint hinge[1]
- Training effects (increased flexion angles) retained by > 50% while not wearing the brace[1]
- Training in a **SINGLE** (one leg brace) with FourcePoint technology results in a 6-fold decrease in non-contact ACL injury rate in both knees[1]
- Inertial sensor-based feedback system used in training during jump landings showed reduced key risk metrics for ACL injury[2]

Training Effects – Group A

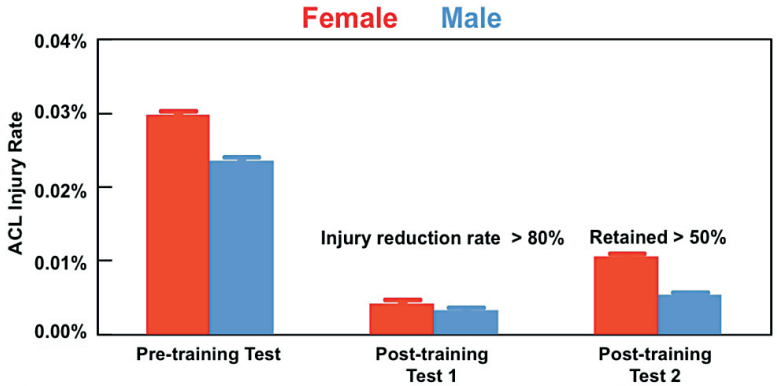
Estimated Non-contact ACL Injury Rate In Stop-Jump Task*



*probability for non-contact ACL injuries (stochastic biomechanical modeling, accepted Feb 2008 in Journal of Biomechanics)

Retention of Training Effects – Group B

Estimated Non-contact ACL Injury Rate in Stop-jump Task*



*probability for non-contact ACL injuries (stochastic biomechanical modeling, accepted Feb 2008 in Journal of Biomechanics)

Subjects wore brace a minimum of one (1) hour 3x per week for 4 weeks

Supporting Studies

1. Lin CH, Liu H, Garrett WE, Yu B. Effects of Knee Extension Constraint Brace on Selected Lower Extremity Motion Patterns During a Stop-Jump Task. Journal of Applied Biomechanics.2008;4;158-165.

2. Dowling A, Farve J, Andriacchi T. Inertial Sensor-Based Feedback Can Reduce Key Risk Metrics for Anterior Cricicate Ligament Injury During Jump Landings. AM J Sports Med. 2012; 40:1075.

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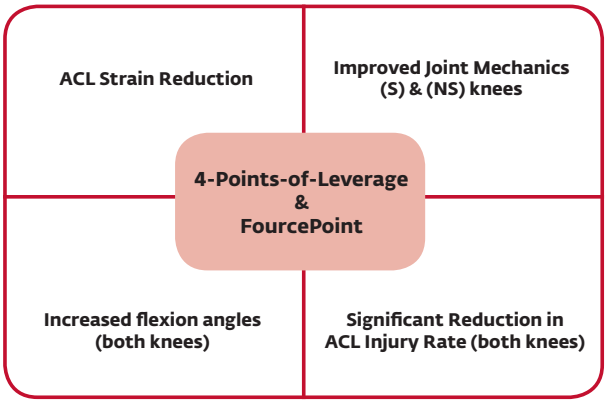
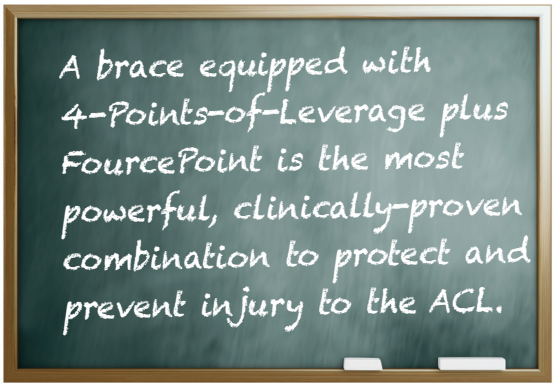
PRESCRIBE CONFIDENCE

Clinical Biomechanics Review

- Training **WITH** FourcePoint hinge will encourage the knee to stay out of the "at risk" position (0º-30º of flexion)
- Training effect **WITH** FourcePoint hinge will be retained despite intermittent brace wear
- Rehab training after ACL reconstruction **WITHOUT** a FourcePoint hinged brace leads to abnormal joint mechanics of **BOTH** knees
- Rehab training after ACL reconstruction **WITH** a FourcePoint hinged brace improves joint mechanics in **BOTH** knees

CLINICAL PERFORMANCE OVERVIEW





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