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# Braden C. Fleming, PhD, recognized by the AAOS and the OREF for research into the long-term outcomes of ACL reconstruction with a focus on post-traumatic osteoarthritis

**ROSEMONT, Ill.** (February 5, 2020)—Braden C. Fleming, PhD, received the Orthopaedic Research and Education Foundation (OREF) Clinical Research Award. The award recognizes outstanding clinical research related to musculoskeletal disease or injury.

As lead researcher, Dr. Fleming, along with co-authors Gary Badger, MS, Paul D. Fadale, MD, Michael J. Hulstyn, MD, Robert M. Shalvoy, MD, and Glenn Tung, MD, spent more than 15 years studying certain mechanical, psychological and biological factors that could lead to the onset and progression of post-traumatic osteoarthritis (PTOA) following anterior cruciate ligament reconstruction (ACLR), a common risk of anterior cruciate ligament (ACL) injury and the ACLR procedure.

Their work primarily studied the tension applied to a graft (a replacement ligament to assume the role of the damaged ACL) used to reconstruct the ACL. The team wanted to determine if the tension difference was a primary factor for developing PTOA since it dictates joint contact conditions. After studying the patient population for seven years post-surgery, the researchers concluded there were no significant differences in the clinical, functional and patient-reported outcomes for the two graft tensioning conditions (one that restores normal laxity and one that makes the knee tighter at the time of surgery).

"As a bioengineer, I wanted to explore the mechanical functions of the knee and the way the joint distributes its force or load during activity to determine if joint stability is related to PTOA risk," said Dr. Fleming, the Lucy Lippitt Professor of Orthopaedics at Brown University. "We studied graft tension to evaluate and explore two schools of thought. One was to apply a tight graft at the time of surgery with the idea that it will stretch over time, and it will basically return to normal. The other was to put the graft in at a low tension and restore normal at the time of surgery, so ideally it won't stretch out."

ACL injuries are one of the most common knee injuries, with approximately 400,000 ACLRs performed in the United States each year<sup>i</sup>.

"While surgical treatment for ACL injuries can be beneficial for patients, many of these patients still present with functional deficits and are now at a higher risk for PTOA," said Dr. Fleming.

In fact, the risk of developing moderate to severe PTOA 10 years after ACLR is 2.3 times greater than a knee conservatively treated without surgery.<sup>ii</sup>

<sup>&</sup>lt;sup>i</sup> Junkin DM, Johnson DL, Fu FH, et al. 2009. Knee Ligament Injuries. In: Kibler WB editor. Orthopaedic Knowledge Update 4: Sports Medicine. Rosemont: American Academy of Orthopaedic Surgeons; pp. 135-153.

<sup>&</sup>lt;sup>ii</sup> Ajuied A, Wong F, Smith C, et al. 2014. Anterior cruciate ligament injury and radiologic progression of knee osteoarthritis: A systematic review and meta-analysis. Am J Sports Med 42:2242-2252.

The primary hypothesis of this trial was that the high-tension group would have improved outcomes compared to the low-tension group at seven years follow up. The second hypothesis was that the outcomes for the high-tension group would be equivalent to the matched control group.

The prospective randomized controlled trial (RCT) analyzed 90 patients over seven years to compare clinical, functional, patient-reported and PTOA imaging outcome measures between the two common graft tension protocols post-surgery. The trial included a matched, uninjured control group of 60 patients of similar age, race, sex and activity level to the ACLR patients in the trial to compare outcomes. Following surgery, outcome measures were assessed at one, three, five and seven years in both groups.

Overall, the clinical, functional, patient-reported and imaging outcomes for the two graft tension groups were similar at seven years. Most of the clinical, functional, patient-reported and PTOA imaging outcome measures also showed that the reconstructed knees, regardless of tension group, did not return to normal.

Additional findings of the RCT revealed:

- The grafts in both groups "stretched out" to the same level over the first year of healing.
- There were no statistically significant differences between the two tension groups (p=.83) when evaluated for function, symptoms, range of knee motion and clinical examination.
- There were no statistically significant differences in the subsequent knee injury rates between the two tension groups (p=.53).
- The 1-leg hop distances (used to measure functional outcomes) for the two tension groups were significantly less than the control group (p<.02), though there was no statistical difference between tension groups (p=.59).

Not only has this research team received additional NIH funding to follow this patient cohort for 12 and 15 years to evaluate longer-term changes, but as a result of their work, their database has led to seven separate studies. These studies are providing additional insight into the causes of PTOA following ACL injury and treatment.

As a previous AAOS award recipient, Dr. Fleming received the Ann Doner Vaughn Kappa Delta Award in 2013 with Martha M. Murray, MD, also an OREF grant recipient, for their research on the use of a "bioenhanced repair" technique for treating ACL tears as an alternative to ligament reconstruction. He was also part of the team that received the Elizabeth Winston Lanier Award in 1994 for "The Biomechanics of the Anterior Cruciate Ligament and Bone-Patella Tendon-Bone Graft in Vivo."

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### About the OREF Clinical Research Award.

The OREF Clinical Research Award was established in 1995 to recognize outstanding clinical research related directly to musculoskeletal disease or injury. All submitted manuscripts are reviewed, graded, and selected by the AAOS Research Development Committee. The award provides \$20,000 to recipients. For more information about the manuscript submission process, please visit <u>aaos.org/kappadelta</u>.

### About the OREF

The Orthopaedic Research and Education Foundation (OREF) is an independent, 501(c)3 non-profit organization that raises funds to support research on diseases and injuries of bones, nerves and muscles and to enhance clinical care leading to improved health, increased activity and a better quality of life for

patients. To further its mission, OREF is committed to exploring ways to partner with others to move the field of musculoskeletal research forward. For more information, visit <u>www.oref.org</u> and follow us on <u>Twitter</u>.

### About the AAOS

With more than 39,000 members, the American Academy of Orthopaedic Surgeons is the world's largest medical association of musculoskeletal specialists. The AAOS is the trusted leader in advancing musculoskeletal health. It provides the highest quality, most comprehensive education to help orthopaedic surgeons and allied health professionals at every career level best treat patients in their daily practices. The AAOS is the source for information on bone and joint conditions, treatments and related musculoskeletal health care issues and it leads the health care discussion on advancing quality.

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#### Disclosure

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Dr. Fleming is a co-founder of Miach Orthopaedics, Inc., a start-up company aimed at translating a new ACL repair strategy to clinical use. He also served as a consultant for New York R&D Center for Translational Medicine and Therapeutics, Inc. (2017). He received travel support to attend an academic conference from Smith & Nephew (2017). He also receives a stipend for his role as an associate editor for the American Journal of Sports Medicine (2013-present), and royalties from Springer Publishing for a book on the ACL (2013-present). None of these disclosures are directly related to the content of this manuscript.