Editorial

Climbing the Level of Evidence Ladder: Prospective, Comparative-Effectiveness Knee ACL and PCL Research

We are firm believers in evidence-based medicine and the importance of denoting and understanding the hierarchy of levels of evidence. While level of evidence is but one measure of the quality of arthroscopic and related research, studies of higher levels of evidence best allow surgeons to determine the answers to clinical questions.[1]

A flaw with most clinical research is the absence of a control group. Unfortunately, while case series (Level IV evidence) remain the most common type of published study in the medical, surgical, orthopaedic surgical, as well as the arthroscopic and related literature, the absence of a control group raises questions: How do we know the treatment offered is superior to other treatment methods? How do we know the treatment offered is superior to no treatment at all?

In the current issue, we publish case series (absent control groups), which we value,[2] as well as systematic reviews and meta-analyses, which we favor.[3] Of course, while we favor systematic reviews, particularly meta-analyses, we acknowledge that these review methods are based on qualitative or quantitative synthesis of previously published original scientific research. Without the time-consuming and expensive effort required to perform original, clinical outcomes study,[4] systematic reviews of the literature, including meta-analyses, would not be possible. As such, our ultimate goal is to publish well-designed scientific research studies of the highest levels of evidence.

In this editorial, we highlight original, clinical, comparative-effectiveness research in the current issue.[5] On review of our level of evidence table, we note that there are three types of comparative, clinical studies. Level III evidence represents retrospective comparative research that has, as limitations, all of the disadvantages of retrospective investigation. Despite the disadvantages of retrospective research, inclusion of a control group does better allow arthroscopic and related researchers to answer clinical questions (when comparing Level III research with Level IV case series). We thus respectfully acknowledge, in the current issue, De Coninck et al. from Ghent University Hospital in Belgium, for their study "Open versus arthroscopic meniscus allograft transplantation: Magnetic resonance imaging study of meniscal radial displacement"[6] and Dejour et al. from France and Brazil for their report on "The diagnostic value of clinical tests, magnetic resonance imaging, and instrumented laxity in the differentiation of complete versus partial anterior cruciate ligament tears."[7] We congratulate them for their important step up the ladder of clinical evidence in their pursuit of Level III, retrospective comparative study.

As we continue to climb the level of evidence ladder, we note with pride the work of Noh et al. of South Korea "Single-bundle anterior cruciate ligament reconstruction in active young men using bone-tendon Achilles allograft versus free tendon Achilles allograft" as Level II evidence.[8] Compared with the highest level of evidence reviewed below, Level II studies are prospective cohort studies or lesser quality randomized controlled trials due to less than 80% follow-up, or show no difference between groups with wide confidence intervals, which may introduce bias. Despite this limitation, Level II, clinical, comparative-effectiveness research is an extremely powerful method of answering a clinical question. Noh et al. prospectively compare the outcomes of two methods of ACL reconstruction in active male patients treated with Achilles allograft: femoral bone plug with metal interference screw fixation and looped soft-tissue graft with femoral cortical suspensory button fixation. With regard to surgical technique, it should be noted that, while both groups had "double fixation" on the tibia (interference screw plus post and washer), the femoral bone plug group had a single strand of whipstiched tibial collagen and the looped soft-tissue graft with femoral cortical suspensory button fixation group had 2 strands of whipstiched tibial collagen. If we can accept the caveat that the difference on the tibial side is not clinically significant, and if we can accept that the Achilles allograft model could be translated to other bone plug or soft tissue graft models, then the results of this study may have clinical relevance and be of significant interest to ACL surgeons and researchers who wish to answer the clinical question about optimal femoral fixation. The obvious challenge in interpreting this or any published research is that, as noted above, we always face caveats and limitations.[9] In addition, there are very well

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done Level II randomized controlled trials, but they lack the rigidity of a Level I randomized controlled trial in that there may be some issue with patient allocation or other selection bias. As such, we admire the Level II research methods, acknowledge that all research has limitations, and invite readers to consider the value of this research in their own clinical practices.

As suggested above, when climbing the proverbial level of evidence ladder, the highest level of evidence for comparative clinical outcomes research is the prospective, randomized controlled trial—Level I evidence—because randomization is the best method for mitigating against selection bias. We tip our hats to Yoon et al. from Seoul, South Korea, for the publication of their randomized controlled trial, "Does cast immobilization contribute to posterior stability after posterior cruciate ligament reconstruction?"[10] This study group was treated postoperatively using a long-leg splint for 1 week, followed by a long-leg cast allowing no range of motion for 4 weeks. The control group was treated postoperatively using a long-leg splint for 1 week, followed by a brace locked in full extension (no range of motion) and no weight bearing for 2 weeks, followed by a brace locked in full extension with gradual knee range of motion and gradual weight bearing for 2 weeks. Obviously, in addition to comparing postoperative casting versus bracing after knee PCL reconstruction, the research methods included different weight-bearing and knee range-of-motion rehabilitation protocols. Nevertheless, taken in sum, two clearly distinct rehabilitation protocols are prospectively evaluated in a manner that easily allows readers to compare the outcomes between groups. A concern is that in contrast to the practice of your editors, who typically reconstruct the knee posterior lateral corner concomitant with PCL reconstruction (noting that grade III PCL injury is associated with significant posterior lateral corner injury in most cases), Yoon et al. excluded "multiple ligament injury" cases. While we note this concern, we clarify that this should not be construed as "criticism" because the authors achieved good or excellent knee stability in both groups. Further, a significant strength of this study is the use of posterior stress radiographs to determine side-to-side laxity differences between the operative and normal knee, a meticulous outcome measure. For surgeons who may be dissatisfied with outcomes after PCL reconstruction, the results of this study could be of clinical interest.

In this editorial, perhaps uncharacteristically, we have shown restraint and self control to avoid playing the role of "spoiler." Thus we have tried not to reveal the conclusions of the Level I and II evidence studies described. We encourage our readers to now turn the pages (or scroll down, or across) and explore the current issue, with a focus on the high level of evidence of these prospective, comparative-effectiveness research studies.

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References

1. Lubowitz JH, Poehling GG. Clinically relevant articles of high levels of evidence are required to change surgical practice. *Arthroscopy* 2007;23:803.
2. Lubowitz JH, Poehling GG. In defense of case series: Hip SCFE, shoulder instability and arthritis, double-bundle ACL cyclops lesions, and elbow OCD. *Arthroscopy* 2010;26:1411-1413.
3. Lubowitz JH, Poehling GG. A new year. *Arthroscopy* 2008;24:2-3.
4. Lubowitz JH, Poehling GG. The research effort. *Arthroscopy* 2007;23:1143-1144.
5. Lubowitz JH, Poehling GG. Comparative effectiveness research: We must lead (so as not to be misled). *Arthroscopy* 2009;25:455-456.
6. De Coninck T, Huysse W, Verdonk R, Verstraete K, Verdonk P. Open versus arthroscopic meniscus allograft transplantation: Magnetic resonance imaging study of meniscal radial displacement. *Arthroscopy* 2013;29:514-521.
7. Dejour D, Ntagiopoulos PG, Saggin PR, Panisset J-C. The diagnostic value of clinical tests, magnetic resonance imaging, and instrumented laxity in the differentiation of complete versus partial anterior cruciate ligament tears. *Arthroscopy* 2013;29:491-499.
8. Noh JH, Yang BG, Yi SR, Roh YH, Lee JS. Single-bundle anterior cruciate ligament reconstruction in active young men using bone-tendon Achilles allograft versus free tendon Achilles allograft. *Arthroscopy* 2013;29:507-513.
9. Lubowitz JH, Poehling GG. Medical literature ahead: Proceed with caution. *Arthroscopy* 2007;23:1255-1256.
10. Yoon KH, Park SW, Lee SH, Kim MH, Park SY, Oh H. Does cast immobilization contribute to posterior stability after posterior cruciate ligament reconstruction? *Arthroscopy* 2013;29:500-506.