

Not the Last Word: In Praise of Ankle Sprain Surgery

Joseph Bernstein MD

Somehow, during the 30 years since I finished medical school, degenerative fraying of the rotator cuff has rebranded itself the “partial-thickness rotator cuff tear.” Along with that, traditional non-operative treatment approaches have been discarded. Borrowing an idea from American military commanders at the Battle of B n Tre in Vietnam who found it “necessary to destroy the town to save it” [28], surgeons are now detaching the tendon in order to

repair it. I still cannot wrap my head around this.

Residents today do not seem to understand my lack of understanding. For them, cutting a frayed tendon in order to repair it (or, as the euphemism has it, “converting it to a full-thickness tear” [17]) is simply what’s done.

I push back by asking the residents to engage in a thought experiment. How would you feel, I ask them, if orthopaedic surgeons one day all decide that acute ankle sprains should be surgically repaired? Wouldn’t it be ridiculous, I propose, for our treatment approach to switch from RICE (“Rest, Ice, Compression, Elevation”) to CORN (“Complete Operative Repair Now!”)?

To be fair, under certain circumstances, operative repair of an ankle sprain might not be so ridiculous. Let’s say some enterprising surgeon develops an ankle sprain repair operation and demonstrates its effectiveness in a carefully controlled pilot study. Let’s further imagine that larger trials replicate the results and validate the indications. Thereafter, the community ensures that only well-trained surgeons perform the procedure, and that they do so only on well-selected patients. Under those circumstances, ankle sprain surgery is exactly what orthopaedic surgeons should offer. Under those circumstances, I would not come to bury the operation but to praise it.

Our problem is that these circumstances are never found. Enterprising surgeons will always develop new operations, but their initial reports tend to be small case series, and the follow-up studies hardly more powerful. Indications are hard to define, and (outside of the American Board of Orthopaedic Surgery [ABOS] oral exam “case collection window” [1]) even harder to enforce.

In response to this phenomenon, some scholars [25] have called for greater regulation of surgical procedures. They note that unlike pharmaceuticals and medical devices, “no state or federal agency either approves the use of new surgical procedures or directly regulates existing procedures” [10]—and suggest that we’d be better off if they did. I am not so sure.

For one, unlike pharmaceuticals and medical devices, surgical procedures are not conducive to study in randomized controlled trials. Robust evidence will always be in short supply, thereby making traditional regulatory approaches of the Food and Drug Administration (FDA) all but impossible.

A second problem is that only newer operations are likely to be scrutinized, with older operations grandfathered. This will impede progress, as some of our older operations are sorely in need of retirement. Too much regulation of innovation will keep us practicing 1970s medicine.

The third and biggest problem is that when an operation is subjected to

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J. Bernstein  , University of Pennsylvania, 424 Stemmler Hall, Philadelphia, PA 19104 USA, Email: orthodoc@uphs.upenn.edu

J. Bernstein, Department of Orthopaedic Surgery, University of Pennsylvania, Philadelphia, PA, USA

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study, there are actually three factors being examined: (1) the operation itself, (2) the surgeon's skill, and (3) the appropriateness of this operation for the clinical situation at hand. Even the best operations can be done by the wrong surgeon, on the wrong patient, or at the wrong time. Poor results, thus, do not necessarily reflect shortcomings with the operation itself.

These problems notwithstanding, we can still do a better job of regulating surgical procedures.

I propose that professional organizations such as the ABOS institute a new professional norm: that all operative reports include a validated measure of the patient's preoperative status and a prediction of the patient's likely postoperative status. (It is this predicted gain that defines the indication for surgery, after all.) The surgeon would also be required to document what Codman [4] called the patient's "end result," at the point of maximal medical improvement.

In the case of a rotator cuff surgery, the surgeon would provide a measure such as the Western Ontario Rotator Cuff Index [19] score at the time surgery was planned, the score predicted at the point of maximal improvement, and the score actually attained. Critically, the ABOS and related organizations would require surgeons to make deidentified copies of these reports available for outside analysis. (To be clear: I would favor deidentifying the surgeon's name as well since the purpose is to examine the operation, not the operator, but surgeons should examine their own results, and the accuracy of their predictions, as a means of getting better at their craft.)

A meta-analysis of these reports is not the same as a carefully controlled trial, but it has the countervailing benefit of showing how the operation performs in the real world. As such,

this form of assessment transcends the usual FDA approach, in which there is scant post-approval review [3].

Although not everyone will agree with what Dr. Codman had to say about partial-thickness rotator cuff tears ("I do not advocate operating upon incomplete cases" [14]), all can endorse his sentiment about determining the end results of our operations: "Every hospital should follow every patient it treats, long enough to determine whether or not the treatment has been successful" [4]. To that end, a new professional norm, that surgeons record enough information for large-scale analysis, should be adopted. This way, we will be on firmer ground praising—or burying—operations old and new.

Nader M. Hebela MD

Orthopaedic Spine Surgeon

Neurological Institute at Cleveland Clinic Abu Dhabi

There is some common ground on which we I can stand in agreement with Dr. Bernstein's column. But there is no logically valid argument that would support the notion that just because a regimen of RICE ("Rest, Ice, Compression, Elevation") and physical therapy do not reach the desired outcome for everybody, that CORN ("Complete Operative Repair Now!") is necessarily the better approach. The illogical conclusion that surgical intervention is beneficial for those patients who have not benefitted from nonsurgical treatment options is best summarized by a colleague who once remarked, "If you don't operate on them, then someone else will." To rephrase his comment: Not performing the operation will result in decreased reimbursement, lower relative

value units (RVUs), and upset the entire medical-industrial complex.

But let's first survey the common ground by examining the controversial role of fusion for degenerative disc disease of the spine surgery. The factors involved in deciding for or against fusion surgery vary considerably in the United States by geographic location, widening indications, and heterogeneous and flawed data [5, 11, 12, 29]. As Dr. Bernstein clearly articulates, we are forced to ask about the operation itself as well as the appropriateness of this operation for the clinical situation at hand.

I venture away from our common ground, however, when examining the role of vertebroplasty for pain relief in osteoporotic compression fractures. In two articles published in the same issue of the *New England Journal of Medicine* [7, 16], two separate groups published multicenter, randomized, double-blinded, placebo-controlled trials to assess the efficacy of vertebroplasty in patients with painful osteoporotic fractures. The authors found no beneficial effect of vertebroplasty over a sham procedure [7, 16]. However, since these studies have been published, researchers have performed more refined randomized controlled trials of subpopulations that may benefit from vertebroplasty [8]. These studies provide us with a more nuanced approach to treating our patients by establishing the appropriateness of the operation for the right patient at the right time. Perhaps we can meet Dr. Bernstein on the common ground established by these randomized clinical trials: Not all of the operations we perform provide better results than nonsurgical care. And perhaps he will agree with our decision to operate after more rigorous clinical trials, not anecdotal reports [24], are published.

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But it goes beyond clinical trials. More stringent guidelines from respective academies are necessary to help guide individual physicians in making informed decisions with their patients. Yet all too often, despite the best intentions, these guidelines hedge their recommendations by understating the lack of true benefits of these unnecessary and unproven surgical interventions [20].

Double-blinded studies can also help guide us toward common ground. If these studies can be done for the treatment of myelomeningoceles for fetal surgery [15], then we can do the same for degenerative rotator cuff tears, degenerative disc disease, or ankle sprains. Placebo-controlled randomized surgical trials, including those done for vertebroplasty [7, 16], knee arthroscopy [18, 26], and epidural injections [13], are an excellent start, but we need to agree that these studies are the ones in which we hold ourselves accountable. We cannot continue to discredit these studies because their (un)intended results decrease our case volumes, RVUs, and reimbursements. The effective use of reporting guidelines to improve the quality of surgical research is another step forward in the right direction. Standardizing how research is conducted and published will bring us a step closer to identifying the right patients for the right operations at the right time [6].

To help integrate some of these concepts, I look to a recent double-blind, multicenter study regarding the efficacy of epidural injections in the lumbar spine, where the authors found that epidural injection of glucocorticoids plus lidocaine offered minimal or no short-term benefit as compared with epidural injection of lidocaine alone [13]. On one hand, the study adhered well to the CONSORT framework and included a flow diagram that addressed enrollment, intervention allocation, follow-up, and

data analysis [21]. On the other hand, the study would have been more convincing had it included a sham arm without any injection at all as that would have helped us ascertain the true placebo effect, if one exists. Without this, we can conveniently ignore these results and continue to perform injections.

As the primary advocates for our patients, we need to find this common ground, both in terms of the low-hanging fruit as well as the canopy overhead. If we do not have the will to consider these changes as physicians and societies of physicians then we risk getting caught in the crossfire unable or unwilling to find that common ground, between governmental organizations, insurers, and the medical-legal establishment, whose primary aims are to cut costs and optimize profits, cutting the frayed tendon in order to repair it.

Robert F. Ostrum MD

Professor of Orthopaedics

University of North Carolina at Chapel Hill

Dr. Bernstein makes the point that changes in surgical technique and implants may not always be for the best. From my experience, I agree and can share that in 1995 at our busy trauma center, my colleagues and I were approached by an orthopaedic device manufacturer to try a novel new retrograde intramedullary nail that they had been working on but had limited clinical experience with. We understood that further investigation was necessary to learn about the insertion site and its effect on the patellofemoral joint, and we did the research [22]. At meetings, this idea was met with skepticism, ridiculed, and strongly criticized by a few but very important surgeons. Today, retrograde

femoral nailing has proven itself to be a valuable innovation.

Our specialty is incredibly fortunate to have had forward thinkers like John Charnley, Gerhard Kuntscher, Charles Neer, and Gavriil Ilizarov just to name a few. These pioneers didn't just take a preexisting implant or idea and modify it; they "invented" something new and game-changing. It is important to remember that every innovation requires change, but not every change is innovation. Innovation in orthopaedic surgery is vital, but at what cost?

It would be disingenuous to say that no new implants have resulted in improved care, because some do. But these are often more expensive and clinically unproven changes on previous innovations. Using the halo effect, we accept an innovation solely based on the reputation, experience, or institution of the developer or think because it is "new" it must be better.

A study at a large trauma center looking at six trauma implants and four vendors with cost labels on the implants (green = least expensive, red = most expensive) was eye-opening [23]. Armed with this knowledge, surgeons went from 30% red and 14% green to 9% red and 70% green and a cost savings of USD 216,495 per year without affecting patient outcomes. Another physician-driven effort looking at joint replacement implant costs, where the surgeons were given pricing and asked to look for "value," realized a volume-adjusted cost difference of USD 1,059,159, a 17.5% decrease [9]. Orthopaedic surgeons and residents are constantly bombarded with information on the latest and greatest implant in its next generation without price considerations. In a study estimating orthopaedic implant costs, residents demonstrated a 73% mean percentage error compared to 59% for attending surgeons, while overall 67% underestimated the costs [27]. In our current

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healthcare market with fixed payments and where an orthopaedic implant can cost more than 50% of the total Medicare payout, it is incumbent upon us to understand value and try to be good stewards of rising healthcare costs.

The Red Queen Effect states that if we stay in one place, we actually fall behind as others around us are improving. We shouldn't accept change for the sake of change, but rather with a real understanding of the important benefits that newer techniques can have for the patient and the surgeon. One study showed that the use of intramedullary fixation of hip fractures went from 3% in 1999 to 67% in 2006 in the ABOS database "despite a lack of evidence in the literature supporting the change and in the face of the potential for more complications" [2]. It is incumbent upon us to get all of the important information before using a new technique or implant, and if it is not available, then we need to research its superiority. This should be the least that we can do for our patients and future generations of orthopaedic surgeons.

Attempts at innovation often are an uphill battle, with multiple speed bumps and detours along the way. John Wooden said: "Failure isn't fatal, but failure to change might be." True innovations are worth the price.

References

- American Board of Orthopaedic Surgery. Case lists. Available at: <https://www.abos.org/certification/part-ii/case-lists/>. Accessed April 9, 2021.
- Anglen JO, Weinstein JN. Nail or plate fixation of intertrochanteric hip fractures: changing pattern of practice. A review of the American Board of Orthopaedic Surgery Database. *J Bone Joint Surg Am*. 2008;90:700-707.
- Bernstein A, Bernstein J. The information prescription for drug regulation. Available at <https://ssrn.com/abstract=902160>. Accessed April 9, 2021.
- Brand RA. Ernest Amory Codman MD, 1869-1940. *Clin Orthop Relat Res*. 2009;467:2763-2765.
- Brinjikji W, Luetmer PH, Comstock B, et al. Systematic literature review of imaging features of spinal degeneration in asymptomatic populations. *AJNR Am J Neuroradiol*. 2015;36:811-816.
- Brooke BS, Ghaferi AA, Kibbe MR. Effective use of reporting guidelines to improve the quality of surgical research. *JAMA Surg*. Published online April 7, 2021. DOI: [10.1001/jamasurg.2021.0519](https://doi.org/10.1001/jamasurg.2021.0519).
- Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med*. 2009;361:557-568.
- Chandra RV, Maingard J, Asadi H, et al. Vertebroplasty and kyphoplasty for osteoporotic vertebral fractures: what are the latest data? *AJNR Am J Neuroradiol*. 2018;39:798-806.
- Christo AE, Bargar WL, Morris E. Prosthesis cost containment in total joint replacement: a physician-driven free-market approach. *Orthopedics*. 2000;23:439-442.
- Darrow JJ. Explaining the absence of surgical procedure regulation. *Cornell J Law Public Policy*. 2017;27:189-206.
- Deyo RA, Gray DT, Kreuter W, Mirza S, Martin BI. United States trends in lumbar fusion surgery for degenerative conditions. *Spine*. 2005;30:1441-1445.
- Deyo RA, Nachemson A, Mirza SK. Spinal-fusion surgery - the case for restraint. *N Engl J Med*. 2004;350:722-726.
- Friedly JL, Comstock BA, Turner JA, et al. A randomized trial of epidural glucocorticoid injections for spinal stenosis. *N Engl J Med*. 2014;371:11-21.
- Fukuda H. Partial-thickness rotator cuff tears: a modern view on Codman's classic. *J Shoulder Elbow Surg*. 2000;9:163-168.
- Houtrow AJ, MacPherson C, Jackson-Coty J, et al. Prenatal repair and physical functioning among children with myelomeningocele: a secondary analysis of a randomized clinical trial. *JAMA Pediatr*. 2021;175:e205674-e205674.
- Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med*. 2009;361:569-579.
- Kirkley A, Alvarez C, Griffin S. The development and evaluation of a disease-specific quality-of-life questionnaire for disorders of the rotator cuff: the Western Ontario Rotator Cuff Index. *Clin J Sport Med*. 2003;13:84-92.
- Kirkley A, Birmingham TB, Litchfield RB, et al. A randomized trial of arthroscopic surgery for osteoarthritis of the knee. *N Engl J Med*. 2008;359:1097-1107.
- Kim KC, Shin HD, Cha SM, Park JY. Repair integrity and functional outcome after arthroscopic conversion to a full-thickness rotator cuff tear: articular- versus bursal-side partial tears. *Am J Sports Med*. 2014;42:451-456.
- Kreiner DS, Matz P, Bono CM, et al. Guideline summary review: an evidence-based clinical guideline for the diagnosis and treatment of low back pain. *Spine J*. 2020;20:998-1024.
- Merkow RP, Kaji AH, Itani KMF. The CONSORT framework. *JAMA Surg*. Published online April 7, 2021. DOI: [10.1001/jamasurg.2021.0549](https://doi.org/10.1001/jamasurg.2021.0549).
- Morgan E, Ostrum RF, DiCicco J, McElroy J, Poka A. Effects of retrograde femoral intramedullary nailing on the patellofemoral articulation. *J Orthop Trauma*. 1999;13:13-16.
- Okike K, Pollak R, O'Toole R, Pollak A. "Red-yellow-green": effect of an initiative to guide surgeon choice of orthopaedic implants. *J Bone Joint Surg Am*. 2017;99 e33.
- Prasad V, Vandross A, Toomey C, et al. A decade of reversal: an analysis of 146 contradicted medical practices. *Mayo Clin Proc*. 2013;88:790-798.
- Roberts DJ, Zygun DA, Ball CG, et al. Challenges and potential solutions to the evaluation, monitoring, and regulation of surgical innovations. *BMC Surg*. 2019;19:119.
- Sihvonen R, Paavola M, Malmivaara A, et al. Arthroscopic partial meniscectomy versus sham surgery for a degenerative meniscal tear. *N Eng J Med*. 2013;369:2515-2524.
- Streit JJ, Youssef A, Coale R, Carpenter JE, Marcus RE. Orthopaedic surgeons frequently underestimate the cost of orthopaedic implants. *Clin Orthop Relat Res*. 2013;4716:1744-1749.
- The New York Times*. Major describes move. February 8, 1968, p. 14.
- Weinstein JN, Lurie JD, Olson PR, Bronner KK, Fisher ES. United States' trends and regional variations in lumbar spine surgery: 1992-2003. *Spine (Phila Pa 1976)*. 2006;31:2707-2714.