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On Patient Safety

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On Patient Safety: Shoulder "Impingement"—Telling a SAD Story About Public Trust

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From the Column Editor: The goal of the On Patient Safety *column is to explore the relationship between patient safety and clinical efficacy. In this month's guest column, Teppo L. N. Järvinen MD, PhD, the head of the Finnish Center for Evidence-Based Orthopedics (FICEBO), gets to the heart of that relationship, as he describes the rise of a once-celebrated procedure and, despite the mounting evidence in front of us, our inability to fully accept its diminishing utility.*

Recognized around the world for producing cutting-edge research on common musculoskeletal problems, FICEBO envisions a world where only practices that are scientifically proven to be effective are offered to patients. We're not there yet, but Prof. Järvinen leads FICEBO's efforts and collaborates with researchers and physicians around the world to develop medical evidence and reduce the use of ineffective procedures.

I found his analysis of the evidence surrounding the efficacy of subacromial decompression and his discussion on the importance of open, honest communication with patients with shoulder disease deeply important. I believe you will too.

— James Rickert MD

Like most orthopaedic surgeons, I have treated many patients for shoulder pain. After all, it's awfully common with around 4.5 million visits a year in the United States alone [19]. About 70% of patients with shoulder pain present with the classic "painful arch" while lifting the arm, which, for decades, had been considered a symptom caused by mechanical impingement of the rotator cuff complex between the humeral head and the undersurface of the acromion. This concept, and the original operation designed to treat it, subacromial decompression (SAD), just "celebrated" its 50th anniversary [17].

The story since then is equally well known: SAD quickly became one of the most commonly performed orthopaedic procedures, an operation whose usage increased five-fold between the 1980s and 2005 in the United States [27]. Usage in the United Kingdom between 2000 and 2010 increased even faster [10].

It's easy to understand our specialty's embrace both of the concept and the operation designed to treat it. They both seemed biologically plausible; that is, they made intuitive sense. Early case series suggested that patients who underwent SAD experienced improved pain and function [4, 18]. Very gratifying.

But this clear and pretty picture soon grew cloudy and dark, although you wouldn't know it by following the exploding usage of the procedure [5, 14]. In the 1990s and early 2000s, studies began to pile up suggesting that SAD might be no more effective than physiotherapy [1, 7, 12, 21]. And the causative link between impingement and the painful arch itself came under scrutiny—so much so that as a community, we had to start shifting our paradigm away from the concept of "impingement" to the still-fuzzier wastebasket term "subacromial pain syndrome" (SAPS) [3]. While this might have felt like progress or even clarity—patients with "painful arch" may have any of several things going on, like bursitis, supraspinatus or

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rotator cuff tendinopathy, rotator cuff degeneration, or biceps tendinitis [3, 5]—it should have caused us to pause. Why, if there were so many causes, should the operation remain essentially the same?

As I came up in the early 2000s, this was on my mind all the time. I work in Finland, where our healthcare system is considered a universal public good, one that has made society-wide commitments to ethical and effective care. This means that as physicians, we need to clear a high bar when it comes to justifying the treatments we offer, including ones like SAD. And working in a universal public system also means we have the means to gather population-level data and perform robust clinical trials, including randomized surgical trials [13, 22] and even placebo-controlled surgical trials [6, 20, 23, 24]. I've been doing exactly this alongside my colleagues at the Finnish Centre for Evidence-Based Orthopaedics (FICEBO) for over 20 years now.

When I come to the United States or to other places where the healthcare system is not nationalized, I often hear that people who volunteer for randomized surgical trials like the ones we perform at FICEBO must be psychological outliers, somehow not representative of the "typical" patient who presents for orthopaedic care [16, 25].

This is not true. Another ancillary benefit of well-run public healthcare systems like what we have in Finland is the high level of public trust they enjoy. As I watched the usage of SAD climb even as the evidence against it mounted [1, 7, 12, 21], it occurred to me how important it is that we not violate this trust. Adding to the pressure was the fact that at that time, orthopaedic surgeons in Finland were embracing SAD even more enthusiastically than were surgeons in most other countries [9]. For that reason, I sought—once again, with my FICEBO collaborators, and the partnership of Finnish patients (who want good answers as much as their surgeons do)—to get some real answers about SAD.

Because the so-called etiologies of SAPS were so disparate, the main endpoint of concern to patients was pain, and we had the Finnish healthcare system willing to support us in the asking of important questions. Indeed, SAD seemed like the perfect candidate operation for the holy grail of surgical research: a randomized trial that involved a surgical placebo arm.

After 5 years of planning, and with generous support from funders who saw the need for this work, we launched the Finnish Subacromial Impingement Arthroscopy Controlled Trial (FIMPACT) in 2005. It took more than a decade of work, but in 2018, we shared our findings: Arthroscopic SAD provided no benefit over diagnostic arthroscopy [20]. By that point, it seemed clear to us that the original diagnostic model had been too simplistic. This led to a simplistic surgical intervention that is no better than a placebo or physical therapy.

I hasten to add that anyone who has followed the SAD saga knows that we weren't the first or only ones to break this news. In fact, the first strong trial questioning the utility of SAD was published 25 years before our own [1]. And as we worked on FIMPACT, another half dozen high-quality trials, all with low risk of bias, also found that SAD provided no clinically relevant improvement over various nonsurgical options or placebo surgery [11, 14].

The evidence at this point is so consistent and so strong that the *BMJ* issued a clinical practice guideline with a rare and unusually decisive clinical recommendation: "The panel concluded that almost all informed patients would choose to avoid surgery because there is no benefit but there are harms, and it is burdensome. Subacromial decompression surgery should not be offered to patients with SAPS" [26].

These kinds of realizations are—or rather, should be—how science and medicine advance.

But have they? To some degree, though not nearly enough. Usage of SAD has dropped dramatically in Finland, and it's generally decreased globally. Yet, despite that, it remains one of the most frequently performed shoulder surgeries in the world. Why?

It seems to me that the main source of the pushback comes from a source that surgeons trust even more than they trust randomized trials—their own "experiences" with an operation. In fairness, our experience does matter, and our motives are good; we want to help. But we have to remember that using our own surgical experiences as a data source suffers from exactly the same problems as do case series, or worse [15]. Two of these shortcomings are follow-up that is insufficiently long or complete (remember, the missing usually are not doing as well as the accounted for, and a lot of patients in a surgical practice do not follow-up as instructed) and the general lack of an objective outcomes tool (our own observations are not very rigorous in this regard). Randomized trials, such as those we perform at FICEBO, avoid those problems—our FIMPACT trial about SAD, for example, followed 81% of enrolled patients for 5 years and evaluated them using validated endpoints that matter to patients—in ways that our own "experience" can't hope to emulate.

I accept that gaps in evidence sometimes force us to rely on our experience to decide whether to operate. But once a well-designed trial or two is out there—and there is more than this

much available that warns us not to perform SAD—it's incumbent on the advocates of a procedure to meet good-quality evidence against the operation with good-quality evidence for it. This does not exist for SAD.

But in the end, we are still surgeons, trying to help our patients. Patients with shoulder pain beg us to end their suffering; sometimes they are in tears. They often have already tried other treatments. They don't want to be told to try another round of physiotherapy or even worse, that they'll just have to endure the pain. What would be so wrong, then, with performing a simple operation, one that results in few (albeit some) serious complications and seems to make some patients feel better?

The answer is that it's dishonest to do so. The very reason patients trust us is that we represent ourselves as science-driven. Procedures that carry greater risk (like shoulder surgery) should be superior to interventions with little or no risk (like shoulder exercises), and certainly superior to placebo interventions. I believe that if patients learned an intervention I recommended does not meet this standard, the patient would not trust me. The patient would be right to feel this way.

No, in this instance, we have to revert to the more time-consuming and less-remunerative tools of caring and empathy. We need to slow down, listen, and share what we know—which includes the limits of what we know and the limits of our interventions—with our patients. We can offer nonsurgical alternatives that have been shown to be as effective as SAD, including exercises (and home exercises seem to work as well as more-expensive formal therapist-supervised programs [2]). We can speak supportively and in ways that convey caring to our patients about the favorable natural history of this condition, much as we have seen with other nonspecific musculoskeletal "diagnoses" like lateral elbow pain [8], for which no surgical treatment has consistently outperformed the natural history of the disease. Being honest and empathic builds trust. Offering operations that are no better than placebo treatment erodes it.

When we lose the trust of our patients, we can't help them at all.

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