

1

Principles of Evidence-Based Orthopedics

¹Niek van der Hoek MD, and ²Paul Tornetta III, MD

¹Department of Surgery, Deventer Ziekenhuis, Deventer, The Netherlands

²Boston University School of Medicine, Boston, MA, USA

Introduction

The traditional approach to clinical problem solving places a great emphasis on professional authority. Decision making is based primarily on the intuition, experience, and rationale of the clinician, and it is heavily influenced by their opinion.¹ Since it is unlikely that the opinion of every physician is identical, it is reasonable to suggest that not all opinions can be correct.² Evidence-based orthopedics does not accept this approach. Although it acknowledges the importance of clinical judgment, it emphasizes that this alone is not enough to make optimal clinical decisions, especially with the large amount of evidence that is available. Evidence-based orthopedics combines the judgment of the clinician and values of the patient with the best available clinical evidence (Figure 1.1). The goal is to use the best available evidence to guide the management of individual patients based on their preferences.

Evidence-based orthopedics is a part of a larger movement called *evidence-based medicine*. This term was first used by Gordon Guyatt in the 1990s in the curriculum of the residency program at McMaster University.³ The term was more formally defined in 1996 by Sackett et al. as “the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients.”⁴ Evidence-based medicine is more than just a positive alternative in patient care, it is on the *British Medical Journal*’s list of the top-15 most important medical milestones along with vaccines, the discovery of DNA structure, and the discovery of antibiotics.⁵

Importance of evidence-based orthopedics

Understanding the importance of evidence-based orthopedics is necessary to fully appreciate its principles. The goal

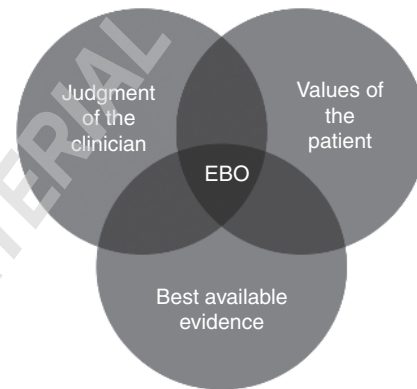


Figure 1.1 Visualization of the different aspects of evidence-based orthopedics (EBO).

of the clinician is to provide individual patients with the best clinical care.² Clinical research can help the clinician achieve this goal. The proper evaluation of clinical trials helps to define the risks and benefits of different treatment options, aiding the clinician and patient in making an optimal treatment decision.⁶

In 1992, Antman et al. compared the data from clinical research with expert opinions on the treatment of myocardial infarction.⁷ This article showed that there was a difference in opinion between clinical experts and that it took experts 10 years for their opinions to catch up with the clinical evidence. While systematic reviews and meta-analyses may make information found in individual trials more accessible, there is still a lag between the publication of high-level evidence and its acceptance.⁸

Top four questions

1. What are the most important principles of evidence-based orthopedics?
2. How do you apply evidence-based orthopedics?

- 3. What is an example of applying evidence-based orthopedics?
- 4. What are the misconceptions of evidence-based orthopedics?

Question 1: What are the most important principles of evidence-based orthopedics?

Evidence is needed for optimal clinical care

Clinicians must acknowledge the importance of evidence and recognize that they need evidence in their daily practice. In evidence-based orthopedics, clinicians actively search for the best available evidence to supplement their judgment. There is a large body of evidence available to assist clinicians in many areas, from assessing the efficacy of treatment modalities to lifestyle recommendations to prevent disease.⁶

Keeping up to date with the growing volume of primary literature can be daunting, but it is incumbent upon all clinicians to do so. Systematic reviews can help the clinician to keep up to date, but these reviews are only one interpretation of the literature and clinicians should be aggressive about reading the original sentinel works. There are several resources to help the clinician find the best current evidence, such as the Cochrane Database of Systematic Reviews or the Clinical Queries feature in PubMed.⁹

Not all evidence is equally useful

There is a vast amount of evidence available and it is important to understand how the quality of the work contributes to its value in answering a clinical question. For example, a case report is much more vulnerable to bias than a randomized controlled trial (RCT). Randomized treatment allocation balances the known and the unknown prognostic factors, making it less vulnerable to bias.¹⁰ Table 1.1 shows the hierarchy of evidence from the least-biased study designs on the top of the hierarchy to the most-biased on the bottom.

Furthermore, there is a difference in the quality of evidence between studies, even those on the same level. For example, not every RCT is equally applicable to a particular clinical question. The inclusion and exclusion criteria must match the patient whom the clinician is treating. Outcomes of trials must be clinically important to the patient. Trials may report statistically different outcomes without a real clinical difference in patient outcomes. Finally, RCTs may have serious flaws, making them vulnerable to bias, such as a large percentage of patients who are lost to follow-up. This type of problem may threaten study validity.¹¹

Table 1.1 The hierarchy of evidence. Source: Modified from Schunemann.¹

Least bias	Meta-analyses of RCTs
	RCTs
	Controlled trials
	Case control studies and cohort studies
	Cross-sectional studies
Most bias	Case reports, case series, and expert opinion

A randomized trial with serious design flaws can no longer qualify as high-quality evidence.

Evidence alone is not enough

In making a clinical decision, published evidence alone is never enough. The best treatment option is influenced by the patient’s lifestyle, specific needs, and preferences as well as the judgment of the clinician. A deep understanding of the patient, their medical history, and the pathophysiology of their disease is necessary. Most important, evidence-based orthopedics supports an active role of the patient in decision making, acknowledging the importance of the values and preferences of the patient. The most common example of this is in cases where multiple reasonable options exist. Patients should be free to choose their treatment based on their own set of goals and their personal assessment of the risk/benefit profile of the treatment options.

Question 2: How do you apply evidence-based orthopedics?

There is a five-step cycle called the *evidence cycle* that can help in applying the evidence-based orthopedics in daily practice.

Assess

A thorough understanding of the clinical situation is essential to develop a treatment plan. This includes a full understanding of the pathophysiology of the patient’s complaints, symptoms, and physical findings in addition to the patient’s medical history. From this, a differential diagnosis is created and whatever further testing is required to confirm a clear diagnosis is performed. Only with a correct diagnosis can the clinician form a clear question to research.

Ask

A well-formed research question is necessary to filter out irrelevant evidence without excluding valuable evidence. The PICO format can be used to compose a research question. In essence, every clinical research question contains four components: a Patient or Population, description of the patient group; the Intervention, the treatment being considered; the Comparison, the alternative treatment(s) that is (are) to be compared; and the Outcome: the eventual goal of treatment or method of assessing treatment.

Acquire

With a well-formed research question, the clinician can start searching for evidence using any of the available search engines, such as PubMed. MeSH (Medical Subject Headings) terms are vocabulary produced by the National Library of Medicine. MeSH terms are used for indexing, cataloging, and searching of biomedical and health-related information. Using the correct MeSH terms and subheadings as well as filters helps to limit the dataset to the most relevant trials or reviews. If needed, a librarian can be of help in finding the right information. Or visit <https://www.nlm.nih.gov/mesh/meshhome.html>.

Appraise

Clinicians must also take it upon themselves to assess the literature for bias and quality. There are several tools available to assess primary literature, such as the Cochrane Collaboration's risk of bias assessment tool.¹²

Apply

Finally, the clinician must view all of the available evidence through the prism of a particular patient's needs. They must determine how the evidence applies to the clinical problem seen in their patient. The clinician must determine if differences exist between their patient and the evidence and judge what effect this might have on the outcome. For example, a trial comparing treatments for fractures in a rheumatoid arthritis population may not apply to a young athlete.

Question 3: What is an example of applying evidence-based orthopedics?

A 48-year-old female arrives at the Emergency Department with pain and deformity of the clavicle after a fall on her shoulder. The patient smokes and there are no other injuries. The X-ray shows a 100% displaced midshaft

clavicular fracture without an obvious shoulder droop. She reports a high degree of pain. The primary goal is to return her to her prior level of activity and have as normal shoulder function as possible. This type of fracture may be managed operatively or nonoperatively.^{13–20}

The midshaft clavicular fracture is the most common fracture of the clavicle and numerous studies have been published on its treatment.^{14–20} A recent meta-analysis of RCTs shows a significant reduction in nonunion rate after plate fixation of midshaft clavicular fractures compared with conservative treatment even though no clinically relevant increase of function was demonstrated.²¹ Secondary operations were common in both groups. Meta-analyses of RCTs offer high-quality evidence and are the least susceptible to bias; however, they can focus only on the outcomes in each and every trial included.¹

The authors of this meta-analysis found that there is insufficient evidence for routine plate fixation of displaced midshaft clavicular fractures, but it is a good option for patients who have risk factors for nonunion, such as smoking, highly displaced and/or comminuted fractures, and for patients who demand a faster recovery and optimal arm function.²¹ Additionally, the patient should be made to understand that if they heal their fracture then their outcome would be as good without surgery and that if it went on to nonunion and were then repaired, they could also expect a good result.^{14, 17, 20–22}

This example shows that evidence can help in making a clinical decision while not replacing the judgment of the clinician and the values of the patient.

Question 4: What are the misconceptions of evidence-based orthopedics?

Evidence-based orthopedics replaces the judgment of the clinician

The judgment of the clinician is necessary in evidence-based orthopedics, the core principle being that evidence alone is not enough. The clinician and the patient are not bound to a certain course of action. While the reported evidence gives important information, the clinical decision remains in the hands of the clinician and the patient.

Only randomized controlled trials are acceptable evidence

RCTs are considered the highest level of evidence, but other types of studies have value also. Not every clinical question can be answered using a RCT. For example, it would

be unethical to determine the negative effects of smoking on bone healing in a RCT. Although not all study designs can produce a definitive clinical answer, they can help to develop a relevant hypothesis.

One needs to be a statistician to practice evidence-based orthopedics

A basic understanding of statistics is attainable by all surgeons. Simply understanding the concepts of power, sample size, minimal clinically important difference, confidence intervals, and p values is all that is needed. This basic understanding can help the clinician independently determine the implications of trials.

Summary of answers

- Evidence-based orthopedics emphasizes that high-quality clinical research is necessary for optimal care.
- There is a large amount of evidence available and not all clinical research is equally useful.
- Critically appraising evidence is essential for evidence-based orthopedics.
- The clinician must determine how the evidence applies to their patient and combine this with the patient's values to find the best treatment together.

References

- Schunemann HJ, Bone L. Evidence-based orthopaedics: a primer. *Clin Orthop Relat Res* 2003;413:117–32.
- Poolman RW, Kerkhoffs GM, Struijs PAA, Bhandari M. Don't be misled by the orthopaedic literature: tips for critical appraisal. *Acta Orthop* 2007;78(2):162–71.
- Evidence-based Medicine Working Group: evidence-based medicine: a new approach to the teaching of medicine. *JAMA* 1992;262:2420–5.
- Sackett DL, Rosenberg WM, Gray JA, et al. Evidence based medicine: what it is and what it isn't. *BMJ* 1996;312:71.
- British Medical Journal. Medical milestones. <http://www.bmj.com/content/medical-milestones>, accessed 29 September 2020.
- Bhandari M, Tornetta P. Issues in the design, analysis, and critical appraisal of orthopaedic clinical research. *Clin Orthop Relat Res* 2003;(413):9–10.
- Antman EM, Lau J, Kupelnick B, et al. A comparison of results of meta-analyses of randomized control trials and recommendations of clinical experts: treatments for myocardial infarction. *JAMA* 1992;268(2):240–8.
- Guyatt G, Rennie D, Meade MO, Cook DJ (eds). *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice*, 3rd ed. McGraw-Hill, New York, 2015.
- Bhandari M, Joensson A. *Clinical Research for Surgeons*. Thieme Medical Publishers, Stuttgart, Germany, 2009.
- Bhandari M, Tornetta P, Guyatt GH. Glossary of evidence-based orthopaedic terminology. *Clin Orthop Relat Res* 2003;413:158–63.
- Zelle BA, Bhandari M, Sanchez AI, Probst C, Pape HC. Loss of follow-up in orthopaedic trauma: is 80% follow-up still acceptable? *J Orthop Trauma* 2013;27(3):177–81.
- Website: The Cochrane Collaboration's tool for assessing risk of bias. Available at: http://handbook-5-1.cochrane.org/chapter_8/table_8_5_a_the_cochrane_collaborations_tool_for_assessing.htm, accessed 17 August 2017.
- Ban I, Nowak J, Virtanen K, Troelsen A. Overtreatment of displaced midshaft clavicle fractures: a survey of hospitals in Sweden, Denmark, and Finland. *Acta Orthop* 87(6):541–5.
- Khorami M, Fakour M, Mokarrami H, et al. The comparison of results of treatment of midshaft clavicle fracture between operative treatment with plate and non-operative treatment. *Arch Bone Jt Surg* 2014;2(3):210–4.
- Robinson CM, Goudie EB, Murray IR, et al. Open reduction and plate fixation versus nonoperative treatment for displaced midshaft clavicular fractures: a multicenter, randomized, controlled trial. *J Bone Joint Surg Am* 2013;95(17):1576–84.
- Ahrens PM, Garlick NI, Barber J, Tims EM, Clavicle Trial Collaborative Group. The clavicle trial: a multicenter randomized controlled trial comparing operative with nonoperative treatment of displaced midshaft clavicle fractures. *J Bone Joint Surg Am* 2017;99(16):1345–54.
- van der Ven Denise JC, Timmers TK, Flikweert PE, et al. Plate fixation versus conservative treatment of displaced midshaft clavicle fractures: functional outcome and patients' satisfaction during a mean follow-up of 5 years. *Injury* 2015;46(11):2223–9.
- Canadian Orthopedic Trauma Society. Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures: a multicenter, randomized clinical trial. *J Bone Joint Surg Am* 2007;89(1):1–10.
- Virtanen KJ, Remes V, Pajarinen J. Sling compared with plate osteosynthesis for treatment of displaced midshaft clavicular fractures: a randomized clinical trial. *J Bone Joint Surg Am* 2012;94(17):1546–53.
- Lenza M, Buchbinder R, Johnston RV, et al. Surgical versus conservative interventions for treating fractures of the middle third of the clavicle. *Cochrane Database Syst Rev* 2013;6:CD009363. doi: <https://doi.org/10.1002/14651858.CD009363.pub2>
- Woltz S, Krijnen P, Schipper IB. Plate fixation versus nonoperative treatment for displaced midshaft clavicular fractures: a meta-analysis of randomized controlled trials. *J Bone Joint Surg Am* 2017;99(12):106–12.
- McKee MD, Wild LM, Schemitsch EH. Midshaft malunions of the clavicle: surgical technique. *J Bone Joint Surg Am* 2004;86-A(Suppl 1):37–43.