

Levels of Evidence For Primary Research Question¹
As Adopted by the North American Spine Society January 2005*

Types of Studies				
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	<ul style="list-style-type: none"> • High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic Review² of Level I RCTs (and study results were homogenous³) 	<ul style="list-style-type: none"> • High quality prospective study⁴ (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) • Systematic review² of Level I studies 	<ul style="list-style-type: none"> • Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) • Systematic review² of Level I studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review² of Level I studies
Level II	<ul style="list-style-type: none"> • Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) • Prospective⁴ comparative study⁵ • Systematic review² of Level II studies or Level I studies with inconsistent results 	<ul style="list-style-type: none"> • Retrospective⁶ study • Untreated controls from an RCT • Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.) • Systematic review² of Level II studies 	<ul style="list-style-type: none"> • Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) • Systematic review² of Level II studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review² of Level II studies
Level III	<ul style="list-style-type: none"> • Case control study⁷ • Retrospective⁶ comparative study⁵ • Systematic review² of Level III studies 	<ul style="list-style-type: none"> • Case control study⁷ 	<ul style="list-style-type: none"> • Study of non-consecutive patients; without consistently applied reference “gold” standard • Systematic review² of Level III studies 	<ul style="list-style-type: none"> • Analyses based on limited alternatives and costs; and poor estimates • Systematic review² of Level III studies
Level IV	Case Series ⁸	Case series	<ul style="list-style-type: none"> • Case-control study • Poor reference standard 	<ul style="list-style-type: none"> • Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called “cases”; e.g. failed total arthroplasty, are compared to those who did not have outcome, called “controls”; e.g. successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

*These documents have also been adopted by the American Academy of Orthopaedic Surgeons, Pediatric Orthopaedic Society of North America, *Clinical Orthopaedics and Related Research*, *Journal of Bone & Joint Surgery* and *Spine*.
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