

Do Promising Biomechanical Research Studies Lead to Clinically Meaningful Results?

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Purpose: Promising biomechanical effects in the laboratory setting often prompt questions about clinical relevance. The aim of this study is to (1) identify prospective randomized clinical trials (RCTs) comparing biomechanically distinct surgical interventions and (2) determine if promising biomechanical studies lead to clinically significant outcomes in orthopaedic surgery.

Methods: PubMed/SCOPUS databases were queried for the keywords: ‘orthopedic or orthopaedic’, and ‘randomized controlled trial’. Inclusion criteria were: RCT, ≥ 2 treatment arms with biomechanically distinct surgical interventions, and existence of an analogous biomechanical study. Studies comparing operative versus nonoperative treatment, duplicate studies, and cadaveric studies were excluded. Statistical analysis utilized a contingency table and a mixed effects logistic regression model.

Results: Initial search returned 14,126 articles. Sports medicine (57%), trauma (22%), and spine (17%) composed the majority of RCTs comparing biomechanical interventions. 23 studies met inclusion criteria. In 17 (74%) of these studies, biomechanical research had identified one treatment that was superior to another. However, only 4 of 17 RCTs (24%) found that a biomechanically superior treatment led to an improved clinical outcome. The mixed effects logistic regression model demonstrated no concordance between the outcomes of biomechanical studies and RCTs.

		Clinically significant		
		Yes	No	Total
Biomechanically significant	Yes	4	14	18
	No	4	2	6
	Total	8	16	24

Conclusion: Orthopaedic implants and techniques with superior biomechanical properties are not associated with improved clinical outcomes when evaluated in RCTs. Surgeons should focus on variables other than biomechanical superiority in an effort to optimize surgical results.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.