Low Replicability of Highly-Cited Studies in Orthopaedics

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INTRODUCTION: Concerns are rising regarding the quality, validity, and reliability of clinical research findings in medical literature. This investigation sought to identify the most cited orthopaedic clinical studies and assess the replicability of the findings reported by the original studies.

METHODS: Web of Science was used to identify the top ten orthopaedic surgery journals by impact factor, from which primary comparative studies cited at least 250 times were identified. A second literature search identified follow-up studies relevant to the respective primary studies. Follow-up studies were screened by independent reviewers. Studies investigating the same intervention via parallel methodology were summarized and their conclusions compared to their respective highly cited primary study.

RESULTS: Seven primary clinical studies met inclusion criteria. A total of 1,163 articles from the literature search were identified and screened. Seventy-nine follow-up studies met inclusion criteria. The average subject cohort size in the follow-up studies was 365.1 patients (range, 10-4564). Of these, 70.9% (56/79) of studies were randomized clinical trials, 7.6% (6/79) were multicenter in nature, and 67% (53/79) were classified as level I evidence. Rate of agreement, or coming to the same conclusion as the primary study, was 45.5% (36/79). Additionally, 26.6% (21/79) did not support the conclusions of the primary studies, 16.5% (13/79) found a weaker correlation, and 11.4% (9/79) neither agreed nor disagreed with the primary study. No significant association existed between study design, level of evidence, or study size and agreement or disagreement with the original paper (p>0.05).

DISCUSSION AND CONCLUSION: Less than fifty percent of replicating follow-up studies support the effects demonstrated by highly-cited comparative studies in orthopaedic literature, which is a lower rate than that reported by other areas of medicine. Difficulty performing large, high-level-of-evidence studies and publication bias likely contribute to this observation. Based on these findings we believe that replication of prior research, emphasis on research quality, and conscious awareness of the limitations of clinical research are critical to the quality of orthopaedic literature.

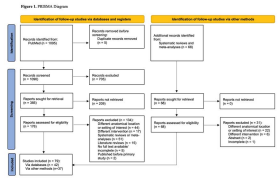

Figure 1. PRISMA Diagram

Table 1. Highly cited "Primary Studies."

Author	Title	Journal	Citations, n	Publication, y	Design	Patients, n
Govender et al.[12]	Recombinant Human Bone Morphogenetic Protein-2 for Treatment of Open Tibial Fractures - A prospective, Controlled, Randomized Study of Four Hundred and Fifty Patients	JBJS Am.	1025	2002	RCT	450
Hewett et al.[13]	The Effect of Neuromuscular Training on the Incidence of Knee Injury in Female Athletes - A Prospective Study	AJSM	978	1999	P	1263
Kammen et al.[14]	Autologous Chondrocyte Implantation Compared with Microfracture in the Knee - A Randomized Trial	JBJS Am.	987	2004	RCT	80
Heckman et al.[15]	Acceleration of Tibial Fracture-Healing by Noninvasive, Low-Intensity Pulsed Ultrasound	JBJS Am.	647	1994	RCT	67
Heidotting et al.[16]	Degenerative Lumbar Spondylolisthesis with Spinal Stenosis - A Prospective Study Comparing Decompression with Decompression and Intertransverse Process Arthrodesis	JBJS Am.	630	1995	P	50
Horns et al.[17]	Autologous Chondrocyte Implantation and Osteochondral Cylinder Transplantation in Cartilage Repair of the Knee Joint - A Prospective, Comparative Trial	JBJS Am.	589	2003	P	40
Canadian Orthopaedic Trauma Society[18]	Nonoperative Treatment Compared with Plate Fixation of Displaced Midshaft Clavicular Fractures - A Multicenter, Randomized Clinical Trial	JBJS Am.	530	2007	RCT, MC	132

JBJS Am = Journal of Bone and Joint Surgery – American Volume
AJSM = American Journal of sports Medicine
RCT = randomized clinical trial. P = prospective study. MC = multicenter.

Table 2. Data on follow-up studies and their conclusions in comparison to their primary study

Original Study	Total, n	Agrees, n	Disagrees, n	Neither, n	Weaker, n
Govender et al.[12]	3	1	2	-	-
Hewett et al.[13]	17	10	2	2	3
Kamsen et al.[14]	23	8	13	-	2
Heckman et al.[15]	6	4	2	-	-
Herkowitz et al.[16]	-	-	-	-	-
Horns et al.[17]	4	-	2	2	-
COTS[18]	26	13	-	5	8
Total, n	79	36 (45.6%)	21 (26.6%)	9 (11.4%)	13 (16.4%)

Agrees = the follow-up study came to the same conclusion as its primary study regarding the effectiveness of the intervention of choice
Disagreed = the follow-up study came to a different conclusion regarding the effectiveness of the intervention of choice
Neither = the follow-up study neither agreed nor disagreed with its primary study
Weaker = the follow-up study found trends, but was underpowered to support or disagree with its primary study regarding the intervention of choice

Table 3. Descriptive data for all follow-up studies in accordance to their conclusion

Descriptive	Total (n=79)	Agrees (n=36)	Disagrees (n=21)	Neither (n=9)	Weaker (n=13)	P.Value
Study Design, n						0.120
RCT	54	25	17	4	10	
Non-RCT	25	11	4	5	3	
Level of Evidence, n						0.309
I	53	24	16	4	9	
II	23	9	5	5	4	
III	3	3	-	-	-	
Patients, mean ± SD	365.1±756.6	464.8±940.6	191.4±310.5	306.8±673.6	409.9±768.1	0.616

RCT = randomized clinical trial