

Transparent and Reproducible Research Practices in the Surgical Literature

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Abstract

Previous studies have established a baseline of minimal reproducibility in the social science and biomedical literature. Clinical research is especially deficient in factors of reproducibility. Surgical journals contain fewer clinical trials than non-surgical ones, suggesting that it should be easier to reproduce the outcomes of surgical literature. In this study, we evaluated a broad range of indicators related to transparency and reproducibility in a random sample of 300 articles published in surgery-related journals between 2014 and 2018. A minority of our sample made available their materials (2/186, 95% C.I. 0–2.2%), protocols (1/196, 0–1.3%), data (19/196, 6.3–13%), or analysis scripts (0/196, 0–1.9%). Only one study was adequately pre-registered. No studies were explicit replications of previous literature. Most studies (162/292 50–61%) declined to provide a funding statement, and few declared conflicts of interest (22/292, 4.8–11%). Most have not been cited by systematic reviews (183/216, 81–89%) or meta-analyses (188/216, 83–91%), and most were behind a paywall (187/292, 58–70%). The transparency of surgical literature could improve with adherence to baseline standards of reproducibility.

Introduction

Reproducibility is the “ability of a researcher to duplicate the results of a prior study using the same materials as were used by the original investigator.”¹ Reproducibility is crucial to scientific advancement. Estimates suggest that less than 50% of clinical research studies are reproducible.²⁻⁵ This widespread and pervasive issue has been dubbed a reproducibility crisis by scientists.⁶ In cancer biology, researchers attempted to reproduce the findings of 50 high-impact publications but had to abandon 32 of these planned reproductions owing to a lack of sufficiently detailed protocols and materials.⁷ Of the 18 remaining attempts, 10 have been completed, of which 5 were largely reproducible, 3 were inconclusive, and 2 were negative.⁸ In psychology, a large-scale reproducibility investigation was conducted on 100 experimental and correlational studies published in prominent psychology journals.⁹ The mean effect size of the reproduced studies was half the magnitude of the original studies. Further, whereas 97% of the original study results were statistically significant, only 36% of results from the reproduced studies reached statistical significance. Investigators of this study found that 47% of the original effect sizes fell within the 95% confidence interval of the reproduced study’s effect size. These findings suggest a reproducibility deficit across disparate fields of study. This problem becomes especially important in clinical research, where participants enroll in clinical trials and expose themselves to therapies with potential risks to improve treatment options for others.

In surgery research, initiatives to promote reproducibility are ongoing. As examples, the *International Journal of Surgical Protocols* publishes research protocols for all surgical specialties. Reporting standards, such as Strengthening the Reporting of Cohort Studies in Surgery (STROCSS)¹⁰ and Preferred Reporting of Case Series in Surgery (PROCESS),¹¹ have been developed to improve the completeness of reporting of surgical studies. The IDEAL Collaboration seeks to improve the quality of surgical research by including recommendations related to reproducibility.¹² Editorials also have been published in academic journals to alert surgeons to the reproducibility problem. One article published in the *Journal of Thoracic and Cardiovascular Surgery* describes the likely effects of the new National

Institutes of Health’s rigor and reproducibility requirements on surgery research. In this editorial, Lawson notes, “we as surgeons are particularly qualified to identify areas in need of improvement in the care for our patients, and we must continue to perform clinical and basic research to move our field into the future.”¹³ A second editorial¹⁴ published in *Plastic and Reconstructive Surgery* calls for improved reproducibility of clinical studies, given the proliferation of big data and, by virtue, increased production of clinical database studies. Aside from these initiatives, very little is known about the state of reproducibility and transparency in surgery research.

Methods

This is a cross-sectional observational study design with data extraction performed in a blind and duplicate fashion. We employed similar methodology to Hardwicke et al.,¹⁵ with minor modifications. We reported each study in accordance with guidelines for meta-epidemiological methodology research.¹⁶ This research was observational and did not include any human subjects or study participants, making it exempt from institutional review board approval prior to initiation.¹⁷ The materials, protocol, and raw data used for this study will be uploaded to the Open Science Framework for public access (<https://osf.io/n4yh5/>).

Journal and Study Selection

We used the U.S. National Library of Medicine catalog to search for all journals using the subject terms tag Surgery[ST]. This search was performed on 05/29/2019. The inclusion criteria required that journals were in “English” and “MEDLINE indexed.” The list of journals in the U.S. National Library of Medicine catalog then were extracted by the electronic or linking International Standard Serial Number (<https://osf.io/t83cy/>), which was used to search PubMed for all publications by these journals. The list of publications included those published between January 1, 2014, and December 31, 2018. From this list, 300 publications were randomly sampled to extract their data (<https://osf.io/r8tx2/>). We randomized all publications within the list to ensure availability of additional publications during the data extraction process, but they were not needed.

Data Extraction

A pilot-tested Google Form was created based on the one provided by Hardwicke et al.,¹⁵ with additions. This form prompted coders to identify whether a study had the necessary information to be reproducible (Supplement 1). The data extracted varied based on the study design. Studies with no empirical data (e.g., editorials, commentaries [without reanalysis], simulations, news, reviews, and poems) were excluded. On our form, we changed the original item for identifying the impact factor of a specific year to two new items, one identifying the 5-year impact factor and one identifying the most recent impact factor. We also expanded the options for study design to include cohort, case series, secondary analysis, chart review, and cross-sectional designs. Finally, we expanded the funding options to be more specific to university, hospital, public, private, industry, or non-profit.

Two authors extracted data from the 300 articles in duplicate and blinded fashion. Prior to data extraction, they underwent a full day of training to ensure reliability between authors. The training began with an in-person session to review the study design, protocol, Google Form, and location of the information in two articles. The authors were given three example articles from which to extract data. Following extraction, the pair reconciled any differences between them. This training session was recorded and posted online for reference. Prior to extracting data from all studies, the two authors extracted data from the first 10 articles in their respective list, followed by a final consensus meeting. Data extraction on the remaining 290 articles was then conducted. A final consensus meeting was held by the pair to resolve disagreements. A third author was available for adjudication, if necessary.

Analysis Plan

We report descriptive statistics for each category using Microsoft Excel. For each analyzed characteristic, 95 percent confidence intervals were generated.

Results

Sample Characteristics

Our search of the U.S. National Library of Medicine database identified 409 surgery journals, with 147 fitting the inclusion criteria. A PubMed search of those 147 journals identified 681,637

publications, with 154,441 published within the specified time-frame. From this list, we randomly sampled 300 publications. Of the 300-article sample, eight (2.7%) full-text documents were unable to be accessed. The remaining coded articles came from a broad range of journals, with a median 5-year impact factor of 2.727 and a most recent impact factor median of 2.471 (data from 2017 and 2018 when available). Impact factor data was unavailable for 26 coded articles. Table 1 lists more sample characteristics.

Access to Articles

Most articles (167, 56%) were accessible only through a paywall (Figure 1). Google Scholar searches on public internet connections provided full-text access to 125 articles (42%), and another 83 (28%) were available through institutional access at Oklahoma State University. This highlights that large portions of the surgical literature are unavailable to surgeons or even researchers with broad academic privileges.

Availability of Materials and Protocols

Virtually all (184, 99%) articles with empirical data did not indicate any materials necessary to replicate their study. Of the two that provided materials statements, one stated that the product used was commercially available, and the other was a table containing ICD-9 coding information. Only one study provided a protocol, in the form of a registration number, which could not be found on the journal's website.

Availability of Data

Nineteen articles (9.7%) indicated data were available, with the distribution of access shown in Figure 2. Most of these could be accessed and contained clearly documented data files, whereas only six (3.1%) contained all the raw data necessary to reproduce the findings reported in the study.

Availability of Analysis Scripts

Of the 197 articles with empirical data, zero indicated that analysis scripts were available. This demonstrates the limitations of published data in surgical journals, even when raw data were available.

Availability of Preregistration Information

Preregistration allows researchers to describe their hypotheses, methods, and analyses before research is conducted, in a way that can be externally verified to avoid bias¹⁸. A large majority of articles (193, 98%) articles did not contain a statement concerning preregistration. Only three provided a related statement, of which two could be accessed and only one contained an explicit hypothesis and methods outline.

Availability of Conflicts of Interest and Funding Statements

Most (197, 68%) articles provided a statement concerning conflicts of interest. Twenty-two of these (7.5%) declared one or more conflicts of interest, and 95 (33%) did not include a conflict of interest statement. Funding sources were slightly more obscure, with 162 (55.5%) declining to provide a funding statement. Of those citing funding, 52.8% stated that their research was not explicitly funded. Public (e.g., NIH) and university funding were most commonly reported in the surgical literature (Figure 1).

Discussion

Our assessment of 300 randomly selected surgery publications indicates that the current body of research lacks basic elements for transparent and reproducible practices. One fundamental principle of the scientific method is that experiments must be reproducible. Scientific validity and knowledge increase when researchers can replicate results from previous experimentation. If an experiment or study can be independently verified, its conclusions can be considered more reliable.² Our results strengthen the current consensus in meta-research literature that both observational^{10,19,20} and experimental^{21,22} studies in many surgical fields are generally deficient in transparency and reproducibility, though previous research has not applied our sampling techniques to enable generalizability. In this section, we discuss several findings with particularly poor results.

Materials and Protocol

The availability of study materials and protocols is fundamental to the reliability of reported outcomes. This reproducibility problem is made worse when funding sources and publishers overvalue high-profile journals and incentivize publication quantity over quality.²³ The NIH has developed a

training program to address this concern,²⁴ though the responsibility often falls on journals to require these elements of reproducibility. Steward et al. describes the economic pressures on scientific journals to truncate the methods section of manuscripts or move it to supplementary information, noting that the section rarely contains enough detail for an exact replication.²⁵ For example, in surgical literature, this protocol should include a careful description of the surgical plan, intraoperative decision making, case variability, and enough detail to standardize the patients' pre- and post-operative medical care. Our analysis validated the hypothesis that few surgical manuscripts provide materials or protocols.²⁶ These findings highlight a costly inefficiency gap in surgical research. It is fundamentally impossible to build on the foundation of surgical knowledge without enough detail to replicate published results. Clinical research is expensive, and confirming results with high-quality replications is even more costly when the original detail is missing and multiple iterations of a protocol are required to complete the replication.^{27,28}

Open Access

The availability, or open access, of a study directly influences the proportion of health professionals who will read and make decisions based on the study. Previous research has shown that articles in clinical medicine are less likely to have open access, compared to those in other fields of study.²⁹ For example, in a study by Hardwicke et al., only 95 of 198 studies performed in three hospital systems were publicly accessible.³⁰ For example, in a study by Hardwicke et al., only 95 of 198 studies performed in three hospital systems were publicly accessible. In our study, we found that less than half of the articles were available through our university's broad institutional access. Thus, smaller universities and unaffiliated researchers who lack comprehensive library subscriptions are at a disadvantage when trying to reproduce a study. Open access should transcend academic affiliation to support sustainable lifelong learning.³¹ Yet, we found that only 42.6% of the articles were available publicly, and 28.6% were not accessible at all. This finding suggests that researchers and physicians lack access to pertinent information relevant to their specialties. Further, paywall restrictions may create preferential disadvantages among rural or hospital-based surgeons who lack affiliations to an academic institution, because their access is limited to abstracts. A study by Marcello et al. demonstrates that clinical decisions

in surgery guided by full-text articles are more accurate than those guided by abstracts alone.³² Previous research indicates that abstracts may not be as informative due to the high incidence of spin, a form of selective reporting bias where the results in an abstract are inconsistent with the actual findings in the body of the paper.^{33–35} As such, these paywalls limit the self-correction of the scientific process and spread of the latest medical research, which is deleterious to patient care. By limiting a physician's ability to effectively analyze the literature, poor clinical decisions become more likely. Self-correction is a necessary safeguard in surgical specialties, limiting poor outcomes and loss of life.

Pre-registration

The subject of pre-registration has garnered increased interest in the medical community.⁴ Study outcomes are frequently interpreted as broad clinical principles rather than solely applicable to the cross-section of conditions for which an intervention has been tested. Pre-registration directly confronts this form of “hypothesizing after the results are known,” or HARKing,⁵ and discourages the use of narrow, context-bound results in broader clinical practice. In our sample, only one randomized controlled trial was adequately pre-registered. Further, of the top-five surgical journals by h-index, none required pre-registration of observational studies.^{36–40} As of 2007, the FDA Amendments Act mandates pre-registration of most clinical trials.^{41,42} A suspiciously sharp fall in positive findings following its implementation suggests a tendency of study authors to engage in selective reporting bias.⁴³ Though efforts like the Consolidated Standards of Reporting Trials (CONSORT)⁴⁴ aim at improving the reporting of randomized controlled trials, this tenant of academic transparency does not currently affect most surgical literature, which consists of observational database studies. For example, of the studies in our sample containing empirical data, we found that 93% were observational in design. Further, healthcare database research has been shown to lack complete reporting of study implementation.²³ Given that pre-registration confronts hindsight bias⁴ and that no gold standard of observational reproducibility exists, it is the opinion of the authors that additional regulation mandating the pre-registration of observational studies would strengthen the field of surgical research.

Strengths and Weaknesses

Our study has many strengths, including the construction of our random sample, generalizability to other areas of clinical medicine, extensive training of our coders, and use of best practices of meta-research. The blinded, double-extraction technique implemented in this study is considered the gold standard for meta-research data extraction,^{45,46} and it increases the validity of our findings. In addition, the robust training provided to investigators prior to the start of coding adds reliability to the study results. We also note some important limitations. First, we acknowledge the inherent possibility of sampling error, though the authors maintain the generalizability of our findings, as we used a random sampling procedure. Second, no authors were contacted to request additional information, so our outcomes are based on published research alone. According to one study on highly cited articles, 68% of contacted authors either did not respond or would not share the data, 18% said the data was partially available, and only 14% offered unrestricted access to the data.³⁰

Lack of reproducibility increases development costs of drugs, medical devices, protocols, and procedures. Most important, it can have deleterious effects on patient health in every stage of surgical research, leading to increased risk of treatment failure.⁴ It is our hope that study authors improve their reporting standards to increase the transparency and reproducibility of surgical research in the name of better science, better outcomes, and progression of the field of surgery.

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Conflict of Interest Statement

All authors declare no conflicts of interest.

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Table 1: Characteristics of Reproducibility in Surgery Studies			
Characteristics		Variables	
		N (%)	95% CI
Funding <i>N=306*</i>	University	16 (5.48)	0.029-0.081
	Hospital	6 (2.05)	0.005-0.037
	Public	22 (7.53)	0.045-0.105
	Private/industry	13 (4.45)	0.021-0.068
	Non-profit	11 (3.77)	0.016-0.059
	No statement listed	162 (55.5)	0.499-0.611
	No funding received	76 (26.0)	0.211-0.310
Conflicts of Interest <i>N=292</i>	Statement, one or more conflicts of interest	22 (7.53)	0.045-0.105
	Statement. no conflict of interest	175 (59.9)	0.544-0.655
	No conflict of interest statement	95 (32.5)	0.272-0.378
Data Availability <i>N=196</i>	Statement, some data are available	19 (9.69)	0.063-0.130
	Statement, data	0	-

	are not available		
	No data availability statement	177 (90.3)	0.870-0.937
Material Availability <i>N=186</i>	Statement, some materials are available	2 (1.08)	0.000-0.022
	Statement, materials are not available	0	-
	No materials availability statement	184 (98.9)	0.978-1.000
Protocol Availability <i>N=196</i>	Full protocol	1 (0.510)	0.000-0.013
	No protocol	195 (99.5)	0.987-1.000
Analysis Scripts <i>N=196</i>	Statement, some analysis scripts are available	0	-
	Statement, analysis scripts are not available	0	-

	No availability statement	196	-
Replication	Novel study	196	-
Studies $N=196$	Replication	0	-
Cited by Systematic Review $N=216$	No citations	183 (84.7)	0.807-0.888
	Single citation	22 (10.2)	0.067-0.136
	One to five citations	9 (4.17)	0.019-0.064
	Greater than five citations	2 (0.926)	0.000-0.020
Cited by Meta-Analysis $N=216$	No citations	188 (87.0)	0.832-0.908
	Single citation	20 (9.26)	0.060-0.125
	One to five citations	8 (3.70)	0.016-0.058
	Greater than five citations	0	-
Pre-registration $N=196$	Statement present, study pre-registered	3 (1.53)	0.001-0.029
	Statement present, study not pre-	0	-

	registered		
	No pre- -registration statement	193 (98.5)	0.971-0.999

Figure 1

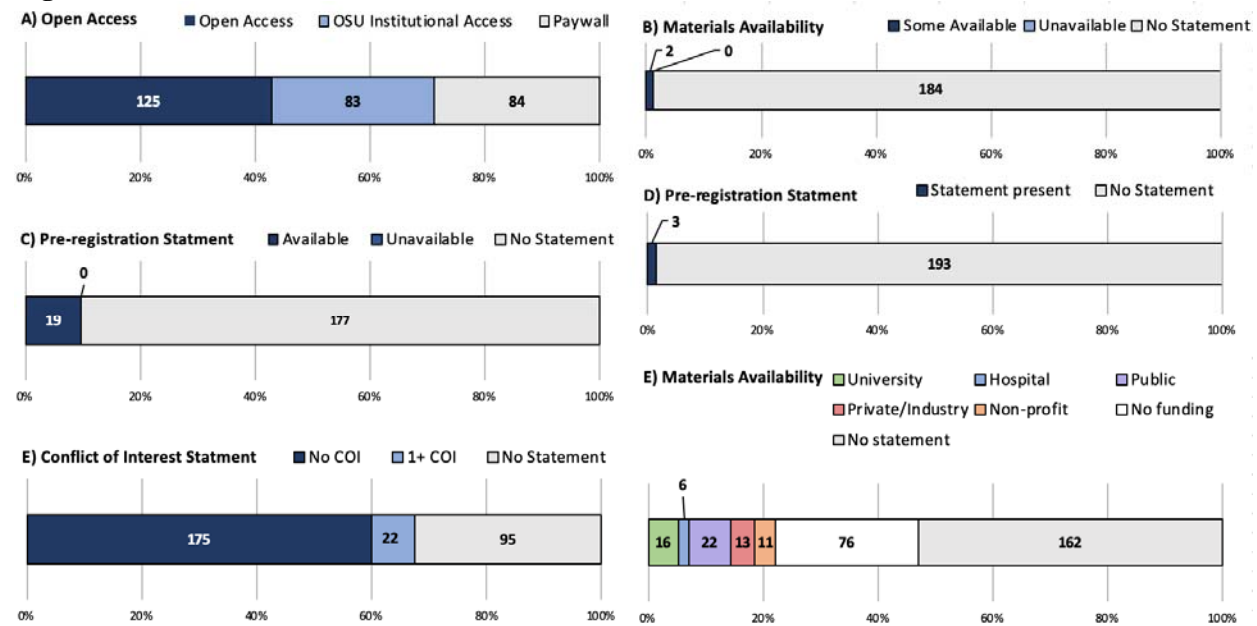
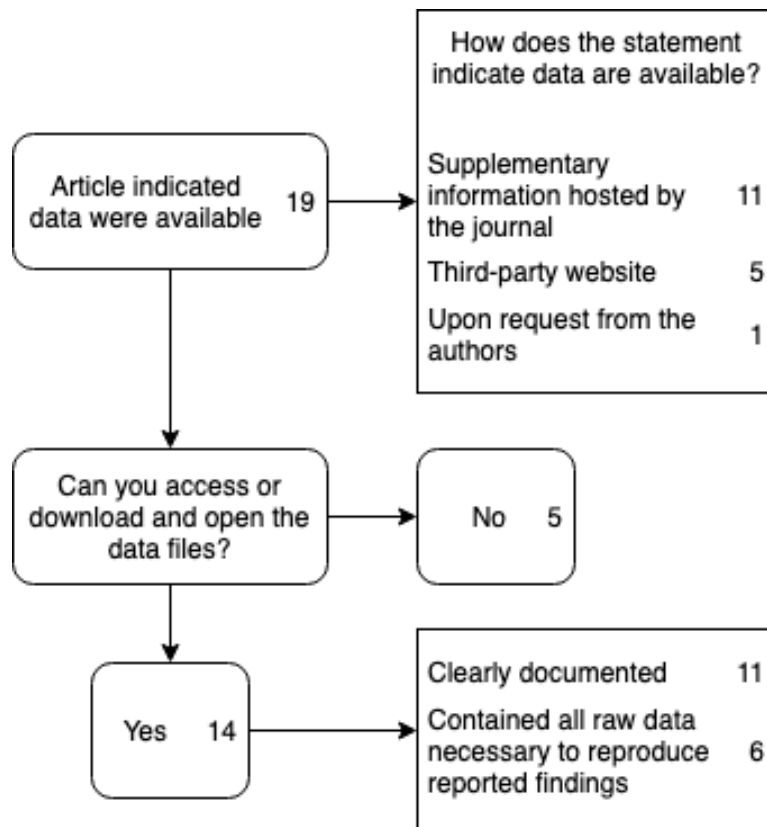


Figure 2



Supplement

Supplemental Table 1: Sample Characteristics of Surgery

Literature

Characteristic		Variables	
		N (%)	95% CI
Test Subjects N=292	Animals	7 (2.40)	0.007-0.041
	Humans	200 (68.5)	0.632-0.737
	Both	0	0
	Neither	85 (29.1)	0.240-0.343
Country of Journal Publication N=292	US	210 (71.9)	0.668-0.770
	UK	44 (15.1)	0.110-0.191
	Germany	6 (2.05)	0.004-0.037
	China	4 (1.37)	0.001-0.027
	Italy	4 (1.37)	0.001-0.027
	France	3 (1.03)	0.000-0.022
	Other	20 (6.85)	0.040-0.097
Country of Corresponding Author N=292	US	112 (38.1)	0.326-0.436
	Japan	18 (6.12)	0.034-0.088
	UK	17 (5.78)	0.031-0.084
	China	16 (5.44)	0.029-0.080
	Italy	12 (4.08)	0.018-0.063
	France	11 (3.74)	0.016-0.059

	Canada	10 (3.40)	0.014-0.055
	Spain	10 (3.40)	0.014-0.055
	Germany	7 (2.38)	0.007-0.041
	India	2 (0.68)	0.000-0.016
	Other	62 (21.68)	0.170-0.263
Open Access N=292	Open access	125 (41.7)	0.361-0.472
	OSU institutional access	83 (27.7)	0.226-0.327
	Paywall	84 (28.0)	0.229-0.331
5-Year Impact Factor N=292	Median	2.727	-
	1st quartile	1.788	-
	3rd quartile	3.798	-
	Interquartile range	2.108-3.533	-
Most Recent Impact Factor Year N=300	2014	0	-
	2015	0	-
	2016	0	-
	2017	268	-
	2018	19	-

	Not found	13	-
Most Recent Impact Factor N=286	Median	2.471	-
	1st quartile	1.586	-
	3rd quartile	3.621	-
Abbreviations: CI, confidence interval			

Supplemental Table 2: Additional Reproducibility Characteristics		
Characteristics		Variables
		No.
Type of Study	No empirical	66
	Systematic review and/or meta-analysis	12
	Clinical trial	14
	Case study	30
	Case series	21
	Cohort	50
	Chart review	19
	Case control	26
	Survey	17
	Laboratory	26
	Commentary	6

	Other	5
Material Availability	Hosted by journal	1
	Third-party website	0
	Commercially available	1
	Upon request	0
	Yes, material was accessible	2
	No, material was not accessible	0
Pre-registration	Pre-registered on ClinicalTrials.gov	5
	Other	1
	Yes, pre-registration was accessible	6
	No, pre-registration was not accessible	0
	Hypothesis was pre-registered	3
	Methods were pre-registered	2
	Analysis plan was pre-registered	3
Protocol	Hypotheses included in protocol	2
	Methods included in protocol	2
	Analysis plan included in protocol	1

* - All raw data was available in the article.