STUDY PROTOCOL

REVISED Ex-vivo experimental strategies for assessing unconstrained shoulder biomechanics: a scoping review protocol [version 3; peer review: 2 approved]

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Abstract

Background: Shoulder biomechanics cannot be measured directly in living persons. While different glenohumeral joint simulators have been developed to investigate the role of the glenohumeral muscles in shoulder biomechanics, a standard for these simulators has not been defined. With this scoping review we want to describe available ex-vivo experimental strategies for assessing unconstrained shoulder biomechanics.

Objective: The scoping review aims at identifying methodological and/or experimental studies describing or involving ex-vivo simulators that assess unconstrained shoulder biomechanics and synthesizing their strengths and limitations.

Inclusion criteria: All unconstrained glenohumeral joint simulators published in connection with ex-vivo or mechanical simulation experiments will be included. Studies on glenohumeral simulators with active components to mimic the muscles will be included. We will exclude studies where the experiment is static or the motion is induced through an external guide, e.g., a robotic device.

Methods: We will perform database searching in PubMed, Embase via Elsevier and Web of Science. Two reviewers will independently assess full texts of selected abstracts. Direct backward and forward citation tracking on included articles will be conducted. We will narratively synthesize the results and derive recommendations for designing ex-vivo simulators for assessing unconstrained shoulder biomechanics.

Open Peer Review

Approval Status ✓ ✓

	1	2
version 3 (revision) 31 Jan 2023	✓ view	
version 2 (revision) 08 Mar 2022	✓ view	✓ view
version 1 21 Jan 2022		

1. **Louis Ferreira**, University of Western Ontario, London, Canada
David Axford, University of Western Ontario, London, Canada

2. **Dirk Maier**, University of Freiburg, Freiburg, Germany

Any reports and responses or comments on the article can be found at the end of the article.

Keywords
Biomechanics, glenohumeral joint, human, muscle, simulator

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Author roles: Genter J: Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Project Administration, Writing – Original Draft Preparation; **Croci E**: Investigation, Methodology, Writing – Review & Editing; **Ewald H**: Conceptualization, Data Curation, Methodology, Writing – Review & Editing; **Müller AM**: Conceptualization, Validation, Writing – Review & Editing; **Mündermann A**: Funding Acquisition, Project Administration, Supervision, Writing – Review & Editing; **Baumgartner D**: Funding Acquisition, Project Administration, Supervision, Writing – Review & Editing

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REVISED **Amendments from Version 2**

In this version we integrated the reviewer's suggestions, which are:

- Exclusion criteria with robotic devices
- Data extraction details
- New draft of the data extraction table

Any further responses from the reviewers can be found at the end of the article

Introduction

The shoulder or glenohumeral joint is one of the most complex joints in the human body. The size of the glenoid fossa is much smaller than the articulating humeral head thereby facilitating a large range of motion but also making the joint prone to instability. Different tissues are present in the shoulder to provide more stability including, most importantly, the rotator cuff muscles. Furthermore, the glenohumeral capsule and some other muscles play a minor role in stabilizing the joint[1].

The glenohumeral joint and its stability has been studied in various conditions. Because joint load cannot be measured directly in the living person, previous studies have used *ex-vivo* approaches with shoulder simulators or in-silico methods such as musculoskeletal modelling approaches. Here, the focus on shoulder simulators aimed at investigating the passive biomechanics of the shoulder, such as joint stability due to joint reaction forces and its concavity[2], glenohumeral capsule stability[3] and overall stability of specific motions[4]. Some research groups have also investigated the role of the muscles for glenohumeral biomechanics. To mimic the forces exerted by the muscles, various shoulder simulators have been developed.

Existing simulators usually consist of a clamping mechanism for the scapula and a cable pulley system that is attached to the tendons inserting at the humerus[5–7]. Although several simulators have been developed, to date there is no standard defining the design and technical requirements of such simulators. Depending on the specific research question, appropriate detailed simulators have been developed. In particular, shoulder simulators vary in three main aspects: the number of cables to mimic the investigated muscles; the degree of freedom (DOF) of the modelled joints; and the way the muscles are actuated. Existing simulators can be further categorized by the technical solution for generating muscle forces. The most trivial simulators have loaded the muscle cable pulley with passive loads such as springs or simply counterweights. More advanced simulators used active actuators such as pneumatic cylinders or motors to mimic the muscle forces. Although these simulators lack precision of the anatomical representation or physiological muscle recruitment, they are sufficient for answering many research questions and identifying new ones. Besides investigating solely the role of the muscles for shoulder biomechanics, these simulators are employed to address various research questions ranging from joint implants loading[8] to the effect of the rotator cuff muscle activation on glenohumeral kinematics[7] to the joint reaction forces during daily activity[9].

We performed a preliminary search in Pubmed and *JBI Evidence Synthesis,* with the search function of the journal's homepage, was conducted and only one systematic review[10] on the topic was identified. Williamson *et al.*[10] have conducted a systematic review on *ex-vivo* experiments for studying rotator cuff tear and instability. While they identified various experimental setups, only few of the included studies used active muscle forces. Furthermore, they categorized the *ex-vivo* experiments into three main topics: scapular orientation and mobility, muscle activation and humeral motion and condition of the glenohumeral capsule. One of the main findings was that the rotator cuff muscles are loaded statically. Moreover, they found that most likely only two simulators had the ability to load the rotator cuff muscles dynamically but did not use the dynamic mode in the presented studies.

In this scoping review, we intend to broaden the search from experimental setups for rotator cuff repair and instability to glenohumeral joint experiments. Specifically, we will describe differences and commonalities of *ex-vivo* glenohumeral experimental set ups and their strengths and limitations.

Objective and review question

This scoping review seeks to identify methodological and experimental studies that describe or involve glenohumeral joint simulators. The characteristics of these simulators will then be assessed to highlight their strengths and limitations. Particularly, the strengths and limitations will be described by answering the following research questions:

- What is the state of art of glenohumeral simulators in research where the muscles are explicitly modeled?
- How accurate are muscle insertion, glenoid fossa and other soft tissues replicated?
- How are the muscles actuated?
- How is the system controlled?

Protocol

Methods

The proposed scoping review will be conducted in accordance with the Joanna Bricks Institute (JBI) methodology for scoping reviews[11]. In particular, the search strategy will be pre-defined. This strategy includes search terms, eligibly criteria and how the study selection is performed. The protocol is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for protocols (PRISMA-P)[12]. The full review will be reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR)[13].

Eligibility criteria

Inclusion. Studies will be included if they are *ex-vivo* (cadaver) or mechanical simulation studies with anatomically accurate artificial humerus and glenoid, and if there are actuated muscle forces of the rotator cuff muscles and deltoid muscle. The motion in the experimental setup has to be induced by at least 3 distinguished actuators of which at least one must be the deltoid muscle and one representing the rotator cuff muscles. There will be no restriction on language and date of publishing.

Exclusion. All studies of in-vivo or animal nature will be excluded. A study will be excluded if the motion is constrained through something other than anatomical structures. Moreover, if all forces or moments in the glenohumeral joint are applied externally, the study will be excluded. Passive movements of the humerus such as guidance through a robotic device are thus generally excluded. However, if the robotic device applies forces with the sole purpose to perturb or induce an additional external load, the study is still included. Static experiments and tendon extrusion experiments are excluded as well. Lastly, computational musculoskeletal simulation without integrating the results into an *ex-vivo* simulator will be excluded.

Search strategy

A medical information specialist (HE) drafted the full search for PubMed using text words with synonyms and word variations as well as subject headings around the topic areas *ex-vivo*, simulator, shoulder muscles and biomechanics. These and possible further pertinent terms were discussed in the team. The search was translated using the Polyglot Search Translator[14] and internally peer reviewed by another information specialist. The full search strategy[15] was used to conduct searches on PubMed, Embase via Elsevier and the Web of Science Core collection.

In addition to the database search, we will conduct backward and forward citation tracking of the included studies using Scopus.

Search management

All retrieved references will be exported to Endnote 20 (Clarivate Analytics, 2020) and database duplicates removed according to the Bramer method (which includes using customized import/export filters and several rounds of manually changing the deduplication configuration to reduce the risk of false duplicate removal)[16]. Zotero could also be used to manage the retrieved references. Additional references identified in backward and forward citation tracking will also be managed the same way.

Study selection/selection of the evidence

Following a pilot test, titles and abstracts will then be screened by two independent reviewers for assessment against the inclusion criteria for the review. Potentially relevant sources will be retrieved in full and their citation details imported into Endnote 20 and retrieved from Endnote and through the University library Basel.

The full text of selected citations will be assessed in detail against the inclusion criteria by two reviewers. Reasons for exclusion of sources of evidence at full text that do not meet the inclusion criteria will be recorded and reported in the scoping review.

Any disagreements that arise between the reviewers at each stage of the selection process will be resolved through discussion, or with an additional reviewer. The results of the search and the study inclusion process will be reported in full in the final scoping review and presented in a PRISMA-ScR flow diagram[13].

Data extraction

The data extracted will include specific details about the ability of the shoulder simulators to simulate physiological conditions and motions. The data will be qualitatively summarized using five categories: (i) mechanical aspects of the shoulder simulator; (ii) sensors used; (iii) research question; (iv) specimen preparation; and (v) control strategies, because most studies will use different methodologies. In category (i) the mechanical will be summarized including scapular actuation and how and how many muscles are actuated. In category, (ii) we will summarize what measurements were performed for data acquisition and for feedback control. In category (iii), we will present what kind of studies were performed with these simulators. In category (iv), we will present which parts of the specimen was used and how they were prepared. Furthermore, we will specify how the scapula was oriented in the simulator. In category (v), the control strategies will be presented. As the glenohumeral joint is an under-deterministic system (i.e., a system with more muscles than degrees of freedom (DOF)) we will elaborate on the researcher's strategy to solve this problem. A draft extraction form is provided (see Table 1). The draft data extraction form will be modified and revised as necessary during the process of extracting data from each included evidence source. Modifications will be detailed in the scoping review. Any disagreements that arise between the reviewers will be resolved through discussion and with an additional reviewer. If appropriate, authors of papers will be contacted to request missing or additional data, where required.

Quality appraisal

Within the framework of this scoping review, no quality appraisal is planned.

Data analysis and presentation

This data will be listed in a tabular form and the studies will be ordered from most to least physiological according to available data. If the physiological level is the same, then the studies will be ordered alphabetically.

In addition to the tabular view, we will narratively analyse the results in the review text. Together, these results will provide a comprehensive scope of past research methodologies on this topic and likely identify opportunities on how to further develop such simulators.

Dissemination of results

The completed review will be published in an open access peer-reviewed journal.

Study status

Start date of search: June 2021; anticipated completion date of review: February 2022.

Table 1. Data extraction sheet template.

General				Mechanical System					Control System		
ID	Country	Specimen type	Research Question	DOF	Active muscles	Passive muscles	Muscle insertion	Measurements	Sensors	Control strategy	Motion

Current study status: preliminary searches, yes; piloting of the study selection process, yes; formal screening of search results against eligibility criteria, no; data extraction, no; data analysis, no.

Data availability

Underlying data

No underlying data are associated with this article.

Extended data

Zenodo: *Ex-vivo* experimental strategies for assessing unconstrained shoulder biomechanics: a scoping review's detailed search strategy. https://doi.org/10.5281/zenodo.5734982[15]

This project contains the following file:

- DOKU_Search-strat_*Ex-vivo*-Sim_20210712_hae.pdf: The search strategy of the scoping review, *Ex-vivo* experimental strategies for assessing unconstrained shoulder biomechanics: a scoping review, is elaborated in detail in this document.

Acknowledgements

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Open Peer Review

Current Peer Review Status: ✔ ✔

Version 3

Reviewer Report 31 January 2023

https://doi.org/10.5256/f1000research.143543.r161882

✔ **Louis Ferreira**
Department of Mechanical & Materials Engineering, University of Western Ontario, London, ON, Canada
David Axford
Department of Mechanical & Materials Engineering, University of Western Ontario, London, ON, Canada

No further comments.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: In-vitro joint motion simulation; shoulder biomechanics; orthopaedic basic research.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 2

Reviewer Report 11 January 2023

https://doi.org/10.5256/f1000research.121948.r156345

✔ **Dirk Maier**

University of Freiburg, Freiburg, Germany

This scoping review aims to benchmark the most advanced glenohumeral simulators. As reviews focusing on unconstrained simulators are scarce, this review provides a good overview of the development of such simulators and their limitations. Thus, it markedly contributes to the improvement of simulators of the next generation. In general, this may be of interest to orthopaedic surgeons and researchers of the shoulder joint, but especially to the biomechanical engineering community, as many aspects of developing and improving such a sophisticated device are being investigated.

I agree with the authors to choose the design of a scoping review, since the literature provides a wide range of simulators and yields heterogenous data. Furthermore, this scoping review provides a good overview of simulators that avoid the usual simplification of constraining the humerus. Many simulators in the literature constrain the humerus to the abduction plane. This reduces the activation of the stabilizing muscles. On one hand this reduces the complexity to control the humerus, but on the other hand it reduces the importance of the rotator cuff muscles as well.

The systematic search is well set up and managed by an information specialist and a wide range of synonyms is used which should identify most relevant simulators.

Current reviews lack the aspect of the control concept, whereas this scoping review aims to identify it. Another strength is that the preparation methods are looked at and how the setup is mechanically designed.

Although I endorse this scoping review, some aspects should be considered. First, I agree with the previous reviewer that the scapula orientation and motion should be identified, as the joint reaction force varies with the orientation of the glenoid. Second, I also agree with the other reviewer that the robotic involvement should have been closer looked at. Although, I suspect there are only a few or no studies that only include a robot to perturbate the humerus.

Lastly, this review is a scoping review and not a systematic review but can be justified as there are too few simulators in the literature to be examined in a meta-analysis. Furthermore, the data is too heterogenous to be included in a statistical analysis.

Overall, the study is thoroughly designed and well described, and relevant previous publications are referenced. In summary, I recommend publication of this scopiong review with some minor revisions.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Shoulder surgery, shoulder biomechanics, rotator cuff lesions

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 23 Jan 2023

Jeremy Genter, IMES, Winterthur, Switzerland

Thank you for highlighting the importance of this scoping review.

Regarding your suggestion:
Thank you for pointing out that the scapula orientation should be consider. We have amended this in section: Data extraction, where we elaborated how we plan to extract this data.

We agree with you that a scoping review is the right choice of methodology.

Thank you for recommending for publication of our protocol

Competing Interests: none to declare

Reviewer Report 19 April 2022

https://doi.org/10.5256/f1000research.121948.r127793

Louis Ferreira
Department of Mechanical & Materials Engineering, University of Western Ontario, London, ON, Canada
David Axford
Department of Mechanical & Materials Engineering, University of Western Ontario, London, ON, Canada

The authors present the rationale and protocol for a review of current ex-vivo experimental methodologies used to study shoulder biomechanics. The main objectives of this study are to determine the state of art of glenohumeral simulators that explicitly model the muscles of the shoulder. The authors intend to determine the accuracy of tissue replication while highlighting how many muscles each system actuates and how those muscles are actuated. Study selection criteria is outlined, and search methodology is described. The authors provide a template that will be used to extract key data from each study reviewed.

I commend the authors for performing this scoping review, which I believe will make it easier to place simulators in the landscape and understand where any gaps in the literature may be. The rationale for this study is clearly outlined. The objectives are clearly described and the need for this review is discussed given the limitations of existing literature review studies.

The authors' study design is partly appropriate for the research question. Although the study design is largely appropriate for the research question, some adjustments to the data extraction form are recommended.

Firstly, although a previous review has been conducted that examined scapular orientation, it is still important to consider scapular orientation/motion when reviewing simulators that replicate shoulder motion since scapular motion plays a significant role in shoulder biomechanics. The rhythm between the humerus and scapula is important to shoulder stability because as the arm abducts, the scapula rotates under to provide support against the gravity load vector. Some simulators offer simple uni-planar scapular rotation and others offer more complex six-axis scapular mobility. Therefore, I suggest that scapular motion methods also be included in the review of functionality.

Secondly, in the "Muscle force estimation" and "Control concept" sections of the form, the questions appear to be tailored towards simulators that operate using force-based control. Although force-based control is the most common method of control, other control schemes exist that may be difficult to categorize based on the questions being asked about the control method. Control methods might be broadly categorized in a four-square in which tendon actuation is either force-based or excursion-based, and the control scheme is either closed-loop or open-loop. There are hybrids to these, but that would cover most. Therefore, I recommend to include some broader questions about the controller design to highlight the differences between control techniques.

I agree with the authors approach that "a study should be excluded if the motion is constrained through something other than anatomical structures". Some simulators use a rail or other passive guide to constrain the humerus within a particular elevation plane; however, the authors should be careful that some of these simulators use such a guide device as an adjunct which is removed for some protocols. It will be important not to exclude these simulators entirely, but I agree that if the complete motion pathway is not achieved without the guide then they should be excluded. The authors also state that "passive movements of the humerus such as guidance through a robotic device are thus generally excluded". This is potentially more difficult to determine. Some simulators are augmented with a robot in order to generate varying external loads during motion, such as forces experienced in activities of daily living. In this scheme, the robot is supposed to be transparent in every other direction – meaning that it should impart zero forces other than the simulated load. In practice, this is very difficult to achieve because it requires near perfect real-time force response. Typically, the robot's presence adds dampening to the whole system which provides a false stability to the motion controller. I suggest that if such a simulator is reported to produce the full motion without the robot, then it might be included; however, I suspect that this will be a difficult criteria to meet. I agree with the authors' general strategy that if anything is in contact with the arm, then the first choice should be to exclude the simulator; though sometimes external augments are added for a purpose, so I would still search for other papers of that same simulator to determine whether it does have the ability to run unconstrained or unassisted.

I see that the search term 'in-vitro' is included in the search strategy. This is important, as some groups use that term instead of ex-vivo. The applicability of the term 'in-vitro' is debatable but it is still important to give it equal weight in the search because some important simulators are not described by their authors as ex-vivo.

The study design is clearly described, and relevant papers are referenced to further describe the methodology. There is sufficient detail to allow replication by others.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Partly

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: in-vitro joint motion simulation; shoulder biomechanics; orthopaedic basic research.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 23 Jan 2023
Jeremy Genter, IMES, Winterthur, Switzerland

Thank you for commending us to perform this scoping review.

Regarding your first adjustment recommendation:
In the extraction sheet, we will record this under DOF and constraints, although we agree it could be more clearly stated. Therefore, we amended the extraction sheet and elaborated how we plan to extract the data in section: Data extraction.

Regarding your second adjustment recommendation:
Thank you for pointing this out. We have amended the extraction sheet and elaborated how we plan to extract the data in section: Data extraction.

Regarding your suggestion on constraint motion and robotic assistance:

Thank you for this suggestion. There are indeed some simulators that constrain the motion in their first-generation of the simulator. We will still exclude these studies, but if the same simulator is unconstraint in another study, it then will be included. We agree that if an external force is applied with the sole purpose to perturb or induce an additional external load the study should be included. We have amended this in the exclusion subsection.

Regarding the search terms:
We agree that "in vitro" and "ex vivo" should be included, thank you.

Competing Interests: none to declare