Editorial

Methods to Improve Arthroscopic and Orthopaedic Biomechanical Investigations: A Few of Our Favorite Things

Abstract: Controlled biomechanical studies, generally in vitro (and often ex vivo), may represent a first step in evaluation of a new arthroscopic or orthopedic implant or technique. The purpose and methods of biomechanical studies must be thoughtfully considered to achieve results translatable to a clinically relevant conclusion. A limitation is that with the exception of animal studies or rare human investigations, most biomechanical studies actually only investigate mechanics and do not study biological healing. We review tips and pearls for performing quality biomechanical investigations.

"My Favorite Things," a song from the 1959 Rodgers and Hammerstein musical *The Sound of Music*,[1] highlights the day-brightening effects of familiar or ordinary sights. At *Arthroscopy*, we too have favorite things, and our tastes are scientific, in addition to humanistic. We have previously proclaimed our proclivity for precisely performed clinical investigations[2-5] and systematic reviews and meta-analyses.[6-8] In addition, we focus on basic-science investigations including biomechanics. Frequently, highly controlled, biomechanical in vitro (and often ex vivo) studies represent a first step in evaluation of new arthroscopic and related implants or techniques.[9] Biomechanical studies (Table 1) ideally translate to a clinically relevant purpose.[7,10]

The word "biomechanics" derives from a combination of "biology" and "mechanics." Strictly speaking, however, the etymology of the term generally exceeds the limits of our investigations because many "bio"-"mechanical" studies, generally involving cadavers, are limited to analysis of time-zero mechanical properties and do not investigate biological healing.[9] As a caveat, improper storage and handling of biological tissues, including multiple cycles of freezing and refreezing, can adversely degrade the mechanical properties of tissues used for biomechanical investigations.[11,12]

Despite inherent limitations, biomechanical investigations can be illuminating. They are ideal for testing the strength, stiffness, strain, displacement, stress, load to failure, mode of failure, fatigue, and elastic modulus of a fixation device or construct.[9] Depending on the methods, these studies can provide a great deal of indirect information resulting in accurate prediction of function based on structure. Similarly to our ability to understand long-extinct dinosaurs while generally limited to investigation of fossil records, cadaveric and other biomechanical studies facilitate acquisition of revelatory information that could be difficult or unethical to determine in human subjects, such as the fatigue properties or mode of failure of a surgical construct.

Biomechanical studies require rational selection of variables related to application of force, including angle, rate, quantity, and load. Ideally, as with clinical investigation methods and variables,[10] the selection of biomechanical parameters will be based on previously published studies and reproduce validated methods and established models. Innovation should be encouraged, but in most cases, sound biomechanical methods have already been well described.

Biomechanical investigations require prospective sample size analysis relating to a primary outcome measure. With regret, historically, prospective power analysis has often been omitted, and many previously published biomechanical analyses have been underpowered, resulting in the potential for a β error (failure to detect a difference between groups that does exist) and setting a precedent for subpar future study design. The limited availability of cadaveric tissue can result in a tendency to limit the number of investigational specimens. However, the number of specimens should be calculated based on the purpose, hypothesis, and primary outcome measure of the study; again, the principles of sample size calculation apply to biomechanical studies in a manner similar to clinical investigation.[10] On the basis of published investigations or pilot

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Table 1. Goals of Biomechanics Investigation and Means to Accomplish Them

Goal	Means to Accomplish Goal
Valid methodology	Previously described methods and protocols with supporting references and rationale should be used for experimental design.
Adequate power	Power analysis should be performed for the primary variable.
Substrate relevant to clinical situation	Age- and/or density-appropriate cadaveric bone or joints, or proxies, should be used when applicable.
Application of force relevant to clinical situation	A preload and submaximal cyclic loading must precede loading to failure.
Suitable assessment of failure	Reproducible measures of gap formation, displacement, or stiffness, in addition to load to failure, should be used.
Accurate conclusions	Conclusions must be based exclusively on the results of the investigation.
Recognition of limitations of mechanical methods	Absent biological healing, conclusions must be based on time-zero outcomes.

studies, prospective determination of a sample size sufficient to mitigate against a β error is required. Furthermore, study design should minimize the risk of bias by thoughtful consideration of pairing strategies or randomization to ensure similarity between study groups as a result of confounding variables and selection bias.

A substrate appropriate to the anatomic situation obviously results in the most seamless translation to clinical medicine. For evaluation of implants and techniques to be used in human subjects, age-appropriate cadaveric bones and joints are generally applicable. When suitable, consideration should also be given to appropriate use of cancellous versus cortical bone. Proxies, such as porcine, bovine, or Sawbones material (Pacific Research Laboratories), may sometimes serve a relevant role. The key point is that mechanical properties differ among various substrates and may favor different devices or procedures[13]; for example, interference screw performance is related to bone mineral density, emphasizing the importance of selecting the correct research materials or model.[14,15]

Cyclic (submaximal) loading usually best replicates arthroscopic and orthopaedic sports medicine activity in the real world, and such testing is thus generally essential. Although catastrophic failure does occur in vivo, surgical and device failure often occurs as a result of repetitive loading. Cyclic load testing could be used to first reproduce a preload and then replicate rehabilitation and activities of daily living. Researchers must be mindful to perform cyclic load testing prior to load-to-failure determination. Biomechanical studies failing to evaluate cycling loading are often deemed “fatally flawed” and generally not accepted for publication in *Arthroscopy*.

Evaluation of gap formation (resulting from imperfect surgical reapproximation of tissue and/or bone) may be measured in many ways including using calipers, crossheads of musculoskeletal testing machines, or even optical markers or video systems. Measurements can be made during or after application of load. Advanced systems, such as optical markers, are able to measure movement in 3 dimensions and have the potential to more closely replicate a clinical scenario. Not every study requires optical markers or robots controlling 6 degrees of freedom of motion, but considered design of mechanical load application and validated measurement tools ensure accurate results.

Soft-tissue grip security can represent a challenge. Advanced cryogenic clamping techniques use liquid nitrogen or dry ice to freeze soft tissue to minimize intrafiber movement[16,17]; however, this may create a stress concentration between the frozen and nonfrozen soft tissue. Soft-tissue grip security continues to advance and must be well controlled.

Animal studies allow researchers to put the “bio” back in biomechanics. Obviously, tissue biological healing will typically result in a higher load to failure and stiffness of surgical repairs. In the age of biologics, animal investigations may play a larger role as we study the effects of diverse biological factors and products on tissue healing.

A most important criterion for research quality is reproducibility. Like a cookbook, authors must provide the exact details of every aspect of every step of the methods; a list of ingredients alone is insufficient for a delicious result. Figures and videos provide great value in clarifying reproducible biomechanical research methods. In terms of results, entire biomechanical data sets must be reported, allowing readers and future researchers to both validate and further explore outcomes as well as compare new investigations to prior publications.

Basic-science authors must avoid the common tendency to overreach when they draw conclusions. Time-zero biomechanical studies have inherent limitations; direct clinical inference is rare when the role of biological healing is not tested.[9] Therefore, the conclusion and the clinical relevance of a biomechanical study must be reported and suggested, respectively, based solely on the actual results of what was studied. A narrow focus is prudent to avoid unsupported extrapolation to untested clinical outcomes.

Like “whiskers on kittens, bright copper kettles and warm woolen mittens,” biomechanical investigations, when well performed, are among a few of our "favorite things."[18]

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