

## Editorial

# Understanding the Limits of Biomechanical Testing

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Vet Comp Orthop Traumatol 2018;31:vi–vii.

Mechanical evaluation of medical materials, devices and implants provides essential information for surgeons to make educated judgements about whether a specific product will be suitable for a particular clinical situation. There are accepted standards for testing of various orthopaedic implants in their primitive form that are maintained by ASTM (American Society of Testing Materials). Specifically, ASTM standards F543–13, F382–14, F1264–16 and F1541–2 detail methods for the evaluation of bone screws, bone plates, intramedullary devices and external fixators, respectively. If standards are followed, then the results can be compared across studies.

However, in many situations, it is also important to assess a construct that attempts to replicate an *in vivo* application. These will involve multiple materials and interactions between different structures. While the specimens may be more clinically relevant, the methods and the data derived will usually require more careful assessment. The impact of the findings will be diminished by the many assumptions and limitations. Despite these concerns, it is important to evaluate these complex systems to understand how the components will interact when a particular combination of elements is chosen.

In order for these studies to be meaningful, they must be well designed and executed. Because the loads on a construct within the patient are complex, a study methodology that evaluates compression, bending (often in two orthogonal directions) and torsion will provide a more complete assessment of implant performance. Also, the *in vivo* environment consists of multiple load events over time during the healing process, so cyclic studies may provide additional information compared with a single load to failure assessment. Choosing a testing methodology that answers the most important clinical question in the correct way requires collaboration between clinicians, who will propose the hypothesis, and engineers, who must design the test so that the data can be related back to the clinical situation. There are many different ways to compress, pull, bend or twist a specimen, and considerable thought must be given to the design. In many situations, a combination of loading methods may be needed to strengthen the conclusions.

Also important in this collaboration is establishing what are the most meaningful data to collect. An engineer's rationale for how data are collected and how calculations are made may be based on her/his experience with non-biological materials. It is important that the clinical relevance of the data to be reported is considered carefully before testing begins. All assumptions made and limitations identified should be well documented at the beginning of the project—it is very disheartening to perform a series of tests on a set of complex specimens only to find that the data you captured do not really answer the question you proposed.

Several common methodological weaknesses are seen in submitted manuscripts and can result in rejection. The equipment must be appropriate for the data being collected. The load cell should be accurate in the range of loads being recorded. In simple tests, crosshead or actuator displacement may accurately represent what is occurring at the point of interest. Grip effects and machine compliance may need to be considered. In more complex situations, and particularly with biological tissues, direct measurement of dimension changes at the site of interest will greatly improve relevance.

While there are some instances where failure load will have clinical significance, yield load is usually more relevant, as it defines the load at which permanent deformation begins. However, it may be a difficult point to identify. It is very important to develop a methodology prior to data collection so that the values will be robust. This will be particularly true if the specimens being compared have somewhat different response profiles. When a yield point is not able to be discerned from a load–displacement curve, an incrementally increasing load protocol may be an approach that will determine a clinically relevant permanent deformation. When yield and/or failure load are reported, the yield and/or failure displacement should also be included. These data add significant relevance to the clinical application of the findings. Another approach that can



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DOI <https://doi.org/10.1055/s-0038-1637025>.  
ISSN 0932-0814.

strengthen a study is to decide beforehand what amount of change (displacement, bend, rotation, gap, etc.) is clinically relevant, and compare load or torque at that point.

Stiffness, and, in some instances, compliance, may be useful parameters by which to compare constructs or specimens. By reporting a single number, the investigator is making the assumption of linearity, but many constructs and most biological tissues do not really have a linear response to load. The methodology used to calculate that singular value must be carefully considered. If a 'toe region' is present at the beginning of the response, it may, or may not, have clinical relevance. For example, when comparing two tendon repair techniques, the stiffness towards the end of loading may be similar, but, if one has a much longer low-stiffness response initially, clinical failure may have occurred prior to the specimen reaching the more stiff region.

There are few instances where stress, strain and Young's modulus calculations are meaningful in clinical biomechanics. They are used to characterize and compare materials. Direct measurement of surface strain can provide very relevant data, though, for biological materials, this is not an easy process.

When a cyclic loading protocol is being designed, the parameters must be carefully considered, and the limitations well understood. The rate, frequency, number and magnitude of the load events often must be a compromise between real life and what is technically feasible. The environmental and specimen temperature may influence the stress accumulation events. The mode of failure must be carefully interpreted, especially as the biological processes that will contribute to the response are not able to be replicated.

To emphasize the importance of relevant, meaningful study design in biomechanical projects, a sentence has been added to the Instructions for Authors document that reminds researchers to consider carefully the assumptions that were made and the limitations that might impact their conclusions *before* they test specimens. The methodology must present the assumptions made and the rationale behind the data points collected, and the method of calculation of those points. The discussion must remind the reader of the limitations that were evident at the beginning of the study, or became apparent as the data were analysed. The conclusions must be tempered by the limitations present.

A handwritten signature in black ink that reads "Simon Cree". The signature is written in a cursive, flowing style.