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Review Article

Mechanical biocompatibility of highly deformable biomedical materials

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ABSTRACT

Mismatch of mechanical properties between highly deformable biomedical materials and adjacent native tissue might lead to short and long term health impairment. The capability of implants to deform at the right level, i.e. similar to the macroscopic mechanical response of the surrounding biological materials, is often associated with dissimilar microstructural deformation mechanisms. This mismatch on smaller length scales might lead to micro-injuries, cell damage, inflammation, fibrosis or necrosis. Hence, the mechanical biocompatibility of soft implants depends not only on the properties and composition of the implant material, but also on its organization, distribution and motion at one or several length scales. The challenges related to the analysis and attainment of mechanical biocompatibility are illustrated with two examples: prosthetic meshes for hernia and pelvic repair and electrospun scaffolds for tissue engineering. For these material systems we describe existing methods for characterization and analysis of the non-linear response to uniaxial and multiaxial stress states, its time and history dependence, and the changes in deformation behavior associated with tissue in-growth and material resorption. We discuss the multi-scale deformation behavior of biomaterials and adjacent tissue, and indicate major interdisciplinary questions to be addressed in future research.

Contents

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1. Introduction

In his seminal paper in this journal Niinomi (2008) reviewed the state of knowledge on mechanical biocompatibility of titanium alloys. The paper identifies key factors related to the deformation and rupture behavior of the material "to be controlled in such a manner that they are at levels suitable for structural biomaterials used in implants that replace hard tissue". These investigated factors include Young's modulus, ductility, strength, fatigue, wear and notch sensitivity. The biomedical material is expected to provide sufficient resistance in order to carry the loads it is exposed to without failure (*rupture behavior*), and to provide a level of compliance minimizing its harm to the adjacent biological tissue (*deformation behavior*). While mechanical integrity is an obvious requirement for fulfillment of the function, the capability to deform at the right level is essential in order to exclude short and long term health impairment, such as too low tissue deformation, stress shielding, bone resorption, or excessive (relative) deformation leading to micro-injuries, and activating the cascade of processes related to the corresponding biological response (cell damage, chronic inflammation, tissue destruction, fibrosis or necrosis (Duscher et al., 2014; Engh et al., 1987)).

The present review discusses mechanical biocompatibility of biomaterials that are subjected to *large deformations*, i.e. with strain in the range of a few percent and more. Examples of such implants include those used in cardio-vascular therapies, e.g. tissue engineered vascular grafts (TEVGs) (Weber et al., 2013), skin replacement (Metcalfe and Ferguson, 2007), support in case of hernia or pelvic floor laxity (Röhrnbauer, 2013), repair of intervertebral disc (Mauck et al., 2009), tissue engineered tendons (Laurent et al., 2012, 2011), or breast implants (Teck Lim et al., 2013). Just as for hard tissue implants, soft tissue replacements have to provide both adequate *rupture* and *deformation behavior*. Unlike the biochemical factors determining biocompatibility, the biological response activated through the *deformation behavior* of soft implants does not only depend on the chemical composition of the implant material, but also on its organization, distribution