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The quantification of biocompatibility: toward a new definition[1]

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Implantable medical devices, and the biomaterials that comprise them, form a $100B business worldwide. Medical devices save lives and/or improve the quality of life for millions. Tissue engineering also makes extensive use of biomaterials – biomaterials are an enabling technology for tissue engineering. A central word to understanding the effectiveness of such materials and devices is biocompatibility. The word "biocompatible" is widely used in reference to biomaterials and medical devices and most everyone has some value understanding of its meaning. Many formal definitions have been proposed for this word, but it is still largely used in an imprecise manner. Four descriptions or definitions of biocompatibility will be reviewed: a widely adopted definition from a consensus conference, a surgeon's perspective on this word, the regulatory agency view and the factors that clearly influence biocompatibility. In this talk, the classical definition of biocompatibility will be contrasted to a newer definition embracing molecular concepts and the understanding of normal wound healing. The biological data on the *in vivo* healing responses of mammals to implants will be described. A strategy to improve the healing of biomaterials will be presented. It is based upon surface molecular engineering. First, non-specific protein adsorption must be inhibited. Strategies to achieve this design parameter will be presented. Then methods to deliver the specific protein signals will be addressed. Matricellular proteins such as osteopontin, thrombospondin 2 and SPARC will be introduced with an emphasis on exploiting the special reactivity of such proteins. A discussion of the influence of surface textures and porosities will also be presented. Finally a new scheme based upon macrophage phenotypic pathways will be proposed that may allow a quantitative measure of extent of biocompatibility.

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