


Chapter 10

Estimating Biosafety of Biodegradable Biomedical Materials From In Vitro Ion Tolerance Parameters and Toxicity of Nanomaterials in Brain

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ABSTRACT

Ensuring human health safety necessitates rigorous biosafety evaluations of substances and materials, particularly in the context of in-vivo exposure. Biodegradable materials, known for their natural decomposition capabilities through biological mechanisms, may exhibit toxicological profiles differing from non-biodegradable substances. Prior to their application in medical devices such as stents and implants, it is imperative to conduct thorough testing to ascertain their safety. This chapter aims to provide a comprehensive assessment of the in-vivo biosafety of various biodegradable materials. The authors employ an integrative approach, combining in-vitro ion-tolerance assays with in-vivo microanalysis techniques. This dual methodology allows for a detailed evaluation of the materials' biocompatibility and potential toxicity, particularly focusing on nanomaterial-induced toxicity in neural tissues. These findings offer critical insights into the safe application of biodegradable biomedical materials, underpinning informed decision-making in their usage for medical applications.

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INTRODUCTION

Numerous research has shown a growing interest in biodegradable materials derived from renewable sources (e.g., Kolybaba et al., 2006; Luzier, 1992). These materials are at the forefront of advancements in innovative design strategies and engineering approaches in biodegradable polymers (Luckachan & Pillai, 2011). Notably, the use of biodegradable materials is prevalent in implantable medical devices (Li et al., 2020), including specific applications like implants and stents (Kwon et al., 2012). However, the potential toxicity and efficacy of these materials must be rigorously evaluated *in vivo* before their clinical application. A significant challenge in this evaluation is understanding how the ionic environment influences the behavior and degradation of biodegradable materials. This aspect is crucial, considering the complexity of biological systems where these materials are intended for use. Biocompatibility, as defined by Chen et al. (2008), refers to the ability of a material to interact with living tissues without inducing negative side effects. This property is essential for materials used in biomedical applications like implants, devices, and drug delivery systems. When these materials come into contact with living tissues, they must not cause harmful effects such as inflammation, infection, or toxicity.

In biomedical research, the interaction of nanoparticles with living cells is an area of growing concern, particularly when considering nanoparticles that do not naturally degrade in the environment. The interactions between these nanoparticles and biological systems can lead to a multitude of harmful effects, as extensively documented in scientific literature. For instance, Park et al. (2011) have noted that these effects can range from inflammation and oxidative stress to DNA damage and cellular death, with the severity of these impacts being highly dependent on the physical attributes of the nanoparticles, such as their size, shape, and surface coating. This variability in response is attributed to how these different physical characteristics influence the particles' interaction with cellular structures and biochemical pathways. Furthermore, the cytotoxic mechanisms of biodegradable or loaded nanoparticles (NPs) present a particularly complex area of study. As pointed out by Frohlich (2013), one of the key challenges in this field is the difficulty in distinguishing whether the observed adverse effects are a result of the nanoparticles themselves or their degradation products. This distinction is crucial for understanding the long-term implications of nanoparticle use in medical applications. The degradation products may have different physicochemical properties and biological activities compared to the intact nanoparticles, potentially leading to unexpected biological responses. Considering these complexities, the ion tolerance of nanoparticles *in vitro* becomes a critical factor in evaluating their biosafety *in vivo*. Ion tolerance refers to the stability and reactivity of nanoparticles in various ionic environments, which can mimic the conditions they would encounter within the human body. Understanding this aspect is vital because the ionic composition of bodily fluids can significantly alter the behavior of nanoparticles.

MAIN FOCUS OF THE CHAPTER

Healthcare innovation plays a pivotal role in transforming medical practices, shaping the future of medicine, and improving patient outcomes (Ofosu-Ampong et al., 2024; Revano & Garcia, 2021). It encompasses a broad range of advancements, from cutting-edge technologies and treatments to novel healthcare strategies and materials (Arayata et al., 2022; Cortez et al., 2022; Parel et al., 2022). These innovations are crucial for addressing current challenges in healthcare, enhancing the quality and accessibility of medical services, and reducing the overall burden of disease. By fostering a culture of research and

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