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Next Generation Combined -Advanced Therapy Medicinal Products in the Electrospinning and Computational Biophysics Landscape

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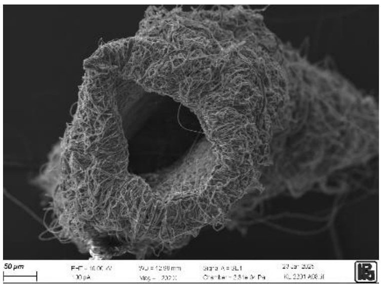
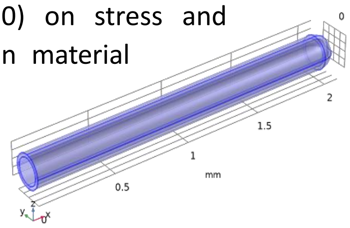


Abstract: Rationally designed biomaterial-based implants evolve as valuable Combined Advanced Therapy Medicinal Products (C-ATMP) bring high promise in systemic malignancies and neurodegenerative disorders, with significant socio-economic impact Within the highly regulated C-ATMP framework, clinically applicable implants in a ready-to-implant state should integrate two critical components: (i) soft extracellular matrix-mimicking structures with slow *in vivo* degradation rate and (ii) precisely engineered cross-linked porous scaffolds that define the implant geometry and provide key mechanical properties for integration with the surrounding tissue. This is meant to (i) ensure controllable growth conditions during preparation and maturation, (ii) guarantee integrity during implantation, and (iii) ensures smooth and safe integration in the tissue, thus reducing the burden-to-use .

Building upon existing prototypes, we present a new generation of immunocompetent medical implants that incorporate advanced biotechnology, nanoengineering, mechanopathology, and multilevel computational biophysics. These implants can monitor, sense, and respond to disease biomarkers through controlled release of personalized therapeutic agents. For brain implants addressing malignancies and neurodegenerative diseases, precise positioning, tissue mechanical compliance, and device integrity are of paramount importance. We employed electrospinning as a versatile fabrication method to create encapsulation devices with tailored properties, informed by brain tissue characterization and simulations of multilevel material interactions. Atomic Force Microscopy (AFM) has been implemented to characterize and quantify Ra (arithmetic roughness) and the Rrms (root mean squared roughness). The mechanical behaviour of a microtube implant, filled with a gel-like scaffold (GLS), within brain tissue was analysed with finite element (FE) simulations conducted in COMSOL Multiphysics. Solid Mechanics and Parametric Sweep analyses disclosed (i) the influence of Young's modulus of the proposed materials of both microtube and gel-like scaffold on the mechanical response, (ii) The effect of environmental pressure (P0) on stress and displacement and (iii) The role of porosity (por_GLS and por_PCL) in material deformation.



The employed computational approach is rationally designed in order to support the development of modular implants with tunable tissue and microenvironment adaptability and long term sustainability.

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