



Comprehensive Review on Dissolving Microneedles for Transdermal Delivery of Therapeutic Macromolecules

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1. ABSTRACT

Delivering large therapeutic biologics—including peptides, proteins, and vaccines—through the skin offers an attractive alternative to traditional needles, yet the dense stratum corneum presents a formidable physical barrier. While standard injections readily bypass this layer, they introduce significant hurdles: needle-related anxiety, sharp-waste hazards, cold-chain dependency, and the routine need for clinical administration. Dissolving microneedles (DMNs) provide an elegant, patient-friendly solution by painlessly piercing the skin barrier and dissolving in situ to release their encapsulated cargo. This review examines the physiological mechanisms governing transdermal macromolecule transport and explores the material science behind common biodegradable matrices, including hyaluronic acid (HA), polyvinylpyrrolidone (PVP), polyvinyl alcohol (PVA), and carboxymethylcellulose (CMC). We examine advanced delivery architectures—such as core-shell systems—alongside key fabrication methods ranging from PDMS micromoulding and 3D printing to mold-free droplet-born air blowing (DAB). Furthermore, we evaluate critical quality attributes, focusing on axial fracture resistance, in vivo dissolution behavior, and ex vivo permeation profiles. Finally, this paper discusses how machine learning models and nanocarrier integration are addressing current scale-up and stability challenges, helping transition dissolving microneedles from proof-of-concept prototypes to viable clinical products.

Keywords-Dissolving microneedles; Transdermal drug delivery; Biomacromolecules; Biodegradable polymers; Droplet-born air blowing; Core-shell architectures; Matrix dynamics.

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