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NEXT-GENERATION ADVANCEMENTS IN POLYMERIC MICRONEEDLES AND NANO CARRIER-MEDIATED TRANSDERMAL DRUG DELIVERY SYSTEMS

Manav Upadhyay*, Dr. Nidhi Chauhan, Yash Sheth, Het Patel, Ayush Mallik, Azba Patel

Department of Pharmaceutics, Laxminarayan Dev College of Pharmacy, Bholav, Bharuch, Gujarat – 392012.

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***Corresponding Author**

Manav Upadhyay

Department of Pharmaceutics, Laxminarayan Dev College of Pharmacy, Bholav, Bharuch, Gujarat - 392012.

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ABSTRACT

Transdermal drug delivery systems (TDDS) provide several advantages over conventional oral and parenteral routes, including avoidance of gastrointestinal degradation and hepatic first-pass metabolism, improved patient compliance, and controlled drug delivery. However, the stratum corneum acts as a major barrier, limiting the passive transport of hydrophilic and high-molecular-weight therapeutic agents. This review focuses on recent advances in polymeric microneedles and nanocarrier-mediated transdermal drug delivery systems developed to overcome these skin-permeation limitations. Literature from PubMed and Scopus was reviewed with emphasis on microneedle classification, polymeric biomaterials, nanocarrier systems, drug-loading capacity, permeation mechanisms, safety, and clinical translation. Polymeric microneedles, including solid, coated, dissolving, hydrogel-forming, and hollow systems, enable controlled and minimally painful delivery by creating temporary microchannels through the stratum corneum. Nanocarriers such as liposomes, ethosomes, solid lipid nanoparticles, nanostructured lipid carriers, polymeric nanoparticles, and inorganic nanoparticles further enhance dermal and transdermal drug transport through lipid fluidization, follicular pathways, and controlled drug deposition. The integration of these technologies provides promising

opportunities for delivering macromolecules, vaccines, and localized therapeutics. Future developments involving stimuli-responsive systems, wearable biosensors, artificial intelligence, microfluidics, and personalized manufacturing may further enhance transdermal therapy. Despite challenges related to manufacturing scalability, regulatory standardization, and long-term biocompatibility, advanced microneedle and nanocarrier platforms have considerable potential for clinical translation and personalized drug delivery. **Background:** Traditional transdermal drug delivery systems (TDDS) provide a non-invasive, patient-compliant route that avoids gastrointestinal degradation and hepatic first-pass metabolism. However, the impermeable lipid matrix of the stratum corneum strictly limits the passive transport of molecules to those possessing specific hydrophobic profiles and low molecular weights. **Objective:** This comprehensive review examines contemporary physical and chemical breakthrough technologies, with specific focus on polymeric microneedles (MNs) and nanocarrier-facilitated delivery platforms engineered to overcome these macro-molecular transport constraints. **Methodology:** A systematic screening of literature from the PubMed and Scopus databases (spanning foundational models through 2026) was conducted to evaluate the mechanical structural properties, biopolymer selections, and systemic pharmacokinetics of advanced skin-permeation platforms. **Results:** Polymeric microneedles (dissolving, hydrogel-forming, and stimuli-responsive types) demonstrate precise disruption of the stratum corneum without contacting dermally located pain-sensitive nerve endings. Concurrently, lipidic, polymeric, and inorganic nanocarriers capitalize on hair follicles and transient lipid fluidization to deposit high-molecular-weight biologics, vaccines, and localized therapeutics. **Conclusion:** Combining active mechanical microneedles with target-specific nanocarriers represents the vanguard of modern personalized diagnostics and therapeutics, bridging laboratory innovation with clinical scale-up paradigms.

KEYWORDS: Transdermal Drug Delivery Systems; Microneedles; Nanocarriers; Stratum Corneum; Biopolymers; Pharmacokinetics.

INTRODUCTION

Transdermal drug delivery systems (TDDS) offer substantial clinical advantages over traditional oral and parenteral administration routes, including the elimination of gastrointestinal tract irritation, avoidance of hepatic first-pass metabolism, and continuous, controlled systemic circulation profiles.[1,2] Historical tracking reveals that primitive forms of localized dermal patches date back to ancient medical plasters.[2] However, modern

pharmaceutical engineering has shifted the objective from localized dermal therapy to continuous systemic delivery.[3]

The primary barrier preventing therapeutic macromolecular flux through the skin is the stratum corneum—the outermost, highly keratinized layer of epidermis operating via a tight "brick-and-mortar" structural paradigm.[4] Passive transdermal patches are typically restricted to lipophilic small-molecule drugs with low molecular weights (\le 500 \text{ Da}) and balanced octanol-water partition coefficients.[1,2]

To overcome these strict biological limitations, the pharmaceutical sector has advanced past simple chemical penetration enhancers toward sophisticated mechanical and physical disruption techniques.[5] Among these, micro-sized needles (microneedles) have emerged as a prominent non-invasive alternative.[1] By perforating the stratum corneum to create microchannels without contacting deep dermal pain receptors, microneedles (MNs) allow the pain-free introduction of hydrophilic macromolecules, genes, and vaccines into systemic circulation.[4,6] Concurrently, nanocarrier matrices (liposomes, polymeric nanoparticles, and solid lipid nanoparticles) fluidize skin lipids to increase the depth and concentration of drug delivery.[5] This comprehensive review clarifies the structural, polymeric, and biochemical breakthroughs governing modern microneedles and nanocarriers, offering a critical comparative evaluation of current innovations and future clinical translation.

METHODOLOGY

A comprehensive literature search was conducted using the PubMed and Scopus databases to extract high-impact peer-reviewed review papers, clinical trials, and fundamental experimental research investigating modern developments in transdermal delivery. Search strings focused on combinations of core index terms, including "transdermal drug delivery systems", "polymeric microneedles", "nanocarriers", "stratum corneum permeation", and "active enhancement techniques".

The screening criteria prioritized studies detailing quantitative mechanism performance, structural biopolymer classification, material safety data, and human clinical trials. Articles evaluating basic chemical enhancers without mechanical validation or missing peer-reviewed verification were excluded. The extracted literature was systematically classified into core thematic sections: biomaterial matrix engineering, mechanical classification profiles, nanocarrier delivery kinetics, and regulatory translational frameworks. Data normalization

across sections was performed to maintain a consistent evaluation of drug loading capacities, safety margins, and kinetic release outcomes across all discussed modalities.

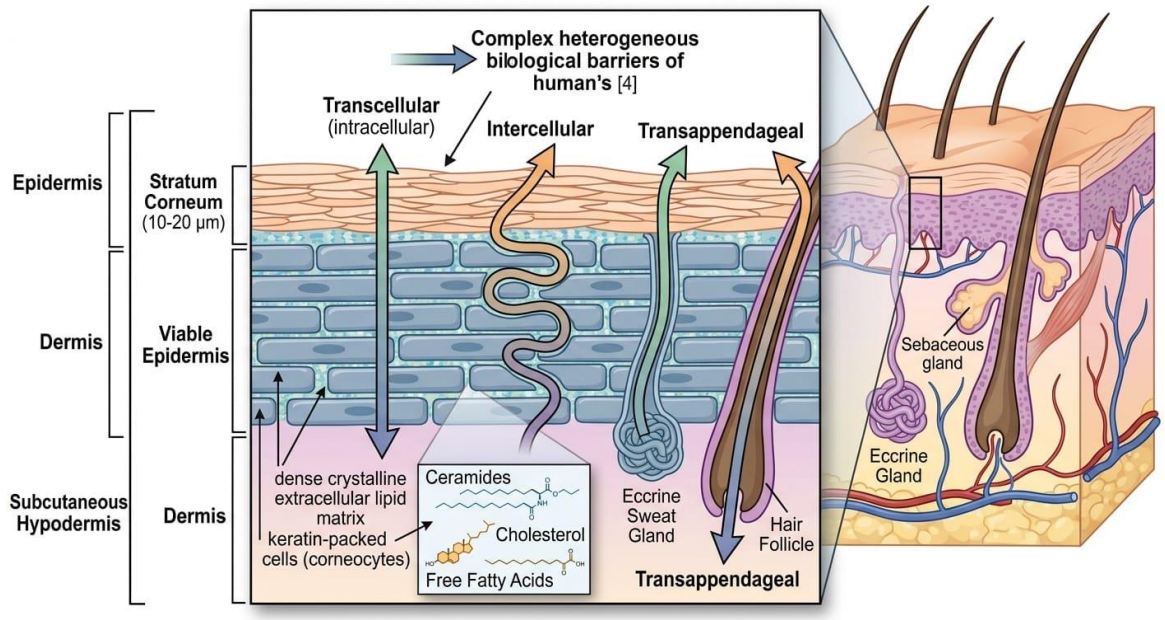
1. Anatomy and permeation barriers of the skin

To effectively design an advanced transdermal platform, one must analyze the heterogeneous biological barriers presented by human skin. The skin consists of three primary functional layers: the epidermis, the dermis, and the subcutaneous hypodermis.[4]

The topmost layer of the epidermis, the stratum corneum (10-20 \ \mu\text{m} thick), serves as the principal physical barrier.[4] It consists of dead, flattened, keratin-packed cells (corneocytes) embedded within a highly organized, dense crystalline extracellular lipid matrix consisting of ceramides, cholesterol, and free fatty acids.[4,5] Transdermal transport through this intact matrix occurs via three distinct pathways:

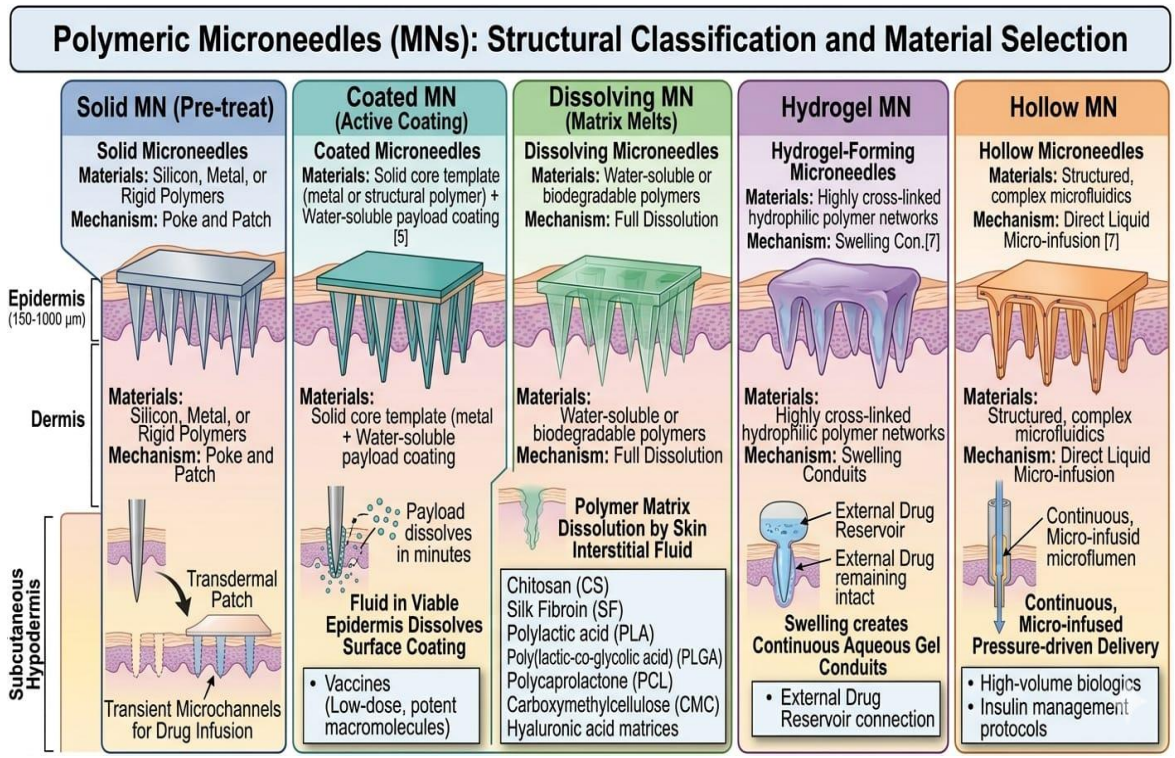
Trancellular (intracellular): Passing directly through the keratinocyte cores.
Intercellular: Winding through the continuous lipid bilayers.
Transappendageal: Leveraging shunt paths through eccrine sweat glands and hair follicles.[5]

Active physical delivery strategies focus on destabilizing or mechanically bypassing this intercellular lipid matrix to establish micro-conduits into the viable epidermis and vascularized dermis.[1]



2. Polymeric microneedles(MNs): structural classification and material selection

Microneedles utilize microscale arrays (ranging from 150 to 1000 \ \mu\text{m} in height) designed to pierce the stratum corneum and generate transient microchannels for drug infusion.[1,6] Because these lengths do not reach the deeper, nerve-dense dermal layers, patient administration remains entirely painless.[6] MN arrays are categorized into distinct structural configurations depending on their material matrix and release mmechanism:



Solid microneedles

Solid microneedles are primarily used for skin pretreatment.[4] Formed from silicon, metal, or rigid polymers, these arrays are pressed into the skin to create microchannels, removed, and then followed by the application of a conventional transdermal patch.[4,5] While highly effective at accelerating subsequent drug diffusion, this "poke-and-patch" method requires a two-step application process that can compromise patient compliance and increase channel contamination risks if not handled sterilely.[4]

Coated microneedles

Coated microneedles utilize a solid core template (typically metal or structural polymer) whose exterior surfaces are layered with a water-soluble formulation containing the therapeutic payload.[4] Upon insertion, the fluid within the viable epidermis rapidly dissolves the surface coating, releasing the drug within minutes.[4] This approach is ideal for low-dose

potent macromolecules, such as vaccines, though it is inherently limited by the restricted surface area available for high-dose drug loading.[4]

Dissolving microneedles

Dissolving microneedles represent a major clinical breakthrough, eliminating sharp biohazardous waste.[4,6] These systems are fabricated entirely from water-soluble or biodegradable polymers encapsulating the drug throughout their internal matrices.[4, 7] Upon insertion, the polymer undergoes full dissolution and degradation by interacting with interstitial skin moisture, releasing the active pharmaceutical ingredient (API) over a predictable time frame.[4,7] Common natural and synthetic polymers used include:

Chitosan (CS)[7]

Silk Fibroin (SF)[7]

Olylactic acid (PLA) [7]

Poly(lactic-co-glycolic acid) (PLGA)[7]

Polycaprolactone (PCL)[7]

Carboxymethylcellulose (CMC) and hyaluronic acid matrices.

These polymers allow engineers to tune degradation kinetics from immediate release to multi-week sustained release profiles by modifying the polymer molecular weight and cross-linking density.[7]

Hydrogel forming microneedles

Unlike dissolving arrays, hydrogel-forming microneedles do not melt or degrade entirely within the tissue.[4] Instead, they are composed of highly cross-linked hydrophilic polymer networks that swell upon absorbing skin interstitial fluid.[4] This swelling transforms the sharp needles into continuous, aqueous gel conduits that connect an attached external drug reservoir directly to the dermal capillary network.[4] After treatment, the intact hydrogel assembly can be peeled off the skin without leaving residual polymer fragments behind.[4]

Hollow microneedles

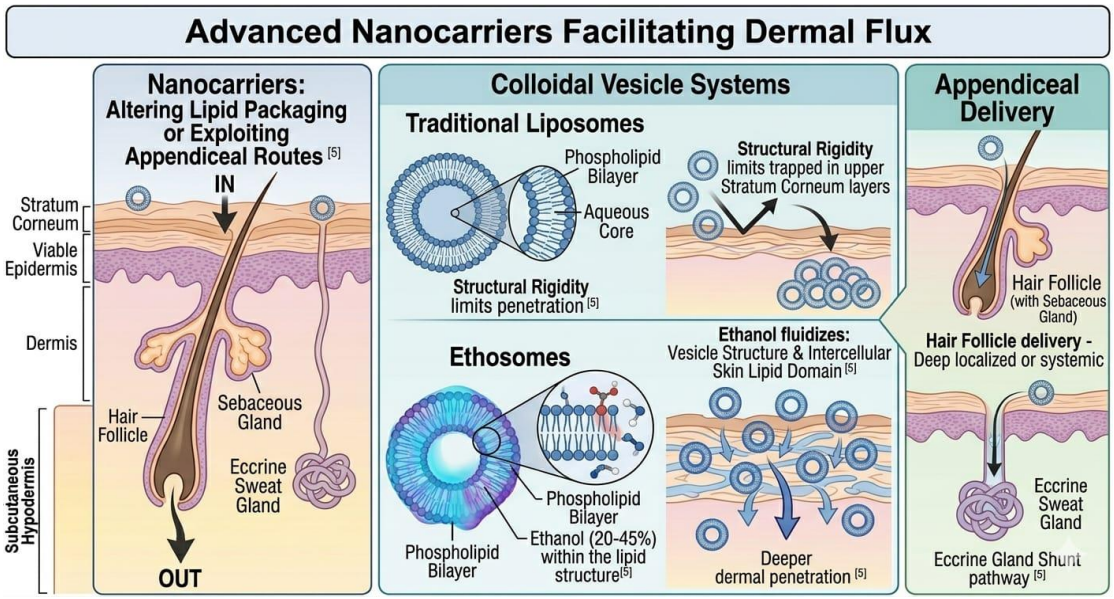
Hollow microneedles feature an open internal lumen that allows for the continuous, micro-infused pressure-driven delivery of liquid drug formulations directly into sub-epidermal layers.[4] This approach mimics traditional hypodermic injections but operates at a micro-scale level, making it well-suited for high-volume biologics and insulin management protocols.[4]

However, these systems require complex microfluidic connections and are susceptible to

clogging during needle insertion,[1,4]

3. Advanced nano carriers facilitating dermal flux

When mechanical arrays are not combined with patches, chemical and colloidal nanocarriers offer an alternate method for transporting therapeutic agents through the stratum corneum.[5] These systems alter the lipid packaging of the skin or exploit appendiceal routes to deliver deep localized or systemic payloads.[5]



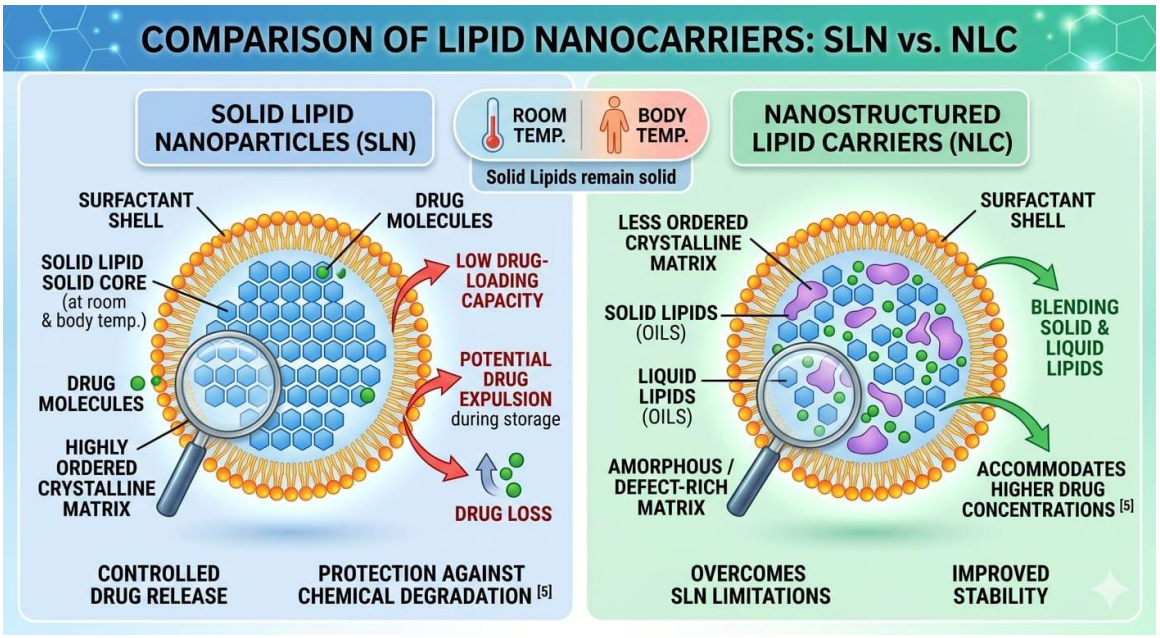
Liposomes and ethosomes

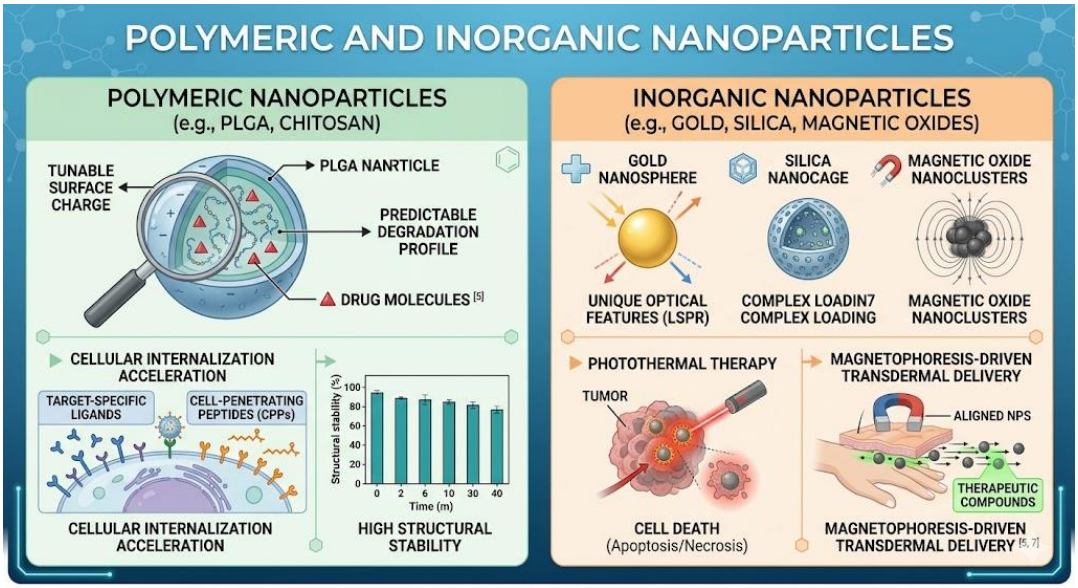
Liposomes are spherical vesicles consisting of phospholipid bilayers enclosing an aqueous core, allowing them to carry both lipophilic and hydrophilic molecules.[5] Traditional liposomes often remain trapped in the upper stratum corneum layers due to their structural rigidity.[5] To improve skin penetration, researchers developed ethosomes by introducing high concentrations of ethanol (20-45\%) into the lipid structure.[5] The ethanol fluidizes both the liposomal vesicle structure and the skin's intercellular lipid domain, providing a flexible pathway for deeper dermal penetration.[5]

Solid lipid nano particles (SLN) and nano structured lipid carriers

SLNs replace liquid lipids with a solid lipid core at room and body temperatures, providing controlled drug release and protection against chemical degradation.[5] To overcome the low drug-loading capacities and potential drug expulsion during crystalline storage common to SLNs, Nanostructured Lipid Carriers (NLCs) were developed.[5] By blending solid lipids with liquid lipids (oils), NLCs form a less ordered crystalline matrix that accommodates higher

concentrations of the target therapeutic compound.[5]





Polymeric and inorganic nanoparticle

Polymeric nanoparticles (such as those derived from PLGA or chitosan) offer high structural stability, tunable surface charges, and predictable degradation profiles.[5] Surface modifications using target-specific ligands or cell-penetrating peptides further accelerate cellular internalization.[5] Inorganic nanoparticles (including gold, silica, and magnetic oxides) are also being investigated for their unique optical, electronic, and thermal features, enabling precision physical therapies like photothermal or magnetophoresis-driven transdermal delivery.[5,7]

Comparative analysis

Understanding the relative clinical and manufacturing trade-offs between different active transdermal technologies is essential for successful translation. The table below summarizes key parameters including delivery mechanisms, macromolecular capacities, patient compliance metrics, and technical constraints across these varied systems.

Table 1: Comprehensive Comparison of Advanced Transdermal Enhancement Technologies.

Technology Modality	Core Transdermal Mechanism	Macromolecular Flux Capacity	Patient Compliance & Sensation	Principal Manufacturing & Operational Limitations	Reference Profiles
Passive Transdermal Patches	Passive concentration gradient diffusion via intercellular pathways.	Extremely low; limited to molecules \le 500 \text{ Da}.	High compliance; simple, painless patch application.	Restricted to lipophilic, low-dose small molecules.	**[1, 2, 3]**
Solid Pretreatment MNs	Mechanical perforation of the stratum corneum followed by separate patch application.	Moderate to High; dependent on stable microchannel lifetime.	Moderate; requires a two-step "poke-and-patc h" clinical workflow.	Risk of microchannel closing and potential infection if contaminated.	**[4, 5]**
Coated Microneedles	Dissolution of a solid-supported surface-dried drug coating layer.	Moderate; restricted by total surface area of the needle tips.	High; rapid single-step application with painless delivery.	Low loading capacity; restricted to highly potent low-dose molecules.	**[4]**
Technology Modality	Core Transdermal Mechanism	Macromolecula r Flux Capacity	Patient Compliance & Sensation	Principal Manufacturing & Operational Limitations	**Reference Profiles**
Dissolving Microneedles	Complete internal matrix dissolution of water-soluble/bi odegradable biopolymers.	High; accommodates peptides, vaccines, and larger proteins.	Excellent; self-disabling design eliminates sharp biohazardous waste.	Requires hygroscopic manufacturing controls and precise polymer selection.	**[4, 6, 7]**
Hydrogel-For ming MNs	In situ interstitial fluid swelling to	High; allows continuous diffusion of	High; pain-free application	Complex multi-layered structural	**[4]**

	form an uninterrupted aqueous gel conduit.	macromolecule s from an attached reservoir.	and clean removal without residue.	manufacturing processes.	
Hollow Microneedles	Active micro-infusion or syringe-driven liquid drug transport through internal lumens.	Very High; supports direct delivery of liquid biological suspensions.	Moderate; minimal sensation, mimicking micro-scale injections.	High risk of needle clogging and complex device engineering.	**[1, 4]**
Ethosomes & Nano-Vesicles	Ethanol-driven lipid fluidization combined with deformable vesicle matrix penetration.	Moderate; dependent on overall vesicle size and surface charge.	High; non-invasive, topical cream or lotion formulation.	Challenges with scale-up stability and potential drug leakage.	**[5]**
Solid Lipid Nanoparticles (SLN/NLC)	Controlled lipid matrix integration that enhances skin occlusion and fluidization.	Moderate; well-suited for lipophilic molecules and small proteins.	High; non-invasive topical application.	Limited loading for hydrophilic drugs; potential polymorphic transition during storage.	**[5]**

Future perspective

The field of transdermal drug delivery systems is transitioning from passive, single-layer drug delivery toward multi-functional, intelligent medical platforms.[1,2] One major development is the integration of closed-loop wearable systems that pair real-time diagnostics with automated therapeutic responses.[1] By incorporating miniaturized biosensors into stimuli-responsive hydrogel microneedle arrays, these devices can continuously monitor specific biomarker concentrations (such as interstitial glucose or tumor markers) and automatically adjust drug release kinetics without patient intervention.[1] Concurrently, artificial intelligence (AI) and computational molecular modeling are accelerating optimization workflows across the industry.[1] AI models allow researchers to screen vast polymer libraries, predict the mechanical stability of complex needle geometries, and simulate drug diffusion profiles through virtual skin models before physical prototyping begins.[1] Furthermore, advanced manufacturing techniques like high-resolution 3D printing are enabling the personalized production of patient-specific patch configurations at the point of care.[1,2] As these closed-loop devices, microfluidics, and digital health applications

continue to merge, the next generation of transdermal therapies is positioned to offer highly personalized, data-driven medical care.[1]

CONCLUSION

Traditional transdermal delivery systems remain constrained by the selective permeability of the stratum corneum. However, modern active methodologies—particularly polymeric microneedles and engineered nanocarriers—effectively overcome this biological barrier.[1,4] These platforms demonstrate that physical disruption at the micro-scale and targeted lipid fluidization can safely deliver large biomolecules, vaccines, and localized therapeutics without causing patient pain or generating biohazardous sharps waste.[4,6]

While challenges remain regarding large-scale manufacturing reproducibility, regulatory standardization, and long-term polymer biocompatibility, the integration of smart, responsive biopolymers and digital health technologies marks a significant shift in patient care.[1,2]

Moving forward, these advancements are set to establish transdermal delivery as a standard of care for chronic disease management, global immunization efforts, and personalized clinical therapies.[1]

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