Int. J. Sci. R. Tech., 2026 3(4)
A Multidisciplinary peer-reviewed Journal
www.ijsrtjournal.com [ISSN: 2394-7063]

Original Article

Microneedle Technology: A Revolutionary Platform in Transdermal Drug Delivery System

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ABSTRACT

The transdermal route for drug administration offers significant advantages over conventional methods, such as improved patient compliance and the avoidance of hepatic first-pass metabolism and gastrointestinal degradation. However, its effectiveness is severely limited by the stratum corneum (SC), the skin's outermost barrier, particularly for large molecules (macromolecules) and hydrophilic compounds. Microneedle (MN) technology has emerged as a groundbreaking "third-generation" transdermal delivery system to physically bypass the SC. MN arrays are devices featuring micron-sized projections that minimally and transiently disrupt the SC without stimulating the underlying nerve endings in the dermis, thus ensuring painless drug delivery. This action creates transient aqueous microchannels, enabling therapeutic agents, including high molecular weight biologics, peptides, and vaccines, to permeate the skin with significantly enhanced bioavailability and rapid onset of action. MNs are fabricated from various biocompatible materials and exist in several structural and functional formats—including solid ("poke-and-patch"), coated ("coat-and-poke"), dissolving ("poke-and-release"), and hollow—each offering tailored drug release kinetics. Given its high efficiency, excellent patient compliance, affordability, enhanced stability for biological cargo, and potential for decentralized self-administration, MN technology is poised to revolutionize the delivery of a wide range of therapeutic substances, leading to profound clinical and public health impacts.

Keywords: Microneedles (MNs), Transdermal Drug Delivery System (TDDS), Stratum Corneum, Biologics, Vaccine Delivery, Macro-molecules

INTRODUCTION

The selection of a drug administration route is fundamental to a therapeutic regimen's efficacy, safety, and patient compliance[1]. While the oral route is convenient, it frequently results in poor bioavailability for numerous drugs, primarily due to degradation in the gastrointestinal tract and the inevitable hepatic first-pass effect[2]. Conversely, parenteral routes (injections) offer high systemic bioavailability but are fraught with disadvantages, including associated pain, risk of infection, phobia (trypanophobia), and the consistent need for trained medical personnel[3,4]. Transdermal Drug Delivery Systems (TDDS) were developed as a non-invasive, patient-friendly alternative, providing controlled and sustained drug release directly into the systemic circulation, thus avoiding first-pass metabolism and maintaining stable plasma concentrations However, the major hurdle for TDDS is the stratum corneum (SC), the outermost layer of the epidermis typically 10–20 µm thick (ranging up to 40 µm in some body sites), which functions as the primary permeability barrier [5,6]This dense, lipid-rich barrier effectively limits the transdermal permeation of most therapeutic agents, particularly those with a molecular weight greater than 500 Da, hydrophilic nature, or ionic charge[7]. The SC consists of corneocytes embedded in a lipid matrix organized in a highly ordered lamellar structure, creating a tortuous pathway that restricts molecular diffusion[8]. To overcome the SC barrier, researchers have developed various physical enhancement techniques, such as iontophoresis, electroporation, sonophoresis, and thermophoresis [9] Among these, Microneedle (MN) technology has emerged as the most promising platform, representing a true "third-generation" transdermal delivery approach that physically and minimally bypasses the SC [10]MN arrays consist of micron-scale projections, typically ranging from 150 to 1500 µm in length, which are long enough to penetrate the non-vascularized epidermis but intentionally too short to

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

reach the underlying pain receptors and capillaries in the dermis[11]. This design enables painless, minimally invasive delivery, facilitating the systemic absorption of both small-molecule drugs and high-molecular-weight biologics[12]. The evolution of MN technology can be traced back to the late 1990s when the first silicon-based microneedle arrays were fabricated using microelectromechanical systems (MEMS) technology[13]. Since then, the field has witnessed exponential growth, with over 1,000 research publications and numerous patents filed annually[14]. The technology has progressed from proof-of-concept studies to clinical trials and, in some cases, commercial products[15,16]

Materials and Methods (Classification, Materials, and Fabrication)

As a comprehensive review, this section details the physical anatomy of microneedle action, the classification by structure and mechanism, the diverse materials utilized, and the sophisticated fabrication techniques employed.

Anatomy and Mechanism of Action

Microneedles exploit the skin's structural anatomy to create transient permeability pathways. The skin comprises three primary layers: the epidermis (50–150 µm thick), dermis (1–3 mm thick), and subcutaneous tissue[17]. The MNs are sized to pierce the SC and the viable epidermis, typically stopping above the dermal layer[2]. The key parameters of MN design—length, tip radius, base width, aspect ratio, and array density—are optimized to maximize penetration efficacy while minimizing dermal stimulation[18]. Upon application, the MNs create microchannels that serve as temporary aqueous shunts, allowing the drug to bypass the lipid-rich SC barrier and move directly into the dermal microcirculation [19]The insertion depth depends on multiple factors including needle geometry, applied force, skin properties (age, hydration, anatomical site), and application technique[20]. These micro-lesions are self-closing, often healing within minutes to hours through the natural wound-healing process, which ensures skin barrier restoration and minimizes the risk of infection[21]. The permeability enhancement created by MNs is quantified by the permeability coefficient and can increase drug flux by several orders of magnitude compared to intact skin[22]. Studies have demonstrated that MN-created microchannels remain patent for 2–48 hours depending on the needle geometry and skin properties, providing sufficient time for drug permeation[23].

Classification and Delivery Mechanisms

Microneedles are classified based on their structure, material composition, and the corresponding drug delivery mechanism, each tailored for a specific therapeutic need[24].

Table 1: Classification of Microneedle Types and Delivery Mechanisms.

Sr. No.	Column 1	Column 2	Column 3
1	Solid MNs	Applied topically after puncture	Passive diffusion through microchannels.
2	Coated MNs	Drug in a thin layer on needle surface	Rapid dissolution of the coating layer in interstitial fluid.
3	Dissolving MNs	Drug encapsulated within needle matrix	Degradation/dissolution of the entire polymer matrix.
4	Hollow MNs	Liquid drug solution in a reservoir	Pressure-driven flow (infusion/perfusion) through the bore.
5	Hydrogel MNs	Drug in a cross-linked polymer matrix	Swelling upon hydration, followed by drug diffusion out of the hydrogel.

Each MN type offers distinct advantages: solid MNs provide robust mechanical properties; coated MNs enable rapid vaccine delivery; dissolving MNs eliminate sharps waste and offer controlled release; hollow MNs allow for high-dose liquid formulations; and hydrogel MNs provide extended release kinetics[25,26]

Materials Used in MN Fabrication

The selection of the fabrication material is paramount, dictating the needle's mechanical strength, stability, biocompatibility, and biofate (non-degradable vs. degradable) [27].

Table 2: Key Materials for Microneedle Fabrication

Sr. No.	Column 1	Column 2	Column 3
1	Non-Degradable Metal	Stainless Steel, Titanium, Nickel	Superior mechanical strength, High fracture toughness, Excellent reproducibility.
2	Non-Degradable Silicon	Crystalline Silicon	High precision, Etching capability for sharp tips, Well-established fabrication protocols.
3	Water-Soluble Polymers	Hyaluronic acid (HA), PVP, PVA, Dextrin, CMC	Excellent biocompatibility, Tunable dissolution rate, No sharp waste, FDA-approved excipients.
4	Biodegradable Polymers	PLGA, Polylactic Acid (PLA), PCL	Controlled degradation rate, FDA-approved (PLGA), Programmable release kinetics.
5	Carbohydrates	Maltose, Sucrose, Trehalose, Glucose	Very high-water solubility, Fast dissolution rate, GRAS status, Protein stabilization.
6	Ceramic Materials	Calcium sulfate, Hydroxyapatite	High mechanical strength, Biocompatible, Osseoconductive properties.

Recent developments have explored composite materials that combine the mechanical strength of one material with the biocompatibility of another[28]. For instance, metal-polymer composites and ceramic-polymer hybrids have shown promise in achieving optimal mechanical and biological properties[29].

Fabrication Techniques

Fabrication aims for high-precision control over needle geometry and array density, with a focus on cost-effective, high-throughput scalability[30].

Table 3: Overview of Microneedle Fabrication Techniques

Sr. No.	Column 1	Column 2	Column 3
1	Micro-Molding/Casting	Polymers (Dissolving, Hydrogel)	Pouring liquid polymer/drug solution into a master mold, followed by curing/drying.
2	Lithography/ Etching	Silicon, Metal (Master Molds)	Utilizes photolithography and Deep Reactive Ion Etching (DRIE) from the semiconductor industry.
3	Laser-Based Techniques	Metal, Solid Polymers	Laser cutting or ablation to define needle structures using focused laser beams.
4	3D Printing (Additive)	Polymers, Composites, Ceramics	Layer-by-layer construction (e.g., micro-stereolithography, two-photon polymerization).
5	Dip-Coating	Solid MNs (Metal, Silicon)	Dipping a solid array into a drug/polymer solution; solvent evaporates leaving a drug layer.
6	Drawing Lithography	Glass, Polymers	Vertical pulling of softened material to create needle-like structures.
7	Injection Molding	Thermoplastics	High-pressure injection of molten polymer into precision molds.

Emerging fabrication techniques include roll-to-roll manufacturing for continuous production[31], electrospinning for creating nanostructured MNs[32], and self-assembly methods for bottom-up fabrication[33]. Quality control parameters such as needle height uniformity, tip sharpness, mechanical strength, and sterility are critical for regulatory approval[34].

RESULTS

This section details the diverse therapeutic, diagnostic, and cosmetic applications of MN technology.

Applications of Microneedle Technology

MN technology's versatility supports a broad range of applications across healthcare[35].

A. Pharmaceutical and Clinical Applications

Vaccine Delivery: The dermis is rich in Antigen-Presenting Cells (APCs), notably Langerhans cells and dermal dendritic cells, making it an ideal target for immunization[36]. MN patches (mostly coated or dissolving) deliver vaccines directly to these immune cells, often requiring a lower dose (up to 90% dose reduction) than intramuscular injection due to enhanced immunogenicity[37]. Crucially, the formulation in a solid-state patch offers thermostability, eliminating the costly and complex "cold chain" required for liquid vaccines, thus simplifying logistics for global immunization efforts[38]. Clinical trials have demonstrated the efficacy of MN-delivered vaccines for multiple diseases. A landmark phase 1/2 trial in The Gambia showed that a measles and rubella vaccine delivered via microneedle patch was safe, well-tolerated, and immunogenic in children[39]. Similarly, influenza vaccine MN patches have completed multiple clinical trials with promising results[40]. COVID-19 vaccine MN platforms have been extensively researched, with several formulations showing stability at room temperature for over 12 months[41]. Other vaccines under development include those for polio, hepatitis B, HPV, and tuberculosis (BCG)[42,43]

Delivery of Biologics and Peptides: The platform is a breakthrough for systemically delivering high molecular weight drugs (macromolecules) that are degraded orally, such as insulin, growth hormones, monoclonal antibodies, and gene therapies[44]. Glucose-responsive MNs, which release insulin only when blood glucose levels are elevated, are a key area of research for closed-loop diabetes management[45]. These "smart" MNs incorporate glucose-oxidase or phenylboronic acid moieties that respond to hyperglycemic conditions[46]. Other biologics successfully delivered via MNs include: parathyroid hormone for osteoporosis[47], erythropoietin for anemia[48], interferons for hepatitis[49], and various monoclonal antibodies for cancer immunotherapy[50]. The MN route offers improved pharmacokinetics compared to subcutaneous injection, with faster onset and more predictable absorption profiles[51].

Localized Treatment: MNs ensure high local drug concentrations with minimal systemic exposure for targeted therapies[52]. This is effective in dermatology for conditions like psoriasis (methotrexate delivery), skin cancers (transdermal chemotherapy with 5-fluorouracil or paclitaxel), alopecia (minoxidil delivery), and acne (tretinoin delivery), delivering potent drugs directly to the lesion site[53]. MN-mediated photodynamic therapy has shown enhanced outcomes for basal cell carcinoma[54].

Diagnostics and Monitoring: Hollow MNs or surface-modified MNs can penetrate the SC to sample interstitial fluid (ISF), a biological fluid rich in biomarkers (e.g., glucose, lactate, K^+, urea, proteins, antibodies), for continuous or on-demand monitoring[55]. The integration of MNs with electrochemical sensors creates wearable biosensors for real-time health monitoring[56]. Recent advances include MN-based continuous glucose monitors that rival commercial subcutaneous sensors in accuracy[57], multiplexed biomarker detection for diabetes management[58], and therapeutic drug monitoring systems[59].

Table 4: Comparison of Various Drug Delivery System

Sr. No.	Column 1	Column 2	Column 3
1	Oral	Low/Variable	Excellent
2	Parenteral (Injection)	High (near 100%)	Low (due to pain/phobia)
3	Conventional TDDS	Low	Good
4	Microneedle (MN)	High/Tunable	Excellent

B. Cosmeceutical and Aesthetic Applications

MNs are used to enhance the penetration of high molecular weight cosmetic agents (e.g., hyaluronic acid, collagen, vitamins C and E, peptides, growth factors) that normally cannot cross the SC[60]. Furthermore, the micro-injuries created by MNs in the dermis trigger a wound-healing cascade, stimulating

the production of new collagen and elastin through increased expression of growth factors like TGF-β and VEGF, a process known as Percutaneous Collagen Induction Therapy (Microneedling), used for scar revision, wrinkle reduction, hyperpigmentation treatment, and anti-aging[61]. Clinical studies have demonstrated significant improvements in facial skin texture, pore size, and elasticity following MN treatments[62]. The combination of MN with radiofrequency energy (RF-MN) has shown enhanced efficacy for skin tightening and rejuvenation[63]. MN-mediated delivery of stem cell-derived exosomes and growth factors represents a frontier in regenerative aesthetics[64].

DISCUSSION

Despite remarkable progress, the clinical and commercial translation of MN technology faces significant hurdles. This section discusses the critical technological and regulatory challenges hindering widespread clinical adoption and explores the future trajectory of the field.

Challenges and Future Trajectory

Table 5: Key Challenge and Proposed Solution for Micro needle Drug Delivery

Sr. No.	Column 1	Column 2	Column 3
1	Mechanical Integrity	Buckling or fracture of needles (especially polymer/sugar MNs) upon insertion force.	Risk of needle residue in the skin, reduced efficacy, safety concern.
2	Dose Limitation	Small surface area of Coated MNs limits the maximum drug load (typically few mg).	Not suitable for drugs requiring high systemic doses.
3	Manufacturing Cost	High capital investment for precision techniques (Lithography, 3D printing).	Increased final product cost, slowing market adoption.
4	Stability & Shelf Life	Fragility of drug-loaded MN patches; stability of biologics in the solid state.	Requires specialized packaging, limits global distribution, cold chain dependency for some formulations.
5	Regulatory Standard	Lack of standardized testing protocols for penetration force, dose accuracy and biocompatibility.	Slows down FDA/EMA approval and clinical translation.
6	Skin Variability	Differences in skin thickness, hydration, age affect penetration efficiency.	Inconsistent drug delivery across patient populations.
7	Infection Risk	Although minimal, risk of microbial contamination through microchannels.	Safety concerns, especially for immunocompromised patients.

The regulatory pathway for MN products remains complex, as they represent a combination drug-device product requiring evaluation under both pharmaceutical and medical device frameworks[65]. The FDA and EMA have issued draft guidance documents, but definitive standards are still evolving[66].

Future Directions and Opportunities

The future of MN technology is focused on integration, intelligence, and accessibility.

Table 6: Emerging Trends and Opportunities

Sr. No.	Column 1	Column 2	Column 3
1	Stimuli-Responsive MNs	MNs made of materials that sense and respond to biological triggers (e.g., pH, temperature, glucose, enzymes, reactive oxygen species).	Closed-loop drug delivery (e.g., auto-insulin release), highly targeted therapy for inflammatory sites, cancer microenvironment-responsive chemotherapy.
2	Integrated Wearable MNs	Combining MN biosensors with microelectronics, wireless	Continuous, painless, real-time health monitoring (e.g., glucose, drug

		communication modules, and power sources.	metabolites, cortisol, electrolytes) in a comfortable patch, IoMT integration.
3	Trans-Mucosal Delivery	Applying MNs to non-skin barriers like ocular, buccal (mouth), vaginal, or nasal mucosa.	Localized treatment of mucosal diseases, systemic delivery bypassing the harsh digestive environment, enhanced vaccine absorption.
4	Combination Therapy MNs	Single MN patch delivering multiple drugs or combining MN action with other enhancement methods (e.g., iontophoresis, sonophoresis).	Synergistic treatment for complex diseases like cancer or chronic wounds, reduced treatment burden, improved adherence.
5	Personalized Fabrication	Utilizing high-speed 3D printing (Additive Manufacturing) to customize dose, geometry, and drug combinations.	MN patch tailored to a patient's specific skin properties, disease state, and dosage requirements, precision medicine applications.
6	Nanoparticle-Loaded MNs	Integration of nanoparticles (liposomes, polymeric NPs, inorganic NPs) within MN matrix for controlled release.	Prolonged drug action, targeted delivery to specific cells, combination of imaging and therapy (theranostics), enhanced protein stability.
7	Artificial Intelligence Integration	AI-driven optimization of MN design, manufacturing, and patient-specific dosing algorithms.	Accelerated development cycles, predictive modeling of drug release, personalized treatment algorithms, quality control automation.

Emerging applications include MN-based delivery of gene editing tools (CRISPR-Cas9) [67], cell-based therapies[68], and probiotics for skin microbiome modulation[69]. The integration of MN technology with organ-on-chip platforms for drug testing represents another frontier[70].

CONCLUSION

Microneedle (MN) technology stands as a powerful, transformative platform for drug delivery, diagnostics, and cosmetology, primarily due to its ability to painlessly and minimally invasively breach the stratum corneum barrier[71]. It successfully addresses several major limitations of conventional administration methods by enabling the efficient transdermal delivery of macromolecules (proteins, peptides, vaccines), significantly improving patient compliance by eliminating needle phobia, and allowing for controlled and sustained drug release profiles[72]. While challenges related to manufacturing scalability, mechanical reliability, dose limitations, and the need for standardized regulatory pathways still exist, the field is rapidly maturing[73]. The convergence of advanced materials science, microfabrication techniques, and digital health technologies is accelerating the translation of MN platforms from laboratory to clinic[74]. The future trajectory involves the commercial launch of highly stable MN-based vaccine and therapeutic products, alongside the widespread development of smart, integrated MNs for continuous monitoring and personalized, closed-loop treatment[75]. Several MN products have already received regulatory approval or are in late-stage clinical trials, signaling the imminent mainstreaming of this technology[76]. Microneedle technology is decisively poised to become a preferred, patient-centric route of administration, revolutionizing drug delivery and diagnosis across the global healthcare sector[77]. As the technology continues to evolve, it holds particular promise for addressing global health challenges in resource-limited settings, where the elimination of cold chain requirements and the potential for self-administration can dramatically improve access to saving vaccines and therapeutics[78].

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HOW TO CITE: Darshil Ingale*, Achal Jane, Microneedle Technology: A Revolutionary Platform in Transdermal Drug Delivery System, Int. J. Sci. R. Tech., 2026, 3 (4), 354-363. https://doi.org/10.5281/zenodo.19543352