International Journal of Web of Multidisciplinary Studies
(Peer-Reviewed, Open Access, Fully Refereed International Journal)
website: *http://ijwos.com*
Vol.02 No.12.
OPEN ACCESS
E-ISSN : 3049-2424
DOI: https://doi.org/10.71366/ijwos

Microneedle-Based Drug Delivery Systems: Advances, Challenges, And Future Prospects

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Article Info

Article History:

Published:25 Dec 2025

Publication Issue:
Volume 2, Issue 12
December-2025

Page Number:
549-565

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Abstract:

Microneedle-based drug delivery systems (MNDDS) represent one of the most innovative developments in transdermal therapeutics. Their ability to painlessly penetrate the stratum corneum and deliver or extract biomolecules has opened new possibilities in vaccination, chronic disease management, long-acting therapeutics, and wearable diagnostic platforms. Recent progress in materials science—including biodegradable polymers, hydrogels, smart composites, and stimuli-responsive systems—has significantly improved mechanical strength, drug-loading capacity, biocompatibility, and patient compliance. Parallel advances in fabrication technologies such as 3D printing, two-photon polymerization, micromolding, and micro-milling have enabled scalable, customizable, and highly precise microneedle manufacturing. Beyond drug delivery, MNDDS have evolved into multifunctional systems capable of interstitial fluid sampling, real-time biosensing, closed-loop therapeutic feedback, and integration with Internet-of-Medical-Things (IoMT) platforms. These capabilities highlight their growing potential in personalized medicine and point-of-care healthcare.

This review provides a comprehensive evaluation of microneedle principles, classifications, materials, fabrication strategies, biomedical applications, safety considerations, and translational limitations. It also discusses regulatory challenges, cost-effectiveness, industrial commercialization pathways, and future opportunities, emphasizing the technological innovations needed for widespread clinical adoption of microneedle-based platforms.

Keywords: Dissolving microneedles; Microneedles; Personalized medicine; Smart microneedles; Transdermal drug delivery; Vaccine delivery

1. Introduction

The skin is a strong biological barrier that restricts the passive permeation of most therapeutic molecules [1]. Although oral and injectable delivery routes are widely used, they present several limitations, such as degradation of sensitive biological molecules, first-pass metabolism, the need for trained personnel, and poor patient compliance [2]. Transdermal delivery systems (TDS) offer important advantages; however, they are limited to small, lipophilic drugs due to low permeability through the skin [3]. Microneedles (MNs), first conceptualized decades ago and practically developed in the late 1990s, have emerged as an effective solution [4]. Microneedles ranging from 50 to 1000 μm

in height penetrate the stratum corneum while avoiding deeper tissues, resulting in nearly painless, bloodless, and self-administrable drug delivery [5].

The global market for microneedle patches is projected to exceed USD 8–10 billion by 2032, driven by increasing demand for minimally invasive systems, vaccination programs, and point-of-care diagnostics [6].

2. Microneedles: Principles, Types, and Working Mechanism

2.1 Fundamental Principles

Microneedles (MNs) work by bypassing the stratum corneum, the main barrier to transdermal drug transport [7]. Despite their small size (usually 50–900 μm), MNs are designed to be long enough to reach the viable epidermis yet short enough to avoid nociceptors and blood vessels in the dermis, ensuring minimally invasive and nearly painless drug delivery [8].

1.Mechanics of Skin Penetration

Effective microneedle insertion relies on several biomechanical factors, including needle tip sharpness, density, insertion velocity, and material stiffness. Optimizing these parameters prevents bending, buckling, or fracture during application and ensures consistent penetration depth [9].

2.Drug Transport Dynamics

Once microneedles create micro-channels in the skin, drug transport can occur through several mechanisms:

Passive diffusion of small or hydrophilic molecules.

Polymer dissolution kinetics, which are especially important for dissolving MNs.

Convective flow in hollow MN systems, where infusion is pressure-driven.

Swelling-induced release in hydrogel-forming MNs [10].

3.Drug Stability:

Solid, coated, and dissolving MNs can encapsulate and protect sensitive therapeutics such as peptides, proteins, and nucleic acids within polymer matrices, improving drug stability, reducing degradation, and sometimes eliminating the need for cold-chain storage [11].

4.Skin Recovery:

The micro-channels created by MN insertion typically self-seal within 1–72 hours, depending on microneedle type, skin hydration, and formulation. This quick healing reduces infection risk and prevents long-term skin damage [12].

2.2 Types of Microneedles

1. Solid Microneedles

Solid microneedles are mainly used for skin pretreatment in the “poke-and-patch” method. They are usually made from metals, silicon, or ceramics and provide high mechanical strength, durability, and easy manufacturing, although they need a separate drug application step. Modern solid MNs are made using stamped metal arrays or laser-milled polymer platforms with high reproducibility [13].

2. Coated Microneedles

Coated MNs deliver drugs applied as a thin layer on the microneedle surface. They are suitable for vaccines and potent biologics due to low dose requirements. However, drug-loading capacity is limited and coating uniformity can be challenging. Drug release occurs rapidly within seconds to minutes after insertion [14].

3.Dissolving Microneedles

Fabricated Dissolving MNs are made from biocompatible and biodegradable polymers such as PVA, HA, CMC, PVP, PLGA, and sugars. After insertion, they dissolve in the skin and release the encapsulated drug, eliminating sharp waste and improving patient safety [15].

4.Hollow Microneedles

Hollow MNs contain micro-scale bores that enable infusion of liquid formulations. They allow precise control of dosing and are commonly used for biologics, continuous infusion therapies, and wearable systems for chronic diseases [16].

5.Hydrogel-Forming Microneedles

Hydrogel-forming MNs consist of crosslinked polymers such as PEG and PHEMA that swell upon insertion to form a porous matrix, enabling sustained drug diffusion and interstitial fluid sampling without leaving residues in the skin [17].

6.Smart / Stimuli-Responsive Microneedles

Smart or stimuli-responsive MNs respond to triggers including pH, temperature, glucose, light, or magnetic fields. They enable intelligent and personalized therapy, particularly for cancer, diabetes, and chronic diseases [18].

2.3 WORKING MECHANISM

Microneedle systems operate through sequential stages that enable efficient and minimally invasive transdermal drug delivery [19].

Working Mechanism Across Microneedle Types

1.Insertion Stage:

MNs penetrate the stratum corneum and create micro-channels [20].

2.Activation Stage:

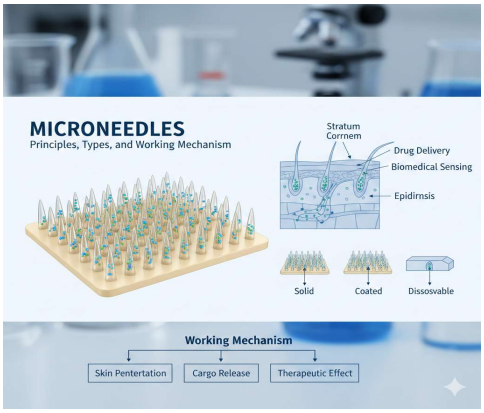
The mechanism of drug release depends on MN type, such as channel formation (solid), rapid coating dissolution (coated), polymer degradation (dissolving), pressure-driven infusion (hollow), swelling and diffusion (hydrogel), or triggered release (smart) [21].

3.Delivery Stage:

Drug molecules are transported into the viable epidermis or dermis through diffusion, polymer erosion, or active pumping [22].

4.Recovery Stage:

Micro-channels close naturally, restoring barrier function with minimal irritation or bleeding [23].



Fig(1) Microneedles: Principles, Types,Working Mechanism

3. Materials Used for Microneedle Fabrication

3.1 METALLIC MICRONEEDLES

Original intent kept — rewritten academically Metallic microneedles are commonly fabricated using laser cutting, electroplating, and micromachining techniques, which allow precise control of tip sharpness and structural uniformity. Stainless steel and titanium are widely used due to their corrosion resistance, mechanical robustness, and proven biocompatibility in medical implants. Nickel–iron alloys such as Invar may offer additional hardness but raise concerns regarding nickel sensitivity in certain patients. Metallic MNs are frequently used in preclinical studies requiring repeated skin insertion, including vaccine research. Their primary limitations include lack of biodegradability and challenges associated with sharp waste disposal [24].

3.2 SILICON MICRONEEDLES

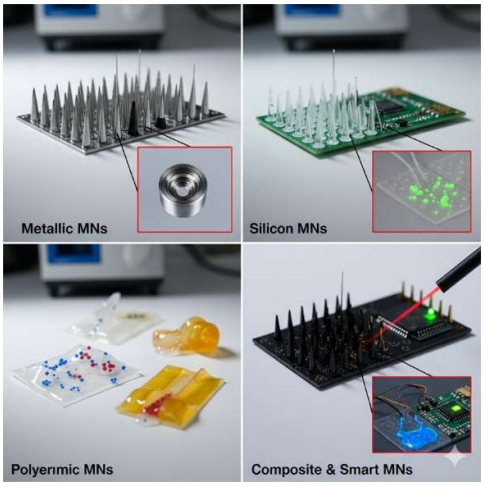
Silicon microneedles fabricated through deep reactive-ion etching (DRIE) achieve high aspect ratios and extremely sharp tips (<10 μm), improving insertion efficiency and reducing failure force. Due to their rigidity and ability to integrate microelectronics or sensors, they are suitable for real-time biomarker monitoring, such as glucose, lactate, and electrolytes. However, silicon is brittle and may fracture under axial stress, posing safety concerns if fragments remain in the skin. In addition, fabrication requires semiconductor-grade processes, increasing production cost and limiting commercialization [25].

3.3 POLYMERIC MICRONEEDLES

Polymers enable fabrication of solid, coated, dissolving, and hydrogel-forming microneedles, making them highly versatile for drug delivery applications. Dissolving MNs composed of polymers such as PVA, PVP, CMC, HA, and sugars encapsulate drug molecules within the needle matrix, eliminating sharp waste and enhancing safety. PLA and PLGA allow sustained or controlled release and are widely explored for vaccines and cancer therapy. Hydrophilic polymers such as HA provide rapid dissolution, making them suitable for dermatological and cosmetic applications. Mechanical properties vary significantly depending on polymer composition and thus require optimization through crosslinking, blending, or composites [26].

3.4 COMPOSITE AND SMART MATERIALS

Composite and smart microneedles incorporate functional additives such as nanoparticles or conductive elements to enhance strength and enable specialized functions. Polymer–nanoparticle composites improve mechanical performance while supporting features such as sustained release, antimicrobial activity, and imaging enhancement. Incorporation of gold nanorods, carbon nanotubes, or graphene facilitates light-responsive or electrically triggered drug release. Conductive hydrogels integrate ionic or electronic pathways, enabling real-time biosensing of analytes including glucose, lactate, inflammatory markers, and hormones. Smart microneedles can simultaneously integrate sensing, controlled release, and actuation, enabling closed-loop therapeutic platforms [27].



Fig(2)Materials Used for Microneedle Fabrication

4. Fabrication Techniques

4.1 MICRO-MOLDING

Micromolding is one of the most common fabrication techniques due to its simplicity, scalability, and low production cost. In this process, pre-formed molds—typically made from polydimethylsiloxane (PDMS) or other elastomeric materials—are filled with polymer solutions or melts, such as polyvinylpyrrolidone (PVP), polyvinyl alcohol (PVA), carboxymethyl cellulose (CMC), or biodegradable polymers including PLGA. Vacuum or centrifugation is often used to ensure complete filling of mold cavities and the removal of air bubbles.

A major advantage of micromolding is its ability to incorporate drugs directly into the microneedle matrix, allowing dissolving or hydrogel-forming microneedles to be produced in a single step. The process also supports multilayer fabrication for controlled drug release. However, fabrication quality heavily depends on mold precision, and mechanical properties may vary based on polymer formulation and curing conditions [28].

4.2 PHOTOLITHOGRAPHY

Photolithography offers highly precise control over microstructures, making it suitable for fabricating silicon, SU-8 photoresist, and metallic microneedles. The process involves coating a substrate with photoresist, exposing it to ultraviolet (UV) light through a patterned mask, and developing the structure to form microneedle templates. Silicon microneedles fabricated via deep reactive-ion etching (DRIE) exhibit excellent mechanical strength and can penetrate thicker skin regions.

The main limitations of photolithography include high production costs, dependence on cleanroom facilities, complex processing steps, and limited material compatibility. Despite these challenges, photolithography remains the gold standard when extremely sharp, uniform, high-aspect-ratio microneedles are needed, especially for transdermal biosensing and implantable diagnostic devices [29].

4.3 LASER CUTTING / MICROMACHINING

Laser micromachining uses high-energy laser pulses (such as femtosecond or CO_2 lasers) to ablate substrates like stainless steel, titanium, or polymer sheets. This method allows rapid prototyping and

is widely used during early device design and optimization. Femtosecond lasers produce minimal thermal damage and can create smooth, precise needle tips.

Laser-cut microneedles are typically made from planar sheets and shaped into 3D arrays through bending, welding, or assembly techniques. Although fast and versatile, challenges include difficulty achieving extremely fine geometries compared to lithographic methods and potential surface roughness that may need additional finishing [30].

4.4 3D PRINTING AND ADDITIVE MANUFACTURING

Additive manufacturing methods—such as stereolithography (SLA), digital light processing (DLP), fused deposition modeling (FDM), and especially two-photon polymerization (2PP)—allow the creation of complex microneedle architectures not possible with traditional techniques.

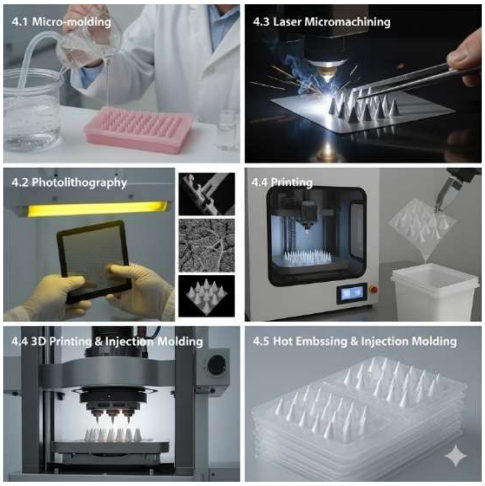
Two-photon polymerization provides sub-micrometer resolution, enabling the fabrication of ultra-sharp tips, curved geometries, and multi-compartment microneedles for smart drug delivery systems. These technologies support rapid prototyping and customization tailored to individual patients, making them ideal for personalized medicine.

Current barriers include slow printing speeds, limited availability of biocompatible resins, and high equipment costs; however, ongoing technological advances are helping to overcome these limitations [31].

4.5 HOT EMBOSSING AND INJECTION MOLDING

Hot embossing and injection molding are high-throughput manufacturing methods suitable for large-scale production. In hot embossing, thermoplastic polymer sheets are heated above their glass transition temperature and pressed against a mold to replicate microneedle structures. Injection molding involves injecting molten polymer into a precise mold under high pressure, resulting in robust microneedles with excellent uniformity and reproducibility.

These techniques provide strong mechanical properties and consistent quality. However, incorporating drugs during fabrication is challenging due to high temperatures, making these methods more appropriate for solid, coated, or hollow microneedles, rather than dissolving drug-loaded systems [32].



Fig(3)Fabrication Techniques

5. Applications of Microneedle Systems

5.1 DRUG DELIVERY APPLICATIONS

5.1.1 Vaccine Delivery

Microneedle-based vaccination has shown significant promise due to the immunological benefits of skin-targeted delivery. The skin contains high densities of antigen-presenting cells, including Langerhans cells and dermal dendritic cells, resulting in stronger immune responses compared to intramuscular injection.

Many microneedle patches enable dry-coated vaccine formulations that remain stable at room temperature for extended periods, reducing dependence on cold-chain logistics in remote or resource-limited settings. Dissolving microneedles also eliminate biohazardous sharps waste and enhance safety.

Their ease of application supports mass immunization campaigns without the need for trained professionals or sterile injection environments. Furthermore, some microneedle vaccine systems have demonstrated improved mucosal immunity, boosting IgA responses critical for respiratory and mucosal diseases [33].

5.1.2 Insulin and Diabetes Management

Microneedle systems offer a minimally invasive alternative to traditional insulin injections, greatly improving comfort and compliance among pediatric patients and individuals with needle phobia.

Smart glucose-responsive microneedles release insulin only when local glucose levels are high, helping prevent hypoglycemia. In closed-loop systems, microneedles incorporate glucose sensors that enable real-time automated insulin release based on continuous monitoring data.

Hollow microneedles with miniaturized reservoirs can provide controlled basal or bolus insulin delivery similar to infusion pumps. Hypoxia-sensitive vesicle systems further support physiological regulation by releasing insulin in response to tissue oxygen reduction associated with hyperglycemia [34].

5.1.3 Cancer Therapy

Microneedle-mediated drug delivery allows localized chemotherapy, increasing drug concentration at tumor sites (such as melanoma) while minimizing systemic toxicity.

Microneedles enhance immunotherapy through local delivery of immune checkpoint inhibitors (e.g., PD-1/PD-L1 antibodies), which boosts tumor-specific immune activation.

Synergistic treatment approaches combining microneedles with photothermal, photodynamic, or nanoparticle-based delivery systems are increasingly popular for precision oncology. Gold nanorods, carbon nanotubes, and quantum dots embedded in microneedles enable controlled activation through external stimuli like light or heat.

This targeted delivery greatly reduces off-target exposure and adverse effects compared with systemic chemotherapy [35].

5.2 DIAGNOSTIC AND BIOSENSING APPLICATIONS

5.2.1 INTERSTITIAL FLUID (ISF) SAMPLING

Microneedles facilitate minimally invasive extraction of interstitial fluid, reducing reliance on venipuncture or finger-prick sampling. ISF closely correlates with blood biomarkers, offering a reliable matrix for glucose, electrolytes, lactate, and therapeutic drug monitoring.

Microneedle sampling devices allow continuous or repeated monitoring without significant tissue damage or discomfort. Their ability to avoid blood contamination improves accuracy and reduces infection risk. These advantages make microneedles valuable for point-of-care diagnostics in critical care and sports medicine [36].

5.2.2 Wearable Integrated Sensors

Smart wearable microneedle platforms combine sensing components with microfluidic or electronic modules for real-time biomarker monitoring, such as glucose, lactate, or cortisol.

Patch-based systems connected to smartphones or cloud platforms via Bluetooth or NFC enable continuous tracking and personalized health management.

Microneedle systems are also being explored for non-invasive blood pressure monitoring through chemical or biomechanical indicators and for functional applications in fitness and sports performance analytics, like lactate-based fatigue monitoring [38].

Fig(4)Applications of Microneedle Systems

6. Safety, Toxicity, and Regulatory Considerations

6.1 SAFETY PROFILE

Microneedle systems are widely recognized for their favorable safety features compared to conventional hypodermic injections. Due to their shallow penetration, microneedles avoid activating deep dermal nociceptors, leading to significantly less pain and discomfort. Clinical studies repeatedly show much lower pain scores for microneedles than for traditional needles.

Similarly, because microneedles usually penetrate only the stratum corneum and upper dermis, bleeding is minimal or absent, and the risk of vascular injury is greatly diminished.

The microchannels created after insertion close quickly—typically within several hours—greatly reducing the chances of infection or prolonged irritation. Biocompatible materials such as medical-grade polymers, stainless steel, silicon, and biodegradable composites help minimize the risk of inflammatory or immune reactions.

Repeated use of microneedles has demonstrated minimal erythema or edema in clinical trials, supporting their safety for both short-term and long-term therapeutic or monitoring purposes [39].

6.2 TOXICOLOGICAL CONCERNS

Despite their benefits, several safety issues must be considered during design and clinical translation:

Polymer residue retention: Dissolving or hydrogel-forming microneedles may leave small amounts of polymer within the skin, possibly causing local irritation or inflammation.

Incomplete microneedle dissolution: brittle or insufficiently soluble formulations can leave fragments embedded in tissue, posing safety risks similar to those of implantable materials.

Needle breakage risk: Solid microneedles, especially those made from ceramics or silicon, may fracture under applied force, raising the potential for fragment retention.

Allergic or immunogenic reactions: Repeated exposure to polymers, stabilizers, or biologics might trigger hypersensitivity or immune responses.
Local cytotoxicity: High concentrations of potent drugs—such as chemotherapeutic agents—may lead to localized tissue necrosis.
Limited long-term data: There is still a lack of sufficient evidence regarding repeated use in vulnerable groups such as pediatric, geriatric, or immunocompromised patients [40].

6.3 REGULATORY CONSIDERATIONS

1. MICRONEEDLE PRODUCT CLASSIFICATION

Regulatory agencies, including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), classify microneedle systems as medical devices, drug–device combination products, or biologics, depending on their structure and intended use.
Dissolving or coated microneedles containing active drugs are typically regulated as combination products, whereas solid or hollow microneedles without drugs are regulated as medical devices [41].

2. Quality and Manufacturing Standards

Microneedle products must comply with Good Manufacturing Practices (GMP), including requirements for sterility, mechanical consistency, structural integrity, and batch-to-batch reproducibility. Mechanical strength testing is essential to ensure safe insertion without tip fracture. Stability evaluations must assess degradation profiles and performance uniformity [42].

3. Clinical Evaluation Requirements

For products delivering vaccines, insulin, peptides, or other biologics, regulatory approval usually requires early-phase clinical studies evaluating:
Safety and tolerability
Accurate and reproducible dosage delivery
Skin healing processes
Pharmacokinetics or pharmacodynamic effects
Immunogenicity outcomes (for vaccines) [43].

4. Sterility and Packaging

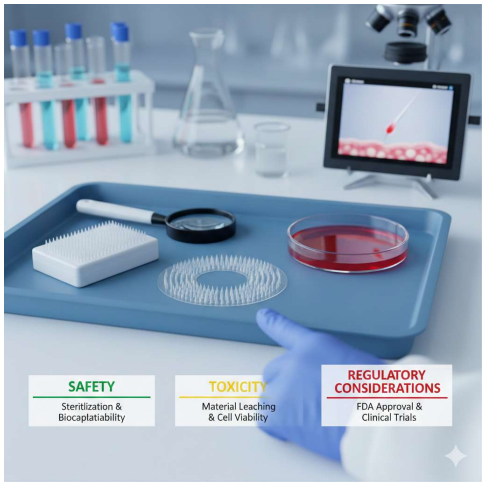
Since microneedles interact with the skin barrier, validated sterilization methods such as gamma irradiation or ethylene oxide are required, along with packaging designed to maintain sterility and mechanical strength during transport and storage [44].

5. Labeling and User Instructions

Regulators require clear labeling for self-administration, including guidance on application pressure, patch duration, storage conditions, and disposal procedures, especially for at-home use by pediatric or elderly patients [45].

6. Evolving Regulatory Frameworks

Given the rapid growth of microneedle technologies, regulatory bodies continue to develop new guidelines addressing dissolution behavior, insertion reliability, long-term use, and complexities related to combination biologic-device systems [46].



Fig(5) Safety, Toxicity, and Regulatory Considerations

7. Challenges and Limitation

7.1Mechanical Strength Issues

Microneedle arrays must have sufficient mechanical strength to penetrate the stratum corneum without bending, buckling, or breaking. Challenges include: insufficient penetration force—some polymeric microneedles, especially those made from soft biodegradable materials, may struggle to reliably breach the skin barrier, particularly in areas with thicker or drier skin, which reduces drug delivery efficiency. Material fatigue—repeated stress during packaging, storage, or transport can weaken tip sharpness or cause micro-cracks, especially in brittle materials like ceramic or silicon. Strength versus biodegradability trade-off—increased biodegradability often leads to lower mechanical strength, requiring careful optimization through crosslinking or composite reinforcement strategies. Insertion variability—manual application can result in inconsistent penetration depths, decreasing dose reproducibility and treatment reliability unless assisted applicators are used [47].

7.2 LIMITED DRUG DOSE CAPACITY

Microneedles naturally have limited internal volume, restricting the amount of drug that can be loaded, especially in dissolving or coated designs. Key challenges include: small loading volume—dissolving and coated microneedles typically hold only 1–2 mg of drug, making them unsuitable for high-dose systemic therapies. Inefficient coating methods—processes such as dip-coating may cause uneven distribution, crystallization, or wastage of drug material. Patch size limitations—increasing microneedle density to boost dose capacity risks greater skin irritation and compromised structural integrity. Hydrophobic drug challenges—hydrophilic polymer matrices poorly encapsulate water-insoluble molecules, requiring complex formulation strategies like nanoparticles or emulsions [48].

7.3 STABILITY DURING FABRICATION

Maintaining drug stability during production and storage remains a significant challenge: temperature and humidity sensitivity—biologic molecules such as peptides, proteins, and vaccines may degrade during thermal processing or drying. Chemical incompatibility—interactions between drug compounds and polymers (e.g., PVA, PVP, sugars) can cause aggregation or loss of function. Residual solvent concerns—solvent-based manufacturing may leave residual chemicals that impact safety or stability. Shear-related degradation—mechanical mixing or ultraviolet exposure during fabrication can

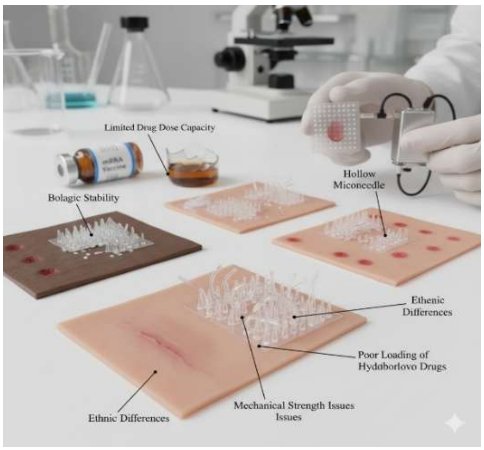
denature sensitive biologics like mRNA or DNA. Long-term storage limitations—achieving a stable shelf life at room temperature is difficult for certain formulations [49].

7.4 SKIN VARIABILITY

The performance of microneedles can vary significantly among individuals due to differences in skin properties: anatomical differences—skin thickness, hydration, and elasticity vary by body site, affecting penetration and dissolution rates. Ethnic variations—melanin content and stratum corneum density may influence microneedle insertion and drug permeation. Age impacts—geriatric skin is thinner but less elastic, while infant skin is more permeable, affecting dosing accuracy. Disease-related changes—conditions such as hyperkeratosis, eczema, diabetic skin stiffening, or scarring can impede insertion reliability. Hydration variability—dry skin increases resistance, while excessive moisture alters dissolution kinetics [50].

7.5 USER TRAINING AND PERCEPTION

Human factors may influence performance and acceptance: incorrect application technique—inadequate pressure or improper angle can cause incomplete insertion and under-dosing. User unfamiliarity—a lack of awareness and limited training can hinder acceptance and proper use. Needle-related phobia—despite minimal pain, visual resemblance to needles may cause hesitation among needle-sensitive individuals. Special population considerations—pediatric and geriatric users may need caregiver assistance or automated applicators. Disposal concerns—even dissolving microneedles raise questions about environmentally safe waste management [51].



Fig(6)Challenges and Limitation

8.Opportunities & Future Directions

8.1 SMART MICRONEEDLES & DIGITAL HEALTH INTEGRATION

- SMART MICRONEEDLE SYSTEM

↓ INTEGRATION OF SENSORS + MICRONEEDLES

↓ REAL-TIME PHYSIOLOGICAL SIGNAL DETECTION

- GLUCOSE CONCENTRATION
- PH LEVELS

- TEMPERATURE VARIATIONS

↓ STIMULI-RESPONSIVE FEEDBACK MECHANISM

- ENZYME-BASED TRIGGERS (E.G., GLUCOSE OXIDASE)
- TEMPERATURE-SENSITIVE POLYMERS
- PH-RESPONSIVE MATERIALS

↓

- AUTOMATED / ON-DEMAND DRUG RELEASE
- INSULIN RELEASED ONLY DURING HYPERGLYCEMIA
- REDUCED HYPOGLYCEMIA RISK
- AVOIDS FREQUENT PAINFUL INJECTIONS

↓ CLOSED-LOOP CONTROLLED THERAPY SYSTEM

- CONTINUOUS SENSING
- AUTOMATIC ADJUSTMENT OF DOSE
- BLUETOOTH / IOT-ENABLED DATA TRANSMISSION

↓ CLINICAL OUTCOMES

- HALER SAFER AND PRECISE TREATMENT
- BETTER DISEASE MONITORING
- IMPROVED ADHERENCE & QUALITY OF LIFE

↓ APPLICATIONS

- DIABETES MANAGEMENT
- CARDIOVASCULAR MONITORING
- CONTINUOUS MONITORING IN CRITICAL CARE [52].

8.2 PERSONALIZED MEDICINE

- Patient Evaluation & Requirements
- Skin thickness & hydration
- Age & disease condition
- Dosage requirements
- Physiological variability

↓ 3D Printing & Additive Manufacturing

- Customized height & geometry
- Personalized drug loading
- Patient-specific polymer or composite materials
- Rapid prototype development

↓ INDIVIDUALIZED MICRONEEDLE PATCH DEVELOPMENT

- Shape optimization
- Controlled release profiles
- Improved tissue compatibility

↓

- Precise & Tailored Drug Delivery
- Increased therapeutic efficacy
- Reduced systemic side effects
- Enhanced safety and patient satisfaction

↓

- Future Impact on Healthcare
- Fully customized MN-based therapies
- Personalized vaccine and cancer treatment
- Patient-specific minimally invasive devices
- Digital-health connected therapies [53].

Fig(7)Opportunities & Future Directions

9. Conclusion

Microneedle-based drug delivery systems are a significant advancement in transdermal therapeutics, providing painless, safe, and efficient delivery of vaccines, biologics, peptides, hormones, and small molecules. Their capability to address the limitations of traditional oral and injectable routes—along with strong patient acceptance—positions them as a transformative technology in contemporary healthcare. Innovative developments such as smart microneedles, biosensing platforms, and 3D-printed personalized systems continue to broaden their clinical potential. Despite current challenges related to drug-loading capacity, mechanical strength, large-scale manufacturing, and regulatory approval pathways, ongoing interdisciplinary research and industrial investments suggest a promising future. With continued progress, microneedle technologies are anticipated to achieve widespread clinical adoption and become central to next-generation personalized and connected healthcare systems.

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