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PAINLESS POKES: MICRONEEDLES FOR DRUG DELIVERY

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ABSTRACT

Microneedle (MN) technology represents a transformative approach in pharmaceutical science, offering a minimally invasive, pain-free method for transdermal drug delivery that bypasses the formidable *stratum corneum* barrier. This review provides a detailed overview of the various types of microneedles viz solid, coated, hollow, dissolving, and hydrogel-forming systems—and the diverse materials (polymers, silicon, metals) used in their construction. Key fabrication techniques, such as micromolding, laser ablation, and 3D printing, are discussed in the context of their impact on MN performance and scalability. Furthermore, the rigorous development and evaluation processes are highlighted, encompassing physical and mechanical characterization (e.g., morphology, insertion efficiency), *in vitro* and *ex vivo* permeation studies, and *in vivo* assessment of pharmacokinetics, safety, and efficacy. The article highlights expanding pharmaceutical applications of MNs, particularly in vaccination, diabetes management, oncology, and cosmetics, their potential to revolutionize patient care by improving therapeutic compliance and bioavailability. Despite ongoing challenges in standardization and clinical translation, continued advancements are poised to establish microneedles as a mainstream drug delivery platform.

Keywords: Microneedles; Transdermal Drug Delivery; Fabrication; Development; Evaluation; Polymers; Pharmaceutical Applications

1. INTRODUCTION TO MICRONEEDLE TECHNOLOGY IN PHARMACY

Microneedles (MNs) represent a sophisticated leap in pharmaceutical science, offering a minimally invasive, pain-free approach to drug delivery that bypasses the *stratum corneum*, the primary barrier of the skin. This detailed review delves into the fundamental aspects of MN technology, encompassing their fabrication, development, and rigorous evaluation processes, alongside diverse pharmaceutical applications.

The pursuit of effective drug delivery methods has long been a central challenge in pharmacy. Traditional methods often face

limitations like oral administration poor bioavailability and first-pass metabolism, while conventional injections induce pain, fear, and generate hazardous waste [1].

Microneedles (MNs) resolve this dilemma. They are micron-scale devices, typically ranging from 25 μm to 2000 μm in height, designed to penetrate the *stratum corneum* and reach the underlying viable epidermis and dermis without stimulating nerve endings or puncturing blood vessels (Figure 1 & 2). This creates temporary microchannels for drug passage, enhancing local and systemic delivery of a wide range of therapeutic agents, including macromolecules, vaccines, and small molecules [2].

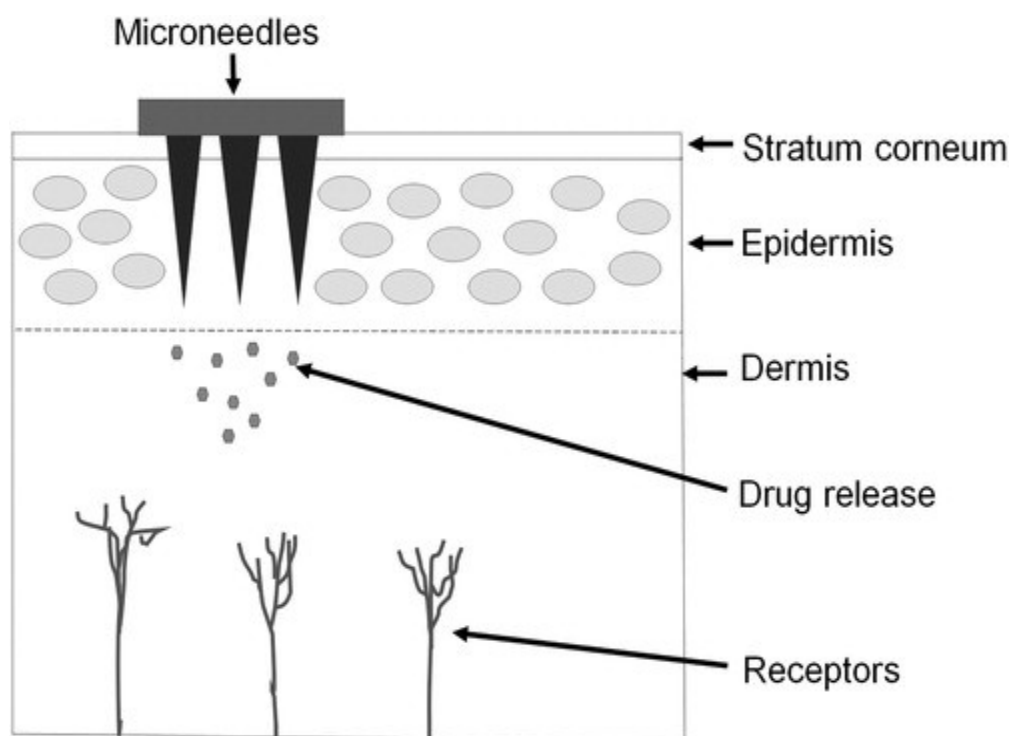


Figure 1: Drug Delivery by using Microneedles

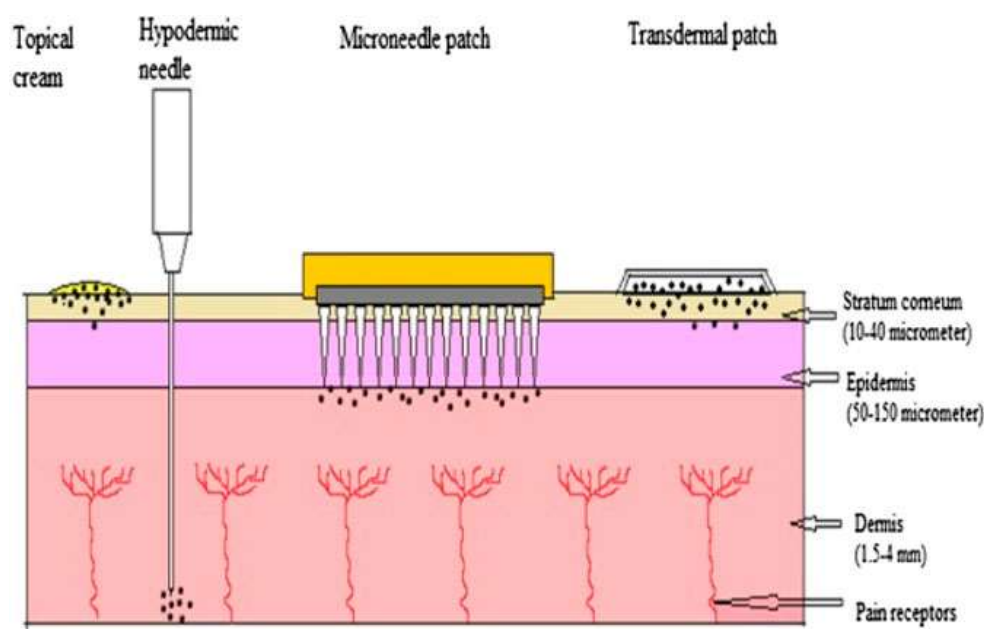


Figure 2: Conventional Injection vs Transdermal delivery

2. TYPES OF MICRONEEDLES

MNs are classified based on their material and drug delivery mechanism (Table 1, Fig. 3& 4.), each type tailored for specific pharmaceutical needs as follows [3].

A) Solid Microneedles (SMNs): Used primarily for skin pre-treatment. They create microchannels, followed by application of a drug-loaded patch or formulation (the "poke-and-patch" approach). They are typically made from silicon, metal, or durable polymers [4].

B) Coated Microneedles (CMNs): SMNs coated with a drug formulation. Upon insertion, the coating rapidly dissolves in the interstitial fluid, releasing the drug ("coat-and-poke"). The amount of

drug is limited by the surface area of the needles [5].

C) Dissolving Microneedles (DMNs): Fabricated entirely from water-soluble, biocompatible polymers (e.g., hyaluronic acid, polyvinyl alcohol, maltose) with the drug encapsulated within the matrix. They dissolve completely in the skin's interstitial fluid, leaving no sharp waste and providing a controlled release profile ("poke-and-release") [6]. This type is highly popular due to its safety and ease of use.

D) Hollow Microneedles (HMNs): Function as micro-syringes. They feature a central lumen allowing a drug solution to be pumped into the skin from an

external reservoir ("poke-and-flow"). They are ideal for larger drug volumes and real-time control over infusion rates [6].

E) Hydrogel-Forming Microneedles (HGFMNs): Made of cross-linked hydrophilic polymers. Once

inserted, they swell by absorbing interstitial fluid, creating a continuous aqueous channel between an on-top reservoir and the dermis for drug diffusion. They offer sustained, long-term delivery capabilities [7].

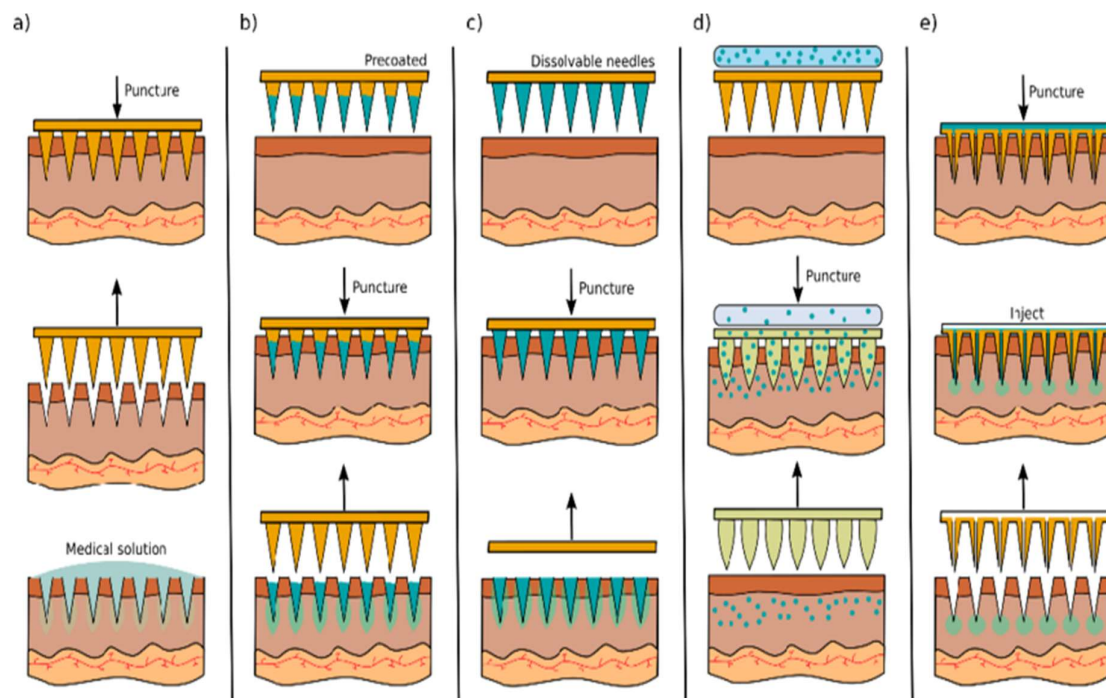


Figure 3: A schematic representation of the five different types of microneedles, (a) solid microneedles, (b) coated microneedles, (c) dissolvable microneedles, (d) hydrogel-forming microneedles, and (e) hollow microneedles

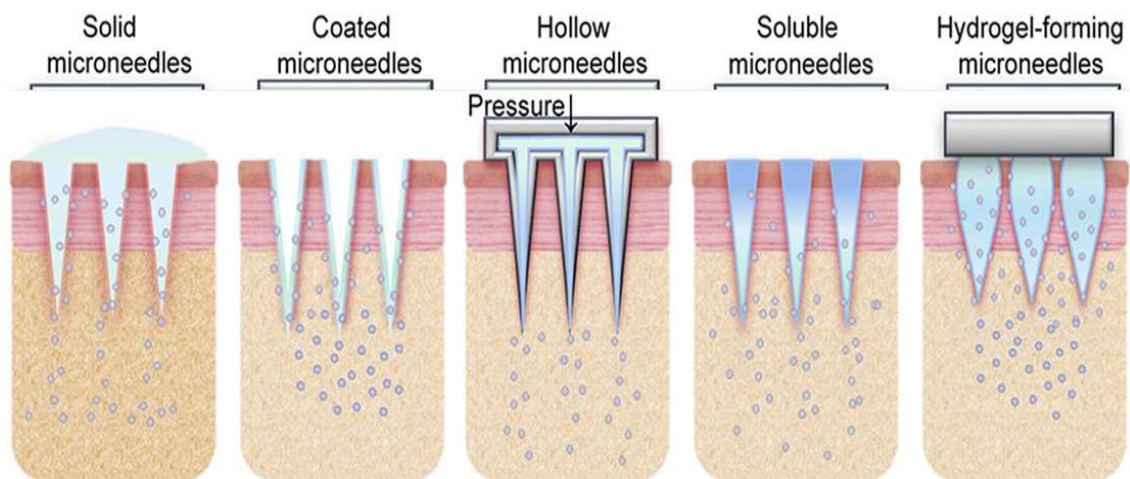


Figure 4: Different Delivery Mechanisms of various types of Microneedles

Table 1: Mechanism of Drug Delivery, Materials used for preparation, Advantages and Disadvantage of various types of Microneedles

Type of Microneedle	Mechanism	Materials	Advantages	Disadvantages
Solid Microneedles	Used in a two-step "poke-and-patch" method. The solid needles first puncture the skin to create temporary micro-channels. The microneedle array is removed, and a separate drug-loaded topical patch, gel, or cream is then applied to the microporated skin, allowing the drug to diffuse through the channels.	Typically made from robust, non-biodegradable materials such as metals (stainless steel, titanium, nickel) or silicon.	Possess high mechanical strength and sharpness for reliable skin penetration; easy to manufacture; can significantly enhance drug permeability.	Requires a two-step application process, which can be inconvenient; leaves sharp bio-hazardous waste; pores may close quickly, limiting the drug delivery window.
Coated Microneedles	Follows a "coat and poke" approach. Solid microneedles are pre-coated with a dry drug formulation, which rapidly dissolves upon insertion into the skin upon contact with interstitial fluid. The needles are then removed.	Uses solid backings (metal or silicon) coated with a drug layer often containing water-soluble excipients (e.g., sugars, polymers) for quick dissolution.	Offers a single-step application; provides rapid drug delivery; requires a lower drug dose compared to some other methods.	Drug loading capacity is limited by the surface area of the needles; potential for the drug coating to detach prematurely during insertion or for cross-infection if reused.
Dissolving Microneedles	Utilizes a "poke and release" method. The entire microneedle structure is made of water-soluble or biodegradable materials that encapsulate the drug. Upon insertion into the skin, the needles completely dissolve within the tissue, releasing the drug payload locally.	Fabricated from biocompatible and biodegradable polymers (e.g., polyvinyl alcohol (PVA), polyvinylpyrrolidone (PVP), hyaluronic acid) and/or sugars (e.g., trehalose, maltose).	Eliminates sharp bio-hazardous waste and needle-stick injuries; offers a simple, one-step, patient-friendly application; allows for precise dosing and high drug-loading capacity.	May have inferior mechanical strength, leading to potential breakage or incomplete insertion; dissolution rate can vary.
Hollow Microneedles	Employs a "poke and flow" method, similar to a traditional hypodermic injection but on a micro-scale. These needles have a hollow bore or lumen through which a liquid drug solution is infused into the skin from an external reservoir or pump after the needles are inserted.	Typically made from metal, silicon, or polymers.	Enables precise control over the drug dose and flow rate; suitable for delivering large-molecule drugs and higher doses; can also be used for extracting interstitial fluid for diagnostics.	Complex fabrication process; potential for needle clogging or leakage; generally less mechanically robust than solid microneedles
Hydrogel-Forming Microneedles (Swellable)	These microneedles are made of a hydrophilic, cross-linked polymer matrix. After insertion, they absorb interstitial fluid from the skin and swell to form a continuous hydrogel conduit connecting a drug reservoir (e.g., a patch on the back) to the dermal microcirculation, allowing the drug to diffuse.	Made from hydrocolloid polymers such as cellulosic derivatives.	Can accommodate a reasonable drug loading; allows for controlled, sustained drug release; the empty needles can be removed without leaving residue.	May exhibit poor mechanical strength and physical stability; drug delivery depends on the rate of fluid absorption and swelling.

3. MATERIALS SELECTION FOR FABRICATION OF MICRONEEDLES

Microneedles are made from a variety of materials, broadly categorized into non-degradable and biodegradable [4]. [Table 2].

a) Silicon: One of the earliest and most common materials due to the adaptability of microelectronics fabrication tools. Silicon MNs are strong and sharp but can be brittle and pose a risk of breaking off in the skin, which is a safety concern as bulk silicon is not biodegradable.

b) Metals: Stainless steel, titanium, nickel, and gold are used for their high mechanical strength and electrical conductivity (for biosensing applications). They are typically non-degradable and primarily used for solid or hollow MNs.

c) Polymers: Polymers are highly versatile and are the basis for most

modern, patient-friendly microneedles. They can be non-degradable

(e.g., polycarbonate, PMMA) or biodegradable/water-soluble

(e.g., polyvinyl alcohol (PVA), polyvinylpyrrolidone

(PVP), hyaluronic acid, poly-lactic-co-glycolic acid (PLGA)).

d) Ceramics and Glass: These materials offer excellent mechanical properties but are brittle and have limited use beyond experimental stages due to complex manufacturing.

Materials must be biocompatible, mechanically robust enough to penetrate the *stratum corneum*, and, for some types, biodegradable or safe for disposal. Common materials include: Silicon and Metals: Offer high mechanical strength but can be brittle (silicon) or pose allergy risks (metals). Polymers and Carbohydrates: Preferred for DMNs and HGFMNs due to their tuneable degradation rates, biocompatibility, and low cost [7].

Table 2: Materials, Advantages, Disadvantages, and Applications of Microneedles

Materials	Advantages	Disadvantages	Application
Silicon	Biocompatible, hard, mature fabrication techniques	Sharp waste, brittle	Solid, Coated, Hollow Microneedles
Glass	Chemically inert, transparent and cheap	Cumbersome fabrication, brittle	Hollow Microneedles
Ceramic materials	Naturally porous	Long fabrication time, significantly brittle	Hollow, Dissolving Microneedles
Metals	Biocompatibility, high conductivity, catalytic activity for some nanometals	High cost for noble metals, allergic risk	Solid, Coated, Hollow Microneedles
Polymers	Biodegradable (some) or swellable, easy fabrication	Low mechanical strength	Solid, Hollow, Coated, Dissolving, Swellable Microneedles
Carbohydrates	Biodegradable, biocompatible	High processing temperatures, low mechanical strength, hygroscopicity	Dissolving Microneedles

4. DEVELOPMENT CONSIDERATIONS FOR MICRONEEDLE PREPARATION

The development process involves careful consideration of several factors [Figure 5] viz. Mechanical Strength, Drug Stability, Drug Loading & Release, Drug Loading & Release and Scalability [8].

- a) **Mechanical Strength:** Microneedles must be strong enough to penetrate the stratum corneum without fracturing or bending. This is influenced by material choice (metals > silicon > polymers) and design (tip angle, aspect ratio).
- b) **Drug Stability:** Fabrication methods involving high heat (e.g., injection molding, some

sintering processes) can damage sensitive biological drugs like proteins or vaccines. Low-temperature methods like solvent casting are preferred for these applications.

- c) **Drug Loading & Release:** Dissolving and hydrogel MNs typically offer higher and more controllable drug loading and release kinetics compared to the limited surface area of coated MNs.
- d) **Scalability:** While MEMS offers high precision, molding and 3D printing techniques are more promising for cost-effective mass production and commercial translation.

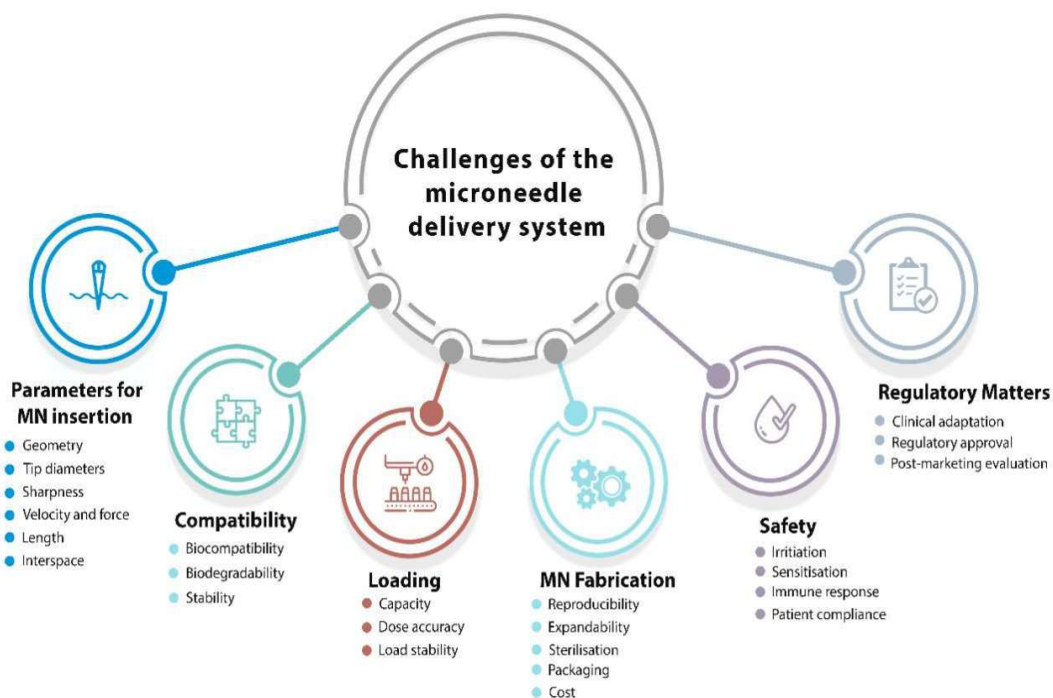


Figure 5: Development considerations for microneedle preparation

5. KEY FABRICATION METHODS USED FOR DEVELOPMENT OF MICRONEEDLES

Microneedle fabrication techniques can be broadly divided into Micro electro-mechanical Systems (MEMS) Technology, Micromolding (Replication) techniques, Laser-Based Methods and 3D printing methods [9] [Table 3]

I. Microelectromechanical Systems (MEMS) Technology

MEMS techniques, originating from the semiconductor industry, are widely used for silicon and metal MNs. They involve precise, multi-step processes in cleanroom facilities.

a) Photolithography: Photolithography is a core technique borrowed from the microelectronics industry, primarily used for fabricating silicon and polymer microneedles (MNs), including solid, hollow, and dissolving types. It involves using light to transfer a geometric pattern onto a photosensitive material (photoresist), followed by **processing** to create the final microstructure.

b) Etching: Etching is a critical subtractive manufacturing process in microfabrication for creating precisely shaped microneedles

(MNs), particularly those made from silicon, glass, and metals. This technique involves removing unwanted material from a substrate using chemical solutions (wet etching) or reactive plasma (dry etching), guided by a patterned mask (usually photoresist or a hard mask like silicon dioxide/nitride) [10].

II. Micromolding (Replication)

This is a predominant and cost-effective method for mass production of polymer, dissolving, and hydrogel MNs. In this Process a master mold (often made by MEMS or laser cutting) with positive needle structures is created. A negative mould (typically polydimethylsiloxane, or PDMS) is cast from the master. The final microneedle material (polymer solution, melt, or slurry) is filled into the negative mould cavities (often using vacuum or centrifugation to ensure complete filling), cured, and then demoulded.

a) Solvent Casting: The method relies on preparing a viscous solution or suspension of the desired polymer (and the drug) in a suitable solvent and then casting this mixture into a micro-mold. The solvent is subsequently removed through evaporation (at ambient or elevated temperature, or under

vacuum), leaving behind a solid microneedle structure with the drug entrapped within the polymer matrix.

b) Hot Embossing: In this method thermoplastic polymer film is placed on a micromachined mould (typically silicon or nickel) and heated to a temperature above its glass transition temperature, making it soft and pliable. A controlled pressure is then applied to push the polymer into the mould cavities. After a short hold time to ensure complete filling, the setup is cooled down, and the solidified microneedle array is peeled off the model

c) Injection Moulding In Injection moulding method Polymer pellets are melted in a heated barrel and then rapidly injected into a cold mold under high pressure. The polymer solidifies quickly upon contact with the cooler mold walls. The mold opens, and the finished microneedle array is ejected [11].

III. Laser-Based Methods

Laser technology provides a rapid prototyping and flexible alternative to traditional microfabrication which involves two methods as discussed below

a) Laser Cutting: Laser cutting and laser ablation are

versatile, high-precision methods primarily used for fabricating metal and polymer microneedles (MNs). This technique is particularly valuable for its direct, cleanroom-free manufacturing and ability to produce specific, highly customized geometries based on computer-aided design (CAD) software. The method involves using a focused, high-intensity laser beam (e.g., infrared, CO₂, UV excimer, or femtosecond laser) to either cut through a material sheet (laser cutting) or remove material layer by layer (laser ablation)

b) Laser Ablation/Engraving: Here the principle relies on the interaction between the laser beam and the material. When a pulsed laser beam is focused onto the substrate surface, the material absorbs the laser energy, heats up rapidly, and is removed through mechanisms like evaporation, sublimation, or plasma formation. By controlling parameters such as laser power, pulse width, scanning speed, and the number of repetitions, complex 3D microstructures can be engineered.

V. Additive Manufacturing (3D Printing)

Additive manufacturing (AM), popularly known as 3D printing, has emerged as a revolutionary and flexible method for fabricating microneedles (MNs). This technology builds 3D objects layer by layer from a computer-aided design (CAD) model, enabling the creation of complex,

customized, and intricate MN geometries that are challenging to produce with conventional methods like micromolding or etching. It may involve different techniques like stereolithography/ Digital Light Processing/ Two-Photon Polymerization/ Fused Deposition Modeling etc.

Table 3: Microneedles: material and fabrication methods

Type of MN's	Material Used for Fabrication	Fabrication Method Used
Solid	Silicon, Titanium, Stainless steel, Glass, Ceramics, Nickel-iron	Laser ablation, Laser cutting, Casting, Electroplating, Lithography, Wet and dry etching method, Metal injection molding, Micromolding, Two photon polymerization
Coated	Metal or silicon materials for solid base	Micromolding, Dip coating, Spray coating, Layer-by-layer manufacturing
Dissolving	Carbohydrates, PVA, PVP, PLA, PLGA, Sodium carboxymethyl cellulose	Mold based techniques, Drawing lithography, UV assisted fabrication, Heat, Droplet air blowing (DAB), Fused deposition modeling, Atomized spray process
Hollow	Silicon, Metal, Polymer, Ceramic, Glass	MEMS, Deep reactive ion etching, Photolithographic, Micromachining, Pipette technique, Deep X-ray lithography

EVALUATION AND CHARACTERIZATION OF MICRONEEDLES

Rigorous evaluation is essential to ensure the safety, efficacy, and quality of MN systems. Evaluation is typically conducted for physical parameters viz morphology and strength, *in vitro* (laboratory settings) and *in vivo* (animal models, and eventually humans) [12].

I. Physical Characterization

a) Morphology and

Dimensions: Scanning electron microscopy (SEM) is used to assess needle shape, length, width, and uniformity [11].

b) Mechanical Strength:

Crucial for ensuring MNs can withstand the

force required for skin insertion without breaking. This is measured using force testing equipment to determine fracture force and failure strain [13].

c) Insertion Studies:

In vitro studies using surrogate materials (e.g., Parafilm M, dermatomed human or animal skin) assess the insertion depth and efficiency. Staining techniques are often used to visualize the microchannels formed [14].

II. Pharmaceutical Evaluation

a) Drug Loading and Content

Uniformity: Analysing the amount of drug encapsulated or coated onto the MNs to ensure consistent dosing [11].

b) **Drug Release Kinetics:** *In vitro* diffusion studies using Franz diffusion cells mimic the skin environment to determine the rate and extent of drug release from the MN patch over time [12].

c) **Permeation Studies:** Measuring the amount of drug that permeates through excised skin (e.g., porcine ear skin, human skin) into a receptor chamber, quantifying the enhancement factor compared to passive diffusion [14].

III. In Vivo Evaluation

a) Pharmacokinetics (PK)

Studies: Animal models (rodents, pigs, non-human primates) are used to measure drug concentration in the bloodstream over time after MN application, determining bioavailability and PK parameters [15].

b) Pharmacodynamics (PD)

Studies: Assessing the therapeutic effect in relevant disease models (e.g., blood glucose reduction in diabetic models for insulin MNs) [16].

c) Safety and

Biocompatibility: Histological analysis of treated skin ensures minimal tissue damage, inflammation, or irritation. Studies

assess skin recovery time and local tolerance [15].

d) **Immunogenicity:** Particularly important for vaccine delivery, where the immune response elicited by MN delivery is compared to traditional routes [17].

7. APPLICATIONS IN PHARMACY

Applications of microneedles in pharmacy span a wide range of therapeutic and diagnostic areas, primarily utilizing their ability to bypass the skin's barrier minimally invasively [3].

I. Vaccine Delivery:

- **Painless Vaccination:** Enables painless administration of vaccines, potentially improving patient compliance, especially in children and individuals with needle phobia.
- **Enhanced Efficacy:** Delivering vaccines directly to immune-rich skin layers (epidermis/dermis) can significantly boost the immune response compared to traditional intramuscular injections, often requiring lower antigen doses.
- **Thermostability:** Dissolving microneedle patches can stabilize vaccines at room temperature, eliminating the need for a "cold chain" for storage and transport, which is crucial for global health initiatives [2].

II. Drug Delivery:

- **Transdermal Delivery of Large Molecules:** Facilitates the delivery of large therapeutic molecules (peptides, proteins, insulin) that cannot pass through the skin via conventional creams or patches.
- **Localized Therapy:** Allows for precise delivery of drugs directly to the site of action, which is beneficial for conditions like skin cancer, psoriasis, and localized pain management, minimizing systemic side effects.
- **Systemic Drug Delivery:** Used for the controlled release of drugs into the bloodstream for systemic effects, such as pain relief (e.g., fentanyl) or hormonal treatments.

III. Chronic Disease Management:

- **Diabetes:** Enabling painless and potentially closed-loop insulin delivery systems, where the microneedles could also monitor glucose levels ("sense and treat" systems).
- **Osteoporosis:** Delivery of drugs like parathyroid hormone fragments (PTH) for treatment.

IV. Diagnostics and Biosensing:

- **Interstitial Fluid (ISF) Extraction:** Hollow microneedles can painlessly extract ISF for biomarker detection (e.g., glucose,

lactate, alcohol, heavy metals), providing real-time health monitoring.

➤ Integrated

Biosensors: Microneedles can be integrated with biosensors to detect biological signals or drug levels in the skin directly.

V. Diagnostics and monitoring

- **Biomarker analysis:** microneedles can painlessly extract interstitial fluid (ISF) for the detection and monitoring of various biomarkers, including glucose, cholesterol, and inflammatory factors.
- **Point-of-Care (PoC) Testing:** When integrated with biosensors and microfluidic chips, microneedles enable real-time, bedside diagnosis and monitoring of diseases, potentially reducing costs and accelerating time to treatment.
- **Disease Diagnosis:** Used to detect specific biomarkers for conditions such as breast cancer (ErbB2) and cutaneous melanoma (tyrosinase) through electrical impedance measurements or biomarker extraction.

VI. Skin Rejuvenation and Anti-Aging:

Enhancing the absorption of active cosmetic ingredients (e.g., hyaluronic acid, vitamin C) for

anti-aging effects and skin rejuvenation.

- VII. **Cosmetic Applications:** Used in microneedling (collagen induction therapy) to enhance the delivery of active ingredients (e.g., hyaluronic acid, vitamins, growth factors) for anti-aging, scar reduction, and skin rejuvenation.
- VIII. **Gene Therapy:** Exploring the use of microneedles to deliver genetic material (e.g., DNA plasmids, siRNA) to skin cells for specific therapeutic effects.
- IX. **Wound Healing and Tissue Regeneration:** MN patches can accelerate wound healing, particularly in diabetic patients, by delivering regenerative molecules or providing a mechanical scaffold that promotes neurovascular regeneration and reduces inflammation.
- X. **Hair Loss Treatment:** Used to deliver agents like minoxidil or other therapeutic compounds to promote hair growth in patients with alopecia [18].

8. CONCLUSION AND FUTURE DIRECTIONS

Microneedle technology is transitioning from a niche research topic to a commercially viable drug delivery platform. The ability to painlessly deliver a wide array

of therapeutics, including complex biologics, positions MNs as a transformative force in modern pharmacy [15]. Continued advancements in fabrication techniques, particularly 3D printing and scalable micromolding, along with robust clinical data from ongoing trials, are expected to pave the way for widespread clinical adoption and revolutionizing patient care [18].

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