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Microneedles: A Revolutionizing Model of Drug Delivery System in Pharmaceutics with Minimal Invasion

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ABSTRACT

One of the most interesting pharmaceutical drug delivery systems with minimally invasive technique are Microneedles. In the recent years, many researchers have concluded that Microneedles can be a leading method in the future. As a drug delivery system, Microneedles can improve drug delivery by avoiding many barriers that were linked with the conventional system, these unique properties could make Microneedles widely used. The primary mechanism for improving drug delivery to the targeted site with minimal complications is by creating micro-sized pores in the skin layer. The growing interest of Microneedles in biomedical and pharmaceutical research is obtained by easy delivery of active ingredient with low invasive technique. Vaccines, peptides, and hormones are examples of molecules delivered by Microneedles. In this review, we will discuss Microneedles efficiency as drug delivery carriers, fabrication materials, and several related patents.
Keywords: Microneedles, Drug delivery systems, low-invasive, Skin permeability, Biomedical applications

1. INTRODUCTION

Oral drug delivery system has been widely used due to better patient compliance by easy administration [1]. From the limitations of oral route of administration is the inability of the drug to cross some barriers of our physiological system by which other drug delivery systems have been considered. For instance, the administration of the drug by outer skin through the external stratum corneum (SC) which is known as transdermal drug delivery system (TDDS) [2]. The SC is the outmost layer which is considered as the primary obstacle for topically administered formulations. This layer permits the cross of molecules that have specific properties such as, low molecular weight (<500 Da), low melting point, and lipophilic in nature. Hence, the interest in Microneedles (MNs) technology have been developed. MNs can reach the dermis layer easily with minimum patient discomfort [3]. The various advantages of MNs as a drug delivery system over conventional one, make it a recognized option.

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One of these advantages is the movement of drug molecules through skin barriers without causing pain or permanent tissue damage. The initial conception of this technology is attributed to Gerstel and Place in 1971.The use of MNs as a drug delivery carrier was in 1990s, it was used a puncturing tool before. Compared to conventional procedures, MNs offers a faster healing rate. Also, it can achieve better pharmacokinetic and pharmacodynamic response by avoiding the first- pass metabolism. A micron-sized channels are produced by MNs for the deliverance of active molecules. MNs can reach the dermis layer easily, their length is 100 µm, 50 to 300 µm wide at the base, and about 1–50 µm at the tip [4]. A wide variety of components were used to fabricate MNs, such as glass, metal, polymer, hydrogel, and silicone. DNA and protein targeted delivery via MNs need to be explored more [5]. Various drug delivery systems including MNs are shown in Figure 1.

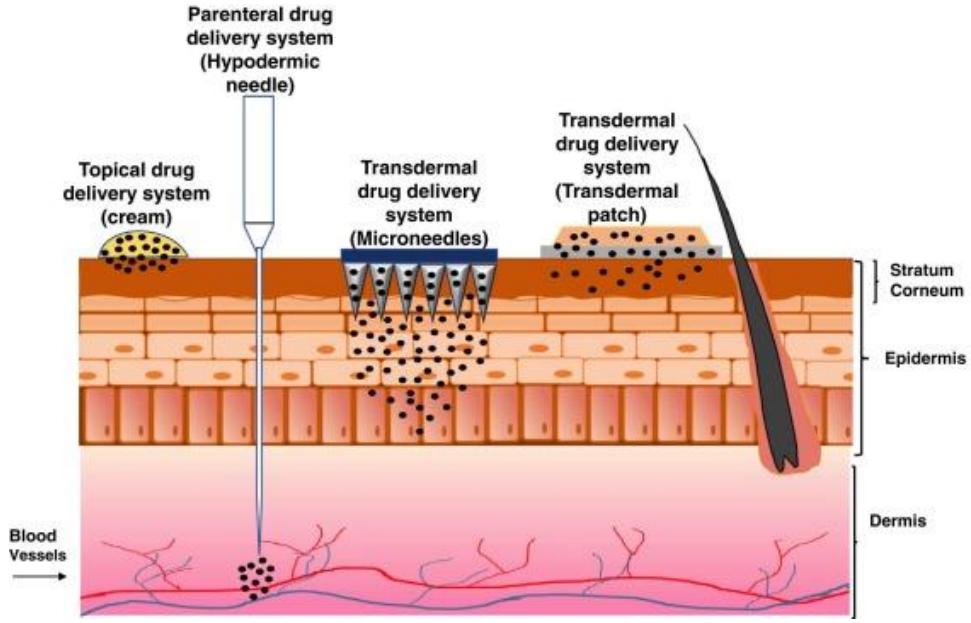

Figure 1: Comparison between various drug delivery systems

2. Advantages of Microneedles:

2.1 Improve drug delivery:

MNs improve drug delivery by transporting the drug directly through the stratum corneum. This will enhance the onset of drug action as there are capillary bed and associated lymphatic vessels in the superficial dermis. They enhance drug bioavailability by avoiding first-pass metabolism. Some MNs formulations can control the delivering of accurate doses. The abundance of immune cells in the dermis layer makes MNs effective delivery system for vaccines [6].

2.2. Improve safety and patient compliance:

The small length and size of MNs makes it safe, painless, and reduces biohazardous sharps waste [6].

2.3. Improve manufacturing process and cost-saving:

MNs patches save cost as they are solid-state formulation which does not need the cold chain system. Also, they reduce the overall size of the drug package as it includes the functionality of the drug, needle, and syringe [6].

3. Disadvantages of Microneedles:

MNs have some limitations such as doses are restricted to small amounts due to the size of MNs patch. Application of MNs can cause temporary inflammation and allergies. Their manufacturing need sophisticated technologies. Some solid MNs when applied can be broken or left in the skin [6].

4. Classification of Microneedles:

Microneedles can be classified according to several ways. The first classification divides them into hollow and solid MNs, the later one are further divided into coated, uncoated, and dissolving MNs. The second classification divides them according to the method of production, this classification includes MNs shafts oriented parallel to the base substrate which is called "in-plane MNs", while MNs shafts bent at 90◦ to the base substrate are called "out-of-plane MNs" [7]. The categorization of MNs into five types are the most common. As shown in (Figure 2), the first type A is solid MNs which used as a pretreatment for skin before administration of medication from the external reservoir; the second (B) is hollow MNs where liquid drug formulation is injected into the skin through the MN bores; the third type (C) is coated solid MNs where a continuous dissolution of the drug in the skin occurred; the fourth (D) one called dissolving MNs which release active ingredients incorporated in its matrix after completely dissolved in the skin; the last type (E) is hydrogel MNs, in this form of MNs upon administration will swell up and the drug will be released from the patch [8] .

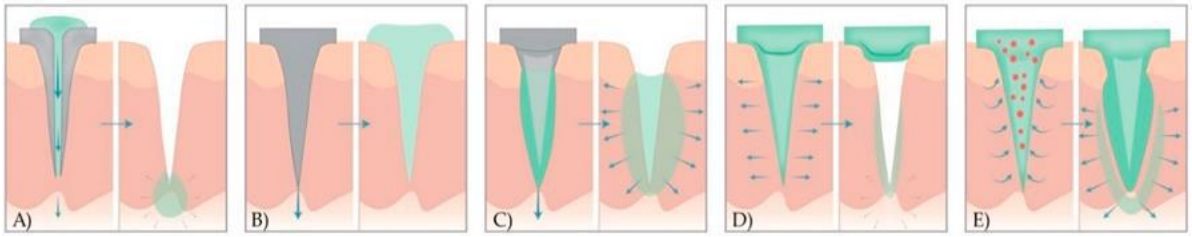

Figure 2: A schematic illustration of drug release methods with different types of MNs.

4.1. Solid Microneedles:

Solid MNs can be applied in the poke and patch approach with or without drug coating. The uncoated MNs create temporary aqueous microchannels in the SC after application to the skin, then the conventional drug formulation is applied such as transdermal patch, solution, cream, or gel. In this manner, the drug will permeate by passive diffusion through these microchannels. The coated MNs which is the second type of solid MNs will serve as drug reservoirs besides piercing the skin. This approach has the advantage of rapid delivery of the drug dose, although, there is a limitation in the drug amount that can be applied on this type of MNs which is usually less than 1 mg [9].

4.2. Hollow Microneedles:

Hollow MNs have a lumen or internal bore (5–70 μm wide) that enable drug transportation by applying pressure (using a syringe, pump, or gas) or by passive diffusion. The flow of liquid formulation from hollow MNs reservoir is about (10–100 μL/min) in a continuous manner. They are commonly used to deliver vaccines and insulin. When comparing hollow MNs to other types, they can deliver higher drug amounts. The main advantages of hollow MNs are; easily manufactured with low costs, and accurate drug release control. Moreover, the incorporation of a micropump or microfluidic chip into MNs array will allow controlled release of the drug. The

integration of the drug reservoir with a heater delivers the drug solution to the skin by spreading the liquid or creating bubbles. By pressing the flexible reservoir, the drug solution is released into the skin. Although this therapeutic strategy requires liquid drug formulation, no reformulation is necessary. However, a challenge is to deliver a dry formulation, generally used to improve drug stability and convenience of patch-based application, without reconstitution. The main limitations are the possibility of clogging the needle tip in the tissue and the resistance to flow due to the density of compressed skin tissue around the MN tip. Therefore, to overcome this disadvantage, a side opening with off-centred holes is designed. Another way is the gradual insertion of the needle [10].

4.3 Coated Microneedles :

The coated microneedles (MNs) are made by coating the solid microneedle structures with a pharmaceutical coating before using them on the skin surfaces (Figure 2C). After the microneedle array of coated microneedles is inserted into the dermis, the pharmaceutical coating is dissolved and the delivery of the coating into the tissue is facilitated (a coat-and-poke methodology is used). This type of microneedles helps in the delivery of large biomolecules such as vaccines, protein therapeutics, peptide compounds and deoxyribonucleic acid (DNA) rapidly. Although coated MNs have the benefit of one-step administration, it has a drawback of limited drug payload capacity on the microneedle surface area. Therefore, coated MNs would be ideal in the delivery of very powerful pharmaceutical agents or therapeutic compounds [11].

4.4 Dissolving Microneedles :

Dissolving MNs consist of active pharmaceutical ingredients (APIs) and a dissolvable polymeric matrix that is made out of biocompatible polymeric material or sugar-based compounds. When the microneedle tips touch the interstitial fluids, dissolution occurs and this leads to the release of the API (using poke-and-release strategy) (Figure 2D). The rate of release of the active compound is proportional to the rate of dissolution of the constituent polymers and thus, by changing the polymeric formulation or changing the production parameters, therapeutic delivery can be controlled. Ling and Chen in their study came with a dissolving MN patch that utilized starch and gelatin which included insulin as the model therapeutic agent. In vitro cell analysis showed that these MNs released almost all of their insulin cargo in a period of 5 minutes. The microneedles were also found to be mechanically sound to ensure the bioactive compounds were encapsulated stably.

Nowadays, there is growing interest in dissolving MNs prepared by using biodegradable materials because such systems are focused on the administration of APIs and elimination of the production of sharp, biologically polluted, and non-biodegradable wastes [12]. More so, in the event where MNs are built using semi-synthetic or fully synthetic polymeric and sugar-amine substances, costs of production are significantly lowered. However, one of the major drawbacks is that there will still be residues of polymer in the skin tissue, and that will be problematic in cases of prolonged or repeated use. As a special form of dissolving MNs, degradable MNs can deliver various hydrophilic therapeutic molecules, including caffeine, lidocaine, metronidazole, ibuprofen, and many biopharmaceutical macromolecules (including low molecular weight heparin, insulin, leuprolide acetate, erythropoietin and human growth hormone) [13].

4.5 Hydrogel Microneedles :

In 2010 a new design of micro needle using hydrogel forming matrices was proposed by the researchers. The design has an open platform base patch that is loaded with the API, up which microprojections of cross-linked polymer spring out. When these needles are inserted in the skin, they become engorged with interstitial fluid, forming structures of migration of drug molecules through the base reservoir to the expanded needle structure (14) (Figure 2E). The manufacturing materials are aqueous solutions of a certain type of polymers such as polymethylvinylether-co-maleic acid (PMVE/MA). Lee et al. have used amylopectin and ultra-low viscosity

carboxymethylcellulose (CMC) to produce their hydrogel MN systems. Their sulforhodamine-loaded, bovine serum albumin-loaded, or lysozyme-loaded formulations were safe in skin dissolution and allowed flexibility of their release patterns, rapid bolus or sustained. The team by Garland showed that the cross-linking density of the hydrogel could control the rate of drug release because the density could be adjusted appropriately. The main advantage is that these MNs do not damage the skin leaving no residual polymer fragments. The swelling process makes the needles too soft to be reused and this is a safety measure of cross-contamination.

One of them is a subcategory referred to as phase transition MNs which works in the hydrogel category. These systems discharge their drug load as the polymer matrix expands by taking up biological fluids. The residual material in the application is left as traces or zero. Despite the higher drug loads that can be delivered in dissolving and degradable formulations of MN types, their matrices; comprising the bulk of the needle volume, stay either in or degrade in the skin tissue. This feature restricts their appropriateness in drugs to be taken frequently. The problem of patient compliance and the possible side effect occurs when polymer residues are deposited due to repeated dosages at the same time or at a short-time interval. An ideal example of application is in the case of vaccines where the deposited amounts of matrices are acceptable because of the single or few dosing schedules.

The best MN design, consequently, has hydrogel materials that are stable in the skin and do not dissolve or degrade and yet attain controlled or continuous release of therapeutic agents [14].

5. Microneedle Production Methods:

5.1 Microelectromechanical Systems (MEMS) :

MEMS technology offers an avenue of developing solid and hollow microneedles, and templates applied in the construction of microneedles, beginning with substrates of base materials. The manufacturing process has three well-controlled processes namely laying down materials, creating patterns, and erasing undesirable places (Figure 3). Three-dimensional forms are complex as different materials react in different ways to removal agents.

The first operation deposits thin coatings - a few billionths of a meter to one-tenth of a millimeter - on a base article. This is achieved in two ways: one way is through chemical reactions in vapor form (CVD) and the other through physical transfer in vapor form (PVD). The physical technique involves the transportation of individual atoms through a gas environment directly out of its area of origin to the foundation. The chemical method forms layers in the event of reaction that occurs at the very outer of the foundation [15].

This is followed by the pattern-creation process wherein a flat master design is copied on to a properly prepared foundation using light-sensitive coating using an existing template. Wafers of silicon are usually used as the substrate and the copying occurs with light or particle beams via one of various imaging modalities- light-based imaging, charged particle imaging or high-energy radiation imaging.

The light-based imaging is the most preferred technique. The method utilizes the abilities of some substances to absorb ultraviolet rays (wavelengths between 193 and 236 nanometers) i.e. some substances absorb the rays, whereas others do not. The process begins with the creation of an optical shield- basically a blocking template which creates the desired pattern on the wafer. This is a shield which is constructed out of crystalline quartz or smooth glass and allows only rays to pass through the definite configurations. To prepare the silicon base, the base is first subjected to steamy environment or moisture containing oxygen at around 900 o C to form an oxide layer. Subsequently, the foundation revolves as it gets a coating of organic matter that reacts with UV rays, which is referred to as photoresist substance. Warming the product between 75 and 100 degrees Celsius and bombing it with ultraviolet laser will evaporate the liquids and create the desired light-reactive pattern. There are two types of light-reactive material; straightforward and inverted. In simple forms, the ultraviolet bombardment splits the

long molecules chains into the material, which is easier to remove in cleaning fluids than inverted ones, which are in fact hardened by the bombardment.

The use of this light technique in creating microneedle templates is also effective. The process involves developing a hard silicone stencil of a raised image, then making an inverted one of poly(dimethylsiloxane) (PDMS), and then finally proceeds with a substance of choice.

In the process, the removal is carried out with high acidic/alkaline chemicals that eat away unprotected regions of the substrate to produce the desired arrangement of surfaces [16].

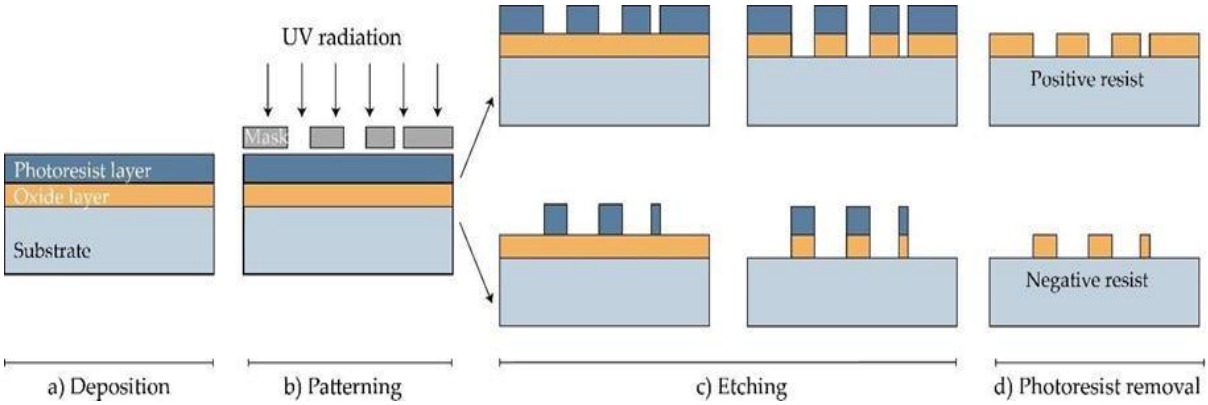

Figure 3: Photolithographic techniques for microneedle fabrication. (a) Material application: Silicon wafer substrates are treated with steam or water to create an oxidized surface layer. After that, a light, sensitive polymer is applied by rotational spreading onto the substrate surface. (b) Design transfer: A template, controlled ultraviolet light reaches the photo, reactive polymer layer. (c) Material dissolution: The removal of the dissolving polymer layer happens, and the silicon dioxide layer is locally etched. (d) Photo, mask removal: In this step, the photo, reactive polymer layer is removed.

5.2 Laser Cutting:

Microneedles made of metal can be fabricated in a variety of ways: Three-dimensional laser cutting methods, laser material removal processes and metal deposition methods (either electroplating or electroless plating) onto raised or recessed microneedle templates.

The manufacture of groups of solid microneedles is carried out by passing infrared laser beams to cut through sheets of stainless steel or titanium to create the microneedle arrangement (Figure 4). The desired form, physical structure, and size parameters of the microneedles are characterised by means of digital design programs (computer-aided design/CAD software). The laser tracks the pre-programmed outline of the needle, which is then followed by washing the microneedles in heated water before being folded at right angles, to be upright in the flat foundation surface. The microneedles are then subjected to an electropolishing process to remove rough edges, reduce the wall thickness and form pointed ends, and then cleaned and dried by using pressurized air. In this fabrication method it is possible to make single lines of microneedles of different shapes, or multiple rows of metallic microneedles [17].

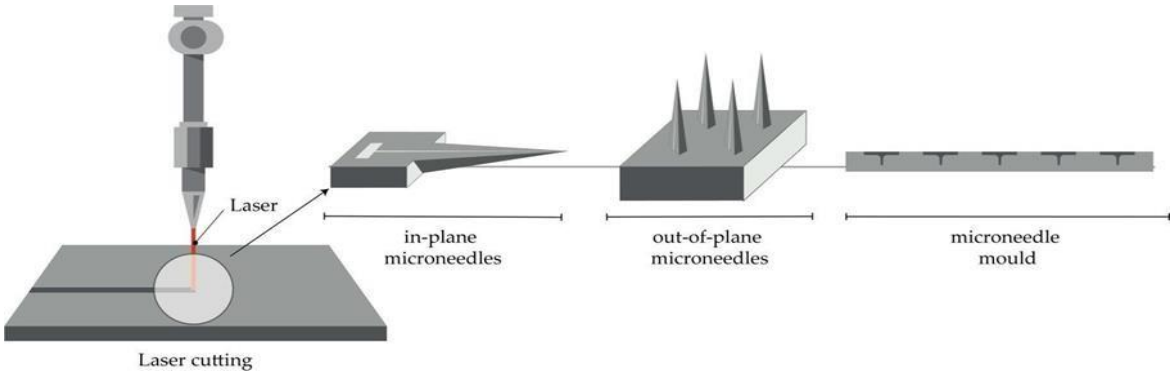

Figure 4: Digital design programs (computer, aided design/CAD) are used to define the desired shape, structural form, and size of microneedles. The laser emission follows the pre, programmed outline of the needle, after which microneedles are cleaned in hot water and folded at right angles so that they stand perpendicular from the base plane. To remove rough edges, reduce microneedle wall thickness, and form pointed ends, microneedles are next subjected to electropolishing treatment, rinsing, and drying with pressurized air. This manufacturing method makes it possible to build either single linear arrays of microneedles with different structural forms, or flat grid arrays of metal, based microneedles.

5.3 Laser Ablation :

This is a process that is used as a material removal method in dealing with such materials as metals. Pulsed light energy forms raised structures of inert metallic surfaces, which have a particular configuration, and make up groupings of microneedles on solid metals. However, the extremely high intensity of laser bursts causes the ionized gas with the charged particles and free electrons, which becomes problematic when constructing structured substances. Therefore, Omatsu invented a new, resource-saving, and fast production plan of producing metal microneedles using spinning polarized light beams of rotational energy, as in Figure 5. The researchers recorded high epithelial structures of tantalum microneedles of greater than 10 micrometers in vertical dimension and exceptionally narrow point dimensions.

Through laser material removal, Evens and colleagues (2020) came up with a new approach to the synthesis of solid polymer microneedles using steel templates. These templates were also applicable in molding injection process of construction of polymer microneedles. This can allow the modulation of microneedles vertical dimensions and attain a very sharp point measurements using this cost-effective manufacturing strategy [18].

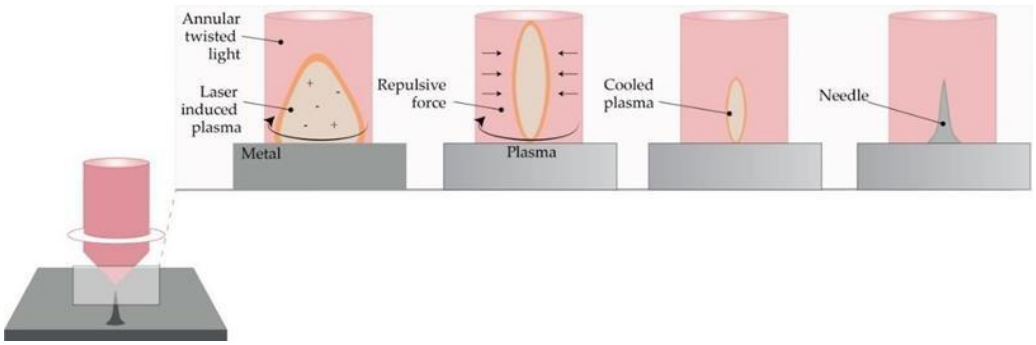

Figure 5: The principle of metal MN fabrication using twisted light with a spin.

2.3 Micromolding Method (Solvent Casting):

Dissolving microneedles usually pass through the preparation by pouring liquid preparations into microneedle templates that have already been prepared. Such templates are typically based on silicon substrates in the form of wafers. This is followed by oxidation of the wafer at 1000 degrees Celsius. The needle arrangement is transferred with photolithographic processes followed by reactive ion etching (RIE) and chemical vapor deposition (CVD) is used to coated wafers. The mixtures of liquid polymers are poured into prepared templates, and any air bubbles trapped are removed by use of vacuum or spinning force. The templates are then dried in an oven after which the microneedles are removed after the temperature decreases (Figure 6). The advantages of this method are that the micro needle development is relatively easy, low in cost, and in room temperature environment. Also, it has been reported that biodegradable polymer microneedles, which include naturally-derived and lab-produced materials, with appropriate structural design and mechanical strength sufficient to overcome skin resistance, have been successfully built. It is worth noting that even micromolding technique has been used to make ceramic microneedles [19].

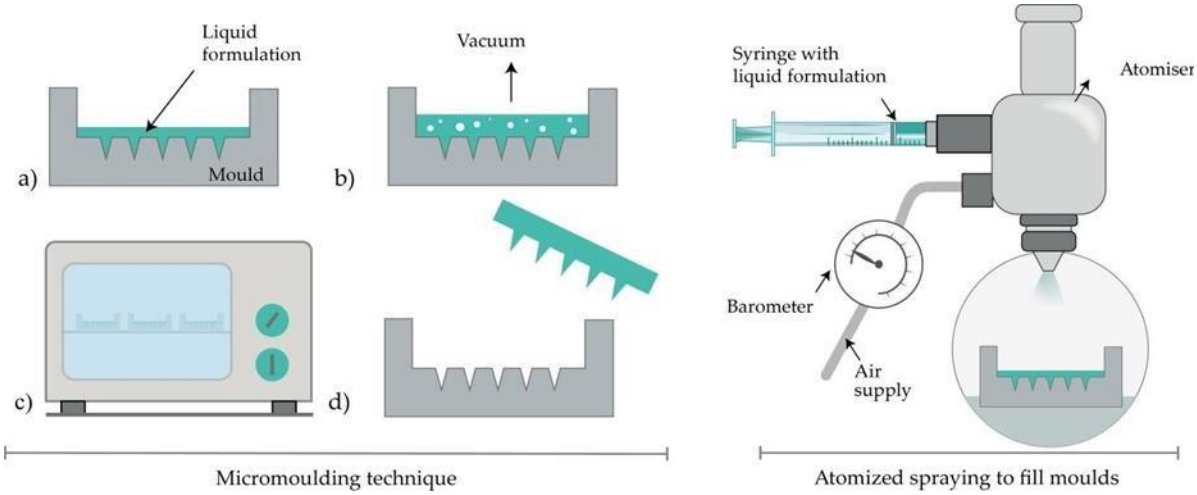

Figure 6: Left: MN production with micromolding (left) consisted of (a) pouring the liquid formulation, (b) vacuum degasification, (c) drying and (d) removal of MNs from the mold. Right: Atomized spraying to fill molds.

5.4 Atomized Spraying Method :

This method is relevant to limited large, scale manufacturing challenges of dissolving microneedles while still retaining the necessary structural design and material properties. Moreover, it is possible to avert complications resulting from liquid interface forces and thickness characteristics during template filling by this method. Dissolving microneedles may be made of sugar compounds (trehalose, fructose, and raffinose) or polymeric substances (PVA, PVP, CMC, HPMC, and sodium alginate). Fundamentally a dispenser connected to a pressurized air supply and liquid preparation produces a fine mist (Figure 6). The preparation is deposited in PDMS templates and dried for two hours at room temperature. Furthermore, this method may also be used to fabricate both stacked, layer and horizontal, layer dissolving microneedles [20].

5.5 Droplet-Born Air Blowing Method (DAB) :

The traditional microneedle manufacturing methods have led to the loss of therapeutic agents due to exposure to harmful conditions such as ultraviolet radiation and heat. The DAB technique which was invented by Kim and his co, workers is a method of pulling lithography that uses polymer droplets to form microneedles by blowing air. It is a method that allows production under mild conditions hence no ultraviolet radiation or heating is necessary. Basically, the method starts with the deposition of the prepared mixture on the two surfaces (top and bottom) and then the top surface is turned down to allow the droplet to contact. The viscous mixture is stretched by the upward movement of the top surface. In the very next step, forced air removes the remaining moisture and solidifies the droplets into the required shape by pulling the droplet away from a support, as shown in Figure 7 [21].

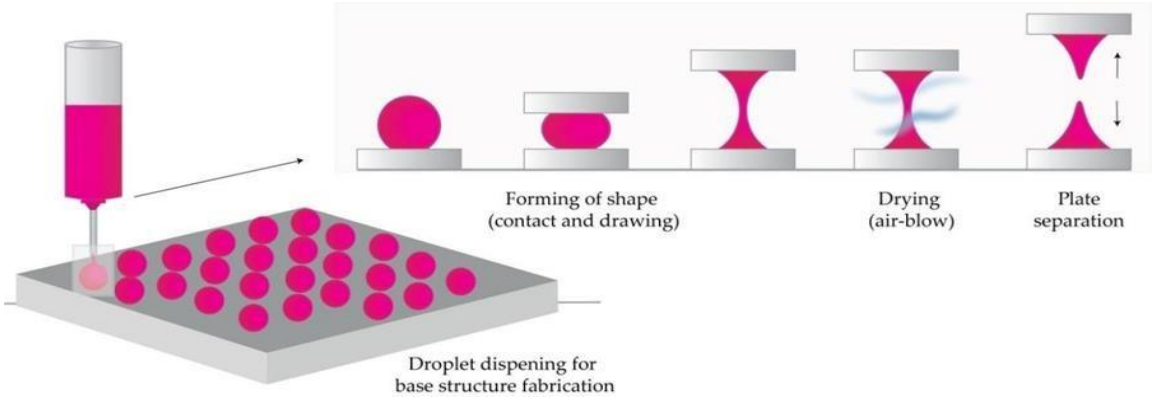

Figure 7: The principle of droplet-born air blowing (DAB) methods.

5.6 Additive Manufacturing (AM) :

Three dimensional printing, often known as additive manufacturing, is a significant new horizon that has attracted the attention of researchers in the development of micro, needles arrays and molds. With all AM technologies, the very first step is the creation of a three, dimensional object model with the help of computer, aided design (CAD) programs. In the next stage, the CAD model is transformed into an STL file, which depicts the 3D shape with triangles and divides it into digital horizontal slices. This STL file is then sent to a printer through a machine control program, and the printer is set up with its operational parameters. The printer builds the part by binding or depositing the proper material (for example, ceramic materials, liquid compounds, heat, softening plastics, plastic materials, light, reactive polymers, granular materials, or biological cells) layer by layer in the horizontal cross, sections of the work [22] .

On a different note, a few AM technologies comprising FDM, light, induced polymerization methods like SLA, DLP, and 2PP have been successfully employed for fabricating microneedle arrays. These novel technologies provide several advantages over the traditional manufacturing method that includes user, friendliness, cost, effectiveness, the ability to fabricate complex geometric structures with the option of changing the original model at any time, and the production of personalized therapeutic devices [23].

5.7 Fused Deposition Modelling (FDM) :

The very first step in directly printing microneedles on conventional FDM standard printers is the fabrication of microneedle schematics through CAD programs and their subsequent conversion of geometric shapes according to the dimensions given by a printer [24]. Next, a material for heat softening appropriately shaped as a single strand is fed into the printer through the rollers, where the heating components slightly raise its temperature above the softening point (glass transition temperature Tg), thus obtaining a molten state. The molten or softened material, oilled by the mechanical parts, is moved to the outlet from where it is pushed out of the printer's outlet component, passing through a hole and then laid down in successive layers along the construction platform, where it cools and solidifies in less than one second (Figure 8).

The most common continuous strands used in FDM printers are acrylonitrile butadiene styrene (ABS), PLA, PVA, high impact polystyrene (HIPS), polyethylene terephthalate glycol, modified (PET, G), and nylon, while the dimensions of continuous strands suitable for commercially available outlet components are between 1.75 mm and 2.853 mm [25].

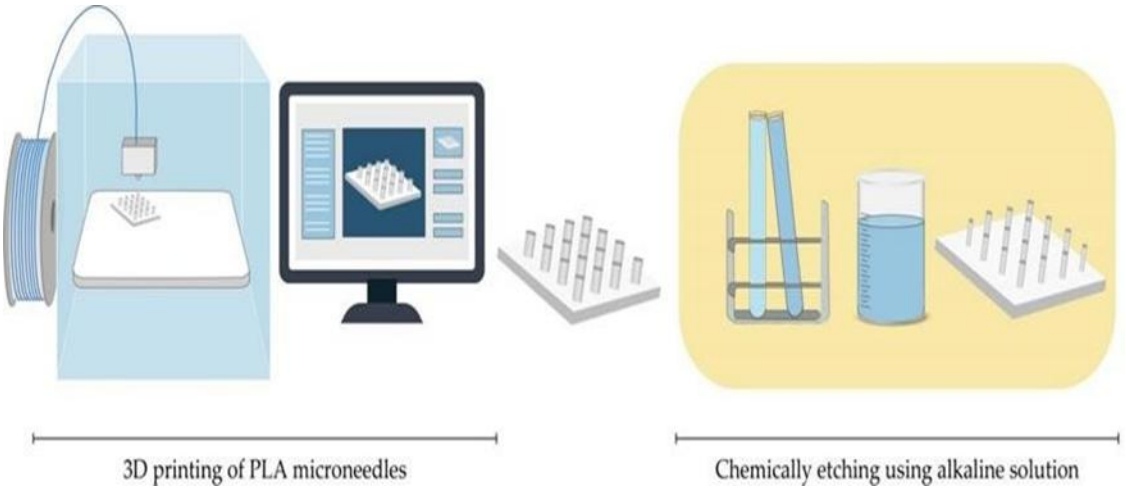

Figure 8: Fabrication of MNs by Fused deposition modelling (FDM) methods, followed by etching in alkaline solution.

5.8 Stereolithography (SLA) :

One of the main reasons for the choice of SLA as a microneedle printing technology is that it achieves high dimensional precision, detailed accuracy, and has a very good surface quality. Ovsianikov et al. first showed that lithography, based multiphoton polymerization 3D printing methods might open up a new way of fabricating microneedle arrays for transdermal drug delivery. The method involves exposing a photosensitive resin made from monomer units to ultraviolet radiation to cause the resin to solidify. The microneedles are built up through sequential hardening of resin vertical layers with each layer being irradiated with a strong energy beam, such as ultraviolet laser emissions directed by reflective scanning components [26].

5.9 Digital Light Processing (DLP) :

DLP is another technology that involves light, activated polymerization of a photosensitive material, and in this case, the polymer is solidified by a projected beam of light. The technique is faster than SLA, where a high, resolution projection system can illuminate the whole cross, section of the object at once using three, dimensional

pixels or voxels. Gittard et al. were the first to report the use of DLP to create microneedles. Their work has successfully introduced DLP as a method of fabricating solid microneedle array structures in different geometrical shapes using tissue engineering acrylate, based, polymer materials [27].

5.10 Two-Photon-Polymerization (2PP) :

2PP enables the development of economical, sequential cross, section rendering of three, dimensional structures of solid, fluid, or granular origination at microscopic and nanoscopic scales of the architectural embodiments. Besides the use of a femtosecond or a picosecond laser beam, the light is focused within a liquid resin drop to trigger polymerization of a microneedle structure. The operation achieves spatiotemporal overlap of photon particles to trigger light, induced polymerization. The advantages of the process are high versatility levels, variable dimensional accuracy, better geometric shape control and, also, the process may be carried out in normal laboratory conditions. [28]

6.Applications of microneedles:

Human skin is an efficient protective barrier and at the same time, a valuable route for the delivery of therapeutic compounds. Therefore, it is heavily used in molecular diagnostic procedures and therapeutic interventions. Microneedles have been primarily used for therapeutics by enhancing substance penetration and facilitating pharmaceutical transport. At present, the application of microneedles is expanding beyond these areas to include the administration of vaccines and biological agents, diagnostics of diseases, and aesthetic procedures [29].

6.1 Disease treatment :

Most biologics, peptides, protein therapeutics, hormonal substances, and naturally, derived agents, that are therapeutic compounds face administration problems due to hepatic first, pass degradation. As a result, it is necessary to resort to subcutaneous injection although the tissue penetration by a needle is uncomfortable. These innovative tools, microneedle patches, are often considered as possible substitutes for subcutaneous injections, thus, they are painless, safer, and patients can easily apply them by themselves. Transdermal drug delivery remains the main area of microneedle use in therapeutics.

6.1.1 Cancer :

Besides curative surgical operation, typically cancer therapies using drugs, and radiation show a wide range of side effects including damage to tissues and the possibility of relapse of the disease. For this reason, with an almost non-invasive treatment option, microneedle patch technology has become very popular which, among other things, provides accurate delivery control, simple use in clinical practice, and possible effectiveness of combined therapy enhancement [30] .

In response to the health challenges, Dong et al., designed dissolvable microneedle arrays made of hyaluronic acid (HA) that carry both the chemotherapeutic agent doxorubicin (DOX) and gold nanocage structures (Fig. 9A). This system allowed chemotherapy and photothermal therapy to be conducted concurrently against tumors accessible to the surface. Also, going one step further, the incorporation of immune checkpoint blockade into the treatment of cancer represents a monumental leap in the field. Ye et al. proposed a microneedle HA-based delivery system comprising anti-PD1 antibody (aPD1) and 1-methyl-D,L-tryptophan (1-MT), small molecule that serves as an inhibitor of immunosuppressive enzyme indoleamine 2,3-dioxygenase (IDO) (Fig. 9B). The presented transdermal immunotherapy device for melanoma relies on HA breakdown brought about by high levels of

hyaluronidase (HAase) typical to tumor milieus and, thus, both checkpoint blocking agents (aPD1 and 1-MT) are released in situ.

In another study, Chen's research team fabricated biodegradable microneedle arrays from poly(vinyl alcohol)/polyvinylpyrrolidone (PVA/PVP) polymers. These structures harbored photothermal nanoparticles combined with anticancer drugs (Fig. 9C). This composition led to tumor elimination of 4T1 cancer models after a week and simultaneously prevented relapse of the disease. As evidenced by such combination, cancer therapy over long periods with several treatment forms can draw a huge benefit from this technology. To initiate strong cytotoxic immune responses as well as to stimulate T, cell populations, van der Maaden's team engineered a hollow microneedle injection device carrying synthetic long peptide sequences for therapeutic vaccination against cancer. The novel delivery method, as compared to conventional intradermal routes, allows drastically lower injection volumes, thus enhancing both the immunogenic capacity and the therapeutic efficacy of anticancer vaccine preparations.

RNA interference technology has been recognized as a breakthrough therapeutic modality for selectively targeting oncogenic genetic sequences. Tang's group of researchers evaluated the use of microneedle arrays as a means to deliver siRNA molecules directly into tumor tissues so as to inhibit cancerous growths. Besides small molecular drugs and RNA, based therapeutics, McCarthy's laboratory has made a landmark technological innovation by employing RALA peptide vectors for the transdermal delivery of E6/E7 plasmid DNA via dissolvable microneedles (Fig. 9D). This system was instrumental in postponing tumorigenesis as well as lessening tumor growth in the therapeutic experimental models [31,32].

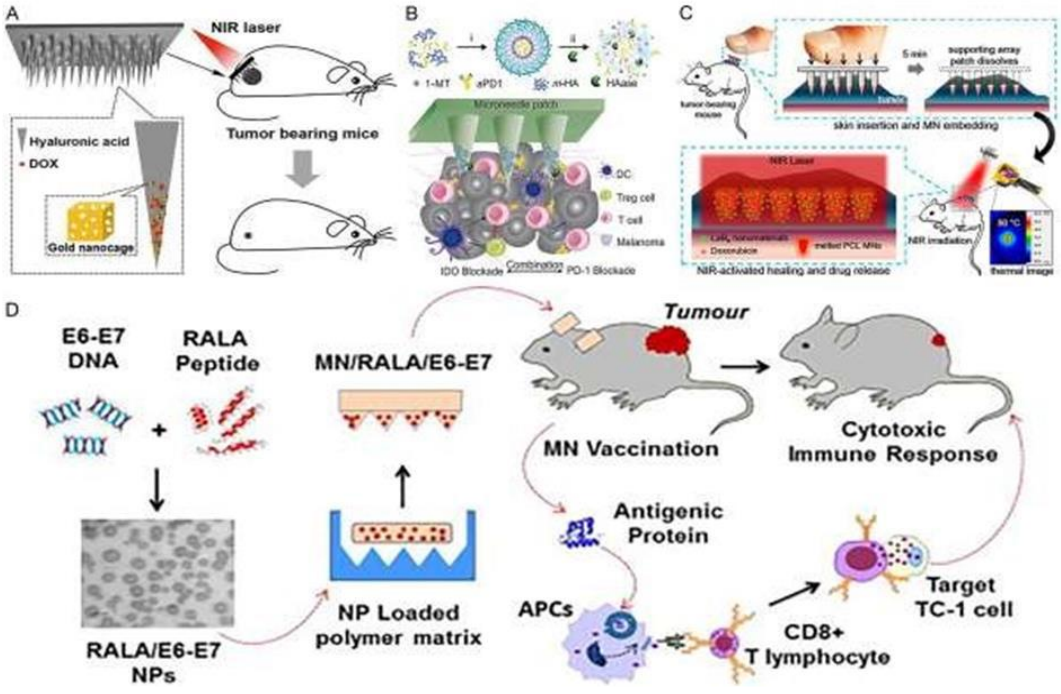

Figure 9: Microneedles in cancer therapy.

6.1.2 Diabetes :

The patient adherence to therapy is often compromised due to the burden of complex treatment protocols that require numerous daily injections. In addition, the increased risk of hypoglycemic episodes due to repeated meal, associated medication administration is a source of considerable concern. To confront these therapeutic barriers, Yu's team developed microneedle array patch devices equipped with glucose, sensing capabilities that regulate blood sugar levels via insulin delivery in a controlled manner for type 1 diabetic patients (Figure 10A). The system uses glucose oxidase as a catalyst that breaks down glucose molecules into gluconic acid and simultaneously depletes oxygen.

When there is high blood glucose or low oxygen, lipophilic 2, nitroimidazole is reduced to hydrophilic 2, aminoimidazoles, which causes hyaluronic acid vesicle structures to be broken down and insulin to be released as a result of the spontaneous reaction triggered. This smart insulin delivery patch made of self, assembling synthetic vesicles is a potential solution for fast glucose, sensing, painless application, and improved safety in diabetes therapy.

In an impressive advancement, Chen and his team have come up with a novel pH-sensitive microneedle patch platform made from alginate polymers which is used for exendin-4 (Ex4) delivery in type 2 diabetes therapy (Figure 10B). This futuristic patch features a dual mineralized peptide/protein nanoparticle system that can differentially control Ex4 release kinetics to avoid a premature drug release to the tissue and hence, the drug depletion is at least partially inhibited and the necessity of multiple injections is completely eliminated. To confirm the sustained glucose-responsive behavior, copper phosphate mineralized particles enveloping glucose oxidase (m-GOx) are the effective converters of glucose into H+ signals during hyperglycemic states, while the calcium phosphate mineralized particles loaded with Ex4 (m-Ex4) are pH-sensitive biomaterials that dissolve in acidic environments to release Ex4. The alginate microneedle patch-based technology is an excellent means for medication simplification in the type 2 diabetes population [33].

Lee's team designed a wearable and portable electrochemical monitoring system, which can be used to monitor the pH level, temperature, moisture content, and glucose concentration in sweat on a real-time basis, along with the provision for thermal activation for the transdermal metformin delivery in diabetes treatment [34] (Figure 10C). Such sophisticated devices are of high value as they can radically change the existing Point-of-Care (POC) detection procedures and personalized therapeutic interventions. The POC patch design used stretchable waterproof material (silicone) incorporating a perspiration-management layer (i and ii), sensor layer (iii–vii), and therapeutic delivery layer (viii–x). In addition, the data about the changes in the patient's condition are sent instantly from the monitoring device to the physician or medical staff via a wireless connection and thus, they are facilitated in their POC diagnostic assessment and diabetes treatment delivery [35].

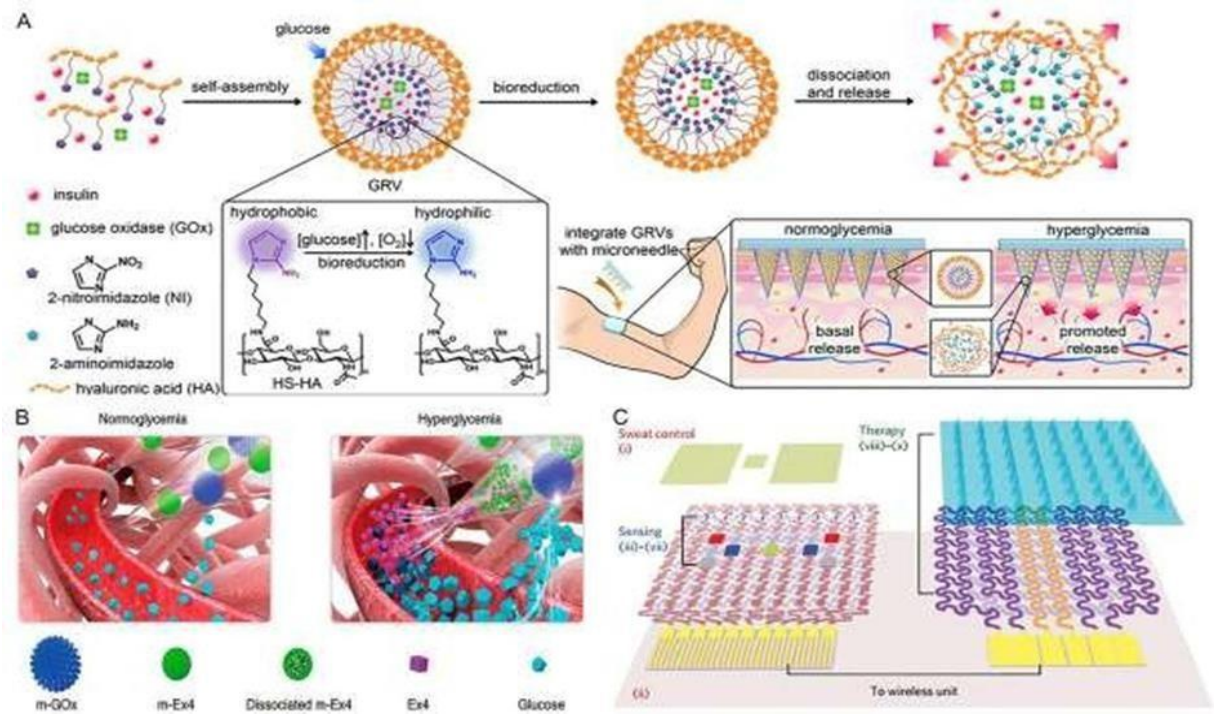

Figure 10: microneedles in diabetes therapy.

6.1.3 Obesity:

Adipose tissue is composed of two types: brown adipose tissue (BAT) and white adipose tissue (WAT). BAT is responsible for thermogenesis, a process that eventually leads to an overall increase in body energy consumption. On the other hand, WAT acts as an energy-storing unit, thus, will increase body mass and might also worsen the metabolic problems by producing reactive oxygen species and releasing free fatty acids. One of the natural products caffeinated tea or coffee may provide is anti-obesity agents. While keeping the safety profileable of humans, caffeine has demonstrated anti-obesity effects. Dangol and his team experimented on the effect of dissolving microneedles made of HA with caffeine-loaded and found significant body weight reduction in mice fed with a high-fat diet (Figure 11A).

Furthermore, their experiment shows that when the efficiency of transdermal delivery is optimized, caffeine has very outstanding therapeutic effects on obesity. A new therapeutic system aimed at obesity management via dissolvable HA-based microneedle technology was achieved (Figure 11B). Browning-inducing compounds, i.e., β3-adrenoceptor agonists and thyroid hormone T3, contribute to the conversion of WAT into BAT by the continuous release from a transdermal dissolving microneedle system, thus, inhibiting weight progress and, at the same time, permitting long-term therapeutic management. The gradual elimination feature of the system makes this transdermal administration method a POC intervention of a longer duration possible.

Moreover, as per the illustration in Figure 11C, Zhang's research team created a local induction of browning patch loaded with rosiglitazone (Rosi) not only for the prevention of adipose tissue accumulation but also for the improvement of insulin sensitivity. This transdermal HA-based delivery system was designed to include

nanoparticles with Rosi encapsulated in dextran matrices as the browning-inducing agent, together with glucose oxidase to create an acidic microenvironment, and catalase (CAT) to remove the unwanted hydrogen peroxide byproducts [36] . Therefore, this advanced drug delivery system was able to carry the browning agent to white adipose tissue to increase energy consumption and thus reduce adipose deposits for obesity therapy [37].

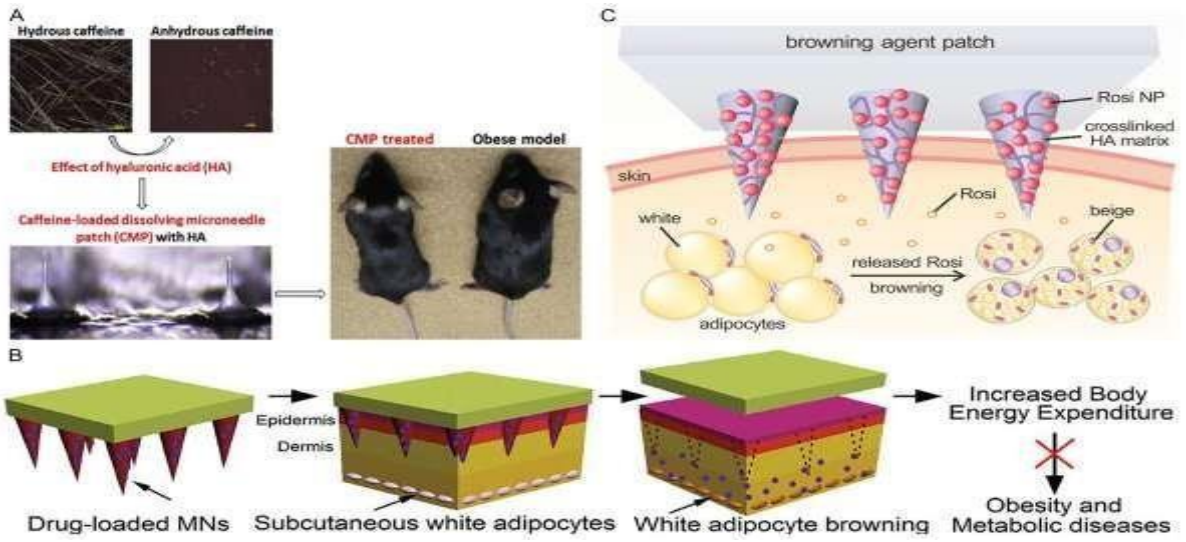

Figure 11: microneedles in obesity treatment.

6.2 Immunobiological administration:

Conventionally, the administration of vaccines or antibody, based therapeutics has been done through hypodermic, intramuscular, or intradermal injection techniques mainly for prophylactic immunization purposes. However, these traditional immunization methods have several drawbacks, such as the anxiety of patients caused by needles and the discomfort resulting from dermal penetration. Thus, needle, free vaccination methods like liquid jet injection systems and microneedle devices have been widely researched.

One of the practical utility issues of vaccines is the thermal stability of their formulations and the antigenic persistence that are still a problem even in high temperatures. Presently, the main alternative to vaccines administration is the use of a technology that combines three different formulations to lengthen the shelf life for the use of a traditional needle, based injection, as shown in the case of hepatitis B vaccination [38] .

Microneedle array devices induce the formation of temporary small channels in the skin tissue that facilitates the movement of immune molecules through skin barriers. The study led by Ding revealed that the immune responses to cholera toxin antigens delivered by microneedle route were significantly higher than those obtained by the standard intramuscular injection method [39].

6.3 Disease diagnosis :

Microneedle arrays can be used to break down skin layers and in this way skin interstitial fluid (SIF) can be collected directly from the epidermal area by means of capillary action or vacuum, assisted extraction. The metabolic components of SIF, thus obtained, are now in vogue for in vivo diagnostic purposes for various pathological conditions like malignancies, atherosclerotic disease, thrombotic disorders, cardiac dysfunction, and metabolic dysregulation.

The very first attempts to monitor glucose concentration in the collected SIF were based on glucose measurement strips, and rigid glass microneedle structures were used for skin penetration. Afterward, SIF collection was carried out through borosilicate glass capillary tubes. This method was so complex and the glass microneedle fragile structure was a big safety risk if it broke and got stuck in the tissue after the application. Over the years the focus of research has changed from such devices to microneedle platforms with incorporated various sensing elements. Amaral's research team was on the way to developing a novel neuroscience tool embedding magnetoresistive sensing technology for single, neuron cellular analysis.

To overcome the long extraction time limitation, polymer, based and hydrogel microneedle patches have been developed that allow rapid SIF collection. Mandal with his team developed a microneedle, based platform by decorating the surfaces of the rigid microneedle with a cross, linked biocompatible polymer. When the alginate, coated structures were inserted into the skin they slowly absorbed water thus converting the swelling process into one with a porous framework for the infiltration of localized leukocytes. In addition to this, Chang's lab created a shape, changing polymeric microneedle diagnostic patch (Figure 12A). However, the method was still considered unworkable due to the necessity of the subsequent centrifugation analysis.

In the most recent years, microneedle enzyme, electrode platforms have been enhanced by layering reagent systems for detecting ethanol in SIF (Figure 12B). By placing platinum and silver wire electrodes through holes in microneedles, immobilized alcohol oxidase enzymes were enabled to facilitate biocatalytic reactions. Besides that, the incorporation of real, time biosensing functionalities for the identification of biomarkers in a single integrated device has attracted a lot of research attention (Figure 12C). The surface of these microneedle platforms was modified with thiol, PEG, biotin molecules, which were then reacted with streptavidin, horseradish peroxidase conjugates. Ultimately, the spectrophotometric recording of the enzyme, mediated oxidation of 3, 3, 5, 5, tetramethylbenzidine (TMB) at the wavelength of 635 nm was used to derive the calibration curve for the direct quantification of streptavidin, as TMB solution with hydrogen peroxide was catalytically converted by streptavidin, horseradish peroxidase complexes.

Ranamukhaarachchi's team reported the design of a hollow metal microneedle with integrated microfluidic channels and photonic detection elements that was made for the selective identification of target biomarkers based on enzyme, linked immunosorbent assay (ELISA) principles. Significantly, Ciui and associates revealed a minimally invasive hollow microneedle device that had been POC sensing tech either stretchable or wearable, styled mounted on bandage platforms and capable of real, time skin tumor diagnosis [40] (Fig. 12D). Tyrosinase enzyme of melanoma biomarker was determined by amperometric measurement combined with flexible soft electronics where oxidation of catechol substrates was catalyzed thus one obtains benzoquinone products which are then converted back to catechol by, 0.25V potential. The detection signals were sent to the mobile devices via Bluetooth connectivity for immediate data access. These integrated wearable diagnostic platforms have great potential for decentralized POC diagnostic applications [41].

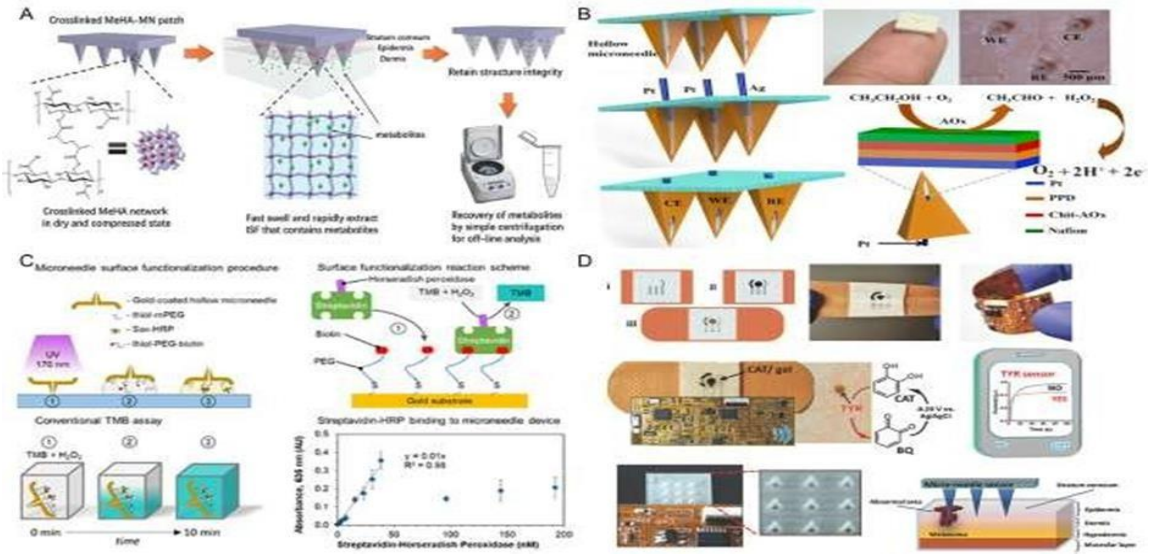

Figure 12: microneedles in disease diagnosis.

6.4 Cosmetic field :

Significant progress has been made in the integration of microneedle technology with cosmetic treatments over the past few years. The launch of several cosmeceutical products indicates the bright commercial future of cosmetic applications. In general, cosmetic applications aim primarily at two things. The first is to support the body's natural healing processes in case of skin damage. The second is to enhance dermal absorption of cosmeceutical compounds. The least invasive method of microneedle delivery causes temporary microperforations in the skin which increases penetration capabilities and at the same time tissue repair is stimulated [42]. In fact, microneedle therapy is very unlikely to result in significant skin redness or pigmentation changes after the treatment as compared to acne scar laser treatment.

Additionally, microneedle devices are capable of delivering the active components of a drug directly to the target site, thus improving the drug's effectiveness and safety by creating tiny openings without damaging the nerve fibers [43]. As a result, a new cosmetic patch formulation with retinyl retinoate and ascorbic acid has been effectively created for wrinkle alleviation without the occurrence of any side effects such as hypersensitivity responses.

Commercial, scale production will be a major player to microneedle product development as the cosmetic industry grows more and more. Generally speaking, these devices fall into two major categories: patch systems and roller gadgets. A slow insertion of a microneedle patch into the skin (e.g., by a gentle manual press) may result in very little penetration, which is mainly due to the elastic nature of the skin (Figures 13A and B). Improvement of penetration efficiency is thus the reason for overriding the limitation of the skin elastic properties by using high, speed application devices that temporarily stiffen the skin even though this consequently results in higher production costs of microneedle patch systems (Figure 13C).

On the other hand, microneedle roller tools that are cosmetically industry most common has been achieved by the use of angled rotational ultraviolet lithography with the polymer films. The three, roller configuration of the BeautyMouse tool (Figure 8D) made by Dermaroller (Germany) is a clear example of the dermal penetration efficiency, resulting in the most excellent penetration depth and surface area, and it is hence 2.5 times more

efficient than the single, roller configuration of the Dermaroller (collective count: 480 needles; needle width: 50 mm) plus a conventional Dermaroller system with 192 needles (Figure 13E). It should be pointed out that the latest generation of the DermaFrac system (Figure 8F) relies on light, emitting technology with specific wavelengths designed only for individualized personalized treatment protocols [44].

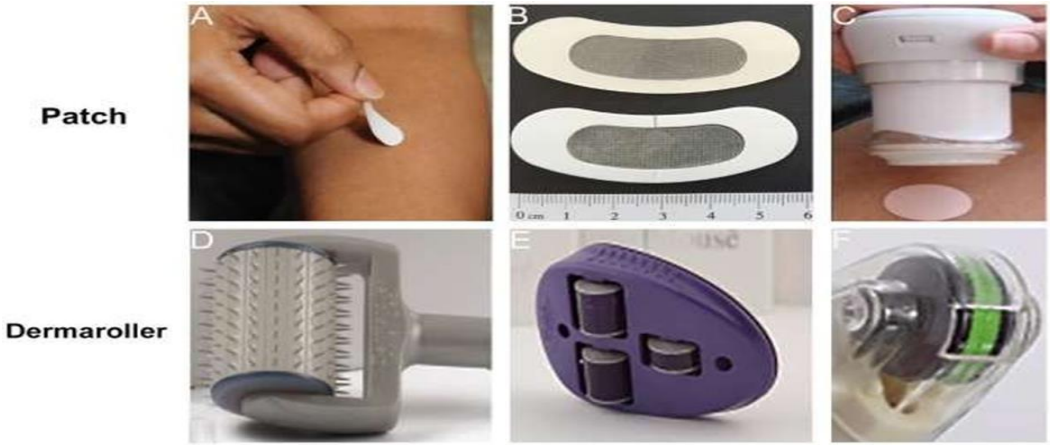

Figure 13: microneedles used in cosmetics.

7. Approved Marketed microneedle Products:

The derma roller is the first microneedle technology that was introduced to the commercial markets. At present, a vast array of microneedle devices have reached the market, each receiving FDA clearance for medical and cosmetic use. There are multiple manufacturers in Germany, the United States, Europe, and Japan that are distributing microneedle technologies [45]. Table 1 lists the FDA, cleared microneedle devices that are available for commercial distribution.

Table 1: FDA-Cleared Microneedle Technologies

Product Designation	Manufacturer	Technical Specifications	Clinical Applications	Ref.
Dermaroller®	Dermaroller® Germany, White Lotus	Cylindrical rolling device featuring solid or metallic microneedles ranging from 0.2-2.5 mm	Enhancement of dermal texture, scar reduction, and pigmentation disorder management	[46]
C-8 (Aesthetic variant)	The Dermaroller Series by Anastassakis K.	Microneedle dimensions of 0.13 mm (130 µm) only	Facilitates improved absorption of topically applied formulations	[47]
CIT-8 (Collagen Stimulation System)	The Dermaroller Series by Anastassakis K.	Microneedle dimensions of 0.5 mm (500 µm)	Applied for collagen synthesis stimulation and dermal restructuring	[47]
MF-8 variant	The Dermaroller Series by Anastassakis K.	Microneedle dimensions of 1.5 mm (1500 µm)	Scar tissue treatment	[47]

MS-4	The Dermaroller Series by Anastassakis K.	Compact cylindrical design measuring 1 cm length by 2 cm diameter, incorporating 4 circular microneedle arrangements of 1.5 mm length	Targeted treatment for facial acne scarring	[47]
MicroHyala®	CosMed transdermal drug delivery	Biodegradable microneedle patch system incorporating hyaluronic acid	Anti-aging wrinkle therapy	[48]
LiteClear®	Nanomed skincare	Rigid silicon microneedles employed as preparatory treatment followed by topical drug application	Management of acne conditions and dermal imperfections	[49,50]

CONCLUSION:

Microneedles (MNs) still hold unique features among many targeted drug delivery systems due to their multiple advantages. The use of MNs to deliver bioactive compounds has opened up revolutionary possibilities in the treatment of severe medical conditions. MN devices have been confirmed as more effective and safer choices compared to other drug delivery methods. The increasing use of MNs has led to a large volume of research work that is still ongoing. Many scientific studies and published articles have highlighted the significance of MN technology in different administration routes to therapeutic delivery. However, a substantial amount of scientific research is still required before MNs can have such a diverse pharmaceutical applications in the next clinical practice.

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CONFLICTS OF INTEREST

The authors did not disclose any conflicts of interest.

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الإبر الميكروية: نموذج ثوري لنظام توصيل الأدوية في الصيدلة مع أقل تدخل

عبدالله قصي خضر[1]، علي قاسم جواد[1] ، ياسر قاسم الماجدي[1] و ماهر عبد الرزاق الحكيم[1]

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الخلاصة :

الإبر الميكروية تعد أحد أكثرأنظمة توصيل الدواء ابتكاراً باستخدام تقنية قليلة التدخّل. وفي السنوات الأخيرة، خلص العديد من الباحثين إلى أن الإبر الميكروية يمكن أن تكون من أبرز طرق التوصيل الدوائي المستقبلية. كمنظومة لتوصيل الدواء، تمتلك الإبر الميكروية القدرة على تحسين إيصال الأدوية من خلال تجاوز العديد من الحواجز المرتبطة بالأنظمة التقليدية، إذ إن خصائصها الفريدة قد تجعل استخدامها واسع الانتشار.

تعتمد آلية عمل الإبر الميكروية في تحسين وصول الدواء إلى الموقع المستهدف مع الحد الأدنى من المضاعفات على إحداث مسامات دقيقة جداً في طبقات الجلد. ويُعزى الاهتمام المتزايد الإبر الميكروية في الأبحاث الدوائية والطب الحيوي إلى قدرتها على إيصال المواد الفعّالة بسهولة وبتقنية قليلة التدخّل. وتشمل الأمثلة على الجزيئات التي يمكن توصيلها باستخدام الإبر الميكروية: اللقاحات، والبيبتيدات، والهرمونات.

في هذا الاستعراض، سنناقش كفاءة الإبر الميكروية كحاملات لتوصيل الدواء، ومواد تصنيعها، بالإضافة إلى عدد من البراءات المرتبطة بها.

الكلمات المفتاحية: الإبر الميكروية ، أنظمة توصيل الدواء، تقنية قليلة التدخّل، التوصيل عبر الجلد، نفاذية الجلد ،التطبيقات الطبية الحيوية .