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Microneedle pill for oral administration

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ABSTRACT

Microneedle delivery technology is an novel technique of administration of drug. Initially they have been used in Dermatological therapies such as acne and dark spots removal and now they are using in vaccination as they causes painless injection of the vaccine and also self-administrable. As it administration is painless and with high efficacy. Based on this technique scientists have developed an oral administrable pill which was more preferable by patients as they are easy way for administration. Microneedle pill was helpful for the patients to come from the disadvantages of injectables. The main advantage of the microneedle pill is painless and direct administration directly in to blood stream with high efficacy and high bioavailability. Microneedle pill administers directly into the blood stream at two different sites of the gastrointestinal tract that is in stomach walls and intestinal walls.

Keywords: Microneedle pill, Microneedle, Oral drug delivery, Hallow microneedle, Solid microneedle Gastrointestinal tract.

INTRODUCTION

Micro needle pill is an novel approach of the drug delivery that can able to replace the painful parenterals without any changes in the bioavailability and on set of action , while as the oral administration having delay to attaing therapeutic concentration and slow onset of action. To overcome these disadvantages scientists had developed the microneedle pill that can be self administrable, painless and with fast onset action as the microneedle administers directly into the blood stream, there are two main sites stomach and intestine in this sites they release the drug as the GI tract is lack of pain receptors they administer painlessly into the blood stream.

Microneedle delivery technology

Microneedles have been in developments in cethelate 80s. But became the subject of significant research starting in the mid1990's. Microneedle based technology has been extensively evaluated for transdermal drug and vaccine delivery to many parts of body like

1. Solid microneedles for skin pretreatment to increasing permeability.
2. Microneedles coated with drug that dissolves off in the skin.
3. Polymer microneedles that encapsulate drug and fully dissolve in the skin.
4. Hollow microneedles for drug infusion into the skin. [1]

Poke with patch approach or Solid microneedles

It involves piercing an array of solid microneedles into the skin followed by application of the drug patch at the treated site. Transport of drug across skin can occur by diffusion or possibly by iontophoresis if an electric field is applied. [2]

Coat and poke approach

In this approach needles are first coated with the drug and then inserted into the skin for drug release by dissolution. The entire drug to be delivered is coated on the needle itself. Dip and scrape approach is a variation of this approach, where microneedles are first dipped into a drug solution and then scraped across the skin surface to leave behind the drug within the microabrasions created by the needles [2].

Biodegradable microneedles or polymer microneedles

It involves encapsulating the drug within the biodegradable, polymeric microneedles, followed by the insertion into the skin for a controlled drug release [2, 3]

Hollow microneedles

It involves injecting the drug through the needle with a hollow bore. This approach is more reminiscent of an injection than a patch [4]. Microneedles was made up of silicon, titanium, stainless steel and polymers [5]. Such that they can easily penetrate into skin. They doesn't leave any scare as holes made by needles are so minute and recovery is fast, painless.

Oral administration via microneedle pill

Researchers have found that insulin can be protected in a chemical coating known as a novel polymer, bringing the chance of oral capsule, ever closer. [12] The coating is a key step to ensure that pill form is not broken down by enzymes and rendered useless before entering the blood stream [10, 11]. Administered into the Gastro intestinal tract (As there are no pain receptors) mainly at two different sites mainly that is at stomach and at intestine. They contain compressed form that facilities quick absorption after administration. [6] There, they have been utilized to painlessly overcome the barrier posed by the stratum corneum, the outermost layer, without eliciting pain receptors in the deeper layers of the skin. The GI tract, unlike the skin, lacks a stratum corneum-like barrier and, instead, is coated by mucus with the GI epithelium immediately accessible underneath. The use of microneedles for oral delivery is motivated by:

1. The potential for a platform capable of delivering orally a wide range of therapeutics with minimal requirement for formulation,
2. The insensate nature of the GI tract enabling painless microinjection,
3. The capacity of the GI tract to tolerate the passage of sharp objects and mucosal disruption as supported by the low rate or lack of complications associated with small sharp body ingestion and polypectomy.

In vivo proof of concept studies surrounding the use of needle-based systems in the GI tract of pigs have recently been carried out. [18] The kinetics of delivery of a model biologic, insulin, were explored as a result of microinjections in various locations in the GI tract and compared to traditional subcutaneous administration. Bio availability is high when administered via microinjection in the stomach and duodenum as compared to the skin. Specifically, onset time was reduced by almost 20 minutes compared to subcutaneous injection. [9]

Administrated in stomach

Generally the food we take was stored in stomach about two hours. So, injection of microneedle made easy and stomach walls are highly reconstructable and painless but there is drawback as in stomach there is vigours movements (peristalsis) of muscles, pH, Temperature and there is chance of exposure of the insulin with food materials and other drugs. [13]

Working of pill

So, to overcome the above drawbacks scientists have developed scientists had developed a ingestible device known as the "Self–Orienting Millimeter Scale Applicator" (SOMA), is inspired by the self orienting leopard tortoise ,a species that can flip itself over when on its back. The SOMA's shape and density distribution were optimizied so that the microneedle lands in stomach in the same orientation every time. Approximately the size of pea, the SOMA houses a needle and its injection is controlled by a spring held in place by a sugar disc. The sugar disc allows the humidity in the stomach to serve as the trigger of the micro – injection, and the solid needle enables delivery of a sufficient dose of the

drug. Its size and material make up are similar to previously approved FDA ingestible devices. [14]

Administrated in intestine

Capsule that are injected in intestine are coated with pH sensitive materials such that drug delivery occur at that particular part. In intestine particularly small intestine is richly supply with the blood vessels there is high absorption rate. [15, 16]

Working

Working or administration into the blood stream is based upon the type of the microneedle. There are two types of microneedles, they are

- Hallow microneedle.
- Solid microneedle

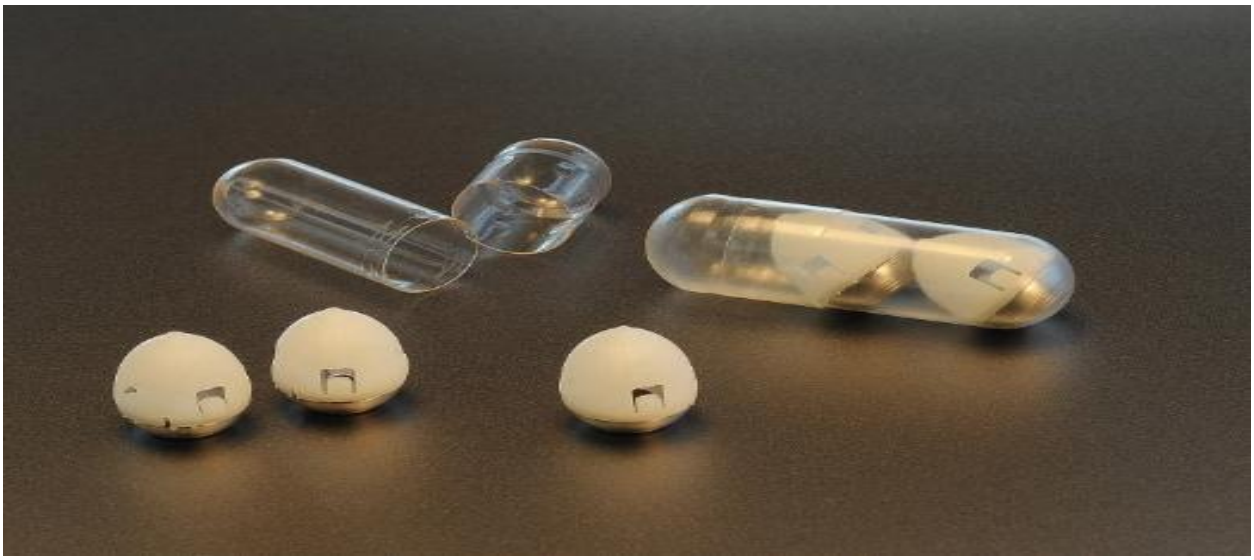

Figure: 1 Microneedle Pill - Inject to Stomach Walls- Soma

Hallow microneedle

In case of hallow microneedle after dissolving the coating, the capsule compress the peristalsis and administer as shown in Figure:-2 [17]

In the above image the mechanism of drug release was shown in 3 steps

a. Entry on pillinto its specific site
b. Dissolving of the outer pill coating
c. Compression of peristalsis and insulin delivery into blood stream

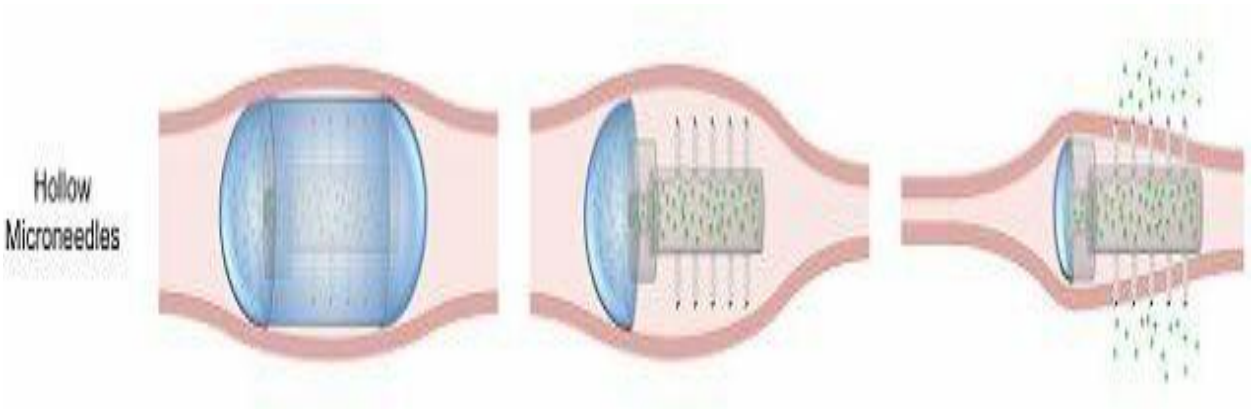

Figure: 2 Hallow Microneedle

Solid microneedles

In case of solid microneedles, the detaches in to small needles and inject them in to the intestinal walls as shown in the Figure: 3
PILL release the insulin 3 steps

a. Compress the peristalsis
b. Dissolving of outer coating
c. Release of microneedles and they are adhering to w

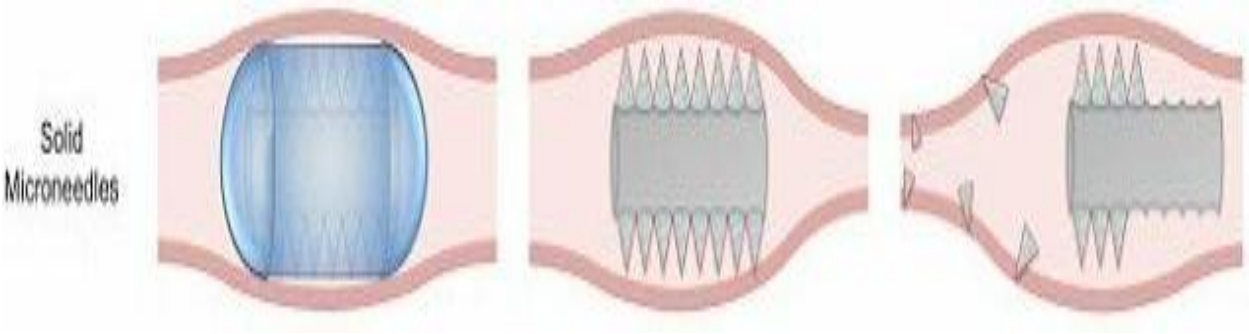

Figure 3: Solid Microneedles

Advantages of microneedle

- Self administrable
- Painless injection.
- Onset of action is fast.
- Microneedle is easily eliminated via faeces.
- Can replace regular of injections.
- High efficacy.

Disadvantages of microneedle pill

- Cannot be given to an uncousious patient.
- Cannot be given to patient who are facing difficulty in swallowing.
- Should be given to the patients who are suffering with Haemoplilia and Inflammatory bowel diesase as they causes internal bleeding. [17]
- Cannot be given to the patients who are suffering with vomitting or diarrheoa as the drug delivery may interecpt.
- Compression of the peristalsis may not completely done.

CONCULSION

In future there will be development and usage of the Microneedle drug delivery technology that promotes bioavailability, usage was simple via oral administration with high efficacy. By using this micro needles may improve the effective drug delivery and recovery from diseases. The clinical trials were performing for the monitoring of the drawbacks and other side effects. The SOMA technique developed has high efficacy in delivery by preventing exposing with other drugs and food materials. By direct injecting into the blood stream via micro needle pill. These micro needle drug deliveries are painless and self-administrable its usage is safe and comfortable.

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