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NEEDLE FREE INJECTION: AN OVERVIEW

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ABSTRACT

Needle free injection technology was developed to reduce the number of needle stick accidents and associated problems. A comprehensive literature review was completed regarding needle free injection technology and its applications, advantages over needle injections, their components and types such as powder injection, liquid injection, depot or projectile injection. This review describes needle free injection technology involving the generation of force by using compressed gas upon actuation in order to deliver a drug at very high speed through a nozzle. This review also describes injection methods that use a spring load jet injector, battery powdered jet injector, and gas powdered jet injector. An overview of marketed products, recent trends and other needleless drug delivery systems is given. Needle free injection technology is growing and has the potential to make the administration of medicine more efficient, safe and convenient.

KEYWORDS: Needle free injection technology, Novel, Powder injection, Liquid injection, Depot, Projectile injection, jet injector.

INTRODUCTION [1-6]

Needle-free injection system or Needle-less injection technology or Needle-free injection technology was first introduced by Marshall Lockhart in 1936. Needle-free technology offers novel ways to introduce various medicines into patients without piercing the skin with a conventional needle.

The term ‘needle free’ is used to describe an extensive range of drug delivery technologies, which consists of technologies that do not have a needle but make use of electrophoresis to drive drugs through the skin, technologies that use one or more very small needles, but needles nevertheless. Needle-free injection (NFI) systems are novel ways to introduce various medicines into patients without piercing the skin with a conventional needle.

Injections are a popular mode for delivering drugs in order to prevent and treat various diseases. But it is an invasive method of drug administration as it causes tissue damage. Injections can be a source of disease transmission, particularly when needles are re used and used incorrectly. To overcome obstacles related to needle-based injections, needle- free injection technologies have gained popularity during the past few years and offer many benefits. These technologies are meant for injecting liquid formulations, as well as injecting drugs and vaccines in a solid particle dosage form.

Needle-less system is based on the principle of electrophoresis to deliver the medicament through the skin. These devices are easy to use; it does not require any skilled person. This review is inclined on the needle-less injection system which gives detail information about the system. Today, they are a steadily developing technology that promises to make the administration of medicine more efficient and less painful.

There appears to be tremendous opportunity for needle-free technology to have major impact in the industry. It is likely that dramatic change may occur only when a large pharmaceutical company adopts needle-free technology and demonstrates its versatility, acceptance and value in major therapeutic area.

ADVANTAGES[7-10]

1. Prevent skin puncture hazards and its destruction; also, does not cause problem of bleeding or bruising and minimal skin response.
2. Imparts fast drug delivery and better reproducibility as compared to invasive drug delivery systems and hence enhance bioavailability when compared with invasive drug delivery systems.
3. Better drug stability during storage as it is delivered in dry powder form especially for water sensitive drugs.
4. Avoids problems of reconstitution and any effect of shearing.
5. Elimination of needle phobia.
6. Self-administration is feasible with needle free injections.
7. Improves immune response to vaccines. Immunization of influenza, tetanus, typhoid, diphtheria, pertussis, and hepatitis A vaccines can be delivered by needle free injections.
8. Bioequivalence has been demonstrated enabling the development of generic drug proteins.

DISADVANTAGES[11-13]

1. Method is complex and expensive.
2. All systems are not fitted into one size.
3. Need for personnel training and maintenance.
4. It is not applicable for Intravenous route.

COMPONENTS[14-20]

Needle-free injection device (Figure 2) consists of 3 main components:

- **Injection device:** It has a drug chamber and is designed such that self administration is possible. The device is made-up of plastic. Sterility is maintained throughout the device. It has a sterilized needle-free syringe which is made of plastic.
- **Nozzle:** The nozzle serves as passage for the drug and serves as the skin contacting surface. The nozzle has an orifice through which the drug enters skin when injected. The diameter of orifice typically is 100 μm. The nozzle releases drug particles at a typical speed of 100 m/s with a depth of 2 mm. The most common orifice size is 0.127 mm, comparable to a 25-gauge needle. Thus, this injection is painless, the patient feels tap of gas on the skin which is like flicking your finger against your skin.
- **Pressure source:** It is important for delivering a drug forcefully into the systemic circulation via the skin. The pressure source can be a mechanical method which stores energy in a spring and is released by pushing a plunger to provide the necessary pressure. It has a pressure storage method that utilizes compressed gas in gas-cartridge. The most popular gases used in devices are carbon dioxide or nitrogen. Pressurized metal air cartridges are often provided for access in portable units. The precision of drug delivery and stress imposed on the product is influenced by device design.

The device must assure the generation of sufficient high pressure to cause skin puncture as well as not harming the drug molecule. Fragile drug molecules are susceptible to damage due to high pressure (e.g., monoclonal antibodies). Hence, devices may vary in design depending upon the drug for which they are used.

TYPES[21-30]

Needle-free injection drug delivery systems are classified as follows:

1. Powder injections
2. Liquid injections
3. Depot or Projectile Injection

❖ **Type 1 - Powder injections**

Design of powder injection systems: These injections consist of a chamber filled with solid drug content and a nozzle for firing drug particles into the skin by utilizing the power source which typically is compressed gas. The injection has a diaphragm (a few microns thick) on either side of the chamber to cover the drug chamber.

Mechanism of powder injection

(a) Particles exist from the nozzle along with a gas stream.
(b) Particles impinge the skin surface leading to formation of a hole into the skin with the progression of the injection.
(c) Drug particles get deposited in a spherical pattern at the end of the hole and penetrate across the stratum corneum.
(d) After their penetration into the skin, drug particles get distributed completely into the stratum corneum and the viable epidermis.

Powder injection is accomplished by a light gas gun. It provides the required particle velocity by use of an accelerating piston which accelerates and carries particles with it. Particles leave piston surface by means of a de- acceleration mechanism which slows down the piston. This leads to ejection of particles that act on the target tissue area.

Ideal characteristics of powder particles

- In the case of powder injections the drug particle size distribution, quality, its physical and chemical stability are extremely important.
- Powder in an injection may be a whole drug or a formulation containing drug with excipients for dilution purposes or to stabilize the product. Therefore, drug and other excipients must be compatible with each other.
- Particle size plays an important role in penetration into the stratum corneum; hence it should remain uniform throughout usage and storage.
- The particles must be robust enough to survive the highly energetic gas jet within the device as well as ballistic impact with the skin.
- As the particles strike the skin at a high velocity, they must be strong. The particles have been clocked as fast as 900 meters per second, with 400 to 600 meters per second being the more typical range.
- In order to exert required effects in the body after being absorbed into systemic circulation, the drug particles should have proper diffusion within the skin.
- For skin penetration at a high velocity, the powders must have particle densities of about 1g/cc and mean diameter greater than 20 μm.
- In these injection systems, the powders are processed by compression, milling, sieving, and more scalable methods like spray drying, freeze drying, fluid bed drying, spray coating of seed particles, solution filling and drying pre formed hydrogel beads and emulsion techniques to form erodible micro particles.

❖ **Type 2 - Liquid injections**

The basic principle of this injection is "if a high enough pressure can be generated by a fluid in intimate contact with the skin, then the liquid will punch a hole in to the skin and be delivered in to the tissues in and under the skin." Although the same principle is applied as in powder, there is a difference in the actual design and operation of the powder injection devices. These systems use gas or spring, pistons, drug loaded compartments and nozzles. Typically, the nozzle has an orifice size of about 150 to 300 μm.

Mechanism of liquid injections

a. Impact of a piston on a liquid reservoir in the nozzle increases the pressure, which shoots the jet out of the nozzle at high velocity (velocity > 100m/s)
b. The effect of the jet on the skin surface starts the formation of a hole in the skin through erosion, fracture, or other skin failure mechanisms.
c. Further impingement of the jet increases the depth of the hole in the skin. If the volumetric rate of hole formation is less than the volumetric rate of jet impinging the skin, then some of the liquid splashes back towards the injector.
d. The accumulation of liquid in the hole occurs because of a deeper hole in skin which slows down the incoming jet. Hence, further development of a hole is stopped. The dimensions of the hole are established very early in the process (a few tens of microseconds) from the time of impact. Stagnation of the jet at the end of the hole disperses the liquid into the skin in a near-spherical shape.

❖ **Type 3 - Depot or projectile injections**

These systems are designed for administration of a drug into muscles. They create a store of drug into muscles that is released continuously over a desired time period. Types of injection methods include:

- Spring load jet injector
- Battery powdered jet injector
- Gas powdered jet injector

Spring load jet injector: The spring is released by hitting trigger leading to generation of jet stream of drug for subcutaneous, intramuscular or transdermal delivery of a drug. The activated spring load must be redrawn manually for the next administration. Examples: Dermojet®, Medi-jector®

Battery powdered jet injector: This method has a small rechargeable battery pack to retract the dosing device. The dosing device has an electric piston which is automatically redrawn after dosing. This is good for continuous use. This type of injector is similar to a battery powered hand drill. Used for subcutaneous, intramuscular or transdermal delivery of drug depending on the recommended method. Examples: Intra Dermal Application of Liquids (IDAL) ® Intervet, Boxmeer.

Gas powdered jet injector: This system consists of an air/gas cartridge which is attached to the gun through a tubing system that delivers power to the piston after trigger actuation; it releases the piston and creates jet stream of drug. It is suitable for subcutaneous, intramuscular or transdermal use. Examples: Biojector®, Pulse® Needle-Free Felton, Lenexa, Ks. Agro-Jet®/Med-Jet®- Mit, Montreal, Quebec, Canada.

MANUFACTURING PROCESS[31-36]

There are several methods for manufacturing the needle-free injection system. Here the process focuses on the production of an air-forced system. These systems are made through the following procedure which involves molding the pieces, assembling them, decorating and labeling. Typically, the individual pieces are produced off-site and assembled by the needle-free injection system manufacturer.

To prevent the spread of disease all the manufacturing processes are done under sterile condition.

Molding: This is the first step of manufacturing process. Here the plastic pellets are kept into a large holding bin on an injection molding machine. The pellets become flowable after attaining the required temperature; then the material is allowed to pass through the hydraulically controlled screw.

Assembling and labeling: The next process is to assemble the pieces and transport the parts to an assembly line. Various events occur during this production phase. Each printing is made by these machines and is so precise because these machines are specially calibrated.

Depending on the complexity of the device, either manually or with the assistance of machinery, the devices are assembled. This involves inserting the various pieces into the main housing and attaching any buttons.

Packaging: The next step after the assembling process is packaging. The systems are wrapped in sterile films before packed into card board boxes or plastic boxes. Packing of each part reduces the movement, which prevents damage. An

instruction manual (includes safety information) is provided for consumer products. Then these boxes are stacked on pallets and shipped via truck to distributors.

Quality Control: Quality control checks are performed throughout the manufacturing process. Checking of the plastic components is done by line inspectors to assure that the needle-free injection devices confirm all the predetermined specifications. The first test method is visual inspections, but to check the dimensions (size and thickness) the measuring equipment is also used; instruments like laser micrometers, calipers and microscopes are used. Inspectors also check to make sure the printing and labeling is correct and that all the parts are included in the final packages.

Each manufacturer must conform to various production standards and specifications. Detailed records related to production and design must be kept because announced and unannounced inspections may occur to ensure that these companies are following good manufacturing practices.

Micro-needle[37-42]

Micro-needle patches, as the name suggest, employs the use of thousands of tiny spikes all around 750 µ long. These patches are pressed onto a person's skin while the spikes pierce the outer most layer of the skin so as to deliver the drug, while the piercing is not deep enough to hit the blood vessels or even the pain receptors so as to cause pain.

Different types of micro-needles have been developed from the sophisticated metallic to plastic ones. While some are just "coated" with the drug, others are hollow having a liquid vaccine or the formulation filled inside. Micro-needle patches have not only proven to be highly effective but have even shown better patient compliance. However, certain limitations are associated with the use of micro-needle patches.

- Larger doses require bigger patch size.
- The formulation must be able to "coat" or "stick" on to the spikes on needle surface.
- In cases, if the needle itself is made of the drug, the formulation must have required the physicochemical property to maintain a sharp tip for adequate skin penetration.
- The depth of penetration of the micro-needle may differ from person to person, based on thickness, the toughness of the skin and reproducibility of the application.
- Movements of the body or the body part upon which the patch is applied may lead to dislodging of the needle.

MARKETED PRODUCTS[43-50]

Product Name	Company	Type of system	Actuation mechanism	Department of penetration	Drug Types
Medi-jector vision	Antares Pharma Inc.	Liquid based needle free injection	Spring	Subcutaneous	Insulin
Biojector 2000	Bioject	Liquid based needle free injection	Compressed gas	Subcutaneous, Intramuscular.	Liquid
Vitajet3	Bioject	Liquid based needle free injection	Spring	Subcutaneous	Insulin
Iject	Bioject	Liquid based needle free injection	Compressed gas	Intramuscular, Subcutaneous, Intradermal.	Liquid
Intraject	Weston medical	Liquid based needle free injection	Compressed gas	Subcutaneous	Liquid
Penjet	Penjet corporation	Liquid based needle free injection	Compressed gas	Intramuscular, Subcutaneous, Intradermal.	Liquid

Injex30	Injex	Liquid based needle free injection	Spring	Subcutaneous	Insulin
Injex150	Injex	Liquid based needle free injection	Spring	Subcutaneous	Insulin
Crossject	Crossject	Liquid based needle free injection	Spring	Intramuscular, Subcutaneous, Intradermal.	Liquid
Depixol Depo injection	Lundbeck Limited	Depot based needle free injection	Compressed gas	Intramuscular	Liquid
Powderject system	Powderject pharmaceuticals	Powder based needle free injection	Compressed gas	Intradermal	Powder
Miniject	Bio valve	Liquid based needle free injection	Spring	Intramuscular, Subcutaneous, Intradermal.	Liquid

CONCLUSION

One advantage of the needle-free technique is that it reduces patients' anxiety about using needles. Among the many additional advantages are extremely quick injections compared to conventional needles and few needle disposal problems. It can help the pharmaceutical sector increase sales of its products. Additionally, it has the potential to improve results and boost adherence to dosing schedules. In order to maximize efficiency, needle-free injection systems may be tailored to each activity. The development of needle-free drug delivery options is being supported by a number of organizations and groups. A number of protein-based treatments are quickly entering the market thanks to the biotech revolution. It might be difficult to use a needle-free method. Any new technology requires training and instruction for workers. The curiosity in such technology may also be impacted by startup and training expenses.

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