Design and Fabrication of Biodegradable Microneedle Using 3D Rapid Prototyping Printer

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Abstract. Microneedle is known as transdermal drug delivery (TDD) devices that uses to deliver biological fluid into veins and needle that use to tear skin to collect blood sample. It involves with various parameters and designs. This device gain attention as its benefit can eliminate pain and more convenient compared to intravenous injection due to its micron size. Typically, microneedle is fabricated using MEMS technology. However, this technology requires few processes such as deposition, etching and moulding, as well as consume much times. This paper presents a work of design and fabrication of solid microneedle using 3D rapid prototype printing. A few types of microneedles are designed and they are analysed in terms of stress and force characteristics. Also, it will study the ability of a few materials to withstand stress while force exerted on it. The selected materials are polyvinyl alcohol (PVA), polylactic acid (PLA), polyester resin and acrylonitrile butadiene styrene (ABS). The results show that PVA has the highest ability to withstand force compared other materials. As conclusion, the design and fabrication of microneedle using 3D rapid prototyping printer is succeed using PVA material and real post-analysis can be conducted to test the capability for medical practice.

1. Introduction
Intravenous injection is a traditional method to deliver drug, but limitations of injection can cause pain and tissue trauma [1-4]. Hence, microneedle is invented as alternative method which may give the same function. Microneedle receive an attention among medical expertise and patients as the penetration of microneedle is painless and convenient since it is smaller in size compared to intravenous injection [5]. Previously, this device is fabricated using micro-electro-mechanical system (MEMS) [6-8]. Although, microneedle receive an attention among medical expertise and patients, this device is not widely used in medical field due to the long fabrication period. Recently, there are studies on microneedle fabrication that implement 3D printer, since it has capable to print in micron size [9-10]. Hence, this study presents a work on solid microneedle design using biodegradable material and will fabricate using 3D rapid prototyping printer.
2. Microneedle Design and Fabrication
Basically, microneedle can be categorised into two types; i. hollow microneedle, and ii. solid microneedle. Hollow microneedle is designed to be used to deliver liquids such as medicines to blood vessel. While, solid microneedle is designed to be similar as lancet to drawing blood. In design studies, there are a few parameters that can be considered, such as the height of needle, shape of needle, materials and the tip. All the parameters need to be analysed before undergo fabrication process.

Previously, microneedle is made up from SU-8, silicon, metals, polymers and glass and silicon dioxide through MEMS technology [7]. Despite that, fabrication period using MEMS technology is too long due to many processes that should be conducted, such as deposition, etching and etc [8]. Nowadays, the 3D printer technology has upgraded in terms of its resolution and accuracy that allow the printer to print using many materials and size in micron. The printing size is suitable with size of microneedle. Hence, many researchers introduce the use of 3D printer to fabricate microneedle.

3. Biodegradable Materials
Biodegradable material can be described as a material that can be decomposed rapidly by action of microorganisms. Material with high ability to withstand force is most likely to be chosen in fabricating microneedle. Four material tested in this study are Acrylonitrile Butadiene Styrene (ABS), Polyester Resin, Polylactic Acid (PLA) and Polyvinyl Alcohol (PVA). Table 1 shows the properties of each materials [11-12].

Table 1. Materials and its properties.

| Material Properties | ABS  | Polyester Resin | PLA  | PVA  |
|---------------------|------|-----------------|------|------|
| Elastic Modulus (GPa) | 2.00 | 4.41            | 3.50 | 41.30|
| Poisson’s Ratio     | 0.394| 0.403           | 0.500| 0.140|
| Shear Modulus (GPa) | 0.32 | 1.40            | 2.40 | 1.90 |
| Mass Density (g/cm³) | 1.02 | 1.2             | 1.3  | 1.31 |
| Tensile Strength (MPa) | 30  | 103             | 50   | 71.1 |
| Thermal Conductivity (W/K.m) | 0.2256 | 0.1700 | 0.1300 | 0.3100 |
| Specific Heat (J/K/kg) | 1386 | 565            | 1800 | 5000 |

4. Methodology
This work has a few stages in order to complete the fabrication process. It consists of design the microneedle (MN) using a few parameters, analyse the design using Solidworks simulation, determination of suitable parameters and material and fabrication process using 3D printer. Fig. 1 shows the flow of the works.
4.1 Design

A SolidWorks 2017 is used to design the microneedle. This study focuses on conical and pyramid design as shown in Fig. 2. Table 2 shows the proposed parameters that will be analysed in order to determine the suitable parameters to be printed for microneedle. The parameters consist of shape, number of needles, base size and height of microneedle as well as materials. The value of pressure and force are set to be constant during the simulation analysis.

![Figure 2. The 3D design of the microneedle; (a) conical design (b) pyramid design.](image)

| Microneedle Design Variable | Value                     | Type of Variable |
|----------------------------|---------------------------|------------------|
| Shape of microneedle       | Conical, Pyramid          | Manipulated      |
| Material                   | ABS, Polyester Resin, PLA, PVA | Manipulated      |
| Base area of microneedle   | $36\pi$, $49\pi$          | Manipulated      |
| (µm)                       | $36 \times 10^4$, $49 \times 10^4$ |               |
| Height of microneedle      | 350, 450                  | Manipulated      |
| (µm)                       |                           |                  |
| Number of needles on patch | Single and triple         | Manipulated      |
| Pressure applied on tip of microneedle | 3.18 MPA | Constant |
| Force applied on base of microneedle patch | 10kPa | Constant |
4.2 Simulation
SolidWorks 2017 provide a simulation features to test the microneedle that implemented with different materials. Human skin exerts 3.18 MPa resistance, which means each needle undergoes a test to resist the pressure exerted by the skin. A force varies from 10 kPa to 100 kPa is placed on the base of the microneedle patch to allowed penetration. However, this paper is focused on 10 kPa force applied. A simulation performed for each design by fixed these two values. The penetration displacement of each design also obtained from the simulation.

4.3 Determination of the suitable parameters and material
From the simulation, the results are coming out according to the selected materials. This stage determines the suitable parameters for conical and pyramid microneedle design that can be applied during microneedle fabrication.

The design that satisfy the ability to withstand stress and penetration of human skin is compared among the fourth materials. The result from study show design with 450 µm height, 49π µm base area and triple needle on a patch for conical design and 450 µm height, 49x10^4 µm base area and triple needle for pyramid design has meet the requirement to penetrate human skin. Table 3 and 4 shows the final comparison of conical and pyramid design for each material.

| Material  | ABS         | Polyester Resin | PLA          | PVA          |
|-----------|-------------|-----------------|--------------|--------------|
| Maximum stress able to withstand (N/m²) | 2.024e+006 | 1.995e+006 | 1.500e+006 | 2.906e+006 |
| Displacement (µm) | 56.66 | 2.514 | 28.13 | 353.9 |

| Material  | ABS         | Polyester Resin | PLA          | PVA          |
|-----------|-------------|-----------------|--------------|--------------|
| Maximum stress able to withstand (N/m²) | 2.202e+006 | 2.191e+006 | 2.070e+006 | 2.890e+006 |
| Displacement (µm) | 49.35 | 2.213 | 24.47 | 394.2 |

4.4 Fabrication
SLA 3D printer is chosen to fabricate a microneedle. The mechanism of this printer is it shines UV light into a vat full of selected material which is PVA to cure each layer. This printer capable of printing layer thinner than 10 microns, making it far more detailed compared to FDM printers. Besides, this printer is a low-cost printer and require minimum thirty minutes for every session for printing the microneedle. Fig. 3 shows the printed microneedle using SLA 3D printer.
5. Result and Discussion

In this study, an ability of material to withstand stress and displacement changes after force applied on the design are focused. 10 kPa force is placed on the base of the microneedle patch and 3.18 MPa pressure is positioned on the top of microneedle. The design undergoes a simulation features using SolidWorks 2017 software. PVA is selected as the practicable material to fabricate a microneedle. Data gain from the simulation shows that PVA has the highest ability to withstand stress (force per unit area). From the simulation features, the displacement shown indicating the potential of each design to penetrate human skin. PVA has shown that it can penetrate the deepest and suitable among the rest materials. PVA able to withstand high stress due to its properties which is high tensile strength and high elastic modulus compared to the rest materials. Final stage of this study is to fabricate the microneedle design using SLA 3D printer. Current limitation of microneedle fabrication is lengthy manufacturing period. SLA 3D printer is one of the latest technologies that allowed fabrication using biodegradable material that low-cost and completed in short period.

6. Conclusion

This study constructed based on the comparison of the design, ability to withstand stress and material selected in fabricating a microneedle that can fulfil the requirement to penetrate human skin and at the same time not cause damage towards skin and the needle itself. The simulation result show that PVA is the most trustworthy material in manufacturing microneedle.

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