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DESIGN AND DEVELOPMENT OF A SINGLE-USE DISPOSABLE SAFETY SYRINGE

MOHD NASRI ISHAK

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By

MOHD NASRI ISHAK

Thesis Submitted to the School of Graduated Studies, University Putra Malaysia, in Fulfillment of the Requirements for Degree of Master of Science

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Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfilment for the Degree of Master of Science

DESIGN AND DEVELOPMENT OF A SINGLE-USE DISPOSABLE SAFETY SYRINGE

By

MOHD NASRI BIN ISHAK

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Chairman : Associate Professor Abd. Rahim Abu Talib, PhD Ir
Faculty : Engineering

Safety syringe is a syringe which has safety features. It is designed to overcome two main problems of using a normal syringe. First is to reduce the use of syringe which may lead to cross-infection of disease and the second is to avoid needle stick and sharp injuries. The need of single-use safety syringe arise due to these concerns. There are a lot of patents found in modern application today. Although many single-use safety syringes have achieved public acceptance and commercial success in the marketplace, many single-use syringes present a variety of problems. To begin with, it is found that some syringes which claim to be "single-use" in actuality can be reused with user intervention. Some syringes are designated as "single-use" solely because they are supposed to be discarded after use by following their instruction; however, nothing prevents their reuse. Some syringe designs expose the drug or bodily fluid contained therein to reactive components of the syringe, e.g. a spring used to retract the plunger. Moreover, some syringes, although cannot be reused, present health risks to the medical personnel handling them. In addition, there are some factors which may need to be considered such as their complex design, and high cost of contemporary components. According to a market survey in Malaysia, safety syringe has to maintain the same procedure to operate as the normal syringe. Eventhough there are a variety of safety syringes available in the market, they do not fulfill the basic requirements of the medical practices. Due to this concern, a new design improvement of safety syringe is proposed to enhance the design of an existing safety syringe.

The objectives of this research are to develop the design of safety syringe, to fabricate the prototype of safety syringe and to test the functionality of the prototype safety syringe. The research starts by identifying the needs and goals. This includes recognizing the client needs, modifying existing product, defining the method to achieve the goals, and clarifying the objectives. Then it proceeds to the next processes which are concept generation, synthesis, and analysis. For these processes, the focus includes the

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morphological chart, product component decomposition diagram, and combining idea concept. Next stage is the preliminary design which includes the product geometry design, configuration design, and parametric design. And after that comes the detail design which consists of drawing development and modelling. The product can only proceed to this stage if the preliminary design satisfies all of the objectives, otherwise the design process will go back to the original concept which are the generation stage, synthesis, and analysis until the design meets the requirements. Then the design can move to the next stage, which is prototype development. The design product is also analysed by using engineering software such as SOLIDWORKS before fabricating a new prototype. The experimental test is carried out in order to validate the prototype. The result of this study is a new design of safety syringe which meets the main characteristics as stated before. The newly designed system will allow the user to use it single-handedly and easy to be disabled after use.

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Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk Ijazah Master Sains

REKA BENTUK DAN PEMBANGUNAN PICAGARI KESELAMATAN PAKAI-BUANG

Oleh

MOHD NASRI BIN ISHAK

Oktober 2017

Pengerusi : Profesor Madya Abd. Rahim Abu Talib, PhD Ir
Fakulti : Kejuruteraan

Picagari keselamatan ialah picagari yang mempunyai ciri-ciri keselamatan. Ia direka untuk mengatasi dua masalah utama menggunakan picagari normal. Pertama, picagari keselamatan dapat mengurangkan penggunaan semula picagari yang boleh membawa kepada jangkitan silang penyakit, dan yang kedua dapat mengelakkan kecederaan yang berpunca dari jarum dan benda tajam. Oleh itu, terdapat keperluan terhadap penggunaan picagari keselamatan sekali guna akibat kebimbangan ini. Terdapat banyak paten dijumpai di dalam aplikasi moden hari ini. Walaupun banyak picagari keselamatan sekali guna telah mencapai penerimaan orang ramai dan kejayaan komersial di pasaran, ada picagari sekali guna yang menghadapi pelbagai masalah. Pertama, didapati bahawa beberapa picagari yang didakwa sebagai "sekali guna" sebenarnya boleh digunakan semula dengan campur tangan pengguna. Sesetengah picagari diletakkan di bawah "sekali guna" semata-mata kerana ia sepatutnya dibuang selepas digunakan jika pengguna menurut peraturan yang ditetapkan; tiada yang menghalang penggunaan semula. Sesetengah reka bentuk picagari mendedahkan dadah atau cecair badan yang terkandung di dalamnya kepada komponen reaktif picagari, contohnya spring yang digunakan untuk menarik balik pelocok. Selain itu, beberapa alat suntikan, walaupun tidak boleh diguna semula, membawa risiko kecederaan kepada kakitangan perubatan yang mengendalikan picagari tersebut. Di samping itu, terdapat beberapa faktor yang perlu dipertimbangkan seperti reka bentuk yang canggih, dan kos komponen kontemporari yang tinggi. Menurut kaji selidik pasaran di Malaysia, picagari keselamatan perlu mengekalkan prosedur yang sama seperti picagari biasa. Walaupun terdapat pelbagai picagari keselamatan di pasaran, ia tidak memenuhi keperluan asas amalan perubatan. Oleh sebab kebimbangan ini, inovasi reka bentuk baru picagari keselamatan diperkenalkan untuk menambah baik reka bentuk picagari keselamatan yang sedia ada.

Objektif kajian ini adalah untuk melakukan penambahbaikan reka bentuk picagari keselamatan, membangunkan prototaip picagari keselamatan, dan menguji prototaip picagari keselamatan. Kajian ini akan bermula dengan mengenal pasti keperluan dan

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matlamat. Ia termasuk mengenal pasti keperluan pelanggan, mengubahsuai produk sedia ada, menentukan kaedah untuk mencapai matlamat dan memperjelas objektif. Kemudian ia akan diteruskan dengan proses seterusnya iaitu membangunkan konsep, dan diikuti dengan sintesis dan analisis. Fokus dalam proses-proses ini termasuklah carta morfologi, gambar rajah penguraian komponen produk dan penggabungan konsep idea. Peringkat seterusnya adalah reka bentuk awal yang merangkumi reka bentuk produk geometri, reka bentuk konfigurasi dan reka bentuk berparameter. Kemudian, reka bentuk terperinci yang terdiri daripada lukisan pembangunan dan pemodelan dibangunkan. Produk ini hanya boleh diteruskan ke peringkat ini jika reka bentuk awal memenuhi matlamat yang ditetapkan. Jika tidak, proses reka bentuk akan kembali kepada peringkat awal iaitu peringkat penjanaan, sintesis, dan analisis sehingga reka bentuk tersebut memenuhi keperluan. Kemudian reka bentuk boleh berpindah ke peringkat seterusnya, yang merupakan pembangunan prototaip. Produk reka bentuk juga akan dianalisis dengan menggunakan perisian kejuruteraan seperti perisian SOLIDWORKS sebelum mereka prototaip baru. Ujian akan dijalankan bagi mengesahkan prototaip. Hasil kajian ini adalah reka bentuk baru picagari keselamatan bagi melahirkan picagari keselamatan yang memenuhi ciri-ciri utama seperti yang dinyatakan sebelum ini. Sistem reka bentuk baru akan membolehkan pengguna untuk menggunakannya secara bersendirian dan mudah dimatikan selepas penggunaan.

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This thesis was submitted to the Senate of Universiti Putra Malaysia and has been accepted as fulfilment of the requirement for the degree of Master of Science. The members of the Supervisory Committee were as follows:

Abd. Rahim Abu Talib, PhD
Associate Professor, Ir
Faculty of Engineering
Universiti Putra Malaysia
(Chairman)

Rizal Zahari, PhD
Associate Professor
Faculty of Engineering
Universiti Putra Malaysia
(Member)

Mohammad Yazdi Harmin, PhD
Senior Lecturer
Faculty of Engineering
Universiti Putra Malaysia
(Member)

_____
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Professor and Dean
School of Graduate Studies
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Supervisory
Committee: Abd. Rahim Abu Talib, PhD

Signature: _____
Name of
Member of
Supervisory
Committee: Rizal Zahari, PhD

Signature: _____
Name of
Member of
Supervisory
Committee: Mohammad Yazdi Harmin, PhD

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LIST OF ABBREVIATIONS

3D	Three Dimensional
AD	Adjustment Disorder
ANA	American Nurses Association
ASTM	American Section of the International Association for Testing Materials
CATIA	Computer Aided Three-Dimensional Interactive Application
CAD	Computer-Aided Design
CAE	Computer-Aided Engineering
CDC	Centres for Disease Control and Prevention
FMEA	Failure Mode Effect Analysis
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
PP	Polypropylene
PTSD	Post-Traumatic Stress Disorder
Sdn Bhd	Sendirian Berhad
TPR	Thermoplastic Resin
UPMC	University of Pittsburgh Medical Centre
UTS	Ultimate Tensile Strength
WHO	World Health Organization

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CHAPTER 1

INTRODUCTION

1.1. Background

Syringe is one of the most crucial medical devices. It is used as an instrument for injecting or mounting fluid such as medicine, drug, vitamin, and vaccine into the body, or for withdrawing liquid or fluid from the body. It is widely used in the medical field not only for injecting medicine, but also for orally controlling liquid medicine to children or animal without using a needle because of the accuracy and precision in measuring the dose and it is easier to squirt the medicine into the mouth instead of using a spoon. Although this device is a simple one, it has a big impact in our lives.

In our modern application today, there are two main types of syringes which are hypodermic (Lawrence, 2002) and oral (Eastwood, 2014). A syringe with a needle that is fine enough to pierce the skin is known as a hypodermic syringe. Calibrating (marked) in cubic centimetres (cc), millilitres (ml), or units, the hypodermic syringe with smaller capacity (1, 2, and 3 ml) are used most often for subcutaneous or intramuscular injections of medication. Meanwhile, the larger sizes (5, 6, 10, and 12 ml) are normally used to withdraw blood or prepare medications for circulatory administration (Robb, 2014).

Figure 1.1: Photo of the Disposable Syringe
(Source: Mediplus, N.d)

Moreover, in research laboratories, medical-grade disposable hypodermic is applied to measure and deliver reagents and solvents when high precision is not needed due to its reasonable cost, easy and suitability application. For precise measuring of chemical solvent or fluid such as dose medicine, microlitre syringe is the best one instead of the

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syringe barrel. Syringe is also useful for adding liquid in very narrowed space by using another application like the needle tip.

In addition, dentists use dental syringe for the injection of an anesthetic, which consists of a breech-loading syringe fitted with a sealed cartridge containing anesthetic solution (Shahidi Bonjar, 2011). Together with a long needle or cannula, syringes are also useful for delivering fluids through rubber septa once atmospheric oxygen or moisture is being excluded. Examples include the transfer of air-sensitive or pyrophoric reagents, for instance *phenyl magnesium* and *n-butyl lithium* respectively. Syringe drivers may be used with the syringe as well. Some culinary uses of syringes include injecting liquids (such as gravy) into other foods, or to produce some candies. Sometimes a large hypodermic syringe is used without a needle for very small baby mammals to suckle from in artificial rearing.

The second type of syringe is an oral syringe. This type of syringe is normally used as a measuring instrument for volume of fluid medicine in millilitres (ml) unit and to dispense liquid medicine into the mouth. An oral syringe has measurement markings on its barrel (Eastwood, 2014). It looks almost identical to a hypodermic syringe used to inject medicine under the skin except that it has no needle. This explains why there is no threaded tips in oral syringe. Instead, oral syringes have an opening that allows liquid medications to be dispensed into the mouth. Oral syringes are most often used to administer liquid medicine to babies, children and pets. An oral syringe contains and directs liquid medicine much better than a spoon. There are numerous sizes of oral syringes available in the market from 1 to 10 ml and larger. The sizes most commonly used are 1 ml, 2.5 ml and 5 ml (Cyprus, 2016).

Syringe comes in a variety of types and sizes, which is specialized to the intended delivery method. Plastic materials such as polypropylene are normally used as the main material to produce the barrel of the syringes (Schönberger & Hoffstetter, 2016). Syringe also has graduated or printed marks indicating the volume of the syringe and its appearance is crystal clear. However, most modern medical syringes are plastic with a thermoplastic gasket because this type seals much better between the gasket and the barrel so that leakage issue does not happen. Furthermore, they are economical enough to be disposed after being used only once, reducing the risk of spreading blood-borne diseases. Silicone oil is also used in syringe manufacturing as a lubricant for the movement of gasket and plunger in the barrel. For that reason, the selection of latex and silicone oil in the design and manufacture of disposable syringes is very crucial (Oberdorfer, 2000). The other part of the syringe is the tip. The tip is the end of the syringe that holds the needle. The blade is locked to the syringe body which comes with a number of different designs. Perhaps the most popular of these is the *Luer* lock, which merely twists the two together. When the syringe is being connected to something that does not feature a screw lock mechanism, the usage of slip tips is useful and beneficial (Darby, 2011).

The needles are made of stainless steel and come in various lengths and diameters. They are packaged with a protective cover that keeps them from being contaminated. The parts of a needle are the hub, which attaches to the syringe; the shaft, the long part of the needle

that is embedded in the hub; and the bevel, the slanted portion of the tip. The length of the needle is the distance from the point to the hub. Length of needles most commonly used in medication administration ranges from 1 inch to 2 inches. The gauge of the needle refers to the thickness of the inside of the needle and varies from 18 g to 28 g (the larger the gauge, the thinner the needle) (Olsen et al., 2012).

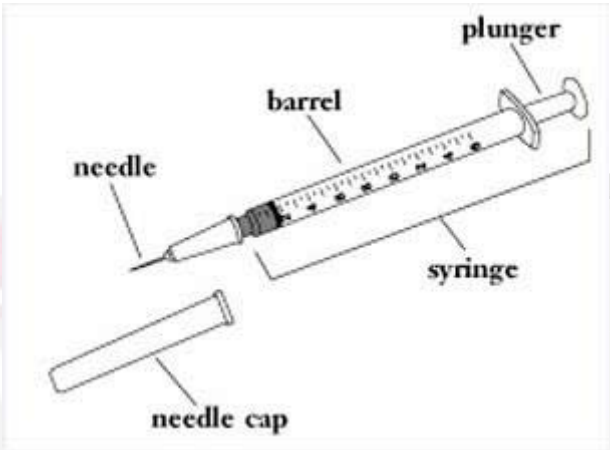

Figure 1.2: The Diagram of the Conventional Syringe and Its Parts
(Source: UPMC, N.d)

In our modern application today, there are two main types of syringes; normal syringe and safety syringe. In some countries, plastic disposable syringe is widely used in hospitals. This type of syringe is low cost, easy to handle and can be thrown away after use (Mazlan et al., 2014). However, the problem occurs when most hospital in some countries does not practice the single use safety syringe, but instead they use the normal syringe. For instance, hospitals in Malaysia do not practice the single-use safety syringe, but they are still using the normal syringe even though they know about the high possibility to get infection (Tong, 2003). For medical syringes, the concern is about the reusability of syringes that can lead to cross-infection of disease and also the issue of needle stick and sharp injuries. Thus the need for a single-use safety syringe arises due to these concerns.

The safety syringe such as "auto disable" or "auto retractable" types are usually imported and expensive to use, and not all the hospitals in some countries can afford to use such safety syringe. Most of the existing inventions are focusing on manually retractable needle, protective cap and plunger as a safety feature. However, most of the existing inventions are designed to retract the needle into the barrel. The design of the existing inventions is good for safety reason, but not convenient for disposal process due to the difficulty of separating the metal (needle) and plastic parts (plunger and barrel). In view of these and other shortcomings of the prior art, there is a need for an improved safety syringe.

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This research presents the design improvement of multi-purpose disposable of safety syringe based on the earlier work reported by Mohd Zabidi (2010) and Abu Talib et al. (2011). The details of the problem and the issue of these existing designs including the difficulty to be manufactured will be discussed in the thesis. Feedbacks from the mould maker and industry experience have also triggered the development of a new design.

1.2. Problem statement

In Malaysia, safety syringe is still not widely used in every hospital. Although there are a variety of safety syringes available in the market, it does not fulfill the basic requirements of the medical practices which are: can be used single-handedly, perform as normal syringe and no additional procedure (Thye & Bakri, 2007). The design by Mohd Zabidi (2010) requires two-handed operation, does not perform like normal syringe and has additional procedure that needs to be followed by the user. While, the design by Basri (2011) does not fulfil the industrial requirement. Due to this concern, a new design of safety syringe is introduced to produce a safety syringe which meets both requirement.

1.3. Research Questions

Below are the research questions which need to be answered in this research:

1. Is the current design (bone structure) workable?
2. What are the criteria to design the best safety syringe?
3. Can this new design be operated and perform as a normal syringe?
4. Can the new design be fabricated?
5. Does the selection of the material affect the production of safety syringe?
6. Why do the industries commonly take *copolymer* as the raw material of the syringe?
7. How much force is needed to operate the design? Is it appropriate by human nature?

1.4. Hypothesis

The current design and patent of safety syringe (bone structure) cannot be fabricated. Thus, a new design which has better safety syringe design is introduced. This new design can be fabricated and can perform its functionality as a normal syringe. The force needed to operate the safety syringe is acceptable in common practice.

1.5. Research Objectives

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The objectives of this research are:

1. To design a multi-purpose disposable safety syringe
2. To fabricate a prototype of multi-purpose disposable safety syringe
3. To test the functionality of the prototype safety syringe

1.6. Scope of Research

This study concentrates on the design of a new multi-purpose disposal safety syringe. Currently, there are a few drawbacks of using safety syringe in the market. Comparing all the designs and patents in the market has given the idea about the characteristic of a new design. Certain tools have been applied such as Failure Mode Effect Analysis (FMEA) and morphological chart. The best three designs are evaluated by using decision matric tools to select the best among them. Furthermore, the prototype of this design will be fabricated and produced. This study also has the scope to deliver the differences and shows the characteristic of *homopolymer* and *copolymer* in term of the strength of the both materials. Besides that, this study also displays the analysis of the design using the software SOLIDWORKS, validate the data with an experimental testing and test the functionality of the safety syringe. For the functionality test, the focus is on the liquid pressure to ensure there is no leakage occur during testing and the minimum force to dismantle the nozzle.

1.7. Thesis Layout

This thesis has been divided into five chapters. The thesis starts with Introduction in Chapter 1, which includes a general background of this study. It contains some explanation of the study, Problem Statement, Research Questions, Hypothesis, Research Objectives and Scope of Research.

Chapter 2 explains the drawbacks of using syringe, the designation of safety syringes and its patents, and the benefits of new development of safety syringe. This chapter also elaborates on the usage of safety syringe in Malaysia. Chapter 3 elaborates on the methodology used that includes conceptualization on designs, material testing, prototype, experimental testing and analysis from software such as SOLIDWORKS.

Chapter 4 shows the results and its discussion on the design analysis from SOLIDWORKS simulation, experimental testing, material testing result, functionality testing result and design itself as well as the corresponding discussions. Chapter 5 displays the conclusion of this project as well as recommendation for future studies.

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