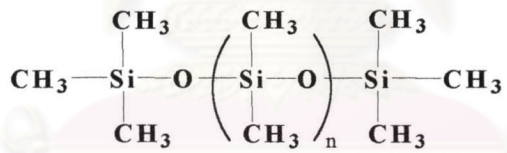
CHAPTER I

INTRODUCTION

1.1 GENERAL INTRODUCTION

Polydimethylsiloxanes (PDMS) or silicones have been utilized extensively for a construction of a wide variety of medical devices owing to their superior stability as well as their outstanding rubber elasticity. The main interests in these are their unique properties such as good low-temperature flexibility, chemical inertness and water repellency. [1] At present, silicones find their ways into an extremely wide range of medical applications and industrial uses. This material was chosen for medical applications because it was biologically inert. The resins have a backbone that consists of alternating silicon and oxygen atoms (-Si-O-Si-). The silicon-oxygen linkage in silicone rubber is similar to the linkage in quartz and glass as shown below.



(n = 0,1,2.....)

1.2 BACKGROUND OF THE INVENTATION

Breast cancer is among the most common malignant forms of cancer. In Bangkok, it's estimated that about 20 women in every 100,000 will be diagnosed with breast cancer. It is well recognized that early detection of breast cancer is the single most important factor predicting the successful cure and treatment of the cancer. Various methods for detecting breast cancer include angiography, ultrasonography, mammography and manual palpation. With the exception of manual palpation, those techniques are time consuming, expensive and require the interpretation of a trained specialist. Manual palpation, on the other hand, can be easily and inexpensively

performed and, with proper training, may be carried out as a self-examination, promoting a greater sense of privacy and increased frequency of examination. [2]

Furthermore, breast cancer training models, which were designed for training across a range of applications including self-diagnosis for nurses and specialists in Thailand, were mostly imported from Japan, Europe or America. Those models possess relatively low strength or durability and are still far from reality. Moreover, the current imported cost of each breast model is more than 30,000 baht which is rather high to be afforded by medics or local hospitals. In this investigation, types of silicone resins, composition of the resin compounds, gel time as well as aging phenomenon of industrial grade silicone elastomers were studied. The relationship between crosslink density, rheological and mechanical properties of these silicone elastomer were also examined.

1.3 DETAILED DESCRIPTION OF BREAST MODEL

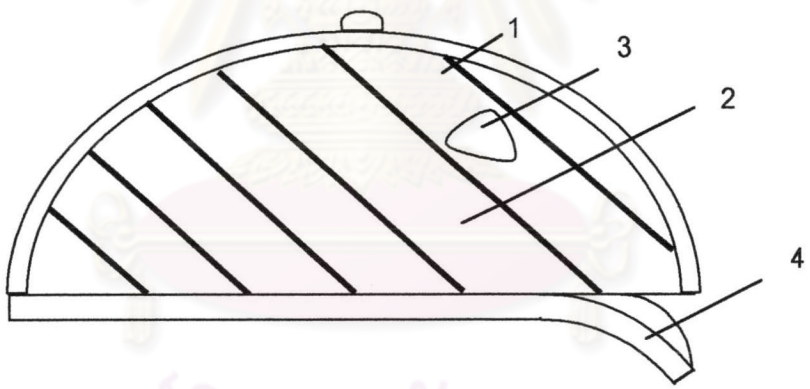


Figure 1.1 Sectional view of embodiment of a breast model according to the present invention

Referring to the drawings, wherein like numerals indicate like elements throughout, there is shown in figure 1.1 a breast model for teaching breast examination. The present invention relates to a method, apparatus and a realistic breast model. The model should have physical characteristics, such as overall shape, and a nipple and areola region, for example, which closely simulate human tissue. The model comprises a gel-like silicone within an elastomeric layer, which serves as a skin. The skin **(1)** may be made of any elastomeric material that closely simulates

human skin. Preferably, the skin comprises elastomeric silicone polymers. Suitable elastomeric silicone polymers are commercially available from domicile. For example, RTV 585 silicone rubber is available as a two-part kit: a resin and a curing agent. The main parts of a breast model are a skin layer and an interior. Satisfactory results for a realistic skin may be obtained by mixing the resin and the curing agent in a ratio of about 100:1.5 by weight. However, greater and lower resin: curing agent ratios may be used to form simulated human skin in accordance with the present invention. Then the interior part **(2)** simulated adipose tissue preferably comprises a gel compound and imparted feeling of a realistic human breast. Examples of suitable gel compounds include RTV 300, silicone oil and curing agent. It is preferred that the gel component comprises in a ratio of about 100:130:1.3 by weight depending on the desired hardness. One skilled in the art will appreciate that other gels having greater and lesser hardness may be used in accordance with the present invention to simulate adipose tissue.

Moreover tumor **(3)** are comprised virtually any material capable of realistically simulating breast tumors, provided that the material is compatible with the other materials used in making the tumor **(3)**. It is comprised of irregular-shaped silicone rubber, which was prepared by combining a silicone rubber with a curing agent (catalyst). Typically such silicone rubber is cured into shapes and sizes depending on those of the simulated tumor desired. The typical artificial tumor composition consists of a silicone and its curing agent of 100:2 mass ratio. As illustrated in Figure 1.1 having an adhesive coating **(4)** on one side thereof is adhesively attached to the backing of the breast appliance.

ศูนย์วิทยทรัพยากร
จุฬาลงกรณ์มหาวิทยาลัย

1.4 OBJECTIVES

1.3.1 To determine the appropriate resin-curing system composition for a breast training model.

1.3.2 To study the effect of network modifier on resulting properties of PDMS.

1.3.3 To determine gel-points of the silicones as to identify the processing time of a breast training model.

1.3.4 To evaluate some important properties of the resulting material for this application i.e. mechanical properties, hardness, crosslink density.

1.5 SCOPES OF WORK

1.4.1 Study the effect of the amount of silicone oil and curing agent on the properties of the silicone elastomer.

1.4.2 Controlled network formation of breast training model to achieve a desirable mechanical and physical properties.

1.4.3 Determine the physical properties of the specimen as follow:

a.) Tensile Strength

b.) Hardness

c.) Gel Time

d.) Tear Strength

ศูนย์วิทยทรัพยากร
จุฬาลงกรณ์มหาวิทยาลัย