

**DESIGN OF MOLD TO YIELD ELASTOMERIC MEMBRANE WHOSE SHAPE AND
SIZE, WHEN INFLATED, IS SIMILAR TO THE SHAPE OF THE HUMAN HEART**

A Thesis

by

AMIT LAGU

Submitted to the Office of Graduate Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

August 2004

Major Subject: Biomedical Engineering

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August 2004

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ABSTRACT

Design of Mold to Yield Elastomeric Membrane Whose Shape and Size, When Inflated, Is Similar to the Shape of the Human Heart. (August 2004)

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Chair of Advisory Committee: Dr. John C. Criscione

Nearly five million Americans are living with heart failure and 550,000 new cases are diagnosed each year in the US. Amongst the new approaches to develop a better solution for Congestive Heart Failure, Ventricular Recovery (VR) holds the most promise. A team, under the guidance of Dr. Criscione in the Cardiac Mechanics Lab at Texas A&M University, is currently developing an investigative device which aims to assist in VR by restoration of physiological strain patterns in the myocardial cells. The contribution of this thesis has been towards the development of a molding apparatus that yields a polymeric membrane whose shape, when inflated, is similar to the shape of the human heart. This membrane would surround the epicardial surface of the heart, when used for the device being discussed and in particular for the prototypes being developed. Contribution also includes a testing apparatus that measures the inflation of a membrane and simulation to predict the behavior of isotropic ellipsoids upon inflation.

After unsuccessful implementations of two processing techniques, the successful design, fabrication implementation and attachment method meets the design criteria and is based on a thermoforming technique. Inflation profiles for membranes developed using this technique were studied at different pressures, with the axis length as variable. At 1kpa, which is the normal coronary arterial pressure, the membrane with an axis length of 140mm was found to show a shape which is similar to the shape of the human heart. In order to better understand and predict the shape an isotropic ellipsoidal membrane would take upon inflation without experimentation, simulations were carried out. Successful conversion of ellipsoidal geometry, with a few degrees of freedom as parameters, aided in simulation.

To my mother, fiancée and the memory of my father.

ACKNOWLEDGMENTS

This thesis has proved to be more of self enlightenment and exploration of designing and basic fundamentals rather than extensive researching where no man has been before. Writing this thesis has proved to be a task as arduous as conducting the research itself, for a non-English major like me. An engineering student can possibly express the right thoughts in the right sequence. But to do all this within the right framework of words has made me realize that to keep me on my course, many people have provided encouragement and helped me focus my thoughts. All of them deserve credit for each one has contributed in their own unique ways.

Dr. John Criscione deserves thanks for tolerating all of my work, the unsuccessful techniques, early drafts and me. Dr. Sam Mannan and Dr. William Hyman deserve thanks, for backing us in what we were doing and for questioning every word and punctuation mark, which made me write to the point. The three of them have given me the courage and knowledge needed to undertake and go through with this task.

I offer my deepest respect to my mother for tolerating my frustrations and supporting my decisions all the way. My fiancée, Bageshri, deserves special mention for believing in me, for never once permitting me to act discouraged and for diverting away my negative thoughts.

Steve Smith, Roger Morgan, Rahul Chutake, David Breeding and Tanya Pankiw are those who, while they had no direct participation in the work done, provided me with words and acts of encouragement, helped me broaden my views or been my critique.

However none of them can stake a claim to the errata in this thesis and I solely claim that.

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1. INTRODUCTION

1.1. Cardiac failure

Cardiac failure can be defined as that condition in which the heart cannot pump blood as a volume adequate to meet the metabolic needs of the various tissues in the body, due to an abnormality of cardiac function [1]. The abnormality in cardiac function can be attributed to any reason ranging from an abnormality in the myocardial cells themselves, termed as myocardial failure, or due to some other abnormality within the structure of the heart, such as valvular stenosis or regurgitation.

Congestive heart failure (CHF) is a syndrome in which elevated pressure inside the heart causes blood to back up in the body. CHF is known to have been caused by prior heart attack, long-standing high blood pressure, diabetes, or a tight / leaking heart valve. However it is more than often, the end stage of cardiac disease. Nearly five million Americans are living with heart failure and 550,000 new cases are diagnosed each year in the United States of America. CHF is a fatal disease more common among the elderly because of accumulated heart damage.

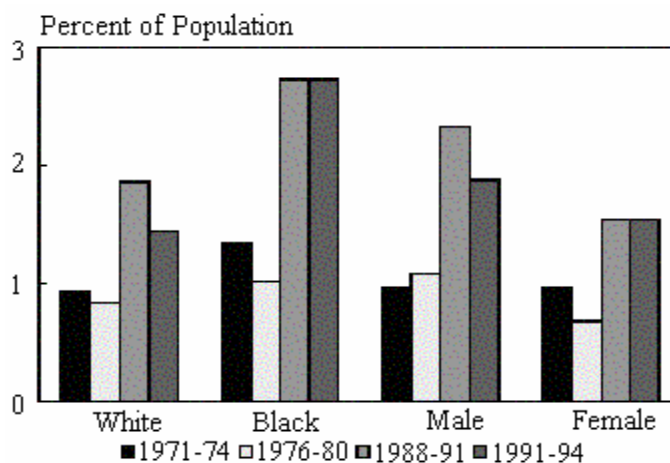


Fig. 1. Age adjusted prevalence of congestive heart failure by race and sex, ages 25-74, U.S., 1971-74 to 1991-94 [2].

Fig. 1, as shown above, illustrates some of the statistics with regards to CHF. In 1999, the United States of America (US) ranked as the ninth highest country worldwide for heart failure mortality in males and seventh highest for females [2].

The figure of 550,000 takes on added dimension when combined with the fact that the US faces a growing number of ageing 'baby boomers'. This ageing of the population will continue for the next few decades and it is estimated that around the year 2030, the elderly will account for more than quarter of the population.

The symptoms directly related to the heart failure range from chest pain, shortness of breath, temporary loss of consciousness, palpitations, cough, fatigue, weakness etc. For patients with CHF, typically the preliminary laboratory examination is a chest x-ray of the failure with a cardiothoracic ratio of more than 0.5 to 0.6. The appearance of the lung fields, serves as an estimate of the pulmonary capillary pressure. An increase in pulmonary pressures, as in case of CHF patients, would cause the upper lobe pulmonary to be more prominent than those in the lower lobe. The electrocardiogram (ECG) would help in defining the underlying etiology of the heart failure as well confirm the presence of CHF. Cardiac catheterization is also sometimes undertaken for defining the underlying abnormality of heart failure. Catheterization may also be useful in assessment of effect of various pharmacological interventions [3].

The emergency room treatments for CHF patients are generally pharmacological in nature and the therapy includes systematic use of several classes of drugs such as diuretics (except spironolactone), angiotensin converting enzyme inhibitors, beta blockers, angiotensin receptor blockers, digitalis glycosides, calcium channel blockers, inotropic agents, anti-thrombotic agents and vasodilators etc [4]. Other general measures include decreasing obesity with diet and stopping cigarette smoking, restriction of sodium intake.

The major parameters with respect to cardiac performance are heart rate, preload, afterload and contractility. These factors primarily determine whether the heart or its substitute will be able to meet the metabolic demands of the body as well as the metabolic demands of the cardiac work. Patients with CHF, exhibit a higher left ventricular end diastolic pressure as compared to normal patients. This results in increased hydrostatic pressure and transudation of fluid in the pulmonary capillaries, with symptoms of pulmonary congestion. Advanced CHF patients exhibit elevated systemic vascular resistance as a compensatory mechanism to maintain systemic blood pressure.

1.2. *Cardiac devices*

The therapy of heart failure for CHF patients should ideally aim towards reducing the workload of the heart and manipulating the various factors that control cardiac performance to maximize the cardiac output without excessive strain on the myocardial cells. There have been many attempts at solving this puzzle.

The use of artificial organs or donor organs has been a mainstay in clinical approaches to treat chronic illnesses for several decades now. Heart transplantation is still considered in some cases the most effective treatment for end-stage heart diseases. Studies have been carried out to evaluate the long-term use of implantable assist devices for the purpose of enhancing survival rates and quality of life and they have concluded the implantable assist devices to be acceptable alternative therapy in selected patients who are not candidates for cardiac transplantation [5]. Advances in artificial heart and cardiac assist technology offer competitive options for the treatment of CHF. The new technologies include new pumping techniques, new power sources, and the combination of mechanical and biological therapies and join the latest in tissue and cellular engineering technologies together with the most recent advances in pumping systems. These developments have proved to be quite successful at relieving the symptoms of CHF and even prolong the life span of the patients.

Some of the types of the devices aimed at treating CHF are mechanical circulatory support systems such as continuous flow left ventricular assist devices, pulsatile flow devices, total artificial hearts, devices without blood contact etc. However most of these devices have proved to be only effective means of providing circulatory support as a bridge to heart transplant.

Continuous flow Left Ventricular Assist Devices are of two basic types – axial flow pumps and centrifugal flow pumps. They have potential advantages over current pulsatile pumps as they are smaller devices and are relatively simple as they have fewer moving parts than pulsatile pumps and thus may be less prone to mechanical failures. They have lower energy requirements and the small size of the device and the pocket is thought to decrease the risk of infection, although this is also unproven. Some of the most well know axial flow pumps are the Nimbus/TCI VAS, the Jarvik 2000 VAS and the DeBakey / MicroMed VAS.

As long-term clinical experience is being gained everyday with circulatory support systems in transplant settings, the performance goals for future devices has to meet standards set by others and excel beyond expectations set by designers, doctors and patients alike.

1.3. *Polymers in cardiac devices and biomaterials*

An outcome of the progress in medical sciences and engineering has been a steadily rising demand for materials and devices, artificial or natural both, which mimic some of the functions of the human body components or their chemical nature. It is from this demand that the multidisciplinary science of 'Biomaterials' has emerged and serves as the storehouse of information which the researcher's continue to fill with new concepts, ideas and materials.

Even though this science was born out of the need to fulfill the demands of patients within the set of restrictions enforced by physician skills, manufacturing industry limitations and human body interactions, today it continues to serve as the melting pot of new ideas and materials. The current definition of 'Biomaterial' can be termed and coined in different ways to convey the same core meaning.

'A biomaterial can be defined as a substance (with the exception of drugs) or a combination of substances (both synthetic and natural) employed for the treatment, improvement or substitution of organism tissues, organs or functions'[6].

A biomaterial is quite different from a biological material such as skin which is produced by a biological system. The range of materials available to a person wanting to use it as a biomaterial is vast and can include unusual or unfamiliar materials as well. The materials available constantly undergo a change, with reasons ranging from development of new material with help of rapid technological developments to removal of certain materials due to research determining negative effects. There are ceramics which can mimic spring action, paper laminates that can behave as a heat insulation material and all this considering the fact that plastics, which have the properties of other generic groups, can be processed more easily and are cheaper as well. Good design engineers should try and avoid the habit of selecting a known material just because it is easier or safer, as each project must be examined from the start and the correct set of requirements be drawn. The design engineer must be aware of the full range of materials available and new formulations being presented else the design might be compromised for company profits.

Currently used biomaterials can be broadly divided into two main categories: biological and synthetic. The biological materials category can be considered to consist of polypeptides (proteins), polysaccharides (Cellulose, Hyaluronate etc), nucleic acids or their composites etc. The synthetic materials category would range from metal implants (Titanium, Ni-Cr, S.S. etc.) to

polymers. A polymer may be defined as a large molecule (macromolecule) built up by the repetition of small, simple chemical units (monomers). Based on the arrangement of these units, the various types of chains that can be synthesized, and the shapes that these chains can assume, result in a class of materials (polymers) characterized by a very broad range of properties.

During the course of this thesis, the focus will be concentrated towards polymers only. Polymers that are designed and employed for medical purposes present very delicate aspects from the viewpoint of interaction between biological systems and synthetic materials [6]. Polymers have already been in use for some years now for prosthetic implants, for extracorporeal purification treatments and even for therapeutically important applications, such as the slow release of drugs or their targeting to specific organs.

The usage of polymers for medical purposes is not limited only to biomaterials. In fact most of the devices used in medical applications nowadays are made of polymers. Examples range from the operation table to syringes to the casing of most medical electronic equipment. The ability of plastics to be molded into very complex shapes gives every designer the opportunity to design products as per the assembly line, which is for reducing overall cost and producing a more efficient end product. The device being discussed in the later portion of this thesis also has a variety of components made from plastics. Due to the complex nature and the variety of polymers and an even wider range of applications, the topics of applications of plastics in medical arena and the involved structure property relationships will not be discussed during the course of this thesis.

The chemical, physical and the processing properties of the polymers finding biomedical uses, can be very different: from water-soluble or bio-degradable ones to rigid, hydrophobic and designed to resist for many years mechanical stress and the hydrolytic action carried out in the human body by chemical or enzymatic agents. Whichever the polymer, design engineers cannot ignore the properties prior to selection of the appropriate material. Additionally the essential requisite for the employment of biomaterials is 'Biocompatibility', which is specific to the application, material and location in the human body. Biocompatibility of materials is sometimes defined as compatibility of a technical system with a biological system [7].

1.4. Systemic aspects of biocompatibility

Biocompatibility is also termed as the ability of a man made material to exist in an in-vivo environment for an acceptable period of time with no observed detrimental effect on the human body. The term biocompatibility covers a wide range of material properties. Some of the properties that gain relevance are chemical inertness, toxicity, resistance to hemolysis, thrombogenicity, resistance to adhesions, protein deposition etc.

The regulations lay down by various governmental agencies such as Food and Drug Administration (FDA), as well as by standardization agencies such as International Organization for Standardization (ISO), address the issue of testing for biocompatibility prior to clinical testing of devices or components. A majority of the tests in place establish specific materials response in vivo and in vitro to predict the biological effects and properties of materials to be used in contact with human tissue. However as with all newly developed materials, the lack of prior data or prior standards stands as an obstacle for FDA approval.

The subject of biocompatibility becomes even more difficult to treat due to the use of additives in improving the material properties or improving the processing. Due to the complex nature and the variety of polymers and an even wider range of additives, this topic will not be discussed during the course of this thesis.

1.5. Recent developments in cardiac devices

The clinical introduction of cardiopulmonary bypass, in 1953, ushered in the era of open heart surgery and fueled the creativity of the cardiovascular device specialists. HeartMate, an implantable, pneumatic left ventricular assist device developed by Thermo Cardiosystems Inc. in 1953 proved to be an effective way of providing long term circulatory support. In 1963, DeBakey tested an implanted pulsatile pump in open heart surgery patients. This pump was air driven with ball valves made of Dacron-reinforced Silastic. Some of the cardiac devices will be discussed to analyze their mechanism and critical components.

1.5.1 Liotta Total Artificial Heart (TAH)

The Liotta TAH, developed in 1969, was diaphragm type and consisted primarily of a pneumatic pump. It was positioned orthotropically, replacing the native ventricles. This device paved the way for evolution of the TAH [8].

1.5.2 MagScrew Total Artificial Heart

The MagScrew TAH consists primarily of a blood pump, actuator and control logic. The TAH device makes use of two pusher plate pumps, in which the pusher plate shafts are guided in the actuator shaft alternatively, thereby always achieving a passive filling response in one section. This device demonstrated good preload sensitivity and no signs of kidney or liver dysfunction [9].

1.5.3 CardioClasp

The CardioClasp, which uses two indenting bars to reshape the left ventricle (LV) and reduce wall stress, claims to improve systolic performance. The three primary components are: two rigid bars with pads and an adjustable tether. The principle underlying the design is to reduce afterload on the myocardial cells. Generally a reduction in afterload is achieved by lowering vascular resistance. However the resulting lower arterial blood pressure can compromise blood flow to other vital organs, such as the brain and kidney. CardioClasp reduced LV diameter by reshaping the left ventricle and thereby decreased LV wall stress and increased the fractional area of contraction [10].

1.5.4 Myosplint

Myosplint implants consist of two epicardial pads or buttons connected by a tension member, which works on a similar principle as CardioClasp. This passive device decreased peak left ventricular systolic wall stress value.

New radical approaches to develop a better and effective treatment option have been Ventricular Recovery (VR), trans-myocardial laser revascularization surgery (TMLR) and xenotransplantation (cross order/breed transplant). However VR holds the most promise amongst these.

It is known that throughout progression and aggravation of heart disease, there is constant dilation of the left ventricular chamber walls. As the left ventricle wall dilates, the radius of curvature increases and thereby increases the load on myocytes. This causes an increase in left ventricle wall tension and hence a decrease in systolic functioning, in accordance with Laplace's law. The term 'Ventricular remodeling' is often used to denote a progressive process of ventricular dilation and dysfunction. Most clinical research related to ventricular remodeling and related effects have been based on echocardiography and radionuclide ventriculography.

VR based treatment options focus on inhibiting or reversing, as in the case of the device being discussed in the next section, the remodeling process. In fact the devices developed previously such as the CardioClasp, have been used in studies to show that the device when used can reshape the left ventricle and improve left ventricular systolic performance in failing hearts [11].

2. ATTEMPTING TO SOLVE THE UNIQUE PROBLEM

2.1. *Problem identification and definition*

There are some groups which are developing novel cardiac assist devices based on the principle of VR. One of the groups is led by Dr. John Criscione at Department of Biomedical Engineering, Texas A&M University. A team under the guidance of Dr. Criscione, in the Cardiac Mechanics Lab at Texas A&M University, is currently developing an investigative device, a portion of which is shown in Fig. 2 below. The device aims to assist in VR by restoration of physiological strain patterns in the myocardial cells. The primary hypothesis being that the restoration of a physiological strain pattern to a failing heart, will promote healthy growth and recovery, which leads to VR [12].

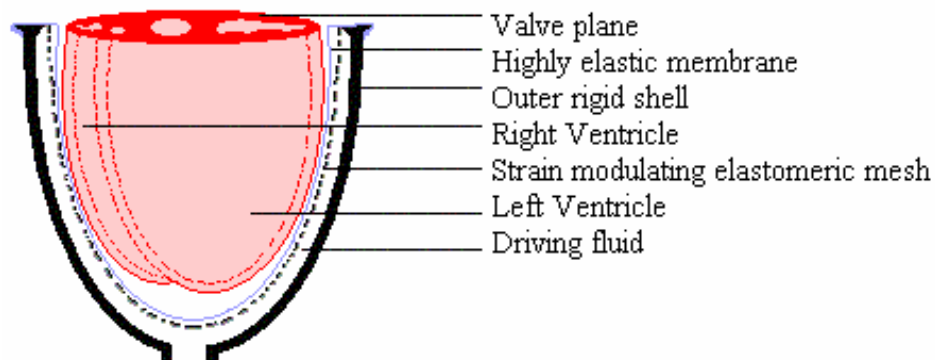


Fig. 2. Schematic of investigative device.

An important component of this device is the deformable inner membrane which modulates the outer-ventricular displacements. This membrane will be in direct contact with the epicardial surface of the heart and will assist in restoration of typical strain pattern, which is hypothesized to lead to good physiological growth, guide myocardial growth, reverse ventricular wall dilation and remodel dilated, failing hearts of CHF patients [12]. The current objective of the group is not whether this can be developed and promoted as a permanent cure or if it is an industry viable technique, but only to test and prove the hypothesis.

As a part of this testing of hypothesis, prototypes have to be made and tested, both in-vitro and in-vivo. Various team members have been involved in the development of various components for prototypes of this investigative device. The scope of this thesis is limited to the work done by the author and limits the discussions to the same.

The scope of the work done for this thesis focuses in particular on the design and fabrication of equipment to develop and test the highly elastic membrane that would surround the epicardial surface of the heart. This work is specific for the specifications of the prototypes being developed by the team and utilizes only the facilities within the Texas A&M University, to avoid any copyright issues, intellectual property or legal complications.

2.2. *Research objectives*

The research has been aimed at developing the highly elastic membrane from an ordinarily available form of polymer (cast sheet, pellet form or block pieces). It is simultaneously aimed at developing permanent polymer processing equipment for making similar membranes and testing setup for inflation testing of membranes for future use by the same group.

This elastic membrane is to be set on the lip of the outer rigid shell such that it nearly matches the shape and size of the outer rigid shell and the extra membrane portion sags towards the base of the rigid shell. In the advanced prototypes, the membrane is going to be attached to the apex of the shell, in some manner yet undecided. The testing technique should note this point and should alter the testing mechanism to accommodate this fact. The testing apparatus, its details and how it adjusts for the above attachment has been discussed in Section 4.1.

An o-ring, having slightly smaller perimeter than the outer rigid shell in the x-y direction, should be fixed to the membrane to enable firm grip with the outer rigid shell and prevent leakages. This fixation may be done preferably as a part of the processing, as it would enable elimination of additional processing steps. The specifications of the shell are set by the problem and are not within the purview of this thesis. The dimensions of the prototype have been measured and the axis measures of the prolate-ellipsoidal shape are 100mm, 75mm and 150mm in the x, y and z direction respectively.

The outer rigid shell of the investigative device has been fabricated such that is also of the shape of the human heart and follows the contours of the heart, though slightly larger in size, so as to accommodate the elastic membrane as well as the strain modulating elastomeric mesh. The

primary reason for having the elastic membrane, strain modulating elastomeric mesh and the outer rigid shell, similar to the shape of the human heart is quite obvious, as they can assist in restoration of typical strain pattern and guide myocardial growth only if they have the right boundary conditions.

The elastic membrane, when inflated by a pumping mechanism in the direction of the apex of the heart, should yield a shape similar to the shape of the human heart, which is known to be prolate-ellipsoidal. Given below in Fig. 3 is a comparison of shapes, each with four nodes and three degrees of freedom per node, to give a better understanding of the difference between planar, cylindrical, spherical and prolate-ellipsoidal. These shapes have been developed using a MATLAB program, coded by the author.

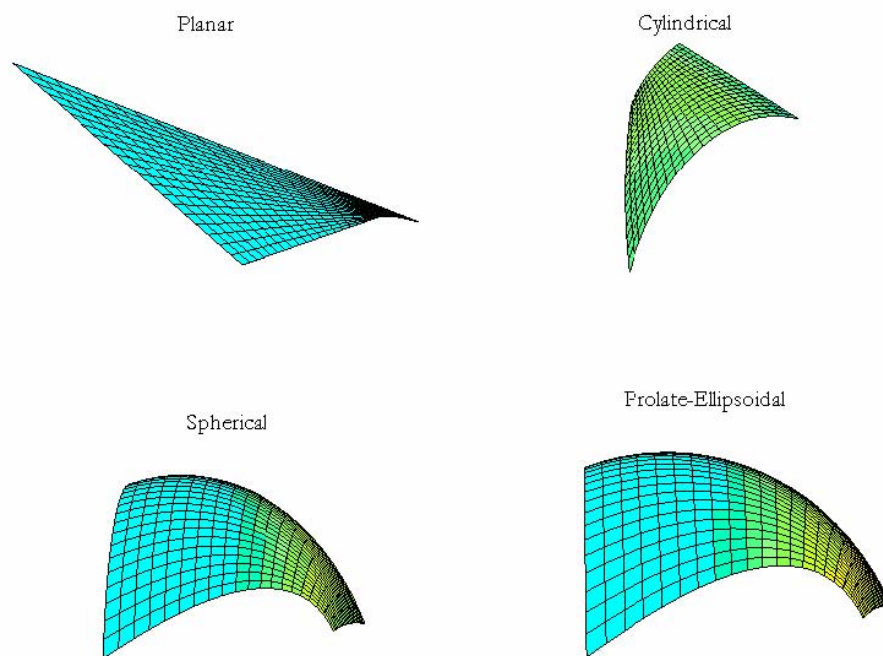


Fig. 3. Comparison of planar, cylindrical, spherical and prolate-ellipsoidal shapes.

The testing technique should make sure that elastic membrane, when stretched or inflated either by suction or pressurization, yields a prolate-ellipsoidal shape. It could be misleadingly assumed that if the elastic membrane when inflated, were to yield a shape similar to the outer

rigid shell, it would be sufficiently prolate-ellipsoidal. It has to be noted that any flat membrane (circular or elliptical or any other shape), when inflated would tend to minimize the surface area and hence would inflate spherically.

2.3. *Inflation*

This section of the thesis is devoted primarily towards understanding, simulating and predicting the inflation of any flat isotropic ellipsoidal shaped membranes.

Based on preliminary assumptions, the pressure inside the membrane remains almost constant, while the volume increases as more air is added. The pressure required to expand the membrane is almost entirely due to expansion of the gas against the earth's atmosphere, plus a small factor to stretch the rubber. Therefore, the pressure remains almost constant, independent of volume. The tearing or breakage of the membrane is not due to the pressure increases, but because the rubber molecules are stretched so far apart that the intermolecular forces can no longer hold them together. In order to study and better understand the shape the isotropic ellipsoidal membrane would take upon inflation, some amount of work has been done to simulate the inflation of membrane. The simulation should account for the basic fact that surfaces tend to minimize their surface energy.

To simulate the 0kpa inflation or no inflation, we use the MATLAB program provided in Appendix A to generate the starting state or reference configuration. The MATLAB program simulates the membrane along the ζ_1 and ζ_2 axis. ζ_1 going from 0 to 1 in the first quadrant along the hoop direction as θ goes from 0 to $\Pi/2$. ζ_2 goes from 0 to 1 in the first quadrant along the arc length direction as the radius goes from 0 to specified radius as shown in Fig. 4.

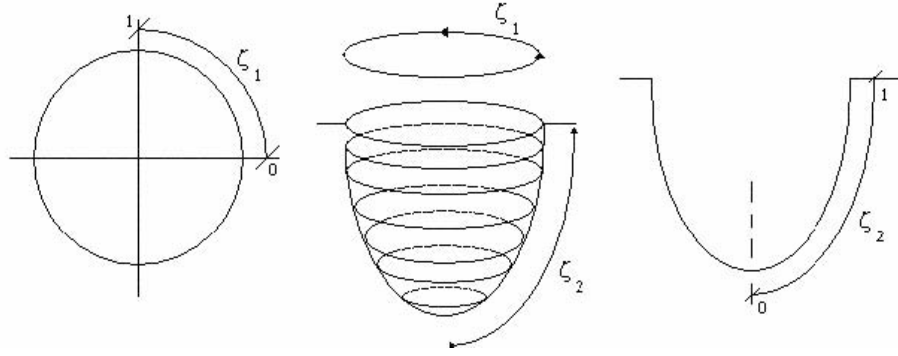


Fig. 4. Axis ζ_1 and ζ_2 and their limits as used in the simulations.

Initially using cylindrical co-ordinate system, we can calculate the r , θ and z coordinates as r and z are dependent on ζ_1 and ζ_2 as follows

$$\begin{aligned} r(\zeta_1, \zeta_2) = & H_1(\zeta_1) \left[H_2(\zeta_2) \frac{\delta r}{\delta \zeta_2} \Big|_{\zeta_2=0}^{\zeta_1=0} + H_3(\zeta_2) R \Big|_{\zeta_2=1}^{\zeta_1=0} + H_4(\zeta_2) \frac{\delta r}{\delta \zeta_2} \Big|_{\zeta_2=1}^{\zeta_1=0} \right] + \\ & H_3(\zeta_1) \left[H_2(\zeta_2) \frac{\delta r}{\delta \zeta_2} \Big|_{\zeta_2=0}^{\zeta_1=1} + H_3(\zeta_2) R \Big|_{\zeta_2=1}^{\zeta_1=1} + H_4(\zeta_2) \frac{\delta r}{\delta \zeta_2} \Big|_{\zeta_2=1}^{\zeta_1=1} \right] \end{aligned} \quad (1)$$

$$\begin{aligned} z(\zeta_1, \zeta_2) = & H_1(\zeta_1) \left[H_2(\zeta_2) \frac{\delta z}{\delta \zeta_2} \Big|_{\zeta_2=0}^{\zeta_1=0} + H_1(\zeta_2) Z \Big|_{\zeta_2=0}^{\zeta_1=0} + H_4(\zeta_2) \frac{\delta z}{\delta \zeta_2} \Big|_{\zeta_2=1}^{\zeta_1=0} \right] + \\ & H_3(\zeta_1) \left[H_2(\zeta_2) \frac{\delta z}{\delta \zeta_2} \Big|_{\zeta_2=0}^{\zeta_1=1} + H_1(\zeta_2) Z \Big|_{\zeta_2=0}^{\zeta_1=1} + H_4(\zeta_2) \frac{\delta z}{\delta \zeta_2} \Big|_{\zeta_2=1}^{\zeta_1=1} \right] \end{aligned} \quad (2)$$

where

$$H_1(\zeta) = 1 - 3\zeta^2 + 2\zeta^3$$

$$H_2(\zeta) = \zeta(\zeta - 1)^2$$

$$H_3(\zeta) = \zeta^2(3 - 2\zeta)$$

$$H_4(\zeta) = \zeta^2(\zeta - 1)$$

θ can be assumed to be a function of the mean change in radius and can be easily calculated as follows:

$$\theta = \frac{\Pi}{2} \times \{H_2(\zeta_1) \times \zeta_{2=0} + H_2(\zeta_1) \times (R_{\min} + R_{\max}) / 2 R_{\min}\} + H_3(\zeta_1) \times \zeta_{2=1} + H_4(\zeta_1) \times (R_{\min} + R_{\max}) / 2 R_{\max}\} \quad (3)$$

The degrees of freedom were identified for the relevant expansion conditions. Due to time constraints, the simulations carried out as a part of this thesis work are only for expansion without rod. Seven degrees of freedom were identified for expansion without rod and are as given below. For simulating the condition of expansion with rod, eight degrees of freedom can be identified and used for the simulation.

- i.) $\left. \frac{\partial r}{\partial \zeta_2} \right|_{\substack{\zeta_1=1 \\ \zeta_2=0}}$ The change in arc length at $\zeta_1 = \pi/2$ at the apex.
- ii.) $\left. \frac{\partial r}{\partial \zeta_2} \right|_{\substack{\zeta_1=1 \\ \zeta_2=1}}$ The change in Arc length at $\zeta_1 = \pi/2$ at the base.
- iii.) θ_1 The angle made by the surface of the membrane with the plane of base at $\zeta_1=0$ at the base.
- iv.) θ_2 The angle made by the surface of the membrane with the plane of base at $\zeta_1= \pi/2$ at the base.
- v.) Z The depth or the distance of the apex from the plane of the base
- vi.) $\left. \frac{\partial r}{\partial \zeta_2} \right|_{\substack{\zeta_1=0 \\ \zeta_2=0}}$ The change in Arc length at $\zeta_1 = 0$ at the apex.
- vii.) $\left. \frac{\partial r}{\partial \zeta_2} \right|_{\substack{\zeta_1=0 \\ \zeta_2=1}}$ The change in Arc length at $\zeta_1 = 0$ at the base.

Then assuming mirror symmetry along the axis since the simulation is being carried out for isotropic material, which has same mechanical properties in all directions, the other portions of the membrane are generated, to give the Fig. 5.

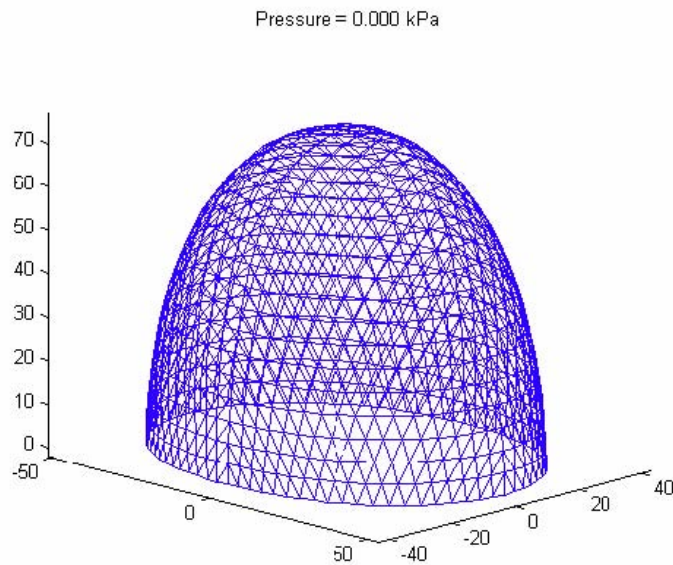


Fig. 5. Simulated starting condition of membrane at 0kpa or reference configuration.

Once this starting condition is achieved and its volume is calculated, the conditions for expansion due to increase in pressure to 1kpa are simulated to find the final resting condition, as shown in Fig. 6, where the surface would tend to minimize its surface energy. The axis ζ_1 and ζ_2 are maintained in the same direction and having the same limits. For the purpose of minimizing, the MATLAB program provided in Appendix A makes use of the constrained nonlinear optimization function: `fmincon`. This function is used to minimize the difference between the sum of energy stored in the membrane and the product of pressure and change in volume. This is done to account for the fact that surfaces tend to minimize their surface energy.

The function '`fmincon`' attempts to find a constrained minimum of a scalar function of several variables starting at an initial estimate. It is also sometimes referred to as nonlinear programming. As used in the code, the function defines a set of lower and upper bounds on the design variables in x , so that the solution is always in the range $lb \leq x \leq ub$. It is recommended to set the arguments `Aeq=[]` and `beq=[]` if no equalities exist, as done in the code in Appendix A. Details on the function, its arguments, algorithm and limitations can be found on the MATLAB internet website.

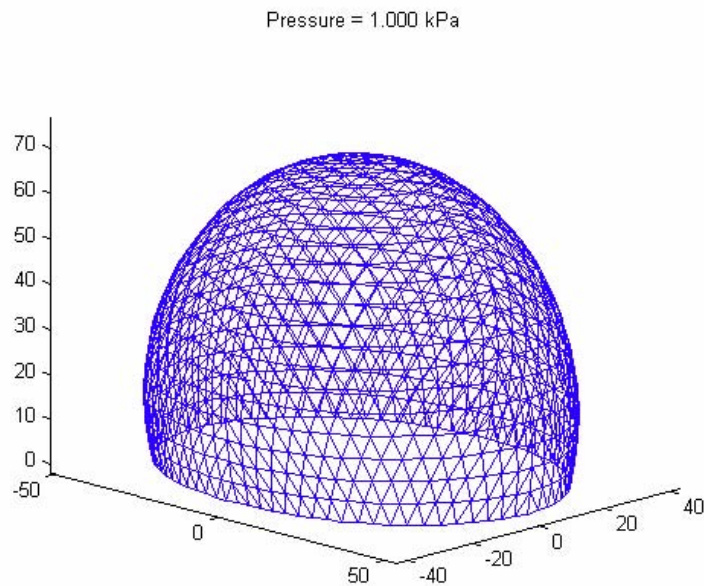


Fig. 6. Simulated final condition of membrane at 1kpa.

Given in Appendix B are the intermediate conditions from 0kpa to 1kpa. These simulation results are corroborated by experimental results. Samples were tested using the testing apparatus discussed in Section 4.1 of this document, sans the plastic rod. As we can see from results given in Appendix C, as the membrane is inflated, the membrane tends to become more spherical.

All of these results, discussed above, are to be expected within the constraints set by the limitations and delimitations and time frame in which the work has been completed.

2.4. *Set of limitation and delimitations for the problem*

As with all research projects, this research work has its own set of limitations and delimitations. These are due to variety of reasons such as the available resources, the timeframe in which the work has been carried out and presence of numerous unknown variables.

The polymeric material selected as a part of the experimentation plays a vital role in the entire device as well as the experimentation, as it essentially determines the physical properties, the chemical interaction, the elongation characteristics and the biocompatibility. However the current issue for the purpose of this thesis remains focused on design, fabrication of equipment

to develop and test the highly elastic membrane that would surround the epicardial surface of the heart as such equipment is not readily available within the Department of Biomedical Engineering. Therefore it has been assumed that the polymeric material selected for experimentation and the prototype membrane, exhibits satisfactory elongation properties and tensile strength. At the same time, it should not exhibit permanent deformation characteristics for the loading used in the techniques.

A major portion of deformation characteristics will be determined by the thickness of the membrane. But the research work for this thesis doesn't cover evaluation and analysis of membrane thickness variation, primarily due to time limitations. However the processing techniques considered, have been developed considering this fact and accommodate for variation in membrane thickness.

It has also been assumed that the polymer complies with all relevant biocompatibility standards, as available resources and the timeframe for work restrict biocompatibility studies on the samples for this thesis.

The losses caused due to the friction between the membrane and all the surfaces it comes into contact with, doesn't fall within the purview of this thesis work. Neither do the losses caused in pressure differences due to small diameter pipes. However they can safely be assumed to be negligible.

The processing technique should be able to address and make sure that the o-ring is completely attached to the membrane as any gaps could possibly result in wrinkle formation, fold formation or possible rupture points if the membrane is too thin. Wrinkle formation, is considered neither a limitation nor problem. Aesthetically it would not have the appeal of smooth membrane, but if in the future this device is used for any animal experimentation, the wrinkles would not affect the functioning in any manner.

2.5. *Previous work and equipment available*

At the Department of Biomedical Engineering, Texas A&M University, there has been no reported work done in the field of investigative cardiac assist devices, VR and development of polymer processing equipment, prior to current work done by the group led by Dr. Criscione. There exists testing apparatus for measurement of mechanical properties within the Department of Biomedical Engineering. The existing apparatus for membrane inflation testing within the

Department of Biomedical Engineering, with the group led by Dr. Humphrey, is for very small membrane inflation and hence a new apparatus setup had to be developed indigenously.

Judging by past experience, available information on similar products and based on available resources, the polymer selected should be in a process-able form, should be readily available in the market and would probably belong to the category of thermoplastics or rubbers. Thermoplastics are linear or branched polymers that can be melted upon the application of heat. Rubbers are materials that exhibit elastomeric properties i.e. they can be stretched easily to high extensions and they tend to restore to their original dimensions upon release of stress.

3. ANALYSIS OF MATERIAL, TECHNIQUE AND MOLD SELECTION

3.1. *Research methodology*

Since there is hardly any previous work done in the fields of investigative cardiac assist devices, polymer processing equipment, membrane inflation testing at the Department of Biomedical Engineering, the methodology heavily depends on text-based knowledge and limited knowledge of the team. Knowledge accrued from texts on subjects of polymer processing and physics of inflation, have helped define and guide the design most of the experimental and testing setups. Inputs from personal knowledge of author and Dr. Criscione have helped fine tune and guide some of the parameters for the experimentation. The primary steps in developing a permanent, polymer processing equipment and testing setup for future use by the group, can be listed sequentially as follows.

A working principle for a polymer processing technique is developed based on literature and is evaluated for feasibility based on shape restrictions and other limitations. A feasible technique is then extended and a working model or mold is drawn up on paper. It follows actual fabrication of the mold, its various components and other accessories, followed by assembly of the setup. A trial run was conducted whenever possible, using wax, which can be considered to exhibit the same melt characteristics as general thermoplastics. Any defects in the functioning of the setup are fine tuned at this stage and prepared for use with polymers. If the technique is successful, the experimental setup is developed using similar procedure as the processing mold setup. The samples are taken and tested, wherein the actual extent of inflation of the membrane is measured.

Only a limited number of elastomers have the demonstrated bio-stability and biocompatibility to serve reliably in long-term medical implants. This can be primarily attributed to the fact that FDA strictly regulates all instances of artificial materials being used inside the human body. For more than thirty years, two biomaterials have been used extensively in implantable devices: cross-linked silicone rubber and thermoplastic polyurethane (TPU). For products that need to combine the need for high wear resistance with long implant time in the human body, TPUs—and the closely related, solvent-cast, segmented polyurethanes (SPUs)—have often been specified. However after deliberation on availability of raw materials and testing needs, the testing for the work in this thesis has been carried out on Natural thin gauge latex rubber sheet 0.006" thick.

3.2. *Available processing techniques*

Molding of plastics and medical devices applications development are always in competition to outperform and leapfrog one another. An increase in functional requirements of molded medical components essentially drives the molding technology advances required and in turn the increased capabilities facilitates for innovations in design of new medical device components.

In the past and present, conventional injection molding technology has proved to be sufficient to meet most of the needs of the applications developed. Injection molding can be described as the process of replication of particular shape, by injection of molten plastic under pressure into the cavity of a mold (replica of wanted shape), followed by cooling and removal of the item.

Injection molding is done by large machines called injection molding machines. The polymer to be cast is usually in the form of pellets and is fed to the machine through the hopper. Upon entering the barrel, the resin is heated to the appropriate melting temperature. A controlled amount of resin is injected into the mold by a reciprocating screw or a ram injector. The mold is the part of the machine that receives and shapes the molten plastic. The mold needs constant cooling to a temperature so that the resin solidifies. The two mold plates are held together by hydraulic or mechanical force.

A modification of the conventional Injection molding has been Liquid injection molding. This process makes use of Liquid Silicone Rubber (LSR), a two-part platinum catalyzed product to mold the desired components. A pumping system mixes the two components in a precision meter-mix process to a given ratio and delivers the mix to the tool in the injection machine to be cast.

Injection molding has always been associated with large quantity production, whereas compression molding is a process where larger control and accuracy can be achieved on a single part. Compression molding is a method of molding in which preheated plastic melt is placed in an open heated mold cavity. The mold is then closed with pressure being applied to force material contact with all mold areas. Heat and pressure is maintained until the molding material has cured. This process is most often used with thermosetting polymers.

In comparison with Injection molding, rotational molding or rotomolding can easily produce both large, small precision and non-precision parts in a cost effective manner. It is

generally recommended for one-of-a-kind prototypes. The process does not require any pressure to be held and rotomolding tooling is far less expensive. Rotomolded parts are formed with heat and rotation, but not with pressure. Therefore, molds don't need to withstand the high pressure of injection molding.

When conventional molding techniques have fallen short, novel improvements and modifications to the process have been devised to provide unique solutions. There have been many such improvements. Pulsed cooling and induction coil heating modification to the conventional molding process add a greater degree of process control. Gas-assisted injection molding and multi-live feed molding are variations of conventional injection molding where auxiliary equipment is incorporated to give better control over component wall thickness. Injection molding of polymers filled with dispersed metallic or ceramic powders is a recognized variation for the production of a large series of complex shaped parts at low cost and with high accuracy.

As a part of this thesis, variations to conventional molding techniques have been sought as the elastic membrane offers unique challenges in junction with the limitations under which work is being carried out.

Conventional extrusion molding or its variations have not been considered as the technique is mainly used for continuous type molding. Conventional rotomolding or its variations have not been considered as the elastic membrane shape is very complex for this processing technique. Conventional injection molding or its variations, such as gas assisted injection molding, have not been considered as the mold making would have to be done with help sought outside the Texas A&M University system, which is beyond the monetary budget constraints and could possibly involve violations of intellectual property issues. Additionally since the raw material is natural latex rubber and its form, thin gauge sheet 0.006" thick, it eliminates usage of all of the above methods.

Additionally all of the above mentioned molding techniques would not provide for a permanent solution to future demands of membrane as the available molding machines are with departments within the Texas A&M University system, other than Department of Biomedical Engineering.

3.3. *Setup and description of failed techniques and molds*

Under the guidance of Dr. Criscione, in the Cardiac Mechanics Lab at Texas A&M University, several attempts were made at developing a polymer membrane within the already discussed set of limitations and delimitations. The first couple of attempts at processing techniques failed. They will be discussed in brief, to highlight the components as well as the failure mode so that any future work in this field, may avoid these pitfalls or overcome the failure points faced by the author.

3.3.1. *Open mold casting*

Casting processes are generally characterized by their use of a molten starting material that is shaped without the application of significant pressure. Pressure can be used in some casting variations provided it is minimal. Some casting processes, for instance, utilize the weight of mold components themselves to exert the minimal pressure. Such uses of pressure are considered insignificant. The absence of significant pressure means that the molds and the assembly used in the process need not be as strong as the ones used in high-pressure molding techniques such as injection molding. Casting molds can be made from wood, plaster, plastic, aluminum, rubber and other materials that may fit application specifications.

External heat is sometimes used to hasten the solidification process, although it is not required. Materials can solidify via various mechanisms such as chemical reaction, external heating and cooling or solvent evaporation.

Casting and its variations are not looked upon, by most of the polymer processing engineers or product development engineers, as a good and viable technique. However it was felt that this situation needed the casting process with natural air cooling and solvent evaporation accounting for material solidification. This was primarily so, because of the prolate ellipsoidal shape and also because at that time, there was ongoing deliberation on thermoplastic to be used and its available form.

The mold, the rendered white part in Figs 7 through 10 as shown below, was machined from a cylindrical block of teflon. One half of the block was machined as one-half of an ellipsoid having radii 0.78", 0.98" and 0.98"; while the rest was left cylindrical. The mold was mounted and connected to a motor via various gear-cam mechanisms. Speed variation was needed as it

was unclear at the time of assembly as to what speed of rotation would be needed. It would depend on polymer viscosity, rate of solvent evaporation and rate of cooling. All this was mounted on a wooden board along with additional safety measures such as spill protection walls. The spill walls were in place to avoid injuries from flying lumps of polymer, if any from the centrifugal force.



Fig. 7. Rendering of frontal view of various components of mold.



Fig. 8. Photograph of frontal view of various components of mold.

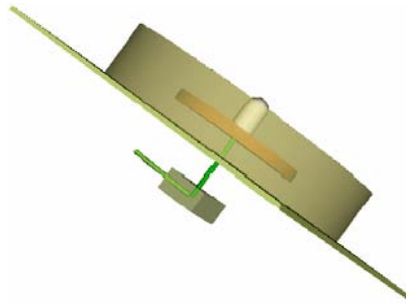


Fig. 9. Rendering of side view of various components of mold.



Fig. 10. Photograph of side view of various components of mold.

The polymer in market form once melted using an oven, would then be poured onto the Teflon mold. The mold, constantly rotated by the motor, was placed at an angle to the horizontal ground since it was fixed to the board. This was done to achieve near simultaneous contact with mold surface and uniform cooling of mold and membrane. It was envisaged that both the gravitation pull and the centrifugal force generated due to mold rotation, would assist in uniform distribution of melt on the mold surface, eventually leading to uniform membrane thickness. Fig. 11 shown below is cartoon depiction of the envisaged melt flow.

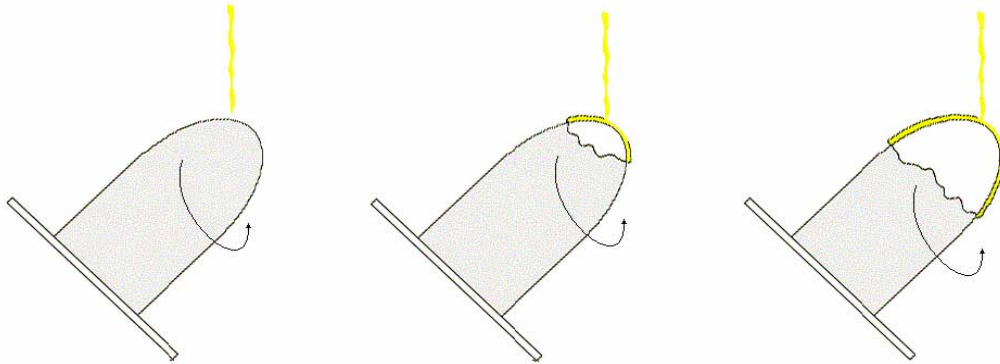


Fig. 11. Cartoon depiction of the envisaged polymer melt flow.

Unlike normally used molds where the melt-mold contact surface is the outer surface of the product, in this case the mold-melt contact surface would be the inner surface of the membrane. This was done intentionally as the inner surface of the membrane, would be in touch with the pericardium, and would need to be smoother than the outer surface. Also this method seemed easier from machining perspective. It had been estimated that the inherent problems of melt lines, warps and defects due to shrinkage would arise. However, it was decided at that point to ignore any such defects in the membrane.

Once the membrane would be formed, while the membrane was still on the mold the o-ring would be slipped on top of the membrane and permanently attached to the membrane using commonly available cyanoacrylate based glues, or Super-Glue as it is known commonly.

This technique was deemed as failed as the membrane formed using this technique was not up to mark. The major reasons seen for this failure were non-uniform cooling of mold as well as melt; formation of lumps and excessive adhesion between mold surface and melt.

3.3.2. *Gated casting*

Upon failure of open mold casting, it was felt that those failures and disadvantages could be overcome using surface / gated casting process with natural air cooling and solvent evaporation accounting for material solidification. It also allowed for better control over thickness variation.

The mold, as shown below in Fig. 12 and Fig. 13, was machined from a cylinder of brass of diameter 6". It consists of two components and the gap between them would allow for the membrane to be cast. Since brass is difficult to machine and precision machining for making matching components is difficult to achieve, especially for prolate-ellipsoid, it was decided that the shape of the cast membrane can be conical. The conical shape is considerably similar a shape to the prolate ellipsoid. Additionally the conical shape of the membrane aided in it being attached to the apex of the shell. The maximum radius of the conical shape fabricated was 4" at distance of 3.5" from the tip.

Screws were mounted all around the circular mold at regular spacing. They served dual purposes - to measure / control the distance between the two mold components and to exert pressure by forcing the two components together.



Fig. 12. Photograph of the two components of mold in open condition.

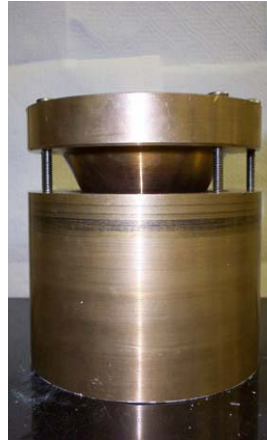


Fig. 13. Photograph of the two components of mold in closed condition.

To reduce temperature gradient between melt and brass mold, the mold was preheated. Once sufficiently heated and the two components were in place, the polymer in market form would be melted using an oven or using an appropriate solvent. The melt would then be poured inside the brass mold via a feed line. It was envisaged that air cooling and solvent evaporation would account for material solidification. Mold release agents were sprayed to ease the removal of membrane from the mold.

Once the membrane would be formed and removed from the mold as shown in Fig. 14, the o-ring would be slipped on top of the membrane via some external mechanism and then permanently attached to the membrane using commonly available cyanoacrylate based glues, or Super-Glue as it is known commonly.

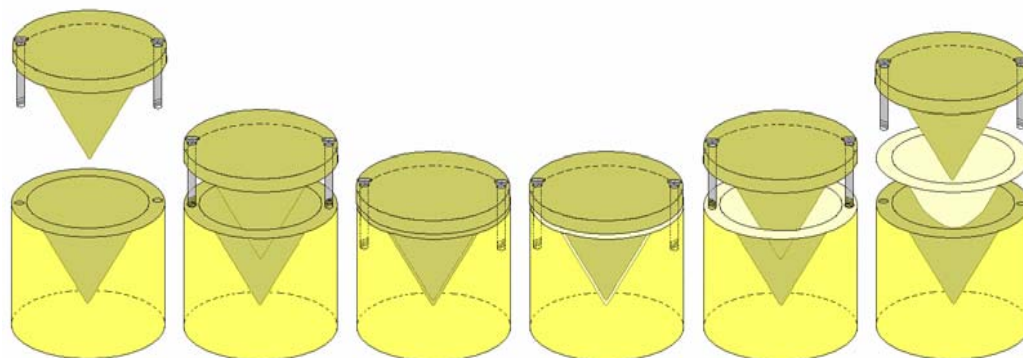


Fig. 14. Cartoon depicting various components of mold in different stages of the membrane forming process.

This technique was deemed as failed as the membrane formed using this technique was not up to mark. The major reasons seen for this failure were non-uniform cooling of mold; release of lethal agents upon heating from solvent and slow delivery of melt to mold. Also it was felt that this method would prove to be difficult for others to replicate easily and safely.

3.4. *Setup and description of successful technique and mold*

Upon failure of two variations of casting, it was felt that those failures and disadvantages could not be overcome using casting process with natural air cooling or solvent evaporation accounting for material solidification.

Since the membrane thickness needed to be quite small, a paradigm shift was the need of the hour for both the raw material as well as the technique. It was decided at that point to use natural latex rubber in the form of thin gauge sheet 0.006" thick, as it would eliminate any heating or cooling. The use of such commercially available forms would also enable the team to include more materials for making this membrane. It also led us to explore the option of thermoforming as the processing technique.

Thermoforming is generally used in low-cost low-end applications and cannot be used to form as rigid shapes as vacuum forming or compression molding is capable of. Thermoplastics

are preferred for use in thermoforming because thermosetting plastics assume their final shape through heat and so can not be molded with this process.

Thermoforming is a process in which sheet plastic is molded into the desired shape using pressure. This pressure is usually applied using wooden or metal shape formers, which press into the sheet.

External heat is used, though rarely, to ease the forming of the sheet plastic although it is not required. Mechanisms such as chemical reaction, external heating and cooling or solvent evaporation are not required as the material is in solid sheet form to begin with.

The equipment prepared consists primarily of three sections viz. an acrylic top and Polyvinyl Chloride (PVC) pipes of two different cross sections. The two pipe sections are connected using an easily available plastic throat. For use in this research, the pipes used were of diameter 3.5" and 4.5", each of length 8" and 3'5" respectively. The length of the latter being more, as it was felt that working at average human arm length would prove to be more convenient. The former was selected as it was found to give better results, by trial and error method. The acrylic top cover was fabricated, from a block of acrylic, having external diameter of 3.5" and was machined as a press fit into the 3.5" PVC pipe section. A taper of 30° and 60°, followed by file and smoothening by sand paper, was added on the upper surface to give a smooth radius of curvature. It was then assembled to get an assembly as shown in Fig. 15 and Fig. 16.

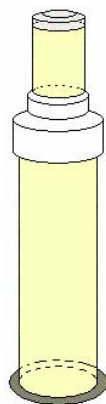


Fig. 15. Cartoon depiction of frontal view of various components of setup.



Fig. 16. Photograph of various components of setup.

Once this assembly was in place, a decision had to be made with regards to the dimensions of the membrane that would need to be produced and whether the problem of wrinkle formation would arise and o-ring attachment over the wrinkles, if any.

Upon inspection and study of the final functioning of the membrane, it was decided that the membrane should be sufficiently taut when placed in the prototype. As per the envisaged functioning, the membrane should be in a stretched condition when the heart would be placed in it. The exact quantification for how much stretch is needed is not available.

The stretch ought to be related to the depth of the outer rigid shell in the z direction. The actual depth of the prototype outer rigid shell was measured to be 75mm or the length the axis (twice the radius) to be 150mm. If the axis length were to be assumed less than 150mm, it would cause the membrane to stretch when used with the actual prototype. Hence this was defined as the variable for the experimentation to be carried out. The choice and selection of axis length values was based on primarily on feasibility and having sufficiently broad range. The values to be studied were fixed as 100mm, 115mm, 130mm, 140mm, 145mm and 150mm.

The perimeter of the outer shell in the XY, YZ and XZ planes is calculated from known axis lengths and for all six values of variable. Then for each variable, an ellipse having major axis as half of XZ perimeter and minor axis as half of YZ perimeter is calculated and drawn using AutoCad. The calculations of perimeter, major axis length and minor axis lengths are given in Appendix D. The natural latex rubber sheet is then cut into parts to fit the exact shape

and size of each ellipse. The outline of ellipse is then traced on the rubber sheet using permanent markers.

Individual latex rubber sheets would then be stretched symmetrically as shown in Fig. 17 below, over the mold. By trial and error, a position was identified on the mold, till where the rubber sheet would need to be stretched such that there would be no wrinkles inside the marked elliptical area. Once the rubber sheet was in required position, it would be fixed using commonly available Duck-tape. The o-ring would then be slipped over the membrane till it matches the marked outline and then permanently attached to the membrane using commonly available cyanoacrylate based glues, or Super-glue as it is known commonly. The membrane would then be tagged for identification purposes and then released by cutting the portions beyond the marked area. This is repeated for all samples.

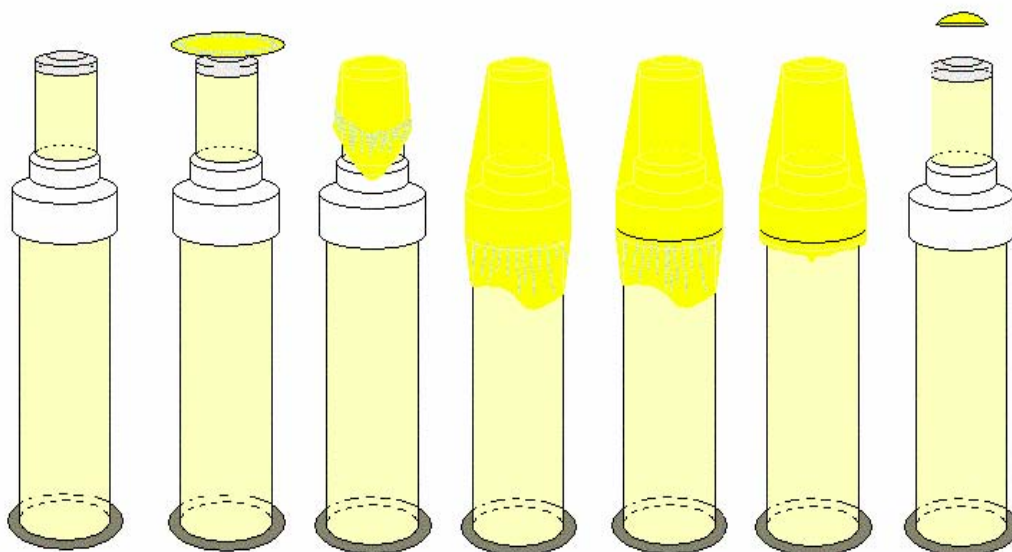


Fig. 17. Cartoon depiction of various stages of membrane preparation.

4. EXPERIMENTATION AND RESULTS

4.1. Test method and setup

At the Department of Biomedical Engineering, Texas A&M University, there exists testing apparatus for measurement of mechanical properties. However no testing apparatus exists for membrane inflation testing within the Department of Biomedical Engineering and had to be developed indigenously.

Judging by past experience and led by testing needs, the testing apparatus was designed and fabricated with the key components being the pressurizing component; pressure measurement and control component and recording component. A cartoon representing the test setup in its entirety is given in Appendix E.

The pressurizing component, as highlighted in Fig. 18, consists of an easily available continuous air pumping unit. For pressure measurement and control, a continuous U tube monometer and reservoir, as shown in Fig. 19, was fabricated and water was used as the medium in the monometer. While positive pressure from the pumping unit was applied to one leg, water was forced down in that leg and up in the other. The difference in height indicated the pressure. Since water was used as the medium in the monometer, the height was calibrated using the known relation of 10.19716cm of water above the outlet for every kilo pascal (kpa) of pressure applied.

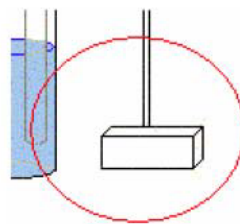


Fig. 18. Air pumping unit (not to scale).

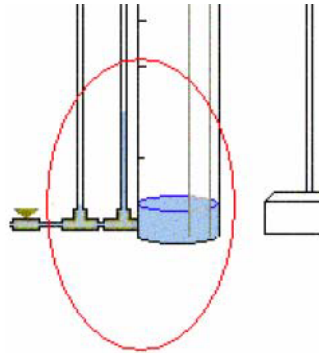


Fig. 19. Monometer and reservoir (not to scale).

The recording component, as highlighted in Fig. 20, consists of an easily available camera positioned to capture the inflation and a setup consisting primarily of the prototype shell. The cross section of this setup is as shown in Fig. 21. The screws, when tightened, force the membrane against a layer of rubber glued to the upper ply, thereby creating a seal which is leak proof. A plastic rod, placed in the center of the prototype shell, helps the testing apparatus account for the discussions in Section 2.3 of this document, where it was proved that pure inflation would result in a spherical shape rather than prolate ellipsoid. The rod also extends the membrane thereby simulating the condition wherein the membrane would be permanently attached to the apex of the shell.

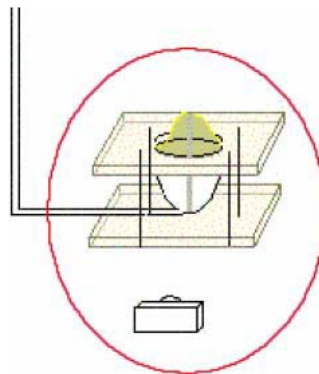


Fig. 20. Camera and inflation (not to scale).

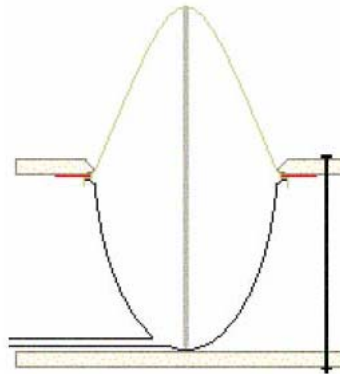


Fig. 21. Cross section (not to scale).

4.2. *Experimental results*

The various membranes were tested using the apparatus discussed in previous section and at different pressures of 0kpa, 1kpa and 2kpa. The inflation for 1kpa is of prime importance as it is known that the pressure in the epicardial region of the heart is about 1kpa. Hence if the membrane deformation at 1kpa matches closely the geometry and contours of the rigid shell, it would be considered to be a good fit. Testing at 0kpa is carried out to have information which might be necessary for implantation surgery as well as for cases of pump failure. Testing at 2kpa is carried out to have information about excessive pumping, a pump failure and to corroborate the results of Section 2.3. The extent of inflation is recorded via the images taken by the camera. The results are as tabulated below in Tables 1 through 6.

Table 1
Results for axis length 100mm







Pressure (kpa)	Image from front	Image from side
0		
1		
2		

Table 2
Results for axis length 115mm






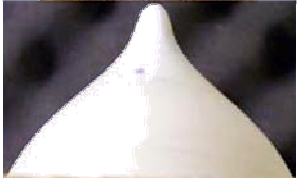
Pressure (kpa)	Image from front	Image from side
0		
1		
2		

Table 3
Results for axis length 130mm







Pressure (kpa)	Image from front	Image from side
0		
1		
2		

Table 4
Results for axis length 140mm







Pressure (kpa)	Image from front	Image from side
0		
1		
2		

Table 5
Results for axis length 145mm













Pressure (kpa)	Image from front	Image from side
0		
1		
2		

Table 6
Results for axis length 150mm

Pressure (kpa)	Image from front	Image from side
0		
1		
2		

4.3. Results analysis

The images then have to be analyzed, scaled and compared to get a better understanding of the test results. The images are analyzed using commonly available software such as Image J or MS Paint and then scaled and compared using MATLAB or MS Excel. The various contours can then be compared against each other as well as the contours of the outer rigid shell, for different pressures or for different values of axis length. Below in Figs 22 through 33, are the comparisons for different values of pressure for each value of axis length.

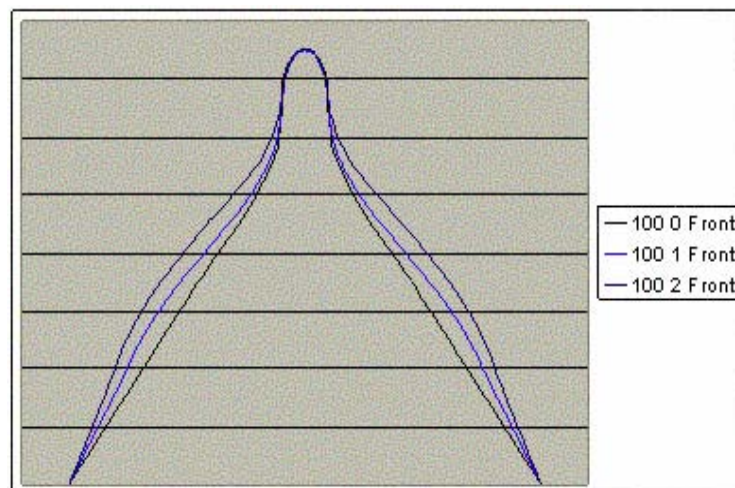


Fig. 22. Front section profiles for axis length 100mm and pressures of 0kpa, 1kpa and 2kpa.

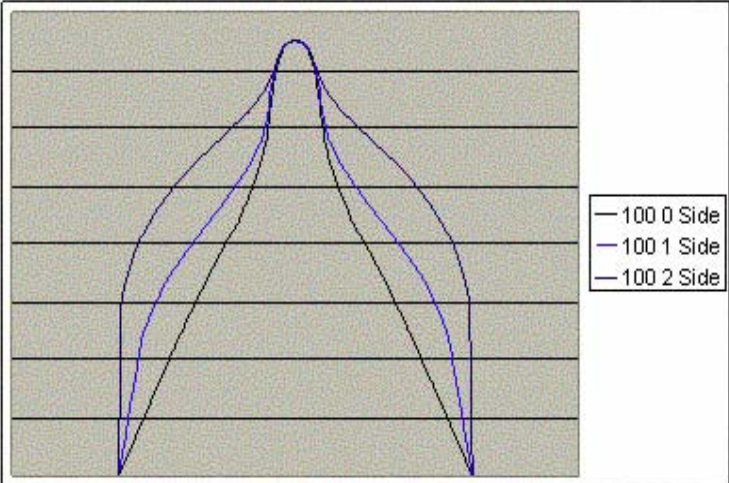


Fig. 23. Side section profiles for axis length 100mm and pressures of 0kpa, 1kpa and 2kpa.

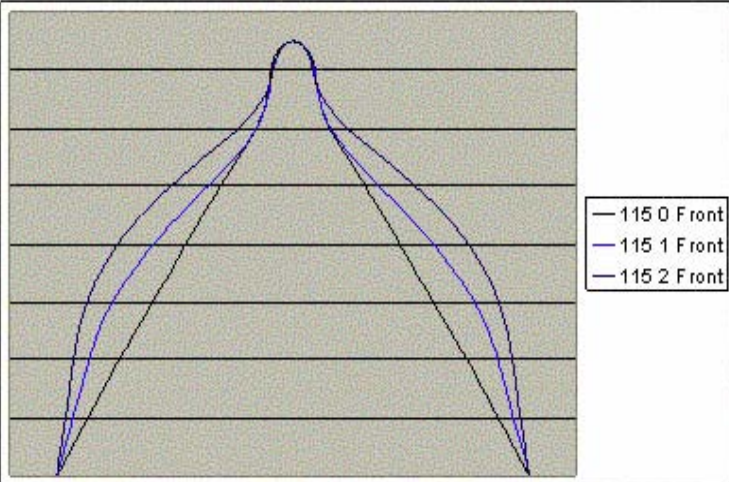


Fig. 24. Front section profiles for axis length 115mm and pressures of 0kpa, 1kpa and 2kpa.

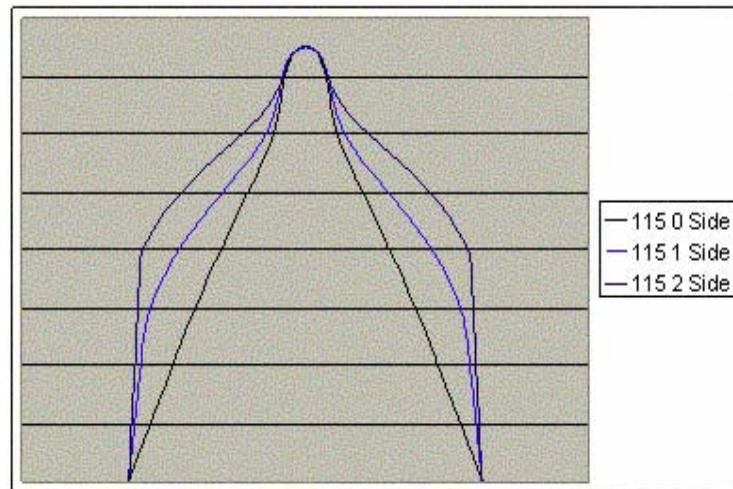


Fig. 25. Side section profiles for axis length 115mm and pressures of 0kpa, 1kpa and 2kpa.

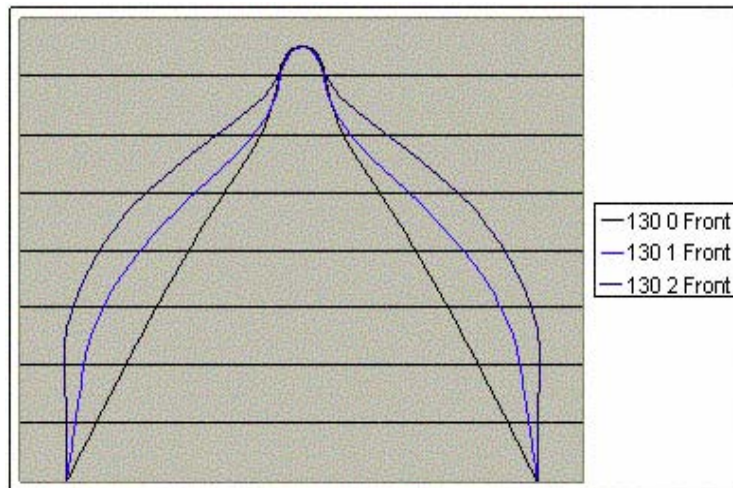


Fig. 26. Front section profiles for axis length 130mm and pressures of 0kpa, 1kpa and 2kpa.

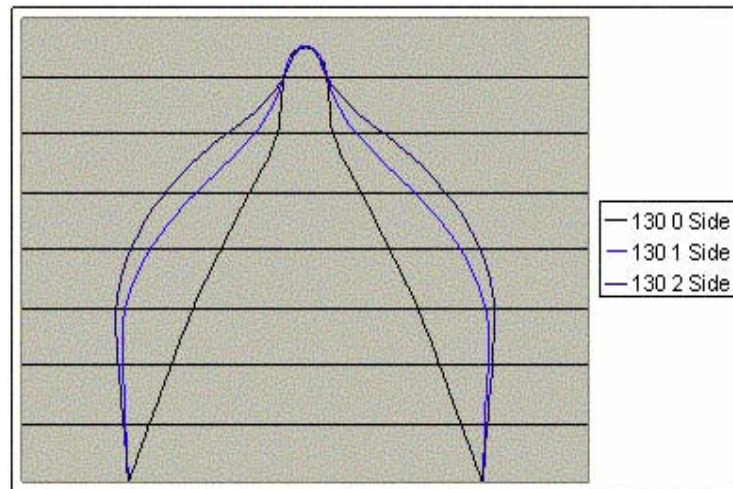


Fig. 27. Side section profiles for axis length 130mm and pressures of 0kpa, 1kpa and 2kpa.

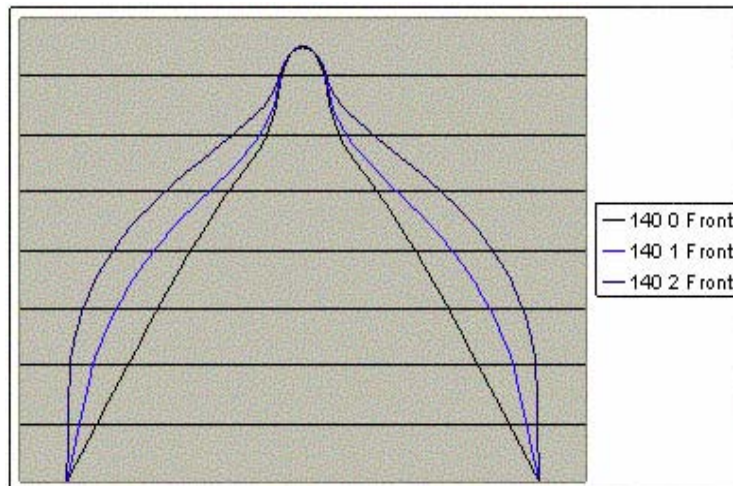


Fig. 28. Front section profiles for axis length 140mm and pressures of 0kpa, 1kpa and 2kpa.

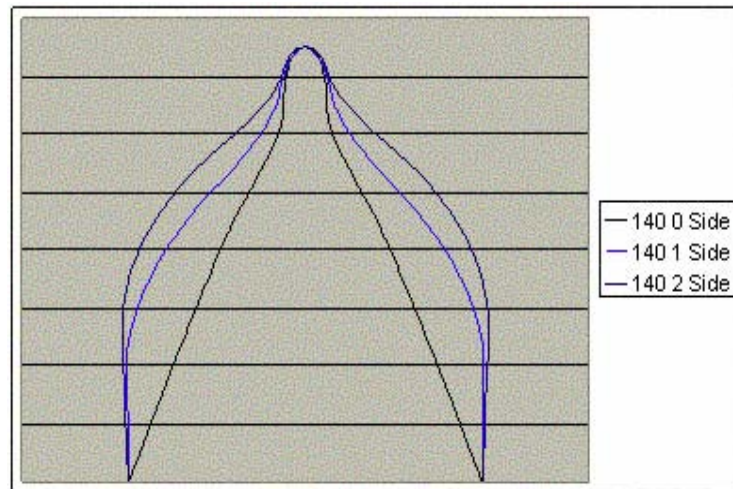


Fig. 29. Side section profiles for axis length 140mm and pressures of 0kpa, 1kpa and 2kpa.

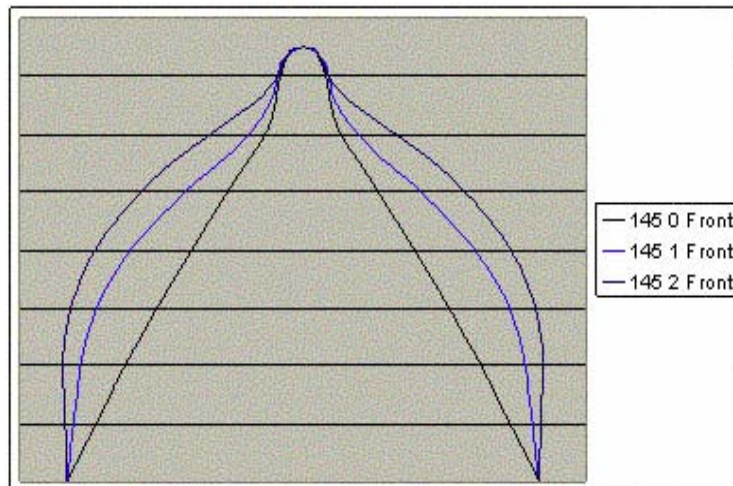


Fig. 30. Front section profiles for axis length 145mm and pressures of 0kpa, 1kpa and 2kpa.

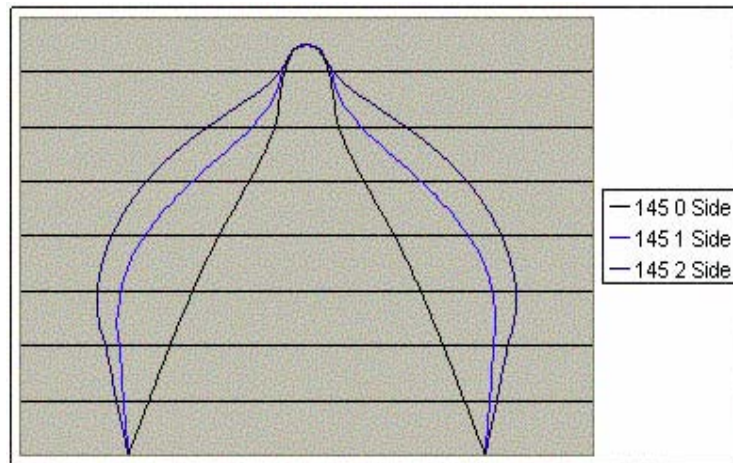


Fig. 31. Side section profiles for axis length 145mm and pressures of 0kpa, 1kpa and 2kpa.

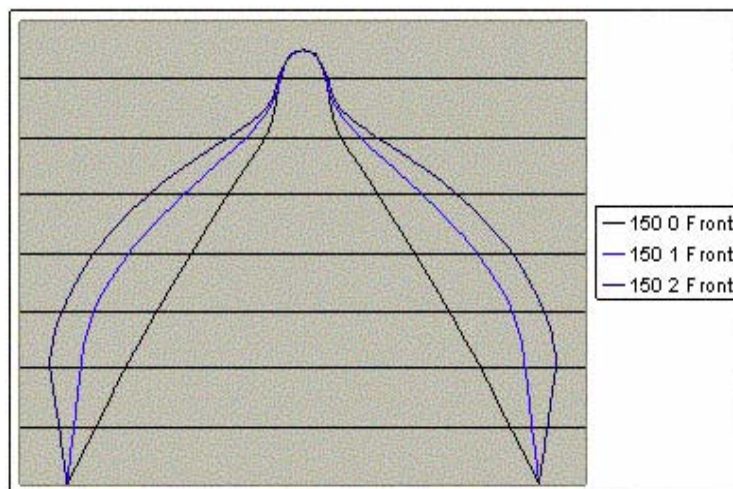


Fig. 32. Front section profiles for axis length 150mm and pressures of 0kpa, 1kpa and 2kpa.

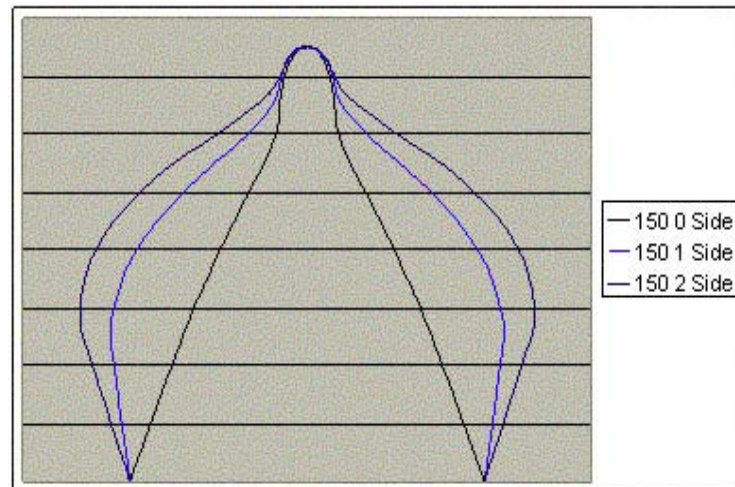


Fig. 33. Side section profiles for axis length 150mm and pressures of 0kpa, 1kpa and 2kpa.

Given below in Fig. 34 and Fig. 35 is a comparison of the actual profile and the three dimensional reconstruction of the profile from the results for axis length 100mm and pressure of 2kpa. Similar reconstructions can be done for all axis lengths and all pressures, to get a better understanding of the three dimensional inflation profiles.



Fig. 34. Actual inflated profile for axis length 100mm and pressure of 2kpa.

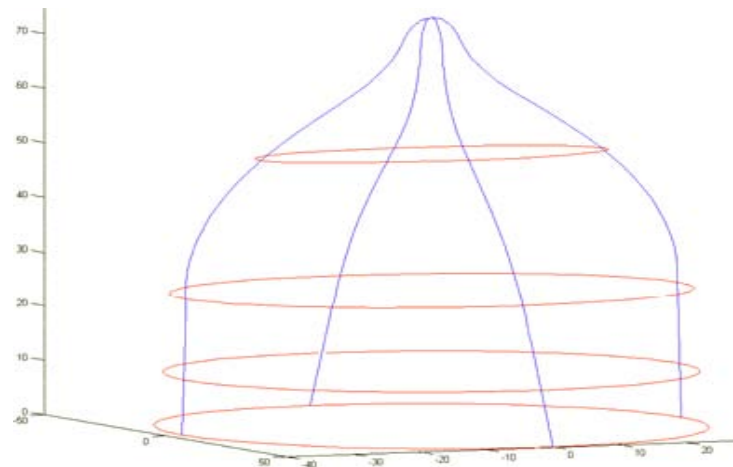


Fig. 35. Three-dimensional reconstruction of inflated profile for axis length 100mm and pressure of 2kpa.

These profiles were then compared to the profile of the heart when at diastole as shown in Fig. 36 below. This was done by matching the inflation profile with the profile of the outer rigid shell, as the rigid shell was prepared using the exact profile and shape of the human heart at diastole.

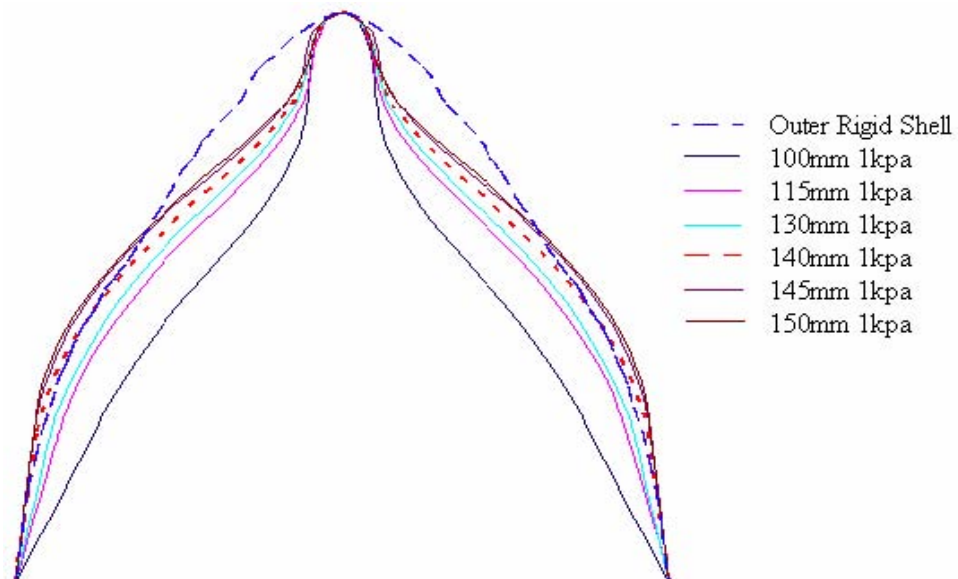


Fig. 36. Comparison of inflation profiles.

As we can clearly see from the results, the best fit was the membrane with axis length of 140mm at 1kpa pressure, which is also the normal coronary arterial pressure.

5. CONCLUSIONS AND FUTURE WORK

5.1. *Conclusions*

The research for this thesis was aimed at developing the highly elastic membrane, from an ordinarily available form of polymer, which would surround the epicardial surface of the heart when used in the investigative device being discussed and specifically for the prototypes being developed.

The inflation profiles of the membranes, developed from the successful implementation of the thermoforming technique, were compared to the profile of the heart when at diastole. This was done by matching the inflation profile with the profile of the outer rigid shell, as the rigid shell was prepared using the exact profile and shape of the human heart at diastole. It was found that out of all the membranes studied at different pressures, the best fit was the membrane with axis length of 140mm at 1kpa pressure, which is also the normal coronary arterial pressure.

The simulation for predicting the behavior of isotropic ellipsoids, upon inflation, was successful in predicting the behavior and was aided by conversion of the ellipsoidal geometry to a few degrees of freedom. Further improvements to the simulation fall beyond the scope of this thesis.

5.2. *Future work*

The immediate future use for the membranes developed using the technique developed would be for use in prototypes being developed by the team led by Dr. Criscione.

Future research work could be carried out in many directions. Hemocompatibility studies to evaluate the interactions of the material and the prototype device with blood can be carried out. Membrane morphology studies and molecular modeling to yield a molecular structure best suited for inflation under current set of limitations would help refine and enable a better usability of these results. Improvements in simulating the inflation behavior of isotropic ellipsoids can be carried out. Simulation can also be carried out to cover the inflation behavior of anisotropic membranes.

5.3. *Brief comparison of various methods*

This section is for a brief comparison and discussion of the various methods of polymer processing discussed previously, from the perspective of industrial implementation and large scale manufacturing of the investigative device and in particular the highly elastic membrane. Here the concerns of intellectual property, monetary limitations and copyright issues would tend to pose diminutive problems than before as an industrial implementation would effectively mean that these and other legal concerns have been met with before the implementation.

Effective comparison of different techniques for companies, on a level playing field would be difficult as it would need to take into account the existing company facilities, workforce skill-sets, available processing equipment, market conditions for the final product and pricing limitations etc. However, the primary concerns and focal points of interest that can be easily identified for this evaluation purposes are:

- **Adaptability of technique to individual heart shapes and sizes:** Even though the human heart can be generalized as being prolate-ellipsoidal in shape and having certain dimensions, individual patients would always have certain uniqueness and the membrane would have to be adapted to each patient. To adapt the open mold and the gated casting techniques to this uniqueness would pose problems, as the molds would need to be altered for each patient. The thermoforming technique would prove to be more adaptable on this count.
- **Cycle time and total production time:** The total production time, as identified while hands on experience in the lab, was shortest for the thermoforming technique. The cycle time, in industrial setting, would probably be shortest in the gated casting technique because of the available expertise and equipment.
- **Rate of production:** If one were to consider just the rate of production based on the cycle time while ignoring the adaptability concern, the gated casting technique would have a higher rate of production. Taking into account the adaptability concern, the thermoforming technique would score nearly equal or slightly better than gated casting.

- Ease of manufacturing mold / processing technique: Based on normally available mold manufacturing techniques and readily available skilled workforce in the mold making industry, none of the three methods would score highly over any else.
- Ease and time required for changing molds: Since the thermoforming technique requires no change of mold to accommodate for any changes in membrane shape, it would score highly over the other two methods on this point.
- Possible production volumes: The gated casting technique would probably have a higher production rate if it were to be assumed that no change in mold would be required. However this assumption would be invalid in most cases in which case none of the three methods would fare any better.
- Need for training personnel on process and intricacies: In view of the fact that most of the skilled workforce that industry would have access to, is trained on injection and extrusion molding, some level of training would need to be imparted for open mold and thermoforming. However enough skilled labor can be found for thermoforming technique as well and would fare evenly with gated casting.
- Limitations to any materials that can be processed using this technique: Gated casting would score heavily on this point as its versatility for materials is well known. Thermoforming would score the least on this point as the starting material would need to be in the form of a sheet.
- Hazardous chemicals involved and related disposal requirements: The gated casting and open mold techniques make use of polymer in the form of pellets and require melting of the polymer. Depending on the polymer being used, the solvent and the additives that could give off toxic vapors on decomposition the hazardous nature would be decided. Since thermoforming involves no melting, it poses little to none toxic hazard. However disposal requirements would be evenly strict for all three techniques.

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APPENDIX A

MATLAB Code

```

% main file for solving the inflation model % requires the
following other m-files to be in the same directory: initvals.m,
getrefnodes.m, getxyz.m, post_process.m, d_energyfcn.m, amit_out

clear all close all

global history_i stardofs N_steps global shear_mod thickness
Aref4els Omg_wts Omg_history num_els
Nz2incs Pts_irow global V_history global nv_history global
max_x_4plots min_x_4plots max_y_4plots min_y_4plots
max_z_4plots min_z_4plots global deltaP P_history

Rad_X=50; % Radius of shell in x direction %
Rad_Y=37.5; % y direction %
Rad_Z=75; % z direction %

max_x_4plots=Rad_X; min_x_4plots=0;
max_y_4plots=Rad_Y; min_y_4plots=0;
max_z_4plots=0; min_z_4plots=-Rad_Z;

P_final=1;
deltaP=0.05;
N_steps=round(P_final/deltaP);

if N_steps < 1; error('number of steps is less than 1'); end
history_i=1;

P_history=zeros(N_steps+1,1);
Omg_history=zeros(N_steps+1,1);
V_history=zeros(N_steps+1,1);
nv_history=zeros(N_steps+1,12);
P_history(history_i)=0;
thickness = 1/6;
shear_mod=4*500;

Per_YZ=2*pi*sqrt(0.5*((Rad_Y^2)+(Rad_Z^2)));
Per_XZ=2*pi*sqrt(0.5*((Rad_X^2)+(Rad_Z^2)));
Arc0=(Per_XZ)/4; % Arc length for z1=0 %
Arc1=(Per_YZ)/4; % z1=pi/2 %

stardofs = [Arc0 Arc1 pi/2 pi/2 Rad_Z Arc0 Arc1];
starnode = getrefnodes(stardofs);
start_nvs = [Rad_X, Rad_Y, starnode];
nv_history(history_i,:) = start_nvs;

```

```

initvals
post_process(start_nvs)
x0=stardofs';
A=[]; Aeq=[];
b=[]; beq=[];

ub=[Arc0*2 Arc1*2 pi pi Rad_Z*4 Arc0*2 Arc1*2]';
lb=[Arc0*0.5 Arc1*0.5 -pi -pi Rad_Z*0.2 Arc0*0.5 Arc1*0.5]';
soln_history=zeros(N_steps+1,7);
soln_history(1,:)=x0';
for i=1:N_steps      x =
fmincon('d_energyfcn',x0,A,b,Aeq,beq,lb,ub); x0=x;

history_i=i+1;      soln_history(history_i,:)=x0';      cur_nvs =
[Rad_X, Rad_Y, getrefnodes(x')];      nv_history(history_i,:) =
cur_nvs;      P_history(history_i) = P_history(history_i-
1)+deltaP;      post_process(cur_nvs)      pause(0.5)
[y] ', 's');user. '); end end

save soln_1 soln_history P_history Omg_history V_history
nv_history z1comps z2comps N_steps max_x_4plots min_x_4plots
max_y_4plots min_y_4plots max_z_4plots min_z_4plots Nz2incs
Pts_irow num_els amitout

```

APPENDIX B

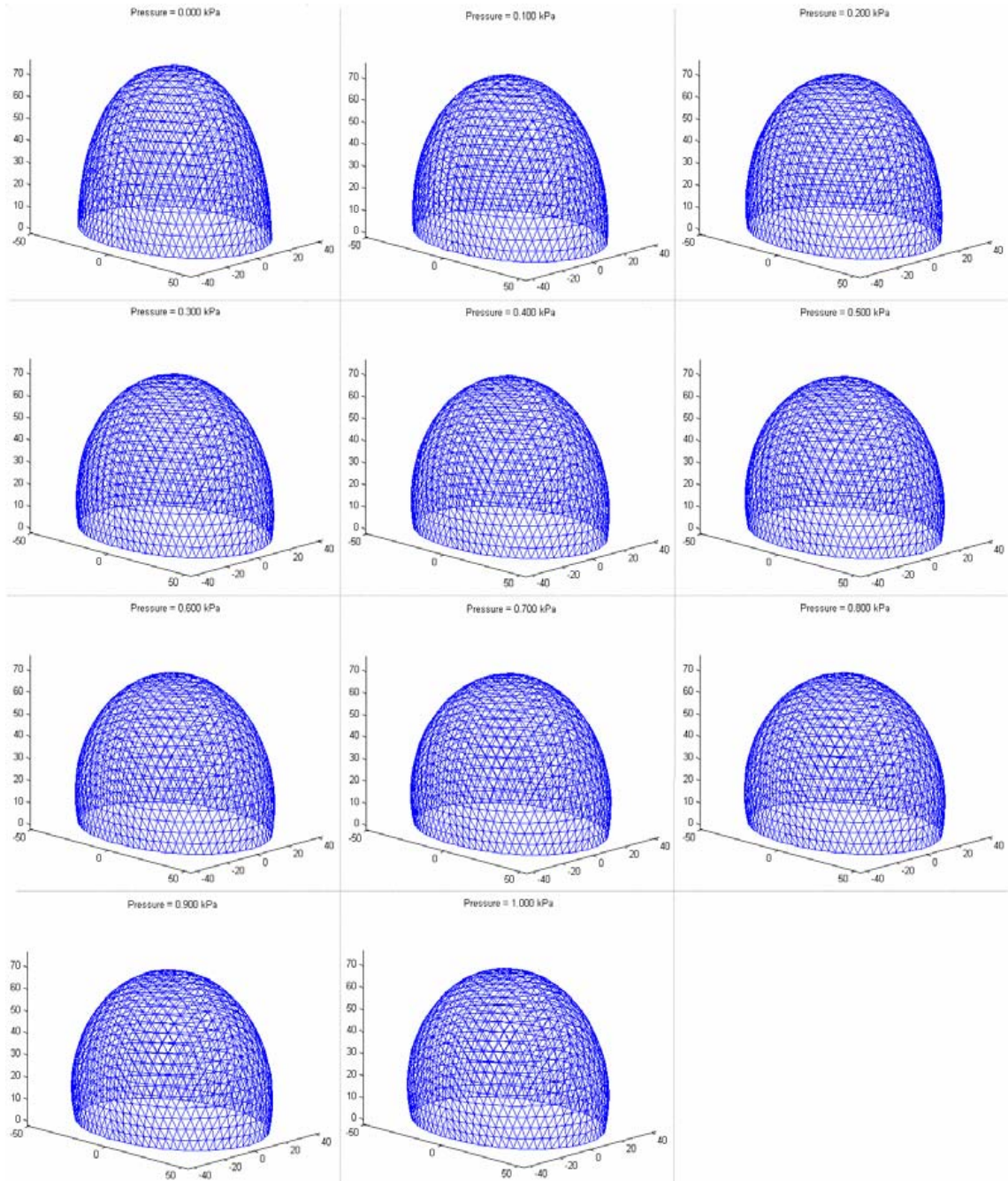


Fig. B-1. Stepwise simulation results.

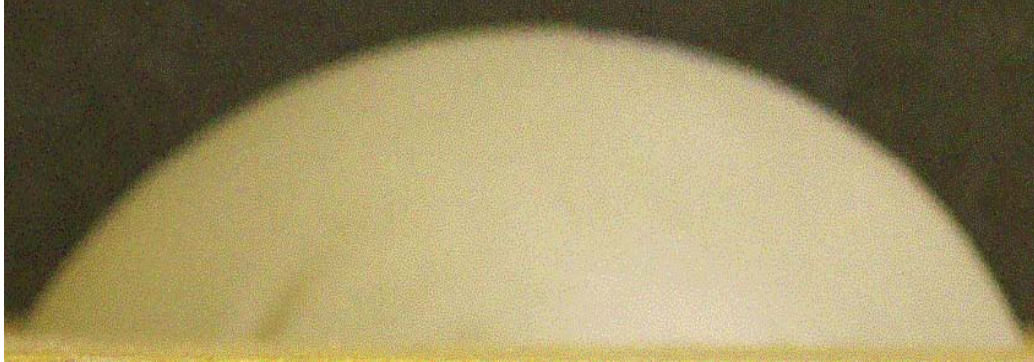
APPENDIX C

Fig. C-1. Actual inflated profile for axis length 140mm and pressure of 1kpa.

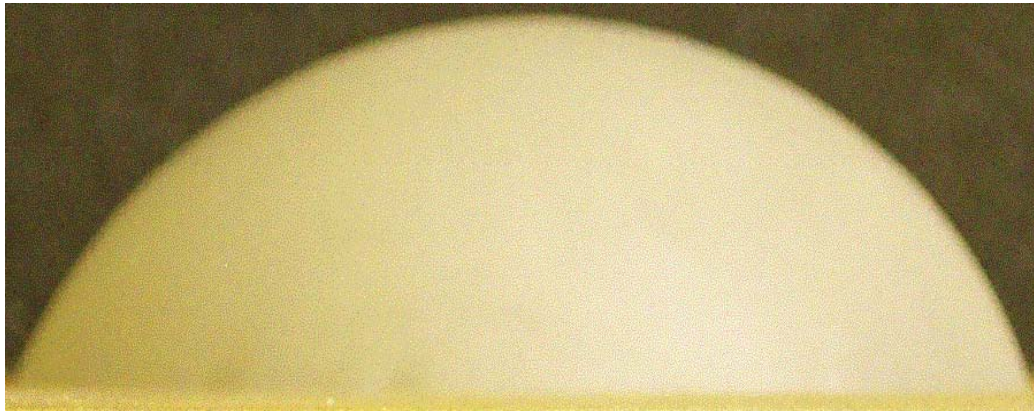


Fig. C-2. Actual inflated profile for axis length 140mm and pressure of 2kpa.

APPENDIX D

Table D-1

Calculations for axis length for each variable

Direction	Wanted Diameter (inches)	Wanted Radius (inches)	XY perimeter	YZ perimeter	XZ perimeter
x	3.938	1.969	10.933	14.667	15.768
y	2.952	1.476			
z	5.906	2.953			
Half of Perimeter (inches) = axis length			5 1/2	7 1/3	7 8/9
x	3.938	1.969	10.933	14.275	15.404
y	2.952	1.476			
z	5.709	2.854			
Half of Perimeter (inches) = axis length			5 1/2	7 1/7	7 5/7
x	3.938	1.969	10.933	13.890	15.048
y	2.952	1.476			
z	5.512	2.756			
Half of Perimeter (inches) = axis length			5 1/2	7	7 1/2
x	3.937	1.969	10.933	13.125	14.345
y	2.952	1.476			
z	5.118	2.559			
Half of Perimeter (inches) = axis length			5 1/2	6 5/9	7 1/6
x	3.937	1.969	10.933	12.007	13.330
y	2.952	1.476			
z	4.528	2.264			
Half of Perimeter (inches) = axis length			5 1/2	6	6 2/3
x	3.938	1.969	10.933	10.933	12.371
y	2.952	1.476			
z	3.937	1.969			
Half of Perimeter (inches) = axis length			5 1/2	5 1/2	6 1/5

APPENDIX E

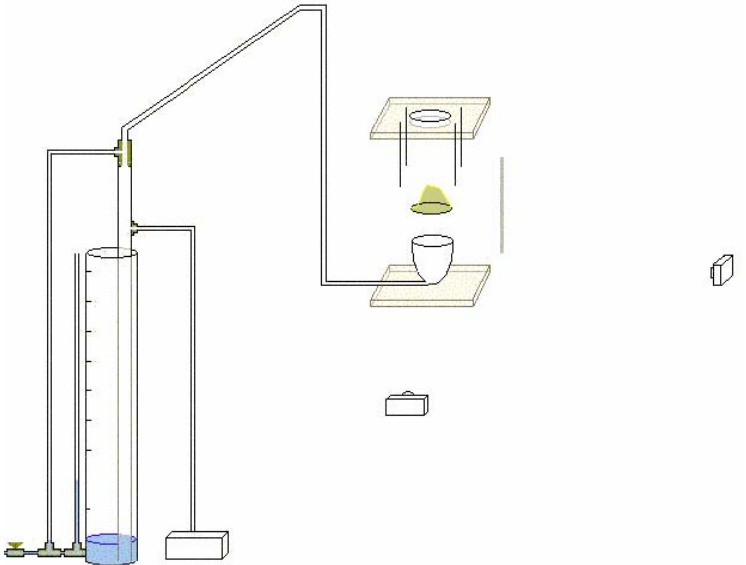


Fig. E-1. Schematic of test setup and various components prior to testing (not to scale).

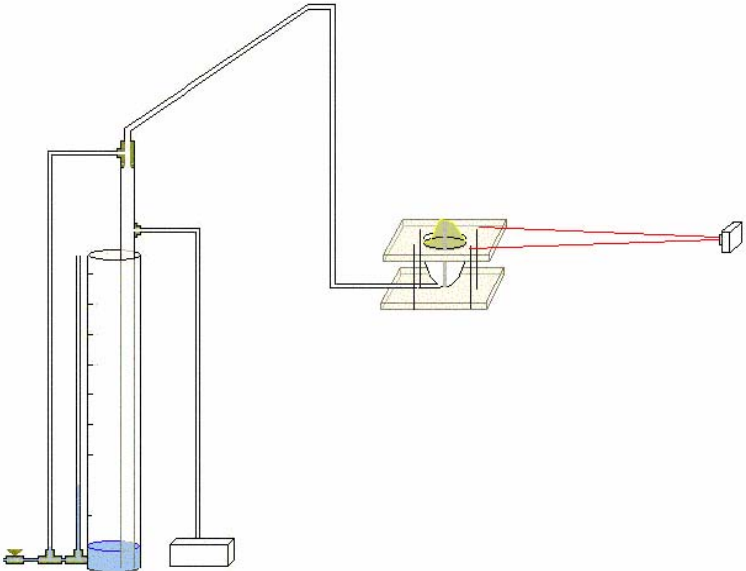


Fig. E-2. Schematic of test setup and various components while testing at 1kpa (not to scale).

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