CHAPTER 1

INTRODUCTION

1.1 Background of Study

Cryosurgery is the specialized field of using extremely low temperatures to destroy pathological tissues. Cryosurgery is not a new concept in the elimination of pain. Hippocrates recognized the analgesic and anti inflammatory properties of ice on injuries in the year 430BC. The cold is introduced through a probe which has liquid nitrogen circulating through it. To destroy diseased tissue, the tissue is cooled to below -20 degrees Celsius. Other procedures that control pain or bleeding are cooled to a lesser degree to prevent tissue damage.

In the past few decades, cryo-technology has been used in the treatment of malignant tumors of the prostrate, liver and other organs. Moreover, cryosurgery is gaining acceptance in dermatology, plastic surgery, urology, pain management and podiatry.

Many other specialties have embraced and refined the technique of cryosurgery. Eye surgeons have used it extensively. The first report of retinal tears treated by freezing came from Bietti in 1933, and when Bellowes reviewed cryotherapy of ocular diseases in 1966 he included cryoextraction of cataracts and treatments for glaucoma and tumours. Cryosurgery still has an important place in modern ophthalmological practice, particularly for eyelash ablation in trichiasis treatment of retinopathy of prematurity and retinaldetachment.

Among the advantages of cryosurgery are known and it seems natural to expect that increasing the power of freezing helps to destroy the large area of biologic tissue. In actuality, the analysis of mechanism of cryodestruction has shown that the basic process of destruction is limited by the forming of ice at the level of micro-circulation because of the high degree of density of biological tissue- 10^{10}- 10^{12} cells in cm^3. To estimate the area of destruction, it is much better to take into consideration the heat from all the mass of human body. It is the main reason of the absence of success of local freezing of large zone of pathological tissue.

While analyzing published data on curves of freezing, we constructed a generalized curve for all regimes of cryo-applications. Effective time of cryodestruction about 10-20 minutes, during when thermodynamic equilibrium is established. The measures of temperatures with the use of thermocouples and other tools reveal a drop in temperature from +37°C at the deep of 1-2 cm to -60°C on the surface, so it is difficult to estimate a real temperature profile. That is why the mathematical simulation of the freezing zone is the best way to find the adequate zone of freezing (Shafranov,Tsyganov & Borkhunova,1998).

1.2 Problem Statement

1.2.1 Need to be solid and simple

The highest incident that cataract occur is in 3rd World country in Africa such as Kenya, Nigeria and India. For example, 47% of all the blinds of partially blinds had been suffering from cataracts. The visits by surgeons to Addis Adaba Hospital in Kenya had found that there are some criteria laid down to make sure the cryogenic application can be used and it must be solid and simple to use .

This tool also must no trailing leads that interfere with surgical manipulation of the instrument and sterilization by any conventional method must be possible

1.2.2 Tool that are heavy and bulky

Most of the tools that are being designed before are heavy and bulky and consume large space. For example, now days, tool are using electric that need to have power supply that are bulky to carry and that is difficult to bring to rural area.

1.2.3 Liquid storage

There are problem in keeping some refrigerant in rural area due to problem in keeping it .So it is a problem to surgeon to use cryosurgery in some places such as the place that are interior in the forest or aborigines places. Due to that this tool must use liquid that is easier to store.

1.3 Objective

The objectives of this project is to design a cryosurgery tool for cataract removal, The following are the main considerations :

i) Redesign a cryosurgical tool for cataract removal application that is small, and easy to transport based on datum design.

ii) Simulate the tool using software to check the temperature

1.4 Scope of Study

In order to complete this system, several scope of study has been achieved. The major scopes are as follows: The scope of study includes studying:-

i) The design for this cryosurgical tool

a) Design using design software (AutoCAD)

b) Simulate and test this tool using software (CFD) to check the temperature

CHAPTER 2

LITERATURE REVIEW

2.1 Background of Literature Review

Development of cryosurgery began when treatment of retinal detachment was attempted by Bietti (1933) and then the same year by Deustchman (1933).During that time, they are using mixture of solid carbon dioxide and acetone in handle of a metal probe.

Cryosurgery is the destruction of the undesired biological tissues by freezing. Cryosurgery has been used to treat many organs that involved cancer and also the one that will need to be repaired such as retina and cataract problem in the eye. It has great potential as an alternative for conventional surgery with minimal damage to the healthy surrounding tissue.

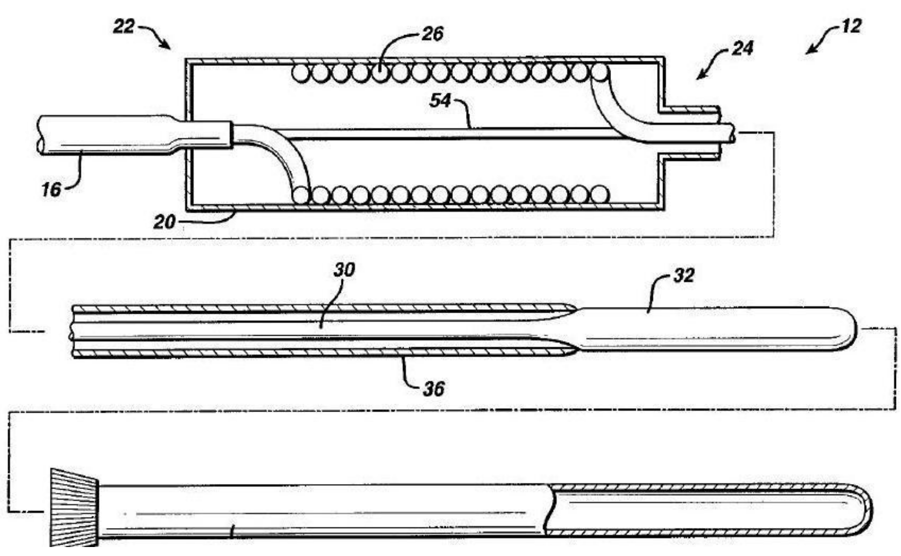


Figure 2.1: Example design of cryosurgery tool *(Forlenza,et al.,2008)*

The current invention about this cryo tool product is generally relates to the system and methods for performing cryosurgery in detail. Cryosurgical probes that are energized by the Joule-Thomson refrigeration cycle appeared in the middle of the twentieth century. These systems utilize a single component working fluid (e.g., Argon), and therefore required high supply pressure to produce a useful amount of cooling. It is not possible to install the multistage compressor required in a portable and practical package. Therefore, the working fluid is obtained from pressurized gas cylinders that are externally filled and consumed in the operating room. These systems are still used commercially today. They are less bulky than the earlier liquid nitrogen cryoprobes but still cannot operate indefinitely and require ventilation (Rubinsky,2000).

A cryogenic surgical tool for substantially freezing over predetermined areas of mammalian body which includes a handle member adapted to be grasped by a user. Additionally, the cryogenic surgical tool includes an applicator member which is releasable secured to the handle member. The applicator member is adapted to contain a cryogenic liquid and an applicator first end having a first end surface for contiguous contact with mammalian body.

So what is a typical cryosurgical procedure? When performing cryosurgery it is extremely important to identify the area or areas of greatest pain. This becomes the target point for the cryoprobe. The area is injected with local anesthesia. A 3mm percutaneous incision is made and a trocar is inserted to separate tissue. After which, the cryoprobe is inserted and depending on the foot pathology the area is treated with 2 cycles of 2-3 minutes with a defrost cycle of 30 seconds in between.

In overall concept, cryosurgery provides the surgical method of destroying tissue without utilization of a scalpel blade, thus providing a likely no scar (Sweren&Schwartz,1988).In engineering field, this cryosurgical tool will permits maximum heat to be extracted through the tip that will ensure no prolonged contact with a portion of human body. This permits maximum heat to be extracted through to the tip to ensure that the contact with human body will not increase the temperature of human body.

So how does cryosurgery work? Cryoanalgesia or cryoablation as it is also called is a minimally invasive procedure that uses extremely cold temperatures to selectively destroy nerve endings. Carbon dioxide is forced under pressure between 600 and 800 psig between the inner and outer tubes of the cryoprobe. The gas is released through a small opening into the chamber at the tip of the probe. As the pressurized gas is released into the chamber it expands and results in a rapid drop in temperature. This is referred to as the Joule- Thompson effect and results in an ice ball forming at the uninsulated tip of the probe. The temperature can reach -70°C and the size of the ice ball can range from 3.5mm to 10 mm depending on the amount of the tube that is uninsulated. This is a closed system therefore no gas escapes from the system (Kite,2006).

In addition, this Joule- Thompson effect is one of the main concept in producing this tool. When a gas expands through a porous plug, a change of temperature occurs, proportional to the pressure difference across the plug. The temperature change is due to a departure of the gas from Joule's laws, the gas performing internal work in overcoming the mutual attractions of the molecules and thus cooling itself; and partly to deviation of the gas from Boyle's law. The latter effect can give rise to either to cooling or heating, depending upon the initial temperature and pressure difference used. For a given mean pressure, the temperature at which the two effects balance, resulting in no alteration of temperature is called the inversion temperature. Gases expanding through a porous plug below their inversion temperature are cooled, otherwise they are heated (Darling,2005).

This cryo tool is preferable to be providing with cryosurgical refrigeration system which can be precooled in a standby mode prior to use. Full probe cooling from the standby mode will be preferably being achieved within several minutes or less under thermal load. It would further be desirable to provide cryosurgical refrigeration system to close the cryosurgical system where sterilization of the probe components of such system is facilitated

2.2 Tools that being manufactured

Cryosurgery tool had been manufactured from 1933 until now is being used widely as the time goes on. There are several example of cryosurgery tool that being manufactured like one tool that was manufactured around 1960s**(** Edward,1970 **)** which is a cryosurgical system that having a pencil-like-hand piece which supplies liquid gas through a very small tube that sprays it to adjacent tip and having an exhaust system connected to a vacuum pump so that gas is quickly evaporated and removed from the probe. This permits maximum heat to be extracted through the tip to insure that no prolonged contacts with a portion human body that cannot increase the temperature of the tip.

When desired, the temperature of the tip can be elevated by flooding the probe with the liquid gas which is still a relatively low temperature but warmer than the temperature produced evaporating liquid. In one embodiment, the flow of liquid gas is controlled from a foot switch while in another is controller from small valve in the pencil-like hand piece. In a third embodiment, a U- shaped probe is utilized and no valve is provided. (See Figure 2.2)

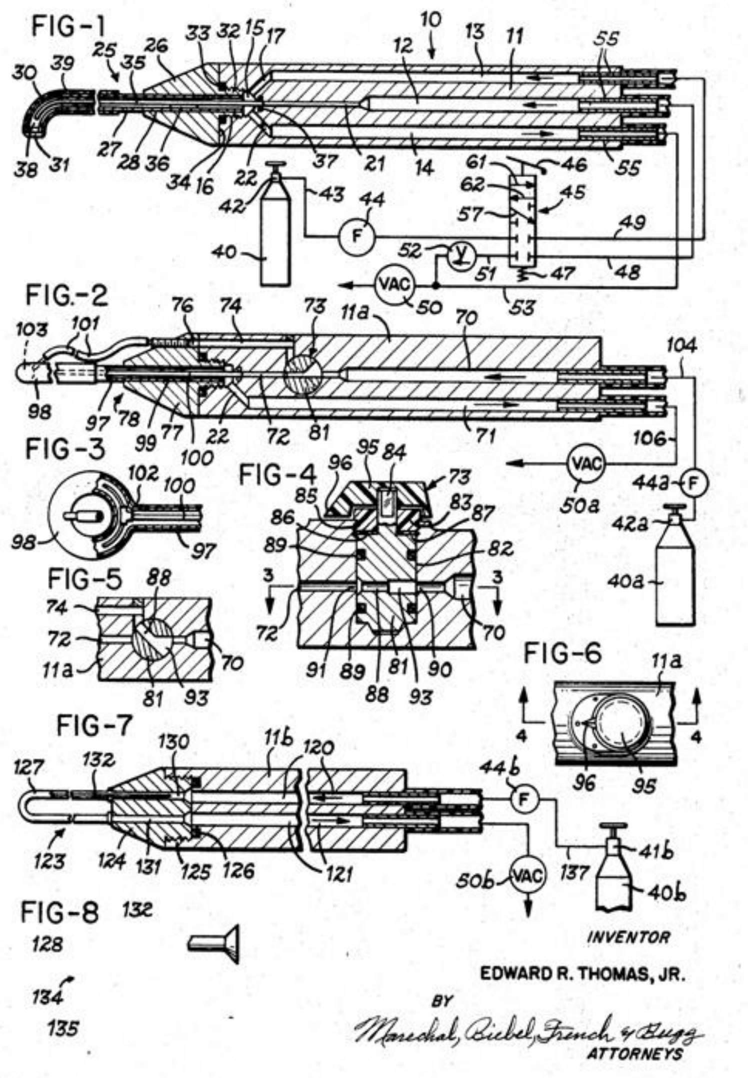


Figure 2.2 : Cryosurgical instrument *(Edward ,1970)*

There are also cryo tool that being used with other application to make sure that the effect is at the optimum such as the Surgical instrument with ultrasound pulse generator. This tool is a combination a cryosurgery method and ultrasonic. This invention is about medical surgical probe that having an ultrasound transducer operatively incorporated into the tip of the probe.The probe having manipulating means for manipulating tissue within human body in a minimally invasive manner. The visualization and localization of the probe tip and the tissue manipulation is enhanced by ultrasound pulses generated at the tip of the probe.

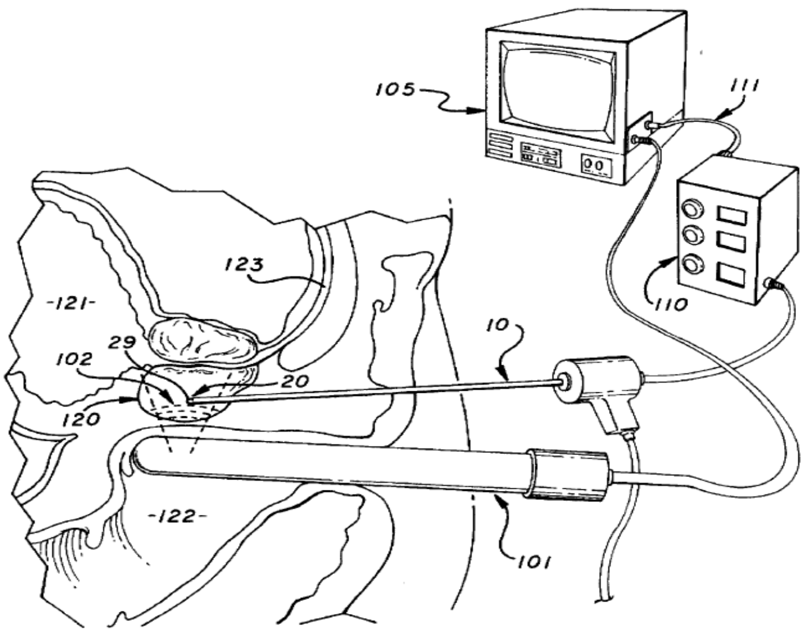


Figure 2.3 : Example full set of cryosurgery tool *(Zupkas,1997)*

Cryosurgical procedures involve deep tissue freezing which results in tissue destruction due to rupture of cells and or cell organelles within the tissue. Deep tissue freezing is effected by insertion of a tip of a cryosurgical device into the tissue, either transperineally , endoscopically or laparoscopically, and a formation of, what is known in the art as, an ice-ball around the tip.

In order to effectively destroy a tissue by such an ice-ball, the diameter of the ball should be substantially larger than the region of the tissue to be treated, which constraint derives from the specific profile of temperature distribution across the ice-ball.

Thus, in order to effectively destroy a tissue there is a need to locate the isothermal surface of-40° C at the periphery of the treated tissue, thereby exposing adjacent, usually healthy, tissues to the external portions of the ice-ball. The application of temperatures of between about -40° C and 0° C to such healthy tissues usually causes substantial damage thereto, which damage may result in temporary or permanent impairment of functional organs.

A classical cryosurgery procedure for treating the prostate includes the introduction of 5-7 probes into the prostate, the probes being typically arranged around the prostatic urethra such that a single probe is located, preferably centered, between the prostatic urethra and the periphery of the prostate. The dimensions of such a single probe are usually adapted for effectively treating the prostatic tissue segment extending from the urethra to the periphery of the prostate, e. g., a tip of 3 millimeters in diameter, generating an ice-ball of 3-4 centimeters in diameter, depending on the size of the prostate. Since a single ice-ball is used for freezing such a prostatic tissue segment, the volume of adjacent tissues exposed to damage is substantially greater than the volume of the treated tissue. For example, if the area of the ice-ball in cross section is zR2, and an effective treatment of at least-40°

Cryosurgery tool for cataract removal also being developed nowadays. Low temperature techniques were used in ophthalmic surgery more than 30 years ago (Bietti, 1933, 1934; Deutschmann, 1935) but interest in cryosurgery has become widespread only in the 1960. In the main, cryosurgical techniques are used to produce controlled necrosis and inflammation in selected areas of tissue. However, Krwawicz (1961) described a new application of cryogenics which involved freezing a small probe onto the lens to provide adhesion for cataract lens extraction. In the last few years, many ophthalmic surgeons have adopted this technique for routine cataract operations because it displays several advantages over other methods used up to this time. It is easier and safer than the conventional method of gripping the lens capsule with forceps, it virtually eliminates capsular rupture and it improves the clinical results Indeed, utilization of low temperature has been acclaimed the most important development of this decade in cataract surgery

The design of the instruments necessitates immersion of the probe into the freezing medium to allow it to cool to a suitable working temperature. The two most universally available and hence the most useful media for this purpose are carbon dioxide snow and liquid nitrogen.Carbon dioxide snow with acetone added to give it a suitable mushy consistency as well as to provide sterility (Drews and Edelmann, 1956) yields a temperature of -79°C. if the probe is immersed for some 15 to 20 seconds. If the probe is incompletely immersed it will need a longer period to reach this temperature.
Liquid nitrogen can be poured into a stainless steel, thermos, pyrex, or plastics container.Complete immersion of the metal probe for about 40 seconds gives a temperature of -196°C., whereas 15 to 20 seconds gives a temperature adequate for cryoextraction. The graph for liquid nitrogen rise in temperature is being shown in Figure 2.4

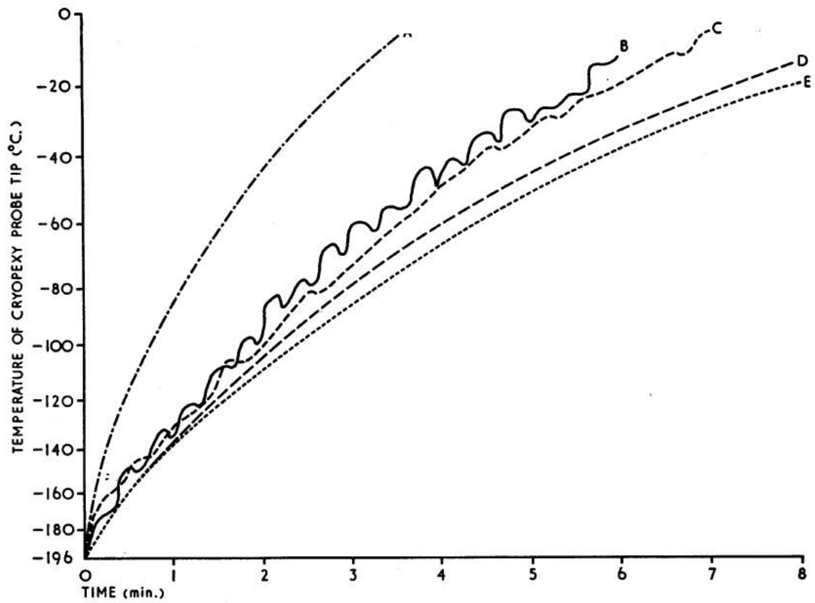


FIG. 3.—Rise in temperature of cryopexor probe tip from −196°C. after immersion in liquid nitrogen measured by copper Constantan thermocouple, with one junction in ice.

E - - - - - - - - - Probe tip at room temperature of 23°C., probe position vertical, tip down and stationary.
D — — — — Probe tip in permanent contact with eye, position constant (eye bath temperature 30°C.).
C - - - - - - - Probe tip moved constantly over surface of the eye (eye bath temperature 36 to 32°C.).
A — - — - — Probe tip exposed to blast of air from hair drier (room temperature).
B ———————— Probe tip applied intermittently: 15 sec. on, 5 off (Low peaks: application to cornea. High peaks: application to conjunctiva and sclera).

Figure 2.4: Graph of rise temperature of cryoprexor after immersion

in liquid nitrogen *(Baissalo,Sandison,Donnelly,Saliken,Muldrew & Rewcastle,2000)*

CHAPTER 3

METHODOLOGY

3.1 Process flowchart

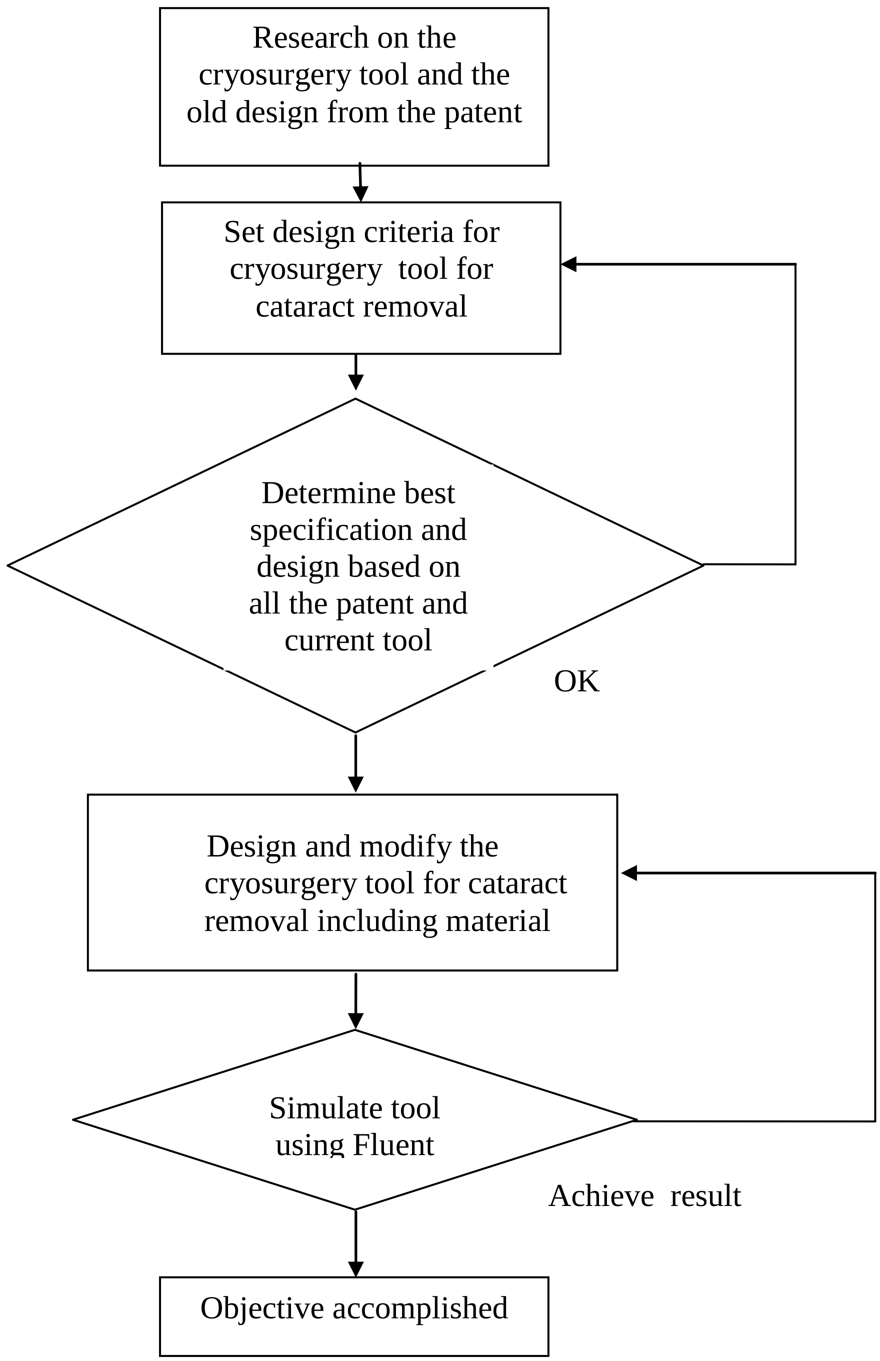


Figure 3.1: Process flowchart for designing cryo tool for cataract removal

3.2 Work Planner

1. Research the previous cryosurgery tool and current tool
    - Studying the cryosurgery tool product that is already has in current market and the entire patent.
    - Getting information about the current situation about the cryo tool based on research.
    - Finding the information before making analysis about the cryosurgery tool for cataract removal.
2. Verify advantages and disadvantages of existing cryosurgical tool
    - The next step is to clarify advantages and disadvantages of the existing cryosurgery tool.
    - All aspects should be considered to ensure the tool is being fully examined.
    - Aspects like cost, material and all the related parameter in manufacturing this cryo tool.
3. Finding all possible solutions based on the study earlier
    - Check all the solution and try to brainstorm any fresh idea for manufacturing the cryosurgery tool and test it.
4. Analyze all solutions and get the best design
    - Last stage will be analyzing all the proposed designs.
    - The best rated and simplest design will be chosen for this project.

For the final step, a model will be made based on the design that had been chosen. This model will be simulated using CFD based on specification that being done before.

3.3 Tools and Equipment

The tools and equipment which are required in this Final Year Project are a Windows based PC together with the programs such as AutoCAD and Fluent which is used to design and simulate the design. This project also required Carbon dioxide tank for the cooling system and machine that will be determined later to manufacture the tool.Indeed, Microsoft Office programs include Microsoft Word used to type reports, Microsoft Excel to draw graphs and rearranging of data.

CHAPTER 4

RESULT AND DISCUSSION

4.1 Design Selection

The design for this cryosurgery tool comes with many possibilities. For this project, the writer has narrowed down the things to be considered into some criterions which are;

i) **Either orifice is being redesigned in front of the tube or not**

ii) **Dimension of the cryosurgery tip**

iii) **Either using liquid nitrogen or carbon dioxide as refrigerant**

Every criterion above has their own values that need to be evaluated in order to decide which the best option is. In deciding the criterion to design this tool, the writer uses Weighted Decision Matrix of selection method. Weighted decision matrix is a method of evaluating completing concepts by ranking the design criteria with weighting factors and scoring the degree to which each design concept meets the criterion. To determine the score, a 5-point scale is used as the criteria for evaluation. Higher points will be given to the criterion that meets the exact condition.

Determining weighting factors for criteria is an inexact process. The weighted values are decided by ranks the criteria based on how important the criteria is for the design. The weight factor value is obtained by multiplying the weight of each values and the weight part itself

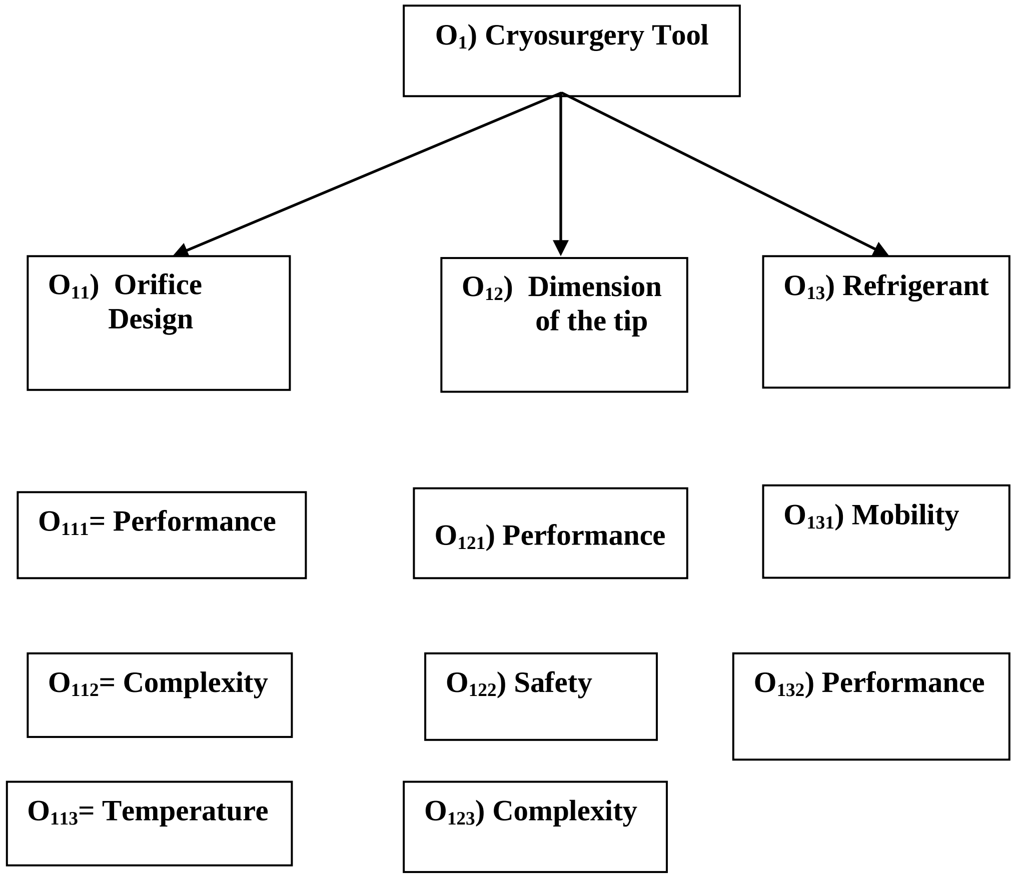


Figure 4.1: Hierarchical objective tree for calculating the weight factor

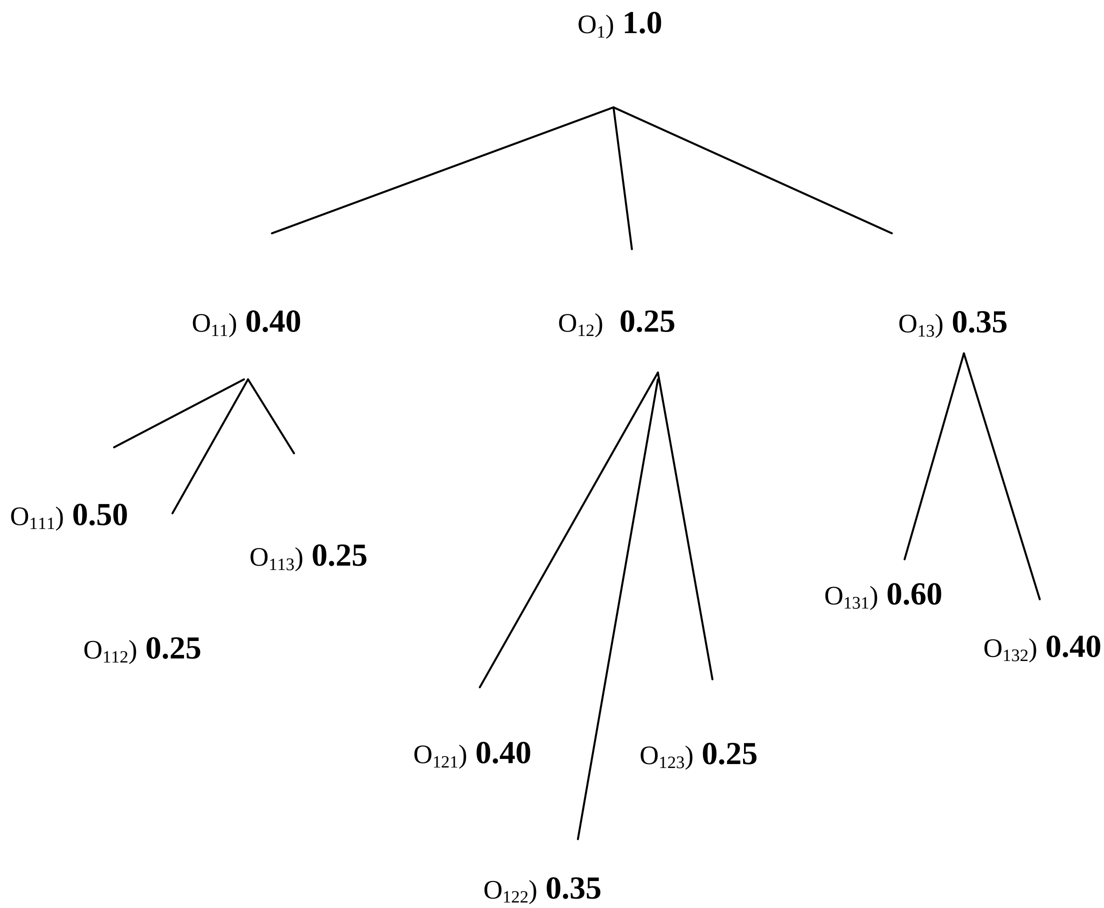


Figure 4.2: The weight tree factor for cryosurgery tool

Orifice Design

Based on Figure 4.2, performance, complexity and temperature weighted 0.5, 0.25 and 0.25 respectively. Performance being weighted as the most important one. Low complexity also plays an important element as it will affect the level of difficulty in manufacturing this tool

- Best performance

  Performance are being rated based on the how fast the tip being cooled and also how the refrigerant being distributed in producing the temperature. There are two ways of putting this orifice

  i) This orifice being set up at the first of injection tube after the refrigerant

  ii) It is being put at the last where the refrigerant is to be distributed.

  Both have different effects on the tool. So orifice that being put in front will have more point since it will distribute the refrigerant more evenly.

- Low complexity

  The design with low complexity will score higher as compared to high complexity. Writer know that this medical tool need to be very accurate since it will affect human life or can cost injury if not being treated well , so it important for this tool to have low complexity to make sure that it is easier for manufacturer to produce and modify.

- Temperature Distribution

  For this tool, the main part is to check whether the temperature meets the requirement to treat the patient, more focally, to treat cataract problem patients. Due to that, it is important for this orifice in the tool will distribute the temperature evenly at the tip

Table 4.1 shows the results of above evaluation. Based on the result, Orifice in the front will be used in the finalized design.

Table 4.1: The results for best design of orifice can be used

Consideration	Weight	Weight Factor	Orifice In front		Orifice At Back	
			Score	Rating	Score	Rating
Better performance	**0.5**	0.200	5	1.000	2.5	0.500
Low complexity	**0.25**	0.100	4	0.400	3	0.300
Temperature Distribution	**0.25**	0.100	2	0.200	3	0.300
Total	**1**	**0.4**		**1.600**		**1.100**

Dimension of the tip

Dimension of the tip is being divided into 3 other criterion that are being considered in setting the dimension of this tip for cryosurgery tool for cataract removal There are two choices of this which are 2mm diameter or 3mm diameter

- Better performance

  In determining best performance, writer is looking at the tip dimension that is suitable with the retina, because it will need to cure and remove the cataract. Due to that, for better performance, the 2mm diameter is preffered because it will need less time to get to the exact temperature compare to the 3mprobe.

- Low complexity

  The design with low complexity will score higher as compared to high complexity. This medical tool need to be very accurate because it will affect human life. Less diameter will score less because it will be more complicated to fabricate compared to the bigger one.

- Safety

  For this tool, one of the criteria in checking the dimension is the safety,since the safety of the eye need to be considered in designing this tool.

Table 4.2 shows the results of the above evaluation. Based on the result, 2mm dimension will be used for the tip

Table 4.2 : The results for best design of cryo tip diameter dimension can be used

Consideration	Weight	Weight Factor	2mm Diameter		3mm Diameter	
			Score	Rating	Score	Rating
Better performance	**0.40**	0.1	4	0.400	3	0.300
Low complexity	**0.25**	0.0625	2	0.125	3	0.1875
Safety	**0.35**	0.0875	3	0.2625	2	0.175
Total	**1**	**0.25**		**0.7875**		**0.6625**

Refrigerant

Choosing refrigerant is also will affect the design because different refrigerant will produce different style of design. There are two type of refrigerant that will be compared, namely carbon dioxide and liquid nitrogen.

- Mobility

  Consideration for this refrigerant is to make sure that this refrigerant can be kept in most of the places with minimum space requirement. So comparing both these refrigerant, we can see carbon dioxide is better because to it can be kept in room temperature compared to liquid nitrogen that need to be kept in paraffin oil.

- Performance

  The design need to consider the temperature that will be getting at the tip for using this refrigerant. Comparing both,liquid nitrogen has better performance compared to carbon dioxide. Its popularity is due to the low temperatures achievable (-197°C), But still carbon dioxide can achieve minimum temperature to perform cataract removal

Table 4.3 shows the results of above evaluation. Based on the result, we will use Carbon dioxide compare to the Liquid nitrogen because mobility is more important in designing this tool

Table 4.3: The results for best refrigerant that can be used

Consideration	**Weight**	**Weight Factor**	**Carbon Dioxide**		**Liquid Nitrogen**	
			Score	**Rating**	**Score**	**Rating**
Better performance	**0.60**	0.25	5	1.25	3	0.75
Performance	**0.40**	0.10	2	0.20	3	0.30
Total	**1**	**0.35**		**1.45**		**1.05**

Based on all the result from Weighted Average, it can be seen that this tool will be using **Orifice at the front**, and also will be using **2mm** dimension for the diameter tip of the tool and will be using **carbon dioxide** as the refrigerant.

4.2 Temperature

In designing this cryosurgery tool for cataract removal, we need to find the temperature that will be used in treating this problem[19] In finding the exact temperature to be used there are optimization equation that can be used where

$F = [w. (T^{pre} – T_i)^2 + \alpha .(T_i\text{-}U^{pre})]+B_j (L_{ij}\text{-}T_i)$....... (1)

Defining the equation is

F is the optimization

Ti is setting temperature that being calculated

T^{pre} is Prescribed Target Volume Temperature

U^{pre} is Prescribed Upper Temperature Limit

L_{ij} is Prescribed Lower Temperature Limit

So we used the setting are

F = 10 (due to the optimization need to be small)

w = 0.05

α = 1

B = 2

U^{pre} = -20°C

L_{ij} = -10°C

So finding $T^{pre,}$

We put in the value in the equation (1), we will get

$10 = 0.05(T^{pre} + 10)^2 + (-10+20) + 2(-10+10)$

$10 = 0.05(T^{pre} + 10)^2 + 10$

$0 \ \ = 0.05(T^{pre} + 10)^2$

$0 \ \ = (T^{pre} + 10)^2$

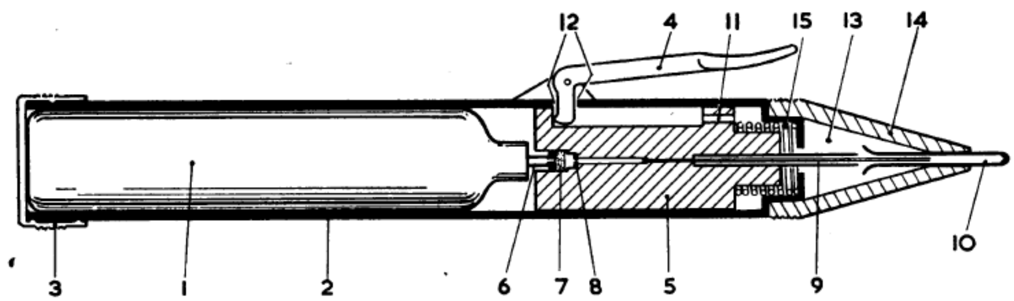
$0 \ \ = (T^{pre} + 10)^2$

$T^{pre} = -10°C$

So from this, writer is getting the temperature that will be used for this tool to cure the cataract which is **-10°C** and also it is the **minimum temperature** to cure the cataract extraction.

4.3 Cryosurgery Tool Datum Design

This specification based on the ASTM standard. This specification of the instrument is shown in Figure 4.3. The dimension and specification can be refered at Table 4.4. It is a portable tool that can be easily used by doctor. This tool also is easy to fabricate and not complex in handling it. So referring to this design as the datum design some modification had been made based on the design selection that being discussed.



51:415-422 J. Edwards,L.L Woodget , F.O Muller ,e.t all, A simple cryosurgical instrument and its application in Ethiopia

Figure 4.3: Schematic 2D diagram of design tool

1) Refrigerant container	8) Flow-restricting orifice
2) Main Body	9) Injection Tube
3) End Cap	10) Probe
4) Control Lever	11) Exhaust channel
5) Insert	12) Vent Holes
6) Nozzle of container	13) Cavity of nose cone
7) Filter	14) Nose Cone
	15) Spring

Table 4.4 : Specification and dimension from Cryosurgery Tool Datum Design

No	Details	Dimension
1	Size of orifice	0.05 mm.
2	Outside diameter of probe	4 mm
3	Projecting length of probe	6 mm.
4	Total length of probe	18mm.
5	Bore diameter of probe	1mm
6	Volume of Nose cone cavity	1.6mm
7	Length of tool	170mm
8	Length of injection tube	25mm
9	Outside diameter of tool	17mm

4.4 Cryosurgery Tool for Cataract Removal Modified Design

There are some modification that being done to the datum tool. Figure 4.4 shows the dimension and parts the tool that had already been modified. The part is the same with the current tool except the orifice situated in front of injection tube. Refer to Figure 4.5 for the part and Table 4.5 for modified detail specification.

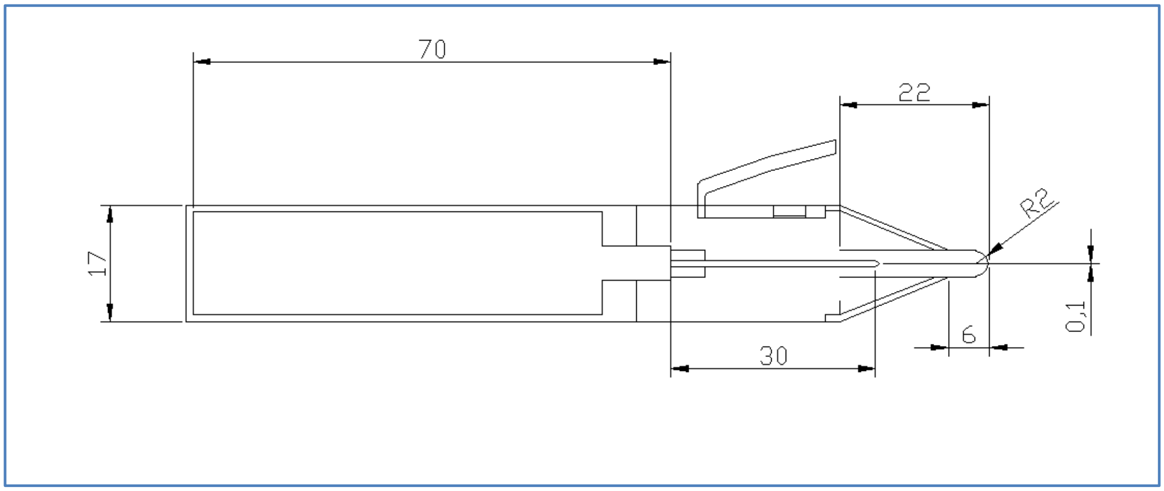


Figure 4.4 – Schematic diagram of modify design tool with dimension

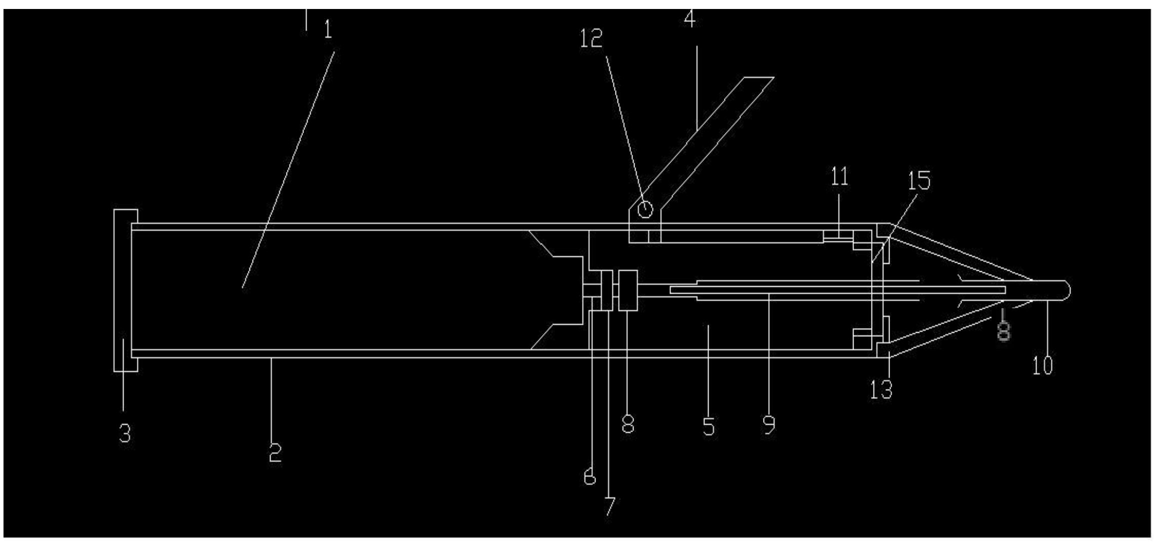


Figure 4.5 – Schematic diagram of modify design tool with part number

1)Refrigerant container	8) Flow-restricting orifice
2) Main Body	9) Injection Tube
3) End Cap	10) Probe
4) Control Lever	11) Exhaust channel
5) Insert	12) Vent Holes
6) Nozzle of container	13) Cavity of nose cone
7) Filter	14) Nose Cone
	15) Spring

Table 4.5 : Specification and dimension from Cryosurgery for Cataract Removal Modified Design

No	Details	Dimension/Material
1	Size of orifice	0.1 mm.
2	Outside diameter of probe	2 mm
3	Projecting length of probe	6 mm.
4	Total length of probe	20 mm.
5	Bore diameter of probe	1mm
6	Volume of Nose cone cavity	1.5mm
7	Length of tool	150mm
8	Length of injection tube	30mm

9	Outside diameter of tool	17mm
10	Material of probe	Stainless steel 316
11	Material of injection	Stainless steel 316

Depression of lever will cause a movable spring loaded insert to be pushed against the nozzle of container This will actuate fluid to release valve inside the container. Then the container allows refrigerant to be forced under pressure through filter , a hollow tube and orifice. Vapour will escape through exhaust channel and vent holes

This tool needs to achieve exact temperature for treatment of cataract. Due to that, the probe must achieve range of temperature in certain period of time. The temperature is **-10°C to -20°C**. The tool must achieve this range of temperature to make sure that it can be used for treatment.

All these specifications had been based by the datum design. Some modification is being done to make sure that it will perform better compared to the datum tool.

4.5 Simulation using CFD

Simulation had been made in CFD to check the temperature distribution of the tool. This tool had been tested by using 2 different pressures which are 40Bar and 80Bar. This simulation purposely to check whether the temperature requirement is met or not and the simulations are also showing the pressure distribution.

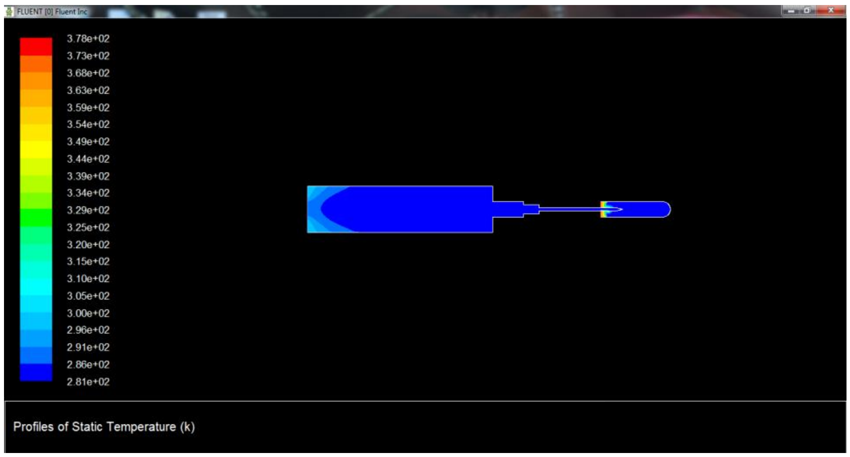


Figure 4.6 : Contour of the temperature tool at the 80Bar Pressure

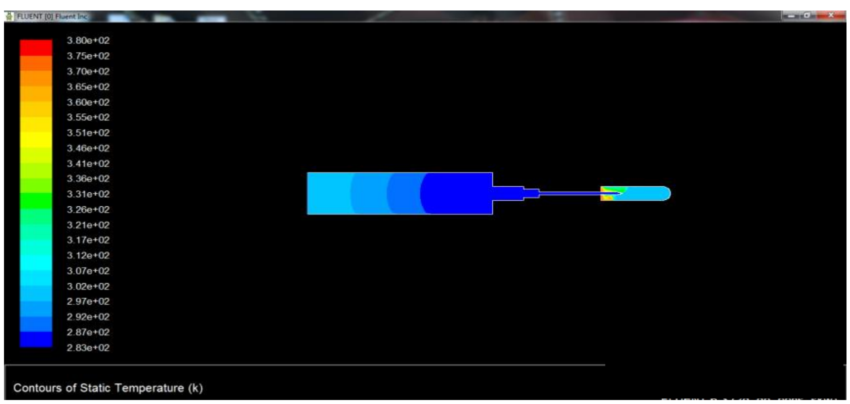


Figure 4.7 : Contour of the temperature tool at the 40Bar Pressure

From both of the contour, we can see that the temperature is the lowest at the tip of the probe. This is as expected in the theoretical activity that the tip will be lowest while the tool functioning. Next, comparing at the temperature graph, we can see that at 80 bar pressure, the distribution are more stable which is good for the tool . It will maintain the temperature at the tip of the tool .The higher the pressure, the lower the temperature produces.

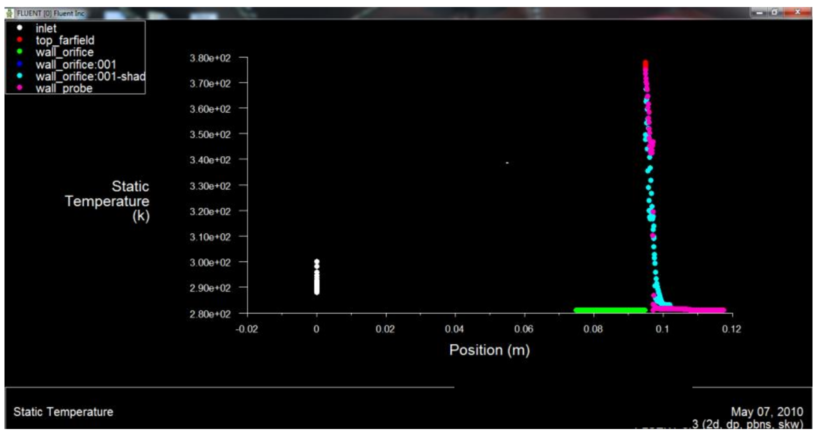


Figure 4.8 : Distribution of Temperature at the 80Bar Pressure

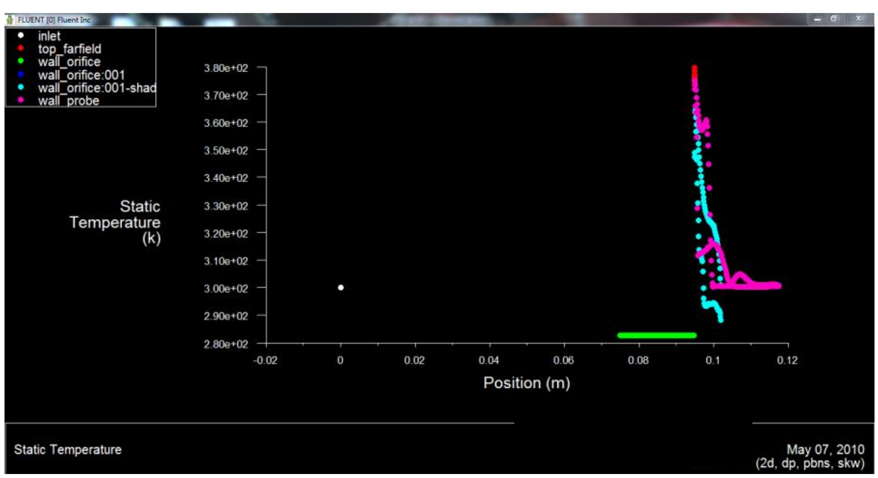


Figure 4.9 : Distribution of Temperature at the 40Bar Pressure

Next, looking at the pressure graph where the distribution temperature at the wall of the probe at 80Bar pressure is more stable compared to the one at 40Bar pressure. Due to that problem it is most desirable to use are 80Bar pressure cartridge. This is certainly due to the 80Bar pressure will give lower temperature and the more stable distribution

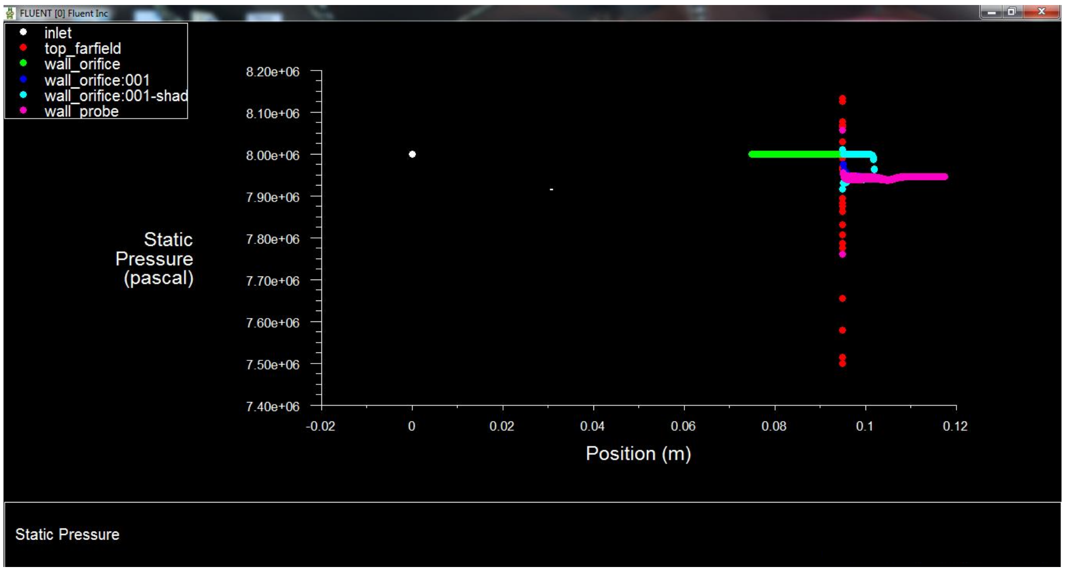


Figure 4.10 : Distribution of Pressure at the 80Bar Pressure

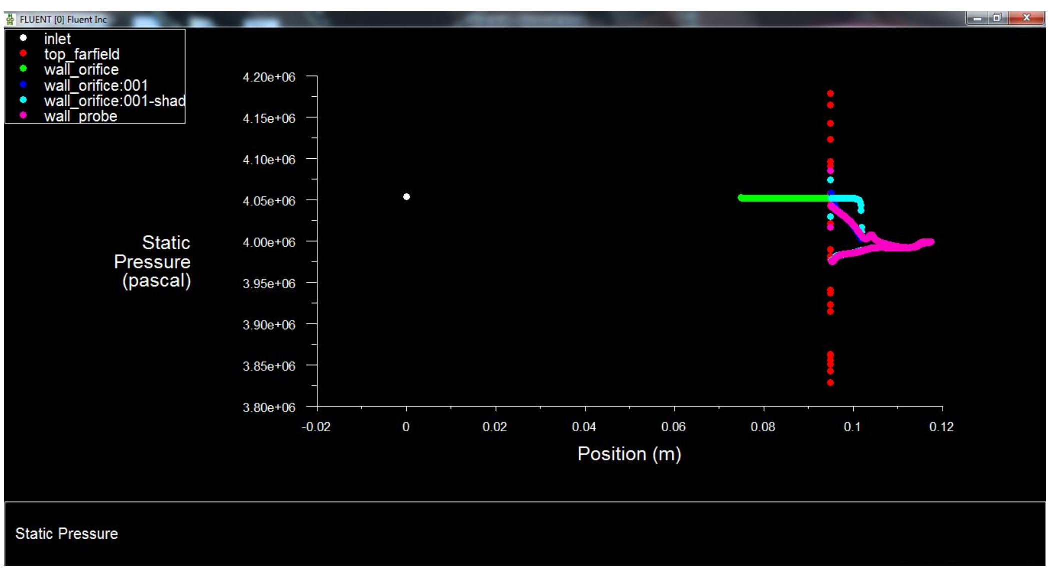


Figure 4.11 : Distribution of Pressure at the 40Bar Pressure

4.6 Material

Figure 4.12 : Selected Carbon Dioxide Cartridge

Figure 4.12 shows cartridge that will be used in cryosurgery tool for cataract removal. The cartridge will be using Carbon Dioxide gas that is in compression state in the cartridge. The pressure that needed will be 40Bar at the minimum. The other specifications are in Table 4.6

Table 4.6 : Specification for the cartridge that will be used for cryosurgery tool

Gas	**Carbon Dioxide**
Nominal Weight	**16g**
Water Capacity	**15ml**
Diameter	**15mm**
Length	**70mm**

Material being used for the probe is stainless steel. The austenitic stainless steels such as 304 (1.4301) and 316 (1.4401) are however 'tough' at cryogenic temperatures and can be classified as 'cryogenic steels'(Refer Table 4.7 and Table 4.8) . They can be considered suitable for sub-zero temperatures sometimes mentioned in service specifications as sub-arctic and arctic applications and locations (typically down to -40°C).

This is the result of the 'fcc' (face centred cube) atomic structure of the austenite, which is the result of the nickel addition to these steels. Comparing of these two materials, both are commonly used for surgical purpose. Due to the density and thermal properties, choosing **stainless steel 316** is better for manufacturing this tool.

Table 4.7 - Table of Properties for Stainless Steel 316

Properties	Value	Comment
Physical Properties		
Density	7.99 g/cc	
Mechanical properties		
Hardness, Rockwell B	79	
Tensile Strength, Ultimate	558 Mpa	
Tensile Strength, Yield	290 Mpa	0.2% YS
Elongation at Break	50%	in 2 inches
Modulus of Elasticity	193 Gpa	tension
Modulus of Elasticity	77 Gpa	torsion
Electrical properties		
Electrical Resistivity,	7.40E-05 ohm-cm	
Magenetic permeability	Max 1.02	H = 200 Oersteds, Annealed
Thermal properties		
CTE, linear 20°C	16 µm/m-°C	0 to 100°C
CTE, linear 20°C	19.9 µm/m-°C	to 871°C
Heat Capacity	0.5 J/g-°C	0°C to 100°
Thermal Conductivity	16.2 W/m-K	100°C
Thermal Conductivity	21.4 W/m-K	500°C
Processing properties		
Melt temperature	1371- 1399 °C	

Table 4.8 Properties for Stainless Steel 304

Properties		
Properties	**Value**	**Comment**
Physical Properties		
Density	8.03 g/cc	
Mechanical properties		
Hardness, Rockwell B	82	
Tensile Strength, Ultimate	621 Mpa (=90100psi)	
Tensile Strength, Yield	290 Mpa (=42100psi)	0.2% YS
Elongation at Break	55%	in 2 inches
Modulus of Elasticity	193 Gpa	tension
Modulus of Elasticity	78 Gpa	torsion
Electrical properties		
Electrical Resistivity	0.000116 ohm-cm	659 °C
Electrical Resistivity	7.2e-005 ohm-cm	
Magenetic permeability	Max 1.02	H = 200 Oersteds, Annealed
Thermal properties		
CTE, linear 20°C	16.9 µm/m-°C	0 to 100°C
CTE, linear 20°C	18.7 µm/m-°C	to 649°C
Heat Capacity	0.5 J/g-°C	0°C to 100°
Thermal Conductivity	16.2 W/m-K	100°C
Thermal Conductivity	21.4 W/m-K	500°C
Processing properties		
Melt temperature	1371- 1399 °C	

4.7 Discussion

i) Simulation

From simulation, writer can see that the minimum temperature that altained is 280K or 7°C at the tip of the probe. This is due to some problem during the simulations which are only simulating certain portion that is affecting the end result for the tip. Other things are leaking of pressure, that is effecting the temperature result

ii) Refrigerant

Liquid nitrogen is by far the most popular cryogen in current use. Its popularity is due to the low temperatures achievable (-197°C), which make it suitable for both benign and malignant lesions. Its effects are predictable and well documented. Carbon dioxide still enjoys some popularity because of its easy storage, but is really only suitable for the occasional user and for treatment of benign lesions.

Comparing of this two liquids , most preferable medium for this cryosurgery tool is carbon dioxide. This is because it is more safe compared to liquid nitrogen and it is easy to store. Furthermore, carbon dioxide will produce enough coldness for cataract treatment. The temperature is based on the seriousness of the treatment needed. This is also to achieve the coldness by applying Joule-Thompson principle.

Cryosurgical tool varies depending on the treatment and injuries that one to be cured. Because of that, we have different specification for every tool. All of these should follow standard specification which are ASTM F882-84(2002) ***Standard Performance and Safety Specification for Cryosurgical Medical Instruments.*** Based on this, we can have standard tool . For removing cataract we have to follow correct specification.

iii) Comparison between datum design and modified design

There are slight change that being redesign from the datum design for this modified tool. These are for the improvement of the tool in achieving the objective of the project. The comparison are being shown in Table 4.9.

Table 4.9: Comparison between datum design and modified design

No	Details	Datum design	Modified Design
1	Size of orifice	0.05 mm.	0.1 mm.
2	Outside diameter of probe	4 mm	2 mm
3	Projecting length of probe	6 mm.	6 mm.
4	Total length of probe	18mm.	20 mm.
5	Bore diameter of probe	1mm	1mm
6	Volume of Nose cone cavity	1.6mm	1.5mm
7	Length of tool	170mm	150mm
8	Length of injection tube	25mm	30mm
9	Outside diameter of tool	17mm	17mm

CHAPTER 5

CONCLUSION AND RECOMMENDATION

5.1 Conclusion

Overall these projects had achieved its objective in designing and simulating the design tool.

This cryo tool for cataract removal has been studied to check the behavior and the common practice that have been practised by others. These tools have different kind of style and type that need to be studied.

Using a datum design, writer had made redesign of the tools that have been improved in certain way. Although this design may not be fully justified that it is better than the datum design, this design had been evaluated using design concept available in engineering field. The studies showed that new design will perform better than the current datum design.

In Chapter 4, Result and Discussion are describing the new design of the cryo tool. Moreover, simulation also had been done in checking the temperature and the pressure that suitable for this tool. Cryosurgery tool for cataract removal should have the minimum temperature of -10°C.

Simulation by CFD software resulted the minimum temperature of 280K at 80Bar pressure. It did not show the exact temperature that should been obtained from theoretical calculation. The reason may be due to the pressure loss in the injection tube and also low pressure in the catridge.

The low temperature occurs due to Joule Thompson Principle when the refrigerant fluid flows from the cartridge to the narrow injection tube and it flows through orifice. Due to the sudden expansion at the orifice, sudden cooling occur at the surrounding tip.

This tool has some good modifications that are suitable and they follow standard specification as per ASTM F882-84(2002) ***Standard Performance and Safety Specification for Cryosurgical Medical Instruments.***

Therefore, this project has successfully achieved the objectives of the project.

5.2 Recommendation

Suggested future work for this project that will improve the quality and result of this project are:

i. Applying **more dynamic analysis** in CFD simulation

ii. Applying more research on current tool and upgrade tool

iii. Fabricate a prototype for this project.

iv. Testing the prototype to get the accurate result by operating with various pressures .

v. Creating a vacuum at the exhaust to increase the rate of cooling.

REFERENCES

R.S Khandpur Biomedical Instrumentation (2005) *Fundamentals of Medical Instrumentation*

S.Cowen,N.Haworth,Sandvik Biolone,J.O.Nilsson Medical Device Materials II *Sandvik Bioline 1RK91-an Advanced Material for Medical Device Manufacture*

Little, William A. (Palo Alto, CA) Sapozhnikov, Igor (San Jose, CA) Thompson, Todd(Pleasanton,CA) Savage, George M. (Portola Valley, CA) , US 6,306129B1 (2001-10-23) , *Cryosurgical system and method.*

Forlenza, Albert Michael (Carrollton, TX, US) Ivey, Samuel Edward (Richardson, TX, US) Krentel, Jerome F. (Covington, LA, US) Williams, John Eglin (Covington, LA, US) Haas, Joanne B. (Covington, LA, US) Schweikert, Paula A. (Abita Springs, LA, US) Kondabatni, Kishore K. Bailey, Richard E. (Mandeville, LA, US) , USD562977 (2008-02-26) ,*Cryosurgical tool.*

Sweren, Ronald J. (17 Farmhouse Ct., Baltimore, MD, 21208) Schwartz, Alan (7 Pomona North #1, Pikesville, MD, 21208), US 4770171 (1988-09-13) , *Cryogenic surgical tool.*

Thomas Jr., Edward R., US 3536075 (1970-10-27) *Cryosurgical instrument.*

Stephen Kite. (2006-03-27). <http://podiatrysource.blogspot.com>, *What is Cryosurgery*

K.V.B.S. Kalyan Kumar[a] and S.K. Choudhury(18 July 2008) Journal of Materials Processing Technology Volume 203, Issues 1-3, , Pages 95-101, *Investigation of tool wear and cutting force in cryogenic machining using design of experiments*

Dieter Fellner (2004-10-12) <http://www.podiatry-arena.com/podiatry-forum/showthread.php?t=66>,*Cryo-Surgery: A lasting solution for a painful problem.*

British Stainless Steel Association <http://www.bssa.org.uk/topics.php?article=41> *Selection of stainless steels for cryogenic applications*

The World Of David Darling <http://www.daviddarling.info/encyclopedia/J/Joule-Thomson_effect.html > *Joule-Thomson Effect*

Paul F Zupkas (San Diego) , 5672172 (1997-09-30) ,S*urgical instrument with ultrasound pulse generator*

VV Shafranov, DI Tsyganov, AV Taganov, EN Borkhunova Pediatric Surgery Department, Russian State Medical University, Moscow, Russia 1998 www.cryoforum.org/Archive/Ice_ball/ice4.html *Some theoretical aspect of cryosurgery*

NewAgeIndustrieshttp,://www.newageindustries.com/nylon_tubing.asp *NylonTubing*

Water treatment solution Lentech <http://www.lenntech.com/stainless-steel-316l.htm >*Stainless Steel 316 L*

Water treatment solution Lentech <http://www.lenntech.com/stainless-steel-304.htm > Stainless Steel 304

J. Edwards,L.L Woodget , F.O Muller ,e.t all. Br J Ophtalmol 1967 51:415-422 , *A simple cryosurgical instrument and its application in Ethiopia*

Rubinsky, B. 2000. Cryosurgery. Annual Review of Biomedical Engineering *2:157-87*

Roustem Baissalo,George A. Sandison,B ryan J. Donnelly, John C. Saliken, Ken Muldrew and John Rewcastle , 2000 , *A semi emperical treatment planning model for optimazation of multiprobe cryosurgery*

George E. Dieter. Linda C. Schmidt (2009), ENGINEERING DESIGN. 4rd Edition.