DESIGNING AN INSTRUMENT FOR CUTTING AND REMOVING VITREOUS MEMBRANES FROM HUMAN EYES

by

Tetsuto Numata

Submitted in Partial Fulfillment

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Degree of Bachelor of Science

at the

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June, 1974

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Department of Mechanical Engineering, May 8, 1974

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Accepted by . . . . . .
Chairman, Departmental Committee on Thesis

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ABSTRACT

Vitreous membranes are scar tissues containing fibrin fibronblast cells, collagen fibers, and mucoproteins that form in the vitreous body of the eye. The vitreous body is a gelatinous substance that occupies a volume in an eye behind the lens. Instruments designed in the past to cut and remove these membranes were not fully satisfactory. "Clamping membranes before cutting" was introduced as a new design concept. Adhesion of membranes to the clamping surface was isolated as a failure mode of the new design concept, and tension, adhesion, and friction tests were planned. The first two tests were carried out. The tension test showed membranes which are aged from four to eight weeks old are from 200 milligrams to 16 grams in strength, thus much stronger than the retinal detachment force of 150 milligrams. The adhesion test showed that a stainless steel probably cannot be used as a clamping surface material as the adhesion force of membranes to the clamping surface was approximately 3.8 times larger than the retinal detachment force. A new design for improving the process of sucking out cut membranes was introduced, and a problem area for carrying out further work on the design was isolated.

ACKNOWLEDGMENTS

I would like to express my gratitude to Professor Daniel E. Whitney for his deep and thorough guidance and assistance from the beginning of this study until its completion as this thesis; Professor Robert W. Mann for his great moral support during the course of this work; and Professor Ernest Rabinowicz for his assistance in carrying out the adhesion experiment. I must express my special gratitude to Professor George Benedek who first introduced me to Dr. Charles L. Schepens and the Retina Foundation from where the present work was conceived. I further express my gratitude to Dr. Charles L. Schepens of the Retina Foundation for introducing me to the field of Ophthalmic surgery and particularly to the present study; also from the Foundation Dr. F. Delori and Mr. O. Pomerantzeff for their kind guidance; Mr. J. Marino and Ms. J. Schneider for getting me through the difficult tension experiment; and special gratitude to Dr. I. J. Constable for his idea of the string method of producing vitreous membranes and his tremendous guidance and assistance in surgery of rabbits. Mr. S. Marcolango of the M.I.T. Mechanical Engineering Department Student Shop for his valuable assistance in making both the tension experiment baths and the adhesion experiment equipment. My colleague, Mr. Gordon Salmela, for drawing the "design concept," and Miss L. Blake for typing up the manuscript. My deep gratitude to Mr. J. P. Reese, my dear friend and colleague, for his moral support throughout this project and his critical reading of the

manuscript. The Retina Foundation, 20 Staniford Street, Boston, Massachusetts, for the use of their facilities and the research fund.

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INTRODUCTION

Objective of This Study

Designing a new instrument for cutting and removing membranes from a vitreous body of a human eye was undertaken. Instruments designed in the past were not fully satisfactory in cutting and removing the membranes. Application of a systematic design process in designing the instrument, undertaking a failure mode analysis of the new design concept, and proposing solutions to analyze failure modes or indicating alternatives were three areas of work performed in this study.

CHAPTER I

NEED FOR DESIGNING SURGICAL INSTRUMENT FOR CUTTING AND REMOVING VITREOUS MEMBRANES

SECTION I. A Vitreous Body, Vitreous Membranes and Vitreous Bands

A vitreous body[1],[2],[3],[4],[5] is a gelatinous substance in an eye which occupies a volume behind a lens as shown in Figure 1. The vitreous body's proposed structure[1] consists of a three-dimensional cube mesh of collagen fibers with water and hyaluronic acid as the mesh's principal constituents. However, a detailed proof for the proposed structure has not been obtained. The vitreous body is not an inert substance and can be damaged easily.

Vitreous membranes[6],[7],[8] and bands form in the vitreous body of an eye. Examples are given schematically in Figure 2. The detailed studies have not been published on the formation and development of these membranes. However, it is thought that the membranes are similar to scar tissues in formation and development. They principally contain fibrin, fibroblast cells, collagen fibers, blood cells, and mucoproteins. Membranes grow and mature in the course of their development, and the composition of the membranes change. At an early stage of their development, membranes contain more fibrin and cells whereas, at a later stage of their development, membranes contain more collagen fibers. Membranes have a larger percentage of cells as compared to bands which have a larger percentage of collagen fibers. *Membranes and bands are often

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*Membranes and bands will be referred to as "membranes" from now on unless otherwise stated.

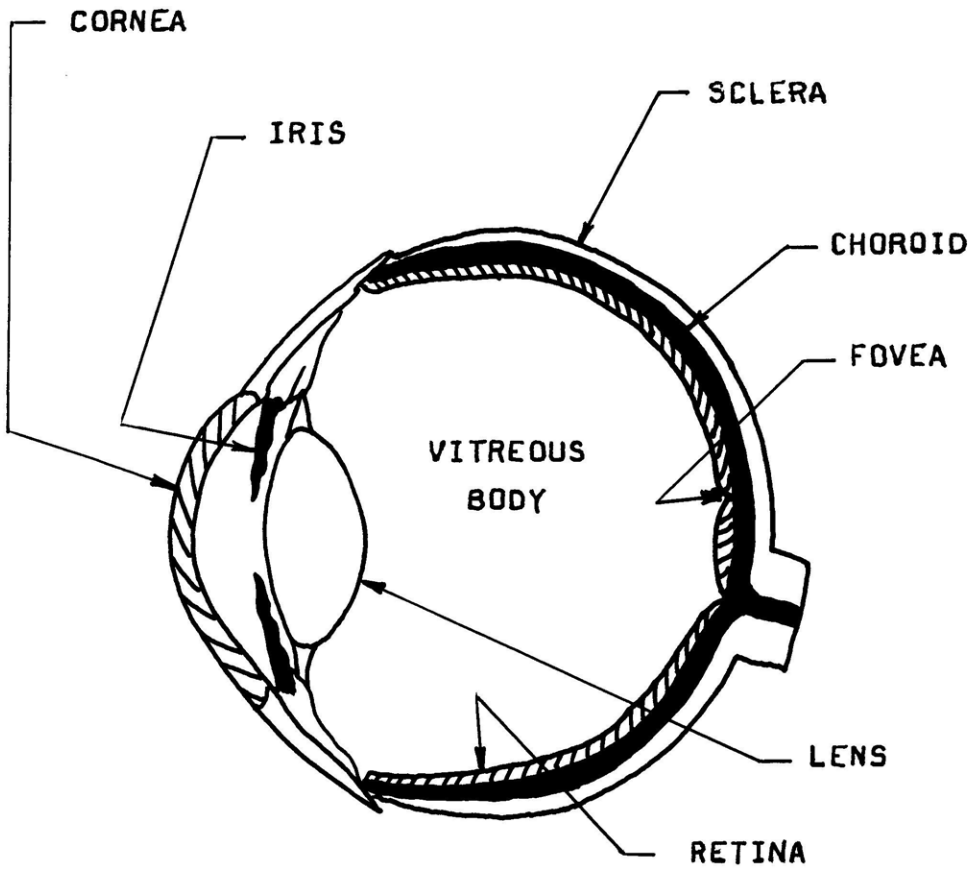
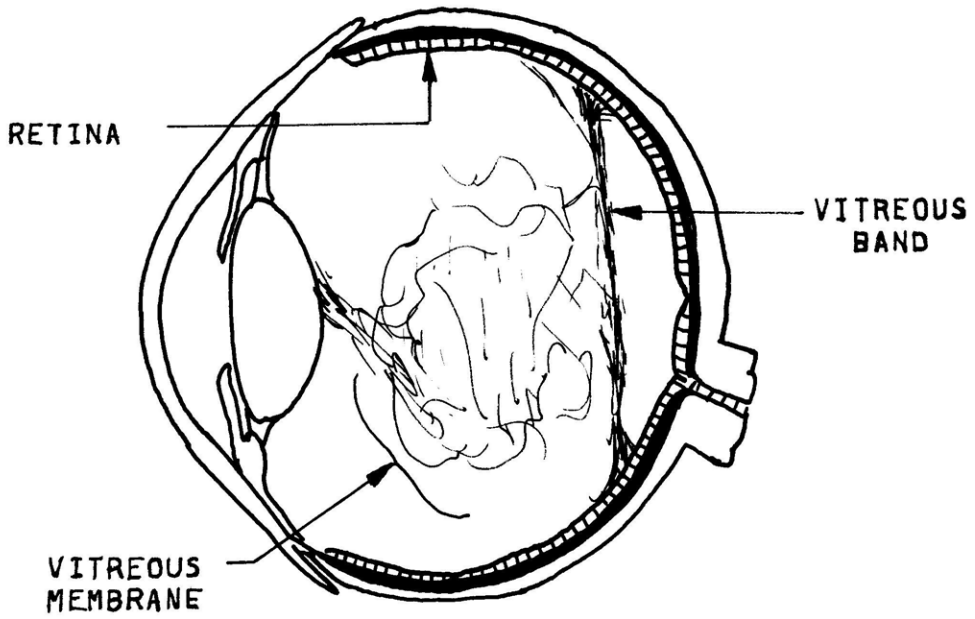


FIGURE 1. The schematic drawing of the gross anatomy of a human eye.



Part 2. The schematic drawing of the vitreous membranes and bands. A case of undetached retina.

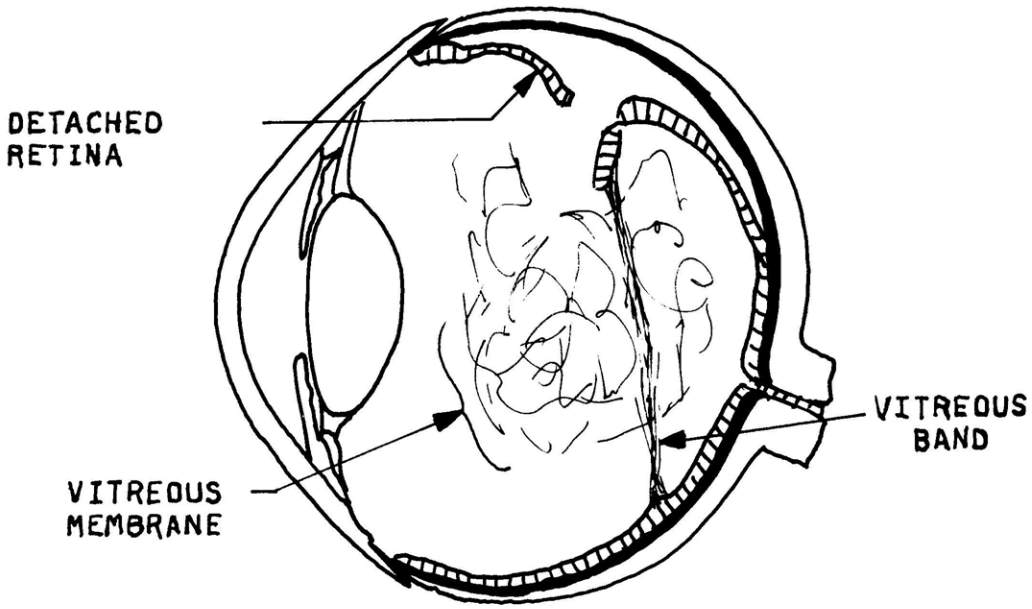


FIGURE 2. Part b. A case of detached retina being pulled by a band.

associated with traumatic physical injuries to an eye,[9] such as caused by a blow with a fist, or by metal fragment, etc. with diseases such as Wagner's disease,[10] Earl's disease, Diabetic retinopathy, and Retrolental fibroplasia[11],[12] and with complications from surgery, such as cataract surgery.

SECTION II. Problems Caused by Vitreous Membranes

Membranes are often attached to the retina in more than two places. (See Figure 2.) As membranes develop and mature, they contract. The loss of sight results from obstructing light rays coming to the retina or by detaching the retina or by preventing the already detached retina from being re-attached through surgery.

Many cases of a retinal detachment can be successfully treated by two operations known as "a scleral buckling" and "a laser photocoagulation." In the scleral buckling operation,[13],[14],[15],[16],[17],[18] a silicone strip is imbedded in the sclera which corresponds to an area behind the detached retina. The subretinal fluid is removed, and the silicone strip is tightened keeping the intraocular pressure between 10 mm Hg and 15 mm Hg. The retina is pushed back to the choroid as shown in Figure 3. In laser photocoagulation, the retina and the choroid is fused by a laser light burn.

Vitreous membranes prevent successful retinal reattachment surgery, and many eyes which could be saved go untreated. There is therefore a great need for an instrument which would cut and remove these membranes efficiently and safely from the vitreous body.

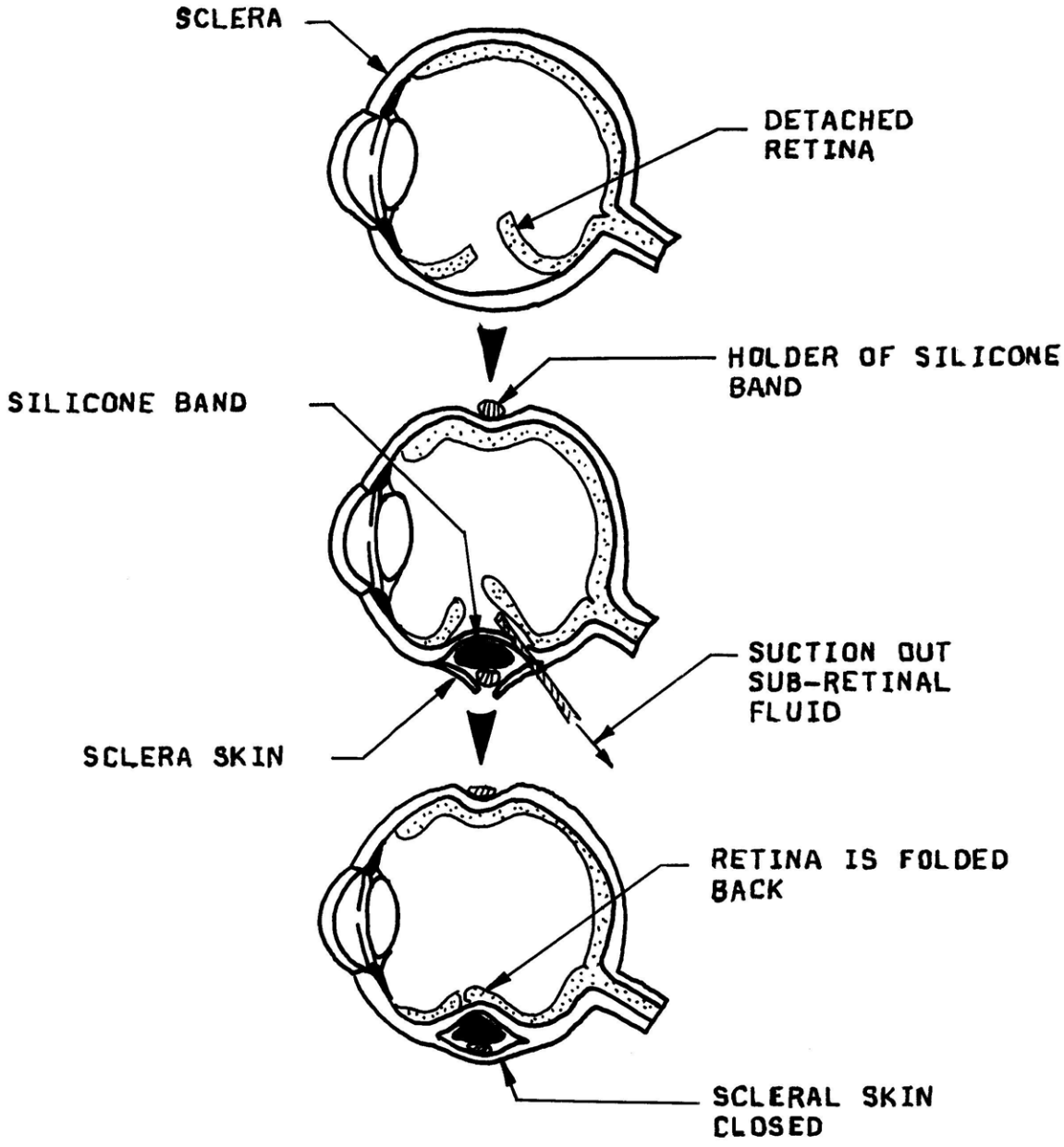


FIGURE 3. Schematic drawing of a scleral buckling operation.

CHAPTER II

OBSERVATIONS ON A MEDICAL INSTRUMENT DESIGN PROCESS

SECTION I. The General Design Process

In design work the mental process of "coming up with an idea" can be truly called a creative process and is certainly very difficult to systematize. However, to a degree, the entire design process can be systematized. Systemization organizes your thinking and focuses it on the crucial portions of your work. It aids in taking greater advantage of an idea that suddenly pops into your mind. It also facilitates the isolation of the problem to be solved and applications of engineering analysis to the design concept. A block diagram of the design process is shown in Figure 4.

Block A in Figure 4 is perhaps one of the most important steps of the design process. Engineering problems in the real world are almost always complicated, and isolation of the problem that must be solved is often very difficult. A transition between block A and B becomes quite difficult unless one has a clear idea of "the problem" to which a development of design concept must be directed. Manufacturing feasibility analysis should be attempted early in design process. The analysis need not be extensive but should be done to get rid of ideas which may be too expensive to build or impossible to build. A design process diagram such as the one shown in Figure 4 is only meant as a quide,and an engineer should feel free to deviate from it whenever he feels such a deviation is necessary. The diagram is simple, and it must be modified to fit a particular field, such as medicine.

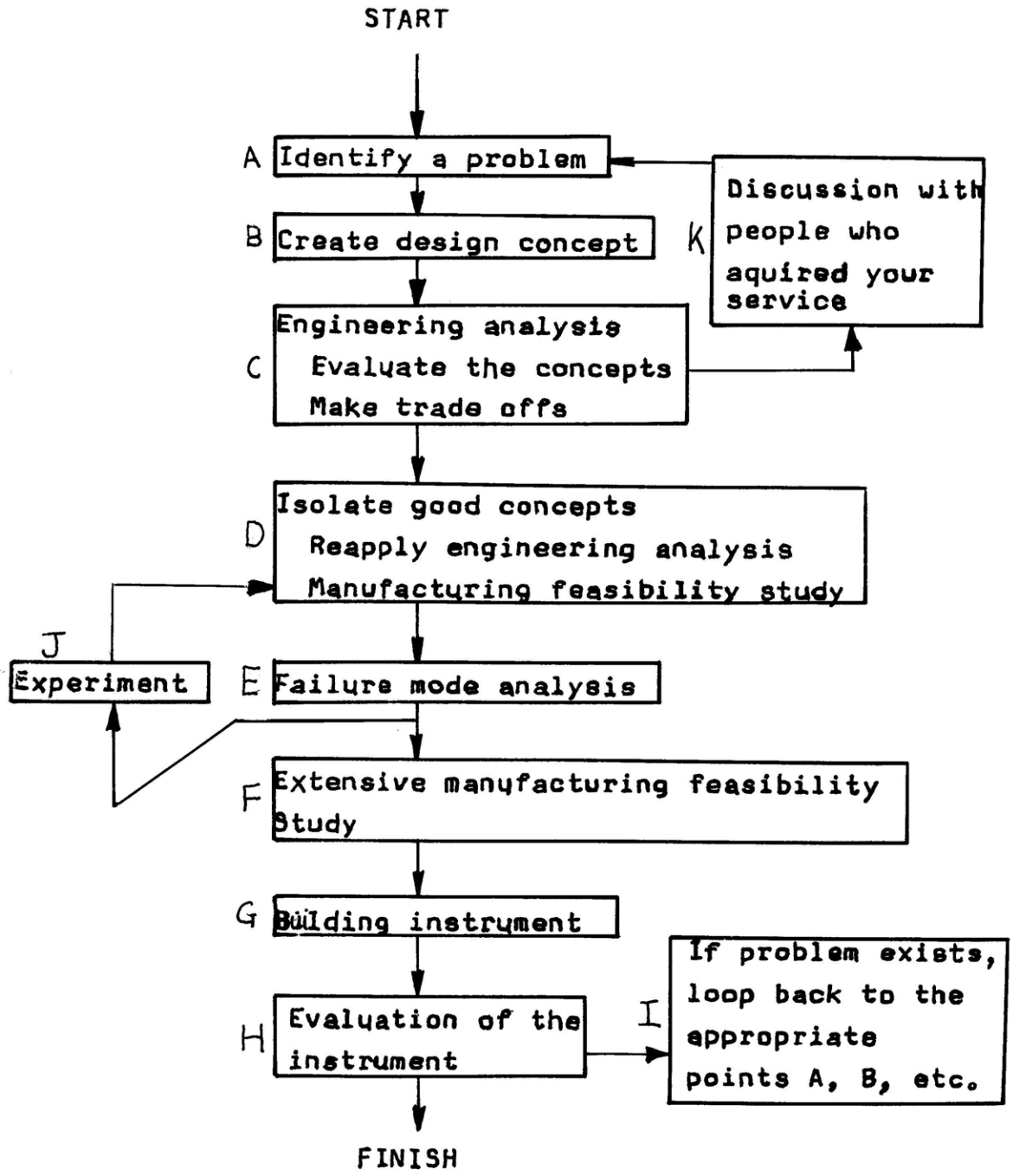


FIGURE 4. The general design process block diagram.

The medical field possesses a large problem in interfacing with the engineering fields. As will be shown, this problem can be overcome by modifying the design process.

SECTION II. The Problem in Designing Medical Instruments

A communication gap between doctors and engineers stands as one of the large problems in designing medical instruments. Instruments are often designed in the following way. The doctor, who usually lacks any engineering background, isolates a problem to be solved. The engineer then takes over the task of designing an instrument. The doctors usually do not understand the importance of a systematic design process or of the engineering principles involved. The engineers are usually unsympathetic toward the doctor's viewpoints and tend to summarize the problem solely by themselves. There is therefore a great lack of information exchange. As a result, the instruments designed often have to be greatly modified or remade. I believe an awareness of this problem is essential in designing a successful instrument with the least waste of energy and money.

SECTION III. The Modified Design Process

The modified design process, shown in Figure 5, models one of the ways this communication problem can be solved. Engineers must hold many discussions with doctors about design problems, as doctors will give out more information based on their experiences as they realize the importance of their experiences to the instrument design. However, this realization usually comes only after extensive discussions.

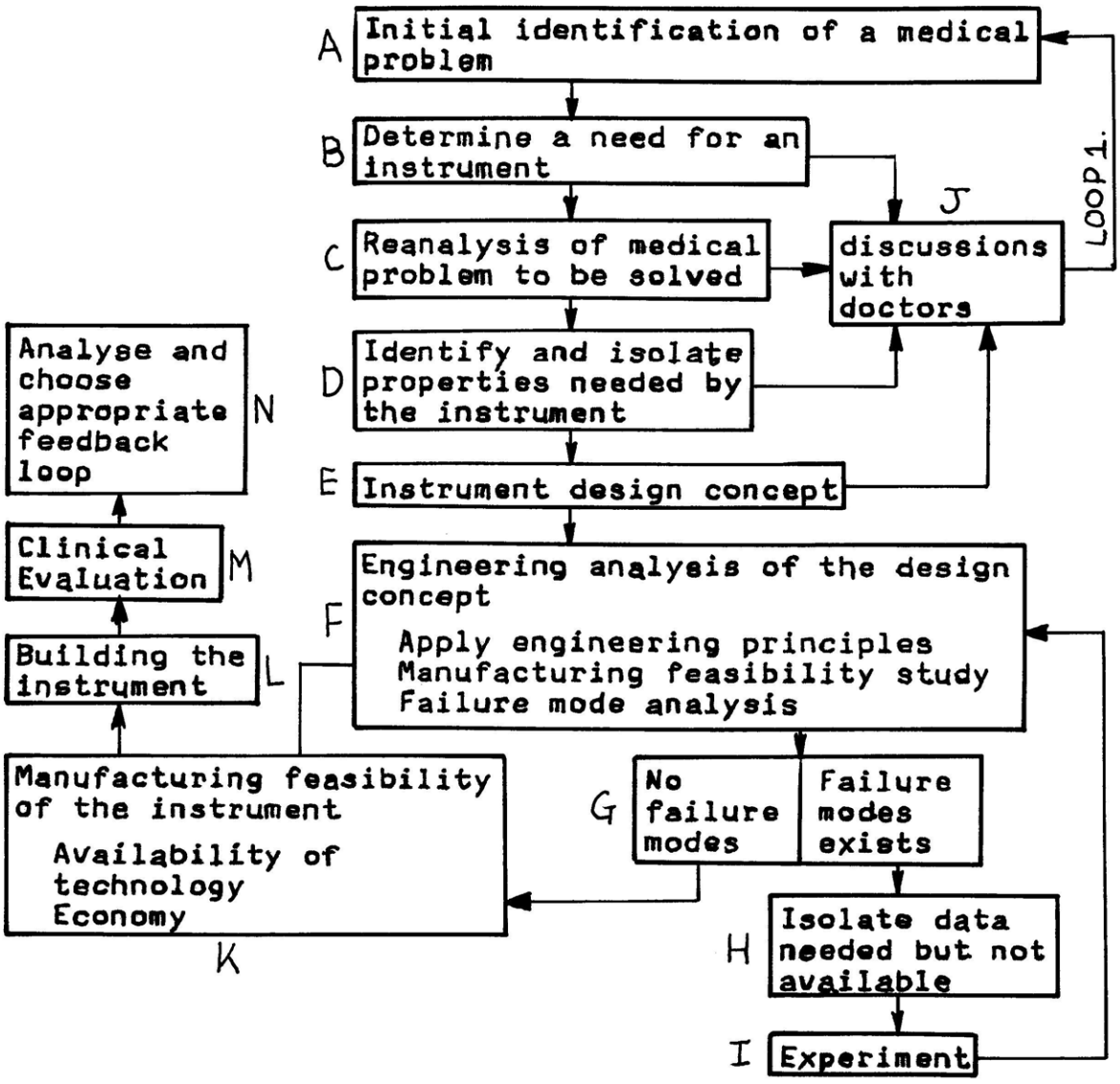


FIGURE 5. The modified design process block diagram.

The block G, failure-mode analysis, is another very important portion of the design process. In medicine, instrument failure can be disastrous; therefore, medical instruments are evaluated for an extensive period--anywhere from several months to years--on animals and on human subjects before it is adopted by the medical profession. Thus, failure to perform the failure-mode analysis of a design concept can be disastrous to engineers or engineering firms in terms of time and money wasted.

CHAPTER III

USING THE MODIFIED DESIGN PROCESS IN DESIGNING THE VITREOUS MEMBRANE CUTTER

SECTION I. The New Design Concept

Part 1. Isolation of Desired Instrument Properties

Eleven properties the instrument must possess were isolated using the loop 1 shown in Figure 5. The instrument must:

1. Cut and remove taut membranes without pulling on the retina, which may or may not be already detached.
2. Maintain constant intraocular pressure. This will maintain good visual image through the cornea for a surgeon during an operation.
3. Be small enough to pass through an incision 4 mm long at pars plana ciliaris.
4. Operate freely. It should not jam as its temperature changes, and it should not clog with cut material. It should not have abnormal ways of operating, which would confuse a surgeon.
5. Possess a cutting tip which can be clearly seen through the cornea.
6. Possess a small head length to allow the cutting tip to approach the retina within 2 mm.
7. Possess a mechanism that detects whether membranes have stuck to its surface or its cutting mechanism.
8. Be easily freed from membranes that stick to its surface.
9. Possess clamping and cutting mechanism that can be made to stop operating at any time during a surgery.

10. Be able to last one complete operation before wear becomes noticeable.
11. Be able to suck out materials smoothly from a vitreous body. Any danger of retina being sucked into the cutting tip resulting from jerky suction must be avoided.

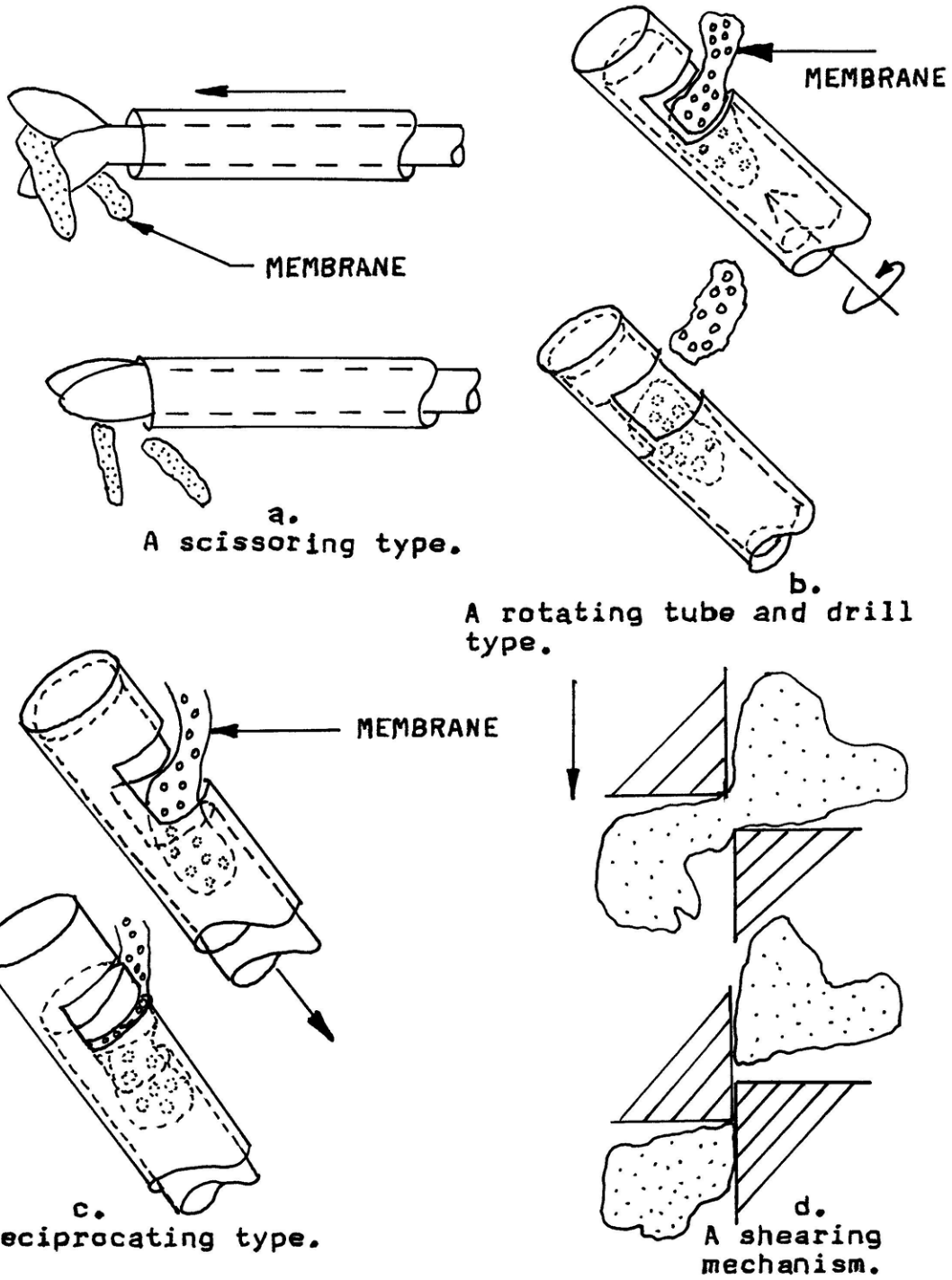
Part 2. Past Instruments

Four different types of instruments were designed in the past. They are the following:

1. A scissor type.[19],[20],[21]
2. A rotating drill type and rotating tube type.[22],[23],[24],[25],[26]
3. A reciprocating type.[27],[28],[29]
4. An electrodischarge type.[30] Drawings of each type are shown in Figure 6. The picture for "4" was not available for a schematic drawing. As shown in Figure 6, Part d, shearing was the cutting mechanism of the first three types of instruments.

Part 3. Problems of Past Instruments

The scissor type is ideal for vitreous membrane problem cases where vitreous bands which have detached the retina or are pulling on the already detached retina are the only membranes visibly present in the vitreous body, and no other complications are caused by unseen vitreous membranes. However, this type of instrument cannot remove materials from eyes. An independent suction tube must be inserted from another incision in pars plana ciliaris or inserted through the same incision as the one used for the instrument. Furthermore, when vitreous membranes are connected to the retina by small, invisible



a.
A scissoring type.

b.
A rotating tube and drill type.

c.
Reciprocating type.

d.
A shearing mechanism.

FIGURE 6. The schematic representations of past vitreous membrane cutters.

strands in many areas of the retina, it is impossible for a surgeon to cut all of these connections with a scissor. (This problem was overcome by removing most of a vitreous body by cutting it up into small chunks and removing only the cut chunks. Any fine strands, which were not lying very close to the retina, were, therefore, removed along with the cut vitreous body.) In attempting to suck out membranes through a tube, the retina may be sucked out as well because of uncut attachments of membranes to the retina. Thus, for many cases of vitreous membrane complications, the scissor type cannot be used with good result.

The rotating type and the reciprocating type were developed to overcome the shortcomings of the scissor types. The rotating and reciprocating types were made, generally, from stainless steel tubes, and, therefore, suction capability was built into them. However, both types did not cut all membranes. The problem seems to have been in maintaining good shearing action between cutting tips. On the other hand, in cases where shearing action between cutting tips was maintained by pressing cutting tips against each other, metal shavings have been observed in eyes after operations. Furthermore, for rotatory types, membranes sometimes wrapped around the rotating tube when they were not completely cut.

A new instrument design was needed to overcome these problems. After much reflection, therefore, I introduced "clamping of the vitreous membranes before cutting" as the new design concept. This concept has several good features: It stablizes membranes during

cutting, so that they would not move out or slide away from the cutting tip; it prevents membranes from wrapping around the instrument; it prevents membranes from detaching the retina during cutting. When membranes are caught in the cutting mechanism, the surgeon can have time to react, and any membranes not cut by the shearing mechanism will be stretched and broken.

The drawings of the new design are given in Figure 7. Tubes B and D have the same inner and outer diameters so that when they touch each other, the surfaces 2 and 1 meet one another. Tubes C and A have the same inner and outer diameters so that tube C slides through the slot in tube A. The operating mechanism of the design is as follows: Tubes A and C are driven by independent mechanisms, but the mechanisms are synchronized during the initial phase of the cutting cycle. Thus, tubes A, B, and C move down together until tube B clamps membranes against tube D between the surfaces 2 and 1. Tube C, therefore, is held stationary, and tube A moves down, cutting membranes with the cutting edge shown in Figure 7. Then, tube A comes up until it almost touches tube C. Thereafter, the synchronization takes over so that tubes A, B, and C move up together to the original position completing one cutting cycle.

SECTION II. Failure Mode Analysis and Experiments

Part 1. The Analysis

The new design concept avoids the failure modes of the past vitreous membrane cutters. However, the new design concept introduces adhesion of membranes to the clamping surface as the new failure mode.

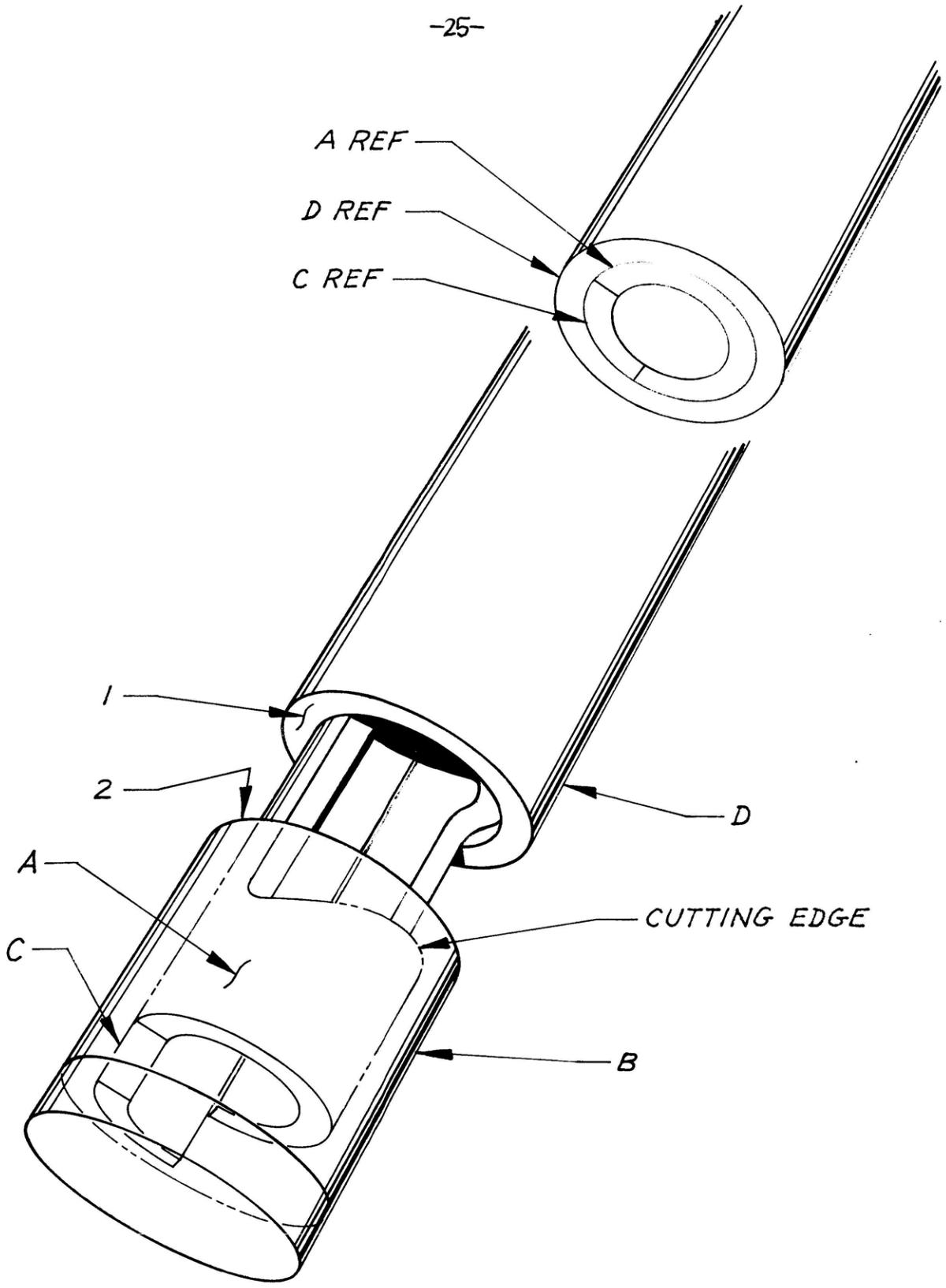


FIGURE 7. NEW DESIGN CONCEPT

Membranes must be clamped hard enough to avoid slippage during cutting. However, membranes may stick to the clamping surface. If this sticking force is greater than the retinal detachment force, then after the first cutting cycle has been completed, the instrument cannot be moved around and failure results.

Three factors--tension, adhesion, and friction of membranes--must be considered. Information needed was: the clamping force at which membranes do not slide; the adhesion force of membranes at that clamping force. Three factors influence each other, and two cases of interactions can be hypothesized: The adhesion force range at the required clamping force exceeds the retinal detachment force;[31][32][33] the adhesion force range at the required clamping force is less than the retinal detachment force. These two cases are shown in Figure 8 in the lower graph designated as case 1 and case 2, respectively. In the upper graph, the pulling force at which membranes break or slide--whichever occurs first--with the clamping force on is plotted against the clamping force. Three kinds of membrane behavior can be hypothesized: The left-hand region indicates membranes that break and possess high tensile strength as well as high coefficient of friction; the middle region indicates membranes that slide away--those with high tensile strength but low coefficient of friction; the right-hand region indicates membranes that break--those with low tensile strength but middle to high coefficient of friction. An experiment which might give this type of data is sketched in Figure 9. In the lower graph, the force required to pull membranes off the

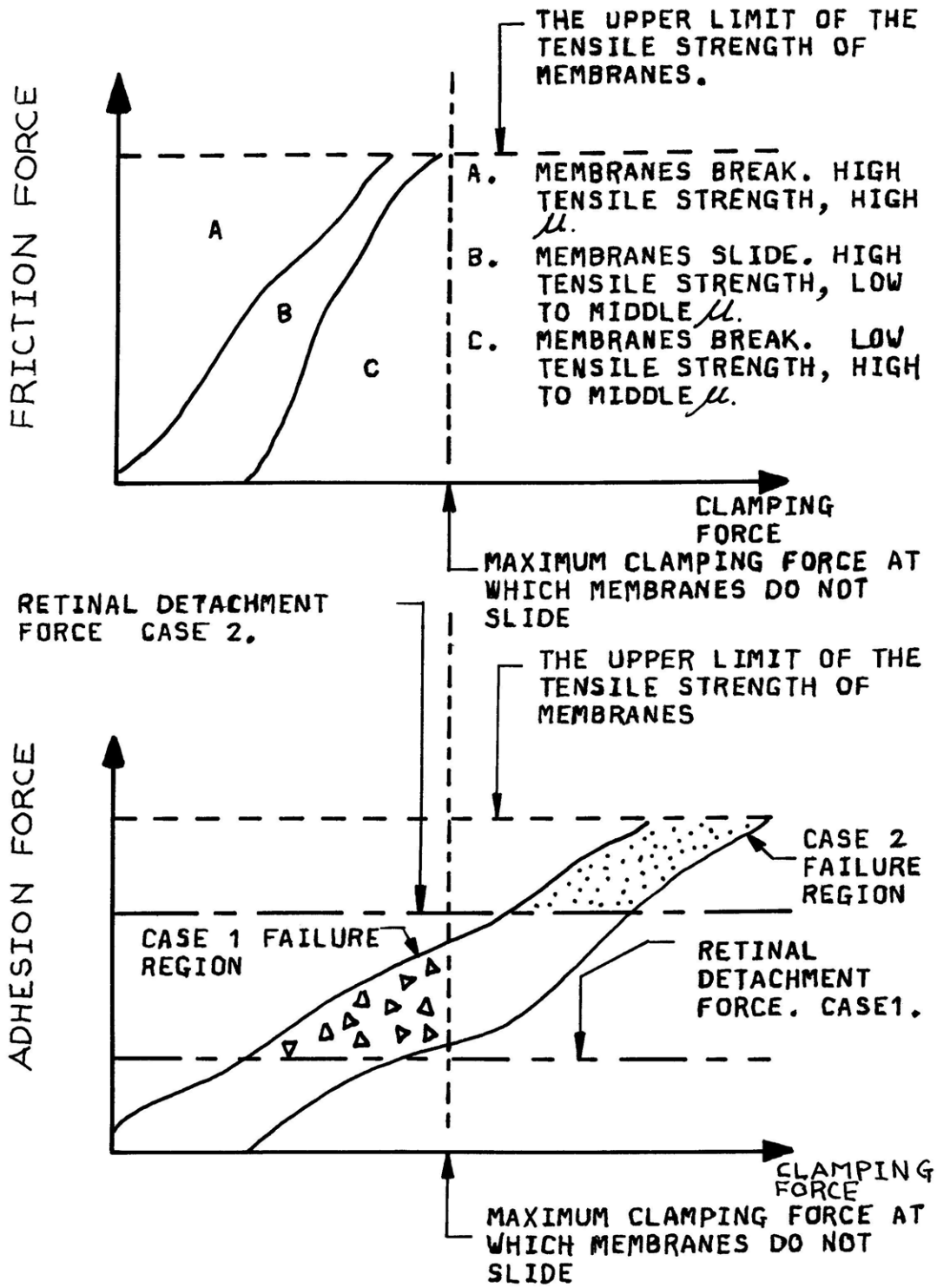


FIGURE 8. ADHESION FAILURE MODE ANALYSIS GRAPH.

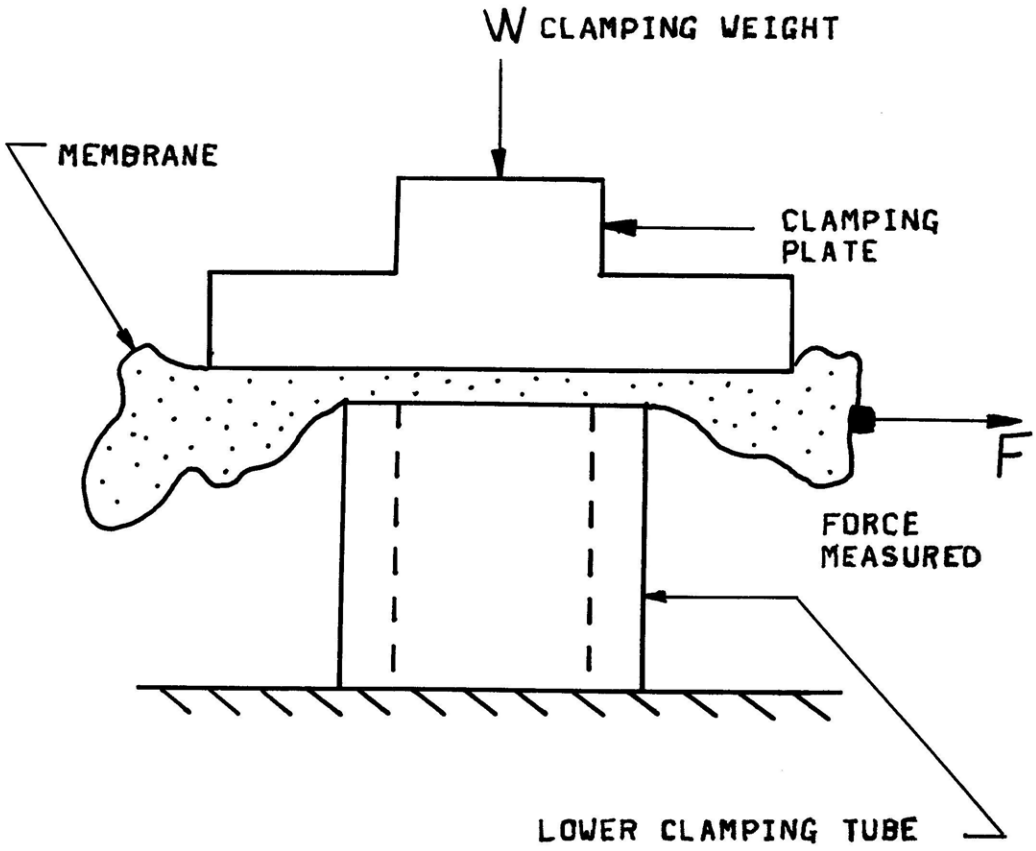


FIGURE 9. Proposed experimental procedure for a friction test.

clamping surface after the clamping force has been removed is plotted against the clamping surface. The retinal detachment force is plotted as a dotted line. The adhesion force is measured with respect to a stainless steel surface with an area of .0057 cm^2.

Both the tensile test and the friction test could have been carried out by devising equipment similar to the one made for the adhesion testing (see Figure 17). However, three separate tests were planned because of the following considerations. Data on mechanical properties of vitreous membranes had not been investigated before, and acquiring good data on each property separately was judged important not only for this work but also for other work connected with vitreous membranes. The tensile test is a destructive test and must be done following the friction test. However, during the handling and testing of membranes for determining the slip criteria, membranes will be pulled and stretched. The effect of stretching on the tensile property was not determinable and could not be assumed negligible. Finally, successfully conducting the experiment to test both friction and tension with equipment and time available was very questionable; therefore, two tests which have been completed are the tension and the adhesion tests.

Part 2. The Experiments

Pigmented and albino rabbits were used. Membranes were grown in a rabbit's eye principally by implanting sterile 4-0 silk sutures in the vitreous body with a needle as shown in Figure 10. Sutures were removed approximately one week later. Membranes formed around sutures

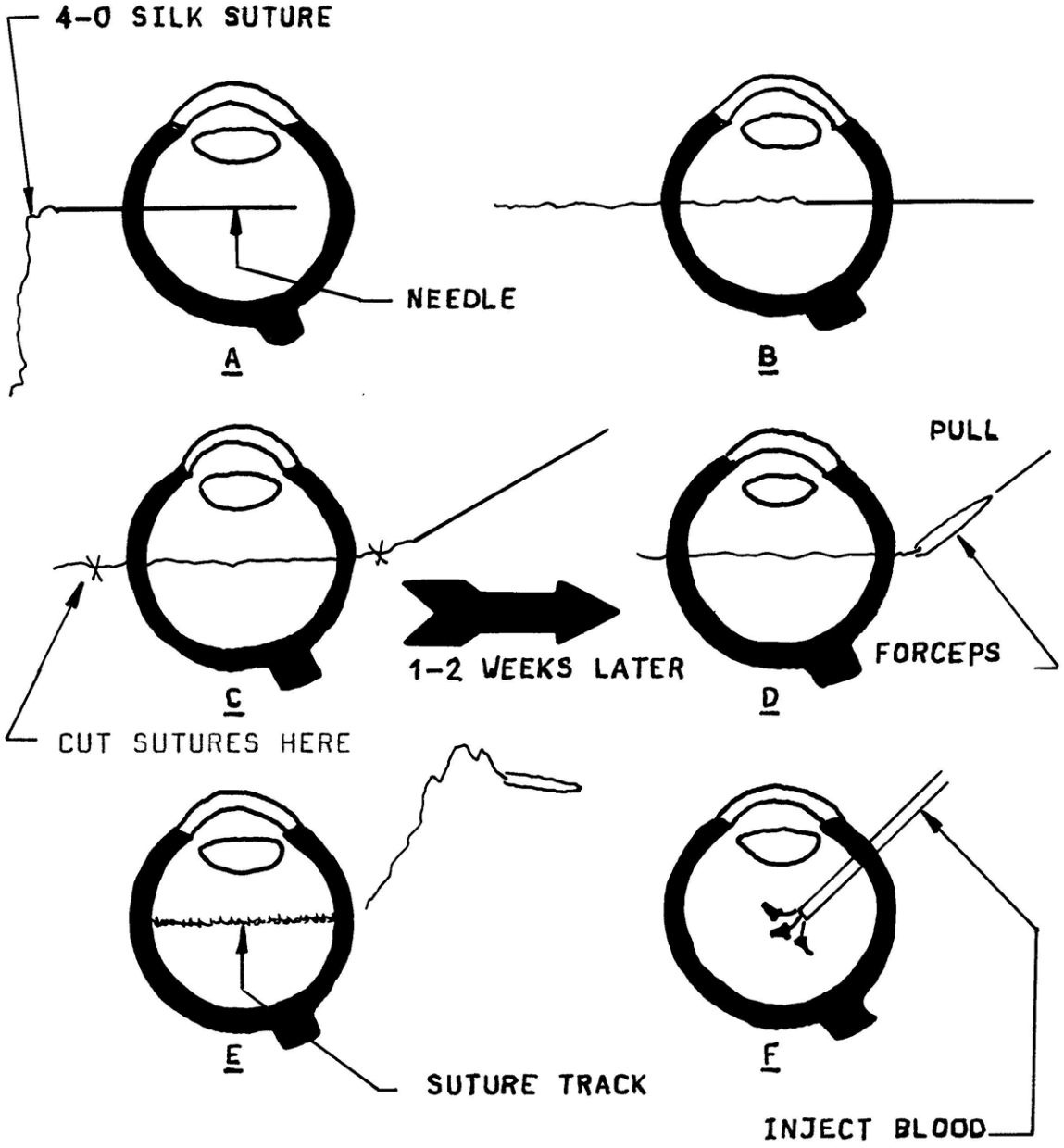


FIGURE 10. Methods used in growing membranes in rabbit's eye. A to E is the suture method and F is the blood method.

and after sutures were removed, membranes continued to form in suture tracks. (See Figures11 and 12.) In a few eyes, hemorrhage occurred, and membranes formed around the hemorrhage. Membranes were also grown in a rabbit's eye by injecting between .1cc to .5cc whole blood taken from another rabbit. (Figure 10)

(i). The Tension Experiment

For this experiment, membranes aged from two to eight weeks were used. The length of membrane specimens tested were variable. However, the width of specimen was kept below 1.5 mm as much as possibly could be managed with surgical scissors. (For explanation, see Appendix A.) Membranes were put between the form clamps as shown in Figure 13. These form clamps were then clamped by larger plexiglass clamps as shown in Figure 14. The plexiglass clamps were dipped in a normal saline bath and pulled up by a thin wire attached to the force transducer (FT.03C Grass Instrument) mounted on a microscope stand as shown in Figure 15. The transducer was moved up and down by the motor (1/2 rph and 1/2 rpm) shown also in Figure 15. The result obtained is shown in Figure 16. The tensile strength band of from 200 milligram to 16 grams was obtained. Thus the test established that: Membrane strengths are variable over a wide range of force; membranes elongate from 50 per cent to 200 per cent; and membranes are much stronger than the force of retinal detachment. The investigation of the adhesion properties of membranes became imperative.

(ii). The Adhesion Experiment

Membranes aged from nine to ten months were used. Membranes were made to adhere to the two surfaces a and b with weights as shown in

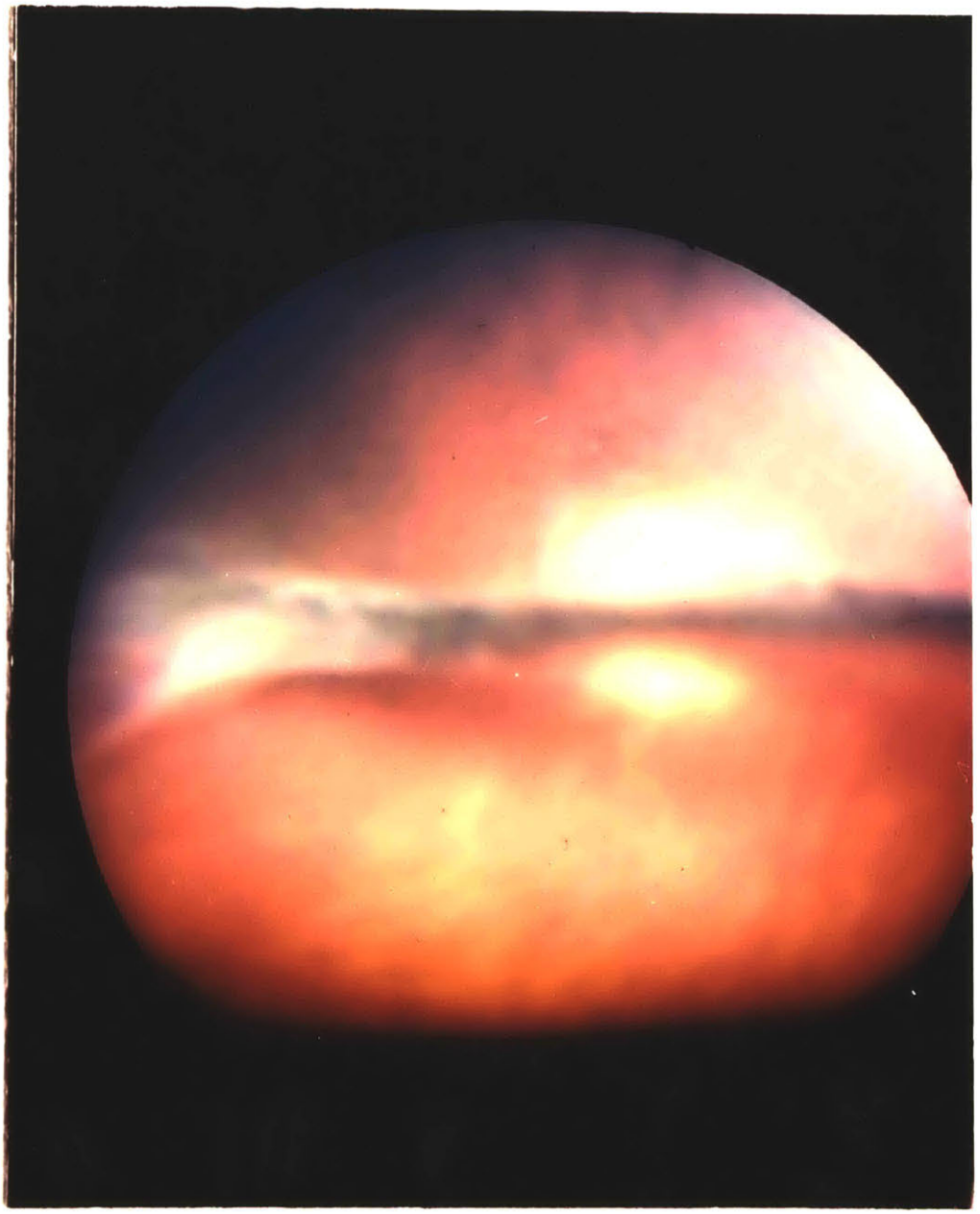


FIGURE II. 4-O SILK SUTURE IN A VITREOUS BODY OF A RABBIT.

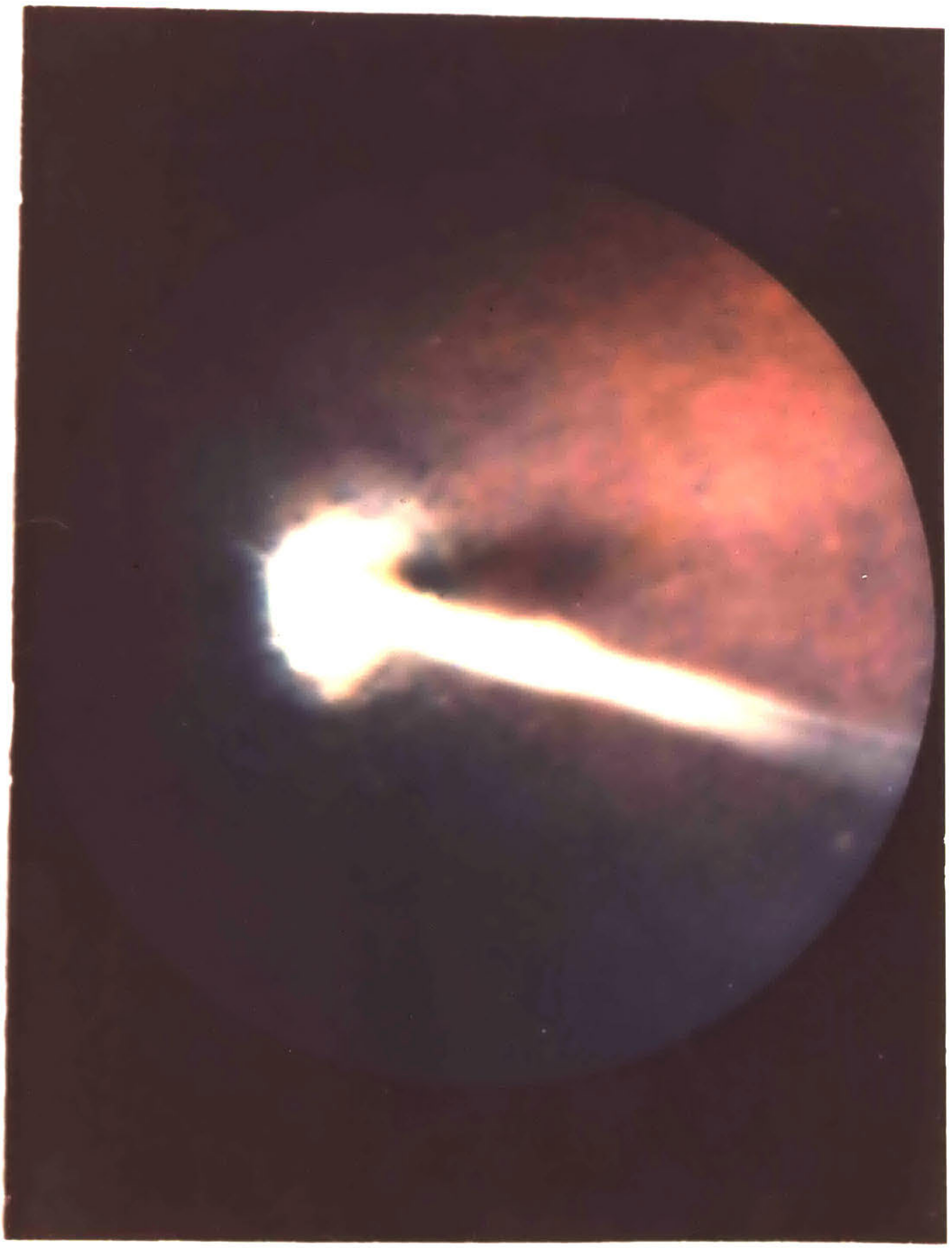


FIGURE 12. A MEMBRANE GROWING THROUGH A SUTURE TRACK.

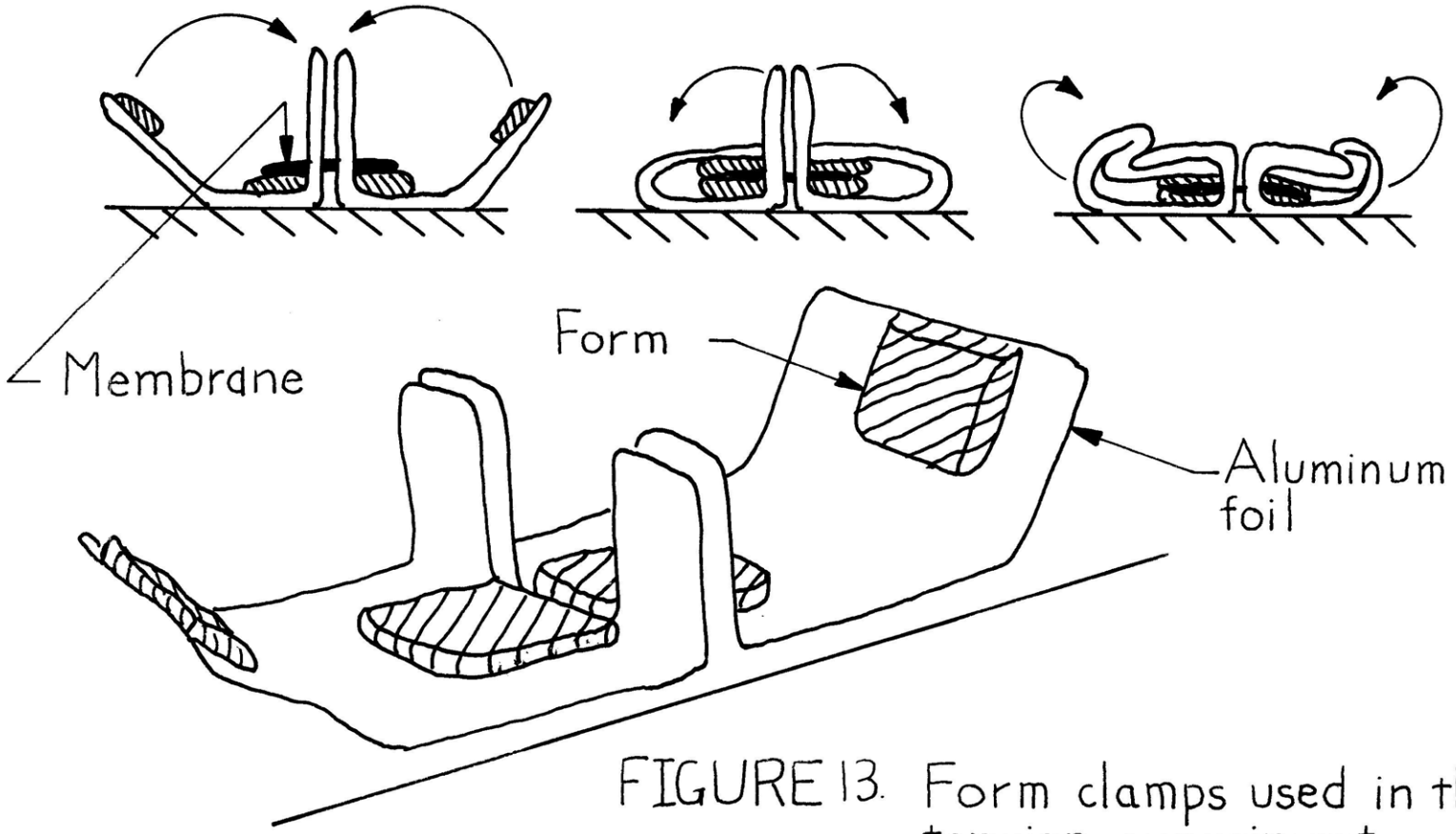
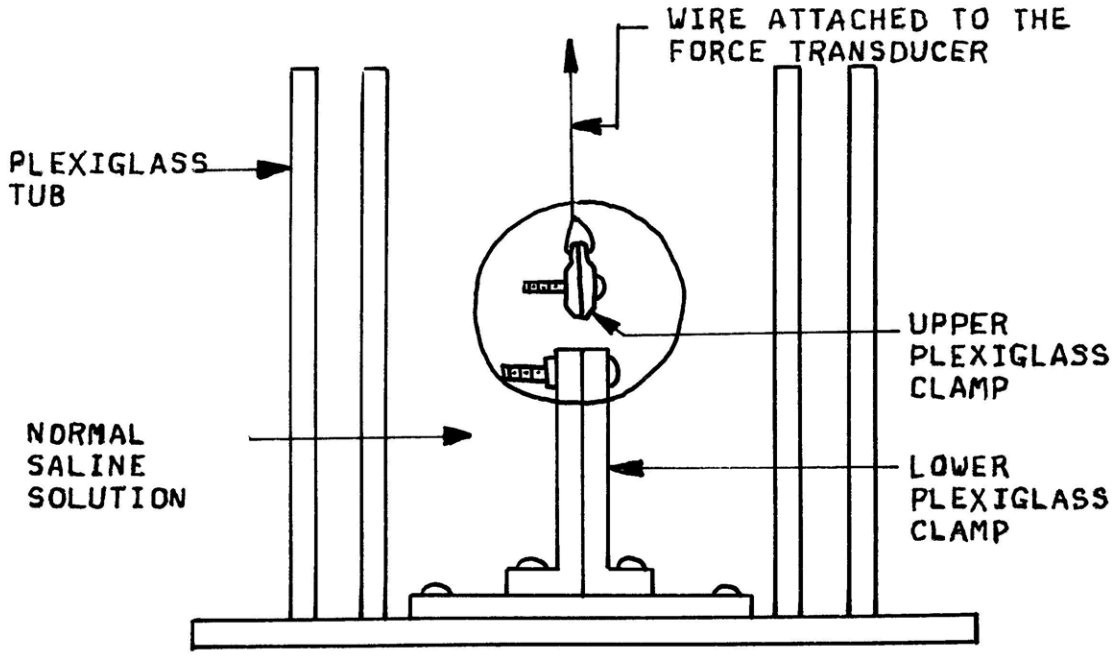
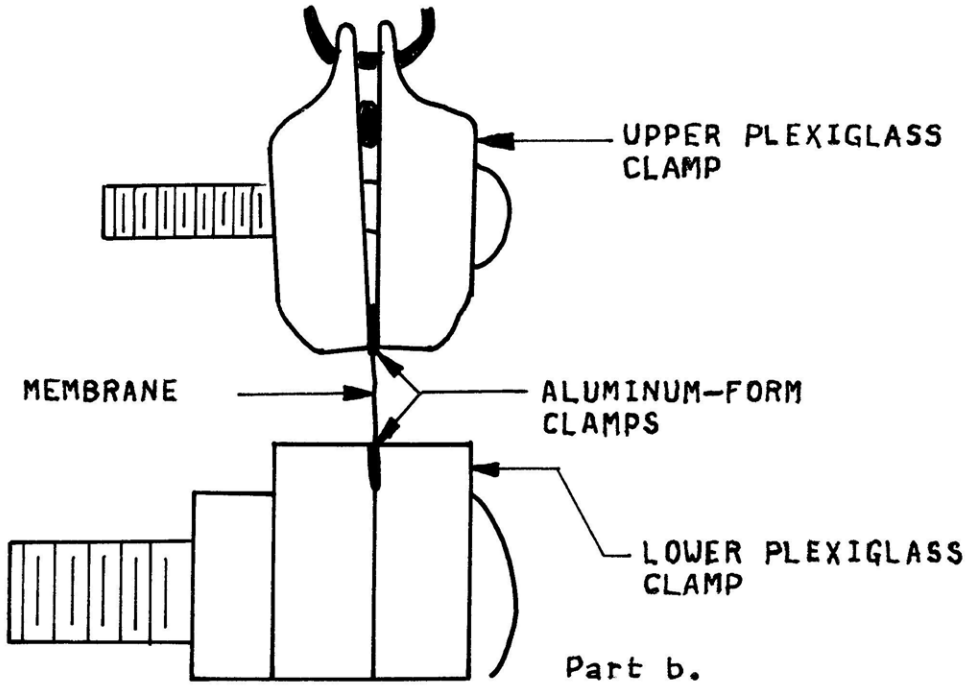


FIGURE 13. Form clamps used in the tension experiment.



Part a. The schematic diagram of the testing bath and the clamps.



Part b.

FIGURE 14. Enlargement of the plexiglass clamps. Membranes were clamped tightly by screw and bolt.

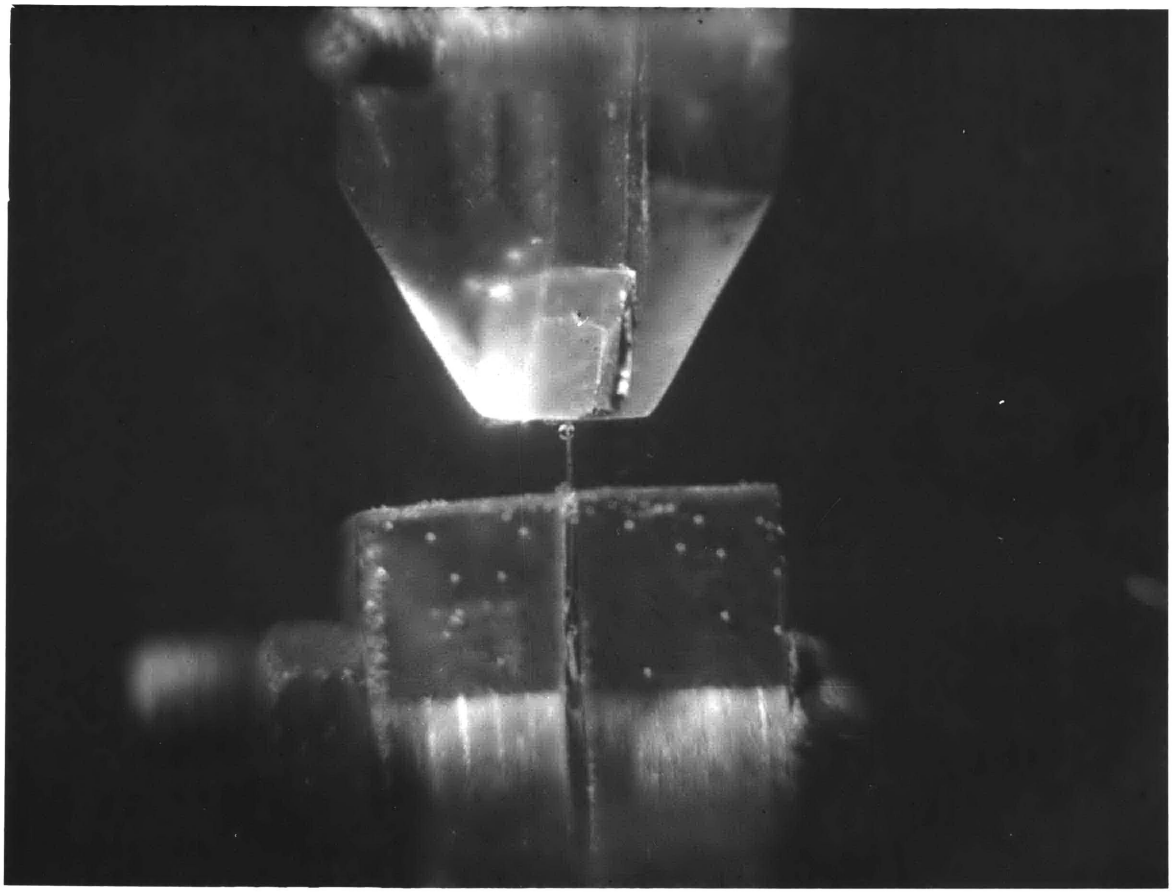


FIGURE 14. PARTC. A MEMBRANE BEING PULLED IN SALINE BATH.

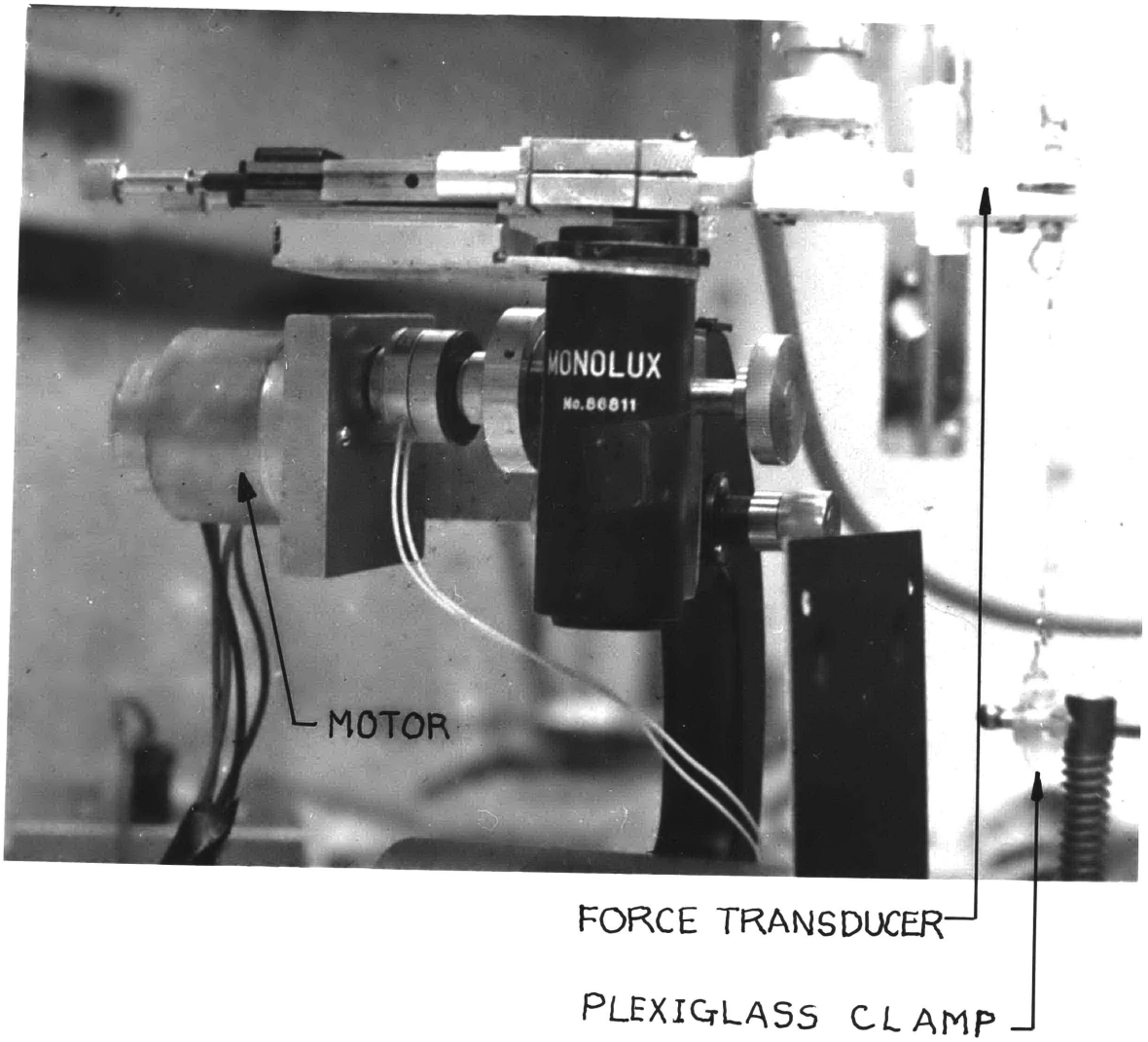


FIGURE 15. The force transducer, Motor, clamp, and microscope stand are shown.

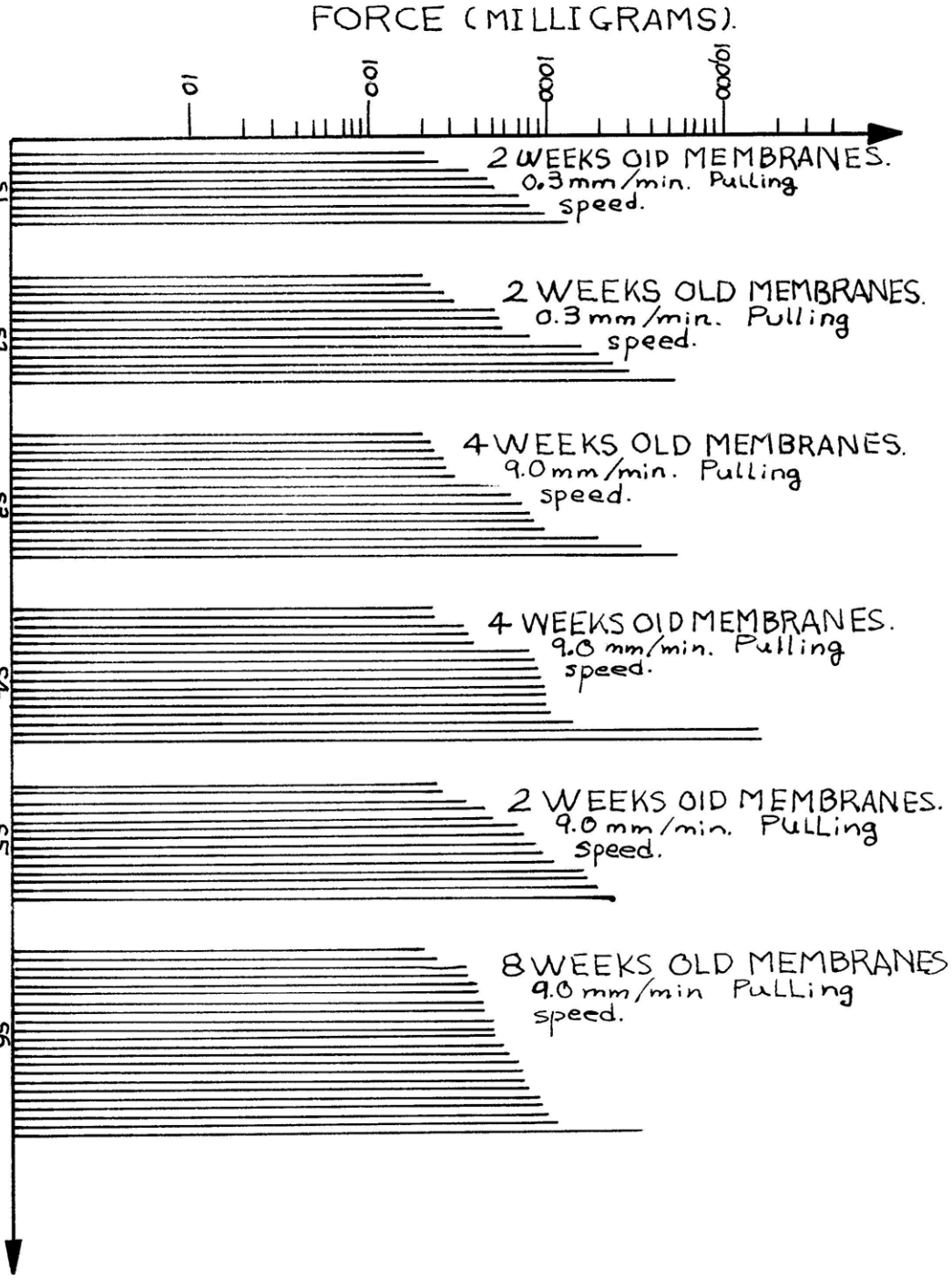


FIGURE 16. TENSION TEST DATA. S1 TO S6 REPRESENT SIX RABBITS TESTED. FORCES MEASURED ARE PLOTTED ON LOG SCALE.

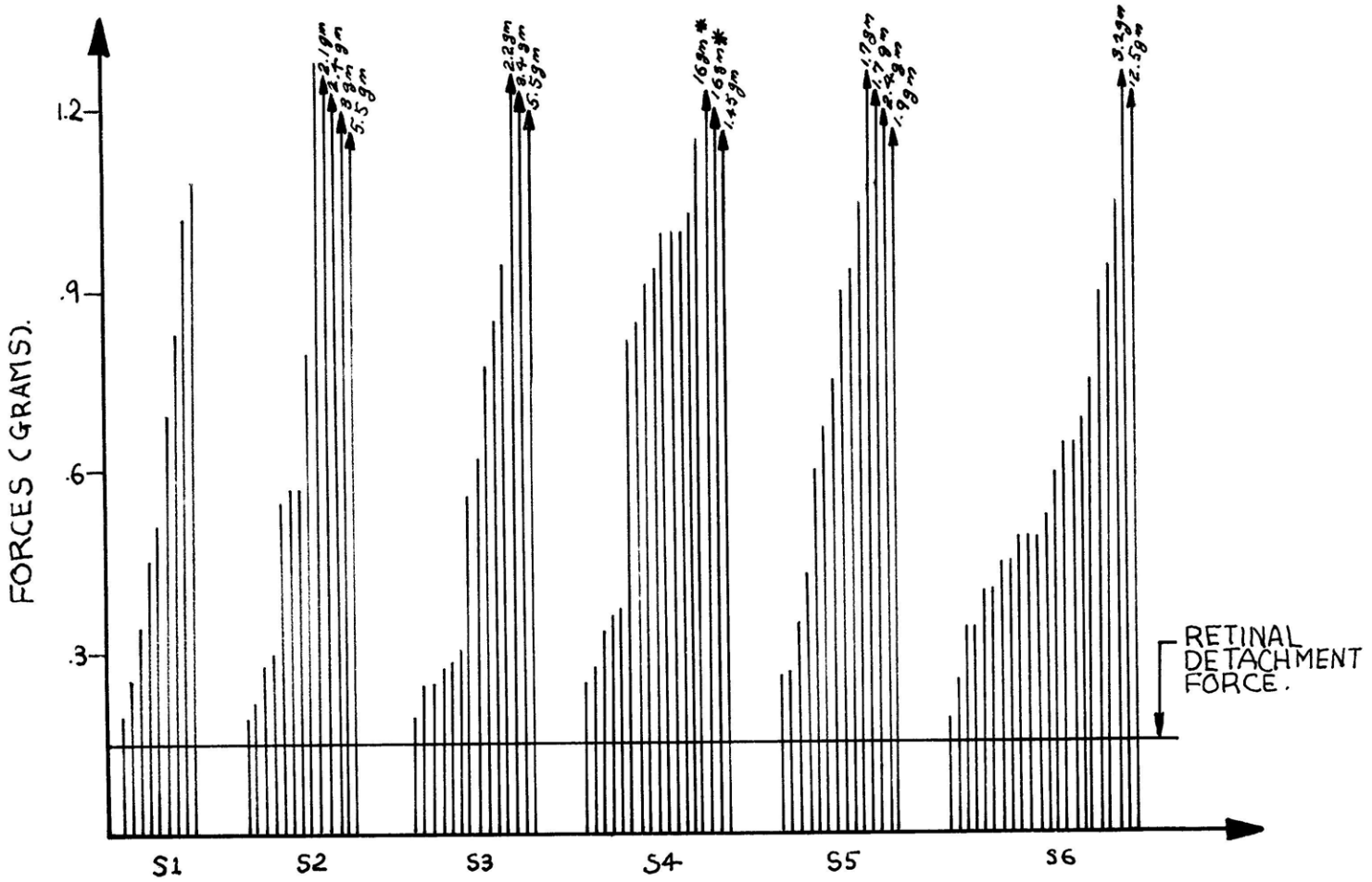


FIGURE 16. TENSION TEST DATA. S1 TO S6 REPRESENT SIX RABBITS TESTED. ARROWS INDICATE LARGER STRENGTH MEMBRANES. FORCES ARE REPRESENTED IN UNITS OF GRAMS. STARRED ARROWS IN MEMBRANE GROUP S4 ARE THE STRONGEST MEMBRANES MEASURED.

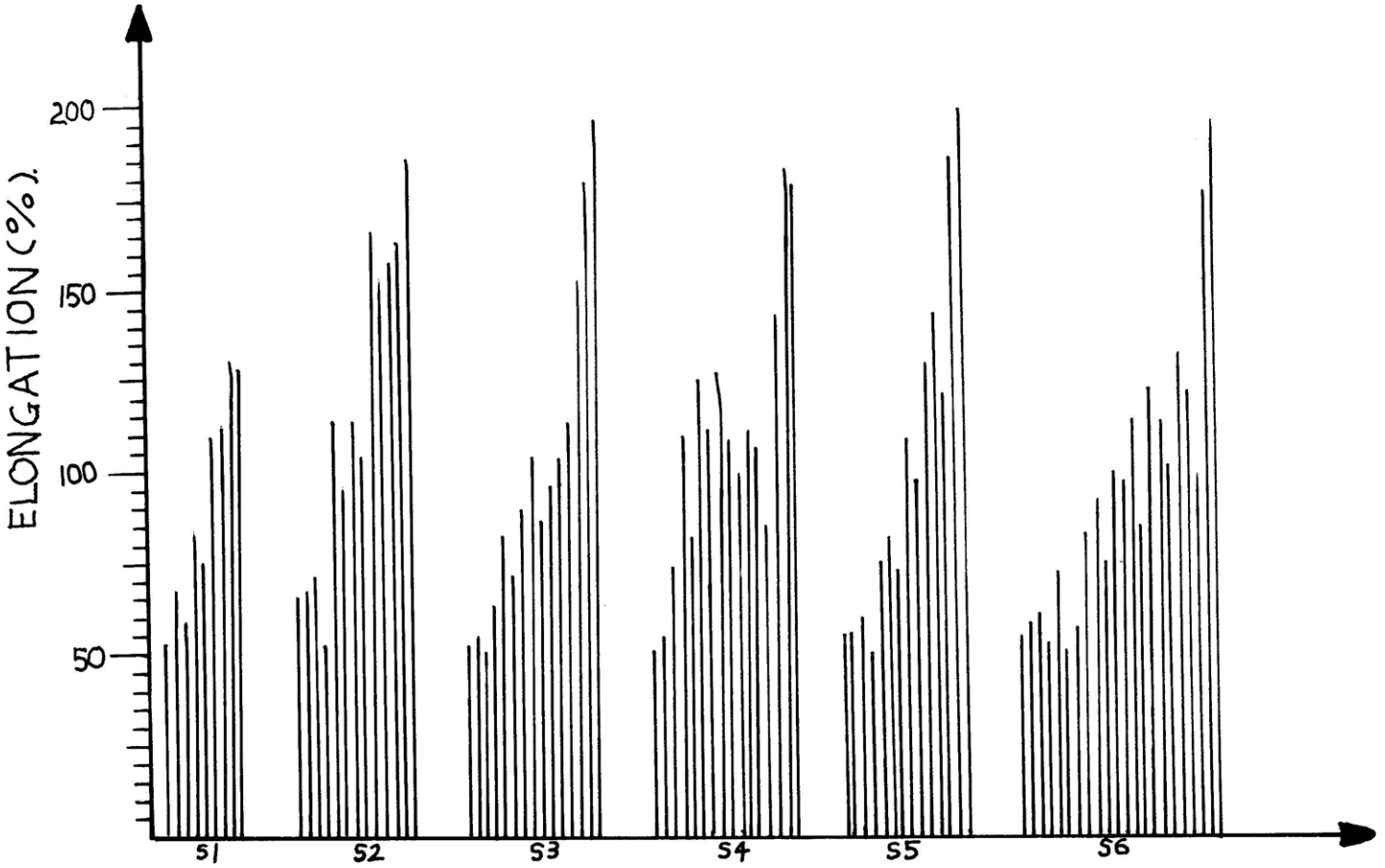
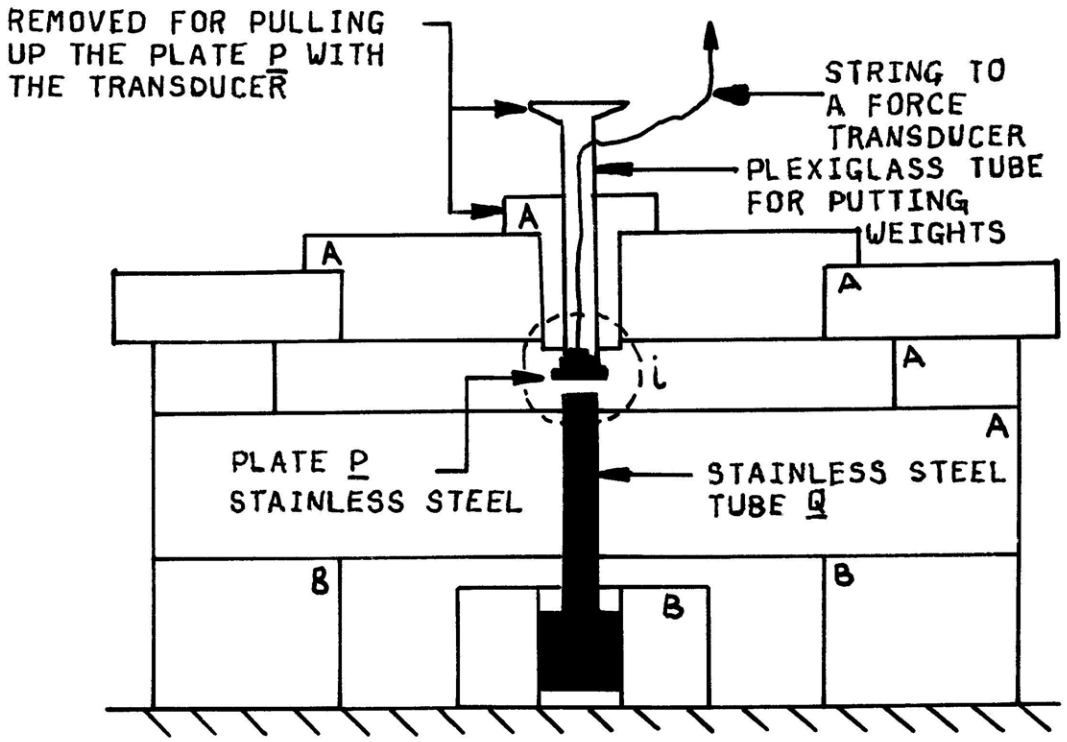


FIGURE 16. MEMBRANE ELONGATION DATA. SPECIMENS ARE PLOTTED EXACTLY IN THE SAME ORDER AS IN FIG. 16 PP 39.

Figure 17. As the plate p moved up, the force transducer recorded the resistive force arising from the adhesion between the membrane and the surfaces a and b. Two modes of separation were expected. In mode one, the membrane separates from the clamping surface. In mode two, the membrane itself divides and separates into two parts, indicating that the cohesive strength of the membrane is weaker than the adhesive strength. The mode two becomes a problem in testing the adhesive strength of membranes because the force measured is the force of membrane cohesion. It does not indicate what the adhesive strength is between the membrane and the surfaces. This problem will be referred to as Problem 1 in the subsequent discussion.

The adhesive force was expected to be approximately the same on both surfaces a and b in Figure 17, since the two surfaces were made from the same material and possessed approximately the same surface finish. On the other hand, the membranes were known to be non-uniform in density, composition, and almost surely in surface texture. Adhesion on one side being significantly stronger than the other side was, therefore, a likely possibility. Under this condition, the adhesive force of the membrane to the surfaces could not be assumed equal to the force measured. Unfortunately, the magnitude of the difference was not calculable; therefore, to counter this problem as well as Problem 1, the membrane was pulled as shown in Figure 18. Membranes were also pulled horizontally with the plate on as shown in Figure 19, to get rid of possible contribution to the force measured from suction as shown in Figure 20. Increasing the clamping force was expected to



Part 1. The cross section of the adhesion testing equipment. A's are 1020 steel and B's are plexiglass. The drawing is X.8 actual size. The plexiglass tube, plate p and Q are drawn larger for better view.

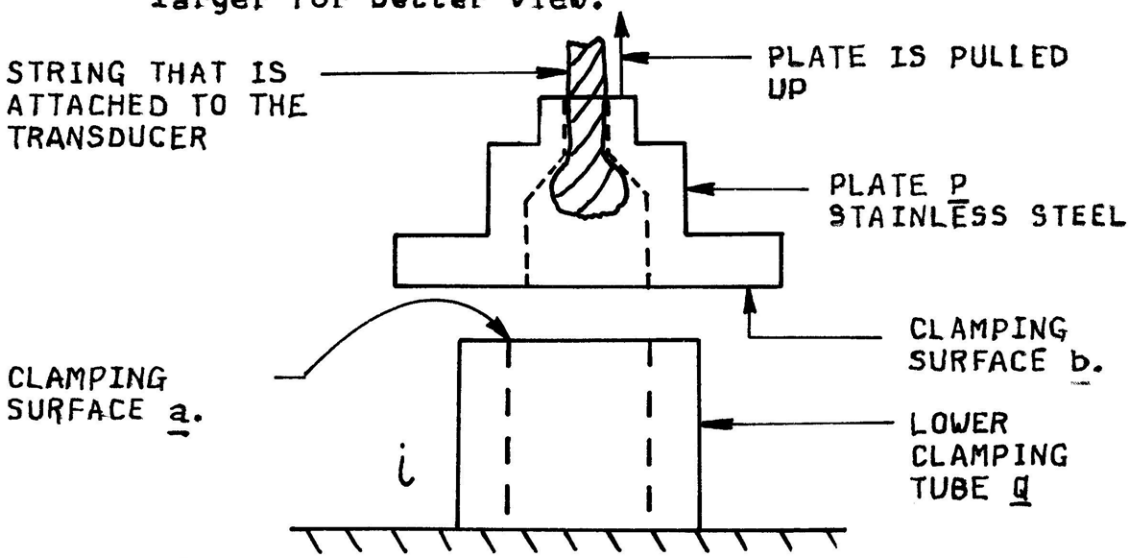


FIGURE 17. Part b. Membrane clamping parts. Surfaces a and b are polished surfaces of a tube and disk respectively. The drawing is X8 actual size.

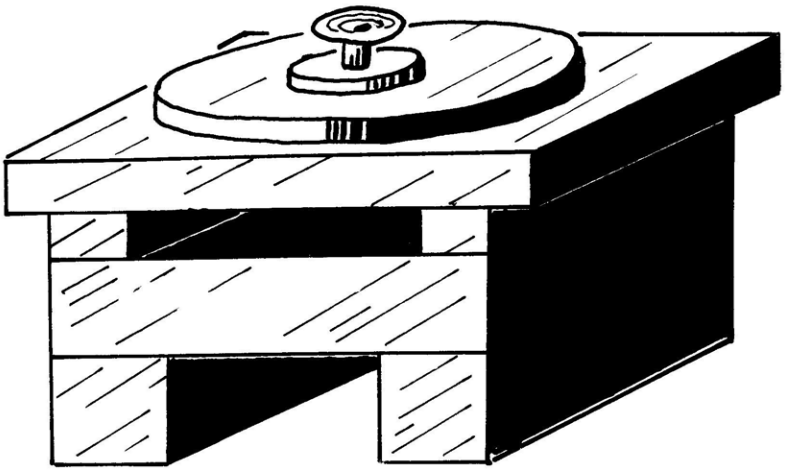
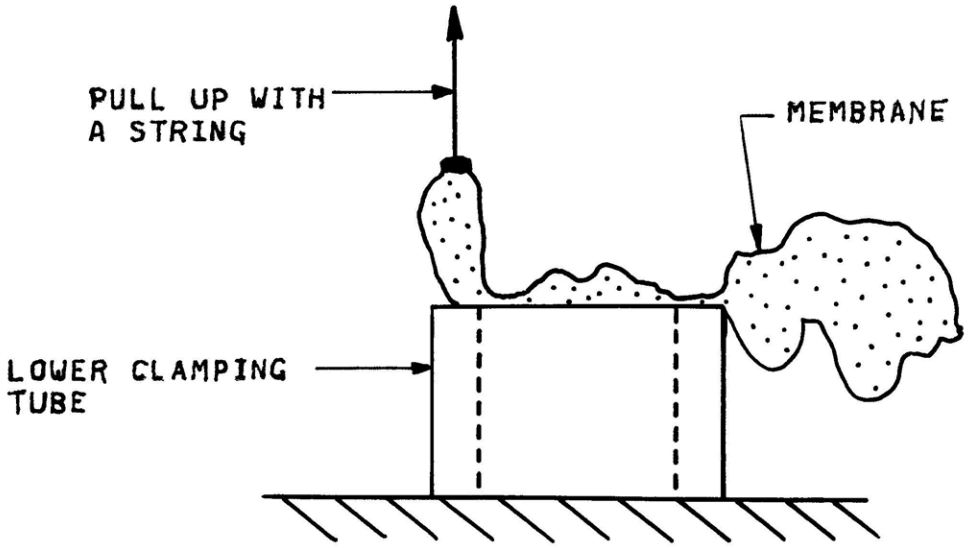


FIGURE 17. Part c. The pictorial drawing.



Part a. The vertical pulling.

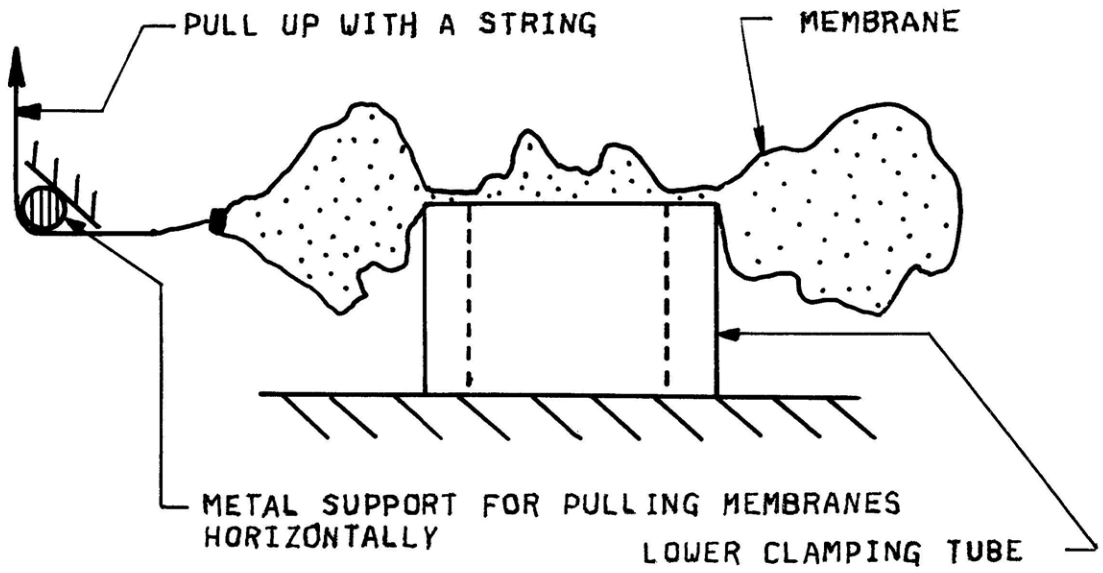


FIGURE 18. Part b. The horizontal pulling of membranes with plate off.

The vertical pull and the horizontal pull modes of testing in the adhesion test.

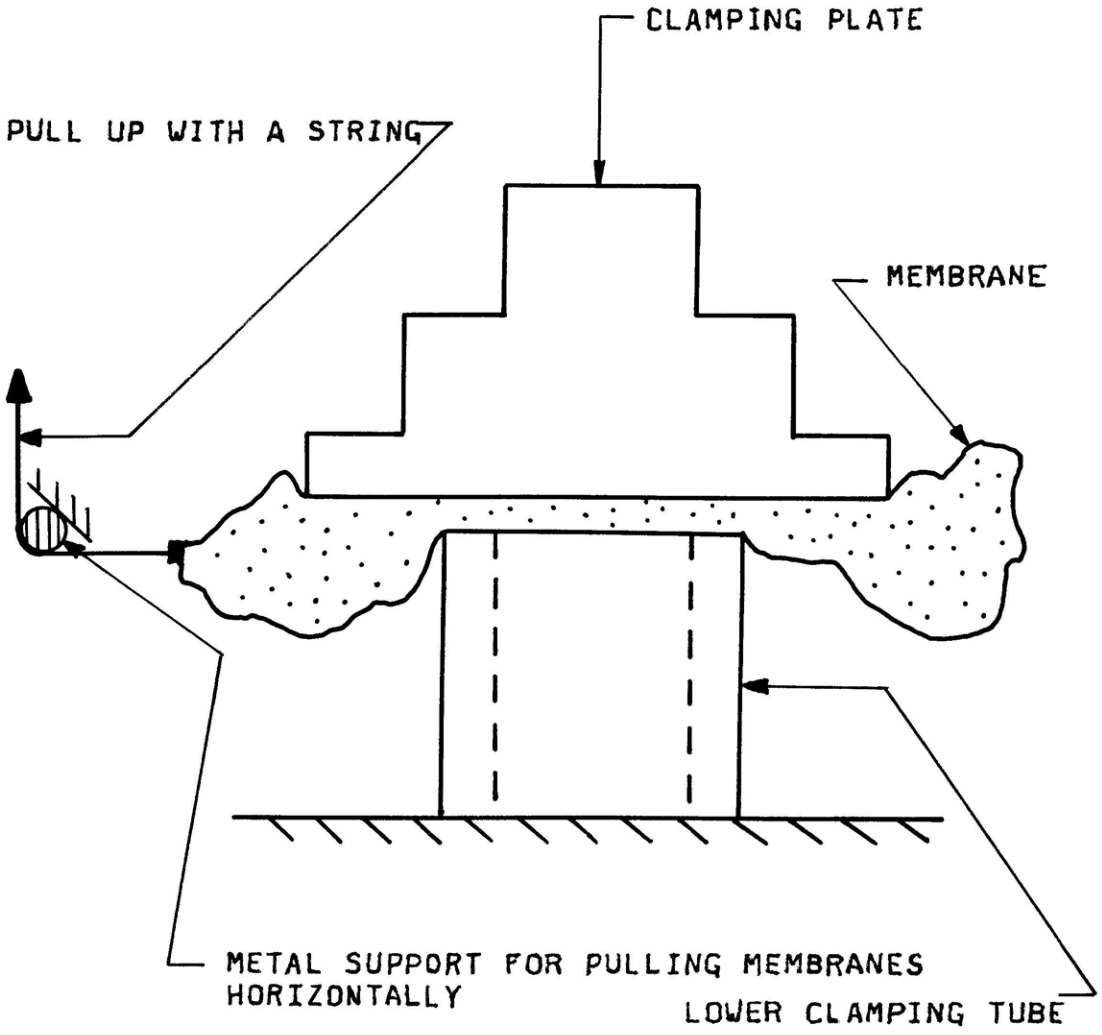


FIGURE 19. Horizontal pulling mode of testing with plate on but a clamping weight removed.

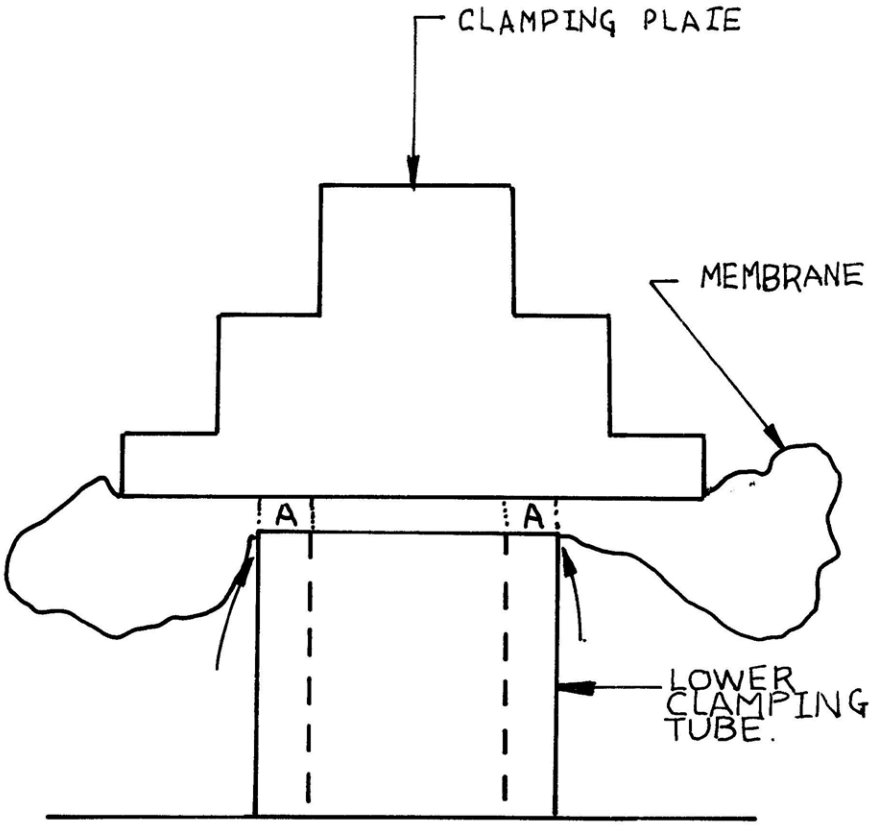


FIGURE 20. When the upper plate is pulled, water may not be able to move into spaces between membrane and the metal surface, so that region A may become lower pressure than the surrounding causing the plate and the tube to press together.

result in the increase of the adhesion force, because the increased clamping force probably increases the actual area of contact between membranes and the clamping surface. The plate and the tube were polished with 9 microinch aluminum oxide power and a polishing cloth following a 600 sandpaper polish. Increasing the surface smoothness was expected to result in the decrease of the adhesion force due to the reduction of surface area available for adhesion. The results of adhesion test are shown in Figure 21.

Membranes from three rabbits were tested, and they are designated R1, R2, and R3, respectively. Within each rabbit data, different specimens of membranes are marked a, b, c, etc. The adhesive force in dynes per cm^2 is plotted against the different specimens. Forces plotted are the largest forces recorded by the transducer for each mode of testing. The different modes are shown in Figures 17 (part a), 18, and 19. The following observations can be made. Forces measured from the horizontal pull of membranes with the plate on were consistently smaller than the forces measured from the pull of plate except for specimen group $R_3 2$ in Figure 21. The difference was probably due to the suction mechanism, discussed earlier. In all cases, forces measured from peeling membranes and from horizontal pulling of membranes following the plate pull were significantly smaller than forces measured from pulling the plate or from the horizontal pulling of membranes with the plate on. I suspect that separating the plate from the tube weakened the adhesion of membranes to the surfaces. The increased clamping force did increase the adhesion force of membranes in two cases: $R_2 c$ compared to $R_2 b$ and $R_2 4c$ compared to $R_2 4a$ or b in Figure 21.

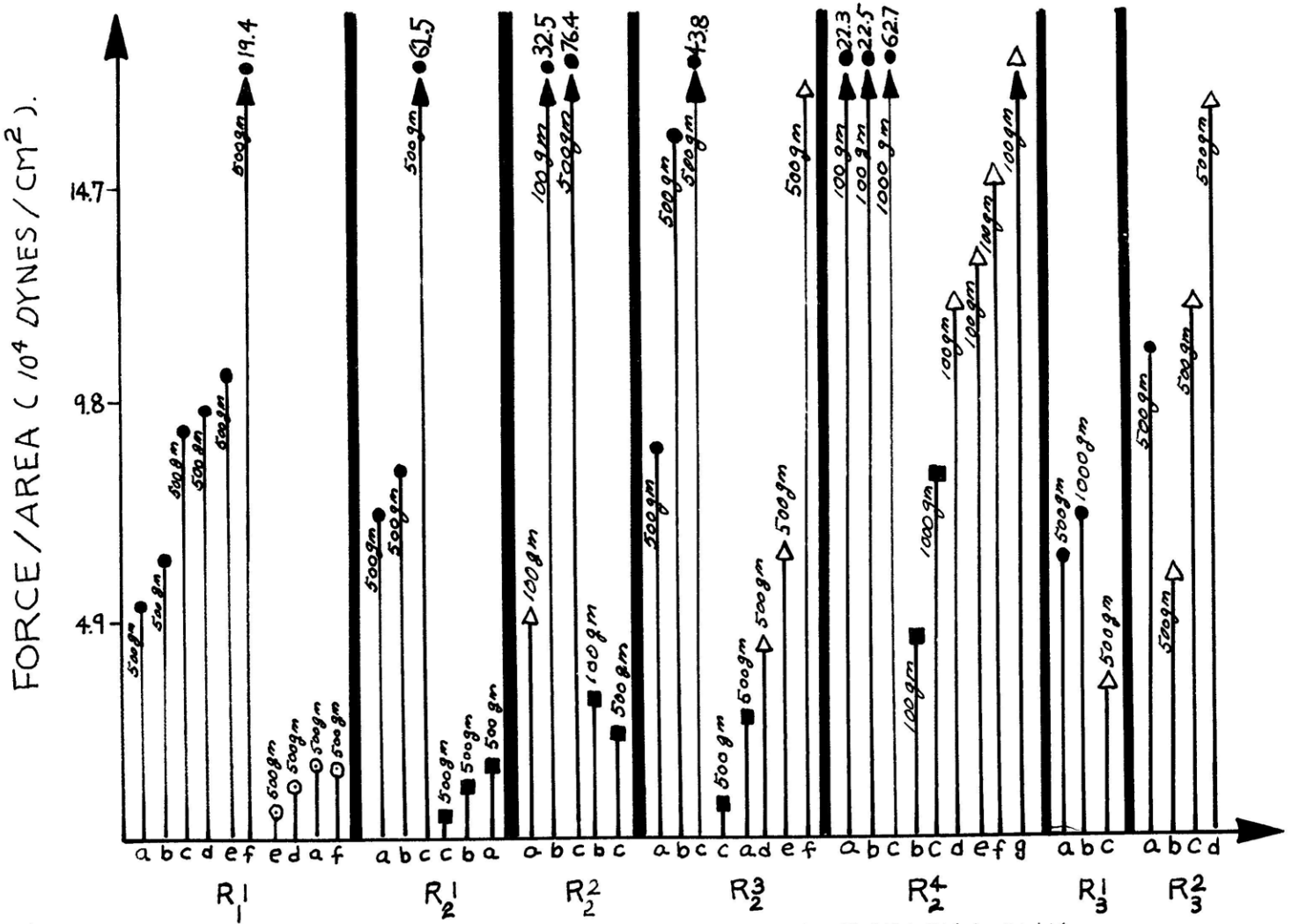


FIGURE 21 ADHESION TEST DATA. R_1, R_2, R_3, ARE RABBITS TESTED. a, b, c, ETC., ARE DIFFERENT MEMBRANES TESTED. CLAMPING WEIGHTS ARE WRITTEN ON THE GRAPH IN GRAMS.

● MODE 1. PLATE PULL ONLY.
△ MODE 3. HORIZONTAL PULL WITH PLATE OFF.
■ MODE 2. HORIZONTAL PULL WITH PLATE ON.
⊙ MODE 4. VERTICAL PULL.

Part 3. Implications of the Results in Evaluating the Design Concept

Increase in the clamping pressure does not result in the significant increase of the horizontal pulling force when the plate is off. Thus, a reduction in clamping area (increase in the clamping pressure) probably will not result in the increased membrane adhesion force after the surfaces have been separated. Under this favorable condition, the upper limit of adhesion force per unit area for most membranes can be taken as 98000 dynes/cm^2. For the clamping surface area of .0057 cm^2 (the clamping area of the design shown in Figure 7), the adhesion force is 559 dynes or 3.8 times larger than 147 dynes, the retinal detachment force; therefore, investigation should turn toward testing new surface materials such as teflon or plastic.

Other vital information gained from the tension experiment is that the upper limit of membrane elongation is approximately 200 per cent. Thus, the cutting stroke must be at least 1 mm long for the new design and probably should be longer. Difficulty existing here is that uncertainty of data is not known, and the safety factor cannot be specified. Thus it is hard to determine whether the stroke length should be 2 mm or 5 mm. This will have to be settled when driving mechanisms are considered.

CHAPTER IV

*FURTHER CONSIDERATIONS FOR THE INSTRUMENT DESIGN

SECTION I. An Infusion System for Maintaining a Proper Intraocular Pressure and an Irrigation System for Creating a Better Suction Capability

The instrument must have an infusion fluid line for maintaining a proper intraocular pressure. One design for accomplishing this task is to attach another tube on the outside of the outer tube, as shown in Figure 22. For this purpose a .008-inch OD and .002-inch nominal wall tube can be used, which can deliver .00028-inch^3/sec (.0045 cc/sec) fluid with 14.6 psi driving pressure or .00020-in^3/sec (.0033 cc/sec) fluid with 10.6 psi. Since only .000078-inch^3/sec (.0012 cc/sec) volume of material is removed each cycle, this flow rate should be sufficient to take care of replacement fluid.

When clamping is in effect, material inside the cutting tube is completely sealed off from the rest of the vitreous body. Thus, cut material is to be sucked out from a closed tube as shown in Figure 23. The cut material will not be sucked out of the tube under such a condition. However, when the next cut is made, some new material will be withdrawn into the tube, and the old material should move down the tube. The schematic picture of several cutting cycles in succession is shown in Figure 24. However, if clogging occurs, there is little that can be accomplished by increasing a suction power. Danger of suddenly sucking in a large volume of vitreous body is increased.

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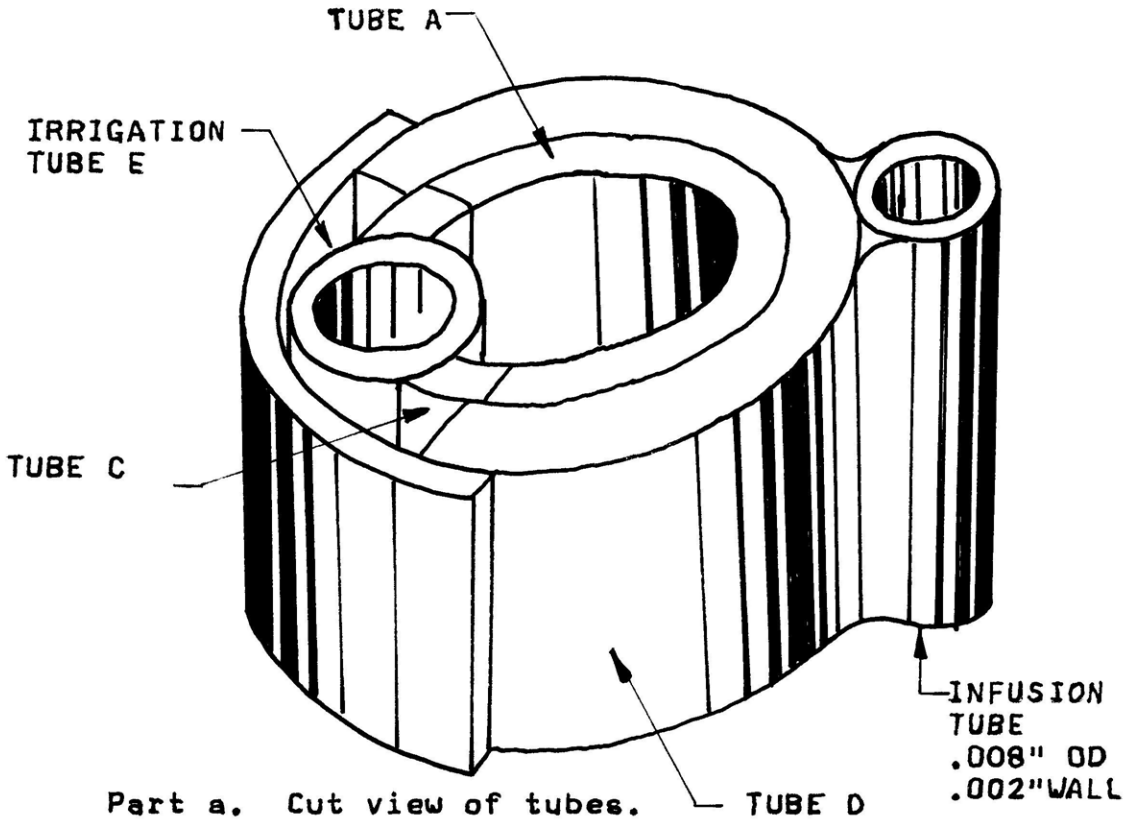
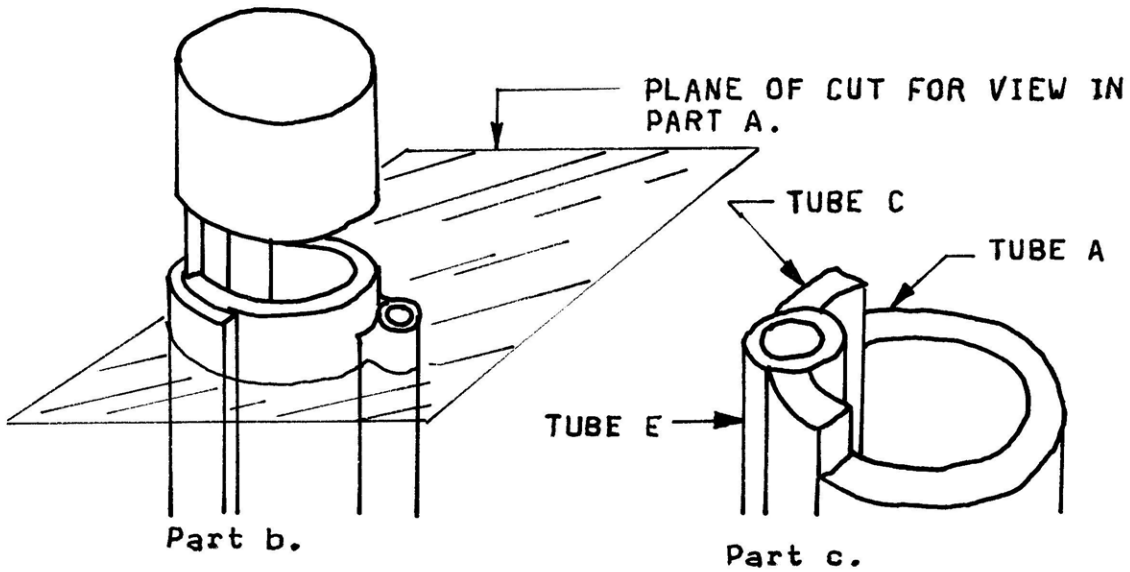
*For all calculations, refer to Appendix B.



Part a. Cut view of tubes.



Part b. Part c.

FIGURE 22. A possible design for the infusion and the irrigation system.

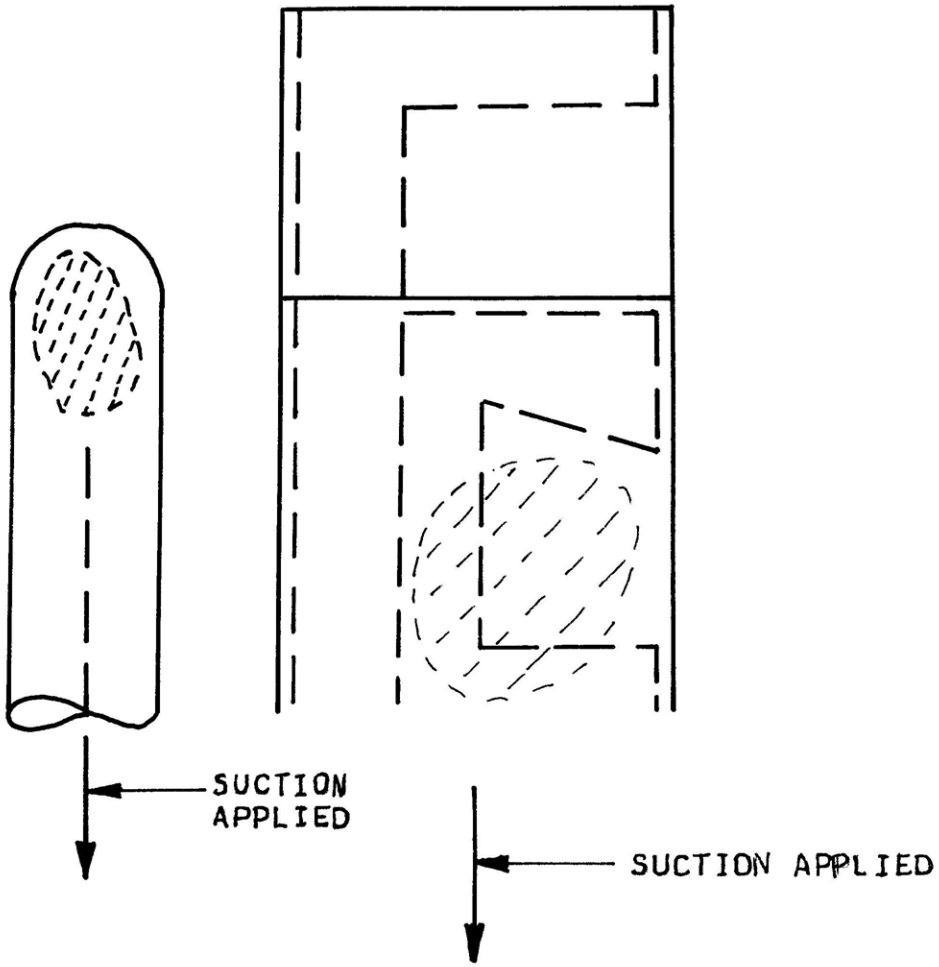


FIGURE 23. A problem in sucking materials out of a closed cutting tube. When cutting is done with tube A, the interior of the tube is completely sealed from the surrounding fluid. Thus, cut material is essentially being sucked out from a closed tube.

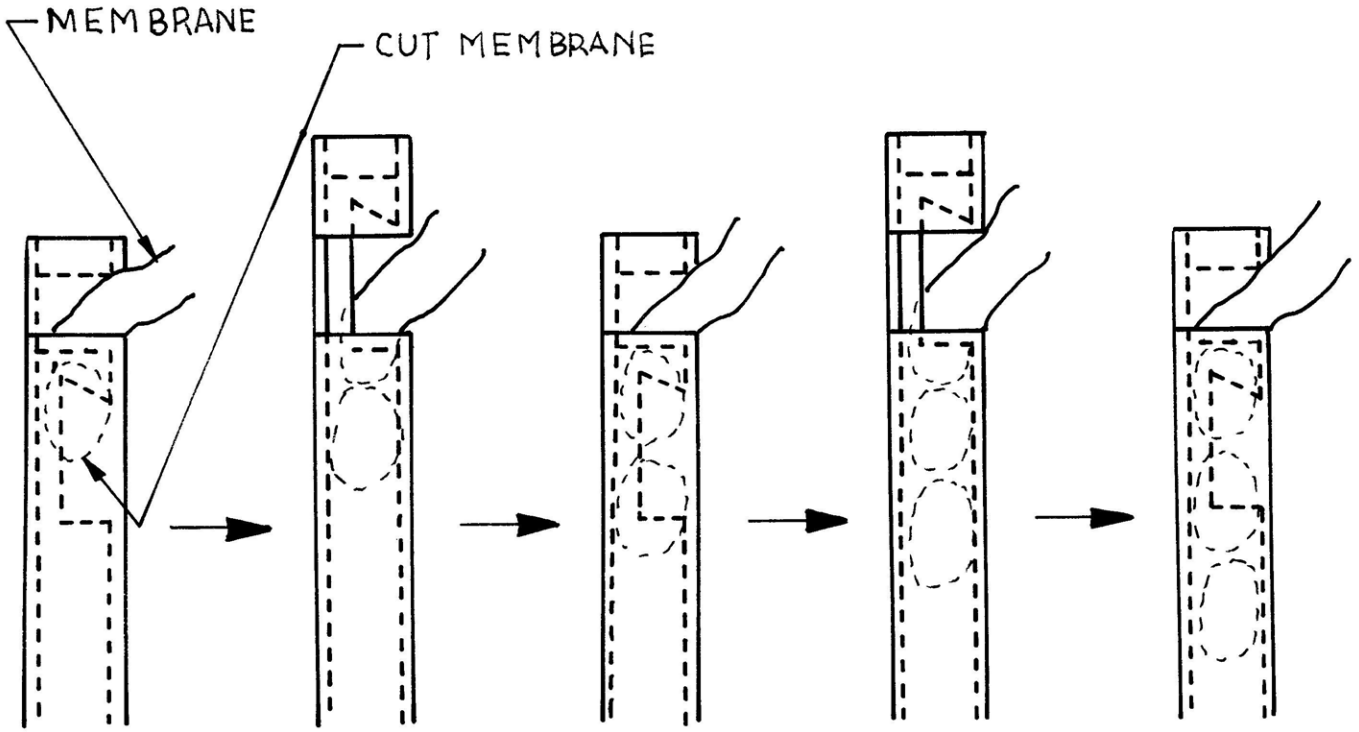


FIGURE 24. THE SCHEMATIC DRAWINGS OF CUTTING SEQUENCE ILLUSTRATING ONE METHOD OF OVERCOMING A PROBLEM OF SUCKING OUT CUT MATERIALS.

One possible solution I have come up with is to provide a fluid irrigation line, tube E shown in Figure 22, and a schematic diagram of its function shown in Figure 25. A calculation shows that with 19.7 psi driving pressure, the tube can supply .5 cc of fluid per second. This is 11.6 times the volume of the suction tube A, shown in Figure 22, which is .043 cc. The tube is attached to the section C, shown in Figure 22, so that it moves with C, and it can deliver the fluid into the clamping head at all times.

SECTION II. Difficulty in Modeling the Clamping System for Analysing Its Dynamic Behavior

Clamping is done inside eyes where the environment surrounding the clamping surface is viscous. As clamping surfaces come together for clamping a membrane, a viscous fluid must be pushed out, and the membrane must be squeezed. The fluid and the membrane both act as a damper. A simple model consisting of mass, spring, and dashpot can be constructed for the clamping system. A mass represents the mass of a tube and a spring, a spring represents a spring producing the clamping force, and a damper represents a sliding friction of a tube as well as of viscous fluid and membranes. The effect of the viscous fluid and membranes becomes greatest when the clamping surfaces are about to meet. Assuming a sinusoidal displacement input, the effect of viscous fluid and membranes is to shorten the time during which actual clamping force is delivered to membranes. This is shown in Figure 26. This effect cannot be assumed negligible, but its magnitude cannot be easily calculated. However, the clamping time required probably will be on the order of 1.4 seconds with .7 seconds cutting

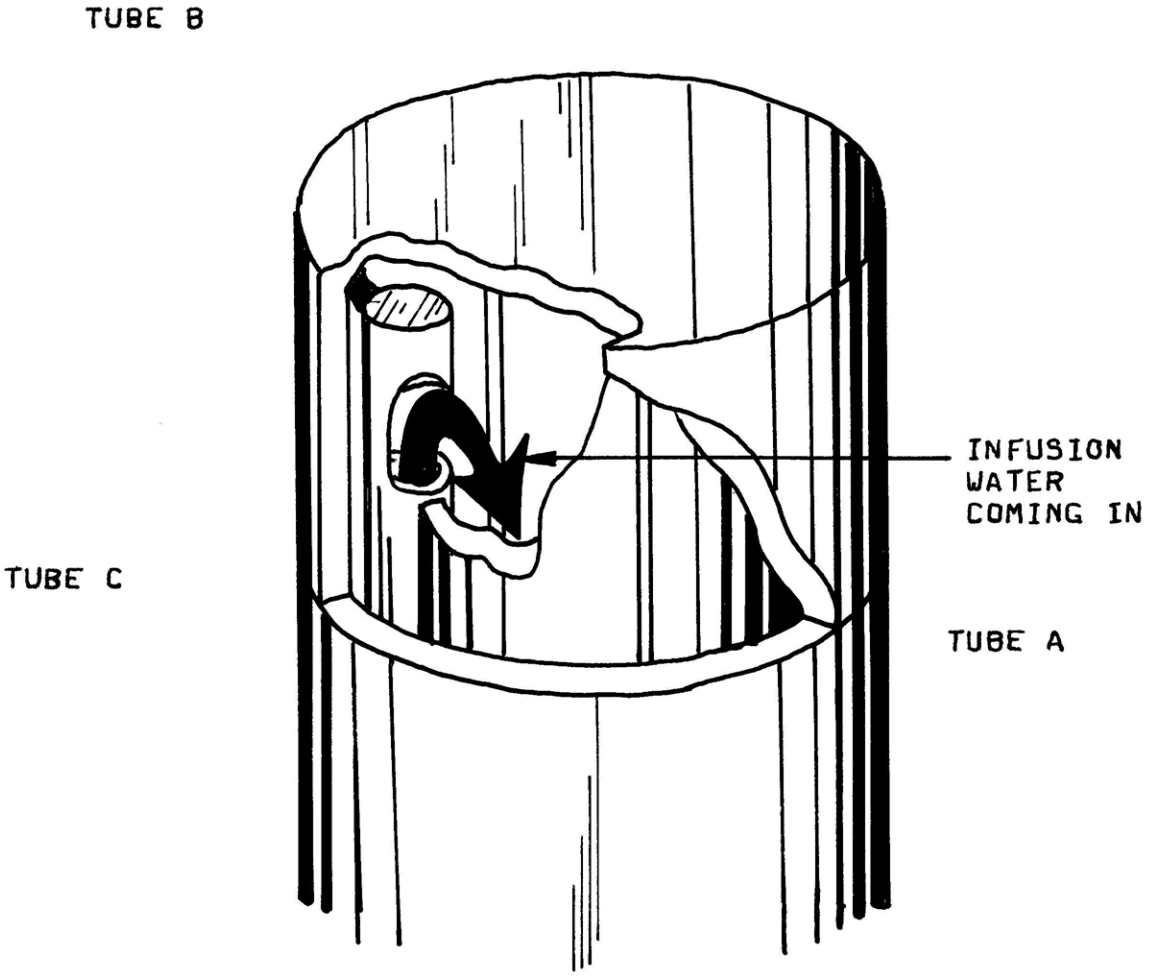


FIGURE 25. The drawing of an irrigation tube inside the cutter. This is a cut away view.

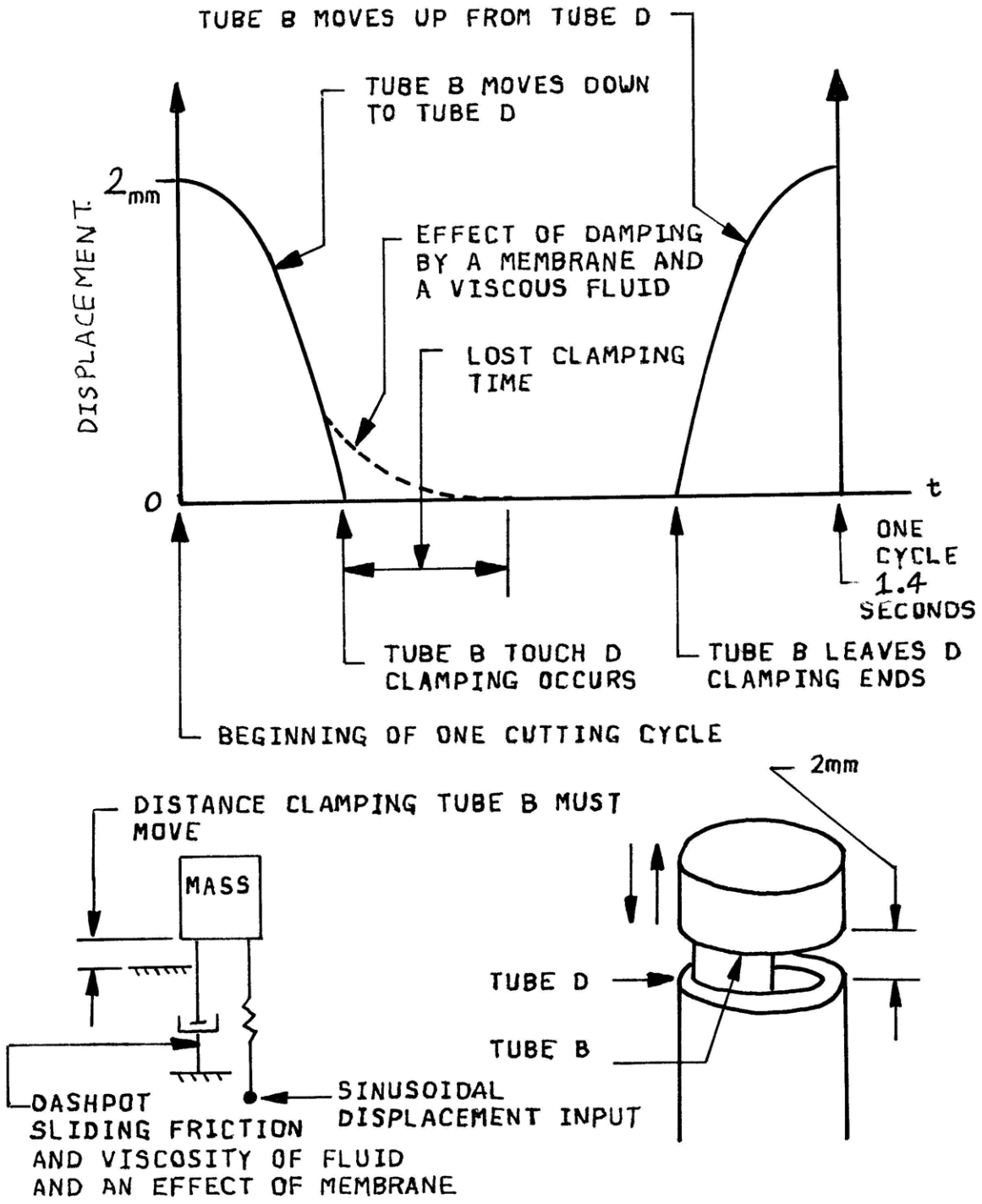


FIGURE 26. The displacement vs time grapn of the clamping system.

cycle. This cycle is very slow especially when the clamping head must move only 2 mm. Thus, the loss of clamping time probably will not become a problem especially if the cutting tube can be operated quickly. This problem should be kept in mind, however, in choosing mechanisms to operate clamping and cutting tubes.

SECTION III. A Refined Design

A refined design of the cutting tip and the approximate shape of the entire instrument is shown in Figures 27 and 28, respectively. The finished instrument probably will be a pen-like, hand-held instrument. The cutting tube A is shaped as shown in Figure 29, so that a membrane will slide to the corner a instead of to the outer part of a tube, b also shown in Figure 29. For lack of time, an entire consideration of possible mechanisms to drive the clamping and the cutting tube has not been included in this thesis.

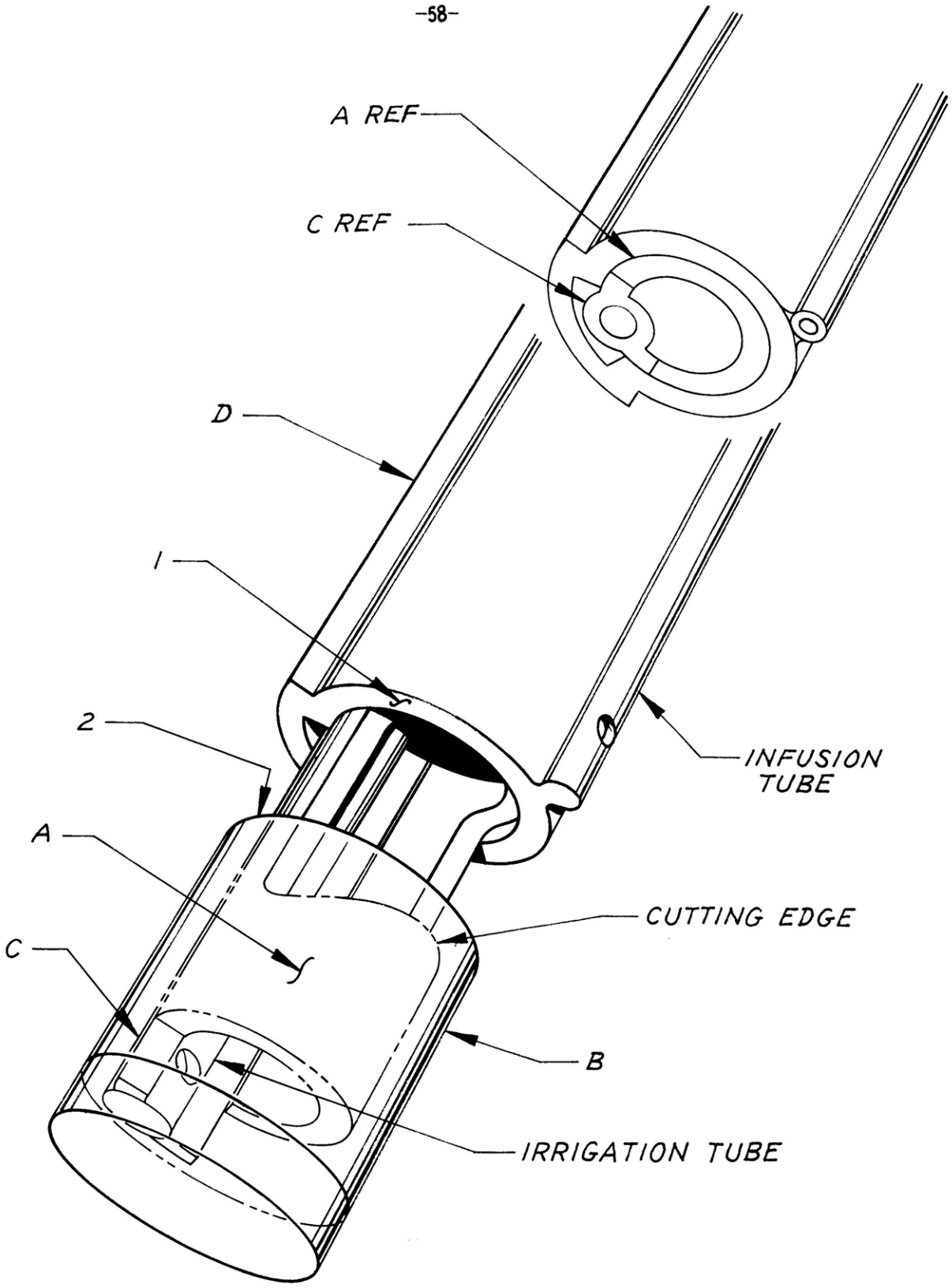


FIGURE 27. MODIFIED DESIGN CONCEPT

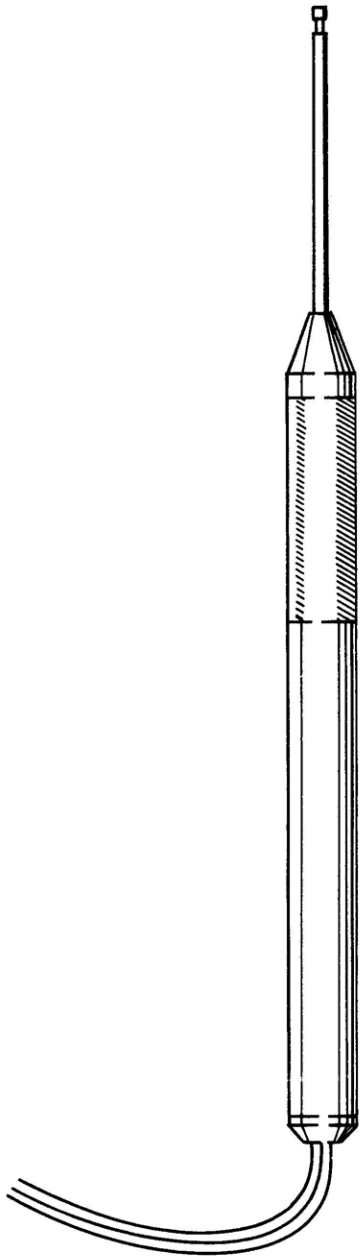
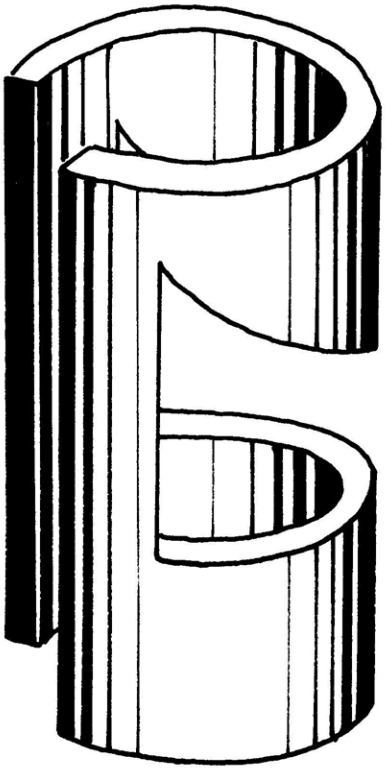
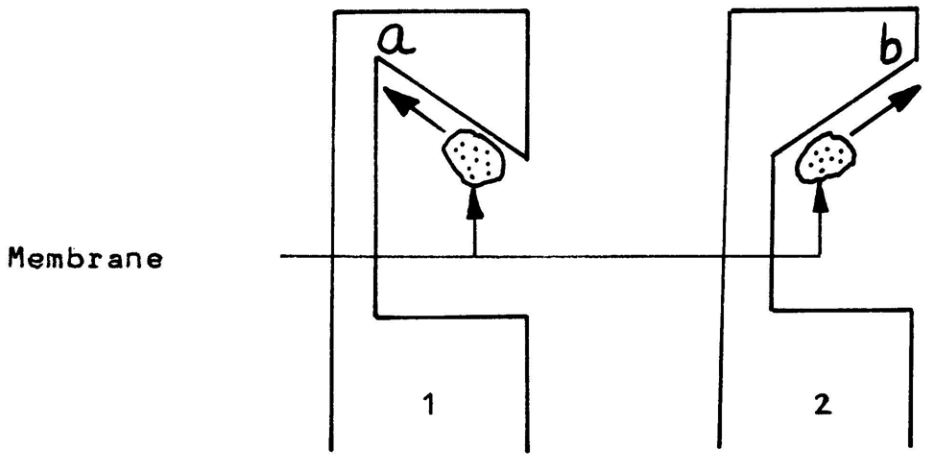


FIGURE 28.
GENERAL CONFIGURATION



Part a. Pictorial view of a cutting tube A.



Part b. Schematic side views of two tube shapes.

Figure 29. The detailed shape of tube A, a cutting tube. The opening is slanted, as in 1, so that membranes will be cornered.

CHAPTER V

CONCLUSION

Designing new instrument for vitreous membrane surgery was undertaken using a systematic design process specifically modified for designing medical instruments. The new design concept, "clamping membranes before cutting," was developed, and its feasibility was investigated. New data for the mechanical properties of membranes--the tensile strength and the adhesive strength--were obtained. The tests performed thus far indicate that a stainless steel probably cannot be used as a material for the clamping surface. However, with different clamping surface materials, such as teflon, a success of the design concept looks very hopeful.

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APPENDIX A

If the clamping area is 180°, as shown in Fig. a, then a membrane that is sucked into the cutting tip will cover the shaded area, as shown, in Fig. b, looking from the top. Thus, the length of tissue being clamped is maximally half the circumference, or

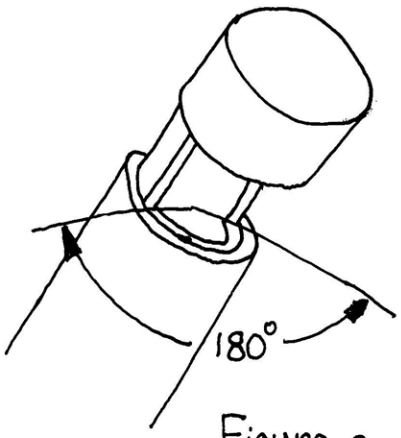


Figure a.

$$\pi D = \pi\left(\frac{.040}{2}\right) = .063 \text{ in} = 1.6 \text{mm}$$

Tissue (membrane) specimens were kept smaller than 1.6–1.5 mm so that forces measured in the tension experiment could be used directly to predict kinds of forces a actual instrument clamping mechanism will experience.

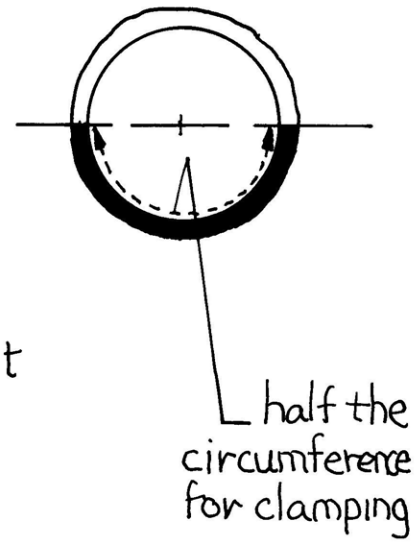
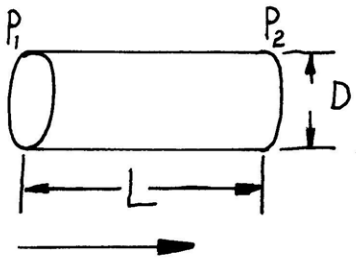


Figure b.

APPENDIX B.

Infusion fluid calculation

The equation for a flow through a tube.



$$P_1 - P_2 = \Delta P = \frac{f L \rho V^2}{2D}$$

L = Length V = velocity
D = diameter ΔP = pressure difference
ρ = density

f = friction factor
= f(Re).

Re = renolds number.

ρ = 1.938 slugs/ft^3 @ 60°F = $\frac{VD}{\nu}$

$= (1.938)\ \frac{lb-sec}{ft^4}$

$= (1.938)(.0000482)\ lb-sec/in^4.$

ν = kinematic viscosity
$= \mu/\rho$

ν_{water} @ 60°F $= \frac{2.359 \times 10^{-5}}{1.938}\ \frac{lb-sec}{ft^2}\ \frac{ft^4}{lb-sec^2}$

$= 1.22 \times 10^{-5}\ \frac{ft^2}{sec}$

$= 1.76 \times 10^{-3}\ \frac{in^2}{sec}$

μ = absolute viscosity.

For the tube: .008" OD; .002" nominal wall.

Area = πr^2

$= \pi \left(\frac{.004}{2}\right)^2\ in^2$

$= .0000125$ in

(a) Velocity of flow $V = \frac{Q}{A}$

Q = Volume flow rate

$V = \frac{Q}{A}$

(b). Renolds number $Re = \frac{VD}{\nu}$

(c). Friction factor $f = f(Re)$
- if $Re > 3000$, get from a graph.
- if $Re < 3000$, use laminar flow "f"

$$f = \frac{64}{Re}.$$

(d). Pressure drop ΔP

$$\Delta P = \frac{(f)(L)(V^2)(\rho)}{2(D)}$$

Using the following flow rate:

.00038 in^3/sec = .0064 cc/sec (i)
.00028 in^3/sec = .0045 cc/sec (ii)
.00020 in^3/sec = .0033 cc/sec (iii)

Calculate V: $V = \frac{Q}{A}$ $A = .0000125$ inch

$\frac{.00038}{.0000125} = 30.4 \frac{in}{sec}$ (i)

$\frac{.00028}{.0000125} = 22.4 \frac{in}{sec}$ (ii)

$\frac{.00020}{.0000125} = 16 \frac{in}{sec}$ (iii)

Calculate Re: $Re = \frac{VD}{\nu}$

$\frac{(30.4)(.004)}{1.76 \times 10^{-3}} = 69$ (i) $Re < 3000$, $f = \frac{64}{Re}$ apply.

$\frac{(22.4)(.004)}{1.76 \times 10^{-3}} = 51$ (ii)

$\frac{(16)(.004)}{1.76 \times 10^{-3}} = 36$ (iii)

Calculate f : $f = 64/Re$.

$\frac{64}{69} = .93$ (i)

$\frac{64}{51} = 1.25$ (ii)

$\frac{64}{36} = 1.78$ (iii)

Calculate ΔP: $\Delta P = \frac{fLV^2\rho}{2D}$

For L = 2 inches.

$\frac{(.93)(2)(30.4)^2(1.938)(.0000483)}{2(.004)} = 20$ psi (i)

$\frac{(1.25)(2)(22.4)^2(1.938)(.0000483)}{2(.004)} = 14.6$ psi (ii)

$\frac{(1.78)(2)(16)^2(1.938)(.0000483)}{2(.004)} = 10.6$ psi (iii)

.00038 in^3/sec = .0064 cc/sec $\Rightarrow$ 20 psi

.00028 in/sec = .0045 cc/sec $\Rightarrow$ 14.6 psi

.00020 in/sec = .0033 cc/sec $\Rightarrow$ 10.6 psi

Irrigation fluid Calculation

Using the following flow rate.

.043 in^3/sec = .7 cc/sec (i)
.031 in^3/sec = .5cc/sec (ii)
.024 in^3/sec = .4 cc/sec (iii)

Calculate V: $V = \frac{Q}{A}$

Data:
D = .012 inch.
L = 2 inches.

$A = \pi r^2$
$= \pi(\frac{.012}{2})^2$
$= .000113\ in^2$

$\frac{.043}{.000113} = 380\ \frac{in}{sec}$ (i)

$\frac{.031}{.000113} = 270\ \frac{in}{sec}$ (ii)

$\frac{.024}{.000113} = 212\ \frac{in}{sec}$ (iii)

Calculate Re: $Re = \frac{VD}{\nu}$

$\frac{(380)(.012)}{1.76 \times 10^{-5}} = 2590$ (i) Use graph in calculating f.

$\frac{(270)(.012)}{1.76 \times 10^{-5}} = 1841$ (ii) Re is under 2000, use $f = \frac{64}{Re}$.

$\frac{(212)(.012)}{1.76 \times 10^{-5}} = 1448$ (iii) Re is under 2000, use $f = \frac{64}{Re}$.

Calculate f:

.023 (i) from "L.F. Moody. Friction factors for Pipe flow. TRANS ASME Vol. 66, No 8, P671, 1944."

$\frac{64}{1841} = .035$ (ii)

$\frac{64}{1448} = .044$ (iii)

Calculate ΔP: $\Delta P = \frac{(f)(L)(\rho)(V^2)}{2(D)}$

$\frac{(.023)(2)(380)^2(1.938)(.0000482)}{2(.012)} = 25.8$ psi (i)

$\frac{(.035)(2)(270)^2(1.938)(.0000482)}{2(.012)} = 19.7$ psi (ii)

$\frac{(.044)(2)(212)^2(1.938)(.0000482)}{2(.012)} = 15.3$ psi (iii)

.043 in^3/sec	= .7 cc/sec	=> 25.8 psi
.031 in^3/sec	= .5 cc/sec	=> 19.7 psi
.024 in^3/sec	= .4 cc/sec	=> 15.3 psi

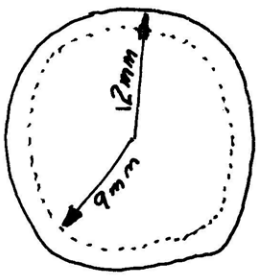
CUTTING CYCLE TIME ESTIMATION

Following assuptions will be made.

1.) One hour is sufficient for the removal of most of a vitreous body with membranes.

2.) Each cut is 100% effective.

Average adult human eye: 24 mm diameter sphere.



Remove 9mm radius sphere of vitreous body.

Volume: $\frac{4}{3}\pi r^3$

$\frac{4}{3}\pi(.9\text{cm})^3 = 3.05\text{ cm}^3$

$= 3.05\text{ cc}$

$= .186\text{ in}^3$

Volume of a material removed by the cutting tube per cut.

Area × Length = Volume.

Area of the tube: $A = \pi r^2$ For .040 in dia. tube.

$A = \pi(\frac{.041}{2})^2$

$= .00126\text{ in}^2$

$= .0081\text{ cm}^2$

Materials are with drawn in to the cutting tube 1.5 mm: $L = 1.5\,mm.$

$= .15\,cm.$

$V_{removed\ per\ cut} = A \times L$

$= (.0081)(.15)$

$= .0012\ cm^3$

V which must be removed per second:

$$\frac{3.05\ cc}{3600\ sec} = .00085\ \frac{cc}{sec}$$

$$\frac{V_{removed\ per\ cut}}{V_{removed\ per\ sec}} = \frac{sec}{cut}$$

$$\frac{.0012\ cm^3}{.00085\ cc}\ \frac{sec}{cut} = 1.4\ \frac{sec}{cut}$$

∴ For 1 hour operation, 1.4 sec/cut is maximum time available.