

# DEVELOPMENT OF A MEDICAL BOUGIE WITH INTEGRAL FORCE TRANSDUCER

by

Brian M. Wiseman

Submitted to the Department of  
Mechanical Engineering in Partial Fulfillment of  
the Requirements for the Degree of

MASTER OF SCIENCE IN MECHANICAL ENGINEERING

at the

MASSACHUSETTS INSTITUTE OF TECHNOLOGY  
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Signature of Author.....

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Chairman, Departmental  
Committee on Graduate  
Studies

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## ABSTRACT

It is estimated that 1 in 3000 to 4000 live births is born with Congenital Esophageal Atresia <1>. This is a condition in which the esophagus is not fully developed and connected to the stomach but instead is "dead-ended". One method of repair to such cases is to periodically, manually elongate the conduit with an instrument called a bougie, thereby overstretching the tissue and causing it to repair itself to a longer length. Once the conduit is long enough it can be connected to its intended site. The process is done by hand and does not quantify the amount of force being used. In addition, saliva that accumulates in the esophagus (in the case of esophageal atresia) is not removed and is questionable to its safety with respect to aspiration by the child.

In this Thesis a suction sump and a force transducer is incorporated into a bougie. The instrument is designed and can be tested on an actual esophagus specimen and a model.

With the amount of force quantitatively known, several benefits result:

- 1) The "stretching" properties of the conduit tissue can be explored for optimal Force vs. Time elongation properties.
- 2) The risk of perforating the conduit under excessive bougienage can be minimized.
- 3) The amount of residual tension can be quantified so that upon final connection the sutures will not tear the tissue.

Thesis Reader: Professor R.W. Mann, Mechanical Engineering

## INTRODUCTION

The Bougie (boo-jee) is a tool. It comes from the French word for taper or candle <2>. Dilators are like bougies because they are geometrically elliptical. Dilators are used to "circumferentially expand" or dilate restrictions (strictures) in cross sectional areas in biological conduits. The bougie is a misnomer to a certain extent as it is most often used by medical practitioners (Physicians) to elongate dead-ended conduits such as the esophagus shown in Figure 1.

The esophagus (Greek: "oize"-to carry out; "phago"-to eat or devour; Latin: "Gullet/Gula"-throat) <2> is an involuntary muscle which displays not only elastic properties but also pseudoplastic properties. This is due to the fact that the muscle can be stretched by the bougie to the end of its elastic range. The muscle grows and the net length is longer yet still elastic.

In Figure 1, the esophagus does not reach the stomach but instead is "dead-ended". This problem is called Congenital Esophageal Atresia. Congenital means to be born with the condition and Atresia (Greek: "A"- without + "tresis"- a hole) means no hole present <2>. This anomaly was first recognized by Steele in 1888 <3>. The ideal remedy for this condition is to join the two ends of the esophagus to provide a continuous, homogeneous conduit. If the gap between the upper (proximal) esophagus and the lower (distal) segments is too large and beyond therapeutic stretching and repair, a piece of the colon is removed and spliced into the esophagus, filling the gap <4>.

If the gap can be closed within the elongation/growth distance of the upper and lower esophagus, Surgeons have different techniques available to elongate the ends towards a final connection <5,6,9,10,11,12>. One of these methods is to manually elongate the esophagus using the bougie. This procedure was published by Howard and Myers in 1965 <5> and has subsequently been used by others <4,6,7,8,9,13>. Over the course of a month or two, the esophagus is repeatedly stretched thereby increasing its overall length using the bougie. The most recent variation on this initial theme, and one of impressive ingenuity, is that of Hendren and Hale <14,15> in which an electromagnetic field is used with "metal bullets" to elongate the esophagus. This approach not only offers a relatively continuous stretching without going through the mouth each time (a somewhat stressful event) but also begins to quantify the elongation forces via the "bullet" masses and electromagnetic field strengths. Hendren and Hale also used this approach to treat another form of dead ended conduit, an imperforate anus <16>. In

light of these and for this thesis, we will be designing for manual bougienage of the esophagus.

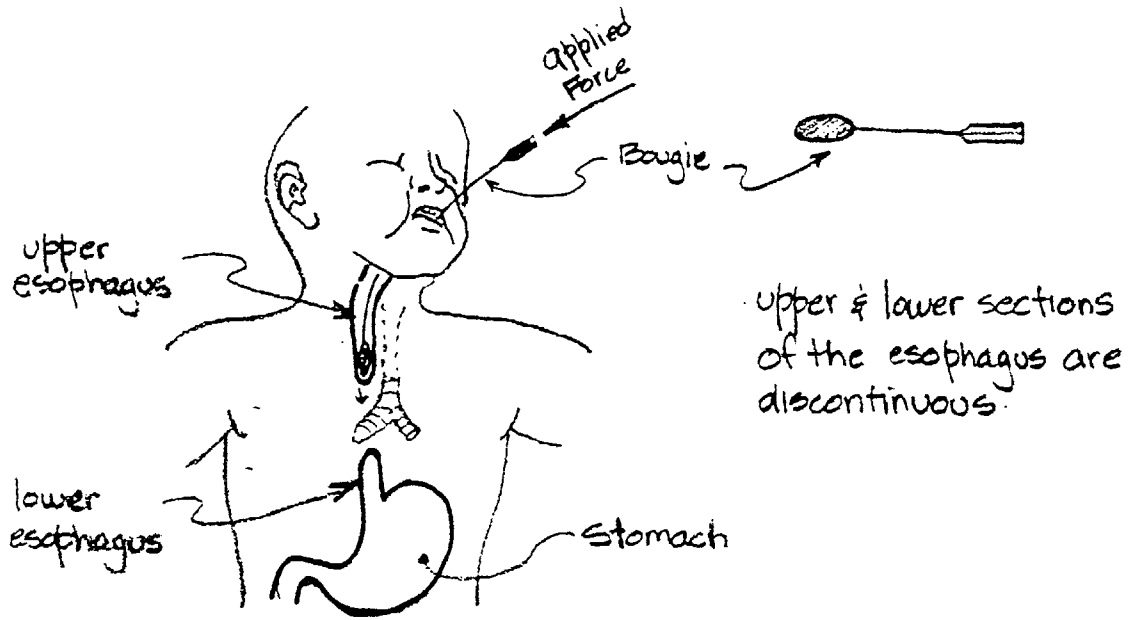


Figure 1. Congenital Esophageal Atresia

How does one know when the esophagus is long enough, i.e. the gap is small enough for repair? During the elongation process, the physician is able to see the remaining gap distance via radiography but cannot quantify the force used to elongate and place the esophagus next to the mating site which precludes when the ends are to be surgically brought together <4>. The ramification is when the ends eventually meet, the residual tension between the ends, upon surgical joining, will not be quantified. If the tension is excessive, the suture at some time could tear the tissue and lead to internal bleeding.

Two other problems exist that are related to not quantifying the applied force during stretching; perforation <7,8> and kinking of the trachea <13>. Perforation occurs when the bougie is pushed too hard and pierces through (perforates) the end of the esophagus. The patients in the cases cited in the references recovered, but delayed proper therapy. The kinking of the trachea was only during application of too much force and did not do any damage. The patient simply "choked" for a brief moment.

From this information, there are born two preliminary goals. The first is to provide the proper force to elongate the esophagus to promote repair/elongation, while not applying too much force that will cause perforation and/or kinking of the trachea. The second goal is to elongate the esophagus to a length where it can be connected without residual tension that will cause the sutures to tear the tissue. The response to these problems is the main topic of this thesis:

To produce a bougie that displays the force used to elongate a dead ended esophagus. The bougie shall be able to be retrofitted with different spring constants so that it can be used on other dead ended conduits (e.g. imperforate Anus).

In addition to the main topic, the bougie is designed to incorporate a suction sump. The purpose of the sump is to evacuate saliva that accumulates in the upper esophagus which if the esophagus "overflows", it can be inhaled (aspirated) and lead to infection. Replogle (and Hendren) <17> incorporated a "maintenance" sump while the patient is not undergoing therapy. Hendren & Hale <15> mention the need for a sump during manual bougienage of the upper esophagus and thus this thesis is addressing that need.

## REQUIREMENTS (DESIGN CRITERIA)

The design of the bougie with its force transducer must satisfy the following general, initial criteria. Not all of the items below may be applicable in the final design:

1. Sterilizable or practically disposable.
2. Incorporate a suction sump for esophageal atresia applications.
3. Capable of measuring force on the order 0.4N (41g) (1.4oz) <14>.
4. Biocompatible materials, voltages, currents and frequencies.
5. Measure longitudinal (elongation) force only, no lateral forces.
6. Temperature immunity or compensation w.r.t. force output reading.
7. Size: 5-9mm diameter and 20mm long <14>.
8. Exhibit good frequency response.
9. Incorporate an audible and visual indication that will prevent excessive force and subsequent perforation.
10. Simple construction and simple electronics so less can go wrong with it.

## EVOLUTION of DESIGN APPROACHES

Initial thoughts for the design of the bougie incorporated analog force transducer technologies (from strain gages to inductive variable transformers) which would provide a continuous readout of applied force. They were not that simple and were questioned if they were really needed. Further thought yielded that the process of bougieing does not require a continuous readout since the integral force spring to be used has a limited force/displacement, i.e. a narrow upper and lower force limit due to its small size constraints.

The following history outlines the "design evolution" of the bougie. It is presented not as a primer in transducers but rather as "food for thought" in showing the logistics in arriving at a basic geometry that satisfies the design intents, i.e. sometimes the simple approaches are overlooked. The final outcome of this evolution is a spring-plunger/spring-force gage arrangement. It was chosen for its flexibility in force/displacement characteristics via changing the type of spring as well as its simplistic mechanical design. Electronics or electrical energy is not needed and thus minimizes maintenance, calibrations, errors and electrical biocompatibility requirements.

1. Evaluation of the most suitable elastic member that will work within the bougie was done first. Figures 2a through 2e display the possible configurations. Since the bougie is slender, the spring configuration in Figure 2e would be the best. It is also a standard off-the-shelf item with known spring constants and fatigue life.
2. Transducers that were compatible with the spring configuration were explored next. The transducer technologies that were evaluated were <18,19,20,21,22>:

Unbonded & Bonded Strain Gage Transduction

Potentiometric Transduction

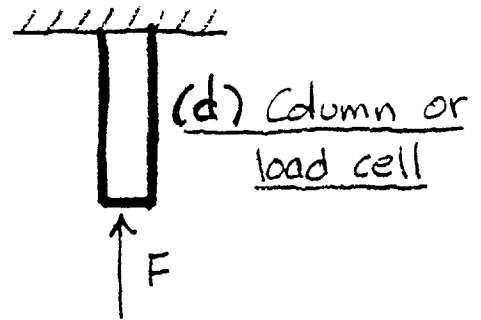
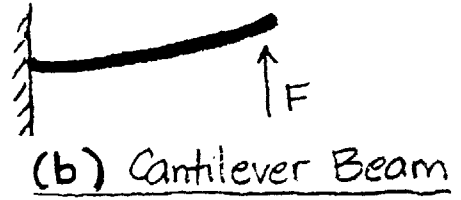
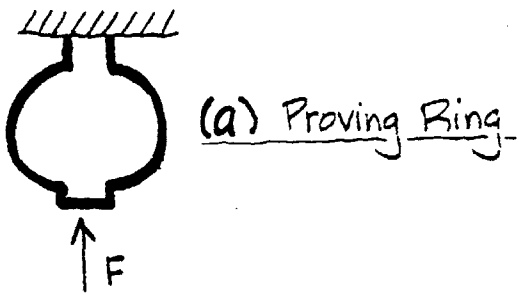
Capacitive Transduction

Piezoelectric Transduction

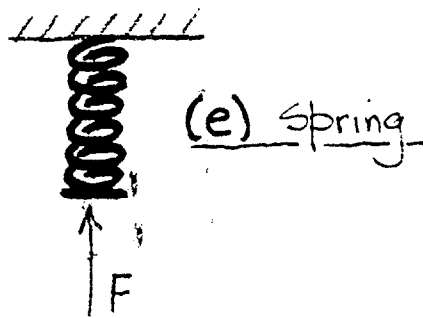
Inductive Transduction

Hydrostatic/Pressure Transduction





(c) Beam or Disc (diaphragm)



Figures 2a, b, c, d & e. Elastic Member Configurations

Strain gages (Figure 3) are basically thin wire/foil that change their resistance with a change in length caused by an imposed stress/strain. They are typically used for small displacements. Unbonded strain gages are fragile. Both the unbonded and bonded strain gages require some degree of temperature compensation. Since bonded gages are typically applied directly to the elastic member being strained, they are usually associated with the elastic member configurations shown in Figures 2a, b, c & d. The spring is not compatible for the application of a direct mounted strain gage.

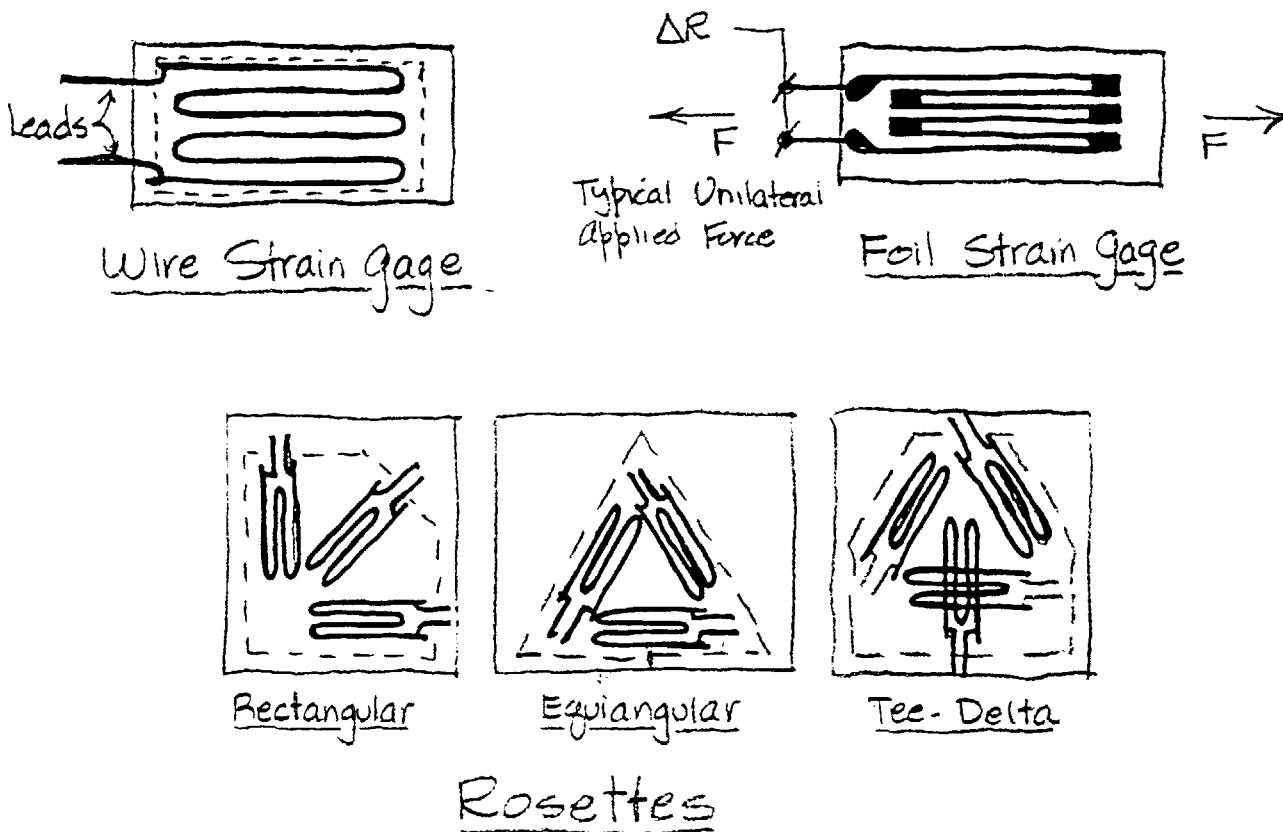


Figure 3. Bonded Metal Strain Gages

Potentiometric transducers (Figure 4) change their resistance with a change in length caused by the position of the conductive wiper. They can measure relatively larger translational displacements exhibited by the spring compared to the strain gage. The potentiometer however requires additional room for a wire wound or impregnated plastic conductor and wiper arm. The wiper imposes friction and possible unrepeatable contact resistance yielding inaccurate results. Similar to strain gages, potentiometric transducers require some degree of temperature compensation.

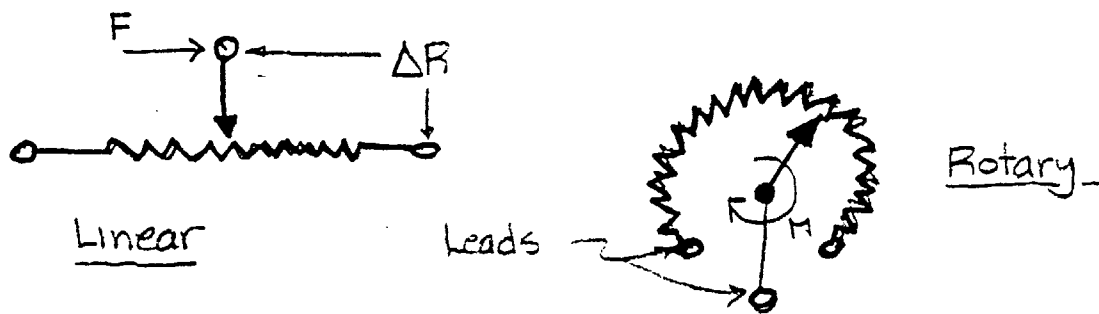


Figure 4. Potentiometric Transduction

Capacitive transducers (Figure 5) incorporate a change in their dielectric constant as a result of a change in distance between two capacitive plates or a change in the dielectric's properties as a result of an imposed stress/strain. They offer small size and offer less temperature sensitivity than strain gages or potentiometric transducers. They do require more complicated electronic instrumentation. Typically the capacitive transducer is used to measure cyclic displacements such as those associated with sound pressure waves impinging on a capacitive (condenser) microphone. In such cases the elastic member is the deflecting diaphragm which changes the distance between it and another base. The dielectric constant between them changes. For our bougie application, the force is more static than cyclic ( $<1$  cps). In addition, the diaphragm is not the geometry of choice for our application.

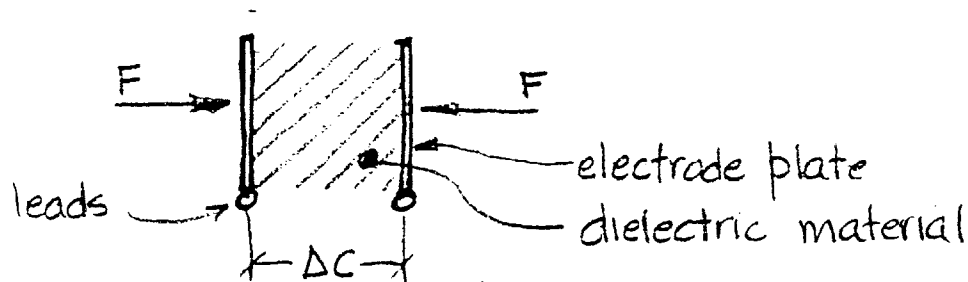


Figure 5. Capacitive Transduction

Piezoelectric transducers (Figure 6) emit a charge from the piezomaterial when it is stressed/strained from it's previous state. They are not typically used for static applications since the behavior of the piezoelectric material only emits an output upon a change in stress. Static measurements can be made by using ultrasonics in which the piezomaterial can act as both the transmitter and the receiver. The waves propagate through the elastic medium (usually a piezo film) which changes thickness upon being stressed. The sound wave's "time of flight" varies as the thickness of the medium varies. Thus a correlation of time of flight and stress can be made. This scheme is attractive for it's size and temperature insensitivity but requires instrumentation that is not relatively simple. It appears that the piezoelectric approach is not good for this application but would be good for measuring hoop stresses in dilators.

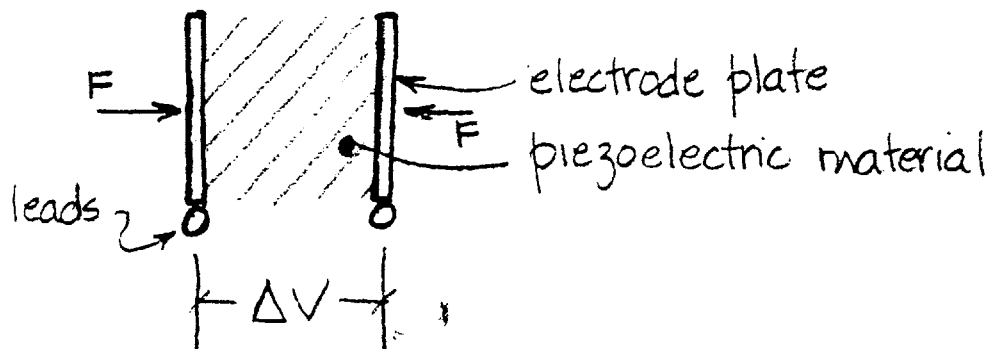


Figure 6. Piezoelectric Transduction

Inductive transducers (Figure 7) incorporate an electric induced magnetic field that changes in response to a positional change of a conducting core. The core's position changes from an imposed displacement. Inductive transducers have several attractive features: They can be used in small configurations; have relatively more temperature insensitivity and require relatively simple instrumentation. It's output sensitivity can be linear when using a Linear Variable Differential Transformer (LVDT) or very nearly linear when using a Variable Transformer within a small displacement range. The LVDT can linearly measure bidirectional displacements and the Variable Transformer typically measures unidirectional displacements. Since we only need to measure a small displacement in one direction, the variable transformer is the best so far of the above mentioned transducer technologies for the continuous, analog readout bougie application.

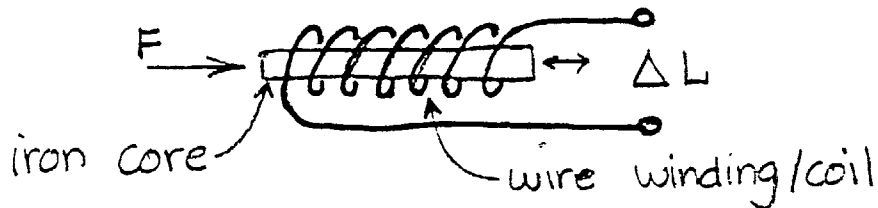


Figure 7. Inductive Transduction

Hydrostatic Pressure Transducers: Thought arose to perhaps use hydrostatics for the bougie (Figure 8). This approach at first seems very attractive. It obviates any electrical components being within the patient and simplifies transduction as pressure transducers are off-the-shelf items. However, further thoughts revealed some barriers. The bougie rod can be bent to different configurations depending on the physician and patient positioning. The bending of the rod would cause hydrostatic displacement and erroneous readings. Other concerns are: Kinking of the rod, leakage at the plunger/diaphragm, temperature affects on fluid volume and subsequent hydrostatic pressure, loss of central core "real estate" in the rod for a suction sump which would be occupied by the hydrostatic fluid.

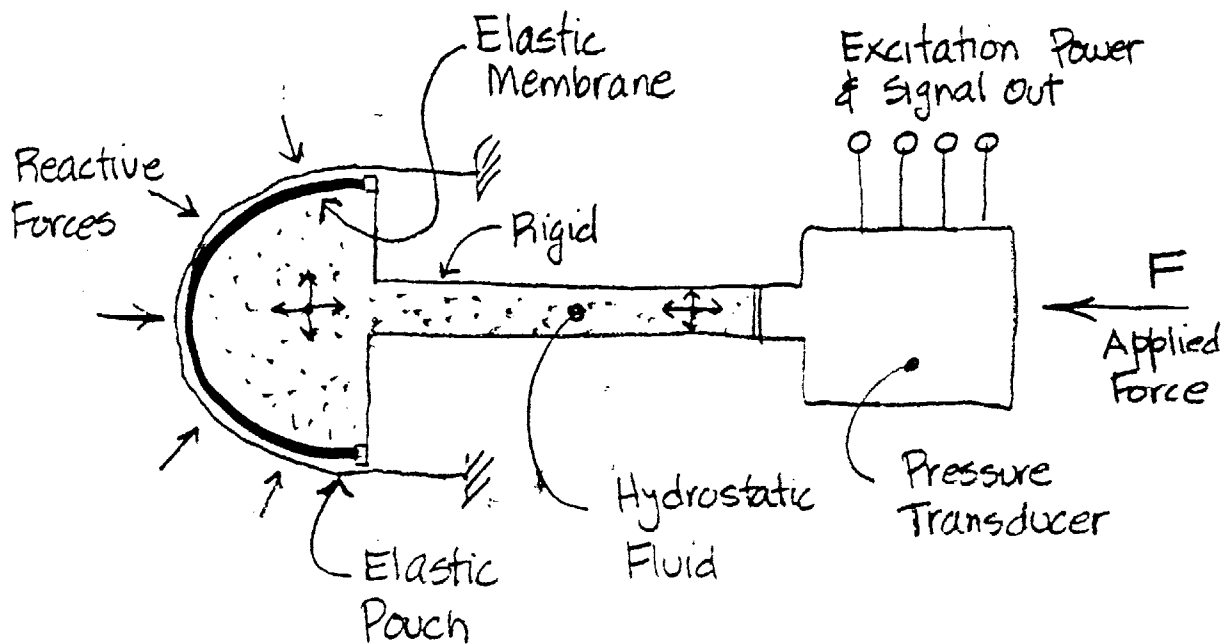


Figure 8. Hydrostatic Transduction

3. Further thoughts of simplifying the design arose after all of the transducers were explored and found to be complex. Such complexity was questionable. The deciding turn in the approach was initiated by realizing that an analog transducer is not needed since the physician is concerned with stretching the esophagus at a predetermined force and is not concerned with the intermediate forces. If the bougie was being used for research in identifying the esophageal elastic properties in vivo, then perhaps an analog force transducer would be appropriate.

However, in light of the relatively simple need, a basic spring force gage with an integral two position switch seemed to be the most attractive approach. The readout instrumentation for this approach was to be simple; reliable; incorporate biocompatible voltages and currents; easy to read and hear; portable; and both mechanically and electrically shock resistant. Figure 9 shows the conceptual design. Since the infant patient will most likely be active during the bougienage, the readout has both visual and audible signalling. A timer is incorporated so that the physician could totalize the time periods of elongation if desired. With respect to biocompatible voltages and currents, the bougie handles 9 Volts D.C. and 50 milliamps. However, the expected leakage current out of the bougie apparatus is approximately 50 microamps. (This will be determined when testing the bougie immersed in a saline solution in the model esophagus). This is one order of magnitude less than the limit of 500 microamps stated by Norton <20>.

4. Figures 10a through 10f show the evolutionary design/iteration approaches. Each of these appeared good, but after further thought were not viable. The items that were not viable have an asterisk next to them.

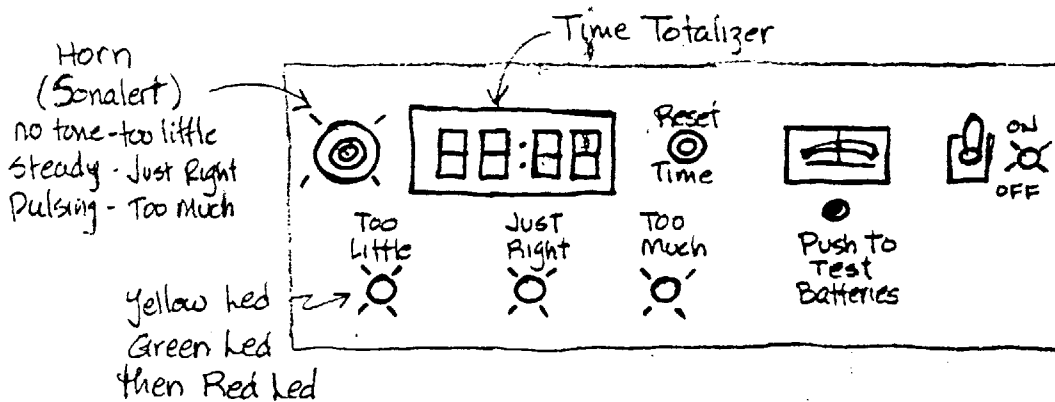
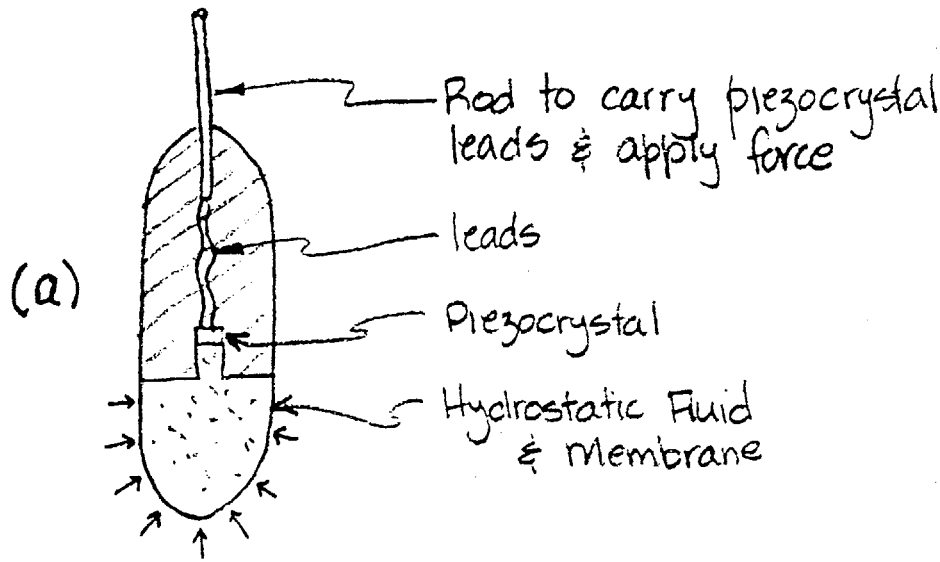


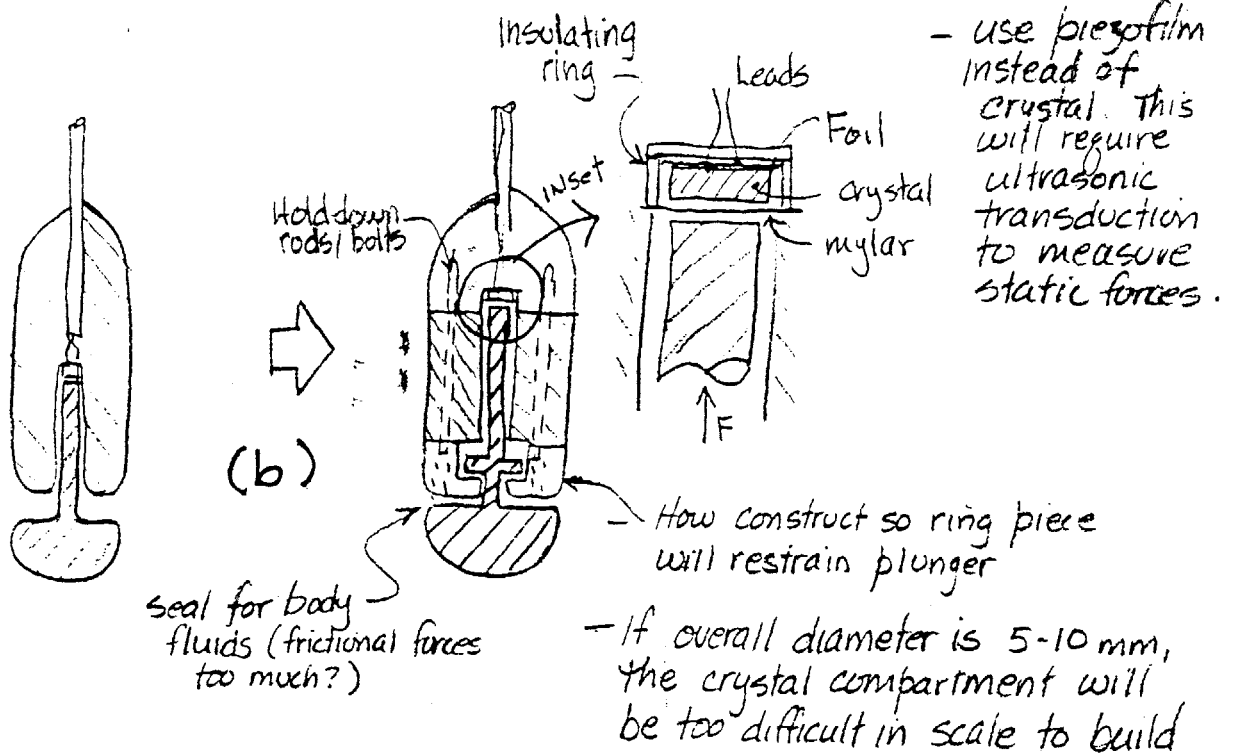
Figure 9. Readout Instrument for Simple Two Position, Electrical Bougie



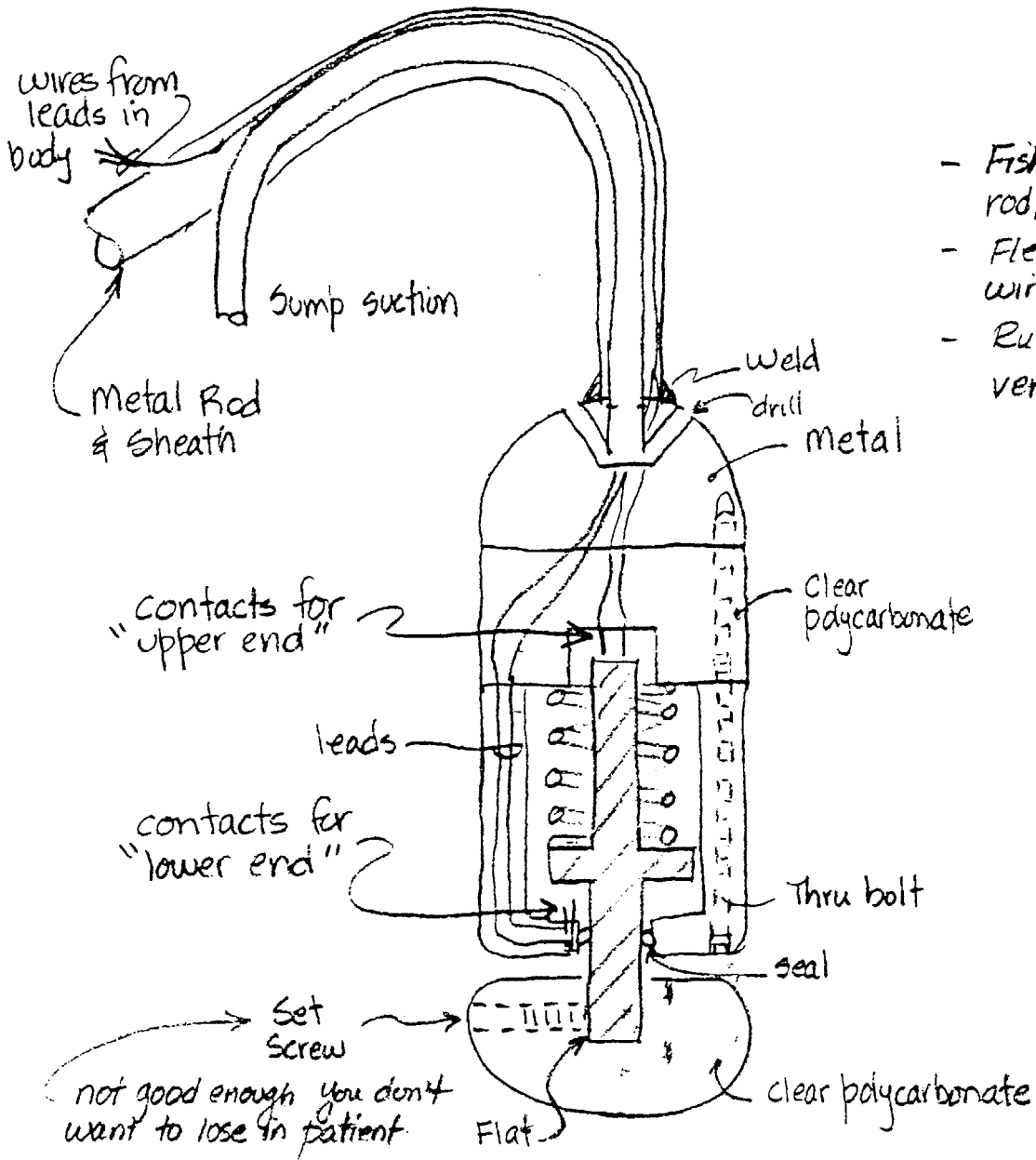


- Leads have to be insulated & thin
- Introduces current into body
- piezo is good for dynamic, not static forces.
- fluid & crystal are temperature sensitive
- leads not tolerant for breakage when rod is bent or flexed.
- need sump

- Applied forces are on the same order of magnitude as temperature effects and thus not a good approach.

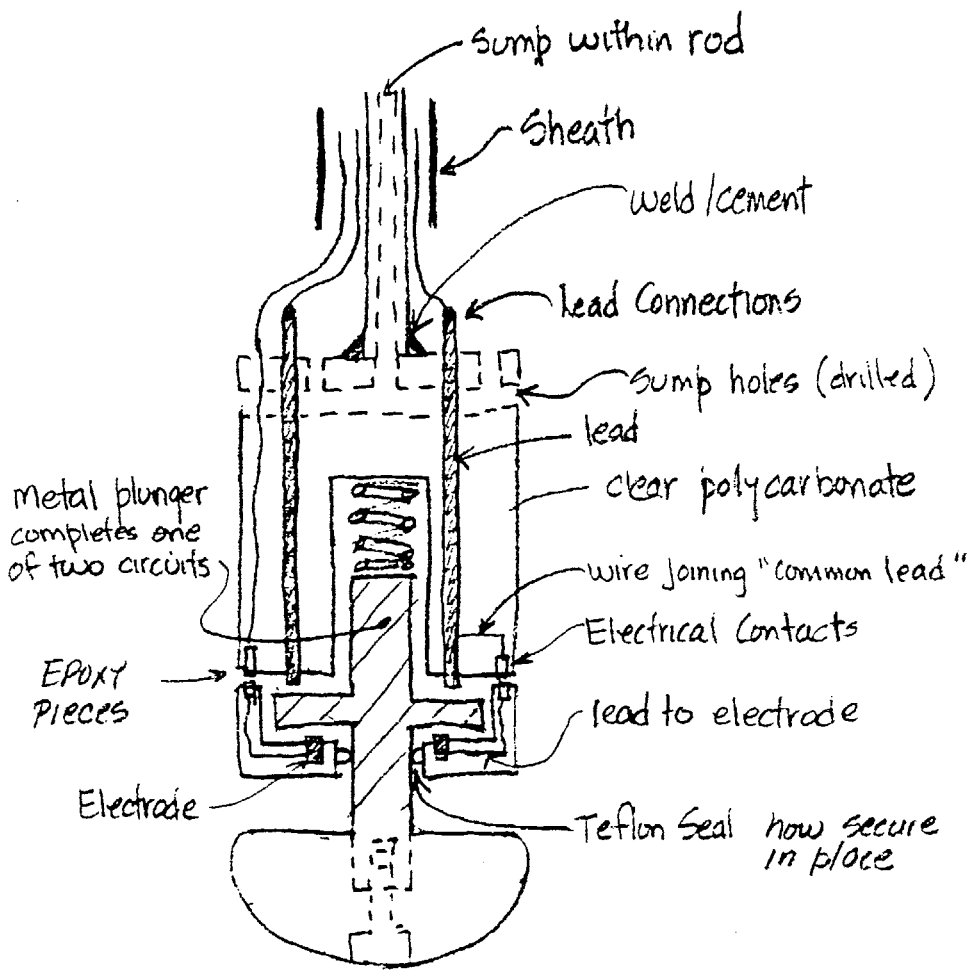


Figures 10 a & b. "Piezoelectric Bougie"



- Fishing sump & leads thru rod/sheath difficult
- Flexing of rod can break wire leads or short-out
- Running leads in body very difficult

Figure 10 c. Two Position Electric Bougie



- lot of components in a small scale - difficult.
- optic fiber instead of wires? Can't, need radius bends. Size constrained.
- lot of alignment for electric contacts so that plunger will contact on an even plane
- wires on rod flex and fatigue life questionable

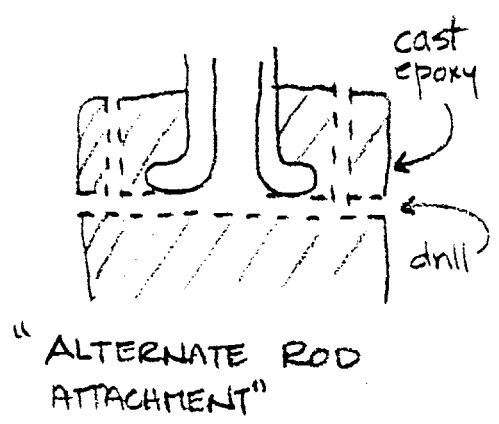
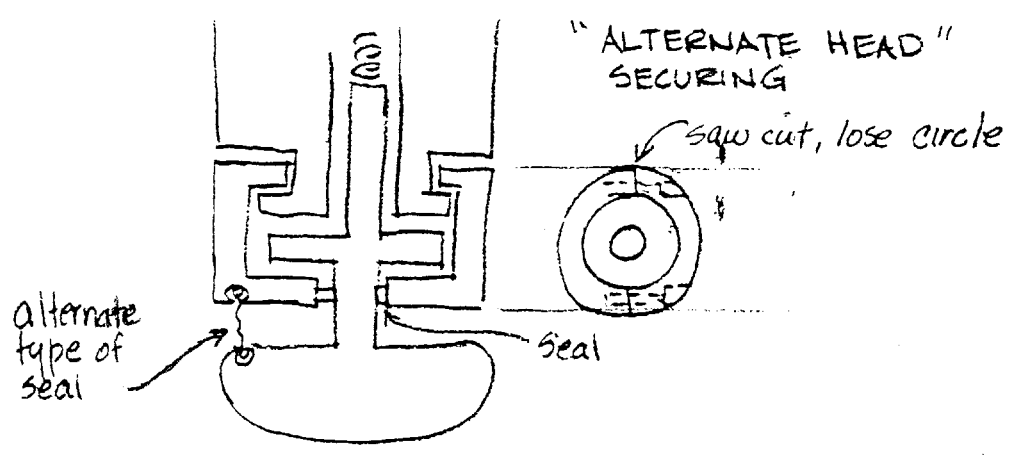
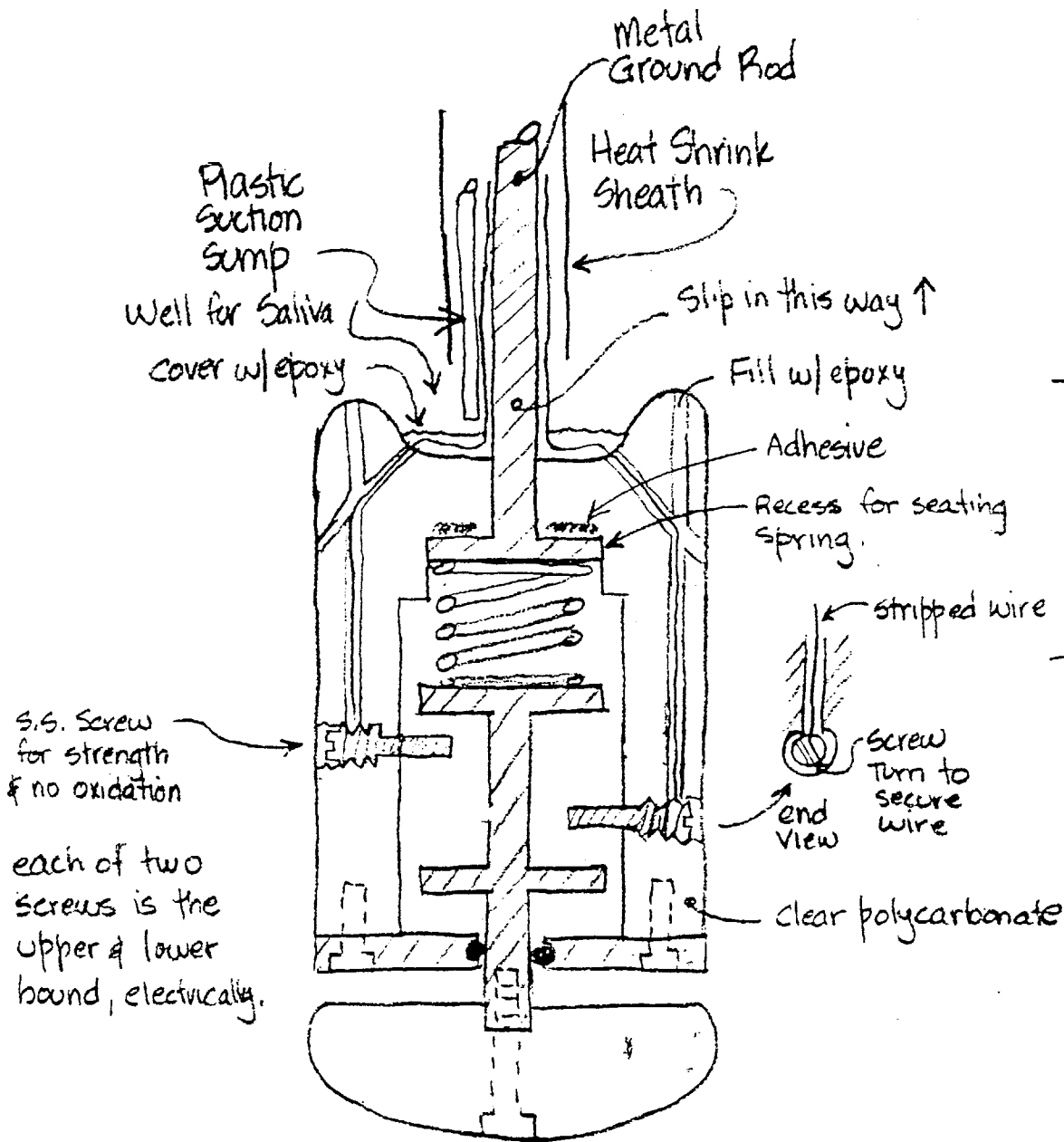


Figure 10d. Two Position Electric Bogie (Variant)

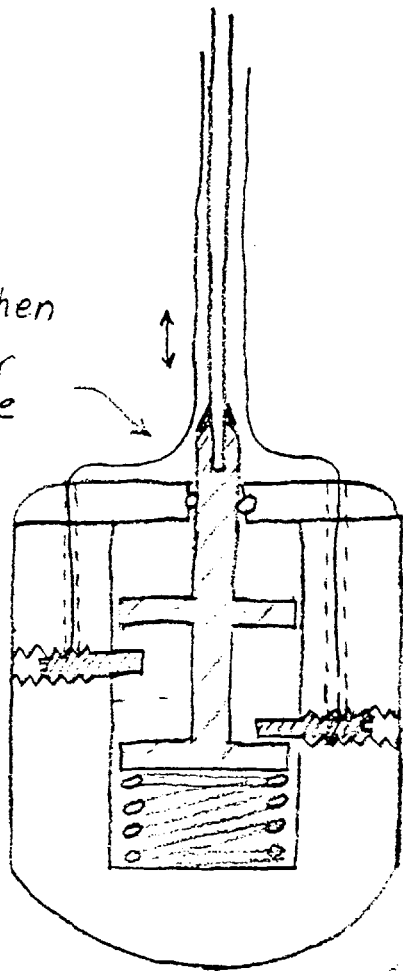


- Body is 5-10 mm diameter. This makes holes and parts ~ 1mm! Too small for standard machining

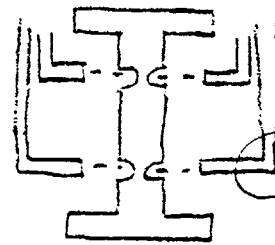
- Spring is not easily replaceable for different applications

Figure 10e. Two Position Electric Bougie (Variant)

- leads flex when bougie plunger travels, cause failure



Body moves wire leads



can't do. Need radius. size constraint won't allow

Plunger Variant using fiber optics.

Figure 10 f. Two Position Electric & Optic Bougie (Variants)

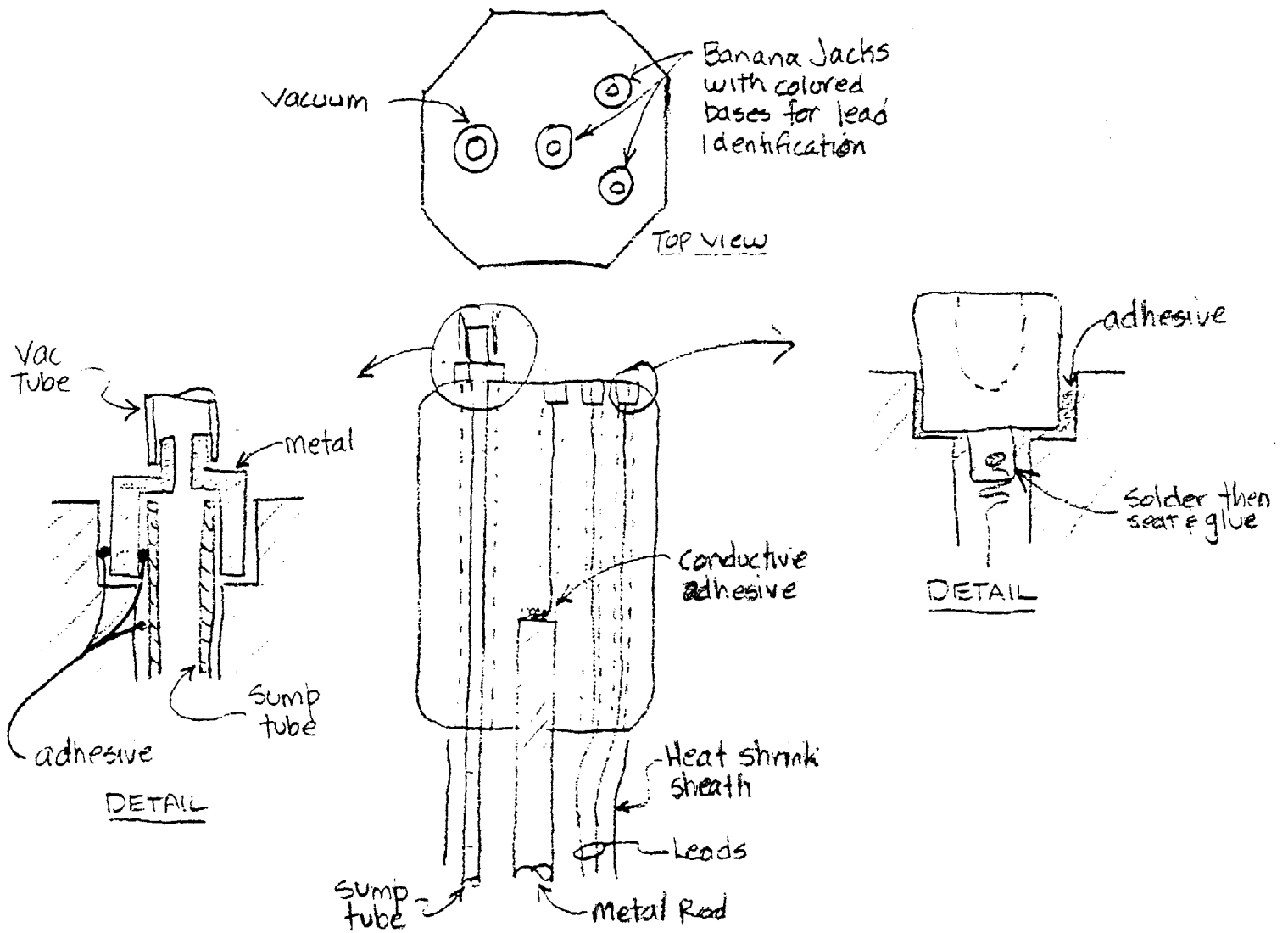


Figure 10g. Baggie Handle Details

## FINAL DESIGN OF THE BOUGIE

The previous design iterations were attempts to satisfy the need for the bougie rod to be curved as shown in the application in Figure 1. In reading Booss and Kotlarski <23>, the patient's posture can be varied in a way to minimize the needed curvature and yet maintain a position to keep the saliva in the pouch for sump suction. A semisitting position shown in Figure 11 is assumed and used for the final design of the bougie.

Since the curvature in Figure 1 is not needed, but as shown in Figure 11, the axial force component is larger. Previously, if a moment was applied, it would end up in an opposing linear, tangential force times the moment arm. Thus the force transducer was located at the equilibrium point as shown in the interim designs. With the "Sword Swallowing" technique shown in Figure 11, the moment force is circumvented and a linear axial force is applied. This allows the transducer to be located as shown in Figure 12, the Final Design. Now that the transducer can be seen during the bougienage, the previous electrical transmission of information is not needed.

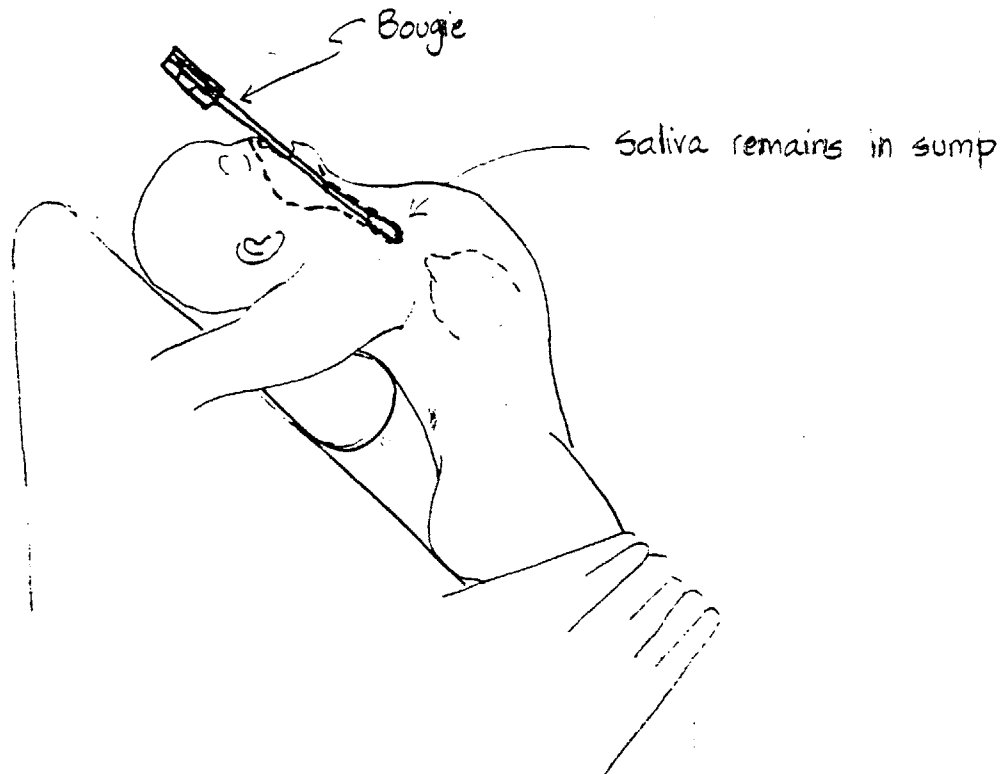
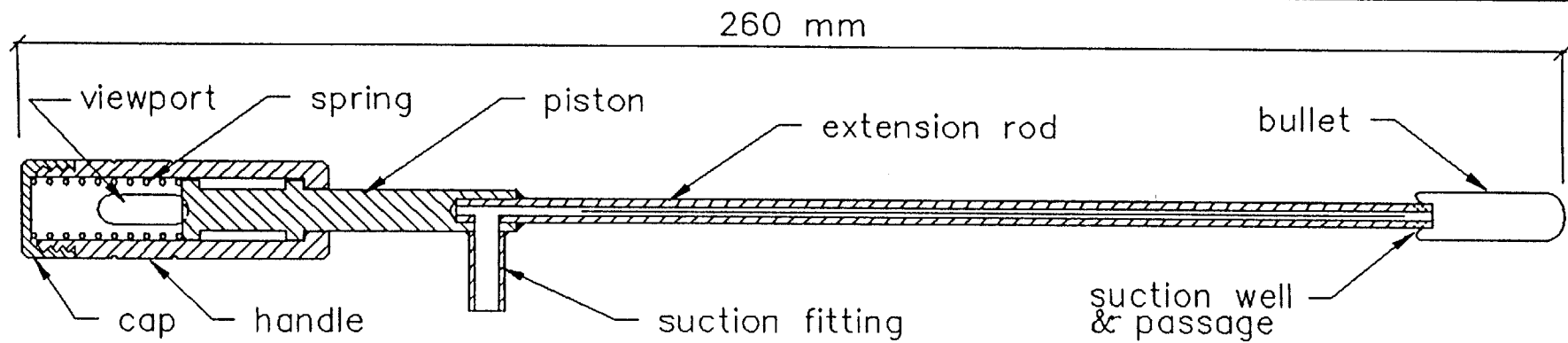


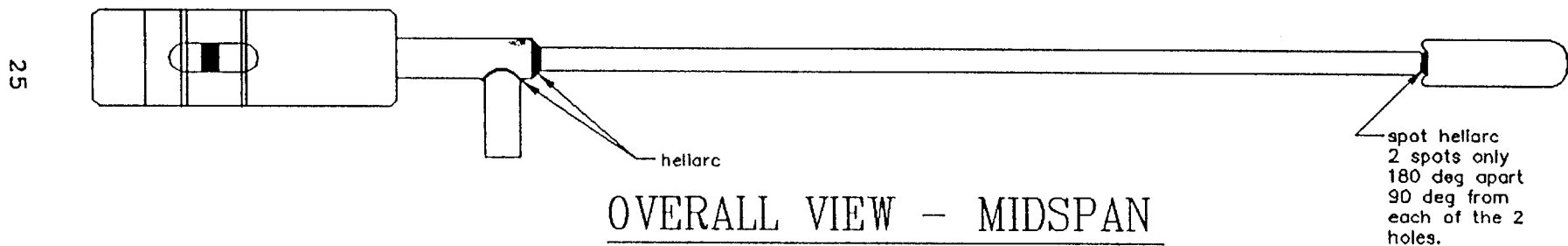
Figure 11. Inclined Positioning & the  
"Sword-Swallowing" Bougie Approach

The next two figures, Figures 12a & 12b (Drawings M1 & M2 respectively), show the bougie's construction. M1 shows the bougie in three discrete positions, indicating the full travel of the instrument. M2 shows the dimensional information used to construct the bougie. The dimensions are shown in millimeters. However, since the machining equipment at MIT is in English units, the dimensional units were converted and the model was built in terms of inches.

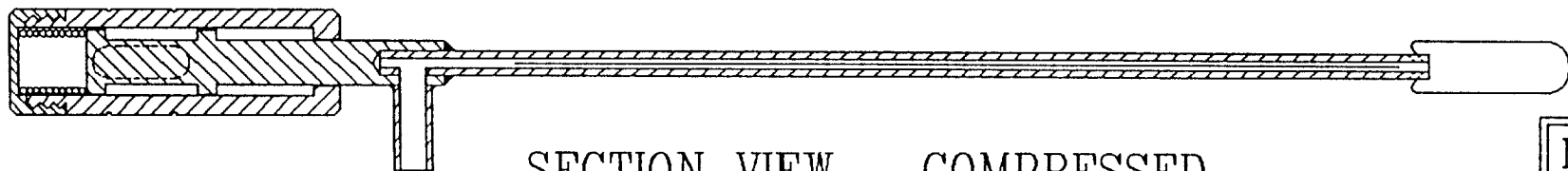




SECTION VIEW - RELAXED



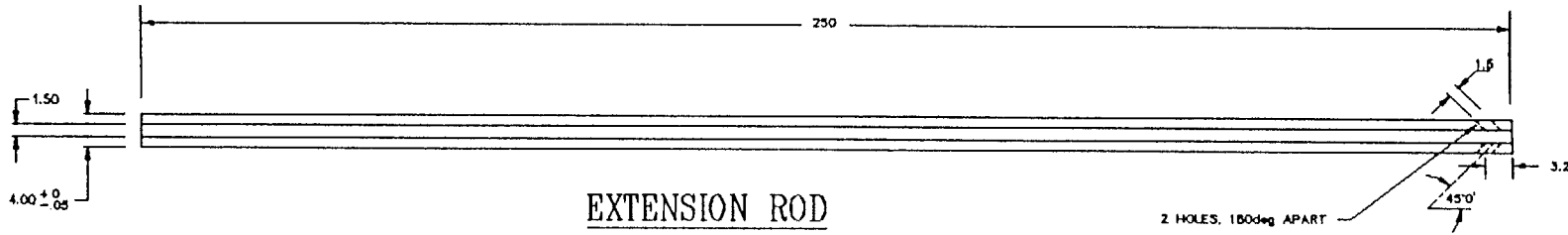
OVERALL VIEW - MIDSPAN



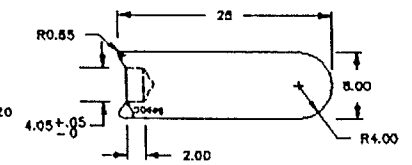
SECTION VIEW - COMPRESSED

Figure 12a

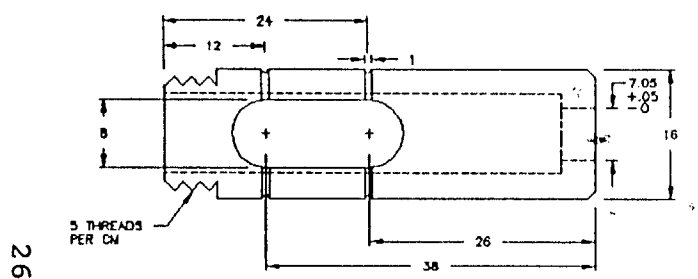
MIT	MASTER'S THESIS
Title ESOPHAGEAL ATRESIA BOUGIE	
Drawing Title OVERALL ASSEMBLY	
Author Prof. R.W. Mann	
Project Manager Design/Construction	
Scale none	M1
Prepared by R.W. Mann	
Drawn by R.W. Mann	Sheet 1 of 2
Date 8-20-91	



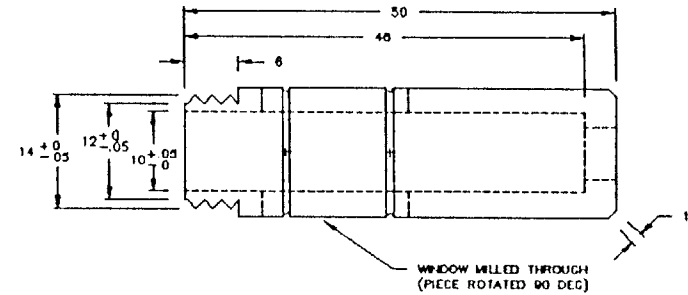
EXTENSION ROD



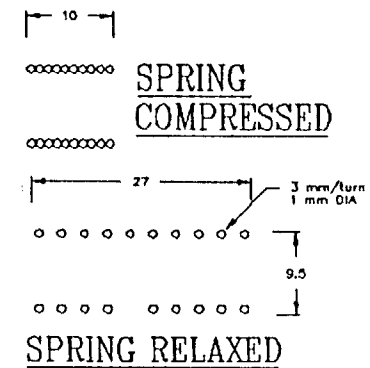
BULLET



HANDLE



HANDLE ROTATED 90deg



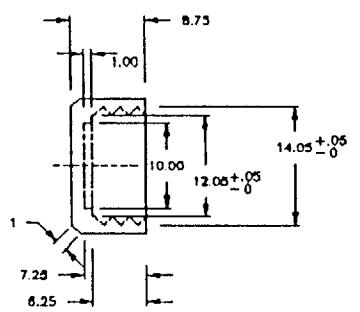
SPRING COMPRESSED

SPRING RELAXED

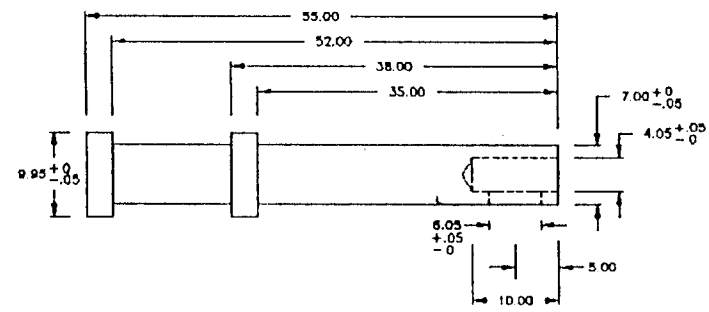
calculate modulus for force-distance  
 $f=kx$   $x_1=4mm$   $x_2=12mm$

26

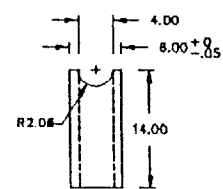
- NOTES:
1. DIMENSIONS ARE IN MILLIMETERS.
  2. TOLERANCES ARE ±.05mm UNLESS NOTED OTHERWISE.
  3. ALL MATERIALS SHALL BE MARTENSITIC STAINLESS STEEL OF TYPE TO BE DETERMINED BY REQUIRED ELASTIC PROPERTIES.



CAP



PISTON



SUCTION FITTING

Figure 12b

MIT		MASTER'S THESIS	
Title ESOPHAGEAL ATRESIA BOUGIE			
Drawing Title COMPONENT SPECIFICATIONS			
Author Prof. R.W. Mann			
Project Stage Design/Construction			
Scale none	Drawing Number M2		
Program Brian Wessman Crack	Date 8-20-91		
		Sheet 2 of 2	

As for the Sump, Replogle <17> showed that a double-lumen catheter sump with a 1/2 to 1/2 area ratio worked best. One lumen is used for suction and the other for a vent, occasional irrigation and radiographic purposes.

The need for a double-lumen was questioned as it posed a challenge to incorporate it with a bougie. The irrigation and radiopaque fluid injection is not applicable during bougienage. The only concern is venting. The Replogle catheter is shown in Figure 13. Replogle states "the second lumen is used as a vent to more effectively clear the pouch as the single lumen suctioned mucosa".

The ports are located on the side of the Replogle Catheter. It's understandable how the sides of the esophagus wall would collapse and be drawn toward the ports, wrapping around the catheter and suctioning mucosa off the lining of the esophagus. With the double-lumen, the vent allows air to be drawn in and prevent collapse. It provides a void in which the lining is not drawn in and allows saliva to accumulate within this sump. Therefore, the void is the objective. Figure 13 shows the bougie with a single-lumen and a built-in, annular void for which the saliva can accumulate and the lining of the esophagus be remote.

Replogle states that on continuous suction, a vacuum of 25 to 30 mm. Hg. is used. Perhaps this value arrives from the vacuum total mass which consists of saliva production rate and the makeup air rate of the vent. For this bougie, the vacuum rate shall also be empirically derived. It's assumed that during bougienage, the saliva production rate is increased from a rest or "maintenance position" as the esophagus is stimulated by the bougie. The removal rate is to match the saliva production rate only. Therefore, it's proposed that with the geometric void and the matching saliva production rate, the vent is not needed.

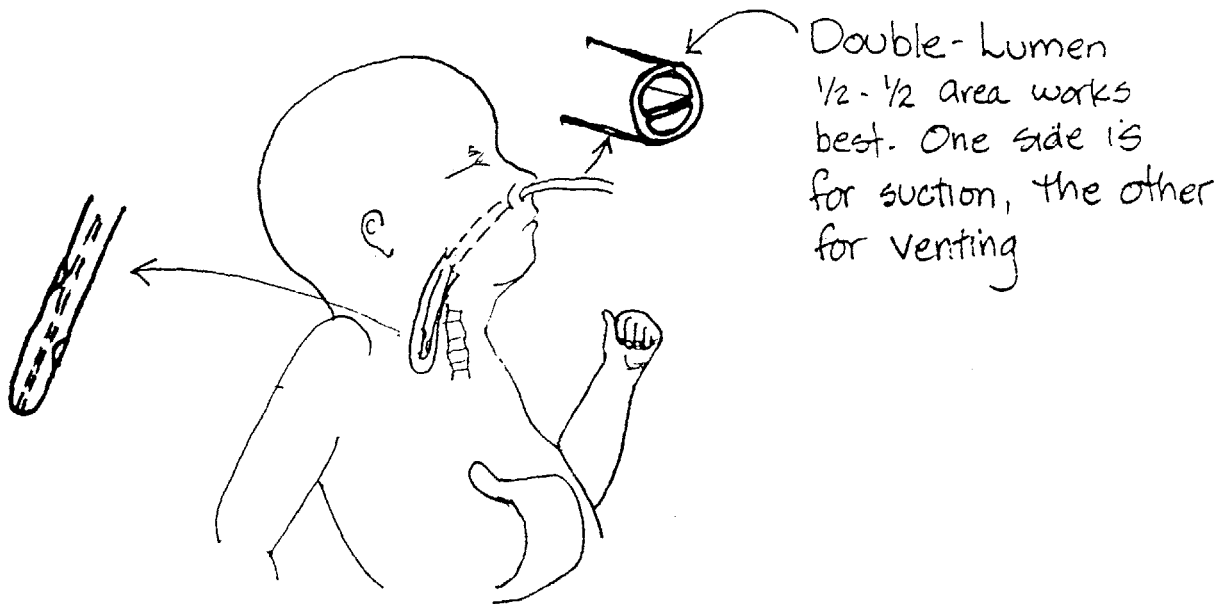


Figure 13. Double-Lumen Replogle Catheter

## ESOPHAGUS MODELLING & TESTING OF THE BOUGIE

In designing the bougie, the proper spring constant needs to be determined. To do this we need to design a model esophagus. The model is used to determine the actual forces involved during bougienage as well as be used for subsequent calibration checks once the bougie is put in service.

Figure 14 shows the design of the mineral oil lined elastic pouch used to simulate the esophagus. The displacement marks are labelled in terms of force. The elastic properties of the elastic pouch should be selected to model those of a human esophagus (request from Harvard Medical School) in the test stand.

We expect the elasticity to be nonlinear and the overall force/displacement to be asymptotic with the limit approaching perforation force or "overstretching" of the esophagus. Since we are interested in the small range of force during overstretching and desire to have the test stand calibrate this force with repeatability, we'll select a linear region about the overstretching force and make this the center of the force/displacement region. With the pouch repeatably elastic in this range, good calibration/checkout of the bougie should be obtained.

The first task with the model setup should be to plot the force/displacement curve using bullet shaped lead weights in 10 gram increments. Secondly, the bougienage forces should be verified with Dr. W. Hardy Hendren of the Children's Hospital, using using a human esophagus in the test stand and our modified spring force compression gage bougie.

Once the force/displacement curve is generated and the linear region is selected about the overstretching force, an elastic material should be selected and constructed. The final material will be selected for other properties such as minimum elastic coefficient drifts, degradation of the material when subject to lubricants, ambient air and ultraviolet light.

Another component of the test stand apparatus is to check the performance of the bougie suction sump. Once the elastic pouch is constructed. it should be filled with water mixed with an additive so that the viscosity will be the same as human saliva. The sump should be hooked up to a vacuum outlet and the rate of removal recorded. The tubing will be clear and a suction canister will be used to observe and quantify the removal rate in conjunction with the fill rate. The vacuum should be adjusted to different values and the corresponding rates recorded. The vacuum value vs. removal rate will help set the vacuum a priori without having to blindly iterate based on patient response.

Once the model/test stand is in service, it should be provided with lead bullets. The bullets are sized to provide a displacement of one tick mark for each bullet. This way the test stand can be checked for accuracy via an elemental procedure. With the test stand in proper order, the bougie can be checked for proper operation by applying it to the model test stand.

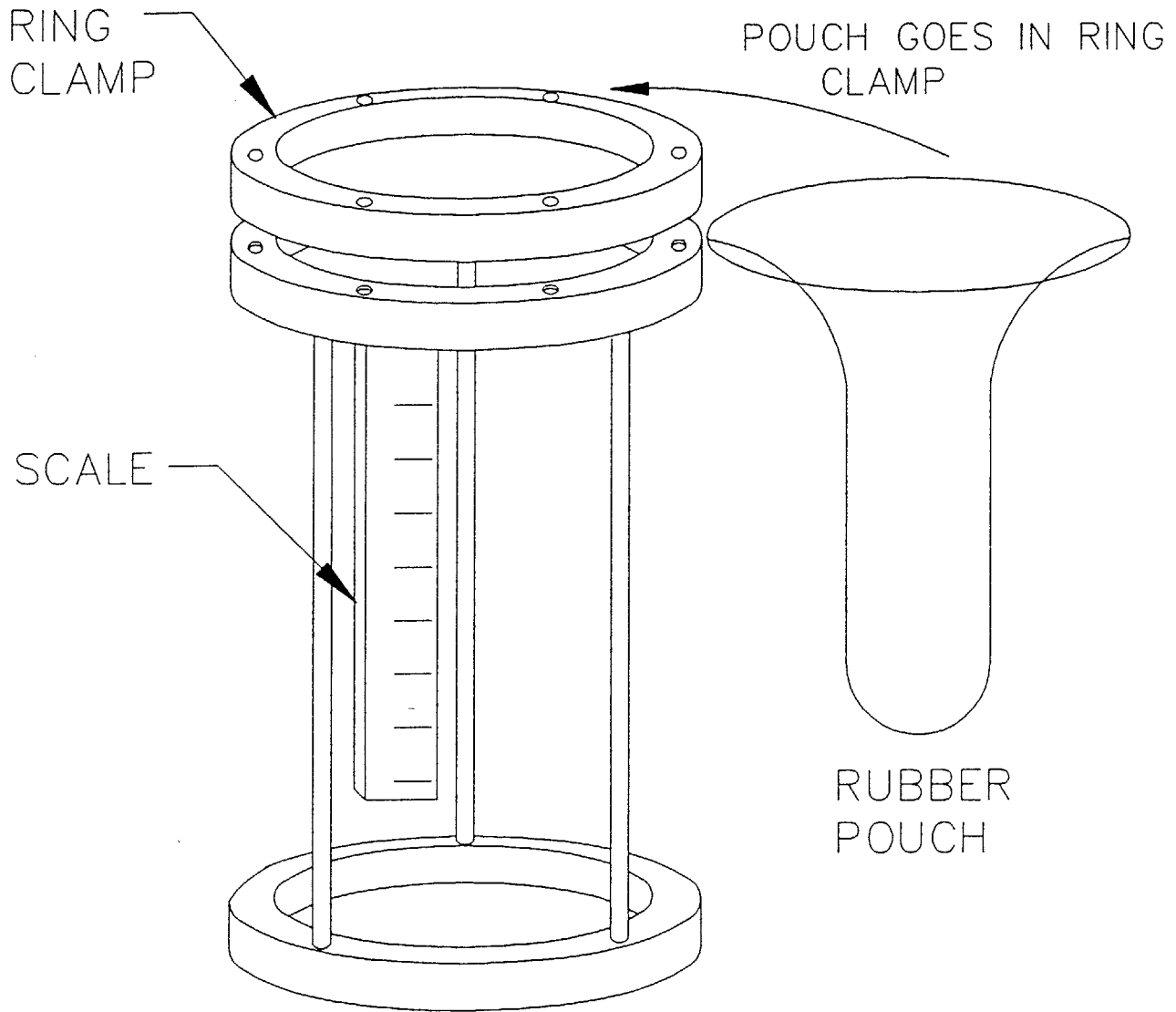


Figure 14

MIT		MASTER'S THESIS	
Title ESOGHAGEAL ATRESIA BOUGIE			
Drawing Title TEST SETUP			
Reader Prof. R.W. Mann			
Project Stage Design/Construction			
Scale none	M1		
Designer Brian Wiseman	M1		
Check			
Date 8-20-91	Sheet 1	of 1	

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