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A tracheoesophageal puncture voice prosthesis

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A TRACHEOESOPHAGEAL PUNCTURE

VOICE PROSTHESIS

by

Georghios Makris

Thesis submitted to the Faculty of the Graduate School of
the New Jersey Institute of Technology in partial fulfillment of
the requirements for the degree of
Master of Science in Mechanical Engineering
1986

APPROVAL SHEET

Title of Thesis: A Tracheoesophageal Puncture Voice
                    Prosthesis.

Name of Candidate: Georghios Makris
                   Master of Science in Mechanical
                   Engineering, 1986.

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A B S T R A C T

Title of Thesis: A Tracheoesophageal Puncture Voice
Prosthesis.

Georghios Makris, Master of Science in Mechanical
Engineering, 1986

Thesis directed by: Dr. Harry Herman, Professor of
Mechanical Engineering

A voice prosthesis was developed that allows verbal communication of laryngectomised patients. The prosthesis requires a superiorly directed tracheoesophageal puncture in which the periscope mounted on the tracheal stoma vent is introduced. The prosthesis is operated by air injection through the periscope. Air injection is achieved by pulmonary pressure after the occlusion of the stoma vent. Stoma vent occlusion can be achieved either by the patient's finger or by the designed cover valve mounted on the prosthesis. The cover valve allows free breathing, hand-free prosthesis use, and it can release excess pressure during coughing. Periscope valve air resistance tests have been performed. The side valve used in the designed voice prosthesis demonstrates lower resistance compared to the duckbill valve in both bench and in vivo tests within the range of flows required for ordinary speech : In addition, tests have been developed that allow objective in vivo resistance measurement for other types of voice prosthesis.

DEDICATED TO MY WIFE

ACKNOWLEDGMENTS

I wish to acknowledge my gratitude to the following people who have been extremely helpful during the preparation of this thesis:

Dr. Harry Herman, Professor of Mechanical Engineering, New Jersey institute of Technology, Newark, New Jersey,

Dr. Myron Shapiro, M.D. Professor of Otorhinolaryngology, University of Medicine and Dentistry of New Jersey, Newark, New Jersey,

for their most meaningful guidance and help throughout, and my wife, for her patience and invaluable support.

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INTRODUCTION

Treatment, by means of laryngectomy, for cancer of the larynx has been successful in saving an overwhelming majority of the patients. One consequence of this procedure is the loss of voice since the trachea does not communicate with the oral cavity but is directed to a stoma constructed at the base of the neck superior to the sternum, and the larynx is removed. Although esophageal speech is the most common method used for voice rehabilitation a large percentage of patients are totally unable to learn it[1].

Several techniques have been developed in order to ore voice. The most commonly used surgical technique consists of the creation of a tracheoesophageal fistula lined with esophageal mucosa. Several types of prosthetic devices have been developed to control leakage of saliva and food, and the spontaneous closure of the fistula. The Singer and Blum[1,3] procedure results in a fistula shunt directed posteriorly. Shapiro[4] has described a surgical-prosthetic method where the fistula is directed superiorly. This method eliminates the majority of the post surgical problems encountered by the posteriorly oriented procedures[5,6].

We have chosen to further the development of the prosthesis used in the Shapiro procedure. From the design

perspective, a tracheoesophageal puncture prosthesis should be minimally resistive to air flow. The prosthesis should not interfere with the effective size of the stoma opening thus not hindering normal respiration. In addition the prostheses should exhibit minimal resistance to air flow through the passage from the trachea to the esophagus. The decreased resistance of these devices results in the ability of the patient to inject larger amounts of air through the prosthesis at more comfortable levels of pressure exertion, resulting in better quantity and quality of voice. The increased efficiency of such a prosthesis would facilitate the use of stoma obstruction valves that allow hand free operation of the voice prosthesis.

We have performed several design modifications to the Shapiro prosthesis that resulted in increased efficiency and higher success rates in voice restoration. In addition tests have been developed that can quantitatively assess the air flow resistance of the device both in vitro and in vivo. We have carried out empirical and theoretical assesments of the performance of the developed prosthesis.

Throughout the redesign and development process we have been in constant contact with the ENT clinic of the University of Medicine and Dentistry of New Jersey, Newark, where each individual change was tested and evaluated with prototype models .

C H A P T E R   II

PART A: THE VOICE PROSTHESIS DESIGN

Dr. M. Shapiro's voice prosthesis is comprised of three main parts made of silicon rubber: the stoma vent, the periscope and the periscope valve (Figure 1). The periscope connects the trachea to the esophagus, allowing injection of pulmonary air into the esophageal region of a total-laryngectomy patient for the purpose of voicing. The periscope valve prevents the entry of food into the trachea (Figure 2). In the original design the valve was of the duckbill type, that is the periscope tube would end in a hemispherical cap, and a razor slit would be made in the cap in the axial direction. In such a design of the periscope valve the sides of the valve come in contact with the esophageal walls. The support lent by the esophageal walls increases the valve stiffness thus increasing the effort needed to open it. The first modification consisted of replacing the original valve by a hinged diaphragm valve mounted on the side of the periscope (Figure 3). Such an arrangement minimizes the stiffening effects introduced by esophageal wall interference. This change would reduce the effort required for voicing had a duckbill valve been used .

Next, the axis of the stoma-vent-tube was changed from a quarter-circle to an elliptical shape which conforms

much more closely with the shape of the trachea into which the stoma vent is inserted. This has resulted in a substantial reduction in the tendency of the tracheal wall to push out the stoma vent during coughing. In addition, the back wall of the stoma vent has been cut back, further reducing the push-out effect and substantially increasing the ease of inserting the prosthesis (Figure 4).

In the original design, the flange is of the same thickness as the stoma vent, and in addition has a stiffening rib at its perimeter. A flat flange of thin silicone rubber has been added at the stoma vent exit. This design modification reduces air leakage around the stoma vent opening since the thin flange conforms to the individual patient's stoma opening architecture. In addition this flange would permit adhesion of the prosthesis to the neck and attachment of the cover valve directly to the prosthesis.

A stoma vent obstruction valve has been designed to allow hand-free speech (i.e. eliminate the need for covering the stoma vent exit by hand). It consists of a combination of a one-way and a pressure release valve (Figures 5). It attaches directly to the stoma vent flange. The valve is normally open and allows bidirectional air flow at rest breathing rates. Higher air flow rates cause the folded

diaphragm to open and rest on the valve retaining ring obstructing the exhaled air flow. The back pressure generated forces air through the periscope. The retaining ring support is designed so that excessive pulmonary pressure (e.g. during coughing) would cause the diaphragm and retaining ring of the cover valve to move outwards, thus reopening the stoma vent,and consequently releasing the developed pressure. This system is controlled by a spring on a theaded post which allows easy regulation of the pressure release threshold. Originally, a model of the valve was made and tested. The patients expressed very positive comments on the concept and the ease with which they could activate the valve. The two negative comments were : air leakage producing background noise and some discomfort in free breathing due to the smaller size opening of the valve. We have redesigned the valve seat to provide an airtight seal between the disk and the valve housing. In addition we have reduced the width of the supporting diagonal member, increasing the cross-sectional area of the passage.

Tests have shown that the periscope length (hence the position of the periscope valve in the esophagus) plays an important role in voicing effectiveness in some individuals. In fact, some individuals who could not produce any voice with the standard length periscope were eminently

successful when the periscope length was suitably adjusted. This observation has led to a design option in which the periscope is inserted as a separate unit (Figure 6). This arrangement allows fitting of different periscope lengths on the same stoma vent. In addition, prosthesis insertion difficulties encountered by some patients with the present design are eliminated, since the periscope is inserted after the stoma vent is in place inside the stoma. In this new design a periscope ring provides safe anchorage of the periscope onto the stoma vent, and provides a constant diameter stoma opening.

PART B: SUMMARY OF CLINICAL EXPERIENCE

Out of 27 patients seen in the clinic 26 elected surgical preparation for the voice prosthesis. Of the 26, 24 (over 90%) have acquired speech successfully. The determining criterion used in defining successful acquisition of speech is the production of speech that is superior to esophageal speech. One patient indicated as a failure did not return to the clinic after surgery to be fitted with a prosthesis, while the second developed fistula leakage to the extent that the fistula had to be sutured closed.

All the patients were initially fitted with the M.

Shapiro prosthesis. Patients that developed problems, such as excessively high pulmonary effort (high air pressure requirements for production of speech), leakage through the fistula or discomfort, were considered for new design changes on the voice prosthesis. Table 1 shows the breakdown of the new design features utilized. In all cases, the redesigned prosthesis led to considerable improvement in performance.

In all the cases, the redesigned prosthesis was fitted with the new type periscope side-valve (figure 3). All but two of these were also equipped with a flat stoma vent flange (figure 4), and in five cases the stoma vent axis was given an elliptic shape.

Two patients have prostheses with the entire set of modifications i.e. elliptical stoma vent, flat stoma vent flange, periscope side valve, and a periscope flange. Two of the patients successfully tested the stoma vent cover valve (figure 5). The advantage of using the vent cover valve is that it allows the patient to speak without using the hand to cover the stoma vent. The cover valve designed at only one standard size does introduce some resistance to breathing. This resistance becomes more apparent in patients with large stoma vents.

C H A P T E R   III

TESTING APPARATUS AND PROCEDURES DEVELOPED

Because of the variation of surgical requirements,
post-surgical reconstruction, tissue regeneration and
individual physiology, it has been found that, in addition
to the evaluation of a voice prosthesis in the laboratory,
it is necessary to test the device in vivo in each
individual case and to allow for substantial modification.
This has been evident from the various design modifications
and their underlying causes discussed above. Thus, the
evaluation of a voice prosthesis requires the establishment
of suitable in vivo tests and the development of pertinent
apparatus. Moreover, because of the dynamic nature of the
phenomenon under study, i.e. the rapid variation of the air
velocity and pressure during speech, the instumentation must
be able to record rapidly varying effects.

Pressure measurements were made and resistance values
calculated for sixteen prostheses of the duckbill type and
sixteen of the new design. Resistance calculations were
obtained under five flow rates (0.2, 0.3, 0.4, 0.5, 0.6
SCFM) which are flowrates used during speech production[1].

Air was supplied from a pressurized air supply tank. A
reducing valve was used to regulate the pressure of the air
supplied. A flowmeter was used to measure the volumetric

flow rate of air supplied to the tested prosthesis. A pressure transducer (range 0-5 psig) was used to pick up the trans-device pressure drop using ambient pressure as the reference. A full bridge amplifier and strip chart recorder were used to record the pressures developed during the tests. Figure 8 shows the instrumental array setup. Reference pressures were established by using the instrumental setup at the test flow rates without the periscopes to be tested mounted on the pressure probes. During testing the prostheses were individually attached to the probe and the pressure for each individual flow rate was recorded. These recorded pressures were then subtracted from the reference pressure of the coresponding flow rate giving us the trans-device pressure.

Two types of pressure probes have been developed. These probes were developed to be used both in bench and in in vivo tests of the prostheses. The total airway resistance probe (Figure 9) is designed for use on voice prostheses without periscopes as well as the M. Shapiro voice prosthesis, with the periscope. The probe is connected to the differential pressure transducer, is held against the stoma and is used to record the pulmonary effort during speech. The periscope airway resistance probe (Figure 10) is designed to exactly duplicate the bench test in vivo. The

probe is inserted in the part of the prosthesis that connects the trachea to the esophagus; air is injected through the probe and the pressure developed is recorded.

For the in vivo testing of the M. Shapiro prosthesis, the periscope probe is introduced into the periscope openning . For prostheses that are similar to the " Bivona low pressure voice prosthesis"^{TM} (i.e.without a stoma vent) the probe is introduced into the prosthesis openning.

A continuously measured amount of air is introduced through the probe and the back pressure developed is recorded on the strip-chart recorder. In addition to the back-pressure recording at the different flow rates, the test allows the determination of the optimal voicing flow rate. During the first part of this test, the patient is asked to maintain a slightly opened mouth and otherwise be relaxed. During the second part of this test, the first part is repeated but this time the patient is asked to phonate. The letters "a" and "o" are sustained for three seconds each. After the optimal flow rate has been established then the alphabet is recited. As noted before, in the in vivo tests it is necessary to make sure that the apparatus response time is suitable for recording the dynamic effects involved. The apparatus has been modified a number of times. The probe with proper time response characteristics has been

designed and fabricated. This probe has been used for the bench periscope resistance tests.

The air resistance characteristics of the side and duckbill valves were investigated in vivo on two patients. In this test, prostheses of identical size but with different periscope valves were used by the patients. The probe developed for this test is shown in figure 9. This was placed in front of the stoma oppening after exhalation. The patient then inhaled and upon the next exalation the valve would close, thus developing a pressure buildup and speech , simulating the actual mode of use of the prosthesis. The differential pressure developed was recorded on a continuous strip chart recorder. Figures 15, 16 show a sample of the recorded pressure variations.

CHAPTER IV

DISCUSSION OF RESULTS

The resistance which voice prostheses offer to the flow of air through them is customarily stated in terms of pressure drop per unit flow of air through the device. We have performed pressure-flow measurements and calculated the resistance values developed for thirty two periscopes. Sixteen periscopes were of the duckbill type and were directly obtained from the manufacturer (Bivona Surgical Inc.). Sixteen periscopes were of the side valve type and were made by us as prototypes of our design. We have used diaphragms obtained from Bivona Surgical identical to the ones used in the low resistance Blum-Singer prosthesis.

Resistance results were obtained for flow rates between 0.2 and 0.6 SCFM which represents the spectrum of flow rate requirements for voice generation. The flow, pressure and resistance characteristics of the tested devices are shown in figures 11 and 12 respectively and in Table 2. The values shown are the average values for each type at the respective flow rate.

The pressure buildup values were obtained as follows:

ΔP_{cal} = Pressure buildup of system + periscope without valve

ΔPtest=Pressure buildup of system + periscope with valve
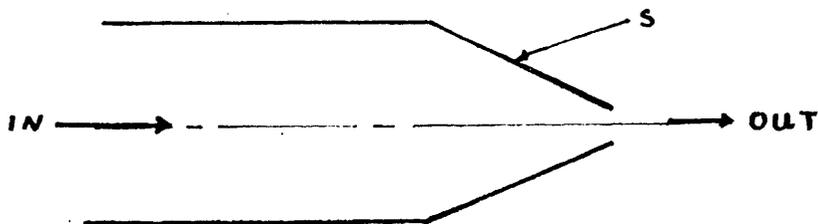
ΔP_i = Pressure buildup due to the valve at flow rate i

$$\Delta P_i = (\Delta P_{test} - \Delta P_{cal\ i})$$

and if R_i = Valve resistance at flow rate i

then
$$Ri= \frac{\Delta Pi}{i}$$

The flow characteristics of the two types of valves used can be analized as follows: We can assume steady non-viscous flow since the pressures and velocities developed in this tests are not substantial.

IN ⟶ ⟶ OUT

SKETCH I

From the Bernoulli equation we have:
$$\Delta P \propto V_{exit}^2$$
and from the continuity equation :

$$Q \propto V_{exit} \, A_{exit}$$

Where   V = Average fluid velocity

Q = Volumetric flow rate

A = Aria perpendiqular to the velocity vector

The basic difference between the two valves is the effect their respective geometries and material characteristics have on the exit areas of the valves.

For the duckbill valve the extent to which the valve would open is proportional to the pressure differential along segment s as indicated in sketch I. This can be expressed as :
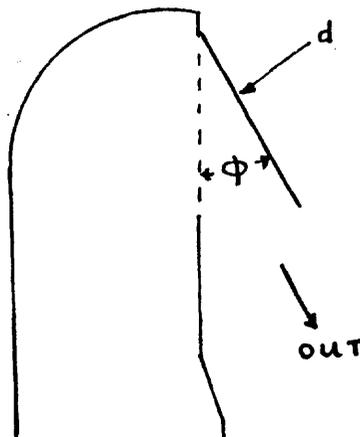
$$A_{exit} \propto \Delta P$$

and from the Bernoulli and continuity equations we get:

$$\Delta P \propto Q^2 / A_{exit}^2$$

$$\text{and} \quad \Delta P \propto Q^2 / P^2$$

Thus we get

$$Q \propto P^{1.5}$$

SKETCH II

14

For the side valve indicated in sketch II, the extent to which the diaphragm would open and consequently affect the exit area is a function of both the pressure differential along the diaphragm as well as the change in the flow momentum due to the diflection by 90-ϕ degrees imposed by the diaphragm's opening angle. The extent to which these factors affect the flow characteristics can be distinguished by the magnitude of   .

For low values of Q, ϕ is small and V is small and the exit area is primarily proportional to the pressure difference across the diaphragm. For high values of Q, ϕ is larger than 30 degrees thus the potential exit area is larger than the entrance to the valve. This is due to the important role played by the change of momentum vector which is proportional to the velocity. The magnitude of the velocity is ideally the same as the entrance velocity to the valve. The force on the diaphragm is due to the change in direction of the velosity vector. Thus there are only minor effects on the pressure outside the valve seat entrance area, and thus:

$$Q \propto \Delta P^{0.5}$$

If we use linear regression for curve fitting of the form:

$$Q = a \, \Delta P^m$$

for the experimental data obtained by the bench periscope resistance test we get for the side valve :

$$Q = 0.869 \, \Delta P^{0.735}$$

and for the duckbill valve we get:

$$Q = 1.342 \, \Delta P^{1.520}$$

The actual behavior of the duckbill valve is closely related to the theoretical expected behaviour and as found previously in the literature[6]. For the side valve, the range of flows investigated falls predominantly in the rangewhere the flow is mainly proportional to the square root of the pressure. In should be noted that the first two test points indicate the deviation from the first to the second mode of behavior as discussed above. This can also be seen in Figure 13 where the flow coefficient values for the relation:

$$Q = C_v \, \Delta P^{0.5}$$

are, for the duckbill linearly proportional to the flow rate over the test range. On the other hand, for the side-valve, at the low flow rates c_v is proportional to Q, but at higher flow rates C_v tends to a constant value.

For the side-valve, the resistance at low flow rates

is much lower than for the duckbill valve. This can be atributed to the very low stiffness of the diaphragm hinge. At high flow rates the valve resistance is due mainly to the pressure drop caused by the direction change of the flow. The duckbill valve on the other hand demonstrates decreasing resistance characteristics which are attributed to the increasing exit area and straight through flow. However this higher rate of flow is outside the flow range required for speech.

The differences between the two valves become more pronounced in vivo. Depending on the patient's anatomy the duckbill valve would be stiffened to a greater or lesser extent by the esophageal wall interacting with the valve's sides. This fact has been the leading factor in the need for redesigning the periscope valve. Figures 15 and 16 show samples of the in vivo total airway resistance test results performed on two patients. In this test the patients were asked to vocalize the numbers from one through five and their pulmonary effort during this count was recorded. The patients used two identical prostheses: one fited with a side-valve and the other with a duckbill valve. The two patients were typical of the two main categories of patients: one patient can use both types of valve comfortably; the second the patient can not use the duckbill

valve comfortably due to the increased effort level needed for voicing. Table III shows the nondimentional effort ratio of the two types of valve for the two patients tested. We define the effort ratio to be:

$$EFR = \Delta P_s / \Delta P_d$$

where subscripts s and d stand for side valve and duckbill valve respectively. We use this ratio to indicate the comparative effectiveness of one device as compared to the other. An EFR value of one indicates identical performance . Values less than one indicate supperior performance of the side valve. For the side valve, the tests demonstrate superior performance with average values of .87 for patient "A", and 0.6 for patient "B" .A bench test duplicating in vivo flow rates gave an averege EFR value of 0.76. These results clearly demonstrate the advantages of the side valve design over the duckbill valve.

CONCLUSIONS

The voice prosthesis designed has clinically demonstrated superior properties over the existing devices, in that it increases the spectrum of candidate patients. In the redesign process we have introduced several changes to the Shapiro prosthesis without compromising any of the original advantages of the device. The elliptical stoma vent conforms with the anatomical construction of the tracheal passage of the post-laryngectomy patient. The side valve has demonstrated low resistance characteristics at voice generation flow levels, and has minimal esophageal wall interaction. The flat and exdented stoma vent flange provides a better stoma seal without compromising comfort. The cover valve allows hand free use of the voice prosthesis with minimal breathing interference and with built in pressure protection. In addition to the above we have developed tests

evaluation of existing and future desings. These test allow the comparison of bench and in vivo resistance measurements.

We recognize that our design is not the ultimate solution to voice rehabilitation for laryngectomized patients, but it does provide a better means of verbal comunication than other commonly used devices.

A P P E N D I X   A

TABLES OF RESULTS

TABLE I

TABLE OF PROSTHESIS MODIFICATIONS FOR TYPICAL PATIENTS

ELLIPTICAL VENT	SIDE VALVE	FLAT STOMA FLANGE	PERISCOPE FLANGE	CONDITION TO BE CORRECTED
*	*	*	*	fm,hp,al
*	*	*	*	fl,hp,us
	*			hp,al
	*	*		ps,hv
	*	*		hp,ws,fl
*	*	*		hp,ps
*	*	*		ps
	*	*		fl
*	*			hp,ss

fm: Fistula migration
hp: High pressure
al: Air leakage
fl: Fluid leakage
ps: Prominent sternomastoids
hv: Hoarse voice
uv: Uncomfortable vent
ss: Shallow stoma
vb: Valve breakdown

T A B L E II

FLOW-PRESSURE, DATA AND RESULTS

| | SIDE VALVE | | | DUCKBILL VALVE | | | |
Q	ΔP	R	C_v	ΔP	R	C_v	EFR
0.2	0.136	0.68	0.54	0.281	1.40	0.38	0.483
0.3	0.240	0.80	0.61	0.389	1.30	0.48	0.616
0.4	0.336	0.84	0.69	0.448	1.12	0.60	0.750
0.5	0.465	0.93	0.73	0.520	1.04	0.69	0.894
0.6	0.618	1.03	0.76	0.582	0.97	0.79	1.062
AVER.	0.359	0.86	0.67	0.444	1.17	0.59	0.76

  Q: Flow rate (SCFM)
ΔP: Pressure differential (psi)
  R: Airway resistance (psi/SCFM)
C_v: Flow coefficient (SCFM/ psi0.5)
EFR: Effort ratio

T A B L E   III

IN VIVO PRESSURE TESTS

	PATIENT "A"			PATIENT "B"		
	SV	DV	EFR	SV	DV	EFR
ONE	7.8	7.6	1.02	5.0	9.0	<0.55
TWO	6.8	6.8	1.00	4.4	6.4	0.69
THREE	6.0	7.6	0.79	4.0	6.6	0.61
FOUR	5.2	7.2	0.72	3.8	6.2	0.61
FIVE	5.2	6.0	0.87	3.0	5.4	0.56
AVERAGE			0.88			0.60

SV: Side valve
DV: Duckbill valve
EFR: Effort ratio

A P P E N D I X   B

FIGURES AND GRAPHS

.

SIDE VALVE

periscope
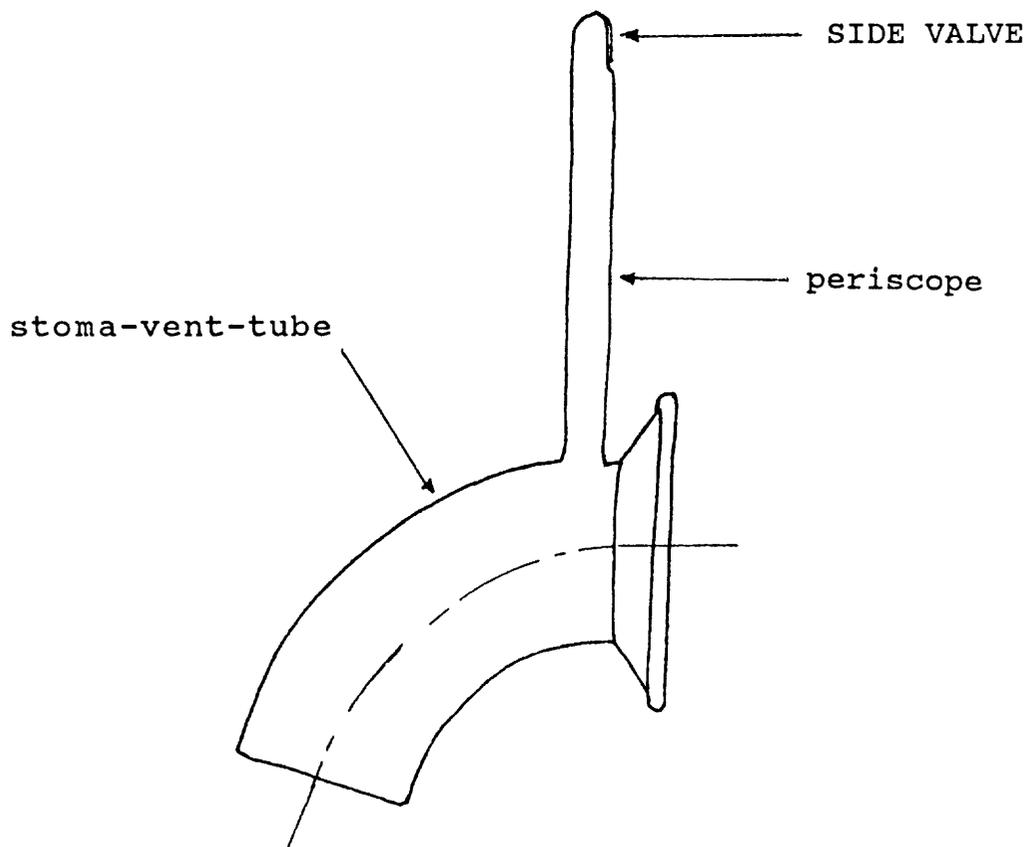
stoma-vent-tube

FIGURE 1. Voice prosthesis with modified periscope.
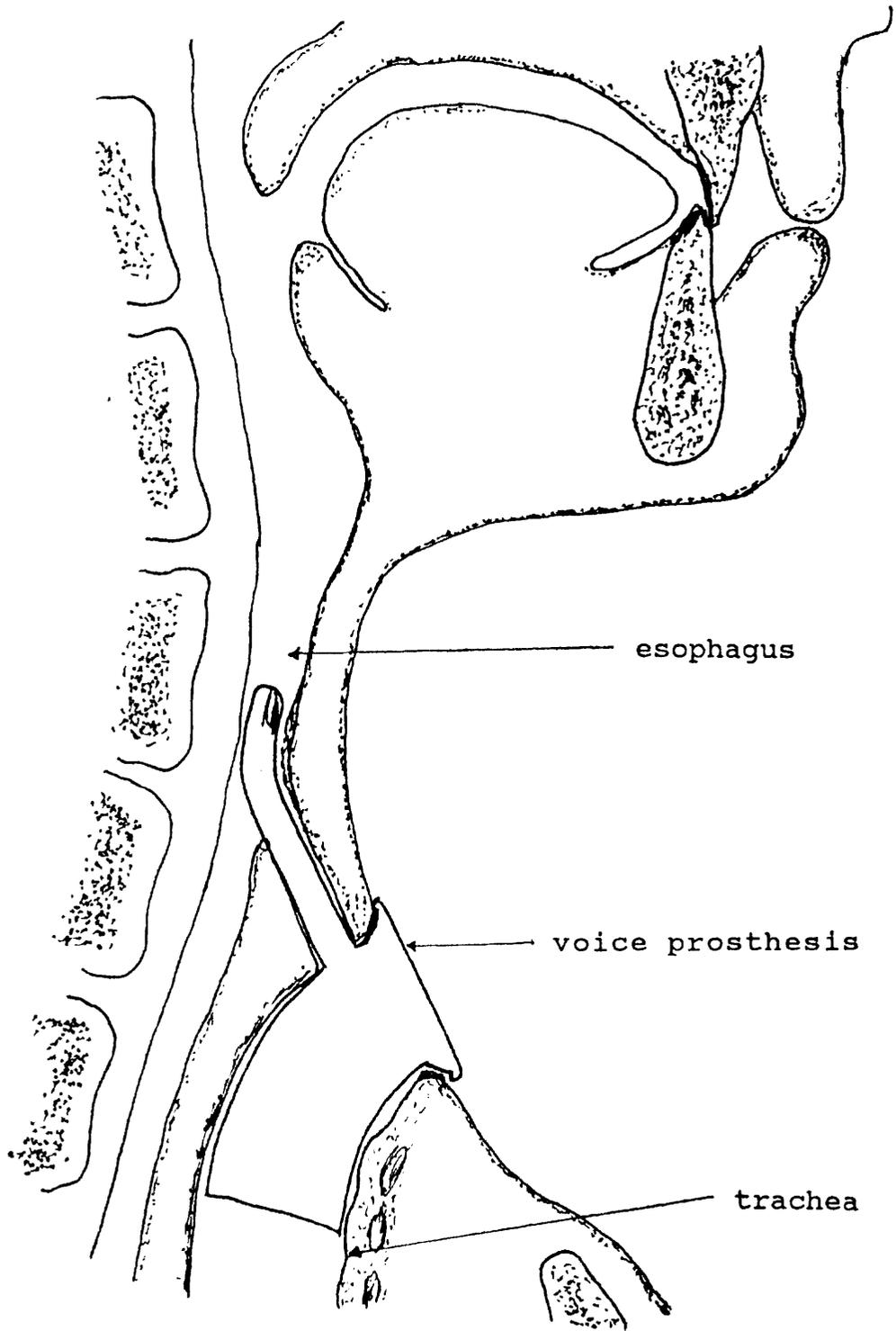
FIGURE 2. Cross section of the neck region with voice
prosthesis on place.

FIGURE 3. Side valve.

FLANGE

COVER VALVE
ATTACHMENT

A

A

SECTION AA

FIGURE 4. Stoma vent.

RETAINING RING

DIAPHRAGM

THREADED POST

SPRING

INITIAL POSITION
OF FOLDED DIAPHRAGM
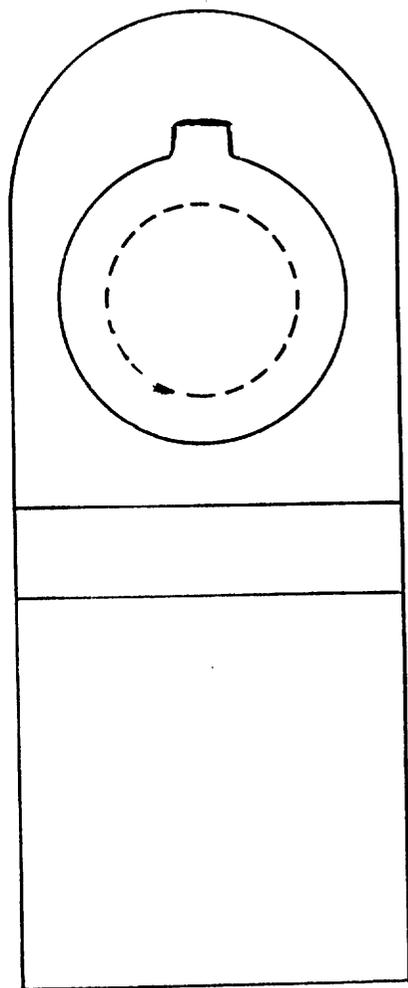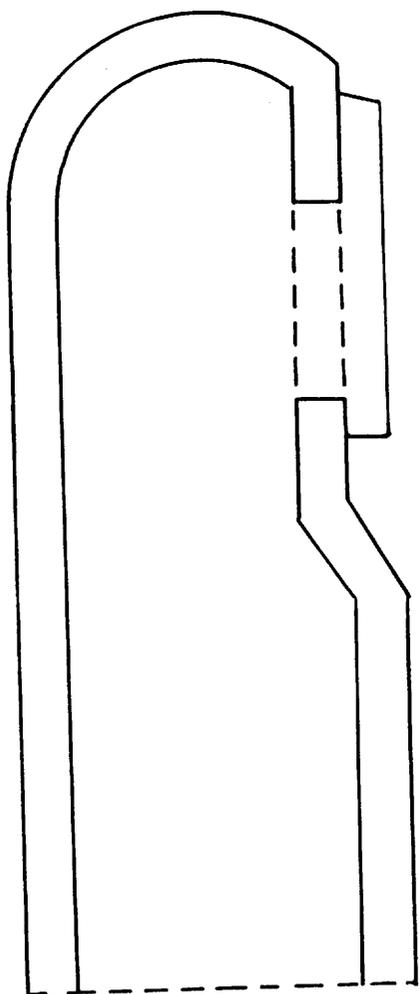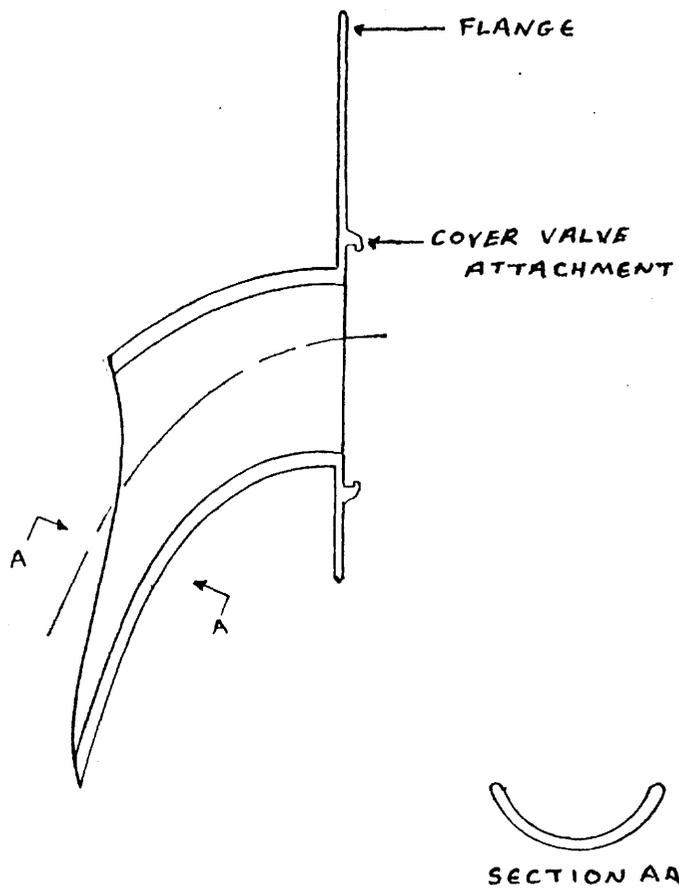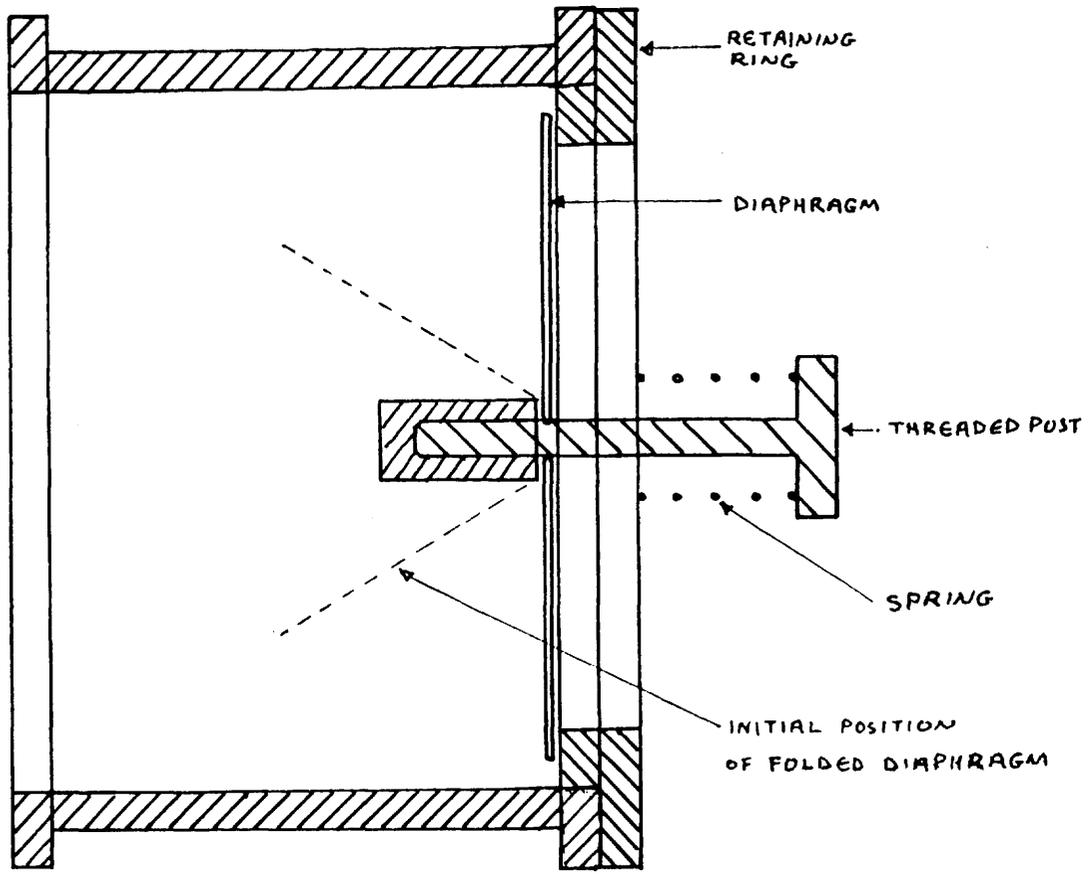
FIGURE 5. Cover valve.
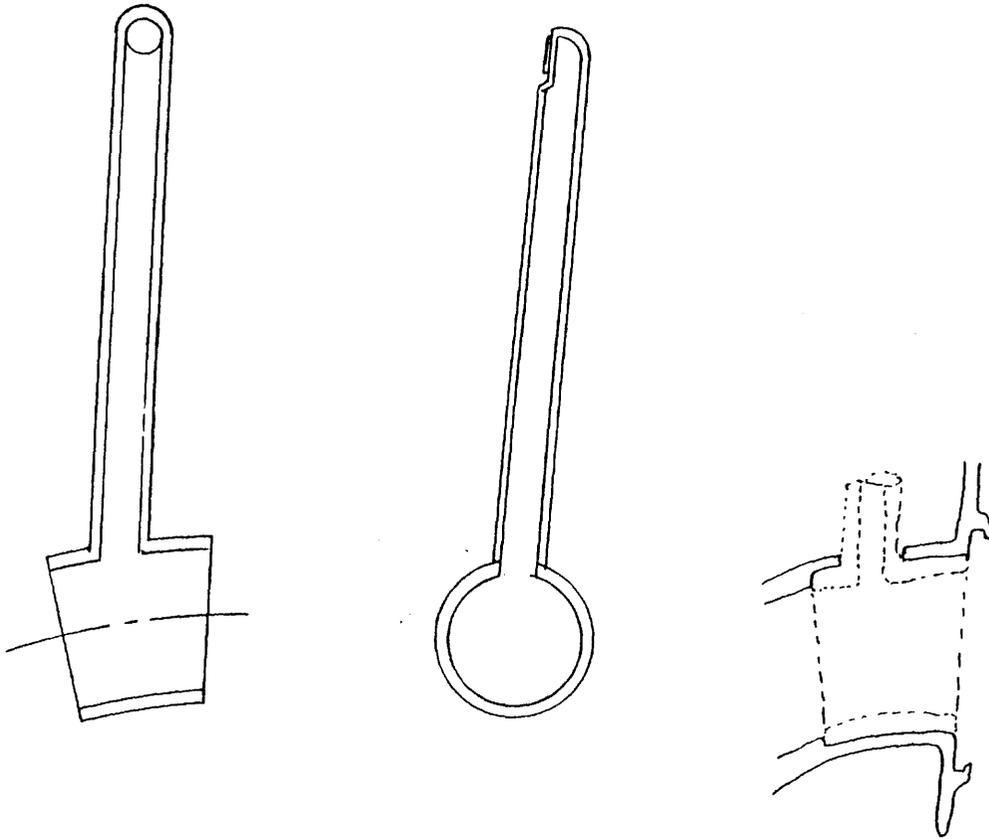
FIGURE 6. Separately attached periscope.

ESOPHAGUS

FLANGE

PERISCOPE

STOMA VENT

TRACHEA
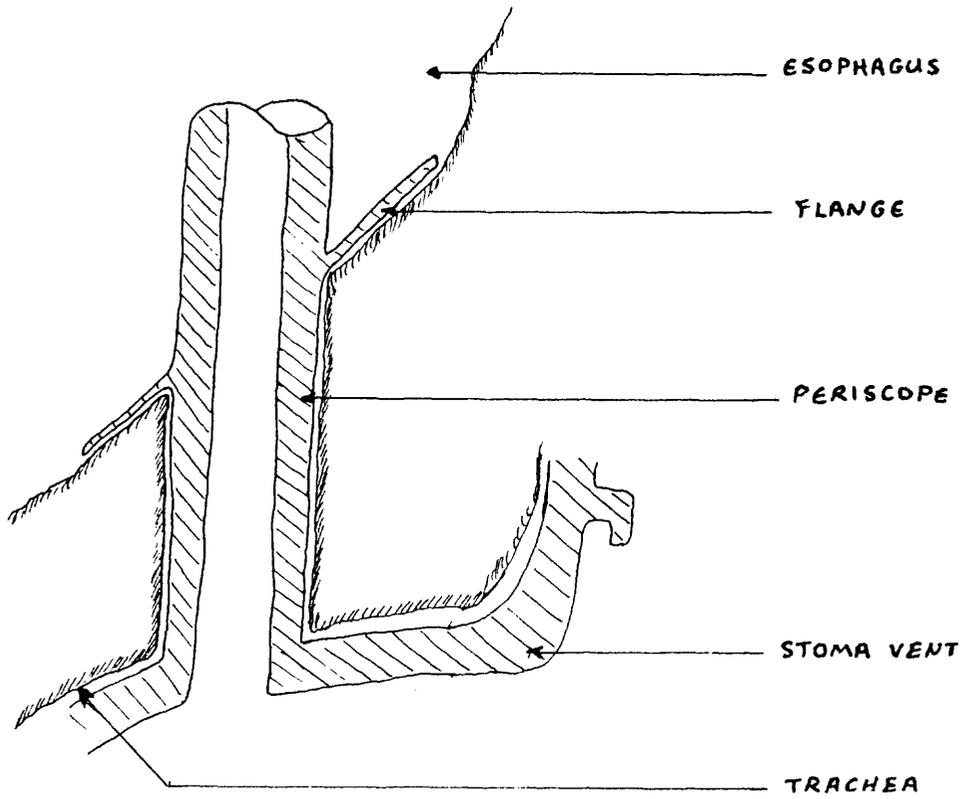
FIGURE 7. Periscope flange.

P R O B E S

A: Regulated air supply.
B: Flow meter.
C: Signal conditioner – Recorder.
D: Differential pressure transducer.
E: Periscope resistance probe.
F: Total resistance probe.
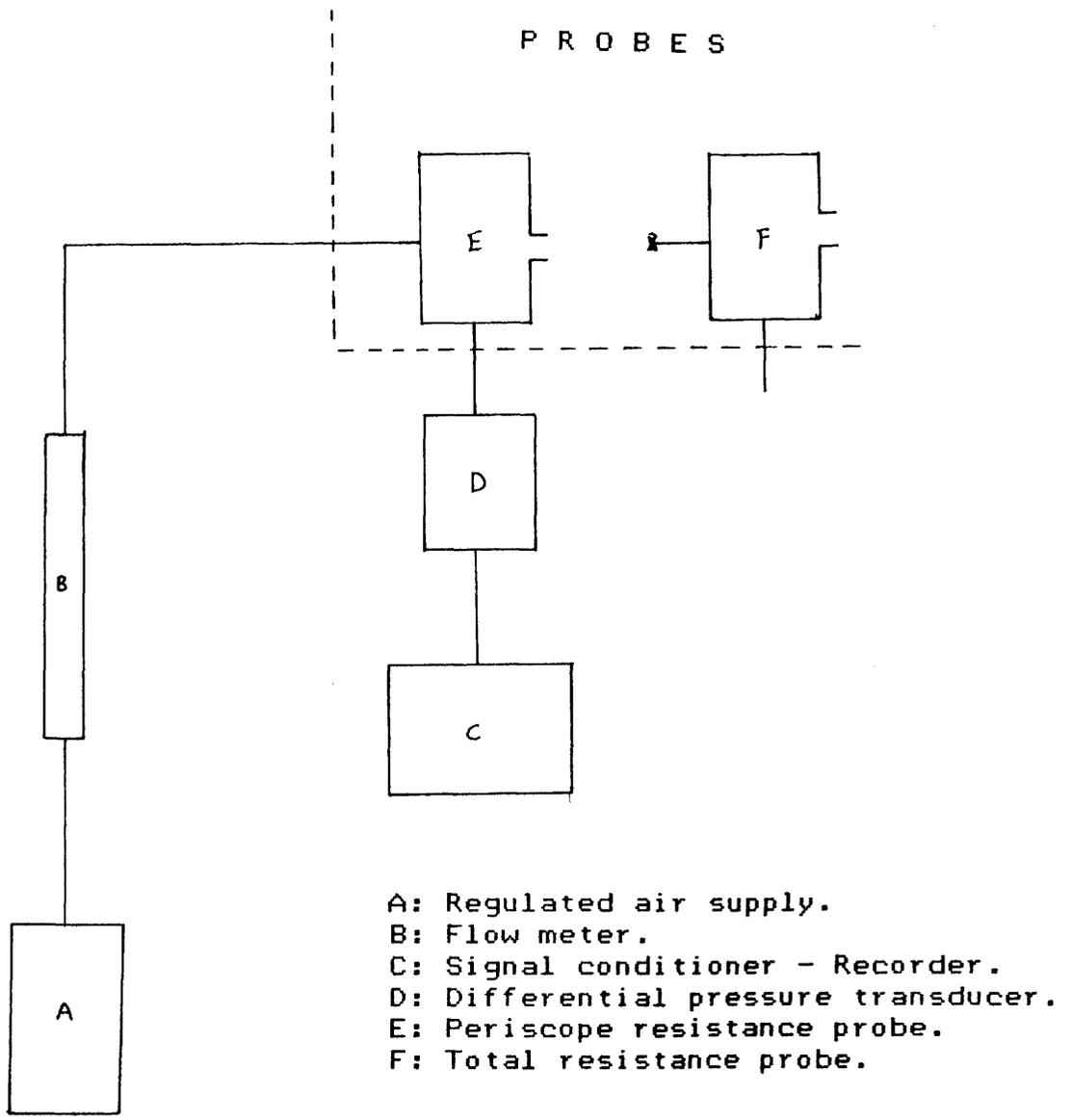
FIGURE 8. Instrumental array for air resistance test.

TO PROSTHESIS
STOMA VENT

TO PRESSURE
TRANSDUSER
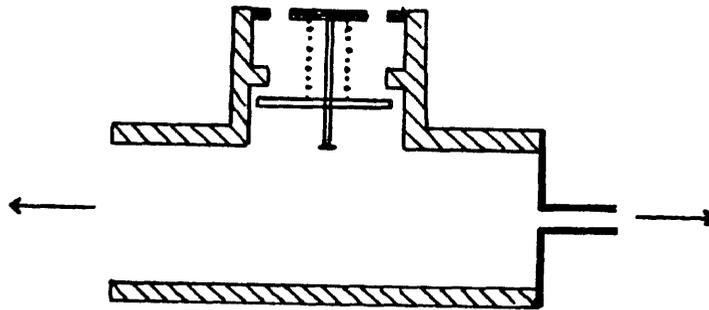
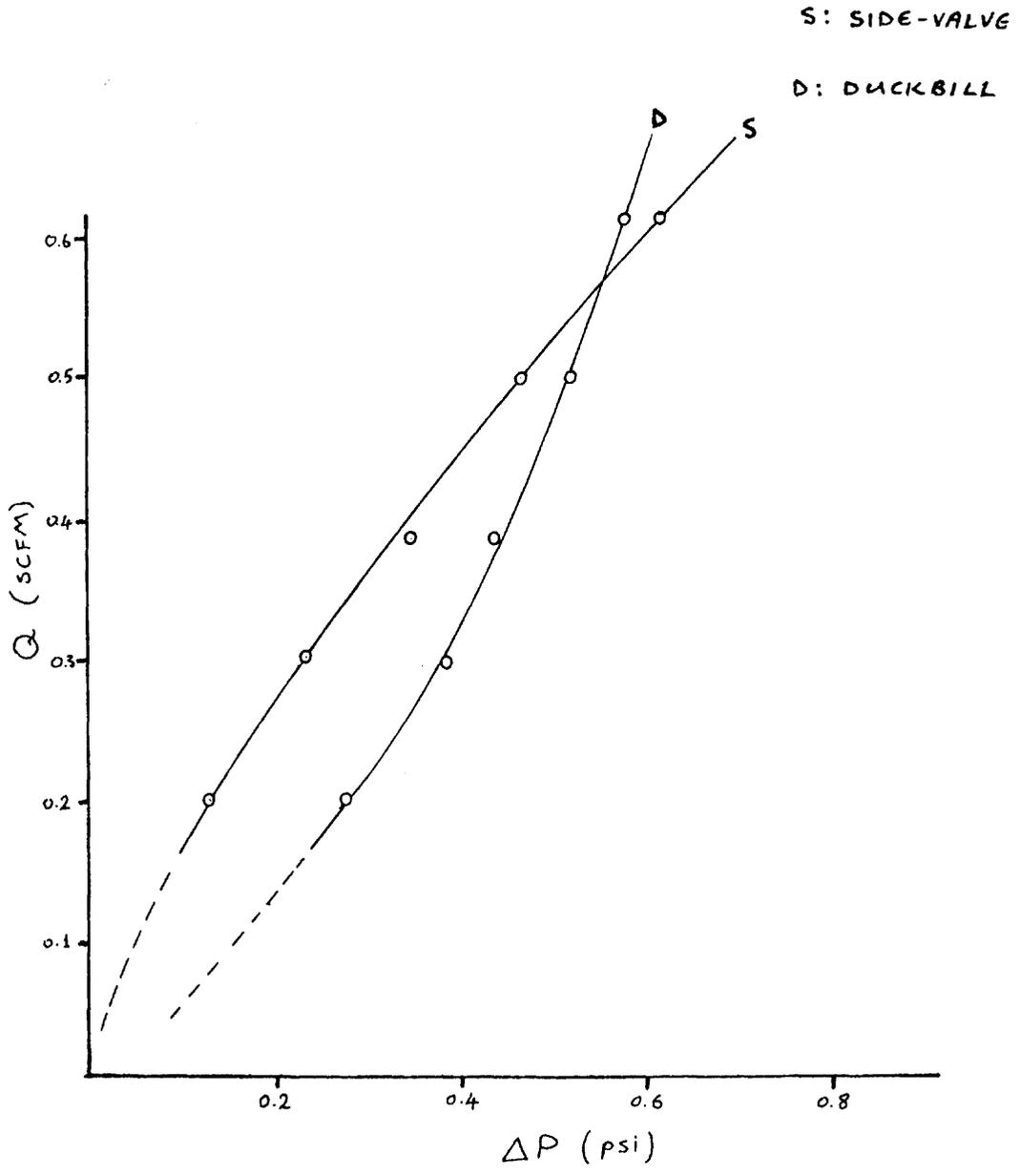FIGURE 9. Total air resistance pressure probe.

TO TESTED PROSTHESIS

TO PRESSURE
TRANSDUSER

TO AIR SUPPLY
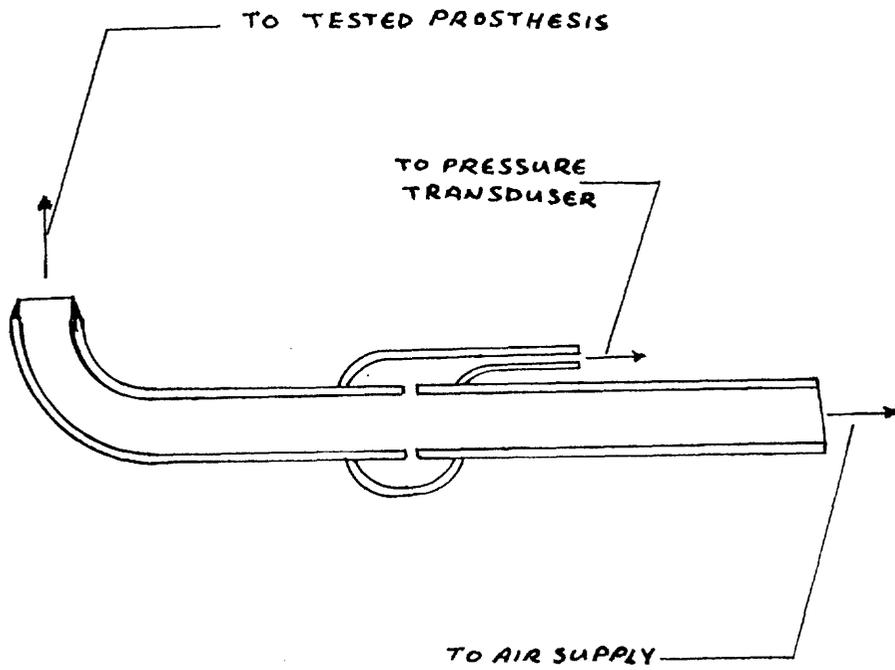
FIGURE 10. Periscope pressure probe.

FIGURE 11. Graph: Bench air resistance test ;
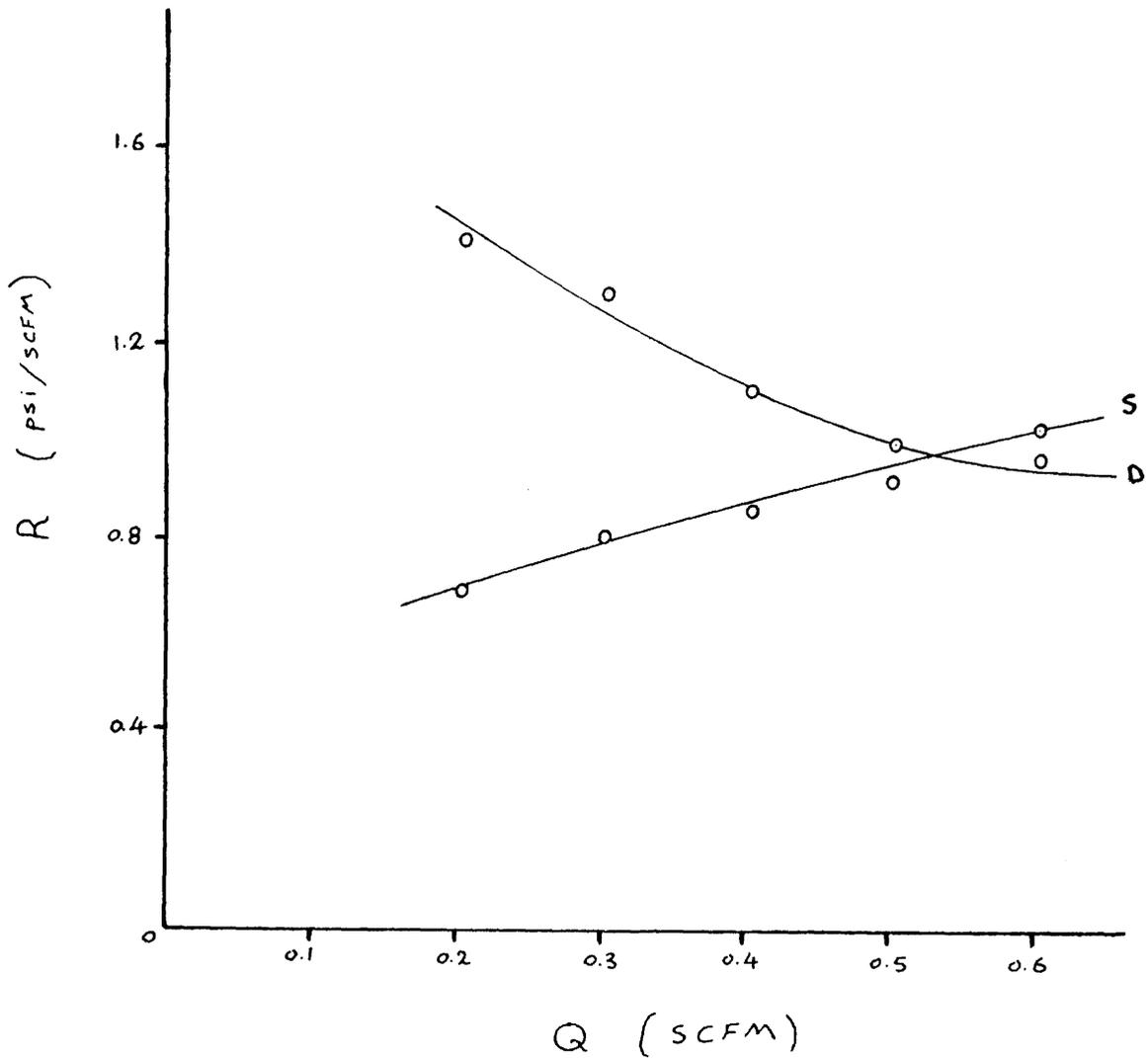   Pressure differential vs. Flow rate.

S: SIDE-VALVE

D: DUCKBILL

FIGURE 12. Graph: Bench air resistance test ;
Flow rate vs. Resistance.
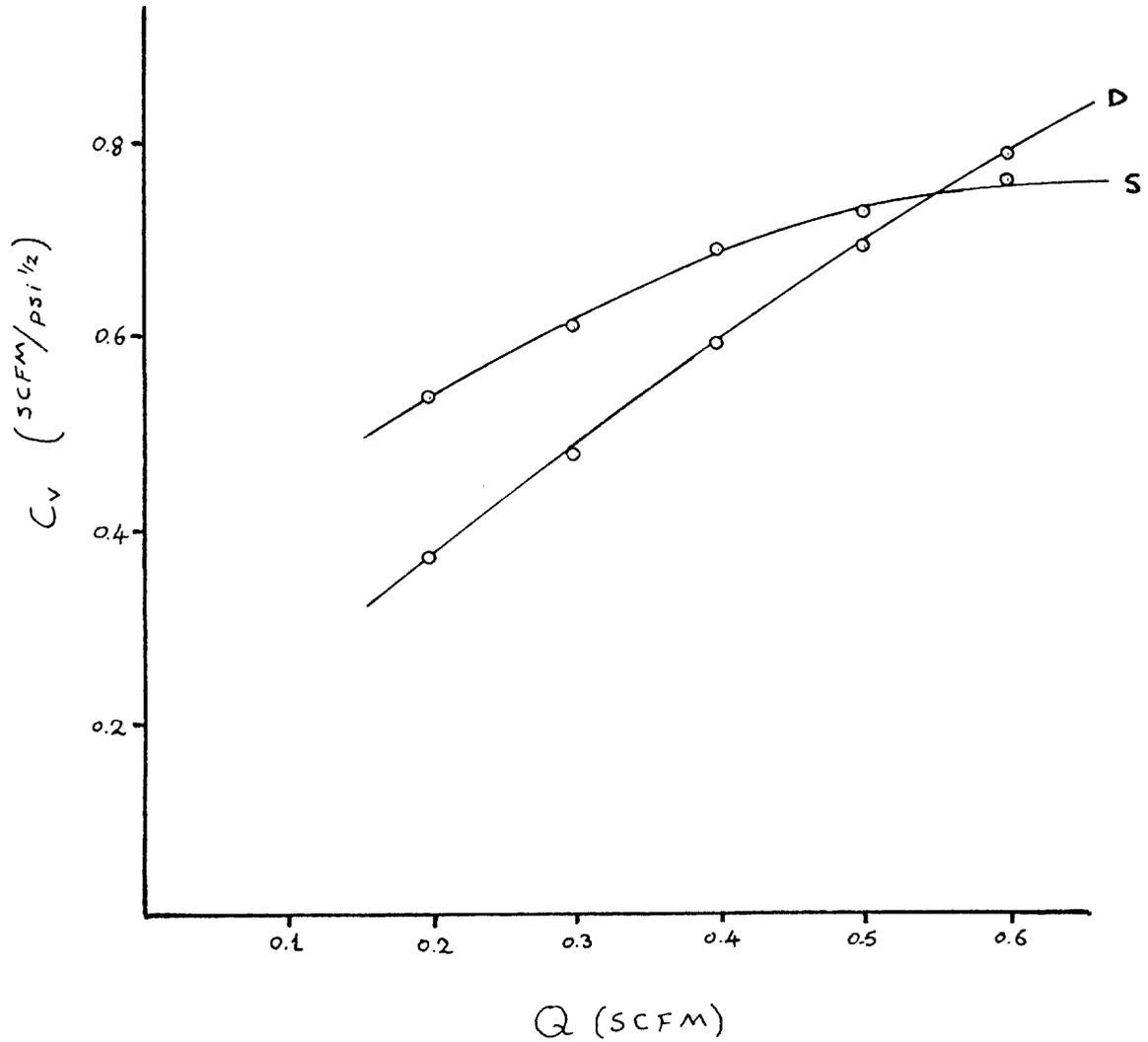
S : SIDE-VALVE

D : DUCKBILL

FIGURE 13. Graph: Bench air resistance test ;
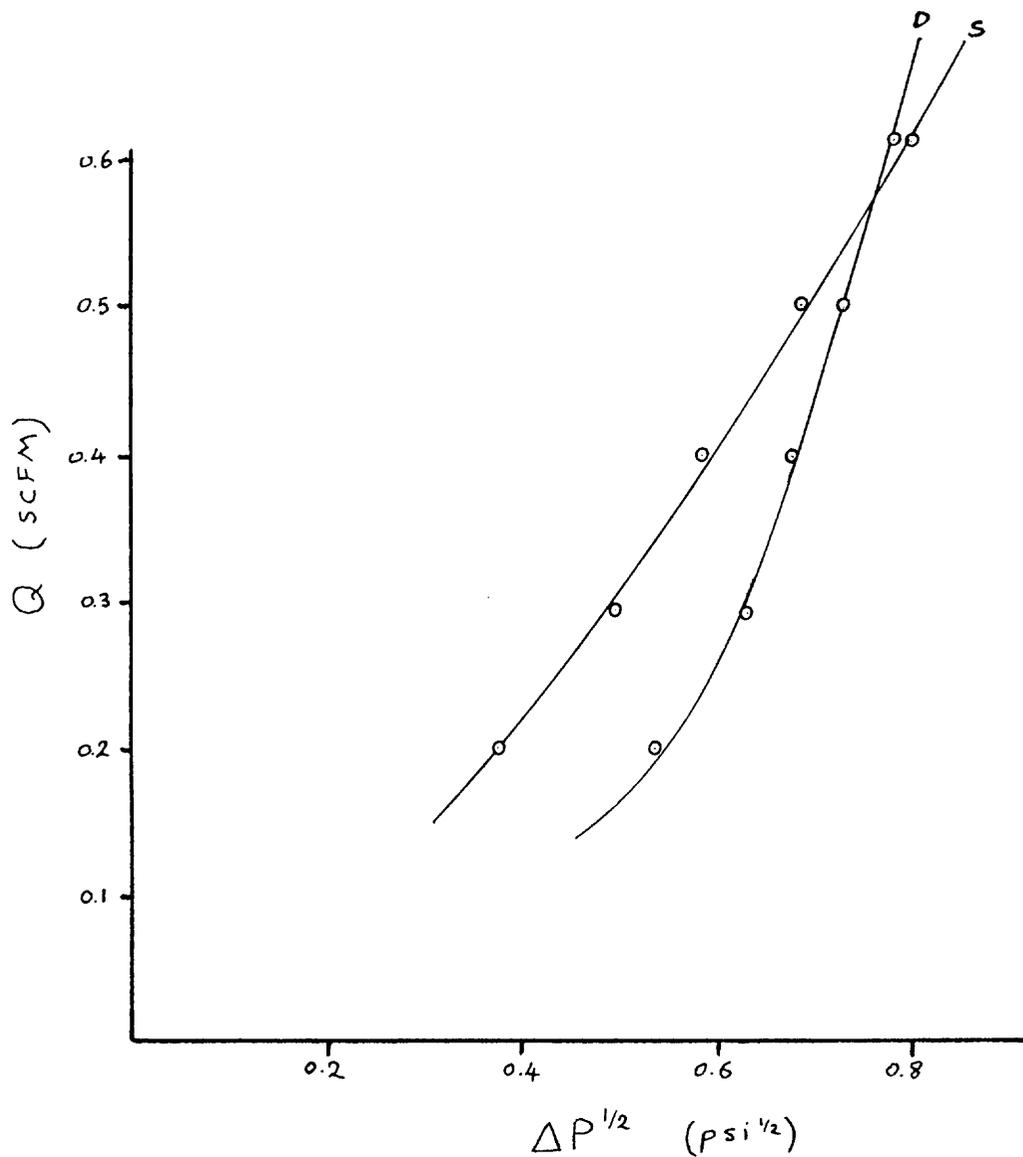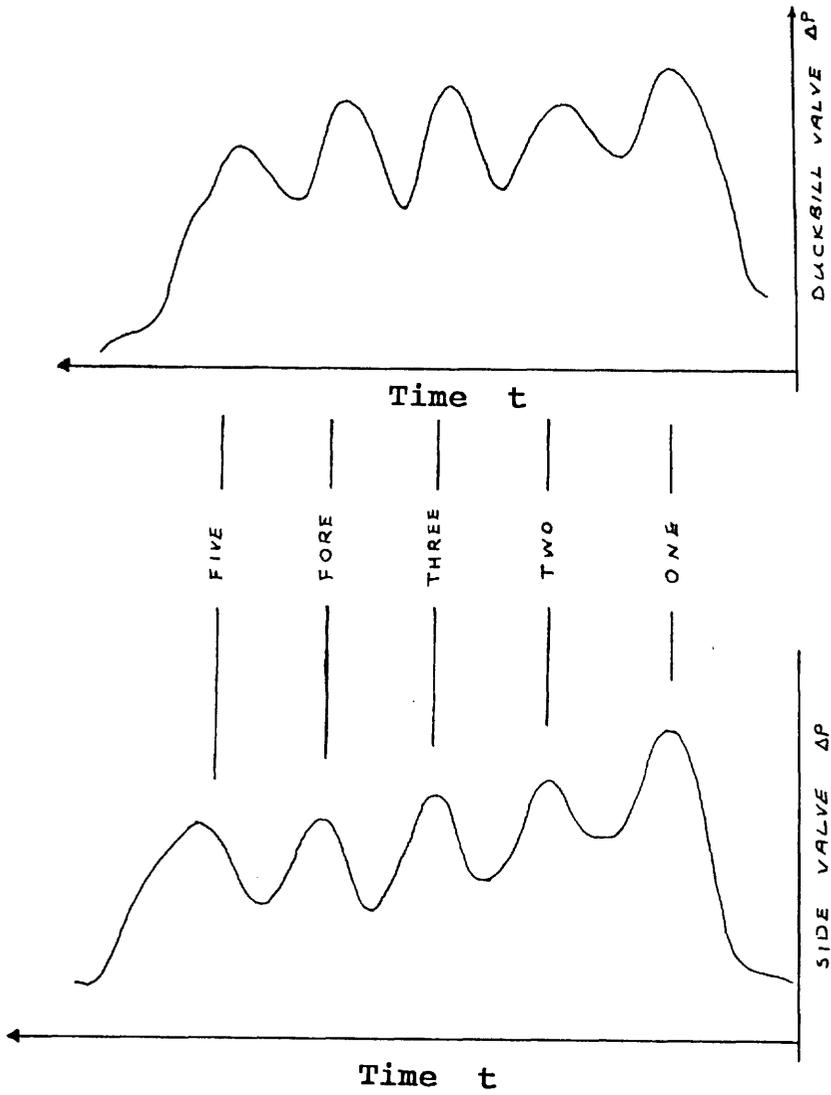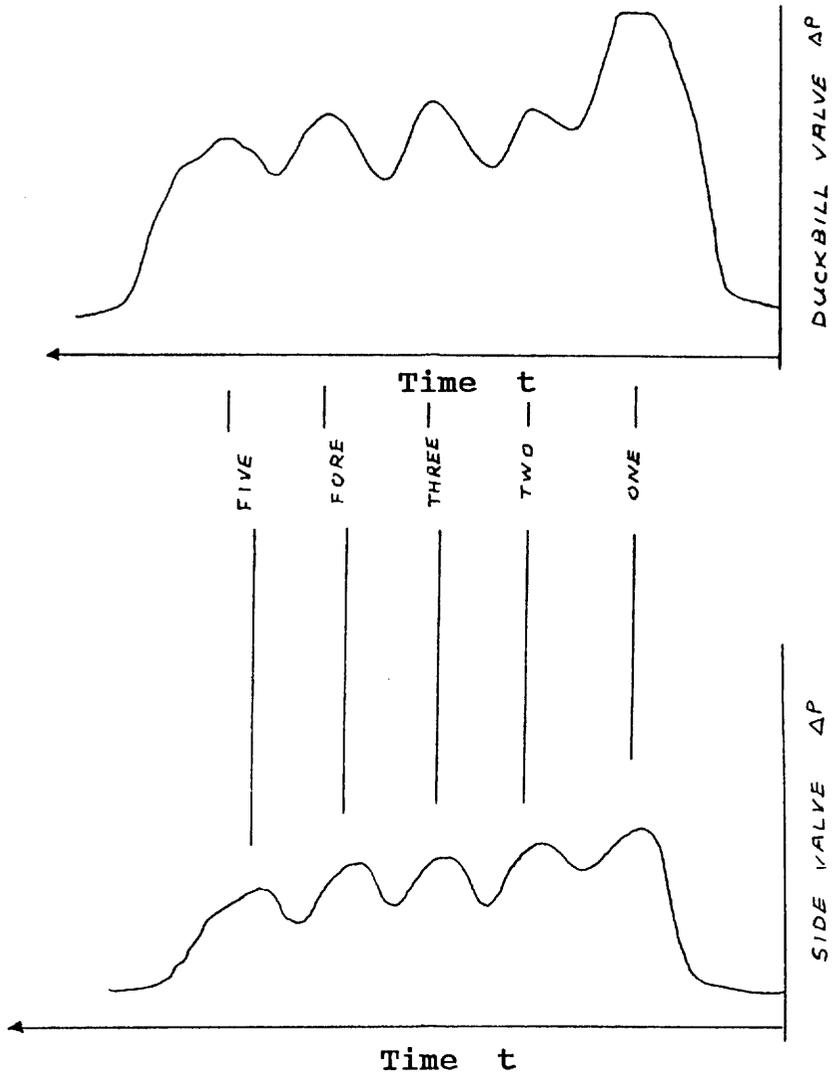Flow rate vs. Flow coefficient.

FIGURE 14. Graph: Bench air resistance test ;
Square root of pressure differential vs. Flow rate.

Note: Δ P and t are not calibrated to specific values

FIGURE 15. Total pressure in vivo (Patient "A")

Note: ΔP and t are not calibrated to specific values

FIGURE 16. Total Pressure in Vivo (Patient "B")

A P P E N D I X   C

LIST OF TEST EQUIPMENT

LIST OF TEST EQUIPMENT

1. Flow meter: Full view rotameter, type 7-111-5-MS

   Full scale 0 - 1.5 S.C.F.M. Air at 70 F and

   14.7 psia, BROOKS INSTRUMENT Co. INC.

2. Strip chart recorder / Amplifier: Recorder 2400S

   System configuration 2107-4202-00,

   GOULD INC.

3. Pressure Transducer: Semiconductor full bridge Diaphragm

   Model PX 126- 005 DV, Range 5.0 psid,

   OMEGA INC.

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