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CHARACTERISTICS OF PRESSURE SENSING BALLOONS MADE OF VARIOUS POLYMERIC MATERIALS

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Abstract. A variety of polymeric materials (polyurethane, polypropylene, polyethylene and polyvinylidine copolymer) have been evaluated for suitability in making of air-filled balloon to detect intraluminal pressure. The polyurethanes, in particular ECD, proved to be most suitable because of the ease of fabrication, low permeability to air and high frequency characteristics. Polyvinylidine copolymer was adequate but suffered from difficulties in fabrication. Polypropylene and polyethylene, available in film, were troublesome in making balloon and displayed low frequency characteristics.

Key words: frequency response, phase lag, intraluminal pressure, polyurethanes, ECD

Pressure detection inside the intestine is usually accomplished using a liquid-filled open-tip catheter attached to an external, rigid manometer. The frequency response of such a fluid system is quite adequate for studying intraluminal pressure (1). However, such a system may not be suitable when the intraluminal pressure is being measured in relation to the study of propulsion of intestinal content. Since the movement of intraluminal contents depends mainly on the absolute pressure difference between adjacent loci, the detection system must be appropriate to measure the absolute pressure inside the gut (2). The magnitude of intraluminal pressure is not large enough to allow one to ignore the liquid head variation which is inevitable in a water-filled system (3). To avoid the problem of hydrostatic pressure, an air-filled system has to be used; and for this purpose latex balloons have so far been used as a pressure-sensing tip. Although a thin latex-balloon provides excellent frequency characteristics as a pressure-sensing device, air leakage may occur when pressue recording is prolonged and this impairs the physical properties of the balloons. On the other hand, a thick latex-balloon providing against air leaking can be made at the expense of frequency characteristics.

The aim of the present experiment was to find some adequate materials which could be used to fabricate a balloon responding with fidelity to physiologic pressure changes. Polymer research has advanced greatly in recent years and a variety of polymeric substances are available, yet few investigations on the suitability of these materials for a pressure-detecting balloon have been reported. In the present experiment, the search for potential materials was concentrated exclusively in the domain of synthetic polymers.

MATERIALS AND METHODS

Materials

Table 1 shows the major classes or readily available compounds which were considered for trial. The substances marked with an asterisk were tested in this paper.

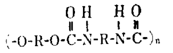
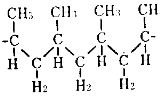
TABLE 1. PRELIMINARY EVALUATION OF THE AVAILABLE POLYMERS

Substance	Preliminary evaluation
I. Rubber	
a. Latex	Absorbs water and becomes weak unless compounded and vulcanized. High permeability to gas and vapor. Compounding introduces chemically active materials.
b. Synthetic	The same objections apply.
II. Cellulose derivatives	
a. Viscose	Stiff and brittle when dry. Weak when wet.
b. Cellulose esters (nitrates, acetates)	Stiff without plasticizers and the latter are chemically active and toxic compounds.
III. Polyesters (Mylar, Dacron)	Available only in films. Hard to shape and requires high temperatures to seal. Stiff in curved form.
IV. Polyethenes	
*a. Polyethylene *b. Polypropylene	Available in films. Chemically inert and resistant to abrasion. Low modulus of elasticity. No plasticizers needed. May be heat-sealed.
*c. Polyvinylidine chloride copolymer (Saran)	Available as films and solution. Quite impermeable to gases and liquids. Very limp and tough. May be easily heat-sealed.
V. Polyurethanes	
*a. Latex	Elastic and limp. Easily handled. Difficult to fuse particles.
*b. Solutions	Satisfactory substances.
VI. Teflon	No solvent available. Both films and dispersions require very high temperatures (650°F) to fuse.

* Substances tested in the present paper.

Segmented polyurethanes. The chemical structure of this group of substances is shown in Table 2. Urethane Latex (Wyandotte) is an aqueous suspension.

TABLE 2. CHEMICAL FORMULAS AND FREQUENCY RESPONSES

Product	Chemical formula	Frequency response
Urethane		
ECD	 $(\text{-O-R-O-}\overset{O}{\overset{\|}{C}}\text{-}\overset{H}{\overset{\vert}{N}}\text{-R-}\overset{H}{\overset{\vert}{N}}\text{-}\overset{O}{\overset{\|}{C}}\text{-})_n$	53 Hz
Estane		
Polyurethane latex		
Polyethylene	$(\text{-CH}_2\text{-CH}_2\text{-})_n$	8 Hz
Polypropylene		29 Hz
Polyvinylidine chloride copolymer (Saran)	$(\text{-CH}_2\text{-CCl}_2\text{-CH}_2\text{-CCl}_2\text{-})_n$	95 Hz

Adiprene (ECD-651, Dupont) is readily soluble in chloroform (dissolved at 3.5% to 6%) and a short period is required to dry the balloon. Estane (B. F. Goodrich) was dissolved (33%) in tetrahydrofuran (THF).

Polyethylene. The chemical structure is shown in Table 2. This substance is available as a powder (U. S. I. Chemical) or as a thin (0.025 mm) film (Dupont).

Polypropylene. The chemical structure is shown in Table 2. This substance is available as a thin (0.013 mm) film (Hercules, Inc.).

Polyvinylidine chloride copolymer. The chemical structure is shown in Table 2. This substance is available as Saran (Dow) in two forms, as a film and as granules. The granules were dissolved at a concentration of 10% in a solution composed of THF and Acetone in the proportions 9 : 1 (vol/vol).

Preparation of Balloons

Balloons were made from liquid (polyurethanes, and polyvinylidine chloride) by dipping a cylindrical glass mold having a rounded tip (5 mm in diameter, shown in Fig. 1) several times into the liquid material and allowing the balloon to dry at room temperature for two to three h between each dipping. After the final dipping, the balloon was allowed to dry for at least 18 h.

In the case of polyurethane latex, dipping the mold into the suspension and the successive drying were repeated 3–10 times as before and thereafter, the urethane latex on the mold was heated to fuse the particles. Various combinations of concentrations of Adiprene (ECD) solution and the number of times dipped were studied preliminarily. A 3.5 to 5% solution with 1–2 dips usually gave satisfactory results. When 33% Estane solution was used, balloons were made by dipping a mold 3 times.

When a thin film of polymer was used to make the balloon, the film was

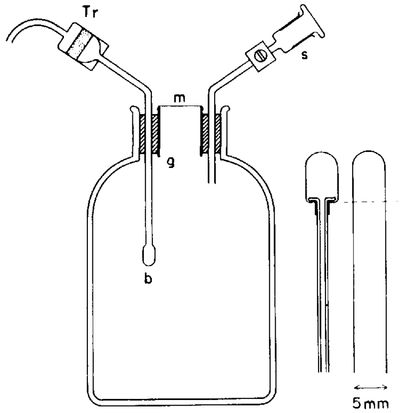


Fig. 1. The system used for determination of the damped natural angular velocity of the balloon. b: small balloon attached to one side of polyethylene catheter; m: thin rubber membrane; s: air-tight syringe with cock; g: a piece of glass tube, inside diameter 3.5 cm; the hatch is a rubber stopper. Volume of the bottle is 1160 cc. A thin rubber membrane was stretched forcefully and covered the wide opening of the glass tube which connected the inside and the outside of the bottle. The pressure inside the bottle was increased up to 10 mmHg and then the inside pressure was suddenly released by rupturing the rubber diaphragm with a 27 gauge needle. At the right hand side, the shape of the mold is depicted. At least 18 h after the final dipping, the thin-molded membrane was removed from the glass mold and fastened to the fringe of the polyethylene catheter.

wrapped very tightly over the glass mold and heat-sealing was made along the seam where the 2 layers meet and the rest of the film was cut off.

Evaluation of the Balloon-Catheter System

Undamped natural angular velocity. The frequency response of the air-filled balloon-catheter system was measured by determining the response to a negative square wave pressure change. One end of a polyethylene catheter (P.E. 190: I.D. =0.119 cm) 120 cm in length was attached to a Statham strain gauge (p23 db); at the other end a cylindrical balloon 1.5 cm in length was attached. Recording was on an Electronics for Medicine DR-8 recorder. As shown in Fig. 1, the pressure sensing tip (balloon) was placed in a closed system, and a static pressure (usually 10 mmHg) was applied to the system. After a sudden release of pressure, oscillating waves occurred with diminishing amplitudes over a short time period. By measuring two consecutive maxima [Y(t) and Y(t+P)] and the period (P) between these two, the damping coefficient $(\frac{R}{2m})$ was calculated from the following equation:

$$\text{In}\frac{Y(t)}{Y\,(t+P)}=\text{In}\;e^{\frac{RP}{2m}}=\frac{RP}{2m}$$

where R is the resistance, and m is the mass of the system (4). After measurement of the damped natural angular velocity w $(\frac{2\pi}{P})$ from the record, the undamped natural angular velocity $\sqrt{\frac{K}{m}}$ was calculated from the following equation*:

$$w=\sqrt{\frac{K}{m}-\frac{R^2}{4m^2}} \qquad (w=\text{radians per second})$$

To obtain information about the frequency characteristics of the balloons, the relative amplitude (Ar) at various frequencies was computed from step function responses. The amplitude (A) of forced oscillation of any applied frequency under steady state conditions is given by the following equation:

$$A=\frac{F}{\sqrt{(K-mw_i^2)^2+(w_iR)^2}}$$

where F stands for applied force; m, the mass of the system; R, the resistance of the system; and K, the spring constant.
By modifying the above equation, the following equation was obtained (4).

$$A\frac{m}{F}=\frac{1}{\sqrt{(\frac{K}{m}-w_i^2)^2+(w_i\frac{R}{m})^2}}$$

$A\frac{m}{F}$ is defined as the relative amplitude. By substituting numerals from 1 to 2,000 into w_i, the relationship between relative amplitude and frequency (frequency characteristics) can be obtained. The damping ratio, h, was calculated using the following equation.

$$h=\frac{R}{2\sqrt{mk}}$$

Up to 5% deviation from flat relative amplitude may be permissible in practical pressure recording and the frequency with 5% deviation defines the upper limit frequency allowing accurate pressure recording (5).

Phase lag. The phase lag between the response and the applied force is another important factor for accurate measurement of the intraluminal pressure. Phase lag at various frequencies under steady state conditions was determined using the following equation (4):

$$\tan^{-1}\theta=\frac{R}{m}\cdot\frac{w_i}{\frac{K}{m}-w_i^2}$$

At various values of w_i, from 1 to 2,000, the relationship between the phase lag and frequency was calculated.

Linearity of the system. A static pressure change was applied stepwise to the pressure-sensing tip in order to check the linearity of the system.

Thickness of the balloon. The thickness of the wall of the balloons was measured by affixing a cut piece of the balloon to a cork and viewing the cut edge of the balloon with a Wild Heerbrugg M-5 stereomicroscope.

Permeability. The permeability of a balloon was determined by putting air under pressure (40 mmHg) into the balloon and maintaining this static pressure for two h. Air leaking from the joint was strictly prevented. Air was the only gas tested.

RESULTS

Polyurethanes

Adiprene (ECD-651, Dupont). The response to a step function of the 5% single-dipped ECD balloon is shown in Fig. 2 and the undamped natural frequency was 53 Hz. The relationship between the relative amplitude and frequency is shown in Fig. 3. A 5% deviation of relative amplitude was noticed at 16 Hz. The balloon was almost impermeable and gave a linear response to a static pressure change (Fig. 4). Phase lag at various frequencies under steady state conditions was calculated and plotted in Fig. 5. As shown in this figure, at

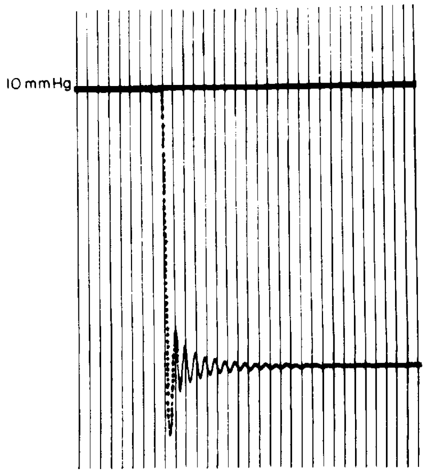


Fig. 2. Response of a polyurethane (5% ECD, dipped one time) balloon to a negative square wave pressure change. The undamped natural frequency is 53 Hz. Time lines are 0.02 s apart.

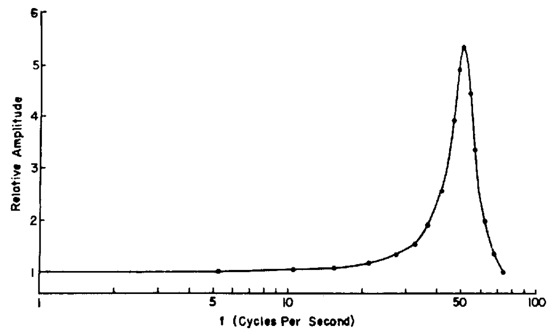


Fig. 3. The relationship between various frequencies and the relative amplitude of the polyurethane (5% ECD, dipped one time) balloon used in Fig. 2.

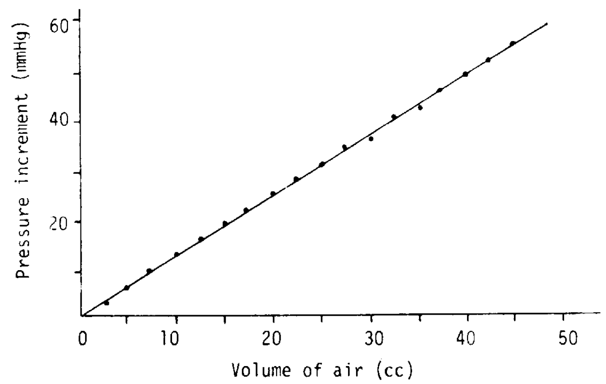


Fig. 4. Linearity of the pressure sensing balloon (5% ECD, dipped 2 times). 5 cc volumes of air were pumped successively into an air-tight glass bottle (873 cc) and pressure recording was made using an ECD balloon-catheter system. Ordinate ; pressure increment in mmHg and abscissa ; volume of air put into bottle (cc).

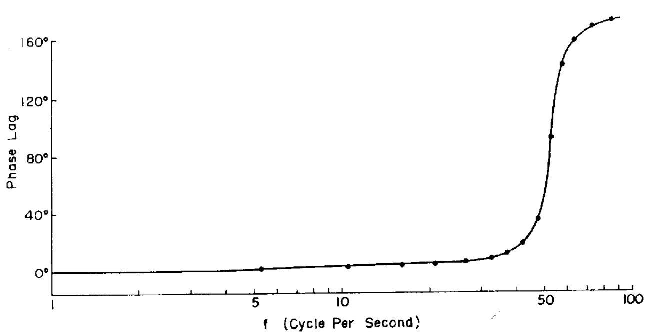


Fig. 5. Phase lag of air-filled polyurethane (5% ECD, dipped one time) balloon-cathteer system.

16 Hz phase lag was less than 5°. When the balloon-catheter system was used to record intraluminal pressure of the small intestine of an unanesthetized dog (6) for periods of 2-3 h, the pressure recording was quite satisfactory and no evidence of air leaking from the balloon was noted after the experiments. In imitation of the balloons located in the small intestine, when a balloon-catheter system was dipped into water and negative square pressure change was given, the response was almost critically damped. As the damping ratio of the system comes close to critical damping, 5% deviation from flat relative amplitude occurs at a frequency fairly close to the natural frequency (7, 8), so that the capability of an ECD balloon to detect the pressure would be improved inside the gut. The 80% decay time was 4 msec.

The thickness of the ECD balloon in various places is shown in Table 3: it was noticed that no remarkable difference in the thickness exists from one portion to another, and an increase in the thickness usually accompanied an increase in the number of dippings. Frequency response of a single material was not appreciably changed by the differences in thickness. This holds true for other balloons made in the same way.

TABLE 3. THICKNESS OF THE BALLOON[a]

	Top	Middle	Bottom
ECD			
5% 1 dip	13.8, 13.8, 13.8	12.8, 12.8, 12.8	13.8, 15.3, 15.3
	15.3, 15.3, 12.4	9.2, 9.2, 15.3	13.8, 12.2, 15.3
2 dips	15.3, 15.3, 12.4	15.3, 15.3, 15.3	15.3, 18.4, 15.3
	31.2	15.3	30.6
6% 1 dip	22.9, 18.4	30.6, 33.7	27.5, 30.6
2 dips	22.9, 18.4	48.9, 27.5	42.8
3 dips	30.6, 12.2	33.7, 30.6	42.6, 30.6
Estane			
33% 3 dips	32.1, 18.4, 30.2	38.3, 15.3, 30.6	15.3, 15.3, 33.6
	45.9	27.5	28.4
Saran			
10% 2 dips	15.3, 15.3, 15.3	15.3, 15.3, 15.3	15.3, 15.3, 15.3
	18.4, 12.4, 15.3	7.7, 9.2, 7.7	12.2, 15.3, 13.8

[a] (μ)

Since a natural latex balloon has long been used as a pressure-sensing tip in air-filled systems, frequency characteristics of a latex balloon were compared to those of an ECD balloon. When a latex balloon dipped 3 times was exposed to a step function, a natural frequency of 11.5 Hz was determined and 5% deviation from relative amplitude began at 5 Hz.

Polyurethane latex. The response of the urethane latex balloon dipped 10 times to the step function is similar to that shown in Fig. 2 before heat fusion. However, polyurethane latex is an aqueous suspension so that heating was necessary for the fusion of particles, otherwise the balloons easily soaked up water, swelled and crumbled shortly after intubation of the balloon-catheter system into the small intestine. Even when heated the fusion of particles is rarely complete and the balloons usually leak; and heating was also liable to cause deformation.

Estane. The undamped natural frequency of Estane balloons was 53 Hz. The system is linear. The balloon, however, is much more permeable to gas than is the ECD balloon. When an Estane balloon-catheter system was inserted in the small intestine of the dog, the balloon collapsed within a half an hour due to the leakage of air out of the balloon and the pressure recording ceased correspondingly.

Polyethylene Group

The response of polyethylene balloons made of a thin film to step function is somewhat different from those of the polyurethane group (Fig. 6). The response is apparently a third order response which is a summation of the first order response and the second order response. Small but rapid pressure changes with decreasing amplitudes (second order response) were superimposed on a slow pressure decrement (first order response). In order to determine the frequency characteristics of a polyethylene balloon, a Bode diagram analysis (9) was employed. The overall gain did not exceed 5% up to 3 Hz which is approximately

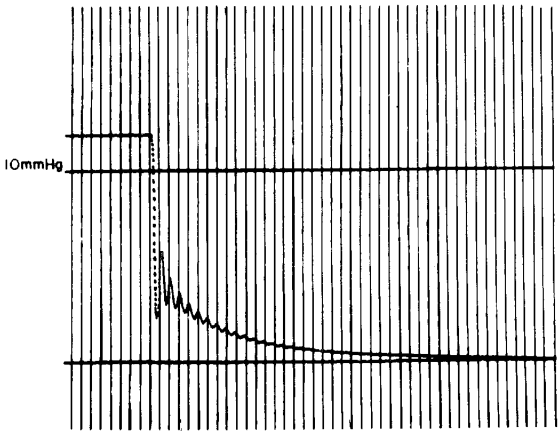


Fig. 6. Response of a polyethylene (0.025 mm thick) balloon to a negative square wave pressure change. A rapid oscillation dying away in a short while (second order response) superimposed on a slow decrement (first order response): overall response defined as a third order response.

the 10th harmonic of the basic rhythm of the intestinal movements. Fig. 7 shows the third order phase lag (ϕ_3) which was synthesized by the summation of the second order phase lag (ϕ_2) and the first order phase lag (ϕ_1) (9).

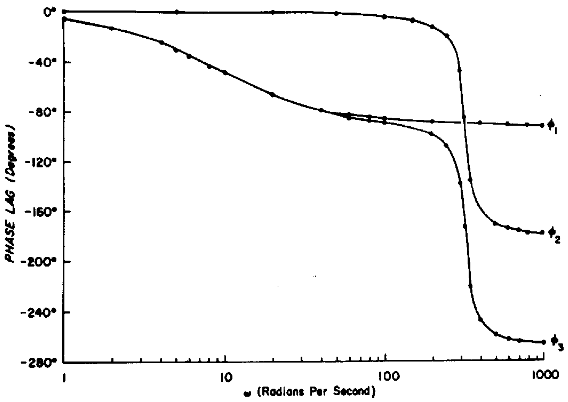


Fig. 7. Synthesis of the third order phase lag of polyethylene film (0.025 mm thick).

When low temperature (70°C) was applied for heat-sealing, this resulted in a smooth, even fusion; but in this case the joint did not withstand a moderate pressure (50 mmHg) applied to the inside of the balloon. High temperatures (100°C or more) brought about a tight seal, but deformation of the balloon was a common occurrence. An attempt to fabricate balloons from polyethylene powder by heat fusion of the particles was difficult to accomplish and was abandoned.

Polypropylene Group

A natural frequency of 29 Hz was determined (Fig. 8), and 5% deviation from

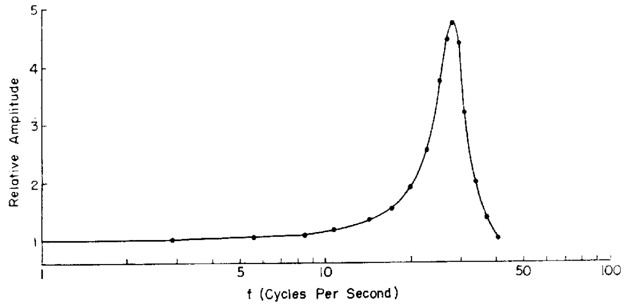


Fig. 8. The relationship between various frequencies and the relative amplitude of polypropylene balloon (0.013 mm thick).

flat relative amplitude occurred at 8.5 Hz which is adequate for pressure detection within the gut. The phase lag was negligible up to 10 Hz. However, the relative difficulty in making standard balloon renders this substance less desirable than others. Even when the balloons were sealed perfectly, they often burst during the process of intubation into an intestinal fistula of the dog. The same holds true for polyethylene balloons.

Polyvinylidine (Saran)

When a balloon made by dipping two times was exposed to a step function, a natural frequency of 53 Hz was determined. However, when a more nearly perfect square wave pressure change was applied, the balloon followed pressure changes oscillating at 95 Hz, but in this case some hysteresis was observed. At 23 Hz, 5% deviation from flat relative amplitude occurred.

The principal difficulty in making the balloon of this material is removing the balloon from the glass mold. After complete drying, the film became exceedingly thin and clung to the mold very tightly. The balloons are quite impermeable to air. When the Saran balloon-catheter system was used in the dog jejunum, the balloon did not leak and the pressure recording was quite satisfactory.

DISCUSSION

As a method for determining the frequency characteristics of a pressure-detecting system, there are two methods available (4, 8): 1) the measurement of the transient response of a system to a pressure step function and the subsequent calculation of the relationship between amplitudes versus frequencies, as employed in the present experiment, and 2) the direct measurent of the amplitudes of the output signals when sine wave pressure changes of constant amplitude are applied to the pressure-detecting system at various frequencies (forced vibration). In the former, it is assumed that the system can be tested as a system with one degree of freedom (lumped system) consisting of a concentrated mass, a spring and a constant friction force. However, this is not exactly true for the present system because of the distributed nature of the catheter, which is indispensable for connecting the balloon to the pressuee transducer. When the out-put signals are measured directly under the forced vibration, it is indispensable to have a very accurate sine wave pressure generator, which is extremely difficult to construct. In relation to this, it has been reported that both the sine wave pressure generator method and the step function method give a true description of the amplitude versus frequency relationship of a given pressure-detecting system, if they are handled properly (10). The frequency responses calculated from step function are quite similar to those measured by a sine wave pressure generator (10). It may not be unreasonable to assume that the calculated frequency response in the present experiment may give a fairly accurate determination of the frequency characteristics of the system.

It has been assumed that when the balloon was made by dipping a mold into liquid, the thickness of the wall would probably differ in different places and this would result in defective frequency characteristics and a distorted linearity. Contrary to expectation, the thickness of the balloon is practically uniform and this may provide satisfactory frequency characteristics of balloons.

In the present experiment, the most satisfactory substance was a polyurethane (ECD). The frequency characteristics were excellent, and the balloons are easy to make and virtually impermeable to air. Polyurethane latex is unsatisfactory because of the necessity for heat fusion which inescapably leads to the deformation of the balloon. Estane balloons meet the frequency characteristics required for intraluminal pressure detection but are too permeable to be used. It is possible that the use of solvents other than THF might give better results. Polyethylene and polypropylene require heat-sealing to make balloons: this is a difficult and tedious procedure. The transient response of polyethylene balloons to a step function is complicated and some hysteresis was noticed. In the case of polypropylene, while the way of making the balloon is similar to that for polyethylene, frequency characteristics are superior to those of polyethylene. The Saran balloon had desirable characteristics, but it is difficult to remove from the molds. Apart from this, Saran is an excellent material.

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