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Fabrication of Microballoons for Interventional Neuroradiology: Preliminary Report

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A simple and inexpensive method of making latex microballoons for neuroradiologic procedures is described. The balloons have been tested in experimental animals and used in human clinical procedures. Preliminary experience and results are presented.

High cost and limited availability of microballoons for neuroradiologic procedures stimulated us to investigate the feasibility of fabricating our own microballoons. We elected to use natural latex rather than synthetic rubber because of its superior elasticity and tensile strength [1].

Materials and Methods

Balloon Fabrication

The latex mixture (H1438, Cure D710; Heveatex Corp., Fall River, MA) is prepared (fig. 1) and allowed to mature at room temperature for 16 hr before use [2]. Before balloon manufacture, the mixture is agitated for 10 sec. The balloon former (tip of "Flow Through Stylet" 14-7032; Biosearch Medical Products, Somerville, NJ) is dipped into the latex mixture, withdrawn slowly, inverted, and allowed to dry at room temperature. This procedure is repeated four more times, producing a balloon with a wall thickness of 0.3 mm. After the fifth dip has dried, the balloon is vulcanized in hot air from a toaster oven, initially at an air temperature of 150°F (65.5°C) for 10 min and then at 250°F (121°C) for 20 min [3] (fig. 1). Stripping the balloon from the former is facilitated by soaking it in water overnight. The balloon is gently eased from the former by applying pressure at its neck. The new balloon is dusted with cornstarch powder to remove tackiness and is stored out of sunlight.

Calibrated-Leak Balloon System (fig. 2) [4]

The neck of a balloon is trimmed to a length of 2 mm. Next, the balloon is pierced with the tip of a thin wire (0.21 mm diam), making sure that the hole is exactly at the apex of the balloon. The tip of a flexible catheter (PUR-SIL-ORX, 0.45 × 0.85 mm; Balt S.A., Montmency, France) is coated with one drop of Bucrylate (Ethicon Inc., Somerville, NJ) and introduced in the dilated neck of the balloon, thus bonding it to the end of the catheter [1]. The attached balloon is inflated with water and its leak examined (fig. 3). If the balloon does not inflate adequately before leaking, it can be "trained" by grasping the pierced segment with Iris forceps and then reinflating the balloon with the hole closed (fig. 2, step 5).

Detachable Balloon System (fig. 4)

This detachable balloon system [5-7] incorporates a simple valve mechanism in the balloon neck. By using two concentric balloons, a valve is created, which eliminates the need for a ligature while retaining balloon detachability. The necks of two balloons are trimmed to lengths of 1 and 10 mm, respectively. The dome of the longer-necked balloon is pierced with the tip of a thin wire (0.26 mm diam), thus making a simple valve. At this stage, a small radiopaque

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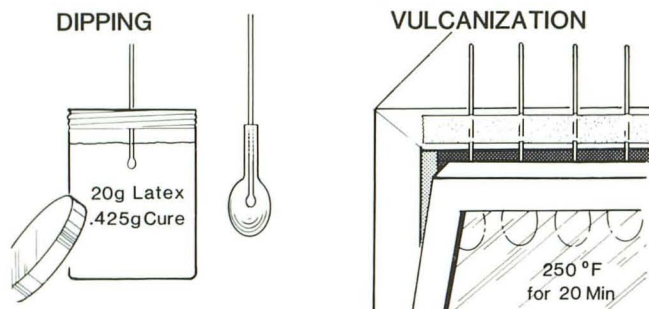


Fig. 1.—Method of balloon manufacture.

CALIBRATED-LEAK BALLOON

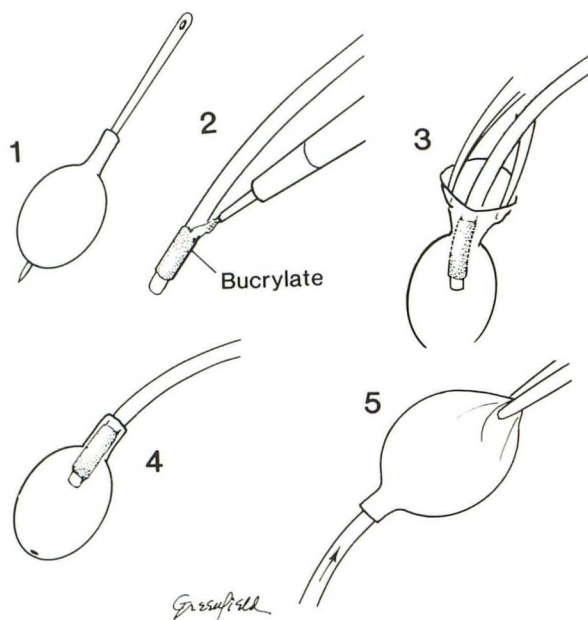


Fig. 2.—Construction of calibrated-leak balloon. Step 5 demonstrates balloon being "trained."

tungsten-carbide ballbearing (0.0275 inch [0.7 mm], Juliar Corp., East Granby, CT) can be introduced into the short neck balloon to act as a fluoroscopic marker. The pierced balloon is inserted into the short neck balloon using two Iris forceps. The necks of the two balloons are bonded together with one drop of Bucrylate, and the neck of the inner balloon is trimmed at the site of the Bucrylate application. The final outside diameters of the detachable balloon are 1.5 mm uninflated and 8.5 mm when inflated with 0.5 ml of fluid (fig. 5).

In vitro testing (fig. 6).—A 1.7 French polyethylene catheter (RPX010 Becton-Dickinson; Rutherford, NJ) with a slightly flared tip and filled with contrast material is introduced into the neck of the detachable balloon. The introduction is facilitated by a small amount of stopcock grease on the catheter tip. The catheter is further advanced until its tip crosses the valve. The integrity of the balloon and valve are tested by inflating the balloon to its maximum volume of 0.5 ml and withdrawing the catheter. The balloon is then deflated with a 23-gauge Luer stub adapter (7565, Clay Adams, Parsippany, NJ) and reattached to the polyethylene catheter for actual use.

In vivo application (figs. 6 and 7).—In the vascular system, the balloon and catheter may be advanced manually or by flow guidance. The balloon, inflated with contrast material, is detached by gentle but

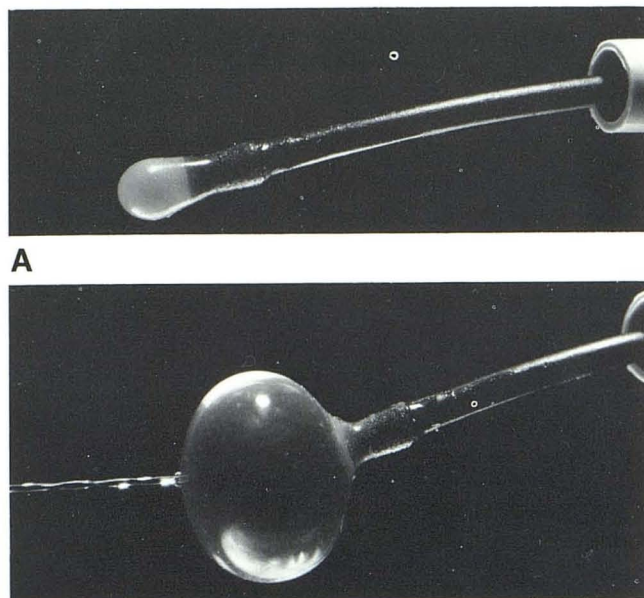


Fig. 3.—A, Calibrated-leak balloon uninflated. B, Inflated calibrated-leak balloon with flow rate of 1 ml/sec.

DETACHABLE-BALLOON

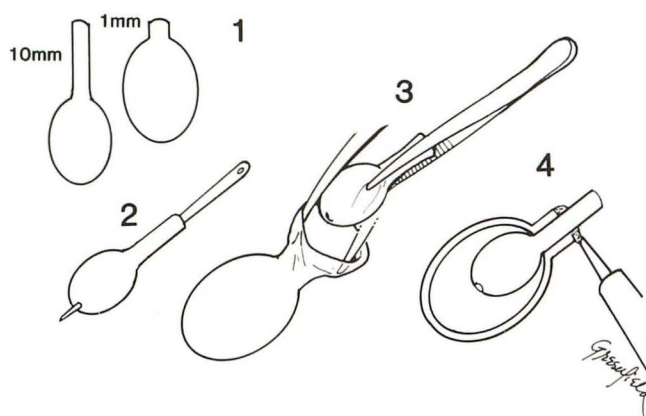


Fig. 4.—Construction of detachable balloon. For illustrative purposes, 10-mm-long-neck balloon has been diagrammatically represented smaller.

steady traction on the catheter. To study balloon reliability and longevity, we have detached 14 balloons in various arteries in four dogs and three rabbits. The balloons were inflated with metrizamide (220 mg I/ml). Weekly radiographs of the balloons were obtained for at least 6 weeks after balloon detachment. The only exception was in one dog that was sacrificed 3 hr after balloon detachment for reasons unrelated to this experiment. Two other dogs were evaluated by follow-up angiography, the first at 1 week and the second at 21 weeks after balloon detachment.

Sterilization of Balloons [8]

This can be achieved by sterilization in cold ethylene oxide gas, provided the balloon is aerated for 24 hr after removal from the gas

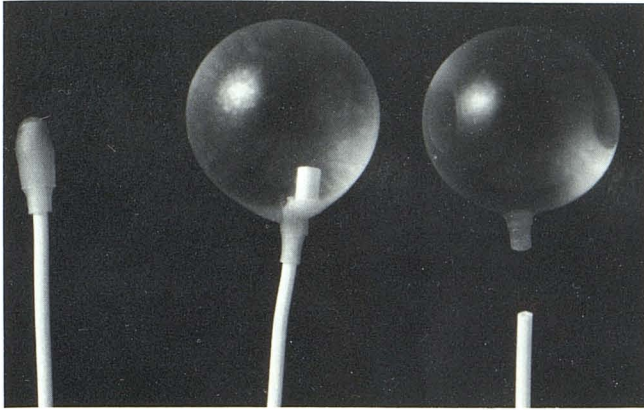
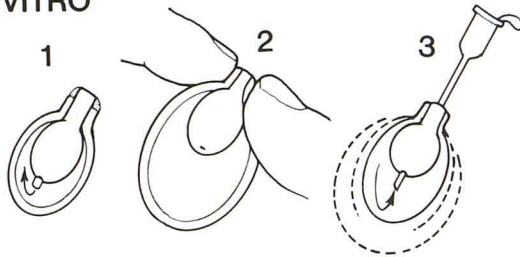


Fig. 5.—Detachable balloon catheter system.

DETACHABLE BALLOON

IN VITRO



IN VIVO

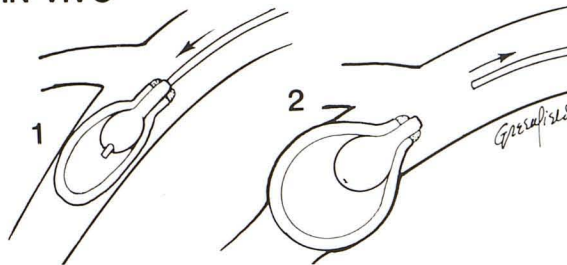


Fig. 6.—Testing and method of balloon detachment.

sterilizer. The detachable balloon, being an implantation device, may need 7 days aeration after sterilization.

Results

We first used the calibrated-leak balloon catheter in an animal model to gain experience with the system. Recently, since FDA approval, we have used this catheter system in 11 patients with no adverse effects. The detachable balloon, however, has so far been confined to animal use. The 14 detached balloons were observed for periods ranging from 3 hr to 21 weeks, depending on when the animals were sacrificed. In no case was the time of sacrifice related to any problem with the catheter-balloon system. The balloon that

was observed for only 3 hr after detachment remained fully inflated during that time. Only one of the 14 balloons exhibited slow deflation with reduction to half size after 1 week, resulting in an angiographically patent artery. All the other balloons (12 balloons) showed negligible or no reduction in size at 4 weeks when compared with the immediate postdetachment radiographs. One of these balloons was observed for 21 weeks, at which time it was estimated to be one-quarter of its original size, though at 8 weeks it had shown negligible deflation (fig. 7D). Angiography at 21 weeks demonstrated focal arterial occlusion by the balloon with the development of collateral vessels circumventing the occlusion.

An additional four balloons deflated immediately after detachment. This occurred early in the experimental series and prompted us to modify the balloon valve from a miter cut to a pinhole.

Discussion

We have found our method of balloon manufacture to be simple and speedy. It takes no more than half an hour to dip 50 balloons, each costing only a few cents. Stripping the balloons from the formers after vulcanization is easier when they have been soaked in water overnight. Our balloon discard rate due to faulty vulcanized latex was less than 10%. Our calibrated-leak balloon has been used for intracranial catheter navigation to enable superselective cerebral angiography, Bucrylate embolization of arteriovenous malformations, and chemotherapeutic perfusion of tumors.

The detachable balloon is easy to assemble, and its design permits testing balloon detachment and permanence of inflation before actual use. The valve and neck of the balloon grip the catheter just proximal to the flared end. This produces a union secure enough to prevent inadvertent balloon detachment. Premature balloon detachment has not occurred in any of our experiments, even with navigation along tortuous vessels. In fact, we are now lubricating around the tip of the catheter with stopcock grease to make balloon detachment easier, as withdrawal of the catheter needs a moderate firm force.

The tungsten-carbide ballbearing is an effective, inexpensive radiopaque marker that is easily inserted with forceps into the balloon before the introduction of the valve. We have not established the biocompatibility of tungsten carbide as an implantation device and therefore, at present, would not recommend its clinical use.

Our choice of balloon filler was arbitrary. We used metrizamide (220 mg I/ml) because of its accepted use and isotonicity in silicone balloons [7]. However, it is probable that natural latex does not possess properties of a semipermeable membrane like synthetic rubber. If this is so, then the tonicity of the contrast material filler is relatively unimportant. It seems that the deflation of a latex balloon with time is a slow leak through the neck of the balloon and depends on the integrity of the valve mechanism, which in most clinical instances has been an elastic ligature [5]. We think that once the pinhole inner balloon valve closes, it may prove to be more watertight than an elastic ligature.

Our limited experimental experience with an integral balloon

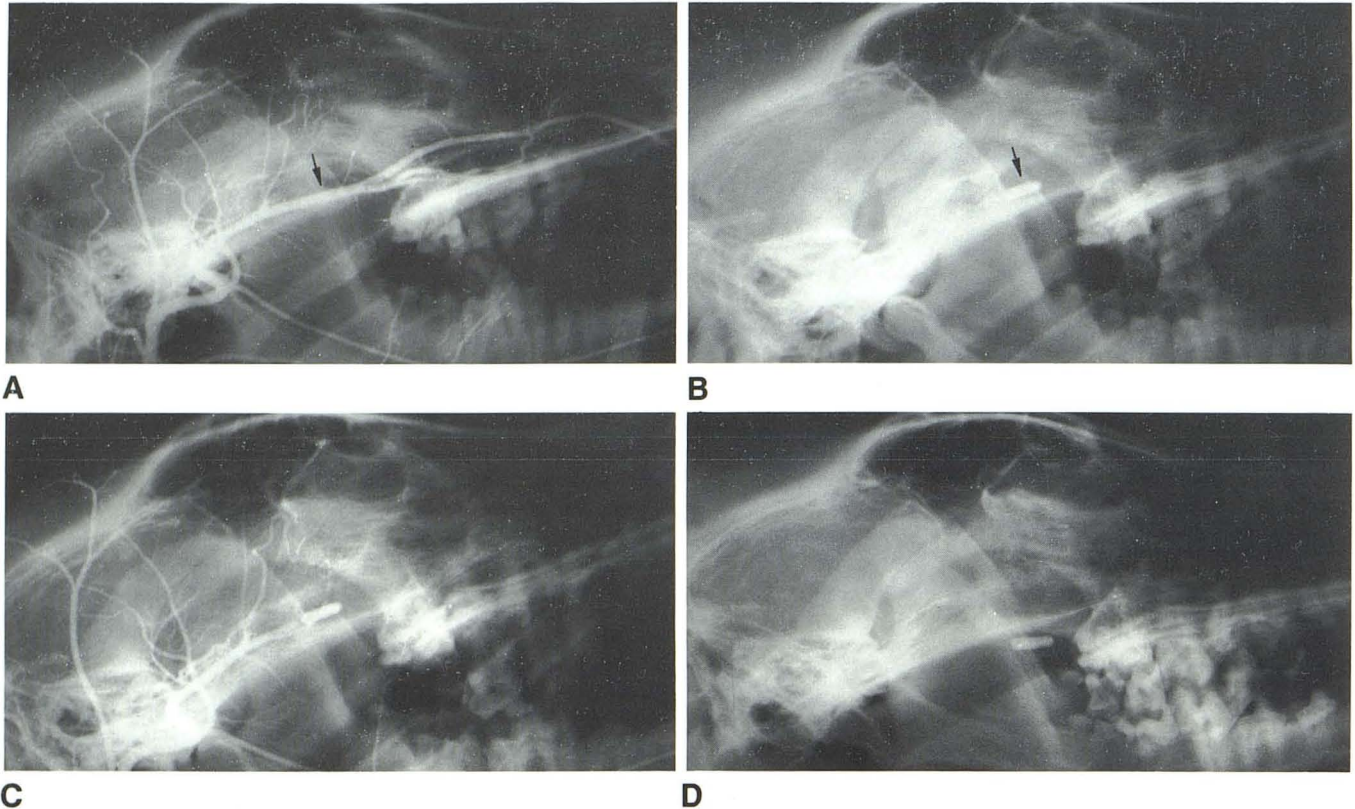


Fig. 7.—**A**, Carotid angiogram of dog shows course of internal maxillary artery (arrow). **B**, Balloon (arrow) attached to catheter positioned in distal internal maxillary artery. **C**, After detachment of balloon, distal internal maxillary

artery is occluded. **D**, 8 weeks later, balloon is still in place and remains inflated. Small tungsten-carbide ballbearing visible in balloon helped identify catheter tip during fluoroscopic manipulation.

valve so far has not been consistent enough to establish it as a clinically reliable alternative to an external elastic ligature. However, this work is preliminary, and we are continuing to adapt and improve our detachable balloon system to eventually assure total reliability for human use.

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