Physical Characteristics of Balloon Catheter Systems Used in Temporary Cerebral Artery Occlusion

John M. Mathis, John D. Barr, Charles A. Jungreis, and Joseph A. Horton

PURPOSE: To compare and contrast the physical characteristics of balloon catheter systems used for temporary cerebrovascular occlusion. **METHOD:** Commonly used temporary occlusion systems were evaluated to determine: (*a*) balloon compliance; (*b*) balloon diameter versus volume; (*c*) balloon pressure versus volume; (*d*) simulated vessel wall pressure versus volume; (*e*) balloon failure volume; and (*f*) balloon deflation rate. Observations were made concerning construction differences that affect the potential safety of a balloon system or the way it is used. **RESULTS:** The nondetachable balloon system demonstrating the best compliance characteristics and lowest radial pressure generation was the nondetachable silicone balloon (Interventional Therapeutics Corporation, San Francisco, Calif). Diameter versus volume curves for all systems reveal an initial nonlinear expansion that could contribute to vessel overexpansion during occlusion. **CONCLUSION:** Balloon systems vary in construction, method of introduction, and compliance. Knowledge of these characteristics, as well as of nonlinear balloon expansion, should aid balloon selection and appropriate use while helping to minimize complications.

Index terms: Catheters and catheterization, balloons; Interventional instrumentation, embolizing systems; Interventional neuroradiology, provocative testing

AJNR Am J Neuroradiol 15:1831–1836, Nov 1994

Balloon test occlusion of the internal carotid artery may be indicated as part of the preoperative work-up of aneurysms and tumors of the head, neck, and skull base when internal carotid artery sacrifice is planned or considered possible as part of therapy. At our institution, more than 500 temporary carotid occlusions have been performed using three types of balloon catheter systems (Mathis JM et al, "Temporary Balloon Test Occlusion of the Internal Carotid Artery: Experience in 500 Cases," presented at the 31st Annual Meeting of the American Society of Neuroradiology, May 14–20, 1993, Vancouver, British Columbia, Canada). The incidence of complications associated with balloon test occlusion was 3.2% in this series, with asymptomatic arterial injury (eg, dissection or pseudoaneurysm) comprising half (1.6%) of these complications. Other authors have reported complication rates as high as 15% (Mehta B et al, "Safety and Cost Effectiveness of Carotid Balloon Occlusion Test," presented at the 31st Annual Meeting of the American Society of Neuroradiology, Vancouver, British Columbia, Canada). The injudicious use of balloon occlusion catheters has been shown to produce significant arterial injury in animals (see Figure 4). Because of the potential for vascular injury, the physical characteristics of nondetachable balloon catheter systems commonly used for temporary carotid occlusion were studied. System characteristics evaluated include: (*a*) unconstrained balloon inflation pressure versus volume; (*b*) balloon diameter versus volume; (*c*) constrained radial pressure generated during inflation; (*d*) balloon failure volume; and (*e*) balloon deflation rate. Better understanding of these characteristics, construction parameters, and introduction requirements are believed to be useful in appropriate system selection for varying clinical situations. Optimal catheter se-

Received September 23, 1993; accepted after revision April 5, 1994.

From the Division of Neuroradiology, University of Pittsburgh.

Address reprint requests to John M. Mathis, MD, MS, Department of Radiology, Division of Neuroradiology, University of Virginia Health Sciences Center, Box 170, Charlottesville, VA 22908.

AJNR 15:1831–1836, Nov 1994 0195-6108/94/1510–1831

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lection and use may help minimize potential complications.

Materials and Methods

Catheter systems included in this evaluation were: (*a*) 5.0-F Swan-Ganz (Edwards Laboratory, Anasco, PR); (*b*) ITC-nondetachable silicone balloon (NDSB) (1509) (Interventional Therapeutics Corp, San Francisco); and (*c*) 5.0-F (OB/5/2/100) and 7.0-F (OB/7/2/100) Meditech (Boston Scientific, Meditech, Watertown, Mass).

The 7.0-F Meditech is only rarely used at our institution. It has, however, been used more regularly by other investigators and is therefore included in this evaluation (1–3).

Unconstrained balloon diameter-versus-volume curves were generated with balloon diameters measured using a digital caliper (Mitutogo, Minato-Ky Tokyo, Japan) during incremental 0.05-mL volume changes between 0 and 1 mL. Accurate volumetric balloon inflation was achieved with an electrical syringe pump (Harvard Pump, Model 975; Harvard Apparatus, South Natick, Mass). Five balloons of each type were tested. Each balloon was inflated twice for measurement. The resulting measurements were averaged.

Unconstrained balloon pressure versus volume measurements were obtained simultaneously. Balloon pressures were monitored in a closed system with a pressure-to-voltage transducer (Model PX105, Omega Instruments, Stamford, Conn) connected to a strip chart recorder (Model 1201, Cole-Palmer Instrument, Niles, Ill). As with the diameter-versus-volume measurements, pressure-versus-volume curves for each balloon type were averaged.

Constrained balloon pressure-versus-volume measurements for these same systems were obtained by inflating the balloons inside a rigid (glass) tube having 0.5-cm internal diameter. The difference between constrained and unconstrained pressures at each balloon volume gives the radial force exerted by the balloon on cylinder wall. This force represents a first-order estimate of the radial force exerted by the balloon on a vessel wall during balloon overinflation (inflation beyond the point at which the balloon surface contacts the inner vessel wall creating occlusion).

Balloon deflation rates were determined using the average times for deflation from a 1-mL volume with a 1-mL syringe. Again, five balloons of each type were tested twice and the resultant times averaged.

Finally, balloon failure volumes were obtained with overinflation of each system until ultimate balloon rupture. Five balloons were examined in each category and the results averaged.

Discussion

Catheter Design

The construction and materials used for these catheter systems vary considerably and affect the manner in which they are used and introduced. The ITC-NDSB balloon is made of silicone with a thin 2-F shaft of polyethylene that is very supple. Both the Swan-Ganz and Meditech balloons are latex. The Swan-Ganz catheter shaft is polyvinyl chloride and less rigid than the similar sized Meditech catheter made of polyethylene. Shaft rigidity was easily demonstrable by holding equal lengths of the catheter shafts horizontally and observing the relative bending. The most supple catheter shaft is that of the ITC-NDSB, followed by the Swan-Ganz. The least supple catheter in this evaluation is the 7.0-F Meditech.

The Swan-Ganz and Meditech systems are double lumen, allowing arterial stump pressure measurements or infusion through the central lumen simultaneously with balloon inflation/occlusion. Visualizing arterial waveform damping during inflation is helpful to achieve the minimal inflation necessary to provide arterial occlusion. Arterial occlusion can be verified by injecting contrast material through the catheter's central lumen and observing the static contrast column produced. The ITC-NDSB balloons have a single-lumen configuration, and arterial measurements or injection through the catheter are not possible. Occlusions with this balloon can be verified by contrast material injection through the guiding sheath used for balloon introduction.

Balloon catheter introduction into the carotid is dictated by catheter design as well. The 5.0-F Swan-Ganz catheter requires a 6.0-F sheath (Terumo, Meditech) for easy insertion into the femoral artery. The catheter can be shaped over steam into a standard cerebral configuration, allowing easy engagement of brachiocephalic origins. It is then flow directed into the carotid artery, obviating the need for an introductory wire under most circumstances. The central lumen is small but will accept a 0.010-inch guide wire (Target Therapeutics, Fremont, Calif). This wire can be useful, on occasion, in directing the catheter tip when simple flow guidance is problematic. The 5.0-F and 7.0-F Meditech catheters can be inserted through 6.0-F and 8.0-F sheaths, respectively. The catheter shafts are rather stiff and are introduced into the carotid artery over a 0.025-inch or 0.038-inch exchange wire, respectively.

The ITC-NDSB is introduced through a long guiding sheath, which also is coaxially placed in the appropriate carotid over an exchange wire.

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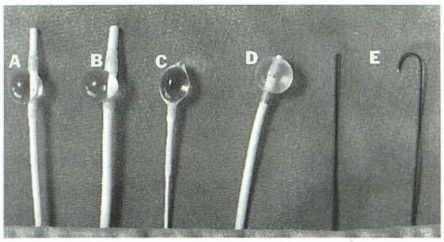

Fig 1. *A*, 5.0-F Meditech; *B*, 7.0-F Meditech; *C*, ITC-NDSB (1509); *D*, 5.0-F Swan-Ganz; and *E*, straight and J-tip exchange wires. All balloons are inflated to 5-mm diameter, which approximates working volume for internal carotid occlusion. Note the asymmetric balloon inflation of Meditech systems (*A* and *B*) relative to the catheter shaft.

The minimum guiding sheath size is 7.3-F, which can be placed through an 8.0-F sheath in the femoral artery. The NDSB catheter is flow directed outside the guiding sheath. The central lumen of the catheter will accept a 0.016-inch guide wire (Target Therapeutics, Fremont, Calif) if slight balloon deflection or torque control is needed. Because the guide wire occupies most of the cross-sectional area of the catheter lumen, passing the wire through the fluid-filled catheter causes the balloon to distend. Slow insertion of the wire is required to prevent inadvertent balloon inflation. The ITC-NDSB catheter is very soft and, in combination with the small balloon size, is the system most easily maneuvered beyond areas of carotid tortuosity or narrowing.

Balloon Inflation Characteristics

Both the Meditech and Swan-Ganz balloons have a nearly spherical configuration during expansion. The Swan-Ganz symmetrically expands around the inner catheter core. The Meditech, at small, physiologic volumes, has a more asymmetric inflation configuration with respect to the catheter shaft, with one side of the balloon expanding away from the catheter (Fig 1). The catheter and balloon-catheter junction are thus forced against the vessel intima during occlusion. Additionally, the Swan-Ganz balloon is mounted more distally on the catheter shaft than is the Meditech. Hence, there is a stiff catheter tip protruding beyond the balloon on the Meditech system. The ITC-NDSB has an elliptical configuration. The short axis of the ellipse increases slowly with inflation, and this balloon conforms well to a tubular vascular lumen. Because the balloon is mounted at the catheter end, there is no protruding tip.

Analysis of balloon expansion revealed nonlinear diameter-versus-volume and pressure-versus-volume curves that were typical of elastic systems (4). Although the pressure/diameter-versus-volume curves were different for each balloon, the general curve appearances were quite similar in each case (Figs 2 and 3). Balloon diameter-versus-volume curves were initially nonlinear, with rapid balloon expansion beginning between 0 and 0.1-mL inflation volume. The human internal carotid artery diameter is approximately 5 mm in diameter above the carotid bulb. This means that balloon volumes between 0.1 and 0.2 mL are needed to produce vessel occlusion. All balloons operated in or near the nonlinear portion of their diameter versus volume curve at these volumes. Operator awareness and careful attention to detail are needed to avoid balloon overinflation during occlusion. The rapid, nonlinear diameter changes may contribute to vascular injury during tempo-

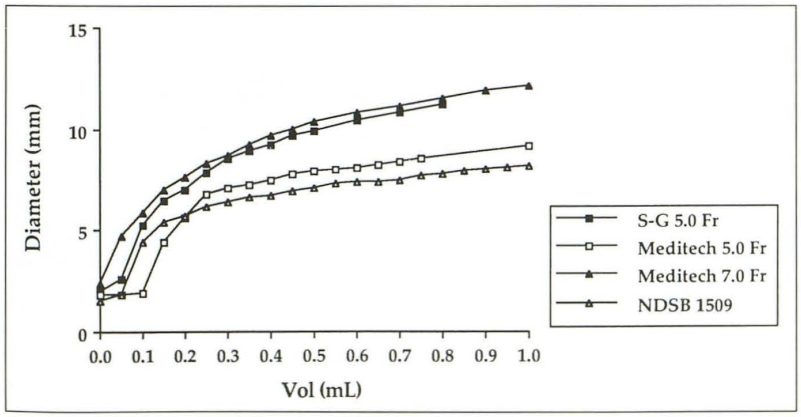

Fig 2. Balloon diameter-versus-volume curves. Note that all balloons exhibit a nonlinear expansion between 0- and 5-mm diameter. This characteristic indicates that small volume changes during inflation result in relatively large changes in diameter.

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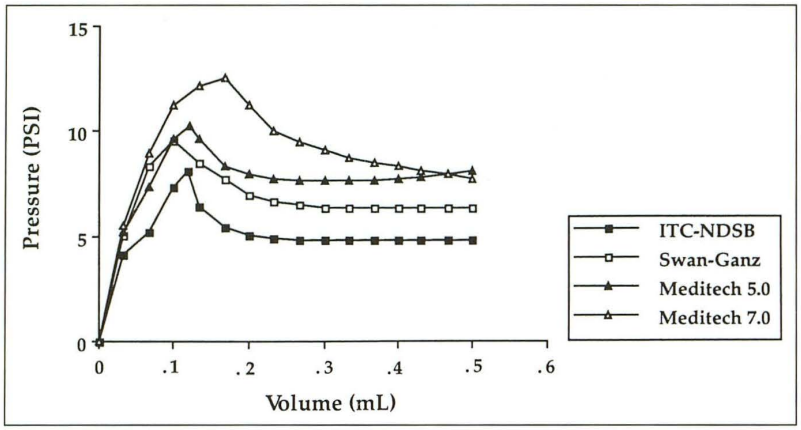

Fig 3. Balloon pressure-versus-volume curves. All balloon curves show a typical high-pressure peak during the early phase of balloon expansion. This high-pressure phase abates as the constituent polymer makeup of an elastic material is altered by expansion. The lowest nonconstrained pressure is found in the ITC-NDSB, whereas the 7.0-F Meditech displayed the largest expansion pressures.

rary occlusion, as shown in a carotid artery of a Rhesus monkey where overinflation of a latex balloon by 0.1 mL resulted in focal wall disruption (Fig 4).

The pressure-versus-volume curves reveal an initial pressure peak coinciding with slow balloon expansion that abates as the constituent polymer makeup of the balloons is altered. Initial high balloon-inflation pressures decrease, and a secondary linear pressure versus volume curve results. Pressure-versus-volume curves for all balloons have similar configurations (Fig 3), with the highest nonconstrained pressure generated in the Meditech 7.0-F. The lowest nonconstrained pressure, signifying the softest and most compliant balloon, is found in the ITC-NDSB.

Constrained pressures generated during balloon inflation inside a rigid cylinder were recorded versus volume. The differential between constrained and unconstrained pressure at each volume represents the radial pressure that the balloon exerts on the rigid cylinder wall during overinflation (inflation beyond what is necessary to produce circumferential contact between the balloon and the cylinder inner wall). This differential pressure also represents a first-order approximation of the force produced on a vessel wall during balloon overinflation. When the balloon is inflated to minimal occlusion diameter, the effective pressure generated on the cylinder wall is zero. With progressive overinflation, the pressure on the restricting cylinder wall increases (Fig 5). The largest differential pressure was produced by the Meditech 7.0-F balloon. The Swan-Ganz and Meditech 5.0-F balloons were intermediate and almost identical. Very little expansile wall pressure was generated during inflation of the ITC-NDSB, because of the more compliant nature of the silicone balloon and its elliptical shape, which allows predominate expansion along the vessel axis rather than perpendicular to the wall. These qualities of the silicone balloon system make it least likely to produce wall damage during inadvertent balloon overexpansion.

Deflation rates for each balloon were analyzed and showed similar and rapid deflation for the Meditech 7.0-F, ITC-NDSB, and Swan-Ganz balloons (Fig 6). The slower rate of deflation for the Meditech 5.0-F indicated a smaller balloon catheter lumen dictated by the 5.0-F outside diameter and double-lumen configuration capable of handling a 0.025-inch guide wire. (The 5.0-F Swan-Ganz has a larger balloon lumen allowing more rapid deflation but a smaller cen-

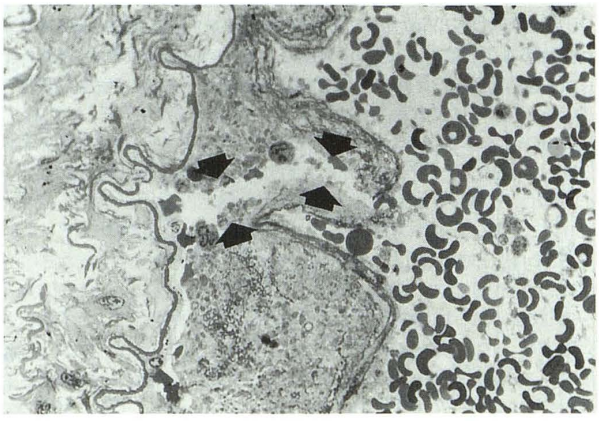

Fig 4. High-power photomicrograph of a rhesus monkey internal carotid artery after temporary balloon occlusion. Transmural arterial injury resulted after 0.1-mL balloon inflation beyond occlusion (*arrows*). Red cells adjacent to the wall injury represent a red cell thrombus in the arterial lumen.

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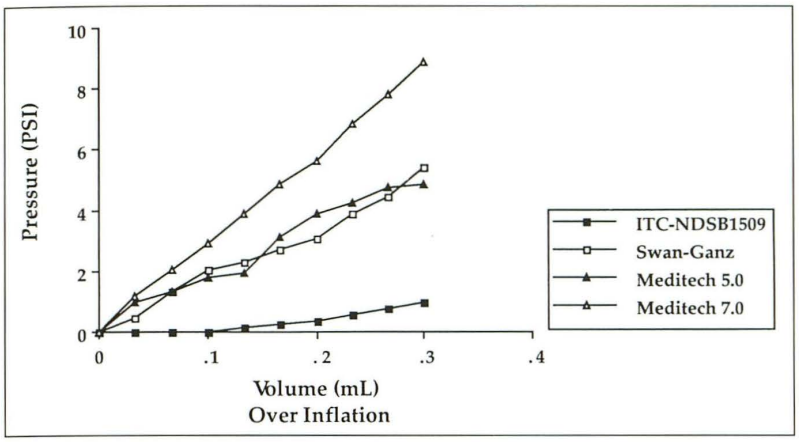

Fig 5. Constrained balloon pressure-versus-volume curves. Radial balloon pressure exerted on the wall of a rigid constraining cylinder is plotted versus balloon inflation beyond the point of luminal occlusion (overinflation). Minimal radial pressure is generated by the silicone balloon (ITC), whereas all latex balloons show a higher pressure per volume of overinflation and faster rate of pressure rise.

tral lumen capable of accepting only the 0.010-inch guide wire.)

Balloon failure was tested, with progressive inflation, to the point of balloon rupture (Fig 7). The volume required to create balloon rupture far exceeded that needed to achieve complete occlusion of the internal carotid artery and in all cases was greater than the maximum the manufacturer recommended.

Electron Microscopy

The balloon surface comes into intimate contact with the vessel wall during occlusion, as may the balloon-catheter junction when there is asymmetric inflation as noted with the Meditech systems. Scanning electron micrographs were obtained of the balloons and balloon-catheter junctions to evaluate for surface irregularities that might cause problems during use. The balloon surfaces were smooth in all cases with no significant surface features greater than 1 μm in size. The balloon-catheter junctions of both latex balloons (Swan-Ganz and Meditech) were somewhat raised or irregular. The height and thickness of this junction was approximately 10 μm in the Meditech system (Fig 8). At physiologic expansion volumes, the nonconcentric expansion of this system could potentially expose this junction to the vascular intima. However, the concentric Swan-Ganz inflation prevents its junction from contacting the vessel wall directly during occlusion (Fig 9). The ITC silicon balloon surface and balloon-catheter junctions were quite smooth by comparison (Fig 10).

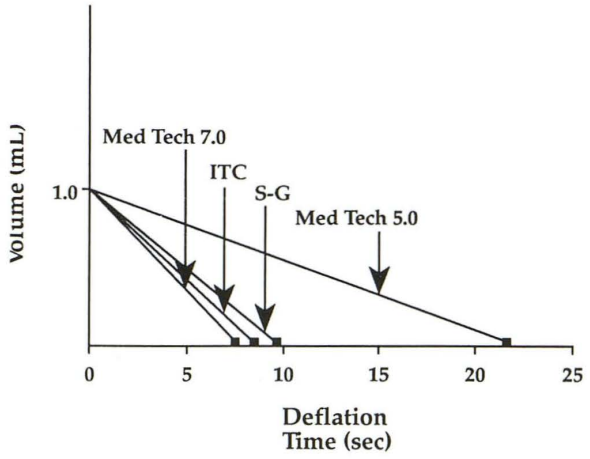

Fig 6. Balloon deflation rate starting from a 1.0-mL initial volume. The considerably slower balloon deflation of the 5.0-F Meditech is created by making a central catheter lumen that will accept a 0.25-inch guide wire at the expense of small balloon catheter lumen.

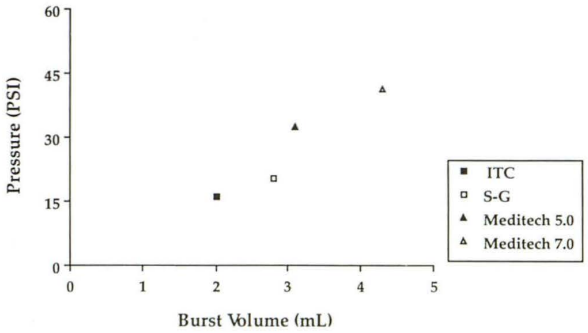

Fig 7. Balloon failure (burst) pressure versus volume. Balloon failure occurs at volumes that greatly exceed the volume needed for temporary carotid occlusion in all systems. (Typical occlusion volumes range between 0.1 and 0.2 mL.)

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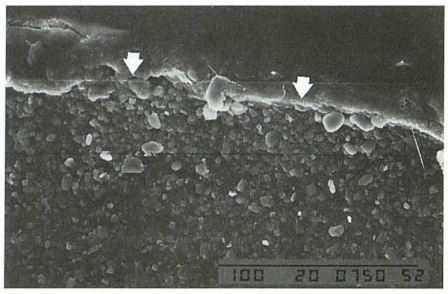

Fig 8. Scanning electron micrograph of Meditech balloon-catheter junction. The linear scale at the bottom is 100 μm. Junction irregularities of approximately 10 μm are present (*arrows*).

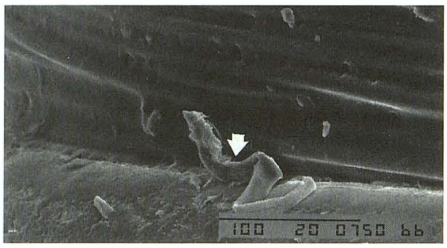

Fig 9. Scanning electron micrograph of Swan-Ganz balloon-catheter junction. (Linear scale, 100 μm.) In general, the junction between the balloon and catheter is smooth. Occasional material artifacts were detected (*arrow*).

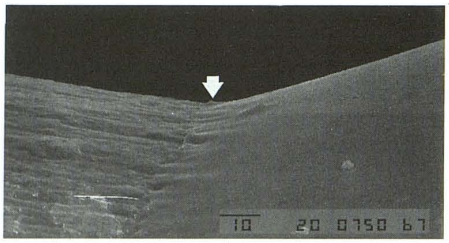

Fig 10. Scanning EM of ITC-NDSB (1509) balloon-catheter junction. (Linear scale, 10 μm.) The balloon-catheter junction (*arrow*) is smooth without significant surface irregularities.

Conclusions

This study demonstrated that the most compliant system was the ITC-NDSB and that inadvertent inflation of this balloon beyond the point of luminal occlusion produced the smallest amount of radial pressure on a constraining wall. The supple catheter shaft and flow-guided placement of this balloon make it likely to be the least traumatic of the nondetachable systems tested when used beyond tortuous or stenotic areas and above the skull base.

The initial asymmetric expansion of the Meditech balloons places a relatively irregular balloon-catheter junction adjacent to the vascular intima during inflation. This irregular junction could represent a possible mechanism for intimal damage and, along with trying to minimize the radial pressure on the arterial wall during occlusion, points out the need to guard against balloon overinflation.

The Swan-Ganz catheter has intermediate compliance characteristics for systems in this evaluation. Its steam-shapeable polyvinyl chloride shaft, double-lumen construction, and flow-guided placement make it a very useful balloon catheter for routine applications.

All catheter systems tested have been used successfully for temporary endovascular occlusion of the internal carotid artery. Appropriate selection of a balloon catheter should be aided by knowledge of the physical characteristics of these systems and of the requirements of each clinical situation. This knowledge combined with careful introduction and inflation by an experienced operator should keep complications to a minimum.

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