

# Evaluation of manufacturing variability, diffusion of filling solutions, and long-term maintenance of occlusion in silicone hydraulic occluders

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**Objective**—To evaluate manufacturing variability, diffusion of filling solutions, and maintenance of occlusion over time in 3 sizes of silicone hydraulic occluders (HOs).

**Sample Population**—2-, 5-, and 20-mm HOs (HO2, HO5, and HO20, respectively).

**Procedures**—Manufacturing variability was analyzed by comparing variation in internal luminal areas and filling volumes within each size group. Occluders were filled to 100% occlusion with air (n = 4), saline (0.9% NaCl) solution (4), or sodium hyaluronate (4) and submerged in simulated body fluid. Changes in luminal area and weight were recorded for 133 days to evaluate maintenance of occlusion.

**Results**—Considerable variability in uninflated luminal area and fill volumes was observed among the 3 sizes of HOs. Loss of occlusion developed in the first 12 hours in all air-filled HOs. Fluid-filled occluders were reliable in maintenance of occlusion after 133 days (99.99% for HO20, 99.59% for HO5, and 90.40% for HO2), although diffusion of saline solution and hyaluronate from all HOs was confirmed by detection of significant decreases in weight over time. There was no significant difference in weight loss between HOs filled with saline solution and HOs filled with sodium hyaluronate.

**Conclusions and Clinical Relevance**—Saline solution or sodium hyaluronate may be used as a filling solution in the HOs tested. Maintenance of occlusion was best in the larger sizes. Saline solution or sodium hyaluronate should be used in future clinical investigations of HOs. Retrograde filling to remove air should be used when filling HOs with fluid. (*Am J Vet Res* 2006;67:1453–1458)

Hydraulic occluders consist of an inflatable silicone membrane inside a polyester-reinforced stretch-resistant cuff. Inflation of the HO can be controlled percutaneously via injection of fluid into an SC injection port attached to the occluder by a length

## ABBREVIATIONS

HO	Hydraulic occluder
SH	Sodium hyaluronate
SBF	Simulated body fluid

of actuating tubing (Figure 1). Chronic implantation of silicone HOs was first described in experimental models in 1969.<sup>1</sup> More recently, clinical applications for HOs in dogs, including use as an artificial urethral sphincter<sup>2</sup> and as a means of gradual venous occlusion for surgical treatment of adrenal gland neoplasia<sup>3</sup> and congenital portosystemic shunts,<sup>4,5</sup> have been reported.

Despite extensive experimental use, little information has been published regarding the precision and reliability of silicone HOs in situations requiring chronic implantation. Hydraulic occluders are individually hand assembled at present by gluing silicone sheets and tubing together in the desired size and configuration with liquid silicone. Early experiences with HOs raised concerns that manufacturing variability could lead to differences in initial lumen size and filling volumes, negatively affecting precision when planning partial occlusion or making adjustments in chronic applications. In addition, silicone acts as a semipermeable membrane, and the diffusion properties of various filling solutions may affect long-term maintenance of occlusion.<sup>6–11</sup> To date, no standard filling solution has been evaluated for long-term maintenance of occlusion. The purposes of the present study were to evaluate different sizes of the same HO models, diffusion of various filling solutions (eg, saline [0.9% NaCl] solution, SH, and air), and maintenance of occlusion in 3 sizes of HO. Our hypotheses were that there would be considerable variation in occluder size as a result of the hand-manufacturing process, that high-molecular-weight filling solutions would undergo the least diffusion and yield the most reliable maintenance of long-term occlusion, and that air would diffuse rapidly through the HO membrane.

## Materials and Methods

**Devices**—Two-, 5-, and 20-mm-internal diameter HOs (HO2, HO5, and HO20, respectively) were obtained from the same manufacturer.<sup>2</sup> Five- and 20-mm HOs were included to represent the range of sizes that would be appropriate for use in dogs with extrahepatic and intrahepatic portosystemic shunts, respectively. Although 2-mm HOs are not intended for use in clinical practice, the HO2 was evaluated in an

Received October 4, 2005.

Accepted February 24, 2006.

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Supported in part by a University of Florida Intramural Resident Research Grant.

Presented as an abstract at the 2005 American College of Veterinary Surgeons Veterinary Symposium, San Diego, October 2005.

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attempt to explain variations in filling volume that were previously reported<sup>5</sup> in a rat model of gradual venous occlusion.

**Preparation of HOs**—All HOs were prepared in a similar manner prior to each experiment. The actuating tubing was cut to a length of 12 cm, and the incomplete ring of each noninflated HO was closed by tying a strand of 3-0 polypropylene suture material<sup>b</sup> through the preexisting holes molded at the ends of the HO cuff. Actuating tubing was secured to an injection port<sup>c</sup> with 2 circumferential ligatures of 3-0 polypropylene. Each HO was leak-tested and exercised by means of 5 cycles of complete inflation and deflation, as recommended by the manufacturer. All injections were performed by use of noncoring huber point needles<sup>d</sup> to minimize the potential for leakage from the membrane of the injection port.

**Evaluation of size differences among HOs**—Five each of the HO2s, HO5s, and HO20s were used to evaluate differences in size among occluders of the same model. The closed, noninflated HOs were placed on a flatbed scanner,<sup>e</sup> and digital images were obtained and saved to a desktop computer for analysis. The internal luminal area of each HO was traced and calculated 3 times by one of the authors (LLA) by use of commercially available software.<sup>f</sup> To minimize measurement error, the mean of those 3 measurements was calculated and used as the luminal area for each HO. Individual luminal area measurements for the 5 HOs were used to calculate a mean value for luminal area for the HO2s, HO5s, and HO20s.

**Variation in filling volume among HOs**—Eight each of the HO2s, HO5s, and HO20s were filled with saline solution (n = 4) or SH<sup>g</sup> (4) with a 1-mL tuberculin syringe for HO2s and HO5s and with a 3-mL syringe for HO20s. Occlusion was confirmed by direct visualization of the occluder lumen, and fluid volumes required to obtain 100% occlusion were recorded to within 0.01 mL.

**Long-term maintenance of occlusion and diffusion of filling solutions**—Eight HOs of each size were randomly assigned to be filled with saline solution (n = 4 each of HO2, HO5, and HO20) or SH (4 each). Saline solution was chosen because it has previously been evaluated<sup>12</sup> and because of its iso-osmolarity, ready availability, and low cost. Sodium hyaluronate, a high-molecular-weight, sterile, isotonic solution, was chosen on the basis of earlier experiences in our laboratory<sup>1</sup> and because of existing literature suggesting that high-molecular-weight fluids are less likely to diffuse through the silicone membrane of the HO.<sup>10</sup> Hydraulic occluders were prepared as described. Injection ports were primed, and HOs were filled in a retrograde direction with a 22-gauge catheter to eliminate air.<sup>4</sup> The closed, noninflated HOs were placed on a flatbed scanner,<sup>e</sup> and digital images were obtained. The HOs were inflated with saline solution or SH through the injection port until complete occlusion of the visible lumen was observed, after which they were digitally scanned to confirm 100% occlusion and weighed to a precision of 10<sup>-3</sup> g on a laboratory scale.<sup>h</sup> Occluders were submerged in a bath of SBF maintained at 37°C.<sup>13</sup> The SBF was replaced weekly. Occluders were removed from the SBF once every 7 days for 56 days and again at 91 and 133 days to be dried, scanned, and weighed. Digital scans were analyzed with a software program to determine mean internal luminal area at each measurement. Those values were compared with the initial noninflated mean luminal area value for each HO to calculate the percentage of occlusion with the following formula<sup>2</sup>:

$$\% \text{ occlusion} = \frac{\text{LA of noninflated occluder (cm}^2\text{)} - \text{LA of inflated occluder (cm}^2\text{)}}{\text{LA of the noninflated occluder (cm}^2\text{)}} \times 100$$

where LA is luminal area.

**Changes in internal pressure**—Single HO2s, HO5s, and HO20s were used to evaluate changes in internal pressure over time. All HOs were exercised prior to use before being prepared for pressure monitoring (Figure 2). Actuating tubing was secured to the injection port, T-port,<sup>i</sup> and brass fitting with 3-0 polypropylene ligatures and additional silicone<sup>l</sup> to eliminate leakage. Normal saline solution was used to prime the injection port and fill the HO, actuating tubing, and brass fitting in a retrograde manner, and care was taken to eliminate air trapped in the closed system. The apparatus was attached to a pressure transducer<sup>k</sup> and process meter,<sup>l</sup> which were in turn connected to a desktop computer for data storage and analysis. After assembly, HOs were filled via the injection port with additional saline solution until occlusion was complete and were scanned to verify 100% occlusion. The occluders, with the injection port and all actuating tubing, were submerged in a bath of SBF that was maintained at 37°C and changed weekly.<sup>13</sup> Pressure monitoring was initiated when HOs were completely

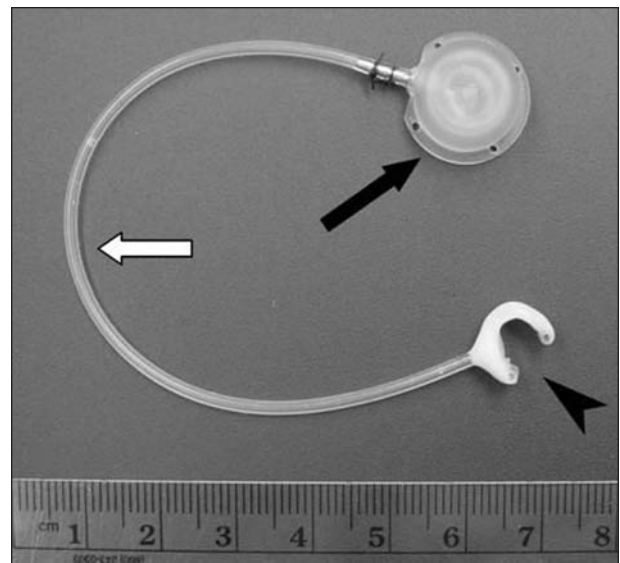


Figure 1—Photograph of an open, noninflated, 2-mm-internal diameter HO (arrowhead) attached to an SC injection port (black arrow) via a length of actuating tubing (white arrow).

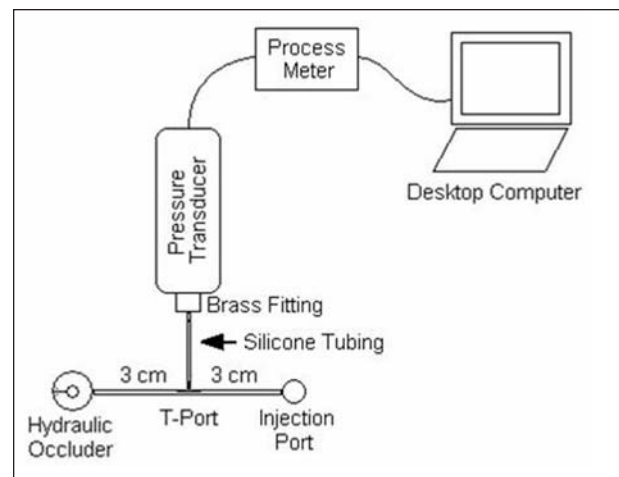


Figure 2—Schematic diagram of the experimental setup used for evaluating changes in internal pressure in HOs. Pressure in the closed system was monitored 24 h/d by the desktop computer; values were recorded hourly, and data were saved for statistical analysis.

occluded and submerged in the SBF. Software that enabled 24-hour pressure monitoring<sup>m</sup> was used to record HO internal pressure hourly for 30 days.

**Diffusion of air through HOs**—Four each of HO2s, HO5s, and HO20s were evaluated. All HOs were tested for leaks and exercised prior to use. All HOs were prepared in a similar fashion, with actuating tubing cut to a length of 12 cm and attached to an injection port by two 3-0 polypropylene ligatures. A huber point needle was used to fill HOs with air until complete occlusion was observed, and inflated HOs were scanned to verify 100% occlusion. Occluders were submerged in a bath of SBF maintained at 37°C and removed once every 4 hours for scanning; images were saved for later analysis. A

computer software program<sup>f</sup> was used to trace and calculate the mean internal luminal area and percentage of occlusion of each HO at each time period for statistical analysis.

**Statistical analysis**—A repeated-measures ANOVA was used to evaluate changes in weight and percentage of occlusion over time. Values of  $P < 0.05$  were considered significant. A Fisher least-squares difference post hoc test was used to test for interactions when appropriate.

## Results

**Evaluation of size differences among HOs**—Mean values for closed, noninflated HOs ranged from 3.80 to 5.30 mm<sup>2</sup> for HO2s, from 15.60 to 18.90 mm<sup>2</sup> for HO5s, and from 222.70 to 285.50 mm<sup>2</sup> for HO20s. Mean luminal area values for each of the 3 HO sizes as well as mean luminal area values and SDs for the 5 individual HOs of each model were summarized (Figure 3).

**Variation in filling volumes**—Filling volumes varied substantially among HOs of the same size. Volumes ranged from 0.05 to 0.10 mL for the HO2s (mean  $\pm$  SD, 0.07  $\pm$  0.015 mL), from 0.11 to 0.26 mL for the HO5s (0.18  $\pm$  0.05 mL), and from 2.4 to 3.0 mL for the HO20s (2.7  $\pm$  0.232 mL). During filling, it was observed that closure of the HOs did not proceed in a circular pattern, but, proceeded primarily from 2 sides, resulting in an oval shape of decreasing width.

**Long-term maintenance of occlusion and diffusion of filling solutions**—A small leak was observed at the seam of the balloon in one of the HOs from the HO5 group during leak testing and filling (Figure 4); data from that HO were omitted from statistical analyses.

A significant ( $P < 0.001$ ) decrease in weight was observed in all HOs, indicating that filling solutions diffused from the HOs in measurable volumes during the 5-month data collection period. However, type of filling solution (saline solution vs SH) had no significant effect on loss of weight over time (HO2,  $P = 0.128$ ; HO5,  $P = 0.281$ ; HO20,  $P = 0.599$ ). Decrease in weight over time was analyzed (Figure 5), and values for mean decrease in weight in both saline solution- and SH-filled HOs were summarized (Table 1). Despite the observed decreases in HO weight, long-term maintenance of luminal occlusion in the HOs was excellent in the HO5 and HO20 groups (99.59% and 99.99%, respectively). However, a significant loss of occlusion was observed in the HO2 group (9.6% loss over 133 days;  $P < 0.001$ ).

Type of filling solution and loss of occlusion over time were significantly ( $P = 0.008$ ) related in the HO2 group. Saline-filled HO2s underwent a mean loss of 18.32%, whereas SH-filled HO2s had a mean loss of 0.81%. Data for changes in percentage of occlusion over time were presented graphically (Figure 6).

Pressure changes over time for HO2s, HO5s, and HO20s were plotted (Figure 7). The smaller HOs generated higher internal pressure at filling and had more

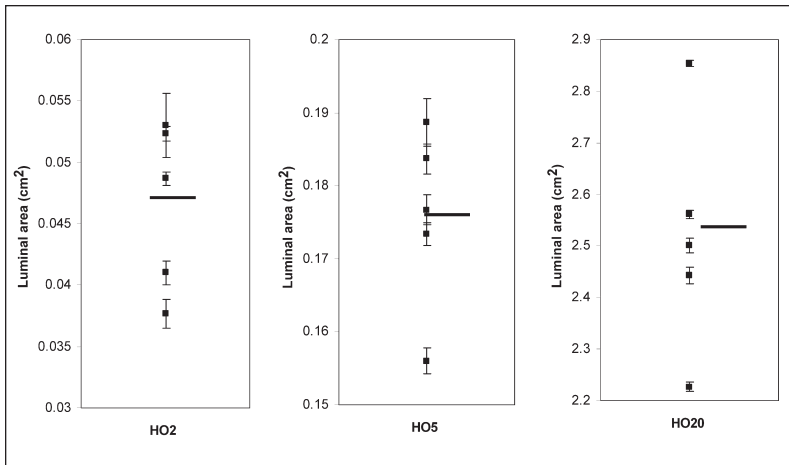


Figure 3—Scatterplots depicting the differences in noninflated luminal area among 5 each of the 2-mm- (HO2), 5-mm- (HO5), and 20-mm- (HO20) internal diameter HOs. Three measurements of luminal area were obtained for each HO. Each square represents the mean luminal area for an individual HO, and error bars represent 1 SD above and below the mean luminal area. Overall mean luminal area for each of the HO sizes is represented by the single bold bar in each plot.



Figure 4—Photograph of an HO5 with a small leak and associated bubble of saline (0.9% NaCl) solution along the seam of the inflatable balloon that was detected during leak testing.

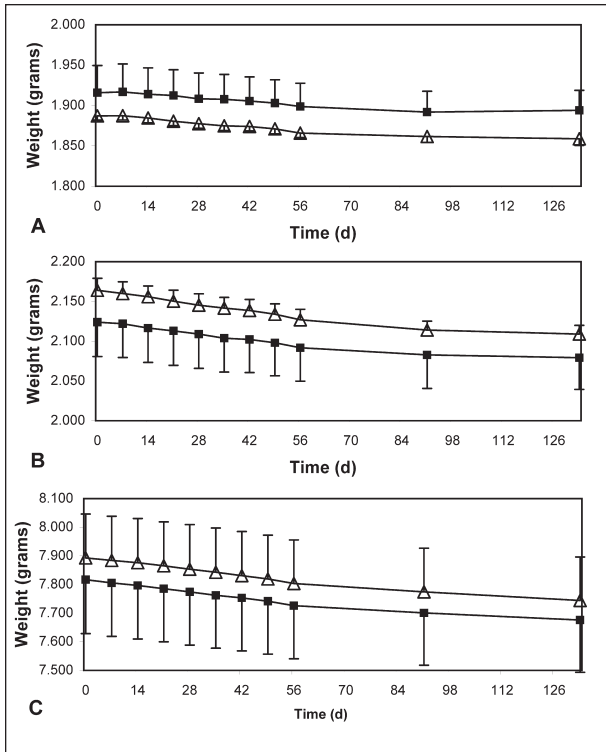


Figure 5—Mean weight loss for HO2s (A), HO5s (B), and HO20s (C) filled with saline solution (triangles) or SH (squares) and submerged in a bath of SBF at 37°C for 133 days. Error bars represent 1 SD.

Table 1—Mean  $\pm$  SD weight loss (in grams) in 2-mm- (HO2), 5-mm- (HO5), and 20-mm- (HO20) internal diameter HOs filled with saline solution or SH and submerged in a bath of SBF for 133 days. Weight loss during that interval was significant ( $P < 0.001$ ) for all HO sizes tested. Notice that type of filling solution was not significantly related to weight loss over time (HO2,  $P = 0.1284$ ; HO5,  $P = 0.281$ ; HO20,  $P = 0.599$ ).

HO size	Type of filling solution	
	Saline solution	SH
2 mm	0.028 $\pm$ 0.002	0.022 $\pm$ 0.008
5 mm	0.055 $\pm$ 0.003	0.045 $\pm$ 0.003
20 mm	0.149 $\pm$ 0.002	0.141 $\pm$ 0.007

rapid loss of pressure, compared with larger HOs. The most important pressure losses in all HOs occurred in the first 5 days.

**Diffusion of air through the HO**—A significant ( $P < 0.001$ ) loss of occlusion was observed in all air-filled HOs during a 12-hour period (Figure 8). A significant ( $P < 0.014$ ) interaction was also observed between change in occlusion over time and HO size, with more rapid loss of occlusion occurring in the smaller HOs.

## Discussion

This in vitro evaluation revealed a number of issues that should be considered prior to clinical application of HOs. First, wide variations in luminal area and filling volume were observed among units obtained from a single manufacturer. In addition, fluid leakage was noticed from a hand-sealed seam in one

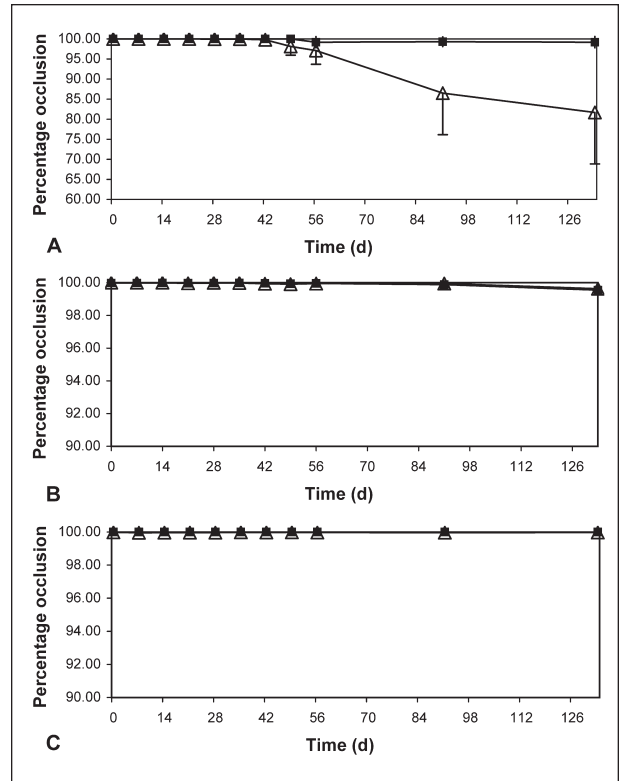


Figure 6—Mean change in percentage of occlusion over time for HO2s (A), HO5s (B), and HO20s (C) filled with saline solution (triangles) or SH (squares) and submerged in a bath of SBF at 37°C for 133 days. Error bars represent 1 SD.

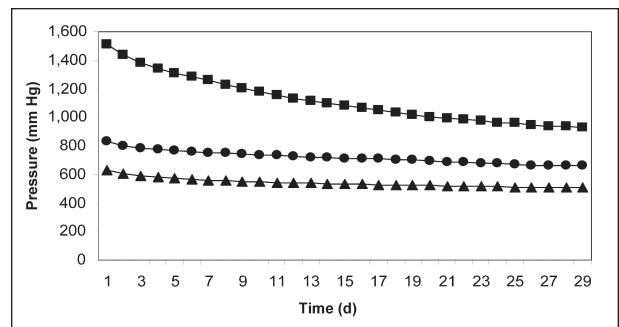


Figure 7—Change in internal pressure for HO2s (squares), HO5s (circles), and HO20s (triangles) filled with saline solution and submerged in a bath of SBF for 29 days.

HO5 during initial leak testing. Manufacturing inconsistencies were most substantial in the smaller HOs, in which small changes in filling volume can represent substantial changes in occlusion. Resolution of these manufacturing inconsistencies would likely require that the current hand-sealed assembly process be replaced by a more precise alternative. We recommend that investigators adhere strictly to manufacturers' recommendations on leak testing prior to use of HOs. We also recommend that investigators determine the filling volume and luminal area for each HO rather than relying on standardized filling schedules during gradual or partial occlusion.

A second concern in long-term biological application of silicone HOs is diffusion of filling solutions and subse-

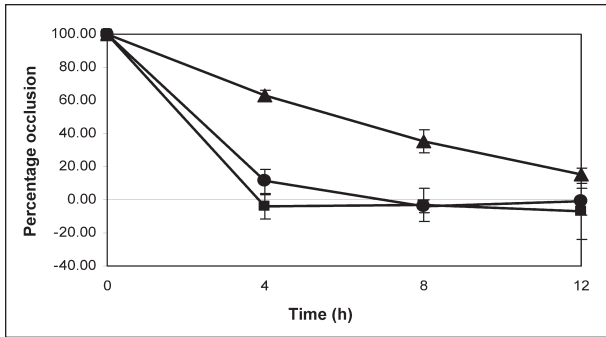


Figure 8—Mean change in occlusion over 12 hours for HO2s (squares), HO5s (circles), and HO20s (triangles) filled with air and submerged in a bath of SBF. Notice the more rapid loss of occlusion in the smaller HOs. Error bars represent 1 SD.

quent deflation of the implant. Polydimethylsiloxane, generally referred to as silicone, is a highly cross-linked, largely bioinert elastomer that has been used extensively in the manufacture of medical implants since the late 1940s.<sup>14,15</sup> It is a semipermeable material, and diffusion of various solutions and solutes across silicone membranes has been well described.<sup>6-11</sup> Various solutions have been used to fill silicone HOs, including normal saline solution,<sup>12</sup> hypertonic saline solution,<sup>16</sup> water,<sup>17</sup> radiographic contrast solutions,<sup>18</sup> indocyanine green dye,<sup>19</sup> and dextrose solution.<sup>20</sup> Despite the permeability of silicone, all of those types of solutions have been used successfully in experimental applications and no ideal filling solution for long-term use has been reported. In the present study, saline solution and SH were reliable at maintaining occlusion during a 133-day period in the larger HOs (ie, HO5 and HO20), although loss of occlusion was observed in 2 HO2s. No significant difference was observed when comparing loss of weight or occlusion between saline solution-filled HOs and those filled with SH in the HO5 or HO20 groups. However, a significant difference in maintenance of occlusion between HO2s filled with saline solution and those filled with SH was observed. Those filled with saline lost occlusion to a greater extent (mean, 18.32%) than those filled with SH (0.81%). Interestingly, no significant difference was detected when comparing changes in weight over time between those 2 groups, suggesting that diffusion of saline solution from the HO was not the cause of the discrepancy. Had more occluders been evaluated in the HO2 group, it is possible that a significant interaction between filling solution and weight loss may have been detected. In addition, loss of occlusion was not consistent among the saline solution-filled HOs. Only 2 HOs in the saline solution-filled HO2 group had significant loss in occlusion, whereas the other 2 saline solution-filled HOs maintained > 98% occlusion. A possible explanation for the loss of occlusion seen in the HO2 is plastic deformation of the silicone actuating tubing or balloon secondary to high initial filling pressures, resulting in greater potential fill volume and therefore an overall loss of occlusion. The HO2 was assembled from the same material as the HO5, but was subjected to higher pressures at filling, which may have increased the likelihood of plastic deformation. However, if pressure-induced plastic deformation was the cause of the loss of occlusion observed in the HO2, it is unclear why only 2 of the 8 HO2s used in this experiment were affected.

To effectively measure and verify the diffusion of filling solution, several conditions must be satisfied. First, the *in vivo* environment of the implant must be closely reproduced in an *in vitro* situation. Next, a baseline value with which changes in filling solution volume can be compared must be established, and third, changes in filling volume must be quantified with a high degree of sensitivity, accuracy, and reproducibility.<sup>10</sup> In the present study, implants were submerged in SBF maintained at 37°C to simulate the temperature, pH, and ion concentrations in plasma.<sup>10,13</sup> Although SBF has been used for evaluating diffusion of filling solutions from silicone implants, the fact that the osmotic environment in which the HOs were tested may not be identical to that found in canine clinical patients must be taken into account. Implants were weighed and noninflated and inflated luminal area determined prior to submersion in SBF to provide a baseline measurement for future comparisons. Weight and luminal area determinations are precise means by which serial measurements could be obtained with a low SD. Measurable weight loss, as well as loss of occlusion, developed in all HOs over time, a finding that suggests gradual loss of filling solution. Small changes in HO weight were noticed prior to visible loss of occlusion. This may be explained by the fact that weight change is a more sensitive test and that small volumes of filling solution may have been lost before it was visibly evident as loss of occlusion. It is also possible that the HOs were inadvertently overinflated while being filled to the point of complete occlusion. In that situation, excess filling solution could initially diffuse out of the HO without affecting occlusion.

Air was displaced from the HO rapidly, compared with saline solution and SH, with significant deflation of the HOs developing over a 12-hour period. Permeation of air and other gases through silicone membranes has been reported and implicated in other biomedical applications.<sup>6</sup> The rapid diffusion of air through the silicone HO has functional pertinence, even when fluid filling solutions are used. Unless great care is exercised during filling of the HOs with fluid solutions, small air bubbles may be trapped in the balloon. Trapped air displaces liquid filling solution upon initial occlusion and may cause rapid deflation as air diffuses from the HO. The effects of loss of such small volumes of air would likely be more important in HO2s than in HO5s and HO20s as a result of the smaller initial filling volume. Interestingly, the data suggest that when proper inflation technique is used with fluid filling solutions (eg, saline solution and SH), diffusion of air bubbles does not appear to cause an acute loss of occlusion in the silicone HO. Thus, results of the present study not only indicated that air diffuses rapidly through the HO membrane and is inappropriate for long-term applications, they also reinforced the importance of eliminating as much air as possible during the fluid-filling process to avoid premature deflation.

The 2-mm HOs were less reliable at maintaining occlusion, compared with the 5- and 20-mm HOs, and

the internal pressure generated in the HOs at complete occlusion was much higher in the smaller implants. The high initial filling pressure creates a hydrostatic pressure gradient that favors diffusion of the filling solution out of the HO. Because HO2s and HO5s are constructed of the same silicone sheeting, the likelihood of filling solution diffusing from the HO2 is greater because of the higher internal pressure. The membrane and actuating tubing used in construction of the HO20 are thicker. This property, in combination with the lower initial filling pressure, makes the HO20 less subject to hydrostatic pressure and diffusion of filling solution than smaller HOs. Despite the high filling pressure and thin materials used in construction of the HO2s, weight changes over time did not support differences in the rate of fluid diffusion from the smaller HOs.

Shortcomings of the present study included the small number of occluders used in each group. Had more HOs been evaluated, small differences between the filling solutions may have been recognized statistically. Although weight changes over time had been previously evaluated in a pilot study and were considered to be reliable, it is possible that incomplete or inconsistent drying or degradation of the silicone over time may have contributed to the changes observed. However, incomplete drying should have resulted in increases in weight over time, as opposed to decreases. The authors are unsure as to whether degradation of silicone would have been important and detectable over the 133-day study period. Instead of using desktop scans to evaluate changes in the HOs, it may have been more ideal to evaluate changes in all 3 dimensions to evaluate external stretching over time.

The present study revealed variable filling volumes and differences in the initial luminal area of 2-, 5-, and 20-mm HOs. In addition, one of the HOs failed an initial leak test because of rupture at a hand-sealed seam. Results suggest that improvements in the manufacturing process are needed to achieve precise and reliable performance. However, with proper leak testing and filling techniques, saline solution and SH yielded reliable maintenance of occlusion over a 133-day period, particularly in the HO5 and HO20 sizes. Air is not an acceptable filling solution for chronic applications because of its rapid diffusion from the HO. Similarly, investigators are cautioned to use a careful retrograde filling technique to ensure air removal during filling with fluid. Smaller HOs such as HO2 were less reliable for maintaining occlusion over extended periods of time; as such, their use in clinical applications may be more limited.

- a. DOCXS Biomedical Products and Accessories, Ukiah, Calif.
- b. Surgilene, Davis and Geck, Wayne, NJ.
- c. ROPAC-3.5, Access Technologies, Skokie, Ill.

- d. Posi-Grip huber point needle, Access Technologies, Skokie, Ill.
- e. HP Scanjet 4470 C, Hewlett-Packard Co, Palo Alto, Calif.
- f. ImageJ 1.27Z, National Institutes of Health, Bethesda, Md.
- g. Hylartin V, Pharmacia & Upjohn Co, Kalamazoo, Mich.
- h. APX-203, Denver Instrument, Arvada, Colo.
- i. T-5S-CS-UF, Access Technologies, Skokie, Ill.
- j. Silastic, Dow Corning Corp, Midland, Mich.
- k. PX 603-030G5V, Omega Engineering Inc, Stamford, Conn.
- l. DP25 B-E-A, Omega Engineering Inc, Stamford, Conn.
- m. IOX 1.6.7.9, EMKA Technologies, Falls Church, Va.

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