Bronchoalveolar Lavage Trap Valve

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Table of Contents

Abstract

Bronchoalveolar lavage is a procedure that obtains a lung effluent sample by injecting saline solution into the lungs, removing it, and depositing it into a specimen trap. If the specimen trap is freely hanging in space, however, manipulation of the bronchoscope can lead to inversion of the trap and loss of sample to the vacuum line. In order to address this issue, we designed a ball and cage attachment to a widely used BAL trap, which acts to cut suction when the trap is inverted, eliminating the risk of losing the effluent sample.

The design attaches a ball and cage valve between the trap and the tubing to the vacuum source to form a seal between the trap and suction when the trap is tipped at least than 90°. The final prototype was manufactured with proprietary plaster powder and a cyanoacrylate glue using a rapid prototyping machine. A steel ball and rubber stopper were then inserted.

Initial testing was completed and dimensions were modified over three prototypes to optimize design performance. Further testing confirmed functionality of the modified prototype. Future work will consider dimension and material changes, restrictions imposed by mass production, and medical standards.

Background

Bronchoalveolar Lavage

Bronchoalveolar lavage (BAL) is a procedure performed on immuno-suppressed patients to collect an aqueous lung tissue sample for laboratory analysis (Prakash *et al.* 2007). Because this analysis often leads to a workable diagnosis, preserving the collected effluent sample safely and consistently is critical to an affected patient's health and comfort (Lee 2004).

The process of BAL involves the skilled use of specialized equipment. A flexible bronchoscope, suction tubing, vacuum source, and sterile collection trap work in unison to obtain the effluent sample (Dugdale and Medoff 2008). The flexible bronchoscope has a long, thin tube with a lighted end to allow the doctor to view the airway (WebMD 2007).

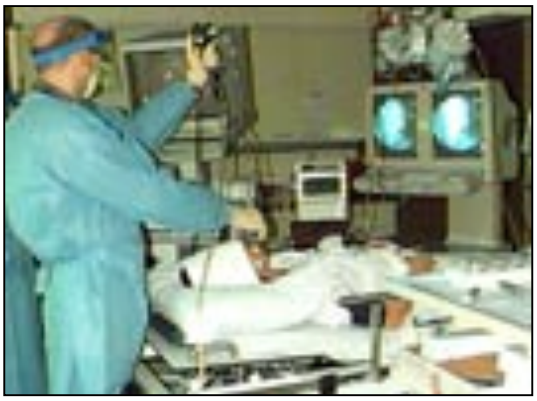

Figure 1. A pulmonary specialist maneuvers flexible bronchoscope within patient.
Image courtesy of Department of Respiratory Care
http://www.uihealthcare.com

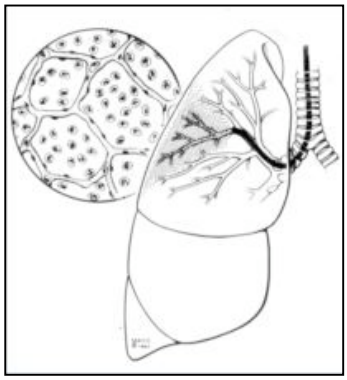

Figure 2. View of flexible bronchoscope wedged into bronchiole. Close-up shows cells that will be washed into effluent solution.
Image courtesy of "The Art of Bronchoscopy"
http://www.bronchoscopy.org

First, the patient is either anesthetized locally or generally, depending on age and condition. Children are usually put under general anesthesia. The flexible bronchoscope is inserted into the trachea via the nose or mouth and maneuvered into one lobe of the lung, where the tip of the scope is then tightly wedged into a bronchiole. A camera located at the tip of the scope allows the specialist to visually investigate the area (NHLBI 2008).
Once the scope is positioned firmly in the bronchiole, the bronchoscope is connected to the vacuum source with tubing that is 1.2 to 2.2 mm in diameter. Approximately 100 mL of 0.9% saline solution is injected through the scope into the bronchiole, washing epithelial cells from the pulmonary wall into the saline solution (Oulu University 2000). These cells represent the contents of millions of alveoli. The aqueous sample is then suctioned out of the bronchiole, and deposited into a specimen trap. Excess sample is suctioned through the trap and into a waste container (Prakash *et al.* 2007).

After the sample is collected, it is sent to a laboratory for analysis and subjected to several tests. The results of these analyses can then be used to diagnose malignancies, alveolar hemorrhage, or infection in the lungs of the patient (American Registry of Pathology 2007).

Problem Statement

In the current procedural setup, the specimen trap is free hanging and unstable (Figure 3). Manipulation of the bronchoscope and surrounding movement can displace the trap resulting in loss of sample to the vacuum line. When the trap is inverted, the vacuum quickly pulls the sample solution to the trash trap where it is irretrievable. The loss of sample can cost up to $4,000 because the procedure may need to be redone. This is inconvenient for all involved, but especially for the patient, as there is special risk associated with a procedure performed under general anesthesia.

Figure 3. The specimen trap is free hanging causing unwanted movement of the trap upon scope movement.

Figure 4. The tubing on specimen trap that connects to the scope can be attached to the vacuum connection to enclose the system.

An additional aspect of the problem with the current trap is the method of transportation to the lab. The sample could ideally be transported in the specimen trap as displayed in Figure 4, however it does not meet the general laboratory transportation requirements. These requirements include a tightly sealed container that could be sent through hospital pneumatic tube systems without concern of sample leakage and thus contamination of the system.

Current Solutions and Competitive Designs

The current solutions to avoid loss of sample are effective but inconvenient. The first solution involves crudely taping the specimen trap to the bronchoscope. This solution, however, prevents the doctor from having a secure grip on the scope and limits ability and accuracy. The second solution requires additional personnel to hold the specimen trap steady and upright throughout the procedure. However effective, this method is undesirable and expensive.

For transportation within the UW Hospital, the current solution is to transfer the sample from the trap to a sterile urine cup. This transfer carries the additional risk of sample loss due to spilling. It is also wasteful and costly since both the trap and urine cup are disposed after use. Although not used by the UW Hospital, Covidien currently sells specimen traps with an extra secure cap to ensure ease of transport (Covidien 2009).

Several patents involving the specimen trap have been issued, but in our research we found none that completely solve the problem of losing sample during the BAL procedure. Some examples of the many specimen trap patents are the "Polyp Screen," which aims at preventing solid samples from being lost to the vacuum source (Rogers & Caldwell 2006) and the "Sterile Specimen Trap," which addresses the issue of sample contamination during transport (Sauer 1974). These designs, however, do not address problems associated with sample loss. Because sample loss is a serious inconvenience for to many patients and physicians, there have been a few notable attempts to design a solution: the "Endoscope Suction Trap" (Nakao *et. al* 1994) and the "In-line Specimen Trap" (French *et. al* 2002).

The "Endoscope Suction Trap" design involves the use of a removable vial (Figure 5). A vial is originally connected to the suction line and the liquid sample can be deposited in it as the sample is suctioned out of the body. Then, the vial can be removed from the vacuum line and there is a sliding piece on the design that can be moved over the empty space to reseal the system. This way, the vial can be removed immediately after the sample is collected, which reduces the

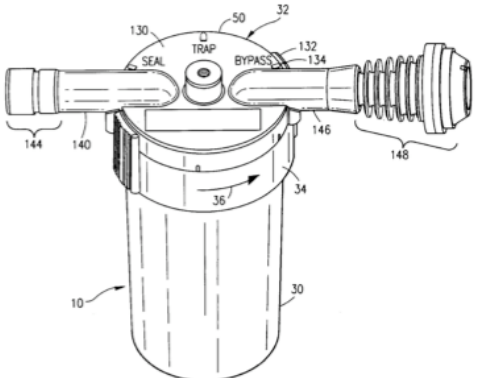

Figure 5. In-line specimen trap showing turning valve to change path of suction.

risk of losing the sample after it has been collected. However, this design does not address the issue of sample loss while the sample is being taken from the patient (Nakao *et. al* 1994).

Another design that addresses the sample loss issue is the "In-line Specimen Trap" (Figure 6). This design has similarities to the previous design in that it only addresses the issue of sample loss after the sample has been collected and not during the procedure. The concept of this design is that sample loss can be avoided by simply redirecting the vacuum line to not be connected to the sample anymore after it is finished collecting. To do this, the medical staff can twist the trap to turn a valve, which closes off the trap to the suction and redirects the suction such that it is only open between the vacuum and the bronchoscope (French *et. al* 2002).

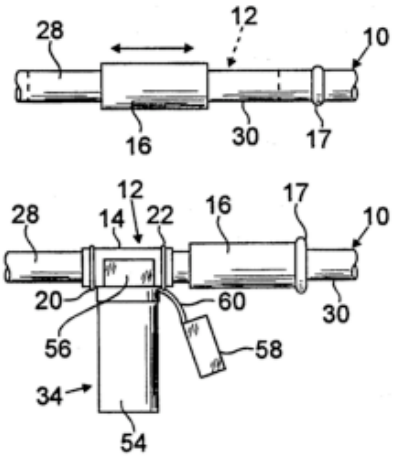

Figure 6. Endoscope suction trap showing removable collection vial.

Neither of these designs, however, have been implemented despite their possible usefulness. There are two likely reasons for this lack of implementation: the medical community is not very open to changing procedures, and the designs do not fully solve the problem of sample loss. Both require that the doctor or another medical staff member in the exam room change the way they perform the procedure. After doctors have had years of experience doing this procedure, it is an inconvenience to change their routine by adding another step to the procedure (either turning the valve after the sample has been collected or removing the vial after the sample has been collected). A common practice performed by many doctors is to remove the specimen trap after the sample has been taken and reconnect the vacuum line to the bronchoscope. This solution addresses the same situation as these designs in a much simpler and more cost efficient way. Additionally, because these designs do not provide a foolproof solution to the sample loss problem (because the sample can still be lost during collection), the medical community is less likely to implement these designs into their BAL procedures.

Ergonomics and Ethics

It was of paramount importance throughout our design process to consider the ethical and ergonomic ramifications of our final design concept. Ethically, we have a responsibility for the safety and comfort of the patient undergoing BAL. In terms of material composition, the design could not contain substances hazardous to patient health. Our design avoids latex, a material that could induce severe allergic reaction should it come in contact with the patient, and also avoids glass, which could react with cells in the

collected effluent. The maintenance of viable effluent, and therefore meaningful laboratory analysis, is crucial to diagnosis and was given consideration throughout the design process. Though our final design does not yet satisfy hospital material compatibility standards, we believe that material changes, such as replacing proprietary plaster powder with high-density polyethylene terephthalate, can be made given sufficient funding. Then testing can be performed to confirm that the effluent passes into the ball and cage design unaltered.

With regard to ergonomics, we primarily considered the confidence and ease with which the team of pulmonary specialists could implement the product, knowing that positive responses in these areas would translate into a positive experience for the patient. Additionally, the assimilation of the device into every procedure would increase due to practitioner acceptance. We considered the consequences of creating a design that significantly altered current procedure for BAL, and concluded that this would be inconvenient for staff and increase error. Our final design is small and unobtrusive. It allows the team to operate exactly as they would in the current procedure, if not more simply, because the trap will not need to be secured manually. Though currently it requires that one extra piece be attached to the collection trap, future plans to integrate the ball and cage valve into the collection trap itself will eliminate even that small procedural modification. The simplicity and minimalist nature of the design allow specialists to focus less on preventing mechanical malfunction and more on patient health.

Future plans to make the cylindrical casing transparent will provide a visual cue for specimen trap operators, since they will be able to see the ball lodged in the stopper, which forms the seal to stop the effluent from being lost. Similarly, they will be able to see the ball drop out of this position upon brief cessation of vacuum suction. All ethical and ergonomic considerations, especially procedural ease and patient health, are intertwined and were constantly considered as the ball and cage design concept was developed. Though time constraints and financial limitations prevented the implementation of all considerations into the final prototype, they were at no point neglected and will continue to be considered as the product is further developed and more testing can be performed directly with practicing BAL teams.

Design Considerations

Since current BAL traps are free hanging and easily shifted out of place, the sample is sometimes accidentally lost to the vacuum source. Our client would like a cost effective trap design to allow manipulation of the bronchoscope without losing the sample. Although the initial prototype and testing may prove to cost up to $100, the final product

should cost less than $10 to be mass-produced or the design is unlikely to be accepted by the medical community. The trap device should ideally be made of plastic in order to avoid problems with latex allergies and cells adhering to the glass surfaces. It must hold at least 40 mL of sample, be able to withstand more than 40 kPa vacuum pressure, and function without disrupting the current procedure (Appendix A).

Upon researching solutions to the transportation problem, a medical supplier (Covidien 2009), not used by the UW Hospital, was found to have already solved the issue by providing an additional secure cap with the specimen trap. Therefore, since this problem has a readily available solution, we decided to focus only on developing a better trap set up. We devised three preliminary design options:

Preliminary Design Ideas

Fixed Long Distance

The fixed long distance design uses a frame to attach the lavage trap close to the vacuum source, extending the length of the tube to about 3 to 4 m to reach the bronchoscope (Figure 7). By fixing the trap in a sturdy location and preventing motion in any direction, the chance of losing the sample is completely eliminated. The frame that attaches the trap in place would have adjustments to allow for any sized trap to fit and be held in place. The advantages of this design are its simplicity and low cost. However, it is not universal between exam rooms since there is no common location where it could be attached because hospitals and exam rooms vary. It is also problematic that the doctor would not be able to see the trap during the procedure and therefore is unable to know when it has been filled. There would be some time delay as well between the suction of lung effluent and the filling of the trap due to tube length between the scope and the trap.

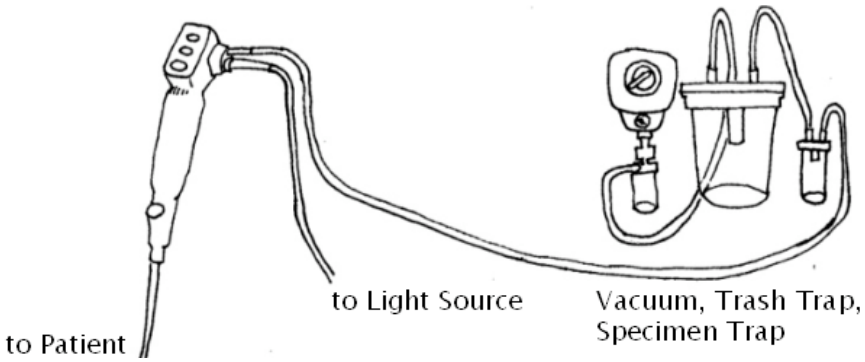

Figure 7. The fixed long distance design involves fixing the specimen trap (80 mL) away from the scope with 4 m of tubing.

Ball and Socket Frame

The ball and socket frame design uses gravity to prevent the trap from being inverted and losing the sample. A fixed frame that includes a ball and socket joint is attached to a sturdy location on the bronchoscope and extends several inches away from the scope (Figure 8). The ball and socket would allow free rotation in almost all directions. If the manipulation of the scope displaced the trap at any angle, the freely moving ball would rotate around in its socket until the trap was once again perpendicular to the ground. Advantages to this design include that it is reusable and universal. The frame could be connected to any bronchoscope because all scopes include a port connecting to the light source that is strong enough to support our frame. Some flaws in the design include its possible inability to realign without sample loss with quick scope movement. The frame is also a bulky attachment that may get in the way of the doctor's manipulations of the scope, perhaps interfering with the procedure.

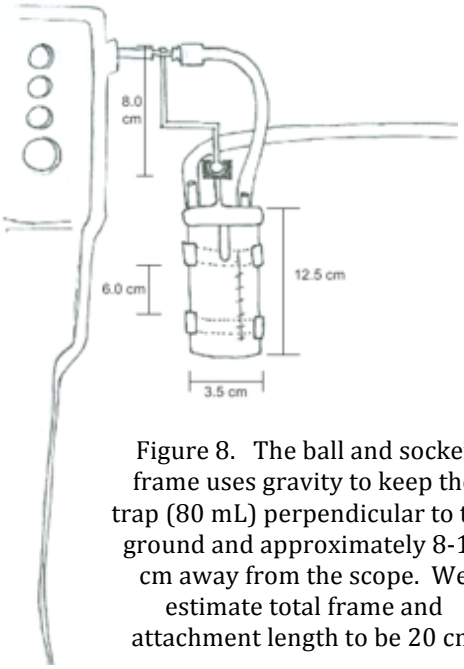

Figure 8. The ball and socket frame uses gravity to keep the trap (80 mL) perpendicular to the ground and approximately 8-10 cm away from the scope. We estimate total frame and attachment length to be 20 cm

Ball and Cage Valve

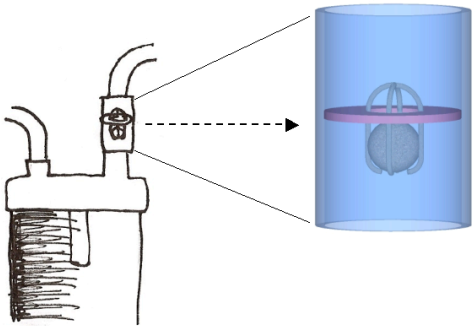

Figure 9. The ball and cage valve with a diameter of approximately 2 cm and a length of 4 cm is an attachment that connects between the trap (80 mL) and vacuum tubing.
Valve constructed in Google Sketch

The ball and cage valve incorporates an internal valve mechanism to prevent fluid flow out of the trap. The assembly includes a sphere enclosed in a cage threaded through a softer, washer-shaped disk. The disk acts as a stopper and seal and is located inside a plastic cylinder. This system is then connected externally between the trap and vacuum tubing (Figure 9). The valve acts as a preventative mechanism to stop the flow of the sample in the trap to the vacuum source on the wall. Once the trap is displaced at the desired angle, the ball will travel along the cage while being pulled up by the vacuum until it is lodged into the soft disk, creating an airtight seal (Figure 10). If the trap is once again returned to its proper configuration perpendicular to the ground, the ball will fall back into place at the bottom of the cage and allow air to pass

around it. An advantage to this design is that it can be used in any setting since it attaches externally to the original trap lid and vacuum tubing. Because the attachment is small, not cumbersome, and presents little change to the current procedure, the design is likely to be accepted among practitioners. The prototype cost for this design may have been slightly higher than the others and it may have been more difficult to calculate the needed details for full functionality; however, the completed prototype will prove an innovative solution.

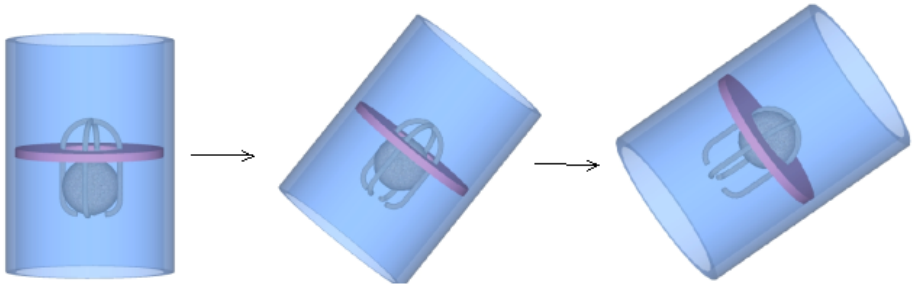

Figure 10. As the trap tips, the sphere starts to travel along the cage and is eventually pulled up into place by the vacuum creating a seal.
Valve constructed in Google Sketch.

Preliminary Design Evaluations

The fixed long distance design, the ball and socket frame and the ball in cage valve were all evaluated on a scale of one to ten and weighted on a variety of design criteria (Table 1). The most important criteria were given more weight in the matrix, which included the mass production cost, the friendliness to the user, the feasibility of building the prototype, and the dependability of the device. These aspects were determined to be the most important design characteristics because they are most important in terms of patient safety and effective functionality of the final product. The mass production cost was considered one of the most important aspects because the problem fixed by our prototype is an annoyance, but not a major problem to the medical community. If our design is expensive—even more than a few extra dollars per procedure—it is unlikely to be used. Prototype cost, universality, acceptability, and bulkiness were determined to be less important, as these characteristics do not directly inhibit effective use of the design in the field, and were therefore weighted less heavily in our analysis. Based on the results, the ball and cage valve is the most favorable and therefore is the design we chose to pursue.

Weight	Design Aspects	Fixed Long Distance	Ball and Socket Frame	Ball in Cage Valve
0.05	Prototype Cost	8	4	6
0.2	Mass Production Cost	8	9	5
0.05	Universality	3	8	10
0.2	User Friendly	3	8	10
0.2	Feasibility	10	7	8
0.05	Acceptability among MDs	3	3	10
0.2	Dependability	8	9	10
0.05	Bulkiness	8	4	10
1	**TOTAL**	**6.9**	**7.6**	**8.4**

Table 1. Design matrix that displays our evaluation on a scale of one to ten and weighted on a variety of design criteria for all three design concepts.

Prototypes

Prototype 1

In order to evaluate the next step with the ball and cage design, the team developed an initial prototype focused more proof of concept rather than practical functionality (Figure 11). The prototype was constructed from readily available materials with a cost of approximately $4.00 (Appendix D): a specimen trap, rubber stopper, wire, and a few short segments of tubing and rigid cylindrical plastic. The specimen trap was used as a shell to contain the ball and cage, and was inverted so that it could attach to a trap filled with fluid. A 9.5 mm hole was drilled into the base of the trap, and a rigid cylinder of plastic was inserted and sealed with plastic models glue into the hole as an attachment for vacuum suction. Separately, a network of 8 wires were threaded through the rubber stopper and bent around each other, leaving approximately 2 cm of cage above the stopper, and 3-4 cm below. This was then inserted into the inverted, modified specimen trap. The cap of the inverted trap was then attached through short segments of flexible tubing to what would be the fluid-containing trap to form the complete prototype. Because the wires did not form a sealed continuous cage, the team was able to open the cage and exchange ball types while testing in order to determine which weight and size of ball would be most appropriate for future

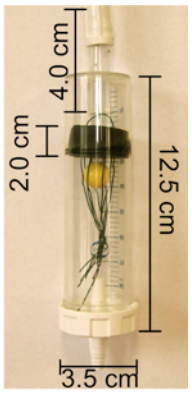

Figure 11. Prototype 1 proves that the design concept works. The cage is adjustable to allow for different lengths and interchangeable balls. Clear casing allows user to see how the parts are interacting. It is a large scale version of our intended design.

prototypes. The total mass of this prototype was 44.75 g. While the prototype proved our design concept was feasible, it was much larger than desired and the connection between the trap and prototype was too flexible.

Prototype 2

To alleviate the issues we experienced with the first prototype, a second prototype was made. First, a three-dimensional rendition was created in SolidWorks. The cylinder has a length of 44.45 mm with a diameter of 23.50 mm (Appendix B). Inside the cylinder, the cage has a length of 19.05 mm and an inside diameter of 9.52 mm. After the digital model was complete, the Design Media Center at the Biotechnology Center of the University of Wisconsin-Madison fabricated the prototype with a rapid prototyping machine (Figure 12). The machine took the digital modeling information and created the form by applying proprietary plaster powder in layers. After completion, the model was coated with cyanoacrylate glue to add strength and water resistance. An 8 mm diameter steel ball with a mass of 2.11 g was then inserted into the cage and a rubber stopper was securely wedged above, resulting in a final total mass of 27.48 g. The total cost of Prototype 2 was about $9.00 (Appendix D). This design had increased functionality over the first prototype, however, we experienced the problem that the required tip angle was over 90^0, and it was still larger than desired.

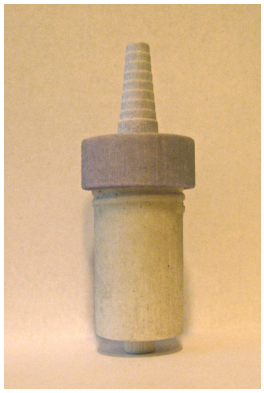

Figure 12. Prototype 2 was made of proprietary plaster powder and cyanoacrylate glue, with a steel ball and rubber stopper inserted. A screw-on cap was included for ease of fabrication. The Christmas tree on top of the cap allows for easy connection to the vacuum and the cylindrical attachment on the bottom can attach to the trap. Dimensions can be found in Appendix B.

Prototype 3

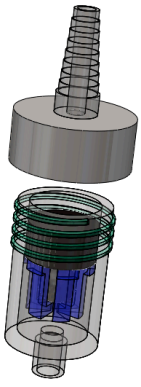

Figure 13. SolidWorks rendition of Prototype 3

Test results of Prototype 2 led to making some dimensional changes to our digital model (Figure 13), so a third prototype was made. For prototype 3 (Figure 14), the cage was shortened to 11.94 mm (Appendix C) so the angle at which the vacuum would pick up the ball would be smaller and closer to 90°. The cylinder was shorted to 36.45 mm to minimize size and weight. The

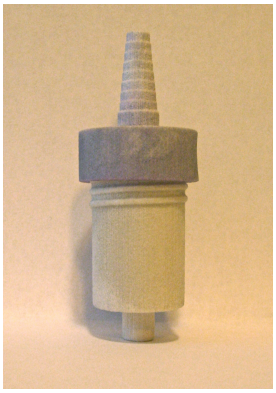

Figure 14. Prototype 3 is a modification of prototype 2 and was made of proprietary plaster powder and cyanoacrylate glue, with a steel ball and rubber stopper inserted. A screw-on cap was included for ease of fabrication. The Christmas tree on top of the cap allows for easy connection to the vacuum and the cylindrical attachment on the bottom can attach to the trap. Dimensions can be found in Appendix C.

bottom trap connection was also lengthened to 8.64 mm to provide a more secure attachment. The threads on the cylinder were also decreased on all sides by 0.0762 mm to account for the additional volume of the glue. Prototype 3 was made like prototype 2 with proprietary plaster powder, cyanoacrylate glue, an 8 mm diameter steel ball and rubber stopper. The mass of prototype 3 was 24.98 g. The total cost of Prototype 3 was about $9.00 (Appendix D).

Testing and Results

Prototype 1 Testing

We tested our first prototype by filling the specimen trap with 60 mL of water and connecting the prototype to the trap and vacuum source. The first issue we realized we would need to address was the vacuum pressure causing the water in the trap to naturally splatter, which causes loss of water without any tipping. According to our client, this is not a significant issue during an actual procedure because the lung and the bronchoscope (which has an opening of only 1.2 mm in diameter) provide more resistance on the other end than the open tube did that we were using. To address this issue, in all subsequent tests we partially blocked the tubing on that end to minimize unrepresentative disturbance of the water (in order to ensure consistency between tests).

To determine the ability of our design to solve the sample loss problem, we tested our first prototype to see how the design concept responded to two main conditions. First, we wanted to determine the angle at which the trap would need to be tipped in order for the ball to cut off vacuum pressure. We determined this angle to be between 80° and 90°, which depended on the velocity of the tip. Additionally, we interchanged balls in the prototype in order to determine the effect of having balls of different mass and diameter in the cage. These tests confirmed that there is a wide range of effective ball sizes that could work for our prototype, though specific details of the ball size were difficult to determine with our first prototype. We also were able to manipulate the wire cage to different lengths, but this also proved difficult to obtain useful information due to extraneous variables. We tested the prototype by tipping the trap full of 60 mL of water about 90° for a short period of time and determined that the volume of water lost to the vacuum was about 10 mL each time (Figure 16).

The next test we did determined if it would be easy to get the ball to fall back down after a tipping incident, allowing vacuum pressure to continue pulling sample out of the patient. We hoped that simply kinking the tubing above the valve would cause the ball to fall back down

and suction to continue so that our valve would not interfere with the procedure. In our testing with this prototype, kinking the tubing worked in exactly this way: the ball quickly fell down to the bottom of the cage when the tubing was kinked, and vacuum suction continued as before. This result was very promising for the feasibility of our design in the medical setting.

Prototype 2 Testing

The first test we did with prototype 2 was to determine the degree to which the trap would need to be tipped in order for the ball to be sucked up by the vacuum and cut off suction. The results showed that the prototype needed to be tipped a little more than 90°. An additional observation that we made during testing was that the seal between the cap and the cylinder of the prototype was not airtight, as we were able to hear air whistling when suction was applied. To compensate for this problem, we applied Vaseline to the threads, and though this helped the problem and did not solve it completely, and would not be appropriate in a final design. Additionally, we noticed that the steel ball used in our design began to rust after exposure to water, indicating this material would not be appropriate in our final design.

We performed several different tests with this prototype in which we started with 60 mL of water in the trap. First, we tipped it slowly to 90°. However, the ball was not sucked up to the stopper and the water was sucked out quickly. Tipping the trap to 90° at a quicker speed, however, did allow the ball to be sucked up and resulted in the loss of 4 mL of water (Figure 16). We also did a test in which we inverted the trap (180°) quickly and corrected the trap again, which resulted in the loss of only 4 mL of water as well. This same test without the prototype on the trap resulted in the loss of over half of the water. Finally, we inverted the trap and held it upside down for 10 seconds with the prototype attached. While the valve leaked a little bit due to an improper seal between the ball and stopper, only 10 mL of water was lost during the test. Without our prototype attached, this test caused the entire volume of water to be lost in less than 3 seconds.

To make sure it wasn't just the impedance of the valve preventing some of the water from passing through in our quick tests, we tried a test with our second prototype in which we removed the ball from the cage and put the rubber stopper back in. In this test, the speed at which the vacuum sucked out the water was comparable to that with just the trap alone. This test convinced us that the ball forming a seal with the stopper was actually the reason that we lost so little volume with the valve on top, not just the extra impedance provided by the extra attachment.

Prototype 3 Testing

With our final prototype, we performed three basic tests with ten replicates each in order to do statistical analyses of the results. These tests were performed with our final prototype attached to the trap as well as with the trap alone (Figure 15).

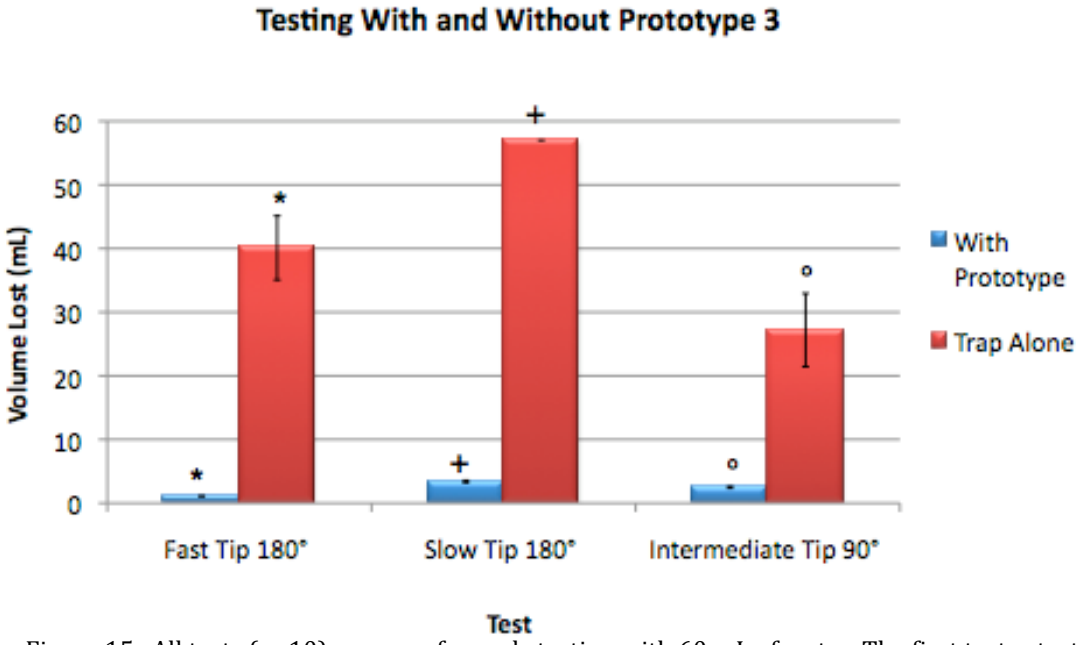

Figure 15. All tests (n=10) were performed starting with 60 mL of water. The first test, a test in which we tipped the trap quickly 180°, resulted in less water loss when we used the prototype on the trap (one-tailed $p<10^{-9}$, $SD_{prototype} = 0.39$, $SD_{trap} = 5.04$). Testing by tipping slowly 180° had similar results (one-tailed $p<10^{-15}$, $SD_{prototype} = 1.26$, $SD_{trap} = 0$). Finally, tipping the trap to 90° also yielded similar results (one-tailed $p<10^{-7}$, $SD_{prototype} = 1.11$, $SD_{trap} = 5.75$).

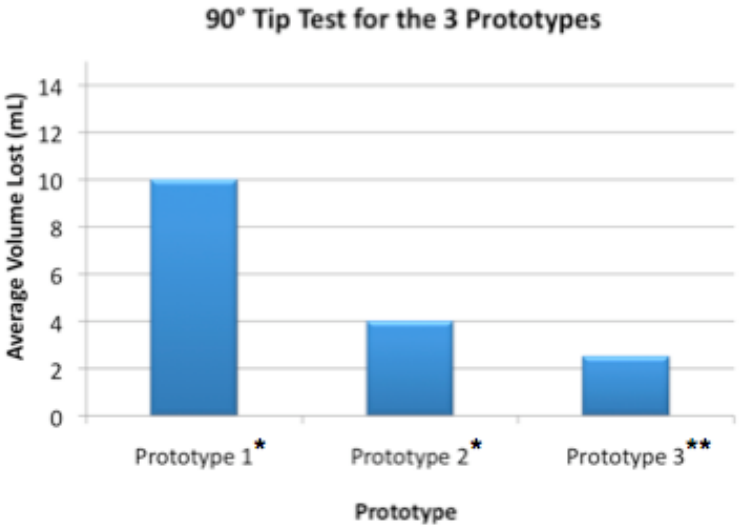

Figure 16. Tests on all prototypes (n=3*,10**)were performed starting with 60 mL of water and tipping the trap 90°.

Test 1: 180° Quick Tip Test

In our first test, we filled the trap with 60 mL of water and quickly inverted it 180°, then turned it back upright again. This test yielded positive results: with our prototype attached, the volume of water lost is much lower (mean = 1.1 mL, SD = 0.394) than testing the same way without our prototype attached (mean = 40.1 mL, SD = 5.04). This difference was statistically significant ($t(9) = 24.38$, $p<10^{-9}$, one-tailed).

Test 2: 180° Slow Tip Test

Testing by placing 60 mL of water in the trap and inverting it slowly over a period of 3 seconds gave good results: with our prototype attached, the volume of water lost is much lower (mean = 3.4 mL, SD = 1.26) than testing the same way without our prototype attached (mean = 57 mL, SD = 0). This difference was statistically significant ($t(9) = -134$, $p<10^{-15}$, one-tailed).

Test 3: 90° Intermediate Speed Tip Test

Testing by placing 60 mL of water in the trap and slowly tipping it 90° yielded positive results: with our prototype attached, the volume of water lost is much lower (mean = 2.5 mL, SD = 1.11) than testing the same way without our prototype attached (mean = 27.2 mL, SD = 5.75). This difference was statistically significant ($t(10) = -13.34$, $p<10^{-7}$, one-tailed).

Additional Testing

In addition to these tests, we also determined that the trap needed to be tipped about 90° in order for the ball to form a seal. In addition, after the ball is sucked up and the trap position is corrected to be vertical again, the tubing did not need to be kinked in order to cause the ball to fall down—it naturally fell about 5 seconds after the trap was vertical again after each time. This result was not intended, but it would be very beneficial if our design were to be used in the procedure because the medical staff in the room would not need to do anything in order to continue suction after a tipping incident.

Future Work

While our prototype is functioning well within our client's specifications, several changes can be made in the future to optimize the design, ensure appropriate operation in a surgical setting, and allow for mass production. While the final prototype we produced only lost about 3 mL of water on average in our testing, ideally the design could be perfected to prevent the loss of the entire sample. It is possible that altering the design of the stopper may help us to reach this goal. If a slight conical-shaped cut could be made on the side of the stopper closest to the ball, this gradation towards the hole may facilitate the formation of a seal between the ball and the stopper. The diameter of the hole in the stopper should also be optimized to let the most vacuum pressure through while continuing to block the ball from passing.

Figure 17. Final prototype connected to specimen trap representing connection to bronchoscope and vacuum.

There are also other changes we would make to this design as a whole. While we were able to shrink the size from our second prototype to our third prototype, the design is still too large. The trap hangs naturally at an angle with our valve attached (Figure 17). This is not ideal since the basis of our design relies on tipping to bring the ball up the cage to cut off the suction. While our testing did not indicate that this positioning affected the operation of the trap and attachment, it would be best to eliminate the possibility by making the device much smaller. Additionally, the cap and cylinder would be sealed together as one continuous piece to ensure that this connection is always airtight. Ideally, it would be best if we could combine our prototype within the actual specimen trap itself. This would allow for practitioners to purchase one device at a more reasonable cost than purchasing both components separately, as well as eliminate the confusion that might occur when attaching the device to the specimen trap and vacuum source.

The materials we used in our prototype to prove our design concept are not appropriate for a medical setting. Single use sterility is our main concern. The proprietary plaster powder with cyanoacrylate glue used in the rapid prototyping process was useful for testing because it was waterproof, durable, and cost efficient. However, we hope to use a transparent, sterile plastic such as high-density polyethylene terephthalate in our final design. The transparency would allow for the doctor to be able to see when the ball has been sucked up, and after pinching the tubing, that the ball has fallen back down to its original position to continue the procedure. The rubber stopper used in our prototype would be changed to a medical grade silicone that has similar material properties. Finally, the metal ball we used in our prototype worked well to help us determine an appropriate

weight, but the final design would use plastic of comparable weight to reduce the cost and eliminate the chance of rusting as we had seen in our testing.

We also want to consider any specific changes that can be made to allow for mass production of the device. Injection molding of the plastic would make mass production easy and would allow for our device to be made cost efficiently. Therefore, a mold should be created that connects all components of the design. There are companies, such as GLS Thermoplastic Elastomers (Dixon, 2009), that produce sterile, medical injected molded equipment.

After all of these changes have been made, further testing should be conducted. A functional pressure range should be determined and documented so that practitioners would know what settings are appropriate to use with the device, and if it changes their procedure in any way. The device should also be tested using a bronchoscope. Our testing qualitatively simulated the changes in pressure experienced by the trap and device by partially plugging the tubing at the end; however, more quantitative data should be obtained while using an actual bronchoscope. Additionally, the materials ultimately chosen should be extensively analyzed for any interference with lab analysis of the BAL sample. Because our device is meant to preserve a testable sample for the lab to avoid repeat procedures, if the material were not compatible with lab analysis, the original problem would not be solved. After full safety tests have been performed, the device and setup should be used in an animal BAL before being tested on a human subject.

Conclusions

We made a successful prototype with our ball and cage valve design. Our final prototype fits well within our design specifications, losing only a few milliliters of sample with each test. Additionally, testing proved that our prototype functions much better than the trap without an attached valve. Despite the success of our final prototype, we look forward to making changes in the future to increase the efficiency and further simplify the use of our design in the BAL system. Some of these changes include: making a material change from proprietary plaster powder to a transparent plastic, changing the rubber stopper to a medical grade silicone, and minimizing the size of the design. Implementation of these modifications has the potential to significantly improve procedures by giving the pulmonary specialist, and the patient, more confidence in a functional BAL system.

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Appendix A: Product Design Specifications

Project Design Specification—BAL Trap Valve

January 30, 2009

Team: Ali Johnson, Kim Kamer, Laura Zeitler, Elise Larson
Client: Christopher G. Green, M.D. UW Department of Pediatrics
Advisor: Brenda Ogle, Ph.D. Biomedical Engineering

Function:

The purpose of the BAL trap is to collect a cell effluent sample from a bronchiole using a lighted bronchoscope attached to a vacuum. Ideally, the setup must always capture and secure the sample; however, sometimes the free hanging trap can tip and the sample is lost to the vacuum source. The solution should eliminate the chance of at least 40 mL of sample being lost as well as be stable, rigid, and cost efficient.

Client Requirements:

- Cost Efficient
- Plastic
- Avoid latex and glass
- Must work for traps filled up to 60 mL effluent
- Must maintain at least 40 mL of sample for lab analysis
- Cannot be attached to bronchoscope handle

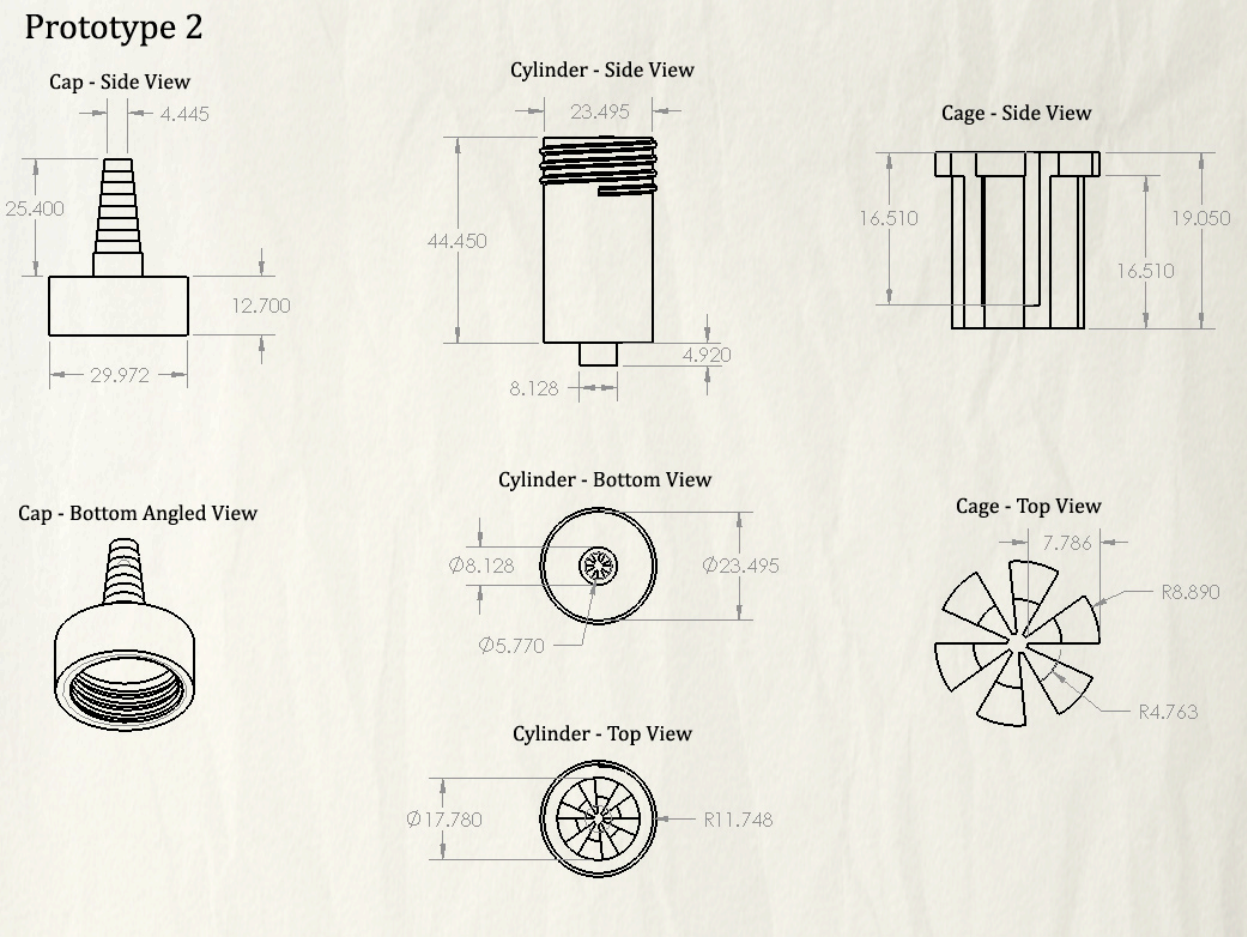
Design Requirements:

1) Physical and Operational Characteristics
    a) *Performance requirements* – Must be able to contain sample despite bronchoscope movement.
    b) *Safety* – Must be sealed tight and a durable container
    c) *Accuracy and Reliability* – Should prevent loss of at least 5 mL or maintain at least 40 mL of solution every time the procedure is executed.
    d) *Life in Service* – One-time use, must have full functionality for entirety of procedure.
    e) *Shelf Life* – Able to withstand a basic medical storage environment.
    f) *Operating Environment* – Must be able to withstand 300 mm Hg.
    g) *Ergonomics and Ethics* – Reduce or maintain complexity of current procedure, ensure a viable effluent sample and patient safety.
    h) *Size* – Minimized to prevent accidental suction of ball
    i) *Weight* – Should be as light as possible, not adding more weight than an additional trap (33.25 g)
    j) *Materials* – Cost-efficient, no latex or glass, sterile plastics preferred
    k) *Aesthetics* – Should be transparent.
2) Production Characteristics

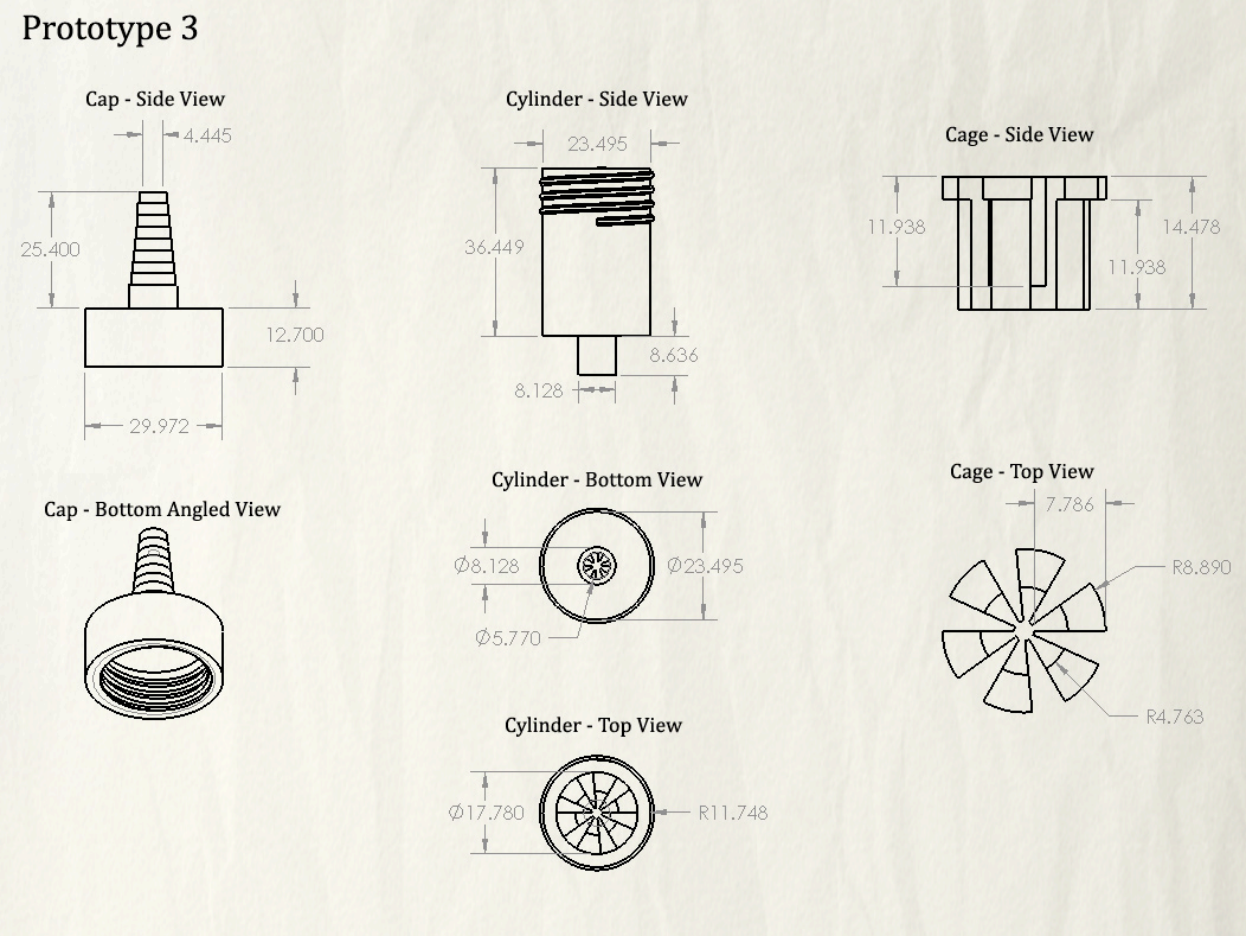
a) *Quantity* – One, but should be designed with the intent of mass production in the future.
b) *Target Product Cost* – Under $10

3) Miscellaneous
   a) *Standards and Specifications* – Should not lose the sample.
   b) *Customer* – Medical community
   c) *Patient-related concerns* – Not include latex to avoid problems with latex allergies.
   d) *Competition* –Current traps lose sample easily. Competing designs do not consider loss of sample during procedure, only after sample has been taken.

Appendix B: Dimensions of Prototype 2



Appendix C: Dimensions of Prototype 3



Appendix D: Expenses

Date	Item	Cost	Comments
3/19/09	Flexible Tubing	$0.60	American Science and Surplus Store
3/19/09	Clear Plastic Container (x2)	$0.40	American Science and Surplus Store
3/19/09	Clear Plastic Dropper	$0.05	American Science and Surplus Store
3/19/09	Steel Ball (8 mm DIA)	$0.20	American Science and Surplus Store
3/19/09	Nylon Bushing (x2)	$0.20	American Science and Surplus Store
3/19/09	Rubber Stopper (x4)	$1.25	American Science and Surplus Store
3/19/09	Bearing	$1.00	American Science and Surplus Store
4/16/09	Prototype 2	$8.44	Biotechnology Media Center
4/24/09	Prototype 3 (without cap)	$4.22	Biotechnology Media Center