BRONCHOALVEOLAR LAVAGE TRAP VALVE

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Abstract

Bronchoalveolar lavage (BAL) 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 sample 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 more than 90º. The final prototype was manufactured using proprietary plaster powder with a cyanoacrylate glue with a rapid prototyping machine. A steel ball and rubber stopper were then inserted.

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

Background

Bronchoalveolar Lavage (BAL) [1,2]

- Noninvasive medical procedure to collect lung effluent sample ranging from $2,000-$4,000 per patient
- Performed on immunosuppressed patients
- Lung effluent sample analyzed in lab to diagnose:
  - Malignancy
  - Alveolar hemorrhage
  - Lung infection

Procedure (*Figure 1*) [2]

- Patient anesthetized
- Bronchoscope inserted, wedged into bronchiole
- 100 mL,0.9% saline solution injected through scope to lung
- Effluent: epithelial cells and solution, suctioned from lung to specimen trap

Figure 1: BAL setup includes a specimen trap (center) connected to a bronchoscope (left) and tubing (right) to vacuum source (not shown).

Motivation

The bronchoalveolar lavage specimen traps currently in use are unstable in space and can invert to lose effluent sample. This requires costly repeat procedures.

Goal: To create a simple, cost effective, efficient attachment to the current bronchoalveolar lavage specimen trap to prevent sample loss during the procedure.

References

[1] Dugdale, D.C., Medoff, B. "Bronchoscopy." Medline Plus. 2008. Viewed on Feb 1, 2009. http://www.nlm.nih.gov/medlineplus/ency/article/003857.htm

[2] Oulu University Library. "Type I and III procollagen propeptides in sarcoidosis, fibrosing alveolitis and asbestos-related lung diseases." 2000. Viewed on January 24, 2009. http://herkules.oulu.fi/isbn9514253728/html/x207.html.

[3] Nakao, N.L., Nakao, M.L. and Mizzi, J.V. (1994). "Endoscope Suction Trap and Associated Method." US Patent 5347991.

[4] French, C.K., Barker, G.L. and Levinson, M.E. (2002). "In-line Specimen Trap." US Patent 6375625.

Final Design

Design Concept

- Ball and cage valve
- Prevents sample loss

When Tipped

- Ball moves up cage
- Ball forms a seal with stopper
- Cuts off vacuum pressure

After Tipped

- Ball falls down when tubing is kinked
- Procedure can continue

Figure 2: Final prototype. The cage (blue), stopper (black) and ball (grey) are all inside a cylinder with threaded (green) cap. See Figure 6 for dimensions and Figure 5 for final prototype. At the bottom of the cylinder is a connection for the specimen trap and at the top, the cap connects to the vacuum tubing.

Figure 3: Prototype 1

Figure 4: Prototype 2

Figure 5: Prototype 3

Prototype 1 (Figure 3)

- Large scale conceptual design
- Materials:
  - Interchangeable balls
  - Rubber stopper
  - Specimen trap
  - Wire
  - Pipette tip
- Cost: $4
- Proved concept

Prototype 2 (Figure 4)

- Full scale design
- Materials:
  - Proprietary plaster powder
  - Cyanoacrylate glue
  - Rubber stopper
  - Steel Ball (d=8 mm)
- Cost: $9
- Proficient – Needs Improvement

Prototype 3 (Figure 5)

- Final design
- Dimension changes from prototype 2
- Materials:
  - Proprietary plaster powder
  - Cyanoacrylate glue
  - Rubber stopper
  - Steel Ball (d=8 mm)
- Cost: $9
- Proficient

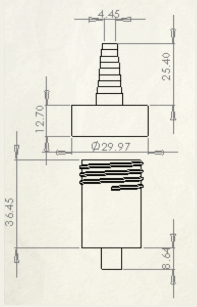


Figure 6: Dimensions for final prototype in mm

Figure 7: Final prototype connected to specimen trap representing connection to bronchoscope and vacuum.

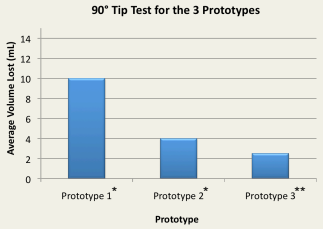


Figure 8: Tests on all prototypes (n=3*,10**)were performed starting with 60 mL of water and tipping the trap 90°.

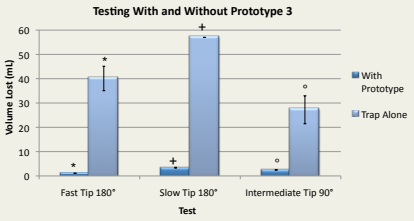


Figure 9: All tests (n=10) were performed starting with 60 mL of water. The first test, a test in which we tipped the trap quickly 180°, resulted in less water loss when we used the prototype on the trap (one-tailed $p<10^{-9}$, $SD_{prototype} = 0.39$, $SD_{trap} = 5.04$). Testing by tipping slowly 180° had similar results (one-tailed $p<10^{-15}$, $SD_{prototype} = 1.26$, $SD_{trap} = 0$). Finally, tipping the trap to 135° also yielded similar results (one-tailed $p<10^{-7}$, $SD_{prototype} = 1.11$, $SD_{trap} = 5.75$).

Competition

Current Solutions

- Medical staff holds trap
- Tape trap to bronchoscope

In-Line Specimen Trap [3] (Figure 10)

- Valve switch vacuum airway to include or exclude specimen trap
- Can still lose sample during procedure

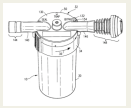
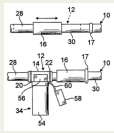


Figure 10: In-line specimen trap showing turning valve to change path of suction.

Figure 11: Endoscope suction trap showing removable collection vial.



Endoscope Suction Trap [4] (Figure 11)

- Method to switch vacuum airway to include or exclude detachable collection vial
- Can still lose sample during collection

Design Criteria

Cost Effective

- Mass production cost under $10 per attachment
- Design and prototype budget under $100

Functional

- Maintain at minimum 40 mL of effluent in trap after tip
- Should work for trap filled to 60 mL
- Must not interfere with procedure
- Simple and easy to implement

Material

- No latex or glass
- Durable
- Sterile

Future Work

Design Optimization

- Minimize size
- One continuous, sealed unit
- Combine trap and attachment
- Cap: *strengthen, shorten connecting piece*
- Stopper: *optimize hole diameter, conical gradation*

Material Changes

- Stopper: *medical grade silicone*
- Ball: *no metal, use comparable plastic*
- Transparent plastic shell

Mass Production Considerations

- Sterile
- Injection-moldable material
- Minimize cost
- One-time use

Further Testing

- Functional pressure range
- Material compatibility with lab analysis
- Operation in realistic setting
  - Attach to bronchoscope, vacuum limitations
  - Use in animal or human procedure

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