Visually-Assisted Split Tip Catheter for Accurate Positioning and Surfactant Administration for Premature Neonates

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Visually-Assisted Split Tip Catheter for Accurate Positioning and Surfactant Administration for Premature Neonates

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Abstract

Respiratory distress affects about 24,000 infants born in the United States every year, especially premature neonates and is presented immediately after birth.[1] This is caused by the inability to produce a sufficient amount of surfactant to decrease surface tension to prevent the collapse of the alveoli as well as interstitial fluid entrance.[2] Surfactant is able to be produced beginning in the 20th week of gestation, during the canalicular stage when lungs start to become viable for gas exchange. Incidence of respiratory distress and subsequent lack of surfactant production increases with decreasing gestational age at the time of birth. Innovation in neonatal medicine has produced exogenous surfactant to improve ventilation and oxygenation in these patients, allowing administration in the delivery room at the time of intubation. Early administration of lung surfactant can increase survival rates to over 90%.[1] Exogenous surfactant is a liquid that is given via endotracheal tube (ETT) or a thin catheter to directly target the lungs, with the aim of placing it in both lungs equally through ideal positioning of the ETT. The aims of this work are to design and develop a catheter device with visual capabilities and a split-tip mechanism that will allow the clinician to clearly visualize catheter placement to ensure the surfactant is administered equally to both lungs. The catheter was designed using Autodesk Fusion 360 and Solidworks to evaluate structural integrity. Theoretical fluid modelling was conducted using the Hagen-Poiseuille equation for laminar flow to evaluate and confirm equal distribution of surfactant using assumed values. The development of this device suggests potential for an improved method of surfactant administration that reduces risk of worsened respiratory conditions, eliminates the need for radiation exposure via X-ray, and reduces the amount of time required for insertion and administration.

Keywords: Respiratory distress syndrome, premature neonates, exogenous surfactant, split-tip catheter

Introduction

Respiratory distress syndrome (RDS) in neonates is a critical health issue, particularly affecting premature infants whose lungs have not yet matured to produce adequate surfactant. Surfactant is essential for keeping the alveoli in the lungs open by reducing surface tension, enabling efficient gas exchange. Without adequate surfactant, the lungs' alveoli are prone to collapse causing increased respiratory effort, hypoxemia, and even respiratory failure.. This issue persists despite advances in neonatal care due the inherent challenges associated with delivering surfactant precisely and bilaterally, leading to several significant issues in neonatal care.[1] There are significant challenges in precise delivery and risk of unilateral administration. The current approach to surfactant administration results in a high risk of delivering the surfactant unevenly across the lungs, resulting in unilateral administration. In neonates, the slight misplacement and lack of visibility during the positioning process of the ETT can lead to one lung receiving an insufficient amount of surfactant.[3] The consequences of unilateral administration are severe. The under treated lung remains prone to collapse, leading to worsening respiratory distress, uneven ventilation, and an increased need for invasive respiratory support.To avoid the risks associated with misplacement, many institutions delay surfactant administration until a chest x-ray is performed to confirm accurate placement of the ETT. However, reliance on radiographic imaging introduces a time delay in critical moments and heighted radiation exposure. The use of x-rays to verify placement prolongs the time from birth to surfactant administration, delaying treatment that could prevent the rapid progression of respiratory distress.

Neonates are particularly vulnerable to the effects of rations, with evidence suggesting that even small doses may increase long-term cancer risks. Radiographic imaging also increases healthcare costs.[4] The delay in administering surfactant and the risk of improper delivery directly impacts neonatal mortality rates. Timely surfactant administration can increase survival rates to over 90% in infants with RDS. However, without previous methods, the risk of surfactant being unevenly distributed or delayed leads to poorer outcomes.[5] Current delivery devices, such as standard ETTs and catheters, are limited in that they lack real time visualization capabilities. Clinicians cannot see directly where the tube is positioned or how surfactant is being distributed within the lungs during administrations. There is no continuous visualization inside the lungs, leaving clinicians unable to monitor the distribution of surfactant in real time. Consequently, surfactant administration remains a blind procedure, with clinicians relying on indirect cues or pre-administration imaging to confirm delivery. The cumulative costs associated with X-rays, extended NICU stays and prolonged ventilatory use place a heavy financial burden on families and healthcare systems. In addition to the direct medical costs, the long-term healthcare needs of infants who develop chronic lung diseases as a result of suboptimal RDS management accrue substantial costs. Further, radiographic imaging may not always be available in lower-resource settings, meaning that neonates in these areas may lack access to timely, effective surfactant treatment altogether. An efficient, real-time solution that minimizes dependence on radiographic imaging while still ensuring accurate delivery could therefore have global implications, making RDS treatment more accessible and cost-effective worldwide. The proposed project addresses these issues by developing a novel catheter device with integrated visual capabilities and a split-tip mechanism, allowing for real-time visualization and targeted, bilateral surfactant administration. By enabling clinicians to observe and guide the placement and distribution of surfactant directly within the lungs, the device will greatly reduce the likelihood of unilateral administration in order to improve survival outcomes for neonates.

Current technologies in neonatal respiratory care—split-tip catheters, fiber optic cameras, and standard neonatal-sized endotracheal tubes (ETTs)—each offer partial solutions for surfactant administration but lack the precision and control necessary for optimal delivery in neonates. The current method of surfactant administration consists of inserting a single lumen catheter into the trachea using an ETT and then positioning the catheter in between the bronchi in the middle of the trachea. This approach is risky as it requires an X-ray to confirm accurate placement before surfactant is administered, and the intended outcome is that the surfactant reaches both lungs equally. With increased accuracy in surfactant delivery, the proposed solution is expected to significantly reduce the rates of RDS complications and improve survival outcomes. Accurate and timely surfactant administration will help minimize the incidence of chronic respiratory conditions and support healthier long-term development in premature infants. The real-time visualization capabilities will eliminate the need for confirmatory X-rays, thereby reducing radiation exposure for neonates and allowing for immediate surfactant delivery. This is critical in the early hours of life, where timely intervention is essential to prevent worsening respiratory distress. By reducing dependency on X-rays and minimizing NICU stay lengths, the device has the potential to lower the cost of care for infants with RDS. Moreover, this simpler, real-time approach to surfactant administration could be implemented in low-resource settings, where access to imaging equipment is limited. This could extend the benefits of effective RDS management to more neonates globally. Split-tip catheters are designed to distribute fluids across multiple sites but lack the real-time visualization required to confirm accurate surfactant distribution to both lungs. Fiber optic cameras offer direct visualization in other medical applications but are not integrated into neonatal catheters, limiting their utility for precise surfactant administration. Neonatal-sized ETTs, the current standard for surfactant delivery, do not have split-tip or imaging capabilities, making them reliant on post-administration X-rays for confirmation, which delays treatment and exposes infants to radiation. The proposed device innovates by integrating a capability for high-definition real-time visualization with a split-tip catheter specifically designed for even surfactant distribution in neonates. This combination allows clinicians to visually confirm catheter placement and bilateral delivery, reducing the risks of misadministration and eliminating the need for post-placement imaging. This streamlined, single-device solution builds upon prior technologies, setting a new standard for precision, safety, and efficiency in neonatal surfactant administration. By ensuring equal distribution and minimizing radiation exposure, the device will significantly improve outcomes for infants with respiratory distress syndrome.

Methods

In this study, two catheter prototypes were developed using Autodesk Fusion 360 CAD to address key limitations in the current practice of surfactant administration for premature neonates. Both designs focused on improving delivery accuracy by incorporating a split-tip geometry, with the second design further integrating structural clips intended to secure a micro-fiberscope. These clips were designed to facilitate real-time visualization of catheter positioning within the trachea and primary bronchi, potentially reducing dependence on radiographic imaging.

The first iteration employed a basic split-tip bifurcation while maintaining a 0.4 mm lumen diameter and an intended outer scale of 1.5 French (Fr). However, due to necessary widening at the bifurcation point to maintain lumen patency and support equal fluid distribution, the effective outer diameter at the widest point measured approximately 2.0 mm. This geometry places the practical diameter closer to a 6 Fr device, a consideration with implications for clinical usability in extremely low birth weight neonates. The second iteration retained the split-tip but introduced grooves along the shaft to accommodate a fiber optic camera with a diameter of 0.5 mm. These clips were also designed to preserve flow symmetry by avoiding intrusion into the central lumen.

Fig. 1. Iteration 1. Catheter design with basic split-tip bifurcation with 0.4 mm lumen diameter with outer scale of 1.5 Fr.

Fig. 2. Iteration 2. Catheter design with split-tip bifurcation with 0.4 mm lumen diameter with outer scale of 1.5 Fr with clips to hold a fiber optic camera with a diameter of 0.5 mm while preserving flow symmetry.

Results

To assess mechanical viability, a static stress analysis was conducted on Iteration 2 using the SolidWorks simulation module. Given the tensile strength of catheter-grade silicone, which ranges between 11–20 MPa depending on formulation and temperature, these results suggest that the catheter clips and shaft are unlikely to undergo structural failure under routine use. Stress maps confirmed uniform distribution along the shaft and clip interfaces, indicating favorable load transfer and minimal stress concentrations.

Force applied to clips	Maximum stress	Minimum stress
0.5 N	3.93 MPa	1.11E-04 MPa
0.75 N	5.90 MPa	1.67E-04 MPa

Fig. 3. Stress Distribution at 0.5 N and 0.75 N. Force values of 0.5 N and 0.75 N were applied to simulate clinician handling during insertion and adjustment. These values were selected based on estimates of average insertion force for thin catheterization procedures in neonatal tracheal anatomy.

To evaluate fluid delivery performance, theoretical flow rate modeling was conducted using the Hagen-Poiseuille equation for laminar flow in cylindrical tubes.

$$Q = \frac{\pi \cdot r^4 \cdot \Delta P}{8 \cdot \mu \cdot L} \Rightarrow Q = 1.84\, mL/min\ per\ arm$$

Eq. 1. Hagen Poiseuille equation for laminar flow in cylindrical tubes. This equation was utilized for flow rate modeling using assumed values where Q is flow, ΔP is pressure difference across the catheter, μ is the viscosity of the liquid and L is the length of the tube.[6]

To confirm even distribution through the bifurcated tip, computational modeling of the velocity profile was performed using simplified assumptions of Newtonian fluid behavior. The model confirmed symmetric bifurcation of fluid through both distal openings, with a parabolic velocity profile and no evidence of preferential flow to either lumen. The results support the claim that the split-tip geometry facilitates equal surfactant distribution, thereby mitigating the risk of unilateral administration commonly observed with traditional single-lumen catheters. Taken together, these results provide preliminary validation of both the mechanical and functional design parameters. The device, in both iterations, demonstrated capacity to withstand anticipated insertion forces and to

deliver fluid volumes consistent with clinical standards. While modeling was limited to static mechanical loading and idealized flow behavior, the combined outcomes establish the feasibility of this catheter design as a candidate for future physical prototyping and in vitro testing.

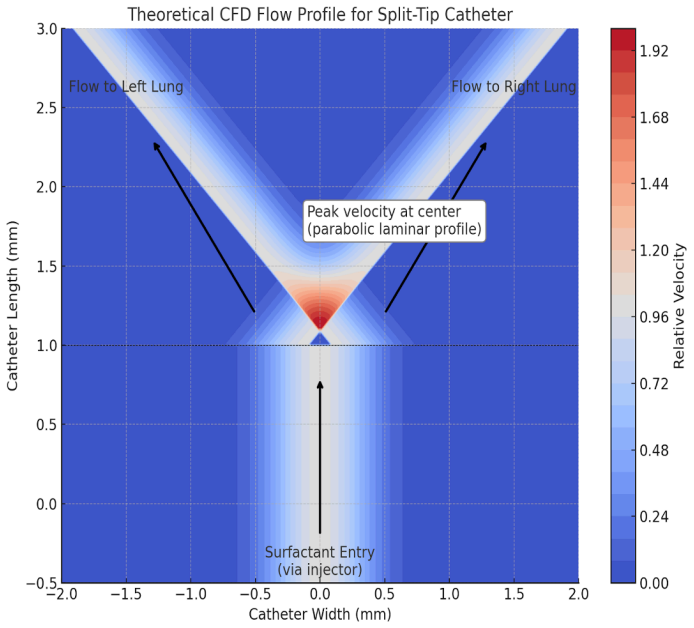

Fig. 4. Theoretical CFD Flow Profile for Split-Tip Catheter. The catheter's lumen radius was set at 0.2 mm, with assumed viscosity values aligned with neonatal surfactant preparations (dynamic viscosity range: 2–4 cP). Flow rate calculations were performed over a range of pressures consistent with clinical administration, targeting delivery of 1.25–2.5 mL within a 30–120 second window. The results yielded a flow rate range of 0.625 to 5.0 mL/min, consistent with the manufacturer dosing guidelines for surfactant preparations such as Curosurf® and Survanta®.[7]

Discussion

The administration of exogenous pulmonary surfactant remains a cornerstone intervention for the management of Neonatal Respiratory Distress Syndrome (NRDS), a condition that disproportionately affects premature infants due to underdeveloped alveolar structures and insufficient endogenous surfactant production. Despite the established efficacy of surfactant therapy, conventional delivery methods continue to present several challenges. These include the risk of incorrect catheter placement, the potential for surfactant to be delivered into only one lung, and the reliance on radiographic imaging to confirm catheter position—all of which introduce risk and complexity into what is often a time-sensitive, high-stakes clinical procedure.

The catheter designs proposed in this project aim to directly address these limitations through the development of a visually assisted, split-tip catheter system. By incorporating a bifurcated distal tip, the design allows for symmetric administration of surfactant into both main bronchi, thereby reducing the incidence of unilateral dosing. Furthermore, the addition of a clip-guided micro-fiberscope in the second iteration introduces the potential for direct visualization of catheter positioning, eliminating or minimizing the need for post-placement imaging. Together, these features introduce both a mechanical and procedural advancement over current tools used in less invasive surfactant administration (LISA) techniques.

From a mechanical standpoint, the stress analysis conducted on the second iteration of the catheter demonstrated its structural resilience under typical insertion conditions. The clip design, a key innovation for visual assistance, was found to remain intact under forces up to 0.75 N—greater than the average required for catheter advancement in neonatal airways. The absence of localized stress concentrations further suggests that the clip-to-shaft interface is mechanically stable and would likely withstand repeated use in clinical handling scenarios. Nevertheless, the analysis was limited to quasi-static loading conditions and did not account for dynamic stresses such as twisting or flexion during difficult insertions. Future work should therefore include cyclic fatigue testing and bend radius analysis to ensure long-term reliability.

The flow modeling results likewise support the functional feasibility of the catheter. Using both analytical and computational approaches, we confirmed that fluid delivery rates through the device fall within the clinical window required for neonatal surfactant administration. More importantly, the velocity profile at the split-tip demonstrated symmetric bifurcation and laminar flow, a critical factor in reducing the risk of over-delivery to one lung. This is a significant improvement over conventional single-lumen catheters, which may be prone to directional bias due to the anatomy of the neonatal trachea, where the right main bronchus is more directly aligned with the tracheal lumen.

Despite these promising results, several trade-offs and design challenges emerged throughout the development process. Chief among these is the increase in outer diameter introduced by the split-tip geometry and camera clip housing. While the original design goal was to

produce a 1.5 Fr catheter—suitable for extremely premature infants—the effective diameter of approximately 2 mm reclassifies the device closer to 6 Fr. This may limit its clinical utility in the most vulnerable patient population unless further miniaturization can be achieved through precision manufacturing or advanced materials. It also raises questions about insertion feasibility, given that tracheal diameters in infants under 28 weeks gestational age may not accommodate a device of this size.

The incorporation of visual assistance introduces additional considerations. While the micro-fiberscope provides real-time positional feedback and improves insertion confidence, it also introduces complexity in terms of sterilization, cost, and handling. In our current design, the fiberscope is intended to be used transiently and removed after placement, reducing the risk of contamination and allowing the scope to be reused across multiple patients. However, the mechanical flexibility of the catheter shaft—particularly when constructed from silicone—may lead to bowing or occlusion during insertion, especially when guided by external visual tethers. These limitations were not apparent in our simulation, but will require empirical evaluation in bench testing and mock airway models.

Clinically, the adoption of this device could reduce reliance on radiographic imaging for placement verification, thereby limiting neonatal exposure to ionizing radiation—a factor associated with long-term risks including increased susceptibility to malignancies and neurodevelopmental impairment. Additionally, by reducing the need for multiple insertion attempts due to misplacement or unilateral dosing, the device may shorten procedure times and improve clinical efficiency. Importantly, the real-time feedback provided by the visualization component could enable even less experienced clinicians to safely administer surfactant, broadening access to this life-saving intervention.

As this device advances from conceptual design to translational prototype, several steps remain. The fabrication of physical models using flexible, biocompatible materials will be critical for evaluating handling characteristics and tip behavior during insertion. Bench studies simulating surfactant administration with analog fluids will be necessary to validate symmetric flow and determine optimal insertion depth. Further, consultation with clinical end-users—including neonatologists, respiratory therapists, and neonatal nurses—will be necessary to refine ergonomic features and operational protocols. Finally, long-term development will require design for manufacturability, cost analysis, and compliance with FDA regulatory requirements for Class II medical devices.

In summary, this project presents a novel catheter design that addresses both mechanical and procedural deficiencies in current neonatal surfactant administration practices. Through simulation and modeling, the design has demonstrated feasibility in maintaining structural integrity, supporting laminar bifurcated flow, and offering real-time visual guidance. Although challenges remain in scaling, material performance, and clinical integration, the foundational data support continued development toward clinical use. The catheter has the potential to significantly improve the safety, efficacy, and accessibility of surfactant delivery in premature infants—a population for whom every second, and every breath, is critical.

End Matter

Author Contributions and Notes

The authors declare no conflict of interest.

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