



### Executive Summary

---

#### Concept Summary

**FloSure** is an alternative bottle feeding system that is specially designed for children born with cleft palate (CP). Babies affected with CP are unable to generate the negative pressure required to draw milk from the bottle. This is due to an incomplete closure of the soft and hard palate normally separating the oral and nasal cavity. This opening causes many problems with the existing feeding process, such as allowing fluid to easily get into the baby's nasal cavity. While several specialized bottles for children with CP exist, feeding remains a critical challenge due to longer feeding times, significantly lower flow rates, and issues of nasal regurgitation. FloSure utilizes the natural oral motions (tongue, jaw) and gravity application of fluid flow to provide children with CP more control over their nutrition intake. FloSure is modified to meet the individual needs of each cleft type (unilateral, bilateral or Pierre Robin Sequence). The flow rate of the bottle is then varied based on three different flow settings (slow, medium, fast) to meet the necessary amount of nutrition changes during the 9-months waiting period prior to reconstructive surgery. FloSure can be interchanged and re-shaped to fit in regular baby bottles, greatly reducing the cost and increasing the accessibility to the parent customers. Due to the alternative flow mechanism that does not require negative pressure this new feeding system can be broadened to babies with severe feeding problems such as Down's Syndrome, neurological dysfunction, bronchopulmonary dysplasia, congenital heart disease, genetic disorders, etc.

#### Value Proposition

Cleft palate is a craniofacial anomaly that affects 1 in 700 children worldwide. Fortunately, CP can be corrected through the process of several reconstructive surgeries, which usually take place between 6-12 months old. This large window of time is extremely crucial in ensuring that the infant is receiving the necessary amount of nutrients required for proper physical growth as well as developing the proper oral-motor skills. For severe cases, some children with CP may require a feeding tube to assist with their nutrition intake. However, research has shown that feeding tubes can lead to other psychological and physical problems. Currently, the physical growth and development of children with CP rests below average on pediatric growth charts, illustrating the need to address the existing feeding mechanisms designed for children with CP. This gap between children with and without CP is largely attributed to the significantly lower flow rates of existing designs, issues of nasal regurgitation through the nasal cavity, longer feeding times, and the amount of energy required from the baby to obtain the fluid.

FloSure can reduce the feeding time and the chance of nasal regurgitation, while increasing the nutrition intake by providing an alternative feeding mechanism. This mechanism only requires the use of the child's tongue and jaw movement to get the fluid out of the artificial nipple. The baby then can manage the amount and the direction of the fluid intake without overworking themselves to try and create suction. Additionally, parents will be less worried about trying to control the feeding rhythm of the baby and spending additional time assisting with the removal of fluid from the nipple. The insufficiency of existing designs is further complicated by the various types (unilateral, bilateral and Pierre Robin Syndrome) and degrees of severity of the cleft palates. In contrast, FloSure is customized specifically based on the specific needs and mechanisms of each cleft type while providing three different flow settings (slow, medium and fast). Our design can be interchanged with the regular bottle designs on the market, which will reduce the cost of the product. Current specialized bottles are also not available in stores such as Toys R' Us, Wal-Mart, etc. Parents have to order online and wait for a period of time in order to buy a specialized bottle. In addition, the cost of specialized bottles is significantly higher when compared to standard bottles, and can range anywhere from \$20.00 to \$100.00 per bottle. By incorporating our design with current brands of standard bottles, it will increase the accessibility for parents to the products.

#### Market Opportunity

The primary target market of our product would be the parents of babies with cleft lips or cleft palates. In the US alone, around 7,000 babies were born with cleft lips or cleft palates in 2013<sup>1</sup>. Approximately every 1 in 700 newborn babies has such birth defects globally. Healthcare providers that routinely purchase specialty feeding bottles would be our secondary target market.

**Revenue Forecast.** In the US, the average price of existing specialty feeding bottles is around 25 US dollars. Assuming the parents will replace the feeding bottles every three months to match the baby's growth before the baby's repair surgery at 1-year-old, we estimate the average spending on specialty feeding bottles for every baby with cleft palate/lip to be around 100 US dollars per year. In total, the expenditure by American parents on their cleft

palate/lip babies will be around  $7,000 * 120 = 700,000$  US dollars per year. Globally, around 120,000 babies are born with cleft palate or cleft lip each year according to a 2011 estimate <sup>ii</sup>. Therefore, the total expenditure on specialty feeding bottles worldwide can be estimated to  $120,000 * 120 = 14,400,000$  US dollars per year. However, this is likely to be a very conservative estimate because babies from developing countries may not receive repair surgery until much later than 1-year-old.

**Competition.** Competitive designs currently available on market include the Haberman feeder manufactured by Medela and the special-needs feeder manufactured by Pigeon Global. Both designs feature a squeezable bottle and one-way valve to allow the parents feed the babies by compressing the bottles. However, these designs only work well for babies with unilateral cleft and could barely function for babies with bilateral cleft or Pierre Robin Sequence. Moreover, both designs would take away the babies' ability to control the flow of fluid voluntarily and practice their oral muscles. Our products are designed to overcome these problems and to replace current designs rather than competing directly with them for market share. As both manufacturers are private companies, we could not obtain sufficient financial information to determine their current market share.

**Success Factors and Risks.** The success of the business would be largely dependent on whether the design can achieve our desired outcome. Currently our design concept has significant competitive advantages against competitive designs. However, the materialization of the design concept is equally essential to our success. Moreover, due to the limited size of the specialty feeding bottle market, a dominant market share may be required for the business to survive and succeed. And this leading market position has to be built on good brand reputation and efficient widespread distribution channels, besides a clearly outstanding design.

**Milestones and Goals.** Our first milestone would be the products' successful acceptance by parents and caregivers at UVA Children's hospital. This milestone would lay a foundation for the product to enter and dominate the wider market. The second milestone would be the recognition of the product by one of the most influential organizations concerning babies with cleft palate/lip such as Operation Smile. Ideally, a formal cooperative relation would be set up with such organizations to distribute the product worldwide, especially in third world countries when there is a high rate of cleft case as well as a much longer wait time for cleft repair surgery. This milestone would mark the initial success of reputation-building and market recognition. The third milestone would be getting more than 50% market share by revenue in the cleft palate/lip specialty bottle market. This milestone would signal the initial success of achieving the dominant market position. In addition to these goals, we also want to customize FloSure's designs for an expanded population of other babies' health conditions with severe feeding issues such as Down syndrome and Congenital Heart disease.

## Product description

We proposed a new bottle feeding mechanism based on studies of oral motions presenting during regular feeding, challenges of the current existing specialized designs, and discussions with our speech pathologist advisor who has years of experience in assisting feeding for special-need children at UVA Hospital Neonatal Care Unit. Most current bottle designs require the assistance of the parents to control the fluid flow as well as direction of the flow. There is a miscommunication between the parents and the child being fed, which lead to an extended feeding time. Our proposed bottle feeding only requires peristaltic tongue movement and lower jaw movement to apply pressure to the artificial nipple in order to obtain fluid. The baby will have more control to the overall feeding process, which supports the adaptation of the baby in feeding even after reconstructive surgery. In addition, utilizing the oral motions and the application of gravity in fluid flow will lessen the energy needed in feeding for children with cleft palate resulting in reduced feeding time. The location of the opening nipple slit is also relocated to obtain maximum pressure as well as change the direction of flow so that fluid will less likely to be shot toward the nasal cavity. This change in slit location helps create a streamline flow of fluid that decreases chance of nasal regurgitation.

Children with cleft palate have slightly differences in feeding mechanism and requirements based on the cleft types. Therefore, the shape of the nipple will be designed specialized base on the specific need of each cleft type (unilateral, bilateral and Pierre Robin sequence syndrome). An addition flow gate control is placed inside the bottle to vary the fluid flow rate based on three different flow setting (slow, medium, fast) to meet the necessary amount of nutrition change during the 9-months waiting period prior the reconstructive surgery.

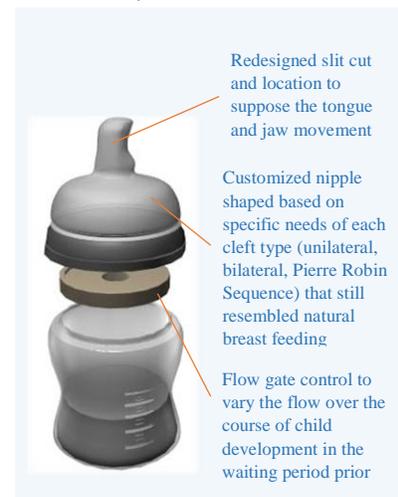


Figure 1: Schematic proposed shape of FloSure

## Management team

**Katrina Shah** is a 4<sup>th</sup> year undergraduate student majoring in Engineering Science-Nanomedicine. She has been working on this project as an independent research in Summer 2014 and now as her Capstone project. Her role in this research is to develop 3D models of the oral cavity for the 3 cleft palate types as well as to design the shape and material for the artificial nipple of the bottle. (Resume attached)

**Aaron Lu** is a 4<sup>th</sup> year undergraduate student in Biomedical Engineering department. He is currently working on this project as his Capstone research. His role in the research is to develop a consistent testing mechanism for the new design as well as to design the shape and material for the artificial nipple of the bottle. (Resume attached)

**Thanh Tran** is a Lab Specialist in Dr. Blemker laboratory. She graduated UVA with a Bachelor degree of Science in Engineering Science- Nanomedicine in May 2014. She has been working on this project as her Capstone project over a year. Currently, she serves as an assistant advisor and a design contributor to the research. (Resume attached)

**Marcelle Huizenga** is 4th-year BME undergraduate student. She worked on this project as her Capstone research last year. (Resume attached)

**Dr. Silvia Salinas Blemker** is the primary advisor of this research. She joined the University of Virginia faculty in January of 2006. She obtained her B.S. and M.S. degrees in Biomedical Engineering from Northwestern University and her Ph.D. degree in Mechanical Engineering from Stanford University. Before coming to UVA, Dr. Blemker worked at Stanford National Center for Biomedical Computation, where she was a post-doctoral Research Associate. Dr. Blemker's research is focused on identifying the relationships between muscle structure, mechanical properties, biology, and function. Her group integrates a variety of computational and experimental approaches to achieve this goal, and they are applying their findings to understanding and improving treatments for muscle impairments.

**Kathleen Borowitz, M.S.** is the secondary advisor of this research. She works as a Speech Pathologist in the Department of Pediatrics at UVA hospital. She received her M.S. degree at Vanderbilt University in 1981. She holds a ABMS certification from American Speech- Language Association.

**Catherine Pelland, B.S.** is the assistant advisor of this research. She is a third-year Mechanical Engineering graduate student in the Multiscale Muscle Mechanics (M3) Lab. She received her undergraduate degree (B.A.) in Mathematics from Pomona College before coming to University of Virginia. She currently works in the field of muscle biomechanics, specifically studying the soft palate musculature, using magnetic resonance imaging and finite-element modeling, with the eventual goal of improving the outcomes of cleft palate repair surgery. She helps with the segmentation of the MRI results.

**Katherine Knaus, B.S.** is the assistant advisor of this research. She is a first year graduate student in the Multiscale Muscle Mechanics lab. Her research involves using advanced medical image processing, 'big data' analysis, and computer modeling to study the functional mechanics of skeletal muscle, specifically the lower limb. Katie received her B.S. from the University of Virginia with a double major in Mechanical Engineering and Physics. She is also the mother of a two year old and has extensive knowledge of feeding infants. She helps provides knowledgeable insight on baby feeding.

## Contact Information:

Katrina Shah ([kas8ct@virginia.edu](mailto:kas8ct@virginia.edu))  
201<sup>th</sup> Street NW, Charlottesville VA 22904 Apartment 2-F  
248-935-9034

---

i. FAQs for Parents of a Newborn – Cleft Palate Foundation. (n.d.). Retrieved from <http://www.cleftline.org/parents-individuals/frequently-asked-questions/>

ii. Prevalence at Birth of Cleft Lip With or Without Cleft Palate: Data From the International Perinatal Database of Typical Oral Clefts (IPDTC). (2010). *The Cleft Palate-Craniofacial Journal*, 48(1), 66–81. doi:10.1597/09-217