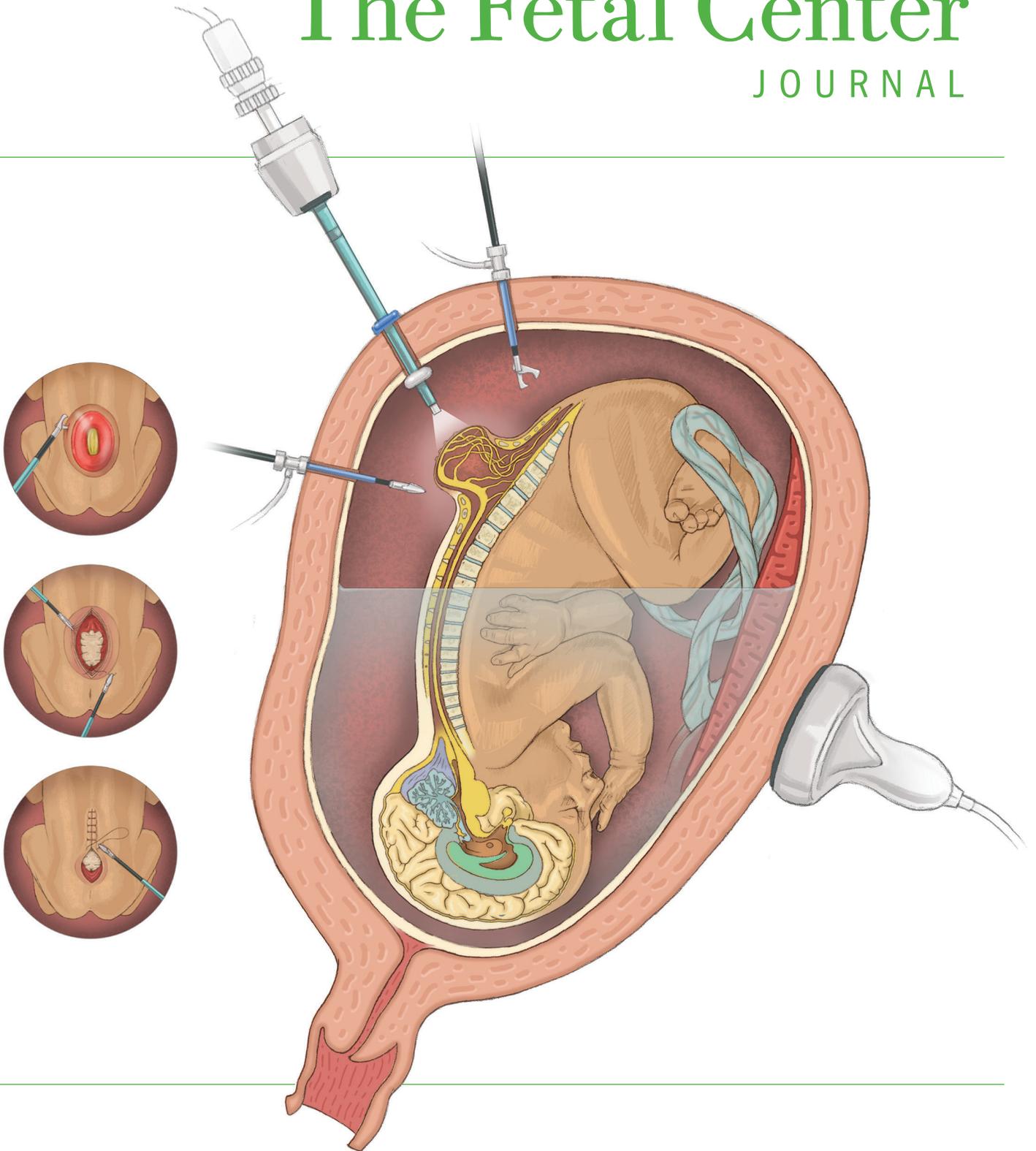


# The Fetal Center

JOURNAL



 UTHealth<sup>®</sup> Houston  
McGovern Medical School

Children's  
MEMORIAL<sup>®</sup>  
HERMANN  
Hospital

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**On the cover:** Three-port fetoscopic spina bifida repair.

# Toward a Safe Method of Minimally Invasive Myelomeningocele Repair

In 2020, Oklahoma resident Hailee Nail became a patient of The Fetal Center at Children’s Memorial Hermann Hospital as well as the beneficiary of more than a decade of research conducted by McGovern Medical School at UTHealth Houston.

Nail delivered her daughter, Lily, vaginally at 39 weeks of pregnancy at Children’s Memorial Hermann Hospital on Dec. 8, 2020, as the first patient enrolled in a single-center trial of fetoscopic myelomeningocele repair of small defects at McGovern Medical School. In 2022, after the successful completion of the single-site feasibility study that included 25 patients, the FDA gave approval to expand the study to 50 patients.

The study is led by Ramesha Papanna, MD, MPH, a professor of maternal-fetal medicine at McGovern Medical School at UTHealth Houston and a co-director of The Fetal Center at Children’s Memorial Hermann Hospital. Dr. Papanna is internationally recognized for his research on improving outcomes following fetal intervention and investigating methods for the prevention of preterm delivery. “Our primary outcome measure for the fetoscopic patch study is successful surgical closure of the spina bifida defect with a watertight patch that regenerates native tissue and allows for the natural growth of the spinal cord,” Dr. Papanna says. “The procedure differs from standard of care of open in utero repair, which requires a large incision on the uterus, covering the spina bifida defect using local tissue pulled over the spinal cord followed by skin closure, and delivery by cesarean section. Instead, we make three tiny holes in the uterus to repair the spina bifida defect in two layers using a fetoscope, a high-resolution camera, and tiny surgical tools. The first layer is closed using the NEOX® Cord 1K patch placed over the spinal cord, followed by a second layer of primary closure of the skin. Mothers can undergo vaginal delivery



unless there is an obstetrical indication for delivery by C-section.”

Developed by Amnio Medical, Inc., the NEOX Cord 1K patch is a cryopreserved human umbilical cord (HUC) patch manufactured by devitalizing all living cells while retaining the extracellular matrix and growth factors/ cytokines within. Laboratory and clinical research on a number of ocular indications<sup>1</sup> has shown that cryopreserved human umbilical cord can help manage inflammation in wounds, facilitate cell proliferation, and create an environment for tissue regeneration.

The study, the first to use an HUC patch to cover the spina bifida defect, enrolls patients ages 18 and older who, like Hailee Nail, have a singleton pregnancy, who qualify for an open in utero repair. A digital image of the fetal repair site is captured immediately after the repair, and efficacy of the repair is assessed after birth by three neurosurgeons who serve as blinded reviewers.

Patients referred to UT Physicians, the clinical practice of McGovern Medical School, and The Fetal Center at Children’s Memorial Hermann Hospital who intend to undergo open in utero spina bifida repair will be offered and screened for the alternative minimally invasive approach. Previous patients enrolled in the trial were required to return to Houston at 34 weeks for delivery and

neonatal care at Children’s Memorial Hermann Hospital. Based on the safety results of the first 25 patients in the study, new patients can return home two weeks after surgery and be delivered locally if specialized care is available at the referring center.

“We published preclinical data and rigorously tested our techniques before taking fetoscopic repair to humans,” Dr. Papanna says. “Our research is changing the way we approach spina bifida to improve closure,

if a fetus undergoes surgery in utero to repair a spina bifida defect, serious complications could be reversed or lessened when compared to infants who underwent repair after birth. The study found that fetal surgery decreased the need for ventriculoperitoneal shunting for infants, and nearly half were able to walk without crutches by the age of 30 months.

Dr. Tsao – who serves as a professor of pediatric surgery at McGovern Medical School, The Children’s Fund, Inc. Distinguished Professor in Pediatric Surgery, and co-director of The Fetal Center at Children’s Memorial Hermann Hospital – and his maternal-fetal medicine colleagues were in the process of screening patients for the study when Faith Hagler’s parents, Ivan and Colette Hagler of Dallas, were referred to The Fetal Center. Based on the MOMS trial protocols, which included medical, psychological, and social criteria, the team determined that Mrs. Hagler, Faith’s mother, was an ideal candidate for the procedure.

After the surgery – the first fetal myelomeningocele repair in Texas – Hagler remained at Children’s Memorial Hermann Hospital and delivered Faith almost nine weeks later on the Fourth of July, a date that Hagler describes as “so symbolic” of the independence her daughter has achieved since her birth. Faith began crawling at 11 months, took her first steps at 21 months, and today, she’s dancing.

For more than a decade, the fetal surgery program at The Fetal Center has continued to produce excellent outcomes with patients chosen based on the selection criteria established in the MOMS trial. The selection process for in utero repair employs a strict prenatal algorithm emphasizing education to prepare families to make an informed decision about treatment.

### Designing a Regenerative Patch for Open In Utero Repair

Initially, the NEOX Cord 1K was used as a skin patch when primary skin closure of the spina bifida defect was not possible in open in-utero surgery. Made from donated human umbilical cord (HUC) of healthy newborns, the patch was used for the repair of large defects in cases performed by UTHealth Houston surgeons at Children’s Memorial Hermann Hospital in 2016. Patients underwent surgery performed by Dr. Stephen Fletcher, a professor of pediatric neurosurgery at McGovern Medical School,

reduce scar tissue formation, reduce neurological deficits, and improve function. With this trial, we hope to show that the cryopreserved human umbilical cord patch optimizes long-term outcomes for these kids.”

### Independence from Spina Bifida: A Decade of Research

In 2011, fetal surgeon KuoJen Tsao, MD, and pediatric neurosurgeon Stephen Fletcher, DO, were following the results of a landmark clinical trial, Management of Myelomeningocele Study (MOMS), which found that



and Dr. Tsao. Many of these patients have good lower-extremity motor and sensory function and three have been able to walk independently.

Fewer than half of the patients who undergo open in utero spina bifida repair with a patch show improvement in spinal cord function, based on the MOMS trial long-term follow-up study. For the past decade, Dr. Papanna and Lovepreet K. Mann, MBBS, an assistant professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at McGovern Medical School, and their research team have been working to gain greater understanding of the lack of complete benefit after fetal surgery. They tested the cryopreserved HUC patch, overlaying the spinal cord below the skin closure, to improve spinal cord function and reduce spinal cord tethering.

“After investigating many types of patches in surgical animal models, we found that the HUC could promote regeneration of the protective layers around the spinal cord after surgery and improve neurological function,” Dr. Papanna says. “We compared the HUC patch to conventionally used methods in an effort to reduce scar formation and improve spinal cord function at and below the defect site.”

Dr. Papanna’s current fetoscopic research builds on his laboratory’s experience with cryopreserved HUC for open in utero spina bifida repair. His findings were published in multiple peer-reviewed journals including the *Journal of Neurosurgery: Spine*,<sup>2</sup> *Journal of Pediatric Neurosurgery*,<sup>3</sup> *Prenatal Diagnosis*,<sup>4</sup> *AJP Reports*,<sup>5</sup> *Obstetrics & Gynecology*,<sup>6</sup> and *Ultrasound in Obstetrics and Gynecology*.<sup>7</sup>

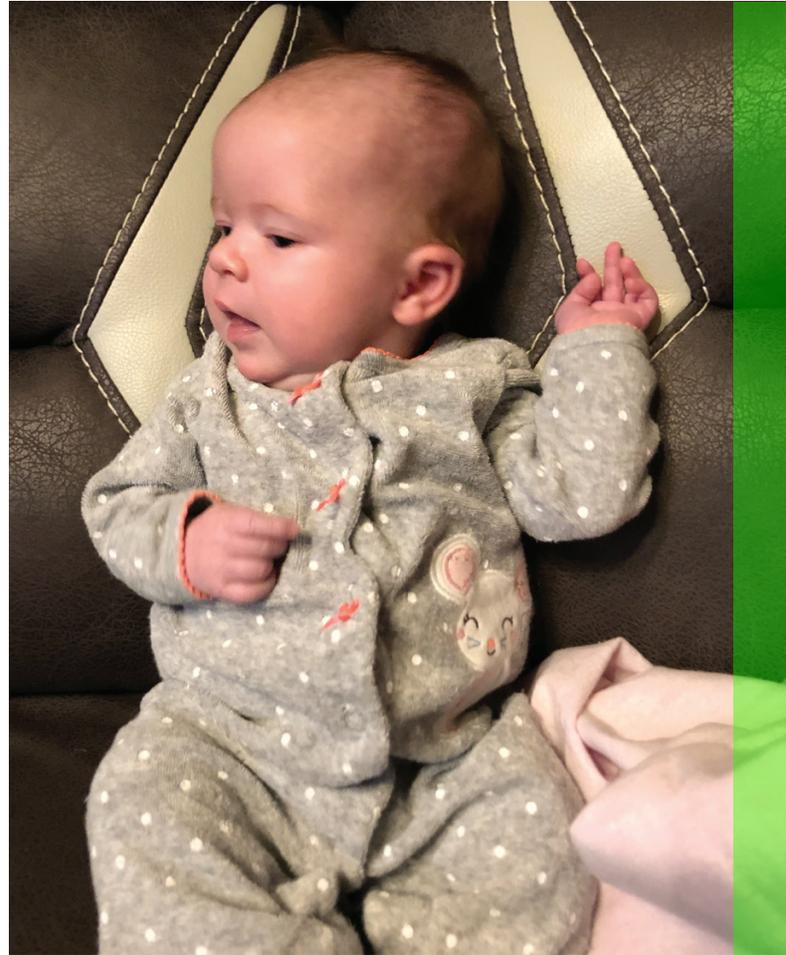
“The HUC patch acts as a watertight scaffold, allowing native tissue to regenerate in an organized manner,” says Dr. Mann. “Preclinical data have shown that the patch promotes organized cell growth, resulting in a spinal cord repair that appears more normal with better function. It also has anti-scarring and anti-inflammatory properties. Preventing the scarring could prevent spinal cord tethering, a common problem with spina bifida, which in turn can prevent further damage to the cord.”

Dr. Mann says the research team is focusing on further improving outcomes by pushing the boundaries of fetal wound healing through regenerative repair. “If we can make a small change and improve the quality of life for these children, we have really accomplished

something,” she says.

Spina bifida is the most common neural tube defect in the United States, affecting about 1,500 to 2,000 of the more than 4 million babies born in the country each year, according to the National Institute of Neurological Disorders and Stroke. Associated disorders include hydrocephalus and learning disability. An estimated 166,000 individuals with spina bifida live in the U.S.

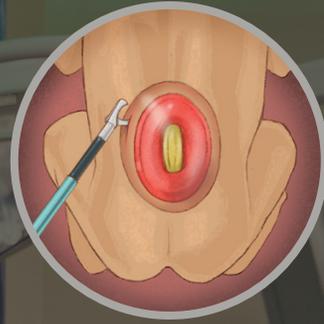
“HUC could be a game changer for spina bifida repair,”



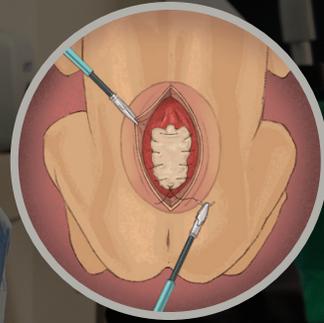
Dr. Papanna says. “Our ultimate goal is to ensure that babies born with the disorder can walk and have improved outcomes. We also think HUC will lead to new paradigms in fetal wound healing for other spinal defects and repairs.”

Currently, the research team is working to find ways to optimize repair in utero and new ways to deploy the patch over the defect site through less invasive means. “We’ve made progress at an incredibly rapid pace,” he says. “Taking an idea from the lab to human use typically

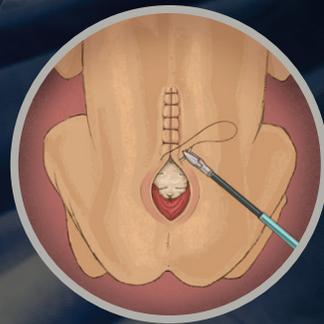




Neural placode dissection



Suture close the umbilical cord as meningeal patch



Primary closure of the skin defect

takes about a decade. We've been able to reduce that time by more than half. We have a good system in place with strong collaborators, all of whom have track records of success in their fields."

"Dr. Papanna is a workhorse for UTHealth and our efforts to further research in a very fast-moving and competitive market," Dr. Fletcher says. "We see patients who come from across the country for treatment at Children's Memorial Hermann Hospital, and when I ask them why they travel so far, they say it's because of the research we're doing at UTHealth Houston. We are leaders in the field, and we're moving forward deliberately to answer every question and avoid the failures that have occurred in other programs."

"After spending nearly 40 years in the field of neurosurgery, it seemed to me that the accepted norm for most patients with open neural tube defects was to have hydrocephalus, some degree of weakness in the extremities, and bladder and bowel disturbances," he adds. "These problems have existed alone or in combination. What a pleasure it is to see, after more than 100 of these surgeries, an increasing number of patients who have no detectable ambulation problems, no hydrocephalus and, remarkably, have normal bladder and bowel function."

### Lily Nail

Hailee Nail learned her baby had spina bifida on August 13, 2020, when she saw her obstetrician in Tulsa, Oklahoma, for her 20-week anatomy scan. "My OB-GYN told me that it would require surgery and gave me the names of several centers, but he said he wanted me to go to Houston," she says.

Nail arrived at The Fetal Center at Children's Memorial Hermann Hospital on August 25 and went through a four-day evaluation with members of the UTHealth Houston spina bifida surgery team. "She came to us when our study of fetoscopic repair using the NEOX Cord 1K patch had just opened," Dr. Papanna says. "She was 19, and it was her first pregnancy. Her baby had a myelomeningocele sac, which allows for easier closure of the skin. Fetoscopic repair will allow for vaginal birth, and she can have more children in the future with less concern for uterine rupture. We offered her open in utero repair or the opportunity to enroll in the fetoscopic clinical trial."

Nail asked a lot of questions and remembers feeling well

informed by Dr. Papanna and by Dr. Fletcher, whose role would be to reveal the spinal cord and sew the patch in place over the small defect on Lily's lumbosacral joint. "I decided to go with fetoscopic repair to give my daughter a better quality of life," she says.

The surgery was scheduled for September 1. "They opened my abdomen vertically from the top of my belly button to midway down the pelvic bone," she says. "When they got to the uterus, they drilled three holes in order to insert two instruments and a camera. In the photos you can see the patch being placed and skin being pulled together and sewn up."

After the surgery, which took six hours, 3 ½ of which were devoted to the fetoscopic repair, Nail returned to Oklahoma for two months before traveling to Houston again to deliver at Children's Memorial Hermann Hospital.

"My recovery was actually really good," Nail says. "I stayed in the hospital for five days and stayed in a hotel room for two weeks after discharge. I went for an ultrasound the first week and second week, then flew home."

Lily entered the world via vaginal birth. "In the end, I had to be induced," Nail says. "Lily is amazing. Her bowel and bladder function are good. She is walking independently. I'm absolutely amazed at how awesome this team is. I'm not one for hospitals, but I loved my care before, during, and after birth."

Nail and her daughter returned to Houston at 12 months after delivery in December 2021. As participants in the clinical trial, they will be back for follow-up exams for the next six years.

"The most important thing is that we work together very well as a team and were able to close the defect," Dr. Papanna says. "Other centers are using two ports to perform a myofascial closure, moving muscle tissue over to the spinal cord and then covering it with skin. The myofascial closure requires a dissection cut into the fetal muscle and sometimes into the bone. This takes more time in the operating room and can cause bleeding and wound healing problems, resulting in a scar. We want to avoid that. We use three ports and a high-resolution camera to place the HUC patch and suture it to create a watertight closure that helps the spinal cord grow and repair the site, reducing the potential for tethering. While most centers want to keep moms there for the remainder

of the pregnancy, we have been able to send them home for delivery. We take extra effort and coordination to help the local specialist to care for these mothers and babies as well as do here.”

“The amazing thing about Hailee is that she was able to go full term with no complications during pregnancy,” he says. “After we induced her, she had 24 hours of labor and then a baby. Lily’s back looked totally normal, with no cerebrospinal fluid leakage. The skin had healed in the uterus, she had no hindbrain herniation, and her legs were moving. Although the HUC is based on very strong preclinical data, we need to complete the test of our methodology and compare it to the more traditional approach. We’re now offering the fetoscopic repair for all spina bifida defects including myelomeningocele more than 4 cm width and myeloschisis.” ☀



<sup>1</sup>He H, Tan Y, Duffort S, Perez VL, Tseng SC. *In vivo* downregulation of innate and adaptive immune responses in corneal allograft rejection by HC-HA/PTX3 complex purified from amniotic membrane. *Invest Ophthalmol Vis Sci.* 2014;55(3):1647-56.

<sup>2</sup>Mann LK, Won JH, Trenton NJ, Garnett J, Snowise S, Fletcher SA, Tseng SCG, Diehl MR, Papanna R. Cryopreserved human umbilical cord versus acellular dermal matrix patches for in-utero fetal spina bifida repair in a pregnant rat model. *J Neurosurg Spine.* 2019 Nov 1;1-11. doi: 10.3171/2019.7.SPINE19468. Epub ahead of print. PMID: 31675701.

<sup>3</sup>Vu T, Mann LK, Fletcher SA, Jain R, Garnett J, Tsao K, Austin MT, Moise KJ Jr, Johnson A, Shah MN, Papanna R. Suture techniques and patch materials using an in-vitro model for watertight closure of in-utero spina bifida repair. *J Pediatr Surg.* 2019 Jun 19;S0022-3468(19):30409-9. doi: 10.1016/j.jpedsurg.2019.05.024. Epub ahead of print. PMID: 31255327.

<sup>4</sup>Snowise S, Mann L, Morales Y, Moise KJ Jr, Johnson A, Fletcher S, Grill RJ, Tseng SCG, Papanna R. Cryopreserved human umbilical cord versus biocellulose film for prenatal spina bifida repair in a physiologic rat model. *Prenat Diagn.* 2017 May;37(5):473-481. doi: 10.1002/pd.5035. Epub 2017 Apr 16. PMID: 28295455.

<sup>5</sup>Papanna R, Mann LK, Snowise S, Morales Y, Prabhu SP, Tseng SC, Grill R, Fletcher S, Moise KJ Jr. Neurological Outcomes after Human Umbilical Cord Patch for In Utero Spina Bifida Repair in a Sheep Model. *AJP Rep.* 2016 Jul;6(3):e309-17. doi: 10.1055/s-0036-1592316. PMID: 27621952; PMCID: PMC5017885.

<sup>6</sup>Papanna R, Fletcher S, Moise KJ Jr, Mann LK, Tseng SC. Cryopreserved Human Umbilical Cord for In Utero Myeloschisis Repair. *Obstet Gynecol.* 2016 Aug;128(2):325-30. doi: 10.1097/AOG.0000000000001512. PMID: 27400004.

<sup>7</sup>Papanna R, Moise KJ Jr, Mann LK, Fletcher S, Schniederjan R, Bhattacharjee MB, Stewart RJ, Kaur S, Prabhu SP, Tseng SC. Cryopreserved human umbilical cord patch for in-utero spina bifida repair. *Ultrasound Obstet Gynecol.* 2016 Feb;47(2):168-76. doi: 10.1002/uog.15790. PMID: 26489897.

*The facts and the physician affiliations discussed in this article were confirmed at the time of the article’s original publication.*

# Tracheal Occlusion To Accelerate Lung Growth (TOTAL) Trial Results

On June 8, 2021, the clinical trial results for the Tracheal Occlusion To Accelerate Lung Growth (TOTAL) Trial, led by Jan Deprest, MD, PhD, Professor of Obstetrics and Gynaecology at the University Hospitals Leuven in Belgium, were published in the *New England Journal of Medicine*.

The TOTAL Trial was an international, multicenter randomized controlled trial with two arms, the Severe Arm and the Moderate Arm, evaluating survival and morbidity in fetuses with congenital diaphragmatic hernia (CDH).

The Severe Arm of the trial evaluated survival in fetuses with severe CDH detected prior to 30 weeks gestation, while the Moderate Arm evaluated survival and morbidity in fetuses with moderate CDH detected prior to 32 weeks gestation.

The findings of the Severe Arm of the trial indicate that prenatal intervention in fetuses with severe, isolated left-sided CDH resulted in a significant benefit over expectant care with respect to survival to discharge, and this benefit was sustained to 6 months of age. The findings of the Moderate Arm of the trial indicate that prenatal intervention in fetuses with moderate, left-sided CDH did not show a significant benefit over expectant care with respect to survival to discharge or the need for oxygen supplementation at 6 months. In both the Severe and Moderate Arms of the TOTAL Trial, prenatal intervention increased the risks of preterm, prelabor rupture of membranes and preterm birth. [Click here to view more details about the TOTAL Trial.](#)

In the ongoing effort to provide optimal care for patients, The Fetal Center, affiliated with Children's Memorial Hermann Hospital (CMHH), McGovern Medical School at UTHealth, and UT Physicians, has been

offering Fetoscopic Endoluminal Tracheal Occlusion (FETO) for the prenatal treatment of CDH through participation in both the Severe and Moderate Arms of the TOTAL Trial. The team of affiliated fetal surgeons, with extensive experience in fetoscopic intervention (> 800 fetoscopic cases), have worked with Professor Deprest in Belgium and in Houston to utilize the FETO technique at The Fetal Center. As a recognized, international leader in the prenatal diagnosis and management of CDH, our fetal center co-director, Anthony Johnson, DO, worked closely with Professor Deprest to lead the process of bringing the trial to the U.S., enrolling and managing these patients, and co-authoring the publication in the *New England Journal of Medicine*. As one of only 10 U.S. fetal centers granted FDA and institutional approval to offer FETO intervention and the only fetal center in the U.S. to participate in both arms of the TOTAL Trial, our Comprehensive Center for CDH Care and entire team are actively engaged and dedicated to improving outcomes for all patients with CDH – mild, moderate or severe.

With one of the most comprehensive CDH programs in the U.S., CMHH and UTHealth together approach every CDH patient as a survivor. With more than 30 years of experience, CMHH is a national referral center for CDH with an integrated team of affiliated specialists from UTHealth including maternal-fetal medicine specialists, neonatologists, pediatric surgeons, pediatric anesthesiologists and pediatric subspecialists. By integrating multidisciplinary expertise, UTHealth and CMHH provides quality care for families beginning at prenatal diagnosis through delivery, postnatal care, and long-term follow-up through childhood – with a smooth transition into adult specialty care. This treatment approach has translated into higher-than-expected risk-stratified survival, as well as one of the highest rates of surgical repair in the world.

The affiliated team at McGovern Medical School and Children's Memorial Hermann is committed to providing specialized care for families affected by CDH. We strive to offer convenience for families and work with

**CMHH and UTHealth together offer a complete approach to caring for CDH patients thanks to various integral components of our Comprehensive Center for CDH Care, including:**

- Establishment of the first comprehensive extra-corporeal membrane oxygen (ECMO) program in Houston, and recognition as a Designated Center of Excellence by the Extracorporeal Life Support Organization (ELSO) since the inception of the award in 2006.
- The Fetal Center, which is an international leader in fetal diagnosis, fetal intervention and comprehensive fetal care for infants with congenital anomalies or genetic abnormalities.
- CMHH's Level IV Neonatal Intensive Care Unit (NICU), providing the highest level of care to the most critically ill newborns. Our neonatologists have unique and focused expertise in the management of patients with CDH.
- Our high-risk, multidisciplinary center for CDH – one of only a few of its kind in the country – is specially designed for CDH patients and their families. Staffed by a multidisciplinary team of affiliated specialists, this center provides patients with a one-stop shop approach that allows families to see all pediatric specialists relevant to their case, in a single visit under one roof. In addition to offering convenience to patients and families, this approach allows our affiliated physicians to optimize patient care, collect data and understand the challenges faced by families of children with CDH in ways that were previously impossible. For our patients from a long distance, we can provide follow up with our state-of-the-art telemedicine program.
- A team of basic, translational, and clinical scientists focused on CDH seeking advances in knowledge and novel therapies. Our team leads international investigative collaborations and our institution has published over 40 original articles in CDH since 2019. In 2020, our team hosted the International Congenital Diaphragmatic Hernia Symposium, a CDH-dedicated educational conference with attendees representing 11 different countries. We are constantly striving to learn more in order to help patients who seek our expertise in Houston and around the world. We are currently conducting the only Phase I trial of stem cells for CDH in the world.
- Our laboratory research programs are looking at ways to improve the lung problems and blood vessel abnormalities seen in CDH, providing novel insights and potentially new therapeutic options.



Dr. Anthony Johnson [C] and Dr. KuoJen Tsao [R], Co-directors of The Fetal Center, and Dr. Eric Bergh [L] Maternal-Fetal Medicine Specialist, work together to perform the fetoscopic endoluminal tracheal occlusion (FETO) procedure on a patient of The Fetal Center affected by congenital diaphragmatic hernia (CDH).

referring physicians to best serve patients. During these unprecedented times, we continue to take extra steps and implement additional safety practices in our patient care process to responsibly serve the community. We are available for in-person consultations and are utilizing telemedicine opportunities to connect with both patients and providers. This includes visits with our team virtually via a computer, or verbally over a phone call. We know that the anxiety of this diagnosis can be overwhelming for families, and we are happy to connect with little notice, any weekday.

We will continue offering the FETO intervention procedure to patients diagnosed with a CDH who qualify. As evidenced by our leadership with and involvement in innovative and collaborative trials like the TOTAL trial, along with our continued quest to advance the care of CDH patients and their families in an unparalleled, comprehensive program, we are confident that we can offer these patients exceptional expertise and uniquely advanced and tailored care. Additionally, we may be able to provide resources for patients who may need financial assistance if traveling to our Center to continue their care. Please contact our Center to inquire about these opportunities. 🌞

# RAFT Trial

The University of Texas Health Science Center at Houston (UTHealth) is one of nine centers in the nation participating in the Renal Anhydramnios Fetal Therapy (RAFT) Trial, sponsored by Johns Hopkins University and funded by the National Institutes of Health.

Mothers who enroll in the trial will be treated at the trial site The Fetal Center at Children’s Memorial Hermann Hospital, an international leader in fetal diagnosis, fetal intervention, and comprehensive multidisciplinary care for infants with congenital anomalies or genetic abnormalities.

Early pregnancy renal anhydramnios (EPRA) is a catastrophic development event of the kidney that leads to failure to produce amniotic fluid in the gestational sac. The absence of amniotic fluid results in fetal deformations, including abnormal posturing of the legs, feet, and hands, and even more important, compression of the baby’s chest and inadequate lung growth (pulmonary hypoplasia). Before 26 weeks, the lack of amniotic fluid is fatal. Patients who choose to continue the pregnancy will have a stillbirth or can expect the baby to die shortly after delivery. Until now, treatment options have been limited to pregnancy continuation or termination.

The RAFT Trial offers eligible pregnant women with a diagnosis of EPRA an experimental therapy of serial amnioinfusions of fluid into the uterus. During the procedure, experts in fetal intervention insert a small needle into the uterus next to the baby to slowly infuse warm sterile fluid with balanced electrolytes and antibiotics. The goal is to help the baby’s lungs grow enough to allow survival after birth. Limited case reports have suggested that serial amnioinfusions may improve outcomes in the baby’s lung function and survival.

Families considering participation in the trial will be counseled by an affiliated pediatric nephrologist, pediatric surgeon, transplant surgery specialist, clinical licensed social worker, genetic counselor, and maternal-fetal medicine specialist. Counseling will address the need for multiple amnioinfusions, the uncertainty of their success in preventing pulmonary hypoplasia, and the risk of early rupture of membranes and premature delivery. In addition, they will be made aware of the postnatal challenges the infant will face. These include the need for dialysis, the need for supplemental nutrition likely by gastrostomy tube, the risk of sepsis, recurrent hospitalizations, the eventual need for kidney transplant, the requirement for immunosuppression after a kidney transplant, and the likely need for urinary tract reconstruction.

Families who choose to continue in the trial will be asked to select the study arm in which they would like to participate. Those who choose Arm 1 will receive serial amnioinfusions; those who choose Arm 2 will not receive amnioinfusions and will be monitored by physicians at The Fetal Center for the remainder of their pregnancy, or may choose to return to their referring physician for monitoring and delivery. Researchers will follow babies and their families until either kidney transplant or death.

Pregnant women with a diagnosis of EPRA may enroll in the trial at The Fetal Center at Children’s Memorial Hermann Hospital or at one of eight other centers across the country. Due to the significant risk of early rupture of membranes and early delivery for patients who receive amnioinfusions, participants will be enrolled using very strict criteria. We also will ensure that they are well informed of these risks before they decide to participate. ☀️

**To learn more about the trial, visit <https://clinicaltrials.gov/ct2/show/NCT03101891>.**

**To refer a patient, please call 832.325.7288 to speak with Anthony Johnson, DO, site principal investigator; Elizabeth Gould, RN; Robyn Torey, BSN; Candice Outlaw, BSN; or Ryan Wynn, PA.**

## Children’s Memorial Hermann Hospital Receives Level 1 Verification by American College of Surgeons

Children’s Memorial Hermann Hospital has been verified as a Level 1 Children’s Surgery Center by the American College of Surgeons (ACS) Children’s Surgery Verification (CSV) Quality Improvement Program. The distinction recognizes pediatric surgery centers that meet the highest standards in surgical quality and have a track record of preventing complications, reducing costs and saving lives.

As one of 28 ACS CSV-verified children’s hospitals in the United States, Children’s Memorial Hermann Hospital has demonstrated it has the resources available to achieve optimal surgical outcomes for pediatric patients.

“The Children’s Surgery Verification means that we have the capability to take care of children with the highest level of quality and safety through optimal resources, continuing education, and quality improvement,” says KuoJen Tsao, MD, professor and chief of the Division of Pediatric General and Thoracic Surgery at McGovern Medical School at UTHealth and co-director of The Fetal Center at Children’s Memorial Hermann Hospital. “Parents can have the utmost confidence when their children undergo surgery at Children’s Memorial Hermann Hospital that the affiliated team offers the highest level of care.” Dr. Tsao is The Children’s Fund Distinguished Professor in Pediatric Surgery at McGovern Medical School.

The CSV program is endorsed by multiple specialty societies, including the American Academy of Pediatrics, American Pediatric Surgical Association and Society of Pediatric Anesthesiology.



## Physician Spotlight: Eric Bergh, MD



Eric Bergh, MD, joined the medical staff at Children’s Memorial Hermann Hospital in September 2020, concurrent with his faculty appointment as assistant professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at McGovern Medical

School at UTHealth. In his role, Dr. Bergh serves as a maternal-fetal medicine specialist affiliated with The Fetal Center and will provide specialized care to patients at Children’s Memorial Hermann Hospital.

Dr. Bergh earned his medical degree at the Robert Wood Johnson School of Medicine at Rutgers University in Piscataway, N.J. He completed both residency training in obstetrics and gynecology and fellowship training in maternal-fetal medicine at the Mount Sinai Hospital in New York City. Subsequently, he completed a fetal intervention fellowship at The Fetal Center, working closely with the Center’s affiliated team.

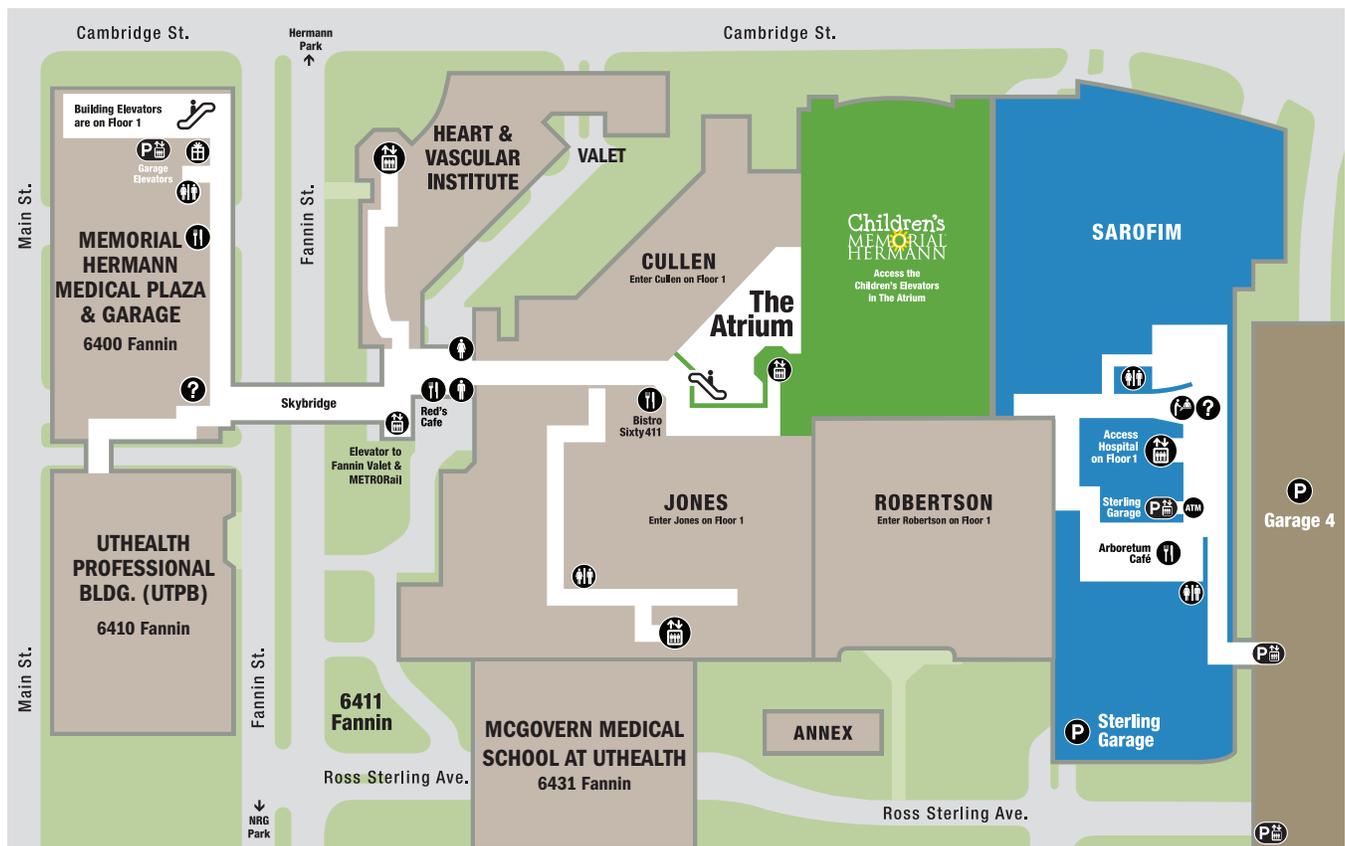
# Contact Us

## THE FETAL CENTER AT CHILDREN'S MEMORIAL HERMANN HOSPITAL

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Located within the Texas Medical Center,  
The Fetal Center is affiliated with McGovern Medical  
School at UTHealth, UT Physicians and Children's  
Memorial Hermann Hospital.

To view The Fetal Center's online resources, visit  
[memorialhermann.org/fetal](http://memorialhermann.org/fetal)





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