So there are some children who are born with this, and then there are some heart defects that actually produce left ventricular heart failure, or dysfunction.

And those that produce the left ventricular heart failure or dysfunction that can be surgically corrected early on in life then may go on to have complete recovery after their left ventricular dysfunction.

For those that are born with diseased myocardium due to genetic disorders, or other reasons, those children generally are looking toward a heart transplantation at some point in their future.

The paradigm to manage children with heart failure, when they failed medical therapy, typically would begin with assessing them for heart transplantation.

Once the heart transplantation evaluation is complete, the assessment would then be made whether to put them on a heart transplant list or not.

If they do get placed on a heart transplant list, many of them are too sick to wait for the average four to six months till a heart arrives, and therefore, they need something to help them achieve that goal.

Historically, we've used assist devices that are surgically implanted into the pumping chamber that doesn't pump well, and it's then surgically attached to the outflow, and helps support the child's heart till heart transplantation.

However, these heart devices and pumps are associated with complications, most commonly clotting, causing strokes.

It can be associated with bleeding, and therefore, it's not a free ride for these children.

Particularly children that are small, less than six months of age and less than six kilos, their risk of having ventricular assist device-related clots and strokes is extremely high-- in the 30% to 50% range.

A novel procedure known as the reversible pulmonary artery band, which had been described in Germany several years ago, is now being revisited and looked at as a therapy for left-sided heart failure, and LV dysfunction.

The procedure works by putting a band around the main pulmonary artery, which exits the right side of the heart.

In doing so, the partition between the right and left heart, known as the ventricular septum, changes its orientation, and moves further towards the left, therefore supporting the left-sided valve and the left-sided pumping chamber.

Typically, what is seen as the pressures that are abnormally high in the left side of the heart, in the 20 to 30 millimeter mercury range, get reduced to the 15 to 20 millimeter mercury range, and produce a moderate benefit to the child.

When the child does receive significant benefit, the child can then be weaned off the ventilator, weaned off the medications required to support the blood pressure, and discharged home.

When the band hasn't worked as well as we'd expect it to, we've found that it's primarily because the right side of the heart is also affected by the heart failure process.

And when the heart failure process is not limited to the left side alone, the pulmonary artery band might put undue stress on the right heart, and therefore produce a biventricular failure, which then would require implantation of an assist device.

So there are two situations that we've found where we've placed these bands around the pulmonary artery, and the children have subsequently been discharged home, and are currently doing well and are not on transplant-- a heart transplant list anymore.

Those were two peculiar situations where the blood flow to the left side of the heart was impaired at birth.

And once we restored blood flow to the left side of the heart, the heart, at the time, would not start up.

And therefore, instead of employing ECMO, which is our first step in acute heart failure, followed by an assist device, we decided to try the reversible pulmonary artery band.

It facilitated getting out of the operating room without needing mechanical support, or ECMO, facilitated having the child's chest closed discharged home, and both children are subsequently doing very well at home.

So those are the two instances where we did find it very helpful.

The point would be to try and keep the band in place until the left heart recovers completely.

That would be one end point, And the second end point would be if the left heart were not to recover completely, and the child still needed a heart transplantation, then to a heart transplantation.

So we think of this as a bridge to a heart transplantation, or a bridge to a ventricular assist device, or even a bridge to recovery.

This is a technique that was described in Germany, and didn't really catch on very much in the United States.

This technique had been used to treat other forms of congenital heart disease, and physiologically, it seemed like it did make sense.

We, along with Loma Linda University and Texas Children's, were the first users of this particular heart failure technique.

It is simple.

It's less invasive than a ventricular assist device.

It's a surgery that requires opening the chest, but it does not require the heart-lung machine.

It does not require the heart to be stopped.

And it's usually a band placed around a big blood vessel that exits the right heart.

So that minimizes the trauma to the blood, the bleeding, and all the other complications associated with the heart-lung machine.

I think the next step would be to evaluate the results worldwide.

Also, oftentimes a child's hemodynamics, or what we call physiology, is a moving target.

It's different under anesthesia, it's different in the ICU, and so the requirements of the pulmonary artery band may be very different under different physiologic situations.

So an ideal situation would be to get a band that could be adjusted.

And we're currently looking into an adjustable band produced in Europe known as the flow watch, and we've applied for permission to assess this adjustable band initially in a computational flow model at Clemson University and at MUSC, and then subsequently in animal models, and then finally, if we feel it's working well, then on the clinical side, too.

So the potential benefit of this procedure is to reduce strokes in the smallest babies that have heart failure and require assist devices, and cannot make it to heart transplantation.

Sometimes, just buying three or four or five months without needing a ventilator, without needing medicines to support their blood pressure, is adequate to get them large enough to then implant ventricular assist device, which will then bridge them successfully and safely to transplantation.