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Authors

Levi, Daniel S.
Danon, Saar
Gordon, Brent
et al.

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Creation of Transcatheter Aortopulmonary and Cavopulmonary Shunts Using Magnetic Catheters: Feasibility Study in Swine

Daniel S. Levi · Saar Danon · Brent Gordon ·
Nicky Virdone · Fernando Vinuela Jr. · Sanjay Shah ·
Greg Carman · John W. Moore

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Abstract Surgical shunts are the basic form of palliation for many types of congenital heart disease. The Glenn shunt (superior cavopulmonary connection) and central shunt (aortopulmonary connection) represent surgical interventions that could potentially be accomplished by transcatheter techniques. We sought to investigate the efficacy of using neodymium iron boron (NdFeB) magnetic catheters to create transcatheter cavopulmonary and aortopulmonary shunts. NdFeB magnets were machined and integrated into catheters. “Target” catheters were placed in the pulmonary arteries (PAs), and radiofrequency “perforation” catheters were placed in either the descending aorta (DAo) for central shunts or the superior vena cava (SVC) for Glenn shunts. The magnet technique or “balloon target” method was used to pass wires from the DAo or the SVC into the PA. Aortopulmonary and cavopulmonary connections were then created using Atrium iCAST covered stents. Magnet catheters were used to perforate the left pulmonary artery from the DAo, thereby establishing a

transcatheter central shunt. Given the orientation of the vasculature, magnetic catheters could not be used for SVC-to-PA connections; however, perforation from the SVC to the right pulmonary artery was accomplished with a trans-septal needle and balloon target. Transcatheter Glenn or central shunts were successfully created in four swine.

Keywords Catheterization · Central shunt · Congenital heart disease · Glenn shunt

Introduction

There are many instances in which two adjacent vascular structures are anastomosed to help treat or palliate a disease. Examples within the field of congenital heart disease include the (1) Glenn shunt (a superior vena cava [SVC]–to–pulmonary artery [PA] connection), (2) Blalock-Taussig and central shunts (aortopulmonary connections), (3) Fontans (inferior vena cava–to–PA connections), and (4) connections between the right ventricle and the PA in pulmonary atresia. In general, these connections are established using surgical techniques; however, some may be amenable to catheter-guided intervention given the proper equipment. For example, transcatheter perforation of the atretic pulmonary valve can be performed using radiofrequency (RF) perforation catheters [1, 6, 9]. However, this procedure could potentially be made safer and more effective if magnetic catheters were used to align the RF perforation catheter in the appropriate direction.

Permanent magnets have been used to mediate procedures in the biliary and gastrointestinal tract [2–4, 7, 8]. In a similar fashion, magnets could be embedded into catheters and used to improve the safety and efficacy of percutaneous vessel-to-vessel vascular connections.

D. S. Levi (✉) · S. Danon · B. Gordon
Division of Pediatric Cardiology, Mattel Children’s Hospital,
University of California Los Angeles, Los Angeles, CA 90095,
USA
e-mail: dlevi@ucla.edu

N. Virdone · S. Shah · G. Carman
Mechanical and Aerospace Engineering, University of California
Los Angeles, Los Angeles, CA 90095, USA

F. Vinuela Jr.
Department of Radiologic Sciences, University of California
Los Angeles, Los Angeles, CA 90095, USA

J. W. Moore
Division of Pediatric Cardiology, Rady Children’s Hospital,
San Diego, CA, USA

This article details efforts to manufacture magnetic catheters and our preliminary experience in using them to create transcatheter aortopulmonary and cavopulmonary shunts in swine.

Materials and Methods

Manufacturing of Catheters

Neodymium iron boron (NdFeB) magnets were custom-machined to maintain polarity along their long axis. All magnets were cylindrical with an outer diameter of 2.5 mm and a length of 5 mm (Fig. 1a through 1d). “Target” magnets were machined with central holes sized to allow for attachment of a long (>220 cm long) 0.018-inch nitinol wire. The wires were threaded through the central holes of the magnets and frayed at the end to prevent the wire from slipping of the central hole of the magnet. Four-French JR 2.5 (Merit Medical, South Jordan, UT) catheters were inserted over the nitinol wire to allow the target magnets to be steered by applying torque to the JR catheters in the traditional manner (Fig. 1d).

“Puncture” catheters were manufactured from two 5-mm magnets identical to those used for the “target” wire. A central hole of 0.040 inches was fashioned to accommodate a Nykanen coaxial catheter and an RF perforation wire (Baylis Medical, Toronto, Canada). A Palmaz (Johnson and Johnson, New Brunswick, NJ) stent was then used to attach the two magnets to the end of a 6F JR coronary guide catheter. The stent was sutured to the catheter and bent around the magnet (Fig. 1b, c).

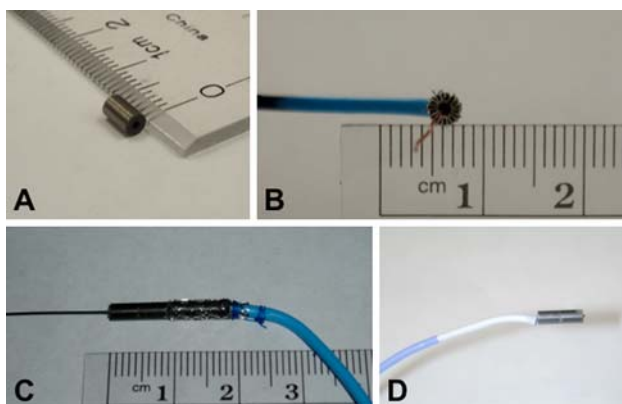


Fig. 1 NdFeB magnet catheters. **a** NdFeB magnets were 5 mm long \times 2.5 mm wide and had a central hole. **b** The perforation catheter was connected to the magnet using a stent and suture such that the lumen of the catheter connected with the central hole in the magnet. **c** Side view of the perforation and target catheters. **d** Use of a Judkins right coronary catheter to steer the target magnet

Laboratory and Animal Testing

Before in vivo studies, NdFeB catheters were tested in cadaveric porcine specimens to ensure that sufficient force was generated to facilitate vessel-to-vessel radiofrequency perforation. Six swine were then catheterized with the intent of creating either a transcatheter Glenn shunt (SVC-to-right pulmonary artery [RPA] connection; $n = 3$) or an aortopulmonary shunt (descending aorta [DAo]-to-left pulmonary artery [LPA] connection; $n = 3$). Approval from the University of California Los Angeles Animal Research Committee was obtained before the commencement of animal studies. All catheterizations were performed with the animal under general anesthesia, and all animals were euthanized immediately after the procedure.

The Seldinger technique was used for femoral arterial and venous access. The external jugular vein was accessed using a “wire target” modified Seldinger technique. A 0.035-inch wire was directed from the femoral vein to the external jugular vein using a 120-cm 4F non-taper angle Glidecath (Terumo Medical, Somerset, NJ), and percutaneous access was obtained using the wire as a guide for fluoroscopic targeting. Biplane angiography was performed in the DAo and the LPA as well as in the SVC and the RPA using 5F Infiniti pigtail catheters (Cordis, Miami, FL).

Directional catheters were used to position 0.035-inch Amplatzer Super Stiff wires (AGA Medical, Golden Valley, MN) in the branch PAs, over which 9F Super-Flex braided sheaths (Arrow International, Reading, PA) were tracked. These sheaths were used to position the “target” magnets into the RPA or the LPA. “Puncture” magnets were preloaded with the Nykanen coaxial wire and the RF perforation catheter and guided into either the DAo (from the femoral artery) or the SVC (from the external jugular vein).

The magnets were positioned as close to one another as possible, and 360° cineangiograms were recorded to document magnet position and orientation (Fig. 2).

Creation of a Transcatheter Central Shunt

If the magnets could be oriented properly in the DAo and the LPA, the Nykanen RF perforation wire and coaxial catheter were gently pushed from the DAo to the LPA during the application of 5 s of RF energy at 5 W total power. If necessary, this step was repeated with up to 10 W total energy. The impedance was monitored on the RF generator. In one case, the Nykanen wire was also used through a second JR 2.5 catheter placed alongside the magnet catheters.

Once the RF wire was successfully positioned in the PA, the Nykanen coaxial wire was advanced from the aorta into the PA. After advancing this system from the LPA to the

RPA, the RF wire was replaced with a stiffer 0.014-inch Iron Man wire (Guidant, Santa Clara, CA). The magnetic catheters were subsequently removed, taking care not to disturb the position of the 0.014-inch wire and Nykanen coaxial catheter. A non-taper angle Glidecath was then advanced from the aortic side (over the Nykanen system and 0.014-inch wire) deep into the RPA. This catheter was then used to position a 0.035-inch Amplatz Super Stiff wire from the DAo into the RPA (Fig. 2a).

The Super Stiff guidewire was then used to position a 6-mm Atrium iCAST covered stent (Atrium, Hudson, NH) from the DAo into the RPA (Fig. 3b through 3e). After stent deployment, all catheters were removed, and proper stent position and shunt patency were assessed by angiography (Fig. 3c, e). All swine were killed immediately after the procedure.

Creation of a Transcatheter Glenn Shunt

Despite multiple attempts, magnet catheters could not be aligned in an orientation suitable for an attempt at RF perforation from the SVC to the RPA (Fig. 2c). Therefore, a “balloon-target” strategy was employed for creation of a transcatheter Glenn shunt. This method was attempted in a total of three swine.

A Cordis Opta-Pro 14 × 4-cm balloon was positioned in the RPA and inflated with a 30% contrast mixture. A Brockenbrough trans-septal needle (Daig, Minnetonka, MN), in a 6F Mullins trans-septal sheath (Bard, Billerica, MA), was advanced into the SVC and aimed at the balloon in the RPA.

Using 360° fluoroscopy, the needle and sheath were advanced from the SVC into the RPA. Once in the RPA, a hand injection was performed through the trans-septal

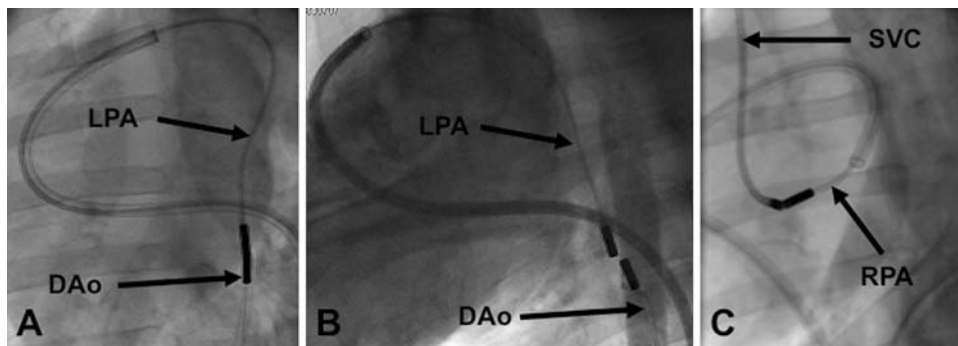
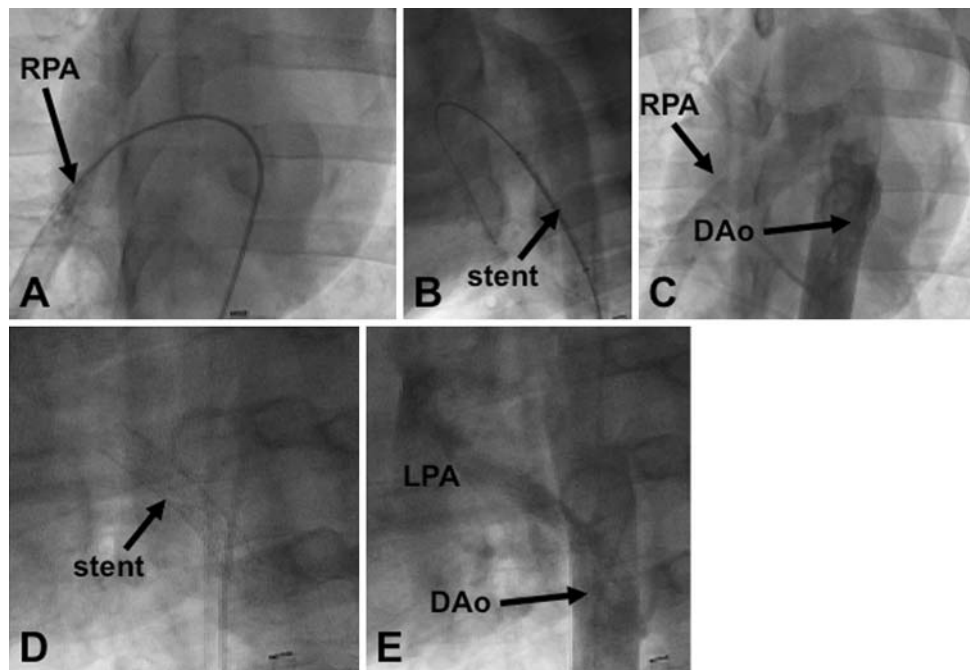


Fig. 2 Magnetic catheters in vivo. **a** A posterior–anterior view of the magnetic catheters positioned and well aligned in the LPA and the DAo. **b** Lateral view of the magnetic catheters positioned and well

aligned in the LPA and the DAo. Contrast has been injected to outline the aorta. **c** Lateral view of magnetic catheters positioned in the SVC and the RPA. Note that the catheters pull together but do not align

Fig. 3 Transcatheter aortopulmonary shunt. **a** Frontal view of a catheter and wire passing up the DAo and into the PA. The distal end of the wire is in the RPA. **b** Positioning of the Atrium iCAST stent from the DAo into the PA (lateral view). **c** Angiogram in the DAo after placement of the transcatheter central shunt. Note contrast filling the PAs. **d** Lateral view of the stent between the LPA and the DAo. **e** Lateral view of DAo angiography showing contrast shunting through the stent into the PAs



needle to confirm proper positioning. An Iron Man wire was then advanced through the needle. The Mullins sheath and dilator were then advanced into the RPA and upsized to a long 9F Cordis Brite Tip sheath. An Amplatzer Super Stiff wire was positioned through this sheath into the distal RPA and used to position a 10-mm Atrium iCAST covered stent between the SVC and the RPA. The stent was deployed by balloon inflation, creating a right-sided uni-directional Glenn shunt. All wires and sheaths were removed. Angiograms were performed with machine injections into a pigtail catheter positioned within the stent (Fig. 4a). Swine were killed immediately after the procedure. Stents were harvested as part of a block of the SVC and the RPA (Fig. 4b).

Results

Magnetic Catheter Construction

Magnet catheters were successfully designed and manufactured using NdFeB magnets (Fig 1). “Target” catheters were able to fit through 8F sheaths. The stent used to hold the magnet onto the “puncture” catheter added bulk to the catheter such that 10–11F sheaths were needed to accommodate these devices. In the laboratory, magnetic catheters were able to pull toward one another when placed in the SVC and RPA or in the DAo and LPA of cadaveric swine specimens. The attractive force was adequate for guidance of radiofrequency perforation from one vessel to another. The magnets did not generate enough force to pull the vessels close enough to allow for mechanical puncture from one vessel into another, but they did have enough strength to pull vessels close enough to pass a radiofrequency perforation wire from one vessel to the next.

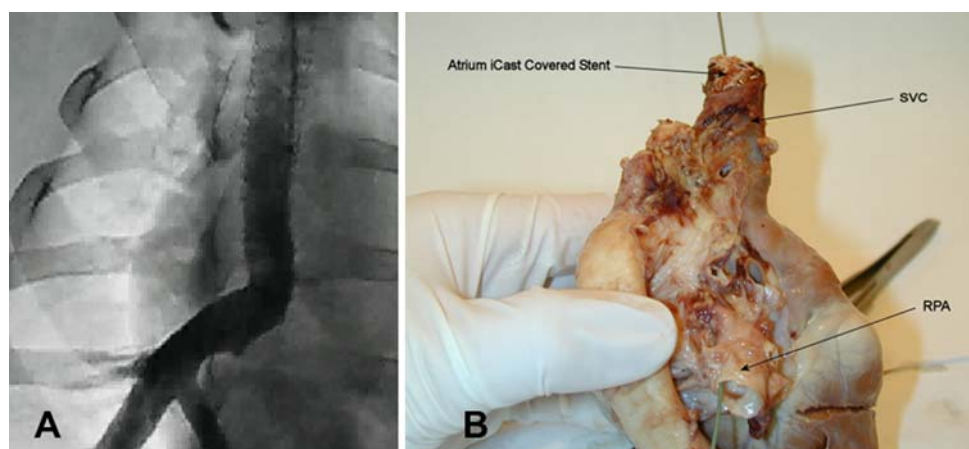
Transcatheter Aortopulmonary Shunt: Animal Testing

As in humans, the porcine DAo and LPA are in close proximity. The magnet catheters were able to align with one another in these vessels and pull together (Fig. 2a, b). Operators were able to feel the magnets pull together, and additional force was required to pull them apart.

In the first pig, the RF perforation system was able to pass easily from the DAo into the LPA, and a successful transcatheter central shunt was created with a covered stent. In the second pig, the RF perforation system did not pass easily into the LPA and was apparently blocked or deflected by the target magnet. Thus, with the magnets in place, the RF wire was passed alongside the magnets rather than through the center of the magnetic catheters. In both cases, the Nykanen coaxial catheter was passed over the RF perforation wire, and this wire–catheter combination passed from the LPA directly into the RPA (Fig. 3b). After removal of the magnet catheters, the Nykanen system was exchanged for an Amplatzer Super Stiff wire, which was used to deploy a 6-mm Atrium iCAST covered stent from the DAo into the LPA (Fig. 3b through 3e). There was no extravasation of contrast on aortograms taken after stent deployment and no evidence of complications in either animal secondary to transcatheter shunt placement. The animals tolerated the procedure without complications, and angiograms demonstrated patent communications between the DAo and the LPA in both cases.

A third pig had been placed under general anesthesia in anticipation of transcatheter central shunt placement, but it died shortly after intubation. This pig had been quarantined for only 2 days before catheterization and was found to have evidence of pneumonia on fluoroscopy. No interventions were attempted on this animal.

Fig. 4 Transcatheter Glenn shunt. **a** Angiogram showing patent covered stent communicating from the SVC to the RPA. **b** Postmortem specimen showing stent extending from the SVC into the PA. A wire has been passed from the SVC stent and emerges from the distal RPA



Transcatheter Glenn Shunt: Animal Testing

Three pigs were obtained for transcatheter Glenn shunt placement. However, initial angiograms performed in the SVC and the RPA of the first pig demonstrated an RPA that traveled inferiorly just beyond the PA bifurcation (Fig. 5). The RPA was therefore found to cross behind the SVC at, or just below, the SVC–right atrial junction in all three pigs. Although magnetic catheters were successfully placed in the SVC and the RPA, they could not be adequately aligned because both catheters were coursing in a nearly perpendicular superior-to-inferior direction. Although slight contact was made, the magnets did not orient in a manner suitable for guidance of a vessel-to-vessel perforation.

Thus, a “balloon-target” method was used to guide trans-septal puncture from the SVC to the RPA. This technique involved placing a balloon filled with contrast medium into the RPA. Using the balloon as a target, a trans-septal needle was used to penetrate from the SVC into the RPA using multiple fluoroscopic views for guidance. This method was successful in two of three swine. One of the pigs developed a large pericardial effusion during the procedure and died of cardiac tamponade before the SVC-to-RPA connection could be made.

In both cases, the largest commercially available Atrium iCAST stent (10-mm diameter) was deployed to connect the SVC to the RPA. Angiograms of the SVC after the procedure showed a widely patent communication (Fig. 4a, b).



Fig. 5 MRI of a swine SVC and RPA (*posterior view*)

Each pig required >1 iCAST stent, which was dilated to 12 mm on the PA side and 14 to 16 mm on the SVC side. Of note, dilation to 16 mm is not recommended by the manufacturer, but it was necessary in this case because of the large size of the SVC in these animals. Consequently, on postmortem examination, a tear was noted in the polytetrafluoroethylene (PTFE) cover material on the SVC side of the stent.

All angiograms demonstrated unobstructed flow from the SVC into the RPA (unidirectional Glenn shunt [Fig. 4a]). In one of the animals, the covered stent communicated only with the distal inferior branch of the RPA. In this animal, flow of contrast into the RPA was sluggish, and small clots were noted to form within the stent before the pig was killed.

Discussion

Our results show that NdFeB magnets can successfully be integrated into catheters for use in cardiovascular applications. In the laboratory, catheters with magnet diameters of 2.5 mm generated enough attractive force to align catheter tips in the appropriate orientation and pull two vessels closer together. Although vessels were not drawn together with enough force to facilitate mechanical perforation, magnetic catheters seem to be the ideal device to guide radiofrequency catheter perforation.

Various methods for augmenting the attractive force induced by the magnets were investigated. Although electromagnets would intuitively seem to be the optimal choice for this application, the small sizes required for pediatric applications limits the number of coils, and thus the strength, that could be obtained using electromagnets. Moreover, a prohibitively large current would be required to achieve an attractive force comparable with that of the NdFeB magnets. Thus, permanent magnets were selected for this study and will likely be a superior choice for this application in the future.

Clearly, the design of catheters used in this study could also be greatly improved. The profile of the catheters could potentially be miniaturized without sacrificing magnetic strength by improving the mechanism of attaching the magnets to the catheters. In addition, improved catheter flexibility would allow for increased maneuverability and steerability, which would facilitate magnet orientation with greater ease.

Magnetic catheters were successfully used to create a transcatheter connection between the DAo and the LPA. Although DAo–LPA connections were successfully created in both attempts, it was difficult to pass the perforation wire from the DAo into the LPA in one pig. During multiple attempts, the perforation wire was deflected by the target

magnet and redirected into an extravascular space. Future designs could include a target magnet that facilitates transcatheter connection by acting as a docking port for the RF wire and catheter. The target magnet could even be designed to attract the perforation catheter into the vessel. Although the catheters used in the present study did not incorporate this strategy, they were able to effectively align the catheters and vessels and mediate a vessel-to-vessel connection between the DAo and the LPA.

Although our initial intent was to investigate the use of magnetic catheters in the creation of transcatheter Glenn shunts, the swine's pulmonary vascular anatomy was not conducive to the magnet catheters that were designed. Although a transcatheter Glenn shunt was created using a trans-septal needle, magnet catheters designed with the polarity necessary for a side-to-side vessel anastomosis, as reported by Erdmann et al. [5], could allow for magnetic catheters to make even this type of vascular anastomosis feasible.

The ideal covered stents for these anastomoses would be premounted, low-profile PTFE covered stents that come in a variety of lengths. Atrium iCAST stents are premounted, low-profile PTFE covered stents that proved to be well suited for these procedures. Because this stent is tightly premounted onto its balloon, one of the transcatheter central shunts was performed by advancing the stent from the DAo into the PA without the use of a long sheath. If these procedures are ever performed in humans, care should be taken to minimize stent overhang into the aorta and pulmonary artery. Customized stents with "cuffed" ends could be of use in these and other transcatheter procedures intended to connect two vascular structures together. This sort of cuffed covered stent is already being used in magnet-assisted gastroenteric anastomoses [4].

Given availability of the appropriate magnetic transcatheter technology, many minimally invasive vascular anastomoses could be of benefit to patients with congenital heart disease. In addition to a Glenn or central shunt, similar technology could be used for transcatheter Fontans, interrupted aortic arches, and many hybrid procedures as well as the creation of nonsurgical arteriovenous fistulas. This technology is especially attractive for perforation of atretic pulmonary valves in infants with pulmonary atresia. With one magnetic catheter in the infundibulum of the RV and one catheter advanced retrograde up the aorta, across the ductus, and into the main PA, magnetic catheters could improve the accuracy of RF energy delivery and could allow for less frequent perforation of the anterior wall of the right ventricle outflow tract/PA.

The combination of magnetic catheters and radiofrequency energy is especially attractive. Even large magnetic catheters are not strong enough to mediate a vessel-to-vessel puncture with mechanical energy as can be done

with a trans-septal needle. RF catheters can cross from one vessel to the next without displacing the magnets.

As noted previously, limitations are associated with the use of a swine model in this study. The vascular anatomy of the swine precluded our attempts at a percutaneous Glenn shunt using magnetic catheters. In addition, the swine SVC carries a much smaller proportion of the total venous return compared with the human SVC (not only is the swine head smaller, but the swine brain is small and gets very little blood flow). Because of this low flow state, once this connection is made in the pig, it would be difficult to keep it patent and free of thrombus.

Because this study was only intended to be a feasibility study for this concept, shunts created with covered stents were patent immediately after being placed but were not studied after surviving the pigs. In addition, it is important to emphasize that this study only showed feasibility but did not demonstrate that these procedures are safe. Two of the six animals in this study died during the procedure, and one of these deaths was clearly a direct result of a procedural complication. Many improvements will be needed in both catheters and stents before these procedures are studied in humans.

Conclusion

Transcatheter Glenn shunts and aortopulmonary connections can be accomplished using transcatheter techniques. The results of this study suggest that magnetic catheters may be useful in improving the safety and reliability of percutaneous vessel-to-vessel connections. However, longer-term animal studies and proper equipment will be required before these techniques can be attempted in humans. Nonetheless, the novel techniques outlined in this study could someday allow for successful palliation of certain forms of congenital heart disease without surgical intervention.

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