

The New Occlutech Duct Occluder: Immediate Results, Procedural Challenges, and Short-Term Follow-Up

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ABSTRACT: Objective. The aim of this study was to assess the immediate and short-term results of transcatheter closure of patent ductus arteriosus (PDA) using the Occlutech duct occluder (ODO). **Background.** The ODO is a new self-expanding nitinol device. Its body is wider at the pulmonary artery end than the aortic end. It is available in longer lengths than the Amplatzer duct occluder. **Methods.** Twenty-two ODO implants were attempted in successive children referred for transcatheter device occlusion of PDAs ≥ 1 mm in diameter. **Results.** Median patient age was 2.4 years [range, 0.7-17.5 years], median weight was 13.1 kg [range, 6.3-40 kg], and median PDA diameter was 1.9 mm [range, 1-4.3 mm]. Twenty-one out of 22 patients [95%] had successful ODO implantation. One device was withdrawn before release because it did not reach the pulmonary artery end of a long duct. Median procedure time was 40 minutes [range, 26-60 minutes] and fluoroscopy time was 4.5 minutes [range, 2.7-13.3 minutes]. Occlusion rates were 19/21 [90%] at the end of the procedure, 20/21 [95%] at 24-48 hours post procedure, and 21/21 [100%] on echocardiography at a median follow-up of 4 weeks [range, 2-16 weeks]. There were no device-related complications. Two infants had femoral artery occlusion, successfully treated by heparinization and thrombolysis. **Conclusion.** This first formal clinical evaluation of the ODO indicates that it is safe and effective in occluding small-to-moderate size ducts, up to a diameter of 4.3 mm. The device produced equivalent results to the Amplatzer duct occluder. Further evaluation is required to assess whether its shape and longer length make it superior for closing large and long ducts.

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Transcatheter device occlusion of patent ductus arteriosus (PDA) has been successfully accomplished using a variety of devices over the last 20 years.¹ At the present time, the most commonly implanted devices are coils and the Amplatzer duct occluder (ADO; St. Jude Medical). Since the ADO was introduced 15 years ago, its design, comprising an expandable nitinol body and aortic retention disc, has resulted in excellent procedural success rates, with 99% duct occlusion at 1-year follow-up and a very low incidence of embolization.²⁻⁷ Radiation dose and procedure times are low because the device is easy to use and has a short learning curve.³⁻⁷ It is easily retrievable while it remains attached to its delivery cable.^{4,8}

When an ADO is correctly implanted, the body of the device is compressed within the duct, so that the pulmonary artery end of the device becomes larger than the rest of the device core, preventing displacement into the aorta. Although complications are rare, when an ADO is undersized, it is not sufficiently compressed and expands to its preformed shape, with a smaller pulmonary end and a larger aortic end, which can compromise device stability and result in embolization.^{4,8} When embolization occurs, the device is difficult to snare and retrieve, as the screw by which it is attached to the delivery cable recesses with the body of the device following release.^{4,5,9}

Procedural difficulties are uncommon. However, implantation cannot always be safely achieved when the

length of the duct greatly exceeds the length of the device. Although traction on the delivery cable, which causes the aortic retention disc to exert longitudinal pressure on the duct, often seems to shorten the duct, this is not always sufficient to ensure that the pulmonary artery end of the device reaches the pulmonary artery end of the duct.¹⁰ The larger Amplatzer devices, from 10/8 to 16/14, are all 8 mm long. Thus, when a large-diameter device is required for a large duct, its length is short in proportion to the overall device size, making it less suitable for long ducts and enhancing concern about embolization. Implantation is not always possible in smaller children, particularly those < 5 kg, as the aortic retention disc may protrude so far into the aorta that it causes significant narrowing of the aortic lumen.^{5,9,10}

A new device, the Occlutech PDA occluder (ODO), has been designed with these concerns in mind. Like the ADO, the ODO is constructed with braided nitinol wires, has an aortic retention disc, and is attached to its delivery cable with a screw thread mechanism. The differences between the ADO and the ODO are shown in Table 1. The device has a titanium oxide coating, which gives it a characteristic golden color, and two polyethylene terephthalate (PET) patches sewn into the device, one in the aortic retention disc and one at the pulmonary end of the device, to promote rapid occlusion (Figure 1). Device specifications are shown in Table 2.

Table 1. Differences between the Occlutech duct occluder and the Amplatzer duct occluder.

Features of Occlutech duct occluder that differ from Amplatzer device	Purpose	Specification
The core of the device is wider at the pulmonary end rather than the aortic end	This “reverse pyramid” is designed to reduce the risk of device embolization into the aorta	The device labeling gives the diameter of the larger pulmonary end
The screw attachment of the device protrudes from the pulmonary end of the device following release	To allow easier snaring, should retrieval be required	
There is a second range of “long-shank” devices	To allow closure of long ducts	2-3 mm longer than the standard devices
The device length increases throughout the range of sizes	To promote stability in longer ducts	
The device has no distal clamp at the aortic end	To reduce the aortic profile	

Table 2. Device specifications (manufacturer’s data).

	D1 (mm)	D2 (mm)	D3 (mm)	Length (mm)	Recommended Delivery Sheath
Standard Occlutech duct occluder					
3.5/5	9	3.5	5	4.25	6 Fr
4/6	10	4	6	5.00	6 Fr
5/7	11	5	7	6.05	6 Fr
6/8	13	6	8	6.30	6 Fr
8/10	16	8	10	7.00	7 Fr
10/12	18	10	12	12.00	7 Fr
12/15	20	12	15	14.00	8 Fr
14/18	24	14	18	16.00	9 Fr
Occlutech duct occluder with long shank					
3.5/5	9	3.5	5	7.00	6 Fr
4/6	10	4	6	7.50	6 Fr
5/7	11	5	7	8.50	6 Fr
6/8	13	6	8	9.00	6 Fr
8/10	16	8	10	10.50	7 Fr
D1 = diameter of aortic retention disc; D2 = diameter of the waist at the aortic end of the device; D3 = diameter of the pulmonary end of the device.					

The aim of this study was to assess the immediate and short-term results of transcatheter closure of PDA in children using the ODO.

Methods

Patients. Twenty-two Occlutech PDA device implants were attempted in 22 consecutive children referred for transcatheter device occlusion of arterial ducts ≥ 1 mm in diameter. The procedures were carried out between May 2013 and October 2013. Median patient age was 2.4 years (range, 0.7–17.5 years) and median weight was 13.1 kg (range, 6.3–40 kg). The PDA was the only cardiac abnormality in 19 patients. Two patients had a ventricular septal defect (VSD), one small and one moderate in size, and 1 patient had a partial atrioventricular septal defect. On echocardiography,

before duct closure, the median PDA diameter was 2.2 mm (range, 1.0–4.3 mm) and the median left ventricular internal dimension in diastole was 3.7 cm (range, 2.5–5.3 cm), with a median z-score of +2.6 (range, 0.2–5.7). Two patients had clinical signs of cardiac failure.

Technical aspects. All procedures were carried out under general anesthesia. Vascular access was via the femoral artery and vein. Either 50 U/kg or 100 U/kg of intravenous heparin were administered, according to operator preference. An aortogram was performed opposite the duct using a marker pigtail catheter. The duct was crossed from the pulmonary artery side and device implantation was carried out using a standard approach.^{2,10} Because the ODO does not yet have a dedicated sheath, either a Mullins sheath (William Cook Europe) or a St Jude 180° curve TorqVue sheath (St. Jude Medical) was used to deploy the device. An aortogram was carried out 1 minute after implantation, while the device remained attached to the delivery cable, to evaluate device position within the duct and residual left-to-right shunting. When immediate occlusion did not occur, the shunt was reassessed after 5 minutes, by angiography or echocardiography. A further assessment was carried out after 15 and 20 minutes if the shunt persisted. Before the device was released, angiography or echocardiography was used to check that the origin of the left pulmonary artery was not obstructed and to confirm that the proximal end of the device had reached beyond the duct into the pulmonary artery.

Device size. The narrower aortic end of the device core, adjacent to the aortic retention disc, was designated the “waist” of the device for the purposes of this study. An ODO with a waist diameter at least 2 mm larger than the minimum diameter of the duct was selected in 14 cases. An ODO with a waist diameter at least 1 mm larger than the minimum diameter of the duct was selected in 8 cases, mostly toward the latter part of our experience. The long-shank ODO was used when the operator judged that the duct was so long that the core of the standard ODO would not extend across the narrowest part of the duct into the pulmonary artery.

Dataset. The medical records were reviewed for demographic characteristics, clinical details, echocardiographic

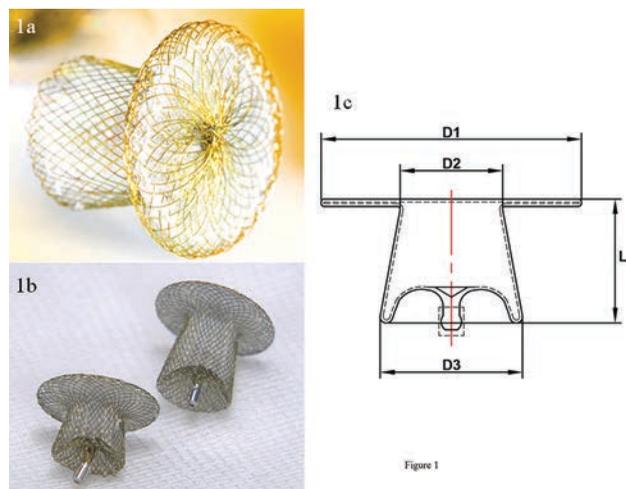


FIGURE 1. (A) Side view of the Occlutech duct occluder (ODO). (B) Short- and long-shank devices of the same diameter. (C) ODO measurements: D1 = diameter of the aortic retention disc; D2 = diameter of the ODO waist at the aortic end of the device; D3 = diameter of the pulmonary end of the device; L = length.

findings and follow-up information. The initial aortogram was used to assess ductal morphology and to measure the minimum diameter of the duct, the diameter of the ductal ampulla, and the length of the duct (Figure 2). Measurements were calibrated against radiographic marker bands on the pigtail catheter in the aorta. The aortogram following device implantation was used to assess the position of the device within the duct and to assess residual left-to-right shunting. The diameter of the device's waist was measured where it was compressed within the narrow point of the duct.

Other technical features recorded were the procedure time, fluoroscopy time, radiation dose, and the size of device implanted. Ease of implantation was assessed, noting whether radiopacity allowed adequate visualization on fluoroscopy. Patients were evaluated clinically and echocardiographically the day after the procedure and on outpatient follow-up, scheduled 4–6 weeks following implantation.

Results

The median angiographic diameter of the duct at its narrowest point was 1.9 mm (range, 1–4.3 mm). The minimum duct diameter was 1–2 mm in 12 patients, 2–3 mm in 6 patients, 3–4 mm in 3 patients, and 4–5 mm in 1 patient. Nineteen patients had Krichenko type-A ducts, 2 had Krichenko type-E, and 1 patient had a long duct with a narrowing at the midpoint anterior to the trachea.¹¹ Occlutech device implantation was successful in 21/22 cases. In the unsuccessful case, an attempt was made to implant a 3.5/5 device (standard 4.25 mm length) in a 1.6 mm minimum diameter, 10 mm-long Krichenko type-E duct. The aortic retention disc of the device was pulled against the mouth of the aortic

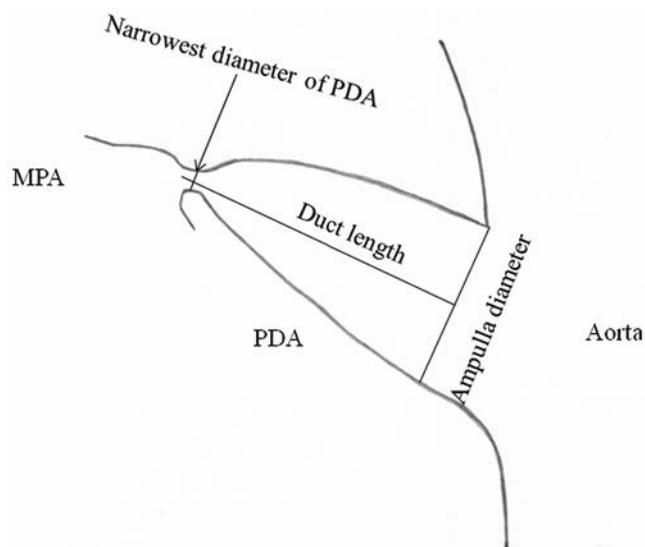


FIGURE 2. Standard measurements taken from the aortogram in a lateral projection. The duct length was measured with a line equidistant from the upper and lower margins of the ampulla. The ampulla diameter was measured by drawing a line perpendicular to the line for duct length, intersecting the upper aortic lip of the ductal ampulla. This ampulla diameter was chosen because it most closely corresponds to the usual position of the aortic retention disc of a duct device. The duct length was measured from the pulmonary end of the narrowest diameter to the line for ampulla diameter.

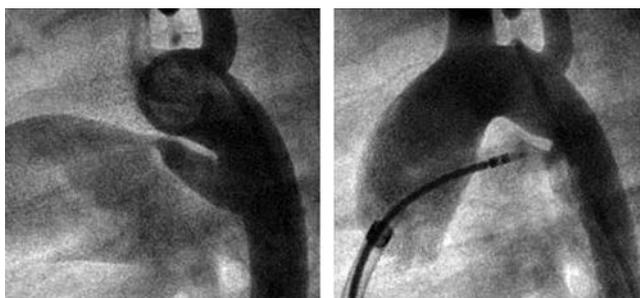


FIGURE 3. Unsuccessful device deployment. (A) Descending aortogram showing 10 mm-long Krichenko type-E duct. (B) The body of the 3.5/5 Occlutech duct occluder deployed entirely within the long ductal ampulla, rather than across the narrow point at the pulmonary artery end of the duct.

ampulla in the normal fashion, without pulling it inside the ampulla. The entire body of the device deployed within the long ductal ampulla rather than across the narrowest point at the pulmonary artery end of the duct (Figure 3). The device was withdrawn, as there was concern that it would embolize into the descending aorta. The duct was closed with a single 5-mm diameter 5-loop Cook coil (William Cook Europe).

Where the device was successfully implanted, the ODO occluded the duct after 1 minute in 1/21 patients; after 5 minutes in 10/21 patients; after 15 minutes in 6/21 patients,

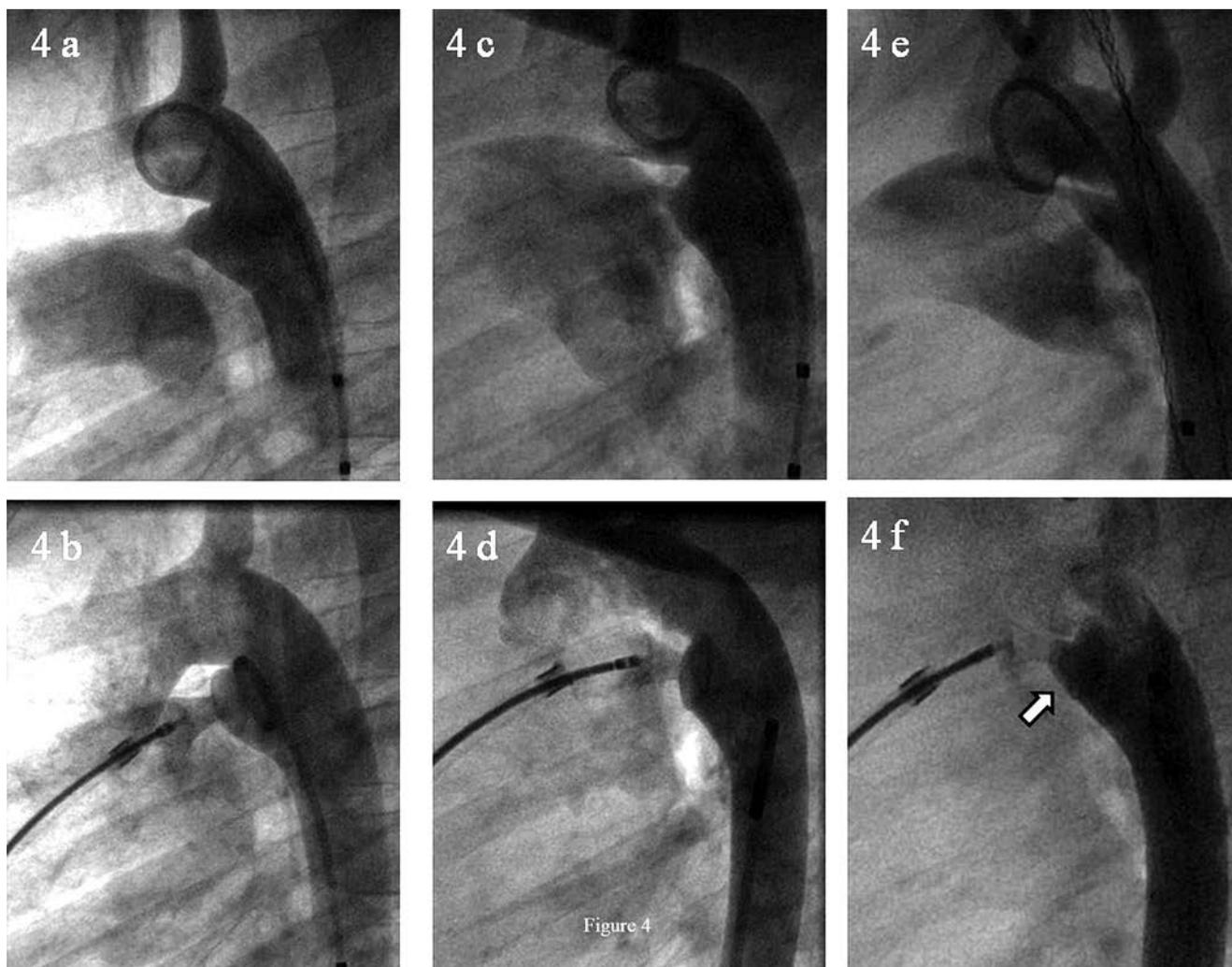


FIGURE 4. The three different positions of the Occlutech duct occluder (ODO). (A) Preimplantation and (B) postimplantation angiogram showing that the aortic retention disc of the ODO has been pulled into the ductal ampulla and the waist of the device is deployed at the narrowest part of the duct. (C) Preimplantation and (D) postimplantation angiogram showing that the aortic retention disc has remained at the mouth of the ductal ampulla and the waist of the device is deployed at the narrowest part of the duct. (E) Preimplantation and (F) postimplantation angiogram showing that the aortic retention disc has remained at the mouth of the ductal ampulla and the waist of the device has not reached the narrowest part of the duct, resulting in contrast around the waist of the ODO (arrow).

and after 20 minutes in 2/21 patients. Two out of 21 patients had a trivial residual left-to-right shunt at the end of the procedure. Both of these patients had complete duct occlusion on echocardiography the following day. One infant, who initially had total occlusion, developed a small shunt through the device on echocardiographic evaluation the following day, while receiving heparin for femoral artery thrombosis. Repeat echocardiography 15 hours after stopping the heparin infusion showed total occlusion. Another infant who also initially had total occlusion required alteplase and heparin for femoral artery occlusion. Echocardiography the day after the procedure, 8 hours after stopping heparin, showed a large shunt through the device. Repeat echocardiography 3 hours later showed only a small residual shunt. At the time

of discharge, 20 out of 21 patients had complete occlusion. All patients had complete occlusion of the duct at a median follow-up of 4 weeks (range, 2-16 weeks).

The pulmonary artery end of the device reached beyond the pulmonary end of the duct into the main pulmonary artery in all cases, except the case where the device was not implanted. The screw of the device did not impinge on the wall of the pulmonary artery in any case. Angiography and echocardiography, with two-dimensional color flow and Doppler assessment, showed no descending aorta or left pulmonary artery obstruction.

The median procedure time was 40 minutes (range, 26-60 minutes), fluoroscopy time was 4.5 minutes (range, 2.7-13.3 minutes), and the radiation dose was 1143 mGy/cm²

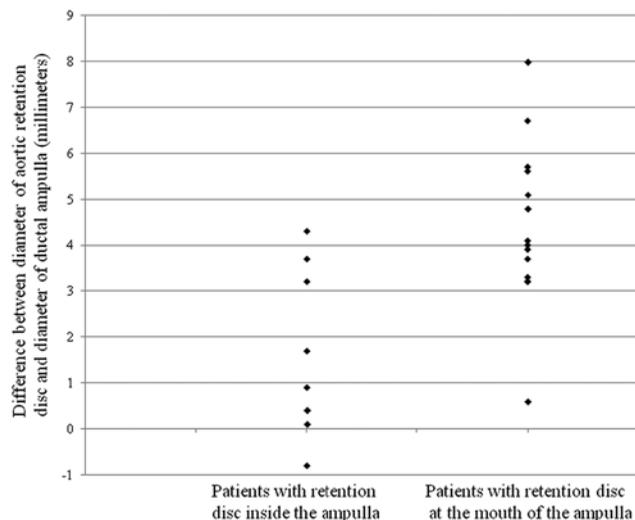


FIGURE 5. The amount by which the diameter of the aortic retention disc exceeded the diameter of the ductal ampulla in cases where the retention disc pulled into the ampulla and those where it did not.

(range, 581–10734 mGy/cm²). The procedure time included up to 15 minutes waiting for duct occlusion following device implantation. A 6 Fr long sheath was used in 19 cases and a 7 Fr sheath in 3 cases. The following devices were used: 3.5/5 (n = 10); 4/6 (n = 4); 5/7 (n = 5); 6/8 (n = 2); and 8/10 (n = 1). A standard-length device was implanted in 16/21 successful cases, with a median ductal length of 7 mm (range, 4.5–9.1 mm). A long-shank device was implanted in 5/21 successful cases, with a median duct length of 8.9 mm (range, 6.3–11.2 mm).

Device position. The implanted device adopted 3 different positions: *Position 1.* In 8 cases, the aortic retention disc of the ODO pulled into the ductal ampulla and the waist of the device was at the narrowest part of the duct (Figures 4A and 4B). *Position 2.* In 7 cases, the aortic retention disc of the ODO remained at the mouth of the ductal ampulla and the waist of the device was at the narrowest part of the duct (Figures 4C and 4D). *Position 3.* In 6 cases, the aortic retention disc of the ODO remained at the mouth of the ductal ampulla, but the waist of the device did not reach the narrowest part of the duct (Figures 4E and 4F). In these cases, part of the body of the device, closer to the wider pulmonary artery end, occluded the narrowest part of the duct. This position was evident when anatomical landmarks showed the waist of the device was distant from the narrow point of the duct (n = 2) or when angiography demonstrated a gap around the waist of the device, where it remained within the ductal ampulla (n = 4).

The difference between the diameter of the aortic retention disc and the diameter of the ductal ampulla was calculated for each case, to assess whether it was possible to predict when a device would pull into the aortic ampulla

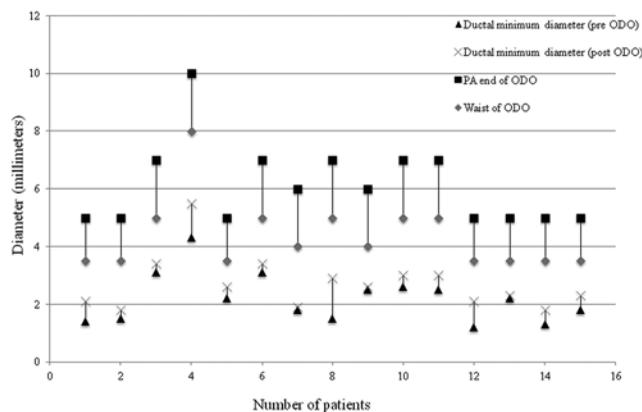


FIGURE 6. Fifteen cases where the waist of the device was deployed at the narrowest part of the duct. The minimum diameter of the duct (on the initial angiogram) and the minimum diameter of the duct device (on the first angiogram after device deployment) are shown, to demonstrate the amount by which the duct expanded following device implantation, in relation to the size of the Occlutech duct occluder deployed.

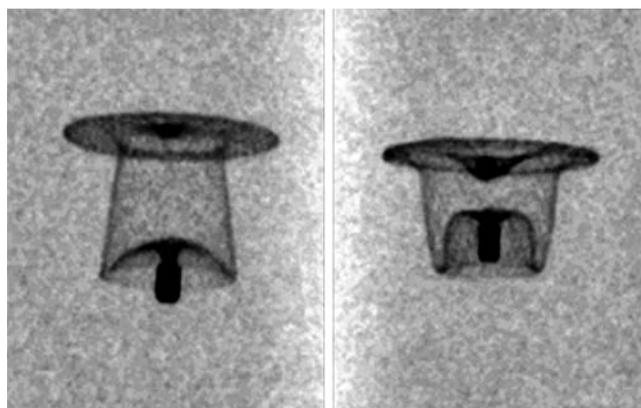


FIGURE 7. Comparative radiopacity at 62 kV, 71 mA, and 15 frames/s. (A) The Occlutech duct occluder. (B) The Amplatzer duct occluder.

(Figure 5). The retention disc did not pull into the ampulla when its diameter exceeded the ampulla diameter by more than 5 mm. The retention disc pulled into the ampulla when its diameter exceeded the ampulla diameter by <2 mm (with the exception of 1 case where the ductal ampulla was very shallow).

Device size. In those cases where the waist of the device was deployed at the narrowest part of the duct (n = 15), the diameter of the duct on the initial angiogram was compared with the diameter of the waist of the device following implantation (Figure 6). The median increase in ductal diameter was 0.5 mm (range, 0.1–1.4 mm).

In those cases where the aortic retention disc remained at the mouth of the ampulla (n = 14), the initial angiographic

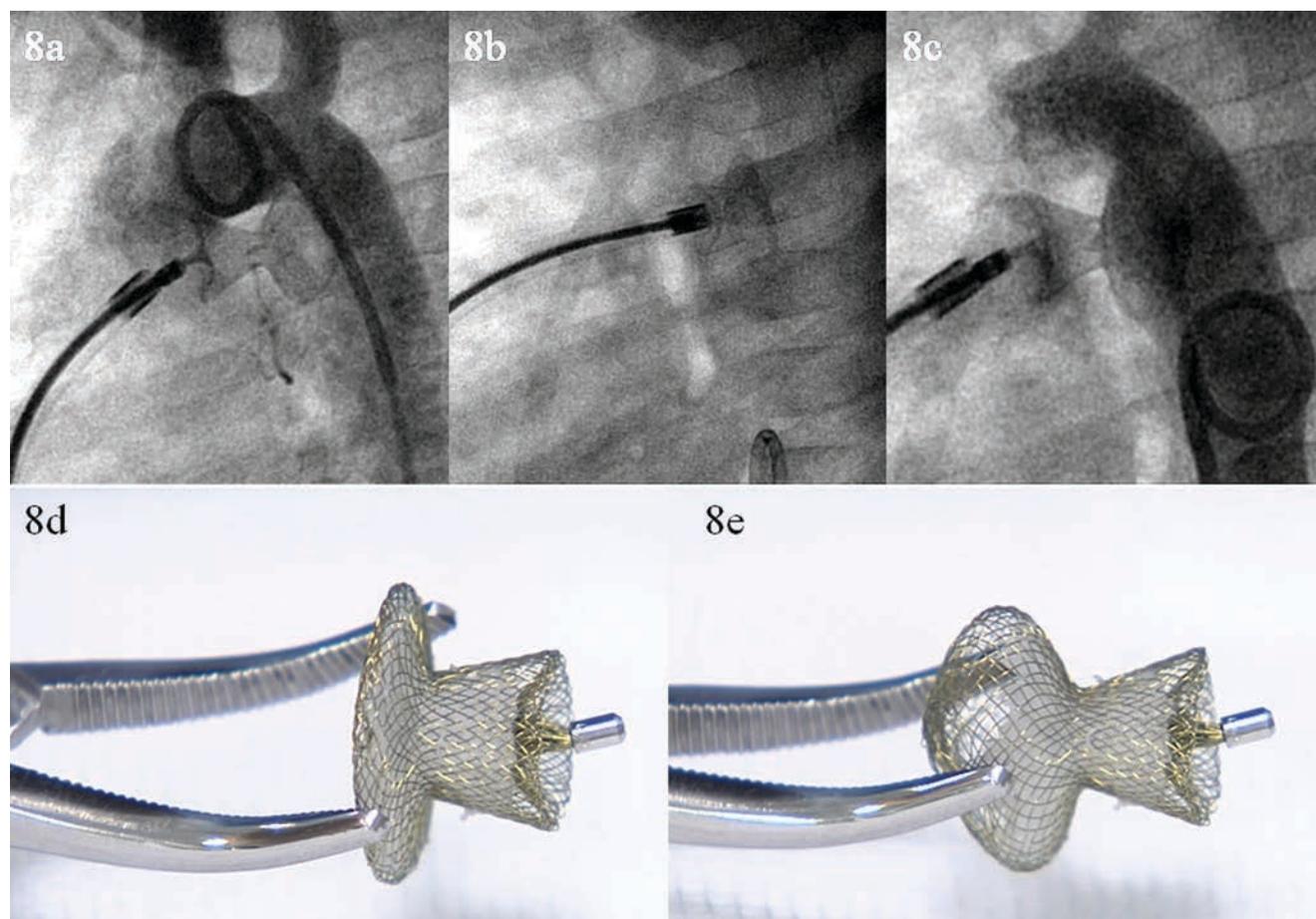


FIGURE 8. The effect of distorting the aortic retention disc on the core of the device. (A) Incomplete expansion of the waist of the Occlutech ductal occluder (ODO) when the aortic retention disc had been pulled firmly into the ductal ampulla. (B) Complete expansion of the ODO unsheathed in the descending aorta. (C) Correct configuration of the ODO following deployment with only gentle traction on the retention disc. This effect on the core can be duplicated outside the body. (D) Device held in neutral position. (E) Forceps closed; squeezing the aortic retention disc causes the waist to underexpand.

length of the duct was compared with the length of the device implanted. In the case where the ODO was not implanted because it did not reach the pulmonary artery end of the duct (Figure 3), the device was 5.8 mm shorter than the duct. However, the device was also shorter than the duct in 8/13 successful implants. In these 8 cases, the median difference between device length and duct length was 1.7 mm (range, 0.3–4.2 mm).

Complications. There were no device-related complications. The only procedural complications were thrombotic occlusion of the femoral artery in 2 infants. One patient required heparin infusion and the other patient required both alteplase (tissue plasminogen activator) and heparin infusion for the restoration of normal limb perfusion and pedal pulses.

Procedural challenges. When a Mullins sheath was used to deploy the ODO, a standard Cordis introducer sheath (Cordis Corporation) was used as a loader. If the tip of the short sheath was pushed too far through the bung of the Mullins, it became longitudinally crimped by the proximal

part of the Mullins sheath distal to the valve, making it impossible to advance the device into the long sheath. This problem has been recognized in other procedures and was easily overcome by advancing the short sheath only about 5 mm through the bung so that it just touched the blue tubing of the Mullins sheath.

Although the ODO was less radiopaque than the Amplatzer device (Figure 7), it could be adequately visualized on fluoroscopy at 15 frames/second.

In 4/22 cases (18%), there were problems with the Occlutech delivery cable. In 2 cases, the vise that is attached to the distal end of the cable would not grip the cable despite maximal tightening of its screw. The cable assembly was exchanged before the device was deployed. In 2 cases, when the vise was rotated to turn the cable, torque would not pass down the cable to release the device. In these cases, the device was released by holding the cable near the sheath with mosquito forceps and spinning the forceps around the axis of the cable.

In 2 cases, the waist of the device did not completely expand when the aortic retention disc had been pulled firmly into the ductal ampulla, so that it took the shape of a cone rather than a disc (Figure 8A). In 1 case, this left a gap between the waist and the wall of the duct. In both cases, the core of the device was recaptured and the device and sheath were advanced back into the aorta. The device was then completely unsheathed in the aorta, to confirm that it configured properly when the aortic retention disc was flat (Figure 8B). The core of the device was then captured once again and redeployed within the duct, applying only gentle traction on the aortic retention disc. When the retention disc remained flat on the second deployment, the core expanded correctly (Figure 8C). This effect on the core can be duplicated outside of the body by squeezing the aortic retention disc (Figures 8D and 8E).

Discussion

Based on these preliminary data, the ODO is safe and effective in closing small-to-moderate size patent arterial ducts. However, coils are equally effective for ducts <2 mm in diameter and offer a cheaper alternative. The ODO does not offer advantages over the Amplatzer device in most cases, but achieves equivalence and is perhaps best indicated for long ducts larger than 2 mm. Like the Amplatzer, it may not be appropriate for short or window-like ducts. Further evaluation in larger ducts is required to assess whether the wider pulmonary artery end of the ODO offers enhanced stability. Antibiotic prophylaxis is recommended for 6 months following device implantation, in accordance with American Heart Association guidelines.¹²

Occlusion rates. Occlusion did not occur immediately, but occurred in all cases by the following day, with the exception of those cases that required heparinization or thrombolysis. There was 100% occlusion at a median follow-up of 4 weeks. We therefore propose that there is no need to check for occlusion at the end of the procedure. It is only necessary to carry out a single angiogram to check device position. Recanalization is likely to occur after thrombolysis, but even a significant shunt resolves when thrombolysis and anticoagulation are stopped.

Device sizing. We speculated that device stability within the arterial duct depends on two factors. First, the pulmonary end of the device must be wider than the waist of the device to prevent displacement toward the aorta. The Amplatzer device must be compressed by the duct to produce this configuration.³⁻¹⁰ The Occlutech device is designed to take this shape without compression. Second, at the narrow point of the duct, the device diameter should exceed the ductal diameter, allowing the device to grip the ductal tissue. In most cases (n = 14) we elected to implant a device with a waist at least 2 mm larger than the minimum diameter of the duct, to allow the device to anchor using both of the above mechanisms. However, during the course of our experience,

we observed that the narrow point of the duct usually expanded <1 mm following device implantation (Figure 6), which constrained the waist of the device to such an extent that the pulmonary end of the device was 3-4 mm larger than the aortic end. Such a size differential seemed unnecessary for stability, based on previous experience with the Amplatzer device.^{4,8,13} We therefore changed the sizing strategy and chose devices with a waist only 1-2 mm larger than the minimum diameter of the duct, as we became more experienced with the device (n = 8). This did not seem to adversely affect stability, though further experience is required.

As all of the successfully implanted devices reached the pulmonary end of the duct and the length of the ODO was often shorter than the length of the duct, ducts must shorten during device implantation. We have also observed this effect when implanting the Amplatzer device. Our limited data suggest that a device can be up to 4 mm shorter than the duct and still reach the pulmonary artery end, achieving a stable position. We recommend that a long-shank device be used if the initial angiogram indicates that the duct length exceeds the length of the standard device by >4 mm. Our data would suggest that had a long-shank device been used in the case where implantation failed, device implantation may well have succeeded because the 7 mm long device would have been only 3 mm shorter than the duct. However, at the time when that procedure was carried out, we did not yet have enough experience with the ODO to know that the long-shank device would reach the pulmonary artery, even though it was shorter than the duct.

Implant technique. The ODO was easy to deploy using the standard approach required to implant the Amplatzer duct occluder.² The device was adequately visualized on fluoroscopy. However, a dedicated long sheath and loader needs to be manufactured, as difficulty may be encountered loading the device into a Mullins sheath. In our view, the delivery cable needs to be modified so that the torquer reliably grips the cable and torque is more efficiently transmitted to the screw attachment of the device. When an ADO is implanted, the operator checks that it is correctly sized and positioned by looking for an "apple-core" device configuration, which occurs when the body of the device is compressed within the duct. As the body of the ODO is already wider at the pulmonary end than the aortic end by design, there is no such obvious shape change on implantation. It is therefore more difficult to be sure that it is properly positioned. In deploying the device, we relied on: (1) angiographic landmarks showing that the wider pulmonary end of the device had reached the pulmonary artery end of the duct; (2) further compression of the waist, which increased the difference between the size of the pulmonary and aortic ends of the device; and (3) angiography immediately following implantation, which opacified the duct while there was still flow through the body of the device, demonstrating that the device was well applied to the duct walls. It was straightforward to identify the position of

the device when the waist of the device was at the narrow point of the duct (Figure 4D). However, when the duct was long (Figure 4F), decision-making was more challenging. In these cases, pulmonary artery angiography through the long sheath can be useful to check that the proximal end of the device has reached the pulmonary artery. In all of the successful implants, echocardiography prior to device release confirmed that the pulmonary end of the device projected into the pulmonary artery, but we were confident on angiography alone that device positioning was satisfactory.

The observation that the waist of the device becomes smaller if the aortic retention disc is compressed may become important when a device is chosen with a waist size close to the minimum diameter of the duct. If the aortic retention disc is pulled firmly into the duct, the device core may not expand properly and there could be a gap around the waist at the point where occlusion is intended. Following this observation, we pulled the device into the duct with lighter pressure than would have been used for an Amplatzer device. In determining when to unsheath the core of the device, we relied more on radiographic markers than the tug on the cable that is felt when the aortic retention disc is pulled firmly into the ampulla. When firm pressure is necessary to shorten a long duct, to allow the pulmonary end of the device to reach the pulmonary artery, it may be better to use a long-shank device rather than firm traction, to avoid incomplete core expansion.

Study limitations. The main limitations of the study are its retrospective design and the small numbers of patients and devices evaluated. Larger numbers will be required to draw definitive conclusions about device sizing and to make comparisons with the Amplatzer device. Further evaluation of the device in larger ducts and long-term follow-up are required.

Conclusion

This is the first in-depth analysis of the performance of the ODO at implantation and at short-term follow-up, with emphasis on occlusion rates, technical challenges, and device sizing. Our experience indicates that the device is safe and effective, with 95% procedural success rates in 1–4 mm diameter ducts, with no device-related complications. Following device implantation, there was 100% duct occlusion at a median follow-up of 4 weeks. The position of the device within the duct is more difficult to assess than Amplatzer device position, because the device is not so obviously compressed when it is implanted.

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