Cardiol Young 2006; 16: 3–10
© Cambridge University Press
ISSN 1047-9511
doi: 10.1017/S1047951105002027

Review

Is interventional closure the current treatment of choice for selected patients with deficient atrial septation?

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Keywords: Devices; CardioSEAL; STARflex; Amplatzer; Helex; cardiac surgery; treatment; complications

INTERVENTIONAL TREATMENT OF CONGENITAL cardiac malformations has become a major part of the work in the catheterisation laboratory. In many institutions, it now accounts for around half the procedures undertaken. A part of this is the closure of atrial septal defects located in the oval fossa. Such treatment was first published 30 years ago,[1] and a number of techniques have been suggested over the years which have followed.[2–9]

Historical review

It was King, in 1976, who first reported sizing and closing an atrial septal defect in a 17-year-old female using a double screen device.[1] Rashkind then redesigned his ductal double umbrella for this purpose, made it five-armed with distal hooks, and covered it with the same polyurethane foam he used in the device intended for the persistently patent duct.[3] None of these devices, however, became available to the community of paediatric cardiologists. Sideris then conceived the "buttoned device". This had only one covering membrane,[7] on the left side of the septum, with a counter occluder fixing it on the right side. It underwent several modifications throughout the years, and was the first device that became available, although never gaining widespread acceptance. This was also the fate of Babic's ASDOS device,[8] a double disc screw-in device inserted over an arteriovenous wire loop, and Das's AngelWings device,[9] the first self-centring device, made of two square conjoined Dacron discs framed with linked nitinol wires. Because of the relatively stiff, rectangular, frame along the sides of the Dacron tissue, AngelWings had corners, which proved to be dangerous in terms of perforation of the aorta or the free atrial wall.[10] Other reports on failures[11] led to its discontinuation. A report on 5 years' follow-up,[12] nonetheless, concluded with this method being "effective and safe". Lock had, in the meantime, expanded further the concept of the Rashkind, and developed the "Clamshell" device. This consisted of two square Dacron patches on a skeleton of four steel arms, each radiating from the centre into one of the corners of the patch. Each arm had a spring at its origin, and another in its middle part.[4] The arms, however, showed a tendency to break,[5] causing the device to be recalled and redesigned. After the redesign, each arm was furnished with two springs in the middle part, offering better flexibility, and was baptised "CardioSEAL" (Fig. 1). The arms still broke, but since the fracture was relabelled as a "stress relieving mechanism", it was now considered a good thing![13] The break-through for interventional closure of atrial septal defects came with the Amplatzer device. This is a plug of nitinol wire mesh including three layers of polyester fibres[14–16] (Fig. 2). It rapidly gained acceptance among interventionists,[17] resulting in big series.[18] It is user-friendly, and the group from Berlin has reported the feasibility of implantations without the use of fluoroscopy.[19]

The CardioSEAL device has now been designed with a centring mechanism of very thin nitinol threads between corresponding corners on the two Dacron patches, and launched as "STARflex".[20,21] Some reports on this device and its predecessor were published at the turn of the century,[13,22] with Carminati pointing out the lower rate of residual shunting when using STARflex as opposed to CardioSEAL.[21] These devices received the mark of "Conformité Européene" (the so-called "CE-mark") in 1999, but are still not yet approved in the United States of America for

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Accepted for publication 6 June 2005

https://doi.org/10.1017/S1047951105002027 Published online by Cambridge University Press

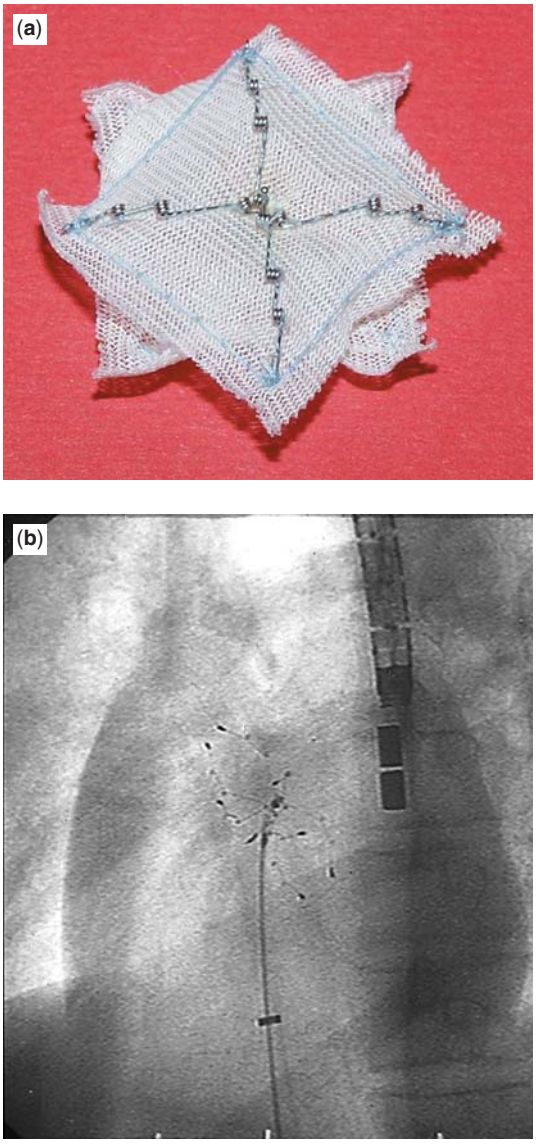

Figure 1.
*(**a**) CardioSEAL device with two springs in the middle of each arm in addition to the spring at the origin of the arms from the centre of the device. The left-sided patch is placed at an angle of 45 degree to the right-sided Dacron patch. Placed like this, the arrangement is flat. The fluoroscopy frame (**b**) shows the device in the left anterior oblique view, still kept on the delivery system. The left-sided and right-sided arms are pushed apart by the thickness of the atrial septum making the whole device much "thicker". The transoesophageal echo probe is readily visible at the top right.*

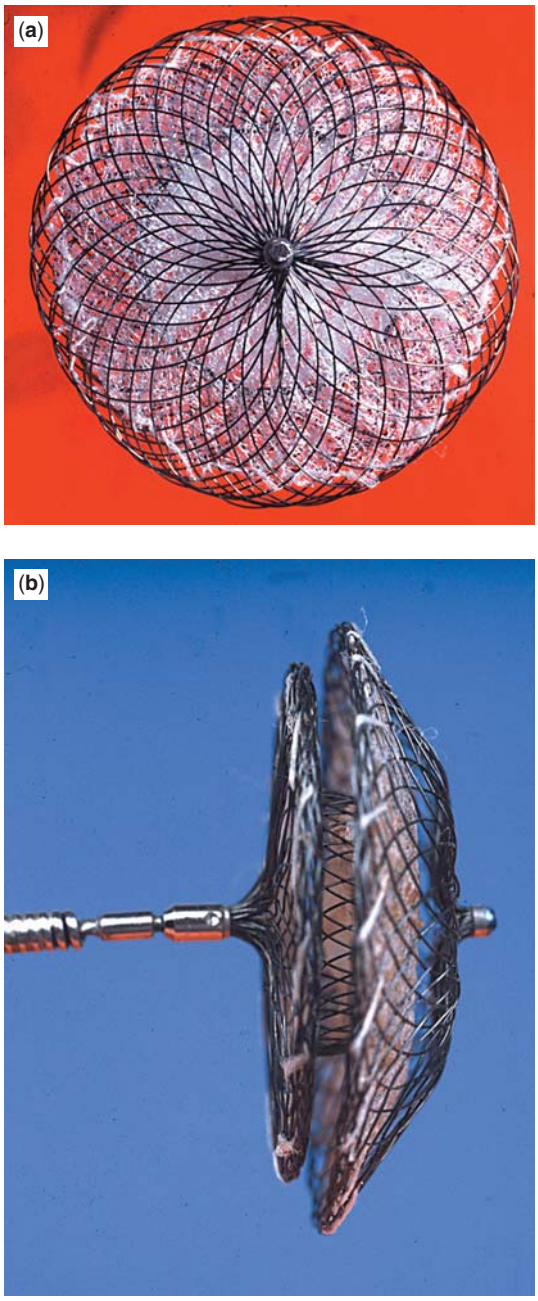

Figure 2.
*The left-sided aspect of the circular Amplatzer device is shown in this photograph (**a**). The device is made of 72 thin nitinol wires and filled with three layers of Dacron fibres. The sutures keeping the fibres in place are well seen on this frame. The lighter circle in the middle indicates the central core being the part that plugs the defect. In the lateral view (**b**), the slimmer right-sided and the heavier left-sided disc are seen. They are supposed to adapt the device to the septum, so, that the central core – visible between the discs – fits into the atrial septal defect. The device is attached to the delivery cable with a microscrew.*

closing of atrial septal defects. Worldwide, the manufacturer estimates that roughly 2500 devices have been implanted (personal communication). The double umbrella concept used in these two versions forms an alternative to the Amplatzer device. Still further devices are currently in different stages of testing, introduction, and implementation. These include the Helex device, a nitinol coil covered with Gore-Tex fabric, forming two discs, one on each side of the atrial septum[23] (Fig. 3). This is a non-centring device. Some devices are still purely investigational, such as the Solysafe device developed in Gothenburg, Sweden,[24] a device from Cardia, and a non-metal Dacron patch

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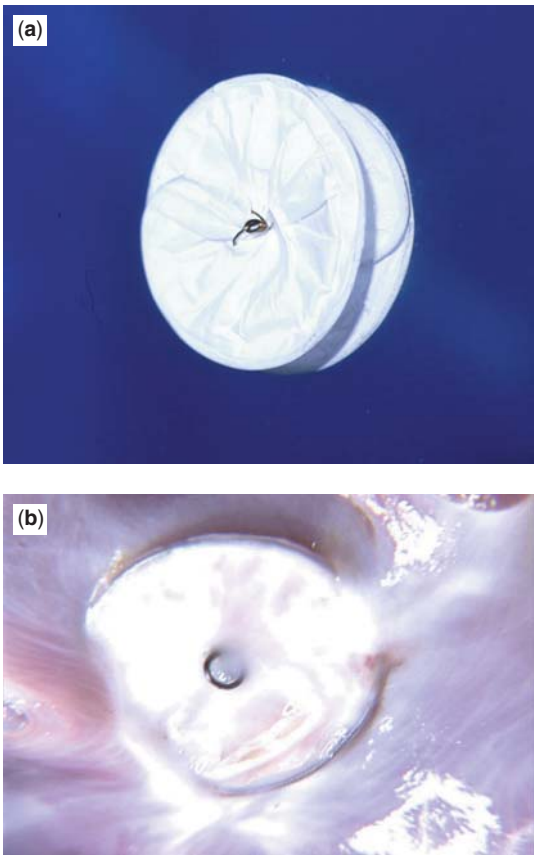

Figure 3.
The Helex device is a Gore-Tex non-centring double disc device. The Gore-Tex material covers one single nitinol wire, which supports the tissue and shapes the device. The lower frame shows its endothelialisation in the animal experiments, demonstrating full overgrowth of this very flat device.

being explored by Sideris.[25,26] In continuing my survey, I will exclude from consideration those devices constructed solely for closure of the persistent oval foramen.

Present state and clinical indications

The defects accessible for closure using a device are those located within the oval fossa, the so-called "secundum" defects. The "primum" defect, in reality an atrioventricular septal defect, and the "sinus venosus" type of defects, are not suitable for closure with current devices. Today, nonetheless, it is widely accepted that devices are of value in closing defects within the oval fossa. Such procedures have reduced the number of patients with such defects needing surgery to one-third, or even one quarter, in some centres. A significant number of reports have been published from all parts of the world.[27–30] Some have questioned the use of the Amplatzer device in smaller children,[31,32] but others have reported good results in children weighing no more than 10 kilograms, with no increased rate of complications, and maybe even shorter procedural times.[33] Thus, there is for practical purposes no need to postpone closure into older age, other than the possible event of spontaneous closure, which probably occurs only in patients in whom the defect was initially no more than a distended persistently patent oval foramen. Our own smallest patient weighted 3.8 kilograms. At the other end of the age spectrum, there also seems to be no upper limit. Even if there is no indication that disturbances of rhythm revert after closure, and that there is no obvious prolongation of life, it is remarkable that two-thirds of patients aged above 50 spontaneously indicate better physical tolerance at follow-up examinations.

The majority of interventionists use the Amplatzer septal occluder, the manufacturer now estimating more than 50,000 implants worldwide.[34] To a lesser degree, the more flexible devices, notably the CardioSEAL and STARflex, are used as alternatives in several centres.[13,21,22,35,36] A disadvantage of the latter devices is that they remain under trial in the United States of America. In smaller defects, those measuring less than 18 millimetres, comparison between the CardioSEAL/STARflex devices and the Amplatzer device has shown a low rate of complications in both, but shorter fluoroscopic and procedural times, as well as higher rates of complete occlusion, in the group of patients closed with the Amplatzer device.[37] The Helex device is now being used for closure of atrial septal defects in selected centres,[23,38,39] albeit that government restrictions apply, especially in the United States of America.

The general opinion is that the indications for closure have not changed, although the mode for defining them are different than they used to be. The gold standard, at the time when surgeons started closing such defects on a regular basis, was diagnostic cardiac catheterisation. Using these criterions, defects were closed if the ratio between pulmonary and systemic flows was greater than 1.5, equal to a shunt volume of one-third of the pulmonary flow. Even though based on the inaccurate oxymetric estimate of the relative excess of pulmonary flow, such an approach was used through decades, reverberates in the literature, and remains a relevant number in the mind of many cardiologists. For years now, however, purely diagnostic catheterisation has been considered unnecessary in patients with atrial septal defects. Surgery in these patients is recommended solely on the base of imaging, be this the old-fashioned two- or the new high-tech three-dimensional approach. When viewed in this light, it is evident that we need parameters other than the inaccurate oxymetric ratio of flows so as to define a significant shunt. At this stage, it would be

https://doi.org/10.1017/S1047951105002027 Published online by Cambridge University Press

anachronistic to reintroduce the use of oxymetry to define the ratio of flows, and reassess the non-invasively based indications for treatment during catheterisation. Echo and Doppler estimates are unreliable. But the concept of ratio of flows based on magnetic resonance imaging seemingly yields reasonably accurate results. We should not rely solely on a number for the volume of the shunt, nor change the indications for treatment simply because interventional treatment apparently is much easier for the patients, and the results seemingly good. We should not deviate from demanding evidence of a significant volume load on the right heart and the pulmonary circuit, and define the load using one or more of the non-invasive methods currently available, from the electrocardiogram and chest X-ray to echocardiography, or some type of computerised tomographic scans. This is more important because interventional catheterisation, seemingly so much easier than traditional surgery, was introduced into general practice no more than a few years ago. As yet, we have no long-time follow-up results available. Further, there are no randomised comparative studies, and there probably never will be. The huge problem of randomising patients into two such obviously very different therapeutic concepts, cardiac surgery or interventional catheterisation, will be that parents and patients would go for the seemingly easier method. If randomised into the surgical group, a significant number of parents would prefer going to another, non-randomising, hospital. When catheter-based therapy is compared with open heart surgery in a non-randomised way, the groups differ in age and size, as well as in size and localisation of the defect.[40,41] Reports are now appearing concerning minimal thoracotomy,[42,43] or minimal invasive surgery,[44,45] which adds to the uncertainty of the superiority of catheter-based closure. Other reports provide evidence for excellent results using a modern surgical approach.[46,47] Since we do not know that the long-time result after interventional closure is superior to that after cardiac surgery, we should be extremely cautious in changing the indications for closure. In our hospital, therefore, in line with other centres, we first define the indications for closure, and only then do we select the patients suitable for interventional catheterisation. The alternative treatment would be surgery.

When selecting which patients are suitable for catheter-based closure, it is mandatory to provide accurate anatomic evaluation using cross-sectional echocardiography. The diameters of the defect or defects must be measured, as well as the size of the surrounding walls, the latter being the most important. Transoesophageal echocardiography is needed to achieve this in adults. Most children up to 8, or maybe 10, years of age, in contrast, can equally well be assessed with transthoracic echocardiography from the subcostal approach. Three-dimensional echocardiography can yield valuable information,[48] and may be a tool for the future.

What, then, are the valid parameters for closure? There are good reasons for demanding definition of a certain haemodynamic load on the right heart and the pulmonary circuit. A defect permitting left-to-right shunting found across the interatrial septum on an echocardiographic examination has to offer some signs of right-sided volume load. These are widening of the right atrium, right ventricle or the pulmonary trunk, movement of the ventricular septum out of phase, or even in paradoxical fashion, and diameters of, and maximal velocities of flow across, the right-sided valves exceeding those for the left-sided valves. In addition, the finding of a pathological electrocardiogram, and a chest X-ray showing an enlarged heart and pulmonary plethora, also contributes in the evaluation. Only when we find some signs of volume load as indicated do we consider the indications for closure to have been satisfied. A certain degree of volume load is necessary, of course, before it is reflected by such parameters, but there is no indication for closing defects in its absence. Although the earlier quantification of atrial shunt had an exact mathematical cut-off, its haemodynamical exactness was far from satisfactory because of poor methodology, consequently resulting in a very approximate lower limit. Our knowledge, though, stems from long-time results in patients undergoing surgical closure of atrial septal defects based on such criterions. In addition, the long-time results for patients with defects not considered sufficiently large to warrant closure are rare and also based on such potentially inadequate criterions.

Issues of technique and equipment

There have been a number of reports concerning breakage of the skeleton of the various devices. This has been true for the family of Clamshell, cardioSEAL, and STARflex devices,[13,28,49] for the ASDOS,[50,51] and for the AngelWings.[12] There have been no such fractures reported in Amplatzer devices. This is probably more due to the lack of methodological possibility of discerning a fracture in the wire mesh, which forms the Amplatzer plug, than the real frequency of such fractures. On the other hand, it is reasonable to believe that the thinner and softer the metal structures are, the less likely they break. In none of the Amplatzer devices explanted from animals or from humans, though, has there been any evidence of fracture.[52] Equally, in no case with a fractured metal skeleton in any of the devices ever implanted have there been reports that such broken pieces embolise or do any further harm. It seems, therefore, that the term "better the arms break than the heart" is valid.

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Both the Amplatzer and the Helex devices use nitinol as their metal, whereas the CardioSEAL and STARflex devices have arms made of stainless steel. There have been concerns about the content of nickel, and possible allergic reactions, with the Amplatzer device. Increasing values of nickel in the serum have been reported after implantation of an Amplatzer device,[53] albeit that this was not confirmed in another study,[52] which noted resistance to corrosion.

The devices differ in their applicability for closure of bigger defects. The range of sizes of defects potentially closed with the Amplatzer device far exceeds those accessible when the umbrella family is used. There used to be a cut-off point at 20 millimetres with the CardioSEAL, but now the company indicates that the STARflex may possibly be used for defects measuring up to 24 millimetres. Helex discourages its use for defects above 20 millimetres. In our own series, with patients of all ages, one-fifth of the children eligible for interventional closure of their atrial septal defect had defects of more than 20 millimetres, whereas this applied for two-thirds of the adults aged over 18 years. As a total, one-third of the patients considered suitable for transcatheter closure had defects bigger than 20 millimetres as sized with a balloon.

The construction of the CardioSEAL devices makes them more flexible on the atrial wall than the more solid Amplatzer device. The umbrella device, often described as the flatter of the two, increases its width, the moment the umbrellas mould themselves to the sides of the atrial septum. The CardioSEAL device then looks different from the image presented prior to implantation (Fig. 1). The Helex device is also flexible, exerting little pressure on to the atrial wall, and is at least as flat as the double umbrella devices. The Amplatzer device has a relatively thick left-sided disc, which protrudes into the left atrium. It is the least flexible of the three.

When considering the process of implantation, then there are differences when using the three available devices. My own experience, mirroring that of other investigators, is that the Amplatzer device is the easiest to implant. The shorter times required for fluoroscopy, and the overall procedure, when implanting the Amplatzer device reflect this fact.[37] When used in children, then it is worthy of note that devices up to 17 millimetres in size can be implanted through a sheath of 7 French calibre, whereas the smallest introducer for the competitors is 9 or 10 French. Another point in favour of the Amplatzer device is its easy retrievability, even after implantation, as long as it has not been disconnected from the delivery cable. This it has in common with the Helex device, whereas the CardioSEAL or STARflex devices are easily retrieved when only the left-sided disc has been unfolded. When both umbrellas have been released from the sheath, the device will be destroyed if retracted. The devices based on the double-umbrella, nonetheless, are easy to handle, especially for those of us who previously worked with the Rashkind umbrella. The Helex device, in contrast, is technically cumbersome, with many details requiring reference to the manual of instructions. Aware of these problems, the producers have undertaken major improvements in their presentations, and a new version has been released which has been granted the so-called "CE mark".

Outcomes in the short- and long-term

Primary results of treatment are excellent. With the Amplatzer device, complete closure has been reported to 94%,[30] 96%,[29] 98%[18] and 100%[16] of patients. Similarly, with the CardioSEAL device, complete closure, including "trivial leaks", was 92.5%.[13] The STARflex device was not quite as good.[21] Both types of devices create complications.[54,55] Since the first implantations took place in the mid-1990's, at this stage it is impossible to describe truly long-time results. Even Mills and King[56] could report follow-up of no more than 27 years after their initial implantations from the late 1970s, describing persistence of the effective occlusion, absence of complications, and no reinterventions. After 5 years, follow-up of the implantations of the AngelWings device is reported to have shown good results, being deemed "effective and safe"[12] in spite of the fact that, in this series, almost one-fifth of patients had residual shunting after two years, one patient had mitral incompetence because of the implantation, and perforations were disregarded! As for the Helex device, Zahn et al.[23] reported complete closure in 24 dogs after 2 weeks, whereas in smaller clinical series, complete closure has been reported at 71%[39] or 85%.[38]

Complications

The most likely complications are embolisation of the device, infection, thromboembolic events, or damage to the heart and vessels. Embolisation of the device is unwanted, but the device may often be retrieved. If not, then the patient must undergo cardiac surgery, which was always the alternative treatment. Infection and thromboembolic events may occur in the setting of any interventional procedure, be it in the catheter laboratory or operating room. Formation of thrombus, nonetheless, is a concern, and according to the big series reported from Frankfurt,[57] this occurs in 1.2% of patients, recognising that there are differences according to the device inserted. Several correspondents, however, commented unfavourably on this review. Interventionists try to prevent such complications with intravenous antibiotics, and with antithrombotic

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therapy. When using antibiotics, note should be taken of the bacteriological flora in the specific centre. Most interventionists probably use some kind of cephalosporin. Heparin is given during the procedure, being monitored with activated clotting time, and either stopped in the catheter laboratory, continued until later the same day, or until the next morning. Different antithrombotic regimes are also available. Some use acetylsalicylic acid alone, or combined with clopidogrel for 3 to 6 months. Others use warfarin for the same period. There have been suggestions that some devices are not completely endothelialised after 6 months, and that the antithrombotic therapy therefore should be prolonged, but most centres recommend treatment for 6 months.

The worrying complication is perforation of the walls of the heart or the vessels. Such events were encountered when the AngleWings[10] and ASDOS[51] devices were inserted, but it was thought that the problem had been overcome with the newer devices. We now know otherwise. Both the double-umbrella device,[28] and the Amplatzer device,[58] can and have led to perforation of the heart. We know that 28 cases of perforation have been reported to one of the manufacturers, 25 of them in patients having deficient rims either adjacent to the aorta or superiorly.[34] The authors of this report[34] warn against overstretching during sizing. It has been suggested that the device inserted should be 2 to 4 millimetres larger than the stretched size if the defect is big. I have always opposed this practice, since sizing with a balloon is already a sort of "oversizing". The report cited above[34] substantiates this warning.

Place in clinical management

The "gold standard" for closure of atrial septal defects has been surgical, using cardiopulmonary bypass having split the sternum. When approached in this way, surgeons are able to close all types of interatrial communications, including the sinus venosus and "primum" types. Surgeons are not restricted by anomalous veins, or by the adjacency of valves and other structures. They are able easily to close defects with "deficient rims", because this does not create surgical problems. When inserting devices, we need careful selection of the patients. In some cases, unfortunately, only the catheterisation itself shows us that the patient is no candidate for interventional closure. Experience has shown that only two-thirds to three-quarters of the patients with defects in the oval fossa will be candidates for closure using a device.[18] These proportions will be even lower for those unable to use the Amplatzer device, especially if applied to an adult population, because of the limitations in the size of the other available devices.

Interventional treatment can be offered to patients otherwise sent for surgery if they are deemed suitable for closure using a device. Patients may be eligible for such treatment at any age, and down to a body weight of 8 to 10 kilograms.[33] In several institutions, closure with a device is now the method of choice, resulting in a steep decline in patients referred for surgical closure.

We will have to match the results of the "gold standard" if we are to recommend catheter-based closure of holes in the oval fossa. As already discussed, studies comparing closure with devices and surgery [41,59,60] have the problem of not being randomised. In most cases, therefore, the treatment of such defects that can be closed interventionally is compared with the surgical treatment of those who cannot. Further, the "gold standard" we used to know with traditional surgery has been modified in many ways[46,47] meaning that, in the modern era, surgery can be a much more palatable option. Moreover, we will never be able to perform the necessary randomised studies showing us "the truth" by comparing two equal groups. This is because experience tells us that, when patients or parents have to choose between the options, with few exceptions they opt for the apparently easier, and less invasive, method. This is even after they have been given the information that they will have a much bigger uncertainty for the long-term results than if they would choose surgery.

In modern paediatric cardiology, the tendency will be to recommend transcatheter treatment for those atrial septal defects that, after non-invasive examination, seem eligible for such treatment. So far, the results seem at least as good as surgery in terms of complete closure, and the rate of complications is lower both for pericardial effusion and for respiratory problems. In our institution, we can currently analyse nine years of experience using the Amplatzer devices. During this time, we have not encountered adverse developments. The long-term experience of others with the double-umbrella discs is similarly good. Compared to the surgical alternative, the length of stay in hospital is shorter, no time is required for convalescence, and the overall cost is lower.

Future outlook

All we know about the future is that it certainly will be different from today. Nevertheless, I can anticipate possible developments. I foresee that transcatheter methods for closure will thrive. As in the past, devices will come and go. Some will be short-lived, whilst other will be long-time winners. Others think that the metal frame will be discarded,[26] or that the device will be constructed with resorbable metal.[61] It has been suggested that the patch will be made with homologous cells, thus facilitating healing,[62] or maybe

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another bioengineered material.[63] I anticipate that some hardy interventionists will respond to the challenge of moving into areas we presently avoid, such as the sinus venosus defects and the atrioventricular septal defect with exclusively atrial shunting. It seems to be overwhelmingly likely that transcatheter closure of the defects in the oval fossa will not disappear. All disbelievers, as well as the cardiac surgeons, must realise that such methods have come to stay, albeit most likely not in their present form.

References

1. King TD, Mills NL. Nonoperative closure of atrial septal defects. Surgery 1974; 75: 383–388.
2. Rashkind WJ. Experimental transvenous closure of atrial and ventricular septal defects. Circulation 1975; 52: II8.
3. Rashkind WJ. Transcatheter closure of atrial septal defects in children. Eur J Cardiol 1977; 8: 119–120.
4. Lock JE, Rome JJ, Davis R, et al. Transcatheter closure of atrial septal defects. Experimental studies. Circulation 1989; 79: 1091–1099.
5. Rome JJ, Keane JF, Perry SB, Spevak PJ, Lock JE. Double-umbrella closure of atrial defects. Initial clinical applications. [see comment]. Circulation 1990; 82: 751–758.
6. Sideris EB, Sideris SE, Thanopoulos BD, Ehly RL, Fowlkes JP. Transvenous atrial septal defect occlusion by the buttoned device. Am J Cardiol 1990; 66: 1524–1526.
7. Sideris EB, Sideris SE, Fowlkes JP, Ehly RL, Smith JE, Gulde RE. Transvenous atrial septal defect occlusion in piglets with a "buttoned" double-disk device. Circulation 1990; 81: 312–318.
8. Babic UU, Grujicic S, Djurisic Z, Vucinic M. Transcatheter closure of atrial septal defects. Lancet 1990; 336: 566–567.
9. Das GS, Voss G, Jarvis G, Wyche K, Gunther R, Wilson RF. Experimental atrial septal defect closure with a new, transcatheter, self-centering device. Circulation 1993; 88: 1754–1764.
10. Rickers C, Hamm C, Stern H, et al. Percutaneous closure of secundum atrial septal defect with a new self centering device ("angel wings"). Heart 1998; 80: 517–521.
11. Agarwal SK, Ghosh PK, Mittal PK. Failure of devices used for closure of atrial septal defects: mechanisms and management. J Thorac Cardiovasc Surg 1996; 112: 21–26.
12. Kay JD, O'Laughlin MP, Ito K, Wang A, Bashore TM, Harrison JK. Five-year clinical and echocardiographic evaluation of the Das AngelWings atrial septal occluder. Am Heart J 2004; 147: 361–368.
13. Carminati M, Giusti S, Hausdorf G, et al. A European multicentric experience using the CardioSEAL and Starflex double umbrella devices to close interatrial communications holes within the oval fossa. Cardiol Young 2000; 10: 519–526.
14. Bjørnstad PG, Smevik B, Fiane A, Tønnessen TI, Fosse E. Catheter-based closure of atrial septal defects with a newly developed nitinol double disc: an experimental study. Cardiol Young 1997; 7: 220–224.
15. Sharafuddin MJ, Gu X, Titus JL, Urness M, Cervera-Ceballos JJ, Amplatz K. Transvenous closure of secundum atrial septal defects: preliminary results with a new self-expanding nitinol prosthesis in a swine model. [erratum appears in Circulation 1998 Feb 3; 97:413]. Circulation 1997; 95: 2162–2168.
16. Bjørnstad PG, Masura J, Thaulow E, et al. Interventional closure of atrial septal defects with the Amplatzer device: first clinical experience. Cardiol Young 1997; 7: 277–283.
17. Masura J, Gavora P, Formanek A, Hijazi ZM. Transcatheter closure of secundum atrial septal defects using the new self-centering Amplatzer septal occluder: initial human experience. Cathet Cardiovasc Diagn 1997; 42: 388–393.
18. Berger F, Ewert P, Bjornstad PG, et al. Transcatheter closure as standard treatment for most interatrial defects: experience in 200 patients treated with the Amplatzer Septal Occluder [see comments]. Cardiol Young 1999; 9: 468–473.
19. Ewert P, Daehnert I, Berger F, et al. Transcatheter closure of atrial septal defects under echocardiographic guidance without X-ray: initial experiences. Cardiol Young 1999; 9: 136–140.
20. Kreutzer J, Ryan CA, Wright Jr JA, et al. Acute animal studies of the STARFlex system: a new self-centering cardioSEAL septal occluder. Cathet Cardiovasc Interv 2000; 49: 225–233.
21. Carminati M, Chessa M, Butera G, et al. Transcatheter closure of atrial septal defects with the STARFlex device: early results and follow-up. J Intervent Cardiol 2001; 14: 319–324.
22. Hausdorf G, Kaulitz R, Paul T, Carminati M, Lock J. Transcatheter closure of atrial septal defect with a new flexible, self-centering device (the STARFlex Occluder). Am J Cardiol 1999; 84: 1113–1116, A10.
23. Zahn EM, Wilson N, Cutright W, Latson LA. Development and testing of the Helex septal occluder, a new expanded polytetrafluoroethylene atrial septal defect occlusion system. Circulation 2001; 104: 711–716.
24. Söderberg B, Solymar L, Larsson M, Thommen D, Bernhard J, Östman-Smith I. The Solysafe septal occluder for atrial septal defects – animal testing of the improved design. Cardiol Young 2005; 15 (Suppl 2): II79.
25. Sideris EB, Sideris CE, Toumanides S, Moulopoulos SD. From disk devices to transcatheter patches: the evolution of wireless heart defect occlusion. J Intervent Cardiol 2001; 14: 211–214.
26. Sideris EB, Toumanides S, Macuil B, et al. Transcatheter patch correction of secundum atrial septal defects. Am J Cardiol 2002; 89: 1082–1086.
27. Wilkinson JL, Goh TH. Early clinical experience with use of the 'Amplatzer Septal Occluder' device for atrial septal defect. Cardiol Young 1998; 8: 295–302.
28. Pedra CA, Pihkala J, Lee KJ, et al. Transcatheter closure of atrial septal defects using the Cardio-Seal implant. Heart 2000; 84: 320–326.
29. Wang JK, Tsai SK, Wu MH, Lin MT, Lue HC. Short- and intermediate-term results of transcatheter closure of atrial septal defect with the Amplatzer Septal Occluder. Am Heart J 2004; 148: 511–517.
30. Fischer G, Stieh J, Uebing A, Hoffmann U, Morf G, Kramer HH. Experience with transcatheter closure of secundum atrial septal defects using the Amplatzer septal occluder: a single centre study in 236 consecutive patients. Heart 2003; 89: 199–204.
31. Rastegari M, Redington AN, Sullivan ID. Influence of the introduction of Amplatzer device on the interventional closure of defects within the oval fossa in children. Cardiol Young 2001; 11: 521–525.
32. Vogel M, Berger F, Dahnert I, Ewert P, Lange PE. Treatment of atrial septal defects in symptomatic children aged less than 2 years of age using the Amplatzer septal occluder. Cardiol Young 2000; 10: 534–537.
33. Bjørnstad PG, Holmstrøm H, Smevik B, Tønnessen TI, Fosse E. Transcatheter closure of atrial septal defects in the oval fossa. Is the method applicable in small children? Cardiol Young 2002; 12: 352–356.
34. Amin Z, Hijazi ZM, Bass JL, Cheatham JP, Hellenbrand WE, Kleinman CS. Erosion of Amplatzer septal occluder device after closure of secundum atrial septal defects. Cathet Cardiovasc Interv 2004; 63: 496–502.
35. Kaulitz R, Paul T, Hausdorf G. Extending the limits of transcatheter closure of atrial septal defects with the double umbrella device (CardioSEAL). Heart 1998; 80: 54–59.
36. Hwang B, Lee PC, Fu YC, et al. Transcatheter closure of atrial septal defect with a CardioSEAL device. Jpn Heart J 2000; 41: 471–480.

https://doi.org/10.1017/S1047951105002027 Published online by Cambridge University Press

37. Butera G, Carminati M, Chessa M, et al. CardioSEAL/STARflex versus Amplatzer devices for percutaneous closure of small to moderate (up to 18 mm) atrial septal defects. Am Heart J 2004; 148: 507–510.
38. Vincent RN, Raviele AA, Diehl HJ. Single-center experience with the HELEX septal occluder for closure of atrial septal defects in children. J Interv Cardiol 2003; 16: 79–82.
39. Pedra CA, Pedra SF, Esteves CA, et al. Initial experience in Brazil with the Helex septal occluder for percutaneous occlusion of atrial septal defects. Arq Brasil Cardiol 2003; 81: 435–452.
40. Hughes ML, Maskell G, Goh TH, Wilkinson JL. Prospective comparison of costs and short term health outcomes of surgical versus device closure of atrial septal defect in children. Heart 2002; 88: 67–70.
41. Du ZD, Hijazi ZM, Kleinman CS, Silverman NH, Larntz K, Amplatzer I. Comparison between transcatheter and surgical closure of secundum atrial septal defect in children and adults: results of a multicenter nonrandomized trial. J Am Coll Cardiol 2002; 39: 1836–1844.
42. Miyaji K, Murakami A, Kobayashi J, Suematsu Y, Takamoto S. Transxiphoid approach for intracardiac repair using video-assisted cardioscopy. Ann Thorac Surg 2001; 71: 1716–1718.
43. Dabritz S, Sachweh J, Walter M, Messmer BJ. Closure of atrial septal defects via limited right anterolateral thoracotomy as a minimal invasive approach in female patients [see comment]. Eur J Cardiothorac Surg 1999; 15: 18–23.
44. Cremer JT, Boning A, Anssar MB, et al. Different approaches for minimally invasive closure of atrial septal defects [see comment]. Ann Thorac Surg 1999; 67: 1648–1652.
45. Black MD, Freedom RM. Minimally invasive repair of atrial septal defects. Ann Thorac Surg 1998; 65: 765–767.
46. Baskett RJ, Tancock E, Ross DB. The gold standard for atrial septal defect closure: current surgical results, with an emphasis on morbidity. Pediatr Cardiol 2003; 24: 444–447.
47. Hopkins RA, Bert AA, Buchholz B, Guarino K, Meyers M. Surgical patch closure of atrial septal defects. Ann Thorac Surg 2004; 77: 2144–2149.
48. Maeno YV, Benson LN, Boutin C. Impact of dynamic 3D transoesophageal echocardiography in the assessment of atrial septal defects and occlusion by the double-umbrella device (CardioSEAL). Cardiol Young 1998; 8: 368–378.
49. Prieto LR, Foreman CK, Cheatham JP, Latson LA. Intermediate-term outcome of transcatheter secundum atrial septal defect closure using the Bard Clamshell Septal Umbrella. Am J Cardiol 1996; 78: 1310–1312.
50. Hausdorf G, Schneider M, Fink C, et al. Transcatheter closure of atrial septal defects within the oval fossa: medium-term results in children using the 'ASDOS'-technique. Cardiol Young 1998; 8: 462–471.
51. Sievert H, Babic UU, Hausdorf G, et al. Transcatheter closure of atrial septal defect and patent foramen ovale with ASDOS device (a multi-institutional European trial). Am J Cardiol 1998; 82: 1405–1413.
52. Kong H, Wilkinson JL, Coe JY, et al. Corrosive behaviour of Amplatzer devices in experimental and biological environments. Cardiol Young 2002; 12: 260–265.
53. Ries MW, Kampmann C, Rupprecht HJ, Hintereder G, Hafner G, Meyer J. Nickel release after implantation of the Amplatzer occluder. Am Heart J 2003; 145: 737–741.
54. Pinto FF, Sousa L, Fragata J. Late cardiac tamponade after transcatheter closure of atrial septal defect with Cardioseal device. Cardiol Young 2001; 11: 233–235.
55. Preventza O, Sampath-Kumar S, Wasnick J, Gold JP. Late cardiac perforation following transcatheter atrial septal defect closure. Ann Thorac Surg 2004; 77: 1435–1437.
56. Mills NL, King TD. Late follow-up of nonoperative closure of secundum atrial septal defects using the King-Mills double-umbrella device. Am J Cardiol 2003; 92: 353–355.
57. Krumsdorf U, Ostermayer S, Billinger K, et al. Incidence and clinical course of thrombus formation on atrial septal defect and patent foramen ovale closure devices in 1000 consecutive patients. J Am Coll Cardiol 2004; 43: 302–309.
58. Divekar A, Gaamangwe T, Shaikh N, Raabe M, Ducas J. Cardiac perforation after device closure of atrial septal defects with the Amplatzer septal occluder. J Am Coll Cardiol 2005; 45: 1213–1218.
59. Berger F, Vogel M, Alexi-Meskishvili V, Lange PE. Comparison of results and complications of surgical and Amplatzer device closure of atrial septal defects. J Thorac Cardiovasc Surg 1999; 118: 674–678.
60. Bialkowski J, Karwot B, Szkutnik M, Banaszak P, Kusa J, Skalski J. Closure of atrial septal defects in children: surgery versus Amplatzer device implantation. Tex Heart Inst J 2004; 31: 220–223.
61. Peuster M, Wohlsein P, Brugmann M, et al. A novel approach to temporary stenting: degradable cardiovascular stents produced from corrodible metal-results 6–18 months after implantation into New Zealand white rabbits. Heart 2001; 86: 563–569.
62. Jux C, Bertram H, Wohlsein P, et al. Experimental ASD closure using autologous cell-seeded interventional closure devices. Cardiovasc Res 2002; 53: 181–191.
63. Jux C, Wohlsein P, Bruegmann M, Zutz M, Franzbach B, Bertram H. New biological matrix for septal occlusion. J Interv Cardiol 2003; 16: 149–152.

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