# New devices for pediatric mechanical circulatory support

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**Current Opinion in Cardiology** 2008, 23:91–96

**Purpose of review**

In adult patients with advanced heart failure, mechanical circulatory support devices (MCSDs) offer a valid treatment option. MCSDs can serve as a bridge to transplant, bridge to recovery or destination therapy. In the REMATCH trial, MCSDs outperformed medical management for long-term support of end-stage heart failure. Until recently, pediatric patients could not fully benefit from this development due to lack of suitable devices. This review provides an overview of pediatric MCSDs currently available in the US and those in the development stage. We discuss the emerging role of extracorporeal membrane oxygenation compared with MCSDs.

**Recent findings**

Small patients with a body-surface area below 0.7 $m^2$ now have access to the pediatric Berlin Heart Excor. For larger children, several adult MCSDs may be suitable, including the Abiomed BVS-5000, Thoratec, HeartMate and DeBakey MCSD. Five pediatric MCSDs supported by NIH contracts issued in 2004 are now in preclinical testing. Other pediatric MCSDs are already in clinical use abroad on a small scale.

**Summary**

There is mounting experience with MCSDs in children with advanced heart failure. MCSDs will increasingly have to be considered as a treatment option for pediatric heart-transplant candidates and may serve as a bridge to recovery.

**Keywords**

extracorporeal membrane oxygenation, neonates and infants, pediatric heart pumps, pediatric mechanical circulatory support devices

Curr Opin Cardiol 23:91–96

0268-4705

## Introduction

Mechanical circulatory support devices (MCSDs) offer a new treatment option for patients in end-stage heart failure [1,2]. They may serve as 'bridge to transplant', 'bridge to recovery' or even as 'destination therapy'. MCSDs are now routinely employed in adults [3], particularly after the REMATCH trial has shown that MCSD treatment was superior to medical management of severe heart failure in patients who were not eligible for cardiac transplantation [4]. Until 2007, however, there were no Federal Drug Administration (FDA)-approved MCSDs for small children in the US.

Early clinical experience, mostly from Europe, indicates improved survival to transplant when MCSDs are used in children and adolescents [5,6••,7]. MCSDs therefore could have a significant impact on the pediatric population, where the heart-transplant waiting list mortality continues to be higher than in adults [8]. For the last 15 years, the number of pediatric heart transplants worldwide has been stable at around 400 procedures annually without further growth [9]. MCSDs may extend the time available for finding a suitable donor organ. MCSDs are also useful in a situation with potential restoration of the patient's own pump function (like acute myocarditis or postcardiotomy) as a bridge to recovery [10–12]. While only a small percentage of adults can be weaned off support, the recent experience with the pediatric Excor from Berlin Heart indicated a 23% recovery based on 32 cases at a single institution [13••]. In other studies, five of 99 pediatric heart-transplant candidates recovered after being placed on MCSDs [6••] and, respectively, one of 10 [5]. With regards to long-term use, the pediatric Berlin Heart has successfully been used for more than a year in at least two children at two different institutions. The significance of pediatric MCSDs, therefore, is their potential to offer a 'bridge to transplant', 'bridge to recovery' or potentially 'destination therapy' for selected patients.

This review briefly compares MCSDs with extracorporeal membrane oxygenation (ECMO), discusses the currently available devices approved for use in the US, present devices under development, and other devices used clinically abroad, and concludes with a brief discussion of the technical challenges of a pediatric-size system.

## Extracorporeal membrane oxygenation compared with mechanical circulatory support devices

Mechanical support with extracorporeal membrane oxygenation in children has been performed successfully since 1975 [14]. The 2007 ELSO registry data show an overall survival to discharge of 65% in the current era but the numbers for cardiac patients, at best, 50%. The best outcomes occurred after short-term use for less than 1 week [Table 1]. Actively discussed issues in pediatric cardiac ECMO include pulsatile flow ECMO [15], early initiation and the concept of 'bridge to bridge therapy' [16,17]. Early use of ECMO in an arrest situation requires rapid set up and mobilization of key personnel. With this approach, a 33% survival rate has been reported [18]. Another new concept is to use ECMO as 'bridge to bridge' [19,20]. Under this strategy, patients would be transitioned from ECMO to MCSD as soon as it becomes apparent that they will require prolonged support. In the future, the role of ECMO in cardiac patients may be to provide a rapidly available first step to be followed by a MCSD.

## Currently available mechanical circulatory support devices for children

Anecdotally, DeBakey was the first to use an adult-size MCSD in a child in 1967 [21]. The first published report dates to 1991 [22]. In 1994, two pediatric-sized MCSDs were introduced in Germany that are still in use today [23•,24,25]. Both the Medos VAD and the Excor Pediatric, manufactured by Berlin Heart, have a pulsatile pneumatic (pusher plate) design [26,27]. In contrast, the Medos deltastream MCSD is based on a rotational design with a diagonally streamed impeller and is in use in Europe but is not approved in the US [15]. Figure 1 shows the three principal design types of MCSD. In the Berlin Heart, the blood runs through a closed polyurethane pouch with an inlet and outlet valve (Fig. 1A). The inside of the pouch is heparin-coated and special silicon cannulae are used to connect the MCSD to the heart. The blood-filled pouch is externally compressed by an air-filled chamber. The resulting output is pulsatile. The principle of the centrifugal pumps is different. Here, blood enters in the center of a rotor and has direct contact with the motor parts. Blood can be accelerated either continuously or in a pulsatile mode (Fig. 1B).

Worldwide, the pediatric-size Berlin Heart has been used in 312 children up to the end of August 2007, including more than 100 cases in North America. Excor Pediatric from Berlin Heart is suitable for children down to 2.5 kg body weight. It comes with stroke volumes between 10 and 60 ml. The Berlin Heart is the only MCSD currently available that is suitable for small children and infants, after it received limited approval for 10 specific pediatric centers.

Before the limited FDA approval of the Berlin Heart Excor in spring 2007, no pediatric MCSDs were available in the US [21,28••]. Through compassionate use or offshore, however, 156 pediatric patients received a MCSD before May 2007 based on the Interagency Registry of Circulatory Support Systems (INTERMAC) [6••]. In selected larger children, the following adult-size devices can be used: Thoratec heart mate II, Abiomed BVS 5000, DeBakey Microtec and Berlin Heart Excor Pediatric (Table 2). The design type is indicated in the table.

The largest pediatric experience exists for the Thoratec devices, including Heart mate and Heart mate II based on the Pierce-Donachy heart developed at Penn State University and approved by the FDA in 1980. By 2005, these devices had already been used in 209 children worldwide [29,30]. The principal design is similar to that of the pediatric Excor Berlin Heart, with a pneumatically driven pulsatile design (Fig. 1). This MCSD, however, is not yet available for patients with a body-surface area of less than 0.7 $m^2$. The DeBakey MCSD is approved for children with a body-surface area between 0.7 and 1.5 $m^2$ for the bridge to transplant indication [31,32]. This device has an axially-rotary design that makes it potentially implantable.

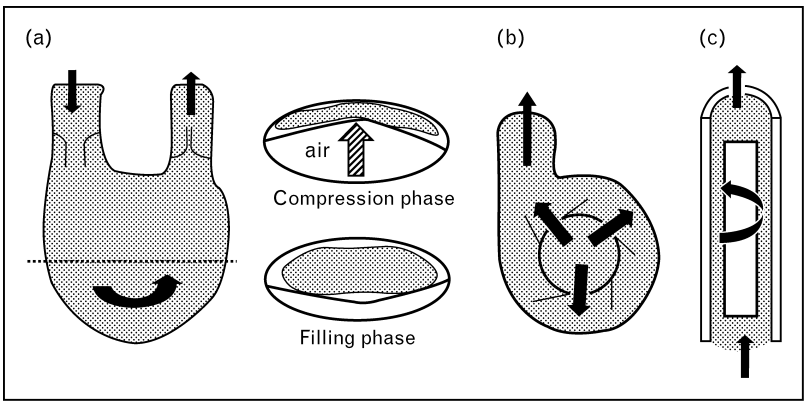
What risks can be expected with the use of MCSDs in pediatric patients? The principal challenges include hemorrhagic events, thromboembolism and infection [6••]. Based on the registry data among 17 casualties on MCSD support while awaiting cardiac transplantation, 65% succumbed to strokes, 17% to infections, 12% to multi-organ failure and 5% to fatal arrhythmias. The risk

**Table 1 Pediatric mechanical circulatory support by extracorporeal membrane oxygenation and mechanical cardiac support device**

| | ECMO | MCSD |
|---|---|---|
| Patient size | Any | Limited options for body-surface area $<0.7$ $m^2$ |
| Experience | Extensive, since 1975 | $<500$ pediatric cases since 1991 |
| Setting | Deep sedation, intensive care unit | Patient can be awake and even ambulatory |
| Blood products | Frequent use | Reduced need |
| Anticoagulation | Strictly required | Depending on device, potentially minimal |
| Long-term use | Problematic | Long-term use for $>1$ year reported |

ECMO, extracorporeal membrane oxygenation; MCSD, mechanical cardiac support device.

**Figure 1 Principal design types of mechanical circulatory support devices**




(a) In the pneumatic pulsatile pusher-plate design, blood enters a polyurethane chamber with an inlet and an outlet valve. The blood-filled chamber is externally compressed by an air-filled chamber via a membrane, thereby creating pulsatile flow. There is no direct contact between the pumping mechanical parts and blood since the blood is contained in the polyurethane bag. (b) In the rotational centrifugal design, blood is accelerated by centrifugal forces. The support of the rotor may also be magnetic to reduce friction and to avoid crevices with low flow. Newer models with this design permit both continuous and pulsatile flow. (c) In the axial rotary design, a rotating impeller is magnetically suspended in a narrow housing and driven by an electrical motor. As the blood flows through the narrow chamber, it is continuously accelerated by the blades of the impeller. These devices have a low profile and may be implanted in a large blood vessel.

of fatal sepsis would thus be approximately 3%. In another case series, the rate of any neurological events with the Thoratec MCSD was reported as 27% during left atrial cannulation and 13% with left ventricular cannulation [30]. This compared with 11% neurological events with the Berlin Heart Excor at the same center [30]. The data from the German Heart Institute in Berlin seem to indicate a decline in the complication rates with increasing experience, again emphasizing the importance of a multidisciplinary team approach [13••]. At this point, it is difficult to predict the complication rate during more routine use of MCSDs in children.

## Pediatric mechanical circulatory support devices under development

In recognition of the need for a pediatric ventricular assist device, the NIH has issued five contracts to develop new devices (Table 3). For comparison, it is estimated that 35 adult devices are in the development stage now. The NHLBI formulated the following goals for an ideal pediatric device: first, start-up time less than 1 h; second, low priming volume; third, flexible cannulation suitable for abnormal anatomy; fourth, minimal blood product exposure; fifth, minimal infection risk; and sixth, suitability for long-term support (6 months) [33•]. All five devices sponsored by the NHLBI are currently in the preclinical development stage.

**Table 2 Federal Drug Administration-approved mechanical cardiac support devices already used in children**

| Device | Maker | Patient size | Type |
|---|---|---|---|
| Heart mate LVAD | Thoratec | BSA>0.7 $m^2$ | Pusher plate |
| Thoratec VAD | Thoratec | BSA>0.7 $m^2$ | Pusher plate |
| Abiomed BVS 5000 | Abiomed | BSA>0.7 $m^2$ | Axial |
| DeBakey VAD | Micro Med Technologies | BSA 0.7–1.5 $m^2$ | Axial |
| Excor Pediatric | Berlin Heart | $\geq$ 2.4 kg | Pusher plate |

BSA, body-surface area.

The Pediaflow VAD is based on a magnetically levitated impeller with a turbodynamic design providing axial acceleration [34]. The prototype of this device weighs 100 g with a length of 51 mm and a width of 28 mm. It is currently in the in-vitro testing stage. The Pedipump developed by the Cleveland Clinic also follows an axial rotary design and will be suitable for the entire pediatric range [35,36]. This device is currently in the in-vivo testing stage in an ovine model [37]. Through its wide range of pump speeds of 5200–16 200 rpm, this MCSD aims at a wide operational range, with flows between 0.5 and 3.2 l/min. The Pediatric Jarvik heart showed promising results *in vitro* and is currently being tested in an ovine model [38]. The pCAS system can deliver both continuous and pulsatile flow [39]. Current efforts involve a comparison of the performance in either mode in a porcine model [39]. The PVAD developed at Penn State University has a pneumatic pulsatile design based on the Pierce-Donachy MCSD. It is currently also in the early stage of in-vivo testing in an animal model.

## Other pediatric mechanical circulatory support devices

The RotaFlow device from Jostra, a centrifugal rotary pump, has been successfully employed for ventricular assistance in children postcardiotomy [12]. Other pediatric pumps under development also follow a

**Table 3 Pediatric mechanical circulatory support devices under development**

| Device | Research institution | Type |
|---|---|---|
| PediaFlow VAD | U Pittsburgh | Axial rotary |
| PediPump | Cleveland Clinic | Axial rotary |
| PCAS | Ension, Inc, U Louisville | Centrifugal rotary |
| Pediatric Jarvik 2000 | Jarvik Heart, U Maryland | Axial rotary, implantable |
| PVAD | Penn State University | Pneumatic pulsatile pusher plate |

PCAS, pediatric circulatory support device; VAD, ventricular assist device.

centrifugal rotary design but are still preclinical. The Miniature Maglev Pump is currently undergoing in-vitro testing, guided by computer fluid dynamic modeling to find the optimal shape of the magnetic rotor [40]. The new PediVAS centrifugal rotary pump is based on the same design as the CentriMag MSCD manufactured by Levitronix, which has been used in 1500 adults already [41]. The TandemHeart Pediatric [42] is designed for short-term support of small patients between 2 and 40 kg body weight, and only requires percutaneous cannulation of peripheral vessels, similar to ECMO. In contrast to ECMO, it requires a smaller priming volume. This MCSD is designed for use up to 2 weeks. Another centrifugal pediatric pump is currently under development at the University of Tokyo; the TinyPump system is suitable for cardiopulmonary bypass, ECMO or as an MCSD [43]. The advantage of the TinyPump would be its small size, with a displacement volume of only 68 ml, rendering this device suitable for implantation. It also has a very small priming volume of only 5 ml. This pump provides continuous flow. It has been tested *in vivo* in a porcine model.

Another device at the design stage specifically aims at support of the systemic venous return in single-ventricle patients palliated with a Fontan operation [44]. This MCSD has a folding propeller design, similar to the motor found on sailing boats. It has not been tested *in vivo* yet.

## Basic science aspects

The original development of MCSDs was mostly based on experimental data [45]. Challenges in developing a miniaturized pediatric device raised awareness of the need for a better theoretical understanding of the flow dynamics of the device with regards to hemolysis, thrombogenesis, immuno-activation (activation of an inflammatory response), and effective energy transmission (specifically continuous compared with pulsatile).

Compared with adult-size devices, pediatric devices have more surface area per blood volume for geometric reasons. In addition, the narrow caliber of the openings and cannulae may promote hemolysis due to increased shear stress during the passage of the red blood cells through the device. The same mechanical forces also impact on leukocytes and may trigger an inflammatory response. The higher flow rates of adult devices are thought to prevent thrombogenesis because they 'wash-out' contact surfaces, thus preventing adhesion and clot formation. Pediatric devices not only have more surface area but also operate at lower flow rates, further raising concerns about an increased risk of thrombogenesis. This may necessitate different strategies to prevent clots [46]. Miniaturization of all components of the system may cause inefficient energy transmission—for instance, at the transition from the tubing to the cannulae. Due to these challenges, it is conceivable that pediatric patients may experience disproportionately greater benefits from pulsatile operation mode than adults because they operate on a narrower margin.

Several investigators now use computational fluid dynamics models to predict the fluid dynamics of the devices [40,44,47]. Ultimately, experimental data will have to prove the feasibility of small pediatric MCSDs with designs other than the pneumatically driven pusher-plate approach that is already successfully used in clinical practice.

## Summary

MCSDs increasingly offer an alternative to pharmacological support of the failing heart. They can potentially serve as a bridge to transplant, bridge to recovery or as destination therapy. The three basic design types are pneumatic pulsatile pusher plate, centrifugal rotary and axial rotary. Clinical experience with pneumatic pulsatile devices is most extensive. These pumps are generally paracorporeal but may permit ambulation. The Pediatric Berlin Heart Excor is suitable for infants as small as 2 kg and is now available in the US. The adult Thoratec MCSD has been used in older children. Centrifugal rotary pumps are widely used during cardiopulmonary bypass and ECMO and can also serve as assist devices. Current models are generally used for short-term support but a number of advanced systems are under development. Miniaturized axial rotary devices could potentially offer very flexible flow rates through variation of the rotation speed. The advantage of this design type is that they are potentially implantable. The DeBakey and the Jarvik heart are examples of this type of MCSD. Important obstacles to the development of a pediatric MCSD

shared by all three design types include hemolysis, thrombogenesis, inflammatory response and ineffective energy transmission.

## Conclusion

There is mounting experience with MCSDs in children with advanced heart failure. MCSDs increasingly will have to be considered as a treatment option for pediatric heart-transplant candidates and may serve as a bridge to recovery.

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