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A New Clip Device for the Construction of Vascular Interrupted Anastomoses in Congenital Cardiac Surgery

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ABSTRACT

Background: Many different mechanical vascular anastomotic devices have been developed recently, mostly rigid stenting mechanisms applicable only in coronary artery bypass grafting surgery. U-Clips, however, allow the precise construction of any vascular interrupted anastomosis, preserving pulsatility and perhaps growth potential.

Methods: We report the first use worldwide of U-Clips for congenital cardiac surgery in 10 pediatric patients (mean age, 2.3 ± 1.7 years). The operations took place between July 2001 and July 2002 for coarctation repair (3 patients), Glenn shunt (5 patients), Blalock-Taussig shunt (1 patient), and arterial switch (1 patient).

Results: Device handling, primary hemostasis, and patency were excellent, and no device-related complications occurred. Because of the learning curve, aortic cross-clamp times were significantly longer for the repair of coarctation with U-Clips than with the running-suture technique (21.7 ± 2.3 minutes versus 14.4 ± 2 minutes; $P = .012$). Postoperative recoveries were uneventful in all patients except for a baby with pulmonary atresia with intact ventricular septum, who died after 62 days. After a mean follow-up period of 11.9 ± 4.4 months, echocardiographic controls of all anastomoses showed nonturbulent flow without any restriction.

Conclusion: The U-Clip device may be a useful adjunct in congenital cardiac surgery for facilitating the creation of interrupted vascular anastomoses. Further evaluation is warranted for determining the long-term benefits of these devices with respect to growth preservation and restenosis.

INTRODUCTION

Construction of a manual vascular anastomosis demands considerable skill and may be very time consuming, especially with interrupted sutures. However, interrupted sutures have the advantages of avoiding a possible purse-string effect on the anastomosis and allow a greater anastomotic diameter, improved pulsatility of the anastomosis, and unrestricted growth potential, compared with running-suture techniques [Chiu 1988, Gillinov 1992, Tozzi 2001]. As a consequence, short-term and long-term patencies as well as clinical outcomes may be improved. Interrupted sutures may therefore be preferable, especially with microvascular anastomoses, in children with growing vascular structures and when low-pressure vessels are involved [Tons 1986, Torsello 1987, von Segesser 1996]. Coalescent Surgical (Sunnyvale, CA, USA) has developed a nitinol self-coiling penetrating clip (U-Clip) (Figure 1) to facilitate the construction of vascular anastomoses in an interrupted fashion [Berdat 2002]. After tests with U-Clips in a bovine model showed excellent graft patency and healing characteristics [Hill 2001] and significantly greater anastomotic compliance and cross-sectional area than with the running-suture technique [Gerdisch 2002], the U-Clip was approved by the US Food and Drug Administration in February 2000 and received the CE mark in October 2000. Preliminary results of an ongoing multicenter study evaluating the use of this device in coronary artery bypass grafting surgery [Caskey 2002, Ono 2002] are very promising. Considering the possible advantages of easily created interrupted sutures, especially for children with growing vessels, we have opted to use the U-Clip in pediatric cardiac surgery to assess its utility and to gain early experience. Here we report the first successful clinical use of the U-Clip worldwide in congenital cardiac surgery.

MATERIALS AND METHODS

Patients

Between July 2001 and July 2002, we successfully used U-Clips in 10 consecutive children who underwent operations by the same surgeon (P.A.B.) for bidirectional Glenn anastomosis (5 patients, Figure 2A), coarctation repair (3 patients, Figure 2B), arterial switch operation (1 patient), and modified Blalock-Taussig shunt (1 patient). Perioperative data are summarized in the Table.

Surgical Technique

The device consists of a vascular needle on a nitinol flexible member 3 cm or 6 cm in length with a nitinol clip mounted on a release mechanism at the end (Figure 1). For the construction

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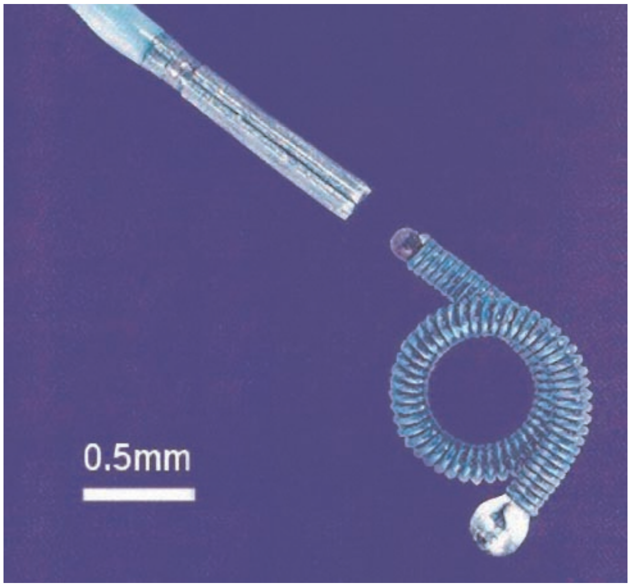

Figure 1. Magnified view of the closed U-Clip, a self-recoiling nitinol clip. Release mechanism on the flexible member is at upper left.

of vascular anastomoses, the needle is passed through both vessel walls (Figure 3A), and the U-Clip is positioned (Figure 3B). Squeezing the release mechanism with the needle holder deploys the clip, which self-recoils and closes (Figure 3C), thereby eliminating knot tying and assisted suture management (Figure 3D). Keeping an even and adequate distance between each clip assures immediate hemostasis. Different sizes of U-Clips exist to fit all kinds of vessels, and the appropriate selection of the correct size is important to obtain immediate anastomotic hemostasis. No special surgical instruments are needed with the use of this device.

Statistics

Data are expressed as the median ± standard deviation. Percentages are given where appropriate. Statistical analysis was performed with Statview 5.0.1 for Windows (SAS Institute, Cary, NC, USA). For univariate analysis, the Mann-Whitney *U* test for continuous data was used. A *P* value of <.05 was considered statistically significant.

RESULTS

The U-Clips allowed easy and precise construction of all anastomoses in an interrupted fashion without any difficulty, and immediate hemostasis was attained. In most cases, U-Clip size 35 or 50, corresponding to suture sizes 6-0 and 5-0, proved to be appropriate (Table).

Early anastomotic patencies, as assessed by intraoperative invasive pressure gradient measurements and/or postoperative echocardiography, were excellent with no flow restriction in any patient. Compared with a contemporary age-matched group of 9 patients who underwent operations for coarctation with continuous suture, the times for the construction of anastomoses for coarctation repair were significantly longer with U-Clips than with continuous suture (21.7 ± 2.3 minutes versus 14.4 ± 2 minutes; *P* = .012). Postoperative recovery was uneventful in all but one case. A baby with pulmonary atresia with intact ventricular septum died after 62 days of a probably

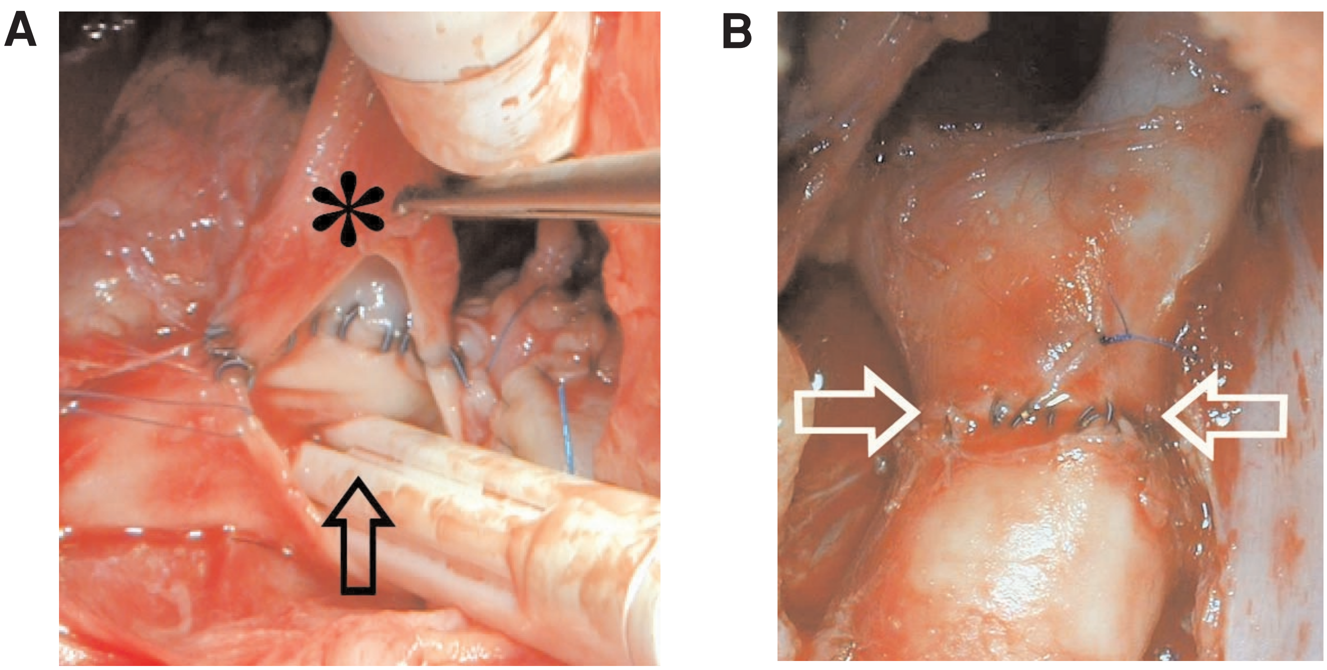

Figure 2. Intraoperative views. A, Bidirectional Glenn anastomosis (asterisk, superior vena cava; arrow, right pulmonary artery) during construction. The dorsal suture line has already been completed. B, Completed end-to-end anastomosis (arrows) of the proximal descending aorta after the resection of coarctation.

Clinical and Perioperative Data*

Patient	Age, y	Diagnosis	Operation	U-Clip Size	Operation Time, min	CPB Time, min	AXC Time, min	Anastomotic Patency†	Postoperative LOS, d	Outcome
1	4.3	Coarctation	ETE	50	135	0	31	Excellent	8	Alive
2	3.7	Coarctation	XETE	35	130	0	32	Excellent	7	Alive
3	4.9	Coarctation	ETE	50	105	0	20	Excellent	7	Alive
4	2.3	SV	BDG	50	205	94	54	Excellent	9	Alive
5	2.0	SV	BDG	35	365	123	89	Excellent	37	Alive
6	0.8	SV	Bilateral BDG	35	240	128	89	Excellent	9	Alive
7	3.1	SV	BDG	35	240	81	44	Excellent	6	Alive
8	4 d	PAIVS	BTS	18	155	0	0	Excellent	61	Died POD 62
9	7 wk	Complex dTGA	Rapid 2-stage ASO	35	300	135	90	Excellent	8	Alive
10	2.3	SV	BDG	35	210	85	35	Excellent	14	Alive
Median ± SD	2.3 ± 1.7				208 ± 81	65 ± 58	48 ± 31		17 ± 18	11.9 ± 4.4 mo‡

*CPB indicates cardiopulmonary bypass; AXC, aortic cross-clamp; LOS, length of hospital stay; ETE, end-to-end repair; XETE, extended end-to-end repair; SV, single ventricle; BDG, bidirectional Glenn; PAIVS, pulmonary atresia with intact ventricular septum; BTS, modified Blalock-Taussig shunt; POD, postoperative day; dTGA, dextro-transposition of great arteries; ASO, arterial switch operation.

†Assessed before discharge by intraoperative invasive measurements or by echocardiography.

‡Mean follow-up time ± SD.

cardiac cause; an autopsy, however, could not be obtained. After a mean follow-up period of 11.9 ± 4.4 months, echocardiographic controls showed that all anastomoses exhibited nonturbulent flow without any restriction.

DISCUSSION

Although interrupted sutures may be superior to running sutures [Baumgartner 1996, Tozzi 2001], especially in growing vessels [Pae 1981, Nakashima 1991, Chen 1993, Soejima 1997] and low-pressure vessels [Tons 1986, Torsello 1987, von Segesser 1996], running sutures are still preferred by many surgeons, because they are faster to perform and afford less manipulation and knot tying. Despite the many different factors that may affect the rates of postoperative anastomotic stricture or restenosis, such as inadequate tissue growth, excessive scar formation, use of foreign material, myointimal hyperplasia, and patient age at repair, the selection of suture material and technique remains important and can be influenced by the surgeon. Furthermore, there is still room for improvement, because reinterventions for stricture or restenosis involving the suture line [Williams 1997] may

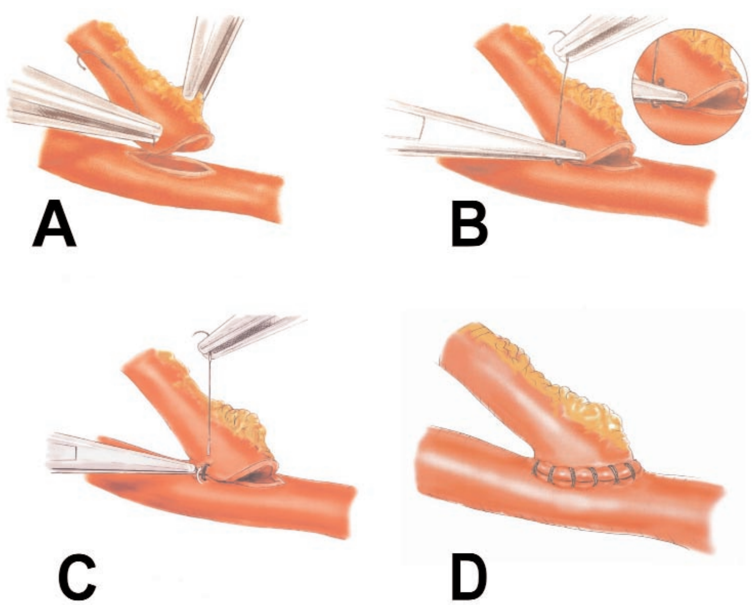

Figure 3. Surgical procedure. A, Passing needle from the outside of the graft to the inside of the native vessel. B, The needle driver is engaged and positioned over the release mechanism. C, The U-Clip is released, and the needle and flexible member are removed. D, Completed U-Clip anastomosis.

contribute considerably to adverse late outcomes in some subsets of patients [Hawkins 1995, Williams 1997, Amato 2000, Losay 2001]. With the availability of the new U-Clip device, most technical disadvantages for the creation of conventional interrupted suture anastomoses are eliminated, providing the surgeon with a tool to easily avoid continuous suture lines in situations where such sutures may compromise vascular growth. In our experience, the U-Clip device not only is suitable for coronary artery bypass grafting surgery [Berdat 2002, Caskey 2002, Ono 2002] but also allows easy and precise construction of vascular anastomoses in an interrupted fashion in pediatric cardiovascular surgery.

The significantly longer time required for anastomosis creation in coarctation repair with U-Clips may reflect the learning curve and is in part due to the frequent image-taking required to document the new procedure. However, the anastomosis time was never extended to the point of compromising the clinical outcome. Furthermore, because no anastomosis was done with conventional interrupted suture, a comparison with this kind of anastomotic technique was not possible.

Although the kind of sutures used in conjunction with prosthetic material is probably less important in the preservation of growth potential, the application of U-Clips was also easy for constructing the anastomoses of a modified Blalock-Taussig shunt. However, because the child with pulmonary atresia and intact ventricular septum died suddenly 2 months later and because no autopsy could be obtained, shunt thrombosis and the possible role of the U-Clips in this fatal outcome could not be ruled out.

Despite the rather short follow-up time and its limitations for assessing anastomotic dimensions, echocardiographic reevaluation of the anastomotic region showed promising results in all patients, suggesting that the application of this device may eventually help preserve growth potential and prevent anastomotic stricture in the pediatric cardiac patient. However, long-term follow-up and a larger randomized trial are warranted to assess the potential clinical benefits of this new device.

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