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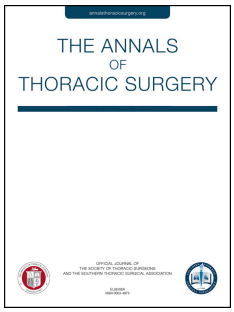

Early-experience with a novel suture device for sternal closure in pediatric cardiac surgery

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PII: S0003-4975(21)01684-2

DOI: https://doi.org/10.1016/j.athoracsur.2021.08.066

Reference: ATS 35642

To appear in: *The Annals of Thoracic Surgery*

Received Date: 2 July 2021

Revised Date: 24 August 2021

Accepted Date: 30 August 2021

Please cite this article as: Heinisch PP, Nucera M, Bartkevics M, Erdoes G, Hutter D, Gloeckler M, Kadner A, Early-experience with a novel suture device for sternal closure in pediatric cardiac surgery, *The Annals of Thoracic Surgery* (2021), doi: https://doi.org/10.1016/j.athoracsur.2021.08.066.

Early-experience with a novel suture device for sternal closure in pediatric cardiac surgery

Running Head: Sternal closure

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Abstract presentation at ECHSA Annual meeting 2021 (11 – 12 June 2021).

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Abstract

Background: Sternal closure by absorbable suture material is an established method for chest closure in pediatric cardiac surgery. However, the formation of granuloma around knotted suture material is frequently observed and has potential for prolonged wound healing and infection, particularly in newborns and infants. This retrospective study analyses the suitability and reliability of a novel absorbable, self-locking, multi-anchor knotless suture with antibacterial technology for sternal closure in pediatric cardiac surgery.

Methods: The applied material (*STRATAFIX^{TM} Symmetric PDS Plus, Ethicon*) presents a poly-dioxanon PDS suture with a self-locking, multi anchor design, which enables a sternal closure in a continuous knotless suture technique. All children undergoing knotless closure after standard median sternotomy were examined for the occurrence of sternal wound infection or sternal instability by applying the screening criteria of the Centers for Disease Control and Prevention at hospital discharge, at 30 and 60 days.

Results: In 130 cases, the new knotless sternal closure was used. Patients` mean age was 19.0±31.9 months (range: 0 to 142 months), mean bodyweight 7.8±6.6 kg (range: 2.4 to 35 kg). Delayed sternal closure occurred in 23 cases with a mean closure time after 2.9±2.6 days. One superficial incisional sternal site infection but no cases of deep sternal site infection or sternal instability were observed.

Conclusions: The application of the absorbable, knotless suture technique provides excellent results regarding the rate of sternal wound infection and improved healing after median sternotomy in pediatric patients.

Abbreviations

PSC	primary sternal closure
DSC	delayed sternal closure
SSI	surgical site infection
DSWI	deep sternal wound infection
ICU	intensive care unit
PICU	pediatric intensive care unit
OR	operating room
FU	Follow up

Surgical site infections (SSI) represent a serious complication after pediatric cardiac surgery. Among patients who suffer from SSI, morbidity, mortality, and health care costs are significantly higher compared to those who do not develop an infection. It is reported that most cases of SSI require surgical debridement as part of the therapy [1-3]. To our knowledge, there are no guidelines for the management of SSIs in congenital cardiac surgery [4]. Commonly known risk factors for SSIs in infants are young age, low weight, DSC and excessive blood loss during operation [4-6]. Several studies described the alteration of different pre- and perioperative strategies such as bathing with skin antiseptics, antibiotic regimes or wound care. These alterations did not show any significant decrease of the rate of SSI [4, 7].

Material and methods of surgical closure may also influence sternal bone healing in terms of stability. However, once sternal bone healing is completed, steel wires or sutures have no further function. Surgical knots commonly used for absorbable vicryl (polyglactin 910) filament sutures can also cause wound seroma and are frequently associated with the formation of suture granulomas around it. An alternative is the application of steel wires, which however permanently rest in place and - particularly in growing children – may lead to discomfort and may require removal [8].

In our institution, we use a poly-dioxanon PDS suture with a self-locking multi anchor design, which enables a sternal closure in a continuous knotless suture technique. This suture is already well established in visceral surgery for fascial closure. It provides a firm and secure tissue adaption achieving better tension control and strength than interrupted suture closure. To our knowledge it has not been used for sternal closure in congenital cardiac surgery yet.

The aim of this retrospective study was to analyze the suitability and reliability of this absorbable, self-locking multi-anchor knotless suture with antibacterial technology for sternal closure in children undergoing pediatric cardiac surgery.

Material and Methods

Study population

A total of 130 pediatric cases with congenital heart disease underwent sternal closure using a knotless absorbable wound closure device at the University Hospital of Bern, Switzerland, from January 2016 to February 2018. The observational retrospective study was approved by the cantonal ethics committee (Approval number 2020-00178).

All patients received antibiotic prophylaxis according to the institutional standards that include a second-generation cephalosporin. The pre-operative administration was given 30 min before skin incision and continued for 24 hours. All patients received wound control by a trained cardiac surgeon to detect the occurrence of SSI. The wounds were assessed for signs of infection such as pain, tenderness, localized swelling, inflammation, or drainage from the incision and sternum stability.

Apart from routine in-hospital wound inspections starting the day after surgery, there were three set follow-ups: The first follow-up was one day before hospital discharge, the second follow-up was 30 days post discharge and the third follow-up was 30 days after the last control. On the day of discharge, the supervising surgeon examined each patient for sternum stability and signs of infection.

Suture material

The STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device is an absorbable triclosan-coated barbed suture which provides wound-holding strength similar to interrupted suturing (Figures 1 and 2, Supplemental Video). Two different kinds of needles and three different types of suture sizes were utilized depending on the body weight of the patients. In children < 5kg a STRATAFIX™ PDS CT-2 (Size: 2-0) was chosen. In patients between >5kg and <10kg body weight the STRATAFIX™ PDS CT-2 (Size: 0) and in patients >10kg and <30kg body weight the STRATAFIX™ PDS OS-6 (Size: 1) was used.

Study Cohort

A consecutive cohort of 130 pediatric cases (aged <18 years) underwent surgery for congenital heart disease between January 1, 2016, and February 28, 2018. Perioperative data were retrieved from our prospectively managed institutional database (Dendrite Clinical Systems Ltd, Henley-on-Thames, UK). Clinical variables included age at operation, bodyweight, height, cardiac diagnosis, duration of open thorax treatment, intraoperative data collection included type of surgery, aortic cross-clamp time and duration of cardiopulmonary bypass.

Surgical Technique

The decision for primary sternal closure or DSC was left at the discretion of the attending cardiac surgeon. The soft tissues and skin were closed using absorbable sutures in a running fashion. There were no changes to the standard techniques for DSC or sternal closure during the study period.

Primary Outcome Definition

Cases of SSI were defined and classified as superficial incisional, deep incisional, or organ/space using published criteria from Centers for Disease Control and Prevention (CDC)[11]. According to these definitions mediastinitis and endocarditis were categorized as organ/space SSI. Consistent with the criteria, the follow-up period during which a SSI could occur was up to 60 days after surgery.

Statistical methods

All consecutively operated patients were included in the analysis. Missing data were not included in the final statistics (accounting for less than 6% of the patients lost for the long-term FU). Values of continuous data are presented as mean ± standard deviation (SD) and those of categorical variables are displayed as frequency distributions (n) and simple percentages (%).

Results

Preoperative Data

This study cohort included 130 pediatric cases of open cardiac surgery and sternal closure using a PDS based knotless tissue control device. The patients' age ranges from the first postnatal day to 142 months with a mean of 19.0 months (SD ±31.9 months) and the bodyweight ranges from 2.4 kg to 35 kg with a mean of 7.8 kg (SD ±6.6 kg). The patients' height was at a mean of 69.3 cm (SD ±24.8 cm). The baseline patient characteristics are shown in Table 1.

The major cardiac pathologies included tetralogy of Fallot (n=25, 25.3%), transposition of the great arteries (n=17, 17.2%), malformation of the aorta (n=9, 9.1%) including hypoplastic aortic arch, interrupted aortic arch and coarctation of the aorta, double outlet right ventricle (n=8, 8.1%), hypoplastic left heart syndrome (HLHS) (n=7, 7.1%), complete atrio-ventricular canal defect (n=7, 7.1%), pulmonary atresia (n=6, 6.1%), ventricular septal defect (n=4, 4.0%), total or partial anomalous pulmonary venous connection (n=4, 4.0%), pulmonary valve stenosis (n=3, 3.0%), aortic valve stenosis (n=3, 3.0%), double inlet left ventricle (n=2, 2.0%), Shone complex (n=2, 2.0%) and truncus arteriosus communis (n=2, 2.0%). Main preoperative diagnoses are shown in Table 2.

Sternal Closure

At the end of the operation, primary closure of the sternum (PSC) was performed in 107 (82%) cases while 23 (18%) cases received delayed sternal closure (DSC). Mean duration of open chest treatment was 2.9 days (SD ±2.6 days) with a range of 1 - 10 days.

There were 45 cases of re-operation due to initial staging operations. In all re-operative cases, PSC was completed in the OR and DSC was not required. The shortest duration of time between primary operation and reoperation was one month. In this patient, we observed a complete resorption of the sternal suture material and an intact sternum (Figure 3).

Follow-up

The first follow-up was performed at discharge and only one (0.8%) early superficial incisional SSI was observed. This patient underwent DSC two days after a switch-operation and needed a pre-sternal surgical debridement 21 days after DSC.

Mean time of follow up is 62.3 days (SD ±16.7 days). All patients concluded the 30 days follow-up period with clinical examinations at our institution. For the 60 days follow-up period only six patients were not clinically examined at our institution. The responsible health care providers of these patients were contacted to provide the necessary information regarding SSI or sternal instability. There were no cases of late SSI or sternal dehiscence in any patient. Furthermore, there were no case of early or late sternum instability (Table 3).

Comment

Although SSI is a well analyzed outcome issue in adults, little is known in children [9,10]. To our knowledge, there are no guidelines for prevention of surgical site infections in children.

Woodward analyzed pre-, peri- and postoperative strategies to prevent SSI out of 38 different pediatric cardiothoracic programs in the United States. Each clinical program had a different approach regarding skin preparation, antibiotic prophylaxis, postoperative wound care, use of steroids, staphylococcus aureus screening and dressings [4]. The overall incidence of SSIs did not change when some of these factors were altered. Sohn et al. focused on identifying potential SSI risk factors including the analysis of RACHS-1 category and ASA. They concluded that current measures of risk adjustment may be insufficient to predict the risk of SSI[6]. A recent published study of our institution in collaboration with the department of infectiology has analyzed invasive bacterial and fungal infections after pediatric cardiac surgery between January 2012 and December 2015. In this study cohort six (17%) surgical site infections were detected [11].

Considering the results of the published series, it seems that the majority of risk factors cannot

be modified or when they will be modified, this has no significant influence on the incidence of infection [1]. Therefore, in our population we did not try to alter pre-, peri- or postoperative factors, but changed the technique of closure itself. Traditionally, sternal closure is performed with a non-absorbable suture (e.g. vicryl) or stainless steel wires. However, these materials may cause discomfort or a long-lasting inflammatory process leading to wound seroma or granulomas particularly at the site of suture knots.

The idea to use an absorbable suture material in a running fashion for sternal closure has been reported before. Schwab presented a follow-up study on the influence of a synthetic PDS loop suture material on sternal stability, wound healing and compatibility in children. They concluded that the use of this material allows an optimal wound healing and is suitable for children weighing up to 30kg. However, the rate of infection was reported between 1.8% and 8.8% and some patients showed hematoma formation in the area of the sternotomy [12].

Keceligil et al. described the use of an absorbable PDS based loop suture material for sternal closure in congenital cardiac surgery. The rate of SSI was 1.5% with wound infection, sternal dehiscence and mediastinitis [8].

In pre-clinical studies, STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device, provided good tissue-edge approximation under tension [13] and demonstrated good efficacy against gram-positive and gram-negative bacteria [14]. Due to its self-locking, multi-anchor design, knotting is not necessary. To reduce SSI and avoid knotting of sutures, which can induce wound seroma and wound granuloma, we decided to use this knotless suture control device with antibacterial technology for sternal closure.

The current study was performed at a single institution. In the present study, the population represents a heterogeneous group of children undergoing surgical correction of a broad spectrum of congenital heart disease. Therefore, the clinical diagnosis differs and the patients' characteristics varied within a great range. This offers a broad review on suitable patients' characteristics. In contrast to other institutions, the spectrum of malformations of the study

group differs due to the correction of frequent malformations, such as ASD, PAPVC and VSD through a minimal invasive right axillary thoracotomy at our institution [15].

We were able to demonstrate that the use of a synthetic resorbable material allows a sufficient wound healing with good stability of the sternum and very good tissue compatibility. The use of STRATAFIX^{TM} PDS knotless suture device is a suitable and reliable method for sternal closure and an interesting alternative to standard sternotomy closure after pediatric cardiac surgery.

Limitation

It was a retrospective analysis of prospective collected data. Information about surgical site infections or instability were limited due to the examination of the surgeon and clinical symptoms of the patients.

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Table 1. Demographics

Number of cases (n)	130
Age (mean ± SD)	19.0 ± 31.9 months
Body weight (mean ± SD)	7.8 ± 6.6 kg
Body height (mean ± SD)	69.3 ± 24.8 cm
Gender	
Female (n, %)	58 (44.6%)
Male (n, %)	72 (55.4%)

Table 2. Pre-operative Diagnosis

Main diagnosis (n, %)	
Tetralogy of Fallot	25 (25.3%)
Transposition of great arteries	17 (17.2%)
Malformation of the aorta*	9 (9.1%)
Double outlet right ventricle	8 (8.1%)
HLHS	7 (7.1%)
Complete atrio-ventricular canal defect	7 (7.1%)
Pulmonary atresia	6 (6.1%)
Ventricular septal defect	4 (4.0%)
TAPVC / PAPVC	4 (4.0%)
Pulmonary valve stenosis	3 (3.0%)
Aortic valve stenosis	3 (3.0%)
Double inlet left ventricle	2 (2.0%)
Shone Complex	2 (2.0%)
Truncus arteriosus communis	2 (2.0%)
Additional Diagnosis (n)	
Ventricular septal defect	22
Atrial septal defect	20
Pulmonary valve stenosis	7
Pulmonary atresia / hypoplasia	4
Malformation of the aorta	3
Others	7
Diagnosis for reoperation ** (n)	
Pulmonary stenosis	7
Endocarditis	3
Conduit stenosis	3
Others	8

* aortic atresia, coarctation of the aorta, hypoplastic aortic arch, interrupted aortic arch, aneurysm of the aorta

** if not due to initial staging operation

Table 3. Results

Perioperative Data	
Cardiopulmonary bypass (n, %)	114, 87.7%
Cardiopulmonary bypass time (mean ±SD)	102.5 ± 49.5 min
Aortic cross-clamp time (mean ±SD)	55.1 ± 22.7 min
Duration of open thorax treatment (mean ±SD)	2.9 ± 2.6 days
Delayed sternal closure (n, %)	23 (18%)
Surgical site infections	
Follow-up (mean ±SD)	62.3±16.7 days
SSI (n, %)	1 (0.8%)
DSWI (n, %)	0 (0%)
Sternal Dehiscence (n, %)	0 (0%)
Seroma / Granuloma	0 (0%)

Figure Legends

Figure 1. A: Sternal closure using the STRATAFIX^{TM} PDS (2-0 / CT2) with an anchor design and pattern. B/C: Sternal closure in running fashion suture technique. D: Fastening and adaption of the sternal edges for tight closure.

Figure 2. Sternal closure using the STRATAFIX^{TM} PDS (2-0 / CT2) in running fashion after fastening of sutures

Figure 3. Re-sternotomy for staging operation: Inspection of sternal closure site one month after initial surgery with complete sternal healing.