



## High rates of metal allergy amongst Nuss procedure patients dictate broader pre-operative testing

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### ABSTRACT

**Purpose:** A previous study from our group estimated that as few as 2.2% of pectus excavatum patients suffered from allergy to the implanted metal bar. We sought to assess recent changes in incidence of metal allergy and identify the benefit of metal allergy testing prior to surgery.

**Methods:** A retrospective review was performed of all consenting patients undergoing pectus repair during the six years between 9/2004 and 12/2010 at our institution. Incidence was based on clinical symptoms and/or T.R.U.E.® patch testing. Demographic data, history of atopy and history of metal allergy were collected. Type and number of bars used, suture site infection, skin rash and wound infection rates were reviewed.

**Results:** Forty one of 639 patients (6.4%) had clinical or patch test evidence of metal allergy. Family history of metal allergy and pre-operative history of metal sensitivity were found to be statistically significant correlates.

**Conclusions:** The rate of metal allergy in the pectus excavatum population may be higher than previously reported. Patient or family history of metal allergy or metal sensitization may indicate increased risk. Metal allergy testing should be performed before Nuss procedure.

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The use of metal implantable devices is common. Metal implants may provide a scaffold, as in the use of plates and screws to stabilize broken bones, or they may replace non-functioning body parts, as in joint replacement. In some cases, metal implants allow minimal disruption of native tissues with results as good as, or better than, operations with significant tissue impact. Pectus excavatum is one such deformity that has benefited from the use of a metal prosthesis to allow for minimally invasive repair.

The Nuss procedure has become the predominant reason for the use of metal implants by pediatric general and thoracic surgeons [1]. The procedure involves substernal placement of one or more metal bars custom-fitted to a patient's chest. The bars are secured and left in place for a minimum of two years, after which they are removed.

Stainless steel bars have been used for correction of pectus excavatum since the development of the Nuss procedure in the late 1980's. However, because of the increased incidence of non-infectious wound complications in patients with implanted stainless steel bars over a 15 year period, we undertook analysis of our database to search for an explanation. Our 2007 report of an eighteen year experience

with the Nuss procedure concluded that the rate of nickel allergy in this population was 2.2% [2]. Because the reported incidence of metal allergy in the general population is even higher, at 10% to 15%, we subsequently initiated a screening process for metal allergy [3,4]. Here we report the result of our experience since that time.

The purpose of this study is to determine whether the incidence of metal allergy has increased in our population, whether there are clinical symptoms that suggest metal allergy, and whether it would be beneficial for all patients receiving metal implants to undergo routine allergy testing.

### 1. Methods

A retrospective review was undertaken for all consenting patients undergoing the Nuss procedure at Children's Hospital of The King's Daughters in Norfolk, Va. during the 6 3/12 years between September 1, 2004 and December 31, 2010. In all patients a detailed personal or family history of allergic reactions to metals or jewelry, environmental allergies, eczema and asthma was taken to screen for metal allergy. Only those patients who had a positive screen underwent patch testing with the Thin-layer Rapid Use Epicutaneous patch (T.R.U.E.®) test. The T.R.U.E.® patch test identifies sensitivity to nickel and chromium, but not the other elements of stainless steel. During this period, the T.R.U.E.® patch was variously applied by the nurses in the

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surgical clinic, by the patient's primary care doctor, or in some cases by a dermatologist or allergist. The overwhelming majority of the interpretations regarding positivity were done by other than dermatology or allergy specialists. Final readings were done at 72 h to be classified as either positive or negative. Patch testing was carried out according to the product information insert of the T.R.U.E.<sup>®</sup> Patch TEST. Positive reactions were interpreted as outlined in the PI, and are consistent with the standardized guidelines of the ICDS:

Weak positive (+) erythema, infiltration, discrete palpable papules

Strong positive (++) erythema, papules, discrete vesicles

Extreme positive (+++) coalescing vesicles, bullous reaction

Data were not recorded regarding the degree of positivity or the time course of reaction to the metal. The test was regarded as binary, either positive or negative. If T.R.U.E.<sup>®</sup> patch testing was positive, titanium bars were placed at operation. In some patients, titanium bars were placed for clinical concern, including for history of environmental allergies, eczema, or asthma, but without patch testing.

Data collected included: age, gender, personal or family history of metal allergy, history of environmental allergies, previous Ravitch or Nuss operations, history of asthma or albuterol use, eczema, food or drug allergy, and preoperative history of metal sensitivity. Operative information included age at time of surgery, number of bars placed, type of bar used, suture site infection, skin rash, wound infection, and T.R.U.E.<sup>®</sup> test patch results if available.

Patients who developed rash, edema, pain, tenderness, or serous drainage with negative cultures for microorganisms were judged to have allergy to the bar after operation even if patch testing was negative postoperatively. Every effort was made to exclude the presence of infection before judging that a patient was allergic to metal. Treatment was continued until resolution of symptoms and normalization of inflammatory markers, or until bar removal at 24–36 months post Nuss procedure.

Statistical analysis was performed using commercially available statistics software with the alpha value set at 0.05 for significance. Fisher's exact test was used to analyze categorical data while the Student's T-test was used for numerical data.

## 2. Results

Between September 2004 and December 2010, 639 patients underwent the Nuss procedure at our facility. Of these patients, 41 (6.4%) were found by patch testing or clinical symptoms to have metal allergy (Table 1). All 26 patients with positive preoperative T.R.U.E.<sup>®</sup> test underwent placement of a titanium bar. One of these was patch tested to silver in addition, and was allergic to silver. Though silver is not a significant component of the 318 stainless steel, a titanium bar was placed as a precaution. Another 11 patients underwent placement of titanium bars for concern about risk of allergy because of their history alone. These patients did not undergo patch testing,

**Table 1**  
Metal allergic patients.

Metal allergic patients (41)	Incidence of bar allergy was based on symptoms consistent with metal allergy post-operatively, and/or T.R.U.E. (Thin layer Rapid Use Epicutaneous) patch testing positivity pre- or post-operatively
Received stainless steel bars (15)	post-op positive patch test (10) post-op allergic incident diagnosed with pre-op patch test negative (1) unknown post-op patch test results with clinical diagnosis (4)
Received titanium bars (26)	pre-op patch test positive (26)

**Table 2**  
Demographics.

	Metal allergic (41)	Non-metal allergic (587)	P Value
Age (5–31 years)	16.1 ± 4.36	16.3 ± 4.36	0.78
Sex:			
Male (521)	27 (65.9%)	494 (84.2%)	0.0027 *
Female (107)	14 (34.1%)	93 (15.8%)	0.0027 *
Family hx of metal allergy (20)	4 (9.8%)	16 (2.7%)	0.0123 *
Hx of Pre-op metal sensitivity (24)	13 (31.7%)	11 (1.9%)	<0.0001 *
Environmental allergies (265)	12 (29.3%)	253 (43.1%)	0.0842 NS
Eczema (12)	2 (4.9%)	10 (1.7%)	0.1482 NS
Previous repair (39)	4 (9.8%)	35 (5.9%)	0.3155 NS
Asthma or history of albuterol use (175)	7 (17.1%)	168 (28.6%)	0.1127 NS
Drugs (122)	12 (29.2%)	110 (18.7%)	0.1006 NS
Food (43)	2 (4.9%)	41 (7.0%)	0.6073 NS

\* P value = <0.05 significance level.

and are not included in patients labeled "allergic". However, a total of 52 or 8.1% of our patients had alteration in their care because of concern for metal allergy.

Fifteen patients who had negative preoperative history screening were found to be metal allergic post operation. Of these, 10 were positive by T.R.U.E.<sup>®</sup> patch, and 5 by clinical criteria. There was a single patient who had a negative preoperative T.R.U.E.<sup>®</sup> test which became positive to nickel post operation. No patient in the allergic group was found to have wound infection. Wound infection was noted in 1.3% of the other patients. A rash was noted in 6 of the 15 patients after operation in the allergic group. Although they gave no history to suggest metal allergy preoperatively, all were positive by T.R.U.E.<sup>®</sup> patch performed after operation due to allergic symptoms. Rash was noted in 27 (5%) of patients that were not metal allergic. Family history of metal allergy and preoperative history of metal sensitivity were found to correlate with subsequent metal allergy. However, a history of previous repair of pectus excavatum, environmental allergies, asthma or albuterol use, food allergy, eczema and drug allergy was not predictive. Girls were more likely to be allergic than boys (13% vs. 5%) (Table 2).

Eighty-five (85) patients had pre-operative or post-operative T.R.U.E.<sup>®</sup> patch testing. There were a total of 36 positive tests (26 preop positive and 10 postop). Of these patients, 32 tested positive for nickel, 1 to both nickel and chromium and 1 to both nickel and copper. Two patients tested positive to cobalt, and no one tested positive to gold – 2 metals also tested in the T.R.U.E.<sup>®</sup> patch testing. All patients were successfully treated until either resolution of symptoms or scheduled bar removal. Treatment for metal allergy included administration of anti-inflammatory medications, usually including steroids. Usually a short course of oral steroids was sufficient, but some patients required long-term administration. Most patients were also administered antibiotics when the redness, swelling, pain and tenderness occurred. No patient needed to have a stainless steel bar removed and replaced with titanium in this group of patients, though that was necessary in two patients in our 2007 report.

## 3. Discussion

Our previous study indicated a metal allergy rate of 2.2% in patients undergoing minimally invasive pectus excavatum repair [1]. We had originally only performed allergy testing in those patients who demonstrated a personal or family history of metal allergy, eczema, or atopic history. Since that time, our practice has seen an increase in titanium bar usage as well as postoperative diagnoses of metal allergy which prompted re-evaluation of our patient population for metal allergy.

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