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Case series of metal allergy following Nuss procedure not only for stainless steel bars

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ABSTRACT

Background: Pectus excavatum is often managed with the Nuss procedure. Metal allergies to pectus bars occur in 5% of patients, though pre-operative testing is not generally routine.

Objectives: This study describes our experience with pre-operative metal allergy testing and post-operative allergic reactions to pectus bars.

Methods: A retrospective study of patients who underwent a Nuss procedure at our institution from 2010–2020 was performed. Patients with documented “metal” allergy, defined by the need for and positive response to steroid treatment and the absence of infection, were included. Data on patient characteristics and clinical course were analyzed.

Results: Five of 204 patients (2.5%) identified developed allergic metal reactions. Three of five patients developed allergic reactions to titanium bars, with two requiring early removal of the bar (< 2–3 years). Four patients required more than one course of steroids, and three required debridements for skin breakdown. All patients have maintained good surgical correction at one- and three-years post removal.

Conclusions: Pectus bar metal allergies occur with both stainless steel and titanium bars. Properly selected patients for pre-operative Finn[®] Chamber testing may reduce the overall incidence of stainless-steel allergies but may miss titanium bar allergies. Early recognition and treatment of bar allergies may salvage the bar and avoid premature removal.

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Introduction

The Nuss procedure involves implanting either stainless steel or titanium composite bar(s) into the chest cavity, beneath the sternum, to correct pectus excavatum chest wall deformity. Allergic reactions to metals are relatively common, estimated to occur with an incidence of 10–15% in the general population [1,2]. The incidence of metal allergy to pectus bar implants, however, is estimated to occur in about 5% of patients and is typically thought to be owing to the nickel contained in the standard stainless steel bar [3]. While reports on allergic reactions to titanium pectus bars are rare, there have been reports described with orthopedic and dental titanium implants [1,4,5].

There has been no consensus as to whether pre-operative metal allergy testing is required to avoid the potential complications of an allergic reaction to the implanted pectus bar. Nevertheless, multiple reports suggest that the incidence of metal allergy may be higher than previously expected. Thus, others have recommended pre-operative metal allergy testing [6,7]. Specific testing types differ at each institution, though most use a variant of contact hypersensitivity allergy dermal patch tests [6,7]. When metal allergy testing is positive, patients receive a titanium bar, in place of the standard stainless-steel bar. However, this requires custom order that may delay the procedure. Some surgeons, therefore, decline testing owing to a relatively low incidence of bar allergy and the additional expense of metal allergy testing and titanium bars [7]. The most recent article to date concerning pectus bar metal allergies by Obermeyer et al. has shown that selective patch metal allergy testing is reasonable, as compared to routine testing, since the incidence of bar allergy is low, but that it may be advisable in females and patients with personal or family history of metal sensitivity [8].

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1. Cobalt Chloride Hexahydrate
2. Titanium oxide
3. Manganese chloride
4. Zirconium oxide
5. Vanadium pentoxide
6. Chromium sulfate hydrate
7. Gold sodium thiosulfate
8. Niobium chloride
9. Nickel sulfate hexahydrate
10. Aluminum hydroxide 10%
11. Titanium 1%
12. Methyl methacrylate 2%
13. Tantalum 1%
14. Copper sulfate pentahydrate 2%
15. Molybdenum chloride 0.5%

Fig. 1. Metal patch testing components for Finn® Chambers.

Allergic reactions to metal pectus bars are defined by their clinical presentations, occurring typically more than one month following bar placement [6,7]. Patients often exhibit extensive skin erythema on the chest wall at the level of the bar and at the parasternal insertion sites [6–9]. Other presenting symptoms include a rash with associated granuloma formation and pleural effusion, as well as elevated serum inflammatory markers such as C- Reactive Protein (CRP) and erythrocyte sedimentation rate (ESR) [7,8]. Many cases are misdiagnosed as surgical site infections. However, management of infectious complications is quite different from an allergic reaction to the Nuss bar. The possibility of deep space or superficial infections of pectus bar implants should be eliminated [7,10]. If metal sensitivity is suspected based on clinical findings, initiation of empiric oral steroid therapy may both confirm the diagnosis and treat the allergic reaction. Given that severe allergic reactions may require premature removal of the bar, pediatric surgeons should be aware of the clinical manifestation of pectus bar allergies. In fact, prompt recognition and treatment of bar allergies may even salvage the bar [7,8].

Here we describe our institutional experience with pre-operative metal allergy testing and post-operative allergic reactions to pectus bars, both steel and titanium, in pediatric patients.

Methods

We performed an IRB approved, retrospective case-control study of all patients who underwent the Nuss procedure for pectus excavatum at our institution from 2010–2020. Patients experiencing a documented “metal” allergy, as defined by the need for and positive response to steroid treatment following bar placement and the absence of infection, were included in the study. Clinically, the recurrence of pain several weeks following the initial procedure; extensive skin erythema, rash, and/or breakdown at the bar insertion or incision sites; elevated serum inflammatory markers ESR and CRP; the absence of an infectious process; and improvement in symptoms with one or more course(s) of steroids were parameters determined to constitute a metal allergy.

Throughout the study period, two patients (#1 and 4) did not undergo pre-operative metal testing prior as it was prior to the establishment of our protocol of routine testing (Table 1).

Neither undergoing pre-operative metal allergy testing nor receiving negative or positive results impacted inclusion in the study. Moreover, those who were found to have surgical site infections post-operatively (as documented by positive wound or blood cultures) or those with no clinical concerns for post-operative metal allergies, were excluded.

Patients who underwent pre-operative testing were evaluated by the placement of Finn Chambers® on Scanpor tape, which tests for several metal types (Fig. 1).

Table 1
Summary of clinical data for each Nuss procedure patient who exhibited post-operative allergic reactions to the stainless-steel or titanium bar.

Patient #	Current age/years	Haller index	Correction Index (%)	Metal Allergy Y/N	Titanium bar Y/N	# Pectus Bars	Bar Removal Y/N	Total Months bar (s) in	Initial Titanium Bar Y/N	I & D Y/N (#)	Steroid Therapy Y/N (#)	Revision Surgery Y/N	Early Bar Removal Y/N	Pectus Correction Maintained Y/N
1*	21/15	4.1	46	NT	N	1	Y	11	N	Y (3)	Y (2)	Y	Y	Y
2	15/12	3.5	32	Y	N	1	Y	35	N	N	Y (1)	N	N	Y
3	19/18	5.5	43	Y	Y	1	Y	8	Y	Y (1)	Y (2)	N	Y	Y
4	21/17	3.8	34	NT	N	2	Y	34	N	Y (3)	Y (3)	N	N	Y
5	13/12	3.2	24	Y	Y	1	N	14	Y	N	Y (2)	N	N	Y

NT= not tested. * Patient #1 first steel bar was removed 4 months after Nuss and replaced with a titanium bar one month later, which was also removed early 7 months later.

Table 2

Clinical aspects of patients testing positive for metal allergy.

Patient #	Male/Female M/F	Positive Metal Allergy	Titanium bar Y/N	Bar allergic reaction Y/N	Family or personal history metal allergy	Bar removed early Y/N	Steroid therapy Y/N	Early bar removal Y/N (months post Nuss)	Titanium bar replacement
1*	M	Ni	Y	Y	Y	Y	Y	Y (7)	Y
2*	M	Ni, Co	N	Y	N	N	Y	N	N
3*	M	Ni, Co	Y	Y	N	Y	Y	Y (8)	NA
4	F	Ni	Y	N	Y	N	N	N	NA
5*	M	Ni	Y	Y	N	N	Y	N	N
6	M	Ni, Co	Y	N	N	N	N	N	N
7	F	Ni	Y	N	Y	N	N	N	N
8	M	Ni	Y	N	N	N	N	N	N
9	F	Ni, Co	Y	N	Y	N	N	N	N
10	F	Ni	Y	N	Y	N	N	N	N
11	M	Ni	Y	N	N	N	N	N	N
12	M	Ni	Y	N	N	N	N	N	N
13	M	Ni	Y	N	N	N	N	N	N
14	F	Cr	Y	N	Y	N	N	N	N
15	M	Co	Y	N	N	N	N	N	N
16	M	Co	Y	N	N	N	N	N	N
17	F	Co, Mn	Y	N	N	N	N	N	N
18	M	Ni	Y	N	Y	N	N	N	N

* Patient #'s correspond to same number patient in Table 1. Ni (Nickel); Co (Cobalt); Mn (Manganese); Cr (Chromium).NA not applicable.

The Finn Chambers® are small containers (usually circular 8–18 mm in diameter) held within a tape, into which tested substances are placed and are held in place on the patient's back with tape. The Finn Chambers® test has the advantage that specific metals may be added for testing, whereas the TRUE test has preloaded standard metals and other components, such as fragrances and dyes. A positive reaction to this test, as defined by a wheal 3 mm or greater than the negative control, led to placement of a titanium bar, except for patient #2 (Table 1) who underwent steel bar placement. For all patients, the Nuss procedure was performed using the standard, minimally invasive technique. Epidemiologic information was collected including the patient's age, sex, comorbidities, general allergy history, Haller index and pre-operative metal allergy results. Clinical course data were also collected, including bar type inserted, number of pectus bars placed, length of time the bar(s) was implanted, removal or re-intervention procedures, prescribed steroid course(s), resolution of symptoms, and maintenance of pectus correction. Re-intervention procedures included incision and drainage, early bar removal, and revision surgery for replacement of a new bar. Analysis of results included descriptive statistics.

Results

From January 2010 to May 2020, 204 patients underwent the Nuss procedure for pectus excavatum at our institution, including 185 males (90.7%) and 19 females (9.3%). Of those, 140 cases were performed during the most recent five-year period. There were 60 patients (29.4%) who underwent pre-operative metal allergy testing (52 males; 8 females), of which 18 patients were identified with metal allergy (30%), including 12 males and 6 females. Findings of the patients with positive metal allergy tests are shown in Table 2. Six of eight females (75%) tested positive versus only 12 of 52 (23%) males. The positive reactions included: ten Nickel; four Nickel and Cobalt; two Cobalt; one Cobalt and Manganese; and one Chromium. Of the six females who tested positive, five (83%) had a personal or family history of metal allergy. During the study period, there were 18 titanium bars placed (8.8%) for positive pre-operative metal allergy testing in 12 males and 6 females, although routine testing was not performed until 2015. A total of five patients (2.5%) exhibited allergic reactions to the implanted pectus bars, thus requiring steroid therapy with or without the need to explant the bar(s) prior to the minimum two-year period post repair. Three of these patients (60%) developed allergic reactions to

a titanium bar, although they tested negative to titanium components in pre-operative testing.

Of all five patients, there were two patients (40%) who required early bar removal (less than two years from implantation) despite steroid therapy, both of which were titanium bars. Currently, four of five patients have had their bar(s) removed, including the two early removals at eight and eleven months' post-Nuss, while 2 other patients completed the treatment course with the implanted bar and had the bar removed at 34 months and 35 months following Nuss repair. Despite the early bar removal, both patients have maintained surgical correction at one- and three-years post-operatively. All patients received at least one course of steroids, specifically oral prednisone 20 mg for 14 days, and tolerated it well. Four (80%) patients required one additional course of steroids.

Additionally, three of the five patients required operative debridement for severe skin breakdown from the allergic reaction. The reactive skin was excised and either primarily closed or closed by secondary intention with negative pressure wound therapy. Antibiotics were not given to any of these patients for more than perioperative dosing. A summary of each patient's clinical course follows in the text and Table 1.

Clinical course

Patient #1

Patient #1 is a 15-year-old male with past medical history significant for osteosarcoma requiring distal femur resection with prosthetic knee replacement, and no longer on active therapy who presented with a pre-operative 4.1 Haller index pectus excavatum deformity. Of note, his knee prosthetic was a titanium-based device. He denied any history of allergies or atopy. He did not undergo pre-operative metal allergy testing and thus, had a stainless-steel bar placed for his Nuss procedure. Post-operatively, he did well initially, though presented at two months with symptoms of chest pain and bilateral thoracic, anterior axillary line incisional serous drainage. He underwent debridements for severe skin reactions of both thoracic incisions. Wound cultures taken at each intervention were negative for bacterial growth. His inflammatory markers were elevated with a CRP of 4.24 mg/dL (normal 0.04–0.79 mg/dL) and an ESR of 39 mm/h (normal 0–20 mm/h). Following the initial reaction, he was prescribed two courses of steroids over two months. Nevertheless, his allergic symptoms persisted and he required early removal of the steel bar four months after insertion owing to persistent pain. Prior to titanium bar inser-

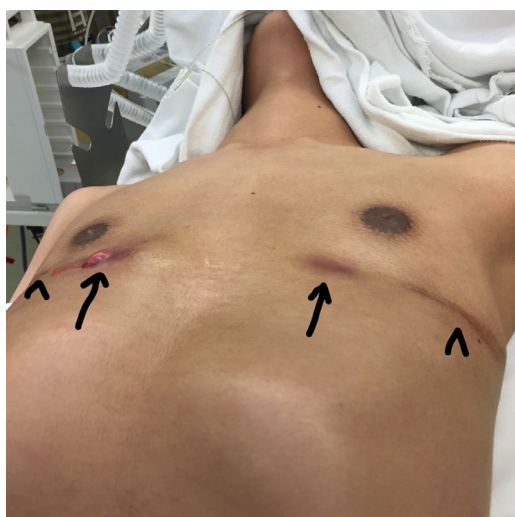


Fig. 2. a: Patient #1 at the time of titanium bar explantation. Arrowheads denote the axillary incision sites, while complete arrows signify parasternal bar insertion areas. **b:** Patient #1 again at the time of titanium bar explantation. Arrow points to the reactive site where the bar entered the chest behind the sternum.



Fig. 2. Continued

tion, he underwent metal allergy testing and was positive only for Nickel (Tables 1, 2).

One month following removal of the stainless-steel bar, he had a titanium bar placed. Five weeks later, he developed an allergic reaction to the titanium bar with ESR elevated at 40 mm/h and he required additional steroid courses, which ultimately relieved his symptoms. He did not undergo operative debridement at this time and cultures taken from serous wound drainage were negative. After 11 total months of treatment between the two bars, the patient elected to undergo bar removal to avoid recurrent chest wall pain and eliminate the need for further steroid therapy (Fig. 2). Additionally, further time with the pectus bar and likely need for additional steroid courses would have delayed his planned limb lengthening procedures for his prosthetic knee. Three years post-bar removal, he has had no recurrence of his pectus excavatum.

Patient #2

Patient #2 is a 12-year-old female transitioning to male on testosterone therapy who presented with a pre-operative 3.5 Haller index pectus excavatum deformity. He denied any history of allergies or atopy. His pre-operative metal allergy testing was pos-

itive for Nickel and Cobalt (Tables 1, 2), though he did not undergo titanium bar placement as the case was scheduled before a custom titanium bar could be ordered. After discussion with the parents on the 5% risk of an allergic reaction, the mutual decision to proceed with stainless-steel bar placement and not delay the procedure was made. Post-operatively, he did well initially, although presented at six weeks with symptoms of chest pain and erythema at bilateral thoracic incisions, though no drainage. He was given one course of steroids, but did not require skin debridement and wound cultures were not performed. Serum inflammatory markers were not drawn as he was seen at an outpatient center without laboratory availability; instead, he was treated empirically with steroids owing to his known positive metal allergy testing pre-operatively. He responded appropriately to oral steroids and did not require additional steroid therapy. His bar was in place for 35 months at the time of removal. Three years post bar-removal, he has had no recurrence of his pectus excavatum.

Patient #3

Patient #3 is an 18-year-old male with past medical history notable for gynecomastia requiring bilateral breast reduction (subcutaneous mastectomy) several years prior who presented with a pre-operative 5.5 Haller index pectus excavatum deformity. He denied any history of allergies or atopy. His pre-operative metal allergy testing was positive for Nickel and Cobalt, so he underwent titanium bar placement at the time of his Nuss procedure (Tables 1, 2). Post-operatively, he did well initially, though presented at three months with symptoms of chest pain, erythema, and serous drainage from his axillary incisions. Both his CRP and ESR were elevated at 6.39 mg/dL and 30 mm/h. He completed two courses of steroids, two months apart, and required one debridement for significant skin breakdown. Wound cultures done at the time of operative debridement were negative. Despite the successful treatment of his allergic symptoms (recurrent pain, wound drainage, and erythema) with steroids, the patient elected to have the bar removed at eight months owing to ongoing chest discomfort. Additionally, he did not want to take steroids long term. After two years post bar removal, he has had no recurrence of his pectus excavatum.

Patient #4

Patient #4 is a 17-year-old male with no significant past medical history who presented with a pre-operative 3.8 Haller index pectus excavatum deformity. He denied any history of allergies or atopy. He did not undergo pre-operative metal allergy testing and had two stainless steel bars placed for his Nuss procedure (Tables 1, 2). Post-operatively, he did well initially, though presented at 3 months with symptoms of chest pain and bilateral thoracic incisional serous drainage. He underwent wound exploration at three-, five- and seven-months post insertion. Intraoperative wound cultures were negative for bacterial growth. His inflammatory markers were elevated with a CRP of 2.83 mg/dL and ESR of 40 mm/h. He completed two courses of steroids (at five- and seven-months post insertion). Following his second course of steroids, he had no further pain or wound issues. He completed his course of pectus repair and had the bars removed at 34 months. Seven months after removal, he has had no recurrence of his pectus excavatum.

Patient #5

Patient #5 is a 12-year-old male with no significant past medical history who presented with a pre-operative 3.2 Haller index pectus excavatum deformity. He denied any history of allergies or atopy. His pre-operative metal testing was positive for Nickel, so he underwent titanium bar placement at the time of his Nuss procedure (Tables 1, 2). Post-operatively, he did well initially, but presented at one month with chest pain, incisional erythema, and serous drainage (culture negative) from the bilateral thoracic incisions. His inflammatory markers were elevated with a CRP of

Table 3

Composition of Stainless Steel and Titanium Pectus Bars from Biomet Microfixation, Jacksonville, FL, USA.

Stainless Steel	Titanium Alloy
Chromium: 17–19%	Aluminum: 5.5–6.5%
Nickel: 13–15%	Vanadium: 3.5–4.5%
Molybdenum: 2.2–3%	Iron: < 0.25%
Manganese: <2%	Oxygen: < 0.13%
Silicone: < 0.75%	Carbon: < 0.08%
Trace amounts of Carbon, Phosphorus, Sulphur, Copper, Nitrogen: < 0.05%	Nitrogen: < 0.5%
Hydrogen: < 0.012%	Titanium: Balance

1.71 mg/dL and ESR of 52 mm/h. He completed two courses of steroids, one month apart, though has not required any further steroids since. Additionally, he did not require skin debridement or antibiotics. His bar has been in place for 12 months and is planned for at least two more years.

Discussion

While titanium bars are frequently used in place of the standard stainless-steel bars in patients who pre-operatively test positive for metal allergies, our institutional experience demonstrated allergic reactions to three titanium bars. All three patients with titanium bars required at least one course of steroids, two required skin debridement, and two required premature removal of the bar for a 60% bar salvage rate following metal allergic reactions, which is similar to that reported at 60–69% by Obermeyer et al. [8]. The importance of eliminating the possibility of a superficial or deep space infection cannot be overemphasized. Obermeyer et al. reported a large series of patients in which bar salvage rate from infectious causes was 90% for superficial infections versus 75% for deep space infections [11]. Thus, it would seem salvage rates for metal allergy may be considerably lower. Fortunately, despite the consequences of these allergic reactions, all five patients, with either stainless-steel or titanium bars, have maintained the surgical correction for their chest wall deformities.

Patients undergoing the Nuss procedure may have significant reactions to both stainless steel and titanium bars, although the components of each bar are different. The composition of stainless steel versus titanium bars is compared in Table 3.

The primary components of the stainless-steel bar, which are presumed to cause the allergic reaction, are Nickel and Chromium [7]. Nickel, in particular, is the most frequent allergen found with diagnostic patch testing [8]. Interestingly, Fortmann and colleagues have even demonstrated the significant systemic release of the trace metal ions, Nickel and Chromium, into the blood and urine of patients with pectus bar implants at the time of bar explantation [12]. Whether this systemic metal contamination is associated with an increased risk of allergic reaction is unknown [12].

There are even less data on allergic reactions to titanium bars, which have been used primarily for patients who test positive to metal allergies pre-operatively [6–8]. In fact, the majority of reports of these rare allergic reactions to titanium have primarily been with orthopedic and dental implants [1,5]. Nevertheless, there have been a few reports of allergies to pectus titanium bars. In fact, in one case report, two patients who pre-operatively tested negative for titanium allergies actually developed titanium bar reactions post placement [4]. We have had one patient test positive for aluminum (a major component of the titanium bar), but he tested negative to any of the components of the stainless-steel bar.

Given the incidence and significant reactions to metal allergies, since 2015, it has become our practice to attempt testing all patients pre-operatively before implanting pectus bars. Currently, while all are recommended to have pre-operative metal testing, approximately 90% of our patients complete the testing prior to

their Nuss procedure. While testing for Nickel allergy may significantly reduce the incidence of an allergic reaction to the stainless-steel bar, it does not preclude an allergic reaction to a titanium bar. Even with testing, there may still be some unexpected or unrecognized allergic reactions. Some patients may test negative for a metal allergy, though subsequently develop an allergic reaction, thus emphasizing not all tests have equal positive predictive values [14–16]. Researchers also suggest some mild allergic reactions at the incision sites may be overlooked and instead attributed to wound healing; thus, the actual incidence of metal bar allergies may be even higher than the estimated 5% [3,6,9,17].

Specific metal allergy tests have been compared head to head for positive predictive value and have demonstrated that the TRUE Test and Finn Chamber Patch techniques exhibited a 67% concordance rate [13]. Others have shown a 21% incidence of metal allergy with Allergete and TruPatch routine testing and thus have suggested “selective” testing for females and those with personal or family history of metal allergy [8]. Of the 60 patients tested in this review, 18 (30%) tested positive; this is slightly higher than others have reported, though is a smaller sample size. Therefore, we cannot conclude whether the Finn® Chamber test is a more sensitive test or whether selection bias existed for those being tested, since not every patient underwent pre-operative testing.

Regardless of the type of metal, the pathophysiology of allergies to metal implants is thought to start with the immune system producing antigen specific T cell lymphocytes once the bar is inserted [7,16]. With continued exposure to the implant, the T cell lymphocytes induce a cell-mediated immune response to the metal antigen and produce the observed allergic reaction [7,16]. Thus, the contact dermatitis associated with pectus bar allergies is considered a type IV hypersensitivity reaction [16].

While titanium bars still appear to be associated with a lower risk of allergic reactions, stainless-steel bars remain the standard bar used for pectus repair [15,17]. Titanium bars are much more expensive than stainless steel bars and are still associated with some risk of an allergic reaction [4]. The average cost of a titanium bar is around \$4000 whereas a stainless-steel bar costs around \$1700 [18]. Additionally, the stabilizers required for the titanium bars are \$3000 each compared to \$1000 for those needed for the stainless steel bars [18]. Titanium bars are typically not kept in stock in hospitals and require customized orders to shape the titanium bar for each patient, thus resulting in a delay in the procedure and increased cost [7,9]. Unlike stainless steel, titanium bars need mirror-smooth finishing of the bar's surface to prevent tissue ingrowth, which further increases its production cost [7].

While this study is limited by small sample size and observational methodology, it still adds to the existing literature on allergies to titanium implants, especially pectus bars. Given the significant reactions associated with pectus bar allergies, the surgeon should have a high index of suspicion for allergic reaction if a rash develops on the chest wall, the patient has recurrent pain (delayed) once the post-operative pain has already resolved or there is ongoing incision site erythema without infectious signs [6,17,19]. Currently, the gold standard for diagnosing allergic contact dermatitis owing to metal implants involves these clinical findings and

dermal patch testing [15,17]. We chose Finn[®] Chamber test (FCT) based upon recommendations from our dermatology colleagues. The TRUE test has an increased false negative rate to fragrances, thiuram, neomycin, cobalt, lanolin, and is missing formaldehyde releasers [20]. From our data, we are unable to determine whether FCT is “more” sensitive than TRUE or other commercial patch testing (PT) as we only selectively tested approximately 30% of our patients over the review period (60/204). Interestingly, of the patients testing positive on FCT, 7/18 reacted to cobalt, which is not a significant component of either steel or titanium bars. Of the five “bar reaction” patients (Table 1), two had positive reactions to cobalt, one of whom received a steel bar (Patient #2) and the other a titanium bar (Patient #3). We did attempt to test patients with history of metal allergies and all females, since previous research suggests they have higher rates of metal allergy in general [8]. This is supported by our 3-fold higher positivity rate of metal PT in females. More studies would be required to determine the sensitivity and specificity of various metal allergy testing kits.

Conclusion

Pectus bar metal allergies may occur with both stainless steel and titanium bars. Properly selected patients for pre-operative Finn[®] Chamber testing may reduce the overall incidence of stainless-steel allergies but may miss titanium bar allergies. Early recognition and treatment of bar allergies may salvage the bar and avoid premature removal. Given the significant reaction associated with bar allergies, we will continue to selectively perform pre-operative metal allergy testing for all patients undergoing the Nuss procedure.

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