

Accepted Manuscript

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PII: S0883-5403(17)30595-8

DOI: [10.1016/j.arth.2017.07.012](https://doi.org/10.1016/j.arth.2017.07.012)

Reference: YARTH 55992

To appear in: *The Journal of Arthroplasty*

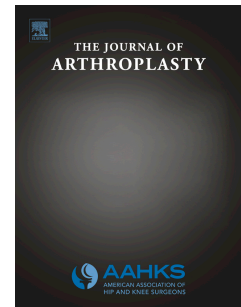
Received Date: 9 June 2017

Revised Date: 6 July 2017

Accepted Date: 11 July 2017

Please cite this article as: Chalmers BP, Melugin HP, Sculco PK, Schoch JJ, Sierra RJ, Pagnano MW, Stuart MJ, Taunton MJ, Characterizing the Diagnosis and Treatment of Allergic Contact Dermatitis to 2-octyl Cyanoacrylate Utilized for Skin Closure in Elective Orthopedic Surgery, *The Journal of Arthroplasty* (2017), doi: 10.1016/j.arth.2017.07.012.

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Characterizing the Diagnosis and Treatment of Allergic Contact Dermatitis to 2-octyl Cyanoacrylate Utilized for Skin Closure in Elective Orthopedic Surgery

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Short Title: Allergic Contact Dermatitis to 2-octyl Cyanoacrylate

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ABSTRACT

INTRODUCTION: While studies have shown that postoperative wound complications can predispose to deep infection following orthopedic surgery, the best form of skin closure has not been elucidated. Further, the unique risks and benefits of each type of wound closure have not been studied. The goal of this study is to present the diagnosis and treatment of patients with allergic contact dermatitis (ACD) from 2-octyl cyanoacrylate, a skin adhesive commonly utilized in wound closure.

METHODS: Twenty-nine patients with ACD to 2-octyl cyanoacrylate (Prineo®, Ethicon, NJ) following elective orthopedic surgeries from 2013- 2016 were retrospectively reviewed; this occurred in 29 of 6,088 units of Prineo® utilized at our institution, for an estimated incidence of 0.5%. Nineteen patients (66%) had knee operations. Mean age was 55 years (range, 15–92 years). We classified patients by symptom severity and treatment requirements into mild, moderate, and severe reactions.

RESULTS: Most reactions were moderate (48%) or severe (38%) reactions. Mean time from surgery to diagnosis was 11.8 days (range, 2–42 days). All patients underwent removal of the Prineo® dressing and daily dressing changes with a specific protocol. Twenty patients (69%) received oral antihistamines, sixteen patients (55%) required topical corticosteroids, and five patients (17%) required oral corticosteroids. All cases of ACD ultimately resolved at a mean of 22 days (range, 13–56 days) postoperatively.

CONCLUSION: 2-octyl cyanoacrylate skin adhesive occurs in an estimated 0.5% of cases and can lead to severe postoperative ACD when used following orthopedic operations. However, with early recognition and appropriate treatment, patients' symptoms resolve without a significant impact on wound healing.

Level of Evidence: Level IV, Retrospective Case Series

Keywords: contact dermatitis; total joint arthroplasty

INTRODUCTION

Surgical site infections (SSIs) are one of the feared complications after elective orthopedic surgery [1]. This is of particular concern in surgical cases that involve orthopedic implants, especially in total joint arthroplasty (TJA), as such implants are avascular foreign bodies that can become a nidus for micro-organism attachment and growth [2]. As such, much time, effort, and research has been dedicated to decreasing postoperative infection rates [1, 3]. Several studies have elucidated a relationship between postoperative wound complications, namely prolonged drainage, and an increased risk for infection [1, 3-5]. Therefore, wound closure technique has been a focus of investigation [6-9]. Alternative methods of wound closure that aim to prevent postoperative wound complications have been employed with varying success [9-13]. These include negative pressure dressings [10-13], antimicrobial dressings [11], occlusive dressings [14], and skin adhesives [9]. However, the best method for wound closure has yet to be determined and specific risks and benefits of each type of closure method is still unknown [1, 3].

Skin adhesive dressings have become an increasingly popular form of wound closure in an attempt to seal the wound, prevent postoperative wound drainage, and augment tissue holding strength [9, 15]. However, recent concern has been raised by the authors and in recent case reports about potential allergic contact dermatitis (ACD) to a specific product containing 2-octyl cyanoacrylate (Prineo®, Ethicon, Somerville, NJ) [15-17]. It has been noted that some patients develop a type IV delayed hypersensitivity reaction with an erythematous, eczematous to urticarial eruption near the incision [16]. In the authors'

experience, this reaction can range from mild to very severe. This is concerning as it not only may mimic a postoperative infection, causing difficulties with accurate diagnosis, but may be an entry point for bacterium secondary to breakdown of the patient's skin. Further, there is little objective data in the literature regarding the diagnosis, treatment, and outcome of such hypersensitivity reactions.

The goal of the current study was to characterize the diagnosis and treatment in patients that experienced an ACD to a specific skin adhesive (Prineo®, Ethicon) utilized during skin closure after elective orthopedic surgery. Further, we attempt to identify a classification system and treatment algorithm to guide other surgeons and standardize recognition and reporting of such complications.

METHODS

Through the use of an institutional surgical and clinical note database, all patients with a potential delayed reaction to Prineo® were identified from January 1st, 2013 to December 31st, 2016. Surgical records were reviewed to confirm that the skin adhesive was utilized during skin closure in each patient. Further, clinical records and all available photographs were reviewed to confirm the diagnosis of a postoperative skin adhesive ACD. Demographic information and treatment history was also collected. In order to estimate an incidence of rate of ACD to 2-octyl cyanoacrylate, we obtained the number of units of Prineo® utilized at our institution (6,008 units) during the study period by the orthopedic surgery department. The diagnosis of a skin adhesive ACD was made by the surgical team based on clinical symptomology, history, and appearance of the wound.

Clinical records, treatment approaches, and photographs were thoroughly reviewed and a spectrum of severity was identified and classified via a severity classification system utilized regularly for patch testing [18] (Table 1). Patients were excluded if it was determined that Prineo® tape was not used, and if the reaction was determined to be infectious (i.e. cellulitis) rather than allergic at final diagnostic evaluation. Finally, we excluded patients if the skin adhesive was not removed as part of management of the potential ACD, as resolution of the skin change with removal of the offending agent was used as a surrogate for diagnostic confirmation of ACD.

Patients

Twenty nine patients undergoing predominantly but not exclusively hip and knee arthroplasty were identified for retrospective review (Table 1). The mean age was 55 years (range, 15 – 92 years) and there were 21 females (72%). The mean BMI was 33 kg/m² (range, 18- 69 kg/m²).

Statistical Methods

Descriptive data is presented as mean values with ranges. Given the nature of this case series, there are no comparative statistics included.

RESULTS

Classification and Diagnosis

Of the twenty-nine patients identified with 2-octyl cyanoacrylate ACD, four (14%) patients had mild reactions (Figure 1), fourteen patients (48%) had moderate reactions

(Figure 2), and eleven patients (38%) had severe reactions (Figure 3, 4) based on the classification system. The mean time from surgery to diagnosis was 11.8 days (range, 2 – 42 days). Three patients were evaluated for prosthetic joint infection (PJI) with inflammatory markers (Erythrocyte Sedimentation Rate (ESR) and C-Reactive Protein (CRP)); one of those patients additionally underwent a total knee arthroplasty (TKA) joint arthrocentesis to evaluate for infection. None of the patients in this series underwent patch testing for an underlying 2-octyl cyanoacrylate reaction.

Treatment

All patients underwent careful removal of the Prineo® skin adhesive as part of their management of a suspected ACD. All patients underwent dressing changes daily until the symptoms resolved; more severe cases (seven patients, 24%) also received application of topical corticosteroids. Twenty patients (69%) received oral antihistamines and sixteen patients (55%) received topical steroids. Five patients (17%) required oral corticosteroids and seven patients (24%) were referred to Dermatology for assistance with management.

Of note, five patients (17%) received intravenous or oral antibiotics as part of the overall treatment of the ACD initially suspected to be potential cellulitis. With removal of the dressing and continued observation, these patients did not develop an infection and had improved symptoms, ultimately diagnosed with an ACD and not an infectious process. However, one patient developed a subcutaneous fluid collection at the incision site at six weeks postoperatively from a medial unicompartmental arthroplasty; the skin adhesive

tape had been removed at one month postoperatively for an ACD, at which time her incision was dry without a subcutaneous fluid collection. She ultimately underwent reoperation for irrigation, debridement, and primary closure. Preoperative aspiration, inflammatory markers, and intraoperative cultures were not consistent with PJI; it was felt that her underlying fluid collection was potentially related to her ACD. She subsequently healed without issue or incidence of infection and was not placed on antibiotics post-debridement.

Resolution

All cases of ACD resolved at a mean of 22 days (range, 13 – 56 days) after the index procedure. There were no other complications or reoperations.

Incidence and Risk Factors

The estimated incidence of ACD to Prineo® was 0.5% (29/6,008). Of the twenty-nine patients identified in this series, eight patients (28%) were determined to have definite previous contact with the specific skin adhesive material from prior surgeries; three (10%) of these patients indicated past, lesser reactions to the skin adhesive. Seven patients (24%) were suspected to have previous contact to the skin adhesive as they were healthcare workers and/or had previous surgery in which they believed a Prineo® type adhesive was utilized. Past contact was undetermined in fourteen patients (48%).

DISCUSSION

In an attempt to prevent postoperative wound complications and potential SSIs, alternative methods of wound closure have become more popular in elective orthopedic surgical procedures, particularly TJA [7-9]. While there is strong evidence linking postoperative wound complications and drainage to the development of a deep infection, there is little evidence indicating the ideal wound closure method [1, 3]. Further, there is little data on the unique advantages and complications associated with each type of wound closure. Recent case reports have raised concern regarding ACD to skin adhesive type dressings, particularly Prineo® [15-17]. The authors present their experience with diagnosing and managing suspected ACD from Prineo® wound closure in the largest series in the literature.

While there is no quick, definitive test for the diagnosis of an ACD secondary to a wound closure skin adhesive, the typical presentation includes a peri-incisional erythematous, eczematous to urticarial dermatitis that develops 5-14 days after surgery in which a skin adhesive was utilized. Peri-incisional pruritus is often associated. A systemic response, known as an id reaction or auto-eczematization, may occur, with a widespread macular to papular eruption and generalized pruritus. Classic signs and symptoms indicative of infection, such as increased surgical site pain, wound drainage, fevers, and chills should prompt a thorough investigation of a SSI rather than an ACD. Other small case series and case reports have recommended patch testing for definitive diagnosis [15, 17]. However, such patch testing is not widely available. Additionally, patch testing requires a minimum of five day to assess for development of a positive result, which limits utility

in the acute setting. Patch testing also typically cannot be completed in patients experiencing auto-eczematization. We recommend collaboration with a dermatologist if the diagnosis is unclear. Patch testing may be useful after treatment of the acute ACD to confirm the diagnosis and to counsel the patient on future product avoidance.

Given the nature of this review and variety of procedures included, we are only able to estimate the incidence of Prineo® ACD based on the number of reactions identified compared to the number of units utilized during the same time period at 0.5%. This is slightly lower than the series by Durando et al [17], which reported an incidence of nearly 2% in a series of 915 consecutive TKAs with the skin adhesive closure. The severity of the reaction ranges significantly, from a mild peri-incisional papular rash (Figure 1) to a severe bullous eruption with systemic symptoms (Figures 3, 4). Likewise, the treatment of a skin adhesive reaction should vary based on severity and patient symptomatology (Figure 5). In this series, all patients underwent removal of the skin adhesive dressing. While maintenance of the dressing could be considered in cases that are minimally symptomatic in a patient at high risk for potential wound drainage, removal of the offending agent is crucial in all allergic reactions. We recommend the following wound care strategy two times daily: one layer of 0.05% Clobetasol cream and two layers of Vanicream; a towel soaked (not dripping) in 8 ounces of water and 1 ounce of white vinegar should cover the creams for 15 minutes. This approach to dressing management, as recommended by our Dermatology colleagues, can decrease inflammation and the incidence of secondary infection. Oral antihistamines and topical corticosteroids, avoiding the incision, are typically the next line of management. Finally, in patients with

systemic reactions, such as whole-body or whole-limb pruritic rashes, often only oral steroids can control the reaction in a timely fashion.

As in all allergic reactions, patients must have contact and sensitization to the offending agent prior to the reaction. In this series, nearly one third of patients had prior reactions to similar skin adhesive wound closure material. Further, in other case reports, some patients had documented reactions to acrylic [15, 16]. If skin adhesive is to be routinely used in skin closure, we recommend surgeons inquire pre-operatively about a history of contact allergies to skin adhesives to prevent potentially avoidable peri-incisional ACD. We do not routinely patch test all patients that will undergo skin adhesive skin closure, but it can be considered in patients with a potential previous reaction. Finally, in the authors' experience, the incidence of ACD to Prineo® is increased on extensor surfaces (i.e., knees) compared to other skin surfaces (i.e., hips). We hypothesize that the tension on the skin adhesive dressing that occurs on extensor surfaces causes micro-fractures of the skin adhesive, potentially releasing more allergen and may cause more skin irritation that initiates the ACD cycle. This may, in part, contribute to the difference between the incidence estimated in this series at 0.5% and the previously described study in TKAs by Durando et al [17] at 2%.

The main limitation to this study is the lack of a comparative or control group. This is a retrospective case series, describing the authors' experiences with an uncommon, largely unrecognized complication with a modern skin closure technique. Further, there is no definitive test or diagnosis of an ACD in the acute setting; however, we were able to

ascertain a probable clinical diagnosis in all patients in this series. Finally, the retrospective nature of the study, lack of a definitive diagnostic test, and lack of a discrete diagnosis code for this complication only allows a best estimate of the incidence of ACD to 2-octyl cyanoacrylate based on the number of patients identified compared to the number of units utilized during the same period, not an exact rate.

ACD, while uncommon, may occur in 0.5 - 2% of patients undergoing Prineo® wound closure. The diagnosis is largely clinical, based upon the appearance of a peri-incisional, erythematous, and eczematous to urticarial eruption. SSI must be excluded based on history, examination, laboratory testing, and further testing as needed. Treatment is dependent on the severity of the reaction, but should include removal of the skin adhesive dressing, topical steroids with specific dressing change regimens as outlined above, and oral antihistamines; these simple measures resolved the reaction in the majority of patients without complication. Oral steroids may be required in the more severe, systemic reactions. Incidence of skin adhesive ACD can be potentially diminished by taking a thorough clinical history of past reactions and selective patch testing. With early recognition and prompt treatment, ACD to skin adhesives utilized in wound closure in elective orthopedic operations can be effectively treated without affecting the impact on wound closure.

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291 **Table 1.** Patient demographics

Patient Demographics	
Mean Age, years (range)	55 (15-92)
Sex (male: female)	8:21
Mean BMI, kg/m ² (range)	33.2 (18.5-69.2)
Previous Contact	8
Definite	7
Suspected Procedure Type	14
Knee arthroplasty	16
Other knee procedures	3
Hip arthroplasty	7

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Table 2. Classification of 2-octyl Cyanoacrylate Reactions

Classification Type	Symptoms
Mild	Erythema, infiltration, possible papules
Moderate	Erythema, infiltration, papules and vesicles
Severe	Spreading reactions (outside of the area of the initial application of the offending agent), bullous reactions, extreme pruritus

LEGENDS

Figure 1: Mild Reaction – 47 year-old female ten days after right clavicle open reduction and internal fixation with maculopapular rash and pruritis. She was treated with careful skin adhesive removal and oral anti-histamines. The reaction resolved eighteen days post operation.

Figure 2: Moderate Reaction – 79 year-old male seven days after right unicompartmental knee arthroplasty. His reaction resolved seventeen days post operation with careful removal of skin adhesive dressing and topical steroids.

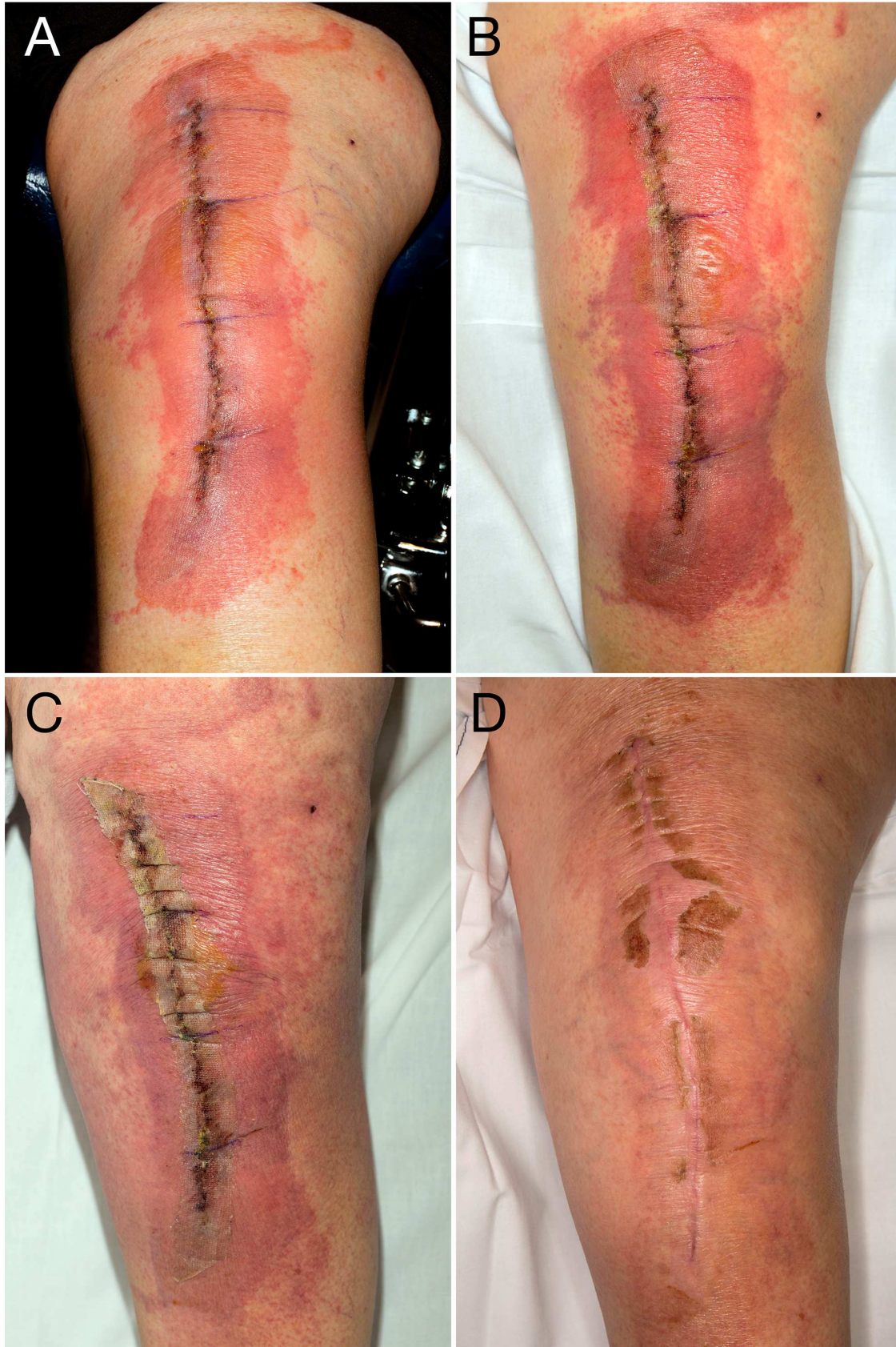
Figure 3: Severe Reaction – 72 year-old female a) five, b) eight, c) twelve, and d) nineteen days following left total knee arthroplasty. Note the severe blistering, bullae, and erythema. After careful skin adhesive removal at five days, she was treated with oral anti-histamines in addition to oral and topical steroids. Her reaction resolved at twenty-one days post operation.

Figure 4: Severe Reaction – 16 year-old male a) three and b) eight days after a right knee extensor mechanism realignment and tibial tubercle osteotomy. Note the severe blistering, bullae, and erythema. His reaction resolved thirty days postoperatively after being treated with dressing removal and topical steroids.

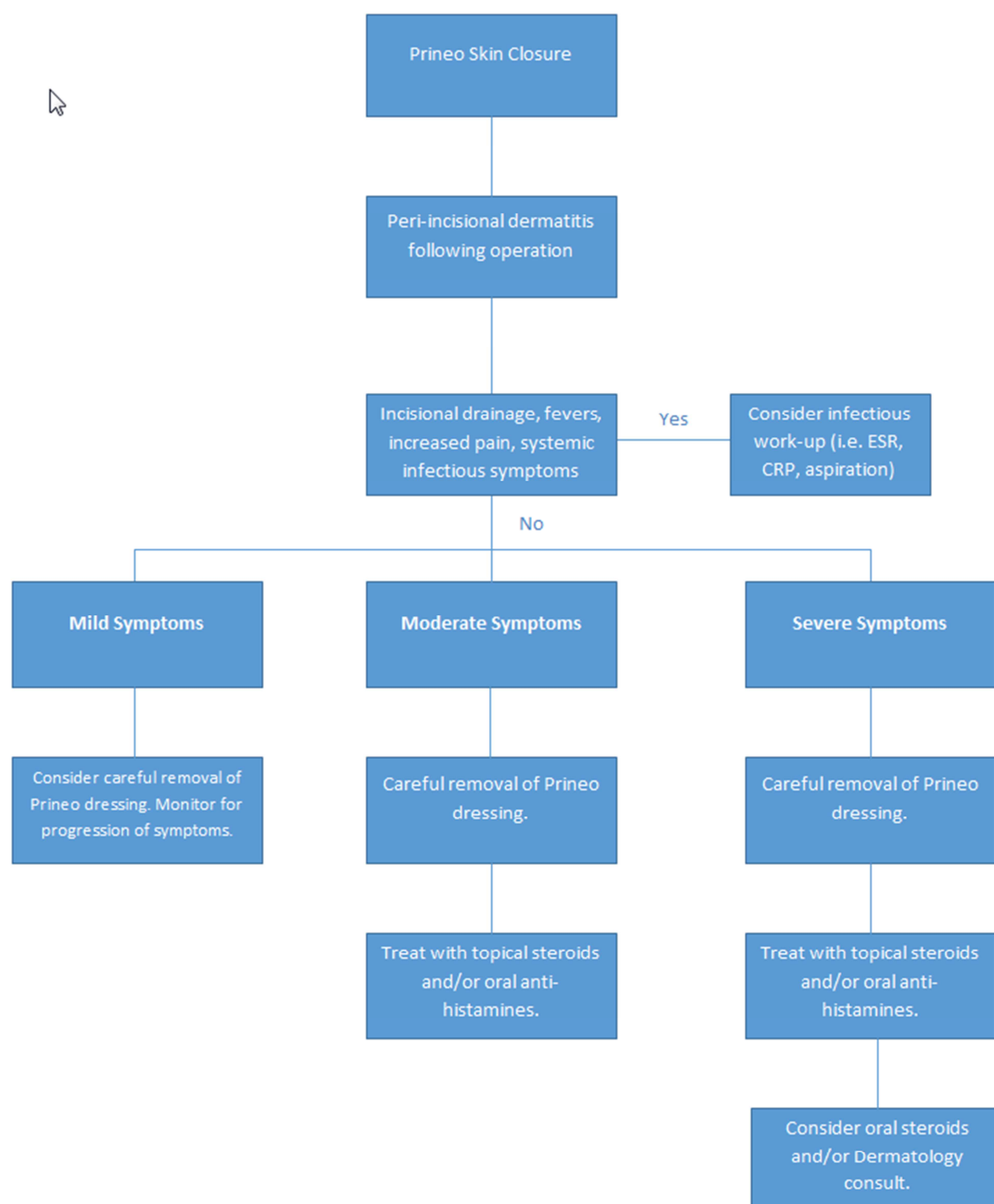
Figure 5: Proposed treatment algorithm based on the clinical severity.











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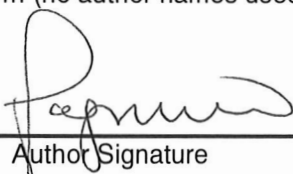
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4. Stock or stock options in a company or supplier (The following conflicts were disclosed)
None
5. Research support from a company or supplier as a Principal Investigator (The following conflicts were disclosed)
None
6. Other financial or material support from a company or supplier (The following conflicts were disclosed)
None
7. Royalties, financial or material support from publishers (The following conflicts were disclosed)
None
8. Medical/Orthopaedic publications editorial/governing board (The following conflicts were disclosed)
None
9. Board member/committee appointments for a society (The following conflicts were disclosed)
Knee Society

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MARK PAGNANO



6-6-17

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Author Signature

Date

CONFLICT OF INTEREST STATEMENT

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1. Royalties from a company or supplier (The following conflicts were disclosed) **None**
2. Speakers bureau/paid presentations for a company or supplier (The following conflicts were disclosed) **None**
- 3A. Paid employee for a company or supplier (The following conflicts were disclosed) **None**
- 3B. Paid consultant for a company or supplier (The following conflicts were disclosed) **None**
- 3C. Unpaid consultants for a company or supplier (The following conflicts were disclosed) **None**
4. Stock or stock options in a company or supplier (The following conflicts were disclosed) **None**
5. Research support from a company or supplier as a Principal Investigator **None**
6. Other financial or material support from a company or supplier (The following conflicts were disclosed) **None**
7. Royalties, financial or material support from publishers (The following conflicts were disclosed) **None**
8. Medical/Orthopaedic publications editorial/governing board (The following conflicts were disclosed) **None**
9. Board member/committee appointments for a society (The following conflicts were disclosed) **None**

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Peter K. Sculco

Peter K. Sculco

6/8/2017

Author Name (Print or Type)

Author Signature

Date

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Zimmer - Biomet

2. Speakers bureau/paid presentations for a company or supplier (The following conflicts were disclosed)

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- 3A. Paid employee for a company or supplier (The following conflicts were disclosed)

∅

- 3B. Paid consultant for a company or supplier (The following conflicts were disclosed)

Link Zimmer Biomet

- 3C. Unpaid consultants for a company or supplier (The following conflicts were disclosed)

∅

4. Stock or stock options in a company or supplier (The following conflicts were disclosed)

∅

5. Research support from a company or supplier as a Principal Investigator (The following conflicts were disclosed)

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6. Other financial or material support from a company or supplier (The following conflicts were disclosed)

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Springer

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9. Board member/committee appointments for a society (The following conflicts were disclosed)

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Author Name (Print or Type)


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1. Royalties from a company or supplier (The following conflicts were disclosed) **ARTHREX**
 2. Speakers bureau/paid presentations for a company or supplier (The following conflicts were disclosed) **NONE**
 - 3A. Paid employee for a company or supplier (The following conflicts were disclosed) **NONE**
 - 3B. Paid consultant for a company or supplier (The following conflicts were disclosed) **ARTHREX**
 - 3C. Unpaid consultants for a company or supplier (The following conflicts were disclosed) **NONE**
 4. Stock or stock options in a company or supplier (The following conflicts were disclosed) **NONE**
 5. Research support from a company or supplier as a Principal Investigator (The following conflicts were disclosed)
STRYKER
 6. Other financial or material support from a company or supplier (The following conflicts were disclosed) **NONE**
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7. Royalties, financial or material support from publishers (The following conflicts were disclosed) **NONE**
 8. Medical/Orthopaedic publications editorial/governing board (The following conflicts were disclosed)
AMERICAN JOURNAL OF SPORTS MEDICINE
 9. Board member/committee appointments for a society (The following conflicts were disclosed) **NONE**

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MICHAEL J. STUART MD *MJ Stuart MD* **5/16/17**
Author Name (Print or Type) Author Signature Date

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1. Royalties from a company or supplier (The following conflicts were disclosed)
DJO Orthopedics
2. Speakers bureau/paid presentations for a company or supplier (The following conflicts were disclosed)
None
- 3A. Paid employee for a company or supplier (The following conflicts were disclosed)
None
- 3B. Paid consultant for a company or supplier (The following conflicts were disclosed)
DJO Orthopedics
- 3C. Unpaid consultants for a company or supplier (The following conflicts were disclosed)
None
4. Stock or stock options in a company or supplier (The following conflicts were disclosed)
None
5. Research support from a company or supplier as a Principal Investigator (The following conflicts were disclosed)
Depuy Orthopedics, Stryker
6. Other financial or material support from a company or supplier (The following conflicts were disclosed)
None
7. Royalties, financial or material support from publishers (The following conflicts were disclosed)
Elsevier
8. Medical/Orthopaedic publications editorial/governing board (The following conflicts were disclosed)
Journal of Arthroplasty Associate Editor
9. Board member/committee appointments for a society (The following conflicts were disclosed)
Minnesota Orthopedic Society, AAOS

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Michael J Taunton MD		5/16/17
Author Name (Print or Type)	Author Signature	Date