Minimising Propionibacterium acnes Contamination in Shoulder Arthroplasty00

Title Page

Minimising Propionibacterium acnes Contamination in Shoulder Arthroplasty: Use of a Wound Protector

Authors:

Mitchell L Smith

MBBS

Melbourne Orthopaedic Group, Windsor, VIC Australia

Robert Gotmaker

MBBS, FANZCA

St Vincent's Hospital, Fitzroy, VIC Australia

Greg A Hoy

MBBS, FRACS(Orth), FAOrthA

Melbourne Orthopaedic Group, Windsor, VIC Australia;

Department of Surgery, Monash University, Clayton, VIC, Australia

Eugene T Ek

MBBS, PhD, FRACS(Orth), FAOrthA

Melbourne Orthopaedic Group, Windsor, VIC Australia;

Department of Surgery, Monash University, Clayton, VIC, Australia

Ashley Carr

MBBS, FRACS(Orth), FAOrthA

Melbourne Orthopaedic Group, Windsor, VIC Australia;

Department of Surgery, Monash University, Clayton, VIC, Australia

Jennifer N Flynn

MBBS, FRACS(Orth), FAOrthA

Epworth Hospital, Richmond, VIC Australia

Matthew C Evans

MBBS, FRACS(Orth), FAOrthA

Melbourne Orthopaedic Group, Windsor, VIC Australia;

Department of Surgery, Monash University, Clayton, VIC, Australia

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: [10.1111/ans.14821](https://doi.org/10.1111/ans.14821)

Disclaimer:

No author, or any member of his or her family received any financial remuneration related to the subject of the article.

Financial biases: None

Ethical Committee Approval:

The Avenue Hospital Human Research Ethics Committee

Study number: 221

Figures:

We kindly ask that the images be printed in colour, and that the copyright statement in "Figure 1" be included.

Figure 1. Proprietary photograph of the Alexis Wound Protector

Figure 2. Wound protector in situ, right shoulder

Table 1. Uni-variable analysis results

Word Count:

Abstract – 199

Text – 1,990

Acknowledgements:

We gratefully acknowledge the Department of Surgery, Monash Medical Centre, Monash University for a Research Grant received in support of this study.

Minimising *Propionibacterium acnes* Contamination in Shoulder Arthroplasty

Corresponding Author:

Dr Mitchell Smith

Melbourne Orthopaedic Group, 33 The Avenue, Windsor 3181, VIC Australia

mitchleighsmith@gmail.com

Abstract

Background:

Propionibacterium acnes (*P. acnes*) may be transmitted from the subdermal tissues to the deeper tissues during shoulder arthroplasty surgery, resulting in deep infection. The aim of this prospective, clinical study was to determine whether the use of a wound protector drape can lower the incidence of *P. acnes* in the wound during shoulder arthroplasty surgery.

Methods:

For a consecutive series of 47 patients undergoing shoulder arthroplasty, a wound protector drape was used during surgery, to isolate the subdermal layer from the surgeons' hands, retractors and other instruments. Microbiological swabs were taken both from the subdermal layer and the exposed drape to determine the incidence of *P. acnes* at both sites.

Results:

Minimising *Propionibacterium acnes* Contamination in Shoulder Arthroplasty

The overall incidence of *P. acnes* in the subdermal layer was 23%. A five-fold decrease in the incidence of *P. Acnes* in the exposed superficial layer was demonstrated by use of the wound protector drape.

Discussion:

Use of a wound protector drape to isolate the superficial tissue layer from the surgeons' gloves, instruments and retractors decreases the incidence of *P. acnes* in the surgical field. This may result in a decreased rate of transmission to the deeper tissues, and a decreased rate of *P. acnes* deep infection.

Key Words:

Propionibacterium acnes; shoulder; arthroplasty; contamination; wound protector; infection

Level of Evidence:

Level 2 Treatment study - a prospective comparative study

Introduction:

Propionibacterium acnes (*P. acnes*) is well recognised as a pathogen responsible for infections following shoulder surgery.¹ Although it can be difficult to culture, *P. acnes* has been demonstrated to be most prevalent in the subdermal tissues, and it may be transmitted to the deeper tissues via instruments or surgical gloves during shoulder operations.^{2,3} A recent publication demonstrated the high prevalence of *P. acnes* in the subdermal layer around the shoulder. It postulated transmission of the bacteria from the subdermal layer to the deeper tissues was a causative factor in the development of *P. acnes* deep infections following shoulder surgery.⁴

In abdominal surgery, wound protector drapes isolating the skin, subdermal and superficial tissues from the abdominal cavity, have been shown to decrease the risk of wound infections, by decreasing the exposure of these tissues to the abdominal contents that may contain bacterial pathogens.⁵ Recently, a wound protector drape (Alexis Orthopaedic Protector (Applied Medical, Rancho Santa Margarita, CA)) has been introduced for use in orthopaedics. It serves to protect the superficial tissues from trauma related to instruments and retractors whilst providing retraction of these tissues to improve visualisation of the surgical field. We postulate that utilization of this drape in surgery of the shoulder may also serve to minimise transfer of *P. acnes* from the superficial tissues to the deeper tissues by forming an impervious barrier between the subdermal layer and the surgical field, thereby decreasing the risk of deep infections related to this organism. For the purpose of this study,

Minimising *Propionibacterium acnes* Contamination in Shoulder Arthroplasty

we have used *P. acnes* contamination of the wound protector drape, as a surrogate marker of deep wound contamination.

The aim of this study is to demonstrate a decreased prevalence of *P. acnes* on the exposed surface of the wound protector drape, when compared with the underlying subdermal tissues during shoulder surgery.

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Minimising *Propionibacterium acnes* Contamination in Shoulder Arthroplasty

Methods:

Consecutive patients undergoing shoulder replacement surgery through a delto-pectoral approach at a single institution (4 surgeons) were recruited over a 6-month period. Patients with a past history of ipsilateral shoulder infection, or previous surgery through the same approach were excluded.

The Alexis Orthopaedic Protector (Applied Medical, Rancho Santa Margarita, CA) consists of two thermoplastic, polyurethane rings, connected by a polyester laminated, polyurethane film. One ring sits on the skin, whilst the other is placed deep to the superficial tissues, and the connecting sheet is then tensioned to create the barrier (Figure 1).

Standardised antibiotic prophylaxis was administered, consisting of 2 grams of cephazolin with induction, and 1 gram every eight hours for 24 hours. For one case vancomycin was used instead of cephazolin due to patient allergy. Skin preparation was either with alcoholic iodine or alcoholic chlorhexidine depending upon surgeon preference, and all patients underwent a pre-operative scrub with the same antiseptic preparation.

The surgical approach was standardised for all surgeons. After dissecting through the delto-pectoral interval, a microbiology swab was taken from the subdermal layer on the medial side of the wound. The wound protector drape was then inserted, with the deep ring placed under the deltoid laterally, and deep to the pectoralis major tendon medially, to isolate the

Minimising *Propionibacterium acnes* Contamination in Shoulder Arthroplasty

superficial tissues (Figure 2). All gloves were then changed and the shoulder replacement proceeded in a routine fashion. Once the prosthesis was implanted, pulsed lavage was used to washout the deep wound, and the subscapularis re-attached. At this point, just prior to removal of the barrier drape, a second microbiological swab was taken, this time from the exposed surface of the barrier drape, overlying the medial edge of the wound. The drape was then removed and a third microbiological swab was taken, from the subdermal layer on the medial side of the wound – the same area as the first swab. The wound was then closed in a routine fashion.

All swabs were transported to the same pathology laboratory (Dorevitch Pathology) and inoculated onto Blood agar and Chocolate agar plates, as well as a cooked meat enrichment medium. Aerobic and anaerobic cultures were then undertaken for 14 days, and the plates then examined specifically for the presence of *P. acnes*.

Local Human Research Ethics approval was obtained for this study (approval number 221).

Statistical analysis

Power analysis was determined based on demonstrating a 25% reduction in *P. acnes* positive cultures between the surface of the barrier drape and the sub-dermal layer at the end of the operation, based on the incidence described by Falconer et al.⁴ To demonstrate a difference

Minimising *Propionibacterium acnes* Contamination in Shoulder Arthroplasty

with a Power of 0.8 and $p < 0.05$, 42 patients were required. We included an additional 10% to be safe, and set our $n=47$.

We summarized continuous and discrete variables by mean and standard deviation (SD) or medians and interquartile range (IQR) as appropriate, and binary variables as proportions.

We performed statistical significance testing of baseline characteristics using Student's t-test, Wilcoxon rank sum, Fisher's exact test or chi-squared tests as appropriate.

The primary outcome was reported as a risk ratio with 95% confidence interval. Since our data were paired, statistical significance was calculated using McNemar's exact test to allow for within patient correlation. All analyses were performed using Stata 14 (Statacorp, Texas, USA).

Results:

Forty-seven patients were included in the study, 22 males and 25 females. The median age was 70 (IQR 65, 77) years, and median BMI was 28.5 (IQR 25.9, 32.3). The primary diagnosis was Osteoarthritis in 23, and Cuff Tear Arthropathy in 24. 1 Hemi-arthroplasty was performed, 22 conventional Total Shoulder Replacements, and 24 Reverse Fulcrum Shoulder Replacements. 27 were right shoulders, whilst 20 were left shoulders. Median total operative time was 81 minutes (IQR 71, 98).

Overall incidence of *P. acnes* positive swabs in the subdermal layer:

Eleven of the 47 patients (23%) had at least one swab, which grew *P. acnes*.

Prior to insertion of the barrier drape, 4 swabs grew *P. acnes* from the subdermal layer. After removal of the barrier drape, 10 swabs grew *P. acnes* from the subdermal layer. Three of the 4 patients who were positive for *P. acnes* on the first swab were also positive on the final swab.

Baseline characteristics of patients are shown in Table 1. Younger age ($p=0.01$) and male gender ($p=0.001$) were associated with an increased incidence *P. acnes* in the subdermal layer. There was no evidence of any difference with regards to body mass index, total operative time, skin preparation or operative diagnosis.

Minimising *Propionibacterium acnes* Contamination in Shoulder Arthroplasty

Incidence of *P. acnes* on the barrier drape:

Two swabs (4.3%) were positive for *P. acnes* on the barrier drape. Both patients who demonstrated *P. acnes* on the barrier drape had positive subdermal swabs after drape removal, but only one had a positive subdermal swab prior to drape insertion.

There was a lower incidence of *P. acnes* on the barrier drape (2/47) compared to the subdermal layer (10/47) at the end of the operation, risk ratio 0.2 (95%CI 0.06, 0.70), $P=0.008$ (McNemar's exact test).

Discussion:

P. acnes is a gram positive bacillus that resides in sebum glands. It is a common contaminant in shoulder surgery, and a potential pathogen in post-operative shoulder infections.^{6,7,8} Recent studies indicate a high incidence of *P. acnes* in the sub-dermal layer, and it is postulated that the organism may be carried into the deeper tissues during surgery by instruments or by hand.^{4,9}

This study demonstrates that a Wound Protector Drape designed to protect the superficial soft tissues from damage from retractors and other surgical instruments, also provides a physical barrier against *P. acnes*. The incidence of *P. acnes* on the exposed surface of the wound protector drape is 5-fold less than its incidence on the otherwise exposed superficial tissues during shoulder replacement surgery. Although we cannot assume that the wound protector drape will prevent *P. Acnes* from passing to the deeper tissues directly, we can assume that this decreased incidence of *P. Acnes* in the exposed superficial wound edges will decrease the chance of indirect transfer of *P. Acnes* to the deeper tissues via gloves or instruments.

A number of factors have been shown to be associated with positive *P. acnes* culture including: male gender, previous shoulder implants, prosthetic joint infection,² presence of hair,^{10,11} longer surgical duration,¹² pre-operative corticosteroid injections¹³ and age <50 years.⁹ As well it has been shown that males have a higher bacterial load than females.¹⁴

Minimising *Propionibacterium acnes* Contamination in Shoulder Arthroplasty

Our study confirms a positive association between younger age, male gender and increased incidence of *P. acnes* in the subdermal layer. We identified no association between diagnosis, body mass Index, or operative time and incidence of *P. acnes* in the sub-dermal tissues.

Interestingly we had one patient who cultured *P. acnes* from the subdermal layer at the start of the operation, but not at the end. ~~This contradicts the theory that this organism lives in the subdermal layer and that its incidence would therefore increase in that region during the time of the operation. We must assume~~ It is likely that this result relates to the difficulty in culturing this organism in general, and underlies the fact that it is probably more prevalent than our current testing identifies.

Although Antibiotic prophylaxis was standardised, skin preparation was variable, with some patients receiving Alcoholic Chlorhexidine, whilst others received Alcoholic iodine. This variability was a result of surgeon preference, and accepted as part of the study protocol, as recent literature does not demonstrate any one method of skin preparation to be more effective at decreasing the incidence of *P. acnes*.¹⁵ This finding was supported by our results.

A weakness of this study is our inability to determine at what time point the wound protector drape became contaminated with *P. acnes*. If this occurred at the time of insertion, then for those patients the wound protector drape has not provided any additional protection against *P. acnes* being passed into the deeper tissues.

Minimising *Propionibacterium acnes* Contamination in Shoulder Arthroplasty

A perceived weakness of this study design is the apparent lack of a control comparator, to determine the incidence of *P. acnes* in the subdermal without the use of the wound protector drape. Our justification for this is that several studies have already reported the incidence of *P. acnes* in the subdermal layer^{2,3,4} and given that our incidence of 23%(positive swabs of the subdermal layer) correlates with those published data, we consider this to be an acceptable comparator.

A potential weakness of this study is that the nature of the drape material may play a role in the ability of *P. acnes* to adhere and hence be swabbed. If *P. acnes* does not adhere to the drape, we may be observing a falsely low rate of culture from the drape, despite higher rates of deep wound contamination, making our surrogate outcome measure invalid. Unfortunately there is no evidence regarding this and further studies would be required to determine the differential adhesiability of *P. acnes*.

The use of the wound protector drape carries a technical learning curve. Sufficient mobilisation of the deltoid and pectoralis major muscles must be achieved to minimise the risk of inadvertent loss of position of the deep ring of the drape. Similarly, delivery of the proximal humerus into the wound can lead to dislodgement of the deep ring of the drape. Alteration in the deltoid tension needs to be considered particularly with trialling component implantation for stability. There was no instance of skin or muscle necrosis with use of this drape, and this has not been reported with its' use elsewhere.

Minimising *Propionibacterium acnes* Contamination in Shoulder Arthroplasty

We conclude that the use of a wound protector drape results in a significantly decreased incidence of *P. acnes* in the exposed surgical field contamination of the drape, compared with the underlying subdermal tissues during shoulder arthroplasty surgery. By decreasing the incidence of *P. acnes* in the surgical field, we postulate that the incidence of indirect transfer of the organism to the deeper tissues will be minimised. This will hopefully result in a decreased incidence of *P. acnes* deep infection following shoulder arthroplasty.

Notwithstanding the change to surgical technique when using the wound protector drape, we recommend considering this device as an adjunct to other measures aimed at decreasing infection risk during shoulder arthroplasty surgery.

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Figure Legends

Figure 1.   Proprietary photograph of the Alexis Wound Protector

Figure 2.   Wound protector in situ, right shoulder

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Author/s:

Smith, ML;Gotmaker, R;Hoy, GA;Ek, ET;Carr, A;Flynn, JN;Evans, MC

Title:

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Date:

2018-11-01

Citation:

Smith, M. L., Gotmaker, R., Hoy, G. A., Ek, E. T., Carr, A., Flynn, J. N. & Evans, M. C. (2018). Minimizing Propionibacterium acnes contamination in shoulder arthroplasty: use of a wound protector. ANZ JOURNAL OF SURGERY, 88 (11), pp.1178-1181. <https://doi.org/10.1111/ans.14821>.

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