Wound Protectors Reduce Bacterial Colonization and Soft Tissue Damage During Total Shoulder Arthroplasty: A Randomized Controlled Trial

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INTRODUCTION: Prosthetic joint infection is a devastating complication of shoulder arthroplasty. Cutibacterium acnes is difficult to prevent due to its prevalence in the sebaceous glands in the shoulder, neck, and upper back area. A proposed method of preventing prosthetic joint infections has been with the use of a wound protection device inserted after superficial exposure. The purpose of this study was to determine if the use of a wound protector decreases the deep wound colonization of c. acnes in primary shoulder arthroplasty and secondarily, the effect of device usage on tissue injury.

METHODS: The study design was a prospective, randomized controlled trial. Patients undergoing primary total shoulder arthroplasty were randomized into two groups: a wound protector group and a control group. The wound protector was inserted after deltopectoral interval exposure with the protector ring placed deep to the deltoid and pectoralis major tendons which remained in place until subscapularis repair. Deep wound culture swabs were taken at the articular margin, rotator cuff insertion, and conjoint tendon after final implantation. The surgeon also graded deltoid, pectoralis major, and cephalic vein injury on a 0 to 3 scale based on modification to the Tscherne classification of soft tissue injury. Additional demographic and surgical data collected included age, sex, Charleson Comorbidity Index, surgery type (anatomic vs reverse), surgical time, blood loss, and indication for surgery. The primary outcome of this study was positive culture results for Cutibacterium acnes. Statistical analysis included a Mann-Whitney U comparative analysis between the two groups to assess for any difference in culture positivity rate and Fisher's Exact Test was used to compare tissue scoring.

RESULTS:

In our study population of 69 patients, the use of a wound protector was associated with a decrease in culture positivity compared to the control group (1/34 vs 9/35, p=0.007). The rates of greater than one positive culture were similar between the two groups (Table 1). The wound protector group had improved soft tissue damage scores for the deltoid muscle (p=<0.001) and pectoralis muscle (p=<0.001). No difference in cephalic vein injury was noted between the two groups (Table 2, Figure 2). The use of the wound protector did not significantly impact surgical time (p=0.920) between the two groups, nor did it impact estimated blood loss (p=0.222).

DISCUSSION AND CONCLUSION:

The use of a surgical wound protector device in total shoulder arthroplasty decreases the incidence of bacterial colonization of the deep wound. Additionally, the qualitative grading of soft tissue damage to the deltoid and pectoralis muscle was less severe in the wound protector group. These findings suggest that this device may be beneficial to the patient in reduction of prosthetic joint infection risk and tissue healing during shoulder arthroplasty.

Figure 1: In Vivo Image of a Wound Protector During Deltopectoral Approach

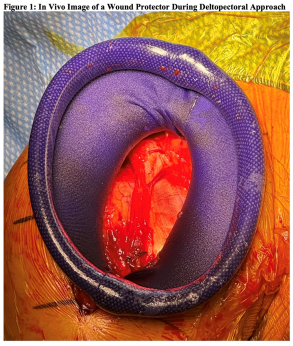

Figure 2: A Graphical Summary of Intraoperative Tissue Scoring

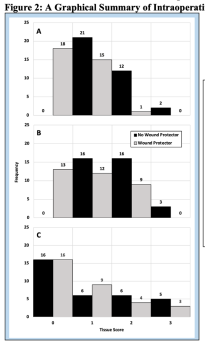

Figure 2: Tissue scoring for the Deltoid (A) P<0.001, Pectoralis (B) P<0.001, and Cephalic Vein (C) P=0.596 are summarized. Scoring is based on a modified 0-3 Tscherne classification

Table 1: Summary of Intraoperative Culture Results

Culture	Control (%)	Wound Protector (%)	P-value
≥1 Positive Culture	9/35 (26)	1/34 (3)	**0.007*[C]**
≥2 Positive Culture	4/35 (11)	0/34 (0)	0.114[F]
≥3 Positive Culture	2/35 (6)	0/34 (0)	0.493[F]
Glenoid Articular Margin	4/35 (11)	0/34 (0)	0.114[F]
Greater Tuberosity of Humerus	4/35 (11)	0/34 (0)	0.114[F]
Conjoint Tendon	7/35 (20)	1/34 (3)	0.055[F]

* = p < 0.05
[C] = Chi-Square Test
[F] = Fisher's Exact Test

Table 2: Summary of Intraoperative Tissue Scoring

Tissue Score	Control mean (SD)	Wound Protector mean (SD)	P-value
Deltoid	1.5 (0.6)	0.5 (0.6)	**<.001***
Pectoralis	1.6 (0.6)	0.8 (0.8)	**<.001***
Cephalic Vein	1.0 (1.1)	0.8 (1.0)	0.596

* = p < 0.05