Abstract Title: Wound protectors reduce bacterial colonization and soft tissue damage during total shoulder arthroplasty: A randomized controlled trial

Authors: Mitchell S. Kirkham BS, mitchell.kirkham@hsc.utah.edu, University of Utah Department of Orthopaedics, USA
Hunter B. Carlson BS, Hunter.Carlson@hsc.utah.edu, University of Utah Department of Orthopaedics, USA
Emma Merrill BS, emma.merrill@hsc.utah.edu, University of Utah Department of Orthopaedics, USA
Peter N. Chalmers MD, peter.chalmers@hsc.utah.edu, University of Utah Department of Orthopaedics, USA
Robert Z. Tashjian MD, robert.tashjian@hsc.utah.edu, University of Utah Department of Orthopaedics, USA
Christopher D. Joyce MD, christopher.joyce@hsc.utah.edu, University of Utah Department of Orthopaedics, USA

Introduction: Prosthetic joint infection (PJI) 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. Published methods of preventing c. acnes infection include pre-operative antibiotics, skin preparation with hydrogen peroxide wash, betadine wash after skin incision, and many others. A relatively novel method of preventing PJI has been with the use of a wound protection device inserted after superficial exposure. While there is some outcome data with the use of these devices in hip arthroplasty, there is minimal data in regards to shoulder arthroplasty. The purpose of the proposed study is to determine if the use of a wound protector deceases 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 anatomic or reverse total shoulder arthroplasty were randomized into one of two groups: Group WP included use of the wound protector device, and group no WP was the control group and did not use a wound protector. The wound protector was be inserted after exposure of the underlying deltopectoral area and after biceps tenodesis with the protector ring placed deep to the deltoid and pectoralis major tendons and remain in place until all implants are placed, and the subscapularis tendon is repaired. Deep wound culture swabs were be taken at the articular margin, rotator cuff insertion, and conjoint tendon after all implants were placed and prior to subscapularis repair. All cultures were sent for aerobic and anaerobic culture and held for 14 days. In addition to culture positivity, the surgeon graded injury to the deltoid, pectoralis major, and cephalic vein on a 0 to 3 scale based on modification to the Tscherne classification of soft tissue injury at a fracture site. Additional demographic and surgical data collected included age, sex, Charleson Comorbidity Index (CCI), surgery type (anatomic vs reverse), surgical time, blood loss, and indication for surgery. The primary outcome for this study was positive culture results for cutibacterium acnes. Power analysis determined that 50 patients per group were ideal. 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 outcomes.

Results:
Incidence of one or more positive culture result were less likely in the wound protector group than the control group (1/26 vs 8/26, p=0.024). Similarly, rates of two or greater, and 3 or greater positive cultures were decreased in the wound protector group relative to the control but did not reach statistical significance (Table 1). The wound protector group had improved soft tissue damage scores for the deltoid muscle (p=<0.001) and pectoralis muscle (p=0.002). No difference in cephalic vein injury was noted between the two groups (Figure 2). Use of the wound protector did not significantly impact surgical time between the two groups, nor did it impact estimated blood loss.

Conclusion:
The use of a surgical wound protector device in total shoulder arthroplasty decreases the incidence of bacterial colonization of the deep wound as well as the amount of soft tissue damage to the deltoid and pectoralis muscle. In this particular study, this midterm analysis was performed at N= 52 patients, and we elected to halt further recruitment into the study due to the strength of the findings.

Funding:
This study was funded by the ASES PJI Research grant

Figure 1: Summary of intraoperative culture results

Culture	Control (%)	Wound Protector (%)	P-value
≥1 Positive culture	8/26 (31)	1/26 (4)	**0.024***
≥2 Positive culture	3/26 (12)	0/26 (0)	0.235
≥3 Positive culture	1/26 (4)	0/26 (0)	1.000
Glenoid Articular Margin	3/26 (12)	0/26 (0)	0.235
Greater Tuberosity of Humerus	3/26 (12)	0/26 (0)	0.235
Conjoint Tendon	6/26 (23)	1/26 (4)	0.099

* = $p < 0.05$

Figure 2: Summary of intraoperative tissue scoring

Tissue Score	Control mean (SD)	Wound Protector mean (SD)	P-value
Deltoid	1.4 (0.6)	0.5 (0.5)	**<.001***
Pectoralis	1.6 (0.6)	0.8 (0.8)	**0.002***
Cephalic Vein	0.9 (1.1)	0.8 (0.9)	0.964

* = $p < 0.05$