A New Tool for *C. acnes* Detection: Antigen Immunoassay

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INTRODUCTION: The management of *Cutibacterium acnes* shoulder infection has been frustrated by controversy regarding isolated positive culture in the absence of an inflammatory host response. Recently, a synovial fluid *C. acnes* antigen immunoassay (CAI), similar to the rapid test for Strep throat, has become available for clinical testing, providing an additional tool for the detection of *C. acnes* in synovial fluid. The purpose of this study was to evaluate the relationship between inflammation, culture results, and CAI results in synovial fluid samples from the shoulder.

METHODS:

A total of 1,827 synovial fluid samples being tested for native (564) or periprosthetic (1263) shoulder infection, from 428 institutions across the USA, were analyzed in a centralized CLIA laboratory from 2018 to 2021. Samples underwent a set of synovial fluid tests, including culture, CAI test, and biomarkers including CRP, alpha-defensin, neutrophil elastase, WBCs, and PMN%. The results of all synovial fluid biomarker results were combined to calculate one standardized inflammatory Z-score per sample. The relationship between the Z score, culture results, and the CAI test results was evaluated.

RESULTS: Among 231 shoulder fluid samples yielding positive cultures, 55 (24%) yielded *C. acnes*. Calculation of the inflammatory Z-score for these 55 culture-positive samples revealed two non-overlapping sample clusters. A non-inflammatory cluster of 21 samples exhibited a mean inflammatory Z score of -0.40 (range: -0.60 to -0.01) and all tested negative for antigen by CAI. An inflammatory cluster of 34 samples exhibited a mean inflammatory Z-score of 1.48 (range: 0.13 to 3.02) and all tested positive for antigen by CAI. The CAI test and Z-score differences between sample clusters yielded $p<0.0001$ for both comparisons.

DISCUSSION AND CONCLUSION: *C. acnes* culture-positive synovial fluid samples from the shoulder can be categorized into two distinct clusters: 1) CAI and host inflammation positive vs. 2) CAI and host inflammation negative. This study demonstrates that *C. acnes* antigen is only detectable in culture-positive synovial fluid when there is an associated host inflammatory response. Clinical outcome studies are necessary to demonstrate whether these findings are sufficient to differentiate between true positive vs. false-positive *C. acnes* culture results.