

Commentary

# Commentary on: The Relationship of Bacterial Biofilms and Capsular Contracture in Breast Implants

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This review by Ajdic et al on the role of bacterial biofilms in capsular contracture, though as stated not intended to be systematic or comprehensive, certainly represents a very useful and informative selection of key papers on the topic.<sup>1</sup> Capsular contracture is indeed among the most frequently discussed complications of breast implants, and as such, has been the subject of considerable thoughts, opinions, studies, and debates, with a range of differing views often held by many on the subject. Some additional perspectives to add to those expressed in this review are included in the discussion that follows.

Biofilms are thought to be involved in an estimated 80% of all human infections,<sup>2</sup> and as reflected in this review, their impact across various fields of medicine is becoming increasingly well recognized. Though the etiology of capsular contracture is certainly multifactorial,<sup>3,4</sup> a vast and ever-expanding body of preclinical and clinical data point specifically to the important role of bacterial biofilms. In addition to the clinical studies that were cited, some additional strong evidence for the role of subclinical infection and bacterial biofilms was provided in a multicenter study by Rieger et al<sup>5</sup> which reported that positive bacterial cultures following sonication of explanted breast implants were strongly correlated ( $P < .001$ ) with the severity of capsular contracture as assessed by the Baker scale. In future studies of capsular contracture, the somewhat subjective Baker scale may be entirely replaced or supplemented with a very promising new research tool developed by Prantl et al<sup>6</sup> that uses a non-invasive ultrasound methodology to semi-quantitatively measure the elasticity/compressibility of the capsule, implant, and surrounding tissue.

The challenge of detecting biofilms is worth emphasizing further. Costerton and DeMeo<sup>2</sup> noted that pathogenic bacteria when present as a biofilm are only detected approximately 30 percent of the time by standard culture methods. Though the sonication methods mentioned in the review can improve detection to a degree, studies in chronic wounds have demonstrated that molecular methods (PCR-identification of bacterial nucleic acid) were able to identify a substantial number of additional species of bacteria that were entirely missed by culture methods.<sup>7</sup> A commercially-available technology that incorporates such molecular methods<sup>8</sup> received a CE-mark for distribution in Europe in December 2014.

The impact of textured versus smooth silicone breast implant surfaces on capsular contracture provides a very good example of the need to consider covariates and not just focus on a single potential risk factor in isolation. Three of the largest prospective, multicenter clinical datasets ever assembled on silicone breast implants – the Core study datasets from Allergan, Mentor, and Sientra – have now clearly demonstrated that there is a marked and statistically significantly reduced incidence of capsular contracture for textured vs smooth round implants in the subglandular, but not in the subpectoral/submuscular plane.<sup>9-11</sup> It was by

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simultaneously analyzing surface and placement that such relationships became clear, and the potential benefits of such stratified analyses would be expected to extend far beyond contracture. Such findings, the explanation for which is still not fully understood, do, in fact, provide clear evidence of a significant impact of shell texture on the development of capsular contracture.

Further support for the potential benefit of nipple shields was recently published by Giordano and Salmi,<sup>12</sup> who reported a significantly lower incidence ( $P = .04$ ) of capsular contracture among primary augmentation patients (mean follow-up of approximately 3 years) where nipple shields were used (0%,  $n = 105$ ) vs not used (5%,  $n = 60$ ). Both groups received topical povidone-iodine and antibiotic pocket irrigation.

With respect to povidone iodine (betadine) immersion of the implant, and/or irrigation of the surgical pocket, the warning language included in breast implant product labeling typically differs for saline- and silicone gel-filled devices, with a more stringent warning included for saline devices. Wiener<sup>13,14</sup> has assembled and presented data that stands in contradiction to FDA's current views. From a broader evidence-based medicine viewpoint, given the perceived potential for reducing infection and capsular contracture, and the counterbalancing concern of wisely limiting to the extent possible use of antimicrobials, there is a real need for higher level evidence studies on surgical pocket irrigation. Given that there is no consensus standard practice for pocket irrigation, a Level 1 randomized controlled clinical should be feasible.

For a complication such as capsular contracture with a multifactorial etiology, it is perhaps worth considering that some of the much older literature should be interpreted with caution in relation to current practice, given potentially strong confounders that were present during those earlier studies. In addition to significantly higher levels of gel bleed associated with the 2nd generation implants from the 1970s and early 1980s, Chandler<sup>15</sup> demonstrated that the presence of talc in the peri-implant capsule was associated with an 18-fold increased risk of capsular contracture ( $P < 1 \times 10^{-9}$ ). The presumed source of the talc, a known fibrogenic agent, was the powder used in surgical gloves up until 1991 when the FDA banned this use.

In terms of preventing biofilm-related capsular contracture, meticulous hemostasis is another very important measure to incorporate, particularly in relation to reducing the potential for biofilm formation.<sup>16,17</sup> Hematomas have long been associated with an increased risk of capsular contracture, and heme provides a rich source of iron that can be an essential nutrient for pathogenic biofilm-forming bacteria.<sup>18</sup>

With respect to the potential use of leukotriene receptor antagonists, further clinical experience and perspectives were published by Huang and Handel.<sup>19</sup> Specifically with respect to zafirlukast, readers are also reminded of the

safety admonitions of Gryskiewicz<sup>20</sup> regarding its use for this application.

Capsular contracture has been a troublesome complication for decades and this review by Ajdic et al certainly provides an informative review of background information on one of the most significant contributing factors. It is hoped that through the future combination of clinical observations and multidisciplinary basic science, a truly effective solution will be developed.

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