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Poster

Application of Smart Acids to Combat Biofilm Development in Breast Augmentation

Olivia Questore [1] , Christopher Capicotto [2] , Katherine Mulquin [1] , Benjamin Lam [1]

1. Department of Plastic and Reconstructive Surgery, Philadelphia College of Osteopathic Medicine (pcom), Philadelphia, USA 2. Department of Plastic and Reconstructive Surgery, Crozer-Keystone Health System, Delaware County, USA

Corresponding author: Olivia Questore, oliviaqu@pcom.edu

Categories: Plastic Surgery
Keywords: capsular contracture, breast augmentation, microbial infiltration, implantation cavity, sat, biofilm, microbicidal, toxic 6-pack

How to cite this poster
Questore O, Capicotto C, Mulquin K, et al. (2018) Application of Smart Acids to Combat Biofilm Development in Breast Augmentation. Cureus 10(10): e.

Abstract

Capsular contracture is among the most common causes for breast surgery revision. Clinically significant capsular contracture is characterized by excessive scar formation, fibrosis around the implant, along with distortion and displacement of the breast implant. Multiple factors likely contribute to contracture, including the presence of biofilms on surgical implants and devices. Biofilms represent a complex problem in wound healing as their makeup can consist of one or numerous species of microorganisms that secrete cross-linking extracellular polymeric substances. Safe Acid Technology (SAT) disinfectant has been developed to destroy microorganisms and the biofilms they create while maintaining an impeccable safety profile for the user.

SAT anti-biofilm testing was administered by the Montana State University Center for BioFilm Engineering using a single species (Pseudomonas aeruginosa) biofilm grown in the CDC reactor according to ASTM E2871-12 on polycarbonate coupons. After establishing biofilms, the polycarbonate coupons were exposed to SAT formulations for multiple exposure times in varied concentrations.

Log reductions of biofilm ranged from 3.61 for treatment C50 at the low end and 4.82 for treatment C25 at the high end, compared to biofilm accumulated on control coupons of Log 8.62.

With biofilm being the leading suspect in the formation of capsular contracture in breast augmentation cases, employing strategies to minimize microbial infiltration of the implantation cavity is critical. SAT has demonstrated strong microbicidal and anti-biofilm action while maintaining a superior safety profile. SAT has achieved Category IV (harmless) designation in the FDA's Toxic 6-Pack assessment. This unique set of dual properties, efficacy vs microbes and nontoxicity, make SAT a promising candidate to use prophylactically in breast augmentation cases.

Open Access
Published 10/17/2018

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O. Questore, C. Capicotto, K. Mulquin, B. Lam
Philadelphia College of Osteopathic Medicine

PHILADELPHIA COLLEGE OF OSTEOPATHIC MEDICINE

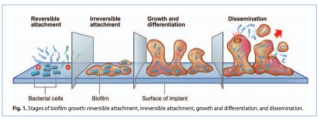

Fig. 1. Stages of biofilm growth: reversible attachment, irreversible attachment, growth and differentiation, and dissemination.

Introduction

Capsular contracture is among the most common causes for breast surgery revision. While the body creates a collagen capsule around the breast implant as part of a normal response to a foreign object, contracture is a pathological process. Clinically significant capsular contracture is characterized by excessive scar formation, fibrosis around the implant, along with distortion and displacement of the breast implant. Multiple factors likely contribute to contracture, including the presence of biofilms on surgical implants and devices. Biofilms represent a complex problem in wound healing as their makeup can consist of one or numerous species of microorganisms that secrete cross-linking extracellular polymeric substances. Safe Acid Technology (SAT) disinfectant has been developed to destroy microorganisms and the biofilms they create while maintaining an impeccable safety profile for the user.

Methods and Materials

SAT anti-biofilm testing was administered by the Montana State University Center for BioFilm Engineering using a single species (*Pseudomonas aeruginosa*) biofilm grown in the CDC reactor according to ASTM E2871-12 on polycarbonate coupons. After establishing biofilms, the polycarbonate coupons were exposed to SAT formulations for multiple exposure times in varied concentrations.

Concentration Matrix

Concentration	Contact Time(s)	
C0400		30 mins
C0200	10 mins	30 mins
C0100	10 mins	30 mins
C0050		30 mins
C0025		30 mins

Table 1. Safe Acid Concentrations used vs. biofilm and exposure times.

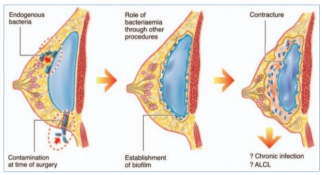

Fig. 2. The subclinical infection hypothesis for breast implants, showing initial contamination, biofilm formation and subsequent inflammation and contracture. Chronic biofilm infections may lead to symptoms and potential malignant transformation of chronically activated lymphocytes.

Results

Log reductions of biofilm ranged from 3.61 for treatment C50 at the low end and 4.82 for treatment C25 at the high end, compared to biofilm accumulated on control coupons of Log 8.62

Formulation	Titration (pH)	Mean Log (CFU/cm^2)	SD	Log Reduction
Control	--	8.62	0.02	N/A
For Contact Time of 30 min				
C0400	0.35	4.21	1.21	4.41
C0200	0.65	4.51	2.13	4.11
C0100	0.90	4.17	1.09	4.45
C0050	1.20	5.01	1.73	3.61
C0025	1.60	3.80	1.69	4.82
For Contact Time of 10 min				
C0200	0.65	4.66	1.58	3.95
C0100	0.90	4.28	0.84	4.34

Table 2. Acid formulations with biofilm log reduction results.

EPA Toxic Six-Pack Testing Criteria

TEST	Category I (Dangerous)	Category II	Category III	Category IV (Harmless)
Acute Oral	≤ 50 mg/kg	> 50 mg/kg ≤ 500 mg/kg	> 500 mg/kg ≤ 5000 mg/kg	> 5000 mg/kg
Acute Dermal	≤ 200 mg/kg	> 200 mg/kg ≤ 2000 mg/kg	> 2000 mg/kg ≤ 5000 mg/kg	> 5000 mg/kg
Acute Inhalation	≤ 0.05 mg/liter	> 0.05 mg/l ≤ 0.5 mg/l	> 0.5 mg/l ≤ 2 mg/l	> 2 mg/l
Primary Eye Irritation	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation that persists for more than 21 days	Corneal involvement or other eye irritation clearing in 8-21 days	Corneal involvement or other eye irritation clearing in 7 days or less	Minimal effects clearing in less than 24 hours
Primary Skin Irritation	Corrosive (tissue destruction into the dermis and/or scarring)	Severe irritation at 72 hours (severe erythema or edema)	Moderate irritation at 72 hours (moderate erythema)	Mild or slight irritation at 72 hours (no irritation or slight erythema)
Skin Sensitisation Test				

SAT Safety Profile

SAFE ACID TECHNOLOGY	CATEGORY
No Mortality (2000 < 5000 mg/kg) Safe if Ingested	Category IV (Harmless)
No Mortality (2000 < 5000 mg/kg) Safe for Skin Contact	Category IV (Harmless)
No Mortality (2562 > 2 mg/l for 4 hrs. Safe if Inhaled	Category IV (Harmless)
Not an eye irritant	Category IV (Harmless)
Not a dermal irritation or corrosive	Category IV (Harmless)
Not Sensitizing	Category IV (Harmless)

Conclusions

Numerous techniques and product innovations have been employed to reduce the risk of capsular contracture following breast surgery. While antibiotics may reduce bacteria in the perioperative period, they have shortcomings when addressing bacterial resistance and inability to penetrate biofilms. Safe Acid technology, which demonstrates non-toxicity to human mucosa and potent anti-biofilm action, may prove effective for reducing the risk of capsular contracture.

With biofilm being the leading suspect in the formation of capsular contracture in breast augmentation cases, employing strategies to minimize microbial infiltration of the implantation cavity is critical. SAT has demonstrated strong microbicidal and anti-biofilm action while maintaining a superior safety profile. SAT has achieved Category IV (harmless) designation in the FDA's Toxic 6-Pack assessment and SAT's ingredients are listed on the EPA's GRAS (generally recognized as safe) list. This unique set of dual properties, efficacy vs microbes and nontoxicity, make SAT a promising candidate to use prophylactically in breast augmentation cases.

Furthermore, SAT may be similarly efficacious in preventing infections associated with other implanted devices. Orthopedic cases can be complicated by infected hardware, which can cause the pain, poor functionality, possible sepsis and the need for revision. Infected hardware significantly increases the economic burden on the healthcare system. SAT may be a promising candidate to help minimize this type of complication which would be of great benefit to both patients and healthcare system.

Contact

Olivia Questore
Philadelphia College of Osteopathic Medicine
Email: oliviaqu@pcom.edu

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