

Long-Term Safety of EXPAREL™ (Bupivacaine Extended Release Liposome Injection) Reveals No Impact On Silicon Breast Implants at up to Two Years Follow-up

Harold Minkowitz MD, John D. Smoot MD

Abstract

Background: EXPAREL is an investigational long-acting local analgesic. Efficacy and safety have been studied in multiple surgical models. An issue specific to the augmentation mammoplasty model is the long-term safety of EXPAREL in the presence of silicon breast implant material; this is investigated herein.

Methods: Prior phase 2 and phase 3 multi-center, randomized, active-control studies with EXPAREL in the presence of a sub-muscular augmentation mammoplasty had been performed. All sites were invited to bring all patients in for a long-term follow-up study, which included a focused history and physical examination to elicit any clinical sequelae due to potential impact of EXPAREL on the silicon prosthesis.

Results: Most patients reported no changes in size/shape of the breast or changes in the skin/nipple. One patient reported signs of irritation or implant leakage; the relevant breast had received 75mg bupivacaine. One patient had one implant removed due to breast cancer 15 months after receiving study drug; the relevant breast had received 100mg bupivacaine.

Conclusions: In this study, at up to two years of follow-up, EXPAREL in the presence of silicon breast implant material did not have any impact on normal healing and there were no drug related late stage clinical sequelae, nor any effect on the implant material.