Breast Implant Capsular Contracture Research Study

BREAST IMPLANT CAPSULAR CONTRACTURE RESEARCH STUDY

Capsular contracture is scar tissue that can form in the breasts of women who have undergone breast implant surgery for cosmetic or reconstructive reasons. Sometimes, this tissue can become firm, painful, and even distort the appearance of the breast. Traditionally, this scar tissue has been treated with surgery.

We are currently recruiting patients to evaluate the effectiveness of a non-invasive device to treat capsular contracture. The device, the Aspen™ Ultrasound System, is an ultrasound machine which may soften breast implant capsules when used in conjunction with home exercises and special compression dressings. This machine is not yet FDA-approved in the United States for this use. The study investigator has no financial affiliation with the manufacturer of the device.
You are a good candidate for the study if you are aged 22 years or older, in good health, and have a history of capsular contracture which occurred following the placement of saline breast implants over the muscle for cosmetic reasons. You are eligible for the study even if you have had prior treatment for capsular contracture (such as medication or surgery) at least one year ago.

To determine if you qualify, you would need to come in for an initial evaluation and a further discussion of the study. The treatment period will consist of ten treatments performed over the course of 5 weeks (i.e., two visits per week for five weeks). We will need to see you again for brief follow-up visits at 6 weeks, 3 months, 6 months, and one year following the last treatment. Each visit will last approximately 30 minutes, and your breasts will be examined and photographed at each visit.

Although compensation is not available for this study, subjects will not be charged for any of the visits, whether or not they qualify for the study and complete all visits. Possible benefits of the study include softening of the breast tissues and implant and improved cosmetic appearance of the breasts. For more information please contact the office of the Investigator, Dr. Nina Naidu at 212-452-1230.

This study has been reviewed and approved by the Institutional Review Board at North Shore/LIJ Health System.

North Shore/LIJ IRB Protocol #
Date of Approval: