

## Review Article

# Multisite Analysis of 177 Consecutive Primary Breast Augmentations: Predictors for Reoperation

Leo R. McCafferty, MD, FACS; Laurie A. Casas, MD; Sandra S. Stinnett, DrPH; Samuel Lin, MD; Jason Rho, BA; and Margaret Skiles, MD

**BACKGROUND:** Plastic surgeons and manufacturers of breast implants have been examining the complication and reoperation rates of primary breast augmentations for more than 18 years. The seemingly high rates reported by the manufacturers to the United States Food and Drug Administration (FDA) were the impetus for this multicenter study.

**OBJECTIVE:** This paper reports on data pooled from three plastic surgery practices that were geographically distributed across the United States and examines the reoperation rate, time to reoperation, the reason for reoperation, and specific complications in 177 consecutive primary breast augmentation patients. These data are statistically compared to the manufacturers' 2005 and 2008 FDA data. In addition, the significance of selected variables from our data are examined as predictors for reoperation.

**METHODS:** Data were retrospectively collected from 177 consecutive primary breast augmentations performed between 2001 and 2004 from three surgical practices. Direct physician-to-patient follow-up periods ranged from 12 to 58 months, with 100% of patients having at least one year of follow-up. Each practice extracted chart data on variables and complications, including reoperations. These data were independently collated and sent to an independent biostatistician for analysis.

**RESULTS:** Our three year Kaplan-Meier (KM) reoperation rate (8%) and capsular contracture rate (2%) were both lower than the manufacturers' KM 3-year rates for reoperation (13%-21%) and capsular contracture (8.2%-9%). Logistic regression identified only simultaneous mastopexy and preexisting ptosis as predictors of reoperation. (*Aesthetic Surg J* 2009;29:213-220.)

## Editor's note:

As of 2006, Allergan completed acquisition of Inamed (Santa Barbara, CA), so all instances of the of the Inamed company name have been changed to reflect the merger.

In 2005 and again in 2008, both Inamed (Allergan) and Mentor Corporations reported seemingly high reoperation and complication

rates in patients who underwent primary breast augmentation with their products.<sup>1,2</sup> Since these reports, other individual plastic surgeons have reported on reoperation and complication rates,<sup>3,4</sup> but there has not been a multicenter study reporting a consecutive series with 100% follow-up. By analyzing 13 independent variables in this diverse patient group, we hoped to identify predictors of reoperation. In addition, we wanted to assess the pooled reoperation rates, complication rates, and time to reoperation for these three plastic surgery practices and compare them to those reported to the United States Food and Drug Administration (FDA) in 2005 and 2008 by the aforementioned implant manufacturers.

## METHODS

This is a retrospective study of 177 consecutive primary breast augmentations performed between 2001 and 2004, with follow-up periods ranging from 12 to 58 months and with all patients having at least one year of follow-up. The

Dr. McCafferty is from the Department of Plastic Surgery, University of Pittsburgh School of Medicine, Pittsburgh, PA. Dr. Casas is from the Department of Surgery, Northwestern University Feinberg School of Medicine, Evanston, IL. Dr. Stinnett is from the Department of Biostatistics and Bioinformatics and the Duke University Eye Center, Department of Ophthalmology, Duke University School of Medicine, Durham, NC. Dr. Lin is from the Division of Plastic Surgery, Department of Surgery, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA. Mr. Rho is a medical student at Northwestern University Feinberg School of Medicine, Evanston, IL. Dr. Skiles is a plastic surgeon in private practice in Yuba City, CA.