

# Cosmetic and reconstructive breast implantation

Establishment of a nationwide registry and prospective evaluation of local complications

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This PhD dissertation was accepted by the Faculty of Medicine of the University of Copenhagen, and defended on March 11, 2005.

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Dan Med Bull 2005;52:99.

## ABSTRACT

This PhD study was performed at the Institute of Cancer Epidemiology, Danish Cancer Society, and summarizes the results of four papers on breast implantation. Breast implants are used increasingly for cosmetic and reconstructive purposes. Most studies of local complications have been retrospective in design and have evaluated earlier generations of implants. Adequate, up-to-date data are requested on the probability of complications associated with current devices and procedures. The main purpose of the PhD study was to develop a nationwide registry, the Danish Registry for Plastic Surgery of the Breast (DPB), which systematically collects baseline and follow-up data on women undergoing mammoplasty. Other aims were to assess the short-term risks of complications following cosmetic and post-mastectomy breast implantation.

All public clinics of plastic surgery and the majority of private clinics performing mammoplasties in Denmark contribute to the registration in the DPB. Pre-operatively, women accepting registration fill in a questionnaire focusing on health and lifestyle factors. Also pre-operatively blood samples obtained with silicone-free materials are sought from all subjects. Surgical data, postoperative results and complications are registered during surgery and at postoperative visits. Within the DPB, all baseline and follow-up data are merged at the patient level, regardless of time since primary operation, and subsequent places of surgery and clinical follow-up. As of April 2004, a total of 6283 women had been enrolled in the DPB at the time of surgery; 4417 in the implantation cohort and 1866 in the breast reduction cohort.

Based on the studies included in this dissertation we conclude that the complication profile depends on indication for implantation (cosmetic versus reconstructive) and the operation type (initial versus subsequent). Following cosmetic implantation most adverse events are clinically insignificant. By contrast, women who undergo post-mastectomy breast implantation frequently experience local complications requiring surgical or medical intervention. Detailed information regarding risk of complications related to the specific indication should be an essential part of the information to women considering breast implantation.

The prospective, nationwide registration of pre-, peri- and post-operative data allows for timely evaluation of potential safety concerns, and serves as a unique basis for research and follow-up of patients after surgery. Our prospective epidemiological studies are among the first on current implant devices and surgical techniques. The studies evaluate risk factors of relevance for clinicians and provide detailed, scientific information that may be highly relevant for future implant recipients.