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Aesthetic and oncologic outcomes after one-stage immediate breast reconstruction using a permanent biodimensional expandable implant

A. Agusti, A. Ward, C. Montgomery, K. Mohammed, G.P.H. Gui*

Academic Surgery (Breast Unit), Royal Marsden NHS Foundation Trust, Fulham Road, London SW3 6JJ, United Kingdom

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Summary *Introduction:* Immediate breast reconstruction (IBR) with implants is the commonest method of reconstructive surgery after mastectomy. With careful patient selection, a stable implant pocket can be created at the primary operation to decrease the likelihood of further surgery to adjust the reconstructed side. One-stage IBR is cost effective but failed procedures requiring early revision may be costly as permanent expanders are expensive.
Methods: Data were prospectively collected on all women undergoing a planned one-stage immediate breast reconstruction between 1997 and 2010. All patients had a Style 150 implant (Allergan, Marlow, UK). Descriptive statistics, Kaplan—Meier plots and, where applicable, Cox Proportional Hazards Regression was used to compare outcomes between groups.
Results: 249 planned one-stage IBRs were performed in 193 women, median age 45 years (range 20—77) with median follow-up of 101 months (range 27—159 months). 18/193 (9%) patients required implant exchange at 12 months and 66% of patients maintained their original implants at the time of census. Implant assisted latissimus appears to be robust even when radiotherapy was delivered. Disease free survival and breast cancer mortality were as expected for the breast cancer stage treated.
Conclusion: With careful patient selection, one-stage implant IBR using a definitive anatomical expandable implant provides good long term reconstruction and safe oncologic outcome. Direct to implant decision algorithms may be influenced by future developments in acellular dermal matrix technology, but the ability to create a single-stage stable implant pocket with good surgical technique should not be forgotten.

* Corresponding author. Tel.: +44 207 808 2783; fax: +44 207 808 2673.
E-mail address: gerald.gui@rmh.nhs.uk (G.P.H. Gui).

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Introduction

Skin-sparing mastectomy is a well-established surgical procedure.[1,2] In the UK, National guidance recommends that immediate breast reconstruction (IBR) should be discussed with all women having a mastectomy.[3] The first UK National Mastectomy and Breast Reconstruction Audit reported that in 2005 and 2006, 43% of women treated surgically for breast cancer underwent mastectomy of whom 11% had IBR.[4] The second Annual Report in 2009[5] identified that 48% of patients who required a mastectomy were offered immediate reconstruction, but only 3217 (21%) women who were offered IBR accepted. The third Annual Report in 2010[6] collected data on patient-reported outcome measures. 90% of women surveyed perceived that they had received appropriate information about their breast reconstructions. In women who had mastectomy only, 65% of women felt that they had received adequate information about IBR to make an informed choice.

The choice of suitable options for IBR should be a decision shared between patient and surgeon, taking into account expectations balanced against potential adverse effects, morbidity associated with donor sites and surgical recovery time. Breast reconstruction is a process of care and secondary procedures to optimize the breast mound and the need for further surgery over time may be necessary. How often such surgery may be required to maintain the aesthetic (such as addressing capsule formation and the natural aging of the contralateral breast) is essential information for patients to decide on reconstruction options. Implants remain the most common method of IBR. Two-stage implant reconstruction is a method utilizing tissue expansion with subsequent exchange for a definitive implant. One-stage IBR aims to create a definitive breast mound without the intent to return to the pocket for scheduled implant-exchange. Planned secondary procedures that do not involve the implant pocket may still be scheduled, including: scar revision, addressing skin folds, nipple reconstruction and surgery to the contralateral breast for symmetry. One-stage IBR is convenient for patients and cost-effective as it results in fewer hospital episodes. On the other hand, failure to create a stable pocket at the primary operation may be costly as permanent expandable devices are more expensive. A saline-based tissue expander is a more efficient method of creating a space under tension compared with an expandable implant.[7] Expandable implants have an anterior chamber of silicone to provide for better texture with a variable fill posterior chamber of saline to enable implant inflation or deflation. Little is known about the long-term implant exchange rates and secondary surgical procedures using a biodimensional anatomical permanent expandable implant. The aim of this study was to: 1) evaluate implant-exchange rates in women selected for one-stage reconstruction; 2) analyze the nature and timing of secondary procedures to optimize the affected and contralateral breast; and 3) define the long-term oncologic outcomes. The results of this study will be of interest to patients and surgeons as important information in implant surgery.

Materials, patients and methods

The Style 150 is a permanent expandable biodimensional anatomical implant. The device was developed by the McGhan Corporation that in 1985 became Inamed, and in 2006 was acquired by Allergan Inc (Irvine, California). The Style-150 has been widely used in the United Kingdom since its introduction in the mid-1990s.[8] Refinements to the device have occurred over the years but the essential properties remain the same. The implant comes in two heights for a given transverse breast width. There are two separate bladders, a fixed-volume silicone bladder containing a moderately cohesive silicone gel and a variable volume posterior chamber that is saline filled. The saline chamber is connected by a short tubing to a remote port that enables inflation or deflation as an outpatient.

One-stage breast reconstruction was defined as the intention to create a stable implant pocket without returning to revise the pocket or to exchange the implant. Patients were selected on the basis of their breast size, the likely available musculo-fascial cover, tissue properties of the soft-tissue envelope, skin elasticity of the trunk and the overall body habitus. Suitable options to one-stage implant based breast reconstruction were discussed with each patient. Patients who were not suitable for a planned one-stage implant reconstruction were offered a standard two-stage expansion technique. The surgical methods we used have been previously described in detail,[9] but a brief outline is provided here for ease of reference. Good quality, vascularized skin flaps are essential for a good one-stage implant reconstruction. For an implant-alone reconstruction, the pectoralis muscle was split 1 cm medial to the lateral free border. The pectoralis muscle was raised medially and the dissection taken inferiorly to lift the lower attachment off the rib cage to enter the plane deep to the anterior rectus sheath. The inferior dissection was taken to the desired inframammary crease height. The lateral pectoralis fibres were raised with the serratus anterior to provide lateral implant cover. Total musculo-fascial cover was achieved in all patients. When the breast skin envelope was to be reduced, a Wise-pattern approach was used. The lower mastectomy flap was de-epithelialized to cover the lower pole of the implant. When a latissimus flap was used, the implant was placed under the harvested myocutaneous tissue.

Examples of surgical outcomes after these forms of IBR are shown in Figure 1.

Data were prospectively collected on all women undergoing a planned one-stage immediate breast reconstruction between 1997 and 2010.

The introduction of acellular dermal matrices (ADM) entered clinical practice in our institution in the last 5 years, and patients who had these procedures were not included into this study. All patients had either the McGhan 150 or Allergan 150 device (hereafter referred to as the Style-150) as the definitive implant.

Where radiotherapy was indicated, the treatment would start a month after completion of chemotherapy (approximately 7 months after surgery) if chemotherapy was given. Where no chemotherapy was indicated, an approximate duration of one month elapsed between surgery and