DOI: 10.26717/BJSTR.2017.01.000432
Sanjay Warrier. Biomed J Sci & Tech Res

BIOMEDICAL Journal of Scientific & Technical Research

ISSN: 2574-1241

Case Report Open Access

Practicing changing cases using ICG technology in Breast Reconstruction

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Received: September 29, 2017; **Published:** October 12, 2017

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Abstract

SPY Elite technology utilizes ICG angiography and is a method of intra-operative tissue perfusion assessment. In breast reconstructive surgery, knowledge of skin flap perfusion can assist intra-operative decision making. Altering the surgical plan accordingly can decrease the risk of ischemic complications. The current case series includes six mastectomy and complex reconstructive operative cases that utilized SPY Elite technology. The cases demonstrate how SPY Elite assessment led to changes in intra-operative decision making in a group of predominantly high risk patients.

Keywords : Elite; Indocyanine Green; Breast Cancer; Mastectomy; Practice Changing

Abbreviations : ADM: A cellular Dermal Matrixes; DCIS: Ductal Carcinoma in-situ; DTI: Direct to Implant; GTN: Glyceryl Trinitrate; ICG: Indocyanine Green; MDT: Multidisciplinary Team; NIR: Near- Infrared; PMRT: Post Mastectomy Radio Therapy; SPY: Spy Elite

Introduction

This case series demonstrates how intraoperative SPY Elite (Novadaq Technologies Inc., Mississauga, Ontario, Canada) (SPY) assessment of skin flaps can influence decision-making in direct to implant (DTI) and expander-based reconstruction. One of the operative concerns with nipple and skin sparing mastectomy patterns is the perfusion of the remaining skin following removal of the vascular inflow from the breast [1,2]. Ischemic complications, particularly necrosis, can lead to failure of reconstruction, which in turn may require further surgical revision and result in delays to adjuvant therapies [3-5]. Additionally, skin complications may negatively impact the aesthetic result of the reconstruction [3,5]. The technique by which implant based reconstruction is performed has evolved to include the use of cellular dermal matrixes (ADM) to support the lower pole of the implant. The popularity of ADMs is predominantly due their ability to allow lower pole coverage in DTI reconstruction without donor site morbidity and allow for better filling of the breast envelope when expanders are used [6]. For an ADM to work it needs to integrate with the skin, which requires adequate blood flow [7]? The SPY Elite system allows for real time assessment of the skin flap perfusion post mastectomy. Knowledge of low perfusion areas within the skin can assist the surgeon in deciding the safest surgical approach for that patient. The purpose of this case series is to demonstrate examples of how SPY technology has led to specific changes in decision making in complicated and high-risk reconstructive cases.

Cases

Ms. CH is a 59 year old female with a background of wide local excision of the right breast for a 4cm area of high-grade ductal carcinoma in-situ in a rural centre. This was on a background of cosmetic augmentation two years prior with sub muscular placement of 300cc Silimed implants. Her wide local excision was carried out through an upper outer quadrant transverse incision. The final pathology demonstrated involvement of all peripheral margins. The decision was made for a nipple sparing mastectomy. The preoperative assessment predicted the implant volumes required to be between 350and 450cc. Mastectomy was performed through an infra-mammary incision. Once the appropriate sizer was in place in the breast pocket, the mastectomy skin flaps were assessed with the SPY Elite system. SPY analysis demonstrated an area of low perfusion inferior to the nipple, spanning seven centimeters. (Absolute values below five) (Figure 1A).

An intraoperative decision was made to delay the reconstruction by one week to allow for skin perfusion to improve. On return to theatre the following week the skin vascularity had clinically improved. This was clinically evident by the appearance of mild

erythema and brisk capillary return in the region of concern. Intra-operatively the sizer was re-inserted and SPY analysis demonstrated that the breast pocket had sufficient perfusion, with absolute values greater than 14 throughout the skin flap (Figure 1B). The patient was able to have a definitive implant directly inserted with inferior pole coverage provided by ADM (FLEX HD®human cadaveric ADM). The patient did not suffer any post-operative complications (Figure 1).

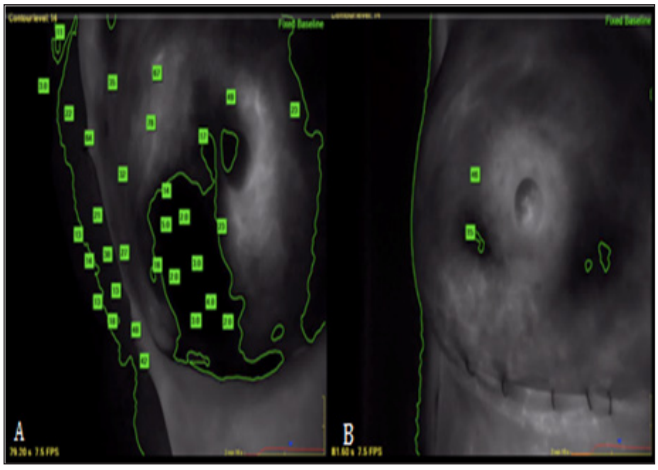

Figure 1 : A. SPY assessment of skin flap perfusion in initial surgery. Low perfusion below nipple with SPY values below five. B. Second surgery one week following initial surgery, breast regained perfusion. Images are taken at 80 seconds with contour level of 14 using ICG as fluorescent dye.

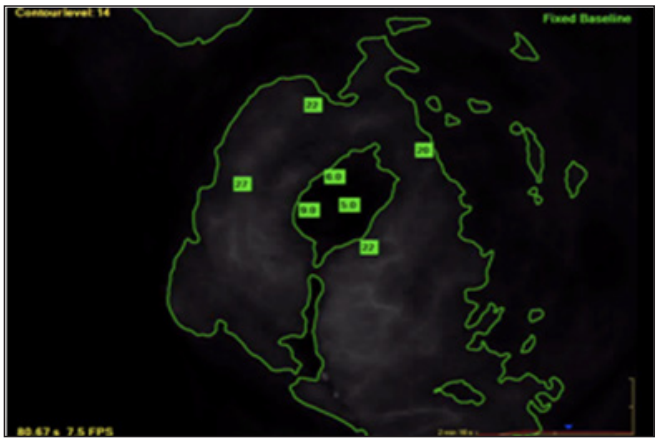

Figure 2 : SPY assessment demonstrates absolute perfusion values of 5-9 revealing a low blood flow region around the right nipple. These findings resulted in the expander being placed sub-pectoral. Image was taken at 80 seconds with contour level of 14 using ICG as fluorescent dye.

Ms. TA is a 32 year old female who presented with a large area of DCIS in her right breast and a biopsy proven positive axillary lymph node metastasis. Her hada background of bilateral wise pattern breast reductions and sub muscular implant placement four years prior to the diagnosis. The initial surgical plan was to perform a nipple sparing mastectomy axillary clearance and expander reconstruction with use of ADM for lower pole coverage. Mastectomy was performed through the vertical limb of her previous breast reduction. Intraoperative SPY assessment with a sizer in situ, revealed a low perfusion area (absolute values between 5 and 7) in a3x4 cm area around the nipple (Figure 2). Based on these perfusion values, an intraoperative decision was made to place a sub-pectoral expander. The 450cc expander was inflated with100 mL, allowing for partial filling of her redundant skin envelope. Postoperative assessment revealed that Ms. TA had micro-invasion the large area of DCIS and no further axillary metastasis. Her post-operative recovery was uncomplicated with a viable nipple (Figure 2).

Ms. PD is a 69 year old female who presented with wide spread high grade DCIS extending to the skin of the right nipple. She had thin skin, minimal ptosis; B cup sized breasts and was a non-smoker. The pre-operative plan was to perform a skin sparing mastectomy and a sentinel node biopsy, with or without ADM for lower pole coverage depending on intra-operative skin perfusion assessment. Following the skin sparing mastectomy, with a sizer in situ, the intraoperative absolute SPY values were between six and eight over an 8cm area in the inferior skin pocket (Figure 3). This was not apparent on clinical assessment. An intraoperative decision was made to place an expander sub-pectoral rather than using the ADM, in order to optimize vascularity to the lower skin flap and avoid complications related to lack of integration of. Her postoperative course was uneventful (Figure 3).

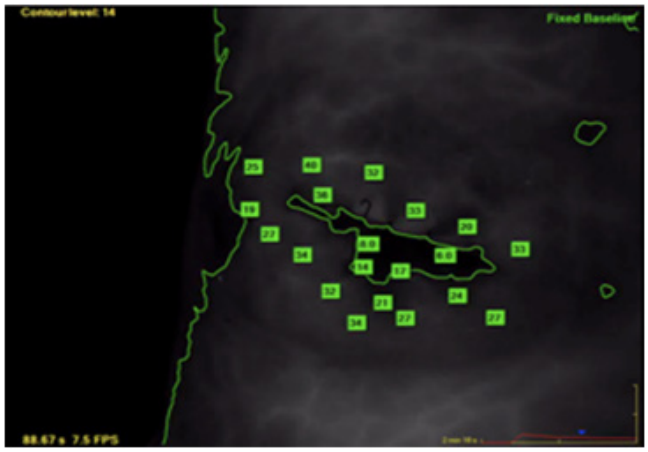

Figure 3 : Low perfusion in the inferior skin pocket of the right breast. Spy values of 6-8. Image was taken at 88 seconds with contour level of 14 using ICG as fluorescent dye.

Ms. ML is a 49 year old female who presented with lower outer quadrant multifocal Luminal A breast cancer of the right breast, with axillary nodal involvement. Her imaging demonstrated suspicious micro calcification sen compassing 40 percent of the breast. She had a background of cosmetic bilateral superior pedicle breast reduction five years prior. She had C cup sized breast with no ptosis due to her prior reduction. The pre-operative MDT consensus was that she was appropriate for mastectomy with skin and nipple preservation. The mastectomy was performed through the vertical limb of the prior reduction and the axillary dissection

was performed through a separate axillary incision. SPY was used to assess nipple perfusion with sizer in situ.

The breast envelope, apart from the nipple areola complex was well perfused at an early stage (30 seconds) in the assessment (Figure 4A). Perfusion at the nipple slowly increased with time, resulting in absolute values of 2-10 at 30 seconds and 5-15 at 50 seconds (Figure 4B). Ultimately, at 90 seconds the absolute values in the region of the nipple areolar complex were greater than 14 (Figure 4C). These late perfusion values allowed for nipple preservation to take place, with confidence that the risk of nipple necrosis was low. An expander was placed with ADM and inflated to 200mls. The patient had an uneventful post-operative course. There were no post-operative complications and had no delay to adjuvant therapies (Figure 4).

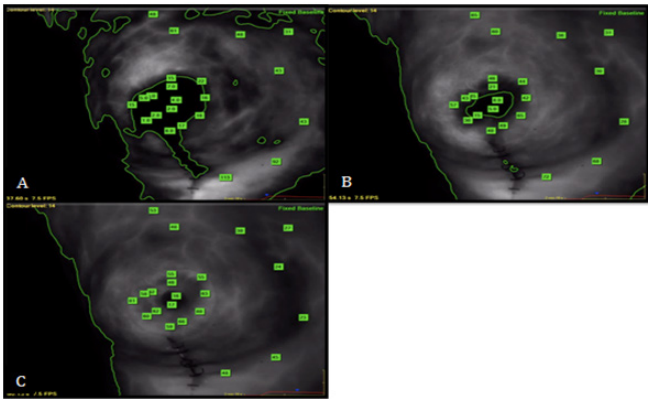

Figure 4 : A. SPY revealed that breast was well perfused at 37 seconds however perfusion was limited in nipple areolar complex (absolute values 2-10). B. SPY assessment demonstrates increasing perfusion in the nipple (absolute values 5-15). C. By 90 seconds breast envelope and nipple areolar complex are safely perfused (SPY values above 14). Imaging contour level of 14 using ICG as fluorescent dye.

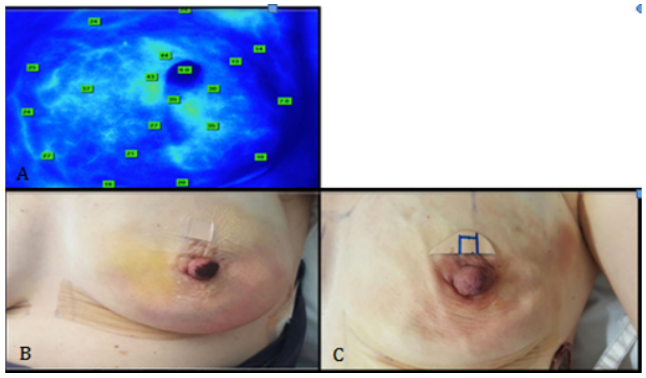

Figure 5 : A. SPY assessment of the left nipple revealed poor perfusion (absolute value of 9). Change to operative approach. Imaging contour level of 14 using ICG as fluorescent dye. B. Clinically evident tip epidermolysis of the nipple. C. Nipple survives post operatively.

Ms. EG is a 36 year old female with prior wide local excision through a peri-areolar incision she had completed chemotherapy and was considered to have a category 3 family history, without a gene mutation. On preoperative appraisal, she had minor ptosis with D cup sized breasts. She decided to undergo risk reducing bilateral nipple sparing mastectomy. Nipple sparing mastectomy was performed via infra mammary incisions. SPY assessment was performed with 450cc sizersin-situ and this demonstrated poor perfusion in the left nipple with an absolute value of nine. This perfusion deficit was not clinically apparent (Figure 5A & 5B). The surgical decision changed from DTI to an expander with ADM and 100mls of filling. In the early post-operative period a glyceryltrinitrate (GTN) patch was applied adjacent to the nipple areolar complex to improve local perfusion. She suffered some minor desquamation (Figure 5C), but not full thickness necrosis.

Ms. LG is a 26 year old female who presented with a 5cm Luminal B Her-2 negative cancer in her right lower breast. Clinically and on imaging the lesion appeared close to, but separate to the skin. The preoperative MDT discussion consensus was that she was appropriate for a skin sparing nipple sacrificing mastecto my with an expander reconstruction and ADM (Flex HD® human cadaveric ADM). Intraoperative dissection allowed for thin but good quality skin flaps with macroscropic clearance from the tumor. SPY assessment demonstrated low numbers (4-13 absolute number range) in the area where the tumor had been resected. An intraoperative decision as made to place a sub pectoral expander allowing for native tissue coverage in the area of concern. The Patient had no postoperative complications. The wound took two weeks to completely heal and Ms. LG then proceeded to adjuvant chemotherapy. We postulate that ADM integration would have been adversely affected leading to further delays in healing.

Discussion

Indocyanine green angiography (ICG) using the SPY Elite imaging system enables tissue perfusion to be assessed in real-time. It is one of different technologies developed to minimize ischemic complication by enhancing intra-operative decision making in breast reconstruction [8]. The ICG fluorescence imaging system measures the fluorescence spectrum of the dye within a near- infrared (NIR) window [9]. This technique has demonstrated a high sensitivity (83%) and specificity (97%) for visualizing poor superficial blood flow [10]. The inherent characteristics of ICG facilitate its desirability for tissue evaluation. ICG has a good safety profile, is non-toxic and non-ionizing, and binds to serum albumin immediately, a property that is ideal for angiography. It also has a short plasma half-life (three minutes), allowing for repeat evaluation during the same operative procedure [11]. Upon excitation by NIR of 760 nm, ICG has an absorption maximum of 805 nm and an excitation maximum of 835 nm when bound to serum albumin [12].The NIR penetration depth is 3-5 mm. ICG cannot be used in patients who have iodide allergies due to the risk of anaphylaxis. However, the incidence of anaphylaxis is low at a rate of 1 in 42,000 [12].

The SPY Elite system produces absolute values that represent blood perfusion according to its fluorescence emission. Based on a review of the literature that reported metrics generated by SPY technology for surgical practice, an absolute value range of 13-24 was accepted as a marker in predicting the future potential

for tissue necrosis [13-16]. Based on this data and our clinical experience, we utilize an absolute value of 14 as a surrogate marker of safely perfused skin. The fluorescent images and the absolute perfusion value produced by SPY can complement clinical judgment in determining areas of poor perfusion. The surgeon can then make real time changes to their surgical plan based on this integrated assessment of skin perfusion. This integrated decision led to a slightly different modification in the different cases within this series.

In case 1, the perfusion assessment demonstrated a large area with very low readings, likely due to recent surgery. Consequently, the surgery was delayed by one week, because it was felt that any additional pressure on this area from an expander could result in skin necrosis.

Cases 2, 3and 6 demonstrate situations where there was change of the intra-operative plan from use of ADM to sub muscular expander placement. In these cases, the low perfusion readings spanned a smaller area and were not as low as those in case 1. Hence it was postulated that ADM integration would have been adversely affected, but that an expander with native tissue cover could be safely placed. The reason for flap hypo-perfusion was likely to be due to previous surgery, poor quality skin, and thin flaps in cases 2, 3 and 6 respectively. However, the perfusion pattern was similar in these patients and hence the same intra-operative decision was made.

Case 4 demonstrated that late perfusion of a flap is still a reliable indicator of skin viability. The initial low perfusion values in the NAC region were thought to be low due to the previous breast reduction; however the late values were consistent with safe perfusion. This correlated with the uncomplicated clinical course despite the use of ADM.

Case 5 showed that a small area that is poorly perfused does not need to negate reconstruction if there is good peripheral inflow of blood. We also used a GTN patch to enhance local perfusion by its vasodilatory effect [17].

A decision support tool such as SPY Elite has the potential to impact surgical practice by assisting decision making that influences the safety of breast reconstruction. It is a useful aid to clinical assessment and particularly useful in high risk or complex reconstructive cases.

Conflict of Interest

The authors report no known conflict of interest.

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