An observational study comparing the SPY-Elite® *vs.* the SPY-PHI QP system in breast reconstructive surgery

Elisabeth Lauritzen^, Rikke Bredgaard, Christian Bonde, Lisa Toft Jensen, Tine Engberg Damsgaard^

Department of Plastic Surgery and Burns Treatment, Copenhagen University Hospital, Copenhagen, Denmark

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Correspondence to: Dr. Elisabeth Lauritzen, MD, PhD-student. Department of Plastic Surgery and Burns Treatment, Copenhagen University Hospital, Blegdamsvej 9, DK-2100 Copenhagen, Denmark. Email: slau0089@regionh.dk.

Background: Indocyanine green angiography (ICG-A) can be applied to visualize per-operative tissue perfusion. Perfusion cut-off values based on ICG-A are important in guiding the intraoperative decision making. Two modalities able to quantify relative tissue perfusion values exist: the SPY-Elite® and the SPY-PHI QP system. We conducted an observational study comparing the quantitative perfusion values of the SPY-Elite® and the SPY-PHI QP with the postoperative outcomes in breast reconstructive procedures.

Methods: Sixteen consecutive patients undergoing breast reconstructive surgery (20 breasts) were included. The SPY-Elite® and the SPY-PHI QP imaging systems were applied simultaneously during surgery. There exists no international consensus on cut-off values, therefore cut-off was set to 33% as previous reported by Moyer *et al.*

Results: Five patients had implant-based breast reconstruction, 4 oncoplastic techniques (volume displacement or replacement), 7 autologous tissues (2 pedicled latissimus dorsi flaps and 5 free deep inferior epigastric artery perforator flaps). In 4/16 cases (25%) results of the imaging systems were unequal in quantifying tissue perfusion. The SPY-PHI QP system yielded a sensitivity of 50%, specificity 77%, positive predictive value 25%, negative predictive value 91% and 73% accuracy. The SPY-Elite® had a sensitivity of 50%, specificity 100%, positive predictive value 100%, negative predictive value 93% and 93% accuracy.

Conclusions: Imaging modalities assessing and quantifying real-time tissue perfusion is a valuable tool in breast reconstructive surgery. We tested the SPY-Elite® and the SPY-PHI QP using a perfusion cut-off value of 33%. The results were not comparable in assessing and quantifying tissue perfusion using the chosen cut-off value. Further studies investigating specific cut-off values for the SPY-PHI QP is needed.

Keywords: Breast reconstruction; indocyanine green angiography (ICG-A); SPY-imaging system; SPY-Elite®; SPY-PHI QP

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^ ORCID: Elisabeth Lauritzen, 0000-0003-1680-0953; Tine Engberg Damsgaard, 0000-0002-1627-9566.

Introduction

Imaging techniques visualizing the per-operative tissue perfusion has been used in plastic surgery for more than 2 decades (1-3). A well-known imaging modality is indocyanine green angiography (ICG-A) which can assist the surgeon in the intraoperative decision making by supplying information on real-time tissue perfusion (4,5). Recent studies have shown that the action taking upon applying ICG-A in breast reconstruction can lead to a decreased risk of postoperative complications including loss of reconstruction (6-9).

Multiple imaging systems are available including the PicoLinker wearable smartglasses (Westunitis Co., Ltd., Osaka, Japan) (10), Fluobeam Clinical System® (Fluoptics, Grenoble, France, https://www.fluoptics.com/), HyperEye Medical Systems® (Mizuho, Tokyo, Japan, http://www.mizuhomedical.co.jp/) and the SPY-Elite® Fluorescence Imaging System/SPY-PHI (Stryker AB, Malmö, Sweden, https://www.stryker.com/) (11).

Two different imaging modalities encompass the capability to assess and quantify the relative perfusion values, namely the SPY-Elite imaging system® and the SPY-PHI QP system (Stryker AB, Malmö, Sweden, https://www.stryker.com/).

The SPY-Elite Fluorescence imaging system®, which is one of the most commonly used systems, contains the SPY-Q-software which is able to quantify the relative perfusion and has been studied by several authors (9,12-15). Based on this system, Moyer *et al.* reported a cut-off value of 33% corresponding with a positive predictive value (PPV) of 88% and a negative predictive value (NPV) of 16% for mastectomy flap necrosis (15).

The SPY-QP® Fluorescence assessment software is an upgrade of the existing SPY Portable Handheld Imaging (SPY-PHI) system, and is the most recent fluorescence assessment technique with software able to quantify the relative perfusion (16). This upgrade, the SPY-PHI QP, consists of integrated software able to assess and quantify the relative tissue perfusion.

The SPY-QP® and the SPY-PHI, combined called SPY-PHI QP, is based on near-infrared (NIR) fluorescence that enables relative quantification of perfusion upon the per-operative intravenous injection of indocyanine green (ICG) (17).

As this technology is constantly evolving, how does the surgeon interpret the per-operative data on the quantitative perfusion?

May the two imaging modalities and quantification systems be equated? How can we translate the relative perfusion data into clinical decision making?

The purpose of this study was to compare the relative tissue perfusion and the quantitative values of the SPY-PHI QP and the SPY-Elite®. Secondly to investigate if the per-operative assessment of the perfusion corresponded to the postoperative events evaluated at 4-week follow-up. We present the following article in accordance with the STARD reporting checklist (available at https://abs.amegroups.com/article/view/10.21037/abs-21-123/rc).

Methods

Patients

Sixteen consecutive patients undergoing either an immediate or delayed breast reconstructive procedure (including breast conserving surgery (BCS), implant-based- or autologous breast reconstruction using pedicled- or free flaps [deep inferior epigastric artery perforator flaps (DIEP-flaps) and latissimus dorsi muscle flaps (LD-flaps)].

Patients were included prospectively from March to April 2021 at the Department of Plastic Surgery and Burns Treatment, Copenhagen University Hospital.

Patient demographics are depicted in *Table 1*. Inclusion criteria were: patient >18 years of age and deemed suitable for a breast reconstructive procedure by the consultant plastic- and breast surgeon. Patients allergic to iodine, pregnant or breastfeeding were excluded.

Data collection

This is an observational study of two imaging modalities already approved for clinical use. There has not been any intervention. Therefore, ethical approval was not required. All data was obtained and stored anonymously. Inform consent was not required. This observational study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

ICG-A methodology

We applied the SPY-PHI QP and the SPY-Elite imaging system® per-operatively on oncoplastic and breast reconstructive procedures, and compared the relative perfusion values of both imaging systems with postoperative complications evaluated 4-week after surgery.

In implant-based immediate breast reconstruction per-operative ICG-A was performed subsequent to mastectomy upon insertion of an appropriate sizer and after temporary

Table 1 Patient characteristics

Characteristics	Values
No. of patients	16
Age (mean), years	52
BMI (mean), kg/m^2	24.8
Immediate breast reconstruction, n	7
Delayed breast reconstruction, n	5
Oncoplastic procedure, n	4
Implant-based reconstruction, n	5
Autologous reconstruction, n	7

BMI, body mass index.

closure of dermis. For the oncoplastic procedures, ICG-A was performed after excision of pathological tissue, before reshaping the breast with replacement- or displacement techniques.

In the autologous reconstructions (pedicled- and free flaps), ICG-A was performed after the flap was raised with complete pedicle dissection and still located at the donor-site.

Regardless of the chosen procedure, an intravenous bolus administration of ICG (VerdyeÒ 5 mg/mL) of 2.5 mg/mL was followed by a 10 ml flush with normal saline. The surgeon refrained from using vasoconstrictive agents (i.e., Klein's fluid-Ringer's lactate, lidocaine and adrenaline) avoiding potential bias of the ICG-A assessment.

The SPY-Elite® and the SPY-PHI QP system were applied simultaneously, and perfusion values scored and quantified by the same operator. Quantification of the relative values was done after 45 seconds of recording (15).

Adjacent healthy tissue outside the surgical field was used as reference point (100% perfusion).

Both imaging modalities were thoroughly tested before initiating the study, minimizing possible user error and device learning curve.

Cut-off perfusion value

When assessing tissue perfusion, the surgeon relies on clinical evaluation which may be supplemented using an imaging modality such as the SPY-PHI QP® or the SPY-Elite imaging system®. ICG-A showing hypoperfusion has been reported to correlate with postoperative complications, making accurate and reliable intraoperative assessment an important factor in identifying areas in risk of potential hypoperfusion (9,14,18-21).

To make the per-operative assessment of the relative tissue perfusion and quantification clinically relevant, there is a need for a cut-off value.

Though investigated by several authors, determining specific cut-off for relative perfusion values remains to be identified (12-15,22-24). For mastectomy skin flap necrosis, Moyer *et al.* suggested a cut-off value of 33% with a PPV of 88% and NPV of 16% (15).

There has not been reported a specific cut-off value for autologous breast reconstruction (6,18,25-28). We used the cut-off value of 33% as described by Moyer *et al.* (15).

Quantification using the SPY-Elite® software

The SPY-Elite® camera is positioned 20 cm perpendicular to the tissue of interest. All light in the OR turned off, and recording of the angiography activated subsequent to injection of ICG and flush with saline. Recording was terminated after reaching 60 seconds. Quantification of the relative perfusion was performed after 45 seconds of recording (15).

For the implant-based breast reconstruction, the breast was divided into 4 quadrants (upper lateral, lower lateral, upper medial and lower medial quadrant). Quantification marks (%) were set in each quadrant and an average perfusion quantification (%) calculated resulting in 4 relative perfusion values (%) for each breast (*Figure 1*).

For the oncoplastic procedures and autologous breast reconstruction, relative perfusion marks were set in the circumference and across the surface, assessing the perfusion of the entire flap (*Figure 2*).

Quantification using the SPY-PHI QP software

This system contains 4 different visualization modes (4 fluorescence imaging modalities) (*Figure 3*) (16). We applied the SPY contrast mode in order to compare the angiographies and to assess the relative perfusion values (% tissue perfusion).

After activating the SPY-PHI QP system, the handheld camera is positioned 10–40 cm above the tissue of interest. Detection of fluorescence initiates an automatic timer on the SPY-PHI QP monitor and a red icon appears to signal onset of fluorescence.

Relative values (% tissue perfusion) can be assessed when the fluorescence signal has stabilized and a green icon appears on the monitor. Quantification mode is enabled, and a small square with a relative number and percentage

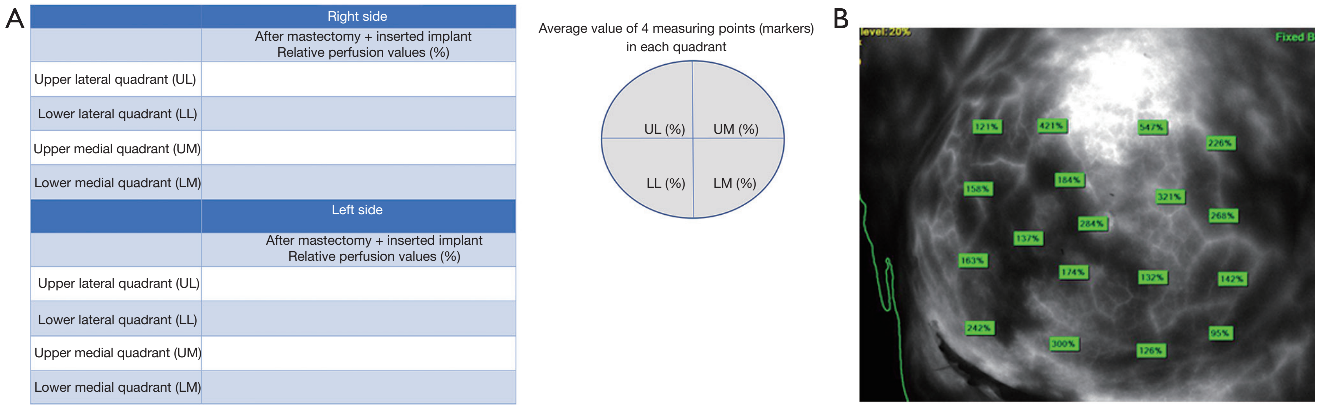


Figure 1 Schematic illustration and clinical example of the per-operative quantification of perfusion using the SPY-Elite® for implant-based breast reconstruction. (A) How the SPY-Elite® system was used in implant-based breast reconstruction. Four marks (%) were set in each quadrant of the breast and an average perfusion (%) were calculated resulting in 4 relative perfusion values (%) for each breast. (B) Per-operative image of ICG-A showing application of the SPY-Elite® system on an implant based breast reconstruction (right breast). ICG-A, indocyanine green angiography.

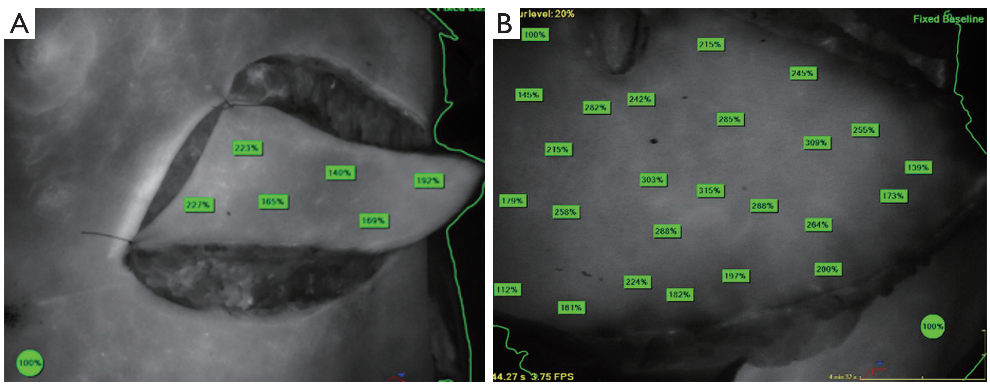


Figure 2 Clinical example on how the SPY-Elite was applied to (A) an oncoplastic breast reconstruction, and (B) an autologous breast reconstruction. Relative perfusion marks were set in the circumference and across the surfaces, assessing the perfusion of the entire flaps. (A) Per-operative image of ICG-A showing application of the SPY-Elite® system on an oncoplastic breast reconstruction (LICAP-flap). (B) Per-operative image of ICG-A showing application of the SPY-Elite® system on an autologous free flap breast reconstruction with a DIEP-flap. LICAP-flap, lateral intercostal artery perforator flap; DIEP-flap, deep inferior epigastric artery perforator flap; ICG-A, indocyanine green angiography.

will appear. To obtain relative tissue perfusion, the cursor is set at a reference point (100% perfusion) and the handheld camera is then positioned back above the tissue of interest.

Video 1 shows how the SPY-PHI QP system was applied in implant-based breast reconstructions. For the autologous breast reconstructions, the SPY-PHI QP was applied in a clock wise manner and crossing the tissue in all directions encompassing the total area of the flap (*Figure 4*, *Videos 2,3*).

Endpoints

Our primary endpoint was to compare the per-operative quantitative perfusion values of both imaging systems. The clinical endpoints were incidence of per-and postoperative complications (including mastectomy skin flap necrosis, flap necrosis, fat necrosis and loss of reconstruction). Major complications were defined as complications requiring surgery/debridement in local- or general anesthesia.

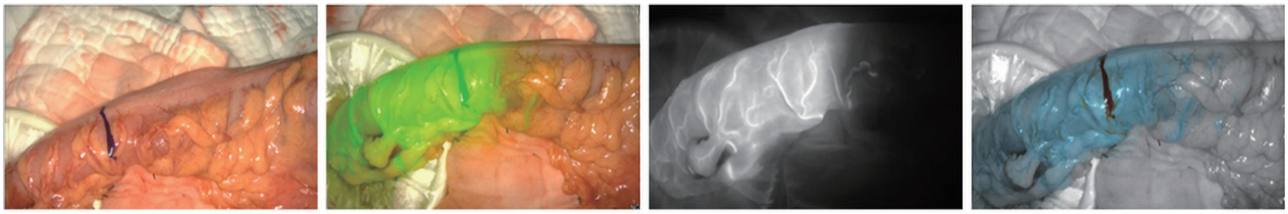
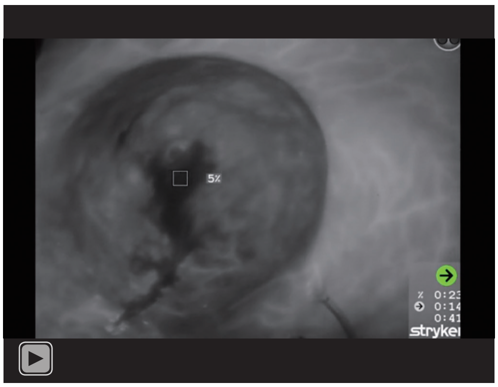


Figure 3 SPY-PHI QP visualization modes. From https://www.stryker.com/us/en/endoscopy/products/spy-phi.html.



Video 1 Video demonstrating use of the SPY-PHI QP measuring relative perfusion values in an implant-based breast reconstruction (right breast).

Video 2 Video demonstrating use of the SPY-PHI QP measuring relative perfusion values in autologous breast reconstructions: illustrated by a latissimus dorsi muscle flap.

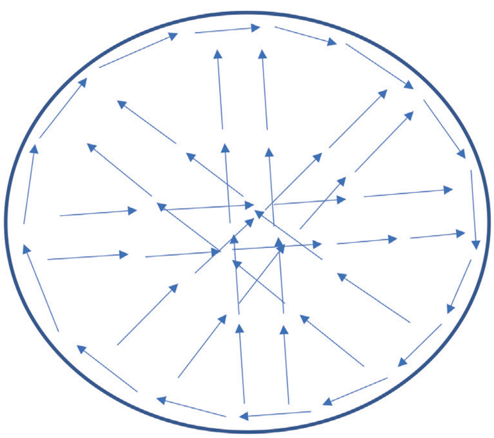
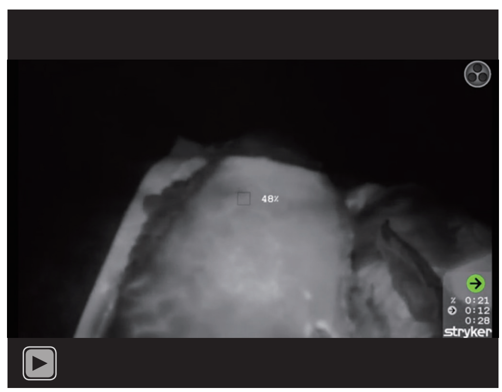


Figure 4 Application of the SPY-PHI QP in autologous breast reconstructions (pedicled- and free flaps). The imaging modality was applied in a clock wise manner and crossing the tissue in all directions to encompass the total area of the flap.



Video 3 Video demonstrating use of the SPY-PHI QP measuring relative perfusion values in autologous breast reconstructions: illustrated by a deep inferior epigastric artery perforator flap (recording from left side).

Table 2 Comparison of quantification by the SPY-Elite® and the SPY-PHI QP—4 weeks follow-up

Case no.	Type of breast reconstruction	I/D	U/B	SPY-Elite® quantification	SPY-PHI QP quantification	Equal quantification?	Eventful healing	Complications
1	Implant-based	I	U	>33%	15–17%	No	–	None
2	Implant-based	I	B	Area with hypoperfusion <33%	Area with hypoperfusion 5–10%	No	+	Breast hematoma, bilat. + bilat. skin necrosis
3	Implant-based	I	B	>33%	<33%	No	–	None
4	Implant-based	I	U	>33%	>33%	Yes	–	None
5	Implant-based	I	B	>33%	>33%	Yes	–	None
6	Oncoplasty D	I	U	>33%	>33%	Yes	–	None
7	Oncoplasty R	I	U	88–104%	28–34%	No	–	None
8	Oncoplasty D	I	U	>33%	>33%	Yes	–	None
9	LD-flap	D	U	>33%	>33%	Yes	–	None
10	LD-flap	I	B	>33%	>33%	Yes	+	Hematoma bilat. breast + back + skin necrosis left breast
11	Oncoplasty R	I	U	>33%	>33%	Yes	–	None
12	DIEP-flap	D	U	>33%	>33%	Yes	+	Postop. PE + melaena*
13	DIEP-flap	D	U	>33%	>33%	Yes	–	None
14	DIEP-flap	I	U	>33%	>33%	Yes	–	None
15	DIEP-flap	D	U	>33%	>33%	Yes	–	None
16	DIEP-flap	D	U	>33%	>33%	Yes	–	None

Total no. of breast: 20. Cases organized by type of surgery. *, melaena due to gastritis. I/D, immediate breast reconstruction, delayed breast reconstruction; U/B, unilateral, bilateral; oncoplasty D/R, D = volume displacement technique, R = volume replacement technique; DIEP-flap, deep inferior epigastric artery perforator flap; LD-flap, latissimus dorsi muscle flap; postop. PE, postoperative pulmonal embolism.

Minor complications were defined as complications treated conservatively (seroma, small hematoma etc.). All patients were followed up 4 weeks after breast reconstruction.

Statistical analysis

Perfusion measurements of the two imaging modalities were performed and compared by calculating sensitivity, specificity, PPV, NPV and accuracies.

Results

Sixteen consecutive patients (20 breasts) were included. Mean age was 52 years (range, 35–74 years). Mean body mass index (BMI) was 24.8 kg/m^2 (range, 19.1–29.6 kg/m^2). One patient was an active smoker until the day of surgery. Seven patients had immediate breast reconstruction, 5 delayed reconstruction and 4 underwent oncoplastic surgeries. Autologous reconstructions constituted 7/16 patients (5 DIEP-flaps and 2 LD-flaps). Radiation was the most frequent adjuvant therapy (9/16 patients) (*Table 1*). The surgical indication was predominantly breast cancer, with 12/16 patients having sentinel node biopsy performed during the oncologic and reconstructive surgery.

Thirteen patients had uneventful healing within the 4-week follow-up. All patients attained reconstructive surgery of the breast and there was no loss of reconstruction.

At 4-week follow up, 3 patients had experienced complications (*Table 2*, Case no. 2, 10 and 12). Case no. 2 developed bilateral full thickness peri incisional skin necroses treated with debridement in local anesthesia, she also had a hematoma evacuated by ultrasound. Case no. 10 developed seroma on both breasts and on the donor-site, treated by ultrasound guided drainage. Case no. 10 also

Table 3 SPY-PHI QP sensitivity, specificity, positive and negative predictive values using cut-off value of 33%

SPY-PHI QP quantification	Eventful healing	Uneventful healing	Number of patients
SPY-QP perfusion <33%	1	3	4
SPY-QP perfusion >33%	1	10	11
Total	2	13	15

Sensitivity: 0.50; specificity: 0.77; PPV: 0.25; NPV: 0.91; accuracy: 0.73. Case no. 12 excluded. PPV, positive predictive value; NPV, negative predictive value.

Table 4 SPY-Elite® sensitivity, specificity, positive and negative predictive values using cut-off value of 33%

SPY-Elite® quantification	Eventful healing	Uneventful healing	Number of patients
SPY-Elite® perfusion <33%	1	0	1
SPY-Elite® perfusion >33%	1	13	14
Total	2	13	15

Sensitivity: 0.50; specificity: 1; PPV: 1; NPV: 0.93; accuracy: 0.93. Case no. 12 excluded. PPV, positive predictive value; NPV, negative predictive value.

Video 4 Per-operative video demonstrating the simultaneous use of SPY-Elite® and the SPY-PHI QP® systems on an implant-based breast reconstruction.

developed unilateral skin necrosis treated conservatively. One patient (Case no. 12) developed a postoperative pulmonary embolism (PE), melaena and gastritis. She was treated with standard protocols.

Total incidence of complications per breast were 2 major complications and 5 minor complications. Case no. 12 was excluded due to postoperative complications not related to the relative tissue perfusion of the breast.

The quantitative perfusion values of the SPY-Elite® was compared with the SPY-PHI QP system (*Table 2*). Measurements were not equal in 4/16 cases (25%), with the SPY-PHI QP quantification being substantially lower than the SPY-Elite®.

One of the 4 cases (25%) where the quantification systems were unequal, developed major complications (Case no. 2, *Table 2*).

There exists no gold standard to investigate per-operative tissue perfusion. To compare the perfusion measurements of the two modalities; sensitivity, specificity, PPV, NPV and accuracies were calculated.

Using a quantitative cut-off value of 33%, the SPY-PHI QP yielded a sensitivity of 50%, specificity 77%, PPV 25%, NPV 91% and accuracy of 73% (*Table 3*). The SPY-Elite® had a sensitivity of 50%, specificity 100%, PPV 100%, NPV 93% and accuracy of 93% (*Table 4*).

Discussion

The present paper describes a pilot study comparing the perfusion assessment and quantification software, applying the SPY-Elite® and the SPY-PHI QP simultaneously (*Video 4*). The main aim was to investigate if the two software systems can be applied and perfusion values interpreted interchangeably. Secondly, to compare the per-operative quantitative perfusion assessment with postoperative outcomes 4-week after surgery.

When looking at the overall accessibility of the SPY-Elite® and the SPY-PHI QP, both systems are user friendly using near-infrared laser and intravenous administration of ICG to obtain the per-operative angiographies.

Figure 5 SPY-PHI QP hand-held camera. From https://www.stryker.com/us/en/endoscopy/products/spy-phi.html.

Figure 6 SPY-Elite Imaging system®. From https://www.stryker.com/us/en/endoscopy/products/spy-elite.html.

The SPY-PHI QP is the newest addition in the line of imaging systems, and has several features. The camera is lightweight, handheld and equipped with relevant control buttons enabling the surgeon to use the camera without leaving the surgical field of interest. The hand-held camera makes the angiography easy to conduct and the user can easily move the camera around (*Figure 5*).

According to the manufacturing company (Stryker AB, Malmö, Sweden, www.stryker.com), the relative values (% tissue perfusion) ought to be independent of the contour of the tissue. Though, in our experience, the relative percentages changed if the camera was not held horizontally to the surface.

In contrast to the SPY-Elite® system, the SPY-PHI QP can be applied independently of the lighting in the operating room, limiting possible interferences with the surgical team.

The SPY-PHI QP-system contains different visualization modes, however only the contrast mode/fluorescence mode was applied in this study.

The SPY-Elite® camera is attached to an arm located on the machine (*Figure 6*). Therefore, the recordings are more inflexible and rigid, though we found the results to be steadier and more comparable when compared to the hand-held recordings of the SPY-PHI QP.

The SPY-Elite® system has a built-in function with laser dots indicating the optimal distance from the tissue of interest. Whereas the SPY-PHI QP is held 10–40 cm from the tissue to obtain optimal recording, difficult to apply in a clinical setting (16,17).

The flexible distance interval of 10–40 cm results in a larger field of vision when using the SPY-PHI QP (*Figure 7*).

Figure 7 Per-operative simultaneous use of the SPY-Elite® and the SPY-PHI QP® systems.

To obtain the quantification of the relative tissue perfusion, the user has to set a reference value (100% tissue perfusion) on e.g., the sternum/thorax or adjacent healthy tissue. When setting the 100% reference using the SPY-PHI QP, the camera needs to be relocated to the reference tissue outside the surgical field which changes the visual field.

After obtaining the 100% reference point, the camera is moved back to the surgical site which can interrupt assessment of perfusion assessment.

Overall, in our experience, the SPY-Elite® is superior in availability, ease of use and clinical applicable assessment of tissue perfusion.

Several authors have investigated cut-off values using the SPY-Q software (12-15). In implant-based breast reconstructions, Diep *et al.* applied a relative tissue perfusion cut-off <20% and Mattison *et al.* used contour values (10%, 15% and 20%) as cut-off values (29,30). Two studies reported a relative tissue perfusion <33% as threshold for tissue excision (15,31).

In autologous reconstruction one study by Wu *et al.* reported a cut-off value of 25% (32), while Alstrup *et al.* used 33% (18). Use of absolute perfusion values instead of relative perfusion have also been reported (12,13,33).

Since there exists no international consensus on specific cut-off values, we applied the relative perfusion cut-off value of 33% as reported by Moyer *et al.* (15,22-24).

Table 2 shows the quantitative measurements for each patient using both SPY-systems. Measurements were not equal in 4/16 cases (25%), but in 12/16 (75%) cases both systems quantified the perfusion above the cut-off value of >33%.

This finding could indicate that though the quantitative measurements of the two imaging systems may not be equated using a 33% cut-off, both systems are clinically applicable in assessing the per-operative perfusion.

Tables 3,4 shows the calculated sensitivity, specificity, PPV and NPV of the SPY-PHI QP and the SPY-Elite® system, respectively.

Overall, the results show that the two quantification software systems are not comparable when using a cut-off value at 33%. The SPY-PHI QP-system yielded a sensitivity of 50% with a PPV of 25%, indicating a low ability to identify cases with perfusion <33% and a corresponding low probability of finding actual cases with hypoperfusion. There was a high specificity of 77% with NPV of 91% indicating high ability to identify cases with sufficient perfusion.

The SPY-Elite® system yielded an equal sensitivity of 50% but with a PPV of 100%, indicating that when the SPY-Elite® detects an area with perfusion <33%, there is a probability of actual hypoperfusion of 100%. The specificity was 100% with an NPV of 100%.

As per standard from the paper by Moyer *et al.*, these results indicate that the SPY-Elite® quantification system equals more valid results that the SPY-PHI QP system, when using a cut-off value of 33% (15).

The SPY-PHI QP had an accuracy of 73%, with the corresponding accuracy for the SPY-Elite® system being 93%. These results indicate that the two quantification software systems cannot be equated, and that we do not know the correct cut-off value for the SPY-PHI QP yet.

The risk equating and interpreting the results of the two systems using a cut-off value of 33%, would result in a substantial risk of (I) not identifying the true cases with hypoperfusion, (II) overestimating areas with hypoperfusion when using the SPY-PHI QP—with a risk of removing viable tissue.

The findings of this observational study support the conclusion, that these 2 quantification systems are not to be used and interpreted equally, though further studies including a larger sample size is needed.

Limitations

This study was conducted as a pilot study on a relatively small number of cases including several different breast reconstructive procedures with different effects on the vascularity. The small sample size and heterogeneity of the cases may limit the conclusions to be drawn from this study and therefore conclusions are suggestive rather than conclusive.

The complications in Case no. 2, 10 and 12 (postoperative hematoma and pulmonary embolism) occurred postoperatively and could possibly have led to decreased perfusion and complications, independently of the per-operative ICG-A.

This study is limited due to the observational and comparative design, and especially due to the small number of patients making the need for further studies with a greater sample size even more essential.

This is the first study to describe a head-to-head comparison of the two existing imaging devices (SPY-Elite imaging system® and the SPY-PHI QP system) able quantify relative tissue perfusion based on ICG-A applied on breast reconstructive surgery.

Conclusions

Using ICG-A for perfusion assessment and quantification is becoming increasing more popular in reconstructive surgery. A new edition to the imaging software systems is the SPY-PHI QP quantification software system.

This paper describes an observational pilot study comparing the SPY-Elite® with the SPY-PHI QP comparing perfusion assessment and quantitative perfusion values compared to postoperative complications.

The two imaging systems may not be applicable using the same cut-off value. Therefore, further studies investigating specific cut-off values for the SPY-QP is needed.

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Footnote

Reporting Checklist: The authors have completed the STARD reporting checklist. Available at https://abs.amegroups.com/article/view/10.21037/abs-21-123/rc

Data Sharing Statement: Available at https://abs.amegroups.com/article/view/10.21037/abs-21-123/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://abs.amegroups.com/article/view/10.21037/abs-21-123/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This is an observational study of two imaging modalities already approved for clinical use. There has not been any intervention. Therefore, ethical approval was not required. All data was obtained and stored anonymously. Inform consent was not required. This observational study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

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