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The development of a low cost 3D surface imaging system to measure breast volume: defining minimum standards using an adapted Delphi consensus study

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Background

Breast reconstructive surgery has become an accepted part of the patient pathway for breast cancer patients requiring mastectomy. Yet the UK National Mastectomy and Breast Reconstruction Audit (2011)[1] identified that one in four women were not satisfied with how their unclothed breasts looked after delayed reconstructive surgery. Women with an intact breast after surgery are generally referred for whole breast irradiation, radiotherapy increases the risk of these women developing breast oedema. Difficulties in diagnosing breast oedema mean many patients live unnecessarily with its dehabilitating, long-term effects.

Three-dimensional (3D) imaging technologies provide non-contact measurements of the breast which are important for breast reconstruction and breast oedema diagnosis (distances, volumes etc.). Current commercial systems are prohibitively expensive and not in widespread use. The manual measurements which are often used to plan reconstructive surgery and assess breast oedema development can result in unsatisfactory reconstruction and mis-diagnosis.

The aim of this project was to develop consensus on the minimum requirements of a 3D surface imaging system from key stakeholders in breast cancer treatment – providing a specification for future system development.

This consensus study focussed on the following questions:

1. What is an acceptable cost?
2. What key features are required?

3. What type of data would be useful for practitioners and patients to maximise patient outcomes?

4. What accuracy is required to be useful in clinical practice?

Method

An adapted Delphi consensus method was employed to elicit views of key professionals and user representatives. Using a questionnaire based approach, consenting participants were asked to provide opinions on product and data requirements of a 3D surface imaging system for use in breast reconstruction and breast oedema diagnosis. Two questionnaire rounds were used. A Delphi approach is useful for structuring group communication and developing consensus and has been used in multiple cancer studies [2-4]. They can be small, medium or large with sample sizes ranging from n=15 to n=62 reported in the health literature [2-5].

Round 1 was information generating; the outcomes of the first questionnaire were used to develop a series of statements for respondents to rate in round 2. Each question had fixed responses as well as the opportunity to provide free text ensuring responses reflected the participants' views. The round 1 survey was pilot tested using staff from the Host Institution. The round 1 panel (n=36) was a purposive sample of professionals with expertise in breast cancer care, including:

- Lymphoedema specialists (n=7)

- Lymphoedema services manager (n=1)

- Radiation therapists in a breast cancer role (n=9)

- Breast surgeon (n=1)

- Oncoplastic breast surgeons (n=10)

- Plastic surgeons (n=1)

- Service users (n=7)

Round 2 focussed on professionals with expertise in surgery and lymphoedema (i.e. oncoplastic breast surgeons, plastic surgeons and lymphoedema specialists n=16) to ensure that the panel had knowledge of the importance and desirability of specific product specifications. A 5-point Likert scale was used with 22 items across 3 criteria (Design Characteristics (DC), Accuracy (A), and Patient Positioning (PP)). Participants were asked to rate each item for importance, desirability and feasibility.

Ethics
The study was approved by Sheffield Hallam University health and social care research ethics subcommittee.

Data Analysis
The importance, feasibility and desirability scores were summed as the starting point for round 2 analyses. This allowed a more detailed analysis to be undertaken even though this involved handling nominal level data as interval data. The mean score provided an opportunity to prioritise those items that were considered by the 2nd panel to be critical. Consensus was assessed using measures of internal consistency (Cronbach Alpha) and assessment of agreement (intra-class correlation). Product specifications were prioritised using the mean score for importance, desirability and feasibility (see Table 1). Items considered most important/desirable for product development were identified using these mean scores.

Results

Table 1 shows individual criteria in order of priority (as determined by the mean scores for importance and desirability) across the three criteria (DC, A, and PP). The intra class correlation coefficients show good agreement between panel members for importance of measurement characteristics, importance, desirability and feasibility of practicality characteristics and positioning points.

Conclusions

This consensus study has been used to develop a product specification for a low cost 3D surface imaging system. Using the mean scores as a way of prioritising characteristics, a system should be able to:

- Calculate breast volume with an accuracy of +/- 5%

- Detect a volume difference of 25cc and over

- Measure distances with an accuracy of ≤5mm

- Be capable of capturing marks placed on the nipple, base width of the breast, lateral edges of the breast, the mid-line of the sternum, inframammary fold, and superior pole of the breast.

- Cost less than £10,000

- Fit a space $<4m^2$ and

- Produce 3D images that are easily manipulated without much prior experience.

Conflicts of interest: None

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Table 1 Accuracy, Design Characteristics and Positioning Points Required

Accuracy of Measuring Breast Volume (N=14)	Importance Mean (% agreement)	Desirability Mean (% agreement)	Feasibility Mean (% agreement)
Calculate Breast Volume	4.64 (93.3)	4.69 (93.3)	4.31 (86.7)
Calculate breast volume to within a level of accuracy of +/- 5%	4.36 (85.7)	4.46 (92.3)	4.15 (92.3)
Detect a volume difference of 25cc and over	4.36 (85.7)	4.46 (92.3)	3.92 (84.6)
Measure between distances on the patient's surface with an accuracy of 5mm or less	4.14 (71.5)	4.31(92.3)	4.08 (84.6)
Quantify changes in shape or size of the breast over time	4.07 (71.4)	4.23 (92.3)	3.92 (84.6)
Measure straight lines from points of interest	3.86 (60)	4.0 (92.3)	4.31 (92.3)
Indicate if changes in volume or size of the breast over time are within	2.79 (28.6)	3.15 (38.5)	3.0 (30.8)

normal menstrual cyclical differences

Cronbach Alpha/av ICC for Breast Volume	**0.81**	**0.638**	**0.688**
Design Characteristics (n=14)	**Importance Mean** (% agreement)	**Desirability Mean** (% agreement)	**Feasibility Mean** (% agreement)
Be Purchased for under £10,000	**4.5 (78.5)**	**4.62 (100)**	**4.17 (76.9)**
Fit a space $< 4m^2$	**4.5 (85.7)**	**4.46 (92.3)**	**3.75 (69.3)**
Produce 3D images that can be easily manipulated without much prior experience	**4.14 (78.6)**	**4.08 (92.3)**	**3.75 (76.9)**
Be portable	**4.07 (71.4)**	**4.38 (84.6)**	**3.58 (61.6)**
Be folded for storage	**4.0 (78.6)**	**4.23 (77.0)**	**3.67 (58.3)**
Be used by health care staff in a clinic with minimal training	**4.0 (78.6)**	**4.08 (84.6)**	**3.58 (69.2)**
Cronbach Alpha/av ICC for Practicality	0.816	0.915	0.923
Positioning Points for Scanning (N=13)	**Importance Mean** (% agreement)	**Desirability Mean** (% agreement)	**Feasibility Mean** (% agreement)
To aid treatment interventions and monitoring of changes in shape and			

size the scanner needs to be capable of…			
capturing marks placed on the nipple	**4.54 (92.3)**	**4.62 (100)**	**4.46 (92.3)**
capturing marks placed on Base width of the breast	**4.54 (92.3)**	**4.46 (92.3)**	**3.85 (61.6)**
capturing marks placed on Lateral edges of the breast	**4.46 (92.3)**	**4.54 (100)**	**4.08 (92.3)**
capturing marks placed on mid line of the sternum	**4.46 (92.3)**	**4.54 (100)**	**4.38 (92.3)**
capturing marks placed on Inframammary fold	**4.31 (84.6)**	**4.38 (92.4)**	**4.0 (69.3)**
capturing marks placed on superior pole of the breast	**4.31 (92.3)**	**4.46 (92.3)**	**4.0 (76.9)**
imaging the patient while standing	**3.92 (71.5)**	**4.31 (100)**	**4.31 (84.7)**
capturing marks placed on Suprasternal notch	**3.85 (76.9)**	**4.23 (84.7)**	**4.38 (92.4)**
capturing marks placed on mid point of the shoulder	**3.62 (61.6)**	**3.69 (69.2)**	**3.92 (76.9)**

Cronbach Alpha/av ICC for Positioning Marks	0.817	0.808	0.917

Likert scale scores 1-5 (Importance 5=very important to 1=most unimportant, Desirability 5= Highly desirable to 1= Highly undesirable, Feasibility 5=Definitely Feasible to 1=Definitely infeasible) % agreement refers to the percentage of panel members that selected 4 or 5 on the likert scale for each criteria.