

# How feedback from human subjects can enhance clinical performance of optical mammography

**N. Morris, J.C. Hebden, L.C. Enfield, A.P. Gibson, A. Sharma and V. Armstrong**

*Departments of Science & Technology Studies, Medical Physics & Bioengineering, & Department of Surgery, Royal Free and University College Medical School, University College London, Gower Street, London, WC1E 6TB, UK  
norma.morris@ucl.ac.uk*

**Abstract:** We report findings of a study aiming to improve research process and outcomes by eliciting detailed feedback on their experience from patient-volunteers taking part in early clinical evaluation of an optical breast imaging system.

©2007 Optical Society of America

**OCIS codes:** 000.1430 Biology and medicine; 170.3830 Mammography; 170.3880 Medical and biological imaging; 170.1610 Clinical applications

## 1. Introduction

We report here on a collaborative study between medical physicists and social scientists aiming to improve research process and outcomes by eliciting detailed feedback on their experience from patients and healthy volunteers taking part in early clinical evaluation of an optical breast imaging system.

The Biomedical Optics Research Laboratory at University College London (UCL) has undertaken a program of clinical tests to assess three-dimensional (3D) time-resolved optical tomography as a means of detecting and specifying breast disease [1,2]. Data is obtained using a 32-channel time-domain system which records the temporal distribution of transmitted light at up to 32 locations on the surface simultaneously in response to illumination by picosecond pulses of light at wavelengths of 780 nm and 815 nm. Images are reconstructed using the TOAST software [3].

Alongside this we have undertaken the collaborative study referred to above, consisting primarily of observation of tests and subsequent in-depth interviews with the human subjects taking part in the trial to elicit their experience of the system and their views on its acceptability to patients. We have obtained qualitative data on some 65 patient/volunteers, spanning 6 years, two different configurations of the patient/machine interface, and a range of technical and procedural improvements and changes. Some findings, relating to priorities, anxieties, performance, motivation, and the researcher-subject relationship, have remained remarkably consistent throughout these changes.

Our initial hypothesis was that qualitative data obtained from the test subjects would usefully complement the physical data collected during the clinical tests, and be of practical value in decision-making about design modifications, development priorities, and improving acceptability to patients. Moreover by engaging with volunteers, and attending to their views, the team would be actively implementing the ethical precept of 'respect for persons' thus contributing to a more satisfactory experience for volunteers. We aimed to test this hypothesis through a 3-part process:

- a) systematic collection and analysis of information from the volunteer human subjects on their experience;
- b) regular feedback of this information into the research and decision-making process;
- c) assessment of its impact on project development and program management.

## 2. The experimental protocol

For preliminary breast studies a conical fiber holder was constructed in the form of a series of rings supported by an adjustable frame [1]. The volunteer leant against the frame with either the left or right breast placed in the ring of fibers. The volunteer sat or stood, with her raised arms and head resting on a cushioned pad mounted on the top of the frame. Each scanning session lasted from 30-40 minutes, including the time required to position the patient/volunteer, and typically involved two separate scans of the volunteer and a calibration measurement.

Experience with this design showed that obtaining good contact between fibers and the breast was problematic, leading to difficulties in positioning volunteers and some additional discomfort to volunteers in sustaining the position for the duration of the test scan, and hence variable quality data. Consequently an alternative scanning mechanism was developed, which involves the volunteer lying prone on a bed with her breast inserted within a hemispherical cup built into the bed [2]. Thirty one optical fibers are supported within the surface of the cup. The

remaining space between the breast and the cup is filled with an intralipid-based fluid, which ensures excellent coupling between the fibers and the breast. The duration of the scanning sessions is reduced to 20-25 minutes by drastically reducing time needed for positioning, eliminating the calibration measurement between breast scans, and improvements to software.

### 3. Protocol for qualitative study relating to volunteer input

The methodology comprised participant observation, interviews, and standard methods of analysis of qualitative data. One of the social scientists was present at scanning sessions, observing and making field-notes or (where feasible) audio recordings of the proceedings. Subsequent to the scan, patient-volunteers were interviewed in a private room, according to a pro-forma which loosely structured the interview round certain themes but gave scope for narrative input and interviewee-led identification of issues. Subject to volunteer agreement all interviews were recorded, transcribed, and subsequently coded and analysed with the help of Atlas-ti qualitative data analysis software. Our approach is complementary to the semi-quantitative survey method used by the group at University of California, Irvine to elicit patient feedback [4].

A further key element of our study was regularly to feed back the understandings gained from the volunteers to the whole research team, for discussion at team meetings and consideration of action required. Documentation of these meetings was supplemented with periodic interviews of medical physics team members, to assist evaluation of this process.

### 4. Results

In this report we concentrate on the input obtained from volunteers and its implications for management of the project. The findings are based on interviews with 65 patient-volunteers and observation of a similar number of scan sessions. Eighteen interviewees (3 healthy volunteers and 15 patient-volunteers) were in the preliminary study – using the frame interface, while 47 (of whom 9 were healthy volunteers) took part in the second series, using the scanning bed. Participation in the research offered no medical benefit but a modest honorarium (£40) was offered. It is also relevant to note that the sample was not representative of all patients attending the referring clinic, but only of a subset showing willingness to participate in research. We group the findings under four main headings:

- *Decision to participate.* Most (60 out of 65) participants gave broadly altruistic reasons when asked directly about their motivation, citing such motives as empathy with other cancer patients, helping medical science to progress, benefits to future generations, giving something back to society or the health services from which they themselves had benefited. It was clear however that this in no way precluded volunteers from undertaking a serious calculation and assessment of risks (including risk of pain) and benefits, prior to agreeing to participate. The women in the study had very clear ideas of the boundaries they set to their participation in research, often sharply distinguished from what would be tolerated in a health care situation. For example, invasion of the bodily boundaries (taking drugs, having injections) was explicitly ruled out in many, though not all, cases. Safety was also assessed: concerns about lasers were open to reassurance, but exposure to x-radiation, though tolerable if part of health care, was considered unacceptable in a research context. As one patient said: “I wouldn’t – for the sake of research – go and have a mammogram ... as long as it’s a safe test I’m happy to do it but I’m not gonna become Madame Curie”. Pain was a third important determinant of participation – the main one for some, and again contrasts with the acceptance (albeit reluctant) of routinely used medical diagnostics, such as mammograms and biopsies, described as ‘torture’ by some volunteers. Contributing to the development of less painful procedures was given as a significant motivation (perhaps as a post-hoc rationalization) by many volunteers. Boundaries around these three issues (invasiveness, risk, pain) appeared to be non-negotiable for many individuals in a situation where there was no medical benefit.
- *Researcher-subject relationships.* The research team was much concerned about the physical comfort of volunteers and how they would react to the laboratory setting in which the tests took place. It emerged clearly from interviews, and to a lesser extent from conversations at scan sessions, that volunteers were chiefly concerned about mental and social comfort [5] – the latter including whether they were performing their task well. For example they frequently asked for reassurance that their breast was well positioned for obtaining good data, asking the researcher “am I far enough in?” and expressing anxiety not to “mess up on it”. In the course of interviews volunteers would present themselves in a number of roles, such as the

altruistic giver, the patient or client, the collaborator. We interpret this as reflecting their search for an appropriate social formula to frame an acceptable working relationship with the researchers [6]. They emphatically did not wish to be cast as guinea pigs, and required a friendly, sociable yet professional attitude from the researchers to assure them of this. Some chose the pre-emptive tactic of calling themselves guinea pigs, to forestall others doing so, but followed this with remarking favorably on not feeling treated as such. Given that volunteers had largely satisfied themselves prior to arrival for the experiment on the issues of invasiveness, safety and pain, their chief anxiety on entering the laboratory was to avoid social embarrassment by establishing a ‘comfortable’ working relationship.

- *Embarrassment.* Many volunteers said embarrassment about having to expose their breasts was their main or only anxiety about taking part in the research. It was not a barrier to participation, and volunteers varied as to where they set the boundary (for example as to how important it was to have an all-female environment), but it put a greater premium on a supportive social environment. It also raises a design consideration: patient anxiety can be reduced if the design (as is fortunately the case with our own instrument) respects personal privacy as far as possible.
- *Influence on design and process.* Volunteer input contributed some minor cosmetic changes to the design of patient interface, and was helpful in establishing the acceptability of the scanning bed design (despite some wry jokes about the ‘warm milk’ in the hemispherical cup). But the rationale for the major interface re-design was technology-driven. Influence on process has been incremental: researchers’ heightened awareness of volunteers’ priorities has helped to build a mutually supportive relationship (in which volunteers are active contributors); pre-formal-consent briefings build on knowledge of previous volunteers’ concerns: gender and professional composition of the experimental team has been adapted to known preferences. This contributes positively to the smooth running of the experiments and volunteer satisfaction.

## 5. Conclusions

The findings from observing and interviewing volunteers discussed above were consistent across both phases of the study despite substantial changes in the physical environment and inclusion of a much greater proportion of seriously ill women in the second phase of study. The understanding gained of volunteers’ concerns and values can be useful in two main ways. First from the perspective of successful achievement of technical objectives, it highlights (a) the issues to be addressed in regard to recruitment (and how far boundaries may be negotiable), (b) the importance of reciprocal efforts to build a good researcher-subject relationship and sensitivity to issues of personal privacy to assure optimum performance and cooperation from volunteers in the course of the experiment. Secondly, it is increasingly incumbent on researchers actively to engage with ‘users’ of their research both to help produce ‘socially robust’ outcomes by giving due weight to public values, and in the case of clinical research as a matter of ethics, to demonstrate respect for human subjects and add to their satisfaction with the experience, by inviting them to contribute to the research with their minds as well as their bodies.

## 6. References

- [1] T. D. Yates, J. C. Hebden, A. P. Gibson, N. L. Everdell, S. R. Arridge, and M. Douek, “Optical tomography of the breast using a multi-channel time-resolved imager,” *Phys Med. Biol.* **50**, 2503-2517 (2005).
- [2] L. C. Enfield, A. P. Gibson, N. L. Everdell, D. T. Delpy, M. Schweiger, S. R. Arridge, C. Richardson, M. Keshtgar, M. Douek, J. C. Hebden “Three-dimensional time-resolved optical mammography of the uncompressed breast”, *Appl. Opt.* **46**, 3628-3638 (2007).
- [3] S. R. Arridge and M. Schweiger, “Image reconstruction in optical tomography,” *Phil. Trans. R. Soc. Lond. B* **352**, 717-726 (1997)
- [4] N. S. Shah, A. E. Cerussi, D. Gordon, A. Durkin, B. Hill, M. Compton, and B. J. Tromberg, “Integration of diffuse optical technology into clinical settings for breast health applications”, *Biomedical Topical Meeting (BIO) 2006*, paper SC2 (2006).
- [5] N. Morris and B. Balmer, “Are you sitting comfortably? Perspectives of the researchers and the researched on ‘being comfortable’ *Accountability in Research*, 13, 111-133 (2006).
- [6] N. Morris and B. Balmer, “Volunteer human subjects’ understandings of their participation in a biomedical research experiment. *Social Science & Medicine*, 62(4), 998-1008 (2006).