User-centred Development of a Clinical Decision-support System for Breast Cancer Diagnosis and Reporting based on Stroke Gestures

Suzanne Kieffer[1][a], Annabelle Gouze[2] and Jean Vanderdonckt[1][b]
[1] *Université catholique de Louvain, Louvain-la-Neuve, Belgium*
[2] *EVS Broadcast Equipment, Rue Bois Saint-Jean 13, B-4102 Seraing, Belgium*

Keywords: Clinical Decision-support System, Stroke Gesture, Multi-fidelity Prototype, User-centred Design.

Abstract: We conducted a user-centred design of a clinical decision-support system for breast cancer screening, diagnosis, and reporting based on stroke gestures. We combined knowledge elicitation interviews, scenario-focused questionnaires and paper mock-ups to understand user needs. Multi-fidelity (low and high) prototypes were designed and compared first *in vitro* in a usability laboratory, then *in vivo* in the real world. The resulting user interface provides radiologists with a platform that integrates domain-oriented tools for the visualisation of mammograms, the manual, and the semi-automatic annotation of breast cancer findings based on stroke gestures. The contribution of this work lies in that, to the best of our knowledge, stroke gestures have not yet been applied to the annotation of mammograms. On the one hand, although there is a substantial amount of research done in stroke-based interaction, none focuses especially on the domain of breast cancer annotation. On the other hand, typical gestures in breast cancer annotation tools are those with a keyboard and a mouse.

1 INTRODUCTION

Breast Cancer (BC) is the most common type of cancer among women worldwide. In particular, one in nine women is expected to develop the disease during her lifetime. In 2050, this number will have doubled. Early detection improves BC treatment and recovery. Actually, 80 percent of the patients recover when the diagnostic is made early, in comparison with only 30 percent when not. At the present time, there are two promising ways to address these issues :

- Screening mammography exams, which aim at discriminating BC findings into benign and malignant lesions; screening mammography programs are promoted to facilitate the early detection of breast cancer for women 50 up to 70 of age.
- Clinical decision support systems (CDSS) (Pawloski et al., 2019) such as *computer-aided diagnosis* (CAD) systems, which rely on image processing and help detecting missed findings.

The screening mammography is the most reliable exam as it enables the early detection of BC disease and its treatment. The exam is composed of four X-ray images, or four standard projections of the breasts: left and right Cranio-Caudal (CC) and Medio-Lateral Oblique (MLO) projection. Recent advances in acquisition system allow to directly producing digital mammography instead of X-ray film. Some performance comparisons demonstrated the benefit of digital mammography over screen-film mammography (Skaane and Skjennald, 2004; Vinnicombe et al., 2009). The screening workflow consists for the radiologist in doing image screening, lesion detection, interpretation and reporting. The report includes the complete and structured description of any significant finding, the comparison to previous studies, the overall diagnosis and follow-up recommendations.

Since digital mammography has replaced screen-film mammography, information and communication technology (ICT) has progressively been introduced in BC screening and diagnosis, leading to an increasing number of supporting devices and interactive tools. Such interactive systems improve the reliability of the diagnosis: *e.g.*, magnification, orientation, brightness, and contrast of the image may be altered after the exam is completed to explore further certain areas. Moreover, such interactive systems improve the productivity of the radiologist: *e.g.*, they improve and facilitate the access and the sharing of medical information (Sainfort and Booske, 2017). However, radiologists still deplore three main issues concerning the current interactive systems supporting

[a] https://orcid.org/0000-0002-5519-8814
[b] https://orcid.org/0000-0003-3275-3333

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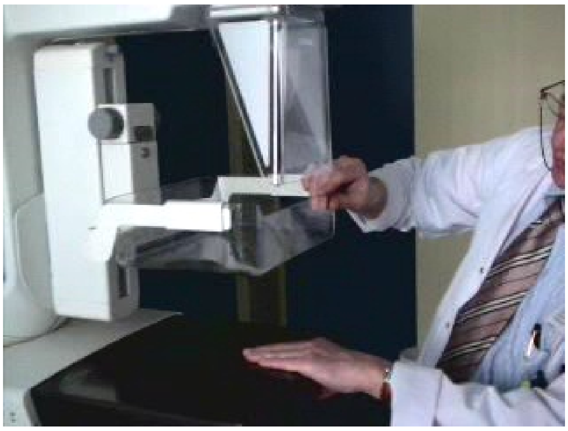


Figure 1: Image acquisition system.

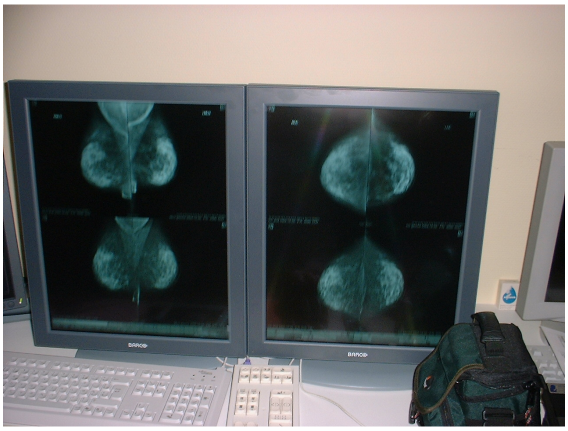


Figure 2: Modality console.

their activity: (1) they are not integrated in a unique system; (2) they do not enable the standardised annotation of BC findings; (3) they do not provide any means to interact with the CAD tools. First, radiologists need a unique and integrated system supporting their activity in order to maximise the image viewing time and minimise any distractions from both the equipment and the software (ACR, 2007). Recent efforts have been made to develop and improve the digital mammography equipment from image acquisition systems (Fig. 1) up to image viewing and analysing systems (Fig. 2). The setting for screening procedures has to be compliant with the European guidelines for quality assurance in BC screening and diagnosis (Perry N., 2006), and is most often composed of two screens, a task-oriented keypad, and a mouse. Moreover, owing to the specificity and the complexity of each task involved in mammogram analysis, research efforts have been focusing mainly on the implementation of task-oriented interactive systems such as image viewers (Fig. 2), radiology information systems (which are used in order to store, manipulate, and distribute the patient radiological data and imagery), CAD software, and digital case databases. Hence, radiologists currently tend to split their work between a growing number of interactive tools (*e.g.*, case retrieval databases, viewers, and CAD tools), workstations, and media (*e.g.*, screen, mouse, keyboard, and handheld recorder). This equipment heterogeneity decreases their productivity.

Second, radiologists need the system to characterise the findings to be compliant with the domain standard. While many research efforts have been carried out separately on the implementation of task-oriented systems, much less effort has been undertaken to the design and the development of technologies compliant with the domain standard, *i.e.*, the Breast Imaging Reporting And Data System (BI-RADS). The BI-RADS is an approved quality insurance system of descriptive terms and reporting guidelines (ACR, 2007). Such tools not only facilitate reporting, providing radiologists with homogeneous, structured, and standardized reports, but lead to data accessibility as well. They enable data exchange and storage, interpretation monitoring (Wittenberg et al., 2007), retrieval of useful and interesting cases for teaching and research purposes (Zheng et al., 2004).

Third, radiologists need the CAD systems to enable the possible modification of the detected area. Mammography is the most commonly used method for BC screening since it enables early detection and treatment. Two important and early signs of the disease in breast tissues are cluster of microcalcifications (small calcium deposit) and masses. The current CAD tools provide radiologists with the automatic detection of possibly missed findings, such as cluster of microcalcifications (CA++) or masses (Cheng et al., 2003). However, radiologists deplore the lack of human-computer interaction with CAD tools. For instance, BC-oriented interactive tools should support both the association of numerical data from the CAD to the standard annotation of BC findings and the modification of these numerical data if required, with the ultimate goal to include these data to the final report. The standard lexicon of mammography terms defined by the BI-RARDS for manual characterisation of findings (ACR, 2007)] is also integrated.

To sum up, there is a need for a CDSS for BC, which integrates domain-oriented functionalities within a unique platform and supports both manual and semi-automatic annotation of significant finding in the breast. This paper presents how we combined different methods and techniques from the human-computer interaction (HCI) and medical imaging fields with the goal to design and test a clinical decision-support system for BC. The objectives and the methodology are presented in the next sections. Then, the system is fully described, and three usability evaluations are reported, before the conclusion and the discussion. The contribution of this work lies in that, to the best of our knowledge, stroke gestures have not yet been applied to the annotation of mammograms. On the one hand, although there is a substantial amount of research done in stroke-based interaction, none focuses especially on the domain of breast cancer annotation. On the other hand, typical gestures in breast cancer annotation tools are those with a keyboard and a mouse.

2 OBJECTIVES

Both utility and usability are widely considered as requirements to meet the goal of the overall acceptability of a system (Nielsen and Molich, 1990). The overall objective of this work is to develop a CDSS for BC which addresses radiologists' needs and expectations. To satisfy both the need of utility and usability, such system system should: (1) integrate both the equipment and the software into a unique platform; (2) support the standardized (manual) annotation of any significant finding; (3) provide relevant feedback functionalities for semi-automatic annotation.

CAD systems were introduced to attract radiologists' attention to the features that might have been overlooked or dismissed and to deliver helpful information for diagnosis. Typically, CAD systems provide an automatic assistance to the spatial detection (localisation) of BC lesions, usually stressed on the mammogram image thanks to markers such as crosses, triangles, or squares. However, CAD data are restricted to the spatial location of the lesions and need to be enhanced by complementary features from segmentation to deliver meaningful information:

- Regarding masses: segmented area (*i.e.*, the area surrounding the mass), location, size, circularity, local contrast, perimeter, mean and luminance.
- Regarding clusters of calcifications: centre location, number of calcifications, length of the convex hull, size of the convex hull, circularity of the convex hull, density, and local contrast.
- Regarding microcalcification: location, size, circularity, and local contrast.

Different factors affect the accuracy of the segmentation: breast composition, missing lesion edge due to the presence of a more marked edge, and missed/false findings. Segmentation outputs might not represent the lesions correctly and may not be meaningful. Consequently, it is mandatory to propose a new interactive method which allows exploiting the radiologist knowledge inside the segmentation process: the relevance feedback (Ruthven and Lalmas, 2003). The main contribution of this work is the improvement of the segmentation process thanks to relevant feedback technique, as it combines both human knowledge and image processing. To the best of our knowledge, the system presented here is the first CDSS for BC providing both manual and semi-automatic means to characterise any finding in compliance with the approved standard of the domain. Such achievement was made possible by the adoption of a user-centered approach as a formal development model.

3 USER-CENTERED APPROACH

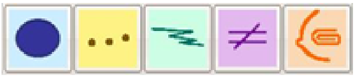
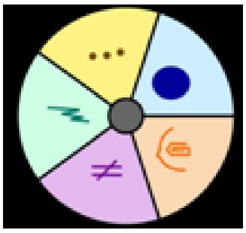
ICT provides nowadays a means to support and facilitate the daily activities of potentially all users. This may be of particular importance for the experts in BC screening and diagnosis, upon condition that the system fit user needs, expectations and requirements. Interests in user-centered approaches stem from the goal to design and implement interactive systems supporting the activities of domain-expert users, who are not necessarily experts in computer science. Important care must be devoted to the study of the needs and the expectations of such domain-expert users (Costabile et al., 2003). In particular, attention must be paid to the user and the usability throughout the software life-cycle in order to design and implement user-friendly and easy-to-use interfaces (Nielsen and Molich, 1990; Organisation, 2018). At different time frames in the life-cycle, the development model relies on user-centred methods such as knowledge elicitation interviews, scenario-focused questionnaires, paper mock-ups, prototyping and user tests.

3.1 Knowledge Elicitation Interview

We carried out knowledge elicitation interviews to gather domain- and task-relevant insights early in the life-cycle. We questioned thoroughly five domain-expert users about the BC domain, the task series involved in their activity, their needs and their expectations regarding a ideal CAD system for BC. The equipment used was paper notes and video recording. The information collected during these interviews included the description and the explanations of the terminology to be used, the setting of the equipment, and the acquisition and the screening procedures. The screening analysis procedure involves six steps:

1. Selection of a case from the list of patients.
2. Analysis of the patient information, such as previous examinations, if available.

Table 1: Scenario-Focused questionnaire. The screening activity is the description of the lesion type (col. 1). Two interactive scenarios support this activity: using an array of buttons (col. 2) or using a pie-menu (col. 3).

Screening activity	Scenario #1	Scenario #2
Lesion type (e.g. mass)	Array of buttons 	Pie menu 

3. Visualisation of the projections on the reading viewers, by usually following this sequence: global view, 2 CC views, 2 MLO views, and global view again.
4. Visualisation of the detailed parts of the projections in order to detect suspicious findings.
5. Interpretation.
6. Briefing and reporting of the screening results.

3.2 Questionnaire and Paper Mock-ups

We used a scenario-focused questionnaire (Table 1) and paper mock-ups (Fig. 3) to define and select the interaction scenarios which would best support user activities (Danli Wang, 2008). Thanks to users' involvement, such a design method proved to reduce both development time and costs, and to improve usability (Danli Wang, 2008; Rosson and Carroll, 2002). Each low-fidelity prototype progressively evolved to a high-fidelity prototype by mapping (Montero et al., 2006), thus resulting into multi-fidelity prototyping (Coyette et al., 2007). Both the questionnaire and the mock-ups were elaborated from the information collected during knowledge elicitation interviews and were presented to six domain-expert users to evaluate the icon framework and the overall spatial organization of the interface, and to select the potential interactive scenarios.

The questionnaire was used by the interviewer as visual aid during face-to-face interviews. Paper mock-ups were preferred to computer prototypes as (1) the available tool did not support the scenarios applying for implementation and (2) the evaluation should lead to a lot of drawings, direct manipulation of paper components and discussions between designers and domain-expert users (Sefelin et al., 2003). The analysis of the data collected from scenario-focused questionnaire and paper mock-ups led to the preliminary expert validation of the user interface in terms of spatial organisation, terminology used, specific components designed, such as icons, colour code, and the interactive scenarios proposed to support the users' activity.

4 DISCUSSION OF THE CDSS

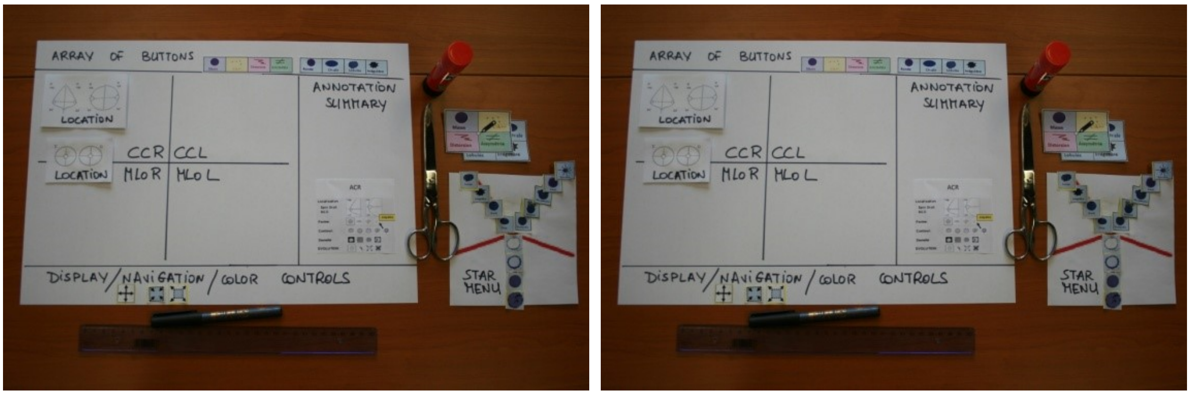
4.1 Gesture-based Interface

Stroke gestures are effective to provide users with an intuitive and convenient interaction (Danli Wang, 2008; Vanderdonckt et al., 2019). Owing to its high naturalness and mainly to its convenience to satisfy the lesion characterisation requirement, stroke gestures with a graphics tablet and a pen were chosen as interaction modality: navigating in a clinical case (*i.e.*, among the mammograms), navigating in a specific mammogram (*i.e.*, zoom-in, zoom-out), sketching a region of interest (ROI) (Kieffer et al., 2010), annotating findings and reporting, and recognition (Vanderdonckt et al., 2018).

4.2 Iconic Representations

The BI-RADS (ACR, 2007) provides a standardised terminology for the description of BC findings. Any finding is described according to a lesion type (*i.e.*, mass, calcification, architectural distortion, special case or associated finding), and type-related characteristics. Beyond the specific characteristics related to a lesion type, the breast imaging report contains the finding location and the comparison to previous studies, whatever the type. We created an icon framework (about 150 different icons) according to this standard to enable any finding to be fully described:

- We assigned a unique icon with any specific term of the BI-RADS lexicon to make the lesion characterization as straightforward and unambiguous as possible;



(a) The experimental material such as paper, glue, and pen.

(b) The device in use.

Figure 3: Paper mock-ups.

- We created a colour code to facilitate the discrimination between the findings: masses in blue, calcifications in yellow, distortions in green, special cases in violet, and associated findings in orange.

The schemes on the icons related to the finding location and the comparison to previous studies are common to all the lesion types; only colours are different. Fig. 4 presents the icons related to the specific characteristics of masses. Masses are characterised by basic shape (round, oval, lobular or irregular), margin (circumscribed, microlobulated, obscured, indistinct or spiculated) and density (high-density, equal density, low-density or fat-containing radiolucent).

4.3 Manual Annotation with the Pie and the Star Menus

Providing experts in BC imaging with an interactive tool supporting their activity is a tough problem of HCI considering the utility and the usability. The utility is ensured by the compliance of the system with domain standards, and by the integration within a single interactive tool of the following features: image visualization, annotation of findings, semi-automatic lesion detection and reporting. To guarantee the usability of the system, especially during the manual annotation of BC findings, sustained attention has been paid to the graphical representation of the mammographic BI-RADS terminology (design of an exhaustive set of icons), to the spatial organization of multidimensional data (Bellik et al., 2009) (overall spatial organisation of the user interface and location of widgets), and to the design of new interactive solutions suited to the finding annotation with a pen on a graphics tablet.

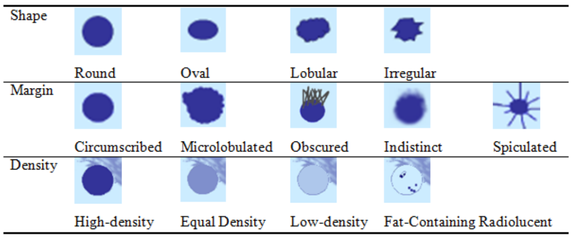


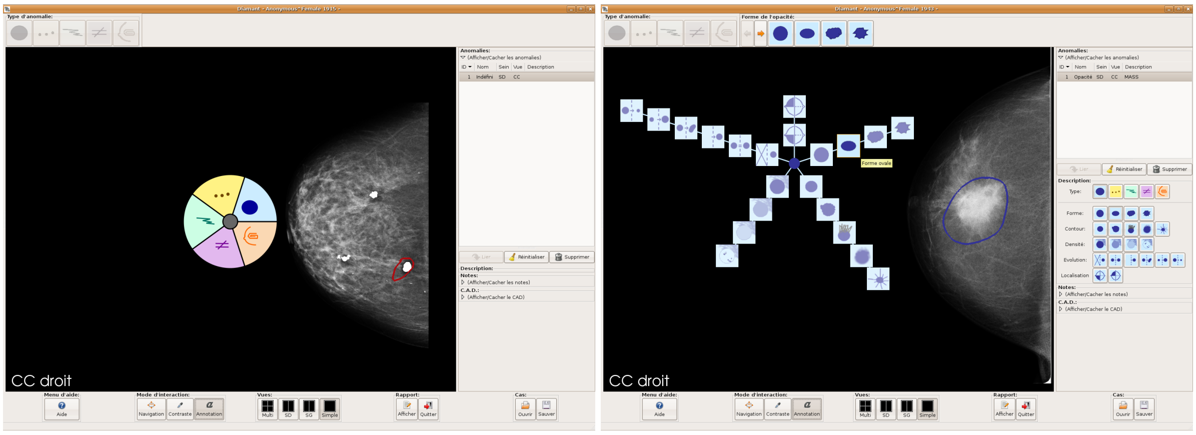
Figure 4: Icons related to the characteristics of masses: shape, margin and density.

Therefore, two alternate menus were implemented to support the gesture-based annotation of BC findings: a pie menu (Callahan et al., 1988) for the gesture-based selection of the lesion type, and a star menu for the gesture-based description of the type-related characteristics of the lesion. The pie menu (5a) was implemented in order to facilitate the pen-based annotation of the lesion type. This format was chosen because it reduces the target seek time and improves the accuracy of target selection (Callahan et al., 1988; Moyle and Cockburn, 2002).

The star menu (5b) was implemented in order to facilitate the pen-based annotation of complementary characteristics by grouping related icons. This format was chosen because such a display layout was proved to be very efficient and accurate for visual inspection or visual detection by comparison with matrix, elliptic and random spatial structures (Simonin et al., 2005). The manual annotation of any significant finding can be performed as follows. First, the suspicious finding is surrounded with the pen. This action corresponds to the ROI drawing. Then, the lesion is annotated thanks to the pie-menu (type of lesion) and the star-menu (characteristics of the specific lesion). Finally, the full description of the lesion is automatically stored into the final report.

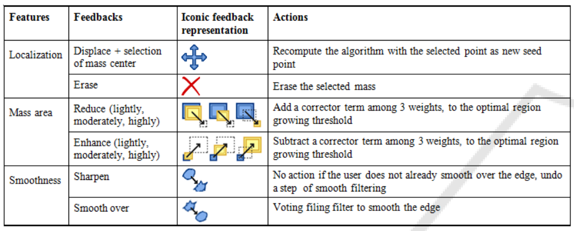
4.4 Semi-automatic Annotation

While the radiologist manually annotates a finding, the segmentation computation and the numerical fea-



(a) Pie menu. (b) Star menu.

Figure 5: Alternate menus for the Decision Support System.

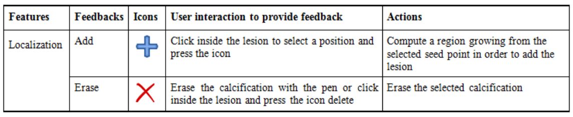


Features	Feedbacks	Iconic feedback representation	Actions
Localization	Displace + selection of mass center	✛	Recompute the algorithm with the selected point as new seed point
	Erase	✗	Erase the selected mass
Mass area	Reduce (lightly, moderately, highly)	↘ ↘ ↘	Add a corrector term among 3 weights, to the optimal region growing threshold
	Enhance (lightly, moderately, highly)	↗ ↗ ↗	Subtract a corrector term among 3 weights, to the optimal region growing threshold
Smoothness	Sharpen	↘	No action if the user does not already smooth over the edge, undo a step of smooth filtering
	Smooth over	↘	Voting filing filter to smooth the edge

Figure 6: Predefined features of masses (col. 1) with their associated feedbacks (col. 2), the representation (col. 3), and the actions (col. 4).

tures extraction are automatically launched inside the ROI. Then, the segmented findings are displayed in red (highlighted edge) together with the relevant numerical features of the segmented objects. The system enables, if required, to "highlight" or to "hide" the edge of the detected mass, the mask of detected microcalcifications, or the convex hull of clusters, by simply pressing a button. It also provides the user with a simple query interface with two modes: (i) the validation mode which enables either the validation or the report of mistakes, and (ii) the (interactive) segmentation mode which enables the radiologist to improve the segmentation by providing new parameters for the segmentation computation. This is the relevant feedback process.

A set of feedback icons was designed to enable the radiologist to easily interact with the system (Figs. 6 and 7). Once the segmentation results are validated, the numerical features are included in the report together with the manual annotation. This combination of manual and semi-automatic annotations of BC findings increases the quality assurance in screening practice. The next sections present the algorithms for the automatic segmentation of masses and microcalcifications, and how relevance improved this segmentation.



Features	Feedbacks	Icons	User interaction to provide feedback	Actions
Localization	Add	✛	Click inside the lesion to select a position and press the icon	Compute a region growing from the selected seed point in order to add the lesion
	Erase	✗	Erase the calcification with the pen or click inside the lesion and press the icon delete	Erase the selected calcification

Figure 7: Predefined features of the microcalcifications for a cluster (col 1.) with their associated feedbacks (col. 2), the iconic representation of feedback (col. 3), the feedback (col 4.), and actions (col. 5).

4.4.1 Automatic Segmentation of BC Findings

Mass segmentation is performed by applying the algorithm of Kupinski and Giger (Kupinski and Giger, 1998), which is based on a region growing process and on probabilistic models. The region growing process starts from a source point, located inside of the ROI where the segmentation has to be computed. Then, this region iteratively grows towards the edge of the object to be segmented, while the pixels bordering the current region are integrated inside the region upon condition that the luminance variation is lower than a given threshold. Different thresholds are applied to obtain different partitions in two regions: the object (lesion) and the background. Then, the probability distribution of luminance inside and outside the object is computed. The probability of the image partition is equal to the product of probabilities at each point. The final mass segmentation corresponds to the partition that maximizes the probability of the partitions.

Microcalcifications are detected by applying the Dengler's algorithm (Dengler et al., 1991) and are gathered into clusters, considering the distance between each other. The Dengler's algorithm combines WDoG (Weighted Difference of Gaussian) and the Top Hat morphological transform.

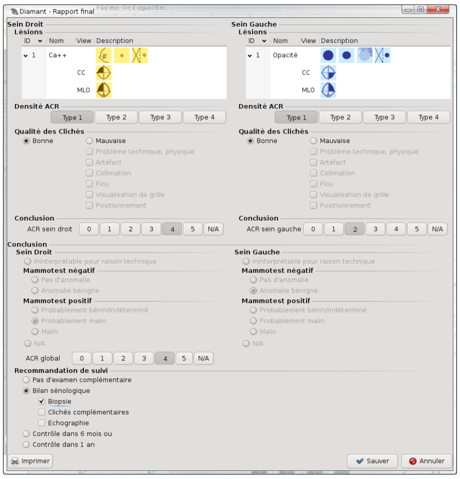
4.4.2 Relevance Feedback

Relevance feedback techniques focus on adjusting features, using the feedback provided by the radiologist about the previous results to improve or validate the system performance (Ruthven and Lalmas, 2003). Relevance feedback requires, for each finding, the selection of the features that best suit the radiologist knowledge acquisition and the segmentation. Then, for each chosen feature, the pre-defined feedbacks and the actions associated with each feedback are introduced. Figs. 6 and 7 introduce for masses and microcalcifications: the relevant features, the definition of the associated feedbacks available for interactive segmentation mode, and the actions to be performed in reply to the user feedback.

The selected relevant features (Figs. 6 and 7) should be represented by numerical values. However, radiologists are not able to evaluate themselves these values. Radiologists can only provide assessments on good or erroneous results and return their subjective feedbacks. Therefore, positive feedbacks imply a validation of the features and negative feedbacks launches a new segmentation with new parameters. Negative feedbacks involve immediate action from a cognitive point of view and the feedback is designed to suggest an action rather than an assertion. If the radiologist judges the mass area to be incorrect and consequently returns a feedback to ”lightly enhance region”, the system allows the interactive icon-based specification of a different area of bigger size. The associated action is to subtract a corrector from the optimal threshold of the region growing algorithm (Kupinski and Giger, 1998) to obtain a bigger area. The validation mode enables the radiologist either to validate the whole of the segmentation results by clicking on the corresponding button, or to validate each feature separately. Validated features are the same as those defined by the interactive segmentation mode. The possible feedbacks are nominal and numerical values. The nominal value is either a validation or a comment to invalidate incorrect features. Indeed, the validation mode feedback allows the results to be commented. For instance, the detected area can be commented as to be ”too small” by the radiologist. The value range is 1-7.

4.5 Reporting

4.5.1 Standardised Reporting System


Diamant - Rapport final

Sein Droit
Lésions

ID	Nom	View	Description
1	Ca++		
		CC	
		MLO	

Densité ACR
[✓ Type 1] Type 2 Type 3 Type 4

Qualité des Clichés
● Bonne ○ Mauvaise
□ Problème technique, physique
□ Artéfact
□ Collimation
□ Flou
□ Visualisation de grille
□ Positionnement

Conclusion
ACR sein droit 0 1 2 3 [✓ 4] 5 N/A

Sein Gauche
Lésions

ID	Nom	View	Description
1	Opacité		
		CC	
		MLO	

Densité ACR
[✓ Type 1] Type 2 Type 3 Type 4

Qualité des Clichés
● Bonne ○ Mauvaise
□ Problème technique, physique
□ Artéfact
□ Collimation
□ Flou
□ Visualisation de grille
□ Positionnement

Conclusion
ACR sein gauche 0 1 [✓ 2] 3 4 5 N/A

Conclusion
Sein Droit
○ Ininterprétable pour raison technique
Mammotest négatif
○ Pas d'anomalie
○ Anomalie bénigne
Mammotest positif
○ Probablement bénin/indéterminé
● Probablement malin
○ Malin
○ N/A

Sein Gauche
○ Ininterprétable pour raison technique
Mammotest négatif
○ Pas d'anomalie
● Anomalie bénigne
Mammotest positif
○ Probablement bénin/indéterminé
○ Probablement malin
○ Malin
○ N/A

ACR global 0 1 2 3 [✓ 4] 5 N/A

Recommandation de suivi
○ Pas d'examen complémentaire
● Bilan sénologique
☑ Biopsie
□ Clichés complémentaires
□ Echographie
○ Contrôle dans 6 mois ou
○ Contrôle dans 1 an

Figure 8: Form for the reporting task.

The ACR promoted the BI-RADS standard to solve problems of non-uniform, vagueness and inconclusive reporting (ACR, 2007). The BI-RADS is an assurance quality system designed to provide a uniform verbal description for any significant finding and a clear, concise and directive reporting in order to reduce complexity and variability of interpretation and of decision-making. The BI-RADS classification and reporting tool improves the biopsy recommendations and the feature analysis agreement with experienced breast imagers (Berg et al., 2002). The report incorporates a structured description of any significant finding, the comparison to previous studies, the overall impression, and follow-up recommendations.

4.5.2 Resulting Reporting Task and Form

The reporting task begins with the manual and the semi-automatic annotation of findings and finishes with a form filling using the reporting tools. The form complies with the standard (Fig. 8). For each breast, the tool displays the summary of the manual annotation. The breast density has to be filled according to four types: *Type 1*=the breast is almost entirely fat, *Type 2*=there are scattered fibroglandular densities, *Type 3*=the breast tissue is heterogeneously dense, which could obscure detection of small masses; and *Type 4*=the breast tissue is extremely dense, this may lower the sensitivity of mammography.

The European guidelines for quality assurance impose the radiologist to evaluate the quality of each view. Then the radiologist final impression for each breast has to be classified among six assessment categories: need imaging evaluation (ACR0), no finding (ACR1), benign finding(s) (ACR2), probably benign finding(s) (ACR3), suspicious abnormality (ACR4), and highly suggestive of malignancy (ACR5). The final recommendation consists in the radiologist decision-making, which is simplified thanks to the ACR assessment categories (ACR, 2007).

5 EXP. #1: PIE VS. STAR MENUS

Objectives. The objective of this study was to evaluate the usability of the pie and star menus (pie-star menus) during the annotation of BC findings. We used task completion, time on task and number of clicks and user satisfaction as usability criteria (Nielsen and Molich, 1990; Organisation, 2018).

Participants. Nine volunteers (3 females) aged between 43 and 58 participated in this study. All were experimented breast radiologists practicing in different hospitals in Belgium. They were recruited regarding their experience in BC screening. Computer skills were assessed thanks to a background questionnaire. All participants were familiar with computers, especially with medical computer-based applications and all were experienced in visual search and navigation activities on computer displays. They were average mouse/keypad users with similar motor abilities.

Tasks. Participants annotated BC findings using pie-star menus or an array of icons. Array and star menu icons were exactly the same in terms of scheme, colour and size. The array allows the sequential selection of finding characteristics in the following order: lesion type, type-related characteristics (each characteristic has to be described one at a time), comparison to previous studies, and location. Fig. 9 presents the array of icons displayed to describe the lesion type (left) and the shape of any mass (right).

Experimental Setup and Apparatus. We employed a 2 × 5 factorial design with two experimental conditions (pie-star menu versus array) and five medical cases to characterize (*i.e.*, five tasks). Each participant carried out ten tasks: five per experimental condition. We used counterbalancing of conditions according to a 2 × 2 Latin Square design. We randomized the order of the five medical cases per condition. Counterbalancing and randomization were used to control task learning effects and inter-individual diversity. The tests were carried out in an isolated room in each hospital. Participants were seated approximately 40 cm from the graphics tablet. Stroke gesture annotation was used as input modality whereas visual display was used as output modality. The computer system used in this study was a computer with an Intel Core2 Duo E8400 (3GHz) processor, 4 GB of DDR SDRAM and a 9600GT Nvidia graphic card. The gesture tablet was a WACOM CINTIQ 21UX. DICOM images were loaded into the viewer.

Procedure. The sessions involved one volunteer at a time. First, participants were given an oral presentation of the project, an explanation of their role in the usability tests, and a demonstration of the functionalities of the tool. Then, they started the training session: one clinical case to annotate per experimental condition. Once they felt comfortable enough with the tool and got used to the manipulation of the pen, they were provided with the paper printed instructions, and the demographic and background questionnaires to fill prior to the actual test. After each condition, they were asked to fill a satisfaction questionnaire. Then, after the two conditions, they were asked to fill the IBM CSUQ (Lewis, 2006), a 19-item questionnaire which aims at evaluating the usability of a system in terms of System Usefulness (SysUse), Information Quality (InfoQual) and Interface Quality (IntQual) on a 7-point Likert scale. The effective tests lasted approximately 30 minutes.

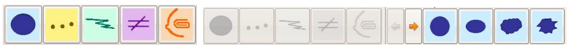


Figure 9: Icons: Lesion type (left), Shape of a mass (right).

Table 2: ANOVA Procedure. DF stands for degree of freedom, AT for annotation time, and NC for number of clicks. Bold used to highlight statistical differences.

Factors	*DF*	*AT* (sec.)		*NC*	
Condition	1	F=3.5605	p=.0605	F=.0216	p=.8832
View	1	F=5.6496	**p=.0183**	F=1.8155	p=.1792
Finding type	4	F=2.7884	**p=.0274**	F=9.0073	p<.0001

Table 3: Means and standard deviations of annotation times.

Factors		N	*M* (sec.)	*SD* (sec.)
Condition	Pie-Star	115	17.3478	12.8070
	Array	105	20.5524	12.3304
View	CC	138	20.5000	1.0629
	MLO	81	16.3457	1.3874
Finding type	Mass	69	16.2609	1.4949
	Calcification	89	20.9438	1.3162
	Arch. Dist.	39	17.6410	1.9883
	Special case	5	31.6000	5.5531
	Associated finding	17	18.8824	3.0116

Results. The sample includes 219 entries. Analyses of variance (ANOVA) were used to examine the presence of significant differences in task performance, as measured by annotation time (sec.) and number of clicks: per conditions (pie-star and array), per view (CC and MLO), and per finding type (mass, calcification, distortion, special case and associated finding).

Annotation times show no statistically significant difference between experimental conditions (Table 2). However, they show a significant view effect (F=5.6496; p=.0183) and finding type effect (F=2.7884; p=.0274). Regarding the number of clicks, Table 2 shows a highly significant finding type effect (F=9.0073; p<.0001). Table 3 shows manual annotation of BC findings with pie-star menus (17.5 sec) is faster than with the array of icons (20.5 sec). This difference may be a matter of visual perception: the star menu displays simultaneously all the icons

Table 4: Means and standard deviations of number of clicks.

Factors		N	*M* (sec.)	*SD* (sec.)
Finding type	Mass	69	5.4637	0.2133
	Calcification	89	4.5842	0.1878
	Arch. Dist.	39	4.0256	0.2837
	Special case	5	4.0000	0.7924
	Associated finding	17	6.5882	0.4297

related to a finding type, whereas the array displays the icons related to one characteristic at a time. By contrast, the star menu enables the users to anticipate their next clicks and, consequently, to be faster.

Furthermore, the results show that the annotation of BC findings is faster in the MLO projection (16.34 sec) than in the CC projection (20.5 sec). This difference may be explained by the combination of the following two reasons. First, in practice, breast radiologists start the diagnostic by the analysis and interpretation of the CC view. It may be natural to adopt the same task order with the interactive tool. And it may be normal that the examination lasts longer in the first projection to be visualised (*i.e.*, the CC projection) than in the second one (*i.e.*, the MLO projection). Second (let us assume that the CC projection was the first to be examined), findings such as masses and calcifications need to be characterized in both views. Thus, a ”Duplicate” button was implemented to reduce the number of clicks necessary for the complete annotation of findings. As a consequence, there were fewer properties to be annotated in the second projection (*i.e.*, the MLO projection).

Finally, the speed and the number of clicks to perform the annotation task depend on the type of the finding under annotation (Tables 2, 3 and 4). This difference may be explained as follows. First, the number of characteristics differs from a finding to another (*i.e.*, six characteristics for calcifications, five for masses, and only three for distortions, special cases and associated findings). Second, the large amount of icons to remember (150) necessarily involves a considerable learning time, and it sounds acceptable that the annotation of unusual findings such as special cases and associated findings requires more time and more clicks in comparison with masses, calcifications and distortions which are more frequent.

User Satisfaction and Preferences. Participants considered the interaction with the system as natural, intuitive and reliable. A majority of participants (8) hesitated less than five times, and all were satisfied with the compliance with the BI-RADS. Five participants expressed very positive judgments on the star menu in terms of information visualization, speed and comfort. They preferred the star menu because ”it enables the parallel visualization of the items thanks to its spatial organization”, ”it is more comfortable thanks to its position close to the centre of the screen”, and ”it is faster [than the array]”. Four participants preferred the array because ”it is usual” and ”the characteristics follow a logical sequence”. These results are consistent with the CSUQ results: SYSUSE (*M*=5.46, *SD*=.96), INFOQUAL (*M*=5.56, *SD*=1.11), INTERQUAL (*M*=5.81, *SD*=0.88), and OVERALL (*M*=5.56, *SD*=1.89) are all above 5. The interface quality, especially, is assessed very positively by the participants.

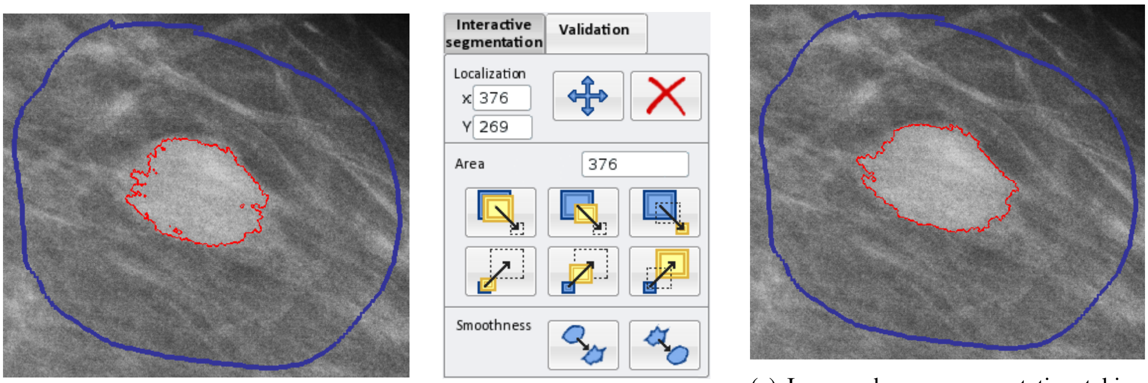
6 EXP.#2: MASS SEGMENTATION

Objectives. The purpose of this study was to evaluate the interactive mass segmentation method, its usability, and the relevance of the features chosen for the user feedback. The field tests took place in radiology department in the presence of both the radiologist and the experimenter. The tests involved three steps: (1) the experimenter presented the instructions, (2) the user drawn a ROI around the masses into the image database; and (3) when the interface highlighted the resulted segmentation, the user gives a feedback for interactive segmentation or for validation.

Method. We employed a think-aloud protocol: participants were asked to comment all steps of their actions and the results obtained. To assess the performances of the algorithm, the extracted features from segmentation together with the feedbacks were automatically collected and recorded into a log file. Since the initial algorithm was chosen from literature, the evaluation of the interactive segmentation consisted in comparing initial and final segmentations. The indicators of performance were: (1) the distance between the initial solution and the final solution (evaluation of the chosen algorithm performance), (2) the number of feedbacks returned by the user to acquire the final solution (validation of the feedback performance and the interactive segment usability), (3) the satisfaction of the user on the final segmentation/detection.

Experimental Set-up and Procedure. Three radiologists annotated 35 masses each: ten circumscribed masses, seven microlobulated masses, one obscured mass, three indistinct masses, and eleven speculated masses. Participants were able to require new segmentation solutions until they were satisfied with the results. Then, they could return a validation feedback and their assessments of the final segmentation. The performance was measured in number of clicks (feedbacks) to get the solution, and the evaluation of the segmentation (Fig. 10).

Results. Since radiologists ask for a good solution with a minimum of clicks, the usability of the



Localization
x 376
Y 269
Area 376

(a) Selection of a ROI (blue) and automatic mass segmentation (red).

(b) User interface dedicated to user feedback.

(c) Improved mass segmentation taking into account the feedback: "enhance moderately" and "smooth over".

Figure 10: Selection of a region of interest.

system directly depends on the number of returned feedbacks and the number of counter-feedbacks (erroneous user actions). The mean number of feedbacks per image relatively to the mass size is as follows: ”reduce” (S+M+L: M=1.94), ”Enhance” (S+M+L: M=1.91), total amount of clicks (M=3.81), and counter-feedbacks (M=.61). For the smoothness of the contour, the results are: ”Sharpen” (M=.52), ”Smooth” (M=1.32), total amount of clicks (M=1.42), and counter-feedbacks (M=.1). Consequently, contours need to be regularized at least once. This change has to be included in the initial segmentation to limit the number of clicks. Participants returned more feedbacks to enhance than to reduce the size of microlobulated and speculated masses and slightly reduced most of the mass areas. Nevertheless, the optimal segmentation threshold could not be automatically reduced to increase these performances, as this would have increased the probability of an erroneous initial segmentation at the same time. The feedbacks related to the seed point displacement show that participants moved in average the seed point 0.16 times per ROI: the mass centre is generally well-localized. These observations and the analysis of the log files show that participants tested the feedback interface on the first cases and gave a large number of counter-feedbacks for these cases.

User Satisfaction. The think-aloud protocol, together with the user feedback in the validation mode, provided an important set of users' subjective opinions. Radiologists underlined that their feedback improve the accuracy of the segmentation. Moreover, they reported that the interactive segmentation design can provide a well-localized solution, even if the initial segmentation failed. In addition, the feedback interface requires the radiologist to return a subjective evaluation of the final segmentation with two scores according to a 7-point Likert scale (1= "the final result is very bad", 7= "the final result is very good"). These two scores measured were: the accuracy of the segmented area (M=5.88) and the accuracy of the contour regularity (M=5.68). Satisfaction scores are high for the final segmentation with a mean score of 5.88. The feedback interactive scenario was approved in terms of graphical design, feedback components, and reactions of the system to the user commands. The system was judged to be easy-to-use and radiologists felt that they had the ability to improve the segmentation results with a simple request on a button.

According to a participant, the feedback design could be improved by leaving open the possibility of selecting and moving the points of the contour. In that case, the algorithm should calculate an optimal segmentation from the current segmentation together with the points moved during the interaction. The radiologists asked for sharp contours surrounding irregular findings and for smooth contour surrounding round or oval ones. The design action for smoothness feedback will be improved with the active contour models.

7 EXP. #3: MICROCALCIFICATION SEGMENTATION

Method. To evaluate the interactive microcalcification detection and segmentation method, field tests based on a think-aloud prototcol were conducted similarly to the experiment #2 with both the radiologist and the experimenter. Features extract from the segmentation together with the user feedback were automatically collected and recorded in a log file according to the same protocol defined in experiment

Table 5: Evaluation of microcalcification detection.

Measure	Value
Number of initially detected microcalcifications	367
Number of microcalcifications after radiologist validation (TP: true positives)	323
Number of added microcalcifications (FN: false negatives)	12
Number of deleted microcalcifications (FP: false positives)	41

#2. Each participant was instructed to annotate 20 clusters, *i.e.*, 323 microcalcifications, and three false clusters to evaluate the performance of the detection. Three radiologists tested the system.

Results. Table 5 reports the results of the microcalcification detection: the false-negative rate is low ($\frac{FN}{TP}=\frac{13}{323}=2.7\%$) for a reasonable false-positive rate ($\frac{FP}{TP}=\frac{41}{323}=12.7\%$). The missed findings are due to the breast image density or the mass densities. The false-positive markers correspond to visual artefacts that the system detects as findings. Thus, the overall sensitivity is equal to $\frac{TP}{TP+FN}=96.4\%$. Participants were instructed to draw a ROI with no findings inside and to annotate it as a cluster of microcalcifications even no microcalcification exists. Regardless to the erroneous annotation, the detection found the true result with zero microcalcification inside the ROI (true-negative).

Participants returned an average number of 2.94 feedbacks per cluster (Table 5: average number of "Add" feedbacks=0.66 plus average number of "Delete" feedbacks=2.27). This average is fair and reasonable depending on the detection rate and the image quality. Some clusters that include many visual artefacts require more user feedbacks. Then, the microcalcification suppression mode is not appropriate for this kind of image. Consequently, radiologists asked for the opportunity to delete at one time several microcalcifications. During the thinking-aloud session, participants underlined the importance of not missing any cluster (one speaks about cluster while three or more microcalcifications are detected). One participant gave a pretty good appreciation, while reporting that missing a microcalcification is less significant than missing a cluster. The importance of computing the number of microcalcifications by cluster was underlined as well. Radiologists' comments were clinically correct, but only a very accurate microcalcification detection can detect all cases.

8 CONCLUSION

This paper presents how a user-centered design process was conducted for an integrated clinical decision support system for breast cancer annotation and reporting. The iterative user-centred design used to best fit radiologists' needs and expectations led to the implementation of multi-fidelity prototypes combined with a scenario-focused questionnaire. Usability evaluations were conducted both *in vitro* (usability laboratory) and *in vivo* (field testing) with high-fidelity prototypes resulting from the previous process. Stroke gesture interaction was initially selected as the input modality to interact with the system, which is natural to annotate regions of interest of medical images. To avoid that the huge amount of possible annotations negatively affect gesture remembrance, two modes for the standardised stroke gesture annotation of BC findings were finally designed: a manual annotation specifically designed and implemented to support radiologists' activities, a semi-automatic annotation relies on image processing, especially on lesion detection and segmentation, combined with relevance feedback to improve the segmentation results.

The user-centered approach combined three usability evaluations with three different methods (*i.e.*, scenario-based design, multi-fidelity prototyping, and lab/field testing): (1) an evaluation of the interaction techniques supporting the manual annotation of BC findings: a combination of pie and star menus; (2) an evaluation of the semi-automatic annotation of masses; and (3) an evaluation of the semi-automatic annotation of (clusters of) microcalcifications.

Participants expressed very positive assessments on the star menu in terms of information visualization, speed and comfort and on the user interface. The feedback interaction was reported as relevant and easy-to-learn. The overall system was perceived easy-to-use and adapted to the human activity. The significance of the work can be highlighted regarding two considerations. First, the attention paid to the users and the usability. Its major benefit is the improvement of the user experience with CDSS, as the resulting platform is not only useful, but also usable. In particular, the pie and the star menus lead to better user performances, although users thus had no previous experience with this unusual interaction style. Second, the development method which combined prototyping tools and techniques. What is relevant and innovative in the method adopted here is, on the one hand, how the design process, the prototypes, and the usability evaluations were unified with the central goal to put the user at the centre of the development process; and, on the other hand, how they provided specific and complementary information. What is promising is how this combination of selected HCI techniques led to the acceptability of the system by the target final users. A major burden was encountered in this process when it required a substantial amount of collected data and individual interviews with a high level of details, the availability of representative end users (who are particularly solicited by their work), and the introduction of non-traditional interaction techniques.

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