Augmented Reality Guidance for Needle Biopsies: A Randomized, Controlled Trial in Phantoms

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Abstract. We report the results of a randomized, controlled trial to compare the accuracy of standard ultrasound-guided needle biopsy to biopsies performed using a 3D Augmented Reality (AR) guidance system. Fifty core biopsies of breast phantoms were conducted by a board-certified radiologist, with each set of five biopsies randomly assigned to one of the methods. The raw ultrasound data from each biopsy was recorded. Another board-certified radiologist, blinded to the actual biopsy guidance mechanism, evaluated the ultrasound recordings and determined the distance of the biopsy from the ideal position. A repeated measures analysis of variance indicated that the head-mounted display method led to a statistically significantly smaller mean deviation from the desired target than did the CRT display method. (2.48mm for control versus 1.62mm for augmented reality, $p < 0.02$). This result suggests that AR systems can offer improved accuracy over traditional biopsy guidance methods.

1 Introduction

Our research group at the University of North Carolina has been working in the area of augmented reality (AR) visualization for ultrasound examinations and ultrasound-guided procedures for nearly a decade [2-5,7,9,10]. The vision for this project is to allow physicians to directly see into a patient, aided by real-time computer graphics and augmented reality technology. The notion of augmenting the view of one's surroundings with computer-generated images has its roots in Ivan Sutherland's seminal paper [12], which described a system with a head-mounted display (HMD) whose synthetic images the user could see optically overlaid on the view of the room around him. Many years of research, both in the general AR field [1] as well as in

specific medical AR applications (for example [6,11]), have resulted in considerable improvement in each of the key technologies.

Using our biopsy guidance system in January 1996, a trained physician (Pisano) was able to guide a needle into a lesion within an artificial breast training phantom and report that the task was "easy" (fig. 1). A subsequent test with a human subject progressed to where the needle was partially inserted towards the target lesion, at which point the physician was forced to abandon the AR guidance and continue the intervention with conventional ultrasound guidance technology. During this and several subsequent experiments it slowly became clear that despite the technological advancements effective patient studies were still not possible. This was mostly due to cumbersome equipment and inadequate tracking technology [3].

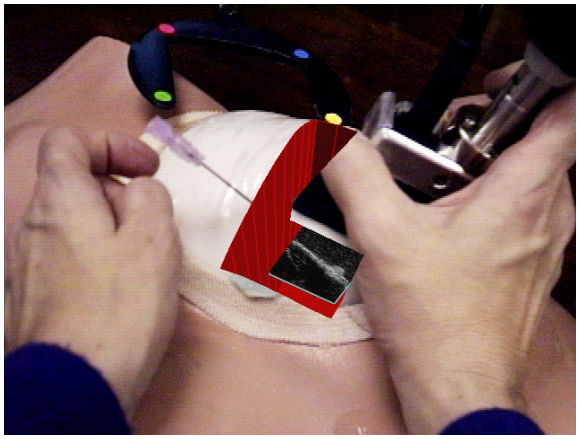

Fig. 1. HMD point of view image from a 1996 AR guidance experiment. The physician has inserted a cyst aspiration needle into a lesion within a breast phantom and holds the ultrasound transducer in her right hand. Correct ultrasound probe calibration and accurate tracking yield lignment between real needle and image of the needle in ultrasound slice. The colored dots in the background are fiducials for head tracking correction (not used in our current system)

We have spent the intervening years developing an enhanced guidance system, which is now being used in live patient studies. In the following sections, we describe the new developments in our guidance system. We also describe the design and report the results of a randomized, controlled study to determine the relative effectiveness of our new AR system versus traditional ultrasound. We conclude with a description of our current and future work.

2 Materials and Methods

Earlier papers have described our system design in detail [3-5,9,10]. In the following sections, we describe the updated components of our system and the design of our recent biopsy accuracy experiment.

2.1 Augmented Reality Guidance System

Our AR guidance system consists of four major components: a head-mounted display (HMD), an instrument tracking system, an ultrasound imaging system, and a graphics and computation platform.

Head-Mounted Display. We have modified a stereoscopic Sony Glasstron LDI-D100 HMD[1] for use as our display system. This HMD provides full color, stereo, SVGA (800x600) resolution displays in a lightweight design. We have added an aluminum superstructure to hold two Toshiba IK-SM43H video cameras for image capture and three infrared LEDs for opto-electronic tracking. Figure 2 shows the latest model of our HMD. This "video see-through" [1] device and its operation are described in detail in [10].

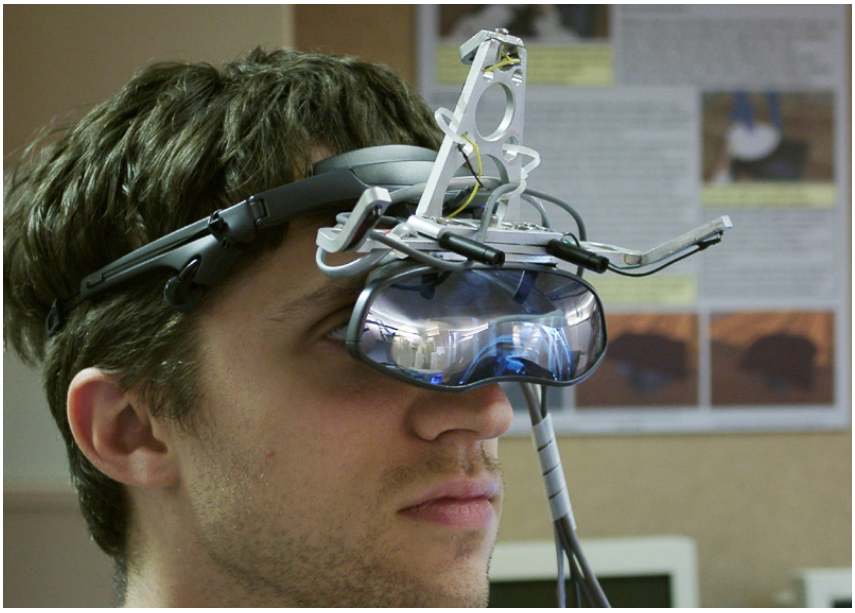

Fig. 2. Video-see-through augmented reality HMD built on the basis of a Sony Glasstron LDI-D100 device. The aluminum superstructure holds two miniature video cameras for image capture and three infrared LEDs for opto-electronic tracking of the HMD

Tracking System. We use an Image-Guided Technologies FlashPoint™ 5000 opto-electronic tracker in our system. The HMD, the ultrasound probe and the biopsy needle are all equipped with infrared LEDs. The FlashPoint delivers sub-millimeter-accurate readings of the positions of these LEDs to the graphics computer. This HMD tracking technology is not quite as accurate as the closed-loop method used in

[1] Alas, Sony is no longer manufacturing the SVGA stereo version of their Glasstron HMD.

our original 1996 system [8], but it is superior to magnetic technologies and does not encumber the user's field of view (and the sterile operating field) with fiducials. The ultrasound probe is also tracked opto-electronically. It uses a specially developed 9-LED device that allows rotations up to 80° to any side without losing acquisition, thus freeing the physician to position and orient the probe in the most adequate way for a particular intervention.

Ultrasound Imaging System. We are using a PIE Medical Ultrasound Scanner 350 to acquire ultrasound images during our experiments. This device was donated by PIE Medical.

Graphics and Computation Platform. The system runs on an SGI Onyx2 Reality Monster™ graphics computer equipped with multiple DIVO digital video input/output boards, allowing simultaneous capture of multiple video streams. The software routinely runs at frame rates of 20-30 Hz in stereo on this platform. Fig. 3 shows imagery displayed by our system during an experiment with a breast training phantom in late 2000.

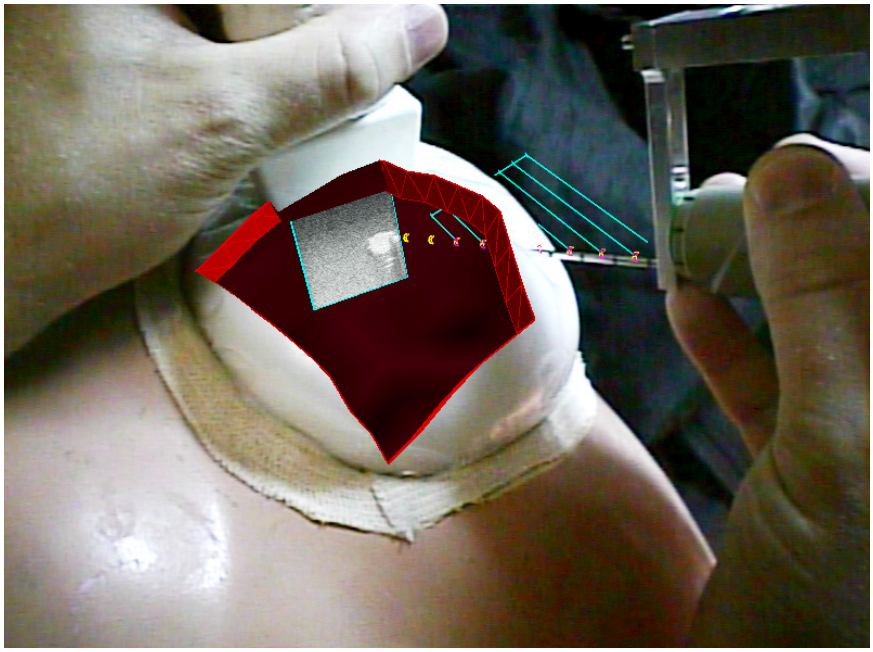

Fig. 3. HMD view during phantom biopsy experiment. Both the ultrasound probe (left hand) and the biopsy needle (right hand) are tracked. The needle aims at the bright lesion visible in the ultrasound slice. The system displays the projection of the needle onto the plane of the ultrasound slice (blue lines) and also displays the projected trajectory of the needle if it were fired at this moment (yellow markers)

2.2 Design of Biopsy Guidance Study

We have performed an experiment to compare our AR guidance system to standard ultrasound guidance for the task of targeting needle biopsies in training phantoms. Our hypothesis was that the two guidance methods would be comparable in terms of needle placement accuracy for this task, indicating that it is safe to evaluate the AR system in humans.

The experimental component of this study was performed using the AR system described above. The control component was performed using only the PIE Medical Ultrasound Scanner 350 component of our system without any computer augmentation.

Biopsy Task. Our task under evaluation was a standard series of core biopsies that would be performed on a solid breast mass. Standard ultrasound training phantoms (Model 52 Biopsy Phantom, Computerized Imaging Reference Systems, Inc., Norfolk, VA) were used as our biopsy subjects. These phantoms each contained six tumor-like targets placed randomly throughout an ultrasound-compatible gel mold. The phantoms are approximately the size and shape of an average human breast. A new phantom was used whenever the radiologist felt that artifacts from previous biopsies were interfering with the current task.

For each selected lesion, biopsies were targeted to the center of the lesion and to the three, six, nine, and twelve o'clock positions around the perimeter of the lesion (as viewed on the plane orthogonal to the axis of the biopsy needle). The biopsies were performed using a 14-gauge Monopty core biopsy needle (C. R. Bard, Inc., Covington, GA). The needle was withdrawn from the phantom after each biopsy attempt. The ultrasound video from each biopsy was reformatted and recorded directly from the ultrasound scanner to DV tape for later evaluation.

Randomization and Control Scheme. This study was designed as a randomized, controlled trial to limit the effects of confounding factors. A single board-certified radiologist (Pisano) performed all of the biopsies in this experiment (fig. 4). Ten targets within the phantoms were sequentially selected; five biopsies were performed on each lesion before selecting the next target. Randomization to the two guidance methods was performed by a coin flip before the selection of each biopsy target.

Evaluation of Accuracy. Another board-certified radiologist (Cherie Kuzmiak, DO) evaluated the ultrasound video to determine the accuracy of each biopsy. The evaluator was blinded to the method of guidance for each biopsy. For each biopsy, she determined the geometric distance (in mm) between the ideal biopsy target point and the actual biopsy positions in the plane orthogonal to the needle. The evaluator also measured the dimensions of the lesions along the needle axis and along two perpendicular directions (approximately vertical and horizontal). These distances were measured on an NTSC display with respect to the reference ruler that was recorded as part of the ultrasound display. The results were later entered into an Excel spreadsheet and associated with the corresponding guidance method.

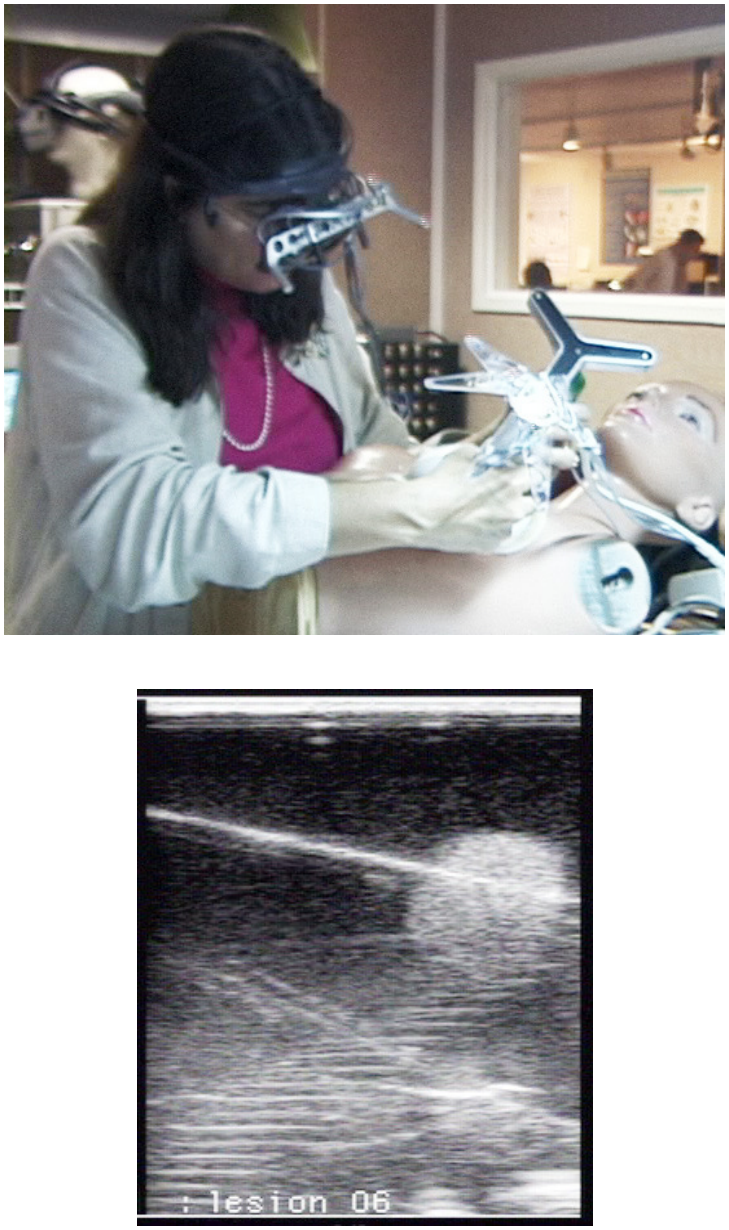

Fig. 4. Lab view (left) and ultrasound image (right) while the physician, wearing the Glasstron-based AR HMD, performs a controlled study with the 2000 AR system. She holds the opto-electronically tracked ultrasound probe and biopsy needle in her left and right hands, respectively. The HMD view was similar to Figure 3

Statistical Analyses. Descriptive statistics (mean ± std) of the error distances were calculated. Separate and combined results were computed for the HMD and CRT display methods for each location, mean error across locations and the mean of the maximum lesion dimension. The primary analysis was a repeated measures analysis of variance (REPM ANOVA) utilized to address the multiple locations targeted within each lesion (a within-'subject' repeated measures dimension). The SAS® procedure GLM was utilized.

To rule out lesion size bias as contributing to the effect attributed to display method in the primary analysis, we performed an exploratory full model in every cell (FMIC) REPM ANOVA analysis to show that the effect due to lesion size was not significant between the display methods. The FMIC was then reduced to a multivariate analysis of covariance (MANCOVA) model and reanalyzed. Maximum lesion dimension (in mm) was the measure we chose to represent lesion size.

3 Results

A total of fifty biopsies were performed: twenty-five in each of the AR guidance and standard guidance groups. The mean error distances for each of these groups are shown in table 1 below. A repeated measures analysis of variance indicated that the HMD display method led to a statistically significantly smaller mean deviation from the desired target than did the CRT display method. (2.48mm for control versus 1.62mm for augmented reality, $p < 0.02$). The biopsy location and the location-display combination did not yield statistically significant effects upon the accuracy.

Table 1. Results from the phantom biopsy study

(All measures in mm, mean ± std dev)	**Standard Guidance**	**AR Guidance**	**Combined Results**
Error at Center	4.20±1.92	1.50±1.41	2.85±2.14
Error at 3 O'clock	2.00±1.87	1.70±0.67	1.85±1.33
Error at 6 O'clock	1.20±0.84	0.90±1.02	1.05±0.90
Error at 9 O'clock	2.00±1.58	0.80±1.30	1.40±1.51
Error at 12 O'clock	3.00±2.00	3.20±2.05	3.10±1.91
Mean Error across Locations	2.48±0.44	1.62±0.48	2.05±0.63
Mean of Maximum Lesion Dimension	10.50±3.26	12.00±2.09	11.25±2.70

The supportive FMIC ANOVA and MANCOVA analyses of the effects of lesion dimensions upon accuracy indicated that the maximum lesion dimension had no significant effect upon placement error ($p > 0.05$ for the main effect and all combinations involving maximum lesion dimension).

4 Conclusions

The results of the above study indicate that the AR guidance system yielded statistically improved accuracy as compared to the standard ultrasound guidance method. In fact, we did not expect the AR system to be as good as the conventional guidance technique, especially for the expert user (Pisano). Our goal was to merely demonstrate the system's effectiveness on a procedure that is simple and not dangerous to the patient. The indication that the AR technique may be better even in this comparison, where the advantage should go to the conventional approach, is both surprising and encouraging. Of course, procedures on phantoms may be more advantageous for the new approach than procedures with live patients, since phantoms have simpler tissue characteristics. We may consider user studies with less experienced physicians, which may show an even more dramatic advantage for our new approach.

Additional studies with human subjects are currently underway to confirm that these benefits translate to real improvements in medical care. Beyond that we are considering two possibly parallel paths of research: 1) Exploring the AR approach for relatively simple medical tasks, such as cyst aspiration, for primary care physicians, and 2) Investigating the AR approach for needle placement in more difficult areas of the body (e.g., liver), in which targets are in heavily vascular regions where avoidance of major vessels is a prime consideration.

While results reported here are preliminary and of limited scope, we believe that they suggest the potential of AR visualization to improve patient care. We hope that the next decade of research will continue to explore the potential of augmented reality for both medical and non-medical applications.

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