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Characterizing the range of simulated prostate abnormalities palpable by digital rectal examination

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ABSTRACT

Background: Although the digital rectal exam (DRE) is a common method of screening for prostate cancer and other abnormalities, the limits of ability to perform this hands-on exam are unknown. Perceptible limits are a function of the size, depth, and hardness of abnormalities within a given prostate stiffness. *Methods:* To better understand the perceptible limits of the DRE, we conducted a psychophysical study with 18 participants using a custom-built apparatus to simulate prostate tissue and abnormalities of varying size, depth, and hardness. Utilizing a modified version of the psychophysical method of constant stimuli, we uncovered thresholds of absolute detection and variance in ability between examiners. *Results:* Within silicone-elastomers that mimic normal prostate tissue (21 kPa), abnormalities of 4 mm diameter (20 mm^3 volume) and greater were consistently detectable (above 75% of the time) but only at a depth of 5 mm. Abnormalities located in simulated tissue of greater stiffness (82 kPa) had to be twice that volume (5 mm diameter, 40 mm^3 volume) to be detectable at the same rate. *Conclusions:* This study finds that the size and depth of abnormalities most influence detectability, while the relative stiffness between abnormalities and substrate also affects detectability for some size/depth combinations. While limits identified here are obtained for idealized substrates, this work is useful for informing the development of training and allowing clinicians to set expectations on performance.

1. Introduction

Prostate cancer has a high incidence rate (one in six for men in the U.S.), with an estimated 192,280 new cases in 2009. When diagnosed in an early and less aggressive stage, the five-year survival rate approaches 100% [1]. To promote early detection, the American Cancer Society advises that screening via the digital rectal examination (DRE) and prostate specific antigen (PSA) blood test be conducted concurrently. The DRE is important because the PSA tends to both over diagnose (65–75% of findings reported as false positives for PSA greater than 4.0 ng/l [2]) and miss cancerous tumors (15.2% of findings reported as false negatives for PSA less than 4.0 ng/l [3]). Although the DRE plays an integral role in early detection and is a skill clinicians are expected to learn, the perceptible limits surrounding this exam are unknown. Therefore, there is no basis from which to set reasonable expectations about clinical performance or to develop appropriate training.

When conducting a DRE, the clinician's task is to detect hard nodules that vary in size, depth and hardness or prostate enlargement that varies in volume change and stiffness. The former typically relate to carcinoma, the latter signal benign prostatic hyperplasia (BPH) or prostatitis [4]. The size, depth, and hardness of nodules and relative stiffness of a given prostate contribute to the perceptible range of abnormalities. At present, neither the thresholds of absolute detection nor variance in ability between examiners have been identified.

In contrast, palpable limits have been studied in terms of the clinical (CBE) and self (BSE) breast exams [5]. In two studies with rubber-like materials, abnormality size emerged as the major dimension affecting the detection of lumps [6,7]. In general, larger lumps in more shallow positions pose the least difficulty. However, simulated lumps as small as 3.0 mm diameter were detectable when embedded in breast-like materials (which is an order of magnitude more pliant than prostate tissue) [9–10]. Aside from the lump size findings, abnormality depth and hardness appear to have a minimal impact, whereas the stiffness of surrounding tissue may decrease one's ability to detect deeper lumps [11].

Hall et al. have shown that training on silicone models effectively increases exam performance on natural breast tissue [12]. Most of their training, and that prescribed by others for use with silicone models [13–17], takes place at the level of hands-on

Abbreviations: DRE, digital rectal examination; PSA, prostate specific antigen; BPH, benign prostatic hyperplasia; CBE, clinical breast examination; BSE, self breast examination; kPa, kilopascals.

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skills. There is a focus on tactile skills because knowledge of disease and attitudes about domain are not strongly related to proficiency [18] and basic rules for diagnosing abnormalities as certain diseases are not difficult to master [19]. One major prerequisite for improving hands-on skills, however, is knowing the limits of tactile sensation, in this case with respect to the DRE.

When characterizing the limits on performance, the DRE differs from the breast exam in several key ways. First, a rectal wall is positioned between the finger and prostate, in addition to a glove and lubricant. Second, the clinician uses a single finger and is more constrained in search movement. Third, the prostate is a stiffer gland with less volume. Fourth, the exam typically takes place in less than 30 s in contrast to 2 min for the breast exam [7,20]. With these differences in mind, one common factor is that clinician performance in both exams does benefit from training.

In this work, the overall goal is to determine the perceptible limits of simulated abnormalities of various size, depth, and hardness within substrates of different stiffness when the examiner is constrained as with a DRE. In addition to determining the thresholds of absolute detection, we seek to determine the degree of variance in ability between examiners.

2. Methods

To analyze the limits of tactile perception in the DRE, we conducted a human-subjects experiment with 18 participants, using simulated prostates where abnormality size, depth, and hardness were varied within substrates of two stiffness levels. The objectives were to determine (1) the size of abnormalities detectable above 75% of the time at three discrete depths, (2) how substrate stiffness impacts the detectability of size/depth combinations, (3) if changes in abnormality hardness (consistent in objectives 1–2) impact detectability over size/depth combinations, (4) if some abnormalities require a minimum hardness be consistently detected, and (5) the variance in ability between participants.

2.1. Apparatus

An apparatus was built specifically for this study. The apparatus utilized silicone-elastomers to simulate the feel of prostate tissue and a rectal wall and employed a computer and electronics to control polyethelene balloons that simulated abnormalities. The computer also monitored the water pressure in the balloons and force on sensors embedded in the simulated tissue. The apparatus design is similar to that described in Ref. [19].

Twenty-three simulated prostates, 30 mm diameter and 20 mm tall, were mounted to a round platform that could be rotated so that the prostate under test was located beneath the examiner's finger. The idealized cyndrilical prostates did not include the surface undulations or an overall walnut shape, although the size was roughly the same as an actual prostate [19]. The platform containing the simulated prostates was housed within a structure that restricted access to and view of the simulated prostates. The examiner inserted his or her finger through an opening in the structure that was built of silicone-elastomer to mimic the rectal wall. The opening was angled at approximately 110° from the participant.

Each simulated prostate included a single polyethelene balloon embedded at one of three depths: 5, 10, and 15 mm. Balloons of seven volumes were used: 20, 40, 80, 200, 470, 1060, and 1770 mm^3 that correspond to diameters of 4.0, 5.0, 7.5, 10.0, 15.0, 17.0, and 20.0 mm, respectively. Preliminary studies found that balloons of 3.0 mm diameter were inconsistently detected in stiffer simulated prostates and were not included. The balloons were filled with water, thereby controlling hardness. Balloons could be inflated to be hard, like a rock, but were not detectable when deflated. In this study, three hardnesses were used: 23, 27, and 31 durometers, type Shore A. These fall within the range used for simulated breast tumors [6,7]. Water pressure sensors (Honeywell, SenSym Pressure Sensor, Model SX100DD4) monitored the water pressure over time, which was logged by the computer.

In addition to factors of depth, size, and abnormality hardness, simulated prostates of two stiffness levels were used: 21 and 82 kPa. These have been evaluated via compression tests and fall into the measured range of prostate stiffness (mean elastic modulus = 44.20 kPa, SD = 25.89 kPa [8]). These stiffness values also fall in line with those deemed "realistic" in a subjective study with resident physicians and nurse practioner students [19]. Located in the backing of each prostate were four, laterally spaced pressure sensors (Flexiforce 0–1 lb, Tekscan, South Boston, MA) which logged the examiner's finger pressure over the simulated prostate.

2.2. Participants

Ten male and eight female participants (mean age = 20.4 years, SD = 1.38) were enrolled in the human-subjects study, approved by the IRB at the University of Virginia. No participant had prior clinical experience. A questionnaire also indicated that no participant had any remarkable prior experience working with his or her hands.

2.3. Experimental design

Using a modified version of the psychophysical method of constant stimuli [21], participants palpated the simulated prostates to determine the presence or absence of abnormalities. Typically the method of constant stimuli employs stimulus and blank trials presented in a randomized fashion where all stimulus combinations are presented an equal number of times. However, in the version we employed, we made three modifications to reduce participant fatigue. First, from all possible combinations (abnormality size, depth, hardness and substrate stiffness) only a subset of stimulus combinations were presented to participants (e.g., size 4 mm was used at 5 and 10 mm depth but not 15 mm depth). Pilot testing was conducted to remove combinations that were detectable 0% or 100% of the time. Second, the number of times that each stimulus combination was presented varied from two to four times depending on the difficulty of detecting the abnormality in the pilot study. Specifically, from the chosen subset of abnormalities, the most difficult to detect were presented four times, while the easiest to detect were presented two times. Third, due to hardware and time limitations, participants were presented with stimuli and blanks in one of six pre-determined random orders. Table 1 shows all stimulus combinations used and the number of times each was presented per participant in the experiment.

2.4. Procedure

Every participant participated in two experimental sessions, held on separate days for 90 min each. In session 1, each participant completed a 5 min pre-test questionnaire, a 5 min hands-on practice, and an 80 min hands-on experiment. During session 2, each participant completed a 5 min hands-on practice, an 80 min hands-on experiment and a 5 min post-test questionnaire. During sessions 1 and 2, participants palpated 96 simulated prostates, half of which contained an abnormality (the balloons were not inflated for the other half). Four participants returned for session 3, which was a 5 min hands-on practice and a 45 min hands-on experiment. Session 3