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A Novel Intermediate Attachment to Reduce Contamination in Reusable Core Needle Biopsy Devices

One barrier to breast cancer diagnosis in low-resource settings is that devices for core needle biopsy (CNB) are either disposable and expensive, or reusable and susceptible to internal contamination. Through interviews with field workers and verification experiments, we identified that a common, commercially available, reusable CNB device allows contaminants to enter the driver chamber during firing, necessitating laborious cleaning of the entire device after every use. We introduce a novel CNB device attachment that eliminates this contamination mode and interfaces with existing commercial reusable drivers and low-cost disposable needles. This attachment repositions the driver–needle connection to the exterior of the driver, preventing retrograde flow of blood. Using an unmodified commercial CNB, we replicate chamber contamination by firing into a body fluid-mimicking glycerol solution. Prototypes were tested for their performance in eliminating this contamination. We tested the effectiveness of a cleaning procedure to reduce trace contamination by using a fluorescent dye and measuring the intensity of fluorescence after cleaning. The device's ability to reliably and consistently biopsy tissue with the novel attachment was evaluated using breast tissue models. In these tests, a reusable CNB with our attachment exhibited no measurable internal contamination, and maintained full biopsy functionality as measured by tissue sample weight and length. Minimizing internal device contamination would simplify the cleaning process for reusable biopsy devices. This would improve the accessibility of breast cancer biopsies in low- and middle-income countries (LMICs). [DOI: 10.1115/1.4045967]

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Introduction

The process of breast cancer diagnosis is often initiated by detecting an abnormality through self-examination, physical examination by a clinician, or screening mammography. A biopsy is a sampling of cells or tissue obtained from the suspicious lesion. In the United States, approximately 5–7% of women who are screened annually for breast cancer will undergo biopsies for suspicious lesions identified on imaging [1,2]. Ultrasound-guided core needle biopsies (CNB) are the standard for ultrasound guided breast biopsies because they are minimally invasive and accurately obtain tissue samples [3]. Typical CNB devices consist of a driver that rapidly deploys and retracts a needle with a hollow core into a lesion to capture a biopsy sample. Disposable CNB devices are frequently used in developed countries, but the accumulated cost of repeatedly purchasing single-use devices makes this option less feasible for hospitals in low resource settings [4].

Reusable CNB devices, composed of a reusable driver that attaches to a disposable needle, represent a cost-saving option over time compared to the standard single-use disposable CNB devices. However, reusable devices face several barriers to widespread use in low resource settings, including: (1) there is a risk that healthcare providers will re-use a disposable needle, and (2) the reusable driver often becomes contaminated from bodily fluids that enter the device (Fig. 1), requiring time-intensive and often ineffective cleaning procedures. While the first barrier applies to both reusable and disposable CNBs, and may be addressed with improved awareness and quality protocols, the second occurs even when the protocol is correctly followed. Contamination is identified even when the device is properly used and must be avoided especially in areas where HIV and multidrug resistant tuberculosis are common. One common reusable CNB requires a nine-step cleaning procedure, demanding 1–2 h of processing time total after each use [5].

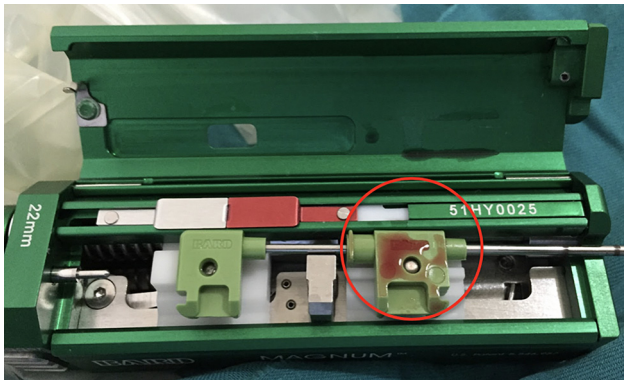

Fig. 1 A current reusable core needle biopsy device (Bard Magnum) is susceptible to contamination. Image of the Bard Magnum reusable core needle biopsy device and blood (red circle) having entered biopsy driver following a core needle biopsy procedure at the Butaro Cancer Center of Excellence in Rwanda. Photograph courtesy of Dr. Sughra Raza, MD.

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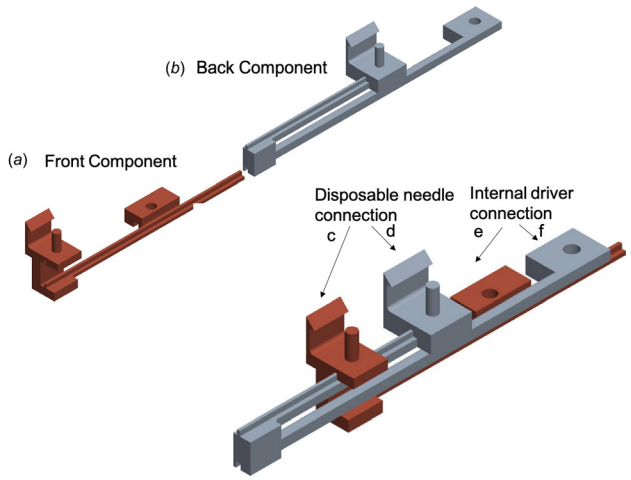

Fig. 2 Front (*a*) and back (*b*) components of intermediate attachment device. Front component of device (red) is composed of (*c*) an external piece that houses the disposable needle via the needle's distal pin and (*d*) an internal piece that fits onto the internal driver device. Back component of device (gray) is composed of (*e*) an external piece that houses the disposable needle via the needle's proximal pin and (*f*) an internal piece that fits onto the internal driver device. Both external pieces utilize an angled tooth locking mechanism to secure the needle in place. The back and front components fit together to enable biopsy firing mechanism that transmits the tissue capture force from the spring-loaded driver to the attachment device. Both exploded ((*a*) and (*b*)) and assembled (*c*-*f*) views are shown.

Design of improved (reusable) devices that enable healthcare providers in low and middle-income countries (LMICs) to collect tissue for biopsies while minimizing contamination risks and (decreasing costs compared to single-use options) would improve the accessibility of earlier breast cancer diagnosis by reducing per-use costs. Moreover, an improved driver platform that avoids complex cleaning requirements may spur future innovation in bringing down prices of simple, disposable needles. This paper describes a reusable novel attachment that allows disposable needles to attach and fire externally to a reusable CNB driver. By mechanically separating the needle from the driver, bodily fluids are prevented from entering the reusable driver of the device, limiting cleaning requirements to the external surface of the driver (Fig. 2).

Design Requirements

We derived a set of design parameters based on discussions with 37 stakeholders, including clinicians, nurses, and hospital staff at 18 hospitals in the United States, South Africa, and India. The following criteria are required for a device to represent a meaningful advancement beyond the standard of care.

(1) The device must reliably prevent internal driver contamination. Meeting this requirement would allow the device to be successfully cleaned via a simple sterilizing procedure [6].
(2) The device must match the standard of care in its ability to extract tissue from breast lesions in tumors larger than 2 cm, which represent the majority of stages III and IV breast cancers, extracting four to five samples per biopsy procedure. These samples must be of comparable weight and length to that of currently used devices (for a diagnostic accuracy $\geq 99\%$) [7].
(3) Compared to existing devices, the device must expose patients to comparable or lower procedural complication risk to the reusable CNB.
(4) The device must be ergonomic and ambidextrous (and thus conducive to easy handling and training using either the left or right hand) in order to be used in environments where providers' experience and skill varies.
(5) To facilitate use among experienced physicians who have been trained using existing devices, the device must have similar length (from end of driver to tip of needle) to existing devices. Current device lengths range from 10–30 cm [8].
(6) The design must be composed of materials that can be sterilized and are durable to reuse across multiple procedures.

Concept/Prototype Development

While modes of contamination for reusable biopsy devices are not specifically documented in the literature, our interviews with experienced users of the Bard Magnum® reusable core needle biopsy device revealed two primary modes of failure.

(1) *Fluid flow between needle and sheath:* Our tests indicate that firing the device causes retrograde flow of blood between the coaxial faces of the needle and sheath into the driver (Fig. 1).
(2) *Contamination via open hatch needle insertion:* Disposable needles are inserted into biopsy drivers through a manually opened hatch. This risks contamination while the hatch is opened during needle-attachment and removal.

Here, we present a design that attaches to the Bard Magnum driver that would prevent these sources of contamination by routing retrograde blood flow away from the interior of the driver and by sealing the driver's hatch. The attachment translates the firing motion of driver outside and above the driver. The attachment features two dovetailed metal rods (Fig. 3) that protrude from the driver via an opening on its front face. The rods bend back around the device to minimize the length added to the biopsy device. These rods connect to biopsy needles via a "post-and-click" mechanism.

The disposable needle sits on posts on top of the attachment. The needle is locked into place by a metal tooth that prevents vertical displacement of the needles. To mitigate the risk of procedural contamination, an adhesive cover protects all seams and orifices of the biopsy driver. The attachment was manufactured using 3D printing in raw aluminum, a material that is suitable for reuse and can withstand multiple cleaning cycles. Additionally, the attachment can be easily disassembled for cleaning, so that all surfaces can be targeted. The external needle connection prevents contaminants from entering the complicated moving spring mechanism of the current reusable driver. Our design thus enables a facile attachment procedure and a secure connection while preventing contamination.

Testing Methods/Setup

Assessing Contamination. We compared internal contamination of the Bard Magnum biopsy device with and without the attachment prototype. A 3:1 glycerol–water ratio solution with comparable viscosity (2.50–3.72 mPa·s at 20 °C) to blood (1.5–3.2 mPa·s at 20 °C) was used as the contaminant [6]. To detect flow of contaminant into the driver, water-contact indicator tape (3M™ Water Contact Indicator Tape, St. Paul, MN) was placed inside the driver. The device was fired by one operator into a glycerol solution 10 times while fixed in a horizontal position. A baseline image of the water-contact indicator tape in the device was taken and segmented before the test began. After each fire, the taped areas (change from white to red on contact) were photographed and manually segmented (IMAGEJ [9]) to calculate area of contamination (mm^2) (Fig. 4). Tests were repeated with water as the contaminant to evaluate the impact of a less viscous fluid on the quantity of internal contamination.

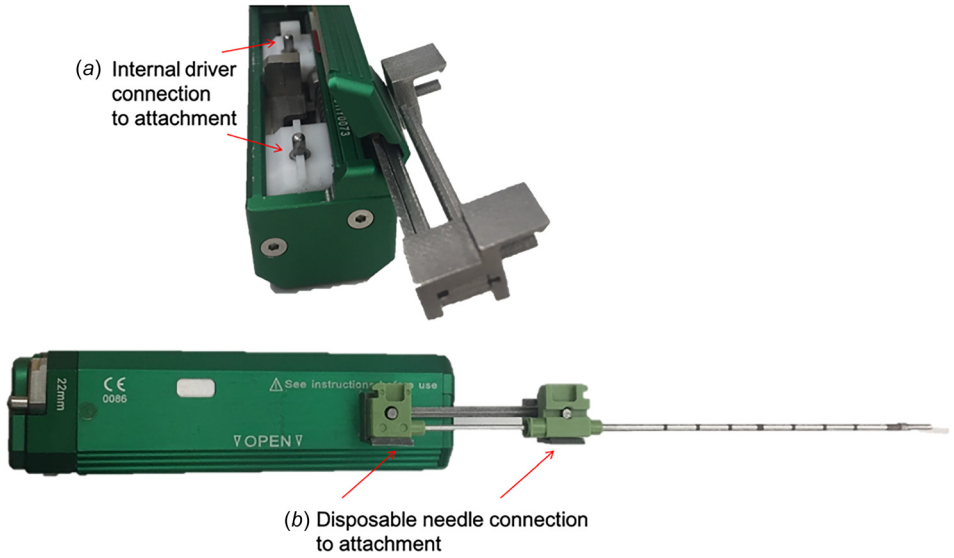

Fig. 3 Attachment device interfaces with Bard Magnum CNB driver to prevent internal contamination: (*a*) attachment device connects to the internal driver using two driver posts that interlock with holes on the attachment components and (*b*) disposable needle connects to the attachment device by fitting over one post on each attachment component

Assessing Performance of Cleaning Procedure. We devised a simple cleaning protocol for the novel attachment, and tested a worst-case contamination by submerging the attachment in a fluorescent contaminant solution to simulate the contact of the device with patient skin and bodily fluid contaminant. Fluorescent dyes like fluorescein are easy to handle, inexpensive, and allow sensitive detection of contamination, making them frequently utilized to measure cross-contamination of medical devices after sterilization procedures [10]. The fluorescent solution was composed of 0.1 g riboflavin and 1 g hydroexylcellulose in 50 mL glycerol solution (3:1 glycerol–water ratio in glycerol solution). Three cleaning regimens were tested: no cleaning, gentle cleaning (wiping three times with 70% isopropyl alcohol pad), and vigorous cleaning (scrubbing 3 min with 70% isopropyl alcohol pad) [11].

Before the test began, a calibration curve was generated via a 10:1 titration of the fluorescent solution in de-ionized water resulting in the linear relationship $y = 1.84x + 0.18$ ($R^2 = 0.99$) and used to correlate relative intensity units output by the Synergy™ H1 microplate reader (Winooski, VT) to concentrations of fluorescent solution on the attachment.

To determine the minimum amount of fluorescent solution that could be correctly detected by the Synergy H1 microplate reader, increasing amounts (0.25 mL, 0.5 mL, and 0.75 mL) of the fluorescent solution were applied to the attachment until a sufficiently nonzero fluorescent:water ratio was measured. This was to ensure that small amounts of remaining contaminant could be detected by the experimental setup. The measured intensities were converted to ratio of fluorescent solution to water based on the linear relationship from the calibration curve. Positive nonzero quantities of fluorescent:water correspond to amounts of contaminant applied to the device that are large enough to be detected.

The attachment was submerged in the fluorescent solution to demonstrate worst case scenario contamination, and subsequently the attachment was placed in a tube with 20 mL of water. The lid was placed on the tube and it was agitated to collect solution from the attachment. 100 mL of liquid from the agitated tube was pipetted in triplicate into a 96 well plate. This process was repeated two more times, following the first isopropyl alcohol wipe and the 3-min contact time with the second isopropyl alcohol wipe. The plate was placed in the Synergy H1 microplate reader and measured at $\lambda = 360$ nm. This protocol was repeated with two control cases: (1) de-ionized water alone and (2) de-ionized water with the novel attachment.

Assessing Biopsy Capture Performance. To test the functionality of the design in capturing tissue, we acquired biopsies from two different breast models and measured the weight and length of the samples. The first model used was ex vivo chicken breast, which is commonly used for breast biopsy training [12]. We assume that the consistency and structure of the chicken breasts remain relatively uniform among samples. The second model utilized two silicone rubber compounds of different densities chosen to simulate breast tumor and tissue [13]. SmoothOn® Ecoflex-30®(mixed viscosity 3000 mPa·s; tensile strength 1.38 MPa) and SmoothOn Oomoo-30® (mixed viscosity 4250 mPa·s; tensile strength 1.66 MPa) were used to model the breast tissue and tumor mass, respectively [14,15]. We assessed the difference in the weight and length of tissue samples acquired using our prototyping compared to the Bard Magnum standard using a paired two-tailed *t*-test. For each of these tests, the device was fired into each model five times by two randomized operators, and the weight (g) and length (mm) of the sample acquired were recorded (Table 1).

Results

Assessing Contamination. Evaluations of internal contamination of the Bard Magnum device and the attachment indicate that the attachment eliminated any detectable contamination of the internal driver. Without the attachment, the average area of contamination after ten consecutive fires of the Bard Magnum into a glycerol solution and water was 12.29 mm^2 and 44.79 mm^2, respectively, over a total scanned area of 2328 mm^2, as shown in Fig. 5. Both the glycerol and water trials yielded no detectable internal contamination when the intermediate attachment was used.

Assessing Performance of Cleaning Procedure. Sensitivity of the experimental setup to varying quantities of contamination was determined by considering zero values of measured florescent solution as not detecting the contaminant. We found that the experimental setup was not sensitive to quantities of fluorescent solution less than 0.25 mL applied to the device, as indicated by a negligible fluorescence:water ratio value (−0.01). However, in cases of 0.50 mL and 0.75 mL applied to the attachment, these amounts of contamination could be detected as indicated by the nonzero, positive ratio values (0.07 and 0.08, respectively). With

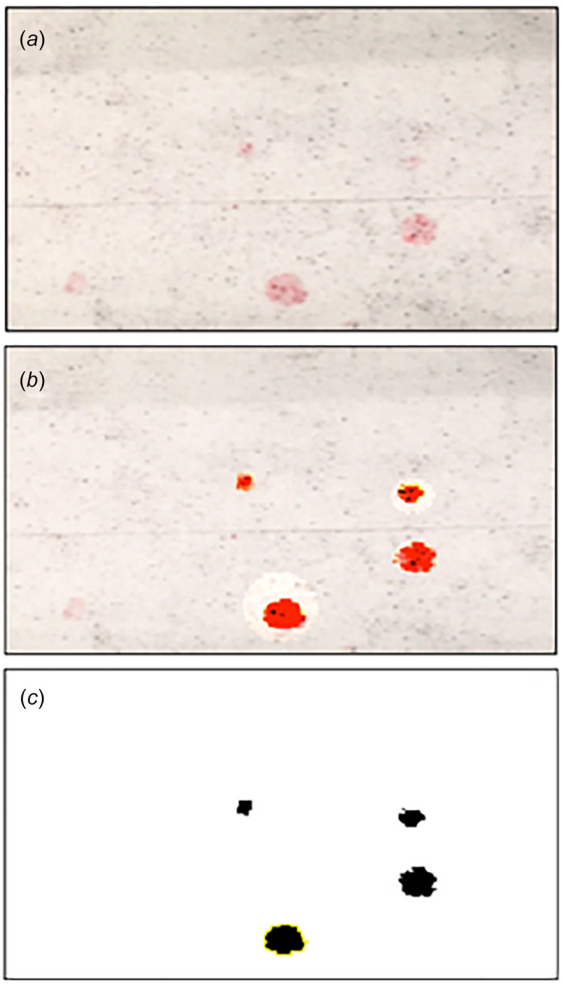

Fig. 4 Representative images of image processing approach to estimate area of contamination with Bard Magnum CNB device: (*a*) raw image of internal contamination observed inside Bard Magnum driver, (*b*) IMAGEJ software was used to segment contaminated region of interest, and (*c*) calculation of area based on pixel intensity threshold

0.75 mL fluorescent solution applied to the device, the ratio of fluorescent solution to water was 0.11, and 0.75 mL of contaminant was thus used for subsequent tests of the cleaning procedure. After gentle and vigorous cleaning protocols, the fluorescent assay indicated no detectable solution remaining on the device (ratios −0.03 and −0.04, respectively).

Assessing Biopsy Capture Performance. In the chicken breast model, the samples acquired by the Bard Magnum had an average weight of 0.022 ± 0.007 g and the samples acquired with the attachment had an average weight of 0.021 ± 0.006 g. In the polymer model, the samples acquired by the Bard Magnum had an average weight of 0.014 ± 0.003 g and the samples acquired with the attachment had an average weight of 0.011 ± 0.004 g (Fig. 6) In both models, there was no statistically significant difference of sample weights between devices ($p = 0.72$ for chicken breast model and $p = 0.10$ for silicone model based on two-tailed paired *T*-test). Average lengths of the samples acquired by the Bard Magnum alone and with the attachment were also comparable (1.03 ± 2.5 mm and 0.93 ± 0.9 mm, respectively, for the chicken breast model, $p = 0.28$; 10.0 ± 4.1 mm and 7.4 ± 2.4 mm, respectively, for the polymer model, $p = 0.17$). These results are summarized in Table 1.

Conclusions and Interpretation

Disposable CNB devices currently dominate the global biopsy devices market; however, the single-use cost of these devices, at $40–200 per procedure, is prohibitively expensive in many LMICs [16]. Reusable devices are cost-saving option that could improve the accessibility of CNB procedures, but the laborious cleaning procedures required to avoid potential infection risk renders these devices poorly suited in contexts where patient volumes are high and cleaning equipment is unavailable. We have designed a novel attachment for the Bard Magnum that can retrieve adequate breast tissue samples while preventing internal driver contamination. Our attachment connects to disposable needles outside of the Magnum's internal chamber, allowing the internal chamber's hatch to remain closed at all times, and thereby avoiding contamination during biopsies. This approach could improve the availability of CNB technology in low-resource settings globally.

Based on design requirements defined by numerous interviews, we tested the device to ensure that it could be easily used and quickly cleaned, and that it did not compromise the quality of biopsy samples collected or introduce changes to recovery time and procedural risk. The isopropyl alcohol cleaning procedure using a 3-min contact time removed all simulated contaminant from the device. Because the attachment does not come in contact with tissue materials during the biopsy collection, this intervention would reduce cleaning time from over an hour to approximately three minutes, while requiring fewer, more readily available materials than the current standard. Function tests of biopsy samples collected using the attachment device indicate that, paired with our attachment, the Bard Magnum device retrieves samples of comparable weight to existing devices in both the chicken breast and silicone rubber model. As the efficacy of a biopsy sample is quantified using the volume and weight of the tissue collected, these findings indicate that the attachment provides similarly efficacious biopsy samples.

Future experiments should be conducted to more rigorously compare contamination levels between devices bearing our attachment and those lacking the attachment. This would measure and compare procedural contamination that is introduced during a complete biopsy procedure. Additionally, current biopsy device users have been noted to prefer the lightweight and ergonomic

Table 1 Function testing of attachment device
Length and weight measurements of biopsy samples using the Bard Magnum driver and attachment device were recorded using ex vivo animal tissue (chicken breast), and a silicone polymer model (Ooomoo).

Parameters	Bard Magnum driver	Attachment with driver	*p* value
Mean length ± SD (cm)			
Ex vivo tissue	10.3 ± 2.5	9.3 ± 0.9	0.28
Polymer model	10.0 ± 4.1	7.4 ± 2.4	0.17
Mean weight ± SD (g)			
Ex vivo tissue	0.022 ± 0.007	0.021 ± 0.006	0.72
Polymer model	0.014 ± 0.003	0.011 ± 0.004	0.10

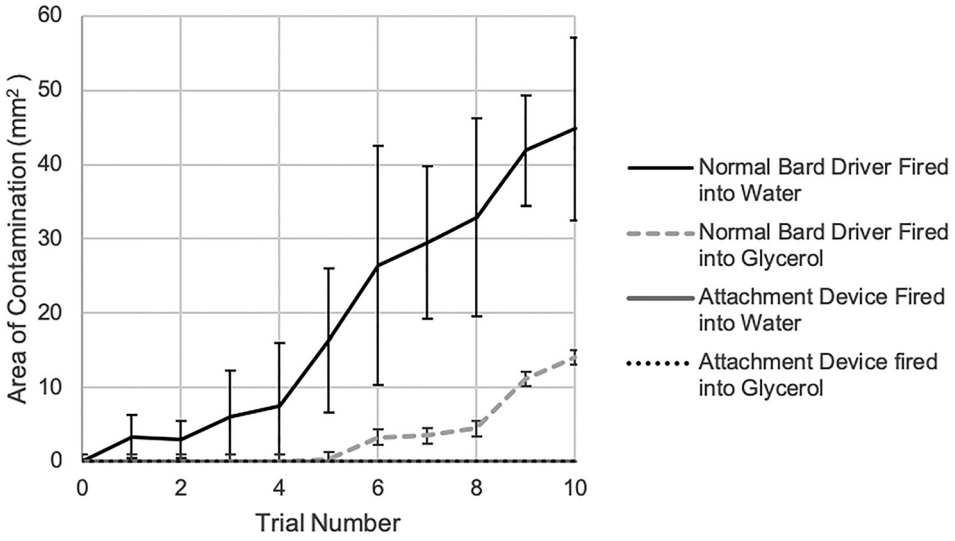

Fig. 5 Area measurements of water-indicating tape show that attachment device eliminates internal contamination. Graph showing the area of contamination inside the driver after each fire when using the normal Bard Magnum needles when treating water and glycerol solution as contaminants. There was no contamination found inside the driver when using the attachment device.

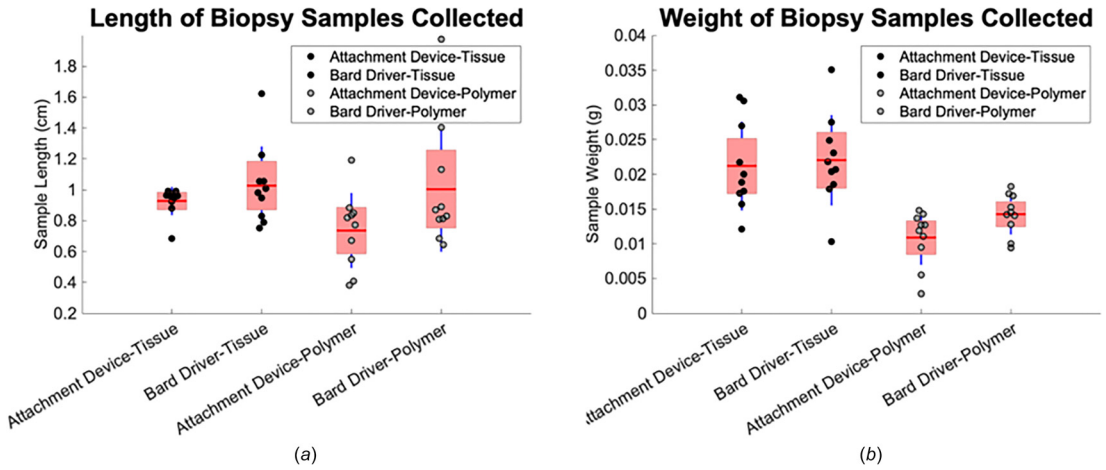

Fig. 6 Length and weight of samples acquired with attachment are sufficiently sized: (*a*) length and (*b*) weight of biopsy sample acquired using the attachment device and the Bard Magnum. Samples acquired with attachment fall within range of samples collected with the Bard Magnum in chicken breast (dark gray) and silicon rubber polymer (light gray) models. Lengths of samples decrease with the denser breast model, the silicon rubber polymer.

qualities of disposable devices. To this end, future iterations toward an ideal device for clinical use would incorporate the attachment into a standalone reusable driver, validated for cleaning efficacy and ease-of-use against existing reusable and disposable CNB devices. Furthermore, the attachment design does not address the risk that healthcare providers may re-use the disposable needle. Future work could incorporate new disposable needle designs that prevent reuse between patients.

In summary, our contamination-reducing attachment device paired with the Bard Magnum could become a more feasible and affordable core needle biopsy option for hospitals in developed and developing settings compared to single-use, disposable devices. This novel intermediate attachment device maintains the ability to acquire adequate tissue biopsy samples while preventing internal contamination and allowing for a simple cleaning procedure. Ultimately, our design has the potential increase availability of breast cancer diagnosis in low resource settings by enabling accessible tissue diagnosis.

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Nomenclature

R^2 = coefficient of determination
SD = standard deviation
x = ratio of fluorescent solution to water solution
y = measured relative intensity units by Synergy H1 microplate reader
λ = wavelength

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