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PAPER

The Design of a Core Biopsy Needle with a Larger Sample Extraction Size

Abdulaziz S. Fakhouri[1,2](✉)

[1]Department of Biomedical Technology, College of Applied Medical Sciences, King Saud University, Riyadh, Saudi Arabia

[2]Center of Excellence in Biotechnology Research, King Saud University, Riyadh, Saudi Arabia

afakhouri@ksu.edu.sa

ABSTRACT

Acquiring core biopsy samples requires a minimally invasive procedure in which tissue samples are collected from internal organs for histologic diagnosis. Usually, a clinician requests and extracts core biopsy samples when there is a suspicious lump in the body. Samples are used to diagnose various forms of cancer and other diseases. However, to have enough sample size to perform histological tests, clinicians must insert/extract the core biopsy needle a couple of times. These multiple insertions/extractions might reduce the healing process and increase the patient's risk of infection, internal organ damage, and unwanted bleeding. To address such an issue, it is recommended to obtain the required amount of tissue sample in a single insertion/extraction. In this study, a 14-gauge core biopsy needle (CBN) design, with four sample notches, was designed instead of the conventional one-sample notch to maximize the size of the sample being collected. Furthermore, sample notches were redesigned in a plus (+) cross-sectional pattern to improve the overall strength of the core biopsy needle at the sample notch area. This plus-shaped design of the sample notch enables the decrease of the thickness of the metal the biopsy needle is made from, increasing the sample notch size and thus increasing the total sample size extracted. In this design, each sample notch can collect 13.14 mm^3 of sample. Hence, with four sample notches, the total sample being collected is 52.56 mm^3 compared to conventional CBNs that can collect a sample size of 30.94 mm^3 only. A significant increase of up to 69.88% in the sample size being collected was calculated compared to 14-gauge conventional CBNs, such as Achieve® biopsy needles.

KEYWORDS

core biopsy needle (CBN), biomedical device design, biomedical instrumentation, 3D computer-assisted design (CAD) modeling, 3D printing, innovation

1 INTRODUCTION

In the practice of medical diagnostics, it is often necessary to perform a biopsy procedure by extracting a sample of a patient's tissue for further histological investigation. Biopsy is useful in diagnosing various forms of cancer and other diseases.

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In some instances, in invasive surgical procedures, biopsy samples are obtained. Yet, invasive procedures impose higher risks on patients and require longer healing durations. Thus, minimally invasive biopsy procedures are often preferred because such procedures are less traumatic to the patient, provide quicker recovery times, and leave smaller scars [1], [2].

Minimally invasive biopsy procedures can be done by either fine needle aspiration (FNA) or core biopsy needle (CBN). FNA is a less expensive, minimally invasive procedure that takes less time to perform the procedure and produce results, as well as causes less pain to the patient compared to CBN. On the other hand, CBN enables the collection of a larger sample size and provides a better representation of the targeted tissue to extract samples from. CBN could be performed after FNA if the results were unsatisfactory [1]. Therefore, CBN procedures are considered a mainstream methodology for extracting tissue samples.

In the case of tumors and the CBN procedure being requested, multiple CBN insertions are usually done. This might occur because the targeted tissue to be extracted was missed. To reduce such an issue, CBN is guided toward the tumor mostly via ultrasound or other imaging techniques, including mammography, magnetic resonance imaging (MRI), and/or computed tomography (CT) scans [1], [3]. Ultrasound is mostly used by clinicians because it's the easiest to use, also for its ability to provide real-time imaging. Moreover, ultrasound is generally known to be safer due to the absence of ionizing radiation [4]. However, imaging is considered an expensive utility in general; therefore, the less imaging used, utilizing different modalities, the cheaper the CBN procedure will be. Hence, a more accurate and reliable CBN is required to reduce the overall cost of the CBN procedure.

Core biopsy needle insertion might cause several complications and serious risks. Complications include hemorrhage, infection, adjacent tissue injury, pain, bleeding, hemoptysis, hemothorax, non-target tissue, organ or vessel perforation, pneumothorax, and air embolism [5]. Multiple insertions of CBN are also done to have samples from different locations or larger sample sizes. Hence, multiple insertions may cause increased risk of complications mentioned above. Multiple insertions of CBN are risky; hence, a CBN that reduces the number of insertions is required.

To address such a problem of multiple insertions, multiple solutions were suggested by inventors. A solution was suggested by McWeeney et al (2016), which was suggested in a patent, maximizing tissue-sampling yield and collecting a cohesive unit of sampled tissue by the use of an exchangeable needle technique. This was done to overcome conventional CBN disadvantages of having an insufficient amount of sample or damaging the sample during the collection process, which will result in multiple insertions of CBN [6]. Another patent published in 2018 by Lash et al. solved another problem facing clinicians, which is the possibility of penetrating a blood vessel by the CBN, causing internal bleeding [7]. The patent proposed placing an optical sensor probe at the tip of the needle that can measure multiple parameters such as tissue oxygen saturation level, total hemoglobin concentration, blood flow, and pulse. Based on these parameters, the presence of the blood vessel at the tip can be detected and hence avoided [7]. Both technologies mentioned above are complicated to prove their concept, which might be impractical. A simpler CBN design to avoid multiple insertions is necessary.

In this project, a core biopsy needle with a larger sample extraction size was designed with 4 sample notches to avoid multiple insertions of CBN due to insufficient sample size, utilizing 3D computer-assisted design (CAD) software. Then, an alpha-phase prototype was 3D printed utilizing computer-assisted manufacturing (CAM). Afterward, the size of the notch of extraction was calculated and compared to the notch size of the conventional CBN as proof of concept.

2 MATERIALS AND METHODS

2.1 Clinical needs analysis

A clinical needs analysis was done by comparing needs obtained by interviewing clinicians who utilize CBN regularly. Clinical need analysis starts with assigning factors to consider in evaluating each need. In this project, eight factors were selected, which are: 1) economic impact, 2) patient impact, 3) existing solutions, 4) occurrence rate, 5) clinicians' suggestions, 6) procedure duration, 7) team's favorite, and 8) project due date. Then, a rating was assigned for each factor based on the nature of that factor to rate each need. Afterward, each need was evaluated with all factors and assigned a rating. This rating provides a numerical value to rank needs and compare each need quantitatively.

2.2 CAD modeling

SolidWorks 2017 software (Dassault Systèmes, France) was used to design and assemble a 14-gauge CBN containing four sample notches instead of one. The four sample notches were shaped similarly to the plus (+) pattern. Needle diameter dimensions were set based on the 14-gauge Achieve® Automatic Biopsy Needle.

A vernier caliper was used to take measurements of the Achieve® Automatic Biopsy Needle. Thus, the inner needle was designed with a 1.8 mm diameter, a sample notch length of 19 mm, and a cutting sheath of 2 mm in diameter, similar to the. Achieve® Automatic Biopsy Needle.

2.3 CAM modeling

A MakerBot 3D printer (MakerBot Industries, LLC, New York, USA) was utilized for 3D printing of the CBN utilizing poly lactic acid (PLA) filament to provide a visual comparison between conventional CBN, such as the Achieve® Automatic Biopsy Needle, and the proposed CBN. The proposed CBN was enlarged in scale by 500% and was 3D printed horizontally on the printing bed with a solid infill.

2.4 Materials

Conventional CBN, such as the Achieve® Automatic Biopsy Needle, is made from plastic housing (handle) and a surgical-grade stainless steel needle [8]. Similarly, the proposed CBN should be made from plastic housing and a surgical-grade stainless steel needle. Such utilized materials enable the manufacturing of cost-effective disposable surgical tools. However, due to technical difficulties in this project, the 3D printing of the proposed CBN was enough to embody the proposed design.

3 RESULTS AND DISCUSSION

3.1 Clinical needs analysis

A breast imaging consultant and a senior registrar radiologist who utilize CBN in their practice were interviewed to explore needs. Four clinical needs were obtained from the clinicians. The first clinical need is related to a loud clicking noise due to the shooting mechanism of the CBN. Such noise might cause an unwanted reaction by the patient out of fear and lead to unwanted and risky body movement during the core biopsy procedure. The second clinical need was related to multiple insertions of CBN, where the clinicians needed to insert the needle more than once to collect enough samples for lab testing. Multiple insertions of CBN may prolong recovery time and increase the risk of having internal bleeding due to possible penetration of the blood vessel or untargeted organs. The third clinical need is related to misguided penetration of the CBN, which causes missing the targeted tissue location. Such a problem causes the retrieval of the CBN and reinserting it again, leading to similar risks of multiple insertions mentioned above. The fourth and final clinical need discussed was related to puncturing unwanted blood vessels. This may cause unwanted internal bleeding, which increases the complexity of the CBN procedure.

Several evaluation factors have been selected to determine which need has the highest priority to address. Table 1 shows a summary of clinical needs that need to be addressed, evaluation factors, ratings, and rankings [9]. The first evaluation factor (F1) is the economic impact, in which the clinical need was rated from 1 to 5, taking into consideration whether it changes the cost of service provided by the clinic or if it will remain the same. If the clinical need causes an increase in the cost of over 50% of a no-complication procedure, the clinical need was rated 5, while if less than 50%, the clinical need was rated 4. If the clinical need does not affect cost, it was rated 3. If clinical need causes a decrease in the cost by less than 50%, it was rated 2, and more than 50% it was rated 1.

Another evaluation factor that has been selected is patient's impact (F2), which focuses on whether the clinical need represents a risk to the patient or not. Clinical needs that could lead to the death of the patients were rated 4, while clinical needs that could lead to corrective surgery were rated 3. Clinical needs that may result in longer recovery time were rated 2, while clinical needs that might cause acute pain were rated 1.

The third evaluation factor (F3) that was selected is related to existing solutions. Clinical needs with no solutions found were rated 2, while existing solutions that solve clinical needs partially were rated 1. Clinical needs with existing solutions that solve them sufficiently were rated 0.

The occurrence rate is an important factor that was considered as the fourth evaluation factor (F4) and reflects the priority of the clinical need to be solved. A rating of 4 was given to clinical needs that usually occur, while a rating of 3 was given for clinical needs that occur often. Clinical needs that occur rarely were rated 2, and clinical needs that never occur were rated 1.

The fifth evaluation factor (F5) was based on the interviewed clinician's suggestions; the clinical need with a required solution was rated 3. Clinical needs that needed a useful solution but were not necessarily rated 2. A clinical need that is not necessary to solve was rated 1.

The sixth evaluation factor (F6) was procedure duration; if the clinical need increased the time needed to complete the procedure, it was rated 2, while if the clinical need did not affect the time needed to complete the procedure, it was rated 1.

The seventh evaluation factor (F7) was related to team interest. If the team was interested in the clinical need, a rating of 2 was assigned, while if the team was not interested in the clinical need, a rating of 1 was assigned.

Finally, taking into consideration the duration available to complete this project, the eighth factor (F8) was selected to reflect the duration expected to work on the clinical need and produce an initial concept. If the concept of the clinical need is expected to require more time than the project deadline, a rating of 1 was assigned. A rating of 2 was assigned if the clinical need concept was expected to be done at the due date. A rating of 3 was assigned if the concept could be done slightly before the due date. A rating of 4 was assigned if the concept of the clinical need was expected to be produced before the due date in a while.

As shown in Table 1, multiple insertion clinical needs ranked first to be solved based on a score of 21 points. While clinical needs of shooting noise and blood vessels ranked second with 19 points. Finally, misguided needles ranked third with 17 points. To obtain enough sample size, clinicians have to insert the CBN more than once, which can lead to an extended healing process and increase the risk of internal bleeding and inflammation [4]. Therefore, the purpose of this project, based on the clinical need analysis, is to maximize the amount of sample size being collected in a single insertion, which might lead to reducing the number of insertions of the CBN in each operation.

Table 1. Clinical needs analysis, evaluation factors, ratings, and clinical needs ranking

Rating Factors/Needs	Shooting Noise	Multiple Insertions	Misguided Needles	Blood Vessel
F1: Economic Impact	3	4	3	5
F2: Patient's Impact	1	2	2	4
F3: Existing Solutions	2	0	2	0
F4: Occurrence Rate	4	4	2	2
F5: Clinicians Suggestions	2	3	2	3
F6: Procedure duration	1	2	2	3
F7: Team's Favourite	2	2	1	1
F8: Project Due Date	4	4	3	1
Total	19	21	17	19

3.2 Four sample notches core biopsy needle design

A 14-gauge CBN with four sample notches and four cutting edge sheaths was designed (Figures 1 and 2), instead of the conventional one-sample notch and one cutting edge sheath. This design enables each notch to collect 13.14 mm^3 of sample size theoretically; therefore, the total sample size could reach 52.56 mm^3. On the other hand, conventional CBN, such as the 14-gauge Achieve® Automatic Biopsy Needle, can only collect a single sample of 30.94 mm^3. This increases the total sample size by 69.88%. This increase in sample size might be a reason to reduce the number of insertions into the patient to extract biopsy samples, thus resulting in less patient pain, less organ damage, and less risk of puncturing a blood vessel.

Fig. 1. Assembled a full view of the designed CBN with 4 sample notches and a 4-cutting-edges sheath (closed cutting sheath)

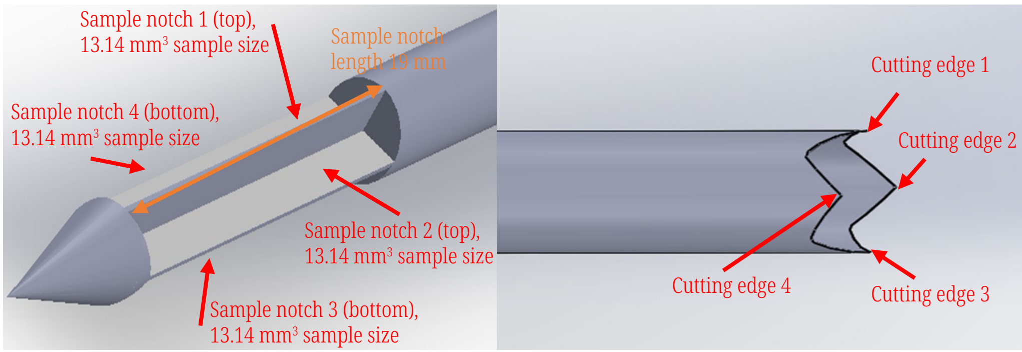

Fig. 2. Disassembled zoomed-in view of the designed CBN with 4 sample notches (left) and 4 cutting edges sheath (right)

Note: Two sample notches are shown in the figure on top, while the other two sample notches are not shown in the figure because they are at the bottom.

The designed CBN had four sample notches in a plus (+) cross-sectional pattern (see Figure 3) to improve the overall strength of the CBN at the sample notches area. This plus (+) cross-sectional pattern enabled increasing the strength of the CBN at the sample notches area (see Figure 3) as a design property. Due to the insertion action, the plus (+) cross-sectional pattern resists forces applied on the X, Y, and Z axes exerted on the sample notch areas. On the contrary, conventional CBN with a single notch resists forces exerted on the sample notch area on the X and Y axes but not the Z axis. Thus, conventional CBN is easily bent at the notch area while insertion.

Furthermore, such a plus (+) cross-sectional pattern (see Figure 3) enabled an increase in the overall capacity at the sample notches area, thus increasing the total size of the extracted sample. Such a plus (+) cross-sectional pattern (see Figure 3) enabled the thickness of the walls in the sample notches area to be reduced to 0.1 mm (refer to Table 2), which is seven times less than the comparable needles at 0.7 mm. Such a decrease in materials increases sample notches capacity and therefore the extracted sample size. Yet, the overall diameter, which is 1.8 mm, was the same as the 14-gauge Achieve® Automatic Biopsy Needle.

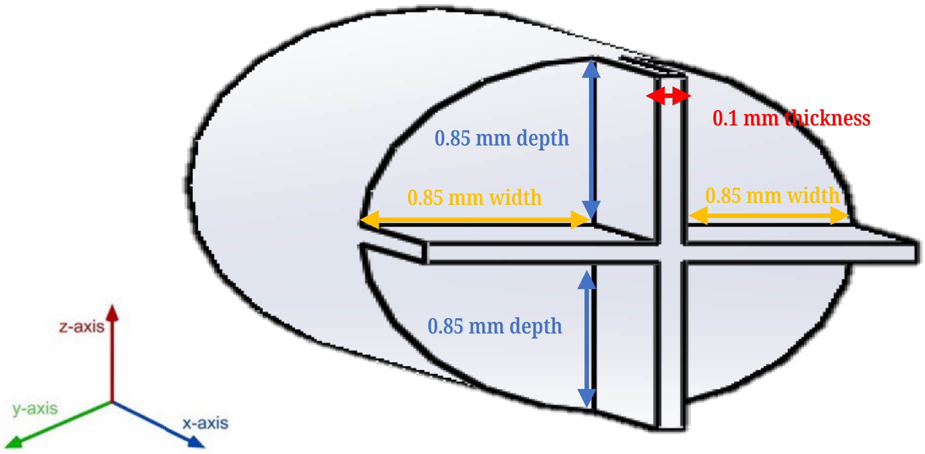

Fig. 3. Cross-sectional view of the sample notch area showing the plus (+) cross-sectional pattern and dimensions

Note: The width and depth of each sample notch is 0.85 mm, while the thickness of the walls of sample notches is 0.1 mm.

Table 2. A summary of a comparison in dimensions of the designed CBN and the conventional CBN

Parameter	Designed CBN with 4 Sample Notches (mm)	Achieve® Automatic Biopsy Needle (mm) (Conventional)	Difference (mm)/(%)
Sheath diameter	2	2	0/0%
Inner needle diameter	1.8	1.8	0/0%
Sample Notch length	19	19	0/0%
Sample Notch depth	0.85	1.1	–0.25/23% less
Sample Notch width	0.85	1.73	–0.88/51% less
Sample Notch Walls Thickness	0.1	0.7	–0.6/86% less

The design of the CBN here was done based on the overall measurements of the conventional CBN used in clinics, which is the 14-gauge Achieve® Automatic Biopsy Needle. Utilizing current CBN measurements as a reference enabled a calculated comparison of the extracted sample size. As a result, a significant increase of up to 69.88% in the sample size was achieved. Table 2 compares the dimensions of the designed CBN and the conventional CBN. Figure 4 illustrates the dimensions of one of the four sample notches.

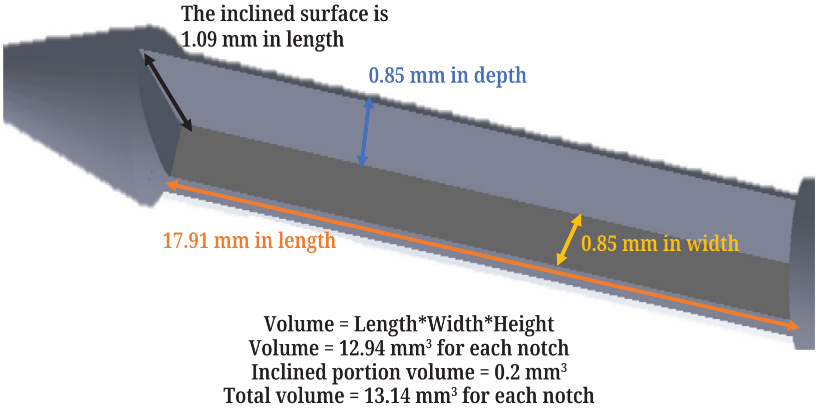

Fig. 4. A zoomed-in view of one of the sample notches

Note: The dimensions of all 4 sample notches are identical to each other; therefore, the sample size calculation was the same for all four sample notches.

The design of the cutting sheath serves as a cutting tool for the target tissue to be extracted and preserved inside the notch. Given that the CBN design contains four notches, a sheath with four cutting edges was designed so each cutting edge will align with each notch to cut and preserve the sample in each notch along the axis of the CBN. Figure 5 illustrates the design of the cutting sheath showing the four sharp tips to pierce and then cut samples of the targeted tissue.

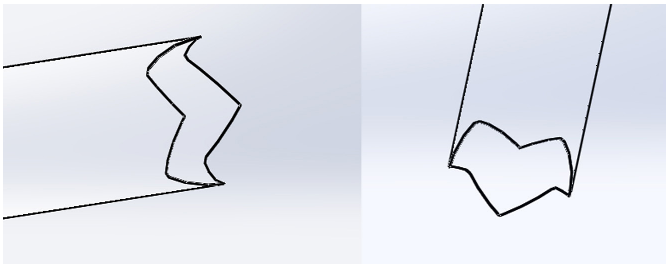

Fig. 5. The design of the cutting sheath, a side view (left) and a top view (right)

3.3 Prototype

A preliminary prototype (alpha phase) was fabricated to visualize the shape and structure of the designed CBN. A MakerBot 3D printer was utilized for the 3D printing of the CBN utilizing PLA filament. However, due to limitations in the 3D printer resolution and printing dimensions, the scale of the prototype was enlarged and focused on the notches area rather than the full length of the CBN. The length was cut in half and the scale was enlarged by 500%. Figure 6 shows a visual comparison between the 14-gauge designed CBN on the left and the conventional 14-gauge Achieve® Automatic Biopsy Needle on the right. It is visually clear that the thickness of the needle at the sample notch area of the Achieve® Automatic Biopsy Needle is thicker than the design CBN. Thus, reflecting on a smaller sample size of the Achieve® Automatic Biopsy Needle.

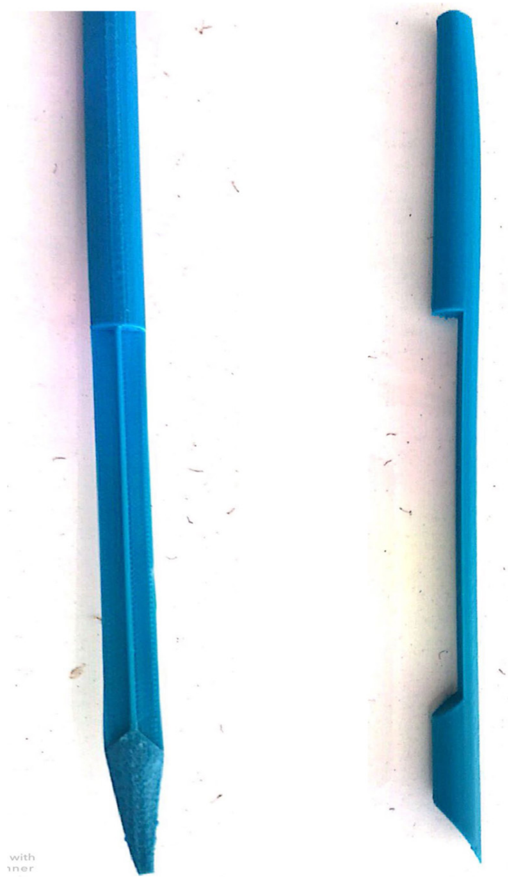

Fig. 6. A visual comparison between the 14-gauge designed CBN on the (left) and the conventional 14-gauge Achieve® Automatic Biopsy Needle on the (right)

3.4 Assembly and operation

The assembly of the CBN is simply by inserting the needle with the sample notches inside the cutting sheath. The tip of the needle protrudes from the inner axis of the cutting sheath to pierce the tissue of interest.

The designed CBN operates similarly to the conventional CBN. At the resting state (CBN not charged), the cutting sheath covers the sample notches of the needle (see Figure 7a). Then to charge the CBN, the clinician pushes the needle forward, piercing into the tissue of interest due to the sharp cone-shaped needle tip. This will allow the cutting sheath to stay in the same previous position and the sample notches to advance into the center of the tissue of interest (see Figure 7b). After that, the CBN needle is fired, pushing the cutting sheath forward rapidly. This will cut through tissue, separating samples from the original tissue in the sample notches area (see Figure 7c).

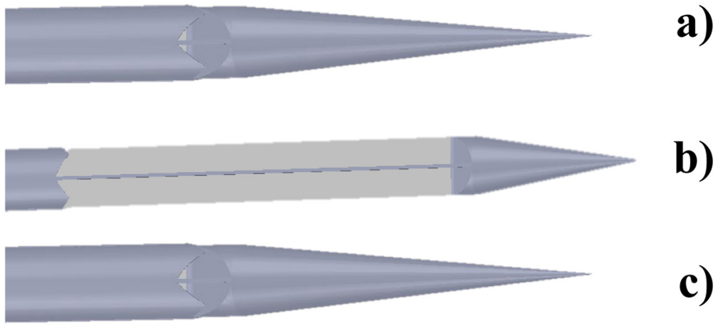

Fig. 7. Assembly and operation of the CBN

Notes: The CBN is in a resting state (not charged) where the needle is inside the cutting sheath (a). The needle is advanced to pierce tissue, and CBN is charged (b). The cutting sheath is fired after to cut tissue of interest and preserve samples in the 4 sample notches simultaneously (c).

4 CONCLUSION

Multiple insertions of the CBN are one of the most occurring problems facing clinicians during biopsy procedures due to their need to have enough samples to be examined. The multiple insertions of the needle into the patient's body may lead to extending the recovery time and increasing the risk of internal bleeding and inflammation. Here, a solution is proposed in this project by designing a CBN containing four sample notches instead of one. Designing notches with the shape of a cross (+) allows for a decrease in the thickness of the metal the biopsy needle is made from, resulting in the increase of sample size extracted. This design allows the clinicians to increase the amount of sample collected in one entry to 69.88% compared to a conventional 14-gauge Achieve® Automatic Biopsy Needle.

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7 AUTHOR

Abdulaziz S. Fakhouri got his Bachelor’s degree from the Biomedical Technology Department at King Saud University (KSU), then his Master’s and Ph.D. in Biosensors from the Biomedical Engineering Department at The Ohio State University, Ohio, USA. Currently, he is an Assistant Professor at the Biomedical Technology Department, College of Applied Medical Sciences (CAMS), and Deputy Director for Scientific Affairs at the Center of Excellence in Biotechnology Research at King Saud University. He previously worked as a Field Service Engineer for GE Healthcare. He also worked as the Head of the Innovation Unit at CAMS, then the Vice Head of the Medical Technologies Innovation Unit at KSU. He also worked as a consultant for the Saudi Authority for Intellectual Property (SAIP), and for Yood Trading Company as a Technical Manager. He is also a certified trainer for Mawhiba’s gifted students. Abdulaziz has three patents and several scientific research papers and presentations related to innovation, innovative biomedical devices, biotechnology, biosensors development, tissue and cell engineering, and cancer research (E-mail: afakhouri@ksu.edu.sa).