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# Bronchoscopic Evaluation of a Steerable Needle for Simulated Tumor Targets in the Lung Periphery: A Feasibility Study (Bullseye)

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## Keywords

Bronchoscopy · Transbronchial needle aspiration · Pulmonary nodules

## Abstract

**Background:** Peripheral bronchoscopy is often performed to biopsy peripheral pulmonary lesions. Despite technological advancements to improve reach and access to the lung periphery, the diagnostic yield of peripheral bronchoscopy has been inconsistent, and challenging, particularly for lesions that are adjacent to peripheral bronchi. Current biopsy instruments are reliant on the catheter or scope to align properly with targeted lesions. **Objectives:** This study evaluates the feasibility of using a steerable biopsy needle to gain access to peripheral tumor targets in a cadaveric model. **Methods:** Simulated tumor targets 10–30 mm in axial diameter were placed into human cadavers. Bronchoscopy was performed using a 4.2 mm OD flexible bronchoscope, CT-anatomic correlation, and multiplanar fluoroscopy for lesion localization. Once at the targeted location, a steerable needle was deployed and the needle position was determined to be in the central zone, peripheral zone, or outside of the lesion by cone beam CT imaging. If the needle position was within the lesion, a fiducial marker was deployed to mark the needle position, and the needle was articulated and/or rotated in an attempt to place another fiducial marker into a different

location within the same lesion. If the needle was outside of the lesion, the bronchoscopist was provided with two additional attempts to gain access to the lesion. **Results:** Fifteen tumor targets were placed with a mean lesion size of 20.4 mm. The majority of lesions were located in the upper lobes. One fiducial marker was placed in 93.3% of lesions and a second fiducial marker was successfully placed in 80% of lesions. A fiducial marker was placed within the central zone in 60% of lesions. **Conclusion:** The steerable needle was successfully placed within 93% of targeted lesions 10–30 mm in diameter in a cadaveric model, with the ability to steer the instrument into another portion of the lesion in 80% of cases. The ability to steer and control needle positioning toward and within peripheral lesions may complement existing catheter and scope technology during peripheral diagnostic procedures.

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## Introduction

Peripheral bronchoscopy is often performed to biopsy peripheral pulmonary lesions (PPLs) for diagnostic purposes. With the results of the National Lung Cancer Screening Trial demonstrating a 20% reduction in lung cancer-related death, widespread adoption of lung

cancer screening programs is expected to result in the detection of significantly increased numbers of pulmonary nodules [1]. While the majority of these nodules may simply require surveillance imaging, many will require biopsy.

Guided bronchoscopic approaches to PPLs are typically performed using flexible bronchoscopes with outer diameters of 4–6 mm and image guidance such as electromagnetic navigation, radial probe endobronchial ultrasound, or virtual bronchoscopic navigation [2–4]. Once the bronchoscopist has positioned the bronchoscope near the targeted lesion, a flexible instrument, such as a needle, brush, or biopsy forceps, is advanced through the bronchoscope toward the lesion and a biopsy is obtained.

Multiple publications have reported that when the targeted lesion surrounds the peripheral bronchus, the diagnostic yield is approximately 80%; however, when the targeted lesion is adjacent to the peripheral bronchus, the diagnostic yield falls to 30–40%. Several publications have reported that this adjacent positioning may occur as frequently as 40–50% of cases [5–8].

Conventional bronchoscopic instrumentation consists of non-directable tools such as needles, forceps, and brushes. These instruments do not allow articulation or “steering” and obtain biopsies directly in line with the tip of the catheter or bronchoscope that are directed towards the lesion.

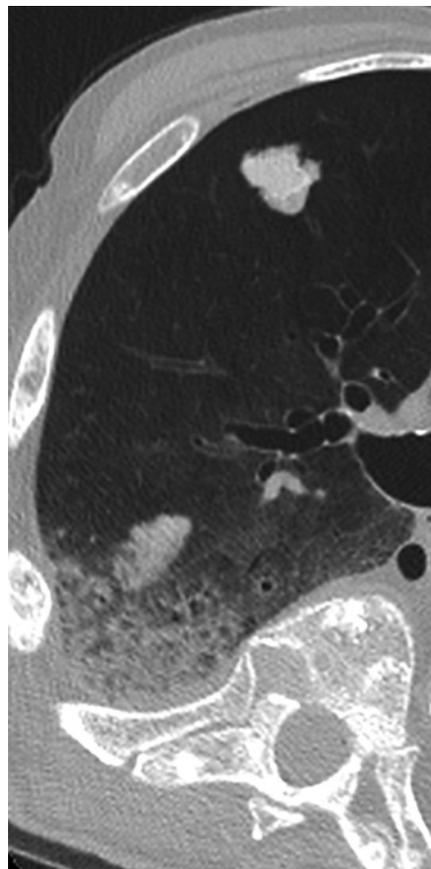
A steerable biopsy device that allows flexion, extension, and rotation may have a theoretical benefit of allowing the bronchoscopist to direct the tip of the instrument into targeted lesions. This feasibility study evaluates the ability of a steerable needle to be placed within tumor targets placed within a cadaveric lung model.

## Methods

This was a single-arm feasibility study evaluating the ability to place a steerable needle into simulated tumor targets within cadaveric lungs. The primary endpoint was the ability to demonstrate successful access into the tumor target, demonstrated by direct visualization of fiducial markers within the targets on post-procedure CT imaging. Additional endpoints included the ability to position the steerable needle within multiple locations within the same tumor target, with an emphasis on targeting the center of the lesion.

### *Cadaver Preparation*

Two fresh human cadavers with intact head and torsos were prepared for this study. Each cadaver was intubated and ventilated for the duration of the procedure. Artificial tumor targets consisted of a mixture of agar, gelatin, and iodinated contrast which was

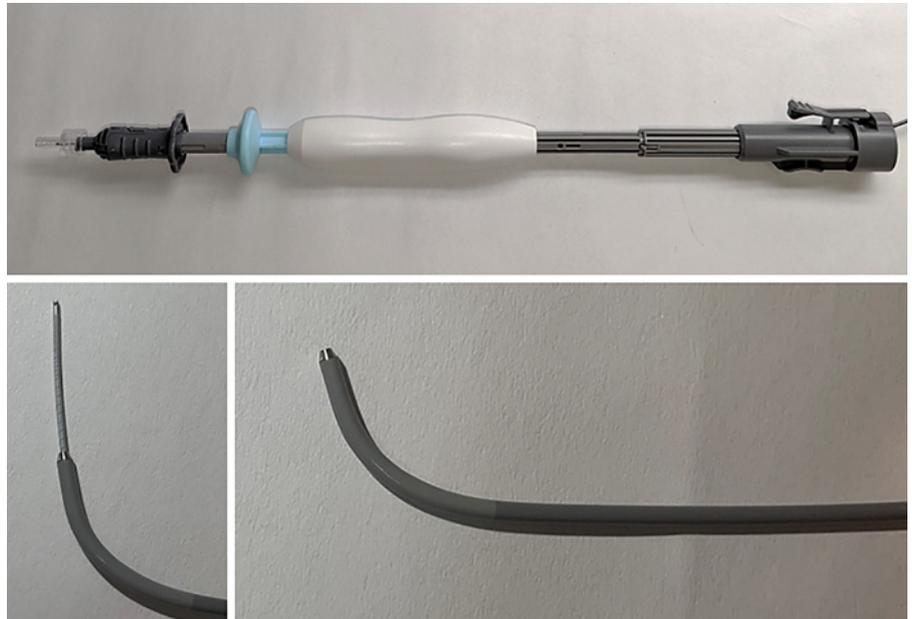


**Fig. 1.** Simulated tumor targets within right lung.

heated to an aqueous solution and injected transthoracically into the lungs using fluoroscopic imaging as guidance (Artis Zee, Siemens). Volume of injected material was controlled to create lesions 10–30 mm in size as measured by axial CT imaging (64 slices, GE Healthcare). Fifteen tumor targets were placed within the two cadavers (Fig. 1). A CT scan was performed of the cadavers following target injection to be used as a reference scan during bronchoscopy.

### *Bronchoscopy and Needle Characteristics*

Study procedures were performed in an independent procedural study suite over a period of 3 days in November 2021. Bronchoscopy was performed using a bronchoscope with 4.2 mm outer diameter and 2 mm working channel (BF-P190, Olympus, Tokyo, Japan). CT-anatomic correlation and fluoroscopy were used to direct the bronchoscope to all tumor targets; no navigational or virtual bronchoscopic image guidance was used. Rotation of the C-arm to provide cross table and oblique views were permitted, whereas cone beam reconstruction was not. Once the bronchoscopist was at the targeted lesion, a 1.9 mm OD, Franseen-tipped unidirectional 22-gauge steerable needle (Compass Steerable Needle; Serpex, Santa Clara, CA, USA) was advanced through the working channel of the bronchoscope. The distal tip of the needle allows articulation to 70°



**Fig. 2.** Steerable needle design.

with 360 degrees of rotation (Fig. 2). The needle was then deployed under fluoroscopic guidance.

#### *Determination of Needle Position and Fiducial Marker Placement*

Following needle deployment, cone-beam imaging was used to determine the location of the needle in relation to the tumor target. If the needle tip was located anywhere within the tumor target based on cone beam imaging, a metallic fiducial marker (Torque-Flex, Cook Medical, Bloomington, IN, USA) was deployed to mark the needle position within the tumor target. This was performed by pushing a metallic fiducial through the lumen of the deployed needle using the stylet and observing deployment using fluoroscopic guidance. If the needle tip was not located within the tumor target, the bronchoscopist was allowed to reposition the bronchoscope and/or needle to attempt to place it within the targeted lesion.

Once the first fiducial marker was placed, the needle position was changed by depressing the plunger mechanism on the handle and articulating and/or rotating the needle into a different position using fluoroscopic guidance to observe changes in needle position (Fig. 3). The objective was to place a second fiducial marker into a different position within the same tumor target. Fiducial placement into the central zone (CZ) of each lesion was prioritized, followed by placement into the peripheral zone (PZ). This was performed by manipulating the needle only. A maximum of three attempts were permitted for each target. A post-procedure chest CT scan was performed which was used to determine the location of all fiducial markers relative to the targeted lesions.

#### *Scoring*

The primary objective was to demonstrate tool in lesion by placing fiducial markers into tumor targets. An additional endpoint was the bronchoscopists' ability to use the steerable needle to access different locations within the target. The CZ of

the tumor target was defined as the central 50% of the target by volume, and the PZ was defined as the outer 50% of the target by volume based on three-dimensional reconstruction (Horos v3.3.6, [www.horosproject.org](http://www.horosproject.org)) of the post-procedure CT scan (Fig. 4). Two points were awarded for fiducial markers placed into the CZ and 1 point was awarded for markers placed into the PZ, for a total of 3 possible points reported for each target.

## **Results**

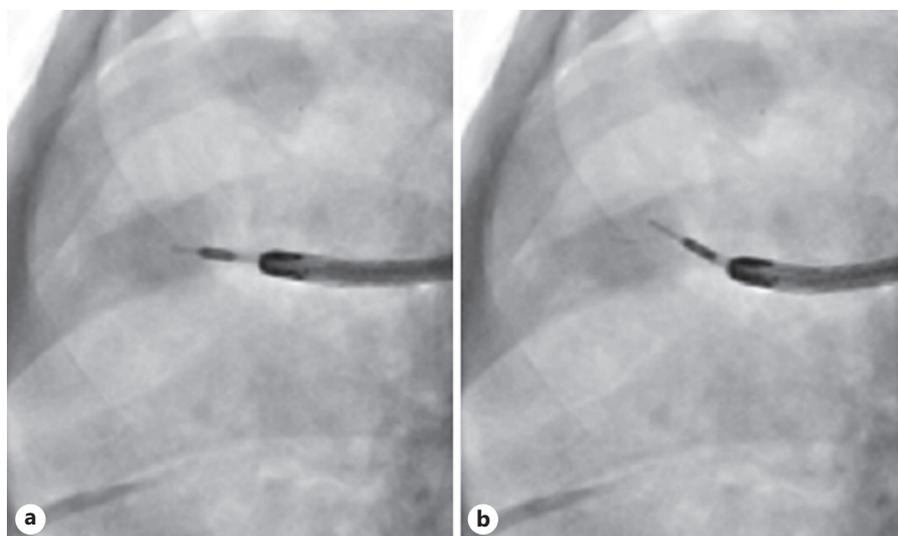
Fifteen lesions were placed in two cadavers. Mean lesion size, measured by the longest axial diameter on CT scan, was 20.4 mm (range 14.3–30.8 mm). Mean distance to the pleura, measured as the distance of the outer edge of the lesion to the nearest pleural surface, was 8.0 mm (range 0–21.7 mm). The majority of lesions (10/15) were located in the upper lobes (Table 1).

#### *Fiducial Marker Placement*

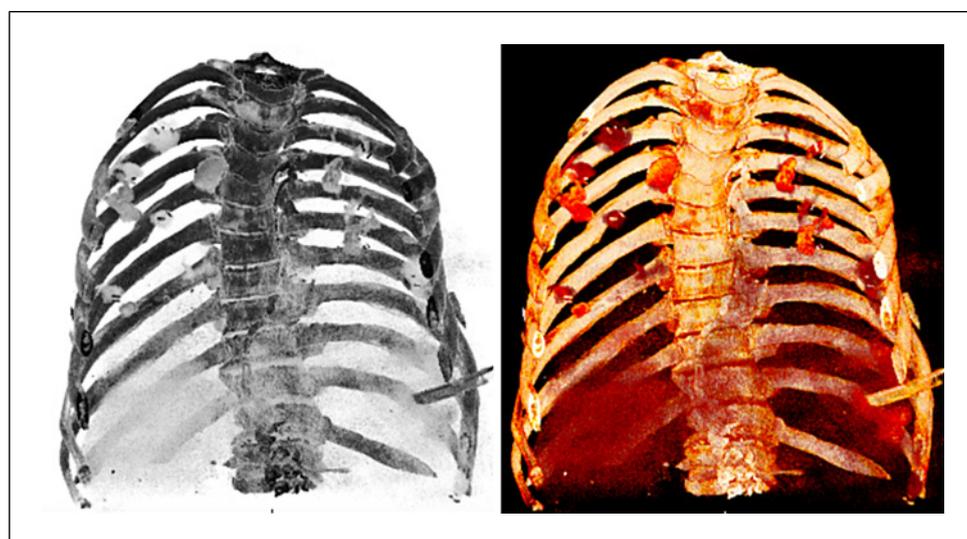
One fiducial marker was successfully placed within 14/15 (93.3%) tumor targets. A second fiducial marker was successfully placed within targets in 12/15 (80.0%) of cases.

#### *Central and PZs*

A fiducial marker was successfully placed within the CZ of targeted lesions in 9/15 (60.0%) cases. Fiducials were also placed within the PZ in 13/15 (86.7%) cases. Fiducial markers were placed in the CZ and PZ within the same target in 8/15 (53.3%) (Fig. 5). Of a total of 45 possible points (2 points for CZ and 1 point for PZ), 35 points were awarded.



**Fig. 3.** Neutral (a) and articulated (b) needle positions within a tumor target.



**Fig. 4.** 3-dimensional reconstruction of CT with tumor targets.

## Discussion

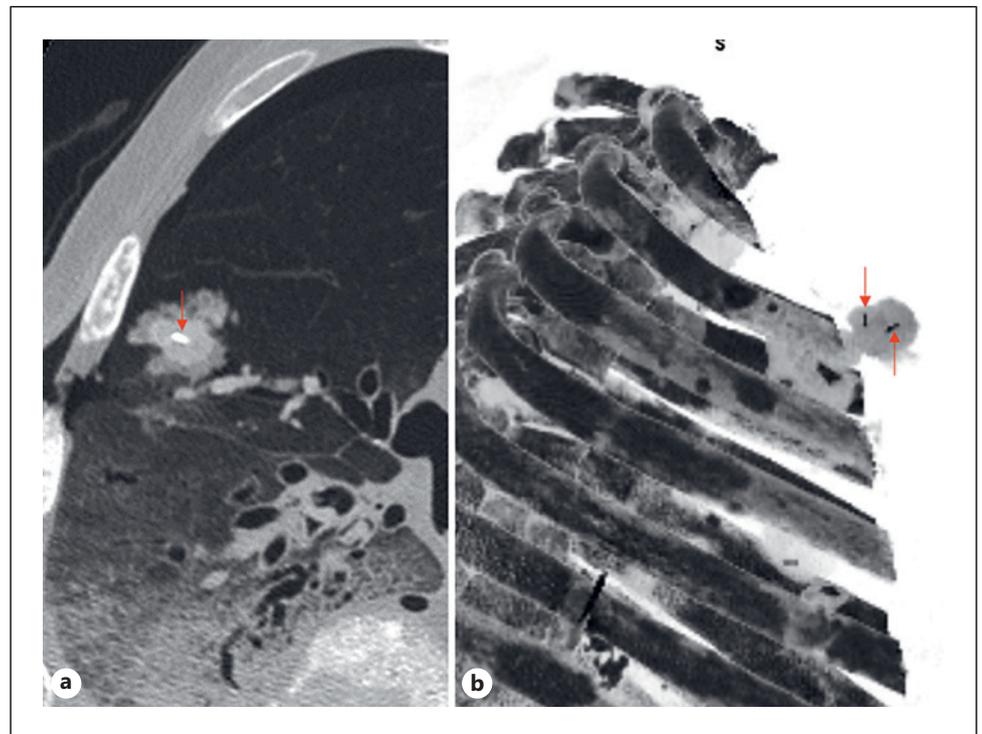
Significant advancements have been made towards improving bronchoscopists' ability to reach the lung periphery and gain proximity to PPLs [8–10]. While enhanced reach alone may be beneficial, additional control and dexterity once within striking distance of peripheral lesions may be equally as important toward optimizing diagnostic yields. To date, placement of biopsy tools within lesions has been dependent upon the bronchoscope or catheter used to gain peripheral access. This study suggests that a steerable needle may be beneficial in positioning tools within lesions and may improve the ability to control needle placement within these lesions.

“Tool in lesion” is a contemporary term used to describe placement of a biopsy instrument within a targeted lesion. When using ultrasound, a concentric or eccentric radial endobronchial ultrasound image is demonstrative of tool in lesion, though one must remove the R-EBUS probe and replace this with a biopsy tool to sample the lesion. For external imaging techniques, an image of a biopsy instrument within the lesion using cone beam CT or 3-dimensional fluoroscopy is demonstrative of tool in lesion. This metric has been used in prior publications where robotic-assisted bronchoscopy was more successful in placing a biopsy tool within a tumor target than electromagnetic navigation or thin bronchoscopy with R-EBUS. In the study by Yarmus and colleagues, the rate

**Table 1.** Results

| Target       | Location | Size, mm | Fiducial 1 (%)   | Fiducial 2 (%)   | CZ (%)        | PZ        | Points    |
|--------------|----------|----------|------------------|------------------|---------------|-----------|-----------|
| 1            | RB1      | 14.88    | X                |                  |               | X         | 1         |
| 2            | RB1      | 29.3     | X                | X                | X             | X         | 3         |
| 3            | RB3      | 24.7     | X                | X                |               | X,X       | 2         |
| 4            | RB3      | 22.2     | X                | X                | X             | X         | 3         |
| 5            | RB3      | 20       | X                | X                | X             | X         | 3         |
| 6            | RB2      | 30.8     | X                | X                | X             | X         | 3         |
| 7            | RB4      | 19.6     | X                | X                | X             | X         | 3         |
| 8            | RB4      | 20.3     | X                |                  | X             |           | 2         |
| 9            | RB8      | 17.1     | X                | X                |               | X,X       | 2         |
| 10           | LB1+2    | 17.6     | X                | X                | X             | X         | 3         |
| 11           | LB4      | 20.2     |                  |                  |               |           |           |
| 12           | LB7+8    | 23.5     | X                | X                | X             | X         | 3         |
| 13           | RB1      | 17.7     | X                | X                |               | X,X       | 2         |
| 14           | RB2      | 12.2     | X                | X                | X             | X         | 3         |
| 15           | RB4      | 15.9     | X                | X                |               | X,X       | 2         |
| <b>Total</b> |          |          | <b>14 (93.3)</b> | <b>12 (80.0)</b> | <b>9 (60)</b> | <b>17</b> | <b>35</b> |

CZ, central zone; PZ, peripheral zone.



**Fig. 5.** Fiducial markers (arrows) within the CZ (a) and CZ and PZ (b).

of lesion puncture (“tool in lesion”) in a cadaver model with simulated tumor targets was 80% (16/20). In this study, fiducial marker placement, used as a surrogate for needle tip position, demonstrated tool in lesion in 93.3% of lesions using a method of CT-anatomic correlation for lesion localization, a 4.2 mm OD flexible bronchoscope, and a 22-gauge steerable needle. While this study used conventional

thin caliber bronchoscopes, updated versions of the steerable needle will also be compatible with robotic systems as needed. Additionally, redirection of the steerable needle resulted in successful placement of a second fiducial marker within the same targeted lesion in 80.0% of cases. Regarding instrument position within the lesion, 60.0% of fiducial markers were placed within the CZ of the lesion using this

approach, which compares favorably to prior studies demonstrating access to the center of the lesion in 10% of cases [11]. This last point may illustrate the role in which steerable biopsy instruments may complement existing technologies. Despite the increased reach and access that catheters, thin bronchoscopes and robotic systems may provide, there may be limitations to the way in which conventional instruments deployed through these systems align with targeted lesions. A steerable needle with the ability to articulate and rotate may allow improved alignment with the central portions of lesions, which may translate into further gains in diagnostic yield.

There are limitations to this study. As an uncontrolled, non-randomized feasibility study, this was not designed to demonstrate superiority to other techniques, and comparison to other studies is intended to illustrate context only. Additionally, there are limitations to extrapolating results from cadaver studies to live patient encounters, though we feel that a mean target size of 20.4 mm in ventilated cadavers presented a reasonably “realistic” procedural scenario. Since radial probe endobronchial ultrasound was not utilized for this study, we are unable to comment on the number of lesions surrounding or adjacent to the peripheral bronchi. However, the method of transthoracic tumor injection here was identical to prior publications that produced an abundance (~80%) of eccentric lesions, suggesting that these findings would be applicable for lesions that are adjacent to peripheral airways [9]. Another confounding variable in this study was the use of cone beam CT imaging, which is not widely available at most centers. Importantly, the use of cone-beam imaging in this study was restricted to “scoring” the needle location either within or outside of the targeted lesion. Cone-beam imaging was not used in cases as a navigational tool to advance the bronchoscope toward the targeted lesions. Lastly, the justification of demonstrating the ability to access multiple locations within the same tumor target was not necessarily based on clinical need, rather to demonstrate the ability of a steerable instrument to specifically target different locations within a small target. In this study, the CZ of lesions was accessed in 60% of cases, though this was likely affected by time and workflow constraints as bronchoscopists were restricted to three attempts to position the needle within targets. Had there been no restrictions, as would occur in clinical practice, we suspect this number would be higher. While placing instruments into the center of lesions may be favorable, the ability to sample from differing locations within the same lesion may be equally important, as suggested by cases using three-dimensional fluoroscopic imaging that have been nondiagnostic despite demonstrating tool in lesion [12]. This suggests that lesions may be heterogeneous in nature

and that the ability to steer a needle into different locations within a targeted lesion may be clinically beneficial.

While significant resources have been utilized to improve reach and access to the lung periphery, placement of conventional biopsy instruments into targeted lesions remains challenging, particularly for lesions that are adjacent to peripheral bronchi. This feasibility study demonstrated successful placement of a steerable needle into 93% of tumor targets in a cadaveric model, with the ability to control and steer needle position into different portions of the target in 80% of cases. The translation of enhanced instrument maneuverability and control toward diagnostic yield will need to be further investigated in subsequent human studies.

### Statement of Ethics

Ethical approval was not required for this study in accordance with local/national guidelines. Written informed consent from participants was not required in accordance with local/national guidelines. No live human subjects were enrolled in this study.

### Conflict of Interest Statement

Alexander Chen, Michael Machuzak, George Cheng, and Momen Wahidi have received consulting fees from Serpex.

### Funding Sources

Alexander Chen, Michael Machuzak, George Cheng, and Momen Wahidi have received consulting fees from the Sponsor of this study, Serpex. No additional funding was received.

### Author Contributions

Alexander Chen, Michael Machuzak, George Cheng, and Momen Wahidi each made substantial contributions to the conception or design of the work, the acquisition, analysis, or interpretation of data for the work, drafted and assisted in critical revisions to the work for important intellectual content, provided final approval of the version to be published, and are in agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

### Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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