Cardiovasc Intervent Radiol (2017) 40:924–929
DOI 10.1007/s00270-017-1597-1

TECHNICAL NOTE

Development and Evaluation of a Novel Curved Biopsy Device for CT-Guided Biopsy of Lesions Unreachable Using Standard Straight Needle Trajectories

Maximilian Franz Schulze-Hagen[1] · Jochen Pfeffer[1] · Markus Zimmermann[1] · Martin Liebl[1] · Saskia Freifrau von Stillfried[2] · Christiane Kuhl[1] · Philipp Bruners[1] · Peter Isfort[1]

Received: 7 October 2016 / Accepted: 31 January 2017 / Published online: 7 February 2017

Abstract
Purpose To evaluate the feasibility of a novel curved CT-guided biopsy needle prototype with shape memory to access otherwise not accessible biopsy targets.
Methods and Materials A biopsy needle curved by 90° with specific radius was designed. It was manufactured using nitinol to acquire shape memory, encased in a straight guiding trocar to be driven out for access of otherwise inaccessible targets. Fifty CT-guided punctures were conducted in a biopsy phantom and 10 CT-guided punctures in a swine corpse. Biposies from porcine liver and muscle tissue were separately gained using the biopsy device, and histological examination was performed subsequently.
Results Mean time for placement of the trocar and deployment of the inner biopsy needle was ~205 ± 69 and ~93 ± 58 s, respectively, with a mean of ~4.5 ± 1.3 steps to reach adequate biopsy position. Mean distance from the tip of the needle to the target was ~0.7 ± 0.8 mm. CT-guided punctures in the swine corpse took relatively longer and required more biopsy steps (~574 ± 107 and ~380 ± 148 s, 8 ± 2.6 steps). Histology demonstrated appropriate tissue samples in nine out of ten cases (90%).
Conclusions Targets that were otherwise inaccessible via standard straight needle trajectories could be successfully reached with the curved biopsy needle prototype. Shape memory and preformed size with specific radius of the curved needle simplify the target accessibility with a low risk of injuring adjacent structures.

Keywords CT-guided biopsy · Curved needle · Curved biopsy device · Nitinol

Introduction

CT-guided percutaneous biopsy is widely used as an effective diagnostic tool in many clinical settings. However, CT-guided biopsies especially of deep abdominal masses may be challenging, because the puncture path is often obstructed by vulnerable structures. In many settings, a biopsy in straight needle trajectory can be therefore very difficult or even impossible [1, 2].

Several techniques can be applied to displace interposed structures such as changing the patient's body position, using hydrodissection, applying external compression or using a double-oblique puncture path. Fine needle aspiration biopsies can be safely performed via a transvenous or transenteral approach. However, the rate of representative or conclusive biopsies is usually inferior compared to core biopsies [3].

In the past decades, only a few studies investigated manual deforming of clinically licensed biopsy devices [4]. These publications showed promising results, although the needle tip was shaped to a limited degree to prevent malfunction, allowing only a slight variation of the puncture path.

To date there is no study that investigated the use of a dedicated biopsy device that allows a stepless variation of the needle angle while performing an image-guided biopsy.

✉ Maximilian Franz Schulze-Hagen
mschulze@ukaachen.de

[1] Department of Diagnostic and Interventional Radiology, University Hospital RWTH Aachen, Pauwelsstraße 30, 52074 Aachen, Germany

[2] Department of Pathology, University Hospital RWTH Aachen, Pauwelsstraße 30, 52074 Aachen, Germany

Therefore, the purpose of this study was to develop a prototype of an extendable, curved biopsy device that allows the access of targets that cannot be reached by means of straight biopsy trajectories and to evaluate its performance in an experimental study.

Methods and Materials

Biopsy Device (Fig. 1)

A prototype of a coaxial biopsy device was designed and manufactured. It consists of a straight guidance needle and an inner biopsy system with a curved needle tip of 90°. The curved biopsy system is inserted in the guidance needle and can be steplessly adjusted to achieve different needle angles from 0° to 90° within a radius of 20 mm.

The Prototype Biopsy Device Consists of the Following Parts

A 13G straight guidance needle made of stainless steel serves as a rigid trocar. The distal end of the trocar tapers and therefore precisely adapts to the inner biopsy system.

The inner biopsy system consists of two separate solid nitinol tubes, which are both curved by 90° with a radius of 20 mm. Nitinol is a metal alloy of nickel and titanium, which exhibits both a shape memory effect and a higher elasticity compared to ordinary metal.

The outer tube has a diameter of 17G. The distal end consists of a diamond-shaped cutting tip to facilitate tissue penetration. A cavity is located on the concave side of the curve, serving as a biopsy receptacle channel.

The inner tube has a diameter of 19G with a cutting edge at the distal tip. It is nested into the outer tube, thereby generating a cutting system. Retracting the inner tube opens the biopsy trough. Pushing it into the outer tube cuts enclosed tissue. Using a 5-ml syringe vacuum can be applied at a side entry on the outer tube to help adhering tissue in the biopsy receptacle channel. The whole biopsy process is demonstrated in Fig. 2.

Biopsy Phantom

A biopsy phantom was built using a lumbar spine model and two silicon tubes filled with contrast agent, simulating the inferior vena cava (IVC) and the aorta. Five glass beads with a diameter of 5 mm are located next to the tubes, one on each lumbar segment, serving as biopsy targets. The tubes and beads are positioned in a random fashion that does not allow straight needle trajectories—not even via a double-angulated approach. All structures were finally embedded in gel wax.

CT Interventions on the Biopsy Phantom (Fig. 3)

CT-guided punctures of five targets were obtained ten times each, resulting in a total of 50 punctures. All studies were performed on a dual source CT scanner (Siemens SOMATOM Definition Flash, Siemens Healthcare) with intermittent CT controls.

The guidance trocar was inserted in the phantom and located in such a fashion that the tip was 2 cm proximal and 2.5 cm lateral of the target. Due to the given radius of the preshaped biopsy needle, this position of the trocar tip

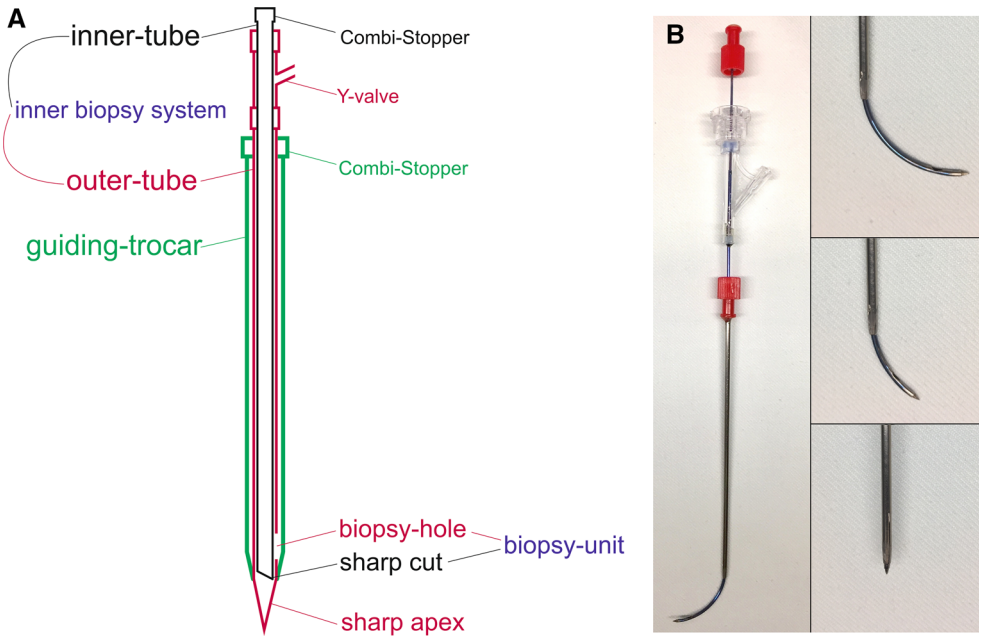

Fig. 1 **A** Prototype curved biopsy device. The inner biopsy system is retracted, allowing straight tissue penetration. **B** Photographs of the prototype curved biopsy device.

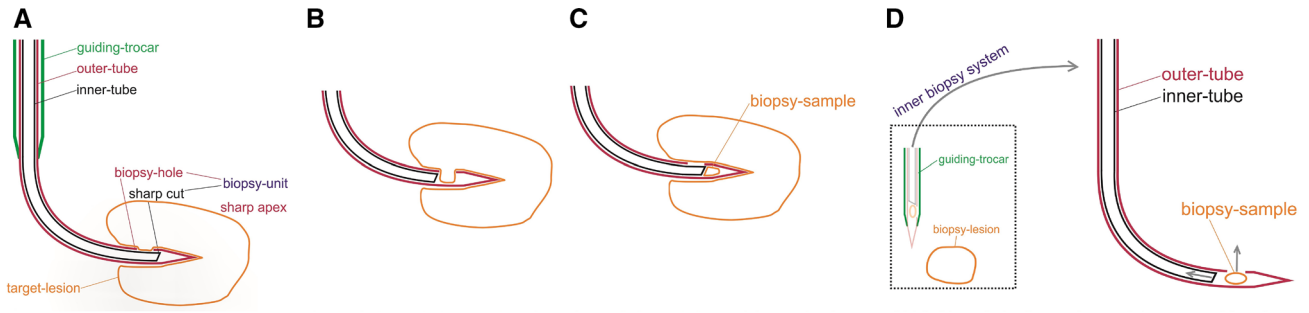

Fig. 2 **A** Inner biopsy system is extended in a curved trajectory of 90° due to the shape memory effect. The cutting tip is located in the target lesion. **B** The inner tube is retracted opening the biopsy trough. Vacuum is applied to the Y valve using a 5-ml syringe allowing target tissue to be sucked into the biopsy trough. **C** The inner tube is pushed forward, separating the biopsy sample from the target lesion. The sample is now located in the biopsy receptacle channel inside the outer tube. **D** The biopsy device (inner and outer tube) is extracted from the guiding trocar, which remains in vivo. The biopsy sample can be removed by slightly retracting the inner tube. The sample can now be extracted by using a needle

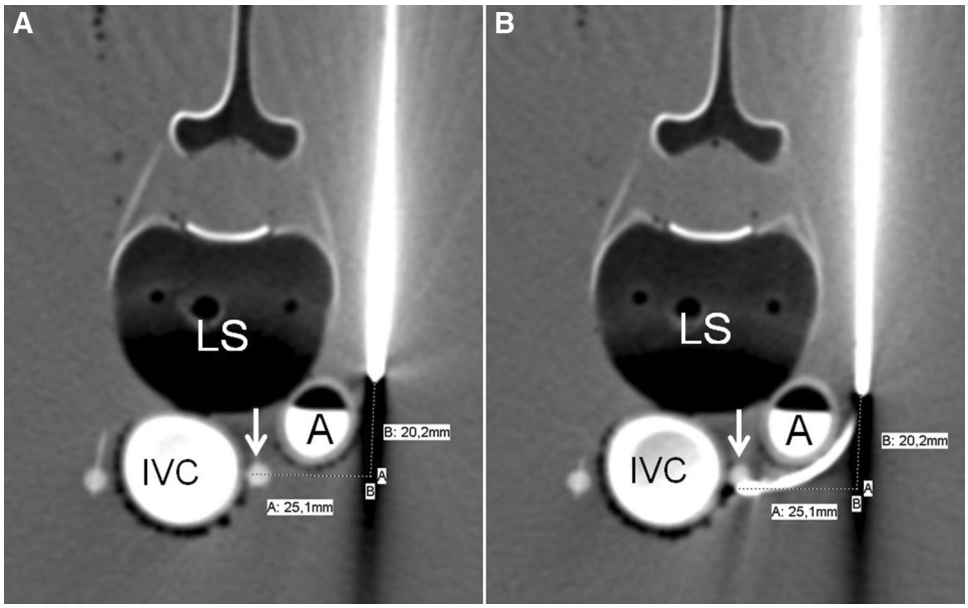

Fig. 3 CT-guided punctures in the biopsy phantom. *LS* lumbar spine; *IVC* inferior vena cava; *A* abdominal aorta; Arrow pointing at biopsy target. Biopsy device in straight configuration for tissue penetration (**A**). Extended inner biopsy system with needle tip next to the biopsy target (**B**)

allowed direct access to the biopsy target. In a second step, the biopsy needle was first rotated in the desired direction while still within the trocar and then pushed out to reach the biopsy position.

A biopsy step was counted if the guidance trocar or the curved biopsy system was repositioned after the first penetration of the phantom's surface. As the targets, represented by glass beads, were impenetrable, the biopsy position was defined as immediate contact of the biopsy unit with the glass bead in the control scan. Time, number of biopsy steps as well as distance to the biopsy targets was assessed for all punctures.

CT Interventions on the Swine Corpse (Fig. 4)

To further examine the handling of the prototype biopsy device in body tissue, 10 CT-guided punctures were performed in a fresh swine corpse. A solution of contrast agent and glue was injected into the liver parenchyma at two different positions to simulate biopsy targets. A total of 10 CT-guided punctures were conducted in an analogue puncture technique as mentioned above. As there was no mechanical obstruction of the straight biopsy path, a randomly percutaneous angle was chosen to access the targets from multiple sides. Parameters were assessed in the same manner as in the phantom study.

Histopathologic Analysis

The biopsy unit was tested using ex vivo porcine liver and muscle. A total of five biopsies were retrieved from each specimen. The biopsies were stained using hematoxylin–eosin technique and further histologically assessed by a pathologist. The biopsies were classified as "utilizable" or

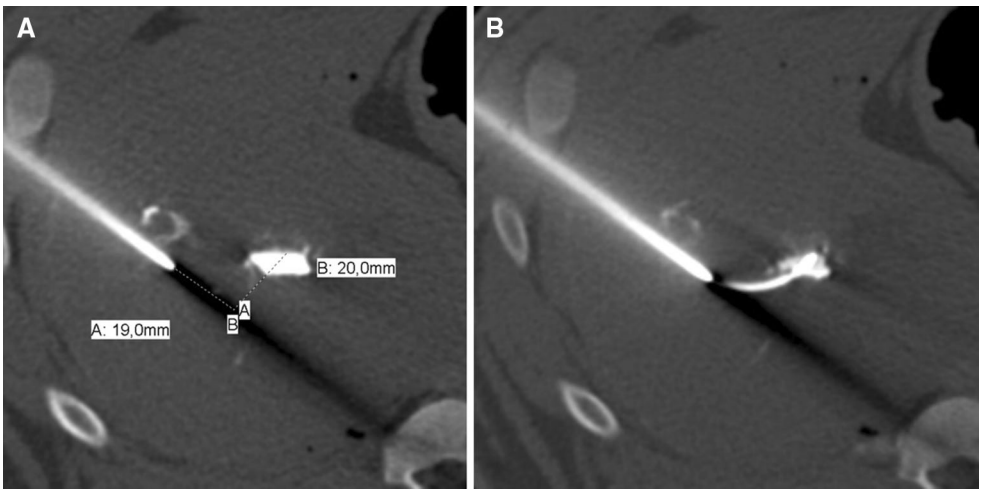

Fig. 4 CT-guided punctures in an ex vivo swine corpse. Biopsy device in straight configuration for tissue penetration (**A**). Extended inner biopsy system with needle tip inside the biopsy target (**B**)

"non-utilizable" for general histopathologic analysis. Examples are shown in Fig. 5.

Results

CT Interventions on the Biopsy Phantom

A total of 50 CT-guided punctures were performed. The mean time to place the guiding trocar and to deploy the biopsy system at the target was $\sim 205 \pm 69$ and $\sim 93 \pm 58$ s, respectively. A mean number of 3.1 ± 1.1 steps were necessary to position the guiding trocar. After the trajectory and position of the trocar were appropriately adjusted, the curved biopsy device was successfully advanced to the biopsy target at the first attempt in 30/50 cases (60%). In 20/50 cases (40%), the needle tip did not reach the biopsy target at the first approach and therefore needed relocation. A mean total number of $\sim 4.5 \pm 1.3$ biopsy steps were necessary to reach the biopsy position. After reaching biopsy position, the distance from the biopsy unit to the target was $\sim 0.7 \pm 0.8$ mm.

CT Interventions on the Swine Corpse

A total of 10 CT-guided punctures were performed. The mean time to place the guiding trocar and to deploy the inner biopsy system in the biopsy target was $\sim 574 \pm 107$ and $\sim 380 \pm 148$ s, respectively. A mean number of 4.4 ± 1.7 steps were necessary to position the guiding trocar and further 3.6 ± 1.2 steps to position the biopsy unit. A mean total number of 8 ± 2.6 biopsy steps were conducted.

After final positioning, the biopsy unit was located inside the target in 8/10 cases (80%), in 2/10 cases (20%) the biopsy unit was located 2–3 mm distant to the target (2 and 3 mm, respectively).

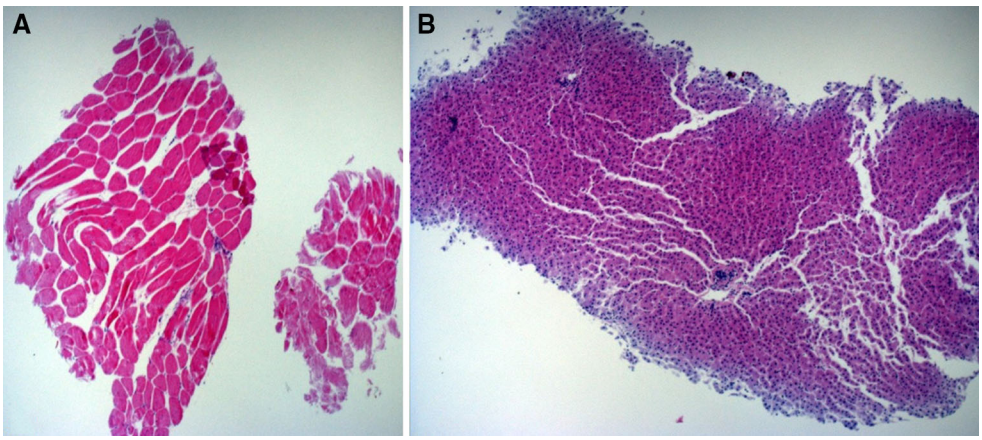

Fig. 5 Histology of an ex vivo muscle biopsy (**A**) and liver biopsy (**B**)

Histopathologic Analysis

9/10 biopsy samples (90%) were classified as utilizable for general histopathologic analysis. One sample was classified as non-utilizable due to small size and crush artifacts.

Discussion

CT-guided biopsy of masses that are not accessible via a straight puncture trajectory remains challenging. Despite specific methods such as a double-angulated techniques, aero- or hydrodissection as well as transosseous and transcaval approaches, a variable number of targets are not accessible with straight biopsy devices.

Using curved biopsy devices per se is not an entirely new approach. Indeed, already in 1984, Levy and Oro [5] were the first to describe aspiration biopsies of intracranial lesions using a curved plastic biopsy needle trough a straight guide catheter. In the same year, Hawkins and Caridi [6] reported on the redirection of a fine needle aspiration cytology system by manually inserting a curved stylus. Later, Corrasco et al. [7] reported on the use of a curved fine needle aspiration cytology system to sample masses adjacent to bone or viscera under fluoroscopic guidance. The first reports on the use of a curved core biopsy system stems from Singh et al. who used a manually shaped 20G core biopsy in 210 procedures [8]. All published studies showed promising results. However, a limitation of these published approaches is that these devices were manually shaped, bending the needle tip to a limited degree (<40°) in order to prevent malfunction. Therefore, these approaches allowed only a slight modification of the puncture path.

Our prototype allowed safe, precise and quick puncture of all otherwise inaccessible targets. Due to the 90° curve of the biopsy system, it was possible to reach targets that are located in a perpendicular trajectory to the direction of the trocar. The system was relatively easy to use but needs little training due to the different biopsy approach.

As mentioned above, the given radius of the preshaped biopsy needle requires a coaxial technique with a guidance trocar, which has to be located in a certain position next to the biopsy target. Therefore, exact planning of the intervention and understanding of the curved needle pathway are important. When the trajectory and position of the trocar had been appropriately adjusted, the biopsy device was successfully advanced to the biopsy target at the first attempt in 60%. In 40%, a reposition was necessary, requiring further 1.4 ± 0.6 biopsy steps. The histopathologic evaluation demonstrated adequate quality of the biopsy probes in the majority of cases.

In our biopsy phantom, the intraabdominal/retroperitoneal space was simulated by gel wax, which has a relatively soft and homogenous consistency. Therefore, the steerability of the biopsy device was better than it is to be expected in an in-vivo setting. To compensate for this, we performed ex vivo examinations on a fresh swine corpse. As one would expect, the biopsy procedures took significantly longer and required more biopsy steps until the target was finally reached. However, in 8/10 cases (80%), the procedures were successful. In the remaining 20%, there was a small offset between the biopsy unit and the target by 2–3 mm. However, we did not encounter a significant deviation of the inner stylet during our biopsies.

The relatively thick diameter of the external trocar (13G) makes it somewhat difficult to control the positioning of the needle especially in tissues that are quite rigid, such as muscle. Also the thick diameter causes relatively strong extinction artifacts. Furthermore, there is still a relatively strong shear force when forwarding the inner needle through the trocar, which makes it sometimes hard to smoothly extend or retract the biopsy device.

Of note, these are the first results on the utility of a prototype device that was hand crafted. Although multiple technical adaptations are conceivable and probably necessary in the future, our first results are encouraging. Systematic technical optimization as well as further in vivo experiments is underway in our department to improve the device and evaluate the clinical utility of the curved core biopsy system.

Compliance with Ethical Standards

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

Ethical Approval All applicable institutional and/or national guidelines for the care and use of animals were followed.

References

1. Gupta S, Madoff DC, Ahrar K, Morello FA, Wallace MJ, Murthy R, et al. CT-guided needle biopsy of deep pelvic lesions by extraperitoneal approach through iliopsoas muscle. Cardiovasc Intervent Radiol. 2003;26:534–8.
2. Gupta S, Ahrar K, Morello FA, Wallace MJ, Madoff DC, Hicks ME. Using a coaxial technique with a curved inner needle for CT-guided fine-needle aspiration biopsy. Am J Roentgenol. 2002;179:109–12.
3. Chojniak R, Isberner R, Viana L, Yu L, Aita A, Soares F. Computed tomography guided needle biopsy: experience from 1,300 procedures. Sao Paulo Med J. 2006;124:10–4.
4. Warnock NG. Technical note. Curved needle technique for the avoidance of interposed structures in CT-guided percutaneous fine needle biopsy. J Comput Assist Tomogr. 1996;20:826–8.
5. Levy WJ, Oro JJ. Curved biopsy needle for stereotactic surgery: a technical note. Neurosurgery. 1984;15:82–5.

6. Hawkins IF, Caridi JG. Curved stylus for redirection of the fine-needle guide. Radiology. 1984;151:530.
7. Carrasco CH, Wallace S, Charnsangavej C. Aspiration biopsy: use of a curved needle. Radiology. 1985;155:254.
8. Singh AK, Leeman J, Shankar S, Ferrucci JT. Core biopsy with curved needle technique. Am J Roentgenol. 2008;191:1745–50.