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Concept for parallel placement of flexible needles for Irreversible Electroporation

Abstract: Irreversible Electroporation (IRE) is a non-thermal tumor ablation treatment applicable for prostate cancer. IRE uses ultra-short but strong electrical pulses to destroy cancer cells nonthermally [1]. Clinically available IRE therapy requires two or more needle electrodes placed around the target tissue to apply the electric fields. A pre-requirement to achieve successful and effective ablation is an accurate and parallel needle placement to cover the tumor zone. Differences in tissue density, organ surface curvature as well as organ and patient motion in combination with long and highly flexible needle electrodes causes difficulties to achieve the desired target accuracy during needle placement process. We propose a concept of a shooting mechanism in combination with a grid template support to improve the parallel needle placement process for prostate cancer treatment. Instead of conventionally inserting the needle in the body by hand, it can be placed with high speed using a shooting device setup, that works similar like a biopsy gun.

Keywords: Irreversible electroporation, Parallel needle placement, Prostate cancer, NanoKnife shooter, Ultrasound imaging.

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1 Introduction

Prostate cancer is one of the most commonly diagnosed malignancies among males worldwide. Prostate is about 3–4 cm in size and surrounds part of the urethra. Prostate glands produce fluid that is part of the semen [2]. The prostate can be grouped into 4 zones based on the internal structure. The anterior zone is mainly muscle and fibrous tissues, the peripheral zone situated toward the back of the gland is where most of the glandular tissue sits, the central zone surrounds the ejaculatory ducts and the transition zone, that surrounds the urethra. Due to this inhomogeneous structure and variations in tissue stiffness, a straight placement of needle electrodes is challenging. Additionally, intrafractional and interfractional movements of prostate gland [3, 4] can hinder a proper placement.

Irreversible Electroporation (IRE) is a non-thermal tumor ablation treatment applicable for prostate cancer. For IRE therapy, two or more needle electrodes must be carefully placed parallel to each other to ensure an even distribution of the electric field between the needles for successful tumor ablation. The pulses to destroy cancer cells are delivered between the needle electrodes. After delivering a sufficient number of high voltage pulses, the cancer cells within the electrical field will be irreversibly damaged. This mechanism causes permanent cell death [1]. Hence, IRE can be a safe, fast and powerful method of tumor treatment in comparison to other ablation technologies.

Location of the treatment zone and planning of the procedure is done on prior diagnostic imaging for therapy of prostate lesions with IRE. While the patient is placed under general anaesthesia, the needle electrodes are placed one by one manually around the target zone under Ultrasound (US) guidance. A commercially available system for IRE is the NanoKnife 3.0 (NK) developed by Angiodynamics. The needle electrodes are 15 cm in length with a 19 gauge tip diameter. The needles are highly flexible what makes parallel placement challenging (see Figure 1).

In this work we propose a concept on how to improve the placement of these flexible needles into an inhomogeneous organ like the prostate.

Figure 1: Deflection and flexibility of a NK needle electrode.

2 Materials and Methods

2.1 Conceptual design and prototype

To create a solution for optimal needle placement in IRE, an analysis of the medical workflow and comparable clinical applications was performed [5]. Additionally, the tissue/needle behavior during needle insertion was studied. Based on the literature review, we decided to use a 20mm precision grid template for guidance known from prostate biopsy procedures [6]. These grid templates have a matrix system of holes, through which needles are inserted in equal distances. To improve needle deformation and motion effects while placement, a fast insertion could be beneficial. Therefore, we decided to copy the principle of needle placement of biopsy guns [7]. A fast shooting of the needle uses the inertia of the target tissue to reduce evasive movement. A shooting device called NanoKnife Shooter (NKS) was designed allowing insertion of standard NanoKnife needles. This device can push the electrode fast forward up to 40mm into the tissue. The device was designed in CAD and built by 3D printing.

The main body (base) of the NKS is a stationary part with a cylindrical guidance to guide the NK holder which is the moving part powered by a spring (see Figure 2).

Figure 2: Trimetric view of CAD illustration of NKS assembly.

The NK holder is fixed with a flexible trigger lock which stops the movable holder in the base body after pulling it backwards in order to load the gun. Hence, it locks the holder in the base part until the dual trigger is pressed to release the

NK holder. The base contains these trigger buttons on both sides respectively. Dual trigger buttons must be pressed simultaneously to shoot the gun. A rubber stopper was used to stop the NK holder at a desired distance and also to avoid the breakage of fasteners due to possible strong collision forces. Front cap was used to keep the cylindrical guidance straight. The length of the NKS device is 10.5 cm and the width is 2.7 cm. NK holder covers a distance of 4.0 cm until it came into rest position after hitting the stopper. This distance range is equal to the maximum active needle tip of NK probe for delivery of IRE treatment. The final prototype is shown in Figure 3.

Figure 3: Top view of activated NKS with loaded NK probe.

After the development of NKS, a stable support was required to reduce recoil and any unwanted hand movement while shooting. This support can be fixed on the ultrasound guidance in clinical application and allow precise alignment with the targeting grid. (see Figure 4).

The NKS support is adjustable in vertical direction.

Figure 4: NKS support (white) attached to the holder structure.

2.2 Testing of the NKS approach

A phantom box was created to hold a prostate replica embedded into gelatine. To visualize the needle path while testing, an US probe on a slider was attached and aligned with the insertion direction. The 2cm thick grid template was fixed in front of the phantom box (Figure 5).

It is important to select a material which can act as a prostate replica inside the gelatin phantom. A potato was selected as an initial potential material to perform needle insertion experiments due to its shape and material density.

Oval shaped potatoes of different sizes mainly 4-6 cm in diameter were used to evaluate the efficiency of the NKS to

Figure 5: Phantom box with a potato and sausage embedded into gelatin to mimic prostate.

avoid needle deflection while hitting a hard surface. Since we were not able to see the needle path inside the potatoes with US imaging, we selected blood sausage (Rotwurst) as prostate replica due to its suitability for US imaging (Figure 5).

To achieve high resolution imaging, an US system (LOGIQ-E, GE Healthcare) with a 9L-RS probe was used. The US probe was attached on ITEM profiles to enable horizontal alignment (left and right) for imaging of different needle insertion locations. The required hardware devices, materials and supporting tools were arranged together in an experimental setup (Figure 6).

Figure 6: Complete test setup at a glance.

2.3 Approaches for needle placement

For the testing and evaluation of the shooting mechanism, three types of needle placement methodologies were selected. (1) Manual insertion by hand, (2) manual insertion with grid template and (3) insertion with NKS and grid template.

Puncture locations with varying target surface angles were selected. Both sides (round surface) and central edges (top/bottom) of each target material were tested to observe multiple needle insertion behaviours. Each puncture location was tested with all the three approaches one by one documented using US imaging from above each puncture plane. Thus, three US images at a same puncture plane on the same phantom setup and prostate material were acquired. For all experiments whether potato or sausage, a bottom to top puncturing approach was used to avoid image artefacts due to air bubbles in the gelatin. The straightness of the needle path and deviation of entry to end point from an ideal horizontal line were analysed.

3 Results and Conclusion

3.1 US image analysis

306 US images were acquired from 102 punctures, 270 US images from potato and 36 US images from sausage.

Values of needle deflection were measured to differentiate the US image results for specific insertion approaches. Each US image was carefully analysed in the ITK-Snap software for the calculation of needle deflection values from the ideal straight path.

In the US image analysis, a green dot represents the point of needle insertion whereas the red dot is placed on the point of maximum visible deflection from its straight path (Figure 7). A horizontal blue dotted line is the reference line (straight line) to visualize the needle deviation from its insertion point. Deflection values are given in yellow colour and are also measured by the ITK-Snap software (Figure 7). Deflection can be seen in needle insertion approaches by hand and by grid (Figure 7), whereas needle followed a straight path and nearly no deflection was occurred in the case of NKS approach as shown in Figure 7 (c).

3.2 Trends and values of needle deflection

Depending upon the needle insertion approach, US images have clearly shown different behaviours of needle deflection.

Figure 7: a) US image of manual insertion by hand (b) US image of insertion with grid support (c) US image of insertion by NKS and grid.

Table 1 shows the results from the 270 US test sets with potato as prostate replica. As expected, manual insertion by hand shows the highest deflection tendency with only 8.62% of the cases without deflection, whereas needle insertion done by NKS and grid shows the lowest tendencies of deflection with no deflection in 51.72%. When inserted only assisted by grid in 31,03% of the cases no deflection appeared.

Table 1: Percentage values of cases showing needle deflection and cases with no needle deflection during needle placement approaches with potato.

Needle insertion approach	Without deflection (%)	With deflection (%)
1- NKS setup	51.72	48.27
2-Grid	31.03	68.96
3-Hand	8.62	91.37

Table 2: Maximum values of needle deflection during specific needle placement approaches with potato.

Needle insertion approach	Maximum deflection surface entry point to needle tip (mm)
1- NKS setup	1.9
2-Grid	2.9
3-Hand	5.6

3.3 Conclusion

The analysis and comparison of the acquired US images has shown, a clear benefit of the NKS plus grid approach. Using only the guidance grid was already significantly better than the hand approach but still needles were seen deflected due to their length and strong flexibility. The insertion of the needle with speed as in case of NKS device keeps the needle on a straight path with minimum trends of deviation after hitting the target material. The chances of error during needle placement by hand can also be caused by motion of the patient. This can be improved by fast placement as well. Additionally, a stable alignment and tool support as in the case of NKS device have shown successful results by eliminating the unwanted misalignments and recoil movements of any type. Thus, it can be concluded that straight or parallel needle placement can be improved by inserting NK needles at a fast speed with the help of shooting mechanism (NKS) rather inserting them by hand. Hence, the parallelism of flexible needles can be optimized by applying a more extended guidance template and shooting mechanism similar to that of biopsy guns.

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