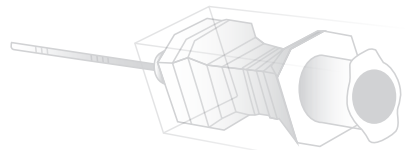


Clinical White Paper eSpatial Navivision

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1. Introduction

1.1 Benefits of ultrasound imaging

Ultrasound imaging is increasingly used to guide Point-of-care procedures, such as peripheral anesthesia, vascular access, musculoskeletal injections, etc. There are several advantages of using ultrasound imaging as a procedural guidance technology compared with other imaging modalities, such as fluoroscopy or computed tomography guidance. Ultrasound imaging offers real-time visualization on both tissue and needle to the clinician. In addition, Ultrasound does not generate ionizing radiation, thus is generally felt to be safe [1]. Moreover, there are convincing data proving the benefits for patients' safety in certain procedures. For example, several trials have demonstrated that real-time ultrasound-guided internal jugular venipuncture have a higher first attempt success rate, reduce the access time and decrease the risk of arterial puncture compared with the palpation or landmark method [2].

1.2 Challenges of traditional ultrasound in puncture

However, ultrasound has certain drawbacks. In the In-Plane puncture, because the ultrasound beam is very thin [3], it is difficult for the operator to keep the needle inside the ultrasound beam during the whole procedure, which may cause a misestimate of the depth of needle tip. Additionally because of the needle shaft's reflection, the steeper insertion angle may lead to poor recognition of the needle [4]. And in the Out-of-Plane puncture, the needle tip cannot be seen until it crosses the ultrasound plane, and it is difficult to determine whether the cross-sectional 'dot' represents the needle shaft or tip, which can similarly lead to needle positioning errors and nearby structures damage. Also accidentally driving the needle excessively deep is a particular concern in Out-of-Plane procedures.

1.3 General introduction of eSpacial Navi

To overcome the above problems and assist ultrasound guided procedure, eSpacial Navi, a new 4D magnetic needle navigation technology, is born. Based on the magnetic induction technology, eSpacial Navi can detect in real time the direction and the relative spacial position to the transducer, and map the needle position information to the ultrasound image. Thus in four dimension (4D) guide the clinicians to plan the puncture path and better recognize needle on the ultrasound image.

Compared with other needle guidance technology, eSpacial Navi does not require the special needles, and does not need any additional complex hardware. It complies with the current puncture process which is familiar by clinicians.

2. Principle

2.1 The transducer with magnetic sensor

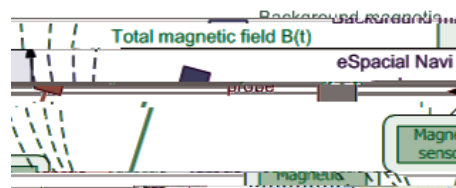
There are magnetic sensors inside the eSpacial Navi probe head. Magnetic field are always existed in the vicinity of the probe due to the Earth magnetic field and other sources - this is called the background magnetic field. Before the needle approaching, the sensors measure the intensity of background magnetic field first. Then the system can compute the signal strength to indicate the user on GUI whether there is interference around. If the signal indicator turns red, it means the background interference is high and the guidance will not be available. User must remove the source of interference away from the eSpacial Navi system.

2.2 Magnetization of the puncture needle

The metallic needle itself does not generate magnetic field, so the needle should be magnetized by inserting it into a magnetizer before puncture. The magnetizer is a small non-electronic device. It is designed to be standing on a flat surface or held in the hand with a needle entry port to insert the needle, which then passes through 2 magnets. The needle should be inserted into the bottom of the magnetizer 1 or 2 seconds and then withdraw quickly. After magnetization, the needle generates a weak magnetic field around which is similar with that of the magnets.

2.3 The principle of realizing puncture guidance

When the needle is approaching the probe, the intensity of magnetic field will be changed. It is a combination of the background magnetic field and magnetic field the needle generated. The sensors detect the change and the system setups a connection with the needle, then get magnetic intensity of the needle from using the total magnetic field intensity minus the background magnetic field intensity. Our algorithm then calculate the real-time spacial coordinates of the needle which is relative to the ultrasound plane from the magnetic field intensity, so the needle visualization information such as needle tip, needle shaft, needle trajectory can be overlaid on the ultrasound image. The whole process is showed as below Figure 1:



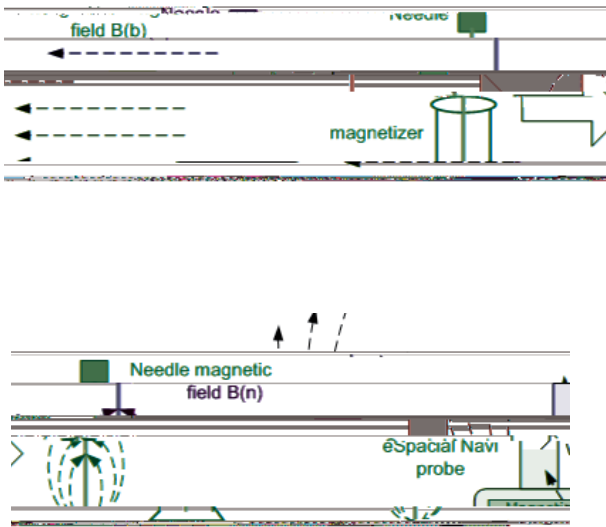


Figure 1. The schematic and principle of eSpacial Navi

3. Benefits

3.1 Puncture trajectory planning

The first benefit of eSpacial Navi is to help operator to plan the puncture. For example, in Out-of-Plane puncture, the operator can adjust the needle angle left and right, or far and near, to place the box on the puncture target, this is better and safer than estimating the puncture trajectory according to experience and can evidently improve the success rate and reduce the operation time.

3.2 In-Plane puncture: Alignment indication

For In-Plane puncture, eSpacial Navi can also help operator align the needle with the ultrasound plane. With the real time feedback of alignment indicator and color-coded visualization information on the ultrasound image, operator can better know the spatial relationship between the probe plane and needle, and adjust the needle to align with the ultrasound plane to get the correct imaging of the needle tip. This can reduce the chance of underestimation of needle tip caused by misaligned needle, thus improve the safety.

3.3 Out-of-Plane puncture: Intersection point estimation

Another benefit of eSpacial Navi is to assist operator better recognize the needle on the ultrasound image. For example, in Out-of-Plane needling, a dotted line with scale between the needle project box and target box shows the distance between the needle tip and ultrasound plane, so the operator can easily know how far the needle tip is approaching the target, and when the needle tip is exactly achieving the ultrasound plane, the needle project box will intersect with the target box and the color of both turns blue, these indicate the cross-sectional 'dot' in the ultrasound image is the needle tip. With the help of visualization information, the operator can explicitly distinguish the needle tip and needle shaft in ultrasound plane, and also reduce the needle positioning errors and damages to nearby structures.

4. Clinical case

Blow we have phantom cases and in-vivo cases to show the function of eSpacial Navi.

4.1 Phantom Study:

In-Plane puncture can perfectly display the needle shaft and needle tip, based on Mindray's advanced platform and promising image quality, even the angle of the needle tip can be clearly shown, see in Figure 2.(A). Out-of-Plane puncture can plan the puncture trajectory and estimate the intersection point, therefore the puncture is not "blind" any more, see in Figure 2.(B).

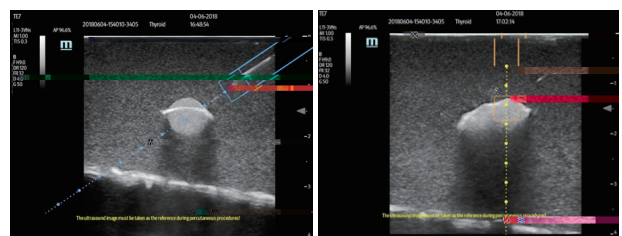


Figure 2. (A) In-Plane puncture

Figure 2. (B) Out-of-Plane Puncture

4.2 In-vivo cases:

In real cases, the environment around puncture target is much more complex than that in phantom, especially in nerve block, a puncture has extraordinary high requirement of precision. Here are two real cases regarding nerve block, Figure 3.(A) shows Stellate ganglion nerve block, Stellate ganglion is just

next to carotid artery, close to vertebral artery, any deviation can lead to critical consequences; the similar scenario in Figure 3.(B), ventral femoral nerve block, close to femoral, cannot be clearly seen in ultrasound B-mode image and deeper depth ask for Out-of-Plane puncture. In such cases, eSpacial Navi shows great value to avoid arteries and plan puncture path beforehand.

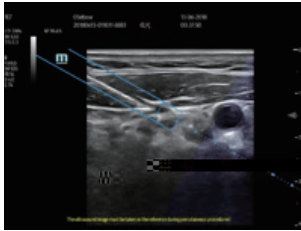


Figure 3. (A) Stellate Ganglion Nerve Block

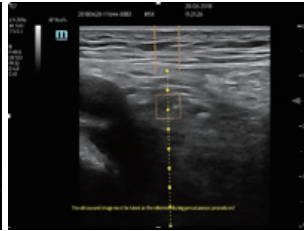


Figure 3. (B) Ventral Femoral Nerve Block

5. Summary

Based on magnetic induction technology, eSpacial Navi can track the magnetized needle and provide the 4D needle visualization information on ultrasound image which helps clinician to better plan puncture and recognize the needle. eSpacial Navi supports a wide range of commercial regular needles and does not require complex hardware. In addition, eSpacial Navi is also easy to learn due to compatibility with current puncture workflow, thus it is a useful and valuable tool for ultrasound guided procedures in regional anesthesia, vascular access, musculoskeletal injections, fine needle biopsy, etc.

Reference

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