A Facile Magnetic System for Tracking of Medical Devices

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The largest disadvantage of modern day minimally invasive surgery is the required use of X-ray or fluoroscopically imaging for locating or tracking medical catheters and tubes. The implications are increased costs and effort, limited availability for instance in less developed countries, and the cumulative exposure to contrast dyes and ionizing radiation are detrimental to health, especially in young patients and neonates with increased sensitivity. In order to reduce the use of X-ray imaging and provide a wider accessibility, a facile magnetic system is proposed for subcutaneous medical device localization. It consists of a lightweight and flexible, biocompatible, and permanent magnet at the tip of the subcutaneous device and a sensing device to scan the dermal surface and locate the magnetic tip. The mechanical and magnetic properties of the magnetic tip are tailored to fit the requirements of the delicate catheter application. Evaluation of the tracking system using a 5 Fr magnetic tip resulted in a depth-dependent position and orientation error of 0.75 mm and 3.7°. Additionally, a maximum placement depth error of 0.96 mm is achieved. Evaluation of the system in vivo revealed its practicality and accuracy as well as the influence of potential user errors.

1. Introduction

Over the previous two decades, minimally invasive surgery and the use of catheters have been widely adopted. By avoiding large incisions, it offers substantial advantages, such as less postoperative pain, shorter hospital stays, improved cosmetic outcomes, fewer wound-related complications and lower costs.[1] In no other field of medicine are the benefits of catheter-based approaches more obvious than in cardiovascular disease treatment, where surgeries are accomplished quicker, with faster postoperative recovery times and improved clinical outcomes, compared to traditional sternotomy procedures.[1,2] However, catheter-based interventions come with a major disadvantage, namely the required use of X-ray or fluoroscopic imaging, which exposes the patients to harmful ionizing radiation and contrast agents. They are particularly harmful to use during the neonatal period, such as umbilical catheterization, which is typically required for preterm infants. Due to the complexity of these interventions, they are also not available in many situations like ambulances, where, for example, the placement of endotracheal tubes still needs to be done without any placement monitoring.

Every year, an estimated 15 million babies are born too early or preterm, i.e., born before 37 weeks of gestation.[3] The treatment of preterm neonates involves administering of fluid nutrition and medicine intravenously, as well as intravenous monitoring of vital signs. An umbilical catheter (UC) is used to gain intrararterial/intravenous access through the umbilical cord after birth. The position of the catheter tip is important as misplacement may result in potentially serious complications, such as intracardiac thrombosis, arrhythmia, endocarditis, potential vein thrombosis, or hepatic necrosis.[4–6] Furthermore, incorrect placement of the UC may result in inaccurate blood sampling or blood pressure monitoring.[7] Therefore, after placement, the position of the catheter tip is confirmed using X-ray imaging, such as thoraco-abdominal anteroposterior X-rays.[6,8–11] Unfortunately, a large number of survivors of high-risk preterm births develop respiratory, gastrointestinal, and neurodevelopmental morbidities that require as much as 30 radiographs within the first 6 weeks of life.[8] As a result, the radiation exposure and its consequences in premature infants has been of increasing concern.[8] With the risk of exposure to ionizing radiation being well documented, new procedures have been...
suggested for reducing the patient and healthcare staff exposure, such as mandatory lead protective gear, gonadal shield for neonates, new guidelines for optimal collimation of the X-ray beam and optimal positioning of the neonates. The implementation of these methods has reduced the exposure to ionizing radiation by 75% in neonatal patients and 100% in healthcare staff. However, the regular use of this method for diagnostic imaging in preterm neonates exposes them to large doses of ionizing radiation during a period when cellular (mitotic) activity and the risk of cancer induction are the highest.

In the search for alternative methods, several works have described attempts for evaluating catheter placement using sonography, which recently became possible with the development of high-resolution transducers. The main advantages of ultrasonographic evaluation over radiographic are the early detection of misplacement and the avoidance of ionizing radiation exposure on the patient. However, the drawback of this method, as with radiographic imaging, is the requirement of highly trained personnel, such as a paediatric radiologist, which is not always accessible, increases costs and causes delays. In many cases, especially in development countries, surgical catheterization procedures are not applicable, due to the lack of bedside imaging units or the lack of access to imaging altogether. Those working in resource-poor nations perpetually face the challenges of lack of expert support (subspecialists), diagnostic facilities (laboratory and radiology), and appropriate medications and equipment. The World Health Organization estimates that while two thirds of the world do not have access to basic radiology services and ultrasound, nearly 50% of X-rays and more than 40% of ultrasounds in resource deprived countries are not fully functional. Massachusetts General hospital in Boston, USA, has 126 radiologists, while the country of Liberia has two.

Magnetic tracking as a potential alternative has significant utility in the biomedical engineering setting, due to the transparency of the human body to static and low-frequency magnetic fields. The concept of magnetic tracking has been investigated by a number of authors over the past decades. Pham et al. have demonstrated the real-time localization of an endoscopic capsule in vivo using four magnetic sensors with a positional error of 5 mm. Ren et al. demonstrated a data acquisition system for magnetic localization and orientation with an error of only 2.1 mm, but required 80 sensors aligned in four planes to achieve this. This is similar to other works that implement a large number of magnetic sensors or sensing coils, which increases the complexity and reduces the likelihood of large-scale adoption, in practice. Mashraei et al. manufactured a flexible tunnel magnetsoresistance sensor that attaches to the tip of a catheter and allows the determination of the catheter orientation using the geomagnetic field. However, this approach suffers from the same drawback as methods that employ sensing coils on the catheter, i.e., they require wires to be integrated into the lumen of the catheter, and it is limited to orientation tracking without providing positional information.

In this paper, we present a versatile, robust, and facile system for tracking of subcutaneous medical devices that entirely avoids X-ray and contrast agents. We demonstrate its efficiency for determining the location and orientation of a UC in an animal model. The system utilizes a magnetic skin to implement a permanent magnetic device tip, which is combined with a handheld sensing and readout device. Localization is achieved by utilizing only two magnetic field sensors; one for sensing the field amplitudes from the catheter tip and another one to compensate the influence of the geomagnetic field.

2. Subcutaneous Magnetic Tracking System

2.1. Concept

The magnetic tracking system localizes a subcutaneous device after placement, by employing a user-friendly technology without the use of X-ray radiation. This is achieved by implementing a permanent magnetic tip at the distal end of the subcutaneous medical device and combining it with near field magnetic tracking via a handheld sensing device. Inspired by the advent of flexible electronics and the recently developed magnetic skin, the magnetic tip is made of a polymer with magnetic fillers. This allows the elastic and magnetic properties to be tailored to the application. This is important in order to maintain, for example, the mechanical properties of the medical device in terms of stiffness, weight, or handling. The magnetic skin can be attached by slipping it onto the tip or connecting it as an extension of the tip. This makes the concept versatile and applicable to many different subcutaneous medical devices, i.e., umbilical catheters or endotracheal tubes.

The magnetic tracking system allows localization of the magnetic tip, hence the subcutaneous device, in the five dimensions, namely the x, y coordinates and the orientation angle θ around the z axis, the inclination angle φ and the depth z, as shown in Figure 1b. The magnetic field source is magnetized along the y-direction, generating a magnetic dipole field, which is detected with the sensing device at the dermal surface. The sensing device utilizes a magnetic field sensor that is sensitive to fields along the z-direction. The z-direction field at the dermal surface corresponding to the x-y plane has a pattern as shown in Figure 1b, with two distinct peaks. These maximum and minimum field values can be related to the location of the front and tail ends of the magnetic tip. In most practical situations, finding the maximum peak, which indicates the tip of the subcutaneous device, will be sufficient for verifying the placement. The vector connecting these two points represents the orientation θ of the catheter tip. The midpoint along this vector between the two points represents the location of the catheter tip’s center. The magnetic tip used in this work is an axially magnetized hollow cylinder. From the magnetic dipole model, the magnetic field H (bold letters indicate vector quantities) can be described as

$$H(r) = \frac{1}{4\pi} \left( \frac{3r(m \cdot r)}{|r|^3} - \frac{m}{|r|^2} \right)$$

Here, r is the coordinate, where the field is measured and m is the magnetic moment. Due to the nonmagnetic measurement environment, the magnetic induction B is given by

$$B(r) = \mu_0 H(r)$$

where $\mu_0$ is the magnetic permeability in vacuum. With the sensing device, the magnetic field in the z-direction, $B_z$, is measured and its maximum and minimum values are located at the coordinates in the x-y plane, namely $B_{Z_{\text{max}}}(x_{\text{max}}, y_{\text{max}})$ and $B_{Z_{\text{min}}}(x_{\text{min}}, y_{\text{min}})$. These two coordinates are at the respective
edges of the magnetic tip, when measured at a distance of \( z = 0 \). As \( z \) increases, the field strength decays at \( 1/r^3 \), and the location of \( B_{x} \) and \( B_{y} \) propagates along the \( y \)-axis to \( B_{x} \) and \( B_{y} \), respectively (as shown experimentally in Figure 6b). Here, the propagation \( y(z) \) is a function of the measurement distance \( z \). However, the center of the magnet is given by the midpoint between \( B_{x} \) and \( B_{y} \), namely

\[
M(x, y) = \left( \frac{x_{\text{max}} + x_{\text{min}}}{2}, \frac{y_{\text{max}} + y_{\text{min}}}{2} \right)
\]

(4)

regardless of the measurement distance \( z \) (depth). The edge of the magnet can be found by adding half the length of the magnet \( L/2 \) to \( M(x, y) \) along the orientational vector \( V \), given as

\[
V = \langle x_{\text{max}} - x_{\text{min}}, y_{\text{max}} - y_{\text{min}} \rangle
\]

(5)

The inclination of the magnetic tip in the \( xz \)-plane is determined by comparing the magnitudes \( B_{x} \) and \( B_{z} \). As the inclination \( \phi \) increases, the magnetic field intensity at the front end will increase compared to the tail end. To correlate the measured field intensities to the angles of inclination, the difference between and the average of the peak values are calculated as

\[
\Delta = \left| B_{x} \right| - \left| B_{z} \right|
\]

(6)

and

\[
\bar{\Delta} = \frac{\left| B_{x} \right| + \left| B_{z} \right|}{2}
\]

(7)

Subsequently, the ratio \( n \) can be calculated as

\[
n = \frac{\Delta}{\bar{\Delta}}
\]

(8)

which increases with an increase in inclination angle. This allows the approximation of the angle of inclination across a specified range \([A_1, A_2]\) using a regression model of the form

\[
\phi(x_1, x_2) = p_1 n^2 + p_2 n + p_3
\]

(9)

which is established experimentally for each catheter tip size and composition. Here, the coefficients \( p_1 - p_3 \) are unique to each catheter tip size and composition and are established during calibration after fabrication. This allows the determination of inclination, without knowing the depth of the catheter. It is important to note, however, that the calculated inclination is an absolute angle between the measurement plane and the inclination of the magnetic tip into the measurement plane. After the inclination has been calculated, the depth of the catheter tip can be determined using a depth classification function.
The classification function is specific to each inclination angle interval (every $5^\circ$ of inclination) and correlates the measured $A$ to the estimated catheter depth, $d_A(\phi)$. Classification functions, of the form

$$ d_A(\phi) = f e^{gA} + k e^{lA} $$

are established for each catheter tip size and composition after fabrication with unique coefficients $f$, $g$, $k$, and $l$. By measuring only the two peak values $B_{Z_{max}}$ and $B_{Z_{min}}$ associated with the front and tail ends of the magnetic tip, the position and orientation of the subcutaneous device in the coronal plane ($x$-$y$ plane) can be found together with its depth below the dermal surface and its inclination angle.

### 2.2. Magnetic Tip Fabrication

While placing a subcutaneous device and especially a catheter, physicians actuate (push and rotate) it and expect movement on the distal end based on the specific device characteristics (weight, stiffness, rigidity, thickness, length). For this reason, the dynamic characteristics of the catheter movement should not be affected by the addition of a magnetic tip to the catheter. Therefore, we implemented the magnetic tip as a lightweight and thin walled permanent magnet attached to the distal end of the catheter. The method of fabrication is versatile, thereby allowing for a bulk cylindrical rod as well as a thin walled cylinder. Figure 2 shows the fabrication process for the catheter tip as a cylindrical sleeve or ring magnet, which is axially magnetized. The tip is made lightweight and flexible by combining polydimethylsiloxane (PDMS) and Neodymium-Iron-Boron (NdFeB) micropowder, as shown in Figure 2a. This material can be molded into any shape and can sustain a high remanence field, when magnetized. The PDMS (Sylgard 184) is mixed at a 1:10 hardener to silicone ratio and the magnetic micropowder is incorporated. Then, the mixture is vacuum desiccated for 10 min and then shaken at 60 Hz for 2 min to remove trapped air, as shown in Figure 2b,c. In order to rely on a scalable fabrication process, the catheter tips are molded using a larger diameter hollow cylinder, and a smaller diameter (same as the outer diameter of the subcutaneous device) cylindrical rod. The mixture is poured into the larger diameter cylinder and, using the smaller diameter rod as a plunger, pressed into the final shape, as shown in Figure 2d–f. The composite material is cured in the mold for 120 min at $60^\circ$C. After curing the composite is removed from the mold and axially magnetized for 1 min in a 1.8 T homogeneous magnetic field (using the primary coils of a Vibrating Sample Magnetometer, PMC Micromag Model 3900 VSM), as shown in Figure 2g,h, respectively. The composite is then cut into sections—the magnetic tips. After fabrication, the magnetic tip is attached to the front of a device or catheter, as

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**Figure 2.** The fabrication process of the magnetic sleeves. a) The PDMS and NdFeB powder are mixed and b) vacuum desiccated and c) shaken to remove trapped air from the mixture. d) The composite mixture is poured into the larger diameter cylinder and e) using the smaller diameter rod as a plunger, f) pressed into the final shape. The composite material is cured, where after g) it is removed from the mold. h) It is then axially magnetized and i) cut into sections. j) The magnetic catheter tip attaches to the distal end of the catheter.
shown in Figure 2j, by sliding it over the catheter or adhering it using a contact adhesive.

2.3. Handheld Sensing Device

The handheld sensing device is used to scan the dermal surface in order to detect the position of the magnetic tip. Multiple sensors and sensor technologies such as MR (Magnetoresistive), GMR (Giant Magnetoresistive), and TMR (Tunnel Magnetoresistive) sensors were considered for their inherently high sensitivity and small size. However, the BM1422 12-bit digital magneto-impedance sensor (Rohm) was chosen due to a 42 nT resolution across a 1200 uT measurement range and digital functionality, which allows for 5 ms sampling times on a I2C line with 0.15 mA operating current. The device is battery-operated and the BM1422 sensor is integrated at the tip of the device, which is made from biocompatible synthetic polymer nylon. A second BM1422 sensor is located inside of the sensing device on the opposite end. Using both sensors, a differential measurement is made to compensate for the Earth’s magnetic field in the relevant sensing direction, namely the z-direction.

The sensing device also includes an Arduino Nano microcontroller for processing and transmitting the measured data to a mobile readout device, as shown in Figure S2 of the Supporting Information. These data are visualized as a real time data feed and the maximum and minimum measured values for a session are recorded. Subsequently, the localizing formulae indicated in Equations (6)–(10) are computed.

3. Characterization

3.1. Magnetic Properties

The distribution of the magnetic powder inside of the polymer is shown in Figure 3a. The magnetic properties of the magnetic tip material can be tailored via the weight ratio of powder to elastomer. As shown in Figure 3b, an increase in saturation and remanence fields with increasing amounts of NdFeB powder to elastomer ratio can be achieved, spanning from a remanence value of 50–360 mT by increasing the weight ratio from 1:0.5 to 1:5 PDMS: NdFeB.

3.2. Elastic Properties

Figure 4a shows the stress–strain curves for different NdFeB powder to elastomer ratios, which indicates that the elastic properties of the magnetic tip material can be tailored via the weight ratio of powder to elastomer. The material possesses Young’s moduli ranging from 2.53 to 8.25 MPa. If required, even softer material properties can be achieved, when the composite is molded using a mixture of PDMS, NdFeB, and Ecoflex.
(Ecoflex 00-10, Smooth-On). In this case, the Young’s Modulus can be as low as 0.13 MPa, as shown in Figure 4b. The Young’s moduli of UV and UA are 2.67 and 9.98 MPa, respectively,[34] which is where the catheter is placed during umbilical catheterization. Ideally, the catheter would have sufficient stiffness to allow robust function and operation, while being soft enough to void the risk of puncturing or pinching the UV or UA lumen.

3.3. Cytotoxicity

3.3.1. Cell Culture

HCT 116 (ATCC CCL247) cells were cultured in McCoy’s medium 5A 1x with l-glutamine with 10% fetal bovine serum and 1% penicillin-streptomycin. To detach and count the cells, trypsin and trypan blue were used, respectively. The cells were grown inside of a 37 °C, humidified incubator with 5% CO2. All of the supplements and the media were bought from Gibco. For the cell viability assays, the skins were placed in 48-well plate (for flow cytometry) or 6-well plate (for confocal microscopy) and washed three times with ethanol followed by three times with 0.01 M PBS. After that, the surface was coated with Fibronectin bovine plasma (10 µg mL⁻¹) (for confocal samples only) for 1 h to enhance the attachment of the cells. Finally, the cells were seeded on top of the skins for 3 days.

3.3.2. Cell Viability

To study the cytotoxicity of the magnetic tips, the LIVE/DEAD Viability/Cytotoxicity Kit (Molecular Probes; Eugene Oregon USA) was used and investigated by confocal microscopy and flow cytometry. Based on the company’s protocol for confocal staining, the cells were stained using a 2 × 10⁻⁶ M calcein AM and 4 × 10⁻⁶ M ethidium homodimer-1 (EthD-1) in PBS for 45 min at room temperature. Then, they were washed with 0.01 M PBS and analyzed by confocal microscopy. In order to quantify the live and dead cells, flow cytometry was used. Based on the company’s protocol, the cells were stained using a 50 × 10⁻⁶ M calcein AM and 4 × 10⁻⁶ M EthD-1 in PBS for 15 min at room temperature. To analyze the data by confocal and flow cytometry, green fluorescence for calcein (488 nm excitation, i.e., 530/30 bandpass) and red fluorescence for ethidium homodimer-1 (610/20 bandpass).

3.3.3. Cell Morphology Using Scanning Electron Microscopy (SEM)

After 3 days of incubating HCT116 cells on different magnetic composites, the cells were washed with 0.01 M PBS and then fixed in 2.5% glutaraldehyde in 0.1 M PBS 4 °C overnight. After fixation, cells were washed with 0.1 M PBS buffer three times for 15 min per wash. The cells were then postfixed in 1% osmium tetroxide in 0.1 M PBS for 1 h in the dark, after which they were washed with deionized water three times for 15 min per wash. This was followed by a serial dehydration using ethanol at 10%, 30%, 50%, 70%, 90%, and 100% for 5 min each. For drying, the sample was left in a 1:2 solution of Hexamethyldisilazane:100% ethanol for 20 min, a 2:1 solution of Hexamethyldisilazane:100% ethanol for 20 min, and 100% Hexamethyldisilazane for 20 min. Then, it was kept open in fresh 100% Hexamethyldisilazane inside the fume hood overnight. The next day, the sample was coated with 5 nm of platinum–palladium before SEM imaging.

3.3.4. Results

The cytotoxicity of different magnetic tips was assessed using a live/dead fluorescence staining method that uses calcein for live cells and ethidium homodimer-1 (EthD-1) for dead cells. The confocal images (Figure 5b–e) confirm the cytotoxicity of the different skin materials with a strong green signal (live cells) and rare red signals (dead cells). The cell viability of the skins was analyzed by quantifying the calcein and EthD-1 signals using flow cytometry (Figure 5k). The results of all the skins are similar, and a viability above 90% is maintained, when cultured for up to 3 days. No significant differences between the skins and the control were observed. Besides, SEM images (Figure 5g–j) confirm the ability of the cell to grow in an adherent way with similar morphology to the control cells (Figure 5f).

4. Experimental Section

The performance of the magnetic tracking system was assessed using an in-house made magnetic field scanner using a BM1422 3-Axis magneto-impedance (BM1422AGV, Rohm) sensor, as described in Figure S1 (Supporting Information). The maximum required depth for the magnetic sleeve is 40 mm. To void the risk of puncturing or pinching the umbilical vein or umbilical artery, the material must be softer than the typical puncture material (E = 8.7 MPa). Therefore, a PDMS: NdFeB ratio of 1:3 (around 75 wt%) with E = 5.51 MPa and Eₘ = 200 mT was chosen. Given that a 5 Fr (OD = 1.67 mm) is used, simulations (Magpylib, Python) were performed to determine the magnetic volume required for detection at 40 mm using the BM1422 sensor and subsequently determine the required length of the magnetic sleeve. Simulation results indicated that a sleeve length between 8 and 11 mm would allow detection while maintaining a sufficient signal to noise ratio. Thus, a magnetic sleeve length of 10 mm was chosen. The 10 mm bulk catheter tip (diameter 1.67 mm) with 73%wt NdFeB is placed on the sample area, as shown in Figure 6a along with the characteristic magnetic field measured in the z-direction. Here the magnetic field profiles are measured for a sample area of 50 × 50 mm² with 0.5 mm step increments. The magnetic field profiles for the depth range 15–23 mm are shown in Figure 6b. Here the inclination angle is 0°, which is controlled by a servo motor attached to the sample bed. The position of the peaks propagates outward from the tip along the length of the catheter tip with increasing distance of measurement, as shown by Figure 6b,c. By determining the midpoint M and the orientational vector $\mathbf{V}$, the midpoint position of the magnetic tip can be found. The midpoint position M along the orientational vector $\mathbf{V}$ measured from distances 12 to 40 mm showed a
The BM1422 sensor that is used has a 42 nT resolution with a standard deviation in measurement of 116 nT about the mean, which translates to 0.75 mm placement error at 40 mm range (less for $z < 40$ mm). Due to the positional error the measured orientation angle of the catheter tip increases from 0° to 3.7° over the measured range, while the actual orientation remained the same. When an angle of inclination is introduced, the magnetic field value at the leading end of the catheter tip (the end pointing toward the sensor) increases, as shown in Figure 6d for 40° of inclination across multiple distances. The ratio $n$ from a training dataset was used to establish the regression model shown in Figure 6e. A dataset refers to a layer-by-layer field measurement made by the magnetic scanner for a given range of depth ($z$) and inclination ($\phi$). The accuracy of the model was evaluated using a test dataset acquired for the same magnetic tip for depths 12–40 mm and inclination angles 0°–40°, as shown in Figure 6f. The largest inclination mean error was $X = 1.15°$, with the largest single error of 4.12° at 20° inclination and 40 mm depth. This is due to the reduced signal-to-noise ratio at increased distances. Depth classification functions of the form shown in Equation (9) calculate the placement depth using the average magnetic field value $\overline{Z}$, and are unique to each inclination angle interval. An inclination angle interval of 5° was used for this dataset, as shown in Figure 6g. Figure 6h shows the depth estimation errors for the test dataset across the depth and inclination range. The largest estimated depth error was 0.96 mm. The depth range included in this model is 12–40 mm. This is because the sensor that was used saturated at high inclination angles for $z < 12$ mm. At depths $z > 40$ mm the smaller signal to noise ratio reduces the repeatability of the measurements.

5. Validation In Vivo

The performance of the subcutaneous magnetic tracking system was evaluated in vivo in a pig using a 5Fr UC, as shown in Figure S2 of the Supporting Information. The magnetic tip is magnetized so that a positive peak is measured at the front end of the device’s tips, and a negative peak is measured at the tail ends. To localize the magnetic tip subdermal, the handheld sensing device and readout device (Section 2.3) are used. The UC placement test was conducted in the animal laboratory at the Faculty of Health Sciences, Stellenbosch University in South Africa in accordance with South African National Standards 10 386. Ethical approval was sought as per the institutional guidelines under protocol number ACU-2019-10728. A C-Arm (Ziehm 8000, Ziehm Imaging) X-ray system was recruited. During the experiment, a large white pig (25 kg) was sedated, intubated, and ventilated under general pain free anesthesia.
Figure 6. a) The magnetic tip (diameter 1.67 mm and 73%wt NdFeB) is shown as it is positioned on the sampling area, with the characteristic magnetic field profile. b) Magnetic field profiles measured for multiple z-layers showing the location of the maximum and minimum field values. The inset shows the magnetic catheter tip that was used. c) Contour plots showing the positions of the peaks and the estimated orientation of the magnetic tip on the xy-plane at various distances. d) Magnetic field profiles for 40° of inclination measured at various distances. e) Approximation of the angle of inclination using ratio n with a 2nd degree polynomial. f) The correlation between the real and estimated angle of inclination for each angle in the range. g) Classification functions for each interval of inclination angle correlating the average magnetic field measurement ($\overline{A}$) to a placement depth estimation. h) Estimated depth error for all inclination angles in the range for each true depth.
according the Geneva Convention directives. The procedure consisted of 3 steps, namely: i) after surgical exposure, introduction of the UC with the magnetic tip in the right carotid artery from a position opposite the C3 vertebra with the tip located about 10 cm caudally; ii) determining the position of the catheter tip applying the magnetic tracking system; and iii) taking an anteroposterior and lateral (or coronal) X-ray to correlate with the former result. This was repeated for multiple placements, namely 5, 7.5, and 10 cm insertion lengths into the carotid artery. This is the insertion length indicated by the markings on the catheter body. After stabilization, the magnetic sensing device was used to find the maximum and minimum field values on the relevant chest area. They were recorded, and the corresponding dermal positions were marked with a radio-opaque marker. After the experiment, the recorded magnetic data were compared to the X-ray imaging of the catheter tip. The accuracy of the system was evaluated by comparing the experimental and theoretical position and orientation of the catheter tip.

5.2. UC Placement Results

Various catheter placements were made inside the carotid artery of a large white pig, as shown in Figure 7a–d. Due to the orientation of the animal during anaesthesia, the measurement orientation using the sensing device and the line of imaging (angle at which the C-Arm is aligned) is shifted by 25°. Visual assessment of the placement reveals a localization error in position of 5.5, 4.5, and 4 mm for the placements shown in Figure 7b,c,d, respectively. This is the distance between the center point of the subdermal tip and the measured center point M. The position error for all placements need to be corrected for the 25° imaging angle by subtracting tan(25°) × d from the separation seen on the image plane, where d is the subdermal depth of the catheter tip. The true depth and inclination of the placements were not validated with a sagittal plane X-ray during this experiment; however, the depth and inclination are determined by measuring the decay of the magnetic field over distance for this particular magnet and sensor combination at various angles of inclination. Furthermore, due to the required angular correction, the orientation errors cannot be calculated. The placement tests conducted in vivo yielded a maximum positional error of less than 5.5 mm at depths up to 40 mm, after correction for the imaging angle. Across all placements there was an average error in depth and inclination estimation of 1 mm and 5.31°, respectively, with the placement shown in Figure 7c having the largest errors of 2.02 mm and 6.03°. Further validation yielded a maximum orientation error of 3.7°, a maximum inclination error of less than 4.15° across the depth range with inclination ranging 0°–40°, and a maximum depth error of 0.96 mm, when comparing the calculated depth to the real depth (z distance).

5.3. Discussion

The results from the experimental validation suggest a position error of 0.75 mm. This is significantly less than the 3.8 mm mean error measured by Quintela et al.\[35\] for ultrasound placement. Localization during the animal placement tests were achieved using a single magnetic field sensor. The depth range

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**Figure 7.** X-Ray imaging of various umbilical catheter placements in vivo. a) Placement of the 5 Fr UC tip inside the carotid artery. The true position of the peaks and the measured position are shown for the catheter placements b–d). All three placements were into the carotid artery (The white line indicates the displacement from the measured center to the actual center). e) The peak magnetic field values measured for each catheter placement are shown with the measured positional errors. f) Schematic showing the alignment of the imaging and sensing device during the test.
of the sensing device that was developed is 12–40 mm. The use of a sensor with a higher magnetic saturation point or a combination of sensors with different saturation points would allow for localization at depths less than 12 mm, if required. The design of the sensing device, using one sensor in the device tip, requires the user to pan the dermal surface to find the peak positions. This manual movement introduces the possibility of user error since it is up to the user to visually identify the peak values from the readout device. A software redundancy records the peak values if they are measured, which reduces the likelihood that the peak is missed by the user. However, a false peak will result in inaccurate localization results. Since the same sensor was used in Sections 4 and 5, the introduction of user error is considered to be the primary reason for the reduced accuracy in the animal placement tests compared to the prior experimental validation. During the experimental validation, the sensor plane was fixed to the horizontal \( z = 0 \) plane. During the in vivo placements, however, the topography of dermal surface was uneven and in places curved (around the neck area of the cadaver and the chest area for the pig). This meant that the inclination angle yielded by the model was measured relative to the scanning plane. Finally, the ease of use and fast rate at which the magnetic tip could be localized during these experiments indicate the potential and efficacy of the newly developed tracking system. It is important to note that the detection and localization of the magnetic tip takes an average of 15 s, compared to 2–3 min for ultrasound and 22–36 min for radiography.\[35,36\]

6. Conclusion

The use of subcutaneous devices has greatly advanced the field of medicine and surgery, however, localizing these devices internally requires imaging techniques, such as X-ray or ultrasound. There has been increasing concerns of the effects of radiation exposure on neonates in recent years. Low birthweights and high mitotic activity increase the risk of cancer induction due to radiation exposure. Various methods have been proposed to reduce the cumulative exposure on neonates during the neonatal period, of which exposure from radiographs after umbilical catheterization is a large contributor. The system presented here uses a standard catheter enhanced by a magnetic tip made of a flexible composite material that is localized subcutaneously using a sensing device in a fast, highly portable and easy-to-use way. The magnetic composite material used as the detectable tip can be tailored within a wide range of magnetic and mechanical properties as well as shapes. Biotoxicity assays revealed a maintained cell viability above 90%, when cultured for up to 3 days on the composite materials. The developed tracking system utilizes only two magnetic field values to determine the catheter position, orientation, inclination, and depth. Experimental analysis of the tracking system shows a position and orientation error of 0.75 mm and 3.7°, respectively. Further analysis of the model revealed a maximum error in placement depth prediction of 0.96 mm. Placement tests conducted in vivo in a large white pig (using a 5 Fr UC) showed that the subcutaneous magnetic tracking system offers an efficient and facile method for catheter localization. Slightly higher estimation errors in placement position, inclination, and depth were observed. The uneven topography of the neck, where the catheter was inserted, and falsely identified peaks, resulting from user errors, are the main contributors to the difference in accuracy from experimental validation. In case a higher detection accuracy would be required for a specific use case, a simple solution for reducing these errors would be using an array of sensors to find the two magnetic field peaks at the same time and avoid manual markings.

The developed system for subcutaneous device tracking has significant potential and applicability for multiple catheter types and minimally invasive surgeries. So far, we have shown the application and suitability of this system for the localization of an umbilical catheter. It allows localization of the subcutaneous devices without using harmful X-ray or fluoroscopic imaging techniques. It is easy to use and highly efficient, being about 10 and 100 times faster than ultrasound and radiography. Finally, a large potential for impact of this technology is in low-income countries, where urban hospitals are overburdened and do not possess the latest healthcare technologies. This is due to the fact that this system is portable, user friendly and significantly less expensive than an X-ray machine, allowing real-time placement verification of subcutaneous devices without exposing the patient to harmful ionizing radiation.

Supporting Information

Supporting Information is available from the Wiley Online Library or from the author.

Conflict of Interest

The authors declare no conflict of interest.

Data Availability Statement

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

Keywords

clinical application, composite material, magnetic tracking, neonate, umbilical catheter

Received: March 21, 2021
Published online: May 5, 2021
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