35th Annual International Conference of the IEEE EMBS
Osaka, Japan, 3 - 7 July, 2013

An impedance-guided intra arterial catheter

P. Schwartz[1], C. Scheffer[1], *Member IEEE,* P.R. Fourie[2] and A.R. Coetzee[3]

Abstract— **Under certain circumstances, the placement of arterial catheters can be difficult. In these instances, a form of guidance is preferred to avoid repeated insertions of the arterial catheter. Ultrasonic guidance is generally used in these instances, but the equipment required is expensive and cumbersome. This study produced an arterial catheter that is guided by the impedance of biological tissue encountered between the patient's skin and the lumen of the artery, with the aim of producing a cheaper and manageable alternative to ultrasonic guidance. Additionally, this study has inspected the impedance of human tissue in order to determine whether or not a sufficient and discernable difference between the impedance of the different tissue types could be identified and thus be used to guide an arterial catheter based on said impedance differences. The results indicate that the difference between subcutaneous tissue, fat tissue and skeletal muscle tissue are not clear enough to make accurate discrimination between tissue types. However, the study shows a clear difference between the impedance of arterial blood and the aforementioned tissue, allowing for the device to determine when accurate placement has been achieved. From the results obtained in the studies, the discrimination between blood and other intermediary tissue can be made with 99,4% confidence.**

I. INTRODUCTION

The placement of arterial catheters is highly common in the medical world and is usually a simple procedure. There are however instances when the location and placement of arterial catheters are difficult due to the lack of visible landmarks required to place the arterial catheters [1-3]. This can be due to numerous reasons such as obesity, collapsed arteries or low blood pressure. Traditionally, ultrasonic guidance is used in these cases and has proven a 71% [4, 5] increased success rate in first time catheterization. The equipment required for ultrasonic guidance is, however, highly expensive, ranging from $70 000 - $140 000. Additionally, 'Doppler-Smart' needles are used in this method of guidance and these specific needles are more expensive than regular arterial catheters [6].

The design of an arterial catheter which can be guided by the electrical impedance of human tissue was developed to be an easier, more cost efficient alternative to ultrasonic guidance in cases where the accuracy of blind placement is not adequate. Utilizing the difference in electrical impedance of different kinds of human tissue encountered between the skin and the lumen of the artery, as well as software and hardware capable of measuring, analyzing and interpreting these differences in electrical impedance allows for the guidance of an arterial catheter.

The concept developed allows the voltage amplitude and phase shift to be measured using two electrodes placed either on the exterior of the cannula of the arterial catheter or one electrode on the exterior of the cannula and the hypodermic needle functioning as the second electrode (the latter can be seen in Figure 1 below). These two electrodes are connected to a signal generator to excite the impedance and an oscilloscope to measure both the source voltage signal and the voltage signal from the tissue at the two electrodes. The oscilloscope is attached to either a computer or a microprocessor capable of using the data from the oscilloscope to calculate the impedance.

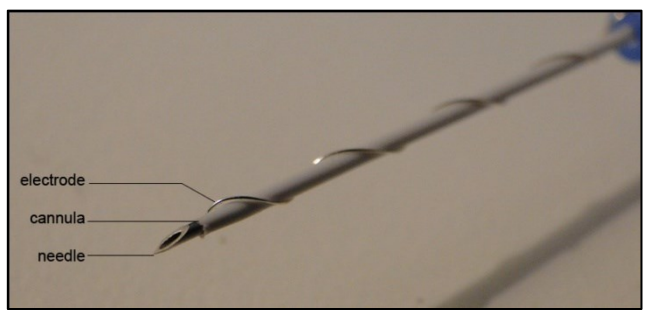

Figure 1: Electrode wound around cannula

II. PRELIMINARY EXPERIMENTATION

A. *In vitro testing*

Early stage tests were conducted on in vitro tissue samples at frequencies between 500 Hz and 100 kHz to validate the reliability of the concept as well as to gather data regarding the impedance of biological tissue. A PC oscilloscope was used and was interfaced with a laptop running MS Excel 2007 which performed the necessary calculations. Two stainless steel needles were used to simulate the electrodes

Manuscript received 17 January, 2013.
Paul Schwartz and Cornie Scheffer are with the Department of Mechanical & Mechanical & Mechatronic Engineering at Stellenbosch University, South Africa (corresponding author: phone: +27218084249; fax: +27218084958; e-mail: cscheffer@ sun.ac.za).
André Coetzee and Pieter Fourie are with the Department of Anaesthesiology and Critical Care, Faculty of Health Sciences, University of Stellenbosch, South Africa.

mentioned in the concept of the design. A hundred measurements were taken per tissue sample per frequency. The tissue samples used were of skeletal muscle, arterial wall (obtained from an aorta) and fat tissue. These samples were obtained on the day of testing and were kept at room temperature for the duration of the experiments. All tissue used in the experiments were porcine tissue. The electrode pair was removed and reinserted into different locations of the tissue in between each test measurement. Figure 2 below illustrates the results of these tests for skeletal muscle, arterial wall and fat tissue. The graph shows a group of three lines per tissue group, one indicating the average impedance magnitude, one indicating the average plus the standard deviation and one indicating the average minus the standard deviation, with the area between the latter two hatched for every tissue type.

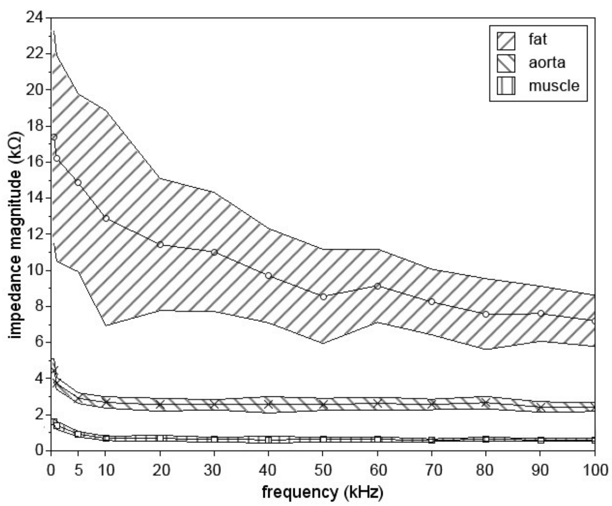

Figure 2: Impedance magnitude of porcine in vitro tissue samples at varying frequencies

The low frequency results obtained from these experiments strongly coincide with the resistivity values for biological tissue in the work done by L.A. Geddes and L.E. Baker [7]. The change in impedance with the change of frequency behaves in the way described by A. Peyman and C. Gabriel [8], proving that the concept works as intended. Additionally, these in vitro tests indicate a difference between the impedance of different tissue types, implying that the concept of catheter guidance by means of tissue impedance is possible.

B. Live animal testing

In order to determine whether living tissue show similar patterns as the results shown in the in vitro experiments, live animal testing was performed on adult porcine subjects. All experiments were approved by the ethics board from Stellenbosch University in accordance with international standard for ethical animal testing. The experiments were done with a modified arterial catheter with one silver electrode embedded with a non-toxic resin to the outside of the cannula, as seen in Figure 1. A signal generator (fixed at 30 kHz, 8 V peak-to-peak, centred on 0 V) was used to excite the impedance, a PC oscilloscope was used to measure the voltage amplitudes and phase shifts and a PC running MS Excel 2007 was used to analyze the data and calculate the impedance. A fixed minimum resistor was included to limit the maximum current applied to the tissue to 4 mA, which is below pain threshold for electrical current in the human body [9,10].

Experiments were performed on six adult porcine subjects, under general anaesthesia. An incision was made in the thigh, in order to expose the femoral artery, as well as all tissue directly between the artery and the skin. The described modified arterial catheter was inserted into a target tissue type, at which point 100 measurements were taken, after which the arterial catheter was removed, cleaned and inserted into a different tissue type. This was repeated until 100 measurements, per tissue type, were taken.

Figure 3 below illustrates the results obtained from the animal testing, in the form of a frequency distribution of the impedance magnitude for blood, skeletal muscle and fat tissue. Arterial wall tissue was excluded from the test, due to the difficulty of obtaining accurate measurements of the thin arterial walls in vivo.

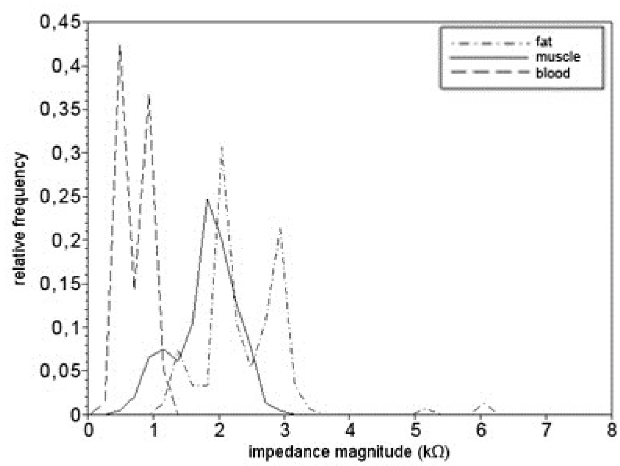

Figure 3: Frequency distribution of impedance magnitude of blood, skeletal muscle and fat tissue

Figure 3 indicates that, in living porcine tissue, the impedance magnitude for skeletal muscle and fat tissue overlap considerably, while there is a substantial divide between blood and the other tissue types.

These results imply that it is possible to determine when catheterization has been successful, based on the lower impedance magnitude of blood relative to the other tissue encountered.

III. CLINICAL TESTS

A. *Experimental setup & procedure*

Clinical testing on the prototype system was performed after approval from the ethics board of Stellenbosch University, in accordance with international standards. All participants gave informed consent. The prototype used for clinical tests replaced the signal generator, PC oscilloscope and PC, in order to reduce the size of the setup. A microprocessor (Arduino Mega2560) was used for the A-D sampling, calculations and processing of data, while an IC (ICL8038) was used to generate a sine wave at 30 kHz to excite the impedance. Measured values are saved on an EEPROM on the Arduino Mega2560 and can be retrieved using the USB output of the device. A control panel is included, to allow for recording, reading and erasing of the data, as well as including an LED to indicate the progress of the different functions. The output voltage is set to 5 V peak-to-peak, centred around 0V and, along with voltage regulators, maintain the maximum current below 2,5 mA. Figure 4 illustrates a diagram of the electronics in the final prototype.

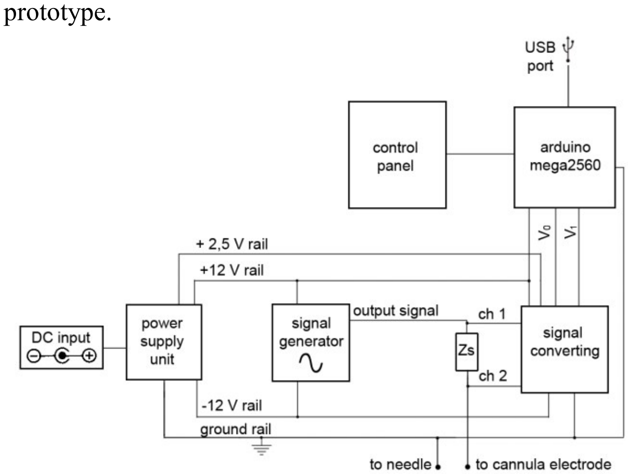

Figure 4: Schematic of electronics used in final prototype

The arterial catheter used in the clinical tests is modified with an insulated silver electrode which is passed through the lumen of the needle and looped back between the needle and the inside of the cannula. The insulation is removed from the outward-facing exposed region of the silver electrode, allowing it to be conductive at the tip of the needle without short circuiting with the needle. The needle is used as the second electrode in this prototype. These modifications were done in order to reduce the extreme diameter of the modified cannula, as it would not have otherwise been accepted for clinical trials, unless the electrodes were embedded into the cannula during its manufacturing, in order to not add to the diameter of the cannula. A picture of this modified arterial catheter can be seen in Figure 5 below.

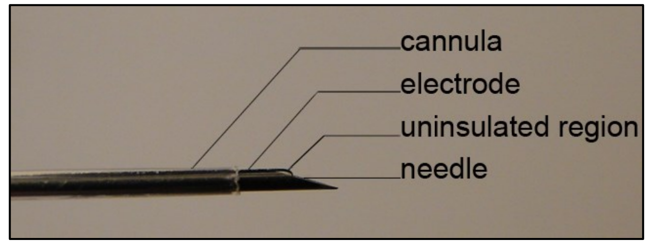

Figure 5: Modified arterial catheter for clinical trials

During the clinical tests, patients were put under general anaesthesia prior to the insertion of the modified arterial catheter. The moment insertion commenced, the device was set to record the impedance measurements for the following 12 seconds. During this time, the relative time of the pulsatile blood return was noted, in order to compare the point of successful catheterization with the measured results. Once the placement was completed, the needle, along with the electrode, was removed and disposed of and the results were transferred to a PC.

B. *Results*

The results obtained from each of the tests produced a graph with the impedance magnitude over time. On each of these graphs, the time of the pulsatile blood return was noted and compared with the results obtained. Additionally, the type of insertion used by the medical practitioner inserting the device was taken into account with the results as the different insertion methods would cause different results.

Figure 6 shows the results from one of the subjects and illustrates a case where the arterial catheter is inserted into and then through the artery, after which the needle is withdrawn and the cannula is pulled back and into the artery. Measurements seized after the needle was withdrawn into the cannula.

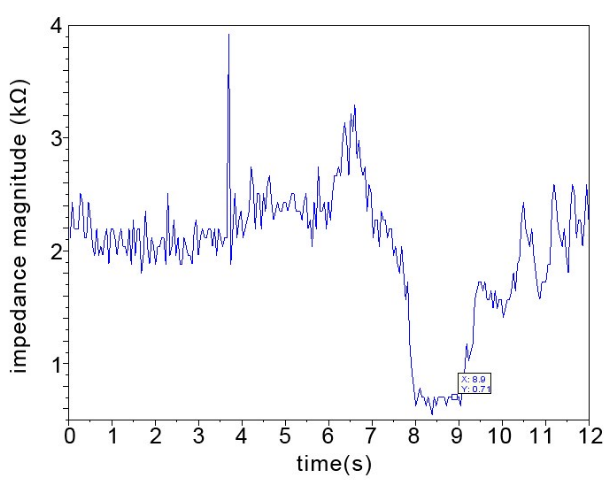

Figure 6: Impedance magnitude over time

From the above figure, it can be seen that there is a clear drop in impedance magnitude at roughly 8 seconds which then rises after 9 seconds again. Furthermore, the label at roughly 9 seconds indicates the moment at which a pulsatile blood return was observed, proving that it was right before 9 seconds that the arterial catheter entered the lumen of the artery. This thus coincides with the low-level impedance illustrated in Figure 6. This behaviour was observed in every subject that was successfully tested on (a total number of seven successful tests were performed out of ten tests, in which external complications arose in the other three tests).

From the results obtained, it could be seen that there is a high level impedance array (referred to as $|\boldsymbol{Z}|_{\mathrm{H}}$) and a low level impedance array (referred to as $|\boldsymbol{Z}|_{\mathrm{L}}$) in each of the resulting data sets, with $|\boldsymbol{Z}|_{\mathrm{L}}$ representing the arterial blood and $|\boldsymbol{Z}|_{\mathrm{H}}$ representing the intermediary tissue between the lumen and the skin. For the impedance guided intra arterial catheter to work, it needs to be able to differentiate between $|\boldsymbol{Z}|_{\mathrm{H}}$ and $|\boldsymbol{Z}|_{\mathrm{L}}$ and thus a theoretical threshold value between these two groups (referred to as $|Z|_{\mathrm{T}}$) must exist. This value is found by analyzing each data set with the following equation:

$$\min_{|Z|_{\mathrm{T}} \in \mathrm{R}} (\mathrm{P}[(|\mathrm{Z}|_{\mathrm{T}} > |\boldsymbol{Z}|_{\mathrm{H}}) \cap (|\mathrm{Z}|_{\mathrm{T}} < |\boldsymbol{Z}|_{\mathrm{L}})])$$

This equation produces the value of $|Z|_{\mathrm{T}}$ which has the lowest probability of going over a value in $|\boldsymbol{Z}|_{\mathrm{H}}$ and going under a value in $|\boldsymbol{Z}|_{\mathrm{L}}$ and thus gives the ideal value for $|Z|_{\mathrm{T}}$ to be used to differentiate between the two impedance magnitude groups. This analysis was done on the results obtained to calculate the probability described in the above equation, for values of $|Z|_{\mathrm{T}}$ between 0,6 and 1,9 kΩ. The probabilities at each value of $|Z|_{\mathrm{T}}$ for the different subjects were averaged. From this analysis, the lowest probability found was for values of $|Z|_{\mathrm{T}}$ between 1,2 and 1,3 kΩ. At these values, the probability of $|Z|_{\mathrm{T}}$ being over a value in $|\boldsymbol{Z}|_{\mathrm{H}}$ and being under a value in $|\boldsymbol{Z}|_{\mathrm{L}}$ (and thus the probability of an error) is 0,006.

IV. DISCUSSION

From the results obtained, it is clear that there is a discernable difference in the electrical impedance of arterial blood and intermediary tissue between the lumen of the artery and the skin. The results obtained are verified to be representative, due to the pulsatile blood return observed, indicating that the low impedance measurements are blood measurements and the high impedance measurements are intermediary tissue. This is reinforced by the values of these measurements being similar to those obtained during the live animal testing phase.

From the probability analysis, it can be seen that the division between high level impedance values and low level impedance values can be made using the calculated value of $|Z|_{\mathrm{T}}$ with an accuracy of 99,4%.

V. CONCLUSION

The results obtained from the different experimental phases of this study clearly indicate that it is possible to perform guided catheterization of the arteries using the impedance of tissue in the human body. The final stages required, before this concept can be turned into a marketable product, are to minimize the electronics, possibly into an attachable handheld device with appropriate feedback, the professional manufacturing of cannulas which include the imbedded electrodes and further clinical trials in order to obtain FDA approval for the device.

ACKNOWLEDGEMENTS

The authors would like to thank Innovus for the financial support in this project, as well as the staff at the Anaesthesiology & Critical Care Department of Tygerberg Hospital, South Africa.

REFERENCES

[1] Ramakrishnan, N., Clermont, G., 1999, Placement and management of arterial catheters

[2] Sechrist, K.R., 1993, Arterial catheter complications and management problems

[3] Lai, S.Y., 2011, Sutures and needles

[4] Lefrant, J.Y., *et al.*, 1998, Pulsed doppler ultrasonography guidance for catheterization of the subclavian vein: a randomized study

[5] Shiloh, A.L., Savel, R.H., Paulin, L.M., Eisen, L.A., 2011, Ultrasound-guided catheterization of the radial artery: a systematic review and meta-analysis of randomized controlled trials.

[6] Rothschild, J.M., Ultrasound Guidance of central vein catheterization,

[7] Geddes, L.A., Baker, L.E., 1967, The specific resistance of biological material - A compendium of data for the biomedical engineer and physiologist

[8] Peyman, A., Gabriel, C., 2005, Dielectric properties of tissues, WHO Workshop on Dosimetry of RF Fields

[9] Joseph C.J., Safety for electronic hobbyists. Popular Electronics. October 1997

[10] Zitzewitz, P.W., Robert N.F., 1995, Merrill Physics, principles and problems.