Avoiding

Epidural anesthesia is a commonly used technique to anaesthetize lower regions of the body. However, the anaesthetizing procedure is risky. To obtain a better insight, a research project was conducted within the Department of Biomedical Engineering of Delft University of Technology, which specifically addressed the design of an epidural needle insertion simulator, psychophysical experiments and clinical results. This article highlights the design considerations of the simulator as well as the experimental results.

• *Luke van Adrichem* •

Besides being used as an anaesthetizing technique during operational procedures within the lower body, epidural anesthesia is also used as a welcome pain relieving mechanism for women who give birth and chronically ill patients. Although numerous applications exist, the anaesthetizing procedure is risky, because delicate tissue is approached with the epidural needle that is used in the process; see Figure 1. Furthermore, the consequence of a failed epidural needle insertion can be severe, such as prolonged headaches and even paralysis. Simplifying the epidural procedure is considered necessary, due to the fact that the demanding technique is difficult to learn and error prone. To obtain better insights into the delicate procedure and reduce the number of failed insertions, intriguing questions need to be answered. Is it possible to identify the procedure in quantifiable parameters to thereafter find improvements of the technique and subsequently increase safety and ease of application?

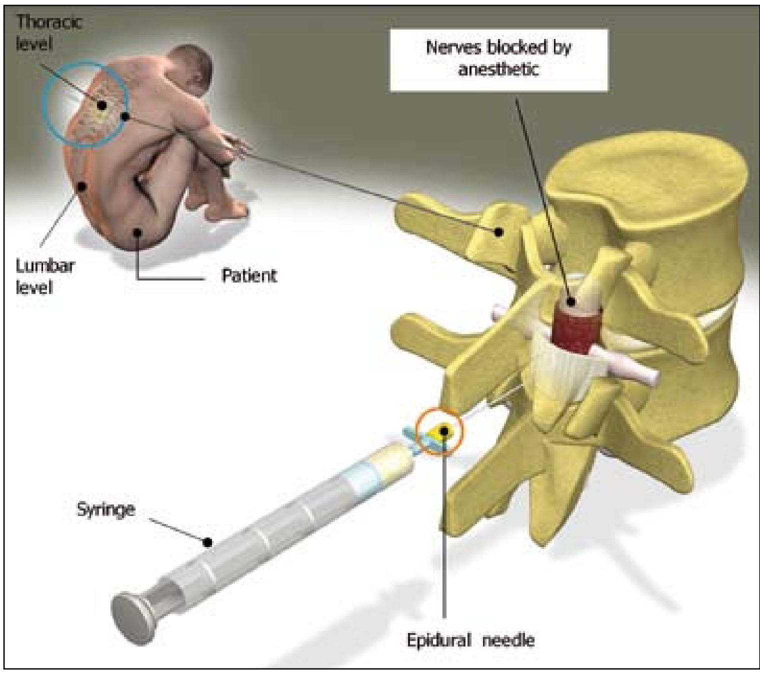

Figure 1. Human spinal anatomy with an epidural needle approaching the epidural space. (Source: Verdult, Kennis in Beeld)

Introduction

Successful epidural needle insertion is a complex procedure requiring penetration of several spinal tissue layers. What makes the task even more daunting is the fact overshoot

that the needle insertion needs to be stopped as soon as the needle tip reaches the space around the spinal cord, also known as epidural space. The distance the needle tip goes into the epidural space is often indicated as 'overshoot'.

The distance from skin to the epidural space in the lumbar region varies from approximately 10 ± 3 mm for small children to 50 ± 12 mm for adults [1] [2]. The depth of the epidural space (distance from start epidural space to spinal cord) depends on the spinal level. For the lumbar and thoracic region variations from 2 to 8 mm have been found [3].

When the epidural needle enters the epidural space, part of the tissue resistive forces disappear abruptly, resulting in a needle overshoot. A large overshoot might damage delicate underlying structures, such as the spinal cord or other neural tissue. The success rate of the insertion is highly dependent on the strategy of application. Part of the problem however is that it is unknown which strategy will yield the best performance. To identify this, it is necessary to fully understand the insertion technique. Understanding the process fully will make it possible to apply novel techniques, such as haptic technology, to improve the needle insertion method.

The haptic feedback during needle insertion depends on needle parameters (e.g. material friction coefficient, diameter, shape), tissue parameters (stiffness, damping, structure), and human factors such as hand position, insertion velocity, and co-contraction in the wrist. Co-contraction is the way people can make a joint 'stiff' by contracting opposite muscle groups. Influence of these parameters on the success rate of the insertion procedure requires investigation. This was achieved by identifying the effect of the parameters on the overshoot of the penetrating needle. These results could thereafter be used as input for improved man-machine interface design and/or improved training.

Haptic epidural simulator

Repeatability and accuracy of measurement are key factors for a psychophysical experiment. Real punctures on porcine specimen or cadavers have relative high haptic resemblance (fidelity) for needle insertion, but are unfavourable for their poor repeatability and accuracy of measurement. Simulators offer both these characteristics, but in general at the cost of fidelity. A simulator should display a typical resistive force pattern of a needle going through the spinal tissue layers, as shown in Figure 2, [4].

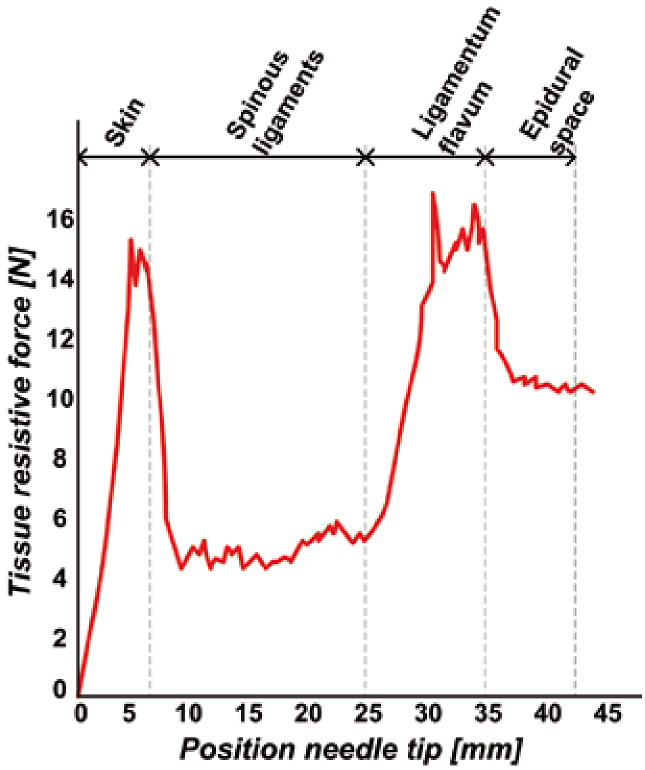

Figure 2: A typical force pattern of a needle penetrating spinal tissue layers as obtained from measurements on porcine specimen. (derived from Brett et al.)

The required accuracy of the resistive force representation is determined by the human haptic abilities. For example, a human is able to perceive only a certain force and position resolution (expressed in Just Noticeable Difference, around 7% in the hands), and force frequency bandwidth – going beyond these thresholds is a waste of effort.

A list of requirements is obtained in order to design a haptic interface with realistic, kinematic, ergonomic and haptic specifications for epidural needle insertion

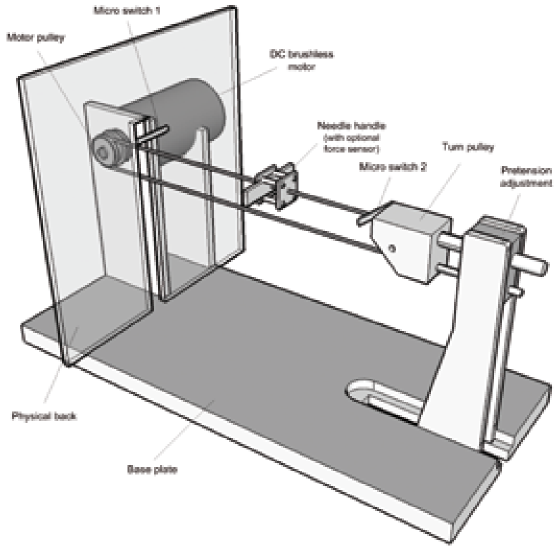

Figure 3. The epidural needle insertion simulator design.

Figure 4. The epidural needle insertion simulator as used for the experiments. (Photo: Manon Eekhout)

experiments; see Table 1. The task is typified as a gradually rising force in one translational degree of freedom, with a sudden force drop resulting in an acceleration (approx. 30 m/s^2). The simulated virtual environment will contain transitions from 'free air' movement towards relatively higher stiffness (approx. 1 N/mm). No hard contacts (e.g. bone contact) have to be simulated. Therefore, the simulator should be optimized more for transmission of high accelerations, rather than for high force or high stiffness. Accordingly, the perceived mass of the needle interface should be in the range of an epidural needle with a fluid filled syringe (approximately 30 grams).
The inherent stiffness of the set-up hardware should be as high as possible in the translational direction. An interface with high stiffness results in a high eigenfrequency, enabling transfer of high-frequency force information.

Table 1. Design requirements.

Requirement	Value	Unit
No. degrees of freedom (DOF)	1	[-]
Range of motion (ROM)	80	[mm]
Force range	0-20	[N]
Stiffness range	0-1,500	[N/m]
Total friction (max)	1	[N]
Perceived mass (max)	50	[g]
Force resolution (min)	0.5	[N]
Position resolution (min)	0.1	[mm]

A realistic needle interface and a physical back for lifelike hand support during needle insertion are qualitative requirements to fulfil. The choice was to make an impedance-controlled system; position-velocity input from the anesthesiologist results in a resistive force output. As a consequence, no force measurements are needed in the control loop, meaning the set-up should be backdriveable and have low friction.

Design

The final design is a simple cable mechanism with two pulleys; see Figures 3 and 4. The brushless dc motor drives one pulley directly without further transmission, avoiding extra friction and play.

The cable is attached to the pulley with soldered steel balls; see Figure 5. By this means the need for high pretension in order to avoid cable slip, is eliminated. The principle of inertial match was used to find the adequate pulley radius for maximal acceleration for the chosen motor.

The implemented Maxon EC40 can withstand a big radial load on the shaft (70 N, 5 mm from the flange), so no extra shaft support (extra bearing, etc.) is needed. A Scancon 2RMHF high resolution encoder (30,000 pulse/rev after quadrature) on the motor shaft is implemented to have high-precision position information and an accurately derived velocity signal. A position accuracy smaller than 0.05 mm was identified.

Figure 5. The motor pulley with the cable attached by means of steel soldered balls.

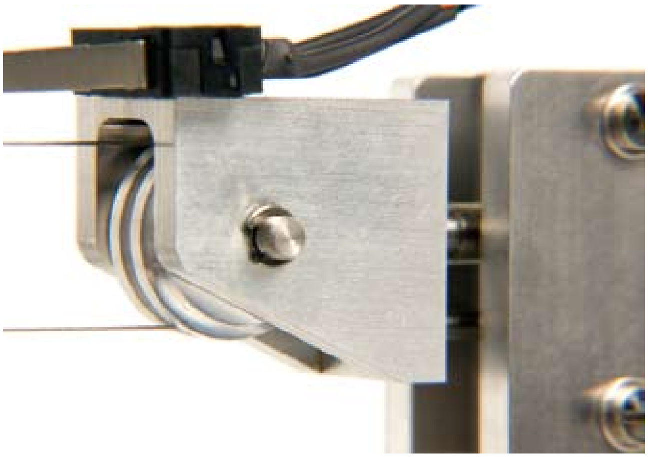

Figure 6: The turn pulley with set screw for application of pretension.

The second pulley is mounted on a slider with a low-pitch set screw for applying pretension (20 N) in the cable; see Figure 6. The two bearings in the second pulley are unshielded and dry (all oil is removed) to minimize friction.

Software

Experiments should ideally be performed under identical conditions. Therefore, secondary computations should not interfere with the controller during the experiments. To this end the simulator works as a stand-alone device in a Matlab® (R2007a) xPC Target (ver.3.2) application. A controller for a virtual haptic environment is modelled in Matlab Simulink and built on the external target pc. A Humusoft MF 624 data acquisition card is built in the external pc. Adaptive windowing is used in the Simulink model for velocity estimation [5]. Adaptive windowing has noise-filtering properties but preserves the velocity transients. The more commonly used filtered derivative for velocity estimation always faces fundamental trade-offs between time lag, phase distortion, attenuation, and cut-off precision. An adaptive window technique selects the window size depending on the signal itself, thereby optimizing for reliability (with high velocity) or precision (with low velocity).

Before conducting the experiments, the system properties were identified according to the guidelines of Hayward et al., and the set-up was calibrated [6]. The Z-width (impedance width) of the virtual environment was determined. The Z-width is a metric indicating the virtual damping and stiffness range a haptic set-up can display in a stable manner [7].

Psychophysics

The experiment was done with the task instruction to perform an optimal epidural needle insertion following a specific strategy as requested, by minimizing the needle overshoot. A group of six anesthesiologists, five residents, and five novices were subjected to these experiments and had to perform multiple needle insertions with nine different strategies. These nine strategies are combinations of three insertion velocities (free, high, low) and three levels of co-contraction (free, high, low). The 'free' velocity or co-contraction implies a speed or co-contraction level assumed by the subject to be optimal for minimal overshoot.

Measurements and results

Position-time data was analyzed and the overshoot determined for all strategy combinations. A typical combined position-time plot for high and low co-contraction is displayed in Figure 7.

From this characteristic the following features can be derived. First, the total overshoot with low co-contraction is significantly bigger than for high co-contraction strategy (average 4.9 ± 0.7 and 1.6 ± 0.6 mm, respectively).
A second observation is the relative short period in which the overshoot develops. The percentage of total overshoot reached after 40 ms is 92 and 82 for high and low co-contraction respectively. The first 40 ms after the moment of entering the epidural space (MEES) is considered as passive; human active response is not expected due to physiological delays. This passivity, of the test subject's muscles or hands can be represented as a simple mass-damper-spring (MBK) model with inherent stiffness and damping. This is partly due to the co-contraction of the wrist. Fitting the MBK on the obtained position data of the first 40 ms after MEES, results in a relation between inherent stiffness and overshoot, as shown in Figure 8. It is clear that an increase of inherent stiffness will reduce the needle overshoot.

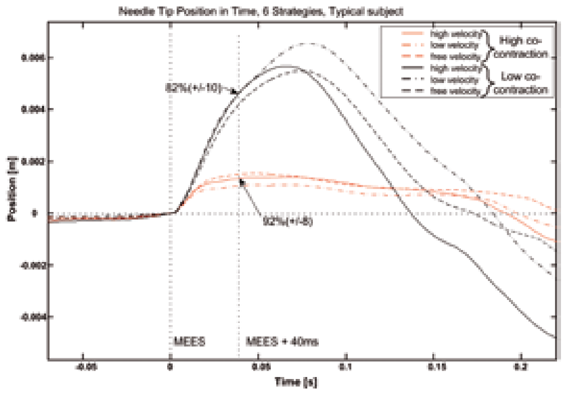

Figure 7. The position of the needle tip penetrating the virtual tissue plotted in time for a typical subject. MEES stands for: moment of entering the epidural space.

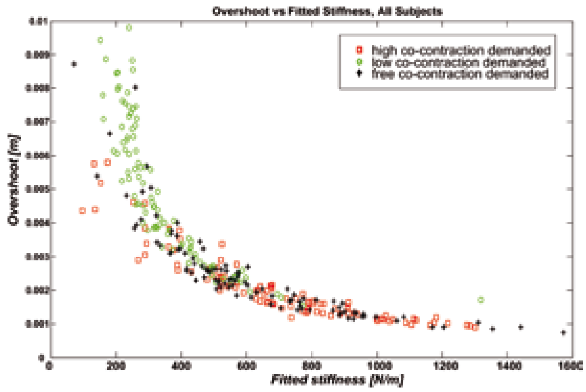

Figure 8. The overshoot as a function of the fitted inherent stiffness. The symbols indicate the co-contraction strategies used.

Conclusions

The performance of an epidural needle insertion is largely determined by the passive response of the human operator as shown in Figure 7. This research showed that increasing the inherent stiffness will result in substantial reduction of overshoot. The increase of impedance can be established by means of higher co-contraction in the wrist. Another way to increase the inherent stiffness is, for instance, the anesthesiologist's hand position/posture on the patient's back. The posture of the fingers determines how the motion can be guided and stopped by restricting the displacement physically. Closely related to the hand posture parameter is the needle length. An anesthesiologist should adjust the length of the needle depending on his estimation on the spinal anatomy out of the patient's physical appearance. An accurate needle length supports correct hand posture.

These findings are currently investigated for their implications on equipment and training, in order to make the epidural needle insertion safer and easier for every patient.
The design process of the epidural needle insertion simulator resulted in a device meeting the requirements as stated in Table 1. The simulator is currently used for further experimentation on other needle parameters and human factors of interest.

Author's note

In April 2008, Luke van Adrichem graduated with honors within the Department of Biomechanical Engineering, Faculty 3mE, Delft University of Technology, the Netherlands. The department's research focus lies in the field of man-machine interface. It participates in the Delft Haptics Laboratory, which explores the role sense of force plays in the man-machine interaction for a number of applications, such as medical, micro-assembly and automotive. This article presents a summary of the author's thesis. The work was conducted within the PhD project of Ruben Lee and was supervised by Prof. Peter Wieringa (Delft University of Technology) and Prof. Dr. André van Zundert (Catharina Hospital, Eindhoven).
Currently, Luke van Adrichem is employed by Temporary Works Design, a small Dutch engineering company that develops installations and structures for the civil and offshore markets. Besides, he is involved in running an agricultural innovation company, TinT.

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Information

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