UNIVERSIDAD AUTÓNOMA DEL ESTADO DE MÉXICO

Facultad de Ingeniería

Criterio para punción mínimamente invasiva

TESIS

Que para obtener el Grado de

Maestro en Ciencias de la Ingeniería

Presenta:

José Angel Alvarez Duarte

Comité de Tutores:

Dr. Juan Carlos Avila Vilchis

Dra. Adriana Vilchis González

Dra. Martha Belem Saldivar Márquez

Toluca, México Enero, 2019

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Minimally invasive puncture criterion

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1 Abstract

The puncture is used for the diagnosis and treatment of different diseases in human body. During needle insertion, several events occur, causing tissue damage during the needle advance into the tissue.

This work focuses on analyzing the needle insertion effects in a single tissue layer. To accomplish this, different forms to characterize tissue damage during the puncture procedure are analyzed. To decrease the damage caused into the tissue, a minimally invasive puncture criterion is established for a single layer needle insertion.

To validate the minimally puncture criterion, a combined mathematical model is presented, which characterizes the needle-tissue dynamics. When performing numerical simulations, the dynamics of the model is analyzed in order to validate the damage criterion. Model simulations verify that a needle insertion velocity increment generates less tissue deformation and rupture force. Taking into account the damage criterion, simulations corroborate that the tissue damage decreases when the needle insertion velocity increases.

Experiments in animal tissue are carried out in order to corroborate the numerical simulations results, due to dynamics of the tissues behavior not included in the model, and confirm the minimally invasive puncture criterion. The animal tissue experiments allow to conclude that puncture the minimally puncture criterion, associated to the surface damage area, is directly proportional to tissue deformation and rupture force and inversely proportional to the respective insertion velocity.

2 Protocol

At present, new less invasive methods are implemented to perform medical procedures such as the percutaneous puncture for cancer treatment or biopsy. Due to several factors as the human tissue elasticity, the complexity of the puncture procedure and the movement of the target inside the human body, surgeons rely heavily on the use of the sense of touch and their experience to perform a successful transcutaneous puncture.

For years, investigations have been conducted to obtain models that characterize the procedure of inserting a needle into the human body [1]-[5], from simple models to those that consider different tissue layers. For this, the forces acting on the needle have to be taken into account, such as friction, cutting and stiffness. Moreover, path tracking methods to determine the insertion angle and the location of needle when tissue deformations occur, represent a current interest in research projects to take actions and correct deviations.

As mentioned above, some medical procedures seek to minimize the invasion on the patient body. Nevertheless and to the best knowledge of the author, an approach for minimally invasive puncture procedures has not been addressed. It will be sought, therefore, to solve the following problem: to establish a criterion in order to minimize the damage that is generated on the tissue during puncture tasks.

2.1. Hypothesis

Minimally invasive puncture can be warranted through a specific criterion related to the kinetic energy of the needle.

2.2. Research objectives

General objective. To establish a puncture criterion that could be considered to minimize patient tissue damage during a transcutaneous puncture process.

2.2.1 Specific objectives

- To review the different methods used to determine needle-tissue interaction.
- To propose a model to represent needle-tissue interaction.
- To characterize damage during puncture procedures.
- To propose a criterion to minimize damage during puncture processes.

- To validate the proposal by numerical simulations and experiments.

2.3. Scope

This research contribute to the realization of any type of puncture using a minimally invasive technique. This research only consider one degree of freedom associated to the insertion of the needle into the tissue; nevertheless, retraction of the needle will not be taken into account. This approach consider a vertical motion that defines a perpendicular orientation with respect to the tissue layer.

It is not considered the deflection of the needle when interacting with tissue or deviations that this can cause. Experiments to define and validate the damage criterion have to be made in artificial and single layer tissues initially, but multiple tissue layers cases could be analyzed.

2.4. Methodology

The methodology that we present allows to develop the research, dividing in stages, which facilitate a better execution.

Literature review. Review bibliographical sources about the topic of needles insertion into tissue, as well as methodologies used to obtain models that describe the interaction between the needle and different tissue layers during a puncture. That will be the basis to develop the necessary theoretical framework in the research, and to provide information on the state of the art and future trends of the subject. The literature review will be carried out continuously until the project ends.

Damage characterization. Will be establish a criterion for assessing the damage caused during the insertion of a needle is necessary to identify some criteria to minimize the damage. These criteria could be validated by the orifice diameter, the rips that the needle leaves on the tissue or by other characteristics. To achieve this, experiments will be developed.

Criteria proposals. Further work will be focused on the evaluation of criteria that minimize the damage caused during a needle insertion. Based on the damage characterization of the experimental results, a criterion will be established.

First experimental tests. To perform the first tests, it will be considered a single tissue layer. Several tissue layers could be taken into account to validate the established criterion.

Mathematical formulation of the selected criterion. A mathematical formulation of the criterion is necessary and could be used with a control strategy to minimize the invasion of puncture procedures.

One layer model selection for puncture. Developing a mathematical model to characterize the interaction between the needle and the tissue is not an objective of this research. Then, already defined models will be analyzed in order to perform numerical simulations for a single tissue layer.

Numerical simulations (phase 1). Conduct simulations of the system under analysis to, possibly, adjust some parameters in order to, iteratively, improve results. For this simulation the model of one single layer that represents the basis to develop the experimental tests will be used.

One layer experiments. Conduct experiments in artificial and in animal tissue limiting them only to needle insertion. During these experiments, it will be performed some adjustments in order to obtain minimum damage. Experimental results will, eventually, validate the damage criterion.

2.5. Theoretical background

Puncture comes from the latin word punctura which means "a pricking", from punctus, latin past participle of pungere "to prick” or “to pierce" [6].

The term puncture is commonly used in medicine to name the practice of inserting a needle or a similar instrument in the human body. Puncture allows extracting liquid from the human body to be analyzed for diagnosis and to determine a treatment according to the condition in question [7].

When this procedure is applied with the help of robots, it would bring benefits to the patient because the damages would be reduced. To accomplish a puncture procedure assisted by robots, it is necessary to develop a model that describes the interaction forces between the needle and the tissues.

$$F(x) = f_s(x) + f_f(x) + f_c(x) \tag{1}$$

where x represents the position of the needle tip with respect to a point (before the insertion), $f_s(x)$, $f_f(x)$ and $f_c(x)$ are the stiffness force, the friction force and the cutting force, respectively.

In order to describe the needle-tissue interaction, equation (1) has been used by many authors where the total force acting on the needle is the result of stiffness, friction and cutting forces.

Barbé et al. [4] report that the Hunt-Crossley model correctly defines the tissue deformation; it assumes the speed of the needle as a constant, and models the stiffness force as $f_s(x) = \mu x^n$; the parameters μ and n are constants depending on the material properties.

The friction force f_f occurs throughout the needle into the tissue and is due to Coulomb friction, adhesion and tissue moisture. Alexandre Carra et al. [3] select the Dahl friction model [8] provided in (2), and got a simplified time domain model, considering the speed always positive, only the phase of insertion of the needle into the tissue is considered.

$$\frac{df_f}{dt} = \frac{df_f}{dx}\frac{dx}{dt} = \sigma(1 - \frac{f_f}{D_p})\dot{x} \qquad (2)$$

In equation (2), σ is the slope of the friction force f_f and D_p is the limit of the friction in the positive direction, when the needle is penetrating.

The cutting force f_c is the force required for the needle tip to penetrate the tissue layer, which according to Alexandre Carra et al. [3] it is modeled by (3),

$$f_c = \begin{Bmatrix} 0, & x \leq d_i, & t < t_p \\ c_{k,} & x > d_i, & t \geq t_p \end{Bmatrix} \qquad (3)$$

where c_k with $k = s, f, m, l$ is a constant depending on the type of the tissue (skin, fat, muscle or liver), t is time and t_p is the insertion time, d_i is the position for the maximum deformation of the tissue surface before puncture.

Obtaining a model represents only the first step to develop a controlled puncture. It is important to highlight that the safety of the patient is a crucial aspect to be considered.

2.5.1. Effects of needle velocity

The insertion speed in puncture processes, depends mostly on the person performing these procedures and of the type of procedure (brachytherapy, epidural, etc.). Some investigations indicate the insertion speed for this procedures.

- Needle insertions velocity for epidurals procedure have been reported between 0.4 mm/s and 10 mm/s [9].
- Insertion velocity for brachytherapy treatment average is 60 mm/s [10].

Toufic Azar et al. [11] analyze a model that takes into account the tissue and the characteristics of the needle based in vivo measurements of needle insertion in pig liver performed by Maurin et al. [12] to estimate the work of fracture during a needle insertion.

In order to observe the cracks in the skin during needle insertion, Toufic Azar et al. [11] performed several insertions with different diameters of the needle in porcine tissue and some results are shown in Figure 1. For crack measuring, it is used a binocular inverted microscope at a magnification X10. From these experiments, authors conclude that a crack is 1.5 times larger than the diameter of the used needle. If the needle has a sharp tip, fissures sizes are approximately equal to the diameter of the needle, but in case of a shorter bevel, the cracks are bigger than the diameter of the needle and a higher insertion force is needed for penetrate the tissue.

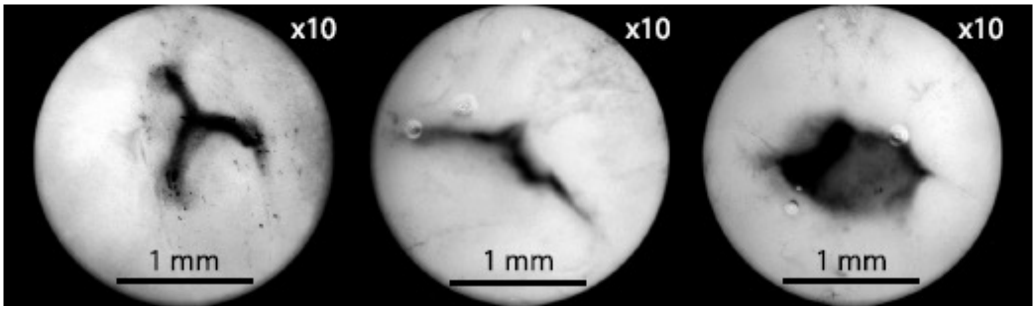


Figure 1: Damage for different needle tip [11].

Mohsen Mahvash et al. [13] analyzed mechanics rupture events, the effect of the speed of the needle in the insertion force, tissue deformation and needle work. Rupture events are modeled as extensions of sharp cracks, produced when the energy is concentrated at the tip of the needle and exceeds the rupture force. With a Kelvin viscoelastic nonlinear model, the authors predicted the relationship between tissue deformation and the rupture force at different speeds. The model predicts that deformation, cracks and work are asymptotically minimized when increasing the speed of the needle.

The saturation velocity v_s, given in (4), is a finite insertion speed that can be used in order to achieve most of the benefit of a greater speed [13].

$$v_s = 5\frac{\delta_r}{\tau_s} \tag{4}$$

In (4), δ_r is the deformation associated to the cracks, due to the speed of insertion and τ_s is the relaxation time that has been determined using a tissue relaxation experiment [13].

Mohsen Mahvash et al. [13] concluded that faster needle insertions can be employed to decrease rupture events and the model developed predicts and calculates a finite-insertion velocity to take advantage of the effects of high-velocity insertions.

The work developed by Mohsen Mahvash et al. [14], corroborates the conclusions provided by the authors of [16]. They consider a biological organ as a viscoelastic body and using a modified nonlinear Kelvin model to calculate the insertion force during an organ puncture. They define the equation (4) as the velocity at which the dynamic force reaches ninety percent of its final value to determinate the tissue deflection [14].

Authors in [14] performed experiments to validate that the force-deflection characteristics of the needle using a modified Kelvin-Voigt model. These experiments were performed on epicardial and myocardial layers and conclude that the deflection, the force and the tool energy in a rupture event were reduced when the needle insertion velocity was increased.

2.6. State of art

When the needle penetrate an animal tissue, the process presents a distinctive pattern which can be divided into two phases. First the needle pushes the tissue constantly increasing the insertion force. During this time the tissue is deformed until it reaches the limit of stress that it can withstand, then the needle pierces the tissue and moves. The advance of the needle into the tissue corresponds to the second stage. This process is repeated when the needle penetrates different tissue layers until it reaches its target.

The force and the deformation necessary to insert a needle into a particular tissue depend mostly of the properties of the tissue, the speed of the needle during insertion and the size and shape of the needle tip [1][15].

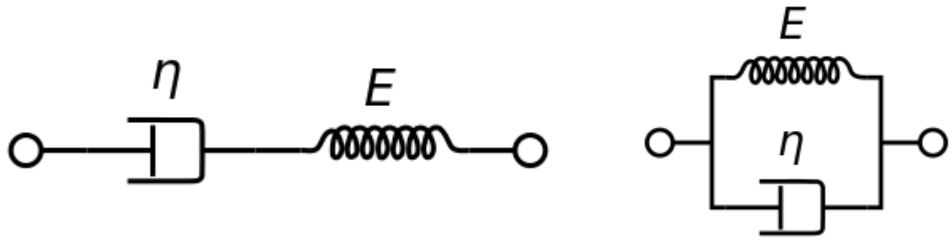
"Human tissue is a viscoelastic material, property that can be used to minimize its deformation. Experimental results indicate that higher needle insertion speeds reduce deformation and insertion force, however, only robots can use high needle insertion speeds safely. Manual insertion requires lower speeds." [16].

To perform puncture while the needle is rotated has been proposed to minimize tissue deformation and deflection of the needle, but experimental results indicate that this technique increases trauma to patients because of the cutting made by the needle tip while the needle is rotating inside the human body [16].

2.6.1. Model for puncture

It is important to understand the interaction between the tissue and the needle to propose control strategies to improve the puncture task using robots. For this it is necessary to obtain a model to characterize this interaction. The deformation of the needle can cause loss of target, besides, the friction must be compensated to maintain a steady insertion.

Maxwell and Kelvin-Voigt models representation, shown in Figure 2, constitute basic descriptions of the viscoelastic properties of the needle-tissue interaction. To characterize this interaction, the first one uses a spring and a damper in a series connected representation where the elements are subject to the same level of stress while the Kelvin-Voigt model uses these same elements interconnected in a parallel form and then they are subject to the same strain. Maxwell model matches in a better way with a viscoelastic fluids behavior than the Kelvin-Voigt model that describes a viscoelastic solid behavior [2].



a) Maxwell model b) Kelvin-Voigt model

Figure 2: Viscoelastic models [2].

Other important work related the obtention of models to characterize the needle-tissue interactions is the equation developed by Okamura et al. [1].

Some works consider the effect of the needle insertion angle, the diameter of the needle and its influence in the deformation and trajectory of the needle to obtain a model [17]-[18]. Alexandre Carra et al. [3] develop a model that represents the force during needle insertion through different tissue layers, shown in Figure 3 (skin, fat and muscle), each of them with specific characteristics.

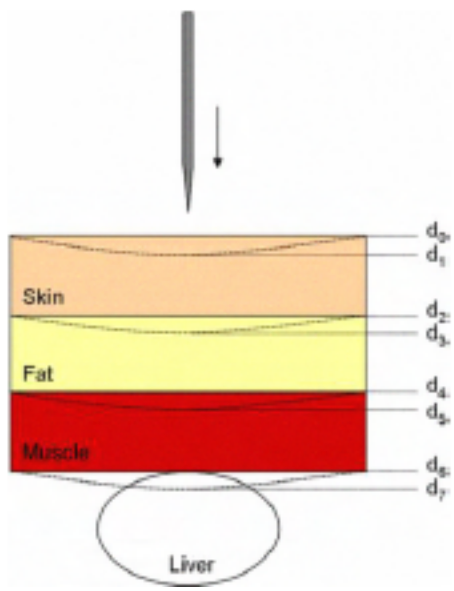


Figure 3: Multilayer tissue [3].

At this moment there are several researches about the interactions that take place between the needle and the tissue during a puncture, but most of them are based or are variations of the rheological models obtained by Fung [19] for living tissues or the equations of the insertion force behavior developed by Okamura et al. [1].

It is noteworthy that tissue properties change from person to person according to age, weight, temperature, etc. Therefore, values that can be obtained from valid models, perhaps are incorrect for a different tissue when are used to validate the model. With the objective to find real values of the mechanical properties for different tissues, some researches have proposed different methods for estimating parameters online; examples of this are Barbé et al. [4] that propose a curve fitting with rheological models and Asadian et al. [5] that propose a Kalman filter to estimate the initial values for the respective parameters.

2.6.2. Trajectory of the needle

When inserting the needle, a deformation occurs in the tissue, the target position could change, so the initial trajectory to reach the target might not be correct and it would be necessary to calculate a new one. To solve this problem, two approaches are used. The first one uses mechanical simulations to calculate a successful trajectory to achieve the target based in a given initial trajectory and the other proposes to change the trajectory of the needle in real time to compensate for the displacement of the target [16].

Examples of mechanical simulation developed in order to obtain a trajectory taking into account the tissue deformation are reported in the works related to the robot for breast cancer treatment developed by Kobayashi et al. [20] and the robot for implanting radioactive seeds in the prostate created by Salcudean et al. [21].

Contrary to trajectories planned in pre-operative phases, flexible needles make use of the deflection to avoid obstacles or sensitive areas. In order to control the direction of the needle, these are rotated on its axis, causing that the force acting on the needle tip changes the needle direction and therefore its trajectory [8].

Although experimental results show the feasibility of using flexible needles for obstacle avoidance and motion compensation of the objectives , most of them are preliminary work done with artificial materials, then it is necessary a validation in living tissue. Furthermore, because the small diameter of these needles (close to 0.05 mm) they have no real application in clinical use yet [16].

As previously explained, mechanical simulations depend on the properties of tissues, a combination of simulations of the needle trajectory tracking, guided by ultrasound image can overcome this problem, but these images are not always clear and the identification of veins, arteries, tissue or needle is not always possible or sometimes is imprecise. Another problem in this context concerns the processing of the image, which must be fast enough to implement an efficient needle trajectory control.

Several medical imaging modalities can be used to control needle insertion trajectories by robots. However, the ultrasound image is the most used, although there are others such as magnetic resonance image (MRI), fluoroscopy or computed tomography (CT). The MRI takes a long time to acquire images with sufficient resolution and cannot be used in real time, also due to the use of strong magnetic fields, strict restrictions on using needles are imposed. Regarding fluoroscopy and CT use low levels of radiation and for safety reasons they must be operated by human beings. Whereby ultrasound image is most often used in medical imaging because of its low cost and high security.

2.6.3. Damage during a puncture task

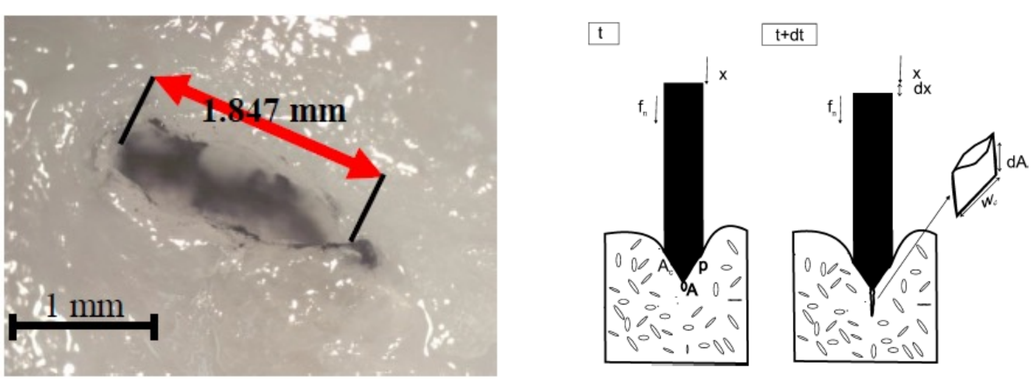
In the literature consulted, different forms to characterize the tissue damage during a puncture procedure have been found. These considerations are based on deformation of the tissue, surface and interior cracks and accumulation of tissue in the needle.

During a puncture procedure, internal and external cracks occur as well as tearing of tissue. All these phenomena are closely related to the events of deformation and rupture in the tissue during the needle advance [11][13][14].

Biological tissues do not have a homogeneous behavior, so insertion of a needle often leads to sudden rupture of tissues or to the growth of unstable cracks, changes in tissue structure affect the energy flow in cracks. The rupture is produced by excessive deformation of the tissue and is followed by the sudden propagation of one or several cracks [14]. During rupture, the energy stored during deformation is suddenly released to the cracks (or micro cracks) in the tissue, Figure 4, and depending on the magnitude of that energy there will be a greater or lesser growth of the cracks.

As a consequence of the viscoelastic properties of biological materials, it is known that faster movements of a sharp tool or needle cause less deformation of the tissue during cutting or penetration, which causes the tissue to store a smaller amount of the energy of the needle to be released in the form of cracks [14].

Toufic Azar et al. [11] also reported changes in tissue deformation and cracks lengths during insertion of a needle when modified the insertion velocity and the diameter of the needle. In [11] concluded that, the increase of the insertion speed diminishes the deformation and the size of the superficial cracks on the tissue and with increasing diameter and changes in the needle bevel, deformation behavior and cracks are affected.



a) Picture of superficial crack [22]. b) Internal Crack Representation [11].

Figure 4. Types of cracks in tissue caused by needle insertion.

2.6.4. Fracture work

Work is the product of a force applied on a body and the displacement of the body in the direction of this force. While work is done on the body, there is a transfer of energy to it, so it can be said that work is energy in movement [23].

Toufic Azar et al. [11] and Barnet [22] define the fracture work δWr as the energy released for the creation of fractures and cracks in the tissue during the insertion of the needle. In (5), $a(d)$ is the length of the crack generated in meters, $J_{ic}(d, v)$ is the mode-I fracture toughness of the tissue in units *J/m2*, d is the outer diameter of the needle in meters, and v is the insertion speed of the needle in m/s.

$$\delta W_r(d, v) = J_{ic}(d, v)\, a(d)\, \delta l \qquad (5)$$

Fracture work was calculated experimentally [11] [22], making two insertions exactly in the same place, measuring the insertion displacement and the needle force. During the first insertion, force values obtained belong to the phases of tissue deformation, surface rupture, tissue rupture during needle advancement and friction between the tissue and the needle. This first force measurement is denoted by the letter *P* and its representation is shown in Figure 5.

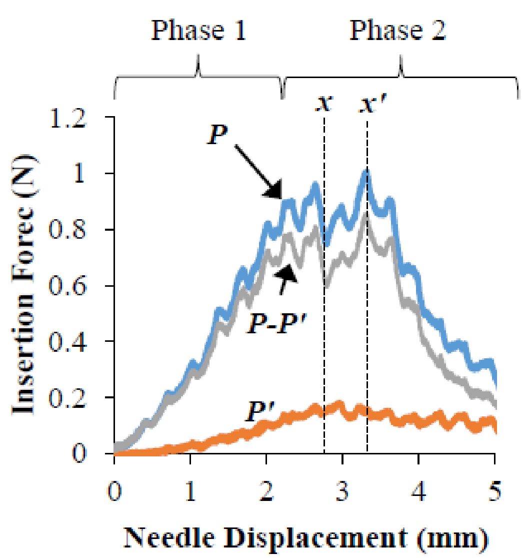


Figure 5: Graph representation of the forces *P* and *P'* [22].

The second insertion is performed in the same position, obtaining the force *P'*, which represents the friction force between the needle and the tissue. All rupture and deformation events occur during the first insertion, where the needle deforms the tissue until the fracture step begins along with the advance of the needle through the tissue [22]. In the experiment, the size of the superficial crack for the first and second insertion is checked using an optical microscope, the depth of insertion must be the same, with what they ensures there are not new rupture events. Toufic Azar et al. [11] and Barnet [22], conclude that the difference between the forces *P'* and *P* shown in Figure 5 constitutes the force used for the creation of fractures and tissue deformation.

The necessary work to create the fractures that allow the advancement of the needle, is the integral of the force difference, *P-P '*, with respect to the depth of insertion.

3 Article

3.1. A minimally invasive puncture criterion

Based on articles 57, 59 and 60 of the REA (Reglamento de Estudios Avanzados) of the UAEM (Universidad Autónoma del Estado de México), this thesis is focused on the **specialized article graduation option**.

The journal that has been selected to submit the article entitled *"A minimally invasive puncture criterion"* is *Transactions on Biomedical Engineering.*

A minimally invasive puncture criterion

José A. Alvarez Duarte[1], Juan Carlos Avila Vilchis[1,2], Adriana H. Vilchis González[1], Belem Saldivar[1,3]

***Abstract*—Several events occur during needle insertion procedures as tissue deformation and rupture. In this paper, the influence of these events is analyzed when a needle is inserted into a tissue sample. In order to reduce the invasion in the tissue or the damage that is produced during puncture, a minimally invasive puncture criterion is established for the first phase (tissue deformation) and the second phases (needle insertion) of the puncture process. A merged mathematical model is presented and used to perform numerical simulations in order to analyze needle-tissue interaction. Experimental results validate the minimally invasive puncture criterion by computing its greatest, smallest and average values under different insertion velocity conditions.**

***Index Terms*—Damage criterion, minimally invasive puncture, puncture damage.**

I. INTRODUCTION

At present, new less invasive methods are implemented to perform medical procedures such as percutaneous puncture for cancer treatment or biopsy. Due to several factors as the human tissue elasticity, the complexity of the puncture procedure and the movement of the target inside the human body, surgeons rely heavily on the use of the sense of touch and their experience to perform a successful transcutaneous puncture.

The lack of precision to reach a target inside a human body generates a potential damage to bone structures or to internal organs representing problems frequently encountered in puncture procedures. To reduce or prevent these kind of problems, the development of mathematical models to represent the forces that a needle endures while performing a puncture is a research topic addressed in several laboratories in this decade. For instance, some studies have developed simulations of mathematical models for medical help as in [1], [2], [3]. The aspects associated to puncture procedures are numerous and different from each other. Among the works that deal with puncture problems, the thesis presented by [4] considers the influence of several factors as the insertion method, the tissue and the needle characteristics and provides reliable experimental data to address needle-tissue interaction problems. The steering guidance work developed by [5] focuses on the detection of the contact forces between the needle tip and human internal structures by a haptic approach. Other woks investigate different aspects related with puncture problems as the needle tip geometries and their effect on the needle forces [6], the force feedback problem tackled in [7] with a finite element method approach and the aim to provide guidance during puncture tasks or the work reported by [8] that focuses on a model that considers the tip geometry of hollow needles to predict the puncture force.

The force and the necessary deformation to insert a needle into a particular tissue depend mostly on the properties of the tissue, on the velocity of the needle during insertion and on the size and shape of the needle tip [9], [10].

In Fig. 1, d_0 represents the tissue surface, d_1 the tissue rupture point and x the needle displacement. When a needle is inserted into a tissue layer, the process presents a distinctive pattern that can be divided into two phases. The first phase concerns the needle deforming the tissue constantly and increasing the insertion force (see Fig. 1a). During this phase, the tissue is deformed ($d_0 < x < d_1$) until it reaches the limit of stress it can withstand. This is the beginning of the second phase when the needle penetrates the tissue and advances inside the tissue ($x > d_1$), as it is illustrated in Fig. 1b.

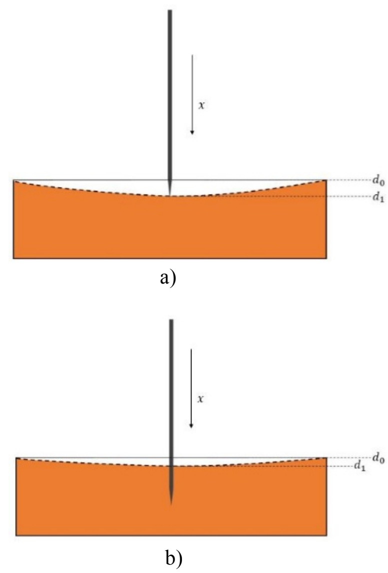


Fig. 1: Tissue deformation in puncture. Modified from [16].

The advance of a needle into multi-layer tissues corresponds to a similar process that the previously described one. This process is repeated when the needle penetrates each tissue layer with specific mechanical properties until it reaches its target.

II. MODELS FOR PUNCTURE

The term puncture is used in medicine to identify the practice of inserting a needle or a similar instrument in the human body. Puncture allows extracting tissue samples or

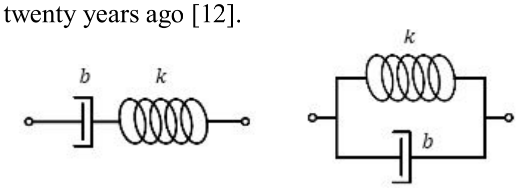
[1]Facultad de Ingeniería, Universidad Autónoma de Estado de México.
[2]correspondence autor: jcavilav@uaemex.mx.
[3]Cátedras CONACyT.

liquid from a patient's body to be analyzed for diagnosis and to determine a treatment according to his/her condition [11] or delivering medicaments inside the human body.

Puncture procedures performed using robots could bring benefits to the patient because the damage could be reduced. To accomplish this, mathematical models that describe the interaction forces between needles and tissues can be used.

Understanding the interaction between tissues and needles allows one to propose control strategies to improve puncture tasks using robots. In this regard, the characterization of the needle-tissue interaction is an essential task. Inside the human body, the needle can bend leading to loss the target. Besides, the friction force between the needle and the tissue must be compensated to maintain a steady insertion.

Maxwell model and Kelvin-Voigt model (see Fig. 2) constitute basic descriptions of the viscoelastic properties of the needle-tissue interaction. To characterize this interaction, the Maxwell model uses a spring (stiffness constant k) and a damper (damping constant b) in a series interconnection where the elements are subject to the same level of stress. The Kelvin-Voigt model uses these same elements interconnected in a parallel form then, the spring and the damper are subject to the same strain. Maxwell model matches in a better way the viscoelastic fluid behavior than the Kelvin-Voigt model that describes a viscoelastic solid behavior. These two models have been used in several investigations and were reported more than twenty years ago [12].



a) Maxwell model. b) Kelvin-Voigt model.

Fig. 2: Viscoelastic models [12].

A reference work developed to characterize the needle-tissue interaction was reported by [13], where the force acting on the needle $F(x)$ is represented as the sum of three forces: the stiffness force $f_{st}(x)$ that corresponds to the viscoelastic interaction between the needle and the tissue surface, the friction force $f_f(x)$ which occurs during the advancement of the needle throughout the tissue and the cutting force $f_c(x)$ that is required for the needle tip to penetrate the tissue layer.

$$F(x) = f_{st}(x) + f_c(x) + f_f(x) \tag{1}$$

The model reported in this paper combines methods based on the mentioned works which, together, represent the needle-tissue interaction as it is shown in next Sections.

A. Deformation Model

Authors in [14] use a modified Kelvin-Voigt (MKV) model whose components change their values according to the advancement of the needle into the tissue. The MKV model is represented in Fig. 3 where the non-linear function $f_s(x)$ defines the behavior of the static component of the needle force $f_n(x,t)$. The lower part of Fig. 3 illustrates the serial interconnection of a spring (stiffness coefficient $k(x)$) and a damper (damping coefficient $b(x)$) that are used to define the dynamic component $f_d(x,t)$ of the needle force given in (2). The MKV model represents the tissue deformation phase of the model that is reported in this paper. The insertion phase of the puncture procedure is defined later.

$$f_n(x,t) = f_s(x) + f_d(x,t) \tag{2}$$

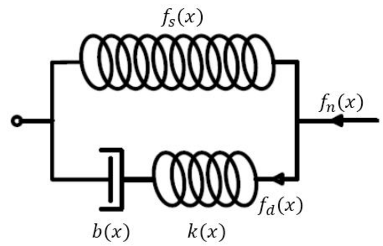


Fig. 3: Modified Kelvin-Voigt model [14].

As shown in (3), the total deformation of the system x is given by the sum of the elastic deformation of the spring x_k and the deformation of the viscous component x_b [14].

$$x = x_k + x_b \tag{3}$$

Since the elements connected in series experience an identical strain [15], the dynamic force $f_d(x,t)$ can be calculated as:

$$f_d(x,t) = k(x)x_k = b(x)\dot{x}_b \tag{4}$$

The relaxation time $\tau_s = \frac{b(x)}{k(x)}$ is defined and estimated experimentally in [14]. In view of (3), it is easy to see that the deformation of the spring can be calculated as [14]:

$$x = \tau_s \dot{x}_b \tag{5}$$

By taking the time derivative of equation (3) and using the relation given in (5), the differential equation for the spring displacement is obtained as:

$$\dot{x}_k + \frac{x_k}{\tau_s} = \dot{x} \tag{6}$$

Its general solution is calculated by considering a constant insertion velocity $\dot{x} = v$ of the needle and is obtained by a convolution integral as in [14]:

$$x_k = \int_0^t \dot{x}(\tau) e^{\left(-\frac{t-\tau}{\tau_s}\right)} d\tau \tag{7}$$

Substituting the solution of (7) in (4), the force $f_d(x,t)$ is provided in (8) [14]:

$$f_d(x,t) = k(x) v \tau_s (1 - e^{-\frac{x}{v\tau_s}}) \tag{8}$$

Then, substituting (8) in (2), the needle force is calculated as:

$$f_n(x) = f_s(x) + k(x)v\tau_s(1 - e^{-\frac{x}{v\tau_s}}) \quad (9)$$

For the tissue deformation stage, equation (9) represents the force-deformation relation as a function of the insertion velocity. It is still necessary to consider friction force between the needle and the tissue and cutting force.

B. Friction Model and Cutting Force

The friction force f_f occurs during the advancement of the needle throughout the tissue and is due to Coulomb friction, adhesion and tissue moisture. A Dahl friction model, provided in equation (10) is selected by [16] to describe the friction force, where a simplified time domain model is obtained by considering positive velocities. In this model, only the insertion phase of the needle into the tissue is considered.

$$\frac{df_f}{dt} = \frac{df_f}{dx}\frac{dx}{dt} = \sigma\left(1 - \frac{f_f}{D_p}\right)\dot{x} \quad (10)$$

In equation (10), σ is the slope of the friction force f_f and D_p is the limit of the friction in the positive direction.

According to [16], the cutting force f_c is modeled by (11).

$$f_c = \begin{Bmatrix} 0 & x < d_1,\ t < t_p \\ c_k & x \geq d_1,\ t \geq t_p \end{Bmatrix} \quad (11)$$

In (11), t is the time, t_p is the rupture time, d_1 is the position for the maximum deformation of the tissue surface before rupture (see Fig. 1) or the rupture point and c_k is a cutting constant depending on the tissue type skin (*s*), fat (*f*), muscle (*m*) or liver (*l*) with $k = s, f, m, l$.

Taking into account the models described above and the needle puncture phases (see Fig. 1), the insertion force of the needle into the tissue can be modeled as follows.

$$F(x) = \begin{Bmatrix} 0 & x < d_0 \\ f_n & d_0 \leq x < d_1 \\ f_f + f_c & x \geq d_1 \end{Bmatrix} \quad (12)$$

Model (12) represents the interaction of a single tissue layer and a needle (see Fig. 1) and is used for numerical simulation purposes.

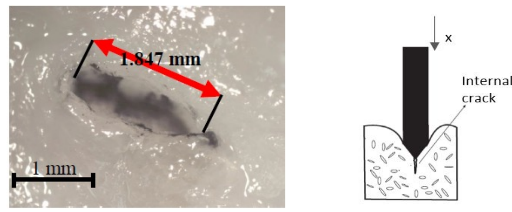
III. Damage in Puncture Procedures

Damage needs to be minimized during puncture processes in order to accomplish minimally invasive puncture tasks. To the best knowledge of the authors, an explicit damage criterion related to puncture processes has not been reported in literature. Then, a criterion that allows to perform controlled puncture procedures, in a minimally invasive puncture context, is the main contribution of this paper.

A. Damage Characterization

During puncture procedures, as it is illustrated in Fig 4, internal and external cracks, as well as tissue tearing, occur. These phenomena are closely related to the events of tissue deformation and rupture during the needle advance [14], [17], [18].

Due to the viscoelastic properties of biological materials, it is well known that fast movements of a sharp tool (a needle by instance) cause less tissue deformation during cutting or penetration. Due to deformation, the tissue store an amount of the needle energy to be released in the form of cracks [17].



a) External crack [19]. b) Internal crack [18].

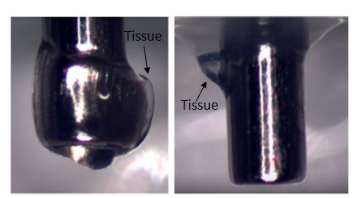
Fig. 4: Types of cracks in tissue.

Authors in [18] report variations in tissue deformation and cracks length during needle insertion while performing experiments under different insertion velocity and needle diameter conditions. Conclusions in [18] establish that the increase of the insertion velocity diminishes the tissue deformation and the size of superficial cracks in the tissue.

By increasing the needle diameter and by changing the needle bevel, tissue deformation and cracks behaviors are affected.

The use of a hydrogel layer is reported in [20] where needle insertions were performed at different velocities. Authors in [20] report that when the needle velocity increases, the perforation hole diameter decreases. In addition, the hydrogel accumulation at the needle tip, as it passes through a hydrogel layer, at 0.2 *mm/s* is bigger than the case when the needle velocity is 1.8 *mm/s*, as it is shown in Fig. 5.

There is a clear relation between the insertion diameter puncture hole and the needle velocity which, in the case of the work reported in [20], causes less reflux when liquid is introduced through an insertion hole associated to a higher insertion velocity.



a) 0.2 *mm/s*. b) 1.8 *mm/s*.

Fig. 5. Hydrogel accumulation at the needle tip [20].

Authors in [18], [19] define the needle energy required to deform and penetrate the tissue as the fracture work. The tissue absorbs this energy during the events of deformation and rupture. Several authors report a decrease in tissue deflection and in the rupture force when the insertion velocity is increased [9], [13] [16], [21]. This is produced by the tissue viscoelastic characteristics which cause less deformation at higher velocities [17], [22].

As it is reported in section V of this paper, the insertion hole created by a bevel tip needle, when penetrating a tissue layer, has an elliptic shape. Then, the degree of damage or invasion produced by a needle can be related to the value of the respective insertion hole ellipse area.

Nevertheless, the mentioned ellipse is, solely, associated to the tissue surface damage. Neither the damage inside the penetration hole nor the cracks are discussed in this paper. Readers interested in puncture cracks are invited to consult [18], [19].

B. Damage Criterion

The needle insertion velocity affects the tissue deformation and the rupture force required to penetrate the tissue. Analyzing Fig. 6 reported by [17], four phases during a puncture procedure corresponding to tissue deformation, tissue rupture, tissue relaxation and needle extraction can be identified. Notice that the 100 *mm/s* needle insertion velocity (red line) produces less rupture force and tissue deformation than the 1 *mm/s* needle insertion velocity (blue line) (see the corresponding rupture points in Fig. 6).

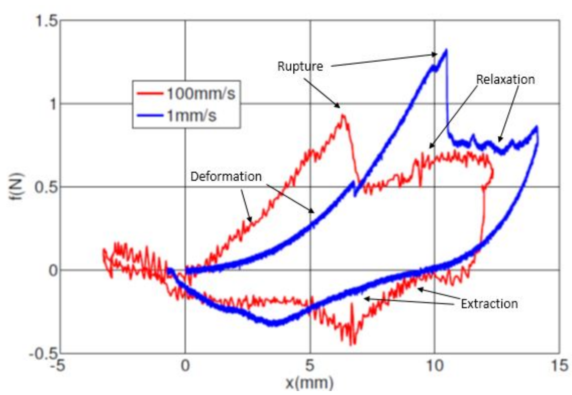


Fig. 6: Graph of force vs. displacement of the needle. Modified from [17].

From what has been reported concerning the dependence of the rupture force and the tissue deformation on the insertion velocity (see for instance [4], [14], [17], [18], [23]), the following facts can be established.

Fact 1. The increase in needle insertion velocity reduces the tissue deformation and the rupture force during puncture procedures.

Fact 2. "Human tissue is a viscoelastic material, property that can be used to minimize its deformation. Experimental results indicate that higher needle insertion speeds reduce deformation and insertion force… However, only robots can use high needle insertion speeds safely. Manual insertion requires lower speeds." [9].

Based on puncture researches dealing with damage (see for instance [14], [16], [19]), the next assumptions are established.

Assumption 1. The energy absorbed by the tissue during puncture is dedicated to cracks generation and to the entry hole creation.

Assumption 2. If tissue deformation and rupture force decrease, the energy absorbed by the tissue will decrease.

Assumption 3. The shape of every insertion hole produced by a needle with bevel tip is an ellipse.

Based on Facts 1 and 2 and on Assumptions 1 to 3, the following Minimally Invasive Puncture Criterion (MIPC) is established.

MIPC. *During puncture procedures with bevel tip needles:*

i. *The smaller the ellipse area of the insertion orifice on the tissue surface, the smaller the surface damage generated by a needle.*
ii. *The higher the insertion velocity, the smaller the tissue deformation, the rupture force and the area of the insertion hole.*

The area A of an ellipse can be computed knowing the lengths of its semi-major axis r_1 and of its semi-minor axis r_2 as in (13) and it will be used to evaluate experimental results.

$$A = \pi r_1 r_2 \tag{13}$$

The following Sections of this paper are focused on two relevant aspects in puncture processes. Numerical simulations are aimed to illustrate the needle-tissue interaction with emphasis on tissue deformation and rupture force as functions of the insertion velocity. Experiments in hog tissue validate the Minimally Invasive Puncture Criterion provided above.

IV. Numerical Simulations

As it has been mentioned previously, the mathematical model used to perform numerical simulations combines the deformation phase model developed by [14] and the insertion phase model reported in [16] to represent the needle-tissue interaction for a single layer puncture system. The needle retraction phase as well as the effect of the needle tip are not discussed in this paper.

Numerical simulations have been carried out using Matlab/Simulink® and are performed under the following hypotheses [16]:

- "The puncture force is purely axial along the trajectory of the needle".
- "There is no deflection in the needle trajectory as it is inserted".
- "The needle is inserted at a constant velocity".

The puncture system considers the force f_u as the applied control force to obtain a constant velocity of the needle, the force F which represents the total force that the needle endures when puncturing and the total mass m including the needle mass and the mechanism mass that moves the needle. These elements are related to the needle displacement by equation (14).

$$F(x, \dot{x}) - f_u = m\ddot{x} \tag{14}$$

A. State Space Variables

The following state space variables are defined. The needle tip displacement $x = x_1$, its velocity $\dot{x} = x_2$ and the friction force $f_f = x_3$. The dynamics associated to the set of chosen state variables can be written as follows:

$$\begin{aligned} \dot{x}_1 &= x_2 \\ \dot{x}_2 &= \ddot{x}_1 \\ \dot{x}_3 &= \dot{f}_f \end{aligned} \tag{15}$$

The system dynamics is divided into two stages. The first one is the tissue deformation phase and the second one corresponds to the needle insertion phase.

Taking into account that $F = f_n$ (see Fig. 3) and that f_{ud} is the control force applied during the deformation phase, the dynamics is defined by equation (16).

$$\begin{aligned} \dot{x}_1 &= x_2 \\ \dot{x}_2 &= \frac{1}{m} f_n - \frac{1}{m} f_{ud} \\ \dot{x}_3 &= 0 \end{aligned} \tag{16}$$

Substituting the needle force $f_n(x,t)$ given in (9) and the static component $f_s(x)$ defined in Table 1, it is easy to see that (16) has the matrix representation given by (17).

$$\dot{x} = \begin{bmatrix} 0 & 1 & 0 \\ \frac{1}{m} g(x_1) & \frac{1}{m} k \tau_s \left(1 - e^{\frac{-x_1}{x_2 \tau_s}}\right) & 0 \\ 0 & 0 & 0 \end{bmatrix} \begin{bmatrix} x_1 \\ x_2 \\ x_3 \end{bmatrix} - \begin{bmatrix} 0 \\ \frac{1}{m} \\ 0 \end{bmatrix} f_{ud} \tag{17}$$

where $g(x_1) = g_1 x_1 + g_2$ and the constants $g_1 = 0.0115$ and $g_2 = 0.0114$ are experimentally obtained in [14].

For the insertion phase and taking into account equations (10), (11), (12) and (15), the corresponding model is represented by equation (18).

$$\begin{aligned} \dot{x}_1 &= x_2 \\ \dot{x}_2 &= \frac{1}{m}(x_3 + b_s x_2 + c_k) - \frac{1}{m} f_{ui} \\ \dot{x}_3 &= \sigma \left(1 - \frac{x_3}{D_p}\right) x_2 \end{aligned} \tag{18}$$

where f_{ui} is the control force applied during the insertion phase and b_s is a damping coefficient reported in [16]. Then, the insertion phase dynamics is provided in a matrix form in (19).

$$\dot{x} = \begin{bmatrix} 0 & 1 & 0 \\ 0 & \frac{b_s}{m} & \frac{1}{m} \\ 0 & \sigma\left(1 - \frac{x_3}{D_p}\right) & 0 \end{bmatrix} \begin{bmatrix} x_1 \\ x_2 \\ x_3 \end{bmatrix} + \begin{bmatrix} 0 \\ c_k \\ 0 \end{bmatrix} - \begin{bmatrix} 0 \\ \frac{1}{m} \\ 0 \end{bmatrix} f_{ui} \tag{19}$$

In order to perform numerical simulations, the values of the deformation and the insertion phases parameters were obtained, mostly, experimentally in [14], [16].

The experimental estimation presented in [14] reports numerical values of the deformation parameters $\tau_s(x_1)$, $f_s(x_1)$ and $k(x_1)$, provided in Table 1, while a needle is inserted into pig tissue.

Table 1. Deformation phase parameters [14].

Needle	$f_s(x_1)mm$	$k(x_1)$	$\tau_s(x_1)$
Bevel	$0.0115{x_1}^2 + 0.0114x_1$	0.0375	0.5

Table 2 provides the numerical values of the parameters associated to the rupture and friction forces. The values of σ, b_s and c_k were taken from [16]. However, the parameter D_p was heuristically established taking into account some values given in literature [16].

Table 2. Insertion phase parameters [16].

Needle	D_p	σ	b_s	c_k
Bevel	5	0.5	3	0.7

Deformation phase simulations represented in Fig. 7 have a similar behavior to that reported in [14]. The needle displacement values for rupture points d_2 and d_3 were experimentally estimated in [14], while that related to the rupture point d_1 was taken from [16]. Due to tissues non-homogeneous properties, it is difficult to compute the values of these rupture points using mathematical models.

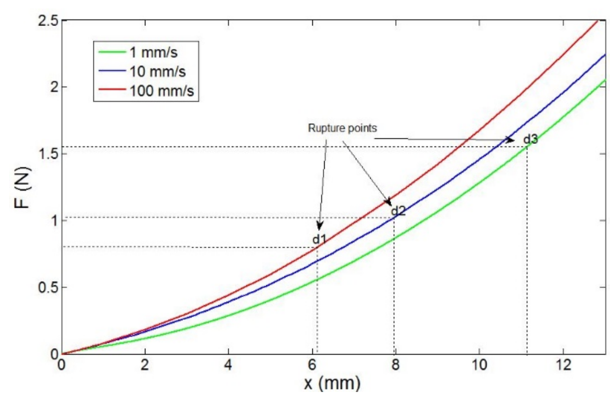


Fig. 7: Deformation phase simulation at different velocities.

In Fig. 7, it is observed that for a 100 *mm/s* needle insertion velocity, the rupture force and the tissue deformation values (point d_1) are lower than those when the needle insertion velocities are 10 *mm/s* (point d_2) or 1 *mm/s* (point d_3).

Based on (12), Fig. 8 shows the force behavior as a function of the needle displacement at two different insertion velocities: $v_1 = 10\,mm/s$ (blue line) and $v_2 = 100\,mm/s$ (red line).

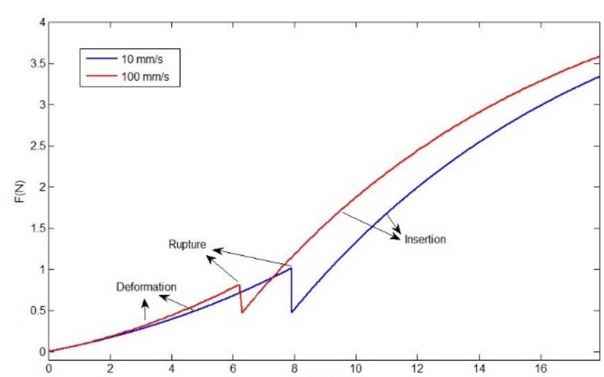


Fig. 8: Needle force behavior.

The increase in force is due to the needle advance into the tissue. The force behavior in Fig. 8 represents three phases: tissue deformation, tissue rupture and needle insertion.

Model simulations verify that a needle insertion velocity increment generates less tissue deformation and rupture force. Taking into account the damage criterion specified in Section III, simulations corroborate that the tissue damage decreases when the needle insertion velocity increases.

From Fig. 8, one can see that the value of the needle force in the deformation phase is higher for a lower insertion velocity while in the insertion phase this behavior is reversed. This can be explained by the fact that, due to tissue viscous properties, a higher insertion velocity causes more friction between the tissue and the needle than a lower one.

B. *Control Strategy*

In order to perform punctures under controlled insertion velocities, different control strategies could be developed. This paper is not focused on control laws designs or control analysis.

Nevertheless, a control strategy is used in this paper to illustrate a way to guarantee constant velocity insertions.

In order to obtain a zero acceleration when puncturing and considering that different dynamics are presented for each needle insertion phase, the control law needs to provide different stages, each one associated to each insertion phase. The control strategy is, then, a switched nonlinear control that uses f_{ud} for the deformation phase and f_{ui} for the insertion phase as it is explained bellow.

For the deformation phase and based on (16) and (9), the control f_{ud} in (20) is proposed.

$$f_{ud} = f_n(x) = f_s(x) + k(x)v\tau_s(1 - e^{-\frac{x}{v\tau_s}}) \quad (20)$$

For the insertion phase, the control strategy f_{ui} is based on (18) and takes the form in (21).

$$f_{ui} = x_3 + b_s x_2 + c_k \quad (21)$$

The switching condition for this control strategy is provided by equation (22), where d_1 represents the rupture point and the exact moment when the dynamics of the system changes.

$$f_u = \begin{Bmatrix} f_{ud} & x < d_1 \\ f_{ui} & x \geq d_1 \end{Bmatrix} \quad (22)$$

Using the control (21) in (18) and the control (20) in (16), it is easy to verify that the velocities of interest are: for the deformation phase $v_d = c_1$ and for the insertion phase $v_i = c_2$, where c_1 and c_2 are constant velocities.

The previous development confirms that the strategy control defined by (20), (21) and (22), guarantees constant velocity insertion for both the deformation and the insertion phases in puncture procedures.

This article does not analyze the effects of the proposed control strategy in relation with the minimally invasive puncture criterion MIPC.

V. Tissue Experiments

A series of needle insertion experiments were performed into animal tissue to validate the damage criterion for minimally invasive puncture by increasing the needle insertion velocity.

The main objective of the experiments is to determine the surface damage generated in hog tissue for different insertion velocities by computing the area of the insertion hole.

A. *Methods and Materials*

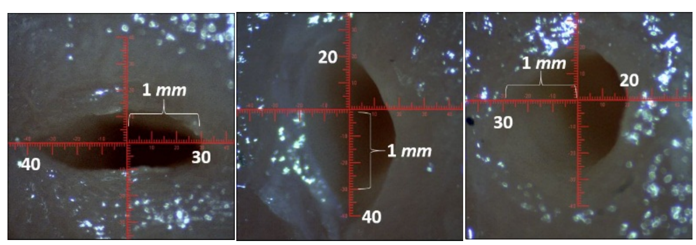
A biopsy needle with a length of 15 *cm* and a diameter of 2.10 *mm* was used to perform the experiments. This needle has a mechanism to remove tissue samples, which will be blocked to prevent tissue tear. The experiments were performed under similar conditions: 19°C and 62 % relative humidity.

Needle insertion tests were performed at different needle velocities in an area of 3 *cm* x 4 *cm* on hog tissue since it has similar properties to those of human tissue [9], [14], [17], [18]. The insertion holes were examined using a stereo microscope with two 10*x* objective lenses, a 0.7*x* to 4*x* variable zoom magnification and high led illumination. A usb microscope camera was used to observe and measure the tissue insertion hole (r_1 and r_2) in order to compute the ellipse area A.

B. *Experimental Results*

Based on the insertion velocities values reported in the literature [14], [16], [17], [18], four insertion velocities were selected (4 *mm/s*, 40 *mm/s*, 80 *mm/s* and 100 *mm/s*) to perform series of 10 hog tissue insertions for each insertion velocity.

Pictures in Fig. 12 show some insertion holes at the insertion velocities of 4 *mm/s*, 40 *mm/s* and 100 *mm/s* using a 30*x* zoom.



a) 4 *mm/s* b) 40 *mm/s* c) 100 *mm/s*

Fig. 9: Insertion holes.

The measurement of the ellipse semi-major and semi-minor axes for each insertion were performed through the camera software WinJoe®, supplied with the camera, which provides a digital rule according to the applied zoom in the microscope.

Table 3 provides the greatest A_M, the smallest A_m and the average A_a insertion hole areas, obtained at four different insertion velocities v. Note that these velocity values correspond to different produced damages.

The results reported in Table 3 show that there is an inverse relation between the insertion velocity and the insertion hole area such that for every performed puncture, one can establish that the area of the insertion hole will decrease while the insertion velocity increases. This validates the minimally invasive puncture criterion established in Section III of this paper.

Table 3. Insertion hole area at different insertion velocities.

v (*mm/s*)	A_M (*mm*^{2})	A_m (*mm*^{2})	A_a (*mm*^{2})
4	3.33	2.45	2.834
40	3.19	2.24	2.78
80	2.40	2.15	2.30
100	1.95	1.22	1.718

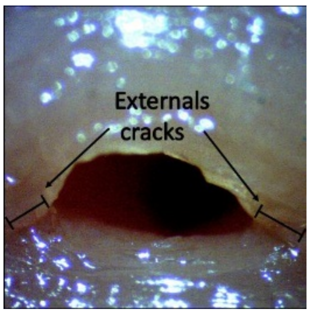


Fig. 10: External cracks.

External cracks were observed during some experiments. These cracks appeared when the insertion velocity was 4 *mm/s* as it is illustrated in Fig. 13. For the other three insertion velocities, external cracks were absent. This behavior could be due to the non-homogeneous characteristics of the tissue.

VI. Conclusion

Based on the ellipse area of the insertion hole created by a bevel tip needle in puncture procedures, an original minimally invasive puncture surface damage criterion was established and called MIPC.

The defined criterion allows to calculate, mathematically, the puncture surface damage as the area of the insertion orifice.

Puncture surface damage is directly proportional to tissue deformation and rupture force and inversely proportional to the respective insertion velocity.

The MIPC was validated with numerical simulations as well as by experimental tests conducted in porcine tissue confirming analytical results.

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3.2. Submission Confirmation

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