

Developing a Needle-Knife Surgical Device

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Research Article

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Abstract

Introduction:

Nowadays, a new era of orthopedic surgery is taking place. Procedures like video surgery, ultrasound-guided interventions, invasive pain interventions, orthopedic procedures, hydro dissection, dry needling, thermography-assisted pain management, and modern acupuncture started to be widely performed^{1,2}.

Background:

In 2011 and 2012, Ravaglia & Cliquet presented papers on an Arthroscopic Needle-Knife Surgical Prototype Device (ANKSD)² in Prague, TWC 2011², and in Dubai, OWC 2012³. It was a paper presenting a prototype of a needle-knife for orthopedic procedures based on an 18G11/2 needle. Ravaglia and Cliquet wrote the paper "Comparison of two different needles used as knife on knee arthroscopic portal scalpel procedures"⁴, which was presented at the XXVI SICOT Triennial World Congress, in Guangzhou, China, in 2015. This research compares arthroscopic portal incisions using an 18G11/2 needle or a metal guide intravenous catheter 14Gx2. They concluded that there were no differences in complications such as infections, wound healing, hematoma, and skin healing time.

After this, these researchers started a virtual development of a new needle-knife surgical device.

Objective:

The aim of the project is a virtual development of a needle-knife surgical device to be useful for minimally invasive ultrasound-assisted orthopedic surgical procedures, videos arthroscopic portals augmentation, and other surgical procedures.

Method:

Three different needle devices were compared. One is a base model 1 and the other two are experimental models (2 and 3). They are based on a metal guide for intravenous catheter 14Gx2". The base one model 1 is the metal guide for intravenous catheter 14Gx2"; the experimental model 2 is a flat beveled edge, and experimental model 3 is a board bevel edge^{6,7,8,9,10,11,12,13,14,15,16}. They are all graduated, parylene-coated, with a stop handle needle guard.

The devices are multifunctional: Infusion, aspiration, and surgical sever.

The devices were developed by 3D Design 3D STEP Standard Format, Catia V5 Format, and 2D Format Design and 3D Model.

They were performed through simulation (Software Simulia Abaqus).

They were biomechanically simulated with Virtual Biomechanical Strength Simulation^{17,18,19,20}.

The Strengths were assessed by Needle Strength Analysis (CAE Simulation)²¹.

Results:

For the displacement result, stiffness assessment, we have 7.48 mm for the baseline needle, 8.08mm for model 2, an increase of 8%, and for model 3 we have 7.75 mm, an increase of 3.6%.

Conclusion:

These devices seem suitable for echo-assisted orthopedic surgery interventions and other procedures according to virtual analysis. Further in vivo procedures shall be performed.

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Results:

Stiffness Calculation:

A Structural Analysis of the component stiffness was performed for the analysis of the proposed designs using the Finite Element Methodology (FEM). A comparative analysis of the needles was performed.

The Finite Element Method (FEM) is a numerical process to determine approximate solutions of boundary values of differential equations. FEM subdivides the problem domain into smaller problems, called finite elements. Finite element models can be formed by quadrilateral, triangular, hexahedral, and tetrahedral elements.

In structural analysis, the purpose of the method is to determine nodal displacements in the structure and, consequently, the deformities and stresses corresponding to the analysis. This way, a discretization of the continuous medium allows the solution of high-complexity real problems. This discretization is popularly known as finite element mesh, which can be of various types, such as two-dimensional and three-dimensional elements.

The two-dimensional elements or 2D elements can be formed through the triangular or quadrilateral element (shown in the figure below), which discretize flat surfaces such as plates, where one of the dimensions is much smaller than the other two.

Three-dimensional elements or 3D elements can be formed through the tetrahedral or hexahedral element, used in meshing solids of complex geometry. **Figure 1**

For the needles mathematical model, 2D and 3D elements were used as quadrilateral, triangular and tetrahedral elements, with the respective total amounts of elements shown below. Figure 2

The load applied was 10N; however, this value may be different during the use of the needle, but for checking the comparative stiffness among the models, it is an adequate value. The objective is to

generate stresses and displacements and to compare in percentage baseline and proposal models 1 and 2. This loading is applied to a finite element model node at the tip of the needle in the Y-axis direction to generate stresses and displacements in the same direction of use of the needle scalpel. **Figure 3**

The restrictions applied to the model were displacement in the x-, y-, and z-axes, only on the needle fixation region on the syringe on the plastic region of the needle, considering this as the only region that 'holds the needle'. This displacement restriction is done through rigid connectors and displacement = 0 at the Node of this connector. The connector represents, in a simplified way, the region where the syringe fits. Figure 4

The material adopted for the needle was SAE1020 and for the plastic part PET (polyethylene terephthalate). Although the specific properties of the product, not found in the bibliography, were not used, this consideration does not change the analysis technical conclusions, as we are doing a comparative study.

To calculate stiffness, the solver used was the Abaqus 2019. Abaqus is a commercial software package for finite element analysis (CAE) developed by HKS Inc., Rhode Island, USA, and is currently marketed by SIMULIA under the brand of Dassault Systèmes S.A. Figure 5

After the model is discretely with the necessary boundary conditions, the matrix calculations that will give us the nodal displacements are performed. The matrix notation expressing these nodal displacements in relation to the external forces applied to the structure is formed by a set of linear algebraic equations, being expressed in matrix form by the equation below.

$$\{f\} = [k] \{u\}$$

Where $\{f\}$ is a column vector containing all the loads applied on the nodes, nodal loads. The matrix $[k]$ represents the stiffness matrix or property matrix, which represents the relationship between the forces and nodal displacements of the structure. For an example of a spring with two nodes in equilibrium, where there are two displacements and two forces, it is written according to the Equation below:

$$\{f_1|f_2\} = [k_{11}|k_{21} \quad k_{12}|k_{22}] \{u_1|u_2\}$$

Where the stiffness matrix of the spring element is defined according to the equation below:

$$K_e = [k|-k \quad -k|k]$$

Also in this step, the approximation function, the interpolation function, and the function optimal adjustment are chosen through the methods mentioned above, and the boundary conditions are added. All calculations of these functions and matrix are made through the solver Abaqus, where the results are later extracted through a graphical interface showing the stress and strain distributions through color scales to facilitate the visualization of results.

As a result, below we can see that stress distribution along the needle remains the same in the three models, but at the tip of the needle where models 2 and 3 were modified, they present slightly higher values due to the decrease in thickness because of the bevel shape. We have the baseline at 164 Mpa, model 2 at 221 Mpa, and model 3 at 190 Mpa.

For the displacement result, stiffness assessment, we have 7.48 mm for the baseline needle, 8.08mm for model 2, an increase of 8%, and for model 3 we have 7.75 mm, an increase of 3.6%. Figure 6

As a comparative evaluation, it can be stated that model 3 showed characteristics that are very similar to the baseline model in terms of stiffness (3.6%). This means that the performance during its application in relation to the baseline (reference) will be very similar. Figure 7

Regarding the stresses obtained, model 3 showed an increase of 15% due to the reduction in thickness generated by the bevel shape, but it is unlikely that a needle tip fracture will occur, considering there is no such problem in the baseline model.

For future studies, it is of significant importance to find the mechanical properties of the needle for greater accuracy of the analysis results, as well as the actual effort on the needle tip, since in addition to what was considered in one direction, other efforts can be made at the time of its use.

For this activity, the solver used was Abaqus 2019. Abaqus is a commercial software package for finite element analysis (CAE) developed by HKS Inc., Rhode Island, USA, and is currently marketed by SIMULIA under the brand of Dassault Systèmes S.A.

The present study compares three models. A control base model 1 and two experimental models, model 2 and model 3. Figure 8

Figure four: Final aspects of the model with sharp hazard cover protection fold and unfold.

Model 3 presented similar stiffness features compared to the baseline model 1 (3.6%). They have similar performance. Figure 9

The tip of model 3 showed increased tension of 15%; but this does not mean fracture risk²². Figure 10

Discussion:

We live in a new era of orthopaedic surgery. Procedures like Video Surgery, Ultrasound-Assisted Surgical Interventions; Invasive Pain Interventions for Orthopaedics; hydrodissection, dry needling, thermography-assisted pain procedures, and modern acupuncture procedures started to be widely performed^{1,2}.

During my medical training in Brazil, busy hospitals faced shortage of basic equipment in the casualty department. Most of them due to logistic issues. It was evidence-based practice to use a 'pink needle' "for abscess drainage, small incisions, and suture removal". Based on this evidence-based practice, this

needle-knife was developed by Ravaglia & Cliquet and presented in papers of 2011 and 2012 on An Arthroscopic Needle-Knife Surgical Prototype Device (ANKSD)² in Prague at TWC 2011² and in Dubai at OWC 2012³. They presented a prototype of a needle-knife for orthopaedic procedures based on an 18G11/2 needle. Ravaglia and Cliquet wrote a paper - "Comparison of two different needles used as knives on knee arthroscopic portal scalpel procedures"⁴ for the XXVI SICOT Triennial World Congress Guangzhou, China, 2015. This research compares arthroscopic portal incisions using an 18G11/2 needle or a metal guide intravenous catheter 14Gx2. They concluded that there were no differences in complications such as infections, wound healing, hematoma, and skin healing time.

They decided to develop a new device with the strength of the metal guide intravenous catheter 14Gx2, the cutting edge similar to the ANKSD, and strong enough to perform orthopaedic ultrasound-assisted procedures. It is a multifunctional, echo translucent, graduated device, able to aspirate and inject fluids, anesthesia, and therapeutic medicine.

The development of this device aims at incision target precision, avoiding soft tissue damage, facilitating ultrasound-assisted surgery, and being a multifunctional tool.

Virtual experiments were developed before in vivo studies.

Conclusion:

These devices seem suitable for echo-assisted orthopaedic surgery interventions and other procedures according to virtual analysis. Further in vivo procedures shall be performed.

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Figures

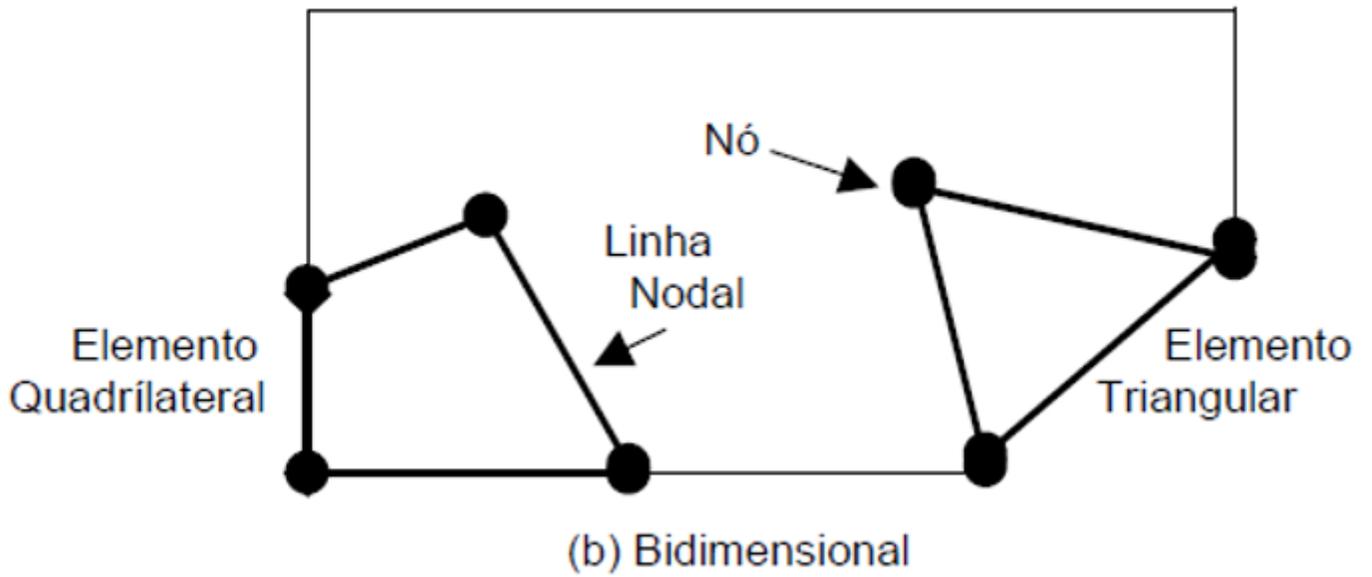


Figure 1

Two-dimensional elements or 2D elements Quadrilateral element Node Nodal line Triangular element (b)
Two-dimensional

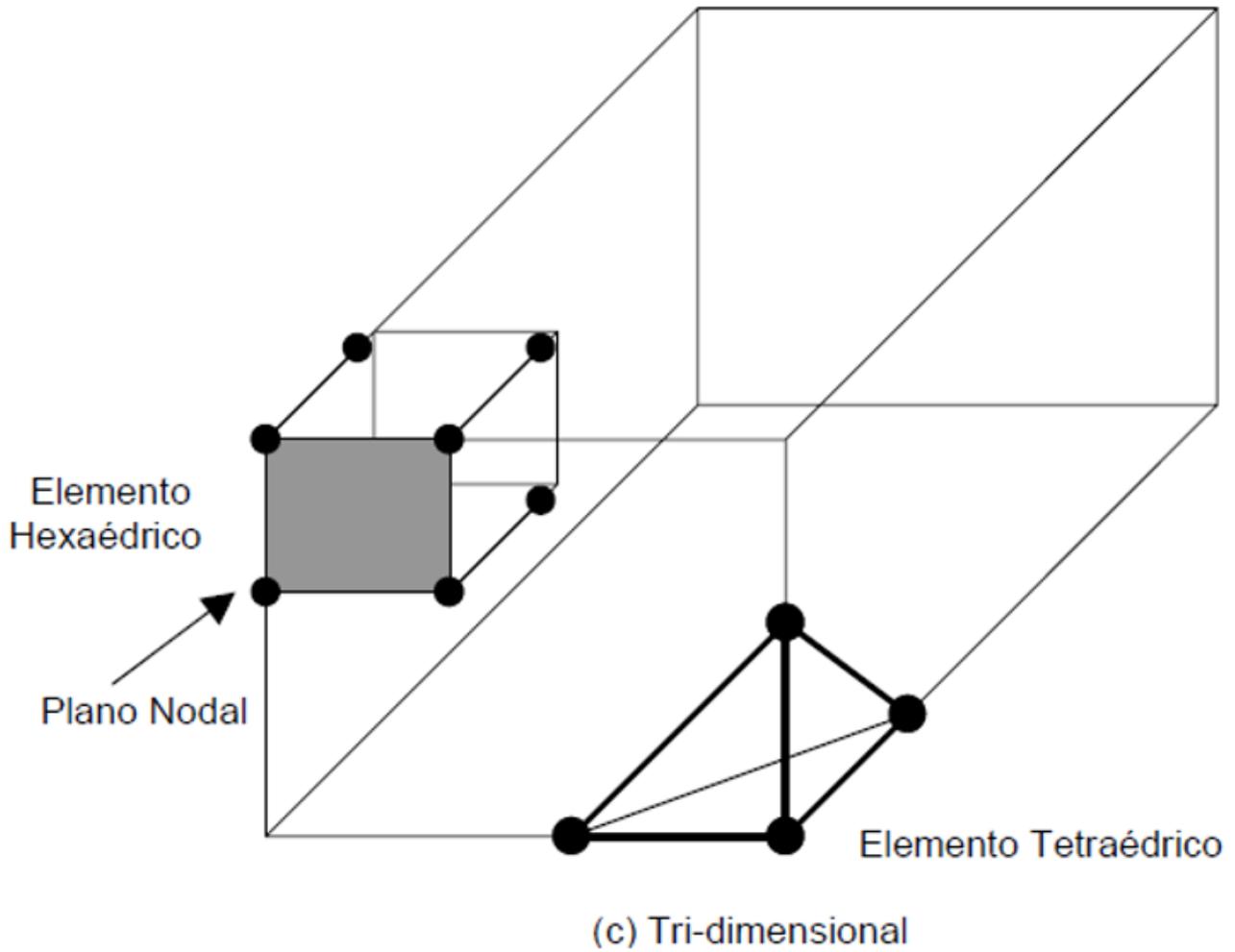


Figure 2

Three-dimensional elements or 3D elements Hexahedral element Nodal Plane Tetrahedral element (c)
 Three-dimensional Source: Chapra (1997)

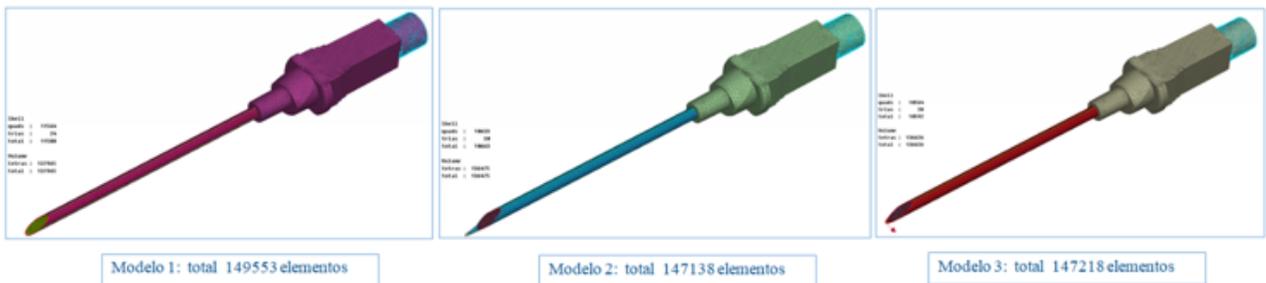


Figure 3

The three Models and their elements: Model 1: total 149553 elements Model 2: total 147138 elements Model 3: total 147218 elements NOTE: All models have an inner stem as a reinforcement for the needle structure modelled as 3D tetrahedral elements.

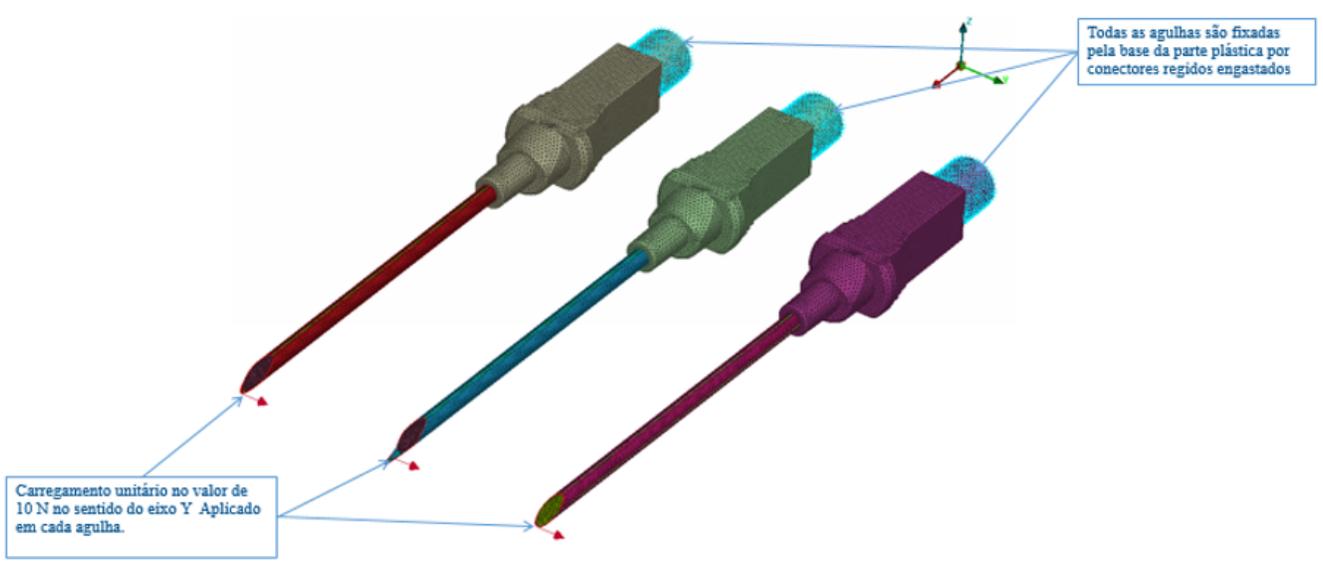


Figure 4

Figure 4: Application of 10N on the tip of the three Models and fixed at the plastic part. All needles are fixed at the base of the plastic part by rigid mounted connectors Single load of 10N in the direction of Y-axis applied on each needle

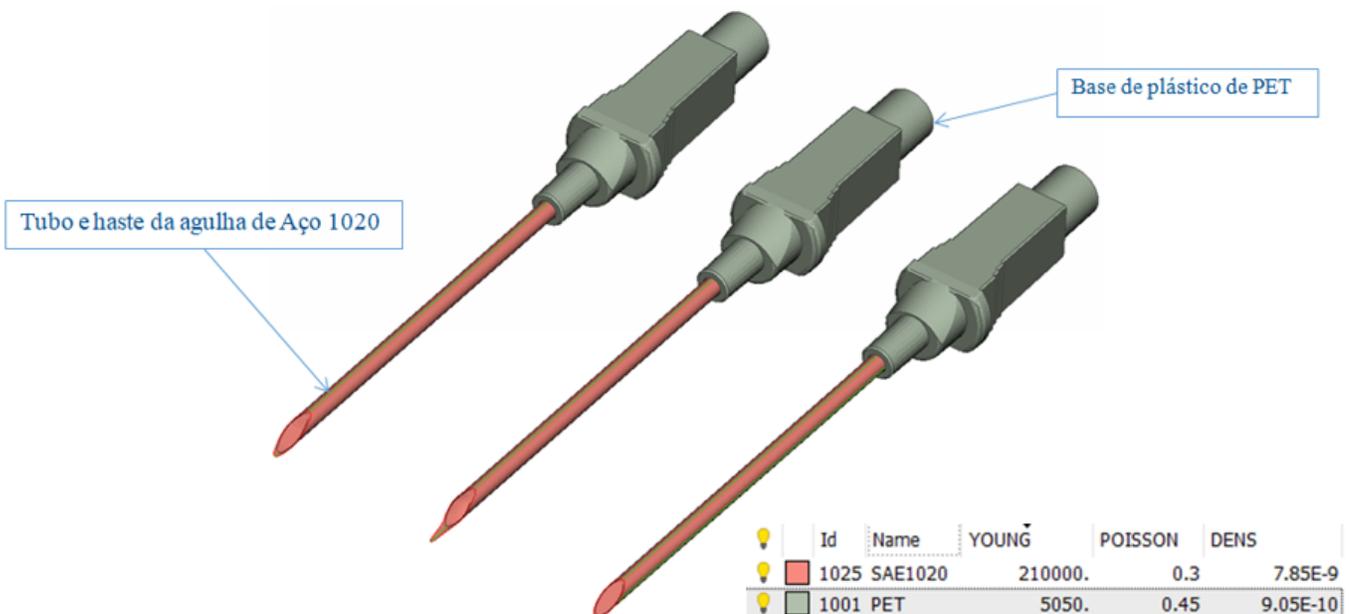


Figure 5

Description of the three needles. Hub and shaft of a 1020 steel needle PET plastic base

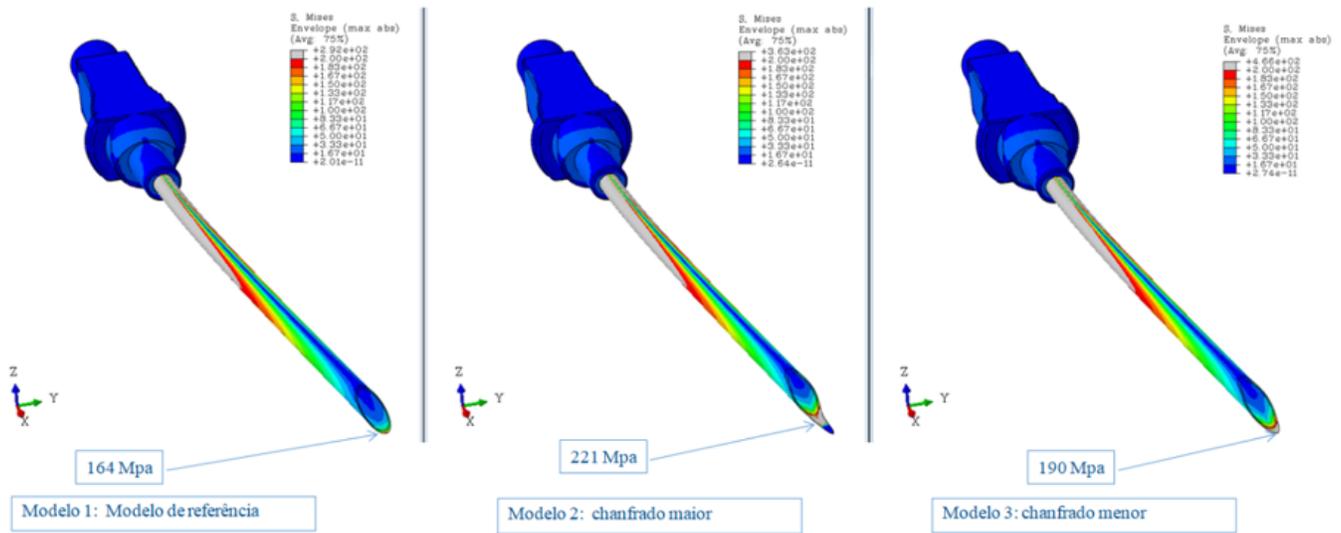


Figure 6

The stress distribution along the three needle Model 1: reference model Model 2: larger bevel Model 3: smaller bevel

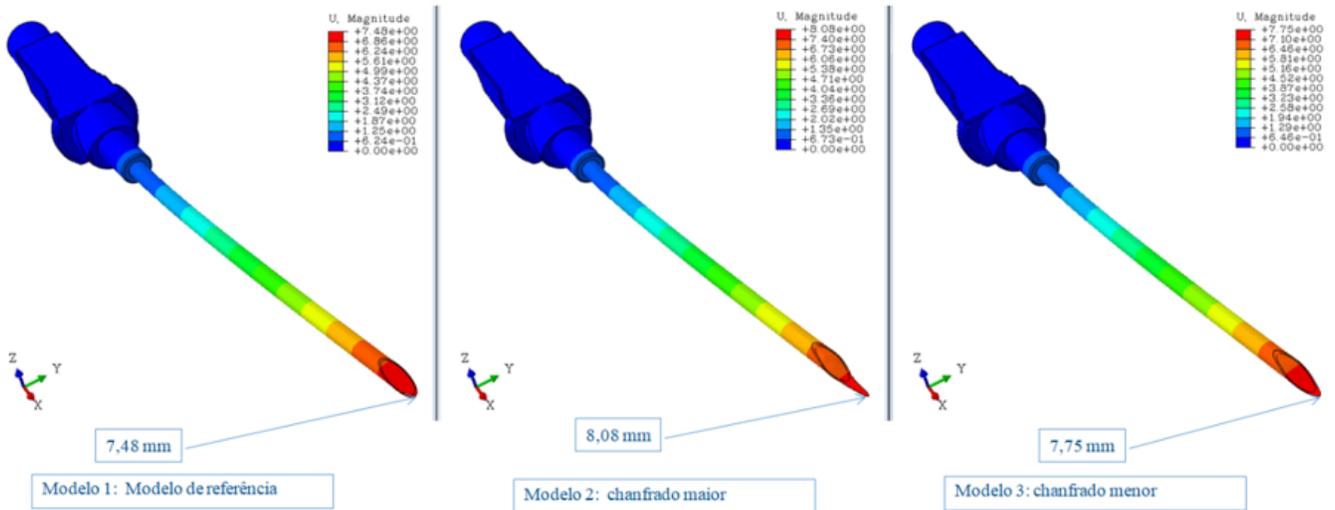


Figure 7

Displacement result and stiffness assessment

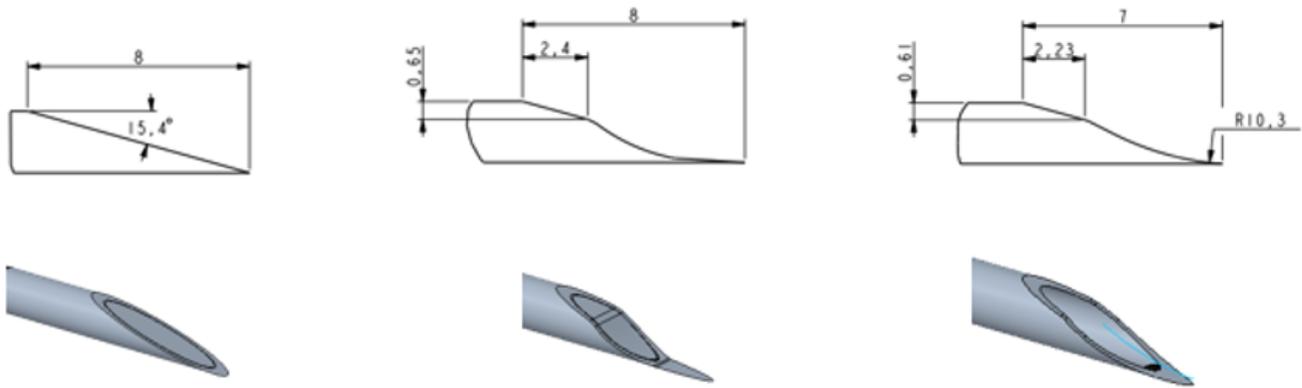


Figure 8

Models' Bisels 1, 2 and 3. Strength tests in all three models:

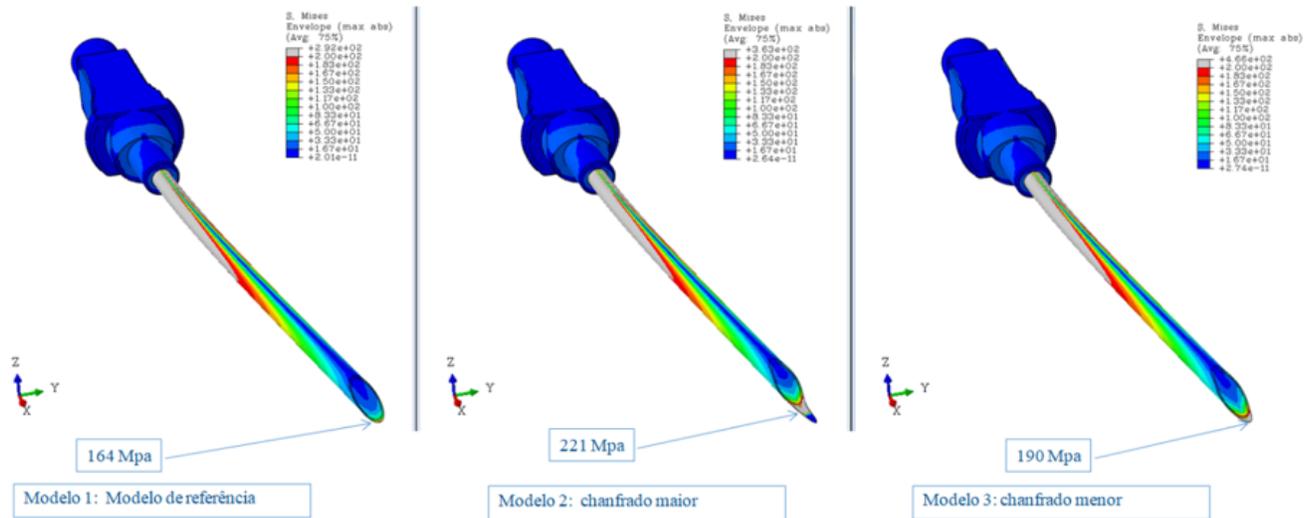


Figure 9

Strength tests results in all three models

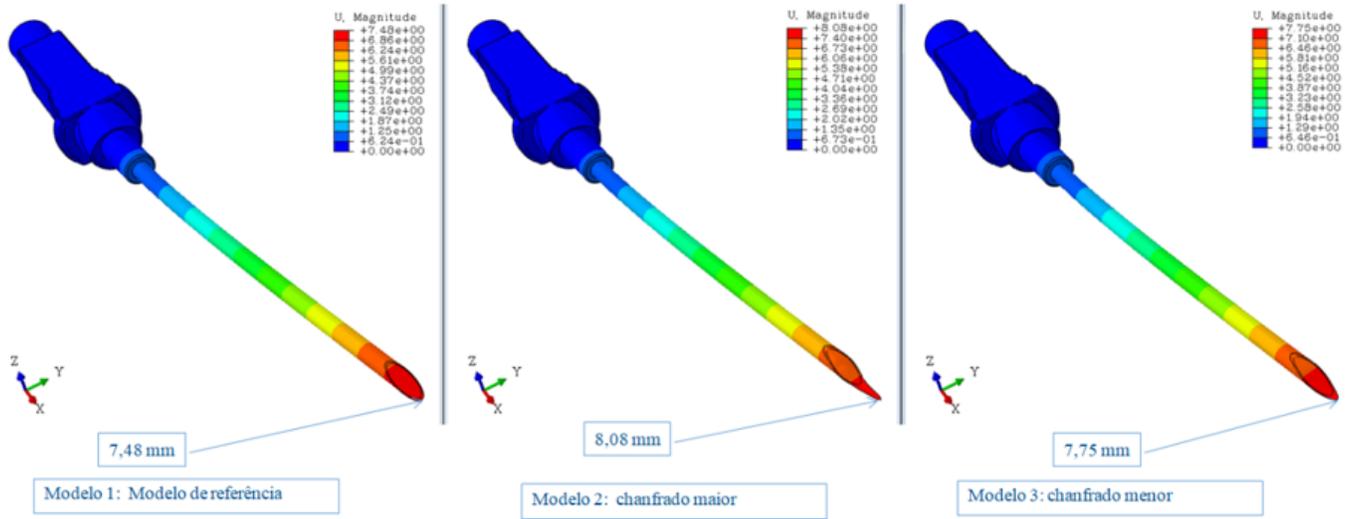


Figure 10

Strength tips tests stress results in all three models