A System for Optimizing Medical Device Development Using Finite Element Analysis Predictions[1]

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1 Background

A virtual prototyping interface has been developed to enable creative forward and inverse design for medical device design evaluation [1]. Two featured wheel plots allow the designers to guide the interface and explore a multiparameter design space. We propose a system to allow computational tools to work effectively with big data and to ultimately achieve simulation-based medical device design [2].

To demonstrate the proposed system, a design example of a vacuum-assisted breast biopsy (VABB) instrument is used. VABB

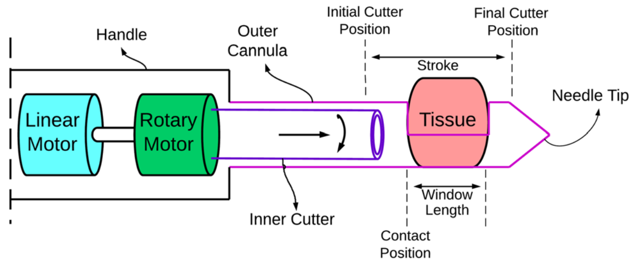

Fig. 1 Problem definition of the VABB cutting

is one of the most common minimally invasive procedures to retrieve tissue samples for breast cancer diagnosis. An accurate diagnosis requires tissue samples with sufficient volume and good contiguity [3]. To satisfy these design requirements, a designer has to be able to evaluate the cutting performance of potential solutions. In addition, tradeoffs for each of the design parameters have to be considered before making design decisions. For example, a solution that provides a higher rotary cutting speed can cut denser tissue more easily [4], but can be heavier or more expensive to produce because of the required motor selection. Therefore, enabling the designer to quickly relate one parameter to the others and find target designs becomes critical. This paper demonstrates an example of creating and exploring a design space for a VABB cutting problem. ANSYS Explicit STR is used to predict tissue-cutting performance for the evaluation of device components on a high-performance computing (HPC) batch system. By exploring the design space with wheel plots, a human designer is brought in the loop to evaluate the designs, balance the tradeoffs, and make informed design decisions.

2 Methods

Vacuum-assisted biopsy uses a rotation/translation coaxial needle and vacuum to sample breast tissue for diagnosis. The coaxial needle, which contains an outer cannula and an inner cutter, is inserted into the abnormal area of breast tissue. Vacuum suction pulls the tissue through an opening window on the cannula into

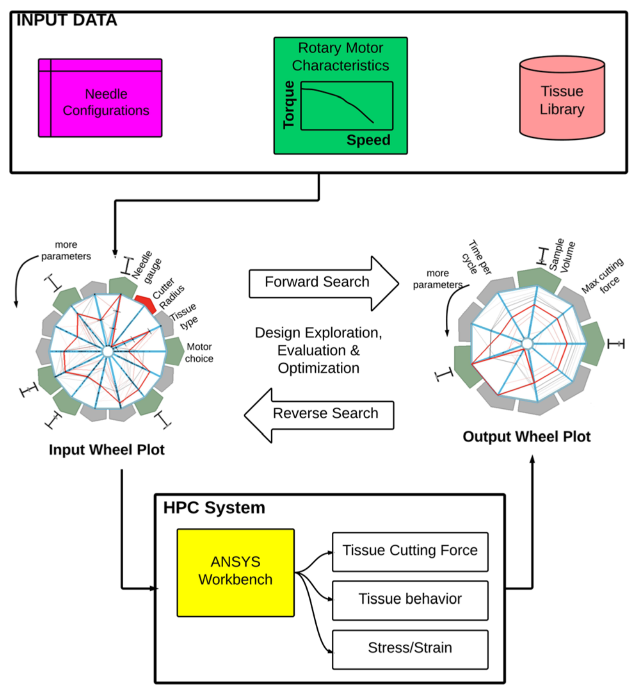

Fig. 2 The proposed system and design process

[1]Accepted and presented at the Design of Medical Devices Conference (DMD2014), Minneapolis, MN, April 7–10, 2014.

DOI: 10.1115/1.4027096
Manuscript received February 21, 2014; final manuscript received March 4, 2014; published online April 28, 2014. Editor: Gerald E. Miller.

Table 1 Critical design inputs for the VABB cutting

Critical parameters	Needle gauge	Window length	Rotation speed	Tissue properties
Values	7–11 G	20, 23 mm	1000, 3000, 5000 rpm	Fat, glandular

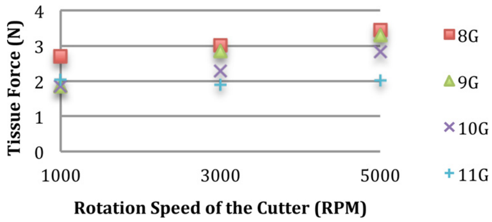

Fig. 3 Maximum tissue forces versus cutter rotation speed

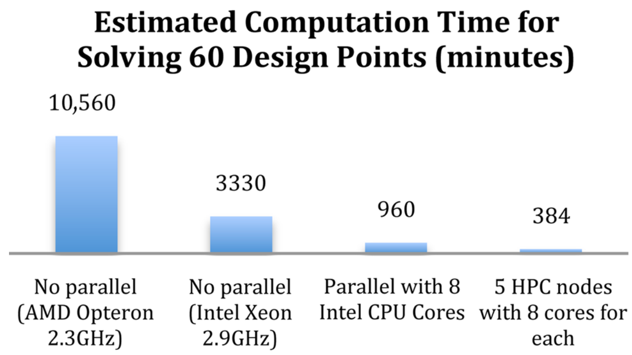

Fig. 4 Comparison of the computational performance

the cannula chamber. Then, the inner cutter is driven by motors to rotate and translate forward simultaneously to cut through the tissue.

We created a virtual VABB model to simulate the tissue cutter interaction during the cutting. As shown in Fig. 1, the model includes three main components: the coaxial needle, the motor system, and the breast tissue. We assumed a cylinder of tissue is drawn into the cannula chamber and fills the opening window region. Different motor selections will result in different rotation speeds to cut through the tissue.

Figure 2 illustrates the proposed system and design process. At the center is a design space represented by two wheel plots, which consist of design input parameters and performance attributes. Each spoke of the wheels corresponds to a single design parameter. The polygon inside the wheel denotes a unique set of parameter selections. The maximum and minimum of a parameter are at the wheel center and perimeter.

In this VABB cutting problem, the design inputs involve three types of data, which are rotary motor data, needle geometric configurations, and tissue library. The motor data provide choices of motors with different torque-speed characteristics. Motor choices affect the rotation speeds of the cutter. The needle configurations list all combinations of the coaxial needle dimensions. The tissue library includes mechanical properties of two main types of the breast tissue, which are fibroglandular and adipose tissue. These properties describe tissue behavior under deformation and fracture. Polynomial hyperelastic models are collected from the literature [5] to describe the tissue under deformation. However, to our knowledge, there is no existing fracture data related to the breast tissue. To be able to simulate the cutting, we assumed that tissue fracture occurs at a fixed strain of 0.6. This assumption can be replaced with more accurate damage models in the future.

Table 1 summarizes critical design input parameters for calculating performance attributes and thus creating the design space. An explicit dynamic model is created in ANSYS Explicit STR 15.0 to simulate tissue cutting. Using all of the design input parameters and their ranges and types, 60 design points are populated in a four-dimensional space. These design points are solved in an HPC batch system and the computation performance is compared with desktop workstations. Simulation results are returned and ready to be used in the wheel plots (see Fig. 2).

3 Results

ANSYS simulations are performed on an HP Linux Cluster with 1134 compute nodes located at Minnesota Supercomputing Institute. Each compute node has two-socket, quad-core 2.8 GHz Intel Xeon X5560 processors. The simulation time for solving a single design point without parallel computation was 111 min. In another test, three compute nodes were used to solve three design points simultaneously. All the design points were solved within 120 min, which showed an excellent scalability of the HPC system. The effect of the parallel computation was also observed by solving a single design point in eight cores. The simulation time was reduced from 111 to 32 min.

A Design of Experiments study was created in ANSYS DesignXplorer using 60 design points. Figure 3 shows a plot of the force computed on the tissue surface toward the cutter versus different rotary cutting speeds. The result showed the tissue force increases as the cutting speed increases and as the contact area becomes larger.

4 Interpretation

One achievement of the proposed system is being able to populate a large design space with significantly reduced computation time. It took more than 175 h to obtain 60 sample solutions on a desktop workstation (first column in Fig. 4). Taking advantage of the HPC, our process is estimated to reduce the total computation time to 384 min. This result demonstrates an enormously high efficiency for populating the solution space for this tissue-device interaction problem.

The other important achievement of the proposed system is providing relationships between design inputs and performance attributes. These relationships are built from different data sources by combing design inputs, finite element analysis predictions and other post calculations. Using these relationships, the designer can quickly explore design options to understand relationships between design parameters. For example, if a design goal is to maintain the tissue cutting force under a certain value to provide a good-quality cutting, the designer can perform an inverse search to find design candidates that satisfy that goal. To accomplish this, the designer indicates an increase on the wheel spoke associated with the peak cutting force; the system then searches through the design point sampling and displays all of the results that produce this increase. Repeating this process, the designer will soon discover that the main factors that several needle dimensions and slice/push ratios (i.e., the ratio of cutting rotary speed to translation speed) mainly affect the cutting force. Then, the designer can lock less critical parameters and find a best solution under the prescribed conditions.

In conclusion, the proposed system creates possibilities to integrate finite element modeling at the early stages of device design. Design exploration in a large design space with multiple data sources is enabled. More design insights can be provided before producing physical prototypes for animal and subject tests. Future work includes improving the accuracy of the cutting model and fully implementing the 4D simulation data into the virtual prototyping system to enable the design exploration with visualization of the tissue-cutter interaction.

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