An Human-Centered Design Approach for Devices Interacting with Soft Tissue

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Background: Computational modeling and simulation technologies have been widely used in the development of medical devices. Design optimization tools and high performance computing have made it possible to efficiently generate extensive analysis data by solving sophisticated models. However, engineers need to be better guided to optimal design solutions when exploring large multi-dimensional data sets. In that context, traditional data visualizations such as 2D and 3D plots are often not sufficient to provide useful information. We propose a new design approach that integrates modeling and simulation data into an interactive design interface: Design by Dragging (DbD) system. The system provides a human-in-the-loop method for exploring design spaces. A design example of vacuum-assisted breast biopsy (VABB) device is used to demonstrate how engineers can participate the design process through interactions with the design space and find best design solutions step-by-step.

Methods: A tissue retrieval process of a VABB device is studied. The problem consists of three main components: a coaxial needle system, a motor system as a driver of the inner needle (cutter) and the breast tissue model. During the biopsy procedure, the needle is inserted into the breast and a portion of the breast tissue is pulled into the outer needle chamber by suction. Then, the inner cutter is driven by the motor system to rotate and translate forward simultaneously to remove a tissue sample. A dynamic finite element model is developed using ANSYS Explicit STR to simulate the tissue-cutter interaction encountered in the cutting process. The model predicts the reaction forces of the tissue on the inner needle during the cutting. The force data is used to evaluate the motor selection. ANSYS Workbench R15 is used to populate and solve 90 finite element analysis (FEA) runs. A customized Matlab program is developed to compute the performance attributes of the device. All of the input and output data forms a design space of 450 design configurations, where many trade-offs exist between the design parameters. The DbD system provides dragging-based manipulations on the data fields to interact with the design space in a predictive manner. In this example, four interaction scenarios are performed to lead to a design solution. Details of each scenario and design insights gained are discussed.

Results: Four critical design parameters and six performance attributes were identified in the design example (see fig. 3 for parameters and their symbols). The generated design space was represented in the DbD system by two wheel plots, one of which corresponds to the input parameter fields while the other corresponds to the output performance fields. Each spoke of the wheels denotes a field parameter with its minimum at the wheel center and maximum at the perimeter. The red polygon inside each wheel signifies the current design configuration. Four dragging interactions were performed to lead to a best design solution. In interaction 1, we studied the effects of the slice-push ratio k (rotary cutting speed to linear cutting speed) on two performance attributes: V_c and m on the cutter. This was done by dragging the spoke of k while other two input spokes, v_l and T, are locked to specific values. The input spoke of M was freed, which indicated that the motor choice was not involved in this interaction. We quickly developed our understanding on the effects of the varying k for different cutting conditions, e.g. cutting adipose tissue when $v_l = 100\,m/s$. Next, interactions 2 and 3 were to study the performance of each motor choice in different v_l values. We easily found which motors had the overload/overheating issue in the required operation time. In interactions 1-3, we mainly manipulated the input fields and saw how output fields responded. This forward search process helped understand the effects of changes in the design parameters. In interaction 4, an inverse design was performed to find designs that provided larger V_s while w and c is reduced. Here, we first set the output spoke of V_s to its maximum. Then, we began to drag the other two spokes. By weighting those three output spokes while freeing the others, the internal algorithms searched the closest neighborhood of $V_{s,max}$ in the design space and suggested a best design solution located at ($v_l = 100\,m/s$, $k = 0.01$, $M = 3$). Another type of inverse search is also made possible by directly dragging on the spatially distributed field in the 3D visualization (fig. 2). For example, the designer can drag a high stress region on the tissue surface and indicate a moving direction. The DbD system will interpret this operation and suggest possible design solutions that result in the high stresses moving to the desired region.

Conclusions: The proposed approach takes a step forward to human-centered, simulation-based medical device design. We have demonstrated this approach in a non-trivial tissue cutting example. The approach is capable of utilizing engineering software tools that are widely used in the industry. Massive simulation data can be processed and imported into the DbD system to enable dragging interactions with the design space. This human-in-the-loop design exploration provides a step-by-step process for experiencing medical device design in real time and guides the designer to optimal design solutions.

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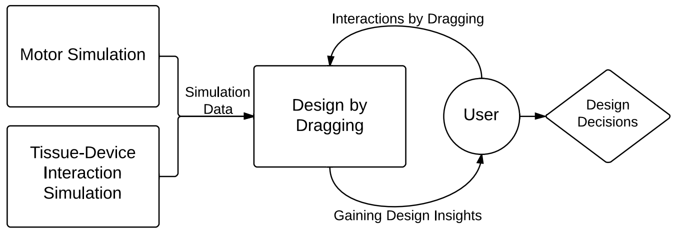

Figure 1: The framework integrates data into DbD system

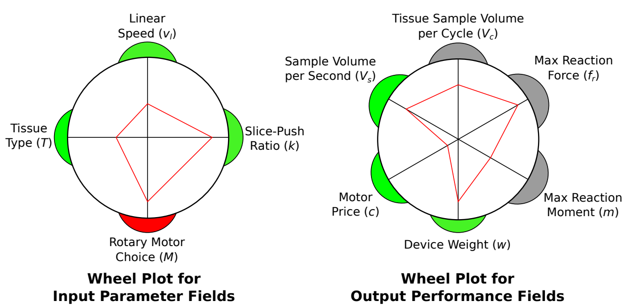

Figure 2: Wheel Plots

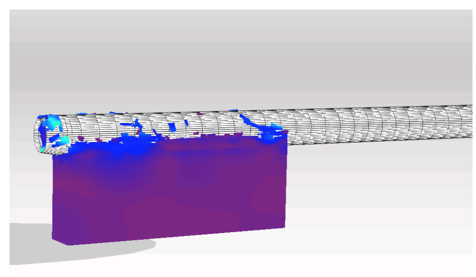

Figure 3: Visualization of the cutting simulation (the outer needle is suppressed)