A Process for Design, Verification, Validation, and Manufacture of Medical Devices Using Immersive VR Environments

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This paper presents a framework and detailed vision for using immersive virtual reality (VR) environments to improve the design, verification, validation, and manufacture of medical devices. Major advances in medical device design and manufacture currently require extensive and expensive product cycles that include animal and clinical trials. The current design process limits opportunities to thoroughly understand and refine current designs and to explore new high-risk, high-payoff designs. For the past 4 years, our interdisciplinary research group has been working toward developing strategies to dramatically increase the role of simulation in medical device engineering, including linking simulations with visualization and interactive design. Although this vision aligns nicely with the stated goals of the FDA and the increasingly important role that simulation plays in engineering, manufacturing, and science today, the interdisciplinary expertise needed to realize a simulation-based visual design environment for real-world medical device design problems makes implementing (and even generating a system-level design for) such a system extremely challenging. In this paper, we present our vision for a new process of simulation-based medical device engineering and the impact it can have within the field. We also present our experiences developing the initial components of a framework to realize this vision and applying them to improve the design of replacement mechanical heart valves. Relative to commercial software packages and other systems used in engineering research, the vision and framework described are unique in the combined emphasis on 3D user interfaces, ensemble visualization, and incorporating state-of-the-art custom computational fluid dynamics codes. We believe that this holistic conception of simulation-based engineering, including abilities to not just simulate with unprecedented accuracy but also to visualize and interact with simulation results, is critical to making simulation-based engineering practical as a tool for major innovation in medical devices. Beyond the medical device arena, the framework and strategies described may well generalize to simulation-based engineering processes in other domains that also involve simulating, visualizing, and interacting with data that describe spatially complex time-varying phenomena. [DOI: 10.1115/1.4002561]

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1 Introduction

From pacemakers to catheter delivery systems to replacement heart values, medical devices impact patient care in both routine and life critical settings. Replacement heart valves, for example, now save thousands of lives annually [1]. Despite the overall success of these devices, both mechanical and tissue-based devices

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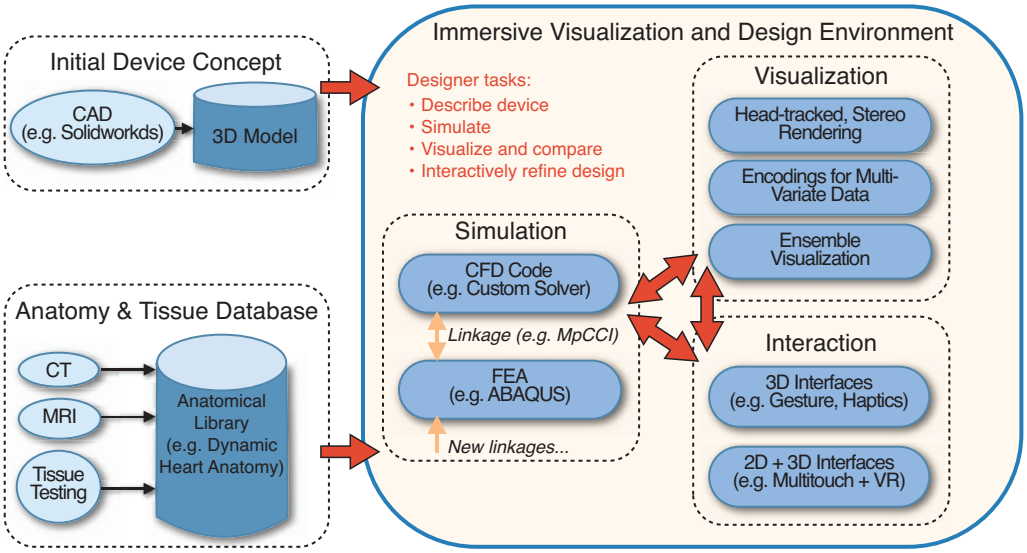

Fig. 1 Schematic of the vision for an immersive simulation-based virtual design environment for medical device designers

fail over time, sometimes within months to several years, and in the best of cases, within 15–25 years [2,3]. Improving the design and manufacture methodology for medical devices, such as replacement heart valves, could have major impacts on patient health.

Unfortunately, major advances in medical device design and manufacture currently require extensive and expensive product cycles that include animal and clinical trials. Competitive pressures often force initiation of animal trials without sufficient understanding of parameter selections based on bench tests and other preliminary analysis. In turn, this may lead to suboptimal results due to the lack of sufficient insight about the true impact of design decisions upon actual device success. An animal trial with a poor to average outcome may well prematurely kill a promising new device or therapy due to time and financial constraints. This is especially true of start-up companies who have limited funding.

This paper presents a vision for how these limitations can be overcome through advancements in simulation-based medical device design and manufacture. Given the increasing prevalence of simulation-based approaches in both engineering and science, moving from physical testing to virtual testing is a logical next step, but it is also an extremely challenging step. One of the primary reasons for this is that it is a multifaceted problem that is very difficult for a single company or research group to tackle. For example, simulating blood flow through the hinging mechanism of replacement heart valves at physiologically accurate conditions is a major research challenge in the area of fluid dynamics; significant advances in this area require new custom computational fluid dynamics (CFD) codes to be developed by researchers with years of experience in CFD techniques. Assuming these codes can be developed, the critical question then becomes, how can medical device designers interpret the massive data sets that result from high-performance simulations and how do they act on the new insights they gain from these data to refine the design of medical devices? It is well known that visualization (e.g., using virtual reality) is one of the best ways to understand simulation results, but it is very difficult to create easily interpretable visualizations of the massive data that result from just a single simulation result. To use simulation in real-world design processes, engineers will need to interpret hundreds of simulation results that will be generated from parameter studies and other sets of simulations. Creating effective visualizations for these data goes far beyond the capabilities of current tools and requires specific expertise in computer graphics visualization methods. Finally, to make simulation-based approaches useful for design, engineers need capabilities to modify complex medical device designs given the insights gained from visualization. This is extremely difficult to do with current approaches because computer-aided design (CAD) tools are not typically integrated with visualization and simulation systems. In the few cases where design, visualization, and simulation are integrated within a single software package, the interaction with the data is terribly limiting compared with what it could be. For example, user input is provided only via classic 2D windows-icons-menus-and-pointer (WIMP) interfaces that do not translate well to the immersive virtual reality (VR) environments that are likely to be so critical in interpreting simulation results.

2 Vision: Immersive Simulation-Based Medical Device Development

An improved medical device design process is outlined here to enhance the results of bench testing by inserting a new immersive simulation and design procedure in the product development process between bench tests and animal trials. The cornerstone of our vision is an immersive virtual environment that serves as the glue connecting multiple forms of simulation with interactive visualization and 3D modeling/design capabilities. If medical device concepts could be explored and tested in such an environment, then we believe this would make possible much more thorough testing and refinement of current device designs and exploration of high-risk, high-payoff ideas that are currently too costly and risky to explore.

2.1 An Immersive Design Environment. The schematic in Fig. 1 describes our vision for a virtual design environment that links together multiple data and simulation sources (e.g., CAD and anatomical models, finite-element analysis (FEA), and CFD analyses) with the goal of capturing the complexity of medical device systems via simulation and using visualization and interactive control to refine designs and ultimately improve medical treatments.

As illustrated in Fig. 1, in our vision, anatomical models that interface with the proposed medical device would be imported into the VR environment from databases built using computed tomography (CT) and magnetic resonance imaging (MRI) data and soft and hard tissue material properties to represent female

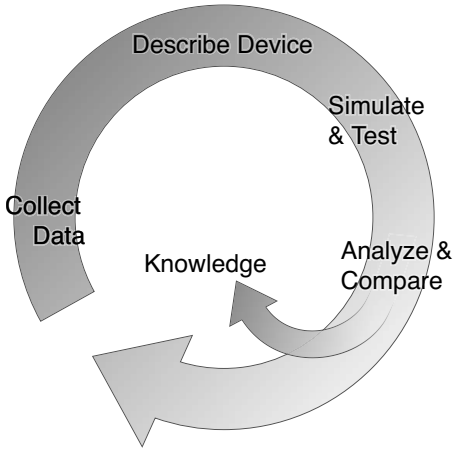

Fig. 2 The iterative design process that we aim to accelerate via an immersive simulation-based virtual design environment

and male norms and extremes. To begin working on a device design, initial device models developed with more traditional tools (e.g., PROE by Parametric Technology Corporation, Needham, MA; SolidWorks by SolidWorks Corp., Concord, MA) could be imported into the environment for simulation and redesign or the designer could start modeling a device from scratch using the built-in modeling interfaces provided within the environment. Intuitive 3D user interfaces, including haptic feedback, would be used to generate 3D device models, position them within anatomical models, trigger simulations, visualize results, and then refine the device design. The designer would be able to control, change, and monitor all significant design parameters and observe the resulting functionality of the device in 3D. Where blood flow is involved, CFD simulations would be used to model the pulsatile flow past implanted devices during both deployment and device use. To account for interactions between multiple types of simulations, the simulations would be coupled, for example, custom CFD simulations would be coupled to FEA simulations using real-time linkages, such as MpCCI. Multifunction devices would be driven by multibody dynamics packages (e.g., MSC ADAMS and PROE MECHANICA).

Such a design environment would be useful for interfacing with both interactive and offline simulations. We believe that there will always be a need to perform simulations at the highest resolutions and accuracies possible, necessitating offline computation—one role for this immersive environment would be to setup the initial conditions necessary to spawn a set of relevant offline simulations and then come back to the environment once they are finished to visualize the results. However, given recent trends in high-performance computing, we believe interactive simulation capabilities at resolutions and accuracies that can be useful for device design processes already exist in limited capacity today, and in the next 5–10 years, these capabilities, fueled by advances in multicore and GPU hardware, will redefine simulation-based engineering to make it a much more interactive process. If emerging interactive simulation capabilities can be coupled with an intuitive, visual design environment, then this could drastically improve the current design process, speeding up design iterations and providing more useful feedback to designers in a form they can easily understand within each iteration.

The iterative process we aim to support is diagramed in Fig. 2. Early design iterations would involve comparison of a number of "what if" scenarios defined via cyber brainstorming supported with 3D interfaces. Later, more detailed parameter studies and comparisons would be performed, supported by the same combination of simulation, visualization, and interactive control. Given that each iteration involves describing or refining a device design, simulating, and testing, and then analyzing and comparing results, it follows naturally that the entire process could be improved and accelerated if these tasks could take place within a single environment where designers can refine the geometry or placement of a device interactively in 3D as they view visualizations of simulation results.

2.2 Relation to Current Directions in the Field: FDA Expressed Need, Standards. Even though medical device companies utilize FEA, CFD, and other analytical tools to assist in understanding device function, there is no standard process across the industry or at FDA, and the use of simulation-based engineering in medical device design still lags far behind its potential. At a 2008 NSF/NIH/FDA meeting on computational tools for cardiovascular application, Dan Schultz, then the director of FDA's Center for Medical Devices and Radiological Health, in his keynote address, called for the community to come together to improve the application of computational tools in device development [4]. Likewise, the FDA's Critical Path Initiative specifically calls for stimulating and facilitating a national effort to modernize the scientific process through which a potential medical device is transformed from a discovery or "proof of concept" into a medical product [5].

Building on these themes, the two subsequent NSF/NIH/FDA meetings have included an increased emphasis on defining acceptable standards for using FEA/CFD simulation for medical device certification. At these meetings, a series of presentations made by medtech companies to FDA panels has made clear the current difficulties of making proper evaluations and making suggestions for how to improve specific methods used. There is growing interest in creating standards, particularly in FEA modeling of specific organs, heat transfer in solids, and interfacing with fluids. Following the June 1–2, 2009 FDA Workshop on Computer Methods for Cardiovascular Devices, the ASME V&V Standards Committee agreed to explore the idea of forming a new V&V Subcommittee related to the application of a verification and validation methodology to medical devices. There are already ASME standards documents for the general areas of computational fluid dynamics and heat transfer (V&V 20-2009) and computational solid mechanics (V&V 10-2006).

From these recent activities and calls to action, it is clear that simulation-based engineering will play a critical role in the future of medical device engineering. Our particular aim is to understand how advances in simulation capabilities (e.g., hardware, software, visualization, interfaces) can best be exploited by device designers to make a real impact in the device development processes and ultimately in the creativity and quality of devices developed.

3 Framework and Initial Results

Given this introduction to our team's high-level vision, we now describe a specific medical device design case study that we have been investigating together with our industry partners, and we describe the immersive VR framework and software tools we have developed to date using this case study as a driving example to propel us toward our long-term vision.

3.1 Application Case Study: Designing Improved Replacement Heart Valves. Each year, 5 million Americans learn they have heart valve disease [3]. Mechanical heart valves are widely used to replace diseased and dysfunctional native valves; 106,000 valve replacement and repair procedures are performed annually [1]. Mechanical valves can function for as long as 25 years [2], but in other cases, valves need to be replaced within months or years after implantation. Thus, improving the longevity of replacement heart valves is an important goal. Although replacement heart valves have been used extensively in clinical practice since the 1950s, current devices are essentially "analogous to the first generation of devices developed 50 years ago" [6]. A fresh, creative approach to refining the design of these devices, especially one that is able to better predict the longevity of proposed

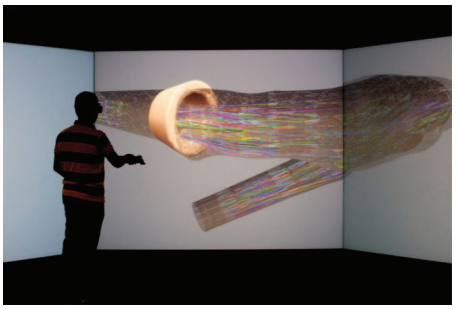

Fig. 3 A virtual reality visualization of simulated blood flow through a replacement heart valve implanted within a model of an aorta constructed from imaging data

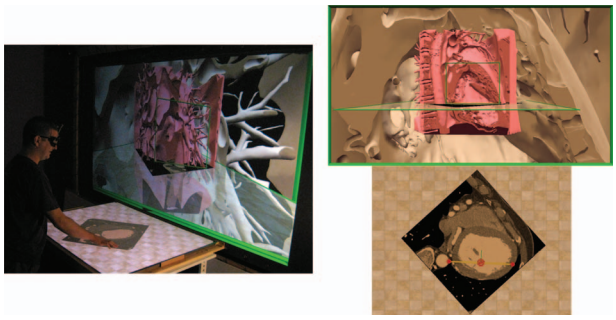

Fig. 4 A multitouch table used in conjunction with a rear-projected VR display to interact with simulation results. Left: The visualization environment. Right top: The imagery shown on the VR wall from the user's perspective. Right bottom: The imagery shown on the table from the user's perspective.

devices, is critically needed.

Once in place, the alignment, size, mechanics, and material properties of replacement heart valves can all have major implications for the success of the device. Considering potential variations in these parameters, the design space for these devices is exceptionally large. Additionally the interactions with blood flow and surrounding tissues are complex and very difficult to simulate. These devices can work perfectly in bench top models, and then fail in animal trials for reasons unknown to the designers.

The design of the pivot or hinge is one of the most important considerations for heart valves. The pivot is generally a recessed area on the inner surface of the annulus. The leaflets fit into these recesses, allowing the leaflets to open and close. The design directly affects the range of motion and acceleration of the leaflets between opening and closing, which in turn has a direct impact on noise, wear, leaflet fracture, and, of course, the flow characteristics of the blood. Recent work has explored both novel hinge designs and the use of polymeric materials to address this challenge [7–9]. However, no industrywide design changes have resulted from this work, and the leaflet and annulus interface remains perhaps the most important focus for future efforts to refine valve design [10].

Complicating the design, a biological concern in this area is that the delicate blood cells have a tendency to be damaged and destroyed if they are trapped between the leaflet ear and the hinge recess. This phenomenon is termed flow stagnation and can lead to thrombus and emboli formation. The formation of thrombus or emboli restricts leaflet motion, resulting in more thrombus formation, which puts the patient at great risk. No current heart valve design has solved this problem; therefore, patients are required to undergo lifelong anticoagulation therapy. Improved pivot design could lead to reductions and eventual elimination of this therapeutic anticoagulant dosage [11].

Our team's work has begun by utilizing existing commercial tools (PTC PRO/E for CAD modeling and MSC ADAMS for mechanical simulation) to generate a series of potential pivot/hinge designs. Our mechanical engineering team members export these designs to our CFD team members, who have developed state-of-the-art CFD simulations to capture the flow of blood past the device geometries. Our visualization and human-computer interaction team members then display the output of the simulations in a virtual reality environment that includes innovative 3D interfaces for interacting with the data. In Secs. 3.2–3.5, we describe some of the details of this design pipeline. As our simulations, visualizations, and interfaces evolve, our goal is to continue to expand the role of the virtual environments pictured in Figs. 3–5, moving ever closer to the integrated vision presented in Fig. 1.

3.2 Physiologically Accurate Simulation. Simulating physiologically accurate blood flow through implanted biomedical devices in patient-specific anatomic geometries requires a powerful CFD methodology. These simulations need to account for the dynamic deformation of the vasculature, for example, by integrating the instantaneous 3D anatomic geometry at every simulated instant during the cardiac cycle as input to the simulation. CFD simulations for this case study also need to be coupled with appropriate finite-element codes in order to model the coupled interaction of hemodynamics with complex medical devices.

Existing CFD software (both commercial and experimental) lack the flexibility and efficiency required to be integrated in the envisioned virtual design environment; thus, our work to date has instead utilized the custom computational research results of the CFD team members, who have worked extensively in the area of CFD modeling for bileaflet mechanical heart valves (BMHVs). Relatively few simulations of BMHV flows previously reported in the literature have employed 3D fluid-structure interaction (FSI) approaches and these have either adopted simplifying symmetry assumptions, which are clearly invalid in anatomic simulations, or used rather coarse numerical resolution yielding a simulated flow environment downstream of the valve leaflets that is significantly simpler than observed in experiments. Therefore, even though the BMHV problem has been tackled before in the literature with custom-made and commercial CFD codes (results appear routinely in advertising brochures and websites of several major CFD vendors), our team members were the first to resolve this complex FSI problem at physiologic conditions and at hemodynamically relevant scales (e.g., Refs. [12–15]), including 3D modeling of flow in the important valve hinge mechanism. In particular, these simulations were the first to capture the explosive transition to a turbulentlike state at peak systole and simulate the actual instantaneous flow environment experienced by blood cells downstream of the valve leaflets.

Developing a virtual environment that can interface with these custom CFD solvers has been an important focus of our work to date. We have created an initial pipeline to support moving from custom simulations to the visualizations pictured in this paper via a series of data processing scripts. This processing transforms the data into a common, extensible format that can be inputted into the virtual reality environment. The format organizes the data according to flow lines that we call "data lines." Each data line

Fig. 5 Gestural 3D input from a 6 degree-of-freedom virtual reality wand is used to implement a selection technique within a VR visualization of blood flow. The user sketches a 3D lasso around a region of the flow.

contains both the pathway that a particle would follow through the computed flow (streamlines, streak lines, or path lines) and an extensible array of data stored for each sample along these lines. The extensible data line format is a critical aspect of the design of our virtual reality system, in that it makes it possible for the VR environment to accept input from both our current custom CFD solver and other simulations. For example, as we work toward our vision, our team is developing infrastructure to couple custom CFD simulations with commercial FEA tools. As new results from these multisource simulations come online, we can easily extend the data line structures that we have built to store additional data variables and geometries in order to facilitate transferring the data into the virtual reality visualization environment. Our current work implements this data pipeline as an offline process, but we are also actively engaged in using new hardware advances (e.g., high-performance computing based on GPU technologies) to enable interactive simulation. Thus, as technology pushes forward, we believe that it will be increasingly practical to simulate medical device related phenomena interactively, rapidly processing the resulting data to prepare it for visualization, and then interactively exploring the visualizations, gaining insight and refining device designs to spawn new simulations, following the iterative process described in Fig. 2.

3.3 Visualizing CFD Simulations in Immersive VR. Immersive environments (VR) offer tremendous potential for visualizing and interacting with spatially complex data. In our work, we have utilized several different VR environments, including a 8.5 $\times$2.3 m, three panel stereoscopic display wall at the Minnesota Supercomputing Institute (see Fig. 3) and a smaller 2.4 m wide VR wall coupled with a multitouch table display (see Fig. 4). To make the rendering interactive, a cluster of computers drives both systems, using open source software we developed to handle input from VR devices and output synchronized stereoscopic imagery to the multiple projectors used in each setup. The software renders a separate computer graphics scene for both the left and right eye and the user wears shutter glasses that are synchronized with the projectors in order to deliver the correct image to each eye so that the user sees in stereo. Another important aspect of these systems is that the user is head tracked, meaning that a tracking system has been installed in each of our VR setup rooms to report the user's head position to the rendering computer in real time as he moves around the display so that the scene can be rendered correctly from the user's viewpoint.

The resulting head-tracked, stereoscopic view is critical to an effective presentation of the data for several reasons. The stereoscopic rendering helps the user understand depth in the scene. For example, the aorta model pictured in Fig. 3 appears to the user to float in the air in front of the projection screen. The head tracking also improves depth perception. Motion parallax is an even more important depth cue than stereo, and with head tracking, motion parallax is created naturally as the user moves around the display and the perspective projection of the graphics updates accordingly. The head tracking also provides the benefit of being an intuitive strategy for navigating around 3D models. To see the aorta pictured in Fig. 3 from a different angle, the user can simply walk around it or duck his head inside the model.

We are using this base level of VR hardware and software infrastructure to develop new visual representations and interaction techniques for exploring complex data sets. Figure 3 shows one of our current visualizations of simulated blood flow through a replacement heart valve implanted within a model of an aorta constructed from imaging data. The data were simulated using the custom flow solvers developed by our CFD team members. In addition to the navigation via the head tracking described earlier, a 3D wand is held in one hand and can be used to reach out and grab the model to rotate and scale it. The flow data are represented by colored particles that animate through the geometry in response to the underlying flow data and change length in response to the speed of the flow. Extending our previous virtual reality visualizations of time-varying flow data [16,17], our current visualization work is focused on advancing this visualization approach to address two main challenges. First, these data are multidimensional. The current visualization displays time, speed, and direction of flow, but not other variables, such as vorticity, pressure, and shear stress. We are developing new visual encodings that facilitate visualizing all of these data together in a single VR display so that correlations may be easily drawn between multiple variables. Second, the visualization pictured in Fig. 3 shows the result from just a single simulation run. For this type of environment to really be useful to device designers, new ensemble visualization capabilities are needed, which make it possible to view results from several to hundreds of simulation runs within a single visualization, so that the impact of various device parameters can be evaluated visually.

3.4 Human-Computer Interfaces for Data Exploration. New human-computer interfaces are necessary to make it possible for medical device designers to more effectively navigate visualizations of simulation results and refine device designs interactively. Figures 4 and 5 demonstrate 3D virtual reality interfaces that begin to make this possible. (See Refs. [16,18] for technical details of these interfaces.) The interface shown in Fig. 4 explores the potential of a unique VR environment that combines the rich input of a multitouch table, which senses input from all of the user's fingers, with a head-tracked stereoscopic vertical VR wall. Using this environment, the user shown in Fig. 4 is navigating through a 3D model of the heart extracted from a CT image using an interaction metaphor intended to overcome the common problem of becoming lost when immersed within complex virtual environments. The interface is based on a "world in miniature" metaphor, similar to using a map to maintain context while exploring a new environment. The table displays a horizontal slice through the CT data. On top of this imagery, several navigation widgets are drawn to indicate the current viewpoint of the user. He can touch these widgets with his fingers and move them on the display to adjust his position, as if pointing to a new landmark on a map. Since the heart is a 3D environment rather than a flat environment, the map metaphor is extended to 3D with a miniature version of the CT data that floats above the table (see Fig. 4, top right). The height of the 2D slice through the CT data can be adjusted in this view. Once a new viewpoint is set, the user is teleported to a new portion of the data, which then fills the large vertical screen, as seen in Fig. 4, left.

This interface makes a rich, fluid style of interaction possible to address the problem of 3D navigation through biomedical environments, which is perhaps the most fundamental interactive need of designers exploring simulated biomedical data. One of our goals in this work is to discover the extent to which multitouch input can facilitate real-world engineering tasks. Given the popularity of commercial products, such as the iPhone and iPad, there is great interest now in multitouch interfaces and general agreement that multitouch can provide very natural styles of interaction. However, to date, the applications that have been developed to use multitouch technology are mostly in the area of entertainment (e.g., photobrowsers). We believe that if appropriate metaphors, such as the world in miniature combined with a table + wall display described above, can be developed, then medical device engineering tasks can be significantly accelerated by combining the intuitive power of multitouch interfaces with the spatial data processing advantages of VR displays.

In addition to navigating through data, device designers also require abilities to select and query data and adjust parameters of VR visualizations. Figure 5 illustrates a VR interface aimed at supporting this style of interactive control of visualizations directly within a VR environment. In large-scale VR environments, such as the one shown here, traditional input from a mouse and keyboard is cumbersome since the user stands up to view the data. Intuitively, the "right" way to interact with such a VR visualization is to leverage the capabilities of the user's hands to work

directly in the same 3D space where the data are visualized. The challenge in supporting this type of 3D interaction is capturing and interpreting 3D input from the hands and then designing appropriate metaphors for interacting with the data based on 3D input.

The metaphor illustrated in Fig. 3 is based on sketching; in VR, this means that the user holds on to a 6 degree-of-freedom tracking device (a wand), and as he moves his hand through the air, a trail of virtual paint is left behind. Since the interaction occurs in the air, the curves drawn do not need to be planar, and sketches can be drawn in and out of the screen as well as in a vertical orientation, as shown in Fig. 5. Within the blood flow visualization shown in Fig. 5, the sketching gestures are interpreted as a 3D selection technique, i.e., the user draws a lasso around the portions of the flow he wishes to select. After selecting a 3D region, the visualization can respond in several ways. One option is to use the selection to filter the data; e.g., only visualize the flow that passes through the selected 3D region. Multiple selections can also be used to customize the visualization. For example, the user can select all of the flow passing through the right side of the anatomy, assign a yellow color to particles flowing through this region, and then select the left side of the anatomy and assign a red color to particles flowing through this region. Then, he can navigate through the VR environment to move downstream to investigate the mixing and spatial patterns formed by the red and yellow regions of flow.

We believe interfaces such as this one can have a major impact on medical device design processes because they enable interactive data exploration. Rather than simply looking at a picture or animated visualization, these 3D gestural interfaces make it possible for designers to truly immersive themselves within data visualizations and interact with the data in 3D. At present, our work has focused primarily on using this style of interaction to adjust visualization parameters; however, as we describe in the vision presented earlier in the paper, we believe that this same type of gestural 3D interface can be used to modify device designs directly within VR.

3.5 Extension to Manufacturing Simulations. A natural extension to the use of 3D VR environments for medical device design is to include manufacturing simulation as well. From component level tolerances and clearances to predictable assembly variations, we envision that the VR environment described here can be naturally extended to support consideration of variations (e.g., geometric dimensions and stiffness) in manufacturing processes. A manufacturing simulation module could enable reliable prediction of properties of devices exiting the manufacturing/assembly process, improve the good manufacturing practice (GMP) results, and help ensure regulatory compliance. Likewise, beyond medical devices, the integrated simulation, visualization, and interaction framework outlined here may apply to a variety of other engineering domains that also require design and analyses of spatially complex and time-varying systems and phenomena.

4 Conclusion

Drastic improvements in high-performance simulation are clearly needed in order to model and test medical devices with high accuracy under realistic conditions, but this is not enough. New strategies are also needed so that designers can interpret the vast amount of data that would result from a device parameter study that might require hundreds of simulation runs. Current custom and commercial design packages continue to advance, but none currently provide an integrated ability to interface with superhigh resolution simulations, use cutting-edge visualization techniques to facilitate data analysis, and use interactive techniques that fit within a designer's workflow to support iterative design refinement. Such a system would not just make new data available to designers; it would radically change their daily workflow. It is this type of close connection between the simulation and the daily engineering activities of medical devices designers that is elusive in practice, but that we believe the process and immersive environment described here can greatly facilitate.

To realize this vision, our team is taking a multidisciplinary approach that includes advancing computational simulation, visualization, and interaction tools in tandem. If successful, we believe the resulting system will enable designers to gain new knowledge about optimal device configurations and deployment strategies; design more robust devices, including patient-specific devices; and reduce cost and the time to market for new devices by accelerating development cycles. Ultimately, this can have a significant impact for future patients, as new and improved medical devices lead to increased quality of and prolonged life.

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