# Grand Challenge: Applying Regulatory Science and Big Data to Improve Medical Device Innovation

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***Abstract*—Understanding how proposed medical devices will interface with humans is a major challenge that impacts both the design of innovative new devices and approval and regulation of existing devices. Today, designing and manufacturing medical devices requires extensive and expensive product cycles. Bench tests and other preliminary analyses are used to understand the range of anatomical conditions, and animal and clinical trials are used to understand the impact of design decisions upon actual device success. Unfortunately, some scenarios are impossible to replicate on the bench, and competitive pressures often accelerate initiation of animal trials without sufficient understanding of parameter selections. We believe that these limitations can be overcome through advancements in data-driven and simulation-based medical device design and manufacturing, a research topic that draws upon and combines emerging work in the areas of Regulatory Science and Big Data. We propose a cross-disciplinary grand challenge to develop and holistically apply new thinking and techniques in these areas to medical devices in order to improve and accelerate medical device innovation.**

***Index Terms*—Big data, medical devices, modeling and simulation, regulatory science, virtual reality, visualization.**

## I. Introduction

ACCELERATING design and development of medical devices and creating novel, improved methods for evaluating proposed devices are some of most challenging and critical topics for biomedical engineering research. We envision a bright future in these areas, but it is clear that many fundamental advances in science and technology are required to realize this future. We argue that by closely interfacing cutting-edge research in several fields, including engineering, life sciences, medicine, and computer science, and by linking research in both academia and industry, we can develop valuable new theories, practices, and technologies that will dramatically improve the ways that we create medical devices. We propose a new interdisciplinary research agenda based upon the grand challenge of applying new approaches from emerging research in regulatory science and big data to improve innovation in medical device design and, ultimately, also the approval process for medical devices.

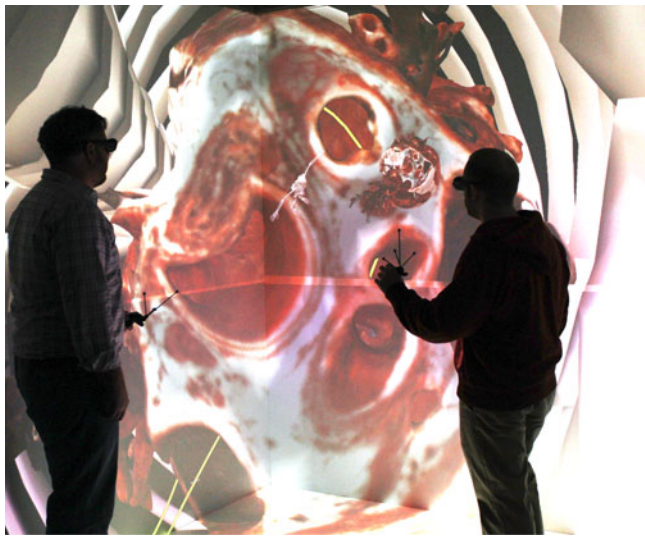

Fig. 1. Large-scale interactive visualization of anatomical data in a four-wall immersive Cave environment. Data: National Library of Medicine Visible Human Project.

The Food and Drug Administration (FDA) defines regulatory science as "the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products" [1]. The FDA's Center for Devices and Radiological Health (CDRH) defines seven key priorities in regulatory science. The first is "Advancing Medical Device Innovation and Evaluating New and Emerging Technologies," and the first point under this heading is "Revolutionizing Device Design Using Computational Modeling" [2]. There is a clear need and urgency to develop the new science base necessary to support innovation in device design, improved quality and manufacturing, and improved analyses of device performance.

We believe that research into novel computational tools for working effectively with big data (see Fig. 1) will become one of the most important aspects of regulatory science, impacting education and practice in both industry and regulatory agencies for years to come. Within the computer science community, J. Gray of Microsoft has dubbed the big data phenomenon, which seems to impact almost every branch of science and engineering, a new "data exploration" paradigm of discovery [3]. How will medical device engineers innovate within this new paradigm? How will regulatory agencies make informed decisions? How will humans move from data to actionable insight? These questions are all fundamental to the future of regulatory science.

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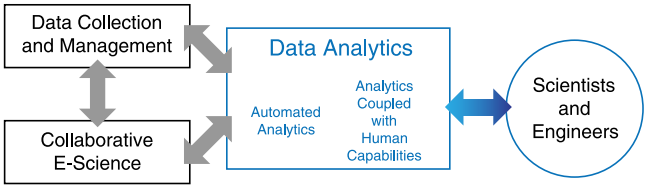


Fig. 2. For regulatory science, one of the most important aspects of big data research is Data Analytics, which is a key for moving from data to human insights.

One way of conceptualizing these questions and challenges is to place them within the context of a broad research agenda in big data science, as diagrammed in Fig. 2. One of the most important big data focus areas for regulatory science is data analytics, as it provides the interface between data and the scientists and engineers who work with these data. We conceive of data analytics as being composed of two complementary and closely intertwined styles of analysis: Automated analytics and analytics coupled with human capabilities. Automated data analysis is critical; for example, consider the essential role that fully automated star template matching plays in the Sloan digital sky survey [4], [5]. Complementing this style of analysis, many tasks also require human engagement at the innermost loop in the data-analysis pipeline. One important example is simulation-based engineering. This powerful methodology involves an iterative process of interpreting multimethod data from finite-element analysis (FEA), computational fluid dynamics (CFD), mechanical, and/or multiphysics simulations; generating new insights and hypotheses based on these interpretations; creatively revising and reworking models and parameters; and then restarting and retargeting simulations to work toward an optimal design. We note that for some simple problems, this process can proceed in an automated way (e.g., via exhaustive search), but, typically, for exciting, high-impact engineering problems, it is the insights and decisions of the engineering team members that make the real difference; thus, new interfaces that bridge the gap between data and human understanding (see, e.g., Fig. 1) are critical.

In the remainder of this paper, we describe how processes, such as data-intensive simulation-based engineering, can make a major impact in the medical devices community and how new research can help to enable this future. We begin with a discussion of current practices in the field and immediate challenges to reenvisioning these practices. We then describe recent initiatives at the FDA, including new partnerships between the FDA and medical device stakeholders, which demonstrate not only the importance and relevance of the grand challenge, but also the willingness of stakeholders across academia, industry, and government to push forward with new initiatives in this area. Finally, we describe a series of recent results from our own research in this area.

## II. Transforming the Medical Device Design Process

### A. Current Practices

The medical devices and equipment industry employs more than 411,400 workers, accounting for nearly one-third of all U.S. bioscience jobs. Innovation in this field can have a direct positive impact on health outcomes. Perhaps, the biggest roadblock facing designers of replacement heart valves, catheter delivery systems, and other important medical devices is the lack of new and deeper insight to bring to bear on these challenging design problems. Currently, major advances in medical device design require extensive and expensive product cycles that usually include animal and clinical trials. Although animal trials yield important insights that may be used to optimize a design, the transition to animal testing is often accompanied by essentially a design freeze, a contributing factor being the high cost of design changes at this stage of the product development process. Thus, there is great motivation to improve the understanding of the device/anatomy interface prior to embarking on animal and human trials.

There have already been some important steps taken in this direction. Computer modeling, using CFD, FEA, and other simulations, is familiar to the medical device industry; however, such modeling is often focused on specific component, subsystem level, and stress–strain relationships. Bench tests and computer modeling and simulation are used currently by some medical device companies to provide preliminary data before entering into animal or clinical trials, but these data are often insufficient to provide a full understanding of the impact of critical design parameters on device function and eventual success. Another complicating factor is that competitive pressures often force initiation of animal trials before there is time to thoroughly explore design alternatives using existing design approaches and tools. These factors all too often lead to suboptimal devices, and, even worse, a premature trial can lead to poor to average results that completely shut down a project that may have eventually resulted in a high-impact device or therapy. Some focused modeling is used in regulatory submissions to examine "worst case" or "extremes" of device design and use, but a company's ability to provide sufficient design rationale for regulatory approval (or for regulatory agencies to properly assess design features) can also be limited. There is a need to extend modeling and simulation practices to system level applications and use modeling and simulation to optimize for a broader set of practices, interfaces, and material variability. If these tools can be coupled with understandable visualization systems, then this also opens up new opportunities for further design input from physicians and patients.

Modeling and simulation have also been utilized extensively in the academic research community. New analytic and finite element models have been developed in order to build surgical simulations or steerable simulation tools (see, e.g., [6]–[9]). Closer to our interests, simulations have been developed and applied directly to device design processes, where both custom and commercial codes have been used to better understand device/anatomy interfaces for radiofrequency ablation [10], endoscopy [11], wearable biomedical sensors [12], spinal implants [13]–[15], middle ear implants [16], head immobilization [17], breast biopsies [18], magnetic resonance imaging coils [19], and even wheelchair seats [20]. These efforts suggest the crucial role that computational methods and big data can play in device design; however, much more can be done.

For example, although several of the examples cited previously include parametric design studies, the scope is limited compared to what is now being enabled by advanced computational techniques and high-performance computing. To scale up to utilize the power of these new computational techniques in design processes the mindset of the designer needs to change, and new tools need to be developed to support this change.

Working toward this change, our experiences with simulation-based engineering (see Section V) suggest first of all that there are great benefits to developing simulation tools that specifically target including humans in the (real-time) design loop. This in itself represents a shift in the way that current simulation tools are typically applied to design. We believe that it is possible to develop new big data design tools that combine the power of computational engines and the ability of the design team steer the optimization process in real time. We argue that this can lead to a vastly improved medical devices solution platform.

Beyond early design efforts, we also foresee a dramatically increased role for simulation and modeling in the device regulation. Collaboration between the FDA and medical device companies in the precompetitive space can not only reduce uncertainty, but also move the entire industry toward a new collaborative model. Indeed, utilizing emerging technology, i.e., new computational tools, to achieve faster device design iterations, more accurate modeling of device/tissue interactions, and more complete data collection is a direction that is closely aligned with the FDA's recent efforts in regulatory science (see Section III).

We do not suggest that computer modeling and simulation will completely replace animal and human trials, but over time, the number of animal and human trials required for proof of safety and efficacy should reduce. Also, there are certain diseases that do not have good animal models, and double blind human trails are not appropriate in many situations. Thus, there is a clear need to use modeling and simulation in regulation. Again, we believe that it is critical to include the human in the loop in the new tools developed for these scenarios. For example, we believe that advanced visualization methods will be critical to enabling the new style of data-intensive communication between industry and regulatory agencies.

### *B. Challenges for Transformation to New Processes*

Modeling and simulation for medical device design is a multifaceted problem. Simulations must account for not only the mechanical properties of a proposed device, but also how it interfaces with different types of tissue and in different usage scenarios. Because of this, many simulations (and different types of simulations, e.g., FEA, CFD) are required to gain a complete understanding of the design problem. Computational methods are becoming a mainstay in product development and reliability determination with recent advances in multiphysics algorithm development and 3-D image reconstructions paving the way for physiologically accurate simulation and optimization of medical devices. Computational methods such as these typically generate very large mesh and simulation datasets. The challenges that come with this deluge of data include: creating, storing, sharing, and preserving big data throughout the design, analysis, and verification process to achieve transformational science and engineering.

In addition to these challenges, there is a need to shift the engineer/designer's mindset—the shift from working with a single dataset at a time to working with many datasets simultaneously. In the past, due to the volume of data produced and the lack of appropriate data analysis tools, designers were time limited when performing complex analyses and proceeded to bench tests and animal trials before they had fully explored analytical simulation options. Our vision is that designers will instead interact directly with an ensemble of thousands of simulation runs integrated into a virtual design environment that supports large-scale multidimensional data analysis and design optimization, leading to an improved, holistic understanding of design spaces supported by big data.

This vision raises new challenges in optimally coupling data-intensive modeling, simulation, and visualization tools with human capabilities. Major advances are required in real-time, scalable visualization and related methods to support human capabilities to see, touch, and ultimately translate data into on-the-fly decision-making. Although interactive data visualization techniques have advanced considerably in recent years [21]–[24], scaling the exciting style of human-in-the-loop computing illustrated in these results (e.g., real-time monitoring of modeling and simulation processes, visualization of large-scale parameter studies) to work with emerging massive datasets remains one of the most important and challenging problems in big data science.

## III. FDA Initiatives

The FDA Commissioner and the Director of the FDA's CDRH have been promoting Regulatory Science as part of new tools for the development of safer and effective medical devices. The CDRH and the Regulatory Review of Computational Modeling working group are leading an effort with the ASME V&V 40 Committee toward the verification & validation of computational modeling for medical devices. The FDA is also developing a virtual physiological patient, a library of models and data, and establishing a public–private partnership to "enable faster and better medical device development and evaluation via computational modeling and simulation."

These efforts will target several key challenges with current uses of modeling and simulation in the medical devices field. For example, one of the major current obstacles is the lack of appropriate standards and protocols. This is an issue in the design phase where models are created and simulations are run and analyzed; it is also an issue when it comes to communicating results to others, an area where we believe that the advanced visualization tools described in this paper may make a significant impact. Sensitivity and uncertainty analyses are also crucial; all models will have some biases, but these are often not appropriately captured and/or made obvious in the methods used to store and present results. Current validation efforts are not adequate; better defining what validation means to the medical devices community is an important challenge. Other challenges include the lack of complete understanding of physiological loads and

variations in patient populations, which are important requirements for both bench and computational studies.

## IV. Public/Private Partnerships

Building on the FDA-specific initiatives described in the previous section, a number of recent activities provide evidence of the ability for public and private medical device stakeholders to work together to address grand challenges. We believe that this model is exactly what is needed to address the big data and regulatory science challenges identified in this paper; we summarize some of the recent developments here.

In the FDA's "CDRH 2012 Strategic Priorities" [26], the following goals are listed under "Strategy 4.3 Strengthen Regulatory Science":

***Goal 4.3.1.*** *By December 31, 2012, CDRH will have in place mechanisms to enable collaborative work between FDA, our federal government partners and external constituencies to advance medical device regulatory science.*

***Goal 4.3.2.*** *By September 30, 2012, CDRH will expand computer modeling and simulation efforts to support regulatory science. CDRH will work collaboratively with our federal government partners and external constituencies to advance medical device regulatory science.*

These goals clearly call for new partnerships and also emphasize themes that are congruent with the challenge areas we describe in this paper. One way that these goals have recently been met is by the creation of a public–private partnership called the Medical Devices Innovation Consortium (MDIC) [27], which builds upon the memorandum of understanding signed in 2011, between the FDA and Life Science Alley, a Minnesota trade association [25].

The first and third authors have been actively involved in launching the MDIC. The following, adapted from the recent MDIC press release, underscores the goals of this new partnership.

The mission of the MDIC is to improve health through the application of shared knowledge in regulatory science to reduce the time and cost of device development, assessment and review, and assure the safety and effectiveness of medical devices through their total product life cycle. The MDIC will pursue several strategies in support of its mission:

1) Create a forum for collaboration and dialogue, working within a flexible governance structure to encourage broad participation from the different industry stakeholders including FDA.
2) Make strategic investments in regulatory science, utilizing working groups to identify and prioritize key issues and to request, evaluate, and implement project proposals that support the MDIC's mission.
3) Provide tools to drive cost effective innovation, emphasizing education, and the development of new methods and approaches with well-documented data and details to enable implementation.

The expected outcomes include meaningful dialogue with different constituents of the industry to identify specific actions that can be taken to

1) foster trust between industry and the FDA;
2) identify constructive ways for all industry members to be active in establishing a future for the med-tech industry;
3) shift the dialogue to a science- and data-driven interaction among the FDA and industry;
4) identify methods to share information among the FDA and industry to help both, become more informed and knowledgeable—these methods should be "institutionalized" versus through the periodic random events of today.

We believe that the opportunity for FDA, medical device companies, professional and trade organizations and academe to collaborate together in the precompetitive space through the MDIC is game changing. All parties agree that this partnership will help improve and make more efficient the U.S. medical device regulatory process. It is envisioned that the future will see better understanding of the complex interfaces between devices and human tissue. More elegant solutions to health care problems will be obtained quicker and with less cost based on much better understanding and confidence in modeling and simulation results by all MDIC parties. This confidence can translate into reducing the magnitude of animal and human trials without sacrificing safety and efficacy.

## V. Recent Advances in Big Data and Regulatory Science

In this section, we describe our recent research at the intersection of regulatory science and big data. At high level, our research shares many goals with the MDIC, and we recognize that the type of collaborations that it is poised to enable are likely the only way of achieving many of these goals:

1) Faster device testing cycles, allowing designers to quickly evaluate the effects of new sets of parameters, thereby lowering the cost of exploring creative new concepts.
2) More accurate modeling of the device/tissue interaction before the start of animal and human trials.
3) Creation of reliable tissue property databases.
4) More complete data collection and analysis than is possible via physical mock-up.
5) Increased modeling versus traditional build/test, predictive engineering, knowledge driven development, and fewer product design cycles.
6) An ability to expand modeling to include combination devices (device/pharma/drug delivery).
7) Eliminating current roadblocks including data accessibility/sharing, anatomical modeling, and 3-D visualization.
8) Dramatic improvement of the regulatory pathway by increasing clarity of technical requirements and streamlining regulatory review with stronger and more uniform and mutually accepted analytical tools.

The following sections describe our recent and planned work toward these goals.

### A. New Computational Approaches to Device Engineering

Fig. 3 illustrates the vision of the future design environment. (Additional detail on this vision is available in a recent article [28].) A team of engineers and doctors work in a collaborative

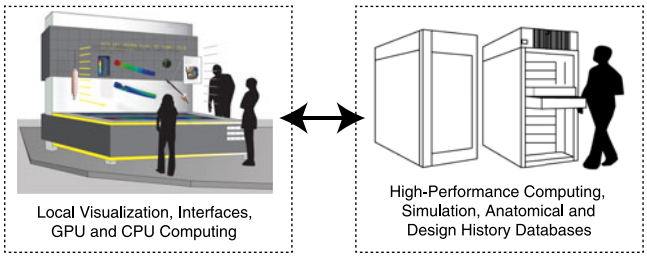


Fig. 3. Our long-term vision for technology that can support a paradigm-shift in simulation-based design of medical devices includes not only high-performance computing but also collaborative design environments that utilize multidimensional data visualization technologies and advanced human–computer interfaces.

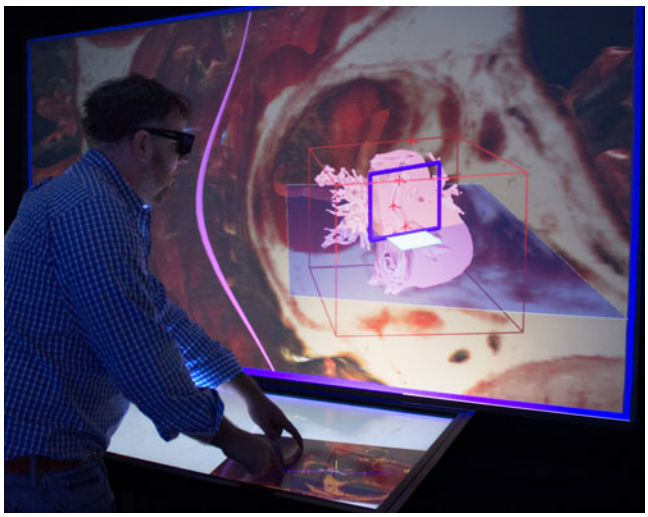

Fig. 4. Three-dimensional Touch Workbench hardware running a custom visualization application that uses multitouch input from the hands to interactively slice through 3-D imaging data. This example shows a 3-D virtual heart. A precise 3-D curve has been plotted through the anatomy to measure the pathway and clearances for a proposed catheter system. Data: National Library of Medicine Visible Human Project.

environment to explore multiple device designs visualized using color, texture, and other cues to depict multidimensional data from a host of simulation and anatomical data sources. Organ models, imaging data, FEA, and other analyses are displayed in a single registered space, which provides a significant advance beyond current tools in itself; however, the key advance is that the team can together explore not just a single data analysis, but rather, an ensemble of relevant modeling and simulation data. Novel interfaces and visualizations are used to do real engineering work directly in this environment—navigating, annotating, and (re)designing with the data. The environment includes a real-time connection to high-performance computing (i.e., supercomputers), providing the ability to visualize results in real time as simulations run on a supercomputer and enabling automatic "just in time" seeding of simulations as engineers explore the massive design space.

Fig. 4 shows one of the first major results working toward this vision, a 3-D visualization system that enables engineers and doctors to quickly explore a variety of multidimensional datasets, including 3-D imaging and device models. Both the

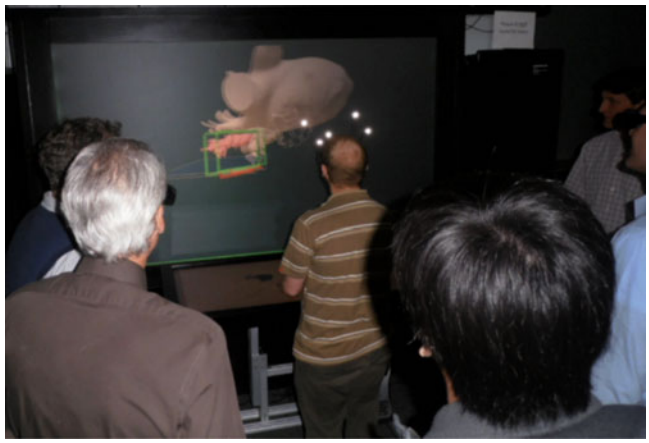

Fig. 5. Visualization of LAA device showing team interaction in a large-scale 3-D interactive environment.

display hardware [29] and interactive visualization software [30] have been custom developed for this application. The software utilizes a new human–computer interface we call the Interactive Slice WIM [23]. Key features include a new ability to slice through 3-D data using multitouch input to move interactive widgets on the table surface while viewing head-tracked stereoscopic imagery on the vertical display screen. An interactive 3-D map of the virtual environment is displayed to provide contextual information on the 3-D data, which is essential for maintaining spatial awareness when this virtual reality visualization environment is used to shrink oneself to the size of a blood cell to view detailed small-scale data. Engineers can export specific data and discoveries from this system, including volumetric selections and/or, as in Fig. 4, proposed 3-D paths that a catheter system might take through the anatomy.

We have developed a series of modules for this environment to support bidirectional communication with modeling and simulation tools that are in current use within industry (e.g., Solidworks, Abacus). This enables the work done in the immersive design environment to mesh with other existing simulation and design workflows. As diagrammed in Fig. 3, our long-term goal is to use this environment as an interface to high-performance computing environments. We have completed some initial demonstrations of this capability, but scaling up these algorithms and approaches to take advantage of large-scale, many-core computing environments remains an exciting challenge for future research.

### *B. Specific Example of Academic/Industry Collaboration*

These tools (hardware and software) have now advanced beyond the research lab and are being used in practice at Boston Scientific Corporation, where visualization has been introduced as another tool in the R&D product development toolkit.

Fig. 5 illustrates a specific example related to developing the WATCHMAN® left atrial appendage (LAA) closure device, which is approved for commercial use in Europe (see Fig. 5). This device is intended to close off the LAA and capture any clots that may form in the appendage, reducing the risk of stroke. It is introduced into the heart via a flexible tube (catheter)

through a vein in the groin. Modeling, simulation, and visualization have enabled engineers, scientists, and designers to gain a new perspective on disease states, anatomical conditions, possible device configurations, device to tissue interactions, and delivery approaches.

The 3-D touch table has enabled discussions with internal and external parties to review delivery practice, implantation techniques, and postimplant tissue remodeling processes. The richer interaction with physicians and customers has led to identifying challenging aspects of current products and practices as well as unmet clinical needs. New thoughts and solutions triggered by colleagues in functions adjacent to core product development (sales, sales training, clinical, medical education, regulatory affairs, and others) have also been valuable and are currently being evaluated.

### C. Future Outlook and Current Work in Progress

These experiences suggest to us that integrating visualization tools with computational tools will significantly improve the practitioner's design capability and capacity. Our outlook for the future is that product designers will have the tool suite needed to optimize configuration, material selection, surface conditions, tissue interaction, stress–strain parameters, and other design and use features. Computational power provided by big data platforms will enable broader assessment of the range of highly variable anatomical and physiological conditions that must be addressed. Such integration will ultimately lead to better, broader, and faster solutions.

Based on the work described previously in tool development and testing to bring human data from CT scans into a new visual presentation; designers, marketers, physicians, and others have already identified clear potential for applications that leverage new, anatomically accurate modeling techniques. The concrete example of analyzing delivery, implantation, and tissue remodeling of the LAA device is important. We have found that sharing the data for this application with physicians and designers experienced with the device has generated deeper discussion than was possible without the modeling and visualization efforts described here. Thus, an important benefit of big data tools is that they enable a broader set of anatomical configurations, device materials, delivery methods, and tissue interactions to be evaluated.

Although it is early, these efforts are now beginning to generate new thinking about simulations that can be validated and lead to reduced testing. Tremendous excitement exists from the early visualization advances that give designers new perspectives on device–body interactions, device delivery and implantation, and anatomical remodeling. We are confident that through continued open discussion, including with representatives of the FDA, there is a clear path toward a dramatically increased role for computational methods in bringing better and safer devices to market.

From a technical standpoint, the logical extension of the work described here is to develop a complete system that enables engineers/researchers to explore, query, and analyze multidimensional time-varying spatial datasets directly via 3-D data displays, and more importantly, to interact with these displays to analyze specific hypotheses, discover new insights, explore a variety of human tissue properties and disease states, and pose new hypotheticals.

Use of this technology is not limited to the heart or cardiovascular applications. Another exciting use of the platform would be an interactive 3-D spine model that could be used to simulate a surgical procedure or a disc replacement. Almost any problem area that includes the need to understand device–tissue interactions in a complex 3-D spatial environment is a good candidate for this type of technology.

Our current work in progress includes increasing the accessibility of tools in this style, for example, making it possible to access simulations and visualizations using a wide range of devices. High-end interfaces include the sophisticated fully immersive cave environment pictured in Fig. 1. This high-end system might not be needed by every engineering group in a company every day, but the immersion offers major benefits for working through major design challenges. The semiimmersive workbench pictured in Figs. 4 and 5 is intended to be the designer's *workbench of the future*. This environment is large enough to support collaboration but also small enough to be used regularly by a single engineer and to be installed without a major investment. We are also working toward smaller, desktop-scale environments that leverage 3-D TV and consumer computer game technologies and/or web-based OpenGL 3-D graphics delivered via a "cloud" client-server infrastructure.

Another major theme in our current work in progress is mixing virtual and physical representations for data. One advantage of our current system is the ability to have a 3-D interface that allows direct manipulation and exploration of the data, including the choice of boundary conditions. One beauty of simulation-based engineering approaches is the ability to quickly ascertain the influence of variations of these boundary conditions on the resulting simulation and conduct sensitivity analyses. Often, boundary conditions change as the device traverses different parts of the anatomy during a procedure. This too can be readily evaluated. Another advantage is to use the same exact 3-D information along with material properties specified in the virtual model to build up a physical model on the bench for validation and verification. Advanced rapid prototyping systems (i.e., additive manufacturing) are now able to print out objects including different durometers in the same run. Together, these technologies can enable a seamless integration of virtual and physical device prototypes. We view this type of *physical data* as an important component of the big data landscape. Big data and physical data both already contribute heavily to the device design process, but they are not as tightly integrated as they could be.

## VI. Conclusion

Today, many leaders in the medical devices industry agree that virtual prototyping (simulation-based engineering) could be the most important emerging supporting technology for making future devices safe and effective and for fostering new innovation in the field. Unfortunately, it is still extremely difficult for

engineers to adopt the most exciting advances in computer science and related disciplines into their daily practice. What makes the technologies and approach that we propose unique is that we embrace a holistic, human-centric approach to the problem of making simulation-based engineering useful. We couple simulation and modeling together with high-end data visualization and exciting human–computer interfaces (multitouch and 3-D input techniques) that are regarded as highly innovative within the academic research community. The result is a dramatically different experience for the medical device designer; simulations become not just a batch-mode tool for verifying a design but rather an integral, real-time tool for exploring design decisions and posing "what-if" scenarios. We are confident that these innovations can be a catalyst for advances in medical devices, and we are convinced that the right path to realize this exciting future is through the type of partnerships between industry and academia that will be made possible by additional university research, industry sponsored research, company funded internal product development projects, and efforts exemplified by the MDIC. As companies and FDA gain experience with computer simulation, the magnitude of animal and human trials will likely diminish, saving time and cost of bringing new medical devices to market.

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