ANALYSIS GUIDE FOR MEDICAL PRODUCT DESIGNERS

Overview

This guide to maximizing productivity gains in the medical design industry provides an overview of the challenges facing medical product designers. With examples from medical devices already developed, you will learn how SolidWorks® Simulation and virtual prototyping tools can help you solve these simultaneous challenges and gain assurance of product quality, reliability, and safety.

SOLIDWORKS

Introduction

Medical product designers and developers face a number of business and design challenges specific to the medical industry. Patient safety is as important a consideration as efficiency, effectiveness, and cost-containment in the design of such products as implants, drug delivery systems, diagnostic equipment, clinical laboratory instruments, surgical devices, and pharmaceutical packaging.

Business challenges

Today's medical industry is highly volatile and competitive, and changes almost on a daily basis. Designers have to develop new products quickly, at lower cost, while making sure of consistently high quality and performance. For example, when Tensys Medical Inc. developed the first noninvasive, continuous arterial blood pressure management system (see Figure 1), the company knew it had a narrow window of opportunity and needed to get the product out to the market quickly. It credits SolidWorks design validation tools with shortening the design cycle by 60 percent and helping it to create a new medical market space.

BENEFITS OF SOLIDWORKS SOFTWARE

- Shorten your design cycle
- Increase the quality and performance of your designs
- Create more innovative products
- Satisfy government mandates
- Reduce material costs

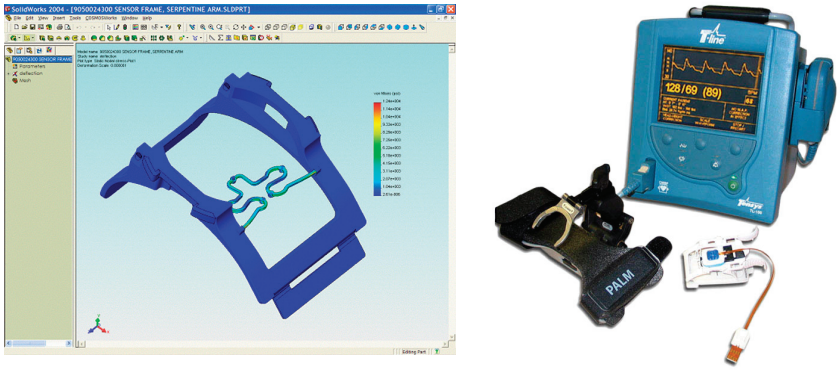

Figure 1: The first noninvasive, continuous arterial blood pressure management system, designed by Tensys Medical Inc.

Medical equipment developers also need to comply with government and consumer agency standards and requirements, while simultaneously adapting products to customer demand. When the Kerr Group designs over-the-counter drug packaging, for example, its designers have to balance childproofing needs with the requirements of senior citizens to be able to open the packages with arthritic hands—and do so to the satisfaction of the Consumer Products Safety Commission.

Engineers at the Kerr Group rely upon SolidWorks Simulation to help them find designs that meet such criteria. Product designers who want to compete successfully in the hectic medical products environment have to work hard at reducing development and manufacturing costs, and minimizing product liability exposure. SolidWorks software's design validation tools help them do so on a daily basis.

Design challenges

In addition to the challenges posed by the rigorous criteria already mentioned, medical product design challenges include being able to understand and design for the ergonomic issues that affect operating time and patient trauma. The ever-increasing cost of medical services makes it essential that products be more efficient and user-friendly to meet the goals of reducing operating time and surgery costs. Medical staff have definite aesthetic requirements that designers also have to meet, along with such functional needs as the range of motion required and the contact force requirements of surgical instruments for specific surgical tasks. Also, the materials used for medical products have become very sophisticated, and designers need to be educated about their strength and conductivity, as well as the effects of sterilization on their material properties.

Implanted devices such as cardiovascular stents have to be perfect—because failure can cause death. Orthopedic implants, such as hip and knee replacements, have to function flawlessly to avoid pain and the danger of fracture to patients. Designers have to predict the life of implantable devices accurately so that patients can have them removed or replaced in a timely, non-life-threatening manner.

The ever-increasing cost of medical services makes it essential that products be more efficient and user-friendly to meet the goals of reducing operating time and surgery costs.

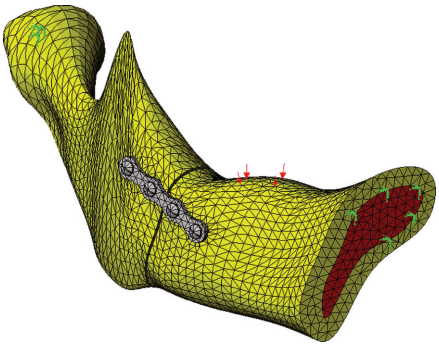

Figure 2: SolidWorks Simulation helped product designers optimize SolidWorks 3D CAD software models, such as the artificial jaw joints used in this jaw reconstruction.

Simulation and virtual prototyping tools can help the designers of medical products balance all these simultaneous needs, and gain assurance of product quality, reliability, and safety. Specific examples of the way they do so will be discussed below.

Design validation for the medical product industry

The purposes for which designers need to perform design analysis include proof of concept, "what if" studies to identify the best design, design verification, and assistance in obtaining regulatory approval. Proof of concept is required early in the development cycle. "What if" studies can include variations in geometry, types of material, and different operating loads. Design verification can help to test product reliability while reducing the number of costly and time-consuming physical prototypes. Drop tests can be performed to ensure the durability of hand-held devices and home-care equipment. The results of all these tests are generally accepted by regulatory agencies when companies seek approval.

The federal Food and Drug Administration (FDA) has three classification levels for medical products:

- Class I products are passive devices that do not enter the patient's body, or contact only the skin.
- Class II products are active devices or devices that are used to administer fluids to the patient's body.
- Class III products are implanted inside the patient's body.

The FDA is familiar with finite element analysis, and even expects design validation results to accompany some submissions—particularly of Class II and III devices. The agency expects such analysis results to match those obtained with established experimental methods.

Simulation with SolidWorks Simulation meets the requirements of regulatory agencies for proof of design reliability.

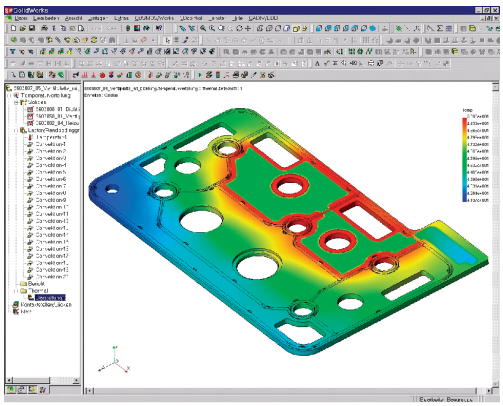

Figure 3: Using SolidWorks Simulation during the redesign of this anesthetic unit, engineers at Dräger Medical, GmbH, reduced the number of prototypes used in the early stages of product development from eight to two.

A number of software tools—finite element analysis (FEA), motion simulation, and computational fluid dynamics (CFD), in conjunction with the CAD used for the designs themselves—are available to help today's medical designer meet the complex requirements of the industry.

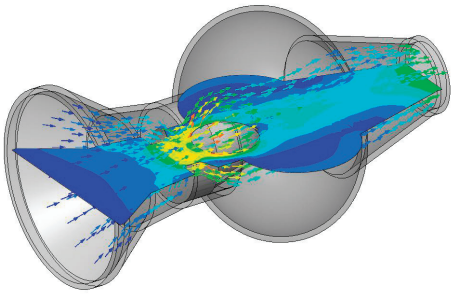

Figure 4: Blood flow simulation through a Starr-Edwards heart valve allowed the engineers to study turbulence, pressure loss, and back pressure created by the valve.

SolidWorks Simulation software

SolidWorks software is the CAD program of choice for many manufacturers of diagnostic and clinical equipment, surgical tools, implants, drug delivery systems, and pharmaceutical packaging systems.

The designers who use SolidWorks software have to resolve such design issues as portability of equipment that often gets moved from one part of a hospital to another; ease of operation, maneuverability, and configurability for use in medical facilities and home care; and—always—safety for consumers and medical personnel.

After a product is designed, however, the next question is whether it will work and behave as desired. SolidWorks Simulation design validation software makes it very easy for SolidWorks 3D CAD software users to perform a variety of studies during the design process without switching between multiple interfaces. SolidWorks Simulation also meets the requirements of regulatory agencies for proof of design reliability.

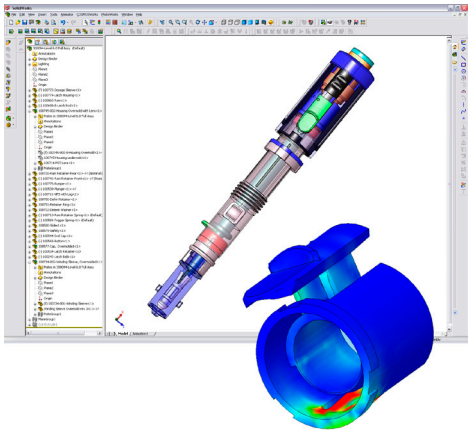

Figure 5: The seamless integration between SolidWorks Simulation and SolidWorks Premium enabled Medi-Ject engineers to spend more time developing products and less time learning a new user interface.

Full integration also makes it possible for medical product designers to perform easy design modifications and configuration-specific studies, to enable the manufacture of products customized to individual needs. They have access to the materials library used by SolidWorks software along with other SolidWorks software references, can use SolidWorks eDrawings® to share analysis results, and leverage additional standard SolidWorks software functionalities. No other design validation program offers this kind of integration.

Proven simulation tools

The analysis capabilities within SolidWorks Simulation grow out of the long-proven experience of powerful SolidWorks software finite element analysis (FEA). SolidWorks Simulation, together with the CFD capabilities of SolidWorks Flow Simulation, and the rigid body motion simulation of SolidWorks Motion, has helped SolidWorks software users test such medical products as orthopedic implants, cardiovascular stents, heart valve replacements, cancer treatment delivery systems, solution pumps, blood pressure monitors, anesthetic units, open oxygen delivery systems, centrifugal blood separators, needle-free drug delivery systems, and many, many more medical products.

SolidWorks Simulation provides validation tools comparable in sophistication to difficult-to-use, costly FEA programs—and builds so much intelligence into the software that it is easy to use by design engineers who don't have the long experience of dedicated analysts.

Full integration between SolidWorks Premium and SolidWorks Simulation makes it possible for medical product designers to perform easy design modifications and configuration-specific studies, to enable the manufacture of products customized to individual needs.

Analysis capabilities

Linear static stress and displacement

The software provides a wide range of analysis capabilities, including static analysis to determine stresses, strain, and deflections. With the information thus provided, medical product designers can avoid catastrophic immediate or long-term failure due to cyclic loading. This most frequently used of all analysis tools helped Tensys Medical to analyze an actuator that moves a sensor over the wrist of a patient during surgery to find the optimal position to produce continuous waveform indication of the patient's blood pressure by a safe, non-invasive device. The geometry of the actuator is complex, and Tensys engineers used SolidWorks Simulation linear stress analysis to locate and then eliminate areas of high stress. The designers then optimized the design for reliability and produced a part with the ability to flex almost indefinitely.

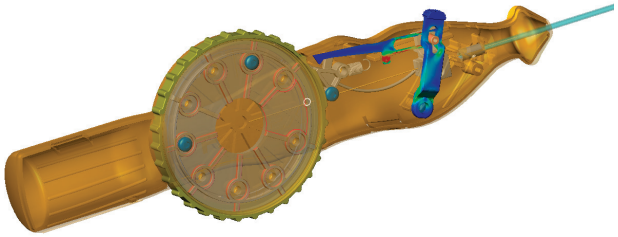

Figure 6: Stress analysis, such as on the control mechanism of the Fibrex Catheter Device™, a medical control product that cleans catheters in the human body, allows medical product designers to know how their designs will behave before they are ever produced.

Thermal

Thermal analyses, of high importance in medical products because of the complex materials they use as well as the possible effects of human body temperatures, can test conductivity, coefficient of thermal expansion, heat capacity, and temperature distribution under specific conditions. SolidWorks Simulation supports thermal analysis of medical products whose material properties may change with temperature variations. Dräger Medical of Germany, a worldwide leader in critical care equipment, used SolidWorks Simulation linear static and thermal analyses to study the performance of a number of different plastic materials from the viewpoints of performance and meeting statutory regulations, when they wanted to change the material used in the respiratory gas unit of a ventilator from aluminum to plastic.

Frequency and vibration

Vibration analysis in SolidWorks Simulation helps designers evaluate such product designs as ultrasonic resonators and other instruments that can be affected by natural frequency problems.

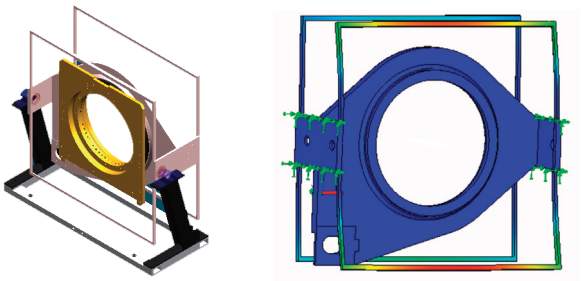

Figure 7: Frequency analysis on a subassembly of a CT scanner

Frequency analysis was particularly important to OLE Technology Co. Ltd., based in China, which recently designed and analyzed a new computerized tomography (CT) scanner. The company needed to know the frequency of a key assembly—and they needed the results very quickly. The head of the CAE department reports that OLE was able to obtain the required results in 20 minutes on a PC—an analysis that he says would have taken a senior engineer several weeks with other tools.

Contact

Contact analysis is important for assemblies in all products, and particularly so in the medical product field where safety is so critical. The same holds true for the ability to determine the desired factor of safety in medical products, where premature failure might cause injuries or deaths. Medi-Ject Corp. developed a needle-free injection system that uses pressure to create a microthin stream of medicine that penetrates the skin and deposits medication into subcutaneous tissue. The company's engineers performed static analysis on the safety mechanism of the device to predict the contact force required to activate it. After several design modifications, SolidWorks Simulation helped them to come up with a final design that exhibited the desired level of activation force required by patients during an emergency.

ANALYSIS CAPABILITIES

- Linear Static
- Thermal
- Frequency and Vibration
- Fatigue
- Optimization
- Contact
- Nonlinear

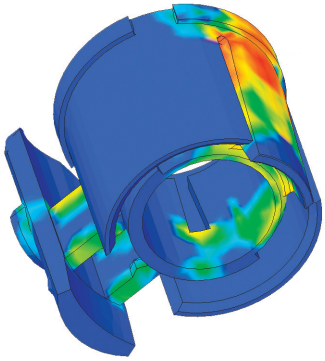

Figure 8: SolidWorks Simulation was used on the trigger mechanism of the Medi-Ject insulin injection device to determine the contact force needed to activate the injection.

Nonlinear

Nonlinear analysis is often critical to medical applications to determine the factors that may cause device failure. The SolidWorks software material database has many nonlinear materials with predefined properties, including one for Nitinol, a shape memory alloy widely used in medical devices. Nonlinear analysis can be used for such tasks as analyzing a catheter going through an artery to simulate the resistance and torsion caused by resistance from human tissue.

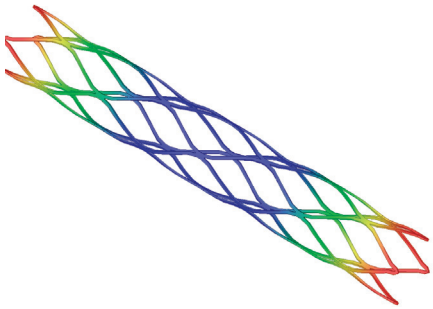

Figure 9: Nonlinear analysis of an expanding stint using Nitinol shape memory material

When designing a new coronary and vascular stent that deforms less on insertion than traditional stents, REVA Medical Inc., working with SolidWorks software, tested the reliability of the device over time with multiple nonlinear analyses. These studies focused primarily upon welded connections that had been designed to be more flexible, fatigue-resistant, and less susceptible to breakage than previous designs. The analyses made it possible to make several design changes that improved performance—and to finalize the product design about 50 percent sooner than had been anticipated.

SolidWorks Simulation nonlinear analyses made it possible for engineers at the Okayama University Faculty of Dentistry to design an artificial jaw joint for patients with broken jaw joints caused by rheumatoid arthritis or by retreated lower jaws. They analyzed different plate and screw models and materials, and, with the help of nonlinear analysis, identified a specific plastic material as the most appropriate material for the replacement jaw.

SolidWorks Simulation nonlinear analysis, in conjunction with linear stress and thermal analyses, helped National University Hospital in Copenhagen, Denmark, to study titanium spinal implants without resorting to invasive tests on people. Because the implants were intended to last the patient's lifetime, the interaction between the titanium and natural bone—a nonlinear material—was of particular importance. The nonlinear analyses showed the researchers how bone would grow around the implants.

Computational fluid dynamics (CFD)

Fluid flow issues also pervade medical applications. Whether for artificial heart valves, solution pumps, oxygen delivery—and a host of other such products—a variety of fluids must move reliably as designed, and at prescribed temperatures. SolidWorks Flow Simulation makes it possible to study such issues in a very straightforward manner. Like SolidWorks Simulation, SolidWorks Flow Simulation is fully integrated within SolidWorks Premium.

SolidWorks Flow Simulation can simulate the flow of Newtonian and non-Newtonian fluids, mixing of fluids, conjugated heat transfer with fluid flow, and external/internal flow.

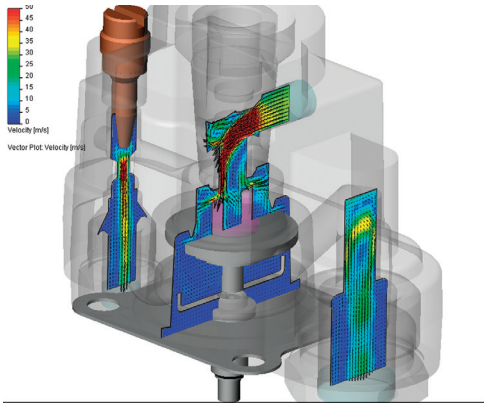

Figure 10: SolidWorks Flow Simulation is the first easy-to-use fluid-flow simulation and thermal analysis program that is fully embedded inside SolidWorks Premium.

It can simulate the flow of fluids (including viscous fluids), mixing of fluids, conjugated heat transfer with fluid flow, and external/internal flow. Blood flow provides a good example of a viscous fluid.

In the case of the Dräger Medical ventilation system, SolidWorks Flow Simulation assisted the designers to study the effects that resulted from changing the position of the gas flow into the ventilation system with the objective of ensuring that patients get enough oxygen. The company reported that use of SolidWorks Flow Simulation along with linear static stress and thermal analyses reduced testing time by about 50 percent, and cut the number of physical prototypes needed by 75 percent.

Canadian medical equipment developer Southmedic™ designed the first minimal contact open oxygen delivery system, the OxyArm™ headset. The technology behind the device is based on torch-like or vortex-like flow patterns generated inside a diffuser cup to deliver the correct concentration level of oxygen to the patient at different flow rates. Analysis required a combination of internal and external flows in the process of mixing air and oxygen. SolidWorks Flow Simulation made it possible to perform these complex CFD analyses very easily. By tweaking the design, Southmedic's engineers quickly obtained the desired level of performance in a process invisible to the naked eye—saving time and money.

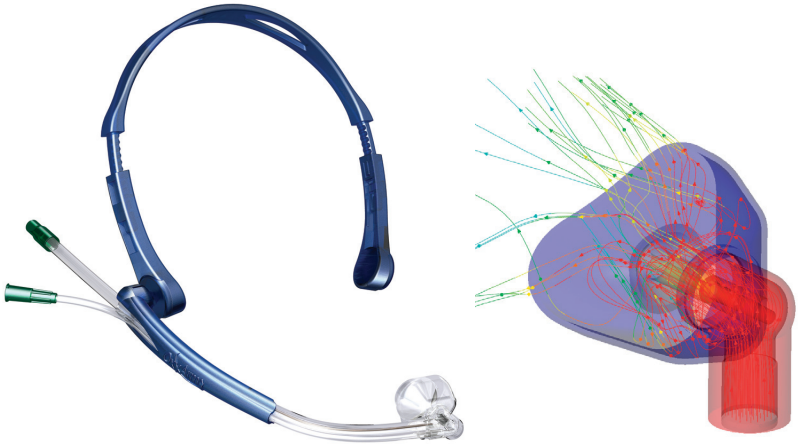

Figure 11: SolidWorks Flow Simulation is the first easy-to-use fluid-flow simulation and thermal analysis program that is fully embedded inside SolidWorks 3D CAD software.

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Motion simulation

SolidWorks Simulation helps medical designers make sure equipment and instruments move smoothly, with no spikes in their motion and load behavior. Load data results of motion simulation can also be transferred to SolidWorks Simulation to check the strength of parts, playing an important role in optimizing medical product design.

For example, a manufacturer of surgical instruments and devices for minimally invasive surgery such as staplers, fasteners, and retrievers, used SolidWorks Simulation to check the load profiles of each component. The company wanted to optimize the force needed for firing and retracting the mechanism of an instrument that holds human tissue during surgery. The designers obtained the force data from motion simulation and then used it to change the design. After just a few iterations, they had optimized the final design, one that was easy for surgeons to use while causing the least possible damage to the patient.

Conclusion

Designers of medical products have to meet the needs of physicians, patient safety, and regulatory agencies. They can never compromise on quality, because lives may depend on product performance. To be certain that they meet all these requirements, medical product designers have a number of design validation software tools available to help them meet their goals, and SolidWorks software analysis products rank high among such programs in terms of widespread use, proven technology, and ease of use.

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