Optimal Design of Medical Devices

Introduction

The design of medical devices presents many challenges, as evidenced by special requirements for innovative materials, rigorous dimensional tolerances and uncompromised product safety and reliability. Advanced engineering skills supported by the use of sophisticated simulation technology are the norm, rather than an exception. The engineering process used today in the design of medical devices emphasizes numerical simulation, or Computer Aided Engineering, over the physical build-and-break prototyping activities for reasons of efficiency and savings in time and costs. But manually iterating on these virtual prototypes still requires a great deal of time and effort, and often does not lead to an optimal solution. Now, automated design optimization tools provide the means to accelerate the design process while increasing the quality of the end result.

The Engineering Process

As powerful and realistic as current numerical simulation tools are, engineers may easily become trapped in the same inefficient and frustrating build-and-break paradigm so well known in the physical testing world. This is due to the fact that even promising initial designs rarely manage to satisfy all of the rigorous performance requirements specified for the device being engineered. This may lead to numerous iterations, where certain input parameters are tweaked or tuned manually, often leading to unexpected answers. Such surprises are often attributed to the overall complexity of the model, which commonly exhibits very nonlinear and/or coupled multi-disciplinary behavior. Traditional iterative design processes, therefore, suffer from predictable inefficiencies due to the fact that only a few parameters are adjusted with the goal of finding a design that meets all specifications. It is simply not possible by traditional means to explore all possible combinations of input variables to arrive at the best design. Hence, all too often designs are chosen which are clearly sub-optimal. Even when most or all requirements are met, often the design is still not optimal from all perspectives.

This standard iterative design loop is illustrated below in Figure 1.

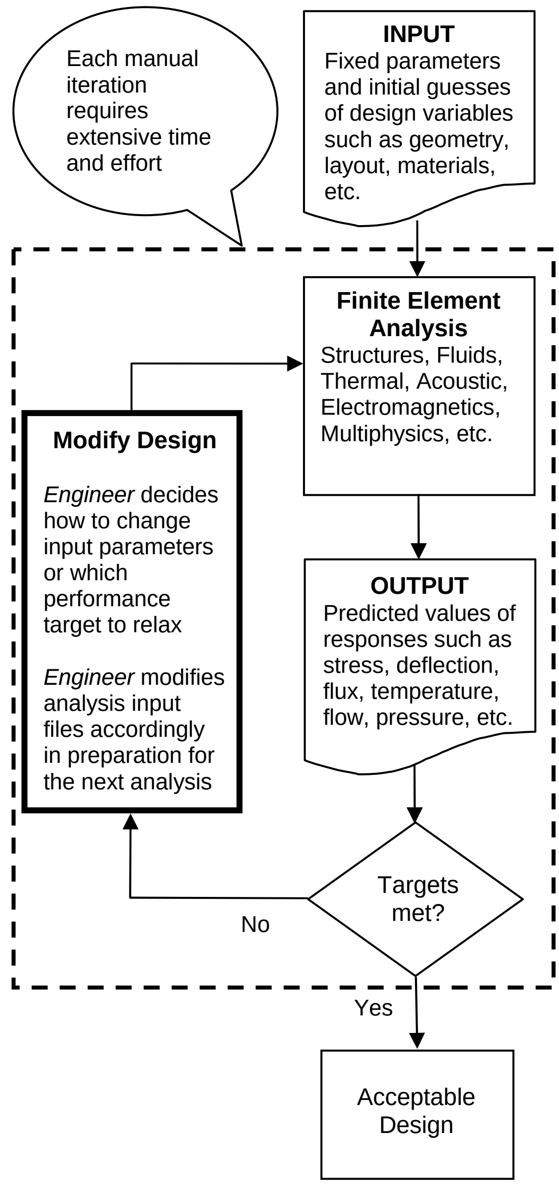

Figure 1. Manual engineering design loop

Its well known drawback is that it requires manual engineering intervention to make changes to the input variables. This process can be highly time consuming and it does not make efficient use of available computing and engineering resources.

An Improved Engineering Process

Rather than relying on the engineer to determine which combination of inputs satisfies the performance targets, we can envision an automated process that allows the input parameters to vary within specified boundaries and performs an intelligent mathematical search for the solution that best satisfies the requirements. HEEDS Professional design optimization software from Red Cedar Technology, Inc. (RCT) uses intelligent hybrid and adaptive search technology to automatically hone in on optimal solutions, which in many cases would escape even the most rigorous and experienced human engineering processes. The utilization of state-of-the-art design optimization is particularly appropriate in the field of medical devices, where speed to market as well as requirements on reliability, efficiency and robustness, are very high. This automated process is illustrated in Figure 2.

In the manual design process, the engineer makes all decisions based on intuition and experience, while in the automated process each new design proposal is determined based on a structured process that is hybrid and adaptive. Perhaps more importantly, in the automated process each new analysis model is created without additional human intervention, which eliminates tedious and error-prone manual model-building steps and yields a much more efficient process. In a given period of time, the automated process can perform a larger number of design analyses than can be performed manually, giving rise to a much more thorough search for the best possible design

An Example Application

Recently RCT performed a design optimization study on a vascular stent made from a Nickel-Titanium (shape memory) alloy. The goal of the study was to find the most suitable shape of the stent to meet the performance criteria while producing acceptable levels of strain during the operating phases.

The previously suggested shape was clearly suboptimal, producing high levels of strain that would shorten the life of the device. By means of a HEEDS optimization process in which shape parameters were optimized, the maximum principal strain in the stent was reduced by a factor of three.

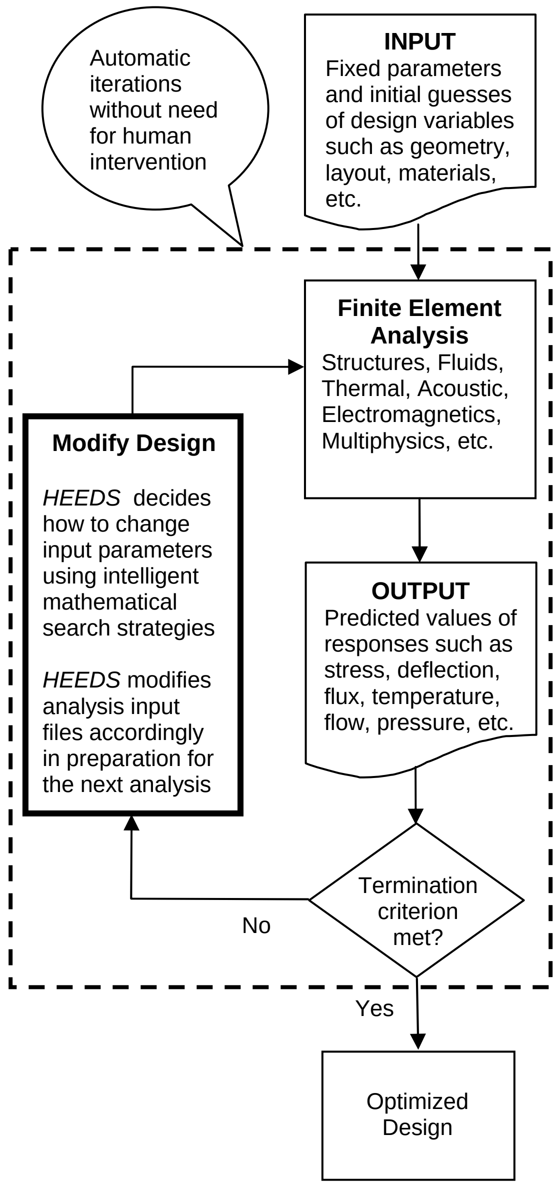

Figure 2. Automated optimal design using HEEDS.

Conclusion

An automated design process can lead to much better designs in much less time than a similar manual process. The advanced design search algorithms in HEEDS are capable of effectively solving multidisciplinary problems with even hundreds of parameters.

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