FINITE ELEMENT ANALYSIS
Predictive Engineering

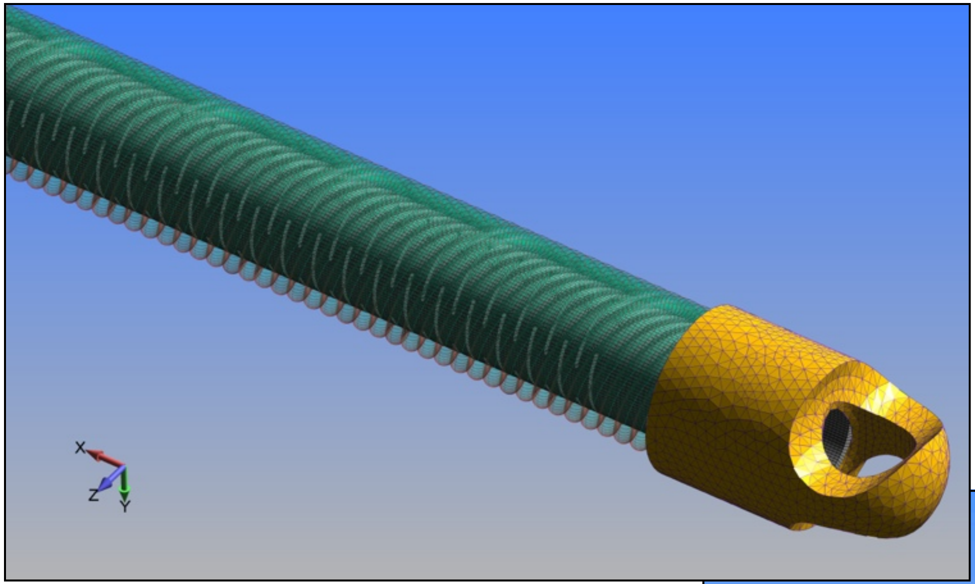
Advanced Stress Analysis of Medical Devices
Project Listing Report

Advanced Stress Analysis of Medical Devices

Predictive Engineering has been involved with the analysis of medical devices since 1995 with its first work on an endoscopic surgical stapler to current work on a bone marrow aspiration tool. In all cases, these projects were benchmarked against experimental results and shown to be in tight correlation.

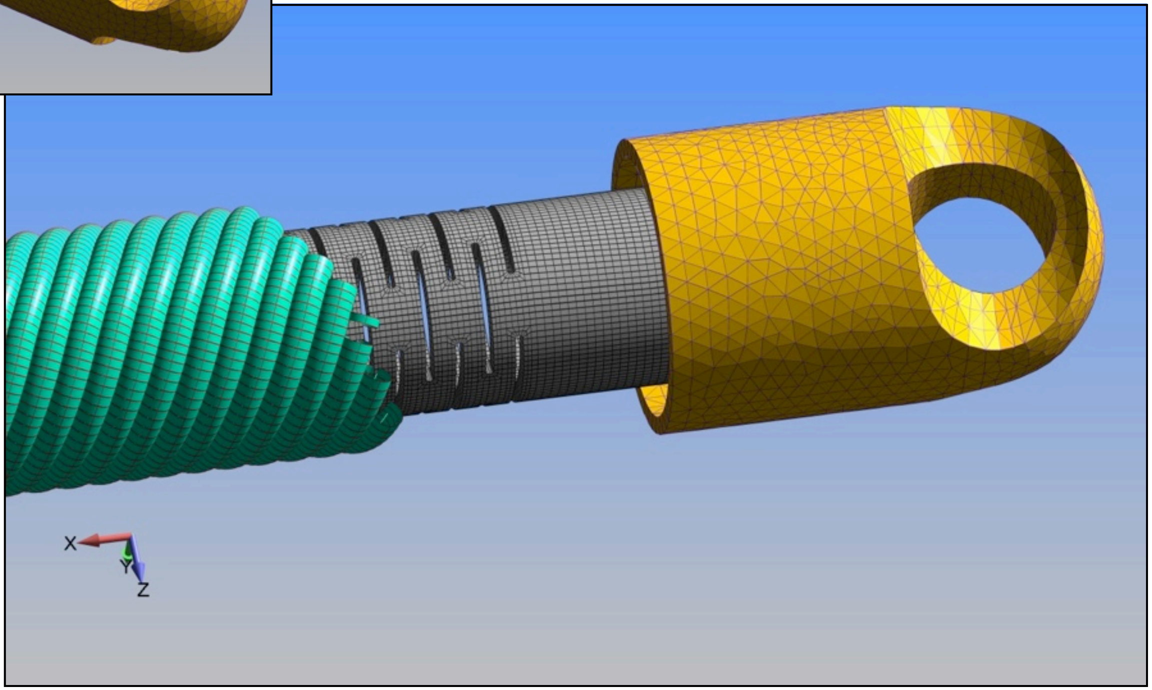
Complex analysis demands were only part of the challenge for these projects since the medical industry also requires extensive documentation and quality assurance that the models are built per specification. Additionally, in several cases the clients required that an accuracy assessment be performed prior to the correlation with experimental results. It was an interesting twist that a prediction was required of the model's accuracy prior to the divulgement of the experimental data.

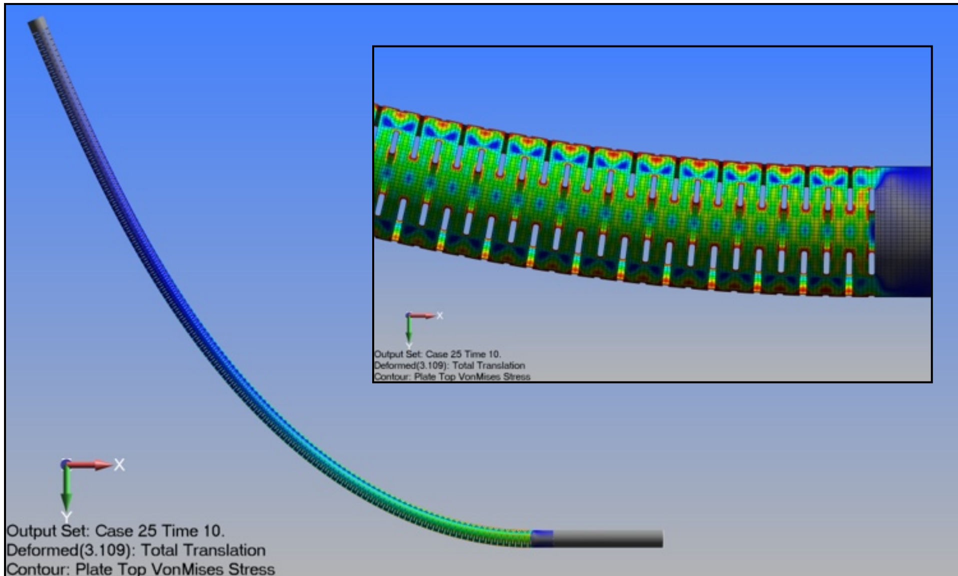
The four project summaries presented, represent a fraction of the total work done over the years but illustrates some of the most complex modeling challenges facing the medical industry with multi-component systems loaded to their failure point and that of elegant numerical simulations where stress waves are propagated through viscoelastic medium (acoustic radiation force impulse imaging).



This medical device is for the aspiration of bone marrow. The probe is rotated and pushed into the femur by the surgeon. A minor vacuum is applied and the bone marrow is conveyed through the center of the flexible shaft.

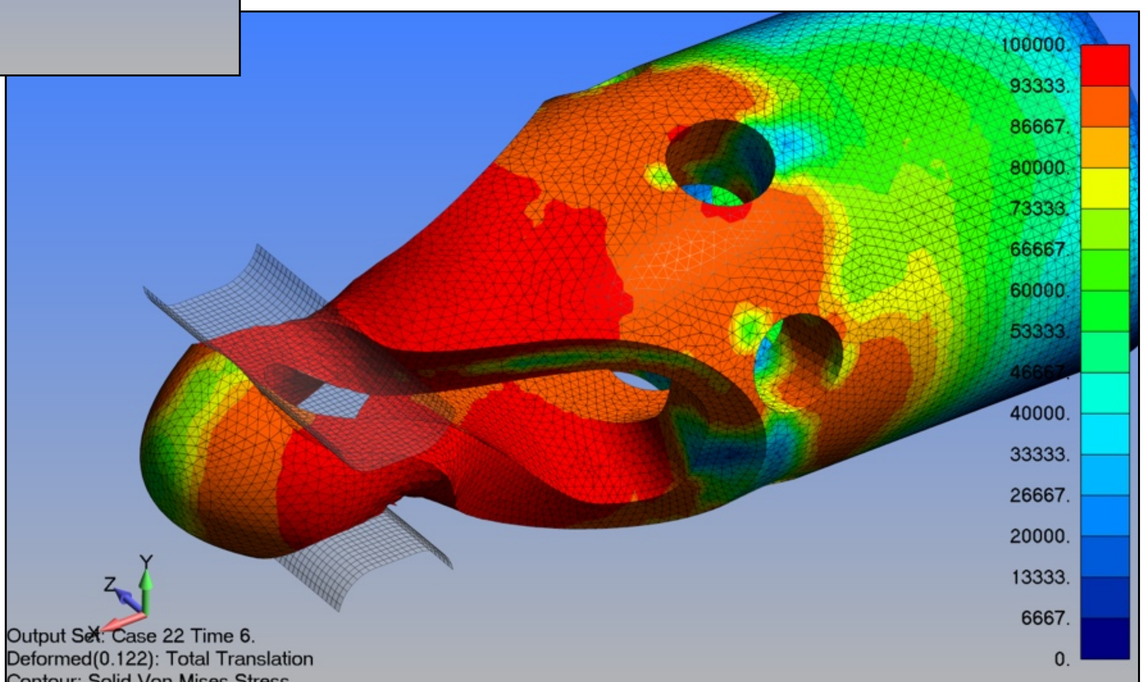
The torque strength of the device is via a tightly wound outer loop of filar cables. The inner tube is a Nitinol titanium shape memory alloy.

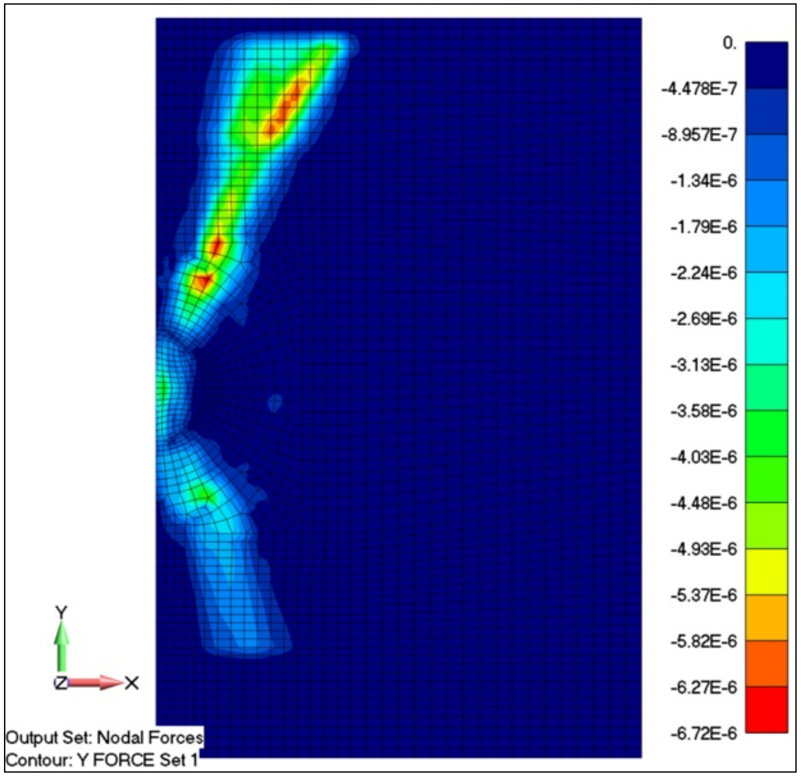


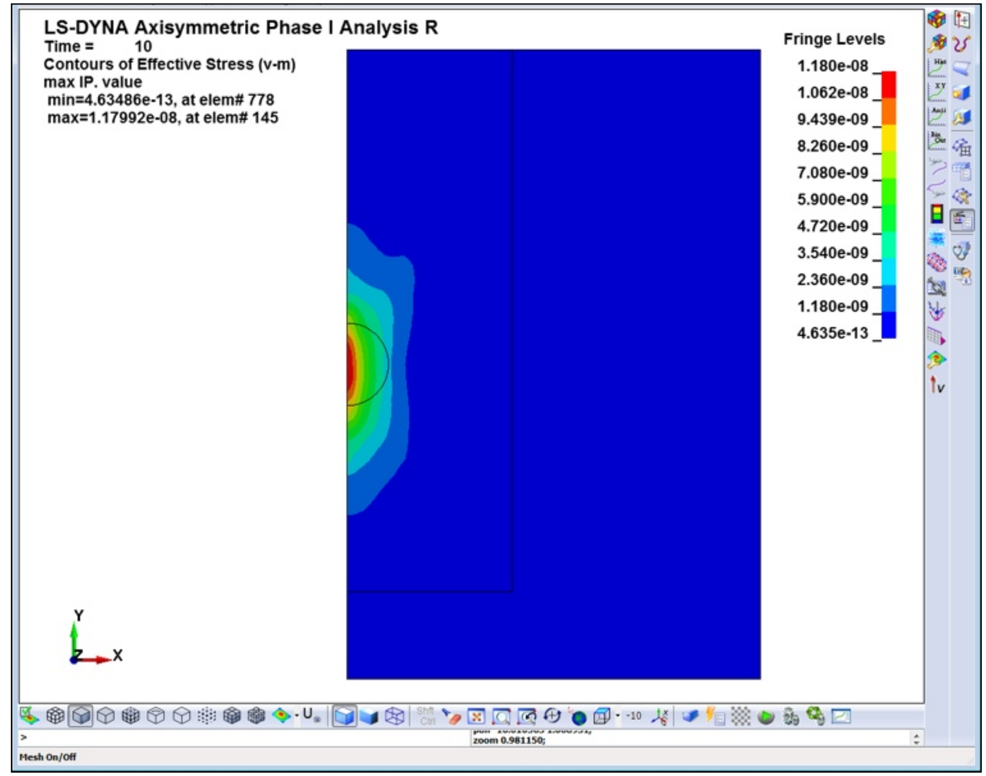


The Nitinol tube and aspiration point were bent and torqued to determine their survivability based on FDA submittal requirements. In both numerical simulations, the results closely matched experimental data. The aspiration tip was made of stainless steel and at full torque, completely yielded across its smallest section.

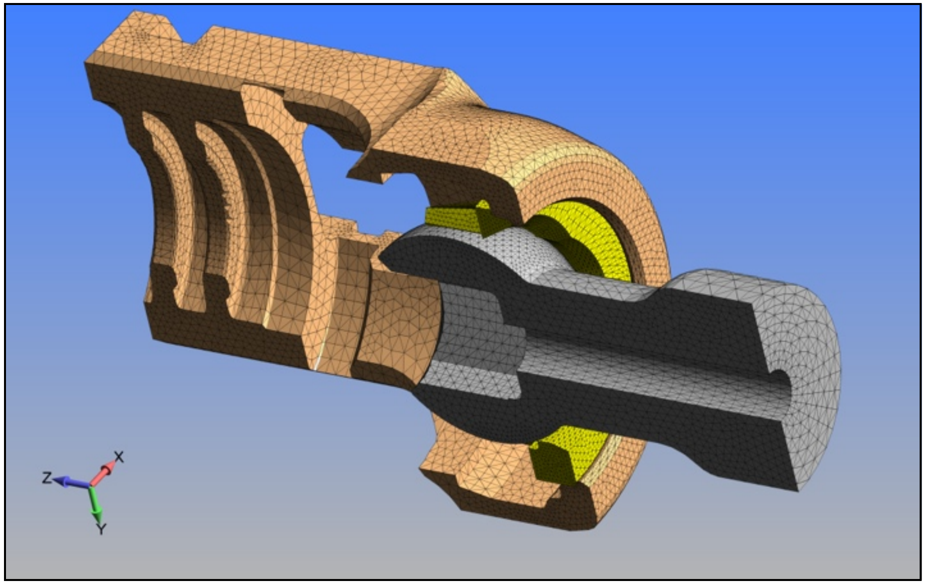
Analysis work was done using NX Nastran and LS-DYNA.



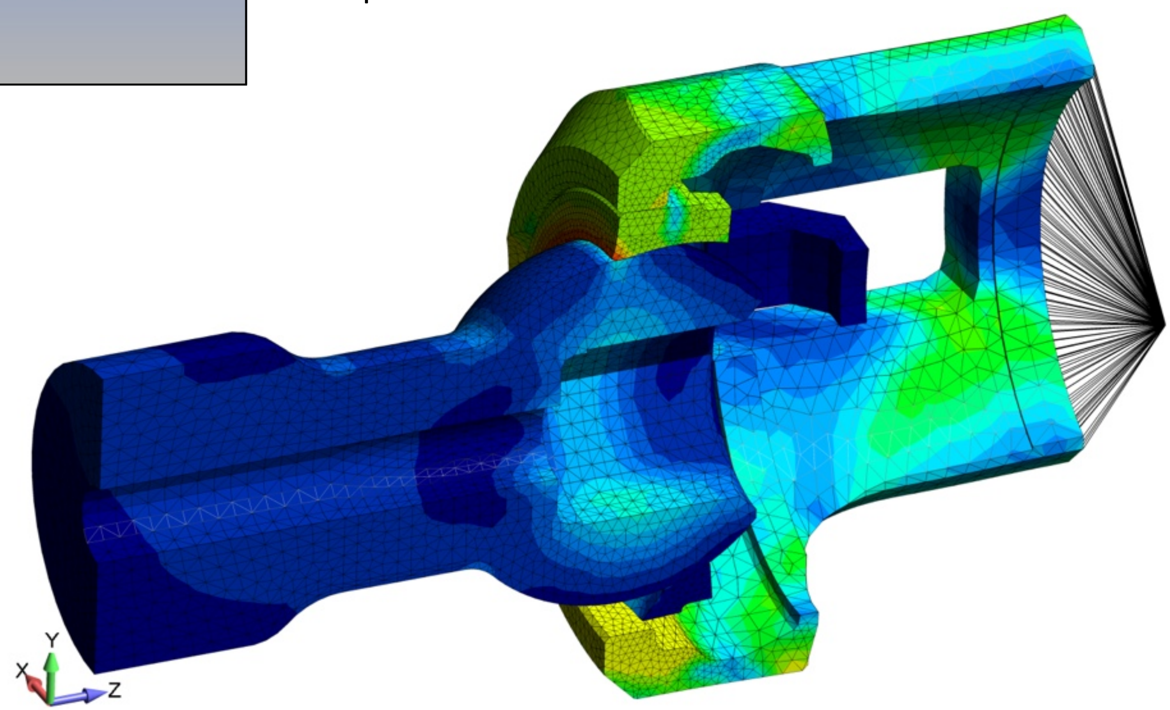


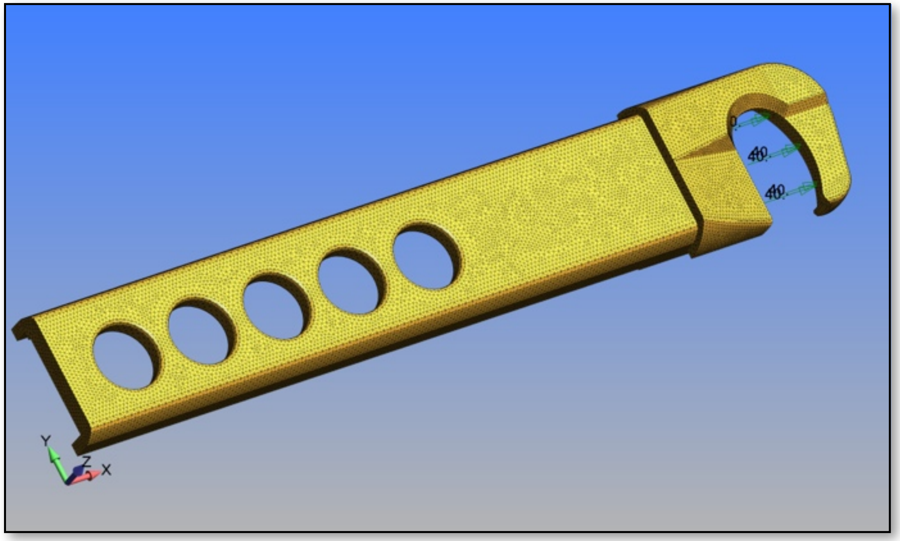


Acoustic radiation force impulse (ARFI) imaging is a recently developed technology for making strain images of human tissue and organs. The technique is similar to ultrasound techniques but sets up a vibration pulse within the tissue and then measures the strain energy emission (i.e., vibratory decay) from a particular region of interest (e.g., a tumor or lesion). The sensitivity of the technique has the potential to allow it to differentiate between tissues that may be cancerous, and even if, it is malignant or benign. An acoustic force (image on the left) is applied and then the vibration pulse behavior is simulated (image on the right) in a visco-elastic material medium. In this work for a major medical company, the goal was to replicate the behavior of phantom gels containing lesions. The numerical work tracked exactly with results obtained from experimental measurements.



Titanium orthopedic screws are a wide-ranging standard yet research and development still continues to offer surgeons more flexibility and a greater range of placement in tight-fitting quarters. Analysis requirements for this type of multi-body, frictional contact analysis with material plasticity are complex. In the analysis shown below the screw ball is allowed to frictionally glide past the retainer clip. The mechanical functionality of these types of FDA approved screws rests on a frictional lock between the titanium components.





This tiny endoscopic surgical stapler anvil (3 cm long) was the source of many interesting discussions. The quality assurance specification test was to hang a 40 lbf weight from its tip. If the part survived, it was sterilized, bagged and shipped. Unfortunately, a few anvils would break during the stapling operation and the patients would end up having a bonus steel part in their body. After extensive FEA work, the anvil's stress still exceeded the yield of the sintered stainless steel material by 1.5x. The final design solution was to change the QA test to 15 lbf and the problem was solved since the true service load was around 12 lbf. There are three morals to this story: loads, loads and loads.