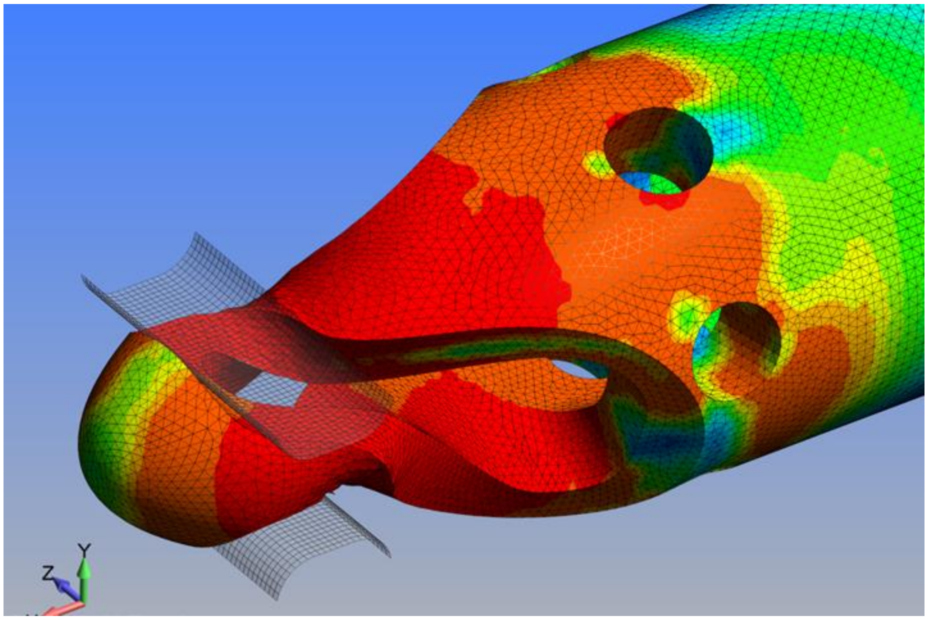
Advanced FEA Stress Analysis of Medical Instruments and Devices using Femap, NX Nastran and LS-DYNA



Title:

Medical device (aspiration tip) for bone marrow extraction for endoscopic surgery

Keywords:

Endoscopic surgical anvil, powder metallurgical medical devices, nonlinear analysis, FEA of plastic structures, FEA simulation of medical devices, Plastic medical syringe, snap-fit analysis, material modeling of Ti-6AL-4V, stress analysis of titanium locking polyaxial pedicle screw, HHS Tube, simulation of Nitinol, bone marrow removal tool, simulation of pedicle screw-rod fixation, simulation of plastics (copolyester, polypropylene and Zytel), plastic medical device analysis, Femap, NX Nastran, LS-DYNA, ADINA,

Project Overview

Predictive Engineering has been involved with the analysis of medical devices since 1995 with its first work on an endoscopic surgical stapler to pedicle screws to all-plastic snap-fit device to our current work with micro-cables and filar wrapped tubes for robotic surgery applications. 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 and enlightening twist that a prediction was required of the model's precision prior to the divulgement of the experimental data.

The projects presented within this Case Study represents a small portion 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 visco-elastic medium (acoustic radiation force imaging).

YouTube Video: FEA Simulation of Medical Devices using Advanced Nonlinear Analysis

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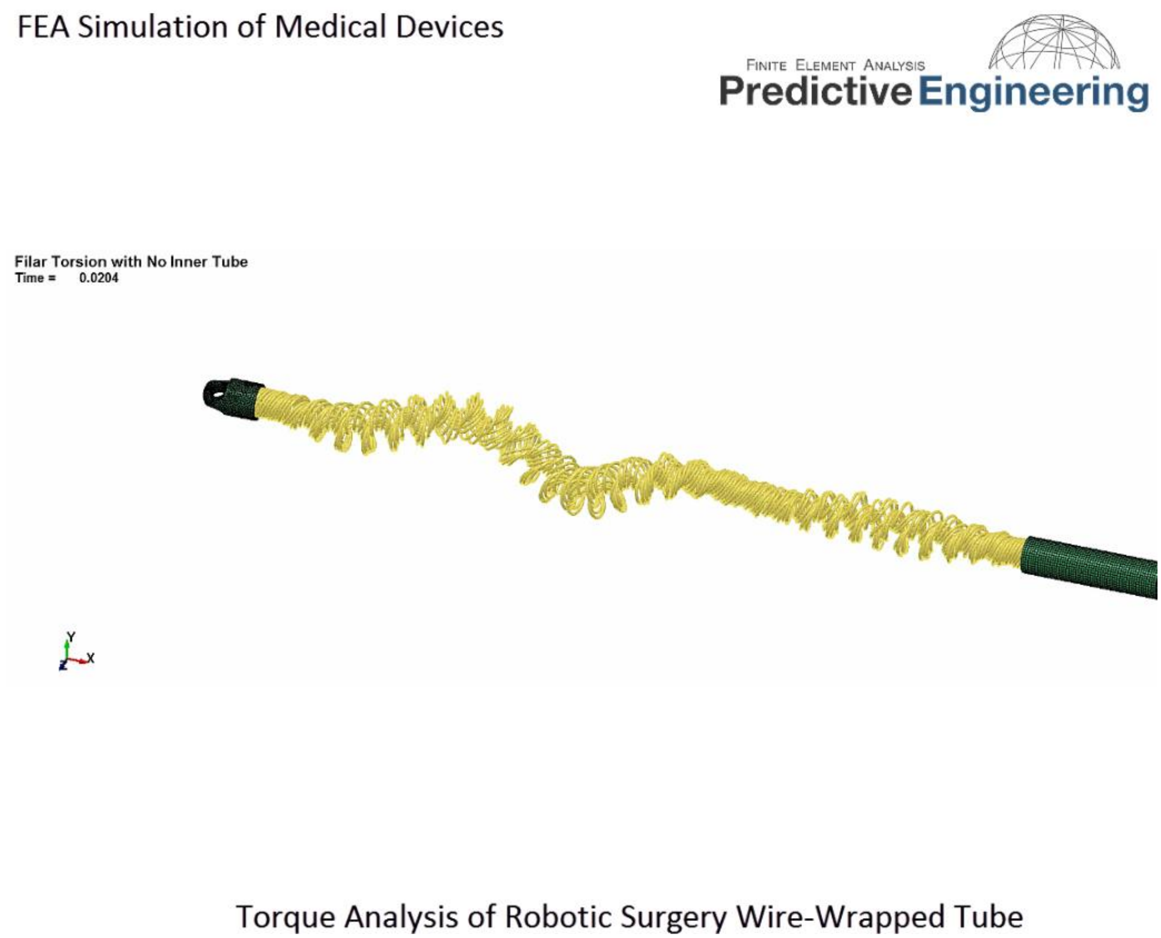


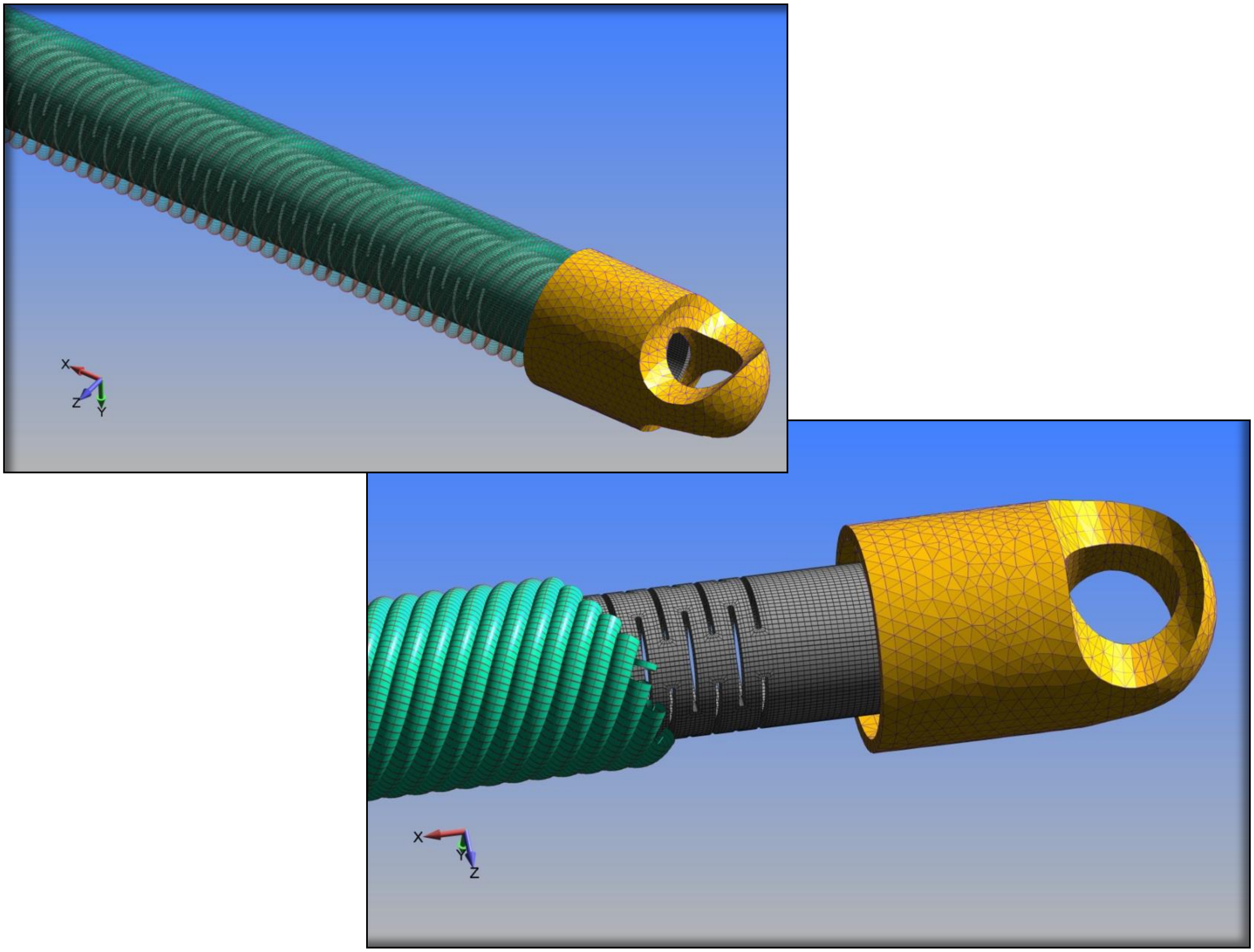


Figure 1: Flexible-shaft medical tool for bone marrow extraction with filar (wire) strands wrapped around a flexible Nitinol tube to provide torsion stiffness while provided an extraction path for the extraction product.

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 cells are conveyed through the center of the flexible shaft (Nitinol tube).

The torque strength of the device is via a tightly wound outer loop of filar high-strength stainless steel wires. The inner tube is a Nitinol titanium shape memory alloy. Material laws for both alloys were developed for the LS-DYNA nonlinear, transient explicit analysis.

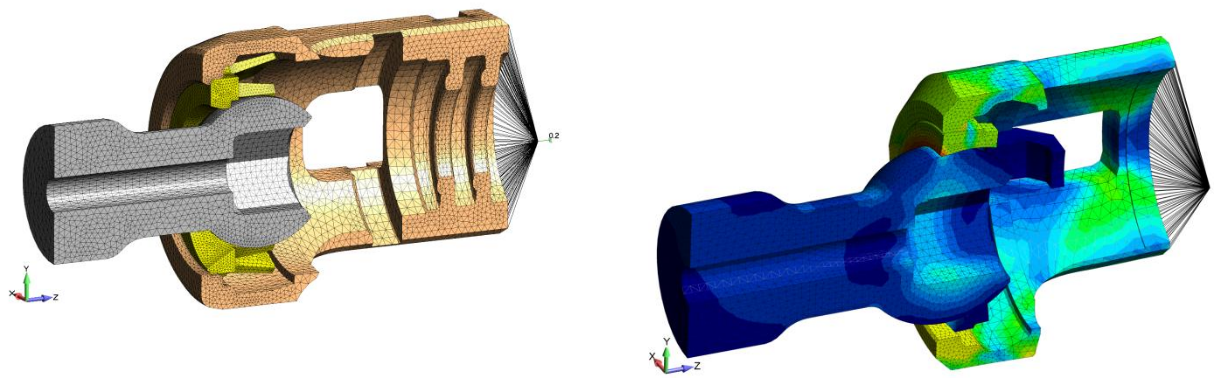


Figure 2: FEA simulation model of titanium locking pedicle screw for spinal surgery as analyzed for its locking capability as a function of interference fit and friction coefficient

Titanium orthopedic locking polyaxial pedicle screws are a common medical device for spine surgery 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 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. The simulation provided quantitative measures of the pull-out force required to remove the locking ball and allowed a faster design optimization path toward the next generation of these devices.

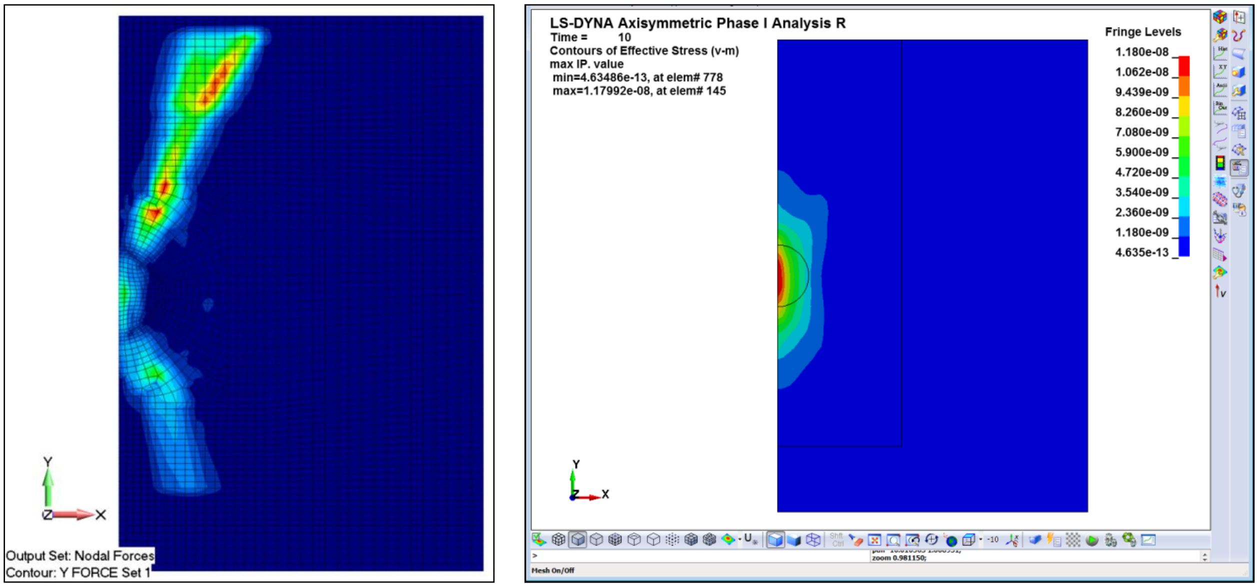
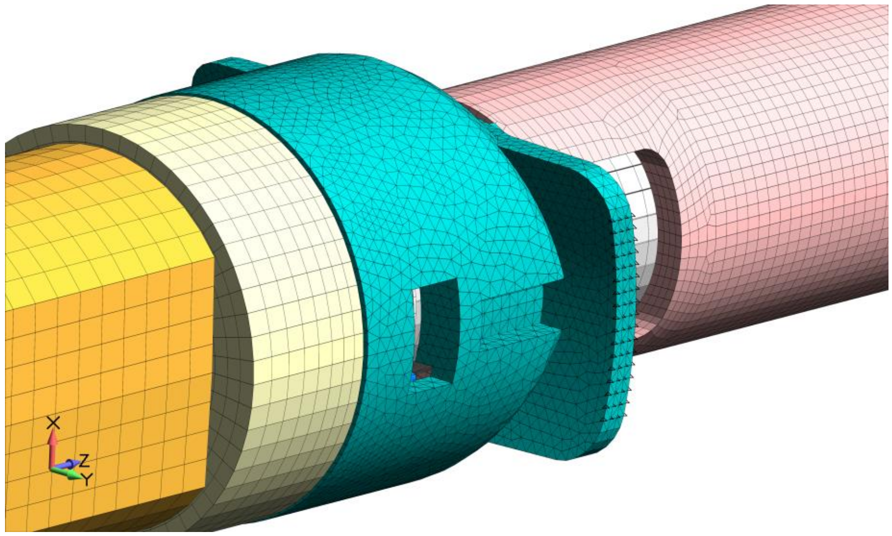


Figure 3: Acoustic radiation force impulse (ARFI) imaging is a recently developed technology for making strain images of human tissue and organs. A FEA simulation was developed to model the ultrasonic radiation in pseudo human tissue.

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 LS-DYNA work tracked exactly with results obtained from experimental measurements. The simulation process involved mapping the acoustic energy as a volumetric force within an axisymmetric FEA model. To perform this load mapping the API within Femap was used to take the client's load and then apply it to the mesh. The model was then exported to LS-DYNA for transient dynamic analysis of the radiation wave front. Results laid out the foundation for future work.



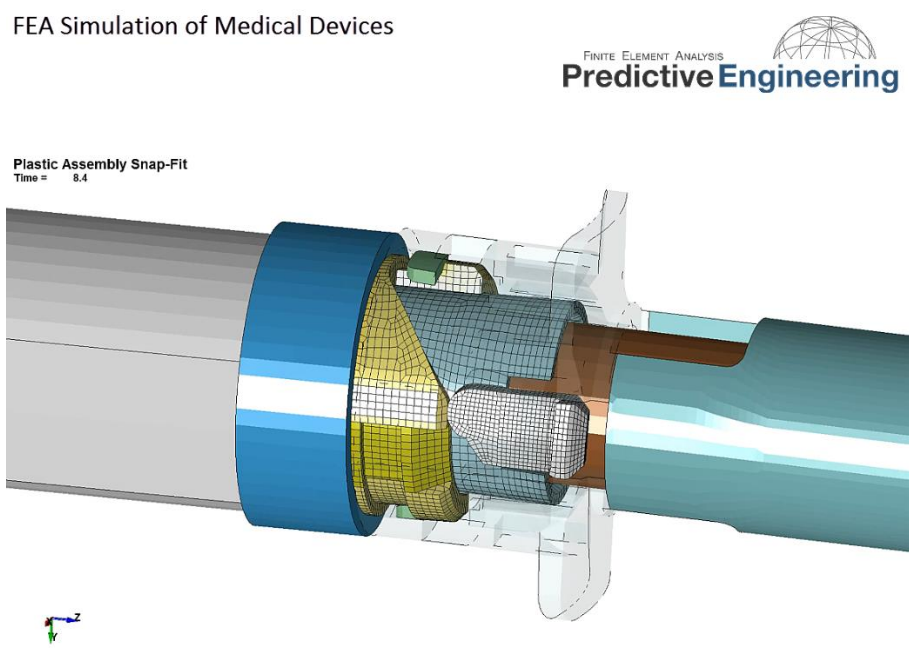


Figure 4: All plastic medical snap-fit design using several different grades of plastics

This analysis work was done to develop a proof-of-concept for an all-plastic snap-fit medical device. By movement of the handle, a snap-fit mechanism would be activated allowing the medical technician. The all plastic device used several grades of materials such as: copolyester, polypropylene and Zytel. Material curves were developed for LS-DYNA and analysis work was done in implicit and explicit solution modes depending upon the type of loading simulation requested by the client.

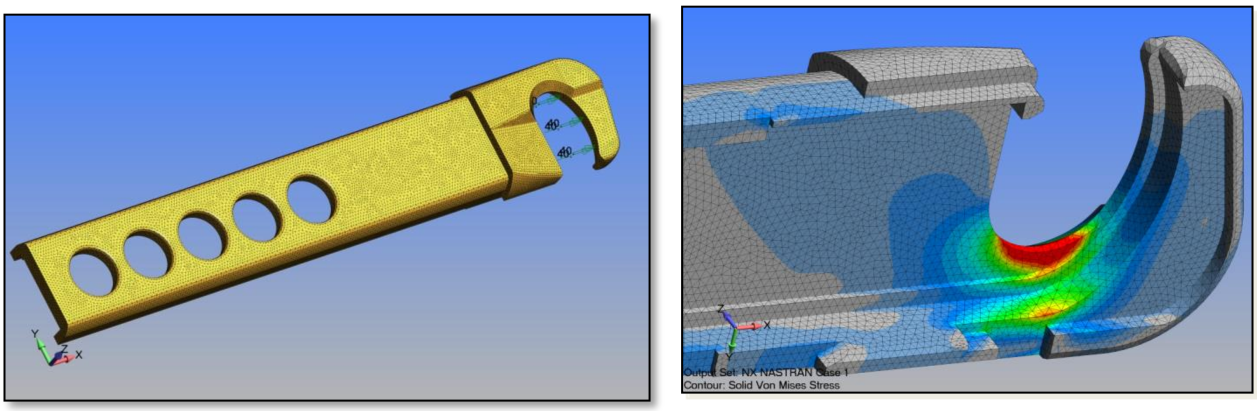


Figure 5: FEA Simulation of endoscopic surgical stapling anvil for ultimate load determination

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.

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