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Process Simulation Applications in the Medical Industry

D. Lambert and J. Walters
Scientific Forming Technologies Corporation, Columbus, Ohio, USA

Abstract

For the last two decades, the automotive industry has used computer simulation to optimize designs in the manufacture of high volume ferrous parts such as crankshafts, connecting rods and control arms. In addition, the aerospace industry has applied modeling to property development in high value added, critical service components such as turbine disks and blades, where exotic nickel and titanium alloys are utilized. Simulation systems are widely used in the above industries and have proved successful in predicting forming laps, quench distortion, die failure and product assembly problems.

In the medical industry, prosthetic devices such as knee and hip joints are made from similar exotic materials to those in the aerospace industry. In addition, such prosthetics can certainly be considered as critical components. As a result of the materials and high value added nature of these medical components, more medical implant manufacturers are turning to simulation for assistance with product improvement and cost reduction. The current work discusses various process simulations applicable to the medical manufacturing industry.

Introduction

Modern day business competition requires that products be manufactured with improved quality and at a lower cost. Reducing the design lead-time, optimizing tooling and minimizing production stoppages are all factors influencing a competitive manufacturing environment. A sound understanding of material, deformation and microstructure evolution during processing is imperative if components are to meet the relevant specifications.

DEFORM™ [1-3] is a Finite Element Method (FEM) analysis tool that has been available for a number of years and has proved very successful in the automotive, aerospace and fastener sectors. The ability to analyze forming defects, incomplete die filling, heat treatment problems and excessive die stresses before any parts have been made, has provided companies running simulation with economic benefits. With increases in stability, speed and accuracy of FEM codes, combined with ever increasing computer power, running 3D simulations is much more routine than in the past [4]. Furthermore, as computer costs have fallen so drastically in recent years, small to mid-sized shops are running 3D simulations on a day to day basis.

Hip Joint Forging

The human hip joint is the ball and socket located where the femur (thighbone) joins the pelvis (see Figure 1). If the joint becomes diseased it may be replaced with an artificial implant (prosthesis) to alleviate pain and restore joint movement. An artificial ball and stem can be fitted into the femur, which swivels inside an artificial cup inserted into the pelvic bone (Figure 1).

The blocker and finisher operations of a hip joint stem implant were simulated as non-isothermal hot forging operations. The preformed part left the furnace environment at a temperature of 1725F and was transferred in air to the blocker dies. Snapshots from the blocker operation can be seen in Figure 2 (left) where the simple preform took the rough shape

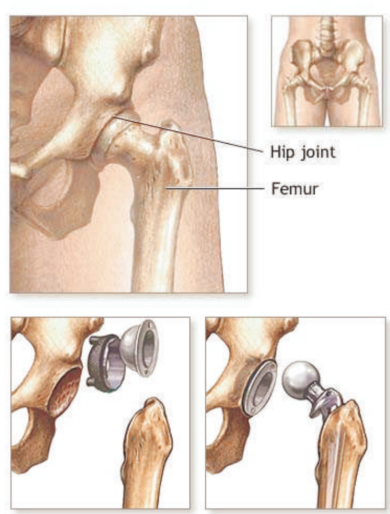

Figure 1: Anatomy of hip joint and location of prosthetic devices should the joint have become diseased.

of the stem. After the blocker operation, the flash was trimmed by a boolean operation and the stem was re-heated to 1700F. After a transfer in air to the finisher dies, the part took the form of the finish-forged implant and snapshots are shown in Figure 2 (right hand side).

Ti-64 material flow stress was imported into the simulation and the component was analyzed as a rigid-plastic object. The dies were considered to be rigid objects with an even temperature of 180F. A friction coefficient of 0.3 was applied to the interface between the deforming object and the dies; this was representative of a lubricated hot forging condition.

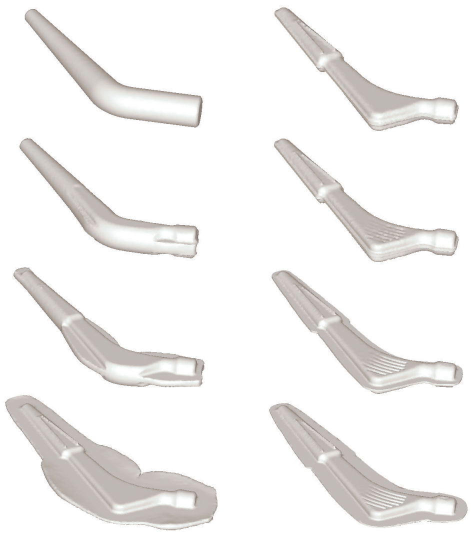

Figure 2: Snapshots of the femural stem implant simulation from the simple preform to the final forging in the blocker (left) and finisher (right) operations.

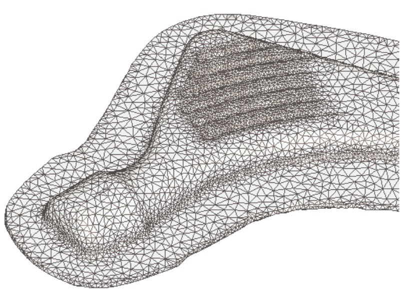

Figure 3: The small rib details were represented quite successfully by the finer mesh elements from the high surface curvature weighting.

The automatic re-meshing capability has been improved and enhanced many times over the life of DEFORM™-3D. By setting high weighting to the surface curvature of the deforming body, the meshing automatically concentrates finer elements into locations with smaller features. An excellent example is illustrated in Figure 3, where many fine elements have been concentrated in the component's thin rib features and flash edges. During this simulation, the number of elements increased from 25K at the start to 120K at the finish. An element size ratio was specified at the start as 4:1.

Knee Joint Forging

Inability to work, sleep or walk more than three blocks because of knee pain can be due to osteoarthritis, the most common cause of knee damage. The orthopedic surgeon can remove the patella (kneecap), shave the heads of the femur and tibia and implant the prosthesis. Special bone cement is used for suitable adhesion and the implants can be seen in their locations in Figure 4.

Figure 4: After surgery – the femural and tibial prosthetic parts are in position securely adhered with bone cement.

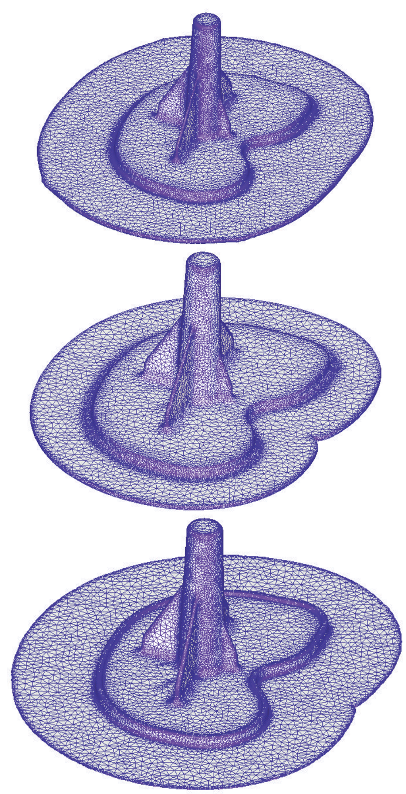

Figure 5: The shape and FEM mesh from the tibial knee joint forming simulations. From top to bottom: at the end of the blocker, finisher and re-strike operations.

An analysis was carried out on he hot forging operations of the tibial part of the knee joint prosthetic device. In this case there were three operations, a blocker, finisher and re-strike operation. Each of the three operations consisted of a furnace heat, forming operation and flash trim. A recently developed friction window facility allowed different lubrication conditions to be simulated for the extruded part and the coined part of the prosthesis. This was important since in practice, only the extruded part of the dies has lubricant applied, the coined section is formed dry. Figure 5 shows the tibial part at the end of the blocker, finisher and re-strike simulations.

Ti-64 from the material library was also used in this analysis where the furnace temperatures were specified as 1725F for the Blocker and 1700F for the finisher and re-strike operations. A rigid-plastic workpiece and rigid dies were used in this analysis. After the blocker operation simulation, a “trim-die” geometry was imported into the FEM pre-processor and positioned over the flashed blocker forging. An example of a trimming “die” or object is shown in Figure 6.

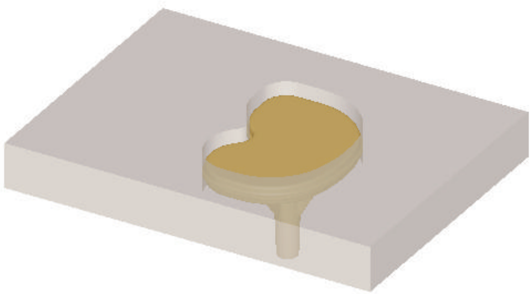

Figure 6: The simulated tibial knee forging implant after trimming in between the blocker and finisher operations.

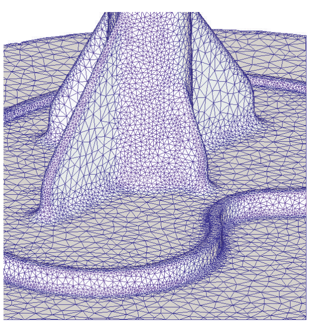

Figure 7: The FEM mesh after the final operation. Note how the finer elements are concentrated in locations of smaller features.

With the current object selected as the workpiece, the “trim-die” was selected as the boolean object and the flash was trimmed. Using this easy-to-use feature, the blocker flash was trimmed within 4-5 mouse clicks.

As with the hip joint forging simulation, the surface curvature weighting was set high in this analysis. As a consequence, the tighter radii of the webs and ribs received a finer element size whereas the larger, flatter surfaces were assigned coarser elements. This is illustrated clearly in Figure 7.

Tube Crimping

The crimping operation of the tube shown in Figure 8 was analyzed as a 3D simulation. The tube was considered as a plastic object and the wire was analyzed as an elasto-plastic entity. This allowed the prediction of springback in the wire in this assembly or installation. Both the tube and the wire had a similar number of elements in their FEM mesh ~ 16,000 elements in each.

The tools and the tube are displayed as sliced objects in Figure 8 and the wire remained un-sliced. Nodal contact is shown (by the dots) in this 3D multi-deforming body simulation. This type of installation may very well lend itself to applications in the automotive, fastener, aerospace and medical fields.

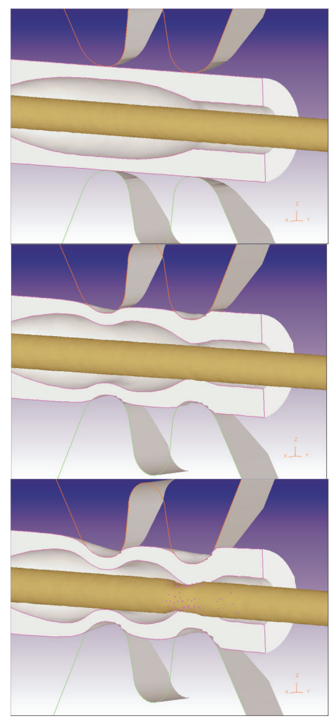

Figure 8: Cut away view showing the tube deforming, the wire being deformed as a result and the nodal contact (dots) between the tube and wire.

Orthopedic Locking Screw Extrusion

The femural and tibial prosthetic knee joint parts discussed previously can become separated from the bones after a number of years in service. One revision procedure is to implant alternative parts and lock them into the femur and tibia via several transverse-locking screws. Figure 9 shows an x-ray illustrating one example of a pair of screws locking a tibial revision prosthetic into the bone.

Figure 9: The transverse locking screws securing the revision prosthetic into the tibia.

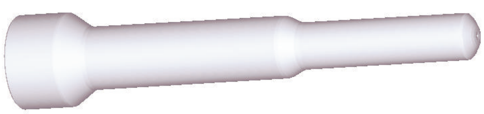

Figure 10: The predicted locking screw shape.

The forming of a transverse locking screw was simulated as an axisymmetric analysis. The simulated part shape is shown in Figure 10. An initial extrusion involved the squaring up of the wire and forming its point. The following free extrusion employed a double reduction. The deformation or effective strain distribution is shown in the locking screw at the end of both extrusion operations in Figure 11.

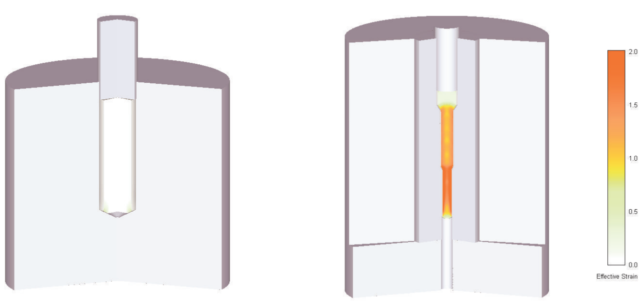

Figure 11: The effective strain distribution in the screw at the end of each extrusion operation.

The second extrusion simulation was run as a coupled die stress analysis. In addition to the workpiece being simulated as a plastic deforming body, the die insert, shrink ring and base plate were considered as elastically deforming bodies. Die stress analysis simulation has proved to be very successful in terms of economic savings [2, 3 & 5].

The die insert was assigned carbide material properties, while the shrink ring and baseplate were given H13 tool steel characteristics. An interference boundary condition was applied at the insert/shrink ring interface. In this 2D analysis, the locking screw was given 1000 elements, the die insert: 1500, the shrink ring: 500 and the base plate: 200. The punch or ram was considered as a rigid object.

An area of high tensile stress was predicted on the inside diameter of the carbide insert at the first reduction (Figure 12). Depending on the magnitude of this tensile stress, carbide fracture may occur. As a general rule, if the carbide can be kept in compression, it should not fail. A similar observation can be made for the second reduction but to a much lesser extent. Under these extrusion conditions, the shrink ring also shows a tensile stress at the insert interface (Figure 12).

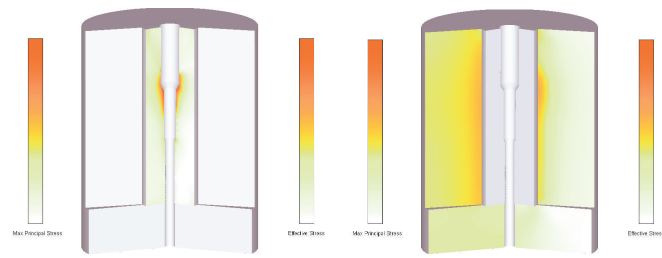

Figure 12: The stress analysis displays the maximum principal (left) and effective stress (right) as scaled for the carbide insert and H13 tool steel components. The dark regions represent high die stresses.

Stress Relief

The heat treatment of the hip joint implant was simulated using DEFORM™-HT. In practice, the heat treatment applied to such prosthetic devices has been an annealing operation to provide as low a stress-state as possible. For this Ti-64 alloy component the annealing conditions for the simulation were: hold at 1400F for 90 minutes followed by a slow cool to room temperature.

The Baily-Norton equation [6, 7] is one of the creep models implemented in the software and relates effective stress to creep strain rate. It is of the form shown below:

$$\dot{\bar{\varepsilon}} = Km\sigma^{n}t^{m-1} + Q\sigma^{r}$$

where *K, m, n, Q, r* are material constants and *t* is time. In the case of the femoral component, the following material constants were used: K: 3e-11, n: 5.2, m: 0.1, Q: 3e-53 and r: 25. Starting the stress relief simulation from a cooled-after-forged condition, the hip joint was heated to 1400F and held for 90 minutes. Following this the part was cooled in air. Figure 13 shows that the annealing operation reduced the tensile maximum principal stress from 207.8 to 110 KSI.

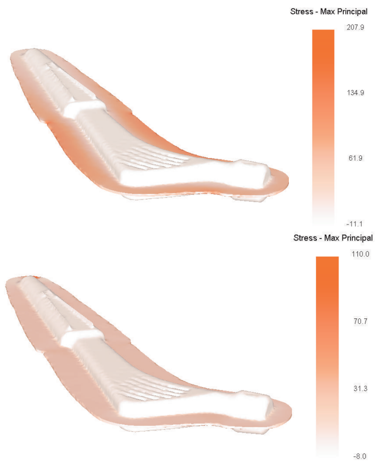

Figure 13: The maximum principal stress distribution in the femur stem after forging and cooling to room temperature (top) and after annealing at 1400F (bottom).

Conclusions

A number of simulation examples have been detailed. The forming of two Ti-64 alloy prosthetic devices were analyzed. Flash was trimmed before finisher (and restrike in the case of the knee joint) operations. Trimming was carried out in the software system as a boolean operation. There was no need to export geometries into a CAD system for the flash trimming. Examples of crimping and die stress during forming operations were also reported. Finally, an example of heat treatment highlighted the stress relief of a hip joint implant.

The examples have shown that computer simulation of metal forming and heat treating operations is definitely not restricted to the automotive and aerospace organizations. The medical industry can certainly benefit from reducing trial and error, not interrupting production and reduced product time to market that computer simulation offers.

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