COMBINING TOLERANCE ANALYSIS, MECHANISMS ANALYSIS & FE ANALYSIS TO CREATE A ROBUST DESIGN OF A DRUG DELIVERY DEVICE.

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SUMMARY

It is important for many devices that they can be produced accurately and that that they operate correctly, and this is particularly important in the medical industry for drug delivery devices. Elite Consulting has used a combination of techniques to determine whether such a device can be produced consistently and operate reliably, so as to deliver a precise dose every time.

The work described here was originally undertaken for a customer in the medical device industry. However due to the restrictions imposed by client confidentiality, what is shown here is an idealised representation of such a device, which shows the principles that were used, but not the actual design. An initial prototype design was produced in Pro/ENGINEER® and because this is a mechanism, the first step was to use the Mechanism Dynamics Option (MDO) in Pro/ENGINEER to analyse the kinematics and dynamics of the mechanism.

Once this had been completed using nominal dimensions, an initial assessment of likely materials and manufacturing process was made and tolerances were added to the parts, based on default tolerances. The next step was to analyse the effect of tolerances on the performance of the device. To do this a 3D statistical tolerance package from Sigmetrix called CETol® was used. This takes in the nominal dimensions directly from the CAD model and then tolerances and manufacturing process capability are added to the relevant dimensions and both a statistical and worse case tolerance analysis are performed.

The results from this analysis not only show whether the device will remain in specification throughout the tolerance range, but also which tolerances show the greatest contribution and sensitivity. Armed with this knowledge, targeted improvements to the design were made. However, because part of the design relies on the flexibility of a spring component, a further step was necessary. This was to conduct a finite element analysis of the spring, not only to achieve the right stiffness and an acceptable stress with the nominal design, but also to assess how stiffness and stress might vary with tolerances of the spring's manufacture. Pro/ENGINEER MECHANICA® software was chosen for

this part of the analysis, because of its ability to conduct sensitivity and optimisation analyses.

The results form these various analyses were then reviewed and design iterations made, knowing which aspects were likely to yield the biggest improvements, because the sensitivities to the various variables were known. Thus using this methodology a robust design was produced that was relatively insensitive to variations in the production processes.

1: Description of Device

This is a hand-held drug delivery designed to deliver a self-administered precise dose of medication. It is operated by the patient turning the handwheel through one revolution. The handwheel serves as a crank connected to a conrod which in turn is connected to a piston. The piston slides in the main body of the device freely until it contacts another piston. Once it makes contact, the 2 pistons move in unison, and the movement of the first piston delivers the dose. Behind the second piston is a spring and this serves to give ‘feel’ to the device, so that the patient can tell when the drug is being delivered. The important features are that the piston moves the correct distance and that the spring has the right characteristic, for correct feel.

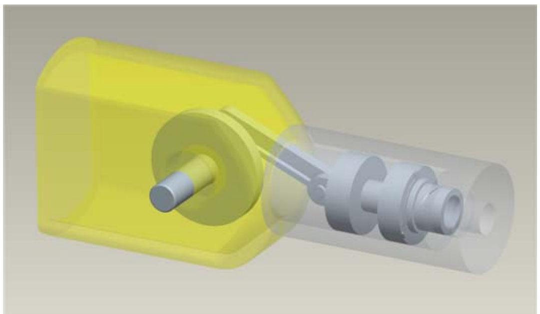

Figure 1: Pro/ENGINEER model of device.

2: Mechanisms Analysis

The device was modelled in Pro/ENGINEER using ‘top-down’ techniques in order to get the overall dimensions and kinematics correct. Then the parts were modelled and assembled using mechanism joints. This enabled a rigid body dynamics analysis to be undertaken using the Mechanism Dynamics Option from within Pro/ENGINEER. From this the torque to turn the handwheel was determined and compared with the specification obtained by a Quality Function Deployment exercise and hence the spring characteristic defined.

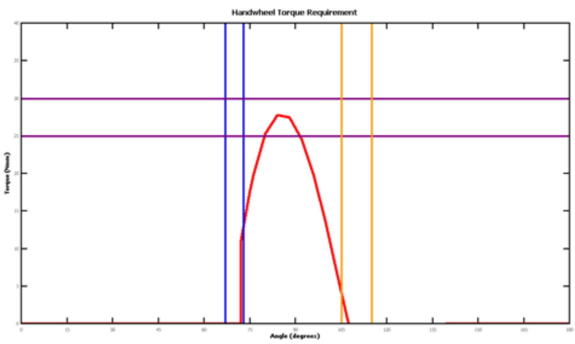

Figure 2: Handwheel Torque

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3: Tolerance Analysis

Once nominal dimensions of the mechanism had been defined in the model, CETol was then used to assess the tolerance stack-up, taking into account manufacturing capability for the various processes. This was done by defining the connections between the parts so that the assembly was perfectly constrained, entering tolerances and manufacturing data for key dimensions and then running an analysis.

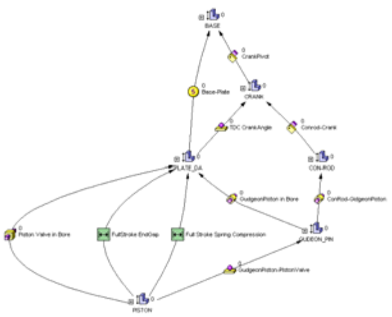

Figure 3: CETol Model Graph showing connections between parts.

The analysis uses a direct solver rather than a Monte Carlo analysis. Both a worse case stack-up and a statistical analysis were done at the same time, enabling a prediction of the number of 'good' components to be made, together with information on the contributions of the different tolerances and their sensitivities.

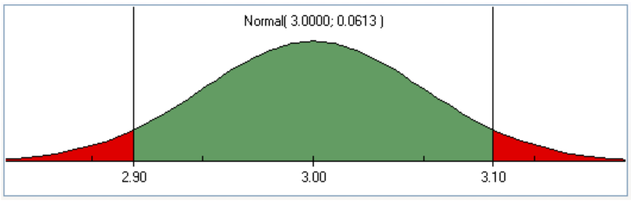

Figure 4: Statistical Tolerance Analysis Result for Spring Compression at Full Stroke.

4: Finite Element Analysis

The mechanism analysis gave the nominal required spring characteristic and the tolerance analysis showed how the engagement point and spring compression might change with tolerance stack up in the assembly. The purpose of the finite element analysis was firstly to optimise the spring design to give the correct characteristic at nominal dimensions and then to see how this varied with spring tolerances and also to take into account the variation caused by tolerance stack up in the assembly. Key dimensions were parameterised in Pro/ENGINEER and then an optimisation analysis was done to obtain the nominal design.

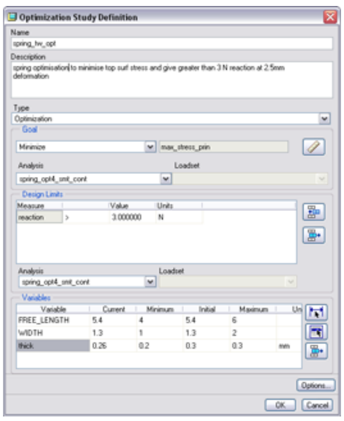

Figure 5: Set up of Optimisation Run.

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A design of experiments (DOE) was set-up using the Taguchi L9 array for 4 variables and 3 levels. The variables chosen were thickness, width and free length. The levels were set at lower tolerance, nominal and upper tolerance.

Run	Force at 3.4 mm defln. (N)	Force at 2.00 height (N)	Stress at 2.0 mm height (MPa)
1	2.785	2.744	743.7
2	2.736	2.736	713.4
3	2.659	2.698	630.2
4	4.939	4.939	1042.1
5	4.969	5.042	970.6
6	4.618	4.550	773.9
7	7.926	8.043	1322.7
8	7.970	7.853	1188.7
9	7.852	7.852	1158.1
Nominal	4.940	4.940	779.0

Figure 6: Global Sensitivity Results.

5: Final Stage

Finally all of these results were brought together and final adjustments made to the design, its tolerances and the manufacturing processes to achieve an optimised robust design of assembly and spring.

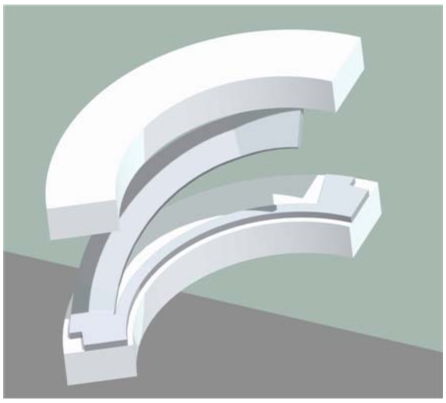

Figure 7: Final Design of Spring (1/3rd shown)

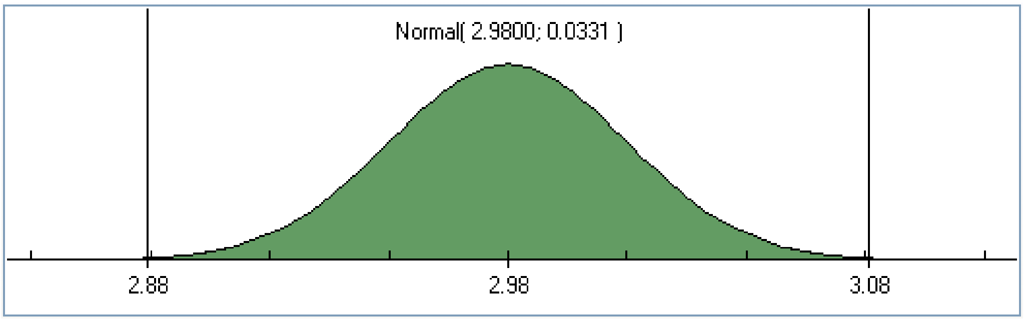

Figure 8: Final Tolerance Analysis Result.