

**Design for 6-Sigma – Integrating
Tolerance Analysis & FEA to Achieve a
Robust Design that can be Made and
Meets Performance Targets**

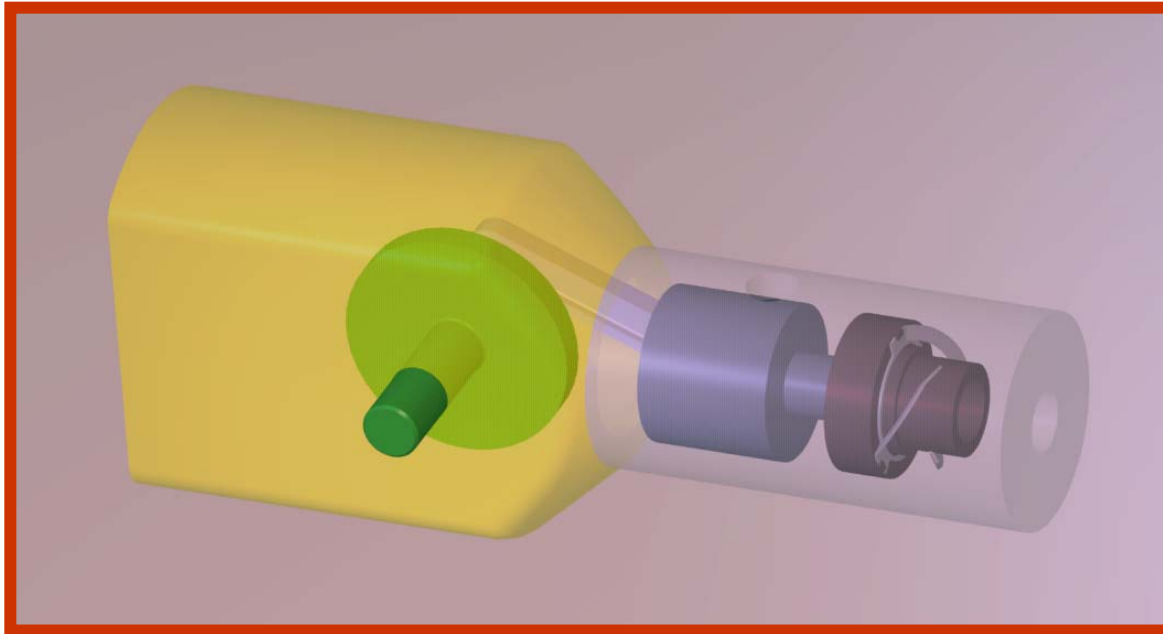
**Ray Ellender & Rod Giles
Elite Consulting Ltd.**

Introduction

- Elite Consulting
 - Formed 1993
 - Based in Northampton, UK
 - Carry out a wide range of analysis types for diverse industrial sectors
- Analysis of Medical/Pharmaceutical Device

Background

- Request from client to optimise and make more robust design of drug delivery device
- Due to confidentiality the real device is not shown



Operation

- The device delivers a precise dose of drug in powder form
- The patient operates the device by turning a handle
- Volume delivered equals piston displacement
- Client carried out a Quality Function Deployment

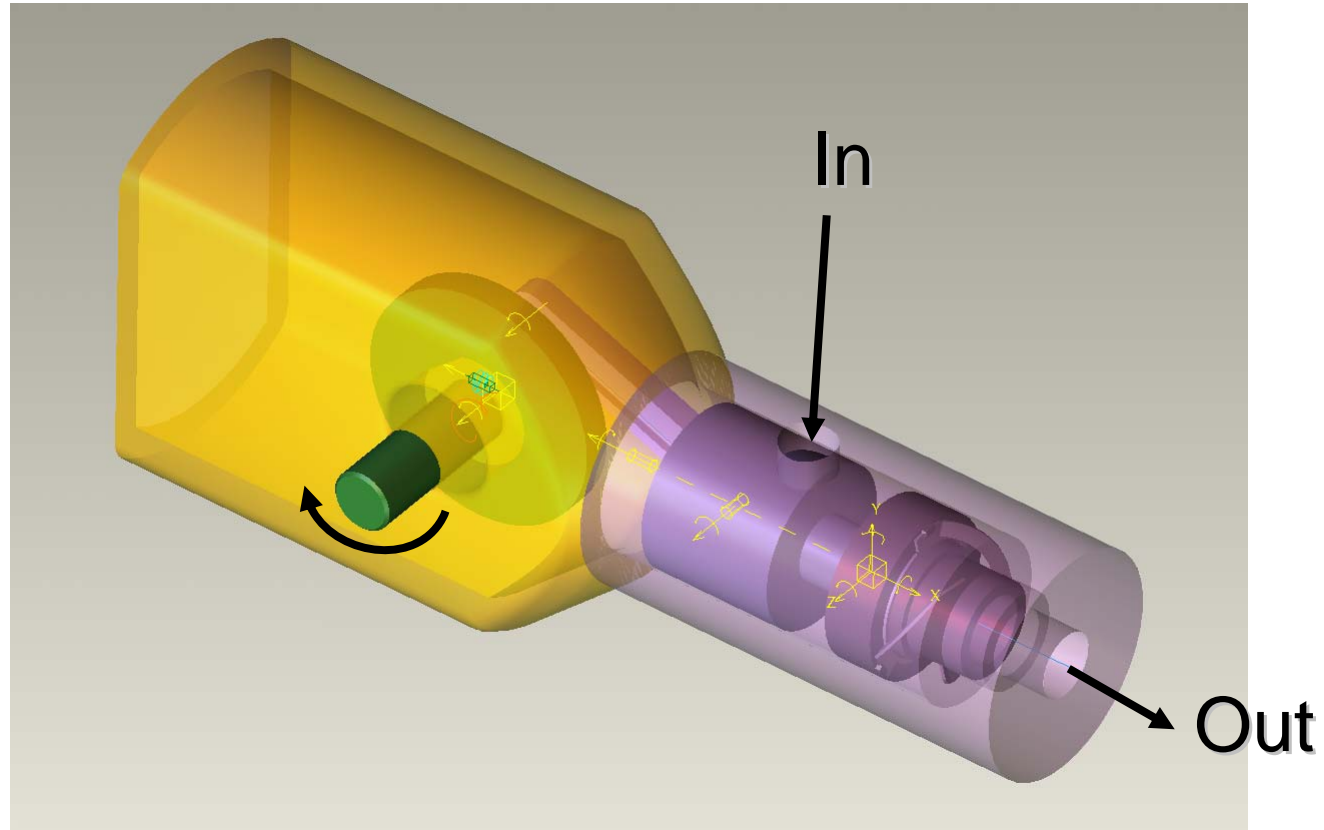
Design Process

- Design Specification
 - Derived from QFD analysis
 - Translate external requirements into detailed design
- Top-down design of mechanism
- Construction of components
- Mechanism Dynamics
- Tolerance Analysis of Mechanism
- Spring Design
 - Finite element analysis & optimisation
 - Design parameter evaluation using Taguchi DoE

Performance

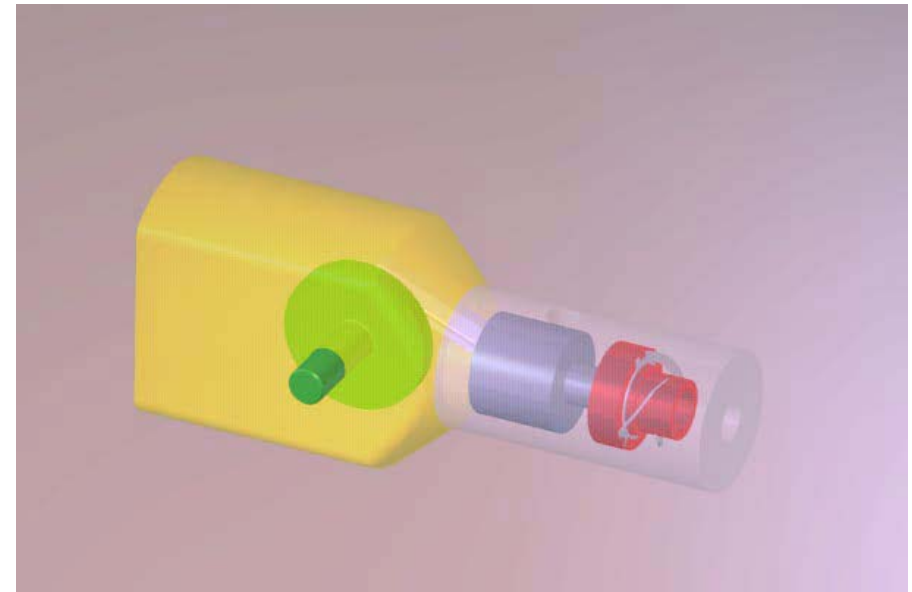
- Deliver known quantity of drug
 - Tolerance based on medical efficacy requirement
- Achieve required turning torque for operator ‘feel’
 - Too low and user would not realize that device had fired
 - Too high and frail users would not be able to operate it

Mechanism Model



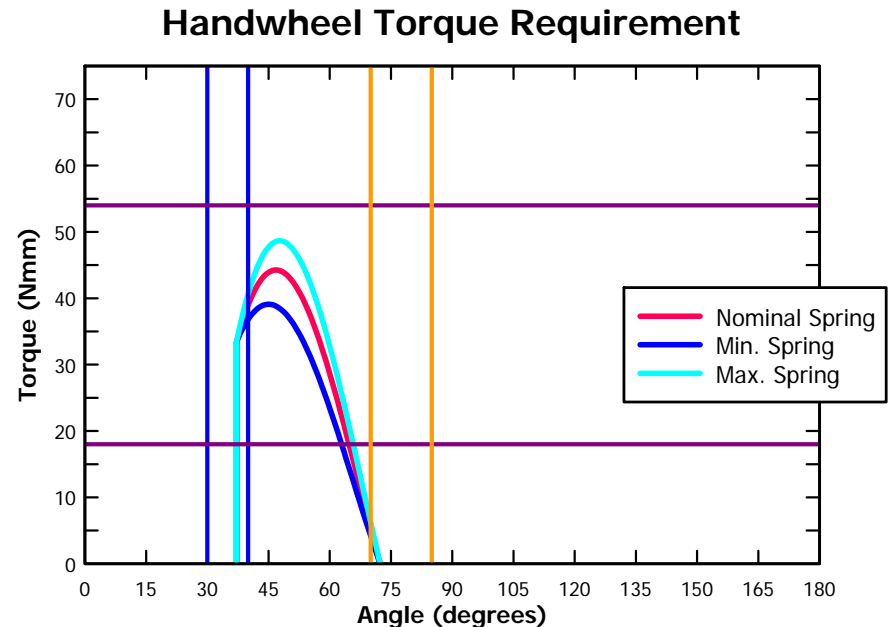
Mechanism Model Operation

- Animation showing operation
- Pre-chamber filled during back-stroke
- Dose metered during front-stroke
- Crank turned by patient



Torque Requirement

- Result of user survey
 - Max. handwheel torque 54 Nmm (1.5 N at 36 mm rad)
 - Min. handwheel torque 18 Nmm (0.5 N at 36 mm rad)
 - Effect of product included - damping added to dynamic model to simulate effect
 - Firing to occur at $35^{\circ} \pm 5^{\circ}$



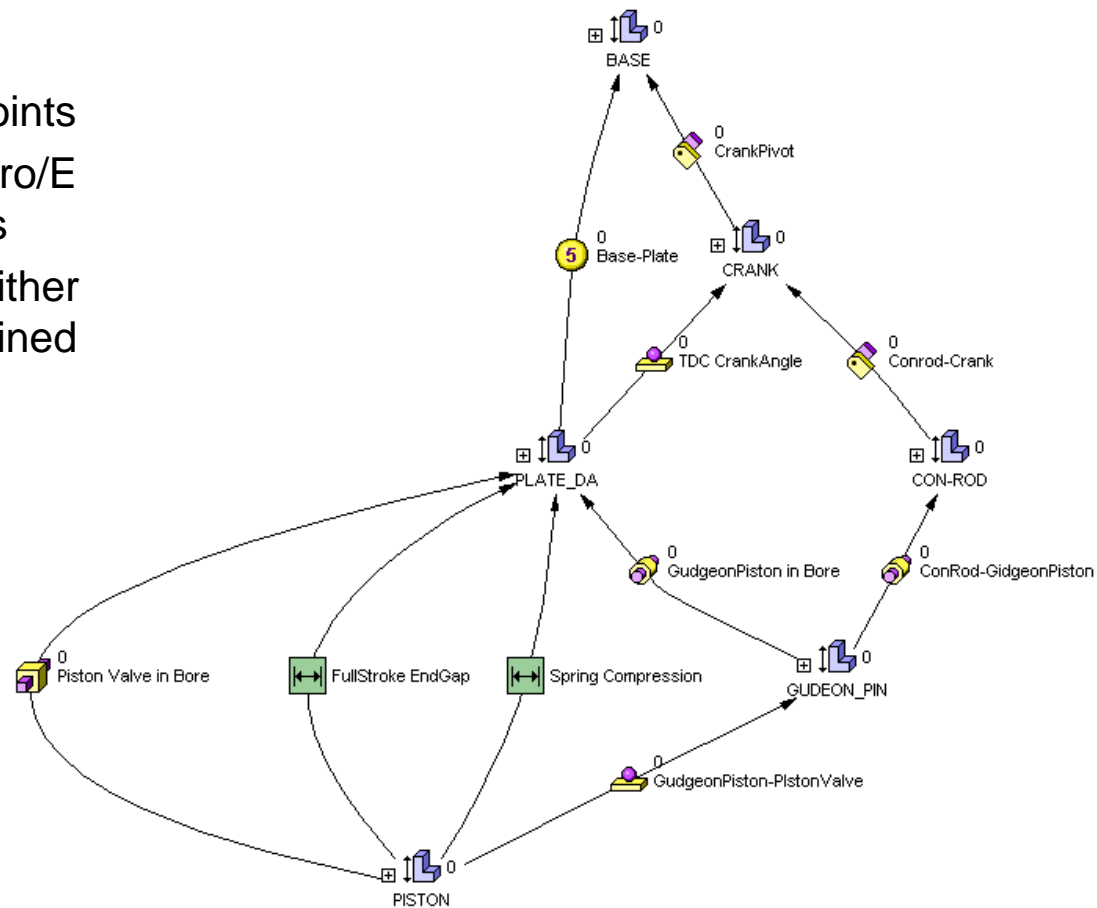
Tolerance Analysis

- Conduct 3D Statistical & Worse Case analysis using CETol software from Sigmatrix
- The process is:
 - Link CETol to Pro/E model
 - Make joint connections between parts in CETol
 - Define ‘Measures’
 - Define Tolerancing scheme for parts
 - Choose initial tolerances and manufacturing processes and process capability
 - Solve to obtain results
 - View Results
 - Modify model to improve results

Tolerance Analysis

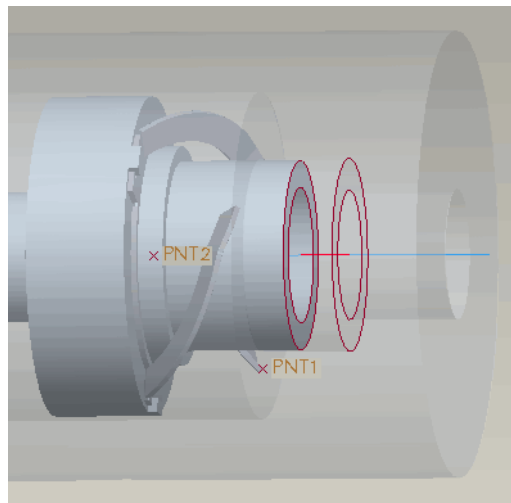
Make joint connections between parts in CETol

- Joints are kinematic joints
- These over-ride the Pro/E assembly connections
- Assembly must be neither over or under-constrained



Tolerance Analysis

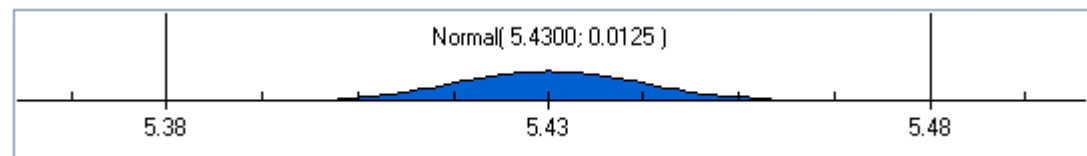
- Define 'Measures' of Key Results in 2 Configurations
 - Just Engaged
 - Handwheel Angle ($35^\circ \pm 5^\circ$)
 - Top Dead Centre
 - End Gap ($+1.60\text{mm}/-0.00\text{mm}$)
 - Spring Compressed Length ($3.00\text{mm} +1.5/-2.4\text{mm}$)



End Gap Measure – Must not close

Tolerance Analysis

- Define Tolerancing Scheme for parts
 - Spring had a tolerance of $\pm 0.05\text{mm}$ on free length
 - All other parts were had a tolerance of $\pm 0.1\text{mm}$ on relevant dimensions
- Define Manufacturing Process Capability
 - All manufacturing processes were assumed to have a process capability of $C_p = 1.33$
 - Note this can be changed if new information becomes available



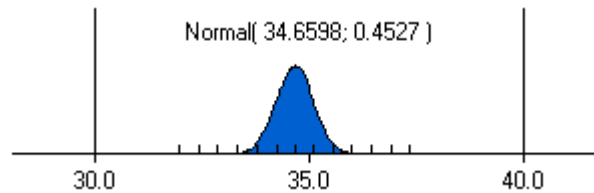
Spring tolerance ± 0.05 with $C_p = 1.33$

Tolerance Analysis

- Conduct Initial Baseline Analysis

- Just Engaged

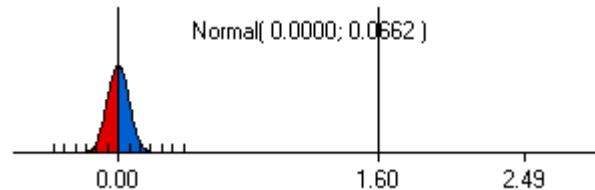
- Handwheel Angle



(0 DPMU)

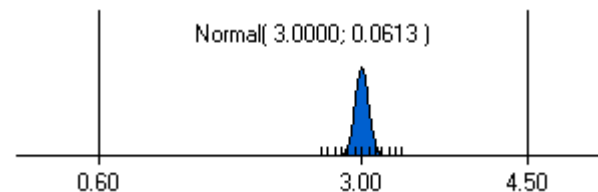
- Top Dead Centre

- End Gap



(500,000 DPMU)

- Spring Compressed Length




(0 DPMU)

DPMU = Defects per Million Units








Tolerance Analysis

- Contribution & Sensitivity
 - End Gap Measure

Contributions

Name	Contributions
BASE : Mating Face : to Crank Pivot Hole Offset	14.29 %
PISTON : End Face : to Piston Face Offset	14.29 %
GUDEON_PIN : Pivot Hole-Conrod : to Piston End Face Offset	14.29 %
CRANK : ConRod Pivot : to Main Pivot Offset	14.29 %
PLATE_DA : Inner End Face Small : to Inner End Face Large Offset	14.29 %
PLATE_DA : Mating Face : to Datum Right Offset	14.29 %
CON-ROD : Pivot Hole-to Crank : to Pivot Boss - To Gudgeon Pin Offset	14.29 %
BASE : Crank Pivot Hole Size 	0.00 %

Sensitivities

Name	Sensitivity
BASE : Mating Face : to Crank Pivot Hole Offset	1 mm/mm 
CRANK : ConRod Pivot : to Main Pivot Offset	-1 mm/mm 
PLATE_DA : Mating Face : to Datum Right Offset	1 mm/mm 
PISTON : End Face : to Piston Face Offset	-1 mm/mm 
GUDEON_PIN : Pivot Hole-Conrod : to Piston End Face Offset	-1 mm/mm 
CON-ROD : Pivot Hole-to Crank : to Pivot Boss - To Gudgeon Pin Offset	-1 mm/mm 
PLATE_DA : Inner End Face Small : to Inner End Face Large Offset	1 mm/mm 
BASE : Crank Pivot Hole Size	0 mm/mm

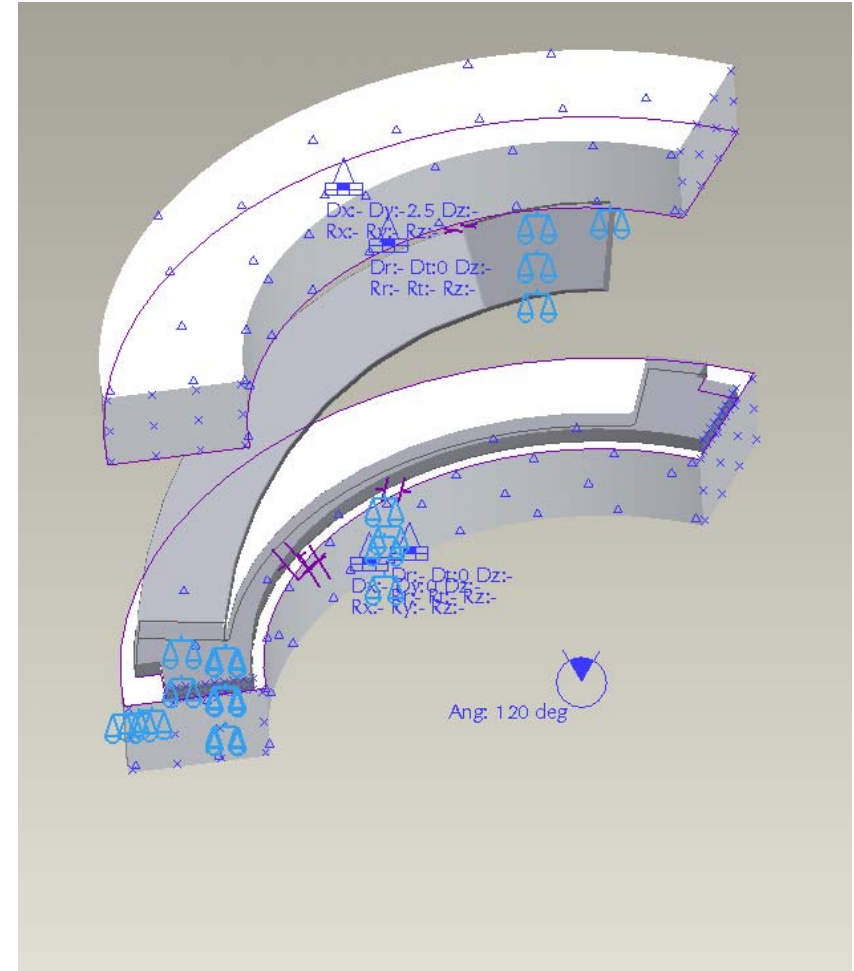
Finite Element Analysis

- Simplified model of spring and abutments
- 1/3 model used, so 1/3rd spring force required
- 9 N at 2.5 mm deflection, 3.6 N/mm (1.2 N/mm for single 'leaf')
- Cyclic symmetry used
- Enforced displacement of 2.5 mm applied to upper surface



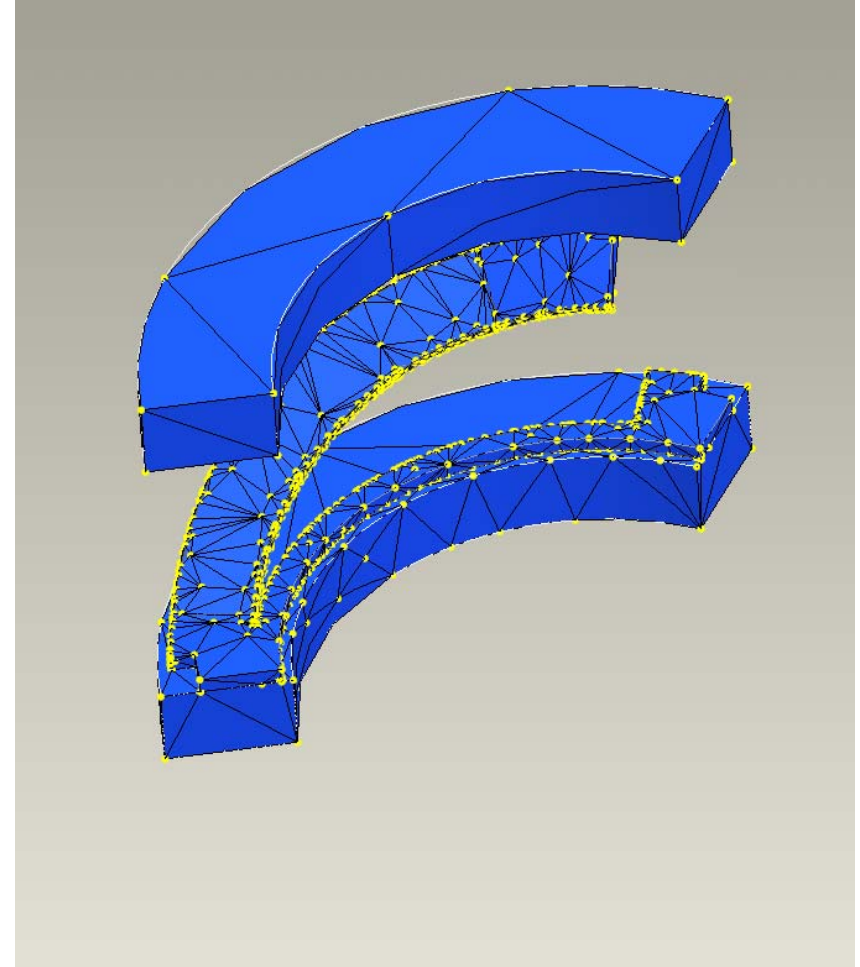
Finite Element Analysis

- Contact regions applied to base and tip
- Spring – stainless steel
- Platen – Acetal
Homopolymer (POM)
- Enforced displacement of upper platen, 2.5 mm nominal (adjusted for changes in free length)



Finite Element Analysis

- 3435 solid tetra adaptive p-elements
- Automatic hp-extension at contact regions
- P-extension at all other places
- Parametric element mesh – mesh updates when geometry changes
- 65,000 DOF, run time approx 40 min



Finite Element Analysis

- Design Parameters
 - Free Length
 - Width
 - Thickness
 - Initial Dimensions
 - 0.3 mm Thickness
 - 1.0 mm Width
 - 5.4 mm Free Length

Optimization Study Definition

Name: spring_tw_opt

Description: spring optimisation to minimise top surf stress and give greater than 3 N reaction at 2.5mm deformation

Type: Optimization

Goal: Minimize max_stress_prin

Analysis: spring_opt4_smt_cont Loadset: []

Design Limits

Measure	Value	Units
reaction	> 3.000000	N

Analysis: spring_opt4_smt_cont Loadset: []

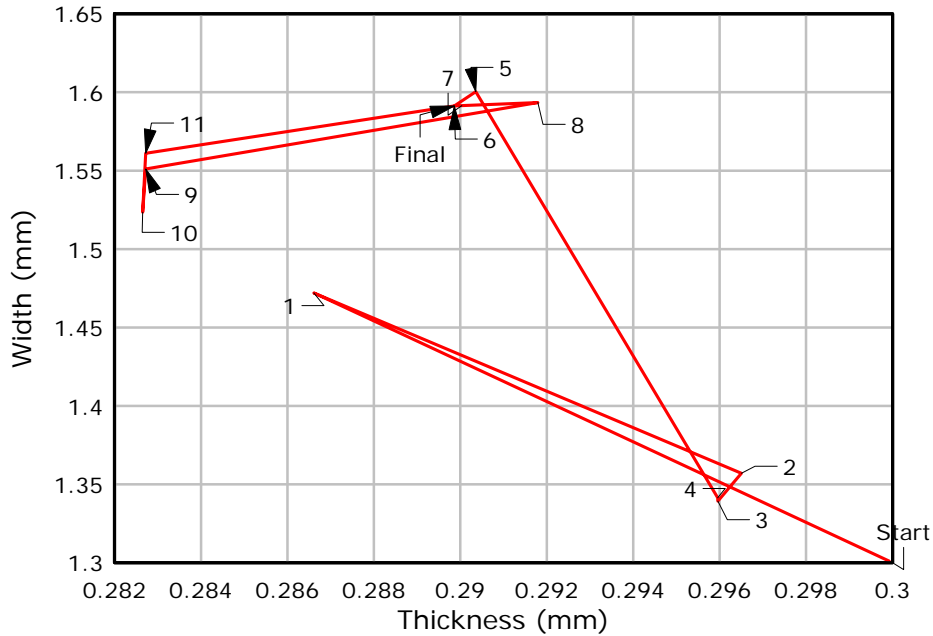
Variables

Variable	Current	Minimum	Initial	Maximum	Units
FREE_LENGTH	5.4	4	5.4	6	
WIDTH	1.3	1	1.3	2	
thick	0.26	0.2	0.3	0.3	mm

Options... OK Cancel

Optimisation Results

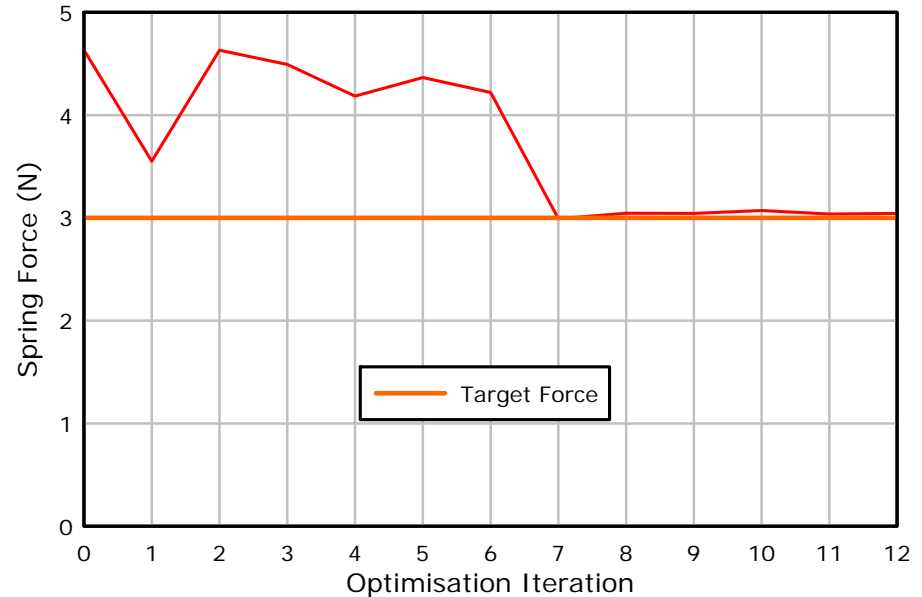
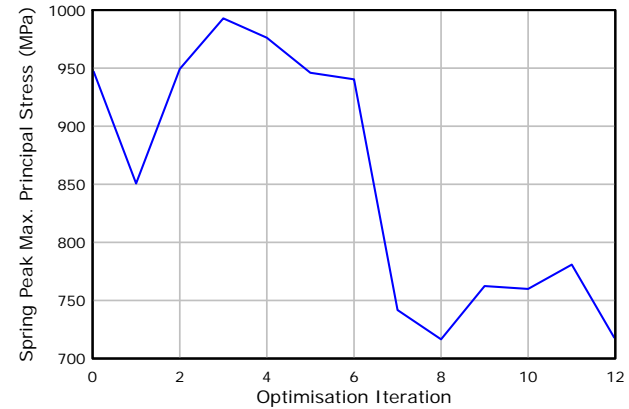
Optimisation Space



	Dimensions		
	Minus	Nominal	Plus
Thick	0.288	0.290	0.291
Width	1.49	1.59	1.69
Free Length	5.35	5.40	5.45

Optimisation Result

Spring Stress at 2.5 mm Deflection



Design of Experiment

Taguchi L9 array Up to 4 variables 3 levels

Taguchi L9				
	Factor			
Run	X1	X2	X3	X4
1	1	1	1	1
2	1	2	2	2
3	1	3	3	3
4	2	1	2	3
5	2	2	3	1
6	2	3	1	2
7	3	1	3	2
8	3	2	1	3
9	3	3	2	1

X1 – free length

X2 – width

X3 – thick

X4 – not used

1 – lower level

2 – nominal

3 – upper level

Design of Experiment

Run	Thick	Width	Free Length	Displacement
1	0.288	1.49	5.35	2.45
2	0.290	1.59	5.35	2.45
3	0.291	1.69	5.35	2.45
4	0.290	1.49	5.40	2.50
5	0.291	1.59	5.40	2.50
6	0.288	1.69	5.40	2.50
7	0.291	1.49	5.45	2.55
8	0.288	1.59	5.45	2.55
9	0.290	1.69	5.45	2.55
Nominal	0.290	1.59	5.40	2.50
Tolerance Range	+0.34% -0.69%	±6.3%	±0.93%	

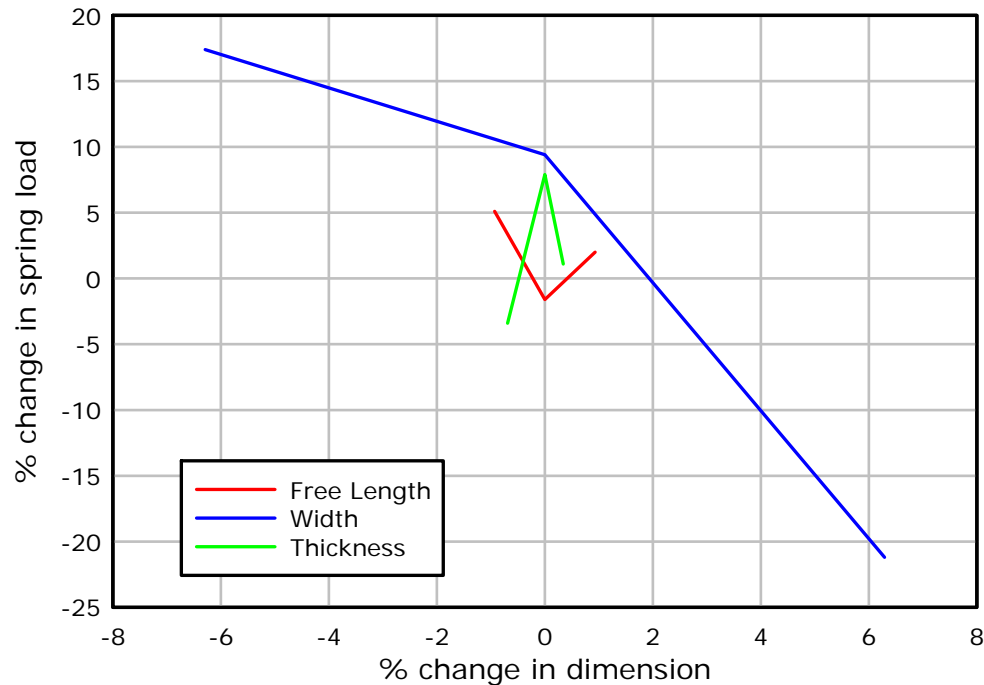
Taguchi DOE L9 Array

Run	Spring Load (N)	Deviation from nominal
1	3.377	+11.3%
2	3.837	+26.4%
3	2.359	-22.3%
4	3.532	+16.4%
5	3.065	+1.0%
6	2.366	-22.0%
7	3.778	+24.5%
8	3.057	+0.7%
9	2.453	-19.2%
Nominal	3.035	-

- Results more difficult to interpret than normal due to the changing deflected length

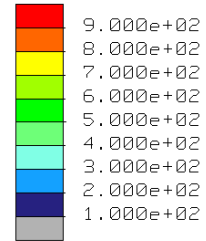
Analysis of Results - Load

	Average Factor X1 - free length		Average Factor X2 - width		Average Factor X3 - Thickness	
Level 1	3.191	+5.1%	3.562	+17.4%	2.933	-3.4%
Level 2	2.988	-1.6%	3.320	+9.4%	3.274	+7.9%
Level 3	3.096	+2.0%	2.393	-21.2%	3.067	+1.1%

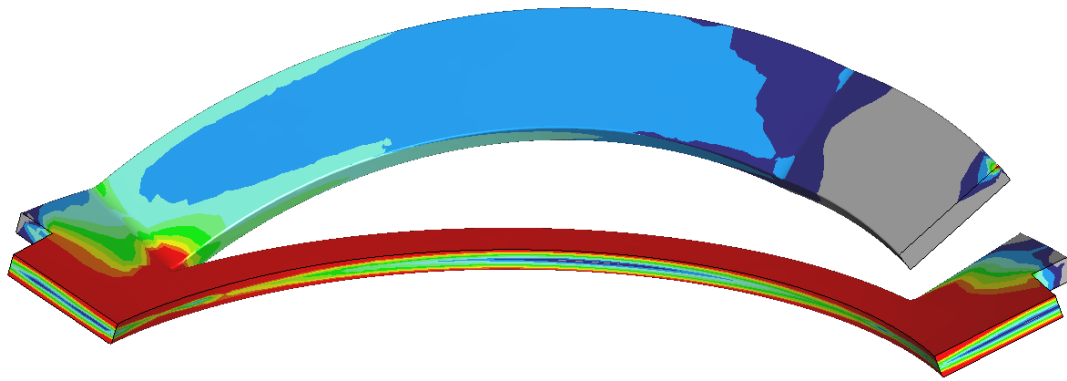


Finite Element Analysis Result

Stress von Mises
(N / mm²)



- Spring acts as a belleville washer as well as a cantilever spring

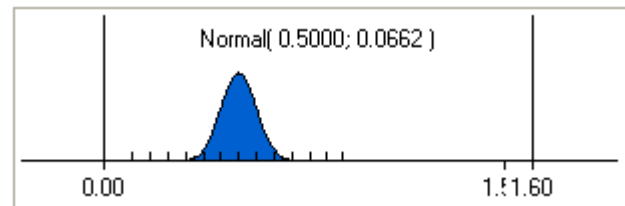


Example – run2 results

Tolerance Analysis

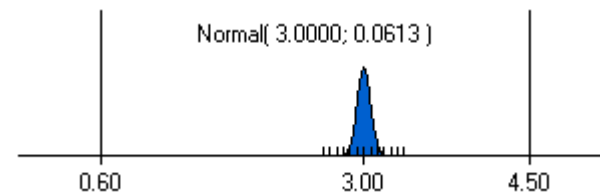
- Modify Design & Conduct Final Analysis
 - Change Nominal for End Gap by 0.5mm
 - Optimised Spring (same free length)
 - Top Dead Centre

- End Gap



(0 DPMU)

- Spring Compressed Length



(0 DPMU)

DPMU = Defects per Million Units

Summary

- 3d model definition, mechanism analysis, tolerance analysis and finite element analysis have all been carried out using the same environment.
- Mechanism includes non-linear effects and is able to translate customer requirements into component specification for the spring.
- The tolerance analysis shows where the nominal design needs to be changed to ensure operation.
- The finite element analysis determined the optimised nominal dimensions for the spring which achieves the customer requirement.
- A 3 factor, 3 level DoE using the tolerance limits for the three design parameters gives a good indication of the 'worst-case' performance, without having to carry out Monte Carlo simulation.
- A final tolerance analysis was carried out to check the performance
- Complex multiple disciplinary analyses are now within the reach of design engineers