Multivariate Optimization Using First Principal Component

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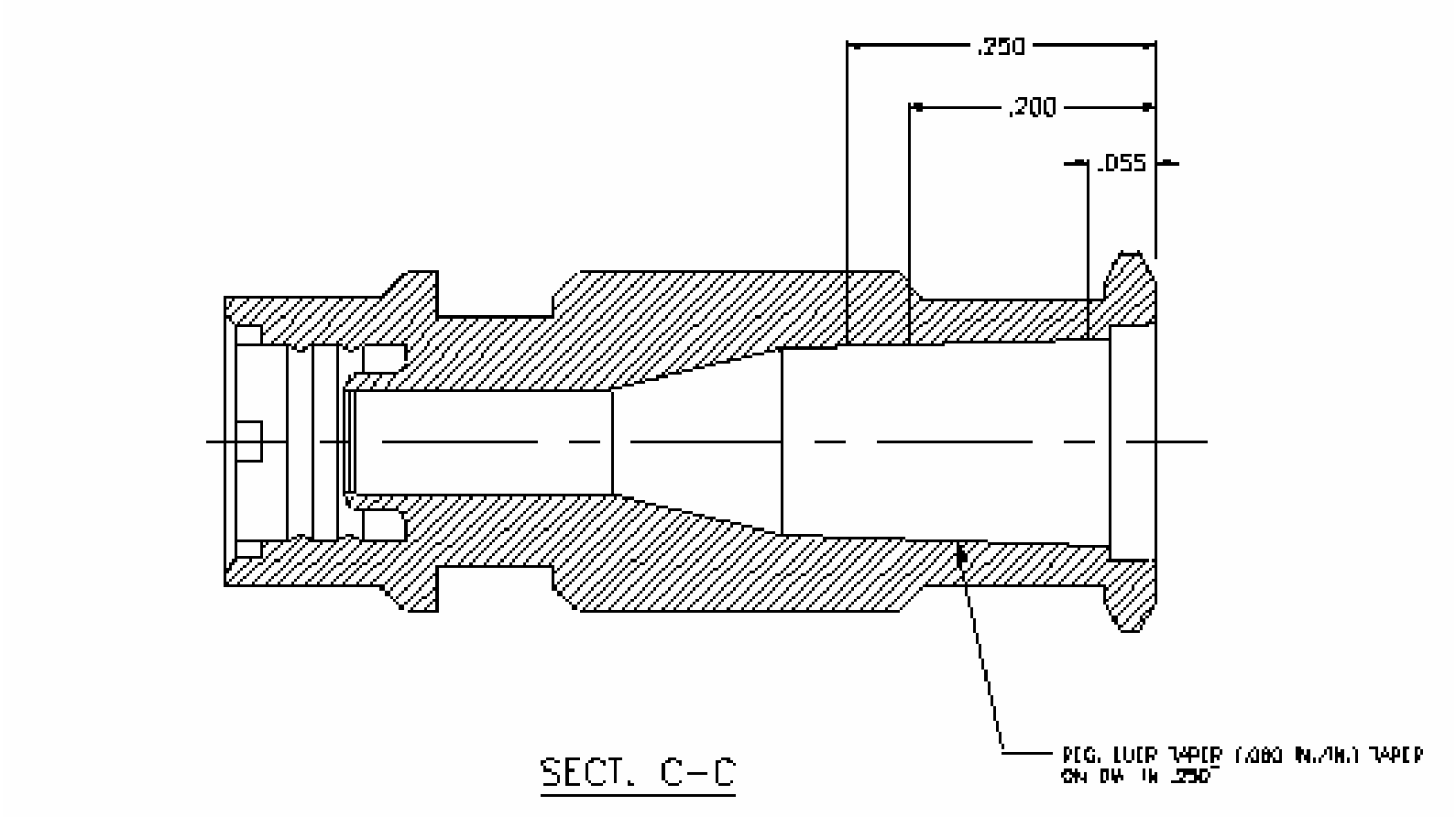
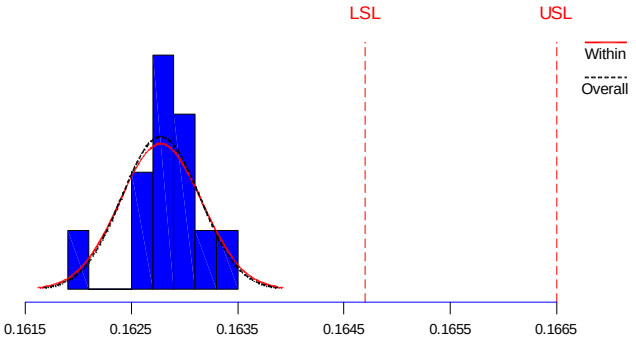
Reduction of Luer taper distortion in the 27 Gauge Spinal Needle hubs



Needles collected from the field were measured and evaluated against the targets to see how they deviate from desired dimension. The diameters and circularities at the various shown depths were measured. One can clearly see that the areas under the curve dimensions at the different depth are not falling within the target area.

This distortion affects these diameters (also the circularity) of the Leaking Product on the Field diameter at 0.055”, at 0.175”, at 0.200”, and at 0.220” depth.

EVALUATION OF KNOWN LEAKING PRODUCTS VS TARGET @ D55 DEPTH

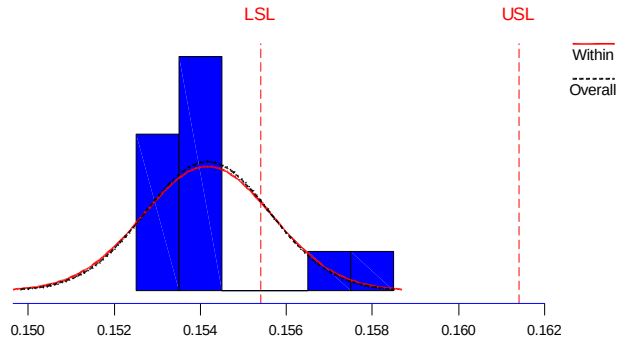


Process Data	
USL	0.166500
Target	*
LSL	0.164700
Mean	0.162775
Sample N	12
StDev (Within)	0.0003857
StDev (Overall)	0.0003679

Potential (Within) Capability	
Cp	0.78
CPU	3.22
CPL	-1.66
Cpk	-1.66
Cpm	*

Overall Capability		Observed Performance		Exp. "Within" Performance		Exp. "Overall" Performance	
Pp	0.82	PPM < LSL	1000000.00	PPM < LSL	999999.70	PPM < LSL	999999.92
PPU	3.38	PPM > USL	0.00	PPM > USL	0.00	PPM > USL	0.00
PPL	-1.74	PPM Total	1000000.00	PPM Total	999999.70	PPM Total	999999.92
Ppk	-1.74						

EVALUATION OF KNOWN LEAKING PRODUCTS VS TARGET @ D175 DEPTH

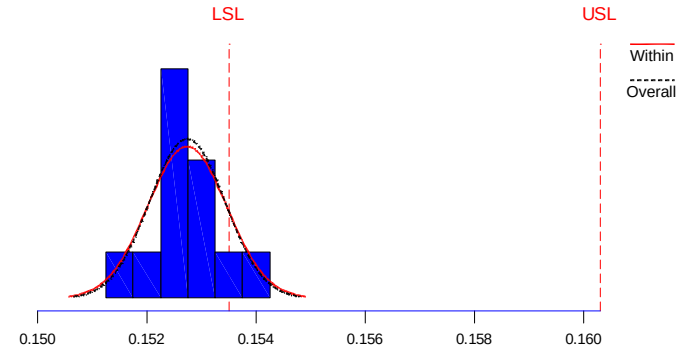


Process Data	
USL	0.161400
Target	*
LSL	0.155400
Mean	0.154167
Sample N	12
StDev (Within)	0.0015051
StDev (Overall)	0.0014495

Potential (Within) Capability	
Cp	0.66
CPU	1.60
CPL	-0.27
Cpk	-0.27
Cpm	*

Overall Capability		Observed Performance		Exp. "Within" Performance		Exp. "Overall" Performance	
Pp	0.69	PPM < LSL	833333.33	PPM < LSL	793738.41	PPM < LSL	802574.66
PPU	1.66	PPM > USL	0.00	PPM > USL	0.77	PPM > USL	0.30
PPL	-0.28	PPM Total	833333.33	PPM Total	793739.18	PPM Total	802574.97
Ppk	-0.28						

EVALUATION OF KNOWN LEAKING PRODUCTS VS TARGET @ D200 DEPTH

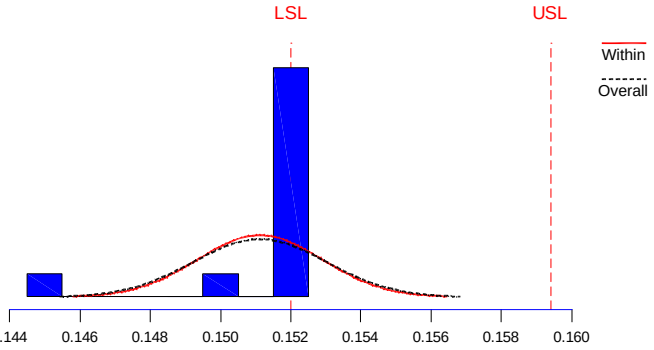


Process Data	
USL	0.160300
Target	*
LSL	0.153500
Mean	0.152733
Sample N	12
StDev (Within)	0.0007256
StDev (Overall)	0.0006915

Potential (Within) Capability	
Cp	1.56
CPU	3.48
CPL	-0.35
Cpk	-0.35
Cpm	*

Overall Capability		Observed Performance		Exp. "Within" Performance		Exp. "Overall" Performance	
Pp	1.64	PPM < LSL	916666.67	PPM < LSL	854645.01	PPM < LSL	866215.76
PPU	3.65	PPM > USL	0.00	PPM > USL	0.00	PPM > USL	0.00
PPL	-0.37	PPM Total	916666.67	PPM Total	854645.01	PPM Total	866215.76
Ppk	-0.37						

EVALUATION OF KNOWN LEAKING PRODUCTS VS TARGET @ D220 DEPTH



Process Data	
USL	0.159400
Target	*
LSL	0.152000
Mean	0.151117
Sample N	12
StDev (Within)	0.0017790
StDev (Overall)	0.0019047

Potential (Within) Capability	
Cp	0.69
CPU	1.55
CPL	-0.17
Cpk	-0.17
Cpm	*

Overall Capability		Observed Performance		Exp. "Within" Performance		Exp. "Overall" Performance	
Pp	0.65	PPM < LSL	750000.00	PPM < LSL	690236.62	PPM < LSL	678589.93
PPU	1.45	PPM > USL	0.00	PPM > USL	1.61	PPM > USL	6.84
PPL	-0.15	PPM Total	750000.00	PPM Total	690238.24	PPM Total	678596.78
Ppk	-0.15						

The most critical KPIVs affecting the CTQ of the measurements of the Luer taper diameters and the circularity at these various depths were found in the Vision molding process. A two level fractional DOE was designed with seven factors: a resolution III design

Run	Melt(F)	Mold(F)	Back(psi)	Pack(psi)	Pack(sec)	Fill(in/sec)	Cool (sec)
1	500	110	300	2500	2	6.00	5.50
2	500	110	500	2500	6	1.00	2.00
3	500	150	300	1200	6	1.00	5.50
4	500	150	500	1200	2	6.00	2.00
5	460	150	500	2500	2	1.00	5.50
6	460	150	300	2500	6	6.00	2.00
7	460	110	500	1200	6	6.00	5.50
8	460	110	300	1200	2	1.00	2.00
9	480	130	400	1850	4	3.50	3.75

Data were collected in a format of **five shots** (replicates) at each of **eight cavities**.

- The sample size of reach run was **40**. The run order was randomized.
- There were **8** response variables. Nominal was at spec center for **4** diameters and was at lower end for **4** circularities.

Index Function: (1) In Spec [0, 1]; (2) Best = 0; (3) Out of Spec > 1

$$Index = \frac{|x - Nominal|}{(USL - LSL)/2} \quad \text{(if Nominal > LSL > 0)}$$

$$Index = \frac{x}{USL} \quad \text{(if Nominal = LSL = 0)}$$

Where x is obtained from one of diameters or circularities.

Principal Components

[1] Apply the Index Function to all responses.
[2] Using the relevant USL, LSL, and Nominal.
[3] STAT > Multivariate > Principal Components.
[4] Select all 8 indexed responses.

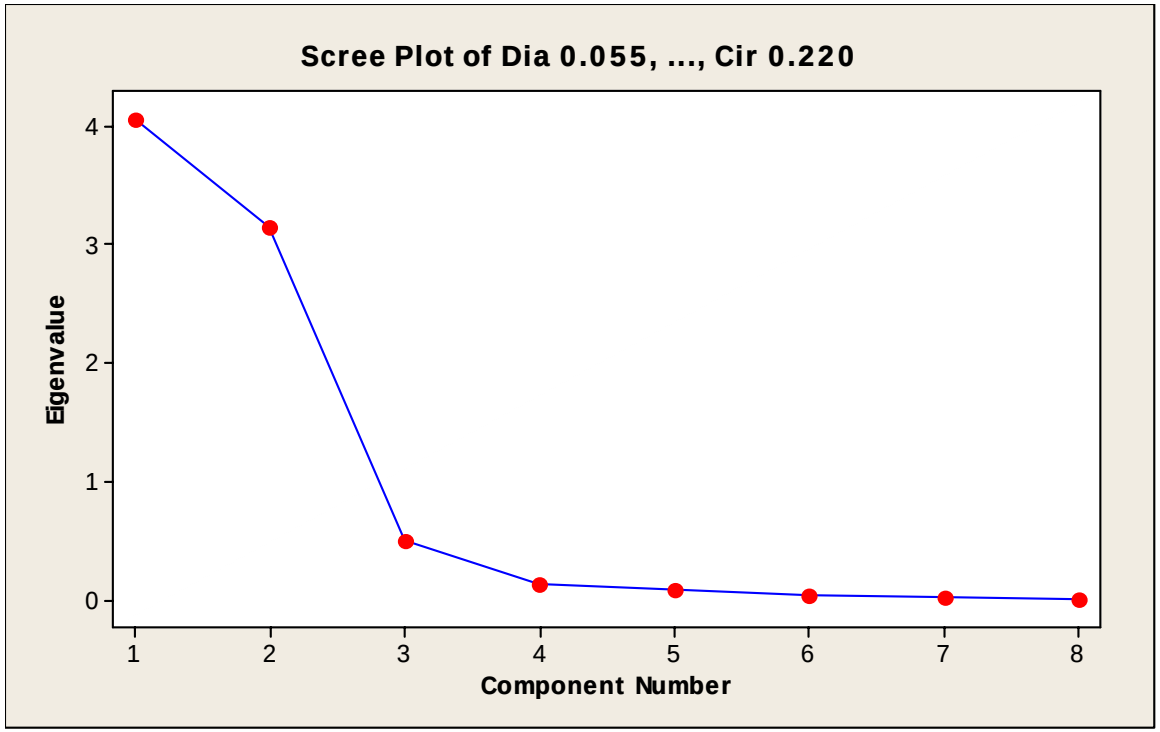
Principal Components

- Eigenanalysis of the Correlation Matrix

Eigenvalue	4.0511	3.1490	0.5004	0.1310	0.0881	0.0432	0.0227	0.0144
Proportion	**0.506**	0.394	0.063	0.016	0.011	0.005	0.003	0.002
Cumulative	0.506	0.900	0.963	0.979	0.990	0.995	0.998	1.000

Variable	PC1	PC2	PC3	PC4	PC5	PC6	PC7	PC8
Dia 0.055	**-0.450**	-0.151	0.203	-0.777	0.284	-0.190	-0.081	-0.083
Cir 0.055	**-0.072**	-0.438	-0.858	-0.164	-0.198	-0.016	-0.002	-0.019
Dia 0.175	**-0.473**	-0.145	0.004	0.174	0.248	0.525	0.493	0.381
Cir 0.175	**0.253**	-0.442	0.394	-0.272	-0.622	0.247	0.253	0.003
Dia 0.200	**-0.478**	-0.119	0.094	0.321	-0.169	0.126	-0.058	-0.773
Cir 0.200	**0.171**	-0.518	0.138	0.135	0.344	0.354	-0.645	0.077
Dia 0.220	**-0.475**	-0.110	0.142	0.255	-0.423	-0.385	-0.333	0.489
Cir 0.220	**0.145**	-0.525	0.138	0.282	0.326	-0.582	0.394	-0.071

Principal Components



Together, the first two and the first three principal components represent 73% and 78%, respectfully, of the total variability. Thus, most of the data structure can be captured in two or three underlying dimensions. The remaining principal components account for a very small proportion of the variability and are probably unimportant.

Principal Components

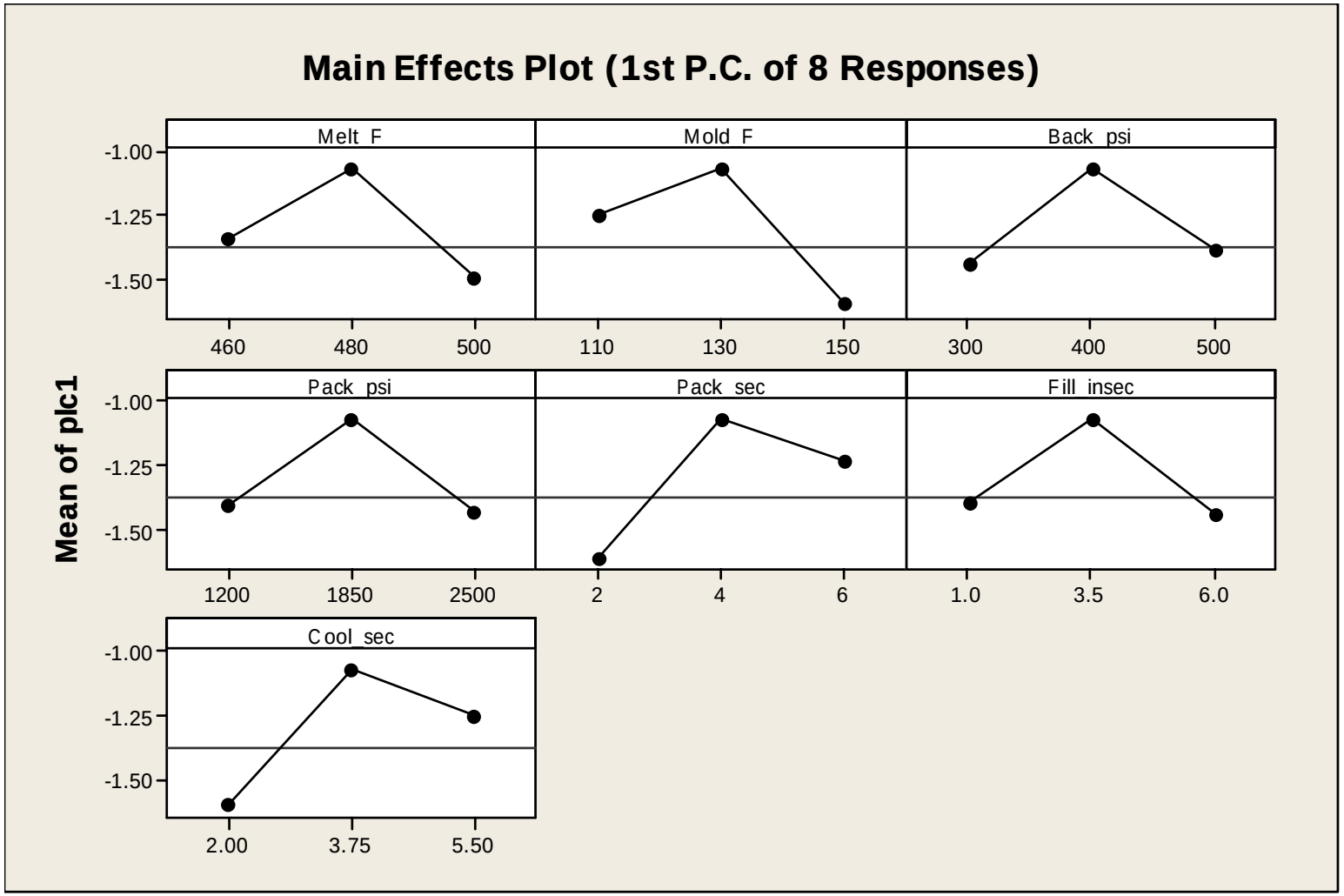
⇛ **Construct a new response variable using the first principal component.**

⇛ **The first principal component has variance (eigenvalue) 4.051 and accounts for 50.6% of the total variance.**

⇛ **The coefficients listed under PC1 show how to calculate the principal component scores:**

New = Dia0.055 * Coef1 + Cir0.055 * Coef2
+ Dia0.175 * Coef3 + Cir0.175 * Coef4
+ Dia0.200 * Coef5 + Cir0.200 * Coef6
+ Dia0.220 * Coef7 + Cir0.220 * Coef8

Main Effect Plots



Analysis of Variance

Estimated Effects and Coefficients for plc1 (coded units)

Term	Effect	Coef	SE Coef	T	P
Constant		-1.436	0.01057	-135.90	0.000
Melt_F	-0.203	-0.102	0.01057	-9.62	0.000
Mold_F	-0.383	-0.192	0.01057	-18.14	0.000
Back_psi	0.012	0.006	0.01057	0.58	0.565
Pack_psi	0.019	0.009	0.01057	0.89	0.375
Pack_sec	0.428	0.214	0.01057	20.23	0.000
Fill_insec	-0.086	-0.043	0.01057	-4.09	0.000
Cool_sec	0.379	0.190	0.01057	17.93	0.000
Ct Pt		0.372	0.03105	11.97	0.000

S = 0.184681 R-Sq = 77.60% R-Sq(adj) = 77.07%

Analysis of Variance for plc1 (coded units)

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Main Effects	7	35.1595	35.7234	5.10335	149.63	0.000
Curvature	1	4.8842	4.8842	4.88416	143.20	0.000
Residual Error	339	11.5623	11.5623	0.03411		
Pure Error	339	11.5623	11.5623	0.03411		
Total	347	51.6060				

Other Options

Instead of constructing a first Principal-Component-connected Index Function,

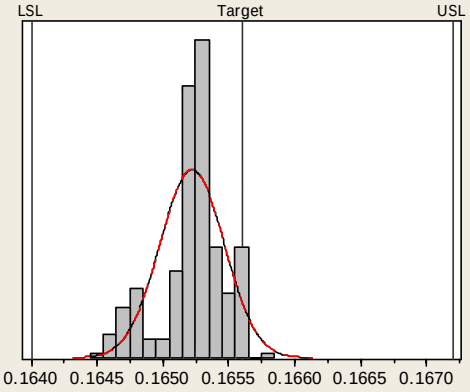
[1] Find the real relationship of the 8 responses: 4 diameters and 4 circularities, from the 4 depths;

[2] Work on Cpk for shots (replicates) and cavities within each run, and maximize it;

[3] Weight the 8 indexed responses by using both the first and the second Principal Component.

Significantly Improved Result at Diam 0.055”, 0.175”, 0.200”, 0.220”

Capability Analysis Diam @0.055 for control phase Analysis
(using 95.0% confidence)



Process Data	
LSL	0.16400
Target	0.16560
USL	0.16720
Sample Mean	0.16522
Sample N	250
StDev(Within)	0.00024
StDev(Overall)	0.00024

Potential (Within) Capability	
Cp	2.18
Lower CL	1.99
Upper CL	2.38
CPL	1.67
CPU	2.70
Cpk	1.67
Lower CL	1.51
Upper CL	1.82
CCpk	2.18

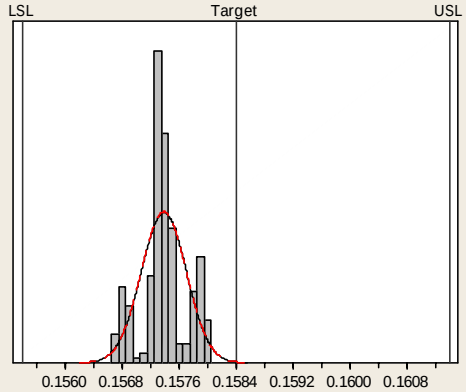
Overall Capability	
Pp	2.19
Lower CL	2.00
Upper CL	2.38
PPL	1.67
PPU	2.71
Ppk	1.67
Lower CL	1.52
Upper CL	1.83
Cpm	1.19
Lower CL	1.11

Observed Performance	
PPM < LSL	0.00
PPM > USL	0.00
PPM Total	0.00

Exp. Within Performance	
PPM < LSL	0.28
PPM > USL	0.00
PPM Total	0.28

Exp. Overall Performance	
PPM < LSL	0.26
PPM > USL	0.00
PPM Total	0.26

Capability Analysis Diam @0.175 for control phase Analysis
(using 95.0% confidence)



Process Data	
LSL	0.15540
Target	0.15840
USL	0.16140
Sample Mean	0.15738
Sample N	250
StDev(Within)	0.00032
StDev(Overall)	0.00032

Potential (Within) Capability	
Cp	3.14
Lower CL	2.86
Upper CL	3.42
CPL	2.07
CPU	4.21
Cpk	2.07
Lower CL	1.88
Upper CL	2.26
CCpk	3.14

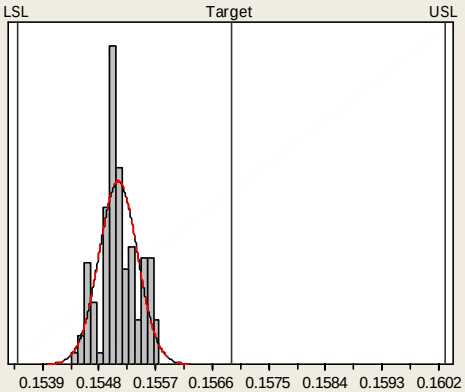
Overall Capability	
Pp	3.16
Lower CL	2.88
Upper CL	3.44
PPL	2.09
PPU	4.24
Ppk	2.09
Lower CL	1.90
Upper CL	2.27
Cpm	0.93
Lower CL	0.90

Observed Performance	
PPM < LSL	0.00
PPM > USL	0.00
PPM Total	0.00

Exp. Within Performance	
PPM < LSL	0.00
PPM > USL	0.00
PPM Total	0.00

Exp. Overall Performance	
PPM < LSL	0.00
PPM > USL	0.00
PPM Total	0.00

Capability Analysis Diam @0.200 for control phase Analysis
(using 95.0% confidence)



Process Data	
LSL	0.15350
Target	0.15690
USL	0.16030
Sample Mean	0.15510
Sample N	250
StDev(Within)	0.00031
StDev(Overall)	0.00030

Potential (Within) Capability	
Cp	3.70
Lower CL	3.37
Upper CL	4.03
CPL	1.74
CPU	5.67
Cpk	1.74
Lower CL	1.58
Upper CL	1.90
CCpk	3.70

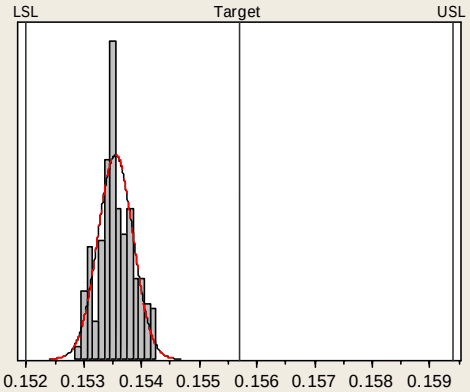
Overall Capability	
Pp	3.72
Lower CL	3.39
Upper CL	4.05
PPL	1.75
PPU	5.70
Ppk	1.75
Lower CL	1.59
Upper CL	1.90
Cpm	0.62
Lower CL	0.61

Observed Performance	
PPM < LSL	0.00
PPM > USL	0.00
PPM Total	0.00

Exp. Within Performance	
PPM < LSL	0.09
PPM > USL	0.00
PPM Total	0.09

Exp. Overall Performance	
PPM < LSL	0.08
PPM > USL	0.00
PPM Total	0.08

Capability Analysis Diam @0.220 for control phase Analysis
(using 95.0% confidence)



Process Data	
LSL	0.15200
Target	0.15570
USL	0.15940
Sample Mean	0.15355
Sample N	250
StDev(Within)	0.00031
StDev(Overall)	0.00030

Potential (Within) Capability	
Cp	4.04
Lower CL	3.68
Upper CL	4.40
CPL	1.69
CPU	6.39
Cpk	1.69
Lower CL	1.53
Upper CL	1.85
CCpk	4.04

Overall Capability	
Pp	4.07
Lower CL	3.71
Upper CL	4.43
PPL	1.70
PPU	6.44
Ppk	1.70
Lower CL	1.55
Upper CL	1.86
Cpm	0.57
Lower CL	0.56

Observed Performance	
PPM < LSL	0.00
PPM > USL	0.00
PPM Total	0.00

Exp. Within Performance	
PPM < LSL	0.19
PPM > USL	0.00
PPM Total	0.19

Exp. Overall Performance	
PPM < LSL	0.16
PPM > USL	0.00
PPM Total	0.16