

Machining Process Characterization for Breakoff Torque on Spinal Implants

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Abstract — Breakoff torque value on Spinal Implants is critical to ensure proper fixation of the system to the human vertebrae. Testing of manufacturing samples involves destructive testing which leads to scrap cost. The ability to predict torque results based on key process input factors not only reduces the setup times but reduces manufacturing costs as well while improving the confidence on the manufacturing process to produce parts that meets the specifications. This paper describes the statistical techniques and testing used to characterize the machining process of Breakoff Set Screws used on spinal implants.

Key Terms — Breakoff Torque, Design of Experiments, Measurement System Analysis, Statistical Process Control.

INTRODUCTION

Spinal implants are used to treat a wide range of spinal conditions, most particularly scoliosis. In order to correct these curvatures, a series of bone screws, rods and set-screws are used.



Figure 1
Scoliosis Treatment Example

Bone screws are implanted to the vertebrae and rods are placed on the head of the screws. Set screws are then used to hold the rods in place. In order to prevent the rods to slip and move, the set screws have to apply a certain axial force. This axial force translates to a specific torque setting that has to be applied to the set screws during the implant. To ensure a specified torque, set screws are designed to break at a certain torque value which is critical to the proper function of the spinal system.

In this article, we describe the selection of key process factors, measuring system analysis, machining process characterization and statistical process control used to control the breakoff torque during manufacturing of the breakoff set screws.

MEASUREMENT SYSTEM ANALYSIS

To ensure the validity of any study, a proper measuring method has to be used. For the purpose of this paper we will discuss the most critical measuring method for the breakoff torque. This method is the Instron® Torsion Tester. The torque test is considered a destructive test since the torsion test involves destroying the test specimen to calculate the torque value at failure. Traditionally, a Nested ANOVA Designs for Gage Repeatability and Reproducibility (GR&R) analysis would be used since there is no true repetition of the measurements. However, if enough homogeneity between the group of parts can be guaranteed, a Crossed ANOVA Design can be used.

Previous GR&R's attempts for the Instron Torsion Tester had resulted in values over 65% tolerance. Such a high result reduced the confidence on the test method and, along with the test method, aroused doubts on the Torque results themselves. These high results were driven by a lack of homogeneity between the test groups when

performing measurement system analysis; therefore, reducing the ability to demonstrate consistency “repeating” and “reproducing” valid results.

To increase the groups homogeneity, the process variation has to be reduced as much as possible. This was accomplished by machining “blank” parts which were composed of a solid shaft instead of a hollow shaft. For the purpose of this test, a blank specimen will be used. This blank specimen has a similar geometry to the 4.75 Reduction Set Screw with the difference that is solid instead of hollow and the neck diameter has been reduce to provide results on the tolerance spectrum of the original Reduction Set Screw. These blank specimens are tested with the Instron in the exact same configuration, using the same fixtures, test parameters and locking mechanism. Since there is only one feature to control (neck diameter) these blanks reduce significantly the part-part variation within the same group of parts; thus, increasing the homogeneity of the group. Group homogeneity is an important factor when testing a gage with a destructive method since the repeatability is confounded with the within group variation.

Break-off Set Screws are designed to break at a certain torque. Due to the circular geometry of these screws they can be treated as a hollow shaft. In the same manner, the proposed blank specimen can be treated as a solid round shaft.

Shear stress occurs when a shaft is placed in torsion. The shear stress at the outer surface of a bar of radius r , which is torsionally loaded by a torque, T , is given by Equation 1:

$$\tau = \frac{Tr}{J} \quad (1)$$

J is the shaft’s polar moment of inertia. For a solid round shaft [1],

$$J = \frac{\pi r^4}{2} \quad (2)$$

For a hollow round shaft the polar moment of inertia is given by Equation 3 [1],

$$J = \frac{\pi}{2}(r_o^4 - r_i^4) \quad (3)$$

Substituting Eq 2 into Eq 1 and solving for T provides the Torque calculation equation for a solid shaft,

$$T = \frac{\tau \pi r^3}{2} \quad (4)$$

Substituting Eq 3 into Eq 1 and resolving for T provides the Torque calculation equation for a hollow shaft,

$$T = \frac{\tau \pi}{2r_o}(r_o^4 - r_i^4) \quad (5)$$

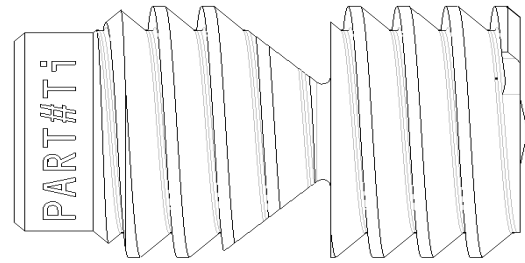


Figure 2
Blank Part Design with Solid Shaft

By using a solid shaft construction for the test specimens instead of a hollow shaft, the inner diameter and it’s machining process, was removed from the study; therefore, reducing the process variation and increasing the homogeneity of the groups. Since there is only one feature to control (neck diameter) these blanks reduce significantly the part-part variation within the same group of parts; thus, increasing the homogeneity of the group. Group homogeneity is an important factor when testing a gage with a destructive method since the repeatability is confounded with the within group variation.

The study design was selected as a Five (5) by Three (3) by Two (2) (5x3x2) whereas the first digit represents the “parts/groups”, the second digit represents the repetitions and the third the operators. Five (5) different groups of parts were used for the study varying the outside diameter of the shaft.

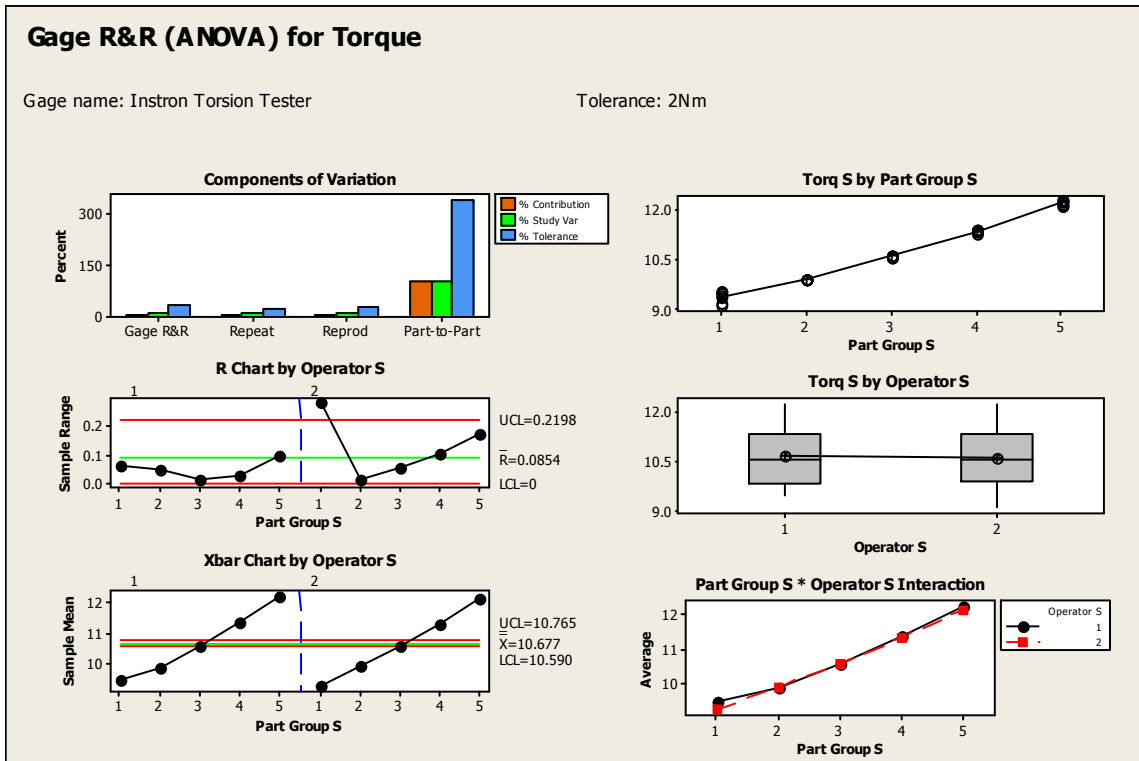


Figure 3
GR&R Graphic Results

The outside diameter of the shaft was calculated to ensure the complete range of the torque specification was covered. Since there are various models tested with the same method and equipment, a range between 9Nm and 12.5Nm was selected for the study. Two (2) different operators were selected for the study to test reproducibility; the ability of the method to be reproduced between different personnel performing the test. Both operators were trained on the Instron equipment and fixtures used for the testing. Three (3) repetitions were selected for each operator and group of parts to show repeatability within the same groups.

Graphic results are shown on figure 3 from which we can observe from the components of variation chart that part to part variation is significantly higher than repeatability and reproducibility components. From the R Chart by Operator we can see a point out of control from “part” 1, operator 2; however, the upper control limit for the range is low at around 10% of the

process tolerance (process tolerance is 2Nm). This out of control point can be explained due to the destructive nature of the test. From the Xbar Chart we can see most of the points out of control, as expected, since enough part to part variation is induced to prove the method capabilities across the tolerance. Torque by Part Group Chart demonstrates the repeatability of the method showing how close the torque results were obtained for the same group of parts. This behavior permits the used of the Crossed method for this destructive GR&R. Torque by Operator Boxplot demonstrates similar variation between both operators. Finally, Part Group by Operator Interaction lines follow each other closely, which demonstrates the reproducibility of the test method.

After analyzing the study results graphically, the analytical results were evaluated. Figure 4 summarizes obtained results:

Source	StdDev (SD)	Study Var (6 * SD)	%Study Var (%SV)	%Tolerance (SV/Toler)
Total Gage R&R	0.09698	0.58185	8.60	29.09
Repeatability	0.06230	0.37378	5.52	18.69
Reproducibility	0.07432	0.44591	6.59	22.30
Operator	0.04351	0.26106	3.86	13.05
Operator*Part Group	0.06025	0.36151	5.34	18.08
Part-To-Part	1.12398	6.74389	99.63	337.19
Total Variation	1.12816	6.76895	100.00	338.45

Number of Distinct Categories = 16

Figure 4
Minitab GR&R Analysis Printout

From the analytical analysis we can conclude that the %tolerance contribution from the Repeatability is 18.69% and from the Reproducibility is 22.30%. The total GR&R percent tolerance is 29.09% which is below the maximum recommended of 30%. Also, the number of distinct categories was 16. This is a measure of how many distinctive parts or “buckets” is method capable of identifying within the process tolerance.

SELECTION OF KEY PROCESS INPUT FACTORS

During any effort to study and later control a process, the first and most crucial step is to select those variables that could have an impact on the process output. These variables are called Key Process Input Factors (KPIF). Due to the design characteristics of the Breakoff Set Screws, we can describe the breakoff section as a hollow shaft. Torque resistance of a hollow shaft is described by the following equation:

$$T = \frac{\pi * \tau (r_o^4 - r_i^4)}{2r_o} \quad (6)$$

Where T stands for Torque, τ for shear stress, r_o for outside radius and r_i for internal radius. Given this information, we can determine that torque resistance will depend on the material strength and part geometry.

Since the design of the set screws have the internal diameter fixed and provides adjustability only for the outside diameter, we determined that wall thickness and material ultimate strength [KSI] are the KPIF of interest for this study.

DESIGN OF EXPERIMENT

Having analyzed the measuring method and selecting the KPIF, the next step is to characterize the process to understand how the Y (troque) behaves in respect with the X (KPIF). To do so we selected Design of Experiment (DOE) methodology. Since there are only two (2) factors of interest a full factorial design was selected. The first design in the 2^k series is one with only two factors, each run at two levels, is called a 2^2 factorial design [2]. Full factorial design for a two (2) factor study has only four (4) treatments (2^2). Eight (8) replicates were selected for a total of thirty-two (32) samples ($2^2 \times 8$). Wall thickness levels were calculated using equation 1 targeting slightly below the Lower Specification Limit (LSL) of 10.5Nm and slightly above the Upper Specification Limit (USL) of 12.5Nm. Material strength levels were selected as wide as possible from the material available. Table 1 summarizes the DOE treatments.

Qty	Break-off ID	Reference Diameter “A”	Material KSI
8	5.350	5.950	152.6
8	5.350	6.040	152.6
8	5.350	5.950	155.0
8	5.350	6.040	155.0

Table 1
DOE Treatments

The samples were Torque tested using an Instron MT-1 Torsion Tester and results were evaluated using DOE function from Minitab 16. Refer to Figure 5 for the Pareto Chart of Standardized Effects:

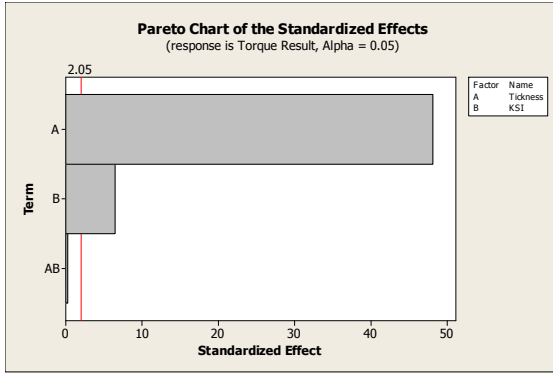


Figure 5
Pareto Chart of the Standardized Effects

It can be determined from Figure 5 that both factors selected for the study were found to be statistically significant since their effect was above the calculated threshold of 2.05 for a 95% confidence. A main effect plot was prepared and shown below:

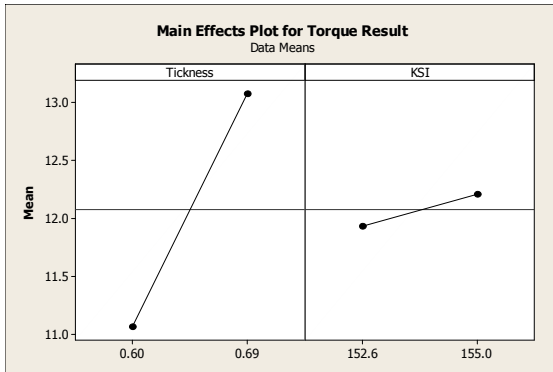


Figure 6
Main Effects Plot for Torque Results

From Figure 6 we can conclude that both factors have a positive directly proportional effect on the result. In other words, as the wall thickness increases, so does the Torque. In the same manner as the material strength increases, the Torque results are higher as well.

In order to calculate a transfer function that would predict the Torque behavior a Regression Analysis was performed with the significant factors. Refer to Figure 7 for results:

Regression Analysis: Torque Result versus Tickness, KSI

The regression equation is
Torque Result = - 19.5 + 22.2 Tickness + 0.112 KSI

Predictor	Coef	SE Coef	T	P	VIF
Constant	-19.465	2.628	-7.41	0.000	
Tickness	22.1931	0.4528	49.01	0.000	1.000
KSI	0.11198	0.01698	6.59	0.000	1.000

S = 0.115262 R-Sq = 98.8% R-Sq(adj) = 98.7%

Figure 7
Minitab Printout for Regression Analysis

R-Sq (adj) provides an explanation of how well the regression equation, or model, explains the behavior of the process. It is a measure of how much variation of the process is explained by the model. In this case we can determine from the regression analysis that the model explains the 98.7% of the variation in the data. Therefore, we can conclude that the torque has a strong relation with the material strength and wall thickness and the model is adequate to predict the Torque results given the Material KSI and Neck Thickness. The following equation is derived from the transfer function in order to calculate the targeted wall thickness:

$$WallThickness = \frac{Torque + 19.5 - 0.112KSI}{22.2} \quad (8)$$

OPERATIONAL QUALIFICATION

Extreme Low and Extreme High Torque settings were challenged with a target window of 0.047mm calculated using Equation 8. The qualification successfully met the criteria of tolerance interval limits between specifications. Refer to Figures 8 and 9 for Tolerance Interval Plots

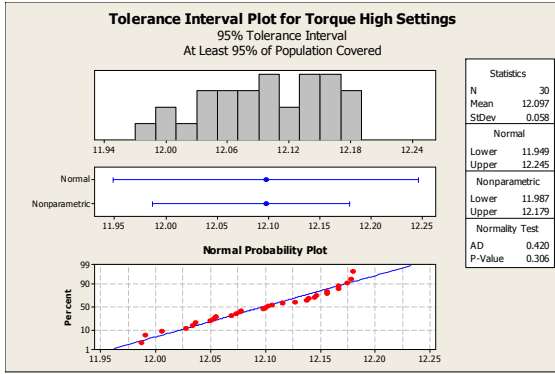


Figure 8

Tolerance Interval Plot for High Torque Settings

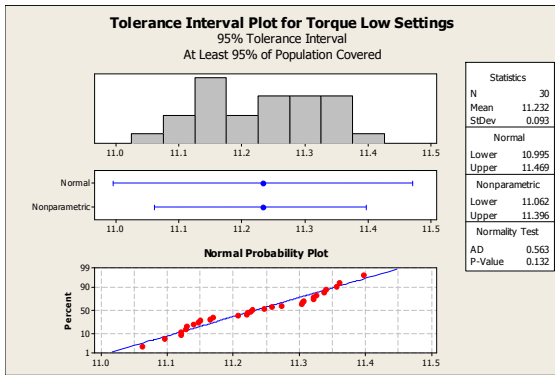


Figure 8

Tolerance Interval Plot for Low Torque Settings

Extreme settings challenge tolerance interval resulted in a window of 10.995Nm to 12.245Nm compared to the specification of 10.5Nm to 12.5Nm. No Cpk analysis was required since these tests purposely induced a bias on the nominal value. The successful completion of extreme value challenges means that Transfer Function mentioned above, successfully predicts the torque results and ensures that when a 0.047mm window is maintained from the calculated wall thickness, the process will remain within specifications with a 95% confidence and 95% reliability. Table 2 provides wall thickness window for several KSI scenarios and was included on manufacturing procedures as a guideline for setting the wall thickness values.

Material KSI	Min Wall Thickness	Max Wall Thickness
150	0.617	0.662
151	0.612	0.657
152	0.607	0.652
153	0.602	0.647
154	0.597	0.642
155	0.592	0.637
156	0.587	0.632
157	0.582	0.627
158	0.577	0.622
159	0.572	0.617
160	0.567	0.612
161	0.562	0.607
162	0.557	0.602
163	0.552	0.597
164	0.546	0.592
165	0.541	0.586

Table 2

Wall Thickness Reference Table Based on Material Strength

CONCLUSION

After the successful completion of this process characterization, the Breakoff Torque process has been understood. The variation of the measuring method was studied by reducing the process component, therefore, increasing the confidence on the measuring method. The controls established on the manufacturing floor ensure that the process will remain within the validated state with a high degree of confidence and reliability.

REFERENCES

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- [2] Montgomery, Douglas C., "Two Level Factorial Design", *Design and Analysis of Experiments*, 6th Edition, 2005, Page 204.