Theory and Application of J Charts for Holistic Risk Based Statistical Adverse Event Trending

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Abstract

The author attempts to postulate a new volumetric complaints and adverse events trending method for holistic risk based statistical trending using a new control chart which is based on the theory of a U chart, as it pertains to medical device failure related adverse events. Mathematical rationale is provided for various control chart parameters like subgroup size and subgroup frequency and correlations to existing literature have been made to justify conclusions. Also, the article features discussion on false alarms and how to use Minitab to minimize them while monitoring incoming complaint variability using a U chart and consequently, the J chart.

Keywords: Medical Device, J Chart, U Chart, False Alarms, Control Chart, Device Failure

Introduction

This is article provides an introduction of the 'J' control chart for statistical complaint and adverse events trending with focus on medical device industry especially surgical implant and instrument failures. Control charts have been demonstrated to be to growing value in the healthcare industry and many studies have shown their analytic capabilities as it relates to hospital infection surveillance [1][2], infection control [3], adverse healthcare events [4][5]. Control charts as a method of statistical process trending and control for comparing performance with historical patterns while assessing variation and stability [6] is well established especially in manufacturing quality engineering but less widespread is the use in trending of complaint and adverse events. Code of Federal Regulations Title 21 Part 820 Subpart O Section 820.250 legally mandates manufacturers of medical devices to establish statistical techniques to control and verify product characteristics [7] and this article aims to satisfy a part of this legal requirement as it pertains to analysis of complaint trends due to failure of medical devices.

Statistical Quality Control is a discipline founded by W.E Deming and W.A. Shewhart who advocated usage of quality tools such as run charts, pareto charts, control charts and histograms to achieve the goal of continuous improvement and quality assurance. Deming himself in 1942 addressed the possibility of usage of his techniques for monitoring disease rates and adverse healthcare events [9] and U.S Center for Disease Control, as well, recently advocated usage of these Deming and Shewhart principles as it pertains to disease and infections rates [8]. This article aims to explain the use of analytical power of U chart and applies its theory to a new control chart for risk based statistical trending of complaints for medical devices.

U Chart Applicability to Medical Device Complaints: The theoretical basis for J Chart

The J chart is based on the mathematical rationale of the U chart and uses the same normalization to generate control limits and same sample count rate. It is therefore important to establish the applicability of the U chart to the process of statistically trending medical device complaints and adverse events.

The U chart is a type of control chart used to monitor discrete or attribute data where the sample size is greater than one, typically, the average number of nonconformities per unit. The role of any control chart is to monitor current variability in terms of non-conformities in historical context. A non-conformity, for purposes of this article, is any part or component related complaint from a surgical event. For example, if a surgery had one screw fractured during insertion and one plate becoming disassembled as a result, the surgical event will have two non-conformities. Unlike C chart, the U chart can deal with varying sample sizes, the sample being number of surgeries or sales within the predefined time frame.

The U chart differs from a C chart in that it accounts for the possibility that the number or size of inspection units for which nonconformities are to be counted may vary [10]. Like the C chart, U chart data must exhibit the following characteristics indicative of Poisson distribution:

1. Discrete distribution

2. Occurrences are independent of each other

3. Occurrences range from 0 to infinity in an interval

A complaints data set for a surgical product like an implant, or, instruments used to install implants in anatomical space, follow Poisson Distribution if the ‘occurrences’ are considered as the ‘failures’ of these implants or instruments which led to a complaint.

Composition and form of a U Chart

The three major lines of note in a U chart (see Fig 1.) are:

1. Upper Control Limit (UCL)

2. Center Line (U bar)

3. Lower Control Limit (LCL)

These three lines together define the central tendency and range of natural variation of the plotted values[11]. The control limits are computed statistically based on Poisson probability distribution as shown below:

$$LCL = \bar{u} - 3\sqrt{\frac{\bar{u}}{n}}$$

$$UCL = \bar{u} + 3\sqrt{\frac{\bar{u}}{n}}$$

Where $\bar{u}$ is the average number of failures in a surgery, n is the sample size, UCL is the upper control limit and LCL is the lower control limit. This formula for control limits is valid only for Poisson probability distribution of data. If the count of non-conformities is extremely small, the distribution of averages is not symmetrical and these equations are not valid. If the count is sufficiently large, according to central limit theorem, the distribution of averages is symmetrical and approaches normal distribution and makes these equations valid. Figure 2 shows the Gaussian distribution curve for the data set (Table 3) used to draw the U chart. 99.73% of the values are not expected to give false alarm. Values that fall outside the three standard deviation control limits would not lead to an excursion only 0.27% of the time. If greater accuracy is desired, the limits can be changed to 3.5 sigma or beyond. Also, the limiting form of Poisson distribution is normal or Gaussian distribution per the Central Limit Theorem as can be seen in the figures to follow. The Gaussian distribution is the most important distribution in probability, due to its role in the Central Limit Theorem, which effectively says that the sum of a large number of independent quantities tends to have a Gaussian form, independent of the PDF(Probability Density Function) of the individual measurements [14].

The U chart diagnostic functionality in Minitab calculates the ratio of observed to expected variation and calculates the false alarm rate by calculating the percentage of subgroups that are deemed 'out of control' when the process is in control. Upon running the data set (Table 3) for Screw Failures through this test it is clear that U chart will not result in an elevated false alarm for this particular data set. The test results can be seen in Figure 5. If the data set fails this test, Laney U chart must be used to trend the data. For more details on Laney U chart see [12].

Subgroup Size Selection

To obtain accurate control limits, data must be sufficient and rich enough to provide needed information. Subgroup size will directly affect sensitivity and must be selected with documented logic to balance size and frequency of subgroups. According to surveyed literature [13], the number of subgroups directly depends on number of defects per subgroup ($\overline{u}$) per the formula shown below:

N x $\overline{u}$ ≥ 0.5

N $\geq \frac{0.5}{\overline{u}}$

N = Subgroup size

For the 'Screw Failures' Data Set (Table 3, U chart illustrated in Fig 1.):

$N \geq 0.5/\frac{19.1}{928}$

$N \geq 25$

It can be seen this formula is quite liberal for subgroup size does not restrict the usage of U chart for surgical complaints trending if the number of surgeries are large enough.

J. C. Benneyan [11] gives three slightly different rules for minimum subgroup sizes (see Table 1).

Rule 1: $n \geq 5/\lambda$

Rule 2: $n \geq -\ln(.05)/\lambda$

Rule 3: $n > k^2 / \lambda$

Where, k = standard deviation multiple, λ = Poisson rate,

To reiterate, the number of instrument and implant failures in the surgery are the ‘defect’ and the surgery is a ‘sample’. The screw failure data set used in this article satisfies all these rules detailed by Benneyan et al [11].These rules are much more conservative than those prescribed by Minitab [13] but are illustrated here for study purposes. The author of this paper recommends using formulae’s detailed by Minitab[13], if Minitab is the software used for statistical analysis. According to published testing by Minitab [13], if the mean defects per subgroup are between 0.5 – 50, the false alarm rate ranges from 1.44% to 0.25%-increasing as the mean number of defects increase.

It is obvious that following the above groups for subgroup size will result in false alarm rate much lower than 0.25% but for the purposes of complaint trending, the subgroup size (which is the number of surgeries) is not changeable if all surgeries are trended for the given time period hence the author of this paper concurs with Minitab white paper [13].

Number of Subgroups

An idea about the number of subgroups is necessary to ensure the false alarm rate is at a low and manageable level. The false alarm rate is considered low at 2% with 95% CI since in many cases the number of defects per subgroups is small which necessitates a large number of subgroups to achieve precision [13].

$$C_c + 3\sqrt{C_c} = \bar{c} + z_{0.99}\sqrt{\bar{c}}$$

where C_c = mean number of defects per subgroup that produces a 1% false alarm rate above the upper control limit, assuming that $\bar{c}$ is the true value of c. Due to symmetry of the control limits, the total false alarm rate becomes 2% when the upper and lower limits are combined[13]].

$\bar{c}$ = average number of defects per subgroup (if the subgroup size varies, the average subgroup size is used)

z_p = inverse cdf evaluated at p for the normal distribution with mean=0 and standard deviation=1

To determine the number of subgroups, we calculate a 95% lower confidence limit for the upper control limit and set it equal to C_c.

$$C_c = \bar{c} - z_{0.95}\sqrt{\frac{\bar{c}}{m}}$$

where m is the number of subgroups.

$$\mathrm{m} = (\bar{c})/ 〖(\bar{c} - C_c)/z_{0.95})〗 \hat{}2$$

The results based on this calculation are shown in Table 2.

For complaint trending by control charts, the no. of subgroups translates to number of time periods (days, weeks, months, quarters, years etc.) the no. of surgeries are measured for. A common practice throughout the medical device industry has been to trend for 12 months or 1 years. We can see the mathematical rationale here for control charts which validates trending time period being used to be between 10 – 14 months only if the defect rate lies between 30 to 10 per unit respectively.

The Excursive Event

The aim of the U chart is to make the quality organization aware of an occurrence breach (based on historically calculated three sigma limits) and guide their efforts towards a corrective action quicker than traditional risk analysis. Once the control charts identify the issue, depending on the data being trended, other quality tools can be used to analyze the excursion further

If a product line (brand) or family of parts is being trended with U charts, all part numbers are trended together. If an excursion occurs, further analysis is needed to pinpoint the reasons for excursion. In the 'Screw Failure' example presented earlier the 'Screw' family containing many parts was trended. To explore the excursion in 'August' further, additional data mining has to be performed. In this case, a Pareto chart of all part number shows us the largest complaint parts, as seen in Fig 6. Pareto charts reveals the next layer of information and tells us which parts are the major culprits leading to excursion in the control chart.

A next layer of analysis may look at the failure modes of either all screws or by a particular part number using a Pareto (Figure 7) or a Pie chart or even another U or C chart. Until now, all trending has been volumetric. After drill down the data as much as needed, detailed risk analysis must be done to decide on need for corrective action. . The J chart adds more value to the excursive event analysis, as will be seen later, but breaking down the contributors of the excursive event in terms of harms listed in the risk document.

The J Chart

The traditional way of assessment of risk (and severity and occurrence) is by performing manual calculations of severity and occurrence. The occurrence rate is generally calculated by dividing the number of complaints events for a particular failure mode by the number of units sold or the number of times the unit was used while the severity is assessed by comparing the available information about the patient harm to the severity scale in the relevant risk document which dictates the severity listed in the FMEA (Failure Mode and Effects Analysis) document. This process is illustrated in a flowchart as shown in Figure 8.

The J chart attempts to represent the failure mode along with severity and occurrence as described in the FMEA in a *graphical way with statistically significant control limits available for comparison*.It adds a visual layer of analysis to the U chart in terms of rate of occurrence of actual harms related to the failure mod.

For example, consider the FMEA Line item as shown in Table 4. A J-chart is an exact conversion of the FMEA line item in a graphical form can be seen in Figure 9. The J Chart is essentially a U chart in which the categorical variables are the number of complaints under study, here for the 'Component Stuck' failure mode per month. The sample subgroup size is the number of units sold of the device in that particular month. The upper control limit is defined by the same formula discussed for UCL for a U chart. Since every complaint counts as a single occurrence for the failure mode of 'Component Stuck', the actual 'Harm' is noted down for each complaint during complaint intake as seen in Table 5. The normalization of every type of 'Harm' is done by dividing the number of harm events by the sales for the applicable time period such that they can be trended complementary to the failure mode. All normalized harms together mathematically make up the 'Failure Mode' trendline. Here, for the chart in Fig. 9, bleeding, hematoma and surgical intervention along with event where the outcome was no harm, together add up to the overall complaint events which are trended by the line 'Failure Mode'.

As discussed in the previous section, the excursive event in the J chart is exactly similar to an event in the J chart. The latter gives more detail in the nature of failure mode in terms of harm and the severity of the harm such that a direct graphical trend-able comparison can be made against the line item in the FMEA or FMECA.

In this case, all resultant harms can be seen for the failure mode under study. E.g., for the month of May, when the excursion occurs, it can be plainly seen what harms are tailing the failure mode of 'Component Stuck' and quick action can be taken if the profile of any the harms trend is different from predetermined severity in the FMEA.

Discussion:

The simplest, fastest and most obvious trending for complaints can be said to be volumetric, based only on occurrences. Another challenge is to define occurrence based triggers for additional analysis or corrective action. Predefined occurrence rates in risk documents may or may not apply fully well to the current state of business or sales and complaints of the products. The sales of a part or product line rise and fall through its lifecycle and a constant occurrence trigger lends itself to follies stated earlier. The U chart solves many of these problems and provides a dynamic trending methodology which is statistically sound and relevant to live data.

The most effective complaint trending is always risk based and volumetric trending is meant to supplement and complement the information from risk based complaint trending. Risk is a combination of occurrence, severity and at times, detection. The most holistic trending philosophy is to chart occurrence and severity together and tie back these quantitatively to predefined values in the risk documents like FMECA's or FMEA's. A J Chart attempts to tie the occurrence and severity together in a visually informative form which can be trended statistically and forms a basis for quantitative comparison to the Occurrence and Severity rates defined in the FMEA or other risk documents. The J chart uses the same theoretical basis and mathematical rationale for a U chart but adds further trendlines to the main one (here, the failure mode) to track the movement and progression of the harm as tied to the failure mode to enable direct graphical visualization of the FMEA in current and historical context with added statistical limits.

References

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[13] http://support.minitab.com/en-us/minitab/17/Assistant_Attribute_Control_Charts.pdf

[14] http://www.roe.ac.uk/japwww/teaching/astrostats/astrostats2012_part2.pdf

Figures

Figure 1: U chart of Screw Failures for all screw part numbers of a family.

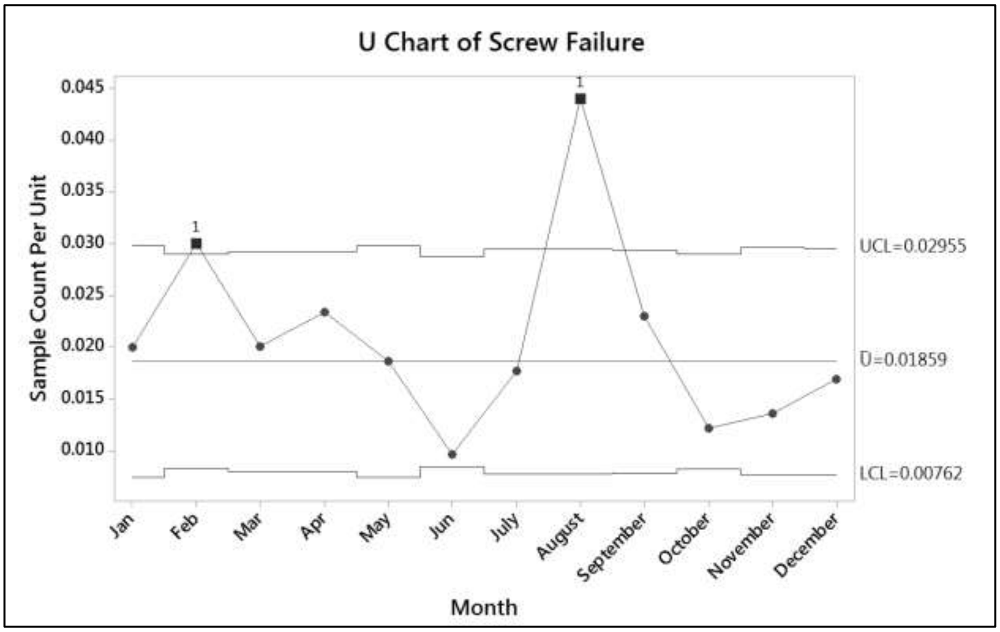


Figure 2 : Control limits and Normal Distribution

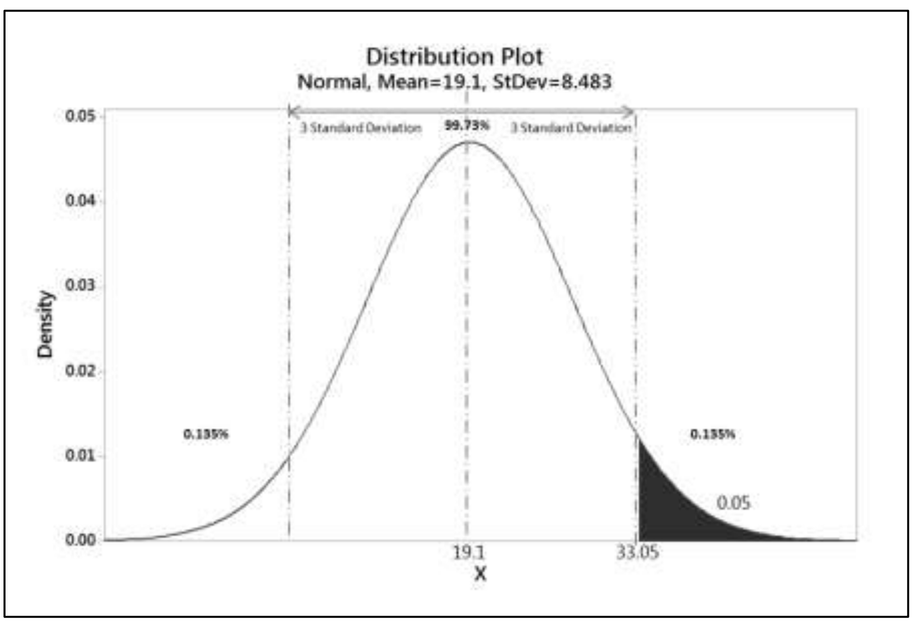


Figure 3: Probability Distribution

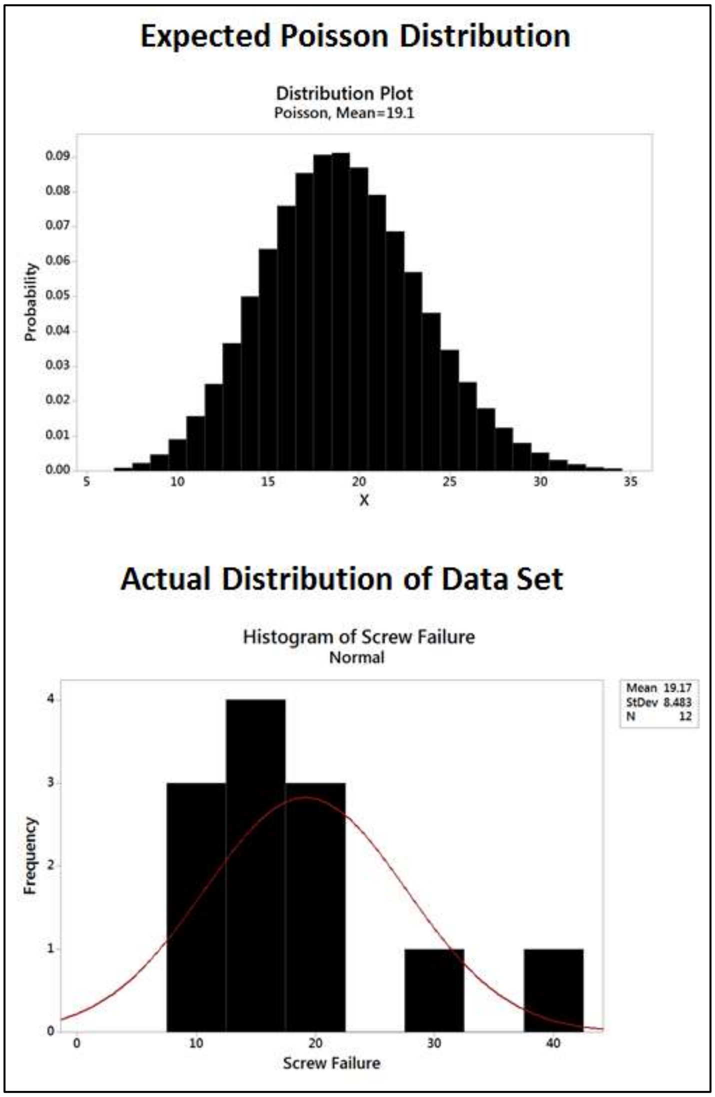


Figure 4. Probability Plot for 'Screw Failures' Data Set

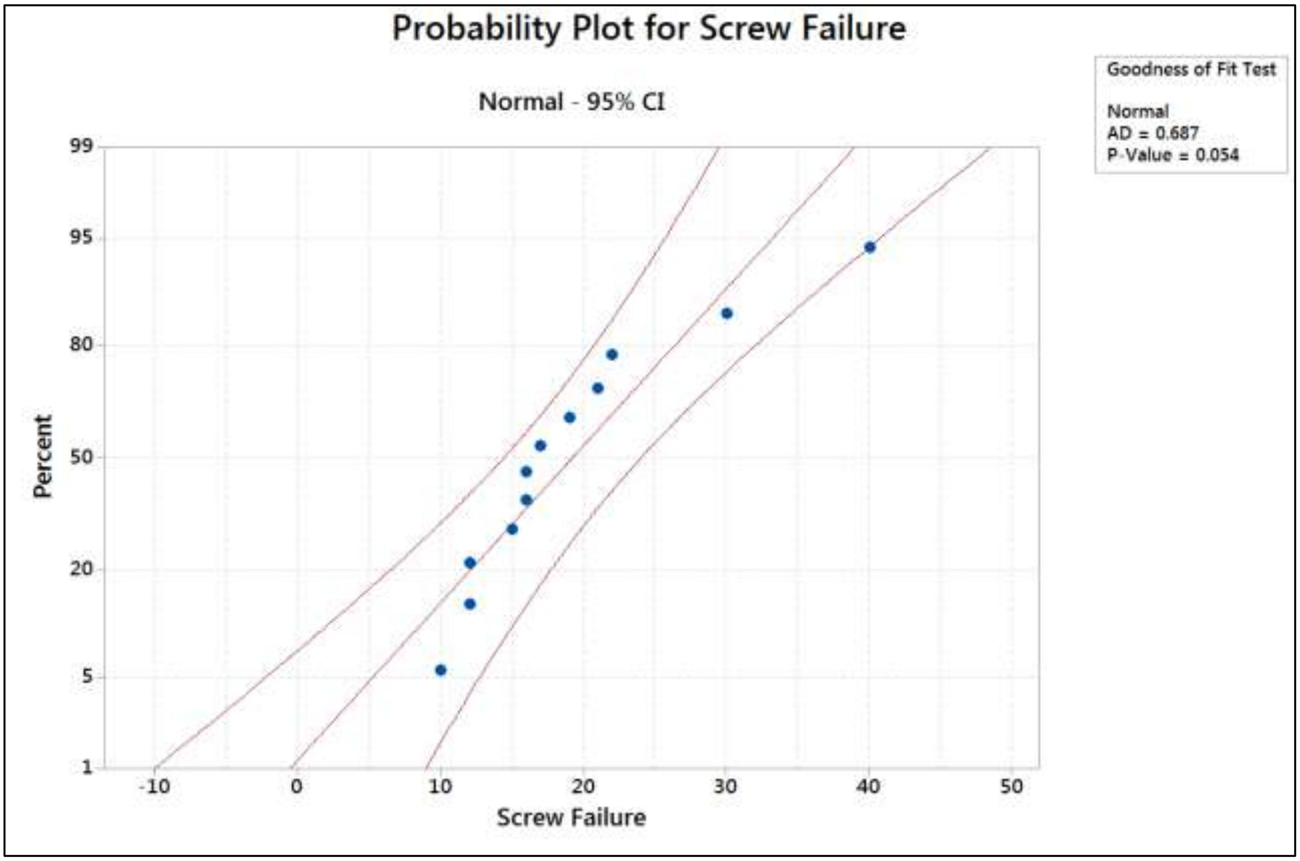


Figure 5: Minitab based U chart Diagnostic for Screw Failures Data Set

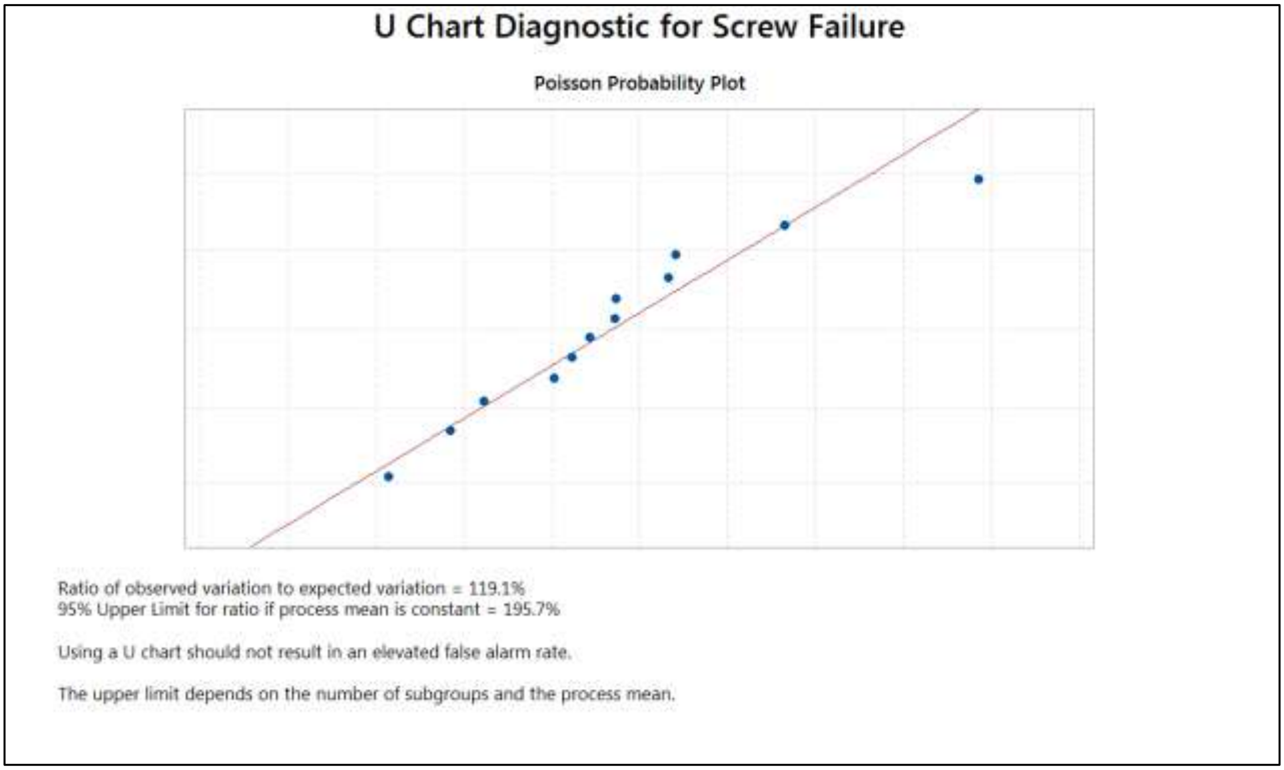


Figure 6 Pareto Chart of all Screw Failures by screw part numbers

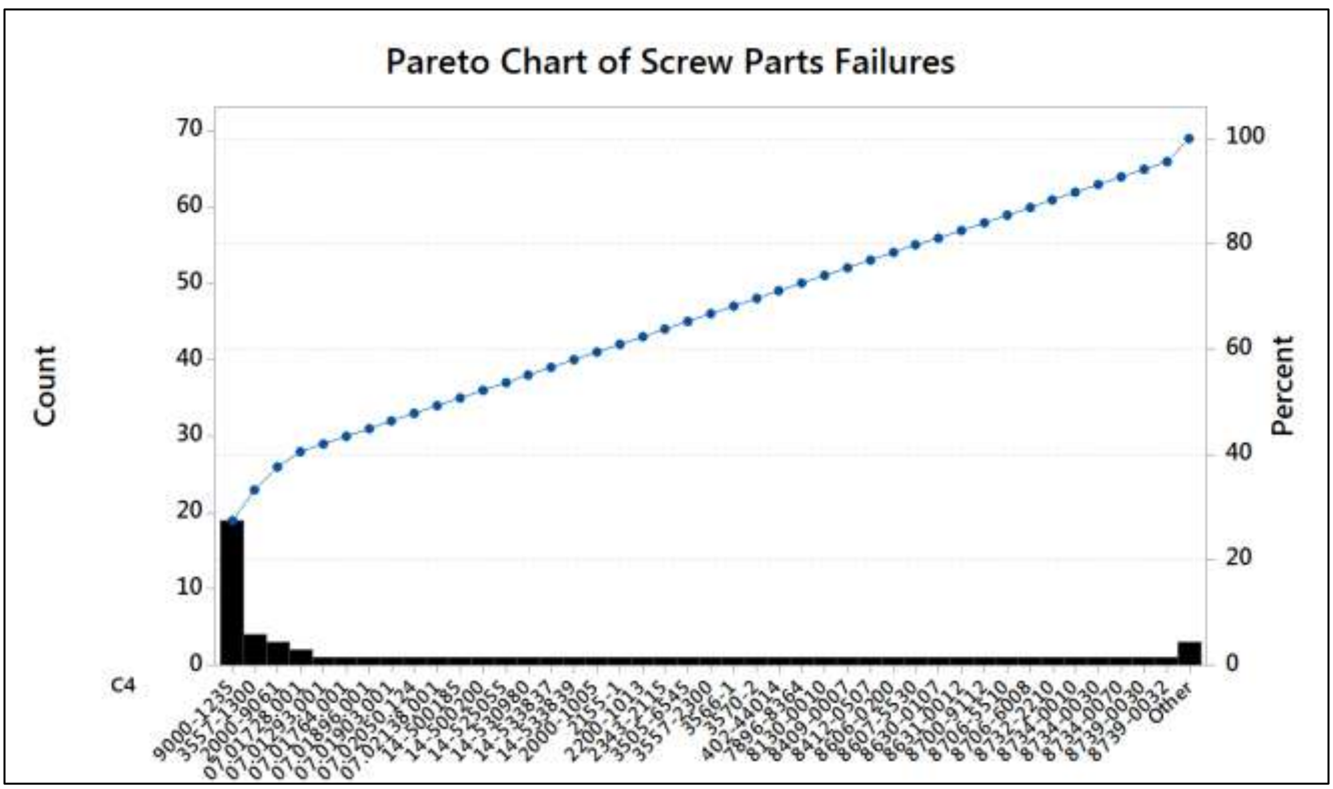


Figure 7: Pareto Chart of all Screw Failure modes

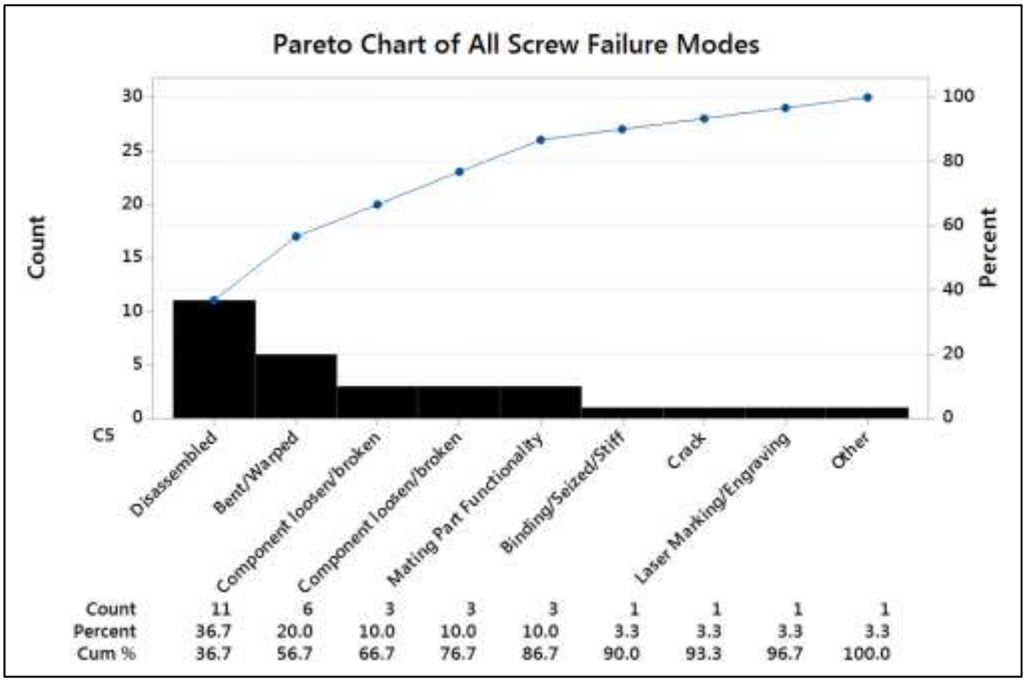


Figure 8: Flowchart for traditional risk analysis using an FMEA

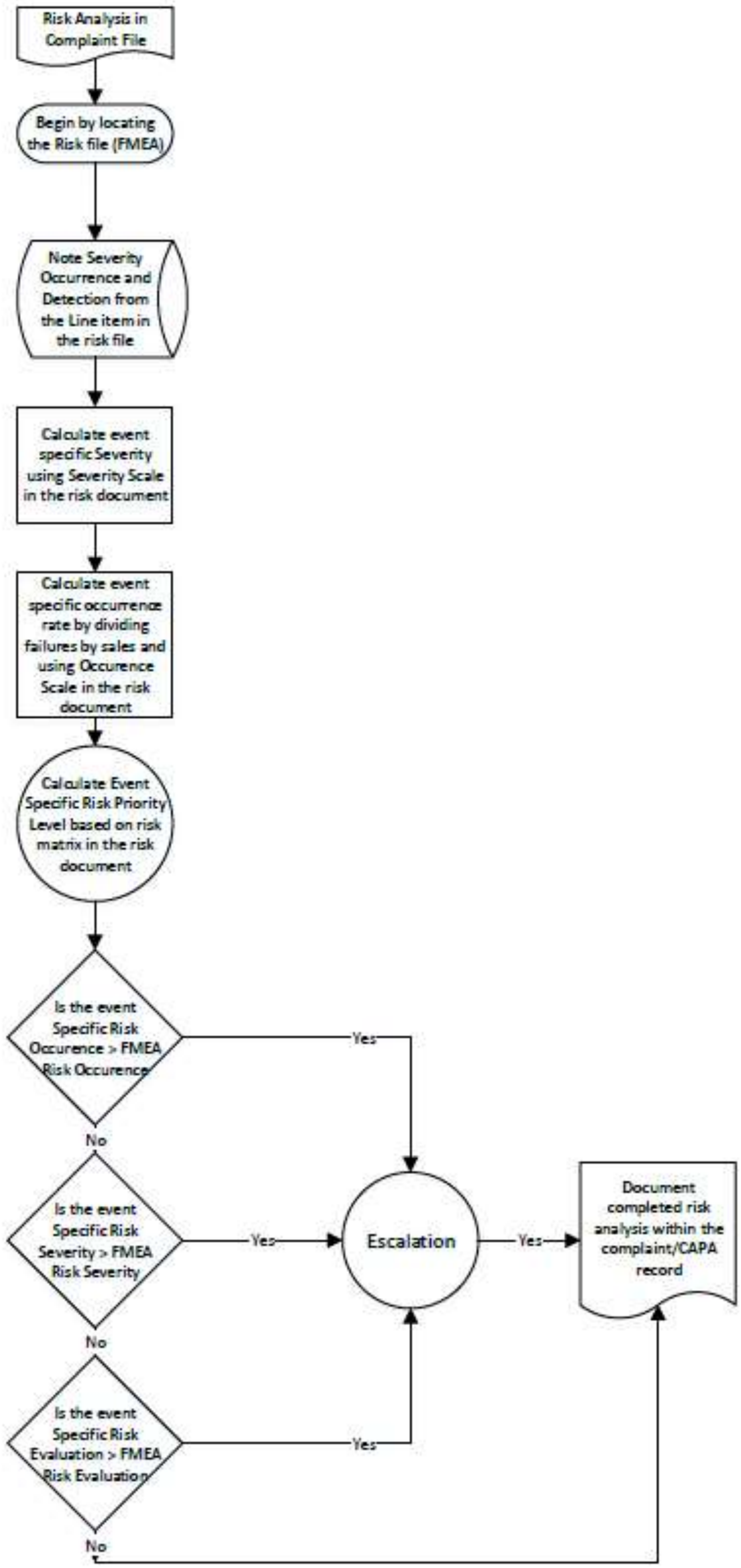
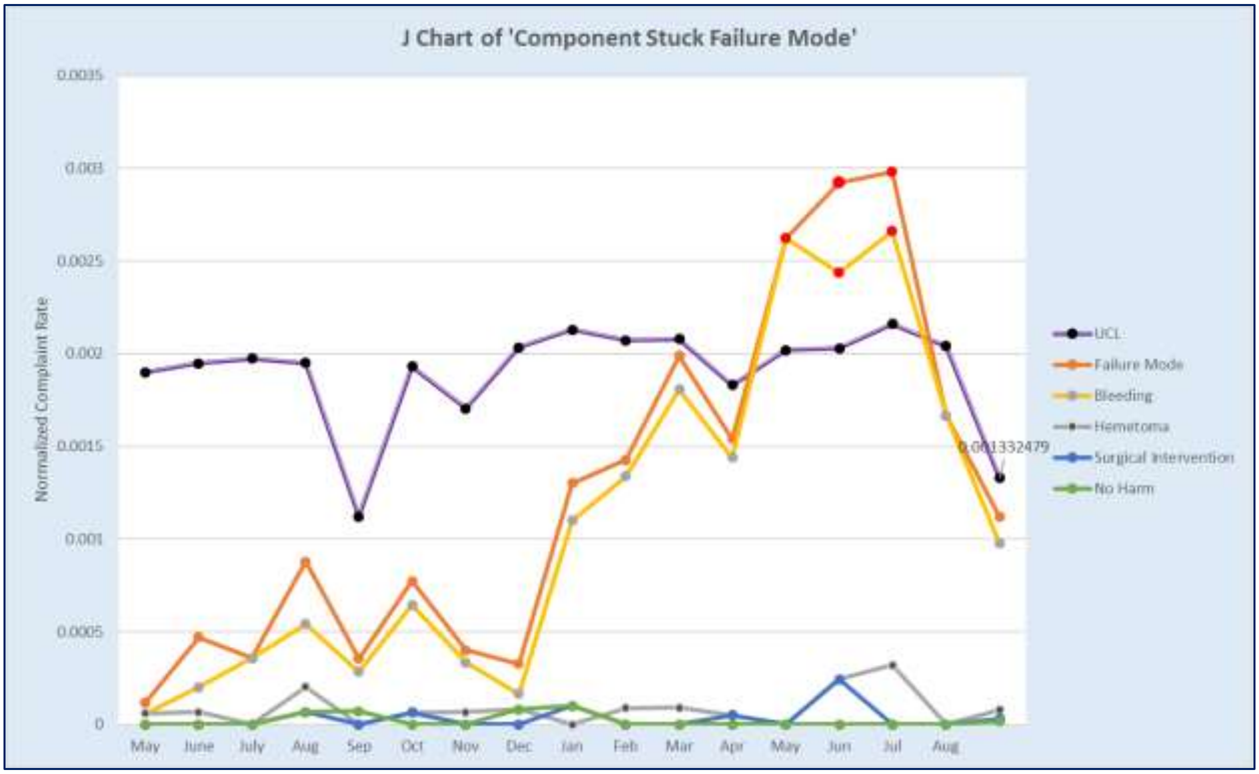


Figure 9: J Chart for failure mode of ‘Component Stuck’



Tables

Table 1: Recommended Subgroup Sizes (Adopted from J.C. Bennyan [11])

For U chart			
Rate per unit (lambda)	**Subgroup Size[1]**		
	Rule 1	**Rule 2**	**Rule 3**
0.025	200	120	361
0.050	100	60	181
0.075	67	40	121
0.100	50	30	91
0.250	20	12	37
0.500	10	6	19
0.750	7	4	13
1.000	5	3	10
1.250	4	3	8
1.500	4	2	7
1.750	3	2	6
2.000	3	2	5
2.250	3	2	5
2.500	2	2	4
2.750	2	2	4
3.000	2	1	4
3.250	2	1	3
3.500	2	1	3
3.750	2	1	3
4.000	2	1	3
4.250	2	1	3
4.500	2	1	3

4.750	2	1	2
5.000	1	1	2

[1]c and u chart rules:

Rule 1: $n \geq 5/\lambda$

Rule 2: $n \geq -\ln(.05)/\lambda$

Rule 3: $n > k^2 / \lambda$

Where, k = standard deviation multiple, p = binomial rate, λ = Poisson rate.

Table 2: No. of Subgroups based on defect rate

C	**No. of Subgroups**
0.1	232
0.3	95
0.5	65
0.7	52
1	41
3	22
5	18
10	14
30	10
50	9

Table 3 : Randomly Generated Raw Data

Month	Screw Failure	Surgeries
Jan	17	852
Feb	30	999
March	19	949
April	22	942
May	16	858
June	10	1037
July	16	904
Aug	40	909
Sep	21	916
Oct	12	990
Nov	12	886
Dec	15	890

Table 4: Sample FMEA Line Item for ‘Component Stuck’ Failure Mode

Failure Mode	Effect of Failure Mode	Severity	Cause of Failure	Occurrence	Mitigation	Risk Index
Component Stuck	Bleeding, Surgical Removal, Hematoma	‘3- Serious’	Incorrect Assembly, Excess off axis force	“1 – 0.003%”	In-Vitro Testing, Mold Design Guidelines	‘A-Acceptable’

Table 5: Complaint count and breakdown by harm

Month	Complaints	Sales	Bleeding with Manual Compression	Hematoma	Surgical Intervention	No harm
May	2	16699	1	1	0	0
June	7	14902	3	1	0	0
July	5	13934	5	0	0	0
Aug	13	14781	8	4	1	1
Sep	5	14010	4	0	0	1
Oct	12	15494	10	1	1	0
Nov	12	29884	10	2	0	0
Dec	4	12193	2	1	0	1
Jan	13	10000	11	2	1	1
Feb	16	11204	15	1	0	0
Mar	22	11061	20	2	0	0
Apr	31	20148	29	1	1	0
May	33	12588	33	0	0	0
Jun	36	12320	30	3	3	0
Jul	28	9390	25	3	0	0
Aug	20	12000	20	0	0	0
Total	259	230608	226	22	7	4

Table 5: Calculation of data points

UCL	Failure Mode	Bleeding	Hemetoma	Surgical Intervention	No Harm
0.001901	0.000119768	5.98838E-05	5.98838E-05	0	0
0.001947	0.000469736	0.000201315	6.71051E-05	0	0
0.001975	0.000358835	0.000358835	0	0	0
0.00195	0.000879507	0.000541235	0.000202963	6.76544E-05	6.77E-05
0.001123	0.000356888	0.00028551	0	0	7.14E-05
0.001931	0.000774493	0.000645411	6.45411E-05	6.45411E-05	0
0.001705	0.000401553	0.000334627	6.69254E-05	0	0
0.002034	0.000328057	0.000164029	8.20143E-05	0	8.2E-05
0.002129	0.0013	0.0011	0	0.0001	0.0001
0.002073	0.001428061	0.001338808	8.92538E-05	0	0
0.002079	0.00198897	0.001808155	9.04077E-05	0	0
0.001831	0.001538614	0.001439349	4.96327E-05	4.96327E-05	0
0.002019	0.002621544	0.002621544	0	0	0
0.002029	0.002922078	0.002435065	0.000243506	0.000243506	0
0.002161	0.002981896	0.002662407	0.000319489	0	0
0.002041	0.001666667	0.001666667	0	0	0
0.001332	0.001123118	0.000980018	7.80545E-05	3.03545E-05	1.73E-05