



2014 Workshop on Accelerated Stress Testing and Reliability



Reliability Modeling Using Conditional Reliability

ASTR Presentation

September 2014

Presenter: Sarah Noschang



2014 Workshop on Accelerated Stress Testing and Reliability



Sarah Noschang

- BS in Mechanical Engineering from University of Cincinnati
 - MBA from University of Cincinnati
- Quality Engineer responsible for design and reliability during New Product Development at Ethicon Endo Surgery a division of Johnson and Johnson for designing Medical Devices
- ASQ Certification
 - CQE, CQA



2014 Workshop on Accelerated Stress Testing and Reliability



Abstract

Reliability Modeling Using Conditional Reliability

Many devices are designed to function for multiple uses under given conditions. The reliability predictions for these products are traced back the test conditions applied and the calculations based on the failure modes. We have found that standard reliability calculations can over predict failures when compared to real life. We think there are several reasons for this to occur that can include an incorrect stressor or an incorrect reliability model. After investigating our test method we examined the method for reliability calculations.

This presentation proposes a method for analyzing a wear out condition known as a conditional reliability. Conditional reliability can be used to predict the ability of the device to achieve $N+m$ cycles past end of life after given test conditions have been applied for the N number of cycles, where N represents the normal use life and $N+m$ represents remaining life in the design.

Limited life devices were tested under simulated conditions to mimic real life use and to simulate the end of life failures. Failures and suspensions were determined, and the overall reliability was estimated using both standard reliability calculations and conditional reliability calculations, for the ability to achieve $N+m$ cycle past end of life.

The results were then compared to real life data to determine which method would better represent the actual results. A comparison of the % survival rate for the standard calculations versus conditional calculations showed that standard calculations significantly over predicted failures while the conditional calculations were closer to the real life condition.



2014 Workshop on Accelerated Stress Testing and Reliability



Background Problem Statement

- Reliability testing is conducted to show that a design will meet with confidence the design life requirements of a re-usable device.
 - Device is disabled at the end of “useful” life
- Testing was conducted and compared to actual results for a known device
- Testing was conducted with a small sample size to understand if results can match / predict real life.
- All of the test samples would pass the design life requirement independently, but the confidence interval projects that the design did not meet the criteria
- To determine if the small sample sizes effects the reliability predicted model and confidence bounds a comparison was done with different reliability models to actual device performance.



2014 Workshop on Accelerated Stress Testing and Reliability



Test Methodology

- The design life requirement was for the device to function for 100 uses.
- Testing was focused on one type of failure examination.
- The reliability test was developed using “worse case” stressors
- For efficiency the testing with done in sets of 10 cycles.
 - After each 10 use cycle the parts were rated as pass-or-fail
- Samples were tested until “failures” were recorded.



2014 Workshop on Accelerated Stress Testing and Reliability



Weibull Test Results

From testing results

The following are the failure times:

Cycles Suspension / Failure

- 90 C - suspend due to special cause
- 110 x - Failure
- 120 x - Failure
- 120 x - Failure
- 130 x - Failure
- 130 x - Failure
- 140 x - Failure
- 140 x - Failure
- 150 x - Failure
- 150 x - Failure
- 170 C - suspend
- 170 C- suspend
- 170 C- suspend
- 170 C- suspend
- 170 C- suspend
- 170 C- suspend

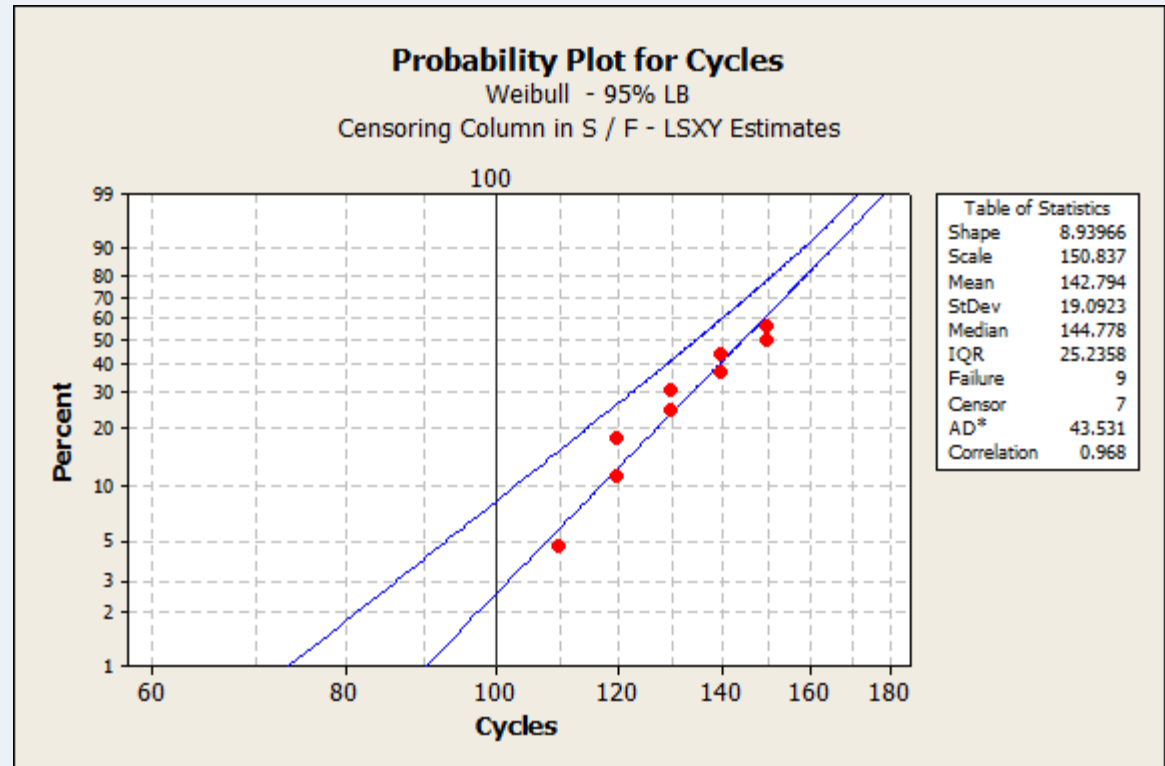
This produces a survival prediction as

Table of Survival Probabilities		
95.0% Normal		
Time	Probability	Lower Bound
100	0.974956	0.887966

This reliability produces an unreliable (number of failure percent) as 1-reliability

@95% confidence: $1 - .887966 = .112034$ translates to **11.2% failures**

@50% confidence: $1 - .974956 = .025044$ translates to **2.5% failures**





Actual Device Performance

- Actual device performance for the devices produced in 2010 was examined.
 - This time frame has been used for a sufficient time to allow for failures.
 - Devices would have been disassembled during analysis to identify failure examined
- 68 confirmed failures
- 21,473 devices manufactured
- Failure rate of 0.3% (68/21473)

- Due to some amount of under-reporting, assume the failure rate is two times higher - 0.6%.

Top AFC	Failures from Mfg year 2010
Blank (not returned)	815
Conforming	433
Failure Mode 1	149
Failure Mode 2	160
Failure Mode 3 (failure examined by testing)	68
Failure Mode 4	52
Other	203
Grand Total	1880

68 confirmed failures 0.31%
 136 2x' s confirmed failures 0.63%
 21,473 Devices produced



2014 Workshop on Accelerated Stress Testing and Reliability



Conclusion

Model	Results	Criteria
Weibull Test	11.2% failures	@.99 reliability with 95% confidence
Field Results	0.6% failures	@ two times reported rate of failure

- The prediction from the reliability testing is higher than actual results
- Why the difference between the reliability model and actual results?
 - Are we over driving the parts during testing?
 - Does the reliability prediction model create an aggressive prediction due to:
 - Predictions beyond failure data?
 - Variability of failures well beyond useful life (some devices don't fail for a long time)?



2014 Workshop on Accelerated Stress Testing and Reliability



Reliability Test Model Examination

- The reliability test model and stressors used were examined.
- The model combined all the highest stressors for each use condition.
- The test method was able to generate representative failures
- It was determine to maintain the test method due to ability to generate representative failures



2014 Workshop on Accelerated Stress Testing and Reliability



Reliability Prediction Examination

- All samples had passed the design life requirement
- Reliability model did not meet design requirement due to confidence intervals.
- Conditional Reliability^[1] model was investigated
- The concept of conditional reliability is that we will expect some time of useful life (T) where failures will not be demonstrated in the test.
- Previous analysis pushed devices into wear-out and then analyzed them as if there was no early or useful life.
- This model takes into account the full reliability bathtub curve.

^[1] The conditional reliability is explained in Kececioglu, Dimitri. Reliability & Life Testing Handbook, Vol 1 on page 62. Prentice-Hall, 1993. There are many other sources on conditional reliability which is a subset of conditional probability. .



2014 Workshop on Accelerated Stress Testing and Reliability



Conditional Reliability

Requirement – The device will demonstrate that entry into wear out will occur at a number of uses greater than 100 with 99% reliability with 95% confidence.

Test Model

- N devices will be pre-conditioned with 100 simulated uses.
- At 101 and beyond, simulated usage and sterilization will continue until failure or censoring per plan.
- At 101, The usage count for the test will be restarted at 1 for each device.
- The criteria for success will be:
 1. No failures under 100 uses
 2. Some acceptable amount of life remains with 99% reliability with 95% confidence. (This acceptable life might be as little as one more use.)



2014 Workshop on Accelerated Stress Testing and Reliability



Same Data with Conditional Reliability

The following are the failure times at N+ cycles

Morgan	Conditional	CM
90	---	Excluded -due to special cause
110	10	x - Failure
120	20	x - Failure
120	20	x - Failure
130	30	x - Failure
130	30	x - Failure
140	40	x - Failure
140	40	x - Failure
150	50	x - Failure
150	50	x - Failure
170	70	C - suspend
170	70	C - suspend
170	70	C - suspend
170	70	C - suspend
170	70	C - suspend
170	70	C - suspend

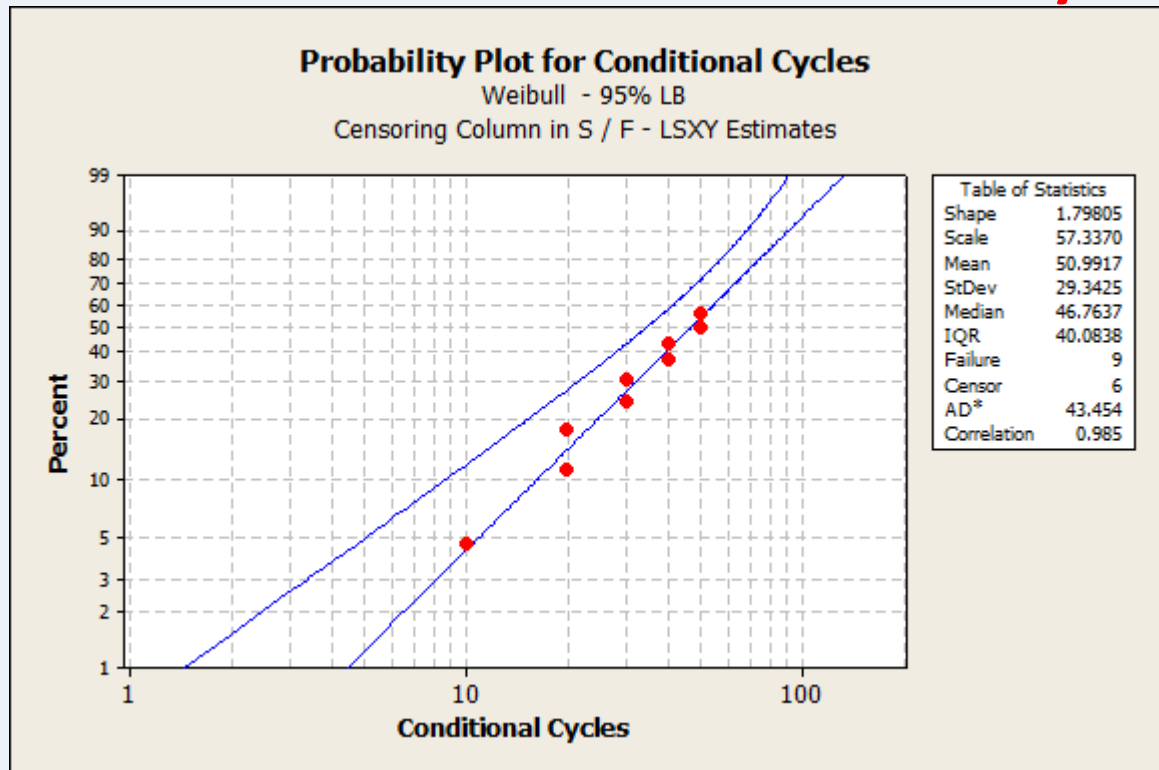


Table of Survival Probabilities

95.0% Normal

Time Probability Lower Bound

1 0.999311 0.985475

This reliability produces an unreliable (number of failure percent) as 1-reliability

@95% confidence: $1 - .985475 = .0145$ translates to 1.45 % failures predicted at 100+1 uses

@50% confidence: $1 - .999311 = .000689$ translates to 0.06% failures predicted at 100+1 uses



2014 Workshop on Accelerated Stress Testing and Reliability



Conclusion

Model	Results	Criteria
Weibull Test	11.2% failures	@.99 reliability with 95% confidence for 100 cycles
Conditional	1.45 % failures	@.99 reliability with 95% confidence for 100+1 cycle
Field Results	0.6% failures	@ two times reported rate of failure

- The conditional model more closely represents the field data.



2014 Workshop on Accelerated Stress Testing and Reliability



Conditional Reliability

- Assumptions:
 - Expected that device will already have some “normal life” and the test is exploring past normal life
 - Discussion on the criteria for success
- Weakness – in conditional
 - Use of condition compared to traditional can look like you are cheating the data to pass
 - If you have failure during “normal use” what does this mean?
 - (special cause or weakness in design)
- Strengths – in conditional
 - Predicting closer to actual test data results.
 - A better regression predication with small sample sizes that fail over time



2014 Workshop on Accelerated Stress Testing and Reliability



Questions / Comments



2014 Workshop on Accelerated Stress Testing and Reliability



Confidence Bounds / Regression

- Formulas on confidence and effect of small sample size.
- Add graphs of how the confidence bounds are further from the data.
- Move the prediction to closer to the data points to better represent rather than draw back so far (regress/ exterpete)
- Add a graph on the regression...