Accelerated Testing for Design Improvement of Harmonic Surgical Blades

ASTR Presentation

September 2014

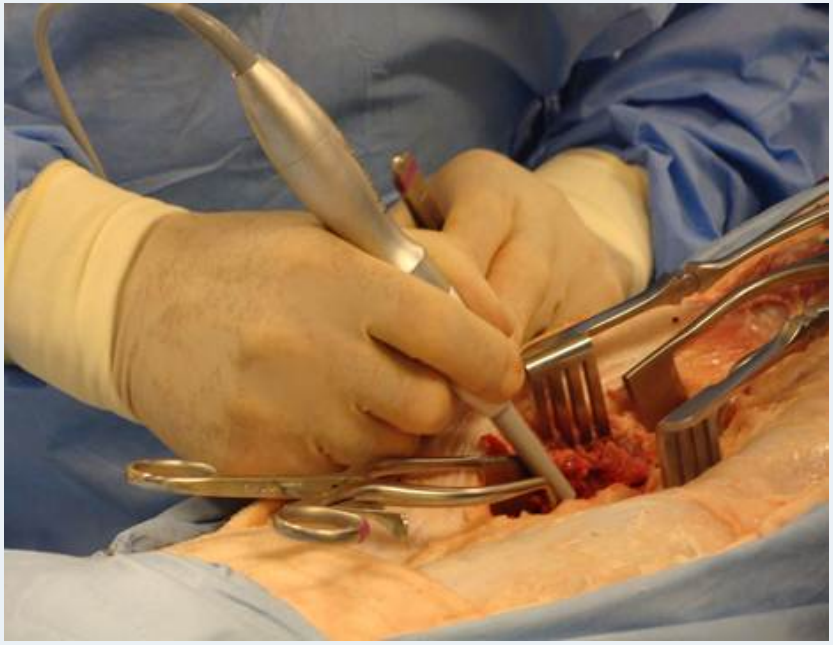
Presenter: Nabeel Jadeed

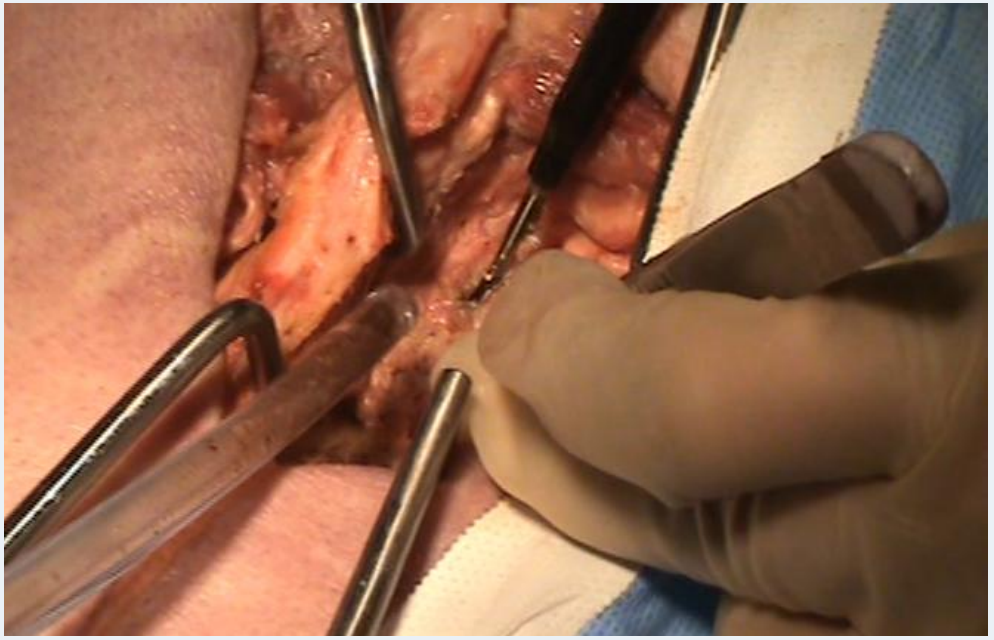
Nabeel Jadeed

- B.S. Materials Science & Engineering
  - University of Cincinnati
- Currently a Quality Engineer (5yrs) at Ethicon in Cincinnati, OH (Johnson & Johnson)
- 16yrs Experience in the medical device field
  - Wide range of product experience (staplers, trocars, clip appliers, energy-based devices) in manufacturing, quality, and R&D
- ASQ Certified Quality Engineer, Reliability Engineer, and Six Sigma Black Belt

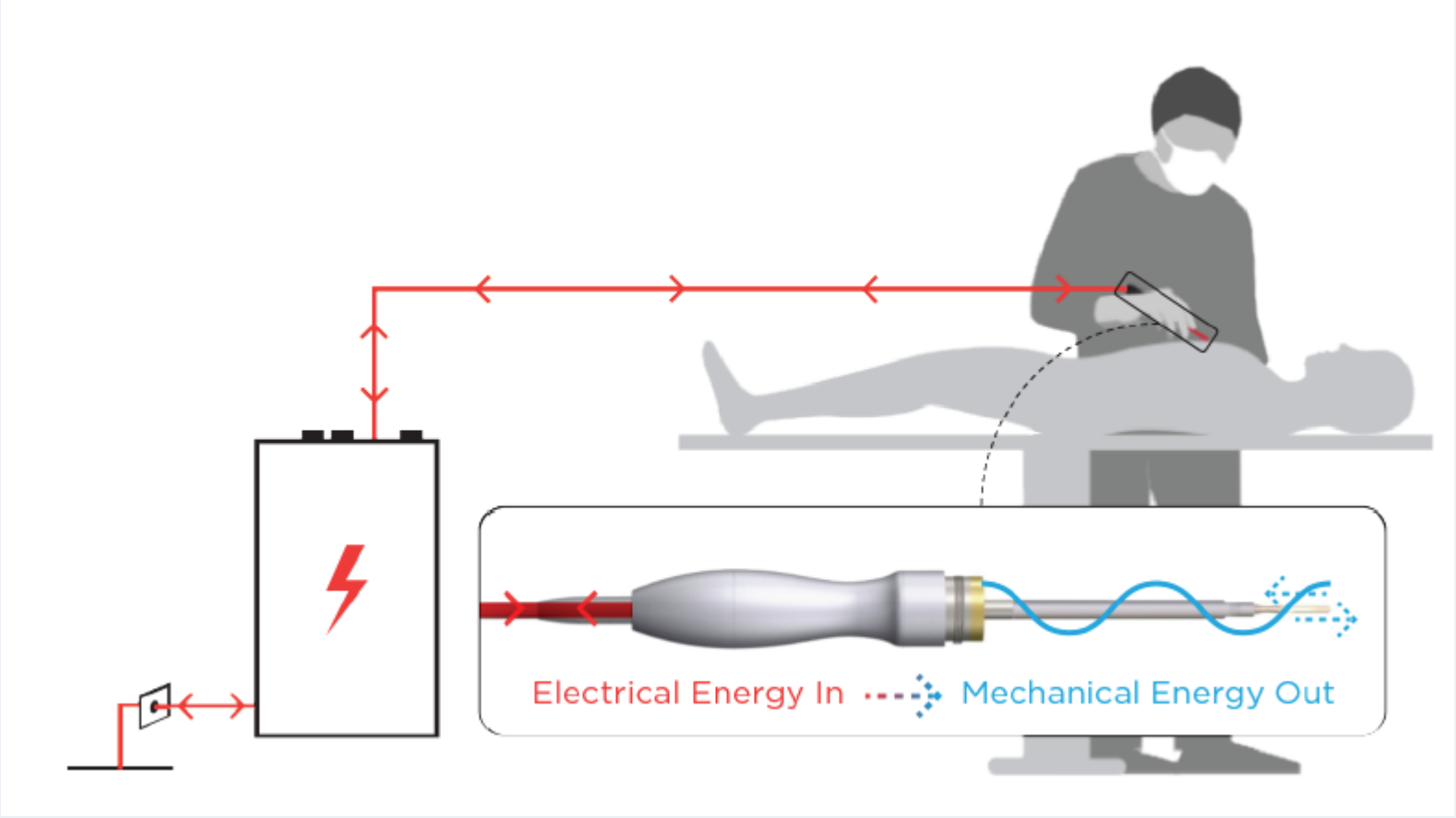
Background

- Harmonic Blades are used for spine soft tissue access.
- Instrument blade can become cracked due to inadvertent contact of active blade by the surgeon with metal objects in surgical field.



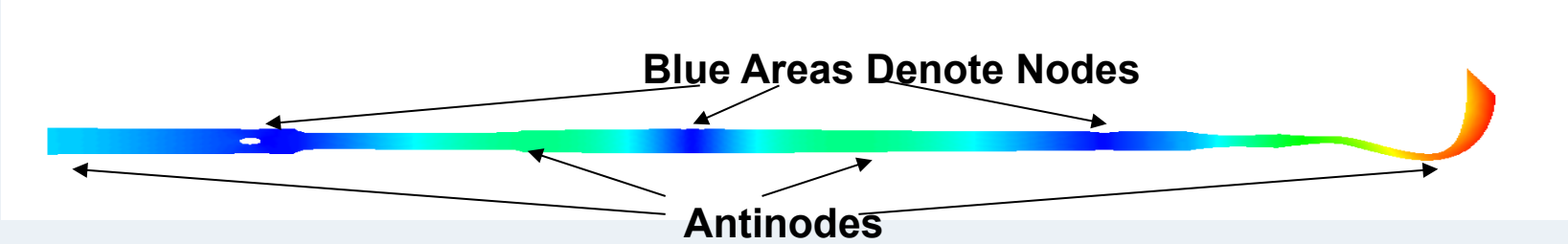


Harmonic Technology Basics



Harmonic Technology Basics

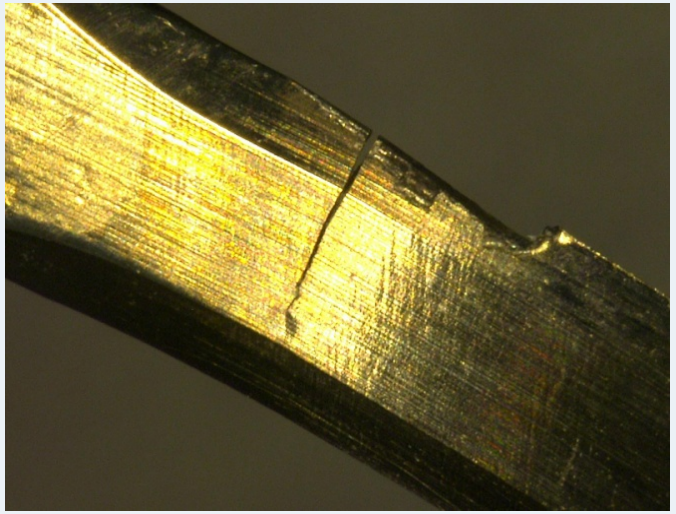
- Energy transformed into mechanical motion, longitudinal vibration at ultrasonic frequencies
- Mechanical motion cuts and coagulates simultaneously

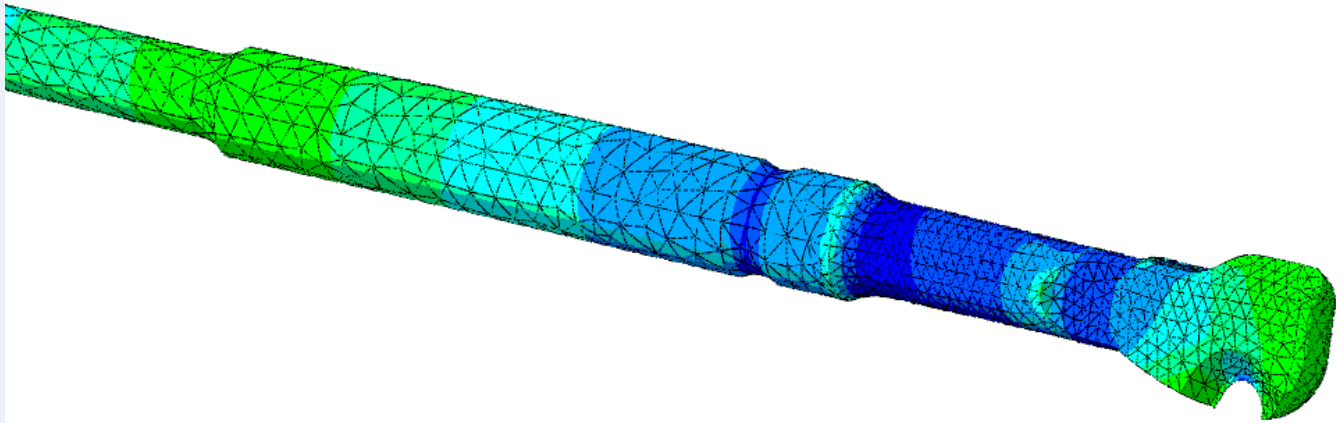


- Nodes:
  - Zero movement
  - Maximum stress and strain
- Anti-nodes
  - Maximum movement
  - Minimum stress and strain

Blade Cracking

- Each Type of Blade Has a Sensitive Area Where Metal to Metal Contact Will Most Easily initiate a crack.
- The Red Areas in FEA show the Most Sensitive Areas of Each Blade.





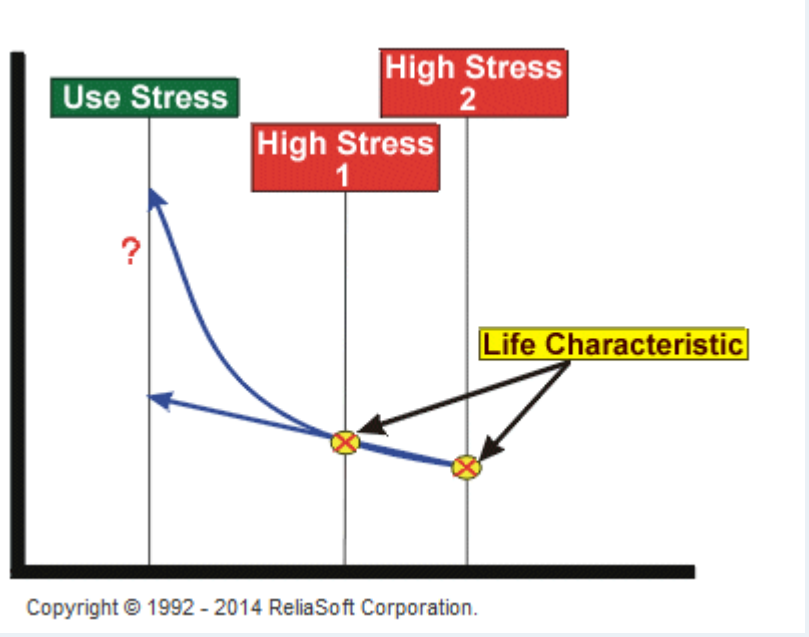
Problem

- Traditional life data analysis proves difficult to compare alternate designs
  - Time consuming due to long failure times with some samples taking days of abuse without failing
  - Inconclusive due to high variability in life data

Difficult for new product teams to make timely design improvement decisions

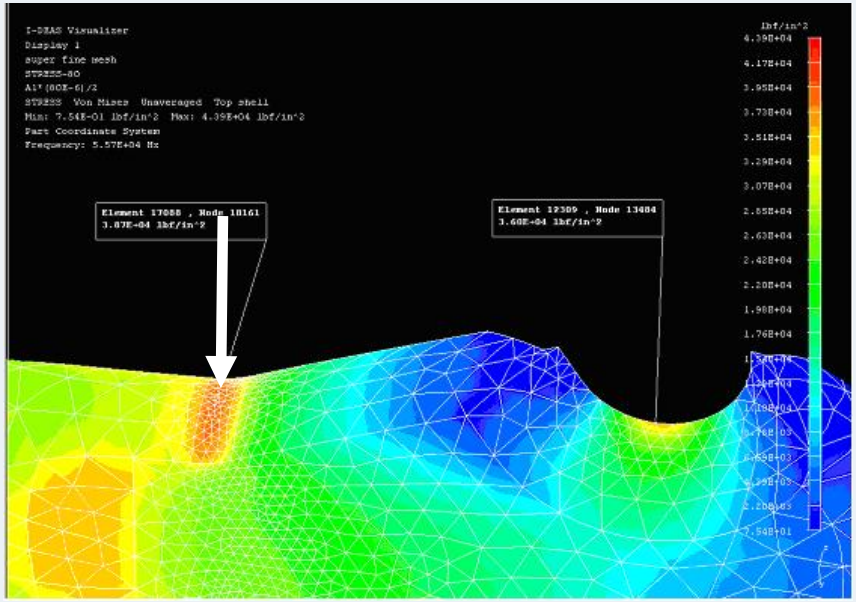
A Better Way

- Accelerated Life Testing
  - Evaluate life using an accelerating stress factor to obtain failures more quickly without inducing unrealistic failures modes[1].
  - In the case of the Harmonic blade, we can use simulated metal contact at increasing levels of contact pressure to accelerate failures.



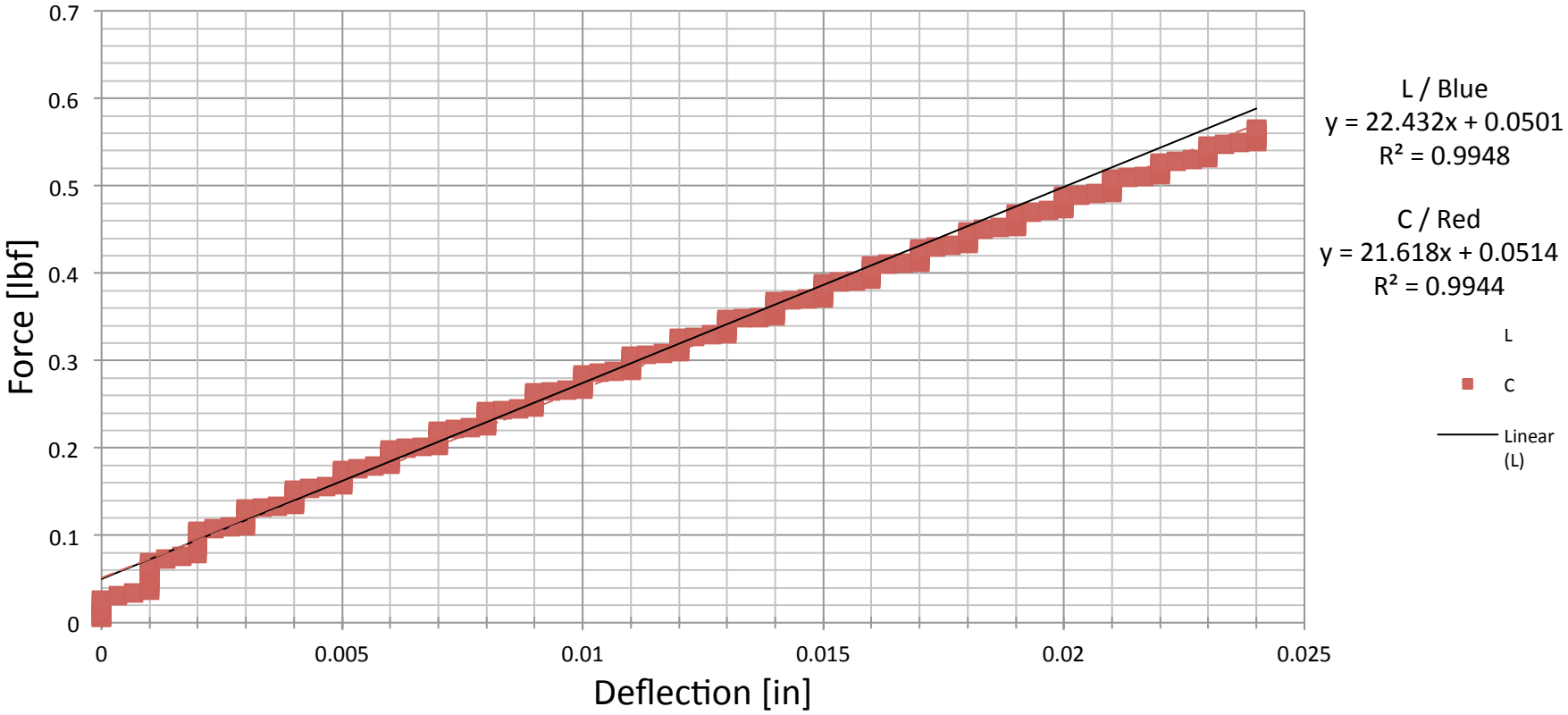
Test Procedure

- Main stressor identified as contact force of metal object at areas of high stress on the tip of the blade.
- Points of high localized stress are identified with FEA
- The points are validated by comparing product returns
- A Carbide “hitter” is positioned at these points to simulate contact with metal while the blade is vibrating



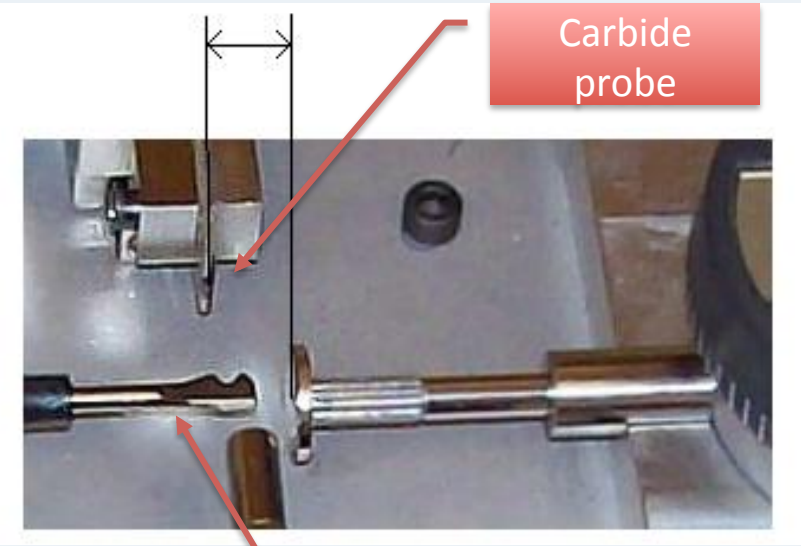
Force – Deflection Curves

- Force-deflection curve are generated as input to the test fixture
- Unique to different designs depending on overall length and location of high stress area.



Test Procedure

- With main stressor identified and force-deflection curves generated suitable stress points were needed.
- These suitable stress points determined through experimentation:
  - Balance between instantaneous cracking and excessive time to failure (>300 sec)



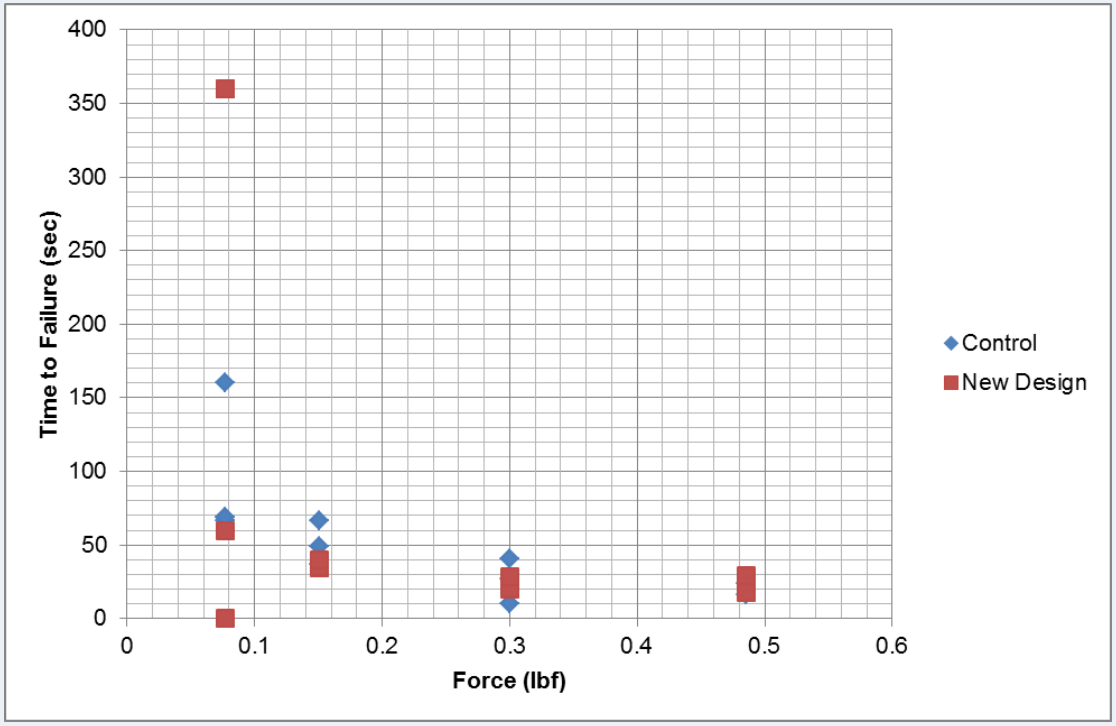
Design Comparison

- New Design
  - More cross-sectional area at high stress areas
  - Blade waveguide optimized for less stress over control blade, i.e. more balanced
  - Minimize stress risers at high points of stress

Life Test Data

Commercially available blade (control) benchmarked against new design

Force (lbf)	Control State (F or S)	Control End Time (sec)	New Design State (F or S)	New Design End Time (sec)
0.0769	F	66.7	- - -	- - -
0.0769	F	68.7	F	59.5
0.0769	F	68.8	S	360
0.0769	F	160.4	S	360
0.151	F	37	F	34.2
0.151	F	48.6	F	35.2
0.151	F	66.5	F	39.9
0.3	F	10.4	F	20
0.3	F	27.1	F	21
0.3	F	40.4	F	28.6
0.4853	F	16.1	F	17.5
0.4853	F	23.5	F	29



Data Analysis – Model Assumptions

- Reliasoft ALTA® used for ALT analysis
- Determining best fit for life distribution:
  - Likelihood values compared for both control and new:

New Design

Weibull
Beta = 1.513228
K = 0.204756
n = 1.596630
LK Value = -43.343574

Exponential
K = 0.242417
n = 1.696578
LK Value = -44.309122

Lognormal
Std = 0.721576
K = 0.192337
n = 1.349473
LK Value = -42.533399

Lognormal best fit for new design

Control

Weibull
Beta = 2.943067
K = 0.096996
n = 0.904398
LK Value = -50.445923

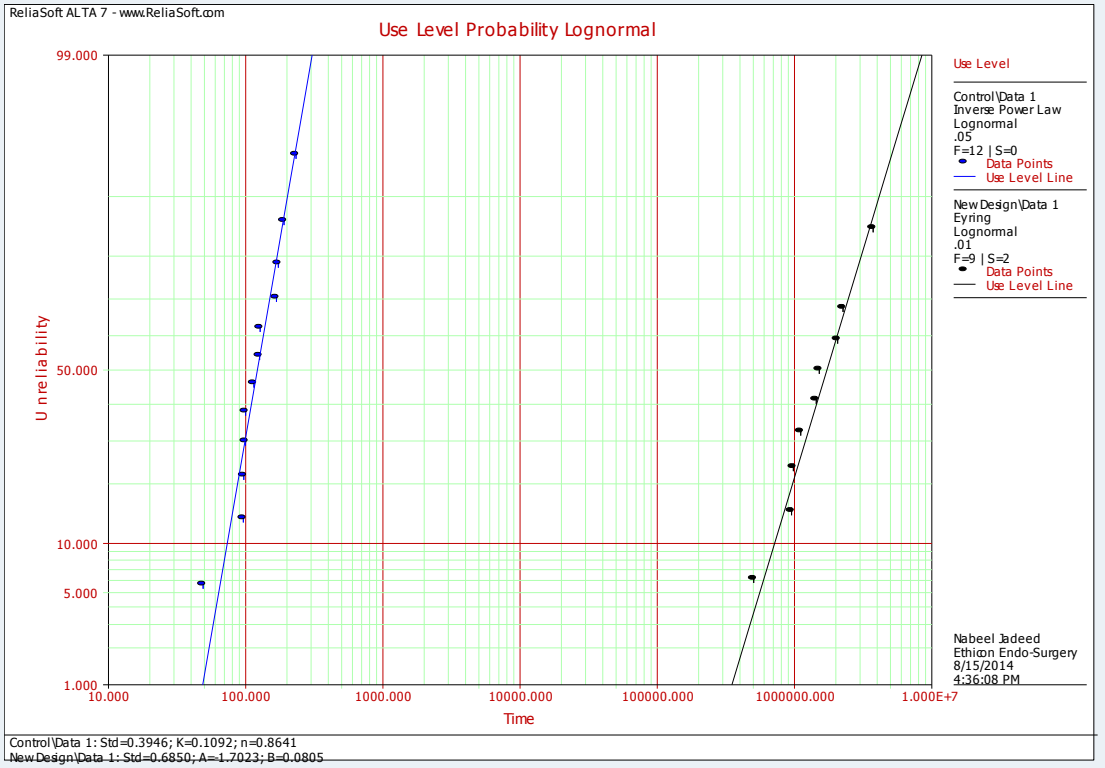
Exponential
K = 0.101116
n = 0.861578
LK Value = -57.582688

Lognormal
Std = 0.394616
K = 0.109249
n = 0.864066
LK Value = -50.575704

Based on similar LK values, lognormal used for consistency

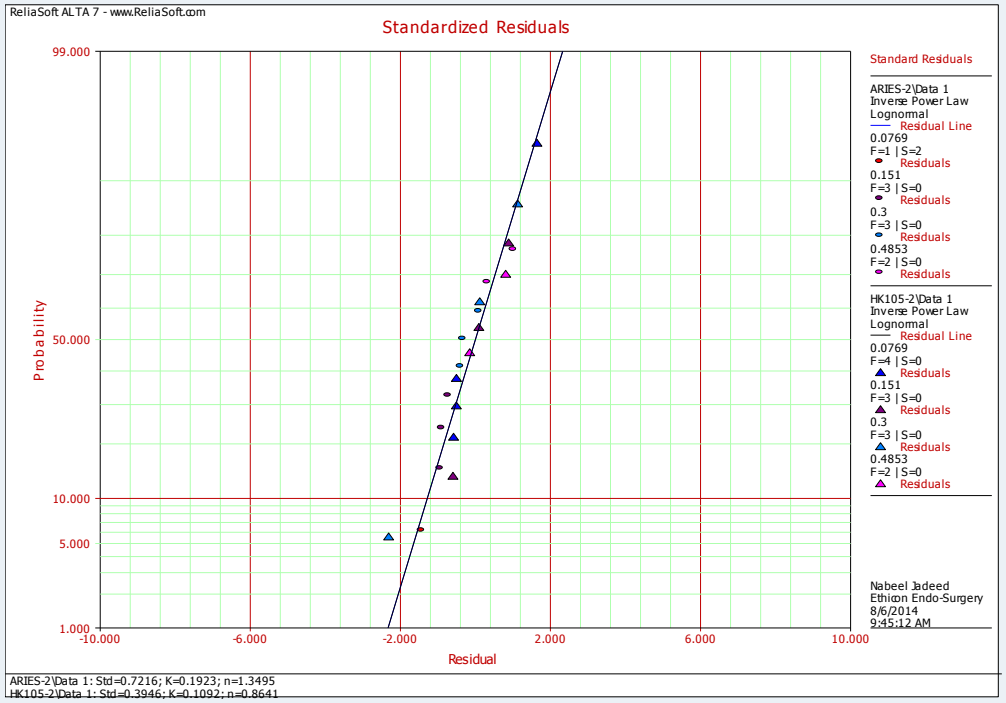
Data Analysis – Model Assumptions

- Lognormal used for life distribution
- Inverse Power Law, common for single, non-thermal stresses[2], was used for Life-Stress model
  - No evidence that shape parameters differ at each stress level based on Likelihood ration test



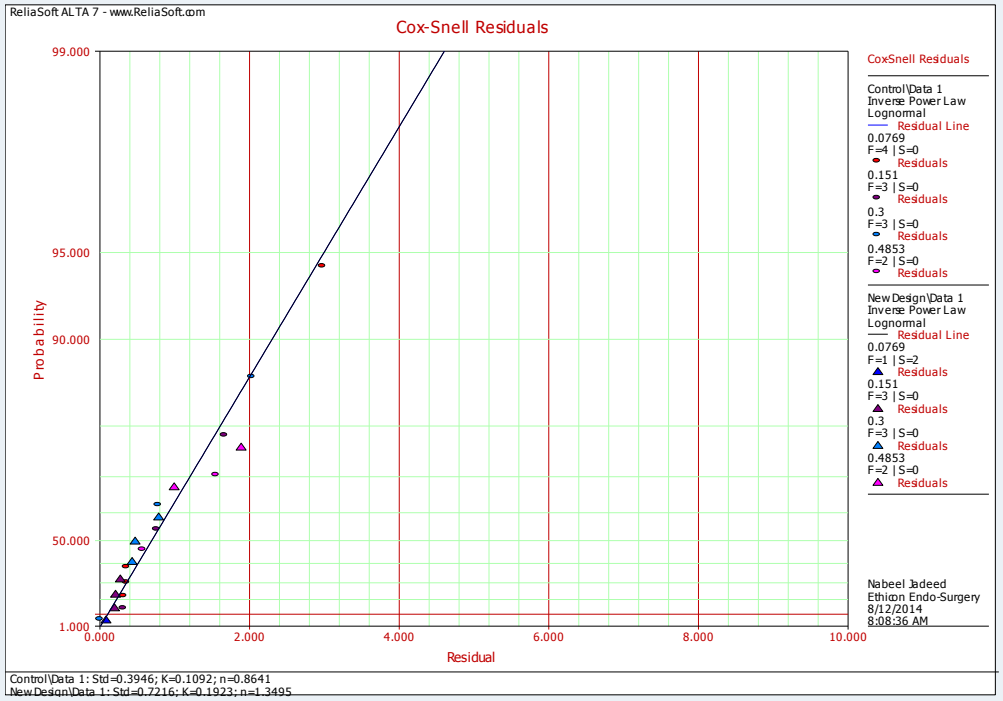
Model Diagnostics

- The standardized residuals should follow a normal distribution if the assumed life-stress model and distribution are a good fit[3].
  - No excessive deviation of residuals from expected values



Model Diagnostics

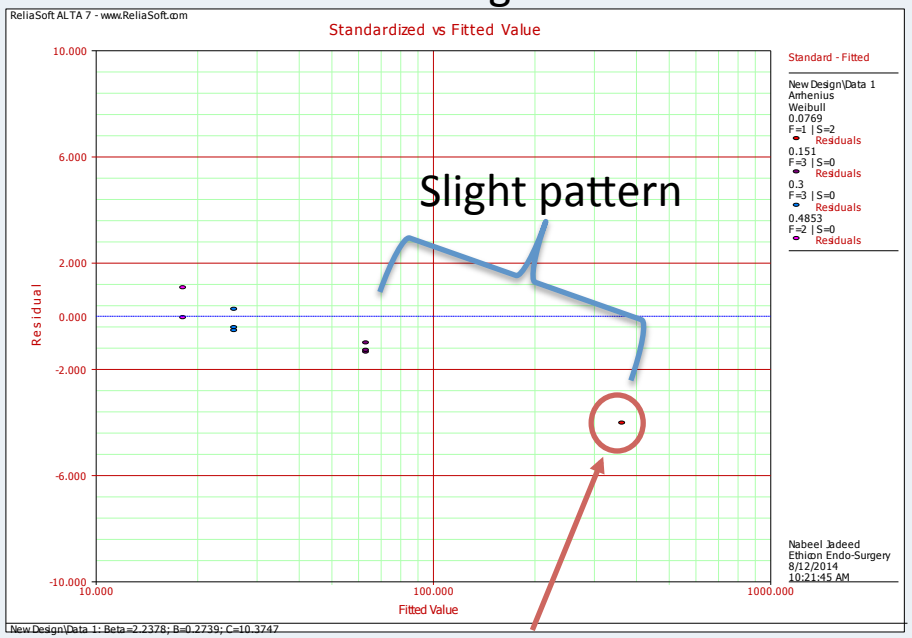
- Cox-Snell residuals should follow an exponential distribution if the assumed life-stress model and distribution are a good fit[3].
  - Residuals are derived from the negative natural log of estimated reliability of each observations, which should be uniform
  - Based on plot. no excessive deviation of residuals from expected values



Model Diagnostics

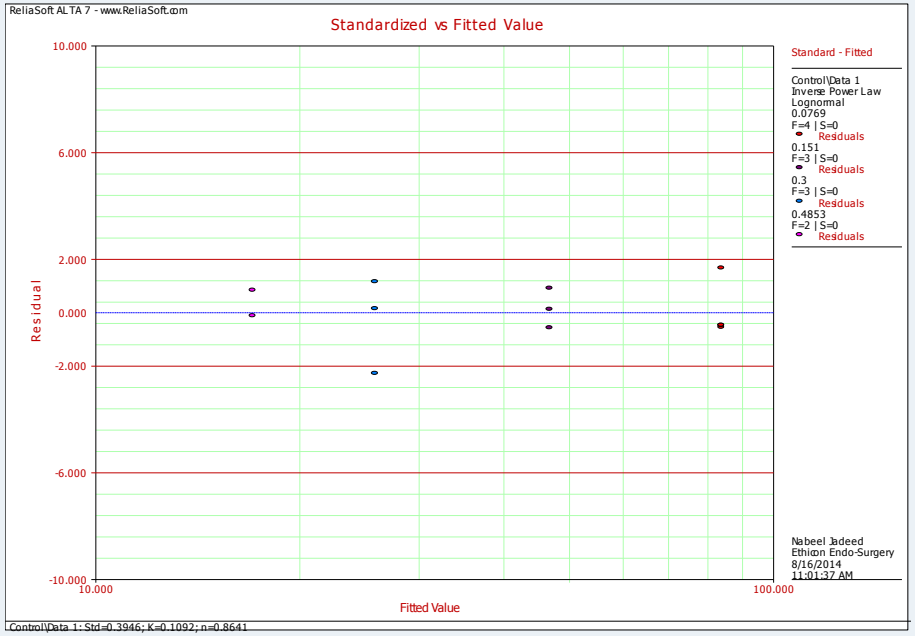
- The residuals vs the fitted values should appear random with minimal outliers.

New Design



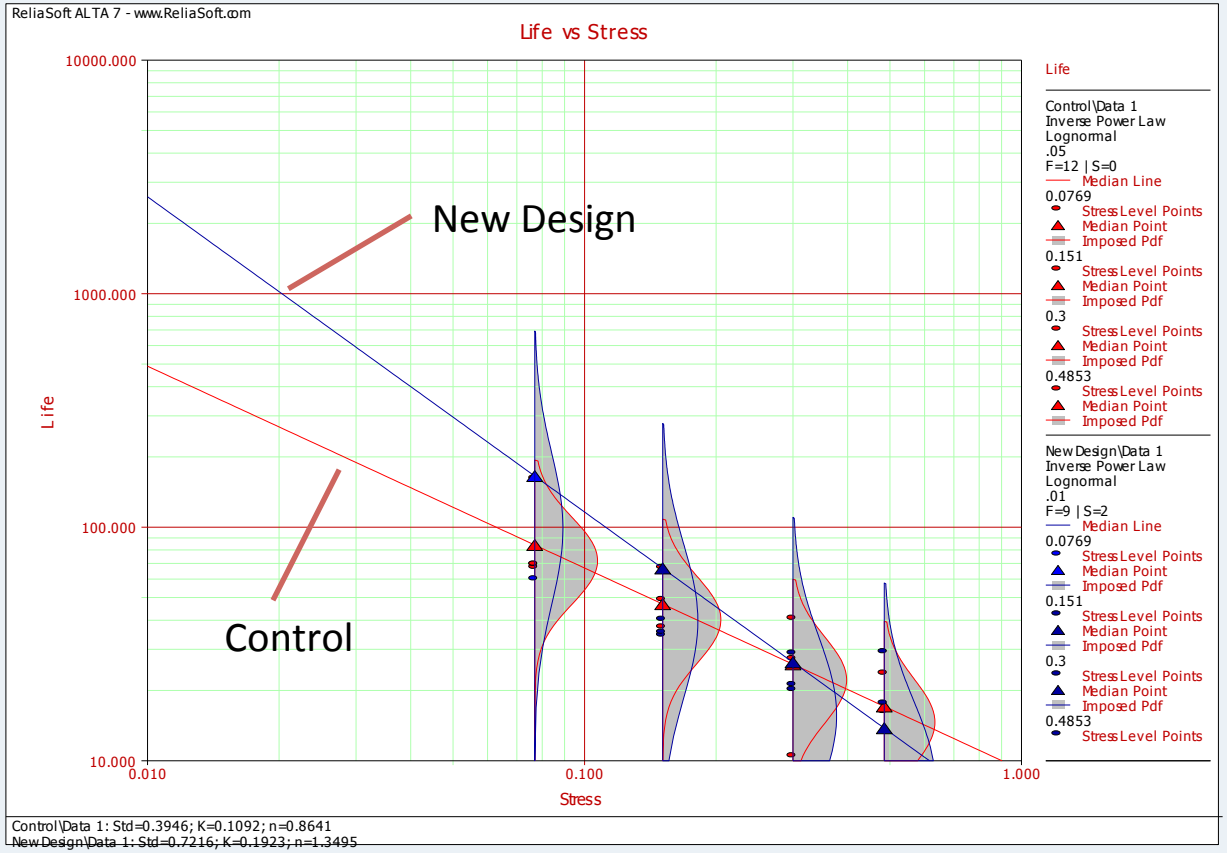
Abnormal behavior at low stress point: 2 out 3 blades suspended at 300 sec.

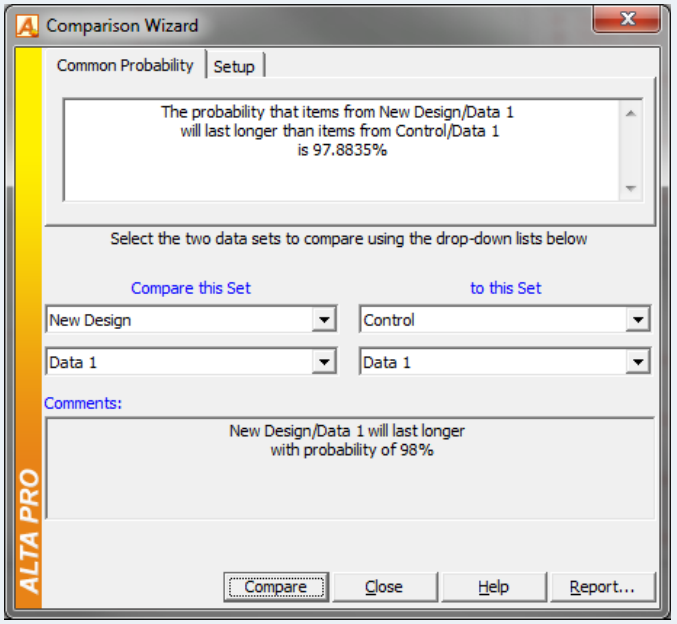
Control



Life Comparison

Control vs. New Design





New design predicted to last longer with a probability of 97.88%

Benefits of this Method

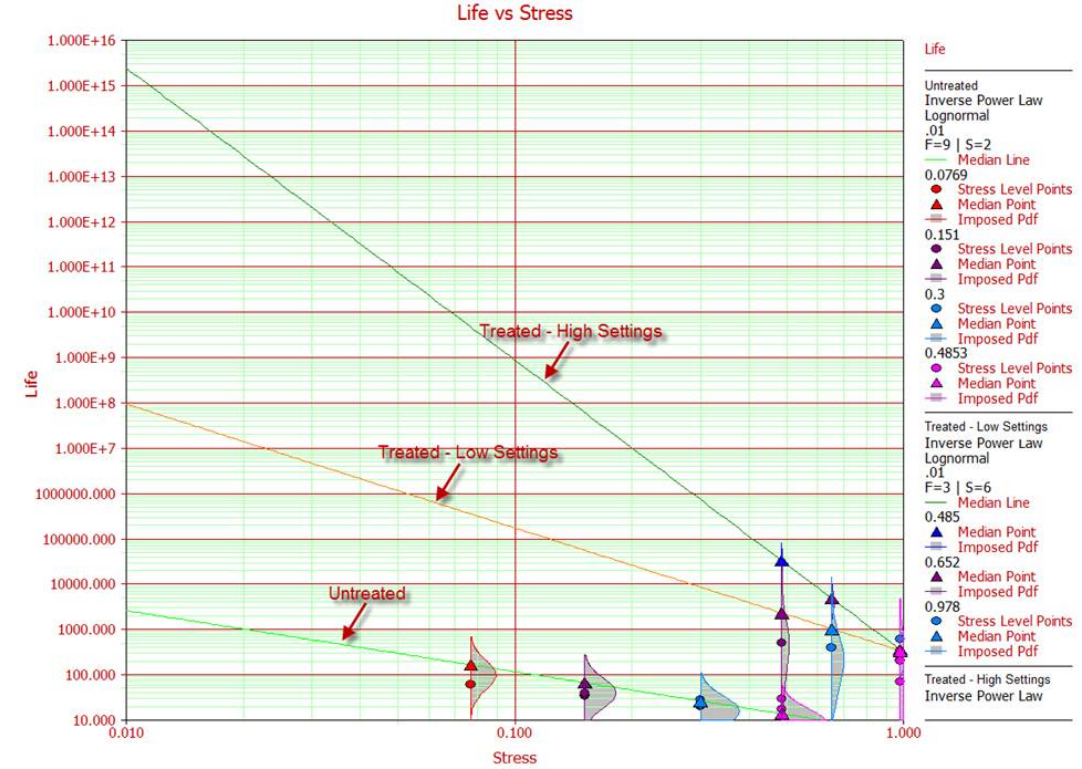
- Faster design iteration - allows for comparison in a matter of 1-2 days.
  - Previous attempts could take several days for 1 blade with inconclusive results
- Anecdotal information from preclinical use in cadaver indicates improved robustness to cracking

Benefits of this Method

- Test has demonstrated a degree of repeatability based on replicated experiments.
  - Repeated twice with new samples of the same design
  - Directionally the same conclusions (new design better than old design)

Benefits of this Method

- Subsequently used to test additional design enhancements (surface treatment)



Potential Weaknesses

- Assumptions:
  - Constant contact pressure not realistic, intermittent in actual practice
  - Metal can contact any part of the blade, not just the high stress areas
  - Blade FEA model accuracy
- Is higher stress creating unrealistic failure modes?
  - Actual use stress difficult to determine

Questions?

References

1. "Quantitative Accelerated Life Testing Data Analysis." *Accelerated Life Testing and Data Analysis*. Reliasoft. Web. 6 Aug. 2014. <http://www.weibull.com/basics/accelerated.htm>.

2. "Inverse Power Law Relationship." *Accelerated Life Testing Data Analysis Reference*, Reliasoft. Web. 6 Aug. 2014. <http://reliawiki.com/index.php/Inverse_Power_Law_(IPL)_Relationship>.

3. "Residual Plots in Accelerated Life Testing Data Analysis." *Reliability Hotwire* 105 (2009). Reliasoft. Web. 6 Aug. 2014. <http://www.weibull.com/hotwire/issue105/index.htm>.