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um 2023

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Sensitivity and Reliability Analysis of a

Catheter Sheath Hemostasis Assembly

to Improve Patient Safety and Reduce Scrap

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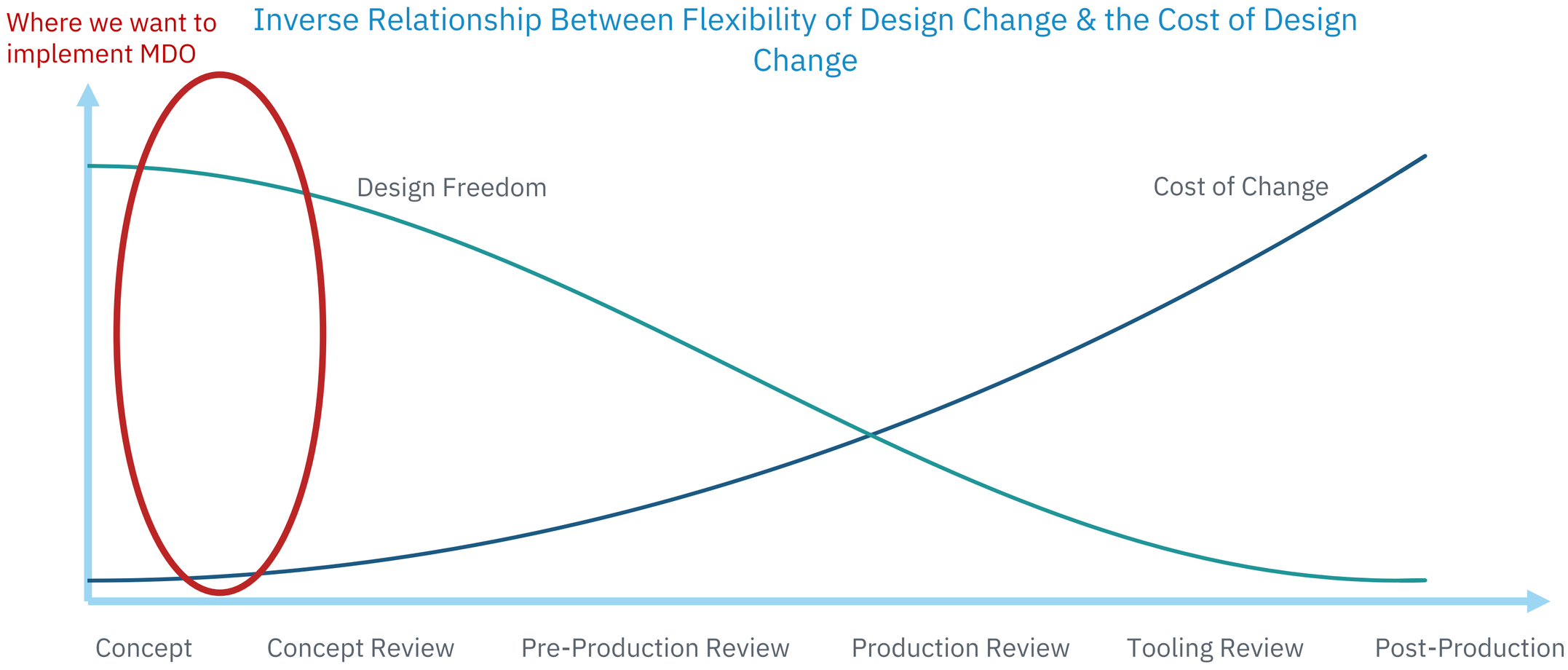
Conclusion & Impact

Implementation of MDO



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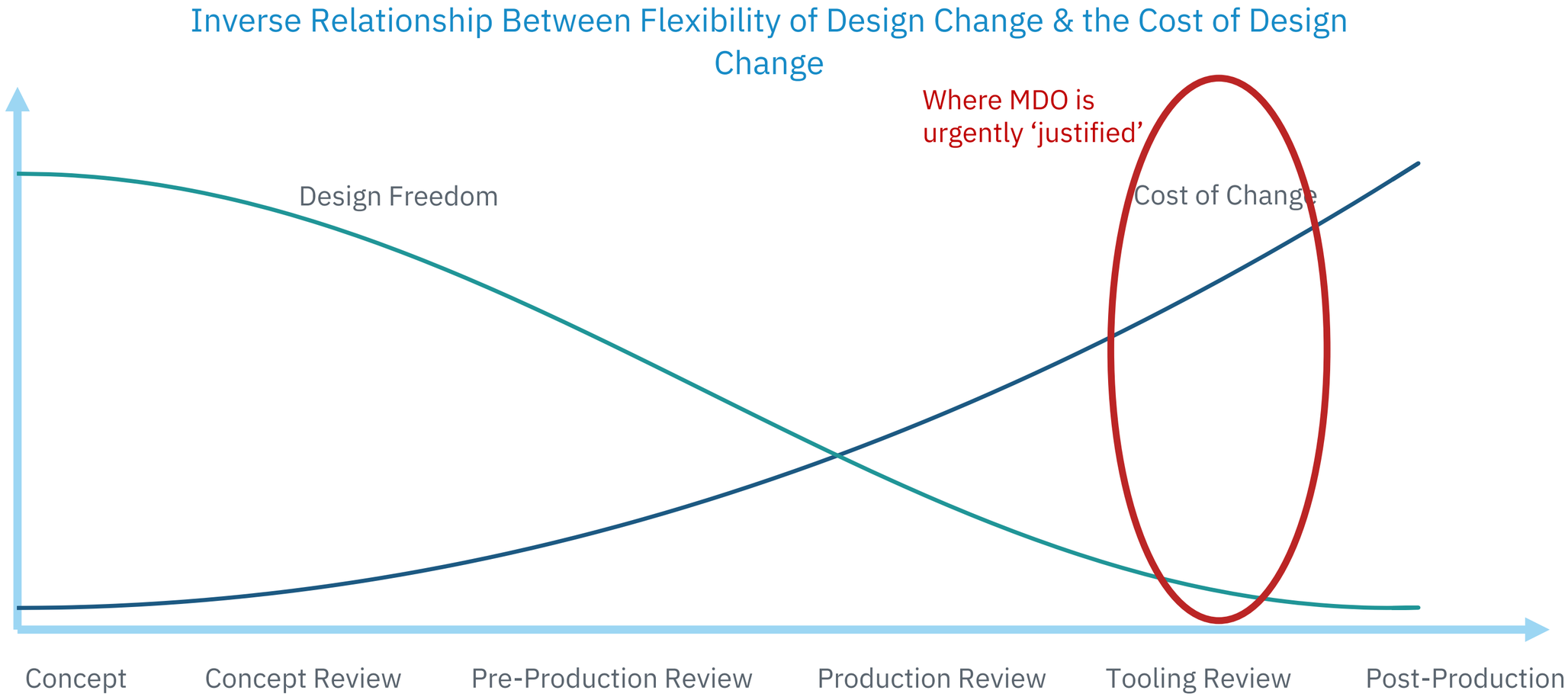
Implementation of MDO



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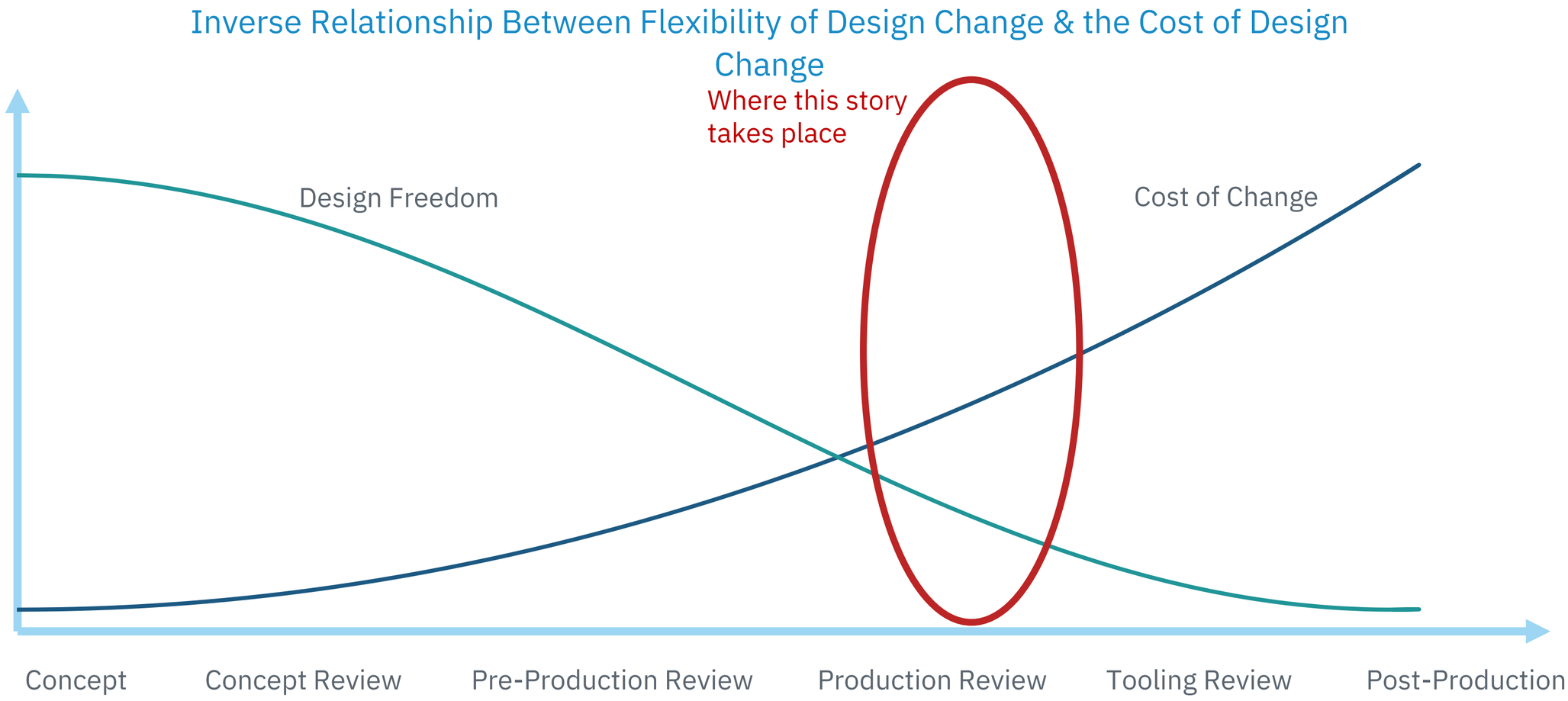
Implementation of MDO



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Introduction and Background

- Hemostasis is the process of preventing bleeding / blood loss.
- Modern irrigated catheters use heparinized saline to ensure no stagnant blood between the sheath and catheter.
- A current R&D program's prototype Hemostasis assemblies were experiencing failures during leak testing at a rate of ~12%.
- Prototype tooling already existed for the program; however, production tooling had not yet been developed.

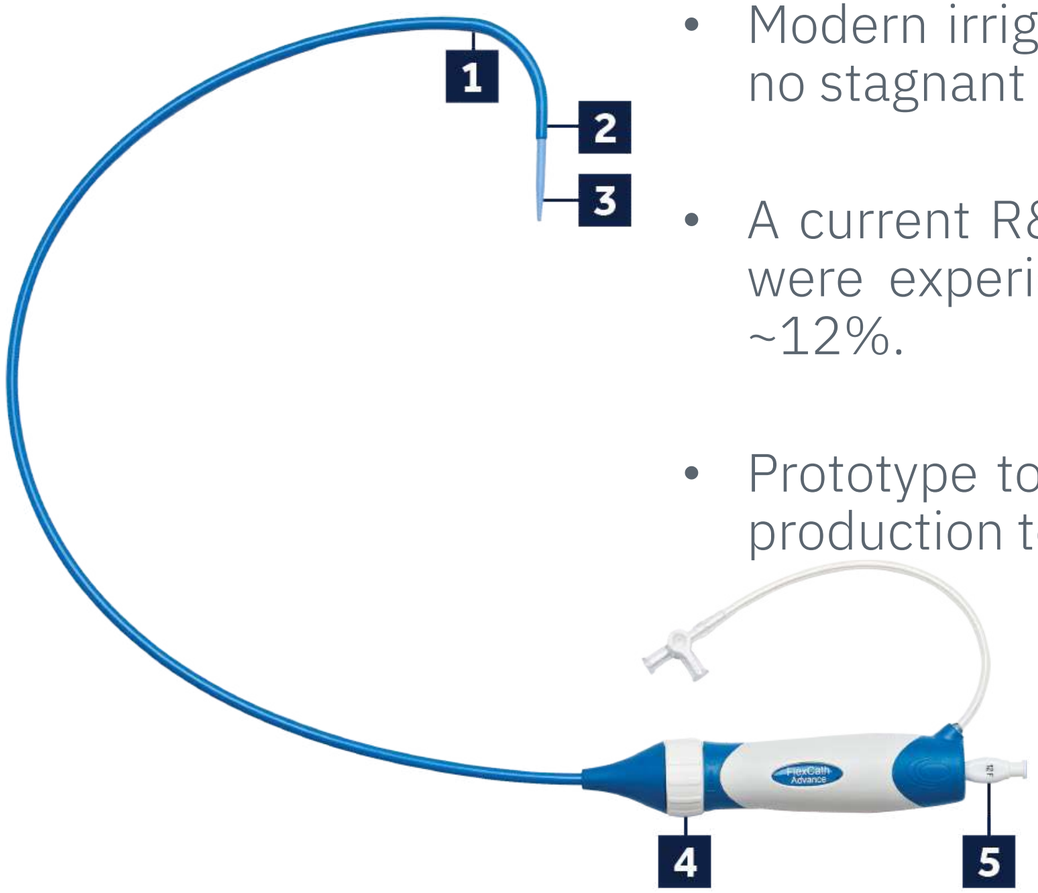

*Image shown is for **architectural reference only**. This is not the prototype project experiencing leakage

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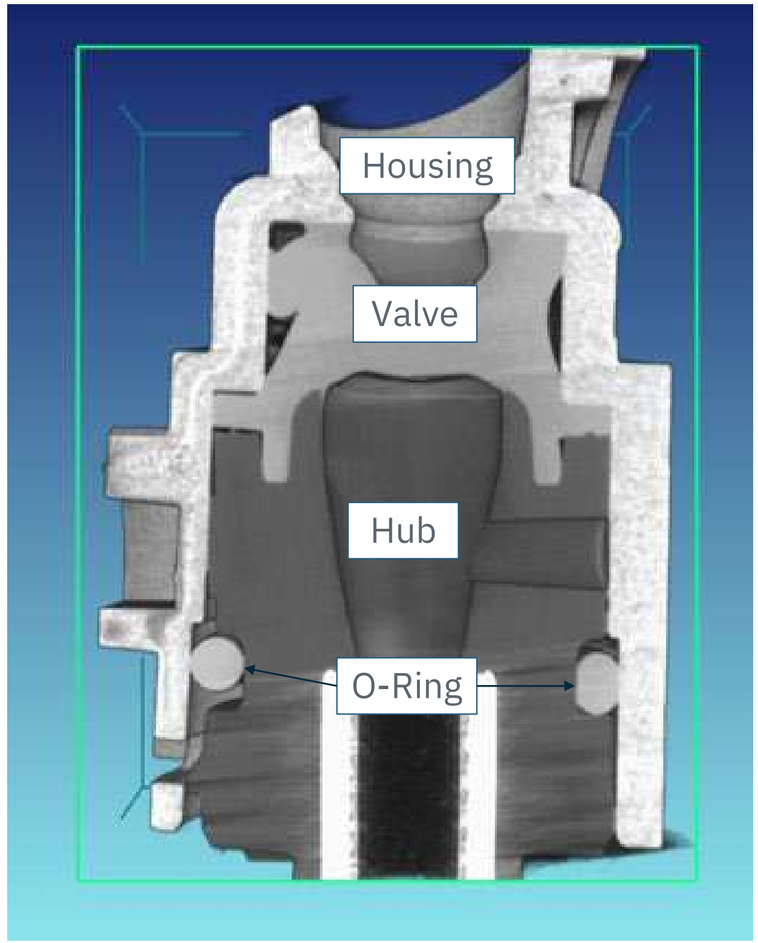
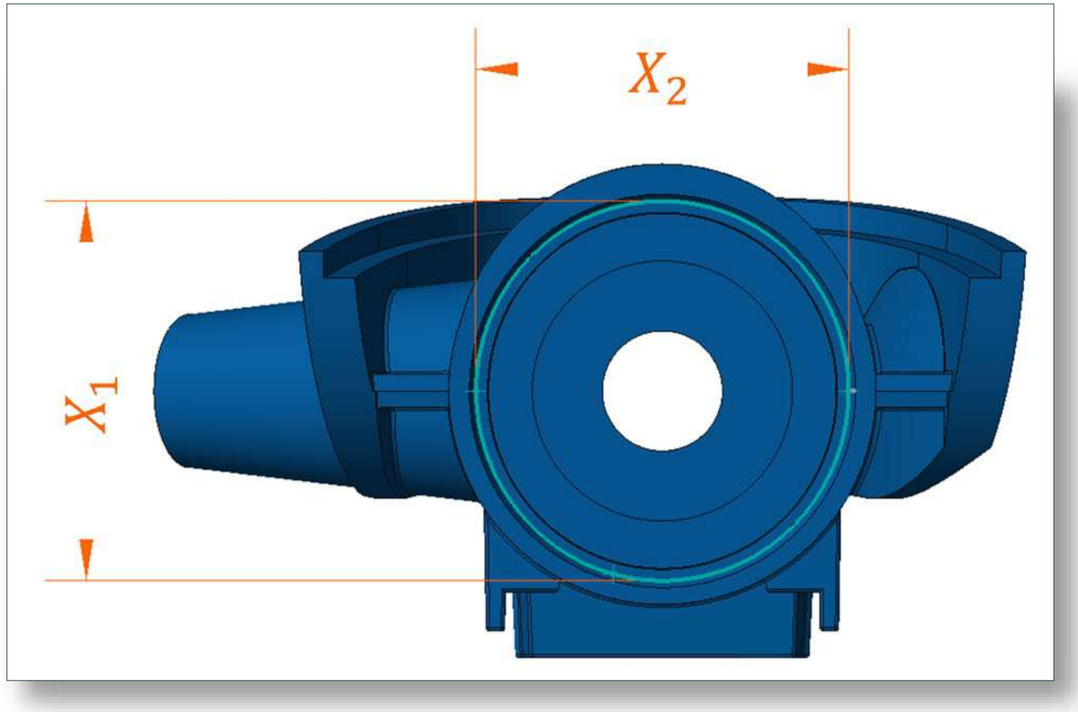
Introduction & Background

Possible Causes





$$X_1 \neq X_2$$

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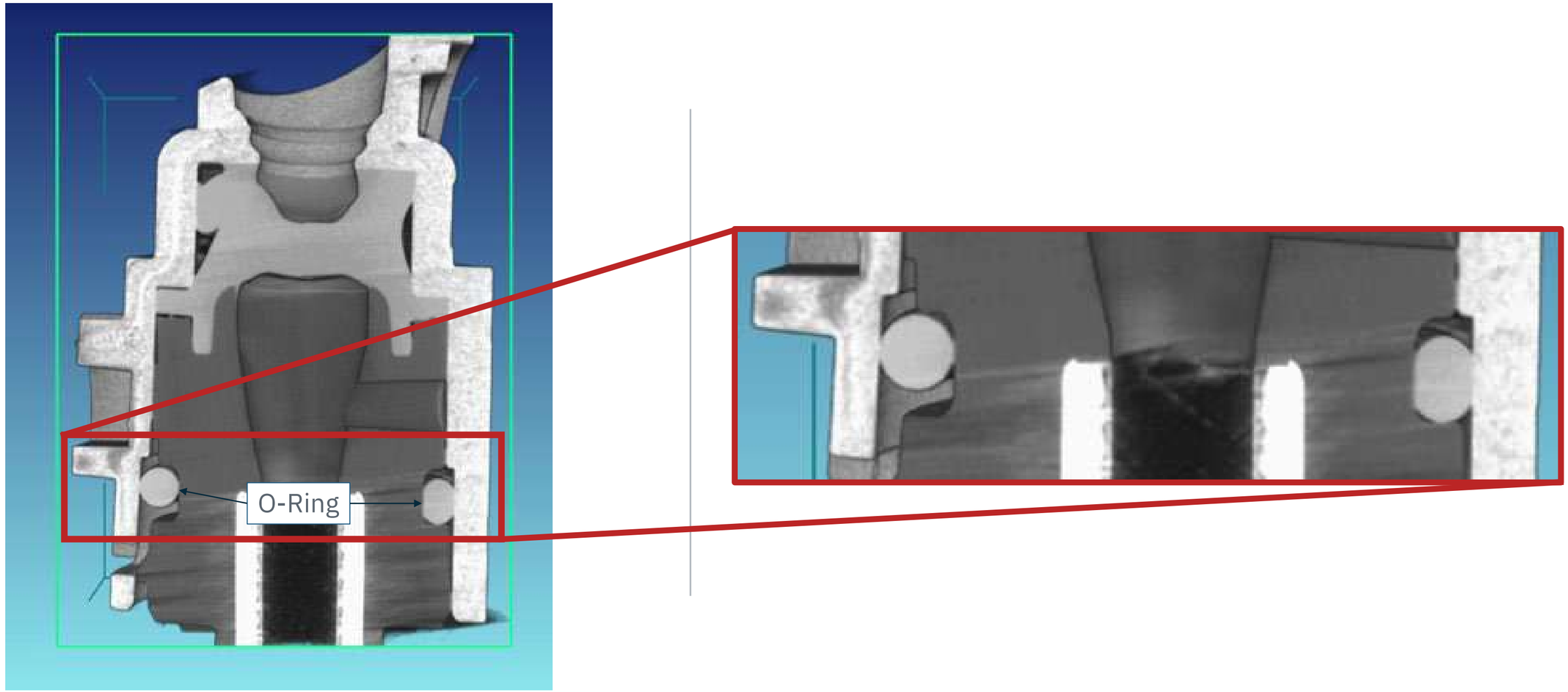
Introduction & Background

Possible Causes



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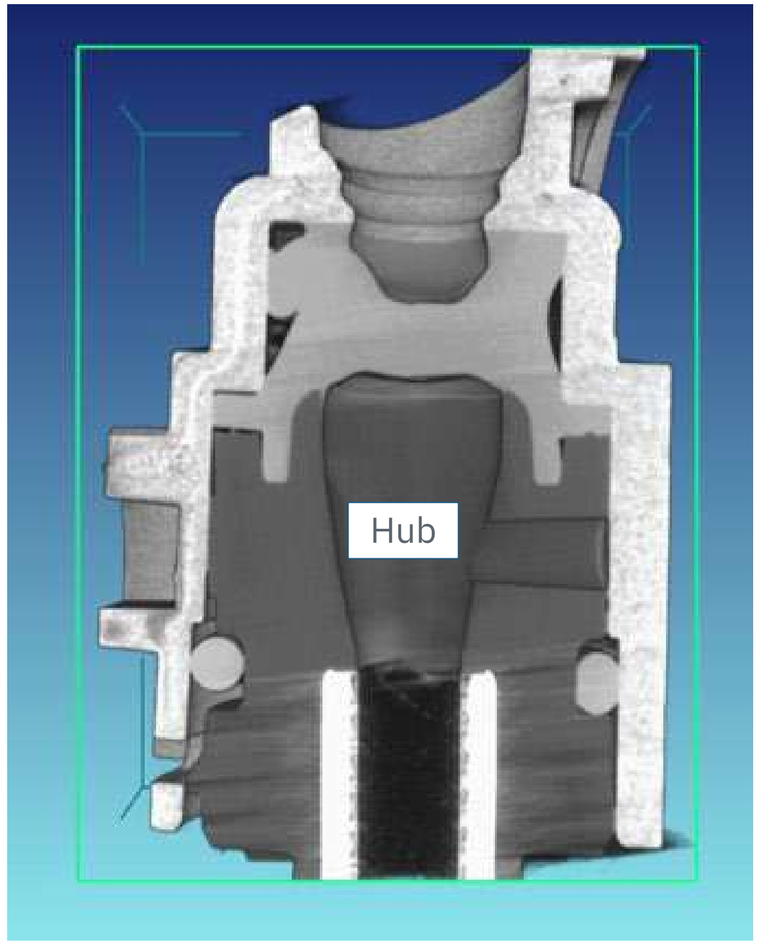
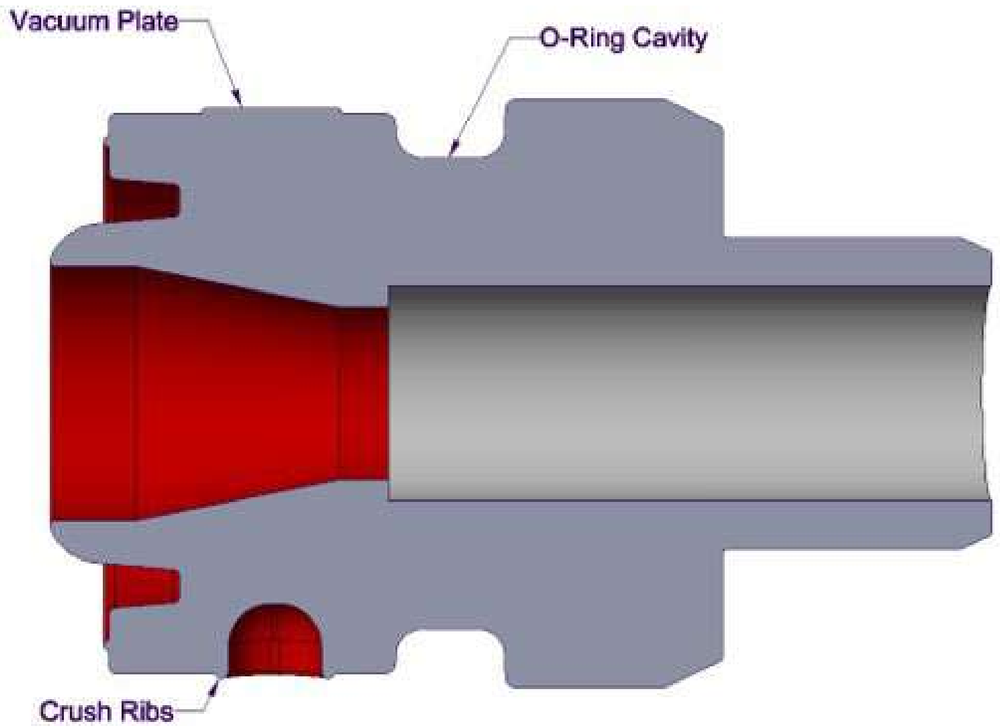
Introduction & Background

Possible Causes





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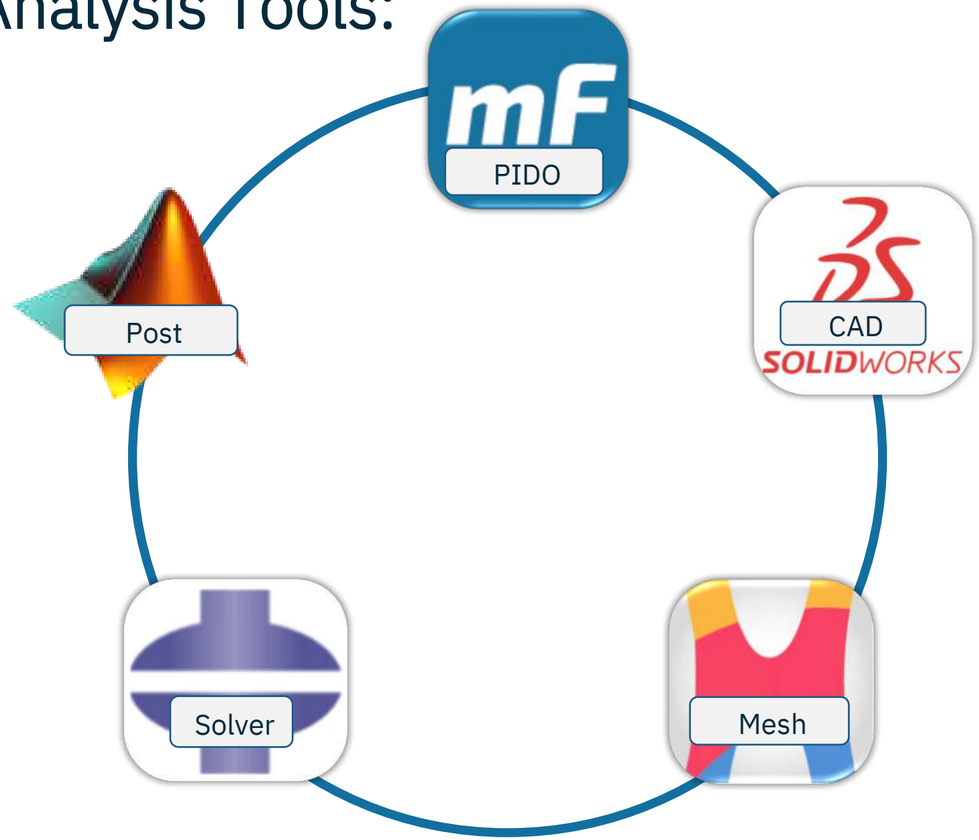
Introduction & Background

Study Objectives and Project Charter

Project Objectives:

- Develop a computational analysis model
- Evaluate “As Manufactured” O-Ring compression
- Determine the critical hub parameters
  - O-Ring compression magnitude
  - O-Ring compression uniformity
  - Robust against misalignment

Analysis Tools:



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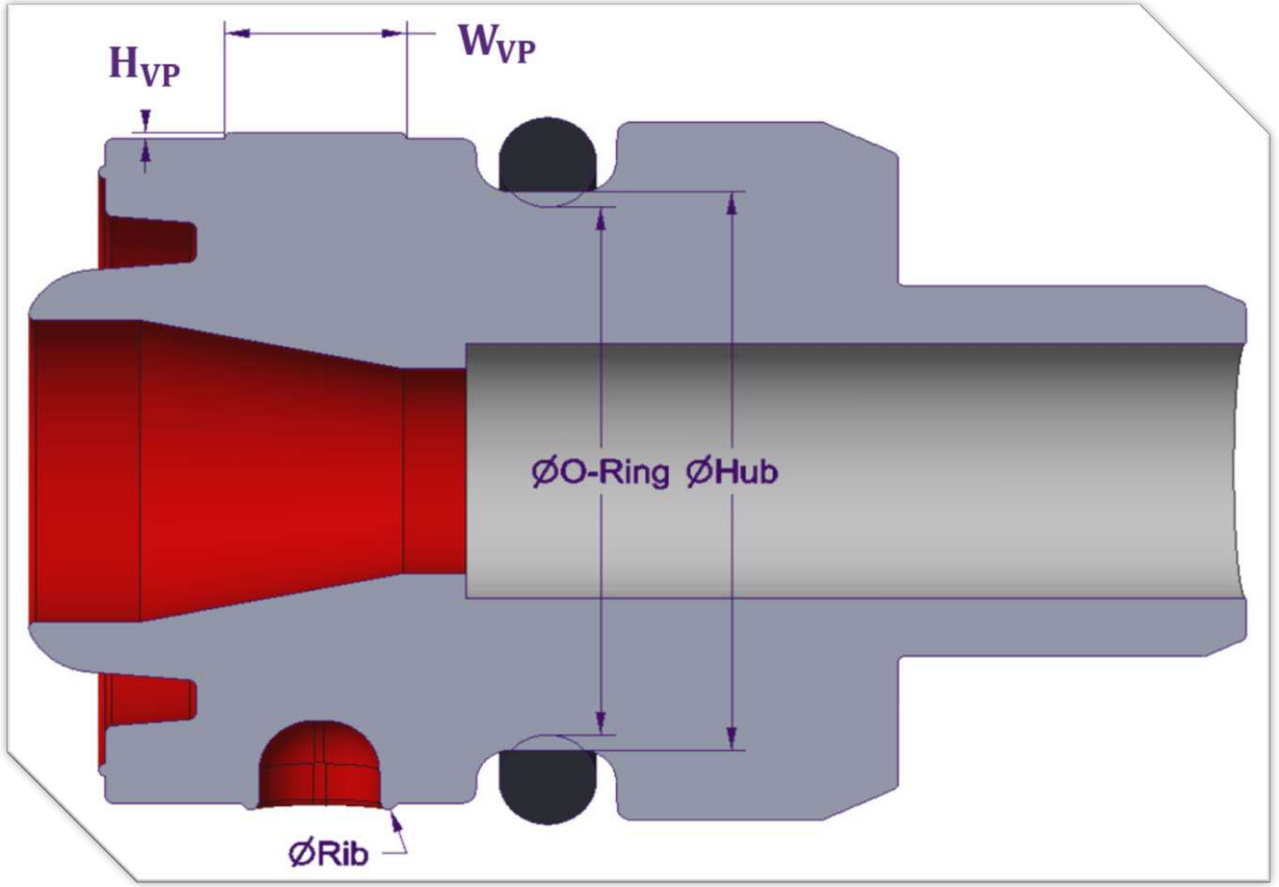
Introduction & Background

Design Space

Design Variable Symbol
$\emptyset_{Rib}$
H_{VP}
W_{VP}
$\emptyset_{Hub}$
$\emptyset_{O-Ring}$



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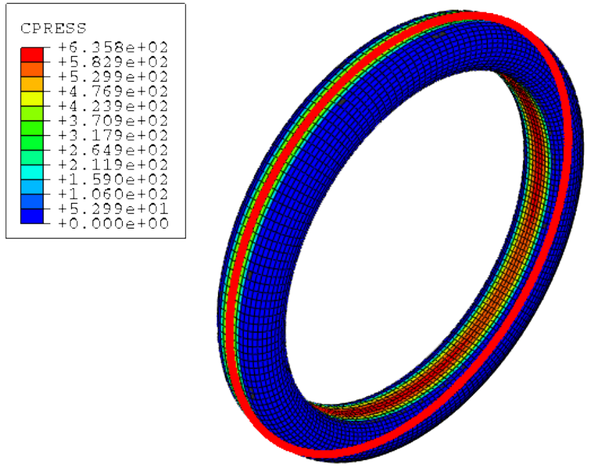
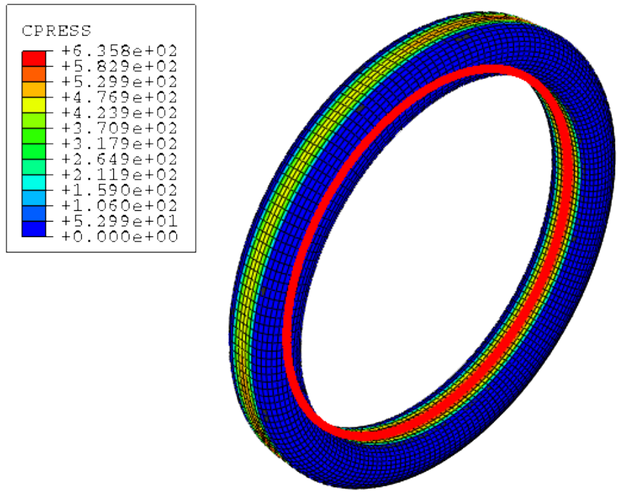
Conclusion & Impact

Workflow Development & Calculations

Workflow Development & Calculations

For each evaluation of the design (evaluated for a = $[0°, 0.25°, 0.5°, 0.75°, 1.0°]$)





- $\overline{CPRESS_{OD}^{(\alpha)}} = mean\left(CPRESS_{OD}^{(\alpha)}\right)$
- $\sigma^2_{CPRESS_{OD}^{(\alpha)}} = var\left(CPRESS_{OD}^{(\alpha)}\right)$
- $\overline{CPRESS_{ID}^{(\alpha)}} = mean\left(CPRESS_{ID}^{(\alpha)}\right)$
- $\sigma^2_{CPRESS_{ID}^{(\alpha)}} = var\left(CPRESS_{ID}^{(\alpha)}\right)$

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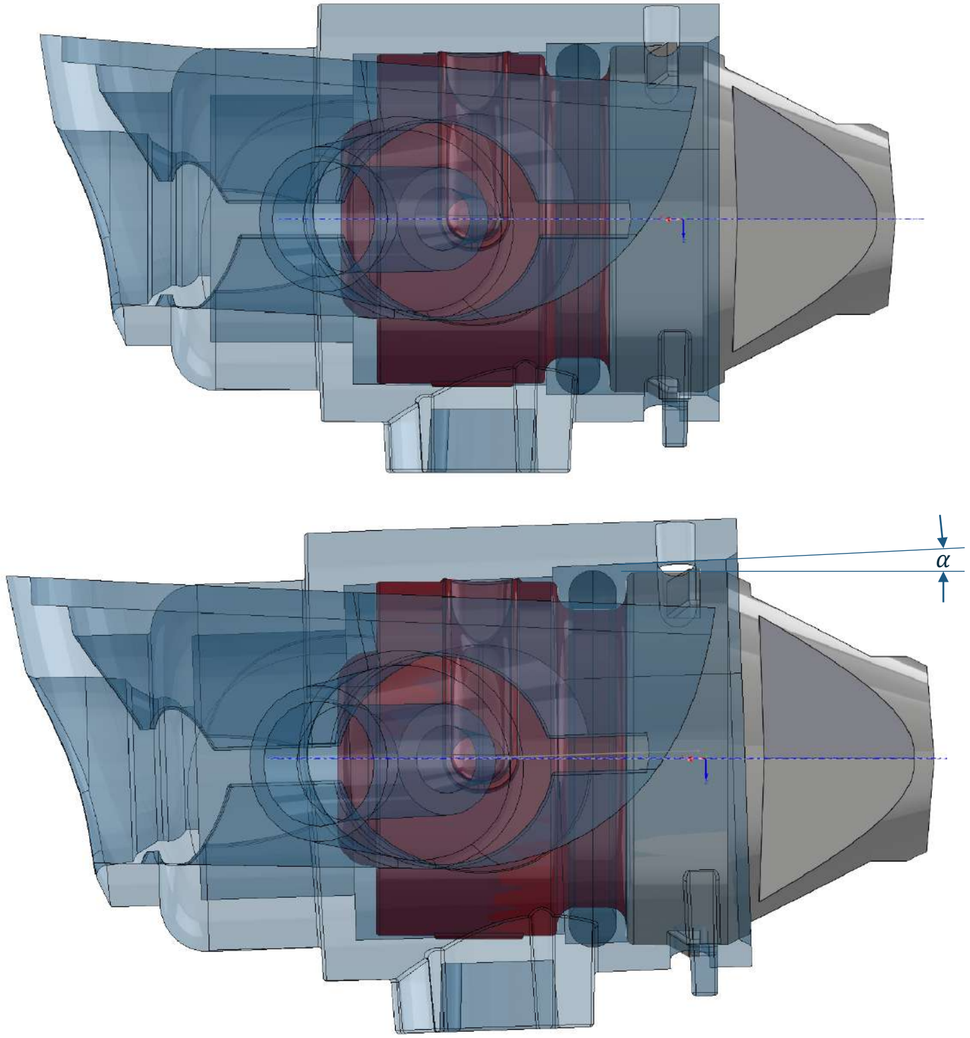
Workflow Development & Calculations

For Each Design



- $CPRESS_{OD\_Robust} = mean(\overline{CPRESS_{OD}})$
- $\sigma^2_{CPRESS_{OD\_Robust}} = var(\overline{CPRESS_{OD}})$
- $\overline{\sigma^2_{CPRESS_{OD}}} = mean(\sigma^2_{CPRESS_{OD}})$
- $CPRESS_{ID\_Robust} = mean(\overline{CPRESS_{ID}})$
- $\sigma^2_{CPRESS_{ID\_Robust}} = var(\overline{CPRESS_{ID}})$
- $\overline{\sigma^2_{CPRESS_{ID}}} = mean(\sigma^2_{CPRESS_{ID}})$

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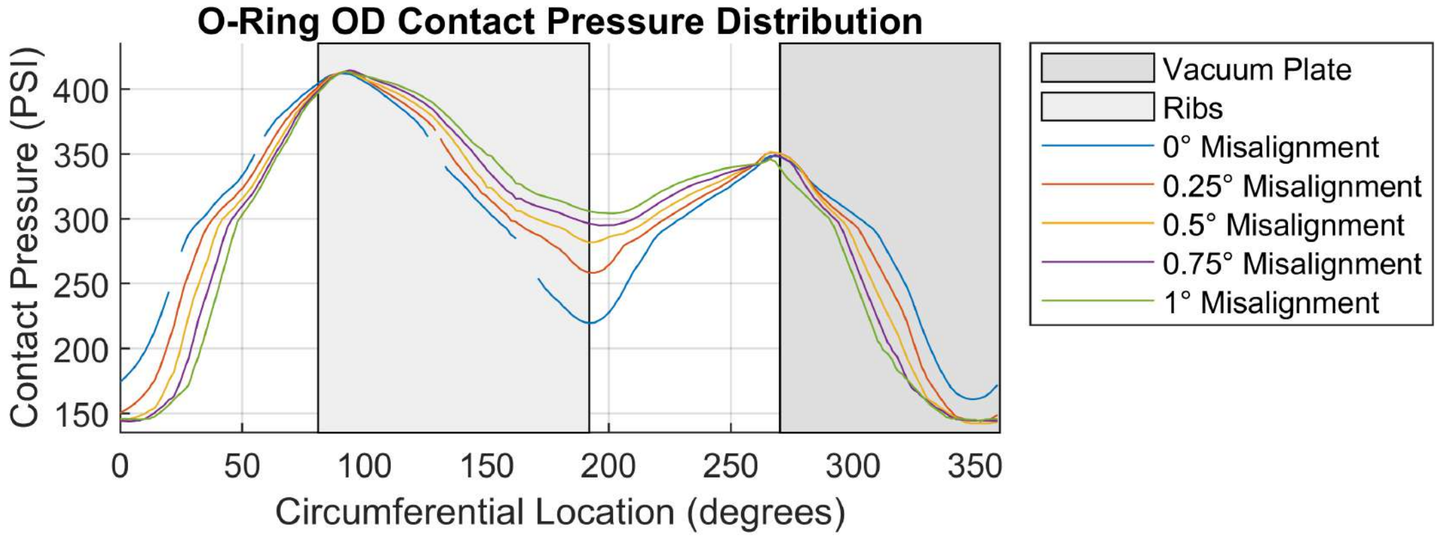
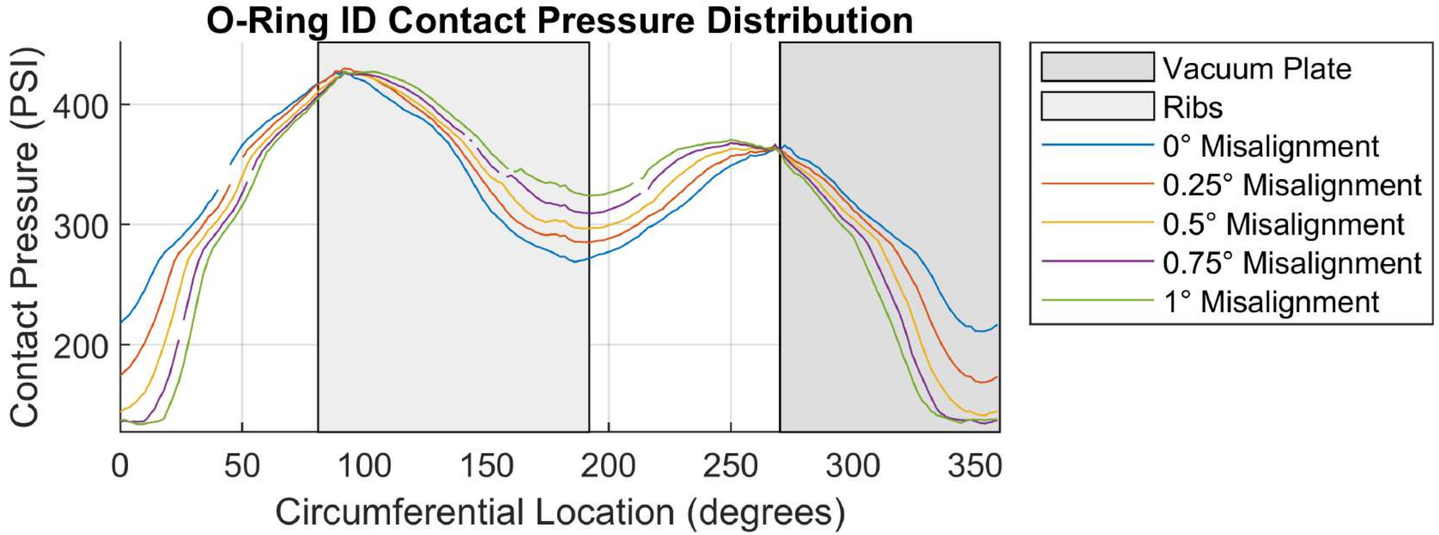
Workflow Development & Calculations

Design Output





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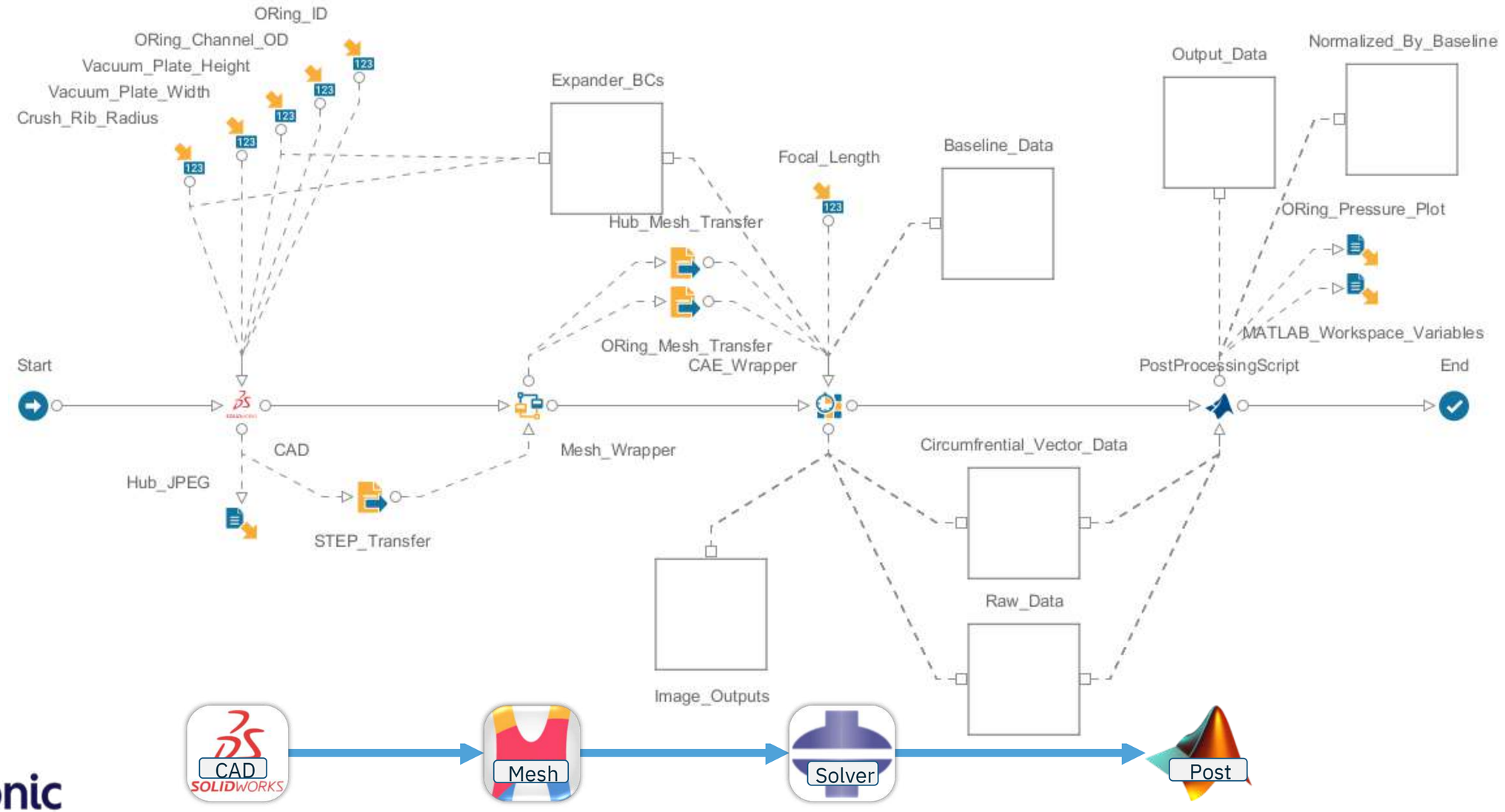
Workflow Development & Calculations

Top Level Workflow



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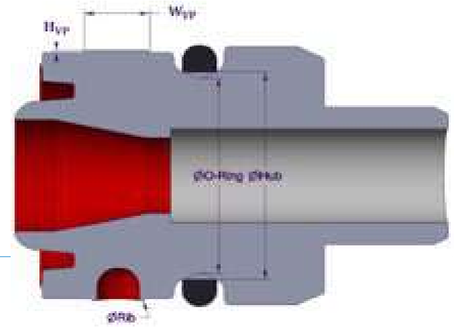
Conclusion & Impact

Results & Discussion

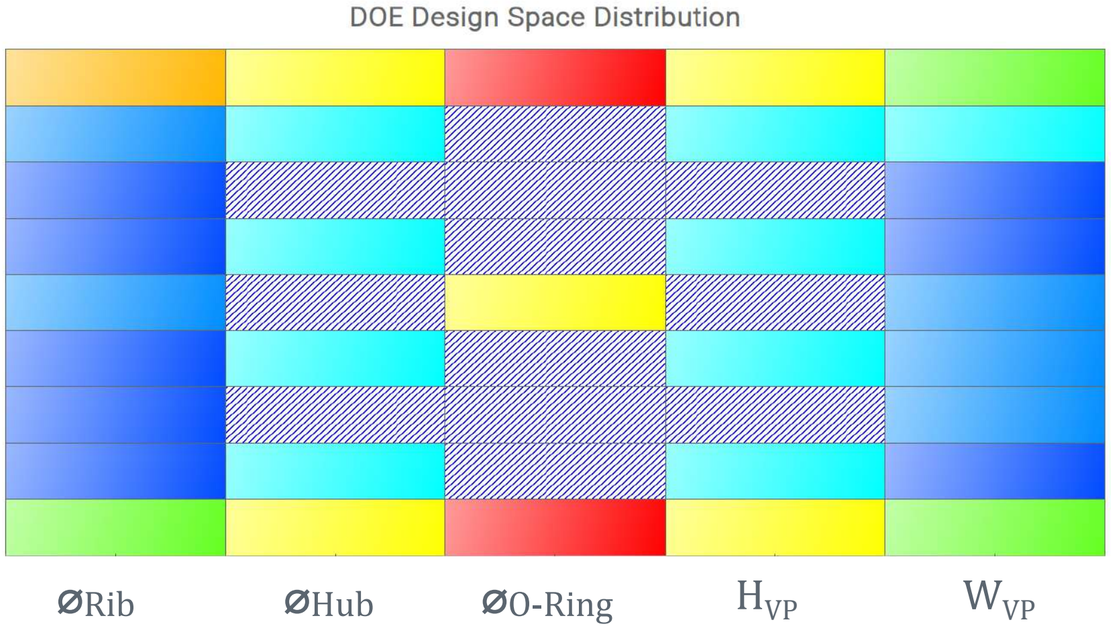
Results & Discussion

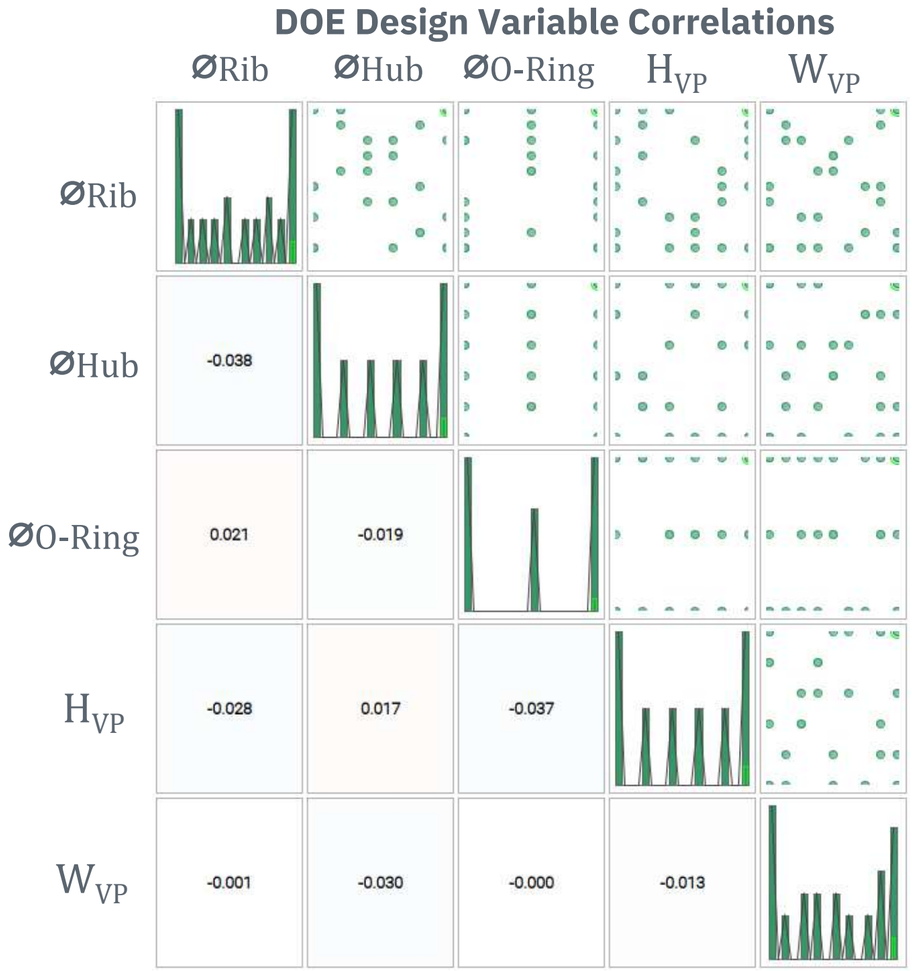
DOE Setup



Number of Designs: 32

- 8 Reduced Factorial
- 26 Uniform Latin Hypercube





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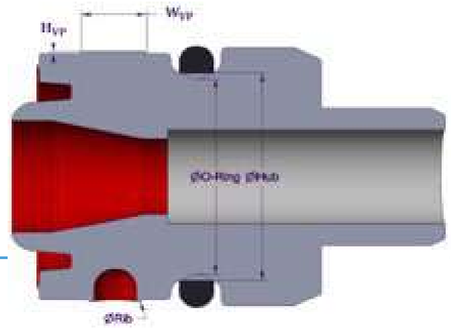
Results & Discussion

Correlation Matrix & Important Relationships



	ØRib	ØHub	ØO-Ring	H_{VP}	W_{VP}	$CPRESS_{OD\_Robust}$	$\sigma^2_{CPRESS_{OD\_Robust}}$	$\overline{\sigma^2_{CPRESS_{OD}}}$
ØRib								
ØHub	0.254							
ØO-Ring	0.070	0.216						
H_{VP}	0.037	-0.179	-0.295					
W_{VP}	-0.149	-0.221	-0.169	0.158				
$CPRESS_{OD\_Robust}$	0.301	0.953	0.482	-0.256	-0.261			
$\sigma^2_{CPRESS_{OD\_Robust}}$	0.123	-0.174	-0.163	0.123	0.224	-0.231		
$\overline{\sigma^2_{CPRESS_{OD}}}$	-0.486	-0.407	-0.324	0.741	0.150	-0.509	0.047	

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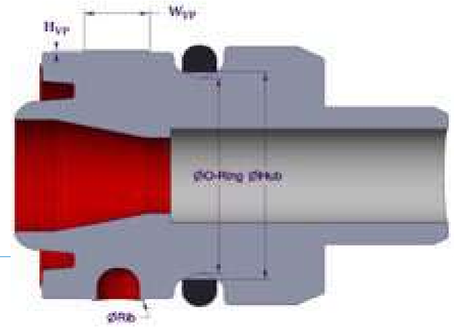
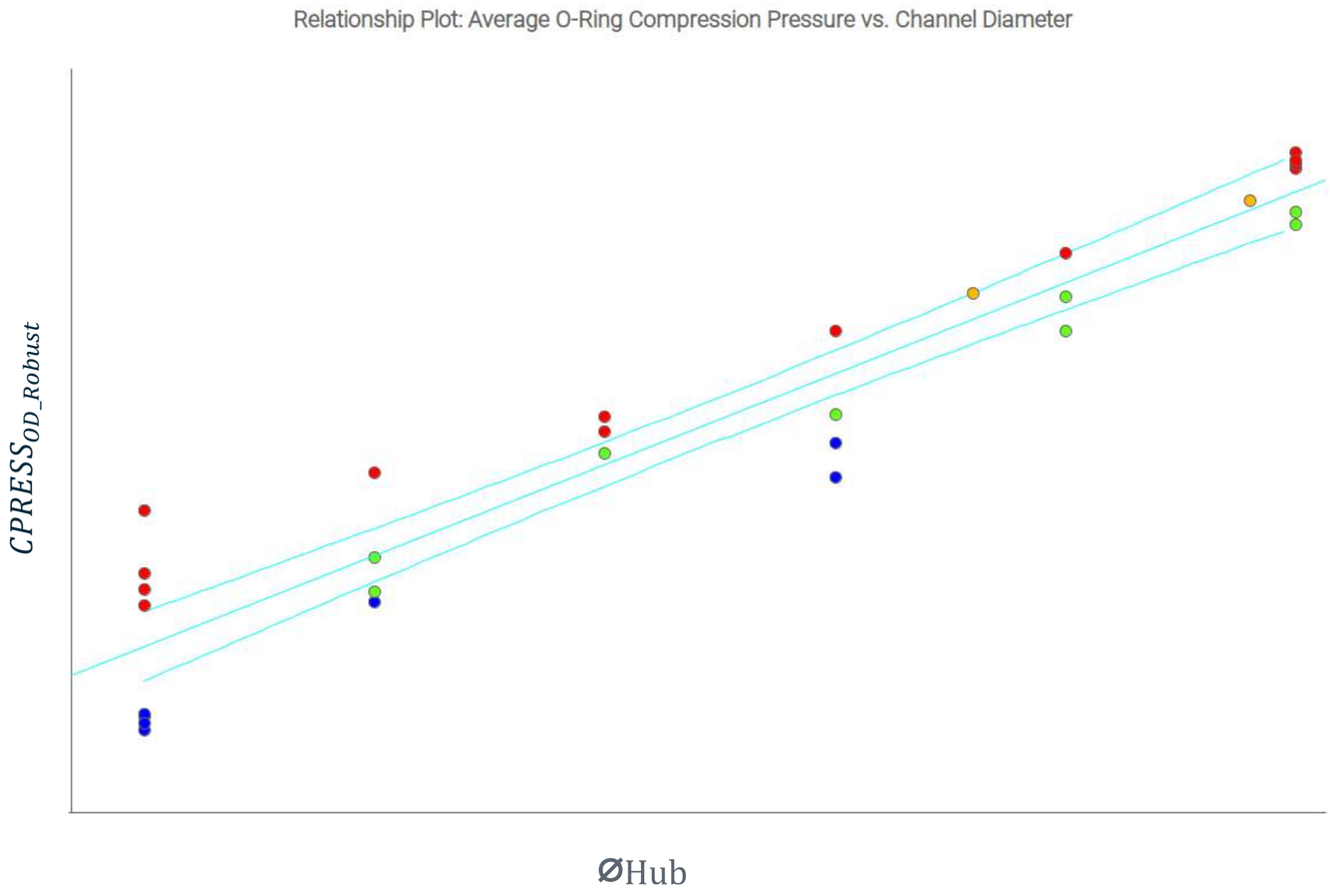
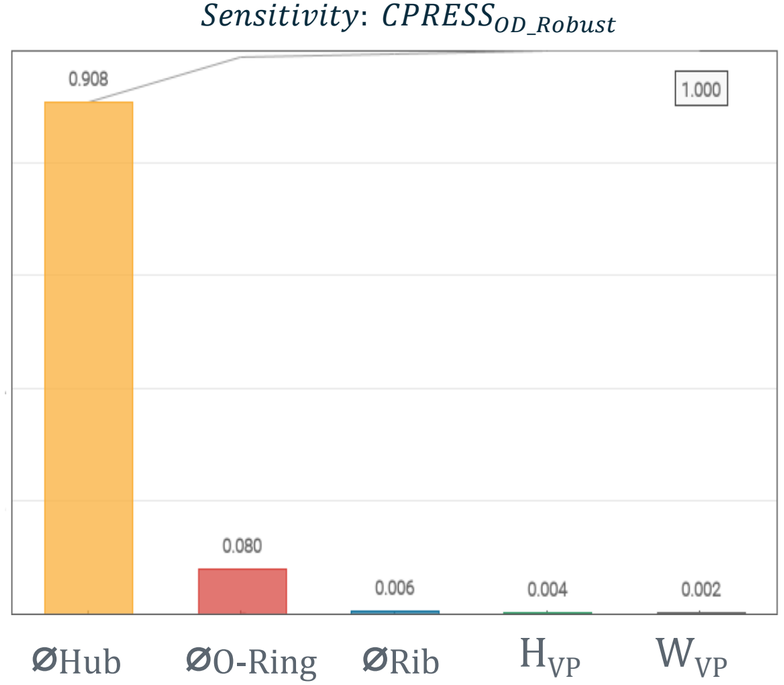
Results & Discussion

Average Contact Pressure: Important Relationships & Sensitivity







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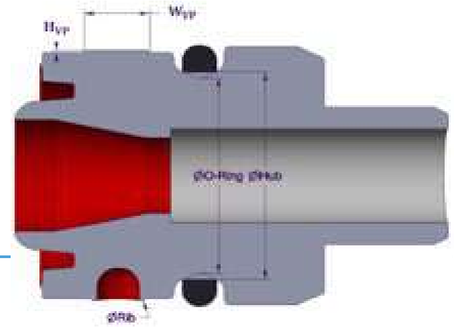
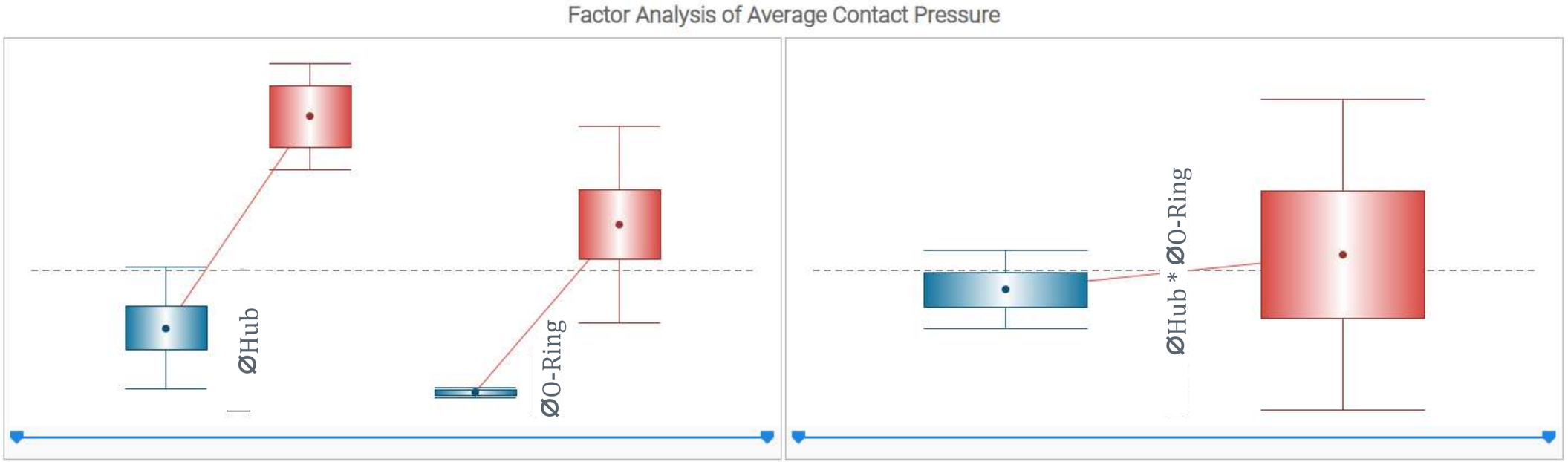
Average Contact Pressure: Factor Analysis





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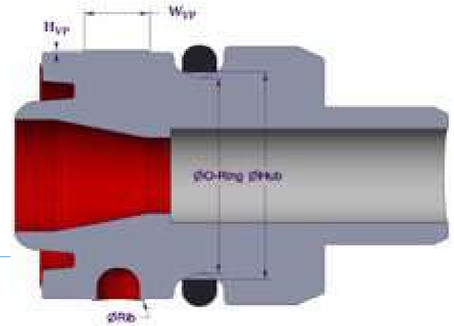
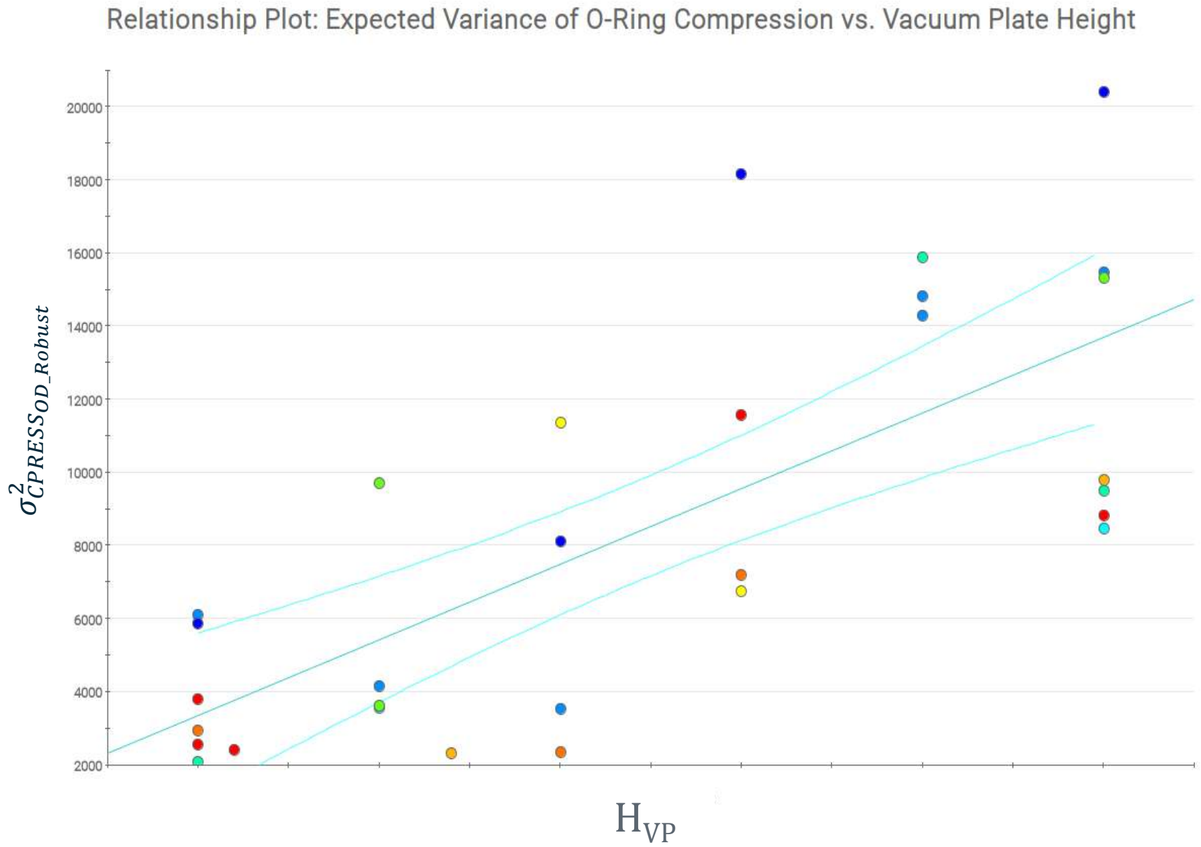
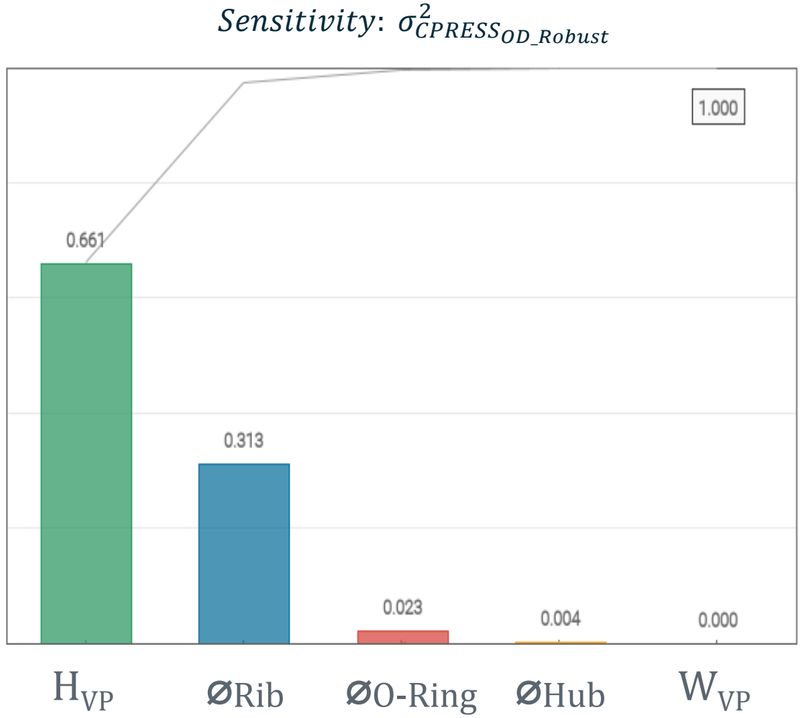
Expected Variance of Contact Pressure







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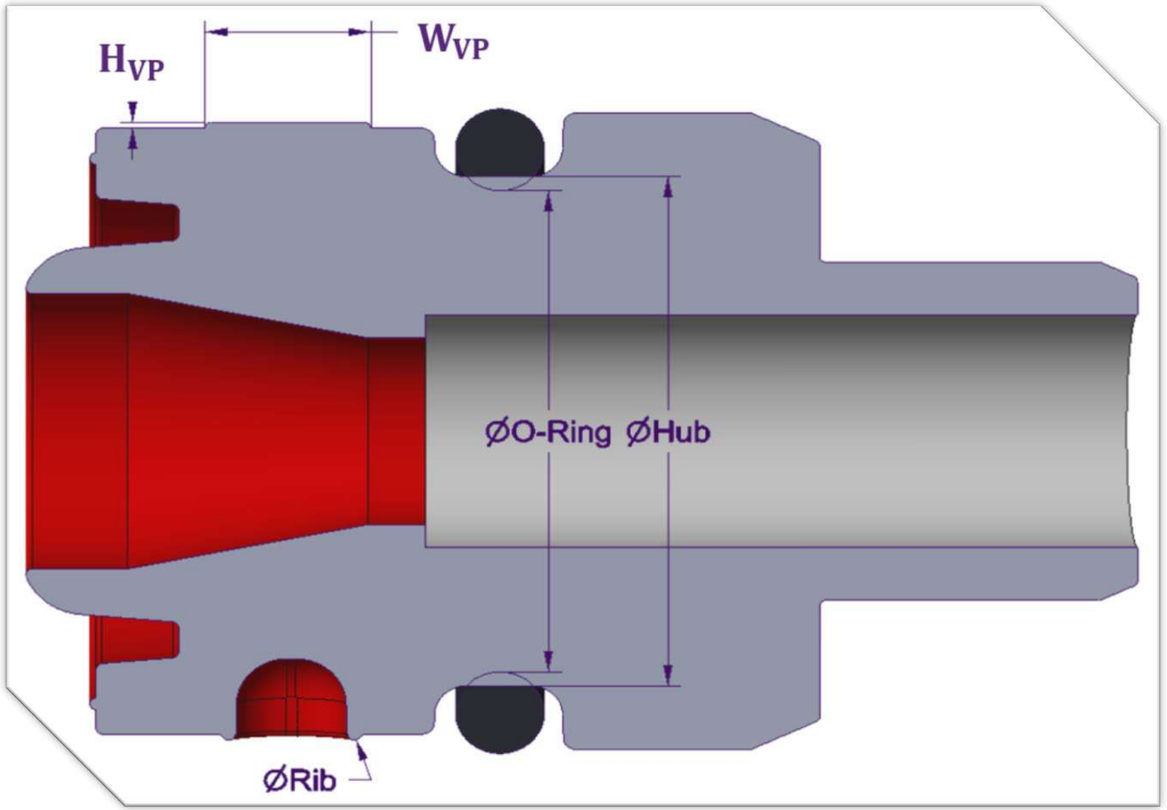
Results & Discussion

Optimal Design Summary

Input Variable	Change Direction	Steel Safe Change
$\emptyset_{Rib}$	↑	No
H_{VP}	↓	Yes
W_{VP}	↓	Yes
$\emptyset_{Hub}$	↑	No
$\emptyset_{O-Ring}$	↑	N/A

Response Parameter	Rel. to Spec'd	Rel. to Mfg'd
$CPRESS_{OD\_Robust}$	0.8648	1.3149
$\overline{\sigma^2_{CPRESS_{OD}}}$	2.5085	0.1851
$CPRESS_{ID\_Robust}$	0.8622	1.2456
$\overline{\sigma^2_{CPRESS_{ID}}}$	3.2266	0.1735



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Results & Discussion

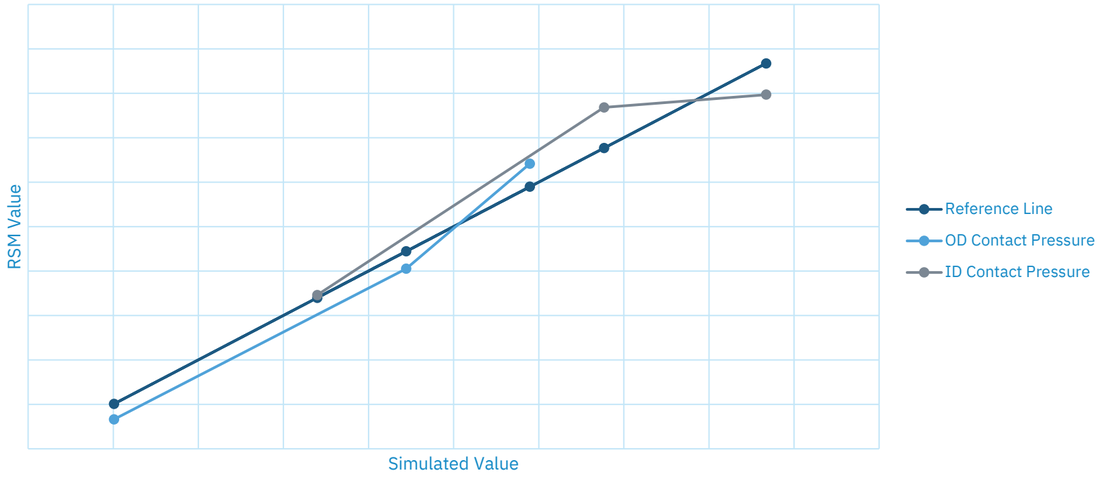
RSM Accuracy

Optimal Design	
Response Parameter	**% Error**
$CPRESS_{OD\_Robust}$	1.16
$\overline{\sigma^2_{CPRESS_{OD}}}$	22.6
$CPRESS_{ID\_Robust}$	-1.46
$\overline{\sigma^2_{CPRESS_{ID}}}$	-11.4

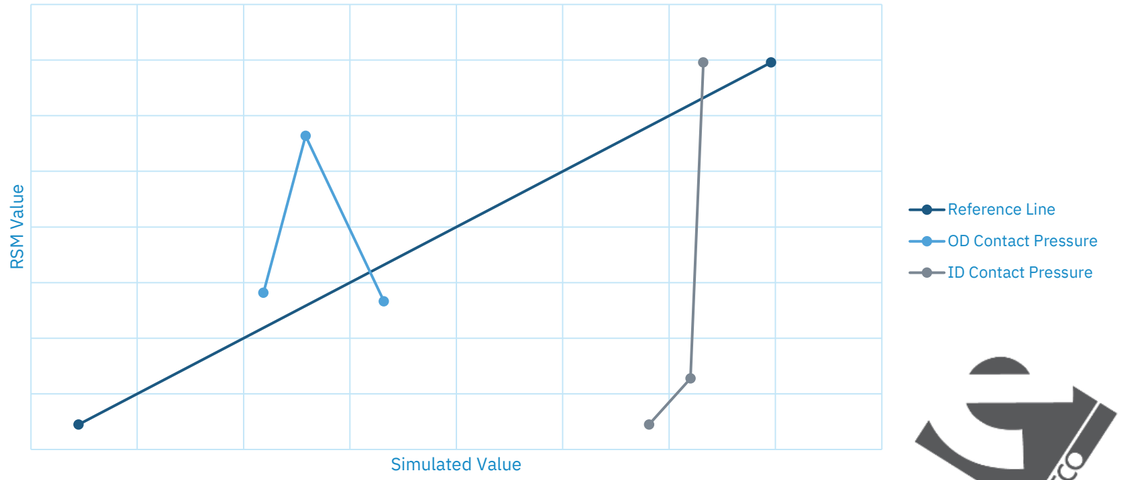
Optimal Proximity Test 1	
Response Parameter	**% Error**
$CPRESS_{OD\_Robust}$	-0.9
$\overline{\sigma^2_{CPRESS_{OD}}}$	26.8
$CPRESS_{ID\_Robust}$	2.00
$\overline{\sigma^2_{CPRESS_{ID}}}$	-34.4

Optimal Proximity Test 2	
Response Parameter	**% Error**
$CPRESS_{OD\_Robust}$	-0.9
$\overline{\sigma^2_{CPRESS_{OD}}}$	35.5
$CPRESS_{ID\_Robust}$	0.2
$\overline{\sigma^2_{CPRESS_{ID}}}$	33.8

Average Contact Pressure RSM Accuracy



Average Contact Pressure Variance RSM Accuracy



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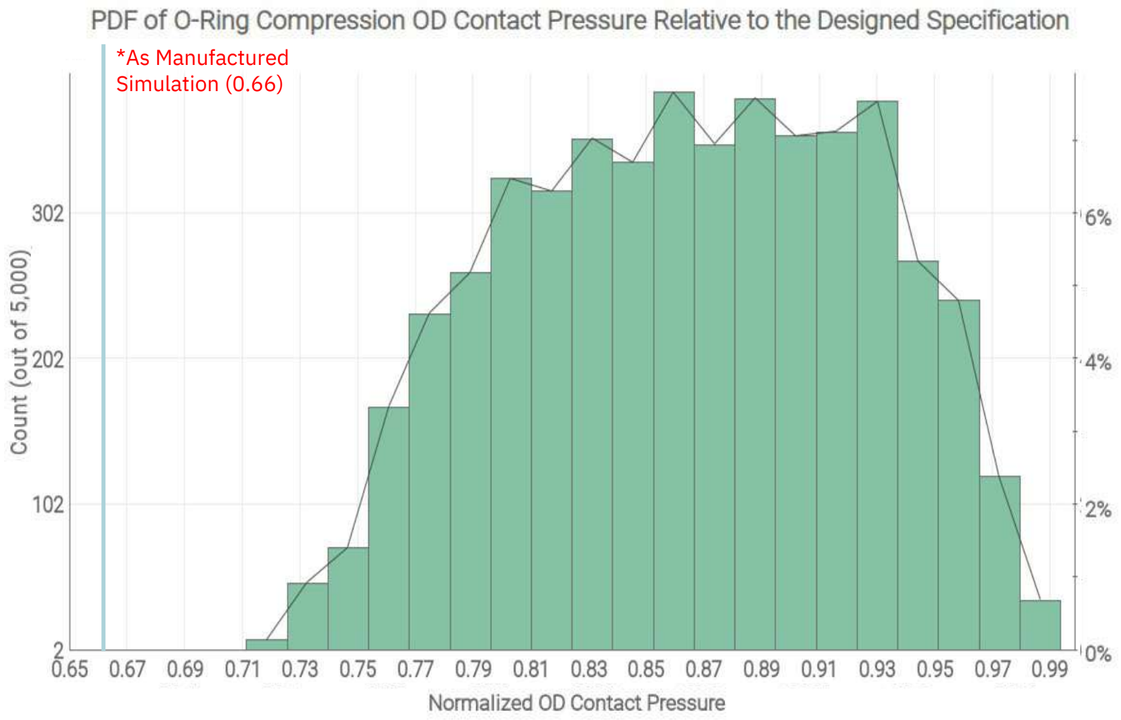
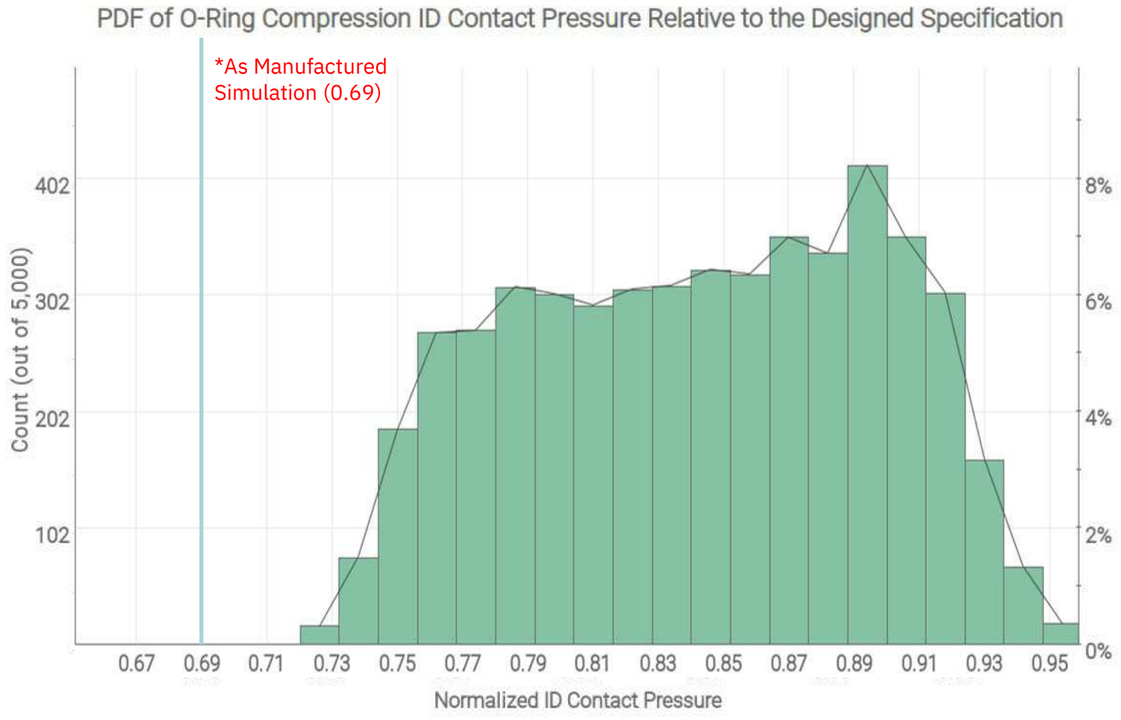
Results and Discussion

Monte Carlo Results





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Conclusion & Impact

Conclusion & Impact

Important Considerations

What we learned from our study…

1. Hub diameter is critical for average O-Ring compression.
2. An increase in the Hub's diameter will increase the average compression (close to the intended value).
3. The Vacuum Plate feature prevents uniformity of O-Ring compression.

What we know from design verification trials…

1. The loose tolerancing schemes cause significant variability in the Hub diameter.
2. Larger Hub OD designs will encounter O-Ring travel during assembly.
3. The loose tolerancing schemes cause significant variability of the vacuum plate feature.

How much can we increase the Hub diameter size?

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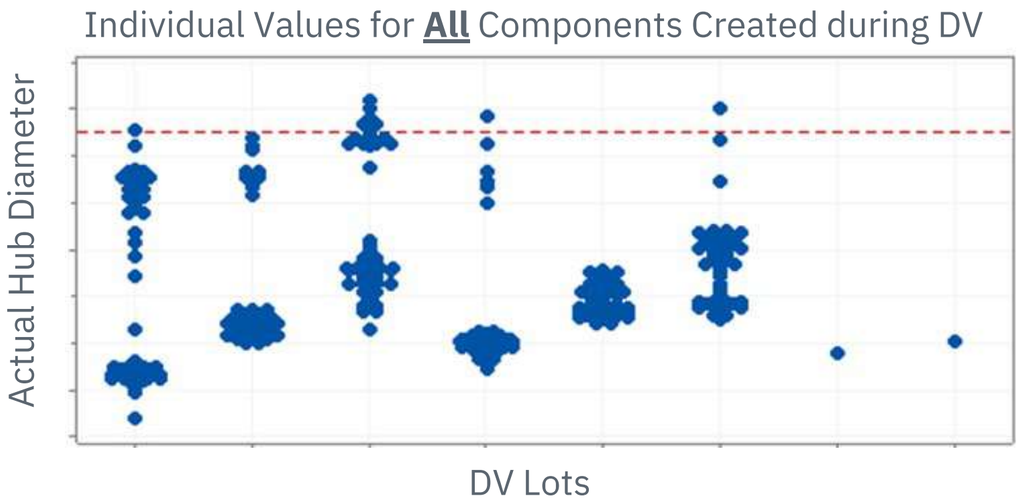
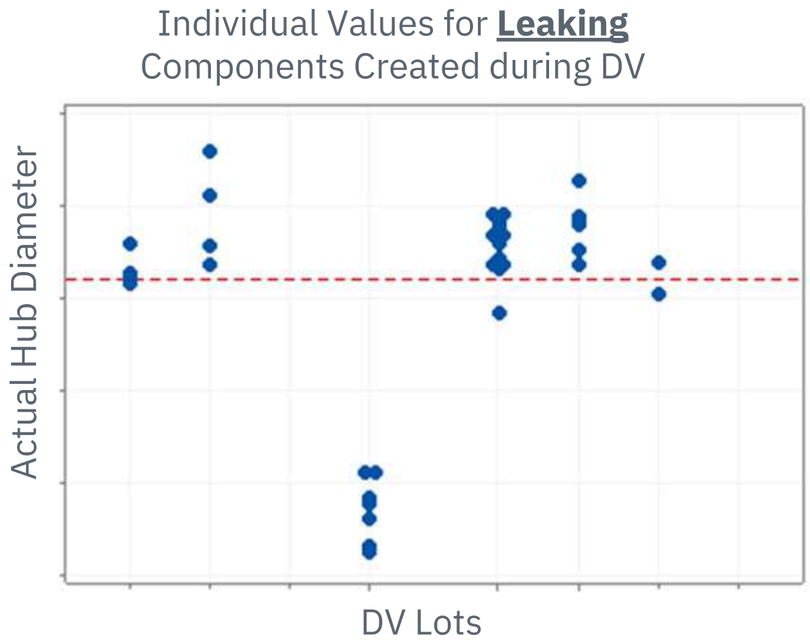
Design Verification Data

Take a look at the DV data under the lens of the insights we gained from our design study…





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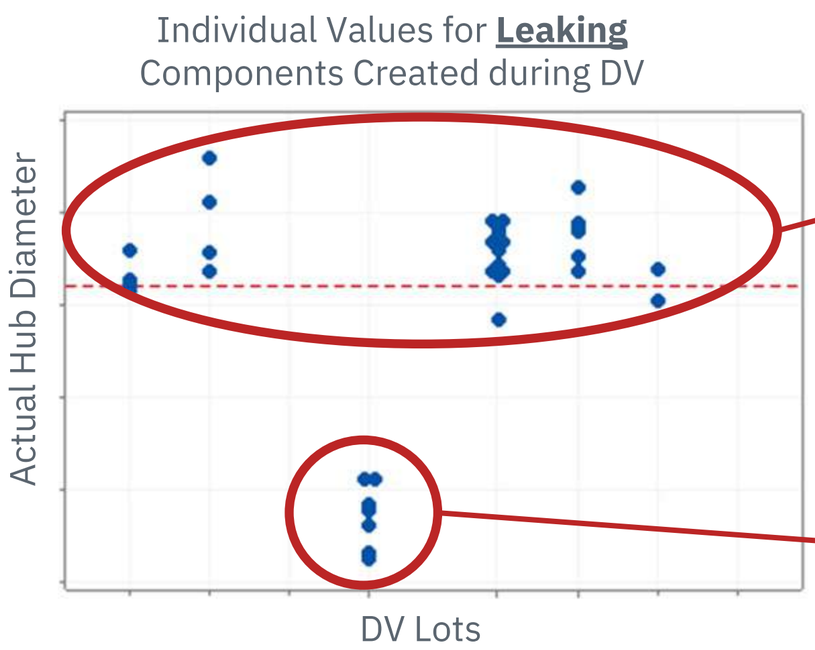
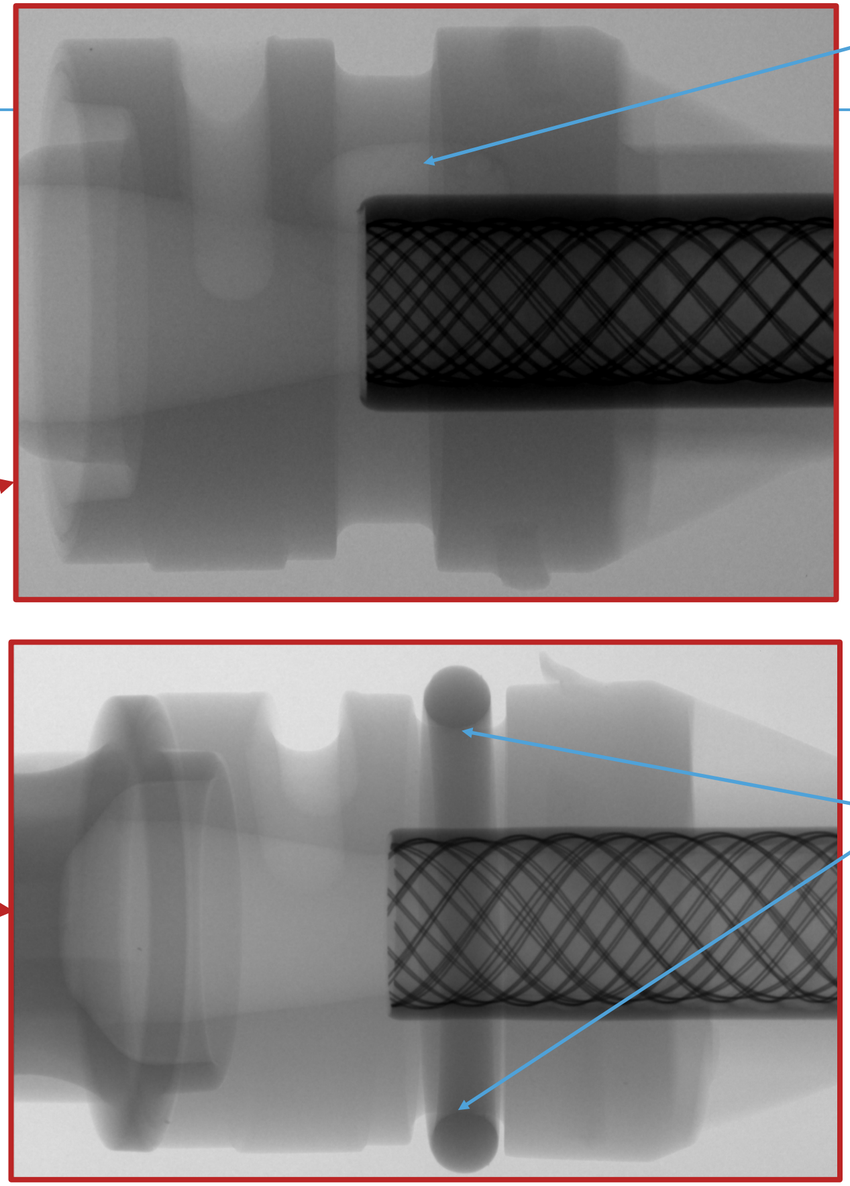
Conclusion & Impact

Design Verification Data





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Summary

- Identified the critical parameters
- Using the critical parameters and DV data, we determined the root cause of failures
- Proposed process solutions (without any late-phase design changes)
- Reduced potential scrap by ~8-9%

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Take-Away Concepts

Even late-phase design studies have tremendous value

Never underestimate the value that an MDO approach can provide, regardless of the current life-cycle phase

The output of a design study does not have to be a design change

A better understanding of the response space can be even more valuable

Understanding critical design parameters can lead to reduced scrap and improved patient care

Understanding critical parameters can reduce the number of prototypes created and iterated, the number of failed production parts created, and the volume of material used for unnecessary design features

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Thank you!

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