Establishing finite element model credibility of a pedicle screw system under compression-bending: An end-to-end example of the ASME V&V 40 standard

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Background

- 2013: Initiate project to investigate credibility/verification/validation of spinal rod models
  - 2018: ASME V&V 40 published
- 2020: Publish manuscript on VVUQ of spinal rod models under 3-point bending
  - 2023: FDA Guidance on Credibility of Computational Modeling published
- 2024: Publish manuscript on credibility of pedicle screw system models

First Publication: VVUQ of 3-Point Bending

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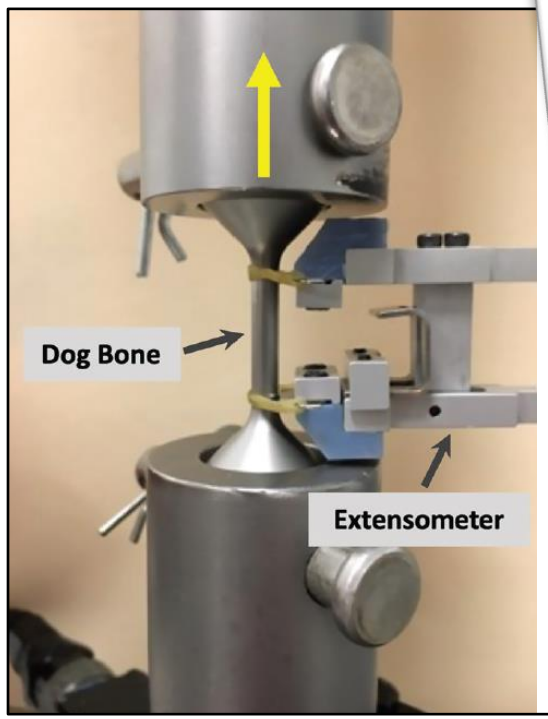

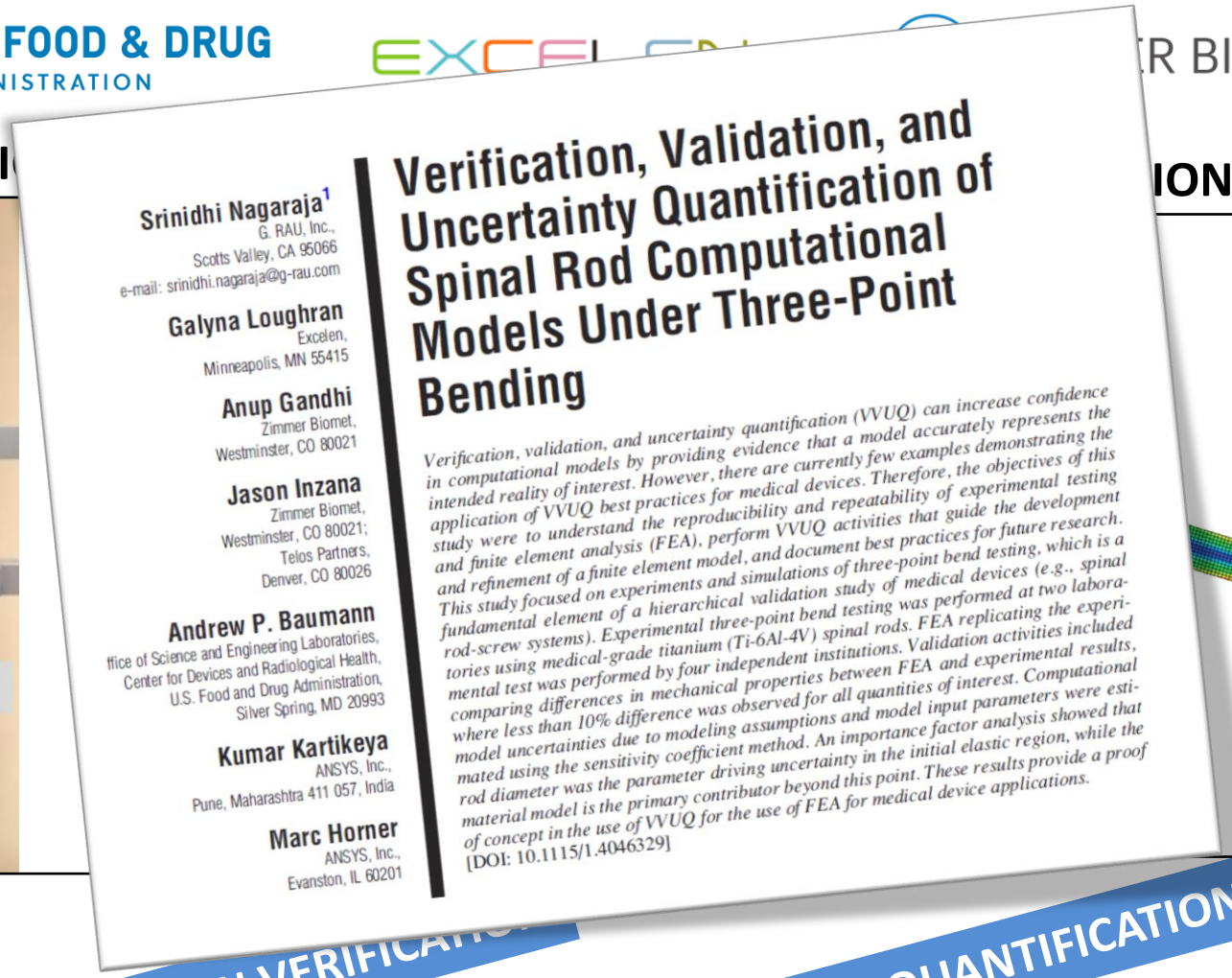

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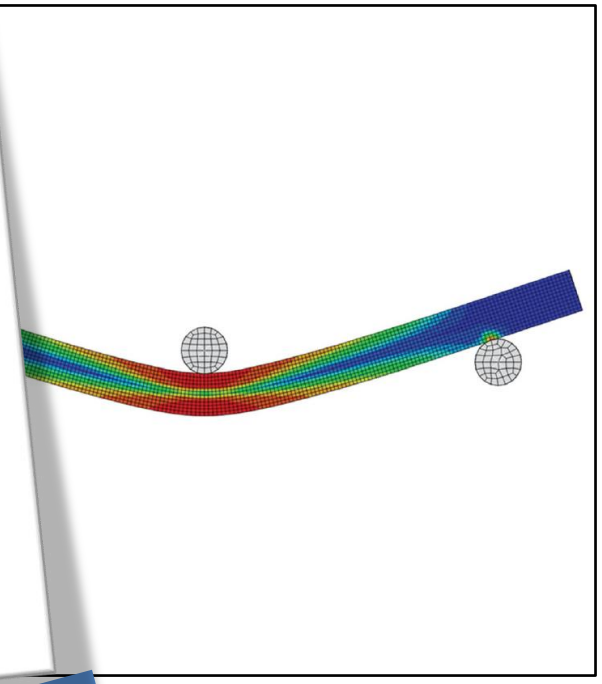
Verification, Validation, and Uncertainty Quantification of Spinal Rod Computational Models Under Three-Point Bending

Verification, validation, and uncertainty quantification (VVUQ) can increase confidence in computational models by providing evidence that a model accurately represents the intended reality of interest. However, there are currently few examples demonstrating the application of VVUQ best practices for medical devices. Therefore, the objectives of this study were to understand the reproducibility and repeatability of experimental testing and finite element analysis (FEA), perform VVUQ activities that guide the development and refinement of a finite element model, and document best practices for future research. This study focused on experiments and simulations of three-point bend testing, which is a fundamental element of a hierarchical validation study of medical devices (e.g., spinal rod-screw systems). Experimental three-point bend testing was performed at two laboratories using medical-grade titanium (Ti-6Al-4V) spinal rods. FEA replicating the experimental test was performed by four independent institutions. Validation activities included comparing differences in mechanical properties between FEA and experimental results, where less than 10% difference was observed for all quantities of interest. Computational model uncertainties due to modeling assumptions and model input parameters were estimated using the sensitivity coefficient method. An importance factor analysis showed that rod diameter was the parameter driving uncertainty in the initial elastic region, while the material model is the primary contributor beyond this point. These results provide a proof of concept in the use of VVUQ for the use of FEA for medical device applications.

[DOI: 10.1115/1.4046329]



CODE VERIFICATION

CALCULATION VERIFICATION

UNCERTAINTY QUANTIFICATION

SENSITIVITY ANALYSIS

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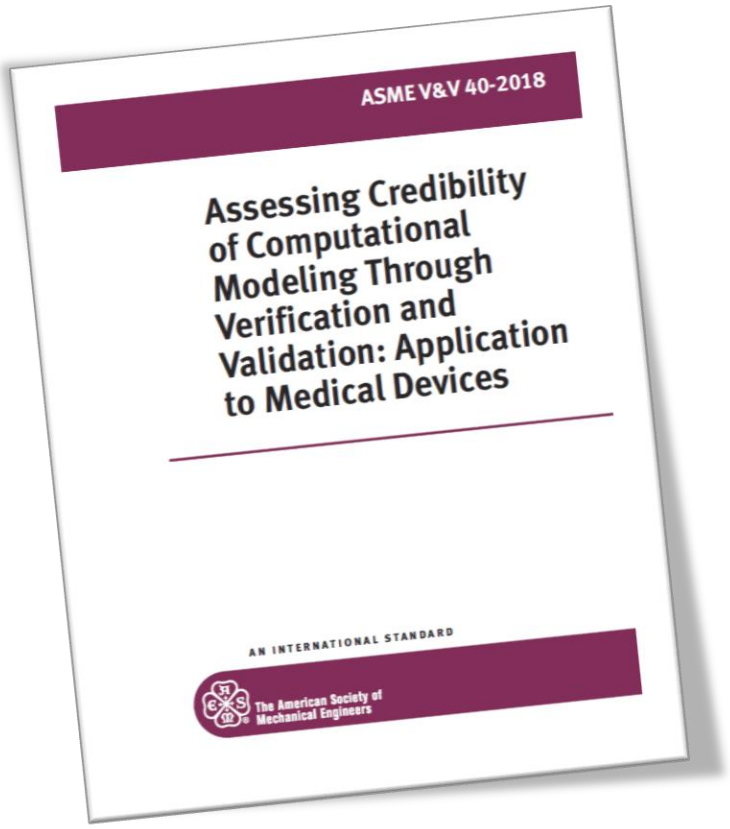
ASME V&V 40 is Published…Now What?



Introduces a risk-based framework for establishing credibility of computational models

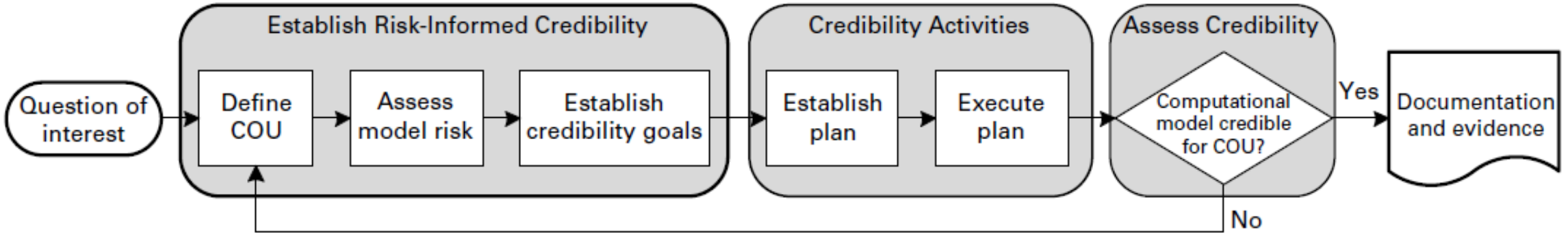
Contains examples with orthopedic devices, but they are not end-to-end (E2E)

We should incorporate the complete V&V 40 framework into the second stage of our hierarchical model validation exercise!

End-to-End Process

- GOAL: Illustrate how to establish the credibility of a computational model intended for use as part of regulatory evaluation through an end-to-end example of the ASME V&V 40 standard

Figure 2.4-1 Process Diagram of the Risk-Informed Credibility Assessment Framework



Question of Interest

- "Regulatory" Scenario: Iterative design change introducing a cannulation to an existing pedicle screw
  - Question of interest (?OI): does adding a 1.6 mm diameter cannulation to an existing 7.5 mm diameter pedicle screw design compromise mechanical performance of the rod-screw construct in static compression-bending?

Designation: F1717 – 21

Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model[1]

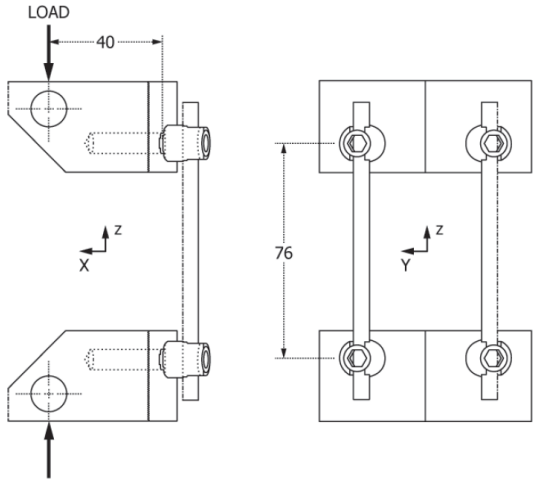
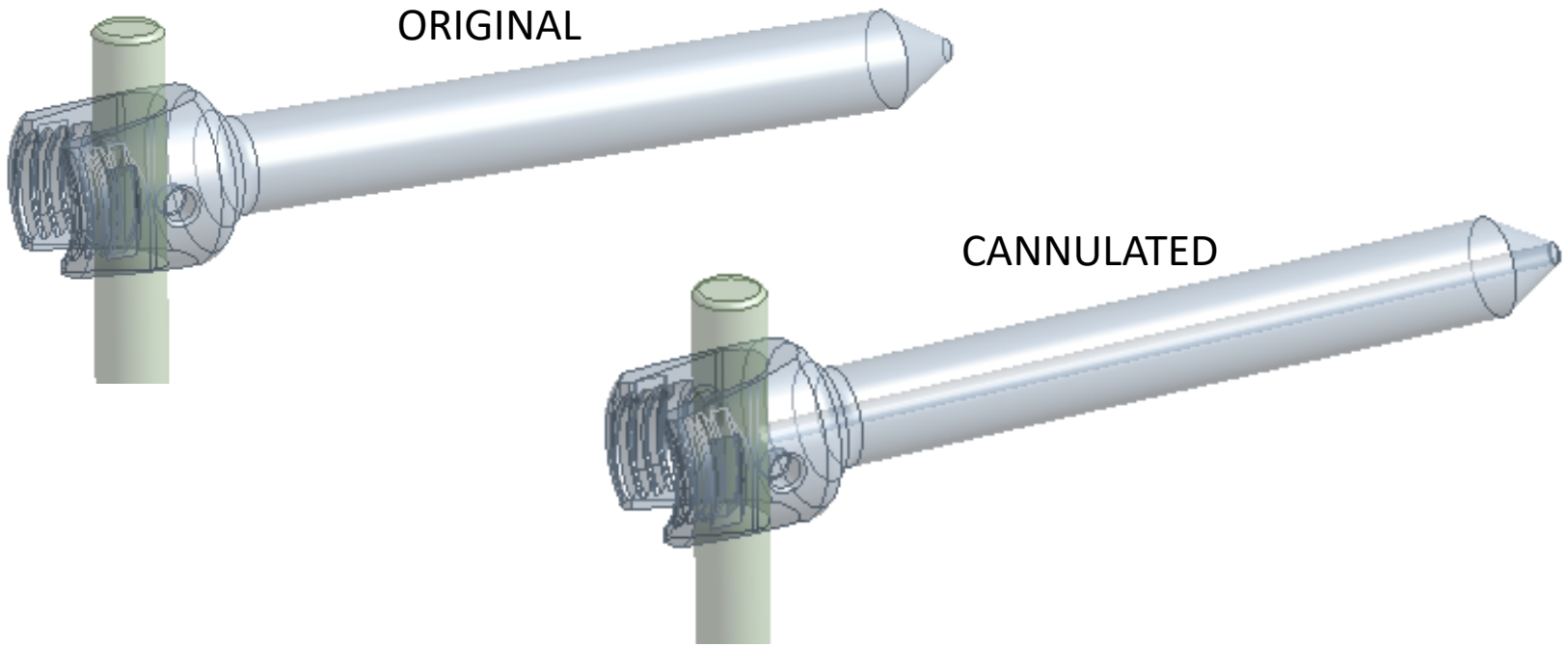


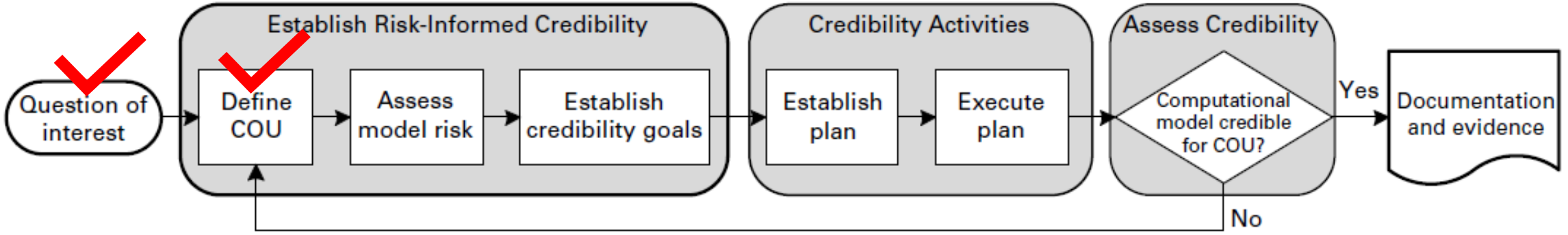
FIG. 2 Typical Bilateral Construct Containing Bone Screws, Rods, and Set Screws



Context of Use

Model predictions of the original non-cannulated screw construct will be validated with benchtop testing per ASTM F1717 static compression bending conditions. The validated model framework will be used to evaluate the cannulated screw design undergoing identical static compression-bending conditions. No benchtop testing on the cannulated screw design will be performed to answer the ?OI.

Figure 2.4-1 Process Diagram of the Risk-Informed Credibility Assessment Framework

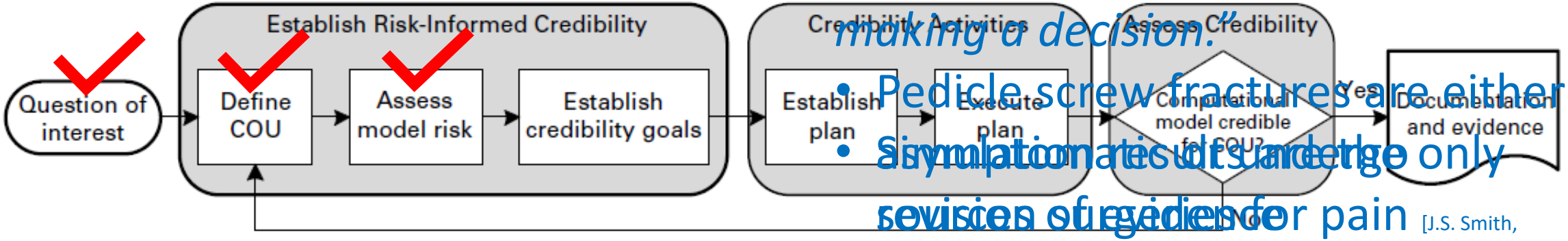


Assess Model Risk

- Model risk is the possibility that the use of the computational model leads to

"The significance of the adverse outcome resulting from an incorrect decision relative to other evidence in making a decision."

Figure 2.4-1 Process Diagram of the Risk-Informed Credibility Assessment Framework



- Pedicle screw fractures are either symptomatic or asymptomatic
- Symptomatic fractures can be only revision surgeries for pain [J.S. Smith, Neurosurgery 2012; C.A. Dickman, J. Neurosurg. 1992]

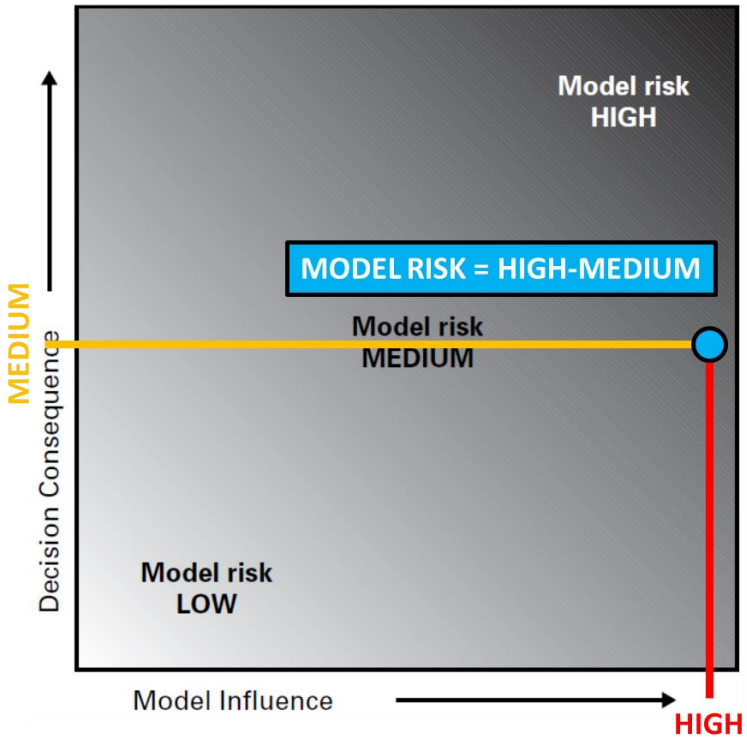
(a) An incorrect decision would not adversely affect patient safety or health, but might result in a nuisance to the physician or have other minor impacts.

(b) An incorrect decision could result in minor patient injury or the need for physician intervention, or have other moderate impacts.

(c) An incorrect decision could result in severe patient injury or death, or have other significant impacts.

Establish Credibility Goals

- Credibility: the trust, established through the collection of evidence, in the predictive capability of a computational model for a context of use.
  - We need to establish a *Credibility Goal* consistent with our *Model Risk*



CREDIBILITY GOAL
=
HIGH-MEDIUM

But what does this look like in practice?

Establish Credibility Goals

- Credibility is established through each of the 23 credibility factors:

Activity	Sub-Activity	Credibility Factor	Credibility Level			
			LOW		MED	HIGH
		Sofware Quality Assurance	a	b	c	
		Measurements of Test Conditions	a	b	c	
		Uncertainty of Test Condition Measurements	a	b	c	d
	Assessment	Equivalency of Input Parameters	a	b	c	
		Output Comparison: Quantity	a		b	
		Output Comparison: Equivalency of Output Parameters	a	b	c	
		Output Comparison: Rigor of Output Comparison	a	b	c	d
		Output Comparison: Agreement of Output Comparison	a	b	c	
Applicability		Relevance of the QOIs	a	b	c	
		Relevance of the Validation Activities to the COU	a	b	c	d

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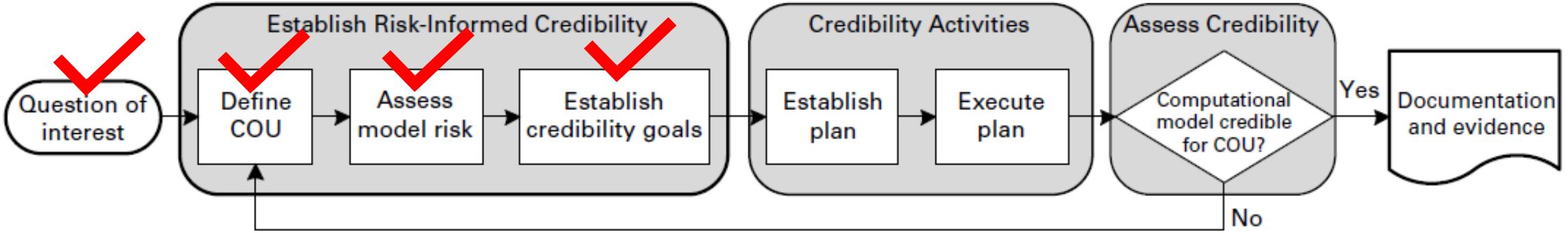


credibility factors with 4 gradations."

Credibility Activities: Plan and Execution

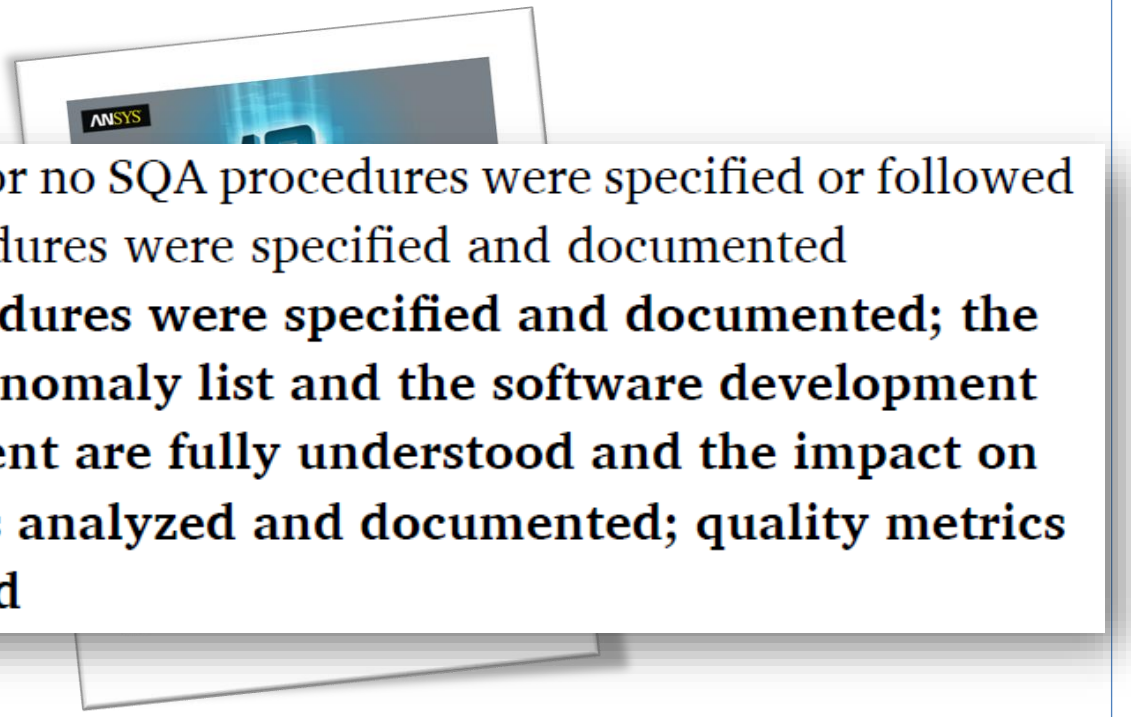
- Let's take a look at two examples…
  - One for Verification
  - Another for Validation

Verification: Plan and Execution

Activity	Sub-Activity	Credibility Factor	Credibility Level			
			LOW		MED	HIGH
Verification	Code Verification	Sofware Quality Assurance	a		b	c
		Numerical Code Verification	a	b	c	d
	Calculation Verification	Discretization Error	a		b	c
		Numerical Solver Error	a		b	c
		Use Error	a	b	c	d

SQA: ensure that the software is functioning correctly and produces repeatable results on a specified computer resource in a specified software environment.

- Modelers (Ansys, DePuy Synthes, and FDA) reviewed the documentation provided by software manufacturers:
  - Release Notes
  - Known Issues and Limitations
  - Verification Manuals



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		Use Error	a	b	c	d

NCV: demonstrate correct implementation and functioning of the numerical algorithms.

- Modelers ran benchmark verification problems
  - Plasticity
  - Cantilevered Beam
- Conducted mesh convergence on verification benchmarks
  - Influence of element type

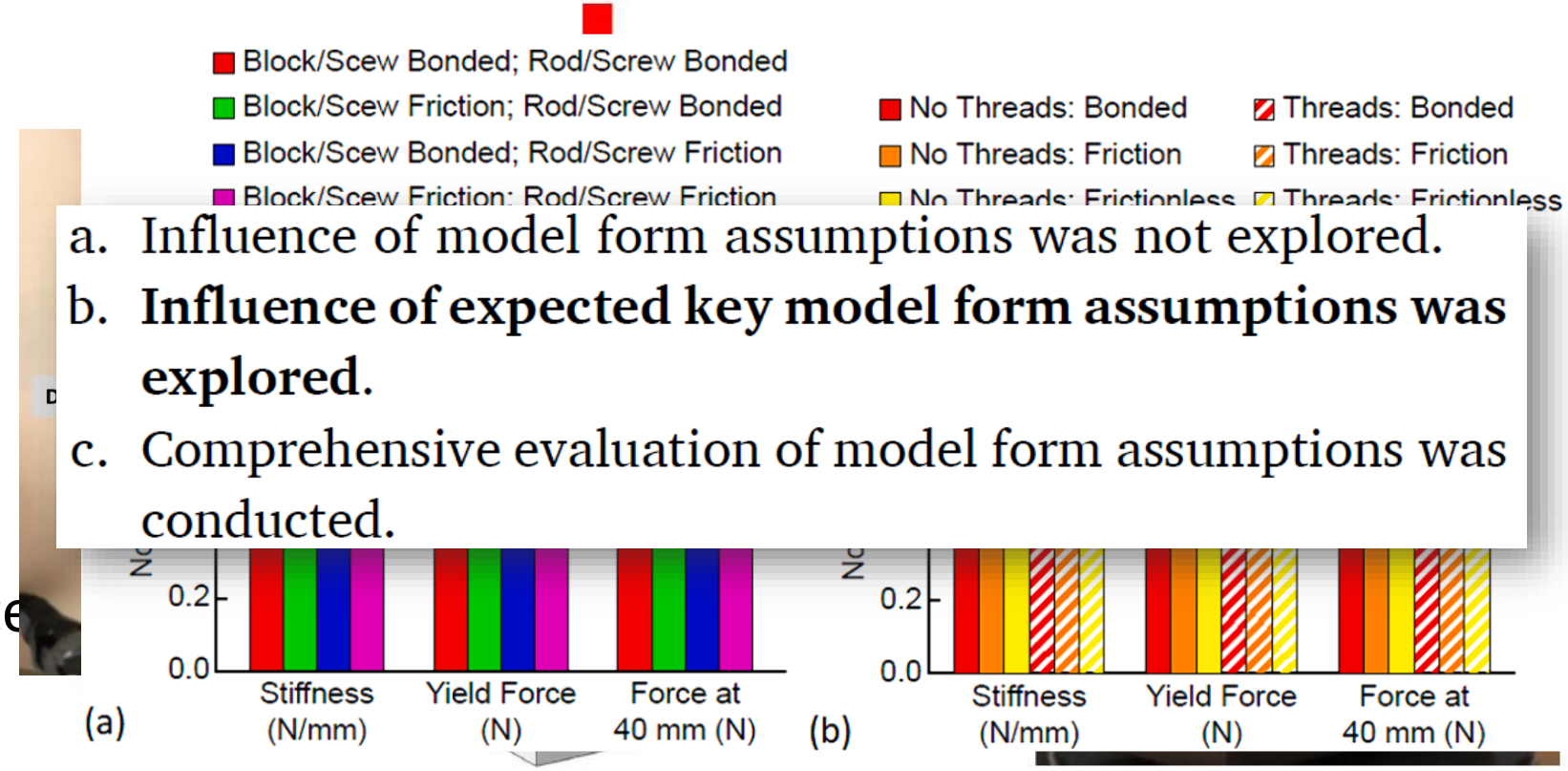
a. NCV was not performed
b. The numerical solution was compared to an accurate benchmark solution from another verified code
c. **Discretization error was quantified by comparison to an exact solution, and a grid convergence study demonstrated that the numerical solution asymptotically approached the exact solution as the discretization was refined.**
d. In addition to (c), the observed order of accuracy was quantified and compared to the theoretical order of accuracy.

Validation: Plan and Execution

Activity	Sub-Activity	Credibility Factor	Credibility Level		
			LOW	MED	HIGH
Validation	Computational Model	Model Form	a	b	c
		Model Inputs: Quantification of Sensitivities	a	b	c
		Model Inputs: Quantification of Uncertainties	a	b	c

Model Form: the conceptual and mathematical formulation of the computational model including the form of the governing equations, the form of the system configuration, system properties, and system conditions.

- All labs simulated F1717 compression-bending
- Rod material model:
  - multi-linear
  - bi-linear
- Element type and size
- Investigation of paramete
  - Contact, threads, and element order



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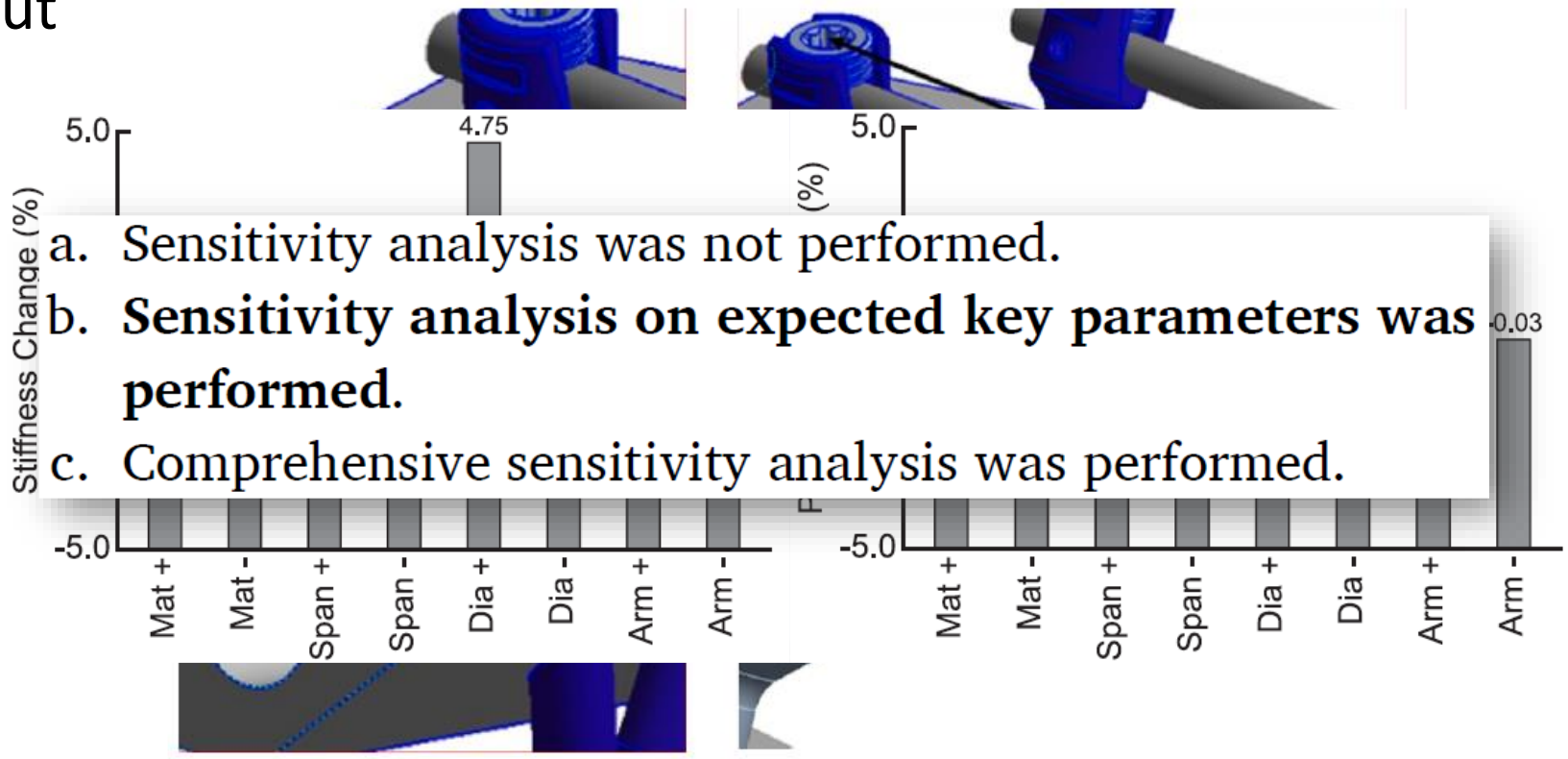
		Model Inputs: Quantification of Uncertainties	a	b	c

Quantification of Sensitivities: the degree to which the model outputs are sensitive to the model inputs.

- Perturbed four model input parameters (± 1 SD):
  - Rod diameter
  - Active length (span)
  - Pin-rod distance (moment arm)
  - Material model
- QOIs examined
  - Stiffness
  - Yield force
  - Force at 40 mm



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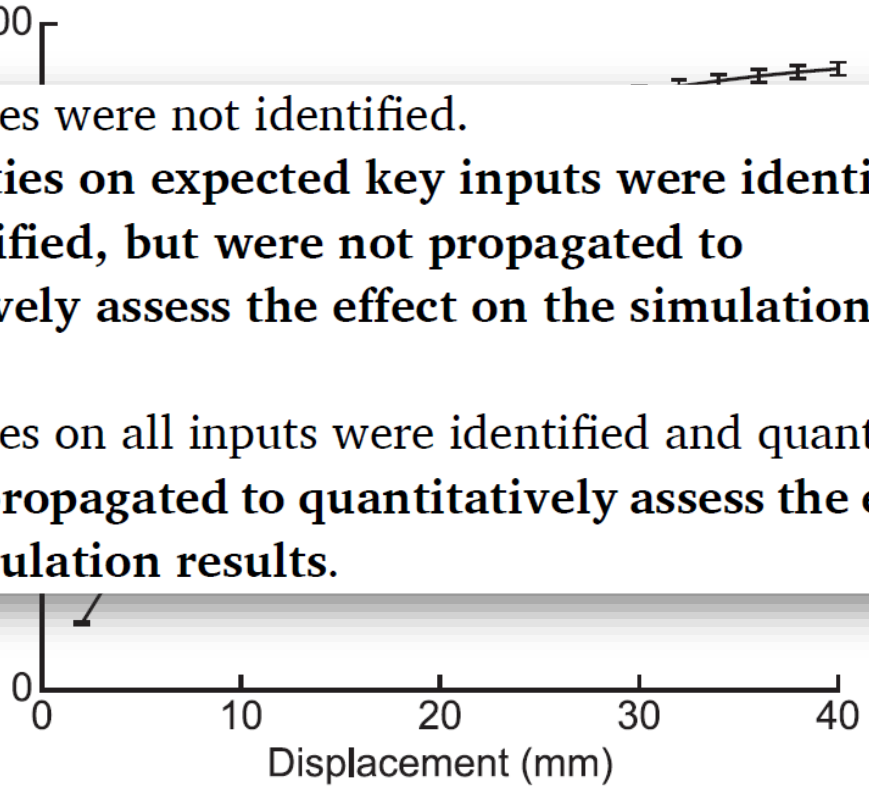
		Model Inputs: Quantification of Sensitivities	a	b	c
		Model Inputs: Quantification of Uncertainties	a	b	c

Quantification of Uncertainties: the degree to which known or assumed uncertainties in the model inputs are propagated to uncertainties in the simulation results.

- Monte Carlo simulation based on a Design of Experiments (DOE)
  - Perturbed active length, rod diameter, and moment arm ± 1 SD
- QOIs were examined (stiffness, yield load, and force at 40 mm) as well as the entire force-displacement curve

a. Uncertainties were not identified.
b. **Uncertainties on expected key inputs were identified and quantified, but were not propagated to quantitatively assess the effect on the simulation results.**
c. Uncertainties on all inputs were identified and quantified, and **were propagated to quantitatively assess the effect on the simulation results.**



Fully Executed Credibility Plan

Activity	Sub-Activity	Credibility Factor	Credibility Level			
			LOW		MED	HIGH
Verification	Code Verification	Sofware Quality Assurance	a	b	c	
		Numerical Code Verification	a	b	c	d
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		Use Error	a	b	c	d

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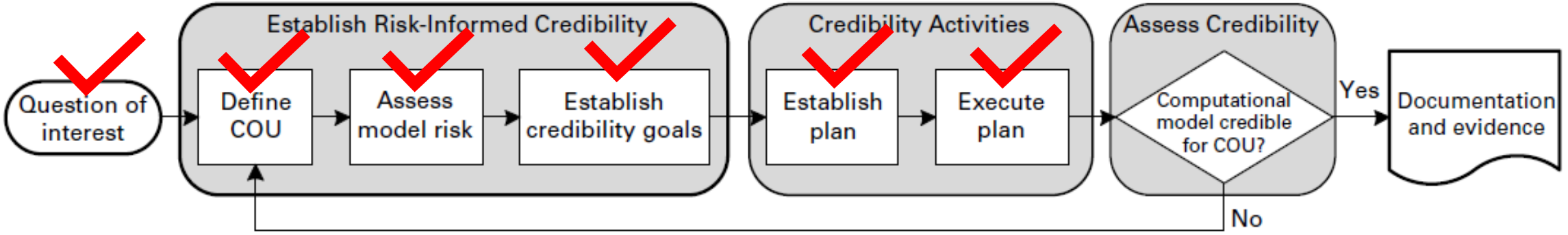
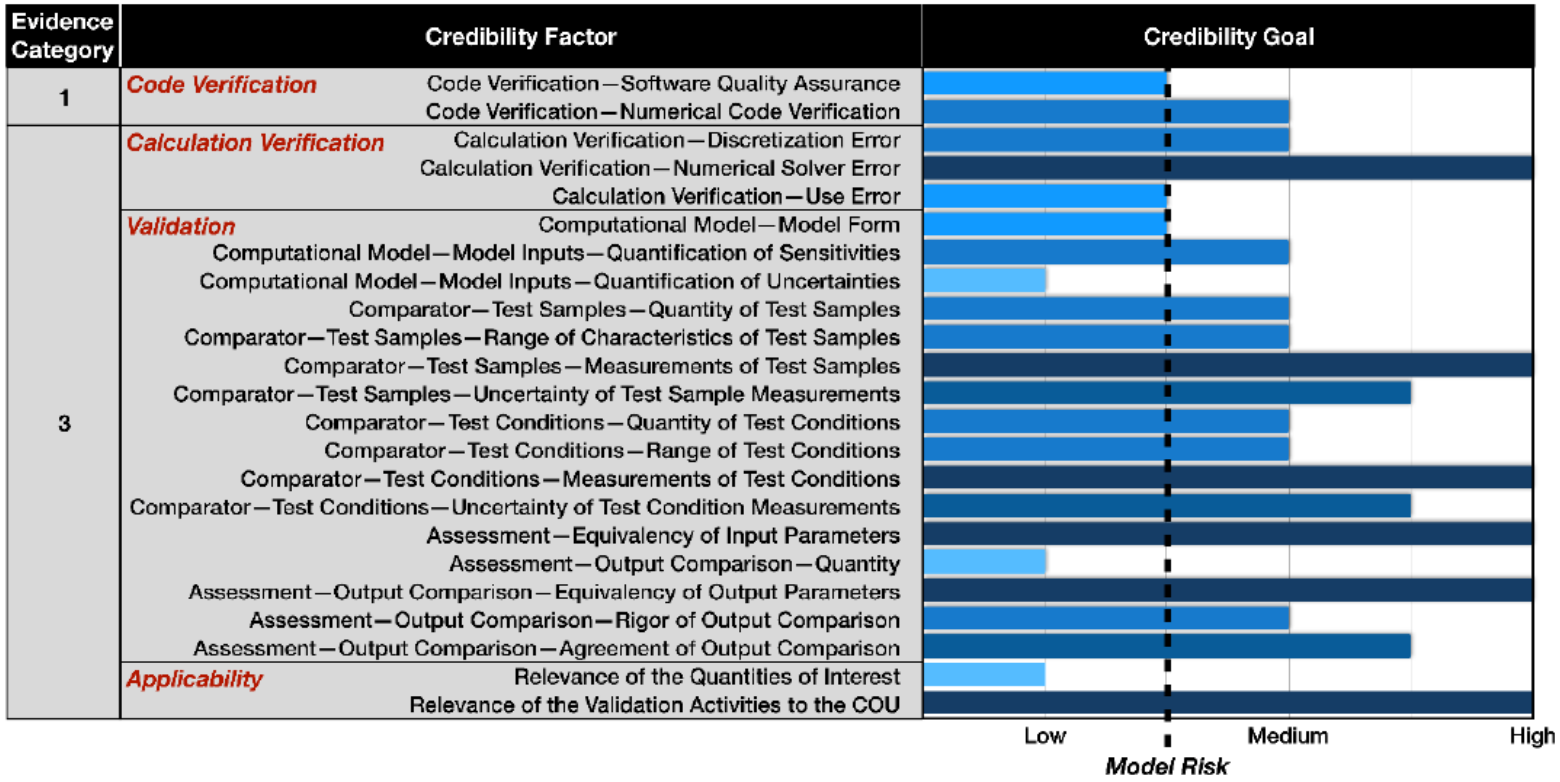


	Assessment	Equivalency of Input Parameters	a	b	c	
		Output Comparison: Quantity	a	b		
		Output Comparison: Equivalency of Output Parameters	a	b	c	
		Output Comparison: Rigor of Output Comparison	a	b	c	d
		Output Comparison: Agreement of Output Comparison	a	b	c	
Applicability	Relevance of the QOIs		a	b	c	
	Relevance of the Validation Activities to the COU		a	b	c	d

Fully Executed Credibility Plan

- Defining gradations/levels for the credibility factors:
  - The FDA Credibility Guidance document recommends defining, “a gradation of activities that describes progressively increasing levels of rigor in investigation.”
  - An example with 5 gradations per credibility factor is illustrated



Fully Executed Credibility Plan

- We defined gradations based on ASME V&V 40
  - (a) through (b)
  - (a) through (c)
  - (a) through (d)
- But, we didn't know how apply a High-Medium Model Risk to these scales
- Quantified the a common der
  - 12
  - High-Medium mapped to 9-10

2

(a) A single output was compared.
(b) Multiple outputs were compared.

3

(a) Influ
(b) Influ
(c) Com

4

(a) Inputs and outputs were not verified.
(b) Key inputs and outputs were verified by the practitioner.
(c) Key inputs and outputs were verified by internal peer review.
(d) Key inputs and outputs were verified by reproducing simulations as part of an external peer review.

Medium-High

	Low				Med							High
	1	2	3	4	5	6	7	8	9	10	11	12
2 Gradations	a						b					
3 Gradations	a				b				c			
4 Gradations	a			b			c			d		

Fully Executed Credibility Plan

- What about the Credibility Factors below our goal?
  - Quantity of Test Conditions
  - Range of Test Conditions

Activity	Sub-Activity	Credibility Factor	Credibility Level			
			LOW		MED	HIGH
	Computational Model	Model Form	a	b	c	
		Model Inputs: Quantification of Sensitivities	a	b	c	
		Model Inputs: Quantification of Uncertainties	a	b*	c	
		Quantity of Test Samples	a	b	c	
		Uncertainty of Test Condition Measurements	a	b	c	d
	Assessment	Equivalency of Input Parameters	a	b	c	
		Output Comparison: Quantity	a	b		
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		Output Comparison: Rigor of Output Comparison	a	b	c	d
		Output Comparison: Agreement of Output Comparison	a	b	c	

"It was decided that the medium and low-medium factors chosen for this study were sufficient as the extra effort to increase model credibility in those specific categories was not needed."

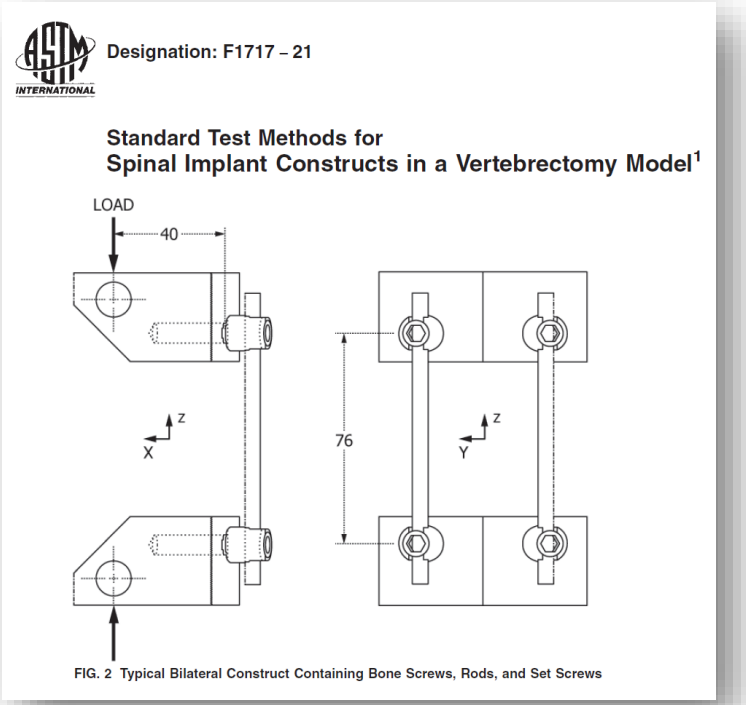
Fully Executed Credibility Plan

- *Quantity of Test Conditions*
- *Range of Test Conditions*

(a) A single test condition was examined.
(b) Multiple (two to four) test conditions were examined.
(c) More than four test conditions were examined.

(a) A single test condition was examined.
(b) Test conditions representing a range of conditions near nominal were examined.
(c) Test conditions representing the expected extreme conditions were examined.
(d) Test conditions representing the entire range of conditions were examined.

  - Our test condition was defined by ASTM F2077
  - Only one condition was relevant to our model, COU, and ?OI


Designation: F1717 – 21

Standard Test Methods for
Spinal Implant Constructs in a Vertebrectomy Model[1]

FIG. 2 Typical Bilateral Construct Containing Bone Screws, Rods, and Set Screws

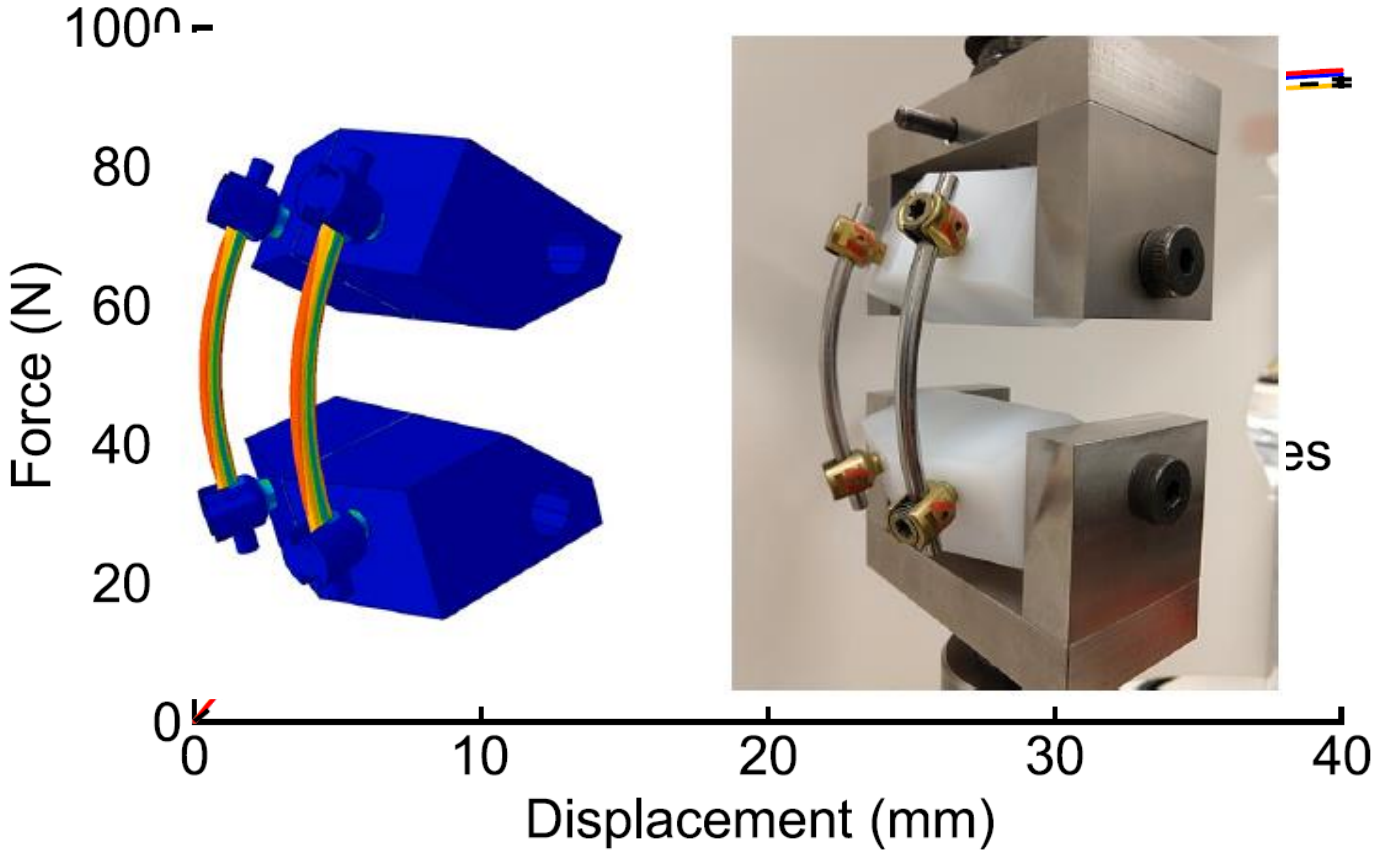
Assess Credibility

- Of the 23 Credibility Factors:
  - 15/23 at high-medium or greater
  - 6/23 at medium
  - 2/23 at low-medium

- “It is possible that upon completion of the credibility activities, the credibility goals might not have been met as initially planned; however, the computational model may still be sufficiently credible for decision-making based on the rationale developed.” – V&V 40

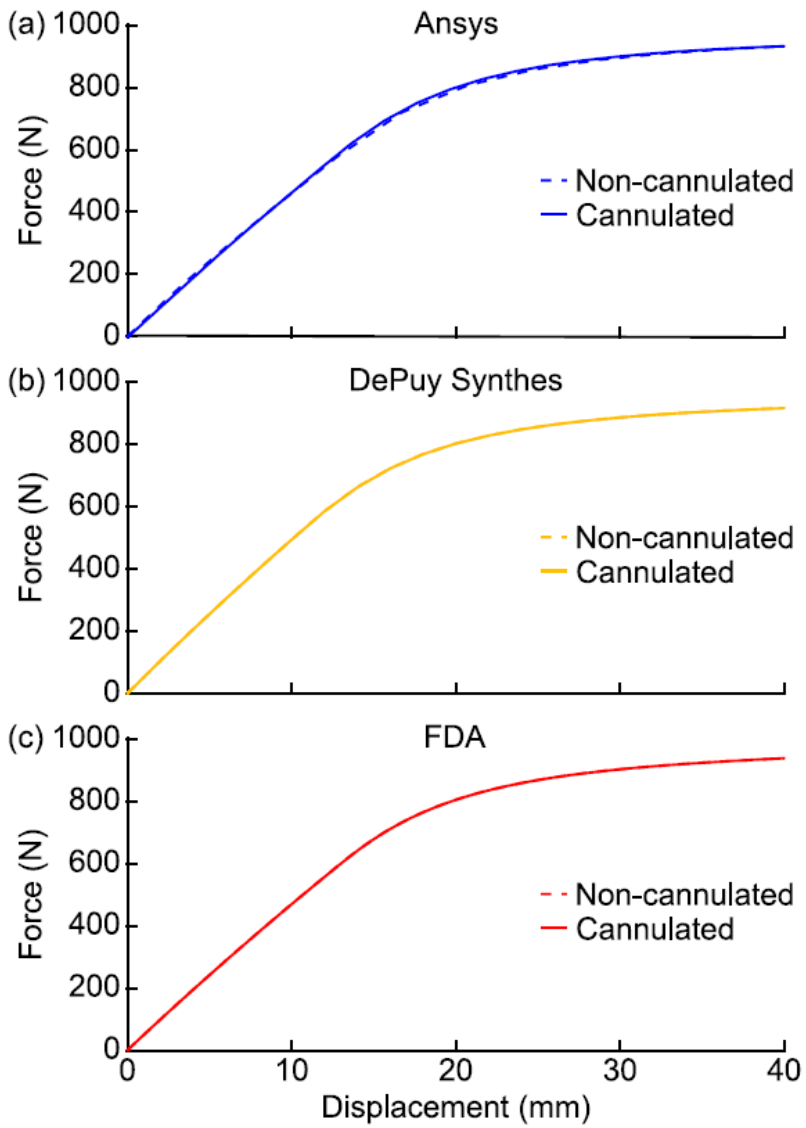
Assess Credibility

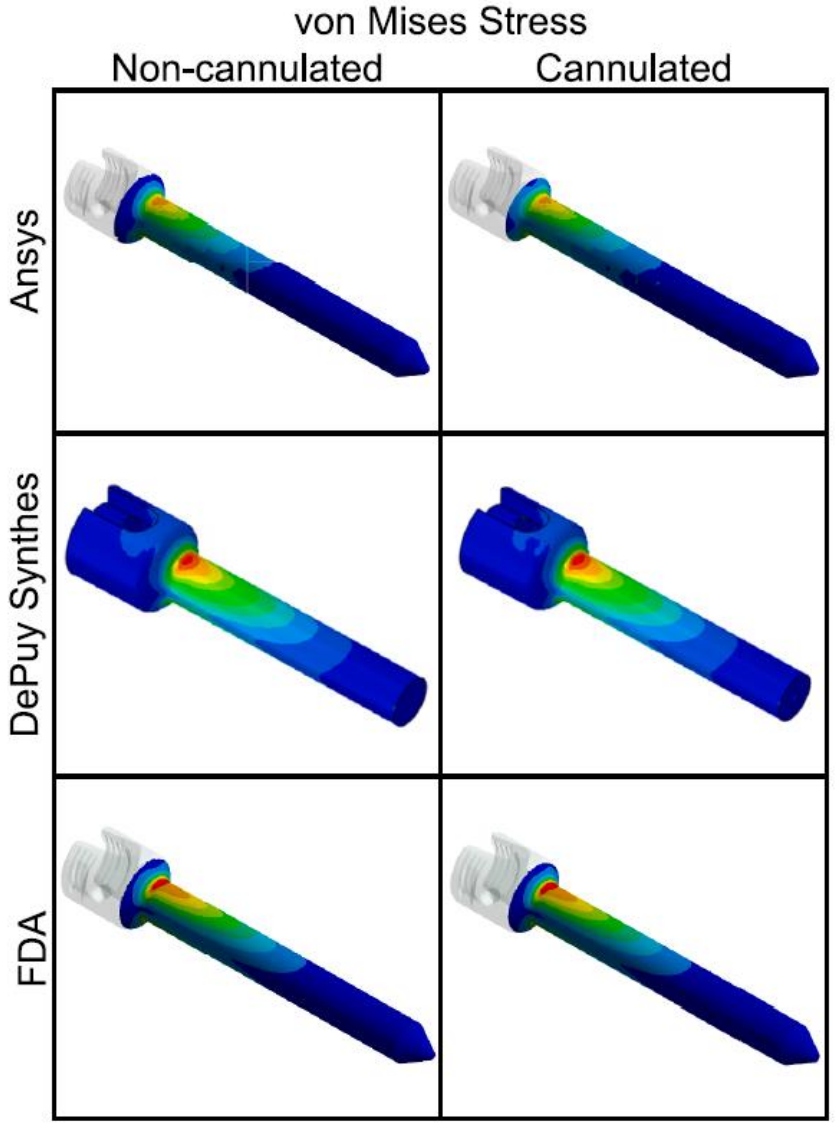
- Non-cannulated screw models showed good agreement with experimental data
  - <8% difference in stiffness
  - <4% difference in yield force
  - <4% difference in force at 40 mm
- Model predicted highest stresses at rod midshaft
  - Consistent with bench test deformation



Answering the ?OI

- Validated model predicted no significant difference between non-cannulated and cannulated constructs
  - Force-displacement
  - Stress distribution

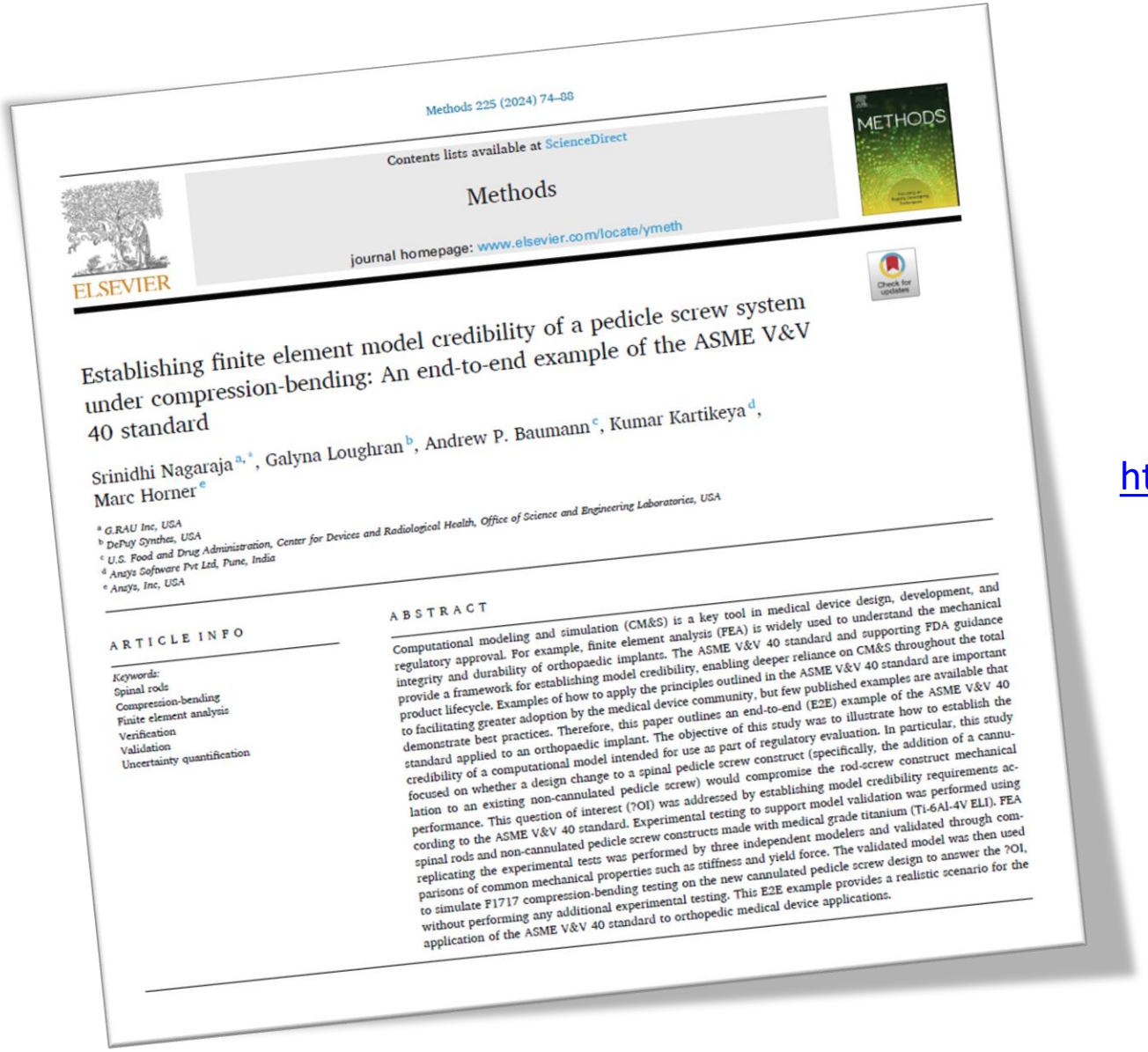




Conclusion

- The V&V 40 standard answered a “regulatory” question for a medical device
  - Cannulated screw was not significantly different than non-cannulated
  - Used only computational modeling—no additional bench testing
- Provided a comprehensive end-to-end example
  - This is a guide, not an SOP
  - Your situation will be different!
- Always refer to other standards and documents to “fill in the blanks”
  - ASME V&V 20
  - FDA Guidance
  - ASTM Standards

For More Information



Methods 225 (2024) 74–88

Contents lists available at ScienceDirect

Methods

journal homepage: www.elsevier.com/locate/ymeth

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[e] Ansys, Inc, USA

ARTICLE INFO

Keywords:
Spinal rods
Compression-bending
Finite element analysis
Verification
Validation
Uncertainty quantification

ABSTRACT

Computational modeling and simulation (CM&S) is a key tool in medical device design, development, and regulatory approval. For example, finite element analysis (FEA) is widely used to understand the mechanical integrity and durability of orthopaedic implants. The ASME V&V 40 standard and supporting FDA guidance provide a framework for establishing model credibility, enabling deeper reliance on CM&S throughout the total product lifecycle. Examples of how to apply the principles outlined in the ASME V&V 40 standard are important to facilitating greater adoption by the medical device community, but few published examples are available that demonstrate best practices. Therefore, this paper outlines an end-to-end (E2E) example of the ASME V&V 40 standard applied to an orthopaedic implant. The objective of this study was to illustrate how to establish the credibility of a computational model intended for use as part of regulatory evaluation. In particular, this study focused on whether a design change to a spinal pedicle screw construct (specifically, the addition of a cannulation to an existing non-cannulated pedicle screw) would compromise the rod-screw construct mechanical performance. This question of interest (?OI) was addressed by establishing model credibility requirements according to the ASME V&V 40 standard. Experimental testing to support model validation was performed using spinal rods and non-cannulated pedicle screw constructs made with medical grade titanium (Ti-6Al-4V ELI). FEA replicating the experimental tests was performed by three independent modelers and validated through comparisons of common mechanical properties such as stiffness and yield force. The validated model was then used to simulate F1717 compression-bending testing on the new cannulated pedicle screw design to answer the ?OI, without performing any additional experimental testing. This E2E example provides a realistic scenario for the application of the ASME V&V 40 standard to orthopedic medical device applications.

https://doi.org/10.1016/j.ymeth.2024.03.003

Acknowledgments

The authors would like to acknowledge Anup Gandhi and ZimVie for providing materials and test data for this study. In addition, we acknowledge Dinesh Kumar of Ansys, Inc. for his contributions to the uncertainty analysis and Gunjan Verma of Ansys, Inc. for his contributions to the FEA studies.

THANK YOU!!!

QUESTIONS?