ASME V&V 40 TIBIAL TRAY EXAMPLE: ASSESSING THE APPLICABILITY OF THE VALIDATION ACTIVITIES TO THE CONTEXT OF USE FOR NON-IDENTICAL QUANTITIES OF INTEREST

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Background

Credibility assessment framework.

“Computational models have been used to support the design of medical devices for many years, without any specific guidance on how to assess their credibility. Device manufacturers therefore use internal approaches and best practices for model verification and validation (V&V). This has created challenges for regulatory agencies to develop consistent, structured approaches for evaluating the legitimacy of model results used to support device safety and/or effectiveness.”
Background

Credibility assessment framework.

Images from Appendix B of ASME V&V 40
Background

Working Group 2 – A single example spanning VVUQ Process

Assessing Computational Model Credibility Using the ASME V&V 40 Risk-Based Framework: Tibial Tray Component Worst-Case Size Identification for Fatigue Testing

Images from ASME V&V 40 and Tridsanu Thopet / Shutterstock
Background
Some definitions

- Question of Interest
- Context of Use
- Quantity of Interest
- Model Risk

“...the possibility that the use of the computational model leads to a decision that results in patient harm and/or other undesirable impacts. It reflects the risk the decision-maker incurs when using a computational model to support a decision.” ASME V&V 40
Background

How are the Question of Interest, COU, and Model Risk used in ASME V&V 40?

Credibility Factor

Gradation of Goals

A
B
C
D

Credibility

YES

NO

Documentation and Evidence
Problem Statement

Relevance of the QOIs credibility factor gradation of goals is challenging.

5.3.1 Relevance of the QOIs. This factor compares the QOIs from the validation activities to the QOIs for the COU. The following is an example gradation of activities, listed from lowest to highest credibility, that reflects the relevance of the QOIs for the COU:
Problem Statement
Why do I want the QOIs to match?

Accuracy of COU Model Prediction
Uncertainty

Images from DALL-E
Common Examples
Medical devices whose QOIs for validation and COU may differ

Orthopaedic:

▪ **COU**: Stress, Fatigue Safety Factor, Force, Displacement

▪ **Validation**: Strain, Force, Displacement, Stiffness
Tibial Tray Example

Question of Interest & Context of Use

Question of Interest:
Does the tibial tray component for each size of the new total knee replacement system meet fatigue performance requirements when one condyle of the femoral component is unsupported?

Context of Use:
FEA will be used to simulate a static version of the cantilever beam dynamic test described in ASTM F1800 with a 900 N load applied to an unsupported portion of the tray. The loading frequency for the dynamic test is deemed to be multiple orders of magnitude below a tibial tray’s resonant frequency, therefore it is not necessary to include vibration and inertial energy effects in the computational model form. The computational model will be used to predict the value and location of the peak maximum principal stress for each size of the proposed metallic tibial tray.

Maximum principal stress will be used to rank order the tibial trays. In this scenario, the tray size with the highest predicted peak maximum principal stress will be identified as the worst-case size. This worst-case size will then be physically tested per the method described in ASTM F1800 to establish its fatigue performance to 10 million cycles of a 900 N load per ASTM F2083. While the model guides the worst-case device selection, the experimental data is the primary source of evidence used to answer the question of interest.
Tibial Tray Example

QOIs for the Context of Use Domain

Image: ASME V&V 40 WG2, Linda Knudson
Tibial Tray Example

Validation testing options

Image: Left – ASTM F1800, Right – ASME V&V 40 WG2, Mehul Dharia
Tibial Tray Example

QOIs for the validation domain

- **Strain**
  - Where would we put gauges? Will they represent peak strain location?
  - Can we claim identical to stress?

- **Displacement**
  - At what load magnitude?
  - Not directly relatable to stress.

- **Bending Stiffness**
  - Not directly relatable to stress.
  - Averaging displacement over a range of load.

- **More than one?**

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Image: ASME V&V 40 WG2, Mehul Dharia and Linda Knudson
Tibial Tray Example

Applicability of the Validation Activities to the COU: Relevance of the QOIs

COU: Peak Maximum Principal Stress

Validation: Bending Stiffness

5.3.1 Relevance of the QOIs. This factor compares the QOIs from the validation activities to the QOIs for the COU. The following is an example gradation of activities, listed from lowest to highest credibility, that reflects the relevance of the QOIs for the COU:

(a) The QOIs from the validation activities were related, though not identical, to those for the COU.
(b) A subset of the QOIs from the validation activities were identical to those for the COU.
(c) The QOIs from the validation activities were identical to those for the COU.

Image: ASME V&V 40 WG2, Mehul Dharia and Linda Knudson

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Model Risk & Medical Device Modeling

The credibility sought (credibility goal) is commensurate with the credibility needed (model risk).

<table>
<thead>
<tr>
<th>Decision Consequence Gradation</th>
<th>Model Influence</th>
<th>Decision Consequence</th>
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- **Model Influence**
  - B
  - C
  - MEDIUM

- **Decision Consequence**
  - **Option**
    - Not requiring professional medical intervention
    - Outlining professional medical intervention
    - Treating injury

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Model Risk & Medical Device Modeling

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Credibility Factor

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<th>Goals</th>
<th>Credibility</th>
<th>Linked Model Risk</th>
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D

?High?
Changing QOI vs Reducing Model Risk vs Seeking a Rationale

Three viable options – though none are easy.

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Image: ASTM F1800
Tibial Tray Example
Rationale for Credibility

- **Bending stiffness** is a single-value result that relates the applied load with the resulting deformation under the specified boundary conditions.

- A similar bending stiffness value does not guarantee an accurate stress calculation, but an accurate stress calculation is very difficult to achieve without an accurate bending stiffness.

- If the model and comparator have a similar bending stiffness, then fundamental credibility in the model form and boundary conditions is established.
Tibial Tray Example
Rationale for Credibility

- Extending the fundamental bending stiffness credibility to a local parameter such as stress can be achieved by ensuring the \textit{discretized representation of the tibial tray is sufficient to capture the local geometric influences on the calculated stress field.}

Images: ASME V&V 40 WG2, Mehul Dharia and Linda Knudson
Tibial Tray Example
Rationale for Credibility

- Therefore, for this specific COU and a Medium model risk, a bending stiffness estimation that meets the credibility goal for the Agreement of Output Comparison credibility factor, combined with a calculation verification study, enables trustworthy predictions of the peak maximum principal stress.
Application to Other Scenarios

Rationale for Credibility

- Think global and local
- If you can match QOI: Is the expense justified for the risk level?
- Other options:
  - Try different methods, such as Digital Image Correlation
  - Try additional validation tests where you can measure the COU QOI, even if it is not the same QOI
  - Use more than one validation QOI that is informative (e.g.; bending resistance and radial force)
- Talk with your cohorts and do not just jump to how to rationalize what you have always done
Credibility is Subjective

Image: Detroit Institute of Art
Conclusion

- There are many medical device applications that require strain or stress, which are difficult or not possible to measure.
- Medical devices by nature include risk to the user.
- Multiple paths to deal with non-identical QOIs: Change risk profile; find a way to obtain data for identical QOIs; and rationalize why it is okay.
- If rationalizing, what value does the QOI for validation bring? Are there other activities that provide confidence that your model will accurately predict the COU QOI?
- Credibility is subjective: Will you trust this model if the goals are met?
Credits & Thank You

Many group members were involved in the discussions and ultimate decision to rationalize why a different QOI for the validation activities and COU was acceptable for this case. These discussions and work have taken place over the last couple of years so I may have missed a couple of names.

- Christopher Basciano – BD
- Linda Knudson – Zimmer Biomet
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- Dana Coombs – Johnson & Johnson
- Sudeep Sastry – W. L. Gore & Associates
- Marc Horner – ANSYS
- Mark Palmer – formerly Medtronic
- Walter Ocampo – Straumann
- Travis Schauer – Boston Scientific
THANK YOU
고맙습니다
고맙습니다
谢谢

OBRIGADO
GRACIAS
THANK YOU
고맙습니다
ありがとう
谢谢

GRAZIE
DANKE
謝謝
TACK
GRACIAS