An End-to-End Example of the ASME V&V 40 Standard

Track 10 VVUQ for Biomedical Engineering

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Provides a framework for

1. Establishing credibility goals for a computational model for a context of use (COU) based on model risk
2. Assessing the relevance and adequacy of completed V&V activities

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Medical Device under Consideration

Total Knee Replacement

Femoral Component
CoCr Alloy

Tibial Insert
UHMWPE

Tibial Tray
Ti or CoCr Alloy

Metal Tibial Tray Component Examples

(a) (b)

Growing Use

Driving Factors

• Aging population
• Obesity
• Use in younger patients (<65)
• Patient demand for maintenance of activity and lifestyle

Source: Kurtz et al., 2007a

Figure 7. Projected Number of Primary Total Knee Arthroplasties in the United States, 2005 to 2030

[11]
Tibial Tray Fractures

**Testing** per ASTM F1800 [5]

- ≤ 30 Hz (typical 5 to 10Hz)
- 10,000,000 cycles
- Load = 900N
- N=5

**Acceptance Criteria** per ASTM F2083 [6]

**FIG. 1 Schematic of Test Setup Without a Central Keel**

**FEA**
Question of Interest

The specific question, decision, or concern that is being addressed [1]

Information to support the Question of Interest can come from:

- *In vitro* testing
- *In vivo* animal testing
- Clinical trials
- Computational modeling

- Are the next-generation tibial baseplate (tray) components sufficiently fatigue resistant?
A finite element model will be used to simulate a static version of the dynamic offset cantilever beam test described in ASTM F1800 with a 900N load.

Context of Use (COU)

The specific role and scope of the computational model used to address the question of interest [1]
A finite element model will be used to simulate a static version of the dynamic offset cantilever beam test described in ASTM F1800 with a 900N load.

For each configuration of the proposed, next-generation metal tibial baseplate component, the computational model will predict a maximum principal stress.
Context of Use (COU)

The specific role and scope of the computational model used to address the question of interest [1]

- A finite element model will be used to simulate a static version of the dynamic offset cantilever beam test described in ASTM F1800 with a 900N load.
- For each configuration of the proposed metal tibial baseplate component, the computational model will predict a maximum principal stress.
- The worst-case component across the proposed product portfolio will be determined by the component with the highest predicted maximum principal stress.
Define Context of Use (COU)

The specific role and scope of the computational model used to address the question of interest [1]

- A finite element model will be used to simulate a static version of the dynamic offset cantilever beam test described in ASTM F1800 with a 900N load.
- For each configuration of the proposed metal tibial baseplate component, the computational model will predict a maximum principal stress.
- The worst-case component across the proposed product portfolio will be determined by the component with the highest predicted maximum principal stress.
- The worst-case component will then be physically tested per the method described in ASTM F1800 to establish its fatigue resistance to 10 million cycles of a 900 N load per ASTM F2083.
**Model Risk**
The possibility that the computational model and the simulation results may lead to an incorrect decision that would lead to an adverse outcome. [1]

**Model Influence**
The contribution of the computational model relative to other contributing evidence in making a decision. [1]

**Decision Consequence**
The significance of an adverse outcome resulting from an incorrect decision. [1]
Decision

- All configurations of the next-generation tibial tray have sufficient fatigue resistance for their intended use.

Consequence

- Device fracture leads to patient injury and revision surgery.

Decision Consequence ISO 14971 [7]

A. Negligible: inconvenience or temporary discomfort
B. Minor: results in temporary injury or impairment not requiring professional medical intervention
C. Serious: results in injury or impairment requiring professional medical intervention
D. Critical: results in permanent impairment or life-threatening injury
E. Catastrophic: results in patient death

The levels for decision consequence are different than those suggested in the standard.
Assess Model Influence

From Context of Use

- The worst-case component will then be physically tested per the method described in ASTM F1800 to establish its fatigue resistance to 10 million cycles of a 900 N load per ASTM F2083.

Model Influence [1]

Simulation outputs from the computational model are:

- A. a minor factor in the decision
- B. a moderate factor in the decision
- C. a significant factor in the decision
- D. the sole factor in the decision

The levels for model influence are different than those suggested in the standard.
**Assess Model Risk**

### Model Risk

<table>
<thead>
<tr>
<th>Decision Consequence</th>
<th>E</th>
<th>Medium</th>
<th>High</th>
<th>High</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td></td>
</tr>
</tbody>
</table>

### Decision Consequence [7]

- **A.** Negligible: inconvenience or temporary discomfort
- **B.** Minor: results in temporary injury or impairment not requiring professional medical intervention
- **C.** Serious: results in injury or impairment requiring professional medical intervention
- **D.** Critical: results in permanent impairment or life-threatening injury
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### Model Influence [1]

Simulation outputs from the computational model are:

- **A.** a minor factor in the decision
- **B.** a moderate factor in the decision
- **C.** a significant factor in the decision
- **D.** the sole factor in the decision
Establish Credibility Goals

Model Risk drives the selection of V&V activities and goals for each credibility factor.

For our example **Model Risk → Medium**

**Model Credibility**

Trust in the predictive capability of the model, established through the collection of evidence from V&V activities, for a given COU.

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For our example **Model Risk → Medium**

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Numerical Code Verification (NCV)
Demonstrate correct implementation and functioning of the numerical algorithms [1]

- The following is the gradation of activities, listed from lowest to highest credibility, that reflects the rigor of NCV:
  a) NCV was not performed. [Low]
  b) The numerical solution was compared to an accurate benchmark solution from another verified code or the exact solution. [Low]
  c) Discretization error was quantified by comparison to an exact solution, and a mesh convergence study demonstrated that the numerical solution asymptotically approached the exact solution as the discretization was refined. [Medium]
  d) In addition to the quantification of discretization error and the execution of a mesh convergence study as described in (c), the observed order of accuracy was quantified and compared to the theoretical order of accuracy. [High]
Numerical Code Verification (NCV)

Typically compares to exact benchmark or analytical solutions

**Cantilever Beam**

\[
\sigma_{\text{max}} = \frac{Mc}{I} = \frac{(100N)(100mm)(5mm)}{2500mm^4} = 20 \text{ MPa}
\]

\[
\delta = \frac{PL^3}{3EI} = \frac{(100N)(120mm)^3}{3(20000N/mm^2)(2500mm^4)} = 0.1152 \text{mm}
\]

<table>
<thead>
<tr>
<th></th>
<th>Maximum Principal Stress (MPa)</th>
<th>Displacement at Tip (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEA</td>
<td>20.097</td>
<td>0.1138</td>
</tr>
<tr>
<td>Analytical</td>
<td>20.000</td>
<td>0.1152</td>
</tr>
<tr>
<td>Error (%)</td>
<td>0.485</td>
<td>-1.22</td>
</tr>
</tbody>
</table>

**Stepped Beam with Pure Moment (Stress Concentration)**

\[
\sigma_{\text{max}} = K_t \frac{Mc}{I} = 1.545 \frac{(10000N/mm)(5mm)}{2500mm^4} = 30.9 \text{ MPa}
\]

<table>
<thead>
<tr>
<th></th>
<th>Maximum Principal Stress (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEA</td>
<td>30.202</td>
</tr>
<tr>
<td>Analytical</td>
<td>30.900</td>
</tr>
<tr>
<td>Error (%)</td>
<td>-2.26</td>
</tr>
</tbody>
</table>
Establish Credibility Goals

<table>
<thead>
<tr>
<th>Activity</th>
<th>Credibility Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verification</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Software quality assurance</td>
</tr>
<tr>
<td></td>
<td>Numerical code verification</td>
</tr>
<tr>
<td>Calculation</td>
<td>Discretization error</td>
</tr>
<tr>
<td></td>
<td>Numerical solver error</td>
</tr>
<tr>
<td></td>
<td>Use error</td>
</tr>
<tr>
<td>Validation</td>
<td></td>
</tr>
<tr>
<td>Computational model</td>
<td>Model form</td>
</tr>
<tr>
<td></td>
<td>Model inputs</td>
</tr>
<tr>
<td>Comparator</td>
<td>Test samples</td>
</tr>
<tr>
<td></td>
<td>Test conditions</td>
</tr>
<tr>
<td>Assessment</td>
<td>Equivalency of input parameters</td>
</tr>
<tr>
<td></td>
<td>Output comparison</td>
</tr>
<tr>
<td>Applicability</td>
<td>Relevance of the quantities of interest</td>
</tr>
<tr>
<td></td>
<td>Relevance of the validation activities to the COU</td>
</tr>
</tbody>
</table>

Move on to the Credibility Factors for computational model validation

Model Risk drives the selection of V&V activities and goals for each credibility factor.

For our example Model Risk ➔ Medium
Model Form

Explore the influence of both the conceptual and mathematical formulation of the computational model. [1]

- The following is the gradation of activities that reflects the extent to which model form assumptions were verified:
  a) Influence of model form assumptions was not explored. [Low]
  b) Influence of expected key model form assumptions was considered. [Medium]
  c) Comprehensive evaluation of model form assumptions was conducted. [High]
### Influence of expected key model form assumptions was explored:

<table>
<thead>
<tr>
<th>Model Form for this Example</th>
<th>Model Form Assumption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Static Solver</td>
<td>Gradual load application. Small deflection.</td>
</tr>
<tr>
<td>Linear Elastic Material Model</td>
<td>Stress values below yield. No need to use elastic-plastic material model.</td>
</tr>
<tr>
<td>Load Application is force applied to an area</td>
<td>Area of interest is away from load application. Unnecessary to model load applicator.</td>
</tr>
<tr>
<td>Bonded contact</td>
<td>No need to model clamp with friction.</td>
</tr>
<tr>
<td>Geometry complexity</td>
<td>Removing small features at perimeter does not influence results.</td>
</tr>
</tbody>
</table>
Establish Credibility Goals

Model Inputs
Refer to the values for parameters used in the governing equations, system configuration, system properties, and system conditions. [1]

Subdivided into:
- Quantification of Sensitivities
- Quantification of Uncertainties
Quantification of Sensitivities

Examines the degree to which the computational model outputs are sensitive to the model inputs. [1]

a) Sensitivity analysis was not performed. [LOW]
b) Sensitivity analysis on expected key parameters was performed. [MEDIUM]
c) Comprehensive sensitivity analysis was performed. [HIGH]

Assuming the model uses linear material properties and there are no contact definitions, the key input parameters would be:

1. Load location
2. Tolerances of select geometry dimensions
3. Modulus of the potting material

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Establish Credibility Goals for each Credibility Factor

- We covered only a few credibility factors related to the model
- Equally important aspects of comparator will be covered in this process
- Then the inputs and outputs of both will be compared to make the assessment of credibility
- Use V&V 40’s Risk-Informed Credibility Assessment Framework to determine the level of rigor of V&V activities.
- Define the Question of Interest and Context of Use (COU) upfront.
- Understand that model risk is a combination of model influence and decision consequence.
- Align V&V activities with model risk to show that your computational model is credible for a specific COU.


Thank you!

- **Linda Knudsen**, Principal Engineer, Syncroness
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