ASME VVUQ 40.1-2026

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

AN ASME TECHNICAL REPORT

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The American Society of Mechanical Engineers
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CONTENTS

Committee Roster v

Correspondence With the VVUQ Committee vii

1 Introduction 1
2 Background 1
3 Tibial Tray Component Example 2
4 Question of Interest 6
5 Context of Use (COU) 6
6 Model Risk 8
7 Model Credibility 11
8 Credibility Assessment 48

Mandatory Appendix

I 50

Nonmandatory Appendices

A Mathematical Derivation for the Linear Relationship Between Alternating Stress and Peak Maximum Principal Stress 52
B Applicability Analysis Based on Pathmanathan et al. (2017) 53
C VVUQ Workflow Summary 58

Figures

1-1 Sections Associated With Each Element of the ASME V&V 40 Risk-Informed Credibility Assessment Framework 1
3-1 Example of a Three-Component Total Knee Replacement 3
3-2 76-mm Medial–Lateral (M–L)/50-mm Anterior–Posterior (A–P) Tibial Tray Design Used for Validation 4
3-3 ISO 14879-1 Test Setup 5
5-1 COU Overview for Modeling and Testing the Tibial Tray Family 7
6.2-1 Decision Consequence Matrix 10
6.3-1 Model Risk Assessment Matrix 11
7.1.1.2-1 Code Verification Problem Details 14
7.1.1.2-2 Representative Computational Mesh Used for the Code Verification Problem With 0.100-mm Element Size on the Surface of the Cavity 15
7.1.1.2-3 Contour Plot of the Maximum Principal Stress, MPa, With 0.025-mm Element Size on the Surface of the Cavity 16
7.1.2.1-1 Mesh Refinement Regions 18
7.1.2.1-2 Two of the Body Element Sizes Used in the Mesh Refinement Study 18
7.1.2.1-3 Four of the Element Sizes Used in Meshing the Posterior Lock Face 20
7.2.1-1 CAD Model of the ISO 14879-1 Tibial Tray Test 23

7.2.1.1-1 Illustration of Model Form for Model 1 (A1–B1–C1) and Model 2 (A2–B1–C1) 26
7.2.1.1-2 Bending Stiffness and Peak Maximum Principal Stress Predictions for Models 1 and 2 26
7.2.1.1-3 Illustration of the Model Form for Models 2 and 3 27
7.2.1.1-4 Bending Stiffness and Peak Maximum Principal Stress Predictions for Models 2 and 3 28
7.2.1.1-5 Illustration of the Model Form for Models 3 and 4 29
7.2.1.1-6 Bending Stiffness and Peak Maximum Principal Stress Predictions for Models 3 and 4 30
7.2.1.1-7 Model 4 (A2–B2–C2) Maximum Principal Stress Contour 31
7.2.1.2.1-1 iPR for Input Sensitivity to Bending Stiffness 33
7.2.1.2.1-2 iPR for Input Sensitivity to Maximum Principal Stress 34
7.3.1-1 Diagram Relating Fatigue Performance, Peak Maximum Principal Stress, and Bending Stiffness 46
B-1-1 Overview of the COU and Validation Domains and Their Associated QOIs 54

Tables

7-1 Verification, Validation, and Applicability Activities and Their Associated Credibility Factors 11
7.1.1.2-1 NCV Study Results 16
7.1.2.1-1 Change in Out-of-Plane Displacement at the Center of the Circular Load Patch With Respect to the Body Element Size 19
7.1.2.1-2 Change in the Peak Maximum Principal Stress With Respect to Face Element Size 21
7.2.1.1-1 Explored Model Form Assumptions 24
7.2.1.1-2 Model Form Assumptions Not Explored 24
7.2.1.1-3 Model Form Assumptions and Test Combinations — Models 1 and 2 25
7.2.1.1-4 Model Form Assumptions and Test Combinations — Models 2 and 3 27
7.2.1.1-5 Model Form Assumptions and Test Combinations — Models 3 and 4. 28
7.2.1.2.1-1 Key Input Parameters Identified for Sensitivity Analysis 35
7.2.1.2.1-2 Sensitivity Analysis Results — Bending Stiffness 35
7.2.1.2.1-3 Sensitivity Analysis Results — Peak Maximum Principal Stress 35
7.2.3.1-1 Equivalency of the Validation Computational Model and Comparator Inputs 43
8-1 Credibility Factors Summary 49
B-2-1 Questions Raised for Aspects of M-VAL and M-COU That Are Identical Regarding Their Applicability to R-COU for Each Difference Between R-VAL and R-COU 57

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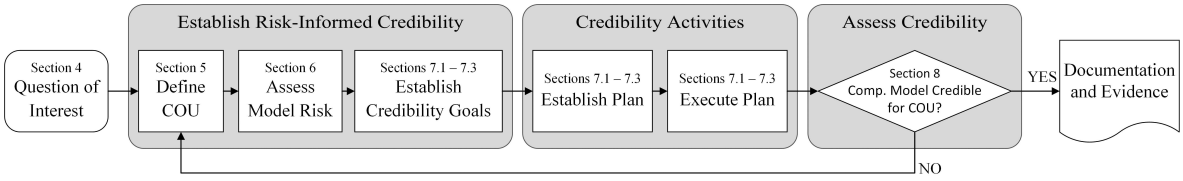
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AN EXAMPLE OF ASSESSING COMPUTATIONAL MODEL CREDIBILITY USING THE ASME V&V 40 RISK-BASED FRAMEWORK: TIBIAL TRAY COMPONENT WORST-CASE SIZE IDENTIFICATION FOR FATIGUE TESTING

1 INTRODUCTION

This Technical Report summarizes the application of the ASME V&V 40 credibility assessment framework to a computational model that simulates a mechanical test based on the ISO 14879-1 standard, which evaluates the fatigue performance of an orthopedic tibial tray component. Section 2 provides background on the credibility assessment framework and guidance on using this Technical Report. Section 3 provides a general overview of tibial tray design and evaluation, including a description of the mechanical test method. Sections 4 through 8 follow the ASME V&V 40 credibility assessment framework up to Documentation and Evidence. Figure 1-1 provides the section number where each element of the ASME V&V 40 credibility assessment framework is examined in this Technical Report.

Figure 1-1
Sections Associated With Each Element of the ASME V&V 40 Risk-Informed Credibility Assessment Framework



2 BACKGROUND

2.1 Incorporation of ASME V&V Standard Series

ASME V&V 40 provides a framework for establishing the risk-informed credibility requirements of a computational model for a context of use (COU). It offers practical insights into computational model credibility assessment that can be applied during medical device development and regulatory review. ASME V&V 10, ASME V&V 10.1, and ASME V&V 20 influenced this Technical Report's verification, validation, and uncertainty quantification (VVUQ) activities.

2.2 How to Use This Technical Report

This Technical Report interprets and applies the ASME V&V 40 standard through a realistic and representative medical device example problem with accompanying commentary. The document is intended to serve as a reference for executing a risk assessment, using the risk assessment results to plan VVUQ activities, and considering the outcomes of the VVUQ activities when assessing the credibility of the computational model for its context of use.

The VVUQ activities, risk assessment, and data presented within this case study should not be construed as guidance for regulatory submissions, nor should this Technical Report be interpreted as a reporting template to regulatory agencies. This example does not provide formal guidance for validating computational models of medical devices.

2.2.1 Question of Interest, Context of Use, and Model Risk Organization. Section 4, Question of Interest; Section 5, Context of Use; and Section 6, Model Risk, are formatted to include Guidance, Application, and Discussion subsections. These subsections contain the following information:

(a) The Guidance subsection provides insight from ASME V&V 40 and other sources with relevant information.