An Integrated Computational Platform to Assess Safety and Compatibility of Orthopedic Devices

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Introduction

Regulatory bodies impose **stringent pre-market controls** to certify the **safety and compatibility** of **medical devices**.

Standard tests required for **regulatory submission** may be **expensive**, **time-consuming** and **challenging** for **orthopedic implants** because of **many possible sizes and configurations**.

Modeling and simulation (M&S) tools can be used to **provide efficiencies** in the **amount of physical testing** to be conducted**.**

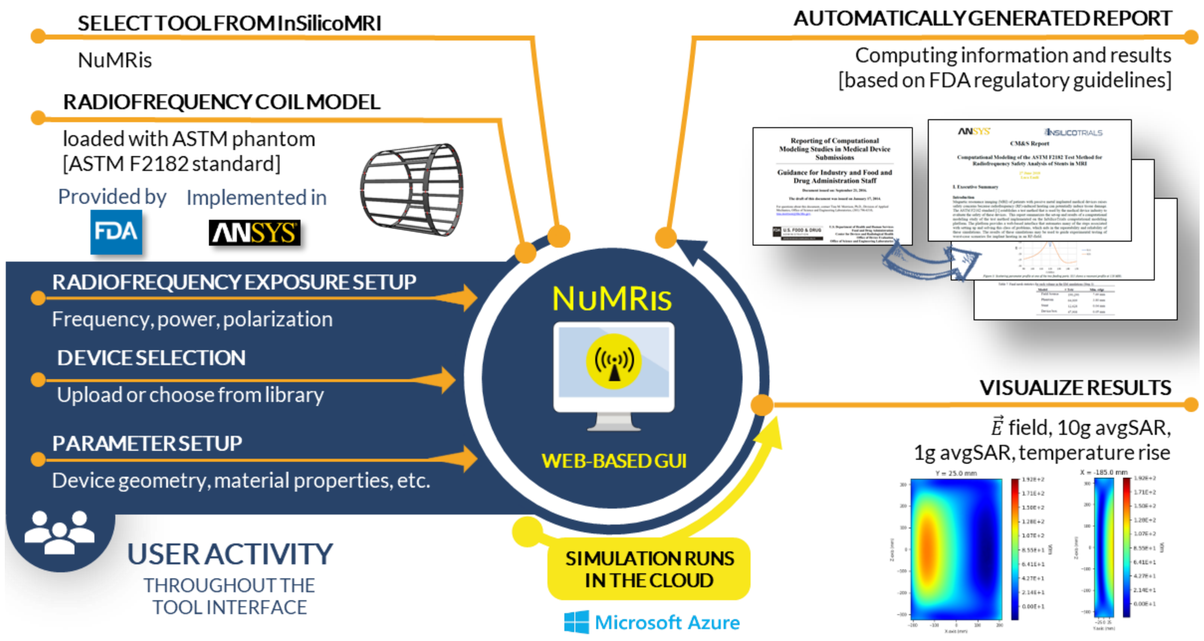
InSilicoTrials.com is an **integrated computational platform** with **several applications** for ***in silico* testing of orthopedic devices**, in line with **recognized standards** and **regulatory guidelines**.

Materials and Methods

Two **ASTM applications** were developed within the **InSilicoOrtho digital library**. The **M&S workflows** were implemented on the **CONSELF platform** (https://conself.com/) using **Salome-Meca 2017** to compute **static implant stresses and strains** on **metallic orthopedic devices**, following the requirements and considerations of **ASTM F2996-13** for non-modular hip femoral stems [1] and **ASTM F3161-16** for total knee femoral components [2]. **Simulation results** were **consistent** with those **reported in the two standards**.

Overview of the InSilicoOrtho cloud-based applications workflow

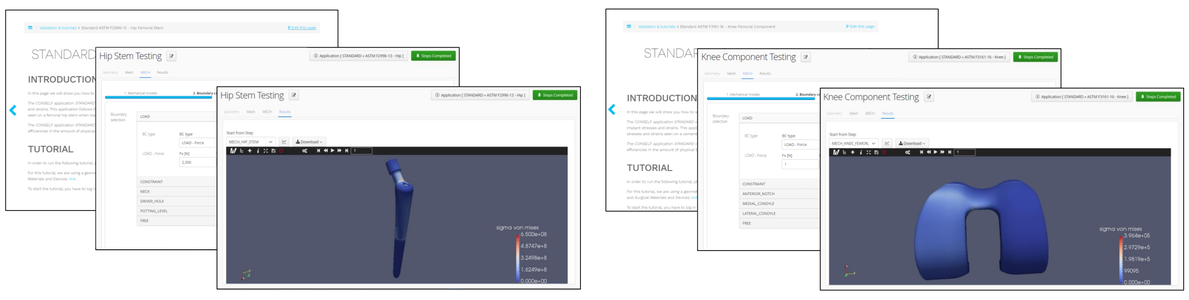
The **NuMRis application** (https://numris.insilicomri.com/) was developed within the **InSilicoMRI digital library**. The **M&S workflow** was implemented using **ANSYS HFSS** and **ANSYS Mechanical 2019R3** to compute **RF energy absorption** and **thermal heating** for **1.5 T and 3 T MRI systems**, replicating the **ASTM F2182-11a Standard Test Method** [3]. **Simulation results** were **validated against in vitro measurements**.



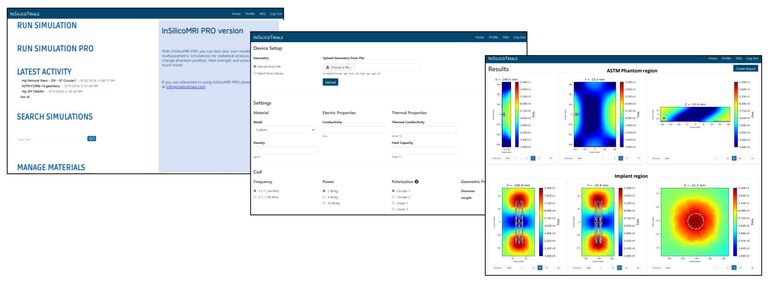
Overview of the NuMRis cloud-based application workflow

Results

The **web interfaces** of the **cloud applications** allow the user to easily **define** the **geometry** and **material parameters** of the **device**, automatically **set-up testing scenarios**, **run simulations** and **process outcome**, with the option to **summarize the results** in accordance with current **FDA guidance on M&S reporting** [4].

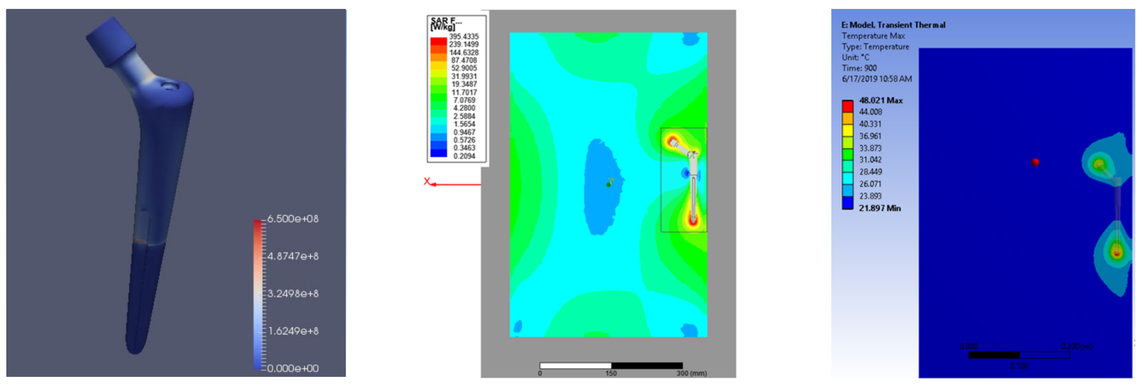


Web interface of the InSilicoOrtho cloud applications



Web interface of the NuMRis cloud applications

The **integrated platform** can be used to **evaluate design alternatives**, test **multi-configuration devices**, perform **multi-objective design optimization** and identify **worst-case scenarios** within a family of implant sizes.



Max Principal Stress (MPa)		Neck length (mm)				
		55	50	45	40	35
Neck angle (°)	135	775.50	754.04	704.22	625.64	452.68
	130	805.75	743.61	693.50	644.62	492.74
	125	773.81	728.69	671.72	648.10	506.06

Max SAR-1g (W/Kg)		Neck length (mm)				
		55	50	45	40	35
Neck angle (°)	135	389.38	393.05	394.42	394.86	395.67
	130	389.01	391.65	394.31	394.19	394.70
	125	388.46	390.88	393.37	395.26	395.62

Max Temp. (°C)		Neck length (mm)				
		55	50	45	40	35
Neck angle (°)	135	46.22	48.17	46.90	45.42	46.70
	130	45.82	45.99	46.99	46.32	46.10
	125	46.04	47.52	46.38	46.85	46.19

Worst-case assessment within a family of hip femoral stems. From left to right: Simulation of Maximum Principal Stress (ASTM F2996-13), Specific Absorption Rate (ASTM F2182-11a) and Temperature Increase (ASTM F2182-11a)

Discussion

InSilicoTrials.com contains a **collection of M&S applications** to assess the **safety** and **compatibility** of **orthopedic implants** before prototyping, **helping manufacturers** to **accelerate time** and **reduce costs** during the **device development**.

***In silico* testing** provide **manufactures** with the **information** they need to **improve design confidence and reliability**, **accelerate design cycles and processes**, and **avoid unnecessary tests**.

The proposed platform promotes the **broader adoption of digital evidence** in preclinical trials, supporting the **device submission process** and **pre-market regulatory evaluation,** and helping **secure regulatory approval**.

References
[1] ASTM F2996-13 – Standard Practice for Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems.
[2] ASTM F3161-16 – Standard Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions.
[3] ASTM F2182-11a - Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging.
[4] Reporting of Computational Modeling Studies in Medical Device Submissions, FDA guidance 2016.