An Integrated Cloud Platform to Perform *In Silico* Standard Testing for Orthopedic Implants

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INTRODUCTION

Regulatory bodies impose **stringent pre-market controls** to certify the **safety, efficacy** and **compatibility** of **orthopedic devices**. However, **standard tests** may be **challenging** because of **many possible sizes and configurations**. Moreover, **cost and time** of standard testing may **nullify** the advantages of **3D-printed custom implants**.

We engineered an **integrated cloud platform** to perform ***in silico* testing** for **orthopedic implants**, assessing **mechanical safety** and **electromagnetic compatibility** in a virtual environment, in line with **recognized standards** and **regulatory guidelines**.

METHODS

The InSilicoTrials.com platform contains two numerical tools for orthopedic implants:

- **CONSELF** (conself.com) uses **Salome-Meca 2017** to compute **static implant stresses** and **strains** on orthopedic devices, following the requirements and considerations of **ASTM F2996-20** Standard Practice for **nonmodular hip femoral stems** [1] and **ASTM F3161-16** Standard Test Method for **total knee femoral components** [2]. **Simulation results** were **consistent** with those **reported** in the two standards.
- **NuMRis** (numris.insilicomri.com) uses **ANSYS HFSS** and **ANSYS Mechanical 2019R3** to compute **radio-frequency energy absorption** and **induced heating** during **MRI** using **1.5T** and **3T coils**, replicating the **ASTM F2182-19e2** Standard Test Method [3]. **Simulation results** were **validated** against **in vitro measurements**.

The **integrated Modeling and Simulation** (M&S) **workflow** on the **cloud platform** allows the user to **upload the 3D geometry** and the **material properties** of the **orthopedic implant** to be tested, automatically **set up** the **standard testing scenarios**, **run simulations**, and **process outcome**, with the option to **summarize the numerical results** in accordance with current **FDA guidance on M&S reporting** [4].

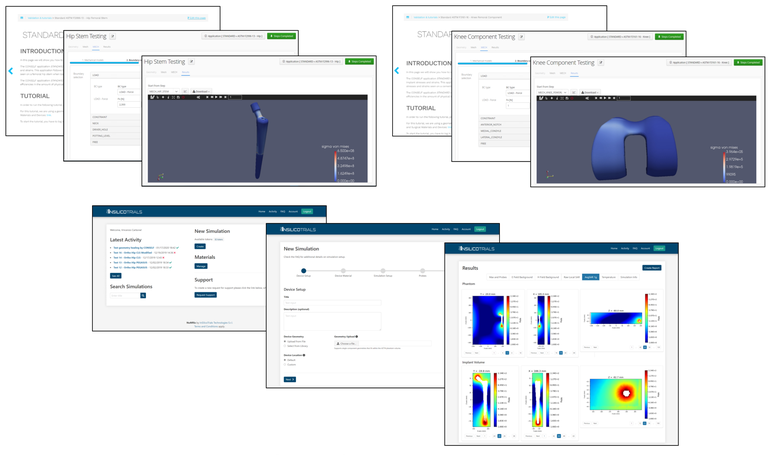

Figure 1: Web interface of the CONSELF and NuMRis tools.

RESULTS AND DISCUSSION

The **easy-to-use interfaces** run through **commercial web browsers**, requiring **no specific computational expertise** and **no additional on-premises software** and **hardware resources**, since all **simulations** are **run remotely on cloud infrastructure**.

The **integrated cloud 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**, thus **reducing the amount of physical testing** to be conducted.

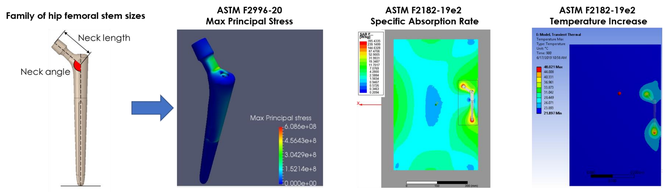

Figure 2: CASE EXAMPLE: Evaluation of design alternatives and identification of worst-case scenarios within a family of implant sizes.

CONCLUSIONS

InSilicoTrials.com is the **first cloud platform** offering a collection of **M&S tools** to perform ***in silico* standard testing** for **orthopedic implants**. The proposed tools allow **manufacturers** and **points-of-care** to **easily assess mechanical safety and electromagnetic compatibility of generic and custom devices before prototyping**, **preventing risks** and **criticalities** for the **patient**, and helping to **accelerate time** and **reduce costs** of **device development**.

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 **accelerate regulatory approval**.

REFERENCES

[1] ASTM F2996-20, ASTM International.
[2] ASTM F3161-16, ASTM International.
[3] ASTM F2182-19e2, ASTM International.
[4] Reporting of Computational Modeling Studies in Medical Device Submissions, FDA guidance, September 2016.