

# Personalized Biomechanics: Computational Modeling & Simulation for Total Shoulder Arthroplasty

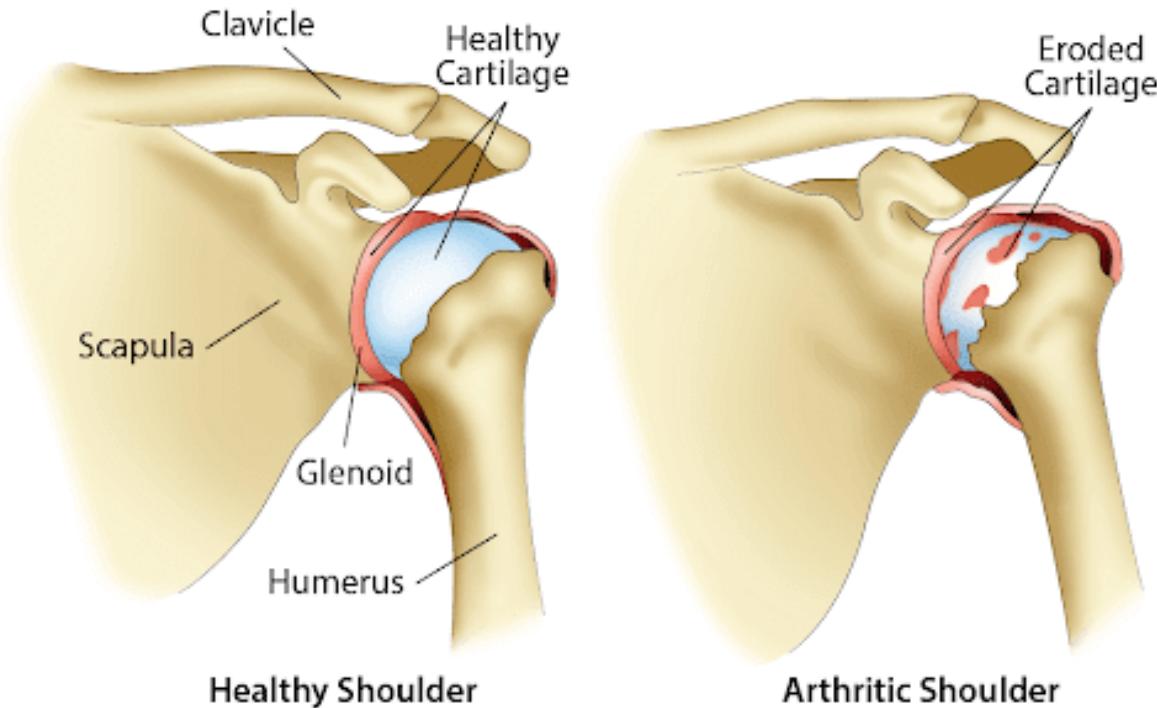
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(EPFL-LBO)

# Overview

- Clinical background
- Research methods (LBO experience)
- Clinical, Cadaveric, Modeling
- MusculoSkeletal Modeling
- Finite Element Modeling
- Deep-Learning Modeling
- Populated models
- Causal Bayesian statistics
- Conclusions

# Clinical background: joint degeneration



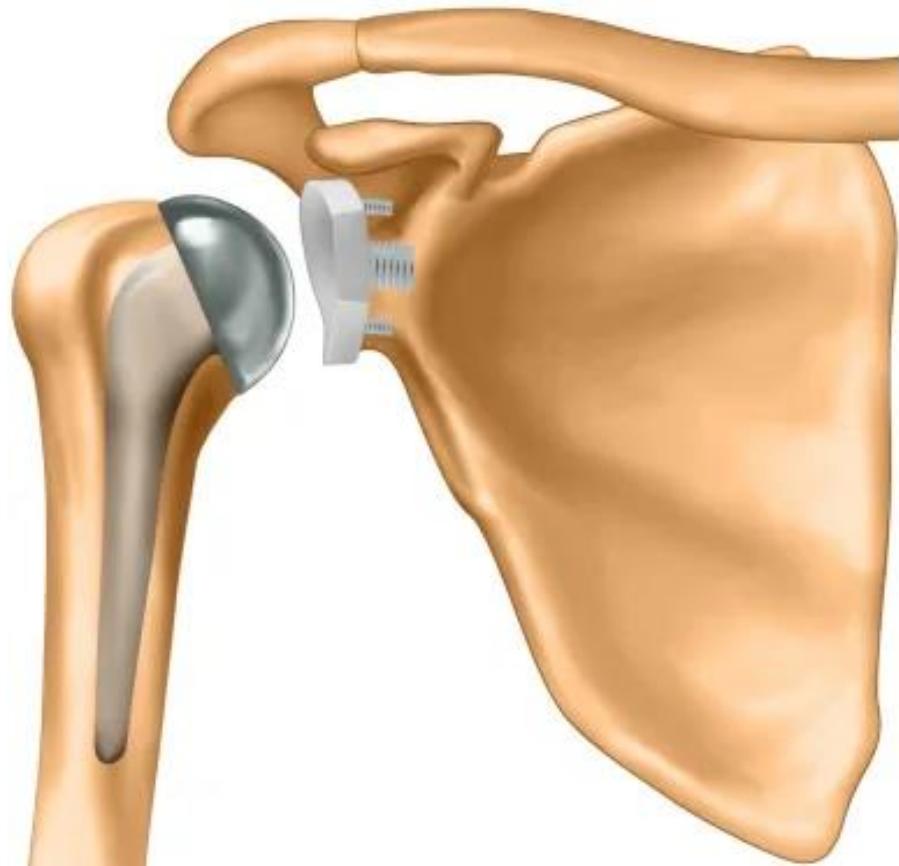
- Osteoarthritis (OA) world's most common joint disease
- Currently no cure
- Glenohumeral osteoarthritis (GHOA) accounts for 5%–17% of patients with shoulder complaints
- Etiology of GHOA is multifactorial

<https://centenoschultz.com/condition/shoulder-arthritis/>

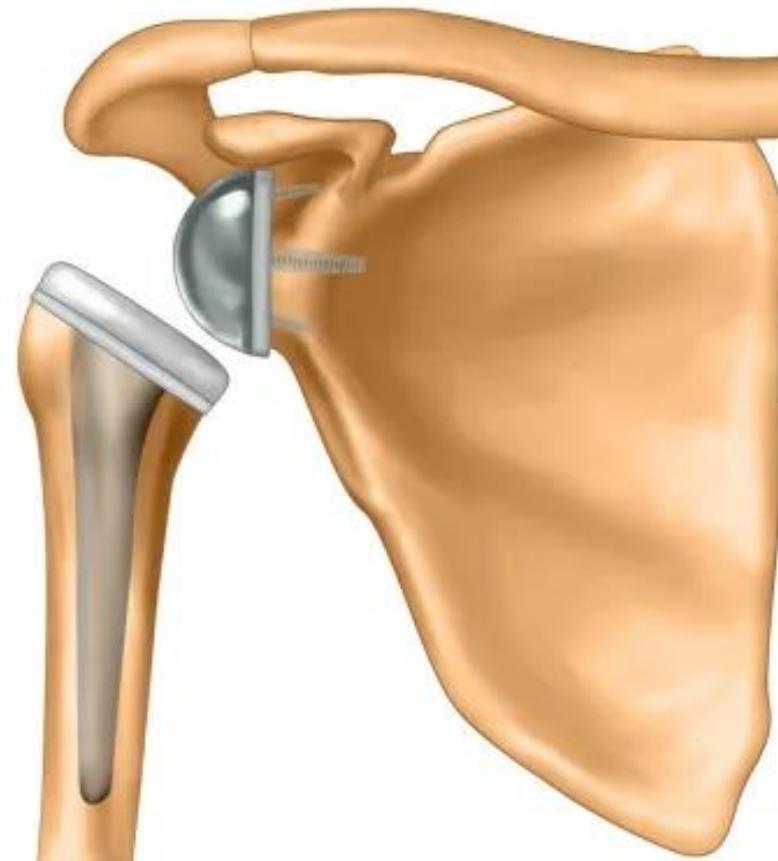
<https://doi.org/10.1177/1457496920935018>

# Clinical background

Anatomic Total Shoulder Arthroplasty  
(ATSA)



Reverse Total Shoulder Arthroplasty  
(RTSA)



# Complications of Shoulder Arthroplasty

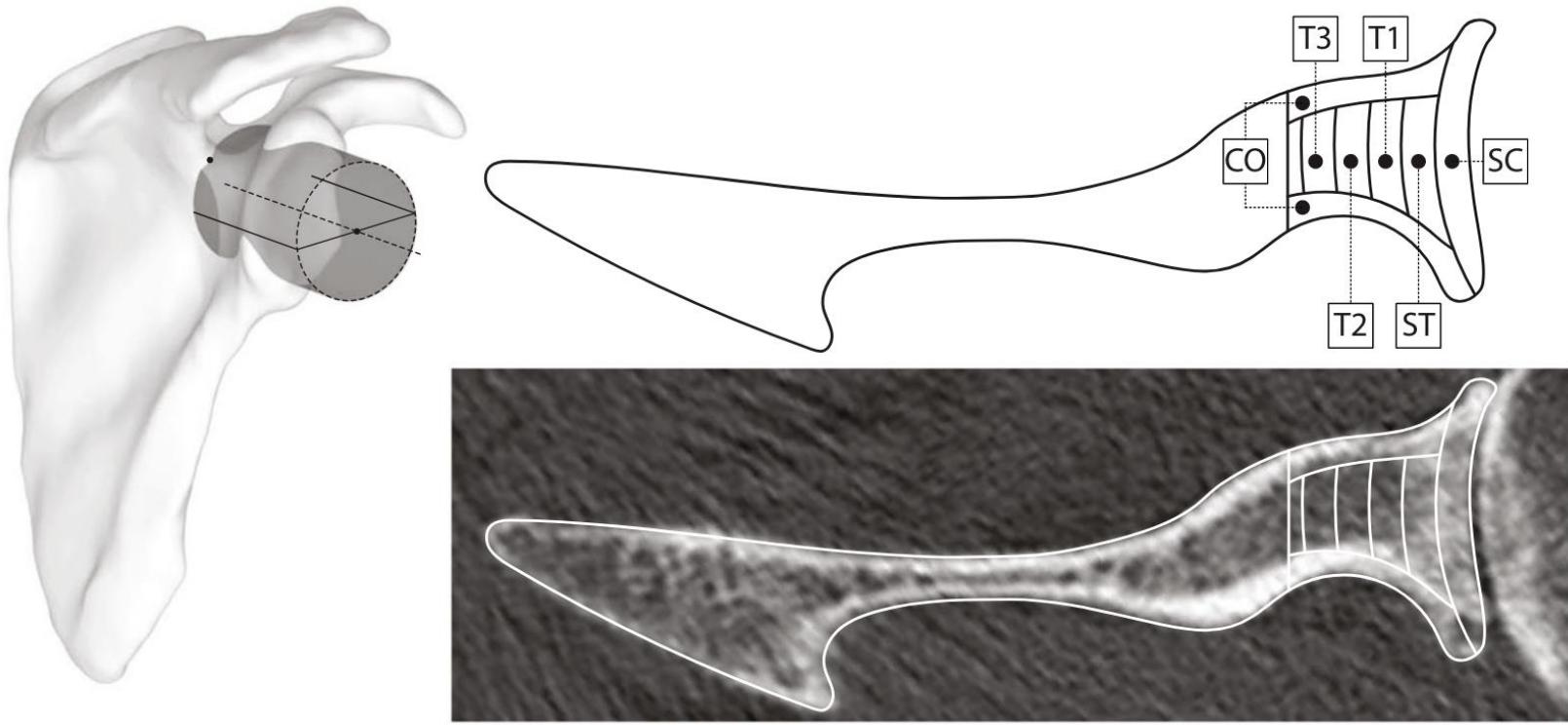
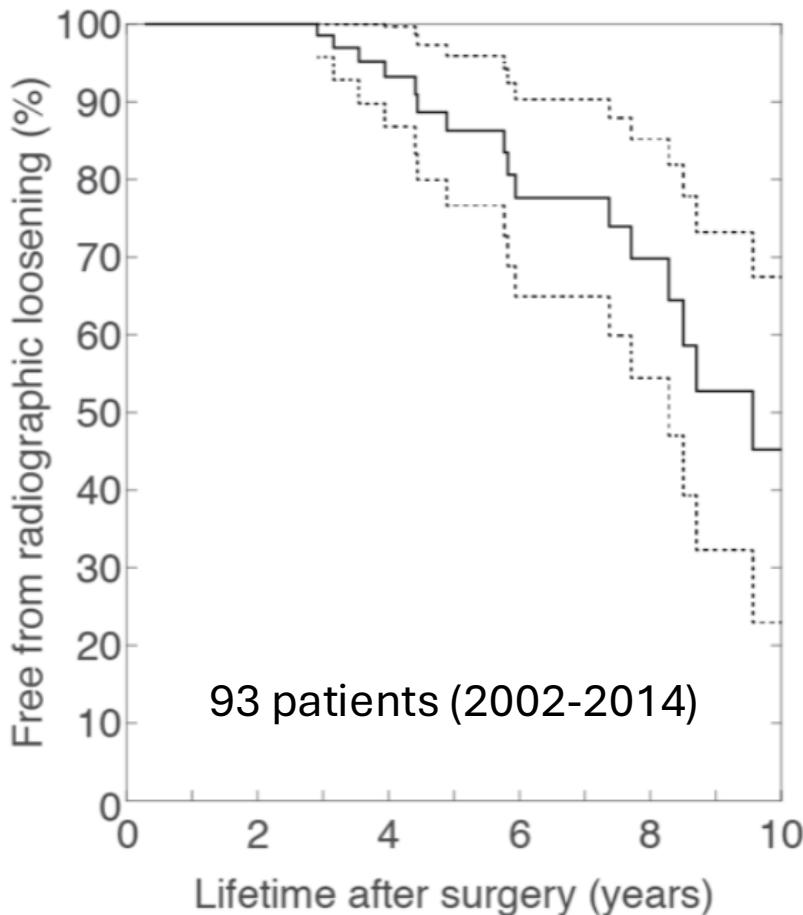
- Meta-analysis of Bohsali et al. (2017)
  - 2006 - 2015, 122 studies, mean follow-up 40.3 months
- ATSA (3360 cases)
  - Complication rate: 10.3%
  - Most frequent: component loosening, glenoid wear, instability
- RTSA (4142 cases)
  - Complication rate: 16.1% for RTSA
  - Most frequent: instability, periprosthetic fracture, infection

# Methods to understand/reduce complications

- Clinical trials (randomized multicenter double-blind)
  - Strongest evidence, but time-consuming and expensive
- Cadaveric experiments
  - Realistic anatomy and biomechanics, but not cheap, not clinical reality
- Numerical modeling
  - Fast, cheap, control all variables, but simplification, validation
- In-silico trials
  - Same as above +
  - Personalization, ethical, but requires a lot of (high-quality) data

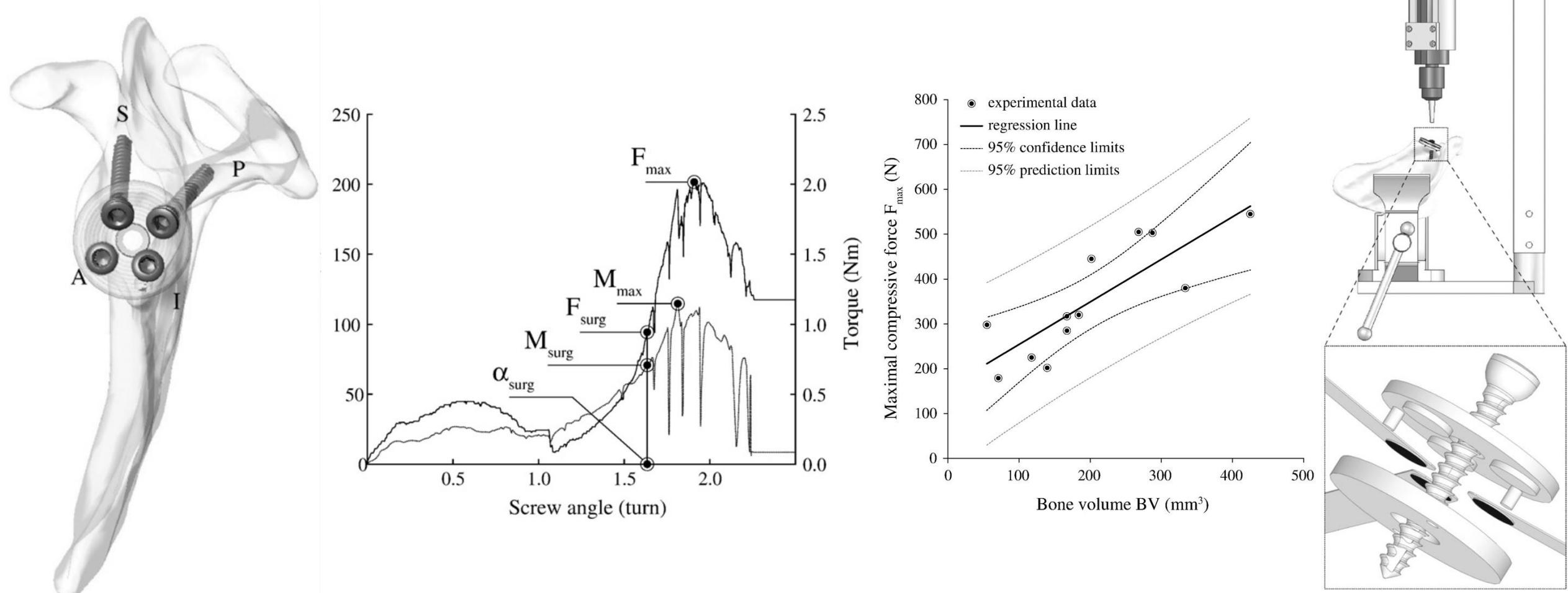
# Clinical trial example

Is preoperative glenoid bone mineral density associated with aseptic glenoid implant loosening in anatomic total shoulder arthroplasty?



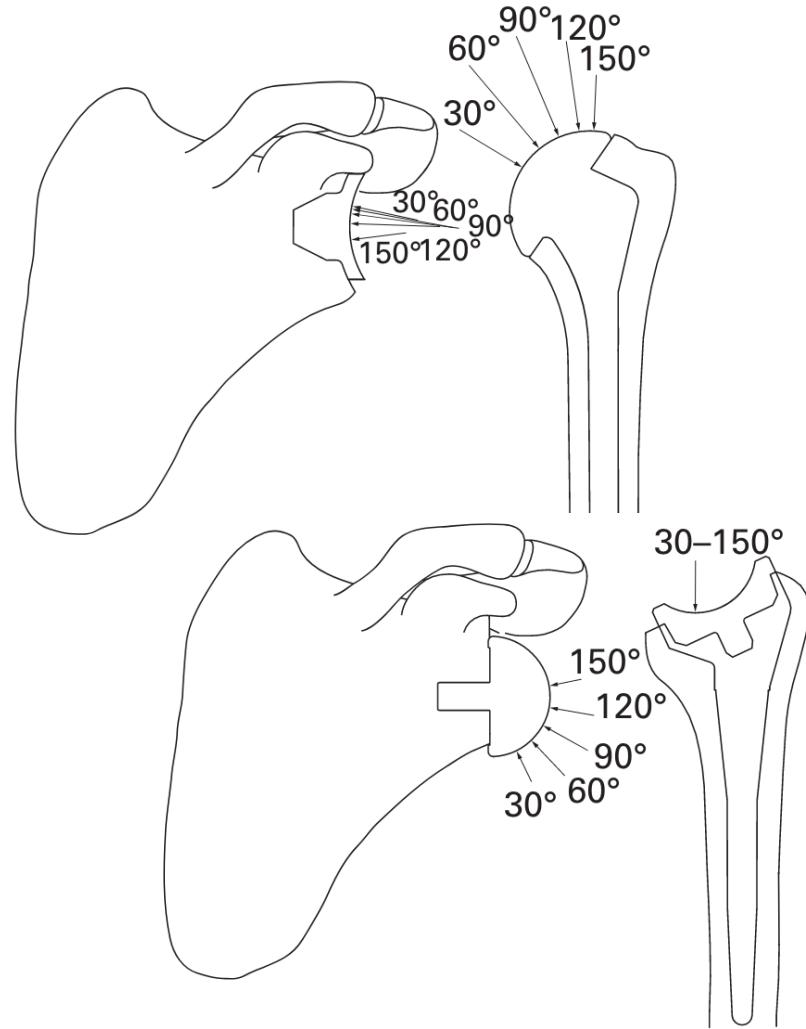
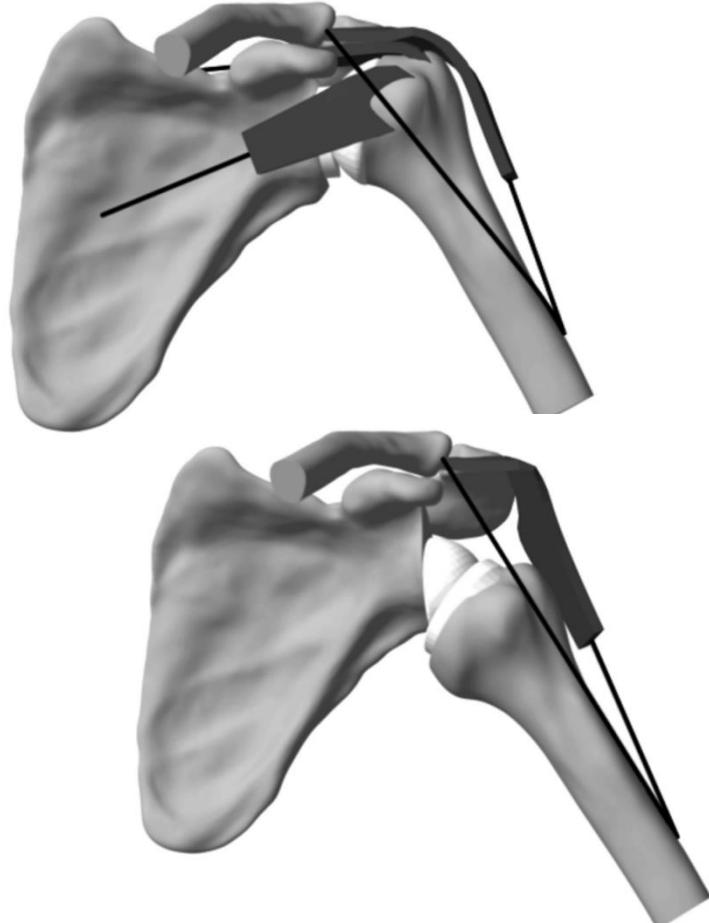
# Cadaveric experiment example

Tightening force and torque of nonlocking screws in a reverse shoulder prosthesis

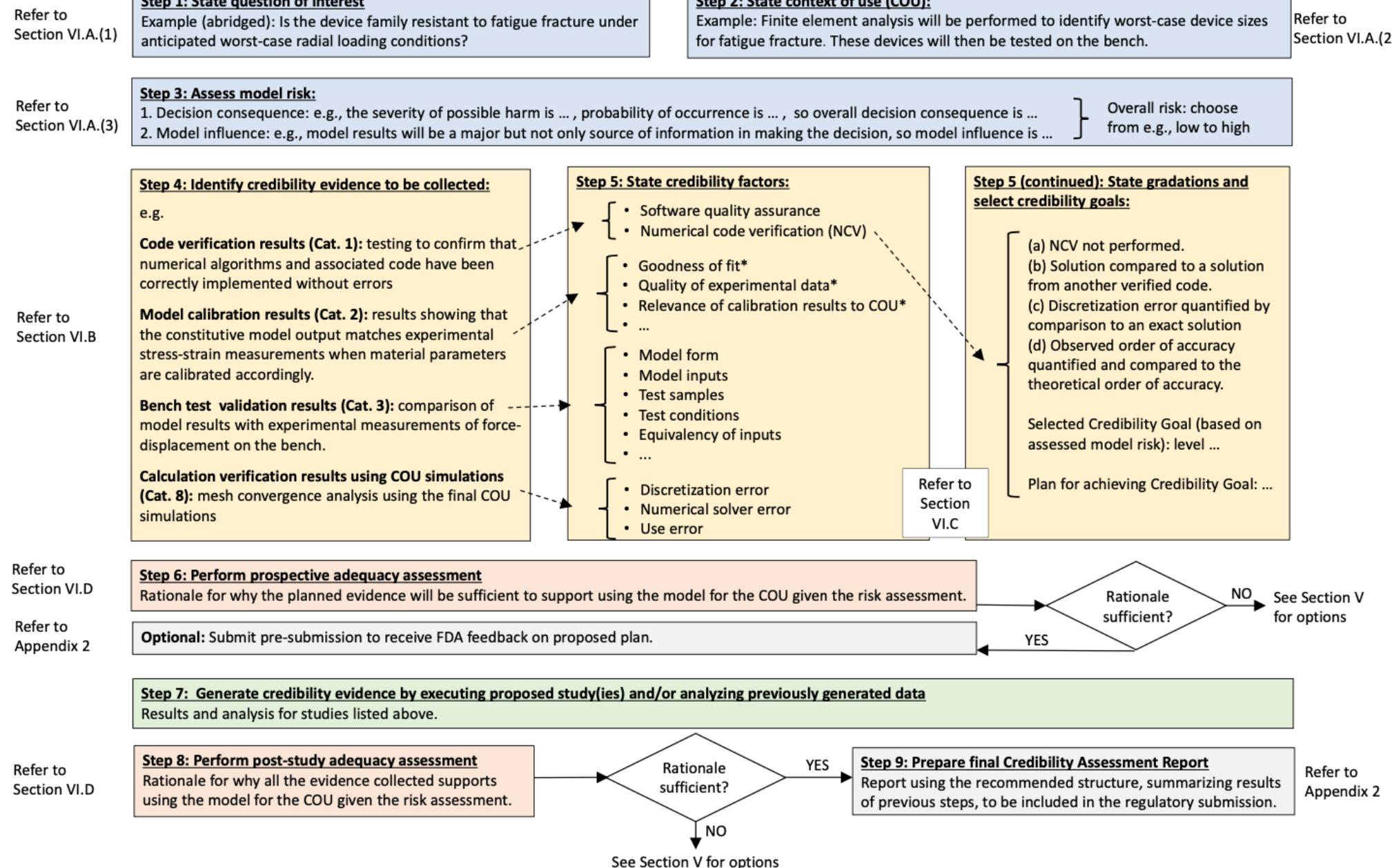


# Numerical model example

Simulated joint and muscle forces in reversed and anatomic shoulder prostheses



# Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions (2023)



# Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions (2023)

Refer to  
Section VI.A.(1)

## Step 1: State question of interest

Example (abridged): Is the device family resistant to fatigue fracture under anticipated worst-case radial loading conditions?

Refer to  
Section VI.A.(2)

Refer to  
Section VI.A.(3)

## Step 2: State context of use (COU):

## Step 3: Assess model risk:

1. Decision consequence: e.g., the severity of possible harm is ... , probability of occurrence is ... , so overall decision consequence is ...
2. Model influence: e.g., model results will be a major but not only source of information in making the decision, so model influence is ...

Overall risk: choose  
from e.g., low to high

## Step 4: Identify credibility evidence to be collected:

## Step 5: State credibility factors:

- Software quality assurance

## Step 5 (continued): State gradations and select credibility goals:

The FDA promotes the use of in silico clinical trials using Computational Modeling and Simulation (CM&S), in which a device is tested on a cohort of virtual patients, which is anticipated to replace or supplement clinical trials.

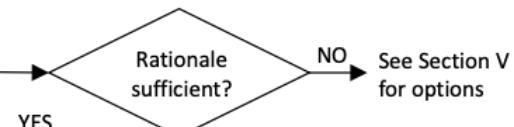
Refer to  
Section VI.D

## Step 6: Perform prospective adequacy assessment

Rationale for why the planned evidence will be sufficient to support using the model for the COU given the risk assessment.

Refer to  
Appendix 2

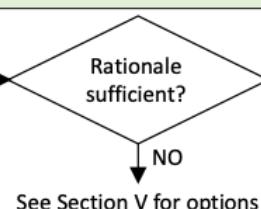
Optional: Submit pre-submission to receive FDA feedback on proposed plan.



Refer to  
Section VI.D

## Step 8: Perform post-study adequacy assessment

Rationale for why all the evidence collected supports using the model for the COU given the risk assessment.



Refer to  
Appendix 2

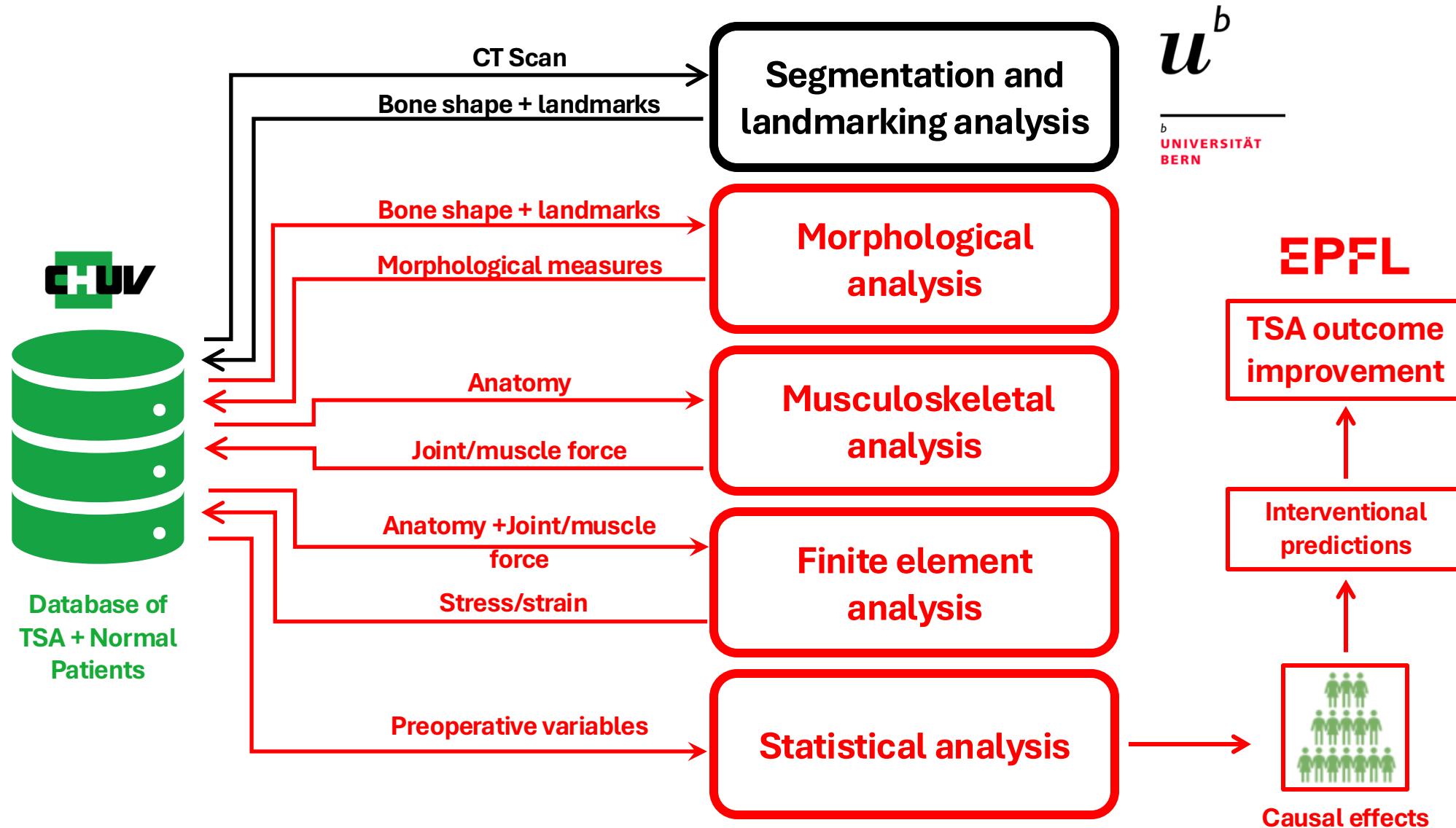
# Comments on FDA recommendations

- Risk analysis
  - Uncertainty of simulation predictions
  - Potential adverse effect of false prediction
- Virtual vs real patients
  - Link with real outcome (for virtual patients)
- Link between simulated quantities and clinical quantities

# Computational modeling

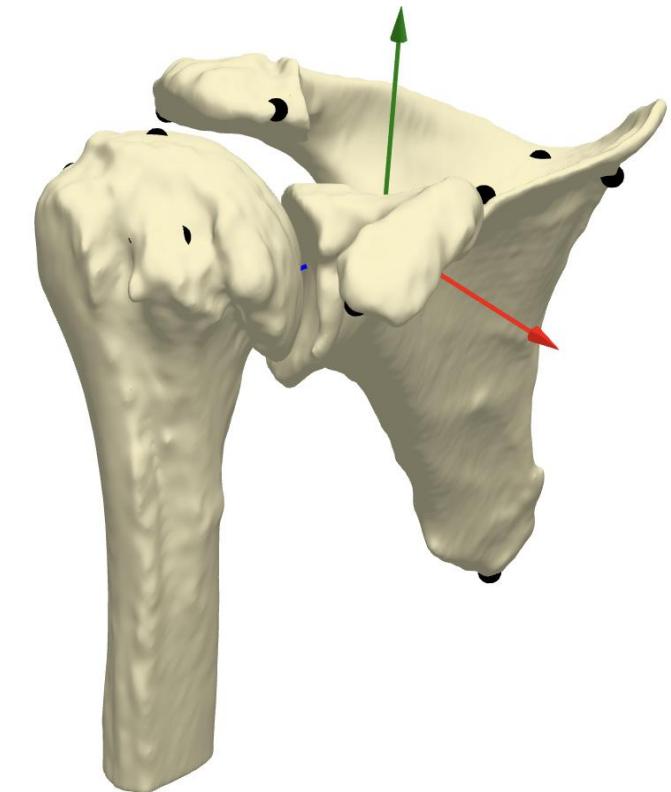
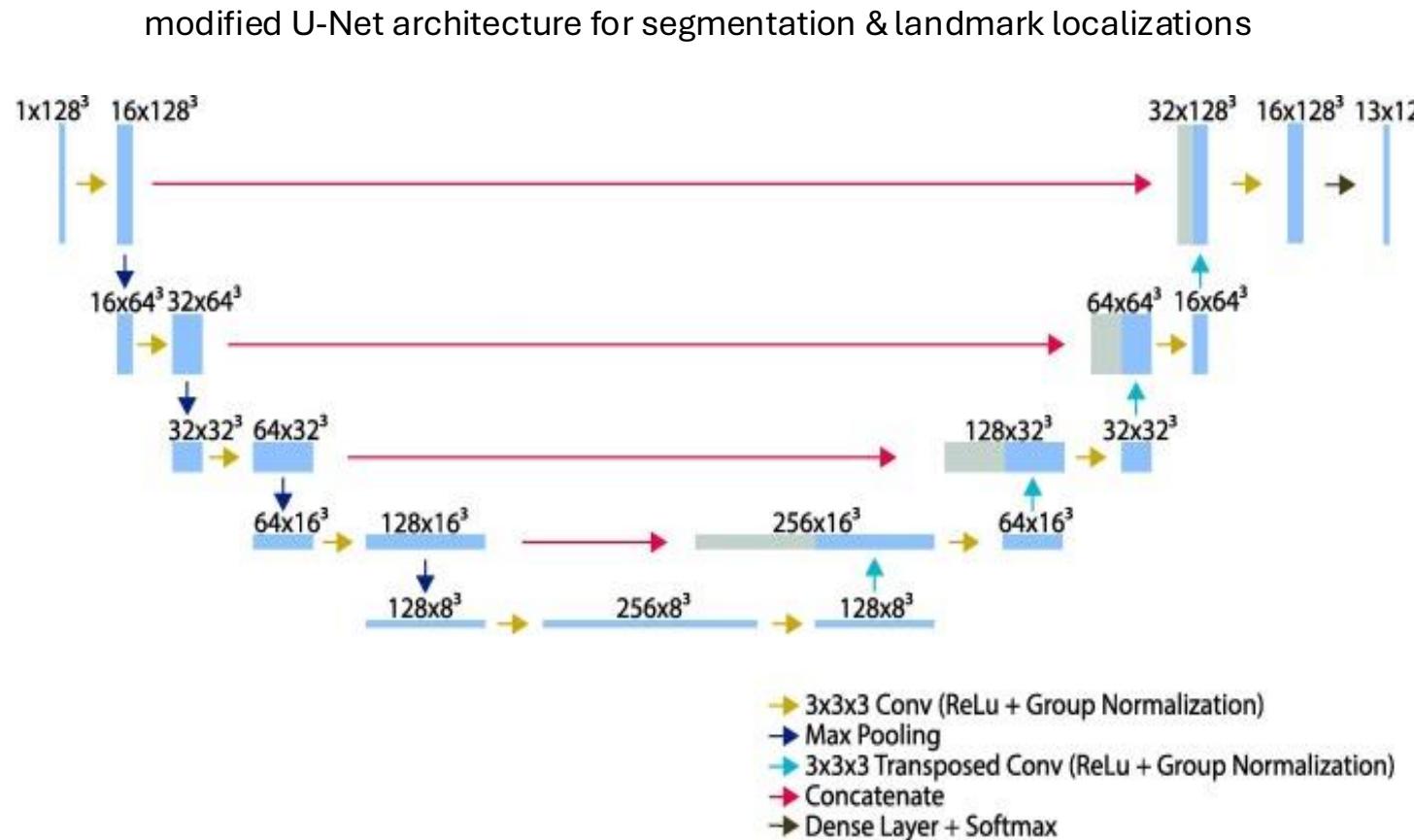
- Importance of Finite Element Modeling (FEM)
- Create FEM from cadaveric data (one or few cases)
- Create FEM from patient data (one or few cases)
- Create FEM from (many) virtual/real patients
- Difficulty in automating the process for a large number of patients
- Importance of statistical methods
- Manage patient variability

# Project: Effect of preop on TSA complications



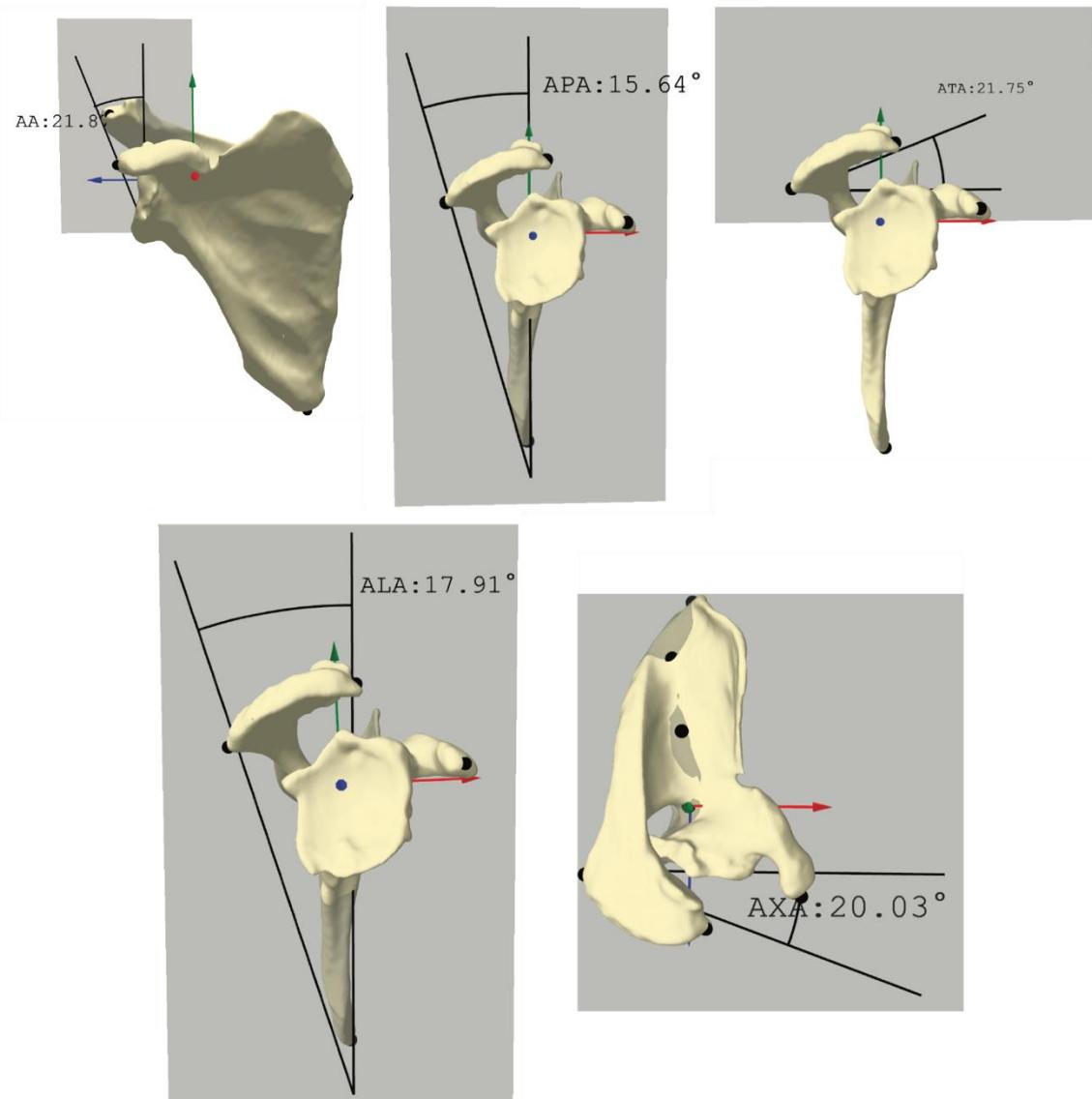
# Deep Learning Model for segmentation

Preop CT scan → surface + anatomical landmarks of scapula + humerus



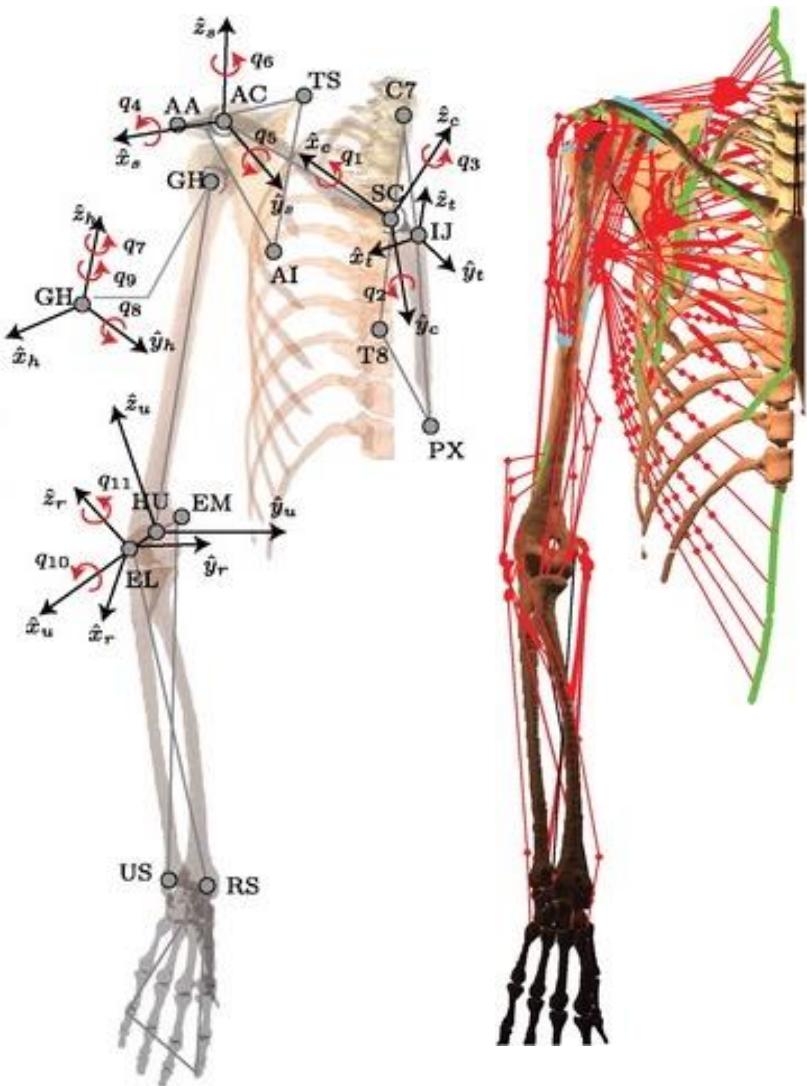
# Morphological analysis

- Glenoid version angle (GVA)
- Glenoid inclination angle (GIA)
- Glenoid bone mineral density (BMD)
- Acromion angle (AA)
- Acromion posterior angle (APA)
- Acromion tilt angle (ATA)
- Acromion length angle (ALA)
- Acromion axial tilt angle (AXA)
- Rotator Cuff Degeneration
- Bone quality



# MusculoSkeletal Model

A Matlab toolbox for scaled-generic modeling of shoulder and elbow

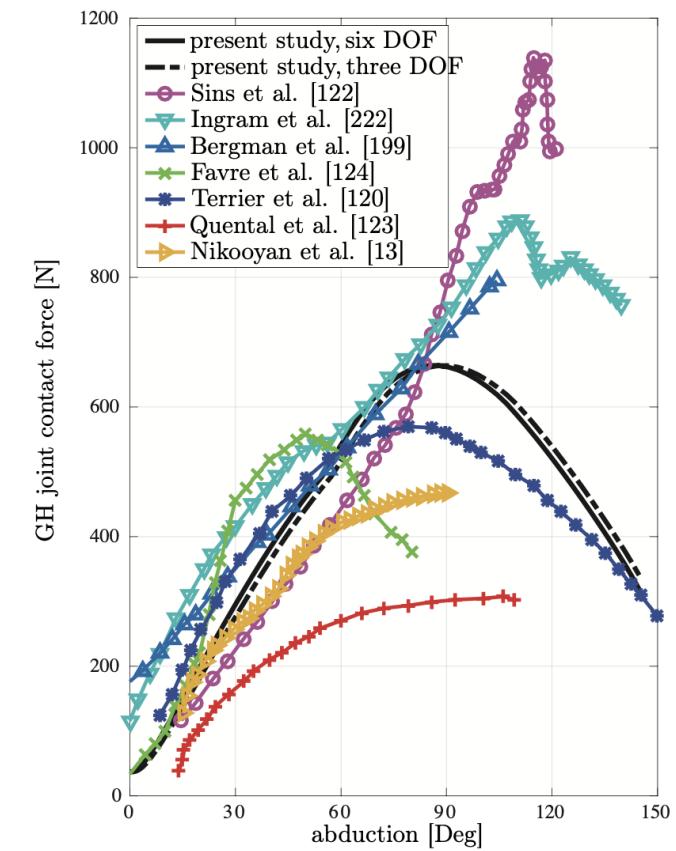


$$\min_{\tilde{f}} \tilde{f}^T P \tilde{f}$$

$$\text{s.t. } \frac{d}{dt} \left( \frac{\partial \mathcal{L}}{\partial \dot{q}} \right) - \frac{\partial \mathcal{L}}{\partial q} = \left[ \frac{\partial \Omega}{\partial \dot{q}} W \quad \frac{\Phi_{TS}}{\partial q} \quad \frac{\Phi_{AI}}{\partial q} \right] \tilde{f}$$

$$\mathbf{0} \leq \tilde{f} \leq \tilde{f}_{\max}$$

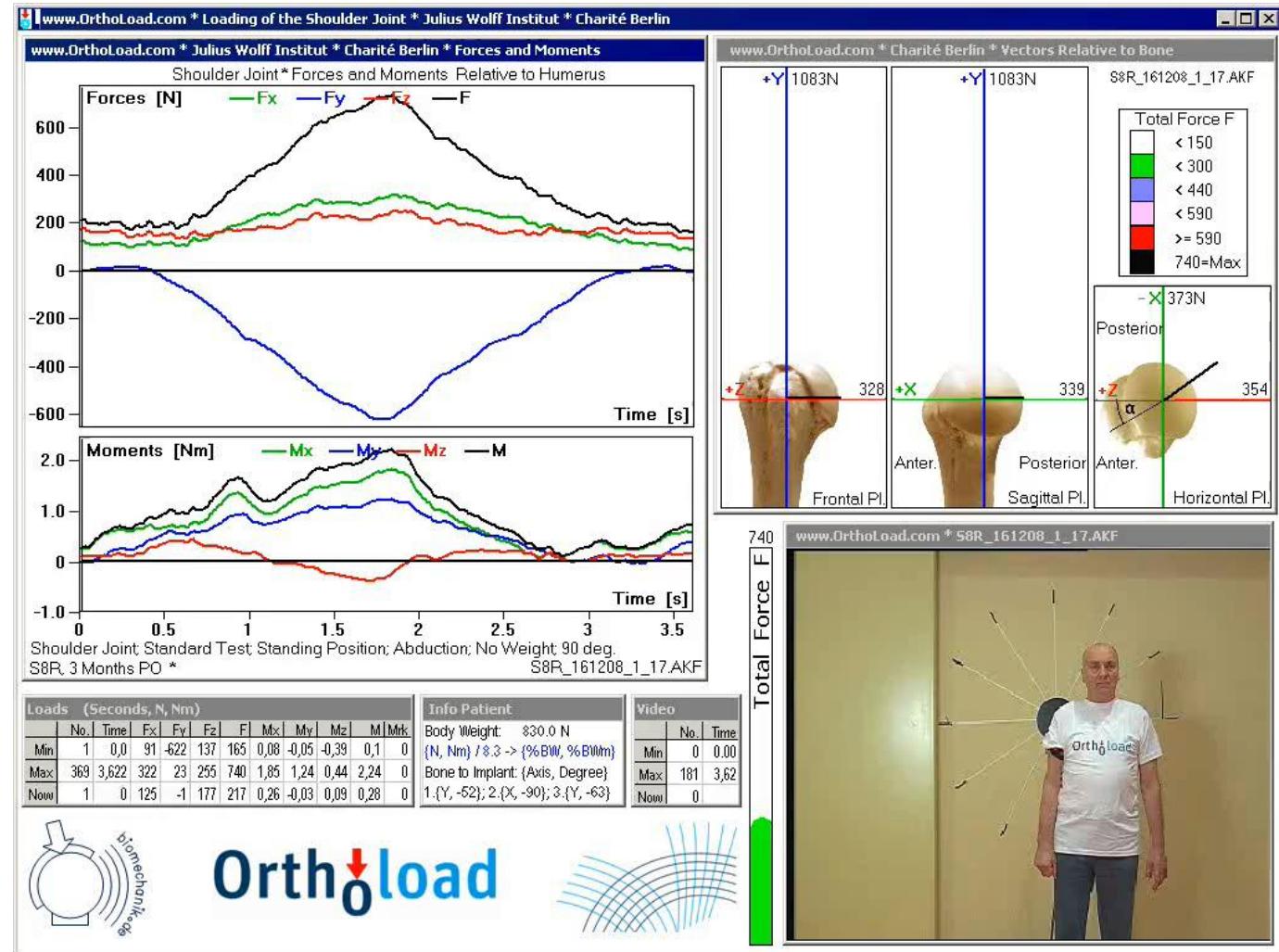
$$\psi(q, \dot{q}, \ddot{q}, \tilde{f}) \leq \mathbf{0}$$



# Measured joint force

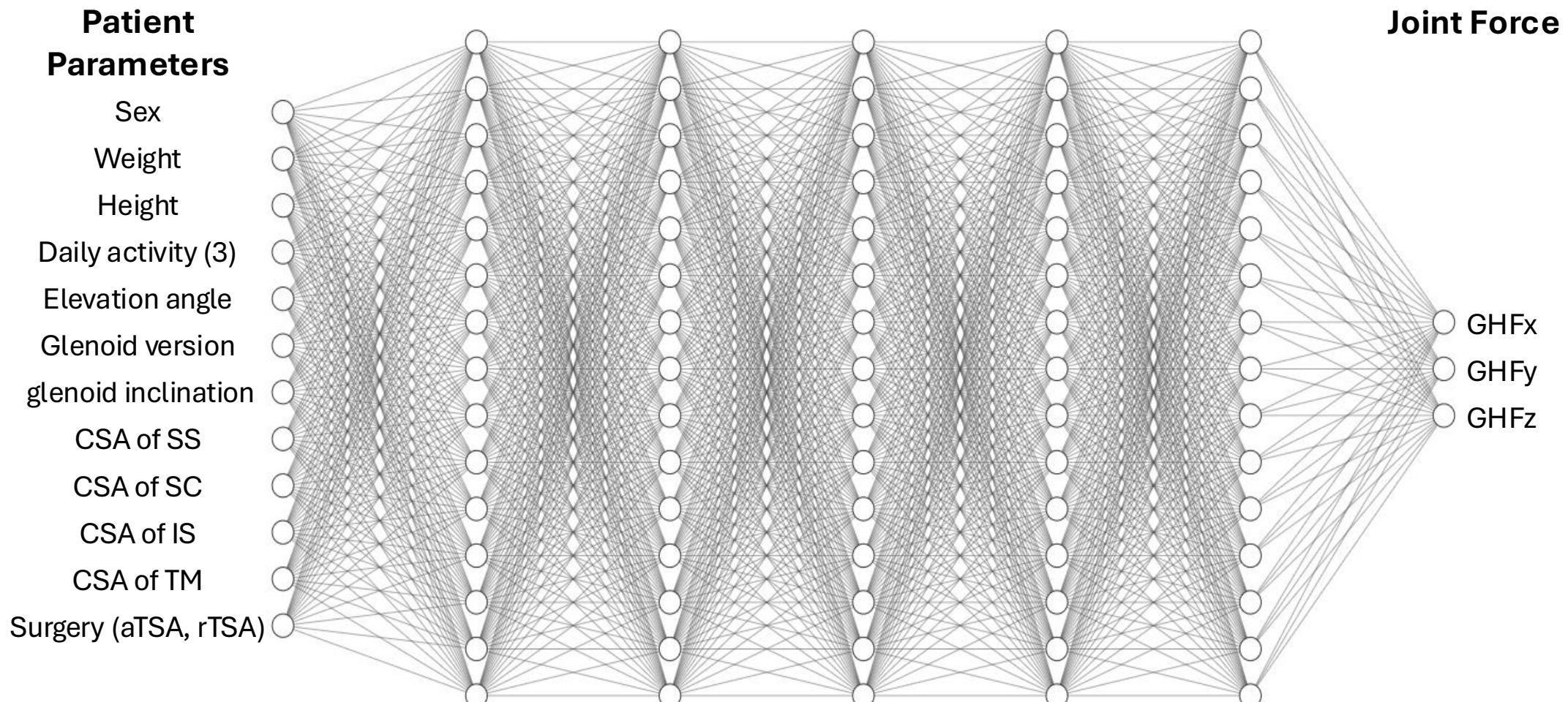


Instrumented  
Prosthesis



# Musculoskeletal Model → Deep Learning Model

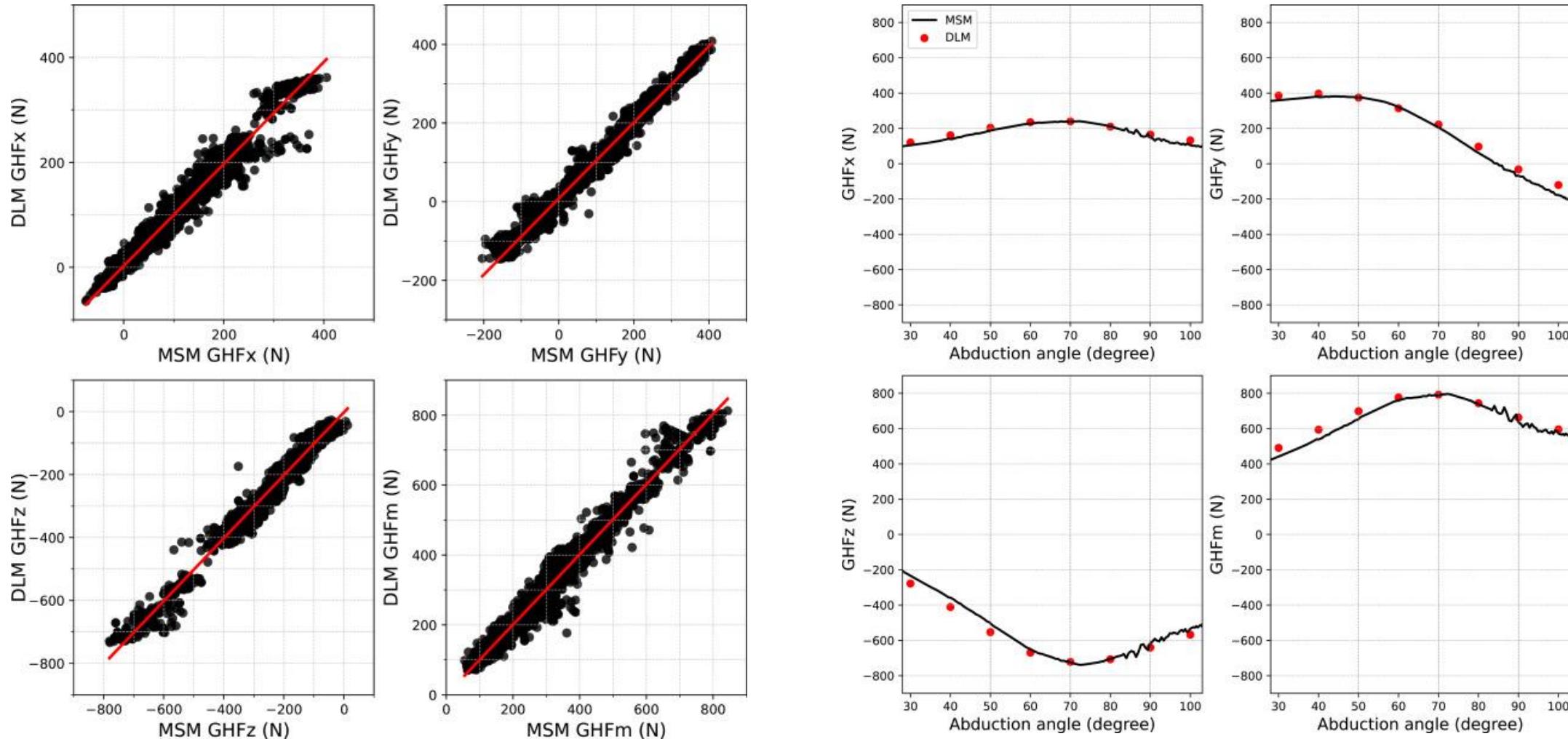
Glenohumeral joint force prediction with deep learning



# Musculoskeletal Model → Deep Learning Model

- 959 virtual subjects
  - Sampling from clinical registry with Markov-Chain-Monte-Carlo
- Training (80% of subjects)
  - Fully-connected neural network
  - Training: backpropagation algorithm, descent gradient, minimize loss function
  - Validation: hyperparameters tuning with Bayesian optimization
    - k-fold validation ( $k=5 \rightarrow 80\% \text{ training} \& 20\% \text{ validation}$ )  
→ 7 hidden layers of 250, 20, 250, 160, 90, 90, 100 neurons
  - Monte-Carlo drop-out (to avoid overfitting)
- Testing (20% of subjects, unseen by training)
  - Evaluating model efficiency

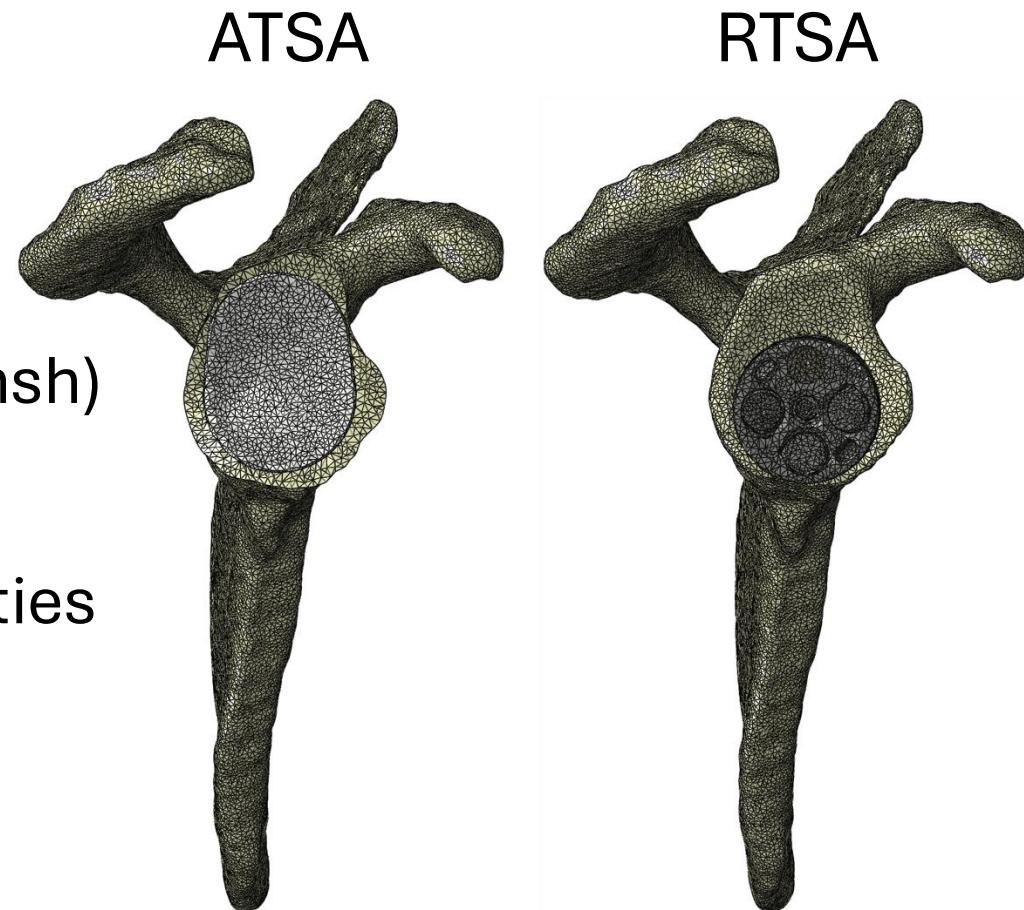
# Musculoskeletal Model → Deep Learning Model



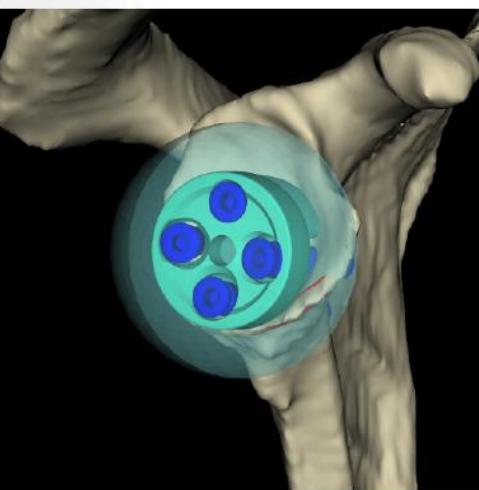
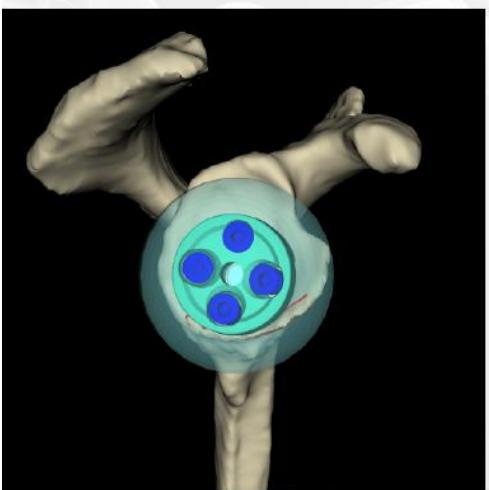
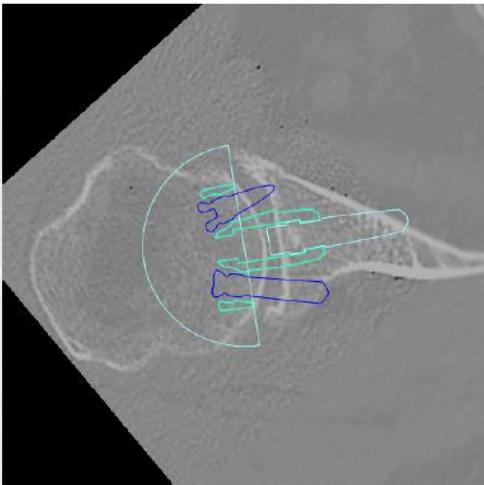
GHFm: Mean Absolute Error = 18.5 N,  $R^2 = 0.97$

# Automated Finite Element Model

- Bone geometry from DL segmentation
- Implant selection and positioning  
(From preoperative planning)
- Scapula and implant tetrahedral mesh (Gmsh)
- Bone reaming (PyMesh)
- Bone inhomogeneous linear elastic properties  
from preoperative CT  
(Python code)
- Force from DL MSM

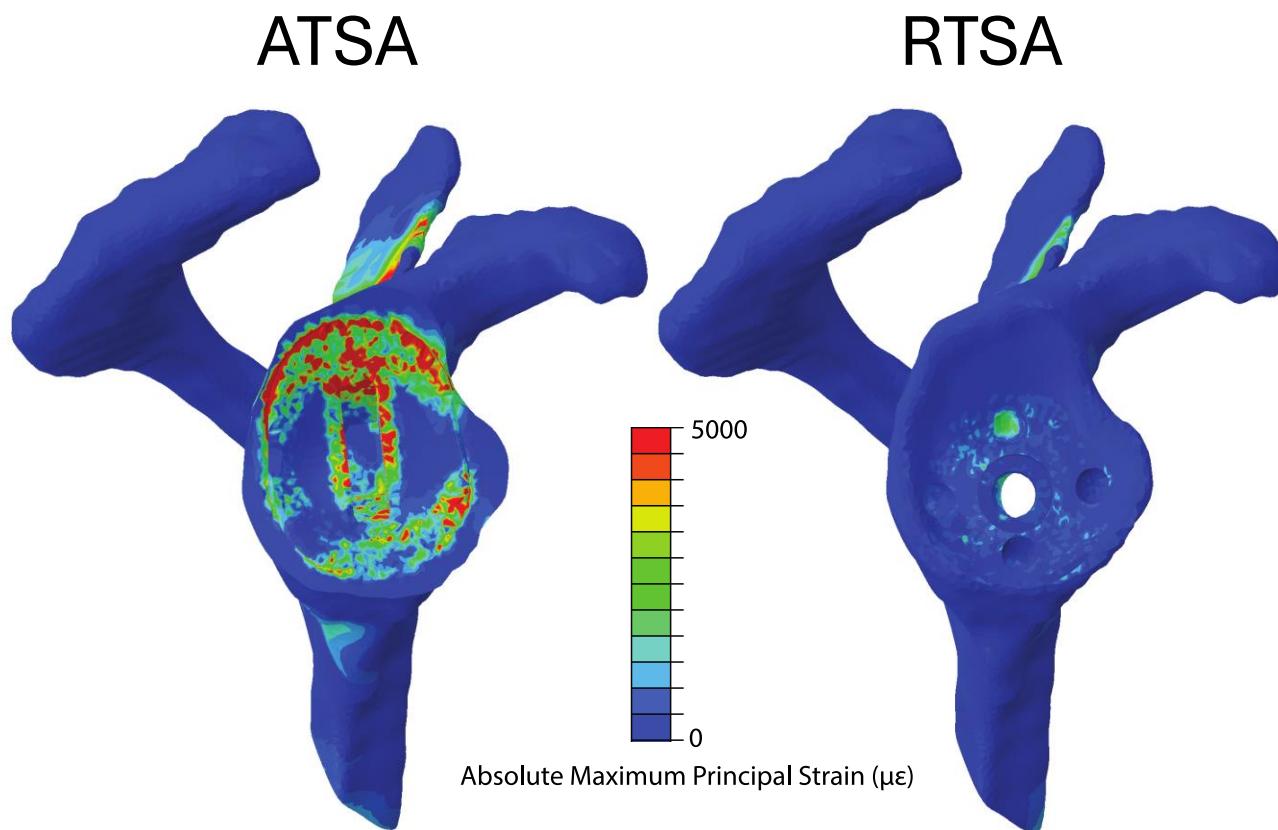


# Preoperative planning

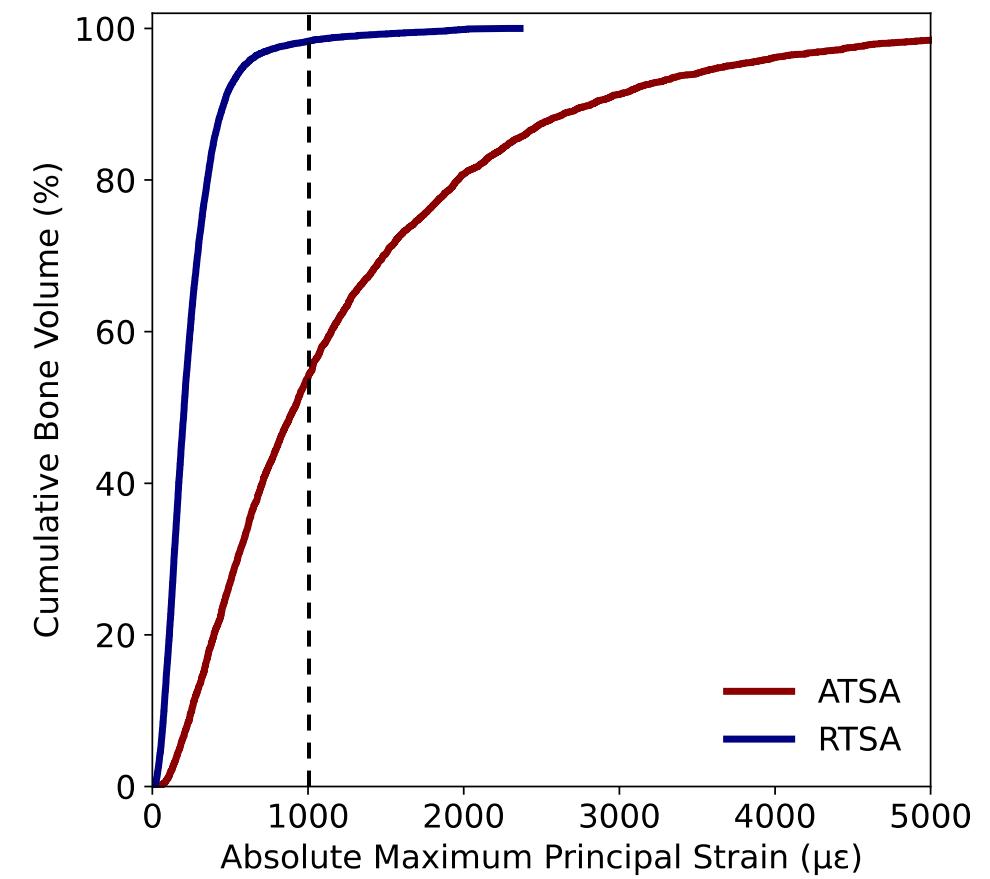


```
GlenoidImplant_PartNumber;DWJ505;;DWJ505
GlenoidImplant_PerformReversedPerforation;0;;0
GlenoidImplant_PerformReversedBasePlate;Wedge;Type de platine;Wedge
GlenoidImplant_PerformReversedBasePlateIsStandard;0;;0
GlenoidImplant_PerformReversedDiameter;25;Diamètre de la platine;25 mm
GlenoidImplant_PerformReversedOffset;0;Offset de la platine;0 mm
GlenoidImplant_PerformReversedAngle;Full;Angle de la platine;Full
GlenoidImplant_PerformReversedFixation;Central Screw;Fixation;Vis centrale
GlenoidImplant_PerformReversedFixationIsCentralPost;0;;0
GlenoidImplant_PerformReversedScrewDiameter;6.5;Diamètre de vis;6.5 mm
GlenoidImplant_PerformReversedScrewLength;30;Longueur de vis;30 mm
GlenoidImplant_PerformReversedCentralScrewPartNumber;DWJ530;;DWJ530
GlenoidImplant_Depth;-1;Médialisation;1 mm
GlenoidImplant_Inclination;4;Inclinaison glénoïdienne sup;4°
GlenoidImplant_Version;-9;Rétroversion glénoïdienne;9°
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# Automated Finite Element Model

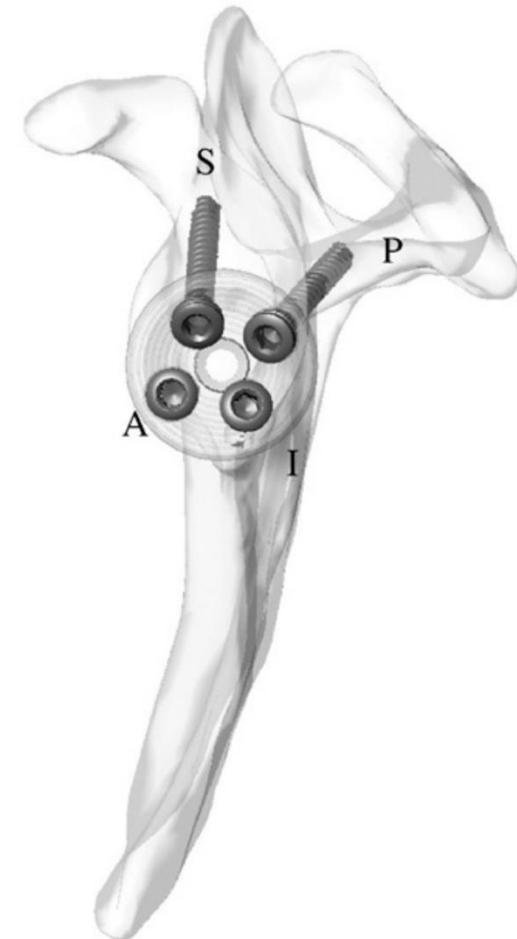


Volume Of Interest (VOI): 10 mm around the prosthesis



# Effect of screws in baseplate stability

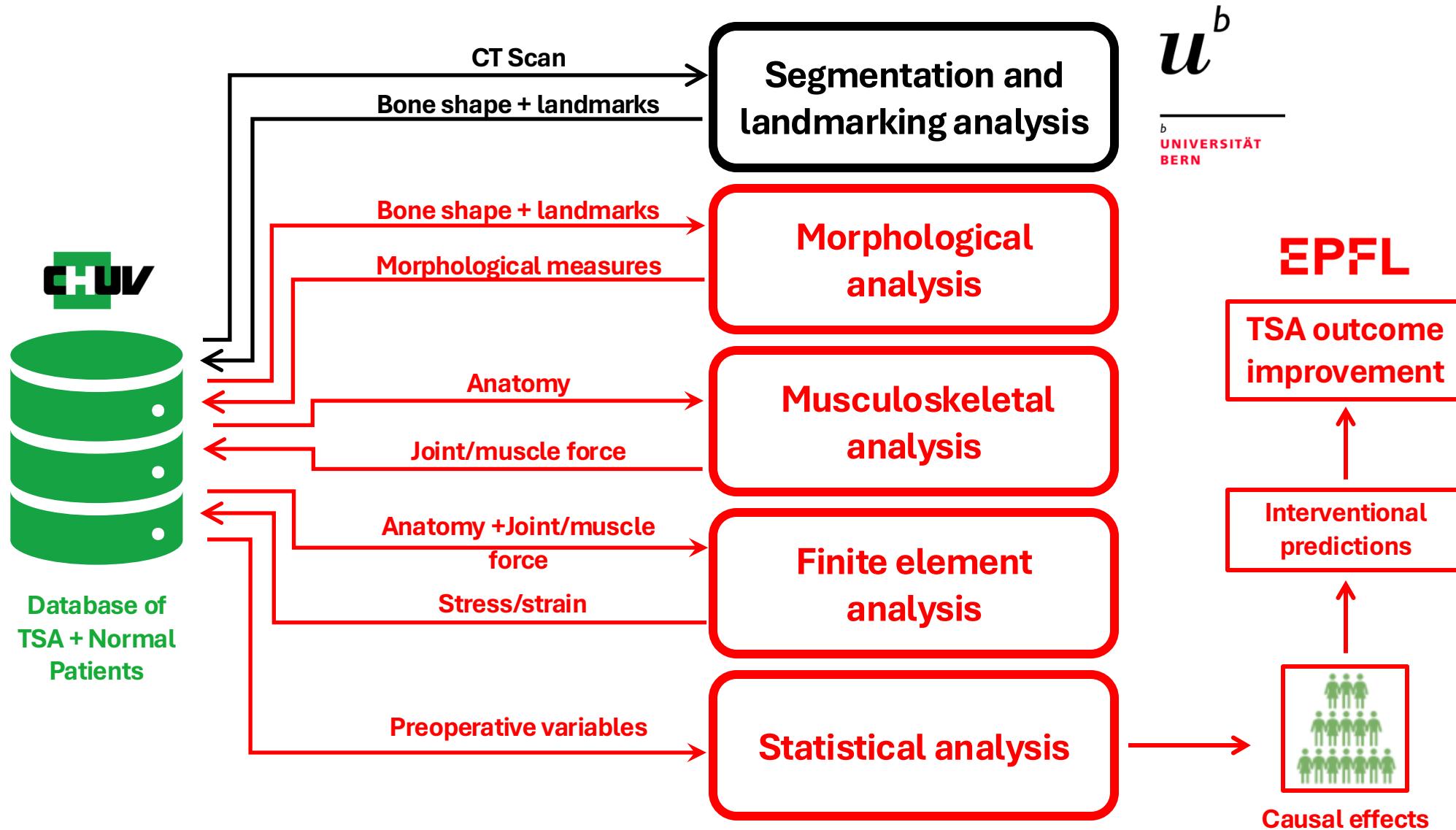
- 4 (standard) vs 2 screws (inf & sup)
- 10 patients (5 females, 56-87 years) planned for RTSA
- Joint force at 60 degrees of abduction
- Bone volume exceeding 1000  $\mu\text{e}$  (BVACS)
- Difference in %BVACS between 4 & 2 screw < 1%
- Results suggest safe to only use the sup. & inf. screws



# Automation

- Entire process controlled by Python workflow
  - CT, patient clinical data (sex, age, weight)
  - Deep-Learning Model → Bone and muscle anatomy, quality
  - Musculoskeletal model → Muscle and joint force
  - FE → Bone strain
  - Merge the clinical and biomechanical data of patients

# Project: Effect of preop on TSA complications



# Statistics

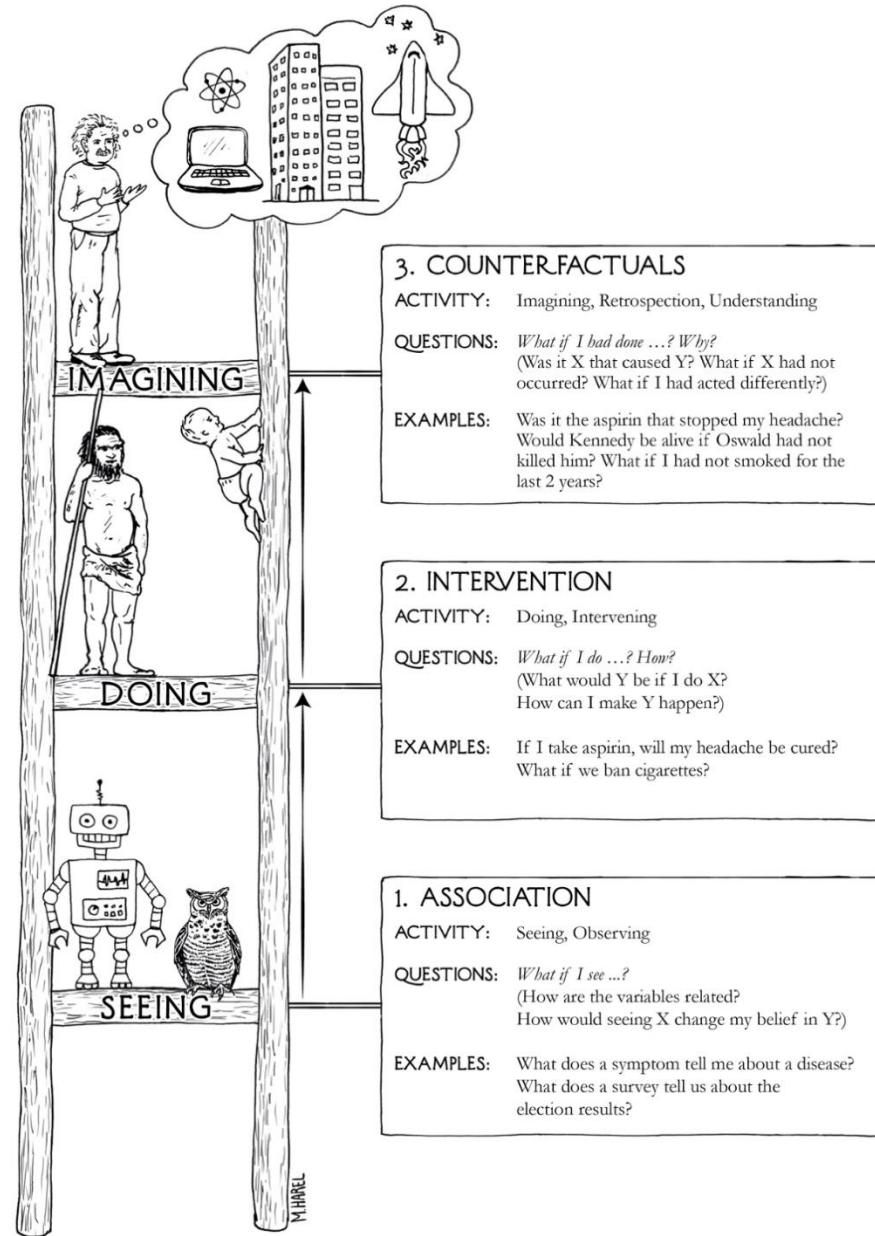
- Why?
  - Accounting for patient variability
- Association inference
  - Correlation between bone morphology/quality and mechanical strength
  - Problem of confounding variables in correctly estimating an effect
    - Both cause and effect variables dependent on a third confounding variable
- Causal inference
  - Is aging causing bone strength to decrease?
  - “Association is not causation”
  - Counterfactual “what if” questions

JUDEA PEARL  
WINNER OF THE TURING AWARD  
AND DANA MACKENZIE

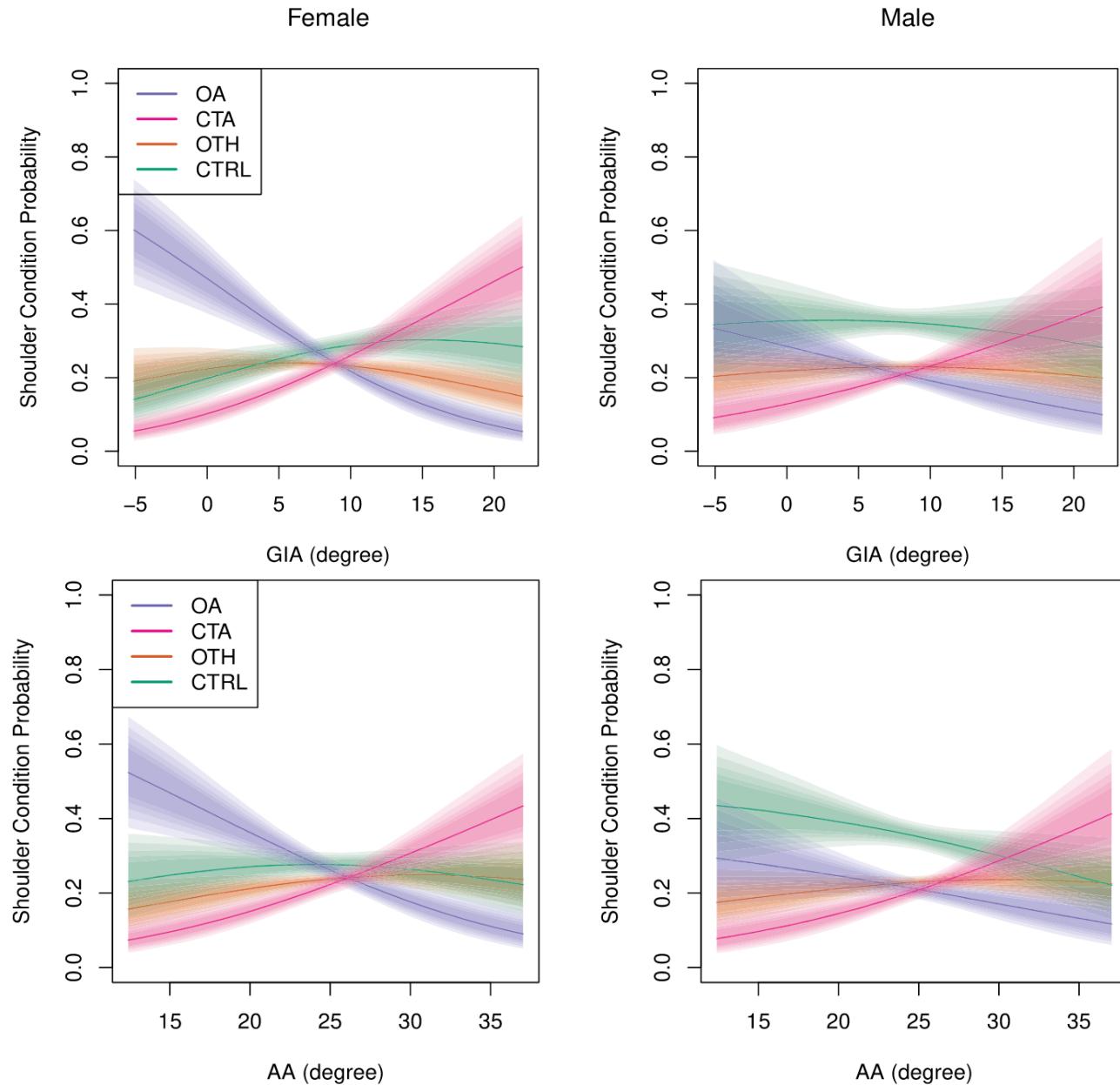
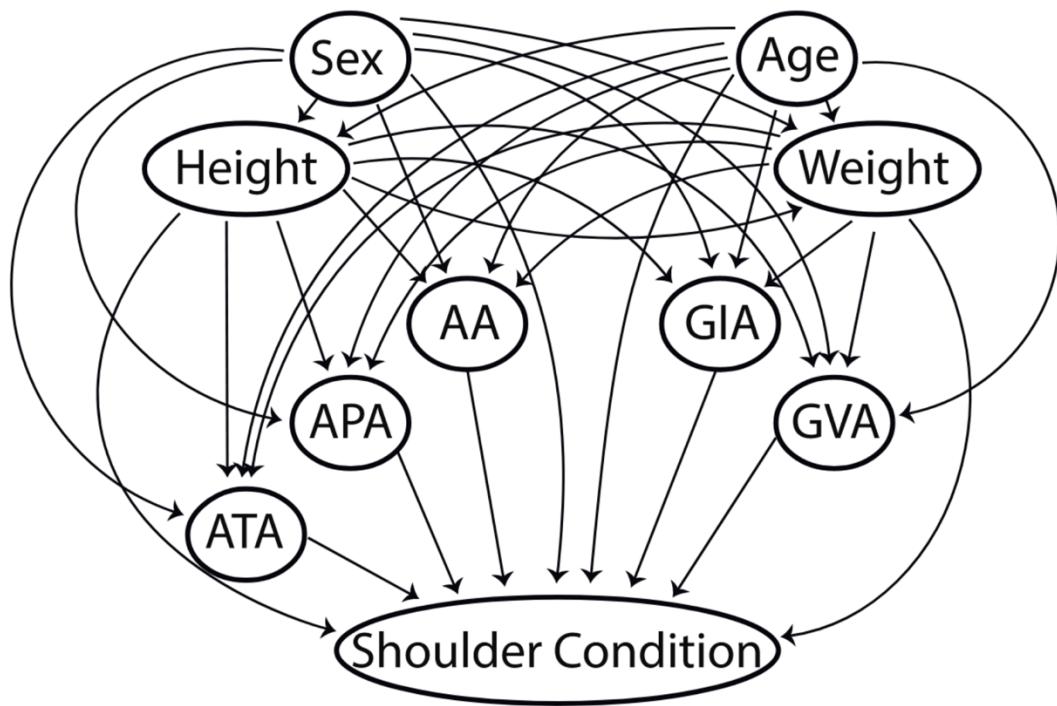
# THE BOOK OF WHY



THE NEW SCIENCE  
OF CAUSE AND EFFECT



# Causal associations between scapular morphology and shoulder condition estimated with Bayesian statistics



# Conclusion

- Computer modeling and simulation for in silico clinical trials
- Engineering background
- Link with clinical world (Surgeon, Patient, Ethics,...)
- Question-driven research
- Critical thinking