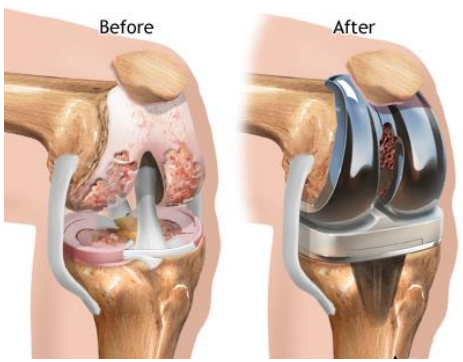
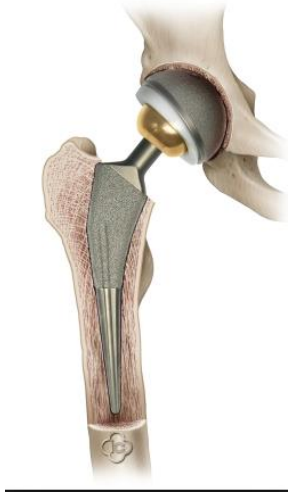
Prostheses

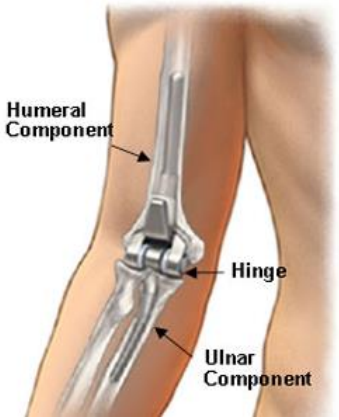
A **prosthesis** is a device designed to replace a missing part of the body, or to make a part of the body work better

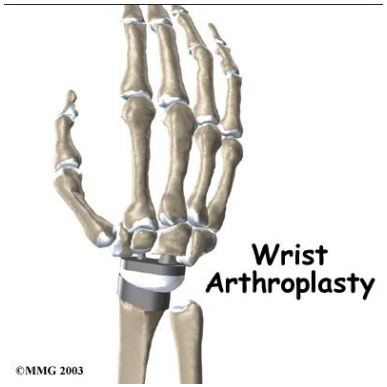
Joint(s) prosthesis is the addition to or replacement of a member(s) or of structural elements within a joint to improve and enhance the function of the joint.

Principal joint prostheses include hip replacement and knee replacement.

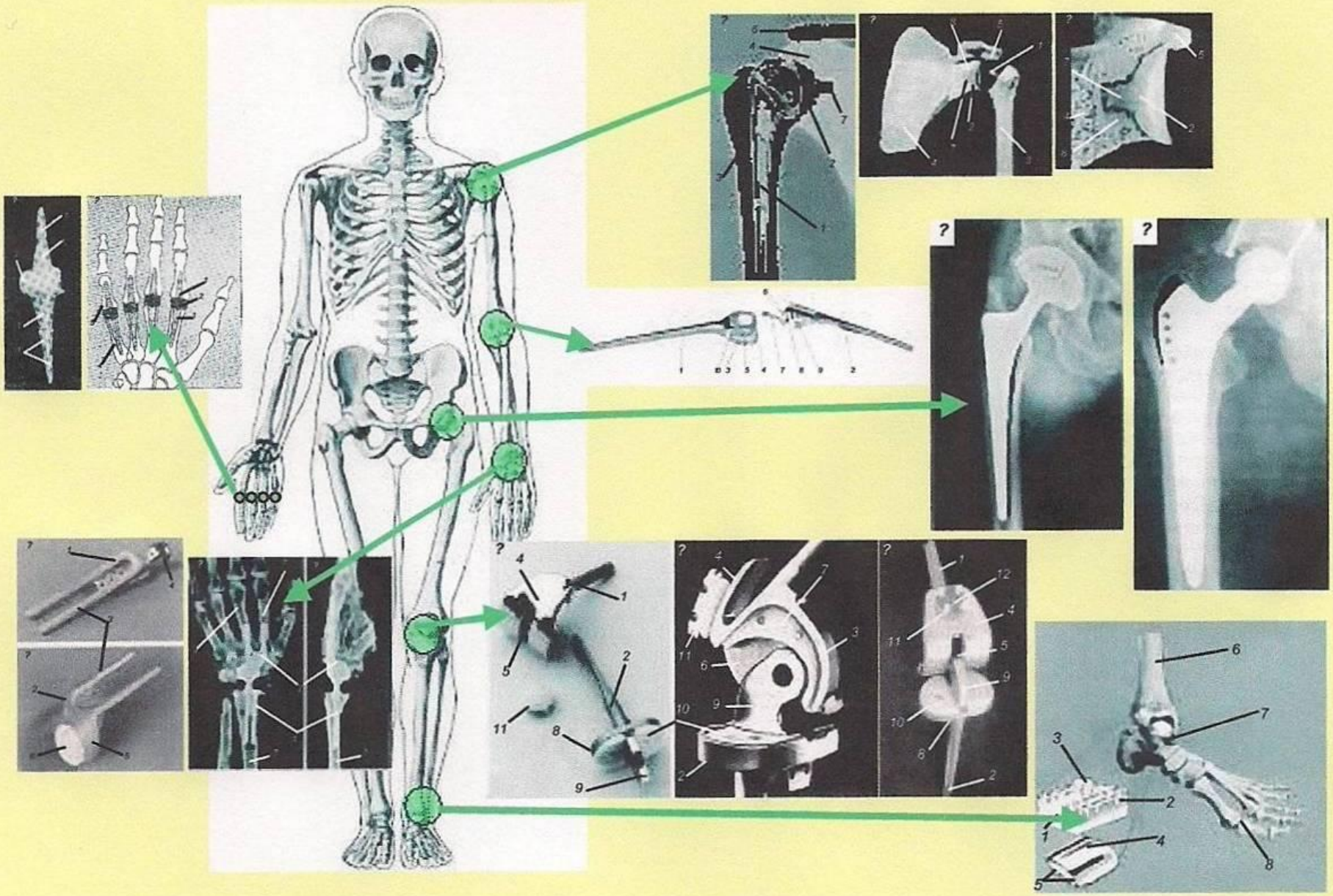






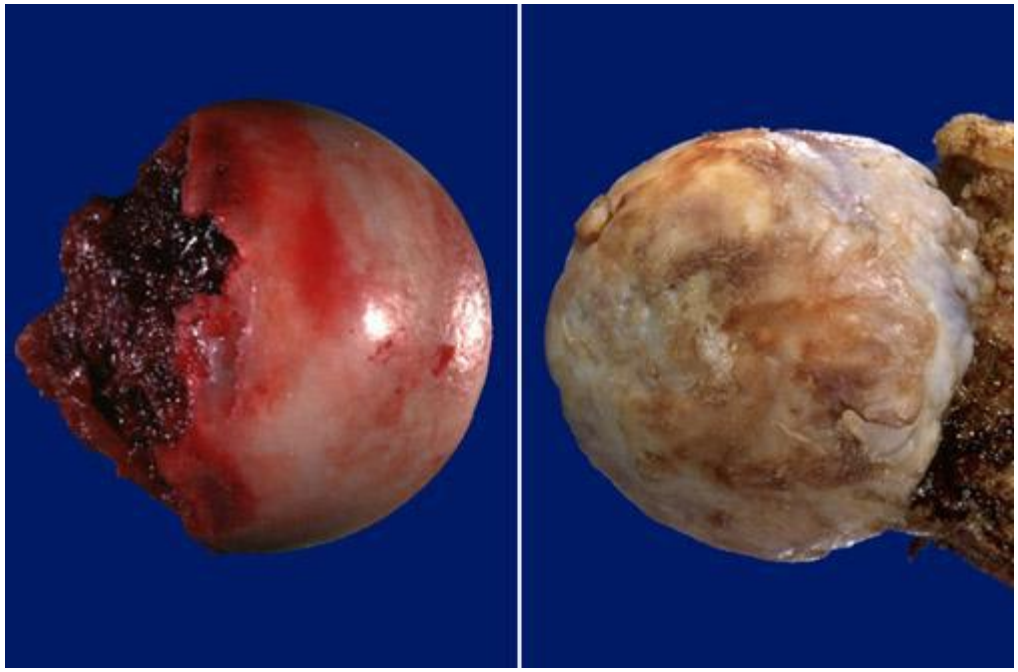


Constructions of different artificial BioJoints

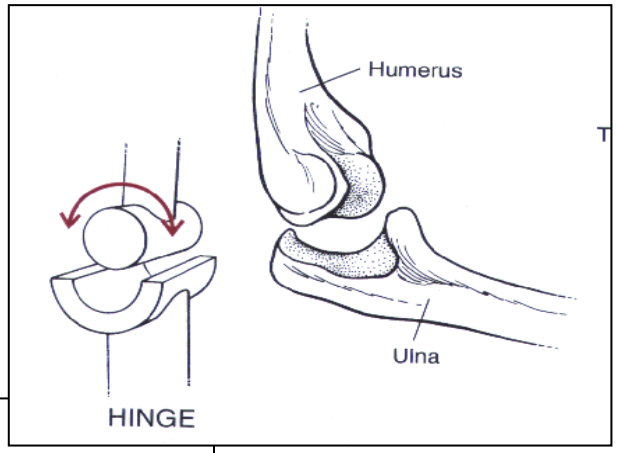


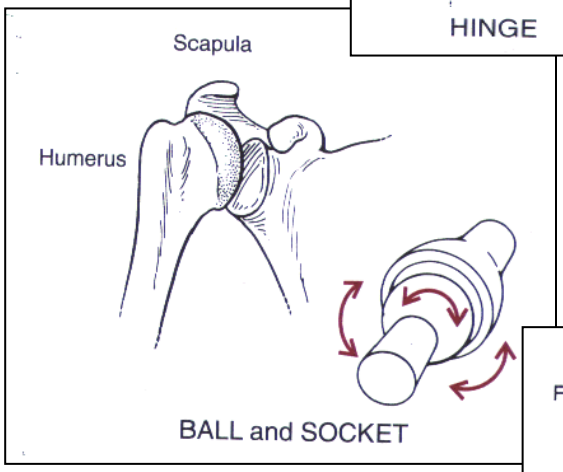
Causes for joint replacement

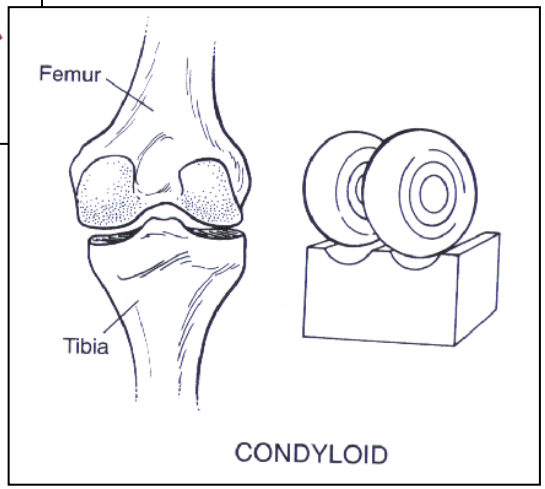
- Accidents (fracture due to osteoporosis)
- Osteoarthritis, rheumatoid arthritis



Joint types







A. Hinge joint
Movement on a single plane (extension, flexion)
Elbow, finger phalanges

B. Ball-and-socket joint
Movement on three planes (extension, flexion - abduction, adduction - rotation)
Hip, shoulder

Γ. Condyloid joint
Movement mainly on a single plane (extension, flexion) with a small rotation
Knee

Orthopedic devices design

The design of devices is controlled by regulatory, such as by the FDA GMP requirements and in the EU by EU Directive MDD 93/42/EC.

Procedure

- Identification of a design opportunity
- Feasibility study: Feasibility studies can be quite complex involving design concept development, manufacturability, patent considerations, regulations, finance, marketing and medical considerations. They may also be quite simple and limited to a single consideration.
- Formulation of a design plan with inputs from regulation and patent expertise
- Design requirements are established
- At least one, preliminary design is developed and evaluated
- Final design is developed through a feed-back process of redesign and reevaluation

- Verification of the Final design through appropriate analysis and testing: the analysis and testing required during design development to verify conformance to the design input or specifications
- Validation of the design and associated manufacturing capability before release for production: the testing of the design and manufacturing process of the production design and the production manufacturing processes to validate conformance to the design input or specifications.
- Post market Surveillance, the collection and analysis of data on the performance and problems with the production design in the field.

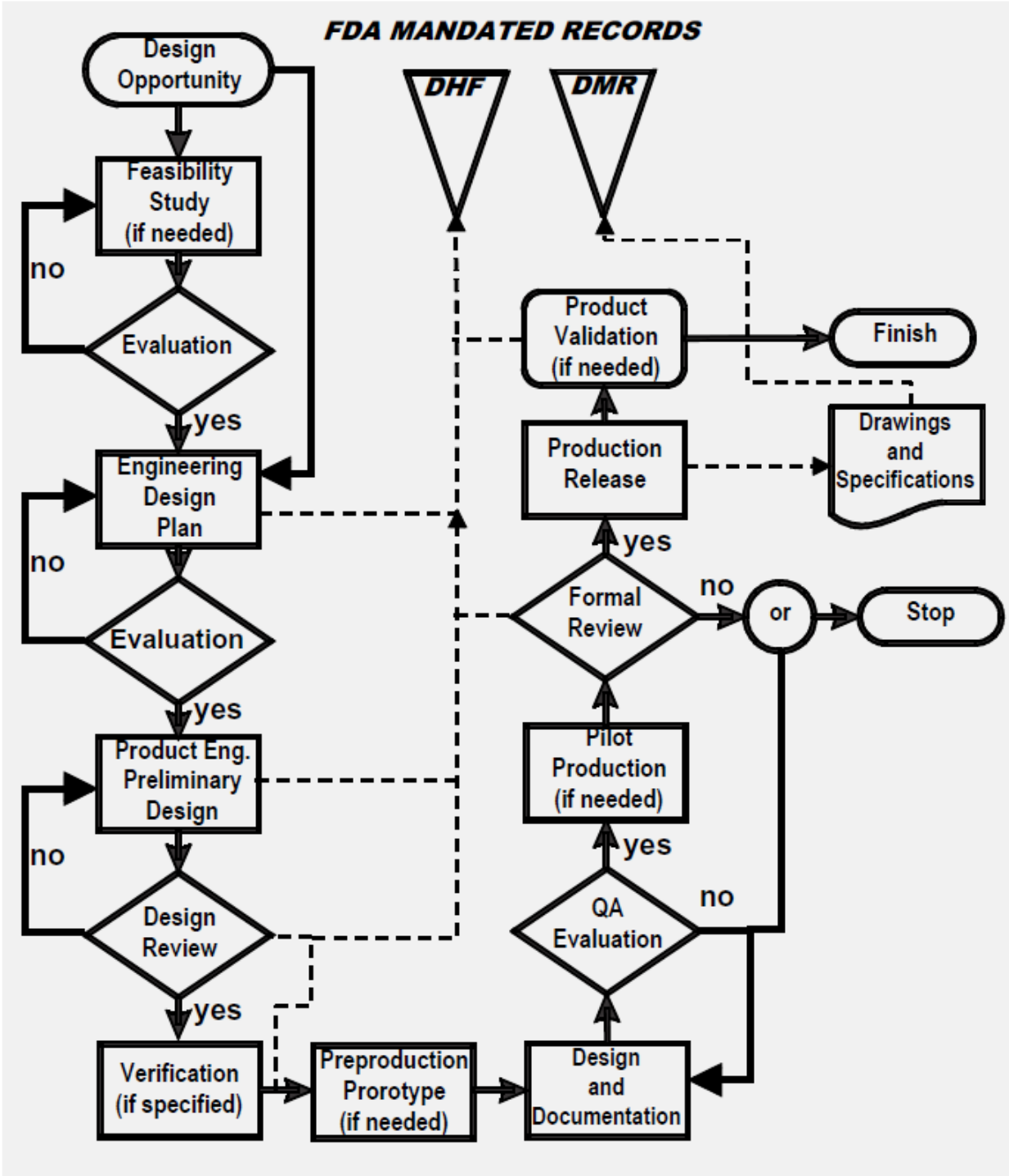
Definitions

- ***Device,*** finished product; an orthopedic implant introduced by surgically penetrating the skin of the body with the intention that it remain within the body following surgery.
- ***Device Instrument***, instrument used during surgical procedure to implant a device.
- ***Humanitarian Use Device****, (HUD),* a medical device that, due to the fact that its use applies to a very limited population, may have a limited target population.
- ***Patient Adapted Device****, (PAD),* product manufactured to specification for distribution with modification or customization, to fit a patient's specific anatomy. The PAD devices that are distributed within the European Union (EU) must be classified and CE marked the same as non-custom devices (Standard Product).
- ***Design History File, (DHF),*** This file should hold information on all design, design modification, validation and verification processes.
- ***Evaluation****,* Design Review and when applicable, other verification/validation of the Design.
- ***Engineering Model****,* a model used to obtain information and data used for design purposes.
- ***Design Requirement*** *(Design Input),* the physical and performance requirements of the product that are used for its design.

- ***Design Output***, the results of a design effort, the added value. At each stage of the design there should be an output that must be reviewed against the input. The *finished design output* should be the documents of the Device Record, i.e. the specifications, drawings, process procedures and work instruction, packaging specifications, labeling, and QA inspection procedures.
- ***Design Documentation*** *(Design Transfer)*, the process of converting the design documents into the production documents that should be used for manufacture.
- ***Verification,*** the analysis and testing required during design development to verify conformance to the design input or specifications.
- ***Validation****, (after initial production)* the testing of the design and manufacturing process of the production design and the production manufacturing processes to validate conformance to the design input or specifications.
- ***Post market Surveillance****,* the collection and analysis of data on the performance and problems with the production design in the field.

Design Process Flowchart

DHF: Design history files
DMR: Design master record



Design Inputs

- Indications/Contraindications/User interfaces
- Performance/Physical/Mechanical characteristics
- Safety risk/benefit ratio requirements
    - Bio-compatibility requirements
    - Clinical requirements
    - Packaging/Labeling requirements
    - Regulatory requirements
    - Manufacturing requirements
    - Physical loading requirements
    - Motion requirements
    - Intended use of the device
    - Measurements and measuring instruments to be used
    - Sterility requirements
    - Lifetime of the device

a) Medical and Engineering Criteria

- Material and wear product compatibility
- Adequate mechanical strength
- Minimization of the joint reaction forces
- Minimization of fixation interface tension
- Avoidance of fixation interface shear
- Uniformity of interface compression
- Duplication of anatomical function
- Adequate fit for the patient population
- Manufacturability
- Inventory costs

b) Medical and Surgical Criteria

- Treatment of a broad variety of pathologies
- Maximal preoperative options
- Maximal intraoperative options
- Maximal postoperative options in case of failure
- Salvagability
- Tolerance for misalignment
- Ease of implantation

Verification

Verification of the design should be performed at designated phases of the design process, to verify that the design output is consistent with the required input, using methods appropriate to the design, as

- Determination of motion
- Stress analysis
- Simulator testing for loading and wear
- Manufacture and testing of prototypes
- Testing of materials
- Biocompatibility studies
- Comparison of the proposed design to similar approved devices on the market, including any clinical investigations
- Risk Analysis using Failure Mode and Effects Analysis (FMEA). or other methods
- Computer Generated Modeling
- Assessments by independent experts

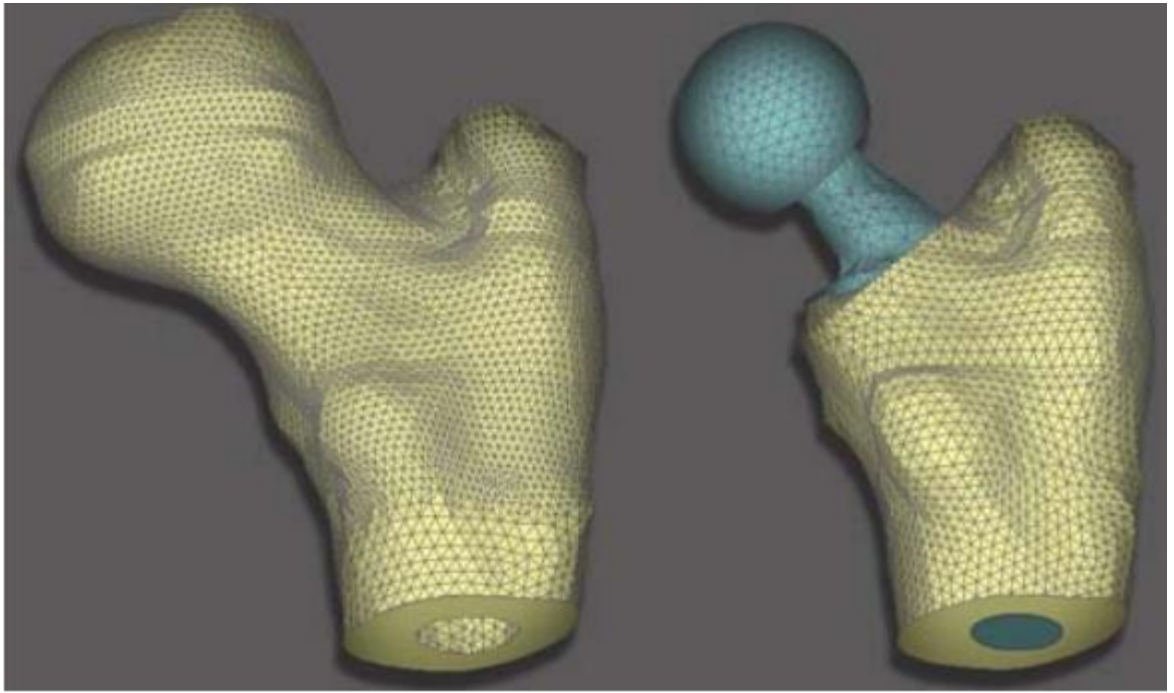
Validation

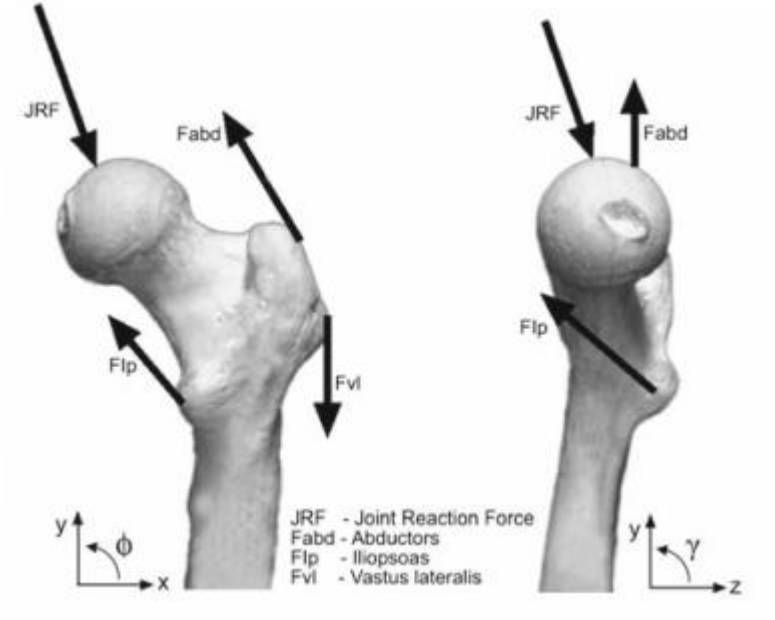
The requirements for the validation should be established in a written protocol which should then be reviewed by the Design Committee prior to performing the validation testing. In general, the protocol should include a clearly defined purpose, test/evaluation methodologies, endpoints wherein the data should be assessed and the criteria to be used for accepting or rejecting its generated results.

Optimization in hip prostheses design

- Goal: To minimize the probability of implant failure
- Problem: Aseptic loosening of the implant is mainly influenced by bone resorption due to stress shielding
- Solution: Reduction of stress concentration at the interface between bone and implant.

Automatic generation of the prosthesis and femur models





Muscle and joint reaction forces			
	resultant force	angle degree	
	(N)	ϕ	γ
joint reaction force	730	291	273
Abductors	300	110	90
Iliopsoas	188	99	137
vastus lateralis	292	270	270

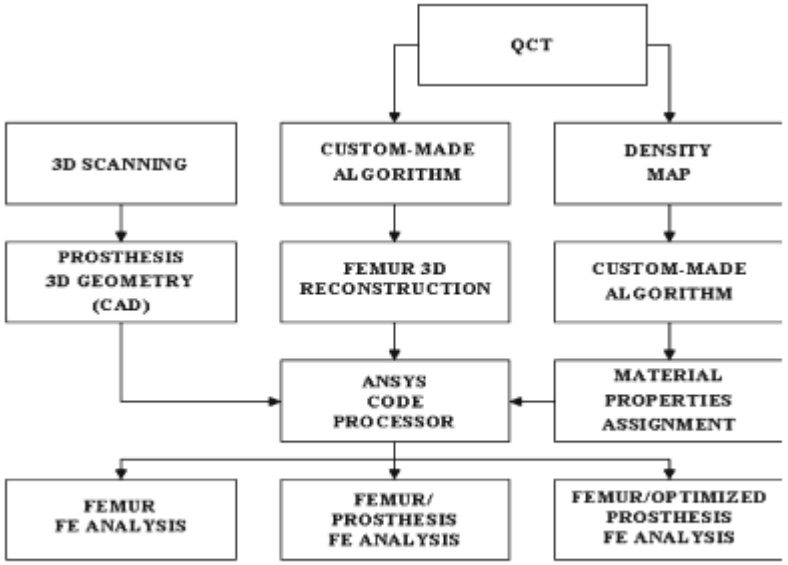
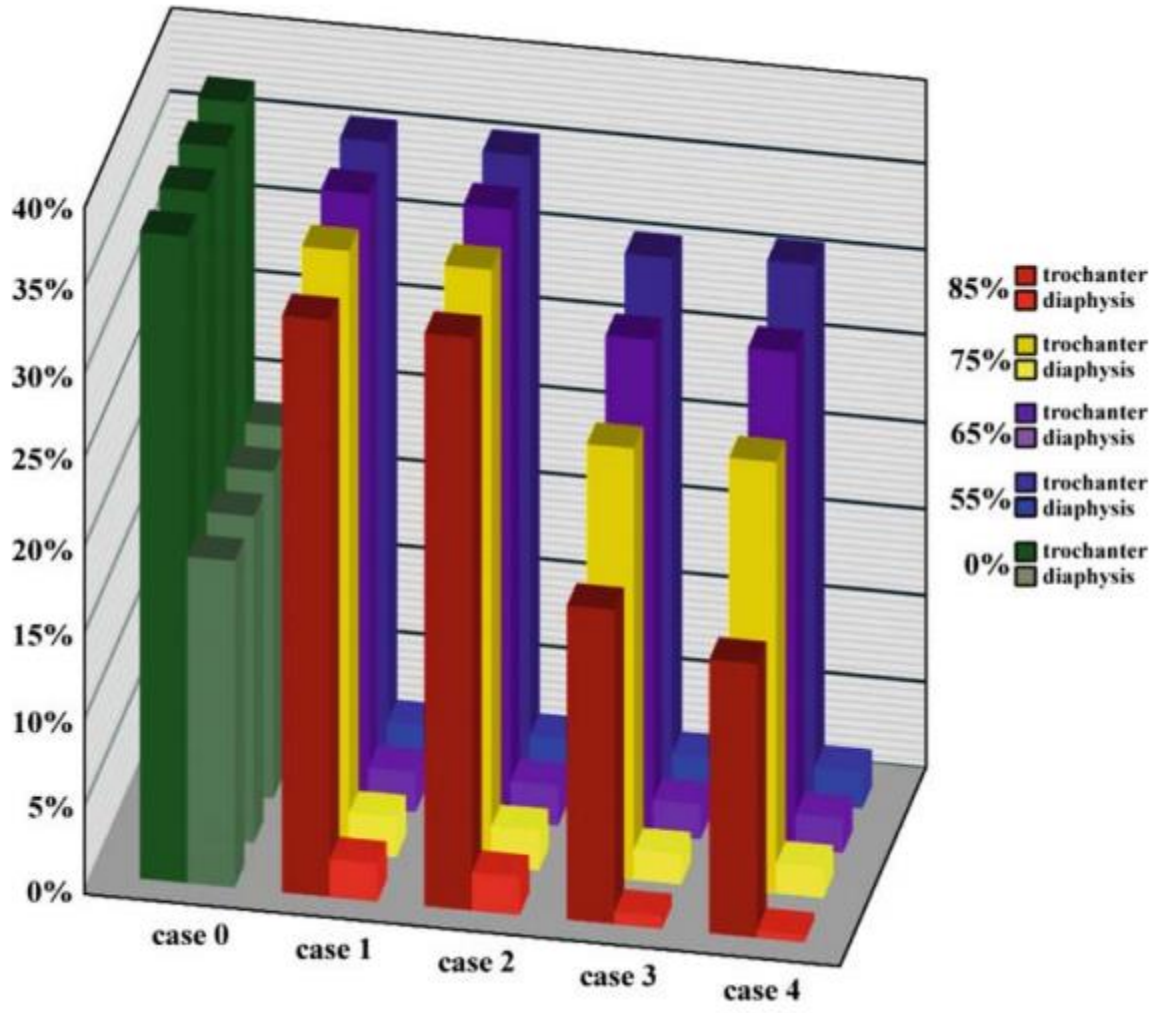


Fig. 5 Flow chart of the numerical procedure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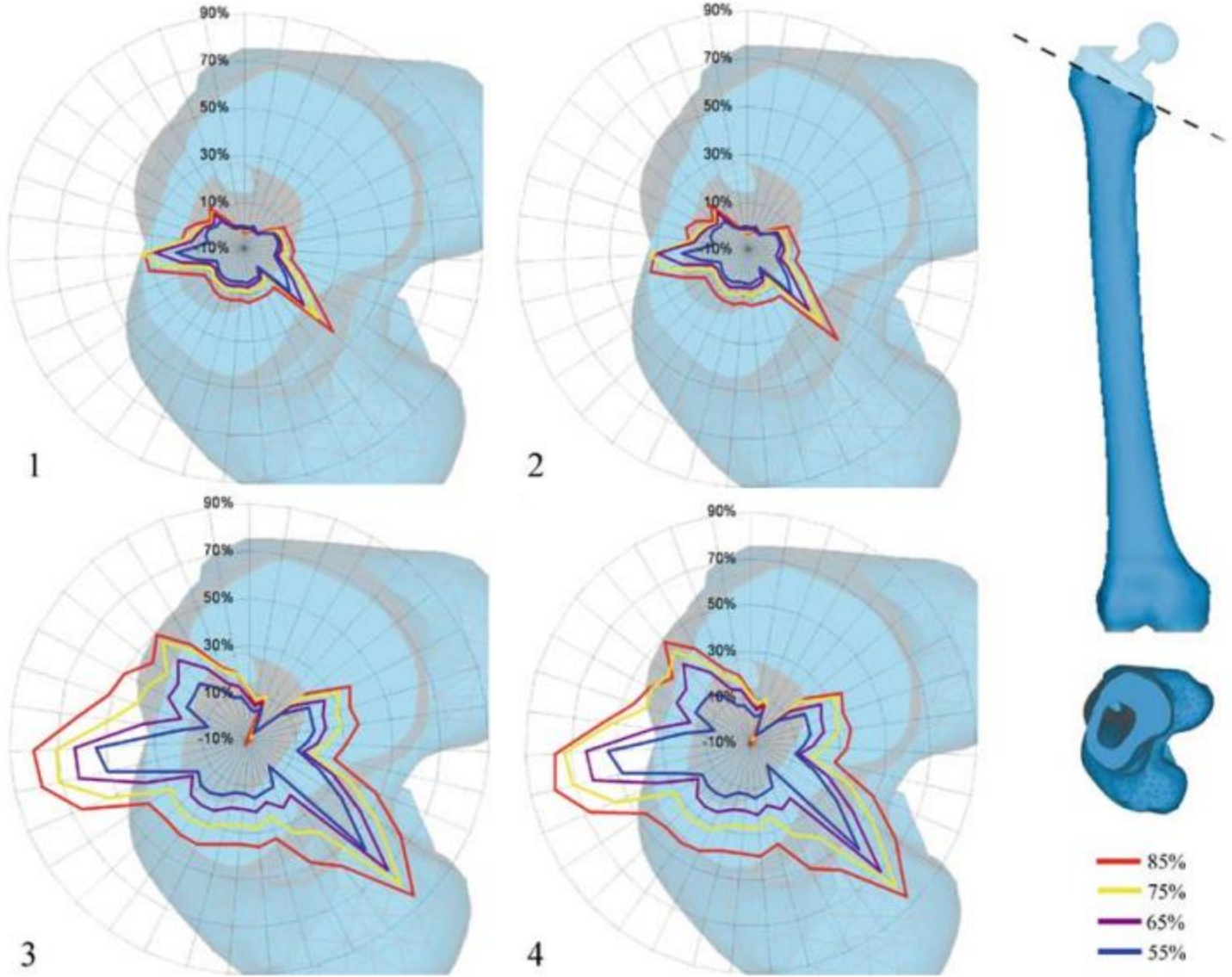
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