Design & evaluation criteria

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Question: who likes coffee?

Faculty of Mechanical, Maritime, and Materials Engineering
Department of BioMechanical Engineering

Example: coffee

Question: how can you define good coffee?
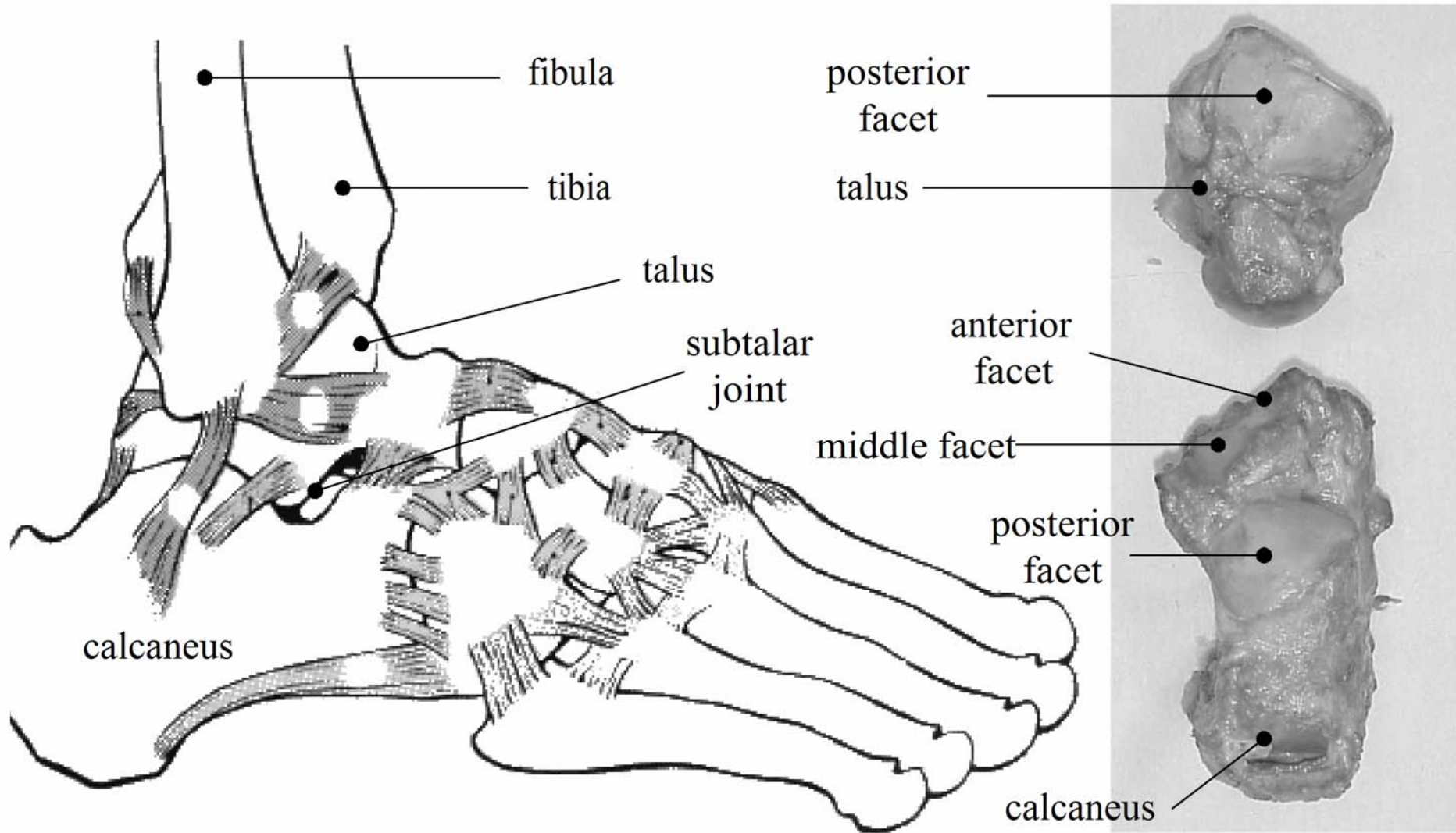
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Example: coffee

- Color
- Cream
- Smell
- Taste
- Temperature
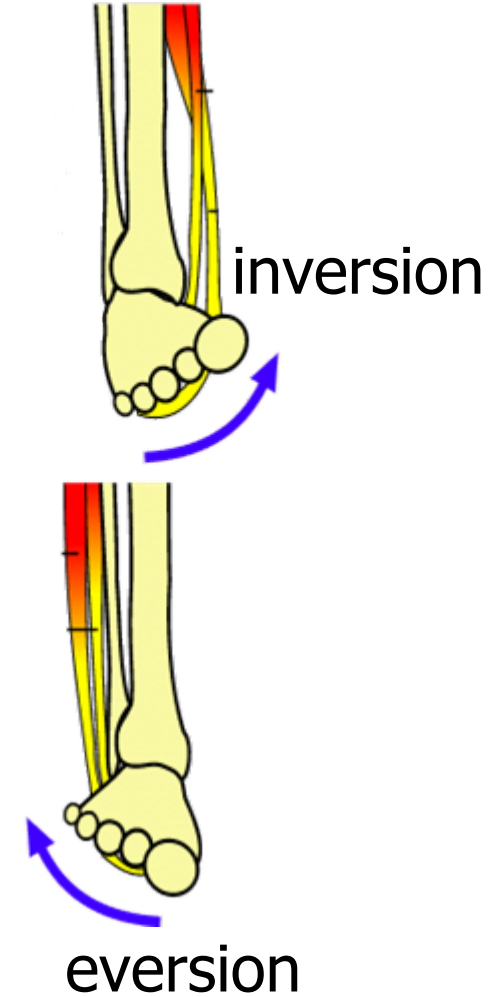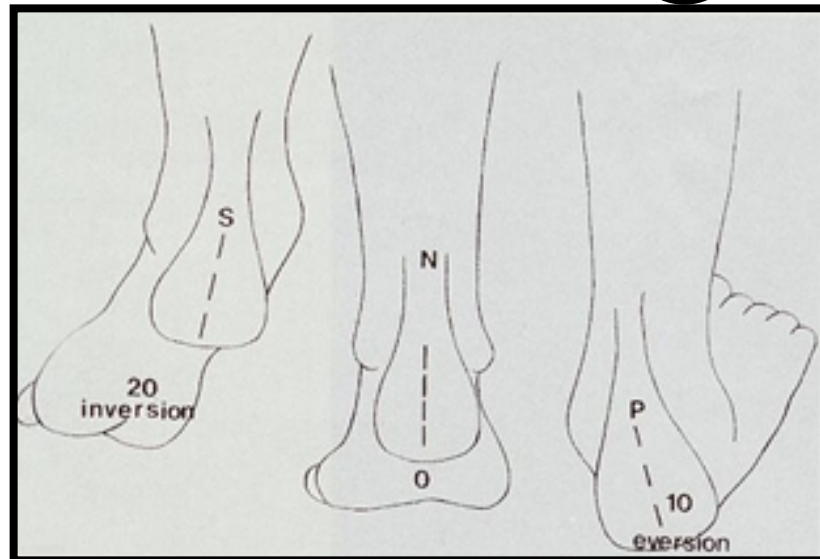
Learning objectives of this lecture

- Set up design criteria

- Translate design criteria into quantitative specifications

- Choose and justify evaluation criteria

Question: what is a proper design criterion?

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Subtalar joint: anatomy

fibula
tibia
talus
subtalar joint
calcaneus

posterior facet
talus
anterior facet
middle facet
posterior facet
calcaneus

Subtalar joint: function
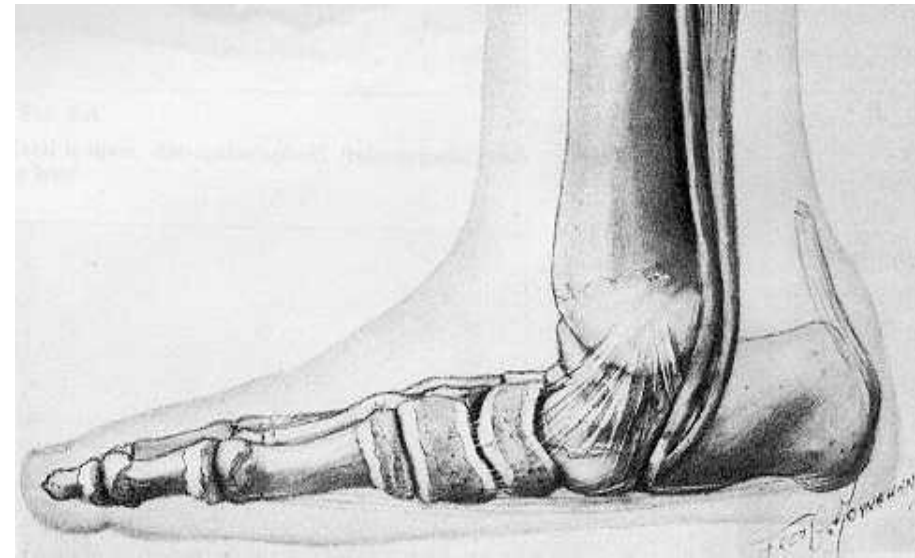

inversion

eversion

Subtalar arthrodesis: pathologies

PAIN

- deformities
- calcaneal fractures
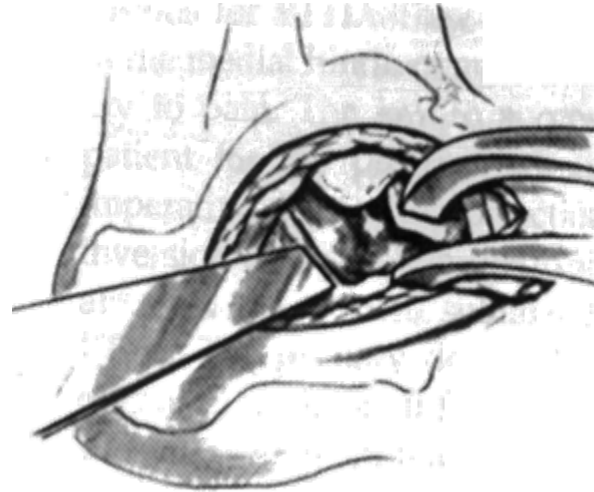- arthritis
- dysfunction of tendons
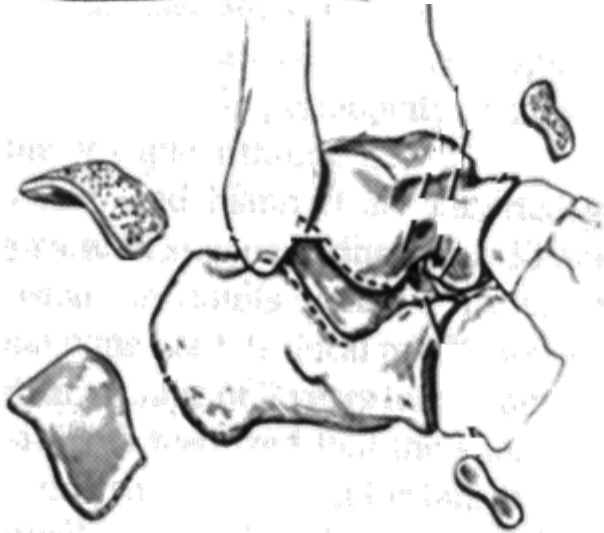
Subtalar arthrodesis: surgical technique

incision

access

cartilage
removal

correction
& fixation

Question: what tools to sue for problem analysis?

Problem analysis: Clinically driven approach

- Literature: 100 papers

- Observations in operating theatre

- Interview: 4 surgeons

- Operation divided in phases

Problem analysis: limitations

- large incision

- open/arthroscopic access requires high skills

- uncertain if entire posterior facet is feathered

- measurement of malalignment

- suboptimal fixation

↓

criteria for a new method

Phases of procedure: **Strategy new technique:**

|		
access	→	arthroscopic, hindfoot access
cartilage removal	→	follow contour, smooth surface, easy
measurement of malalignment	→	in OR, quantitative, objective
correction	→	insertion via portals or incorporated in fixation device
fixation	→	optimal compression force and location

Question: design criteria for a cutter?

Design criteria: arthroscopic cutter

- bleeding contact surfaces

- complete removal of cartilage layer

- preservation of joint shape

- smooth surface

- easy control

- quick

- safe & simple

Question: quantify design criteria?
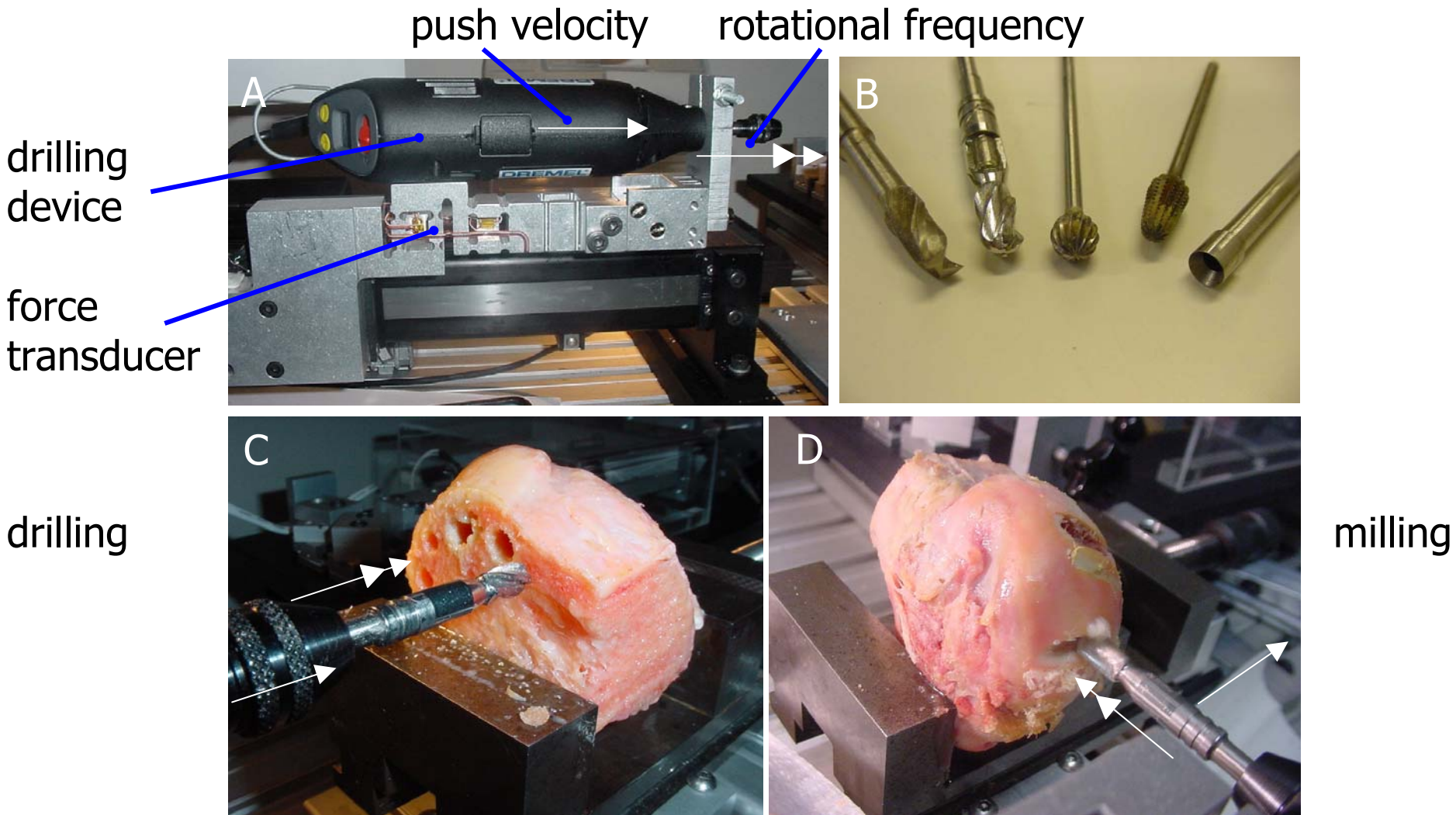
Quantification of criteria: geometry
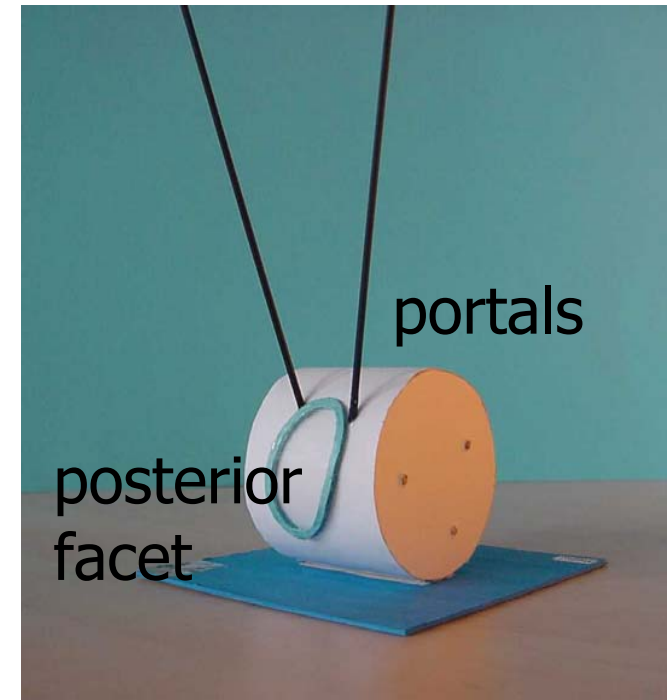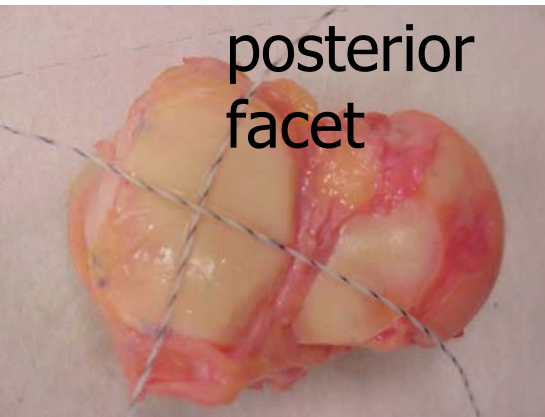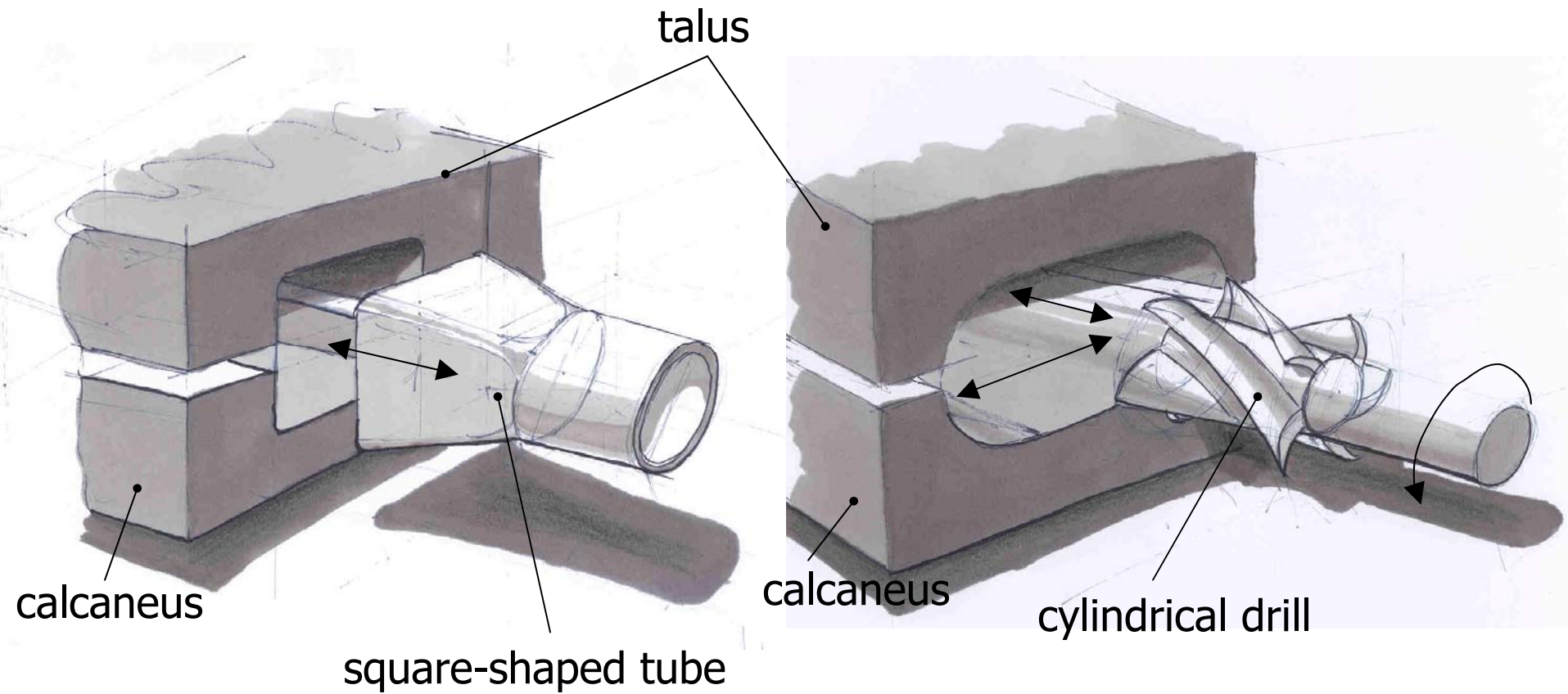

Guidelines for optimal portal placement

Required flexibility: minimal curve diameter is 24 mm

Required diameter: 7 mm
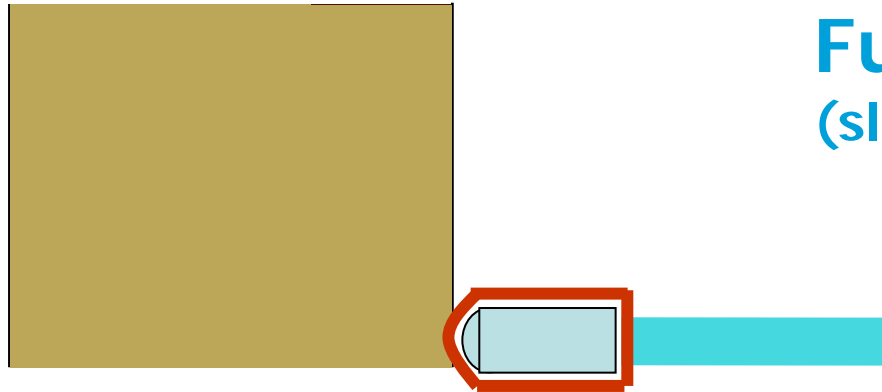
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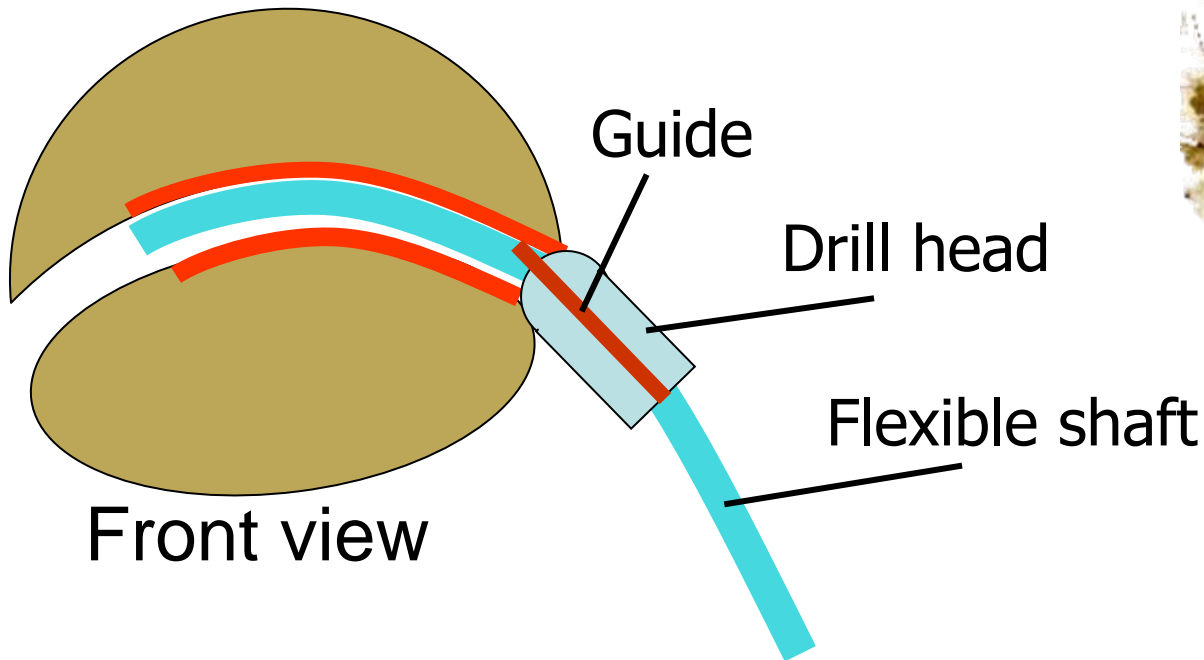# Quantification of criteria: cutting force 50N

push velocity rotational frequency

drilling device

force transducer

drilling

milling

Two concepts

talus

calcaneus

square-shaped tube

calcaneus

cylindrical drill

Functionality cutter
(slide made by F. Eeuwe)

Top view

Front view

Guide

Drill head

Flexible shaft

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Calculations

A **B** **C**
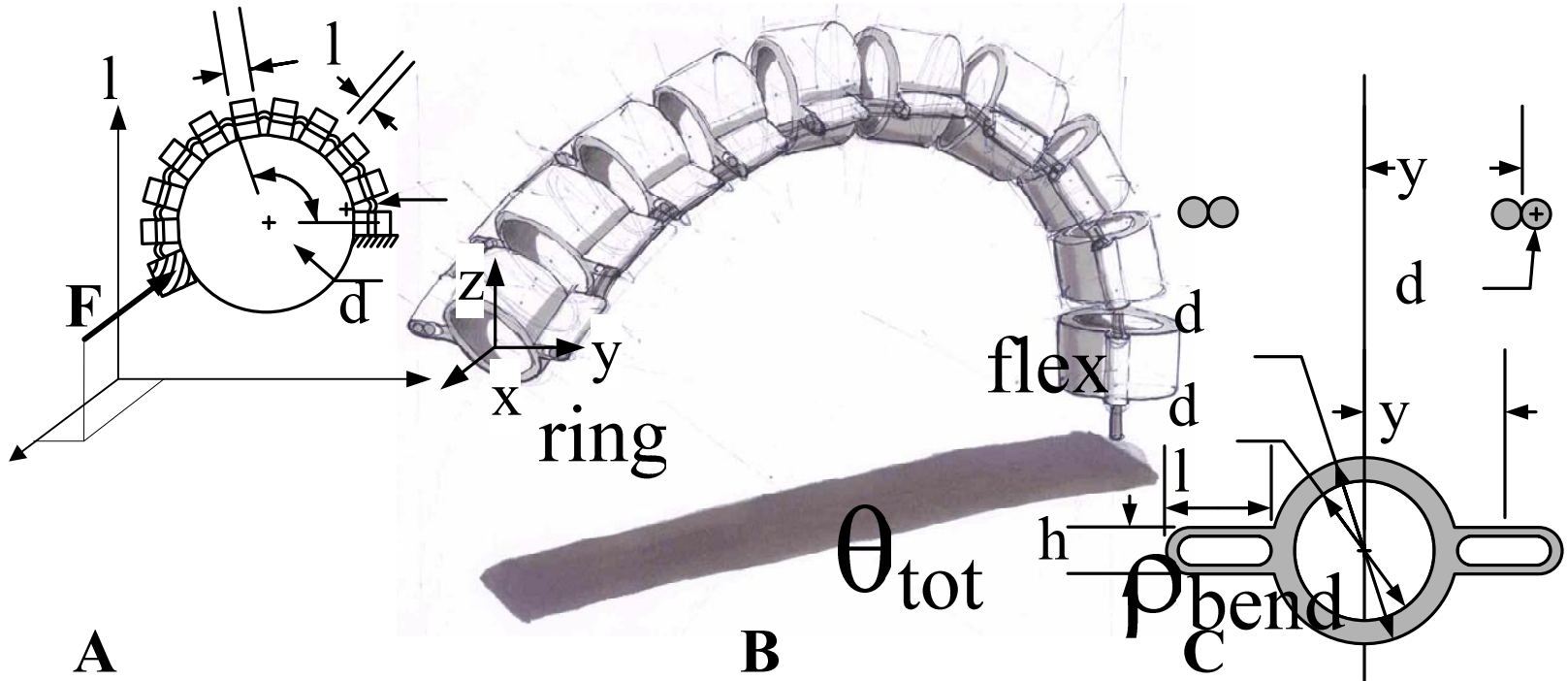
$$K_z = \frac{F_z}{\delta_z}$$

c

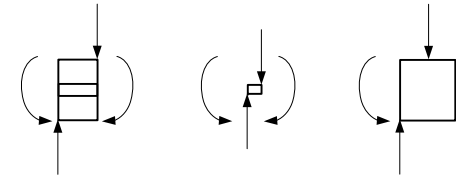# Calculations

Forces

$$K_z = \frac{F_z}{\delta_z}$$

Displacement

$$\delta_p = \frac{F \cdot \left(\frac{1}{2} d_c\right)^3}{EJ}\left[\left(\cos^2\theta_{tot} + \tfrac{1}{2}\right)\theta - 2\cos\theta_{tot}\sin\theta + \tfrac{1}{4}\sin(2\theta)\right]_{\theta_i}^{\theta_{i+1}}$$

$$+ \frac{F \cdot \left(\frac{1}{2} d_c\right)^3}{GJ_p}\left[\left(\sin^2\theta_{tot} + \tfrac{1}{2}\right)\theta + 2\sin\theta_{tot}\cos\theta - \tfrac{1}{4}\sin(2\theta)\right]_{\theta_i}^{\theta_{i+1}}$$

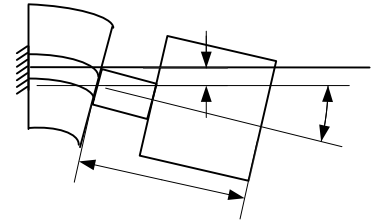$$J_{ring,z} = \frac{\pi \cdot (d_{ring,out}^{\,4} - d_{ring,in}^{\,4})}{64} + 2 \cdot \frac{l_{wing} \cdot h_{wing}^{\,3}}{12}$$
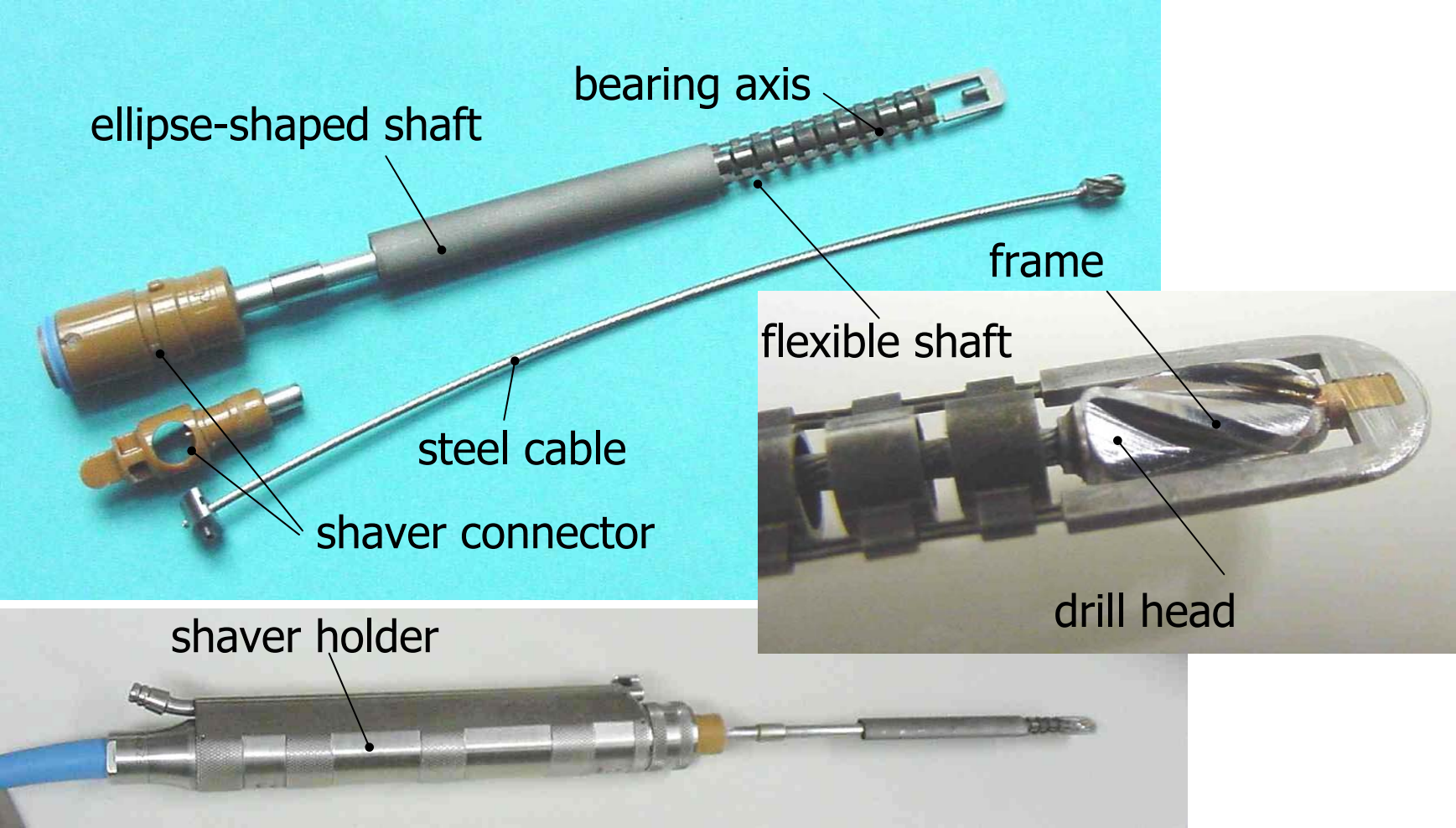
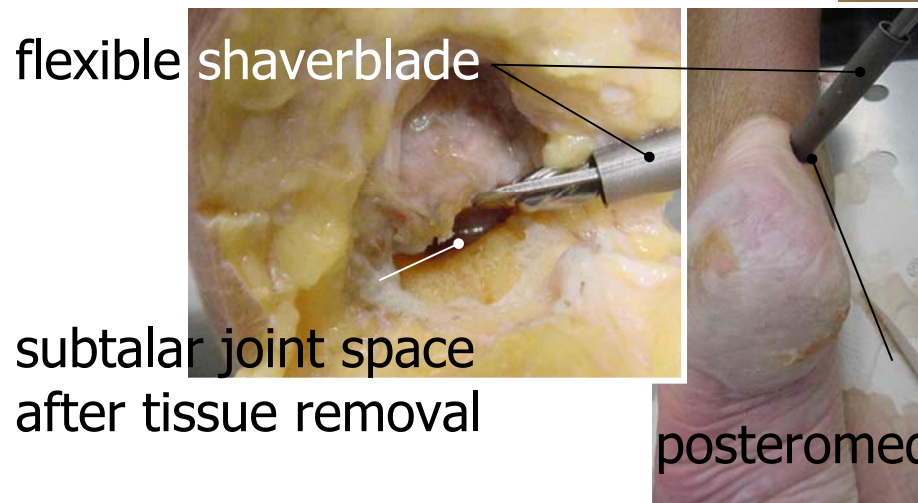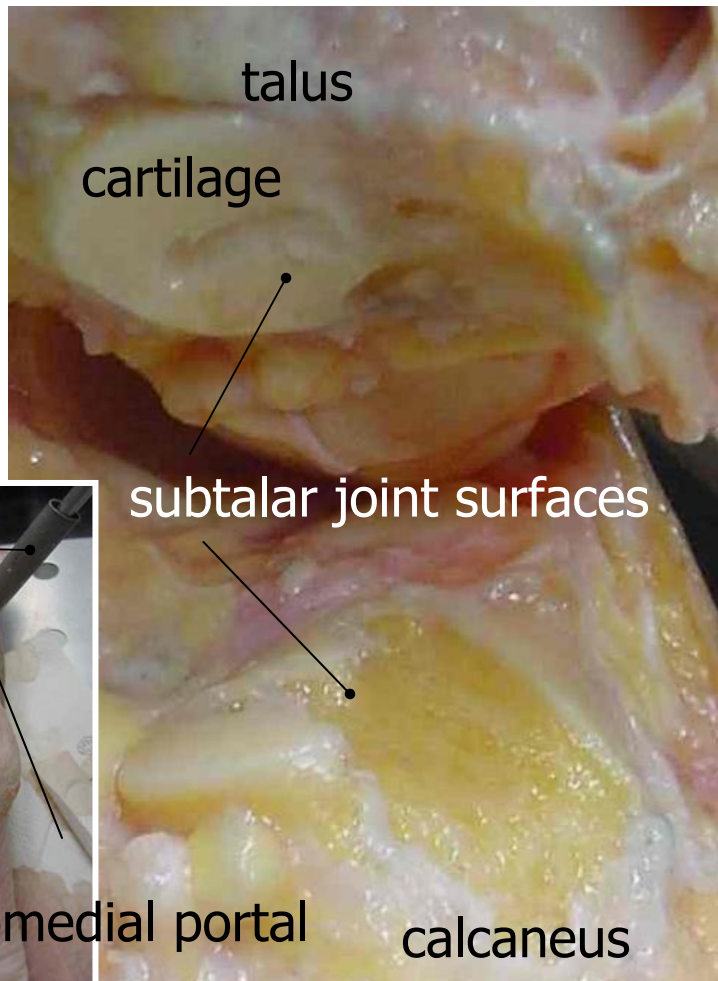$$J_{flex,z} = 2 \cdot \frac{\pi \cdot d_{flex}^{\,4}}{64}$$

Prototype

ellipse-shaped shaft

bearing axis

frame

flexible shaft

steel cable

shaver connector

drill head

shaver holder

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Evaluation in cadaver specimen

talus

subtalar joint surfaces

calcaneus

talus

cartilage

subtalar joint surfaces

flexible shaverblade

subtalar joint space after tissue removal

posteromedial portal

calcaneus
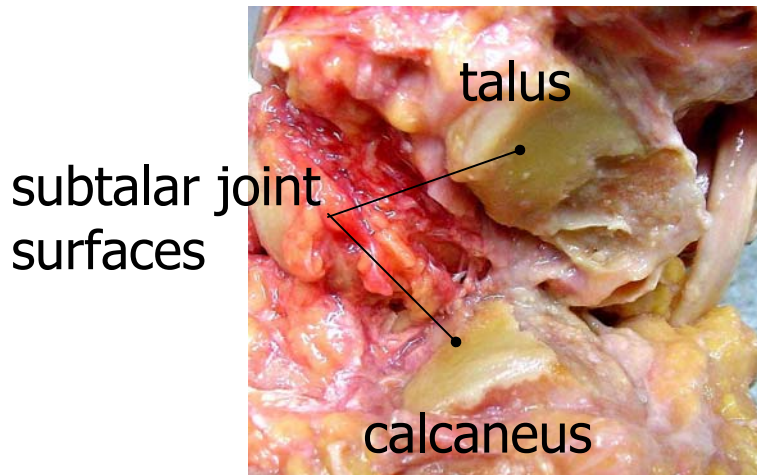
Question: what is important?

Phases of procedure: **Strategy new technique:**

access   →   arthroscopic, hindfoot access

cartilage removal   →   follow contour, smooth surface, easy

measurement of malalignment   →   in OR, quantitative, objective

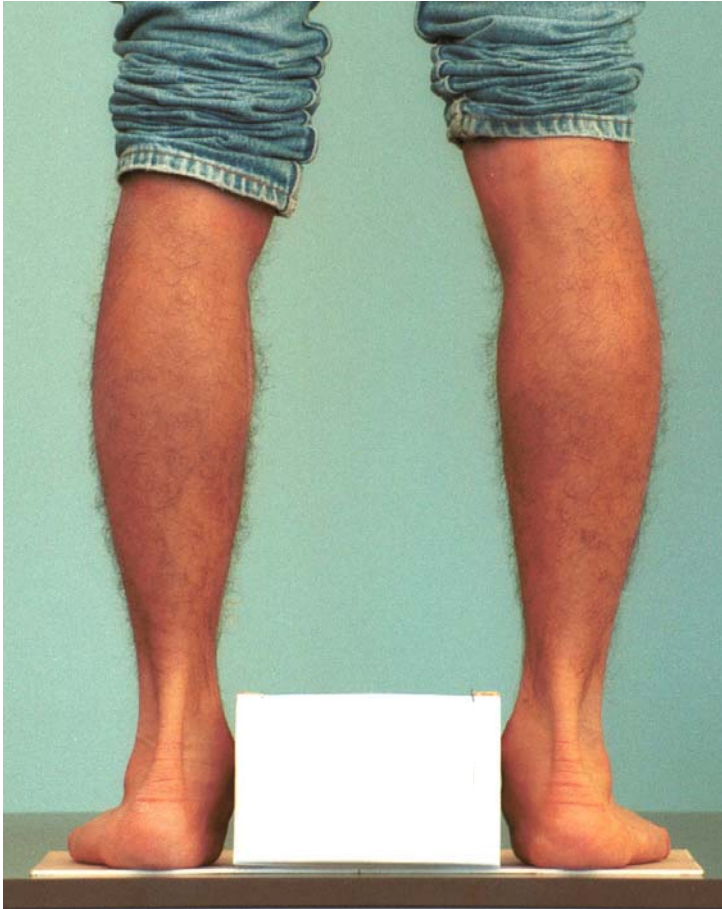correction   →   insertion via portals or incorporated in fixation device

fixation   →   optimal compression force and location

Question: design criteria for malalignment?

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Hindfoot alignment: what is good?

Question: what is good alignment?

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Hindfoot alignment: literature

- Hindfoot measurements on radiographs & with goniometers ill-defined

- No consensus for SA: symmetry vs 5° valgus

- 3D imaging to complicated

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Hindfoot alignment: expert opinion

- 66 experts
- Consensus on descriptive definitions of hindfoot alignment
- No consensus on measurement protocol

Hindfoot alignment: limitations

- No clearly defined quantatitive measurement

- No measurement in OR

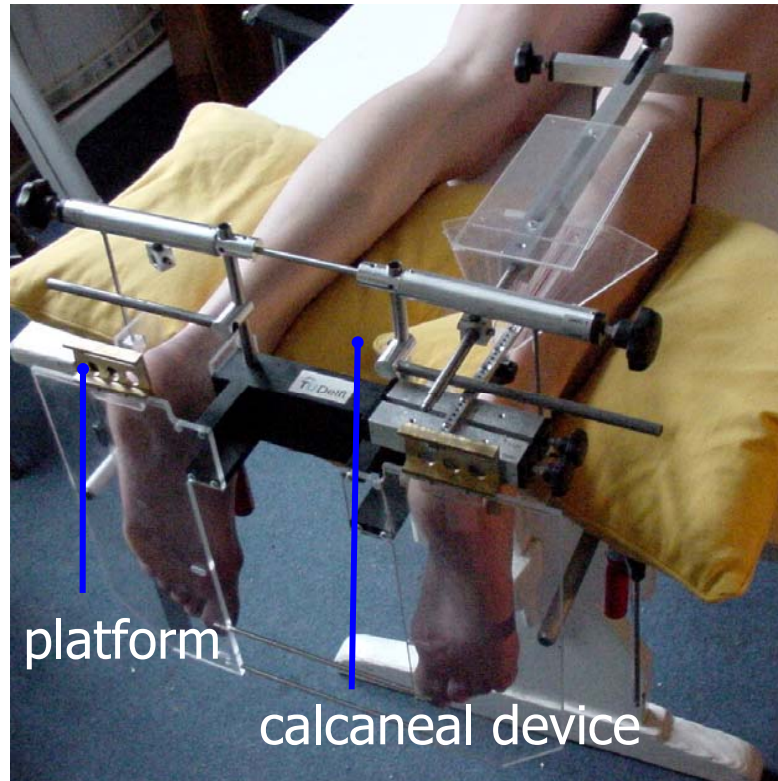- Radiograph unreliable

- Ideal foot alignment is unclear

varus

valgus
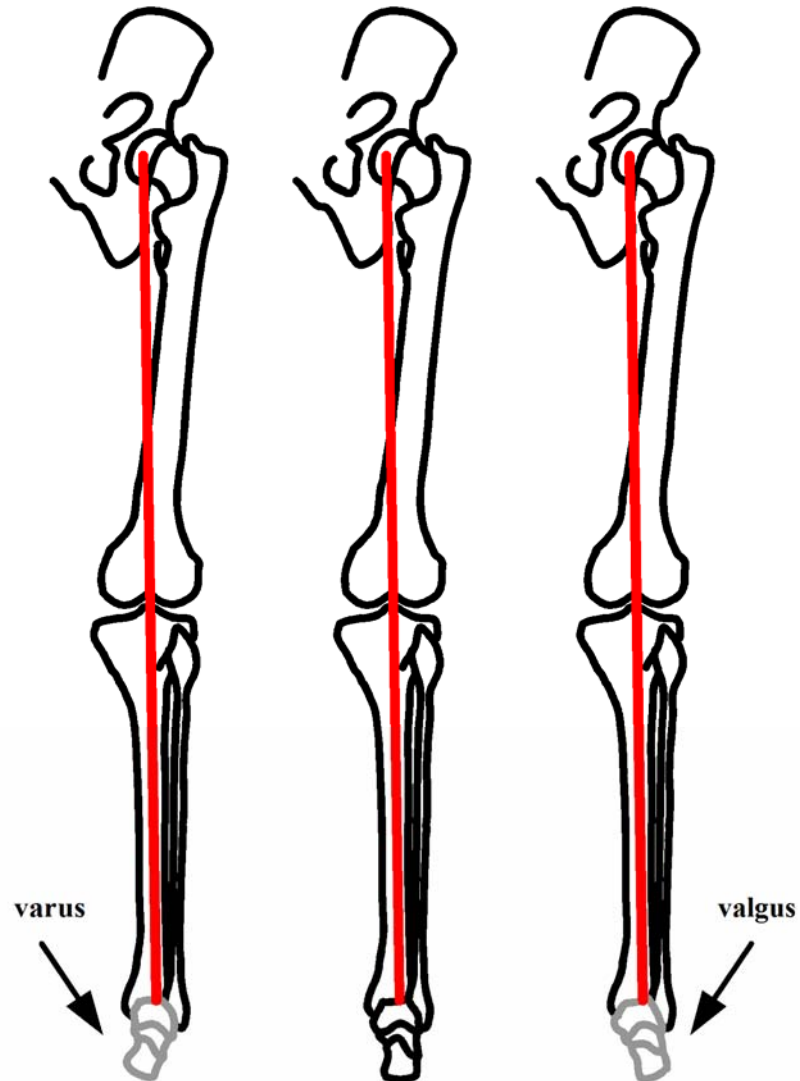
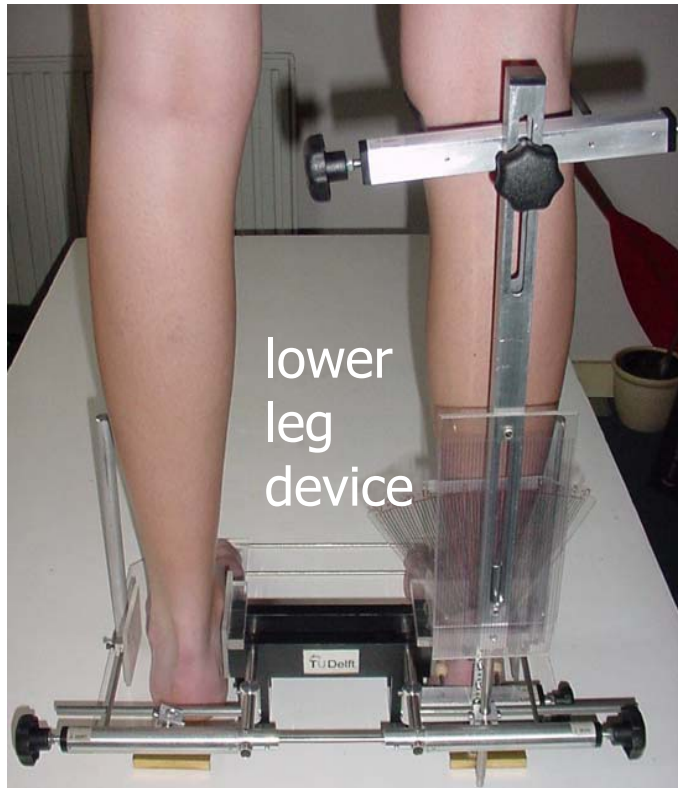# Hindfoot alignment: design criteria

- Peroperative measurement ⟶
  (non)weightbearing
- Hindfoot angle
  clear definition ⟶
  Accuracy 1°

talus

b_{talus} $H_{bonegraft}$

subtalar joint

$\delta_{correction}$

calcaneus
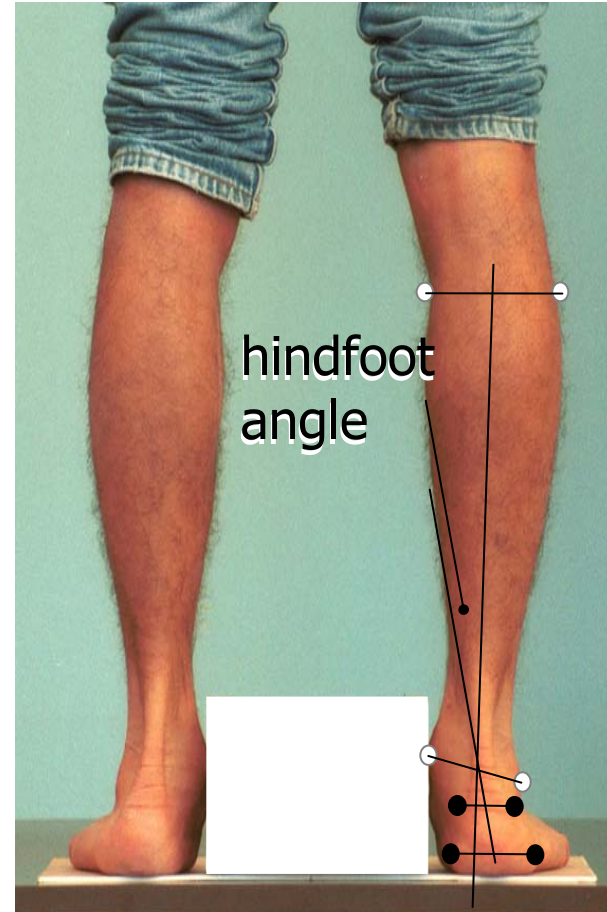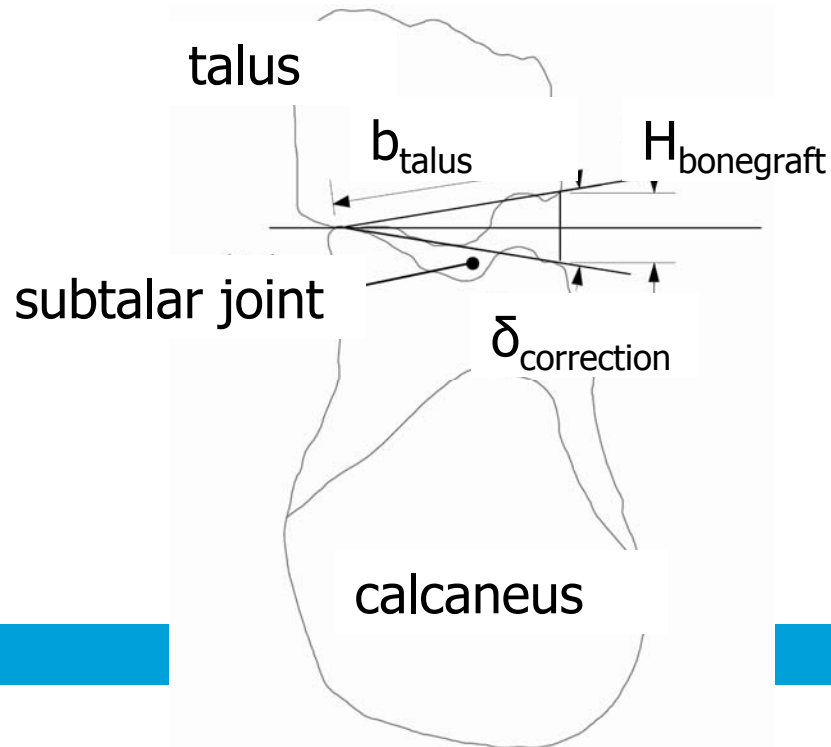
hindfoot angle

Hindfoot alignment: solution

lower leg device

platform

calcaneal device

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Hindfoot alignment: results

condition	intratester reliability			intertester reliability		
	ICC	average SD	SEM	ICC	average SD	SEM
weightbearing	0.88	1.3°	0.5°	0.68	1.8°	1.0°
nonweightbearing	0.82	1.3°	0.6°	0.63	1.6°	1.0°

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Summary

- Some design criteria integrated in concept, some can be used as for evaluation

- If no quantitative data are available, perform experiments or initial calculations to get the order of magnitude

- The set up of criteria & the actual design can be performed interactively