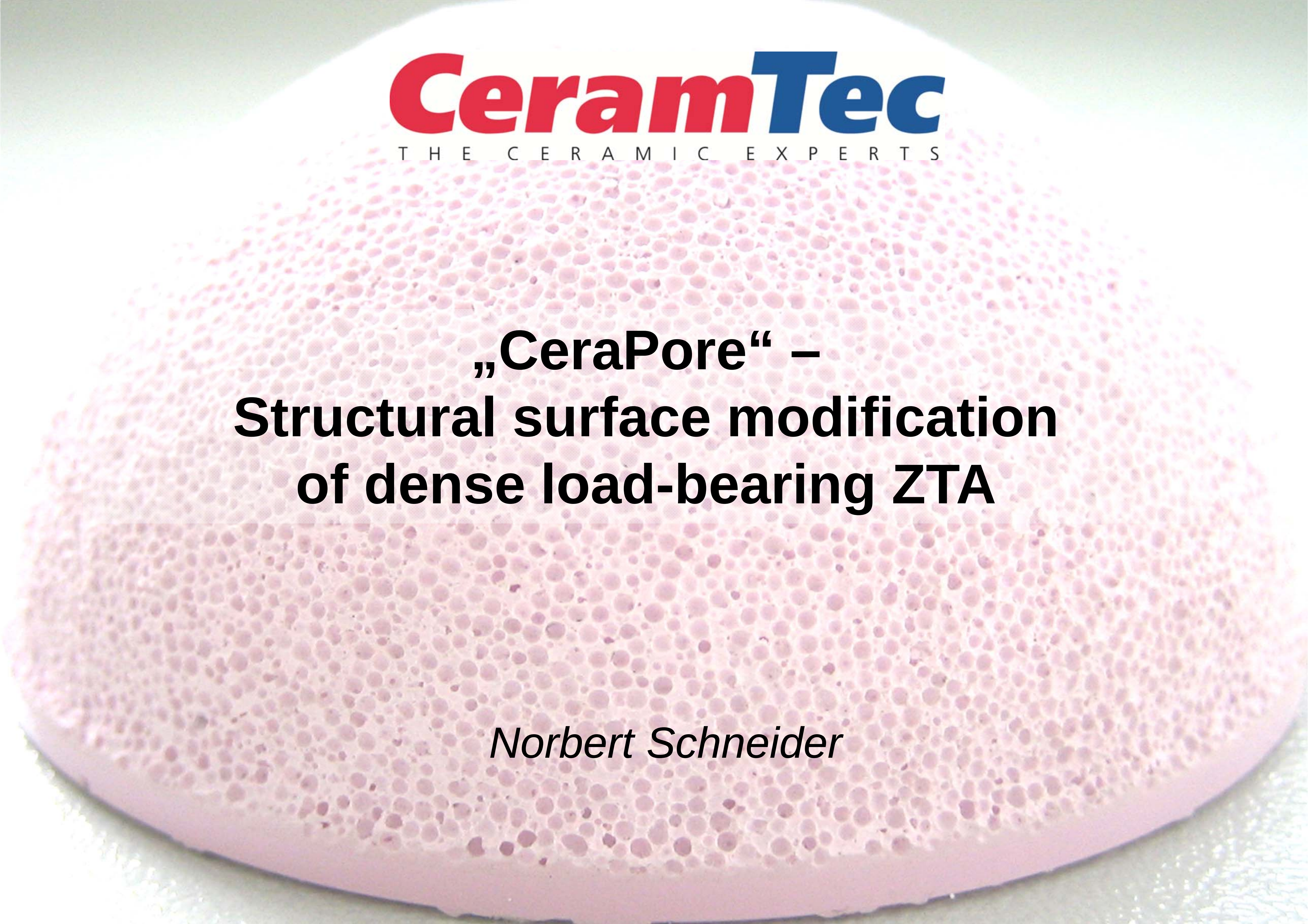


CeramTec
THE CERAMIC EXPERTS

„CeraPore“ – Structural surface modification of dense load-bearing ZTA

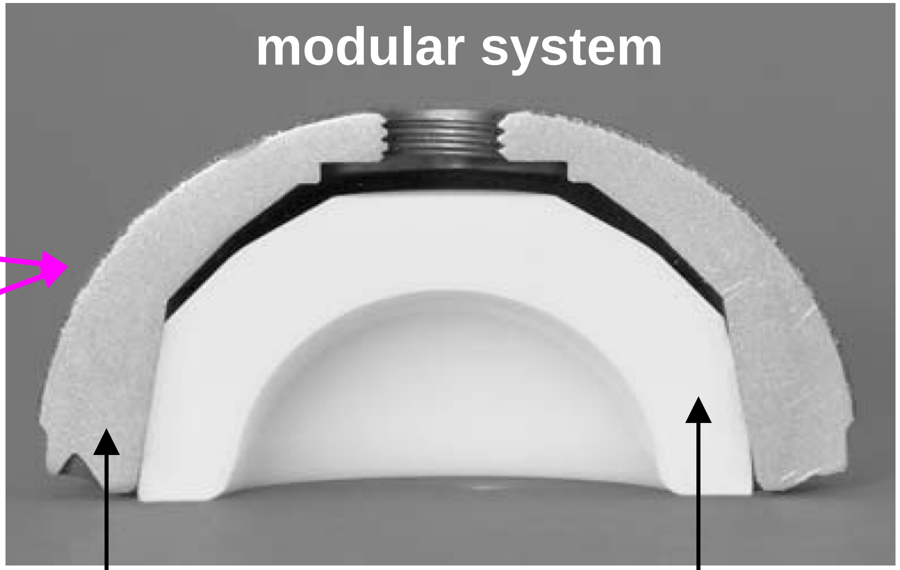
Norbert Schneider

Content

- **Background**
- Coating and sintering process
- Surface properties
- Mechanical properties
- Cellbiological / Clinical results
- Regulatory aspects
- General project risks

Background

Trilogy® IT Acetabular System by Zimmer



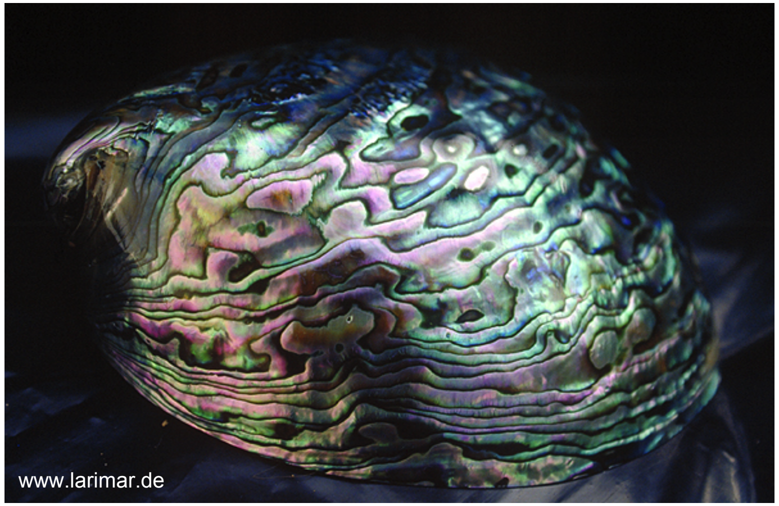
metal shell with osseointegrative coating (ingrowth of bone)

ceramic insert excellent tribological performance

- high wall thickness of the system
- risk of surgical error when seating ceramic insert
- risk of aseptic loosening due to metal ions

intelligent composite materials

nacre



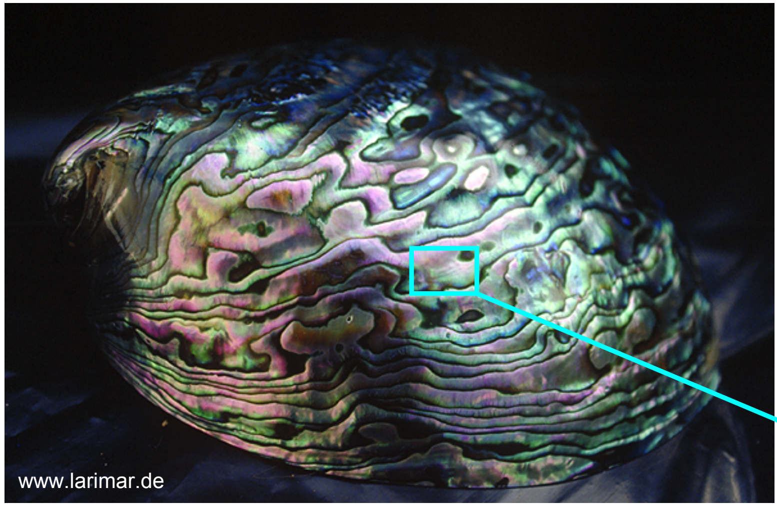
bone

Damascene-steel

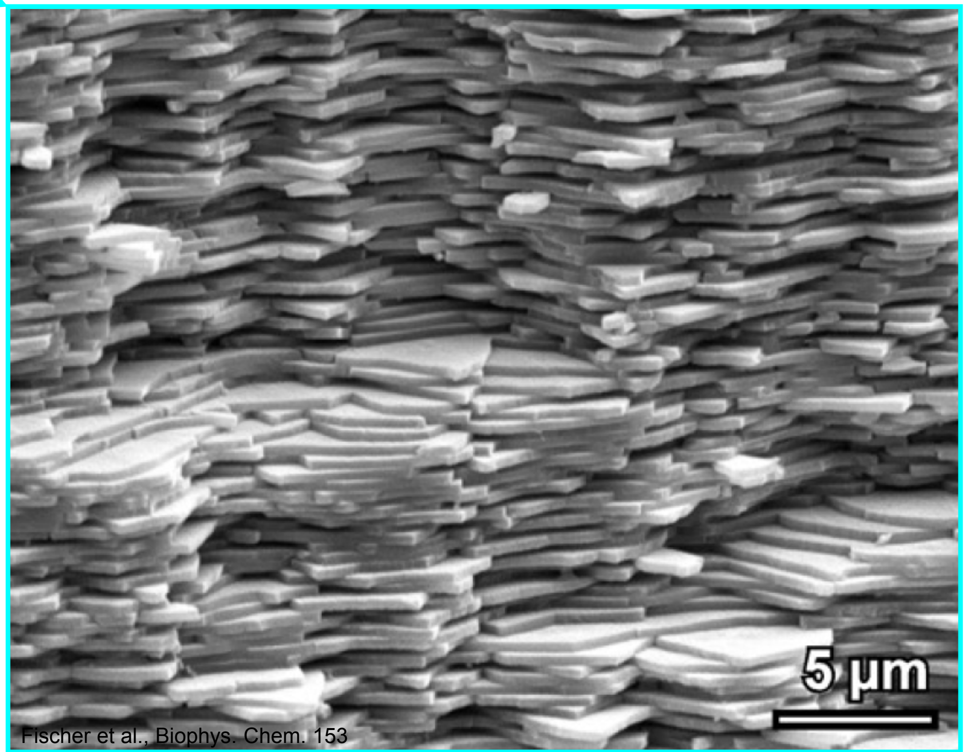
BIOLOX®*delta*

nacre

- nacre

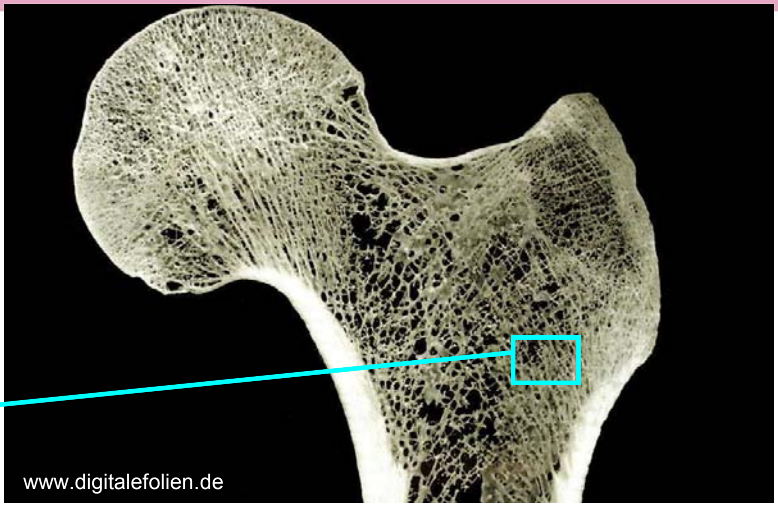


- **composite-Werkstoff:**
  95 % aragonite
  5 % proteins & chitin
- **Young's modulus:**
  up to 80 GPa
- **fracture toughness:**
  1 - 8 MPa $m^{1/2}$



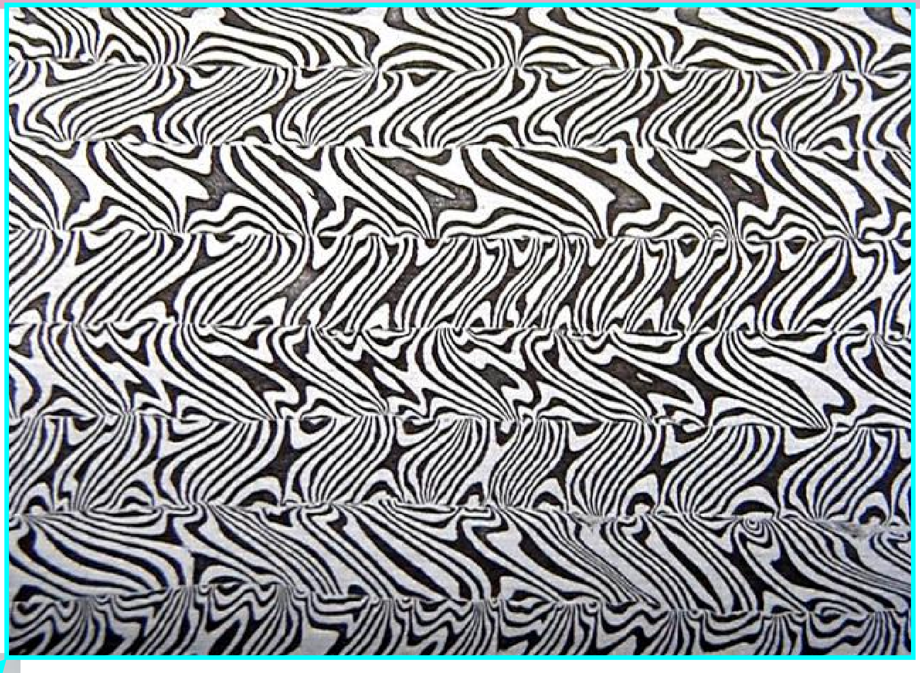
bone

- bone



- **composite-material:**
  70 % hydroxyapatite & calciumphosphate
  20 % collagen & proteoglycane
  10 % water
- **Young's modulus:**
  appr. 30 GPa
- **fracture toughness:**
  2 – 12 MPa $m^{1/2}$

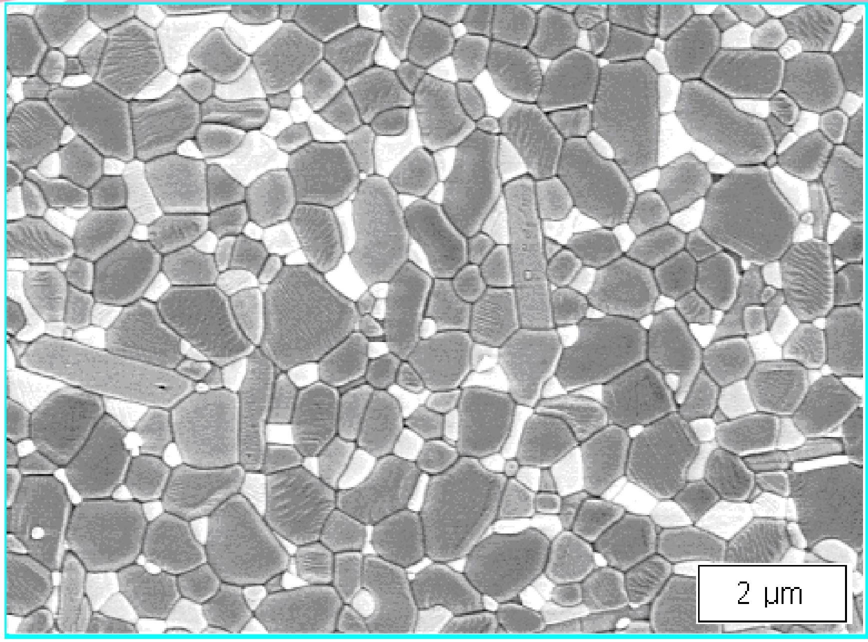
Damascene steel



Damascene-steel

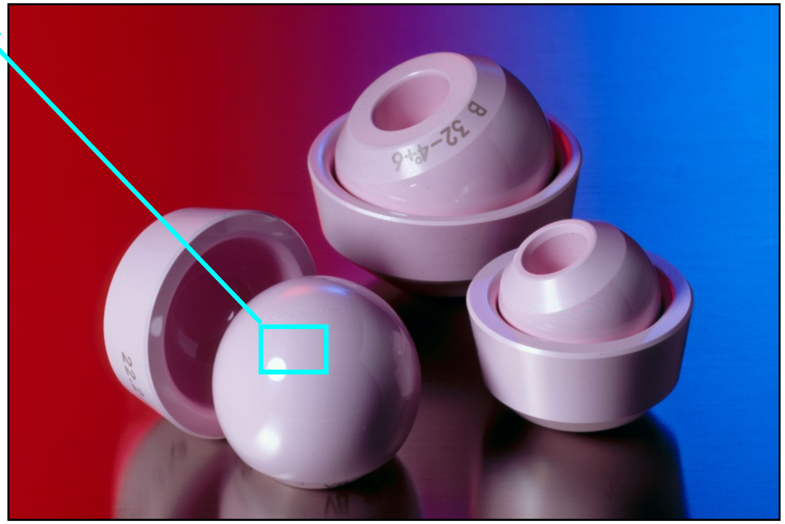
- **composite-material:**
  50 % low-C steel
  50 % rich-C- or P steel
- **Young‘s-modulus:**
  210 GPa
- **fracture toughness:**
  50 MPa $m^{1/2}$

BIOLOX®*delta*



- **composite-material:**
  80 % Al_2O_3
  17 % ZrO_2
  3 % toughening platelets
- **Young‘s modulus:**
  360 GPa
- **fracture toughness:**
  6.5 MPa $m^{1/2}$

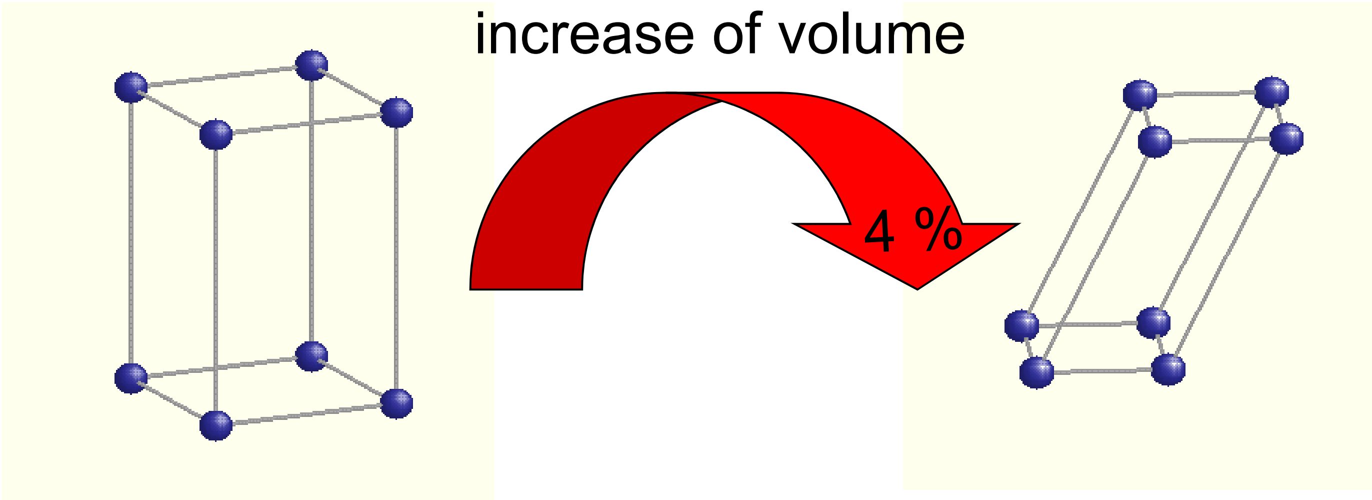
BIOLOX®*delta*



Transformation toughening of ZrO_2

tetragonal:
ρ = 6,10 g/cm³

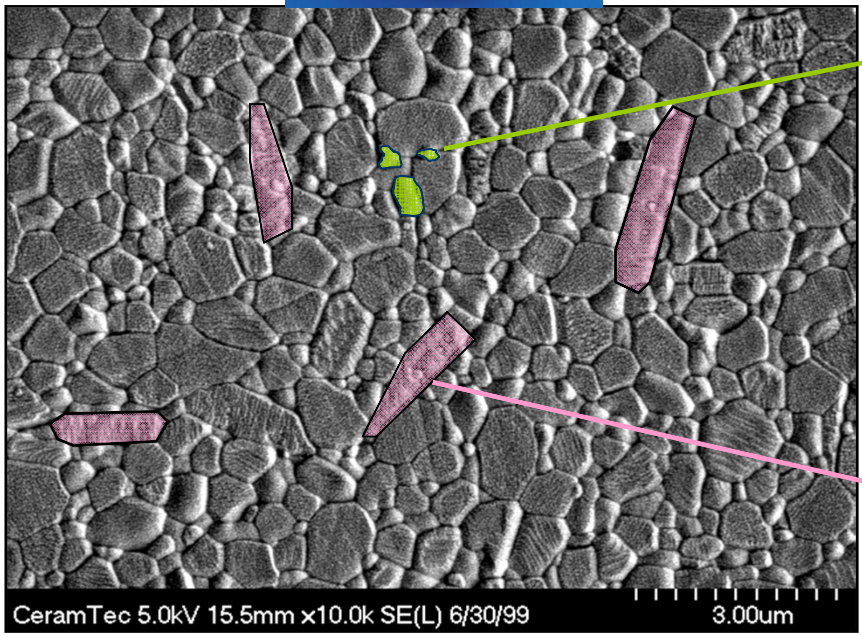
monoclinic:
ρ = 5,85 g/cm³

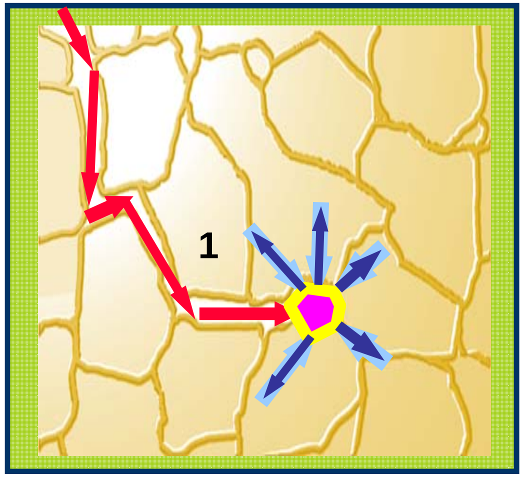


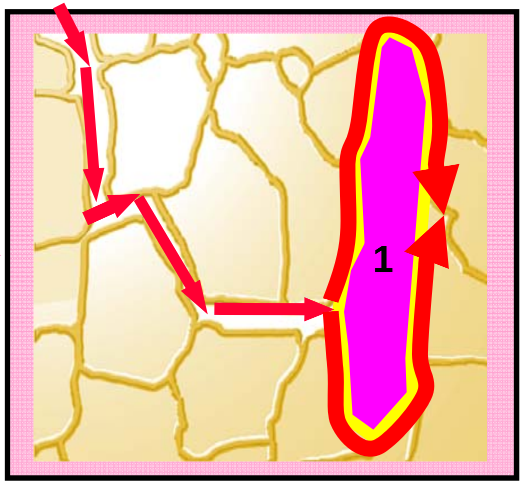
1170 °C < T

T < 1170 °C

Toughening mechanisms in BIOLOX®*delta*

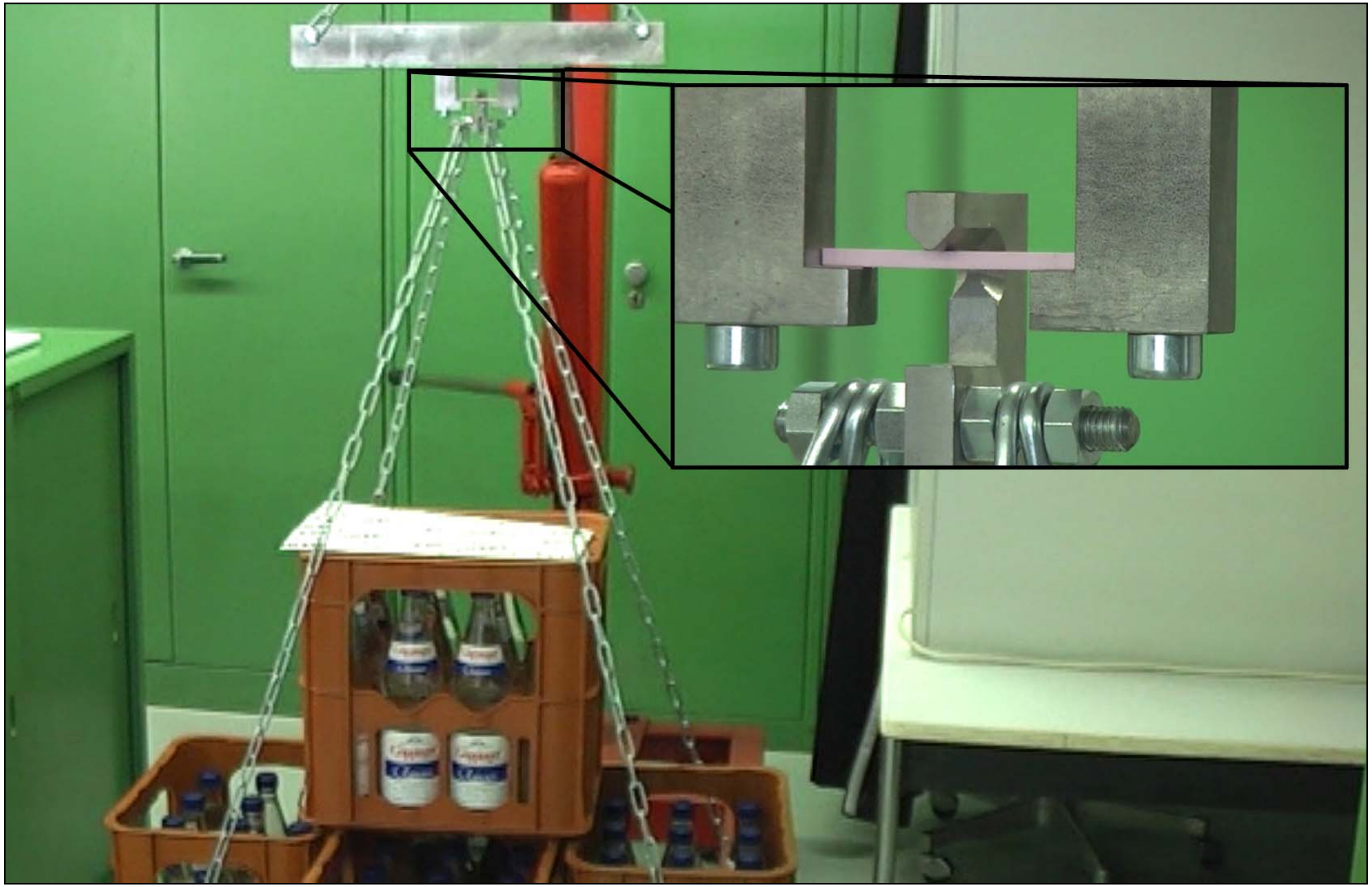






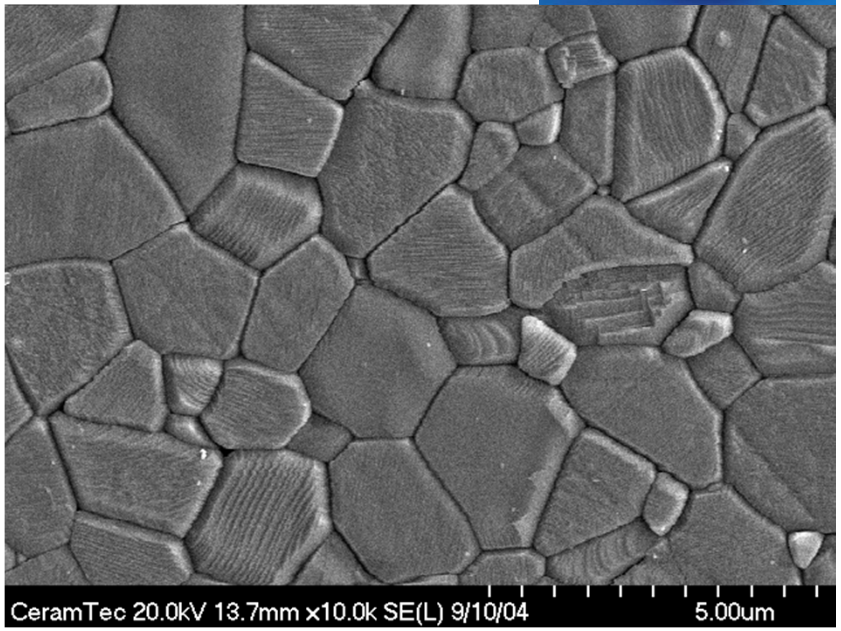
BIOLOX® inside

3-point-bending strength



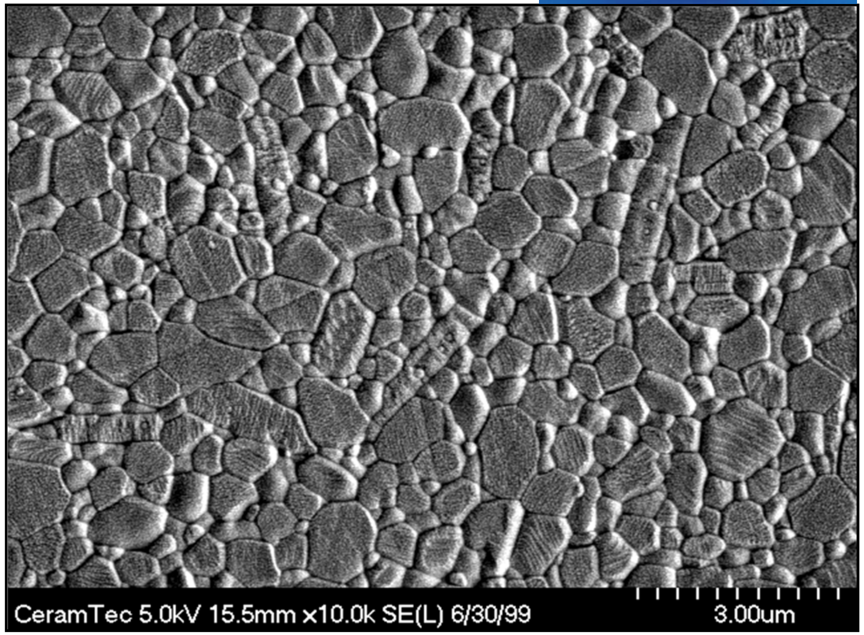
Microstructure of BIOLOX® ceramics

BIOLOX®*forte*



99,8 Vol.% Al_2O_3 +
0,2 Vol.% other oxides

BIOLOX®*delta*



80 Vol.% Al_2O_3 + 17 Vol.% ZrO_2 +
3 Vol.% other oxides

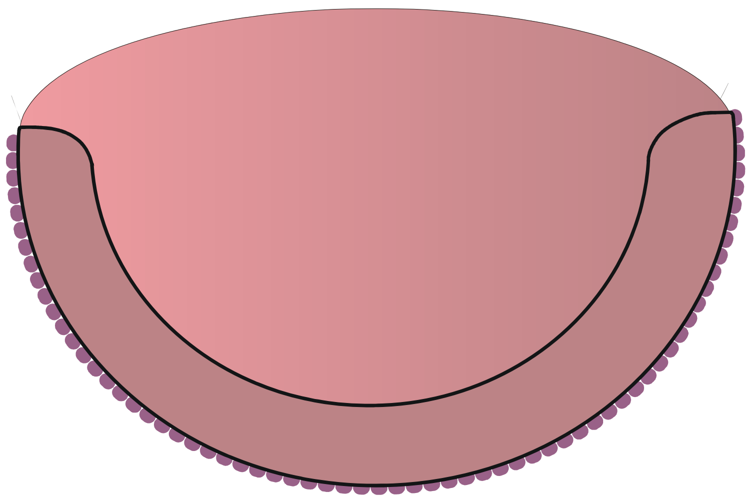
BIOLOX® inside

Material properties of BIOLOX®-ceramics

		BIOLOX®*forte*	BIOLOX®*delta*
Variable	**Unit**	**Mean value**	**Mean value**
Al_2O_3	Vol.%	99,8	80
ZrO_2	Vol.%	n.a.	17
mean grain size	µm	1,75	0,56
4-point-bending-strength	MPa	631	1384
Young's modulus	GPa	407	358
frac. toughn. K_{IC}	MPa $m^{1/2}$	3,2	6,5

Aim of the project

- development of a porous ceramic coating based on BIOLOX®*delta* for all-ceramic joint replacement



- reduced wall thickness (3 mm) → lower outer diameter
- improved functionality → combination of superior tribological properties of ceramics and direct osseointegration
- monolithical system → simplified implantation, avoiding surgical errors

Content

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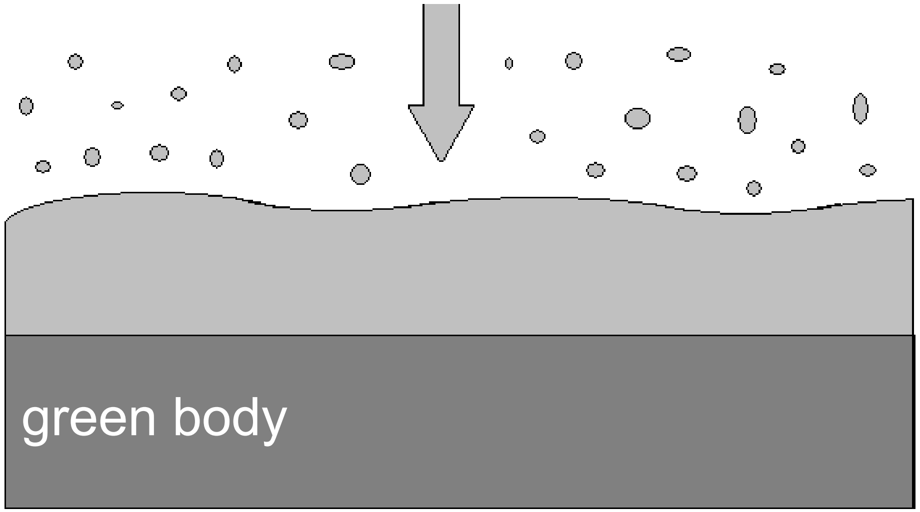
Coating process

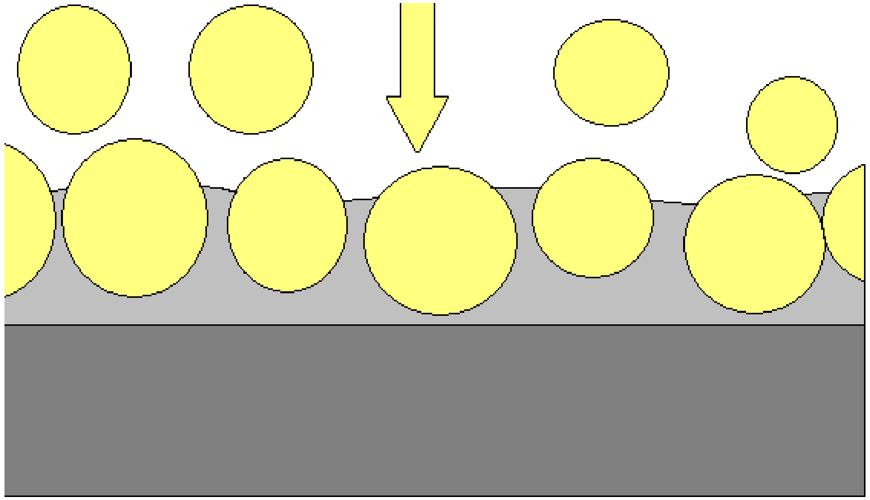
spraying of ceramic slurry



- semi - automated process

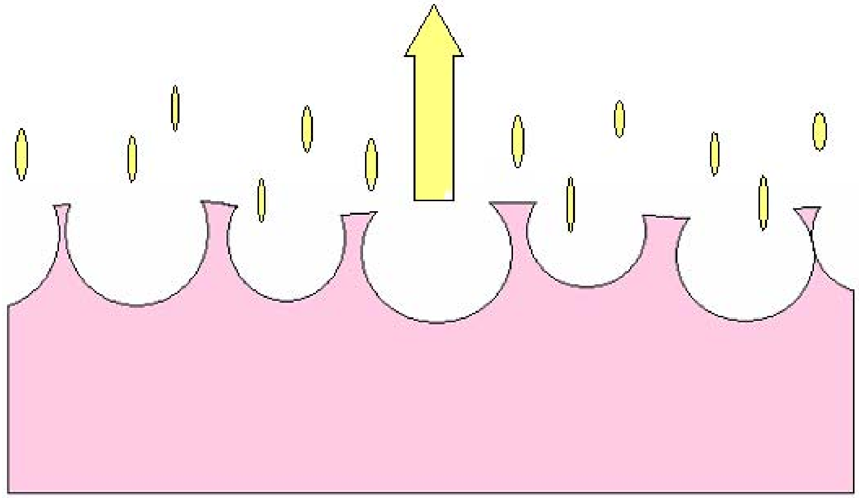
Coating process

spraying of pore forming agent

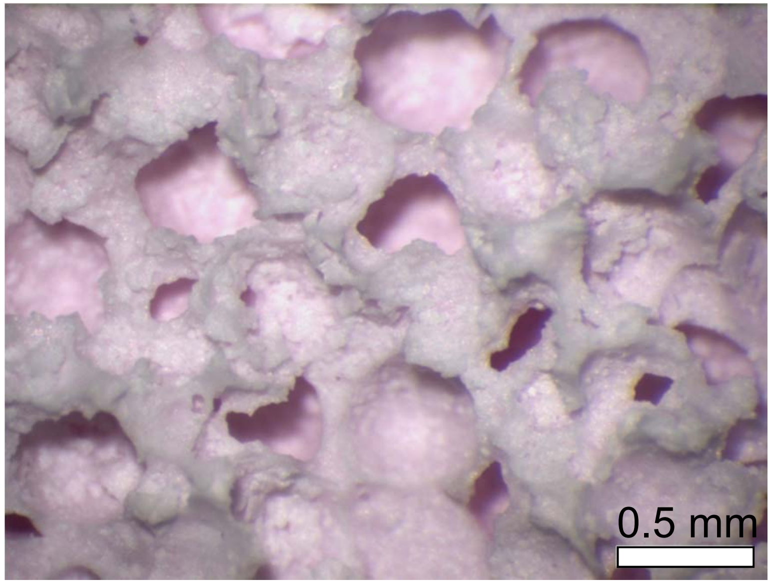


- pore forming agent: organic material
- pore forming agent is completely removed during sintering process

Sintering process



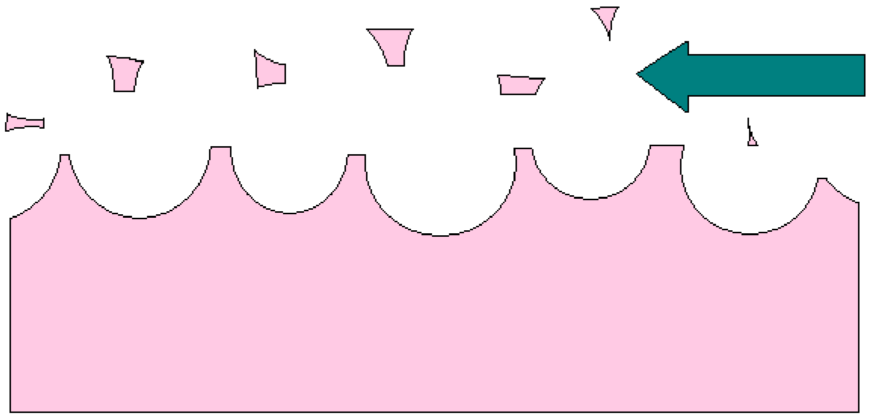
sintered coating



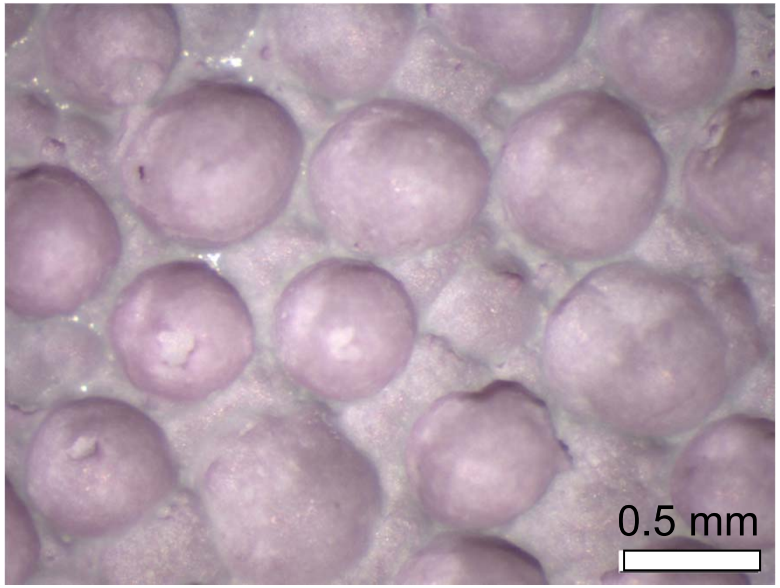
- thermical removing of pore forming agent
- properties of coating depend on sintering temperature, pressure and sintering time

Surface treatment after sintering

blasting process

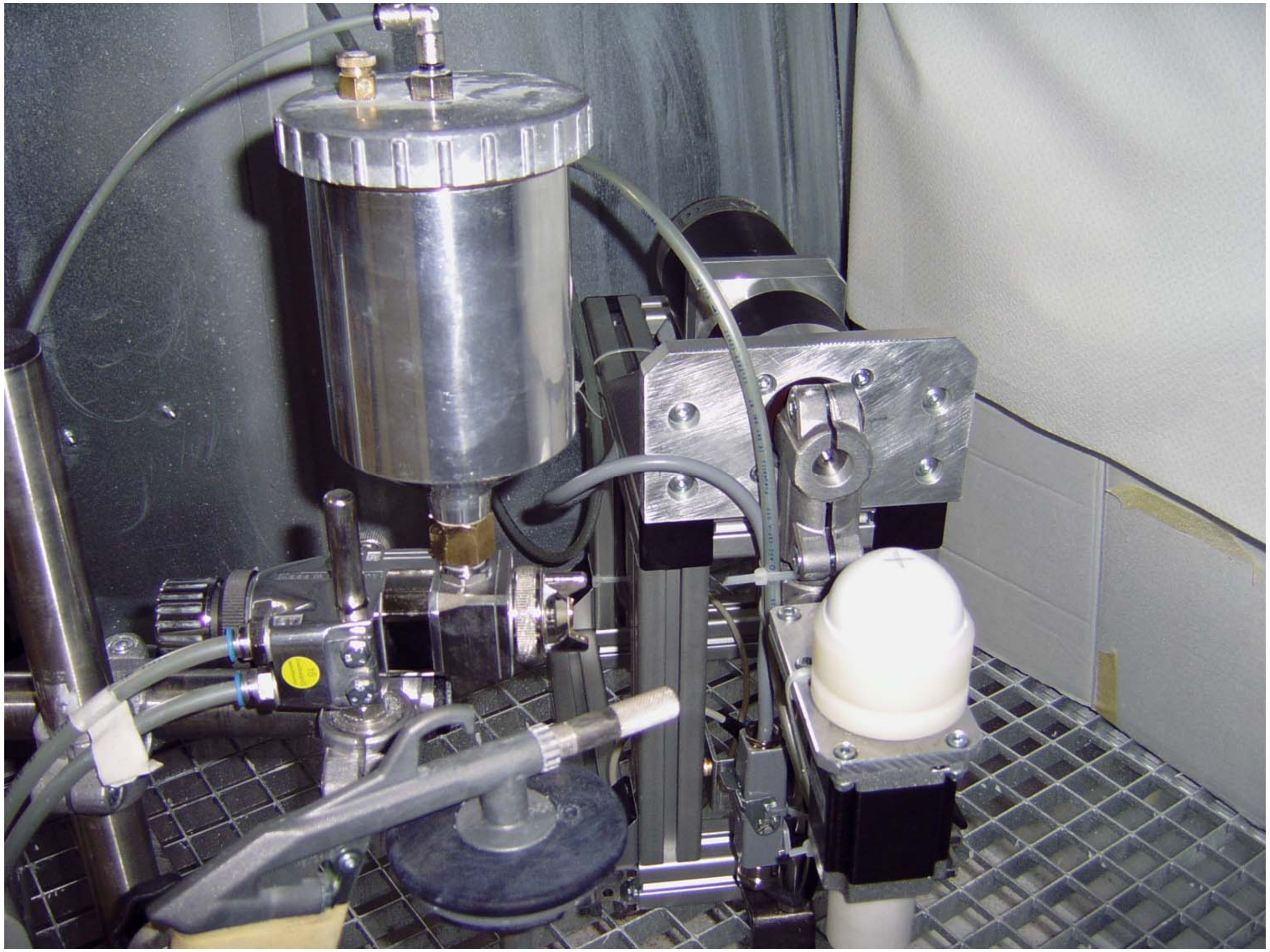


finished coating surface



- removing mechanically instable parts of the coating
- pore opening

Coating process



Coating process is bench-scale unit

Content

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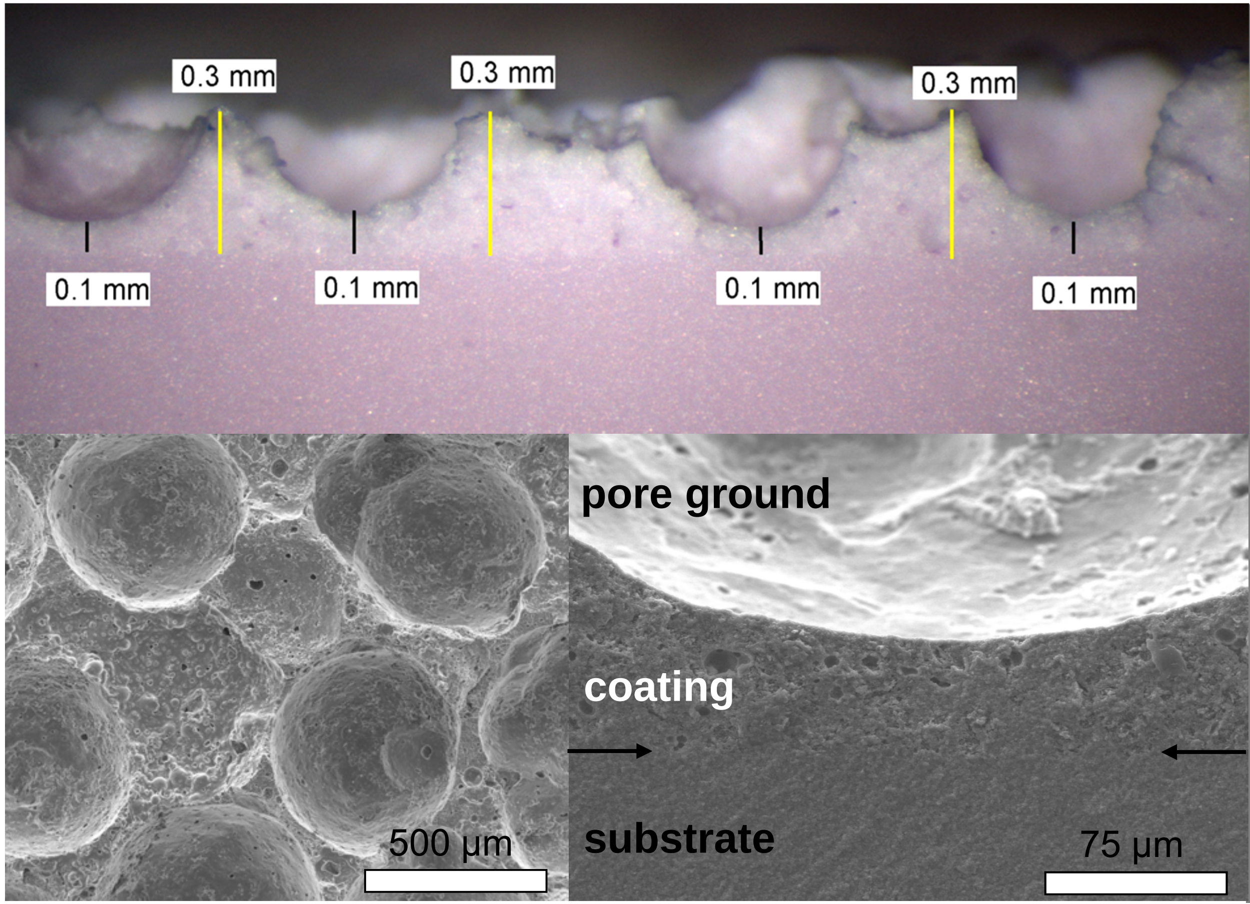
Characterization: optical microscope / SEM

BIOLOX® inside



→ surface porosity
app. 47 %

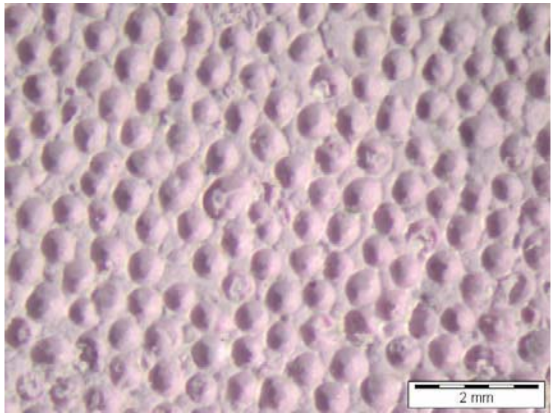
→ pore size (diameter)
200 – 500 µm

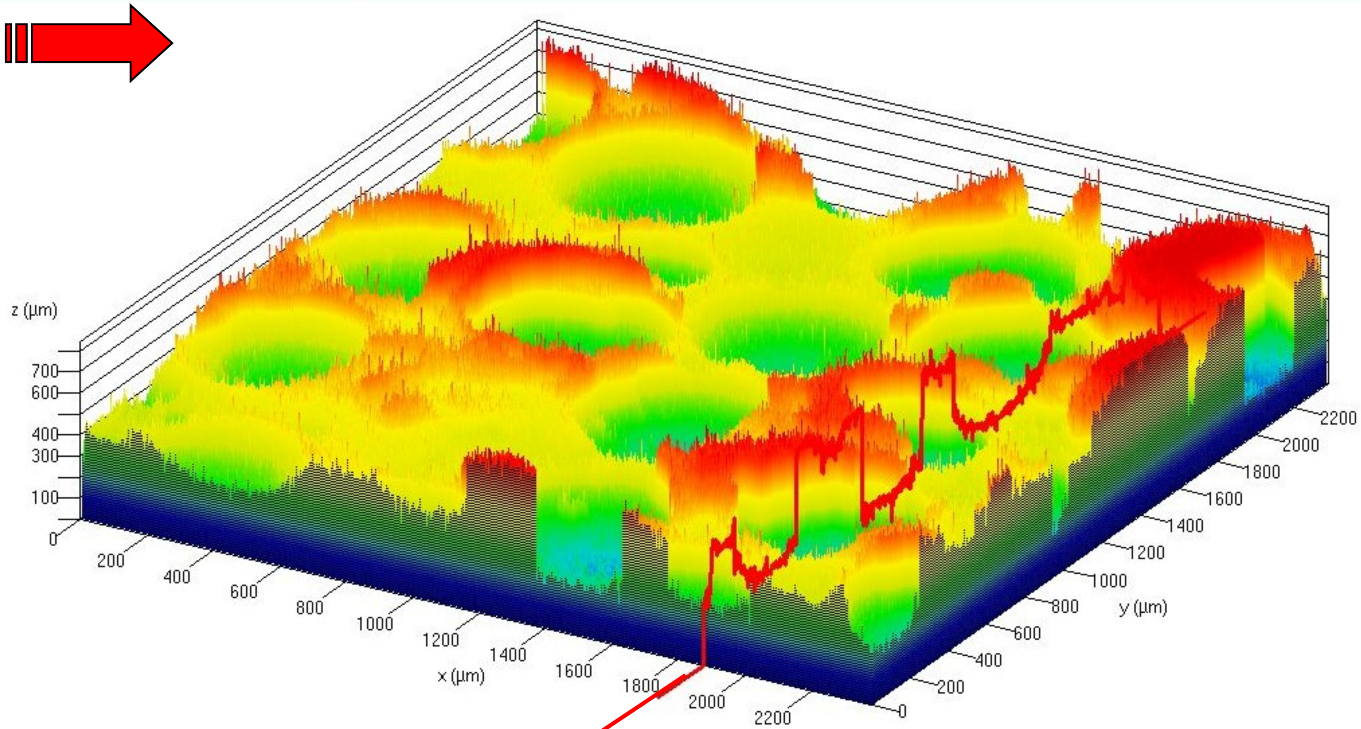
→ hemispherical pores

→ surface enlargement by
factor 2 to 3

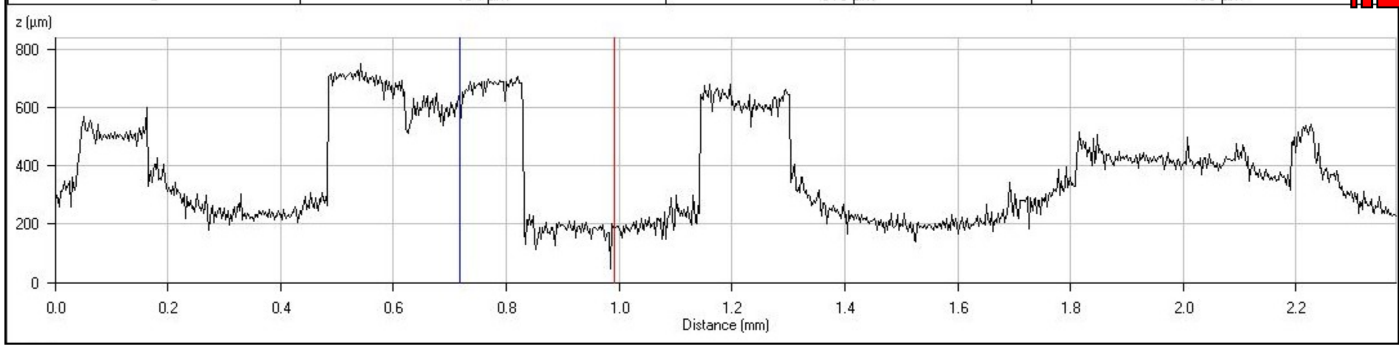
highly reproducible surface structure

Characterization: Laser-scanning-microscope



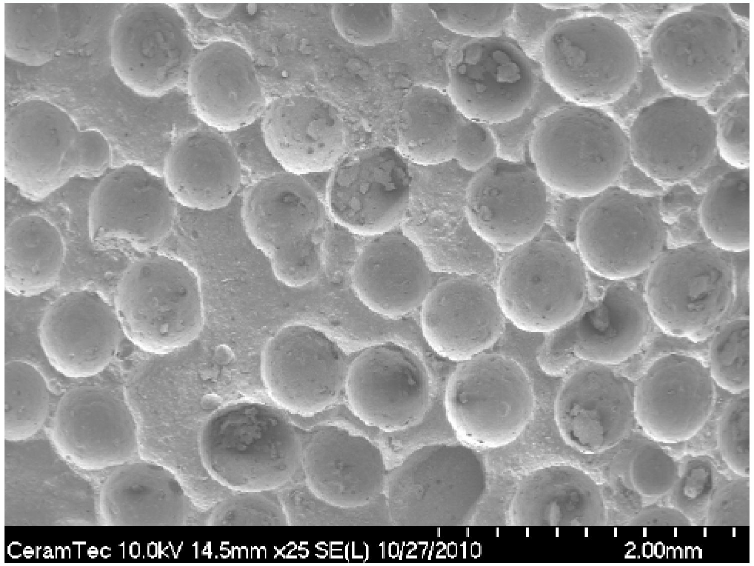


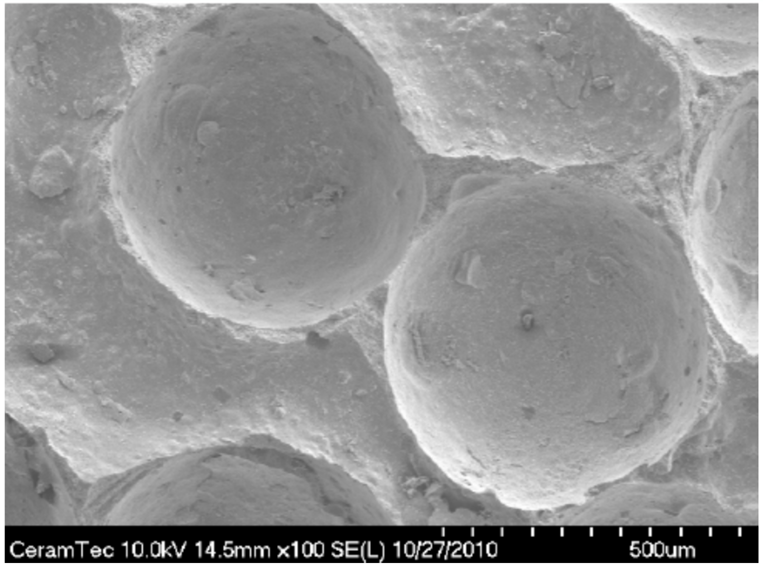
	Marker 1	Marker 2	Difference
x	0.9927 mm	0.7184 mm	-0.2743 mm
z	184 µm	619 µm	435 µm

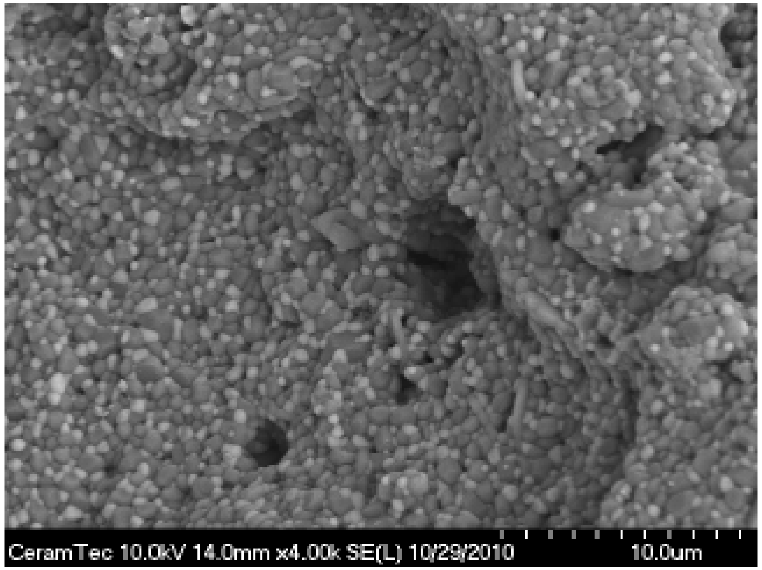


roughness:
R_z = 435 µm

SEM-pictures







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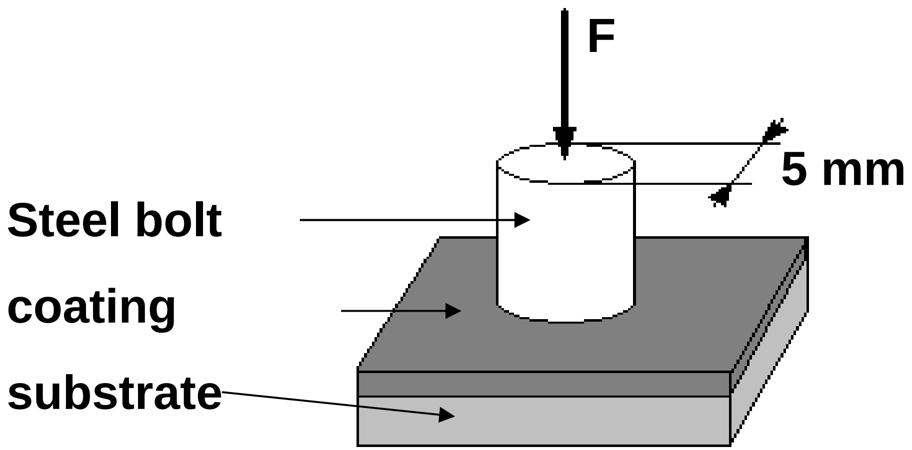
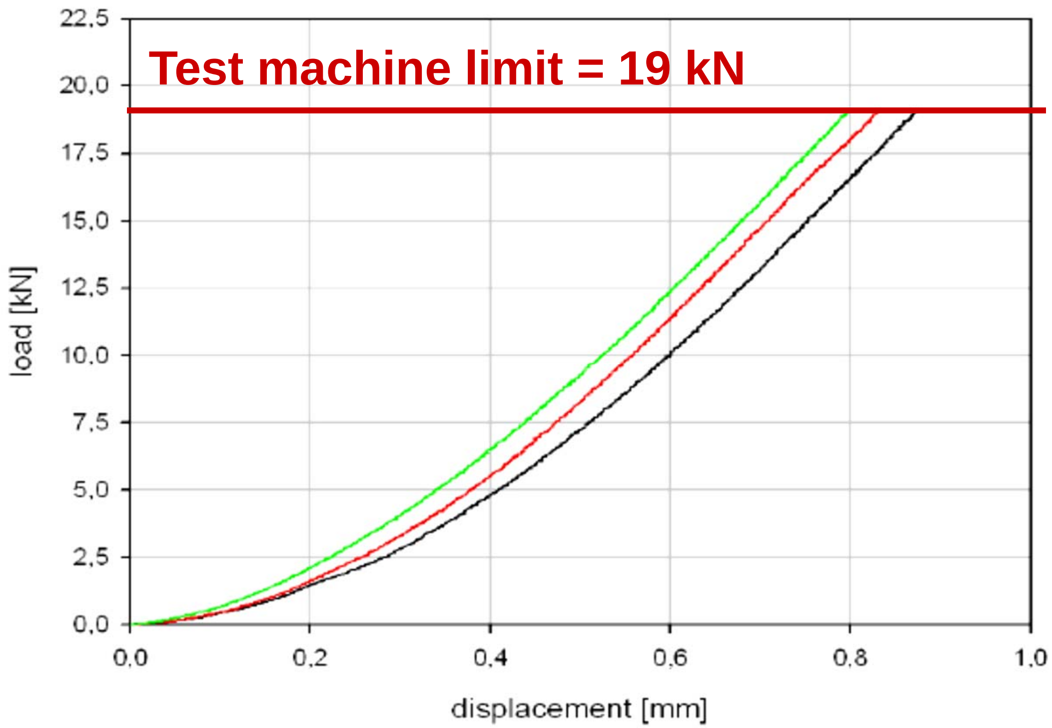
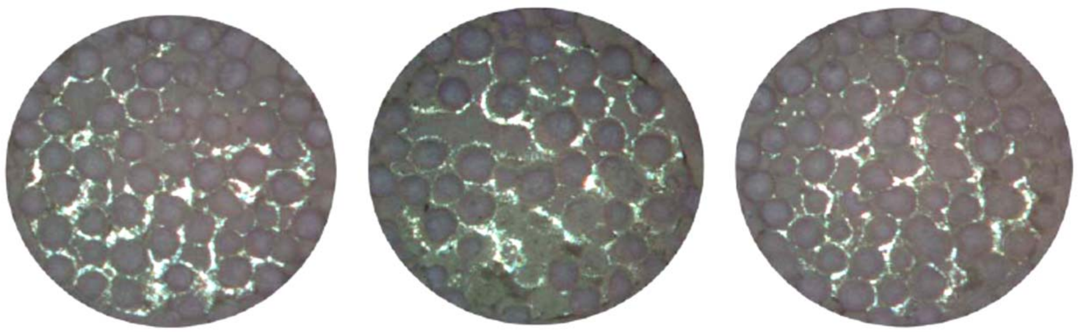
Characterization: compression strength





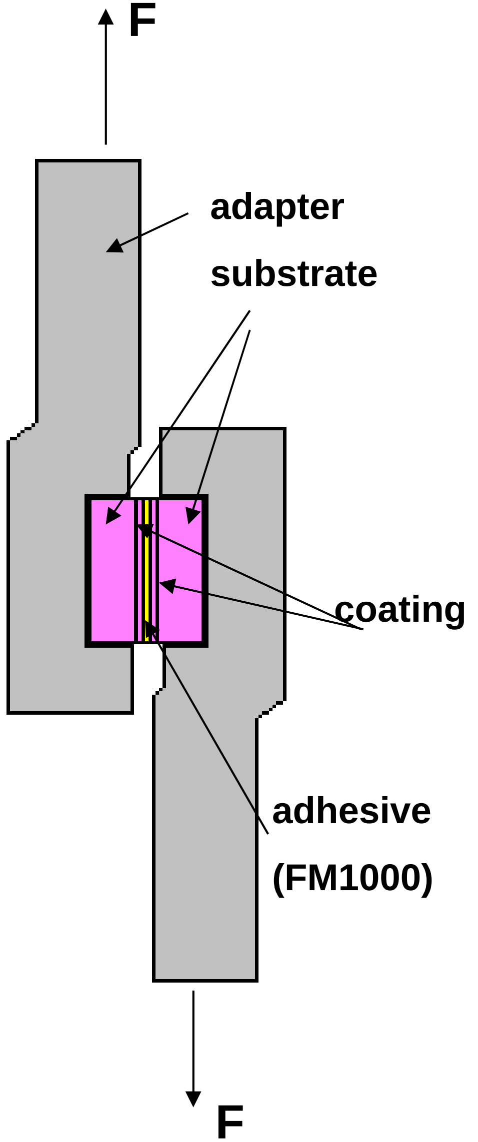


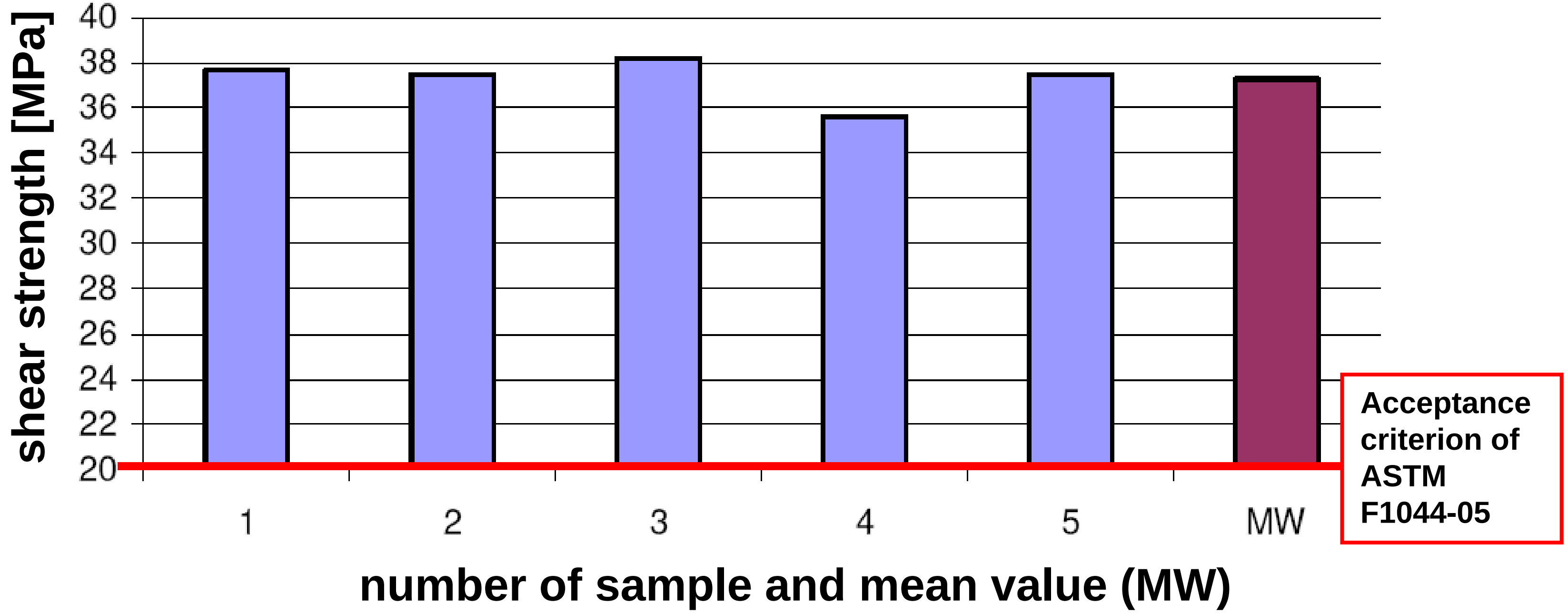
→ weight equivalent 1,9 t

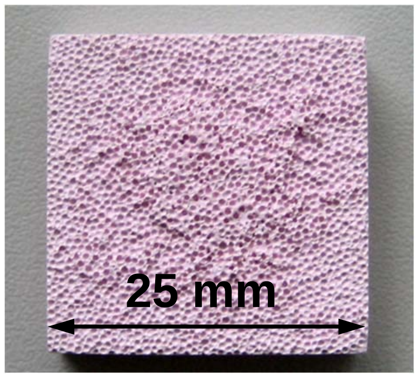
→ steel bolts were deformed

→ no damage occured at the coating

Characterization: shear strength

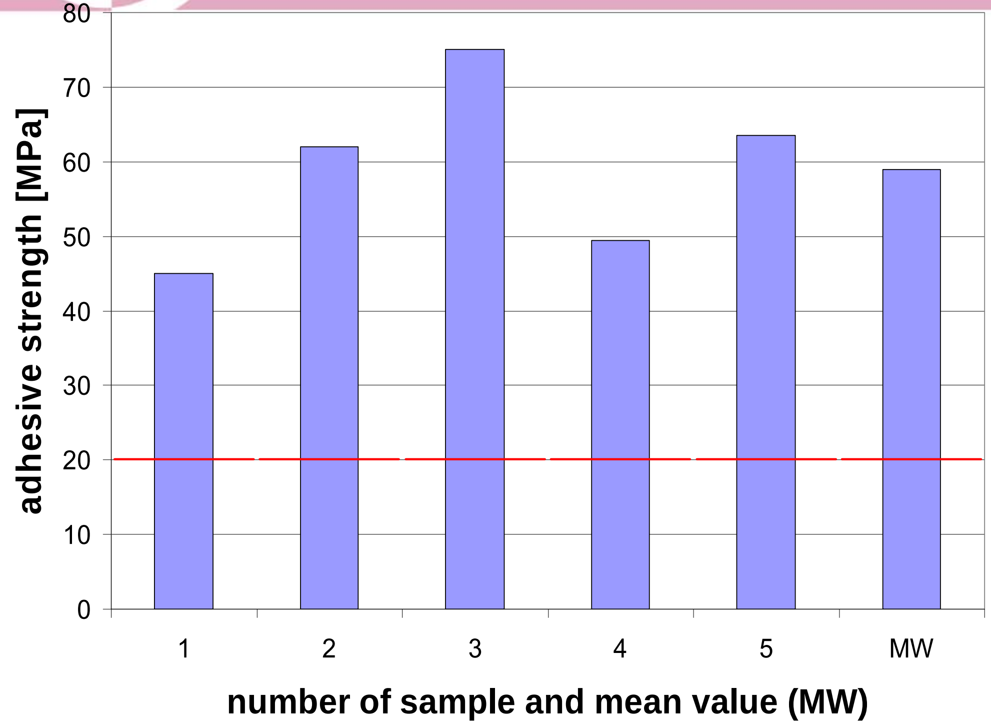


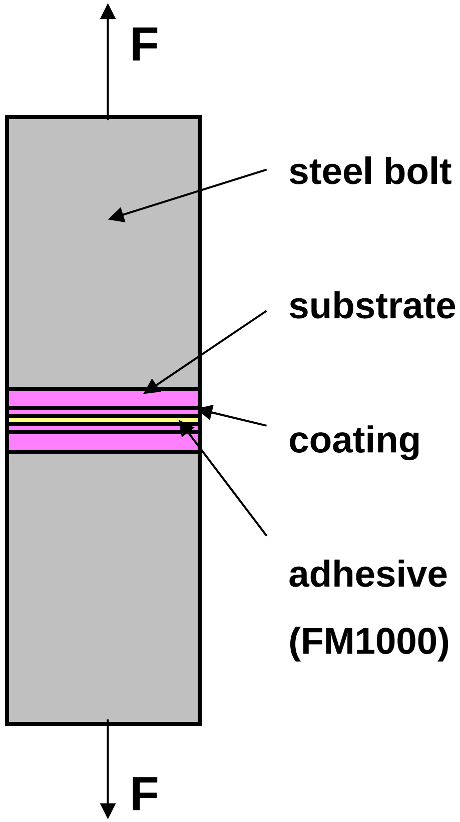


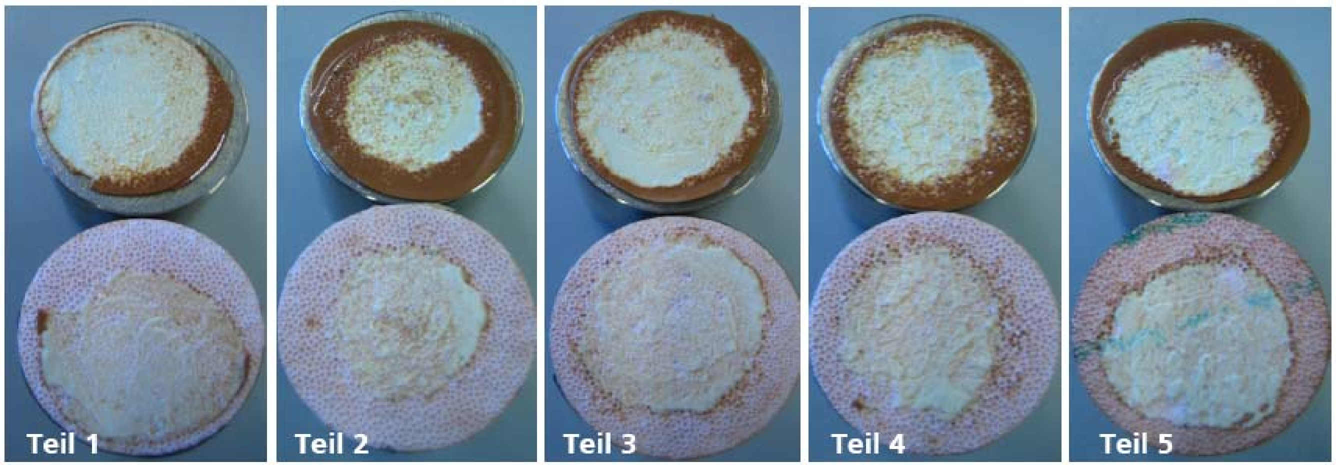


▶ no delamination of the coating

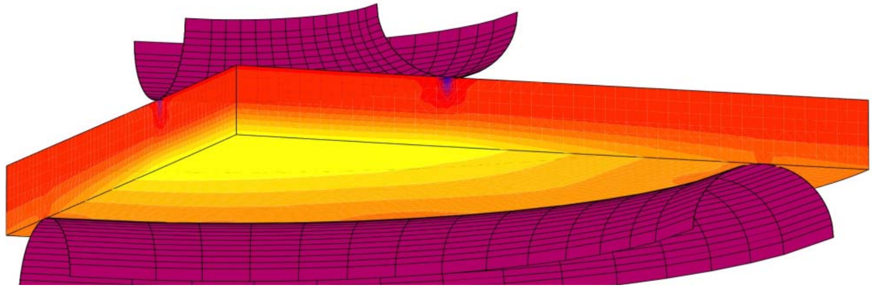
Characterization: adhesive strength

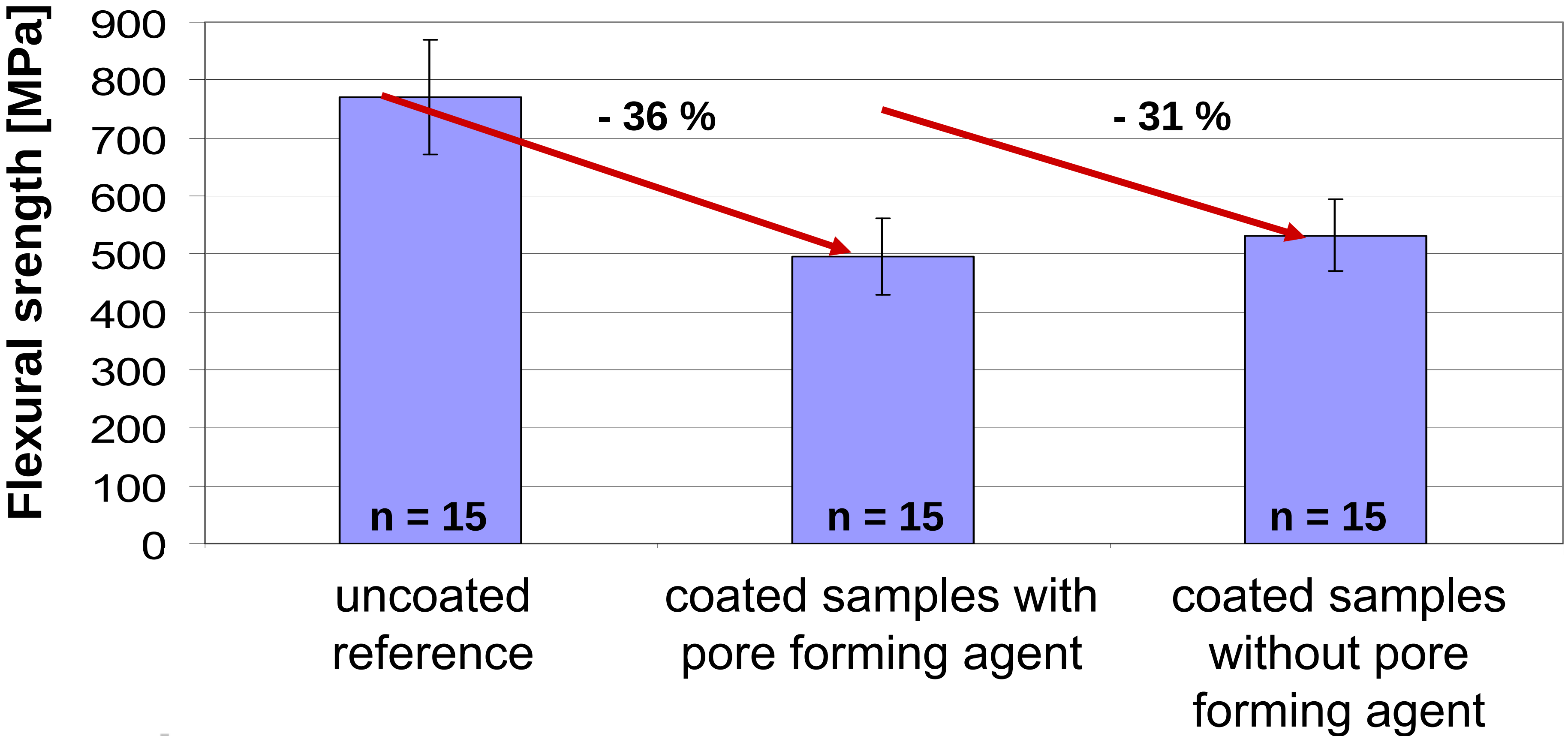




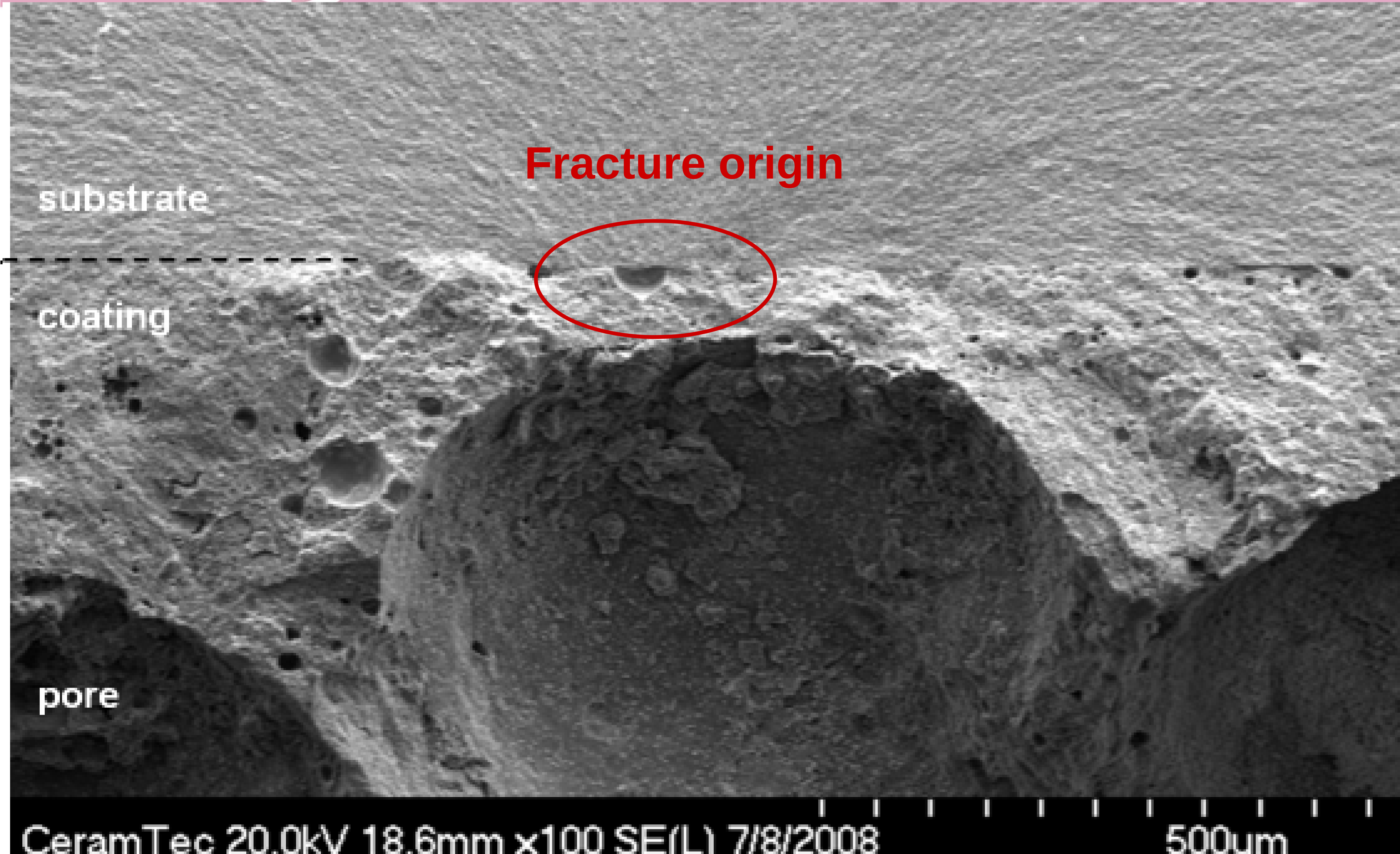


Characterization: biaxial bending strength





Analysis of fracture origin



prototype design

BIOLOX® inside

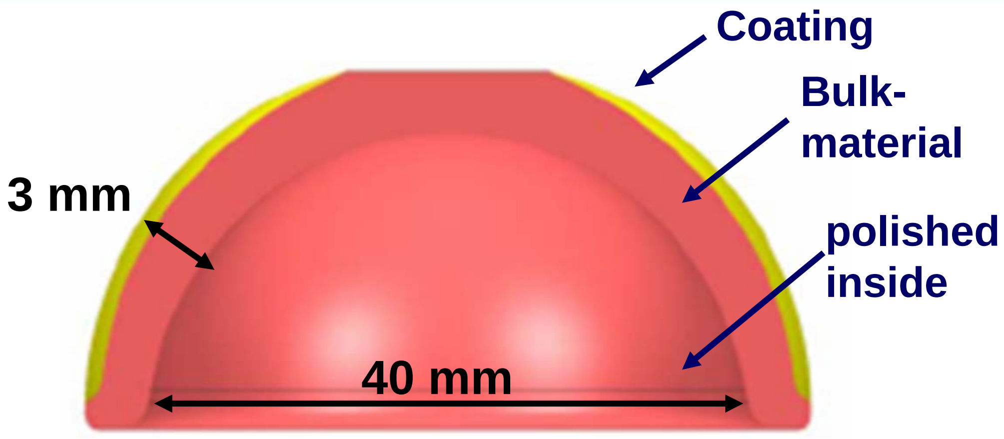
Requirements:

→ Testing geometry hip joint cup

→ bearing couple 40 mm diameter

→ wall thickness as small as possible

(minimized space requirement)



Prototype CAD-Model

Cup-Design relates to:

→ range of motion

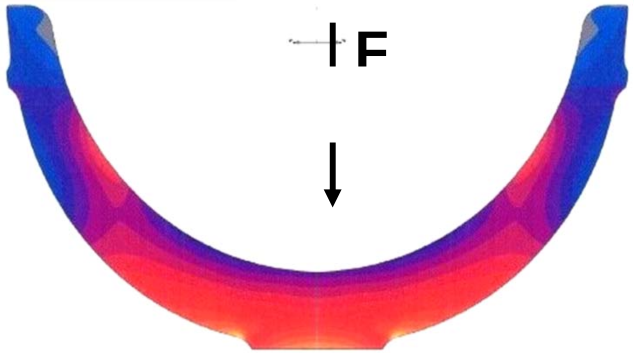
→ luxation stability

→ mechanical stability

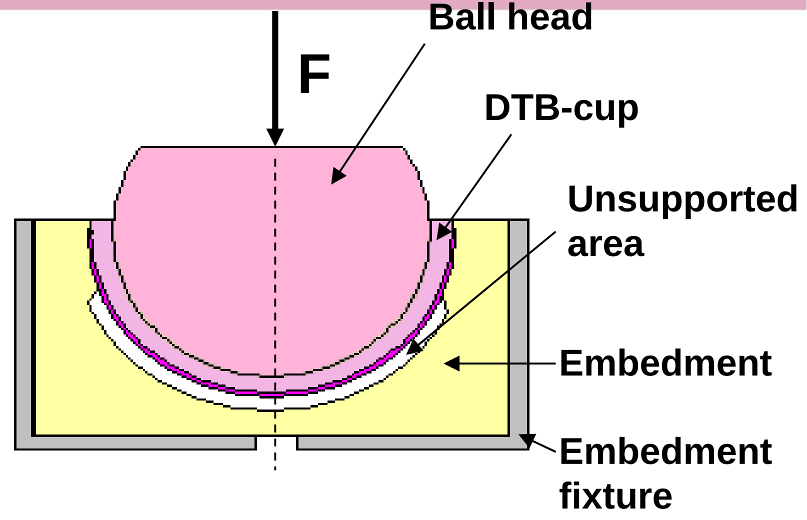
→ production process

Prototype

In-vivo like burst-test without backside support



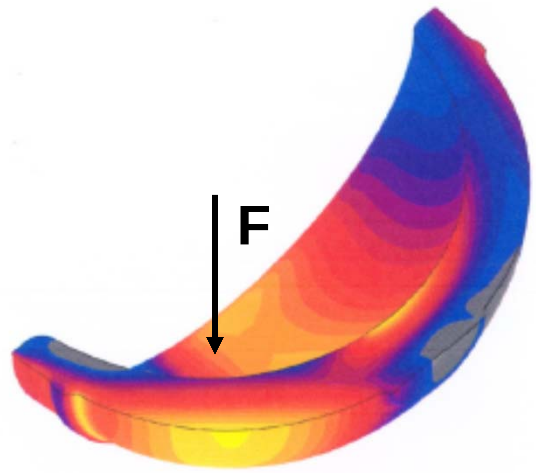
Burst-Test axial



Stress-analysis

(Finite Element Methode)

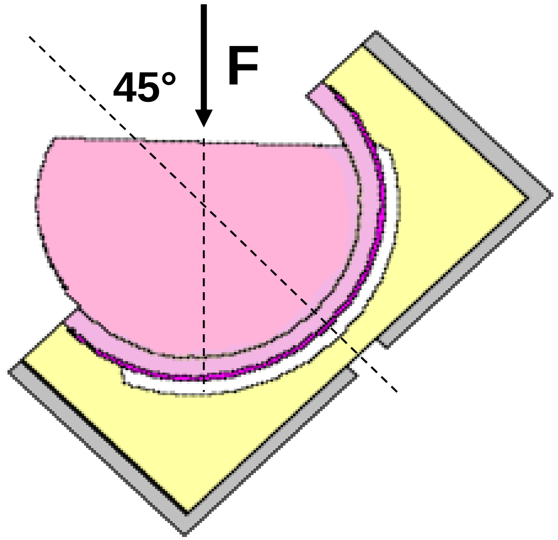
Test Setup



Burst-Test 45°

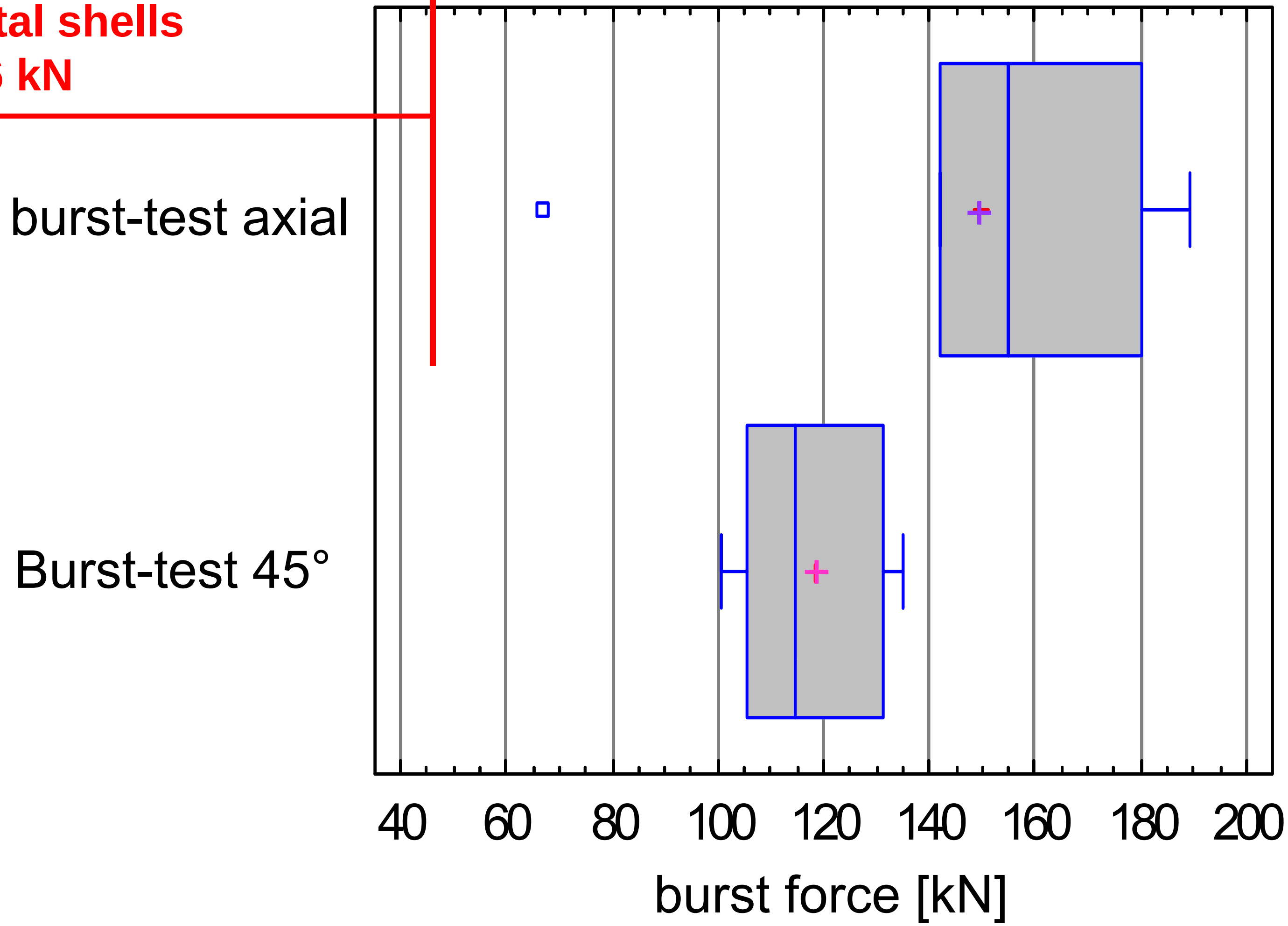
according

„upright standing“



Results of burst-test

Acceptance criteria for regular ceramic inserts in metal shells
F ≥ 46 kN



+ mean value
150 kN
std. dev. 40 kN
n = 7

+ mean value
118 kN
std. dev. 14 kN
n = 7

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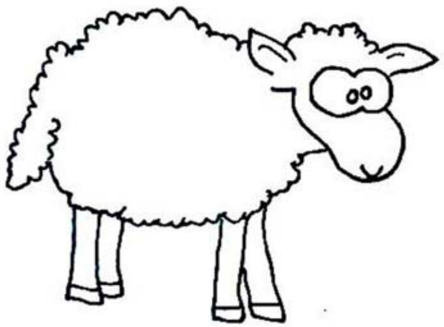
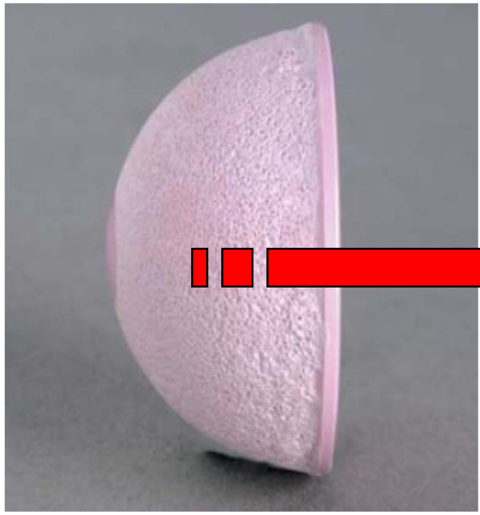
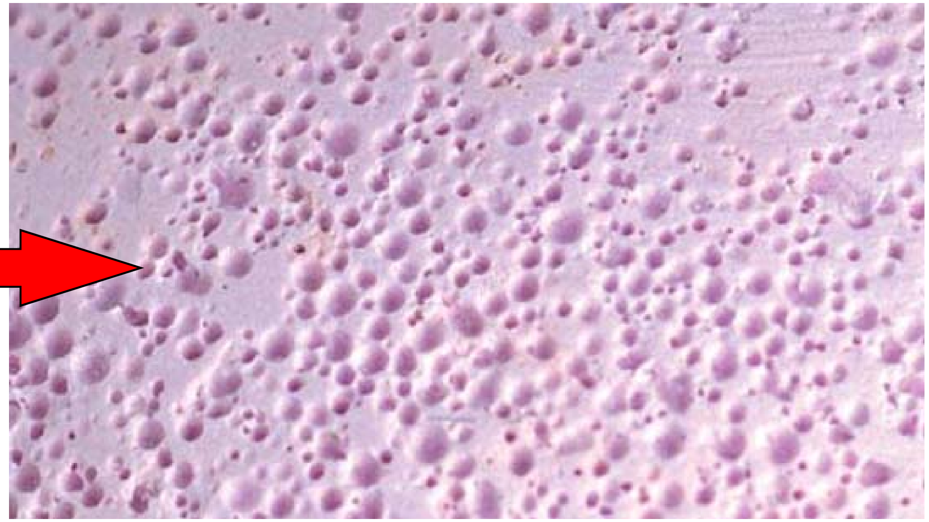
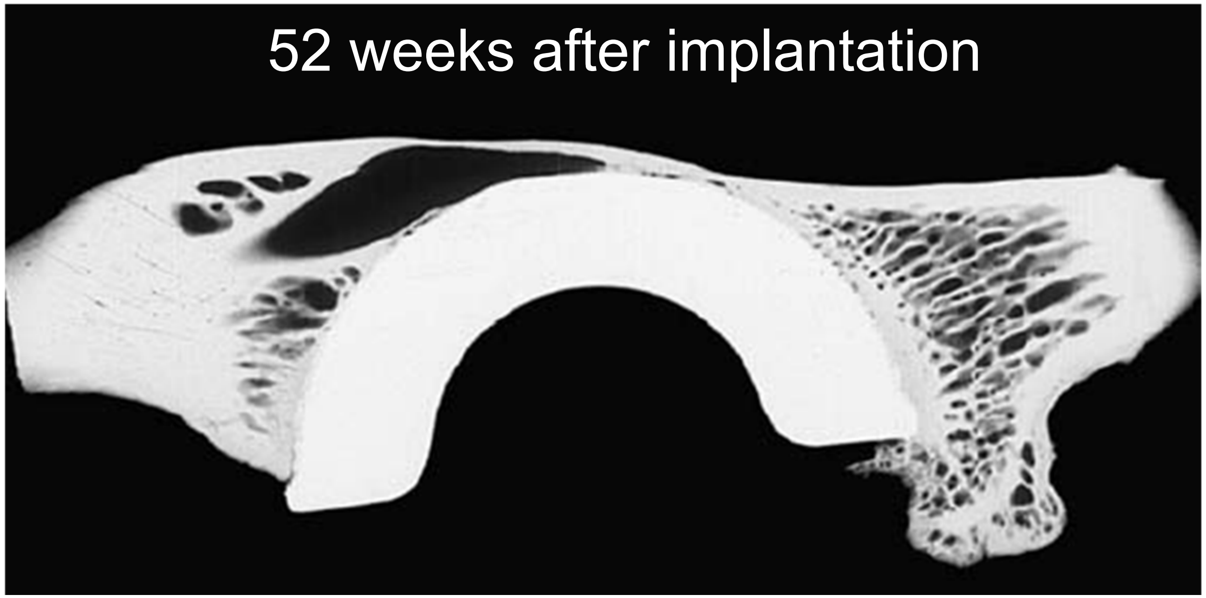
Osseointegration in biological study







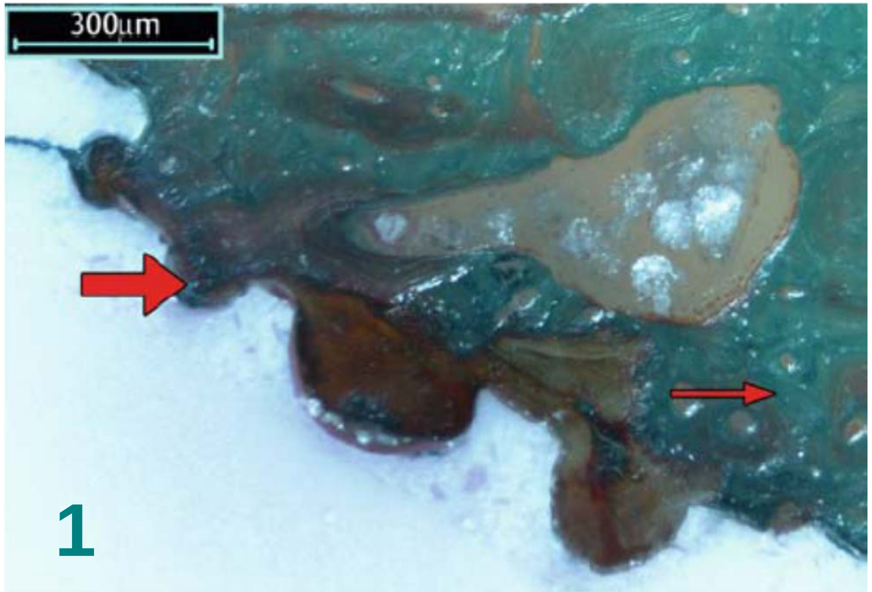
Schreiner, Schulze, Schwarz et al., ZOrthopUnfall 2011

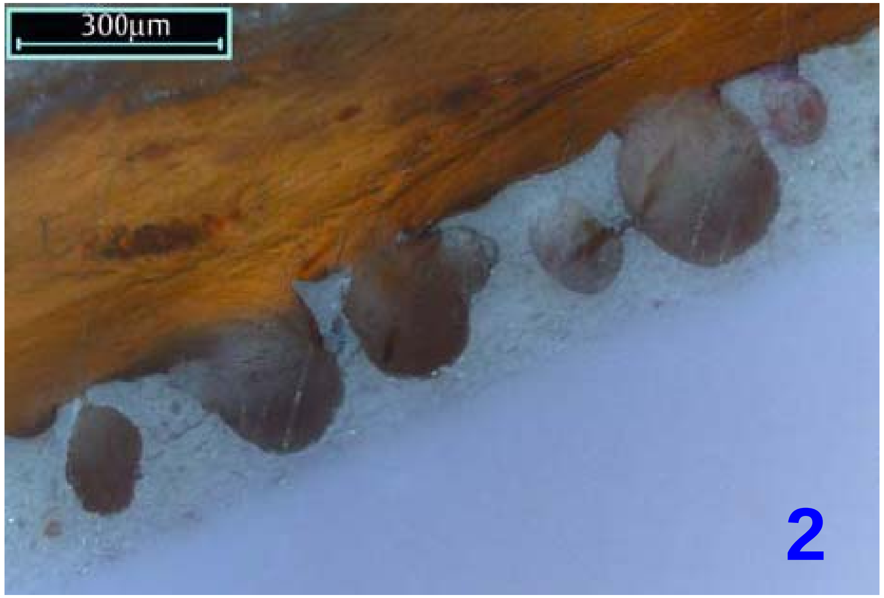


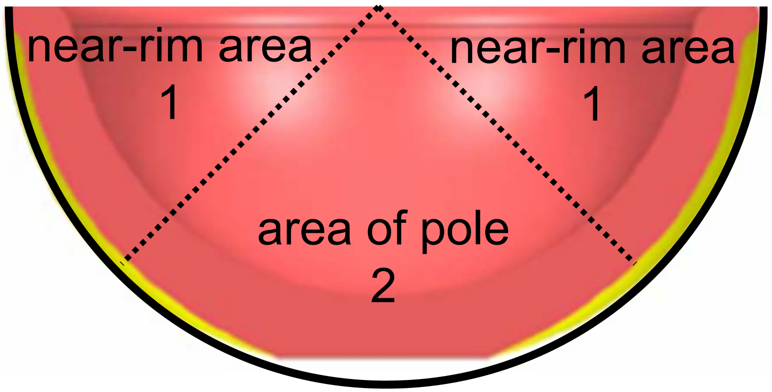
Osseointegration in biological study

Masson-Goldner stain

Schreiner, Schulze, Schwarz et al., ZOrthopUnfall 2011

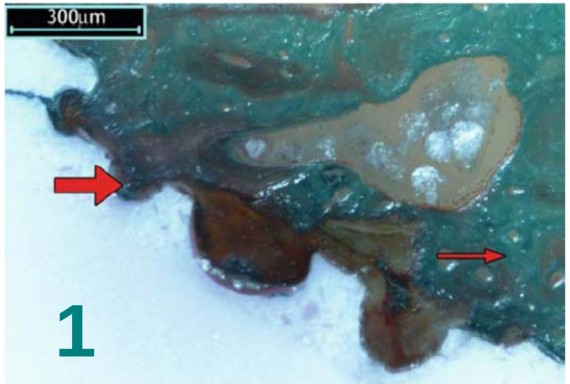




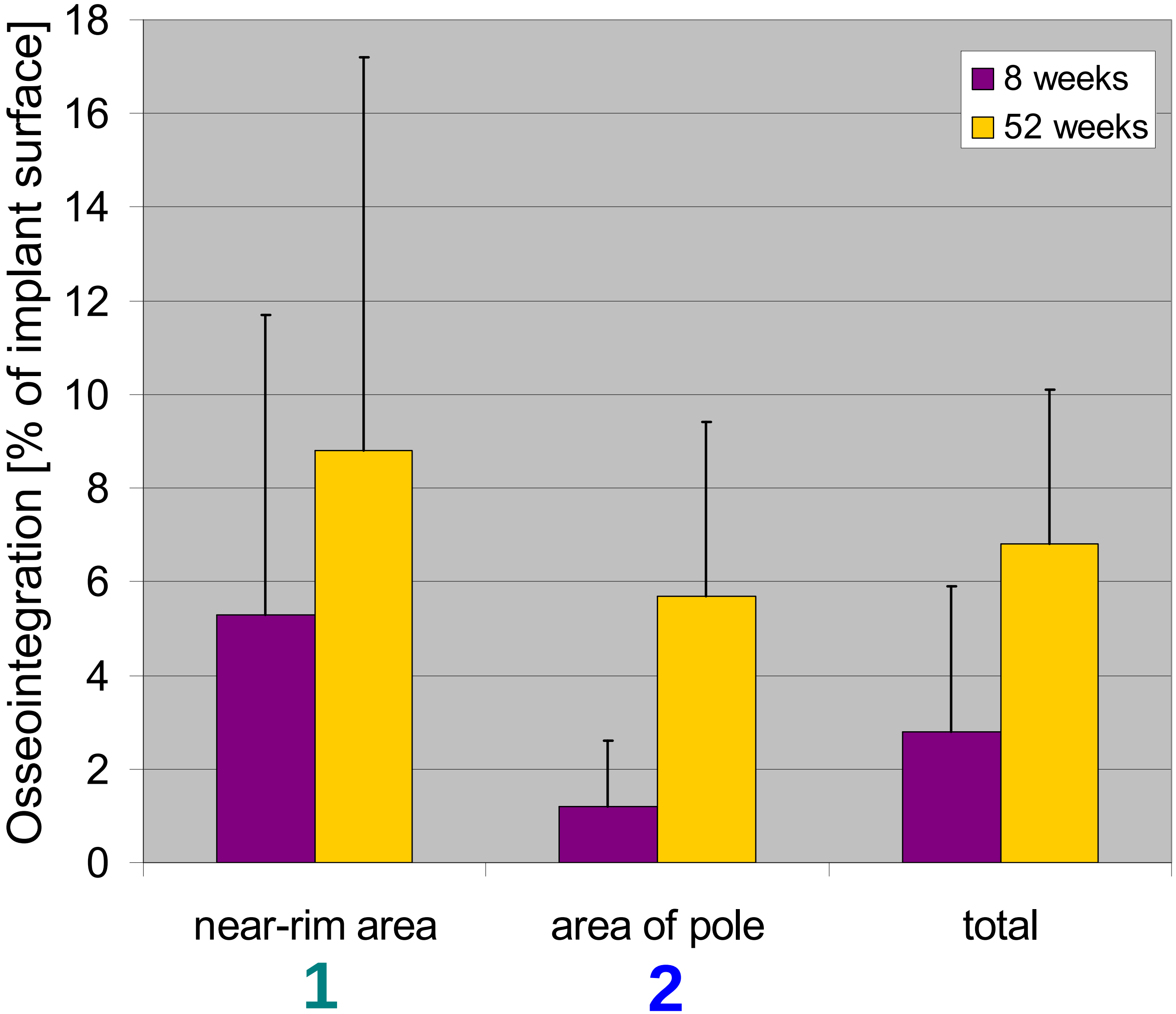


Osseointegration in biological study

BIOLOX® inside



Schreiner, Schulze, Schwarz et al., ZOrthopUnfall 2011

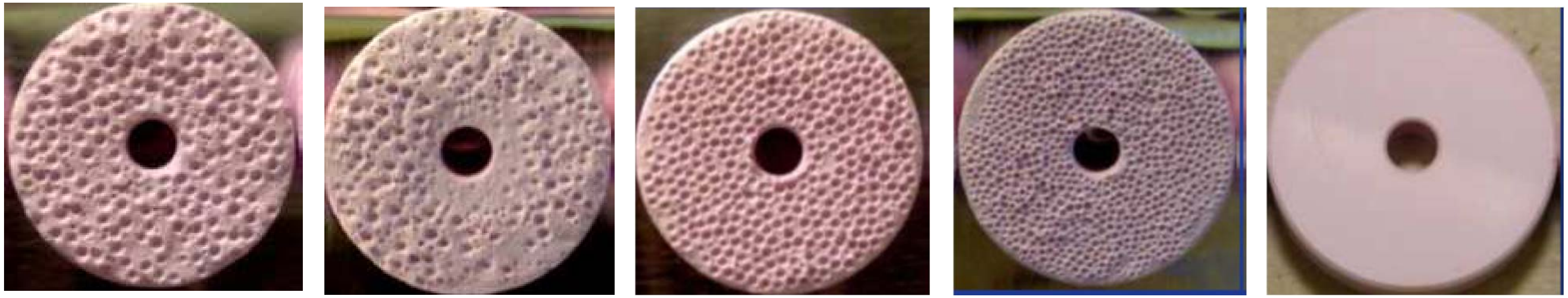


COST — European Cooperation in Science and Technology

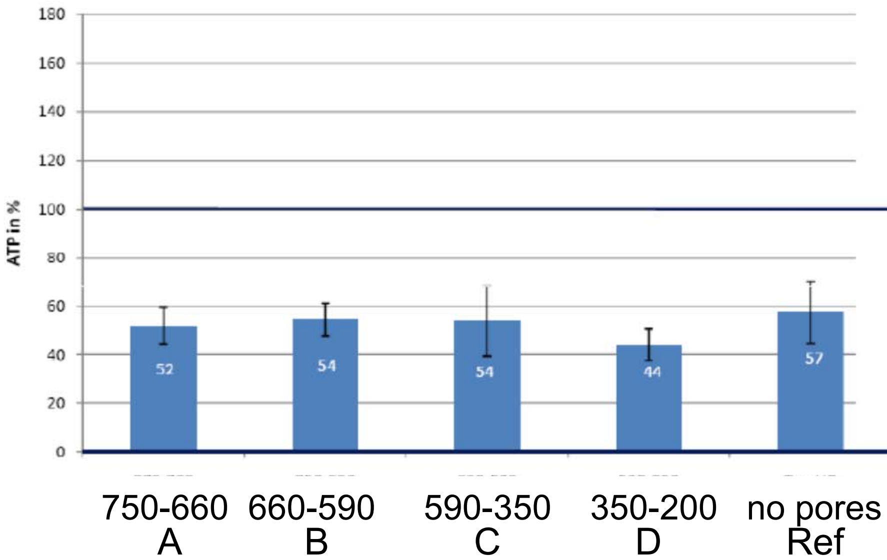
CeramTec

Cell-tests (humane osteoblasts) of different pore size distributions

A B C D Ref

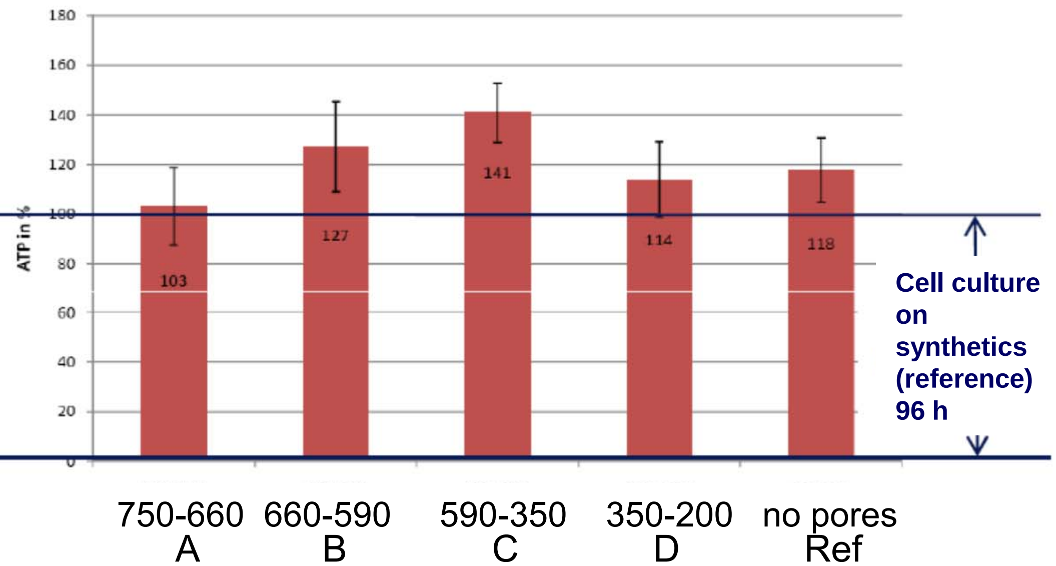


Proliferation after 24 h (n=14)



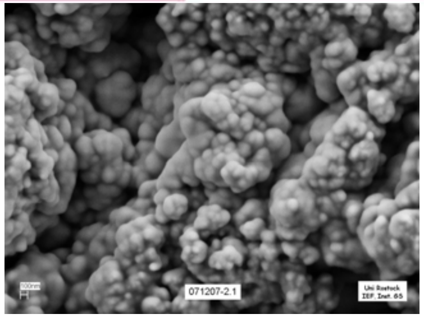
Pore size (diameter) [µm]

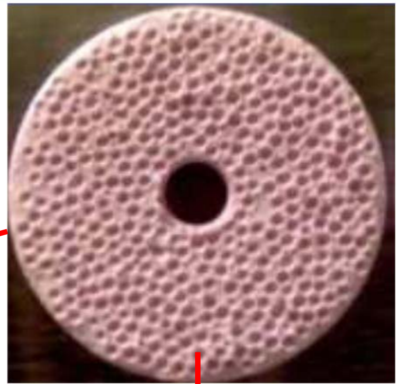
Proliferation after 96 h (n=14)

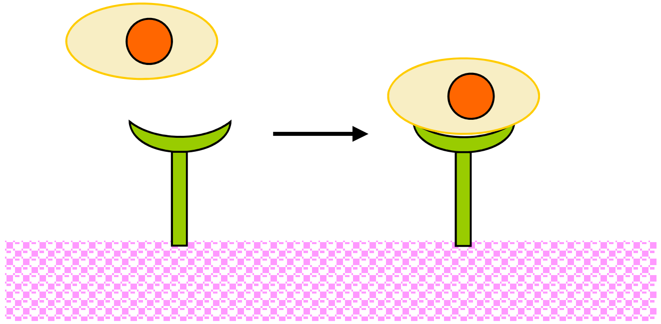


Pore size (diameter) [µm]

Test of osseointegration







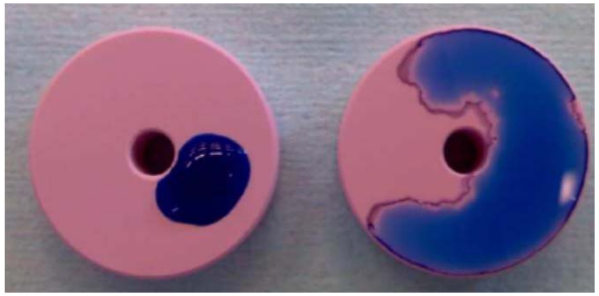
+ Hydroxyapatite, $Ca_5[OH(PO_4)_3]$

- inorganic part of bone
- no development of connective tissue

+ RGD-Peptides

- protein of extracellular matrix
- adhesion of cells using Integrin-coupling
- mechanically stable cell network

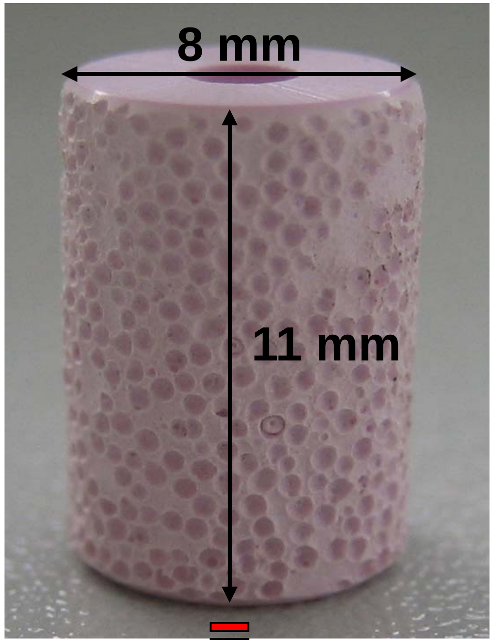
+ Plasma-activation

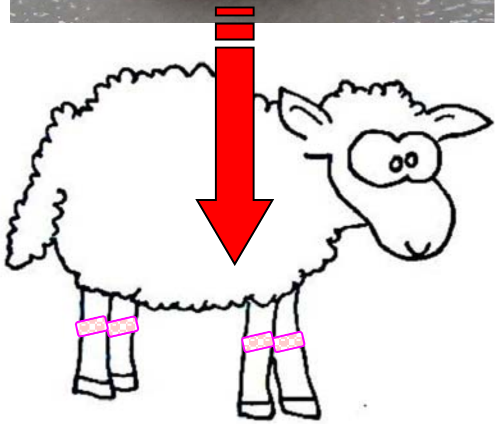


not activated | with O_2-Plasma activated

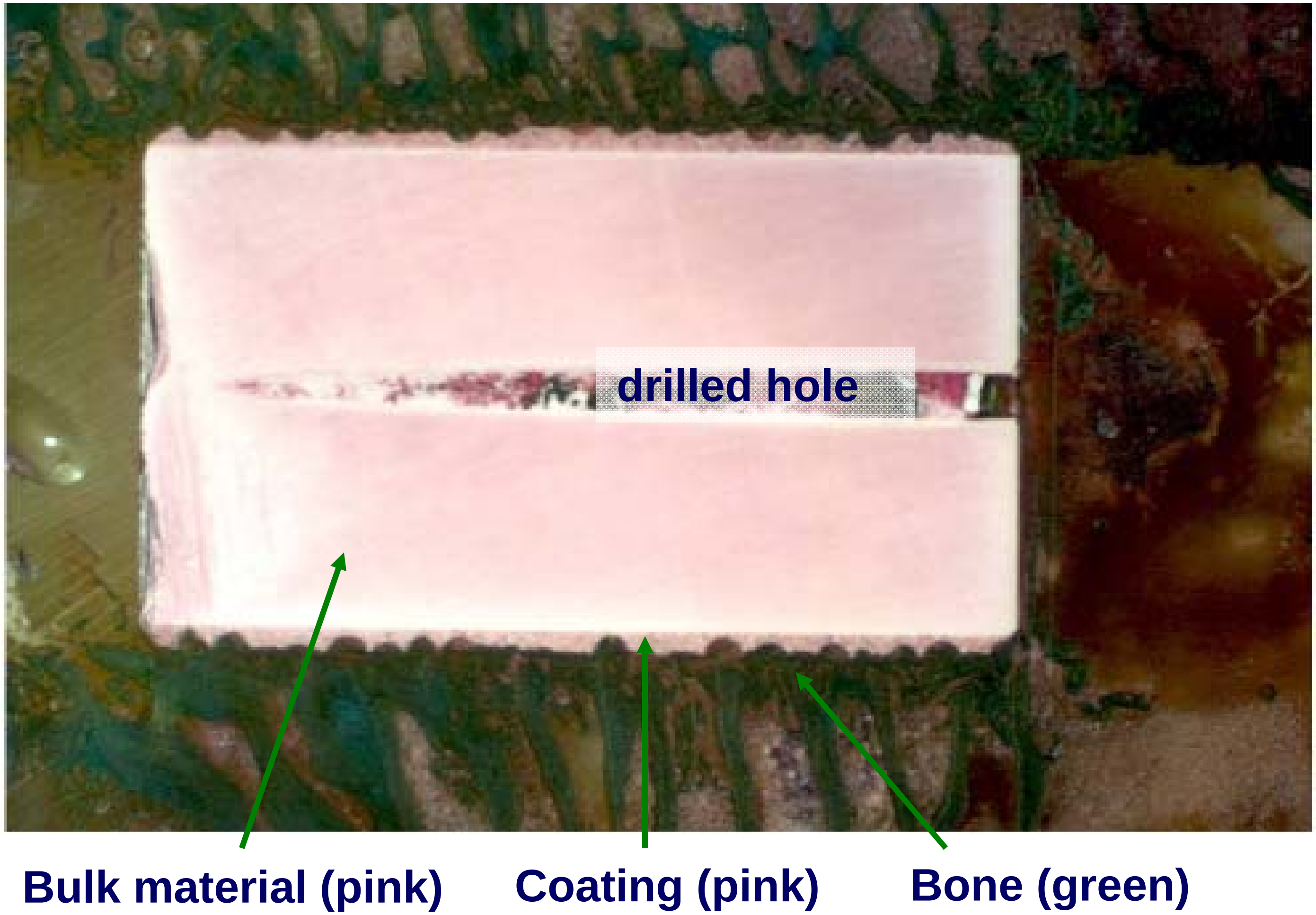
- decrease of contact angel (↓) increase of surface energy (↑), leads to higher adhesion of bone cells
- reaction gas: oxygen
- durability: 4 days (reversible reaction)

Osseointegration in biological study (sheep)



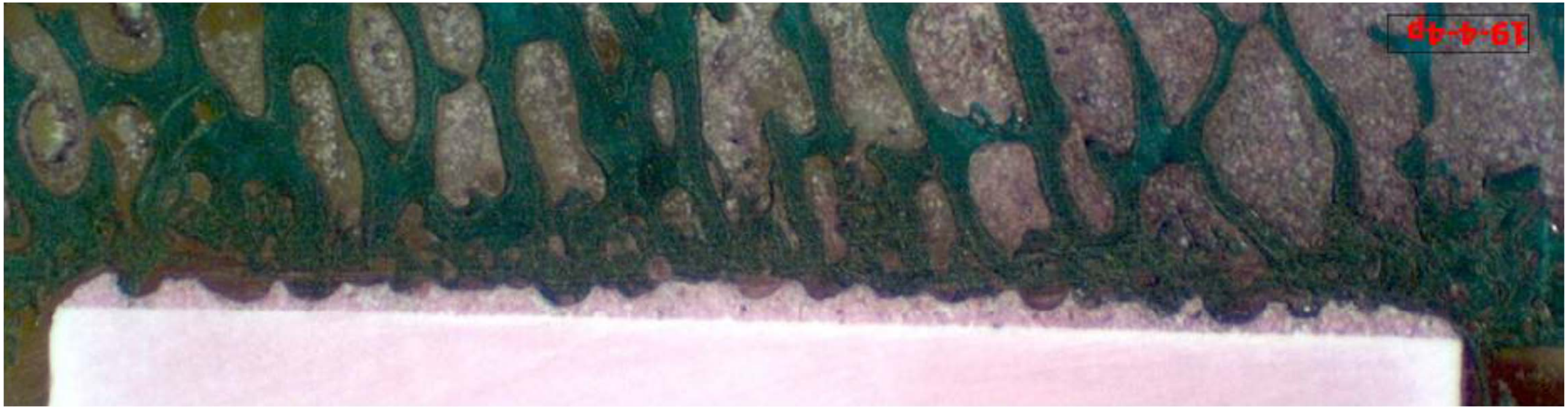


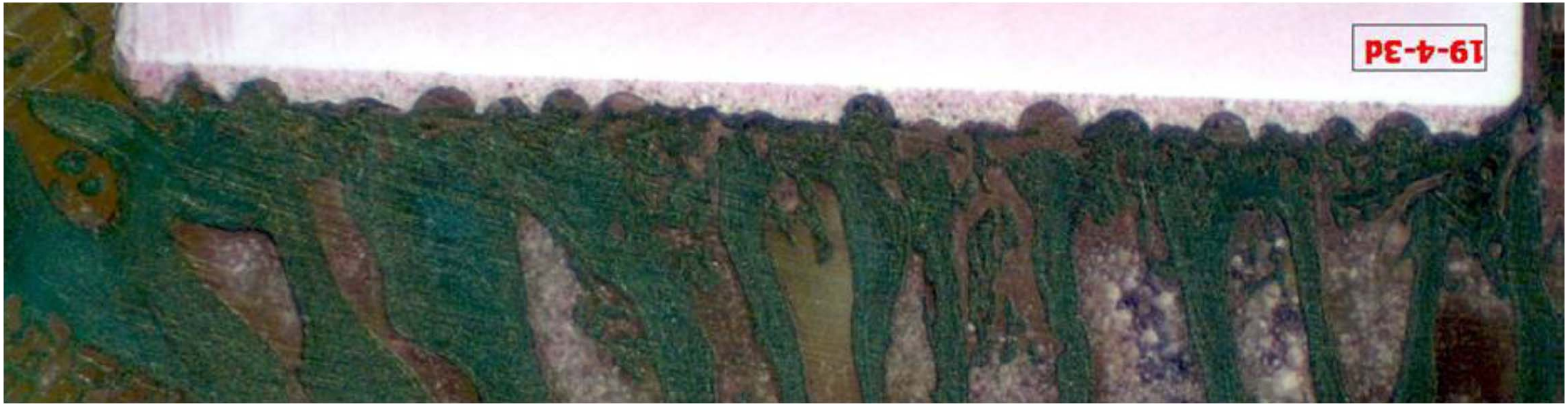
4 implants per leg



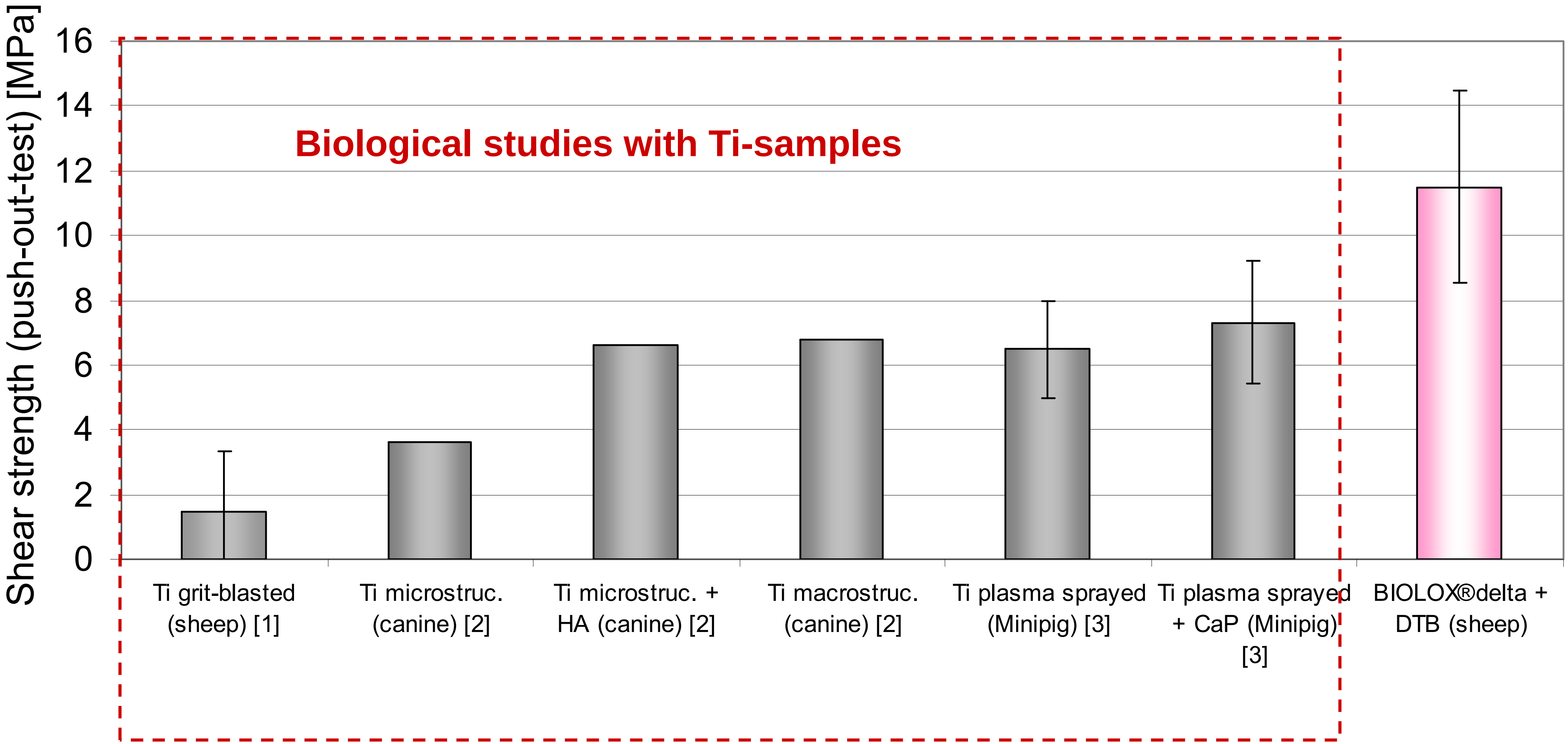
BIOLOX® inside

Osseointegration in biological study (sheep)





Biological study – comp. to literature

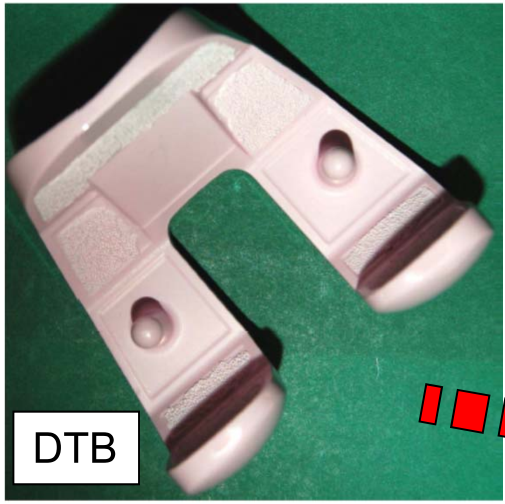


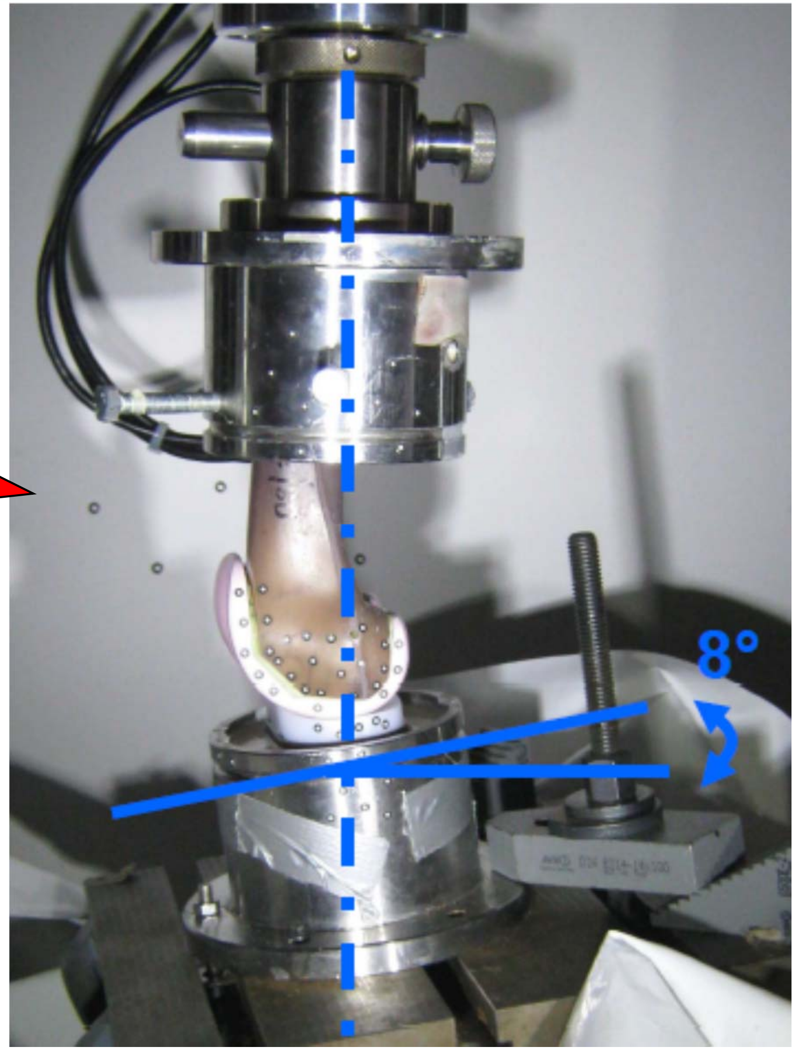
[1] H. Hartwig, L. Rehak, et al., Biomed. Tech. 1995 *40, S.* 99-105

[2] R. Rack et al., Bioceramics in Joint Arthroplasty Stuttgart, New York: Thieme 2001, S. 103-108

[3] E. Steinhauser, R. Bader, et al., Materialprüfung 2005 *47* S. 197-202

Cement compatibility





fatigue-test:

cementing on Sawbone® using Palacos®R,

1.5 million cycles, 5 Hz

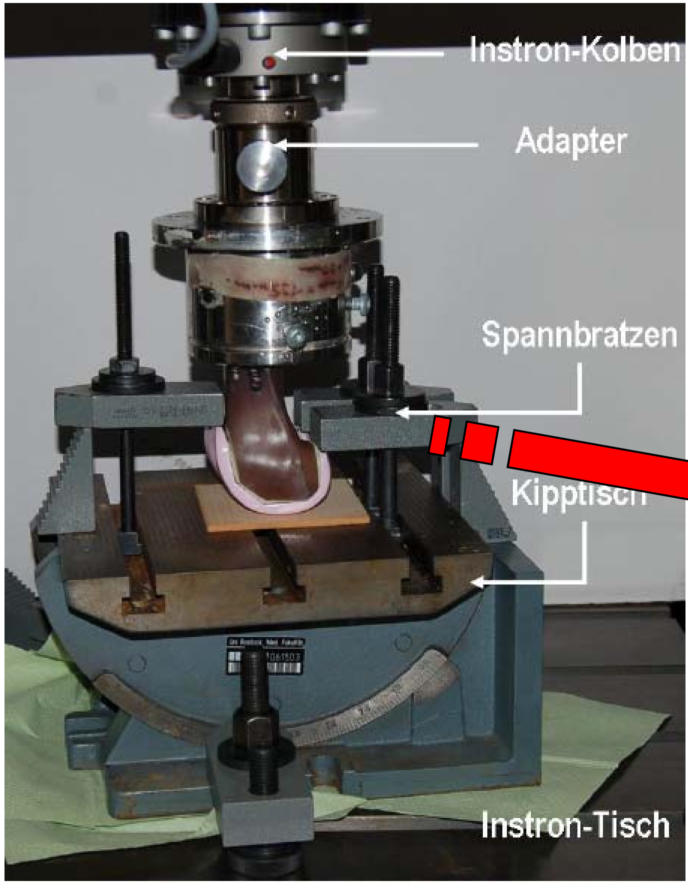
with flexion angles of 8°, 15° and 110°

highest load 2.6 kN

lowest load 168 N

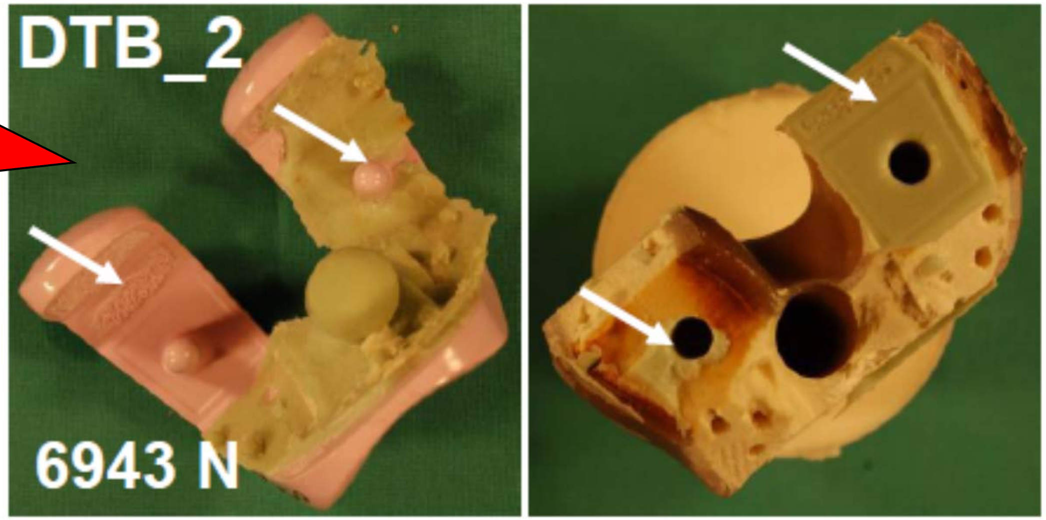
outer/inner rotation between -1.9° and +5.7°

Cement compatibility



Post-fatigue pull-off test:

way-controlled, 5 mm/min



BIOLOX® inside

Summary

- Coating process is reproducible
- Alumina-Zirconia-ceramics are biocompatible materials
- porous coating leads to bone ingrowth ⇨ shear strength of bone and implant is comparable with Titanium implants
- Coating is fully bonded to substrate during sintering ⇨ very good mechanical testing results ⇨ acceptance criteria of FDA passed!

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