Velox®

Smooth as silk, hard as a rock
Clinical challenges

Proximal Tibia Fracture: X-Ray
Clinical challenges

Proximal Tibia Fracture: Incision
Clinical challenges

Proximal Tibia Fracture: Reduction
Clinical challenges

Proximal Tibia Fracture: Filling of Defect
Clinical challenges

Proximal Tibia Fracture: K-Wire Fixation
Clinical challenges

Proximal Tibia Fracture: Plate Osteosynthesis

- ≈ 87’000 Fractures of the proximal tibia in the EU
- 1/3 > 65 years

*Based on German incidence rates «Gesundheitsberichterstattung des Bundes 2016»
Clinical challenges

Proximal Tibia Fracture Meta Study

Use of bone graft substitutes in the management of tibial plateau fractures

Thomas Goff, Nikolaos K. Kanakaris, Peter V. Giannoudis

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Clinical challenges

Proximal Tibia Fracture Meta Study

- Analysis of 674 proximal tibia fractures
- Patient age: 50 years
- Bone substitutes used: Allograft / DBM / Xenograft
- Uneventful healing in 90% of patients
- Secondary collapse of joint surface > 2mm: 8.6% (58 patients)
Clinical challenges

Proximal Humerus Fracture
Clinical challenges

Proximal Humerus Fracture
Clinical challenges

Proximal Humerus Fracture
Clinical challenges

Proximal Humerus Fracture: Reduction
Clinical challenges

Proximal Humerus Fracture: Preliminary Fixation
Clinical challenges

Proximal Humerus Fracture: Preliminary Plate Fixation
Clinical challenges

Proximal Humerus Fracture: Final Plate Fixation
Clinical challenges

Proximal Humerus Fracture: Final Plate Fixation

• ≈ 257'000 fractures of the proximal humerus in the EU
• 3/4 > 65 years

*Based on German incidence rates «Gesundheitsberichterstattung des Bundes 2016»
Clinical challenges

Proximal Humerus Fracture

Fracture site augmentation with calcium phosphate cement reduces screw penetration after open reduction—internal fixation of proximal humeral fractures

Kenneth A. Egol, MD*, Michelle T. Sugi, MD, Crispin C. Ong, MD, Nicole Montero, MD, Roy Davidovitch, MD, Joseph D. Zuckerman, MD

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Clinical challenges

Proximal Humerus Fracture

• Analysis of 92 proximal humerus fractures
• Patient age: 61 years
• Augmentation used: allogenic
• Uneventful healing in 100% of patients
• Settling: 0.8 mm
• Screw penetration: 19%
Clinical challenges

**Critical size bone defects**

- Proximal tibia
- Proximal humerus
- Calcaneus
- Further metaphyseal bone defects
- Bone defects after removal of cysts, benign tumours
- Defects after revision arthoplasty
- etc.
Clinical challenges

**Insufficient abutment in bone**

Challenging osteosynthesis in case of:

- Insufficient fracture reduction
- Poor implant placement
- **Low bone density**
Clinical challenges

Global dimension of clinical problem

- 692'600 bone graft procedures in the EU (2015)\textsuperscript{1}
- 1'187'600 bone graft procedures in the US (2015)\textsuperscript{2}
- More than 2.5 M. bone graft procedures p.a. globally
- Growth rate: 6.9\%\textsuperscript{1,2}

\textsuperscript{1} EU Markets for Biomaterials, 2012, MRG
\textsuperscript{2} US Markets for Biomaterials, 2012, iData
Current solutions

- Autologous bone
- Allogenic bone
- Xenogenic bone
- Growth factors
- **Synthetic bone substitutes**
Current solutions

Synthetic bone substitutes

1st Generation:
Ceramic granules and scaffolds

ARGO Medical

2nd Generation:
Ceramic pastes, putties & cements

DePuy Synthes
Clinical challenges

**Proximal Tibia Fracture Meta Study**

*Use of bone graft substitutes in the management of tibial plateau fractures*

Thomas Goff, Nikolaos K. Kanakaris, Peter V. Giannoudis *

_Academic Department of Trauma and Orthopaedics, Leeds Teaching Hospitals NHS Trust, Leeds, UK_

**Secondary Collapse of Joint Surface**

- **Allograft/DBM/Xenograft**: 58 patients
- **Calcium Phosphate Cement**: 25 patients
Clinical challenges

**Proximal Humerus Fracture**

Fracture site augmentation with calcium phosphate cement reduces screw penetration after open reduction—internal fixation of proximal humeral fractures

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![Screw Penetration Graph](image-url)

- No Augmentation: 7 patients
- Calcium Phosphate Cement Augmentation: 0 patients
Current solutions

Synthetic bone substitutes: properties

Pros: Ceramic pastes & putties
- Easy preparation
- Easy handling
- No time pressure
- Complete defect filling

Cons: Ceramic pastes & putties
- No structural support
- Insufficient cohesion
- Wash-out / implant migration

Pros: Ceramic cements
- Structural support
- Complete filling
- Reduced wash-out / implant migration

Cons: Ceramic cements
- Complex preparation & mixing
- Time pressure
- Additional devices
Current solutions

Comparison of synthetic ceramic cements

Preparation of Hydroset (Stryker)
- 9:30’ preparation
- Surgical technique: 555 words / 16 pages
- 5 cautions
- Injection time: 2:30’

Preparation of chronOS Inject (DPS)
- 13’ preparation
- Surgical technique: 1’033 words / 22 pages
- 8 cautions
- Injection time: 3’

Preparation of Velox® (InnoTERE)
- 5” preparation
- Surgical technique: 2 words / 1 line
- 0 cautions
- Injection time: ∞
Velox®

Bone out of a syringe that...

• ...is **ready-to-use**
• ...causes **no time pressure** during application
• ...can be applied **minimally invasive**
• ...has **unique flow properties**
• ...requires **no additional devices** for preparation
• ...**requires no training** of preparation / application
• ...creates **potential for innovations**
Velox®

Product Specification

- 1 * 3 ml; 2 * 3 ml; 3 * 3 ml
- Contents is 3.5 ml
- Includes an application cannula that can be shortened intraoperatively
- γ-sterilised, double blister
- Shelf life: 2 years
Composition

4 Calcium Powders + Salt

1 Oil + 2 Surfactants

wt.%:
- 59% α-Ca₃(PO₄)₂
- 25% CaHPO₄
- 10% CaCO₃
- 4% pH₄
- 2% K₂HPO₄

w/w:
- 80% synthetic short chain triglyceride
- 15% castor oil ethoxylate 35
- 5% hexadecyl-phosphate
Mode of Action: Setting Reaction

Outside in

Injection
10 minutes
24 hours
48 - 96 hours

Smooth Paste
Crust
Cancellous Bone
Oak
Mode of Action: Setting Reaction

Injection | 10 minutes | 24 hours | 48 - 96 hours

Compressive Strength (MPa)

Setting time (h)

Cancellous Bone
Mode of Action: Setting Reaction

**Compressive Strength**

**Velox® vs Norian FSP**

- **Velox®**
- **Norian FSP**

<table>
<thead>
<tr>
<th>Time (hr)</th>
<th>Velox®</th>
<th>Norian FSP</th>
</tr>
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<tbody>
<tr>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td></td>
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<tr>
<td>24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>72</td>
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</tbody>
</table>

**Graph:**
- **x-axis:** Time (7 hr, 16 hr, 24 hr, 72 hr)
- **y-axis:** Compressive strength (MPa)
- **Legend:** Velox® (blue), Norian FSP (red)
Mode of Action: Injection Properties

- Cohesion
- Flow Characteristics
- Viscosity
Injection Properties: Cohesion

• Particle release of standard CaP cement: 0.57%
• Particle release of VELOX®: 0.2%
• Less wash out
• Less implant migration

Velox®
Injection Properties: Flow Characteristics

- Velox® is a Non-Newtonian Fluid

- Rheopexy:
  - Increasing viscosity with increasing mechanical load
  - Decreasing viscosity w/o mechanical load

- Implication:
  - High viscosity at injection
  - Medium viscosity in defect
  - High viscosity at the end of defect filling
VeloX®

Injection Properties: Flow Characteristics

![Graph showing flow characteristics](image-url)
Injection Property: HIGH in the cannula
Injection Property: MEDIUM in the defect
Injection Property: HIGH in the cancellous bone
InnoTERE

THE BONE MAKERS.

Erich Roethlisberger

Injection Properties: Flow Characteristics

Standard CaP cement: extravasation from fx gap & beneath screw head

Velox®: filling of cavities, no extravasation through fx gap or along screw
Velox®

Injection Properties: Clinical Experience

Priv.-Doz. Dr. Ch. Kleber, Charité, Berlin
InnoTERE

THE BONE MAKERS.

Erich Roethlisberger

Injection Properties: Viscosity

Viscosity of fluids / PMMA

High viscosity

Medium viscosity

Low viscosity

Blood  Honey  Ketchup  Molten chocolate  Peanut butter  VELOX®

in Pa s
Velox® after completed setting process: Microcrystalline Hydroxy Apatite
Velox®

Animal Study

Design

• Tibial head & femoral condyle defects
• 10 mm dia.; 20 mm deep
• 1, 3, 6 and 18 months
• 5 sheep / group
Velox®

Animal Study

Results

• Excellent handling

• Complete defect filling

• No implant migration

• No inflammation or rejection reaction
Animal Study

Results: 3 months

• Direct bone attachment
• Nearly complete osteointegration
Animal Study

Results: 6 months

• Bone on-growth & ingrowth
• Fragmenting
• Change from woven bone to lamellar bone formation
Animal Study

Results: 18 months

• Ongoing (cell mediated) slow remodelling process
• Similar results to standard CaP cements
Velox®

Clinical Applications

PMCF Study

• University Clinic Dresden, Dr. A. Biewener
• Prox. Humerus, defect filling & screw augmentation
• 35 patients
Velox®

Clinical Applications

Juvenile Cyst

- Prox. Femur
- University Clinic Dresden,
  Dr. F. Thielemann
Clinical Applications

Minimally Invasive

• Städtisches Krankenhaus Friedrichstadt Dresden, Dr. S. Schmidt
• Prox. tibia defect filling
Handling: Tips & Tricks

1. Before mounting the cannula: **eject a strand of 1 cm**

2. **Shorten the cannula** to reduce injection force

3. Fill the cannula with cement to make it **radio-opaque**

4. Apply a **slow and continuous pressure** on the syringe plunger
InnoTERE

- Founded in 2005 as a GmbH
- Based in Radebeul / Dresden / Germany
- 20 employees
- In house production, R&D, marketing
- Certified quality system
  (ISO 13485, TÜV Rheinland)
- Granted technology patents
Velox®

- Only bone substitute that turns from paste to cement
- Only bone substitute cement that needs no preparation
- Only bone substitute cement that adds no stress during application
- Only bone substitute cements that requires no training
- Bone substitute cement that does not require additional instruments
- Cement technology with innovation potential