Mechanical properties and clinical results of novel bio-absorbable plates for the treatment of the metacarpal fractures

Yukichi Zenke,
Toshihisa Oshige, Kunitaka Menuki, Takafumi Tajima, Kenji Kosugi, Yoshiaki Yamanaka, Akinori Sakai

University of Occupational and Environmental Health, Japan
55° CFSC in Paris

COI disclosure

Univ. of Occupational and Environmental Health, Japan

Yukichi Zenke

No conflicts of interests to disclose concerning this presentation
Contents

➢ Basic data
  - Mechanical strength
  - Histology in the animal fracture model

➢ Treatment of hand fractures
  - Surgical technique
  - Clinical results in metacarpal fractures
Contents

- **Basic data**
  - Mechanical strength
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- **Treatment of hand fractures**
  - Surgical technique
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Bioabsorbable Plate

- **u-HA** (unsintered hydroxyapatite) + **PLLA** (poly-L-lactate)
  - 40% u-HA
  - 60% PLLA

Resorbable osteosynthetic bone fixation implants

“Bioabsorbability”

Clinical application for fractures
* Officially permitted
  - April, 2010 in Japan

“Osteoconductivity”

Super-Fixsorb® MX40 mesh (Johnson & Johnson / Takiron)
Bio-absorbable plates and screws

Mesh sheets

Size: 50 mm X 50 mm, thick 0.7 mm
Price: 118,650 yen/sheet

PLL A 60%
(Poly-L-Lactide)

Function: molding • strength
Absorption status: hydrolysis

uHA 40%
(unsintered Hydroxyapatite)

Size: diameter 2.0 mm x 8 - 16 mm
Price: 35,600 yen/screw

bone conduction
osteoclastic resorption
Bending strength

Experiment: fixed PEEK rod

3 pointed

Mechanical performance

Stability against torque

Torque force (Ncm)
Experiment: Rabbit fracture model

Post-op 4w

Humeral diaphysis is cut and fixed with each material

Bio-absorbable

Titanium

CT
Experiment: Rabbit fracture model

**Post-op 4w**

**Bio-absorbable**

- Directly bonding
- Cortical bone
- Undecalcifiedated (grinded) sample
- Villanueva Goldner staining

**Titanium**

- Fibrous tissue
- Cortical bone
The fracture union is promoted in the bio-absorbable plate.
**PLLA/uHA** does not impair nervous systems

**Experiment:** rabbit laminectomy (L4, 5) model

**PLLA/uHA** film was kept in **epidural**, **inter-vertebral**, and **subcutaneous space**. Histological finding of spinal cord and nerve root is not changed at all.

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Procedure of making plate and fixation

Making plate

- Bending plates in hot water at 68°C
- Fixing plates with Φ2.0 mm bio-absorbable screws
- Covering plates with fascia

Cut by scissors

To avoid the friction of plate and tendon
July, 2008 ~ Dec, 2018

For osteosynthesis 90 cases 98 fractures

1. Metacarpal
   44 cases 51 fx
   Age Ave. 35.5 yo

2. Distal ulna
   26 cases 27 fx
   Age Ave. 75.6 yo

3. Distal radius (dorsal)
   12 fx
   Age Ave. 56.5 yo

4. Proximal radius (Radial head and neck)
   8 fx
   Age Ave. 50.9 yo
Non-union 2.2% (2/90)
* 2 cases; radial head/neck fractures

Removal 3.3% (3/90)
* 3 cases; metacarpal 2, radial head/neck fracture 1
* Reasons: screw back-out 2, limited ROM 1

Age 51.0 y.o. (13~90)
Follow up: 3 m~8 y 6 m

*No post-op displacement
No aseptic swelling
Case 1

30 y.o. male, traffic accident
Rt. 2nd・3rd・4th metacarpal fx

Plain X-ray

First visit

CT
dorsal
palmar
After surgery

Post-op 10 days
immobilization with splint

personalized plates
Post-op 6m.

MP ROM:
Ext/Flex 10°/84°

Grip strength:
Fx 31.6 kg (Non-fx 44.4 kg)

Return to the previous job
DASH score: 0 point
Case 2

54 y.o. male

Post-op 6w.

Post-op 12 w.
**Titanium plates versus Bio-absorbable plates for metacarpal fractures**

*Comparative study of consecutive case series*

<table>
<thead>
<tr>
<th></th>
<th>[Titanium plates]</th>
<th>[Bio-absorbable plates]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(5 cases 6 fractures)</td>
<td>(11 cases 16 fractures)</td>
</tr>
<tr>
<td>Bone union</td>
<td>all cases</td>
<td>all cases</td>
</tr>
<tr>
<td>Immob. (days)</td>
<td>20.6 +/- 12.9</td>
<td>8.7 +/- 2.6</td>
</tr>
<tr>
<td>Final TAM (°)</td>
<td>250.0 +/- 28.3</td>
<td>267.0 +/- 6.0</td>
</tr>
<tr>
<td>Grip strength</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(% of non-fx side)</td>
<td>86.4 +/- 28.6</td>
<td>92.7 +/- 19.7</td>
</tr>
<tr>
<td>Complication</td>
<td>none</td>
<td>none</td>
</tr>
</tbody>
</table>

- n.s.

*TAM: total range of active motion, mean +/- SD  
The results of long-term outcomes??

To clarify the **long-term outcomes** (>5Y) of surgically treated metacarpal fractures using bioabsorbable plates.
Subjects

【Inclusion Criteria】
✓ 2009.3 〜 2017.9
✓ Metacarpal Fractures
✓ Using Bioabsorbable Plates
✓ Follow up period ≥ 5 years

8 fingers of 6 patients
(Male: 4  Female: 2)
Outcomes
(Final F/u)

✓ Active ROM for wrist and forearm
✓ Grip strength ratio (G-S ratio, %)
✓ Q-DASH score
✓ Bone union on plain X-ray
✓ Resorption status on plain CT
## Results

<table>
<thead>
<tr>
<th>Case</th>
<th>Sex</th>
<th>Age</th>
<th>F/u</th>
<th>Limited ROM</th>
<th>G-S ratio</th>
<th>Q-DASH</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>16</td>
<td>5Y8M</td>
<td>No</td>
<td>79.2</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>54</td>
<td>6Y5M</td>
<td>No</td>
<td>104.5</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>17</td>
<td>6Y7M</td>
<td>No</td>
<td>100.7</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>18</td>
<td>6Y8M</td>
<td>Yes</td>
<td>78.5</td>
<td>34.09</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>52</td>
<td>7Y2M</td>
<td>No</td>
<td>91.1</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>20</td>
<td>8Y5M</td>
<td>No</td>
<td>56.8</td>
<td>34.09</td>
</tr>
<tr>
<td>Ave.</td>
<td></td>
<td></td>
<td>29.5±7.5</td>
<td>6Y9M</td>
<td>85.1±7.2</td>
<td>11.36±7.19</td>
</tr>
</tbody>
</table>

- **Union rate** 100 %
- **Implants Specific Complications (Infections and Aseptic Swelling)** 0 %

Ave.
The process of bioabsorption in metacarpal fractures may take at least about 8 years.

The absorption speeds may be different between inside and outside the bones.
Case 3

82 y.o. Female

volar
dorsal
Dual window approach

One incision

It’s easy for visualization at lunate facet & DRUJ area

Radial window

Two window

Ulnar window
Four-corner Fusion
Advantages

① Freely Moldable

② Can be fixed in any screw holes available

③ Visible on X-ray, CT

④ No Need for Removal

⑤ Available for Metal Allergic Patients
Appropriate indication for bioabsorbable plate?
Bioabsorbable plate & screw

Promising implant

Future development is expected!
Merci de votre attention.