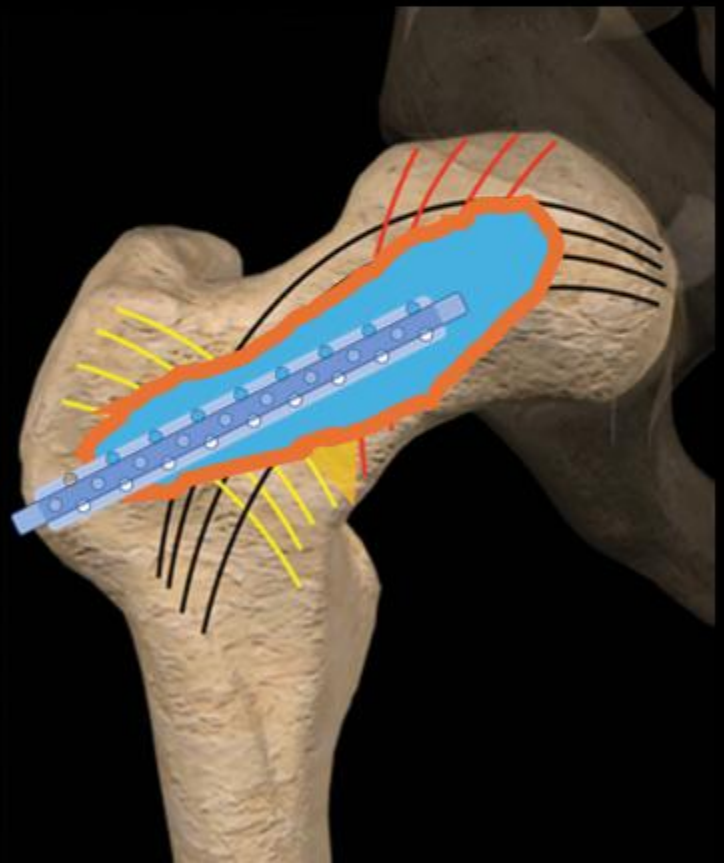
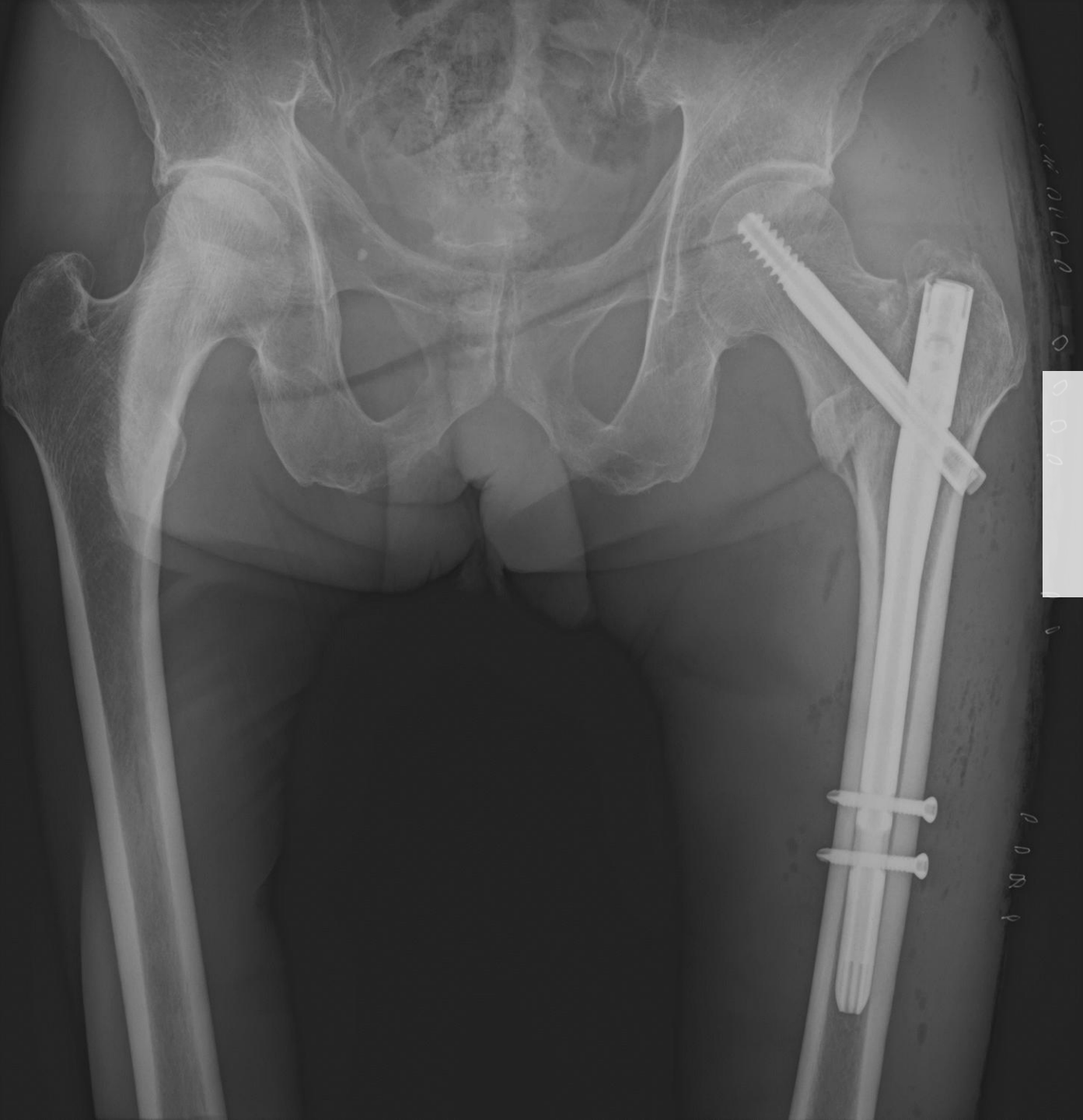
医療機器
クラスIII

低侵襲骨粗鬆症治療デバイスの開発

二度目の骨折は起こさせない



整形外科　前　裕和



BioJapan2025

Research and Development of Innovative Osteoporosis Treatment Devices Using Composite Materials

Hirokazu Mae

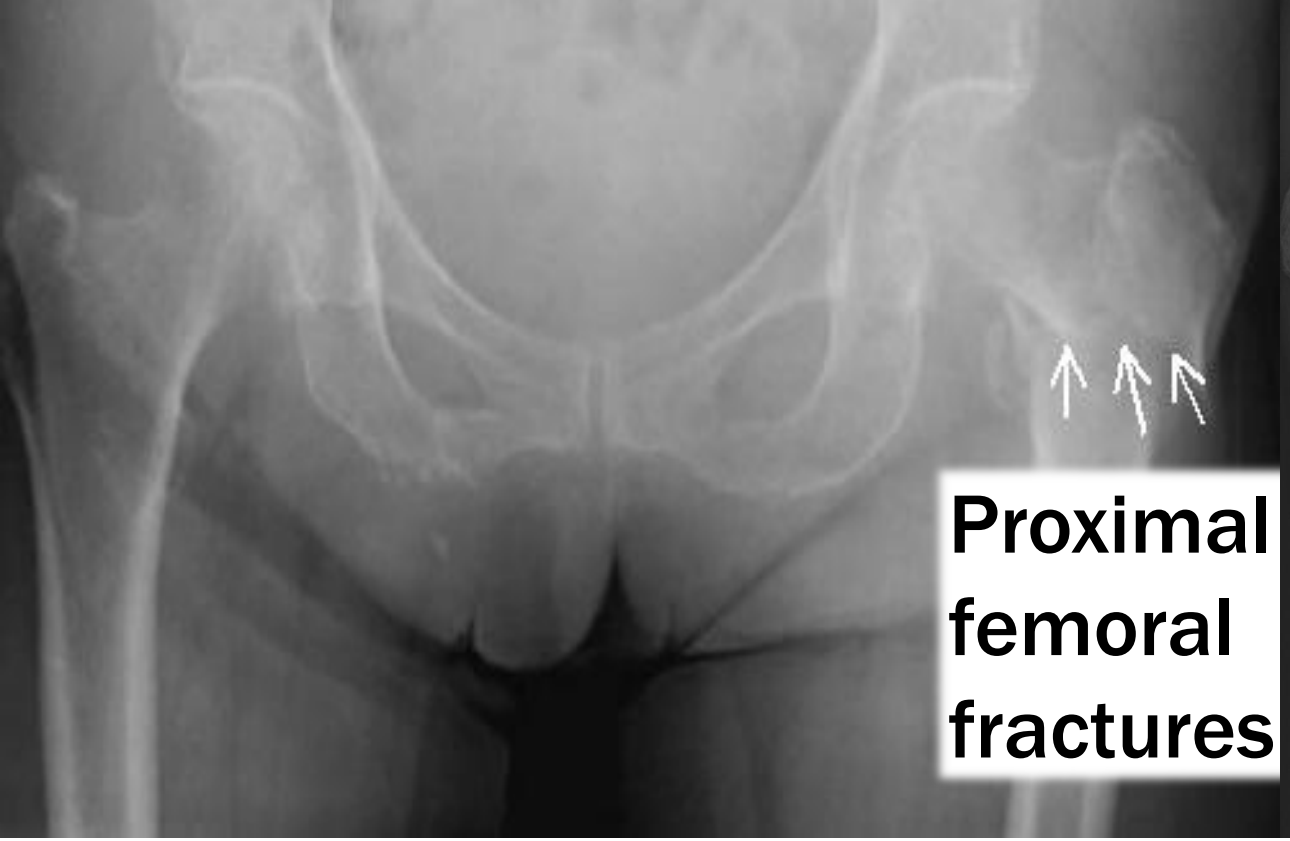
The University of Osaka

Department of Orthopedics

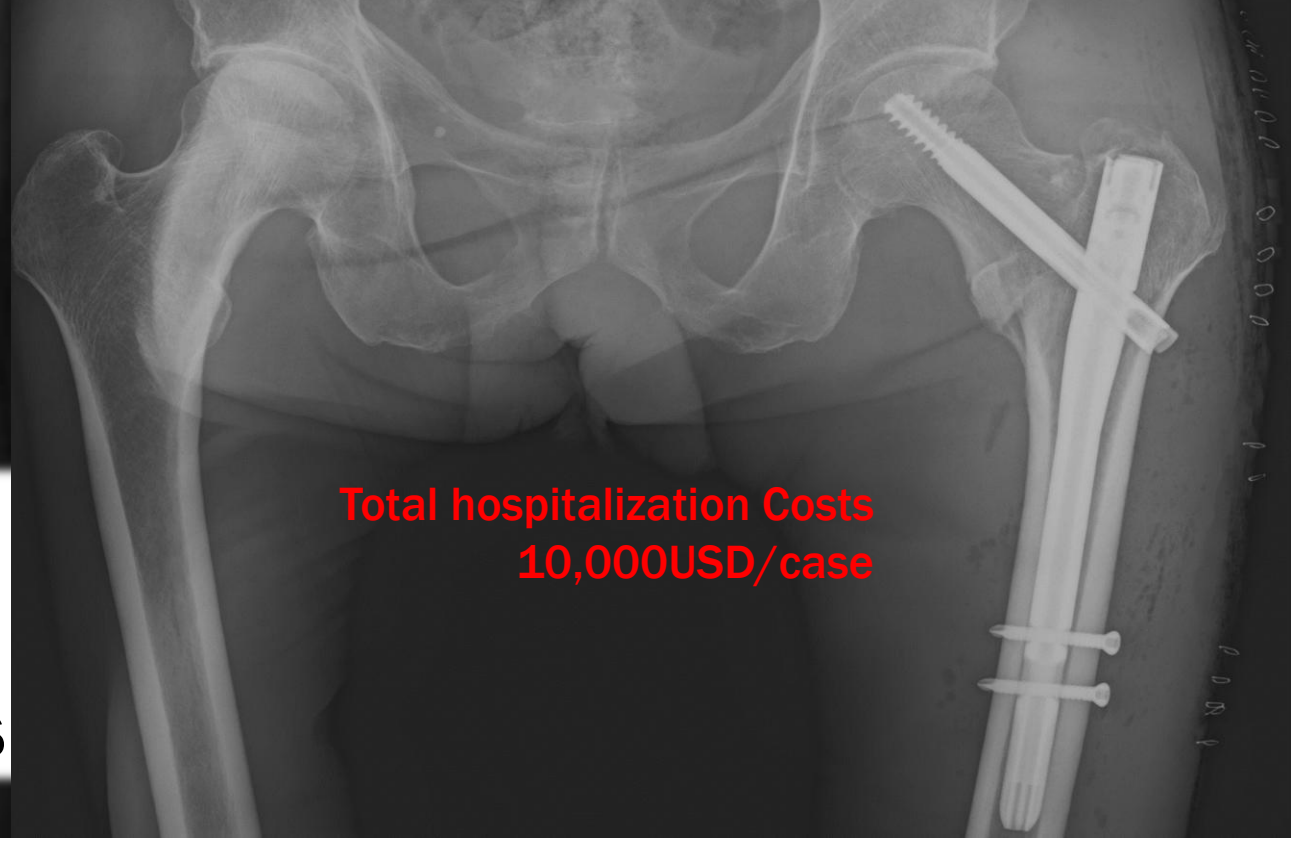
Background

Osteoporosis:
13 million patients in Japan

Osteoporosis makes bones prone to fractures even with minimal force.



Proximal femoral fractures



Total hospitalization Costs
10,000USD/case

OPE

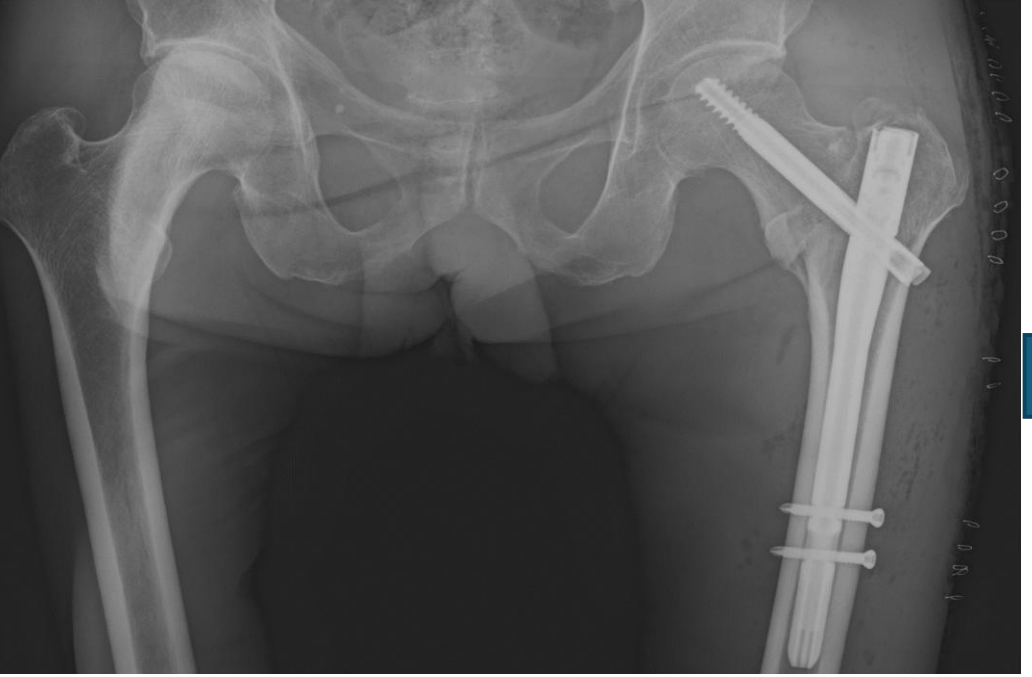
Proximal femoral fractures affect 150,000 people annually in Japan.

(Hagino H, et al.Osteoporos Int. 2009)

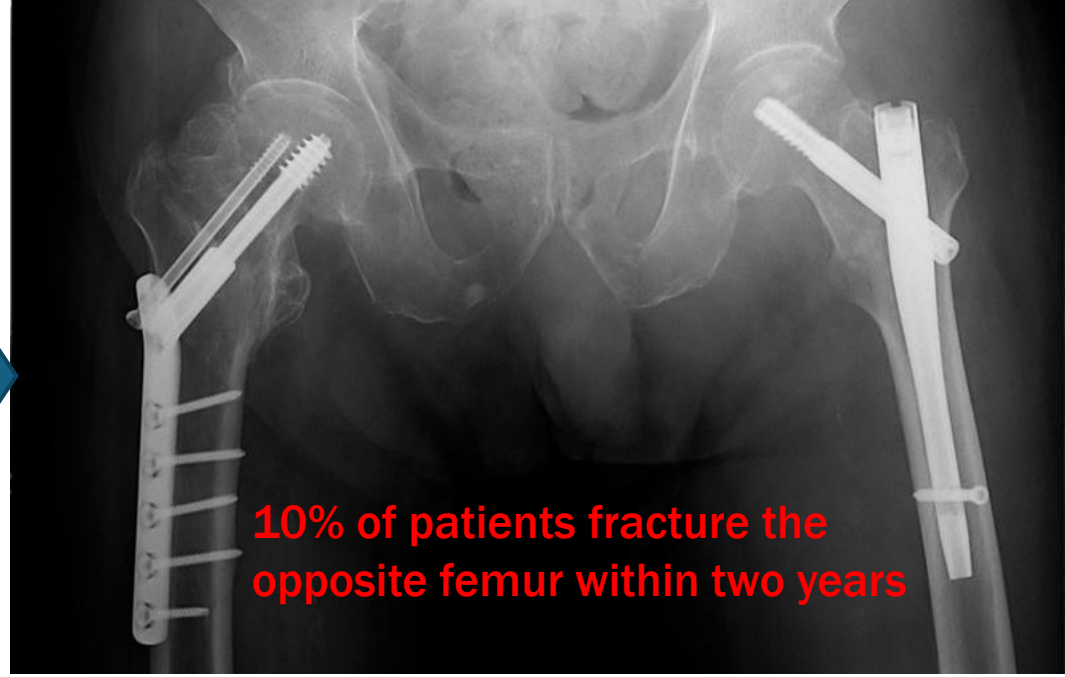
50 %

some walking ability decline

(Fukui N, et al. J Orthop Trauma 2012)



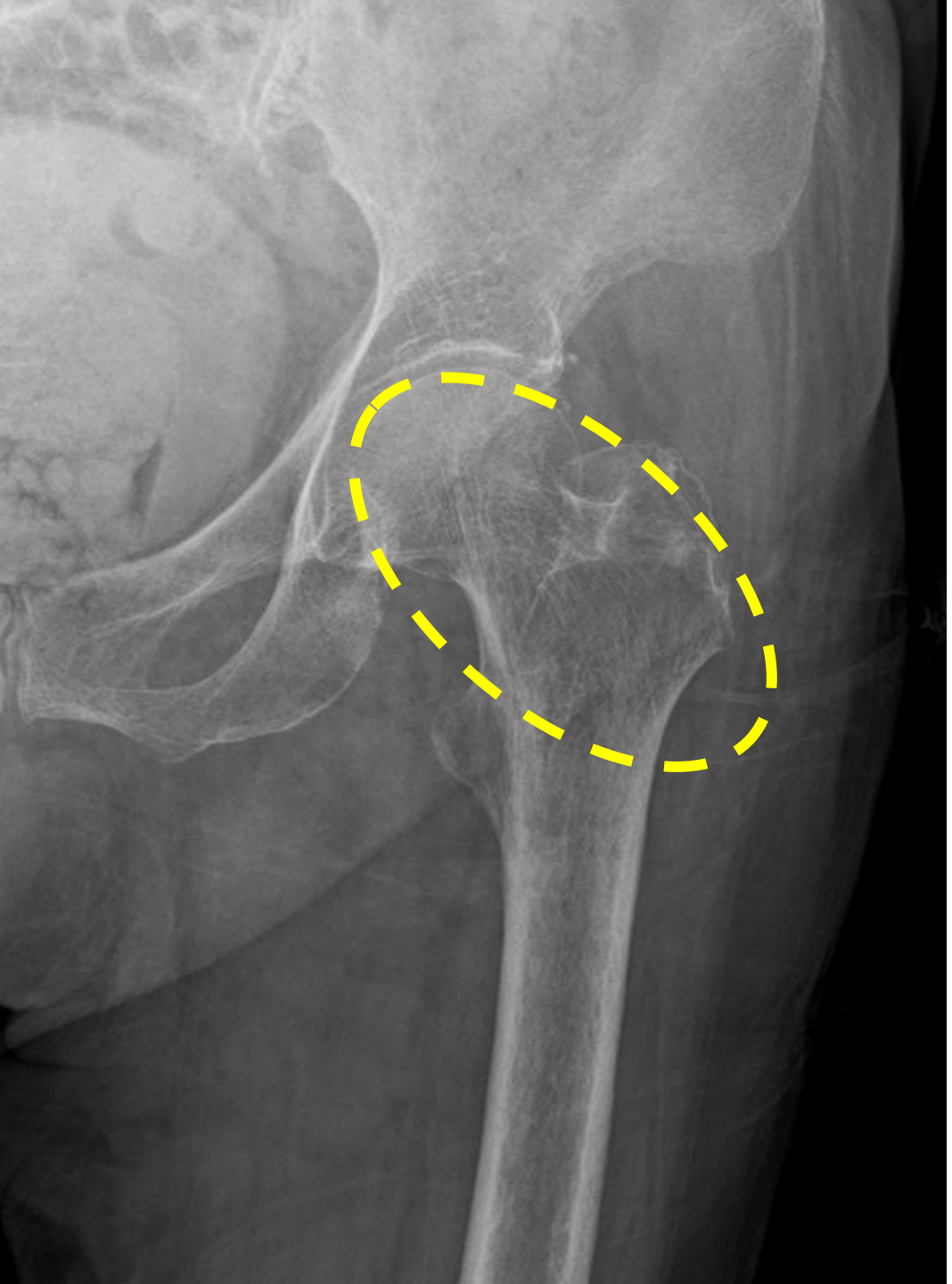
falls again



The unfractured side is also osteoporotic.

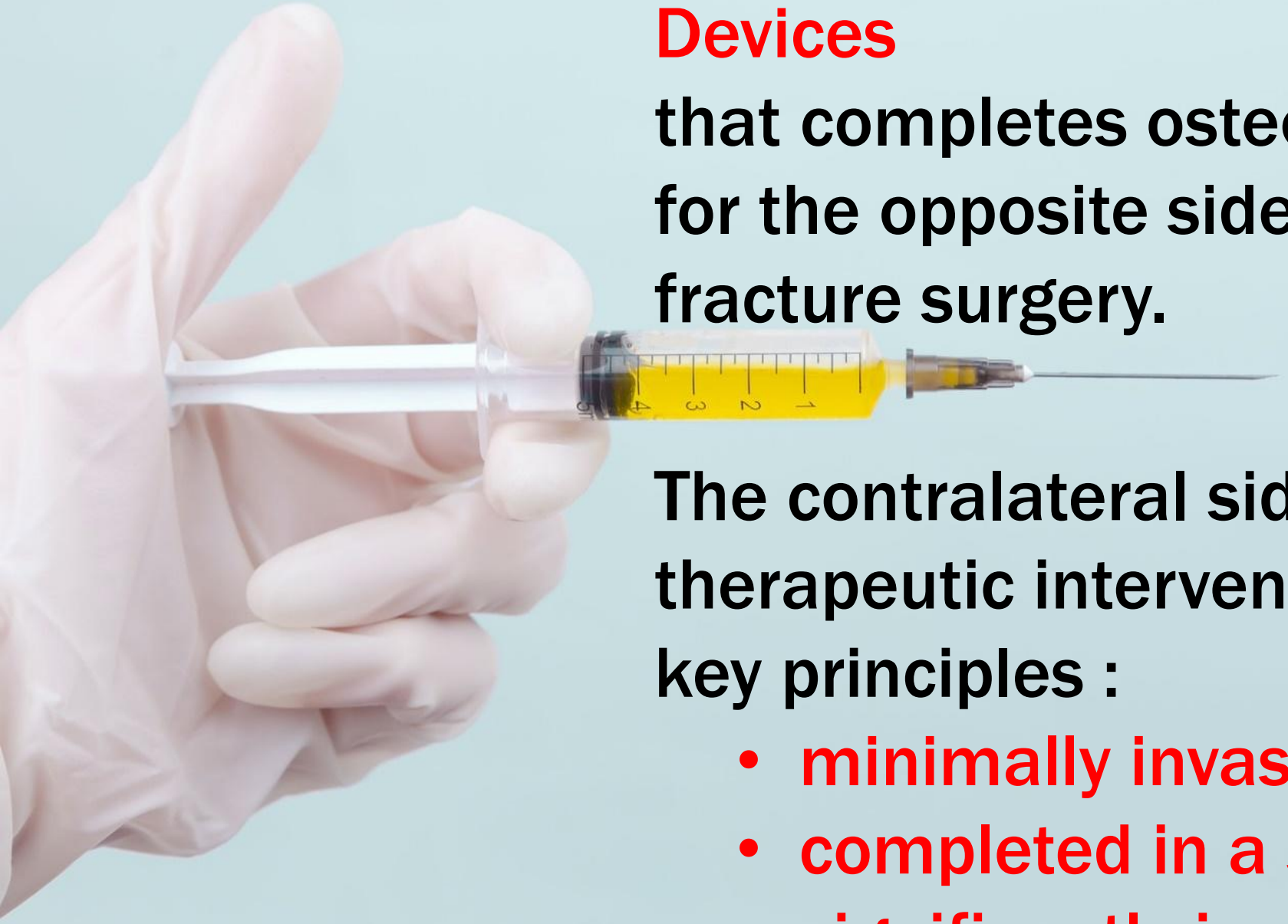
50 % of these patients become unable to walk, leading to bedridden states

A strong need to prevent secondary fractures in patients who have already experienced one fracture.



Our solution

Strengthen the bone to prevent fractures.



Innovative Osteoporosis Treatment Devices

that completes osteoporosis treatment for the opposite side during the first fracture surgery.

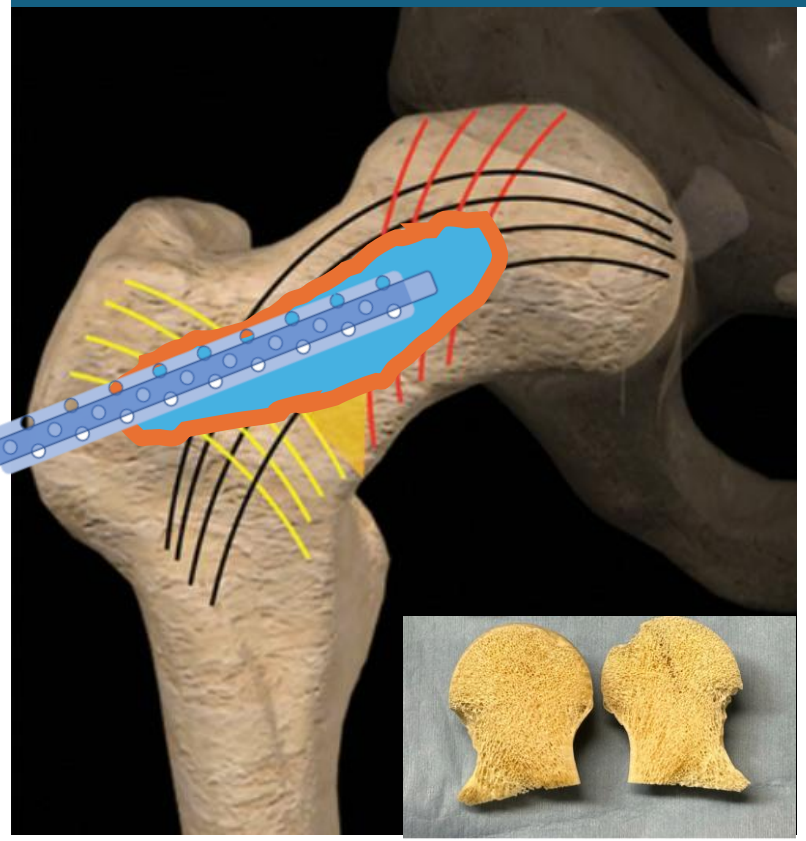
The contralateral side requires early therapeutic intervention.

key principles :

- minimally invasive
- completed in a single treatment
- significantly increases bone strength

Our New Device Overview

Our device allows for easy injection of high-strength composite materials into bone under x-ray guidance.



【Usage Instructions】

- Identify the treatment site under X-ray fluoroscopy.
- Insert the device for injecting the material.
- Inject the high-strength injectable composite material.
- Confirm the material filling using X-ray imaging.
- After confirming hardening, remove the device.

※ *Composite materials have been approved and used in the medical field (see next slide).*

Infuse the composite material into the bone, solidify it, and enhance bone strength.

Issues of the current treatment

Lack of **high-efficacy** and **rapid-acting** solutions for osteoporosis

high

Low

efficacy

short

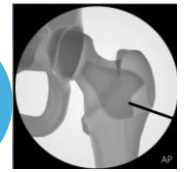
time

long

Our Device

Competing Technologies

AGN1 LOEP hip Kit



Flowbone

waiting for bone regeneration

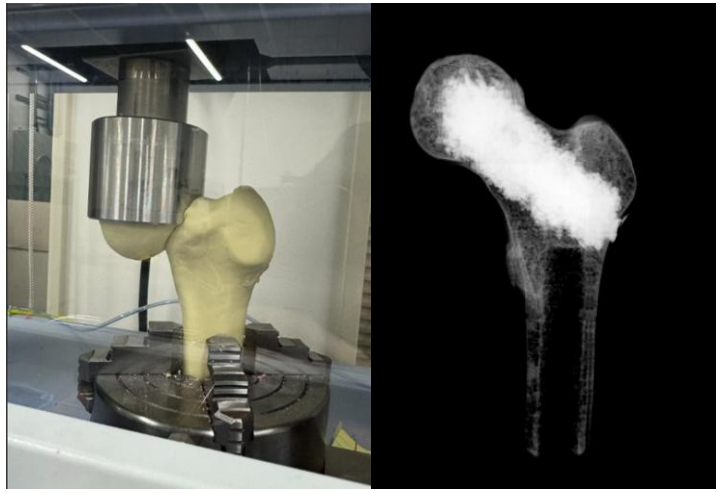
prevention rates (30–50%)

Injection

takes long time

Oral

Our key data for a new device

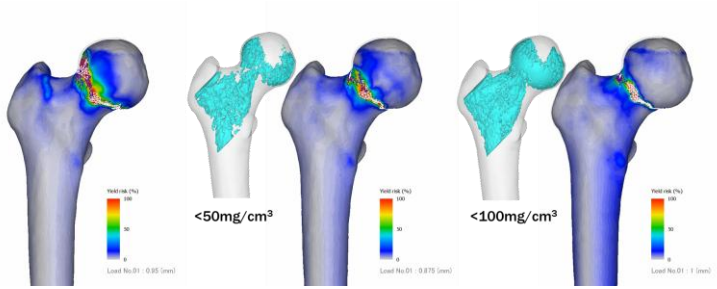


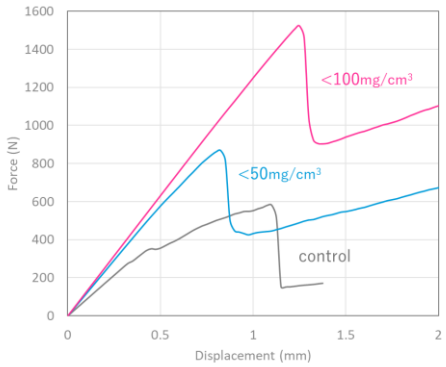
Injecting the material increased the force to cause a fracture.

We did Experiments using

- Finite element analysis
- synthetic bones
- porcine bones
- human cadaveric bones

※Results shall be disclosable under an NDA





Patent status;

Device patents;

- WO2024/181411A1 filed in Feb 2024
- New patent is under preparation

Material patent;

- 2025-032211 filed in Feb 2025

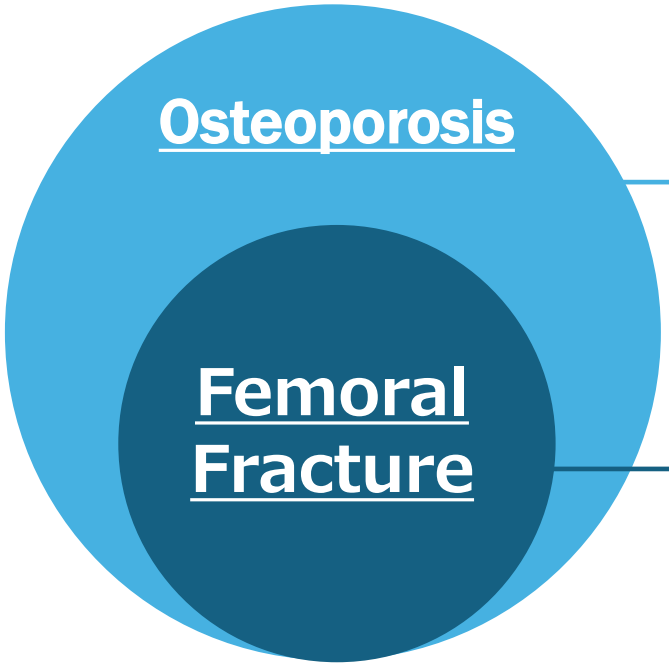
We are still deciding between using an existing material and our own new material in development.

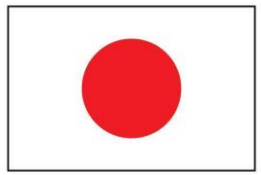
Market Potential

Estimated Value

Patient × Device Price (USD2,000)

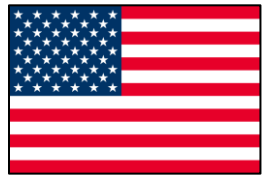
A similar product is 2,000 USD.





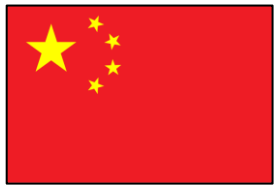
USD 1.5 billion
750,000 patients/year

USD 300 million
150,000 patients/year



USD 3.0 billion
1,500,000 patients /year

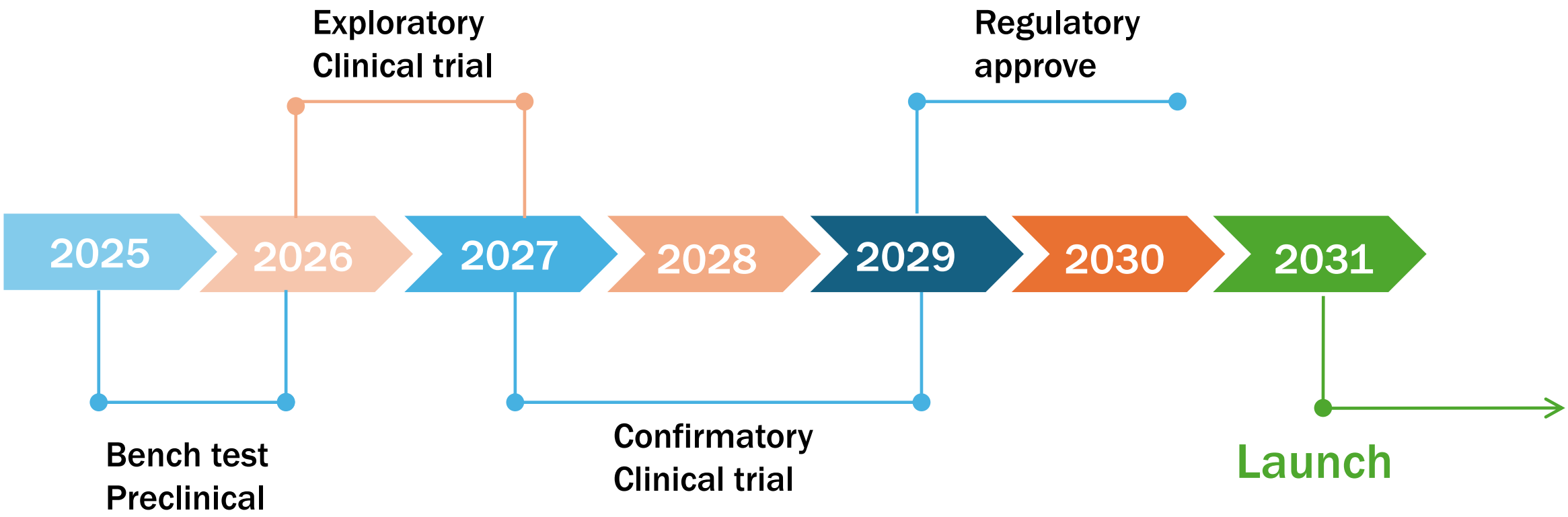
USD 600 million
300,000 patients /year



USD 6.0 billion
3,000,000 patients /year

USD 1.2 billion
600,000 patients /year

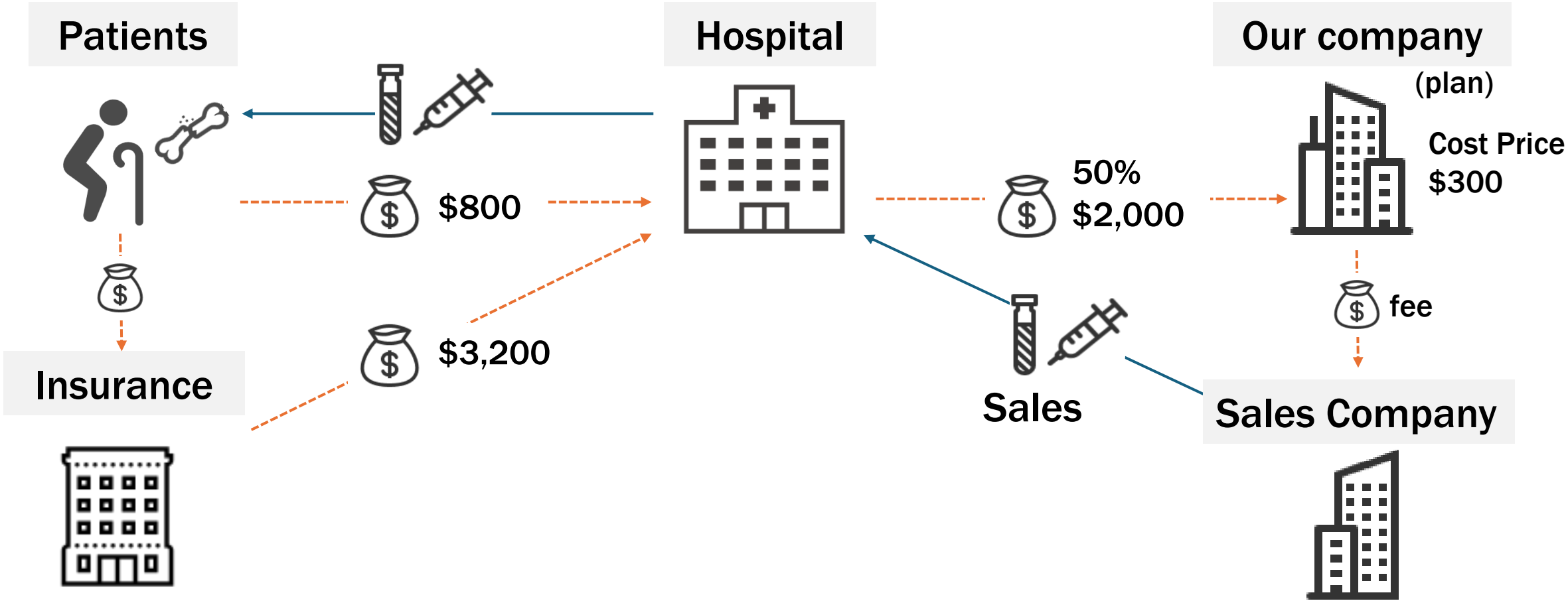
Growth Timeline



To establish
SU Company

Business Model

The same as an Implant Device's Business Model



Proposed Partnership with Company

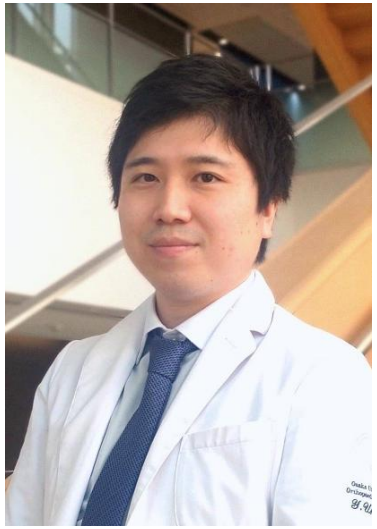
- To collaborate as future MA holder of the device and/or material
  - Our role:
    - During development phase:
      - to develop device and new material
    - After completion of development:
      - to maintain patents
  - Company role:
    - During development phase:
      a. to collaborate as development partner with us or
      b. to advice to device and/or material as future MA holder
    - After completion of development:
      - to take initiative as MA holder for filling NDA and entering market
- To invest development costs to device development and/or SU company

Team members

Hirokazu Mae
MD,PhD
Hip Surgeon

Animal Testing
CEO

The University of Osaka



Yuichiro Ukon
MD,PhD
Spine Surgeon

Device Development
CTO

The University of Osaka

Watari Akihiro
R&D Support

Regulatory Affairs &
Insurance

The University of Osaka

Yu-I-HSU
PhD
in Engineering

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Development

The University of Osaka

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