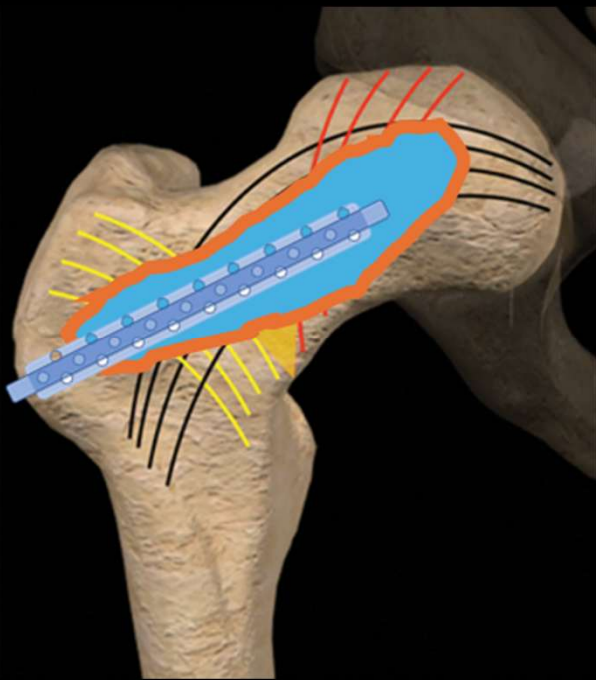


医療機器
クラスIII

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！



**Research and Development of
Innovative Osteoporosis Treatment
Devices Using Composite Materials**

Hirokazu Mae

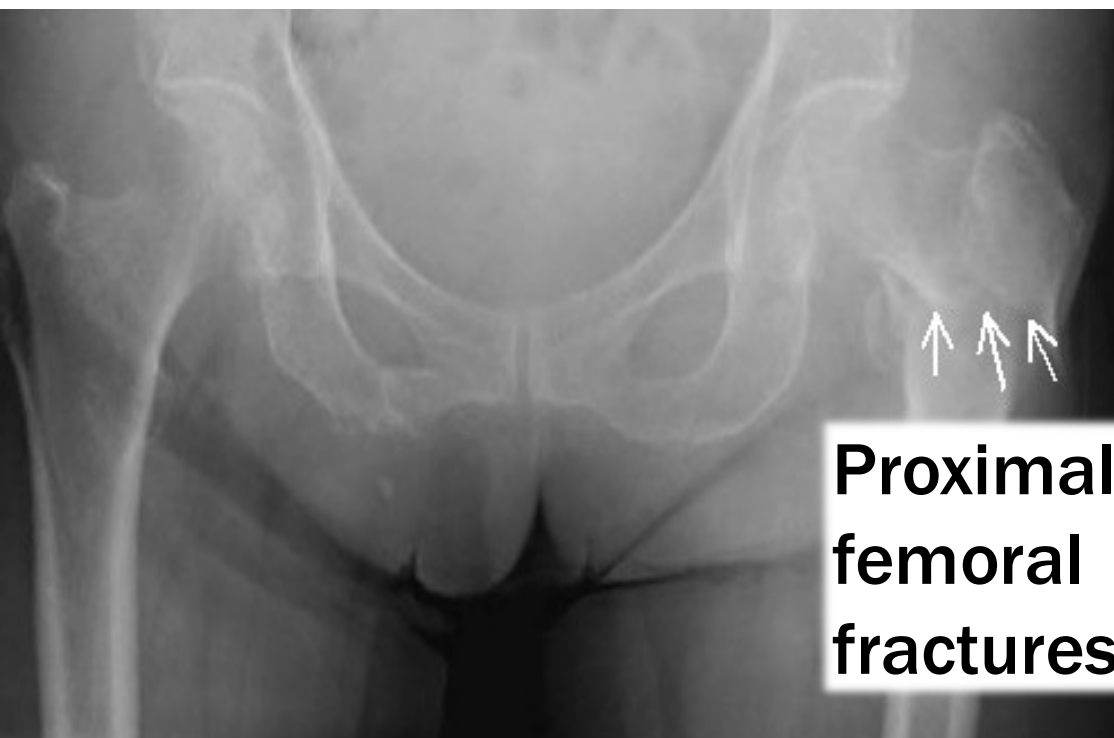
**The University of Osaka
Department of Orthopedics**

Background

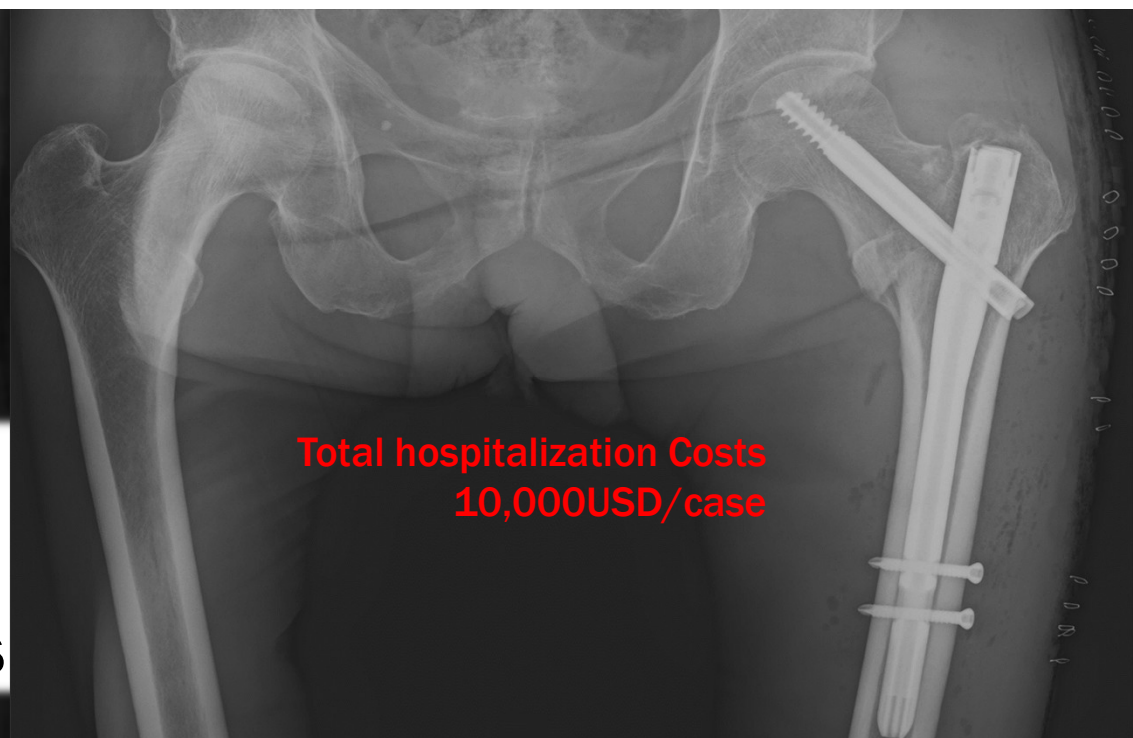
**Osteoporosis:
13 million patients in Japan**

**Osteoporosis makes bones prone to
fractures even with minimal force.**





**Proximal
femoral
fractures**



**Total hospitalization Costs
10,000USD/case**



OPE

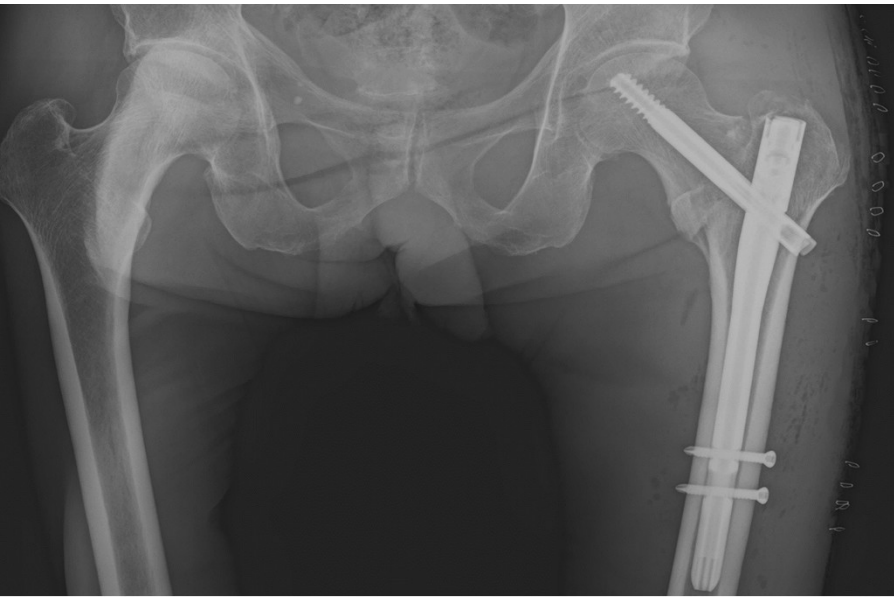
**Proximal femoral fractures affect
150,000 people annually in Japan.**

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

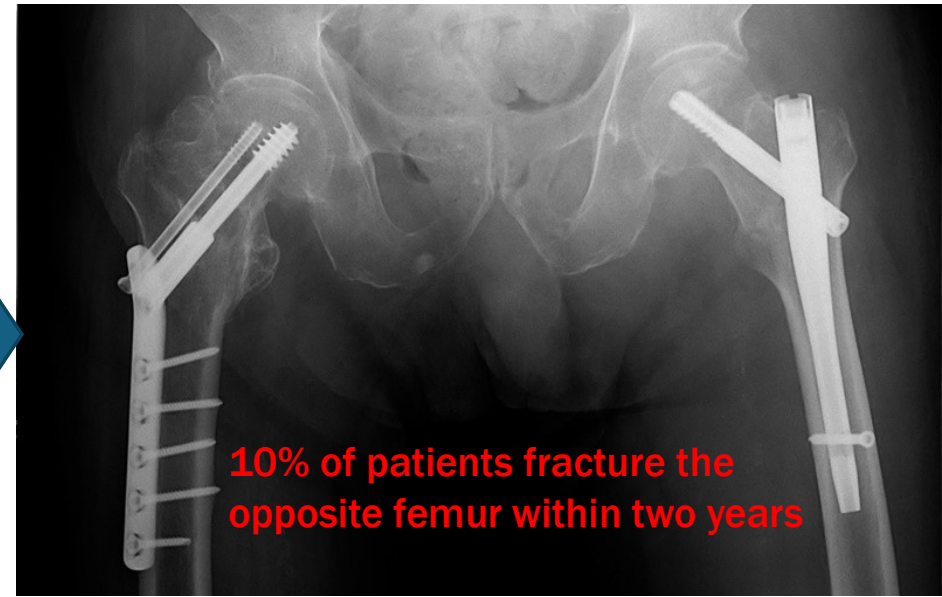
50 %

some walking ability decline

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



falls again

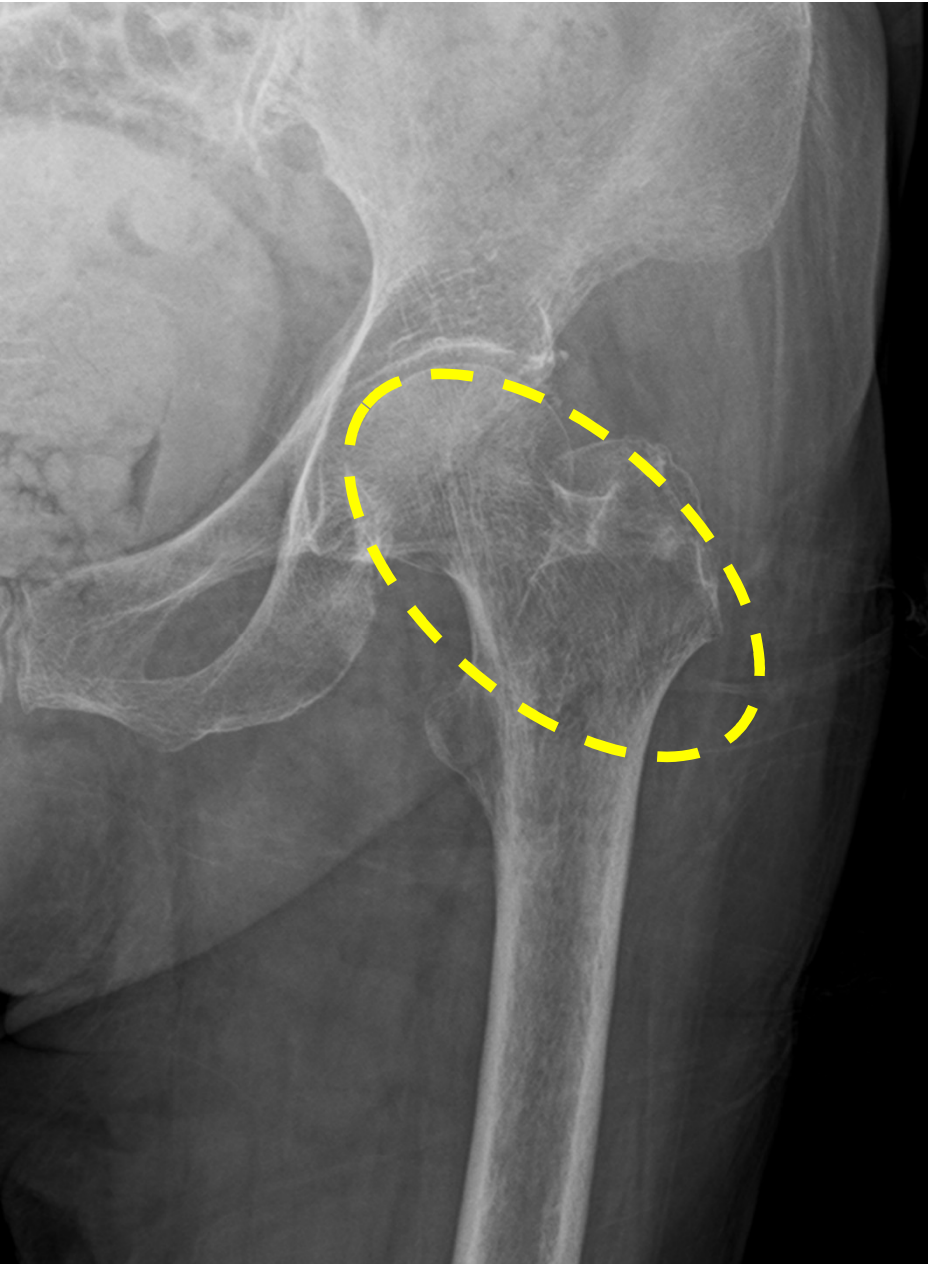


10% of patients fracture the
opposite femur within two years

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.**

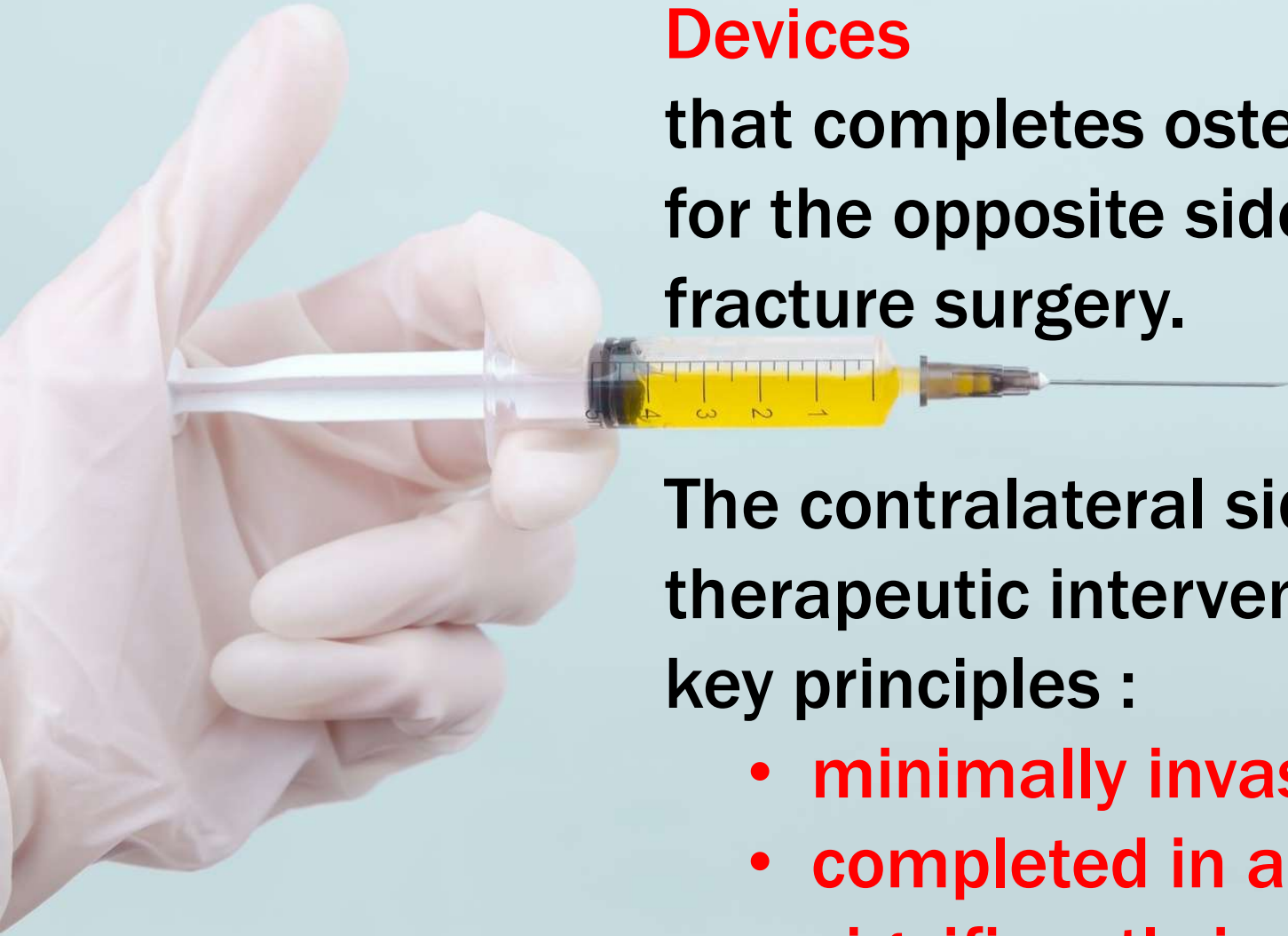
Innovative Osteoporosis Treatment Devices

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

The contralateral side requires early therapeutic intervention.

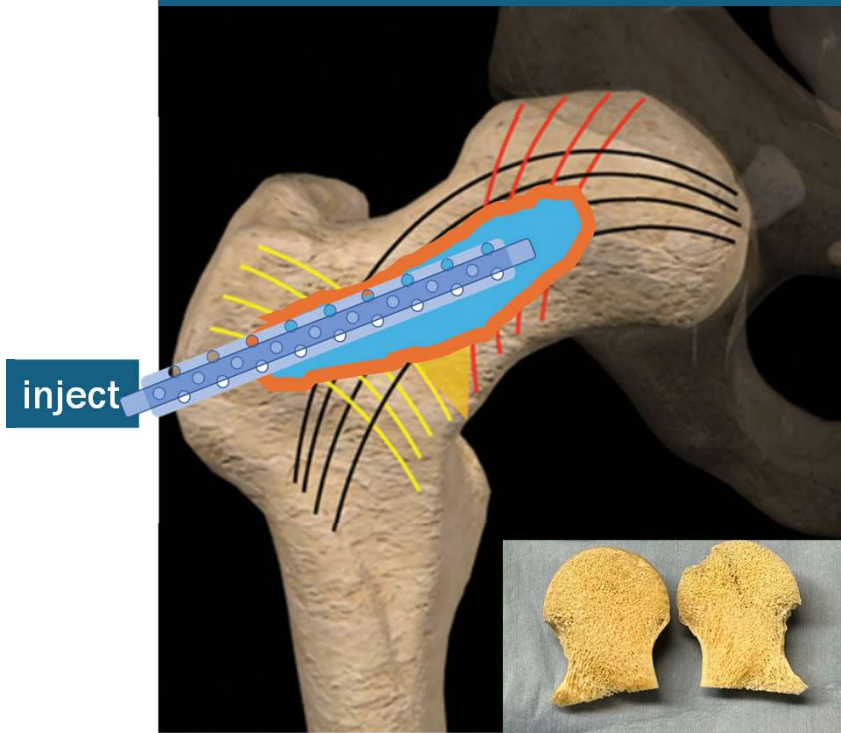
key principles :

- **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】

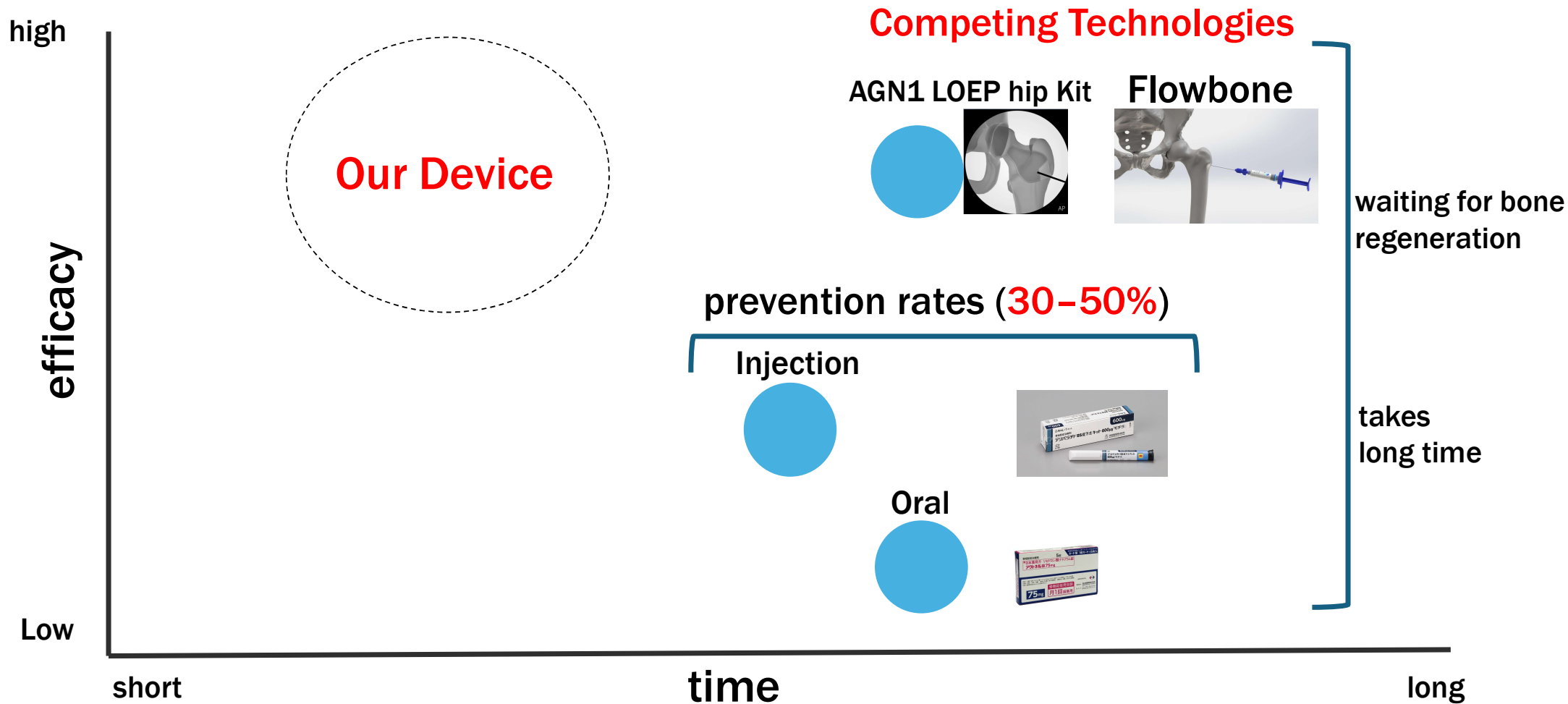
- Identify the treatment site under X-ray fluoroscopy.
- Insert the device for injecting the material.
- Inject the high-strength injectable composite material.
- Confirm the material filling using X-ray imaging.
- After confirming hardening, remove the device.

※ *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



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;

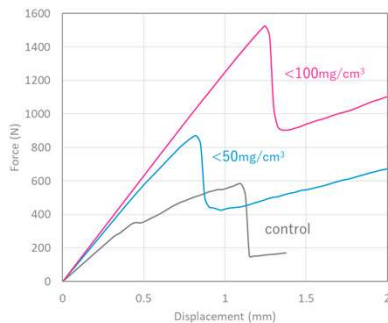
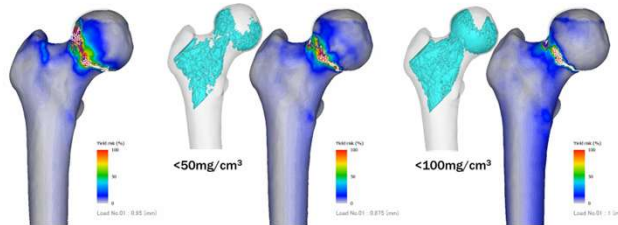
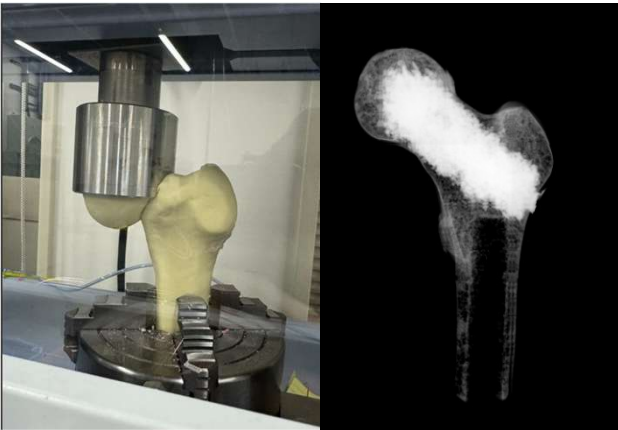
Device patents;

- W02024/181411A1 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.

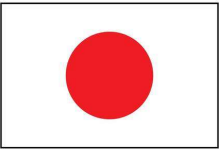


Market Potential

Estimated Value

Patient × **Device Price (USD2,000)**

A similar product is 2,000 USD.



Osteoporosis

USD 1.5 billion
750,000 patients/year

USD 3.0 billion
1,500,000 patients /year

USD 6.0 billion
3,000,000 patients /year

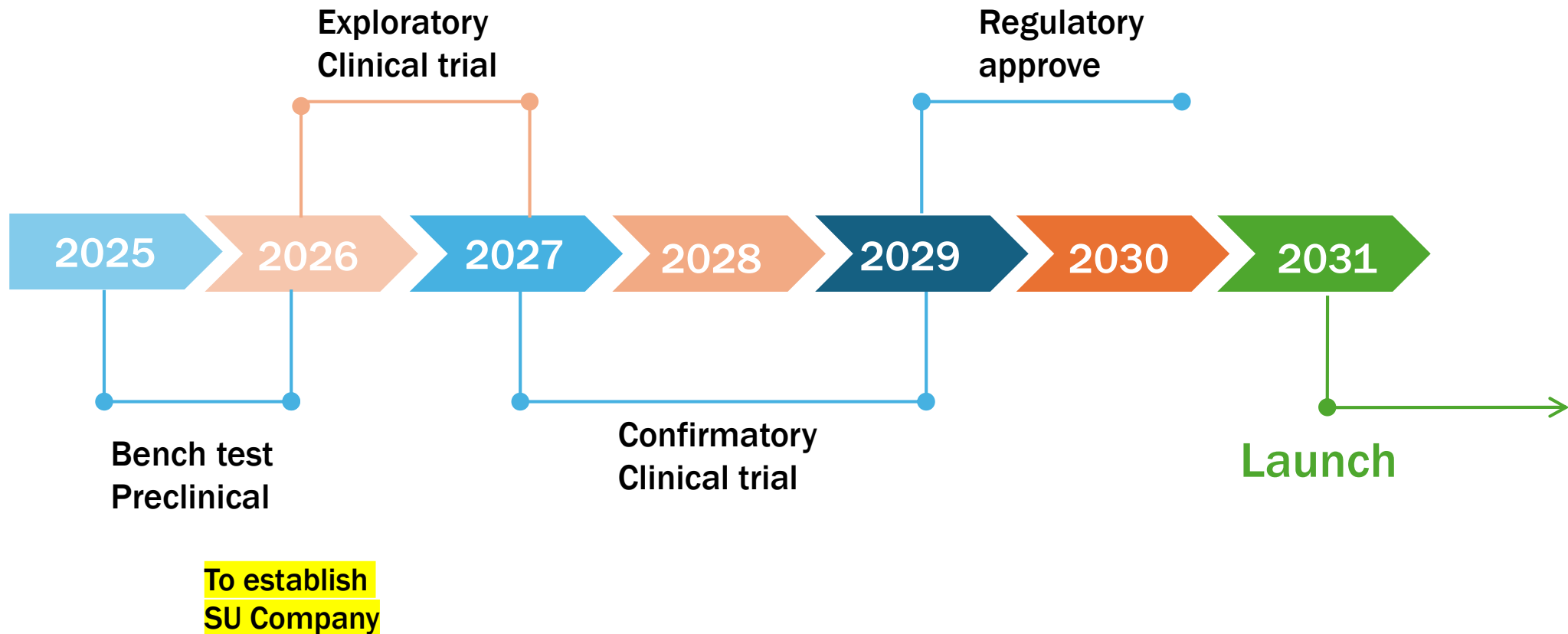
Femoral Fracture

USD 300 million
150,000 patients/year

USD 600 million
300,000 patients /year

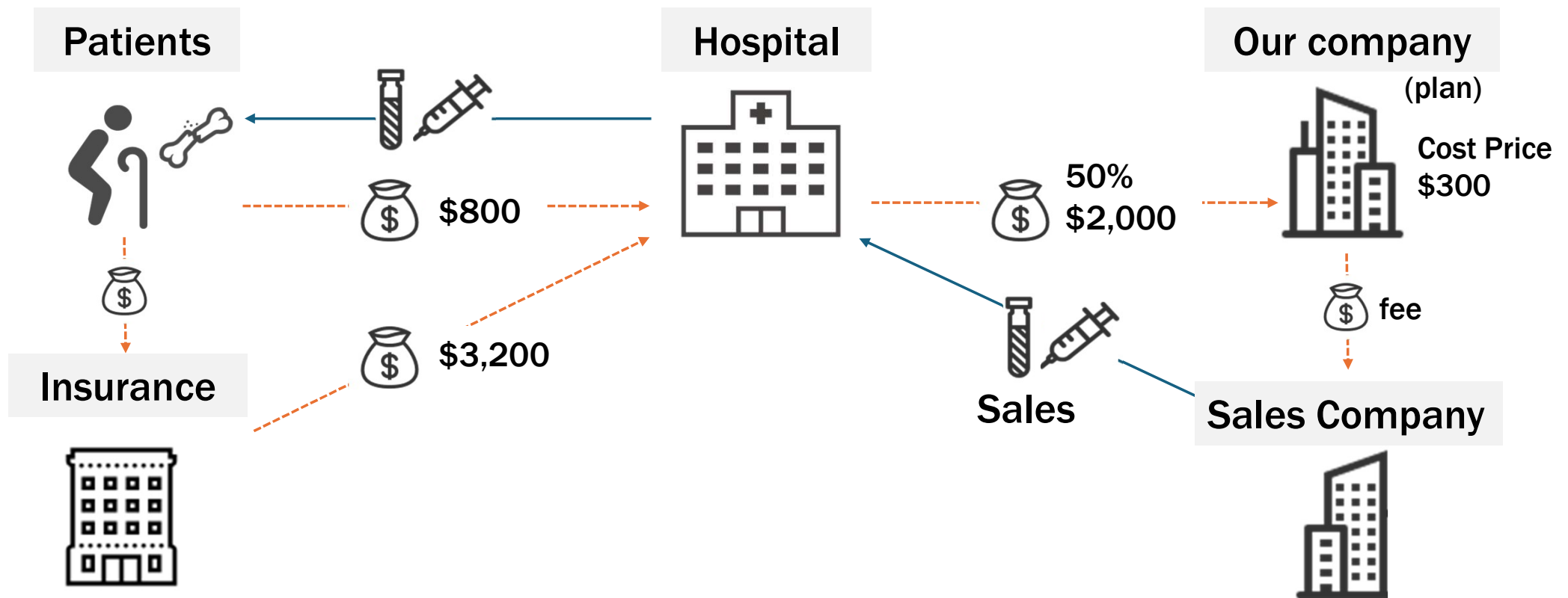
USD 1.2 billion
600,000 patients /year

Growth Timeline



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



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Hip Surgeon

Animal Testing
CEO

The University of Osaka



Yuichiro Ukon
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Spine Surgeon

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CTO

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