# Development of Titanium Alloys for Load Bearing Implant Devices through Focusing on Young's Modulus Control

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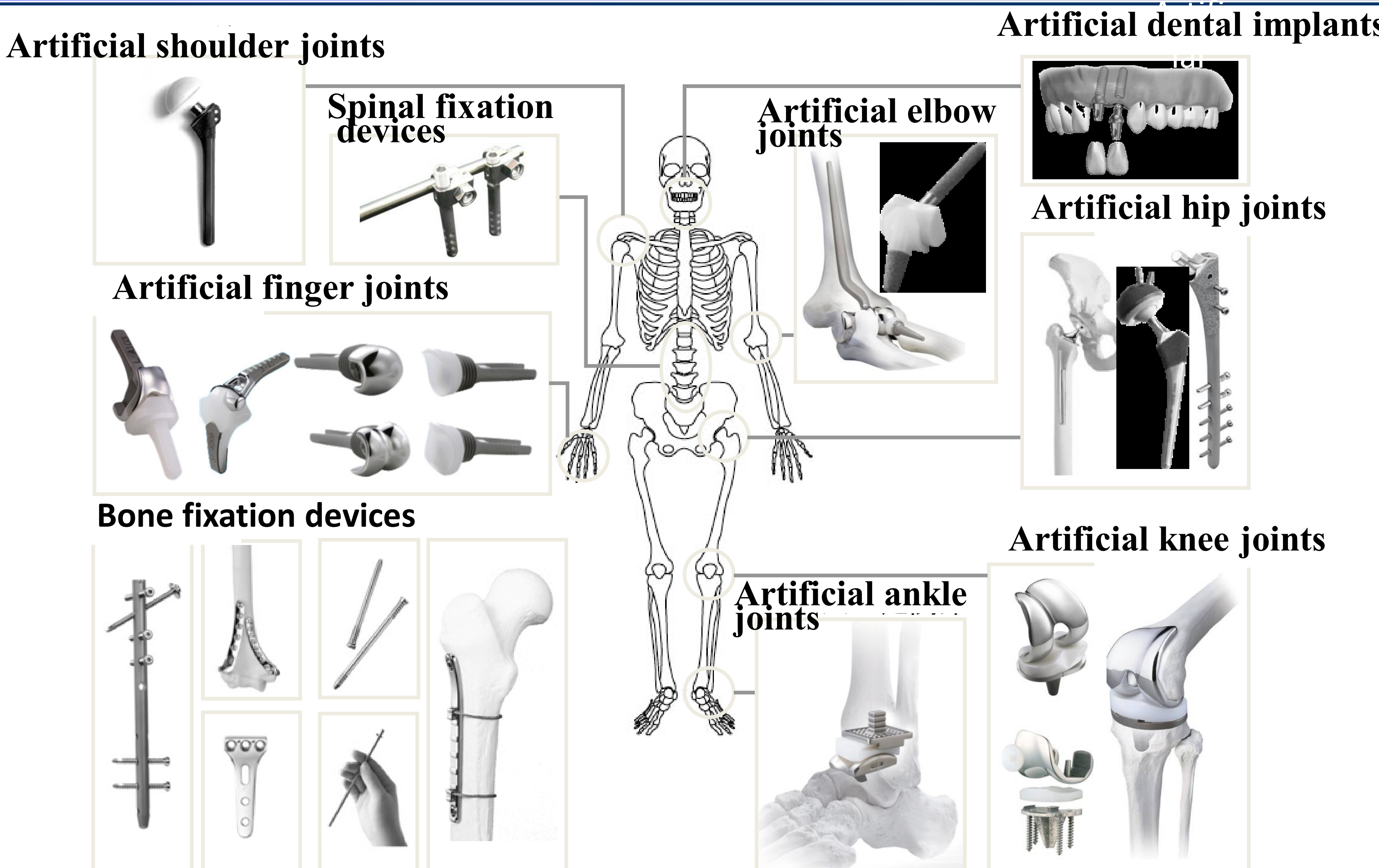
# Properties required for medical metallic materials

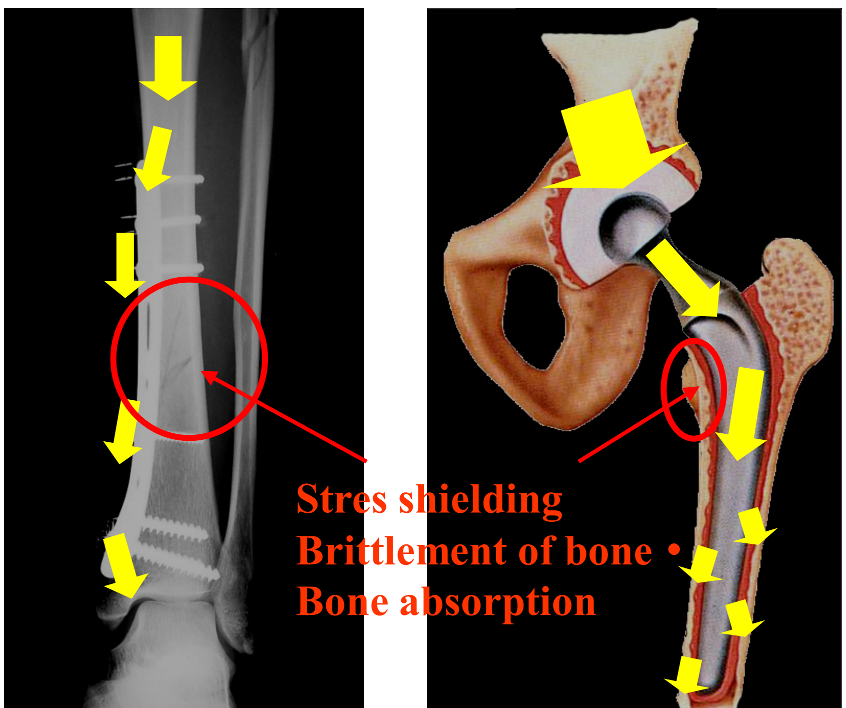



High mechanical reliability

# Properties required for medical metallic materials

## Reducing stress shielding

**Bone absorption or shrinking occurs due to the remodeling according to the decrease in mechanical stimulation when, for example, the artificial joints or bone plates made of the conventional high modulus metallic materials are implanted or fixed to the fractured bone. They become to be the causes loosening of the artificial hip joints or re-fracture of bone after extraction.**

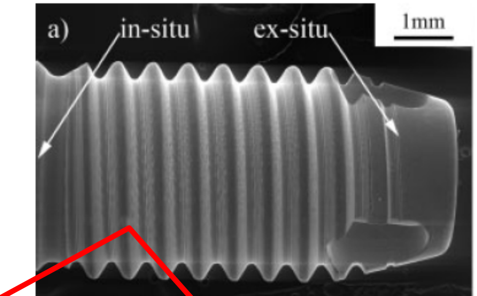


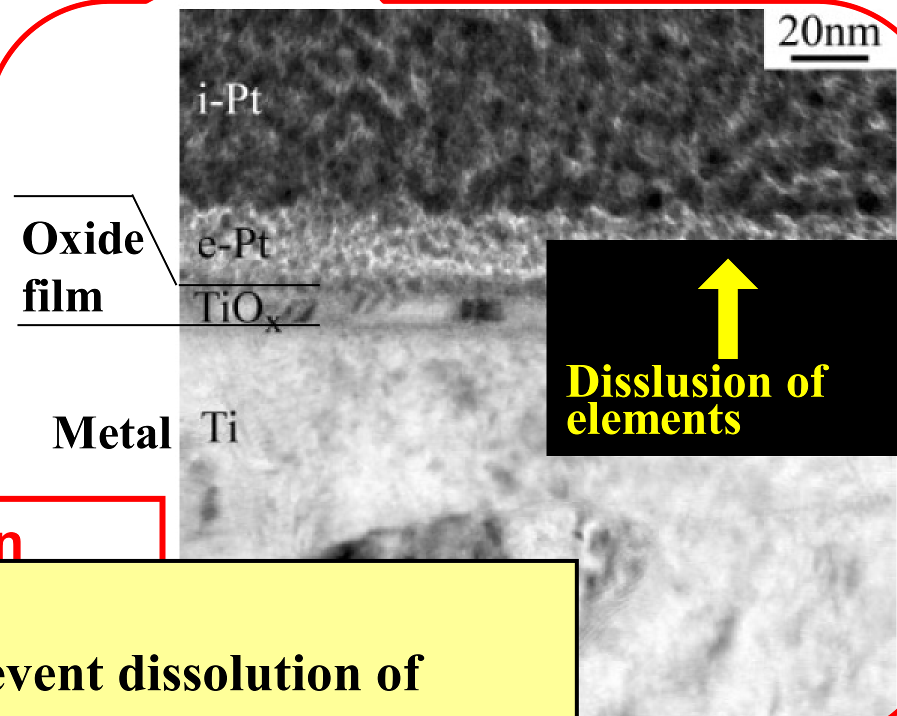

**Development of metallic materials with low moduli, which are similar to that of the cortical bone is required.**

**SUS316L stainless steel: 180 GPa**
**Co-Cr alloys : 210 GPa**
**Ti-6Al-4V ELI: 110 GPa**
**Cortical bone: 10-30 GPa**

# Properties required for medical metallic materials

**Allergy problems appeared on fingers and hands due to metals in the mouse**




ph of the *in situ* sample
he layer covering the Ti
ence between the electron
osited Pt layers.

T. Jarmar et al., J. Biomed. Mater. Res. A 87 (2008) 1003-1009.

**Allergic and toxic problems happen**
**w**
**e**

**Required properties:**

1. High corrosion resistance to prevent dissolution of metallic elements.
2. Using elements showing low toxicity and allergic problems

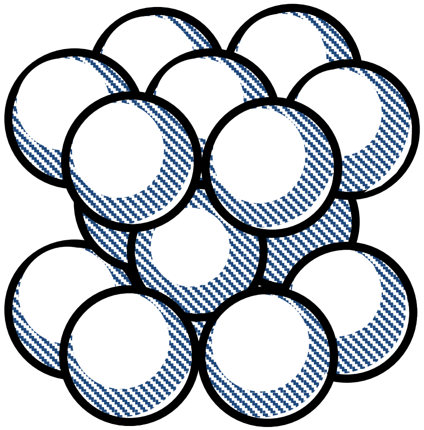
# Properties required for medical metallic materials

- **High mechanical reliability**
- **High corrosion resistance to prevent dissolution of metallic elements**
- **Using elements showing low toxicity and allergic problems**
- **Low Young's modulus close to that of bone**

**Table Biocompatibility of various biomaterials judged by patterns of osteogenisis**

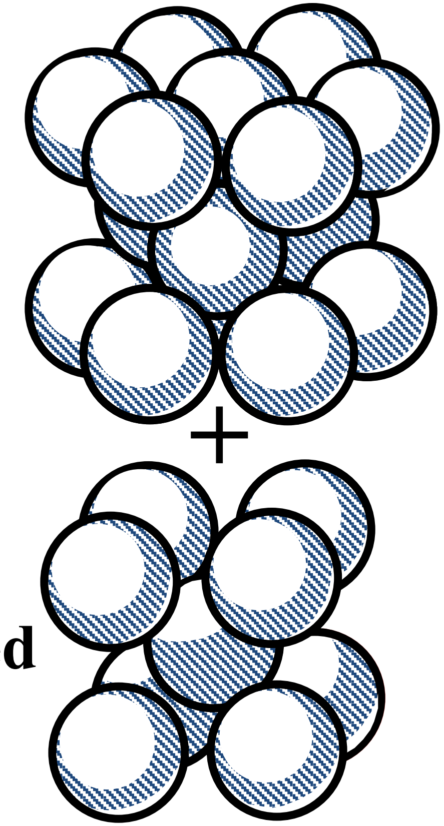
| Pattern of osteogenisis | Biomaterials | |
|---|---|---|
| Intervend osteoginisis | Stainless steel, Vitallium, PMMA (Polymethyl methacrylate) | Biotolerant materials |
| Contact osteogenisis | Titanium, Tianium alloys, Carbon, Alumina, Zirconia, Titania, TiN, $Si_3N_4$ | Bioinert materials |
| Bonding osteogenisis | Bioglass, Ceravital, Tricalcium phosphate, Hydroxyapatite, A-W glass ceramic | Bioactive materials |

# Crystal structures of titanium alloys



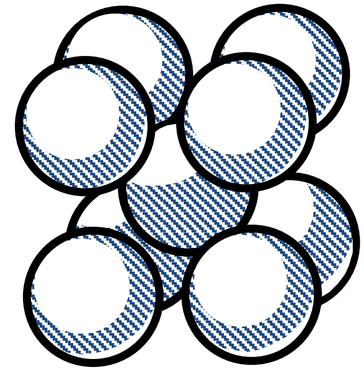
(a)Hexagonal close packed structure (HCP)

α-type titanium alloy



(b) HCP＋BCC

(α+ β) -type titanium alloy



(c) Body centered structure (BCC)

β -type titanium alloy

Fig. Schematic explanation of α-, (α + β)-, and β-type titanium alloys based on crystal structure.

**β-type titanium alloys are advantageous for developing low Young's modulus medical metallic biomaterials.**

***Many kinds of low modulus β-type titanium alloys with non-toxic and allergy-free elements have been developted,.***

**Representative ones , for example, are as follows:**

- **Ti-13Nb-13Zr (ASTM F1713-96) : near β type, Low modulus**
- **Ti-12Mo-6Zr-2Fe (ASTM F1813-97): β type, Low modulus**
- **Ti-15Mo : β type (ASTM F2066) (U.S.A.), Low modulus**
- **Ti-16Nb-10Hf : β type, Low modulus**
- **Ti-15Mo-2.8Nb-0.2Si-0.26O : β type, Low, modulus**
- **Ti-35Nb-7Zr-5Ta (TNZT) : β type, Low modulus**
- **Ti-29Nb-13Ta-4.6Zr (TNTZ): β type, Low modulus**
- **Ti-Mo-Sn : β type, Low modulus**
- **Ti-40Ta, Ti-50Ta : β type, High corrosion resistance**

# Selection of non-toxic and allergy-free elements

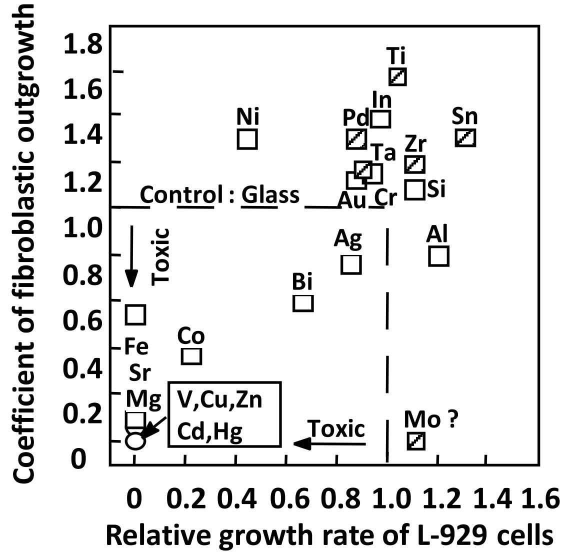



Fig. Cyto-toxicity of pure metals

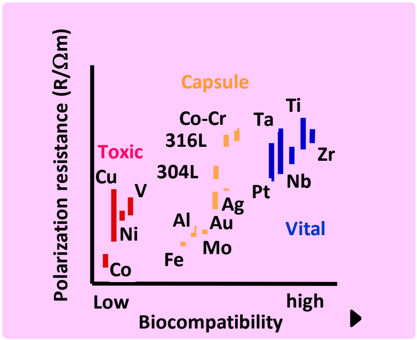



Fig. Corrosion resistance and biocompatibility of representative pure metals and metallic biomaterials

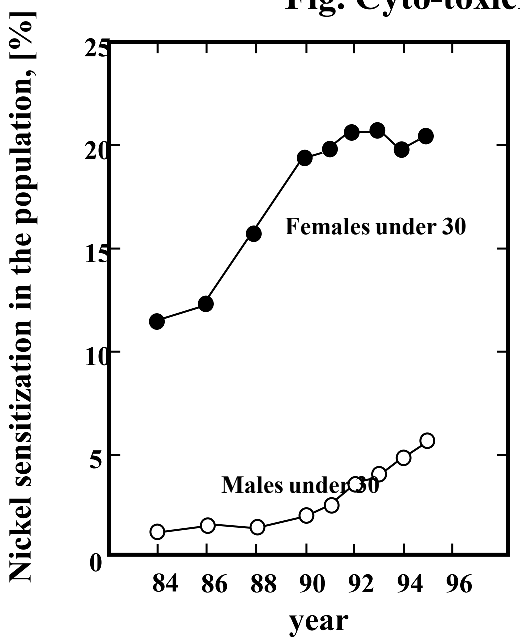



Fig. Frequency of nickel sensitization in the population.

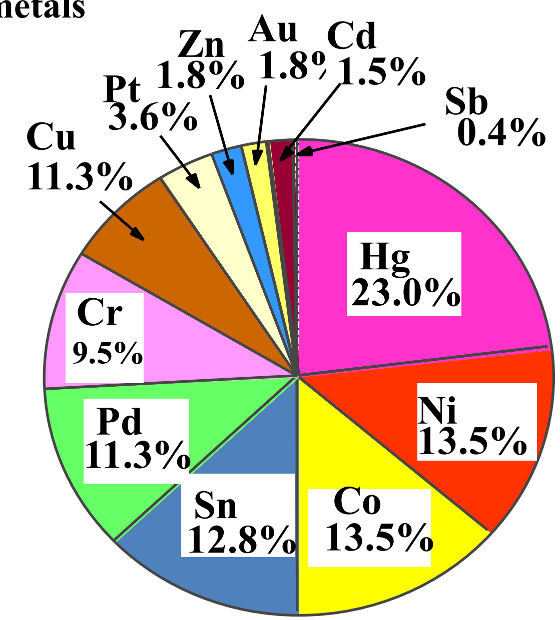
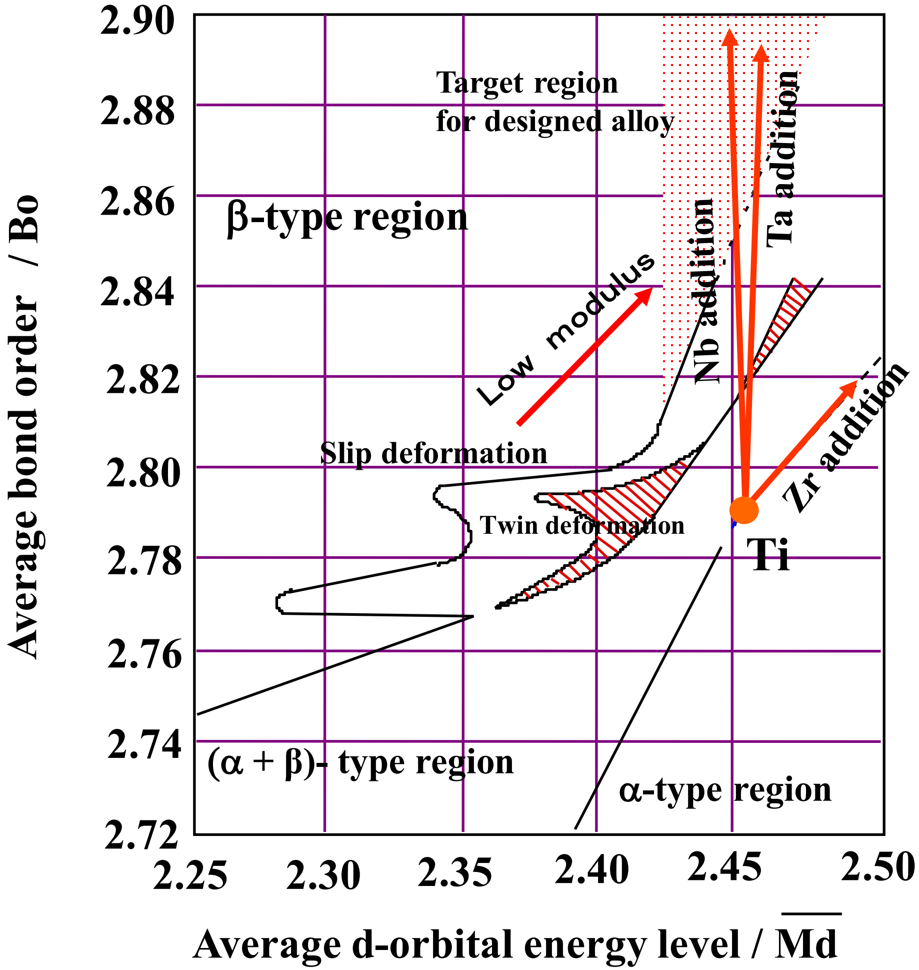



Fig. Rate of metallic allergy of each pure metal.




Bo-Md map.

**Nb, Ta, and Zr are the most suitable for alloying elements.**

**Low Young's modulus β-type Ti-Nb--Ta-Zr alloys**

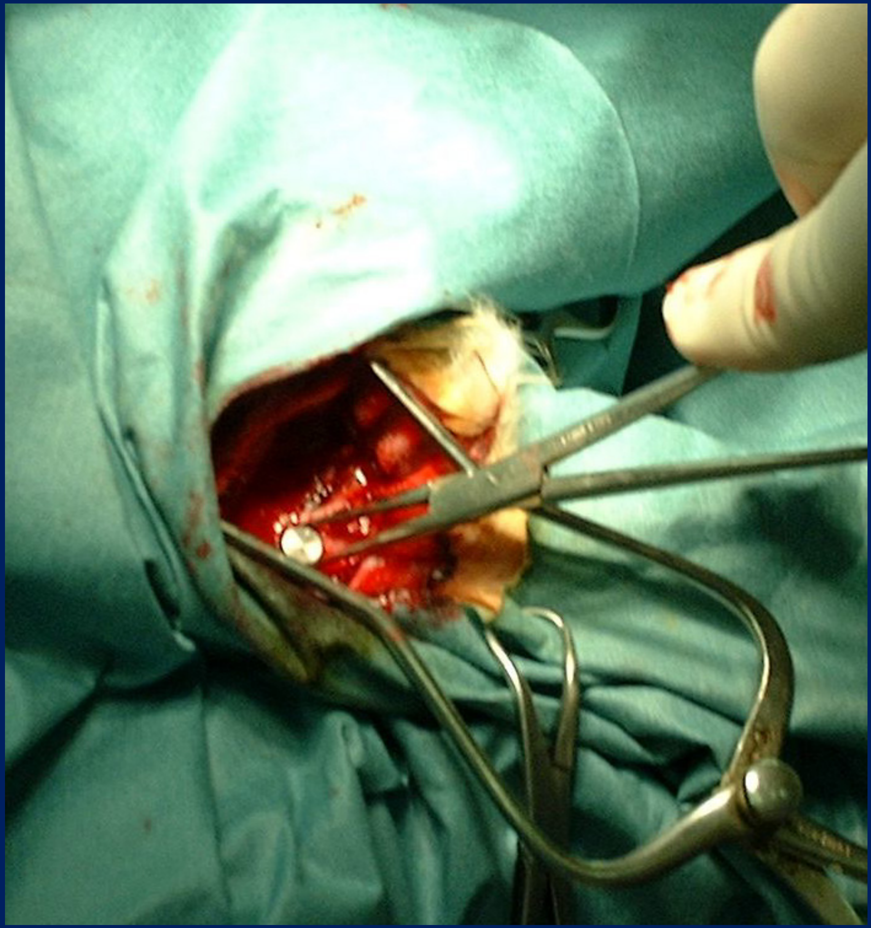
**Ti-29Nb-13Ta-4.6Zr(TNTZ)**

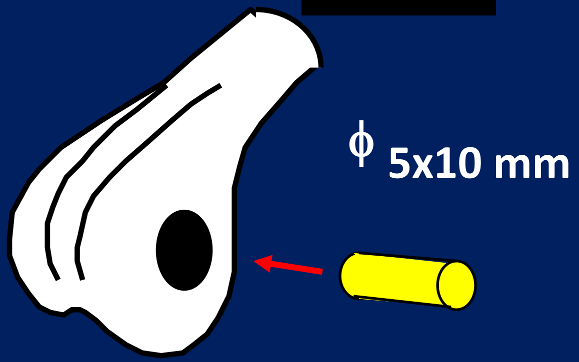
*Table Young's moduli of $(\alpha + \beta)$– type Ti-6Al-4V ELI , $\beta$-type Ti-29Nb-13Ta-4.6Zr (TNTZ), and cortical bone.*

| Material | Young's modulus (GPa) |
| --- | --- |
| Ti-6Al-4V ELI (WQ) | 110 |
| Ti-29Nb-13Ta-4.6Zr<br>▪WQ<br>▪WQ + aged at 673 K for 3.6 k<br>▪WQ + CW | <br>63<br>97<br>55 - 60 |
| Cortical bone | 10 - 30 |

WQ: Water quenching after solution treatment
AC: Air cooling after solution treatment
CW: Cold working

# EXPERIMENT 1: BIOCOMPATIBILITY TEST

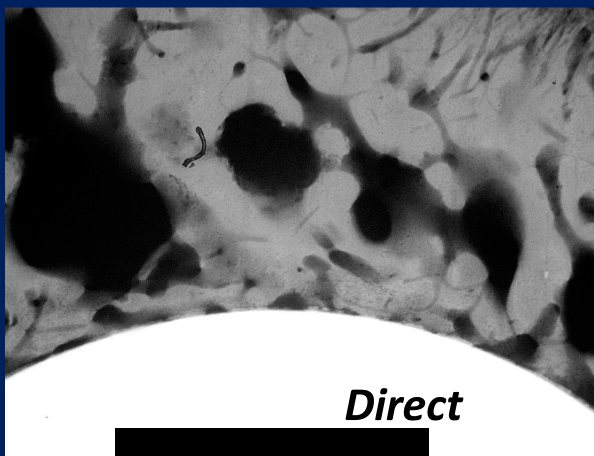




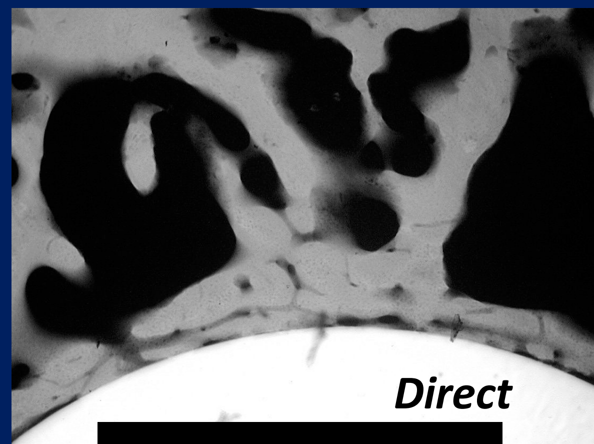

Implantation of columnar specimen into lateral femoral condyle under intravenous anesthesia.

C. M. R of boundary of bone and columnar specimen implanted into lateral femoral condyle of rabbit at 8 weeks after implantation.

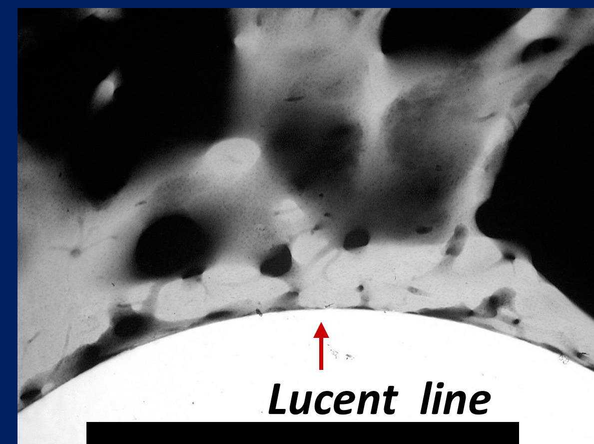
# C.M.R.




TNTZ




Ti6Al4V




SUS316L

Regarding biocompatibility, TNTZ is equal to or possibly greater than Ti6Al4V both showing direct contact, and much better than SUS316L with a radio lucent line.

# Evaluation of bone formation versus low modulus

## Experiment 1 : Intramedullary fixation

Intramedullary rods made of Ti-29Nb-13Ta-4.6Zr (TNTZ), Ti-6Al-4V ELI and SUS 316 L stainless steel

Experimental fracture of the tibia

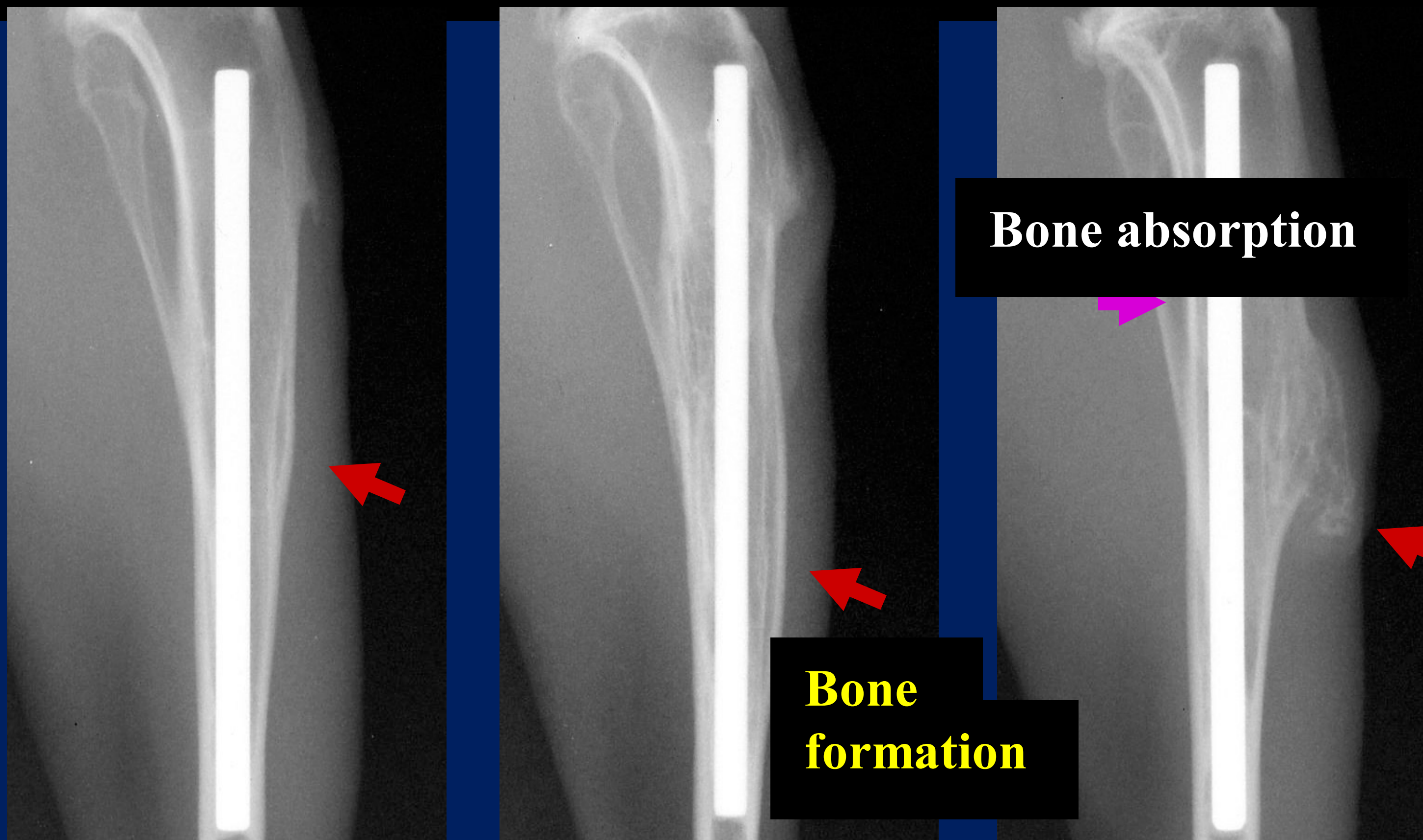
Keeping Fibula intact

1.


2.

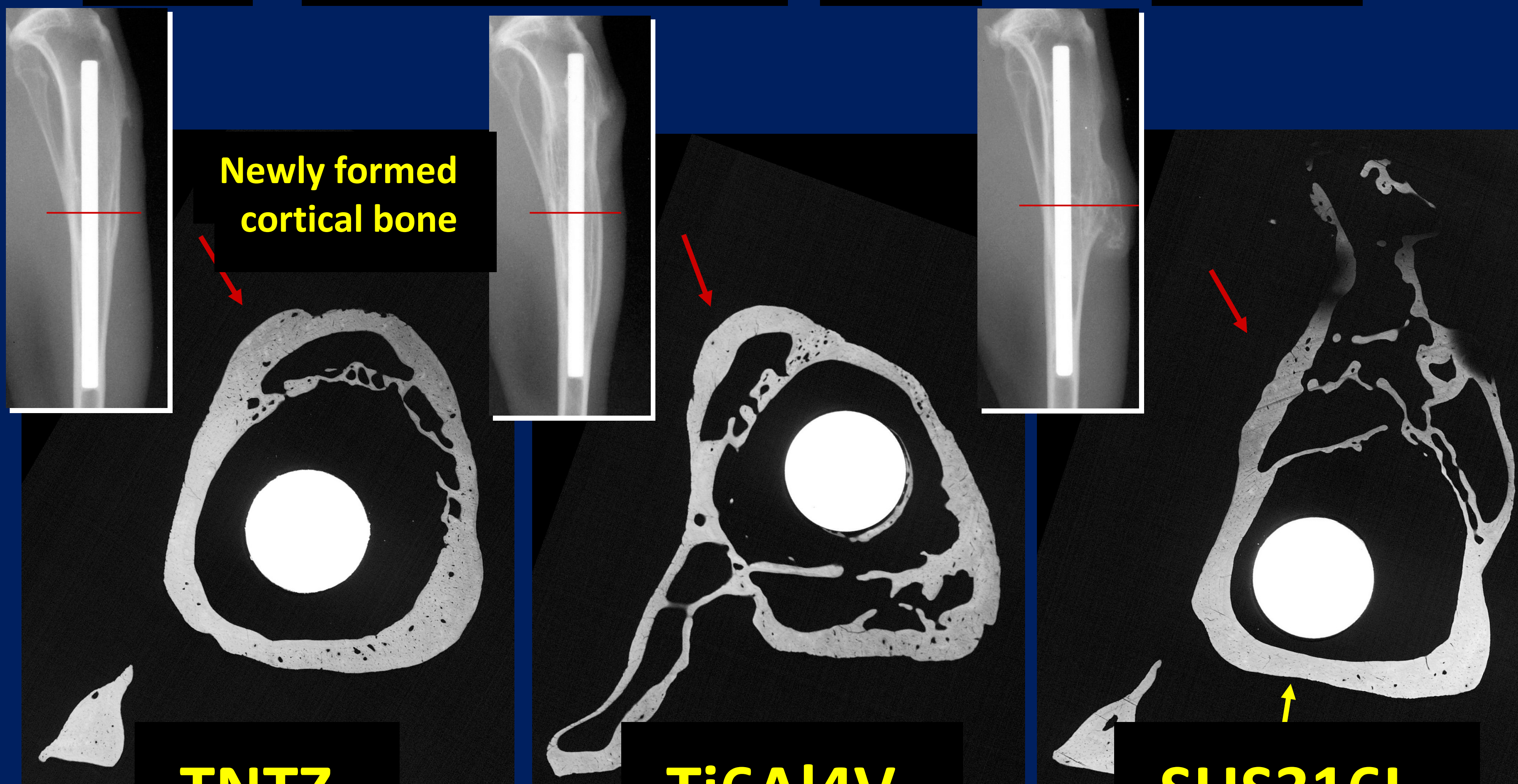

3.

# Remodeling at 24 weeks after implantation




TNTZ Ti-6Al-4V ELI SUS316L

# Result 2: C.M.R. Cross Section at 24w

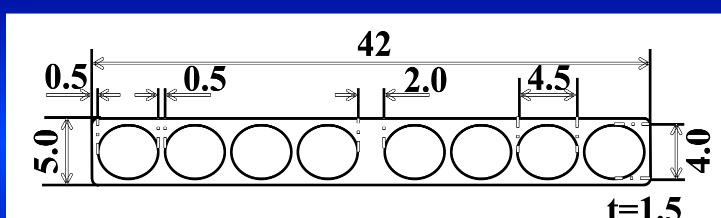



**TNTZ** (around 60 GPa)

**Ti6Al4V** (around 110 GPa)

**SUS316L** (around 160 GPa)

AO mini dynamic compression plate
(AO mini DCP)

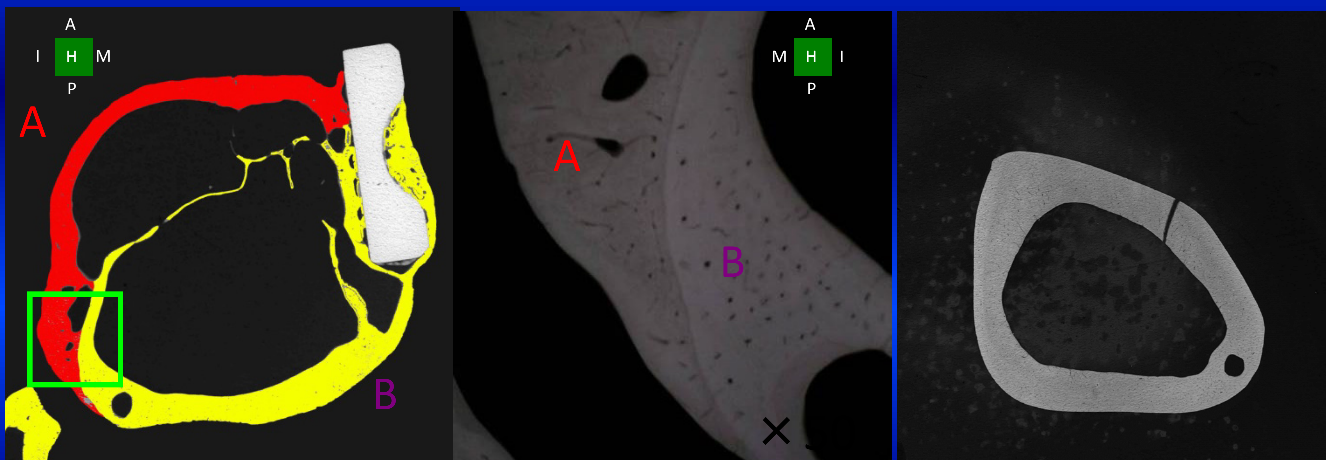



**Based on the design of AO mini DCP for human finger, the bone plate were made of TNTZ.**

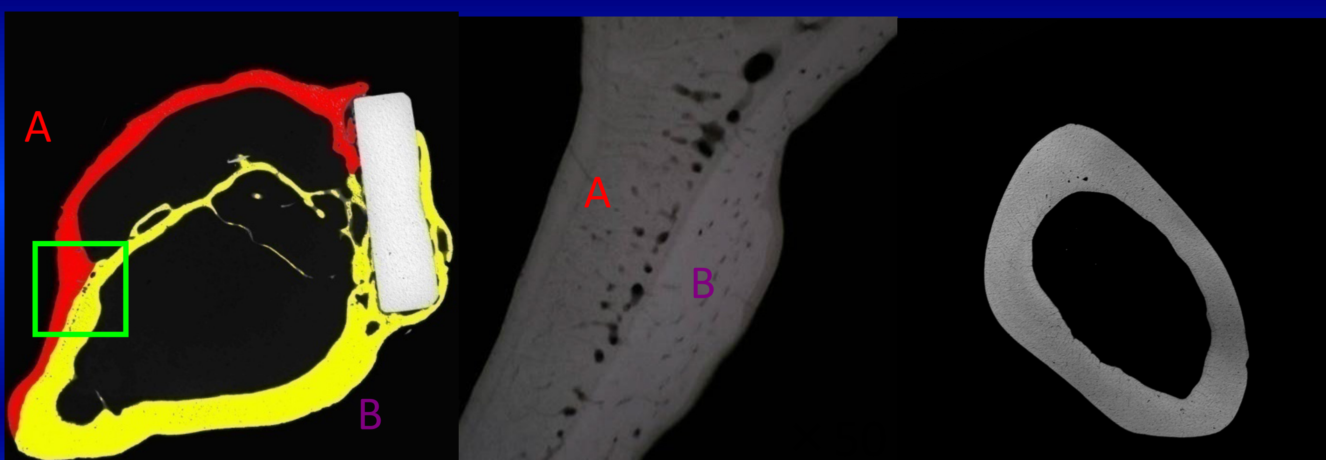
**The plate and screws of Ti-6Al-4V and SUS316L were also provided as control.**

**As experimental animal, mature New Zealand white rabbits (all male, weight about 3kg) were used.**

# Increase of tibia diameter in TNTZ




Middle




Distal

The double wall structure is observed with different X-P densities and a clear boundary line at the middle and distal levels is observed

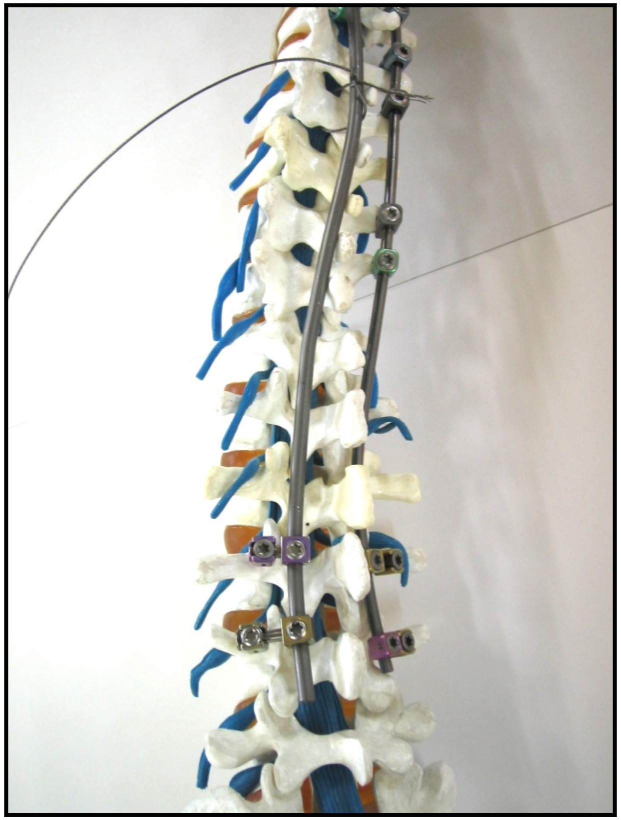
The shape of the inner wall is close to the original cortical bone,

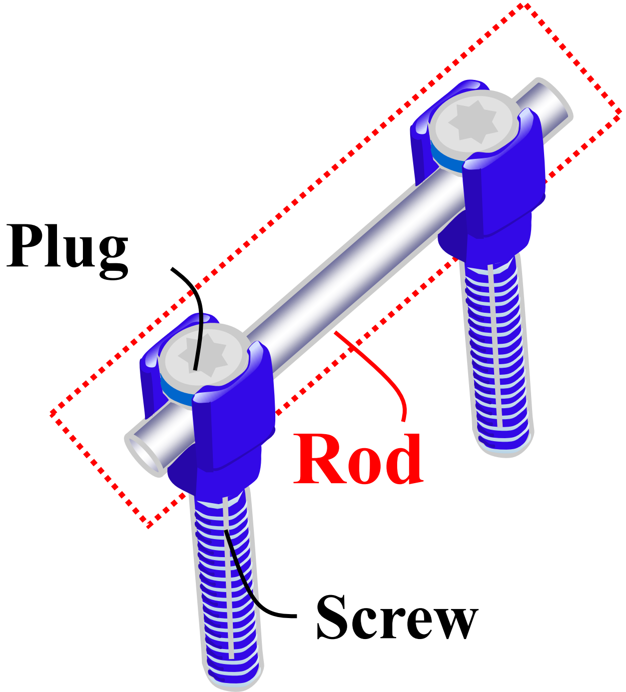
The outer wall seems to be newly formed cortical bone.

The inner wall seems to be the remains of old cortical bone.

Bone remodeling according to the stress condition occurs

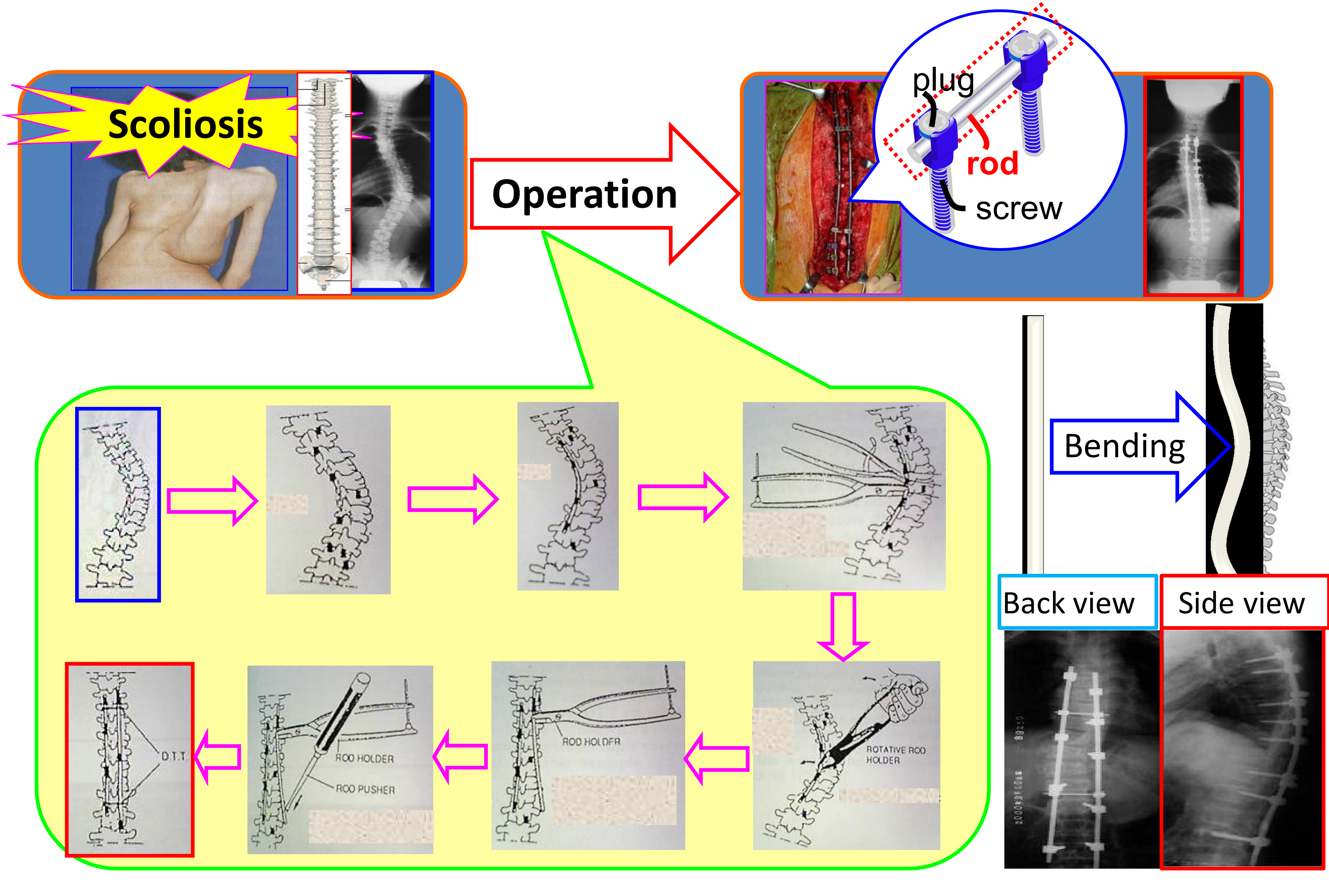
# Material development for specific devices





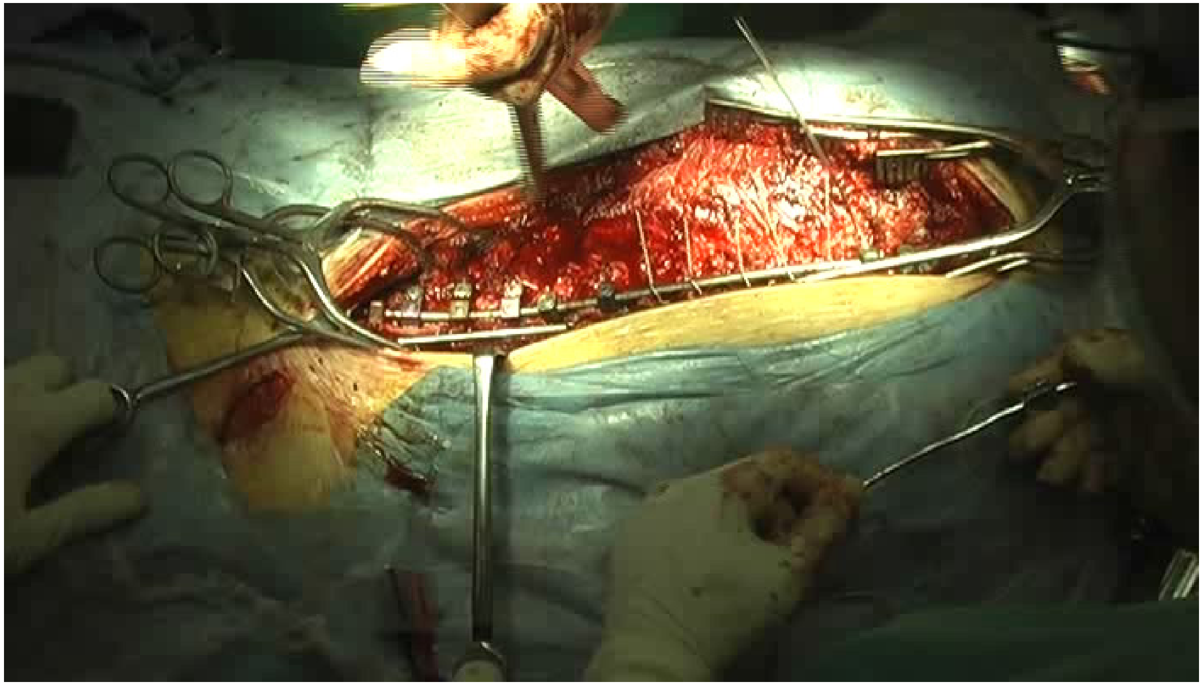

Spinal fixation device is composed of tree parts of rod, screw and plug. Spine is corrected to be normal shape using two rods.

# Principle for developing new medical devices



# Principle for developing new medical devices

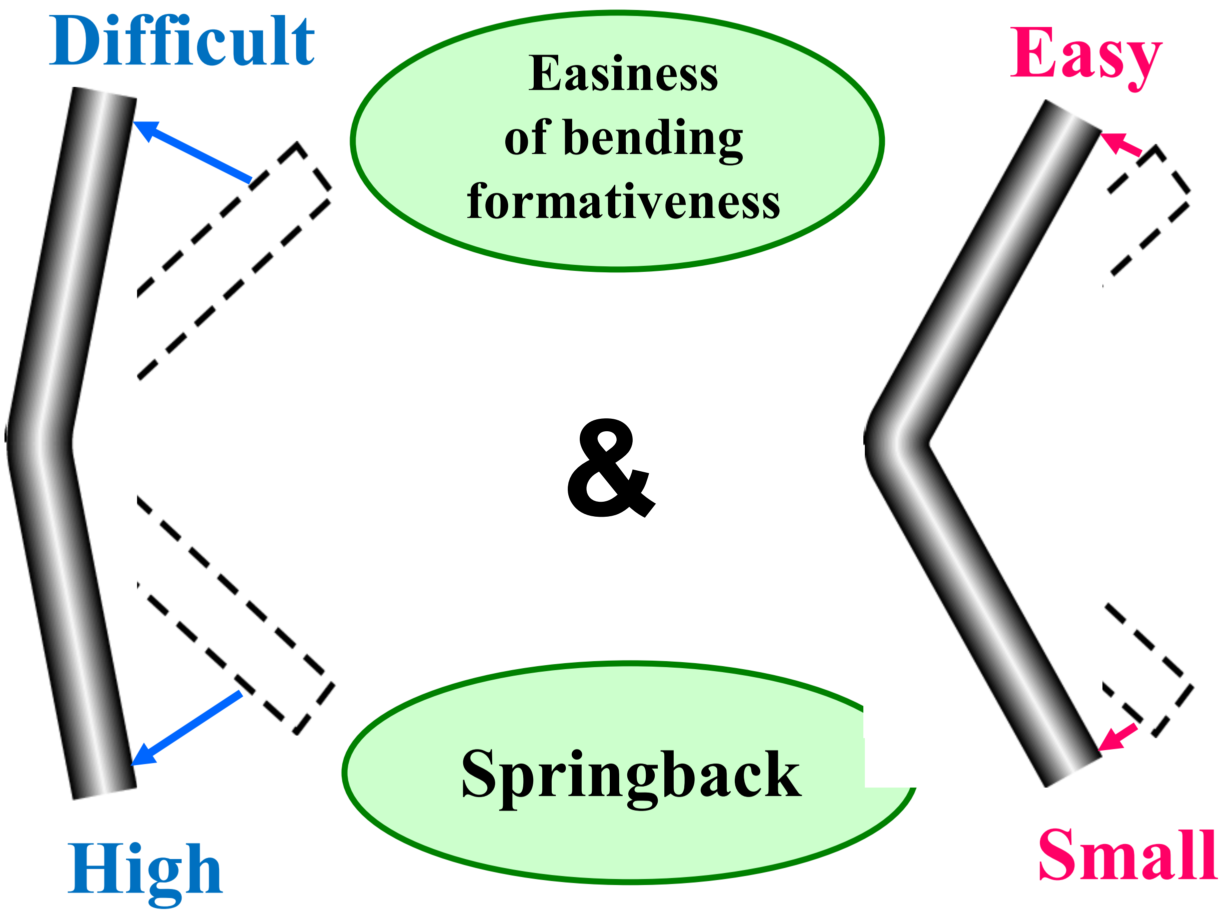
## Operation with spinal fixture



**Bend during operation→ Portion needed bending is unknown before operation**
**(treatment before operation is difficult)**
**Space for bending is narrow → High bending formativeness is required.**
**Scratch is formed by contacting with bending device. → Fatigue strength is degraded by notch effect.**

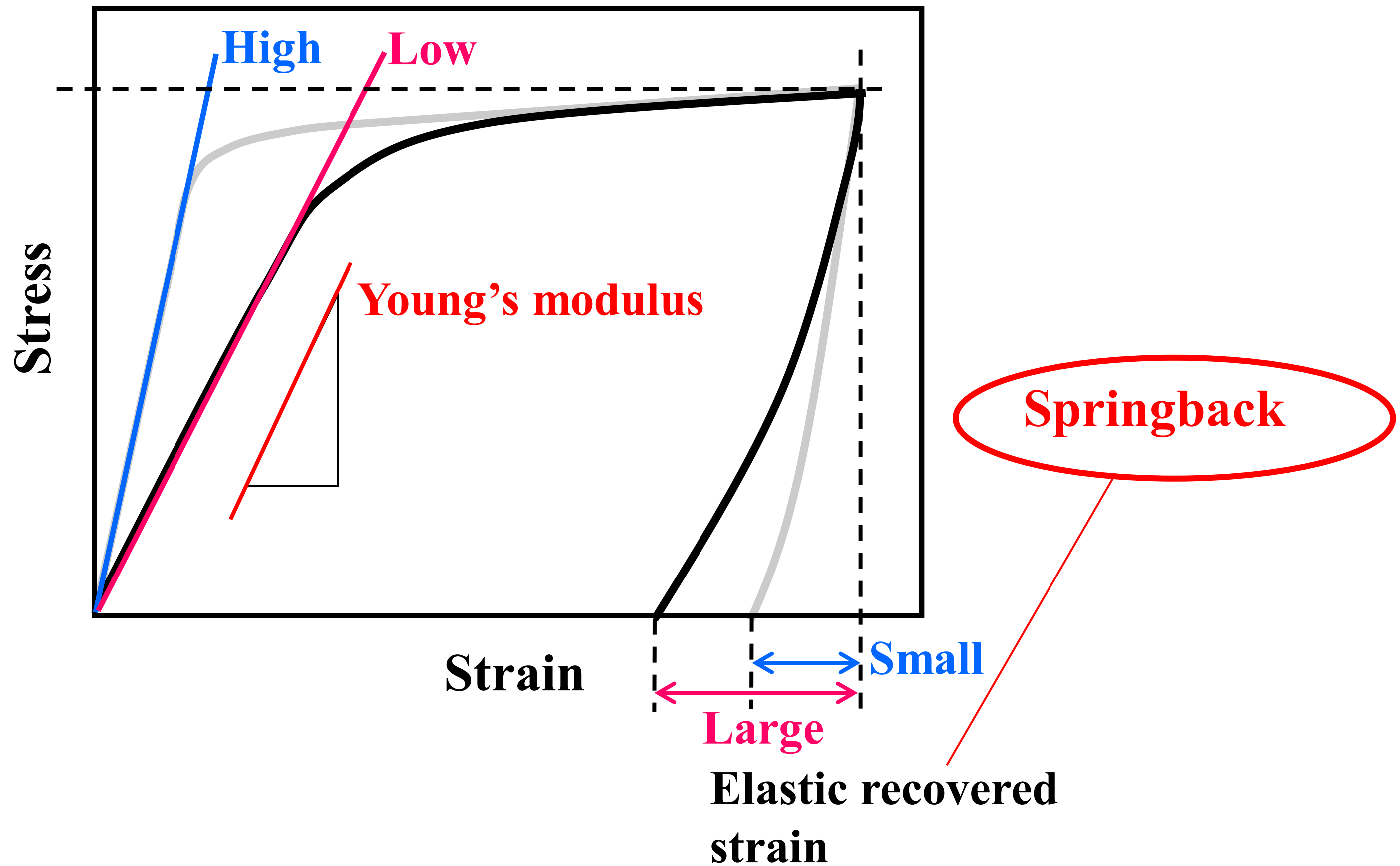
Required property: bending formativeness
(easy operation)

## Factor, which determines bending formativeness




**Bending formativeness is higher with decreasing springback.**

# Concept of supressing springback




**Springback is smaller with increasing Young's modulus**

Fig. The relationship between Young's modulus and springback

# Principle for developing new medical devices

## Young’s modulus required for spinal fixation devices

Suregeons

High formativeness is required.

High Young’s modulus

Conflicting requirement

Patients

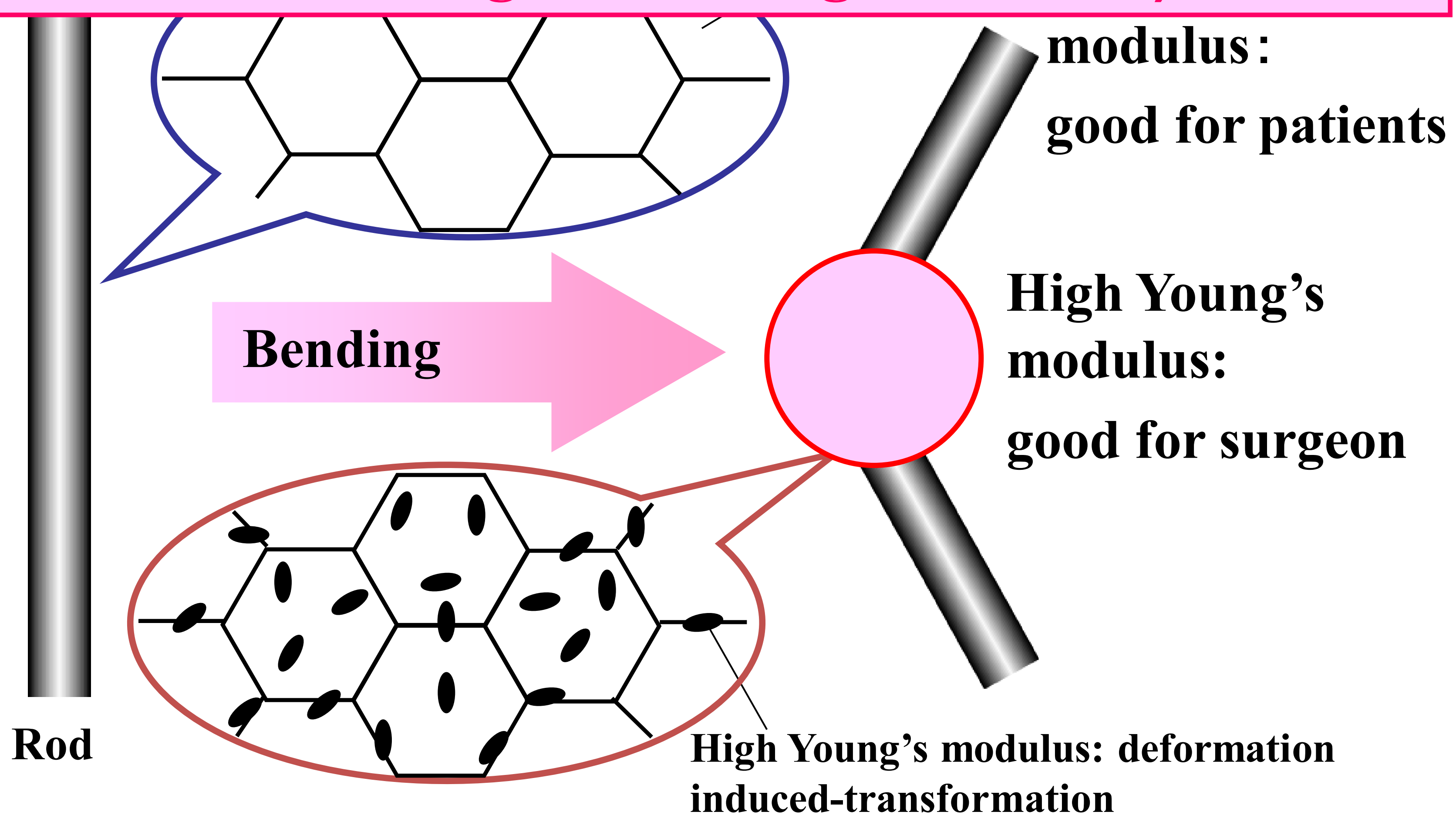
Suppressing stress shielding is required.

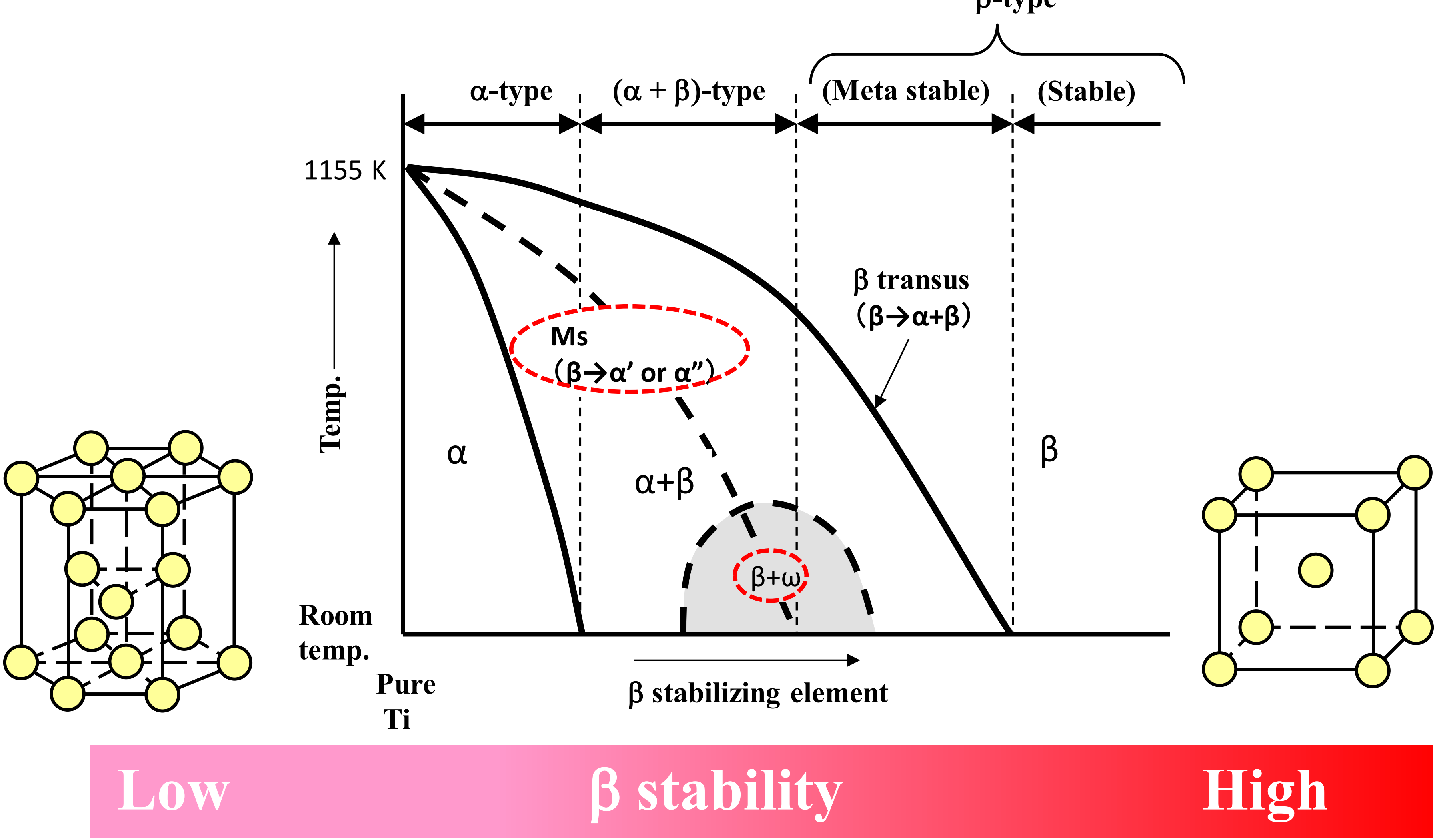
Low Young’s modulus

**Achieving Young’s modulus satisfying both requirements of surgeons and patients.**

# Principle for developing new medical devices

**Titanium alloy of which Young's modulus is changed during operation**
**(Biomedical titanium alloys with changeable Young's modulus)**






hcp-α phase

hcp-α′ phase

orthorhombic-α″ phase

hexagonal-(trigonal-)ω phase

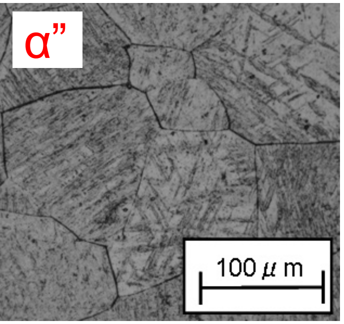
bcc-β phase

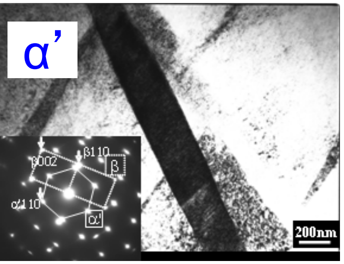
**Relationship between schematic phase diagram of tittanium alloys and β stability.**

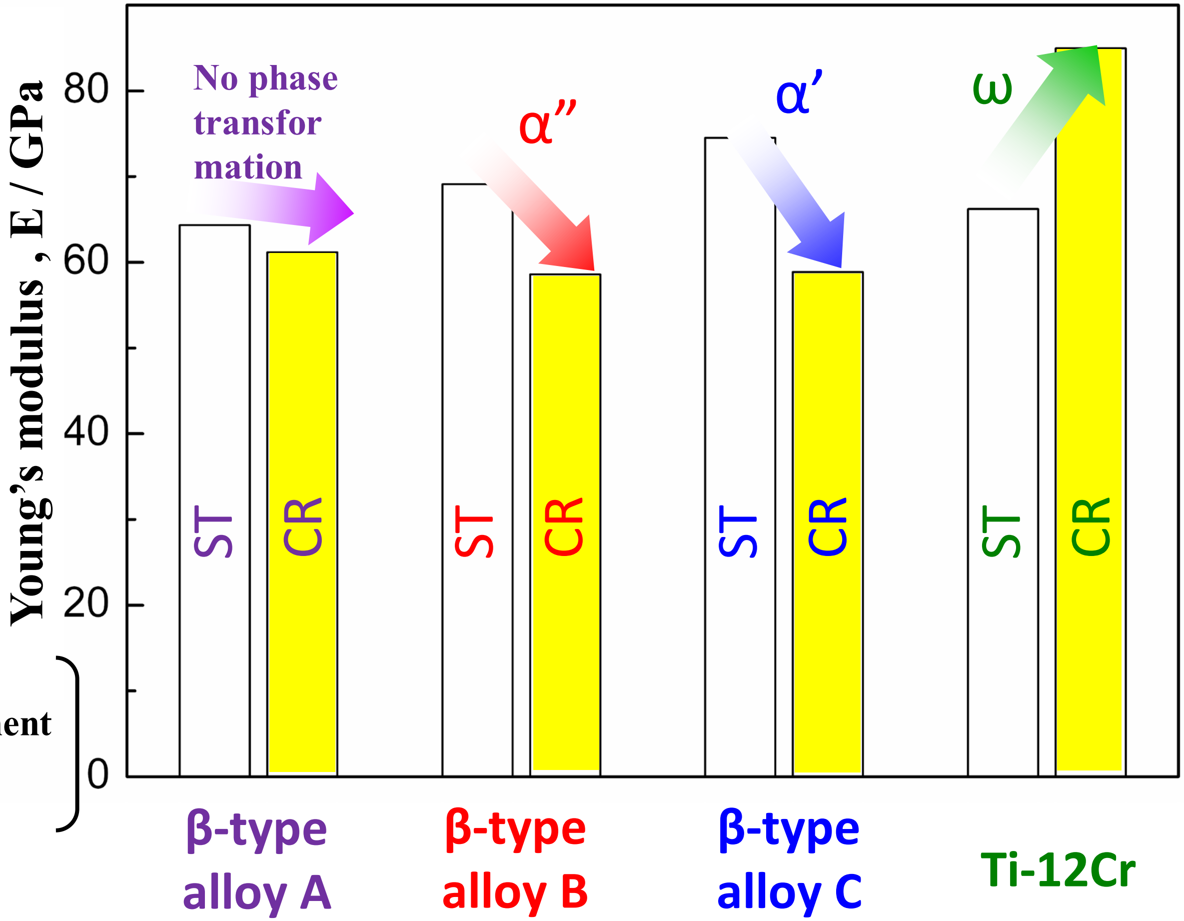
# Determining deformation induced phase

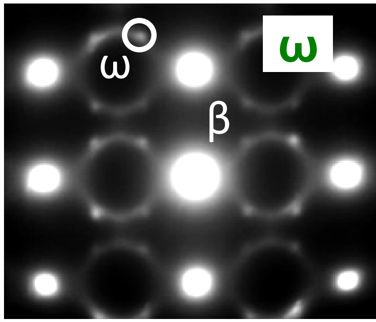
## Change in Young's modulus due to deformation

**Realization of increase in Young's modulus by deformation**



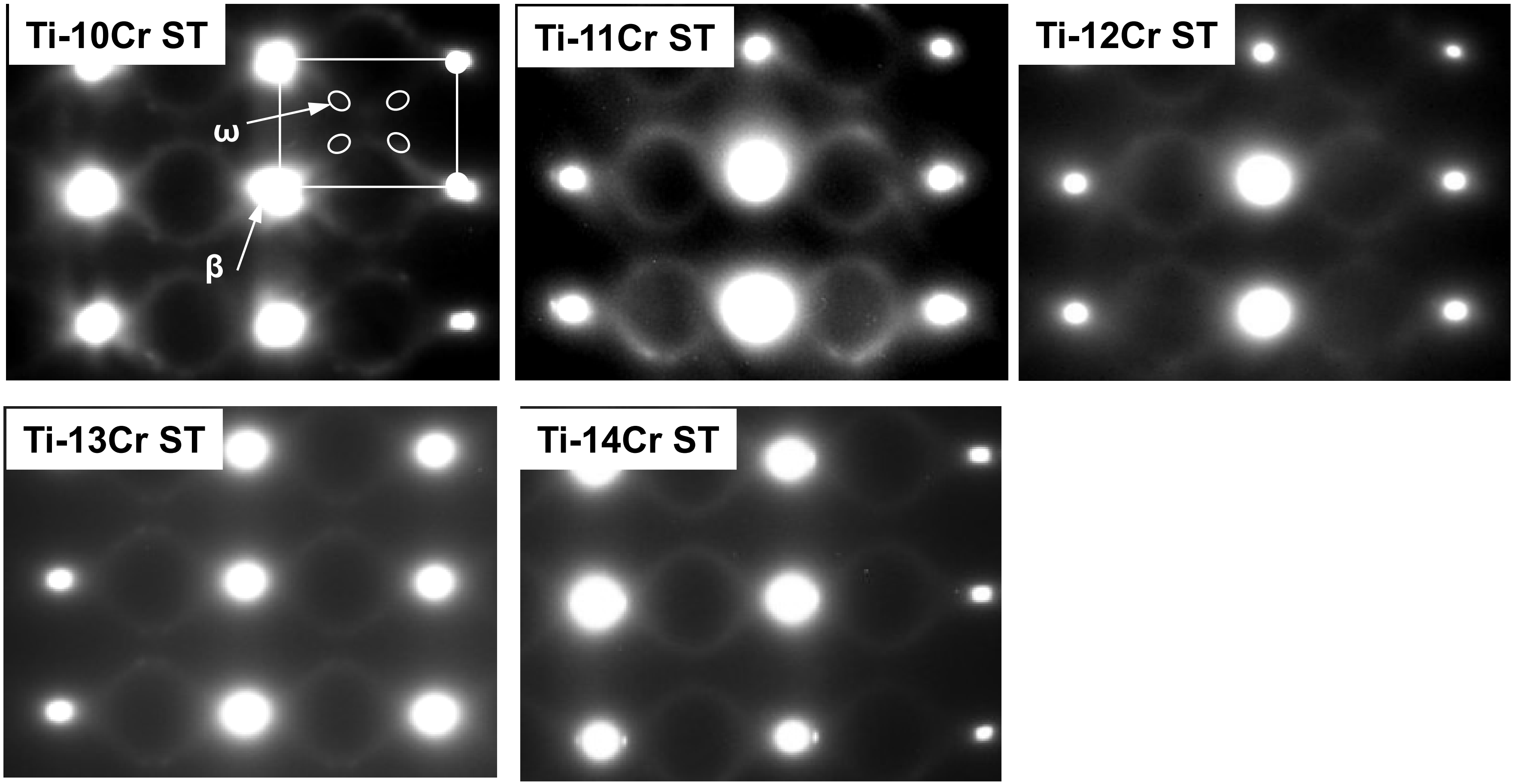




**ST:** Solution treatment
**CR:** Cold rolling

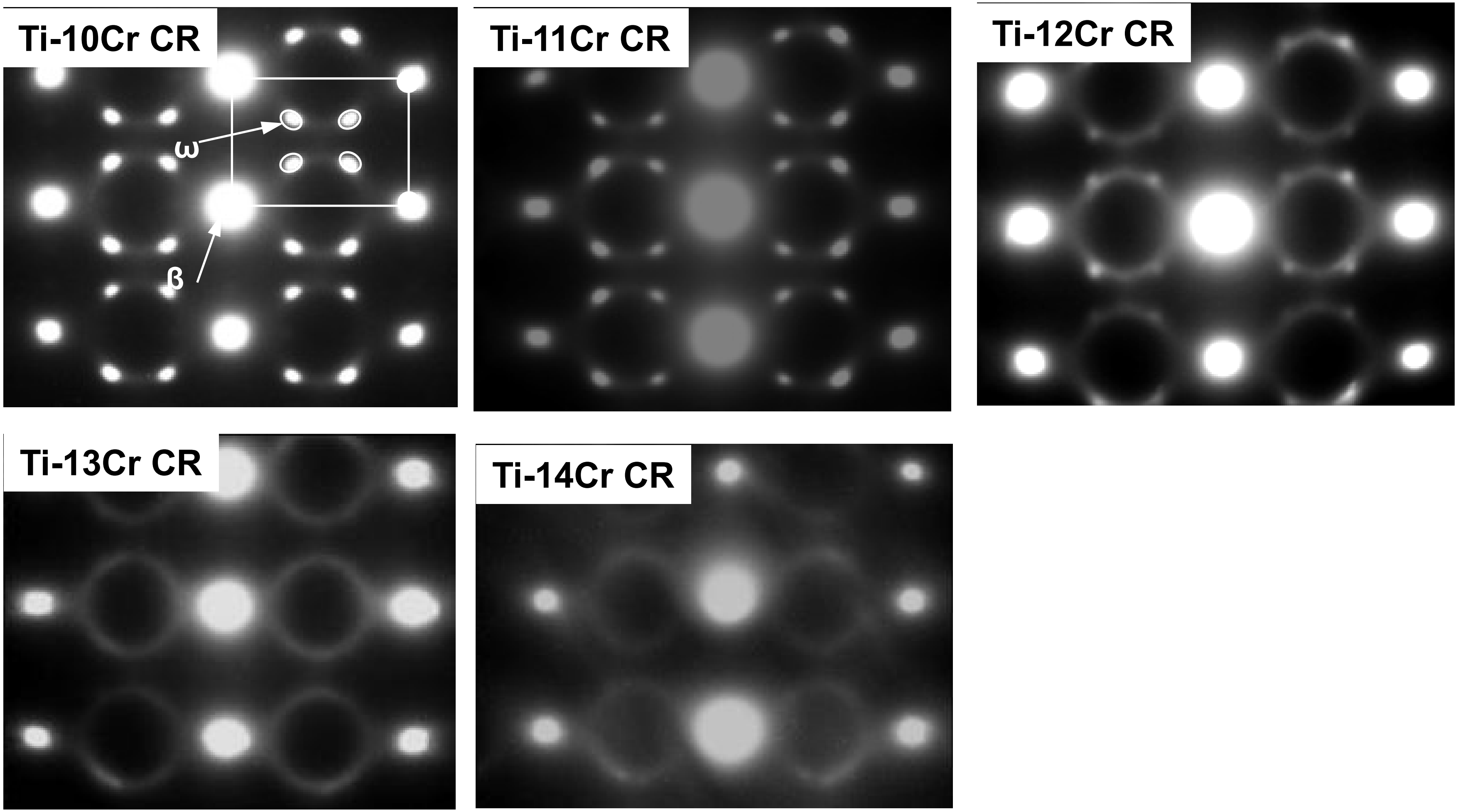
**Utilizing ω phase is effective to increase Young's modulus by deformation.**

# Optimizing alloy composition (example of Ti-12Cr)




Circular streaks related to athermal ω phase are recognized.
Amount of athermal ω phase is decreased due to increase in β stability.

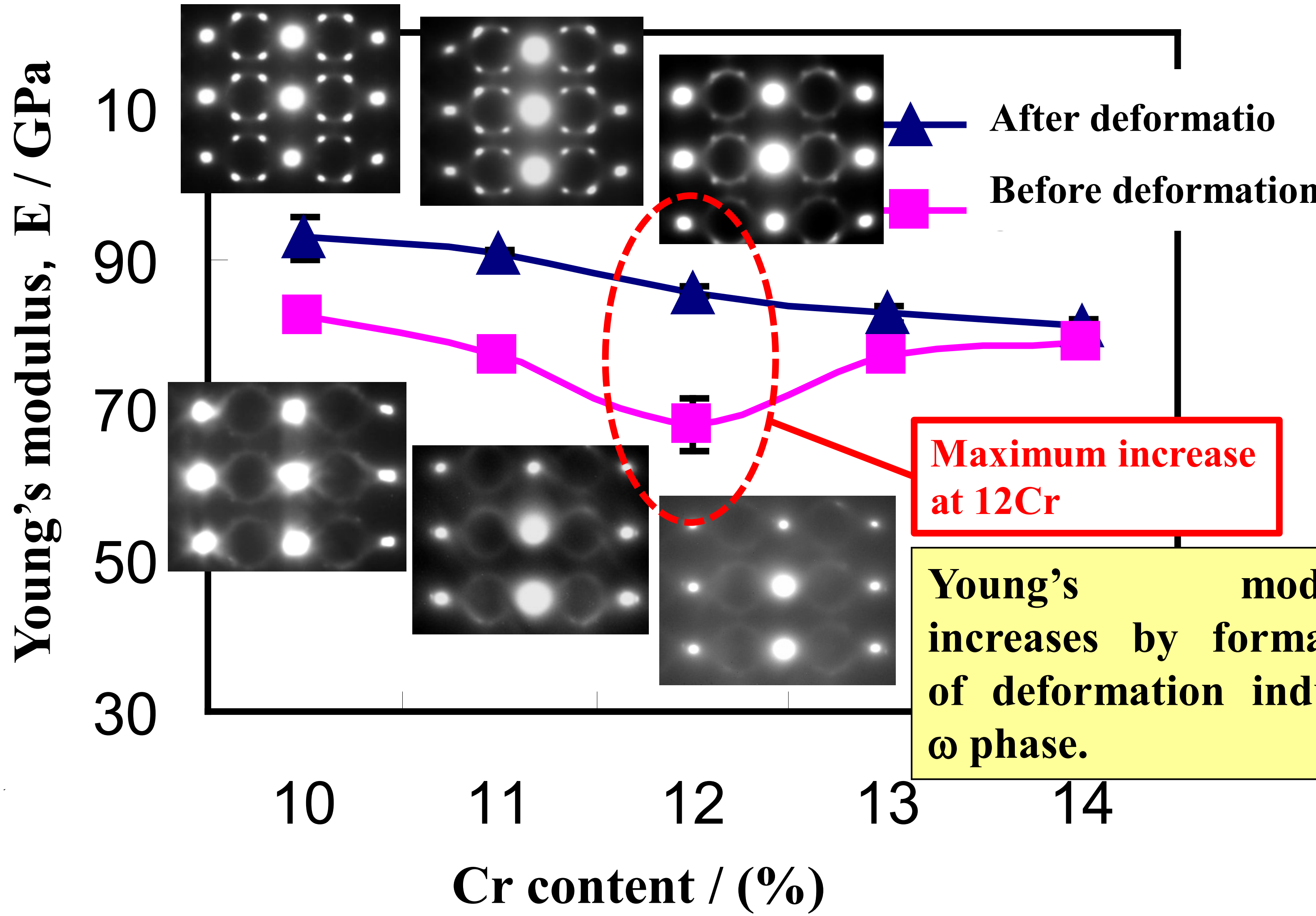
# Optimizing alloy composition (example of Ti-12Cr)




**Deflection from ω phase becomes to be strong → Formation of deformation induced ω phase**

# Determining deformation induced phase

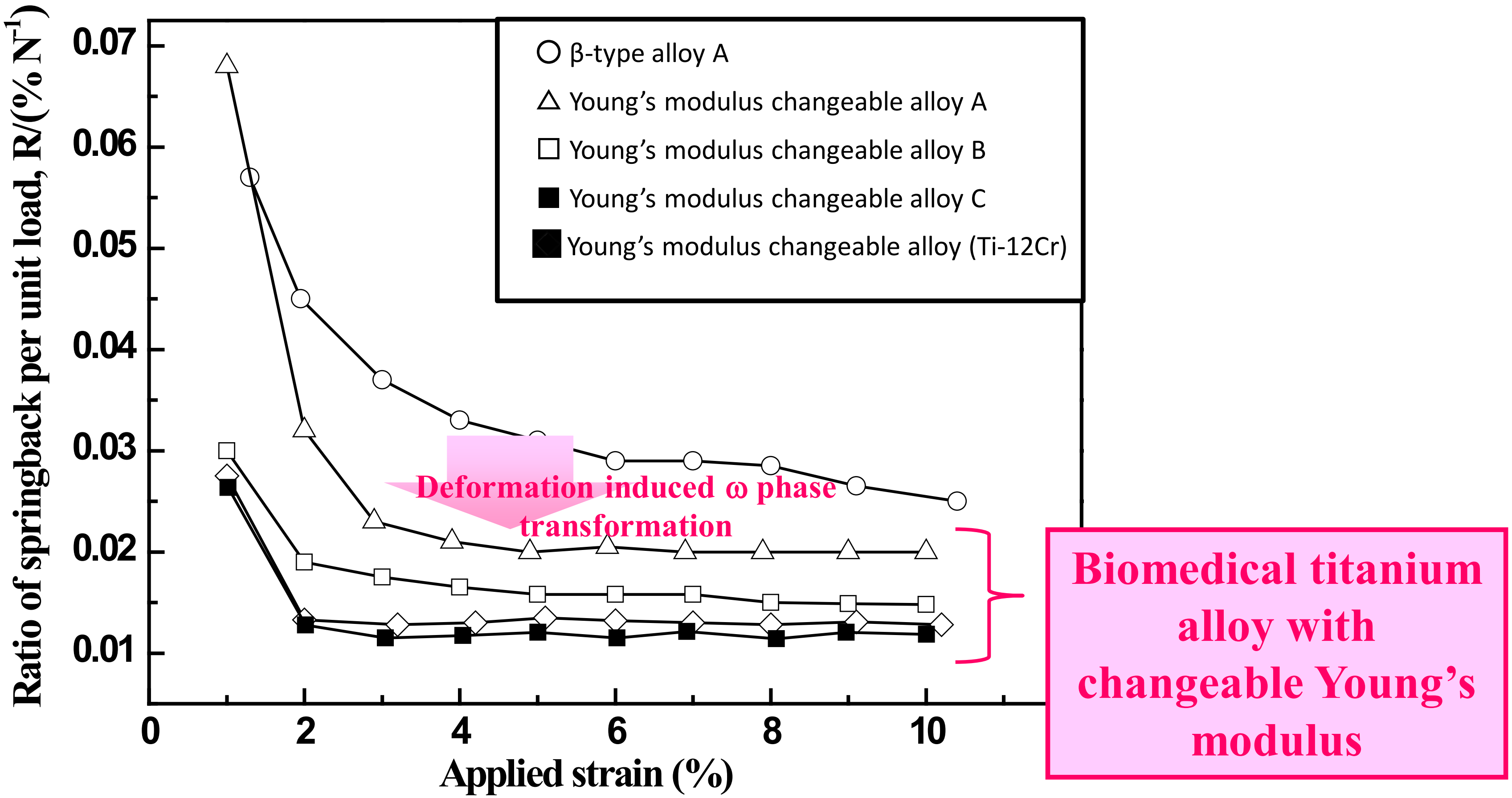
## Change in Young's modulus and microstructure due to deformation




**Young's modulus increases by formation of deformation induced ω phase.**

# Characteristics of Ti-12Cr

## Springback




Springback is supressed by increasing Young's modulus due to deformation induced w phase transformation.

# Future of titanium alloys with changeable Young's modulus for biomedical applications

## New usage of deformation induced ω phase

**Spinal fixation devices**

Utilize deformation
Induced ω phase
transformationto
supress springback

**Self-tunable Young's modulus**

Utilize deformation induced ω phase to controlling shape

**Expanding scope of applications**

**Intramedullary rods**

**Artificial hip joints**

**Cerebral aneurysm**

**Bone fracture fixation devices**

Strengthening of loading portion by deformation induced ω phase

**Stress responding self-strengthening function**

**Metallic medical devices, which exhibit optimized mechanical functionality according to the indivisual usage conditions such as treated area, sex, year, living circumstances like living tissues can be developed.**

**Thank you very much for your kind attention!**