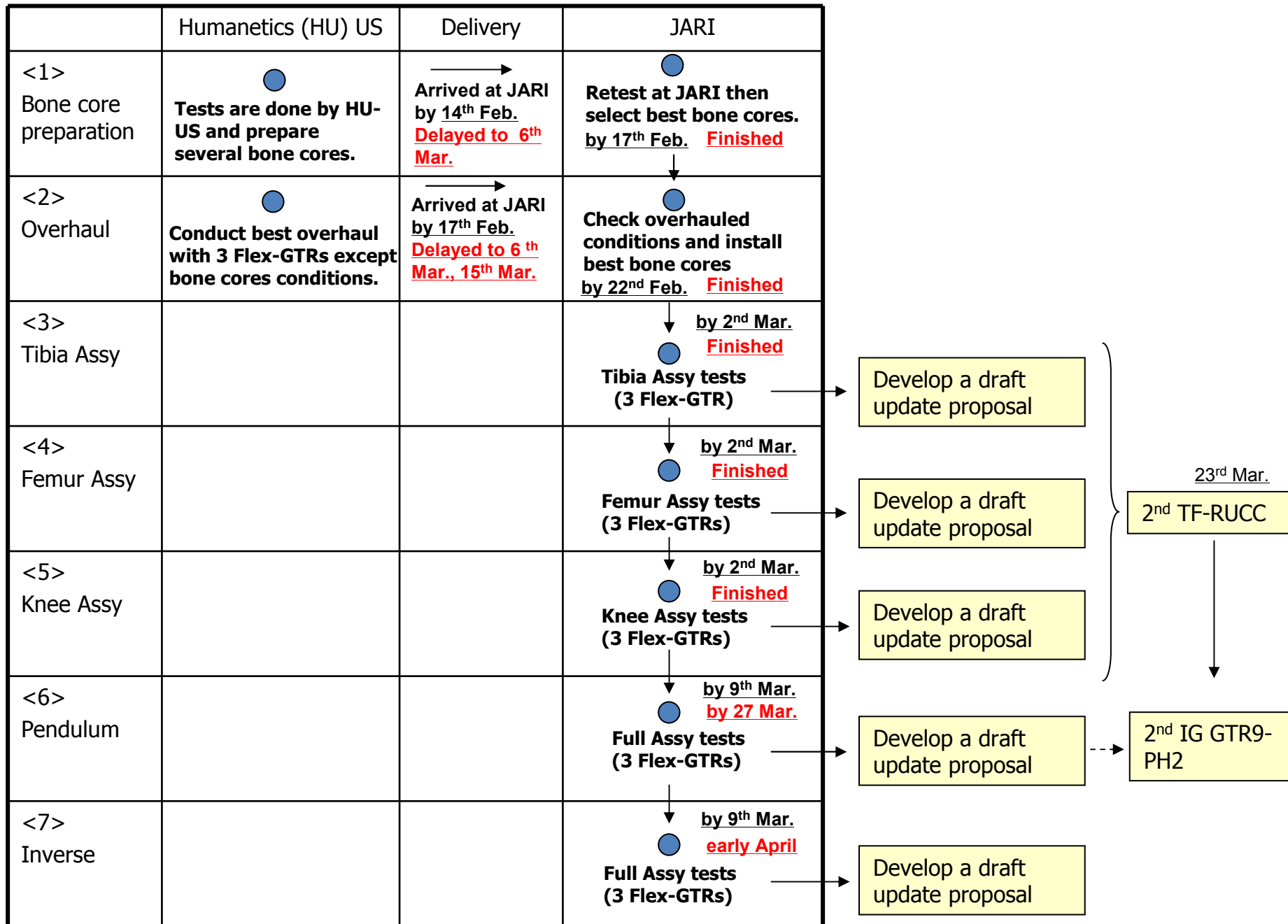


23 March 2012
Japan

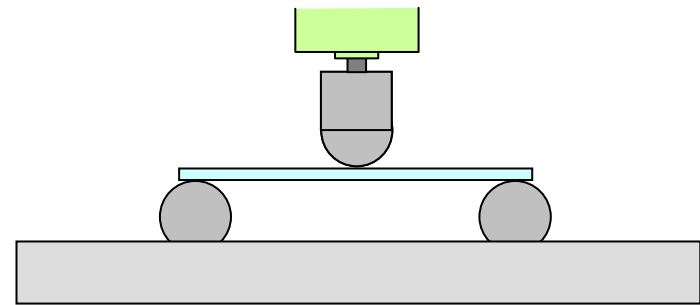
Japan Progress Report
Review and Update Certification
Test Corridors and Test Methods

Working Schedule (current status)

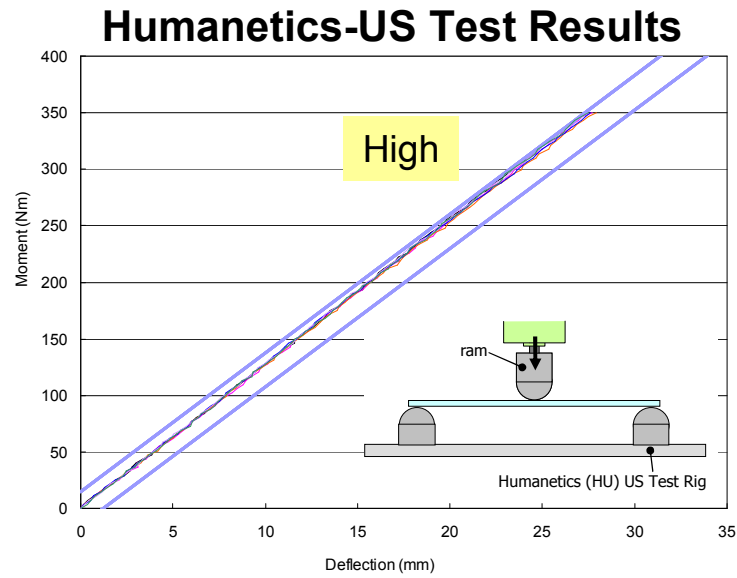


1. Bone core preparations

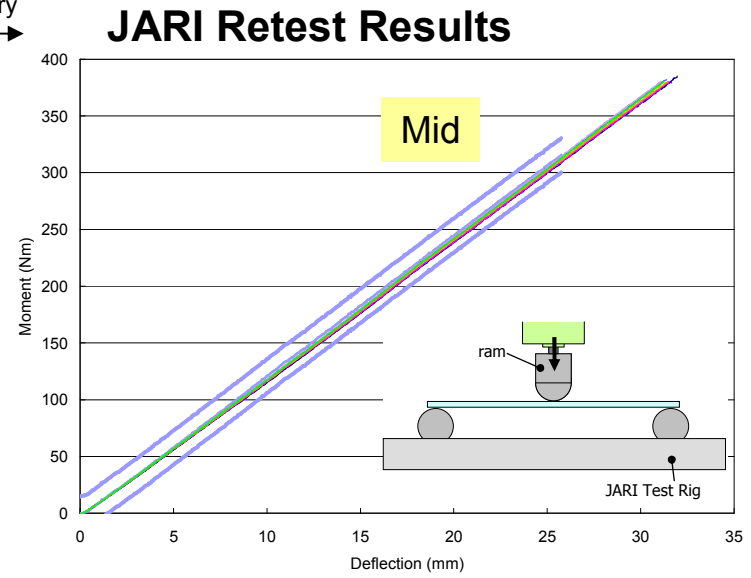
1.1. Retest at JARI for bone cores
Comparison of Test Results between
Humanetics-US and JARI



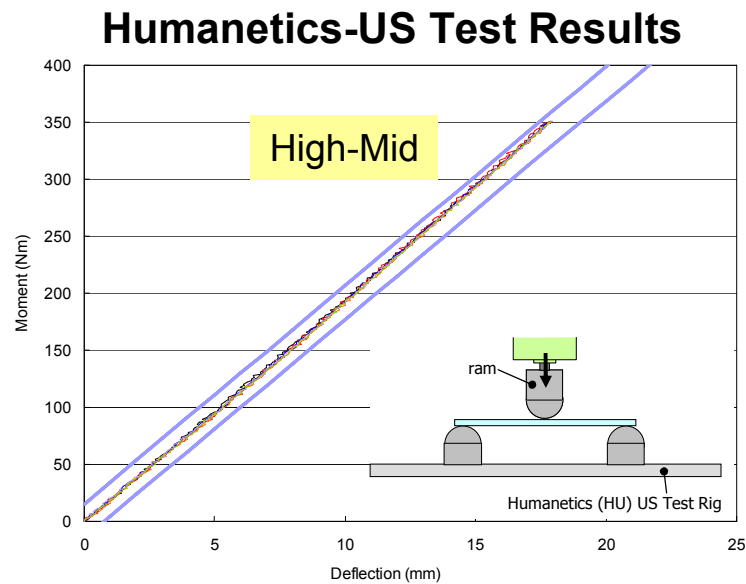
Tibia Bone cores



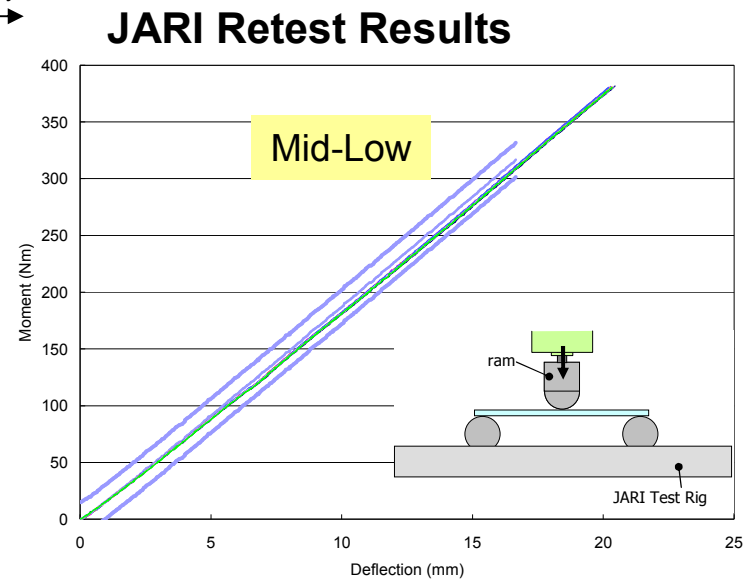
Bone cores
delivery
→



Femur Bone cores



Bone cores
delivery
→

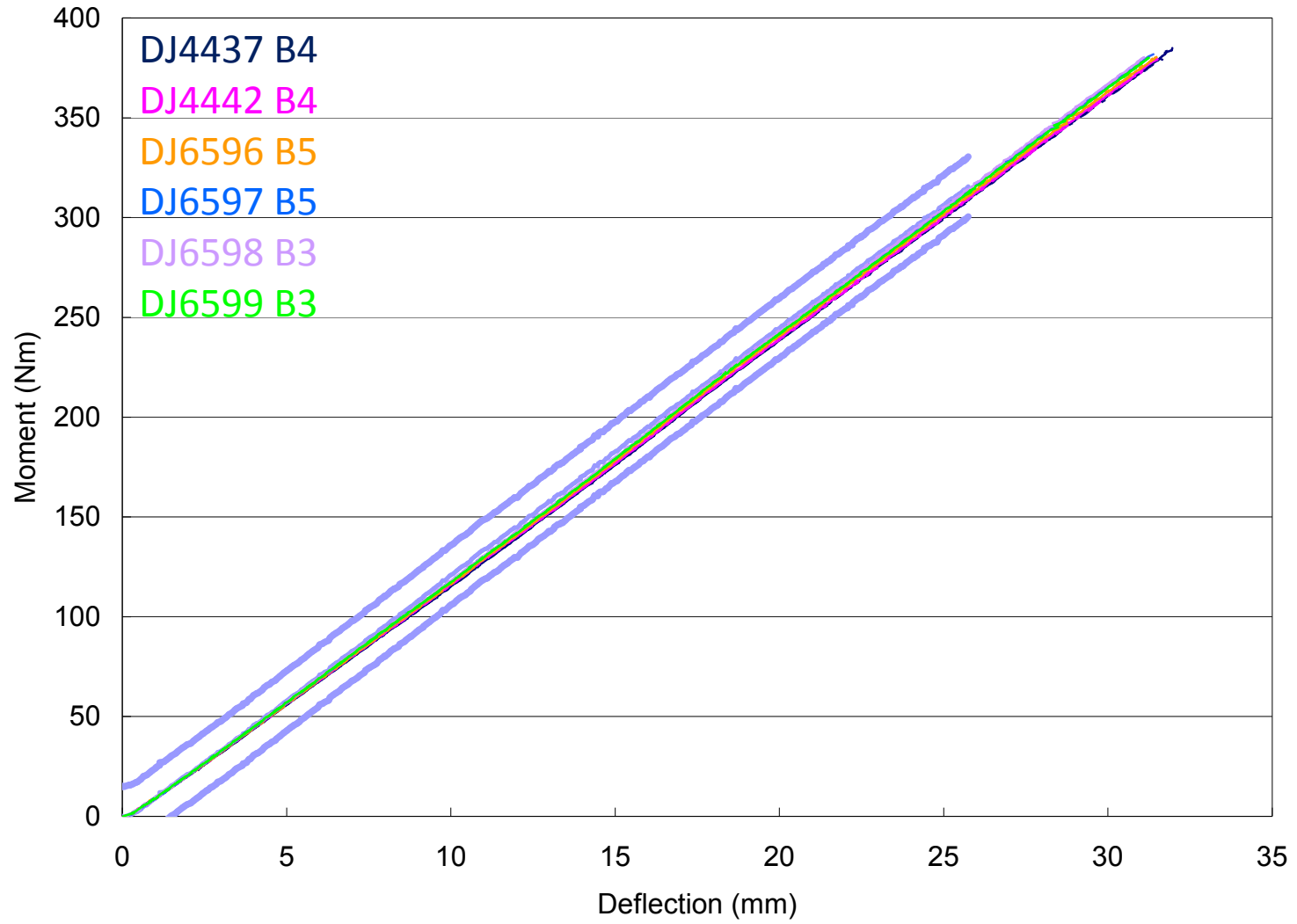


- Humanetics-US and JARI test results show some differences (Same tendency described in the TF-RUCC-1-04)
- JARI is master test lab for bone core testing, so we decide to use JARI test results hereafter.

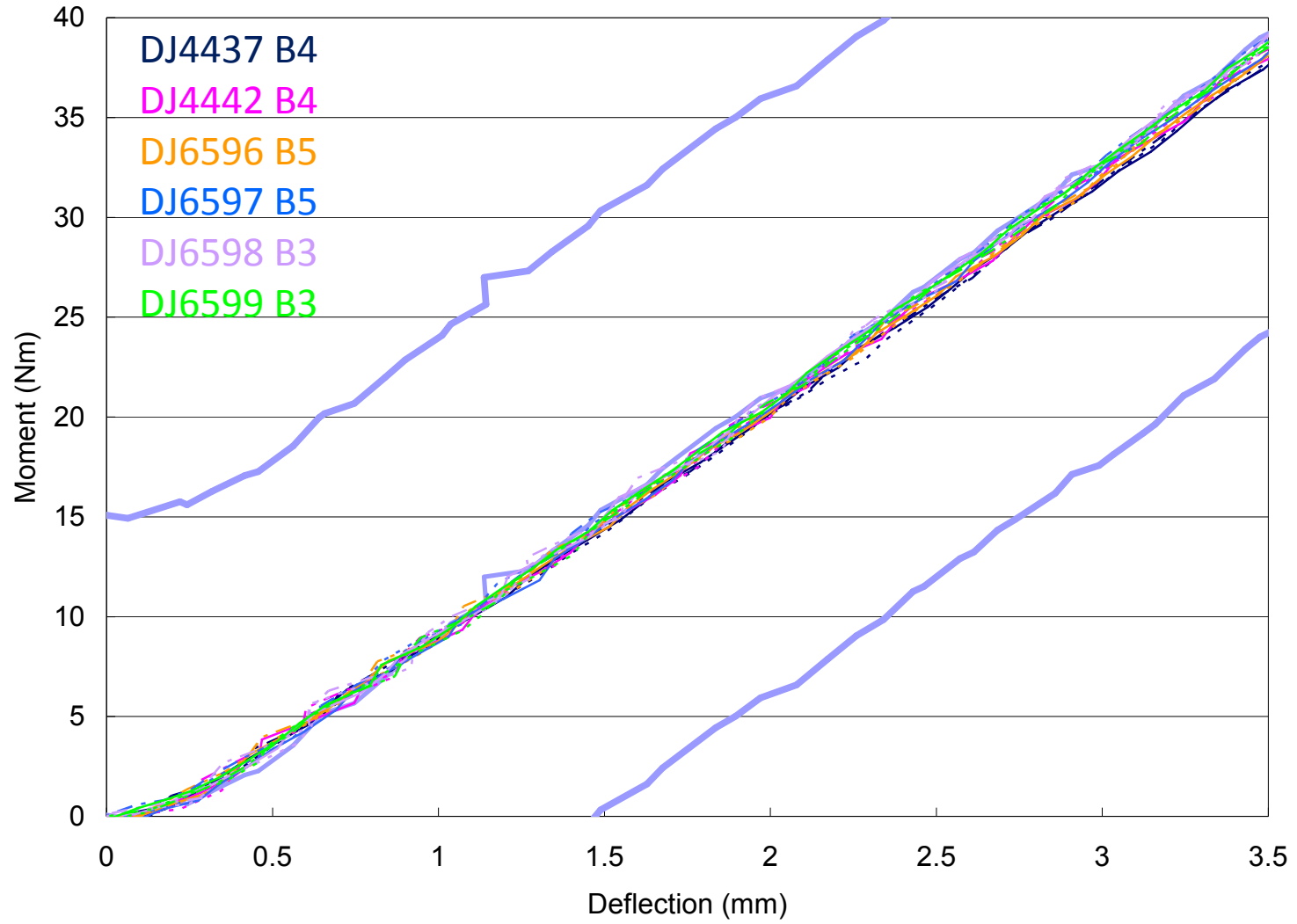
1.2. Tibia bone core selection

Base on JARI test results

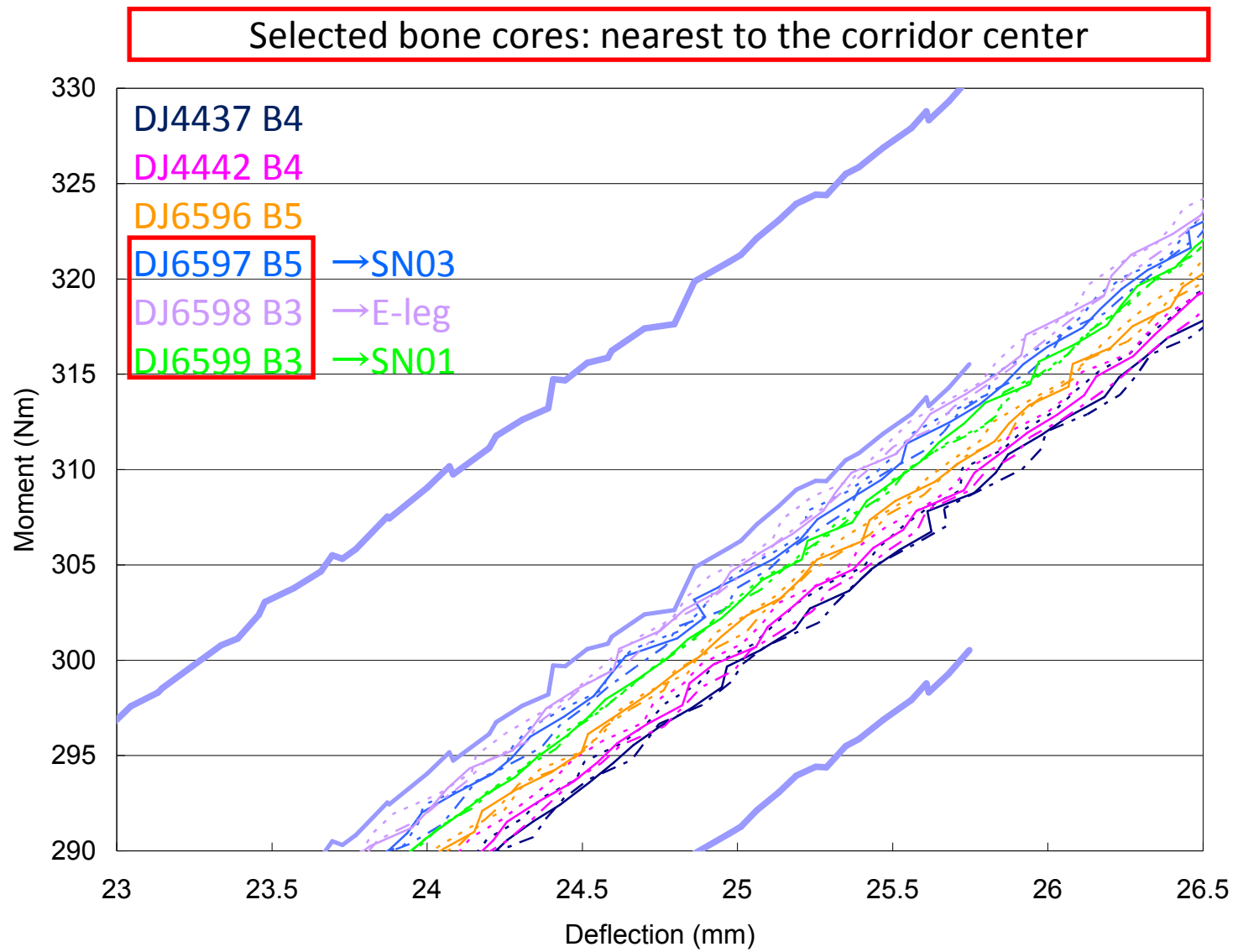
Tibia Bone cores (over view)



Tibia Bone cores (close look at around 0Nm)

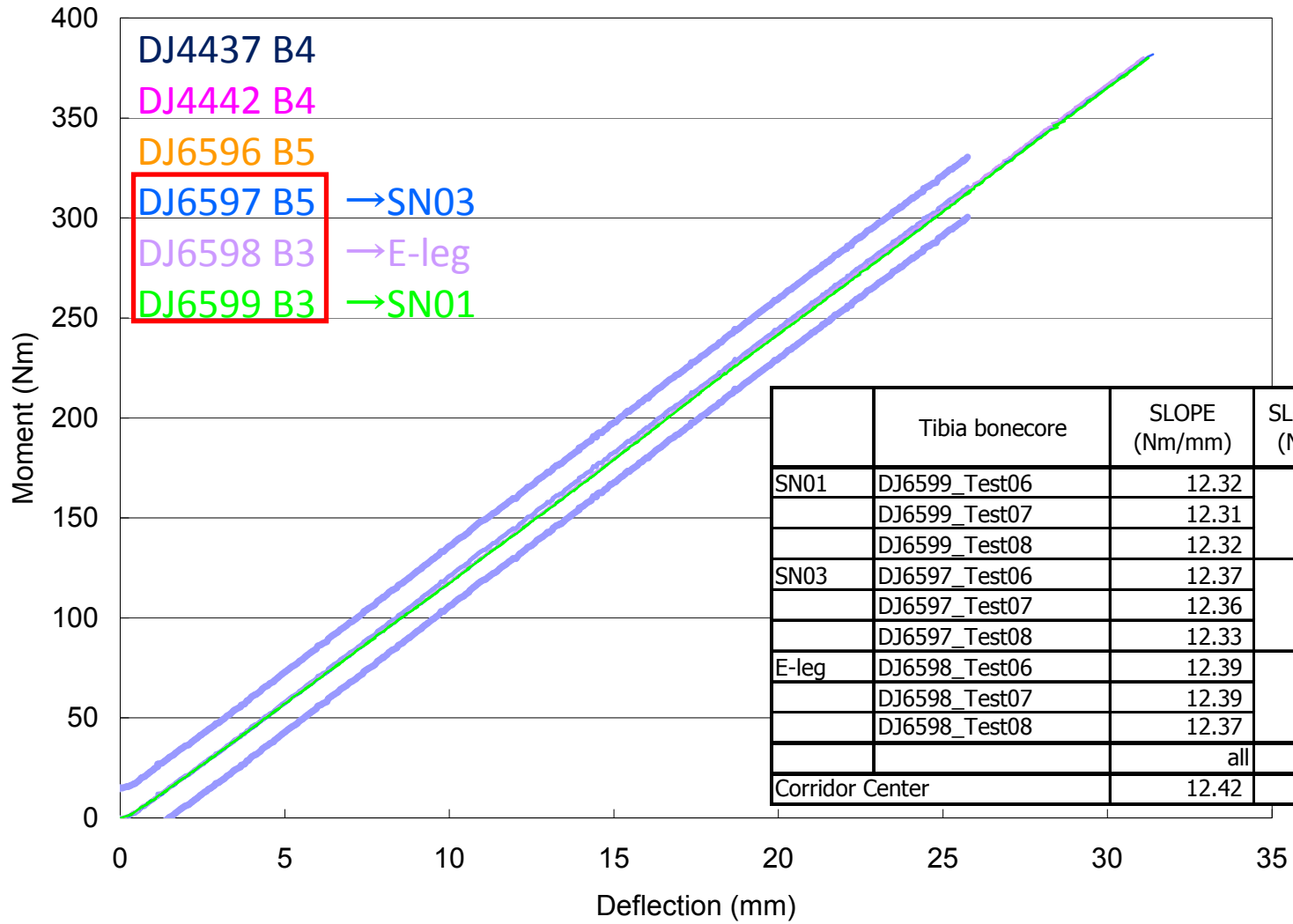


Tibia Bone cores (close look at around 300 Nm)



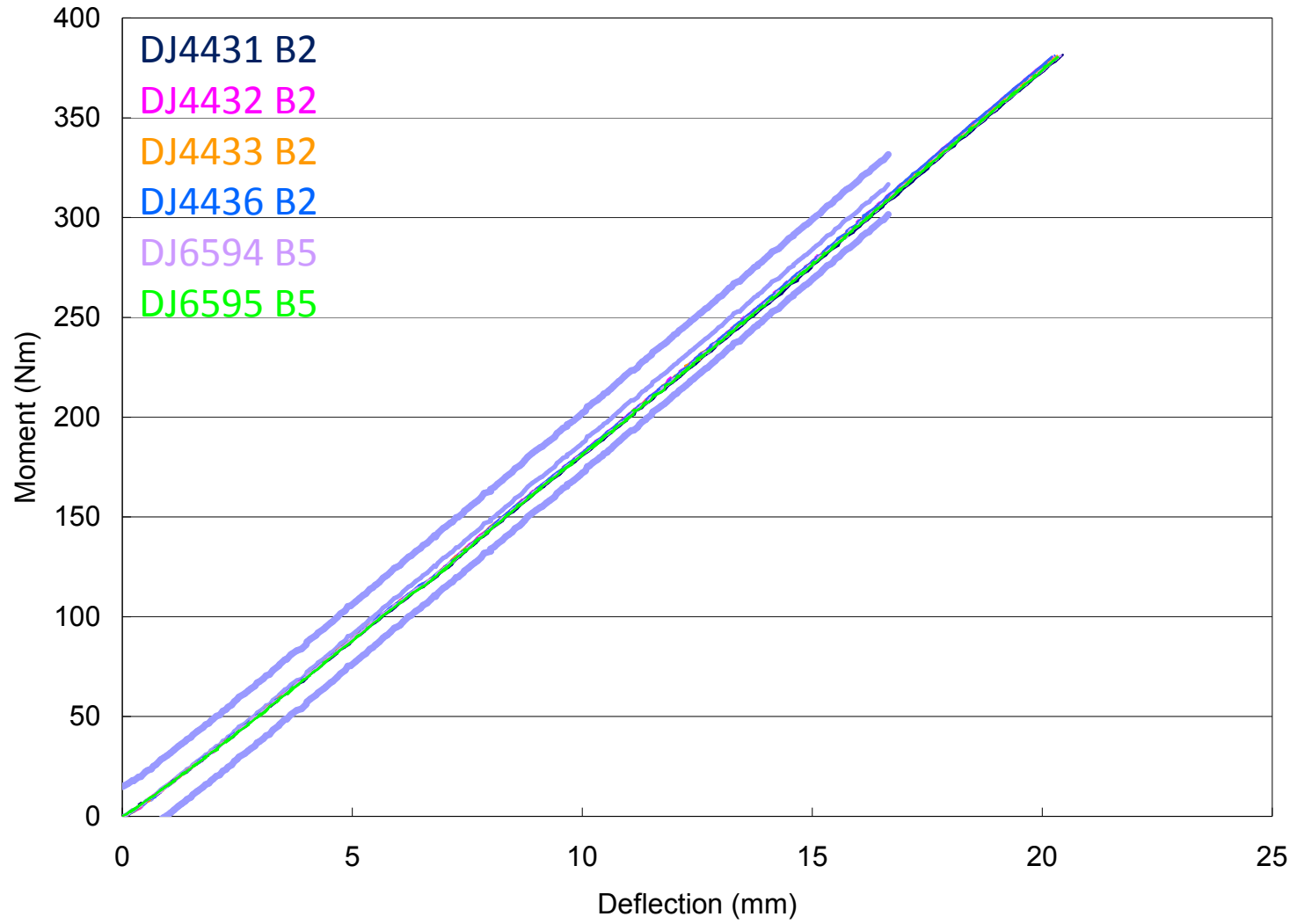
Tibia Bone core (only show selected bone cores)

Selected bone cores: nearest to the corridor center

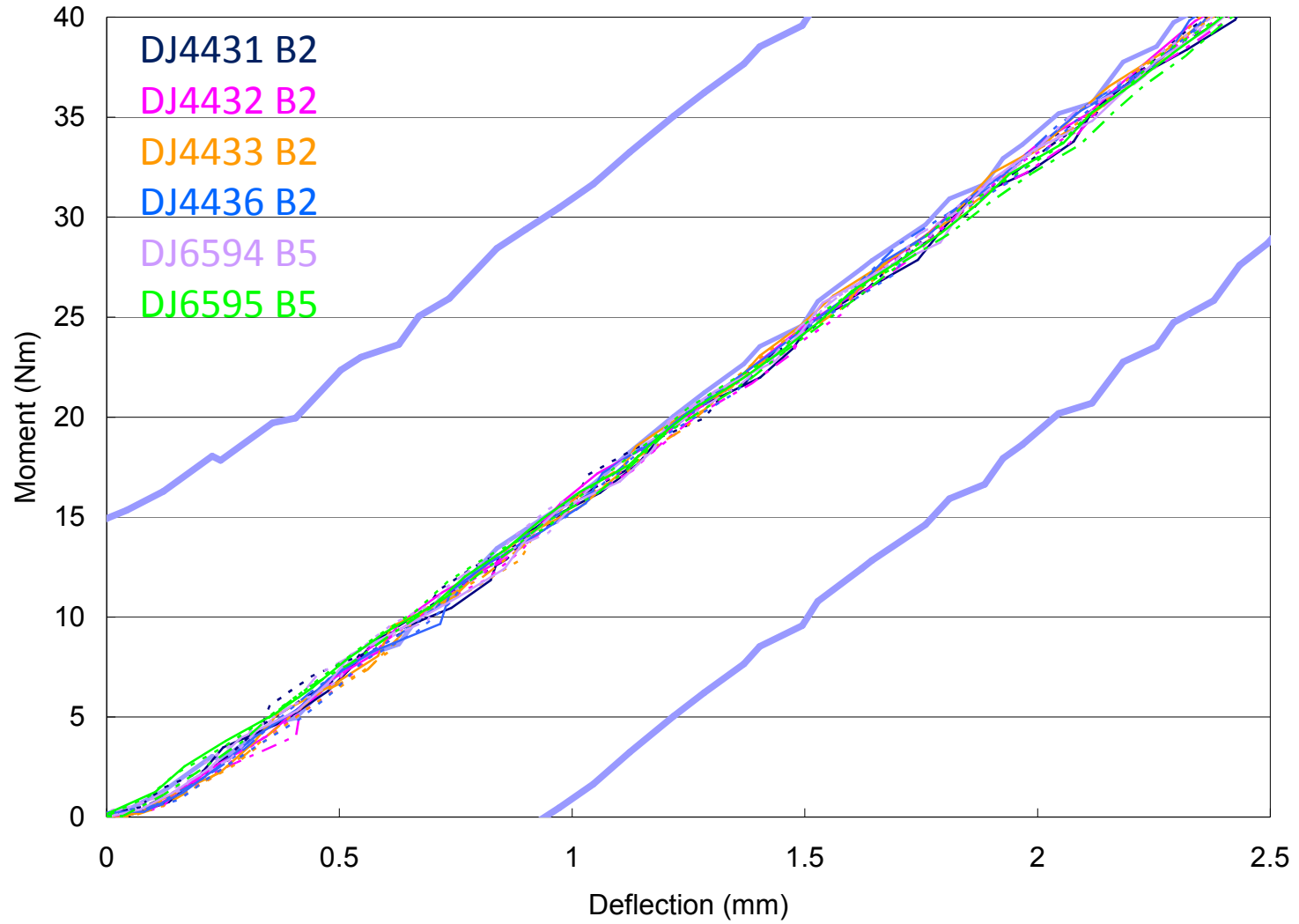


1.3. Femur bone cores selection Based on JARI test results

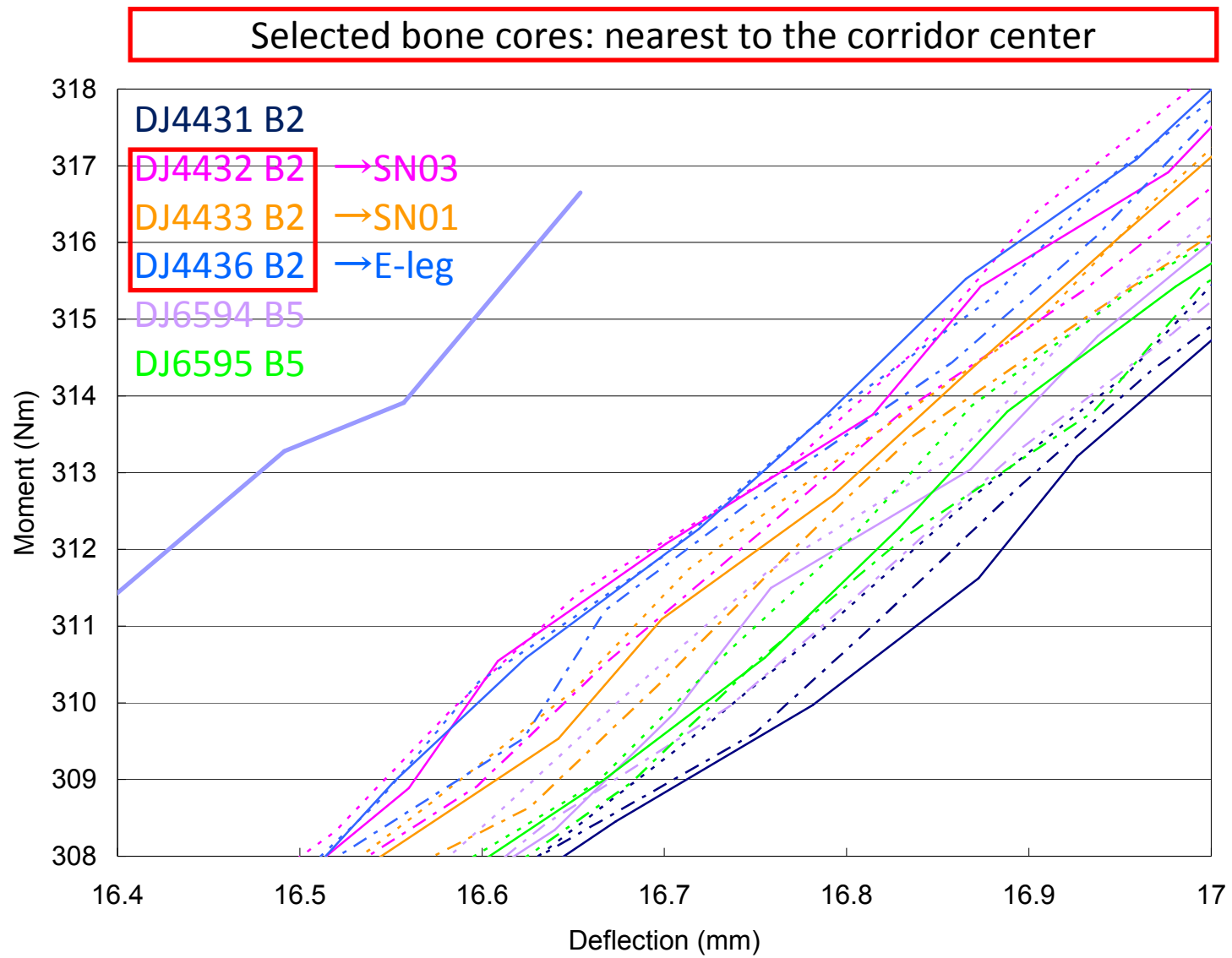
Femur Bone core (over view)



Femur Bone cores (close to 0 Nm)

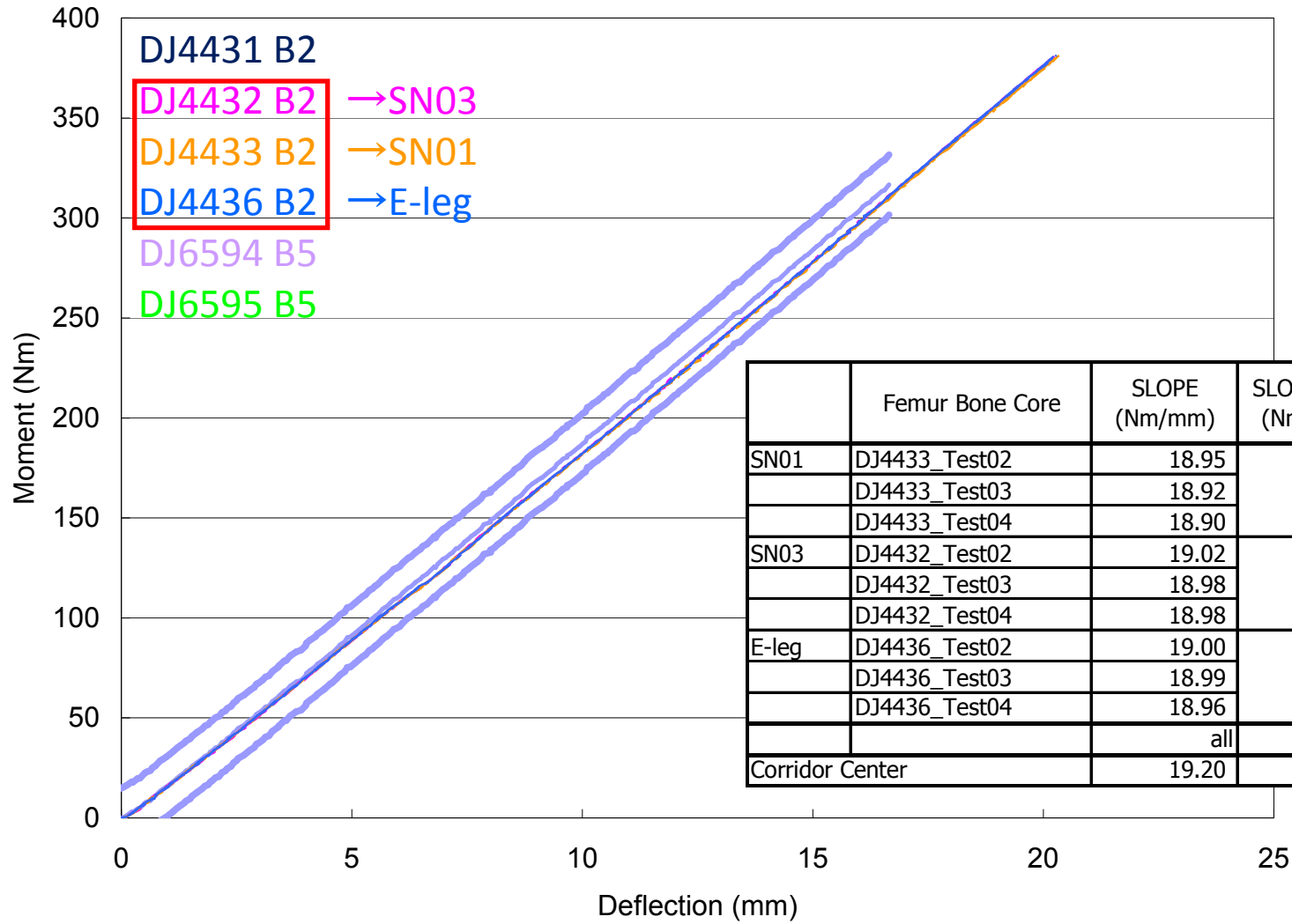


Femur Bone cores (close look at around 300 Nm)



Femur Bone cores (only show selected bone cores)

Selected bone cores: nearest to the corridor center



	Femur Bone Core	SLOPE (Nm/mm)	SLOPE avg. (Nm/mm)	Corridor Center SLOPE /SLOPE avg.
SN01	DJ4433_Test02	18.95	18.92	1.015
	DJ4433_Test03	18.92		
	DJ4433_Test04	18.90		
SN03	DJ4432_Test02	19.02	18.99	1.011
	DJ4432_Test03	18.98		
	DJ4432_Test04	18.98		
E-leg	DJ4436_Test02	19.00	18.98	1.012
	DJ4436_Test03	18.99		
	DJ4436_Test04	18.96		
	all		18.97	1.013
Corridor Center		19.20		

- Tibia and Femur bone cores are selected based on JARI test results.
- Selected tibia bone cores are very close to the center of bone core corridor (Difference: Corridor center/SLOPE avg. all = 1.006).
- Selected femur bone cores are close to the center of bone core corridor (Difference: Corridor center/SLOPE avg. all = 1.013).

2. Overhaul

- SN01, SN02 and Engineering leg were overhauled at Humanetics-US.
- JARI installed selected tibia and femur bone cores into Tibia Assy and Femur Assy of SN01, SN02 and Engineering leg.
- JARI checked Knee condition by conducting 3 point bending tests.

2.1. Retest at JARI for Knee
Comparison of Test Results
between Humanetics-US and JARI

Humanetics Test Data

SN01

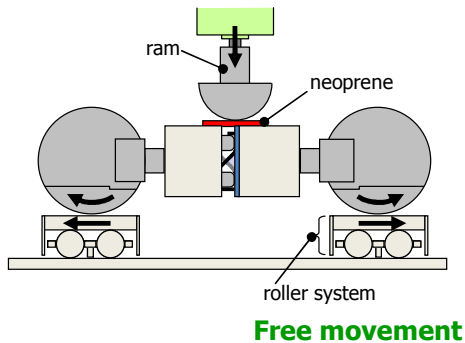
<Slightly Knee twisted condition>

SN03

<Slightly Knee twisted condition>

Engineering leg (E-leg)

<Slightly Knee twisted condition>



JARI Test Data

SN01

<Slightly Knee twisted condition>

•120314_SN01_Test03

•120314_SN01_Test04

<Removed Knee twisted condition>

•120314_SN01_Test01

•120314_SN01_Test02

SN03

<Slightly Knee twisted condition>

120313_SN03_Test01

120313_SN03_Test02

<Removed Knee twisted condition>

120314_SN03_Test01

120314_SN03_Test02

Engineering leg (E-leg)

<Slightly Knee twisted condition>

•120313_E-leg_Test01

•120313_E-leg_Test02

<Removed Knee twisted condition>

•120313_E-leg_Test03

•120313_E-leg_Test04

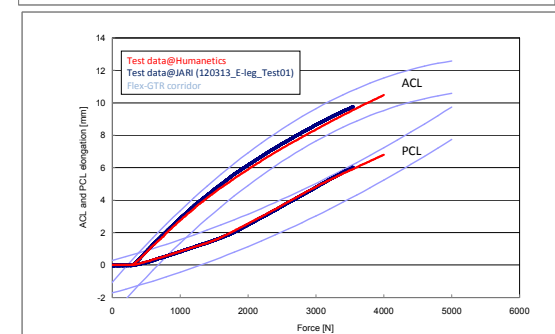
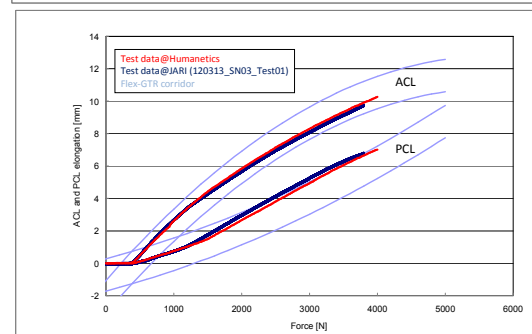
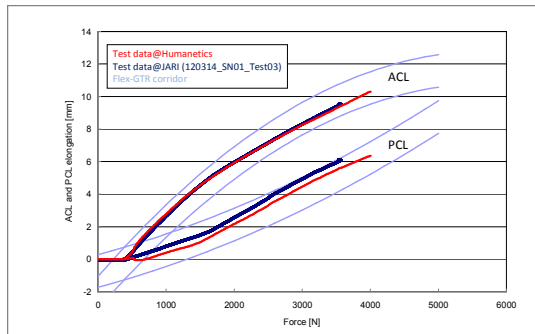
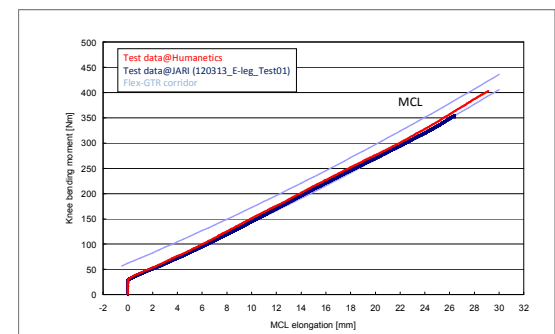
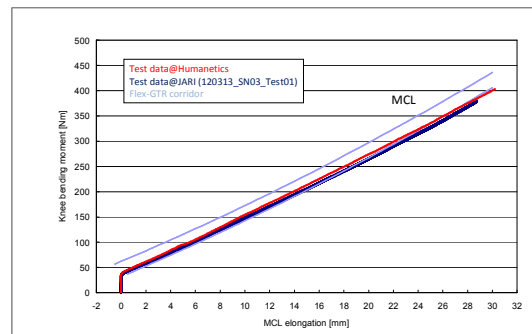
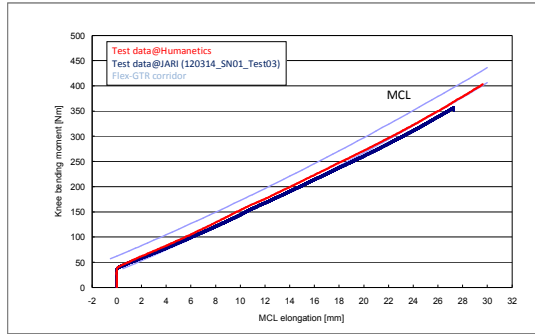
<Slightly Knee twisted condition>
were compared

SN01

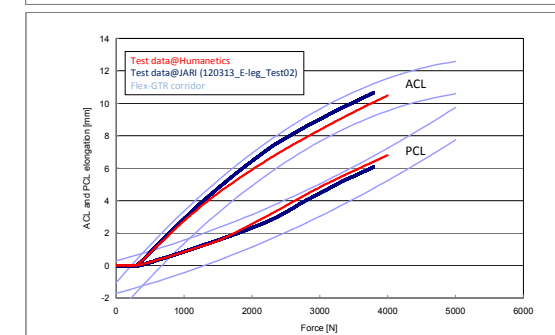
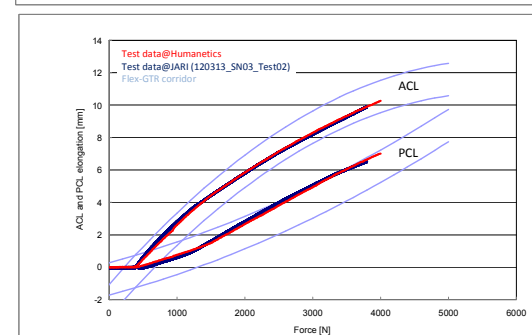
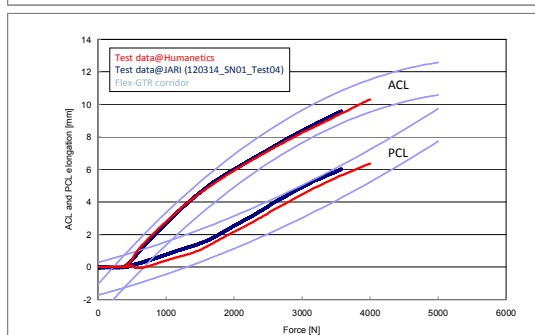
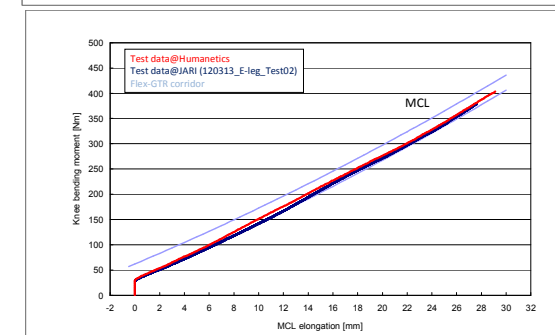
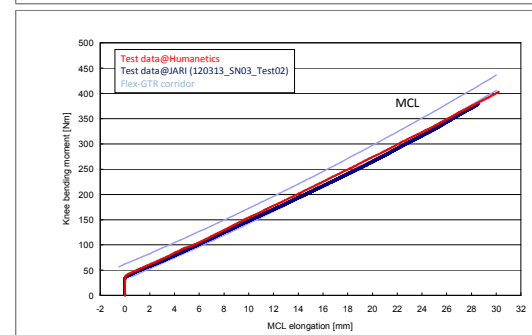
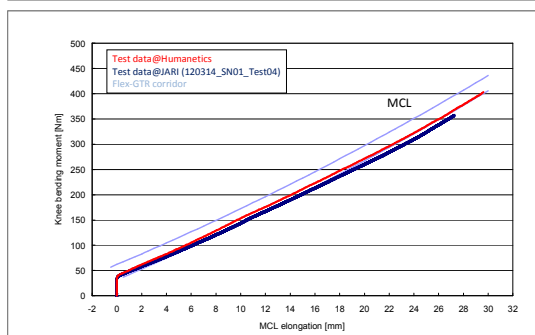
SN03

E-leg

1st test
at JARI

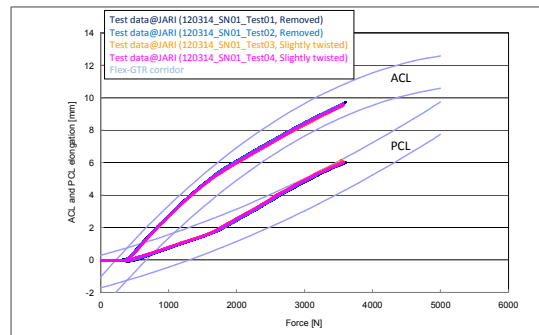
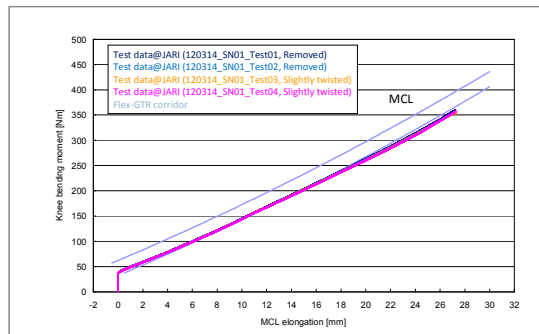


2nd test
at JARI

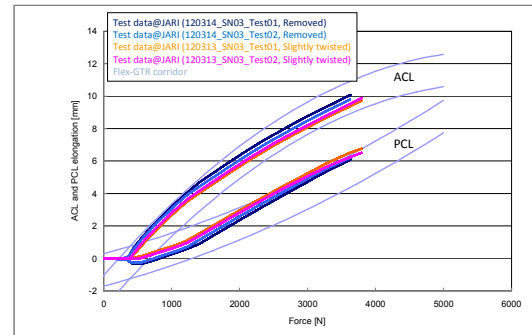
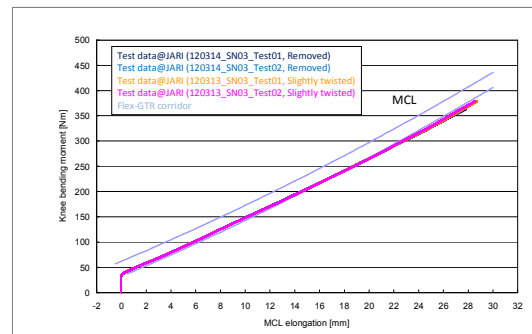


- Humanetics-US and JARI test results are comparable.
- However, 'Slightly twisted' knee conditions are not adequate to make update corridor.
- Difference of 'Slightly twisted' and 'Removed twisted' conditions are shown in bellows.
- Slight difference exists especially for ACL and PCL elongation output.
- We decided to use 'Removed twisted' knee conditions hereafter.

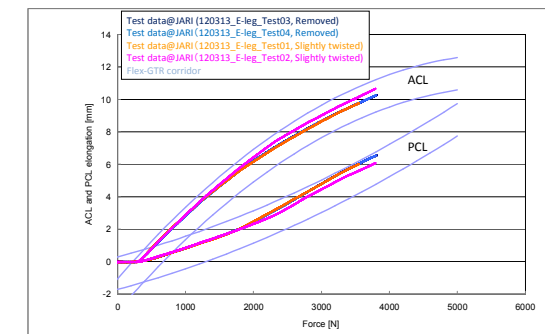
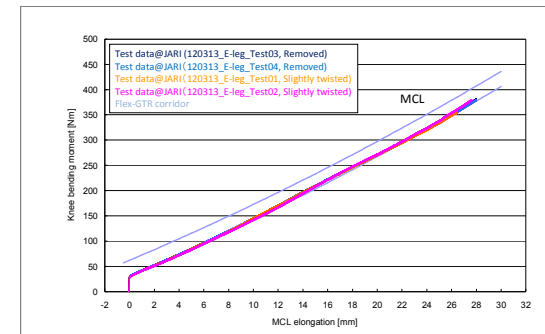
SN01



SN03



E-leg

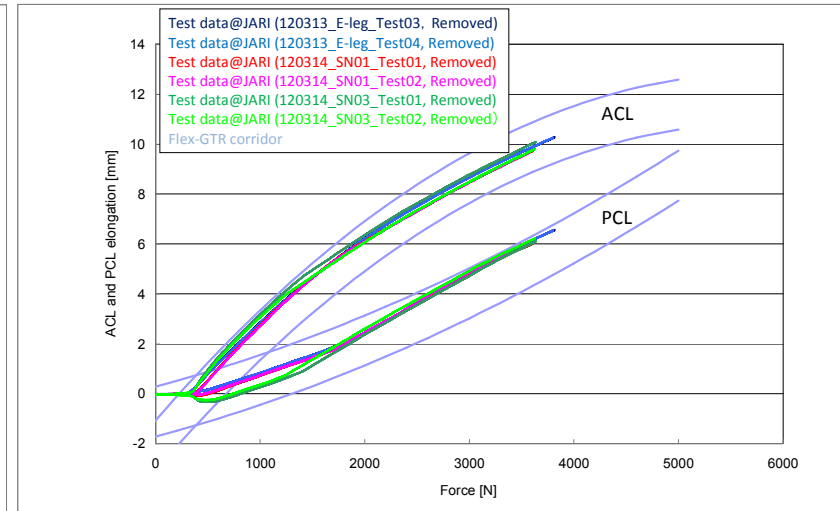
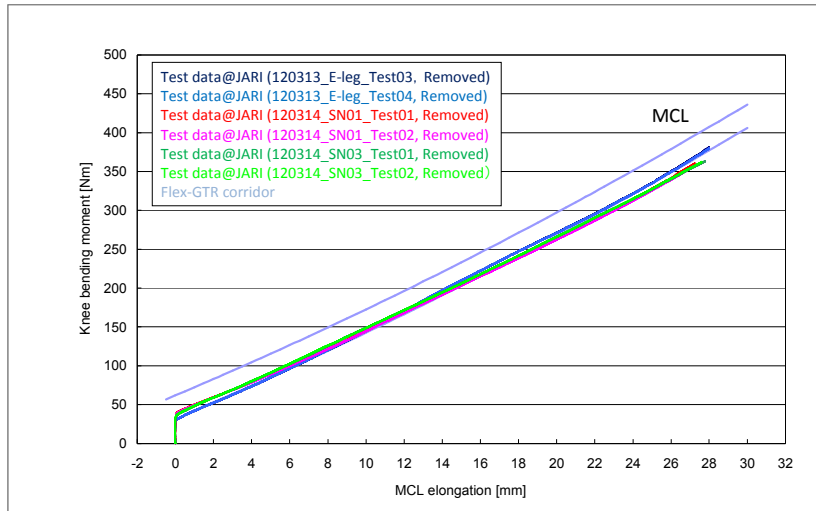


——— 'Removed twisted' knee conditions
——— 'Slightly twisted' knee conditions

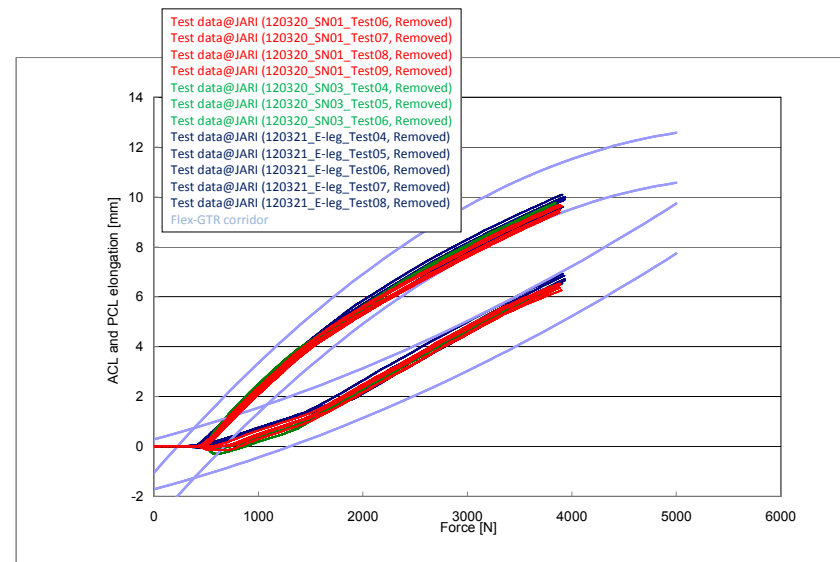
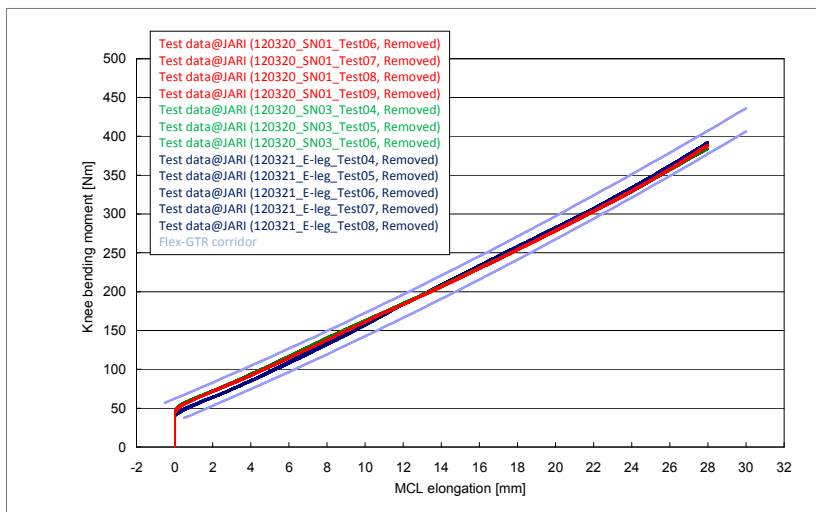
2.2. Knee Adjustment

- When we check the delivered knees condition by using 'Removed twisted' test data, it was found that the delivered knees have slightly soft stiffness based on current MCL corridor.
- We therefore adjusted initial tension of knee springs to obtain better matching with current MCL corridor.

Delivered



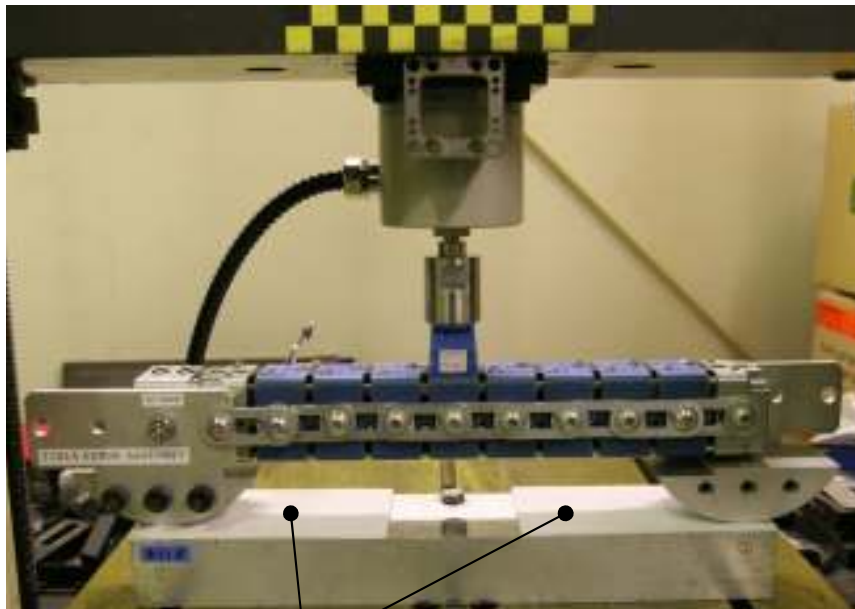
Adjusted



3. Tibia Assy

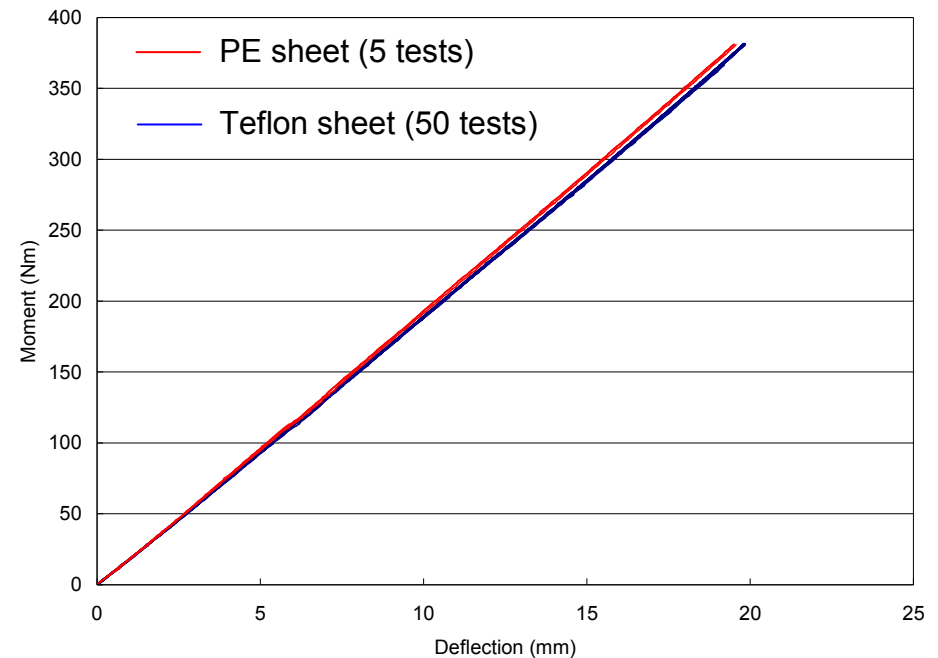
- We conducted Tibia Assy 3 point bending test with Teflon sheet.
- We did not use PE sheet because it is not available now (can not buy).
- On the other hand, Teflon sheet is available now from Humanetics, so we decided to use Teflon sheet instead of PE sheet.
- Before to use Teflon sheet, we conducted Teflon sheet evaluation tests.
- As a result, Teflon sheet shows good repeatability and durability.

Tibia Assy 3 point bending test



Teflon sheet

Teflon sheet evaluation tests



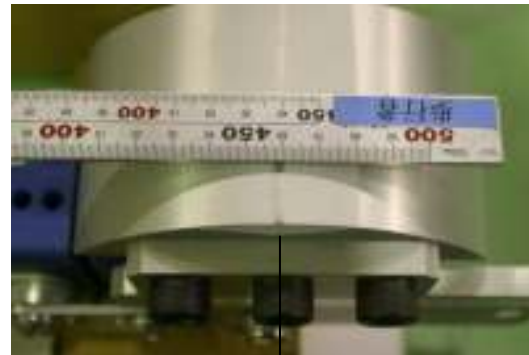
Measurement of Support Length



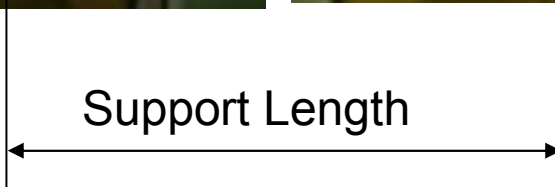
Support Length		Ideal (mm)	Measured (mm)	Difference (mm)
Tibia Assy (SN01)	DJ6599	410	408.50	-1.50
Tibia Assy (SN03)	DJ6597	410	408.00	-2.00
Tibia Assy (E-leg)	DJ6598	410	409.00	-1.00

Impactor Length		Ideal (mm)	Measured (mm)	Difference (mm)
Tibia Assy (SN01)	DJ6599	360	360.50	0.50
Tibia Assy (SN03)	DJ6597	360	360.50	0.50
Tibia Assy (E-leg)	DJ6598	360	361.00	1.00

* 10 connection bolts distance.

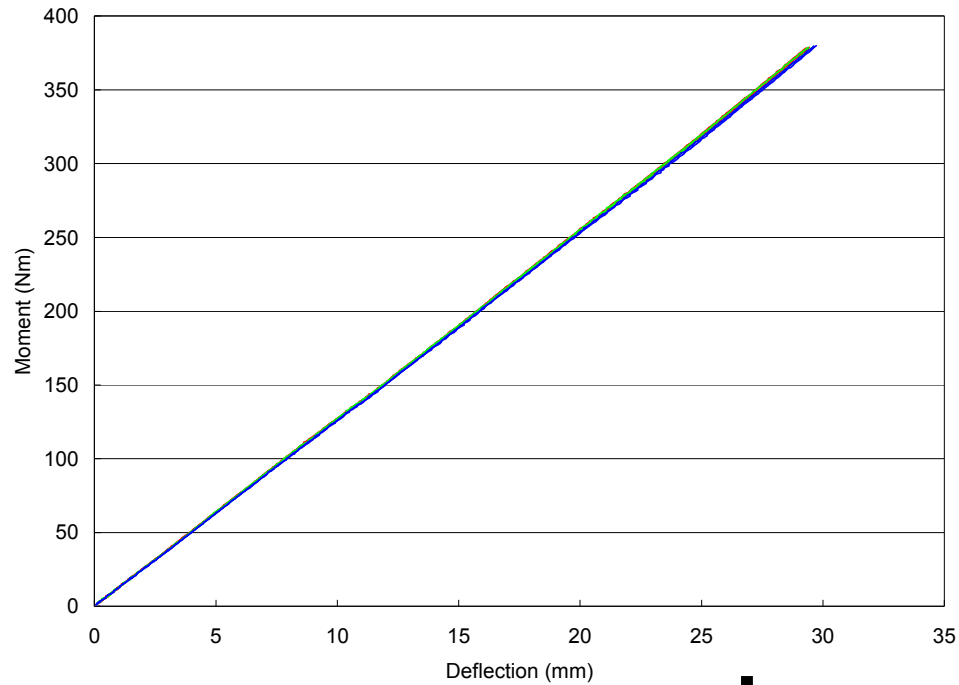


Support Length



- We used ideal support length to calculate bending moment at center of tibia/femur/knee so far.
- To consider the difference between ideal support length and actual support length, we measured actual support length at this time.
- It shows some differences, so we decided to use measured actual support length hereafter.

Tibia Assy 3 point bending test results



— SN01
— SN03
— E-leg

• After we obtained test data for SN01, SN03 and E-leg, we adjusted those SLOPE values by using following procedures



	Tibia Assy	SLOPE (Nm/mm)	SLOPE avg. (Nm/mm)	Adjustment Factors		Adjusted
				by Bone core stiffness	by Support Length	SLOPE avg. (Nm/mm)
SN01	DJ6599_Test02	12.84	12.81	1.008	0.993	12.83
	DJ6599_Test07	12.79				
SN03	DJ6597_Test02	12.83	12.80	1.005	0.990	12.74
	DJ6597_Test12	12.76				
E-leg	DJ6598_Test02	12.76	12.74	1.003	0.995	12.72
	DJ6598_Test10	12.72				
		all	12.78			12.76

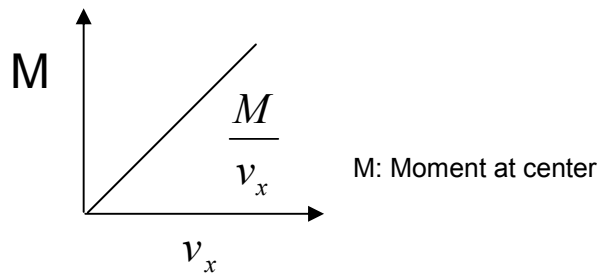
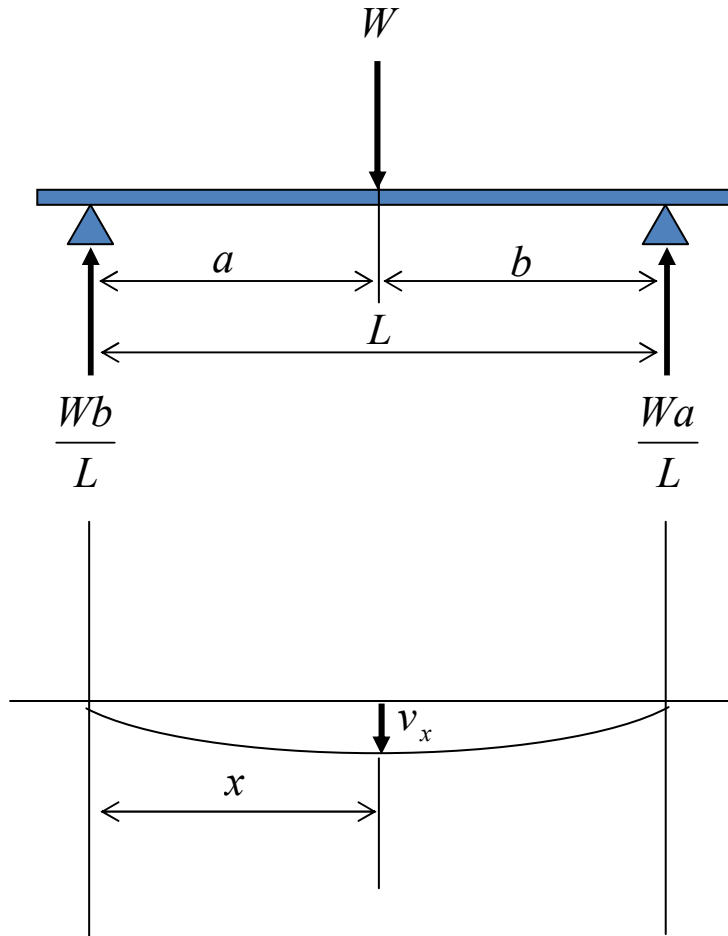
* Corridor Center SLOPE/SLOPE avg.

** $(\text{Measured Support Length})^2 / (\text{Ideal Support Length})^2$

if impactor has bone core which can meet exact corridor center

if impactor is tested by ideal support length

Influence of Support Length (L)



$$v_x = \frac{Wa}{6EI} (L-x) \left\{ -(L-x)^2 + b(2a+b) \right\}$$

$$\frac{W}{v_x} = \frac{6EI}{a(L-x) \left\{ -(L-x)^2 + b(2a+b) \right\}}$$

, where $x = a, b = a, L = 2a$

$$\frac{W}{v_x} = \frac{6EI \times 2a}{a(2a-a) \left\{ -(2a-a)^2 + a(2a+a) \right\}}$$

$$\frac{W}{v_x} = \frac{6EI}{a^3} \quad , \text{ where } C = 6EI$$

$$\frac{W}{v_x} = \frac{C}{a^3} \quad , \text{ where } M = W \times \frac{a}{2}$$

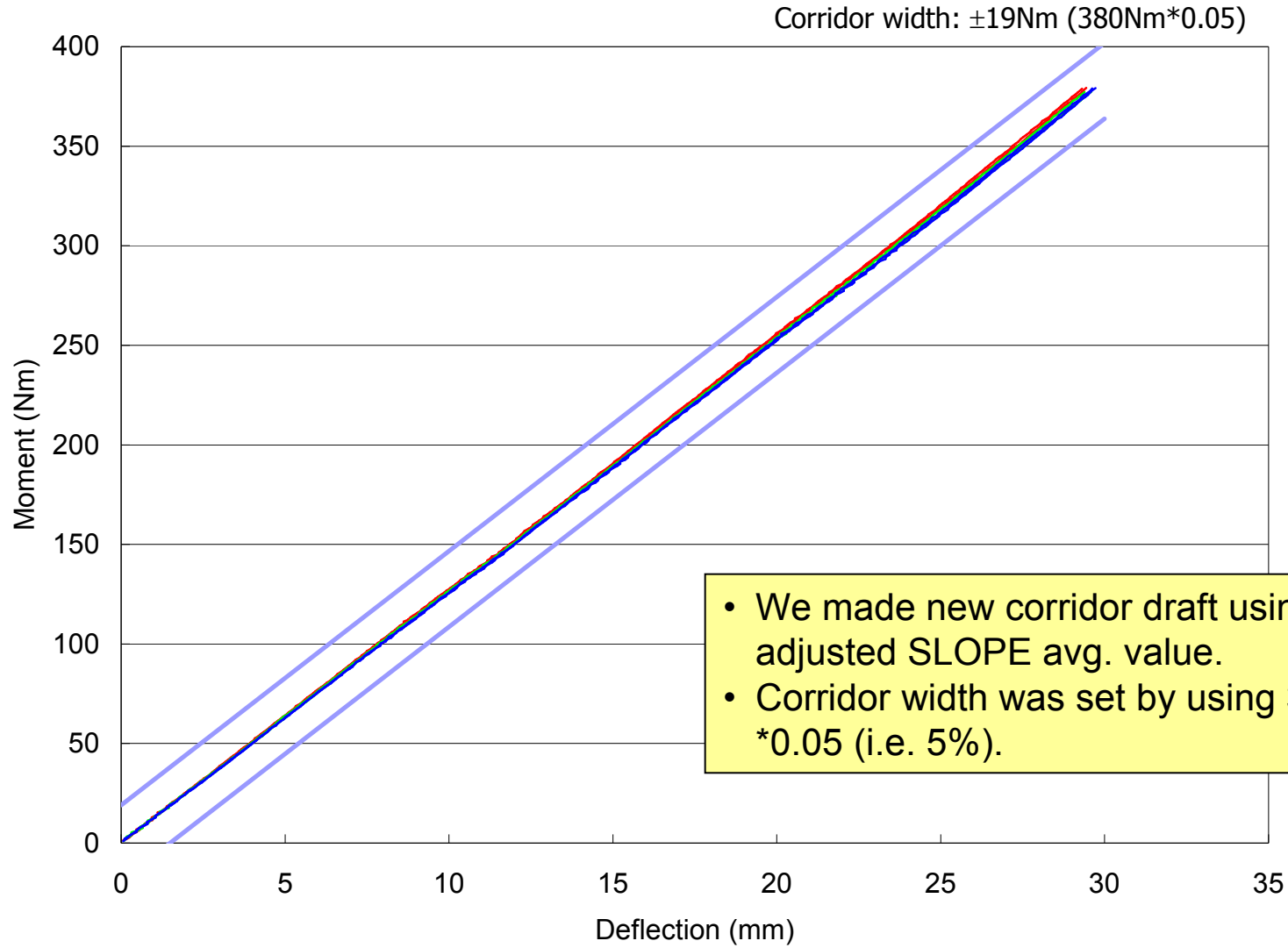
M: Moment at center

$$\frac{M}{v_x} = \frac{W}{v_x} \times \frac{a}{2} = \frac{C}{a^3} \times \frac{a}{2}$$

$$\frac{M}{v_x} = \frac{C}{2a^2} \quad , \text{ where } a = \frac{L}{2} \quad \frac{M}{v_x} = \frac{2C}{L^2}$$

New GTR Corridor: Tibia Assy (DRAFT)

— New GTR Corridor
— : Tibia Assy
— SN01 (Adjusted)
— SN03 (Adjusted)
— E-leg (Adjusted)

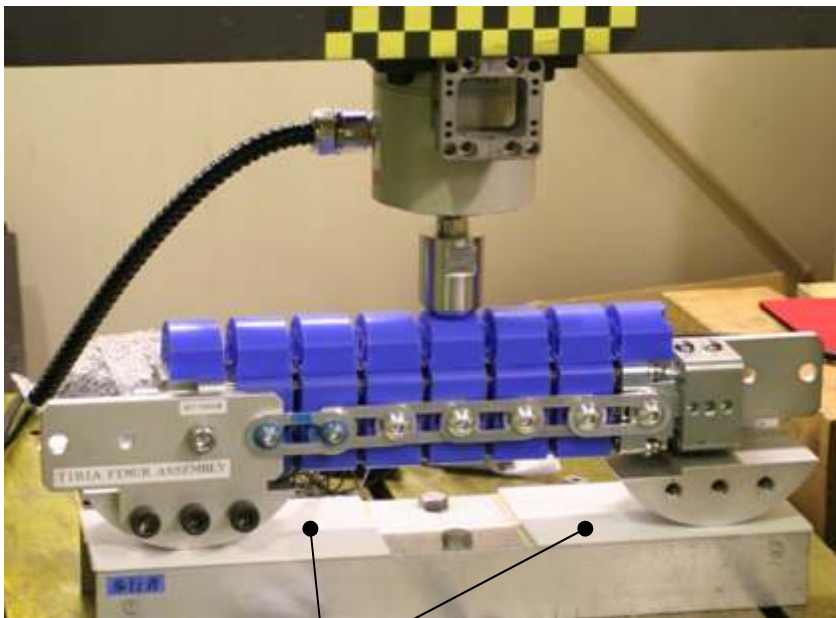


- We made new corridor draft using adjusted SLOPE avg. value.
- Corridor width was set by using $380\text{Nm} \cdot 0.05$ (i.e. 5%).

4. Femur Assy

- We conducted Femur Assy 3 point bending test with Teflon sheet.
- Besides, we measured actual support length to use for the bending moment calculation at center.

Femur Assy 3 point bending test



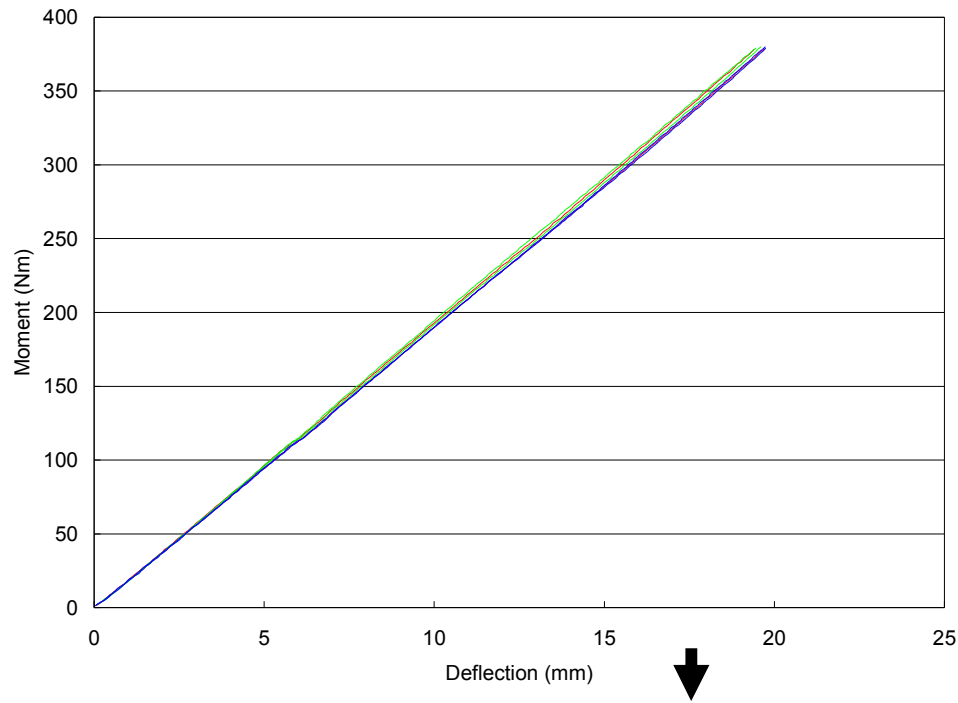
Teflon sheet

Support Length		Ideal (mm)	Measured (mm)	Difference (mm)
Femur Assy (SN01)	DJ4433	330	328.00	-2.00
Femur Assy (SN03)	DJ4432	330	328.50	-1.50
Femur Assy (E-leg)	DJ4436	330	328.50	-1.50

Impactor Length		Ideal (mm)	Measured (mm)	Difference (mm)
Femur Assy (SN01)	DJ4433	280	280.50	0.50
Femur Assy (SN03)	DJ4432	280	280.00	0.00
Femur Assy (E-leg)	DJ4436	280	281.00	1.00

* 8 connetction bolts distance.

Femur Assy 3 point bending test results



— SN01
— SN03
— E-leg

• After we obtained test data for SN01, SN03 and E-leg, we adjusted those SLOPE values by using following procedures

	Femur Assy	SLOPE (Nm/mm)	SLOPE avg. (Nm/mm)	Adjustment Factors		Adjusted
				by Bone core stiffness*	by Support Length**	SLOPE avg. (Nm/mm)
SN01	DJ4433_Test02	19.45	19.32	1.015	0.988	19.37
	DJ4433_Test05	19.19				
SN03	DJ4432_Test01	19.56	19.45	1.011	0.991	19.49
	DJ4432_Test09	19.35				
E-leg	DJ4436_Test02	19.27	19.19	1.012	0.991	19.24
	DJ4436_Test03	19.11				
		all	19.32			19.37

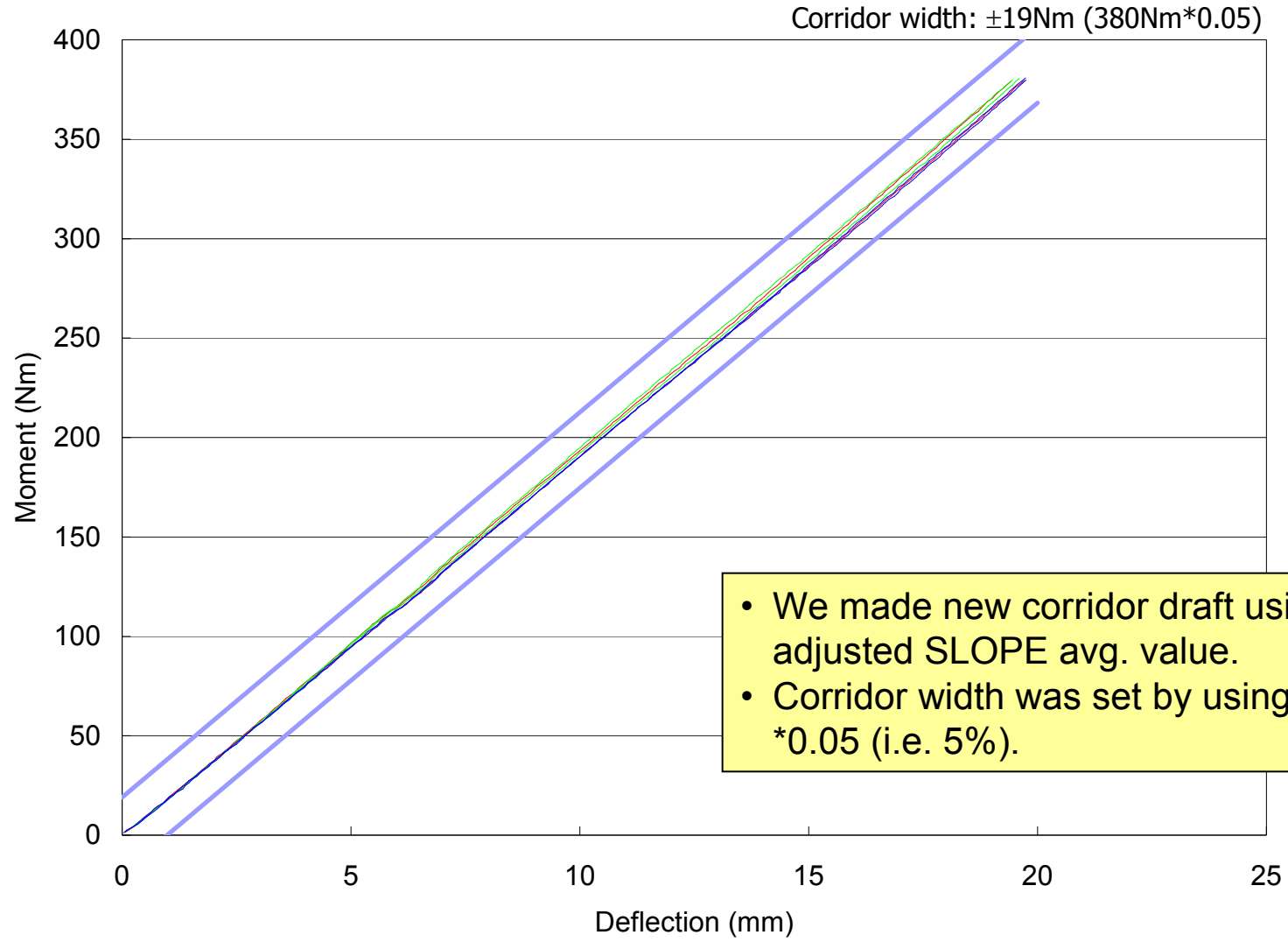
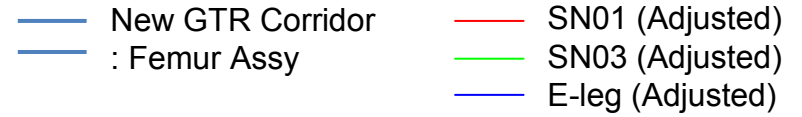
* Corridor Center SLOPE/SLOPE avg.

** $(\text{Measured Support Length})^2 / (\text{Ideal Support Length})^2$

if impactor has bone core which can meet exact corridor center

if impactor is tested by ideal support length

New GTR Corridor: Femur Assy (DRAFT)

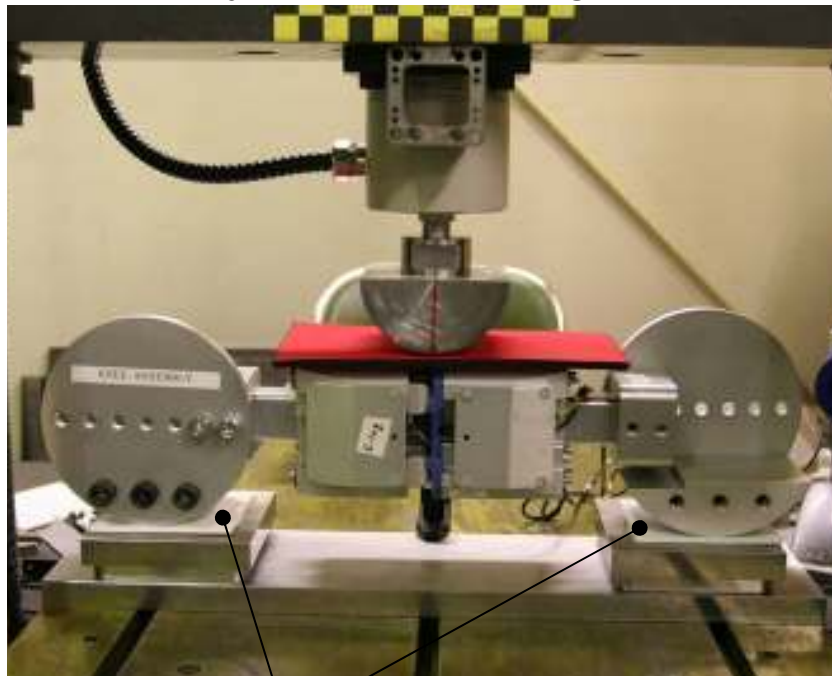


- We made new corridor draft using adjusted SLOPE avg. value.
- Corridor width was set by using $380\text{Nm} \times 0.05$ (i.e. 5%).

5. Knee Assy

- We conducted Knee Assy 3 point bending test with Teflon sheet.
- Besides, we measured actual support length to use for the bending moment calculation at center.

Knee Assy 3 point bending test



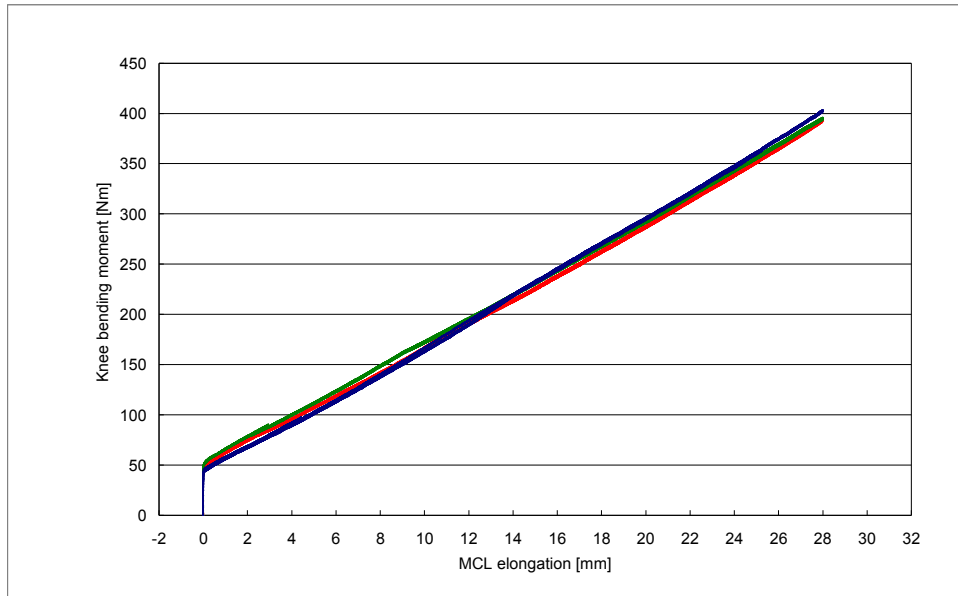
Teflon sheet

Support Lenght		Ideal (mm)	Measured (mm)	Difference (mm)
Knee Assy (SN01)		400	398.25	-1.75
Knee Assy (SN03)		400	398.50	-1.50
Knee Assy (E-leg)		400	398.00	-2.00

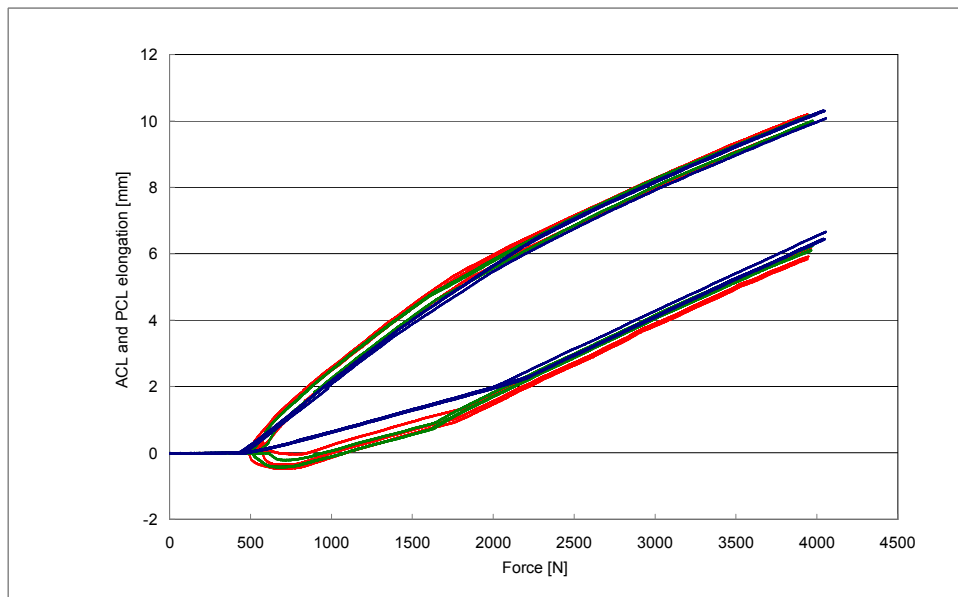
Impactor Lenght		Ideal (mm)	Measured (mm)	Difference (mm)
Knee Assy (SN01)		169	169.00	0.00
Knee Assy (SN03)		169	169.00	0.00
Knee Assy (E-leg)		169	168.75	-0.25

* Connection bolts (near side of tibia/femur) distance.

Knee Assy 3 point bending test results

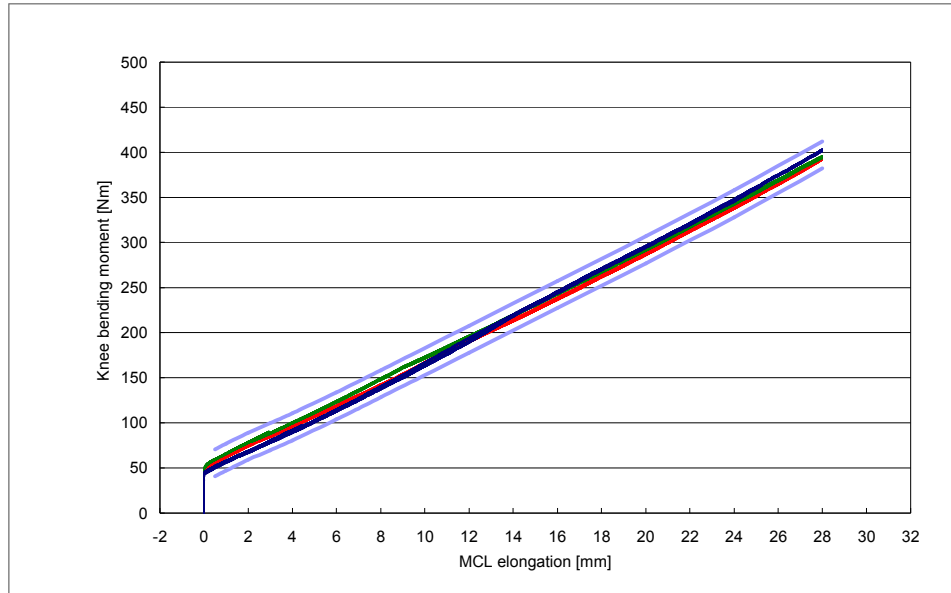


- SN01
- SN03
- E-leg



- Knee is not simple bar construction, so we just used this data to make new corridor.

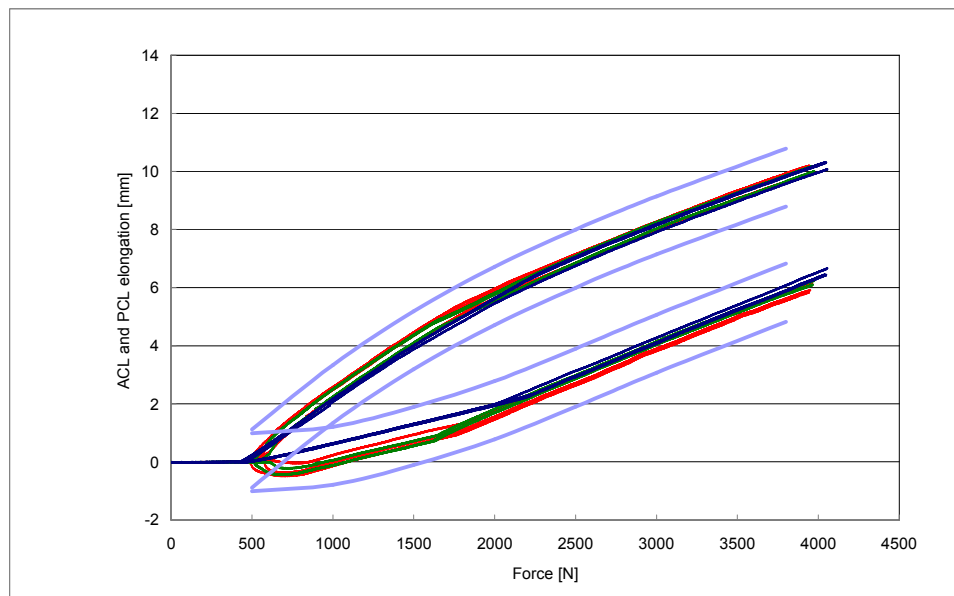
New GTR Corridor: Knee Assy (DRAFT)



— SN01
— SN03
— E-leg

— New GTR Corridor
— : Knee Assy for MCL

Corridor width: $\pm 15\text{Nm}$ (same as current width)



— SN01
— SN03
— E-leg

— New GTR Corridor
— : Knee Assy for MCL

Corridor width: $\pm 1\text{mm}$ (same as current width)

- We made new corridor draft using averaged waveforms.
- Corridor width was set by using current corridor width.

Thank you for your attention!