Japan Observations and Proposals

1st TF-RUCC meeting
26 Jan. 2012
Japan

Background

- At the TF-RUCC kickoff meeting in Nov. 2011, Japan was assigned a task to review Flex-GTR current corridors as well as test conditions.
- JAMA-JARI have conducted the review and obtained some observations.
- Japan would like to share our observations as well as Japan proposals as to how to update the corridors hereafter.
- Basic ideas behind the Japan proposals:
  - Re-examine the current static assembly and dynamic certification corridors based on the current bone core corridors such that one single impactor with mid-corridor bone cores falls in the middle of all the rest of the corridors to avoid going back to the injury threshold discussions
  - All the tests for the re-examination shall be performed by a single test lab to avoid unreasonable widening of the corridors by introducing lab-to-lab variability from the beginning
  - JARI is the most appropriate test lab to conduct the tests for the re-examination because JARI has developed most of the corridors except those for the inverse test
  - Round-robin tests shall be performed at different labs after re-examining the corridors where the causes of the lab-to-lab variability shall be carefully investigated and slight modifications to the re-examined corridors be considered as necessary
  - Target schedule of IG GTR9-PH2 also needs to be taken into account and the most efficient way of achieving the goal needs to be sought for

Japan Observations and Proposals

1. Bone Core 3 Point Bending Test Results

- Test results differ between Humanetics and JARI.
  - The difference came from the difference of the test rig and maybe from the difference of test lab (sensors, settings, etc.).
  - Flex-GTR bone core characteristic shall be investigated/certified by JARI because JARI is the master test lab that developed the corridors using the master test rig.

2. Femur Assy, Tibia Assy and Knee Assy 3 Point Bending Test Results

- The roller support system causes high variations in the test results.
- The plastic plate support system, used for Flex-GT, provides stable test results.
  - Recommend to use the plastic plate support system for Flex-GTR certification tests.
  - Need to update the Flex-GTR component corridors.
  - Draft proposal shall be developed by mid March 2012 using JARI test data.

Japan Observations and Proposals

3. Full Assy Pendulum Test

- Not brand-knew knees were used to develop the current pendulum test corridors.
- Bone core bending characteristics were unclear.
  - Need to update the current pendulum test corridors using brand-knew/overhauled impactors.
  - Draft proposal shall be developed by mid March 2012 using JARI test data.

4. Full Assy Inverse Test

- Short flesh rubber as well as not brand-new bone cores were used to develop the current inverse test corridors.
  - Need to update the current inverse test corridors using brand-knew/overhauled impactors.
  - Draft proposal shall be developed by mid March 2012 using JARI test data.

Working Schedule (Japan Proposals)

	Humanetics (HU) US	Delivery	JARI
Bone core preparation	**Tests are done by HU-US and prepare several bone cores.**	**Arrived at JARI by 14th Feb.**	**by 17th Feb.** **Retest at JARI then select best bone cores.**
Overhaul	**Conduct best overhaul with 3 Flex-GTRs except bone cores conditions.**	**Arrived at JARI by 17th Feb.**	**by 22nd Feb.** **Check overhauled conditions and install best bone cores**
Tibia Assy			**by 2nd Mar.** **Tibia Assy tests (3 Flex-GTR)** → Develop a draft update proposal
Femur Assy			**by 2nd Mar.** **Femur Assy tests (3 Flex-GTRs)** → Develop a draft update proposal
Knee Assy			**by 2nd Mar.** **Knee Assy tests (3 Flex-GTRs)** → Develop a draft update proposal
Pendulum			**by 9th Mar.** **Full Assy tests (3 Flex-GTRs)** → Develop a draft update proposal
Inverse			**by 9th Mar.** **Full Assy tests (3 Flex-GTRs)** → Develop a draft update proposal

submit by 19th Mar.

TF-RUCC/ 2nd IG GTR9-PH2

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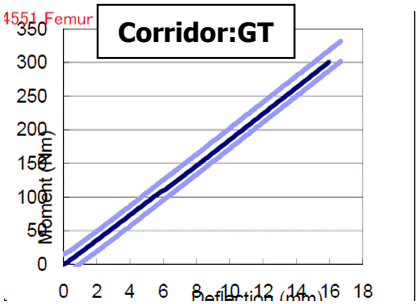
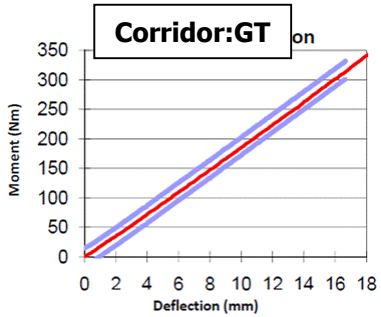
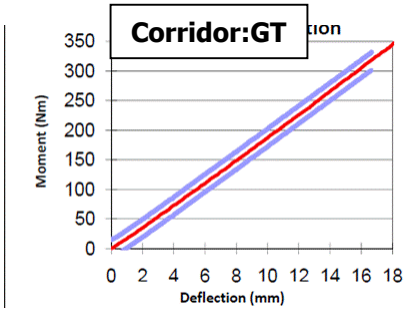
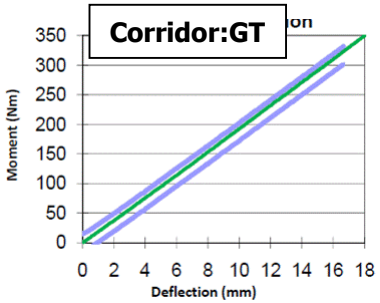
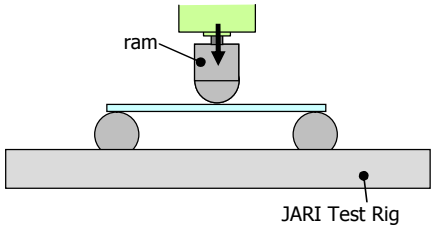
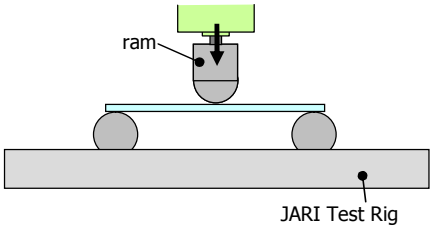
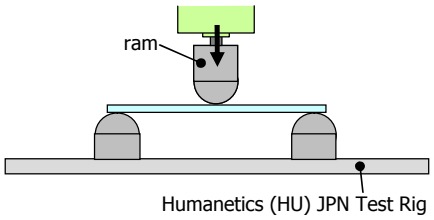
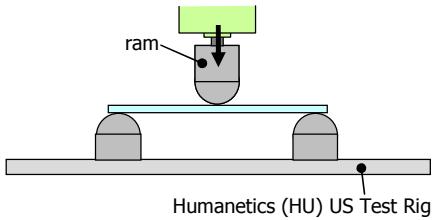
Go to Lab. Difference Check

Appendix

1. Bone Core 3 Point Bending Test Results

Femur Bone Core

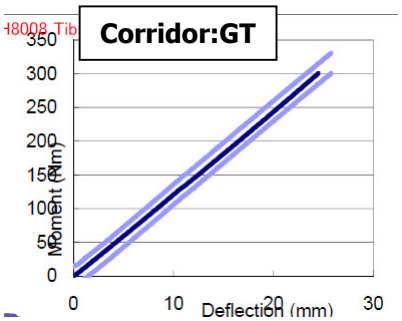
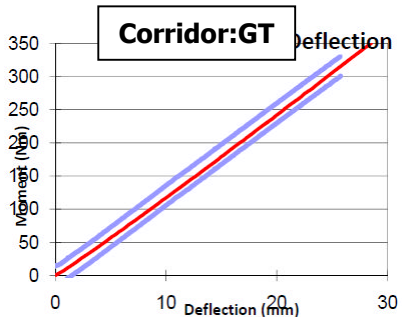
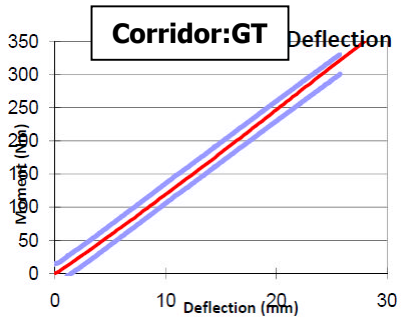
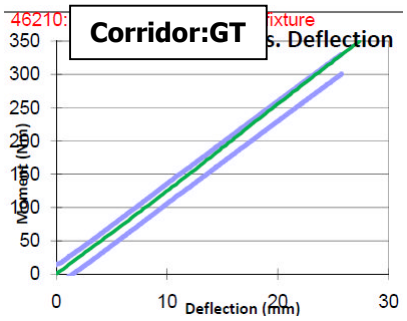
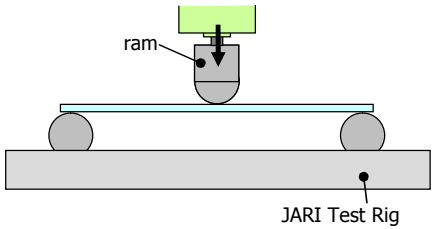
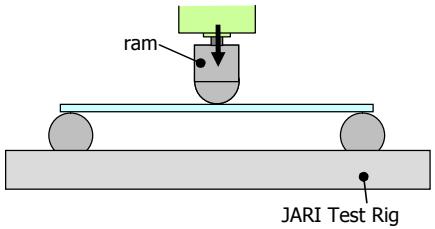
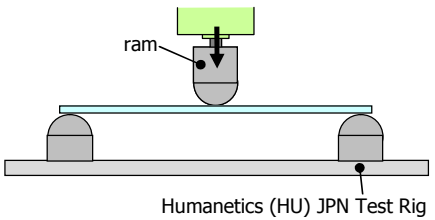
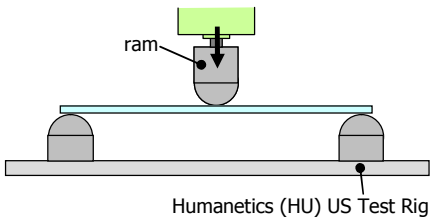
JARI Lab.	HU-JPN Lab.		HU-US Lab.
JARI Test Rig	**JARI Test Rig**	**HU-JPN Test Rig**	**HU-US Test Rig**
			
			
mid in corridor	**mid in corridor**	**mid-high in corridor**	**high in corridor**

JARI Test Rig

Humentics (HU) JPN Test Rig

1. Bone Core 3 Point Bending Test Results

Tibia Bone Core

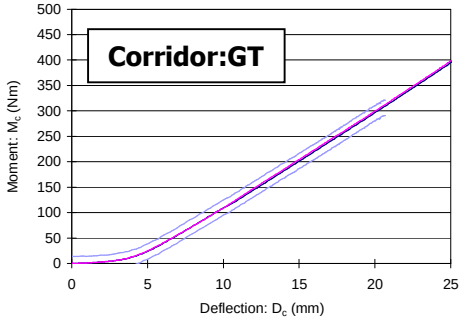
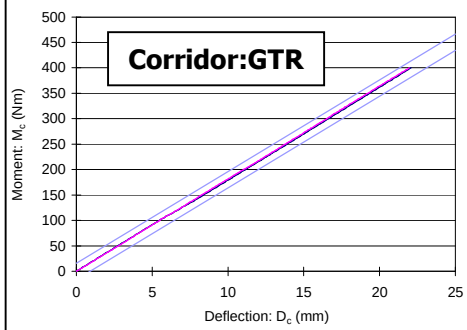
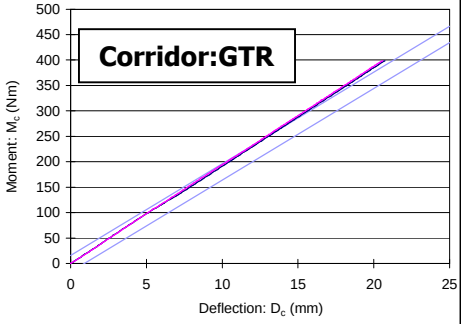
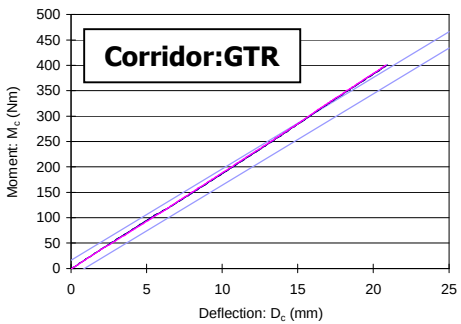
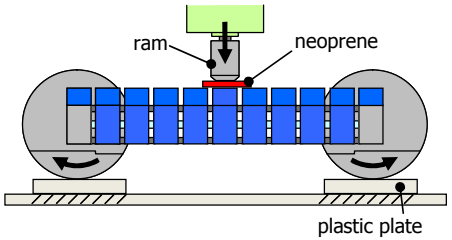
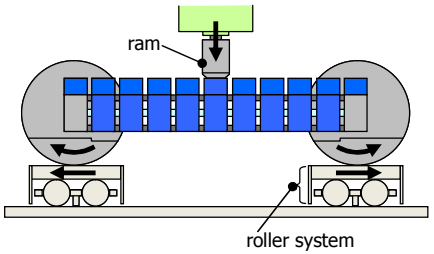
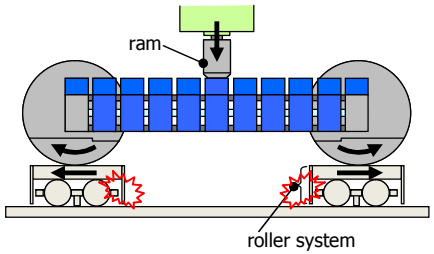
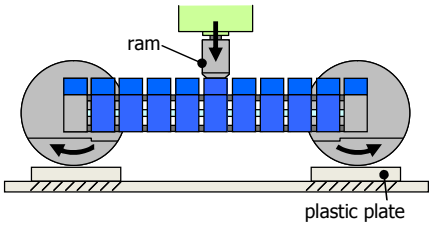
JARI Test Lab.	HU-JPN Test Lab.		HU-US Test Lab.
JARI Test Rig	**JARI Test Rig**	**HU-JPN Test Rig**	**HU-US Test Rig**
			
			
mid in corridor	**mid in corridor**	**mid-high in corridor**	**high in corridor**

JARI Test Rig

Humentics (HU) JPN Test Rig

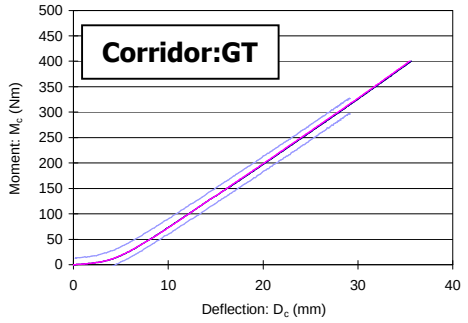
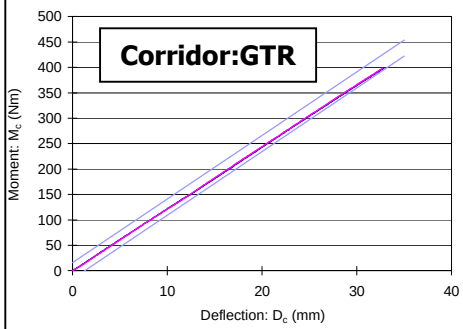
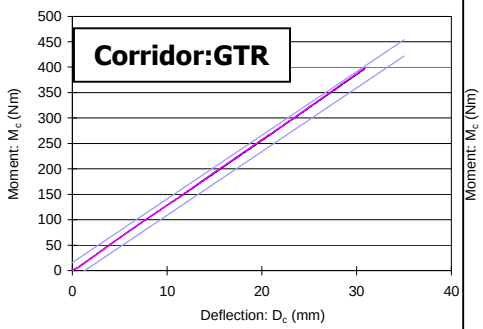
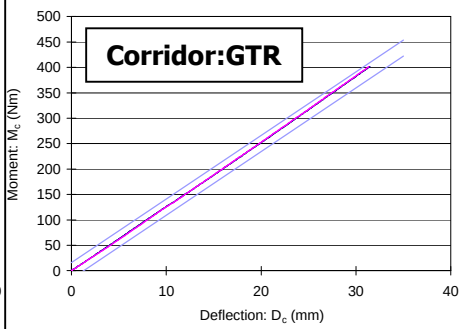
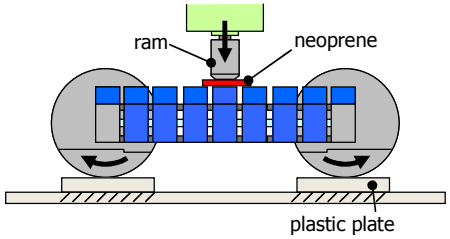
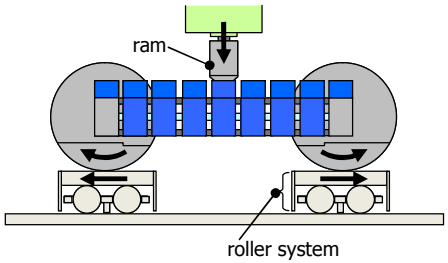
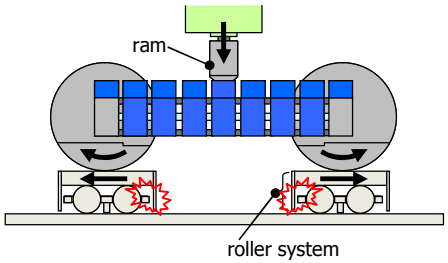
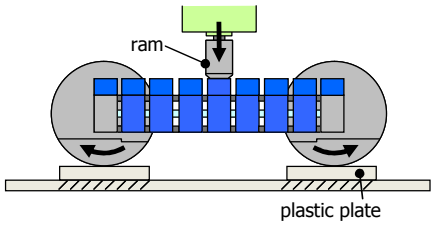
2. Femur Assy, Tibia Assy and Knee Assy 3 Point Bending Test Results

Femur Assy

With Neoprene	No Neoprene		
Plastic Plate	Roller System		Plastic Plate
	Gap	No gap	
			
	 **Free movement**	 **Contact to housing**	
• easy setting • good repeatability	• difficult setting • difficult to control which data can be obtained		• easy setting • good repeatability

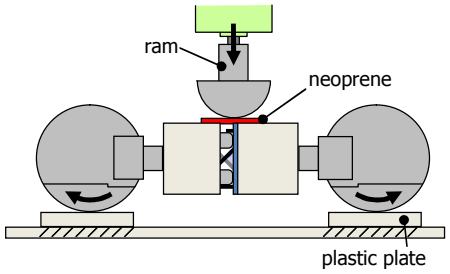
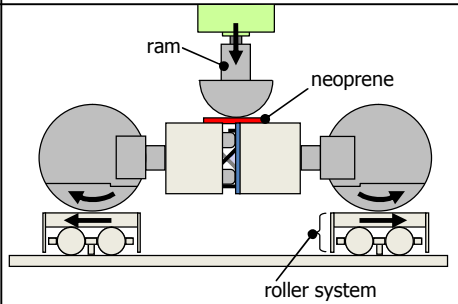
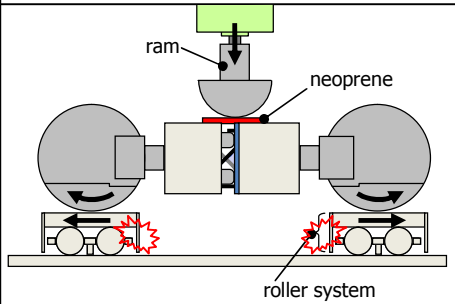
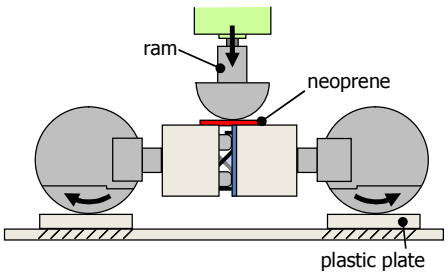
2. Femur Assy, Tibia Assy and Knee Assy 3 Point Bending Test Results

Tibia Assy

With Neoprene	No Neoprene		
Plastic Plate	Roller System		Plastic Plate
	Gap	No Gap	
			
	 Free movement	 Contact to housing	
• easy setting • good repeatability	• difficult setting • difficult to control which data can be obtained		• easy setting • good repeatability

Knee Assy

With Neoprene

Plastic Plate	Roller System		Plastic Plate
	Gap	No Gap	
MCL **Corridor:GT**	**Corridor:GTR**	**Corridor:GTR**	**Corridor:GTR**
ACL, PCL **Corridor:GT**	**Corridor:GTR**	**Corridor:GTR**	**Corridor:GTR**
	 **Free movement**	 **Contact to housing**	
•**easy setting** •**good repeatability**	•**difficult setting** •**difficult to control which data can be obtained**		•**easy setting** •**good repeatability**