

First Technology Safety Systems

Design Freeze Status

Flex-PLI-GTR Development Full Calibration Test Procedures

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Comments addressed from Design Freeze meeting
February 20th 2008, JARI, Tsukuba, Japan
Update March 31st, 2008

Current Status

- Flexible bone material calls for new approach and new lines of thought
- Some details presented may change

Flex-GTR Full Calibration Test Procedures (Overview)

- ✓ Evaluate Long Bone Cores Bending Characteristic
- ✓ Obtain Strain (mV) to Moment Conversion values
- ✓ Frequency
 - ✓ After manufacturing
 - ✓ Each year
 - ✓ [After exceeding 400Nm (~125% of IARV*)]
 - ✓ After failure of dynamic test

- ✓ Evaluate Assembly Bending Characteristics
- ✓ Check ultimate bending moment
- ✓ Frequency
 - ✓ After manufacturing
 - ✓ Each year
 - ✓ [After exceeding 400 Nm (~125% of IARV)]
 - ✓ After femur or tibia assembly-/parts exchange
 - ✓ After failure of dynamic test

- ✓ Evaluate Knee Bending Characteristics
- ✓ Evaluate Knee Ligament Elongation Values
- ✓ Frequency
 - ✓ After manufacturing
 - ✓ Each year
 - ✓ [After exceeding IARV]
 - ✓ After knee assembly-/parts exchange
 - ✓ After failure of dynamic test

- ✓ Evaluate consistency of the assembly
- ✓ Frequency
 - ✓ Each [1-10] tests
 - ✓ After exceeding IARV
 - ✓ After knee or femur or tibia assembly-/parts exchange

Step 1: Bone Core 7 tests

Quasi-static 3-Point Bending Test
(Femur bone core, Tibia bone core)



Step 2: Femur and Tibia 2 tests

Quasi-static 3-Point Bending Test
(Femur, Tibia)



Step 3: Knee, 1 test

Quasi-static 3-Point Bending Test

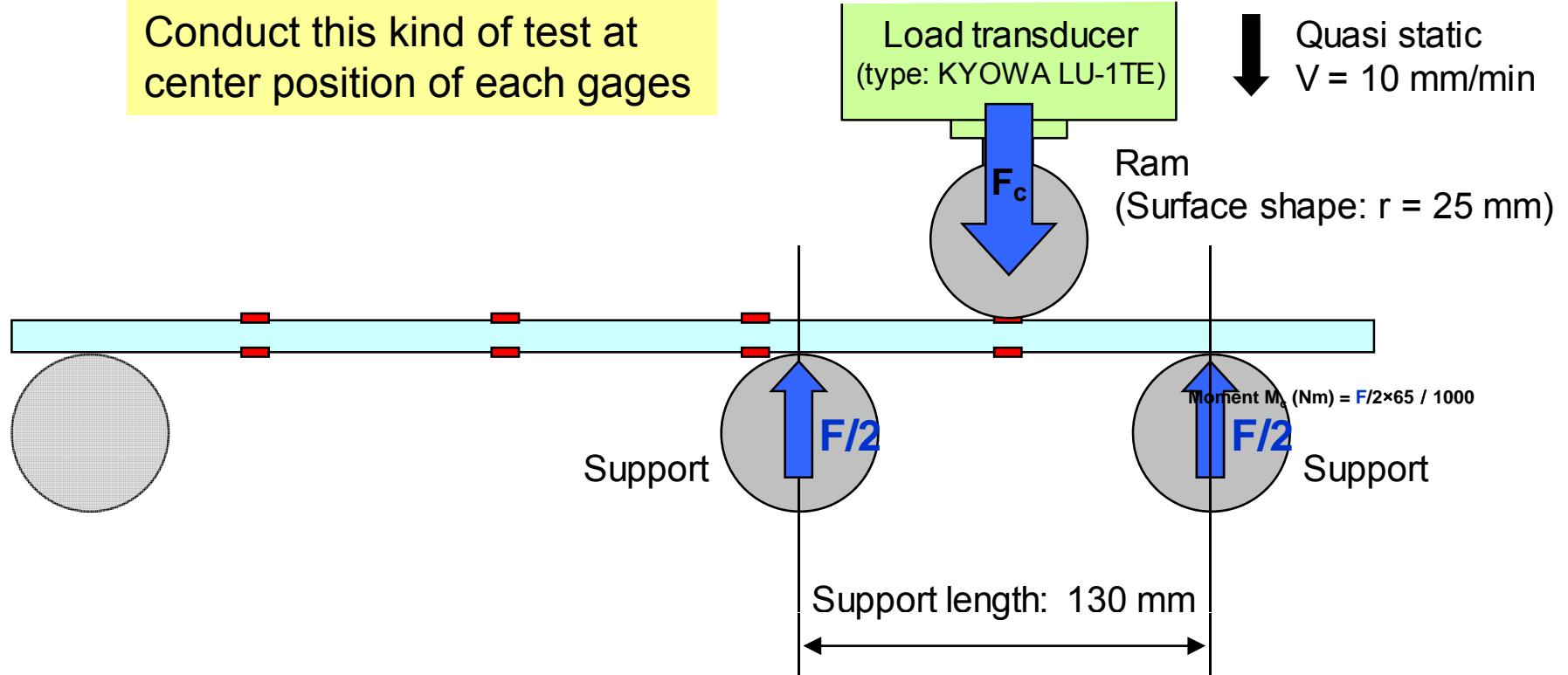


Step 4: Assembly 1 test

Femur-Knee-Tibia
Dynamic Calibration Test

*IARV : Injury Assessment Reference Value

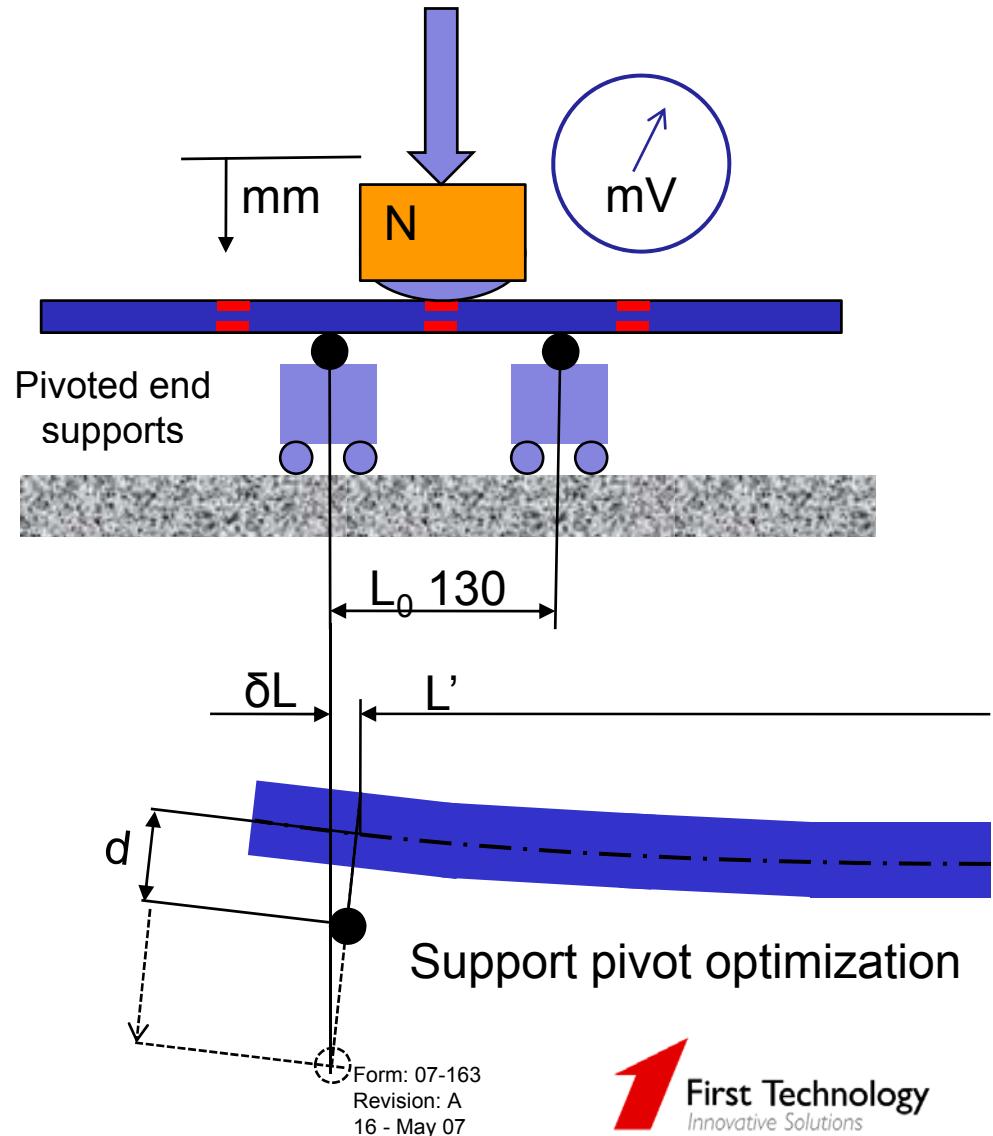
NEW JARI Proposals February 01



Step 1: Bone Core 7 tests

Quasi-static 3-Point Bending Test

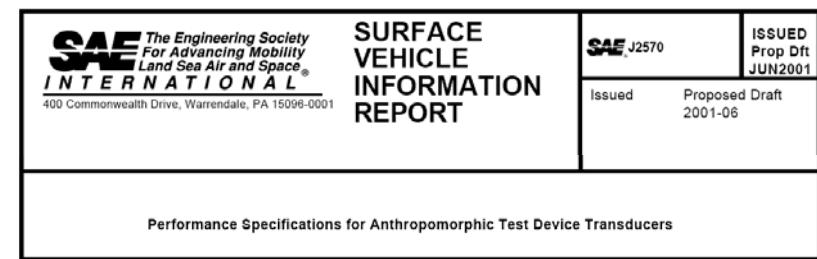
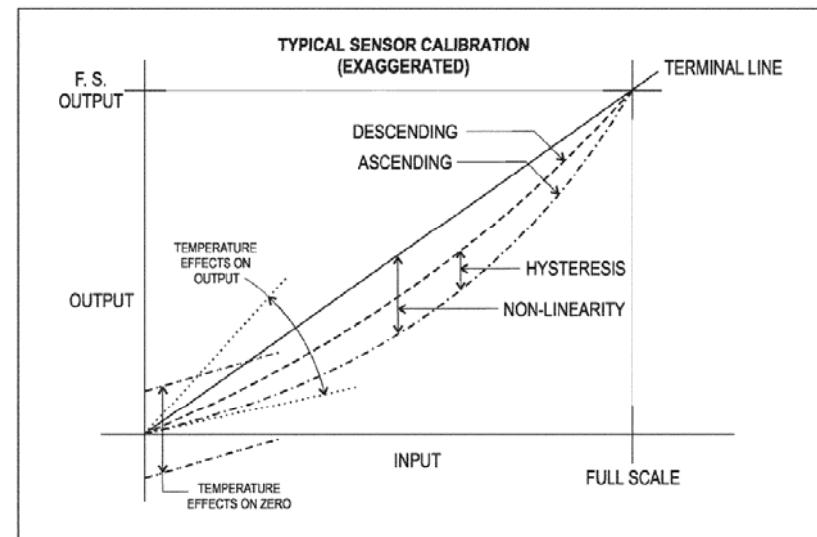
- Quasi static test
 - Loading rate 10mm/min.
- Calibration of bone only
 - Supply of calibrated spare parts
- Measurement of test force, deflection and strain gauge voltage
- Force deflection corridor
- Accurate control of probe and support distance L_0
- Roller support to annihilate tension - compression in bone
- Compensation for support distance change δL due to bending



SAE J2570

Performance Specification Transducers

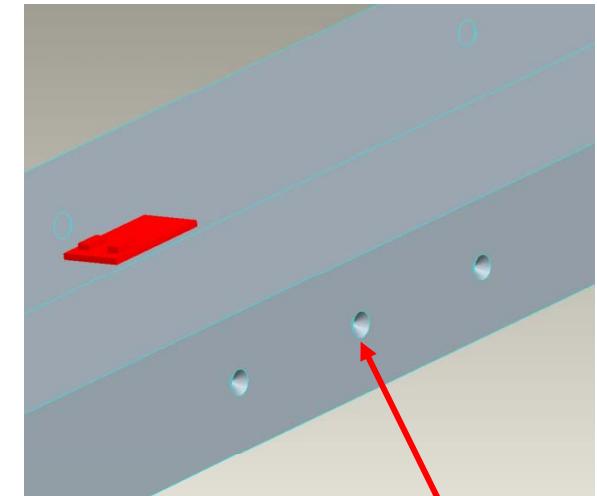
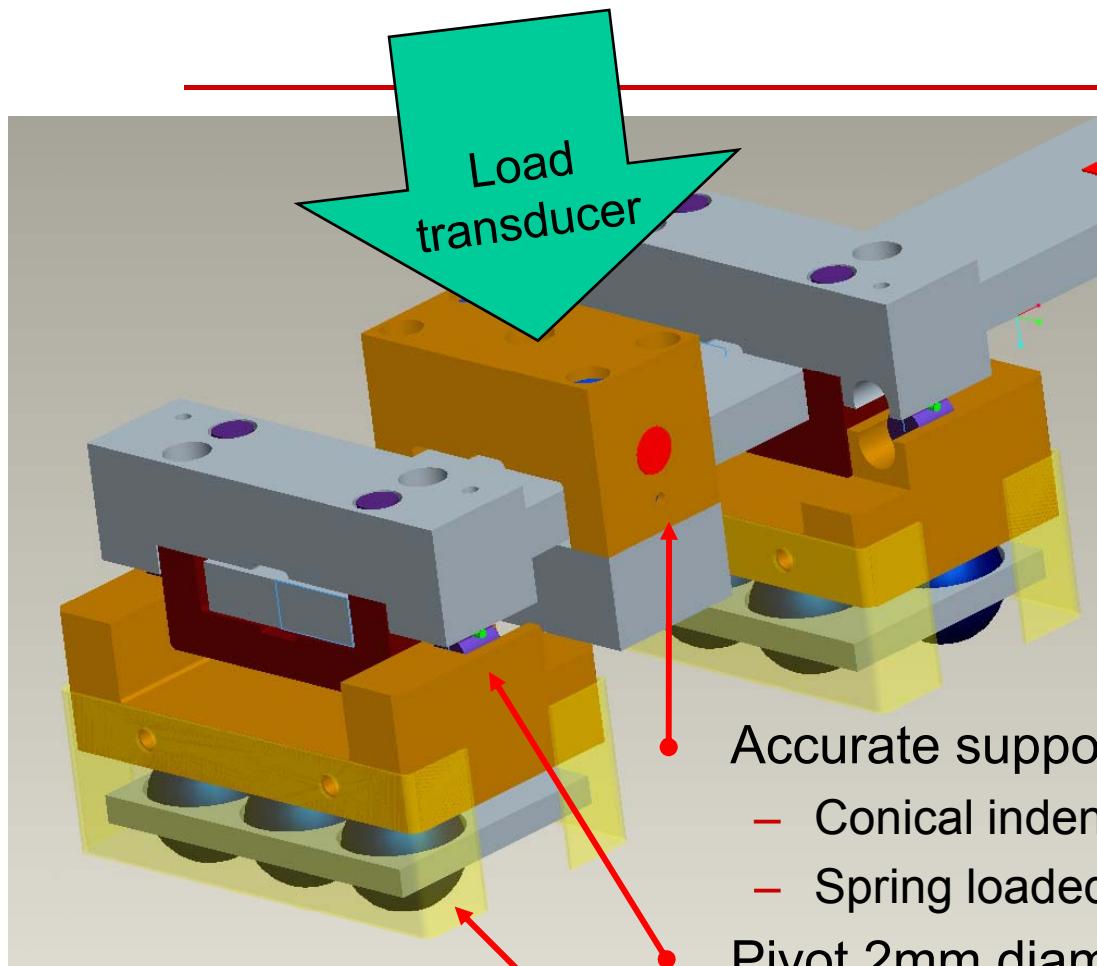
- SAE J2570 is not applicable to FLEX-PLI bone by definition
 - Max deflection < 0.254mm
- Relevant criteria
 - Hysteresis \leq 1% of full scale capacity
 - Non-linearity \leq 1% of full scale capacity
- These are design goals!
- May be difficult to meet due to flexible nature of the bone
- Little experience with high deflection!



Bone Calibration Analysis

Bone Calibration Procedure	GTR
thickness [mm]	10.5
Width [mm]	40
Youngs modulus JARI spec F45 4500 kg/mm^2 [N/mm^2]	44145
Ultimate strength 70kg/mm^2 [N/mm^2]	687
Distance support [mm]	130
Test load [N]	10000
Test load centre [N*m] (peak 350 Nm)	325
Bone bending Radius at loading point [mm]	524.1
Vertical deflection [mm]	2.69
Horizontal bone shortening estimate triangle [mm]	0.19
Horizontal bone shortening estimate Circle [mm]	0.33
Horizontal bone shortening average Circle/triangle [mm]	0.26
Error due to support distance variation [%]	-0.00247
Error due to support distance accuracy 0.2mm [%]	0.15385
Error due to friction roll pin 2.0mm diam [%]	0.15385
Max error due to calibration load cell [%]	0.12000
Total error [%]	0.43017
Peak strain [micro strain]	10.0

Details of Calibration Fixtures



Accurate support distance control

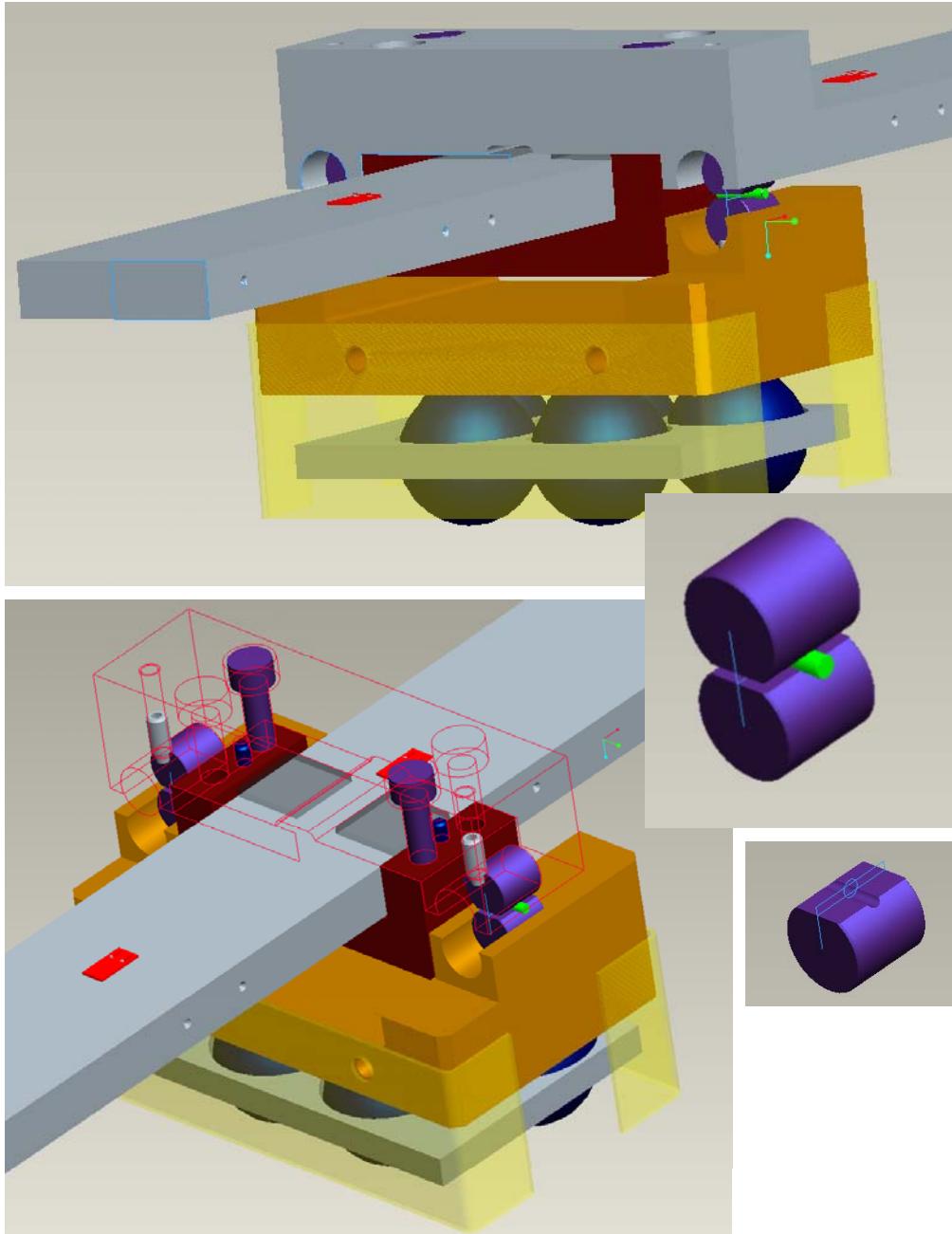
- Conical indents on sides at neutral plane of bone
- Spring loaded ball for positioning

Pivot 2mm diameter for minimum friction

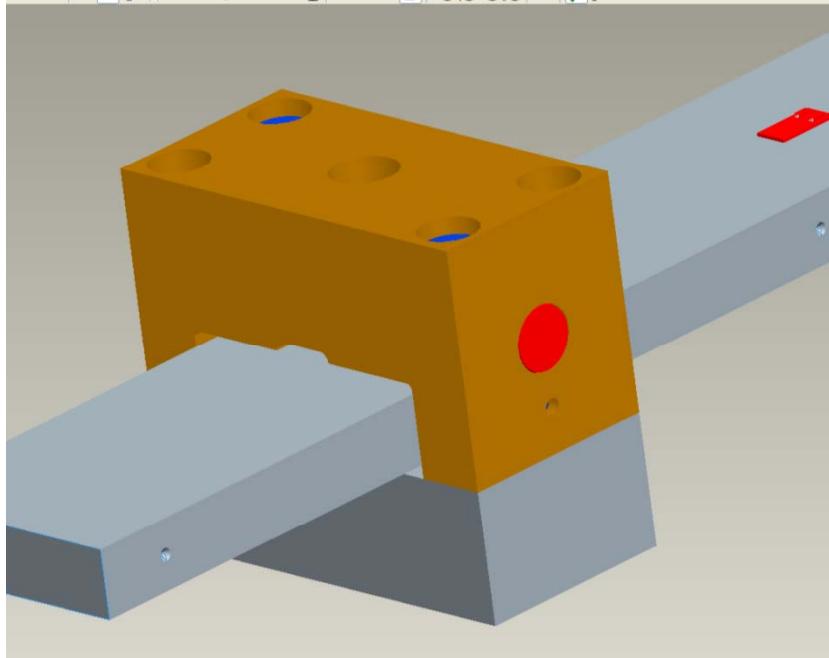
- Hardened steel pin 60HRc

Roller end supports

End fixtures

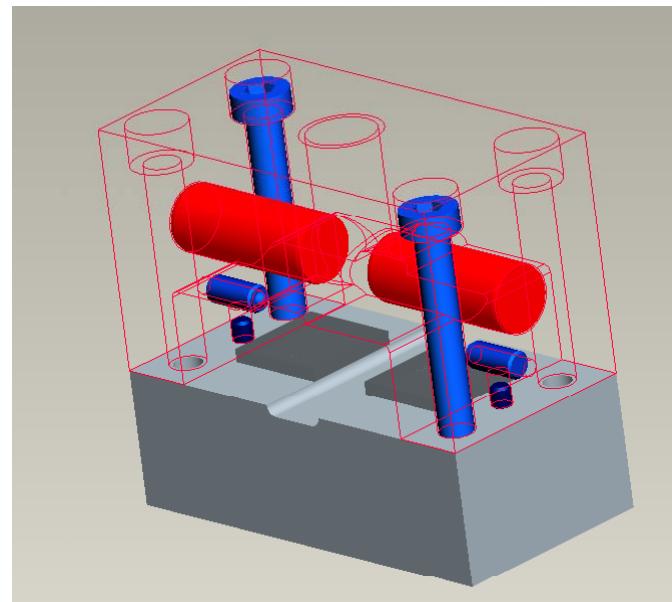
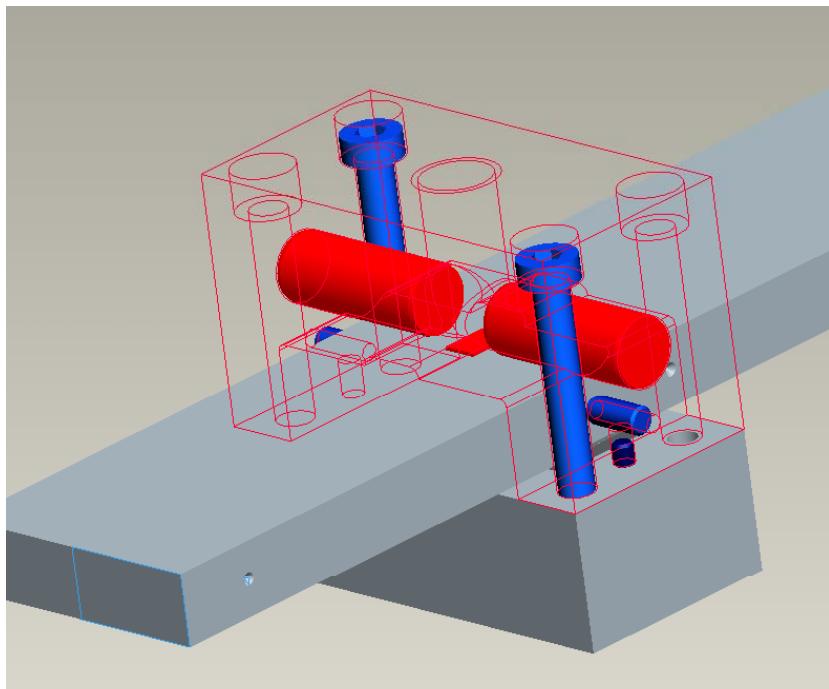


- Pivots made from hardened dowels
- Simple parts and easy replacement
- 2mm diameter pivot
- 10mm diameter with ground flat and groove
- 10mm dowels allow alignment and load distribution of 2mm dowel
 - Surface strain on 2mm dowel 290MPa, 60HRc equals 2300MPa ($1\text{MPa}=1\text{N/mm}^2$)
 - Surface strain on 10mm dowels 25MPa
- Rubber pads to fill space and clamp



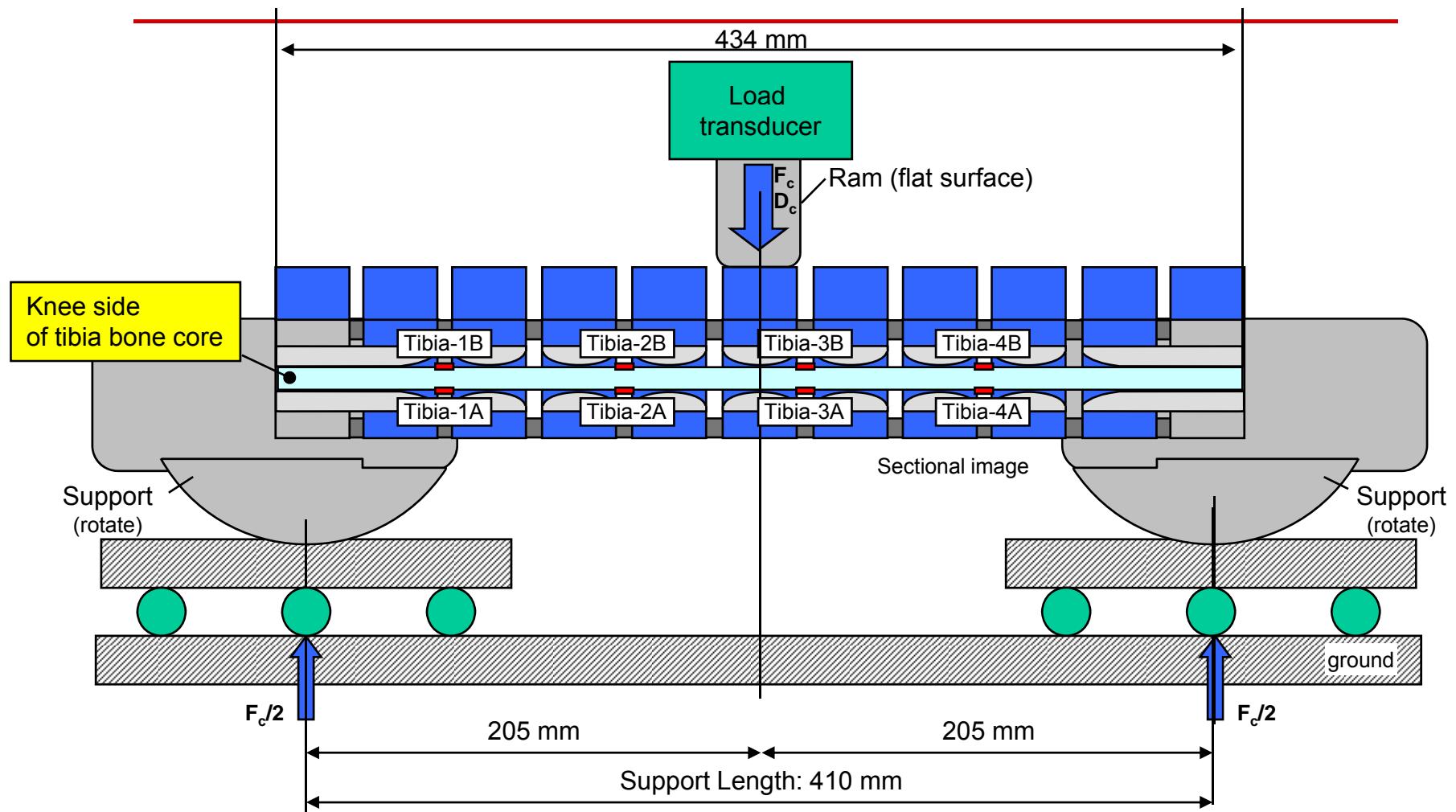
Middle loading fixtures

- Loading point with 10mm dowels
- Rubber pads to fill space and clamp
- Central threaded hole for connection to calibration load cell
- Accurate positioning to bone



Form: 07-163
Revision: A
16 - May 07

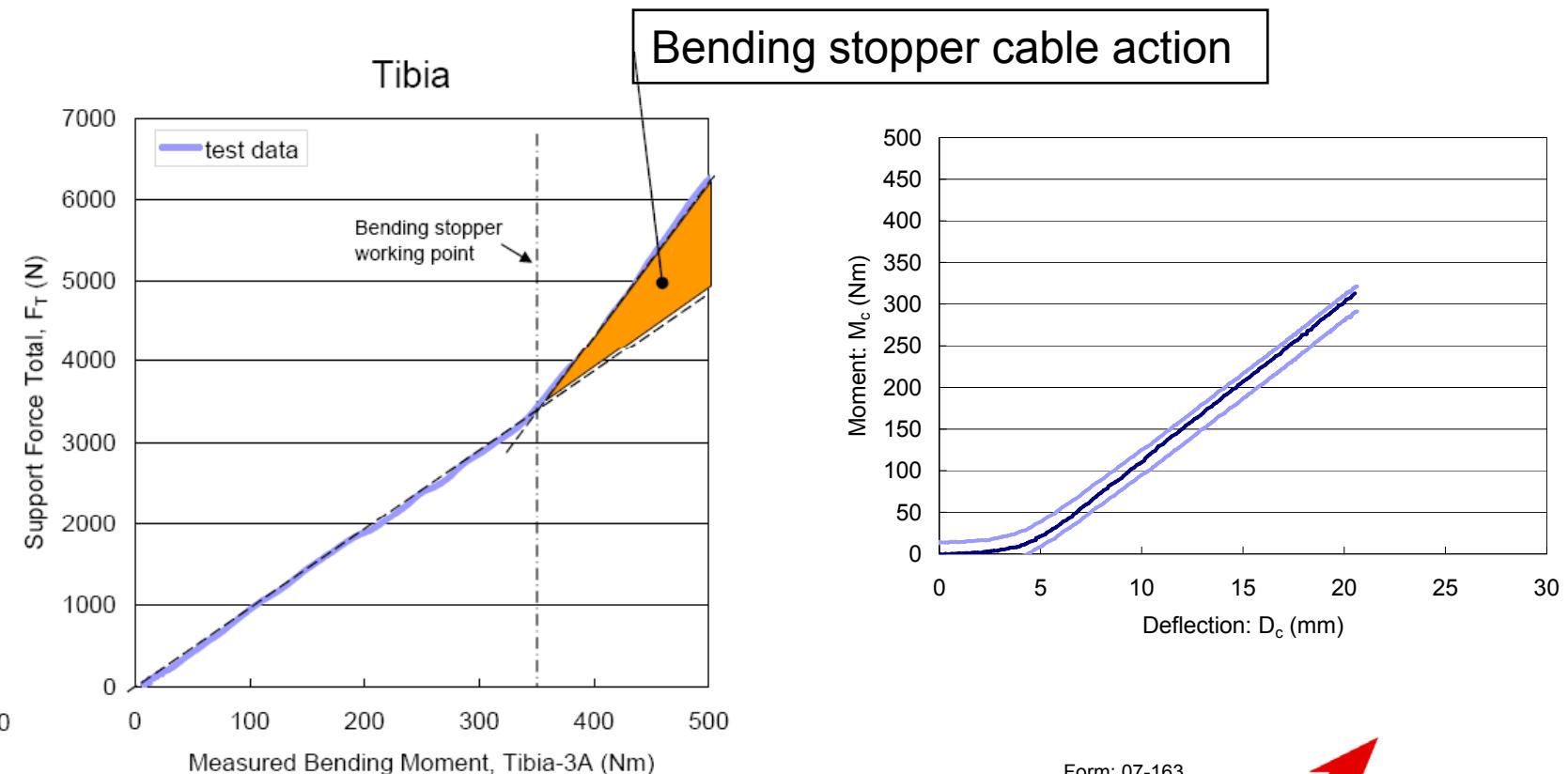
Step 2: Long Bone Tibia and Femur Quasi-static 3-Point Bending Test



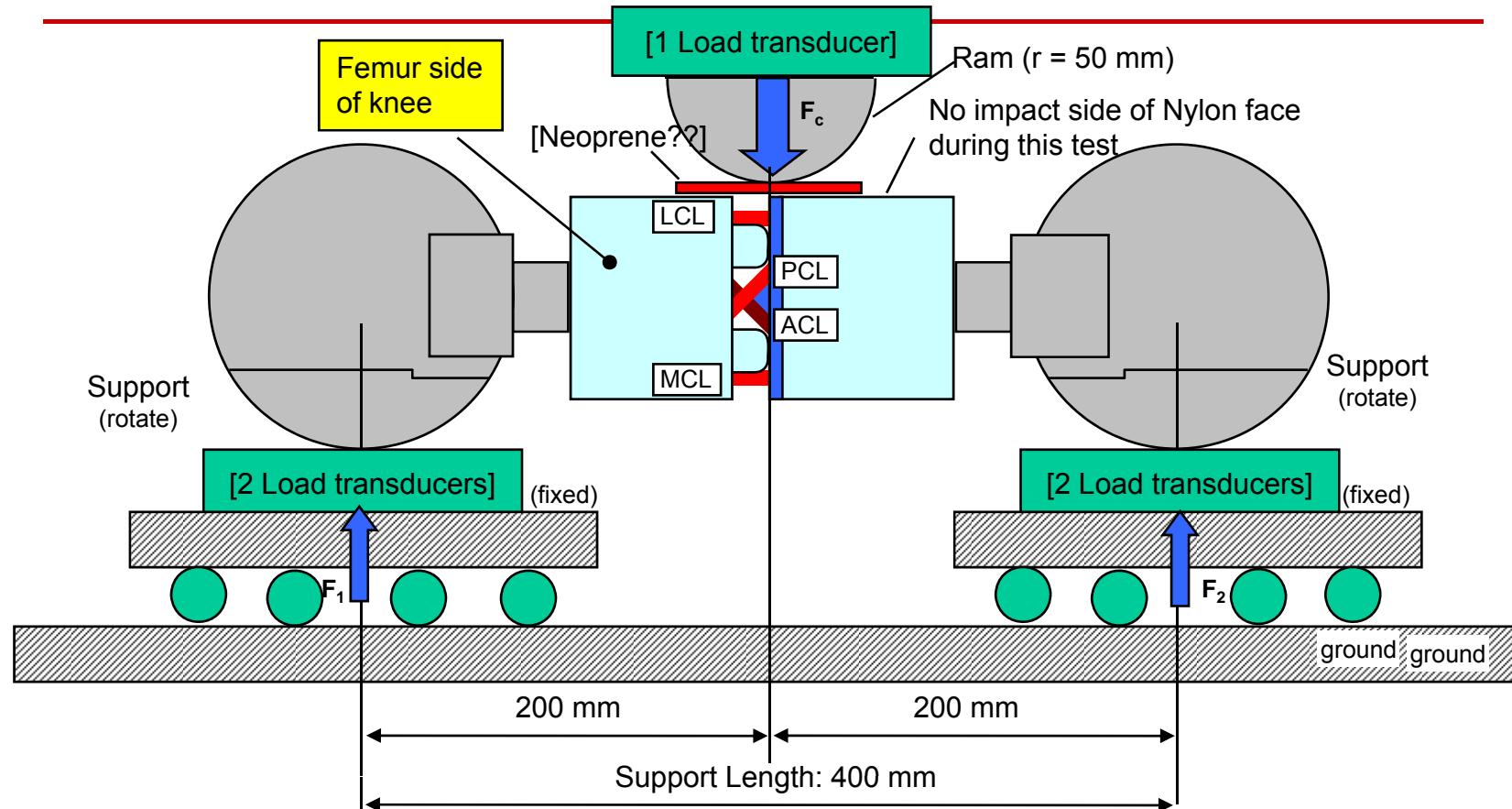
- Maintain existing procedure, Without Neoprene layer Drawings of the fixtures available

Long Bone Assembly Calibration

- Load up to IARV [300Nm] to ensure correct IARV measurement below bending stopper working point



Step 3: Knee Quasi-static 3-Point Bending Test



- May use single central load cell
- if loading position well controlled

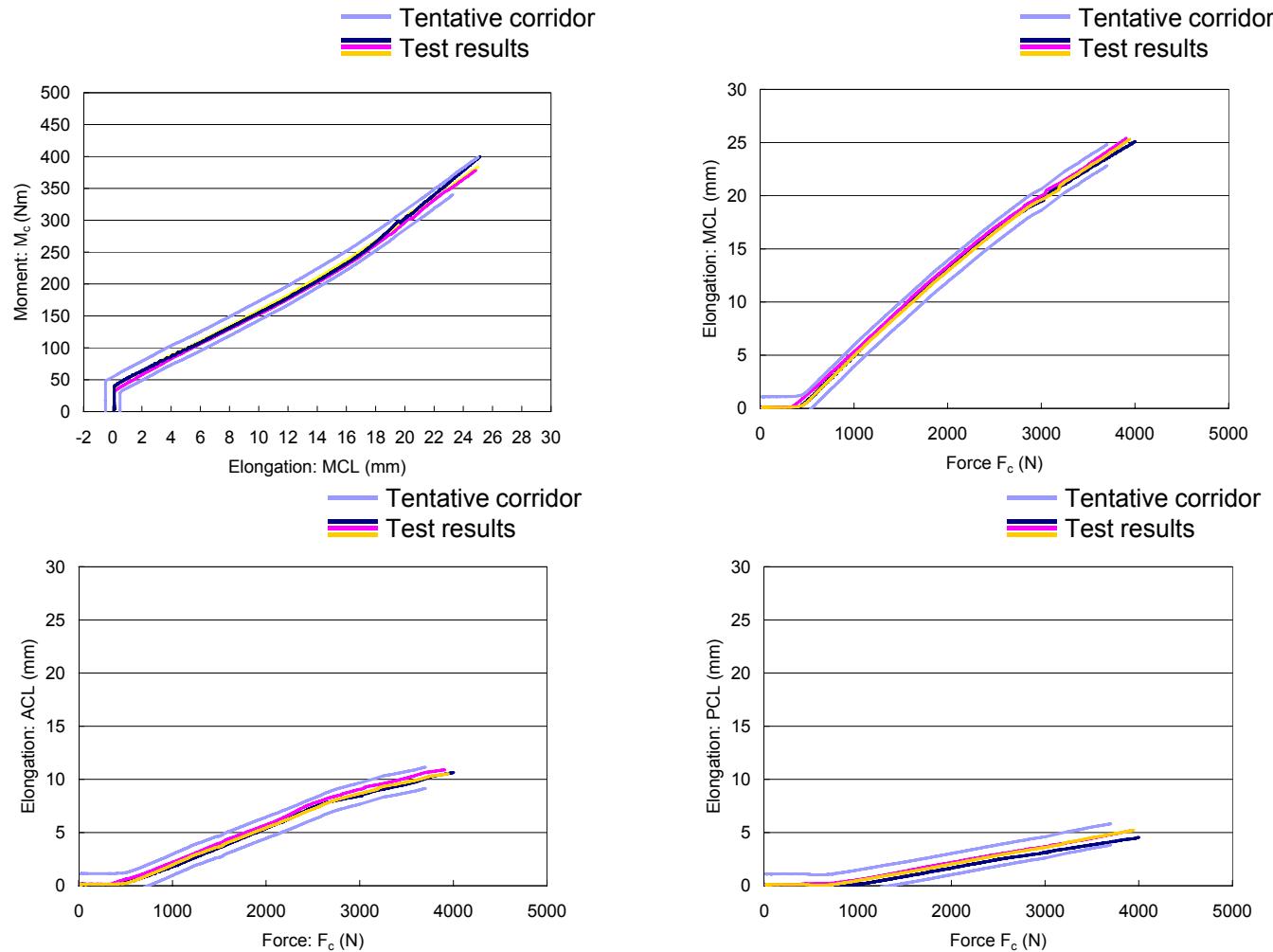
FLEX-PLI-GTR Development, March 31st, 2008

F_1 : Support force of Femur side of knee
 M_c : Moment Center - at Knee joint surface (Nm) = F_1 (N) \times 0.2 (m)

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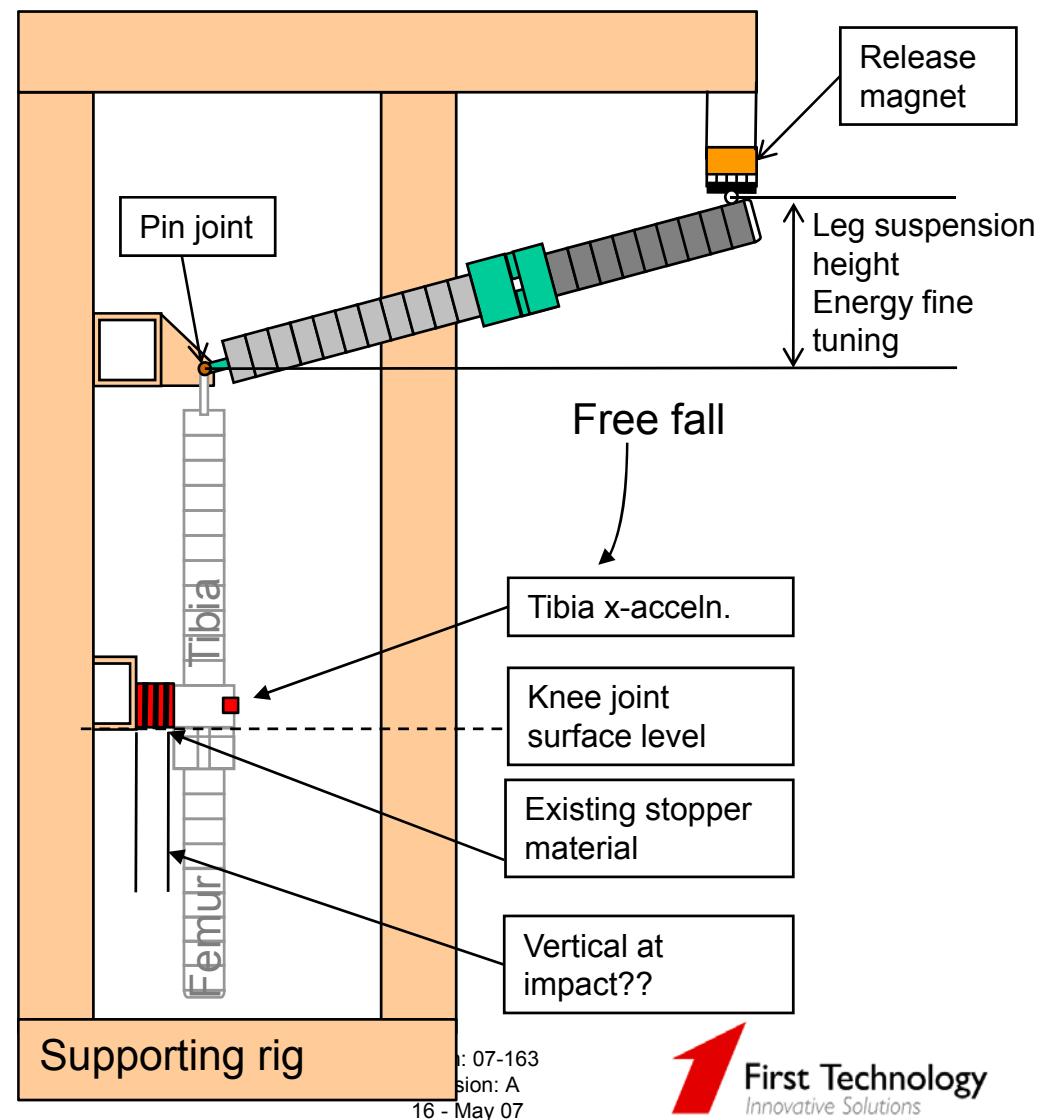
Step 2: Knee

Quasi-static 3-Point Bending Test



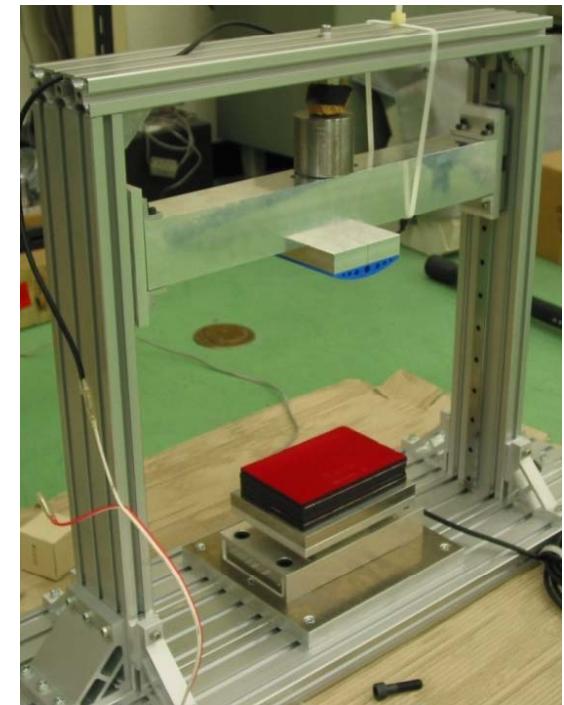
Dynamic Calibration Procedure

- Calibration rig with support arm and release magnet
- Control input pulse with tibia x-acceleration
- Control parameters
 - Drop height
 - Ax tibia proximal
 - MCL, ACL, PCL (and LCL)
 - Tibia bending moments
 - No pass-fail parameter femur bending moments
 - Target corridor $\pm 10\%$ from average



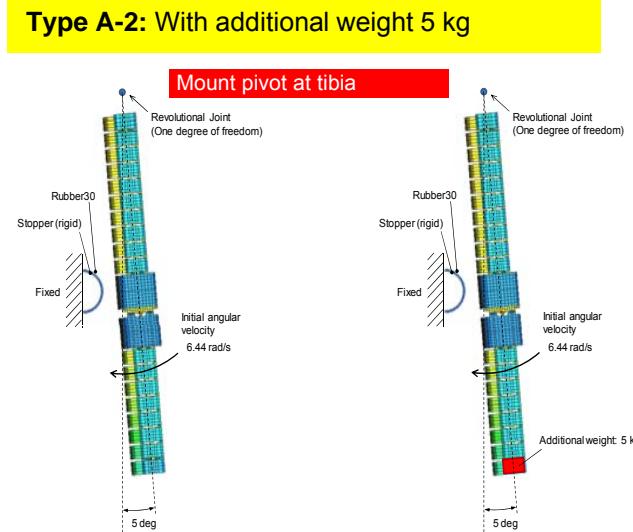
Stopper material consistency test

- Tibia acceleration may be dependent from two parameters
 - stopper material
 - tibia response
- To be able to identify problem in case of calibration failure: tibia or stopper material
- Need to have additional procedure for stopper material test
 - Control stopper material over extended time of loading/use
 - FTSS to make proposal for dynamic (drop?) test



Dynamic Calibration Development Testing

- Continue JARI FE Model study parameter variation for calibration development
- Complete test matrix (example)
 - Base line test
 - Mount at Tibia (upside down)
 - Added mass to bottom segment
 - [Free fall height increase]
 - Loading surface Flat and Curved
- Decide on final procedure parameters based on model parameter variation
- Verify procedure details with FLEX-PLI-GT
- Calibrate GTR prototypes with final procedures



Design frozen!

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Revision: A
16 - May 07

