Humanetics Innovative Solutions, Inc.

TF-RUCC FLEX PLI TASK FORCE PRESENTATION

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Introduction

- Show results of Humanetic's Flex PLI Static Leg studies.
- Make recommendations from the data results and on protocols for leg testing.
- To agree build procedure for round robin leg set up

Long rubber verses short rubber effects on the Pendulum and Inverse test

- It was understood that short rubber flesh was used when Inverse corridors were developed.
- Humanetics carried out tests to compare the difference using internal engineering leg.
  - The Long and Short rubber had more affect on the Inverse than the Pendulum tests.
  - The short rubber Tibia Inverse moments increased 3 – 6.4 Nm. The Pendulum short rubber Tibia moments increase .5 to 1.3Nm.
  - Very little effect on MCL, PCL, and ACL

Long rubber verses short rubber effects on the Inverse test

Three test were run on short and long rubber. The difference is calculated from the average peaks

	GTR Inverse corridor			Difference short to long rubber	% Difference from Mid Corridor
Pre Impact velocity	10.9	11.3	m/sec	0.0000	0.00%
Peak Moment @ T1	237	277	N-m	3.1300	1.13%
Peak Moment @ T2	223	269	N-m	5.0033	1.86%
Peak Moment @ T3	176	204	N-m	6.3733	3.12%
Peak Moment @ T4	98	120	N-m	5.8000	4.83%
Peak ACL Elongation	8.5	10.5	mm	0.4267	4.06%
Peak MCL Elongation	18	23	mm	0.2300	1.00%
Peak PCL Elongation	4.5	6	mm	0.0300	0.50%
Temperature	18	22	degC		
Humidity	10	70	%		

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Long rubber verses short rubber effects on the Pendulum test

Three test were run on short and long Rubber. The difference is calculated from the average peaks

	GTR inverse corridor			Difference short to long rubber	% Difference from Mid Corridor
Peak Moment @ T1	235	272	N-m	0.7400	0.27%
Peak Moment @ T2	185	211	N-m	0.5400	0.26%
Peak Moment @ T3	135	160	N-m	1.0667	0.67%
Peak Moment @ T4	94	108	N-m	1.2933	1.20%
Peak ACL Elongation	9	11	mm	0.4367	3.97%
Peak MCL Elongation	23	26	mm	0.2600	1.00%
Peak PCL Elongation	4	5.4	mm	0.1367	2.53%
Temperature	20.6	22.2	degC		
Humidty	10	70	%		

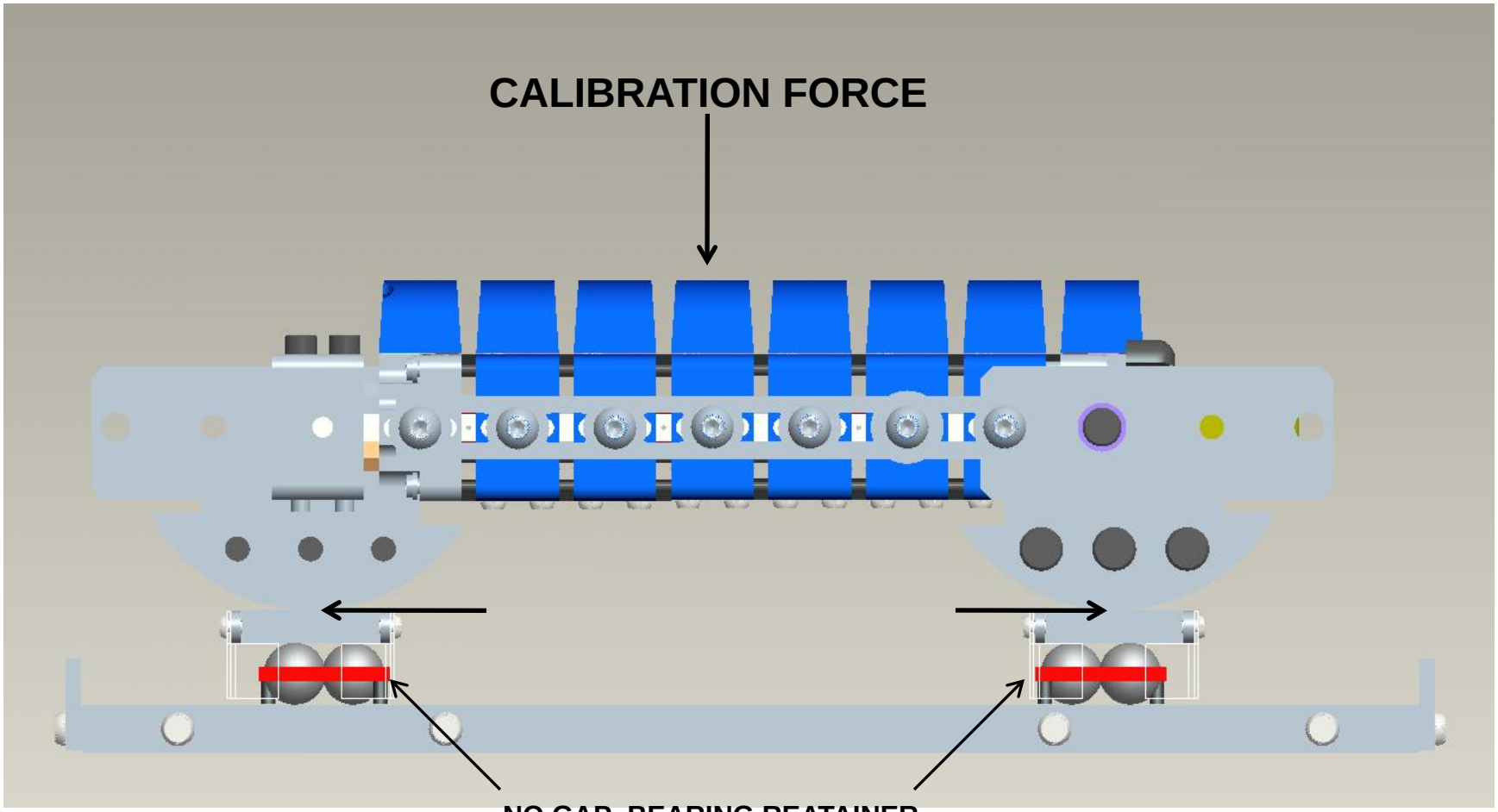
PE sheet verses bearing assembly Summary

- No comparison was made between roller bearings and the original JARI test set up with PE sheet before being agreed with the TEG
- Humanetics conducted Quasistatic Tests on a FLEX-PLI tibia assembly in the following conditions:
  - Roller support fixture with “NO GAP” between carriage and bearing retainer plate
  - Roller support fixture with a “GAP” between the carriage and bearing retainer plate
  - JARI Polyethelyne Sheet

- The observed responses are as follows.
  - The roller support fixture causes more variability in the responses than the PE sheet. The PE sheet is at least 10 times more repeatable than the bearing with Gap or no Gap.
  - The PE sheet is much easier to control in production and less liable to error.

- A tibia static assembly was run with the PE sheet at 300Nm, 350Nm, and 400Nm. The repeatability for all three loads was under a 0.3%.

“NO GAP” BETWEEN BEARING RETAINER AND CARRIAGE SKIRT INSIDE WALL



NO GAP, BEARING REATAINER CONTACTING CARRIAGE SKIRT INSIDE WALL

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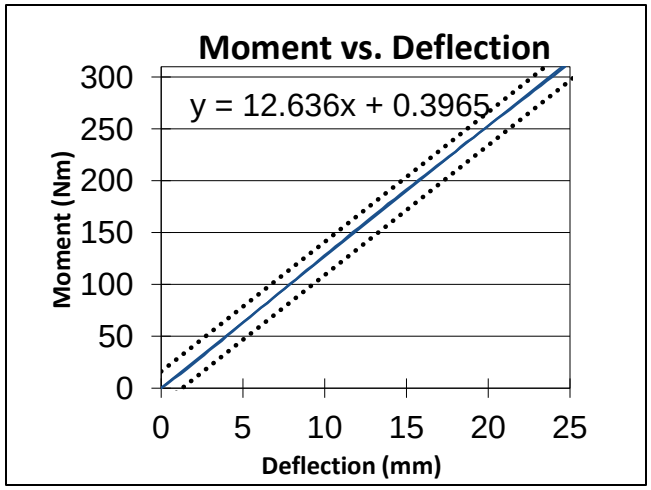
"NO GAP" CONDITION-CARRIAGE SKIRT CONTACTING BEARING RETAINER

TEST 1



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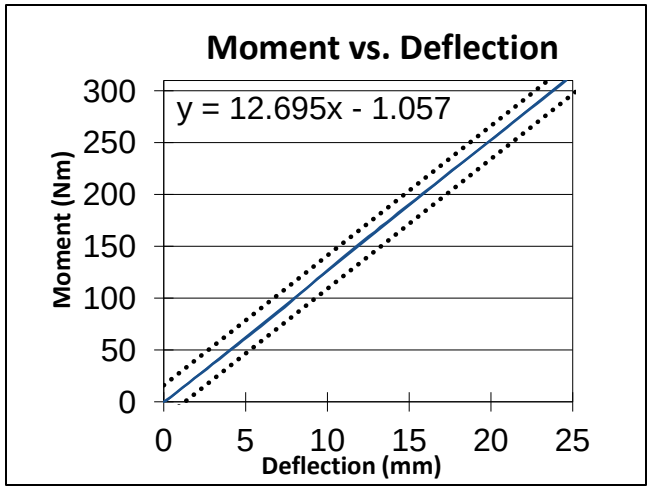

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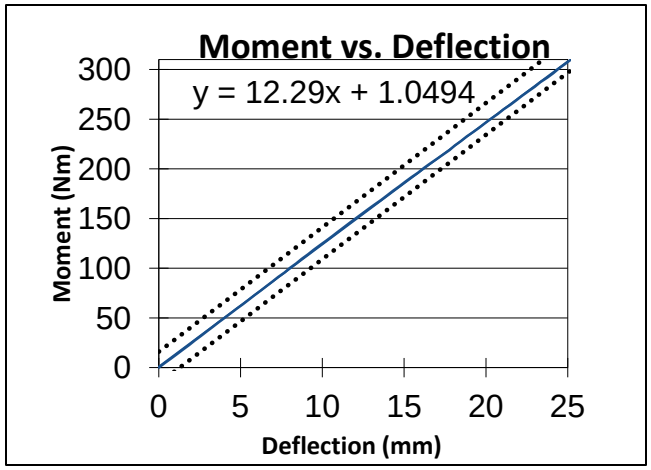

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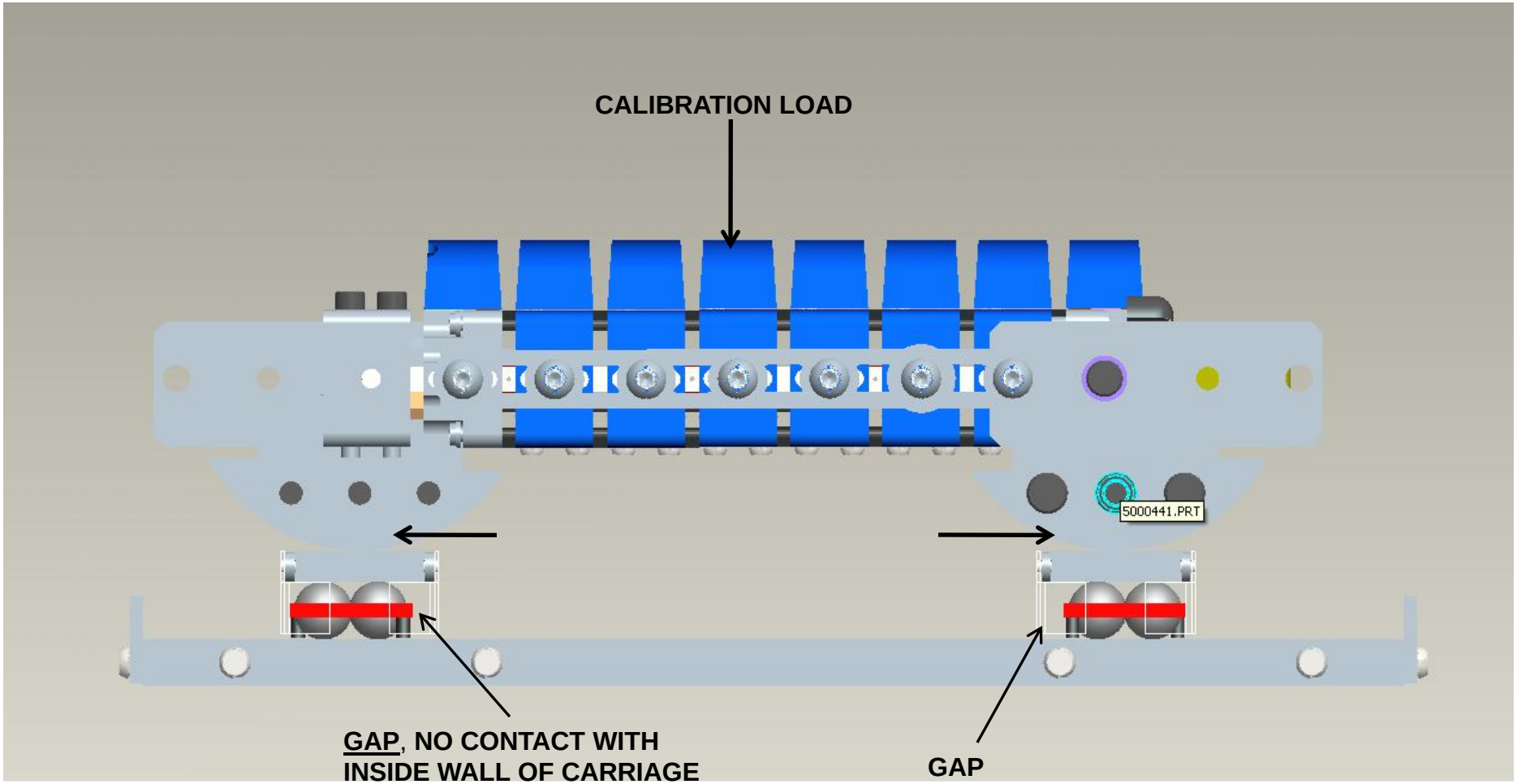
“GAP” BETWEEN BEARING RETAINER AND INSIDE CARRIAGE SKIRT WALL



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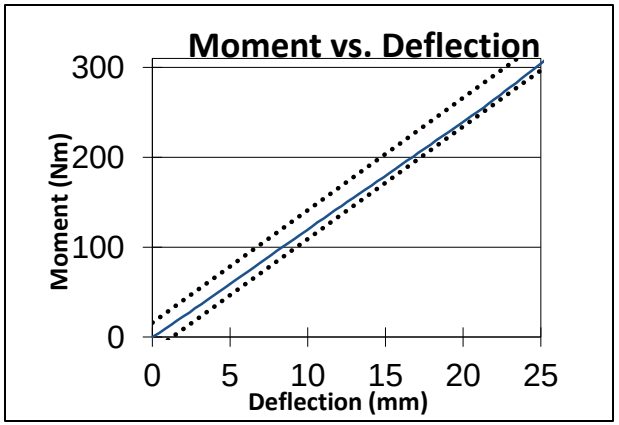
Gap Condition-Carriage NOT Contacting Bearing Retainer

TEST 1



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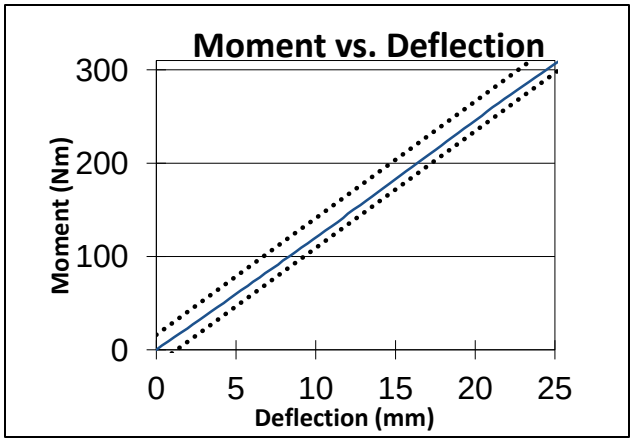
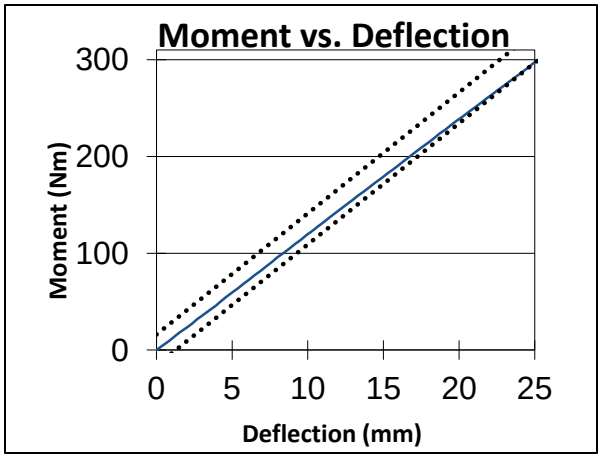
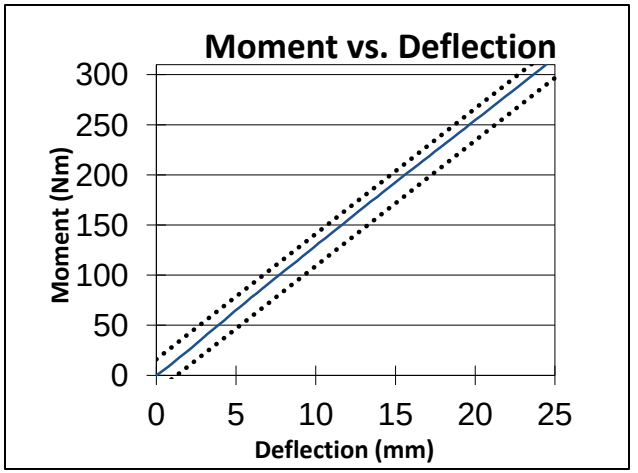


TEST 3



TEST 4 comparison no gap



TEST 4: **NO GAP**; SHIFTS CURVE TOWARD UP IN CORRIDOR

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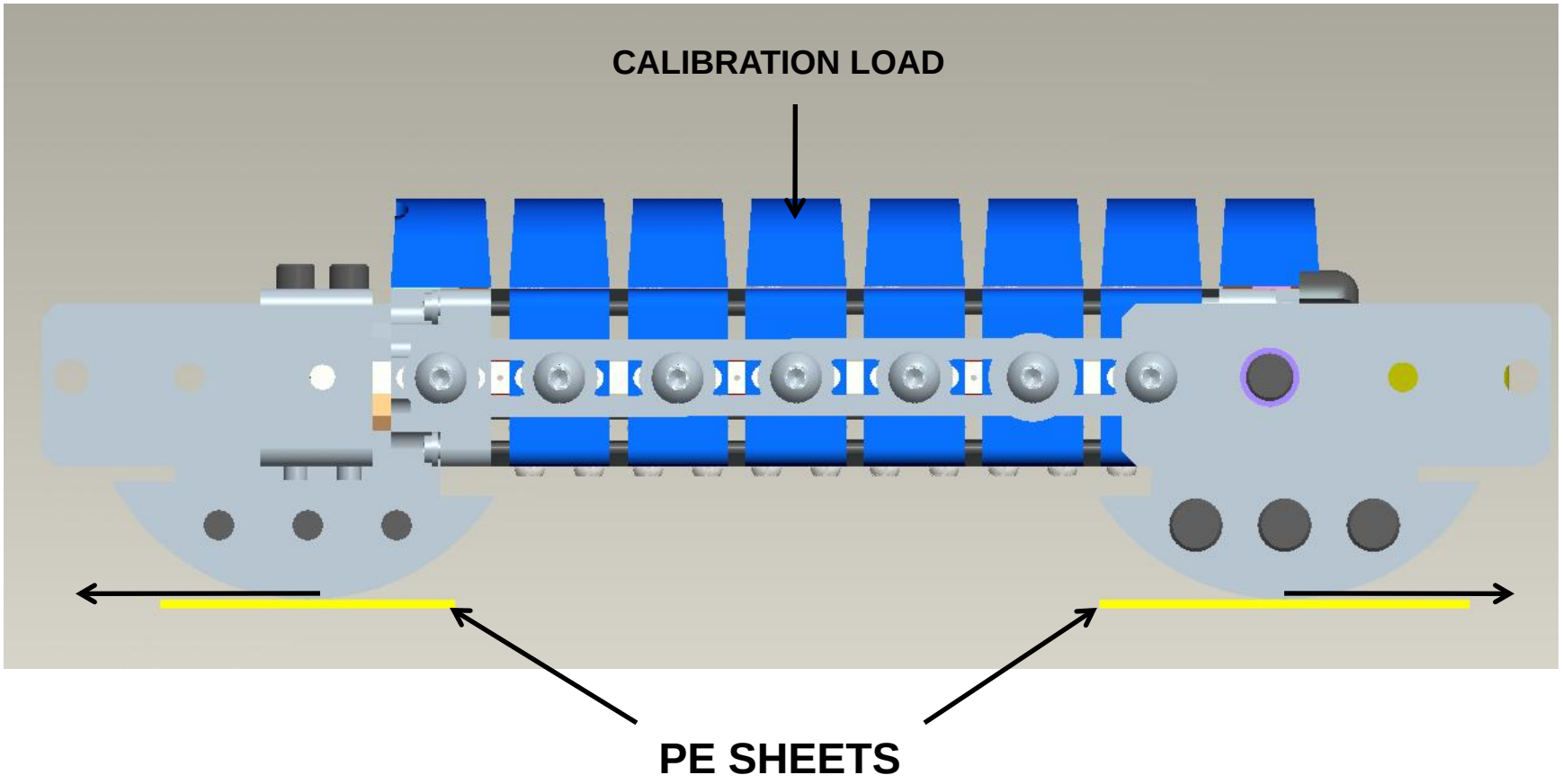
POLYETHYLENE SHEETS



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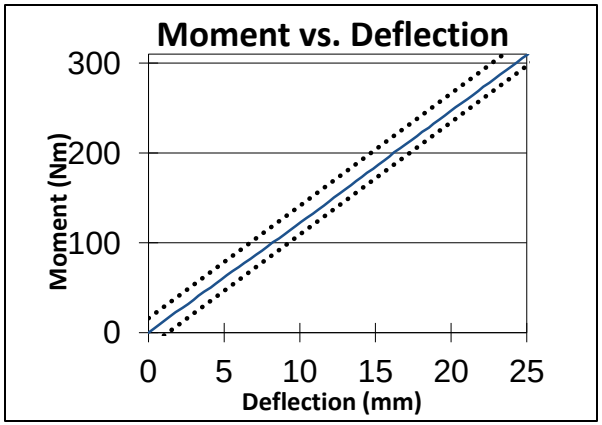
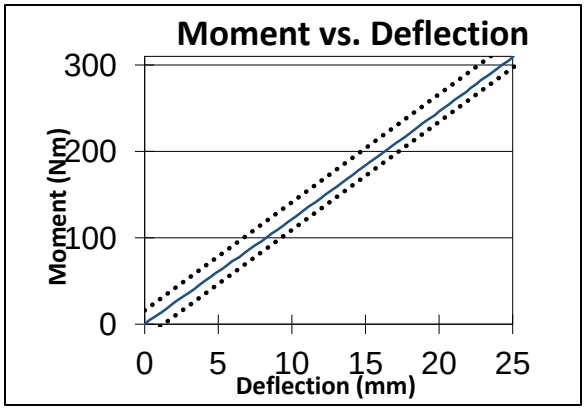
Polyethylene Sheet

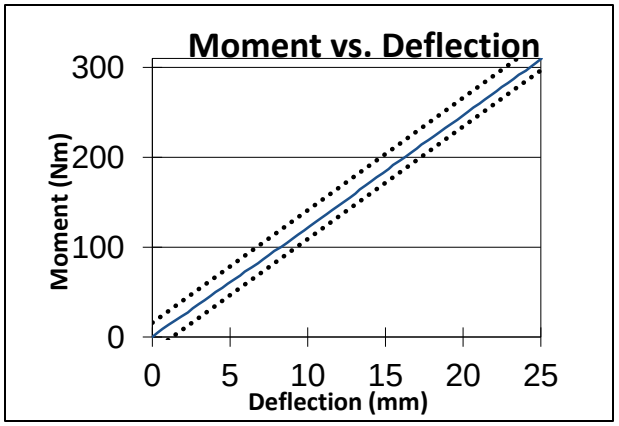
TEST 1



TEST 2



TEST 3



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Repeatability PE Sheet, Bearings Gap, Bearing no Gap at 310Nm

Bone snDH5239 B2 Bone PE sheet

	Test 1 (mV/V)	Test 2 (mV/V)	Test 3 (mV/V)
	13-Dec-11	13-Dec-11	13-Dec-11
Tibia G1	2.8252	2.8121	2.8088
Tibia G2	6.8432	6.833	6.8255
Tibia G3	8.8224	8.8069	8.8
Tibia G4	4.8693	4.8613	4.855

Max	Min	STDEV	AVERAGE	REPEATABLITY
2.8252	2.8088	0.0087	2.8154	0.31%
6.8432	6.8255	0.0089	6.8339	0.13%
8.8224	8.8000	0.0115	8.8098	0.13%
4.8693	4.8550	0.0072	4.8619	0.15%

Bone snDH5239 B2 bone No Gap

	Test 1 (mV/V)	Test 2 (mV/V)	Test 3(mV/V)	Test 4 (mV/V) *
	13-Dec-11	13-Dec-11	13-Dec-11	13-Dec-11
Tibia G1	2.6091	2.639	2.9735	2.6146
Tibia G2	6.6423	6.6836	6.8648	6.6508
Tibia G3	8.626	8.6711	8.8616	8.6734
Tibia G4	4.6629	4.6815	4.7924	4.6865

Max	Min	STDEV	AVERAGE	REPEATABILITY
2.9735	2.6091	0.1768	2.7091	6.53%
6.8648	6.6423	0.1045	6.7104	1.56%
8.8616	8.6260	0.1047	8.7080	1.20%
4.7924	4.6629	0.0586	4.7058	1.25%

* Test 4 was performed with a gap

Bone snDH5239 B2 bone With Gap

	Test 1 (mV/V)	Test 2 (mV/V)	Test 3 (mV/V)
	13-Dec-11	13-Dec-11	13-Dec-11
Tibia G1	2.993	2.7031	3.0612
Tibia G2	6.9039	6.8685	7.0549
Tibia G3	8.8937	8.8659	9.0449
Tibia G4	4.8508	5.0088	5.1084

Max	Min	STDEV	AVERAGE	REPEATABILITY
3.0612	2.7031	0.1901	2.9191	6.51%
7.0549	6.8685	0.0990	6.9424	1.43%
9.0449	8.8659	0.0963	8.9348	1.08%
5.1084	4.8508	0.1299	4.9893	2.60%

Repeatability PE Sheet testing 310, 350, & 400Nm

Bone snDH5255 B4 Bone PE sheet 310Nm

	Test 1 (mV/V)	Test 2 (mV/V)	Test 3 (mV/V)
	1/17/2012	1/17/2012	1/17/2012
Tibia G1	2.6867	2.6949	2.6982
Tibia G2	6.4230	6.4312	6.4299
Tibia G3	8.2923	8.3078	8.3073
Tibia G4	4.5694	4.5785	4.5790

STDEV	AVERAGE	REPEATABLITY
0.0059	2.6933	0.220%
0.0044	6.4280	0.069%
0.0088	8.3025	0.106%
0.0054	4.5756	0.118%
	AVERAGE	0.128%

Bone snDH5255 B4 Bone PE sheet 350Nm

	Test 1 (mV/V)	Test 2 (mV/V)	Test 3 (mV/V)
	1/17/2012	1/17/2012	1/17/2012
Tibia G1	3.0350	3.0488	3.0492
Tibia G2	7.2428	7.2578	7.2584
Tibia G3	9.3581	9.3729	9.3728
Tibia G4	5.1602	5.1741	5.1739

STDEV	AVERAGE	REPEATABLITY
0.0081	3.0443	0.266%
0.0088	7.2530	0.122%
0.0085	9.3679	0.091%
0.0080	5.1694	0.154%
	AVERAGE	0.158%

Bone snDH5255 B4 Bone PE sheet 400Nm

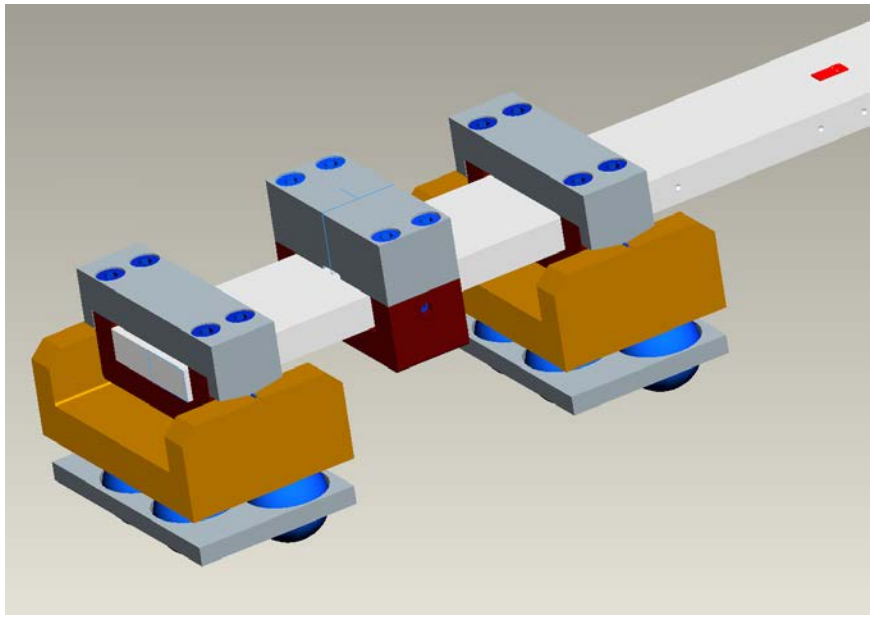
	Test 1 (mV/V)	Test 2 (mV/V)	Test 3 (mV/V)
	1/17/2012	1/17/2012	1/17/2012
Tibia G1	3.4662	3.4561	3.4627
Tibia G2	8.2435	8.2300	8.2442
Tibia G3	10.6432	10.6330	10.6452
Tibia G4	5.8755	5.8633	5.8731

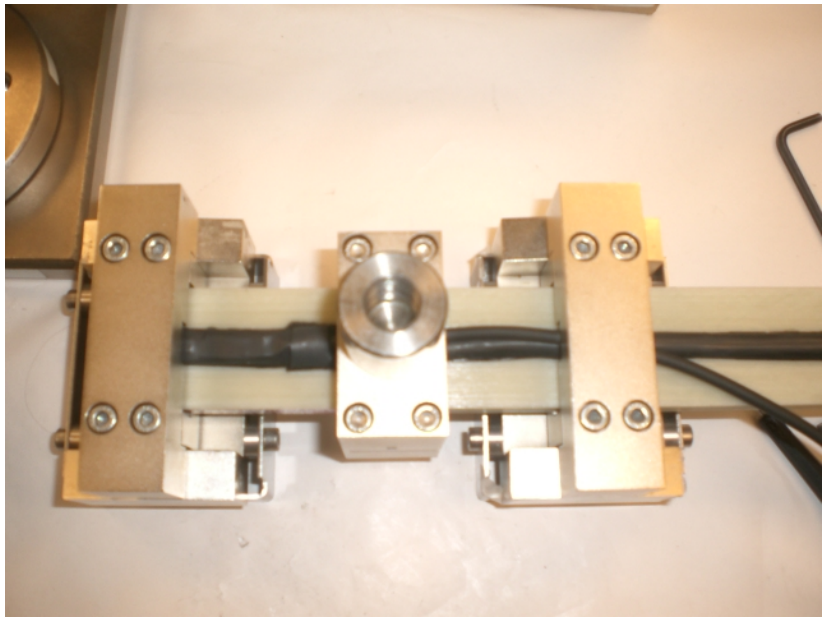
STDEV	AVERAGE	REPEATABLITY
0.0051	3.4617	0.148%
0.0080	8.2392	0.097%
0.0065	10.6405	0.061%
0.0065	5.8706	0.110%
	AVERAGE	0.104%

Bone sensitivity tests at 310Nm, 360Nm, and 400Nm

- Gage Sensitivities were calculated at 325Nm, 360Nm, and 400Nm for Tibia Bridge#3 for 4 separate bones.
- The greatest change in Nm due to the Sensitivities at 325Nm, 360Nm, and 400Nm is less than 1.7 Nm over all four bones after removing outliners.

Gage Calibration Fixture





Fixture used to establish gage sensitivity for each gage set. This has not changed roller pivots are used as agreed with TEG

BONE SN5255 SENSITIVITY

Test Bone DH5255			Load	Output	SENSITIVIITY
CALNUMBER	DATE	COMMENTS	Nm	mV/V	mV/V/Nm
48395	1/11/2012	Load #1	325.0	-9.847	-0.03030
48396	1/11/2012	Load #2	360.0	-10.936	-0.03038
48397	1/11/2012	Load #3	325.0	-9.851	-0.03031
48398	1/11/2012	Load #4	360.0	-10.929	-0.03036
48399	1/11/2012	Load #5	400.0	-12.111	-0.03028
48400	1/11/2012	Load #6	360.0	-10.925	-0.03035
48401	1/11/2012	Load #7	325.0	-9.846	-0.03030
48402	1/11/2012	Load #8	360.0	-10.934	-0.03037
48403	1/11/2012	Load #9	400.0	-12.118	-0.03030
48404	1/11/2012	Load #10	360.0	-10.934	-0.03037
48405	1/11/2012	Load #11	325.0	-9.846	-0.03030
48406	1/11/2012	Load #12	360.0	-10.929	-0.03036
48407	1/11/2012	Load #14	400.0	-12.118	-0.03029
48408	1/11/2012	Load #15	360.0	-10.930	-0.03036
48409	1/11/2012	Load #16	325.0	-9.844	-0.03029
	Sensitivity calculated at		400Nm	max	-0.03028
	Sensitivity calculated at		360Nm	min	-0.03038

Calculated output in mV at 300Nm, max sensitivity and 10Vdc -90.83153

Calculated output in mV at 300Nm, max sensitivity and 10Vdc -91.13192

Difference in Nm from max to min sensitivity at 300Nm 0.992

***Sensitivities are calculated at 325Nm, 360Nm, and 400Nm for Tibia Bridge#3.**

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BONE SN5239 SENSITIVITY

B2 Bone DH5239			Load	Output	SENSITIVIITY
CALNUMBER	DATE	COMMENTS	Nm	mV/V	mV/V/Nm
48591	1/19/2012	Load #1	325	-10.468	-0.03221
48592	1/19/2012	Load #2	360	-11.619	-0.03228
48593	1/19/2012	Load #3	400	-12.856	-0.03214
48594	1/19/2012	Load #4	360	-11.618	-0.03227
48595	1/19/2012	Load #5	325	-10.474	-0.03223
48596	1/19/2012	Load #6	360	-11.617	-0.03227
48597	1/19/2012	Load #7	400	-12.844	-0.03211
48598	1/19/2012	Load #8	360	-11.620	-0.03228
48599	1/19/2012	Load #9	325	-10.466	-0.03220
48600	1/19/2012	Load #10	360	-11.616	-0.03227
48601	1/19/2012	Load #11	400	-12.856	-0.03214
48602	1/19/2012	Load #12	360	-11.606	-0.03224
48603	1/19/2012	Load #13	325	-10.469	-0.03221
	Sensitivity calculated at		400Nm	max	-0.03211
	Sensitivity calculated at		360Nm	min	-0.03228

Calculated output in mV at 300Nm, max sensitivity and 10Vdc	-96.32940
Calculated output in mV at 300Nm, max sensitivity and 10Vdc	-96.83592
Difference in Nm from max to min sensitivity at 300Nm	1.577

***Sensitivities are calculated at 325Nm, 360Nm, and 400Nm for Tibia Bridge#3.**

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BONE SN5242 SENSITIVITY

B3 Bone DH5242			Load	Output	SENSITIVIITY
CALNUMBER	DATE	COMMENTS	Nm	mV/V	mV/V/Nm
48565	1/19/2012	Load #1 B3	325	-9.647	-0.02968
48566	1/19/2012	Load #2 B3	360	-10.992	-0.03053
48567	1/19/2012	Load #3 B3	400	-12.169	-0.03042
48568	1/19/2012	Load #4 B3	360	-11.000	-0.03056
48569	1/19/2012	Load #5 B3	325	-9.925	-0.03054
48570	1/19/2012	Load #6 B3	360	-11.015	-0.03060
48571	1/19/2012	Load #7 B3	400	-12.177	-0.03044
48572	1/19/2012	Load #8 B3	360	-11.010	-0.03058
48573	1/19/2012	Load #9 B3	325	-9.923	-0.03053
48574	1/19/2012	Load #10 B3	360	-11.012	-0.03059
48575	1/19/2012	Load #11 B3	400	-12.184	-0.03046
48576	1/19/2012	Load #12 B3	360	-11.009	-0.03058
48577	1/19/2012	Load #13 B3	325	-9.928	-0.03055
	Sensitivity calculated at		325Nm	max	-0.02968
	Sensitivity calculated at		360Nm	min	-0.03060
Calculated output in mV at 300Nm, max sensitivity and 10Vdc				-89.05265	
Calculated output in mV at 300Nm, max sensitivity and 10Vdc				-91.78792	
Difference in Nm from max to min sensitivity at 300Nm				9.215	
Take out -0.02968 sensitivity because is a outliner					
	Sensitivity calculated at		400Nm	max	-0.03042
	Sensitivity calculated at		360Nm	min	-0.03060
Calculated output in mV at 300Nm, max sensitivity and 10Vdc				-91.26803	
Calculated output in mV at 300Nm, max sensitivity and 10Vdc				-91.78792	
Difference in Nm from max to min sensitivity at 300Nm				1.709	

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BONE SN3439 SENSITIVITY

B4 Bone DI3490			Load	Output	SENSITIVIITY
CALNUMBER	DATE	COMMENTS	Nm	mV/V	mV/V/Nm
48578	1/19/2012	Load #1 B4	325	-9.862	-0.03035
48579	1/19/2012	Load #2 B4	360	-11.140	-0.03095
48580	1/19/2012	Load #3 B4	400	-12.339	-0.03085
48581	1/19/2012	Load #4 B4	360	-11.158	-0.03099
48582	1/19/2012	Load #5 B4	325	-10.065	-0.03097
48583	1/19/2012	Load #6 B4	360	-11.161	-0.03100
48584	1/19/2012	Load #7 B4	400	-12.350	-0.03088
48585	1/19/2012	Load #8 B4	360	-11.168	-0.03102
48586	1/19/2012	Load #9 B4	325	-10.062	-0.03096
48587	1/19/2012	Load #10 B4	360	-11.165	-0.03101
48588	1/19/2012	Load #11 B4	400	-12.356	-0.03089
48589	1/19/2012	Load #12 B4	360	-11.161	-0.03100
48590	1/19/2012	Load #13 B4	325	-10.062	-0.03096
	Sensitivity calculated at		325Nm	max	-0.03035
	Sensitivity calculated at		360Nm	min	-0.03102

Calculated output in mV at 300Nm, max sensitivity and 10Vdc -91.03625

Calculated output in mV at 300Nm, max sensitivity and 10Vdc -93.06417

Difference in Nm from max to min sensitivity at 300Nm 6.683

Take out -0.03035 sensitivity because is a outliner

	Sensitivity calculated at	400Nm	max	-0.03085
	Sensitivity calculated at	360Nm	min	-0.03102

Calculated output in mV at 300Nm, max sensitivity and 10Vdc -92.54123

Calculated output in mV at 300Nm, max sensitivity and 10Vdc -93.06417

Difference in Nm from max to min sensitivity at 300Nm 1.695

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Round Robin test series available legs

- SN02, 03, Eng leg
- SN 01 from Ford (end of January)
- SN05 (end of January)
- Ford U.S has offered to run round robin testing on inverse only
- Old legs to be refurbished new meniscus, covers and any worn parts.

Round Robin Test Requirements Discussion

- Data to Record
- Inverse Test
  - Hexcell used
  - Velocity measurement system used
  - Record Impact location
  - Weight of probe
  - Describe system
    - Air, hydraulic
  - Pictures of set up
    - Preparation and post test
  - Movies, if possible
- Pendulum Test
  - Angle of drop
  - Weight of leg and additional mass
  - Confirm GTR rig dimension requirements
  - Pictures of set up/movies if possible
- Test Series
  - 5 Pendulum
  - 5 inverse test
  - Propose use onboard DAS, provide with each leg. This is how it is tested and gives more accurate result due to shorter cables.
  - Laptop/s can be provided with legs as option to run both DAS systems?
  - Which labs are willing to participate in RR testing?
  - Format for recording data?
  - Set up checks according to manual

Proposed FLEX-PLI Round Robin Legs Receive and Build Structure

- Photograph contents of case on arrival.
- Document the serial numbers of all existing parts. Parts not being used for RR to be stored in dedicated box.
- Disassemble the knee, check condition of parts for wear or damage. Calibrate the GTR ligament string pots. If any parts need replacement replace and add to dedicated box.
- Reassemble the knee. Adjust the springs so that washers are flush with knee block. Place knee calibration data, ligament calibration data and accelerometer calibration data in a folder and in its case.
- Fit onboard DAS and check and record weight and cg. Send to JARI for testing
- Prepare 6-10 sets of bones, mid corridor on JARI bone fixture
- Disassemble the tibia assembly. Place the original instrumented tibia bone in the removed parts box. Check condition of parts for wear or damage. Bag tibia parts and ship to JARI with new bones.

Proposed FLEX-PLI Round Robin Legs Receive and Build Structure continued

- JARI tests bones to check mid corridor stiffness
- JARI builds the tibia assembly as per manual instruction and calibrates. Assemblies then sent back to Humanetics.
- Humanetics rechecks component assembly and records tibia weight and cg on test rig
- Femur instruction to be as tibia above
- After parts have been calibrated, assemble the leg as per manual instruction. Check and record leg total weight with flesh.
- Perform 5 dynamic pendulum tests.
- Perform 5 dynamic inverse tests
- After testing remove flesh from leg and box up so that it can be shipped to JARI

Time Table

- January – February
  - Humanetics prepares 6 to 10 bone sets for JARI bone check and component testing including knee
  - Humanetics will need JARI bone fixture to confirm set up of bones in middle of corridor before sending.
- February –March
  - JARI checks bones are in the middle of the bone stiffness corridor, assemble and carry out component sub assemble test and set corridors as required.
- March-April
  - JARI sends component assemblies to Humanetics to retest and compare results
- April-June
  - Humanetics sends legs to JARI for dynamic testing. Start round robin. Humanetics and JARI analyze results and set corridors for agreement with Informal Group

CONCLUSIONS

- Propose use of PE sheet for static testing
- Propose gage sensitivity is calculated at 340 Nm to provide accurate result at injury threshold
- Send out revised manual for build and leg use