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

- Short rubber flesh was discovered to be used when Inverse corridors were developed.
- Tests were carried out to compare the difference.
  - The Long and Short rubber had more affect on the Inverse than the Pendulum tests.
  - The short rubber Tibia Inverse moments increase 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

				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	%		

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

				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	%		

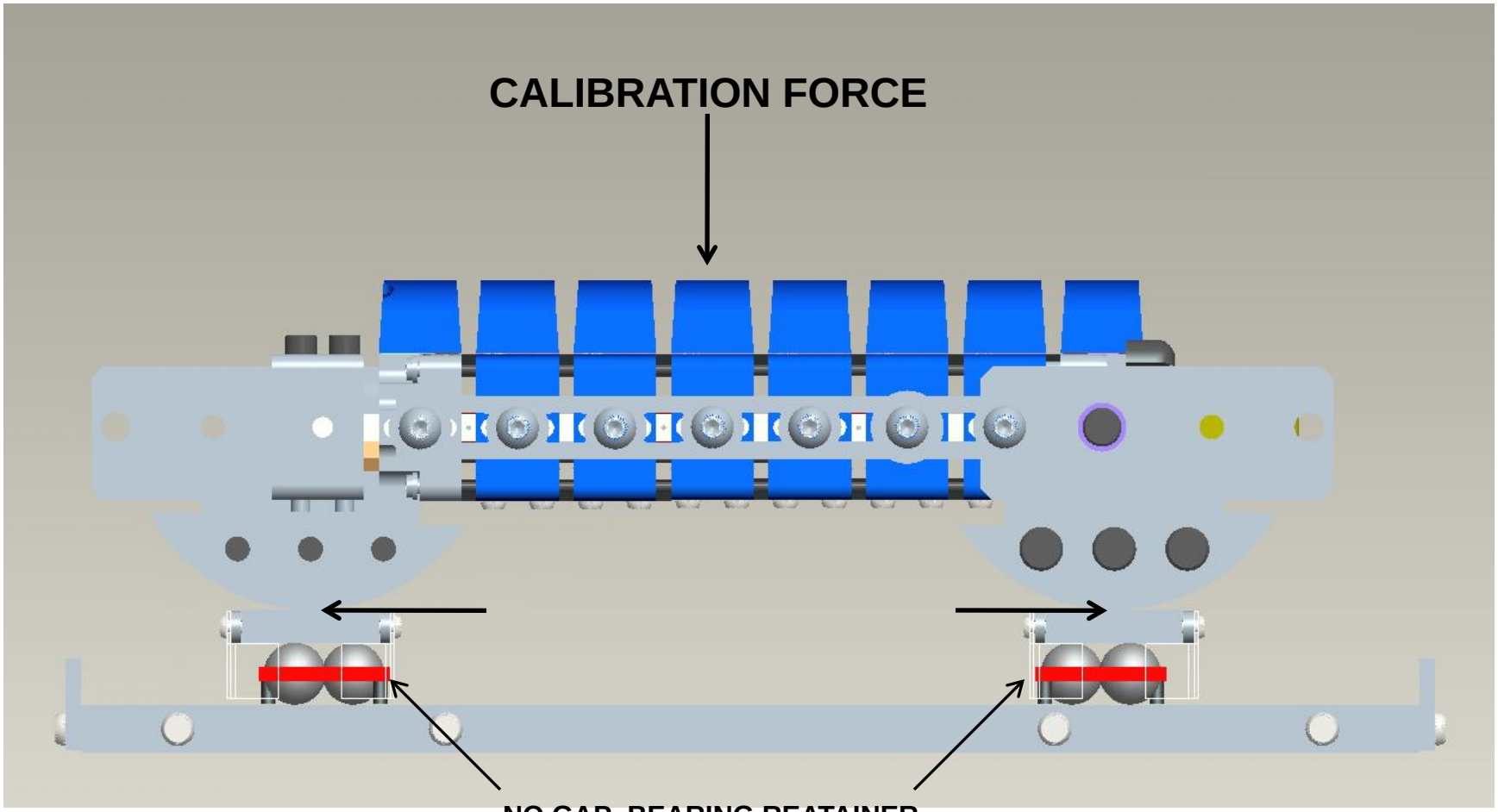
PE sheet verses bearing assembly Summary

- 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:
  - Humanetics fixture with “NO GAP” between carriage and bearing retainer plate
  - Humanetics fixture with a “GAP” between the carriage and bearing retainer plate
  - JARI Polyethelyne Sheet

- The observed responses are as follows.
  - The Humanetics 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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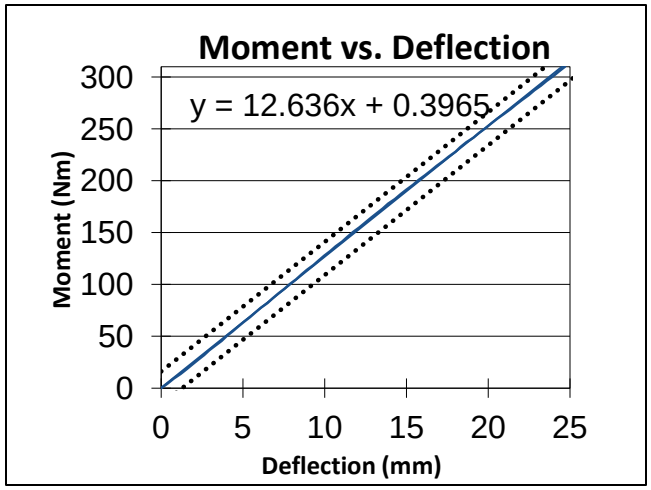
"NO GAP" CONDITION-CARRIAGE SKIRT CONTACTING BEARING RETAINER

TEST 1



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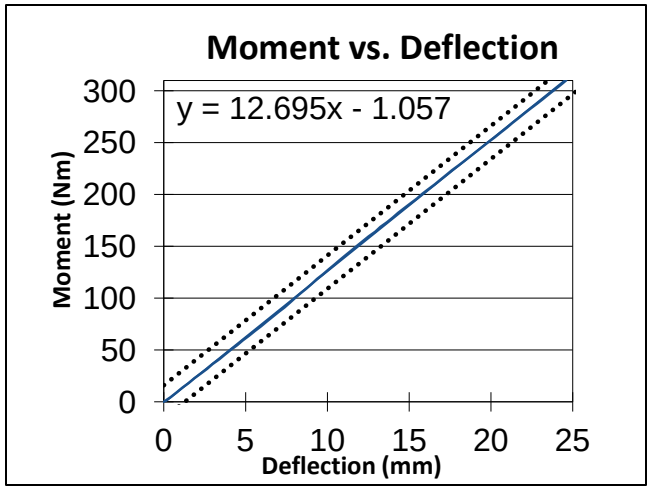
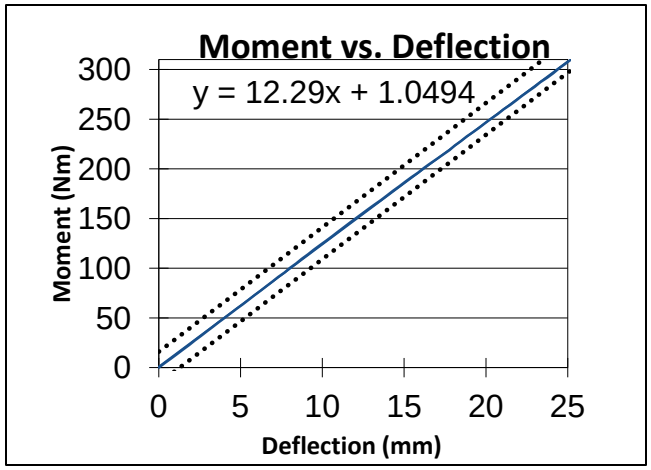


TEST 3



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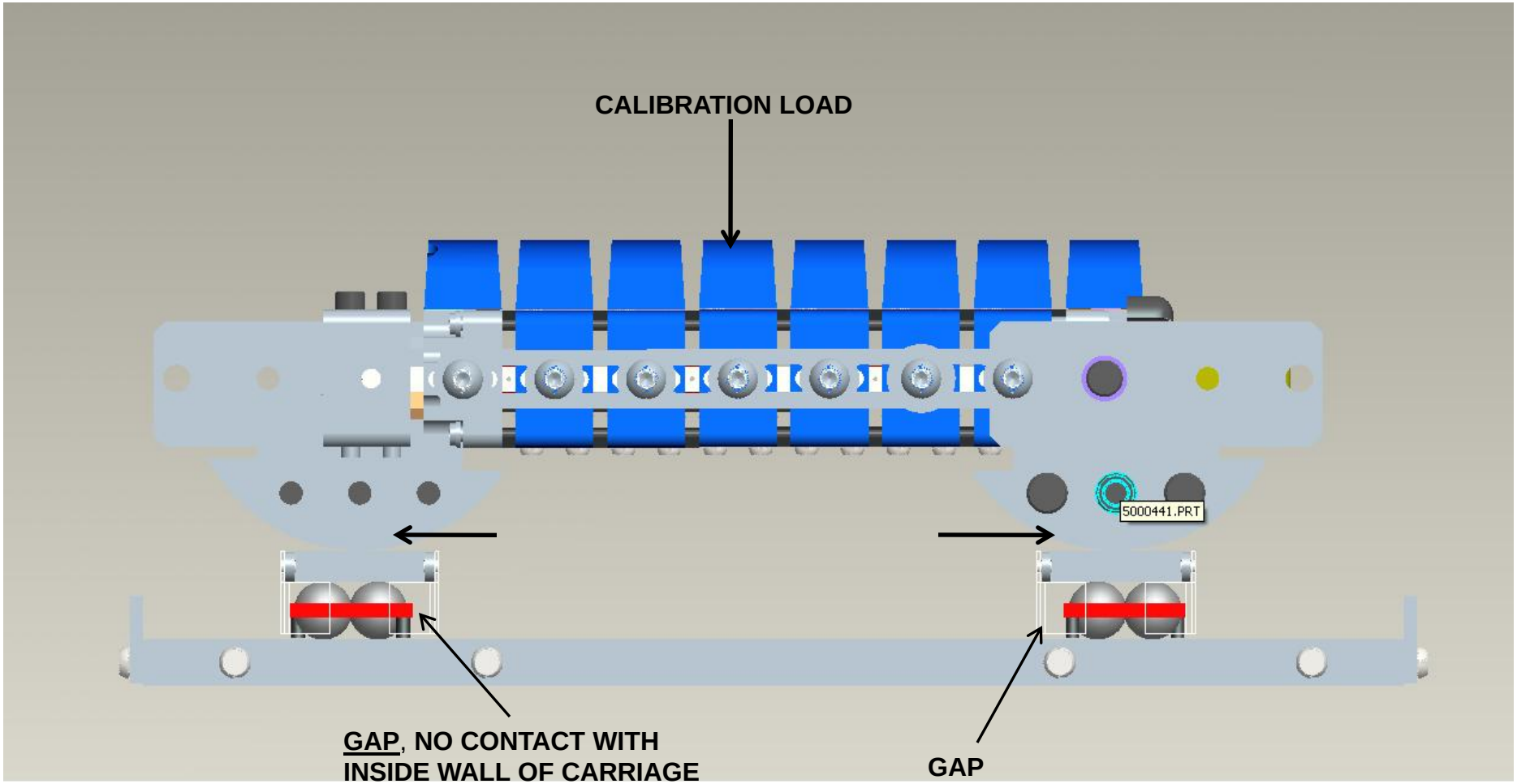
“GAP” BETWEEN BEARING RETAINER AND INSIDE CARRIAGE SKIRT WALL



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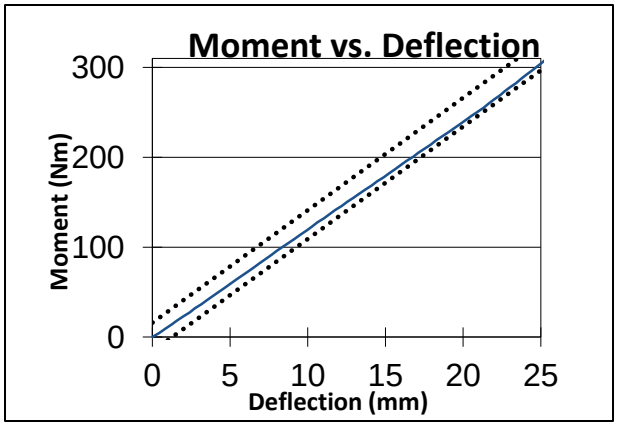
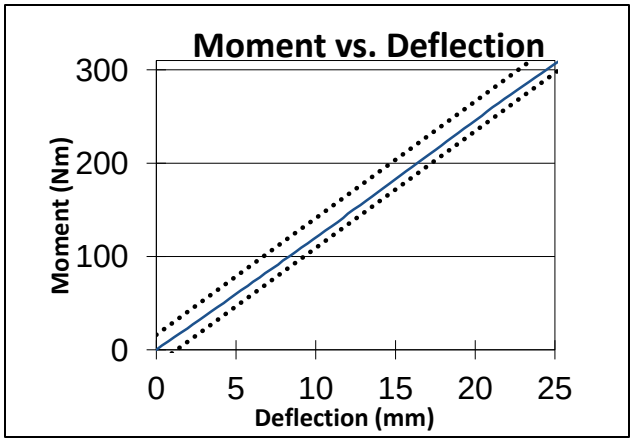
Gap Condition-Carriage NOT Contacting Bearing Retainer

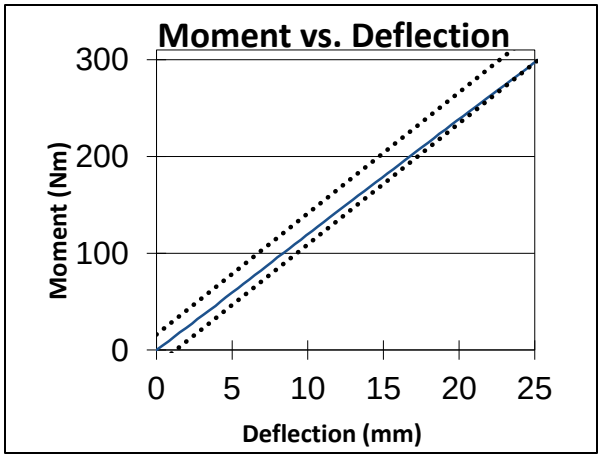
TEST 1



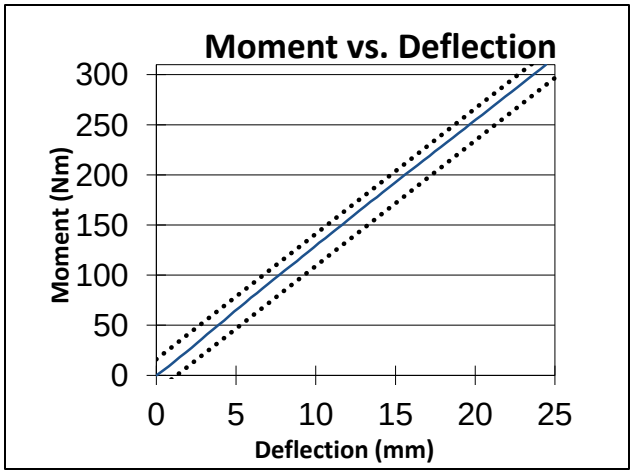
TEST 2



TEST 3



TEST 4 comparison no gap



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

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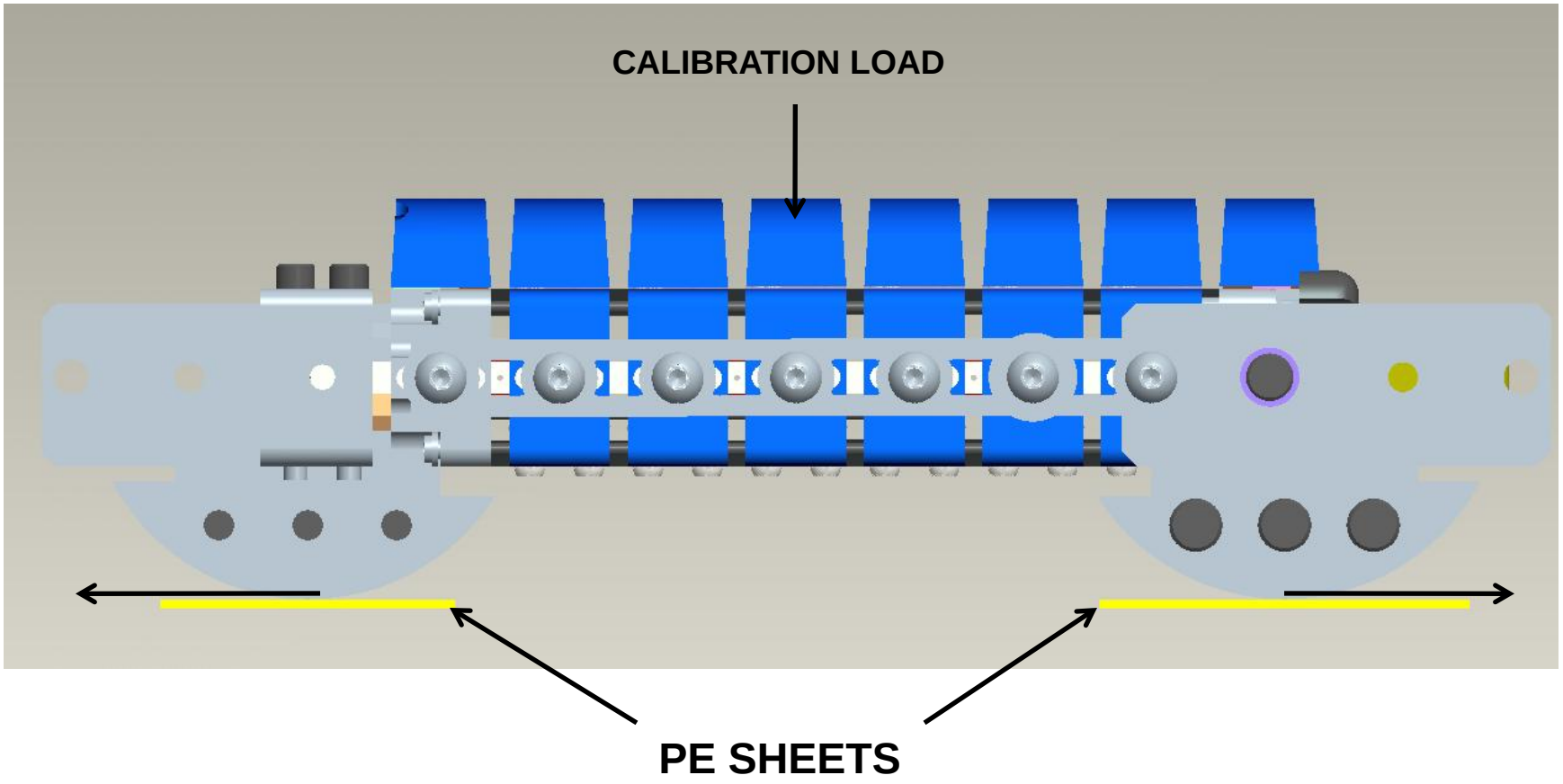
POLYETHYLENE SHEETS



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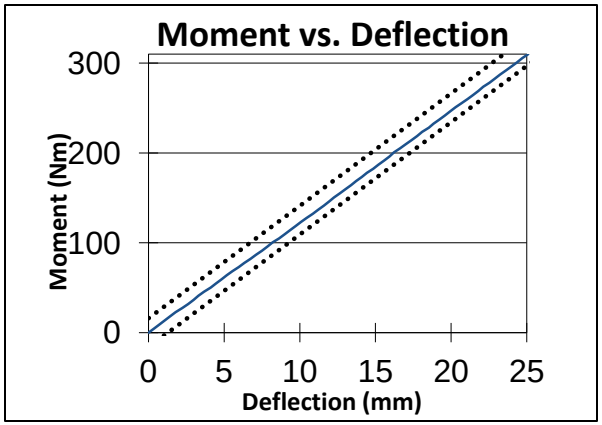
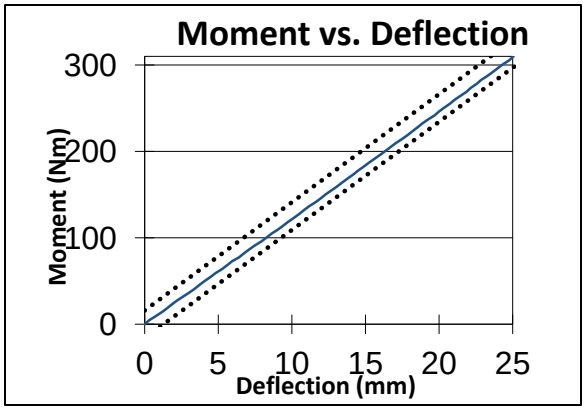
Polyethylene Sheet

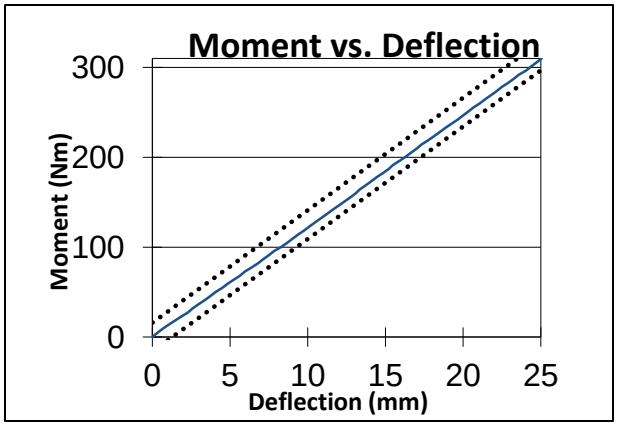
TEST 1



TEST 2



TEST 3



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Repeatability PE Sheet, Bearings Gap, Bearing no Gap

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 Nm over all four bones.

BONE SN5255 SENSITIVITY

FLEX PLI BONE SENSITIVITY REPEATILIBILITY TEST

Test Bone DH5255

Load	Output	SENSITIVIITY
325.0	-9.847	-0.03030
360.0	-10.936	-0.03038
325.0	-9.851	-0.03031
360.0	-10.929	-0.03036
400.0	-12.111	-0.03028
360.0	-10.925	-0.03035
325.0	-9.846	-0.03030
360.0	-10.934	-0.03037
400.0	-12.118	-0.03030
360.0	-10.934	-0.03037
325.0	-9.846	-0.03030
360.0	-10.929	-0.03036
400.0	-12.118	-0.03029
360.0	-10.930	-0.03036
325.0	-9.844	-0.03029

SENSITIVITY 325 Nm	SENSITIVITY 360Nm	SENSITIVITY 400Nm
AVG	AVG	AVG
-0.03030	-0.03036	-0.03029
% DIFFERENCE 325 to 360Nm	% DIFFERENCE 325 to 400Nm	% DIFFERENCE 360 to 400Nm
0.00218	0.00028	0.00247
STDEV	STDEV	STDEV
0.000008	0.000010	0.000010
REPEATILBILITY	REPEATILBILITY	REPEATILBILITY
-0.027%	-0.032%	-0.034%

DIFFERENCE BECAUSE SENSITIVITY LOAD CHANGE IN Nm AT MID CORRIDOR

T1	0.6337	T2	0.6066
T3	0.4685	T4	0.2688

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

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BONE SN5239 SENSITIVITY

FLEX PLI BONE SENSITIVITY REPEATILIBILITY TEST

Test Bone DH5239

Load	Output	SENSITIVIITY
325.0	-10.468	-0.03221
360.0	-11.619	-0.03228
400.0	-12.856	-0.03214
360.0	-11.618	-0.03227
325.0	-10.474	-0.03223
360.0	-11.617	-0.03227
400.0	-12.844	-0.03211
360.0	-11.620	-0.03228
325.0	-10.466	-0.03220
360.0	-11.616	-0.03227
400.0	-12.856	-0.03214
360.0	-11.606	-0.03224
325.0	-10.469	-0.03221

SENSITIVITY 325 Nm	SENSITIVITY 360Nm	SENSITIVITY 400Nm
AVG	AVG	AVG
-0.03221	-0.03227	-0.03213
% DIFFERENCE 325 to 360Nm	% DIFFERENCE 325 to 400Nm	% DIFFERENCE 360 to 400Nm
0.00168	0.00258	0.00426
STDEV	STDEV	STDEV
0.000010	0.000015	0.000017
REPEATILBILITY	REPEATILBILITY	REPEATILBILITY
-0.032%	-0.046%	-0.053%

DIFFERENCE BECAUSE SENSITIVITY LOAD CHANGE IN Nm AT MID CORRIDOR

T1	0.6638	T2	0.6354
T3	0.4908	T4	0.2815

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

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BONE SN3490 SENSITIVITY

FLEX PLI BONE SENSITIVITY REPEATILIBILITY TEST

B4 Bone DI3490			SENSITIVITY	SENSITIVITY	SENSITIVITY
Load	Output	SENSITIVIITY	325 Nm	360Nm	400Nm
325.0	-9.862	-0.03035	AVG	AVG	AVG
360.0	-11.140	-0.03095	-0.03081	-0.03100	-0.03087
400.0	-12.339	-0.03085			
360.0	-11.158	-0.03099	% DIFFERENCE	% DIFFERENCE	% DIFFERENCE
325.0	-10.065	-0.03097	325 to 360Nm	325 to 400Nm	360 to 400Nm
360.0	-11.161	-0.03100	0.61%	-0.20%	0.41%
400.0	-12.350	-0.03088			
360.0	-11.168	-0.03102	STDEV	STDEV	STDEV
325.0	-10.062	-0.03096	0.000309	0.000027	0.000022
360.0	-11.165	-0.03101			
400.0	-12.356	-0.03089	REPEATILBILITY	REPEATILBILITY	REPEATILBILITY
360.0	-11.161	-0.03100	-1.002%	-0.087%	-0.071%
325.0	-10.062	-0.03096			

DIFFERENCE BECAUSE SENSITIVITY LOAD CHANGE IN Nm AT MID CORRIDOR

T1	0.5214	T2	0.4991
T3	0.3854	T4	0.2211

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

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BONE SN5239 SENSITIVITY

FLEX PLI BONE SENSITIVITY REPEATILIBILITY TEST

B3 Bone DH5242			SENSITIVITY	SENSITIVITY	SENSITIVITY
Load	Output	SENSITIVIITY	325 Nm	360Nm	400Nm
325.0	-9.647	-0.02968	AVG	AVG	AVG
360.0	-10.992	-0.03053	-0.03033	-0.03057	-0.03044
400.0	-12.169	-0.03042			
360.0	-11.000	-0.03056	% DIFFERENCE	% DIFFERENCE	% DIFFERENCE
325.0	-9.925	-0.03054	325 to 360Nm	325 to 400Nm	360 to 400Nm
360.0	-11.015	-0.03060	0.81%	-0.38%	0.43%
400.0	-12.177	-0.03044			
360.0	-11.010	-0.03058	STDEV	STDEV	STDEV
325.0	-9.923	-0.03053	0.000428	0.000024	0.000018
360.0	-11.012	-0.03059			
400.0	-12.184	-0.03046	REPEATILBILITY	REPEATILBILITY	REPEATILBILITY
360.0	-11.009	-0.03058	-1.411%	-0.078%	-0.060%
325.0	-9.928	-0.03055			

DIFFERENCE BECAUSE SENSITIVITY LOAD CHANGE IN Nm AT MID CORRIDOR

T1	0.9748	T2	0.9331
T3	0.7207	T4	0.4134

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

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Round Robin test series 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

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
- 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?

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