First Technology Safety Systems

Design Freeze Status

Flex-PLI-GTR Development
Full Calibration Test Procedures

Bernard Been
FTSS Europe
Comments addressed from Design Freeze meeting
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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)

1. **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

2. **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

3. **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

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

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*IARV : Injury Assessment Reference Value*
Conduct this kind of test at center position of each gages

Load transducer (type: KYOWA LU-1TE)

Quasi static
$V = 10 \text{ mm/min}$

Ram
(Surface shape: $r = 25 \text{ mm}$)

Support length: 130 mm

$F_c$ $\frac{F}{2}$ $\frac{F}{2}$

Moment $M$ (Nm) = $\frac{F}{2} \times 65 / 1000$
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 $\delta L$ 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 ≤ 1% of full scale capacity
  - Non-linearity ≤ 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

<table>
<thead>
<tr>
<th>Bone Calibration Procedure</th>
<th>GTR</th>
</tr>
</thead>
<tbody>
<tr>
<td>thickness [mm]</td>
<td>10.5</td>
</tr>
<tr>
<td>Width [mm]</td>
<td>40</td>
</tr>
<tr>
<td>Youngs modulus JARI spec F45 <strong>4500 kg/mm²</strong></td>
<td>44145</td>
</tr>
<tr>
<td>Ultimate strength <strong>70kg/mm²</strong> [N/mm²]</td>
<td>687</td>
</tr>
<tr>
<td>Distance support [mm]</td>
<td>130</td>
</tr>
<tr>
<td>Test load [N]</td>
<td><strong>10000</strong></td>
</tr>
<tr>
<td>Test load centre [N*m] (peak 350Nm)</td>
<td>325</td>
</tr>
<tr>
<td>Bone bending Radius at loading point [mm]</td>
<td>524.1</td>
</tr>
<tr>
<td>Vertical deflection [mm]</td>
<td>2.69</td>
</tr>
<tr>
<td>Horizontal bone shortening estimate triangle [mm]</td>
<td>0.19</td>
</tr>
<tr>
<td>Horizontal bone shortening estimate Circle [mm]</td>
<td>0.33</td>
</tr>
<tr>
<td>Horizontal bone shortening average Circle/triangle [mm]</td>
<td><strong>0.26</strong></td>
</tr>
<tr>
<td>Error due to support distance variation [%]</td>
<td>-0.00247</td>
</tr>
<tr>
<td>Error due to support distance accuracy 0.2mm [%]</td>
<td>0.15385</td>
</tr>
<tr>
<td>Error due to friction roll pin 2.0mm diam [%]</td>
<td>0.15385</td>
</tr>
<tr>
<td>Max error due to calibration load cell [%]</td>
<td>0.12000</td>
</tr>
<tr>
<td><strong>Total error [%]</strong></td>
<td><strong>0.43017</strong></td>
</tr>
<tr>
<td>Peak strain [micro strain]</td>
<td>10.0</td>
</tr>
</tbody>
</table>
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 (1MPa=1N/mm²)
  - 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
Step 2: Long Bone Tibia and Femur
Quasi-static 3-Point Bending Test

Knee side of tibia bone core

Support (rotate)

205 mm

Support Length: 410 mm

$F_{c/2}$

$F_{p}$

$D_{c}$

Sectional image

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

FLEX-PLI-GTR Development, March 31st, 2008
Long Bone Assembly Calibration

- Load up to IRAV [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
Step 2: Knee
Quasi-static 3-Point Bending Test

Tentative corridor
Test results

Tentative corridor
Test results

Tentative corridor
Test results

Tentative corridor
Test results

Moment: Mc (Nm)

Elongation: MCL (mm)

Elongation: ACL (mm)

Elongation: PCL (mm)

Force: Fc (N)
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 ±10% from average

FLEX-PLI-GTR Development, January 4, 2008
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

Type A-2: With additional weight 5 kg

Mount pivot at tibia
Design frozen!