LDA®, Automated Dynamic Laximetry

Knee ligament analysis

- in tibial translation
- in tibial rotation
The company GENOUROB specializes in design, production and marketing of medical devices for the evaluation of the state and performance of the ligamentous structures of the knee.

We invite you with this document to discover the method LDA®, Automated Dynamic Laximetry, with its devices and their patented innovations.

We thank you for your interest and we remain at your disposal for any further information.

Stéphane Nouveau
President and CEO
NEW: inclusion of the slopes parameter in the functional analysis

So far only measuring the laxity differential, without consideration of the gradients of the curves (inverse of the stiffness) did not allow a comprehensive analysis of the ligament status (Bercovy and Weber*). The LDA®, during translation pushes from 1 to 200 N (300 N maximum), registers more than 50 values of displacement, thus establishing accurate elongation curves with calculated slopes, giving objective assessment of the state of resistance of the Anterior Cruciate Ligament (H. Robert**).

The GNRB® detects incomplete and complete ACL ruptures and allows a functional analysis of the ligament.

NEW: induced medial rotation

The detection of incomplete ACL injuries is optimized by registering the medial rotation coupled to the anterior tibial translation. In this, a variation of rotation is measured, validated, thus indicating the risk of a partial ACL injury (P. Christel***). This innovation characterizes the GNRB Rotab.

PCL injuries

Lesions of the Posterior Cruciate Ligament are likewise detectable with the LCP module (option), providing an automated posterior translation.

GNRB, more than just simple Laximetry!

Many technical innovations such as a biofeedback system avoiding false negatives, characterize the GNRB to optimize the accuracy and the reproducibility of the tests.

* M. Bercovy & al. RCO; 1995; 81, 114-127,
** H. Robert, & al. OTSR.2009; 95, 171-176
Parameters in automated tibial translation

Automated tibial translation parameters

**GNRB - GNRB Rotab** (H. Robert, Isakos, Rio 2011)

<table>
<thead>
<tr>
<th>Differential of displacements ((\Delta 134) in mm)</th>
<th>Ligament state</th>
</tr>
</thead>
<tbody>
<tr>
<td>(\Delta 134 &gt; 3)</td>
<td>Complete lesion (according to (\Delta P2))</td>
</tr>
<tr>
<td>(1 &lt; \Delta 134 &lt; 3)</td>
<td>Partial lesion (according to (\Delta P2))</td>
</tr>
<tr>
<td>(\Delta 134 &lt; 1)</td>
<td>No lesion</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Differential of slopes ((\Delta P2) in (\mu m/N))</th>
<th>Risk of functional instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>(\Delta P2 &gt; 10)</td>
<td>High</td>
</tr>
<tr>
<td>(5 &lt; \Delta P2 &lt; 10)</td>
<td>Medium</td>
</tr>
<tr>
<td>(\Delta P2 &lt; 5)</td>
<td>Low</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Differential of rotations ((\Delta \theta) in degree)</th>
<th>Risk of lesion of PL bundle</th>
</tr>
</thead>
<tbody>
<tr>
<td>(\Delta \theta &gt; 3)</td>
<td>High</td>
</tr>
<tr>
<td>(\Delta \theta &lt; 3)</td>
<td>Low</td>
</tr>
</tbody>
</table>

At induced medial rotation / GNRB Rotab

For identical \(\Delta 134\), only the inclusion of the differential of the slopes permits an efficient functional analysis of the ligament state. This one is different according to the differential of the slopes \(\Delta P2\) (parallelism or divergence of the curves) associated with the differential of the displacements \(\Delta 134\).

For identical \(\Delta 134\), only the inclusion of the differential of the slopes permits an efficient functional analysis of the ligament state. This one is different according to the differential of the slopes \(\Delta P2\) (parallelism or divergence of the curves) associated with the differential of the displacements \(\Delta 134\).

To the left: no risk of functional instability

To the right: risk of functional instability

Preoperative control

\(\Delta 134 = 5,2, \Delta P2 = 15, \Delta \theta = 2\)

Objectification of a clinical Lachman's test (GNRB Rotab)

Complete rupture (no resistance to the push; high inclination...)

Similar \(\Delta 134 = 1,5\) mm but different slopes of curves

DIFFERENT FUNCTIONAL ANALYSIS
An additional evaluation of the peripheral knee ligament structures

The innovation of the LDA® measurement of controlled tibial rotation is to permit an objective and rigorous evaluation of the rotational laxities.

The LDA® method allows a new approach to lesional damages of the peripheral ligament structures that may be involved in the rotational instability.

A simple and fast method

Patient data is stored and the fixation parameters of the ankle and the femur are saved, a motor-torque of 1 to 8 Nm is applied to the tibia-ankle-foot block with a registration of the provoked rotation, as well medial as lateral.

The very strict and tight fixation of the tibia ensures a clear measurement of the tibial rotation without reading errors by parasite movements of the foot joints.

By comparing the measurements, the LDA® software displays the ligament elongation curves and the differential of rotation of both knees.

Automated measurements, reproducible and accurate!

Many technical innovations in the laximetry, such as the Biofeedback system detecting the hamstring muscle contractions (risk of false negatives), also characterize the ROTAM.

Objective preoperative assessments

Clinical or by MRI, lesions of peripheral ligament structures are sometimes difficult to verify and to quantify accurately.

The test in controlled tibial rotation stresses these structures to detect the peripheral lesions.

- In medial rotation: an important differential of rotation indicates an affected ACL and anterior-lateral tibial structure (possible choice of an additional extra-articular surgery in association with ACL).
- In lateral rotation: an important differential of rotation indicates an affected ACL and posterior-lateral tibial structure (possible choice of an additional extra-articular surgery in association with ACL).

Controlling postoperative results

Postoperative, the LDA® test of controlled tibial rotation demonstrates the efficacy of the "rotational brakes" and the quality of repairs at the ACL and at the peripheral structures.

The complementary partners ROTAM and GNRB

The ROTAM is the first motorized arthrometer dedicated to the objective dynamic evaluation of rotational laxity. It is the ideal complement to the GNRB, the automated laximeter to measure sagittal laxity.
Parameters in controlled tibial rotation

**Test ROTAM at 5 Nm in controlled rotation**

<table>
<thead>
<tr>
<th>Differential of rotation</th>
<th>Differential of rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\Delta^r &gt; 6^\circ$</td>
<td>$\Delta^r &lt; 6^\circ$</td>
</tr>
</tbody>
</table>

**Analysis**
- Severe affection of the anterior-lateral peripheral structures
- No severe affection of the anterior-lateral peripheral structures

**Surgery (plastic) extra-articular**
- Recommended
- Not recommended


**Some examples:**

- **Preoperative**
  - $\Delta^r < 6^\circ$
  - Normal state of peripheral ligament structures
  - Lateral rotation
  - Medial rotation
  - Torque (Nm)

- **Postoperative**
  - $\Delta^r > 6^\circ$
  - Divergent curves
  - Pathological state of ligaments
  - Extra-articular surgery recommended
  - Lateral rotation
  - Medial rotation
  - Torque (Nm)

- **Postoperative**
  - $\Delta^r = 0$
  - Successful reconstruction
  - Parallel curves
  - Good ligament resistance
  - Lateral rotation
  - Medial rotation
  - Torque (Nm)

- **Postoperative**
  - $\Delta^r > 6^\circ$
  - Parallel curves, but high risk of relapse
  - Lateral rotation
  - Medial rotation
  - Torque (Nm)
The devices for the Automated Dynamic Laximetry

The range of our devices also includes the REHAB and the IP3, all of them can be combined and connected to the autonomous LDA® Station.
Progressive tibial translation
Adjustable (1 to 300 N) or pre-selected (134 N, 150 N,...) the progressive pushing force adapts to the individual need and guarantees a comfortable test for the patient.

High precision laximetry
The sensor positioned on the anterior tibial tuberosity records 1/10 of a mm, and at each push, more than 50 tibial displacement values!
An unmatched dynamic accuracy!

Induced tibial rotation
GNRB Rotab
The integrated electronic goniometer measures the tibial rotation induced by the anterior translation of the tibia. The distance of the foot positioning on GNRB and ROTAM devices is saved for a better reproducibility of tests.

Reproducible laximetry comparison
The patellar shell cap fixates the femur (patella against the femoral trochlea) with an individualized force, registered for each patient. This force applied identically to both knees warrants the comparison of the measurements and the reproducibility of the tests.

Controlled medial and lateral tibial rotation
ROTAM
A torque force (in Nm) is progressively applied with the help of a motor to the unit tibia-ankle-foot. The device measures the provoked medial and lateral rotation to the degree and compares them with the values of the opposite knee.
Accessories and options

Station LDA®
With centralized control for several devices at choice and for the LDA® couch.

Assistant LDA®
For PC, Printer and Device.

Specific electrical couch for LDA®
With special guide plate for GNRB and ROTAM devices and a removable leg section for configuration in the examination couch.
## Comparison chart and characteristics

<table>
<thead>
<tr>
<th>Technical details</th>
<th>Gnrb</th>
<th>GnrB</th>
<th>Rotam</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Measures</strong></td>
<td>Translation</td>
<td>Translation + medial rotation</td>
<td>Medial + lateral rotation</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>0,1 mm</td>
<td>0,1 mm / 1 Degree</td>
<td>1 Degree</td>
</tr>
<tr>
<td><strong>Method of measurement in 50 points</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Manual selection of force / torque</strong></td>
<td>✓ from 1 to 300 N</td>
<td>✓ from 1 to 300 N</td>
<td>✓ from 1 to 8 Nm</td>
</tr>
<tr>
<td><strong>Automatic preselection of force / torque</strong></td>
<td>✓ 134 - 150 - 200 - 250 N</td>
<td>✓ 134 - 150 - 200 - 250 N</td>
<td>✓ 3 - 5 - 8 Nm</td>
</tr>
<tr>
<td><strong>Automatic Repetition of reading</strong></td>
<td>✓ 1 to 3</td>
<td>✓ 1 to 3</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Detection and registration of muscular contractions (Biofeedback)</strong></td>
<td>Option</td>
<td>Option</td>
<td>Option</td>
</tr>
<tr>
<td><strong>Automatic registration of femur fixation force</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Registration of leg position</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Registration of patient data file</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Specific LDA® software</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Maintenance software integrated</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Dimensions and weights</strong></td>
<td>845 x 270 mm (15 kg)</td>
<td>845 x 270 mm (17 kg)</td>
<td>845 x 270 mm (20 kg)</td>
</tr>
</tbody>
</table>

### Results analysis

<table>
<thead>
<tr>
<th></th>
<th>Gnrb</th>
<th>GnrB</th>
<th>Rotam</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chart of measured values of displacements and rotations</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Display of Laximetry curves</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Calculation of rotation and translation differential between both knees</strong></td>
<td>✓ Translation</td>
<td>✓ Translation and rotation</td>
<td>✓ Medial and lateral rotation</td>
</tr>
<tr>
<td><strong>Calculation of inclination gradient and differential of the curves</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Printing and data transfer by network</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

### Various options

<table>
<thead>
<tr>
<th></th>
<th>Gnrb</th>
<th>GnrB</th>
<th>Rotam</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specific electrical couch for LDA®</strong></td>
<td>✓</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td><strong>PC / Notebook - Printer</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Assistant LDA®</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

### Quality Standards

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td><strong>Warranty</strong></td>
<td>2 years</td>
<td>2 years</td>
<td>2 years</td>
</tr>
</tbody>
</table>
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Quality Certificates
- NF IN ISO 13485 (2012)
- ISO 9001 (2008)

Patents
- French patents (INPI): FR 0608725 and FR 0608726
- European patent: EP 0782090.0-1526
- USA patent: Nr. 13/502790

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