Genourob®

INNOVATIVE LAXIMETRY

LDA®, Automated Dynamic Laximetry

Knee ligament analysis

- in tibial translation
- in tibial rotation

Genourob®

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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

Automated Dynamic Laximetry measurements / LDA®
in automated tibial TRANSLATION

The LDA® method a fully automated Lachman's test

The innovation **"Automated Dynamic Laximetry"** *(Laxity Measurement)* offers an objective and reproducible method to perform Lachman's test, allowing an evaluation with accurate figures of ligament laxity of the knee at an automated translation.

A simple and fast test providing precise results

Once patient's data registered, the fixing parameters of ankle and femur stored, the sensor is placed on the ATT (Anterior Tibial Tuberosity), which measures **the forward translation of the tibia, provoked by an automated push on the calf** (proximal part).

By comparison of the measurements of both knees, the LDA® software **displays the laxity curves, calculates the differential of the displacements and of the slopes.**

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

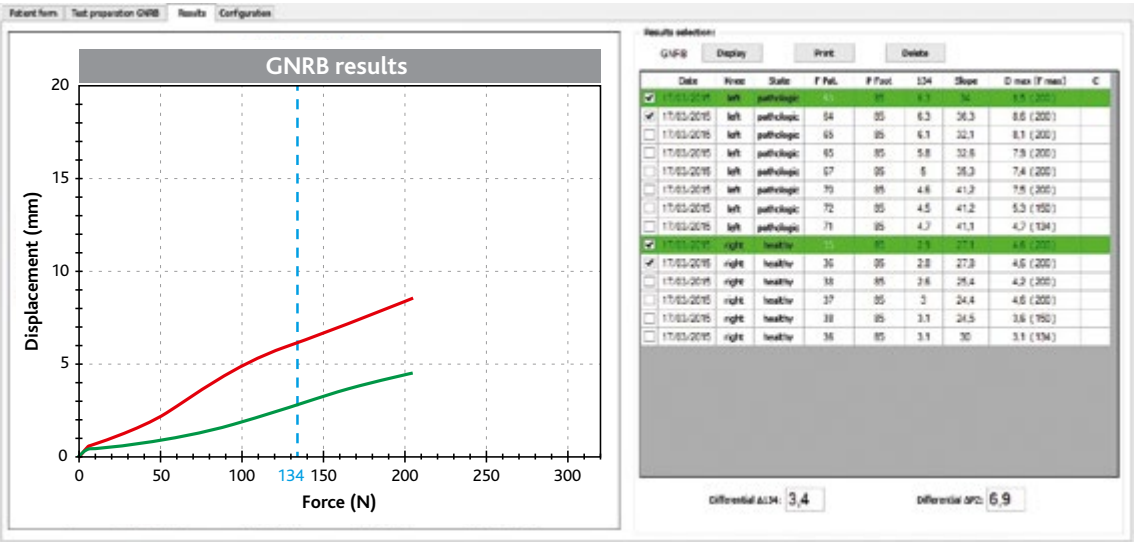
Lesions of the Posterior Cruciate Ligament are likewise detectable with the **LCP module (option), providing an automated posterior translation.**

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
*** P. Christel & al. J Bone Joint Surg Br 2012; 94-B: 68-74

Parameters in automated tibial translation



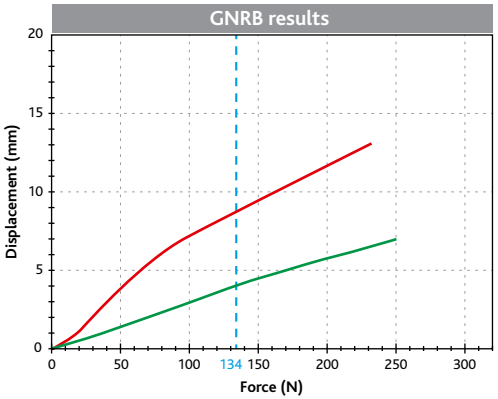
Automated tibial translation parameters
GNRB - GNRB Rotab *(H. Robert, Isakos, Rio 2011)*

Differential of displacements at 134 N (Δ134 in mm)	Ligament state
Δ134 > 3	Complete lesion (according to ΔP2)
1 < Δ134 < 3	Partial lesion (according to ΔP2)
Δ134 < 1	No lesion

Differential of slopes (ΔP2 in µm/N)	Risk of functional instability
ΔP2 > 10	High
5 < ΔP2 < 10	Medium
ΔP2 < 5	Low

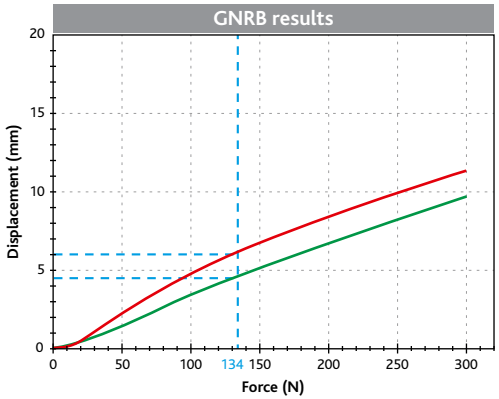
At induced medial rotation / GNRB Rotab

Differential of rotations (Δ° in degree)	Risk of lesion of PL bundle
Δ° > 3	High
Δ° < 3	Low



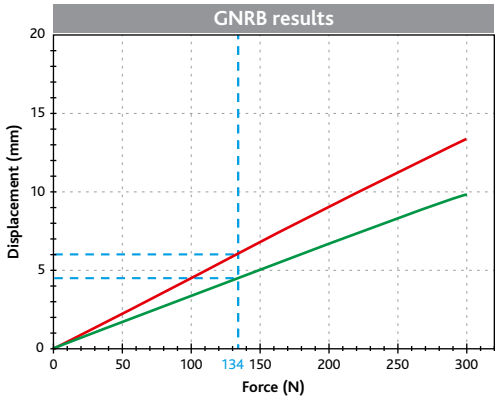
Preoperative control

Δ134 = 5,2, ΔP2 = 15, Δ°= 2
Objectification of a clinical Lachman's test (GNRB Rotab)
Complete rupture (no resistance to the push; high inclination…)



Similar
Δ134 = 1,5 mm
but
different slopes
of curves

DIFFERENT FUNCTIONAL ANALYSIS



For identical Δ134, 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 ΔP2 (parallelism or divergence of the curves) associated with the differential of the displacements Δ134.

To the left: no risk of functional instability

To the right: risk of functional instability

Automated Dynamic Laximetry measurements / LDA®
in controlled tibial ROTATION

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.

rotam

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).

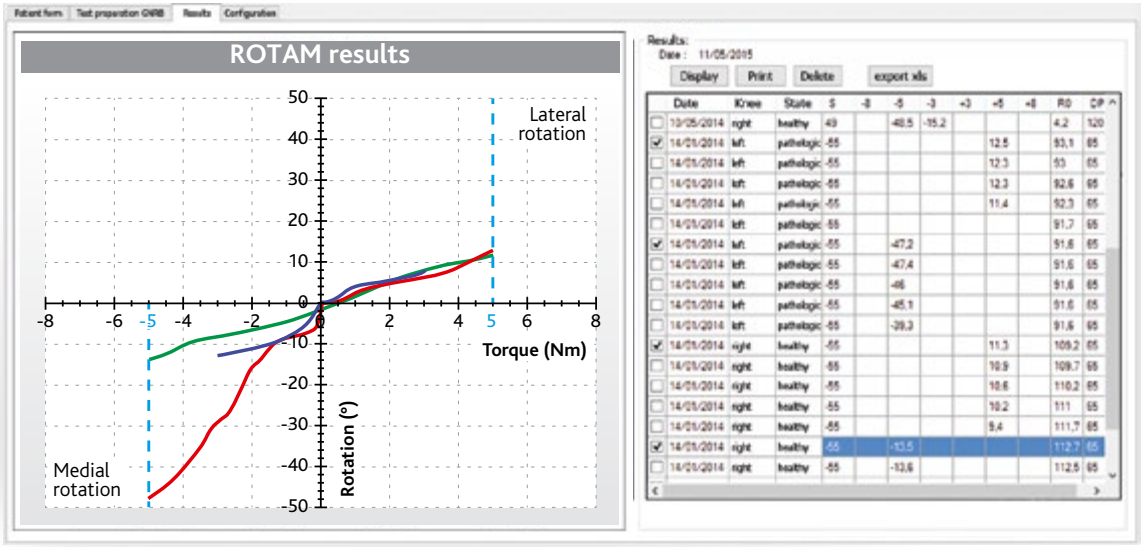
Controlling postoperative results

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

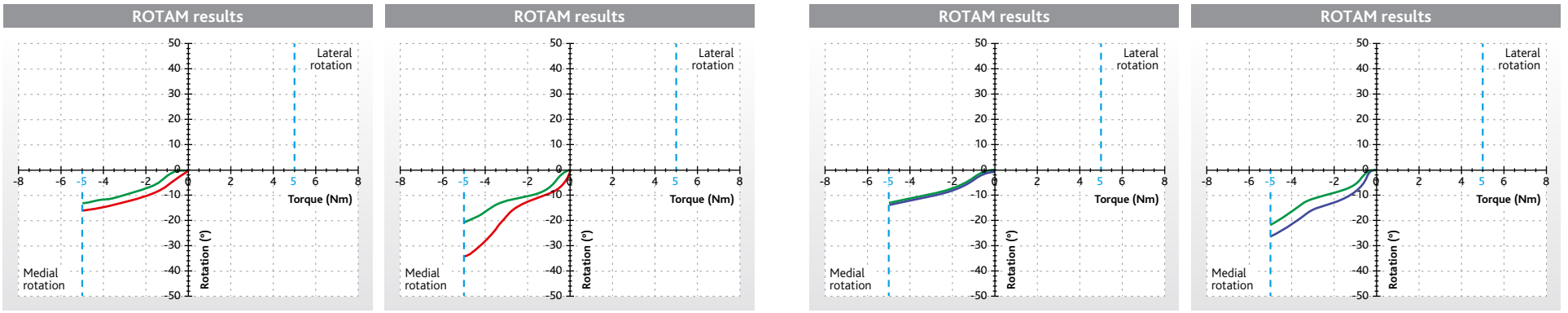


Test ROTAM at 5 Nm in controlled rotation	Differential of rotation Δ°r > 6°	Differential of rotation Δ°r < 6°
Analysis	Severe affection of the anterior-lateral peripheral structures	No severe affection of the anterior-lateral peripheral structures
Surgery (plastic) extra-articular	Recommended	Not recommended

(O. Lorbach, KSSTA, 2011 / H. Robert, ESSKA-SFA, 2014)

Knee
Healthy Pathologic Operated

Some examples:



Preoperative

Δ°r < 6
Normal state
of peripheral ligament structures

Δ°r > 6
Divergent curves
Pathological state of ligaments
Extra-articular surgery recommended

Postoperative

Δ°r = 0
Successful reconstruction
Parallel curves
Good ligament resistance

Δ°r > 6
Parallel curves,
but high risk of relapse

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.

Technical details and innovations

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!

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.

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.

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

Technical details	gnrb	rotab gnrb	rotam
Type of Measures	Translation	Translation + medial rotation	Medial + lateral rotation
Accuracy	0,1 mm	0,1 mm / 1 Degree	1 Degree
Method of measurement in 50 points	✓	✓	✓
Manual selection of force / torque	✓ from 1 to 300 N	✓ from 1 to 300 N	✓ from 1 to 8 Nm
Automatic preselection of force / torque	✓ 134 - 150 - 200 - 250 N	✓ 134 - 150 - 200 - 250 N	✓ 3 - 5 - 8 Nm
Automatic Repetition of reading	✓ 1 to 3	✓ 1 to 3	✓
Detection and registration of muscular contractions (Biofeedback)	Option	Option	Option
Automatic registration of femur fixation force	✓	✓	✓
Registration of leg position	✓	✓	✓
Registration of patient data file	✓	✓	✓
Specific LDA® software	✓	✓	✓
Maintenance software integrated	✓	✓	✓
Dimensions and weights	845 x 270 mm (15 kg)	845 x 270 mm (17 kg)	845 x 270 mm (20 kg)
Results analysis			
Chart of measured values of displacements and rotations	✓	✓	✓
Display of Laximetry curves	✓	✓	✓
Calculation of rotation and translation differential between both knees	✓ Translation	✓ Translation and rotation	✓ Medial and lateral rotation
Calculation of inclination gradient and differential of the curves	✓	✓	✓
Printing and data transfer by network	✓	✓	✓
Various options			
Specific electrical couch for LDA®	✓	Required	Required
PC / Notebook - Printer	✓	✓	✓
Assistant LDA®	✓	✓	✓
Quality Standards	**ISO 9001: 2008, ISO 13485**	**ISO 9001: 2008, ISO 13485**	**ISO 9001: 2008, ISO 13485**
Warranty	2 years	2 years	2 years

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Quality Certificates

- NF IN ISO 13485 (2012)
- ISO 9001 (2008)
- ISO 13485 (2003)

Patents

- French patents (INPI): FR 0608725 and FR 0608726
- European patent: EP 078209.0-1526
- USA patent: Nr. 13/502790

gnrb

rotam

rehab

rotab gnrb

lcp gnrb

radio gnrb

ip3 rehab

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