PLUS ORTHOPEDICS | NAVIGATION

Know-how brings motion back to life.℠

PiGalileo TKR

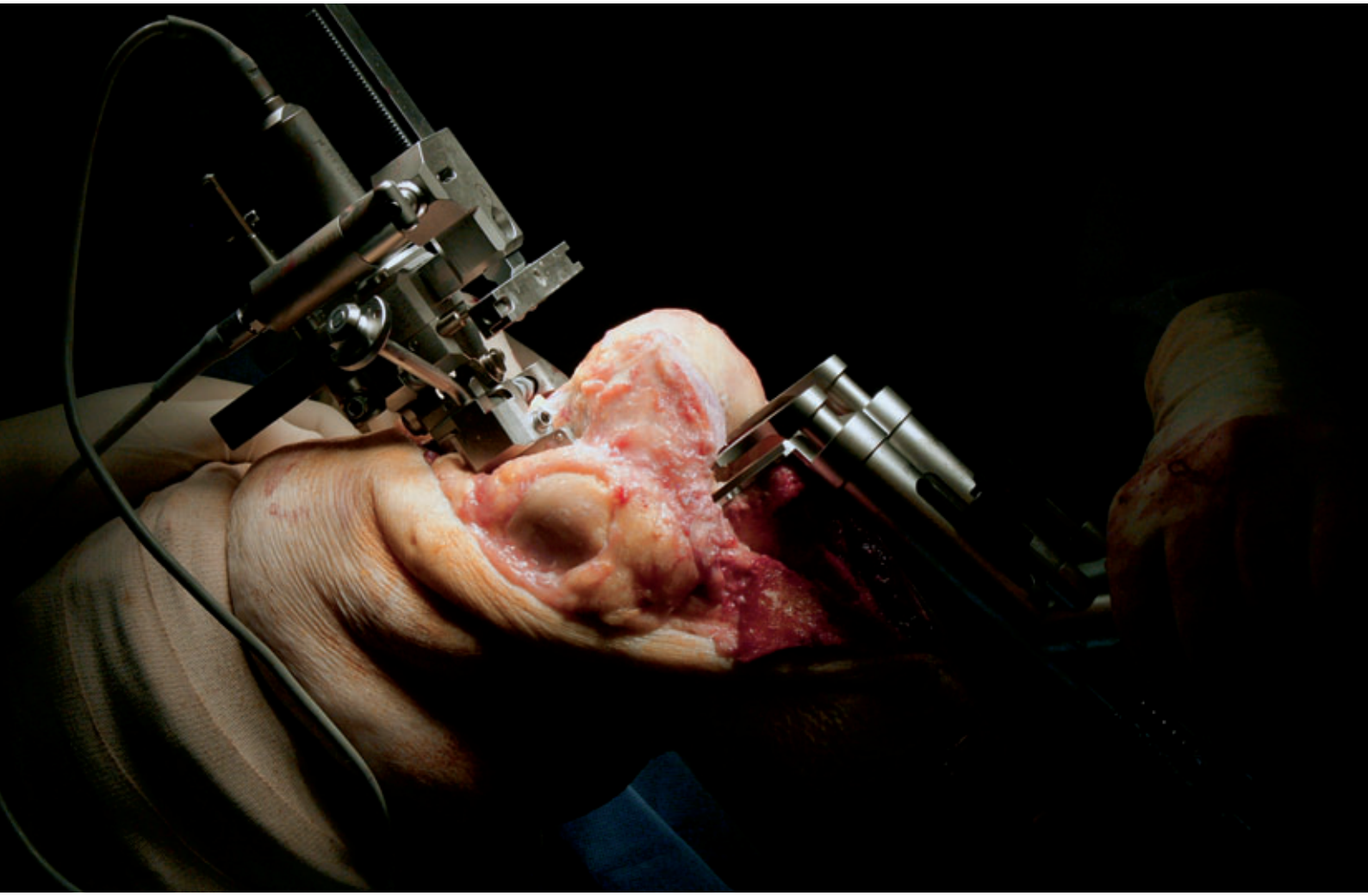
Navigation for Total Knee Replacement with Computer Positioned Cutting Guide CAS

Focus on Surgery

PiGalileo TKR

Navigation for Total Knee Replacement with Computer Positioned Cutting Guide CAS

Navigation combined with the unique computer positioned cutting guide CAS is a modern, yet application-oriented tool for total knee replacement. The mini-robotic CAS offers a third hand, which is precise to 1/10th of a millimeter, absolutely steady, and under the surgeon's control at any time.



Prof. Dr. Peter Ritschl
Orthopädisches Krankenhaus Gersthof, Vienna

It is the Surgeon's Decision

«The surgeon is free to make his own decisions at all times during the different stages of the operation.

He can alter the course of the operation, check and override the computer's suggestions, and he can remove the CAS mini robot from the operating area whenever desired, in order to make soft-tissue corrections. This is what makes PiGalileo so special.»

The PlusPoints

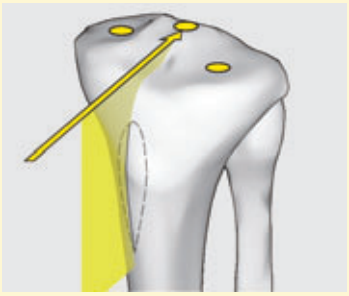
- **Precise Axial Alignment**
  Safe navigation algorithms and adjustable resection guides enable the surgeon to reliably reconstruct the mechanical leg axis.
- **Optimized Implant Position**
  The computer positioned cutting guide CAS allows for precise and individual positioning of the resections and works without accessing the intramedullary canal.
- **Anatomical or Biomechanical Reconstruction**
  Bony reference points as well as the soft tissue situation and the knee biomechanics are the base for an individually adjusted implantation.
- **Safety and Efficacy**
  The trouble-free interaction of navigation, implant and proven surgical technique allows the surgeon to focus on the surgery.

PiGalileo TKR

Navigation for Total Knee Replacement
with Computer Positioned Cutting Guide CAS

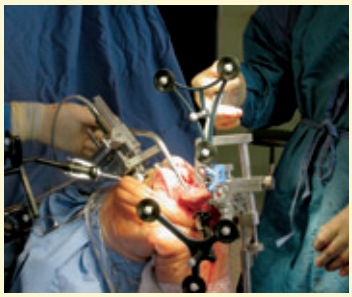
PiGalileo NAV

Bone Referencing Surgical Technique (BR)[1)]



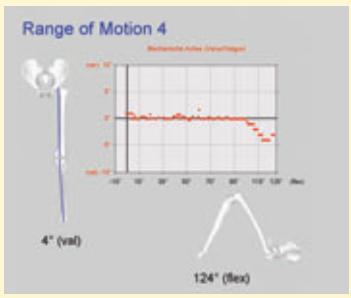
Measure Tibia

- Navigated palpation of anatomical landmarks



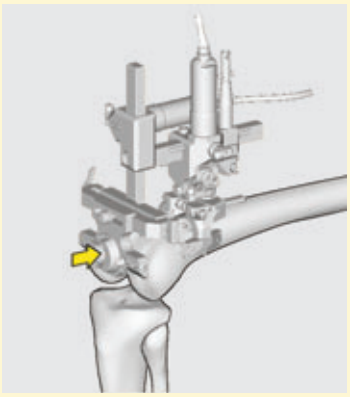
Align and Resect Tibia

- Navigation-supported adjustment of the cutting guide after pinning



Final Check

- Measurement of leg axis and «Range of Motion»
- Printout of the surgical protocol to document the result



Revisions

- Navigating the few available landmarks and combining it with the computer positioned cutting guide CAS also generates good results with revisions

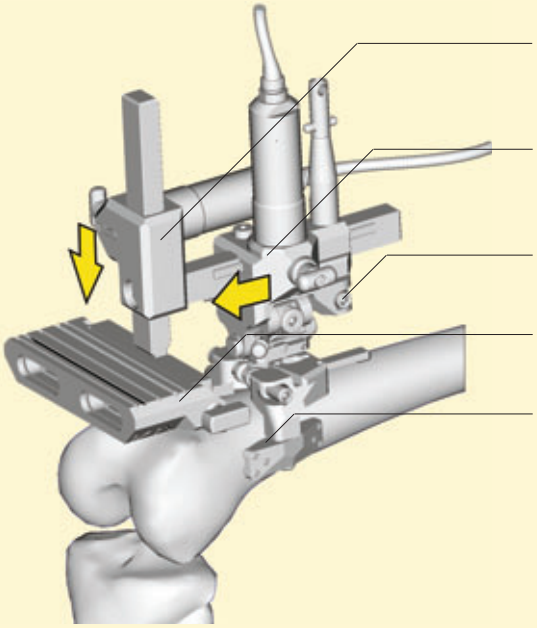
[1)] Available surgical techniques: femur first, tibia first

[2)] Available surgical techniques: tibia first

«The system's practical suitability is impressive and the additional time required is minimal.»

Dr. med. Marc Marty,
Dr. med. Ulrich Steiger

Computer Positioned Cutting Guide CAS

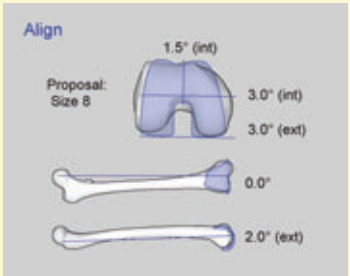


Measure Femur

- Kinematical determination of the hip center of rotation with ensured accuracy
- Navigated palpation of the anatomical landmarks

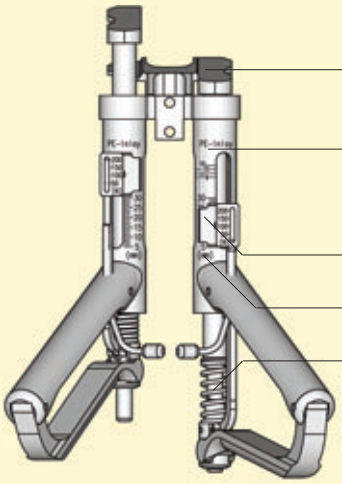
Align and Resect Femur

- Navigation-supported alignment of the CAS
- Manual double check with mechanical gages
- Shifting and optimizing the implant position in 0.5 mm steps

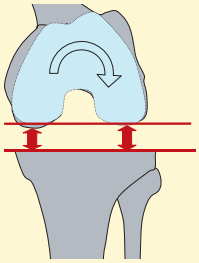


Ligament Balancing Surgical Technique (LB) [2)]

Force Controlled Ligament Tensioner

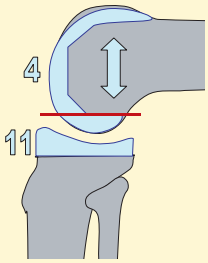


- Highly precise mechanical design for frictionless measurement
- PE scale:
  TC-PLUS™ Solution 9, 11, 13, 15 mm
  VKS™ 10, 12, 14, 17 mm
- Force scale 0...150 N per condyle
- Joint gap measurement 5...30 mm
- Ergonomic and simple mechanism for sensitive tensioning of the knee ligaments



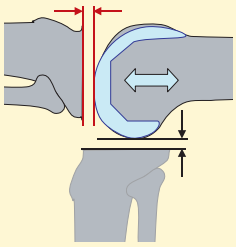
Balance Flexion Gap

- Tibia resection and preliminary release in extension
- Tension in flexion
- Rotate femoral component and/or release → parallel flexion gap



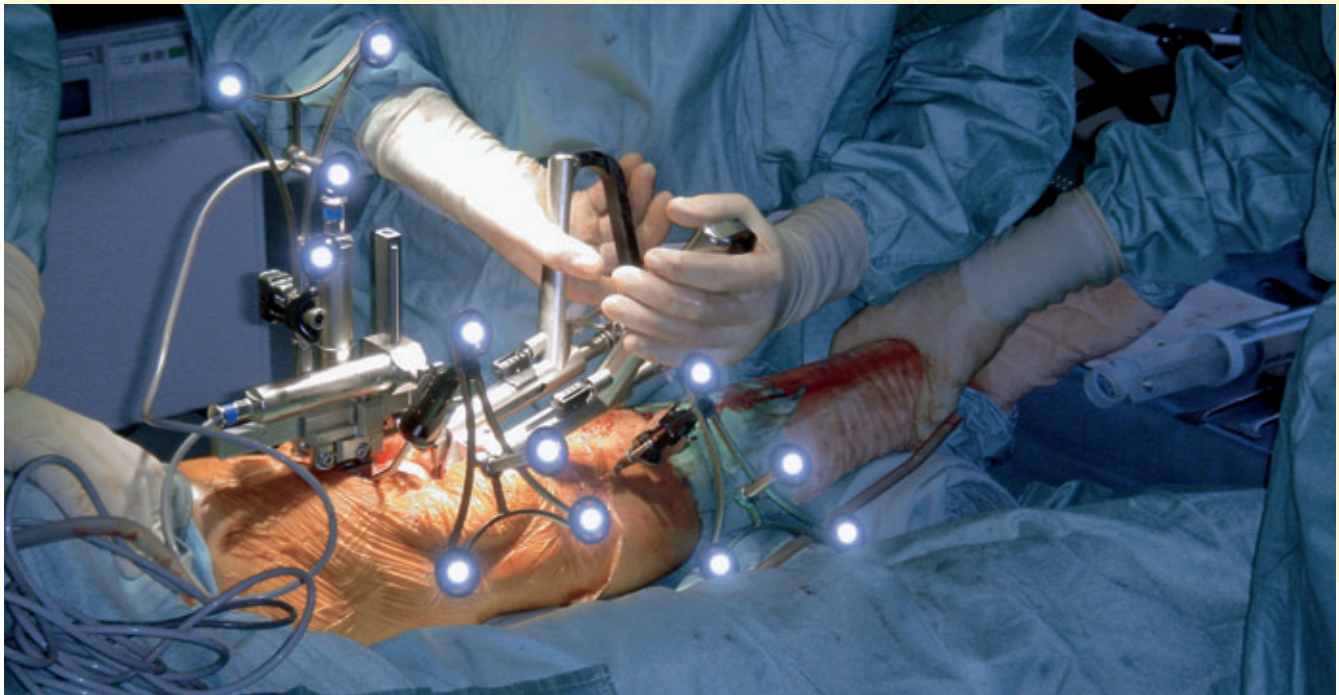
Define Flexion Gap

- Define A/P-position and size of femoral component
- Execute flexion resection
- Conclude PE thickness



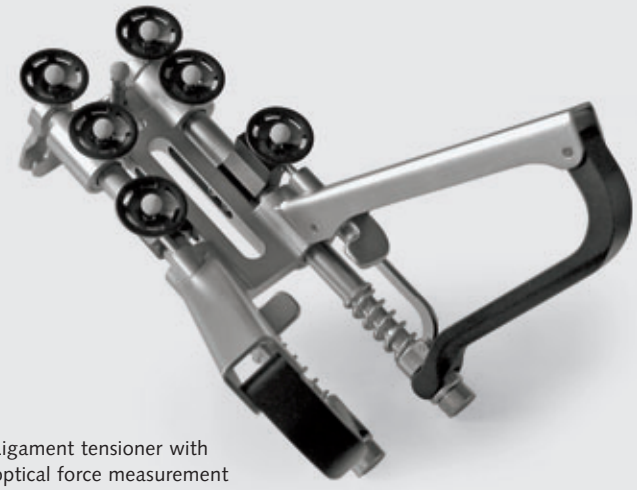
Adjust Extension Gap

- Tension in extension
- Measure extension gap and leg axis under tension
- Proposal for distal resection such that extension gap = flexion gap



Current Research on Ligament Balancing

Ongoing multi-center study



Ligament tensioner with optical force measurement for the intra-operative determination of the force-displacement curve.

Question

Which forces have to be applied to the knee in flexion and in extension to achieve optimal clinical results with ligament balancing surgical techniques?

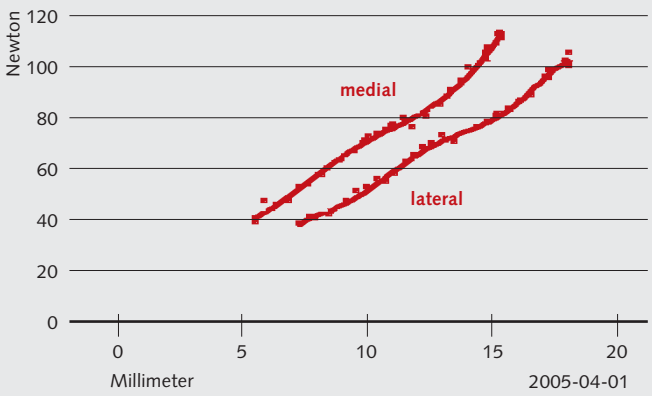
Material and Method

Based on a ligament tensioner with optical force measurement, an intra-operative protocol was defined, which allows the registration of the patient's individual force-displacement curve.

Result and Discussion

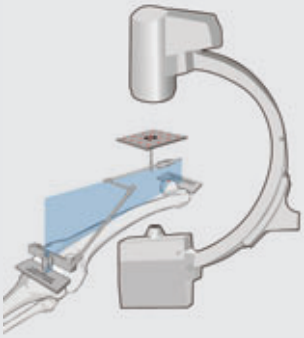
The individual biomechanical parameters of the patient can be measured and printed out intra-operatively. With statistical methods and further examinations quantifiable stability criteria are being developed.

Exemplary force-displacement curve in flexion.

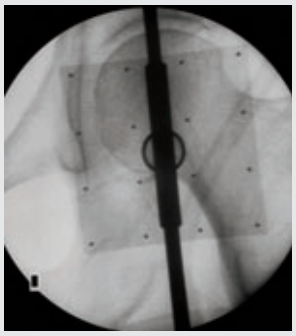


Parallax-free Measurement of the Leg Axis

Precision measurement of the navigated, reconstructed mechanical leg axis in implanting a total knee prosthesis. Ritschl et. al. Poster CAOS 2002, Santa Fe

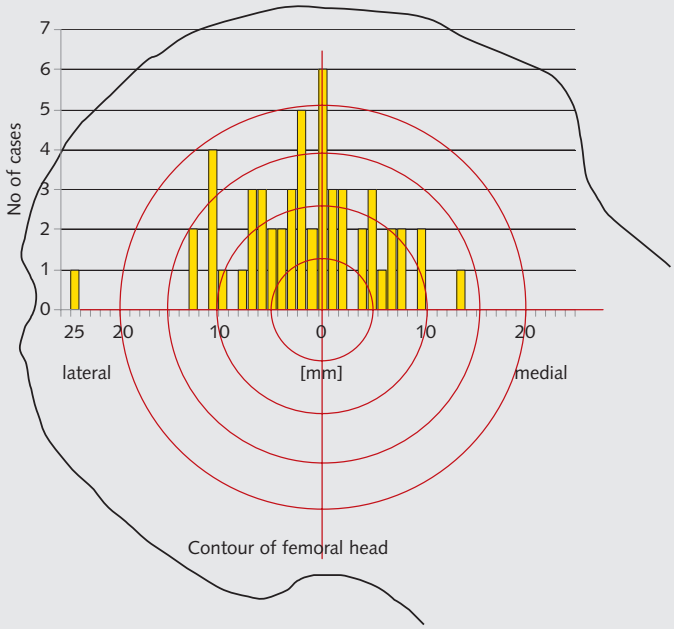


Principle of the parallax-free intra-operative measurement of the leg axis using fluoroscopy.



The rod indicates the axial alignment proposed by the navigation system. The ring allows for parallax-free adjustment.

Axial Deviation at the Proximal Femur



Question

The post-operative full standing x-ray is not accurate enough to quantify axial malalignment of less than 3°, a range which can be expected with navigated TKR.

Material and Method

For the intra-operative determination of the leg axis and its intersection with the center of the hip joint on one side and the ankle on the other side a parallax-corrected projection method was developed using a calibrated c-arm. The method allows the measurement of the leg axis with a validated accuracy of 0.5°. PiGalileo was used for the implantations.

Results

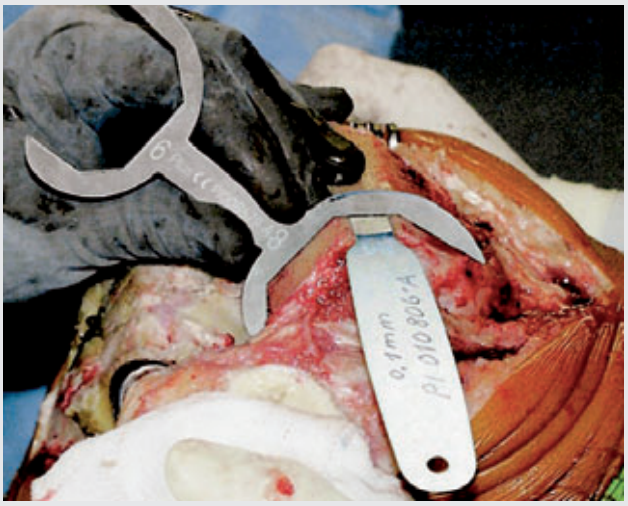
Intra-operative measurements in 54 consecutive cases show a reconstruction accuracy of 0.95° in 68.3% of the cases (3.1° in 99.9%). On the tibia the axis was reconstructed with an accuracy of 1.2° in 68.3% of 25 consecutive cases (4.1° in 99.9%).

Discussion

With the proposed method, the accuracy of the axis reconstruction can be determined with precision. PiGalileo allows the reconstruction of the mechanical leg axis within a safe range of ±3°.

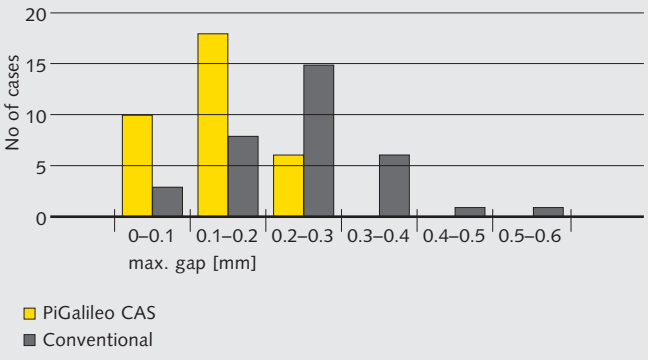
Resection Accuracy and OR-Time

Computer-assisted cutting guide for total knee replacement.
First clinical experiences Gellner et. al. Poster CAOS 2001, Davos

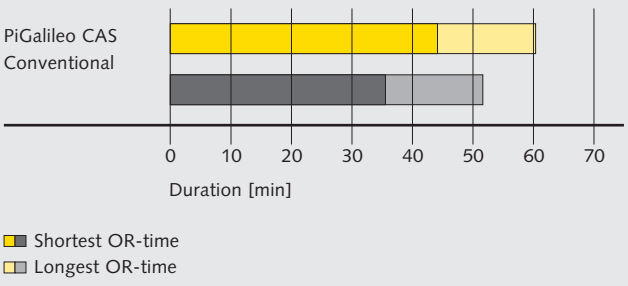


Measurement of the resection accuracy with a feeler gage.

Improved resection accuracy with PiGalileo CAS



Minor increase of OR-time



Question

Influence of PiGalileo CAS on resection accuracy, OR-time and surgical preparation.

Material and Method

During 34 TKR surgeries, each conventional and CAS-supported, the resection accuracy was determined using a template and a feeler gage. Furthermore the incision length and the OR-time were measured.

Result

The measurement showed smaller gaps in all CAS-supported TKR cases. The incision was approx. 20 mm longer due to the femoral clamp of the CAS. 10 minutes additional OR-time were required for the PiGalileo cases, however this can be reduced by frequent use of the system.

Discussion

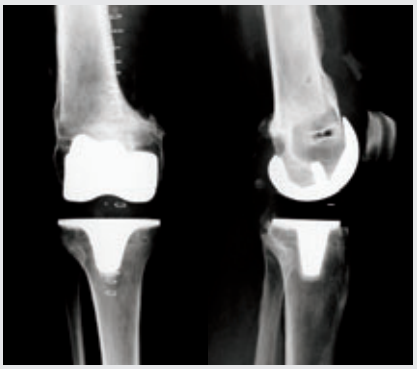
Using the mini-robotic PiGalileo CAS leads to more precise bone resection compared to conventionally performed resections. This is an important prerequisite for higher primary stability and improved bone apposition.

Patients operated with PiGalileo

Prof. Dr. Peter Ritschl, Orthopädisches Krankenhaus Gersthof, Vienna

Case 1
Patient: female, 64 years old
Situation after supracondylar correction osteotomy at the right knee
Implant: TC-PLUS™ SB Solution (rotating platform)

Pre-operative



Post-operative

Case 2
Patient male, 80 years old
Situation after distal tibia fracture, extra-anatomical mal-alignment at the knee
Implant: TC-PLUS™ SB Solution (rotating platform)

5 years post-operative

This is one of the first patients worldwide operated with PiGalileo worldwide. In spite of the difficult anatomical circumstances at the tibia the outcome is very positive.

2 years post-operative

«The reconstruction of the leg axis can be successfully achieved with high reliability and the implant can be optimally positioned even with insufficient anatomical landmarks.»
Prof. Dr. Niklaus Friederich

«PiGalileo is very helpful in Japan where we have a special anatomy and particularly severe cases of arthrosis.»
Prof. M. D. Fujio Higuchi

We express our sincere thanks to our medical partners for their pictures, work and quotes used in this brochure: Dr. Ritschl, Orthopädisches Krankenhaus Gersthof, Wien AT; Drs. Friederich and Müller, Bruderholz Spital, Basel CH; Drs. Dinges and Gramlich, Westpfalz-Klinikum, Kusel DE; Dr. Koenig, Mercy Medical Center, Rockville Centre USA; Drs. Marty and Steiger, Hirslanden Klinik, Zürich CH; Dr. Gellner, Helios Klinik, Blankenhain DE; Dr. Higuchi, Kurume University Medical Center, Kurume JP.

Distribution

Sales Partners in:

Australia
Baltic countries (EE, LT, LV)
Belarus
Bosnia
Brazil
Bulgaria
India
Indonesia
Iran
Croatia
Kuwait
Malaysia
Norway
Russia
Slovakia
Slovenia
South Africa
South Korea
Thailand
Czech Republic
Turkey

China
Plus Orthopedics (Beijing) Co., Ltd.
7th Floor, Modern Palace, No. 20 Daluyuan
Dongsanhuan Nanlu, Chaoyang District
Beijing 100022, P.R. China
Phone +86 10 8778 3322, Fax +86 10 6776 3622

Germany
Plus Orthopedics GmbH
Mainstrasse 2, 45768 Marl
Phone +49 2365 91 81 0, Fax +49 2365 91 81 10

France
Plus Orthopedics France Sarl
40, rue du Moulin des Bruyères, 92400 Courbevoie
Phone +33 1 4997 04 60, Fax +33 147 680 936

Greece
Plus Orthopedics Hellas S.A.
Kleanthous Street 8, GR 16346 Ilioupoli, Athens
Phone +30 2 10 99 13 190, Fax +30 2 10 99 31 809

United Kingdom
Plus Orthopedics (UK) Limited, Barbury House
Stonehill Green, Westlea, Swindon SN5 7HB
Phone +44 1793 719 222, Fax +44 1793 619 222

The Netherlands
Plus Orthopedics Netherlands BV
Postbus 785, 2700 AT Zoetermeer
Phone +31 793 41 7071, Fax +31 793 42 5601

Italy
Plus Orthopedics Italy Srl
Via Archimede 76, 20041 Agrate Brianza (MI)
Phone +39 039 657 921, Fax +39 039 657 92 35

Japan
Plus Orthopedics K.K., Tomigaya-Ogawa Bldg. 2-41-12
Tomigaya, Shibuya-ku, Tokyo 151-0063
Phone +81 3 3467 5581, Fax +81 3 3467 5582

Austria
Plus Orthopedics GmbH
Grenzgasse 38a, 2340 Mödling
Phone +43 (0)2236/48 407-0, Fax +43 (0)2236/41 149-4

Switzerland
Plus Orthopedics Schweiz AG
Erlenstrasse 4a, 6343 Rotkreuz
Phone +41 (0)41 798 41 11, Fax +41 (0)41 798 41 00

Spain
Plus Orthopedics España S.A.
c/Islas Aleutianas n 4, 28035 Madrid
Phone +34 91 376 86 20, Fax +34 91 376 86 21

USA
Plus Orthopedics USA, Inc.
10188 Telesis Court, San Diego, CA 92121
Phone +1 858 550 3800, Fax +1 858 457 56 18

Switzerland
Plus Orthopedics AG (Manufacturer)
Erlenstrasse 4a, 6343 Rotkreuz
Phone +41 (0)41 798 41 11, Fax +41 (0)41 798 41 00

info@plusorthopedics.com
www.plusorthopedics.com

Lit. No.1445-e Ed.06/05 500 Ex. 10/05

CE 0123