Modern Navigated Ligament Balancing in Total Knee Arthroplasty with the PiGalileo System

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Introduction

Ligament balancing of the knee is one of the cornerstones for the function and longevity of a knee endoprosthesis. »Size and shape of the flexion gap should be equal to the extension gap« as Insall [1] put it. In Insall's concept the gaps should be rectangular for the same ligament tension at the medial and lateral side. The decisive point of the gap technique is that it is oriented towards the status and condition of the soft tissue. During the process the posterior cruciate ligament is resected [2]. Reconstruction of the joint line is not taken into account. No data regarding the measure of the ligament tension are provided. The gap technique then met some competition from the »Measured Resection Technique« [3]. The principle of this implantation philosophy consists in the measurement of the resection being replaced by the corresponding implant thickness, both at the femur and the tibia. Unlike the gap technique, the posterior cruciate ligament is preserved in this process. The joint line can consequently largely be preserved and reconstructed. For knee joints that are not significantly deformed, it is thus possible to restore the original conditions of the ligaments. Ligament tension in the joint compartments themselves results from the selected thickness of the implant, and is thus determined by subjective assessment of the surgeon.

The LCS Total Knee Arthroplasty according to Buechel and Pappas [4] simultaneously integrates the rotation of the femur component when determining flexion gap and ligament tension. During this, following the tibial incision, the rotation of the femoral resection level and the width of the flexion gap for evenly stretched ligaments in flexion are initially simultaneously determined through a spacer block. The thus obtained height of the flexion gap is subsequently transferred to the extension gap. In this implantation technique as well, the extent of the ligament tension is determined by subjective assessment of the surgeon. Little significance is attached to the reconstruction of the joint line.

What all these methods have in common is the fact that ligament tension in flexion and extension is defined through individual subjective assessment of the surgeon. No special attention is given to any external influences, such as that of an everted patella, especially in flexion, or the use of a thigh tourniquet. Such subjective assessment of ligament tension is frequently the source of complications. Major revision statistics indicate instability as the reason for a revision in 1/5 – 1/3 of revision operations [5, 6]. As revision operations are usually only performed where clinically particularly abnormal instabilities are present, it must be assumed that the estimated number of unknown cases of sub-clinical instable knees is high.

Using surgical navigation systems, it is possible to quantify and thus objectify factors that have conventionally been determined through subjective assessment, such as ligament tension and joint stability. Software modules to support both implantation techniques are usually available. »Bone referencing« modules are oriented towards the »Measured Resection Technique« and are used for »straight forward« knees, i.e. for knees without any major bone or ligament deformities. In addition to landmark-oriented navigation, »ligament-based« modules, in particular those of the PiGalileo Systems (Plus Orthopedics Aarau, Switzerland), also offer the possibility of force-controlled recording of ligament tension using a ligament balancer, and integrating it in the operative implantation management. Those integrative operation steps comprise for the flexion gap:

- determination of ligament tension,
- determination of femur rotation, and
- implant planning with joint line optimising.

The thus determined flexion gap is then transferred to the extension gap.
In the following, the individual operation steps will be presented and described, and first clinical results will be reported on. Finally, future aspects involving individual ligament tension measurement will be discussed.

Method

The PI-Galileo system is an optical landmark-based navigation system. The navigation camera (Axios 3D, Oldenburg, Germany) has a precision of 0.2 mm and offers the possibility to accurately record forces and distances through differentiation measurements. A computer-controlled, motor-operated two-axis positioning unit of the (»five in one«) femoral incision gauge is an integral part of the navigation system (Fig. 17.1a). Ligament tension and gap size are measured using a ligament balancer with force and distance scale (Fig. 17.1b).

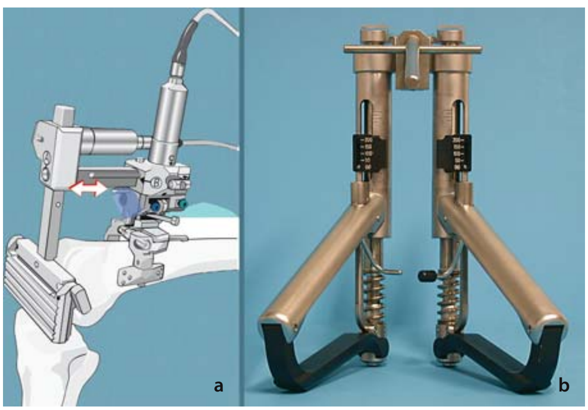

Fig. 17.1. a The computer- controlled motor unit drives a five-in-one cutting block into the pre-calculated position for the femoral cuts. **b** The »double spring« ligament balancer comprises a scale for measuring the force in Newton

In the following, only the operation steps that are relevant to ligament tension will be described.

Step 1: Visualization of Preoperative Deformity and Stability

Following digitalizing of the femoral and tibial landmarks and calculation of the three-dimensional position of the short and long axes, the existing mal-position and ligament stability/instability are visualized.

During pre-operative measurement, 2 parameters are evaluated on the display:

Deformity in Extension, Flexion and Over the Full Range of Motion

It is clearly visible that the deformity in this case (Fig. 17.2) is present mainly in extension, but not in flexion. The minor valgus deviation in flexion was attributable to a cartilage defect of the lateral-dorsal condyle.

Extent of Instability

Point cloud distribution covers 7° (2°–9°) in extension. In flexion the knee is considerably more stable. The point cloud shows significantly lower deflection.

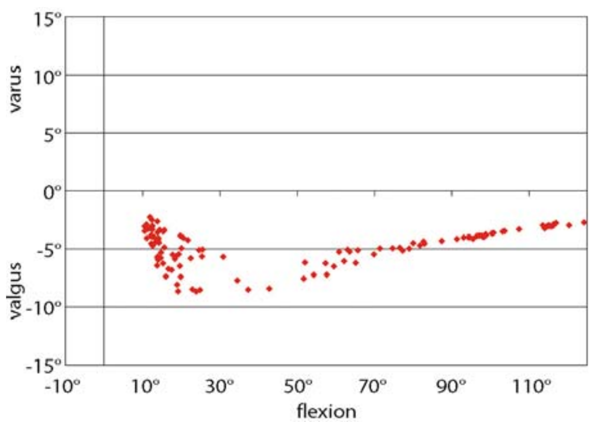

Fig. 17.2. Pre-operative leg-axis measurement reveals an obstructed extension of 10° and an average valgus deformity of 6°. Instability ranges from 2° to 9° in maximum extension. In flexion, taut ligament control is present. Bone deformity is responsible for a valgus deformity of 2° and 3°

The extent of the instability is due to ligament laxity as well as the cartilage/bone defect.

Following visualization of the deformity, it must be concluded that a soft tissue release is only required in extension, but **not** in flexion.

Step 2: Ligament Balancing in Extension

Following osteotomy of the tibial plateau and removal of the osteophytes, ligament tension is initially determined in extension. For this a strictly repeating algorithm is used:

1. Positioning of the ligament balancer *without* clamping it
2. Alignment of the extremity along the visualized mechanical axis
3. Tensioning of the ligament balancer at 100 Newton in extension and determination of any possible mal-position of the axis.
4. If any mal-position is present, execution of a sequential release in extension.

The result of this step is a knee, which is axis-corrected in extension and balanced with 100 Newton both medially and laterally (Fig. 17.3).

Step 3: Ligament Balancing in Flexion and Determination of the Rotation of the Femur Component

Ligament tension in flexion is determined using the same algorithm as describe above. The patella is not everted, but rather held in a laterally subluxed position. Once the ligament balancer has been positioned without clamping and the leg position and femoral rotation in flexion have been checked on the screen, the balancer is clamped at 70–80 Newton, both medially and laterally (Fig. 17.4).

On the display, the flexion gap appears as a rectangular or trapezoidal bar. The target position is a rectangular flexion gap for correct femoral rotation. Rotation of the femur relative to the 3 rotation landmarks (a.p.-line, epicondyle line, dorsal condyle line) is displayed on the screen in real time. Minor adjustment to obtain a rectangular gap can be carried out by changing the rotation at the PI-Galileo motor unit, while observing the rotation landmarks.

The rectangular shape of the bar (and thus of the flexion gap) might also be impaired because of a strong lateral constraint of the extensor apparatus, in particular when the patella is everted. In such a case the preoperatively determined ligament condition (Fig. 17.2) will be helpful to decide whether a soft tissue release is necessary. Before carrying out the dorsal femoral cut, size and position of the femoral prosthesis component must be planned and polyethylene thickness must be determined.

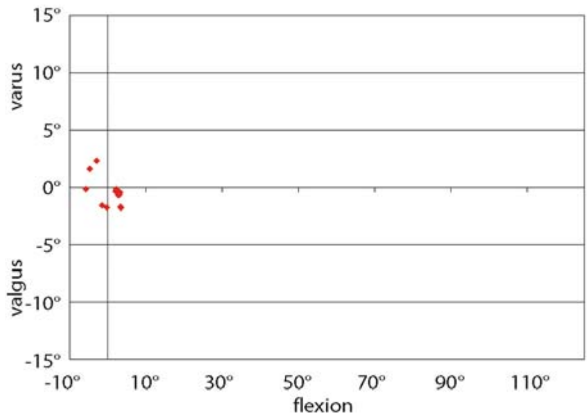

Fig. 17.3. Following ligament balancing in extension, symmetric stability with correct axis orientation is obtained in spite of any femoral bone defects

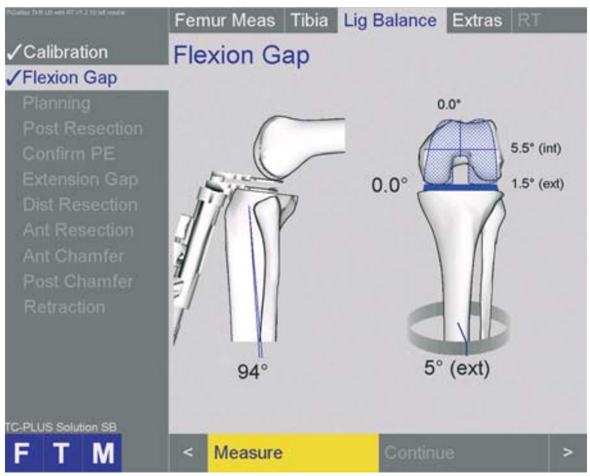

Fig. 17.4. Following alignment of the extremity in rotation and flexion, the ligament balancer is positioned and clamped at 70 to 80 Newton on the medial and lateral side. Rotation of the dorsal femoral cut is determined in consideration of the bony landmarks. The blue bar symbolizes the flexion gap which is rectangular in this case

Step 4: Selection of the Prosthesis Components to Optimize Joint Line and Ligament Stability

Based on the data provided, the computer calculates the femoral prosthesis size and the respective polyethylene height. The objectives are the reconstruction of the joint line and the correct resection height of the dorsal condyles. This results in a balanced flexion gap so that the entire implant can be positioned with the desired flexion stability. Since the number of prostheses sizes is limited a fine tuning by the surgeon might be necessary. Such adjustments can be made by changing the prosthesis size, the polyethylene thickness or by an a.p.-shift of the femur component in steps of 0.5 mm. It is thus possible to achieve an ideal prosthesis position with controlled stability, optimized joint line and the best fitting component sizes (Fig. 17.5).

Once all of these parameters have been determined, the motor unit will drive the cutting block to the pre-calculated position, and the surgeon will cut the dorsal condyles.

Step 5: Transfer of the Flexion Gap to the Extension Gap

Following the dorsal femoral cut and removal of dorsal osteophytes, the polyethylene height under the determined ligament tension is checked once again. Removing larger dorsal osteophytes occasionally causes widening of the flexion gap, which can be compensated for by increasing the polyethylene height. Once the definitive polyethylene height has been confirmed, the size and configuration of the flexion gap is determined.

The height of the flexion gap is then transferred to the extension gap. After the ligament balancer has been positioned, the extremity is aligned according to the mechanical axis (screen controlled), the ligament balancer is clamped at 100 Newton and the orientation of the axis is checked for a second time. This second evaluation of the stable axis in extension serves as a control measure following any release in flexion that might have occurred.

The rectangular configuration and width of the extension gap appears on the screen. After confirmation, the motor unit drives the cutting block into the pre-calculated position for the distal cut, which is performed now. The height of the distal femoral resection is shown on the screen, and it is possible to shift the distal cut in half-millimeter steps in proximal or distal direction whenever individual adjustment is desired.

Thereafter, the motor unit drives to all the remaining femoral resection positions (anterior and chamfer cuts) and the resections are carried out. Following positioning of the trial implants, the reconstructed joint line is checked once again and the result with regard to ligament tension is visualized (Fig. 17.6).

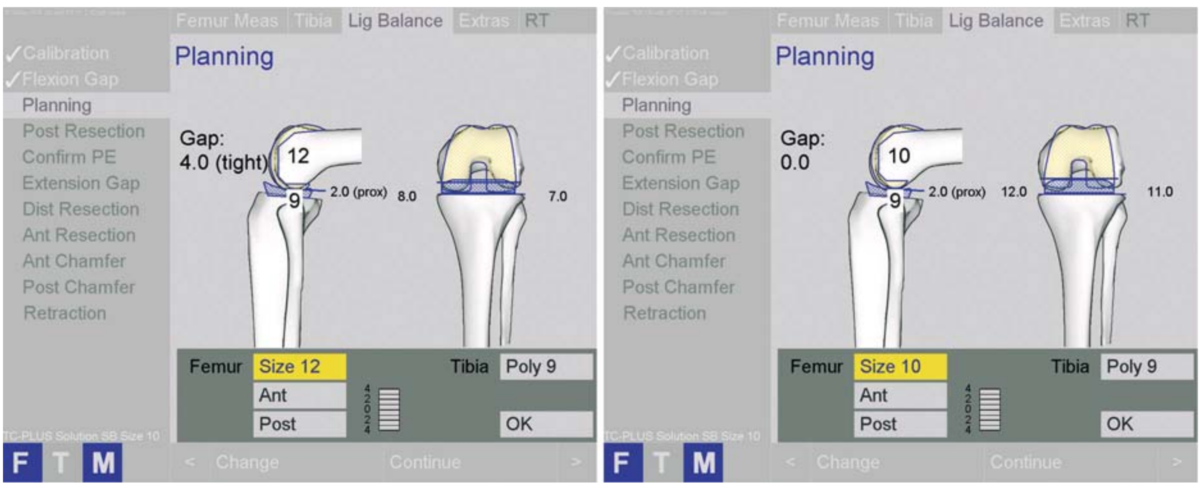

Fig. 17.5. The planning step initially shows a flexion gap that is too narrow by 4 mm for a femur size of 12. Femur size is reduced to 10 after which the flexion gap has the ideal size for the implants used. Changing the femur component does not change the joint line, however, the resection of the dorsal condyles increases

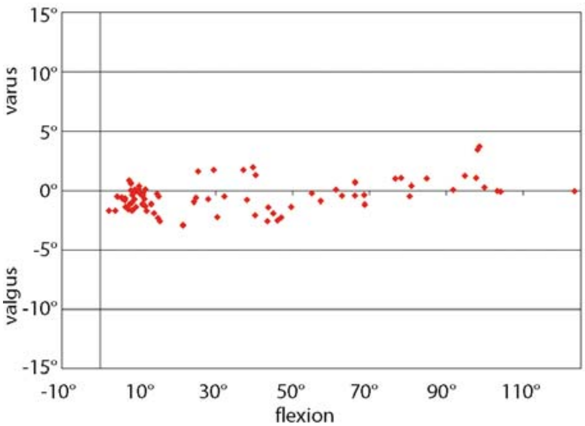

Fig. 17.6. Checking of the operation result with the achieved stability and axis orientation: For varus and valgus stress, the resulting ease of opening is 2.5° over the entire ROM. The axis is correct and the leg is almost fully extended

Table 17.1. The postoperative outcome showed a better function and knee score in the group with ligament balancing technique

	Knee Society Score	Function Score
Preoperative		
A	40	57
B	48	55
16 months follow up		
A	89.3	89.4
B	87.7	83.6

Clinical Results

In a group comparison, the effect of the ligament tension measurement was evaluated. The same implant (TC Plus-SB, Plus Orthopedics, Rotkreuz) and the same implantation technique with the PI Galileo system were used for both groups. All patients were operated by one surgeon.

- Group A with ligament tension technique comprised 61 patients (average age 71.1)
- Group B without ligament tension technique consisted of 60 patients (average age 74.4).

Evaluation was done using the American Knee Society Score. The time of post-operative observation was 15.7 months for Group A, and 17.2 months for Group B.

Both with regard to the function score and the knee score, the group comparison showed better results in Group A with ligament tension measurement.

For almost the same pre-operative initial value, in Group A (ligament tension measurement) the average function score is higher by 5.8 points and the knee score by 1.6 points (Table 17.1).

Discussion

The PI-Galileo system is the first method to implement the principle of quantitatively force-controlled ligament balancing. Existing concepts use spacer blocks or ligament balancers for ligament balancing, on which, however, the applied force cannot be determined as they do not include a scale. Knee stability is therefore subjectively assessed by the surgeon. This can constantly result in sub-clinical, and sometimes also clinically manifested instabilities [5–7]. The forces that are specified for a sufficient ligament stability range from 140 to 160 Newton in flexion (70–80 Newton both medially and laterally) and about 200 Newton in extension (100 Newton both medially and laterally) [8].

Ligament balancing begins in extension. Initially, the pre-operative ligament deformity is determined and visualized on the screen. During this the extent of laxity of the knee joint as well as cartilage and bone defects become visible over the full range of motion. Once the tibial resection has been performed, ligament tension measurement is carried out according to a specially defined algorithm. (step 2). This algorithm is important in order to exclude or to minimize any interfering lever effects on ligament tension measurement.

If the pre-operative ligament tension measurement does not reveal any deformity for 90° flexion, it is not necessary to carry out a release in flexion. However, if a ligament deformity is present also for 90° flexion, a ligament release must be carried out during ligament tension measurement. The subluxed patella is another factor, that has an effect on ligament tension and its influence can currently only be estimated.

The concept of this »load depending gap balancing« has been integrated into the principle of »Measured Resection Technique«. With the help of navigation femoral and tibial resection heights are accurately determined. The achievable joint line, axis orientation, and resection heights for the defined ligament tension can be seen on the display. By adjusting planning steps it is possible to plan an optimal composition of the prosthesis in terms of size, polyethylene height, ap prosthesis position and joint line, as well as tension of ligaments, and to implement these factors during the individual operation steps.

However, the influence of some factors such as the contribution of the laterally subluxed patella on ligament tension in flexion is still uncertain. Furthermore, there are uncertainties with regard to the correct ligament tension in flexion and extension for the individual patient. Individual factors such as gender, size, age, level of activity, individual ligament characteristics in terms of stiffness of the ligaments, etc. have not quantitatively been described to date. Computerized analysis of the individual ligament tension should therefore be aimed at. During such a process the individual stability point of the individual patient knee has to be determined through corresponding calculation steps.

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