INTRODUCTION: The assumption that symmetric flexion-extension gaps improve the femoral condylar lift-off phenomenon and the fact that proprioception in Total knee arthroplasty (TKA) is now widely accepted. Although the expensive navigation system allows a significant improvement in the accuracy of implantations in relation to the mechanical axis, the management of soft tissue balancing during surgery remains difficult – for this reason, much reliance is placed on the surgeon’s feel and experience. Furthermore, little is known about the differences of the characteristics of the soft tissue of the medial and lateral compartments and their individuality, nonetheless it has a deep connection with the achievement of appropriate gaps when accomplished through surgery utilizing a balanced gap technique. Our previous study demonstrated an in vivo biomechanical characteristic of the soft tissue stiffness (STS) in each compartment by intra-operative measurement using a newly developed tensioning device. The purpose of this study was to determine the relationships between the patient’s factor, STS, intra-operative joint gap kinematics and the post-operative flexion balance assessed by radiographic examination, which may provide reference data for clarifying the appropriate joint distraction force for individual patients in postoperative-stabilized TKA after undergoing surgery using the balanced gap technique.

MATERIALS AND METHODS: Patients: In this prospective study, 39 consecutive patients were included with medial osteoarthritis (OA) undergoing a primary posterior-stabilized TKA (NexGen LPS-Flex, Zimmer, Warsaw, USA) in 2010 and 2011. All provided their informed consent. One patient who needed lateral retinaculum was released after the component gap measurement was excluded from this study. A total of 42 knees in 38 patients were investigated. The patient population was composed of 6 men and 32 women with a mean age of 73 ± 7.7 years. The average height, weight, BMI, weight-bearing FTA, and the patella height (Insall-Salvati ratio: T/P ratio) were 150.3 ± 7.2cm, 60.2 ± 11.3 kg, 26.6 ± 4.3, 185.1 ± 5.7° and 0.92 ± 0.14 respectively.

New tensor device: In this study, we used a versatile new tensor device which had been introduced in 56th ORS 2010. It can measure the medial and lateral compartment gaps individually and make use of the balance gap technique guide with patello-femoral joint reduction even in severely deformed knees which need metal augmentations.

Surgical procedure according to the balanced gap technique: 1. After arthroscopy, sacrificing ACL and PCL, and medial release according to Clayton’s staged release method. (No pes anserinus was released in this study.) 2. Distal femoral osteotomy using intra medullary (I.M.) guide referred to extra medullary (Ex.M.) alignment rod. 3. Proximal tibia osteotomy perpendicular to the tibial axis using I.M. guide referred to Ex. M. alignment rod. 4. Femoral postero-medial capsular release if necessary. 5. Tibial tray sizing and finishing cut. All soft tissue clearance, release and osteophyte resection should be completed, and the appropriate extension gap and balance should be obtained in this step. 6. Extension and flexion gap measurement, and decision on the rotational alignment and the component size of the femur using a new tensor device. 7. Posterior femoral condyle osteotomy and femoral finishing cut. 8. Component gap (CG) measurement fitting with femoral trial prosthesis. Flexion CG measurement and STS calculation: First, a femoral trial prosthesis was fitted with patello-femoral joint reduction. Then, the medial and lateral gaps were measured when various distraction forces (70-140 N) were loaded in the knee at 90° flexion position. The STS (N/mm) was calculated from a load displacement curve generated by the CG data and joint distraction force of a new tensor device. Postoperative radiographic examination: To assess the rotation alignment of a femoral component, a condylar twist angle (CTA) was evaluated using computed tomography (CT). And to assess the postoperative balance in flexion position of the knee, condylar lift-off angle (LOA) was evaluated using the epicondylar view radiographs by adding a 1.5 kg weight at the ankle for reproducible visualization of the flexion gap. These radiographic examinations were obtained at 3 weeks after the operation.

Statistical Analysis: Data were expressed as mean ± SD and analyzed with Stat View version 5.0 (SAS Institute Inc.). Comparisons were made by one-way ANOVA post hoc analysis with Fisher’s PLSD test and Wilcoxon single-ranks test. Correlations were analyzed with Pearson’s correlation coefficient and Fisher’s z transformation of r. Predictive variables were analyzed with Stepwise regression. A value of P<0.05 was considered significant.

RESULTS: 1. In calculated STS, the medial compartment (24.8 ± 9.3 N/mm) showed significant higher stiffness than the lateral compartment (18.7 ± 6.4 N/mm) (P<0.0001). In addition, the STS of medial compartment significantly correlated with T/P ratio (r=0.318, P=0.040), and that of the lateral compartment significantly negatively correlated with the patient’s height (r=-0.388, P=0.011), weight-bearing FTA (r=-0.309, P=0.046) and the flexion CG discrepancy between the medial and the lateral compartments at 140 N of a joint distraction force (r=0.345, P=0.0247).

2. The flexion CG discrepancy between the medial and the lateral compartments at various joint distraction forces significantly tended to increase as the force dependent manner (0.94 ± 1.6 mm at 70 N, 1.95 ± 1.83 mm at 105 N, 3.0 ± 1.9 mm at 140 N) (P=0.008) and significantly correlated with the ratio of medial to lateral compartment STS (r=0.407 at 105 N, r=0.480 at 140 N). The LOA significantly correlated with the patient’s height (r=0.347, P=0.024), weight-bearing FTA (r=0.360, P=0.018) and the flexion CG at 70 N (r=0.328, P=0.033), 105 N (r=0.401, P=0.008) and 140 N (r=0.401, P=0.008). Moreover, the predictive variables of the LOA was indicated as the following; LOA = 18.677 + 0.045 x (weight) – 0.118 x (weight-bearing FTA) + 0.406 x (the discrepancy of the flexion CG between the medial and the lateral compartments at 140 N) (R=0.644, P=0.0001).

4. The average of the LOA and the CTA were 0.82 ± 2.50° and 0.82 ± 1.77°, respectively. No significant correlation was observed in between the LOA and the CTA (r=0.16, P=0.31).

DISCUSSION: The results demonstrated that the early postoperative flexion gap balance is affected by not only the intra-operative gap balance acquired by an operation technique but also by some factors relating to the patient. Furthermore, the amount of intra-operative gap measurement is dependent on the joint distraction force and the STS. Here, we should also notice the significant difference of the STS between the medial and lateral compartments in the knee 90° flexion position and the ratio of the medial to lateral compartments STS ratio of the medial compartment; STS has a strong influence on the joint gap balance during surgery, especially when the balanced gap technique is used. In other words, it suggests the importance of refinement of the joint distraction force for individual patients based on their own characteristics of soft tissue. Further studies are needed to clarify the individually appropriate joint distraction force for the balanced gap technique in the light of the clinical outcome.

CONFLICT OF INTEREST: The authors have no conflict of interest.