Title: Gap Balanced vs Measured Resection Total Knee Arthroplasty: A Functional Outcome Comparison

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Abstract

Background: Gap Balancing and Measured Resection techniques are currently acceptable methods for balancing Total Knee Arthroplasty. This study compares functional outcomes of these two techniques using accepted patient reported outcome scores as well as range of motion.

Methods: 106 patients with a diagnosis of degenerative osteoarthritis of the knee who failed non-operative management were enrolled in this study. At the time of surgery, each subject was randomized to undergo primary total knee arthroplasty utilizing either a measured resection or a gap balancing technique. Functional outcome scores as well as range of motion were compared between the two groups at 2 years post operatively.

Results: No statistically significant difference was found in range of motion at 2 years or any patient reported outcome measures at 2 years post operatively including Knee Society Score, Knee Injury and Osteoarthritis Outcome Score (KOOS), or the Forgotten Joint Score (FJS).

Conclusion: Both the gap balancing and measured resection techniques achieved excellent postoperative functional outcomes at two-year follow-up in this prospective, randomized trial.

Trial Registration: This trial was not registered as it was not considered a human intervention because the techniques used are different types of standards of care.

Keywords: Gap Balancing, Measured Resection, TKA, FuZion Balancer, eLibra Sensor, patient reported outcomes

Manuscript

Background

Total knee arthroplasty (TKA) is a historically proven technique in treating various arthritic conditions of the knee. In experienced hands, this procedure provides patients with decreased pain as well as improved range of motion and function which restores quality of life. Correcting alignment with bone resection and balancing of the surrounding soft tissue envelope are two key steps in the ultimate success of this procedure.

Much attention has been directed at instrumentation utilized to perform bone cuts in TKA since Insall's original summary of the procedure 30 years ago [1]. Currently, both intramedullary and extramedullary techniques are used extensively. Ligamentous stability remains a key component to TKA success despite the importance of proper bone cuts and restored alignment. Instability and problems with ligament balance have been shown to lead to early failure secondary to condylar liftoff, flexion instability, accelerated bearing surface wear, loosening, pain, patellar maltracking, and material failure [2-8].

Total knee kinematics are affected by the position of the femoral component as all 3 planes need to be appreciated. Because of this importance, various intraoperative femoral preparation techniques have been developed to properly align the femoral component. "Measured resection" uses distal femur anatomic landmarks (the trans-epicondylar axis (TEA), posterior condylar axis (PCA), and the anteroposterior axis (AP axis, Whiteside Line)) to position the femoral cutting block prior to performing condylar and chamfer resections. Ligament releases and soft tissue balancing generally follows this step during trialing of components. This technique ensures proper flexion-extension and patellofemoral motion kinematics.

Another technique embraced by many authors (1,2,11,12,17,18,19,20) is "gap balancing, which sets the femoral rotation in flexion by relying on soft tissue tension. After the distal femur and proximal tibia cuts are performed soft tissue releases are performed with the knee in extension on either the medial or lateral side to create a rectangular extension gap. A spacer block or tensioning device is then inserted into the extension gap to record insert thickness as well as collateral tension achieved.   Next, with the knee flexed 90 degrees, a tensioning device is inserted between the resected tibial plateau and the posterior femoral condyles. The flexion gap is then "tensioned" to a similar force achieved in extension and the femoral cutting block is positioned on the resected distal femoral surface such that the posterior condylar cuts are parallel to the tibial plateau the gap to be created is symmetrical to the extension space previously recorded. Tensioning devices utilize various techniques which ensure that the flexion gap is rectangular while allowing the surgeon to alter the “thickness” of the gap by positioning the femoral drill holes more anterior or posterior on the resected distal femoral surface.

Despite the abundance of studies summarized on both measured resection and gap balancing techniques in TKA, little has been written on direct comparison of functional outcomes between the two approaches. The authors propose a prospective, randomized study comparing functional outcomes between measured resection and gap balancing techniques.

Methods

106 patients were enrolled in the study after appropriate IRB approval. Enrollees had a diagnosis of degenerative arthritis of the knee and demonstrated failure of non-arthroplasty management. At the time of surgery, each subject was randomized to undergo primary total knee arthroplasty utilizing either a measured resection technique or a gap balancing technique. Variability between the two groups were minimized by using similar surgical protocols throughout the study period. Zimmer Persona, Posterior Stabilized implants (Zimmer Biomet Warsaw, Indiana) were used in all cases. Patients underwent spinal anesthesia with a single-shot adductor canal block, as is standard at our institution. Pre-operative antibiotics were administered per protocol. Surgery was performed utilizing a standard anterior, midline longitudinal incision followed by a medial parapatellar arthrotomy. Limited soft tissue release was performed for exposure. The patella was retracted laterally and not everted during exposure and balancing steps of the procedure. The order of boney resection were similar in all cases beginning with the proximal tibia, using extramedullary guidance, followed by the distal femur with intramedullary referencing in 5^{o} valgus. Extension gap assessment was made to ensure adequate bony resection and appropriate extension balancing was achieved.

In the case of the measured resection technique, once the distal femur was cut, a posterior condylar referencing jig was applied, which allowed for femoral sizing as well as the 4-in-1 cutting block localization. Rotation was set on the approximation to the transverse epicondylar axis. After the femoral cuts were performed, flexion gap was assessed to evaluate any additional soft tissue releases that may have been needed to equalize the medial and lateral gaps.

For the gap balancing technique, similar extension balancing was performed as in the measured resection technique; however, femoral rotation and translation was determined using a ligament tensioning device (Fuzion balance, Zimmer). The balancer was initially placed in extension then tensioned with a torque hex driver until appropriate gap thickness was achieved and this torque measurement was recorded (Figure 1). The balancer was subsequently applied between the resected proximal tibia and native posterior condyles with the knee in 90º of flexion. Torque was applied to tension the flexion space matching the torque measurement achieved in extension. With this jig, the femur then rotates freely based on lateral and medial soft tissue tension allowing for appropriate rotation and translation of the implant for appropriate soft tissue balancing in flexion (figure 2).

At the time of surgery, femoral component rotation, posterior condylar cut thickness, and intercompartmental forces were measured using an intraop force senser (Figure 3). This previously published data showed greater femoral rotation (1.5, vs 3.1 degrees, P<0.05), posterior condylar cut thickness (10.2, vs 9.0mm medially and 8.5 vs 6.4mm laterally), and decreased intercompartmental force in full flexion (0.8 vs 2.0u, 1u=15N, P<0.05) in the gap balanced cohort [21].

Standardized rehabilitation and pain management protocols were utilized for both patient groups in the postoperative period. Patients were followed at regular intervals (6 weeks, 3 months, 6 months, 12 months, and 24 months) with Knee Society Score (KSS), Knee Injury and Osteoarthritis Outcome Score (KOOS), and Forgotten Joint Score (FJS) scores at each visit. Standard AP, lateral and sunrise radiographs will be evaluated and compared over time.

Results

Patient Demographics

A total of 106 patients were included in this study. There were 54 patients included in the measured resection (MR) cohort, and 52 patients in the gap balanced (GB) cohort. There were 47 (45.1%) females and 59 (54.9%) males. There were similar rates of men in each group (GB 23, 48%; MR 17, 40%). The average age in the study was 62.3 (range 47.9-73.9) years. After matching, there were no statistically significant differences between the two cohorts regarding age, sex, ASA score, surgery duration, or medical comorbidities.

Range of Motion

There were no significant differences for the mean range of motion between the GB and MR groups at the two-year follow up (0.54° to 125.6° ± 6.9° vs 0.80° to 123.6°± 6.7°, p > .05) (Table 1). There was a negative correlation found between the intraoperative compartment pressures with respect to postoperative Range of Motion (ROM)(r = -.027, p <.02); however, no statistically significant differences were found between the two surgical groups.

Functional Outcome Scores

No statistically significant difference was found in any patient reported outcome between the GB and MR cohorts at two-year follow up, which can be seen in Table 2 including the Knee Society Scores (93.46 ± 11.52 vs 92.59 ± 8.74, p > .05), Knee Injury and Osteoarthritis Outcomes Score (KOOS) (84.68 ± 13.7 vs 81.22 ± 16.5, p > .05), and Forgotten Joint Score (FJS) (65.39 ± 31.02 vs 60.53 ± 33.64, p > .05).

There were no reoperations in either cohort during the two-year follow up span for septic or aseptic causes.

Discussion

Total knee arthroplasty is still the gold standard treatment option for osteoarthritis in the elderly population. Soft tissue balancing and femoral rotational alignment are important factors for optimal results. The measured resection and gap balanced techniques are the two most commonly employed techniques for TKAs.

In the setting of measured resection, anatomic landmarks are referenced in order to determine femoral rotation. Accuracy of identifying these necessary landmarks can be variable. Whiteside showed improved patellar tracking as well as stability in patients with valgus knees who underwent TKA utilizing the AP axis to set femoral rotation compared to the posterior condyles [9], however, Yau demonstrated a 32º range of error using the AP axis (15º of internal rotation to 17º of external rotation) [11]. Nagamine additionally found external rotation errors using the AP axis in varus knees with medial compartment degenerative disease [10].

The trans-epicondylar (TEA) axis is another, well recognized landmark to assist in setting femoral rotation. Scott demonstrated the TEA was more accurate and resulted in a rectangular flexion space within ±3º 90 percent of the time when compared to posterior condylar axis [16]. However, Kinzel demonstrated that the TEA is correctly identified within ±3º only 75% of the time using postoperative CT scans to check accuracy [13]. Additionally, the previously mentioned study by Yau demonstrated, errors with identifying the TEA ranging from 11º of external rotation to 17º of internal rotation [11]. These studies bring into question the use of these landmarks in an effort to create a rectangular flexion space.

Studies have documented that the posterior condylar axis is rotated an average of 3º relative to the TEA [14, 15]. This fact provides a reproducible technique which is employed by many TKA instrumentation systems currently in use in an effort to parallel the TEA. Deficiencies exist with use of the PCA, however, as there is a high degree of anatomic variability within patient populations. For example, knees with valgus deformities often display hypoplasia of the lateral femoral condyle, which will result in internal rotation of the femoral component when strictly relying on this landmark as a reference point.

As previously mentioned, gap balancing relies on soft tissue tension to set femoral rotation rather than anatomic landmarks. Fehring previously compared a balanced technique to measured resection in 100 TKAs and showed a trapezoidal flexion space 45% of the time in the measured resection cohort as compared to the gap balanced cohort [18]. Dennis previously demonstrated only 43% of cases using TEA to set femoral rotation matched balanced alignment within 3º [20] as well as less condylar lift off in those performed using gap balancing technique [2].

While the literature is vast on the benefits of both measured resection and gap balanced techniques as well as difference in femoral rotation based on technique, the question still remains as to the effect on patient functional outcomes given this well described variability. This study's previously published data demonstrated that the GB group resulted in greater variability as well as larger posterior condylar cut thickness compared to the MR group. Because the GB technique is dependent on soft-tissue tensioning to determine the femoral rotational axis, and not purely dependent on set anatomical landmarks as performed via the MR technique, it is not surprising that there is more variation in the posterior condylar cut thickness with the GB cohort given patient variability. Although the greater posterior condylar cut thickness resulted in greater flexion space in the GB cohort, it was not statistically significant in improving postoperative ROM, and additionally showed no statistically significant difference between intracompartmental force differences in the medial and lateral joint space between gap balanced and measured resection techniques in full extension, but did show a difference at full flexion, which showed a statistically higher force in the medial compartment than the lateral in measured resection technique compared with gap balanced technique [21].

The results of this study show that both the GB and MR techniques achieved excellent postoperative ROM and functional outcome scores at two-year follow-up. The average ROM between the two cohorts did not differ significantly. While there was no statistically significant differences were identified between the two cohorts with respect to the KSS, KOOS, and FJS functional outcome scores, each of the functional outcome scores did trend towards higher scores in the gap balanced cohort. Larger study population or longer follow up time points may be needed to show significance. Our findings are generally consistent with prior literature comparing the two techniques.

A recent meta-analysis of 2259 cases found statistically significant increases in Knee Society Scores at one year utilizing the GB technique, compared to MR technique, but the mean difference was well below the minimal clinical important difference [22]. Clement et al retrospectively reviewed 113 patients, 44 GB and 69 MR at a mean follow up of five years and found a statistically significant difference between the GB and MR groups with regards to Oxford Knee Scores 36.9 and 33.6, respectively [23]. However, the clinical significance of a 3.3 difference comes into question, especially with no statistically significant difference seen between the groups in patient satisfaction. A retrospective review of 221 TKAs comparing the two techniques found no statistically significant difference in Knee Society Scores between the two groups at three-year follow up [24]. These early findings of equality were also seen in a medium-term follow up study of 164 patients [25]. At ten-year follow up, the statistically significant increase in Knee Society Score in the GB group was interpreted as “trivially different” and not clinically relevant.

This study does have limitations. Our limited follow up of two-year makes it difficult to generalize functional outcomes between the two techniques. However, to our knowledge, there is no other study with clinical outcome data including the Knee Society, KOOS, and Forgotten Joint Scores comparing the two techniques. Future clinical outcomes will be monitored in this patient population.

Conclusions

In this randomized, prospective series no difference was observed with respect to functional and patient reported outcomes comparing gap-balanced and measured resection techniques when performing total knee arthroplasty. Intraoperative compartment pressures measured at surgery appeared to impact post-operative ROM negatively but this was not significant in our patient cohort at the two-year post operative time point.

The results of this study show that both the GB and MR techniques achieved excellent postoperative functional outcomes at two-year follow-up. This demonstrates that both surgical techniques can be utilized to achieve a well-balanced knee with similar short-term outcomes.

List of Abbreviations

- Total knee arthroplasty (TKA)
- Trans-epicondylar axis (TEA)
- Posterior condylar axis (PCA)
- Anteroposterior axis (AP axis)
- Knee Society Score (KSS)
- Knee Injury and Osteoarthritis Outcome Score (KOOS)
- Forgotten Joint Score (FJS)
- Measured resection (MR)
- Gap balanced (GB)
- Range of Motion (ROM)

Declarations

Ethics approval and consent to participate

This study has IRB approval for enrollment of human subjects. WCG IRB is the central IRB that reviewed the Protocol and Consent form and granted initial approval on September 29th, 2015. The tracking number for this study with WCG IRB is 20151553.

Consent for publication

Consent for publication was obtained from all subjects enrolled into this study. This was part of the subjects signing the consent form. Specifically, the authorization form of the ICF states that it allows all information gathered for this study to be published.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due containing subject PHI but are available from the corresponding author on reasonable request. The data shared will be deidentified.

Competing Interests

The authors declare that they have no competing interests

Funding

No funding was provided for this study. The study was investigator initiated.

Author's contributions

NN, SD performed the total knee arthroplasty surgeries using the two techniques. MD and AL collected all the data for the study. NN, SD, MD, AL all analyzed the data and were major contributors in writing the manuscript. All authors read and approved the final manuscript.

Acknowledgments

Not applicable.

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Appendix (Figures and Tables)

Figure 1. – FuZion Balancing Jig

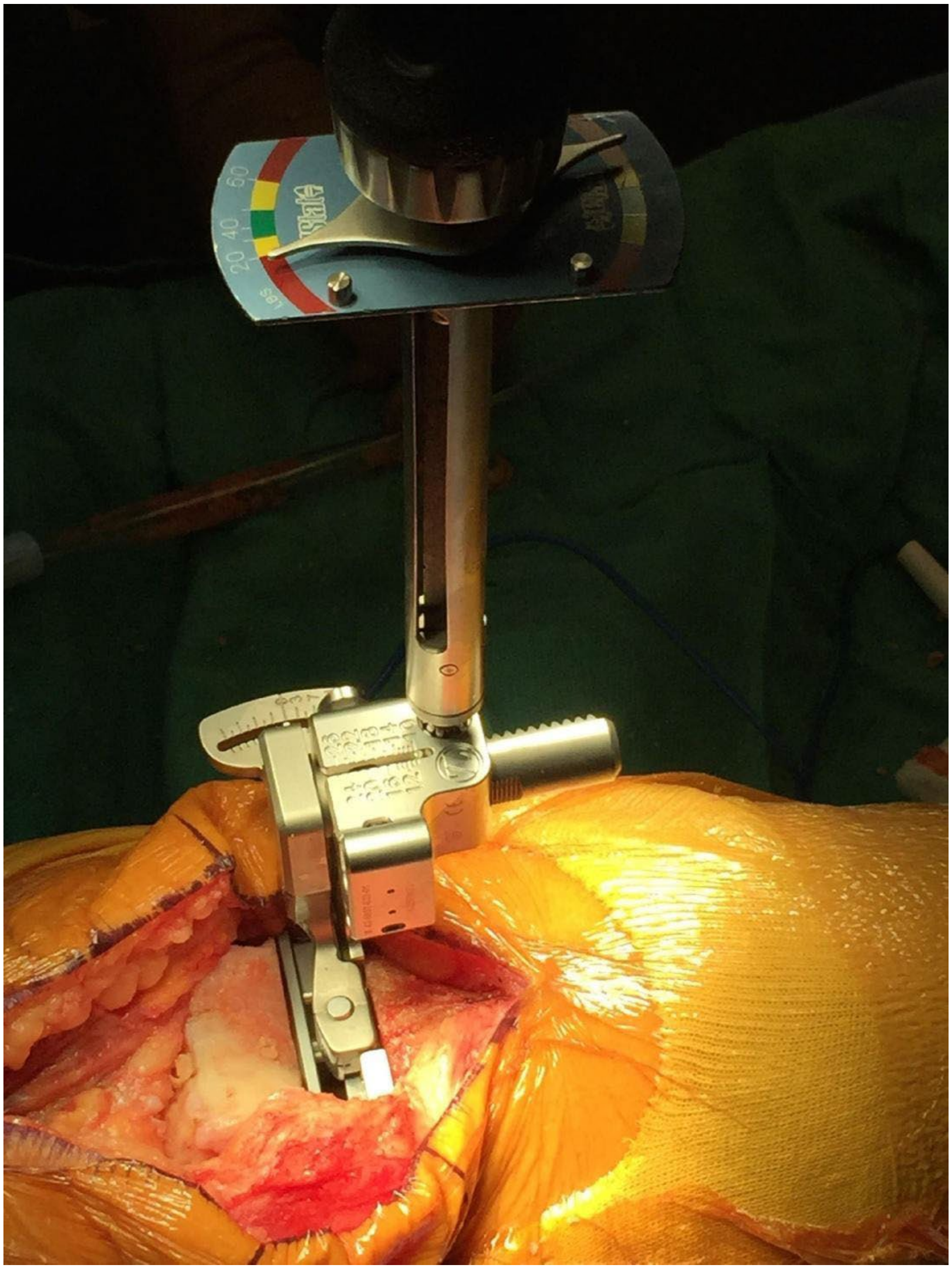

Figure 2. – Flexion Gap Drill Guide

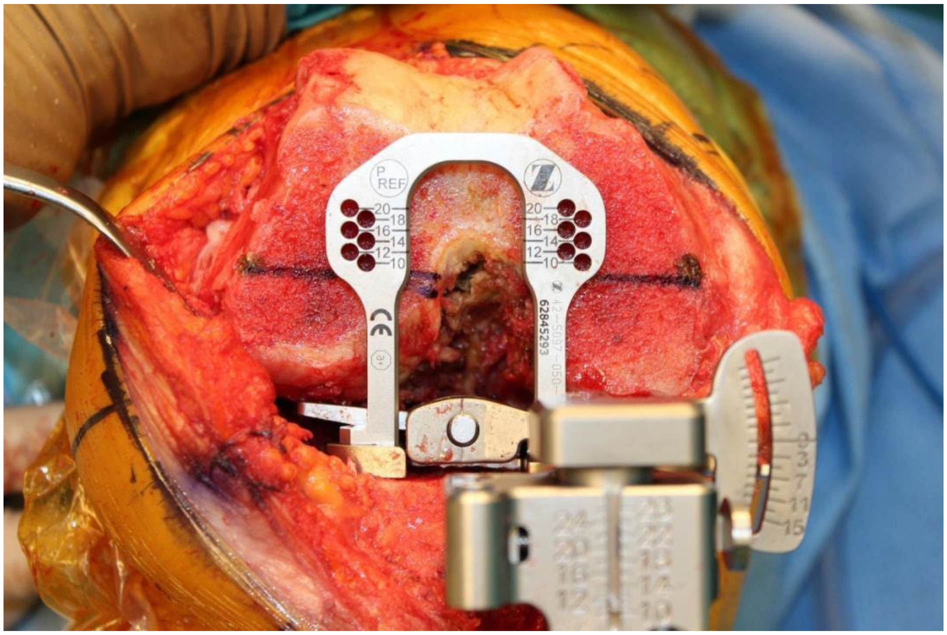

Figure 3. – Intraoperative force sensor measurement

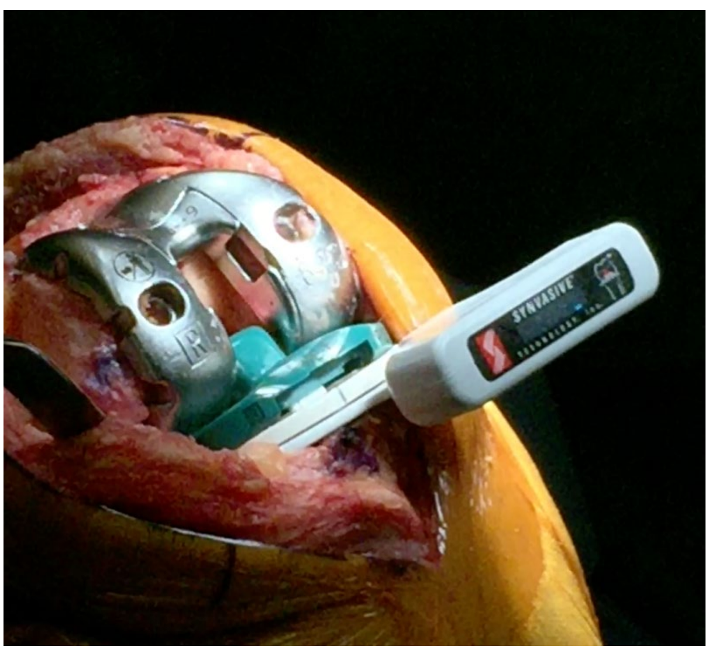

Table 1. Range of motion comparison between gap balanced and measured resection techniques.

	Gap Balanced		Measured Resection	
	Mean	Std. Deviation	Mean	Std. Deviation
Preop Flexion	117.06	8.96	117.67	10.29
Preop Extension	3.77	4.19	3.79	3.54
6 week Flexion	116.23	10.81	112.31	16.86
6 week Extension	1.52	2.29	2.84	3.52
1yr Flexion	126.79	7.75	123.72	5.89
1yr Extension	0.29	1.08	0.55	1.38
2yr Flexion	125.61	6.90	123.60	6.71
2yr Extension	0.54	1.26	0.80	1.58

Table 2: Patient Reported Outcomes at 2 year follow up

		Mean	Std. Deviation	alpha
2yr ROM Flexion	Gap Balanced	125.61	6.90	0.642
	Measured Resection	123.60	6.71	
2yr ROM Extension	Gap Balanced	0.54	1.26	0.164
	Measured Resection	0.80	1.58	
2yr KS SCORE	Gap Balanced	93.46	11.52	0.567
	Measured Resection	92.59	8.74	
2yr Koos	Gap Balanced	84.68	13.7	0.570
	Measured Resection	81.22	16.5	
2yr Forgotten Joint	Gap Balanced	65.39	31.02	0.580
	Measured Resection	60.53	33.64	