The Journal of Arthroplasty 29 (2014) 950–954

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Gap Balancing Sacrifices Joint-Line Maintenance to Improve Gap Symmetry: A Randomized Controlled Trial Comparing Gap Balancing and Measured Resection

Sina Babazadeh, PhD [a,b], Michelle M. Dowsey, PhD [a,b], James D. Stoney, MB, BS [a], Peter F.M. Choong, MD [a,b]

[a] St. Vincent's Hospital (Melbourne), Department of Orthopaedics, Fitzroy, Victoria, Australia
[b] University of Melbourne, Department of Surgery

ARTICLE INFO

Article history:
Received 1 July 2013
Accepted 23 September 2013

Keywords:
knee
arthroplasty
gap balancing
measured resection
function

ABSTRACT

A total knee arthroplasty can be completed using two techniques; measured resection or gap balancing. A prospective blinded randomized controlled trial was completed with 103 patients randomized to measured resection (n=52) or gap balancing (n=51). Primary outcome measure was femoral component rotation. Secondary outcome measures were joint-line change, gap symmetry and function and quality-of-life outcomes. Gap balancing resulted in a significantly raised joint-line compared to measured resection. Gap symmetry was significantly better using gap balancing. Functional outcomes and quality-of-life were not significantly different at 24 months. Using computer navigation, gap balancing significantly raises the joint-line in order to improve gap symmetry. This does not result in a clinical difference in function or quality of life at 24 months.

To achieve a balanced knee, two distinct methods of knee prosthesis implantation have been described: measured resection (MR) and gap balancing (GB), or balanced resection. These employ different techniques to determine femoral component rotation and ligament balancing.

The "measured resection" technique [1] aims to resect an amount of bone equal in thickness to the prosthesis to be implanted. Distal femoral resection is angled in respect to the femoral shaft [2]. Bony landmarks are used to determine femoral component rotation [3–7]. The femoral antero-posterior (AP) resection relies on one of three bony landmarks; being the posterior condylar axis, the epicondylar axis or the AP trochlear axis (Whiteside's line) [8]. The tibial resection is done independently, perpendicular to the tibial axis. Ligament balancing is then undertaken once the trial components are in-situ.

It has been reported to have a high variability and reduced reliability [3,9]. It relies on the subjective judgement of the operating surgeon to determine the bony landmarks [10]. Also, it does not take into account changes in laxity and joint gap that can occur in flexion, once the knee is balanced in extension, this may result in joint-gap mismatch [4].

Using "gap balancing" the distal femoral and proximal tibial resections are performed first. Soft tissues are then balanced in extension, to result in a rectangular and equal extension gap. The knee is then placed in flexion, where the joint space is distracted using lamina spreaders, tensor balancers or joint distracters. The posterior femoral resection is subsequently made parallel to the resected surface of the tibia, ensuring a rectangular flexion gap, matching the extension gap [4,11–13].

The benefits of gap balancing include the ability to compensate for femoral bone loss. Also, this technique has the ability to compensate for the effects of gap changes and soft-tissue laxity that occurs in flexion once ligament balancing has been performed in extension. It has been reported to be more accurate in determining femoral component rotation [14].

Direct comparisons between these two techniques are few. Gap balancing is thought to result in significantly less condylar lift-off [11] and result in more accurate gap symmetry [15]. Femoral component rotation as determined by gap balancing has been noted to be different to that determined by measured resection [4,14]. The joint-line has also been noted to be raised using gap balancing [2]. No comparison has determined whether either technique results in improved patient function or quality of life.

Limitations of comparisons include different prostheses and implantation methods and patient selection bias between groups. To control these biases and limitations a randomized controlled trial was undertaken to investigate primarily whether gap-balancing can improve femoral component rotation and the flexion–extension gap whilst maintaining the joint-line and secondarily whether this translates to improved functional outcomes and quality of life as measured by patient-centred surveys.

Patients and Methods

Study Design

A blinded randomised controlled trial was conducted within two tertiary hospitals. The study was approved by the hospitals' Human Research and Ethics committee (HREC-A 021/09; February 2009) and

The Conflict of Interest statement associated with this article can be found at http://dx.doi.org/10.1016/j.arth.2013.09.036.

Reprint requests: Sina Babazadeh, PhD, St. Vincent's Hospital (Melbourne), University of Melbourne PO Box 2900, Fitzroy, Victoria 3065, Australia.

0883-5403/2905-0018$36.00/0 – see front matter © 2014 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.arth.2013.09.036

was in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000. The study was registered with the Australian and New Zealand Clinical Trials Registry.

Participants and Exclusion Criteria

All patients on the waiting list of the two participating surgeons, scheduled for an elective primary knee arthroplasty, between October 2009 and February 2011 were eligible for enrolment into the study. Patients were invited to participate during routine preadmission clinic 4 weeks prior to their surgery. Patients were only excluded if they were not suitable for the primary condylar prosthesis mentioned below.

Sample Size

The power of the study was based on demonstrating a clinically relevant 2 degree difference in femoral component rotation between these groups. From previous studies, a standard deviation of 2.56° for femoral component rotation was used. To achieve an alpha of 0.8 and $P < .05$, would require a minimum of 27 patients in each group. This was achieved. Sample size was increased to at least 50 patients per cohort to achieve adequate power for secondary outcomes.

Data Collection

The patients were examined and pre-operative International Knee Society Score (IKSS) and Short-Form 12 (SF-12) were collected.

Intra-operatively all navigational data regarding resection levels and joint gap measurements were recorded. Notably these data included resection levels and lateral and medial joint gap measures in both flexion and extension.

Post-operatively the patients were reviewed at 6 weeks, 3 months, 6 months, 12 months and 24 months. A Hollywood CT Pert-Protocol [16] Protocol was performed at the 6-week visit to determine femoral component rotation.

The IKSS and SF-12 surveys were completed at the 3, 6, 12 and 24 month visits, with examinations of the knee also undertaken during these visits.

Interventions

All patients received a modular, total condylar primary prosthesis (PFC Depuy, Warsaw, IN), with femoral, tibial and patellar components cemented in all cases. Two patients (1.9%) received a posterior stabilized implant while the remainder received a cruciate retaining implant. Posterior stabilized implants were reserved for those patients with an incompetent PCL, which could not be corrected by a cruciate retaining prosthesis. These patients have been included in the analysis as per intent-to-treat requirements of the CONSORT statement [17].

A computer navigated imageless system (Ci System, Depuy) was used in all cases. Computer navigation was used to allow a real-time and accurate measure of all joint-gaps and bone resection levels. The tibial resection was performed first in both techniques, being perpendicular to the tibial axis with a posterior slope of 3° using computer navigation.

With the measured resection cohort, attention was at this point diverted to the femur. Femoral bone resection was performed, guided by the navigation system, independent of the tibial cut. Whiteside's line was used to determine femoral component rotation. Trial prostheses were then inserted and the ligaments balanced to achieve even tension in flexion, extension and range-of-motion before the final components were cemented in place.

With the gap balancing group, a standardized spring loaded device was used to distract the joint in full extension with 12 kg of tension on each condyle (Sensor Tensor XF, Depuy, J&J Leeds, UK). Varus/valgus stability and tension were tested in extension (0°) and relevant ligaments released as required providing a rectangular extension gap and correction of any femoral flexion contractures. The knee was subsequently placed in 90° of flexion and the same spring loaded device placed to distract the joint. Femoral posterior condyle resection was made parallel to the resected tibial surface using computer navigation. This ensured that the femoral component rotation was parallel to and determined by the proximal tibial resection, being perpendicular to the long-axis of the tibia. No ligamentous balancing was carried out in flexion. Depth of resection was determined by computer algorithm using the initial extension gap; to match the resulting flexion gap to the extension gap which had previously been balanced, measured and stored.

Randomisation

Randomisation was performed by an independent research fellow using a computer generated number with the surgeon informed of the results on the day prior to surgery.

Blinding

Both patients and researcher were blinded to the technique of surgery performed until all radiographic measurements and all clinical follow-up were completed and analysed. Navigation data was analysed via data tables produced by the navigation program, with the method of operation removed.

Statistical Analysis

Mixed data sets were analysed using the t-test. All statistical outcomes where re-checked for accuracy and correct methodology by a tertiary qualified biostatistician. A P value of 0.05 was regarded as significant for all statistical tests.

Results

One-hundred and seven consecutive patients were approached during the recruitment period. One patient was excluded as the patient was deemed to require a stemmed prosthesis due to gross instability. Three patients refused to participate in the study leaving 103 consented patients. Fifty-two patients were randomized to measured resection (MR) and fifty-one patients were randomized to gap balancing (GB) (Fig. 1). Two patients failed to complete their operation as per randomization. Of these two, one patient had failure of the computer navigation system, and in the other patient the infra-red arrays moved intra-operatively. Both patients were converted to conventional jig-based arthroplasty. Both patients were initially randomized to measured resection and were included in the analysis of this group, meeting "intent to treat" guidelines. No patient was lost to follow-up.

Patient Demographics

All preoperative characteristics were collected prospectively and are represented in Table 1. No significant differences were found between the measured resection and gap balancing groups.

Radiological Outcomes

Femoral component rotation was calculated using the Hollywood Perth-Protocol CT-scan [16] as the difference between the trans-epicondylar axis of the knee and the femoral component. This was