ORIGINAL ARTICLE

Clinico-Radiological and Functional Results of the Navigated Gradius (Gradually Reducing Radius) Knee Prosthesis at Short to Mid-Term Follow-Up

Mrinal Sharma^{1,2} · Bharat Dhanjani¹ · Jibran Bashir¹ · Anshu Kumar Anshu¹

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Abstract

Background Navigated total knee replacements (TKR) have shown better knee function and quality of life. It also reduces revision rates. The aim of our study is to evaluate short to mid-term clinico-radiological and functional results, survival rate and complications of Gradius knee prosthesis implanted using computer navigation.

Methods We retrospectively reviewed 120 Gradius knee prosthesis, implanted in 68 patients (52 bilateral TKR and 16 unilateral TKR) and followed from Jan 2015 till Jan 2020. Pre-operative & post-operative radiographs, knee society scores (KSS), range of motion (ROM), deformity assessment and gait video recordings were done for all patients.

Results The mean follow-up was 3.8 years (minimum 2–5 years). The mean ROM was 2° (0–10) extension to 135° (128°–138°) flexion. The KSS pain score improved from mean of 38.3 (range 26–44) to 90.4 (mean 88–92). The KSS functional score improved from 36.2 (range 28–39) to 92.6 (range 86–94). All patients had excellent to good function during successive follow-ups. The coronal alignment improved from 8° varus to 0.3° varus. Sagittal alignment was corrected from 8° (4°–18°) preoperatively to 2° (0°–8°) postoperatively

Conclusion At mid-term our series outlines the better functional and radiological results of Gradius knee prosthesis using navigation as a tool. We recommend a prospective randomized controlled trials comparing navigated versus non-navigated for Gradius knee prosthesis with long-term follow-up.

Keywords Total knee replacement · Navigation · Range of motion · Gradius knee prosthesis · Knee society score

Introduction

Although use of computer navigation in knee replacement surgery started 20 years ago, it has still not gained widespread popularity despite the proven advantages of placing the prosthesis in correct alignment, less blood loss and less chances of fat embolism [1]. Computer navigation has also shown to reduce outliers in post-operative alignment compared to conventional and patient-specific instrumentation [2]. Navigated total knee replacements have also been reported to have a better knee function and quality of life [3].

It has also been proven to reduce revision rates in patients less than 65 years of age [4]. Lako et al. reported that computer navigation allowed a less experienced and low-volume orthopaedic surgeon to make the implantation of endoprosthesis more accurate, to decrease the total revision rate, and thus to ensure a higher probability of long-term survival of total knee arthroplasties [5]. Computer navigation has also proven advantageous in obese patients undergoing total knee replacement (TKR) by reducing outliers in terms of coronal alignment and it also does not increase the operative time as compared to performing TKR in obese patients without navigation [6]. So far navigation has proven its benefits in total knee replacement surgery. Aim of our study is to report short to mid-term clinic-radiological and functional results, incidence of complications and survival rate of Gradius knee prosthesis (Depuy synthes) implanted using computer navigation (knee brain lab software).

✉ Mrinal Sharma
dr.mrinalsharma@gmail.com

¹ Department of Orthopedic Surgery, Asian Institute of Medical Sciences, Faridabad, Haryana, India

² 1203, Imperial Court Tower 2, Jaypee Greens Wish Town, Gautam Budh Nagar, Noida, Uttar Pradesh 201304, India

Material and Methods

It was a retrospective study conducted using Attune total knee replacement prosthesis over a period of 5 years (Jan 2015 till Jan 2020). Over this period 120 Gradius knee prosthesis were implanted using computer navigation in 68 patients (52 underwent bilateral TKR and 16 underwent unilateral TKR). The age of patients was from 54 to 78 years (mean 66 years). There were 52 females and 16 males included in this study. The average BMI was $26.2 \pm 4 \text{ kg/m}^2$ ($24\text{--}35 \text{ kg/m}^2$). All had advanced osteoarthritis of the knee with moderate to severe varus deformation including those with fixed flexion deformity. Rheumatoid knees with valgus deformation were not included in the study. Complex deformities like post high tibial osteotomy, fused knees, extra-articular deformities and knee with severe varus deformation and associated bone defects that might require constrained implants, stem extenders and bone grafts were also not included in the study. All the surgeries were done by the same surgeon (MS) using the knee Brain lab navigation software. All bilateral TKR were done in the same sitting one by one and tourniquet time recorded. All patients were given pre surgery before induction of tourniquet and 6 h post surgery tranexamic acid (10 mg/kg body weight) to reduce blood loss. Bilateral TKR were done under combined spinal epidural followed by ropivacaine infusion for post op pain relief and single TKR were done under spinal anaesthesia supplemented by femoral/adductor canal blocks. Pre-operative and post-operative radiographs, knee society scores (KSS), range of motion (ROM), deformity assessment and gait video recordings were done for all patients after appropriate required consent.

Surgical Approach

All patients were operated using the medial parapatellar approach. A separate small incision was given onto tibial shin to place two unicortical pins into the anteromedial aspect of middle of tibia for attaching the trackers assembly for tibia. Similarly two unicortical femoral pins were placed into the anteromedial aspect of supracondylar distal femur, away from the placement of implants, through the medial parapatellar incision. Unicortical pins prevent iatrogenic fractures and two pin placement reduces chances of pin loosening. All the anatomical landmarks such as hip rotation centre, proximal medial and lateral tibia, centre of tibial spine, centre of tibial condyles for rotation, medial and lateral malleolus, whiteside line, femoral epicondyles, medial and lateral distal femoral condyles, anterior femoral cortex and posterior femoral condyles

were registered into computer as guided by the software. Proximal tibia (8 mm from the less eroded side; lateral proximal tibia) and distal femoral cuts (9 mm from medial femoral condyle) were taken under navigation control and cross checked with a calliper and also with a verification instrument available with the navigation software. Sequential medial release was done in the following order starting with deep medial collateral ligament, posteromedial capsule followed by semimembranosus release (was done in severe deformities and those with fixed flexion deformities). In severe deformity cases a reduction osteotomy of medial proximal tibia was done to balance the knee, if the soft tissue releases failed to balance the knee. Balancing was done under navigation control to the nearest mm and continued till the final alignment was within 3° of neutral. Navigation also helped in proper rotation of femoral rotation and implant sizing. Final implantation was done using Gradius knee cemented (antibiotic simplex) posterior stabilised femur and tibia and a fixed bearing high flexion cross linked polyethylene insert was implanted. All the patella were resurfaced using the anatomical patella. Final intra-operative (ROM) achieved was recorded. All recordings and final alignment chart were stored in the computer for future correlation. A three layered standard closure was done. No suction drains were used. All patients on blood thinners had them stopped 5 days before surgery. Post operatively DVT prophylaxis was given to all patients (subcutaneous 0.4 ml low molecular weight heparin for two days followed by aspirin 150 mg at bed time for 15 days post surgery). Post-op x-ray of knee were recorded. All underwent rigorous inpatient physiotherapy as per protocol set by our physiotherapy team and were discharged at 5 days. Patients were followed at 15 days (stitch removal), 6 weeks, 3 months, 6 months and then yearly. Post-op x-rays, KSS, ROM was recorded at each follow-up (Figs. 1 and 2).

Results

All patients were followed for 2–5 years (minimum 2 years, mean 3.8 years). Two patients were lost to follow up. Finally 118 knees were available for final evaluation. The mean ROM was 2° ($0\text{--}10$) extension to 135° ($128^\circ\text{--}138^\circ$) flexion. The KSS pain score improved from mean of 38.3 (range 26–44) preoperatively to 90.4 (mean 88–92). The KSS functional score improved from 36.2 (range 28–39) to 92.6 (range 86–94). All the patients had excellent to good function during successive follow-ups. The average tourniquet time (incision till closure of quadriceps layer) was 68 min (range 52–90 min). The post-op fall in haemoglobin was 0.8 gm/dl (range 0.1–1.5 gm/dl). None of the patients required any blood transfusions. The pre-op coronal alignment

Fig. 1 **a** Pre-operative standing radiographs AP views of right knee (grade IV osteoarthritis) and left knee (grade III osteoarthritis) respectively. **b** Pre-operative standing radiographs lateral view of right knee. **c** Assessment of the deformity before the desired cuts

using navigation. **d** final proximal tibial cut under navigation guidance (blue lines). **e** Final distal femoral cut under navigation guidance (blue lines). **f** Final alignment graph. **g** Postoperative radiographs AP & Lateral views at 2 year follow up

Fig. 2 **a** Pre-operative standing radiographs AP & Lateral views of bilateral knees in a patient with severe osteoarthritis. **b** Assessment of the deformity before the desired cuts using navigation. **c** Final proximal tibial cut under navigation guidance (blue lines). **d** Final distal

femoral cut under navigation guidance (blue lines). **e** final alignment graph. **f–h** Postoperative radiographs AP, Lateral & 45° skyline views of bilateral knees at 3 year follow up

improved from 8° varus (range 4°–18°) to 0.3° varus (0–3° varus) post-operatively (Figs. 1, 2). The sagittal correction improved from 8° (4°–18°) preoperatively to 2° (0°–8°) postoperatively. We found that three knees (in two patients) developed a flexion contracture of almost 8°–10° which did not improve despite physiotherapy and persisted even on long-term follow-up. We attribute these to the increased slope of the tibial component during implantation as seen on the post op x-rays. Although we had no intra-operative peri-prosthetic fractures, we found that the keel of the tibial prosthesis in an attune rests closer to the posterior cortex of tibia on a lateral view of knee joint and this should be taken care of while preparing the tibial implant as there is a theoretical risk of iatrogenic fracture of proximal tibia.

There was one superficial infection (treated with dressings and antibiotic suppression) and one case of asymptomatic deep vein thrombosis (despite prophylaxis). None of the cases had pin tract infections or pin tract associated fractures. We attribute this to the use of two unicortical pins rather than a single bi-cortical pin. None of the patients had anterior notching as evident from the post op x-rays. Twelve knees had crepitus during range of motion, among those two had painful crepitus on knee flexion, seven reported anterior knee pain despite the patella being replaced. All the replaced patella tracked well. None of the patients required any lateral release for patella. One patient has a history of fall 2 months after surgery and developed instability. He was later revised to a constrained implant (Fig. 3). Aseptic loosening was not noticed in any of the patients on serial knee radiographs over the period of follow-up.

Discussion

We found the alignment in our series to be an average 0.3° of varus (no outliers). Similar results of better alignment using navigation have been reports in literature. Suero et al. compared navigation with conventional methods and patient-specific instrumentation (PSI) and found that the risk of post-operative mechanical alignment outliers (> 3°) was reduced by 89% in the navigated group (4% outliers) compared to the conventional group (35%) (RR = 0.11; $p < 0.0001$). No significant improvement was observed in the PSI group (27%) (RR = 0.91; $p = 0.772$)².

The mean operative time was 68 min in our series and the decrease in haemoglobin was 0.8 gm/dl. These findings correlates with other studies that have reported longer operative timing with navigation and less blood loss. Hsu et al. compared the radiographic and functional outcomes between CAS (Computer Assisted Surgery) and Conventional TKA in the same patient who underwent staged bilateral TKAs (CAS TKA in 1 knee and conventional TKA in the other knee) at mid-term follow-up. Navigation was associated with

longer operative time and less blood loss. They found no difference between CAS and conventional TKA regarding functional outcomes. They recommended that CAS TKA is probably not advantageous for the typical patient with osteoarthritis and maybe more beneficial in selected patients with severe deformity of the knee joint, extra-articular deformities, and severe femoral bowing [7]. Yu et al. have shown that navigation prolongs the operative time, reduces blood loss and need for transfusions, ideal recovery of joint function, less complications, safety and reliability. We agree to the above findings as they correlate with our results [8].

The KSS pain and function scores reported by us at mid-term follow up using Gradius knee prosthesis implanted with computer navigation are higher than those reported in literature. Panjwani et al. in a meta-analysis of 18 studies 3060 knees (1538 underwent TKA with CAS and 1522 underwent conventional TKA) reported limited evidence of better results in favour of computer navigation at 5–8 year followup [9]. Cip et al. demonstrated higher KSS pain and function scores 60 months after navigated TKAs, but the observed differences were below the minimum clinically important difference, suggesting that patients are unlikely to perceive the differences as clinically important [10]. Lutzner et al. reported better knee society scores and quality of life scores at 5 years in patients operated with navigation compared to those operated with conventional methods, although the difference was not statistically significant [11]. Baumbach et al. have also reported a 98% survival for navigation assisted TKA (50 knees) compared to 87% for conventional TKA (46 knees) at 120 months follow-up. They also reported an overall global KSS of 141(navigated) versus 135 for the conventional TKA [12]. According to the review of literature, navigated TKA has always proven to be giving better functional results.

We reported a lower incidence of anterior knee pain (7 knees) and painful crepitus (2 knees) in our series. We believe that the anatomical medialised dome patella and the femoral design accounts for the above findings in our series and so there was no need for any lateral releases as well. Webb et al. and Martin et al. have shown that implant design decreases the incidence of painful crepitus and need for lateral releases [13, 14]. White et al. have proven the role of anatomical patella of attune knees in reducing the incidence of anterior knee pain. They also reported a similar lesser incidence of anterior knee pain (10 knees) and painful crepitus [15]. The incidence of anterior knee pain has been less in patients operated with Attune knees as compared to depuy PFC sigma [16]. None of the patient had anterior notching in our series. Anterior notching has been reported in literature when using computer navigation. Kim et al. have recently studied patients at 14 years follow-up and showed that computer navigation does not provide any advantage in terms of pain relief, function or survivor. They did not recommend

Fig. 3 **a** Pre-operative standing radiographs AP and Lateral views of bilateral knees in a patient with grade IV osteoarthritis. **b** Post-operative radiographs AP & lateral views of bilateral knees. **c** Radiographs AP & lateral views of bilateral knees after 2 months of the primary

surgery in which right radiograph showing instability after history of fall. **d** Post-operative radiographs AP & lateral views of right knee after revision surgery showing constrained implants

computer navigation because of the complication such as femoral notching and pin site fractures and attendant costs [17]. Kim et al. reported a 5% rate on anterior femoral notching compared to 0.6% for the conventional group [18]. We believe that anterior femoral notching using navigation is overstated in literature and is surgeon dependent.

Staats et al. have reported a higher incidence of radiolucencies on the tibial side at 12 months in Attune group (276) compared to its predecessor PFC sigma(253) although

it showed no difference in revision free survival or revision rate [19]. In contrast we did not find any progressive radiolucencies over a period of 3–5 years. Bonutti et al. have reported an unusually high rates of failure of tibial component failures. They attributed it to less implant cement pockets, less tibial keel rotational stabilisers, less surface roughness and more constraint [20]. In contrast we found no such cases of tibial loosening or poly wear in our series. Jorgenson et al. have shown in a study of 478,081 TKA from

Australian national registry that computer navigation has shown a lower incidence of major aseptic revisions followed at 15 years [21].

On the contrary Ollivier et al. have shown no added advantage of using navigation in TKA in patients followed for 10 years [22]. Rhee et al. in a recent meta-analysis of RCT comparing navigation with conventional knee replacements concluded that although computer-navigated total knee arthroplasty resulted in better outcomes in post-operative component alignment than conventional total knee arthroplasty, there were no significant differences in long-term functional outcomes and survivorship between the 2 techniques [23]. These findings have also been documented by other observers in other studies with less than 5 years followup [24–26].

Conclusion

At mid-term our series outlines the better functional and radiological results of Gradius knee prosthesis using navigation as a tool. Navigation has proven that not only does it give better alignment, it improves functional outcome. We recommend a prospective randomised controlled trials comparing navigated versus non-navigated for Attune with long-term follow-up.

Author Contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by all the authors. The final draft of the manuscript was written by senior author (MS) and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Compliance with Ethical Standards

Conflict of Interest All authors declare that they have no conflict of interest.

Ethical Approval The study was approved by ethical review committee of our hospital.

Informed Consent Written informed consent was taken from all the patients included in the study before writing this article.

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