Navigation assisted total knee arthroplasty - Evaluation of correction of clinico - Radiological parameters in substantial varus deformity

Dev Krishan Sharma, Murtuza Rassiwala and Pramod P Neema

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Abstract
Background: In the present scenario arthritis of knee joint is inevitable. Total-knee replacement is the final solution in severely deformed joints for pain free mobility. Longevity of the replaced joint is mainly dependent on good mechanical alignment. The navigation system was introduced with a claim to achieve near normal parameters of weight bearing axis thereby increasing the life of implanted knee.

Material and Method: This was a prospective study from January 2012 to August 2015 done in Department of Orthopaedics at our institute. A cohort of 20 patients were taken with varus deformity more than 15 degree and operated with the help of navigation system. The result were compared with a cohort of 20 patients suffering from more than 15 degree varus deformity and operated without navigation. Informed consent was taken. Clearance from ethical committee of the institute was taken. Patients were evaluated pre operatively and post operatively at 1, 3, 6 and 12 months post operatively with the help of knee society knee score and function score and radiographically.

Results: Using computer assisted navigation and measured resection technique of ligament balancing in total knee replacement, mean tibio-femoral angle of 16.40 degrees varus preoperatively (range, 15degrees -24 degrees) was corrected to 2.4 degrees varus (range 5 degree valgus- 4 degree varus) postoperatively. Mean Knee Society score improved from 23.4 (range 0-44) to 86 (range 72 -98), and function score from 21 (range, 0-46) to 98.50 (range 55-100) at 12 months (range 12 month -34 months).No patient reported significant instability. Correction of severe varus deformity by the technique reported can successfully restore alignment, pain free motion, and stability.

Conclusion: Substantial Varus knee deformity is very well corrected when total knee arthroplasty is done with the help of navigation system. Here, in our study, either no varus or residual varus deformity was 1-2 degree. Navigation system assisted surgery produces good functional outcome and near normal radiological parameters.

Keywords: TKR, navigation, varus, arthroplasty, CAS, TKA

Introduction
Knee pathology and especially total knee replacement (TKR) have been the focus of research over the last ten years with controversy still existing regarding best practice for the treatment of the degenerative joint [1]. The prevalence of knee arthritis in the population is significant and has been estimated as two to ten percent for men and one and a half to fifteen percent for women [2, 3].

Total knee replacement, is a highly successful surgical procedure which involves replacement of all three compartments of the knee -the medial compartment, the lateral compartment and the patello femoral compartment. Longevity of the implanted joint is mainly dependent on good mechanical alignment.

To improve precision of implant positioning, various mechanical alignment guides are used, both intramedullary and extramedullary, but technical errors with these conventional surgical techniques still occur.

Computer assisted navigation surgery (CAS) has been performed in total knee arthroplasty (TKA) for approximately 10 years. This technique offers experienced and inexperienced surgeons improved control and reproducible results.

During the last decades CAS instrumentations have been improved in accuracy and various studies have been made to analyse results using this technique in TKA surgery.
Advocates of this technique in total knee replacement claim benefits in terms of improving accuracy for alignment of the leg and orientation of the components, as well as a reduction in blood loss and a lower rate of intracranial micro emboli compared with traditional surgery.

The survival rate for modern total knee arthroplasty is reported between 80% to 95% after 10 years of follow up [4, 5]. The most important factor of failure is malalignment of mechanical axis [6, 7]. However, no clear published results are available associated with superior clinical and patients perceived functional results and consequently longer survival rate [8].

Computer-assisted navigation seems to be helpful in those difficult situations where accurate alignment remains crucial but traditional instrumentation is not applicable. Traditional cutting guides during knee arthroplasty relies on intramedullary (IM) femoral instruments and either intramedullary or extramedullary (EM) tibial instruments to obtain proper axial alignment.

Intramedullary instruments cannot be used in patients with:
- Retained hardware that would be difficult or inadvisable to remove or longstemmed hip implants that could obstruct introduction of long IM instruments.
- Severe posttraumatic extrarticular femoral deformity when one is unable to pass an IM guide to accurately make a distal femoral cut.
- IM guides may increase the infection risk in patients with history of focal diaphyseal osteomyelitis around the knee joint [9].
- Patients with severe cardiopulmonary disease or a history of patent foramen ovale who maybe at risk for embolic dissemination because of femoral IM instrumentation [10].

These problems can be avoided with Computer-assisted navigation.

Varus deformity can be classified as intra or extra articular. There have been several studies to define what a “severe” varus is. Ritter et al. in 2004 defined massive varus as a tibio-femoral angle of more than or equal to 20 degrees [11]. In a similar study in 2005, Mullaji AB et al. also defined severe varus deformity as more than or equal to 20 degrees of tibio-femoral angle [12]. Recently, a new classification for the severity of arthritic disease was proposed using simple semantic terms that will allow surgeons to compare deformities in the near future. Mechanical alignment within 3° was considered normal and a deformity within 4-10° a common deformity. With increments of 10°, the classification considers 11-20° a substantial deformity, 21-30° an important deformity, and >30° an extreme deformity [13].

The Hospital for Special Surgery Rating System (HSS) [14] and the Knee Society Clinical Rating System (KSS) [15] are the two most widely used scoring systems for the evaluation of the outcome of knee arthroplasty.

KSS has become the standard tool for the clinical evaluation and reporting of the results of TKA surgery. Most major journals in this field of study strongly encourage the use of the KSS score as an evaluation tool so that qualified information would be available on the outcome and to enable a comparison of different studies. The KSS system deals separately with the status of the operated knee and the function score of the patient, which solves the problem with interference by comorbid conditions. The Knee Score consists of scores for pain, range of motion and stability in both the coronal and sagittal planes, with deductions for fixed deformities and extensor lag.

The Function Score consists of scores for the ability to walk on a level surface and to ascend and descend stairs, with deductions for the use of external supporting devices. These two subscales of KSS are usually recorded separately as two scores, the KSS Knee Score and KSS Function Score, rather than as one summation score.

**Material and Method**

Aim of this study was to assess correction of clinical and radiological parameters; to evaluate accuracy and efficacy of results obtained in navigation assisted Total Knee Arthroplasty in patient suffering from severe varus knee deformity.

This was a prospective study from January 2012 to August 2015 done in Department of Orthopaedics at our institute with a minimum follow up period of 12 months (range 12-34 months). A cohort of 20 patients were taken with varus deformity more than 15 degree and operated with the help of navigation system. The result were compared with a cohort of 20 patients suffering from more than 15 degree varus deformity and operated without navigation.

The two groups were matched for age, sex, deformity and mean knee society knee score and function score and the type of implant used.

**Inclusion criteria**

1. varus knee deformity more than 15 degree.
2. Age less than 75 years.

**Exclusion criteria**

1. Patients suffering from valgus deformity and varus less than 15 degree.
2. Age >75.
3. Hip and ankle pathologies.
5. Ongoing infection of knee joint.

**Knee Society Knee Score**

**Pain score (0-50)**

**Range of motion (5 degrees = 1 point)**

**Stability**

Medio lateral (0-15 points)
Anteroposterior (0-15 points)

**Deductions**

Malalignment (range 0 to -20 points)
Flexion contracture (-2/-5/-10/-15 points)
Extensor lag (-5/-10/-15 points)

**Function Score (0-100 points)**

Walking (0-50 points)
Stairs (0-50 points)

**Deductions**

Cane/walker (range 0 to -20)

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*CAS is the solution for severe varus*
**Outcome measures**

2. Functional – Knee society knee score.
3. Radiological- Limb alignment assessed with navigation intra op, immediate post-operative and follow up at 1 month, 3 month, 6 month, 1 year with x rays.

**Operative procedure**

All patients were operated by anterior midline incision. Joint was approached through the medial parapatellar capsular approach extended proximally to the inferior margin of the rectus femoris and distally to the medial margin of the tibial tubercle. The medial side of the knee was exposed by subperiosteally stripping the anteromedial capsule and deep medial collateral ligament off the tibia to the posteromedial corner of the knee. 

Patella was then everted laterally with knee in extension. If needed, lateral patella femoral plicae release and release of adhesions was done. ACL along with both menisci were excised. Then tibia was subluxated anteriorly and externally rotated. Release of the medial structures (superficial and deep parts of medial collateral ligament, semi-membranous tendon, pes anserinus and part of posterior capsule) as per demand in the individual case was done. All osteophytes were removed.

**Anatomy Registration In navigation system**

**Determination of Femoral head center**

Hip joint center is identified by circumduction of the hip with hip and knee flexed. The software geometrically produces the center of femoral head within 1mm of accuracy. This is the most accurate way of identifying the center of rotation of the femoral head.

**Distal Femur Mapping**

We determined the center of femur and femoral Antero posterior axis at first. For the femoral Anterior posterior axis (white side's line), the pointer's axis was aligned with the most anterior point of the intercondylar groove.

**Proximal Tibia Mapping**

The center of tibial plateau and antero posterior axis are also marked digitalized.

**Determination of the center of the ankle**

The medial and lateral malleolus are digitalized and computer determines the center of ankle as a reference for the anatomic axis of the tibia and the mechanical axis of the limb.

The computer then gives the information regarding the orientation of bony cuts, implant sizing and soft tissue tension

**Implementation and verification**

The essential components after registration are setting up of the cutting blocks and rechecking of the cuts. The alignment is confirmed on the computer screen. The hardware used is similar in most systems. The computer receives the information from an infrared camera. This in turn transfers signals from the beacons fixed to the patient. The computer screen provides the visual images required for the surgery.

The software provides a structural model which provides interactive images and allows storage of data that describe the surgery.
Pre op weight bearing x ray AP view  
pre op x ray lateral view

Full correction of varus deformity  
intra op full correction of deformity

Intra op full correction of deformity

Follow up X-ray  
post op x ray AP and Lateral View
We applied unpaired t test for the evaluation of the results and two tailed p value was considered the criteria for statistical significance.
### Table 1

<table>
<thead>
<tr>
<th>Post operative period</th>
<th>Mean Knee ROM</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With navigation</td>
<td>Without navigation</td>
</tr>
<tr>
<td>Pre operative</td>
<td>67.3°</td>
<td>66.5°</td>
</tr>
<tr>
<td>1 month</td>
<td>88.85°</td>
<td>80.3°</td>
</tr>
<tr>
<td>3 month</td>
<td>107°</td>
<td>92.45°</td>
</tr>
<tr>
<td>6 month</td>
<td>116.55°</td>
<td>101°</td>
</tr>
<tr>
<td>1 year</td>
<td>121.95°</td>
<td>105.9°</td>
</tr>
</tbody>
</table>

The p values and hence the results at 1, 3, 6 months and 1 year follow up for mean knee range of motion are extremely statistically significant.

### Table 2

<table>
<thead>
<tr>
<th>Post operative period</th>
<th>Mean Tibio femoral angle (varus)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With navigation</td>
<td>Without navigation</td>
</tr>
<tr>
<td>Pre operative</td>
<td>16.40°</td>
<td>16.55°</td>
</tr>
<tr>
<td>Immediate post operative</td>
<td>0.15°</td>
<td>1.15°</td>
</tr>
</tbody>
</table>

The p values and hence the results at 1, 3, 6 months and 1 year follow up for Mean Tibio femoral angle (varus) are not statistically significant.

### Table 3

<table>
<thead>
<tr>
<th>Post operative period</th>
<th>Mean Fixed Flexion Deformity</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With navigation</td>
<td>Without navigation</td>
</tr>
<tr>
<td>1 month</td>
<td>7.35°</td>
<td>8.95°</td>
</tr>
<tr>
<td>3 month</td>
<td>5.3°</td>
<td>6.55°</td>
</tr>
<tr>
<td>6 month</td>
<td>4.5°</td>
<td>5.8°</td>
</tr>
<tr>
<td>1 year</td>
<td>3.3°</td>
<td>4.85°</td>
</tr>
</tbody>
</table>

The p values and hence the results at 1, 3, 6 months and 1 year follow up for mean fixed flexion deformity are statistically significant.

### Table 4

<table>
<thead>
<tr>
<th>Post operative period</th>
<th>Mean Knee Society Knee Score</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With navigation</td>
<td>Without navigation</td>
</tr>
<tr>
<td>Pre operative</td>
<td>23.2</td>
<td>23.8</td>
</tr>
<tr>
<td>1 month</td>
<td>71.15</td>
<td>68.55</td>
</tr>
<tr>
<td>3 month</td>
<td>77.95</td>
<td>70.30</td>
</tr>
<tr>
<td>6 month</td>
<td>84.05</td>
<td>77.95</td>
</tr>
<tr>
<td>1 year</td>
<td>84.45</td>
<td>83.00</td>
</tr>
</tbody>
</table>

The p values and hence the results at 1 month and 1 year follow up for mean knee society knee score are extremely statistically significant. The p values and hence the results at 3 and 6 months follow up for mean knee society knee score are statistically significant.

### Table 5

<table>
<thead>
<tr>
<th>Post operative period</th>
<th>Mean Knee Society Function Score</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With navigation</td>
<td>Without navigation</td>
</tr>
<tr>
<td>Pre operative</td>
<td>21</td>
<td>21.25</td>
</tr>
<tr>
<td>1 month</td>
<td>69.50</td>
<td>65.25</td>
</tr>
<tr>
<td>3 month</td>
<td>87.75</td>
<td>86.50</td>
</tr>
<tr>
<td>6 month</td>
<td>97.75</td>
<td>96.75</td>
</tr>
<tr>
<td>1 year</td>
<td>98.50</td>
<td>97.50</td>
</tr>
</tbody>
</table>

The p values and hence the results at 1, 3, 6 months and 1 year follow up for mean Knee Society Function Score are not statistically significant.
**Discussion**
Several technical requirements during TKA are important to obtain good results:
- correction of deformities;
- achievement of functional joint motion and stability;
- optimal balancing of soft tissues;
- satisfactory alignment in the frontal, sagittal and horizontal planes.

**Massive Varus-Challenges**

**1. Anatomical Alignment**
Historical literature showed that neutral mechanical alignment (HKA 180°) with outliers within three degrees was the best guarantee for long-term survival of a TKR [10]. From literature data alignment in frontal plane must be into 2º or 3º range around a neutral alignment; this thought is demonstrated by Ritter at al who observed that prostheses implanted in varus position had a lower survival rate than prostheses implanted in a neutral or valgus position [17]. Jeffery at al observed that when mechanical axis was in 3º valgus-varus range, the loosening rate was 3%, whereas it’s 24% when the alignment was out of this range [18].

**2. Ligament Balancing**
The arthritic process leading to a total knee replacement causes joint deformity and osteophytes. This joint deformity can cause both irreversible ligament shortening on the collapsed side and elongated ligaments on the convex side. Osteophytes can cause tightness by tenting the ligaments resulting in restriction of movement and flexion contractures [19]. Ligament balancing attempts to counter these changes. This is achieved usually by removing osteophytes and lengthening and dissecting tight ligaments in sequence. Tightening lax ligaments, albeit more difficult and rarely used, also can play a role [20,21].

A balanced knee has many postoperative advantages, and this is supported by the literature, although randomized control studies of ligament balancing are limited [19,22-24].

Ligament balancing has been shown to be important in producing better limb alignment [22]. A series of normally aligned knees that went on to develop early medial insert wear progressing to varus malalignment pointed toward inadequate medial compartment ligament balancing as a possible cause [23]. Ligament balancing is a recognized key determinant of postoperative stability [24-27], and has been described as a possible preventative cause of the 27% of early knee revisions owing to instability [29].

**3. Deficient Bone Stock**
Bone deficiencies are frequently encountered during TKR in cases of severe varus deformities. The method used to compensate for a given bone defect depends on the size and the location of the defect. Rand classified these defects which is also very useful for deciding the management of these defects. Contained defects can be filled with small cancellous bone grafts whereas larger defects may require metal wedges or screws with cement/bone graft. The use of screw with cement is demonstrated in two cases in our study (case 1 and case 2).

**Conclusion**
In our study, Computer assisted total-knee arthroplasty gave excellent to good result in terms of clinical and radiological parameters and good functional outcome with a minimum follow up period of 12 months.

Majority of studies show that navigated TKR decreases the malalignment of the mechanical limb axis compared with conventional TKR. Whether this marginal benefit makes any significant difference in long term outcome of the patient needs follow up studies equal to the studies done on conventional TKR. The technology of navigation, though appears promising in complex primary like severe varus deformities.

It is important to realise that conventional techniques in TKR surgery have resulted in high prosthesis survival rate lasting up to 15–20 years. As the CAS has survived its infancy, it is therefore important that functional and clinical outcomes be collected on a regular basis in order to elucidate the role of it. Hence, further multicentre randomised controlled clinical trials comparing conventional TKR with CAS need to be undertaken with long follow up to demonstrate better clinical and functional outcomes, lesser complication rate along with cost effectiveness of the CAS procedure over conventional primary TKR surgery to make it universally acceptable.

**References**
3. Ackerman IN, Osborne RH. Obesity and increased burden of hip and knee joint disease in Australia. 4. Buechel FF. Long term follow up after mobile-bearing total knee replacement. Clin Orthop Relat Res, 2002; 404:40. ISSN 1528-1132


