Navigated versus Conventional Technique in High Tibial Osteotomy: A Meta-Analysis Focusing on Weight Bearing Effect

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Purpose: We aimed to determine whether navigated opening wedge high tibial osteotomy (HTO) is superior to the conventional technique in terms of accuracy of the coronal and sagittal alignment correction, functional outcome, and operative time.

Methods: Studies comparing navigated and conventional HTO were included in this meta-analysis. We compared the incidence of radiological outliers in coronal alignment and tibial slope maintenance, mean differences in functional outcome scales, and operative time. Subgroup analyses were performed on coronal alignment accuracy based on the intraoperative method of alignment confirmation: fluoroscopy vs. gap measurement method.

Results: Twelve studies were included: there were 434 knees in the navigated HTO studies and 405 knees in the conventional HTO studies. The risk of outlier was lower in navigated HTO than in conventional HTO; however, the difference was not significant when navigated HTO was compared with conventional HTO performed using the gap measurement method. Tibial slope maintenance was comparable or better in navigated HTO. No difference was found in the American Knee Society function and Lysholm scores. Navigated HTO necessitated a longer operative time of approximately 10 minutes.

Conclusions: The use of navigation in HTO can improve accuracy in both coronal and sagittal alignments, but its clinical benefit is unclear.

Keywords: Knee, Osteoarthritis, Tibia, Osteotomy, Computer-assisted surgery, Meta-analysis

Introduction

High tibial osteotomy (HTO) is an established surgical treatment option for younger patients with medial compartment knee osteoarthritis (OA) with varus deformity that shifts the load on the knee joint by changing lower limb alignment2. Optimal limb alignment is a paramount factor for satisfactory surgical results of HTO3 because poorly corrected alignment has been reported as one of the important causes of unsatisfactory clinical outcome after HTO3–5.

Navigation was introduced in HTO to improve the accuracy of alignment correction6,7, but it is still unclear whether navigated HTO is superior to the conventional technique regarding the achievement of the target coronal alignment. Recent systematic reviews or meta-analyses reported that the use of navigation in HTO could improve the precision of coronal alignment correction8–10. However, there is conflicting evidence showing less outlier in the conventional HTO using the weight bearing scanogram technique11 or comparable accuracy in coronal alignment12–16. Conventional HTO can be divided into different categories based on the detailed surgical technique, particularly by the method for...
intraoperative confirmation of the correction amount. Fluoroscopy method is used to confirm the corrected alignment by using a cable or metal rod under fluoroscopy. Gap measurement, which is preoperatively planned on a weight bearing scanogram, is sometime preferred. The former method relies on the information obtained in the supine position without loading on the joint, which is the same in navigated HTO. Although a recent study reported a linear relationship between mechanical axis deviation measured in intraoperative post-osteotomy fluoroscopy and that in postoperative standing radiography, the greater discrepancy can be associated with the higher joint line convergence angle. Lee et al. reported an unsatisfactory correlation of coronal alignment measurement between navigation and postoperative standing radiography, suggesting the measurement in supine position without weight bearing effect as the inherent limitation of navigation. Specogna et al. reported the difference of the coronal alignment in the supine position and that in the standing position influenced by the weight bearing effect. Previous systematic reviews and meta-analyses did not take much consideration into the weight bearing effect in the comparison of the navigation and conventional techniques.

Even if navigated HTO can improve the accuracy of the alignment correction, whether the improved accuracy will lead to better clinical outcomes is still controversial. Compared with the conventional technique, the navigation technique requires additional procedures, such as tracker fixation and registration; hence, the longer operative time can be a disadvantage of navigated HTO. Even if navigated HTO can improve the accuracy of the alignment correction, whether the improved accuracy will lead to better clinical outcomes is still controversial. Compared with the conventional technique, the navigation technique requires additional procedures, such as tracker fixation and registration; hence, the longer operative time can be a disadvantage of navigated HTO. However, the operative time was not investigated in the previous meta-analysis. In addition, theoretically, tracker fixation can cause specific navigation-related complications, such as screw site fracture or infection and neurovascular injury.

This meta-analysis aimed to determine whether navigated opening wedge HTO is superior to the conventional technique in terms of the accuracy of the coronal and sagittal alignment correction, functional outcome, operative time, and complication rate. Regarding the coronal alignment accuracy, we specifically focused on the weight bearing effect associated with the intraoperative surgical technique of conventional HTO. We hypothesized that the use of navigation would improve the accuracy of alignment correction but it would not offer clinical benefit superior to that of the conventional technique in medial opening wedge HTO.

Materials and Methods

This meta-analysis was conducted according the guidelines of the preferred reporting items for systematic reviews and meta-analysis (PRISMA) statement (http://www.prisma-statement.org).

1. Data and Literature Sources

This study was based on Cochrane Review Methods. Multiple comprehensive databases, including MEDLINE, EMBASE, Web of Science, SCOPUS, and the Cochrane Library, were searched for studies that compared the outcome of the navigated and conventional HTO. The language was restricted to English, and the publication date was limited from January 1, 2000 to August 15, 2016. The following keywords were used in the title, abstract, MeSH (Medical Subject Headings), and keyword fields: knee or tibia, OA, genu varum, osteotomy, computer-assisted, navigation, fluoroscopy, cable method, weight bearing, load bearing, axial load, axial force, and standing. Different search protocols were used for each database, and the detailed search strategy is described in Appendix 1. After the initial electronic search, relevant articles and their bibliographies were manually searched. The identified articles were assessed individually for inclusion.

2. Study Selection

Study inclusion was decided independently by two reviewers on the basis of the predefined selection criteria. Titles and abstracts were read; the full article was evaluated if suitability could not be determined. Studies were included in the meta-analysis if they (1) compared radiologic and/or clinical outcomes in patients who underwent opening wedge HTO using either the navigation or conventional technique (either randomized controlled trials or retrospective studies); (2) included data on at least one of the radiographic outcome parameters regarding the accuracy of the coronal alignment. Studies were excluded if they met the following exclusion criteria: (1) closing wedge HTO or dome osteotomy; (2) double-level osteotomy; (3) combined procedure; (4) not comparative studies (case series or case report); (5) systematic review, meta-analysis, or proceeding; (6) not involving humans (i.e., cadaveric or animal study); or (7) not written in English. Institutional Review Board approval or informed consent (written/oral) from the participants was not needed because all analyses were based on previously published studies.

3. Data Extraction

Two investigators independently recorded data from each study by using a predefined data extraction form. The extracted data were then cross-checked by the two investigators. Any unresolved disagreement between the two reviewers was reviewed by a third
investigator. Recorded variables were as follows: study characteristics (author, country, publication year, study period, study design, and level of evidence), patient demographics (number of knees and patients, age, and sex), surgical technique (type of navigation, fixation device, gap filling method and material, preoperative planning method, intraoperative alignment confirmation, and follow-up period), radiographic parameters (correction target, acceptable range, postoperative coronal and sagittal alignments, and incidence of outlier), functional outcomes (American Knee Society [AKS] knee and function score, Lysholm score, and other scores), and operative time.

4. Assessment of Methodological Quality
Two investigators independently assessed the methodological quality of each study by using the Newcastle–Ottawa Scale, as recommended by the Cochrane Non-randomized Studies Methods Working Group. The Newcastle–Ottawa Scale's star system includes three domains: selection of the study groups, comparability of the groups, and ascertainment of the exposure or outcome of interest for case-control or cohort studies. Each assessed study could be awarded a maximum of one star for each numbered item within the selection (four items) and outcome (three items) domain. A maximum of two stars could be awarded for comparability (one item). Studies with scores higher than six points were considered high quality. Any unresolved disagreements between investigators were resolved by consensus or by consultation with a third investigator.

5. Data Synthesis and Analysis
The main outcomes of the meta-analysis were the proportion of the coronal and sagittal alignment outliers after HTO, functional outcomes, and operative time. Random-effects meta-analyses were performed to pool these outcomes across included studies. The continuous variables were assessed using the mean difference (MD) with 95% confidence interval (CI), whereas dichotomous data were assessed using the odds ratio (OR) and its 95% CI. Statistical significance was considered if p<0.05. Heterogeneity was determined using the I² statistics, which estimates the proportion of between-study inconsistencies due to actual differences between studies, rather than differences due to a random error. The value of I² ranged from 0% (complete consistency) to 100% (complete inconsistency). The I² statistics with values of 25%, 50%, and 75% indicated low, moderate, and high heterogeneity, respectively. For the coronal alignment outlier, we performed subgroup analysis based on the intraoperative alignment confirmation method, to explore a potential source of heterogeneity. Forest plots were used to graphically present the results of individual studies and the respective pooled estimate of effect size. All statistical analyses were performed using RevMan ver. 5.3 (The Cochrane Collaboration, Copenhagen, Denmark).

Results

1. Identification of Studies
Fig. 1 shows the details of study identification, inclusion, and exclusion. An electronic search yielded 387 studies in MEDLINE, 525 in EMBASE, 481 in SCOPUS, 348 in Web of Science, and 22 in the Cochrane Library. One additional publication was identified through manual searching. After removal of 986 duplications, 777 studies remained; of these, 723 were excluded after review of the abstracts and full-text articles, and an additional 43 studies were excluded for various reasons according to the exclusion criteria. Finally, 12 studies were included in this meta-analysis.

2. Study Characteristics and Patient Populations
The 12 included studies involved 434 knees and 405 knees that underwent navigated HTO and conventional opening wedge HTO, respectively (Table 1). Three studies were the randomized controlled trials, one was a prospective comparative study, and the other eight studies were retrospective comparative studies. Ten studies reported the proportion of the outlier in coronal alignment after HTO, and only two studies reported those in sagittal alignment (Table 2). Five studies reported functional outcome with AKS knee and function score, Lysholm score, Hospital for Special Surgery (HSS) score, and modified Cincinnati Rating System Questionnaire (Table 3). Information regarding the operative time was reported in seven studies.

3. Methodological Quality Assessment
The quality of the 12 studies included in the meta-analysis is summarized in Table 4. All the included studies were of high quality (Newcastle–Ottawa Scale >6). All 12 studies included in this meta-analysis had a low risk of selection bias and compared demographic data of patients undergoing opening wedge HTO. The follow-up of <3 months for radiographic evaluation was considered to have a higher risk of bias because radiographic measurements of coronal alignment may change over time.

4. Coronal Alignment
The target correction angle in coronal alignment was presented with different radiographic parameters in each study: hip–knee–
ankle angle (HKA) in seven studies \(^{14,15,17,18,20,24,31}\), femorotibial angle (FTA) in two studies, which were reports of the same authors \(^{12,13}\), and weight bearing line coordinate (WBL) in seven studies (Table 2) \(^{11,13,14,16,18,19,31}\). The target was similar but not perfectly identical across the studies. Among the 12 studies, 5 studies reported a better accuracy of coronal alignment correction in the navigated HTO group \(^{17-20,24}\), whereas 6 studies found no difference between the navigated and conventional HTO groups \(^{12-16,31}\), and 1 study reported a better outcome in the conventional HTO group \(^{11}\). In the pooled results of aggregate analysis for comparison of navigated and conventional HTO regarding accuracy of coronal alignment, using the outlier proportion as the outcome parameter, which was reported in 10 studies, navigated HTO showed a lower risk of outlier than conventional HTO (OR, 0.42; 95% CI, 0.21–0.85) (Fig. 2). We performed a subgroup analysis based on the method of intraoperative alignment confirmation. The risk of outlier was lower in navigated HTO than that in conventional HTO using fluoroscopy to confirm intraoperative alignment (OR, 0.18; 95% CI, 0.06–0.57). However, no significant difference was found between navigated HTO and conventional HTO using intraoperative gap measurement method (OR, 0.80; 95% CI, 0.36–1.76). We also performed a subgroup analysis based on the type of fixation device, locking plates vs. non-locking plates (Fig. 3). Navigated HTO showed less risk of outlier than conventional HTO did when the locking plates were used (OR, 0.42; 95% CI, 0.22–0.81), whereas the difference was not significant when non-locking devices were used (OR, 0.38; 95% CI, 0.08–1.91).

5. Sagittal Alignment

Of the 12 studies, eight reported the postoperative tibial slope and/or its change before and after HTO \(^{11,15,17,18,31}\). Among the eight studies, five reported better accuracy of sagittal alignment maintenance after navigated HTO \(^{12,14,17,31}\), whereas three found no difference between the navigated and conventional HTO \(^{11,15,18}\). Pooled analysis was performed using only two studies that reported the outlier proportion after HTO \(^{12,17}\). Navigated HTO showed less risk of outlier than the conventional HTO did (OR, 0.06; 95% CI, 0.01–0.62) (Fig. 4). However, the limited number of studies included in the pooled analysis made it difficult to determine the comparative risk of outlier in the sagittal alignment between the navigated and conventional HTO.

6. Functional Outcome

Among the 12 studies included in the current meta-analysis, only 5 studies reported functional outcome with different measures: AKS knee score in three studies \(^{12,13,17}\), AKS function score in two studies \(^{12,13}\), Lysholm score in four studies \(^{12,13,18,31}\), HSS
Table 1. Detailed Characteristics of Included Studies

| Study          | Country  | Study design (level of evidence) | Study period (yr) | No. of knees (patients) | Sex (M/F) | Age (yr) | Type of navigation | Fixation device | Gap filling | Preop planning method | F/U Correction target | Radio- graphic evaluation | Functional evaluation | HKA (°) | FTA (°) | WBL (%) |
|----------------|----------|----------------------------------|-------------------|-------------------------|-----------|----------|---------------------|-----------------|-------------|-----------------------|--------------------------|--------------------------|------------------------|----------|---------|---------|
| Saragaglia and Roberts 2005 | France   | Retrospective, comparative study (III) | N: 2001–2002 C: 1997–2000 | N: 28 (N/A) C: 28 (N/A) | N/A | N: 54 (35–71) C: 55 (27–70) | Orthopilot (B. Braun Aesculap, Tuttingen, Germany) | AO T-plate (Synthes, Solothum, Switzerland) | TCP wedge | Dugdale (2–6° valgus or 182–186° of HKA) | N: navigation C: fluoroscopy (cable) | 3 mo | N/A | 4 | N/A | N/A |
| Maurer and Wassmer 2006 | Germany  | Retrospective, comparative study (III) | N: 2003–2006 C: 2003–2006 | N: 44 (N/A) C: 23 (N/A) | 33 F | Mostly 50–70 | Orthopilot (HTO ver. 1.3; B. Braun Aesculap, Tuttingen, Germany) | Not clear | Dugdale | N: navigation C: not clear | Before discharge | N/A | 3 | N/A | N/A |
| Kim et al. 2009 | Korea    | Retrospective, comparative study (III) | N: 2005–2007 C: 2004–2005 | N: 47 (45) C: 43 (40) | 38/5 | N: 43±4.8 C: 53.5±5.8 | Orthopilot (B. Braun Aesculap, Tuttingen, Germany) | N: dual open wedge plates (Aesculap, Seoul, Korea) C: modified Puddu plate (Taesan Sol., Seoul, Korea) | N: allogenicous chip bone C: autogenous tricortical bone | Dugdale | N: navigation C: fluoroscopy (cable) | 1 yr | 1 yr | 3–5 | N/A | 62 |
| Akamatsu et al. 2012 | Japan    | Retrospective, comparative study (III) | N: 2006–2009 C: 2003–2006 | N: 31 (26) C: 5/21 | 11/11 | N: 62±9 C: 57±9 | Orthopilot (HTO ver. 1.3; B. Braun Aesculap, Tuttingen, Germany) | TomoFix (Synthes, Solothum, Switzerland) | β-Tricalcium phosphate wedges (Olympus Terumo Biomaterials, Tokyo, Japan) | N: Dugdale C: Miniaci | N: navigation (amount of change on planning) C: gap measurement | 12 mo | 12 mo | N/A | 170 | 62 |
| Study     | Country      | Study design (level of evidence) | Study period (yr) | No. of knees (patients) | Sex (M/F) | Age (yr) | Type of navigation | Fixation device | Gap filling | Preop planning method | F/U | Correction target |
|-----------|--------------|----------------------------------|-------------------|-------------------------|-----------|----------|---------------------|-----------------|-------------|-----------------------|-----|---------------------|
| Iorio et al. (2013) | Italy | RCT (I) | N/A | N: 14 (13) C: 13 (11) | N: 7/6 C: 7/4 | N: 56.5±6.2 (40–62) C: median 54.8 (38–67) | Kinematics-based image-free navigation system (OrthoPilot; B. Braun Aesculap, Tuttlingen, Germany) with HTO software ver. 1.4 (3D Open-wedge; B. Braun Aesculap) | Position HTO Plate (B. Braun Aesculap) | Dehydrated | Position HTO Plate (B. Braun Aesculap) | 3 mo | Median of 39 mo (range, 12–72 mo) |
| Reising et al. (2013) | Germany | Retrospective matched group comparative study (III) | N: 2005–2009 C: 2005–2009 | N: 40 (40) C: 40 (40) | N: 32/8 C: 32/8 | N: 43.6±11.4 C: 43.6±11.5 | Orthopilot (Aesculap Co., Tuttlingen, Germany; Software: Orthopilot-software for HTO V 1.5) | TomoFix (Synthes, Solothurn, Switzerland) | Not clear | Done but not clear | 2–45 day | N/A |
| Lee et al. (2014) | Korea | Prospective comparison study (II) | N/A | N: 40 (40) C: 40 (38) | N: 9/31 C: 8/30 | N: 51.9 (40–64) C: 54.4 (48–63) | Orthopilot® HTO 1.4 (B. Braun Aesculap, Tuttlingen, Germany) navigation system | N: plate with interlocking screws C: AO T-plate (Synthes, Solothurn, Switzerland) | N: allogeneous chip bone C: autogeneous tricortical bone | N: Miniaci C: Dugdale (WBS preinted on the real-sized paper) | 8 wk | N/A |
| Ribeiro et al. (2014) | Brazil | Retrospective, comparative study (III) | 2004–2012 | N: 18 (18) C: 20 (20) | N: 17/1 C: 12/8 | N: 46.6 C: 48.4 | HTO ver. 1.5 OrthoPilot® system (Aesculap, Tuttlingen, Germany) | N: HTO® plate (Aesculap) C: Anthony® plate (France Bloc S.A) | N: no C: Dugdale | N: no C: Dugdale | 12 mo | N/A |

N/A N/A
| Study Country | Study design (level of evidence) | Study period (yr) | No. of knees (patients) | Sex (M/F) | Age (yr) | Type of navigation | Fixation device | Gap filling | Preoperative planning method | Intraoperative alignment confirmation | F/U | Correction target |
|---------------|---------------------------------|------------------|------------------------|-----------|----------|-------------------|----------------|-------------|-----------------------------|----------------------------------------|-----|-----------------|
| Akamatsu et al. 2016 Japan | RCT (I) | 2010–2012 | N: 31 (31) C: 31 (31) | N: 8/23 C: 8/23 | N: 63.6±8.4 C: 66.3±8.4 | CT-based OrthoMap 3D navigation (OrthoMap3D, Stryker, Kalamazoo, MI, USA) and image-free knee Navigation software in the Stryker Navigation System (Stryker) | TomoFix (Synthes, Solothurn, Switzerland) | 2 b-TCP wedges (Olympus Terumo Biomaterials, Tokyo, Japan) | N: navigation C: Miniaci gap measurement | N: navigation C: gap measurement | 24 mo (CT: 3 mo) | N/A | FTA | N/A | 170 |
| Na et al. 2016 Korea | Retrospective, comparative study (III) | N: 2012–2013 C: 2010–2012 | N: 40 (34) C: 20 (17) | N: 7/33 C: 9/11 | N: 55.4±5.8 C: 43(73) 50±9.5 (29–60) | OrthoPilot (B. Braun Aesculap, Tuttingen, Germany) | TomoFix (Synthes, Solothurn, Switzerland) | Allogeneous chip bone | Dugdale | N: navigation C: gap measurement | >3 mo | >3 mo | 3 | N/A | 62 |
| Schröter et al. 2016 Germany | RCT (I) | N/A | N: 56 (56) C: 57 (57) | N: 47±8 C: 47±8 | N: 45±8 C: 36±21 | OrthoPilot (B. Braun Aesculap, Tuttingen, Germany) | TomoFix (Synthes, Solothurn, Switzerland) | No | Dugdale (medi-CAD) | N: navigation C: gap measurement | 6 wk | 6 wk | 2–3 | N/A | N/A |
| Stanley et al. 2016 Australia | Retrospective, comparative study (III) | 2007–2013 | N: 52 (50) C: 65 (61) | N: 39/11 C: 53/8 | 49.2 (30–64) | (Brainlab AG, Feldkirchen, Bayem, Germany) | N: Puddu plate (Arthrex, Naples, FL, USA) C: Dynafix vs. Osteotomy System (EBI-Biomet, Parsippany, NJ, USA) | Either allograft bone or synthetic bone substitute. | Dugdale (58%) | N: navigation C: fluoroscopy | 12 mo | N/A | N/A | N/A | 58 |

M: male, F: female, Preop: Preoperative, F/U: follow-up, HKA: hip–knee–ankle angle, FTA: femorotibial angle, WBL: weight bearing line coordinate, N: navigation, C: conventional, N/A: not available, TCP: tricalcium phosphate, HTO: high tibial osteotomy, RCT: randomized controlled trial, WBS: weight bearing scanogram, CT: computed tomography.
| Study                          | Target (acceptable range) | Postop alignment (coronal) | Postop alignment (sagittal) | Outlier % (coronal) | Outlier % (sagittal) | Conclusion                  | Conclusion                  |
|-------------------------------|----------------------------|----------------------------|----------------------------|--------------------|--------------------|----------------------------|----------------------------|
| Saragaglia and Roberts 2005   | 4 (2–6)                    | N/A                        | N/A                        | N/A                | N/A                | N/A                        | N/A                        |
| Maurer and Wässmer 2006       | 3 (2–5)                    | N/A                        | N/A                        | N/A                | N/A                | N/A                        | N/A                        |
| Kim et al. 2009               | 3–5 (N/A)                  | 62                         | 0 (N/A)                    | Postop;            | FTA>173;           | N/A                        | N/A                        |
| Akamatsu et al. 2012          | N/A                        | 170 (167–173)              | N/A                        | N/A                | N/A                | N/A                        | N/A                        |
| Iorio et al. 2013             | 2–6                        | N/A                        | N/A                        | N/A                | N/A                | N/A                        | N/A                        |
| Reising et al. 2013           | N/A                        | 62 (50–70)                 | N/A                        | WBL;              | WBL;              | N/A                        | N/A                        |
| Lee et al. 2014               | N/A                        | 62 (50–70)                 | N/A                        | WBL;              | N/A                | N/A                        | N/A                        |
| Study                        | Target (acceptable range) | Postop alignment (coronal) | Postop alignment (sagittal) | Outlier % (coronal) | Outlier % (sagittal) | Conclusion |
|-----------------------------|---------------------------|---------------------------|----------------------------|---------------------|---------------------|-------------|
|                             |                           | HKA (°)                    | FTA (°)                    | Tibial slope       | Under-correction | Over-correction | Total | Tibial slope | change |
|                             |                           |                           |                           | Change (°)         |                     |             |       |             |        |
| Ribeiro et al. (31) 2014    | 3–6 N/A                   | 65–70 (N/A)               | N/A                       | N/A                 | N/A                 | N/A          |       | N/A          |        |
|                             |                           |                           |                           |                     |                     |               |       | Coronal: N/D | Sagittal: N>C |
| Akamatsu et al. (12) 2016   | N/A                       | 170 (165–175)             | 0 (±2.5)                  | N/A                 | N/A                 | N/A          |       | N/A          |        |
|                             |                           |                           |                           |                     |                     |               |       | Coronal: N/D | Sagittal: N>C |
| Na et al. (14) 2016 3 (2–6)| N/A                       | 62 (55–70)                | N/A                       | N/A                 | N/A                 | N/A          |       | N/A          |        |
|                             |                           |                           |                           |                     |                     |               |       | Coronal: N/D | Sagittal: N>C |
| Study                | Target (acceptable range) | Postop alignment (coronal) | Postop alignment (sagittal) | Outlier % (coronal) | Outlier % (sagittal) | Conclusion |
|---------------------|---------------------------|---------------------------|-----------------------------|--------------------|---------------------|-------------|
|                     | HKA (°)                   | FTA (°)                   | Tibial slope change (°)     | HKA (°)            | FTA (°)             | WBL (%)     |
| Schröter et al.     | N/A                       | N/A                       | N/A                         | N/A                | N/A                 | N/A         |
| 2016                | Indivisualized, typically 2–3 for moderate OA | 1:8±2.1                  | 1:7±2.2 (n.s.)              | 1:8±2.1            | 1:7±2.2 (n.s.)     | N/A         |
|                     |                           |                           |                             |                     |                     | N/A         |
|                     |                           |                           |                             |                     |                     | HKA; N: 6/56 (11) C: 5/57 (8) |
|                     |                           |                           |                             |                     |                     | Coronal: N/D Sagittal: N/D |
| Stanley et al.      | N/A                       | N/A                       | N/A                         | N/A                | N/A                 | N/A         |
| 2016                | 58                        | (5 error: 53–63; 10 error: 48–68) | 2:1 (–5.0 to 11.0)          | 2:1 (–5.0 to 11.0) | 2:1 (–5.0 to 11.0) | N/A         |
|                     |                           |                           | C: 1.1 (–9.1 to 7.6)        | C: 1.1 (–9.1 to 7.6) | C: 1.1 (–9.1 to 7.6) | (p=0.08)   |
|                     |                           |                           |                             |                     |                     | N/A         |
|                     |                           |                           |                             |                     |                     | WBL: 1) 53–63 N: 25/52 (48.1) C: 40/65 (61.5) (p=0.13) 2) 48–68 N: 15/52 (28.8) C: 24/65 (36.9) (p=0.10) WBL<20%; 1) 53–63 N: 10/19 (52.6) C: 21/31 (67.7) (p=0.15) 2) 48–68 N: 7/19 (36.8) C: 12/31 (38.7) (p=0.02) |

Postop: postoperative, HKA: hip–knee–ankle angle, FTA: femorotibial angle, WBL: weight bearing line coordinate, N/A: not available, N: navigation, C: conventional, N>C: navigated group shows better result, n.s.: no significant difference between groups, N/D: no difference, N<C: conventional group shows better result, OA: osteoarthritis.
Table 3. Operative Time and Functional Outcomes

| Study               | Operative time (min) | AKS-knee | AKS-function | Lysholm | Other score                  | Conclusion | Operative time | Function |
|---------------------|----------------------|----------|--------------|---------|-----------------------------|------------|----------------|----------|
| Kim et al. 2009     | N: 78.8±3.9          | N/A      | N/A          | Preop;  | HSS score:                  | N/D        | N/D            | N>C      |
|                     | C: 77.8±3.5 (p=0.516)|          |              | N: 56±6 | Preop;                      |            |                |          |
|                     |                      |          |              | C: 55±5  | Postop;                     |            |                |          |
|                     |                      |          |              | N: 85±6  | Postop;                     |            |                |          |
|                     |                      |          |              | C: 83±5  | Postop;                     |            |                |          |
| Akamatsu et al. 2012| N: 112±21            | Preop;   | Preop;       | Preop;  | N/A                         | Longer in navigation | N/D    |          |
|                     | C: 96±10 (p<0.001)   | N: 52±11 | N: 60±16     | N: 53±11|                           |            |                |          |
|                     |                      | C: 49±12 (n.s.)| C: 56±14 (n.s.)| C: 53±12 (n.s.)|                           |            |                |          |
|                     |                      | Postop;  | Postop;      | Postop; |                           |            |                |          |
|                     |                      | N: 88±8  | N: 97±7      | N: 95±5 |                           |            |                |          |
|                     |                      | C: 84±8  | C: 96±8      | C: 96±6 |                           |            |                |          |
| Iorio et al. 2013   | C: 23 min shorter (p<0.001) | Preop;   | N/A          | N/A     | Modified Cincinnati Rating System Questionnaire: | Longer in navigation (23 min) | N/D    |          |
|                     |                      | N: 51.4±9.9|              |         | Preop;                      |            |                |          |
|                     |                      | C: 54.7±11.8 (n.s.)|              |         | N: 46.5±7.2               |            |                |          |
|                     |                      | Postop;  |              |         | C: 46.1±7.9               |            |                |          |
|                     |                      | N: 85.1±7.3|              |         | Postop;                     |            |                |          |
|                     |                      | C: 79.4±6.2 (n.s.)|              |         | Postop;                     |            |                |          |
|                     |                      |          |              |         | N: 84.6±8                 |            |                |          |
|                     |                      |          |              |         | C: 67.7±13.3               |            |                |          |
| Reising et al. 2013 | N: 141 (90–223) min  | N/A      | N/A          | N/A     | N/A                         | N/D        | N/D            | N/A      |
|                     | C: 141 (82–246) min (n.s.)|          |              |         | N/A                         |            |                |          |
|                     |                      |          |              |         | N/A                         |            |                |          |
|                     |                      |          |              |         | N/A                         |            |                |          |
|                     |                      |          |              |         | N/A                         |            |                |          |
| Ribeiro et al. 2014 | N/A                  | N/A      | N/A          | Preop;  | N/A                         | N/A        | N/A            | N>C      |
|                     |                      |          |              | N: 46.83±16.86|                          |            |                |          |
|                     |                      |          |              | C: 40.85±15.46|                          |            |                |          |
|                     |                      |          |              | (p=0.357) |                          |            |                |          |
|                     |                      |          |              | Postop;  |                          |            |                |          |
|                     |                      |          |              | N: 91.9±11.67|                          |            |                |          |
|                     |                      |          |              | C: 87.6±11.12|                          |            |                |          |
|                     |                      |          |              | (p=0.033) |                          |            |                |          |
and modified Cincinnati Rating System Questionnaire in one study. Among the five studies that reported the functional outcome, two reported better functional outcome in navigated HTO, whereas others found no difference between navigated and conventional HTO. The results of the aggregate analysis based on each functional outcome measure are shown in Fig. 5. Navigated HTO showed better AKS knee score than conventional HTO did, but no difference was found in the AKS function and Lysholm scores. However, comparison of the functional outcome between navigated and conventional HTO was limited by the paucity of studies reporting functional outcome. In addition, two studies that provided the majority of the functional outcome data were conducted by Akamatsu et al., which might have substantially affected the results of the pooled analysis.

7. Operative Time

Of the 12 studies, 7 reported the operative time of navigated and conventional HTO. Four studies reported longer operative time in the navigated HTO group than that in the conventional HTO group, whereas three studies reported comparable operative time between the two groups. Pool analysis was available for five studies that reported both mean values and standard deviations of the operative time: the operative time was longer as much as 9.91 minutes (95% CI, 3.60–16.22) in the navigated HTO group than that in the conventional HTO group (Fig. 6).

8. Complications

Only three studies compared the complication rate between the
navigation and conventional groups. Kim et al. observed two delayed unions and one varus collapse of the 47 cases of navigated HTO (6.3%), whereas two cases of delayed union was observed among 43 cases of conventional HTO (4.7%). They found that all these complications were related to the breakage of the lateral tibial cortex during opening of the osteotomy site. Aka­matsu et al. reported lateral unstable knees but found no difference between the groups: 2 knees with lateral cortex breakage and 3 knees with lateral tibial plateau fracture in the navigated HTO group (16.1%), whereas 4 knees with lateral cortex break­age in the conventional group (14.3%). Iorio et al. reported only two cases of broken screws in the conventional HTO group (15.4%). Three studies reported no major complication in their series. The other studies did not report any results regarding complications, or complicated patients were excluded from the studies. The paucity of the studies reporting complications hindered quantitative comparison of the complication rates between the navigation and conventional methods.

Discussion

The most important findings of this meta-analysis are that navigated HTO improved the accuracy of alignment correction in the coronal plane and maintained the tibial slope better than conventional HTO did but there was no difference in the functional outcome. Furthermore, with use of gap measurement for intraoperative alignment confirmation in the conventional procedure, the accuracy of the coronal alignment correction of conventional HTO was comparable to that of navigated HTO that required a longer operative time. These findings imply there is lack of evidence to support the routine use of navigation in medial opening wedge HTO.

In this meta-analysis, compared with the conventional method, navigated HTO showed superior accuracy in coronal alignment correction based on the assessment of the outlier risk. Our findings were consistent with those of the previous meta-analysis and systematic reviews that compared conventional and navigated HTO and concluded that the use of navigation improves the accuracy of coronal alignment correction. However, interest-
ingly, the subgroup analysis showed that the outlier incidence did not differ between navigated HTO and the conventional HTO performed using the gap measurement technique for intraoperative alignment confirmation. Specogna et al. reported the MD of coronal alignment between the supine and standing positions affected by the weight bearing effect as 1.6°. Brouwer et al. also reported more varus deviation by a mean of 2° in the standing position than in the supine position in patients with varus alignment. The results of the previous studies imply that fluoroscopic information obtained in the supine position can be a potential source of correction error. Considering the smaller amount of varus deformity in the supine position, we can infer that the fluoroscopy method tends to result in unintended undercorrection and the same is true for navigated HTO that uses information obtained in supine position without loading. In contrast, gap measurement methods depend on the results of the preoperative planning, which typically uses a full-length weight bearing scanogram taken in standing position; thus, the weight bearing

| Study or subgroup | Navigation Events | Conventional Events | Total Events | Weight (%) | Odds ratio M-H, random, 95% CI | Year | Odds ratio M-H, random, 95% CI |
|-------------------|-------------------|---------------------|-------------|------------|-------------------------------|------|-------------------------------|
| **1.2.1 Non-locking plates** | | | | | | | |
| Saragaglia and Roberts (25) 2005 | 1 | 28 | 8 | 28 | 6.5 | 0.09 [0.01, 0.80] | 2005 | | |
| Iorio et al. (17) 2013 | 14 | 14 | 10 | 13 | 7.3 | 0.05 [0.01, 0.36] | 2013 | | |
| Lee et al. (11) 2014 | 10 | 40 | 4 | 40 | 11.3 | 3.00 [0.85, 10.54] | 2014 | | |
| Stanley et al. (16) 2016 | 15 | 52 | 24 | 65 | 14.5 | 0.69 [0.32, 1.52] | 2016 | | |
| **Subtotal (95% CI)** | | | | | | | |
| Total events | 28 | 46 | | | | | |
| Heterogeneity: Tau²=2.05, Chi²=15.40, df=3 (p=0.002); I²=81% | | | | | | | |
| Test for overall effect: Z=1.17 (p=0.24) | | | | | | | |
| **1.2.2 Locking plates** | | | | | | | |
| Maurer and Wassmer (24) 2006 | 14 | 37 | 14 | 20 | 11.9 | 0.26 [0.08, 0.84] | 2006 | | |
| Akamatsu et al. (13) 2012 | 4 | 31 | 9 | 28 | 10.9 | 0.31 [0.08, 1.17] | 2012 | | |
| Reising et al. (19) 2013 | 0 | 40 | 9 | 40 | 4.4 | 0.04 [0.00, 0.73] | 2013 | | |
| Akamatsu et al. (17) 2016 | 4 | 31 | 7 | 31 | 10.7 | 0.51 [0.13, 1.95] | 2016 | | |
| Na et al. (20) 2016 | 7 | 40 | 6 | 20 | 11.3 | 0.49 [0.14, 1.74] | 2016 | | |
| Schröter et al. (15) 2016 | 6 | 56 | 5 | 57 | 11.3 | 1.25 [0.36, 4.35] | 2016 | | |
| **Subtotal (95% CI)** | | | | | | | |
| Total events | 35 | 50 | | | | | |
| Heterogeneity: Tau²=0.15, Chi²=6.56, df=5 (p=0.26); I²=24% | | | | | | | |
| Test for overall effect: Z=2.60 (p=0.009) | | | | | | | |

Fig. 3. Results of aggregate analysis for comparison of navigated and conventional high tibial osteotomy regarding the accuracy of coronal alignment, including a subgroup analysis by the fixation device: non-locking plates vs. locking plates. Numbers for "Events" refer to outlier; numbers for "Total" refer to total evaluated patients; "Weight" is calculated as 1/(within-study variation+between-study variation). M-H: Mantel–Haenszel estimation method, CI: confidence interval, df: degree of freedom.

| Study or subgroup | Navigation Events | Conventional Events | Total Events | Weight (%) | Odds ratio M-H, random, 95% CI | Year | Odds ratio M-H, random, 95% CI |
|-------------------|-------------------|---------------------|-------------|------------|-------------------------------|------|-------------------------------|
| **2.2 Varus vs. Valgus** | | | | | | | |
| Iorio et al. (17) 2013 | 0 | 14 | 10 | 13 | 34.0 | 0.01 [0.00, 0.25] | 2013 | | |
| Akamatsu et al. (17) 2016 | 4 | 31 | 16 | 31 | 68.9 | 0.14 [0.04, 0.49] | 2016 | | |
| **Total (95% CI)** | | | | | | | |
| Total events | 4 | 26 | | | | | |
| Heterogeneity: Tau²=1.75, Chi²=2.22, df=1 (p=0.14); I²=55% | | | | | | | |
| Test for overall effect: Z=2.36 (p=0.02) | | | | | | | |

Fig. 4. Results of aggregate analysis for comparison of navigated and conventional high tibial osteotomy regarding the accuracy of sagittal alignment. Numbers for "Events" refer to outlier; numbers for "Total" refer to total evaluated patients; "Weight" is calculated as 1/ (within-study variation+between-study variation). M-H: Mantel–Haenszel estimation method, CI: confidence interval, df: degree of freedom.
The effect of the coronal alignment is reflected in the preoperatively planned correction amount. The well-controlled preoperative scanogram taken with the patella facing forward might also reduce the risk of rotation error than intraoperative fluoroscopy. Our findings of the meta-analysis with subgroup analysis suggest that conventional HTO can be as useful as navigated HTO in terms of the accuracy in coronal alignment when performed using the gap measurement methods for intraoperative alignment confirmation, although the navigation technique generally proves the accuracy of coronal alignment correction.

Posterior tibial slope tends to increase after opening wedge HTO and can affect the biomechanics of the knee. An increased tibial slope can cause overload of the anterior cruciate ligament (ACL); hence, the maintenance of the tibial slope is an important factor in opening wedge HTO, particularly in a patient with ACL insufficiency. In the current meta-analysis, we found that five studies reported better accuracy of sagittal alignment maintenance in navigated HTO compared with the conventional method.
ventional method, whereas three studies showed no difference. However, comparison of the sagittal alignment of the two methods is not feasible because the measurement methods of the tibial slope vary among studies and there is no recommended target of the absolute value\(^{34}\). Therefore, comparison of the changes in the tibial slope before and after HTO is more reasonable. Only two studies reported the change in the tibial slope after HTO. In the aggregate analysis, the navigated HTO showed better tibial slope maintenance. However, we cannot determine whether such difference is clinically significant because a recent meta-analysis reported that the MD of the tibial slope change in the opening wedge HTO was only 2.02\(^{\circ}\). Giffin et al.\(^ {38}\) reported that small increases in tibial slope do not affect anterior–posterior translation or in situ forces in the cruciate ligaments, even with the approximately 5\(^{\circ}\) increase of tibial slope after osteotomy. Therefore, we concluded that the use of navigation in HTO is beneficial in maintaining the posterior tibial slope but the clinical significance should be investigated in further research.

The functional benefit of the use of navigation in HTO was not evident in this meta-analysis. Although the pooled data of AKS knee score showed a better result in the navigation group compared with the conventional group, only three studies were included, and even two of these studies were conducted by the same authors\(^ {12,13} \). The aggregate analysis using the AKS function score also included only the two studies of Akamatsu et al.\(^ {12,13} \), which limits the drawing of a valid conclusion. Lysholm score, the most frequently reported outcome measure, was not different between the two groups. Due to the paucity of the studies reporting functional outcome, it was difficult to determine the superiority of the techniques in terms of functional outcome. In addition, most of the studies failed to demonstrate clinically significant differences in functional scores. Our analysis results were congruent with those of previous meta-analysis and systematic review with regard to the functional outcome, because the clinical benefit of navigated HTO over the conventional technique was unclear\(^ {10} \).

The present study confirmed that navigated HTO required longer operative time than the conventional technique did. Among the seven studies that reported the operative time, four reported longer operative time in the navigated HTO group than the conventional HTO group\(^ {12,13,15,17} \). In the pooled analysis, the operative time was 9.91 minutes longer in navigated HTO than the conventional procedure, which is a similar difference reported in a recent systematic review of navigated HTO with a difference of 8.7 minutes\(^ {30} \). Iorio et al.\(^ {17} \) even reported 23 minutes longer operative time in navigated HTO, although this study was not included in the aggregate analysis. Three studies reported comparable operative time between both groups, but the reason for the different result was not revealed clearly in this meta-analysis. We assume that the operators’ experience might affect the result because navigation requires a long learning curve.

This study has several limitations. First, the level of evidence of the included studies was not high because only three randomized controlled studies were included\(^ {12,15,17} \). This can be a potential source of bias. Further well-designed studies are warranted. Second, the sample size of each included study was mostly small, typically <50 in each comparison arm. Third, we just followed the outlier definition described in each study rather than establishing unified criteria for the pooling of the result. The correction target of the coronal plane was similar across the studies but different radiographic parameters, such as HKA, FTA, and WBL, were presented in each study. In addition, although the acceptable range in each study was not identical, we simply used the reported incidence of each study for aggregate analysis of the outlier incidence. However, the study sample size of navigated and conventional HTO groups was not substantially different in most studies, and we believe this limitation did not skew the result significantly. Fourth, a solid conclusion on the functional benefit of the use of navigation in HTO was limited by the paucity of the studies reporting functional outcome and the diversity of the scoring measures. Fifth, the definition of the operative time was not identical among the studies that reported the data with a different starting point and/or final time point. However, it did not seem to affect the result of the pooled analysis because the MD was considered in the analysis. Sixth, the time point of radiographic and/or functional outcome evaluation varied among the included studies. Alignment can change over time, hence, the different follow-up period and the time point of the radiographic evaluation may affect the result\(^ {39} \) including the functional outcome; substantial heterogeneity of included studies is the inherent limitation of meta-analyses. Finally, the long-term result was not investigated. The rationale for the use of navigation in HTO is that it will improve the longevity of HTO by promoting accurate alignment correction. However, we could not ascertain the clinical efficacy of navigated HTO because of the lack of evidence of better long-term results as well as the longer operative time and the comparable short-term functional outcome.

**Conclusions**

This meta-analysis showed that the use of navigation in HTO could improve accuracy in both coronal and sagittal alignments.
but its clinical benefit is unclear. On the accuracy of alignment, conventional HTO with the intraoperative gap measurement technique could provide comparable results. Therefore, in the absence of sufficient evidence of clinical benefit of navigation, navigated HTO cannot be recommended as a routine procedure.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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