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Original article

No definite advantage of a portable accelerometer-based navigation system over conventional technique in total knee arthroplasty: A systematic review and meta-analysis

Tomonori Shigemura*, Yasuaki Murata, Yohei Yamamoto, Norichika Mizuki, Yasunori Toki, Yuichi Wada

Department of Orthopaedic Surgery, Teikyo University Chiba Medical Center, 3426-3 Anesaki, 299-0111 Ichihara, Chiba, Japan

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ABSTRACT

Background: Precise implant alignment is a crucial prognostic factor in total knee arthroplasty (TKA). Portable navigation systems (PN-TKA) were reported to be better than the conventional technique (CON-TKA). We hypothesized that PN-TKA offered greater radiologic precision than CON-TKA in mechanically aligning components. We investigated whether (1) it improved global mechanical alignment, and (2) optimized component placement with respect to the tibial and femoral mechanical axes.
Patients and methods: A systematic literature review compared PN-TKA versus CON-TKA. PubMed, Web of Science and Cochrane Library search retrieved ten studies. Their data were pooled using RevMan 5.3. Odds ratios (OR) for dichotomous data were calculated with 95% confidence intervals (CIs) for each outcome. Statistical heterogeneity was assessed as I^2 using a standard χ^2 test. $I^2 > 50\%$ denoted significant heterogeneity requiring a random effects model; otherwise, a fixed effects model was applied.
Results: There were significantly fewer outliers for mechanical axis ($I^2 = 24\%$, OR = 0.62, 95% CI = 0.42–0.91, $p = 0.02$) and coronal femoral component angle ($I^2 = 58\%$, OR = 0.31, 95% CI = 0.13–0.73, $p = 0.007$) using PN-TKA; however, no significant difference was observed for coronal tibial component angle outliers ($I^2 = 0\%$, OR = 0.66, 95% CI = 0.38–1.15, $p = 0.14$).
Discussion: Although PN-TKA appeared to improve global alignment, it had no effect on coronal tibial alignment, which is a key factor in predicting the long-term success of component fixation. There thus appeared to be no definite advantage of PN-TKA over CON-TKA.
Level of evidence: III.

1. Introduction

In total knee arthroplasty (TKA), precise implant alignment is a crucial prognostic factor in terms of wear and subsequent loosening [1–7]. Methods of aligning TKA components involve intramedullary and extramedullary alignment guides, although they have limited accuracy [8]. Therefore, computer-assisted surgery (CAS) has been introduced to improve precision [9–17] and reduce blood loss by not invading the intramedullary canal [18–20]. However, it has several limitations, such as high initial start-up costs, additional incisions and complications related to pin insertion, and the need for large consoles for registration and alignment feedback. An accelerometer-based portable navigation (PN-TKA) device aims to achieve the same accuracy as CAS while using a smaller hand-held surgical instrument. However, it is unclear whether precision is improved: one prospective randomized controlled trial (RCT) reported that outliers in the lower limb mechanical axis (MA), coronal femoral component angle (CFA) and coronal tibial component angle (CTA) were not significantly different from these of the conventional technique (CON-TKA) [21], whereas another RCT reported significantly fewer outliers using PN-TKA [22]. Therefore, we conducted a systematic review and meta-analysis comparing PN-TKA with CON-TKA. We hypothesized that PN-TKA offered greater radiological precision than CON-TKA in mechanically aligning components. We investigated whether:

- it improved global mechanical alignment, and;
- optimized component placement with respect to the tibial and femoral mechanical axes.

* Corresponding author.
E-mail address: tshigepon@yahoo.co.jp (T. Shigemura).

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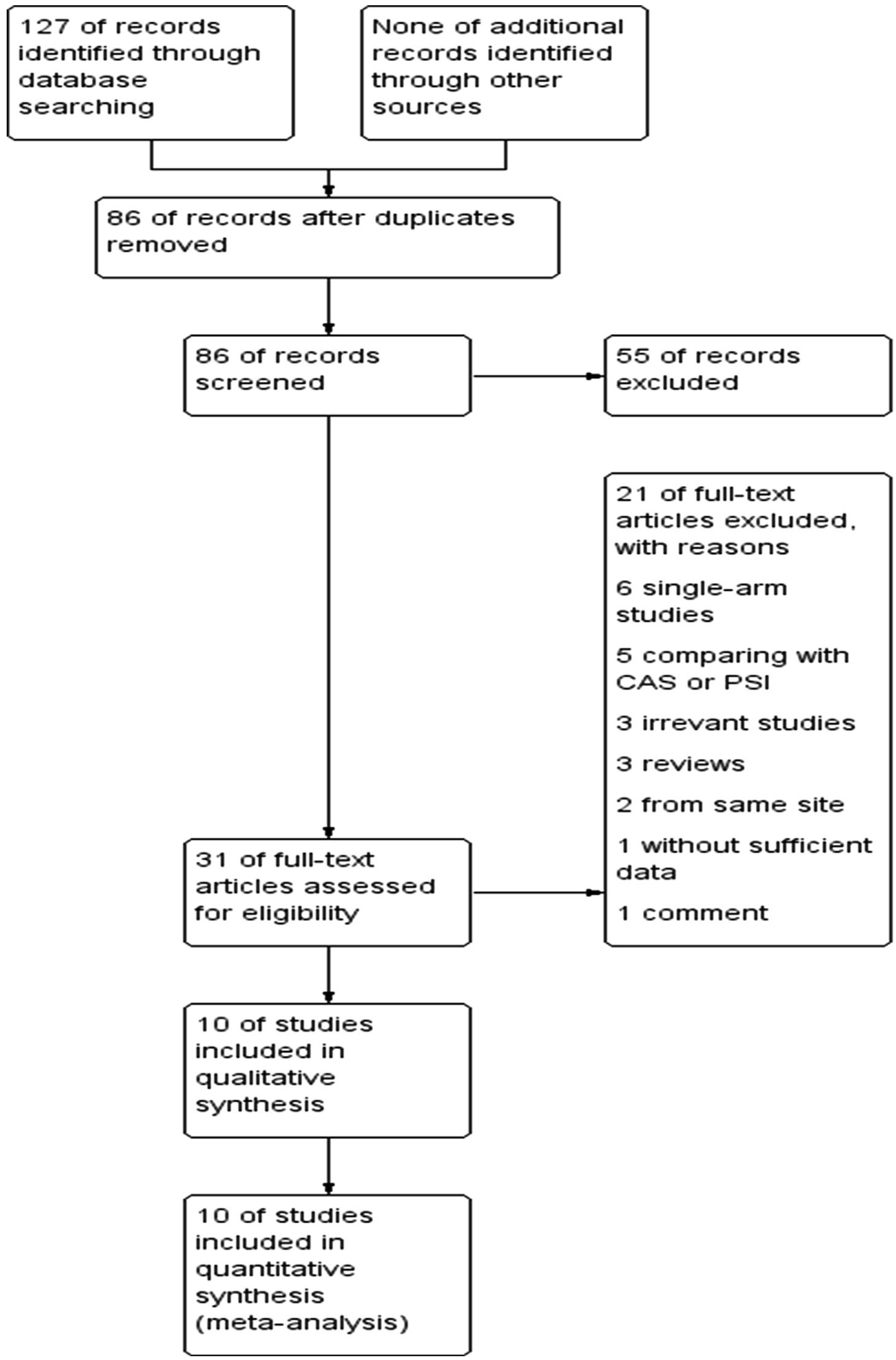

Fig. 1. Flowchart of literature screening. CAS: computer-assisted surgery; PSI: patient specific instrumentation.

2. Materials and methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement [23] was followed, as described in a previously published protocol at PROSPERO (CRD42018105474). In July 2018, we systematically searched PubMed, Web of Science and the Cochrane Library for relevant articles, using the following search strings: ("knee arthroplasty" or "knee replacement") and ("assisted" or "navigated" or "navigation") and ("hand-held" or "handheld" or "accelerometer" or "portable"). We further checked the reference lists of the retrieved articles so as to include additional studies. Selection involved randomized or non-randomized prospective or retrospective comparative studies focusing on differences between PN-TKA and CON-TKA. Studies were required to report radiological parameters, as our primary endpoint was the number of outliers in lower limb mechanical alignment (MA), and our secondary endpoints were outliers in femoral component alignment (CFA) and tibial component alignment (CTA). The lower limb MA was defined by the angle between the mechanical axes of the femur and tibia [24]; CFA was the angle between the inferior bicondylar line and the mechanical axis of the femur; and CTA was the angle formed by the base plate and the mechanical axis of the tibia. Outliers were defined as being outside a 3° interval around the neutral value.

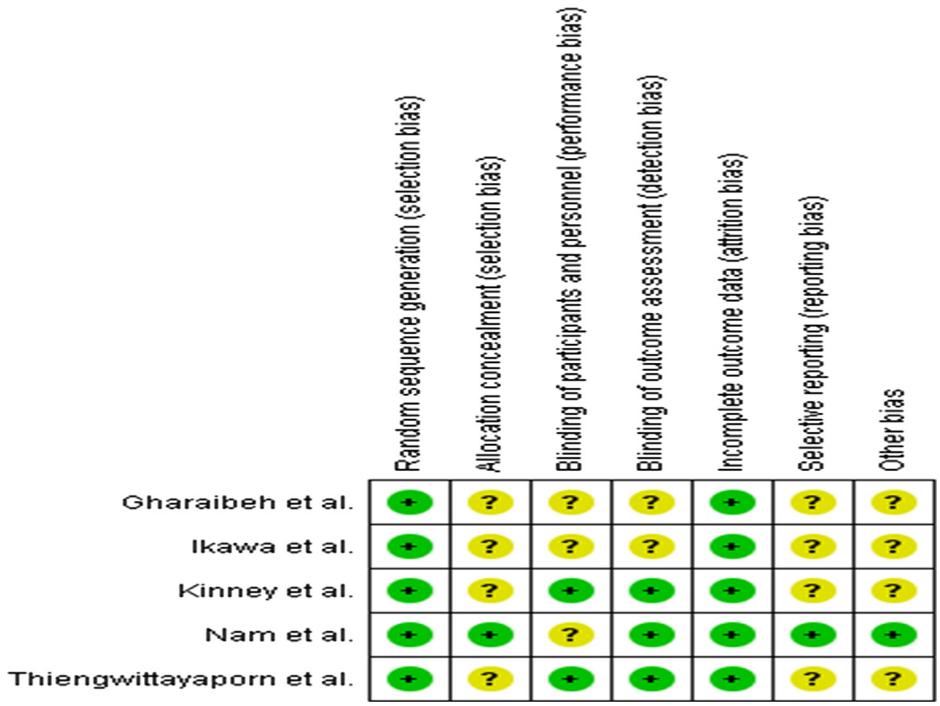

Fig. 2. Methodological quality of the included studies, with an evaluation of bias (+: low risk of bias; −: high risk of bias; ?: unclear risk of bias).

Table 1
Characteristics of the selected studies.

Authors	Year	Country	Study design	Portable navigation group					
				Cases (knees)	Gender (M/F)	Age (years)	BMI (kg/m^2)	Side (L/R)	Device of navigation
Nam et al. [25]	2014	US	RCT	47 (47)	18/29	67.1 ± 7.5	31.1 ± 5.9	28/19	KA
Thiengwittayaporn et al. [22]	2016	TH	RCT	40 (40)	8/32	68.0 ± 8.0	26.6 ± 3.7	18/22	IA
Gharaibeh et al. [21]	2017	AU	RCT	89 (89)	34/55	69.2 ± 8.7	29.2 ± 4.8	44/45	KA
Fujimoto et al. [26]	2017	JP	RCS	48 (48)	N/A	N/A	N/A	N/A	KA2
Ikawa et al. [27]	2017	JP	RCT	121 (121)	15/106	74.0 ± 6.8	26.1 ± 3.7	N/A	KA2
Ueyama et al. [28]	2017	JP	RCS	67 (67)	8/59	76.9 ± 4.8	26 ± 3.8	N/A	KA2
Matsumoto et al. [29]	2018	JP	PCS	46 (50)	11/39	74.7 (49–90)	25.4 (17.1–39.3)	N/A	KA2
Goh et al. [30]	2018	SG	PCS	38 (38)	10/28	63.9 ± 7.4	28.9 ± 5.7	19/19	IA
Kinney et al. [31]	2018	US	RCT	24 (25)	12/13	66.4 ± 2.3	30.4 ± 1.2	N/A	IA
Moo et al. [32]	2018	SG	RCS	30 (30)	10/20	67 (59, 76)[a]	26.2 (23.4, 30.3)[a]	13/17	IA

Authors	Year	Country	Study design	Conventional group					
				Cases(knees)	Gender(M/F)	Age (years)	BMI (kg/m^2)	Side(L/R)	Device of navigation
Nam et al. [25]	2014	US	RCT	47 (47)	20/27	66.1 ± 10.1	31.2 ± 5.6	26/21	Femur; IM, tibia; EM
Thiengwittayaporn et al. [22]	2016	TH	RCT	40/40	6/34	65.9 ± 6.3	26.2 ± 3.2	18/22	Femur; IM, tibia; EM
Gharaibeh et al. [21]	2017	AU	RCT	90 (90)	39/50	69 ± 8.3	29.6 ± 5.4	33/57	Femur; IM, tibia; IM
Fujimoto et al. [26]	2017	JP	RCS	47 (47)	5/42	N/A	N/A	N/A	Femur; IM, tibia; EM
Ikawa et al. [27]	2017	JP	RCT	120 (120)	19/101	74.1 ± 6.8	26.8 ± 4.1	N/A	Femur; IM, tibia; EM
Ueyama et al. [28]	2017	JP	RCS	75 (75)	14/61	78.1 ± 5.1	25.1 ± 4.4	N/A	Femur; IM, tibia; EM
Matsumoto et al. [29]	2018	JP	PCS	41 (50)	13/37	73.1 (36–86)	26.4 (17.3–37.7)	N/A	Femur; IM, tibia; EM
Goh et al. [30]	2018	SG	PCS	76 (76)	20/56	66.4 ± 7.3	27.6 ± 5.4	37/39	N/A
Kinney et al. [31]	2018	US	RCT	23 (25)	9/16	65.0 ± 2.0	31.1 ± 1.2	N/A	Femur; IM, tibia; EM
Moo et al. [32]	2018	SG	RCS	30 (30)	12/18	64 (59, 73)	27.5 (23.1, 29.8)[a]	14/16	Femur; IM, tibia; EM

US: United States; TH: Thailand; AU: Australia; JP: Japan; SG: Singapore; RCT: randomized controlled trial; RCS: retrospective comparative study; PCS: prospective comparative study; BMI: body mass index; KA: KneeAlign; IA: iASSIST; IM: intramedullary; EM: extramedullary.

[a] Values are expressed as medians, with interquartile range in brackets.

Following a preliminary review of 127 articles, we excluded 41 duplicate studies, and 55 more after scanning titles and Abstracts. By screening their full text, 21 articles were further excluded (Fig. 1), leaving finally 10 studies, with 555 knees in the PN-TKA and 600 in the CON-TKA group [21,22,25–32] (Table 1). In the PN-TKA group, six studies [21,25–29] used KneeAlign (KA; OrthoAlign Inc., Aliso Viejo, CA, USA) and 4 studies [22,30–32] used the iASSIST™ Knee System (IA; Zimmer, Warsaw, IN, USA).

Two of the present authors independently assessed the quality of the included studies, and any disagreement between them was

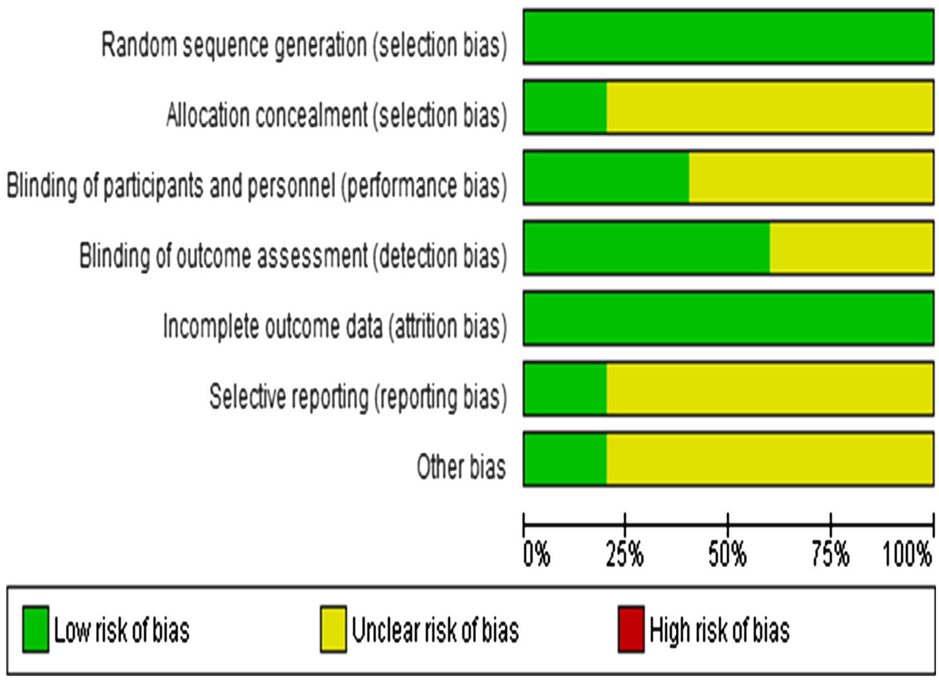

Fig. 3. Risk of bias. Each risk of bias item is presented as the percentage across all the included studies, which indicates the proportion of different levels of risk of bias for each item.

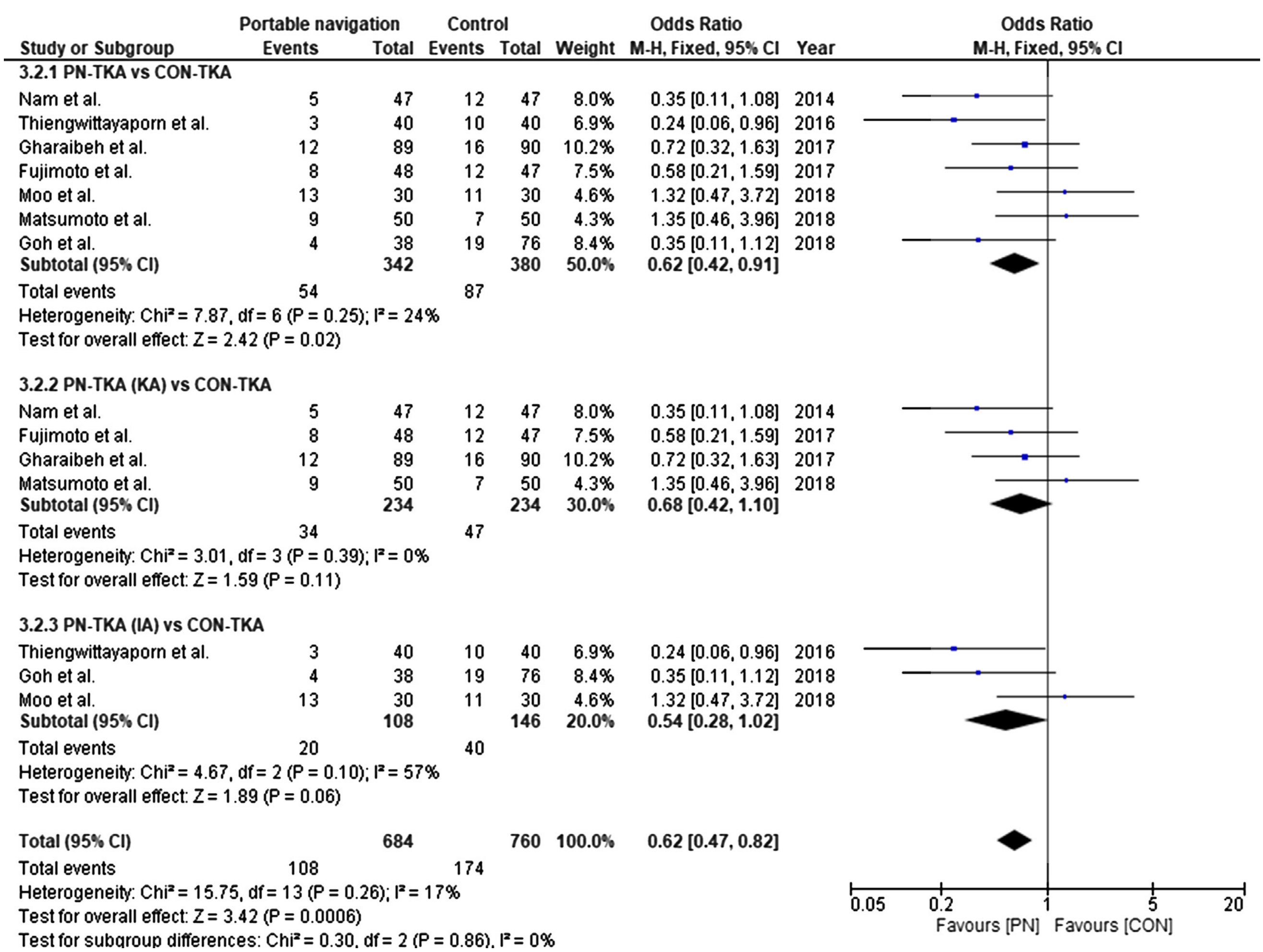

Fig. 4. Lower limb MA outliers: forest plot. MA: mechanical axis; M-H: Mantel-Haenszel method; CI: confidence intervals; df: degrees of freedom; PN: accelerometer-based portable navigation; CON: conventional; KA: KneeAlign; IA: iASSIST.

Table 2
Newcastle-Ottawa Scale for the included studies.

Authors	Selection	Comparability	Outcome
Fujimoto et al. [26]	XX	XX	X
Ueyama et al. [28]	XX	XX	X
Matsumoto et al. [29]	XX	XX	X
Goh et al. [30]	XX	XX	XX
Moo et al. [32]	XX	XX	X

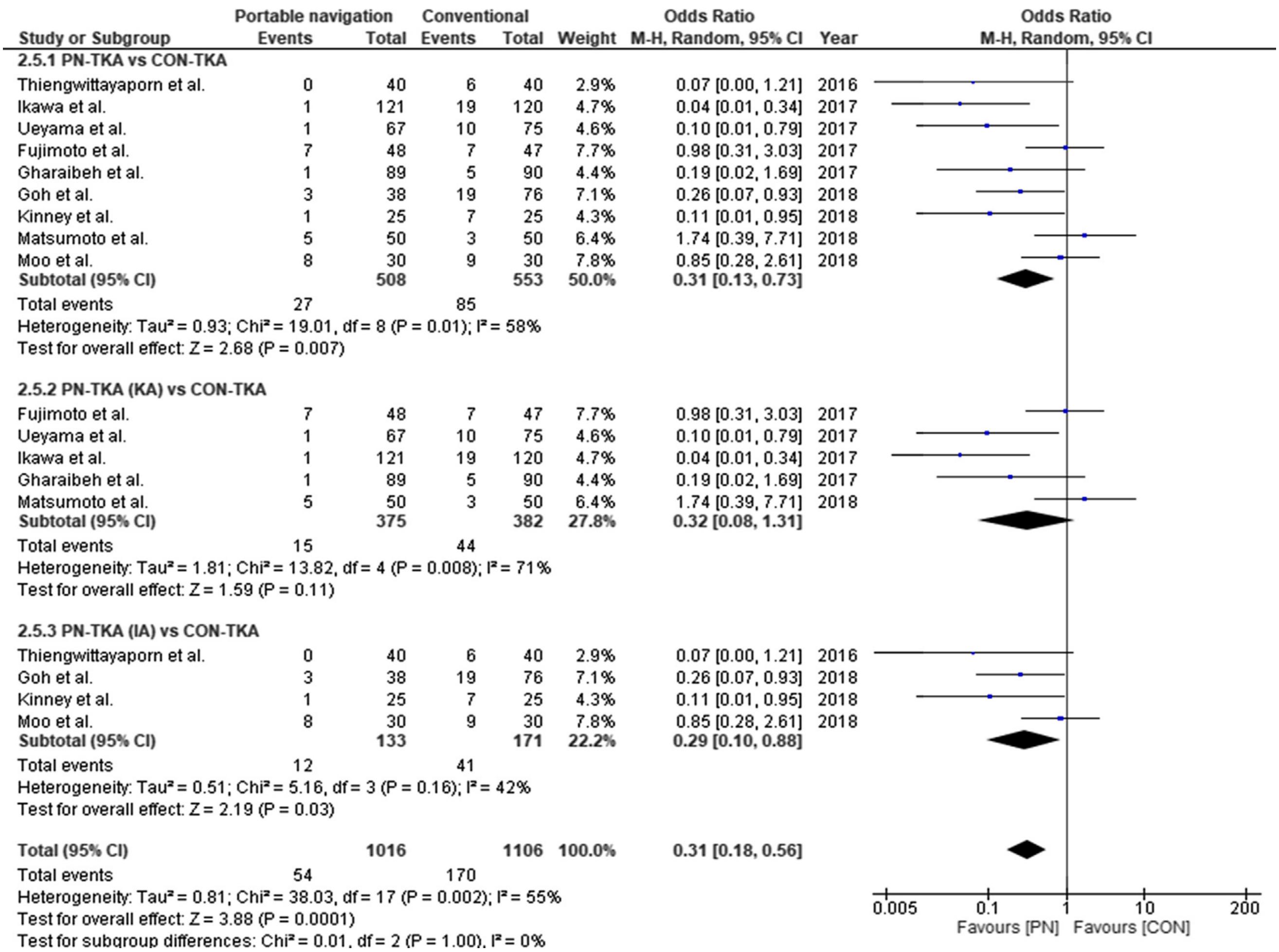

Fig. 5. CFA outliers: forest plot. CFA: coronal femoral component alignment; M-H: Mantel-Haenszel method; CI: confidence interval; df: degrees of freedom; PN: accelerometer-based portable navigation; CON: conventional; KA: KneeAlign; IA: iASSIST.

resolved through discussion. Five studies [21,22,25,27,31] were assessed using the Cochrane Collaboration's tool (Fig. 2). Judgements on each risk of bias item are presented as percentages across all included studies (Fig. 3). The Newcastle-Ottawa Scale (NOS) was used to assess the eligibility of the other five studies [26,28–30,32]. All the articles were scored according to the three sections of the NOS: selection, comparability and outcome (Table 2).

2.1. Statistical analysis

Data were pooled using RevMan software (version 5.3, Cochrane Collaboration, Oxford, UK). The p-values < 0.05 were considered significant. We calculated the odds ratios (OR) for dichotomous data with 95% confidence intervals (CIs) for each outcome. Statistical heterogeneity was assessed as I^2 using a standard χ^2 test. $I^2 > 50\%$ denoted significant heterogeneity, and a random effects model was then applied to the meta-analysis; otherwise, a fixed effects model was applied. Publication bias was estimated by observing asymmetry in a funnel plot. In addition, sensitivity analysis was performed. To explore clinical heterogeneity between the trials, subgroup analyses based on the type of navigation system were conducted.

3. Results

Seven articles (722 knees) [21,22,25,26,29,30,32] reported the number of MA outliers, with no significant heterogeneity ($I^2 = 24\%$). Pooled data showed that the number of MA outliers was significantly smaller in the PN-TKA group than in the CON-TKA group (OR = 0.62, 95% CI = 0.42–0.91, $p = 0.02$; Fig. 4). A subgroup analysis of the four studies (468 knees) [21,25,26,29] using KA in the PN-TKA group found no significant difference in MA outliers (OR = 0.68, 95% CI = 0.42–1.10, $p = 0.11$; Fig. 4); the three studies (254 knees)

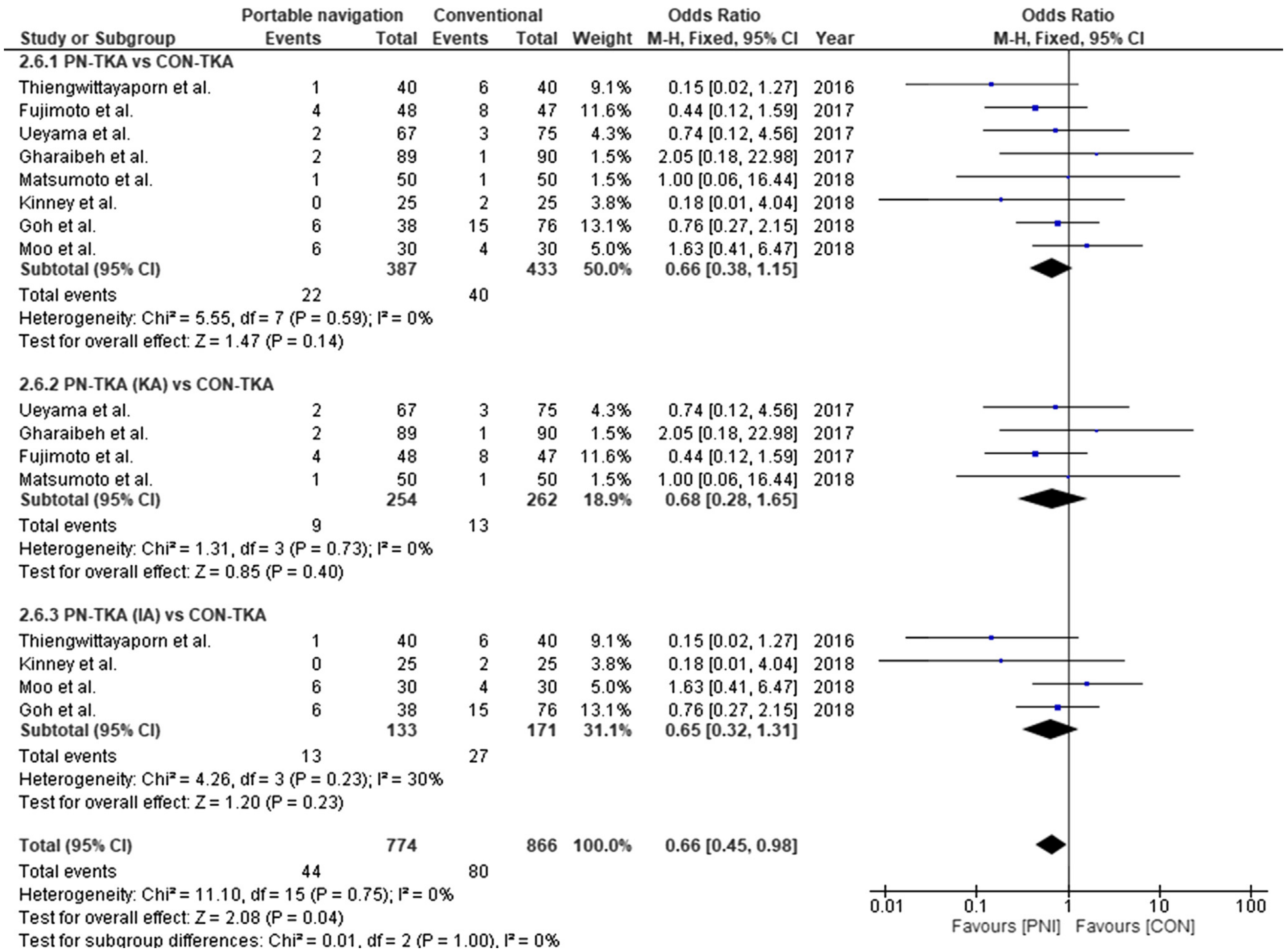

Fig. 6. CFA outliers: funnel plot.

[22,30,32] using IA also showed no significant difference in MA outliers compared to CON-TKA (OR = 0.54, 95% CI = 0.28–1.02, p = 0.06; Fig. 4).

Nine articles (1,061 knees) [21,22,26–32] reported the number of CFA outliers, with significant heterogeneity (I^2 = 58%). Pooled data showed that the number of CFA outliers was significantly smaller in the PN-TKA group (OR = 0.31, 95% CI = 0.13–0.73, p = 0.007; Fig. 5). A subgroup analysis of the five studies (757 knees) [21,26–29] using KA in the PN-TKA group found that there was no significant difference in CFA outliers (OR = 0.32, 95% CI = 0.08–1.31, p = 0.11; Fig. 5), while subgroup analysis of the 4 studies (304 knees) [22,30–32] using IA showed fewer CFA outliers in the PN-TKA group (OR = 0.29, 95% CI = 0.10–0.88, p = 0.03; Fig. 5). A funnel plot for CFA outliers showed asymmetry, indicating publication bias (Fig. 6), although only nine studies were included in the funnel plot.

Eight articles (820 knees) [21,22,26,28–32] reported the number of CTA outliers, with no significant heterogeneity (I^2 = 0%). Pooled data showed that there was no significant difference in the number of CTA outliers between the groups (OR = 0.66, 95% CI = 0.38–1.15, p = 0.14; Fig. 7). Subgroup analysis of the four studies (516 knees) [21,26,28,29] using KA in the PN-TKA group found no significant difference in the number of CTA outliers (OR = 0.68, 95% CI = 0.28–1.65, p = 0.40; Fig. 6); subgroup analysis of the four studies (304 knees) [22,30–32] using IA in the PN-TKA group also showed no significant difference in CTA outliers compared to CON-TKA (OR = 0.65, 95% CI = 0.32–1.31, p = 0.23; Fig. 7).

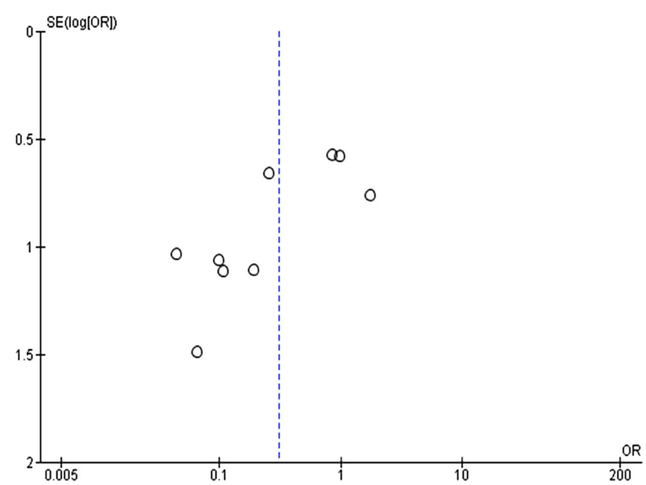

Fig. 7. CTA outliers: forest plot. CTA: coronal tibial component alignment; M-H: Mantel-Haenszel method; CI: confidence interval; df: degrees of freedom; PN: accelerometer-based portable navigation; CON: conventional; KA: KneeAlign; IA: iASSIST.

Sensitivity analysis omitting non-RCTs revealed a similar trend for all items. Most studies used standing anteroposterior radiographs, except one [21] that used non-weighted CT helical scan. Omitting this study, results remains unchanged.

4. Discussion

The present meta-analysis showed that lower limb MA and CFA outliers were significantly fewer in the PN-TKA group than in the CON-TKA group, whereas there was no significant difference for CTA outliers.

The better results of PN-TKA concerning CFA outliers may be explained by better detection of the biomechanical center of the hip [28,32], although Fujimoto et al. [26] reported technical issues due to hip adduction during registration. In contrast, detection of the ankle center remains imprecise and surgeon-dependent whatever the method [28,32].

This may be a limitation of PN-TKA if tibial malalignment is considered as a factor of poor long-term survival [1,33–35].

The present study had several limitations.

Firstly, significant heterogeneity was observed for CFA outliers ($I^2 = 58\%$), possibly because of differences in surgeons' skills, types of cut guide used in the CON-TKA group, navigation devices and patient characteristics. Subgroup analysis according to type of navigation device did not reduce heterogeneity.

Secondly, the small number of randomized studies weakened the analysis.

Thirdly, because of insufficient data, we could not analyze sagittal alignment, patient-reported outcomes, clinical scores, complication rates, reoperation rates, costs or long-term survival. Therefore, further studies are needed.

Fourthly, numerical data could not be exploited because of differences in definition of MA, CFA and CTA.

5. Conclusion

Within the limits of the present study, PN appeared to improve femoral component alignment but not tibial component alignment.

Disclosure of interest

The authors declare that they have no competing interest.

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No funding was received for this study.

Contributions

Shigemura: study design, drafting of manuscript.
Murata and Yamamoto: acquisition of data.
Mizuki and Toki: analysis and interpretation of data.
Wada: critical revision.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at: https://doi.org/10.1016/j.otsr.2019.03.006.

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