


# Shorter survival rate in varus-aligned knees after total knee arthroplasty

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## Abstract

**Purpose** One long-held tenet of total knee arthroplasty (TKA) is that post-operative neutral limb alignment promotes implant durability. Recently, the concept of generic safe zone ( $0^\circ \pm 3^\circ$ ) has been challenged. This meta-analysis aimed to evaluate whether neutral alignment was superior to malalignment in long-term survival of TKAs.

**Methods** The MEDLINE, Embase, Cochrane Library, China National Knowledge Infrastructure, Wan Fang Chinese Periodical, Google and reference lists of all the included studies were searched. Of the 1512 studies initially identified, ten met the eligibility criteria, including eight case-control studies and two cohort trials. Relative risks of implant failure were compared between post-operative neutrally aligned and malaligned knees.

**Results** Post-operative malalignment showed higher failure rate of knee implants compared with neutral alignment (95 % CI 1.00–1.88,  $P = 0.05$ ). Failure rate in knees with varus alignment was significantly higher than with neutral alignment (95 % CI 1.07–2.55,  $P = 0.02$ ). There was no significant difference in the likelihood of implant failure between knees with valgus and neutral alignment (95 % CI 0.78–2.41, n.s.). No significant difference of failure rate was noted between neutral alignment and malalignment for fixed-bearing prosthesis (95 %

CI 0.94–1.95, n.s.) or rotating-platform prosthesis (95 % CI 0.75–2.73, n.s.). There was no significant difference of failure rate between knees with neutral alignment and malalignment for studies with a mean follow-up of more than 10 years (95 % CI 0.81–2.01, n.s.) or studies using long-leg weight-bearing radiographs (95 % CI 0.79–1.79, n.s.).

**Conclusions** Post-operative varus alignment results in shorter survival rate after TKA. Not only neutral limb alignment but also the valgus alignment promotes implant durability. Neutral or valgus alignment rather than varus alignment is essential to achieve long-term survival of TKAs and patient satisfaction.

**Level of evidence** III.

**Keywords** Meta-analysis · Alignment · Total knee arthroplasty · Survival · Valgus · Varus

## Introduction

The primary total knee arthroplasty (TKA) has been proved to be successful surgery with long-term survival. One long-held tenet of TKA is that post-operative neutral limb alignment promotes implant durability. If incorrect, they can lead to abnormal wear, premature loosening and patellofemoral problems [2]. A series of studies demonstrate that restoring the mechanical axis of the lower extremity in neutral alignment contributes to a more durable implant and, otherwise, increases the incidence of loosening of the knee prosthesis [8, 12, 23–26]. Not only prodigious clinical evidences support the concept of neutral coronal alignment favouring long-term survival of prosthesis, but also numerous contemporary biomechanical and finite element studies [10, 17, 19] have demonstrated that malalignment, particularly varus, is associated with increased medial tibial

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surface strain, leading to medial cancellous bone overload and eventual failure through medial tibial collapse.

However, several recently published studies [18–21] demonstrating no significant difference in survivorship when comparing well-aligned versus malaligned TKAs have challenged the concept of generic safe zone, traditionally within  $3^\circ$  of neutral. Parratte et al. [21] found that a post-operative mechanical axis of  $0^\circ \pm 3^\circ$  did not improve the survival rate 15 years post-operatively, and concluded that the description of alignment as a dichotomous variable (neutrally aligned vs. malaligned) provided little value in regard to durability. After a review of the available literature, one conventional clinical trial [22] also suggested that knee arthroplasties were unable to confirm the importance of alignment in the long-term survival of knee implants. Thus, whether neutral alignment would contribute to longer survival rate after TKAs has become a controversial new topic.

The traditional main concept in TKAs is aiming the exact mechanical alignment of the lower limb. Recently, however, the concept of anatomical restoration has gained interest among knee surgeons [11]. Howell et al. [11] found that varus alignment of the knee did not adversely affect implant survival or function after kinematically aligned TKA with a mean follow-up of 6.3 years and suggested kinematic alignment as an alternative to mechanical alignment for performing primary TKA. However, whether the varus alignment and oblique joint line would change the stress distribution and affect the long-term survival was questioned [14]. In addition, since constitutional varus alignment of the lower limb was fairly common in normal adults [27], restoration of mechanical alignment to neutral in these cases seemed to be not desirable and would be unnatural for them [3, 30]. Although anatomical restoration of alignment was proposed in these patients with constitutional varus [30], whether post-operative varus alignment would result in short survival rate remained unclear. Moreover, since the severity of pre-operative varus deformity may influence post-operative alignment, some surgeons suggested that ensuring an accurate alignment was important [2], and others argued that correction towards their original status could be a more physiological option [3, 30].

Thus, a meta-analysis of survival of TKAs with post-operative neutral alignment versus malalignment was conducted. Our hypothesis was that restoration of neutral mechanical alignment in theory might lead to longer survival rate compared with malalignment after TKAs; therefore, it could potentially be beneficial to patients. The objectives of our study were: firstly, to examine whether neutral alignment took advantage over either varus or valgus alignment for survival of TKAs, and secondly, to conduct subgroup analysis of TKA survival with neutral alignment versus malalignment according to fixation type of

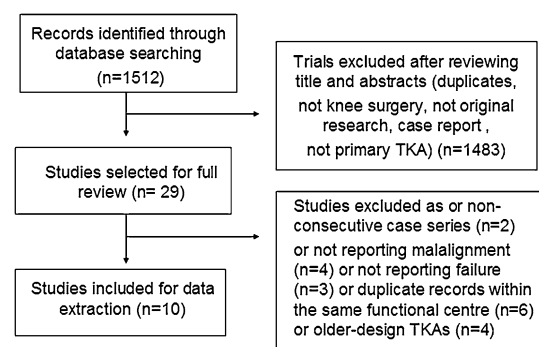
implant, duration of follow-up and measurement method of lower limb alignment. If the hypothesis is confirmed and neutral mechanical alignment indeed shows longer survival rate of TKA than either varus or valgus alignment, it could confirm that malalignment placed a risk of failure after TKA and should be avoided.

## Materials and methods

A meta-analysis of all English and non-English articles identified from electronic databases including MEDLINE, Embase, Cochrane Library, China National Knowledge Infrastructure, Wan Fang Chinese Periodical and Google was conducted. In addition, further relevant studies including those of reference lists of all the included studies were also manually searched. The last search was carried out on 3 December 2014. The following key words: arthroplasty, replacement, knee, total knee arthroplasty, alignment, failure, revision, survival and survivorship, in combination with the Boolean operators AND or OR were used. The search strategy is presented in Fig. 1.

## Inclusion and exclusion criteria

All published randomized control trials, non-randomized cohort trials and case-control studies evaluating the survival rate of knee prosthesis with neutral alignment and malalignment were included. Inclusion criteria comprised the following: primary TKA; description of limb axial alignment as a dichotomous variable (neutral aligned vs. malaligned, neutral vs. varus or neutral vs. valgus); reporting failure rate, revision rate or survival rate; and reporting post-operative malalignment (malaligned, varus or valgus). Exclusion criteria comprised the following: not original research, non-consecutive case series, unicompartmental knee arthroplasty, revision TKA, a zero failure rate of TKA, older-design TKAs with high failure rates and duplicate records within the same functional centre.



**Fig. 1** Flow chart of the study selection and inclusion process

## Data extraction

For each eligible study, two of the authors independently extracted all relevant data. Disagreement was resolved by discussion with a third investigator. The following variables were abstracted: authors, year of publication, country, study design, sample size, patient gender, mean age, TKA system, measurement method of alignment, evaluating time of implant failure or mean duration of follow-up, and failure rates in all groups (neutral, varus and valgus alignments). When data were incomplete or unclear, attempts were made to contact the investigators for clarification. Regarding the cause of knee replacement failure, only mechanical failure was included, such as aseptic loosening, radiographic wear and patellar complications [5, 21]. Neutral alignment was within  $0^\circ \pm 3^\circ$  in reference to mechanical axis or  $2.4^\circ$ – $7.2^\circ$  of valgus in anatomical femoral–tibial angle. Several studies describing slightly different criteria for neutral alignments, such as  $3^\circ$ – $7.5^\circ$  of valgus in femoral–tibial angle, were also included.

## Quality criteria

The quality assessment of included studies was based on the Newcastle–Ottawa scale (NOS) [28]. Using the tool, each study was judged on eight items, categorized into three groups: the selection of the study groups; the comparability of the groups; and the ascertainment of either the exposure or outcome of interest for case–control or cohort studies, respectively. Stars awarded for each quality item serve as a quick visual assessment. Stars are awarded as such that the highest quality studies are awarded up to nine stars.

## Analysis of data

This meta-analysis was undertaken using RevMan 5.0 (Cochrane Collaboration, Oxford, UK). We assessed the statistical heterogeneity using a standard Chi-square test (statistical heterogeneity was considered to be present at  $P < 0.1$  and  $I^2$  values  $>50\%$ ). Pooled data were meta-analysed using a fixation effects model as no heterogeneity exhibited comparing these trials. Adjusted risk ratio (RR) and 95 % CIs were calculated for generic inverse variance outcomes. Where an adjusted RR of  $<1$  favoured malalignment, an adjusted RR of 1 suggested no difference between neutral alignment and malalignment, and an adjusted RR  $>1$  favoured neutral alignment. For the publication with zero events in one group, each cell in the contingency table was inflated by adding 0.5.

## Results

There were 1512 potentially relevant papers. By screening titles and reading the abstracts and entire articles, ten studies with 12,278 knees were included in the final meta-analysis (Fig. 1). All of these trials were published in English. The sample sizes ranged from 168 to 6070 knees. There were eight case–control studies [5, 8, 15, 16, 18, 20, 21, 26] and two cohort trials [12, 13]. Fixed-bearing prostheses for TKAs were used in seven studies, and rotating-platform prostheses were used in three studies. There were four studies with a mean follow-up of more than 10 years. Long-leg weight-bearing radiographs were used for alignment measurement in seven studies and anteroposterior knee radiographs in three studies. Table 1 summarizes the key characteristics of the included trials. The methodology quality of the ten included studies is presented in Table 2.

The pooled results indicated that the failure rate of implant was higher in knees with post-operative malalignment compared with neutral alignment (95 % CI 1.00–1.88,  $P = 0.05$ , Fig. 2). Failure rate in knees with post-operative varus alignment, reported in five studies, was higher compared with neutral alignment (95 % CI 1.07–2.55,  $P = 0.02$ , Fig. 3). Comparison of failure rate between knees with valgus and neutral alignment was conducted in four studies with no significant difference (n.s., Fig. 4). Subgroup analysis was conducted according to the fixation type of prosthesis in TKA. No significant difference of failure rate was noted between neutral alignment and malalignment for fixed-bearing prostheses (n.s., Fig. 5) or rotating-platform prostheses (n.s., Fig. 5). Four studies with a mean follow-up of more than 10 years showed no significant difference of failure rate between knees with neutral alignment and malalignment (n.s., Fig. 6). Seven studies using long-leg weight-bearing radiographs showed no significant difference of failure rate between knees with neutral alignment and malalignment (n.s., Fig. 7). Three studies using anteroposterior knee radiographs showed neutral alignment taking advantage over malalignment (95 % CI 1.03–2.80,  $P = 0.04$ , Fig. 7).

## Discussion

The most important findings of the present study were the post-operative varus alignment (beyond  $3^\circ$ ) indeed, as hypothesized, showing a higher failure rate of knee implants than the neutral alignment in patients undergone primary TKA. However, it was unexpected that no sufficient evidence proved the difference of failure rate between knees with neutral alignment and valgus alignment.

**Table 1** Characteristics of the included studies

References	Country	Level of evidence	Included knees	Age (years)	Gender	Prosthesis of TKA (corpo-radio-ration)	Long-leg graphs	Evaluate time/follow-up	Implant failure rate		
									Neutral	Varus	Valgus
Ritter [26]	USA	III	351 TKAs	NA	Female 257 Male 0	Posterior Cruciate Condylar TKA System	No	2 months–13 years	3/234	5/35	0/82
Morgan [20]	UK	III	197 TKAs	64.9 ± 8.9	Female 109 Male 44	PCR TKA System	Yes	9 ± 2.2 years	3/73	2/66	1/58
Fang [8]	USA	III	6070 TKAs	70.1 ± 8.6	Female 2436 Male 1556	PCR, Anatomically Graduated Components System (Biomet)	No	6.6 ± 3.5 years	21/4236	18/1015	12/819
Parratte [21]	USA	III	398 TKAs	70 ± 8.5	Female 138 Male 142	Kinematic Condylar II (Howmedica) Press-Fit Condylar (DePuy) Genesis (Smith & Nephew)	Yes	15 years	27/292	8/106	8/106
Bonner [5]	England	III	270 TKAs	70 (41–88)	Female 261 Male 197	Cemented/Cementless Press-Fit Condylar PCR system (Johnson & Johnson)	Yes	10 years	11/227	6/43	6/43
Lee [15]	Korea	III	168 TKAs	66 (40–88)	Female 156 Male 12	NexGen Legacy Posterior Stabilized prosthesis (Zimmer)	Only pre-operative	7 years	1/143	1/25	1/25
Magnussen [18]	France	III	533 TKAs	72.2 ± 7.5 72.8 ± 6.3	Female 351 Male 166	Cemented HLS2 prostheses (Tornier)	Yes	4.7 years (2–19.8 years)	7/352	1/181	NA
Kim [13]	Korea	I	1040 TKAs	68(49–88)	Female 452 Male 68	PCR Rotation-platform (Sigma/DePuy)	Yes	10.8 years	9/916	1/124	1/124
Kim [12]	Korea	II	3048 TKAs	61.2 ± 9.6	Female 1584 Male 112	Rotation-platform LCS system (DePuy)	Yes	15.8 years (11–18 years)	11/1928	15/664	4/456

**Table 1** continued

References	Country	Level of evidence	Included knees	Age (years)	Gender	Prosthesis of Long-leg TKA (corpo-radiographs)		Evaluate time/follow-up	Implant failure rate		
									Neutral	Varus	Valgus
Lee [16]	Korea	III	203 TKAs	65.9 ± 3.4	Female 166 Male 6	Rotating-platform LCS posterior stabilized system	Yes	6 years	4/145	2/58	2/58

TKA total knee arthroplasty, LCS low contact stress, LPS legacy posterior stabilized, PCR posterior cruciate retaining, NA not available

**Table 2** Quality assessment of included studies basing on the Newcastle–Ottawa scale

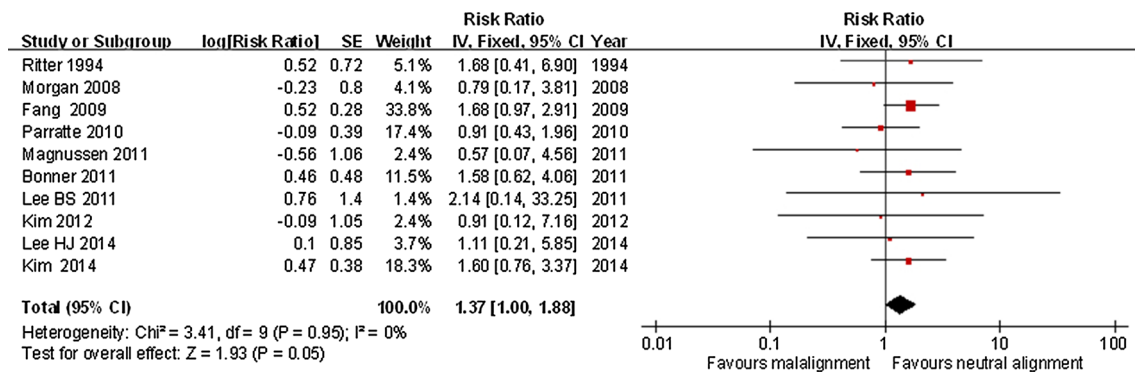
Studt ID	Selection				Comparability		Exposure			Total	
	S1	S2	S3	S4	C1	C2	E1a	E1b	E2		E3
<i>Case-control studies</i>											
Ritter [26]	*	*	*	*	–	–	*	–	*	–	6
Morgan [20]	*	*	*	*	–	–	*	–	*	–	6
Fang [8]	*	*	*	*	–	–	*	–	*	–	6
Parratte [21]	*	*	*	*	*	–	*	–	*	*	8
Bonner [5]	*	*	*	*	–	–	*	–	*	–	6
Lee [15]	*	*	*	*	–	–	*	–	*	–	6
Magnussen [18]	*	*	*	*	*	–	*	–	*	–	7
Lee [16]	*	*	*	*	*	*	*	–	*	*	9
<i>Cohort studies</i>											
Kim [12]	*	*	*	*	*	*	*	–	*	*	9
Kim [13]	*	*	*	*	–	–	*	*	*	*	8

Newcastle–Ottawa scale for case–control/cohort studies. S1: adequate definition of cases/representativeness of exposed cohort, S2: consecutive representative cases/selection of the non-exposed cohort, S3: adequate community controls/ascertainment of exposure, S4: adequate definition of controls/outcome of interest was not present at start of study. C1: matching for the most important factor, C2: matching for additional factor, E1: ascertainment of exposure (a) secure record, (b) structured interview where blind/assessment of outcome (a) independent blind assessment (b) record linkage. E2: same method of ascertainment for cases and controls/follow-up long enough for outcomes to occur, E3: non-response rate/adequacy of follow-up of cohorts

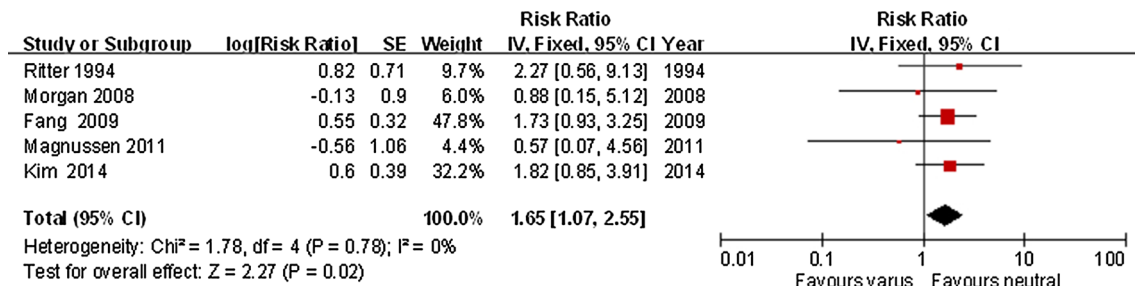
Most surgeons have accepted the premise that the deviation beyond 3° of varus mechanical axis is associated with worse implant survival following total knee arthroplasty [4, 8, 9, 12, 23–26]. This is consistent with the results of current meta-analysis. Clinical evidences show that varus alignment is associated with a significant loss of polyethylene thickness in the medial compartment of the tibial component, which also leads to higher failure rates and poorer outcomes [4, 5, 15]. Moreover, a mechanical axis beyond 3° of varus in the coronal plane remains a less satisfactory target in TKA surgery if the biomechanical evidence,

retrieval evidence, computer predictions and clinical evidence are considered together.

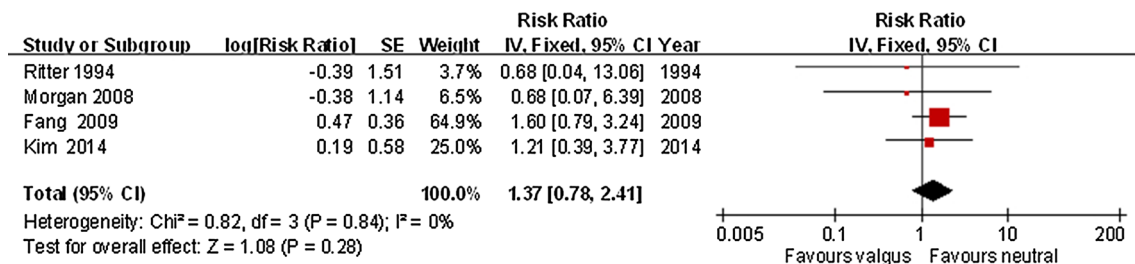
When neutral mechanical alignment is restored, the mechanical axis of the leg passes through the centre of the knee, which leads to an even mediolateral load distribution and a minimized risk of implant wear and component loosening [31]. Malalignment of the lower limb could affect load distribution of the medial and lateral regions of the tibial plateau. The load over the medial tibial plateau shares between 70 and 77 % when the limb alignment is left 3° varus [9, 10]. Then, adduction overloads the medial



**Fig. 2** Post-operative neutral alignment versus malalignment for survival of knee implants



**Fig. 3** Post-operative neutral alignment versus varus alignment for survival of knee implants



**Fig. 4** Post-operative neutral alignment versus valgus alignment for survival of knee implants

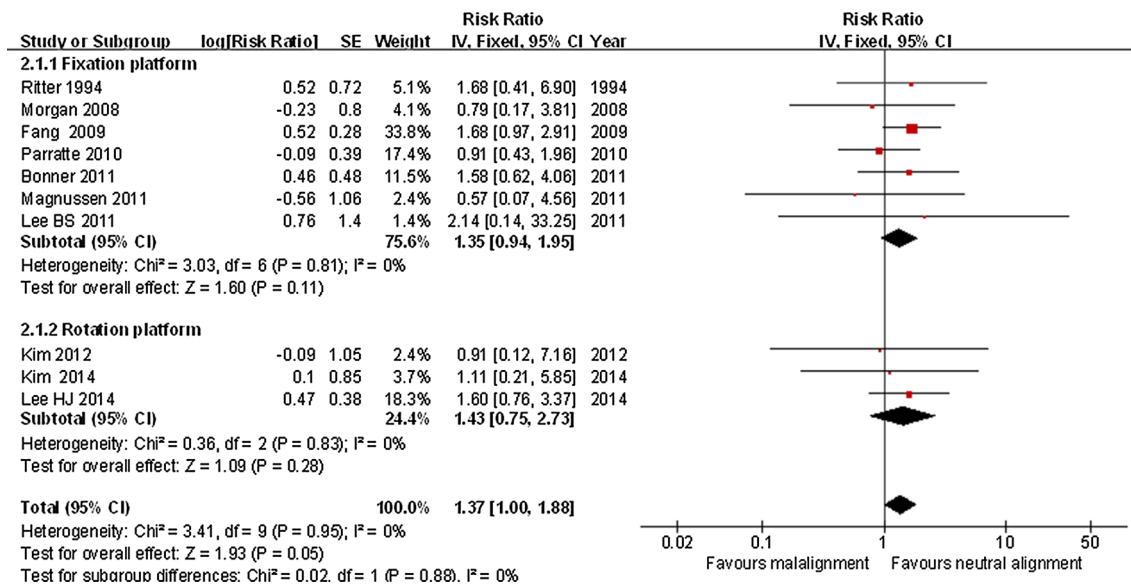
compartment and may cause asymmetrical polyethylene liner wear, tibial component loosening and mechanical failure [11].

Although the neutral mechanical axis is a valuable intra-operative target [1, 13, 16], its achievement does not necessarily confer better implant survival over valgus alignment in current meta-analysis. This could be explained as follows: valgus alignment leads to increased forces passing through the lateral tibial plateau; however, both proximal tibiofibular joint and lateral tibiofemoral joint perform weight-bearing function [6]. Thus, compared with varus alignment, valgus alignment reduces the possibility of tibial collapse and polyethylene thickness loss. Although no statistical difference of failure rate of TKAs is noted between

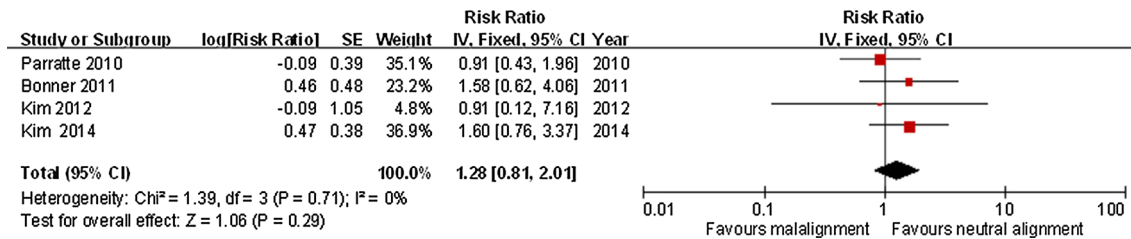
valgus and neutrally aligned knees, the trend is towards fewer revisions in neutral alignment. As few studies report the relative failure rate for TKAs aligned in valgus, it remains for future investigations to determine whether neutral alignment takes advantage over valgus alignment in improving the long-term survival of TKAs.

A number of patients with so-called constitutional varus knees have had varus alignment since they reached skeletal maturity. Some surgeons suggested that correction towards their original constitutional status could be a more physiological option [3, 30] and residual varus alignment did not compromise results of TKAs but improved functional scores in patients with pre-operative varus (more than  $10^\circ$ ) [10, 18], while this concept was confirmed in another study,

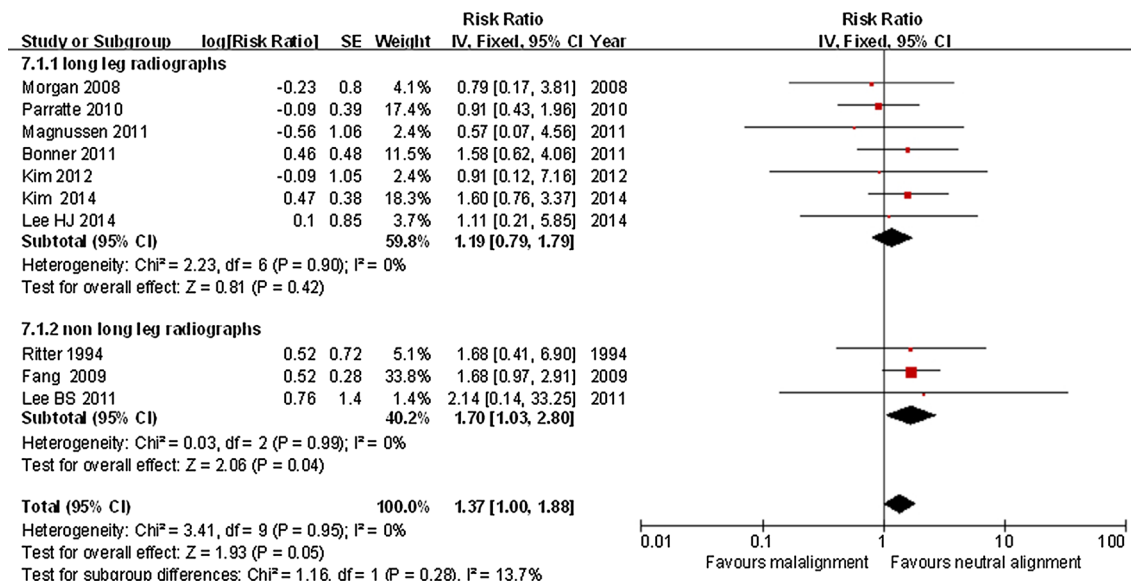




**Fig. 5** Postoperative neutral alignment versus malalignment for survival of knee implants with two different types of protheses



**Fig. 6** Post-operative neutral alignment versus malalignment for more than 10-year survival of knee implants



**Fig. 7** Post-operative neutral alignment versus malalignment for survival of knee implants with two methods measuring the leg alignment

which noted that patients with pre-operative varus had better clinical and functional outcome scores if the alignment was left in mild varus, compared to patients with an alignment correction to neutral [29]. Thus, restoration of constitutional alignment within the “safe zone” of  $0^\circ \pm 3^\circ$  during TKA could lead to more physiological peri-articular soft tissue strains and good function. However, excessive varus alignment ( $>3^\circ$ ) might increase the risk of early failure and should not be a target of post-operative alignment.

Kinematically aligned TKA has gained interest because of its good function and contact kinematics [11]. The goal of kinematically aligned TKA is to position the femoral and tibial components so that the angles and levels of the distal and posterior femoral joint lines and the tibial joint line are each restored to the patient’s natural alignment and not to a neutral limb alignment. The kinematically aligned knee provided neutral limb alignment with mean  $0.3^\circ$  for hip–knee–ankle angle and oblique joint line with mean  $1.4^\circ$  valgus for the femoral component and mean  $2.4^\circ$  varus for the tibial component [7]. In addition, biomechanical study suggested that varus alignment showed a significant posterior displacement of the medial femoral condyle and anterior displacement of the lateral femoral condyle as compared to the normal alignment [9]. Assuming that the principle of aligning the limb on the mechanical axis is important for longevity of the prosthesis, then kinematic alignment method should have similar durability compared with mechanical alignment. However, previously published alignment data for these patients showed that kinematic alignment did not preclude lower limb malalignment [11]. Moreover, excessive oblique tibial joint line angle ( $>3^\circ$ ) might increase shear stress on the medial proximal tibia, which might place the TKA at a high risk of early failure [14].

The current meta-analysis has several limitations. Firstly, like most studies of alignment after TKA, the present study focused on the static, coronal plane alignment and did not specifically evaluate either sagittal plane or rotational alignment or the dynamic impact of gait on alignment. Secondly, one study [26] did not state the reasons for implant failure. Apart from aseptic mechanical failure, if other reasons, such as fracture and infection, were presented, which could possibly bias the results. Thirdly, as no consensus whether the anatomical or mechanical axis was used to describe overall coronal alignment, both  $2.4^\circ$ – $7.2^\circ$  of valgus in anatomical tibiofemoral angle and mechanical axis within  $0^\circ \pm 3^\circ$  were considered to be neutral alignment that could possibly bias the results. Since each subgroup analysis shows no significant difference of failure rate between neutral alignment and malalignment (fixed-bearing prosthesis, rotating-platform prosthesis, follow-up of more than 10 years, long-leg weight-bearing radiographs

for alignment measurement), further researches on these matter are necessary to support the conclusion.

The post-operative alignment of the knee is still the most important factor affecting the survival rate of knee implants. These findings contribute to gaining a proper understanding that more than  $3^\circ$  post-operative varus alignment should be avoided in both mechanically and kinematically aligned TKAs, including patients with pre-operative severe varus deformity or constitutional varus. It might be useful for orthopaedic surgeons in achieving long-term survival of TKAs and patient satisfaction.

## Conclusion

More than  $3^\circ$  post-operative varus alignment results in shorter survival rate after TKA compared with neutral alignment. Both neutral limb alignment and valgus alignment promote implant durability.

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