Does Imageless Computer-assisted TKA Lead to Improved Rotational Alignment or Fewer Outliers? A Systematic Review

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Abstract

Background Computer-assisted surgery (CAS) has been developed to enhance prosthetic alignment during primary TKAs. Imageless CAS improves coronal and sagittal alignment compared with conventional TKA. However, the effect of imageless CAS on rotational alignment remains unclear. **Questions/purposes** We conducted a systematic and qualitative review of the current literature regarding the effectiveness of imageless CAS during TKA on (1) rotational alignment of the femoral and tibial components and tibiofemoral mismatch in terms of deviation from neutral rotation, and (2) the number of femoral and tibial rotational outliers.

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Methods Data sources included PubMed, MEDLINE, and EMBASE. Study selection, data extraction, and methodologic quality assessment were conducted independently by two reviewers. Standardized mean difference with 95% CI was calculated for continuous variables (rotational alignment of the femoral or tibial component and tibiofemoral mismatch). To compare the number of outliers for femoral and tibial component rotation, the odds ratio and 95% CI were calculated. The literature search produced 657 potentially relevant studies, 17 of which met the inclusion criteria. One study was considered as having high methodologic quality, 15 studies had medium, and one study had low quality.

Results Conflicting evidence was found for all outcome measures except for tibiofemoral mismatch. Moderate evidence was found that imageless CAS had no influence on postoperative tibiofemoral mismatch. The measurement protocol for measuring tibial rotation varied among the studies and in only one of the studies was the sample size calculation based on one of the outcome measures used in our systematic review.

Conclusions More studies of high methodologic quality and with a sample size calculation based on the outcome measures will be helpful to assess whether an imageless CAS TKA improves femoral and tibial rotational alignment and tibiofemoral mismatch or decreases the number of femoral and tibial rotational outliers. To statistically analyze the results of different studies, the same measurement protocol should be used among the studies.

Introduction

The main reason for revision TKA is aseptic loosening, which in two studies caused 30% and 42% of all revisions, respectively [1, 45]. Malpositioning of a knee prosthesis

leads to worse functional outcome and increased wear, which eventually may lead to revision [2, 39], and malalignment in some planes has been shown to result in an increased risk of aseptic loosening. Specifically, malalignment in the coronal and sagittal planes results in an increased risk of aseptic loosening, pain, and instability [16, 25, 30, 40], and rotational malalignment has a negative effect on patellar tracking, stability, pain, and joint biomechanics [3, 15, 24, 33, 36]. Good alignment correlates with better functional outcome, as measured by The Knee Society Score[®] and Short Form-12, and faster rehabilitation after TKA [13, 29]. Owing to the importance of correct alignment, computer-assisted surgery (CAS) was developed. There are two different CAS techniques: image-based and imageless computer navigation. When using image-based navigation, preoperative CT, MRI, or intraoperative fluoroscopy is used for the software to generate a lower-limb model. With imageless CAS, the lower-limb model is made based on anatomic landmarks that are marked preoperatively. With a CAS TKA, imageless navigation is used mostly in daily practice. The use of imageless CAS has been shown to improve coronal and sagittal alignment compared with conventional TKA [5, 6, 12, 23, 43, 47]. Whether the use of imageless CAS also improves clinical or functional outcome or survivorship is unknown, since studies regarding this are scarce and have short followups [18, 19, 26].

However, the influence of imageless CAS on rotational alignment is unclear. To date, three reviews have taken the influence of rotational component orientation into account [7, 11, 20]. Burnett and Barrack [7] performed a narrative review and found limited evidence of improvement of rotational alignment. They concluded that strong statistical heterogeneity existed among the studies. A systematic review by Cheng et al. [11] showed no decrease in the number of rotational alignment outliers of the femoral or tibial component after imageless CAS TKA. In another systematic review, Hetaimish et al. [20] also found no decrease in the number of femoral rotational outliers after imageless CAS TKA. However, these conclusions should be interpreted with caution. First, the number of included studies in both systematic reviews was low: only six [11] and four [20] studies were included. Second, only randomized controlled trials (RCTs), quasi-RCTs, and prospective comparative studies were included. Including studies other than RCTs may provide important additional information [42]. Third, neither systematic review [11, 20] took into account the methodologic quality of the studies. Finally, Hetaimish et al. [20] and Cheng et al. [11] covered published evidence until November 30, 2009, and August 30, 2010, respectively. Since August 30, 2010, six studies comparing alignment after imageless CAS TKA versus conventional TKA have been published [5, 22, 32, 41, 47, 48].

The aim of our study was to conduct a systematic and qualitative review of the current literature on the effectiveness of imageless CAS during TKA on (1) rotational alignment of the femoral and tibial components and tibiofemoral mismatch in terms of deviation from neutral rotation, and (2) the number of femoral and tibial rotational outliers.

Search Strategy and Criteria

This systematic review was conducted according to the guidelines presented in the PRISMA Statement [34]. An electronic literature search was conducted in PubMed, MEDLINE, and EMBASE for all studies published between 1991 and April 2, 2013. The search strategy consisted of the following components plus related MESH and free field terms for each: “knee arthroplasty”, “computer assisted surgery”, “conventional”, and “rotation”. The search strategy was formulated and performed by an experienced medical librarian (TvI). To find more studies, the reference lists of all relevant studies were reviewed for potential articles.

We decided to include only imageless CAS and to exclude image-based CAS because imageless navigation systems are most commonly used in TKA. A study was included if (1) rotational alignment after imageless CAS TKA was compared with rotational alignment after conventional TKA; (2) the study design contained an intervention group and a control group, for example RCTs, cohort studies with a historical cohort as a control group, or cadaveric studies with a control group; (3) the study subjects were 18 years or older; (4) the study and control groups were similar at baseline; (5) the study was published in English, Dutch, French, German, or Spanish; and, (6) at least one of the following outcome measures was assessed: rotational alignment of the femoral or tibial component, tibiofemoral mismatch, or number of rotational outliers of the femoral or tibial component. Rotation of the femoral component had to be measured relative to the epicondylar axis. Studies were excluded when rotational alignment was assessed using plain radiographs and when rotation of the femoral component was not determined according to the epicondylar axis [4, 21]. A femoral rotational outlier was defined as greater than 3° deviation from the neutral position. As no gold standard exists for measuring tibial component rotation, we did not exclude studies regarding the tibial measurement protocol. A tibial rotational outlier was defined as greater than 3° deviation from the neutral position as determined in the measurement protocol used in the study. Tibiofemoral mismatch is the angle between the posterior condylar line of the femoral component and the AP line of the tibial component.

Fig. 1 The flow chart shows the inclusion procedure. RCT = randomized controlled trial; CCT = controlled clinical trial.

The procedure for inclusion of studies was performed in two stages according to the recommendations of van Tulder et al. [46]. Two reviewers (MFM, IHFR) independently selected the studies based on title, abstract, and full text. Disagreement was resolved by consensus, and if agreement was not achieved, a third reviewer was consulted (MS). The same two reviewers also extracted the data from the included studies independently. After conducting the electronic search and removing double citations, 657 potentially relevant studies remained (Fig. 1). After the selection procedure, 17 studies were included (Appendix 1. Supplemental material is available with the online version of CORR).

The two reviewers independently assessed methodologic quality of the included studies according to criteria

described by van Tulder et al. [46]. Their 11 criteria relate to selection, performance, attrition, and detection bias. Adjustments had to be made to use their criteria for assessing methodologic quality in our systematic review. The requirement of blinding the patients or care providers was excluded because this is not possible in these types of studies. Blinding the orthopaedic surgeon is not possible because he or she performs the surgery. Blinding the patient is not possible because an extra incision at the distal tibia has to be made to place the navigation trackers when CAS is used during TKA. Patients who underwent conventional TKA do not have this extra incision. The requirement of acceptable compliance to the intervention also was excluded because this is not applicable in this type

of intervention. Eight questions thus remained to be answered regarding methodologic quality of the studies. We added one more question: “Was a sample size calculation performed based on one of the three outcomes?” Insufficient power of a study has a low probability of detecting a statistically significant difference. All criteria were answered with “yes,” “no,” or “unclear.” A study was considered of high methodologic quality when at least six criteria were answered with “yes”, a score of 3 to 5 was considered medium quality, and a score less than 3 was considered low quality. Methodologic quality of most studies was found to be medium. One study was considered high methodologic quality, 15 studies were medium quality, and one was low quality. The sample size calculation in only one of the included studies was based on one of the outcome measures used in this systematic review (Table 1) [38, 46].

Analysis of the extracted data was conducted according to the guidelines for systematic reviews provided by the Cochrane Collaboration Group [46] using Review Manager 5 (Version 5.1; The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark). The standardized mean difference (SMD) with a 95% CI was calculated when possible for continuous variables (femoral and tibial component rotation and tibiofemoral mismatch). The SMDs

were interpreted according to Cohen [14]: an SMD of 0.2 to 0.4 was considered a small effect, 0.5 to 0.7 moderate, and 0.8 or greater was considered a large effect. To compare the number of outliers for femoral and tibial component rotation, the odds ratio (OR) and 95% CI were calculated. Angles with a deviation greater than 3° internal or external rotation from the neutral rotational angle were considered outliers [3]. The OR represents the odds of outliers occurring in the CAS group compared with the conventional group with an OR less than 1 favoring the CAS group. The OR is considered statistically significant when the 95% CI does not include the value of 1.

Authors of articles were contacted to retrieve data of means and SDs to compute effect sizes or ORs where these data were not reported. Five authors sent additional data. The results were summarized by means of a qualitative analysis using a rating system that consists of five levels of scientific evidence taking into account the methodologic quality and outcome of the original studies (best evidence synthesis according to van Tulder et al. [46]). Scientific evidence was considered strong when there were consistent findings among multiple high-quality trials. Evidence was considered moderate when consistent findings were found in multiple low-quality trials and/or one high-quality trial. Evidence was considered limited when there were consistent

Table 1. Results of the methodologic quality assessment*†

Study	Fulfilled validity criteria				Unfulfilled validity criteria	Incomplete information for validity assessment	Internal validity score	Methodologic quality	Power analysis
	Selection bias (1, 2, 3)	Performance bias (5)	Attrition bias (6, 8)	Detection bias (4, 7)					
Schmitt et al. [41]	1, 2, 3	—	8	4, 7	6	5	6	High	Unclear
Matos et al. [32]	1, 3	—	6, 8	7	—	2, 4, 5	5	Medium	Unclear
Chauhan et al. [10]	1, 2, 3	—	8	7	—	4, 5, 6	5	Medium	Unclear
Kim et al. [28]	1, 3	—	6, 8	4	—	2, 5, 7	5	Medium	Unclear
Lutzner et al. [31]	1, 3	—	6, 8	7	—	2, 4, 5	5	Medium	Yes
Mombert et al. [35]	1, 3	—	6, 8	7	—	2, 4, 5	5	Medium	Unclear
Blakeney et al. [5]	1, 3	—	—	4, 7	—	2, 5, 6, 8	4	Medium	No
Chauhan et al. [9]	3	—	6, 8	7	—	1, 2, 4, 5	4	Medium	Unclear
Han et al. [17]	1, 3	—	6, 8	—	—	2, 4, 5, 7	4	Medium	Unclear
Matziolis et al. [33]	1, 3	—	6, 8	—	—	2, 4, 5, 7	4	Medium	Unclear
Zhang et al. [47]	3	—	6, 8	4	—	1, 2, 5, 7	4	Medium	Unclear
Carter et al. [8]	3	—	6	4	1, 2, 7	5, 8	3	Medium	Unclear
Choong et al. [13]	1, 3	—	—	7	8	2, 4, 5, 6	3	Medium	No
Hiscox et al. [22]	—	—	6	4, 7	—	1, 2, 3, 5, 8	3	Medium	Unclear
Kim et al. [27]	3	—	8	4	—	1, 2, 5, 6, 7	3	Medium	Unclear
Zhang et al. [48]	1, 3	—	6	—	8	2, 4, 5, 7	3	Medium	Unclear
Stockl et al. [44]	1, 3	—	—	—	—	2, 4, 5, 6, 7, 8	2	Low	Unclear

* Methodologic quality criteria were described by van Tulder et al. [46]; †Adapted from Reininga IH, Zijlstra W, Wagenmakers R, Boerboom AL, Huijbers BP, Groothoff JW, Bulstra SK, Stevens SM. Minimally invasive and computer-navigated total hip arthroplasty: a qualitative and systematic review of the literature. *BMC Musculoskelet Disord* 2010;11:92.

findings in at least one low-quality trial. Evidence was considered conflicting when the findings among multiple trials (high- and/or low-quality trials) were inconsistent. There was no evidence when findings of the eligible trials did not meet the criteria for one of the levels of evidence as stated above, or when there were no eligible trials available. Consistent findings were defined as 75% or more of the trials showing results in the same direction [46]. We performed a sensitivity analysis to examine what the findings of the review would have been had we chosen different cutoff points to interpret the methodologic quality. For the sensitivity analysis, an internal validity score of 5 or greater was considered high quality, a score of 3 to 4 medium, and a score of 2 or less was considered low methodologic quality.

Results

Conflicting evidence was found among eligible studies for the effect of imageless CAS on femoral and tibial component rotation, and moderate evidence was identified that showed imageless CAS does not improve tibiofemoral mismatch. Thirteen studies reported on postoperative rotation of the femoral component (Table 2). Three medium- and one low-quality study reported a significant decrease in deviation from neutral rotation of the femoral component with use of imageless CAS. Eight medium-quality studies did not find a significant difference. One medium-quality study showed an increase in deviation from neutral rotation of the femoral component (Fig. 2).

Eight studies reported on rotation of the tibial component (Table 2). One medium-quality study reported a significant decrease in deviation from neutral rotation of the tibial component by using imageless CAS. One high-quality study and four medium-quality studies did not find a significant difference. Two medium-quality studies found an increase in deviation (Fig. 3). Four studies reported on tibiofemoral mismatch (Table 2). None of the studies showed a significant difference. A sensitivity analysis using different cutoff points for methodologic quality also showed conflicting evidence regarding femoral and tibial rotation, and moderate evidence that imageless CAS does not improve tibiofemoral mismatch (Fig. 4).

Conflicting evidence was found regarding the effect of imageless CAS on the number of femoral and tibial outliers. The number of femoral rotational outliers was reported in 11 studies (Table 3). Two medium-quality studies found a decrease in the number of outliers, whereas seven studies of medium quality showed no significant difference. Two medium-quality studies found a significant increase in the number of femoral rotational outliers (Fig. 5). The number of tibial rotational outliers was compared in seven studies (Table 3). One study of medium methodologic quality showed a significant decrease. No significant difference between the two groups was found in one high-quality and four medium-quality studies. One medium-quality study reported a significant increase in the number of tibial outliers (Fig. 6). A sensitivity analysis also showed conflicting evidence regarding the effect of imageless CAS on the number of femoral and tibial outliers.

Table 2. Results of postoperative rotational alignment of components

Study	Methodologic quality	Number of patients	Femoral rotation SMD (95% CI) *	Tibial rotation SMD (95% CI)*	Tibiofemoral mismatch SMD (95% CI)*
Schmitt et al. [41]	High	47	NR	0.18 (−0.40 to 0.75)	NR
Kim et al. [28]	Medium	200	−0.47 (−0.75 to −0.19)	0.00 (−0.28 to 0.28)	NR
Lutzner et al. [31]	Medium	80	1.90 (1.37, 2.44)	−1.93 (−2.46 to −1.39)	NR
Mombert et al. [35]	Medium	42	NE (NS)	NR	NR
Blakeney et al. [5]	Medium	66	−0.19 (−0.68 to 0.29)	NR	−0.23 (−0.72 to 0.25)
Han et al. [17]	Medium	120	−0.05 (−0.58 to 0.48)	NR	NR
Matziolis et al. [33]	Medium	60	0.11 (−0.40 to 0.62)	−0.11 (−0.62 to 0.40)	NR
Zhang et al. [47]	Medium	64	0.19 (−0.30 to 0.68)	NR	NR
Carter et al. [8]	Medium	200	0.17 (−0.10 to 0.45)	0.47 (0.19–0.75)	NR
Choong et al. [13]	Medium	104	NE (NS)	NR	NR
Hiscox et al. [22]	Medium	32	0.62 (−0.09 to 1.33)	0.21 (−0.49 to 0.90)	−0.38 (−1.08 to 0.32)
Kim et al. [27]	Medium	320	−0.32 (−0.54 to −0.10)	0.41 (0.18–0.63)	NR
Zhang et al. [48]	Medium	81	−0.64 (−1.09 to −0.19)	−0.16 (−0.59 to 0.28)	−0.49 (−0.93 to −0.04)
Stockl et al. [44]	Low	64	NE (S, decrease)	NR	NE (NS)

* Negative SMD with 95% CI indicates a decrease in deviation of neutral rotation in favor of intervention group; SMD = standardized mean difference; NE = SMD not estimable; S = significant; NS = not significant; NR = not reported.

Fig. 2 The forest plot compares imageless CAS TKA with conventional TKA in terms of femoral rotation. CAS = computer-assisted surgery; Std = Standardized; IV = Inverse Variance; df = degrees of freedom.

Fig. 3 A comparison of tibial rotation for imageless CAS TKA and conventional TKA is shown. CAS = computer-assisted surgery; Std = Standardized; IV = Inverse Variance; df = degrees of freedom.

Fig. 4 Imageless CAS TKA was compared with conventional TKA for tibiofemoral mismatch. CAS = computer-assisted surgery; Std = Standardized; IV = Inverse Variance; df = degrees of freedom.

Discussion

The use of imageless CAS during TKA has been shown to improve coronal and sagittal knee prosthetic alignment [5, 12, 23, 43, 47]. However, whether imageless computer navigation influences rotational alignment was unclear. Our aim therefore was to review the literature and evaluate

the effectiveness of imageless CAS during TKA on rotational alignment of the femoral and tibial components and tibiofemoral mismatch and the number of femoral and tibial rotational outliers. The results of this systematic review showed no evidence that a TKA with imageless CAS leads to better rotational alignment of the femoral or tibial component or tibiofemoral mismatch. Furthermore,

Table 3. Rotational outliers

Study	Methodologic quality	Number of outliers femur			Number of outliers tibia		
		Study group	Control group	OR (95% CI)*	Study group	Control group	OR (95% CI)*
Schmitt et al. [41]	High	NR	NR	NR	12/22	17/25	0.56 (0.17–1.85)
Matos et al. [32]	Medium	13/21	4/21	6.91 (1.70–28.03)	NR	NR	NR
Chauhan et al. [10]	Medium	3/35	11/40	0.25 (0.06–0.97)	14/35	13/36	1.18 (0.45–3.08)
Kim et al. [28]	Medium	29/100	15/100	2.31 (1.15–4.65)	54/100	49/100	1.22 (0.70–2.13)
Lützner et al. [31]	Medium	6/40	2/40	3.35 (0.63–17.74)	27/40	26/40	1.12 (0.44–2.83)
Blakeney et al. [5]	Medium	8/34	11/32	0.59 (0.20–1.72)	NR	NR	NR
Chauhan et al. [9]	Medium	0/6	3/6	0.08 (0.00–1.96)	NR	NR	NR
Han et al. [17]	Medium	5/27	6/28	0.83 (0.22–3.14)	NR	NR	NR
Matziolis et al. [33]	Medium	1/32	3/28	0.27 (0.03–2.75)	NR	NR	NR
Carter et al. [8]	Medium	15/100	11/100	1.43 (0.62–3.28)	76/100	55/100	2.59 (1.42–4.74)
Kim et al. [27]	Medium	19/160	21/160	0.89 (0.46–1.73)	34/160	38/160	0.87 (0.51–1.47)
Zhang et al. [48]	Medium	5/40	13/41	0.31 (0.10–0.97)	6/40	15/41	0.31 (0.10–0.90)

* An OR less than 1 with 95% CI indicates lower odds outliers in favor of the intervention group; OR = odds ratio; NR = not reported.

Fig. 5 A comparison of femoral rotational outliers for CAS TKA and conventional TKA is shown in this forest plot. CAS = computer-assisted surgery; M-H = Mantel-Haenszel; df = degrees of freedom.

no evidence was found that imageless CAS results in a decrease of the number of outliers in terms of femoral or tibial component orientation.

Our study has some limitations. First, only studies published in English, Dutch, German, French, or Spanish were included. This may have led to selection bias. However, we excluded only two studies based on language. Therefore we expect that this selection procedure had minimal influence on selection bias. Second, only studies using imageless navigation were included. There are two different techniques in CAS: image-based and imageless computer navigation. With a CAS TKA, imageless navigation is used mostly in daily practice. Therefore, we

included only studies in which an imageless navigation system was used.

In addition to coronal and sagittal prosthetic alignment, only one narrative review by Burnett and Barrack [7] took into account femoral and tibial rotational alignment. They concluded that use of imageless CAS during TKA did not improve femoral or tibial rotational alignment. However, methodologic quality of the studies considered and they did not perform a statistical analysis. Moreover, the number of included studies was low (nine studies). Our systematic review confirms that TKA with imageless CAS does not improve femoral or tibial rotational alignment. To our knowledge, our review is the first to analyze the effect of

Fig. 6 A comparison of imageless CAS TKA and conventional TKA for the number of tibial rotational outliers is shown. CAS = computer-assisted surgery; M-H = Mantel-Haenszel; df = degrees of freedom.

imageless CAS on postoperative tibiofemoral mismatch and we did not find an improvement for this outcome either. We assessed whether the sample size calculation of the included studies was based on one of the outcome measures used in this review. This was the case for only one study reporting femoral and tibial rotational alignment [31]. It is possible that the included studies failed to have sufficient power to assess significant differences in these outcome measures. No gold standard exists for determining rotational alignment of the tibial component. Five different measurement protocols were used in the included studies. The protocol of Berger et al. [3] (center of proximal tibial plateau relative to the tip of the tubercle) was used in three studies [8, 22, 48], that of Matziolis et al. [33] (tibial fins relative to the line between the medial third of the tubercle and the geometric center of gravity of the tibia) in three studies [27, 31, 33], and the Perth protocol (posterior tibial condyles relative to the tuberosity) [9] in one study [10]. Tibial component rotation relative to the ankle was used in one study [41], and tibial component rotation relative to the posterior border of the proximal tibia also was used in one study [28]. These protocols use different anatomic landmarks to assess rotational tibial alignment; therefore, results of the influence of imageless CAS in tibial rotational alignment should be interpreted with caution because no gold standard for this measurement exists. In clinical practice, rotational alignment of the femoral component generally is measured relative to the epicondylar axis [4]; therefore, three studies in which this was not the case were excluded.

One narrative review [7] and two systematic reviews [11, 20] evaluated the effect of TKA with imageless CAS on the number of postoperative femoral and tibial rotational outliers. The conclusion of these reviews was that TKA using imageless CAS did not decrease the number of tibial and femoral rotational outliers [11, 20]. The number of studies

included in the three reviews was low, methodologic quality was not taken into account, and strong heterogeneity existed. Our systematic review confirms the results of the previous reviews that TKA with imageless CAS does not decrease the number of femoral or tibial rotational outliers. The sample size calculation was based on one of the outcome measures in only one study, thus the included studies in our review may be underpowered. To include as many studies as possible, we used a broad search strategy. In contrast to previous systematic reviews [11, 20], clinical controlled trials and cadaveric studies also were included. As a result, we included 17 studies in total, whereas a maximum of six studies was included in previous systematic reviews [11, 20]. Including studies other than RCTs or Level I studies may provide important information or can be of high reporting quality [37, 42]. Because no gold standard exists for measuring tibial rotation, five different measurement protocols were used in the included studies. Therefore, results of the influence of imageless CAS in tibial rotational alignment should be interpreted with caution. Three studies in which femoral rotation was not measured relative to the epicondylar axis were excluded.

Results of our review show no evidence that TKA with imageless CAS leads to better rotational alignment of the femoral or tibial component or tibiofemoral mismatch. No evidence was found that imageless CAS results in a decrease in the number of outliers for femoral or tibial component orientation. To our knowledge, this is the first review to systematically analyze the influence of imageless CAS on postoperative deviation of prosthetic components from the neutral rotational axis. Previous reviews did not take into account the methodologic quality or sample size calculation of the included studies. In addition, to our knowledge, the effect on tibiofemoral mismatch has not been described before. Even so, these conclusions should be interpreted with caution. The number of included studies

was low, only one of the 17 included studies was considered of high methodologic quality, and different methods for assessing tibial component rotation were used in the studies. The sample size calculation was based on one of the outcome measures in only one of the included studies. To gain more insight into the effect of TKA with imageless CAS on rotational alignment, a systematic review should be performed that includes more studies and of high methodologic quality with sample size calculations based on one of the outcome measures. The outcome measures have to be measured using the same measurement protocol.

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