Prognostics of outcome of total knee replacement: on patient selection and intraoperative issues

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Chapter 7

Similar outcome after retention or sacrifice of the posterior cruciate ligament in total knee replacement

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Abstract

Background. To retain or to sacrifice the posterior cruciate ligament (PCL) in total knee replacement (TKR) remains a matter of discussion. This systematic review aims to find differences in functional and clinical outcome between PCL retention and sacrifice.

Methods. A systematic review and meta-analysis was conducted including all RCT's and quasi RCT's comparing PCL retention with PCL sacrifice in TKR with a minimum of 1 year follow-up. Primary outcome was range of motion. Secondary outcomes were knee pain and, preferably validated, clinical scoring systems (PROM's). Quality of evidence was graded using the GRADE-approach. All outcomes available for data-pooling were used for meta-analysis.

Results. Twenty studies (1.877 patients, 2.347 knees) were included. In meta-analysis the postoperative flexion angle had a mean difference of 2.1 degrees (95%-CI 0.23, 3.98 p=0.03) and the KSS functional score was 2.4 points higher (95%-CI 0.41; 4.30 p=0.02) in favor of PCL sacrifice. Analysis showed no further statistical difference with respect to other measured clinical outcomes like, WOMAC, KSS pain, clinical and overall score, HSS score, SF-12, radiolucencies, femoro-tibial angle, and tibial slope. The quality of the studies was highly variable with moderate to high risk of bias.

Interpretation. There are no clinically relevant differences between PCL retention and PCL sacrifice in TKR in terms of functional and clinical outcomes. Quality of the studies ranged from moderate to low. Based on the current evidence no recommendation can be made whether to retain-or to sacrifice the PCL.

Introduction

The debate whether to retain or to sacrifice the posterior cruciate ligament (PCL) during TKR surgery is ongoing. Arguments for PCL retention are maintenance of the natural movements of the knee while maintaining stability from extension to flexion.[1,2] Furthermore, the PCL is supposed to have different types of mechanoreceptors detecting joint position (proprioception) and joint motion (kinesthesia), thus the PCL might yield a better "sense" of the postoperative knee.[3,4] Retention of the PCL leads to the need of adequate balancing of the ligament. Inadequate balancing of the PCL (i.e. when the PCL is either too tight or too loose after placement of the TKR) leads to a deficient knee with pain, deteriorated range of motion and instability.[5,6] On the other hand, sacrificing the PCL could be helpful in balancing knees with deformities or contractures. Another advantage of sacrificing the PCL is preventing paradoxal femoral rollback as demonstrated by PCL retaining implants.[7] Femoro-tibial movement will then be dictated by the degree of congruency between the femur and the tibial insert.[8] Sacrificing the PCL leads to an increase in the flexion gap and to a lesser extent an increase in the extension gap.[2,9] A Cochrane systematic review in 2005 could not indicate what treatment option is best regarding functional, clinical and radiological outcome parameters.[10] An update of this review was published (in Cochrane) in 2013 still showing no relevant differences between both groups.[11]

Since the aforementioned literature search, several new reports of randomized controlled trials (RCT's) have been published that compare PCL retention with PCL sacrifice, necessitating an update of the current evidence. We aimed to find differences in functional, clinical and radiological outcome between PCL retaining and PCL sacrificing TKR within the current literature.

Methods

Literature search and study selection

We used the same study protocol as developed for our Cochrane systematic review and meta-analysis.[10,11] We conducted a sensitive search in order to retrieve all available literature. In consultation with an experienced librarian (JS) of the medical library of the Leiden University Medical Centre we searched the following databases:

Medline (via PubMed), the Cochrane Central Register of Controlled Trials, Embase, Web of Science, CINAHL, Academic Search Premier, Current Contents Connect, and Science Direct. All databases were searched up to May 19th 2014 using an adapted syntax for every single database (Appendix table A). No restrictions or limits were formulated. A final check that no relevant articles were missed was carried out by screening the references from the articles and by performing citation tracking on the articles that were included.

Articles were selected in two steps. In the first step only title and abstract were available. In the second step, articles which passed the first step were retrieved full text and again evaluated against the in-and exclusion criteria. These criteria were:

- The intervention evaluated in the trials had to be primary TKR comparing PCL retention with sacrifice.
- The indication for TKR had to be osteoarthritis.
- Minimal follow-up had to be twelve months.
- Studies had to be RCT's or quasi RCT's. Quasi RCT's are studies using for example date of birth, patient identification numbers or alternating sequences for randomization.

Two reviewers (WV, LB) independently selected the trials to be included in the review. Disagreements were resolved by consensus. When no consensus could be reached, a third reviewer (WJ) was available for the decisive vote.

Data collection

A pre-developed and tested data extraction form was used to extract data from the included studies. Items collected were study design features, population data, statistical analysis techniques, intervention characteristics and all reported outcome parameters, including results. The primary outcome was range of motion (ROM), including flexion and extension angle separately. Secondary outcomes were knee pain (Visual Analogue Scale, Knee Society clinical pain sub-score), validated clinical scoring instruments (such as Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Knee Osteoarthritis Outcome Scale (KOOS), Oxford knee score), other clinical questionnaire-scores (such as the Knee Society Score

(KSS), Hospital for Special Surgery score (HSS), etc.), radiological implant migration (preferably using radiostereometric analysis (RSA)), complication rate, and other radiological outcomes (such as rollback, radiolucencies). All data were entered into Review Manager 5.2 (The Cochrane Collaboration, 2012).

The risk of bias (e.g. selection bias, performance bias, detection bias, attrition bias) was assessed for every study. The risk of selection bias was judged by assessing how the randomization sequence was generated and by assessing how the treatment allocation was concealed. Risk of performance-and detection bias was judged by evaluating the blinding methods of participants, personnel and observers, as described in the studies. Risk of attrition bias was assessed by judging the completeness of the data, including the follow-up rate. The possible judgements that could be made were low risk of bias, high risk of bias and unclear risk of bias.

The quality of the evidence was assessed using the GRADE approach.[12] In this method for grading quality, RCT's are considered as high quality evidence; however this can be downgraded to moderate, low, or very low quality for several reasons. These reasons are study limitations (e.g. high risk of bias), inconsistent results, indirectness of evidence, imprecision or publication bias. The Cochrane collaboration recommends using this approach to grade the quality of studies in systematic reviews.[13]

Analysis

Statistical analyses were conducted using Review Manager 5.2. Continuous data were entered as means and standard deviations, dichotomous outcomes as number of events. Standard deviations were used when available. If not provided, standard deviations were imputed from comparable studies or from original scores (i.e. confidence intervals). In the meta-analysis, if the studies (patients, interventions, outcomes) were regarded to be clinically homogeneous, heterogeneity was first assessed by visual inspection of the forest plots. Furthermore it was investigated with the I^2-statistic and, if significant ($p<0.05$ using the Q statistic), the source of heterogeneity was investigated by doing a sensitivity analysis and considering additional clinical reasons for potential clinical heterogeneity. In the absence of significant heterogeneity, and given sufficient included trials, results were combined

Table 7.1: Characteristics of the studies

Authors	Sample size			TKR type		Mean age		Female (%)		Outcome	Follow-up
	Patients	*Knees*	*OA (%)*	*CR*	*CS*	*CR*	*CS*	*CR*	*CS*		
Aglietti 2005	197	210	100	103	107	71	69.5	86	81	ROM, VAS pain, KSS and radiographic evaluation system, mechanical axis, radiolucencies	Up to 4y
Catani 2004	40	40	100	20	20	70 +/-6.0	71 +/-7.0	65	75	ROM, RSA, KSS, HSS	2y
Chaudhary 2008	100	100		51	49	69.2 +/-9.1	70.2 +/-8.4	53	45	ROM, RAND-36, WOMAC	2y
Clark 2001	128	128	97	59	69	71.8 +/-12.2	71.2 +/-13.6	n/a	n/a	ROM, KSS, SF-12, WOMAC	Up to 3y
de Andrade 2009	85	85	89.4	36	49	66.3 (41-78)		74		KSS (overall)	1.3y
Harato et al. 2008	192	222	100	111	111	68.3	66.0	34	34	KSS, WOMAC, SF-12, radiolucencies, kinematics	5.0-7.3y
Kim 2009	250	500	100	250	250	71.6 +/-6.0		96		ROM, KSS, HSS, WOMAC pain, radiological	2.3y
Maruyama 2004	20	40	100	20	20	74.3 (65-84)		60		ROM, KSS, joint line	Up to 2.6y
Matsumoto 2012	41	41	100	19	22	73.5 +/-1.3	74.4 +/-0.9	100	100	ROM, KSS, laxity	5y
Misra 2012	103	105	92	51	54	66.8	67.2	67	59	ROM, HSS, satisfaction score (1-10), radiological outcomes	4.8y
Roh 2012	86	86	100	42	44	69.8 +/-4.7	71.0 +/-4.9	95	93	ROM, tibiofemoral angle, KSS, HSS, WOMAC	Up to 3.1y

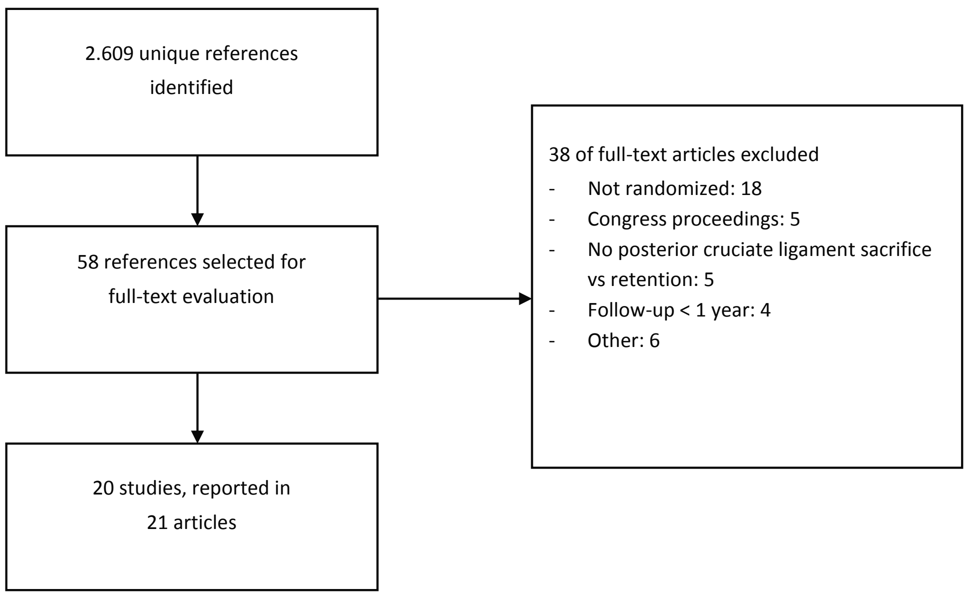
Seon 2011	95	95	100	48	47	68.2 +/-7.0	69.1 +/-6.7	91		ROM, HSS, WOMAC, tibiofemoral angle and kinematics	2y
Shoji 1994	28	56	54	28	28	60.2 (48-85)		71		ROM, HSS	Up to 4.5y
Straw 2003	*167*	*167*		*66*	*101*	*72.6*	72.6 (PS) 74.1 (resection)	*44*	*45*	ROM, KSS, pain score, stability knee	Up to 6.5y
Tanzer 2002	37	40	97	20	20	68.0	66.0	75	80	Flexion angle, KSS	2y
Thomsen 2013	36	72	97	36	36	67.2 (49-84)		58		ROM, knee pain, satisfaction score, ability to perform ADL, SF-36	1y
Wang 2004	185	224	91	128	96	54.5	55.0	80	80	ROM, KSS, tibiofemoral angle, radiolucencies, SF-12 functional score, ligament laxity	Up to 5.5y
Yagishita 2012	29	58	100	29	29	74.3 +/-7.2		86		ROM, KSS, pain score, radiolucencies	5y
Yansheng 2013	38	38	100	19	19	65.9	63.9	68	63	ROM, WOMAC, proprioception	Up to 1.4y
Yoshiya 2005	20	40	100	20	20	73.8 (62-84)		66		ROM, KSS, fluoroscopic motion analysis	Up to 4.4y

CR: (posterior) cruciate retaining, CS: cruciate sacrificing, ROM: range of motion, VAS: visual analogue scale, RSA: radiostereometric analysis, WOMAC: Western Ontario and McMasters Osteoarthritis Index, SF: short form, KSS: Knee Society Score, HSS: Hospital Special Surgery score, ADL: activities of daily living using mean differences for continuous data, and relative risk for dichotomous data. A random effects model was used for all analyses.

Results

A total of 2.609 unique references were identified. A total of 58 articles were selected for further evaluation, resulting in twenty-one full-text papers used for analysis (Figure 7.1, PRISMA flowchart).[14-34]

Figure 7.1: Flow-chart study selection



The article of Victor et al. described a population that is also part of the study population of Harato et al.[19,30] Data from both articles were used only once. The article from de Andrade et al. was written in Portuguese and the article from Yansheng et al. was written in Chinese.[18,33] Data were extracted by professional translators. Characteristics of the studies are presented in table 7.1.

Study characteristics

The twenty studies included 1.877 patients and 2.347 knees. In seventeen studies the comparison between the two arms was PCL retention with a cruciate-retaining design versus PCL-sacrifice using a posterior stabilized design.[14-22,25,28,29,30-34] In three studies the same (cruciate-retaining) TKR design was used for both groups.[23,24,26] One study used all three treatments (i.e. cruciate retaining design with ligament retention and with ligament sacrifice and posterior stabilized design.[27]

All studies used a clinical rating scale, either well-validated (e.g. WOMAC) or less validated (e.g. Knee Society Score or Hospital for Special Surgery score) and reported range of motion or flexion measurements. The report of radiostereometric analyses (RSA) was scarce.

Risk of bias and quality of evidence

Twenty-five percent of the included studies were assessed as having ‘low risk of bias’. Five studies (25%) described how the randomization sequence was generated.[16,19,23,24,29] The method of concealment of allocation was reported in six studies (30%).[16,19,20,22,25,29] Three studies used quasi-randomization; Aglietti et al. based treatment choice on odd/even patient identification numbers, Maruyama et al., used alternating sequences and Wang et al. used hospital admission moment to base treatment on.[14,21,31] Blinding of the outcome assessor was reported in ten studies.[14,16,18,20,22,23,25,27-29] Seon et al. explicitly reported that no blinding was applied.[25]

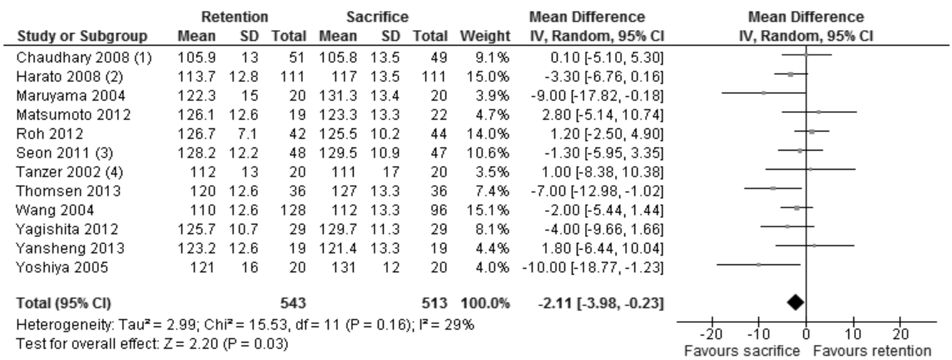
Studies reporting on the primary outcome of knee flexion were graded according to the GRADE approach. These studies were assessed, on average, as being of low quality. Quality was downgraded due to the high amount of studies with unclear risk of bias and the presence of studies rated with high risk of bias. Also studies reporting on the secondary outcomes were graded as being of average to low quality.

Meta-analysis

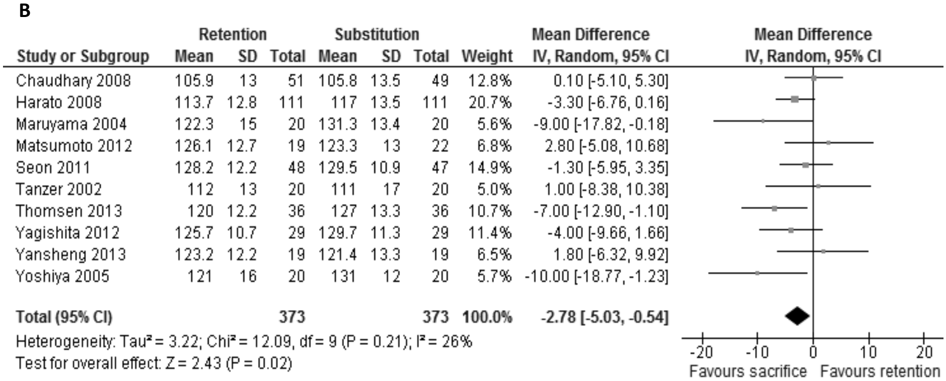
There is low quality of evidence from twelve studies (1.056 knees) that PCL sacrifice results in a better flexion angle, with a mean difference of 2.1 degrees (95%-CI 0.2; 4.0, p=0.03). This is a homogeneous result (I^2 =29%, p=0.16). Furthermore, there is low quality of evidence from nine studies (1.530 knees) that PCL sacrifice results in a higher Knee Society Score functional score of 2.4 points (95%-CI 0.4; 4.3 p=0.02) (Figure 7.2). These are the only homogeneous and statistically significant differences between PCL retention and sacrifice. The WOMAC score was used in five studies; there was a 0.7 points difference between both groups (95%-CI -0.4; 1.8, p=0.19) in favor of PCL sacrifice. See Figure 7.2.

Figure 7.2: Forest plots. **A**. Knee flexion from all PCL sacrificing and retaining TKR's. **B**. Knee flexion from PCL retaining design vs. PS design. **C.** Knee Society Score functional score **D.** WOMAC score

A



B

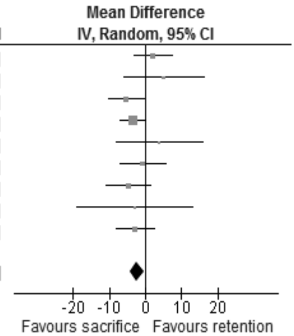


C

Study or Subgroup	Retention Mean	Retention SD	Retention Total	Sacrifice Mean	Sacrifice SD	Sacrifice Total	Weight	Mean Difference IV, Random, 95% CI
Aglietti 2005	84	19.7	103	82	19.6	107	13.4%	2.00 [-3.32, 7.32]
Catani 2004	81	17	20	76	19	20	3.0%	5.00 [-6.17, 16.17]
Harato 2008	69.6	19.7	111	74.9	18.7	111	14.8%	-5.30 [-10.35, -0.25]
Kim 2009 (1)	80.2	19.7	250	83.7	19.6	250	31.9%	-3.50 [-6.94, -0.06]
Matsumoto 2012	88.6	19.7	19	84.8	19.6	22	2.6%	3.80 [-8.26, 15.86]
Roh 2012	83.8	16.6	42	84.6	13.6	44	9.2%	-0.80 [-7.23, 5.63]
Straw 2003 (2)	69	19.7	66	73.7	19.6	101	10.2%	-4.70 [-10.80, 1.40]
Tanzer 2002	73	24	20	76	28	20	1.5%	-3.00 [-19.16, 13.16]
Wang 2004	84.2	20.8	128	87	19.6	96	13.4%	-2.80 [-8.13, 2.53]
Total (95% CI)			**759**			**771**	**100.0%**	**-2.36 [-4.30, -0.41]**

Heterogeneity: Tau² = 0.00; Chi² = 7.80, df = 8 (P = 0.45); I² = 0%
Test for overall effect: Z = 2.37 (P = 0.02)

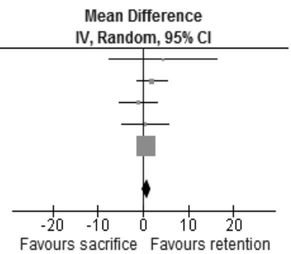
(1) Weighted average sd from reported sd's in studies
(2) Weighted average sd from reported sd's in studies



D

Study or Subgroup	Retention Mean	Retention SD	Retention Total	Sacrifice Mean	Sacrifice SD	Sacrifice Total	Weight	Mean Difference IV, Random, 95% CI
Clark 2001	22.8	35.4	59	18.5	32.9	69	0.8%	4.30 [-7.61, 16.21]
Harato 2008	10.4	13.4	111	8.5	12.3	111	10.0%	1.90 [-1.48, 5.28]
Roh 2012	15.9	8.6	42	17	10.7	44	6.8%	-1.10 [-5.19, 2.99]
Seon 2011	28.4	13.8	48	27.9	12.2	47	4.2%	0.50 [-4.74, 5.74]
Yansheng 2013 (1)	10	1.9	19	9.3	1.9	19	78.2%	0.70 [-0.51, 1.91]
Total (95% CI)			**279**			**290**	**100.0%**	**0.72 [-0.35, 1.79]**

Heterogeneity: Tau² = 0.00; Chi² = 1.58, df = 4 (P = 0.81); I² = 0%
Test for overall effect: Z = 1.32 (P = 0.19)



No other validated scoring systems were available for meta-analysis. Meta-analyses on the outcomes: KSS pain, KSS clinical score, KSS overall score, HSS score, SF-12 mental, radio-lucent lines, femoro-tibial angle, and tibial slope showed no significant differences and were comparable in terms of statistical homogeneity.

Sub-analyzing outcomes of low quality studies comparing PCL retention with sacrifice using the same, PCL-retaining, TKR design in both groups, showed no significant differences. Comparing knee flexion in PCL retention with the PCL sacrificing PS design ten studies of moderate quality (746 knees) demonstrated a 2.8 degrees mean difference in favor of posterior stabilization (95%-CI 0.54; 5.03 p=0.02).

Complications were reported in twelve studies.[14-16,19-24,29,32,33] Reported complications ranged from anterior knee pain and femoral notching to deep infection. Table 7.2 lists the complications per study.

Table 7.2: Complications reported in the selected studies

Study	PCL retention	PCL sacrifice
Aglietti 2005	None	Septic loosening: 1
Catani 2004	Anterior knee pain: 1 Limited ROM: 1	Anterior knee pain: 2
Chaudhary 2008	Deep infection: 1	Limited ROM: 1
Harato 2008	Stiff knee (< 90^0 flexion): 7 Knee pain: 5 Infection: 1	Stiff knee: 1 Knee pain: 2 Infection: 3
Kim 2009	Femoral notching: 2 Superficial infection: 1	Femoral notching: 3 Superficial infection: 1
Maruyama 2004	None	None
Matsumoto 2012	None	Deep venous thrombosis: 1
Misra 2003	Stiff knee (< 30^0 flexion): 2 Infection: 1 Aseptic loosening: 2 Instability: 3	Stiff knee: 2 Aseptic loosening: 3 Dystrophy: 1 Instability: 3
Roh 2012	PCL laxity: 2 PCL tightness: 1	None
Thomsen 2013	Infection: 1	None
Yagishita 2012	None	Deep venous thrombosis: 1
Yansheng 2013	None	None

PCL = posterior cruciate ligament, ROM = range of motion

Discussion

In this study of the current literature comparing PCL retention with PCL sacrifice in TKR no clinical relevant differences were seen between the two TKR groups. Based on the data of the 1.877 patients (2.347 knees) in twenty RCT's, a statistical significant difference existed of 2.1 degrees of flexion and a difference of 2.4 points in the Knee Society functional score, both in favor of the PCL sacrifice, which are not clinically relevant. Furthermore, the RCT's were graded having low to moderate quality of evidence. This study was performed according to the Cochrane guidelines a described in the Cochrane Handbook for Systematic Reviews.[13] An extensive report on this topic analyzing seventeen studies, was published by our group in 2013 within the Cochrane library of systematic reviews, the newly added studies did not add new evidence on this topic.[11]

The twenty selected studies are the best available evidence to date to evaluate the difference between PCL retention and PCL sacrifice in TKR. The assessment of the quality of the evidence showed that evidence was low to moderate. Incompleteness of reporting issues such as failure to quote randomization methods and blinding raises the likelihood of bias in the studies resulting in lower quality of evidence grades. However, an improving trend in reporting is seen, as the chronologically more recent publications were generally assessed as having a lower risk of bias.

Despite the fact that RCT's are qualified as providing the least biased evidence they are not suited for all outcomes. Survival analysis of the TKR cannot be easily investigated by RCT's, and in addition classic survival analyses can be biased by competing risks, which should be issued for valid outcome interpretation.[35,36] Observational, long-term follow-up cohort studies are valuable alternatives. Survivorship analyses of, relatively large cohorts, showed a ten-or fifteen year survival of 91% and 90% respectively in the PCL retaining group and 76% and 75% in the PCL sacrificing, posterior stabilized group.[37,38] However, other factors could influence these results such as differences in TKR design or materials between PCL retaining and stabilizing components.[39] A minimum data set for cohort studies has been advocated by the AQUILA consortium.[40] Furthermore, a topic under-discussed in the current RCT's on PCL retention versus sacrifice in TKR is the issue of secondary anterior-posterior instability due to secondary insufficiency of the PCL. Probably because no long term follow-up reports of RCT's are published, this issue has not been described.

This study has several strengths. We used a very sensitive search in eight relevant databases with no language limitations. We also checked references and used citation tracking. Recently published meta-analyses found and included only between eight and twelve articles instead of twenty-one.[41-43] We excluded several RCT's because of follow-up less than a year.[4,44-46] Since our study was performed according to the Cochrane guidelines, an elaborate and systematic assessment of quality of evidence and risk of bias was performed. In the meta-analysis we analyzed the subgroups of PCL sacrifice using a PCL retaining design and PCL sacrifice using a posterior stabilized design versus PCL retention separately.

A limitation is the lack of high quality evidence in meta-analysis. Furthermore we could not present information on outcome measures like patient experience and satisfaction, gait analysis, micro-motion of the components (RSA) and kinematic outcomes measures such as antero-posterior stability and contact position. The importance of the predictive value of RSA and survival in TKR had been extensively analyzed.[47,48]

Future research in the field of PCL retention or sacrifice in TKR should consist of RCT's that have identical follow-up moments, that include long(er) term follow-up in their protocols and that add outcome measures such as patient experience and satisfaction, gait analysis, antero-posterior stability of the knee, and contact position. To study long-term TKR survival or complications large observational studies are needed focusing on PCL retention versus sacrifice. Furthermore reporting of future studies have to be more complete in describing study methods in order to reduce the likelihood of bias and should also mention important confounders for outcome like preoperative ROM measurements.

Conclusion

Based on this systematic review and meta-analysis of all currently available RCT's there are no clinically relevant differences between retention or sacrifice of the PCL in terms of clinical, functional or radiological outcome.

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Appendix table A: Syntax used for Medline search

Search strategy syntax adopted for Medline (Pubmed)
("Arthroplasty, Replacement, Knee"[Mesh] OR "Knee Prosthesis"[Mesh] OR "knee replacement arthroplasty"[tw] OR "total knee arthroplasty"[tw] OR "total knee"[tw] OR tka[tw] OR "total knee replacement"[tw] OR "knee prosthesis"[tw] OR "knee implantation"[tw] OR "knee implant"[tw] OR "knee implants"[tw] OR "knee prosthesis"[tw] OR "knee joint replacement"[tw] OR "knee joint arthroplasty"[tw] OR tkr[tw] OR "Knee Replacement Arthroplasties"[tw] OR "Total Knee Replacements"[tw] OR "Knee Prostheses"[tw] OR "Knee endoprosthesis"[tw] OR "Knee endoprostheses"[tw] OR "Knee joint arthroplasty"[tw] OR "Knee joint arthroplasties"[tw] OR "knee joint prosthesis"[tw] OR "knee joint prostheses"[tw] OR "knee prosthetic"[tw] OR "Knee endoprosthetic"[tw] OR "knee joint prosthetic"[tw] OR "Knee joint endoprosthetic"[tw] OR "knee prosthetics"[tw] OR "Knee endoprosthetics"[tw] OR "knee joint prosthetics"[tw] OR "Knee joint endoprosthetics"[tw] OR "Knee replacement"[tw] OR "Knee replacements"[tw] OR "knee arthroplasty"[tw] OR "knee arthroplasties"[tw]) AND ("osteoarthritis"[Mesh] OR "arthritis"[Mesh] OR "posterior cruciate ligament"[Mesh] OR Osteoarthrosis[tw] OR Osteoarthroses[tw] OR Osteoarthritides[tw] OR Osteoarthritis[tw] OR Osteoartrosis[tw] OR Osteoartroses[tw] OR Osteoartritides[tw] OR Osteoartritis[tw] OR Degenerative Arthritis[tw] OR Degenerative Arthritides[tw] OR Degenerative Artritis[tw] OR Degenerative Artritides[tw] OR Arthrosis[tw] OR Arthroses[tw] OR Arthritides[tw] OR Arthritis[tw] OR arthritic[tw] OR RA[tw] OR rheumatoid[tw] OR rheumatic[tw] OR Artrosis[tw] OR Artroses[tw] OR Artritides[tw] OR Artritis[tw] OR Osteoarthrosis Deformans[tw] OR Osteoartrosis Deformans[tw] OR Posterior Cruciate Ligament[tw] OR Posterior Cruciate Ligaments[tw] OR Cruciate[tw] OR PCL[tw]) AND ("randomized controlled trial"[Publication Type] OR "randomized controlled trials as topic"[Mesh] OR "random allocation"[Mesh] OR "double-blind method"[Mesh] OR "single-blind method"[Mesh] OR "placebos"[Mesh] OR random*[tw] OR ramdom*[tw] OR ramdon*[tw] OR randon*[tw] OR rct[tw] OR rct's[tw] OR rcts[tw] OR ((single[tw] OR double[tw] OR treble[tw] OR triple[tw]) AND (mask*[tw] OR blind*[tw])) OR placebo*[tw] OR random*[tw] OR compare*[ti] OR versus[ti] OR vs[ti])