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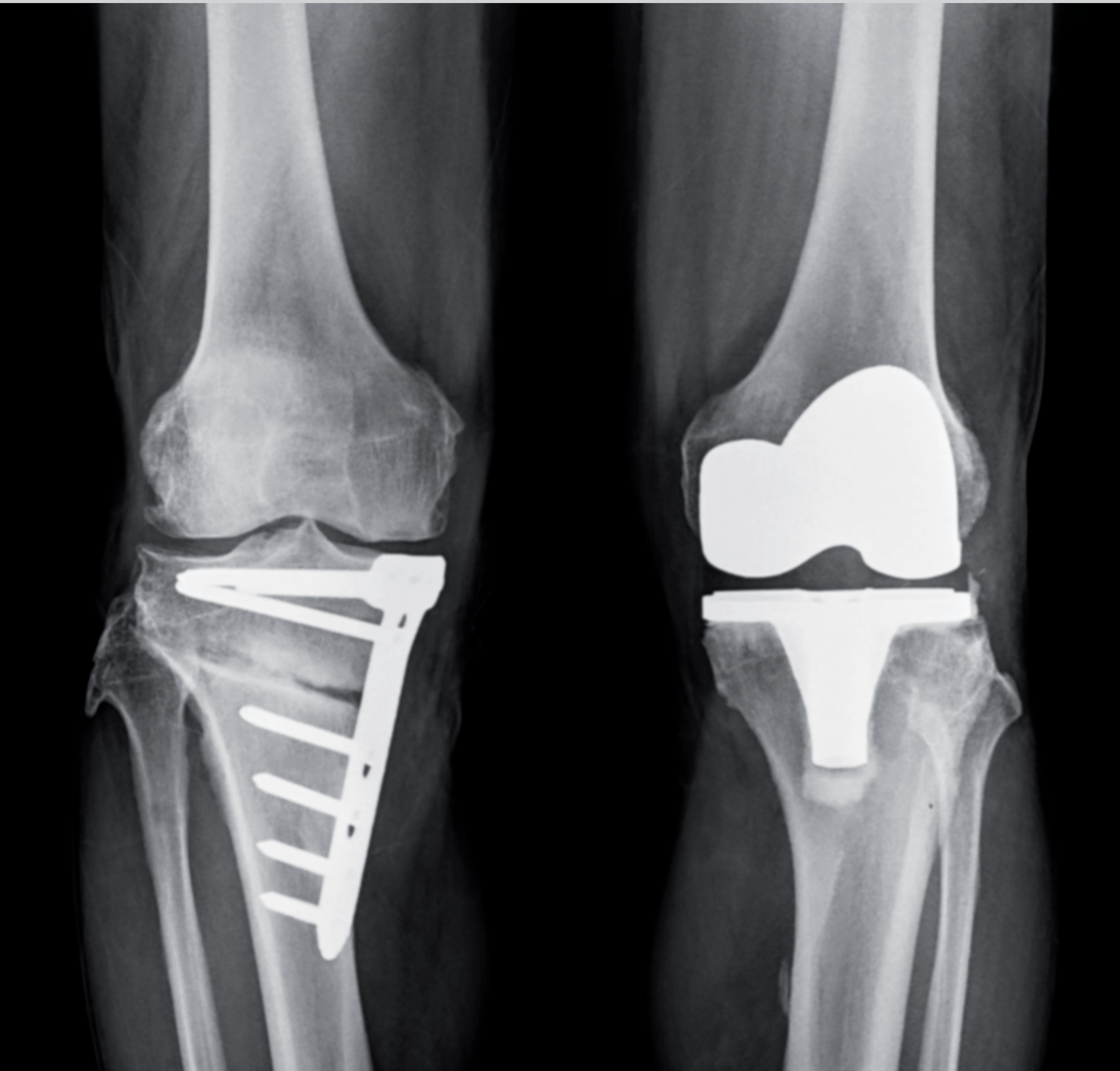
Willem van Lieshout



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A search to optimize patient outcome for Medial Closed Wedge High Tibial Osteotomy and Total Knee Arthroplasty in the context of stability of the knee

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Chapter 1

General Introduction

INTRODUCTION

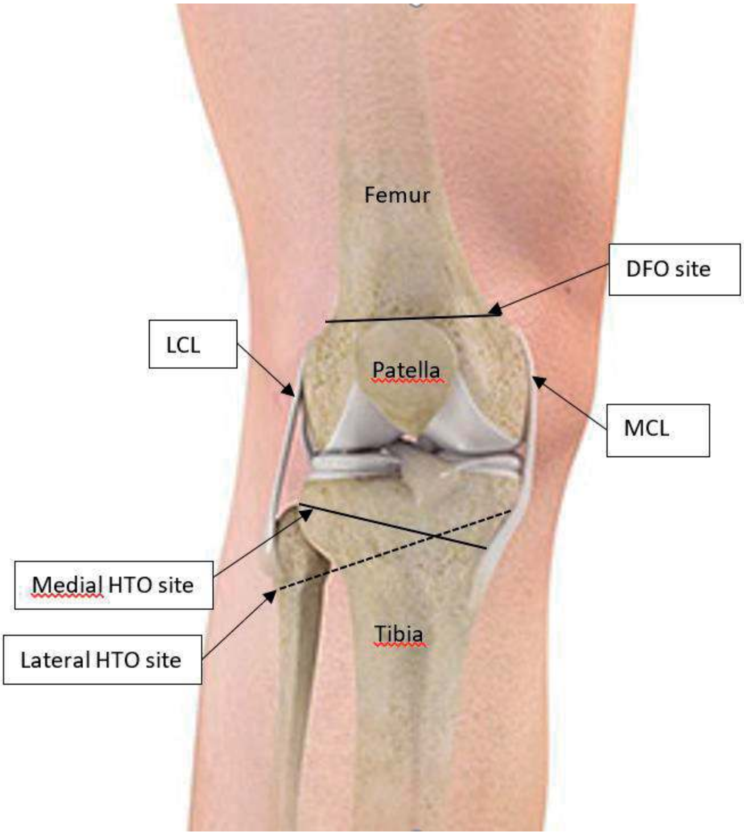
Stability of the knee

There are three main bones that make up the human knee joint: femur, tibia and patella. The femur and tibia form the femorotibial joint and are responsible for the weight-bearing component of the knee. The anteriorly situated patella bone acts as a fulcrum to increase the quadriceps power and reduces friction forces on the femur. The knee joint is primarily a hinge joint, but both rotational and varus-valgus movements are possible as well as translation (rollback). Four major ligaments primarily stabilize the knee being the two cruciate ligaments and the medial and lateral collateral ligament. The surrounding muscles that dynamically reinforce the stability of the knee facilitate secondary knee stabilization (Kakarlapudi and Bickerstaff 2000). When the stability of the native knee is compromised due to injury, patients frequently experience pain and inability to perform normal daily activities. Self-reported knee instability as well as greater dynamic varus-valgus stress are associated with worse self-reported knee confidence (Skou et al. 2014). This worse self-reported knee confidence has also been shown to predict functional decline in people with knee osteoarthritis (OA) (Colbert et al. 2012). Frequently this affects daily physical function (van der Esch et al. 2016). When conservative treatment for knee OA fails and patients require a surgical intervention, stability is therefore, a factor of most importance. Depending on the stage of the OA different surgical options are possible, i.e. osteotomy or arthroplasty. This thesis focused on stability changes after these surgical options. Both the objective measurable coronal laxity of knee, as well as subjective reported stability by the patient were of interest. Since the surgical interventions differed in great matter with regards to the anatomical changes in the knee, this thesis was split in two.

Part 1: Osteotomy

High Tibial Osteotomy (HTO) and Distal Femur Osteotomy (DFO) are surgical options to correct malalignment of the leg. Both have proven to be good therapeutic options for delaying and potentially preventing progression of knee OA. An osteotomy is most favorably performed in the more active and younger patient in whom total knee arthroplasty (TKA) is less desirable (W-Dahl, Robertsson, and Lohmander 2012). Operative (osteotomy) procedures are well described, in particular for varus malalignment. Valgus malalignment deformity of the knee is much less frequent (2%-2,8%) (Johan Bellemans et al. 2012). If a corrective procedure is performed in these valgus knees (i.e. varus producing osteotomy), it is historically preferably done at the distal femur. Correction in the proximal (or high) tibia for valgus malalignment is much less frequent. However, if the valgus leg deformity is located in the tibia, a tibial correction should be performed to prevent an abnormal knee joint line obliquity (Hofmann S, Paszicneyk T 2004). Nowadays, whether a DFO or HTO (or a combination) is the most appropriate treatment depends on the location of the deformity as formulated by Paley (Paley 2002).

Both osteotomies are located around the knee and therefore possibly affect the stability of the knee. However, the location of the DFO is proximal of the origin of the four major stabilizing ligament so the direct stability of the knee is not compromised (Fig 1). The lateral HTO, open or closed, has no direct effect on the stability of the knee since none of the 4 major ligaments insertion positions are compromised. However, for the medial HTO the location for the osteotomy lies in the proximal tibia thus affects the insertion for the superficial medial collateral ligament (sMCL) and therefore is of interest to this thesis.



The origin for the lateral collateral ligament (LCL) is the lateral epicondyle of the distal femur and the LCL insertion is the fibular head. The medial collateral ligament (MCL) consists of a deep part (dMCL) and a superficial part (sMCL). Both fibrous structures share the same origin just proximal of the medial epicondyle of the femur, but their insertion on the tibia is different. The dMCL inserts just distal of the tibial joint line were the sMCL has a 5-7cm broad insertion distal to the tibia metaphysis, approximately 6cm below the joint line (LaPrade et al. 2007). (Original figure: https://www.herrerasportsmedicine.com/knee-miami-institute.html)

The medial open wedge HTO and the subsequent release of the sMCL insertion is well described in the literature. Agneskirchner and colleagues proved that a full release of the sMCL is necessary to cause a cartilage pressure redistribution to the lateral compartment (Agneskirchner et al. 2007). This release of the MCL has no effect on postoperative valgus laxity as was recently published by Seo and Song (Seon and Song 2016). The medial open wedge HTO has shown to relieve pain and restore function and has an expected survivorship of 95-98% after 5 years (Schallberger et al. 2011; Schröter et al. 2013; Hui et al. 2011). Where the medial open wedge HTO and its effect on coronal laxity is widely described in the literature and accepted as a treatment, it is totally different for the medial closed wedge HTO. As an osteotomy pioneer, Coventry described the varus producing medial closing wedge HTO to treat valgus malalignment of the knee (Coventry 1985, 1987). He stated that, by removing a bony wedge on the medial side of the proximal tibia, a laxity of the sMCL is introduced. He therefore suggested to perform a surgical reefing procedure at all times to tighten the MCL. There are some studies that report on outcome after an medial closed wedge HTO with regards to patient satisfaction, reported stability and survival (Coventry 1987; Shoji and Insall 1973; Chambat et al. 2000; van Egmond et al. 2017). However, the effect on knee laxity before and after medial closed wedge HTO is not yet described. Therefore, the suggested MCL-reefingplasty by Coventry is, till date, an extra procedure without the data to support its beneficial effects to the patient.

Thus, although in medial open wedge HTO the effect of the sMCL on laxity and patient reported stability is well documented, it remains unclear what happens to coronal knee laxity after a medial closed wedge HTO and whether this affects patients outcome and stability. The proposed MCL-reefingplasty by Coventry is nowadays not performed in the standard care for patients undergoing medial closed wedge HTO although we are not sure if it would be better to add the procedure. Therefore research questions were: *1) what is the effect of a medial closed wedge HTO without a MCL-reefingplasty on coronal knee laxity and how does this relate to patient reported outcome?* and *2) What is the prevalence of subjective knee instability in patients who underwent medial closed wedge HTO without MCL-reefingplasty and does aforementioned subjective knee instability relate to patient reported outcome and survival?*

Part 2: Arthroplasty

Total knee arthroplasty (TKA) is an effective surgical intervention in patients with end-stage knee joint degeneration (Kahn, Soheili, and Schwarzkopf 2013). It has proven to alleviate pain, restore function and improve patients' quality of life (Anderson et al. 1996; Ethgen et al. 2004). However, approximately 1 out of 5 patients is dissatisfied at 1 year postoperative (Bourne et al. 2010; Scott et al. 2010). A possible cause for these mediocre results might be that in TKA patients the biomechanics of the knee change intensively. After TKA the joint line is transformed from an oblique to horizontal situation and the rotational capabilities are diminished. Moreover, the leg alignment is corrected to neutral. These factors might have effect on the outcome and satisfaction of the patient. However, these alterations are deemed necessary to avoided early failure of the TKA (Ritter et al. 2011; Fang, Ritter, and Davis 2009). From a surgical point of view joint line elevation and subsequent laxity changes after TKA are considered to have a negative effect on postoperative outcome and these might be avoidable.

For TKA the effects of joint line elevation and coronal laxity changes are still subject of debate since it is unclear how much is acceptable. Mean joint line elevation after primary TKA varies between 1.1mm up to 5.6mm (Selvarajah and Hooper 2009; Snider and Macdonald 2009). This elevation of the joint line alters the biomechanics of the knee. In order to maintain a symmetrical flexion and extension gap the posterior condylar offset (PCO) needs to be decreased as well. Therefore, the flexion axis of the knee will be positioned more proximal and ventral and the medial collateral ligament will lose its isometric function which results in mid-flexion instability (0–90° flexion). The theory that a raised joint line results in mid-flexion instability has been proven in a cadaver study by Cross and colleagues (Cross et al. 2012). In addition, as a consequence of the elevated joint line and decreased PCO, negative effects on flexion angle and the extensor mechanism strength have been described (J Bellemans et al. 2002; Martin and Whiteside 1990). However, if these alterations in the biomechanics of the knee affects patient outcome, especially subjective stability and functional outcome, remains unclear. Since stability is of great importance for a patient in the native knee, it is expected to play a vital role in TKA as well. Therefore it's advocated restoring the medial joint line height to its pre-disease height to ensure coronal stability to achieve a balanced knee (Victor 2017).

For this reason, the Flexion First Balancer (FFB) technique was developed. This new technique for TKA was designed to enable the surgeon to reproducibly retain MCL isometry through preservation of the medial PCO and thereby replicate the medial pre-disease joint line height. Because of the intact MCL isometry, mid-flexion instability presumably would not occur. The hypothesis for this new technique was that with retained MCL isometry and subsequent restoration of the medial joint line, less objective knee laxity would be present. This, in term, should result in better patient reported outcome, more subjective knee stability, and higher functional performance for these patients.

Patient satisfaction after TKA is still limited and a possible contributing factor might be joint line elevation with subsequent coronal mid-flexion laxity changes. The effect of joint line elevation and mid-flexion laxity on patient outcome is still unclear. A new developed technique for TKA, the Flexion First Balancer technique, might improve prosthesis placement but no studies have investigated its presumed benefits. Therefore research questions are:

3) What is the effect of joint line elevation after Total Knee Arthroplasty on patient reported outcome?, 4) Is the new FFB technique feasible?, 5) What is the effect of the used Flexion First Balancer technique on patient reported outcome and complications compared to the standard Measured Resection technique? and *6) Is there a difference in mid-flexion laxity and functional outcome and stability between the Flexion First Balancer technique and the standard Measured Resection technique?*

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PART 1

OSTEOTOMY

chapter 2

Medial collateral ligament laxity in valgus knee deformity before and after medial closing wedge high tibial osteotomy. Instrumented laxity measurements and patient reported outcome

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ABSTRACT

Introduction

Medial closing wedge high tibial osteotomy (CWHTO) for valgus deformity correction was first described by Coventry whom performed an additional reefing of the medial collateral ligament (MCL) to prevent instability postoperative. In our clinic the additional reefing procedure has never been performed and instability has not been reported routinely by patients. Using instrumented laxity testing, pre- and postoperative valgus and varus knee laxity can be measured objectively. We hypothesize that absence of changes in laxity testing and subjective knee stability scores support that no additional reefing procedure is necessary.

Materials and methods

In a prospective cohort study 11 consecutive patients indicated for medial CWHTO were subjected to pre- and postoperative stress X-rays in 30° and 70° of flexion and opening of the joint line was measured in degrees on the radiographs. Patient reported outcome scores were documented with the KOOS, Lysholm, SF36, Oxford Knee Score and a VAS instability scoring tool.

Results

All patients (7 females) completed the study, mean age was 46 years. Mean preoperative Hip Knee Ankle angle 6.4° valgus was corrected to mean postoperative alignment 0.1° valgus. A significant difference was measured between mean pre- and postoperative 30° valgus laxity (2.8° vs 5.3°, $P = 0.005$), 30° varus laxity (6.7° vs 3.2°, $P = 0.005$) and 70° valgus laxity (2.0° vs 4.8°, $P = 0.008$). Postoperative patient-reported knee instability as measured with the Lysholm questionnaire was significantly improved compared to preoperative instability ($P = 0.006$). VAS instability improved, but didn't reach significance (8.0 preoperative and 5.5 postoperative ($P = 0.127$). Other outcome measures showed improvement as well. No correlations between radiological findings and outcome scores were found.

Conclusion

A significant increase in postoperative valgus laxity in 30° and 70° of flexion deems reconsidering addition of MCL reefingplasty to the medial CWHTO although patient reported outcome on subjective stability scores fails to report increase of instability in this study population. Instrumented laxity measurements of medial CWHTO patients treated with additional medial reefingplasty should be performed to prove the value of this procedure.

INTRODUCTION

Osteotomy procedures for varus malalignment are frequently performed. Valgus malalignment deformity of the knee however, is much less frequent (2%-2,8%) (Bellemans et al. 2012) and a corrective procedure i.e. a varus producing osteotomy in these valgus knees is most often performed in the distal femur (Haviv et al. 2013; Puddu et al. 2010). Correction in the proximal (or high) tibia is much less frequent. However, if the valgus leg deformity is located in the tibia a tibial correction should be performed to prevent an abnormal knee joint line obliquity (van Egmond et al. 2017; Hofmann et al. 2004).

As an osteotomy pioneer, Coventry (1985, 1987) described the varus producing medial closing wedge high tibial osteotomy (CWHTO) to treat valgus malalignment of the knee (Coventry 1985; Coventry 1987). He stated that, by removing a bony wedge on the medial side of the proximal tibia, a laxity of the superficial medial collateral ligament (MCL) is introduced. He therefore suggests to perform a surgical reefing procedure at all times to tighten the MCL (Coventry 1985; Coventry 1987). Shoji and Insall also described this procedure in some patients (Shoji and Insall 1973). However, in our clinic no reefing procedures of the MCL are performed and patients have not reported routinely on knee instability after this procedure. Till date no study has evaluated the MCL-laxity before and after a varus producing medial CWHTO for valgus malalignment of the knee.

The MCL consists of a deep part and a superficial part that have different functions while together providing normal laxity during knee range of motion (Wymenga et al. 2006). Instrumented laxity measurements has proven that collateral laxity of the knee differs in flexion and extension in healthy subjects (Deep et al. 2015; Heesterbeek et al. 2008; Yoo et al. 2006). The collateral ligament laxity is variable in different persons and ligaments in women are more lax than in men especially in valgus stress. These reference values in healthy volunteers have been measured with knees positioned in varying flexion angles and with different types of instrumented laxity measurement methods.

Whereas laxity can be measured and quantified instability can be defined as the clinical manifestation of patient's perceived increased laxity in the knee and is scored on subjective scales. Self-reported knee instability as well as greater dynamic varus-valgus stress are associated with worse self-reported knee confidence (Skou et al. 2014). This worse self-reported knee confidence has also been shown to predict functional decline in people with OA (Colbert et al. 2012). An absence of change to the MCL laxity as well as an unchanged sense of knee stability therefore is vital to a good outcome for a medial CWHTO.

The aim of this pilot study was to evaluate the effect of a medial CWHTO in varus-valgus laxity changes radiologically and subjectively and to report if these correlated to each other. We hypothesize that both MCL and LCL laxity do not change after a medial CWHTO, that self-reported knee instability also does not change and as a result, no additional surgical reefing procedure of the MCL is necessary.

MATERIAL AND METHODS

Between May 2015 to March 2016 eleven consecutive patients were included in this study. Inclusion criteria were symptomatic valgus malalignment located in the proximal (high) tibia, indication for a medial CWHTO, based on the severity of the complaints and the observed deformity according to Paley (Paley 2002), age 18–65 years and no history of knee ligament injuries. Exclusion criteria were previous MCL surgery, previous ipsilateral total hip replacement because of planned instrumented flexion laxity measurements, BMI higher than 30 kg/m2. All patients reported to the outpatient clinic and were seen and operated on by a single orthopaedic surgeon (RvH). The operative procedure consisted of surgical removal of a pre-planned bone wedge after which the created gap was closed to straighten the leg. Fixation after closure was performed with an angle stable Tomofix-plate. The location of the wedge removal is distal to the attachment of the deep part of the MCL and within the attachment of the superficial part of the MCL on the medial proximal tibia (Fig.1). This study was approved by the Medical Research and Ethical Committee, and all patients provided written informed consent for participation in the study. Being a pilot study, no power analyses were done.

Radiographic measurements

Pre- and postoperative long-leg radiographs were obtained for each patient. Subsequently every patient received varus and valgus stress radiographs in 30° and 70° flexion. On the day of surgery, after either spinal or total anaesthetics were applied, radiographs were made before surgery started. The postoperative radiographs were performed three to six months post-surgery in the outpatient clinic without the use of anaesthetics. At that time the subjects were instructed to relax their thigh muscles to minimize the role of the dynamic knee stabilizers when conducting the radiographs in 30° and 70° flexion in the postoperative setting.

Varus and valgus laxity of the knee in 30° flexion was assessed using the Telos device (Fa Telos, Medizinisch-Technische GmbH, Griesheim, Germany) with the subject lying in a supine position with leg muscles relaxed. The knee was positioned in an approximately 30° angle by putting a 15 cm diameter plastic pipe under the knee to ensure a reproducible angle pre- and postoperative. The Telos device was applied with 15 Nm load on the leg relative to the level of the knee joint line. While medial and lateral forces were applied, radiographs were obtained in the anteroposterior view. The direction of the X-rays was parallel to the tibia joint surface, centred on the middle of the femoral-tibial joint space.

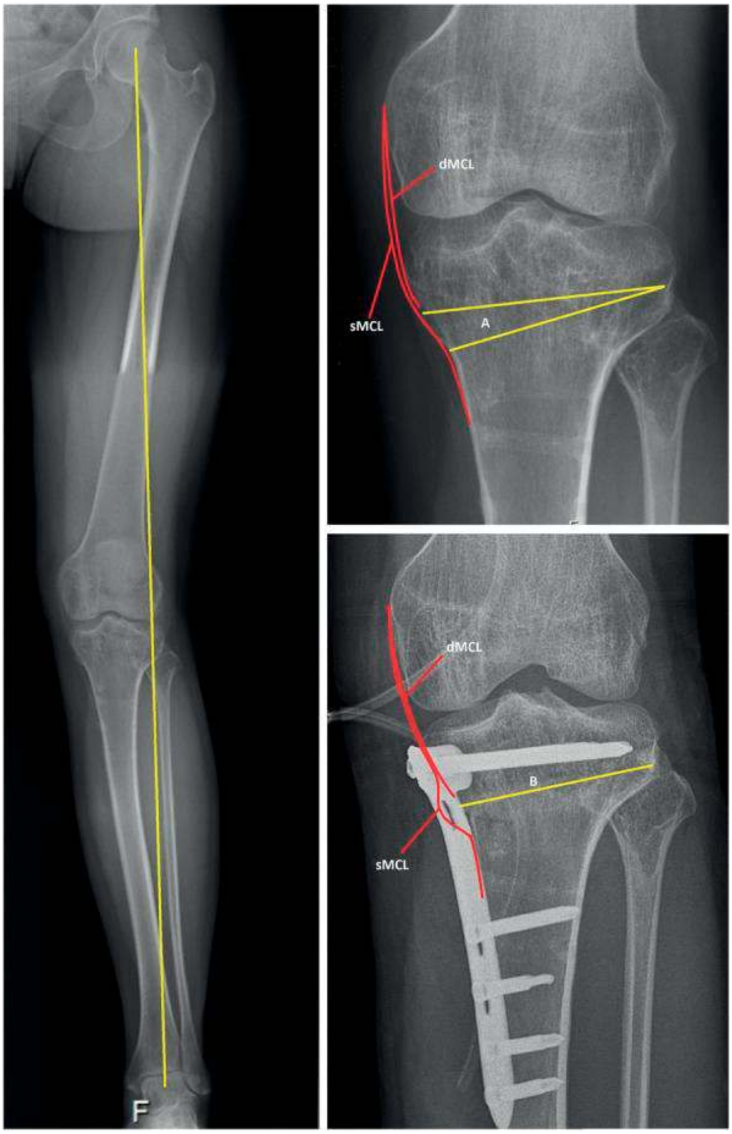

Fig 1. Preoperative and postoperative radiographs of the osteotomy site in relation to the medial collateral ligament.

The left figure shows a pre-operative long-leg radiographs with valgus malalignment. The right figures show a preoperative (above) and postoperative (below) radiograph of the knee. The osteotomy site (A and B) is below the insertion of the deep medial collateral ligament (dMCL). In the postoperative situation a pseudo laxity of the superficial medial collateral ligament (sMCL) is created.

For varus and valgus laxity of the knee in 70° flexion, a custom-made stress device was used to stress the knee and to produce reproducible measurements. An external load of 15 Nm was applied at the knee joint using 50 N on a pulley 0.30 m distal from the joint line. The knee was stressed medially and laterally. Radiographs were made with the X-ray direction parallel to the tibia joint surface in the conditions varus, valgus or no moment applied. This method has previously been described and validated by Heesterbeek et al. (Heesterbeek et al. 2008).

The angle between a tangent line on the femur condyles and a line through the deepest tibial joint surfaces was determined on the varus, valgus and neutral radiographs using the measurement tool within the radiographic database program (Sectra workstation IDS7, version 16.1.22.1566 (2015), Sectra AB, Linköping, Sweden) (Fig.2). Valgus laxity was defined as the difference between the medial stress radiograph and the neutral radiograph, varus laxity as the difference between the lateral stress radiograph and the neutral radiograph. The measurements were made to the nearest 0.1°. The radiographic measurements were done by two authors (WvL, CM) independently. When the independent measurements differed (> 1° apart) consensus was made. A third independent experienced orthopaedic surgeon was asked to review a sample of the measurements and reported similar measurements.

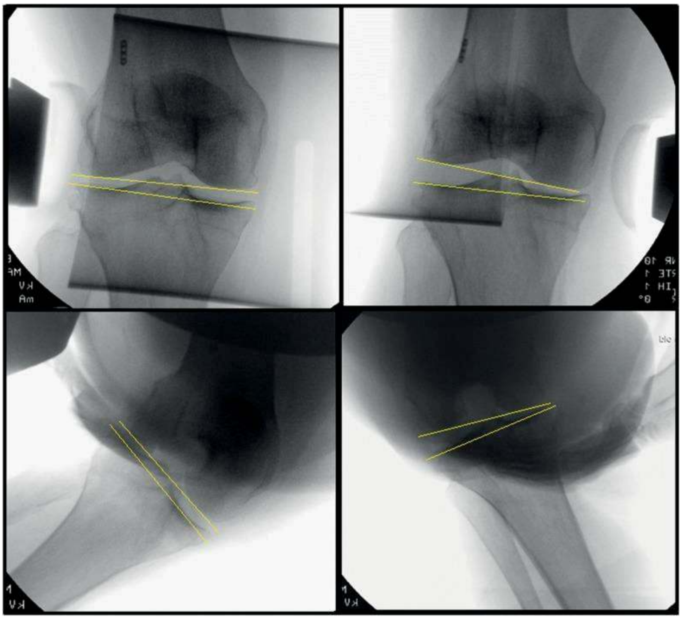

Fig 2. Valgus and varus laxity stress radiographs with joint space opening.
Pre-operative stress radiographs of the knee in 30° and 70° of knee flexion in an anaesthetized patient. The upper two figures show radiographs in 30° of flexion with varus (left) and valgus (right) stress. The lower two figures show radiographs in 70° of flexion in varus (left) and valgus (right) stress. The angle between a tangent line on the femur condyles and a line through the deepest tibial joint surfaces was determined and compared to the natural (unstressed) knee joint line congruence angle.

Questionnaires

Patients were asked to fill in questionnaires preoperative and at six months postoperative. The validated Dutch Knee Injury and Osteoarthritis Outcome Score (KOOS) was used to assess subjective knee function and quality of life and consists of 5 different subscales: (1) pain, (2) symptoms, (3) function in daily living, (4) function in sport and recreation, and (5) knee-related quality of life. The score for each subscale was calculated, where 0 indicates severe knee problems and 100 indicates no knee problems (de Groot et al. 2008; Roos and Toksvig-Larsen 2003). The validated Dutch International Knee Documentation Committee (IKDC) Subjective Knee Form was used to assess symptoms and limitations in function and sports. A higher score indicates a better function (0–100 scale) (Haverkamp et al. 2006; Irrgang et al. 2001). The IKDC Current Health Assessment Form (SF36 form) was used to measure health status with respect to different dimensions: (1) physical functioning, (2) social functioning, (3) role limitations due to physical problems, (4) role limitations due to emotional problems, (5) bodily pain, (6) mental health, (7) vitality, (8) general health perception, and (10) change in perceived health during the last 12 months. All raw scores were converted to a 0–100 scale, with higher scores indicating higher levels of functioning or well-being (Haverkamp et al. 2006; Ware and Sherbourne 1992). The validated Dutch Oxford Knee Score (OKS) questionnaire was used to assess function and pain after surgery. A lower score indicates a better outcome (range 12–60) (Dawson et al. 1998; Haverkamp et al. 2005). The Lysholm knee scale was used to assess ligament injuries of the knee. A higher score indicates a better outcome (range 0–100) (Eshuis et al. 2016; Kocher et al. 2004). In addition, patients were asked to fill in a visual analogue scale (VAS) Instability, with a higher score indicating more instability of the operated knee (range 0–10).

Statistical analysis

Differences in varus and valgus laxity of the knee in 30° and 70° flexion pre- and postoperative were assessed using nonparametric Wilcoxon signed-rank tests. Also differences in subjective scores (IKDC, Oxford, Lysholm and VAS Instability) were assessed using nonparametric Wilcoxon signed-rank tests. Results were presented as medians with range. All tests were performed with a level of significance of 0.05.

Results

Eleven patients were included in this study, with a median age at the time of operation of 46 years (range 24–66 years). One patient was 66 at the time of operation but was accepted for this study as she was still 65 years old when put on the waiting list for this surgery. Seven patients were female and 4 were male. In one patient preoperative 30° flexion X-rays could not be obtained due to a technical error. All eleven patients completed the study. Preoperative mean hip-knee-ankle (HKA) angle was 6.4° valgus (12° valgus to 1° valgus) and this was restored postoperative to a mean HKA angle of 0.1° (5.8° valgus to 5° varus). In one patient the postoperative long leg radiograph was missing.

Stress X-rays in 30° and 70° flexion

After separate radiological assessment by the two authors consensus had to be made for 6 patients regarding at least one value. Pre- and postoperative measurements for every single stress X-ray group are presented in Table 1. Overall, in the preoperative setting patients had higher varus laxity values compared to valgus laxity in both 30° and 70° flexion. Postoperative, this differentiated collateral laxity of knee shifted to a more distinguished valgus laxity and a decrease in varus laxity of the knee. This indicated tighter knees on the lateral side and increased laxity on the medial side of the knees.

Table 1. Differences in varus and valgus laxity in 30° and 70° flexion of the knee

	Preoperative*	**Postoperative***	***P* value**
30° Valgus Laxity	2.8° (−4.0–4.3°)	5.3° (2.5° – 7.1°)	0.005*
30° Varus Laxity	6.7° (3.7° – 9.3°)	3.2° (− 0.9° – 4.9°)	0.005*
70° Valgus Laxity	2.0° (−2.6° – 5.4°)	4.8° (0.4° – 7.6°)	0.008*
70° Varus Laxity	3.8° (− 3.2° – 9.0°)	1.3° (− 0.1° – 8.3°)	0.113

Values are presented as: median (range)
* Significant difference ($P < 0.05$)

When comparing the pre- and postoperative results for each condition, there was a statistically significant difference between the pre- and postoperative 30° valgus laxity (respectively 2.8° and 5.3° ($P = 0.005$)), 30° varus laxity (respectively 6.7° and 3.2° ($P = 0.005$)) and 70° valgus laxity (respectively 2.0° and 4.8° ($P = 0.008$)). The difference between the pre- and postoperative 70° varus laxity did not reach significance (3.8° versus 1,3° ($P = 0.113$)).

Patient reported outcome scores

Patient-reported outcome results are presented in Tables 2, 3, and 4. Postoperative patient-reported knee instability as measured with the Lysholm questionnaire was significantly improved compared to preoperative instability ($P = 0.006$, Table 2). The VAS knee instability score also improved, but didn't reach significance (8.0 preoperative and 5.5 postoperative ($P = 0.127$, Table 2)). Knee function, knee pain and knee-related quality of life as measured with the IKDC Knee evaluation form, Oxford Knee Score and the KOOS all showed significant improvements postoperative as shown in Table 3. Only the quality of life domains 'Physical functioning' and 'Bodily pain' of the IKDC Current Health Assessment Form showed significant improvements (Table 4).

Table 2. Differences in patient-reported knee instability as measured with the Lysholm and VAS

	Preoperative	Postoperative	P value
Lysholm	42 (26–75)	67 (27–90)	0.006*
VAS knee instability	8.0 (2.5–9.0)	5.5 (1.0–8.0)	0.127

Values are presented as: median (range)
* Significant difference ($P < 0.05$) Abbreviations: VAS Visual Analogue Scale

Table 3. Differences in knee function, pain and knee-related quality of life as measured with PROMs

	Preoperative	Postoperative	P value
IKDC Knee Evaluation	32 (13–51)	60 (24–82)	0.004*
Oxford Knee Score	35.0 (20–47)	23.5 (15–51)	0.017*
KOOS Pain	42 (17–75)	72 (22–92)	0.041*
KOOS Symptom	43 (12–86)	68 (54–96)	0.007*
KOOS ADL	53 (21–90)	81 (35–97)	0.008*
KOOS Sport & Recreation	0 (0–25)	35 (0–70)	0.020*
KOOS QoL	25 (6–50)	38 (6–63)	0.044*

Values are presented as: median (range)
* Significant difference ($P < 0.05$) Abbreviations: PROMs patient reported outcome measures, IKDC International Knee Documentation Committee; KOOS Knee Injury and Osteoarthritis Outcome Score, ADL activities of daily living, QoL Quality of life

Table 4. Differences in health-related quality of life as measured with the IKDC Current Health Assessment Form

	Preoperative	Postoperative	P value
Physical functioning	55.0 (5–85)	75.0 (40–95)	0.020*
Physical role functioning	62.5 (0–100)	87.5 (0–100)	0.357
Bodily pain	51.0 (0–74)	62.0 (41–84)	0.014*
General Health	72.0 (52–97)	82.0 (52–95)	0.420
Vitality	65.0 (50–90)	65.0 (55–90)	0.475
Social functioning	88.0 (38–100)	100.0 (50–100)	0.596
Emotional role functioning	100.0 (67–100)	100.0 (0–100)	0.157
Mental Health	88.0 (52–100)	88.0 (68–100)	0.157

Values are presented as: median (range)
* Significant difference ($P < 0.05$)

No correlations were found between radiological findings and patient reported outcome scores.

DISCUSSION

This study has shown a significant increase in valgus laxity in both 30° and 70° of flexion after medial closing wedge HTO, which indicates a change of laxity of the medial collateral ligament. Furthermore, a significant decrease in varus laxity in 30° of flexion and a non-significant decrease in 70° flexion, was found. These findings are not correlated to subjective knee stability and outcome scores which all improved after the operation. Therefore, our hypothesis is false.

Our preoperative valgus and varus laxity values in 70° of flexion are comparable with the normal values in healthy individuals. Our reported valgus and varus laxity in 70° flexion are 2.0° and 3.8° versus 2.5° and 3.1° as found in the study of Heesterbeek et al. who performed instrumented laxity measurements with the same measurement device and are therefore comparable (Heesterbeek et al. 2008). In a study conducted by Deep the varus and valgus laxity was measured with instrumented laxity measurements in 15° flexion in healthy individuals. This study showed that the femorotibial mechanical angle (FTMA) changed with a mean of 6.9° when 10 Nm varus torque was applied. With valgus torque the mean change in FTMA was 7.9°. The unstressed FTMA was 1.2° varus (Deep 2014). Our reported varus and valgus laxity in 30° flexion preoperative were respectively 6.7° and 2.8°. Our values are therefore lower than reported by Deep, however, we performed the tests in 30° of flexion. This might influence the results.

Our postoperative results cannot be compared to the literature since this is the first study to our knowledge to investigate the change in knee laxity after a medial CWHTO. Moreover, due to the difference in radiological measurement settings (i.e. under anaesthetics preoperative and non-anaesthetized conditions postoperative) we have possibly inflicted a non-comparable situation especially as regards the varus laxity measurements. Tsukeoka and Tsuneizumi proved that anaesthesia significantly influenced knee joint laxity on both the medial and lateral side after TKA. They reported a positive correlation between the laxity under anaesthesia and the amount of change in laxity on the lateral side ($r = 0.57$; $p = 0.0022$). They found an increase in laxity for varus stress with mean of 1° under anaesthetics in a 15 degree flexion angle of the knee. Moreover, in 23% of their patients they reported an increase of > 3° in laxity measured under anaesthesia as compared to non-anesthetized patients (Tsukeoka and Tsuneizumi 2016). The decrease of varus laxity comparing the postoperative non-anesthetized results to the preoperative anesthetized results may be contributed solely to the effect of anaesthesia and may in fact display the same unchanged lateral collateral laxity. Therefore, the different measurement setting is a plausible explanation for the unexpected decrease in varus laxity in this patient population.

However, in valgus laxity there is an increase in laxity postoperative even though the postoperative X-rays were performed without the use of anaesthetics. Therefore, the difference in measurement settings cannot explain the increased valgus laxity. A previous study by Mains et al. studied the influence of the separate ligaments with regards to stability of the knee. They have shown that the superficial MCL (sMCL) is the main stabilizer for valgus stress. After sectioning the sMCL the abduction increased with 4.8° in 20–25° of knee flexion and for 40–45° of knee flexion this increase in abduction was 4.3° (Mains et al. 1977). These findings are in correspondence with our increase in valgus laxity after the operation. Hence, we noted less increase in valgus laxity but this may again be explained due to the different setting during the radiological measurements (anaesthesia or not).

An explanation for the increase in valgus laxity can be found in the surgical technique for medial CWHTO. The MCL is composed of a superficial and a deep component originating from the medial epicondyle of the femur. The deep component inserts directly into the edge of the tibia plateau and therefore will not be affected by the osteotomy. Mains et al. showed that the deep MCL tightens at 45° flexion but is less powerful as a stabilizing factor for valgus stress compared to the superficial MCL (Mains et al. 1977). Griffith et al. showed that cutting the deep MCL resulted in increased valgus laxity in 60 degrees of knee flexion. This was not recorded for 0, 20, 30 or 90 degrees of knee flexion (Griffith et al. 2009). The superficial component is attached to the tibia approximately 6 cm beneath the joint line and has a broad insertion up to 12 cm below the joint line (LaPrade et al. 2007). The superficial MCL provides the primary resistance against valgus stress and external rotation (Griffith et al. 2009; Mains et al. 1977). When performing the medial CWHTO part of the sMCL is pushed dorsal at the location of the osteotomy when inserting a retractor subperiostially around the posteromedial tibia to protect the soft tissues while performing the osteotomy. Although care is taken not to loosen the MCL fibres during insertion of the retractor the removal of the bone wedge and the gap closure afterwards causes a relative lengthening of the MCL similar to the amount of bone resected on the medial cortex as the insertion of the sMCL remains unchanged (Fig. 1). So the superficial component fibers themselves have the same length but their underlying surface is shortened due to the removed bony wedge resulting in a pseudo laxity of the MCL and thereby introducing increased valgus laxity.

The documented significant changes in laxity in the coronal plane have to be compared with the patient reported outcome score, to identify whether they have any clinical relevance. Patients experience walking with a deformed leg, whether valgus or varus, often as an instability in walking. Patient reported outcome measures after the medial CWHTO showed significant less knee instability and knee instability-related problems 6 months after the surgery that corrected their leg to neutral as measured with the Lysholm scoring tool. The VAS instability score, solely developed to assess the patients subjective stability feeling of the knee, also improved postoperative however, did not reach significance. Due to our short follow up time (6 months) no comparisons can be made with previous studies (Coventry 1987, Shoji and Insall 1973, Chambat et al. 2000, Van Egmond et al. 2017) that reported on outcome after an medial CWHTO. Furthermore, no long-term conclusions can be drawn based on our outcome scores. However, the findings do support our hypothesis that patients do not experience a disadvantage of the increase in laxity of the MCL. In our department as yet unpublished data among 113 comparable patients showed a 77% satisfaction after a medial CWHTO with a mean follow up of four years (van Lieshout WAM et al. 2019).

Our study has several limitations. First, because this study is a pilot study the sample size is small. Nevertheless we reached significant changes for varus and valgus laxity for pre- and postoperative results. Second, the fact that the preoperative laxity measurements were performed after either spinal or total anaesthetics and the postoperative measurements in a normal non-anesthetized state is a confounding factor as mentioned before. However, as we thought it unethical to re-apply spinal or total anaesthesia for the sole purpose of laxity measurements, this was the only way to perform the present study in our patients. Thirdly, our patient reported outcome scores were only available at six months postoperative. Therefore no long-term conclusion regarding outcome can be drawn from them. We conducted these surveys to evaluated patient reported instability before and after medial CWHTO. Since full-weight bearing without the use of walking aids was allowed after 4 weeks we believe that a normal walking pattern and reliable patient reported stability complaints can be obtained after 6 months. A last remark has to be made why we choose to perform a medial CWHTO. Our inclusion criteria were symptomatic valgus malalignment located in the proximal (high) tibia for which an indication for a medial CWHTO is the treatment of choice as deformities localized in the tibia need to be corrected in the tibia. In distal femoral valgus corrections the osteotomies are performed proximal of collateral ligaments attachments and no changes in ligament laxity will result from corrections in the femur. However, when a distal femur correction is performed in a patient with valgus localized in the tibia an unintended obliquity of the knee joint line will be created which may cause new complaints.

In conclusion, this study shows a significant increase in postoperative valgus laxity in 30° and 70° of flexion after medial closing wedge HTO which deems reconsidering addition of a MCL reefingplasty to the medial CWHTO although patient reported outcome on subjective stability scores fails to report increase of instability in this study population. Instrumented laxity measurements of medial CWHTO patients treated with additional medial reefingplasty should be performed to prove the value of this procedure.

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chapter 3

Medial closing wedge high tibial osteotomy for valgus tibial deformities: good clinical results and survival with a mean 4.5 years of follow-up in 113 patients

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ABSTRACT

Purpose

A varus-producing medial closing wedge high tibial osteotomy (MCWHTO) is an uncommon procedure. The aim of this retrospective study was to assess the survivorship and prevalence of post-operative subjective knee laxity and satisfaction in a large cohort of patients with a MCWHTO performed without a MCL-reefing procedure.

Methods

All patients (n = 176) who underwent a MCWHTO in our clinic between 2008 and 2016 were approached to participate. After review of patient charts, questionnaires were sent to willingly patients. Primary outcome was the survivorship of the MCWHTO; secondary outcome was patient-reported instability and satisfaction.

Results

One-hundred and thirteen patients participated in the study. The 5-year survival rate of the MCWHTO was almost 80%. A total of 77% of the patients was satisfied with the treatment. With regard to post-operative subjective knee laxity, 26% of the patients experienced instability of the knee post-operation. Instability was significantly correlated with the KOOS domains, the Lysholm score, the IKDC knee function score and the Physical and Mental Health Domains of the SF-36.

Conclusion

Medial closing wedge high tibial osteotomy provides good results regarding survivorship and patient satisfaction for patients with a valgus deformity which is located in the proximal tibia. Clinically relevant is that in the surgical technique without MCL-reefplasty instability is significantly correlated with worse patient-reported outcome measures. The addition of a MCL reefing procedure will improve outcome in selected patients.

INTRODUCTION

High tibial osteotomy (HTO) is a surgical method to correct malalignment of the leg and has proven to be a good therapeutic option for delaying and potentially preventing the progression of knee OA. HTO is most favorably performed in the more active and younger patient in whom total knee arthroplasty (TKA) is less desirable (W-Dahl, Robertsson, and Lohmander 2012).

Osteotomy procedures for varus malalignment are frequently performed. Valgus malalignment deformity of the knee, however, is much less frequent (2-2.8%) (Bellemans et al. 2012). The corrective procedure, i.e. a varus-producing osteotomy in these valgus knees, is most often performed in the distal femur (Haviv et al. 2013; Puddu et al. 2010). Correction in the proximal (or high) tibia is much less common. However, if the valgus leg deformity is located in the tibia, the correction should be performed in the tibia to prevent an abnormal knee joint line obliquity (van Egmond et al. 2017; Hofmann S, Paszicneyk T 2004). Besides the lateral open wedge HTO technique alternatively, a medial closing wedge HTO (MCWHTO) can be performed to correct the valgus leg alignment (Cerciello et al. 2017; Chambat et al. 2000).

A recent study by Mirouse et al. showed unsatisfactory medium-term outcomes for high tibial varus osteotomies (Mirouse et al. 2017). In 19 consecutive patients they reported an overall failure rate of 52% at mean follow-up of 4.3 years and they concluded that this procedure should not be performed in valgus osteoarthritic patients. In contrast, good clinical scores were reported previously in a gait analysis study showing kinetics and kinematics of gait after a varus producing HTO similar to that of a healthy control group (van Egmond et al. 2017). Furthermore, in a recent prospective short term study investigating laxity after MCWHTO performed in our own clinic, significant short term improvements in patient-reported outcome scores, such as knee pain, functioning and quality of life (QoL) were found in all 11 patients (van Lieshout et al. 2018). However, also increased MCL laxity at mean 6 months post-operation was found which urged us to review our MCWHTO-patient population.

The medial collateral ligament laxity has been found to increase in instrumented laxity measurements performed pre- and post-operatively after MCWHTO (van Lieshout et al. 2018). The risk of increased laxity after MCWHTO had been described by Coventry in the past. He stated that, by removing a bony wedge on the medial side of the proximal tibia, a laxity of the superficial medial collateral ligament (MCL) is introduced and he, therefore, suggests to perform a surgical reefing procedure at all times to tighten the MCL (Coventry 1985; Coventry 1987). Historically, in our clinic no reefing procedures of the MCL have been performed during MCWHTO as wedge removal was performed below the level indicated by other authors. Therefore, the complete deep MCL and part of the superficial MCL inserts proximal of the osteotomy cuts and instability has not been a common complaint by our patients after these procedures.

The aim of this retrospective study was to assess the survivorship and prevalence of subjective knee laxity in a large cohort of patients who underwent MCWHTO without MCL-reefing-plasty. We hypothesize that subjective knee laxity does not occur more often in MCWHTO without MCL-reefingplasty compared to historic MCWHTO cohorts with reefingplasty and, therefore, we expect comparable outcomes regarding patient satisfaction and survival. In addition, the possible relationships between instability and knee pain, functioning and QoL were explored. Furthermore, we tried to identify possible factors that may influence knee instability post-operation.

Materials and methods

All patients older than 18 years who underwent a unilateral or bilateral varus-producing MCWHTO between 2008 and 2016 in the Sint Maartenskliniek were selected from the hospitals electronical medical record system. Minimal follow-up was set at 6 months. Since full weight-bearing without the use of walking aids was allowed after 4 weeks, reliable outcomes can be expected at this follow-up time. The surgery criteria were symptomatic valgus malalignment located in the proximal tibia, indication for a medial CWHTO, based on the severity of the complaints and the observed deformity according to Paley (Paley 2002). Patients were excluded if they had a double-level osteotomy of the knee, were lost to follow-up after the surgery, had an amputation of the operated leg, underwent a medial reefing procedure, initially or after the MCWHTO or were deceased. Patients were contacted by telephone and asked if they were willing to participate in the study, including a telephone survey and a questionnaire. If patients were not available by phone after multiple attempts, background information and questionnaires were sent by mail. This study was approved by the local Medical Research and Ethical Committee of the Maartenskliniek Woerden. Medical ethical approval number: (0665).

Surgical technique

The operations were performed by three different orthopaedic surgeons using the same technique consisting of oblique transverse cuts and a biplanar tuberosity cut correcting to neutral mechanical alignment (Fig. 1). The osteotomy site is located at approximately 4 cm below the medial tibia plateau and runs oblique towards the tip of the fibula. The biplanar tuberosity cut is performed in a proximal direction to ensure compression on the osteotellar tendon. Fixation after closure was performed with an angle-stable Tomofix plate. The location of the wedge removal is distal to the attachment of the deep part of the MCL and just within the attachment of the superficial part of the MCL on the medial proximal tibia

(LaPrada et al. 2007). Post-operative full weight-bearing was allowed directly post-operation. After 4 weeks no walking aids were mandatory.

Fig 1. Pre- and post-operative radiographs of a medial closing wedge high tibia osteotomy.
The pre-operative alignment is shown in the long-leg radiograph (A). The osteotomy pre- and post-operative views in the coronal plane are shown in B and C. D, E, show the lateral view of the pre- and post-operative knee. In D the biplanar tuberosity cut is clearly shown.

Measurements

When the patient agreed to participate, patient charts were consulted to gather information about the patient's amount of correction, indication of surgery, re-operations, time to re-operation, and the occurrence of plate removal. Pre- and post-operative hip-knee-ankle angle measurements were made to the nearest 0.1° with use of the measurement tool within the radiographic database programme (Sectra workstation IDS7, version 16.1.22.1566 (2015), Sectra AB, Linköping, Sweden). During the telephone interview, patients were asked to indicate if they experienced instability of the operated knee at this moment and if they had experienced instability of the operated knee at the moment of full weight-bearing after surgery. Also, re-operations and the satisfaction about the result of the surgery were evaluated. Finally, patients were asked to fill in questionnaires, patient-reported outcome measurements (PROMs), documenting subjective knee laxity, functioning and quality of life.

The validated Dutch Knee Injury and Osteoarthritis Outcome Score (KOOS) was used to assess subjective knee function and quality of life and consists of five different subscales: (1) pain, (2) symptoms, (3) function in daily living, (4) function in sports and recreation, and (5) knee-related quality of life (de Groot et al. 2008; Roos and Toksvig-Larsen 2003). The score for each subscale was calculated, where 0 indicates severe knee problems and 100 indicates no knee problems. The validated Dutch International Knee Documentation Committee (IKDC) Subjective Knee Form was used to assess symptoms and limitations in function and sports. A higher score indicates a better function (0-100 scale) (Haverkamp et al. 2006; Irrgang et al. 2001). The IKDC Current Health Assessment Form (SF36 form) was used to measure health status with respect to different dimensions: (1) physical functioning, (2) social functioning, (3) role limitations due to physical problems, (4) role limitations due to emotional problems, (5) bodily pain, (6) mental health, (7) vitality, (8) general health perception, and (10) change in perceived health during the last 12 months. All raw scores were converted to a 0-100 scale, with higher scores indicating higher levels of functioning or well-being. The Lysholm knee scale was used to ment injuries of the knee (Eshuis et al. 2016; Kocher et al. 2004). In addition, patients were asked to fill in a NRS Instability, with a higher score indicating more instability of the operated knee at this moment (range 0-10).

Statistical analysis

Patient characteristics, feeling of instability and patient satisfaction with the treatment were analyzed descriptively and reported as means with standtions and ranges or as numbers and percentages. The Kaplan-Meier method was used to estimate the probability of survival of the MCWHTO. Failure of the MCWHTO was defined as a redo HTO or TKA. The NRS Instability score were compared between (1) patients who at the time of the survey experiencing instability of the operated knee and patients who did not, (2) patients with a post-traumatic indication for correction and patients who had not, and (3) patients who had a redo HTO or TKA and patients who had not. Mann-Whitney U tests were used for the analysis. The correlation between the amount of post-operatively correction in mm and the severity of knee instability as measured with the NRS Instability score was analyzed using Spearman's correlation. To assess possible relationships between the severity of knee instability as measured with the NRS Instability score and the (1) KOOS, (2) SF36 form and (3) Lysholm knee scale, also Spearman's correlation was used.

Results

A total of 176 patients underwent a unilateral or bilateral varus-producing MCWHTO between 6 in the Maartenskliniek Woerden. Indications varied from valgus leg deformity acquired after growth disorders without osteoarthritis, post-meniscectomy lateral compartment osteoarthritis, primary lateral compartment osteoarthritis, post-traumatic lateral osteoarthritis after malunited tibia plateau fractures, and salvage realignment procedures preceding TKR placement. Figure 2 shows the flow diagram of patients included in the study. Of the 142 patients who were approached, 113 patients (80%) agreed to participate in the study. Patient characteristics are given in Table 1. Mean age was 50 years (SD 11.5); two-thirds

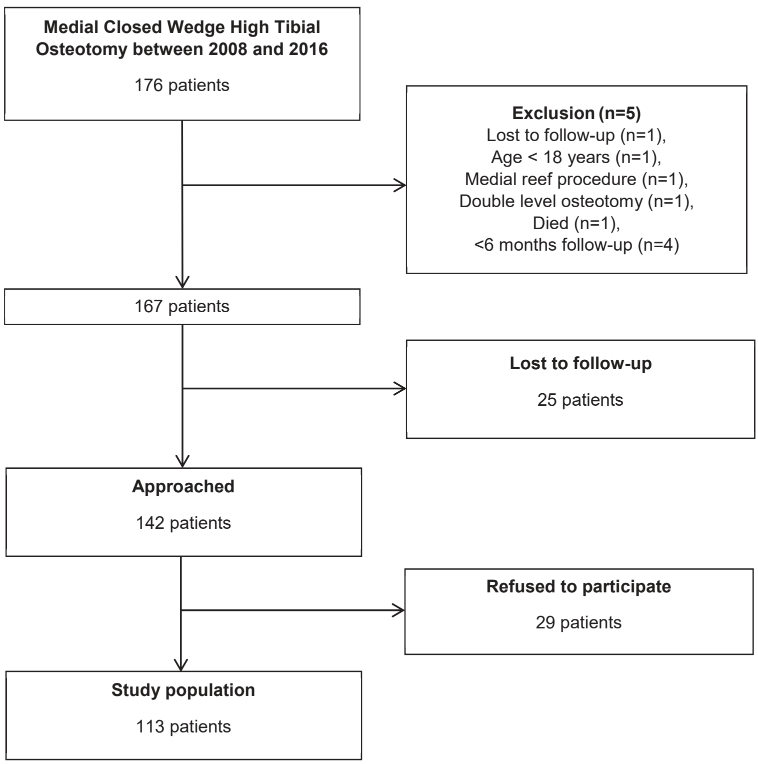

Fig 2. Flow diagram of patients included in the study

Table 1 Patient characteristics

Patient characteristics	N=113
Sex, n (%)	
Male	35 (31%)
Female	78 (69%)
Age, mean (SD, range min-max) in years	50 (11.5, 20-71)
BMI, mean (SD, range min-max) in kg/m2	27 (4.4, 18-39)
Time postoperative, mean (SD, range min-max) in months	56 (38.4, 6-202)
HKA angle pre[a], mean (SD, range min–max) in degrees	5.9° (4.3, − 1 to 18)
HKA angle post[b], mean (SD, range min–max) in degrees	− 0.1° (3.4, − 7 to 12)
Work, n (%)	
Yes	83 (73%)
No	28 (25%)
Missing	2 (2%)
Smoking, n (%)	
Yes	19 (17%)
No	94 (83%)
Sports, n (%)	
Regularly	27 (24%)
Sometimes	42 (37%)
Not at all	44 (39%)
Satisfied with the treatment, n (%)	
Yes	88 (78%)
No	14 (12%)
Don't know	1 (1%)
Missing	10 (9%)
Recommend to others, n (%)	
Yes	88 (78%)
No	12 (10%)
Don't know	3 (3%)
Missing	10 (9%)

BMI body mass index, HKA hip–knee–ankle angle
a n = 105
b n = 79

of the patients were female (69%). The hip-knee-ankle (HKA) angle was changed from a pre-operative mean of 5.9° valgus (SD 4.3) to a mean of 0.1° varus (SD 3.4) post-operatively. The mean time post-surgery was 56 months and varied from 6 months to almost 17 years. The majority of the patients reported to have a job (74%) and a small majority participated in sports (62%).

Knee laxity

A total of 28 patients experienced instability of the operated knee at the time of the survey. 27 patients indicated that they experienced instability of the operated knee starting at the moment of full weight-bearing after surgery (see Table 2). 19 out of the 27 pients who experienced instability of the operated knee after surgery still experienced knee instability at follow-up. 66 out of the 74 patients that did not experience instability of the operated knee after surgery still had no instability complaints at follow-up. The remaining eight patients developed instability over time. There was a significant difference in NRS Instability score between patients who were currently experiencing instability of the operated knee and patients who were not: 6.7 (± 2.4) and 3.2 (± 2.7) ($p<0.01$).

Further subgroup analysis based on indication for surgery showed no significn NRS Instability scores between patients with a post-traumatic or salvage indication for correction and patients in any of the other indication groups: 4.5 (± 3.2) and 4.2 (± 3.0) (n.s.). No correlation was found between the amount of post-operative correction and the severity of knee laxity as measured with the NRS Instability score.

Table 2 Knee instability at two different time moments

Knee laxity	Post-operation	At time of survey
Yes, *n* (%)	27 (24%)	28 (25%)
No, *n* (%)	74 (65%)	74 (65%)
Don't know, *n* (%)	2 (2%)	1 (1%)
Missing, *n* (%)	10 (9%)	10 (9%)

Re-operations and survival

A total of 39 patients underwent at least one type of re-operation in our clinic or elsewhere. The type of operation was either an arthroscopy of the ipsilateral knee (n=22), a redo HTO due to overcorrection (n=3) or total knee arthroplasty (TKA, n=14). Year of re-operation was missing in ten patients. A subgroup analysis for time to re-operation showed 19 patients with a re-operation <2 years versus 10 patients with a late re-operation. No significant difference in NRS stability was found between these two groups: 4.8 (± 2.7) vs 6.3 (± 3.3) (n.s.).

Failed MCWHTO was present in 17 patients after a mean of 3.0 (± 2.6) years (n=16, year of redo HTO/TKA is missing in 1 patient). The NRS Instability score was not different between patients who had a redo HTO or TKA and patients who had not: 4.6 (± 3.3) and 4.3 (± 3.0) (n.s.). The 5-year survival without a redo HTO or TKA was 79.9% (Fig. 3). A total of 5 out of the 17 patients with a failed MCWHTO indicated that they experienced instability of the operated knee post-surgery. There was no difference in the prevalence of failed MCWHTO between patients with or without instability of the operated knee post-surgery (n.s.).

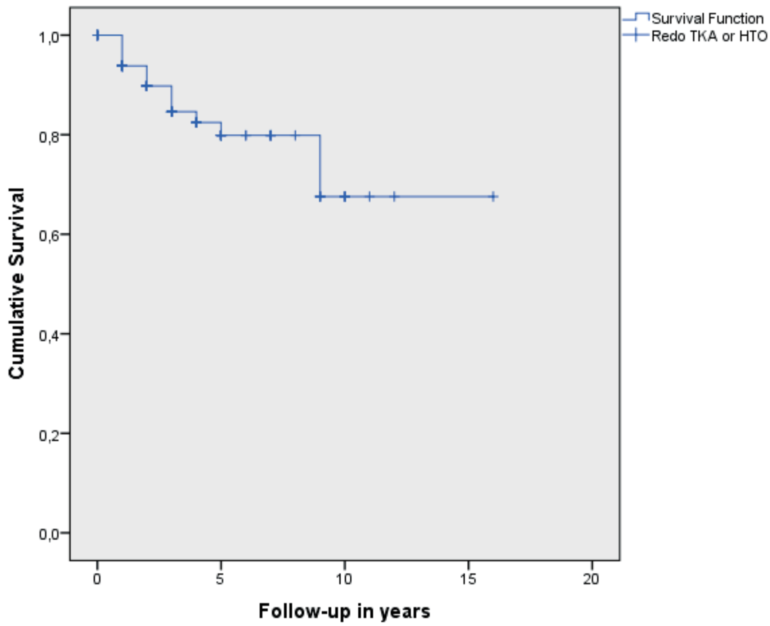

Fig 3. Kaplan-Meier curve illustrates the survival of the Medial Closed Wedge High Tibial Osteotomy. Five-year survival rate was 79.9% ±5.2% (95% CI).

Patient-reported outcome and correlation to knee instability

Table 3 shows the mean outcome scores in functioning and quality of life for the KOOS, SF36 and Lysholm knee scale. Knee instability was significantly correlated with the KOOS domains, the Lysholm score, the IKDC knee function score, and the Physical and Mental Health Domains of the SF36, indicating a higher subjective knee laxity score is being associated with worse scores on knee functioning and health status (Table 4).

The majority of the patients, 88 out of the 113 (78%) were satisfied with the surgery and would recommend the treatment to others, (see Table 1). Patients that were satisfied with the surgery had a significantly lower NRS Instability score compared to patients who were not satisfied: 3.81 (± 3.0) and 6.58 (± 2.2) ($p<0.01$). Patients who underwent a re-operation were significantly less satisfied compared to those patients who did not need a re-operation ($p=0.02$).

Table 3 Mean scores (SD, ranges) for KOOS, IKDC, SF36 form and Lysholm knee scale

Outcome score	*N*=113
KOOS	
Pain	68.7 (24.4, 8-100)
Symptoms	67.5 (21.0, 7-100)
ADL	73.5 (22.6, 15-100)
Sport/Rec	31.7 (30.5, 0-100)
QOL	48.0 (25.8, 0-100)
IKDC	
IKDC knee function score	54.5 (21.7, 9-99)
SF-36 form	
Physical functioning	65.7 (25.8, 5-100)
Role physical	70.4 (40.0, 0-100)
Body pain	58.0 (26.6, 0-100)
General health	63.1 (20.7, 10-100)
Vitality	61.9 (19.9, 15-100)
Social functioning	74.7 (24.4, 13-100)
Role emotional	82.3 (35.4, 0-100)
Mental health	76.5 (17.6, 32-100)
Physical Health Domain	*63.8 (20.8, 12-96)*
Mental Health Domain	*71.7 (18.7, 15-99)*
Lysholm	
Lysholm score	64.5 (22.5, 12-100)

KOOS Knee Injury and Osteoarthritis Outcome Score, IKDC International Knee Documentation Committee, SF-36 Short Form 36, ADL activities of daily life, QoL quality of life

DISCUSSION

The most important finding of the present study was that the 5-year survival rate of MCWHTO's performed without MCL-reefingplasty was almost 80%. This is the largest cohort study to date to analyze patients who underwent a medial closing wedge high tibial osteotomy and a total of 78% of the patients was satisfied with the treatment. With regard to post-operative knee laxity, 25% of the patients experienced instability of the knee post-operative at the start of full weight-bearing and 70% remained to have instability complaints at 4.5-year follow-up. A negative correlation was found between instability and PROMs. No factors could be identified that could predict knee instability post-operation.

The 5-year survival rate of the present study (79.9%) shows a far better result compared to the 57.5% presented in the recent study by Mirouse et al. (Mirouse et al. 2017). The only other study that published results with regard to survival rate after medial CWHTO is the

Table 4 Spearman correlation coefficients for the relationships between subjective knee laxity and outcome measurements

Outcome score	**NRS knee instability**	
	Rs	***p*-value**
KOOS		
Â KOOS pain	-0.64	< 0.01*
Â KOOS symptom	-0.54	<0.01*
Â KOOS ADL	-0.63	<0.01*
Â KOOS sports recreation	-0.66	<0.01*
Â KOOS QOL	-0.66	<0.01*
IKDC		
Â IKDC knee function score	-0.72	<0.01*
SF-36 form		
Â Physical health domain	-0.43	<0.01*
Â Mental health domain	-0.24	0.01*
Lysholm		
Â Lysholm score	-0.70	<0.01*

KOOS Knee Injury and Osteoarthritis Outcome Score, *IKDC* International Knee Documentation Committee, *SF-36* Short Form 36, *ADL* activities of daily life, *QoL* quality of life
*Significant (<0.05) correlation

study by Coventry (Coventry 1987). He reported seven failures in 31 osteotomies (22.6%): one unicondylar prosthesis implantation 1 year after the osteotomy and six TKA placements with a mean time to re-surgery of 9.8 years. The high failure rate in the study of Mirouse et al. may for the MCWHTO with disregard to the deformity evaluation. If the valgus deformity is in the femur and the correction is made in the proximal tibia, this will inflict joint line obliquity and may lead to persistent pain and HTO failure (Coventry 1987; Shoji and Insall 1973). As Coventry already stated in 1987: the final decision of whether to do an osteotomy of the proximal part of the tibia or of the distal part of the femur depends on the assessment of both the anatomical axis and the tilt of the tibial plateau. One must not be considered without the other (Coventry 1987). The present study shows that with proper patient selection, paying attention to deformity analysis and only indicating patients with a tibial valgus deformity for a MCWHTO, the survivorship after MCWHTO seems within well acceptable limits. Furthermore, a gait analysis study on three patient groups after varization osteotomies correcting valgus leg alignment confirms the importance of leg correction at the location of the deformity preventing an abnormal joint line obliquity (van Egmond et al. 2017).

The prevalence of patient-reported knee laxity (25%) in this study is slightly higher than found in previous studies. Only two studies have studied this matter. Coventry assessed the knee laxity at 1-year post-operation after MCWHTO for 31 patients and documented four patients with marked laxity and 3 patients with a moderate laxity. This results in 22% laxity in their cohort. Coventry performed a reefing of the MCL in all his patients (Coventry 1987). Shoji and Insall reported on 49 knees after MCWHTO. They reported instability as the presence of a thrust while walking. Although the number of patients with a thrust was 30 out of the 49, only a total of 10 patients (20%) complained about instability post-operation. They performed a distal advancement of the MCL in only 5 of the 49 patients with satisfactory results for 3 patients (Shoji and Insall 1973). In this study, no MCL-reefingplasty has been performed in any of the patients and this may have resulted in a varus laxity as was previously shown in a cohort prospectively analyzed with instrumented laxity measurements (van Lieshout et al. 2018). As no objective laxity measurements had been performed pre-operatively and post-operatively in the patients of the present study, the subjective knee instability reported by the patients cannot be related to increased laxity caused by the MCWHTO. However, the lack of an MCL-reefingplasty in our patients might still explain the slightly higher prevalence of subjective knee instability in comparison with the other two studies. It remains uncertain whether all patients need an extra MCL-reefingplasty re-tensioning the MCL. Probably only those patients with clear per-operative MCL tension loss after wedge resection may benefit from this additional treatment.

A total of 78% of the patients was satisfied with the surgery and an equal amount would recommend this type of surgery to other persons. This result is in agreement with other studies. Coventry found major pain relief in 77% of his patients with a follow-up of 3-17 years (Coventry 1987). Shoji and Insall reported 28 patients (57%) who were satisfied and 21 unsatisfied patients, with persistent pain being the mean reason for dissatisfaction (Shoji and Insall 1973). They also noted that all of the 21 unsatisfied patients showed some form of instability. Another study by Chambat et al. reviewed 47 patients and reported a 'very good' or 'good' outcome with the Guépar score in 34 (72%) of their patients. The remaining 13 patients (28%) scored 'fair' and 'bad' but reflected patients with a very long follow-up (Chambat et al. 2000). In a recent study, Mirouse et al. described knee functional outcome in 19 patients after MCWHTO using the International Knee Society (IKS) score as primary outcome measure. They stated that an IKS score <140 was undesirable and found that only nine patients (47%) had a score of 140 or higher (Mirouse et al. 2017). However, as mentioned above inclusion criteria including valgus less than 10° for tibial correction irrespective of pre-operative valgus deformity in the femur are questionable and may cause worse results in their study. Using a lateral opening wedge varization HTO, an alternative to the MCWHTO technique described in the present study, Marti et al. reported an excellent or good knee score in 88% of their well selected patients with a mean follow-up of 11 years of 36 osteotomies (Marti et al. 2001).

Although we have found a good patient satisfaction in 88 of the 113 cases (78%), still almost a quarter of the patients indicated to be dissatisfied. We have shown that the patients who were dissatisfied with the surgery showed significant lower NRS instability scores compared to the satisfied patient group, so patient satisfaction may be influenced by knee instability. This result is also visible in the significant negative correlations regarding the PROMS. Almost all analyzed PROMS showed fair to strong negative correlation with subjective knee laxity reported by the patients. The key element, therefore, will be to identify which patients will be prone to develop this knee instability and may benefit from the reefing procedure of the MCL as was previously described by Coventry (Coventry 1985; Coventry 1987). However, to date no predictable model is available to select those patients who would benefit from this extra procedure. Therefore, we suggest that the surgeon intra-operatively checks the valgus laxity in flexion angles of 30° and 70° before and after performing the MCWHTO and if deemed necessary performs a reefingplasty of the MCL. This might prevent instability complaints post-operation and thereby might increase overall patient satisfaction.

The current study has some limitations. The retrospective nature is less reliable for evaluating patient outcome, especially the directly post-operative experienced subjective knee laxity. For some patients this was more than 10 years ago. Moreover, the wide range in follow-up, 6 months-17 years, is less reliable for survival analysis. Ideally, a minimal 2 years of follow-up would provide some more information with regard to early failure rates (within 1 year). However, due to a very limited number of studies regarding the varus-producing HTO, we believe this study will still contain valuable information to prove that a MCWHTO is a viable treatment option for patients with a tibial valgus deformity. Especially, long-term survival, outcome scores and subjective knee laxity after a MCWHTO without MCL-reefingplasty are of interest in answering our hypothesis. Another limitation is the rather large loss to follow-up group and the number of patients that were not willing to participate. We were only able to approach 142 patients of the total 167 eligible patients, and 113 of the 142 were willing to participate. This might inflict a bias in outcome. What the effect of this bias may be is hard to predict. Either really dissatisfied patients may refuse to participate or very satisfied patients for whom the operation was performed a long time ago. Therefore, we have assumed that the results are a good reflection of the cohort that was operated on between 2008 and 2016. Moreover, being the largest cohort on this type of surgery this study is clinically relevant as only a few studies with low patient numbers and conflicting results are available in the literature. Furthermore, this study has shown that a medial closing wedge HTO improves knee function and decreases complaints in a diverse population of patients with a tibial valgus malalignment. Instability possibly caused by increase of laxity after MCWHTO correlates negatively with outcome so intra-operative laxity testing is advised after MCWHTO, as an additional MCL-reefingplasty in patients with increased laxity may improve outcome.

CONCLUSION

This study shows that a medial closed wedge high tibial osteotomy without medial reefing-plasty provides good results regarding survivorship and patient satisfaction for patients with a valgus deformity located in the proximal tibia despite slightly higher subjective knee laxity findings post-operation. Instability is significantly correlated with worse outcome and, therefore, a MCL-reefingplasty can improve the outcome in selected patients with an increase in MCL laxity per-operatively and as a result this laxity should be tested during surgery.

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PART 2

ATHROPLASTY

Chapter 4

The negative effect of joint line elevation after total knee arthroplasty on outcome

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ABSTRACT

Purpose

Total knee arthroplasty (TKA) is widely used as a treatment for knee osteoarthritis. However, still up to 20% of the patients are dissatisfied. Joint line elevation after TKA might be a contributing factor as it alters knee kinematics. The aim of this study was to investigate the effect of joint line elevation on outcome.

Methods

A systematic review of the literature was performed to select studies that reported on joint line alterations after primary or revision TKA and outcome. Studies with comparable outcome parameters were included in a correlation analysis.

Results

In total, 396 studies were identified, of which 27 met the inclusion criteria. 8 studies could be included in the correlation analysis. Mean joint line elevation after primary TKA was 3.0 mm and after revision TKA this was 3.6 mm. A statistically significant negative correlation was found between joint line elevation and the postoperative Knee Society Score (KSS) function score ($\rho = -0.496$, $p < 0.001$). In a pooled analysis, the maintained joint line revision TKA group had statistically significant better postoperative KSS total scores compared to an elevated joint line group ($p < 0.001$).

Conclusion

In this systematic review, a negative correlation between joint line elevation and outcome was found. Furthermore, revision TKAs with a maintained joint line have statistically significant better postoperative KSS scores compared to an elevated joint line group. To achieve optimal outcome after TKA, restoration of the joint line is one of the parameters that should be pursued and introduced elevation should not exceed 4 mm.

INTRODUCTION

Satisfaction after Total Knee Arthroplasty ranges between 75 to 90% (Bourne et al. 2010; Choi and Ra 2016; Clement et al. 2018; Lange et al. 2018). Different contributing factors for dissatisfaction after TKA have been identified like socioeconomic status, mental wellbeing, fulfilment of expectation and the post-operative general physical health of the patient (N. D. Clement 2013). From a surgical point of view joint line elevation, among other factors, is considered to have a negative effect on postoperative outcome since it alters the biomechanics of the knee. By changing the centre of rotation of the knee, the isometry of the Medial Collateral Ligament (MCL) is changed, with mid-flexion instability as a result (Cross et al. 2012; Thomas Luyckx et al. 2018). In addition, as a consequence of the elevated joint line, the posterior condylar offset (PCO) is likely to be reduced, which negatively influences flexion angle and the extensor mechanism strength, and resolves in mid-flexion instability (Bellemans et al. 2002; Martin and Whiteside 1990; Matziolis et al. 2017).

Mean joint line elevation after primary TKA varies between 1.1mm up to 5.6mm (Selvarajah and Hooper 2009; Snider and Macdonald 2009). For revision TKA this number is even higher, up to a mean of 8mm (Partington et al. 1999). Some studies report a correlation between a raised joint line and patient reported outcome measures (PROMs) (Clavé et al. 2016; Figgie et al. 1986; Partington et al. 1999), while others do not find this correlation (Yang et al. 2009). Therefore, there is still debate if minor joint line elevation affects PROMs after TKA (Selvarajah and Hooper 2009), and if so, what amount of joint line elevation is acceptable after TKA.

Therefore, the aim of the present study was (1) to examine the effect of joint line alteration on outcome measures after primary and revision TKA and (2) to investigate whether practical recommendations can be made concerning acceptable joint line alterations after (revision) TKA.

MATERIALS AND METHODS

Identification of studies

A systematic literature search was performed with the help of a clinical librarian. Search terms were: knee arthroplasty, knee replacement, knee surgery, TKA, joint line, outcome, joint instability, knee kinematics, range of motion. The following databases were searched: PubMed/Medline, the Cochrane Clinical Trial Register, and Embase. The search was limited to English, German, Dutch and Spanish languages without limitation of publication date. The search was performed August 2017. The reference lists of the included studies were searched for any studies that might potentially meet the inclusion criteria.

Inclusion and exclusion

PRISMA methodology was used for the analysis and reporting of the systematic review (Moher et al. 2009). Titles and abstracts from potentially relevant studies were reviewed using a set of predefined inclusion and exclusion criteria. Studies were included when they reported both joint line alterations after TKA surgery and an outcome measurement. Both primary as well as revision TKA studies were included in our study. Studies reporting on (revision) uni-compartmental knee arthroplasty and knee arthroplasty after high tibial osteotomy (HTO) were excluded.

Two reviewers (WvL and KV) independently screened the titles and abstracts of the studies that could meet the inclusion criteria. A list of studies to be reviewed in full text was composed from the input of both reviewers. Finally, these selected full text studies were judged on in- and exclusion criteria and a definite selection of studies was made. Disagreement in the selection process was debated on and, if necessary, resolved in a group discussion with the third author (KK).

Data extraction

The following data was extracted from the included studies: number of TKAs, patient demographics, primary or revision TKA, type of prosthesis [cruciate retaining (CR), posterior stabilized (PS)], method of joint line assessment, mean joint line alteration, outcome scores and follow up time. The methodological quality of the included studies was assessed by assigning levels of evidence as defined by the Oxford Centre for Evidence-Based Medicine (Howick et al. 2011). Levels of evidence were assigned by two reviewers (WvL and KV). Disagreement was resolved by consensus. A grade of recommendation was added to our findings based on the methodological quality of the included studies in the systematic review (Guyatt et al. 2008).

Statistical analysis

Statistical analysis was done using IBM SPSS version 24.0. In the analysis, the joint line alteration and TKA outcome scores were weighted by the number of patients. Normal distribution was evaluated by frequency histograms. Degree of correlation (with 95% confidence intervals (CIs)) between mean postoperative joint line alteration and outcome scores was calculated. The preferred test for correlation analysis depends on the distribution of the data; for normally distributed data, Pearson's correlation is used, for not normally distributed data Spearman's rho is used. Significance was set at the 1% (0.01). A small effect size is defined as ρ between 0.10 and 0.30, a medium effect size as ρ between 0.30 and 0.50, and a large effect size is operationally defined as one that yields $\rho \geq 0.50$ (Cohen 1988). An independent-sample t-test (confidence interval 95%) was used to compare the outcome of revision TKA groups with the joint line maintained versus elevated.

Registration

The systematic review was registered in the Prospero Database CRD42017057320.

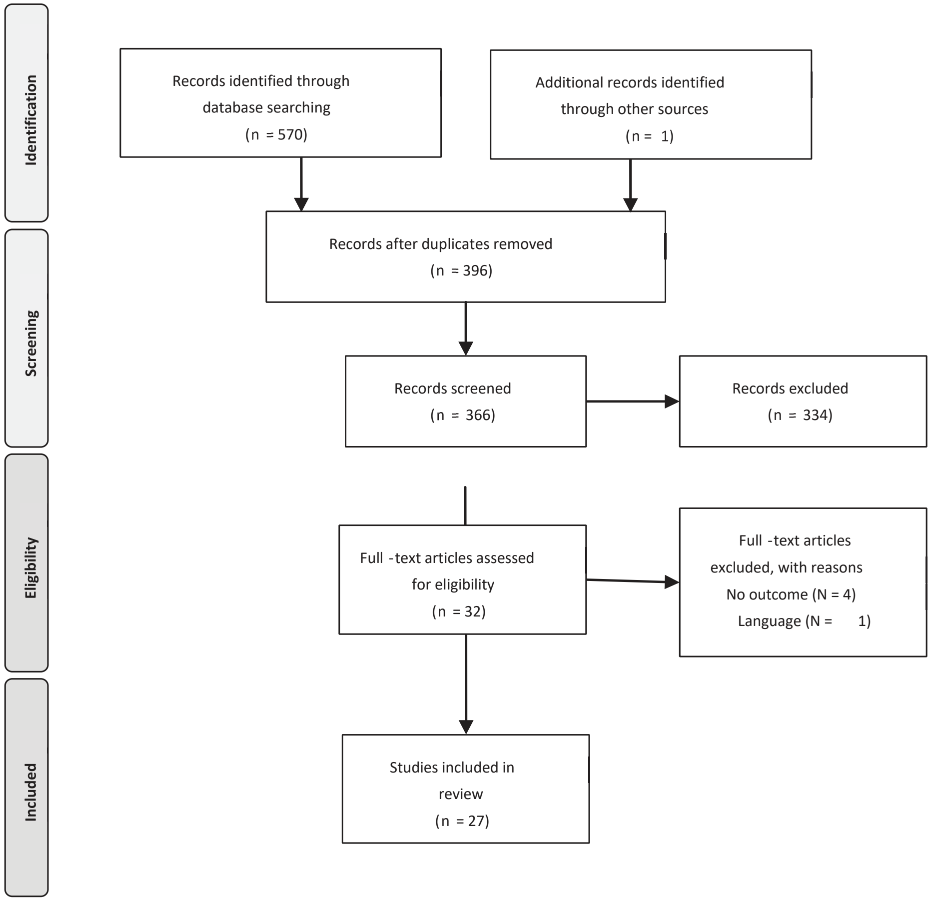

Fig 1. Flowchart Systematic review

Results

After performing the search 396 studies were identified. A total of 27 studies met the inclusion criteria and were included (Fig 1) (Bin Abd Razak et al. 2013; S Babazadeh et al. 2011; Sina Babazadeh et al. 2014; Bae et al. 2017; Bieger et al. 2014; Clavé et al. 2016; N. Clement and MacDonald 2017; Figgie et al. 1986; Goh et al. 2016; Hofmann et al. 2006; Huang et al. 2014; Ji et al. 2015; Kannan et al. 2015; Kawamura and Bourne 2001; Kazemi et al. 2011; H. J. Lee et al. 2011; Liow et al. 2014; Mahoney and Kinsey 2006; Pang et al. 2013; Partington et al. 1999; Porteous, Hassaballa, and Newman 2008; Ryu et al. 1993; Selvarajah and Hooper 2009; Seon and Song 2016; Snider and Macdonald 2009; Vera-Aviles and Jimenez-Aquino 2012;

Table 1. Study inclusion systematic review; study characteristics table

Study	Level of evidence	Study population	Primary/ Revision	Joint line assessment method	Joint line presentation	Outcome measurement	Follow up time
Bae 2017	II	32 TKA after HTO 32 TKA	Primary TKA	Fibular head	Absolute values	KSS, WOMAC	6 years
Babazadeh 2011	II	45 MR TKA 49 CAS TKA	Primary TKA	Fibular head; Adductor Tubercle	Absolute values and subgroups	KSS; SF12; ROM	2 years
Babazadeh 2014	II	52 MR TKA 51 GB TKA	Primary TKA	Resected bone vs. prosthesis thickness	Absolute values	KSS; SF12	2 years
Bieger 2014	IV	69 TKA	Revision TKA	Tibial Tubercle; Epicondyle Ratio	Subgroups	KSS	2 years
Bin Abd Razak 2013	III	195 CAS TKA	Primary TKA	Resected bone vs. prosthesis thickness	Absolute values	KSS; SF36; OKS; ROM	2 years
Clave 2016	III	85 TKA	Revision TKA	Fibular head; Contra lateral healthy side	Absolute values and subgroups	KSS	NA
Clement 2017	III	107 TKA	Revision TKA	Tibial tubercle	No absolute values	OKS, SF12	1 year
Figgie 1986	IV	116 MR TKA	Primary TKA	Tibial tubercle	Absolute values and subgroups	Mayo Clinical Knee Score; ROM	30-60 months
Goh 2016	III	38 CAS TKA 38 iAssist TKA	Primary TKA	Fibular head	Absolute values	KSS; OKS; ROM	6 months
Huang 2014	III	36 MR TKA 34 CAS TKA	Primary TKA	Tibial Tubercle	Absolute values	KSS; patella score; ROM	5-10 years
Hofmann 2006	IV	89 TKA	Revision TKA	Adductor Tubercle; Contra lateral side	Absolute values and subgroups	KSS	>2 years
Jie 2015	III	55 MR TKA	Primary TKA	Adductor Tubercle	Subgroups	KSS; patella score; ROM	1 year
Kannan 2015	IV	37 TKA	Revision TKA	Adductor Ratio	Absolute values	Modified KSS	NA
Kawamura 2001	III	73 TKA	Primary TKA	Fibular head	Absolute values	ROM	2 years
Kazemi 2011	IV	60 TKA	Primary TKA	Blackburn-Peel index	Subgroups	KSS; ROM	2 years

Lee 2011	III	15 NA-MR TKA 15 NA-GB TKA	Primary TKA	Fibular head; Tibial tubercle	Absolute values	KSS; ROM	2 years
Liow 2014	II	31 CAS TKA 29 MR TKA	Primary TKA	Fibular head	Absolute values and subgroups	KSS; OKS; SF36; ROM	6 months
Mahoney 2006	IV	22 TKA	Revision TKA	Tibial Tubercle	Absolute values and subgroups	KSS	2 years
Pang 2013	III	100 MR TKA	Primary TKA	Fibular head; Tibial Tubercle	Absolute values	KSS; OKS; SF36	2 years
Partington 1999	IV	107 TKA	Revision TKA	Tibial Tubercle	Absolute values and subgroups	KSS	2 years
Porteous 2008	III	114 TKA	Revision TKA	Tibial Tubercle	Subgroups	Bristol Knee Score	1 years
Ryu 1993	IV	90 MR TKA	Primary TKA	Tibial Tubercle	Absolute values	ROM	25-90 months
Selvarajah 2009	IV	76 TKA	Primary TKA	Tibial Tubercle	Absolute values	Modified KSS;ROM	>30 months
Seon 2016	IV	74 TKA	Revision TKA	Fibular head	Absolute values	KSS; WOMAC	NA
Snider 2009	IV	200 TKA	Primary TKA	Fibular head; Tibial Tubercle	Absolute values and subgroups	KSS	2 years
Yang 2009	IV	50 CAS TKA	Primary TKA	Resected bone vs. prosthesis thickness	Subgroup	KSS; ROM	39-55 months
Vera 2012	III	32 TKA	Primary TKA	Adductor Tubercle	Subgroups	KSS; ROM	NA

MR: measured resection; TKA: Total Knee Arthroplasty; HTO: High Tibial Osteotomy; CAS: Computer Assisted Surgery; GB: Gab Balancing; NA: Navigation assisted; KSS: Knee Society Score; OKS: Oxford Knee Score; ROM: Range of Motion; WOMAC: Western Ontario and McMaster Universities Osteoarthritis

Yang et al. 2009). These studies were published between 1986 and 2017. A total of 18 studies reported on primary TKA and 9 on revision TKA. The level of evidence for the included studies was Level II for 4 studies, Level III for 11 studies, and the remaining 12 studies were classified as level IV.

A great diversity was found across papers in the way joint line deviation was measured (Table 1). Revision TKA joint line alteration is defined as the joint line position postoperative compared to either the preoperative or the healthy contra lateral knee joint line position. Studies that reported absolute joint line changes were combined to establish a mean joint line change after (r)TKA, see table 1 for eligible studies. For 1225 primary TKAs the mean joint line was raised with 3.0mm. For 355 revision TKAs the mean joint line elevation was 3.6mm.

Functional assessments were done with the Oxford Knee Score, Short Form 12 (SF-12), Short Form 36 (SF-36) and Knee Society Score (KSS). The KSS is divided in two separate components (knee and function) and some studies reported these two components separately and some presented the score in total. One study used the Mayo Clinical Score, one the Bristol Knee score and one used the patellar-score (Feller, Bartlett, and Lang 1996) to present their results. All studies reported an improvement in clinical scores after TKA. In most studies the patients were assigned to subgroups with related cut-off values for joint line alterations (i.e. joint line alterations <4mm or >4mm). In the group of studies on primary TKA, in 6 out of 18 studies statistically significant lower outcome scores were found when the joint line was elevated. In the group of studies on revision TKA, five out of nine studies reported statistically significant better outcome scores for patients with an adequately re-created joint line compared to those with an elevated joint line (i.e. joint line reconstruction within 4mm of the preoperative or healthy contra-lateral knee joint line height).

Eight out of 18 studies on primary TKA could be included in a correlation analysis of the postoperative KSS knee and function scores and postoperative joint line alteration (mm). The remaining 10 studies did not report absolute joint line alteration values or used a different outcome measurement. Seven studies (664 patients) compared two surgical techniques and in one study (32 patients) one treatment arm could be included in the correlation analysis (Table 2). The other arm contained patients with TKA after HTO which was an exclusion criteria. A statistically significant negative correlation was found between joint line elevation and postoperative KSS Functional score ($\rho = -0.496$, $p<0.001$, Fig 2) and KSS Total score ($\rho = -0.425$, $p<0.001$, Fig 3). No significant correlation was found between joint line and KSS Knee score ($\rho = -0.052$, $p=0.17$, Fig 4).

Table 2. Studies included for data correlation analysis for primary TKA

Study	Number of TKA	Mean JL alteration (mm) *	JL assessment method	KSS Knee score postop	KSS Function score postop
Bae 2017	32	-1.6	Fibular head	89.4	88.8
Babazadeh 2014	52	-1.5	Resected bone	83.1	71.6
	51	2.1	Resected bone	84.4	71.3
Bin Abd Razak 2013	112	1.7	Resected bone	86.2	72.7
	83	2.3	Resected bone	86.4	71.8
Goh 2016	38	2.2	Fibular head	75.6	72.2
	38	2.3	Fibular head	79.8	70.8
Huang 2014	34	1.3	Tibial tubercle	96.7	96.3
	36	2.2	Tibial tubercle	95.2	94.6
Lee 2013	30	2.2	Tibial tubercle	95.1	96.2
	30	3.8	Tibial tubercle	94.6	95.5
Liow 2014	31	1.9	Fibular head	80.8	71.3
	29	3.5	Fibular head	82.6	70
Pang 2013	50	2.4	Tibial tubercle	86.9	66.2
	50	8	Tibial tubercle	84	48

* *negative values represent joint line decrease ; positive values represent joint line elevation*
TKA: Total Knee Arthroplasty; JL: Joint Line; KSS: Knee Society Score

Table 3. Studies NOT included for data correlation analysis for primary TKA

Study	Outcome measurement	Joint line method / cut-off value	Findings regarding joint line elevation and outcome
Babazadeh 2011	KSS, SF12	Maintained within 2mm, depressed of elevated	KSS: Significantly higher changes in KSS total and KSS sub scores in maintained joint line group SF12: no differences between subgroups
Figgie 1986	Mayo Clinic Knee score	Absolute measurements and <8mm or >8mm	Negative correlation between joint line elevation and outcome rho -0.42 (p=0.0001)
Jie 2015	KKS	>4mm	lower scores for >4mm joint line elevation compared to the literature
Kazemi 2011	KSS	Pseudo-patella Baja and/or patella baja vs no patella baja	No differences between the subgroups for KSS Total score. Significant lower KSS pain scores for no patella baja group
Selvarajah 2009	Modified KSS	Absolute measurement	No statistical correlation between joint line elevation and outcome
Snider 2009	KSS	<8mm or >8mm	Non-significant better total KSS scores for maintained joint line group (p=0.17)
Yang 2009	KSS	<3mm or >3mm	No differences between subgroups
Vera 2012	KSS subscales (poor, regular, good, excellent)	<4mm or >4mm	Statistically significant better postoperative score for KSS for maintained joint line group

TKA: total knee arthroplasty; KSS: Knee Society Score; SF12: Short Form 12

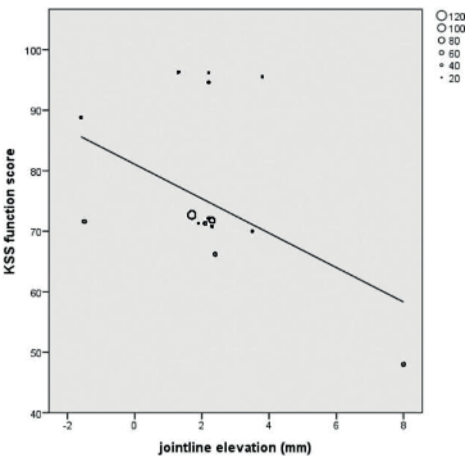

Fig 2. Correlation analysis KSS Function versus joint line alteration in primary TKA

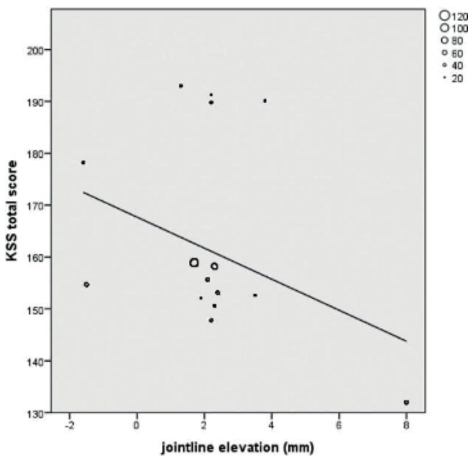

Fig 3. Correlation analysis KSS Total versus joint line alteration in primary TKA

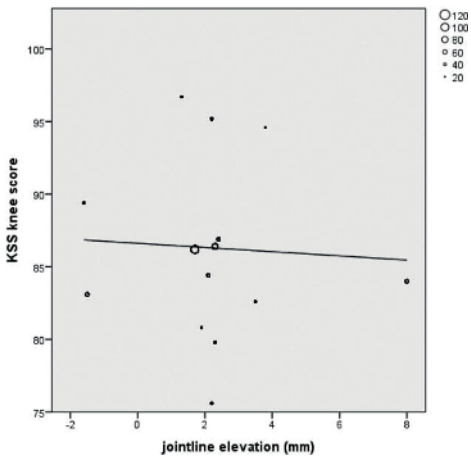

Fig 4. Correlation analysis KSS Knee versus joint line alteration in primary TKA

Other PROMs presented in the included studies were SF-36 and OKS. Only the study by Liow et al. reported a statistically significant result. In their subgroup analysis (<5mm or >5mm joint line shift) the elevated joint line group had a statistically significant lower physical function in the SF-36 questionnaire (45 vs. 67) (Liow et al. 2014). No significant differences between joint line position subgroups and OKS outcome were reported. The results of the remaining studies that could not be included in the correlation analysis are presented in Table 3. Regarding range of motion (ROM) a wide variety with regards to the notification was observed (i.e. absolute ROM, delta ROM, only maximum flexion) which limited further analysis. Two studies reported ROM as their sole outcome measurement and therefore, are not presented in Table 3 (Kawamura and Bourne 2001; Ryu et al. 1993).

Nine studies reported TKA revision outcome data with joint line measurement. (Table 4) Indications for revision were infection, aseptic loosening, instability, polyethylene wear, pain and/or stiffness or peri-prosthetic fracture. No studies reported TKA revision for joint line elevation as its sole reason. Due to heterogeneity of joint line measurements and outcome data no correlation-analysis could be performed. In four studies patients with a maintained joint line (i.e. <4mm, <5mm or <8mm joint line elevation) were compared to patients with an elevated joint line after revision TKA. In this analysis 187 pooled patients in the maintained joint line group were compared with 96 patients in the elevated joint line group (Bieger et al. 2014; Clavé et al. 2016; Mahoney and Kinsey 2006; Partington et al. 1999). A statistically significant ($p<0.001$) higher postoperative total KSS score was found for the maintained joint line group (149; SD=10) compared to the elevated joint line group (129; SD=5). Of the five studies that could not be included in the pooled-analysis, two studies found better postoperative outcome scores for their maintained joint line group (Hofmann et al. 2006; Porteous, Hassaballa, and Newman 2008) and three studies did not find a significant correlation (N. Clement and MacDonald 2017; Kannan et al. 2015; Seon and Song 2016).

DISCUSSION

The most important finding of the present study was that joint line elevation has a negative effect on outcome after TKA. A statistically significant negative correlation between joint line elevation and the KSS functional and total score after primary TKA was established. For revision TKA it was found that a correctly re-created joint line results in statistically significant better postoperative KSS total scores, compared to knees in which the joint line was not adequately re-created.

The statistically significant negative correlation between postoperative joint line elevation and KSS functional scores for primary TKAs is in accordance with several studies that could not be included in the correlation analysis (S Babazadeh et al. 2011; Figgie et al. 1986; Ji et al. 2015; Snider and Macdonald 2009; Vera-Aviles and Jimenez-Aquino 2012). Four studies did not find a correlation between joint line elevation and outcome scores (Bin Abd Razak et al. 2013; Sina Babazadeh et al. 2014; Goh et al. 2016; Yang et al. 2009). These four studies reported only minor mean joint line elevation postoperative (0- 2.3mm). Studies with a larger range in joint line alteration and those who chose a higher cut-off value for joint line analysis did find differences in outcome (Figgie et al. 1986; Liow et al. 2014; Snider and Macdonald 2009; Vera-Aviles and Jimenez-Aquino 2012). In contrast, those with lower cut-off values (e.g. 3mm) did not find any difference in outcome (S Babazadeh et al. 2011; Yang et al. 2009).

Table 4. Revision TKA studies

Study	JL assessment method	Outcome measurement	Subgroup	Number of rTKA	Outcome KSS total	Knee score Postop	Function score Postop	P value
Bieger 2014	Medial Epicondyle ratio	KSS	< 5mm	46	164			<0.0001
			> 5mm	23	138			
	Tibial tubercle	KSS	< 5mm	24	157			0.819
			> 5mm	45	155			
Clave 2016	Fibular head	KSS	< 4mm	56	142	74	68	Knee non-significant Function 0.014
			> 4mm	25	130	71	59	
Clement 2017	Tibial tubercle	OKS, SF12	None	107				-
Hofmann 2006	Adductor tubercle	KSS	-4 to 4mm	59	-			0.04 between subgroups in favor of restored group
			<-4mm or > 4mm	17	-			
Kannan 2014	Adductor ratio	Modified KSS	-	37				0.58
Mahoney 2006	Tibial tubercle	KSS	-	22	158	90.7	66.8	Non-significant
Partington 1999	Tibial tubercle	KSS	< 8mm	107 knees in total	141			0.05
			> 8mm		125			
Porteous 2008	Tibial tubercle	Bristol Knee Score	< 5mm	73		83.7	20.3	Knee <0.01
			> 5mm	41		76.1	17.6	Function < 0.005
Seon 2016	Fibular head	KSS; WOMAC	NR	74				No correlation JL and outcome

JL: joint line ; rTKA: revision Total Knee Arthroplasty ; NR: not reported ; KSS: Knee Society Score ; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index;

Five out of nine studies reporting on revision TKAs found statistically significant better outcome scores for maintained compared to elevated joint line groups (Bieger et al. 2014; Clavé et al. 2016; Hofmann et al. 2006; Partington et al. 1999; Porteous, Hassaballa, and Newman 2008). In the pooled-analysis of four studies a statistically significant higher post-operative total KSS score was found for the maintained joint line group compared to the elevated group. This finding was in accordance with two studies that could not be included in this pooled analysis (Hofmann et al. 2006; Porteous, Hassaballa, and Newman 2008). The studies of Kannan et al. and Clement et al. reported no effect of joint line position on outcome, however, the joint line alteration was not specified (N. Clement and MacDonald 2017; Kannan et al. 2015). Seon et al. compared two-stage revision TKAs for prosthetic joint infection versus one-stage revision for other reasons. Their subgroup analysis for elevated joint line (>5mm) versus the maintained joint line group did not show any differences in outcome scores. However, this result is most likely influenced by the distribution of septic patients amongst their groups since the septic group reported statistically significantly lower outcomes (Seon and Song 2016).

It is questionable how much joint line elevation can be accepted. Several studies in primary as well as revision TKA have shown statistically significantly lower outcome scores when a cut-off value of 4mm joint line elevation is exceeded (Clavé et al. 2016; Hofmann et al. 2006; Vera-Aviles and Jimenez-Aquino 2012). Babazadeh et al. and Yang et al. used respectively 2mm and 3mm as cut-off point and they did not find any difference between their groups (S Babazadeh et al. 2011; Yang et al. 2009). Therefore, the aim should be to restore the joint line to its native position and not to accept more than 4mm of joint line elevation.

Some surgical aspects should be taken into consideration with regards to joint line preservation. Firstly, in case of distal femoral bone loss, the distal femoral bone cut should be reduced. Secondly, in case of a tight extension gap, it is advised to remove all posterior osteophytes before recutting the distal femur since posterior osteophytes tend to tighter up the posterior capsule and, consequently reduce the extension gap. Furthermore, Computer Assisted Surgery and Patient Specific Instruments can be supportive and promising results with regards to joint line reconstruction are being published (Bin Abd Razak et al. 2013; Goh et al. 2016; K.-J. Lee et al. 2012; Liow et al. 2014). In revision TKA, joint line restoration can be more challenging due to bone loss and the absence of landmarks to determine the original joint line height. Undersizing the femoral component should be avoided and distal and posterior bone loss should be accounted for with augments, thereby restoring the joint line position and the PCO (Bellemans 2004). The three-step technique described by Vince et al. can be a valuable tool to achieve these goals (Vince, Droll, and Chivas 2008). The medial adductor tubercle is identifiable in most cases and can be used for preoperative planning and perioperative reference (Sadaka et al. 2015). Preoperative planning, e.g. radiographs of the contralateral knee, can help the surgeon to determine the exact native joint line distance to this landmark before surgery (Bellemans 2004).

A major limitation of the current study was the heterogeneity of the data. For both joint line assessment as well as outcome measures a variety of measurements was reported. This impeded a correlation analysis of the TKA revision studies and of the primary TKA studies only 8 out of 18 primary TKA studies could be included. Furthermore, joint line assessment was performed with a variety of methods which could have influenced the results. However, all reported methods have acceptable inter and intra observer reliability (Bea et al. 2017; Iacono et al. 2013; Porteous, Hassaballa, and Newman 2008) and only absolute changes were used in the analysis, which in theory should be interchangeable between the methods. Most of the included studies used the KSS to evaluated patient outcome. It is questionable, however, if this questionnaire is a valid tool to identify symptoms related to joint line alterations (i.e. mid-flexion instability, loss of flexion due to loss of PCO). Functional tests like a 6 minute walk test and the stair climbing test have shown to correlate well with mid-flexion instability and might give better insight in functional outcome (Freisinger et al. 2017).

Although it was shown by Luyckx et al. that the use of ratio measurements (i.e. Medial epicondyle ratio, Adductor ratio) is more reliable and reproducible for joint line assessment and reconstruction in revision TKA (T Luyckx et al. 2014), most commonly the tibial tubercle or the fibular head landmarks are used for evaluating joint line position. These measurements, however, are affected by tibial slope change and if the joint line is only assessed from the tibial side, femoral sided joint line alterations are unrecognized. Therefore, the ideal joint line assessment would include a separate tibial and femoral referenced measurement. Since only one primary TKA (S Babazadeh et al. 2011) and one revision TKA study (Bieger et al. 2014) reported separate data for the femoral and tibial sided joint line alterations, a separate tibial and femoral analysis could not be performed. Interestingly, both studies illustrated discrepancies between tibial and femoral based joint line measurements. However, correlations of these measurements with outcome scores showed conflicting results. Due to the relatively low level of evidence of the included studies, a weak recommendation can be assigned to the suggested cut-off value of 4mm maximal acceptable joint line elevation.

CONCLUSION

In this systematic review a negative correlation between joint line elevation and outcome was found, with an elevation of more than 4mm resulting in statistically significant lower outcome scores. Hence, it is advised not to exceed 4mm of joint line elevation in primary TKA. For revision TKAs the aim should be to restore the joint line to its native height.

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chapter 5

Flexion First Balancer: description of new technique in TKA to reproduce joint line and pre-disease mechanical alignment

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ABSTRACT

A considerable proportion of patients (19%) are dissatisfied after total knee arthroplasty (TKA). Possible factors contributing to this dissatisfaction are decreased posterior condylar offset (PCO) with subsequent joint line elevation, leading to mid-flexion instability. Secondly, the pre-disease mechanical alignment is changed into a neutral alignment. The Flexion First Balancer was developed to avoid these problems. This technique aims to maintain MCL isometry by restoring medial PCO and medial joint line to its pre-disease level. Also, to reconstruct the pre-disease mechanical alignment by adjusting the distal femoral angle. In this study we provide a detailed technical overview of the Flexion First Balancer technique.

BACKGROUND

Total knee arthroplasty (TKA) is an effective surgical intervention for patients with knee osteoarthritis (Sugita et al. 2015). In order to achieve optimal function and a stable TKA, a well-balanced knee in flexion and extension is essential. This is achieved by creating a symmetrical flexion and extension gap (Laskin 1995), restoring the native joint line (Martin and Whiteside 1990) and reaching a neutral mechanical axis (Fang, Ritter, and Davis 2009; M. A. Ritter et al. 1994). The two main surgical philosophies in achieving a balanced neutrally aligned TKA are the measured resection technique and the balanced gap technique (Daines and Dennis 2014). Both of these provide comparatively positive results and are widely accepted (Singh et al. 2012). Despite this, 19% of the TKA patients are dissatisfied (Bourne et al. 2010). Multiple factors for dissatisfaction after TKA have been identified, both surgically (Tan et al. 2014) and psychologically (Scott et al. 2010).

A mechanical explanation for dissatisfaction after TKA might be that the current procedures do not reproduce the native joint kinematics and biomechanics. This is due to alterations made in the joint line height and the constitutional alignment. On average, the joint line is raised 3.0mm after primary TKA (van Lieshout et al. 2019). The literature shows that more than 5mm joint line elevation results in a worse clinical outcome (Liow et al. 2014). This could perhaps be explained by the fact that elevation in joint line results in mid flexion instability (Martin and Whiteside 1990). This theory was reinforced by the findings of the study of Cross et al. which showed that by elevating the joint line the centre of rotation is placed more proximally and ventrally to its natural position, resulting in an unstable knee in the mid flexion range (Cross et al. 2012).

In a further attempt to improve functional outcomes, the concept of restoring constitutional alignment was introduced by Bellemans and colleagues. They showed that in the general population, 32% of men and 17% of women have a constitutional varus alignment (Bellemans et al. 2012). Inevitably, correction of this pre-disease mechanical alignment during TKA to a neutral alignment requires ligament release(s). However, for these patients the most appropriate approach might be to restore their pre-disease mechanical alignment. With the current conventional techniques, the measured resection and the balanced gap techniques, constitutional alignment cannot be reproduced accurately, except by using navigation, robotic and/or patient specific instruments.

In an attempt to minimize mid-flexion instability and improve functional outcome, a new technique for TKA was developed: the Flexion First Balancer. This technique also offers the surgeon the ability to adjust the distal femoral angle based on the collateral ligament tension. Subsequently, the pre-disease mechanical alignment (i.e. soft tissue alignment) is restored, possibly resulting in a more 'normal' feeling knee. In this study a technical note is provided for this new technique.

Aims of the Flexion First Balancer technique

The Flexion First Balancer technique has been developed with the aim of improving patient outcome. The philosophy behind this technique is that with preservation of the isometric function of the medial collateral ligament (MCL) the postoperative mid-flexion instability is minimized. It has been shown that a reduced posterior condylar offset (PCO) and subsequent joint line elevation will result in coronal laxity in the mid-flexion range since the axis for rotation of the knee is proximalized and ventralized (Figure 1) (Luyckx et al. 2018). The MCL isometry can only be preserved by fully restoring the medial PCO and the medial joint line height. By preservation of the medial anatomy of the knee (i.e. medial PCO and joint line) a balanced knee can be achieved and maintained throughout full range of motion. To achieve these goals, this technique uses the medial PCO as a reference for prosthesis positioning. By fully restoring the medial PCO, the natural medial joint line height can be recreated. This differs from conventional techniques where the average of the medial and lateral PCO is used, resulting in decrease of the medial PCO with subsequent mid-flexion instability (Figure 2). When the joint line is set in flexion, the extension gap is matched to the flexion gap. By applying tension to the collateral ligaments with a balancer the distal femoral resection level and angle are determined. The Flexion First Balancer allows for restoration of the pre-disease mechanical varus or valgus alignment by adjusting the distal femoral angle. The distal femoral angle can be adjusted to balance the extension gap using wedges. This way natural soft tissue alignment is reconstructed and thereby also the pre-disease mechanical alignment. The restored alignment will presumably contribute to a more natural feeling of the TKA (Vanlommel et al. 2013).

Operative technique

A standard midline skin incision and medial para-patellar arthrotomy is performed. The first step is the tibial cut. An extra- or intramedullary resection guide is placed. The height of the cut should be set to six millimetres below the intact medial posterior cartilage of the tibia plateau. The cutting block is fixed and a perpendicular tibial cut is made. The technique aims to recreate the natural medial tibial slope of the patient. Generally, this can be achieved with a neutral cut to the mechanical axis of the tibia combined with the 4 degrees of slope of the CR insert. The thickness of the cut is slightly greater than in standard procedures in order to accommodate the implant without causing joint line elevation.

A straight intramedullary rod is now inserted into the femur and a standard distal femur cutting block is mounted to perform a preliminary five millimetre thick distal femur cut in 5o valgus. The aim is to achieve a flat surface on the distal femoral condyles for the next step. The orthopaedic surgeon must avoid cutting in the trochlea. When the distal medial condyle is worn and no cartilage is present, we suggest only removing a four millimetre thick slice of bone from the medial condyle. In this manner, there is often only minimal contact on the lateral condyle.

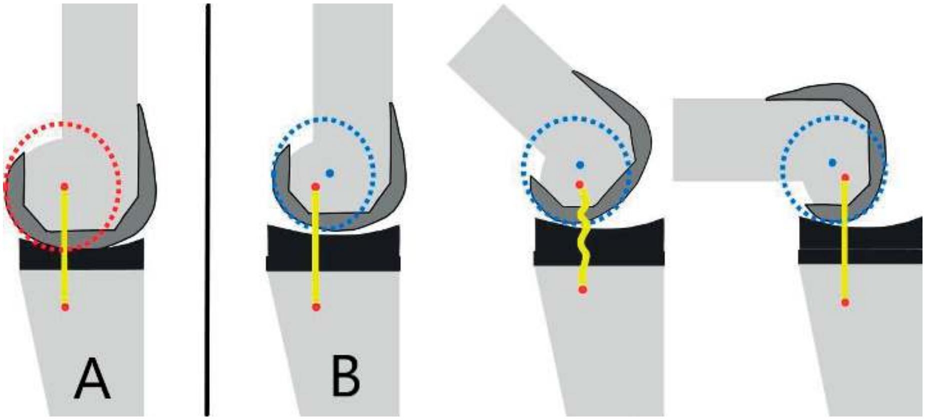

Fig 1. Mid-flexion instability after joint line elevation
Situation A represents a non-elevated joint line TKA, the center of rotation (red/blue dot) is restored by complete restoration of the posterior condylar offset and joint line height. The medial collateral ligament (marked yellow) will keep its isometry throughout the entire range of motion.
Situation B represents an elevated joint line TKA with ticker insert to compensate. The axis of flexion (blue dot) no longer coincides with the MCL insertion (red dot). Therefore, the knee is stable in extension and 90° of flexion but laxity occurs in the mid-flexion range. The medial collateral ligament loses its isometric function in mid-flexion.

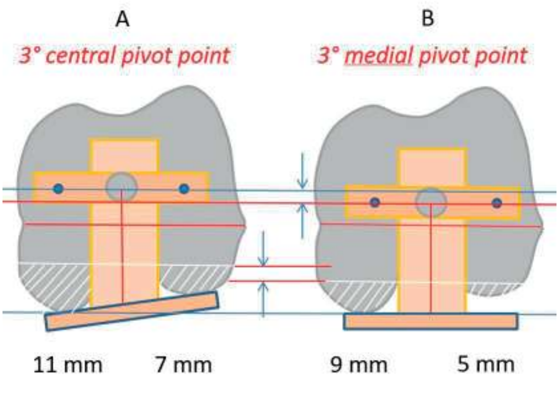

Fig 2. Differences in medial posterior condylar offset between conventional posterior reference technique and Flexion First Balancer technique
These figures show the differences in posterior condylar offset between conventional posterior referenced TKA systems (A) and the Flexion First Balancer (B). Both systems are set in 3° of exo-rotation for the posterior condyles (parallel to the trans-epicondylar axis). However, standard systems use a central pivot point and therefore averages the medial and lateral posterior condylar offset (PCO). As a result the medial PCO is not fully restored and this potentially leads to mid-flexion instability. The Flexion First Balancer technique pivots medially and thereby fully restores the medial PCO. The numbers in the bottom indicate the amount of resected bone from the medial and lateral PCO.

The following step is the posterior condyle cut. Medial and lateral osteophytes are removed in this stage as these might interfere with ligament tension. In the native knee, in flexion, the lateral compartment is more lax than the medial compartment. This induces a medial pivot and allows for a more pronounced lateral roll back. When both collateral ligaments are tensioned using the FFB technique both ligaments are equally tensioned, the component is slightly externally rotated due to the lateral laxity, and these functional intercompartmental differences are lost. To preserve the correct rotation, the medial pivot and the slightly lax lateral compartment, the build-up of the PCO is reduced with 1 mm. Thus, a +1 lateral bushing and the neutral medial bushing are used to ensure slightly more laxity in flexion of the lateral side. The flexion balancer is placed and tensioned with the distractor (Figure 3). The flexion space is presented on the cutting block and should read at least ten millimetres to accommodate for 10mm bearing thickness. Otherwise an additional tibial cut is required. With the distractor in place, drill pins are placed in the medial and lateral hole. The distractor is removed, and the femur is sized by referencing the anterior cortex on the lateral side. The pins are then removed. A slotted four-in-one cutting guide is placed and the posterior and anterior cuts can be made, the chamfer cuts are not performed yet.

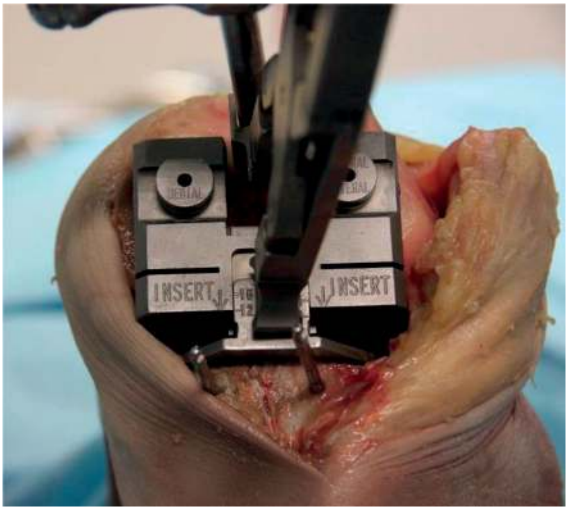

Fig 3. Flexion Balancer
The Flexion Balancer placed in a 90 degrees flexion setting with the distractor in situ to tension the flexion gap. The flexion gap should read at least 10mm; in presented patient this gap reads 12mm.

All instruments are subsequently removed. The flexion gap should now be rigorously cleaned out. Posterior osteophytes are removed with the use of a curved osteotome, designed to fit snugly behind the size matched osteophyte resection guide (if in between sizes, the smaller size is used). If a flexion contracture was present before surgery, a posterior capsular release should be performed at this stage. In case of a fixed valgus deformity we suggest a release of the postero-lateral capsule at this point. In doing so, extension and alignment can be achieved more easily. Subsequently, the flexion gap can be checked with the standard spacer blocks. The femoral spacer plate is then placed.

At this stage the flexion gap is set and the extension gap is matched to the flexion gap. The knee is extended with the tibia spacerplate and femoral spacerplate in situ. Spacer blocks are placed with increasing thickness until the extension gap is tight (Figure 4). In case of a trapezoid extension gap the medial collateral ligament (MCL) and lateral collateral ligament (LCL) can be tensioned equally by using wedges. These come in 1, 2, 3 and 4 degrees of varus or valgus. By using wedged spacer blocks the valgus angle of the femur is adjusted to create a rectangular extension gap. When the extension gap is adequately balanced the drill guide is placed and the flexion gap is copied by drilling pins into the same indicators as previously measured (i.e. ten millimetres) (Figure 5). After resection check the extension gap with the standard spacer blocks. All instruments are removed with exception of the drill pins. The distal femur cutting block is placed using the most proximal pinholes and the final distal femoral cut is made. With this step the femoral angle is adjusted to match the extension gap to the flexion gap without having to perform a partial release of the collateral ligaments. Then the chamfers cuts are finally made through the previously used slotted 4-in-1 cutting guide.

Fig 4. Tibial and femoral spacerplate
The femoral and tibial spacerplates are shown in situ to copy the flexion gap to the extension gap. The femoral spacerplate has a posterior condyle part which ensures a proper posterior capsule tightness.

The orthopaedic surgeon now continues with the standard procedure to finish preparing the femur, tibia and patella. A cruciate retained (CR) type, Vanguard Complete Knee System (Biomet Orthopedics, Warsaw, IN, USA) implant is used. After placement of the components, the tension of the iliotibial band must be checked. Due to the build-up of the lateral condyle, the iliotibial band may be tight in slight flexion. If so, a (partial) release of the iliotibial band is advised.

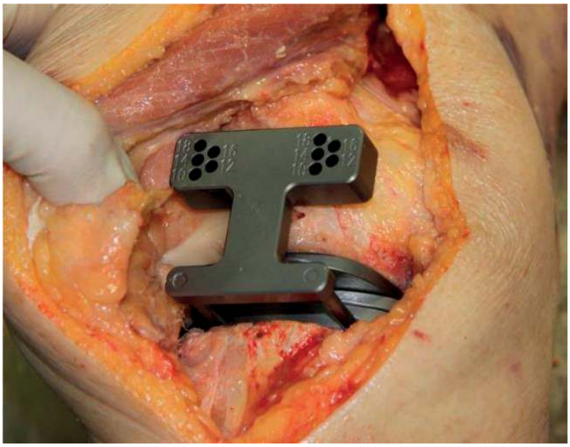

Fig 5. Drill guide for extension gap
The flexion gap is copied to the extension gap using the drill guide which is placed in the tibial spacerplate. Pins are subsequently drilled in the corresponding indicator holes in the femur.

DISCUSSION

This paper describes the new Flexion First Balancer technique, developed to restore the MCL isometry in order to achieve a stable knee throughout full range of motion. Key to achieving this goal is reconstruction of the medial anatomy of the knee. The Flexion First Balancer technique therefore uses the medial PCO as a reference. Hereby, the medial joint line is preserved, and the flexion gap is set. Now the extension gap is matched to the flexion gap. By reconstructing the medial PCO and joint line to their pre-disease level the isometric function of the MCL is preserved.

The philosophy of matching the extension gap to the flexion gap has been described in the past by pioneers in TKA surgery like Freeman and Insall. However, in the 70s, there was not the wide availability of the many different sizes of prosthetics we have today. Frequently the PCO was decreased to fit the femoral component without notching or overstuffing the patella-femoral joint. As a result the joint line was elevated, with its inherent risks (Figgie et al. 1986; Martin and Whiteside 1990). The flexion first technique was therefore replaced with the extension gap first technique to gain control over the joint line position. Today, the quality and availability of prosthetics and instruments has improved enormously. As described above, the Flexion First Balancer provides an easy and reproducible technique to reconstruct the medial anatomy of the knee and thereby maintain the MCL isometry.

Beside preservation of MCL isometry, the Flexion First Balancer also balances the knee through an adjustable distal femoral angle using the collateral ligaments tension in extension, subsequently reconstructing pre-disease mechanical alignment. Previously, other techniques have been reported to achieve the same goal. Howell and colleagues described techniques to restore constitutional alignment by adjusting the tibial cut leading to a restoration in kinematical alignment (Howell et al. 2013). However, this technique has some disadvantages. The tibial resection needs to be adjusted to match the varus in the proximal tibia. This leads to an increased valgus angle for the femoral component, which should be parallel to the femoral flexion-extension axis. These alterations might affect patellar tracking, as the femoral component is not designed for this alternative position. Secondly, moving away from a perpendicular tibia cut is correlated with high failure rates due to tibial loosening and/or ligament instability (Ritter et al. 2011). There is no consensus concerning which method is ideal for the patient. However, the Flexion First Balancer provides a reproducible and easy technique to recreate the natural soft tissue alignment by adjusting the distal femoral angle with a neutral tibia plateau without compromising patellar tracking. More importantly, since this new technique uses a perpendicular tibial cut, the risks of increased tibial loosening can, via this method, be avoided (Ritter et al. 2011).

New techniques carry the risk of introducing new negative side effects. Theoretically, a potential negative side effect could be lateral tightness of the knee. Due to the build-up of the lateral posterior condyle this could result in a tight flexion gap on the lateral side. This phenomenon also occurs in normal TKA techniques, however in the FFB technique this build-up is increased and the joint line on the lateral side is more distalized compared to normal TKA techniques. This could result in a tighter lateral compartment, especially in mid-flexion when the iliotibial band (ITB) crosses the lateral condyle at 30 degrees of flexion (Fairclough et al. 2006). Theoretically resulting in pain on the lateral side of the knee and difficulties in bending the knee as is seen in the iliotibial band syndrome. Therefore, we suggest checking the lateral tightness per-operatively and if applicable a (partial) release of the ITB should be performed. A potential complication is that by changing the valgus angle of the femur, a HKA angle is created that is outside the presumed safe zone of -3 to +3 degrees to the neutral mechanical axis. Traditionally this was considered an important aspect of TKA. However, present literature is less convincing. Hadi et al. performed a review of the literature and showed no correlation between outliers in HKA in the coronal plane after TKA and revision rates (Hadi et al. 2015).

A limitation of the current study is that it does not provide patient data to support the presumed benefits of the Flexion First Balancer method. However, another recent publication discussed PROMS and patient complication rates in a comparison of the standard MR procedure and this new technique. (van Lieshout et al. 2019). Therefore, the main focus of this article is to provide a clear description of the technical application of the Flexion First Balancer method.

Conclusions

In conclusion the Flexion First Balancer technique offers the surgeon the ability to recreate the medial anatomy of the native knee in order to maintain the isometry of the medial collateral ligament, which is considered essential to prevent mid-flexion laxity.

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chapter 6

Adequate joint line restoration and good clinical outcomes after total knee arthroplasty using the Flexion First Balancer technique

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The Knee 2019

ABSTRACT

Introduction

Up to 20% of patients are dissatisfied after total knee arthroplasty (TKA). Factors which could possibly contribute to this dissatisfaction are a decreased posterior condylar offset (PCO) and subsequent joint line elevation which leads to mid-flexion instability. The Flexion First Balancer (FFB) technique aims to adequately restore the medial PCO and thereby reconstruct the medial native joint line to its pre-disease height.

Methods

A retrospective cohort of 59 patients operated using the FFB technique was analyzed and matched with a historic measured resection (MR) cohort of 59 patients. Groups were matched for age, gender, BMI and ASA classification. Joint line and PCO changes as well as patient reported outcome measurement scores (PROMs) were evaluated at one year [1 – 1.6] postoperatively.

Results

Radiographic evaluation revealed no changes in joint line height in the FFB group, whereas an elevation in joint line was seen in the MR group (P=0.002). The PCO increased after surgery in both group without any statistically significant differences. Evaluation of PROMs found no differences between the two groups for total OKS and KOOS scores, nor in re-operation or complication rates.

Conclusion

The FFB technique seems to be a safe technique to use in TKA and reconstructs the pre-disease joint line in contrast to the MR technique. The clinical outcomes were comparable between both groups.

INTRODUCTION

Total knee arthroplasty (TKA) is an effective surgical intervention in patients with end-stage knee joint degeneration (Kahn, Soheili, and Schwarzkopf 2013). It has proven to alleviate pain, restore function and improve patients' quality of life (Anderson et al. 1996; Ethgen O, Bruyère O, Richy F, Dardennes C 2004). However, approximately 1 out of 5 patients undergoing this type of surgery are dissatisfied at 1 year postoperatively (Bourne et al. 2010; Scott et al. 2010). From a surgeon's perspective, optimal prosthesis placement is key for a good functional outcome. Therefore, restoring the joint line to its pre-disease height might improve post-operative clinical outcomes after TKA (Van Lieshout et al. 2018).

Primary TKA surgery leads to a mean joint line elevation of 3 millimeters (mm) (Van Lieshout et al. 2018). In order to maintain a symmetrical flexion and extension gap the posterior condylar offset needs to decrease as well. Therefore, the flexion axis of the knee will be positioned more proximally and ventrally and the medial collateral ligament will lose its isometric contraction ability in the mid-flexion range (0-90° flexion). The theory that a raised joint line results in mid-flexion instability has been proven in a cadaver studies (Cross et al. 2012; Thomas Luyckx et al. 2018). Restoring the medial joint line height to its pre-disease height is advocated by experts to achieve a balanced knee (Victor 2017).

For this reason, the Flexion First Balancer (FFB) has been developed. This new technique was designed to enable the surgeon to reproduce the medial pre-disease joint line and PCO. It restores the medial PCO, which is used to determine the tibial build-up. When the joint line is set in the flexion position (i.e. tibial and posterior femoral cuts are performed), the extension gap is subsequently matched to the flexion gap with the use of a balancer. With the use of balancers, the distal femoral resection level and angle and femoral component rotation are determined. No additional ligament releases are performed.

The aim of this study was to compare the FFB technique to a matched control group, using the conventional measured resection technique (MR), and evaluate the post-operative changes in joint line height and PCO. Furthermore, complication rates, reoperation rates and patient reported outcome measures scores (PROMs) were compared after 1 year of follow-up. Our hypothesis was that the joint line height is better restored in the FFB group , which leads to superior PROMs scores.

MATERIAL AND METHODS

Study design

The Flexion First Balancer technique was introduced in September 2015. A cohort of patients who underwent TKA that were performed with the use of the FFB technique by two orthopedic surgeons in the period between September 2015 to September 2016 was studied retrospectively. A matched control group was composed from a historic cohort of patients who underwent TKAs that were performed using the MR technique by the same orthopedic surgeons between September 2014 and August 2015 (RvG or LE). In all patients a cruciate retained (CR) type, Vanguard Complete Knee System (Biomet Orthopedics, Warsaw, IN, USA) implant was used. Matching was performed based on age, gender, Body Mass Index (BMI), and American Society of Anesthesiologists (ASA) classification. No Medical Ethical Committee approval was needed for this retrospective chart study, as no addition radiographs or questionnaires were obtained.

Surgical technique FFB

A standard midline skin incision and medial para-patellar arthrotomy is followed by a perpendicular tibial cut. This is set at six millimeters below the intact medial posterior cartilage. A preliminary five millimeters distal femur cut is made to obtain a flat surface for the following steps. After removal of medial and lateral osteophytes the Flexion Balancer is placed with the knee in 90 degrees of flexion to determine the correct posterior offset. The system references of the intact posterior cartilage of the medial femur condyle to recreate the joint line height and uses ligament tension to set femoral rotation. The flexion gap should read at least 10mm, if not, an extra tibial cut should be performed to accommodate the implant. This way joint line elevation is prevented. Drill holes are made through the balancer and a slotted four-in-one cutting guide is placed. The posterior and anterior cuts can be made at this point. After removing posterior osteophytes the extension gap is matched to the flexion gap with the use of balancers. In case of a trapezoid extension gap the medial collateral ligament (MCL) and lateral collateral ligament (LCL) can be tensioned equally with the use of wedges. These come in one, two, three and four degrees of varus or valgus. By using wedged spacer blocks the distal valgus angle of the femur is adjusted to create a rectangular extension gap. When the extension gap is adequately balanced the drill guide is placed to set the final distal resection level. Finally, the chamfers cuts are made through the previously used slotted four-in-one cutting guide. From this point on, the orthopedic surgeon continues with the standard technique to finish preparing the femur, tibia and patella and prosthesis placement.

Data collection

Patient medical records were reviewed, and data was collected preoperatively and at six weeks and one year postoperative (as standard practice in our hospital). No patients were lost to radiographic follow-up. Collected data consisted of the maximum degree of flexion of the knee, the occurrence of complications, and the need for re-operations. PROMs data were gathered for all included patients preoperatively and at three and 12 months post-operatively. Standard PROMs consisted of the Oxford Knee Score (OKS) (Haverkamp et al. 2005), the Knee injury and Osteoarthritis Outcome Score (KOOS) (de Groot et al. 2008), and Visual Analogue Scale (VAS) scores regarding pain, disability and satisfaction. VAS scores range from 0 to 100, in which a score of 100 is the worst possible outcome.

Radiological analysis

For radiographic analysis JiveX software (Visus Technology Transfer GmbH, version 4.7.1.10, Bochem Germany) was used. The researcher was blinded for the operation technique while performing the radiological measurements. Joint line changes were assessed on antero-posterior (AP) weight-bearing X-rays of the knee, in which we used the medial adductor tubercle as reference point. The joint line height was defined as the perpendicular distance between the adductor tubercle and the joint line (ATJL) (Fig 1). This reference point has proven to be accurate and reproducible to evaluate joint line height pre- and postoperatively (Hofmann et al. 2006). Hence, a decrease in ATJL indicates a proximalization of the joint line. To minimize the error in the measurement of the ATJL, only patients without bone-loss on the preoperative AP radiographs were included in the analysis. With regards to the preoperative X-rays, a line tangent to both distal femoral condyles was used as the joint line reference. Postoperatively, the distal border of the femoral component was used (i.e. actual joint line) (Fig 1). To estimate the true pre-disease joint line, one must compensate for the standard error in the pre-operative measurement, because the cartilage thickness was not included in this measurement (as it is not seen on X-ray imaging). A corrected ATJL (cATJL) was defined by adding the average cartilage thickness of the distal femoral condyl of 2.15mm to the preoperative measured ATJL distance (Shepherd and Seedhom 1999). To correct for magnification errors we calculated the adductor ratio, which was defined as the ratio between the adductor height (ATJL) divided by the coronal femoral width (FW). The coronal FW is defined by the distance between the most external points of the medial and lateral epicondyles (Fig 1) (T Luyckx et al. 2014). Preoperatively the cATJL was used and for postoperative calculations the ATJL was used.

Lateral X-rays of the knee were used to measure PCO. To minimize the error in the measurement of PCO, only patients of which true lateral radiographs were performed were included in the analysis. Radiographs in which complete overlap of the medial and lateral femoral condyles were defined as true lateral knee radiographs, as described by Hanratty et al. (Hanratty et al. 2007). The preoperative PCO was measured on the true lateral radiograph, as the tangential distance between the posterior cortex of the femoral diaphysis and the apex of the posterior femoral condyle. The postoperative PCO was measured as the tangential distance between the posterior cortex of the femoral diaphysis and the apex of the posterior femoral component post-operatively. The lateral femoral width (FW) was defined as the tangential distance between two parallel lines through the anterior and posterior cortex of the femoral diaphysis (Fig 2). In the pre-operative PCO distance the cartilage thickness was not included in the measurement. Therefore, the corrected PCO (cPCO) was defined by adding the average cartilage thickness of the posterior femoral condyl of 2.15mm to the preoperative measured PCO distance (Shepherd and Seedhom 1999). A ratio was then calculated for PCO, the PCO ratio, to adjust for radiographic magnification errors. Preoperative PCO ratio was calculated using the formula: cPCO/(cPCO + lateral FW). Likewise, postoperative PCO ratio was calculated using the formula: PCO/(PCO + lateral FW). A similar method has previously been used by Yang et al. (Yang et al. 2016).

Statistical analysis

Baseline characteristics were compared between the groups using Chi-square tests for categorical and independent samples t-tests for continuous data. Flexion and extension data, radiological outcome parameters and PROMs were analyzed with two-way repeated measures (RM) ANOVA with time as "within subjects" factor and group (MR vs. FFB) as "between subjects" factor. With regards to missing data, analyses were restricted to individuals with complete data on all variables required for a particular analysis. Fixed varus/valgus, complication rates, reoperation rates were compared between the two groups using Fisher's Exact tests. Significance level was set at $p < 0.05$.

RESULTS

A total of 118 patients were included in this study: 59 patients who underwent TKA using the FFB technique and 59 patients who underwent TKAs using the MR technique. There were no statistically significant differences in baseline characteristics between the groups for age, ASA, gender and BMI and fixed varus or valgus deformities (Table 1). Surgery time increased with 10 minutes with the use of the FFB technique (76.6 min (SD 14.6) vs 64.4 min (SD 11.4) ($p<.001$). Blood loss was significantly higher in the FFB group (300 ml (IQR: 150-350) vs 120 ml (IQR: 0-200) ($P<.001$). All patients were evaluated after one year of follow-up (mean: 1.03 SD 0.07 (range 1.0 – 1.6 year)). One patient had 1.63 years of follow for the PROMs questionnaire. If excluded, the range was one to 1.2 years.

Pre- and postoperative radiographs were available for all patients, however, bone-loss was present in 15 patients (eight FFB; seven MR) resulting in 103 patients who were evaluated for joint line changes. Two-way RM ANOVA revealed that the adductor ratio had a significant interaction effect ($p=0.002$), which permits evaluation of the data per group.

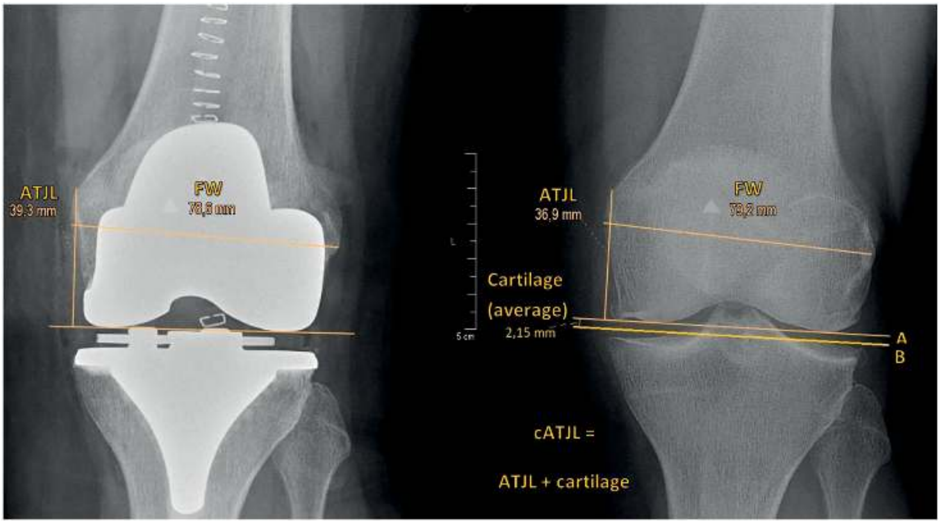

Fig 1. Radiological measurements for joint line changes pre- and postoperative
The right preoperative figure was taken 8 years before surgery. At the time of surgery the patient had bone-to-bone osteoarthritis on the medial side. This radiograph was selected to elaborate more clearly the preoperative radiological measurement correction. *Abbreviations: ATJL: Adductor tubercle joint line distance; FW: Femoral width; cATJL: corrected adductor tubercle joint line distance; A: joint line bony edge femur; B: actual joint position*

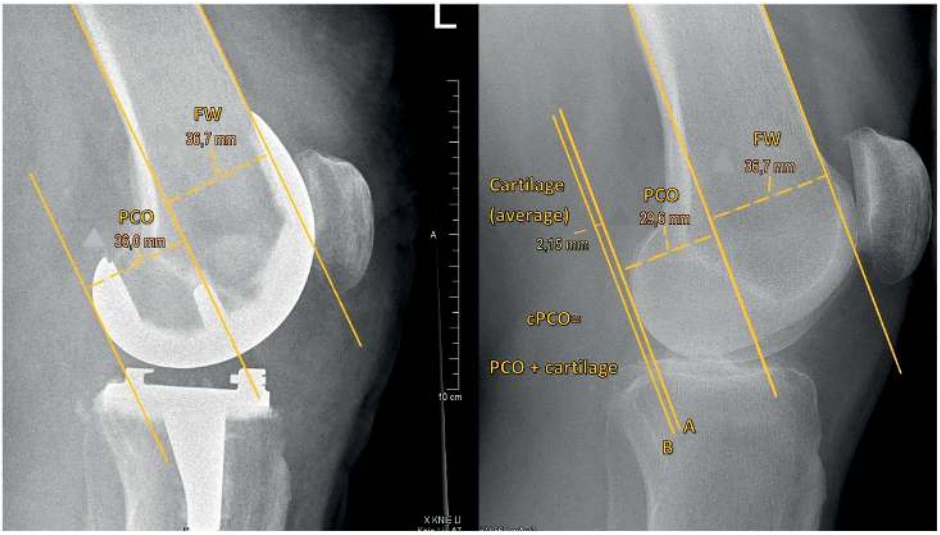

Fig 2. Radiological measurements for posterior conylar offset changes
The right figure shows a preoperative true lateral radiograph with complete overlap of the medial and lateral posterior condyl. The left figure shows a postoperative true lateral radiograph. *Abbreviations: PCO: posterior condylar offset line distance; FW: Femoral width; cPCO: corrected posterior condylar offset distance; A: joint line bony edge femur; B: actual joint position*

Table 1. Patient characteristics

	FFB group N = 59	MR group N = 59	p-value
Gender (no. male)	21 (36%)	21 (36%)	N.S.
Age (mean ± SD)	66.8 (8.9)	68.1 (9.0)	N.S.
ASA (no. per category)			N.S.
I	10 (17%)	10 (17%)	
II	42 (71%)	42 (71%)	
III-IV	7 (12%)	7 (12%)	
BMI (mean ± SD)	29.5 (4.7)	29.4 (4.5)	N.S.
Fixed varus	1	2	N.S.
Fixed valgus	8	6	N.S.
Surgery time (mean ± SD)	76.6 min (14.6)	64.4 min (11.4)	< .001
Blood loss (median + IQR)	300 ml (150-350)	120 ml (0-200)	< .001

N.S. indicates a non-significant difference between the groups
ASA: American Society of Anesthesiologists; BMI: : Body Mass Index; SD: standard deviation; IQR: inter quartile range; FFB: Flexion First Balancer; MR: Measured resection

While comparing pre- and postoperative radiographs, there were no joint line changes in the FFB group (p=0.304). In the MR control group there was a significant decrease in the adductor ratio of 0.015 (p=0.002), which indicates a significant joint line elevation (Fig 3).

With regard to PCO measurements, only 26 FFB and 17 MR patients had true lateral X-rays pre- and postoperatively and could therefore be analysed. Two-way RM ANOVA revealed no interaction effect (p=0.48) and no statistically significant difference between the groups (p=0.91), but it did demonstrate an overall increase in PCO ratio of 0.05 comparing pre and post-operative values (p<0.01) (Fig 4).

PROMs data, available for 2/3 of the patients, showed improvements in OKS, VAS and KOOS scores in both the FFB and the MR groups (Table 2 and 3). With regards to the OKS, VAS and KOOS scores, no interaction effect was found. Only the sport and recreation subscales of the KOOS showed a significant group effect, lower KOOS values were reported for the FFB group across all time points. The KOOS sport and recreation was already significant different at baseline. For maximum flexion no interaction effect nor differences were found between the two groups, but a statistically significant time effect was found at the 6 weeks post-operative time interval (Table 2, Fig 5). No differences between the groups were reported regarding complications and re-operations. Documented complications were stiffness (six in the FFB and two in the MR group, p=0.14 (Post-hoc Power 30.4%)), which resulted in two manipulations under anaesthesia (MUA) in each group. Four patients in the FFB group showed an improved in their maximum flexion range between six and 12 weeks follow-up and therefor did not require a MUA. Furthermore, one infection and one wound

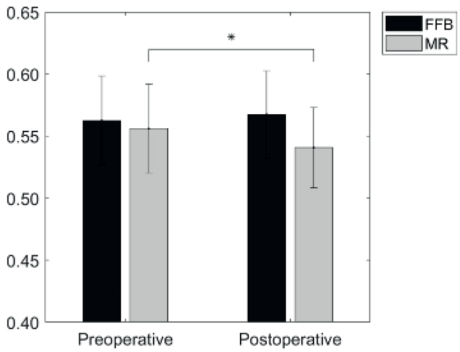

Fig 3. Joint line adductor ratio results for the FFB and MR group

Black bars present the data of the FFB group and the grey bars present the data of the MR group. The left side demonstrates the preoperative data and the right part the postoperative data. Error-bars represent one standard deviation. (Note that a decrease in joint line adductor ratio represents an increase in joint line). *FFB: Flexion First Balancer group; MR: Measured Resection group; *: significant effect (P<0.05)*

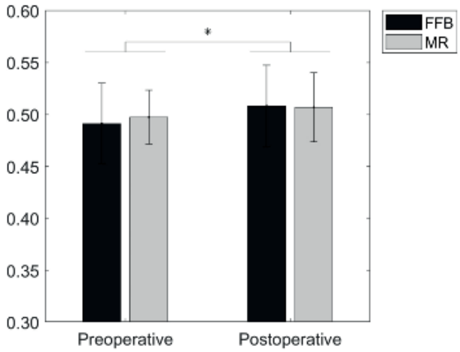

Fig 4. Posterior condylar offset ratio results for the FFB and MR group

Black bars present the data of the FFB group and the grey bars present the data of the MR group. The left side demonstrates the preoperative data and the right part the postoperative data. Error-bars represent one standard deviation. *FFB: Flexion First Balancer group; MR: Measured Resection group; * indicates an overall significant increase in PCO ratio after surgery (P<0.05)*

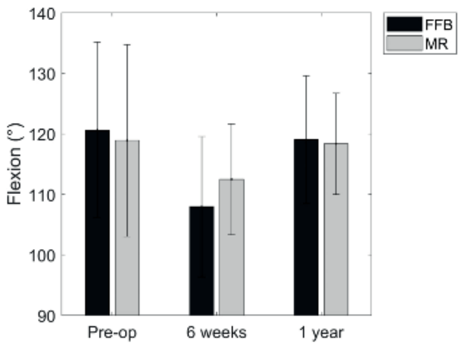

Fig 5. Maximum flexion results for both the FFB and MR group

Black bars present the data of the FFB group and the grey bars present the data of the MR group for the three time intervals. Error-bars represent one standard deviation. *FFB: Flexion First Balancer group; MR: Measured Resection group; Overall there is a significant time effect for the 6 weeks' time interval, no differences between the groups*

problem were recorded, both in the MR group. Documented re-operations were five in total. Two insert changes were performed: one due to a case of stiffness in the FFB group and one case of instability in the MR group. Two additional releases were needed because of (postero) lateral knee pain: one case with fabella resection in the MR group and one extra release of the iliotibial tract in the FFB group. These re-operations were equally divided between the two groups. Furthermore, there was one deep infection which was treated by debridement, insert exchange and antibiotics (in the MR group).

Table 2. OKS,VAS scores and maximum flexion outcome for the FFB and MR technique

	Groups	Pre-operative	6 weeks / 3 months $	12 months	Statistics with 2-way repeated ANOVO
OKS	MR (n=41)	26.0 (±9.6)	36.5 (±7.6)	40.0 (±7.5)	*Time effect*
	FFB (n=44)	23.9 (±6.8)	34.4 (±8.3)	39.0 (±8.0)	
VAS Pain	MR (n=40)	51.1 (±28.7)	22.9 (±23.8)	16.4 (±24.6)	*Time effect*
	FFB (n=39)	56.1 (±21.8)	25.7 (±21.8)	15.8 (±20.4)	
VAS Disability	MR (n=40)	50.7 (±27.2)	22.6 (±20.3)	15.6 (±21.6)	*Time effect*
	FFB (n=39)	52.9 (±25.6)	22.8 (±20.0)	16.3 (±20.2)	
VAS Satisfaction	MR (n=31)	63.6 (±30.2)	29.9 (±26.1)	23.8 (±28.4)	*Time effect*
	FFB (n=36)	61.8 (±22.7)	28.1 (±27.9)	18.4 (±25.0)	
Flexion	MR (n=46)	119° (±16°)	113° (±9°)	118° (±9°)	*Time effect*
	FFB (n=47)	121° (±15°)	108° (±12°)	119° (±11°)	

The number of complete filled out questionnaires per group is indicated in the "groups" column
$ Flexion data was collected at 6 weeks postoperative. VAS and OKS data were collected at 3 months postoperative; The data is shown as mean with standard deviation. *OKS: Oxford Knee Score; VAS: Visual Analogue Scale score*

Table 3. KOOS subscales outcome for the FFB and MR technique

	Groups	Pre-operative	3 months	12 months	Statistics with 2-way repeated ANOVO
KOOS Symptoms	MR (n=41)	53.1 (±23.1)	73.0 (±17.2)	82.9 (±17.6)	*Time effect*
	FFB (n=43)	49.0 (±16.3)	65.6 (±20.0)	78.7 (±18.0)	
KOOS Pain	MR (n=41)	48.2 (±25.6)	76.4 (±21.0)	84.8 (±16.6)	*Time effect*
	FFB (n=43)	42.2 (±13.3)	71.1 (±18.7)	81.3 (±22.0)	
KOOS ADL	MR (n=41)	50.6 (±26.1)	78.5 (±16.2)	85.3 (±14.9)	*Time effect*
	FFB (n=39)	47.4 (±14.0)	75.0 (±16.7)	82.3 (±19.9)	
KOOS Sport/Rec	MR (n=38)	23.2 (±25.9)	36.5 (±30.1)	46.8 (±31.5)	*Group and Time effect*
	FFB (n=34)	10.4 (±19.1)	27.5 (±26.0)	37.2 (±26.2)	
KOOS QoL	MR (n=41)	26.2 (±19.6)	54.6 (±23.0)	68.6 (±22.5)	*Time effect*
	FFB (n=40)	24.1 (±15.6)	52.3 (±19.4)	62.8 (±24.1)	

The number of complete filled out KOOS subscales per group is indicated in the "groups" column
KOOS: Knee injury and Osteoarthritis Outcome Score; ADL: Activities of Daily Living; Sport/Rec: Sport and Recreation Function; QoL: Quality of Life; MR: measured resection; FFB: Flexion First Balancer

DISCUSSION

The main finding of this study was that with the novel Flexion First Balancer technique the pre-disease joint line height can be restored more accurately in comparison to the standard measured resection technique. While comparing TKA using Flexion First Balancer and MR technique there were no statistically significant differences in complication rates. Hence, the FFB technique is a safe technique for TKA. Despite the expected improvements in clinical outcome and PROMs after adequate joint line reconstruction, no differences in PROMs were observed when compared to the measured resection technique.

Since no calibrated radiographs were available for this study we validated our results to previous reports for joint line measurements performed with calibrated radiographs. Our mean coronal FW of 86.1mm observed in our cohort is in line previous studies reporting a coronal FW of 85.4mm and 89.7mm (Iacono et al. 2015; T Luyckx et al. 2014). Our mean ATJL distance is 46.7mm, in contrast to 44.6mm and 48.7mm for respectively the cohort of Luyckx et al. and Iacone et al. (Iacono et al. 2015; T Luyckx et al. 2014). Joint line alterations measured with the adductor ratio, to compare our preoperative results with the literature we had to corrected the previous reported adductor ratios with the average cartilage thickness (ATJL + 2.15mm) (Shepherd and Seedhom 1999). Our adductor ratio of 0.56 is comparable with previously reported ratios. The study by Luyckx et al. reported an adductor ratio of 0.52 and after our correction for cartilage thickness this is 0.55 (T Luyckx et al. 2014). The study by Iacono et al. reported an adductor ratio of 0.54 and after correction for cartilage thickness this is 0.57 (Iacono et al. 2015). These results are completely comparable and therefore our absolute measurements are expected to contain no systematic error. The significant decrease of 0.015 in adductor ratio in the MR group therefore corresponds with an elevation in joint line of 1.3mm. A recent systematic review showed that a joint line elevation of >4mm results in worse PROMs (Van Lieshout et al. 2018). This small difference between the groups makes it questionable if this can be detected with PROMs. However, PROMs are not the ideal way to assess mid-flexion instability. An increase in mid-flexion instability has a negative effect on stair climbing abilities and walking speed in contrast to PROMs (Freisinger et al. 2017). The FFB technique enabled us to reconstruct the joint line without any elevation, potentially decreasing mid flexion instability. This could improve the functional ability of the patient. In conclusion, the FFB technique showed better reconstruction of the joint line position compared to the MR technique. This could result in less mid-flexion instability which is previously shown in the literature (Cross et al. 2012; Thomas Luyckx et al. 2018).

With regards to the PCO, we documented an increase in PCO for both groups. For the FFB technique the medial PCO is the reference for the posterior femoral resection. This differs to the MR technique, in which the average of the medial and lateral PCO is used as reference for the posterior femoral resection. However, no statistically significant differences in PCO changes were documented between the groups. Our PCO ratio findings are slightly higher than previously reported values by Yang et al. (Yang et al. 2016). The significant increase in PCO ratio of 0.05 in both groups was an unexpected finding. This might be explained due to an error in radiological measurement. In the native knee, the lateral PCO is smaller than the medial PCO and therefore, a slight exorotation of the knee is required to obtain a true lateral view. The measured preoperative PCO on a true lateral radiograph is the average distance of the medial and lateral PCO. Postoperatively, the medial and lateral PCO distance is the same for the Vanguard knee prosthesis. Therefore, the actual PCO is measured on the postoperative true lateral radiograph. This radiological error could possibly explain the minor statistically significant increase in PCO in both groups. An increase in 0.05 in the PCO ratio corresponds with an increase of 1.7mm (mean lateral FW 33.3mm). Changes in PCO >2mm are correlated to mid-flexion instability ($p = 0.017$) (Matziolis et al. 2017). At 1 year postoperatively, one patient in the MR group had instability in the coronal plane with the need for an insert exchange. No relation with an increased PCO was seen in this patient. It is questionable if PCO changes can be accurately documented on plain radiographs. Previously, Ishii et al. studied the changes in PCO after TKA and compared radiographs with CT imaging. They reported no correlation between PCO changes on pre- and postoperative radiographs and the actual changes on CT imaging of the medial and lateral PCO after TKA (Ishii et al. 2011). However, plain radiographs are used routinely and several studies have been conducted with true lateral radiographs of the knee. Moreover, the patient is less exposed to radiation, which can justify the use of plain radiographs for evaluation of the PCO.

With regards to PROMs outcome only a difference between the two groups was recorded for KOOS sports and recreation. The significant lower KOOS at baseline in the FFB group is however responsible for this group effect. Hence, both groups showed a comparable increase in KOOS sport and recreation. Our postoperative PROMs scores are comparable with outcomes of the registry data regarding outcomes after TKA. At one year postoperatively, the range for OKS in the literature varies between 36.1 at six months to 39.5 at one year postoperatively (Liddle et al. 2015; Online LROI annual report 2017: 10 years of registration, a wealth of information 2017, The New Zealand Joint Registry Eighteen Year Report, New Zealand Orthopaedic Association 2017). Our postoperative OKS scores were respectively 38 for the FFB group and 40 for the MR group at one year follow-up. With regards to the KOOS, comparable results to ours are presented in the literature and registry data for the KOOS subscales at one year (Steinhoff and Bugbee 2016; Swedish Knee Arthroplasty Register Annual Report 2017). These results indicates that the new technique, the FFB, is a safe alternative in TKA.

Our hypothesis that a reconstruction of the medial PCO and subsequently the medial joint line would result in better PROMs was not established in this study. It may be that the difference between the two groups is not large enough to be clinical important. Or it may be that the outcome measurements used (i.e. OKS and KOOS) do not represent the functional ability of the patient detailed enough. This is supported by a previous study that showed that the KOOS did not capture the extent of persistent deficits in function at six months postoperative (Stevens-Lapsley, Schenkman, and Dayton 2011). Moreover, a study by Freisinger et al. showed that there is no correlation between the KOOS and varus-valgus laxity in the osteoarthritic knee, this was in contrast to functional tests like a 6-minute walk test (Freisinger et al. 2017). This varus-valgus laxity is to be expected in the mid-flexion range in TKA patients with an elevated joint line (Cross et al. 2012; Thomas Luyckx et al. 2018). Therefore, future research including functional tests are needed to establish a possible benefit of FFB technique. Since the FFB technique restores the joint line more accurate than the MR technique an increase in functional outcome could be expected.

The new technique might have some downsides. The operating time and the accompanied blood loss are significantly higher compared to the standard technique. This might be explained by a learning curve for using this new technique, since even the first FFB patient was included in this study. However, another explanation for the increased blood loss might be the gradually declining use of a tourniquet in our clinic during TKA surgery. Another possible downside of total knee arthroplasty via the new technique is the extra build-up of the lateral PCO due to medial PCO referencing. This might inflict tightness on the lateral side which may lead to pain and a decline in range of motion. Although the difference was not significant as a result of lack of power in the current study, the six stiff knees reported in the outpatient clinic after six weeks of surgery versus two in the MR group might be an indication of this tightness of the knee. At six weeks postoperative, both the FFB and MR group showed a significant lower flexion range angle (107° vs 112°) compared to preoperative and one year postoperative values. The maximum flexion recovered at one year postoperative and no statistical differences in flexion angles were observed between the groups. Moreover, no differences in lateral knee pain were observed and MUA was performed equally between the two groups. This suggests that the build-up of the lateral PCO does not affect patient outcome, but there are some indications that at 6sixweeks postoperative patients in the FFB group may suffer from more flexion contractures.

A limitation of this study is its retrospective design which resulted in an incomplete dataset. PROMs data at all time points was only available in approximately 2/3 of the patients. However, follow-up data including complications and reoperations was available for all patients. The follow-up of one year is rather short for prosthesis replacement surgery, hence these outcomes are classified as preliminary results. However, recent literature has proven that PROMs do not change between 12 and 24 months for TKA and therefore the results of the current study are valid (Ramkumar et al. 2018). As radiological analysis could only be performed on cases with minimal bone loss, the findings can only be generalized to this category of cases, not all. Another limitation is the lack of calibrated radiographs. For ratio calculations this is no problem, for absolute measurements this could result in an measurement error. However, when validating our results to the literature this possible error seems ruled out. Furthermore, as mentioned above, CT imaging would have been a more reliable method to determine PCO changes and functional tests might have been more sensitive to detect a change in mid-flexion stability. Therefore, future studies should consider using CT-scan to analyze PCO and functional tests like the 6-minute walk test and stairclimbing test to asses functional outcome after TKA surgery.

CONCLUSION

The FFB technique seems to be a safe technique to use in TKA, which can improve reconstruction of the native joint line. Unlike the MR technique, the FFB technique does not lead to elevation of the joint line. The clinical outcomes were comparable in both groups for both PROMs and complication rates.

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chapter 7

The effect of restored medial knee anatomy in Total Knee Arthroplasty with the Flexion First Balancer technique on mid-flexion laxity and functional outcome

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ABSTRACT

Background

The Flexion First Balancer (FFB) technique for total knee arthroplasty (TKA) was developed to maintain the isometry of the medial collateral ligament (MCL) by restoring the medial anatomy of the knee. Inability to correct MCL isometry could hypothetically result in an increased mid-flexion laxity. The aim of the current study was to evaluate if the FFB technique results in improved functional outcome and less mid-flexion laxity compared to Measured Resection (MR).

Methods

A cross-sectional study was performed comparing 27 FFB patients with 28 matched MR patients. Groups were matched for age, gender, BMI and ASA classification. All patient received the cruciate retained type, Vanguard Complete Knee System (Biomet Orthopedics, Warsaw, IN, USA). Stress X-rays of the knee with 30 degrees of flexion were made to assess varus-valgus laxity. Furthermore, three tests were conducted to asses functional outcome: a 6 minute walk test, a stair climb test and quadriceps peak force measurements. Mean follow-up was respectively 2.6 and 3.9 years.

Results

The MR group showed a postoperative elevation in joint line in contrast to the FFB group, the mean difference between the two groups was 3mm ($p<0.001$). No differences in total laxity between the two groups was found. The FFB group showed a higher quadriceps peak force (1.67 N/BMI) in comparison with the MR group (1.38 N/BMI) ($p<0.05$). All other outcome parameters were comparable between the two groups (p: n.s.). Correlation analysis showed a moderate negative correlation between joint line elevation and quadriceps peak force ($r= -0.29$, $p<0.05$).

Conclusion

With the FFB technique the medial joint line is well restored but this did not lead to less coronal laxity in the mid-flexion range compared to MR. Although peak quadriceps power was significantly higher for the FFB group no clinically relevant benefits could be identified for the patients with regards to functional outcome.

INTRODUCTION

With the standard Measured Resection (MR) technique in total knee arthroplasty (TKA) the medial posterior condylar offset and joint line height are regularly not fully restored resulting in an elevation of the joint line (W.A.M. van Lieshout et al. 2019). For gap balancing techniques this is even slightly higher (Moon et al. 2016). This elevation of the joint line hypothetically results in an increased mid-flexion laxity due to loss of isometry for the medial collateral ligament (MCL) (Cross et al. 2012; Luyckx et al. 2018). Restoring the medial joint line height to its pre-disease height is advocated to achieve a balanced knee (Victor 2017).

The Flexion First Balancer (FFB) technique for TKA was developed to maintain the isometry of the MCL by restoring the medial anatomy of the knee (W.A.M. van Lieshout et al. 2020). Although in a previous report joint line reconstruction with FFB was achieved in contrast to MR, this did not result in better patient reported outcome measures (PROMs) (W.A.M. van Lieshout et al. 2019), a correlation with functional outcome tests however can be expected (Freisinger et al. 2017).

In recent literature extra focus on flexion gap balancing during TKA is seen to achieve better performance (D'Elicio et al. 2021; Moon et al. 2016). But where these previous studies focused on antero-posterior stability of the knee or patella tracking, the current study focused on medio-lateral stability which still is considered the key to achieve satisfactory results.

The aim of the current study was to investigate the effect of the FFB technique on postoperative coronal laxity in the mid-flexion range and functional outcome. Our hypothesis was that since the FFB technique restores the joint line to its pre-disease height this would result in less coronal mid-flexion laxity. Which, in term could result in better functional outcome compared to the standard MR technique due to increased stability in the knee.

MATERIAL AND METHODS

Study population

Patients who underwent TKA surgery via the FFB technique for Kellgren-Lawrence grade 3-4 osteoarthritis and were treated between September 2015 and November 2016 were included in the present study. A historical matched cohort of patients who were operated using the standard MR technique between September 2014 and July 2015 was used as control group. The MR group was matched to the FFB group based on age, gender, Body mass index (BMI) and American Society of Anesthesiologists (ASA) classification, using frequency matching. Patients were operated by two surgeons, using the FFB technique as well as the MR technique for TKA as standard care. In all patients a cruciate retained (CR) type, Vanguard Complete Knee System (Biomet Orthopedics, Warsaw, IN, USA) implant was used. Inclusion criteria for analysis were primary cruciate retaining TKA with at least one year of follow up. Exclusion criteria were ill health influencing functional tests (e.g. severe chronic obstructive pulmonary disease or congestive heart failure), degenerative diseases (e.g. rheumatoid arthritis) or development of severe osteoarthritis in other lower extremity joints that would influence functional test outcomes, complications requiring consecutive surgery, a hip replacement or contralateral TKA within the past year or previous knee surgery which could influence the laxity of the knee (MCL or LCL reconstruction/reefing). All patients gave written informed consent prior to the investigation. A total of 55 patients were included, 27 patients in the FFB group and 28 patients in the MR group resulting in 27 FFB knees and 28 MR knees included in this study (Figure 1). Baseline characteristics regarding patients and type and severity of arthrosis were comparable between the matched groups (Table 1). The study protocol was evaluated and approved by the Dutch medical ethical committee MEC-U (protocol ID: NL65535.100.18).

For this cross-sectional study, patients were asked to visit our hospital for further evaluation. This consisted of extra radiographs to test mid-flexion laxity, three functional tests, and two questionnaires.

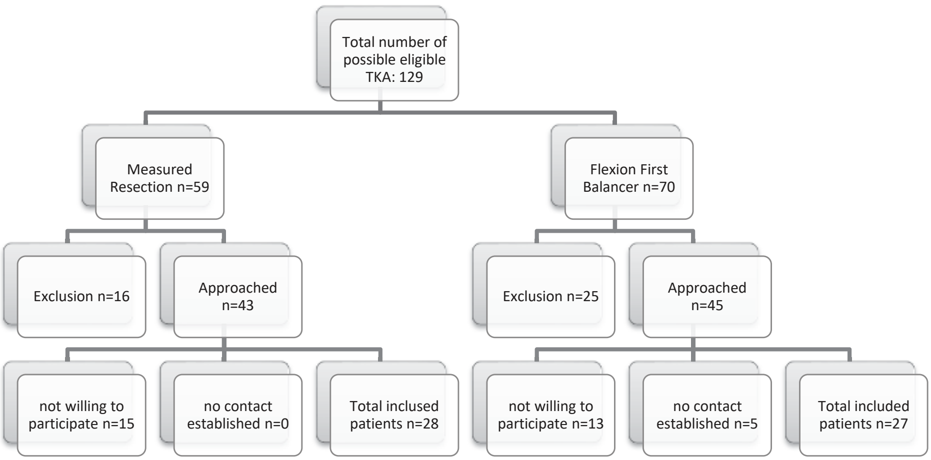

Fig 1. Flow chart MIFO study

Table 1. Baseline characteristics

	MR (n=28)	FFB (n=27)	p-value
Age, mean (sd)	67.0 (7.7)	66.4 (7.9)	N.S.
Gender, no. male (%)	11 (39.3)	15 (55.6)	N.S.
BMI, mean (sd)	30.2 (4.9)	29.2 (3.9)	N.S.
ASA, no. (%)			N.S.
I	5 (17.9)	6 (22.2)	
II	17 (60.7)	20 (74.1)	
III-IV	6 (21.4)	1 (3.7)	
Follow up, mean (sd)	3.9 yrs (0.2)	2.6 yrs (0.4)	N.A.
Type of arthrosis (Medial/ Lateral/Multi/PF)	14 / 3 / 10 / 1	9 / 6 / 11 / 1	N.S
FTA, mean (sd)	3.1 (4.8)	3.0 (5.4)	N.S.
Bone-loss	2	6	N.S.

Abbreviations: MR: measured resection; FFB: Flexion First Balancer; sd: standard deviation; BMI: body mass index; ASA: American Standardization Association; PF: patella-femoral; FTA: femoral tibial angle; N.A.: not applicable; N.S.: non-significant

Surgical technique FFB

A standard midline skin incision and medial para-patellar arthrotomy is followed by a perpendicular tibial cut. This is set at six millimeters below the intact medial posterior cartilage. A preliminary five millimeters distal femur cut is made to obtain a flat surface for the following steps. After removal of medial and lateral osteophytes the Flexion Balancer is placed with the knee in 90 degrees of flexion to determine the correct posterior offset. The system references of the intact posterior cartilage of the medial femur condyle to recreate the joint line height and uses ligament tension to set femoral rotation. The flexion gap should read at least 10mm, if not, an extra tibial cut should be performed to accommodate the implant. This way joint line elevation is prevented. Drill holes are made through the balancer and a slotted four-in-one cutting guide is placed. The posterior and anterior cuts can be made at this point. After removing posterior osteophytes the extension gap is matched to the flexion gap with the use of balancers. In case of a trapezoid extension gap the medial collateral ligament (MCL) and lateral collateral ligament (LCL) can be tensioned equally with the use of wedges. These come in one, two, three and four degrees of varus or valgus. By using wedged spacer blocks the distal valgus angle of the femur is adjusted to create a rectangular extension gap. When the extension gap is adequately balanced the drill guide is placed to set the final distal resection level. Finally, the chamfers cuts are made through the previously used slotted four-in-one cutting guide. From this point on, the orthopedic surgeon continues with the standard technique to finish preparing the femur, tibia and patella and prosthesis placement (W.A.M. van Lieshout et al. 2019).

Radiological analysis

To determine mid-flexion laxity of the knee, three anterior-posterior radiographs of the knee were ordered. The knee was positioned in an angle of approximately 30° using a 15cm high triangle cushion under the knee for all three radiographs. Firstly, a neutral radiograph was obtained. Subsequently, two radiographs were obtained while medial or lateral forces were applied to the knee. The direction of the X-rays were parallel to the tibia joint surface, centered on the middle of the femorotibial joint space. Varus and valgus stress were applied to the knee with a load of 15 Nm using the Telos device (Fa Telos, Medizinisch-Technische GmbH, Griesheim, Germany). Patients were in a supine position with leg muscles relaxed. For joint line measurements standard AP radiographs of the knee were used. Preoperatively, pre-disease (i.e. without cartilage loss) X-rays were analysed and compared with the 1-year postoperative X-rays. The femoral tibial angle (FTA) was determined to assess pre-operative alignment. For the preoperative FTA we used the last X-ray before surgery. Femoral-tibial angle was defined as the angle between the anatomical axis of the femur and the tibia in the anteroposterior view of the knee.

To determine changes in joint line level the adductor ratio was calculated with correction for cartilage depth as described in a previous study comparing FFB and MR for PROMs and outcome (W. A.M. van Lieshout et al. 2019). For the coronal mid-flexion laxity measurements the angle between a line through the distal femoral component condyles and a line through the tibia component was determined. This was done on the varus, valgus and neutral radiographs using the measurement tool within the radiographic JiveX software (Visus Technology Transfer GmbH, version 4.7.1.10, Bochem Germany). With this software, measurements with an accuracy of 0.1° were possible. Valgus laxity was defined as the difference in angles between the medial stress radiograph and the neutral radiograph, varus laxity as the difference between the lateral stress radiograph and the neutral radiograph. Total laxity was defined as the total of the varus and valgus laxity achievable in the knee. This method has previously successfully been used and described by Heesterbeek et al. (Heesterbeek, Verdonschot, and Wymenga 2008) although real validation is lacking in literature it is frequently used. To assess the validity of the measurement itself we calculated the ICC by re-measuring the first 10 sets of radiographs (neutral, varus and valgus stress). This provided us with an ICC of respectively 0.991, 0.995 and 0.998.

Other outcome measures

During the visit, patients were asked to fill out the validated Dutch EQ-5D-5L and Lysholm questionnaire (Eshuis et al. 2016; Herdman et al. 2011; Kocher et al. 2004; Versteegh et al. 2016). The first questionnaire evaluates (EQ-5D-5L) the quality of life experienced by the patient at the time of the survey. The second test (Lysholm) evaluates the knee stability experienced by the patient and the ability to perform daily living activities. The aim for these questionnaires was to evaluate if a more specific questionnaire on QOL and knee stability could detect differences between the two groups.

Finally, the patients were asked to perform three functional tests in the following fixed order: a timed stair climbing test (SCT), a 6-minute walking test (6MWT) and a static quadriceps peak force test. These three test have been shown to correlate with passive mid-flexion laxity in a recent study (Freisinger et al. 2017). The SCT was measured as the time necessary to ascend and descend a 10-step staircase as previously described (Almeida et al. 2010). The participants were instructed to complete the task as quickly and safely as possible. They were encouraged not to use the handrail unless necessary. The 6MWT was measured as the distance a participant could walk around a 25m indoor track in 6 minutes. Patients were instructed to walk as far as possible in a safe manner. They were encouraged not to take any breaks or to use a walking aid unless this was necessary to complete the task (Enright 2003; Enright et al. 2003). For the static quadriceps peak force test patients were asked to sit on the edge of a table with their knees in 90 degrees flexion holding the lower leg parallel to the table leg. The lower leg was then non-elastically strapped 5 cm above the medial malleolus to a hand-held dynamometer (HHD) meter which was positioned on the posterior side of the table leg (Figure 2). Patients were instructed to hold their arms in front of their chest and apply maximum amount of knee extension for 5 seconds. This modified method of testing with a HHD has proven to be highly reliable (Koblbauer et al. 2011). The first test outcome was recorded as a trial followed by two recorded outcomes.

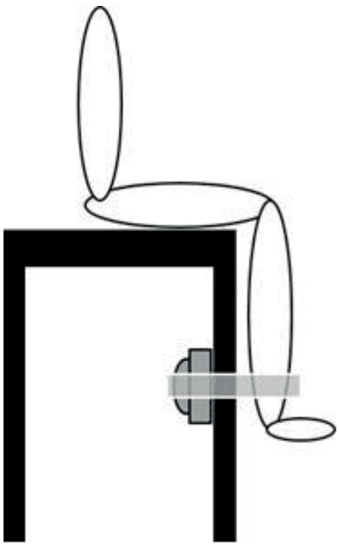

Fig 2. Experimental setup for the quadriceps force measurements.

Patients asked to sit on a table. The hand held dynamometer (represented by the dark gray element) was fixed at the posterior side of the table leg. The strap (represented by the light gray bar) was then positioned around the lower leg and the hand held dynamometer. The standard height of the strap was 5cm above the medial malleolus.

Data- and statistical analyses

The two quadriceps force measurements were averaged and divided by the BMI of the patient. Normally distributed continuous data were compared between the groups using unpaired samples T-tests, otherwise Mann-Whitney U Tests were used. Categorical data was compared between groups using Chi-square tests. To evaluate changes in outcome parameters over time (e.g. the adductor ratio) paired samples T-tests were used. Pearson's correlation coefficients were determined to evaluate the association between joint line changes and laxity and between these parameters and the functional outcome parameters. Sample size calculations were based on mid-flexion stability as our primary outcome measure. Based on a clinical relevant difference of 0.5mm, an SD of 0.5mm, an alpha of 0.05 and a power of 0.95, two groups of 24 patients was needed (Matziolis et al. 2016). To allow for possible exclusions we aimed to include a maximum of 30 patients per group. P-values below 0.05 were considered as significant. SPSS statistics (version 25, Armonk, NY: IBM Corp SPSS Statistics) was used to perform the statistical analyses.

RESULTS

Mean follow up for the 27 patients in the FFB group was 2.6 years (SD 0.4) and 3.9 years for the 28 patients in the MR group with the shortest follow up being 15 months for 1 FFB patients. The difference in technique between the MR and FFB technique with regard to joint line position was demonstrated by a significantly higher joint line after surgery in the MR group compared to the FFB group. I.e. the preoperative adductor ratio was comparable between the two groups (MR: 0.552±0.033 vs. FFB: 0.554±0.034, p=0.80), but after surgery a significant difference between the groups was found in the delta score of the adductor ratio (MR:-0.014±0.024 vs. FFB: 0.015±0.021, p<0.001), indicative of an absolute difference of 3 mm between the two groups. The adductor ratio in the MR group decreased significantly (p<0.01) and in the FFB group a significant increase was found (p<0.005).

With respect to the primary outcome, no difference was seen in medial laxity (p=0.78), lateral laxity (p=0.10) and total laxity (p=0.14) between the FFB group and the MR group (Figure 3). The secondary outcomes demonstrated a significantly higher quadriceps peak force in the FFB group compared to the MR group (p<0.05). In respect of the other functional tests (6MWT and SCT) and the questionnaires, no differences between the two groups were found (Table 2).

For the total group (MR and FFB combined), no correlations were seen between the change in joint line height and the medial (r=0.16 , p=0.24), lateral (r=-0.08 , p=0.57) or total laxity (r=0.17, p=0.22). Therefore, subsequent correlation analyses were only performed between the change in joint line height (not for laxity) and the functional outcomes. A significant moderate negative correlation was found between joint line elevation and quadriceps peak force ($r=-0.29$, $p<0.05$). No significant correlations were found with the 6MWT ($r=0.23$, $p=0.10$), SCT ($r=0.05$, $p=0.70$), or Lysholm score ($r=0.09$, $p=0.52$).

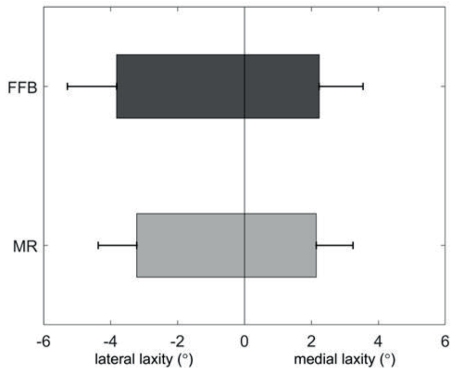

Figure 3. Medial and lateral mid-flexion laxity in the FFB vs MR group.
The boxplots show the mean lateral and medial laxity in 30 degrees of knee flexion for the Flexion First Balancer (FFB) group and of the Measured Resection (MR) group. Together this shows the total laxity per group. Represented on the left side is the mean lateral laxity for FFB: 3.8° (SD 1.5°) and for MR: 3.2° (SD 1.2°). Represented on the right side is the mean medial laxity for FFB: 2.2° (SD 1.3°) and for MR: 2.1° (SD 2.1°). All data comparisons were non-significant.

Table 2. Secondary outcome measures; functional test and questionnaires

	MR (n=28)	FFB (n=27)	p-value
6 MWT, mean (sd)	425 (44)	437 (80)	0.50
Stair climb test, mean (sd)	14.0 (3.6)	14.4 (4.1)	0.69
Peak quadriceps force (N/BMI), mean (sd)	1.38 (0.48)	1.67 (0.55)	**0.03**
EQ-5D-5L utility, median (IQR)	1.0 (0.8-1.0)	0.9 (0.8-1.0)	0.32
EQ-5D-5L VAS, median (IQR)	82.5 (80.0-95.0)	90.0 (75.0-95.0)	0.63
Lysholm Total score grouped			0.94
Excellent	10 (35.7)	9 (33.3)	
Good	4 (14.3)	5 (18.5)	
Fair	8 (28.6)	8 (29.6)	
Poor	6 (21.4)	5 (18.5)	

Abbreviations: MR: measured resection; FFB: Flexion First Balancer; 6MWT: 6-minute walking test; sd: standard deviation; IQR: interquartile range; N/BMI: newton / body mass index; VAS: visual analogue scale; N.A.

DISCUSSION

The main finding of this study illustrated no difference in mid-flexion laxity between the new FFB technique and the MR technique in TKA. The previously established joint line difference between FFB and MR after surgery was reconfirmed but no correlation between joint line elevation and laxity was found. The reconstructed joint line resulted in a higher quadriceps peak force for patients in the FFB technique group. This was emphasized by the negative moderate correlation found between joint line elevation and quadriceps peak force. All other functional outcome measures were comparable between the two groups.

The mid-flexion laxity (30 degrees flexion) found in our study was comparable with previously reported coronal laxity after TKA in 0 to 30 degrees flexion (Van Der Esch et al. 2006; Heesterbeek, Keijsers, and Wymenga 2010). Although cadaver studies clearly demonstrated the effect of joint line height on mid-flexion laxity (Cross et al. 2012; Luyckx et al. 2018), the difference in joint line change between the MR and FFB group in the current study did not result in a difference in mid-flexion laxity. A possible explanation for this discrepancy might be that the difference in joint line height between the two groups in the current study was too small. Cross and colleagues showed that a 2mm joint line elevation resulted in minor mid-flexion laxity and 4mm elevation in clear mid-flexion laxity (Cross et al. 2012). The difference in joint line position between our two groups was only 3mm. This hypothesis was recently confirmed in a study by Minoda and colleagues, who showed no difference in mid-flexion laxity after a 2mm joint line elevation during TKA surgery (Minoda et al. 2020). A second explanation could be that the results found in cadaver studies are not viable for in vivo testing. Patients need to fully relax the examined leg during the varus and valgus testing. Possibly, in conscious patients a compensatory effect of muscle tension is present. This assumption is underlined by the finding that ligament laxity increases after general anesthesia (Tsukeoka and Tsuneizumi 2016). Thus, the limited amount of joint line elevation and the active muscle tension might have counter-acted possible mid-flexion laxity.

With regards to the secondary outcomes, only a significant higher peak quadriceps force was found for the FFB group compared to the MR group. Since the study lacks pre-operative functional test results this could in theory be a confounding result. But since other functional test were comparable between the two matched groups, we expect comparable fitness levels between the two groups. The higher peak quadriceps force can be explained by the increased joint line and the compensatory reduced posterior condylar offset in the MR group. The posterior condylar offset acts as a lever arm for the quadriceps muscle and if this arm is reduced this negatively affects the quadriceps strength. The FFB technique restores the medial condylar offset and therefore does not affect the quadriceps strength. This was also supported by the finding of a significant negative correlation between joint line elevation and peak quadriceps force in the total cohort. The outcomes of the functional tests and questionnaires revealed no differences between the groups. Our findings for 6MWT, SCT and peak quadriceps force were comparable to the literature (Alnahdi, Zeni, and Snyder-Mackler 2011; van Onsem et al. 2018; Stevens-Lapsley, Schenkman, and Dayton 2011). The hypothesis that a reconstructed joint line would result in less laxity, thus improving relevant clinical functional outcome was not proven. Moreover, no correlation was found between joint line elevation and 6MWT and SCT. A possible factor might be the previously stated minimal difference in joint line height between the two groups, which resulted in comparable laxity results. Since our sample size calculation was based on medial and lateral laxity as the primary outcome, group sizes might have been too small for the functional outcome tests to show any differences between the two groups. Nevertheless, the negative correlation between joint line elevation after TKA and postoperative quadriceps force seems clinically relevant and should lead to extra care taken on joint line reconstruction during TKA placement.

The FFB technique has been a regular part of our practice for several years. Multiple studies hinted to the possible benefits of this new technique. With the FFB technique it is safely possible to reconstruct the joint line however this does not result in better PROMs (W. A.M. van Lieshout et al. 2019). Hence the current study, that focused on coronal laxity and functional outcome. With exception for a higher peak quadriceps force in the FFB group no other benefits could be identified. It can therefore be concluded that the FFB technique is safe to use and is without negative side effects. However, demonstrating actual improvements in clinical outcome for patients after TKA is difficult. Apart from increased peak quadriceps force, due to a better reconstructed joint line, no other benefits for the patient could be identified. As with all ligament balancing systems, extreme deformities and insufficient collateral ligaments are a contraindication for this technique (Easley, Cushner, and Scott 2001).

There are some limitations regarding this research. This cross-sectional study compared two techniques without blinding and randomization. And although the results in this study were prospectively acquired, the preoperative values were retrospectively collected. In 2015 we started using the FFB technique exclusively for TKA. Therefore, no direct comparison between the two groups has been possible. There is very little difference shown in follow-up between the two cohorts but short follow-up time (15 months for 1 patient) could be an limitation. However, since both cohorts had more than 12 months of follow-up an effect on the outcome measures is not expected as was concluded in a recently published systematic review by Ramkumar and colleagues (Ramkumar et al. 2018). Secondly, the power-calculation was performed for varus-valgus laxity, which might have resulted in underpowered results for the functional tests and questionnaires. But early studies concerning functional outcome with similar group sizes were however able to find significant differences between groups so it could be argued that group sizes were sufficient (Ko et al. 2013; van Onsem et al. 2018). Thirdly, due to the nature of this cross-sectional study preoperative quadriceps force is missing for patients which might be a confounder for the reported significant difference between the two groups. Finally, with regards to validity for stress radiographs, for anterior-posterior instability of the knee this is well documented however, for coronal laxity this information is still missing. Since these stress radiographs are widely used in preoperative as well as research settings, this should be addressed in future research.

CONCLUSION

With the FFB technique the medial joint line is well restored but this did not reduce coronal laxity in the mid-flexion range compared to MR. Although peak quadriceps power was significantly higher for the FFB group no clinically relevant benefits could be identified regarding functional outcome. Finally the negative correlation between joint line elevation after TKA and postoperative quadriceps force seems clinically relevant. The Flexion First gap balancing method might provide a more controlled joint line reconstruction in TKA.

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PART 3

CONCLUSION AND DISCUSSION

chapter 8

Summary, general discussion and conclusion

SUMMARY

The overall aim of this thesis was to investigate the effect of surgical procedures for the osteoarthritic knee on coronal laxity, subjective instability and patient outcome. The two parts of this thesis consecutively described: 1) the medial closed wedge high tibal osteotomy (HTO) and 2) Total Knee Arthroplasty (TKA).

Part 1: Medial Closed Wedge HTO

Changes in coronal knee laxity after osteotomy might affect patient outcome since stability of the knee is an important factor in patient satisfaction. For a medial closed wedge HTO the effect of the procedure on objective laxity was unclear. Moreover, additional reefing of the MCL to correct the hypothetical MCL laxity increase as has been suggested by Coventry is nowadays not standard care (Coventry 1985, 1987). Therefore, in this part of the thesis the effect of a medial closed wedge HTO without MCL-reefingplasty on coronal laxity and patient outcome was studied. Chapter 2 focused on coronal laxity changes and presented instrumented laxity measurements in 11 consecutive patients. In conclusion, this study showed a significant increase in postoperative valgus laxity in 30° and 70° of flexion after medial closing wedge HTO without MCL-reefingplasty. This result deems reconsidering of the addition of a MCL-reefingplasty to the medial closed wedge HTO although patient reported outcome on subjective stability scores failed to report increase of instability in this small study population. Therefore, in chapter 3 the focus was on a large retrospective cohort of patients who had undergone a medial closed wedge HTO without MCL-reefingplasty. The aim was to assess the patient reported stability and survival and compare these to historical patient cohorts. This chapter showed that a medial closed wedge HTO without MCL-reefingplasty provides good results regarding survivorship and patient satisfaction. Slightly higher subjective knee laxity findings postoperative were present when compared to historical cohorts of patients who had undergone medial closed wedge HTO with a MCL-reefingplasty. The study also showed that knee instability was significantly correlated with worse patient reported outcome scores. It was concluded that an MCL-reefingplasty should be reconsidered in selected patients.

Part 2: Total Knee Arthroplasty

Cadaver studies showed that joint line elevation after TKA leads to loss of the isometry of the medial collateral ligament which in turn leads to coronal mid-flexion laxity (Cross et al. 2012; Luyckx et al. 2018). This joint line elevation and subsequent increased coronal laxity might affect patient outcome and therefore should be carefully evaluated in TKA (Martin and Whiteside 1990). However, contradicting results have been published with regards to joint line elevation, laxity and patient outcome. Therefore, in this part of the thesis the effect of loss of isometry of the medial collateral ligament and the subsequent of joint line height elevation and mid-flexion instability was studied to possibly improve patient outcome after TKA. In chapter 4 the effect of joint line elevation on patient reported outcome scores was studied in a systematic review. This chapter showed that an increased joint line height after primary TKA is negatively correlated with patient reported outcome. Furthermore, it showed that after revision TKA with a maintained joint line, patients had statistically significant better postoperative outcome scores compared to those with an elevated joint line. Based on the results of this study a recommendation was given to pursue restoration of the joint line to the pre-disease height and not to exceed 4mm of joint line elevation as this negatively affected patient outcome.

Since joint line elevation affects patient outcome, in this thesis a new technique for TKA was introduced to reduce joint line elevation: the Flexion First Balancer (FFB). This technique is designed to enable the surgeon retain the isometry of the MCL by reconstruction of the medial pre-disease joint line height and medial posterior condylar offset (PCO). Presumably this would result in better outcome since mid-flexion instability is the result of loss of isometry of the medial collateral ligament (Cross et al. 2012; Luyckx et al. 2018). In chapter 5 this new technique was described and possible side effects of this new technique were discussed. To assess if the theoretical concept would lead to better prosthesis position and patient outcome, two additional studies were conducted: the new technique was compared to the standard measured resection (MR) technique for TKA. In chapter 6 a retrospective cohort of 59 patients operated using the FFB technique was analysed and matched with a historical MR cohort of 59 patients. In this chapter it was shown that with the FFB the joint line is reconstructed to the pre-disease height in contrast to the MR cohort in which the joint line was elevated. However, evaluation of the PCO revealed no differences between the two groups. The studied outcome measurements showed comparable results for patient reported outcome measurements (PROMs) as well as re-operations and complication rates. So, it was concluded that the new technique is safe to use and results in joint line restoration but this did not lead to better PROMs. Finally, in chapter 7 the effect of this new technique on coronal laxity, functional outcome and reported stability was evaluated. In this chapter a cross-sectional study is presented which compared 27 FFB patients to a matched cohort of 28 MR patients. Postoperative coronal laxity in mid-flexion was radiologically assessed, functional tests were obtained to assess functional outcome and a questionnaire was taken to assess patient reported stability. No differences in coronal laxity were shown between the two groups despite significant differences in joint line height. Patient reported stability was also comparable between the two groups. Furthermore, although the FFB group had higher quadriceps peak force compared to the MR group this did not result in improved relevant clinical functional outcome (i.e. walking distance or stairclimbing abilities). So it was concluded that even though better prothesis position is possible with the FFB technique, this does not lead to better outcome for the patient.

General discussion and future perspectives

The aim of this thesis was to assess how coronal laxity changes after knee surgery affects patient outcome. In this thesis it was proven that increased valgus laxity occurs after a medial closed wedge HTO without an MCL-reefingplasty. Furthermore, in the largest cohort of patients presented in the literature so far, a slightly higher percentage of patients reported postoperative instability as compared to previous reports (Coventry 1987; Shoji and Insall 1973). The lack of an MCL-reefingplasty in the cohort presented in this thesis might explain the slightly higher prevalence of subjective knee instability in comparison with the other two studies. Although survival and patient satisfaction was high, it was shown that instability negatively correlates with PROMs. Still almost a quarter of the patients presented in this thesis were unsatisfied with the operation there might be something to gain with regards to outcome. It remains uncertain whether all patients need an extra MCL-reefingplasty to re-tension the MCL. The key element is to identify which patients will be prone to develop this knee instability and may benefit from the reefing procedure of the MCL as was previously described by Coventry (Coventry 1985, 1987). However, to date no predictable model is available to select those patients who would benefit from this extra procedure. Therefore, in this thesis it was suggested that the surgeon intra-operatively checks the valgus laxity in flexion angles of 30° and 70° before and after performing the medial closed wedge HTO and if deemed necessary performs a reefingplasty of the MCL. This might prevent instability complaints postoperative and therefore might increase overall patient satisfaction. Future research focus should be on instrumented laxity measurements of medial closed wedge HTO patients treated with the additional medial reefingplasty to prove the value of this procedure. Secondly, a comparative study between the two surgical methods should be conducted to evaluate if a decrease in valgus laxity results in increased stability and better outcome scores and survival for the patient.

In the second part of this thesis it was stated that joint line elevation after TKA potentially affects patient outcome. The new Flexion First Balancer technique, which was presented in this thesis, is designed to maintain isometry of the medial collateral ligament through preservation of the medial posterior condylar offset and joint line. When combining the results of the chapters 6 and 7 the conclusion is that the FFB technique is safe to use, restores the joint line and results in higher quadriceps peak force. However, despite joint line restoration to the pre-disease height, no improvements in coronal laxity were noted and no relevant clinical benefits for the patient could be identified in outcome. Possibly, the differences in joint line height between the two techniques found in the studies presented in this thesis were too small to induce the expected differences in outcome. The presented data in chapter 6 of this thesis showed a 1.3mm elevation in joint line in the MR group, in contrast to a maintained joint line in the FFB group. The results of this study and those of the systematic review as presented in chapter 4 of this thesis lead to the conclusion that more deviation from the original joint line height is associated with inferior outcome but only if this exceeds 4 mm. Small deviations after TKA seem acceptable and do not compromise the studied outcome parameters. The results of this thesis regarding joint line height and measured laxity are in contrast to previously reported cadaver studies (Cross et al. 2012; Luyckx et al. 2018). Those reported increased mid-flexion laxity after just 2mm of joint line elevation. However, in line with the results of this thesis, in a recently published article no increase in mid-flexion laxity has been found after a 2mm joint line elevation measured in patients undergoing a TKA for varus osteoarthritis (Minoda et al. 2019). Thus, it is debatable whether or not the results found in cadaver studies are directly applicable to patients with osteoarthritis. Another factor that might affect mid-flexion stability after TKA is the effect of the secondary stabilizers of the knee. It has been proven that coronal laxity changes after general anaesthesia (Tsukeoka and Tsuneizumi 2016). Due to relaxation of the muscles around the knee only the primary stabilizers of the knee constrain the valgus-varus motion. However, in the awake postoperative patient these secondary stabilizers seem to correct some of the measurable laxity. This could counter-act the slight increase in coronal laxity and might account for the normal subjective knee stability reported by the patients.

This raises the question of how much laxity is acceptable during surgery since correlating laxity to stability remains difficult. In this thesis we were not able to correlate laxity changes to subjective reported instability. However, a recently published systematic review showed that there is a relationship between coronal laxity and patient outcome. This was only present in 80-90 degrees of flexion for medial laxity, i.e. during valgus stress. For the range between 0 to 30 degrees of flexion none of the 11 studies included could establish statistically significant association between laxity and outcome scores (Kappel et al. 2019). Another recent article published by Kamenaga and colleagues showed that medial stability at both extension and flexion played an important role in beneficial 1-year postoperative functional outcomes and patient satisfaction (Kamenaga et al. 2018). In contrast to these publications, Altubasi was not able to find a contribution of coronal laxity in the relationship between quadriceps muscle strength and physical function in patients with osteoarthritis (Altubasi 2018). Furthermore, a review article by Wallace et al. clearly shows the contradicting results in the literature with regards to measurable laxity, reported stability and their relation to outcome for patient with osteoarthritis (Wallace, Riches, and Picard 2019). These recent published reports showed that there is still no clear answer on how laxity relates to stability and patient satisfaction.

In conclusion, it can be argued that after knee surgery for the osteoarthritic knee the role of stability, as opposed to the measured laxity, is more important. A possible biomechanical factor involved might be that osteoarthritic surgical procedures around the knee alter knee kinematics significantly. Contribution factors might be changes made to alignment of the leg, the removal of the cruciate ligament and changes in measurable laxity. This remains speculation, it has not been investigated in the studies presented in this thesis and should be further investigated. Furthermore, the methods used to study coronal laxity vary widely in the literature. From passive laxity measurements during surgery, to passive testing in awake patients and finally gait analysis before and after surgery. Moreover, even the techniques used for passive laxity testing differ in the literature. Therefore, standardized methods for analysing laxity and subjective stability should be developed as this would make results comparable. Then future research should focus on postoperative laxity changes and investigate how this relates to subjective stability and functional outcome. This would enable future researchers to provide a clear answer on research questions on the topic of laxity changes and how this relates to reported stability after knee surgery. With these answers the next step towards improving patient outcome after knee surgery can be made.

The following main findings and future perspectives are the take home message of this thesis. For the medial closed wedge high tibial osteotomy without MCL-reefingplasty an increased coronal laxity was reported postoperative. Despite good postoperative results, patient reported outcome and stability might improve when MCL-reefingplasty is applied in selected patients. This thesis thus advised that for those patients in which an increase in MCL laxity is observed per-operatively a MCL-reefingplasty should be considered. For Total Knee Arthroplasty this thesis showed a negative correlation between joint line elevation and patient reported outcome. This joint line elevation results in coronal laxity in the mid-flexion range and should therefore be minimized. The new Flexion First Balancer technique presented in this thesis was able to reconstruct the joint line of the knee however, no improvements in patient reported outcome and stability were reported. As is shown in this thesis it remains difficult to correlate objective laxity measurements to patient reported stability. Standardized methods for analysing laxity and subjective stability should be developed as this would make results comparable for future research. With these standardized methods research should be focussed on the correlation between per-operative laxity, postoperative laxity and patient reported stability after surgical procedures for the osteoarthritic knee. This knowledge can provide answers that potentially lead to the next step in improving patient outcome after TKA.

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Appendix

List of abbreviations
Nederlandse samenvatting
Curriculum Vitae
Dankwoord

List of abbreviations

6MWT	6-minutes walk test
ASA	American Standardization Association
Amsterdam UMC	Amsterdam Universitair Medische Centra
(c)ATJL	(corrected) adductor tubercle joint line distance
CAS	Computer-assisted surgery
CR	Cruciate retained
CWHTO	Closing wedge high tibial osteotomy
BMI	Body mass index
dMCL	Deep portion of the medial collateral ligament
FFB	Flexion First Balancer
FTMA	Femoral tibial mechanical angle
FW	Femoral width
GB	Gap balancing
HKA	Hip–knee–ankle
HTO	High tibial osteotomy
IKDC	International Knee Documentation Committee
IQR	Interquartile range
ITB	Iliotibial Band
JL	Joint line
KOOS	Knee Injury and Osteoarthritis Outcome Score
KSS	Knee society score
LCL	Lateral Collateral Ligament
MCL	Medial Collateral Ligament
MCWHTO	Medial closing wedge high tibial osteotomy
MR	Measured resection
NA	Navigation assisted
NRS	Numeric rating scale
OA	Osteoarthritis
OKS	Oxford knee score
(c)PCO	(corrected) Posterior Condylar Offset
PROMS	Patient-reported outcome measurement scores
QoL	Quality of life
SCT	Stair climb test
SD	Standard deviation
SF-36	Short Form 36
sMCL	Superficial portion of the medial collateral ligament
TKA	Total Knee Arthroplasty
VAS	Visual analogue scale

HET EFFECT VAN CHIRURGISCHE OPERATIES VOOR DE ARTROSE KNIE OP CORONALE LAXITEIT EN PATIËNT UITKOMST

Nederlandse samenvatting

De doelstelling van deze thesis was om te onderzoeken wat het effect is van operatieve ingrepen voor knie artrose op coronale laxiteit, subjectieve instabiliteit en patiënten uitkomstmaten. De thesis is opgedeeld in twee delen en deze beschrijven de volgende ingrepen: 1) mediaal gesloten wig osteotomie van de proximale tibia en 2) totale knie prothese.

Deel 1: Mediaal gesloten wig osteotomie van de proximale tibia

Veranderingen in coronale laxiteit na een osteotomie hebben mogelijk effect op de postoperatieve uitkomst omdat stabiliteit van de knie een belangrijke rol speelt in patiënten tevredenheid. Voor een gesloten wig osteotomie van de proximale tibia is het onduidelijk wat het effect is van de ingreep op deze laxiteit. Daarnaast is de, in 1985, door Coventry geïntroduceerde reefplastiek van het mediale collaterale ligament (MCL), om de hypothetische toename in laxiteit op te vangen, tegenwoordig geen standaard behandeling (Coventry 1985, 1987). In dit deel van de thesis werd daarom onderzocht wat het effect is van de mediaal gesloten wig van de proximale tibia op coronale laxiteit en patiënten uitkomst. In **hoofdstuk 2** werd onderzocht wat de veranderingen zijn in coronale laxiteit met behulp van gevalideerde laxiteit metingen voor en na de operatie bij 11 opeenvolgende patiënten. De conclusie van deze studie was dat er sprake is van een significante toename in valgus laxiteit in zowel 30° en 70° knie flexie na de osteotomie zonder de MCL reefplastiek. Derhalve zou men kunnen overwegen dat de MCL reefplastiek toch van toegevoegde waarde is, ondanks het feit dat er geen toename werd gezien van gerapporteerd instabiliteit door de patiënten in deze kleine studie populatie. Om meer duidelijkheid te verschaffen over dit laatste punt werd in **hoofdstuk 3** een groot retrospectief cohort van patiënten onderzocht die een mediaal gesloten wig van de proximale tibia hebben ondergaan. Het doel was om inzicht te verkrijgen in de patiënt gerapporteerde stabiliteit na de operatie en de gemiddelde overleving van een dergelijke operatie te onderzoeken. Deze uitkomsten werden vervolgens vergeleken met historische cohorten. In dit hoofdstuk werd bewezen dat zowel de overleving van een mediaal gesloten wig osteotomie van de proximale tibia zonder MCL reefplastiek en de patiënt tevredenheid na de operatie goed zijn. Echter werd er wel een mild hogere subjectieve instabiliteit gevonden in dit cohort in vergelijking met de historische cohorten waarbij er wel een MCL reefplastiek was toegepast. Tevens werd in de studie aangetoond dat er een correlatie bestaat tussen subjectieve instabiliteitsklachten en slechtere patiënt gerapporteerde uitkomstmaten. Zodoende werd geconcludeerd dat, in geselecteerde patiënten, de MCL reefplastiek toch moet worden overwogen.

Deel 2: Totale knie prothese

Kadaverstudies hebben aangetoond dat gewrichtsvlak verhoging na totale knie prothese (TKP) leidt tot isometrieverlies van het MCL met als gevolg coronale midflexie laxiteit (Cross et al. 2012; Luyckx et al. 2018). De gewrichtsvlak verhoging met daarbij de coronale laxiteit verandering heeft mogelijk effect op de patiënten uitkomst en derhalve moet dit goed gecontroleerd worden bij TKP plaatsing (Martin and Whiteside 1990). Echter is er in de literatuur geen consensus met betrekking tot optimale gewrichtsvlak positie, laxiteit en patiënten uitkomst. Met dit in het achterhoofd werd in dit deel van de thesis het effect onderzocht van het isometrieverlies van het MCL als gevolg van een gewrichtsvlak verhoging op midflexie laxiteit, met als doel om zodoende mogelijk de uitkomst na TKP plaatsing te verbeteren. In **hoofdstuk 4** werd het effect van gewrichtsvlak verhoging na TKP op patiënt gerapporteerde uitkomstmaten bestudeerd middels een systematische review van de literatuur. Dit hoofdstuk toonde aan dat er een negatieve correlatie bestaat tussen verhoging van het gewrichtsvlak en patiënt gerapporteerd uitkomstmaten voor primaire TKP plaatsing. Tevens liet dit hoofdstuk zien dat voor revisie knieprotheses geldt dat patiënten met een hersteld gewrichtsvlak significant betere postoperatieve scores hebben in vergelijking met patiënten waarbij het gewrichtsvlak verhoogd is na de operatie. Gebaseerd op deze feiten werd een advies afgegeven om te streven naar een herstel van het gewrichtsvlak na de originele hoogte en niet meer dan 4mm verhoging van het gewrichtsvlak te accepteren omdat dit een negatief effect heeft op de patiënten uitkomst.

Omdat gewrichtsvlak verhoging effect heeft op de patiënten uitkomst na TKP, werd een nieuwe techniek geïntroduceerd in deze thesis waarmee het gewrichtvlak beter te herstellen is: de Flexion First Balancer (FFB). Deze techniek is ontwikkeld met als doel om de isometrie van het MCL te behouden. Door het herstellen van het mediale gewrichtsvlak en de femorale posterieure condylaire offset (PCO) wordt de originele gewrichtsvlak hoogte hersteld met behoud van isometrie van het MCL. Dit zou in theorie moeten leiden tot betere uitkomsten voor de patiënt omdat er dan geen sprake zou zijn van midflexie laxiteit (Cross et al. 2012; Luyckx et al. 2018). In **hoofdstuk 5** werd de nieuwe techniek geïntroduceerd en beschreven waarbij tevens de mogelijke nadelen werden besproken. Om te beoordelen of het theoretische concept ook daadwerkelijk leidt tot betere prothese plaatsing en patiënt uitkomsten werden nog 2 studies uitgevoerd waarbij de nieuwe techniek werd vergeleken met de standaard techniek voor TKP plaatsing, de Measured Resection (MR) techniek. In **hoofdstuk 6** werd een retrospectief cohort van 59 FFB patiënten geanalyseerd en vergeleken met een gematcht cohort van 59 MR patiënten. In dit hoofdstuk werd aangetoond dat met de nieuwe techniek, FFB, de gewrichtsvlak hoogte werd hersteld naar het originele niveau in tegenstelling tot bij de MR patiënten waar het gewrichtsvlak werd verhoogd. Voor de PCO werd er echter geen verschil aangetoond tussen de groepen. De resultaten van de klinische uitkomsten waren overeenkomstig tussen beide technieken voor zowel de patiënt gerapporteerde uitkomstenmaten als ook voor de complicaties en de re-operaties. Derhalve werd geconcludeerd dat de nieuwe techniek veilig is om te gebruiken en dat dit leidt tot beter herstel van het gewrichtsvlak echter dat dit niet resulteert in een betere patiënt gerapporteerde uitkomstmaten. In **hoofdstuk 7** werd vervolgens het effect bestudeerd van de FFB techniek op coronale laxiteit, functionele uitkomst voor de patiënt en subjectieve gerapporteerde stabiliteit. Middels een cross-sectionele studie werden 27 FFB patiënten vergeleken met 28 gematchte MR patiënten. Tijdens de studie werd de postoperatieve mid-flexie laxiteit radiologisch beoordeeld en werden functionele testen en een vragenlijst over stabiliteit afgenomen. De resultaten toonde geen verschil voor midflexie laxiteit ondanks een significant verschil in gewrichtsvlak hoogte tussen de twee groepen. Ook de patiënt gerapporteerde stabiliteit was vergelijkbaar tussen de beide groep. Verder werden, ondanks een significant verschil in maximale quadricepskracht in het voordeel voor de FFB groep, geen klinisch relevante verschillen in de functionele testen genoteerd (loopafstand, traploop snelheid). Derhalve werd geconcludeerd dat, ondanks betere prothese plaatsing met de FFB techniek, dit niet direct leidt tot een meetbaar voordeel voor de patiënt uitkomst.

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Curriculum Vitae

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