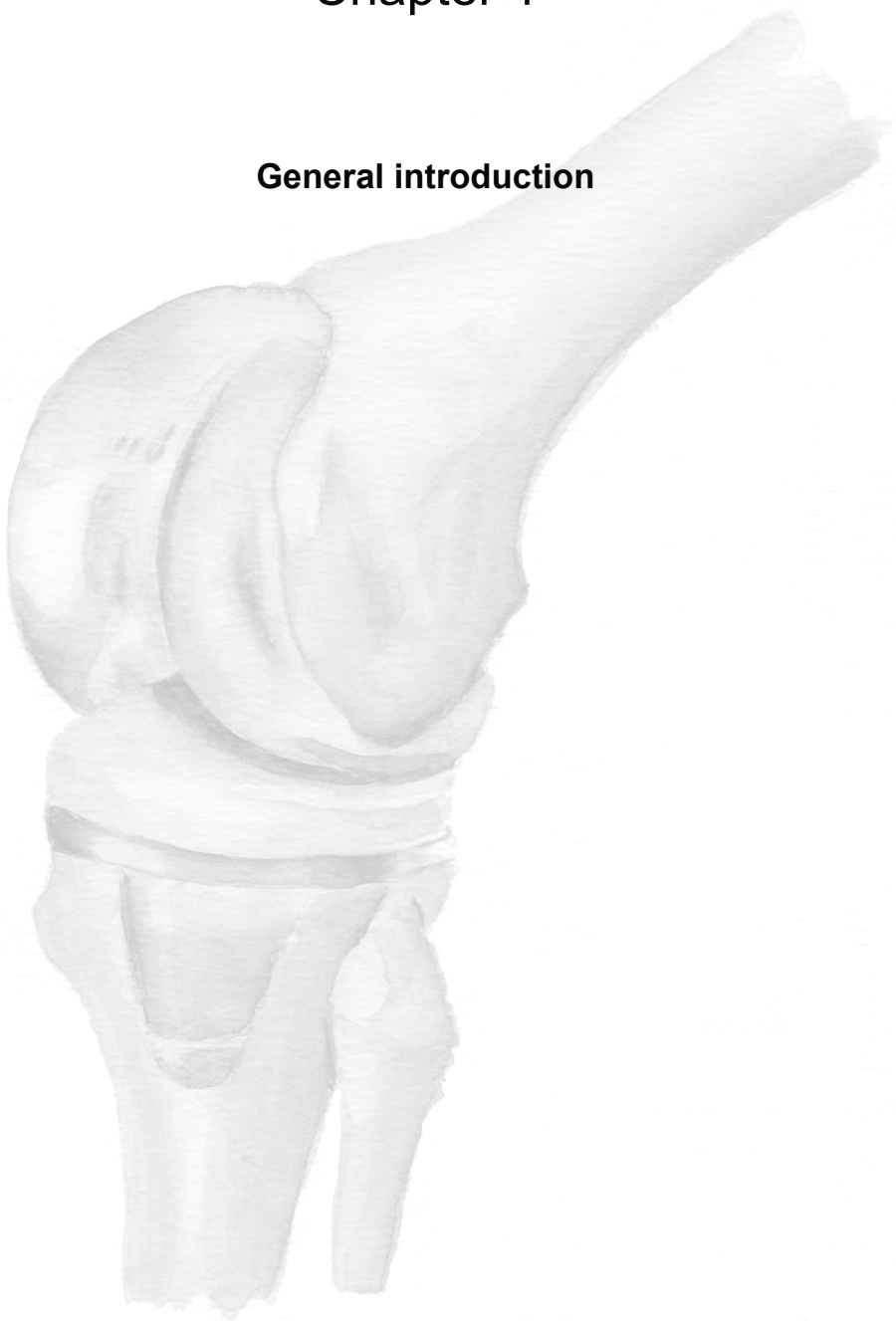
Prognostics of outcome of total knee replacement: on patient selection and intraoperative issues

Verra, W.C.

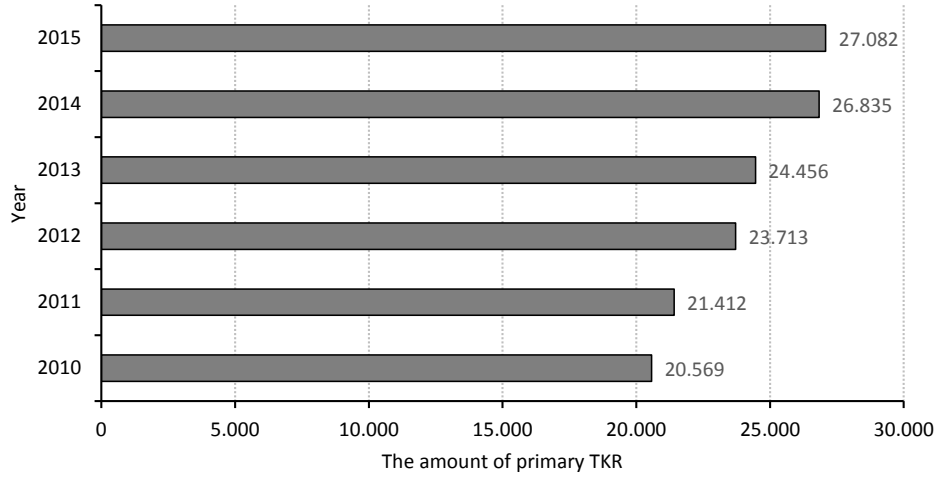
Chapter 1

General introduction



Osteoarthritis (OA) of the knee is a degenerative disease concerning the entire knee joint including the cartilage and its underlying bone, the ligaments, and other soft tissues.[1] The lifetime risk of developing symptomatic OA of the knee is almost 50%.[2] The one-year prevalence in the Netherlands of OA of the knee is almost 550.000 patients (www.volksgezondheidenzorg.info). As for treatment options; the vast majority of patients will have conservative treatment that will be patient specific. For mid-stage OA, besides conservative treatment, surgical options could be performed like osteotomies. For end-stage OA a total knee replacement (TKR) is the treatment of choice. In the Netherlands about 28.000 TKR's are performed annually.[3] TKR is an effective treatment in terms of improving knee function, reducing pain and improving quality of life.[4,5] The number of TKR's performed worldwide, and also in the Netherlands, is still rising.[3,6] According to the latest report of the Dutch Arthroplasty Registry, the LROI, in 2015 over 27.000 primary TKR's were performed (Figure 1.1), which is about 26% more compared to 2010.[3]

Figure 1.1: The amount of primary TKR registered within the LROI in the years 2010-2015 (With permission from LROI)



In 1891 the first attempt to resurface the knee joint was performed by a German surgeon, dr. Th. Gluck. He implanted a hinged knee prosthesis made of ivory.[7,8]

The subsequent versions following this prosthesis, several decades later, made of metal and plastic components, suffered from high rates of loosening due to the constraint character of these hinged types of implants. Again decades later, in the 1970s, the development of total knee replacement had a boost due to, amongst others, Gunston who used an implant with two separate tibial and femoral condylar components. Yamamoto in Japan was the first to develop a total condylar (non-hinged) type of design in the 1970s, which was followed, probably parallel, in the USA by Insall in the mid-seventies.[7,9] New issues on implant design were the use of implants of a single-piece femoral component covering both condyles, as well as the use of a monoblock resurfacing tibial component. Furthermore poly-methyl-methacrylate (PMMA) was used for fixation of the components (i.e. bone cement). In the 1970s different groups in Japan, the United States, United Kingdom, and Germany made efforts to improve TKR design. For the 1980s and the 1990s issues like patello-femoral joint replacement, resection of the anterior and/or posterior cruciate ligament, metal-backing, fixed or mobile bearing inserts and improvements in contact surfaces (like femoro-tibial congruency) are examples of issues surgeons and engineers encountered, discussed and tried to solve.[7] Although changes of the TKR systems became smaller, compared to the early 1970s, names of the TKR's changed frequently, even after minor adjustments, mainly for marketing reasons. Furthermore these design ameliorations, neither the ones of this millennium, improved final clinical outcome for patients a lot, while some of these new designs resulted in worse clinical outcome.[10]

Success of joint replacement surgery is traditionally evaluated by survival of the implant or revision rates.[11] Furthermore outcome measures such as range of motion and the presence of (anterior) knee pain were recorded. In the last decade a shift has occurred towards patient reported outcomes (PROM's). Although these PROM's are considered by some to give a good representation of patients' satisfaction and functional gain, one should be aware that they also present only the perceived outcome of the pre-, intra- and postoperative complexity of TKR.[12]

Literature about short- and midterm follow-up shows that not all patients are satisfied with the result of their TKR. Satisfaction rates after TKR are lower than rates after

total hip replacement (THR).[13-19] Literature on long-term follow-up patient satisfaction is scarce.[20,21] Within this thesis, patient satisfaction and quality of life at long-term follow-up (i.e. ten years or more after surgery) after TKR and THR is evaluated in a cohort from the TACTICS trial **(chapter 2)**. This trial is a randomized controlled study on the effect of leukocyte depleted red blood cell transfusions versus transfusions packed cells containing leucocytes after TKR and THR surgery.[22] Surgery was performed in 2000/2001 with the last clinical (i.e. PROM's) follow-up in 2012/2013.

An important issue to address before considering TKR surgery is the indication for the operation (i.e. patient selection). One of the reasons for unsatisfied patients after TKR could be that the decision to perform TKR was erroneous. The question of which patients should and which patients should not have a TKR, has been addressed by others as well.[23,24] The indication to perform TKR and the selection of which patient will benefit most from surgery appears to be very important in the outcome of TKR.[12,18,25 ,26] In **chapter 3 and 4** two studies investigating the indication for TKR are reported.

The overall global population in the Western part and parts of Asia is aging.[27] Patients with and without total joint replacement (TKR or THR) in the past become increasingly older as well. Patients of 85 years-old and older are considered the oldest old. Whether this oldest old patients regained their functional level and health status after a total joint replacement in the past is compared to oldest old without total joint replacement. In **chapter 5** a study using the Leiden 85+ database is reported.

The second part of this thesis focuses on more medical technical aspects that possibly can improve outcome of TKR. These are related to TKR design and materials, but also patient blood management.[7,28,29] Tranexamic acid, vacuum drainage systems, EPO administration etcetera, have all been investigated for its use in reducing blood loss during and after TKR.[30] Topical application of a fibrin sealant to reduce blood loss during and after TKR surgery has been investigated since the late 1990s.[31] Some literature has been published in the years after, however all studies were performed in small patient groups and focused on transfusion frequency and hemoglobin loss as primary outcomes, and not on patient reported outcome measures nor on functional gain for these patients.[32,33] Furthermore, since

transfusion rates have dramatically decreased during the last ten years due to restrictive protocols, different outcome metrics are needed, with focus on functionality for patients and not on the transfusion rate as such.[34] **Chapter 6** reports the results of a large randomized study using fibrin sealant focusing on functional outcome after TKR.

A TKR related issue on functional outcome might be preservation or resection of the posterior cruciate ligament (PCL). Advocates of PCL retention pose that retaining the PCL is important to remain an as natural movement pattern of the knee as is possible in TKR.[35] Furthermore, retention of the PCL might yield a better sense after TKR, due to mechanoreceptors for proprioception and kinesthesia within the PCL.[36,37] Sacrificing the PCL subtracts one factor that might complicate adequate ligament balancing, sacrificing the PCL could also prevent paradoxal femoral rollback.[38,39] A systematic review and meta-analysis on this topic is reported in **chapter 7** of this thesis.

Prosthetic joint infection is a feared complication after TKR. Mild hypothermia, defined as a body temperature between 34.0 and 36.0 ^{o}C, during surgery is associated with an increased risk of infection in primary TKR and THR.[40] Warming of the patient has become routine practice. Clean laminar airflow in operating rooms is considered to reduce risk of infection too. A forced-air warming blanket might disrupt laminar airflow and could potentially increase infection risk.[41] We performed a randomized, non-inferiority trial, to evaluate the prevention of hypothermia in patients who received warming by a forced-air blanket or an active self-heating blanket. Results are reported in **chapter 8**.

The aims of this thesis are related to clinical outcome of Total Knee Replacement

1. *Investigating patient satisfaction and quality of life at least ten years after total knee or hip replacement (Chapter 2).*
2. *Patient characteristics that are most probably related to the indication for TKR surgery by Dutch orthopedic surgeons were studied (Chapter 3) as well as international differences (9 countries) for the indication of TKR (chapter 4).*
    a. Three patient related variables were chosen; age of the patient (old versus young age), severity of radiological knee osteoarthritis (OA) and severity of pain.
    b. International comparison was done using a large database from the OARSI/OMERACT initiative, with characteristics of over 1.900 patients with either knee or hip OA were recorded from nine different countries (including the Netherlands).
3. *Age as a predictor for outcome was studies in oldest-old patients who received total joint replacement in the past (chapter 5).*
    a. To this end the Leiden 85+ database was used. A well-documented cohort of oldest-old patients from the Leiden area who were included around the start of this millennium and have annual follow-up moments.

The second part of the thesis focuses on medical technical aspects of TKR, related to both the patient in general as well as to the TKR implant.

4. *Evaluation of the use of an intraoperative topical fibrin sealant on the surgical field on functional outcome (extension of the leg) after TKR (Chapter 6).*
5. *A meta-analysis on the functional, clinical and radiological outcome of TKR after retention or sacrifice of the PCL (Chapter 7).*
6. *A randomized, non-inferiority trial analyzing the prevention of hypothermia in patients who received forced-air warming or active self-heating (Chapter 8).*

References

1. Bijlsma JW, Berenbaum F, Lafeber FP. Osteoarthritis: an update with relevance for clinical practice. Lancet 2011;18-377:2115-26.
2. Murphy L, Schwartz TA, Helmick CG, et al. Lifetime risk of symptomatic knee osteoarthritis. Arthritis Rheum 2008;59-9:1207-13.
3. LROI – Nederlandse Orthopedische Vereniging, Dutch Arthroplasty Registry, Report 2015 www.lroi.nl
4. Ethgen O, Bruyere O, Richy F, Dardennes C, Reginster JY. Health-related quality of life in total hip and total knee arthroplasty. A qualitative and systematic review of the literature. J Bone Joint Surg Am 2004;86-A-5:963-74.
5. Carr AJ, Robertsson O, Graves S, et al. Knee replacement. Lancet 2012;7-379:1331-40.
6. Kurtz S, Mowat F, Ong K, et al. Prevalence of primary and revision total hip and knee arthroplasty in the United States from 1990 through 2002. J Bone Joint Surg Am 2005;87:1487-97.
7. Ranawat CS. History of total knee replacement. J Southern Orthop Assoc 2002 vol 11(4); 218-26.
8. Gluck Th. Autoplastik – Transplantation – Implantation von Fremdkörpern. 1890 19(5):421-7.
9. Insall J, Ranawat CS, Scott WN, Walker P. Total condylar knee replacement: preliminary report. Clin Orthop Relat Res 1976;120:149-54.
10. Nieuwenhuijse MJ, Nelissen RG, Schoones JW, Sedrakyan A. Appraisal of evidence base for introduction of new implants in hip and knee replacement: a systematic review of five widely used device technologies. BMJ 2014;349(9):g5133.
11. Nelissen RG, Brand R, Rozing PM. Survivorship analysis in total condylar knee arthroplasty. A statistical review. J Bone Joint Surg Am 1992;74(3):383-9.
12. Rolfson O, Wissig S, van Maasakkers L, et al. Defining an international standard set of outcome measures for patients with hip or knee osteoarthritis: consensus of the international consortium for health outcomes measurement hip and knee osteoarthritis working group. Arthritis Care & Res 2016 (11); 68:1631-9.
13. Haanstra TM, van den Berg T, Ostelo RW, et al. Systematic review: do patient expectations influence treatment outcomes in total knee and total hip arthroplasty? Health Qual Life Outcomes. 2012;10:152.
14. Nilsdotter AK, Toksvig-Larsen S, Roos EM. Knee arthroplasty: are patients' expectations fulfilled? A prospective study of pain and function in 102 patients with 5-years follow-up. Acta Orthop. 2009;80(1):55-61.

15. Dunbar MJ, Richardson G, Robertsson O. I can't get no satisfaction after my total knee replacement: rhymes and reasons. Bone Joint J. 2013;95(11sA):148-52.

16. Keurentjes JC, van Tol FR, Fiocco M, Schoones JW, Nelissen RG. Minimal clinically important differences in health-related quality of life after total hip or knee replacement: a systematic review. Bone Joint Res. 2012;1(1):71-7.

17. Keurentjes JC, Fiocco M, So-Osman C, et al. Patients with severe radiographic osteoarthritis have a better prognosis in physical functioning after hip and knee replacement: a cohort study. PLoS One 2013;8(4):e59500.

18. Keurentjes JC, Blane D, Bartley M, Keurentjes JJ, Fiocco M, Nelissen RG. Socio-economic position has no effect on improvement in health-related quality of life and patient satisfaction in total hip and knee replacement: a cohort study. PLoS One 2013;8(3):e56785.

19. Keurentjes JC, Fiocco M, Nelissen RG. Willingness to undergo surgery again validated clinically important differences in health-related quality of life after total hip replacement or total knee replacement surgery. J Clin Epidemiol. 2014;67(1):114-20.

20. Loughead JM, Malhan K, Mitchell SY, et al. Outcome following knee arthroplasty beyond 15 years. Knee.2008;15(2):85-90.

21. Beverland D. Patient satisfaction following TKA: bless them all! Orthopedics. 2010;33(9):657.

22. van Hilten JA, van de Watering LM, van Bockel JH, et al. Effects of transfusion with red cells filtered to remove leucocytes: randomized controlled trial in patients undergoing major surgery. BMJ. 2004;328(7451):1281.

23. Gossec L, Paternotte S, Maillefert JF, et al. The role of pain and functional impairment in the decision to recommend total joint replacement in hip and knee osteoarthritis: an international cross-sectional study of 1909 patients. Report of the OARSI-OMERACT task force on total joint replacement. Osteoarthritis Cartilage 2011 19(2):147-54.

24. Skou ST, Roos EM, Laursen MB, et al. A randomized controlled trial of total knee replacement. N Eng J Med 2015;373(17):1597-606.

25. Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, part I: critical appraisal of existing treatment guidelines and systematic review of current research evidence. Osteoarthritis Cartilage 2007 15(9):981-1000.

26. Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage 2008; 16(2):137-62.

27. Prince M, Bryce R, Albanese E, Wimo A, Ribeiro W, Ferri CP. The global prevalence of dementia: a systematic review and meta-analyses. Alzheimers Dement 2013(1)9;63-75.

28. Shander A, van Aken H, Colomina MJ, et al. Patient blood management in Europe. Br J Anaesth 2012; 109(1): 55-68.

29. So-Osman C, Nelissen R, Te Slaa R et al. A randomized comparison of transfusion triggers in elective orthopaedic surgery using leucocyte-deplete red blood cells. Vox Sang 2010;98:56-64.

30. Munoz M, Garcia-Erce JA, Villar I, et al. Blood conservation strategies in major orthopaedic surgery: efficacy, safety and European regulations. Vox Sang 2009 96:1-13.

31. Levy O, Martinowitz U, Oran A, et al. The use of fibrin tissue adhesive to reduce blood loss and the need for blood transfusion after total knee arthroplasty. A prospective randomized, multicenter study. J Bone Joint Surg Am 1999;81:1580-8.

32. Wang H, Shan L, Zeng H, et al. Is fibrin sealant effective and safe in total knee arthroplasty? A meta-analysis of randomized trials. J Orthop Res 2014;36(9).

33. Li ZJ, Fu X, Tian P, et al. Fibrin sealant before wound closure in total knee arthroplasty reduced blood loss: a meta-analysis. Knee Surg Sports Traumatol Arthrosc 2015 23(7):2019-25.

34. So-Osman C, Nelissen RG, Koopman-van Gemert AW, et al. Patient blood management in elective total hip-and knee replacement surgery. Anesthesiology 2014;120(4):839-60.

35. Lombardi AV, Mallory TH, Fada RA, et al. An algorithm for the posterior cruciate ligament in total knee arthroplasty. Clin Orthop Relat Res 2001;75-87.

36. Nelissen RG, Hogendoorn PC. Retain or sacrifice the posterior cruciate ligament in total knee arthroplasty? A histopathological study of the cruciate ligament in osteoarthritic and rheumatoid disease. J Clin Pathol 2001;54:381-84.

37. Swanik CB, Lephart SM, Rubash HE. Proprioception, kinesthesia, and balance after total knee arthroplasty with cruciate-retaining and posterior stabilized prostheses. J Bone Joint Surg Am 2004;86-A:328-34.

38. Pagnano MW, Hanssen AD, Lewallen DG, et al. Flexion instability after primary posterior cruciate retaining total knee arthroplasty. Clin Orthop Relat Res1998;39-46.

39. Dennis DA, Komistek RD, Mahfouz MR, et al. A multicenter analysis of axial femorotibial rotation after total knee arthroplasty. Clin Orthop Relat Res 2004;428(11):180-9.

40. Kurz A, Sessler DI, Lenhardt R, et al. Perioperative normothermia to reduce the incidence of surgical wound infection and shorten hospitalization. N Eng J Med 1996 9;334(19):347-52.

41. Kellam MD, Dieckmann LS, Austin PN. Forced-air warming devices and the risk of surgical site infections. AORN J 2013 98:356-66.