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

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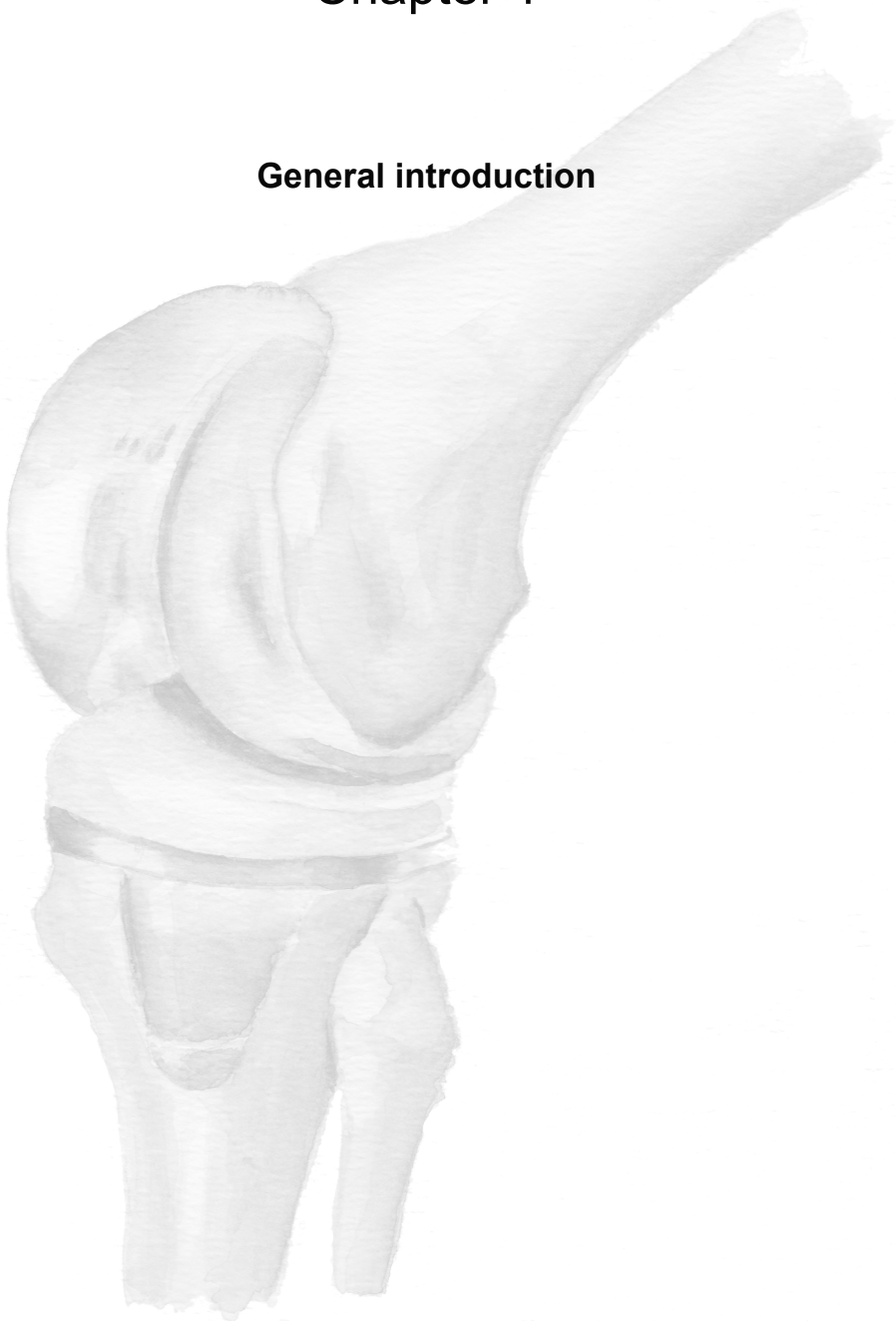
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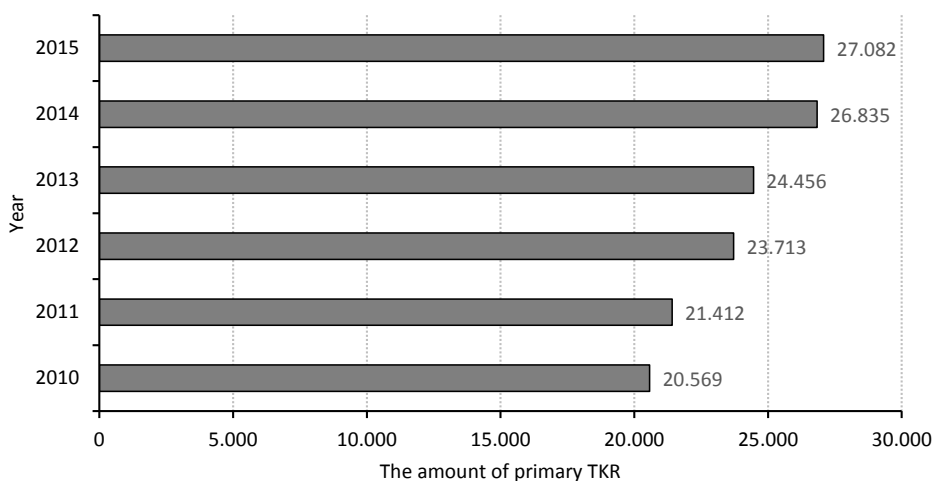
Chapter 1

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 °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 studied 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).*

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Chapter 1

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