Department of Public Health
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IMPACT OF TECHNOLOGICAL CHANGE ON QUALITY OF CARE

STUDIES ON TOTAL HIP AND KNEE REPLACEMENT

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ACADEMIC DISSERTATION

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To my family

ABSTRACT

This thesis analysed the impact that the introduction of new technology may have on the quality of care in a hospital setting. Technological change in medicine is rapid, as new devices are constantly taken into use in patient care, and new methods of delivering the care to patients are introduced, replacing existing routines and creating new practices – all with the aim of benefitting patients. The present thesis focused on total hip and knee replacement, by analysing the introduction of implants, and by assessing the effects that a change in the production network (technology) via the launch or closure of an entire unit performing arthroplasty had on the quality of surgery as assessed by revision risk.

Data for this study came from the Finnish Arthroplasty Register data on total joint replacements, Finnish administrative data on hospital discharges, prescribed medication, special reimbursements to medication and cause-of-death statistics. All total hip and knee replacements performed because of primary osteoarthritis in the period 1998 to 2011 were included. Survival analysis, with the revision of the joint in the follow-up as the outcome measure, was applied in the studies.

For both total hip and knee replacement, the introduction of an implant in a hospital increases the risk of revision within three to five years, respectively, after the primary operation. The risk was higher for knee implants. For both surgeries, this learning effect was found to be implant specific. Of the analysed ten most common total hip and knee implant models, one hip and four knee implant models showed a learning curve, with the risk for reoperation decreasing with the greater number of surgeries performed with the implant model. Launching of arthroplasty surgery in a unit was not associated with a learning curve, but in units terminating total hip replacement surgery, the last 100 patients had worse short-term implant survivorship compared to patients who had had surgery in these units before the closure stage.

The introduction of total hip and knee implants in a hospital was associated with increased revision risk in the introductory phase for some implant models. The introduction of new medical devices should be carefully considered in hospitals. The personnel acquiring new devices for use in a hospital should base their decisions on solid evidence of the efficiency of the technology and practice beforehand with the new devices. In addition, patients should be informed when new technology is introduced in their treatment and given the possibility to decline its use. On the health system level, health policy makers should take into account the result that unit closures may affect the quality of care in the closure stage, and try to guarantee stable operation settings for patients.

Keywords: Total joint replacement, learning curve, endoprosthesis

TIIVISTELMÄ

Sairaanhoitoa tarvitsevien potilaiden paremman ja tehokkaamman hoidon tavoittelemisessa tärkeänä osana on uusien hoitomenetelmien ja -välineiden kehittäminen ja käyttöönotto hoitotyössä. Uuden teknologian käyttöönottoon kuuluu sen käytön opettelu arjen hoitoympäristössä. Ns. oppimiskäyrällä tarkoitetaan ilmiötä, jossa inhimillisen toiminnan osana on toiminnan muuttuminen kokemuksen karttumisen seurauksena. Tässä väitöskirjassa tarkastellaan sairaaloissa tapahtuvan teknologisen muutoksen vaikutusta potilaiden hoidon laatuun lonkan ja polven tekonivelleikkauksissa.

Väitöskirjassa arvioidaan mikä on sairaalassa suoritetun uuden lonkan tai polven tekonivelmallin käyttöönoton vaikutus nivelen uusintaleikkausriskiin. Erityisesti tarkastelun kohteena on sairaalassa aiemmin käyttämättömän tekonivelmallin käyttöönoton vaikutus potilaiden lyhyen ajan uusintaleikkauksen todennäköisyyteen. Lisäksi väitöskirjassa tutkitaan suuremman teknologisen kokonaisuuden muutoksen vaikutusta lonkan ja polven tekonivelleikkausten laatuun arvioimalla koko tekonivelleikkaustoiminnan aloittamiseen ja lopettamiseen liittyvää hoitotoiminnan laadun muutosta käyttämällä laadun mittarina uusintaleikkausta.

Tutkimukset perustuvat suomalaisiin terveydenhuollon rekisteriaineistoihin. Vuosien 1998 ja 2011 välisenä aikana Manner-Suomessa tehdyt lonkan ja polven kokotekonivelleikkausten tiedot ja seuranta vuoden 2013 loppuun saakka potilaille tehdyistä uusintaleikkauksista kerättiin terveydenhuollon hoitoilmoitusrekisteristä ja implanttirekisteristä. Mukaan tarkasteluihin otettiin primaarin nivelrikon vuoksi tehdyt tekonivelleikkaukset. Sairaalalle uusien tekonivelmallien käyttöönottoon sekä sairaalan tekonivelleikkaustoiminnan aloittamis- tai lopettamisvaiheeseen liittyvää uusintaleikkausriskiä tutkittiin eloonjäämisanalyysin avulla.

Lonkan ja polven tekonivelleikkauksissa uuden tekonivelmallin käyttöönottoon sairaalassa liittyy kohonnut varhaisen eli 3-5 vuoden kuluessa ensitekonivelleikkauksesta tehdyn uusintaleikkauksen riski. Polven tekonivelleikkausten kohdalla uuden tekonivelmallin käyttöönottoon liittyvä uusintaleikkausriski oli lonkan tekonivelleikkaukseen liittyvää uusintaleikkausriskiä korkeampi. Keskimäärin oppimiskäyrä oli nopea, sillä uuden implanttimallin käyttöönoton kohdalla vain 15 sairaalassa ensimmäisenä uudella tekonivelmallilla tehtyä leikkausta olivat tilastollisesti merkitsevästi suuremmassa vaarassa uusintaleikkaukselle. Tekonivelmallikohtaisten tarkastelujen perusteella sekä lonkan että polven tekonivelleikkauksissa oppimiskäyrä liittyi joihinkin tekonivelmalleihin mutta ei kaikkien mallien käyttöönottoon.

Suuremman teknologisen muutoksen kohdalla uusintaleikkausriskin ei havaittu olevan poikkeava lonkan tai polven tekonivelleikkaustoiminnan aloittamisvaiheessa. Lonkan ja polven tekonivelleikkaustoiminnan päättymistä edeltävässä toiminnan lopettamisvaiheessa viimeisen 100 leikkauksen joukossa tehtyjen lonkan tekonivelleikkausten uusintaleikkausriski oli suurempi kuin samoissa sairaaloissa ennen tätä vaihetta tehtyjen tekonivelleikkausten kohdalla.

Uusien tekonivelmallien käyttöönottoon liittyy riski aloitusvaiheen leikkausten heikommasta laadusta mikä näkyi tutkimuksessa kohonneena uusintaleikkauksen todennäköisyytenä. Uusien tekonivelmallien käyttöönotto sairaaloissa tulee harkita tarkkaan ja käyttöönottopäätösten tulee perustua tieteelliseen näyttöön tekonivelmallien toimivuudesta ja pysyvyydestä. Tekonivelleikkauksiin osallistuvan henkilöstön tulee harjoitella uusien tekonivelten käyttöä ja potilaille tulee kertoa mikäli heille ollaan suunnittelemassa tekonivelleikkausta sairaalassa hiljattain käyttöönotetulla tekonivelmallilla. Terveydenhuollossa järjestelmätasolla tulee huomioida toiminnan keskittämisen myötä tehtävien yksiköiden lopettamisten seurauksena tulevat laatuvaikutukset ja pyrkiä takaamaan potilaiden laadukas hoito myös terveydenhuoltojärjestelmän murrosvaiheissa.

Avainsanat: Tekonivelkirurgia, oppimiskäyrä, endoproteesi

CONTENTS

LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following publications:

I

Peltola M, Malmivaara A, Paavola M. Introducing a Knee Endoprosthesis Model Increases Risk of Early Revision Surgery. Clinical Orthopaedics and Related Research® 2012, Vol. 470, No. 6, 1711-1717.

II

Peltola M, Malmivaara A, Paavola M. Hip Prosthesis Introduction and Early Revision Risk: A Nationwide Population Based Study Covering 39 125 Operations. Acta Orthopaedica 2013, Vol. 84(1), Pages 25-31. doi:10.3109/17453674.2013.771299.

III

Peltola M, Malmivaara A, Paavola M. Learning curve for new technology? A nationwide register-based study of 46 363 total knee arthroplasties. The Journal of Bone and Joint Surgery 2013; 95(23): 2097-2103.

IV

Peltola M, Malmivaara A, Paavola M, Seitsalo S. Elevated risk of early reoperation in total hip replacement during the stage of unit closure. Acta Orthopaedica 2016; 87(2): 126-131.

The publications are referred to in the text by their roman numerals.

ABBREVIATIONS

CE	Conformité Européenne
e.g.	exempli gratia
EUDAMED	European Databank on Medical Devices
FAR	Finnish arthroplasty register
FDA	United States Food and Drug Administration
FHDR	Finnish hospital discharge register
HTA	Health technology assessment
i.e.	id est
NARA	Nordic Arthroplasty Register Association
OARSI	Osteoarthritis Research Society International
PIC	Personal Identity Code
PMA	Premarket Approval Application
SII	Social Insurance Institution
THL	National Institute for Health and Welfare, Finland
THR	Total hip replacement
TJR	Total joint replacement
TKR	Total knee replacement
UK	United Kingdom
US	United States

1 INTRODUCTION

In health care, changes over time in the manner of how services are produced and in the details of how a specific treatment is performed are constantly taking place. Advances in medicine have been extraordinary over time and the evolution of medicine has generated a lot of health and wellbeing for humankind. Today, the health care market is vast and the possibility to make profits encourages entrepreneurs to develop new medical technology for the market. New innovations are introduced in patient care with the aim of increasing the quality of treatment and improving patient wellbeing. Patients and doctors are attracted to new technology and are often eager to press it into service, sometimes even without scientific evidence of the safety and efficacy of the technology. However, it is not automatically true that new technology is beneficial for patients.

This thesis studies the effects of introducing medical devices and a change in the manner of production in the specialty of orthopaedics. By way of an example of newly introduced technology, the effects that new hip or knee implant models have on the quality of treatment are investigated. The new devices taken into use may show a learning curve, i.e. the skill that is needed to master the technology may develop gradually. This learning process may show as a change in the quality of care over time, with more experience with the technology improving the outcome of care. Importantly, the thesis shows how a learning curve related to a medical device can be assessed with nationwide administrative data.

Total hip and knee replacements (THR and TKR, respectively) are well-established treatments for severe osteoarthritis. They increase patient quality of life substantially. THR has been referred to as the operation of the century (Learmonth, Young & Rorabeck 2007) to highlight its importance in medicine and to honour the innovators of joint replacement surgery. THR and TKR are procedures that consume the largest share of resources among individual surgical treatments in specialized health care in Finland (Remes et al. 2015). However, despite the expenditure, it's a very cost-effective treatment (Lehto, Jämsen & Rissanen 2005).

In these two surgeries there have been a number of innovations over the last decades that have affected the surgical techniques and instrumentation involved. Advances have been made for example with implant designs and materials and with preoperative planning. In total, these innovations together with the accumulation of knowledge of how to perform total joint replacement (TJR) have led to major improvements in the surgical treatment of severe osteoarthritis. The survivorship of many implant models is well documented (i.e. whether the implant is still physically in the patient or has been removed), and it is known that the implant models in both hip and knee replacement show different survivorships. However, the impact of the introduction of new implant models in a hospital has not been investigated extensively, and attention has not been paid sufficiently to the introductory phase.

Numerous hip and knee implant models are used in Finnish hospitals and the available selection of implant models varies between hospitals. Every now and then a hospital may change the selection of implants that is used in the hospital by introducing implants not previously used in the hospital. The reasons for a change in implant usage vary but typically implants are taken into use due to their better survivorship, durability and lower cost. As a result, some patients are operated on with the newly introduced implant. Gradually, as the number of surgeries with the implant model grows, the implant becomes familiar to the surgical staff. An introduced implant model may have a learning curve that shows the rate at which the skill of working with the entire instrumentation around the implant model is acquired. This acquisition of know-how may vary between implants. An implant manifesting a learning curve may have poorer patient outcomes in the introductory phase. In this study, revision surgery (hereafter revision) within a relatively short-term follow-up after the primary surgery are studied as an indicator of quality of care. In this thesis a revision refers to any reoperation involving the removal, exchange or addition of an implant component.

Similarly to micro-level changes such as an implant introduction, a macro-level change in the manner of production may affect care quality. The learning curve may also be related to the organization of care. Performing arthroplasty is teamwork, where the expertise of every member of the team is needed in order to guarantee the success of the operation. In addition, the whole care pathway has an effect on patient outcomes, where the team's performance is pronounced. The building of these teams takes time, as the professional first need to be recruited and then they need to learn how to best cooperate with each other. Any abrupt changes in such a team may show up as deteriorated quality.

The teams that perform total joint replacements are set up when a unit launches arthroplasty, and they disband when arthroplasty is terminated in a unit. These clear starts and ends of operational function – in contrast with the steady phase of the function - are natural points to study the effects that these changes in the operating environment can have on the quality of care. In addition to studying implant-related learning curves, hospital unit launches and closures are analysed in order to find out if they have an effect on short-term revision rates of arthroplasty patients.

In Finland, the health care system is publicly funded. There are both private and public hospitals that perform total joint arthroplasty, but the public hospitals dominate the market and a significant majority of operations are carried out in public hospitals (around 60 hospitals). Over the years, there has been some pressure to centralize the public production, especially for specialized treatments like total joint arthroplasty. During the last 20 years, a number of clinics performing arthroplasty have quit performing TJR.

At the same time, new and mostly private clinics have begun to perform total joint arthroplasty.

The projected increase in the number of TJRs may also affect the production environment, as new units performing arthroplasties are likely to be opened in many countries. On the other hand, with limited resources available for health care, and attempts to increase system efficiency, this may lead to the closure of units through a centralisation of surgery. Thus, the effects that launches and closures of surgical units may have on the quality of care at the launch or closure phase, are of importance to health policy.

In TJR some studies have tried to quantify the learning curve effect for some implant models (e.g. (Santini, Raut 2008, Sansone, da Gama Malcher 2004)), although most studies have been based on consecutive operations in a single hospital and have not been able to reliably confirm any model-specific learning curve effects on the outcome of TJR. The learning curve as a concept in surgery is usually associated with a physician in the early phase of his/her career, but the learning effect (i.e. greater variation of operation-related patient outcomes) related to instrumentation or new technology has not been analysed to any great extent.

Both introducing implants and restructuring the organisation of care are results of decisions that can and should be evaluated. As shown in this thesis, the quality aspects brought about with these kinds of changes ought to be taken into account whenever managers are exerting power to adjust the production processes, be it at the level of a single hospital or a clinic, or at the level of the entire health care system. This thesis supplies information and tools that can be utilized at the health system level (regulation of medical devices, organization of services), while the results of this thesis have practical importance for a wide audience, ranging from orthopaedists, patients, health care managers, to the scientific community.

The thesis consisted of four studies and of unpublished research. These are summarized according to the following structure: Chapter 2 gives an introduction to THR and TKR, presents an overview of the implant models in Finland, reviews literature on the learning curve in THR and TKR, and introduces the literature on hospital unit launches and closures. The aims of the thesis are presented in Chapter 3. Chapter 4 describes the data used and the methods applied in the thesis. The main results are summarized in Chapter 5. Chapter 6 reflects on the findings of the thesis in the context of existing literature, briefly summarizes the strengths and limitations of the studies, discusses the implications of the studies, and gives suggestions for further research. Chapter 7 concludes the thesis.

2 BACKGROUND AND REVIEW OF THE LITERATURE

2.1 TOTAL HIP AND KNEE REPLACEMENT

In total joint replacement (TJR), parts of a damaged or arthritic joint are removed and replaced with a device made of combinations of materials, such as metal, plastic or ceramic. The implant, or prosthesis, is designed to mimic the function of a healthy joint. The most common TJR surgeries are performed on the hip and knee joints.

Total joint replacement of the hip has a long history in medicine. The first documented attempts to treat severe hip joint disorders were done with rudimentary surgery in the 1800s (Park 1782, White 1849). At the turn of the 20th century surgeons had introduced methods to perform interpositional hip arthroplasty and a number of materials to cover reconstructed femoral heads (Gomez, Morcuende 2005). The early prostheses were made of rubber, ivory, and acryl, to name a few materials, with the first metal prosthesis introduced in the 1930s, and component fixation methods and materials developed alongside them, with some of the early innovations showing moderate results, though some were catastrophic (Gomez, Morcuende 2005). In the 1960s, the stage was set for successful surgery performed by Sir John Charnley (Charnley 1961), the inventor of modern THR, showing very good long-term results (Berry et al. 2002).

Following THR, in the 1970s an explosion of ideas was seen in the field of prosthetic knee arthroplasty and most innovations on TKR took place during that decade (Robinson 2005). The first total condylar knee was introduced in 1974, and in March 1974 the first total condylar knee design with a tibial stem was implanted (Ranawat 2002). By 1980, a large share of the designs and surgical techniques used today in TKR had been developed (Robinson 2005). A number of engineers and surgeons enabled this development (Ranawat 2002, Robinson 2005). Today, TKR is a multibillion dollar industry with millions of TKRs performed worldwide annually (Kurtz et al. 2011).

The most common condition for performing THR and TKR is osteoarthritis (Robertsson et al. 2001). Osteoarthritis is the most common disease of the hip and knee joints and a major cause of mobility disability and chronic musculoskeletal pain in the elderly worldwide (Peat, McCarney & Croft 2001, Dawson et al. 2004, Dunlop et al. 2003). Older adults with symptomatic arthritis have higher health care utilization and thereof costs than people without arthritis (Dunlop et al. 2003). THR and TKR are among the most successful and reliable orthopaedic procedures for pain relief in patients with advanced osteoarthritis (Ethgen et al. 2004).

In Finland, 5 % of Finnish men and 7 % of Finnish women aged over 30 are diagnosed with osteoarthritis of the knee, and 5 % and 4 % with osteoarthritis of the hip, respectively (Heliövaara 2008). The prevalence of osteoarthritis increases with ageing. In Finland, of women aged 75 to 84, 32 % have been estimated to suffer from knee osteoarthritis and 20 % from hip osteoarthritis (Arokoski et al. 2007). For men of this age, the prevalence of knee osteoarthritis was estimated to be at 16 % and hip osteoarthritis at 20 % (Arokoski et al. 2007).

Due to its disabling nature, osteoarthritis has been estimated to impose significant costs on Finnish society. In 2000, osteoarthritis was estimated to be associated with 613 000 physician visits, and in 2005 there were more than 100 000 hospital stays with surgical procedures related to musculoskeletal diseases in Finland (Heliövaara 2008). In 2003, the primary THR and TKR surgeries performed due to primary osteoarthritis in Finland were estimated to have direct medical costs of EUR 84 million (Remes et al. 2007). The greatest costs incurred by Finnish society from osteoarthritis arise due to the disability and loss of functional ability: at the end of 2014, 21 524 people were entitled to disability pension because of musculoskeletal diseases, with a total benefit of more than EUR 5 million per month (Kelasto, statistical database of the Social Insurance Institution [SII], http://www.kela.fi/kelasto, accessed on November 29, 2015). In 2008, Heliövaara estimated the direct and indirect costs of osteoarthritis to Finnish society to be around EUR 1 billion per year.

To reflect the prevalence of osteoarthritis and the costs related to it, a number of international recommendations have been published regarding the management of hip and knee osteoarthritis (e.g. (Jordan et al. 2003, Zhang et al. 2005, Zhang et al. 2008)) and non-surgical treatment of osteoarthritis, for example, by the Osteoarthritis Research Society International (OARSI, http://oarsi.org/education/oarsi-guidelines). A review published in 2008 appraised the quality and consistency of the clinical practice guidelines from the years 1996 to 2005 and concluded that the quality of the guidelines varied considerably (Misso et al. 2008). In Finland, the Current Care Guidelines for hip and knee osteoarthritis were introduced in 2014 (Osteoarthritis of the hip and knee: Current Care Guidelines, 2014),

The incidence of TJR has increased steadily in Finland (Mäkelä et al. 2010, Skyttä et al. 2011, Pamilo et al. 2015), as well as internationally (Kurtz et al. 2005, Nemes et al. 2014) over recent years. In a study of 18 countries with a combined population of 755 million, more than 1 million TKRs were performed annually (Kurtz et al. 2011). In 2013, more than 10 000 THR and 11 000 TKR surgeries were performed in Finland (Rainio, Perälä 2014). Worldwide, more than a million total joint replacements (TJR) are performed each year, while the rates of THR and TKR in different populations vary to a great extent (Pabinger, Geissler 2014, Pabinger, Lothaller & Geissler 2015, Pivec et al. 2012). The projections made for THR and TKR volumes in the future show growth for these procedures (e.g. (Kurtz et al. 2007b, Kurtz et al. 2014, Nemes et al. 2014)). In Finland, the incidence of osteoarthritis of the hip and osteoarthritis of the knee in men has remained stable between the 1980s and the first decade of the 21st century (Heliövaara 2008). In women, however, the osteoarthritis of the knee has halved in the 20 years since 1981 (Heliövaara 2008).

Modern TJR has revolutionized the treatment of patients disabled by osteoarthritis. Initially, the indications for THR were mostly restricted to the decrepit and elderly or people with locomotor limitations jointly with other comorbidities (Learmonth, Young & Rorabeck 2007). Since then the indications have widened and today a compromise in quality of life due to osteoarthritis of the hip is considered a valid indication for THR (Learmonth, Young & Rorabeck 2007). In Finland, a patient representing with osteoarthritis of the hip that is not responding to non-surgical treatment and has restrictions in mobility is eligible for THR (Current Care Guidelines, http://www.kaypahoito.fi/web/english/guidelineabstracts/guideline?id=ccs00030, accessed 16 January 2016), and the Ministry of Health and Social Affairs has published criteria for care of TJR in Finland (www.terveysportti.fi). The Finnish Arthroplasty Association (Suomen Artroplastiayhdistys) published recommendations on performance of THR and TKR in 2010, and updated the recommendation in 2015 (Remes et al. 2015).

THR and TKR both substantially improve health-related quality of life (Ethgen et al. 2004, Towheed, Hochberg 1996, Skou et al. 2015, Rissanen et al. 1996) and are considered cost-effective treatments for osteoarthritis of the hip and knee (McMurray et al. 2002, Walker et al. 2002, Zhang, Glynn & Felson 1996, Dakin et al. 2012, Rissanen et al. 1997). The improvements in health-related quality of life also are sustained for years after the surgery (Bruyère et al. 2012). TJR has been increasingly performed in younger patients (Pabinger, Geissler 2014, Pabinger, Lothaller & Geissler 2015), and it has been shown that these patients return to work after surgery (Lombardi et al. 2014).

2.2 INTRODUCTION OF NEW IMPLANTS TO THE MARKET

The market for THR and TKR is big in economic terms and very attractive for manufacturers of medical devices. For this market there are currently numerous models of hip and knee implants available and new models will emerge due to the drive for new technology and marketing, as well as the expansion of the market because of increases in the incidence of THR and TKR (Dixon et al. 2004, Jain et al. 2005, Kim 2008, Kurtz et al. 2007a, Kurtz et al. 2014, Nemes et al. 2014). Since Charnley introduced the cemented low-friction hip arthroplasty, numerous advancements in technology concerning

THR have been made (Learmonth, Young & Rorabeck 2007). Similarly, in TKR a number of innovations have been introduced since the 1970s (Zanasi 2011).

Comparisons of implant survivorship show that the implant model has an effect on the risk for revision surgery (Furnes et al. 2002, Koskinen et al. 2008, Rand et al. 2003, Robertsson et al. 2001, Mäkelä et al. 2008, Mäkelä et al. 2010). New technology is taken into clinical use as the clinicians perceive the new products and techniques as advantageous for their patients; they believe that new implants improve clinical results (Sharkey et al. 1999).

However, the new technology may not always automatically lead to better patient outcomes. For example, regarding the implants used in THR and TKR, Anand et al. (2011) have shown that more than a quarter of the new implant models introduced in Australia had a higher revision rate than established models in 5 years of follow-up and none of the new introduced hip and knee implants had better survivorship than the established implants. A systematic literature review assessing the effectiveness and safety of five recent devices in TJR did not find convincing evidence supporting the use of these device innovations in orthopaedic surgery, concluding that the existing devices may be safer (Nieuwenhuijse et al. 2014). There may also be publication bias regarding survivorship of hip and knee implants, as there is limited evidence of long-term revision rates of many hip and knee implant models, and the reporting of revisions as an outcome measure has been poor in non-registry studies that form the majority of the evidence on implants' survivorship (Pabinger et al. 2013, Pabinger et al. 2015a, Pabinger et al. 2015b).

Hip and knee implants may be introduced in a market without solid scientific evidence of safety and effectiveness (Kesselheim, Avorn 2013). Countries differ in their approaches to the adoption of new technology. Most of the research concerning the topic has been made in the United States (US), the biggest medical device market in the world, where regulations on the introduction of new medical devices, especially for high risk devices, is more rigorous than for example in the European Union (Kramer, Xu & Kesselheim 2012). In 2013, a systematic review found that nearly a quarter of the hip replacement implant models that were used by surgeons in the United Kingdom (UK) had no scientific evidence for their clinical effectiveness (Kynaston-Pearson et al. 2013). Overall, medical devices undergo heath technology assessment (HTA) less often than pharmaceuticals, and the share of HTAs on devices has remained steady over the period 2010–2014 whilst the number of HTAs on pharmaceuticals increase annually (Lie et al. 2015).

In the USA, the medical devices introduced in the field of orthopaedics need to fulfil certain requirements prior to acceptance for marketing by the US Food and Drug Administration (FDA) (Sheth et al. 2009). Novel devices need to pass the premarket approval (PMA) process to demonstrate the effectiveness and safety of the new device with clinical evidence (Samuel et al. 2016). However, medical devices, including hip and knee implants, may receive prompt approval by demonstrating the new product is 'substantially equivalent' to an existing and approved implant. This premarket notification (known as 510(k)) allows manufacturers to avoid the use of clinical trials, and is the route of most medical devices to the market in the USA (Sheth et al. 2009).

Recently, Samuel et al. (2016) investigated all original orthopaedic devices that had received FDA PMA approval and their subsequent post-market device changes in the USA between 1982 and 2014. They identified only 70 devices, a big contrast, for example, to the over 169 different high-risk metal-on-metal hip implants introduced to the market with the use of premarket notification by December 2015. In another study, 701 new THR devices were introduced to the market between 1976 and 1996 via the 510(k) pathway against 34 via the PMA process (Mahomed et al. 2008). Of the 70 devices identified by Samuel et al., 34 were peripheral joint implants, 18 spinal implants, and 18 other materials or devices. Median of the number of post-market changes the devices had undergone was 6.5, with the rate of post-market device changes having increased throughout the study time span. For the analysed devices, there had been 765 post-market changes in total. The authors highlight that even devices that have initially been approved via the PMA process may experience changes that may affect their effectiveness and safety.

The orthopaedic community has acknowledged the problems in taking new devices into use (Zuckerman, Brown & Nissen 2011, Samuel et al. 2016, Thompson et al. 2011, Kynaston-Pearson et al. 2013, Nieuwenhuijse et al. 2014) and a number of suggestions have been made to improve the process (Mahomed et al. 2008, Callaghan et al. 2005, Schemitsch et al. 2010, Malchau 2000). Post-market surveillance of the introduced devices has also been shown to be insufficient, as for example in the USA, the existing mandatory device reporting system may capture only a small fraction of the serious adverse events (Mahomed et al. 2008).

In the post-marketing phase, in the USA units using approved devices are obliged to report serious adverse events related to the device to the FDA and the manufacturer, and the reports are available in a public Manufacturer and User Facility Device Experience database (Kramer, Xu & Kesselheim 2012). In the EU, manufacturers are required to report serious adverse events to the Competent Authorities and since 1998, each Competent Authority has had access to data that stores information on data of approvals, clinical studies, and details on post-market events (European Databank on Medical Devices, EUDAMED). Since 2011, manufacturers of medical devices are required to report events directly to EUDAMED. In Europe, an analysis made of device failures proved that there are problems in accessing data on individual devices, and the authors gave recommendations on how the system should be changed (Thompson et al. 2011).

There has been no country-specific regulation in Finland concerning the introduction of implants in THR and TKR. In Finland, all devices with a

Conformité Européenne (CE) mark can be marketed and used in hospitals. In 2015, the Finnish Arthroplasty Association has updated its guidelines on the performance of THR and TKR in Finland, and added a chapter on the introduction of new implants to give guidance to orthopaedists on the introduction of new devices in their practice (Remes et al. 2015). According to the guidelines, before introducing a model in a hospital, the implant model should have gone through biomechanical and laboratory testing, and have clinical results. The model should have demonstrated better clinical performance or it should be more economically viable than models already in use in the hospital. The guidelines also state that when a new implant model is introduced, it should be accompanied by a training program and that the new devices need to be actively monitored. Although in Finland the Finnish Arthroplasty Register (FAR) includes data on implant titles and could be used for this kind of monitoring, implant-specific survivorship results have not been regularly published. Finally, in Finland there is no national regulation concerning the introduction and the selection of implants in hospitals. In practice, the hospitals and the orthopaedists are in charge of the implant selection and the implant stock of the hospitals.

In addition to the introduction of new devices to the market, already existing and used devices may be combined, thus creating new device entities. In THR, the stem (femoral) and cup (acetabular) components may be mixed, i.e. the stem and cup models from different manufacturers and product lines are used interchangeably. Mixing of components is a relatively common practice in THR (Tucker et al. 2015), but quite uncommon in TKR. The mixing of components is a somewhat strange practice by the surgeons, since it is against the manufacturers' directions and regulatory guidance (Tucker et al. 2015). From a methodological point of view, the mixing of components complicates the analysis of implant survivorship, as the different components may contribute to survivorship of the pair of components differently. In THR, the mixing of components has been shown to be associated with a higher revision rate when heads from one manufacturer are combined with stems from another (Tucker et al. 2015). On the other hand, mixing a cemented stem and a polyethylene cup from different manufacturers is associated with a decreased risk for revision (Tucker et al. 2015). Results concerning component mixing in Finland are presented in this work, in Section 5.1 for an overall picture of THR and TKR, and in Study II for THR.

2.3 LEARNING CURVE IN ARTHROPLASTY

Learning curve, in general, refers to the rate of learning a new skill ("Learning Curve." Merriam-Webster.com. Accessed January 19, 2016. http://www.merriam-webster.com/dictionary/learning%20curve). A learning curve can be used to visually describe this rate. The concept of a learning curve was coupled with the rate of increase in productivity in aviation manufacturing by T P Wright in the 1930s and it was later adapted to medicine (Le Morvan, Stock 2005). Le Morvan and Stock (2005) point out three relevant notions about typical medical learning: patients are exposed to excess risk, learning is ubiquitous, and the problems inherent in the learning process are not solved with consent procedures. In medicine, the skills needed are not all learned from the textbooks and it takes practice to learn and improve. This is widely agreed upon, although it is usually unknown how much practice is necessary to attain an optimal level of performance.

Although the concept of a learning curve is known across the areas of medicine, the effects of learning are most dramatic in surgery (Hopper, Jamison & Lewis 2007). One study argues that 'surgeons have always recognised the concept of a learning curve when undertaking a new procedure' and 'learning a new technique, even for an established consultant, requires some sort of learning curve' (Hasan, Pozzi & Hamilton 2000).

While learning curves are widely acknowledged in medicine, they have also been studied to a great extent. A review of learning curves in medicine published in the year 2000 found 559 articles fulfilling the inclusion criteria and published before April 1999 (Ramsay et al. 2000). In an industry like airplane manufacturing, the performance is rather easily measurable in terms of, for example, cost or production time, but assessing the performance of a clinician, hospital or a medical device is not as straightforward (Hopper, Jamison & Lewis 2007). The measures of performance in surgery can be classified into measures of the surgical process (e.g. operative time, blood loss, technical adequacy) and measures of patient outcome (e.g. morbidity, mortality) (Hopper, Jamison & Lewis 2007). Measures of the process are more often used because of the ease of implementation, but they are not necessarily directly related to patient outcomes (Ramsay et al. 2000).

According to a systematic review, the methods used in the investigation of learning curves under health technology assessment had only rarely formally assessed a learning curve (Ramsay et al. 2000). It has been shown that the methods used in the learning curve literature are weak and the reporting of the studies has a number of shortcomings (Ramsay et al. 2000). Presumably the learning curve literature has accumulated since the review was conducted, but there exists no data on the amount of literature and, consequently, the methodological quality of the literature that analyses learning effects has not been systematically evaluated.

The systematic review of Ramsay et al. (2000) collected studies on learning curves in medicine up to April 1999, with two papers on TJR included. For this thesis, published studies on learning curves dealing with techniques and devices related to THR and TKR were searched for in PubMed and Google Scholar. In total, 47 studies were identified and included in this thesis (Table 1). Only two studies were identified that were published prior to the year 2000, and both of these were also included in the work of Ramsay et al. (2000). The bibliography of Ramsay et al. (2000) that was examined after the literature search provided no additional studies that handled arthroplasty or related procedures.

Table 1. *Identified learning curve studies related to total hip and knee replacement.*

Authors	Year	Joint	Object	Measures of learning
Abane et al.	2015	Knee	Patient-specific instrumentation	Mechanical axis, component positioning, operating time, Knee Society and Oxford knee scores, blood loss, length of hospital stay
Archibeck et al.	2004	Hip	Surgical technique	Operative time, fluoroscopy time, complications
Berend et al.	2011	Hip	Hip resurfacing	Complication rate, types of complications, and outcomes
Callaghan et al.	1992	Hip	Implant type, THR	Femoral fit, acetabular cup angle, femoral fracture rate, minimum two-year clinical hip ratings, clinical symptoms
Cheng et al.	2011	Knee	TKR	Infection, mortality
Chinnappa et al.	2015	Knee	Patient-specific instrumentation	Operative time and post-operative multi-planar alignments
Cobb et al.	2007	Hip	Computer-assisted surgery	Accuracy of implantation
Confalonieri et al.	2012	Knee	Computer-assisted surgery	Frequency of errors in intraoperative bone cuts and implant alignment, and operative time
Daniilidis & Tibesku	2014	Knee	Patient-specific instrumentation	Component alignment
D'Arrigo et al.	2009	Hip	Surgical technique	Blood loss, functional scores, complication rate
Daubresse et al.	2005	Knee	Computer-assisted surgery	Postoperative leg coronal alignment
de Steiger et al.	2015	Hip	Surgical technique	Revision
Flamme et al.	2006	Hip	THR	Perioperative complications and postoperative radiographs
Goytia et al.	2012	Hip	Surgical technique	Surgical and fluoroscopy times, estimated blood loss, intraoperative and postoperative complications, patient comorbidities, component position, and leg-length discrepancy

Hamilton et al.	2010	Knee	Surgical technique	Revision and reoperation rates
Jablonski et al.	2009	Hip	Surgical technique	Intraoperative complications
Jenny et al.	2008	Knee	Computer-assisted surgery	Implantation accuracy, clinical outcome, operation time and complications
Jiménez-Cristóbal et al.	2011	Knee	Surgical technique	Hospitalisation in days, radiological angles, length of incision, tourniquet time, complications, Hospital for Special Surgery (HSS) score, haemoglobin values and need for blood transfusion
Kashyap et al.	2009	Knee	Surgical technique	Oxford Knee Score, Knee Society Score, alignment, complications
King et al.	2007	Knee	Surgical technique	Operative time, implant alignment, and clinical outcomes
Laffosse et al.	2006	Hip	Surgical technique	Implant positioning, intraoperative complications, revision
Lee et al.	2014	Hip	Surgical technique	Cup positioning
Lubowitz et al.	2007	Knee	Surgical technique	Operative time
Maniar et al.	2011	Knee	Computer-assisted surgery	Alignment of the mechanical axis and femoral and tibial components
Manzotti et al.	2010	Knee	Computer-assisted surgery	Errors in intraoperative bone cuts and implant alignment, postoperative frontal femoral component angle, frontal tibial component angle, hip–knee–ankle angle and component slopes
Melman et al.	2015	Hip	Surgical technique	Technical complication rate and operating time
Mohaddes et al.	2016	Hip	Implant type	Revision
Müller et al.	2014	Hip	Surgical technique	Implant positioning, revision
Nicholson et al.	2013	Knee	TKR	Mechanical axis
Nunley et al.	2010	Hip	Hip resurfacing	Early complications
Pogliacomi et al.	2012	Hip	Surgical technique	Operation and hospitalisation times, blood loss, number of transfusions, peri-operative complications and

				femoral/acetabular component placement were monitored
Rasuli & Gofton	2015	Hip	Surgical technique	Operative time
Redmond et al.	2015	Hip	Computer-assisted surgery	Component position, operative time, and complications
Romanowski & Swank	2008	Hip	Computer-assisted surgery	Intraoperative femoral and acetabular component parameters were compared with postoperative radiographic alignment values. Within this single surgeon series, operative time, intraoperative cup inclination and femoral stem-shaft angles, and postoperative cup inclination and femoral stem-shaft angles were measured
Saithna & Dekker	2009	Hip	Computer-assisted surgery	Literature review
Salai et al.	1997	Hip	THR	Harris Hip score
Sansone & de Gama Malcher	2004	Knee	Implant type	Knee Society Score, complications
Santini & Raut	2008	Knee	Implant type	Revision, aseptic loosening, loose joint
Schnurr et al.	2011	Knee	Computer-assisted surgery	Operation time
Seng et al.	2009	Hip	Surgical technique	Operation time, blood loss
Seyler et al.	2008	Hip	Computer-assisted surgery	Accuracy of positioning the femoral component was analyzed radiographically
Smith et al.	2010	Knee	Computer-assisted surgery	Alignment, Oxford score, mechanical axis and range of movement
Spaans et al.	2012	Hip	Surgical technique	Blood loss, clinical outcome, complication rate, revision
Stiehler et al.	2015	Hip	Computer-assisted surgery	Precision of femoral component positioning, notching, and oversizing rate, as well as operative time

Thorey et al.	2009	Hip	Computer-assisted surgery	Intraoperative acetabular component parameters (inclination, anteversion), operating and anesthesia times
Van Oldenrijk et al.	2013	Hip	Surgical technique	Duration and efficiency of individual actions
Zhang et al.	2014	Knee	Implant type	Duration of surgery, blood loss, Hospital for Special Surgery score, range of motion, complications, and the radiographical position of the implant

From the author's literature search it can be concluded that analyses of learning curves in arthroplasty have increased since the year 2000, as at least altogether 45 studies have been published in the 21st century. Between 2000 and 2009, 18 studies were published. Twenty-seven of the included studies have been published since the beginning of 2010, suggesting an increasing publishing rate. This may reflect increased interest in the learning curve in arthroplasty, or it may be a result of an accelerated introduction of new surgical techniques or devices. The full bibliographic details of the studies included in Table 1 are given in Appendix 1.

The works presented in Table 1 show that studies on learning curves in TJR have mostly dealt with surgical technique, patient-specific instrumentation or computer-assisted surgery. An early study in THR showed that there is a learning curve for a surgeon when starting their career (Callaghan et al. 1992). Since then, a number of studies have evaluated individual surgeon's learning curve in both hip and knee arthroplasties when a new technology has been implemented. The measures that have been used to assess the learning curve show a wide range of methods for quantifying the learning. The published papers do not always explicitly state the number of surgeons that had performed the surgeries, but at least in 16 of the included studies a single surgeon had performed the surgeries. Similarly, the methods for including the patients in the studies were not always fully described. In at least 20 studies the material consisted of some kind of consecutive series of patients in a single institution. Only three of the studies were register-based (Cheng, Cheng & Chen 2011, de Steiger, Lorimer & Solomon 2015, Mohaddes et al. 2016) and one was a multi-centre study (Jenny, Miehlke & Giurea 2008).

All the identified studies suggest that there is some learning curve in the technique or technology investigated. Some studies have quantified the learning curve in the number of surgeries or as time in months needed to perform in order to become proficient in the technique or technology. The range in the number of surgeries varied from 10 (Lubowitz, Sahasrabudhe & Appleby 2007) to more than 100 (Nunley et al. 2010).

Two studies were identified that assessed specific implant types in conventional arthroplasty and evaluated the learning curve associated with the introduction of the implants. In the first of these studies, Sansone and da Gama Malchèr (2004) analysed the first 110 consecutive knees operated on between 1991 and 1995. In the follow-up (range 5–9 years) four cases required revision surgery for causes specifically related to the implant and three were revised for other reasons. The revised cases were all such that they were operated on during the first three years of the surgeons' experience, and the authors concluded that there is a learning curve with this implant. The surgeries they analysed were not performed in the early stage of the career of an orthopaedic surgeon. Thus, this study can also be considered as an investigation in which the learning curves associated with the introduction of a new device are being analysed.

In the second implant-specific study that did not involve a change in surgical technique or computer-assisted navigation by Santini & Raut (2008), 99 of the first TKRs of a surgeon were included. In the long-term follow-up (average 8 years and 8 months) four patients were revised, and three of the revisions occurred in the first six patients operated upon. The authors concluded that a learning curve may exist when a surgeon is starting his or her career.

One study showed that for a surgeon experienced in conventional TKR, switching back to conventional TKR after a series of TKRs performed with computer-assisted navigation, a learning curve of 30 surgeries was necessary to obtain a good implant alignment (Nicholson, Trofa & Smith 2013). This idea is close to the idea of the present thesis, as it depicts the learning curve after switching technology in conventional TJR surgery.

No studies were identified that had analysed the learning curve possibly associated with the introduction of an implant in a hospital and had been published prior to the author's studies. An institutional learning curve, i.e. the improvement of surgical results in THR over time as experience of the procedure has been gained, has been suggested in literature (e.g. (Salai et al. 1997)). Related to this kind of institutional learning curve is the idea of a relationship between the surgical volume of a hospital and the outcome of surgery, also suggesting a learning effect depending on the experience (e.g. (Cheng, Cheng & Chen 2011)).

2.4 LAUNCH AND CLOSURE OF HOSPITALS AND UNITS

In Finland, the health service network is mostly organized by the public sector. There are, in addition to the public providers, a number of private providers, although the private producers are small volume actors and their share of the market in specialized health care is rather modest. In arthroplasty, however, there is one private hospital that performs a significant number of TJRs. The network performing TJR has remained rather stable in the past 20 years, while some units have closed and others have launched TJR activity over time. In the future, the publicly funded hospital network performing TJRs may experience major changes, as there is pressure to concentrate the services into units with bigger annual volumes. This would naturally lead to closures of some units. On the other hand, the need for TJR has been projected to increase and the number of surgeries to grow in Finland (Mäkelä et al. 2010, Skyttä et al. 2011, Pamilo et al. 2015), thus also making it possible to launch new surgical units. It is natural to think that changes in the organization of care may have consequences on the quality of care given for the last patients in the closed units as well as for the first patients in the newly launched units. For hospital managers and health policy makers, information about these consequences is important. However, reliable scientific data on this is scarce.

The effects of hospital closure have been analysed from a number of points of view. In the health economics literature, it has been shown that hospital closures reduce health care costs, although they also reduce the welfare of the patients living close to the hospital that is closed (Capps, Dranove & Lindrooth 2010). Lindrooth et al. (2003) (Lindrooth, Lo Sasso & Bazzoli 2003) have shown that the hospitals that were closed were inefficient compared to the remaining hospitals, and therefore the closures have led to a decline in the average cost per admission. In a study dealing with closures of nursing homes, the quality of care was found to be lower in the units that had been closed (Castle 2005).

Thus, it should be taken into account that there may be selection regarding closures of units performing TJR. The closed units may have had a lower quality of care and they may have been inefficient in their production. In addition, it should be kept in mind that the reasons behind hospital closures and launches may be different across different health care systems.

When a hospital is closed, the distance to the nearest hospital in the population at hand may change, and this may have consequences for the population health or mortality, but the results are conflicting. For example, in one study increased mortality due to heart attacks and unintentional injuries after hospital closure has been found (Buchmueller, Jacobson & Wold 2006). Another study that identified 195 hospital closures in the US found no significant difference in annual mortality of populations in the areas affected by hospital closures, nor in all-cause mortality rates following hospitalization (Joynt et al. 2015). A Canadian study concluded that hospital closures led to more favourable outcomes in coronary artery bypass grafting patients (Hemmelgarn, Ghali & Quan 2001).

A number of studies have investigated how financial pressure on hospitals has influenced the care given to patients. For example, reductions in service intensity and length of stay in hospital have been found (Hadley, Zuckerman & Feder 1989, Dranove, White 1998). Shen (2003) (Shen 2003) showed that financial pressure was associated with an increase in the adverse short-term outcomes in patients suffering from acute myocardial infarction. A contracting economy and financial pressure may also lead to cuts in a hospital's investments in equipment and maintenance. The consequences of diminished net patient revenues on hospital infrastructure and processes supporting the delivery of care in a hospital have been studied in the USA, and the authors suggest that as a consequence of these cuts the quality of care may have deteriorated (Bazzoli et al. 2007). In another study, Encinosa and Bernard (2005) (Encinosa, Bernard 2005) showed that declining hospital operating margins had an adverse effect on patient safety indicators related to surgery.

Although the consequences of increased financial pressure on hospitals have been investigated, to my best knowledge, no studies have been carried out to analyse the effects of hospital or unit closure on the quality of care that would have used the last treated patients' quality of care as the outcome. As there is a learning curve for an individual surgeon when starting surgery with a new surgical technique, there might be an institutional learning curve when TJR surgery is launched in a unit. Variations in the quality of an activity might appear when a specific treatment is launched or when it is being discontinued in a hospital.

It is known that good teamwork is important for good quality care (e.g. Manser 2009, Bosch et al. 2009, Weaver et al. 2010, Leonard, Frankel 2011). When a new procedure is launched in a hospital, the operating team needs education and learning-by-doing to achieve better performance. In TJR, operating room teamwork plays a major role in good quality of care, with communication within the team being especially important (Wong et al. 2009, Kellett, Mackay & Smith 2012, Van Strien et al. 2011). Therefore, successful recruitment and team-building may have an impact on the quality of care. Teams performing replacement surgery may have a learning curve too (Reagans, Argote & Brooks 2005).

In labour economics it is hypothesized that when it is announced that a plant is to be closed or downsized to a large extent, the most skilled workers leave the company before the closure happens. Thus, when a unit performing arthroplasty announces it is to be shut down (or that the performing of arthroplasty in the unit will cease), the surgeons, nurses or other members of the orthopaedic teams are in danger of becoming redundant. Some of the team members, presumably the most skilled ones, are likely to seek employment in other units. This extra turnover, or even lack of skilled personnel (it may be hard to find replacements with temporary contracts), may cause the quality of the care given by the team to deteriorate, leading to a compromising of the quality of the treatment and worsening patient outcomes.

During hospital or unit closures, the operating room team members might lose motivation or find employment elsewhere, affecting the quality of care (Cavanagh 1989, Cummings, Estabrooks 2003, Misra-Hebert, Kay & Stoller 2004, Buchan 2010). A review of studies analysing the effects of hospital consolidations on the quality of care found conflicting results between the concentration of care and the quality of care (Vogt, Town & Williams 2006).

Of the 10 reviewed studies, five found that for some procedures, a concentration in the hospital market reduced quality, four studies found the opposite and three studies found no effect between concentration of care and the quality of care.

3 THE AIM OF THE RESEARCH

The study questions and the hypotheses set in this thesis were as follows:

1. To assess the learning curve associated with the introduction of new total hip and knee implants in a hospital. To meet this aim, I asked whether the first patients operated on with any new implant type in a hospital had a higher revision rate than patients whose implants were routinely used in the hospital. As a secondary analysis, the risk of early revision owing to characteristics related to the operation, patient, and hospital were investigated.

2. To study if in total hip and knee replacement, the learning curves were dependent on the implant model, i.e. if some implants are easier and safer to take into use than others. Using Cox proportional hazards regression modelling and data on THR and TKR surgeries with the ten most common implant models in Finland, the implant model specific learning curves were quantified with outcome measured as the risk of early revision surgery. In addition, for the analysed knee implant models, an analysis of the three-, five-, and ten-year survivorship was performed. In THR, analysis of the differences between femoral stem and acetabular cup models in the early revision risk during the implementation phase was made by focusing on the ten most common stem and cup pairs in the data.

3. To study the learning curve associated with the launch of a TJR unit and the effects of a TJR unit closure on the quality of care in the last performed surgeries. In the hospital launch and closure study it was hypothesized that (1) the early revision risk after THR and TKR is not significantly different for the first patients operated on in a launched unit and that (2) the early revision risk after THR and TKR is not significantly different for the first patients operated on in a closing unit from the early revision risk following these operations in the same units during a stable production phase.

4 DATA AND METHODS

4.1 HEALTH CARE REGISTER DATA

Finland has a long tradition in administrative health care data, as the routine nationwide collection of hospital discharge data was started in 1967 (Sund 2012). In 1969, personal identity codes (PIC) were introduced in the Finnish Hospital Discharge Register (FHDR), and FHDR data since that year are nowadays accessible in electronic format (Sund 2012). The PIC enables the linkage of FHDR records of the same person and makes it possible to follow health service use over time. In addition, as the PIC is included in other administrative register data available in Finland as well, the records of a person can be linked between different registers. Typically, FHDR data is linked with data from other register data when large research databases are created (e.g. Peltola et al. 2011). The Finnish register data covering the use of health care services and prescribed medication have been well described elsewhere (e.g. Gissler, Haukka 2004). These register data have been used in a great number of scientific peer-reviewed publications.

In this study, the two most important registers used were the FHDR and the Finnish Arthroplasty Register (FAR). Both these registers are currently maintained by the National Institute for Health and Welfare (THL). In addition to these, register data on special reimbursements of medicine (since 1964) and prescribed medicine (since 1996), both administered by the Social Insurance Institution (SII), and cause of death statistics by Statistics Finland were utilized.

Each visit to or a stay in an institute in Finland providing specialised health care is recorded in the FHDR. Collecting and reporting the data to THL is mandatory, and all the institutions located in Finland have to provide the data annually to the FHDR. The key data content of the FHDR are the dates of admission and discharge, the PIC of the patient, and the institution where the person was treated. In addition, diagnoses and procedures for each hospital stay or visit are recorded. Sund (2008) has noted that 'hospital admission and discharge days are easily observable facts [...] which are correctly and completely recorded in the Finnish data.' In this study, the empirical work is based on these facts, and the diagnoses and procedure codes included in the FHDR are used in a supporting role.

In 1980, the Finnish Orthopaedic Association started registration of TJRs in Finland. The main purpose was to assess and ensure the quality of the implants, for the patients' benefit. A few years later, in 1987, the management of the register was transferred to national authorities. At first, the registration of TJRs was voluntary, but it became obligatory in 1997 (Puolakka et al. 2001) so that all units, both private and public, performing

TJR in Finland had to report their surgeries to the FAR. Both primary and secondary TJRs are included in the FAR.

PIC is also used in FAR, and the two data are thus easily linkable at the individual level. FAR includes information on the date, joint, and side of surgery, the cause for surgery and unit where the surgery was performed at. In addition, component names and fixation methods are given in FAR. The form used in the registration for hip and knee replacements for the period that the current study is based on is given in Puolakka et al. (2001). The contents of the FAR have recently been updated and enriched, and the registration process has been fully automatized in 2015, having been synchronized with an online reporting platform.

A systematic review conducted in 2012 that gathered all published studies assessing the validity of the FHDR found that the coverage, reliability and positive predicted value of the FHDR are good (Sund 2012). In the review, 32 studies that had compared the FHDR with external audit data were identified. The FHDR has not been validated on TJR specifically. A validation study covering hip fracture has been conducted, where the coverage, sensitivity, and positive predicted value were all evaluated to be 98 %, indicating that the register data on a surgical treatment in the FHDR is of a very high standard (Sund et al. 2007). Regarding the register of prescribed medicine, the concordance between the database and self-reported medication has been found to be high (Haukka et al. 2007). The validity of the cause of death statistics has also been reported to be reliable (Pajunen et al. 2005).

There have been no studies that would have scientifically assessed the validity of the FAR. In the early 1990s, the average registration of surgeries in the FAR has been found to vary significantly between hospitals, and at the turn of the millennium the overall completeness was estimated to be 95 % (Puolakka et al. 2001). According to the online publication of the FAR, the completeness of the FAR has been more than 90 % for both primary and revision surgeries between 2008 and 2013 (ENDOnet, https://www2.thl.fi/endo/report/#data/completeness, accessed on December 21, 2015). Regarding the content of the register, the FAR requires input on implant components, and in the case of missing information attempts are made to retrieve information manually (Jämsen et al. 2009). In a study by Jämsen et al. (2009), the primary TKRs in FAR could be paired with supplementing data in FHDR in over 95 % of the cases and for about 91 % of the revision surgeries.

4.2 INNOVATION: CHRONOLOGICAL USE OF REGISTER DATA

In the present thesis, studies I–IV were all based on the chronological use of data from both the FHDR and the FAR. The data allow an ordering of the surgeries in time, starting from either the first or the last, and thus the surgeries can be assigned order numberings. Using the content of the registers, the data can be arranged chronologically in various ways. For example, using data on all primary TJRs in Finland, with data on the date of the primary surgery and the unit performing the operation, the order numbers of primary TJRs can be issued for each hospital separately. The ordering of data by date makes it possible to easily identify the first and last events. Adding dimensions to the ordering, it is possible to identify the first operations performed with a certain implant model in a hospital.

By including all TJRs, it is possible to define the order number of all TJRs in a hospital. The order numbers can as easily be defined separately for THR and TKR as well. With utilization of information on the implant model, the order numbering in a hospital can be extended to be implant-specific. It should be noted, that as said above, the dates and the places (unit) can be considered facts, as they are easy to define and measure. This simple innovation of chronological use of register data is a strength of the approach.

4.3 DEFINITION OF IMPLANT INTRODUCTION

Chronological ordering of the surgeries combined with data on the implant components used in the operation makes it possible to number all the different components for all TJRs in each hospital separately. From such ordering, the first surgeries with a new implant to the hospital are easily identified. In studies I–III, data on these component-specific order numbers was used to identify the introductions of new components to a hospital. A component was considered to have been introduced in a hospital if it had not been used in the same hospital earlier.

When performing TJR in Finland, in TKR the femoral and tibial components are only rarely mixed. However, in THR the mixing of femoral and acetabular components is much more common (Section 5.1, ibid). In the studies included in the present thesis, each component was issued an order number in each hospital, and the component pairs were taken into account when defining the order number for the component pair.

When there are two components used, and each component can have its own order number, the pair can have two possibly different order numbers. In THR the pair consisting of femoral and acetabular components, and in TKR, the pair of femoral and tibial components were used in defining the pair-specific order numbers. In the studies concerning TKR (studies I and III), the pair-specific order number that was used in the analysis of learning curves was based on the minimum order number of the component order numbers in the pair, i.e. the assumption made was that when a new component was introduced in a pair, it was considered to be a new implant introduction. In study II that dealt with THR, the analyses were made using both the minimum and the maximum of the component order numbers in a pair. When the maximum order number of the components in the pair is used as the basis for the order numbering of the pair, it is assumed that the more familiar component gives confidence to the surgeon and the component that is less used in the hospital is dominated by the more familiar component.

4.4 DEFINITIONS OF UNIT LAUNCH AND CLOSURE

Chronological arranging of TJR data as described above was the fundamental building block in the analysis of the effects that institutional learning curves and closure had on the quality of surgery. Definitions of launched and closed units were developed on the basis of the TJR data arranged chronologically. First, a unit that had started to perform TJR in Finland between the years 1998 and 2011 was defined to be a launched unit. The launch stage was defined as consisting of the first 100 TJRs performed in the unit. A unit that had not performed TJR in the preceding year but had performed TJR earlier was also defined as having launched TJR. So, a unit may have more than one launch of TJR over time. This kind of re-launch was considered to be a launch of TJR since a year's gap in TJR performance may be long enough for the surgical team to have disbanded, the team's skills and communication to have deteriorated, or the personnel in the team to have changed.

Similarly, TJR surgeries in each unit were given order numbers from the last surgery to the first, in order to identify the last patients operated on in a unit. Units that had totally discontinued TJR in the period 1998 to 2011, or that had not performed TJR in some calendar year during the period, were defined as closed units.

Within the launched and closed units, TJR surgeries were arranged chronologically and issued order numbers. With these order numbers, the first 100 and the last 100 TJRs in a unit were identified. When a unit was launched, the first 100 TJRs were defined to constitute the early stage of operation (i.e. the launch stage). Similarly, for the closed units the last 100 TJRs were defined as having been performed in the closure stage of the unit. This pre-set choice of the first or last 100 TJRs was not based on literature or data mining with the available study data, but was arbitrary.

4.5 DATA AND METHODS IN STUDIES I-IV

The register data used in the thesis has origins in the PERFECT (Performance, effectiveness and cost of treatment episodes) project (Häkkinen 2011). In PERFECT, all the primary TJRs performed due to primary osteoarthritis have been included from the year 1998 onwards in a national database that is used for benchmarking of units performing THR and TKR in Finland (Mäkelä et al. 2011). In THR, hip resurfacing is excluded from the database. The principles of data processing and the inclusion and exclusion criteria for THR and TKR are described elsewhere (Mäkelä et al. 2011, Peltola et al. 2011). In brief, TJR surgeries are identified in the FHDR, and then data from the FHDR is complemented with data from the FAR, SII and Statistic Finland's cause of death statistics databases. The database is surgery-specific, i.e. an individual may have several primary TJRs (observations) in the data. For each surgery of an individual, there is a follow-down and follow-up for comorbid diseases (see e.g. Jämsen et al. 2013), and for previous and later primary TJRs and revisions. Ålandians and foreigners have been excluded, since their hospital service use cannot be reliably tracked with Finnish registers only. Table 2 summarizes the main feature of data in the Studies I–IV.

Table 2. *Summary of data in Studies I-IV.*

Study number	Surgery	Years covered	Number of observations
I	TKR	1998-2004	27 105
II	THR	1998-2007	39 125
III	TKR	1998-2007	46 363
IV	THR, TKR	1998-2011	150 038

For the studies included in the thesis, revision surgery was the measure of quality. In Study I, a follow-up of five years was used to track the revisions of the primary surgeries, while in the other studies a follow-up of three years was applied. Revisions are considered to be reliably recorded in the used registers, while in register-based TJR research they are an accepted outcome measure (e.g. Robertsson 2007, Serra-Sutton et al. 2009). Revisions were tracked from both the FAR and the FHDR. In all the studies, reoperations due to exchange or removals of implants were defined as revisions. In addition, in TKR, the insertion of a patellar component after the primary surgery was considered to be a revision. This definition is slightly wider than normally used for TKR and may thus result in a somewhat greater number of revisions.

In studies I–III that dealt with the introduction of implants in a hospital, the surgeries were classified using the order number into five groups: Group A (first 15 surgeries), Group B (surgeries 16 to 30), Group C (surgeries 31 to 50), Group D (surgeries 51 to 100), and Group E (surgeries with order number greater than 100). In these studies, the surgeries in Group A to D were compared to the surgeries in Group E. The surgeries performed with an order number greater than 100 (Group E) were considered to be performed in 'established practice', i.e. at the plateau of the learning curve. In the study of TJR launches and closures, the first and last 100 TJRs in the launched or closed units were compared to surgeries in the same units after the launch stage or before the closure stage.

All studies used Cox's proportional hazard regression modelling to compare the groups. With this modelling technique, the censoring of cases due to death and timing of the revision were taken into account and the time in days from the primary surgery to the revision surgery or censoring was used as the dependent variable. In addition, with Cox's regression modelling, it is possible to adjust for confounding factors. In the studies, a number of confounders were used, for example, fixation technique, comorbid diseases, year of surgery, and patient age and sex.

5 RESULTS

This chapter first gives some novel unpublished results characterizing the hip and knee implant market in Finland and then summarizes the results of the four studies included in the thesis.

5.1 DESCRIPTIVE RESULTS ON THE IMPLANT MARKET IN FINLAND BETWEEN 1980 AND 2013

The number of TJRs has steadily increased in Finland since 1980. The growth in the number of operations has been greater in TKR, and the annual number of TKR surpassed THR in 2002 (Figure 1). In 2013, 8943 primary THR and 10 596 primary TKR surgeries were performed. In the same year, 1730 hip revisions and 836 knee revisions were done.

In these primary TJRs in Finland, a far larger number of different implants have been used in THR than in TKR. In 2013, there were more than 50 acetabulum and femoral components used in THR (Figure 2), whereas TKRs were performed with 22 femur and 23 tibia components (Figure 3).

In THR, the number of acetabulum and femur combinations peaked in 2011, with 285 different implant combinations (Figure 2). Regarding the combinations of cups and stems used in primary THR in Finland between the years 1980 and 2013 there were altogether 1735 different acetabulum and femur pairs used in the primary THRs in the data. The number of implant combinations in THR has decreased since 2011. In 2013 there were 236 different femur and acetabulum pairs observed in the primary THR surgeries.

The annual numbers of implant model introductions by component for both THR and TKR are shown in Figure 4, and Figure 5 gives the annual numbers of pairwise introductions.

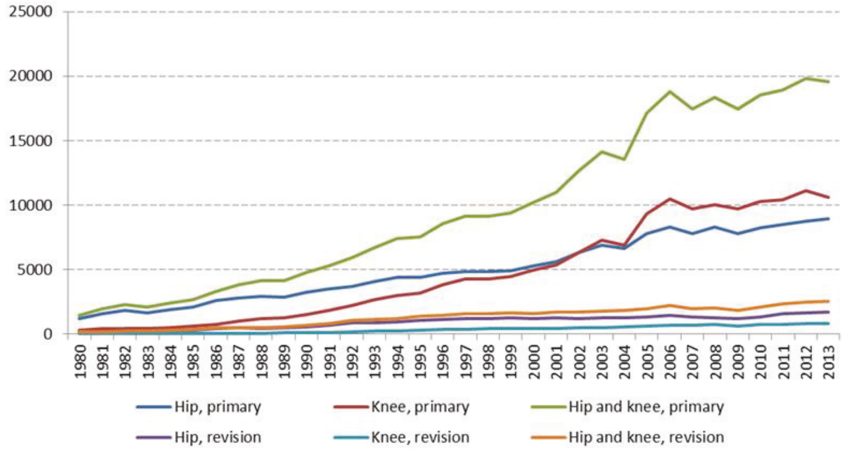

Figure 1 The number of primary and revision total hip and knee replacements in Finland as reported in the Finnish Arthroplasty Register in the period 1982 to 2013.

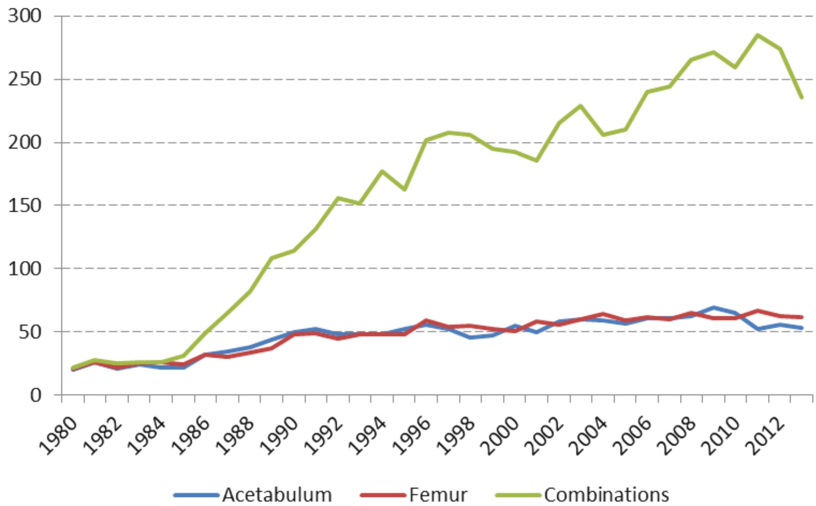

Figure 2 The number of acetabulum and femur implants and their combinations in primary total hip replacement in Finland in the period 1980 to 2013.

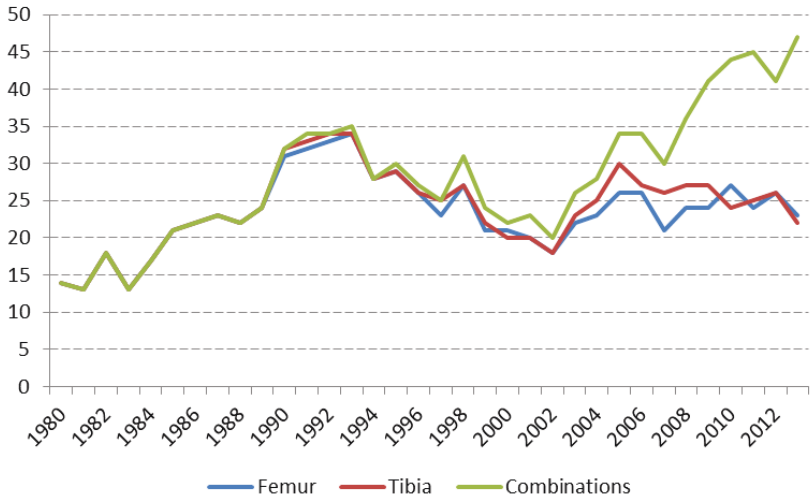

Figure 3 The number of acetabulum and femur implants and their combinations in primary total hip replacement in Finland in the period 1980 to 2013.

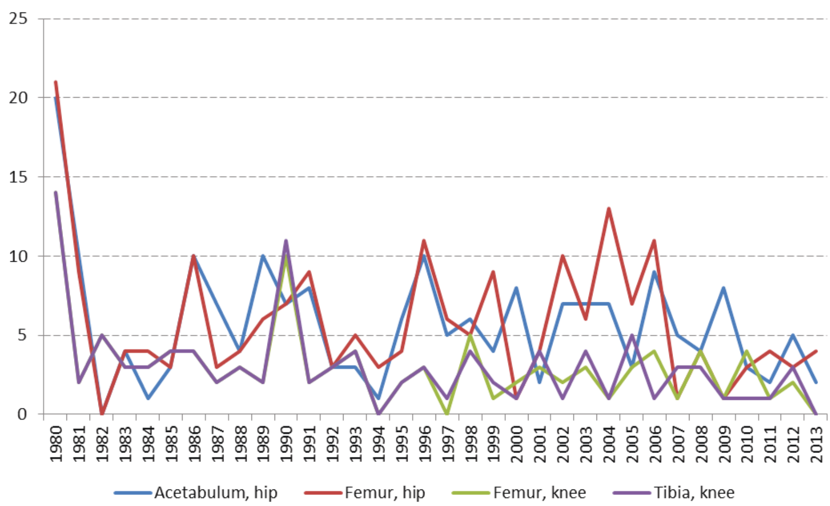

Figure 4 Introductions of new acetabulum, femur and tibia components in primary total hip and knee replacement in Finland in the period 1980 to 2013.

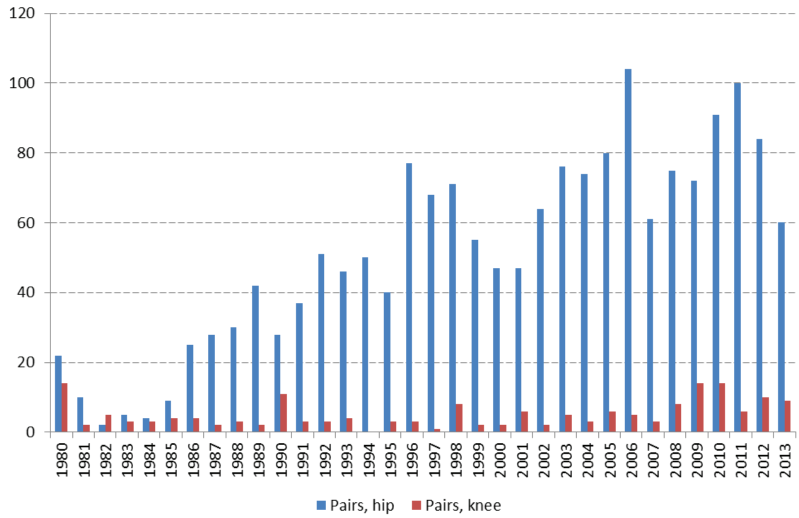

Figure 5 The number of introductions of new implant pairs in primary total hip and knee replacement in Finland in the period 1980 to 2013.

5.2 LEARNING CURVE IN TOTAL HIP AND KNEE REPLACEMENT

Studies I and III assessed if there was a general learning curve when introducing hip and knee implant models in a hospital.

Between 1 January, 1998, and 31 December, 2007, 33 819 patients with 39 125 THRs were included in the final study data to assess if there was a learning curve when new hip implant models were introduced in a hospital. Altogether 1269 revisions were performed on these patients during a 3-year follow-up period. In the 10-year study period, 96 stem models and 85 cup models were used in these surgeries, and these components were used in 467 different combinations, i.e. forming different stem and cup pairs. A large share of the stem and cup models had been used in a small number of operations. In total, 62 out of the 96 stem models and 47 of the 85 cup models had been used in less than 100 surgeries in the study data, accounting only about 3 % of the THRs.

In the study period, 87 stem and 79 cup models were introduced in at least one hospital, and these introductions contributed to 5967 surgeries in the first stage of the implant introduction (the first 15 THRs with an implant model in a hospital). Of all the studied surgeries, almost one in six was performed in the first stage of introduction.

In analysis concerning the existence of a learning curve in general in THR implant model introductions in hospitals it was found that the first 15 operations had a higher risk for early revision for the order numbering of both stem and cup models, and for the combined order numbering as well (hazard ratio 1.3, 95 % confidence interval 1.1-1.5). As a result, In THR, there appears to be a learning curve due to the introduction of a new stem or cup model.

For the analysis of the overall learning curves at the introduction of a new knee implant model in a hospital, all primary TKRs performed due to primary osteoarthritis in Finland between January 1, 1998 and December 31, 2004, having complete data on implant models were analysed. The data comprised 22 551 individuals with 27 105 TKRs. In the five-year follow-up, 1000 revisions were performed on these patients. Over the period, 27 tibial and 34 femoral implant models were introduced in the study population. In total, 66 surgical units took new knee implant models into use, adding up to 339 implant model introductions at the hospital level, affecting altogether 5085 patients undergoing TKR in the introductory phase (the first 15 surgeries with an implant model) in these hospitals.

When adjusted for all baseline characteristics, the patients operated on in the introductory phase had a 1.5-fold risk (95 % confidence interval 1.1-1.9) for revision surgery when compared with patients that received an implant that had been used at least in 100 TKRs in the hospital. The risk for revision surgery was not elevated in patients numbered 16–30, 31–50, or 51–100 operated on in the next stages of implant use in a hospital, indicating that the learning curve smoothed rapidly.

In the study, the characteristics of the patients being among the first 15 patients having TKR in a hospital and the patients operated on with an implant that had been used at least 100 times in the hospital showed differences. The patients among the first 15 TKRs were slightly older and were more likely females than patients having surgery with implant model used routinely.

5.3 LEARNING CURVES OF THE MOST COMMON IMPLANTS

Studies II and III included model-specific analyses of the learning curves. For both total hip and knee replacements, the ten most common implant models that were used in Finland were included in the studies.

In order to find out if the learning effect in TKR was implant model specific, all 54 925 patients undergoing a total of 66 098 primary knee replacements due to primary osteoarthritis between January 1, 1998 and December 31, 2007 in Finland were identified. With these data the ten most common total knee implant models used were identified, and 39 528 patients who received these implant models in 46 363 TKRs were included in the analysis. The patients were followed up for three years.

The top ten knee implant models in Finland were used in more than two thirds of all the primary total knee replacements that were performed in Finland in the study period. The most common femoral implant was used in almost every third surgery in the data. With the ten most common knee implant models, 2493 surgeries were performed in the introductory phase of an implant during the study period.

The statistical analyses supported the hypothesis that learning curves following the introduction of a new femoral or tibial implant model in hospital practice have model-specific differences. Out of the ten analysed models, four had a higher risk for early revision in the surgeries performed in the introductory phase of the implant. With these four implant models, the first 15 patients operated on, the risk of early revision was statistically significantly higher compared to the risk of revision of the same implant that had been used in the hospital in more than 100 knee surgeries. For one of the four implant models the learning curve affected the revision risk of the 30 first patients.

After the implementation phases hypothesized to influence implant survivorship of the first 100 patients operated on with an implant model introduced in a hospital due to the learning curve, the implant-specific revision risks were also analysed in established practice. Of the ten most common knee implant models, two models had a statistically significantly lower risk for revision in three years follow-up period than the most common implant. Three out of ten implants showed an increased risk of early revision in routine use.

Similarly, analyses of the ten most common stem and cup pairs used in THR in Finland were committed in order to analyse the pair-specific learning effect. From the THR data described in section 5.2, the ten most common stem and cup pairs were included in the model specific study. Altogether 22 271 primary total hip replacements performed due to osteoarthritis were included in the analysis. The stem and cup specific differences in the early revision risk for different stages of implant introduction were analysed compared to the operations with the same stem and cup pair having an order number greater than 100. These model-specific analyses showed that three pairs had an increased early revision risk at the first introductory phase.

5.4 HOSPITAL LAUNCH AND CLOSURE

After applying the inclusion and exclusion criteria to the FHDR and FAR data, 150 038 TJRs were included in the study data. In total, 83 units reported THR and TKR to the FAR in the period 1998 to 2011. In this period, 19 units launched TJR in Finland; 8 of the launched units performed more than 200 surgeries. TJR was discontinued in 30 units, with 20 of these having a total volume of more than 200 TJRs since 1998 prior to unit closure. Of the included TJRs, 7678 were THR and 10 674 TKR surgeries performed in the units that had launched surgery. In the analysis of the revision risk at the closure stage, 10 650 THRs and 12 746 TKRs were included.

The risk-adjusted three-year revision rates showed that units (with at least 100 surgeries in the individual-level data) varied in their patients' risk of revision, for both THR and TKR (Figure 6). The figure also suggests that a units' risk-adjusted revision rate in THR was not always on a par with its performance in TKR.

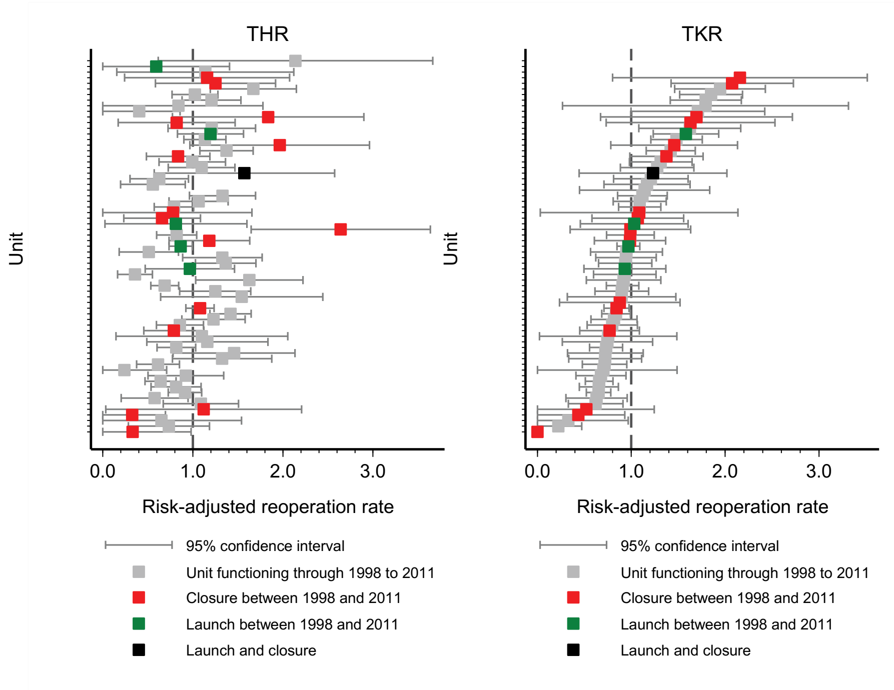

Figure 6 Risk-adjusted 3-year revision rate with 95 % confidence interval for units that performed total joint replacements in the period 1998 to 2011 in Finland. Total hip and knee replacement shown separately, ordered by risk-adjusted total knee replacement revision rate.

The performance of THR in the launched units was average or better than average compared to all THR units. One of the launched TKR units showed a poorer performance than TKR units on average. In contrast, the closed THR and TKR units' performance was distributed across the whole spectrum of performance.

Launching THR or TKR surgery in a unit did not entail different implant survivorship in the early stage of functioning than surgeries after the early stage of functioning in these units. However, THRs performed in the closure stage showed worse implant survivorship than THRs prior to the closure stage. In TKR a similar increase in the revision risk at the closure stage was not found.

6 DISCUSSION

6.1 MAIN RESULTS AND PREVIOUS LITERATURE

Introduction of a new total hip or knee implant in a hospital was found to be associated with a learning curve. On average, the first fifteen patients operated on with an implant that had not been used before in the hospital had an increased risk of early revision. This learning curve varies across both hip and knee implant models, as in the implant-specific studies, not all of the analysed implants showed a learning curve. Regarding the launch and closure of TJR surgery in a unit, it was found that in general the launches and closures were not associated with poor quality at the launch and closure stages, respectively, when compared to the units' performance outside these stages, with the exception of an increased risk of early revision in THR at the closure stage.

The works in the thesis present a completely novel approach to assessing the introduction of new technology and the changing of technology on a nationwide level. By including a number of different implants in the study, the selected implants' performance could be compared with each other, both in the introductory phase as well as in established practice. In addition, in the study settings the learning curves of different devices could be compared against each other.

The availability of administrative data enables the assessment of introductions of new medical devices and technology when the coding used to record diagnoses, procedures, or devices and surgical techniques allow for the identification of these new approaches. This thesis gives a practical example of how administrative data can also be applied in the analysis of the effects of restructuring hospital services or a treatment, such as TJR, on the outcomes of treatment in the different stages of production.

By applying this approach to the Finnish administrative data on TJR, novel results were produced regarding the introduction of implant models in hospitals and the launch and closure of TJR units. To my knowledge, this approach has not been used earlier in a register-based analysis of the effects of introducing new technology in health care on a level covering an entire population of patients and covering a relatively long period of time.

In orthopaedics, learning curves have been analysed to some extent, ranging from a system-level approach to the survivorship of implants over three decades or a system-level analysis of the effect of surgical volume on the learning curve (e.g. Salai et al. 1997, Robertsson et al. 2001, Cheng, Cheng & Chen 2011) to single-surgeon-based studies of operation time at the introduction of a new technique (e.g. Callaghan et al. 1992, Goytia, Jones & Hungerford 2012, King et al. 2007, Lubowitz, Sahasrabudhe & Appleby 2007, Melman et al. 2015). A large majority of the studies have used data gathered in a single institution, and the surgeries included in these studies have typically been performed by the authors of the papers. According to my literature search (Table 1; bibliographies listed in Appendix 1), there have been two multi-centre studies (Abane et al. 2015, Jenny, Miehlke & Giurea 2008) and one randomized controlled trial without real patients (Cobb et al. 2007) that have focused on analysing the learning curve.

All of the identified 47 studies suggest that with the procedure that the studies were looking at, there was some kind of learning curve based on some used measure. However, quantifying the learning curve has been difficult and only a few of the included studies give a quantitative estimate of the learning curve, either as the number of surgeries or as the time needed for the performance to reach an acceptable level.

Within arthroplasty, most of the studies on the learning curves identified in this thesis have dealt with surgical technique, patient-specific instrumentation or computer-assisted surgery, whereas only four of the identified studies have assessed the learning curve of named implant types (Table 1). Of the identified studies, 26 had evaluated learning curve in relation to surgery of the hip joint and 20 surgery in relation to the knee joint. The most typical outcome measures were operative time, implantation accuracy, and blood loss. Eleven studies had assessed the risk of revision or reoperation, with a varying follow-up time from 1 month to 9 years, with six focusing on hip and five on knee joint (Archibeck, White 2004, Berend et al. 2011, de Steiger, Lorimer & Solomon 2015, Hamilton et al. 2010, Jenny, Miehlke & Giurea 2008, Laffosse et al. 2006, Muller, Zingg & Dora 2014, Sansone, da Gama Malcher 2004, Santini, Raut 2008, Zhang et al. 2014) replacement. In these studies, the number of patients was generally low, ranging from 50 to 479 in ten of the studies. In the study by de Steiger et al. (2015), Australian register data were used and the number of analysed cases was much greater, at 4138. In five studies, all the included cases were operated on by one surgeon. Other studies had data based on surgeries of 2, 3, 4, 13, and 49 surgeons, respectively, and in one study, the number of surgeons participating was unknown.

Of the identified studies using revision as the measure for learning curve, only the study by de Steiger et al. (2015) found a statistically significant relationship between revisions and the number of surgeries that needed to be performed for the learning effect to become attenuated. They found that the learning curve for performing THR with an anterior approach and an implant specifically meant for the approach was more than 50 cases. The other studies identified were not able to give a reliable estimate of the learning curve measured with revision surgery due to the low number of cases included in the studies. In the study by Archibeck et al. (2004), 479 surgeries performed by 49 surgeons were evaluated for revision, but as each surgeon had only reported ten first THRs with the two-incision technique, the study is not completely adequate for assessing the learning curve of this surgical technique. In a study by Hamilton et al. (2010), minimally invasive unicompartmental knee replacement was analysed with data on 445 consecutive surgeries by four surgeons. They found that there was a learning curve of 30 cases for the operative time to reach a plateau, but they did not find a statistically significant learning curve measured with revision, although they concluded that revision rate decreased over time.

Finally, no studies were identified that would have assessed the learning curve quantified with a revision rate at the introduction of any new implants in a hospital with data from a number of hospitals or units. In addition, no studies were identified that would have had included more than one implant. Therefore, the works included in this thesis appear to be the first attempts to quantify the learning effect related to the introduction of any new device in a hospital and also to have assessed a number of implants in the same study.

The existence of learning curves has long been acknowledged, but attempts to assess the impact that learning curves would have on revision risk in TJR at the system level were not found. This thesis has set up a framework for how this kind of measuring could potentially be carried out. In addition, in this thesis the learning curves found were generated in routine clinical practice, contrary to studies based on a series of patients in a single hospital operated on by a single surgeon, and thus the results of this thesis are generalisable to other health care settings as well.

The existing literature relating to hospital launches and closures has, for example, analysed the effects of hospital closure on the use of emergency services of the patient population that the hospital has served in order to draw conclusions on the health effects of a concentration of health services. However, to my knowledge, this type of research has not looked at elective procedures like TJR, and the direct effects on quality of care of hospital launches on the first TJRs and closures on the last TJRs that a hospital has carried out have not been analysed previously. The study included in the present work dealing with unit closures showed that in some cases, a closure may lead to deteriorated patient outcomes in the last treated patients. However, there are no other studies on the topic dealing with TJR. Thus, there is room for more research on the effects of unit closures on the outcomes of care in TJR, and also regarding other procedures. The findings of the analyses of hospital launches and closures highlight that restructuring health care services needs careful planning and management.

The studies included in this thesis have received attention within the scientific community. In Australia, de Steiger et al. (2015) analysed with register data the learning curve associated with the anterior approach for THR, adopting the methodology presented in the studies of the thesis. They found that there is a learning curve in adopting a new surgical approach, and that the learning curve was more than 50 cases. In Sweden, Mohaddes et al. (2016) applied a similar approach described in this thesis with the Swedish register data. Contrary to this thesis's results concerning learning curve in THA in Finland, they found no increased risk of early revision associated to the implementation of new cup designs in THA.

In the Finnish recommendation on how to perform THR and TKR by the Finnish Arthroplasty Association, a chapter dealing with the introduction of new implants has been added to the 2015 version of the recommendation. It states that if a new implant is to be introduced, it should solve a problem that cannot be dealt with by a previously used device, it should be cheaper, or it should have better characteristics from a surgical or a maintenance point of view.

6.2 LIMITATIONS AND STRENGTHS OF THE STUDIES

There are a number of limitations in the studies included in the thesis that deserve to be pointed out. The used registers did not include a time stamp of the surgeries, only the date of surgery. Therefore, if a unit performed more than one THR or TKR per diem, the order of these same-day surgeries of a joint is not known. However, the number of surgeries per day in an institution was relatively low in Finland, and as the order number was used as a classifier for surgeries, the uncertainty of order numbers from these surgeries is unlikely to have affected the results regarding learning curves.

Despite limitations the register data offer very rich possibilities for analysing learning effects. Individual surgeons' learning curves, if their identification is possible in the data, can be assessed – and not only with regards to an overall learning curve. New surgical techniques may be assessed if the classifications concerning the surgery are up to date. And, as in case of TJR, learning effects related to new medical devices can be assessed. In the present studies, the identification of the surgeons was not possible and this may have affected the results, as the surgeon’s experience could not be taken into account.

In the analyses of implant-specific learning curves for new implant types, the amount of technical change with respect to the previously used implants in the hospital could not be quantified. However, the data on previously used implants in a hospital are available, and with careful but time-consuming expert input, the implant introductions could likely be classified into simple and challenging introductions. The findings may also suggest that there was patient selection; surgeons make patient selection when doing surgery with an implant model that they are inexperienced with. The differences in the observed characteristics were taken into account in the analysis, but there may be other patient characteristics that we were not able to control for that may have biased the analyses

Using revision as the measure of poor quality is susceptible to both supply and demand related factors. Not all patients with pain and disability after failed TJR are automatically revised, and the thresholds for revision may vary slightly across providers. Data on patients' body mass index and physical activity would also help in achieving more precise estimates of implant-specific learning curves, since these characteristics may have an influence on the choice of implant. The quality of bone stock, bone loss and degree of acetabular sclerosis in THR and deformity, instability and bone loss in TKR may also have an effect on the choice of implant for the patient, but this data were not available in the administrative data used.

In the analysis of the launch and closure of TJR units no detailed data on the hospital characteristics were available. In particular, it would be valuable to have data on operating room personnel and personnel turnover. This kind of data were unavailable in routine registers.

In both the implant-specific learning curve analyses and the analysis of TJR unit launches and closures, the number of observations available for analysis restricted the functional form of the learning curve. Especially in the hospital unit launch and closure study, the limit of 100 surgeries may be too restrictive, particularly regarding closures. The low number of launches and closures in the data limited the choice of learning curve definition for TJRs to be applied for the launch and closure stages. As shown in learning curve studies, the learning curve may be less than 20 cases, and thus the usage of 100 cases may mask the learning effect entailed in a unit launch. Instead of using order number of surgeries for each closure, the data would be preferably organized according to calendar dates of the announcement of the closure and the closure data, instead of using the arbitrary number of TJRs in the analysis.

A strength of all the studies is that they cover the entire number of TJRs performed due to osteoarthritis. Also, loss in follow-up was a very minor issue. It should be stressed the data arise from ordinary practice. Registers have gained popularity worldwide (e.g. in Australia, England and Wales, and in Germany, to give a few examples). The next logical step after having set up sub-national and national registries is to bring forth efforts to merge data in these local registers to enable more international work. An important example of this is the work by the Nordic Arthroplasty Register Association (NARA) to bring together data in the national registers of Denmark, Finland, Norway and Sweden.

6.3 IMPLICATIONS

The findings have a number of implications for patients, surgeons, hospital managers and health policy makers. Patients are not always aware of the survivorship of implants they are offered by surgeons, and they are not necessarily informed about the history of the implant use in the hospital and by the surgeon who is to operate on the patient. The patients should have the right to know if they are to be operated on with a completely new device or a combination of components or during the learning curve stage.

Similarly, surgeons should be aware of the implant survivorship and learning curve related to the implant. The surgeons should not take into use new implants without strong scientific evidence of the superior performance of the device. When a surgeon is about to take a new implant or technique into use, she or he should carefully practice with, for example, cadavers or bone models and take part in training before performing surgery him- or herself with the new technology. Together with surgeons, hospitals should also take more responsibility over the implant selection they offer to their patients.

The regulation and processes for the introduction of implants to the orthopaedic market has been discussed a lot in the medical literature recently (e.g. (Nieuwenhuijse et al. 2014, Kesselheim, Avorn 2013, Kesselheim, Rajan 2014, Wilmshurst 2011, Curfman, Redberg 2011)). It has been argued that 'the standards for device approval and surveillance have fallen far below those for drugs' (Avorn 2010). The findings regarding the introduction of implants in this thesis support the critics' scepticism regarding the present approval processes and also the calls to develop them. Implant manufacturers should pay attention to safe introduction when designing and developing new implants and instrumentation, and ensure that there is sufficient training arranged for each surgeon prior to operating on patients with the new technology.

In the IDEAL (innovation, development, exploration, assessment and long-term study) recommendations for the safe introduction of surgical innovations, the importance of several stages of assessment has been emphasised (McCulloch et al. 2009). These principles should be strengthened and the approval processes for new medical devices should likewise follow these. The findings of the present thesis would not have been possible without register data, and the registers of medical devices should be perceived as an important means in the assessment and long-term evaluation stages.

In this work, some introduced implants were shown to have a learning curve during which the implantations failed more often than those made in the established practice phase of implant usage in a hospital. However, if the devices with a learning curve are superior to the existing devices in the long-term following comparison with the implantations in the established practice, there is a trade-off between risking the first patients and the better survivorship of the patients operated on when sufficient experience has accumulated. In the orthopaedic community it should be debated how this trade-off should be addressed and what kinds of learning curves are acceptable.

Research on the effects of hospital unit launches and closures on the quality of care is a completely novel topic in orthopaedics. The topic is very relevant especially for nations with a public health care system where health policy makers make the decisions on resource allocation. However, launches and closures are also of importance to patients when they are about to use the services in these units at stages when there may be turbulence in the production of services. Especially if the patients do not have the possibility to choose the provider, they should be aware of whether the quality of the services is affected by organizational changes. There are published recommendations on how to manage hospital downsizing and closures. When in such a situation, the decision-makers and managers should pay attention to this literature (see e.g. van der Wal, Bouthillette & Havlovic 1998, Davis, Savage & Stewart 2003).

6.4 SUGGESTIONS FOR FUTURE RESEARCH

Learning curves have been analysed to a great extent in the medical literature, covering many specialties. However, the methodology has suffered from a number of deficits, as most of the studies are dealing with a single physician or are based on consecutive patients in a single hospital (Ramsay et al. 2000). This thesis extends basis for the analysis of learning curves to cover nationwide data. The approach of the thesis acknowledges that real-life data is very valuable in the analysis of learning curves, as in evidence-based medicine (Malmivaara 2013).

This thesis has applied real-life data available in Finland. Although the studies included are thought to have results that are generalizable to other health care settings, it is preferable that in countries with similar data available, the methods applied in the thesis are implemented. Replication of the studies in other health care settings would increase knowledge of the learning effect in TJR, and support or dispute the hypotheses set out and the results achieved in this work. Debate around learning curves would be beneficial to medical professionals and patients alike.

The approach developed in this work could be introduced in other countries with register databases on arthroplasty so as to study implant models not used in Finland, or models that were not among the most used implants in the present work and thus their learning curves were not evaluated. The worldwide market for hip and knee implants is extensive, with hundreds of implant models in both hip and knee replacement and these works have only touched upon the surface. More implant models should be analysed for their learning curves. The studies of named implant models included only a few models, 10 of the most common hip and knee prostheses. The research method could be applied to register data in other countries where the introduced implant models may be different, and thus evidence of implant-specific learning effects would accumulate. In addition, the learning effects associated with the models included in this thesis could be evaluated in other settings.

With more numerous data (i.e. data covering a wider population of TJRs) the functional form of the learning effect could be analysed more carefully. With more data, the learning curve could be made more flexible in the modelling stage. This work applied a static classification of the order numbers of the implant models, and future work should try to relax the assumptions and try to apply a continuous function on the learning curve.

In orthopaedics, a routine evaluation of newly introduced implants should be carried out regularly. The analysis of learning curves should be complemented with an analysis of the implant-specific risk of reoperation and preferably other outcomes should be included to give a more precise picture of different implants' performance. This would be possible with real-time register data on TJR, with a linkage of records between information sources enabled with the use of PIC. In Finland, the FAR has recently been rebuilt and in the future this kind of analysis becomes feasible.

Furthermore, analyses of the implant survivorship and learning curve should be coupled with data on implant cost in order to establish the cost-effectiveness of different implants. Importantly, the costs in such an analysis should take into account the costs incurred from revisions due to a possibly higher revision risk in the learning phase of implanting the device. Research should provide insight for the hospital managers choosing medical technology to be used in a hospital on the marginal utility of a Euro spent on a device, for example, asking what is the price difference of an implant that justifies an introduction of a device to a hospital.

In the present work, analyses of introductions of implant models were performed for total hip and knee implants. However, an important share of the surgical treatment to alleviate patient suffering from osteoarthritis and other disabling conditions is performed using implant designs not included in the thesis, for example, unicompartmental knee implants or hip resurfacing. Register-based analysis of learning effects associated with these devices and surgical techniques would be an important step to take.

The methodology presented in this work enables the analysis of new surgical techniques, given that the classifications used to code these procedures are sufficiently precise, are introduced in a timely fashion, and are well-coded in the clinics. In the quality registers established to collect data on arthroplasties, the techniques and surgical approaches used might be readily available to researchers, and any possible elevated risks related to the introduction of these could be investigated. In addition, the quality registers might include data on outcomes other than revision risk (e.g. patient-related outcome measures, reoperations other than revisions, and other short-term adverse events) that should be assessed in relation to introductions.

The surgeon’s experience may affect the steepness of the learning curve and this merits further research. By using data that included a surgeon identifier, a major shortcoming of the present thesis could be tested. As the Finnish Arthroplasty Register used in the thesis did not include data on the surgeon, it was not possible to take into account the surgeon's skill level. This may have biased the results, but unfortunately this could not be tested with the available data. However, register data that includes data on the surgeon may exist in other countries, which would allow for the surgeon effect to be adjusted for. Furthermore, such data would render the analysis of surgeon-specific learning curves analysable. In addition, with such data, the analysis of a surgeon's learning curve could be carried out on a completely new level.

Within orthopaedics, to my best knowledge, the surgeon's learning curve has not been assessed with nationwide register data. However, this seems a self-evident thing to do.

It would be very important to establish outcome measures that are applicable in a relatively short time period after the surgery, and would be highly correlated with the long-term survivorship of the implants. As new implants may be introduced simultaneously worldwide and the introduction does not necessitate evidence of implant survivorship, an implant may be used in a great number of patients prior to having reliable data on its performance. Patient satisfaction, surveyed perhaps six months after the surgery, could be used to assess implant performance, and the same measure could be used in the analysis of implant-specific learning curves. With modern computer technology, patient-reported outcome measures could be collected at a reasonable cost, and linked to the surgery.

Hip and knee implants are not the only joint replacement devices implanted into people. For instance, surgery performed on the shoulder has gained popularity, and the study of the implant-specific performance with a view to the learning curve could be performed in this field too. With the principles introduced in this work, such analyses could be made in any setting where there is suitable administrative data available.

The field of analyses regarding learning curves in medicine has not been critically appraised since Ramsay et al. (2000). Thus, a literature review covering the years 2000 to 2015 would be valuable, as it would give information about the state of learning-curve research in the 21st century. As new medical technology is being increasingly introduced, the methodology of the analysis should have learned from the critique presented in the earlier review. It should be assessed if research has met the challenge posed by the increased technological change. Although a simple fact, it would be of value to know if the number of learning curve studies has increased over the years in a way that matches the introduction of new medical technology.

The effects of organizational changes, especially on the quality of care, merit further research. The result of this thesis that the last 100 TJRs in a hospital unit prior to closure could be investigated in these units by interviewing the people involved, both health care professionals and patients, to collect their experiences during the closure stage and to find out the possible reasons that lead to quality deterioration.

The processes of hospital unit launches and closures should be more thoroughly analysed in future works. Research that investigates the possible reasons for quality could be performed, since finding out the reasons behind changes in the quality of care would help decision-makers to minimize changes in quality of care in the event that a unit is to be closed and provide tools to improve the quality of care – not only in the event of closures and other events possibly leading to changes in the quality of care – but also to give possible insights into issues that would help to improve the quality of care overall.

7 CONCLUSIONS

This was the first research project to assess learning curves in orthopaedics with administrative, nationwide data. In particular, studies I, II and III included in the thesis were the first to assess the learning effect related to the introduction of new devices in a hospital, in both THR and TKR. Similarly, study IV is pioneering in the field of analysing changes in the quality of care in units performing TJR in the event that units are launched or closed.

The data show that there is an increased risk of early revision surgery for the first patients obtaining a knee or a hip implant model previously unused in a hospital. Some knee and hip prosthesis models have a clear learning curve with high early revision risk at the implementation phase. Patients should be informed if there is a plan to introduce a new model and offered the possibility to choose a conventional implant model instead. In addition, surgeons should be aware of the risks and preferably practice beforehand with the new model using them, for example, with cadavers or plastic bone models. Units performing arthroplasties might consider introducing implant models.

The outcome of total joint replacements is not independent of changes in the production environment. In particular, prior to closing a unit, decision-makers should also pay attention to the quality perspective. Our findings highlight that closures need to be managed carefully to prevent quality from deteriorating when performing the last arthroplasties in a unit.

It was found that there is an overall learning curve in TKR and THR, but that the learning curves for components are different. The findings are a signal to the entire orthopaedic community of the importance of balancing the benefits and risks of introducing new devices and techniques. Introduction of implants to the market is not strictly regulated, but no doctor should take into use technology whose efficacy has not been scientifically proved.

Both introducing new implants and restructuring the organisation of care are results of decisions that can and should be evaluated. As shown, the quality aspects brought about with these kinds of changes ought to be taken into account whenever the managers are exerting power to adjust the production processes, be it at the level of a single hospital or a clinic, or at the level of the entire health care system.

It is noteworthy that the studies included in the thesis are based on data that reflect routine clinical practice in Finland, and there was no selection of hospitals or units that would hinder the generalizability of the results. Administrative data can serve as a very important means to meet many ends on various levels of interest, ranging from the patient level to the health-system level.

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APPENDIX: LITERATURE ON LEARNING CURVE IN TOTAL HIP AND KNEE REPLACEMENT

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